To: Anthony, Simon J.[sja2127@cumc.columbia.edu]; Kirsten Gilardi[kvgilardi@ucdavis.edu]; Jonna Mazet[jkmazet@ucdavis.edu]
From: Baric, Ralph S[/O=UNC EXCHANGE/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=RBARIC]
Sent: Tue 3/21/2017 3:34:31 PM (UTC-04:00)
Subject: RE: mBio press release

OK! Press is good!

From: Anthony, Simon J. [mailto:sja2127@cumc.columbia.edu]
Sent: Tuesday, March 21, 2017 3:25 PM
To: Kirsten Gilardi; Jonna Mazet; Baric, Ralph S
Subject: mBio press release

Dear all -

Just spoke to a science writer who is doing a piece for mBio on the MERS-like paper. I recommended she (Karen Blum) contact each of you to get insights for into the sample collection (Kirsten), PREDICT (Jonna) and the reverse genetics (Ralph). Hope that is ok.

Cheers
S.

Simon J Anthony, D.Phil
Assistant Professor, Department of Epidemiology
Center for Infection and Immunity, Columbia University

722 West 168th Street, 17th Floor
NY, NY, 10032

Email: sja2127@cumc.columbia.edu
Mobile: 760-500-4639
Office: 212-342-0558

Cc: Kirkpatrick, Beth D.[beth.kirkpatrick@med.uvm.edu]; Diehl, Sean A[Sean.Diehl@med.uvm.edu]; Lee, Benjamin[Benjamin.Lee.1@med.uvm.edu]; Pierce, Kristen K.[kristen.pierce@uvmhealth.org]; Lyon, Caroline E.[caroline.lyon@uvmhealth.org]; Colgate, Ross[ross.colgate@med.uvm.edu]; Walsh, Mary Claire Ruth[mary-claire.walsh@med.uvm.edu]; Dickson, Dorothy M[Dorothy.Dickson@med.uvm.edu]; Carmolli, Marya[marya.carmolli@med.uvm.edu]; Anna Durbin (adurbin1@jhu.edu)[adurbin1@jhu.edu]; Desilva, Aravinda M[aravinda_desilva@med.unc.edu]; Baric, Ralph S[rbaric@email.unc.edu]; alex@liai.org[alex@liai.org]; Daniela Weiskopf[dweiskopf@liai.org]; Lynda Stuart (Lynda.Stuart@gatesfoundation.org)[Lynda.Stuart@gatesfoundation.org]; Beulah Sabundayo[bsabund1@jhu.edu]; Ventrone, Cassandra H[cassandra.ventrone@med.uvm.edu]; Sendra, Eli A[Eli.Sendra@med.uvm.edu]
To: Larsson, Catherine J.[cathy.larsson@med.uvm.edu]
From: Alex Sette[alex@lji.org]
Sent: Fri 9/8/2017 5:04:59 PM (UTC-04:00)
Subject: Re: Congratulations to Steve Whitehead!

Hurray and congrats!

Sent from my iPhone

On Sep 8, 2017, at 2:03 PM, Larsson, Catherine J. <cathy.larsson@med.uvm.edu> wrote:

Congratulations Steve!!!

From: Kirkpatrick, Beth D.
Sent: Friday, September 08, 2017 3:57 PM
To: Diehl, Sean A <Sean.Diehl@med.uvm.edu>; Lee, Benjamin <Benjamin.Lee.1@med.uvm.edu>; Pierce, Kristen K. <kristen.pierce@uvmhealth.org>; Lyon, Caroline E. <caroline.lyon@uvmhealth.org>; Colgate, Ross <ross.colgate@med.uvm.edu>; Walsh, Mary Claire Ruth <mary-claire.walsh@med.uvm.edu>; Dickson, Dorothy M <Dorothy.Dickson@med.uvm.edu>; Carmolli, Marya <marya.carmolli@med.uvm.edu>; Anna Durbin (adurbin1@jhu.edu) <adurbin1@jhu.edu>; Desilva, Aravinda M <aravinda_desilva@med.unc.edu>; Ralph S Baric <rbaric@email.unc.edu>; alex@liai.org; Daniela Weiskopf <dweiskopf@liai.org>; Lynda Stuart (Lynda.Stuart@gatesfoundation.org) <Lynda.Stuart@gatesfoundation.org>; Beulah Sabundayo <bsabund1@jhu.edu>; Ventrone, Cassandra H <cassandra.ventrone@med.uvm.edu>; Sendra, Eli A <Eli.Sendra@med.uvm.edu>; Larsson, Catherine J. <cathy.larsson@med.uvm.edu>
Subject: Congratulations to Steve Whitehead!
Importance: High

Dear all,
Please join me in congratulating our friend and colleague Steve Whitehead, who has been selected as the 2018 recipient of the prestigious Maurice Hilleman Award from the American Society for Microbiology. This major award honors major contributions to pathogenesis, vaccine discovery, vaccine development and/or control of vaccine-preventable diseases. It is in memory of Maurice Hilleman, the development of many well- known and critically essential vaccines.

Please note (links below), other well-known recipients of this award and in case you don't know who Maurice Hilleman is…please see second link!

As ASM notes, this is a "singular" honor. Indeed it is.

So our hats off to Steve-a dedicated and fantastic scientist!

Congratulations Steve!

Best, Beth

https://www.asm.org/index.php/awards2/140-awards-a-grants/past-laureates/7794-maurice-hilleman-merck-award-past-laureates
http://www.nature.com/nm/journal/v11/n4s/full/nm1223.html?foxtrotcallback=true

To: Lyon, Caroline E.[caroline.lyon@uvmhealth.org]; Walsh, Mary Claire Ruth[mary-claire.walsh@med.uvm.edu]; Daniela Weiskopf[dweiskopf@liai.org]; Desilva, Aravinda M[aravinda_desilva@med.unc.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Anna Durbin (adurbin1@jhu.edu)[adurbin1@jhu.edu]; Sendra, Eli A[Eli.Sendra@med.uvm.edu]; Beulah Sabundayo[bsabund1@jhu.edu]; Diehl, Sean A[Sean.Diehl@med.uvm.edu]; Kirkpatrick, Beth D.[beth.kirkpatrick@med.uvm.edu]; Lynda Stuart (Lynda.Stuart@gatesfoundation.org)[Lynda.Stuart@gatesfoundation.org]; Colgate, Ross[ross.colgate@med.uvm.edu]; Ventrone, Cassandra H[cassandra.ventrone@med.uvm.edu]; Pierce, Kristen K.[kristen.pierce@uvmhealth.org]; Carmolli, Marya[marya.carmolli@med.uvm.edu]; Dickson, Dorothy M[Dorothy.Dickson@med.uvm.edu]; Larsson, Catherine J.[cathy.larsson@med.uvm.edu]; alex@liai.org[alex@liai.org]
From: Lee, Benjamin[Benjamin.Lee.1@med.uvm.edu]
Sent: Mon 9/11/2017 9:47:13 AM (UTC-04:00)
Subject: RE: Congratulations to Steve Whitehead!

Congratulations Steve!

-Ben

From: Lyon, Caroline E. [mailto:Caroline.Lyon@uvmhealth.org]
Sent: Saturday, September 09, 2017 10:22 AM
To: Walsh, Mary Claire Ruth <mary-claire.walsh@med.uvm.edu>; Daniela Weiskopf <dweiskopf@liai.org>; Desilva, Aravinda M <aravinda_desilva@med.unc.edu>; Ralph S Baric <rbaric@email.unc.edu>; Anna Durbin (adurbin1@jhu.edu) <adurbin1@jhu.edu>; Sendra, Eli A <Eli.Sendra@med.uvm.edu>; Beulah Sabundayo <bsabund1@jhu.edu>; Diehl, Sean A <Sean.Diehl@med.uvm.edu>; Kirkpatrick, Beth D. <beth.kirkpatrick@med.uvm.edu>; Lynda Stuart (Lynda.Stuart@gatesfoundation.org) <Lynda.Stuart@gatesfoundation.org>; Colgate, Ross <ross.colgate@med.uvm.edu>; Ventrone, Cassandra H <cassandra.ventrone@med.uvm.edu>; Lee, Benjamin <Benjamin.Lee.1@med.uvm.edu>; Pierce, Kristen K. <kristen.pierce@uvmhealth.org>; Carmolli, Marya <marya.carmolli@med.uvm.edu>; Dickson, Dorothy M <Dorothy.Dickson@med.uvm.edu>; Larsson, Catherine J. <cathy.larsson@med.uvm.edu>; alex@liai.org
Subject: RE: Congratulations to Steve Whitehead!

Wow!! Wonderful news - congrats, Steve!!

Carrie

From: Larsson, Catherine J. <cathy.larsson@med.uvm.edu>
Date: September 8, 2017 at 5:04:27 PM EDT
To: Desilva, Aravinda M <aravinda_desilva@med.unc.edu>, Sendra, Eli A <eli.sendra@med.uvm.edu>, Dickson, Dorothy M <dorothy.dickson@med.uvm.edu>, Colgate, Ross <ross.colgate@med.uvm.edu>, Lyon, Caroline E. <Caroline.Lyon@uvmhealth.org>, Walsh, Mary Claire Ruth <mary-claire.walsh@med.uvm.edu>, Diehl, Sean A <sean.diehl@med.uvm.edu>, Kirkpatrick, Beth D. <beth.kirkpatrick@med.uvm.edu>, Beulah Sabundayo <bsabund1@jhu.edu>, Lynda Stuart (Lynda.Stuart@gatesfoundation.org) <Lynda.Stuart@gatesfoundation.org>, Daniela Weiskopf <dweiskopf@liai.org>, Pierce, Kristen K. <Kristen.Pierce@uvmhealth.org>, Ventrone, Cassandra H <cassandra.ventrone@med.uvm.edu>, Carmolli, Marya <marya.carmolli@med.uvm.edu>, Lee, Benjamin <benjamin.lee.1@med.uvm.edu>, alex@liai.org <alex@liai.org>, Anna Durbin (adurbin1@jhu.edu) <adurbin1@jhu.edu>, Ralph S Baric <rbaric@email.unc.edu>
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Ventrone, Cassandra H <cassandra.ventrone@med.uvm.edu>; Sendra, Eli A <Eli.Sendra@med.uvm.edu>; Larsson, Catherine J. <cathy.larsson@med.uvm.edu>
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Importance: High

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http://www.nature.com/nm/journal/v11/n4s/full/nm1223.html?foxtrotcallback=true

To: Damania, Blossom A[blossom_damania@med.unc.edu]; fruehk@ohsu.edu[fruehk@ohsu.edu]; mgack@uchicago.edu[mgack@uchicago.edu]; shoujiag@usc.edu[shoujiag@usc.edu]; mossk@mcmaster.ca[mossk@mcmaster.ca]; karl.munger@tufts.edu[karl.munger@tufts.edu]; kmunger@gmail.com[kmunger@gmail.com]; sspeck@emory.edu[sspeck@emory.edu]; amcbride@nih.gov[amcbride@nih.gov]; amcbride@niaid.nih.gov[amcbride@niaid.nih.gov]; benedict@liai.org[benedict@liai.org]; wbritt@peds.uab.edu[wbritt@peds.uab.edu]; cherrys@mail.med.upenn.edu[cherrys@mail.med.upenn.edu]; lcoscoy@berkeley.edu[lcoscoy@berkeley.edu]; Dittmer, Dirk P[dirk_dittmer@med.unc.edu]; pinghuif@med.usc.edu[pinghuif@med.usc.edu]; eflemin@tulane.edu[eflemin@tulane.edu]; fremont@pathology.wustl.edu[fremont@pathology.wustl.edu]; dgallowa@fhcrc.org[dgallowa@fhcrc.org]; phearing@ms.cc.sunysb.edu[phearing@ms.cc.sunysb.edu]; patrick.hearing@stonybrook.edu[patrick.hearing@stonybrook.edu]; LHuttf@lsuhsc.edu[LHuttf@lsuhsc.edu]; rfkalejta@wisc.edu[rfkalejta@wisc.edu]; 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gsilves@emory.edu[gsilves@emory.edu]; Swanstrom, Ronald I[ron_swanstrom@med.unc.edu]; Swanstrom, Ronald I[ron_swanstrom@med.unc.edu]; trkola.alexandra@virology.uzh.ch[trkola.alexandra@virology.uzh.ch]; alex.a@unimelb.edu.au[alex.a@unimelb.edu.au]; sfiller@ucla.edu[sfiller@ucla.edu]; apm1@andrew.cmu.edu[apm1@andrew.cmu.edu]; leah.cowen@utoronto.ca[leah.cowen@utoronto.ca]; robert.a.cramer.jr@dartmouth.edu[robert.a.cramer.jr@dartmouth.edu]; doering@borcim.wustl.edu[doering@borcim.wustl.edu]; mfeldmesse@northwell.edu[mfeldmesse@northwell.edu]; sig65@pitt.edu[sig65@pitt.edu]; Deborah.A.Hogan@Dartmouth.EDU[Deborah.A.Hogan@Dartmouth.EDU]; bsklein@wisc.edu[bsklein@wisc.edu]; Damian_Krysan@URMC.Rochester.edu[Damian_Krysan@URMC.Rochester.edu]; xlin@bio.tamu.edu[xlin@bio.tamu.edu]; r.c.may@bham.ac.uk[r.c.may@bham.ac.uk]; sil@cgl.ucsf.edu[sil@cgl.ucsf.edu]; bruce.mcdonald@usys.ethz.ch[bruce.mcdonald@usys.ethz.ch]; hitenmadhani@gmail.com[hitenmadhani@gmail.com]; vcarruth@umich.edu[vcarruth@umich.edu]; kwd2001@med.cornell.edu[kwd2001@med.cornell.edu]; d.horn@dundee.ac.uk[d.horn@dundee.ac.uk]; james.kazura@case.edu[james.kazura@case.edu]; jxk14@po.cwru.edu[jxk14@po.cwru.edu]; kami.kim@einstein.yu.edu[kami.kim@einstein.yu.edu]; pearceed@ie-freiburg.mpg.de[pearceed@ie-freiburg.mpg.de]; Eleanor.Riley@roslin.ed.ac.uk[Eleanor.Riley@roslin.ed.ac.uk]; dsacks@nih.gov[dsacks@nih.gov]; DSACKS@niaid.nih.gov[DSACKS@niaid.nih.gov]; XSU@niaid.nih.gov[XSU@niaid.nih.gov]; Png.Loke@nyumc.org[Png.Loke@nyumc.org]; twynn@niaid.nih.gov[twynn@niaid.nih.gov]; nbesansk@nd.edu[nbesansk@nd.edu]; beverley@borcim.wustl.edu[beverley@borcim.wustl.edu]; gibbs@borcim.wustl.edu[gibbs@borcim.wustl.edu]; ob4@sanger.ac.uk[ob4@sanger.ac.uk]; Mike.Blackman@crick.ac.uk[Mike.Blackman@crick.ac.uk]; JamesJ.Collins@UTSouthwestern.edu[JamesJ.Collins@UTSouthwestern.edu]; icoppens@jhsph.edu[icoppens@jhsph.edu]; eyd1@cornell.edu[eyd1@cornell.edu]; christian.engwerda@qimrberghofer.edu.au[christian.engwerda@qimrberghofer.edu.au]; gausewc@njms.rutgers.edu[gausewc@njms.rutgers.edu]; ricardo.gazzinelli@umassmed.edu[ricardo.gazzinelli@umassmed.edu]; ritoga@cpqrr.fiocruz.br[ritoga@cpqrr.fiocruz.br]; kenthill@microbio.ucla.edu[kenthill@microbio.ucla.edu]; johnsonp@ucla.edu[johnsonp@ucla.edu]; jean.langhorne@crick.ac.uk[jean.langhorne@crick.ac.uk]; beth.mcgraw@monash.edu[beth.mcgraw@monash.edu]; edward.mitre@usuhs.edu[edward.mitre@usuhs.edu]; mmota@fm.ul.pt[mmota@fm.ul.pt]; mmota@igc.gulbenkian.pt[mmota@igc.gulbenkian.pt]; i.muller@imperial.ac.uk[i.muller@imperial.ac.uk]; TNUTMAN@niaid.nih.gov[TNUTMAN@niaid.nih.gov]; wap3g@virginia.edu[wap3g@virginia.edu]; margaret.phillips@UTSouthwestern.edu[margaret.phillips@UTSouthwestern.edu]; david.schneider@stanford.edu[david.schneider@stanford.edu]; joe.smith@seattlebiomed.org[joe.smith@seattlebiomed.org]; Dominique.Soldati-Favre@unige.ch[Dominique.Soldati-Favre@unige.ch]; mary.stevenson@mcgill.ca[mary.stevenson@mcgill.ca]; kvernick@pasteur.fr[kvernick@pasteur.fr]; david_l_williams@rush.edu[david_l_williams@rush.edu]; sibley@borcim.wustl.edu[sibley@borcim.wustl.edu]; 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Cc: plospathogens@plos.prg[plospathogens@plos.prg]
From: PLOS Pathogens[plospathogens@plos.org]
Sent: Fri 10/27/2017 4:35:13 PM (UTC-04:00)
Subject: Accept to ONE Update--PLOS Pathogens
Accept to PLOS ONE Manual.pdf

Dear editors,

Following our recent update on the ‘Accept to ONE’ project, we are writing to provide some further guidance on offering acceptance into *PLOS ONE*. **Attached to this email, you will find a guide to the steps involved in offering acceptance in *PLOS ONE*,** including new, simplified decision names.

We would also like to encourage you to make use of this option when possible, as uptake of Accept to ONE by the *PLOS Pathogens* and *PLOS Computational Biology* editors has not been as strong as it has on the other community journals - we have seen 7 Accept to ONE offers sent by *PLOS Pathogens* editors, and 12 on *PLOS Computational Biology*, versus 23 on *PLOS Neglected Tropical Diseases* and 19 on *PLOS Genetics*. If you would like to take up the option of Accept to ONE but aren’t sure how, or you have feedback on any aspect of the project, please don’t hesitate to direct your questions and comments to us at the journal email address (plospathogens@plos.org).

Finally, we would just like to remind you of a few pointers to ensure that the Accept to ONE process runs as smoothly as possible:

- As already mentioned, we have **simplified the Accept to ONE decision names** as follows:

- **PLOS ONE: Revise Before Accept**
- **PLOS ONE: Accept Revision**
- **PLOS ONE: Reject Revision**
- **PLOS ONE: Accept As Is (After Review)**

More information about each of these decisions is available in the attached documentation.

- Authors may request that their rejected manuscript is accepted in *PLOS ONE* if this option is not offered to them; however, you should never feel obliged to agree to this if you do not think it appropriate. You should ensure that you are happy for **your name to appear** on any articles accepted into *PLOS ONE* before offering this to authors.

- Please **avoid returning a submission to reviewers** after minor revision (i.e. ‘PLOS ONE: Revise Before Accept’) if possible. Before sending a ‘PLOS ONE: Revise Before Accept’ decision, you should ensure that the required revisions are limited enough that you are able to assess them yourself; otherwise, a standard reject or major revision would be the appropriate decision.

Thanks again for all the time and energy which you put into *PLOS Pathogens*, and we look forward to seeing more Accept to ONE decisions in future!

Best wishes,

The *PLOS Pathogens* team

Accept to *PLOS ONE* Manual

For Community Journal Editors

Overview
This service offers a quick path to publication for Research Article submissions that are scientifically rigorous, but would otherwise be rejected after review from one of the Community Journals solely on the basis of novelty or impact. The Associate Editor or Guest Editor can offer acceptance to *PLOS ONE* as the manuscript stands or after minor revisions.

Note that this is not a standard transfer, but a decision to accept a peer reviewed paper to *PLOS ONE*. This process is not suitable for manuscripts that require additional cycles of peer review.

How it works
1. The editors decide that the manuscript is not suitable to publish in the Community Journal but offer the authors the option to accept their manuscript to *PLOS ONE*.
2. Before sending an offer of acceptance, editors have the option to confer with a *PLOS ONE* editor if there is a question about the eligibility of the manuscript.
3. Any minor revisions will be completed in the Community Journal before the submission is formally rejected from this journal and transferred to *PLOS ONE* for acceptance.
4. The manuscript proceeds to publication if the authors accept the transfer, and the Associate Editor from the Community Journal is named Editor on the published article in *PLOS ONE*.

Who is Involved
PLOS Community Journal Associate Editor
PLOS Community Journal Section/Deputy Editor
PLOS ONE Associate Editor (optional)

Contents

Requirements for *PLOS ONE*

PLOS ONE publishes scientifically rigorous peer-reviewed Research Articles. Read *PLOS ONE's* full publication criteria.

Submissions in the following areas are not eligible for acceptance to *PLOS ONE*:

- Non-primary research; e.g., reviews, opinions, study protocols, rebuttals
- Tobacco-funded research

PLOS ONE has specific editorial policies in the following areas:

- Research using vertebrate animal models in which death is an endpoint
- Clinical trials

To ensure a manuscript's successful acceptance to *PLOS ONE*, Community Journal editors should refer to the humane endpoints policy and the clinical trials policy to confirm compliance. If questions arise, editors are encouraged to discuss with a *PLOS ONE* staff member before offering acceptance.

Submissions with the following editorial issues are not eligible for acceptance to *PLOS ONE* via this process:

- Submissions unsuitable for peer review
- Submissions that require major revisions

Evaluation Procedure

Assessment for the Community Journal

As an Associate Editor, determine whether the manuscript is suitable to publish in the Community Journal when it returns from peer review.

If the manuscript is	***Take the following action***
Publishable in the Community Journal	Use one of the decision types available to that journal: • **Accept** • **Major Revision** • **Minor Revision** Review the *Associate Editor Handbook* in the Editorial Board Knowledge Base for the list of standard decision types.
Not publishable in the Community Journal	↪ If the decision is to **reject** the manuscript after review on the grounds of **novelty or impact**, continue to the next section and assess the manuscript's eligibility for *PLOS ONE* before issuing a decision. OR ↪ If the decision is to reject for any other reason, issue a standard **Reject After Review** decision from the Community Journal.

Assessment for *PLOS ONE*

1. As an Associate Editor, draw the following preliminary conclusions about the submission to consider it for *PLOS ONE*:

    ↪ It will be rejected from the Community Journal on the grounds of an insufficient strength of advance.

    ↪ It is ready for publication as is.

    OR

    ↪ It can publish after minor revisions that can be evaluated without additional reviewer feedback.

2. Confirm that the manuscript meets *PLOS ONE*'s publication requirements.

3. If there are questions regarding the manuscript's suitability for *PLOS ONE*, consult with a *PLOS ONE* Associate Editor by starting a discussion in Editorial Manager.

> When conferring with a *PLOS ONE* editor, wait until the editor has responded before submitting a decision. This will prevent the need to withdraw the offer of acceptance if the *PLOS ONE* editor determines that the paper is unsuitable for the journal.

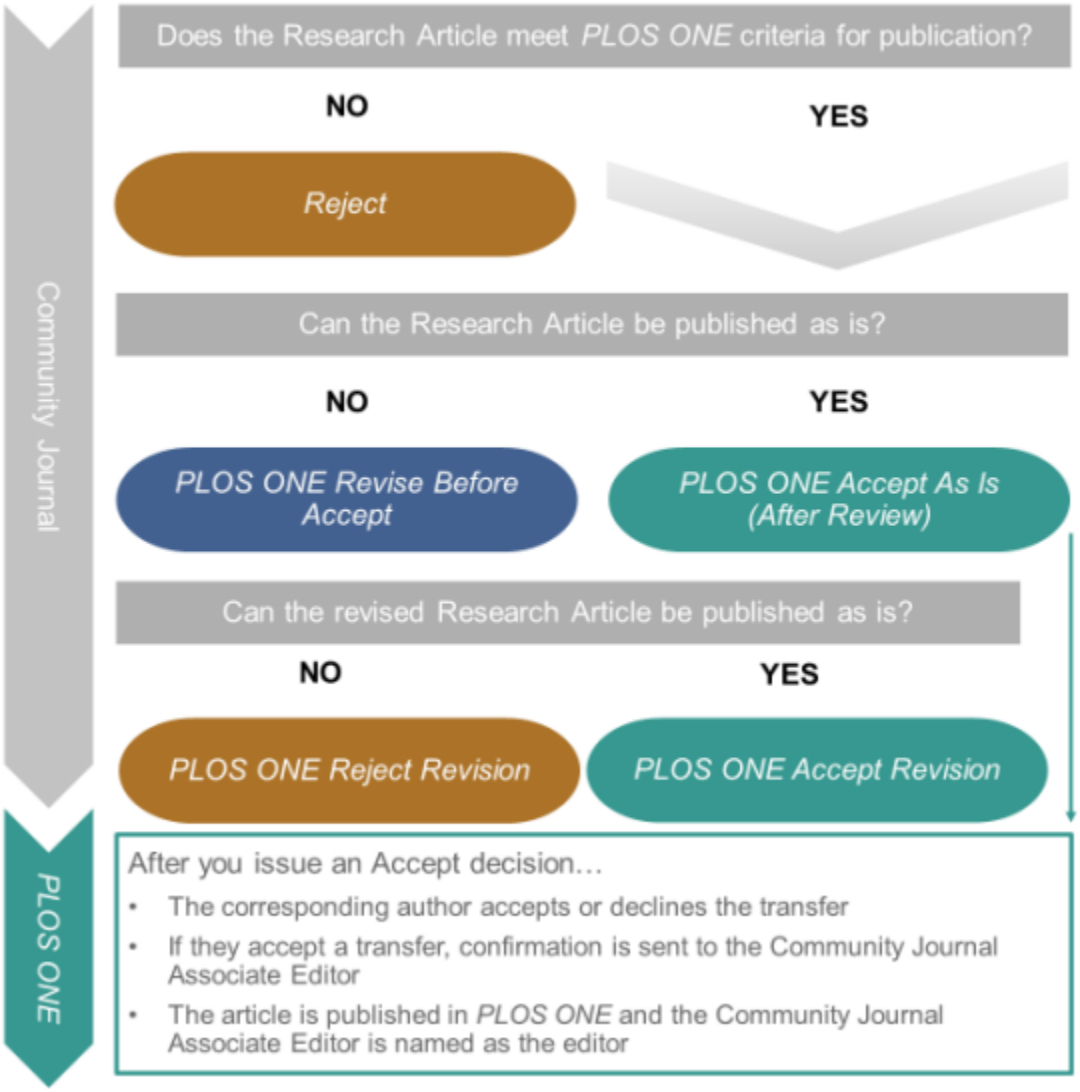
4. Reject the manuscript or continue with a transfer:

    ↪ If the manuscript does not meet the requirements for *PLOS ONE*, issue a standard **Reject After Review** decision from the Community Journal.

    OR

    ↪ If the manuscript is publishable in *PLOS ONE*, proceed to the next section to issue a decision that will initiate the transfer.

Use the following flowchart as a quick reference guide when going through this decision process.



Transfer to *PLOS ONE*

1. From the decision form in Editorial Manager, select the appropriate **PLOS ONE** decision from the drop-down menu to initiate the transfer process:

    ↪ If the manuscript is ready for publication without changes, issue the decision **PLOS ONE: Accept As Is (After Review)**.

    OR

    ↪ If the manuscript requires only minor revisions, issue the decision **PLOS ONE: Revise Before Accept**.

    a. Edit the decision letter to detail the minor changes the authors need to make.

    b. When the manuscript comes back from the authors, evaluate whether the authors have addressed the points raised. Do not send the manuscript back to the reviewers.

    ↪ If the authors have adequately revised the manuscript, issue a decision of **PLOS ONE: Accept Revision**.

    OR

    ↪ If the authors have not adequately revised the manuscript, select **Reject After [Peer] Review** in the decision form. Then, select **PLOS ONE: Reject Revision** from the Modify Letter menu.

> When issuing a decision for *PLOS Pathogens*, select the decision **Reject After Review (closed)**. Modify the letter as indicated in the instruction above.

2. The Section/Deputy Editor will receive the Associate Editor's draft decision, review it, and send it to the authors, per the usual process.

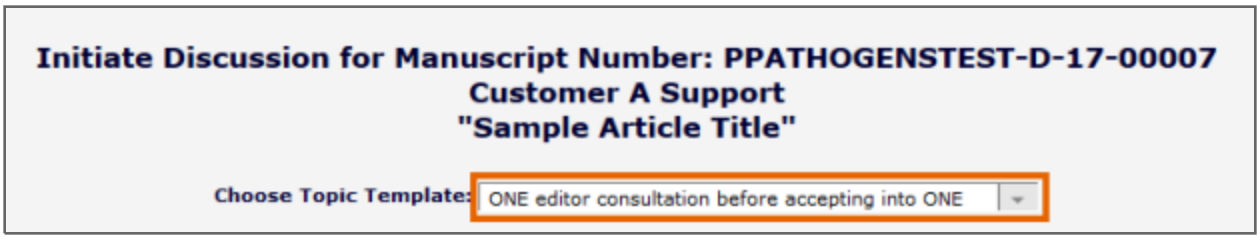
Decision Matrix

Refer to the decision matrix for details about what happens after the decision is sent, or use it as a quick reference for decision-making.

Decision Type	*Render this decision if*	*After the decision is made*
PLOS ONE: Accept As Is (After Review)	• The manuscript has undergone peer review and is scientifically sound. • The subject matter is outside the scope of the journal or does not meet its standards for novelty and impact. • The manuscript meets the *PLOS ONE* requirements. • The manuscript is ready to publish.	• The Section/Deputy Editor checks the decision and may consult further with the Associate Editor and/or *PLOS ONE* if they have any concern of the manuscript's eligibility for *PLOS ONE*. • Authors have 3 weeks to accept the transfer to *PLOS ONE*. • The Associate Editor receives an email confirming that the transfer is complete. • The Associate Editor is named Editor on the published article in *PLOS ONE*.
PLOS ONE: Revise Before Accept	• The manuscript has undergone peer review and is scientifically sound. • The subject matter is outside the scope of the journal or does not meet its standards for novelty and impact. • The manuscript meets the *PLOS ONE* requirements. • Minor revisions are needed, but the manuscript does not require additional oversight by the reviewers. The revisions required should be minimal enough that the Associate Editor can evaluate them independently. Detail the minor revisions required for acceptance in the space provided in the draft decision letter.	• Authors have 3 weeks to revise and resubmit their work. • Upon resubmission, Associate Editors reevaluate the manuscript to see if it satisfies the editorial revision requests and is ready for acceptance to *PLOS ONE*. • The Section/Deputy Editor checks the decision and may consult further with the Associate Editor and/or *PLOS ONE* if they have any concern of the manuscript's eligibility for *PLOS ONE*.
PLOS ONE: Accept Revision	• The editors previously issued a **PLOS ONE: Revise Before Accept** decision. • The authors have successfully addressed all minor points the editors identified for revision. • The manuscript meets the *PLOS ONE* requirements. • The manuscript is ready to publish.	• The Section/Deputy Editor checks the decision and may consult further with the Associate Editor and/or *PLOS ONE* if they have any concern of the manuscript's eligibility *PLOS ONE*. • Authors have 3 weeks to accept the transfer to *PLOS ONE*. • The Associate Editor receives an email confirming that the transfer is complete. • The Associate Editor is named Editor on the published article in *PLOS ONE*.
PLOS ONE: Reject Revision	• The editors previously issued a **PLOS ONE: Revise Before Accept** decision. • The editors determine that the revisions are not adequate. • The manuscript is not ready to publish.	• The Section/Deputy Editor checks the decision before sending it to the authors.

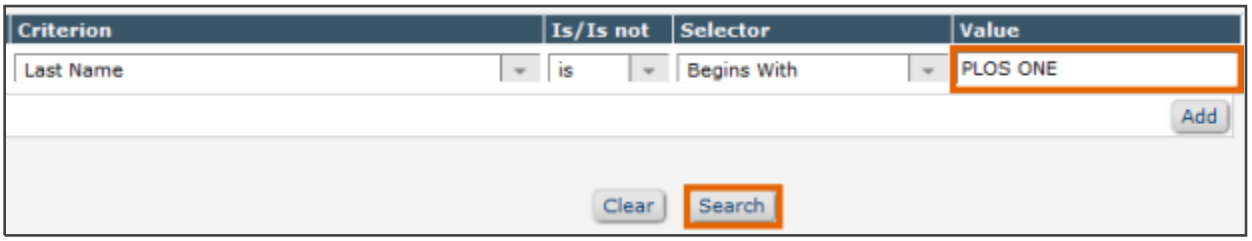
How to Open a Discussion with a *PLOS ONE* Editor

1. Click **Initiate Discussion** from the manuscript action links.
2. Choose the topic template **ONE editor consultation before accepting into ONE**.

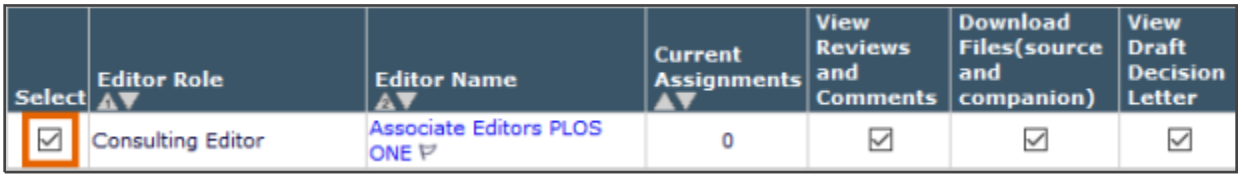


3. Edit the template text to add details or questions about the manuscript, as needed.
4. Add the *PLOS ONE* Associate Editor account to the discussion.

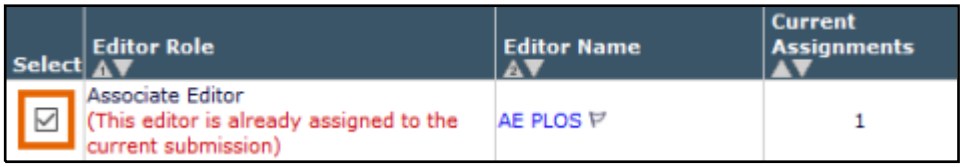
    a. Search for “PLOS ONE” in the Editor Candidates section of the page.



    b. Check off the box next to the Consulting Editor role. The editor name is **Associate Editors PLOS ONE.**



5. If you are a starting the discussion as a Section/Deputy Editor, search for the name of the Associate Editor handling the manuscript. Check off the box next to the name to add this person to the discussion.



6. Once all participants are selected, click **Proceed to Customize Letters**.

Do not click **Start a Discussion Without Sending Letters**, because it will start the thread without notifying participants.

Editorial Board Handbooks

Sign in to the journal's Editorial Board Knowledge Base to download and review the Associate Editor handbook for each of the Community Journals:

- *PLOS Computational Biology*
- *PLOS Genetics*
- *PLOS Neglected Tropical Diseases*
- *PLOS Pathogens*

To: Baric, Ralph S[rbaric@email.unc.edu]
From: Alison Andre[andre@ecohealthalliance.org]
Sent: Fri 3/9/2018 11:00:01 AM (UTC-05:00)
Subject: Virologica Sinica Wang et al paper
Wang et al. Bat SARSr coronavirus serology in people in Yunnan%2c China.pdf

Hi Ralph,

Attached is a PDF version of the Wang et al paper “Serological Evidence of Bat SARS-Related Coronavirus Infection in Humans, China."

Best,
Alison

Alison Andre
Executive Assistant to the President

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LETTER

Serological Evidence of Bat SARS-Related Coronavirus Infection in Humans, China

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Received 21 November 2017 / Accepted 8 January 2018

Dear Editor,

Severe acute respiratory syndrome coronavirus (SARS-CoV) is the causative agent of the 2002–2003 SARS pandemic, which resulted in more than 8000 human infections worldwide and an approximately 10% fatality rate (Ksiazek et al. 2003; Peiris et al. 2004). The virus infects both upper airway and alveolar epithelial cells, resulting in mild to severe lung injury in humans (Peiris et al. 2003).

During the SARS outbreak investigation, epidemiological evidence of a zoonotic origin of SARS-CoV was identified (Xu et al. 2004). Isolation of SARS-related coronavirus (SARSr-CoVs) from masked palm civets and the detection of SARS-CoV infection in humans working at wet markets where civets were sold suggested that masked palm civets could serve as a source of human infection (Guan et al. 2003). Subsequent work identified genetically diverse SARSr-CoVs in Chinese horseshoe bats (Rhinolophus sinicus) in a county of Yunnan Province, China and provided strong evidence that bats are the natural reservoir of SARS-CoV (Ge et al. 2013; Li et al. 2005; Yang et al. 2016). Since then, diverse SARS-related coronaviruses (SARSr-CoVs) have been detected and reported in bats in different regions globally (Hu et al. 2015). Importantly, SARSr-CoVs that use the SARS-CoV receptor, angiotensin converting enzyme 2 (ACE2) have been isolated (Ge et al. 2013). These results indicate that some SARSr-CoVs may have high potential to infect human cells, without the necessity for an intermediate host. However, to date, no evidence of direct transmission of SARSr-CoVs from bats to people has been reported.

In this study, we performed serological surveillance on people who live in close proximity to caves where bats that carry diverse SARSr-CoVs roost. In October 2015, we collected serum samples from 218 residents in four villages in Jinning County, Yunnan province, China (Fig. 1A), located 1.1–6.0 km from two caves (Yanzi and Shitou). We have been conducting longitudinal molecular surveillance of bats for CoVs in these caves since 2011 and have found that they are inhabited by large numbers of bats including Rhinolophus spp., a major reservoir of SARSr-CoVs. This region was not involved in the 2002–2003 SARS outbreaks and none of the subjects exhibited any evident respiratory illness during sampling. Among those sampled, 139 are female and 79 male, and the median age is 48 (range 12–80). Occupational data were obtained for 208 (95.4%) participants: 85.3% farmers and 8.7% students. Most (81.2%) kept or owned livestock or pets, and the majority (97.2%) had a history of exposure to or contact with livestock or wild animals. Importantly, 20 (9.1%) participants witnessed bats flying close to their houses, and one had handled a bat corpse. As a control, we also collected 240 serum samples from random blood donors in 2015 in

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s12250-018-0012-7) contains supplementary material, which is available to authorized users.

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Published online: 02 March 2018

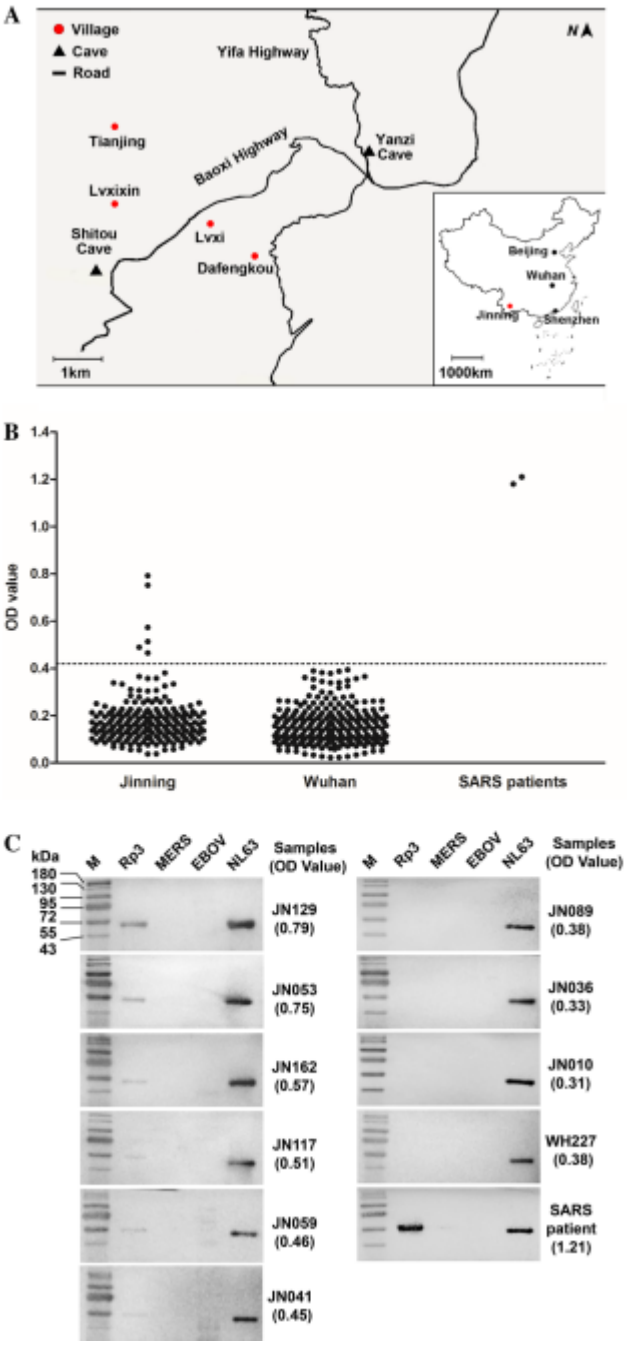

Fig. 1 SARSr-CoV serosurveillance. (A) Map of Xiyang town, Jinning County, Yunnan Province, China. Shown here is the location of the 4 villages (Tianjing, Dafengkou, Lvxi, Lvxixin) around 2 bat caves (Yanzi Cave and Shitou Cave) chosen for this study. The map of China is also shown in the inset indicating the location of Wuhan, where the negative control sera were collected, in relation to Jinning, Shenzhen and the capital Beijing. Serological reactivity of serum samples with recombinant SARSr-CoV NP protein. B ELISA test. The dotted line represents the cutoff of the test. C Western blot analysis. Numbers on the left are molecular masses in kDa.

Wuhan, Hubei Province more than 1000 km away from Jinning (Fig. 1A) and where inhabitants have a much lower likelihood of contact with bats due to its urban setting. None of the donors had knowledge of prior SARS infection or known contact with SARS patients.

His-tagged nucleocapsid protein (NP) of the following viruses were expressed and purified in E. coli for this study: SARSr-CoV Rp3; human coronaviruses (HCoVs) HKU1, OC43, 229E, NL63; Middle East Respiratory Syndrome Coronavirus (MERS-CoV); and Ebola virus (EBOV). In addition, the receptor binding domains (RBD) of the spike protein (S) from SARS-CoV, bat SARSr-CoVs Rp3, WIV1, and SHC014 were produced in mammalian cells (Ge et al. 2013; Yang et al. 2016).

Polyclonal antibodies against each of the six NPs were prepared in rabbits as previously published (He et al. 2006). Cross-activity was evaluated with ELISA and Western blot (Supplementary Figures S1, S2). No significant cross-activity was detected among NPs and their corresponding antibodies for Rp3, MERS-CoV, NL63, or 229E. Cross-reaction was detected between OC43 and HKU1 as reported previously (Lehmann et al. 2008).

The Rp3 NP was chosen to develop a SARSr-CoV specific ELISA for serosurveillance. Micro-titer plates were coated with 100 ng/well of recombinant Rp3 NP and incubated with human sera in duplicates at a dilution of 1:20, followed by detection with HRP labeled goat anti-human IgG antibodies (Proteintech, Wuhan, China) at a dilution of 1:20,000. The 240 random serum samples collected in Wuhan and two SARS positive samples from Zhujiang Hospital, Southern Medical University (kindly provided by Prof. Xiaoyan Che)[1] were used to set a cutoff value. We used the mean OD value of the 240 samples plus three standard deviations to set the cutoff value at 0.41. A total of six positive samples were detected by ELISA (Fig. 1B). The specificity of these positive samples was confirmed by Western blot with recombinant Rp3 NP (Fig. 1C) together with NP of NL63, MERS-CoV and EBOV. The degree of reactivity in Western blot correlated well with the ELISA OD readings, providing further confidence in the ELISA screening method. None of the sera reacted with NPs of either MERS-CoV or EBOV. On the other hand, all 10 human sera (9 from Jinning and 1 from Wuhan), regardless of their Rp3 NP reactivity, reacted strongly with the NL63 NP as expected due to high prevalence of NL63 infection in humans worldwide (Abdul-Rasool and Fielding 2010).

We conducted a virus neutralization test for the six positive samples targeting two SARSr-CoVs, WIV1 and WIV16 (Ge et al. 2013; Yang et al. 2016). None of them were able to neutralize either virus. These sera also failed to react by Western blot with any of the recombinant RBD proteins from SARS-CoV or the three bat SARSr-CoVs Rp3, WIV1, and SHC014. We also performed viral nucleic

[1] Prof. Xiaoyan Che—deceased

acid detection in oral and fecal swabs and blood cells, and none of these were positive.

The demography and travel histories of the six positive individuals (four male, two female) are as follows. Two males (JN162, 45 years old, JN129, 51 years old) are from the Dafengkou village; two males (JN117, 49 years old, JN059, 57 years old) from Lvxi village; and two females (JN053, JN041, both 55 years old), from Tianjing village. In the 12 months prior to the sampling date, JN041 was the only individual who travelled outside of Yunnan, to Shenzhen, a city 1400 km away from her home village (Fig. 1A). JN053 and JN059 had travelled to another county 1.4 km away from their village. JN162 had travelled to Kunming, the capital of Yunnan, 63 km away. JN129 and JN117 had never left the village. It is worth noting that all of them had observed bats flying in their villages.

Our study provides the first serological evidence of likely human infection by bat SARSr-CoVs or, potentially, related viruses. The lack of prior exposure to SARS patients by the people surveyed, their lack of prior travel to areas heavily affected by SARS during the outbreak, and the rapid decline of detectable antibodies to SARS-CoV in recovered patients within 2–3 years after infection strongly suggests that positive serology obtained in this study is not due to prior infection with SARS-CoV (Wu et al. 2007). The 2.7% seropositivity for the high risk group of residents living in close proximity to bat colonies suggests that spillover is a relatively rare event, however this depends on how long antibodies persist in people, since other individuals may have been exposed and antibodies waned. During questioning, none of the 6 seropositive subjects could recall any clinical symptoms in the past 12 months, suggesting that their bat SARSr-CoV infection either occurred before the time of sampling, or that infections were subclinical or caused only mild symptoms. Our previous work based on cellular and humanized mouse infection studies suggest that these viruses are less virulent than SARS-CoV (Ge et al. 2013; Menachery et al. 2016; Yang et al. 2016). Masked palm civets appeared to play a role as intermediate hosts of SARS-CoV in the 2002–2003 outbreak (Guan et al. 2003). However, considering that these individuals have a high chance of direct exposure to bat secretion in their villages, this study further supports the notion that some bat SARSr-CoVs are able to directly infect humans without intermediate hosts, as suggested by receptor entry and animal infection studies (Menachery et al. 2016).

The failure of these NP ELISA positive sera to either neutralize live virus or react with RBD proteins in Western blot could be explained by at least two hypotheses. First, the immune response to the bat SARSr-CoV S protein may be weaker than that to the NP protein or may wane more rapidly, especially in subclinical infections, resulting in antibody levels is too low to be detected by our assays. Secondly, other bat SARSr-CoV variants may be circulating in bats in these villages that have highly divergent S proteins and have not yet been detected in our surveillance studies.

Coronaviruses are known to have a high mutation rate during replication and are prone to recombination if different viruses infect the same individual (Knipe et al. 2013). From our previous studies of bat SARSr-CoVs in the two caves near these villages, we have found genetically highly diverse bat SARSr-CoVs and evidence of frequent coinfection of two or more different SARSr-CoVs in the same bat (Ge et al. 2013). Our current study suggests that our surveillance is not exhaustive, as one would have expected, and that further, more extensive surveillance in this region is warranted. It might also be prudent to combine serological surveillance with molecular surveillance of bats in future, despite the technological challenges that this represents.

Acknowledgements This study was jointly funded by the National Natural Science Foundation of China Grant (81290341) to ZLS; the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (Award Number R01AI110964) to PD and ZLS, United States Agency for International Development (USAID) Emerging Pandemic Threats PREDICT project Grant (Cooperative Agreement No. AID-OAA-A-14-00102) to PD; and Singapore NRF-CRP Grant (NRF2012NRF-CRP001–056) and CD-PHRG Grant (CDPHRG/0006/2014) to LFW.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Animal and Human Rights This study was approved by the Wuhan Institute of Virology Institutional Review Board (China) and by Hummingbird IRB (USA).

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Cc: Allison Yang/MDPI AG (allison.yang@mdpi.com)[allison.yang@mdpi.com]; viruses@mdpi.com[viruses@mdpi.com]; Du, Lanying[LDu@nybc.org]
From: Fang Li[lifang@umn.edu]
Sent: Thur 3/29/2018 11:32:55 AM (UTC-04:00)
Subject: Invitation to contribute an article: [Viruses] journal Special Issue on "MERS-CoV "

Dear Dr. Baric,
The following Special Issue of which Dr. Lanying Du and I are serving as Guest Editors will be published in *Viruses* (IF 3.465, http://www.mdpi.com/journal/viruses), and is now open to receive submissions of full research articles and comprehensive review papers for peer-review and possible publication:
Special Issue: MERS-CoV
Website: http://www.mdpi.com/journal/viruses/special_issues/MERS_CoV
Deadline for submissions: 30 November 2018
Given your interesting work in the MERS-CoV field, we invite you and your colleagues to submit a research or review article for this special issue, in which some of the leading experts will describe their work, ideas and findings. Topics on MERS-CoV animal models and pathogenesis would be greatly appreciated. Please feel free to choose your topic if needed.

Viruses is an Open Access journal and indexed by Web of Science, PubMed and other databases. It will charge a modest processing fee to publish your manuscript. *Viruses* places a high priority on rapid publication. All papers accepted for publication will be immediately published.
You may send your manuscript now and until the deadline 30 November 2018. For further details on the submission process, please see the instructions for authors at the journal website (http://www.mdpi.com/journal/viruses/instructions).
If you accept our invitation, please send a tentative title or short abstract to us (lifang@umn.edu; LDu@nybc.org) and the Editorial Office (viruses@mdpi.com) in advance.
Please do not hesitate to contact us if you need any further information.
We hope to get your positive reply soon.
Best regards,
Fang Li
Lanying Du
Guest Editors
Viruses

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Cc: Fang Li[lifang@umn.edu]; viruses@mdpi.com[viruses@mdpi.com]; Du, Lanying[LDu@nybc.org]
From: Allison Yang/MDPI[allison.yang@mdpi.com]
Sent: Tue 4/17/2018 1:50:21 AM (UTC-04:00)
Subject: Reminder: Invitation to contribute an article: [Viruses] journal Special Issue on "MERS-CoV "

Dear Dr. Baric,

I would like to follow up on the invitation from Dr. Fang Li and Dr. Lanying Du (CC here) and to check with you if you plan to submit something to this special issue.

Here is the special issue website: http://www.mdpi.com/journal/viruses/special_issues/MERS_CoV, and our instructions for authors can be found here: http://www.mdpi.com/journal/viruses/instructions

Please note that suitable manuscripts are sent to peer-review as soon as they are submitted. If you are not able to meet the deadline (**30 November 2018**) and need an extension to have your paper ready, please feel free to contact the editorial office.

Regarding the format, *Viruses* has no restrictions on the length of manuscripts, provided that the text is concise and comprehensive. If possible, the abstract should be limited to 200 words and we ask you to provide 3-10 keywords describing the content of the review for future indexing.

We would be appreciate if you could submit your research work to this special issue. Please let me know if you have any questions. Thank you again for your consideration.

Kind regards,
Dr. Allison Yang
Assistant Editor
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On 3/29/2018 11:32 PM, Fang Li wrote:

> Dear Dr. Baric,
> The following Special Issue of which Dr. Lanying Du and I are serving as Guest Editors will be published in *Viruses* (IF 3.465, http://www.mdpi.com/journal/viruses), and is now open to receive submissions of full research articles and comprehensive review papers for peer-review and possible publication:
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> Website: http://www.mdpi.com/journal/viruses/special_issues/MERS_CoV
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> Given your interesting work in the MERS-CoV field, we invite you and your colleagues to submit a research or review article for this special issue, in which some of the leading experts will describe their work, ideas and findings. Topics on MERS-CoV animal models and pathogenesis would be greatly appreciated. Please feel free to choose your topic if needed.

Viruses is an Open Access journal and indexed by Web of Science, PubMed and other databases. It will charge a modest processing fee to publish your manuscript. *Viruses* places a high priority on rapid publication. All papers accepted for publication will be immediately published.
You may send your manuscript now and until the deadline 30 November 2018. For further details on the submission process, please see the instructions for authors at the journal website (http://www.mdpi.com/journal/viruses/instructions).
If you accept our invitation, please send a tentative title or short abstract to us (lifang@umn.edu; LDu@nybc.org) and the Editorial Office (viruses@mdpi.com) in advance.
Please do not hesitate to contact us if you need any further information.
We hope to get your positive reply soon.
Best regards,
Fang Li
Lanying Du
Guest Editors
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Cc: Wingate, Vicki J[wingate@med.unc.edu]; Heise, Mark T[mark_heisem@med.unc.edu]; Baric, Ralph S[rbaric@email.unc.edu]; rjohnston@globalvaccines.org[rjohnston@globalvaccines.org]
From: CEPI Pipeline[pipeline@cepi.net]
Sent: Mon 7/2/2018 8:55:35 AM (UTC-04:00)
Subject: CEPI Pre-invitation to Request for Information (5th July)

Dear Dr. William Roper and Colleagues,

We would like to inform you that CEPI is planning to launch a new Request for Information (RfI) on 5 July, and that we will be sending you a formal invitation to participate.

In this RfI we will be requesting information for vaccine R&D candidates focused specifically on MERS, Nipah, Lassa and Chikungunya, in advance of a potential 3rd Call for Proposals (CfP) in autumn of this year. This RfI will ask for high level project information to help us understand a bit more in depth the maturity of the available vaccine candidates in the pipeline for these diseases, and to support the business case for such a CfP, particularly on R&D phase scope and budget ceilings for the CfP.

Please look for the official invitation on Thursday 5 July, and we hope you will consider participating. In the meantime, please do not hesitate to contact us for any clarifications.

Thanks in advance for your consideration.

Kind regards,

Dimitrios Gouglas
Portfolio Manager
CEPI – Coalition for Epidemic Preparedness Innovations
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From: CEPI Pipeline
Sent: onsdag 10. januar 2018 14:24
To: Roper@med.unc.edu
Cc: wingate@med.unc.edu; heisem@med.unc.edu; rbaric@email.unc.edu; rjohnston@globalvaccines.org
Subject: RE: CEPI invitation to vaccine R&D pipeline and cost tracking survey against epidemic infectious diseases

Dear Dr. William Roper and Colleagues,
I hope this email finds you well. We have now received a substantial number of responses to our vaccine R&D pipeline and cost tracking survey and we are planning on launching a list of vaccine R&D candidates on the CEPI website, following on permission and text suggestions by the owners of these candidates.
Given that we have not received a response from you yet, I was wondering if you would still like to take the opportunity to complete the survey, and if you would also like your vaccine R&D candidates to be included in the CEPI website list. Specifically, we would only make the following information fields available:

Disease	Vaccine	Platform technology	Sub-Platform technology	
Lassa fever	GPC441-449 subunit	Sub-Unit Protein, Viral	Delivery System	University of Vermont College MWH Laboratories; La Jolla Institute of Allergy an PaxVax, Inc.,; University of C
MERS-CoV	RABV-MERS RABV contains spike protein of the MERS-CoV S1 domain fused to the RABV G protein C terminus (BNSP333-S1). Live and	Non-Replicating, Viral	Prime-boost imm. Homo, Vectored (Chimeric)	Thomas Jefferson University; I Allergy and Infectious Disease University of North Carolina; U

	deactivated irons			
MERS-CoV	Venezuelan equine encephalitis replicons (VRP) expressing nucleocapsid proteins	Non-Replicating, Viral	Prime-boost imm. Homo, Vectored (Chimeric)	University of Iowa; The First A University; University of North
MERS-CoV	VRP expressing spike protein	Non-Replicating, Viral	Vectored (Chimeric)	University of Iowa; University
Rift Valley fever	Gn-C3d: Gn glycoprotein fused with C3d Rep-Gn: Alpha virus replicons expressing Gn Gn-C3d/Rep-Gn: combination	Non-Replicating, Viral, DNA, Viral	Recombinant Protein, Delivery System	University of Pittsburgh; University of North Carolina
Rift Valley fever	Gn-C3d: Gn glycoprotein fused with C3d Rep-Gn: Alpha virus replicons expressing Gn Gn-C3d/Rep-Gn: combination	Non-Replicating, Viral, DNA, Viral	Recombinant Protein, Delivery System	University of Pittsburgh; University of North Carolina
Rift Valley fever	Sindbis virus expressing the RVFV Gn and Gc glycoproteins, nsM protein	Non-Replicating, Viral	Vectored (Chimeric)	University of North Carolina; National Institute for Commun University of the Free State

*development status would not be presented on CEPI website in the next update
We are planning on launching the list of vaccine R&D candidates on 26th January. After the deadline, we will use the data related to your organization from other available sources.
Thanks again for your time and effort.
Best regards,

Dimitrios Gouglas
Portfolio Manager
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c/o Norwegian Institute of Public Health
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CEPI

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Subject: RE: CEPI invitation to vaccine R&D pipeline and cost tracking survey against epidemic infectious diseases

Dear Dr. William Roper and Colleagues,

I hope this email finds you well. As you are aware, the deadline for responses to CEPI's vaccine R&D pipeline and cost tracking survey has now passed.

Given your organization's role and insights in this space, your participation in the survey is highly valued. We would be happy to extend the deadline until 30th November 2017 in case you need additional time to respond to our request.

Your contributions will indeed be critical for informing gaps and plans for future investment opportunities in the field of emerging infectious disease vaccine R&D.

We look forward to hearing back from you.

Best regards,

Dimitrios Gouglas
Senior Advisor
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c/o Norwegian Institute of Public Health
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From: CEPI Pipeline
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Cc: 'wingate@med.unc.edu' <wingate@med.unc.edu>; 'heisem@med.unc.edu' <heisem@med.unc.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'rjohnston@globalvaccines.org' <rjohnston@globalvaccines.org>
Subject: RE: CEPI invitation to vaccine R&D pipeline and cost tracking survey against epidemic infectious diseases

Dear Dr. William Roper and Colleagues,

This is a kind reminder about our invitation to participate in a survey tracking vaccine R&D pipelines and associated funding needs against epidemic infectious diseases.

The survey is open until **10 November 2017**.

We hope that you will be able to complete the survey. Please do let us know in case you need additional time to respond to our request.

Your input is critical for informing CEPI's mapping of vaccine R&D efforts and for the planning of future investment opportunities in this space. We hope to hear back from you soon.

Best regards,

Dimitrios Gouglas
Senior Advisor
CEPI – Coalition for Epidemic Preparedness Innovations
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Cc: 'wingate@med.unc.edu' <wingate@med.unc.edu>; 'raquel_hernandez@ncsu.edu' <raquel_hernandez@ncsu.edu>;

'heisem@med.unc.edu' <heisem@med.unc.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'rjohnston@globalvaccines.org' <rjohnston@globalvaccines.org>
Subject: RE: CEPI invitation to vaccine R&D pipeline and cost tracking survey against epidemic infectious diseases

Dear Dr. William Roper and Colleagues,

This is a reminder about our invitation to participate in a survey to map status of vaccine R&D pipelines and associated funding needs against epidemic infectious diseases.

The survey is open until **10 November 2017**.

Your information will help CEPI identify vaccine R&D opportunities and funding needs to support future investments in this field.

We sincerely hope that you will be able to respond to our survey request.

Best regards,

Dimitrios Gouglas

Senior Advisor

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From: CEPI Pipeline
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Subject: CEPI invitation to vaccine R&D pipeline and cost tracking survey against epidemic infectious diseases

Dear Dr. William Roper and Colleagues,

I hope this email finds you well. Last week we launched a small survey to map status of vaccine R&D pipelines against epidemic infectious diseases and associated costs and funding need estimates. I am writing today to confirm whether you have received the invitation, whether you have been able to access the survey template, and whether you have any questions requiring clarification from us at this point.

We sincerely hope that you will be able to respond to our survey request. Your information will be critical for identifying vaccine R&D gaps, costs and funding needs, and for guiding CEPI plans for new vaccine R&D funding opportunities in the field in the near

future.

The survey is open until **10 November 2017**.

Thanks again in advance for taking part in this important effort. Please do not hesitate to contact us in case of any queries for clarification.

Best regards,

Dimitrios Gouglas

Senior Advisor

CEPI – Coalition for Epidemic Preparedness Innovations

c/o Norwegian Institute of Public Health

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Visiting address: Marcus Thranes Gate 3, Oslo, Norway

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www.cepi.net

CEPI

From: CEPI Pipeline
Sent: Wednesday, September 27, 2017 12:57 PM
To: 'Roper@med.unc.edu' <Roper@med.unc.edu>
Cc: 'wingate@med.unc.edu' <wingate@med.unc.edu>; 'raquel_hernandez@ncsu.edu' <raquel_hernandez@ncsu.edu>; 'heisem@med.unc.edu' <heisem@med.unc.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'rjohnston@globalvaccines.org' <rjohnston@globalvaccines.org>
Subject: CEPI invitation to vaccine R&D pipeline and cost tracking survey against epidemic infectious diseases

Dear Dr. William Roper and Colleagues,

CEPI, the Coalition of Epidemic Preparedness Innovations, is inviting you to participate in a survey that is mapping vaccine research and development (R&D) pipelines and associated costs for emerging infectious diseases.

The survey is open until **10 November 2017**.

CEPI: http://cepi.net/mission
CEPI is a new alliance between governments, industry, academia, philanthropy, intergovernmental institutions, such as the World Health Organization, and civil society, aiming to finance and coordinate the development of new vaccines to contain infectious disease epidemics and to prevent them becoming public health emergencies.

To achieve its strategic objectives, and to make efficient use of its financial resources, CEPI needs to draw on a variety of vaccine candidates and leverage diversity of product development partners. CEPI is currently building up a comprehensive knowledge base on available vaccine candidates and their current status, in order to serve vaccine preparedness needs against non-commercial epidemic disease threats.

Through the mapping of existing vaccine R&D pipelines, CEPI will be in a better position to efficiently and proactively invest in the development and manufacturing of vaccines against priority epidemic infectious diseases. This is relevant both for targeted Calls for Proposals as well as CEPI's overall strategic plan for responding to the newly emerging/unexpected pathogen outbreaks.

Our request

Through this survey, you are asked to:

- **Validate** the current status of development of a pre-filled list of vaccine candidates that our team has collated via literature searches, grant database searches and clinical trial registries searches over the past 12 months; including information on disease, stage of development, vaccine technology type, and product development partners.
- **Clarify** current sources of funding, development costs incurred and future funding needs for bringing the vaccines through phase II and potentially phase III in response to potential disease outbreaks.
- **Specify** main drivers of R&D costs and technical success to date and identify potential drivers of future costs and technical risks for bringing your vaccine candidates through late stages of clinical development.

Please note that CEPI is only requesting information through this survey on non-commercial epidemic infectious disease of interest to CEPI. This is not a broad industry database survey and there is no interest in collecting any information related to commercial R&D programs.

Diseases in scope

- Diseases that are of main interest to CEPI include those listed by the WHO Blueprint as priority diseases: Crimean Congo haemorrhagic fever, Lassa fever, MERS-CoV, Severe acute respiratory syndrome, Nipah, Rift Valley Fever, Chikungunya, Zika, Severe fever with thrombocytopaenia syndrome, Ebola, Marburg. (For more details, see http://www.who.int/blueprint/priority-diseases/en/).
- Other diseases that have epidemic potential and which are not included in the WHO priority list.

Survey findings will be used to create a deep and broad knowledge of the vaccine landscape pertinent to CEPI's mission and funding scope, analysis of survey data will contribute to understanding expected CEPI portfolio costs, likely resource mobilization and investment allocation needs in the near future. Aggregate, yet anonymized, vaccine pipeline and associated cost findings will be made publicly available in order to inform target audiences about the future funding needs to support CEPI's mission.

Please note that:

- Confidentiality of any reported, unpublished data will be strictly maintained including by not making any personally identifiable information publicly available.
- All survey data will be stored in a secure database.
- In case of any survey findings made publicly available, you will be contacted, notified about the intended format and purpose and asked for permission prior to any public sharing of any of your data.

If you have confidentiality concerns with disclosing data in this survey, please contact us. We are happy to provide you with a confidentiality agreement upon specific request.

Thank you in advance for taking part in this important effort. We look forward to sharing the results with you once our analysis is complete. Please do not hesitate to contact us in case of any clarifications required.

Kind regards,

Dimitrios Gouglas
Senior Advisor
CEPI – Coalition for Epidemic Preparedness Innovations
c/o Norwegian Institute of Public Health
Postal address: PO Box 4404, N-0403 Oslo, Norway
Visiting address: Marcus Thranes Gate 3, Oslo, Norway
Mob: (+47) 9865 7142
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CEPI

To: Roper, William L[william_roper@med.unc.edu]
Cc: Wingate, Vicki J[wingate@med.unc.edu]; Heise, Mark T[mark_heisem@med.unc.edu]; Baric, Ralph S[rbaric@email.unc.edu]; rjohnston@globalvaccines.org[rjohnston@globalvaccines.org]
From: CEPI Pipeline[pipeline@cepi.net]
Sent: Thur 7/5/2018 5:56:39 AM (UTC-04:00)
Subject: Invitation to CEPI RfI (MERS, Lassa, Nipah, Chikungunya)
CEPI Project Description Template_RfI Lassa MERS Nipah Chikungunya_July 2018.docx

Dear Dr. William Roper and Colleagues,
The Coalition for Epidemic Preparedness Innovations (CEPI) is pleased to invite you to participate in a Request for Information (RfI) to inform the potential development of a future Call for Proposals (CfP) on vaccine development for one or more of the following pathogens: Lassa, MERS, Nipah and Chikungunya; with R&D scope from preclinical through Phase II for Lassa, MERS, Nipah; and from preclinical through Phase III for Chikungunya.
More detailed instructions concerning requirements, content, criteria, and submission can be found below. The project description template with instructions is attached.
If you are interested in submitting an Expression of Interest, please send the completed project description template and any relevant attachments to pipeline@cepi.net by **4pm CEST on Friday, 3rd August 2018**.
If you are planning on submitting an Expression of Interest, please let us know by 12th July so that we can ensure sufficient human resource capacity will be in place to assess your proposal.
Please feel free to contact us with any questions concerning the development or submission of Expressions of Interest.
Many thanks for your time and consideration.
Kind regards,

Dimitrios Gouglas
Portfolio Manager
CEPI – Coalition for Epidemic Preparedness Innovations
Postal address: P.O. BOX 123, Torshov, 0412 Oslo
Visiting address: Marcus Thranes Gate 2, Oslo, Norway
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www.cepi.net

CEPI

Request for Information on vaccine development projects for Lassa, MERS, Nipah and Chikungunya

The Coalition for Epidemic Preparedness Innovations (CEPI) is conducting an assessment of vaccine technologies that could be used to address epidemic preparedness and response needs against Lassa, MERS, Nipah and Chikungunya. The information gathered through this Request for Information (RfI) will be used to inform the potential development of a future Call for Proposals (CfP) on vaccine development targeting one or more of these diseases. Expressions of interest to this RfI will help CEPI define the scope and overall budget ceiling for such a CfP. If a decision is made to go ahead with a CfP, it would likely be launched in late 2018 or 2019.

Intended recipients for this RfI

This RfI is open for all interested parties within the field of vaccine development. Information submitted through this RfI will be owned by CEPI, stored in a secure database and accessed only by staff of the organization. None of the information obtained through this RfI will be shared publicly.

Applicants who submitted proposals to the CEPI Lassa-MERS-Nipah CfP issued on 19 January 2017 are encouraged to adapt their applications to this RFI, highlighting areas of potential improvements or new data in relation to previous applications.

Minimum requirement for those submitting information to this RfI

- Organizations (not-for-profit, public, academic, industry, NGO, governmental and other) that can develop vaccines for at least one of the four target diseases.

- Preclinical data, ideally showing proof of concept of the platform on any of the four target diseases, in relevant animal models.

Criteria to be addressed in the Expression of Interest in response to this RfI

Criterion	Aspects to consider
1. Applicant competencies, experience & track-record	• Technical competency/expertise of project staff • Experience in preclinical testing of vaccines • Experience in conduct of clinical vaccine trials • Experience in regulatory interactions with competent authorities and licensing of vaccines • Manufacturing capabilities and skills
2. Technical feasibility	• Scientific rationale • Current development status/technical readiness of the platform • Reasonableness of the high-level preclinical development approach • Reasonableness of the high-level clinical development and regulatory approach
3. Manufacturing scalability & speed	• Soundness of manufacturing processes/technologies supporting the candidate vaccine • Current status/availability of manufacturing • Reasonableness of the high-level CMC approach
4. Use potential for target pathogens	• Suitability of the candidate vaccine for outbreak control • Suitability of the candidate vaccine for routine use
5. Use potential for new pathogens	• Suitability of the technology platform for other pathogens of the WHO priority list of emerging infectious diseases • Suitability of the technology platform for other pathogens beyond the WHO priority list of emerging infectious diseases

How to respond to this RfI

A project description template is attached. Applicants are encouraged to complete all fields. The Expression of Interest should communicate evidence on the current development status of the applicant's vaccine technology, plans for its preclinical and clinical development for one of the four target diseases, and budget required by R&D phase to advance its development from preclinical through late stages of clinical testing.

Deadline: 4 pm Central European Summer Time on 3rd of August 2018.

Submit the completed Expression of Interest template directly to pipeline@cepi.net. Your submission should include only one completed project description template per vaccine candidate. Additional attachments, including CVs, detailed budget estimates, and preclinical or clinical information are encouraged.

Important clarifications:

1. The applicant must have freedom to operate as related to IP, including consent from others where applicable.

2. Applicants should highlight areas in project description templates that contain sensitive or confidential information. Responses to this RfI will be reviewed by CEPI staff and experts who will be assigned following a thorough Conflict of Interest screening and will be bound by CEPI's Confidentiality and Transparency policy.

3. This RfI does not constitute any guarantee of CEPI funding.

4. Any additional information is welcome on vaccine candidates currently being developed for other WHO priority pathogens, or for any other infectious pathogen of epidemic preparedness importance (See section 10 of the project description template).

Important disclaimer:
This is the "Project description" template for the Request for Information (RfI) on Lassa, MERS, Nipah and Chikungunya vaccines, with scope from a) preclinical through Phase II for Lassa, MERS, Nipah; and b) preclinical through Phase III for Chikungunya. Instructions on how to complete the project description form are presented in *italics*. **You are encouraged to be as thorough as possible** in the given format as indicated. Before submission, please delete this disclaimer text, as well as all *guideline text* that is in *italics* in sections throughout this document, and replace with your own text. Please keep the headings in **bold** under each section and indicate if not applicable.

The text format requirements for the Project description template are:
- Arial Narrow theme font size 11
- Single spacing
- Preferred maximum page length for sections 2, 3, and 4: **10 pages**.
- No page length limitation for other sections.

In addition to this project description, you are encouraged to also submit:
- CVs or bio sketches of key staff
- Any additional material (e.g. publications or unpublished data) containing useful information on the maturity of the vaccine candidate or the organization's capabilities

Note that:
- The project description form should be returned to Alison Bettis, at pipeline@cepi.net .
- Information submitted to this RfI will be accessed by the CEPI Secretariat and External reviewers, who are bound by CEPI's Confidentiality and Transparency policy.

Deadline for proposal submission: **4p.m. Central European Summer Time, 3 August 2018**

1. Project summary

1.1. Project Title

Please give the title of the project.

1.2. Project summary (500 words)

Please give a summary of the proposed project, including rationale, technology, targeted pathogen, R&D objectives and expected outcomes, project duration and total project costs.

Please identify the development status of the candidate vaccine:
- *Current phase of vaccine development.*
  - *Choose one of the following categories:*
    - *Preclinical (candidate constructed, AND/OR immunogenicity data, AND/OR challenge data, AND/OR ready for Phase I clinical trial)*
    - *In Phase I clinical trials*
    - *Ready for Phase IIb / III clinical trials*
    - *In Phase IIb / III clinical trials*
- *Preclinical vaccine candidate which has shown:*
  - *Immunogenicity in small animal models: binding antibodies and / or functional antibodies*
  - *Protection in relevant animal models*
  - *Passive transfer protection*

- *Clinical vaccine candidate with:*
    - *FIH safety and immunogenicity data*
- *Safety and immunogenicity data in target population.*

In case you have previously submitted a proposal for funding to CEPI, please specify how the current proposal improves on previous submission(s) including an indication of new evidence generated to support such improvement.

2. About the applicant organization / consortium

2.1. About the applicant organization and cooperating partner(s)

Provide a brief description of the organization and cooperating partners. Describe size - number and experience of leadership and senior employees, key project staff R&D achievements, number of years in operation, research environment, any affiliations to national and international R&D networks, etc.

2.2. The experience and track record of applicant organization, principal investigator and cooperating partner(s)

Describe competence and experience in relation to the project, including:

Preclinical studies

Describe the experience and capacities for preclinical studies and investigations, including availability of animal facilities and testing experience in the project consortium for performing the project.

Phase I / II clinical vaccine trials

Describe the experience of applicant organization or consortium in clinical trials, including:

- *Previous clinical testing of vaccines in high-income countries*
- *Previous clinical testing of vaccines in low- and middle-income country settings (LMICs)*
- *Previous clinical testing of vaccines based on the proposed technology platform*
- *Establishing and running clinical trial sites*
- *Systems to ensure and track-record of GCP audits/inspections*

Bringing vaccine to IND and Phase II enabling studies

Describe the experience in bringing vaccine candidates to IND and Phase II enabling activities.

Phase III clinical efficacy vaccine trials

Describe the experience of applicant organization or consortium in clinical trials, including:

- *Previous experience with bringing vaccine projects through clinical development to licensure*
- *Previous clinical testing of vaccines in high-income countries*
- *Previous clinical testing of vaccines in low- and middle-income country settings (LMICs)*
- *Previous clinical testing of vaccines based on the proposed technology platform*
- *Establishing and managing clinical trial sites*

Bringing vaccines through a regulatory pathway over the past 10 years

Describe the experience in bringing vaccine candidates through standard regulatory pathways for market authorization, your track-record of licensing vaccines through alternative regulatory pathways for product registration and / or delivery for emergency use to national (e.g. US FDA's "Animal Rule") or supranational organizations (e.g. WHO EUAL). Include experience with WHO prequalification.

Manufacturing

Describe the manufacturing experience at various scales, including an overview of the manufacturing process steps and timing, and any form / fill / finish experience and timing for pandemic response (as needed).

Infrastructures and facilities in-house

Describe any infrastructure and facilities available to support the project.

Vaccine trials and associated results published by the applicant's PI in the last 5 years

Please list clinical trials, with trial ID hyperlink and associated results published by PI in the last 5 years.

2.3. Project governance and partners

Describe anticipated collaborations with key partners/vendors at a high level and the approach to manage all partners and deliverables. If partners / vendors have not yet been identified, simply list as "TBD".

3. Project status

3.1. The proposed vaccine candidate

Please describe the immunological principle, construct, formulation and proposed administration of the vaccine candidate.

3.2. Scientific rationale

Please describe the scientific rationale for:

- *The proposed vaccine candidate technology, rationale for antigen choice, antigen presentation and platform*
- *The immune response induced and likely mechanism for providing protection against the target pathogen*
- *The mode and route of vaccine application*
- *If an adjuvant is used, rationale for its use/selection*

3.3. Preclinical evidence to date

Please describe the current state of preclinical development for the proposed vaccine candidate, including:

- *Data on immunogenicity for the targeted or relevant pathogens including functional antibody responses and protective immunity*
- *Data on protection in relevant animal challenge models*
- *Data on passive protection (transfer of antibodies or lymphocytes)*
- *Data on toxicology studies relevant for the planned trial*

3.4. Clinical evidence to date

Please describe any safety and immunogenicity data from Phase I / First in human (FIH) trials if available. Include safety, reactogenicity and immunogenicity data, study population, assays validates, and any concerns/observations.

3.5. Assays, animal models and supporting relevant data developed

Please provide a brief description of research achievements produced by your consortium that will directly support the development of the candidate in this proposed project, such as:

- *Assays suitable for assessment of immunological responses to vaccine for targeted or relevant pathogen*
- *Animal models developed*
- *Antigen characterization*
- *Protective mechanism studies relevant for the target pathogens*

3.6. Evidence from other pathogens

Please give a description of any data available on the same vaccine platform for pathogens other than Lassa, Nipah, MERS-CoV, or Chikungunya, including preclinical, toxicology, safety and reactogenicity profiles, especially data from candidates in a more advanced stage of development or already licensed. Also include if there are any particular points of attention based on the experience to date with the candidate vaccine or the platform, such as points raised by ethical committees / DSMBs / regulatory agencies.

3.7. Evidence on Chemistry, Manufacturing & Control (CMC)

Describe the status of Good Manufacturing Practice (GMP) activities (as needed), including information (if possible) on any of the following areas (the areas to include depend on the phase of development):

- *Drug substance & drug product / vaccine CMC activities (e.g. Analytical methods; Purity & impurity characterization; Quality assurance / control)*
- *Manufacturing capacity*
- *Costs Of Goods Sold (COGS) and/or estimates including rationale for these*

4. Project approach

4.1. Non / preclinical product development approach

Provide initial thoughts on a preclinical/non-clinical development approach including any high-level plans and rationale for:

- *Establishing key immunogenicity/efficacy data in relevant animal models*
- *Dose-ranging/rationale for doses for clinical testing*

4.2. Clinical Development approach

Provide initial thoughts on a clinical development approach through Phase I, Phase IIa and Phase IIb / III (if applicable), including high-level clarifications on:

- *Likely clinical objectives and anticipated endpoints*
- *Possible clinical trial plans, locations and numbers of study subjects for safety, immunogenicity and efficacy studies*
- *Target study populations*

4.3. Strategy for regulatory approval of trials and product

Describe your initial thoughts on a regulatory strategy that you would take to be under review within WHO emergency use assessment and listing procedure (EUAL), when applicable[1].

Provide a high-level thinking for obtaining regulatory advice with respect to preclinical and clinical development, regulatory approval to conduct clinical trials including in low- and middle-income countries (LMICs), and regulatory approval for licensure.

4.4. Chemistry, Manufacturing & Control (CMC) approach

Provide initial thoughts on a CMC approach, including high-level clarifications on:

- *Production processes from preclinical through Phase I ("First-in-Man") to end of Phase II studies and beyond (if relevant)*
- *Platform validation with regards to purity, safety, stability and BSE risk*
- *Other Quality assurance/ control processes (as relevant)*

[1] http://www.who.int/medicines/news/public_consult_med_prods/en/

5. Timeline

5.1. Time-to-completion

Include a preliminary timeline for vaccine development from preclinical through clinical phases of development, including initial thoughts on critical milestones by R&D phase. (Note: the purpose of this timeline is to understand the high-level intent).

6. Target Product Profile

Please describe the Target Product Profile (TPP) for the vaccine candidate in the table below and how this could affect the use of the vaccine or response to emergency situations. Where a WHO TPP already exists (i.e., for Lassa, Nipah, and MERS vaccines), please highlight any deviations from this TPP.

Vaccine characteristics	Expected	Rationale / Justification
Indication for use	*Include contra-indications*	
Target population		
Safety/Reactogenicity		
Measures of efficacy	*Include response time for protective immunity*	
Dose regimen		
Duration of protection		
Route of administration		
Coverage		
Product stability and storage		
Presentation		
Registration and prequalification		

7. Risk assessment

Describe your initial view of challenges to the success of this project and any preliminary thoughts on mitigation.

8. Anticipated use potential

8.1. Suitability of the vaccine candidate for use in disease outbreak settings

Describe how the vaccine candidate would be used in an outbreak situation, highlighting aspects of the expected target product profile especially suitable for an outbreak response. Include aspects related to the expected product profile.

8.2. Suitability of the vaccine candidate for routine use

Describe whether and how the vaccine candidate could and would be used routinely (e.g. expanded programmes on immunization, especially relevant for Lassa and Chikungunya).

8.3. Application to other pathogens

Describe if the platform has been or could be suitable for other pathogens, including those of the WHO priority list of emerging infectious diseases.

9. Budget and sources of funding

9.1. Sources of funding

Please indicate the overall budget required for developing the proposed vaccine candidate, including an overall justification of your estimate, explaining where possible the key drivers of costs by R&D phase.

9.2. Budget

Please provide a high-level indication of budget by phase of development, including an overall justification of your cost estimates.

	Total budget (US$)	***FTE (#)***	***Total indirect costs (as percentage of total costs %)***	***Rationale / Comments / Justification***
Preclinical				- *e.g. for immunology, challenge studies, stability and toxicology studies* - *e.g. for production of Phase I clinical trial material (CTM)* - *e.g. for program management or other*
Phase I				- *e.g. Phase I trial planning and execution costs* - *e.g. Phase II CMC enabling costs* - *e.g. program management or other*
Phase II				- *e.g. Phase II trial planning and execution costs* - *e.g. Phase III CMC enabling costs* - *e.g. program management or other*
Phase III (where relevant)				- *e.g. Phase III trial planning and execution costs* - *e.g. CMC costs* - *e.g. program management or other*
Total costs				

10. Other information

10.1. Status of vaccine pipeline in other pathogens of epidemic importance

Please indicate any other vaccine that you are currently actively developing or that is on hold due to financing constraints, and which is targeting one of the WHO priority pathogens, or any other infectious pathogen of epidemic preparedness importance. Please clarify:

- *Name of vaccine candidate*
- *Type of platform technology*
- *Current phase of development (discovery; preclinical; Phase I; Phase II; Phase III)*
- *Current status of development (active; on hold)*
- *Funding need (in US$) to advance the vaccine candidate through preclinical, Phase I, Phase II, stockpiles for Phase IIb / III, Phase III, and stockpiles for emergency use (up to 1m doses) – as relevant*

To: Roper, William L[william_roper@med.unc.edu]
Cc: Wingate, Vicki J[wingate@med.unc.edu]; Heise, Mark T[mark_heisem@med.unc.edu]; Baric, Ralph S[rbaric@email.unc.edu]; rjohnston@globalvaccines.org[rjohnston@globalvaccines.org]
From: CEPI Pipeline[pipeline@cepi.net]
Sent: Wed 7/11/2018 6:47:51 AM (UTC-04:00)
Subject: RE: Invitation to CEPI RfI (MERS, Lassa, Nipah, Chikungunya)

Dear Dr. William Roper and Colleagues,

This is a kind reminder that anyone planning to submit an Expression of Interest (EoI) in response to this Request for Information (RfI) should inform CEPI of their plans by **tomorrow, 12 July 2018**.

Please note: All communication that takes place after 12 July (submission guidance, answering FAQs, etc.) will be directed **only to groups that have indicated their plans to submit an EoI**. If you haven't informed CEPI of your plans to submit an EoI, you will not receive this important information.

The deadline for EoI submission is Friday, 03 August. More information, including instructions and the project description template, can be found in the previous email (below). Please let us know if you have any questions.

Kind regards,

Alison Bettis

Project Manager
CEPI – Coalition for Epidemic Preparedness Innovations
Visiting address: Marcus Thranses gate 2, 0473 Oslo, Norway
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E-mail: alison.bettis@cepi.net
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CEPI

From: CEPI Pipeline
Sent: torsdag 5. juli 2018 11:57
To: Roper@med.unc.edu
Cc: wingate@med.unc.edu; heisem@med.unc.edu; rbaric@email.unc.edu; rjohnston@globalvaccines.org
Subject: Invitation to CEPI RfI (MERS, Lassa, Nipah, Chikungunya)

Dear Dr. William Roper and Colleagues,
The Coalition for Epidemic Preparedness Innovations (CEPI) is pleased to invite you to participate in a Request for Information (RfI) to inform the potential development of a future Call for Proposals (CfP) on vaccine development for one or more of the following pathogens: Lassa, MERS, Nipah and Chikungunya; with R&D scope from preclinical through Phase II for Lassa, MERS, Nipah; and from preclinical through Phase III for Chikungunya.
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Please feel free to contact us with any questions concerning the development or submission of Expressions of Interest.
Many thanks for your time and consideration.
Kind regards,

Dimitrios Gouglas
Portfolio Manager
CEPI – Coalition for Epidemic Preparedness Innovations
Postal address: P.O. BOX 123, Torshov, 0412 Oslo
Visiting address: Marcus Thranes Gate 2, Oslo, Norway
e: dimitrios.gouglas@cepi.net

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CEPI

Request for Information on vaccine development projects for Lassa, MERS, Nipah and Chikungunya

The Coalition for Epidemic Preparedness Innovations (CEPI) is conducting an assessment of vaccine technologies that could be used to address epidemic preparedness and response needs against Lassa, MERS, Nipah and Chikungunya. The information gathered through this Request for Information (RfI) will be used to inform the potential development of a future Call for Proposals (CfP) on vaccine development targeting one or more of these diseases. Expressions of interest to this RfI will help CEPI define the scope and overall budget ceiling for such a CfP. If a decision is made to go ahead with a CfP, it would likely be launched in late 2018 or 2019.

Intended recipients for this RfI

This RfI is open for all interested parties within the field of vaccine development. Information submitted through this RfI will be owned by CEPI, stored in a secure database and accessed only by staff of the organization. None of the information obtained through this RfI will be shared publicly.

Applicants who submitted proposals to the CEPI Lassa-MERS-Nipah CfP issued on 19 January 2017 are encouraged to adapt their applications to this RFI, highlighting areas of potential improvements or new data in relation to previous applications.

Minimum requirement for those submitting information to this RfI

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- Preclinical data, ideally showing proof of concept of the platform on any of the four target diseases, in relevant animal models.

Criteria to be addressed in the Expression of Interest in response to this RfI

Criterion	Aspects to consider
1. Applicant competencies, experience & track-record	• Technical competency/expertise of project staff • Experience in preclinical testing of vaccines • Experience in conduct of clinical vaccine trials • Experience in regulatory interactions with competent authorities and licensing of vaccines • Manufacturing capabilities and skills
2. Technical feasibility	• Scientific rationale • Current development status/technical readiness of the platform • Reasonableness of the high-level preclinical development approach • Reasonableness of the high-level clinical development and regulatory approach
3. Manufacturing	* Soundness of manufacturing processes/technologies supporting the

scalability & speed	candidate vaccine • Current status/availability of manufacturing • Reasonableness of the high-level CMC approach
4. Use potential for target pathogens	• Suitability of the candidate vaccine for outbreak control • Suitability of the candidate vaccine for routine use
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How to respond to this RfI

A project description template is attached. Applicants are encouraged to complete all fields. The Expression of Interest should communicate evidence on the current development status of the applicant's vaccine technology, plans for its preclinical and clinical development for one of the four target diseases, and budget required by R&D phase to advance its development from preclinical through late stages of clinical testing.

Deadline: 4 pm Central European Summer Time on 3rd of August 2018.

Submit the completed Expression of Interest template directly to pipeline@cepi.net. Your submission should include only one completed project description template per vaccine candidate. Additional attachments, including CVs, detailed budget estimates, and preclinical or clinical information are encouraged.

Important clarifications:

1. The applicant must have freedom to operate as related to IP, including consent from others where applicable.

2. Applicants should highlight areas in project description templates that contain sensitive or confidential information. Responses to this RfI will be reviewed by CEPI staff and experts who will be assigned following a thorough Conflict of Interest screening and will be bound by CEPI's Confidentiality and Transparency policy.

3. This RfI does not constitute any guarantee of CEPI funding.

4. Any additional information is welcome on vaccine candidates currently being developed for other WHO priority pathogens, or for any other infectious pathogen of epidemic preparedness importance (See section 10 of the project description template).

To: Baric, Ralph S[rbaric@email.unc.edu]
From: Fang Li[lifang@umn.edu]
Sent: Thur 1/9/2020 1:12:41 AM (UTC-05:00)
Subject: new coronavirus from Wuhan

Hi Ralph,

I assume you have heard the news. Will you be available to talk on the phone?

Best,
Fang

--
****
Fang Li, Ph.D.
Associate Professor
Department of Veterinary and Biomedical Sciences
University of Minnesota Twin Cities
612-625-6149, lifang@umn.edu
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****

Organizer: Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]

From: Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]

Attendees: Webby, Richard; malik; Ghazi Kayali; Yoshi Kawaoka; R.A.M. Fouchier; 'adolfo.garcia-sastre@mssm.edu'; Richard Rothman; Pekosz, Andrew S. (apekosz@jhsph.edu); Schultz-Cherry, Stacey; 'david_topham@urmc.rochester.edu'; Orenstein, Walter; Lowen, Anice; Baric, Ralph S; 'Perlman, Stanley'; daszak@ecohealthalliance.org; Post, Diane (NIH/NIAID) [E]; lsauer2@jhmi.edu; Ryan Camping; Melissa Uccellini; McKenzie, Pamela; Neu, Donna; Kathryn Shaw-Saliba; Collins, Erin-Joi; Stemmy, Erik (NIH/NIAID) [E]; Lampley, Rebecca (NIH/VRC) [F]; Andy Pekosz; Baric, Toni C

Location: GoToMeeting- updated information below

Importance: High

Subject: Wuhan Pneumonia response - setting up a call

Start Time: Tue 1/14/2020 10:00:00 AM (UTC-05:00)

End Time: Tue 1/14/2020 11:00:00 AM (UTC-05:00)

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Wuhan Pneumonia response

Tue, Jan 14, 2020 10:00 AM - 11:00 AM (EST)

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Cc: 'ryan.camping@mssm.edu' <ryan.camping@mssm.edu>; 'Melissa Uccellini' <melissa.uccellini@mssm.edu>; 'McKenzie, Pamela' <Pamela.McKenzie@STJUDE.ORG>; 'Neu, Donna' <Donna_Neu@URMC.Rochester.edu>; 'Kathryn Shaw-Saliba' <kshaw15@jhu.edu>; 'Collins, Erin-Joi' <emcneal@emory.edu>; Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>; Lampley,

Rebecca (NIH/VRC) [F] <rebecca.lampley@nih.gov>
Subject: RE: Wuhan Pneumonia response - setting up a call
Importance: High

Hi everyone,

Thanks for your responses to the poll. It looks like **Tuesday January 14th at 10am ET** will be the best time to meet. I'll send a placeholder invitation shortly with call-in information to follow.

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Marciela

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Hi all,

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I know it is already such a busy time – but I'm hopeful since we know the drill for these sorts of things that preparing now will help us.

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(Coordinators – this is FYI only and for scheduling, you don't have to be on the call)

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Location: GoToMeeting- updated information below

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Wuhan Pneumonia response

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To: William Dowling[william.dowling@cepi.net]
Cc: Baric, Toni C[antoinette_baric@med.unc.edu]
From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]
Sent: Thur 1/23/2020 10:19:57 PM (UTC-05:00)
Subject: RE: WHO Consultation regarding the Wuhan coronavirus

I can make the call, which is 3PM Eastern Standard Time in the US. ralph

---

From: William Dowling <william.dowling@cepi.net>
Sent: Thursday, January 23, 2020 4:40 PM
To: Carolyn Clark <carolyn.clark@cepi.net>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; larry.wolfraim@nih.gov; Raul Gomez Roman <raul.gomezroman@cepi.net>; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S <rbaric@email.unc.edu>; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL) <Vasan.Vasan@csiro.au>; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; christian.brechot@pasteur.fr; Kayvon Modjarrad <kmodjarrad@eidresearch.org>
Cc: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; GSELL, Pierre <gsellp@who.int>; COSTA, Alejandro Javier <costaa@who.int>; RIVEROS BALTA, Alina Ximena <lauriex@who.int>
Subject: WHO Consultation regarding the Wuhan coronavirus

Hello all,

On behalf of the WHO R&D Blueprint team, I am writing to request your participation on a call tomorrow at 9 PM Central European time (which will be Saturday morning for some of you). The purpose of the call is to lend your expertise to coordination of WHO response efforts. To that end , we would like to discuss the current status of efforts to culture the Wuhan coronavirus (or generate a recombinant virus); recent sequence data and modeling of the Spike protein; and potential next steps to assess cross reactivity with other coronaviruses. We realize that this is very short notice, but the situation is very dynamic. This would be an initial call with lengthier and more detailed calls in the near future.

Also, for those who have not seen them, I am attaching two reports on this topic that just came out and are highly relevant to the conversation.

Please let us know if you can make it. Call in details will be sent tomorrow.

Thank you,

Bill Dowling (seconded to WHO)

William Dowling, PhD

Non-Clinical Vaccine Development Leader

CEPI New vaccines for a safer world

(+1) 202 800-3148 (o)
(+1) 202 897-8180 (m)

William.dowling@cepi.net

1901 Pensylvania Ave, NW, Suite 1003, Washington, DC 20006 USA

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www.cepi.net

To: Wang Linfa[linfa.wang@duke-nus.edu.sg]; Carolyn Clark[carolyn.clark@cepi.net]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; larry.wolfraim@nih.gov[larry.wolfraim@nih.gov]; Raul Gomez Roman[raul.gomezroman@cepi.net]; Miles.Carroll@phe.gov.uk[Miles.Carroll@phe.gov.uk]; barney.graham@nih.gov[barney.graham@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; Baric, Ralph S[rbaric@email.unc.edu]; vincent.munster@nih.gov[vincent.munster@nih.gov]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; Vasan, Vasan (H&B, Geelong AAHL)[Vasan.Vasan@csiro.au]; jokim@ivi.int[jokim@ivi.int]; mksong@ivi.int[mksong@ivi.int]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; leejooyeon@korea.kr[leejooyeon@korea.kr]; limhy0919@korea.kr[limhy0919@korea.kr]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; christian.brechot@pasteur.fr[christian.brechot@pasteur.fr]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]
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From: William Dowling[william.dowling@cepi.net]
Sent: Fri 1/24/2020 3:47:40 AM (UTC-05:00)
Subject: RE: WHO Consultation regarding the Wuhan coronavirus

Dear Lin-Fa,
This is 9 PM Central Europe time on Friday Jan 24. I will be sending an outlook invite shortly with call -in details and agenda.
Thank you
Bill

From: Wang Linfa <linfa.wang@duke-nus.edu.sg>
Sent: Friday, January 24, 2020 9:10 AM
To: William Dowling <william.dowling@cepi.net>; Carolyn Clark <carolyn.clark@cepi.net>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; larry.wolfraim@nih.gov; Raul Gomez Roman <raul.gomezroman@cepi.net>; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; rbaric@email.unc.edu; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL) <Vasan.Vasan@csiro.au>; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; christian.brechot@pasteur.fr; Kayvon Modjarrad <kmodjarrad@eidresearch.org>
Cc: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; GSELL, Pierre <gsellp@who.int>; COSTA, Alejandro Javier <costaa@who.int>; RIVEROS BALTA, Alina Ximena <lauriex@who.int>
Subject: RE: WHO Consultation regarding the Wuhan coronavirus

Dear Bill,

Just to follow up with the exact timing of the meeting.

Do you mean 9 PM Central European time on Friday 24 Jan or Saturday 25 Jan as we received your email on Friday 24 Jan.

Thanks

LF

Linfa (Lin-Fa) WANG, PhD FTSE
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From: William Dowling <william.dowling@cepi.net>
Sent: Friday, 24 January 2020 5:40 AM
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Cc: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; GSELL, Pierre <gsellp@who.int>; COSTA, Alejandro Javier <costaa@who.int>; RIVEROS BALTA, Alina Ximena <lauriex@who.int>
Subject: WHO Consultation regarding the Wuhan coronavirus

Hello all,

On behalf of the WHO R&D Blueprint team, I am writing to request your participation on a call tomorrow at 9 PM Central European time (which will be Saturday morning for some of you). The purpose of the call is to lend your expertise to coordination of WHO response efforts. To that end , we would like to discuss the current status of efforts to culture the Wuhan coronavirus (or generate a recombinant virus); recent sequence data and modeling of the Spike protein; and potential next steps to assess cross reactivity with other coronaviruses. We realize that this is very short notice, but the situation is very dynamic. This would be an initial call with lengthier and more detailed calls in the near future.

Also, for those who have not seen them, I am attaching two reports on this topic that just came out and are highly relevant to the conversation.

Please let us know if you can make it. Call in details will be sent tomorrow.

Thank you,

Bill Dowling (seconded to WHO)

William Dowling, PhD

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Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation regarding the Wuhan coronavirus

Start Time: Fri 1/24/2020 3:00:00 PM (UTC-05:00)

End Time: Fri 1/24/2020 4:00:00 PM (UTC-05:00)

Required Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E]; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL); linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot@pasteur.fr; Kayvon Modjarrad

Letko_2020_receptor usage of 2019 nCoV.pdf

Zhao et al 2020 supp data.pdf

Zhou et al 2020.pdf

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Please let us know if you can make it. Call in details are below.

Thank you,

Bill Dowling (seconded to WHO)

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Functional assessment of cell entry and receptor usage for lineage B β-coronaviruses, including 2019-nCoV

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Abstract

Over the past 20 years, several coronaviruses have crossed the species barrier into humans, causing outbreaks of severe, and often fatal, respiratory illness. Since SARS-CoV was first identified in animal markets, global viromics projects have discovered thousands of coronavirus sequences in diverse animals and geographic regions. Unfortunately, there are few tools available to functionally test these novel viruses for their ability to infect humans, which has severely hampered efforts to predict the next zoonotic viral outbreak. Here we developed an approach to rapidly screen lineage B betacoronaviruses, such as SARS-CoV and the recent 2019-nCoV, for receptor usage and their ability to infect cell types from different species. We show that host protease processing during viral entry is a significant barrier for several lineage B viruses and that bypassing this barrier allows several lineage B viruses to enter human cells through an unknown receptor. We also demonstrate how different lineage B viruses can recombine to gain entry into human cells and confirm that human ACE2 is the receptor for the recently emerging 2019-nCoV.

Introduction

Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) first emerged in humans in 2003 after transmitting from animals in open air markets in China[1,2]. Shortly thereafter, several genetically related viruses were identified in Chinese Horseshoes bats (*Rhinolophus sinicus*)[3-7]. At the same time, improvements in next generation sequencing technology lead to a boom of virus discovery, uncovering thousands of novel virus sequences in wild animal populations around the world. While most of these viruses have never been found in humans, many are genetically similar to known human viruses within the betacoronaviruses (β-CoV) genus. The β-CoVs are further divided into four lineages: lineage B, which includes SARS-CoV and the newly emerging 2019-nCoV, has approximately 200 published virus sequences whereas lineage C, which includes MERS-CoV, has over 500 viral sequences.

Every year, additional novel CoV sequences are discovered. However, there is a massive knowledge gap in the field as very little work is performed after the viral sequences are published. Therefore, it is unknown whether these novel viruses have the potential to emerge in human populations.

Current methods for studying novel β-CoVs are technically demanding. Viral isolation from field samples is rarely successful and reverse genetics recovery of recombinant virus is labor-intensive, and expensive as synthesis of a single genome can cost upwards of $15,000. These limitations are prohibitive to studying novel CoVs at the scale in which they are discovered.

Cell entry is an essential component of cross-species transmission, especially for the β-CoVs. All CoVs encode a surface glycoprotein, spike, which binds to the host-cell

receptor and mediates viral entry[8]. For β-CoVs, a single region of the spike protein called the receptor binding domain (RBD) mediates the interaction with the host cell receptor. After binding the receptor, a nearby host protease cleaves the spike, which releases the spike fusion peptide, facilitating virus entry[9-12]. Known host receptors for β-CoVs include angiotensin converting enzyme 2 (ACE2) for SARS-CoV and dipeptidyl peptidase 4 (DPP4) for MERS-CoV[13,14].

Structural studies of coronaviruses have shown that the spike RBD is capable of folding independently from the rest of the spike protein and contains all of the structural information for host receptor binding[15]. Additionally, a previous study showed that replacing the RBD of the lineage B bat virus, Rp3, allowed the virus to enter cells expressing human ACE2 (hACE2)[16]. We therefore developed a method to functionally test the RBDs from novel lineage B β-CoVs in place of the SARS-CoV spike RBD (figure 1). Synthesizing just the RBD of spike is much faster and cost-effective than conventional pseudotyping methods that rely on synthesis of the full ~4kb spike sequence for novel CoVs: a process that can take weeks and is cost-prohibitive for large panels of spike sequences. The short turnaround time for our approach allowed us to test the receptor usage of all published, unique RBD sequences in lineage B, and also rapidly confirm the ACE2 receptor usage of the 2019-nCoV spike, which emerged in China in January 2020 as our study was ongoing.

We show that lineage B RBDs divide into functionally distinct clades and that several previously-unappreciated viruses exhibit compatibility with an unknown receptor on human cells. We also show that these clades are capable of recombining to impart human host-cell entry phenotypes, and that, beyond the RDB-receptor interaction, host

protease processing is another species barrier encountered by lineage B β-CoVs during cell entry.

Methods

Cells

293T, A549, BHK, Caco-2, Huh-7.5, PK-15, and Vero cells were maintained in DMEM (Sigma) supplemented with 10% FBS, penicillin/streptomycin, and L-glutamine. RhiNi/40.1, AJ-primary, AJ*i*, HypNi, RaKSM-2.5i, RhiLu, and RhiNi cells were maintained in DMEM/F12 (Gibco) supplemented with 12% FBS, penicillin/streptomycin, non-essential amino acids, sodium pyruvate and L-glutamine. AJ-primary cells were immortalized with a lentiviral vector expressing SV40 T-antigen following the manufacturer's instructions to generate AJ*i* cells (abm; #G203). RaKSM-2.5 primary cells have been previously described and were immortalized in this study similar to AJ*i* cells[17].

Plasmids

The spike coding sequences for SARS-CoV Urbani, As6526, and BM48-31 were codon optimized for human cells, appended with a 5' kozak expression sequence (GCCACC) and 3' tetra-glycine linker followed by nucleotides encoding a FLAG tag sequence (DYKDDDDK). For SARS-CoV spike, silent mutations were introduced around codons 308 and 519 to form KpnI and XhoI digest sites. For As6526 spike, silent mutations were introduced around codons 290 and 501 to form AflII and HindIII digest sites. For BM48-31 spike, silent mutations were introduced around codons 295 and 501 to form AflII and HindIII digest sites. These engineered spike sequences were synthesized and cloned into pcDNA3.1+ (GenScript).

Spike RBDs were first codon-optimized for human cells, appended with regions of the target spike backbone to facilitate Infusion cloning and synthesized as double

stranded DNA fragments (IDT DNA). SARS-CoV, As6526 or BM48-31 engineered spike plasmids were digested with their corresponding restriction enzymes and gel purified. RBD inserts were resuspended in water and Infusion cloned into gel purified, digested spike backbone vectors (Takara).

Human ACE2 (Q9BYF1.2), DPP4 (XM_005246371.3), or APN (NP_001141.2) were synthesized and cloned into pcDNA3.1+ (GenScript). All DNA constructs were verified by Sanger sequencing (ACGT Inc.).

Receptor transfection

BHK cells were seeded in black 96-well plates and transfected the next day with 100ng plasmid DNA encoding human ACE2, DPP4, APN or empty vector, using polyethyleneimine (Polysciences). All downstream experiments were performed 24 hours post-transfection.

Pseudotype production

Pseudotypes were produced as previously described[18]. 293T cells were seeded onto 6-well plates pre-coated with poly-L-lysine (Sigma) and transfected the next day with 1200ng empty plasmid and 400ng of plasmid encoding coronavirus spike or GFP as a no pseudotype control. Twenty-four hours later, transfected cells were infected with VSVΔG particles pseudotyped with VSV-g as previously described[19]. After one hour of incubating at 37°C, cells were washed three times and incubated in 2mL DMEM supplemented with 2% FBS, penicillin/streptomycin, and L-glutamine for 48 hours. Supernatants were collected, centrifuged at 500xG for 5 minutes, aliquoted and stored at -80.

Luciferase-based cell entry assay

Target cells were seeded in black 96-well plates and inoculated, in triplicate, with equivalent volumes of pseudotype stocks. For trypsin experiments, pseudotype stocks were diluted 1:1 in DMEM without FBS, trypsin was added to a final concentration of 2500µg/mL and samples were incubated at 37°C for 15 minutes. Samples were then diluted again 1:1 in cold DMEM supplemented with 2% FBS and added to cells. Inoculated plates were centrifuged at 1200xG, 4°C, for 1 hour and incubated over night at 37°C. Approximately 18-20 hours post-infection, Bright-Glo luciferase reagent (Promega) was added to each well, 1:1, without removing culture media and luciferase was measured. Relative entry was calculated by normalizing the relative light unit (RLU) for spike pseudotypes to the plate RLU average for the “no pseudotype control.”

Western blot

Producer cells (spike-transfected 293T) were lysed in 1%SDS, 150mM NaCl, 50mM Tris-HCl, 5mM EDTA and clarified by centrifugation at 14000xG for 20 minutes. Pseudotyped particles were concentrated from producer cell lysates that were overlaid a 10% OptiPrep cushion in PBS (Sigma) and centrifuged at 20,000× g for 2 hours at 4 °C. Lysates and concentrated particles were analyzed for FLAG, GAPDH and/or VSV-m expression on 10% Bis-Tris PAGE gel (ThermoFisher).

Accession numbers

Accession numbers for all spike sequences used here can be found in figure s1b.

Results

ACE2 entry is lineage B clade 1-specific

The receptor binding domain (RBD) of lineage B β-CoVs is a single, continuous domain that contains all structural information necessary to interact with the host receptor (figure 1a, b). We introduced silent mutations in the codon optimized coding sequence for SARS-CoV to facilitate replacing the SARS RBD with the RBD from other lineage B viruses (figure 1b). All lineage B sequences were downloaded from online repositories and parsed to 29 unique RBD sequences, representing all published variations of the lineage B RBD (supp. fig 1a, b). The panel of 29 RBDs phylogenetically cluster into 3 clades, as previously described[5], but these RBD clades were not apparent in phylogenetic analysis of other viral sequences, such as the RNA-dependent RNA polymerase (supp. fig 1c). All 29 RBDs were codon optimized, synthesized and cloned in place of the SARS RBD, effectively generating chimeric spike expression constructs. We then generated VSV-luciferase reporter particles pseudotyped with the chimeric spikes (figure 1c). We chose VSV over lentiviruses as our pseudotype platform because a lentiviral pseudotypes have failed to accurately reflect viral entry with novel bat coronavirus spike protein[7]. All constructs exhibited similar levels of expression in producer cells and incorporation into VSV pseudotypes, except the chimera with BM48-31 which displayed somewhat reduced expression compared to WT SARS spike (figure 1d). We then infected BHK cells expressing the receptor for SARS-CoV or empty vector (figure 1e) and observed only clade 1, which includes SARS-CoV, WIV1 and SHC014, could enter cells transfected with human ACE2 (figure 1e).

Protease enhances clade 2 entry

After binding the host receptor, host-cell protease cleaves spike, releasing the fusion peptide and allowing for host cell entry [20]. Previous studies have shown that absence of the host protease or incompatibility between the host protease and viral spike can block viral entry [21-24]. To circumvent host-cell protease incompatibility or absence, we treated our lineage B pseudotype panel and infected a wide variety of cell types from different host species (figure 2, supp. fig. 2). In the absence of exogenous protease, only clade 1 infected cells from African green monkey kidney, human gastrointestinal tract, human liver, and porcine kidney, in agreement with previous studies (figure 2; supp. fig. 2a, b). Surprisingly, exogenous protease enhanced entry of a subset of clade 2 spike chimeras in nonhuman primate, bat and human cells (figure 2). Importantly, VSV-g pseudotyped particles were able to produce luciferase signal in all cell lines tested in this study (supp. fig. 2c).

Clade 2 entry is receptor-dependent

We next tested human variants of known β-CoV receptors for their ability to mediate cell entry of clade 2 and 3 spike chimeras. We also tested human aminopeptidase N (APN), a receptor for alphacoronaviruses, which have been shown to utilize either human ACE2 or human APN for cell entry (figure 3a). Protease treatment only enhanced entry of clade 1 RBDs on cells expressing human ACE2, but not human DPP4 or APN. No entry was observed with clade 2 or 3 spikes, regardless of receptor or protease addition. Human dipeptidyl peptidase IV (DPP4), the receptor for the lineage C β-CoVs, MERS-CoV, only mediated entry of MERS-CoV (figure 2b, middle panels).

Importantly, in the absence of receptor, no entry was observed for any of the pseudotypes, suggesting that protease-mediated entry is receptor-dependent (figure 2b, right panels).

Receptor usage of 2019-nCoV

While our study was ongoing, a novel lineage B virus tentatively named 2019-nCoV was identified as the cause of a pneumonia outbreak in Hubei, China. Once the sequence was publicly available, we synthesized, cloned and tested the RBD from 2019-nCoV in our assay with human variants of known coronavirus receptors. The chimeric SARS-2019-nCoV spike protein expressed and was incorporated into particles similarly to other clade 1 chimeric spikes (figure 3c). The 2019-nCoV RBD was capable of entering cells expressing human ACE2, but not any of the other receptors tested (figure 3d; s3).

Clade determinants for ACE2 usage

Consensus sequences of the three lineage B clades showed several key differences between these groups. Only clade 1 RBDs contain all 14 residues that have been shown through crystallography, to interact with human ACE2 (figure 4a; s4). The majority of these residues are absent from clades 2 and 3, which contain additional deletions in surface exposed loops that cluster at the interface with ACE2 (figure 4 a, b). We generated a series of clade consensus RBD variants to determine the minimum number of mutations needed to impart ACE2 function on clade 2 and 3 RBDs (figure 4c). Introducing the two loop deletions from clade 1 in clade 2 results in a reduced spike expression, impaired pseudotype incorporation and loss of cell entry (figure 4c, d).

Restoring these loops in clade 2 and 3 from the loops found in clade 1 did not enhance entry with ACE2 (figure 4c; 2→1 and 3→1 version 1). Introducing all 14 ACE2 contact points in clade 2 or 3 also failed to restore ACE2 entry (figure 4c; 2→1 and 3→1 version 2). Only replacing all 14 contact points and the surrounding amino acids (also known as the receptor binding motif, RBM) lead to increased ACE2 entry with clade 2 and 3 RBDs (figure 4c; 2→1 version 3 = clade 2 residues 322-400 + clade 1 residues 400-501; 3→1 version 3 = clade 3 residues 322-385 + clade 1 residues 386-501). Taken together, these results show that the entire RBM from clade 1 is needed for ACE2 entry.

Full-spike and RBD chimeras are comparable

We next synthesized full-length clade 2 and 3 spikes to compare to our RBD chimeras. We selected the clade 2 spike, As6526, because it consistently gave strong entry signal in human cells following protease-treatment (figure 2b) as well as BM48-31, the only clade 3 spike in our panel. As we did for SARS-CoV spike, clade 2 and 3 spikes were codon optimized, FLAG-tagged and silent mutations were introduced to facilitate replacing their RBD with the consensus RBD from clade 1 (figure 5a). All chimeric constructs expressed similarly, with the exception for the SARS-BM48-31 RBD chimera, which exhibited reduced expression and incorporation (figure 5b). Protease treatment enhanced entry of both the As6526 clade 2 RBD chimera and full-length spike entry into Huh cells (figure 5c). Protease treatment had no effect on either the BM48-31 clade 3 chimera or full-length spike (figure 5c). Taken together, these findings show that SARS-lineage B RBD chimeras reflect the entry phenotype of full-length lineage B spikes.

Finally, we tested if receptor-binding and protease processing are coupled. We replaced the RBD of full-length clade 2 and 3 spike with the consensus RBD from clade 1 and tested pseudotypes on cells expressing the clade 1 receptor. The clade 1 consensus RBD efficiently facilitated entry of both As6526 and BM48-31 spike only following protease treatment. These findings show that even though BHK-hACE2 cells support full-length clade 1 spike entry, just having the RBD from a clade 1 virus is insufficient to mediate entry. As seen in our previous experiments, protease treatment did not enhance pseudotype entry in the absence of host receptor (figure 5).

Discussion

Despite significant advances in next generation sequencing technologies, which have facilitated the discovery of thousands of novel animal-derived viruses, tools for downstream functional assessment of these novel sequences are lacking. To gain traction on this ever-growing problem, we took a reductionist approach to coronavirus entry and developed a scalable, BSL2-compatible method for testing only the minimal region of the virus essential for interacting with the host receptor (figure 1, figure s1a). Because most of these viruses have never been isolated, we resorted to synthetic biology and molecular engineering to reduce the burden of gene synthesis to just a small fragment. Thus, the cost and synthesis production time for testing several spikes for entry in our system is dramatically reduced (figure s1d). In theory, this approach to functional viromics should be applicable to a wide variety of virus-host proteins and interactions.

Coronavirus entry is a multi-step process involving multiple, distinct domains in spike that mediate virus attachment to the cell surface, receptor engagement, protease processing and membrane fusion[8]. While the RBD:receptor interaction is most studied in this process, recent studies have highlighted the major role host protease processing plays as a species barrier[22,25-27]. Lineage C coronaviruses include MERS-CoV as well as distantly related viruses such as HKU4, HKU5 and PDF-2180 [28,29]. Studies have shown that HKU4 can bind human DPP4 but requires addition of exogenous trypsin to facilitate cell entry and that HKU5 and PDF-2180 spikes can enter human cells through an unidentified receptor with protease treatment[22,26]. Analogous to these earlier studies of lineage C CoVs, we observed protease-enhanced entry of lineage B CoVs (figure 2, 3, 5). While it has been shown that host proteases cleave spike, allowing for downstream

membrane fusion, other evidence suggests that protease may act on the receptor as well to activate it[30]. Addition of protease during the course of SARS-CoV infection facilitated entry in cells with low-expression of ACE2 that is normally insufficient to support virus entry[30]. Indeed, we saw evidence of residual trypsin activity on the cells after infection in our studies as the cell monolayer was loose compared to the untreated condition. Similarly, Menachery et al. also observed cell rounding during their trypsin infections[26]. Therefore, further studies are needed to assess where trypsin is enhancing entry of coronaviruses: at the level of spike, the receptor, or both.

In the absence of exogenous protease, only clade 1 RBDs entered nonhuman primate, human and porcine cell lines (figure 2a, b, s2a, b). These findings are in strong agreement with previous studies that have either isolated virus (WIV1) or rescued recombinant chimeric viruses (SHC014, Rs4231, Rs7237)[5,7,31]. However, with trypsin, a subset of genetically-similar clade 2 RBDs gained entry in these cells, suggesting their barrier is at the level of protease processing (figure 2a, b). The other spike from clade 2 and 3 did not enter the cells we tested, regardless of protease addition, suggesting an absent or incompatible receptor. Surprisingly, the protease-dependent entry phenotype was consistent in the reverse spike chimeras in which we replaced the RBD in clade 2 or 3 spike with a clade 1 RBD (figure 5d), suggesting that either the protease site between S1/S2 is not compatible with the chimeric spike backbone or the protease is not expressed in these cells (figure s5). Because clade 1 spikes enter cells expressing human ACE2 without addition of protease but clade2-clade1 chimeras require protease, our data suggests the spike protease cleavage site is adapted to the protease environment of the receptor-bound RBD (figure s5).

None of the spike pseudotypes efficiently entered *Rhinolophus* cells, which has been observed in previous studies using these cells[32,33] (figure 2c). Surprisingly, AJi cells were selectively permissive for only clade 2 entry following protease treatment, which suggests that clade 2 RBDs interact with a receptor that is distinct from clade 1 (figure 2c).

Our results show that, despite all being classified as the same virus species, most lineage B β-CoVs do not use currently known coronavirus receptors (figure 1e, 3a, b). Critically, we did not observe any pseudotype entry in the presence of protease and absence of receptor, suggesting that lineage B cell entry is still receptor-dependent following protease treatment (figure 3b). While our study was ongoing, a novel lineage B β-CoV was identified as the etiological agent behind an outbreak of pneumonia in Wuhan, Hubei, China (2019-nCoV). The RBD for 2019-nCoV has residues and motifs found in all 3 clades but forms a distinct clade, so we tested it for receptor usage and observed entry only with human ACE2 but not other known coronavirus receptors (figure 3d). Interestingly, within the backbone of SARS-CoV spike, cell entry of 2019-nCoV was similar to the other clade 1 spikes tested, including SARS-CoV. These finding suggests 2019-nCoV is capable of using human ACE2 as efficiently as SARS-CoV, which may help explain the human-to-human transmissibility of this virus. More studies are needed with the full spike sequence and, ideally, a viral isolate.

The receptor binding motif (RBM) is a small region in the C-terminal half of the RBD and contains all the residues that interface with the host receptor (figure 3a)[15]. The 14 contact points in the co-structure of the SARS-RBD bound to human ACE2 are largely absent from clade 2 and 3 RBDs, which also contain deletions compared to clade 1 RBMs (figure 4a, b, s4a). Simply mutating clade 2 and 3 to have the 14 contact points was

insufficient to impart human ACE2 usage (figure 4c). This is likely because the non-contact residues in the RBM play a supportive and structural role for these contact points, and indeed, these non-contact residues are different between the clades (figure s4).

In contrast to changing individual amino acids, our chimeric RBD constructs show that clade 2 and 3 RBD containing the clade 1 RBM are compatible with human ACE2. Coronaviruses frequently undergo recombination, gaining large swaths of genetic material at once [34,35]. Taken together with our data, it is possible that recombination with a clade 1 virus will impart compatibility with human ACE2. Interestingly, the 2019-nCoV RBD forms a clade that is distinct from the other 3 clades (figure s1c). However, the 2019-nCoV RBD contains most of the contact points with human ACE2 that are found in clade 1 as well as some amino acid variations that are unique to clade 2 and 3 (figure s4b). Taken together with our receptor assay results, it may be possible that 2019-nCoV arose from recombination between clade 1 and the other clades.

As we saw with the SARS-As6526 RBD (clade 2) spike chimera, full length As6526 spike entered cells following protease treatment, but BM48-31 (clade 3) spike did not (figure 2, 5c). These data show that the chimeric spikes generally reproduce the entry phenotypes of full-length spikes. Notably, the full length As6526 spike did not enter cells as efficiently as the SARS-As6526 chimera, suggesting that other human-cell adaptations are likely needed in As6526 spike.

The capacity to predict the zoonotic potential of newly detected viruses has been severely hindered by a lack of functional data for these novel animal virus sequences. Here, we have developed a rapid and cost-effective platform to functionally test large groups of related viruses for zoonotic potential. We found that several other lineage B

coronaviruses are capable of entering human cells through an unknown receptor and that lineage B spike proteins can recombine to gain entry with a known host-receptor. Taken together with the latest outbreak of 2019-nCoV in humans, these findings underscore the importance of continued surveillance of coronaviruses at the sequence and functional levels in order to better prepare for the next emerging virus.

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Declarations of Interests

The authors declare no competing interests.

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Figures

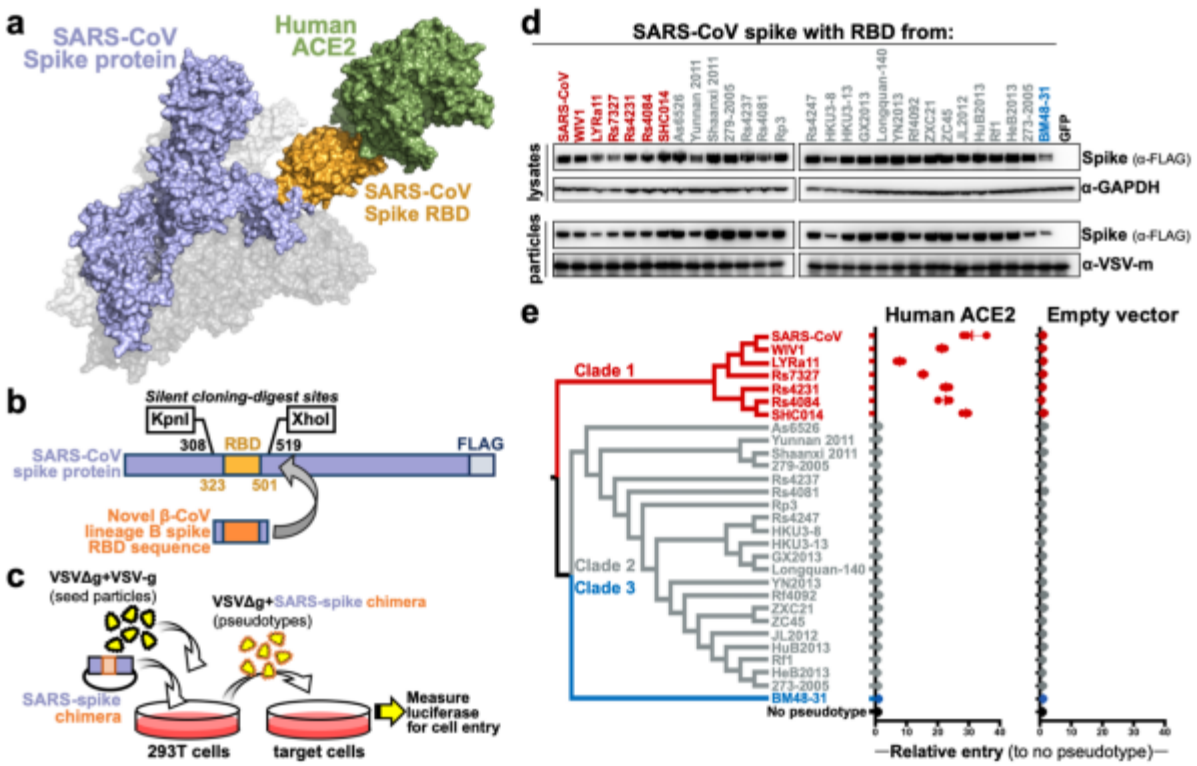

Figure 1: β-Coronavirus lineage B entry with human ACE2 is clade-specific

a, β-Coronaviruses, including SARS-CoV, interact with the host cell receptor via the Receptor Binding Domain (RBD) in spike (PDB: 5X5B, 2AJF) . **b,** SARS-CoV spike was engineered with silent mutations to facilitate cloning novel RBD sequences in place of the SARS spike RBD. SARS spike amino acid numbers are indicated for silent cloning sites and the RBD in grey and orange, respectively. **c,** outline of experimental workflow. **d,** Westernblot of producer cell lysates and concentrated reporter particles. **e,** BHK cells were transfected with either human ACE2 or empty vector, subsequently infected with VSV-reporter particles pseudotyped with chimeric spikes, luciferase was measured and normalized to no pseudotype as a readout for cell entry. Shown are the data for 3 replicates.

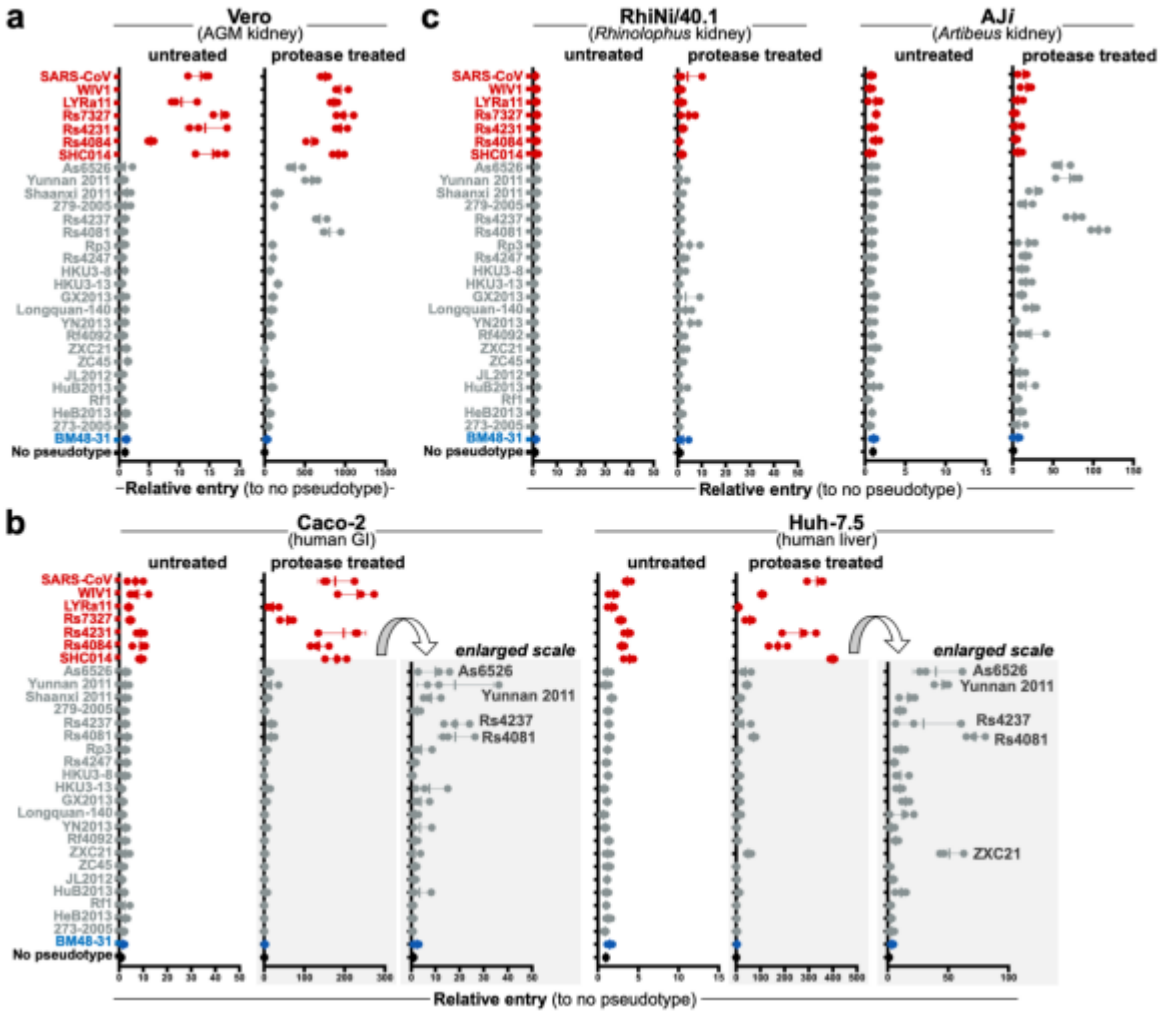

Figure 2: Trypsin enhances lineage B entry in various cell lines

a, Primate cells, **b,** human cells or **c,** bat cells were infected with VSV-particles pseudotyped with the lineage B chimeric spike panel. Pseudotypes were either left untreated or incubated with trypsin before addition to the cells. Luciferase was measured and normalized to particles produced without pseudotype. Shown are the data for 3 replicates.

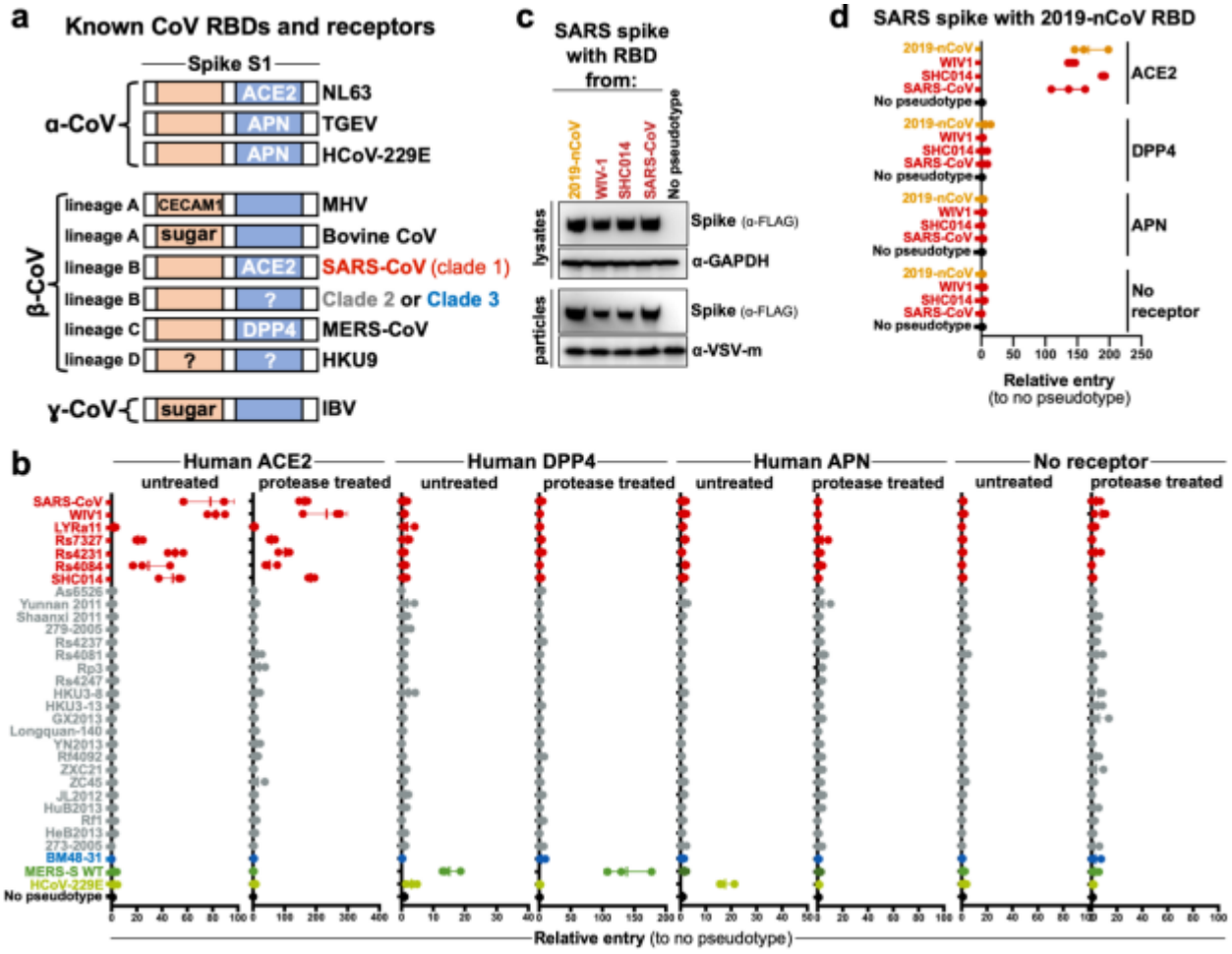

Figure 3: Lineage B entry into cells with known CoV receptors

a, Schematic of known coronavirus RBDs and their receptors. **b,** Pseudotyped particles were either left untreated and treated with trypsin and subsequently used to infect BHK cells transfected with the coronavirus receptor indicated. Shown are data from 3 replicates. **c,** Expression and pseudotype incorporation of SARS-S-2019-nCoV RBD chimeras. **d,** Pseudotypes were used to infect cells expressing hACE2, hDPP4, hAPN, or empty vector, without protease treatment.

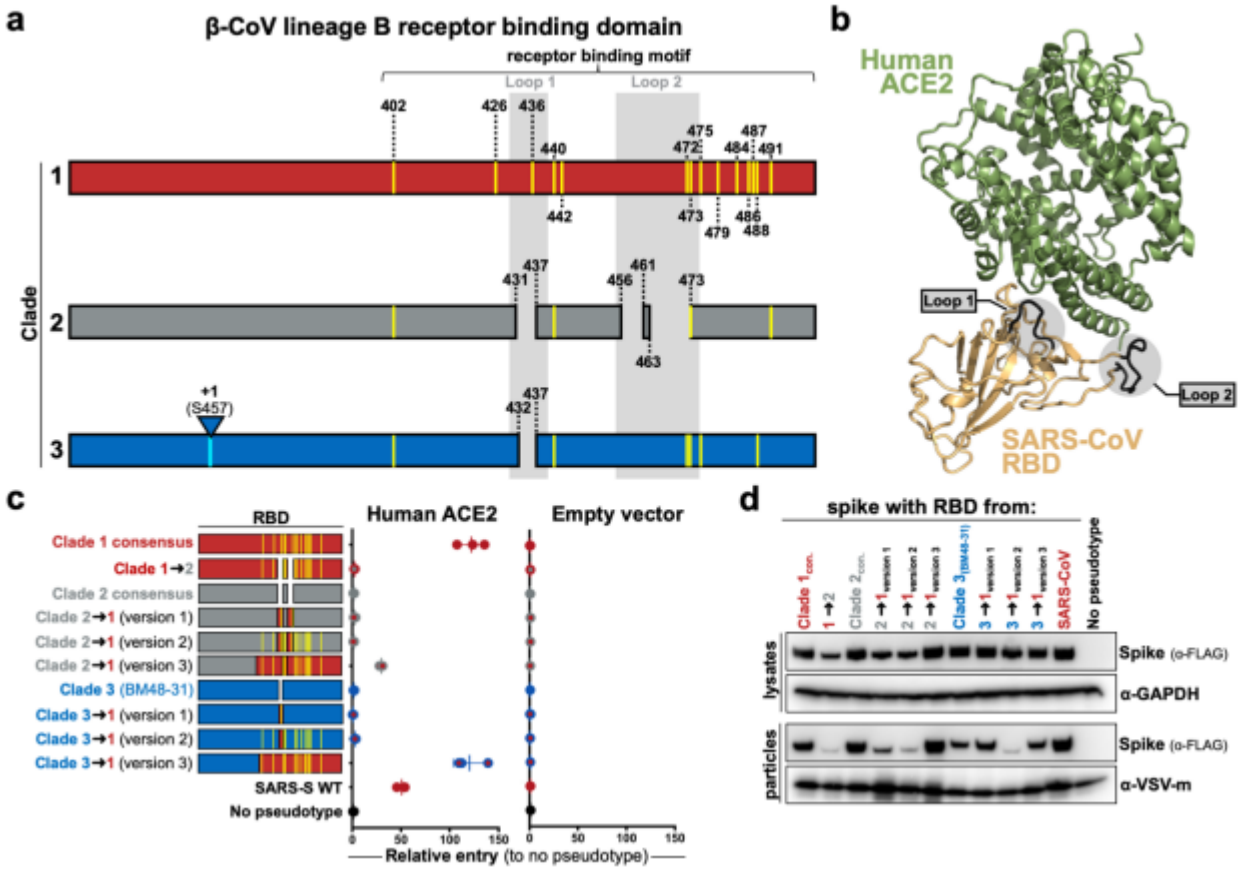

Figure 4: Lineage B clade-specific determinants for human ACE2 usage

a, Schematic overview of clade 1, 2 and 3. Highlighted in yellow are the 14 residues that contact human ACE2. Deletions in loops 1 and 2 are indicated for clades 2 and 3. **b,** Structure of human ACE2 and the SARS-S RBD (PDB: 2AJF), with loops highlighted in gray. **c,** VSV pseudotypes were generated with the indicated RBD and used to infect BHKs transfected with either human ACE2 or empty vector. Shown are data for 3 replicates. **d,** Westernblot of producer cell lysates and concentrated pseudotyped particles.

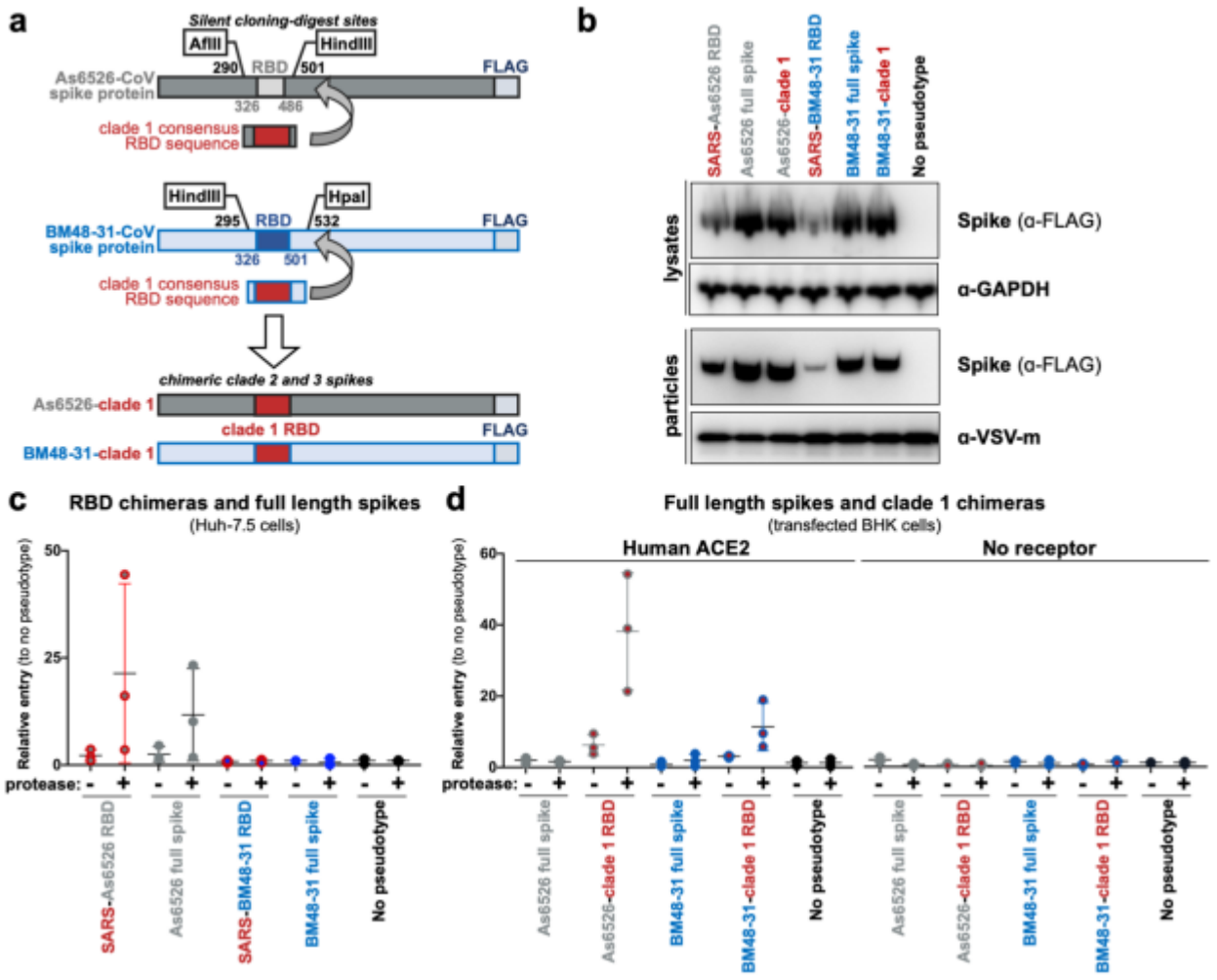

Figure 5: Comparison of chimeric and full-length clade 2 and 3 spikes

a, Full length spike sequences from As6526 (clade 2) and BM48-31 (clade 3) were codon optimized, FLAG tagged and synthesized. Silent mutations flanking the RBD facilitated replacing the native RBD with the clade 1 consensus RBD. **b,** Westernblot of producer cell lysates and concentrated pseudotypes particles. **c,** Pseudotypes with indicated spike constructs were left untreated or treated with trypsin and subsequently used to infect Huh-7.5 cells. Shown are data for 3 replicates. **d,** Pseudotypes with indicated spike constructs were left untreated or treated with trypsin and subsequently used to infect BHK cells transfected with human ACE2. Shown are data for 3 replicates.

Supplementary materials

Discovery of a novel coronavirus associated with the recent pneumonia outbreak in humans and its potential bat origin

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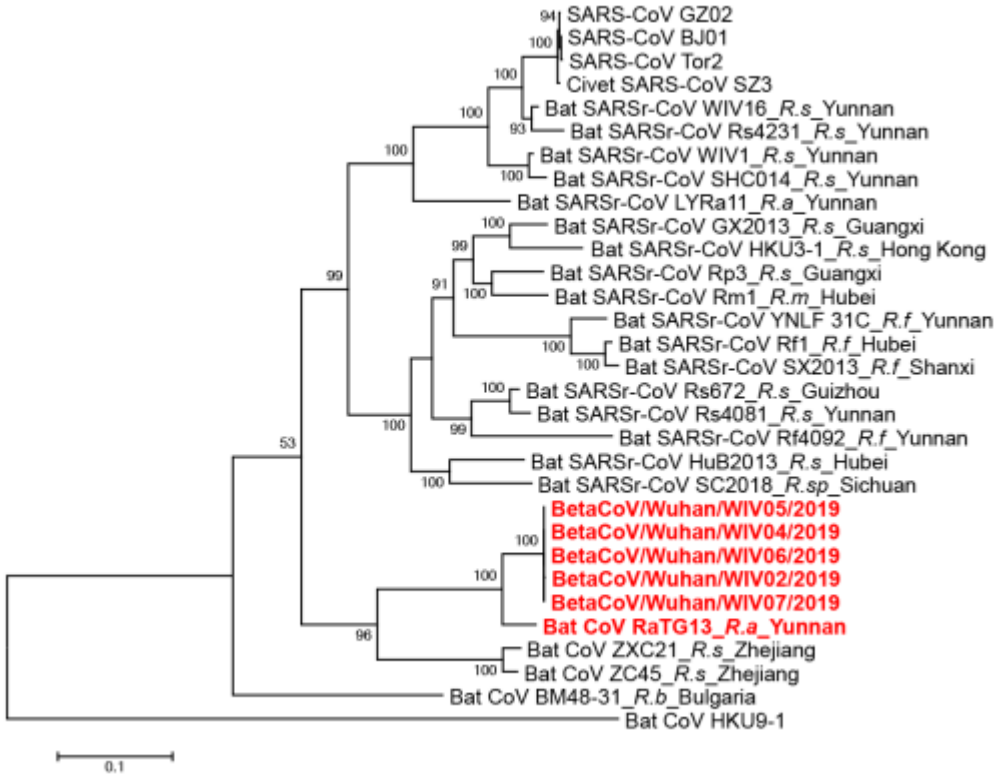
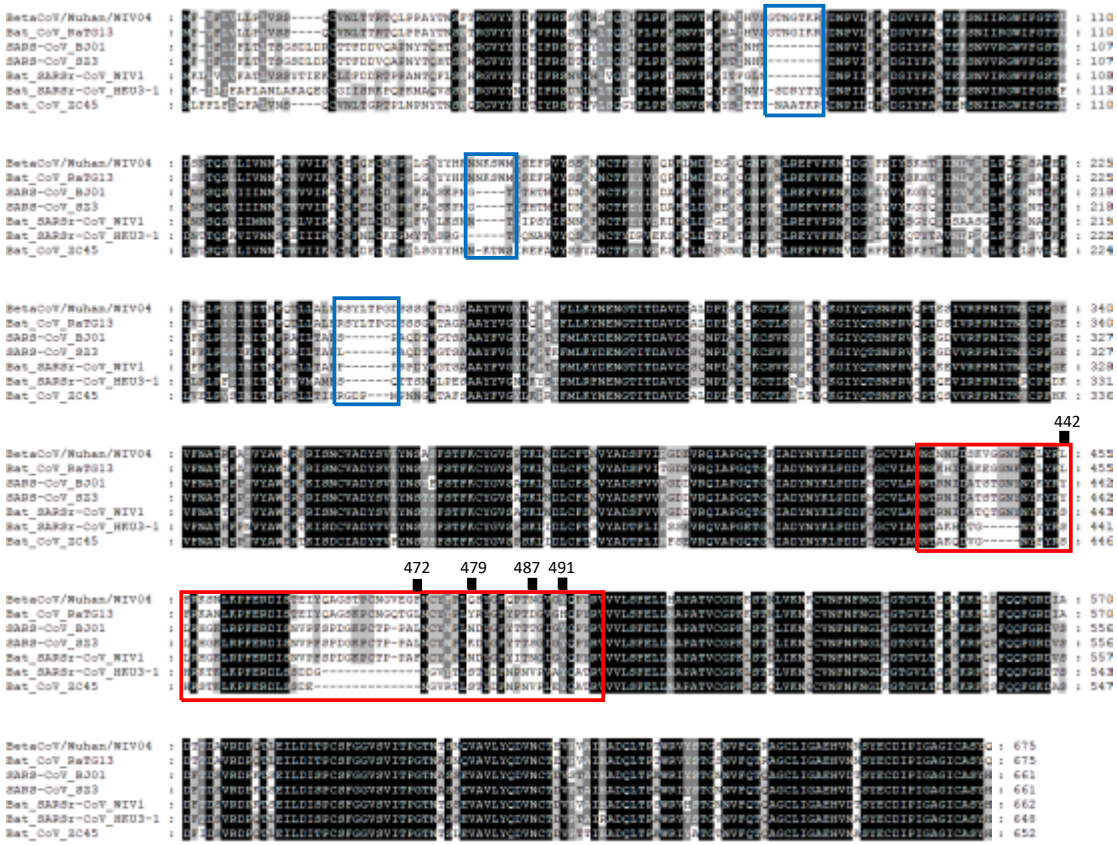
Extended Data Fig. 1 | Map of Wuhan. Wuhan, located in central China Hubei province (circled), has more than 11 million citizens.

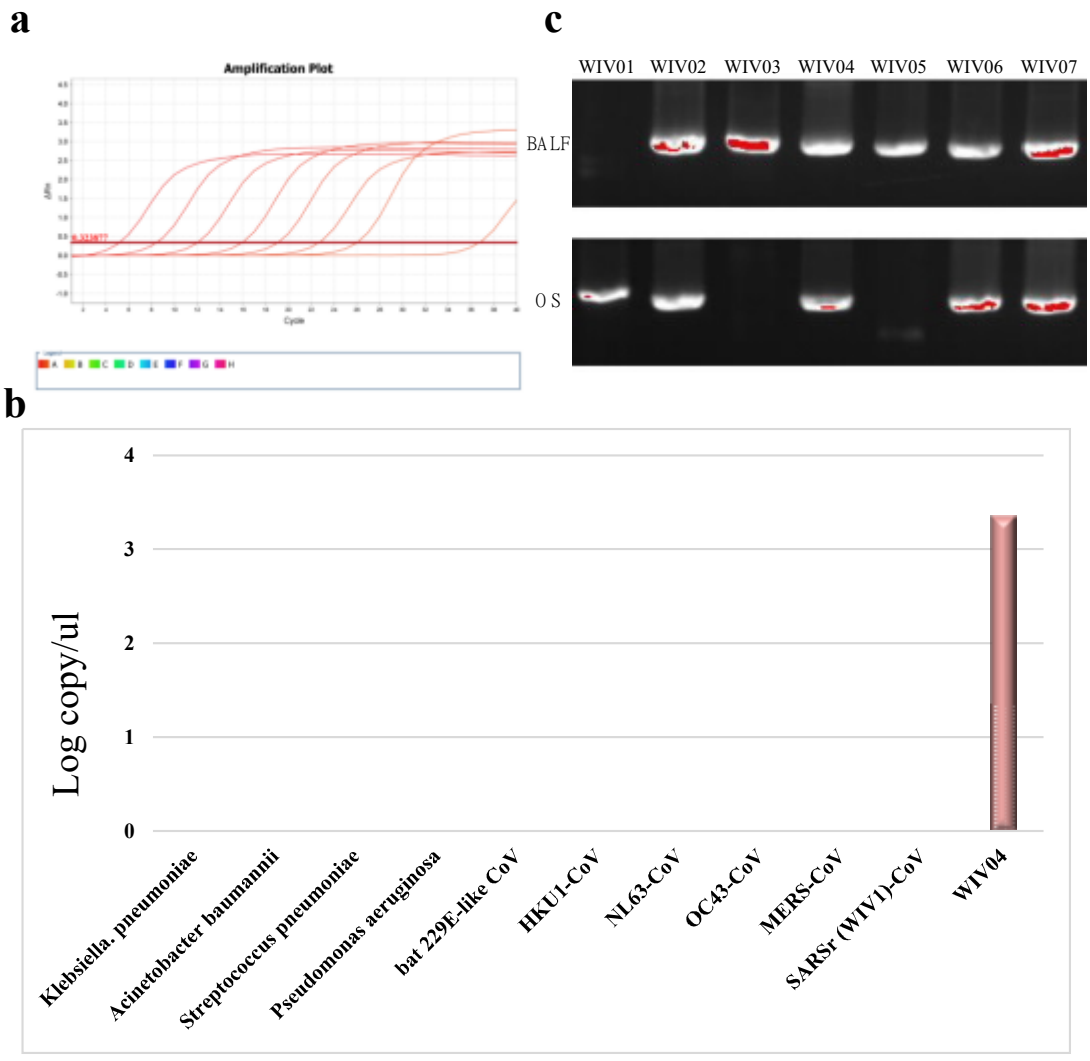
Extended Data Fig. 2 | Phylogenetic tree base on the complete S gene sequence. nCoV-2019 and bat CoV RaTG13 are in bold. R.s, *Rhinolophus sinicus*; R.a, *Rhinolophus affinis*; R.f, *Rhinolophus ferrumequinum*; R.m, *Rhinolophus macrotis*; R.b, *Rhinolophus blasii*. Bat CoV HKU9-1 was used as outgroup. The trees were constructed by the maximum likelihood method using the Jukes-Cantor model with bootstrap values determined by 1000 replicates. Bootstraps > 50% are shown.



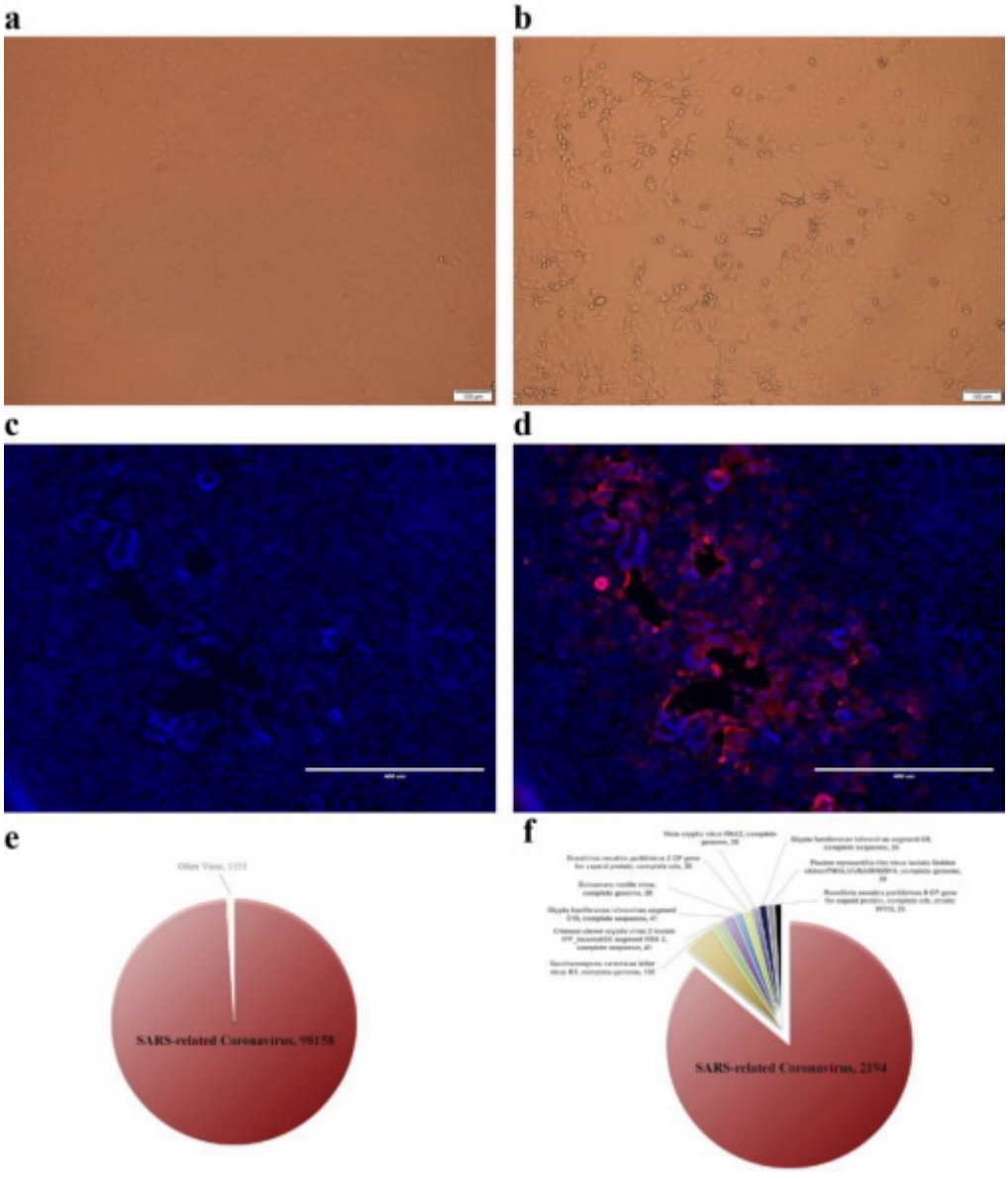
Extended Data Fig. 3 | Amino acid sequence alignment of the S1 protein of the nCoV-2019 with SARS-CoV and selected bat SARSr-CoVs. The receptor-binding motif of SARS-CoV and the homologous region of other coronaviruses are indicated by the red box. The key amino acid residues involved in the interaction with human ACE2 are numbered on top of the aligned sequences. The short insertions in the N-terminal domain of the novel coronavirus are indicated by the blue boxes. Bat CoV RaTG13 was identified from *R. affinis* in Yunnan Province. Bat CoV ZC45 was identified from *R. sinicus* in Zhejiang Province.



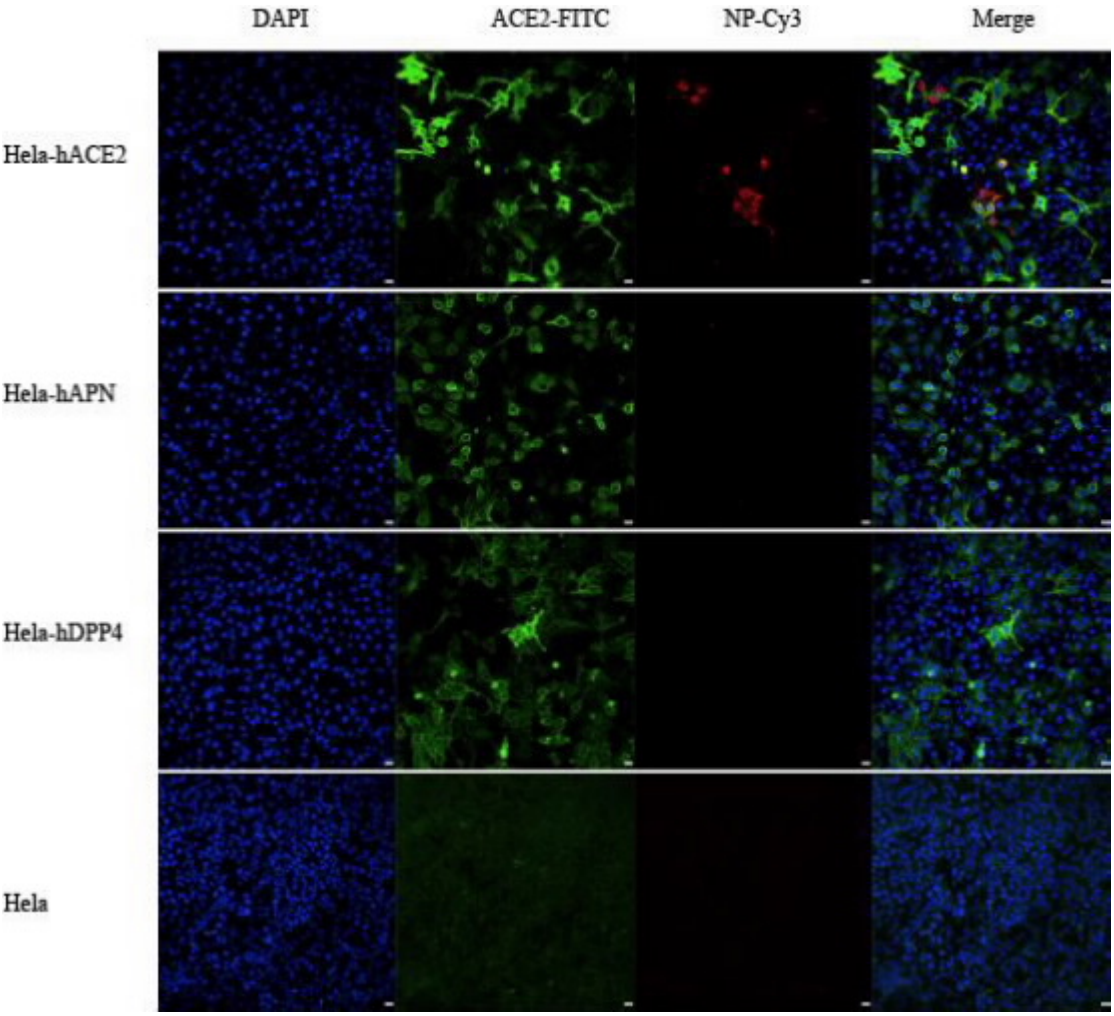
Extended Data Fig. 4 | Molecular detection method set up for nCoV-2019. **a**, molecular detection using conventional PCR. Primer sequence can be found in material and methods. **b**, standard curve for qPCR primers. PCR product of spike gene that was serial diluted to 10^8 to 10^1 (from left to right) was used as template. Primer sequence and experiment condition can be found in material and methods. **c**, specificity of qPCR primers. Nucleotide samples from the indicated pathogens were used.



Extended Data Fig. 5 | Isolation and antigenic characterization of nCoV-2019. Vero E6 cells are shown at 24 hours post infection with mock (**a**) or nCoV-2019 (**b**). **c** and **d** are mock or nCoV-2019 infected samples stained with rabbit serum raised against recombinant SARSr-CoV Rp3 N protein (red) and DAPI (blue). The experiment was conducted two times independently with similar results. **e** and **f,** pie charts illustrating ratio of reads number related to nCoV-2019 among total viral related reads in metagenomics analysis of Vero (**e**) and Huh7 (**f**) cell culture supernatant.



Extended Data Fig. 6 | Analysis of nCoV-2019 receptor usage. Determination of virus infectivity in HeLa cells with or without the expression of human APN and DPP4. ACE2 protein (green), viral protein (red) and nuclei (blue) were shown. Scale bar=10 um.



Extended Data Table 1 | Patient information and their diagnosis history (some records are missing). All patients are fresh seafood market peddlers or deliverymen except ICU-01, whose contact history is unclear. All patients were in intensive care unit (ICU) during the first investigation, and now in stable condition. Blood IgM tests have been performed for the following respiratory pathogens for all patients: legionella pneumophilia, mycoplasma pneumoniae, chlamydia pneumoniae, respiratory syncytial virus, adenovirus, rickettsia, influenza A virus, influenza B virus, parainfluenza virus.

Patient No.	Gender	Age	Date of Onset	Date of Admission	Symptoms When Admitted	Current Status (2020.01.13)	Diagnosis history
ICU-01*	Male	62	2019.12.12	2019.12.27	fever	recover, discharged	negative
ICU-04	Male	32	2019.12.19	2019.12.29	fever, cough, dyspnea	fever, intermittent cough	negative
ICU-05	Male	40	2019.12.17	2019.12.27	fever (38 ºC), expectoration, malaise, dyspnea	fever, malaise, intermittent cough	AdV (IgM)
ICU-06	Female	49	2019.12.23	2019.12.27	fever (37.9 ºC), palpitation	fever, malaise, cough	Coronavirus (nt)
ICU-08	Female	52	2019.12.22	2019.12.29	fever (38.5 ºC), expectoration, malaise, dyspnea	recover, discharged	Streptococcus pneumoniae (nt)
ICU-09	Male	40	2019.12.22	2019.12.28	fever (38.5 ºC), expectoration	fever (38.5 ºC), malaise, expectoration, dizziness	negative
ICU-10	Male	56	2019.12.20	2019.12.20	fever, dyspnea, chest tightness	fever, malaise, cough, dyspnea	negative

Extended Data Table 2 | Laboratory detection results. Samples from two patients (ICU-01 and ICU-08) were not available during the second investigation. They have been discharged from hospital. We did serial test for ICU-06 patient at the following date: 19.12.30, 19.12.31, 20.01.01 and 20.01.10, corresponding to seven, eight, nine and eighteen days upon disease onset (19.12.23). Table shows molecular and serological (IgM and IgG) detection results for nCoV-2019.

		First sampling-2019.12.30			Second sampling-2020.01.10			
Patient No.	Test No.	BALF	Oral Swab	Blood (Ab)	Oral Swab	Anal Swab	Blood (PCR)	Blood (Ab)
ICU-01	WIV01	-	+	NA	NA	NA	NA	NA
ICU-04	WIV02[#]	+	+	NA	-	-	-	+
ICU-05	WIV03	+	+	NA	-	-	-	+
ICU-06	WIV04[#*]	+	+	+	-	-	-	+
ICU-08	WIV05[#]	+	-	NA	NA	NA	NA	NA
ICU-09	WIV06[#]	+	+	NA	-	-	-	+
ICU-10	WIV07[#]	+	+	NA	-	-	-	+

Extended Data Table 3 | Genomic comparison of nCoV-2019 WIV04 with SARS-CoVs and bat SARSr-CoVs.

	Sequence identities with SARS-CoVs & bat SARSr-CoVs (nt/aa %)											
	Full-length genome	ORF1a	ORF1b	S	ORF3a	E	M	ORF6	ORF7a	ORF7b	ORF8	N
SARS-CoV GZ02	79.6	76.0/80.9	86.2/95.7	73.4/77.0	75.6/73.4	94.7/96.0	85.4/90.5	76.3/68.9	82.8/86.0	84.8/81.4	52.0/31.6	87.7/91.2
SARS-CoV BJ01	79.6	76.0/80.8	86.2/95.7	73.4/76.9	75.3/72.6	94.7/96.0	85.6/90.5	75.8/67.2	82.8/86.0	84.8/81.4	51.1/-	88.8/91.2
SARS-CoV Tor2	79.6	76.0/80.9	86.2/95.8	73.4/76.7	75.4/72.6	94.7/96.0	85.6/90.5	76.3/68.9	82.8/86.0	84.8/81.4	51.1/-	88.8/91.2
SARS-CoV SZ3	79.6	76.0/81.0	86.2/95.8	73.4/76.9	75.4/72.6	94.7/96.0	85.3/90.0	76.3/68.9	82.8/86.0	84.8/81.4	52.3/31.6	88.8/91.2
SARS-CoV PC4-227	79.5	76.0/80.8	86.1/95.6	73.4/76.7	75.5/72.6	94.7/96.0	85.1/90.0	75.8/68.9	82.8/86.0	84.8/81.4	52.3/-	88.5/90.7
Bat SARr-CoV RaTG13	96.2	96.0/98.0	97.3/99.3	93.1/97.7	96.3/97.8	99.6/100	95.5/99.6	98.4/100	95.6/97.5	99.2/97.7	97.0/95.0	96.9/99.0
Bat SARr-CoV WIV1	79.7	76.0/80.7	85.9/95.8	73.4/77.6	76.1/74.5	95.6/96.0	84.8/90.0	78.0/73.8	85.0/88.4	85.6/83.7	65.8/57.9	88.5/90.9
Bat SARSr-CoV WIV16	79.7	75.9/81.0	86.1/95.6	73.1/77.8	76.1/74.5	95.6/96.0	84.8/90.0	77.4/72.1	85.0/88.4	85.6/83.7	65.3/57.9	88.6/90.9
Bat SARSr-CoV SHC014	79.6	75.9/80.9	85.9/95.8	73.3/77.7	76.1/74.5	95.6/96.0	84.8/90.0	78.0/70.5	84.4/88.4	85.6/83.7	65.8/58.7	88.6/90.9
Bat SARSr-CoV Rs4231	79.7	76.0/81.0	86.2/95.8	72.9/77.5	75.8/74.1	94.3/94.7	84.4/90.0	76.9/67.2	85.0/88.4	85.6/83.7	65.3/57.9	88.8/91.4
Bat SARSr-CoV YNLF31C	79.0	75.7/80.6	85.8/95.7	71.4/75.5	75.0/71.2	94.3/96.0	84.7/89.6	76.9/70.5	83.1/87.6	86.4/83.7	50.3/31.3	88.3/90.5
Bat SARSr-CoV LYRa11	79.6	75.8/80.6	85.7/95.6	73.9/77.3	77.2/76.3	94.7/94.7	85.1/90.0	78.5/70.5	82.0/85.1	81.1/81.4	66.7/57.9	89.0/91.6
Bat SARSr-CoV ZC45	88.1	91.0/95.7	86.1/96.0	77.8/82.3	87.8/90.9	98.7/100	93.4/98.6	95.2/93.4	88.8/87.6	94.7/93.0	88.5/94.2	91.1/94.3
Bat SARSr-CoV ZXC21	88.0	90.9/95.7	86.2/95.8	77.1/81.7	88.9/92.0	98.7/100	93.4/98.6	95.2/93.4	89.1/88.4	95.5/93.0	88.5/94.2	91.2/94.3
Bat SARSr-CoV HuB2013	79.6	76.3/81.2	85.3/95.7	73.1/76.8	75.4/75.5	95.2/94.7	85.3/91.0	76.3/68.9	84.2/87.6	85.6/83.7	62.0/49.6	88.9/91.6
Bat SARSr-CoV GX2013	79.1	75.9/80.8	86.0/95.9	73.1/77.1	75.6/73.0	94.7/96.0	84.8/91.4	77.4/68.9	85.0/86.8	84.1/79.1	51.4/31.6	87.9/90.2
Bat SARSr-CoV SX2013	78.9	76.2/80.6	85.1/95.5	71.2/75.5	74.7/71.2	94.3/93.3	83.0/89.6	77.4/68.9	84.2/86.8	85.6/83.7	49.7/30.4	86.9/90.2
Bat SARSr-CoV SC2018	79.4	75.8/80.7	85.5/95.2	72.7/76.4	75.0/71.2	94.3/96.0	84.7/90.0	80.0/71.8	85.2/87.6	84.8/83.7	66.1/55.4	88.2/91.2
Bat SARSr-CoV Rs672	79.6	76.0/80.9	85.9/95.8	72.8/76.2	75.2/71.9	95.2/96.0	84.8/89.6	78.5/70.5	84.7/88.4	85.6/83.7	65.8/58.7	87.9/91.2
Bat SARSr-CoV Rp3	79.5	75.9/80.5	86.0/95.7	73.1/77.2	74.9/74.8	95.2/96.0	85.1/90.0	76.9/68.9	83.9/89.3	84.8/83.7	66.4/56.2	88.4/90.7
Bat SARSr-CoV Rf1	78.8	76.2/80.6	84.8/95.3	71.1/75.7	74.3/69.0	94.3/94.7	83.3/89.6	79.0/68.9	84.2/86.8	84.1/83.7	50.6/31.3	86.8/89.5
Bat SARSr-CoV HKU3-1	79.4	76.1/80.9	84.9/95.1	73.4/77.9	75.8/73.4	95.2/96.0	84.7/91.0	75.3/67.2	85.0/89.3	84.1/79.1	66.4/57.0	88.3/90.0

Extended Data Table 4 | Virus neutralization test (VNT) of serum samples. Each serum sample was tested in triplicate. Two healthy people from Wuhan, five patient serum samples and a horse anti-SARS-CoV anti-serum were used. 120 $TCID_{50}$ virus was used each well. Serum samples were used in a dilution from 1:10, 1:20, 1:40 to 1:80.

Samples	VNT titre for nCoV-2019
Healthy people #1 from Wuhan	neg
Healthy people #2 from Wuhan	neg
Horse anti-SARS-CoV serum	>1:80
WIV02	>1:80
WIV03	1:40
WIV04	>1:80
WIV06	>1:80
WIV07	>1:80

Discovery of a novel coronavirus associated with the recent pneumonia outbreak in humans and its potential bat origin

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Since the SARS outbreak 18 years ago, a large number of severe acute respiratory syndrome related coronaviruses (SARSr-CoV) have been discovered in their natural reservoir host, bats[1-4]. Previous studies indicated that some of those bat SARSr-CoVs have the potential to infect humans[5-7]. Here we report the identification and characterization of a novel coronavirus (nCoV-2019) which caused an epidemic of acute respiratory syndrome in humans, in Wuhan, China. The epidemic, started from December 12th, 2019, has caused 198 laboratory confirmed infections with three fatal cases by January 20th, 2020. Full-length genome sequences were obtained from five patients at the early stage of the outbreak. They are almost identical to each other and share 79.5% sequence identify to SARS-CoV. Furthermore, it was found that nCoV-2019 is 96% identical at the whole genome level to a bat coronavirus. The pairwise protein sequence analysis of seven conserved non-structural proteins show that this virus belongs to the species of SARSr-CoV. The nCoV-2019 virus was then isolated from the bronchoalveolar lavage fluid of a critically ill patient, which can be neutralized by sera from several patients. Importantly, we have confirmed that this novel CoV uses the same cell entry receptor, ACE2, as SARS-CoV.

Coronavirus has caused two large-scale pandemic in the last two decades, SARS and MERS (Middle East respiratory syndrome)[8,9]. It was generally believed that SARSr-CoV, mainly found in bats, might cause future disease outbreak[10,11]. Here we report on a series of unidentified pneumonia disease outbreaks in Wuhan, Hubei province, central China (Extended Data Figure 1). Started from a local fresh seafood market, the epidemic has resulted in 198 laboratory confirmed cases with three death according to authorities so far[12]. Typical clinical symptoms of these patients are fever, dry cough,

dyspnea, headache, and pneumonia. Disease onset may result in progressive respiratory failure due to alveolar damage and even death. The disease was determined as viral induced pneumonia by clinicians according to clinical symptoms and other criteria including body temperature rising, lymphocytes and white blood cells decreasing (sometimes normal for the later), new pulmonary infiltrates on chest radiography, and no obvious improvement upon three days antibiotics treatment. It appears most of the early cases had contact history with the original seafood market, and no large scale of human-to-human transmission was observed so far.

Samples from seven patients with severe pneumonia (six are seafood market peddlers or delivers), who were enrolled in intensive unit cares at the beginning of the outbreak, were sent to WIV laboratory for pathogen diagnosis (Extended Data Table 1). As a CoV lab, we first used pan-CoV PCR primers to test these samples[13], considering the outbreak happened in winter and in a market, same environment as SARS. We found five PCR positive. A sample (WIV04) collected from bronchoalveolar lavage fluid (BALF) was analysed by metagenomics analysis using next-generation sequencing (NGS) to identify potential etiological agents. Of the 1582 total reads obtained after human genome filtering, 1378 (87.1%) matched sequences of SARSr-CoV (Fig. 1a). By *de novo* assembly and targeted PCR, we obtained a 29,891-bp CoV genome that shared 79.5% sequence identity to SARS-CoV BJ01 (GenBank accession number AY278488.2). This sequence has been submitted to GISAID (accession no. EPI_ISL_402124). Following the name by WHO, we tentatively call it novel coronavirus 2019 (nCoV-2019). Four more full-length genome sequences of nCoV-2019 (WIV02, WIV05, WIV06, and WIV07) (GISAID accession nos.

EPI_ISL_402127-402130) that were above 99.9% identical to each other were subsequently obtained from other four patients (Extended Data Table 2).

The virus genome consists of six major open reading frames (ORFs) common to coronaviruses and a number of other accessory genes (Fig. 1b). Further analysis indicates that some of the nCoV-2019 genes shared less than 80% nt sequence identity to SARS-CoV. However, the seven conserved replicase domains in ORF1ab that were used for CoV species classification, are 94.6% aa sequence identical between nCoV-2019 and SARS-CoV, implying the two belong to same species (Extended Data Table 3).

We then found a short RdRp region from a bat coronavirus termed BatCoV RaTG13 which we previously detected in *Rhinolophus affinis* from Yunnan Province showed high sequence identity to nCoV-2019. We did full-length sequencing to this RNA sample. Simplot analysis showed that nCoV-2019 was highly similar throughout the genome to RaTG13 (Fig. 1c), with 96.2% overall genome sequence identity. The phylogenetic analysis also showed that RaTG13 is the closest relative of the nCoV-2019 and form a distinct lineage from other SARSr-CoVs (Fig. 1d). The receptor binding protein spike (S) gene was highly divergent to other CoVs (Extended Data Figure 2), with less than 75% nt sequence identity to all previously described SARSr-CoVs except a 93.1% nt identity to RaTG13 (Extended Data Table 3). The S genes of nCoV-2019 and RaTG13 S gene are longer than other SARSr-CoVs. The major differences in nCoV-2019 are the three short insertions in the N-terminal domain, and four out of five key residues changes in the receptor-binding motif, in comparison

with SARS-CoV (Extended Data Figure 3). The close phylogenetic relationship to RaTG13 provides evidence for a bat origin of nCoV-2019.

We rapidly developed a qPCR detection based on the receptor-binding domain of spike gene, the most variable region among genome (Fig. 1c). Our data show the primers could differentiate nCoV-2019 with all other human coronaviruses including bat SARSr-CoV WIV1, which is 95% identity to SARS-CoV (Extended Data Figure 4a and 4b). From the seven patients, we found nCoV-2019 positive in six BALF and five oral swab samples during the first sampling by qPCR and conventional PCR (Extended Data Figure 4c). However, we can no longer find viral positive in oral swabs, anal swabs, and blood from these patients during the second sampling (Fig. 2a). Based on these findings, we conclude that the disease should be transmitted through airway, yet we can't rule out other possibilities if the investigation extended to include more patients.

For serological detection of nCoV-2019, we used previously developed bat SARSr-CoV Rp3 nucleocapsid protein (NP) as antigen in IgG and IgM ELISA test, which showed no cross-reactivity against other human coronaviruses except SARSr-CoV[7]. As a research lab, we were only able to get five serum samples from the seven viral infected patients. We monitored viral antibody levels in one patient (ICU-06) at seven, eight, nine, and eighteen days after disease onset (Extended Data Table 2). A clear trend of IgG and IgM titre (decreased at the last day) increase was observed (Fig. 2b). For a second investigation, we tested viral antibody for five of the seven viral positive patients around twenty days after disease onset (Extended Data Table 1 and 2). All

patient samples, but not samples from healthy people, showed strong viral IgG positive (Fig. 2b). We also found three IgM positive, indicating acute infection.

We then successfully isolated the virus (named nCoV-2019 BetaCoV/Wuhan/WIV04/2019), in Vero and Huh7 cells using BALF sample from ICU-06 patient. Clear cytopathogenic effects were observed in cells after three days incubation (Extended Data Figure 5a and 5b). The identity of the strain WIV04 was verified in Vero E6 cells by immunofluorescence microscopy using cross-reactive viral NP antibody (Extended Data Figure 5c and 5d), and by metagenomic sequencing, from which most of the reads mapped to nCoV-2019 (Extended Data Figure 5e and 5f). Viral partials in ultrathin sections of infected cells displayed typical coronavirus morphology under electron microscopy (Fig. 3). To further confirm the neutralization activity of the viral IgG positive samples, we conducted serum-neutralization assays in Vero E6 cells using the five IgG positive patient sera. We demonstrate that all samples were able to neutralize 120 TCID50 nCoV-2019 at a dilution of 1:40-1:80. We also show that this virus could be cross-neutralized by horse anti-SARS-CoV serum at dilutions 1:80, further confirming the relationship of the two viruses (Extended Data Table 4).

Angiotensin converting enzyme II (ACE2) was known as cell receptor for SARS-CoV[14]. To determine whether nCoV-2019 also use ACE2 as a cellular entry receptor, we conducted virus infectivity studies using HeLa cells expressing or not expressing ACE2 proteins from humans, Chinese horseshoe bats, civet, pig, and mouse. We show that nCoV-2019 is able to use all but mouse ACE2 as an entry receptor in the ACE2-expressing cells, but not cells without ACE2, indicating which is likely the cell

145 receptor of nCoV-2019 (Fig. 4). We also proved that nCoV-2019 does not use other
146 coronavirus receptors, aminopeptidase N and dipeptidyl peptidase 4 (Extended Data
147 Figure 6).
148
149 The study provides the first detailed report on nCoV-2019, the likely etiology agent
150 responsible for ongoing acute respiratory syndrome epidemic in Wuhan, central China.
151 Viral specific nucleotide positive and viral protein seroconversion observed in all
152 patients tested provides evidence of an association between the disease and the
153 presence of this virus. However, there are still many urgent questions to be answered.
154 We need more clinical data and samples to confirm if this virus is indeed the etiology
155 agent for this epidemic. In addition, we still don't know if this virus continue evolving
156 and become more transmissible between human-to-human. Moreover, we don't know
157 the transmission routine of this virus among hosts yet. We showed viral positive in
158 oral swabs, implying nCoV-2019 may be transmitted through airway. However, this
159 needs to be confirmed by extending detection range. Finally, based on our results, it
160 should be expected and worth to test if ACE2 targeting or SARS-CoV targeting drugs
161 can be used for nCoV-2019 patients. At this stage, we know very little about the virus,
162 including basic biology, animal source or any specific treatment. The almost identical
163 sequences of this virus in different patients imply a probably recent introduction in
164 humans, thus future surveillance on viral mutation and transmission ability and
165 further global research attention are urgently needed.
166
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AUTHOR CONTRIBUTIONS: Z.L.S., P.Z., Y.Y.W., and G.F.X. conceived the study. G.S.W., C.L.H., H.D.C., F.D., Q.J.C., F.X.Z., and LLL., collected patient samples. X.L.Y., B.Y., W.Z., B.L., J.C., X.S.Z., Y.L., H.G., R.D.J., M.Q.L., Y. Chen, X.W., X.R.S., and K.Z. performed qPCR, serology, and virus culturing. L.Z., Y.Z., H.R.S., and B.H. performed genome sequencing and annotations. The authors declare no competing financial interests. Correspondence and requests for materials should be addressed to ZLS (zlshi@wh.iov.cn).

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Supplementary Information is available in the online version of the paper.

Main Figure Legend

234 **Fig. 1 | Genome characterization of** nCoV-2019**. a**, pie chart showing
235 metagenomics analysis of next-generation sequencing of bronchoalveolar lavage fluid
236 from patient ICU06. **b**, Genomic organization of nCoV-2019 WIV04. **c**, Similarity
237 plot based on the full-length genome sequence of nCoV-2019 WIV04. Full-length
238 genome sequences of SARS-CoV BJ01, bat SARSr-CoV WIV1, bat coronavirus
239 RaTG13 and ZC45 were used as reference sequences. **d**, Phylogenetic tree based on
240 nucleotide sequences of complete ORF1b of coronaviruses. Software used and
241 settings can be found in material and method section.
242

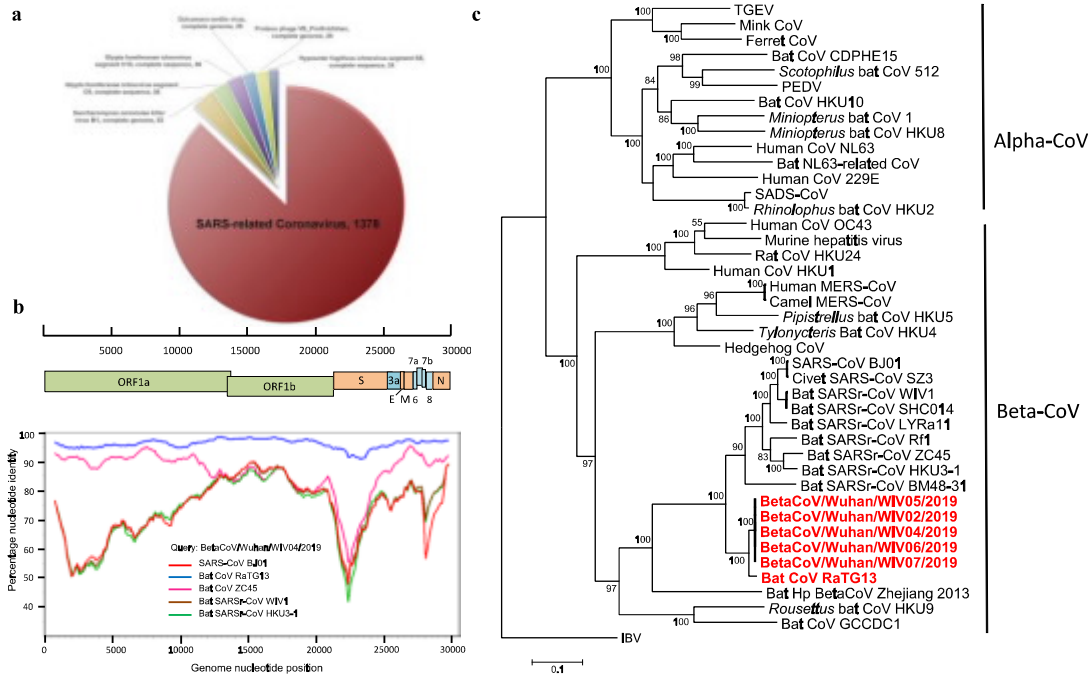

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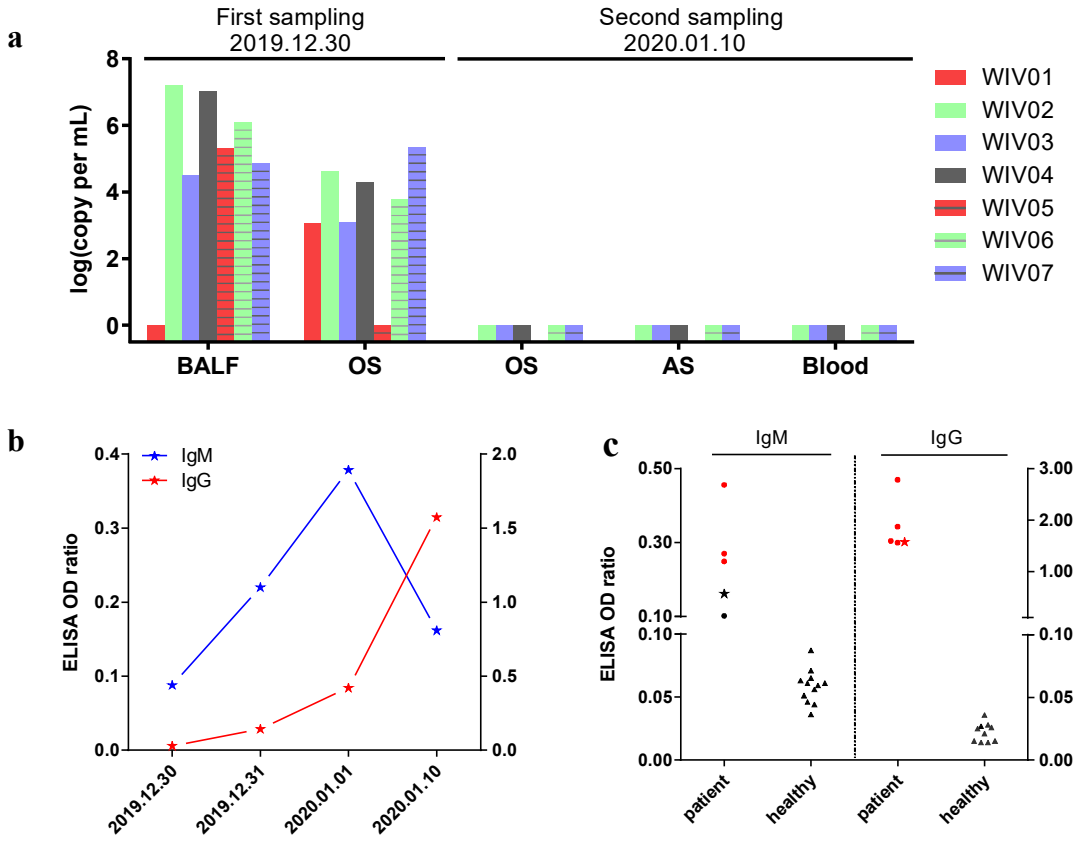
Fig. 2 | Molecular and serological investigation of patient samples. a, molecular detection of nCoV-2019 in seven patients during two times of sampling. Patient information can be found in Extended Data Table 1 and 2. Details on detection method can be found in material and methods. BALF, bronchoalveolar lavage fluid; OS, oral swab; AS, anal swab. **b**, dynamics of nCoV-2019 antibodies in one patient who showed sign of disease on 2019.12.23 (ICU-06). **c**, serological test of nCoV-2019 antibodies in five patients (more information can be found in Extended Data Table 2). Star indicates data collected from patient ICU-06 on 2020.01.10. For b and c, cut-off was set up as 0.2 for IgM test and 0.3 for IgG test, according to healthy controls.



263 **Fig. 3 | Virions. a**, viral particles in the ultrathin sections under electron microscope

264 at 200 kV, sample from viral infected Vero E6 cells

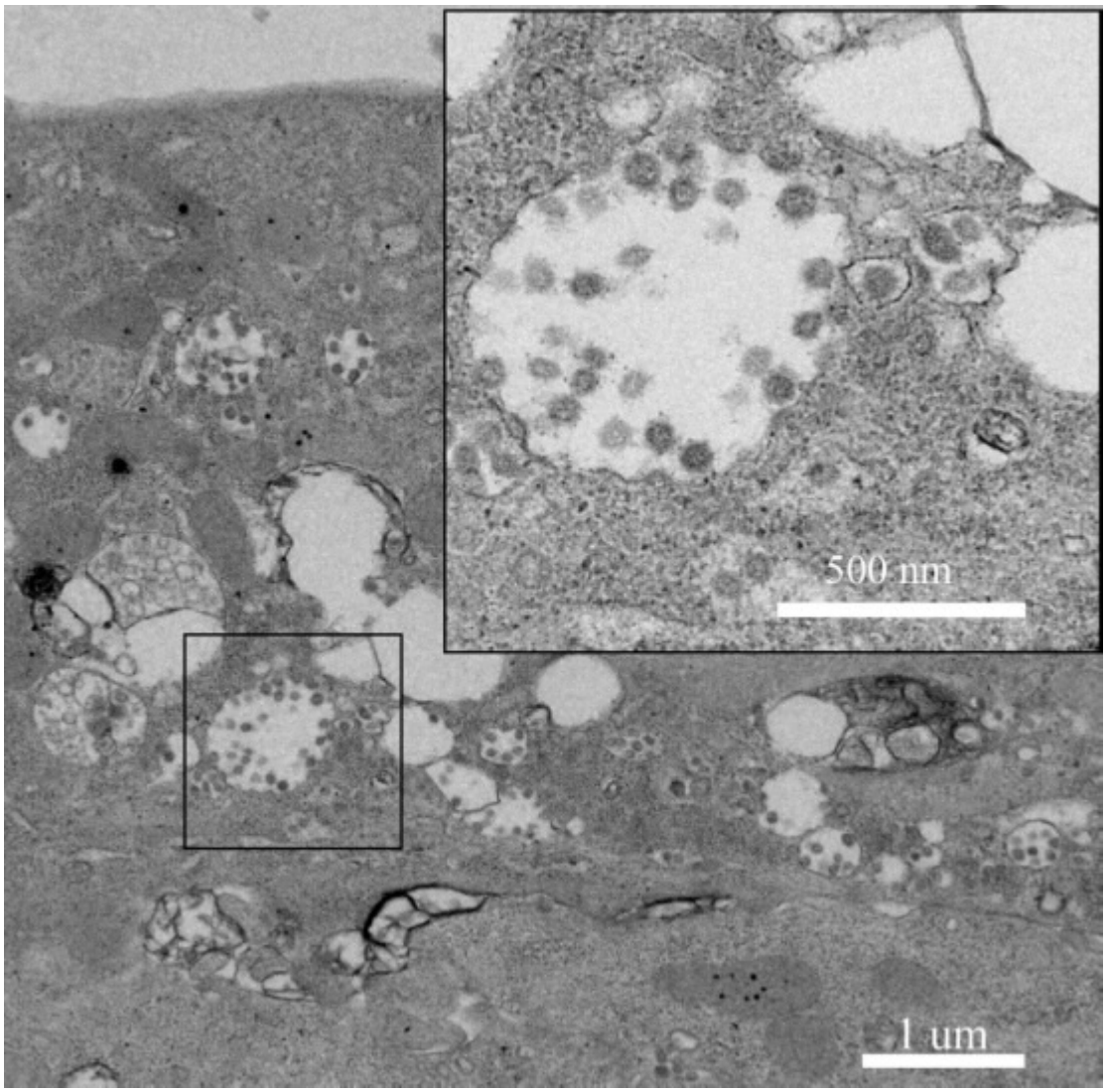


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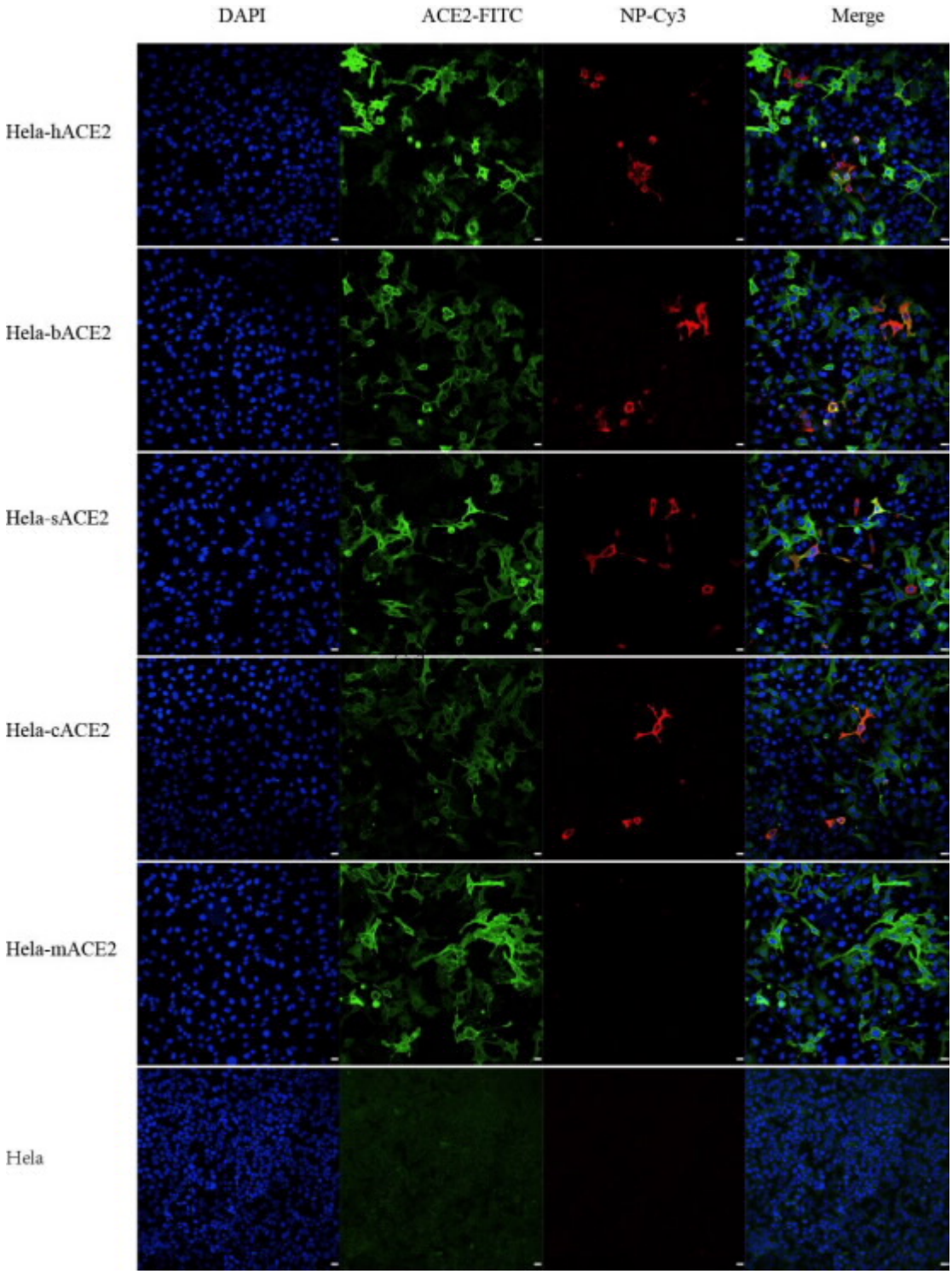
Fig. 4 | Analysis of nCoV-2019 receptor usage. Determination of virus infectivity in HeLa cells with or without the expression of ACE2. h, human; b, *Rhinolophus sinicus* bat; c, civet; s, swine (pig); m, mouse. ACE2 protein (green), viral protein (red) and nuclei (blue) was shown. Scale bar=10 um.



METHODS

Sample collection. Human samples, including oral swabs, anal swabs, blood, and BALF samples were collected by Jinyintan hospital (Wuhan) with the consent from all patients. Patients were sampled without gender or age preference unless where indicated. For swabs, 1.5 ml DMEM+2% FBS medium was added each tube. Supernatant was collected after 2500 rpm, 60 s vortex and 15-30 min standing. Supernatant from swabs or BALF (no pretreatment) was added to either lysis buffer for RNA extraction or to viral transport medium (VTM) for virus isolation. VTM composed of Hank's balanced salt solution at pH7.4 containing BSA (1%), amphotericin (15 μg/ml), penicillin G (100 units/ml), and streptomycin (50 μg/ml). Serum was separated by centrifugation at 3,000 *g* for 15 min within 24 h of collection, followed by 56 ^{0}C 30 min inactivation, and then stored at 4 ^{0}C until use.

Virus isolation, cell infection, electron microscope and neutralization assay. The following cells were used for virus isolation in this study: Vero, Vero E6, and Huh7 that were cultured in DMEM +10% FBS. A list of cells were used for susceptibility test (Extended Data Fig. 6). All cell lines were tested free of mycoplasma contamination, applied to species identification and authenticated by microscopic morphologic evaluation. None of cell lines was on the list of commonly misidentified cell lines (by ICLAC).

Cultured cell monolayers were maintained in their respective medium. PCR-positive BALF sample from ICU-06 patient was spin at 8,000 g for 15 min, filtered and diluted 1:2 with DMEM supplied with 16 μg/ml trypsin before adding to cells. After incubation at 37 ^{0}C for 1 h, the inoculum was removed and replaced with fresh culture

298 medium containing antibiotics (below) and 16 μg/ml trypsin. The cells were incubated
299 at 37 ^{0}C and observed daily for cytopathic effect (CPE). The culture supernatant was
300 examined for presence of virus by qRT-PCR developed in this study, and cells were
301 examined by immunofluorescent using SARSr-CoV Rp3 NP antibody made in house
302 (1:100). Penicillin (100 units/ml) and streptomycin (15 μg/ml) were included in all
303 tissue culture media.
304
305 The Vero E6 cells were infected with new virus at MOI of 0.5 and harvested 48 hpi.
306 Cells were fixed with 2.5% (wt/vol) glutaraldehyde and 1% osmium tetroxide, and
307 then dehydrated through a graded series of ethanol concentrations (from 30 to 100%),
308 and embedded with epoxy resin. Ultrathin sections (80 nm) of embedded cells were
309 prepared, deposited onto Formvar-coated copper grids (200 mesh), stained with
310 uranyl acetate and lead citrate, then observed under 200 kV Tecnai G2 electron
311 microscope.
312
313 The virus neutralization test was carried out in a 48-well plate. The patient serum
314 samples were heat-inactivated by incubation at 56 ^{0}C for 30 min before use. The
315 serum samples (5 μL) were diluted to 1:10, 1:20, 1:40 or 1:80, and then an equal
316 volume of virus stock was added and incubated at 37 ^{0}C for 60 min in a 5% CO_2
317 incubator. Diluted horse anti SARS-CoV serum or serum samples from healthy
318 people were used as control. After incubation, 100 μL mixtures were inoculated onto
319 monolayer Vero E6 cells in a 48-well plate for 1 hour. Each serum were repeated
320 triplicate. After removing the supernatant, the plate was washed twice with DMEM
321 medium. Cells were incubated with DMEM supplemented with 2% FBS for 24 hours.
322 Then the cells were fixed with 4% formaldehyde. And the virus were detected using

SL-CoV Rp3 NP antibody followed by Cy3-conjugated mouse anti-rabbit IgG. Nuclei were stained with DAPI. Infected cell number was counted by high-content cytometers.

RNA extraction and PCR. Whenever commercial kits were used, manufacturer's instructions were followed without modification. RNA was extracted from 200 µl of samples with the High Pure Viral RNA Kit (Roche). RNA was eluted in 50 µl of elution buffer and used as the template for RT-PCR.

For qPCR analysis, primers based on nCoV-2019 S gene was designed: RBD-qF1: 5'-CAATGGTTTAACAGGCACAGG-3'; RBD-qR1: 5'-CTCAAGTGTCTGTGGATCACG-3'. RNA extracted from above used in qPCR by HiScript® II One Step qRT-PCR SYBR® Green Kit (Vazyme Biotech Co.,Ltd). Conventional PCR test was also performed using the following primer pairs: ND-CoVs-951F TGTKAGRTTYCCTAAYATTAC; ND-CoVs-1805R ACATCYTGATANARAACAGC[13]. The 20 µl qPCR reaction mix contained 10 µl 2× One Step SYBR Green Mix, 1 µl One Step SYBR Green Enzyme Mix, 0.4 µl 50 × ROX Reference Dye 1, 0.4 µl of each primer (10 uM) and 2 µl template RNA. Amplification was performed as follows: 50 ^{0}C for 3 min, 95 ^{0}C for 30 s followed by 40 cycles consisting of 95 ^{0}C for 10 s, 60 ^{0}C for 30 s, and a default melting curve step in an ABI 7700 machine.

Serological test. In-house anti-SARSr-CoV IgG and IgM ELISA kits were developed using SARSr-CoV Rp3 NP as antigen, which shared above 90% amino acid identity to all SARSr-CoVs[2]. For IgG test, MaxiSorp Nunc-immuno 96 well ELISA plates

348 were coated (100 ng/well) overnight with recombinant NP. Human sera were used at
349 1:20 dilution for 1 h at 37 ^{0}C. An anti-Human IgG-HRP conjugated monoclonal
350 antibody (Kyab Biotech Co., Ltd, Wuhan, China) was used at a dilution of 1:40000.
351 The OD value (450–630) was calculated. For IgM test, MaxiSorp Nunc-immuno 96
352 wellELISA plates were coated (500 ng/well) overnight with anti-human IgM (μ
353 chain). Human sera were used at 1:100 dilution for 40 min at 37 ^{0}C, followed by anti-
354 Rp3 NP-HRP conjugated (Kyab Biotech Co., Ltd, Wuhan, China) at a dilution of
355 1:4000. The OD value (450–630) was calculated.
356
357 **Examination of ACE2 receptor for nCoV-2019 infection.** HeLa cells transiently
358 expressing ACE2 were prepared by a lipofectamine 3000 system (Thermo Fisher
359 Scientific) in 96-well plate, with mock-transfected cells as controls. nCoV-2019
360 grown from Vero E6 cells was used for infection at multiplicity of infection 0.05.
361 Same for testing of APN and DPP4. The inoculum was removed after 1 h absorption
362 and washed twice with PBS and supplemented with medium. At 24 hpi, cells were
363 washed with PBS and fixed with 4% formaldehyde in PBS (pH 7.4) for 20 min at
364 room temperature. ACE2 expression was detected using mouse anti-S tag monoclonal
365 antibody followed by FITC-labelled goat anti-mouse IgG H&L (Abcam, ab96879).
366 Viral replication was detected using rabbit antibody against the Rp3 NP protein (made
367 in house, 1:100) followed by cyanin 3-conjugated goat anti-rabbit IgG (1:50, Abcam,
368 ab6939). Nucleus was stained with DAPI (Beyotime). Staining patterns were
369 examined using the FV1200 confocal microscopy (Olympus).
370
371 **High throughput sequencing, pathogen screening and genome assembly.** Samples
372 from patient BALF or from virus culture supernatant were used for RNA extraction

and next-generation sequencing using Illumina MiSeq 3000 sequencer. Metagenomic analysis was carried out mainly base on the bioinformatics platform MGmapper (PE_2.24 and SE_2.24). The raw NGS reads were firstly processed by Cutadapt (v1.18) with minimum read length of 30bp. BWA (v0.7.12-r1039) was utilized to align reads to local database with a filter hits parameter at 0.8 FMM value and minimum alignment score at 30. Parameters for post-processing of assigned reads was set with minimum size normalized abundance at 0.01, minimum read count at 20 and other default parameters. A local nucleic acid database for human and mammals was employed to filter reads of host genomes before mapping reads to virus database. The results of metagenomic analysis were displayed through pie charts using WPS Office 2010. NGS reads were assembled into genomes using Geneious (v11.0.3) and MEGAHIT (v1.2.9). PCR and Sanger sequencing was performed to fill gaps in the genome. 5'-RACE was performed to determine the 5'-end of the genomes using SMARTer RACE 5'/3' Kit (Takara). Genomes were annotated using Clone Manager Professional Suite 8 (Sci-Ed Software).

Phylogenetic analysis. Routine sequence management and analysis was carried out using DNAStar. Sequence alignment and editing were conducted using ClustalW and GeneDoc. Maximum Likelihood phylogenetic trees based on nucleotide sequences of full-length ORF1b and S genes were constructed using the Jukes-Cantor model with bootstrap values determined by 1000 replicates in the MEGA6 software package.

Data Availability statement. Sequence data that support the findings of this study have been deposited in GISAID with the accession no. EPI_ISL_402124 and EPI_ISL_402127-402130.

To: Carolyn Clark[carolyn.clark@cepi.net]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; larry.wolfraim@nih.gov[larry.wolfraim@nih.gov]; Raul Gomez Roman[raul.gomezroman@cepi.net]; Miles.Carroll@phe.gov.uk[Miles.Carroll@phe.gov.uk]; barney.graham@nih.gov[barney.graham@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; Baric, Ralph S[rbaric@email.unc.edu]; vincent.munster@nih.gov[vincent.munster@nih.gov]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; Vasan, Vasan (H&B, Geelong AAHL)[Vasan.Vasan@csiro.au]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; jokim@ivi.int[jokim@ivi.int]; mksong@ivi.int[mksong@ivi.int]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; leejooyeon@korea.kr[leejooyeon@korea.kr]; limhy0919@korea.kr[limhy0919@korea.kr]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; christian.brechot[christian.brechot@pasteur.fr]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]
Cc: HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; GSELL, Pierre[gsellp@who.int]; COSTA, Alejandro Javier[costaa@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]
From: William Dowling[william.dowling@cepi.net]
Sent: Fri 1/24/2020 2:40:40 PM (UTC-05:00)
Subject: RE: WHO Consultation regarding the Wuhan coronavirus

Hello all
I sent an outlook invite to everyone on this list. But if you did not get it, the call in information is below.
Bill

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From: William Dowling
Sent: Thursday, January 23, 2020 10:40 PM
To: Carolyn Clark <carolyn.clark@cepi.net>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; larry.wolfraim@nih.gov; Raul Gomez Roman <raul.gomezroman@cepi.net>; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; rbaric@email.unc.edu; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL) <Vasan.Vasan@csiro.au>; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Iad7@cdc.gov; christian.brechot@pasteur.fr; Kayvon Modjarrad <kmodjarrad@eidresearch.org>
Cc: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; GSELL, Pierre <gsellp@who.int>; COSTA, Alejandro Javier <costaa@who.int>; RIVEROS BALTA, Alina Ximena <lauriex@who.int>
Subject: WHO Consultation regarding the Wuhan coronavirus

Hello all,

On behalf of the WHO R&D Blueprint team, I am writing to request your participation on a call tomorrow at 9 PM Central European time (which will be Saturday morning for some of you). The purpose of the call is to lend your expertise to coordination of WHO response efforts. To that end , we would like to discuss the current status of efforts to culture the Wuhan coronavirus (or generate a recombinant virus); recent sequence data and modeling of the Spike protein; and potential next steps to assess cross reactivity with other coronaviruses. We realize that this is very short notice, but the situation is very dynamic. This would be an initial call with lengthier and more detailed calls in the near future.

Also, for those who have not seen them, I am attaching two reports on this topic that just came out and are highly relevant to the conversation.

Please let us know if you can make it. Call in details will be sent tomorrow.

Thank you,

Bill Dowling (seconded to WHO)

William Dowling, PhD

Non-Clinical Vaccine Development Leader

CEPI New vaccines for a safer world

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From: Baric, Ralph S[rbaric@email.unc.edu]
Sent: Fri 1/24/2020 3:46:49 PM (UTC-05:00)
Subject: WHO Consultation regarding the Wuhan coronavirus

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity

Start Time: Thur 1/30/2020 7:30:00 AM (UTC-05:00)

End Time: Thur 1/30/2020 8:30:00 AM (UTC-05:00)

Required Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans

Hello all,
We are going to meet again to discuss updates on generation of reagents and materials as well as new data regarding potential cross reactivity with SARS. If there are others that ought to be included, please let me know.

Bill Dowling, working on behalf of WHO

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Organizer: William Dowling[william.dowling@cepi.net]

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity

Start Time: Thur 1/30/2020 7:30:00 AM (UTC-05:00)

End Time: Thur 1/30/2020 8:30:00 AM (UTC-05:00)

Required Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD)

Optional Attendees: Carroll, Darin (CDC/DDID/NCEZID/OD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil

Hello all,
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Organizer: GSELL, Pierre[gsellp@who.int]

From: GSELL, Pierre[gsellp@who.int]

Attendees: philip.krause@fda.hhs.gov; A.Salvati@aifa.gov.it; barney.graham@nih.gov; jokim@ivi.int; b.haagmans@erasmusmc.nl; Baric, Ralph S; connie.schmaljohn@nih.gov; malik@hku.hk; linfa.wang@duke-nus.edu.sg; stanley.plotkin@vaxconsult.com; kmodjarrad@eidresearch.org; ilongini; Peter Smith; Murray.Lumpkin@gatesfoundation.org; fgh@virginia.edu; Donis, Ruben (OS/ASPR/BARDA); richard.hatchett@cepi.net; COSTA, Alejandro Javier; William Dowling; HENAO RESTREPO, Ana Maria; PREZIOSI, Marie-pierre; (SPmig) ralf wagner; alan.embry@nih.gov; Cavaleri Marco; Michael.c.kaufmann@pwc.com; COOKE, Emer; Jean-pierre Amorij; Rene.Gysin@swissmedic.ch; michael.rosu-myles@canada.ca; guillaume.poliquin@canada.ca; Lakshmi.Krishnan@nrc-cnrc.gc.ca; kmaustria-lock@fda.gov.ph; g.pistritto@aifa.gov.it; Mike.Udell@mhra.gov.uk; Nicola.Rose@nibsc.org; Poonepalli_ANURADHA@hsa.gov.sg; aportela@aemps.es; alopezn@aemps.es; Lukasz.Montewka@urpl.gov.pl; madelaine claire; Alicia Rosello; Embry, Alan (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; PLUUT, Elisabeth; MUBANGIZI, Deusdedit; RODRIGUEZ HERNANDEZ, Carmen A.

Location: +41.58.26.20722 / Participant code: 998602

Importance: Normal

Subject: WHO nCoV R&D Summit 11-12 February - Vaccine R&D Working Group - 1st preparatory call

Start Time: Wed 2/5/2020 7:00:00 AM (UTC-05:00)

End Time: Wed 2/5/2020 8:00:00 AM (UTC-05:00)

Required Attendees: philip.krause@fda.hhs.gov; A.Salvati@aifa.gov.it; barney.graham@nih.gov; jokim@ivi.int; b.haagmans@erasmusmc.nl; Baric, Ralph S; connie.schmaljohn@nih.gov; malik@hku.hk; linfa.wang@duke-nus.edu.sg; stanley.plotkin@vaxconsult.com; kmodjarrad@eidresearch.org; ilongini; Peter Smith; Murray.Lumpkin@gatesfoundation.org; fgh@virginia.edu; Donis, Ruben (OS/ASPR/BARDA); richard.hatchett@cepi.net; COSTA, Alejandro Javier; William Dowling; HENAO RESTREPO, Ana Maria; PREZIOSI, Marie-pierre; (SPmig) ralf wagner; alan.embry@nih.gov; Cavaleri Marco; Michael.c.kaufmann@pwc.com; COOKE, Emer; Jean-pierre Amorij; Rene.Gysin@swissmedic.ch; michael.rosu-myles@canada.ca; guillaume.poliquin@canada.ca; Lakshmi.Krishnan@nrc-cnrc.gc.ca; kmaustria-lock@fda.gov.ph; g.pistritto@aifa.gov.it; Mike.Udell@mhra.gov.uk; Nicola.Rose@nibsc.org; Poonepalli_ANURADHA@hsa.gov.sg; aportela@aemps.es; alopezn@aemps.es; Lukasz.Montewka@urpl.gov.pl

Optional Attendees: madelaine claire; Alicia Rosello; Embry, Alan (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; PLUUT, Elisabeth; MUBANGIZI, Deusdedit; RODRIGUEZ HERNANDEZ, Carmen A.

2019 nCoV_Global conference_Feb 3 .pptx

Dear All,

We hope your travel is being safely arranged to Geneva for Feb 11-12.

We are very pleased to invite you to participate to the WG on Vaccine R&D, one of the thematic area of the summit.
The aim of this WG is as follow:
1. Overview of state of the art
2. Identification of key knowledge gaps
3. Preliminary list of research priorities

To best prepare the meeting, we would like to convene you to a first teleconference – Tomorrow WEDNESDAY 5 FEBRUARY – 1 pm Geneva time

Dial- in Details
+41.58.26.20722 / Participant code: 998624

Kind regards
Pierre on behalf of the Blueprint

Global research & innovation forum:

towards a roadmap for the novel Coronavirus meeting

11-12 February 2020 WHO
Executive Board Room, Geneva, Switzerland

R&D Blueprint

Powering research
to prevent epidemics

Global research and innovation forum:
towards a roadmap for the novel Coronavirus meeting

Purpose:

To enable identification of key knowledge gaps, and research priorities and thereby accelerate generate of scientific information and the most needed medical products to control the 2019-nCoV emergency

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to prevent epidemics

Global research and innovation forum:
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Expected outcomes

A concerted global research agenda, including priorities and frameworks for global coordination and implementation

R&DBlueprint
Powering research
to prevent epidemics

Global research and innovation forum:
towards a roadmap for the novel Coronavirus meeting

Who is being invited?

- representatives from the scientific community
- public health agencies
- regulatory authorities
- member state representatives from affected countries, from Ministries of Health
- research funders
- bioethicists with expertise in emergencies
- Coronavirus experts
- Funders and heads of major research institutions

R&DBlueprint
Powering research
to prevent epidemics

Global research and innovation forum:
towards a roadmap for the novel Coronavirus meeting

Who is supporting it?

- GLOPID R

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DAY 1

SETTING THE SCENE
Outbreak
Ongoing research

IDENTIFYING PRIORITY RESEARCH AND GOVERNANCE FRAMEWORK

Parallel sessions by thematic area

DAY 2

A GLOBAL RESEARCH AGENDA
Priorities by topic
Gaps
Cross cutting issues

IDENTIFYING PRIORITY RESEARCH AND GOVERNANCE FRAMEWORK

Next steps

lueprint
arch
demics

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towards a roadmap for the novel Coronavirus meeting

Overview of ongoing research activities by thematic area	CHAIRPERSON	WHO FOCAL PERSON / RESPONSIBLE
1. Virus– natural history and transmission and diagnostics	1. Malik Peiris/TBD	1. Vasee/Mark Perkins
2. Animal and environmental investigations to identify the zoonotic source	2. William B Karesh	2. Marie-Pierre/ Peter Ben Embarek
3. Epidemiological studies	3. TBD/TBD	3. Maria/Oliver
4. HCWs protection and IPC	4. TBD	4. Bennedetta/April
5. Clinical characterization and management	5. John Marshall/ Srinivas Moorthy	5. Janet
6. Therapeutics R&D	6. Marco Cavalieri	6. Ana Maria /Marie-Pierre
7. Candidate vaccine R&D	7. Phil Krause	7. Ana Maria /Marie-Pierre
8. Ethical considerations	8. TBD/TBD	8. Andreas/ Katherine
9. Data, sample and sequence sharing	9. Marie Paule Kieny	9. Vasee/Anne/ Stefanie
10. Integrating social sciences in the outbreak response	10. Nina Gobal/TBD	10. Fernanda/Lina

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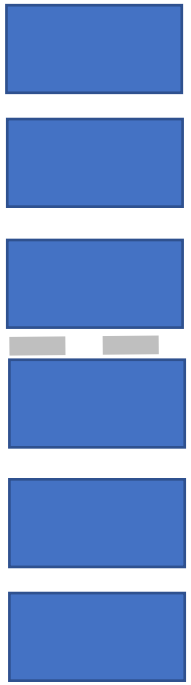


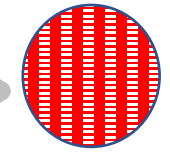
Each with a Chair, a focal point from WHO

Working Parties by topic

Teleconferences - at least 2

- Review state of the art
- Summarize ongoing research
- Identify research gaps
- Agree on research priorities
- Propose framework for collaboration

Background document + slides prepared for Conference



TODAY
Jan 28

Feb 11-12

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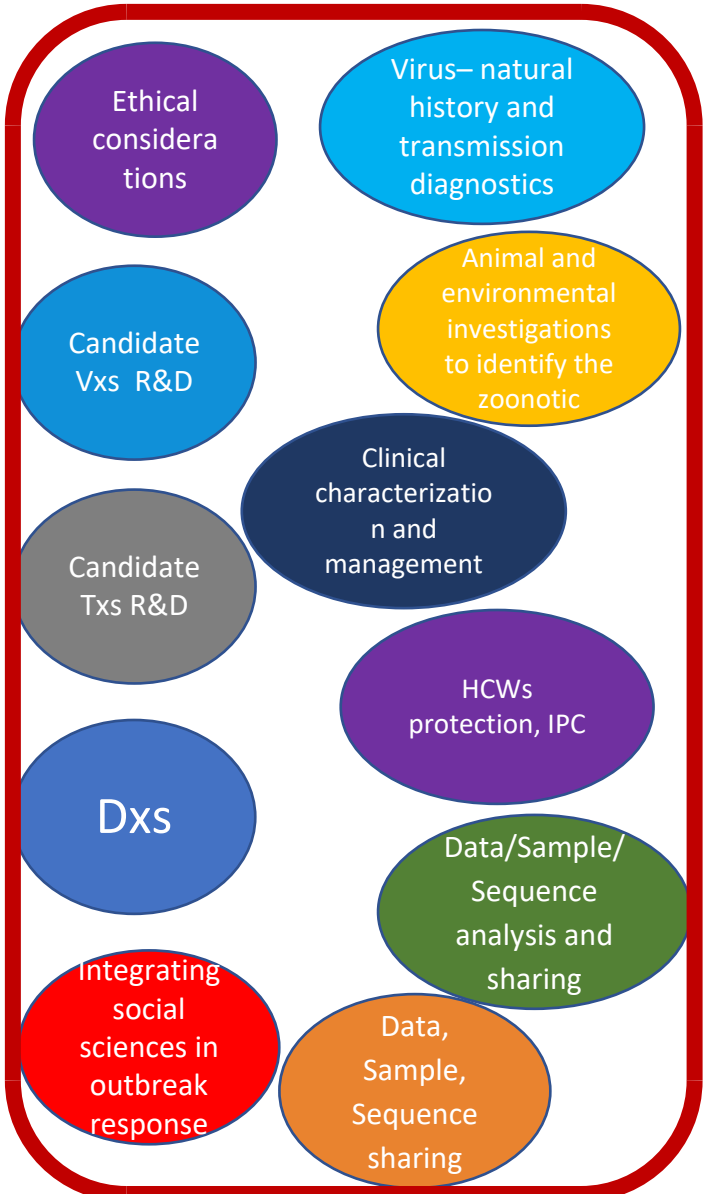

1. Overview of *state of the art*
2. Identification of key knowledge gaps
3. Preliminary list of research priorities

Teleconferences by thematic area
3-10 February, 2020

1. Overview of *state of the art*
2. Identification of key knowledge gaps
3. Preliminary list of research priorities
4. Governnace framework

11-12 February 2020
WHO
Executive Board Room,
Geneva, Switzerland

EXPECTED OUTCOMES

Accelerate generation of scientific information.

Advancement of most needed medical products to control the 2019-nCoV outbreak

Asks for today

- Off line suggestions on wording of titles
- Info on progress with thematic areas – NFR of calls
- Calendar of calls per thematic area
- Final review of CRITICAL participants

FOCUS ON CONTENT

To: Baric, Ralph S[rbaric@email.unc.edu]
From: Jon Epstein[epstein@ecohealthalliance.org]
Sent: Tue 2/4/2020 3:45:57 PM (UTC-05:00)
Subject: NY TImes inquiry

Hi Ralph,
I referred a NY Times reporter, James Gorman, your way. We were talking about how to investigate the spillover of 2019nCoV from bats. I told him about discussions you and I had had about the assumed directionality of SARS transmission from civets to humans, but that the genetics might suggest people infected civets. I thought he'd be interested in speaking with you directly about what we can infer from mutations in the genome when we get isolates from animals and people.

Anyway, I hope you're well. I'm sure you're busy.

Cheers,
Jon

--
Jonathan H. Epstein DVM, MPH, PhD

Vice President for Science and Outreach

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From: GSELL, Pierre[gsellp@who.int]

Attendees: philip.krause@fda.hhs.gov; A.Salvati@aifa.gov.it; barney.graham@nih.gov; jokim@ivi.int; b.haagmans@erasmusmc.nl; Baric, Ralph S; connie.schmaljohn@nih.gov; malik@hku.hk; linfa.wang@duke-nus.edu.sg; stanley.plotkin@vaxconsult.com; kmodjarrad@eidresearch.org; ilongini; Peter Smith; Murray.Lumpkin@gatesfoundation.org; fgh@virginia.edu; Donis, Ruben (OS/ASPR/BARDA); richard.hatchett@cepi.net; COSTA, Alejandro Javier; William Dowling; HENAO RESTREPO, Ana Maria; madelaine claire; Alicia Rosello; PREZIOSI, Marie-pierre; (SPmig) ralf wagner; alan.embry@nih.gov; Cavaleri Marco; Embry, Alan (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]

Location: +41.58.262.0722 / Participant code: 998602

Importance: Normal

Subject: WHO nCoV R&D Summit 11-12 February - Vaccine R&D Working Group - 2nd preparatory call

Start Time: Fri 2/7/2020 7:00:00 AM (UTC-05:00)

End Time: Fri 2/7/2020 8:00:00 AM (UTC-05:00)

Required Attendees: philip.krause@fda.hhs.gov; A.Salvati@aifa.gov.it; barney.graham@nih.gov; jokim@ivi.int; b.haagmans@erasmusmc.nl; Baric, Ralph S; connie.schmaljohn@nih.gov; malik@hku.hk; linfa.wang@duke-nus.edu.sg; stanley.plotkin@vaxconsult.com; kmodjarrad@eidresearch.org; ilongini; Peter Smith; Murray.Lumpkin@gatesfoundation.org; fgh@virginia.edu; Donis, Ruben (OS/ASPR/BARDA); richard.hatchett@cepi.net; COSTA, Alejandro Javier; William Dowling; HENAO RESTREPO, Ana Maria; madelaine claire; Alicia Rosello; PREZIOSI, Marie-pierre; (SPmig) ralf wagner; alan.embry@nih.gov; Cavaleri Marco; Embry, Alan (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]

From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]

Importance: Normal

Subject: Meeting Forward Notification: WHO Consultation regarding nCoV Reagents and Cross -Reactivity

Start Time: Wed 2/5/2020 12:30:00 PM (UTC-05:00)

End Time: Wed 2/5/2020 1:00:00 PM (UTC-05:00)

Required Attendees: William Dowling

Your meeting was forwarded

Baric, Ralph S has forwarded your meeting request to additional people.

Required Attendees: William Dowling

Meeting

WHO Consultation regarding nCoV Reagents and Cross -Reactivity

Required Attendees: William Dowling

Required Attendees: William Dowling

Meeting Time

Friday, February 7, 2020 6:00 AM - Friday, February 7, 2020 7:00 AM

Required Attendees: William Dowling

Required Attendees: William Dowling

Recipients

Baric, Toni C

Required Attendees: William Dowling

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]
Location: dial +41 22 791 21 22 and after the message dial 16820
Importance: Normal
Subject: FW: WHO Consultation regarding nCoV Reagents and Cross -Reactivity
Start Time: Fri 2/7/2020 6:00:00 AM (UTC-05:00)
End Time: Fri 2/7/2020 7:00:00 AM (UTC-05:00)
Required Attendees: Baric, Toni C

-----Original Appointment-----
From: William Dowling <william.dowling@cepi.net>
Sent: Wednesday, February 5, 2020 11:30 AM
To: William Dowling; cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr
Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity
When: Friday, February 7, 2020 12:00 PM-1:00 PM (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna.
Where: dial +41 22 791 21 22 and after the message dial 16820

Hello all
We will meet again on Friday at 12 PM Central European Time. I apologize to those in the US for the early time on the call, but we cannot do it later due to a vaccine coordination call. I will be sending draft minutes from the last two meetings shortly – please take a look and send me any corrections. Also, in advance of the meeting , if there are new public findings, please send to me , and I will circulate. For example. I would bring to everyone's attention 2 publication regarding cross reactivity here – https://www.biorxiv.org/content/10.1101/2020.01.28.923011v1 and https://www.biorxiv.org/content/10.1101/2020.01.31.929042v1.full.pdf.

If there is any person or institution I have missed that ought to be on this invite, please let me know.

Lastly, if you cannot make the call, can you please provide me updates by email that I can share with the group?

Thank you,
Bill

To: Krause, Philip[Philip.Krause@fda.hhs.gov]; GSELL, Pierre[gsellp@who.int]; A.Salvati@aifa.gov.it[A.Salvati@aifa.gov.it]; barney.graham@nih.gov[barney.graham@nih.gov]; jokim@ivi.int[jokim@ivi.int]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; Baric, Ralph S[rbaric@email.unc.edu]; Schmaljohn, Connie S (NIH)[connie.schmaljohn@nih.gov]; malik@hku.hk[malik@hku.hk]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; stanley.plotkin@vaxconsult.com[stanley.plotkin@vaxconsult.com]; kmodjarrad@eidresearch.org[kmodjarrad@eidresearch.org]; ilongini[ilongini@ufl.edu]; Murray.Lumpkin@gatesfoundation.org[Murray.Lumpkin@gatesfoundation.org]; fgh@virginia.edu[fgh@virginia.edu]; Donis, Ruben (OS)[Ruben.Donis@hhs.gov]; richard.hatchett@cepi.net[richard.hatchett@cepi.net]; COSTA, Alejandro Javier[costaa@who.int]; William Dowling[william.dowling@cepi.net]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; PREZIOSI, Marie-pierre[preziosim@who.int]; (SPmig) ralf wagner[ralf.wagner@pei.de]; alan.embry@nih.gov[alan.embry@nih.gov]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; Michael.c.kaufmann@pwc.com[Michael.c.kaufmann@pwc.com]; COOKE, Emer[cookee@who.int]; Jean-pierre Amorij[jamorij@unicef.org]; Rene.Gysin@swissmedic.ch[Rene.Gysin@swissmedic.ch]; michael.rosu-myles@canada.ca[michael.rosu-myles@canada.ca]; guillaume.poliquin@canada.ca[guillaume.poliquin@canada.ca]; Lakshmi.Krishnan@nrc-cnrc.gc.ca[Lakshmi.Krishnan@nrc-cnrc.gc.ca]; kmaustria-lock@fda.gov.ph[kmaustria-lock@fda.gov.ph]; g.pistritto@aifa.gov.it[g.pistritto@aifa.gov.it]; Mike.Udell@mhra.gov.uk[Mike.Udell@mhra.gov.uk]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Poonepalli_ANURADHA@hsa.gov.sg[Poonepalli_ANURADHA@hsa.gov.sg]; aportela@aemps.es[aportela@aemps.es]; alopezn@aemps.es[alopezn@aemps.es]; Lukasz.Montewka@urpl.gov.pl[Lukasz.Montewka@urpl.gov.pl]; Levis, Robin[Robin.Levis@fda.hhs.gov]
Cc: madelaine claire[claire_madelaine@yahoo.fr]; Alicia Rosello[Alicia.Rosello@lshtm.ac.uk]; Embry, Alan C (NIH)[embrya@niaid.nih.gov]; Stemmy, Erik J (NIH)[erik.stemmy@nih.gov]; PLUUT, Elisabeth[pluute@who.int]; MUBANGIZI, Deusdedit[mubangizid@who.int]; RODRIGUEZ HERNANDEZ, Carmen A.[rodriguezhernandezc@who.int]
From: Peter Smith[Peter.Smith@lshtm.ac.uk]
Sent: Thur 2/6/2020 1:22:47 PM (UTC-05:00)
Subject: RE: WHO nCoV R&D Summit 11-12 February - Vaccine R&D Working Group - 1st preparatory call

Dear Phil,

Sorry I could not make the call. I think it is not too early to start planning for the design of Phase 1/2 studies – size, target groups, populations. Also some planning for Phase 3/4 evaluations would be appropriate, even though they are a little way away.

There is a TPP for vaccines against disease X. I do not know if this has been modified yet for nCoV but, if not, this would seem an urgent priority.

Peter

Prof Peter Smith, MRC Tropical Epidemiology Group,
London School of Hygiene & Tropical Medicine,Keppel St, London WC1E 7HT. Tel: +44 20 7927 2246

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: 06 February 2020 15:11
To: GSELL, Pierre <gsellp@who.int>; A.Salvati@aifa.gov.it; barney.graham@nih.gov; jokim@ivi.int; b.haagmans@erasmusmc.nl; rbaric@email.unc.edu; Schmaljohn, Connie S (NIH) <connie.schmaljohn@nih.gov>; malik@hku.hk; linfa.wang@duke-nus.edu.sg; stanley.plotkin@vaxconsult.com; kmodjarrad@eidresearch.org; ilongini <ilongini@ufl.edu>; Peter Smith <Peter.Smith@lshtm.ac.uk>; Murray.Lumpkin@gatesfoundation.org; fgh@virginia.edu; Donis, Ruben (OS) <Ruben.Donis@hhs.gov>; richard.hatchett@cepi.net; COSTA, Alejandro Javier <costaa@who.int>; William Dowling <william.dowling@cepi.net>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; PREZIOSI, Marie-pierre <preziosim@who.int>; (SPmig) ralf wagner <ralf.wagner@pei.de>; alan.embry@nih.gov; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>; Michael.c.kaufmann@pwc.com; COOKE, Emer <cookee@who.int>; Jean-pierre Amorij <jamorij@unicef.org>; Rene.Gysin@swissmedic.ch; michael.rosu-myles@canada.ca; guillaume.poliquin@canada.ca; Lakshmi.Krishnan@nrc-cnrc.gc.ca; kmaustria-lock@fda.gov.ph; g.pistritto@aifa.gov.it; Mike.Udell@mhra.gov.uk; Nicola.Rose@nibsc.org; Poonepalli_ANURADHA@hsa.gov.sg; aportela@aemps.es; alopezn@aemps.es; Lukasz.Montewka@urpl.gov.pl; Levis, Robin <Robin.Levis@fda.hhs.gov>
Cc: madelaine claire <claire_madelaine@yahoo.fr>; Alicia Rosello <Alicia.Rosello@lshtm.ac.uk>; Embry, Alan C (NIH) <embrya@niaid.nih.gov>; Stemmy, Erik J (NIH) <erik.stemmy@nih.gov>; PLUUT, Elisabeth <pluute@who.int>; MUBANGIZI, Deusdedit <mubangizid@who.int>; RODRIGUEZ HERNANDEZ, Carmen A. <rodriguezhernandezc@who.int>
Subject: RE: WHO nCoV R&D Summit 11-12 February - Vaccine R&D Working Group - 1st preparatory call

Dear Colleagues,

Thank you for your participation in yesterday's call to discuss nCoV vaccine R&D. In the attached document, I've tried to categorize key discussion points made yesterday, with some embellishments in places where I thought further discussion may be useful. I'd like to use this as a general outline for tomorrow morning's call. In the meantime, if each of you can take a look at this and identify what you think is missing from the outline and let either Ana Maria and me or the entire group know via e-mail, we can improve the outline even before tomorrow's discussion at 1300 CET. Obviously, we'd like to make as much progress as is possible between now and the meeting in Geneva next week, so your rapid input is greatly appreciated!

Thanks,

Phil

-----Original Appointment-----
From: GSELL, Pierre <gsellp@who.int>
Sent: Tuesday, February 4, 2020 7:00 AM
To: GSELL, Pierre; Krause, Philip; A.Salvati@aifa.gov.it; barney.graham@nih.gov; jokim@ivi.int; b.haagmans@erasmusmc.nl; rbaric@email.unc.edu; Schmaljohn, Connie S (NIH); malik@hku.hk; linfa.wang@duke-nus.edu.sg; stanley.plotkin@vaxconsult.com; kmodjarrad@eidresearch.org; ilongini; Peter Smith; Murray.Lumpkin@gatesfoundation.org; fgh@virginia.edu; Donis, Ruben (OS); richard.hatchett@cepi.net; COSTA, Alejandro Javier; William Dowling; HENAO RESTREPO, Ana Maria; PREZIOSI, Marie-pierre; (SPmig) ralf wagner; alan.embry@nih.gov; Cavaleri Marco; Michael.c.kaufmann@pwc.com; COOKE, Emer; Jean-pierre Amorij; Rene.Gysin@swissmedic.ch; michael.rosu-myles@canada.ca; guillaume.poliquin@canada.ca; Lakshmi.Krishnan@nrc-cnrc.gc.ca; kmaustria-lock@fda.gov.ph; g.pistritto@aifa.gov.it; Mike.Udell@mhra.gov.uk; Nicola.Rose@nibsc.org; Poonepalli_ANURADHA@hsa.gov.sg; aportela@aemps.es; alopezn@aemps.es; Lukasz.Montewka@urpl.gov.pl
Cc: madelaine claire; Alicia Rosello; Embry, Alan C (NIH); Stemmy, Erik J (NIH); PLUUT, Elisabeth; MUBANGIZI, Deusdedit; RODRIGUEZ HERNANDEZ, Carmen A.
Subject: WHO nCoV R&D Summit 11-12 February - Vaccine R&D Working Group - 1st preparatory call
When: Wednesday, February 5, 2020 1:00 PM-2:00 PM (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna.
Where: +41.58.26.20722 / Participant code: 998602

Dear All,

We hope your travel is being safely arranged to Geneva for Feb 11-12.

We are very pleased to invite you to participate to the WG on Vaccine R&D, one of the thematic area of the summit.
The aim of this WG is as follow:
1. Overview of state of the art
2. Identification of key knowledge gaps
3. Preliminary list of research priorities

To best prepare the meeting, we would like to convene you to a first teleconference – Tomorrow WEDNESDAY 5 FEBRUARY – 1 pm Geneva time

Dial- in Details
+41.58.26.20722 / Participant code: 998624

Kind regards
Pierre on behalf of the Blueprint

Cc: Isabel Sola[isola@cnb.csic.es]; Leo Poon[llmpoon@hku.hk]; Baric, Ralph S[rbaric@email.unc.edu]; A.E.Gorbalenya@lumc.nl[A.E.Gorbalenya@lumc.nl]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; Sbaker1@luc.edu[Sbaker1@luc.edu]; bneuman@tamut.edu[bneuman@tamut.edu]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; R.J.deGroot@uu.nl[R.J.deGroot@uu.nl]; llmpoon@hkucc.hku.hk[llmpoon@hkucc.hku.hk]; christian.drosten@charite.de[christian.drosten@charite.de]
To: guodeyin@mail.sysu.edu.cn[guodeyin@mail.sysu.edu.cn]; shibojiang@fudan.edu.cn[shibojiang@fudan.edu.cn]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]
From: John Ziebuhr[john.ziebuhr@viro.med.uni-giessen.de]
Sent: Fri 2/14/2020 9:26:34 AM (UTC-05:00)
Subject: virus name

Dear Deyin, dear Zhengli, dear Shibo, dear colleagues,

Thank you very much for sharing your thoughts with me and other members of the CSG. Obviously, I (personally) cannot speak for other CSG members but would like to tell you and your colleagues that I am very grateful for your very thoughtful and balanced statement.

I am pleased that you agree with the study group's decision to assign this newly discovered coronavirus to the species *Severe acute respiratory syndrome-related coronavirus*. The scientific basis for the assignment and naming has been laid out in the paper we recently published in a manuscript submitted to the bioRxiv preprint server and, at this stage, I cannot add much to this. There is one key point, however, that I would like to stress again: In their decision on the virus name, the CSG did not intend to make any reference to a specific disease (for example a severe respiratory disease in humans) when introducing yet another virus name derived from the term "SARS". The universal use of "SARS(r)" in names of viruses in this species just serves to underline the close genetic relatedness of these viruses. A large proportion of viruses in this virus species have been identified in bats and other animals in China and a few other countries, and virtually all these viruses were named SARS or SARS-related coronaviruses – most of them not because of their association with a disease (called SARS) in humans but because of their close genetic relatedness with a previously described VIRUS (called SARS-CoV) and clearly NOT the DISEASE that this particular virus caused. This (and nothing else) was the reasoning behind the study group's decision to continue the naming tradition established by researchers studying animal and human viruses of this virus species.

In a slightly different context, I would like to point out that it is not within the remit of the CSG to decide on names for clinical manifestations, progression, transmissibility etc. of coronavirus-associated diseases. This lies within the responsibility of WHO. Obviously, Chinese clinicians involved in the clinical management of patients infected with SARS-CoV-2 would be in the best position to provide advise to WHO officials on that matter. On a more personal note (and outside my role as member of the ICTV and chair of the CSG), I feel that your suggestion to name the disease "Transmissible acute respiratory syndrome (TARS)" could be a very good starting point for discussions with WHO. In my opinion, the recently introduced disease name COVID-19 could be improved and I would encourage you to enter or renew discussions with WHO on this matter.

I very much hope that I was able to convince you that the CSG's decision on this particular virus name was made with the very best intentions and based purely on SCIENTIFIC judgement. Personally, I feel reassured by the positive response I have been receiving over the past few days from other colleagues, ICTV, NCBI and other players and believe that the CSG has made a decision that will facilitate future communication among virologists studying these viruses. As part of these efforts, the CSG also suggested a naming convention to be used for specific SARS-CoV-2 isolates (and other coronavirus isolates).

With many thanks and kind regards,

John Ziebuhr

—
Prof. Dr. John Ziebuhr
Institute of Medical Virology
Justus Liebig University Giessen
Schubertstrasse 81 (BFS)
35392 Giessen
Germany
Tel.: +49-641-9941200
Fax: +49-641-9941209
E-mail: john.ziebuhr@viro.med.uni-giessen.de

To: Dean, Charity A@CDPH[Charity.Dean@cdph.ca.gov]; Caneva, Duane[duane.caneva@hq.dhs.gov]; Richard Hatchett[richard.hatchett@cepi.net]; Lawler, James V[james.lawler@unmc.edu]; Kadlec, Robert (OS/ASPR/IO)[Robert.Kadlec@hhs.gov]
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From: Carter Mecher[cmecher@charter.net]
Sent: Fri 2/14/2020 12:35:05 PM (UTC-05:00)
Subject: RE: Isolation and Quarantine for HCWs
NPIs in the healthcare setting.docx

A couple of days ago I queried the group about application of NPIs in the healthcare setting. Would really be interested in your thoughts (or thoughts of other people you know who have had time to think this thru).

I excerpted the questions below:

Voluntary home quarantine for household contacts is likely to be a key NPI. I suspect that CDC is struggling with the questions I'm going to pose. If CDC is unable to state something definitively, public health and healthcare leaders will be struggling to answer the questions I'm about to pose.

1. If an ER or ICU physician or nurse has a sick family member at home with confirmed COVID-2019, will you recommend letting them continue to work (assuming you are short-staffed and overwhelmed with high demand for patient care), or will you advise that they remain home in voluntary self-quarantine for 14 days? What if it is an employee working in finance or billing or medical records? Would you apply differently across staff or would apply it consistently across the board?
2. What if you have an ER or ICU physician or nurse who has a febrile resp illness but tests negative for COVID-2019? You are short-staffed and have high demand for patient care—especially ER and ICU care. Will you only recommend isolation for confirmed COVID-2019? What about influenza? What about a viral URI (not flu and not CPVID-2019)?
3. How are you going to operationalize this? At the beginning of each shift, will you screen all employees for illness (fever) or confirmed COVID in their household? Will you screen any employee with a fever and resp symptoms for the diseases that you would enforce home isolation? (COVID, or flu)?
4. There might be other critical sectors that will be short staffed and overwhelmed because of intense demand for a service or a product or the service is ultra critical (police/fire/EMS, manufacturing of RPDs, medical supplies, nuclear power plant, water and wastewater treatment facilities, transportation, electrical lineman, etc.). Think about how we should advise them? They will be sure to raise these questions—I certainly would. Does it matter if a long distance truck driver (as long he isn't interacting with people at gas stations and diners, etc.) has someone sick at home or is mildly ill? Could there be practical solutions to both reduce transmission and keep things going?

One observation, staff who live alone are going to be prized during this event. You don't ever need to worry about home quarantine for household contacts. (interesting stat, 25% of all households in the US are single individuals).

So I decided to crowdsource this problem and reach out to a number of people who are on the ground working in healthcare. Here are a couple responses.

Response #1:
At some point, you will need to be pragmatic with your decisions.

If I'm suffering with an overwhelming influx of patients and short staff, I would not be inclined to send clinicians and nurses home because they are asymptomatic contacts of someone Ill. Rather, I would ask them to work in the COVID unit. Maybe with symptoms screening. They are already exposed at home, so incremental risk is small, and if they were to develop symptoms then chances are everyone around them would be either already infected or wearing PPE.

Similar risk assessment for other situations. Hope we don't get to that, but if we do it will not be business as usual.

Response #2:
The answers will change depending on need.

Sick family member? Early on, stay home. With critical staffing – maybe mask and work and monitor symptoms.
Sick staff? Definitely stay home now for any respiratory illness. Later, stay home if too sick to work. If staffing is critical, mildly ill staff who want to work may need to (voluntarily) mask and work (and disclose status to patients). Again, if critical, may need to think creatively, e.g., voluntarily cohorting (COVID-19 + staff w COVID-19 + patients and flu+ staff w flu + patients)– presumably we'd have fewer staff with flu although we don't know our staff immunization rates. We'll need our ethicists.

There is a difference between what we ask of front line/clinical staff and administrative staff. A sick/exposed person who can do their job from home should be home. Hospital staff don't get that latitude because our job involves contact and we are not always simple to replace. We receive warnings that we will be AWOL if we don't show up for our tour, during declared states of emergency when the public is asked to stay off the roads. This is routine practice in our non-critical clinics (primary care). I don't support this, but there is certainly a precedent for asking hospital staff to put themselves at risk to come to work. If we come to that discussion, I will put my two cents in to avoid the AWOL language and ask for volunteers, but I am hopeful that we won't.

The other question is – if our front line staff is depleted, what can we reasonably/ethically ask of our other (non EM, non inpatient) staff? We could ask almost any physician or advanced practitioner to complete VOD (telemedicine) visits. I don't think we can tell providers to work in the ER/inpatient setting if that isn't their contracted role.
We could probably ethically shift primary care to urgent care by stopping routine follow ups and running all day 'gap/urgent care' PC visits, and we can always ask for volunteers among our non front-line clinical staff.

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From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]

Importance: Normal

Subject: Meeting Forward Notification: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 1 PM CET

Start Time: Sat 2/15/2020 12:00:00 PM (UTC-05:00)

End Time: Sat 2/15/2020 12:30:00 PM (UTC-05:00)

Required Attendees: William Dowling

Your meeting was forwarded

Baric, Ralph S has forwarded your meeting request to additional people.

Required Attendees: William Dowling

Meeting

WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 1 PM CET

Required Attendees: William Dowling

Required Attendees: William Dowling

Meeting Time

Tuesday, February 18, 2020 7:00 AM - Tuesday, February 18, 2020 8:00 AM

Required Attendees: William Dowling

Required Attendees: William Dowling

Recipients

Baric, Toni C

Required Attendees: William Dowling

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET

Start Time: Tue 2/25/2020 9:00:00 AM (UTC-05:00)

End Time: Tue 2/25/2020 10:00:00 AM (UTC-05:00)

Required Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de

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Organizer: William Dowling[william.dowling@cepi.net]

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET

Start Time: Thur 2/27/2020 9:00:00 AM (UTC-05:00)

End Time: Thur 2/27/2020 10:00:00 AM (UTC-05:00)

Required Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int

Optional Attendees: Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole

Hello all

I am sorry to change the time after some have accepted this meeting, but it has been brought to my attention that there is a competing meeting involving many invitees of this call, and we wish to have as many on the call as possible. I am therefore moving this to Thursday, 2/27 at 3 PM CET . I will send the draft minutes from last meeting and updated tables in advance.

Bill

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To: cheryl@gisaid.org[cheryl@gisaid.org]; peter@gisaid.org[peter@gisaid.org]; Carolyn Clark[carolyn.clark@cepi.net]; Florence, Clint (NIH/NIAID) [E[clint.florence@nih.gov]; larry.wolfraim@nih.gov[larry.wolfraim@nih.gov]; Raul Gomez Roman[raul.gomezroman@cepi.net]; Miles.Carroll@phe.gov.uk[Miles.Carroll@phe.gov.uk]; barney.graham@nih.gov[barney.graham@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; Baric, Ralph S[rbaric@email.unc.edu]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; GSELL, Pierre[gsellp@who.int]; COSTA, Alejandro Javier[costaa@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; vincent.munster@nih.gov[vincent.munster@nih.gov]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; Vasan, Vasan (H&B, Geelong AAHL[Vasan.Vasan@csiro.au]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; jokim@ivi.int[jokim@ivi.int]; mksong@ivi.int[mksong@ivi.int]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; leejooyeon@korea.kr[leejooyeon@korea.kr]; limhy0919@korea.kr[limhy0919@korea.kr]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; christian.brechot[christian.brechot@pasteur.fr]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Mark Page[Mark.Page@nibsc.org]; Graham, Barney (NIH/VRC) [E[bgraham@mail.nih.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; Thue, Tracey[tracey.thue@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Napper, Scott[scott.napper@usask.ca]; Nicola Rose[Nicola.Rose@nibsc.org]; M.P.G. Koopmans[m.koopmans@erasmusmc.nl]; sgerber@cdc.gov[sgerber@cdc.gov]; djernigan@cdc.gov[djernigan@cdc.gov]; Gerber, Susan I. (CDC/DDID/NCIRD/DVD)[bhx1@cdc.gov]; Carroll, Darin (CDC/DDID/NCEZID/OD)[zuz4@cdc.gov]; Watson, John (CDC/DDID/NCIRD/DVD)[acq4@cdc.gov]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; gustavo.f.palacios.civ@mail.mil[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; SPoehlmann@dpz.eu[SPoehlmann@dpz.eu]; mhoffmann@dpz.eu[mhoffmann@dpz.eu]; sylvie.van-der-werf@pasteur.fr[sylvie.van-der-werf@pasteur.fr]; Nelson Michelle[MNELSON@dstl.gov.uk]; Lever Steve[MSLEVER@dstl.gov.uk]; Prior Joann L[JLPRIOR@dstl.gov.uk]; Marston, Hilary (NIH/NIAID) [E][hilary.marston@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; mit666666@pitt.edu[mit666666@pitt.edu]; Mellors, John W[jwm1@pitt.edu]; tlying@fudan.edu.cn[tlying@fudan.edu.cn]; christian.drosten@charite.de[christian.drosten@charite.de]
Cc: Guthrie, Erica (CDC/DDID/NCIRD/ID)[ilj2@cdc.gov]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]
From: William Dowling[william.dowling@cepi.net]
Sent: Mon 2/24/2020 2:17:52 PM (UTC-05:00)
Subject: RE: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - change of date from 3 PM CET Tuesday 2/25 to 3 PM CET Thursday 2/27

Hello all

I am sorry to change the time after some have accepted this meeting, but it has been brought to my attention that there is a competing meeting involving many invitees of this call, and we wish to have as many on the call as possible. I am therefore moving this to Thursday, 2/27 at 3 PM CET . I will send the draft minutes from last meeting and updated tables in advance.

Bill

-----Original Appointment-----
From: William Dowling
Sent: Sunday, February 23, 2020 9:27 PM
To: William Dowling; cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; rbaric@email.unc.edu; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Iad7@cdc.gov; christian.brechot@pasteur.fr; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de
Cc: Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD)
Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET
When: Thursday, February 27, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Skype Meeting

Hello all
I am sorry to change the time after some have accepted this meeting, but it has been brought to my attention that there is a competing meeting involving many invitees of this call, and we wish to have as many on the call as possible. I am therefore moving this to Thursday, 2/27 at 3 PM CET . I will send the draft minutes from last meeting and updated tables in advance.

Bill

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From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]
Location: Skype Meeting
Importance: Normal
Subject: FW: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET
Start Time: Thur 2/27/2020 9:00:00 AM (UTC-05:00)
End Time: Thur 2/27/2020 10:00:00 AM (UTC-05:00)
Required Attendees: Baric, Toni C

-----Original Appointment-----
From: William Dowling <william.dowling@cepi.net>
Sent: Sunday, February 23, 2020 9:27 PM
To: William Dowling; cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de
Cc: Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD)
Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET
When: Thursday, February 27, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Skype Meeting

Hello all
I am sorry to change the time after some have accepted this meeting, but it has been brought to my attention that there is a competing meeting involving many invitees of this call, and we wish to have as many on the call as possible. I am therefore moving this to Thursday, 2/27 at 3 PM CET . I will send the draft minutes from last meeting and updated tables in advance.

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From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]

Importance: Normal

Subject: Meeting Forward Notification: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET

Start Time: Mon 2/24/2020 4:00:00 PM (UTC-05:00)

End Time: Mon 2/24/2020 4:30:00 PM (UTC-05:00)

Required Attendees: William Dowling

Your meeting was forwarded

Baric, Ralph S has forwarded your meeting request to additional people.

Required Attendees: William Dowling

Meeting

WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET

Required Attendees: William Dowling

Required Attendees: William Dowling

Meeting Time

Thursday, February 27, 2020 9:00 AM - Thursday, February 27, 2020 10:00 AM

Required Attendees: William Dowling

Required Attendees: William Dowling

Recipients

Baric, Toni C

Required Attendees: William Dowling

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

From:	Kayvon Modjarrad[kmodjarrad@eidresearch.org]
Attendees:	william.dowling@cepi.net; cheryl@gisaid.org; peter@gisaid.org; carolyn.clark@cepi.net; clint.florence@nih.gov; larry.wolfraim@nih.gov; raul.gomezroman@cepi.net; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Connie.schmaljohn@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; henaorestrepoa@who.int; gsellp@who.int; costaa@who.int; lauriex@who.int; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan.Vasan@csiro.au; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; iad7@cdc.gov; christian.brechot@pasteur.fr; amy.c.shurtleff@cepi.net; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark.Page@nibsc.org; bgraham@mail.nih.gov; darryl.falzarano@usask.ca; tracey.thue@usask.ca; paul.hodgson@usask.ca; scott.napper@usask.ca; Nicola.Rose@nibsc.org; m.koopmans@erasmusmc.nl; sgerber@cdc.gov; djernigan@cdc.gov; bhx1@cdc.gov; zuz4@cdc.gov; acq4@cdc.gov; janet.lathey@nih.gov; marciela.degrace@nih.gov; moorthyv@who.int; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; MNELSON@dstl.gov.uk; MSLEVER@dstl.gov.uk; JLPRIOR@dstl.gov.uk; hilary.marston@nih.gov; emmie.dewit@nih.gov; mit666666@pitt.edu; jwm1@pitt.edu; tlying@fudan.edu.cn; christian.drosten@charite.de
Importance:	Normal
Subject:	[EXTERNAL] RE: WHO Consultation regarding nCoV Reagents and Cross - Reactivity - change of date from 3 PM CET Tuesday 2/25 to 3 PM CET Thursday 2/27
Start Time:	Thur 2/27/2020 8:00:00 AM (UTC-05:00)
End Time:	Thur 2/27/2020 8:30:00 AM (UTC-05:00)
Required Attendees:	william.dowling@cepi.net; cheryl@gisaid.org; peter@gisaid.org; carolyn.clark@cepi.net; clint.florence@nih.gov; larry.wolfraim@nih.gov; raul.gomezroman@cepi.net; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Connie.schmaljohn@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; henaorestrepoa@who.int; gsellp@who.int; costaa@who.int; lauriex@who.int; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan.Vasan@csiro.au; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; iad7@cdc.gov; christian.brechot@pasteur.fr; amy.c.shurtleff@cepi.net; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark.Page@nibsc.org; bgraham@mail.nih.gov; darryl.falzarano@usask.ca; tracey.thue@usask.ca; paul.hodgson@usask.ca; scott.napper@usask.ca; Nicola.Rose@nibsc.org; m.koopmans@erasmusmc.nl; sgerber@cdc.gov; djernigan@cdc.gov; bhx1@cdc.gov; zuz4@cdc.gov; acq4@cdc.gov; janet.lathey@nih.gov; marciela.degrace@nih.gov; moorthyv@who.int; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; MNELSON@dstl.gov.uk; MSLEVER@dstl.gov.uk; JLPRIOR@dstl.gov.uk; hilary.marston@nih.gov; emmie.dewit@nih.gov; mit666666@pitt.edu; jwm1@pitt.edu; tlying@fudan.edu.cn; christian.drosten@charite.de

I am therefore moving this to Thursday, 2/27 at 3 PM CET .

****

Organizer: Kayvon Modjarrad[kmodjarrad@eidresearch.org]

From: Kayvon Modjarrad[kmodjarrad@eidresearch.org]

Attendees: william.dowling@cepi.net; cheryl@gisaid.org; peter@gisaid.org; carolyn.clark@cepi.net; clint.florence@nih.gov; larry.wolfraim@nih.gov; raul.gomezroman@cepi.net; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Connie.schmaljohn@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; henaorestrepoa@who.int; gsellp@who.int; costaa@who.int; lauriex@who.int; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan.Vasan@csiro.au; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; iad7@cdc.gov; christian.brechot@pasteur.fr; amy.c.shurtleff@cepi.net; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark.Page@nibsc.org; bgraham@mail.nih.gov; darryl.falzarano@usask.ca; tracey.thue@usask.ca; paul.hodgson@usask.ca; scott.napper@usask.ca; Nicola.Rose@nibsc.org; m.koopmans@erasmusmc.nl; sgerber@cdc.gov; djernigan@cdc.gov; bhx1@cdc.gov; zuz4@cdc.gov; acq4@cdc.gov; janet.lathey@nih.gov; marciela.degrace@nih.gov; moorthyv@who.int; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; MNELSON@dstl.gov.uk; MSLEVER@dstl.gov.uk; JLPRIOR@dstl.gov.uk; hilary.marston@nih.gov; emmie.dewit@nih.gov; mit666666@pitt.edu; jwm1@pitt.edu; tlying@fudan.edu.cn; christian.drosten@charite.de

Importance: Normal

Subject: Canceled: Canceled: [EXTERNAL] RE: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - change of date from 3 PM CET Tuesday 2/25 to 3 PM CET Thursday 2/27

Start Time: Thur 2/27/2020 8:00:00 AM (UTC-05:00)

End Time: Thur 2/27/2020 8:30:00 AM (UTC-05:00)

Required Attendees: william.dowling@cepi.net; cheryl@gisaid.org; peter@gisaid.org; carolyn.clark@cepi.net; clint.florence@nih.gov; larry.wolfraim@nih.gov; raul.gomezroman@cepi.net; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Connie.schmaljohn@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; henaorestrepoa@who.int; gsellp@who.int; costaa@who.int; lauriex@who.int; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan.Vasan@csiro.au; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; iad7@cdc.gov; christian.brechot@pasteur.fr; amy.c.shurtleff@cepi.net; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark.Page@nibsc.org; bgraham@mail.nih.gov; darryl.falzarano@usask.ca; tracey.thue@usask.ca; paul.hodgson@usask.ca; scott.napper@usask.ca; Nicola.Rose@nibsc.org; m.koopmans@erasmusmc.nl; sgerber@cdc.gov; djernigan@cdc.gov; bhx1@cdc.gov; zuz4@cdc.gov; acq4@cdc.gov; janet.lathey@nih.gov; marciela.degrace@nih.gov; moorthyv@who.int; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; MNELSON@dstl.gov.uk; MSLEVER@dstl.gov.uk; JLPRIOR@dstl.gov.uk; hilary.marston@nih.gov; emmie.dewit@nih.gov; mit666666@pitt.edu; jwm1@pitt.edu; tlying@fudan.edu.cn; christian.drosten@charite.de

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Organizer: Kayvon Modjarrad[kmodjarrad@eidresearch.org]

From: Kayvon Modjarrad[kmodjarrad@eidresearch.org]

Attendees: william.dowling@cepi.net; cheryl@gisaid.org; peter@gisaid.org; carolyn.clark@cepi.net; clint.florence@nih.gov; larry.wolfraim@nih.gov; raul.gomezroman@cepi.net; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Connie.schmaljohn@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; henaorestrepoa@who.int; gsellp@who.int; costaa@who.int; lauriex@who.int; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan.Vasan@csiro.au; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; iad7@cdc.gov; christian.brechot@pasteur.fr; amy.c.shurtleff@cepi.net; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark.Page@nibsc.org; bgraham@mail.nih.gov; darryl.falzarano@usask.ca; tracey.thue@usask.ca; paul.hodgson@usask.ca; scott.napper@usask.ca; Nicola.Rose@nibsc.org; m.koopmans@erasmusmc.nl; sgerber@cdc.gov; djernigan@cdc.gov; bhx1@cdc.gov; zuz4@cdc.gov; acq4@cdc.gov; janet.lathey@nih.gov; marciela.degrace@nih.gov; moorthyv@who.int; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; MNELSON@dstl.gov.uk; MSLEVER@dstl.gov.uk; JLPRIOR@dstl.gov.uk; hilary.marston@nih.gov; emmie.dewit@nih.gov; mit666666@pitt.edu; jwm1@pitt.edu; tlying@fudan.edu.cn; christian.drosten@charite.de

Importance: High

Subject: Canceled: Canceled: [EXTERNAL] RE: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - change of date from 3 PM CET Tuesday 2/25 to 3 PM CET Thursday 2/27

Start Time: Thur 2/27/2020 8:00:00 AM (UTC-05:00)

End Time: Thur 2/27/2020 8:30:00 AM (UTC-05:00)

Required Attendees: william.dowling@cepi.net; cheryl@gisaid.org; peter@gisaid.org; carolyn.clark@cepi.net; clint.florence@nih.gov; larry.wolfraim@nih.gov; raul.gomezroman@cepi.net; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Connie.schmaljohn@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; henaorestrepoa@who.int; gsellp@who.int; costaa@who.int; lauriex@who.int; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan.Vasan@csiro.au; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; iad7@cdc.gov; christian.brechot@pasteur.fr; amy.c.shurtleff@cepi.net; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark.Page@nibsc.org; bgraham@mail.nih.gov; darryl.falzarano@usask.ca; tracey.thue@usask.ca; paul.hodgson@usask.ca; scott.napper@usask.ca; Nicola.Rose@nibsc.org; m.koopmans@erasmusmc.nl; sgerber@cdc.gov; djernigan@cdc.gov; bhx1@cdc.gov; zuz4@cdc.gov; acq4@cdc.gov; janet.lathey@nih.gov; marciela.degrace@nih.gov; moorthyv@who.int; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; MNELSON@dstl.gov.uk; MSLEVER@dstl.gov.uk; JLPRIOR@dstl.gov.uk; hilary.marston@nih.gov; emmie.dewit@nih.gov; mit666666@pitt.edu; jwm1@pitt.edu; tlying@fudan.edu.cn; christian.drosten@charite.de

---

To: M.P.G. Koopmans[m.koopmans@erasmusmc.nl]
Cc: William Dowling[william.dowling@cepi.net]; cheryl@gisaid.org[cheryl@gisaid.org]; peter@gisaid.org[peter@gisaid.org]; Carolyn Clark[carolyn.clark@cepi.net]; Florence, Clint (NIH/NIAID) [E[clint.florence@nih.gov]; larry.wolfraim@nih.gov[larry.wolfraim@nih.gov]; Raul Gomez Roman[raul.gomezroman@cepi.net]; Miles.Carroll@phe.gov.uk[Miles.Carroll@phe.gov.uk]; barney.graham@nih.gov[barney.graham@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; Baric, Ralph S[rbaric@email.unc.edu]; GSELL, Pierre[gsellp@who.int]; COSTA, Alejandro Javier[costaa@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; vincent.munster@nih.gov[vincent.munster@nih.gov]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; B.L. Haagmans[b.haagmans@erasmusmc.nl]; Vasan, Vasan (H&B, Geelong AAHL[Vasan.Vasan@csiro.au]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; jokim@ivi.int[jokim@ivi.int]; mksong@ivi.int[mksong@ivi.int]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Giada Mattiuzzo[Giada.Mattiuzzo@nibsc.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; leejooyeon@korea.kr[leejooyeon@korea.kr]; limhy0919@korea.kr[limhy0919@korea.kr]; Damon, Inger K. (CDC/DDID/NCEZID/DHCPP)[iad7@cdc.gov]; christian.brechot[christian.brechot@pasteur.fr]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Mark Page[Mark.Page@nibsc.org]; Graham, Barney (NIH/VRC) [E[bgraham@mail.nih.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; Thue, Tracey[tracey.thue@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Napper, Scott[scott.napper@usask.ca]; Nicola Rose[Nicola.Rose@nibsc.org]; sgerber@cdc.gov[sgerber@cdc.gov]; djernigan@cdc.gov[djernigan@cdc.gov]; Gerber, Susan I. (CDC/DDID/NCIRD/DVD)[bhx1@cdc.gov]; Carroll, Darin (CDC/DDID/NCEZID/OD)[zuz4@cdc.gov]; Watson, John (CDC/DDID/NCIRD/DVD)[acq4@cdc.gov]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; gustavo.f.palacios.civ@mail.mil[gustavo.f.palacios.civ@mail.mil]; Mark Pallansch[map1@cdc.gov]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; SPoehlmann@dpz.eu[SPoehlmann@dpz.eu]; mhoffmann@dpz.eu[mhoffmann@dpz.eu]; sylvie.van-der-werf[sylvie.van-der-werf@pasteur.fr]; Nelson Michelle[MNELSON@dstl.gov.uk]; Lever Steve[MSLEVER@dstl.gov.uk]; Prior Joann L[JLPRIOR@dstl.gov.uk]; Hillary Marston[hilary.marston@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; mit666666@pitt.edu[mit666666@pitt.edu]; Mellors, John W[jwm1@pitt.edu]; tlying@fudan.edu.cn[tlying@fudan.edu.cn]; christian.drosten@charite.de[christian.drosten@charite.de]; David Vaughn[David.Vaughn@gatesfoundation.org]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; Guthrie, Erica (CDC/DDID/NCIRD/ID)[ilj2@cdc.gov]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; Baric, Toni C[antoinette_baric@med.unc.edu]
From: HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
Sent: Wed 2/26/2020 5:10:44 AM (UTC-05:00)
Subject: Re: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - Double invites for tomorrow?

Dear Marion,
We understand your commitments and appreciate your support.

We think that in this phase is initial to maintain fluid communication and deliberate.

We will reach out to the GLOPID R leadership to see if they can join some of the calls instead of organising new ones.

There is a series of new approaches and objectives- following the forum discussions- that we want to discuss with this community.

We trust that someone from your group could attained.

All the best and kind regards,

Ana Maria

Ana Maria Henao-Restrepo MD, MSc
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On 26 Feb 2020, at 11:04, M.P.G. Koopmans <m.koopmans@erasmusmc.nl> wrote:

Hi
I think we need to start thinking of a different mechanism for updating, and decide whether this group or subgroups jointly are going for specific funding or not. . I think the coordination meeting and calls have been very useful, but right now, it seems that all that followed from that is more calls, and that is not helping advance the science.

There is an idea of a priority research agenda. Is the plan to go jointly or in subgroups for specific calls for funding? Then I would prefer if we can start working on a clear proposal, jointly. Of course all of us are doing that through different channels.

Just some thoughts……
I know GLOPID r are looking a several calls to be launched, but of course eligibility criteria make it difficult to go as a global group. But if there are concrete plans, we could try and bring that to their attention

Marion Koopmans

> On 26 Feb 2020, at 10:54, William Dowling <william.dowling@cepi.net> wrote:
>
> Hello all
> Some of you may have gotten two invites for tomorrow , one for a half hour meeting at 2 PM CET from Kayvon Modjarrad and another for an hour meeting at 3 PM CET from me. I don't know how the 2 PM invite was generated, but please delete it. Our call is at 3 PM CET. Sorry for any confusion.
> Bill
>
> -----Original Appointment-----
> **From:** William Dowling
> **Sent:** Monday, February 24, 2020 3:27 AM
> **To:** William Dowling; cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; rbaric@email.unc.edu; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; lad7@cdc.gov; christian.brechot@pasteur.fr; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John

W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar
Cc: Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C
Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET
When: Thursday, February 27, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Skype Meeting

Hello all
I am sorry to change the time after some have accepted this meeting, but it has been brought to my attention that there is a competing meeting involving many invitees of this call, and we wish to have as many on the call as possible. I am therefore moving this to Thursday, 2/27 at 3 PM CET . I will send the draft minutes from last meeting and updated tables in advance.

Bill

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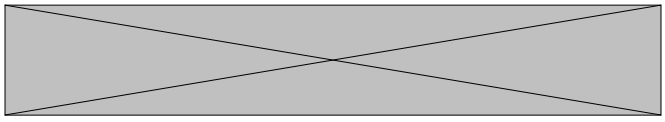

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To: William Dowling[william.dowling@cepi.net]; cheryl@gisaid.org[cheryl@gisaid.org]; peter@gisaid.org[peter@gisaid.org]; Carolyn Clark[carolyn.clark@cepi.net]; Florence, Clint (NIH/NIAID) [E[clint.florence@nih.gov]; larry.wolfraim@nih.gov[larry.wolfraim@nih.gov]; Raul Gomez Roman[raul.gomezroman@cepi.net]; Miles.Carroll@phe.gov.uk[Miles.Carroll@phe.gov.uk]; barney.graham@nih.gov[barney.graham@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; Baric, Ralph S[rbaric@email.unc.edu]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; GSELL, Pierre[gsellp@who.int]; COSTA, Alejandro Javier[costaa@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; vincent.munster@nih.gov[vincent.munster@nih.gov]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; Vasan, Vasan (H&B, Geelong AAHL[Vasan.Vasan@csiro.au]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; jokim@ivi.int[jokim@ivi.int]; mksong@ivi.int[mksong@ivi.int]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; leejooyeon@korea.kr[leejooyeon@korea.kr]; limhy0919@korea.kr[limhy0919@korea.kr]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; christian.brechot[christian.brechot@pasteur.fr]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Mark Page[Mark.Page@nibsc.org]; Graham, Barney (NIH/VRC) [E[bgraham@mail.nih.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; Thue, Tracey[tracey.thue@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Napper, Scott[scott.napper@usask.ca]; Nicola Rose[Nicola.Rose@nibsc.org]; M.P.G. Koopmans[m.koopmans@erasmusmc.nl]; sgerber@cdc.gov[sgerber@cdc.gov]; djernigan@cdc.gov[djernigan@cdc.gov]; Gerber, Susan I. (CDC/DDID/NCIRD/DVD)[bhx1@cdc.gov]; Carroll, Darin (CDC/DDID/NCEZID/OD)[zuz4@cdc.gov]; Watson, John (CDC/DDID/NCIRD/DVD)[acq4@cdc.gov]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; gustavo.f.palacios.civ@mail.mil[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; SPoehlmann@dpz.eu[SPoehlmann@dpz.eu]; mhoffmann@dpz.eu[mhoffmann@dpz.eu]; sylvie.van-der-werf@pasteur.fr[sylvie.van-der-werf@pasteur.fr]; Nelson Michelle[MNELSON@dstl.gov.uk]; Lever Steve[MSLEVER@dstl.gov.uk]; Prior Joann L[JLPRIOR@dstl.gov.uk]; Marston, Hilary (NIH/NIAID) [E][hilary.marston@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; mit666666@pitt.edu[mit666666@pitt.edu]; Mellors, John W[jwm1@pitt.edu]; tlying@fudan.edu.cn[tlying@fudan.edu.cn]; christian.drosten@charite.de[christian.drosten@charite.de]; David Vaughn[David.Vaughn@gatesfoundation.org]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]
Cc: Guthrie, Erica (CDC/DDID/NCIRD/ID)[ilj2@cdc.gov]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; Baric, Toni C[antoinette_baric@med.unc.edu]
From: Kayvon Modjarrad[kmodjarrad@eidresearch.org]
Sent: Wed 2/26/2020 7:59:47 AM (UTC-05:00)
Subject: Re: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - Double invites for tomorrow?

My apologies all. When I accepted Bill's invitation, somehow an invitation was sent out from my email in error and then I paid the price of receiving all your acceptance emails. Per Bill, the invitation from me is erroneous.

Kayvon

From: William Dowling <william.dowling@cepi.net>
Sent: Wednesday, February 26, 2020 4:54 AM
To: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; rbaric@email.unc.edu; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W;

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Subject: [EXTERNAL] WHO Consultation regarding nCoV Reagents and Cross -Reactivity - Double invites for tomorrow?

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Bill

-----Original Appointment-----
From: William Dowling
Sent: Monday, February 24, 2020 3:27 AM
To: William Dowling; cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; rbaric@email.unc.edu; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Iad7@cdc.gov; christian.brechot@pasteur.fr; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar
Cc: Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C
Subject: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - 3 PM CET
When: Thursday, February 27, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Skype Meeting

Hello all
I am sorry to change the time after some have accepted this meeting, but it has been brought to my attention that there is a competing meeting involving many invitees of this call, and we wish to have as many on the call as possible. I am therefore moving this to Thursday, 2/27 at 3 PM CET . I will send the draft minutes from last meeting and updated tables in advance.

Bill

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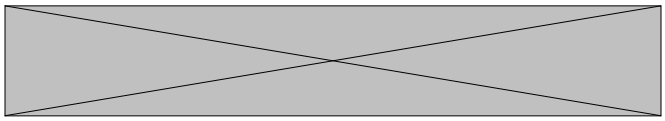

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To: Peter Daszak[daszak@ecohealthalliance.org]; Baric, Ralph S[rbaric@email.unc.edu]
Cc: Wang, Qiuhong[wang.655@osu.edu]; Kenney, Scott P.[kenney.157@osu.edu]; Vlasova, Anastasia[vlasova.1@osu.edu]
From: Saif, Linda[saif.2@osu.edu]
Sent: Wed 2/26/2020 2:50:30 PM (UTC-05:00)
Subject: m sphere paper
mSphere-2020-Inglesby-e00990-19.full.pdf

Hi
Have either of you seen this? Surprised NAS/IOM did not take active lead on this!
Regards,
Linda

Linda J. Saif, PhD
Distinguished University Professor
Food Animal Health Research Program
OARDC/The Ohio State University
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COMMENTARY
Synthetic Biology

Proposed Changes to U.S. Policy on Potential Pandemic Pathogen Oversight and Implementation

Thomas V. Inglesby[a], Marc Lipsitch[b]

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ABSTRACT We propose here changes to the U.S. government policy on potential pandemic pathogen (PPP) oversight and implementation, emphasizing transparency of the review process and the content of the review, publication of the review in advance, responsible publication of enhanced PPP research, high-level signoff on approvals of enhanced PPP experiments, and the need for a significant effort to establish a common international approach to enhanced PPP work. We advocate that the U.S. government recommend, and non-U.S. government funders and journals adopt, a set of best practices that would extend important considerations of biosafety and biosecurity to all work on enhanced potential pandemic pathogens regardless of funding source.

KEYWORDS biosafety, biosecurity, policy, potential pandemic pathogen, research regulation

In December 2017, the U.S. Department of Health and Human Services (HHS) published the *HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) (1). This framework was based on earlier guidance on this subject issued by the White House Office of Science and Technology Policy (OSTP) in January 2017 (2). The HHS framework defines a potential pandemic pathogen (PPP) as a pathogen that is both "likely highly transmissible and likely capable of wide and uncontrolled spread in human populations" and "likely highly virulent and likely to cause significant morbidity and mortality in humans." In January 2019, it was reported (3) that HHS approved new enhanced PPP experiments, and this occurred without public notification or public description of the process related to their approval.

The OSTP guidance included a plan for evaluation of agency actions. It called for an OSTP assessment of the impact of the policy on research programs and institutions, of the impact on enhanced PPP research, and of "how to provide transparency, public engagement, and continued dialogue about enhanced PPP research" (2). In addition, in January 2020 there will be a meeting of the National Science Advisory Board for Biosecurity (NSABB), which will focus on balancing the issues of transparency and security when communicating about research involving pathogens with pandemic potential. Given the requirement for an OSTP assessment of the guidance and HHS Framework and the planned NSABB meeting, we have a number of recommendations regarding how the HHS Framework and the OSTP guidance should be amended so that "biosafety and biosecurity risks associated with undertaking such research [are] adequately considered and appropriately mitigated in order to safely realize the potential benefits" (1).

Citation Inglesby TV, Lipsitch M. 2020. Proposed changes to U.S. policy on potential pandemic pathogen oversight and implementation. mSphere 5:e00990-19. https://doi.org/10.1128/mSphere.00990-19.

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Proposed Changes to US Policy on Potential Pandemic Pathogen Oversight and Implementation: @T_Inglesby and @mlipsitch call for transparency in US Govt review and best practices for other funders and journals.

Published 22 January 2020

MAKE THE HHS REVIEW OF ENHANCED PPP EXPERIMENTS TRANSPARENT

Currently, none of the HHS departmental review process for approving enhanced PPP experiments is public. This is inconsistent with the OSTP guidance which said: "To the maximum extent possible, agencies' enhanced PPP review mechanisms should provide transparency to the public regarding funded projects involving the creation, transfer or use of enhanced PPPs" (2). To that end, the HHS review should make public who participates in the review, as well as the basis of the decision that the research is acceptable to fund, including the U.S. government's (USG's) calculation of the potential benefits and risks of the proposed enhanced PPP research.

The HHS P3CO Framework says that the following disciplines should be represented in the HHS review: "scientific research, biosafety, biosecurity, MCM development and availability, law, ethics, public health preparedness and response, biodefense, select agent regulations, and public health policy." But there has been no public description of who has been part of these reviews. This is distinct from NIH reviews where review committee rosters are public. Public description of who has been represented in the review is important for public accountability to ensure the Framework is being followed appropriately. While full independence of reviewers as in the scientific grant review process may not be practical in this setting, and the guidance indicates that it should include "funding agency perspectives," the review will gain credibility if the majority of the experts assembled for this work are free of institutional conflict of interest (e.g., employment by the funding agency or its parent or sister agencies), a goal most readily achieved by using experts from the academic or nonprofit sectors.

In addition, the approval of state public health authorities (or local designates, as appropriate) should be required for enhanced PPP experiments, as was required for the approval of the biosafety level 4 (BL4) lab in Boston, MA (4). That process reflected the fact that BL4 laboratories could pose local risks of infections to laboratory personnel and immediate contacts. Public health approval of enhanced PPP experiments would reflect that this research could pose a risk of a local epidemic, which could further expand to a global pandemic in case of failure of local control. For potential pandemic pathogens, local awareness and acceptance of biosafety risks are all the more pressing than with less transmissible pathogens often studied in BL4 labs, because of the global stakes when PPPs are involved.

Beyond the procedural points made so far, the substance of the deliberations should also be public. None of the details of the analysis related to the HHS decisions approving the 2019 enhanced PPP experiments has been publicly released. Without a publicly released analysis of these experiments, there is no basis for understanding the HHS decision that the research is acceptable. The USG should provide its official assessment of the potential benefits and risks of any PPP experiment that is approved. The USG has not published qualitative or quantitative benefit and risk assessments for the specific 2019 enhanced PPP research that it has already approved. These analyses should be publicly released now so that the scientific community and the public can understand HHS decision-making.

For any future proposed enhanced PPP research, this kind of risk assessment, including any dissenting views, should be published in advance of the provision of any funding of the experiments. It is recognized that this exceeds the level of transparency required for ordinary public funding reviews. No reviews are publicly released for a typical NIH grant—appropriately reflecting that the decision is a competition between different scientific uses of scarce funds and the risk of choosing one is simply the opportunity cost of not choosing another. The unprecedented risk posed by PPP research justifies a higher level of transparency, appropriately balancing public safety (rather than just the public purse) against the private interests of researchers in the confidentiality of their science. Where possible without compromising transparency of the decision, particular details of the proposed experiments may be omitted from public disclosures if revealing them would compromise the competitive position of the

researchers, but the guiding principle should be that a concern for transparently guaranteeing public safety outweighs a concern for researchers' trade secrets.

PROVIDE THE PLAN FOR "RESPONSIBLE" PUBLICATION OF ENHANCED PPP RESEARCH

The HHS P3CO Framework states: "if funded, research that is reasonably anticipated to create, transfer or use an enhanced PPP may require additional risk mitigation strategies which may include, but are not limited to: . . .methodologies for responsible communication of results." There is no definition or clarity in the Framework regarding methodologies of responsible communication of results. Given the appropriate requirement of funders like NIH for open publication of results, the results of NIH-funded PPP work will be available everywhere globally from that point forward. Sequence data would facilitate the reconstruction of the enhanced potential pandemic pathogen. It is impossible to control where such efforts to duplicate the work would take place. Moreover, journal requirements for resource sharing postpublication might require researchers to share enhanced PPPs or reagents to create them with parties whose possession of them would threaten security and/or safety. While HHS might have determined that the original enhanced PPP experiments were taking place at an institution capable of sufficient biosafety and biosecurity controls, they cannot know the context or biosafety or biosecurity conditions that other scientists will employ in efforts to reproduce the research or use the products thereof.

On the other hand, if the work is done in a classified setting (e.g., if supported by an agency, such as the Department of Defense, which funds classified research), other countries may be concerned that these experiments are secret and being done behind closed doors. For this reason, it is important that HHS explains now, before additional decisions are made regarding the approval and funding of this work, what its requirements will be regarding "responsible communication" of the results of this research.

When enhanced PPP work is performed with USG funding, special consideration should be given to policies on resource sharing and related issues, to prevent the sharing of enhanced PPPs or the reagents to create them if such sharing could itself create an unacceptable biosafety or biosecurity risk. In cases of research approved under the HHS P3CO Framework, the presumption should be against resource sharing, in contrast to ordinary science where the presumption (or even requirement) is in the other direction.

ESTABLISH A COMMON INTERNATIONAL APPROACH TO ENHANCED PPP RESEARCH

The January 2017 OSTP P3CO guidance stated that "the US government should engage with other countries about policies concerning creation, transfer and use of enhanced PPP, encouraging the development of harmonized policy guidance" (2). However, to our knowledge there has been no robust attempt at international consensus building or harmonization since the publication of this policy. Given the high stakes involved and the leadership role that the United States has in the life sciences globally, the United States can and should take the lead internationally in establishing discussions with other science funding agencies and national academies on enhanced PPP issues. Without clear international outreach from the USG, countries can assume that since the United States is approving and funding this work, they too should be able to approve and fund this work. However, it is not in the interest of the United States or any country for countries to be funding this work without a very compelling rationale, rigorous reviews, and the highest possible biosafety and biosecurity standards in place.

If this work is going to be funded by the USG and other governments, it would be in the interest of all countries if this work was restricted to the smallest number of laboratories that have globally exceptional records of biosafety and biosecurity, experience with dangerous pathogens of the type under study, staff training, strong security procedures, and state-of-the-art-facilities that operate under an appropriate national policy framework that ensures the safety of the work.

REQUIRE A HIGH-LEVEL OFFICIAL, SUCH AS THE NIH DIRECTOR OR HHS SECRETARY, TO APPROVE ENHANCED PPP RESEARCH

The *NIH Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules* states that "the deliberate transfer of a drug resistance trait to a microorganism when such resistance could compromise the ability to control the disease agent in humans, veterinary medicine, or agriculture" requires "Major Action," which is the requirement for the signature of the NIH Director (5). Given that the potential consequences of enhanced PPP research are the initiation of an epidemic or pandemic that may not be able to be stopped with a vaccine or antiviral, it seems like this approval should similarly require the signature approval of the NIH Director or HHS Secretary. Currently, it is not clear at what level of government this approval is made.

DEVELOP GUIDANCE FOR JOURNALS AND OTHER FUNDERS OF BIOMEDICAL RESEARCH TO EMBODY THE SPIRIT AND GOALS OF THE HHS P3CO FRAMEWORK

Best-practice guidance should be developed to encourage responsible actions by non-USG funders and by publishers of scientific journals. Such best practices should be institutionalized, for example, according to the precedent of NIH recombinant DNA guidelines, which apply to research at institutions receiving federal funding for recombinant DNA work and their collaborators, regardless of the direct source of the funds for the specific research in question (6). These best practices should include the following:

For funders:

1. Funders should establish a set of criteria for flagging research of potential concern for enhanced PPP work, ideally following the USG criteria.
2. Funders should establish policies and procedures for high-level review of research meeting such criteria, again mirroring to the extent possible the USG policies and procedures. This is consistent with OSTP guidance on this issue which called for consideration of extending P3CO policy guidance in ways that "would enable oversight of all relevant research activities, regardless of funding source" (2). A best practice would be to establish a transparent review committee with comparable disciplinary expertise to that laid out in the P3CO guidance for USG funding decisions; public disclosure prior to approval of the deliberations, decision, and reasoning of the review committee, including dissenting views; and approval by the top official of the funding body only upon a favorable finding by the review committee.

For publishers:

1. Any journal submission of enhanced PPP work, as defined by the P3CO guidance, regardless of funding source, should be considered for publication only upon submission of the transparent reporting of the funding source, USG or otherwise, of the reviews described above and in the P3CO guidance, including the identity of reviewers, their qualifications, the risk and benefit calculations, and dissenting views if present.
2. Enhanced PPP work as defined by the P3CO guidance should be peer reviewed by experts in biosafety and biosecurity along with scientific reviewers, regardless of funding source. These reviewers should be asked to flag any specific issues of biosafety and biosecurity raised by the publication of the work, as well as evaluating the adequacy of the risk-benefit assessment. Publication should be contingent on the acceptance of these reviewers that the publication would be acceptable from a biosafety and biosecurity perspective.
3. Journals should make exceptions to policies on reproducibility and resource sharing that normally apply to all published articles in the event that such sharing would create a concern of biosafety or biosecurity. For example, enhanced PPPs produced by a published article or the reagents to create them, sharing of which might normally be required by journal policies, might be

exempted from such policies except in cases where the receiving party has a demonstrated need for them and a valid set of permissions from relevant authorities to work with them. Details of this policy would need further development.

CONCLUSION

The HHS P3CO Framework was created to guide funding decisions for enhanced potential pandemic pathogens because it was recognized that such work posed biosecurity and biosafety risks at the population level that required special consideration and approaches. In order to properly address such risks, this framework and its implementation should become transparent, articulate its plan for responsible communication, robustly pursue international engagement and harmonization, require the signature approval of the HHS secretary or NIH Director for funding of enhanced PPP research, and develop guidance for nongovernmental funders and publishers of this work. These changes would substantially increase scientific and public understanding of this process and lower the risks associated with PPP research.

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From: Kayvon Modjarrad[kmodjarrad@eidresearch.org]

Importance: Normal

Subject: Canceled: [EXTERNAL] RE: WHO Consultation regarding nCoV Reagents and Cross -Reactivity - change of date from 3 PM CET Tuesday 2/25 to 3 PM CET Thursday 2/27

Start Time: Thur 2/27/2020 8:00:00 AM (UTC-05:00)

End Time: Thur 2/27/2020 8:30:00 AM (UTC-05:00)

Required Attendees: william.dowling@cepi.net; cheryl@gisaid.org; peter@gisaid.org; carolyn.clark@cepi.net; clint.florence@nih.gov; larry.wolfraim@nih.gov; raul.gomezroman@cepi.net; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Connie.schmaljohn@nih.gov; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; henaorestrepoa@who.int; gsellp@who.int; costaa@who.int; lauriex@who.int; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan.Vasan@csiro.au; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; iad7@cdc.gov; christian.brechot@pasteur.fr; amy.c.shurtleff@cepi.net; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark.Page@nibsc.org; bgraham@mail.nih.gov; darryl.falzarano@usask.ca; tracey.thue@usask.ca; paul.hodgson@usask.ca; scott.napper@usask.ca; Nicola.Rose@nibsc.org; m.koopmans@erasmusmc.nl; sgerber@cdc.gov; djernigan@cdc.gov; bhx1@cdc.gov; zuz4@cdc.gov; acq4@cdc.gov; janet.lathey@nih.gov; marciela.degrace@nih.gov; moorthyv@who.int; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; MNELSON@dstl.gov.uk; MSLEVER@dstl.gov.uk; JLPRIOR@dstl.gov.uk; hilary.marston@nih.gov; emmie.dewit@nih.gov; mit666666@pitt.edu; jwm1@pitt.edu; tlying@fudan.edu.cn; christian.drosten@charite.de

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Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 3 PM CET

Start Time: Wed 3/4/2020 9:00:00 AM (UTC-05:00)

End Time: Wed 3/4/2020 10:00:00 AM (UTC-05:00)

Required Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int

Optional Attendees: Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell

Hello all
We will meet on wed this week. I will send minutes and tables shortly. Let me know if Wed is a good day for this meeting going forward.
thanks
Bill

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Organizer: William Dowling[william.dowling@cepi.net]

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; peter@gisaid.org; Carolyn Clark; Florence, Clint (NIH/NIAID) [E; larry.wolfraim@nih.gov; Raul Gomez Roman; Miles.Carroll@phe.gov.uk; barney.graham@nih.gov; Schmaljohn, Connie (NIH/NIAID) [E]; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Greg Kulnis; Luc Gagnon

Location: TBD

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 3 PM CET

Start Time: Wed 3/4/2020 9:00:00 AM (UTC-05:00)

End Time: Wed 3/4/2020 10:00:00 AM (UTC-05:00)

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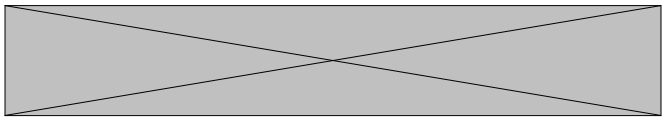

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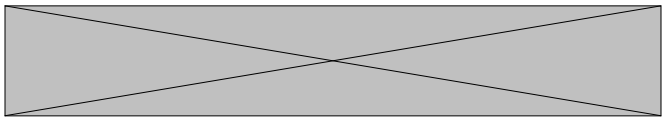

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To: daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; Baric, Ralph S[rbaric@email.unc.edu]
From: Saif, Linda[saif.2@osu.edu]
Sent: Wed 3/4/2020 9:31:02 AM (UTC-05:00)
Subject: Fwd: NYTimes: When an Epidemic Looms, Gagging Scientists Is a Terrible Idea

Great editorial!
Take heart!
Linda

Sent from my iPhone

Begin forwarded message:

> **From:** "Saif, Linda" <saif.2@osu.edu>
> **Date:** March 4, 2020 at 9:26:47 AM EST
> **To:** "Saif, Linda" <saif.2@osu.edu>
> **Subject: NYTimes: When an Epidemic Looms, Gagging Scientists Is a Terrible Idea**
>
> When an Epidemic Looms, Gagging Scientists Is a Terrible Idea
> https://www.nytimes.com/2020/02/28/health/coronavirus-pence-messaging.html?referringSource=articleShare
>
> Sent from my iPhone

From: gsellp@who.int[gsellp@who.int]
Attendees: Baric, Ralph S
Location: Webex
Importance: Normal
Subject: FW: COVID-19 Models for Vx and Rx development working group
Start Time: Thur 3/5/2020 9:00:00 AM (UTC-05:00)
End Time: Thur 3/5/2020 10:30:00 AM (UTC-05:00)
Required Attendees: Baric, Ralph S

Hello all

We will be having our second call on Thursday 3 PM CET. We request that those at the same institution try to call from a single location to minimize the number or lines we need to manage on Webex. Also, if anyone does not have access to the sharepoint site , please let us know.

Agenda :

1. Updates on ongoing COVID-19 animal studies - 45 min
2. Potential for disease enhancement following challenge in vaccinated individuals and how to model this. – 45min

Jakob Cramer from CEPI and Simon Funnell from PHE will give brief presentations followed by group discussion.

If you have an update with an ongoing study that can be presented, please let us know and please send any slides in advance.

Also, there is a pre-print of a rhesus macaque study from China at https://www.researchsquare.com/article/rs-15756/v1. We will invite the authors to present during the updates.

WEBEX INFO;

Required Attendees: Baric, Ralph S

Meeting number (access code): 928 022 593

Required Attendees: Baric, Ralph S
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Meeting password: AZfQbmmW268

Thursday, March 5, 2020

3:00 pm | Europe Time (Paris, GMT+01:00) | 1 hr 20 mins

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To: shanchao@wh.iov.cn[shanchao@wh.iov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; Palacios, Gustavo F CIV USARMY MEDCOM USAMRIID (USA)[gustavo.f.palacios.civ@mail.mil]; pauline.maisonnasse@cea.fr[pauline.maisonnasse@cea.fr]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Estefania Rodriguez-Burgos[estefania.rodriguez-burgos@leibniz-hpi.de]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; sktseng@utmb.edu[sktseng@UTMB.EDU]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; nnagata@nih.go.jp[nnagata@nih.go.jp]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 3/4/2020 9:47:07 AM (UTC-05:00)
Subject: Webex meeting invitation: 2nd teleconference - WHO Ad hoc Expert Group on preclinical models of COVID-19 disease
Mail Attachment.ics
Webex_Meeting.ics

Dear colleagues,
Please find below the details to join the 2nd teleconference on the WHO Ad hoc Expert Group on preclinical models of COVID-19 disease.

Best regards

César.

Neddy MAFUNGA invites you to join this Webex meeting.

Meeting number (access code): 928 022 593

Meeting password: AZfQbmmW268

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Organizer:	MAFUNGA, Neddy **:** mafungan@who.int
Subject:	FW: Webex meeting invitation: 2nd teleconference - Animal models COVID19
Location:	https://who.webex.com/who/j.php?MTID=m62dab470c96e1c6ac4b4df0ed68a6f1f
Start Time:	2020-03-05T15:00:00+01:00
End Time:	2020-03-05T16:20:00+01:00
Attendees:	William Dowling **:** william.dowling@cepi.net**,** Simon Funnell **:** simon.funnell@phe.gov.uk**,** Cesar Munoz-Fontela **:** munoz-fontela@bnitm.de

CID:C14B879A80149A48AA4FA509512BE777@eurprd01.prod.exchangelabs.com

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Organizer: Neddy MAFUNGA : mafungan@who.int
Subject: 2nd teleconference - Animal models COVID19
Location: https://who.webex.com/who/j.php?MTID=m62dab470c96e1c6ac4b4df0ed68a6f1f
Start Time: 2020-03-05T15:00:00+01:00
End Time: 2020-03-05T16:20:00+01:00
Attendees: : gsellp@who.int

When it's time, join the Webex meeting here.

Meeting number (access code): 928 022 593
Meeting password:AZfQbmmW268

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To: Fang, Ying[yingf@illinois.edu]; Baric, Ralph S[rbaric@email.unc.edu]; zlshi[zlshi@wh.iov.cn]; Baker, Susan[sbaker1@luc.edu]; e.j.snijder@lumc.nl[e.j.snijder@lumc.nl]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; B.L. Haagmans[b.haagmans@erasmusmc.nl]
Cc: m.kikkert@lumc.nl[m.kikkert@lumc.nl]; Bosch, B.J. (Berend Jan)[b.j.bosch@uu.nl]
From: malik[malik@hku.hk]
Sent: Sun 3/8/2020 5:18:40 AM (UTC-04:00)
Subject: Re: NIDO2020 meeting

Dear Bart and Colleagues,

I do think postponing the meeting would be the better option. I think it is likely that many labs are going to be under severe pressure in the next few monhs. Travel will also be a problem.

Malik

Get Outlook for Android

From: B.L. Haagmans <b.haagmans@erasmusmc.nl>
Sent: Sunday, March 8, 2020 5:05:42 PM
To: Fang, Ying <yingf@illinois.edu>; malik <malik@hku.hk>; Baric, Ralph S <rbaric@email.unc.edu>; zlshi <zlshi@wh.iov.cn>; Baker, Susan <Sbaker1@luc.edu>; e.j.snijder@lumc.nl <E.J.Snijder@lumc.nl>; Luis Enjuanes <l.enjuanes@cnb.csic.es>
Cc: m.kikkert@lumc.nl <m.kikkert@lumc.nl>; Bosch, B.J. (Berend Jan) <B.J.Bosch@uu.nl>
Subject: NIDO2020 meeting

dear members of the scientific advisory board of the NIDO2020 meeting,

As you all know and some of you experienced this already, the travel restrictions due to the COVID-19 outbreak have also consequences for those who want to visit conferences and symposia during the coming weeks.

Given the fact that the NIDO2020 meeting is scheduled in two months from now we need to decide how to move on. We feel that there might be a considerable risk that many participants will or cannot make it.

Therefore we ask your opinion on this issue and whether you think it still would be feasible to organize the meeting in May or organize a video conference instead. Alternatively we could shift the date, if possible, to a later time point this year (e.g. September) or move it one year later (NDO2021).

Please let us know ASAP as we need to decide quickly because of the cancellation policy and the costs related to that...

best regards,

Bart, Berend Jan and Marjolein

To: B.L. Haagmans[b.haagmans@erasmusmc.nl]; Fang, Ying[yingf@illinois.edu]; malik[malik@hku.hk]; Baric, Ralph S[rbaric@email.unc.edu]; zlshi[zlshi@wh.iov.cn]; Baker, Susan[Sbaker1@luc.edu]; e.j.snijder@lumc.nl[E.J.Snijder@lumc.nl]; Luis Enjuanes[l.enjuanes@cnb.csic.es]
Cc: m.kikkert@lumc.nl[m.kikkert@lumc.nl]; Bosch, B.J. (Berend Jan)[B.J.Bosch@uu.nl]
From: Luis Enjuanes[lenjuanes@cnb.csic.es]
Sent: Sun 3/8/2020 5:49:40 AM (UTC-04:00)
Subject: Re: NIDO2020 meeting

Dear all,

Myself, and also all our laboratory, strongly votes for a delay, either to September-October this year or, even safer, to next year.

All the best,

Luis

El 8/3/20 a las 10:05, B.L. Haagmans escribió:

> dear members of the scientific advisory board of the NIDO2020 meeting,
>
> As you all know and some of you experienced this already, the travel restrictions due to the COVID-19 outbreak have also consequences for those who want to visit conferences and symposia during the coming weeks.
>
> Given the fact that the NIDO2020 meeting is scheduled in two months from now we need to decide how to move on. We feel that there might be a considerable risk that many participants will or cannot make it.
>
> Therefore we ask your opinion on this issue and whether you think it still would be feasible to organize the meeting in May or organize a video conference instead. Alternatively we could shift the date, if possible, to a later time point this year (e.g. September) or move it one year later (NDO2021).
>
> Please let us know ASAP as we need to decide quickly because of the cancellation policy and the costs related to that...
>
> best regards,
>
> Bart, Berend Jan and Marjolein

To: Baker, Susan[Sbaker1@luc.edu]; E.J.Snijder@lumc.nl[E.J.Snijder@lumc.nl]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; malik[malik@hku.hk]; Baric, Ralph S[rbaric@email.unc.edu]; zlshi[zlshi@wh.iov.cn]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; m.kikkert@lumc.nl[m.kikkert@lumc.nl]; B.J.Bosch@uu.nl[B.J.Bosch@uu.nl]
From: Fang, Ying[yingf@illinois.edu]
Sent: Sun 3/8/2020 12:37:30 PM (UTC-04:00)
Subject: Re: NIDO2020 meeting

Dear all,

I would vote to delay the meeting to next year (Nido2021).

Since Nido2020 already has the organization structure and website, we could use this platform to form a formal nidovirus organization/collaborative network to facility the disease control and prevention. We could consider small group video conference(s) with targeted topics this year.

Best wishes,

Ying

From: Baker, Susan <Sbaker1@luc.edu>
Sent: Sunday, March 8, 2020 9:38 AM
To: E.J.Snijder@lumc.nl <E.J.Snijder@lumc.nl>
Cc: b.haagmans@erasmusmc.nl <b.haagmans@erasmusmc.nl>; Fang, Ying <yingf@illinois.edu>; malik@hku.hk <malik@hku.hk>; rbaric@email.unc.edu <rbaric@email.unc.edu>; zlshi@wh.iov.cn <zlshi@wh.iov.cn>; l.enjuanes@cnb.csic.es <l.enjuanes@cnb.csic.es>; M.Kikkert@lumc.nl <M.Kikkert@lumc.nl>; B.J.Bosch@uu.nl <B.J.Bosch@uu.nl>
Subject: Re: NIDO2020 meeting

Yes, probably makes sense to delay the meeting. A very difficult decision.
Susan B

Sent from my iPhone

> On Mar 8, 2020, at 2:46 PM, "E.J.Snijder@lumc.nl" <E.J.Snijder@lumc.nl> wrote:
>
> Dear colleagues,
>
> With pain in my heart, I have to agree with the previous speakers. We just went from 1 to 200 cases in the Netherlands in 10 days, and I am pessimistic about our chances to get rid of this virus soon. Moreover, as corona(nido)virologists we will simply have to set an example (like the organizers of ISAR/ICAR meeting in Seattle (end of March), which was just converted into an e-meeting).
>
> I agree that moving it down by a whole year probably makes most sense. In the meantime, it might be useful to have some kind of electronic platform where thoughts, data and collaborations could be discussed within the nidovirus community?
>
> Take care,
>
> - Eric -
>
> ---
>
> **From:** B.L. Haagmans <b.haagmans@erasmusmc.nl>

Sent: zondag 8 maart 2020 10:06
To: Fang, Ying <yingf@illinois.edu>; malik <malik@hku.hk>; Baric, Ralph S <rbaric@email.unc.edu>; zlshi <zlshi@wh.iov.cn>; Baker, Susan <Sbaker1@luc.edu>; Snijder, E.J. (MM) <E.J.Snijder@lumc.nl>; Luis Enjuanes <l.enjuanes@cnb.csic.es>
Cc: Kikkert, M. (MM) <M.Kikkert@lumc.nl>; Bosch, B.J. (Berend Jan) <B.J.Bosch@uu.nl>
Subject: NIDO2020 meeting

dear members of the scientific advisory board of the NIDO2020 meeting,

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Please let us know ASAP as we need to decide quickly because of the cancellation policy and the costs related to that...

best regards,

Bart, Berend Jan and Marjolein

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji

Location: Telecon

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 1 PM CET

Start Time: Wed 3/11/2020 8:00:00 AM (UTC-04:00)

End Time: Wed 3/11/2020 9:00:00 AM (UTC-04:00)

Required Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji

Hello all

The next meeting will be at 1 PM CET on Wednesday. The agenda and other materials will be uploaded in advance of the meeting. Also, this will use a WHO HQ phone line rather than Skype. There are not multiple numbers, so please try to plan accordingly.

+41.58.26.20722 / Participant code: 998628

Thanks

Bill

Cc: Simon Funnell[Simon.Funnell@phe.gov.uk]; William Dowling[william.dowling@cepi.net]; GSELL, Pierre[gsellp@who.int]; Alina Ximena Riveros Balta[lauriex@who.int]; COSTA, Alejandro Javier[costaa@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; randy.albrecht@mssm.edu[randy.albrecht@mssm.edu]; Alyson Kelvin[AKelvin@dal.ca]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Baric, Ralph S[rbaric@email.unc.edu]; dbarouch@bidmc.harvard.edu[dbarouch@bidmc.harvard.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; rcarrion@txbiomed.org[rcarrion@txbiomed.org]; Miles Carroll[Miles.Carroll@phe.gov.uk]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; Carolyn Clark[carolyn.clark@cepi.net]; sandra cordo[scordo@qb.fcen.uba.ar]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Duprex, Paul[pduprex@pitt.edu]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; darryl.falzarano@usask.ca[darryl.falzarano@usask.ca]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; raul.gomezroman@cepi.net[raul.gomezroman@cepi.net]; barney.graham@nih.gov[barney.graham@nih.gov]; B.L. Haagmans[b.haagmans@erasmusmc.nl]; Yper.Hall@phe.gov.uk[Yper.Hall@phe.gov.uk]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; paul.hodgson@usask.ca[paul.hodgson@usask.ca]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; sekim@krict.re.kr[sekim@krict.re.kr]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; jeroen.kortekaas@wur.nl[jeroen.kortekaas@wur.nl]; florian.krammer@mssm.edu[florian.krammer@mssm.edu]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; roger.le-grand@cea.fr[roger.le-grand@cea.fr]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; James.Little@hhs.gov[James.Little@hhs.gov]; ldenisy@yahoo.com[ldenisy@yahoo.com]; pauline.maisonnasse@cea.fr[pauline.maisonnasse@cea.fr]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; kmodjarrad@eidresearch.org[kmodjarrad@eidresearch.org]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; nnagata@niid.go.jp[nnagata@niid.go.jp]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; dhoconno@wisc.edu[dhoconno@wisc.edu]; nadia.oreshkova@wur.nl[nadia.oreshkova@wur.nl]; Mark.Page@nibsc.org[Mark.Page@nibsc.org]; Palacios, Gustavo F CIV USARMY MEDCOM USAMRIID (USA)[gustavo.f.palacios.civ@mail.mil]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; 秦川[qinchuan@pumc.edu.cn]; alr2105@columbia.edu[alr2105@columbia.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; b.rockx@erasmusmc.nl[b.rockx@erasmusmc.nl]; Rodriguez-Burgos, Estefania[estefania.rodriguez-burgos@leibniz-hpi.de]; Roy, Chad J[croy@tulane.edu]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; mksong@ivi.int[mksong@ivi.int]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; nax3@cdc.gov[nax3@cdc.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Vasan.Vasan@csiro.au[Vasan.Vasan@csiro.au]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; tony.wang@fda.hhs.gov[tony.wang@fda.hhs.gov]; dj56wood@gmail.com[dj56wood@gmail.com]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Mon 3/9/2020 3:40:42 PM (UTC-04:00)
Subject: WEBEX call-WHO ad hoc working group on COVID-19 modelling
WHO COVID-19 Modelling Agenda 11Mar2020.docx
Webex_Meeting.ics

Dear colleagues,
Please find below the details to join this week's call of the WHO ad hoc working group on COVID-19 animal models. Attached is also the meeting agenda.

Please note that this week the call will take place on **Wednesday (Mar11) at 2PM CET (Geneva time)**.

Also, I would like to ask all presenters to please send us the slides in advance.

Thank you all very much

César Muñoz-Fontela, Simon Funnell and William Dowling (seconded to WHO).

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 929 848 465

Meeting password: 667NhJMPYwp

Wednesday, March 11, 2020

2:00 pm | Europe Time (Paris, GMT+01:00) | 1 hr 30 mins

Join meeting

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WHO *ad hoc* working group on COVID-19 modelling
Agenda for Wednesday 11th MARCH 2020

1. **Modelling updates (NHP focus)**

    a. NIAID-RML NHP (5 min)

    b. Korea Research Institute of Chemical Technology (5 min) (to be confirmed)

    c. Erasmus NHP (5 min/verbal update)

    d. Tulane NHP (5 min)

    e. Updated NHP summary table and comment – (5 min)

    f. Summary update ferrets (5min)

    g. Updates on mouse models? (5 min)

2. **Disease enhancement discussion**

    a. Best model/vaccine formulations to assess putative disease enhancement (5 min)

    c. Discussion (10 min)

3. **Challenges**

    a. How do we advance testing of therapeutics *in vivo*? (5 min)

4. **Identified needs**
    1. Summary of needs identified (5 min)

5. **Next meeting**
    a. Thursday 19th March at 14:00-15:30 CET

Organizer: Pierre GSELL : gsellp@who.int
Subject: WHO Animal Model 3rd call
Location: https://who.webex.com/who/j.php?MTID=m4f73a511518600b9184ca04ec3c67b71
Start Time: 2020-03-11T14:00:00+01:00
End Time: 2020-03-11T15:30:00+01:00
Attendees: Pierre GSELL : gsellp@who.int

When it's time, join the Webex meeting here.

Meeting number (access code): 929 848 465
Meeting password:667NhJMPYwp

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To: B.L. Haagmans[b.haagmans@erasmusmc.nl]
Cc: Fang, Ying[yingf@illinois.edu]; malik[malik@hku.hk]; Baric, Ralph S[rbaric@email.unc.edu]; Baker, Susan[Sbaker1@luc.edu]; e.j.snijder@lumc.nl[E.J.Snijder@lumc.nl]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; m.kikkert@lumc.nl[m.kikkert@lumc.nl]; Bosch, B.J. (Berend Jan)[B.J.Bosch@uu.nl]
From: 石正丽[zlshi@wh.iov.cn]
Sent: Tue 3/10/2020 5:40:36 AM (UTC-04:00)
Subject: Re: RE: NIDO2020 meeting

Noted with thanks.

-----原始邮件-----
发件人:"B.L. Haagmans" <b.haagmans@erasmusmc.nl>
发送时间:2020-03-10 17:35:19 (星期二)
收件人: "'石正丽'" <zlshi@wh.iov.cn>
抄送: "Fang, Ying" <yingf@illinois.edu>, malik <malik@hku.hk>, "Baric, Ralph S" <rbaric@email.unc.edu>, "Baker, Susan" <Sbaker1@luc.edu>, "e.j.snijder@lumc.nl" <E.J.Snijder@lumc.nl>, "Luis Enjuanes" <l.enjuanes@cnb.csic.es>, "m.kikkert@lumc.nl" <m.kikkert@lumc.nl>, "Bosch, B.J. (Berend Jan)" <B.J.Bosch@uu.nl>
主题: RE: NIDO2020 meeting

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We will take effort to keep the program of invited and keynote speakers intact as much as possible, but we would like to ask your understanding for having to make changes here and there for the postponed version of the meeting.

Best regards

Bart, Berend Jan and Marjolein

Van: 石正丽 <zlshi@wh.iov.cn>
Verzonden: maandag 9 maart 2020 00:51
Aan: B.L. Haagmans <b.haagmans@erasmusmc.nl>
CC: Fang, Ying <yingf@illinois.edu>; malik <malik@hku.hk>; Baric, Ralph S <rbaric@email.unc.edu>; Baker, Susan <Sbaker1@luc.edu>; e.j.snijder@lumc.nl; Luis Enjuanes <l.enjuanes@cnb.csic.es>; m.kikkert@lumc.nl; Bosch, B.J. (Berend Jan) <B.J.Bosch@uu.nl>
Onderwerp: Re: NIDO2020 meeting

I would vote for the delay.

-----原始邮件-----
发件人:"B.L. Haagmans" <b.haagmans@erasmusmc.nl>
发送时间:2020-03-08 17:05:42 (星期日)
收件人: "Fang, Ying" <yingf@illinois.edu>, malik <malik@hku.hk>, "Baric, Ralph S" <rbaric@email.unc.edu>, zlshi <zlshi@wh.iov.cn>, "Baker, Susan" <Sbaker1@luc.edu>, "e.j.snijder@lumc.nl" <E.J.Snijder@lumc.nl>, "Luis Enjuanes" <l.enjuanes@cnb.csic.es>
抄送: "m.kikkert@lumc.nl" <m.kikkert@lumc.nl>, "Bosch, B.J. (Berend Jan)" <B.J.Bosch@uu.nl>
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Please let us know ASAP as we need to decide quickly because of the cancellation policy and the costs related to that...

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To: B.L. Haagmans[b.haagmans@erasmusmc.nl]; '石正丽'[zlshi@wh.iov.cn]
Cc: Fang, Ying[yingf@illinois.edu]; malik[malik@hku.hk]; Baker, Susan[Sbaker1@luc.edu]; e.j.snijder@lumc.nl[E.J.Snijder@lumc.nl]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; m.kikkert@lumc.nl[m.kikkert@lumc.nl]; Bosch, B.J. (Berend Jan)[B.J.Bosch@uu.nl]
From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]
Sent: Tue 3/10/2020 8:01:51 AM (UTC-04:00)
Subject: RE: NIDO2020 meeting

Appropriate Call. All the Best to the group during these trying times. ralph

---

From: B.L. Haagmans <b.haagmans@erasmusmc.nl>
Sent: Tuesday, March 10, 2020 5:35 AM
To: '石正丽' <zlshi@wh.iov.cn>
Cc: Fang, Ying <yingf@illinois.edu>; malik <malik@hku.hk>; Baric, Ralph S <rbaric@email.unc.edu>; Baker, Susan <Sbaker1@luc.edu>; e.j.snijder@lumc.nl; Luis Enjuanes <l.enjuanes@cnb.csic.es>; m.kikkert@lumc.nl; Bosch, B.J. (Berend Jan) <B.J.Bosch@uu.nl>
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Best regards

Bart, Berend Jan and Marjolein

Van: 石正丽 <zlshi@wh.iov.cn>
Verzonden: maandag 9 maart 2020 00:51
Aan: B.L. Haagmans <b.haagmans@erasmusmc.nl>
CC: Fang, Ying <yingf@illinois.edu>; malik <malik@hku.hk>; Baric, Ralph S <rbaric@email.unc.edu>; Baker, Susan <Sbaker1@luc.edu>; e.j.snijder@lumc.nl; Luis Enjuanes <l.enjuanes@cnb.csic.es>; m.kikkert@lumc.nl; Bosch, B.J. (Berend Jan) <B.J.Bosch@uu.nl>
Onderwerp: Re: NIDO2020 meeting

I would vote for the delay.

-----原始邮件-----
发件人:"B.L. Haagmans" <b.haagmans@erasmusmc.nl>
发送时间:2020-03-08 17:05:42 (星期日)
收件人: "Fang, Ying" <yingf@illinois.edu>, malik <malik@hku.hk>, "Baric, Ralph S" <rbaric@email.unc.edu>, zlshi <zlshi@wh.iov.cn>, "Baker, Susan" <Sbaker1@luc.edu>, "e.j.snijder@lumc.nl" <E.J.Snijder@lumc.nl>, "Luis Enjuanes" <l.enjuanes@cnb.csic.es>
抄送: "m.kikkert@lumc.nl" <m.kikkert@lumc.nl>, "Bosch, B.J. (Berend Jan)" <B.J.Bosch@uu.nl>
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To: B.L. Haagmans[b.haagmans@erasmusmc.nl]; '石正丽'[zlshi@wh.iov.cn]
Cc: Fang, Ying[yingf@illinois.edu]; malik[malik@hku.hk]; Baric, Ralph S[rbaric@email.unc.edu]; Baker, Susan[Sbaker1@luc.edu]; e.j.snijder@lumc.nl[E.J.Snijder@lumc.nl]; m.kikkert@lumc.nl[m.kikkert@lumc.nl]; Bosch, B.J. (Berend Jan)[B.J.Bosch@uu.nl]
From: Luis Enjuanes[l.enjuanes@cnb.csic.es]
Sent: Tue 3/10/2020 12:29:25 PM (UTC-04:00)
Subject: Re: NIDO2020 meeting

Dear All,

Congratulations, I think that this was hard but needed decision.

I will support NIDO2021 !!

All the best,

Luis

El 10/3/20 a las 10:35, B.L. Haagmans escribió:

> dear members of the scientific advisory board of the NIDO2020 meeting,
>
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>
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>
> **Van:** 石正丽 <zlshi@wh.iov.cn>
> **Verzonden:** maandag 9 maart 2020 00:51
> **Aan:** B.L. Haagmans <b.haagmans@erasmusmc.nl>
> **CC:** Fang, Ying <yingf@illinois.edu>; malik <malik@hku.hk>; Baric, Ralph S <rbaric@email.unc.edu>; Baker, Susan <Sbaker1@luc.edu>; e.j.snijder@lumc.nl; Luis Enjuanes <l.enjuanes@cnb.csic.es>; m.kikkert@lumc.nl; Bosch, B.J. (Berend Jan) <B.J.Bosch@uu.nl>
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best regards,

Bart, Berend Jan and Marjolein

From: Anna Nelson[annelson@usaid.gov]
Sent: Wed 3/11/2020 3:49:08 PM (UTC-04:00)
Subject: USAID grant.gov Opportunity Number 7200AA20RFA00007

Good morning.
USAID would like to call your attention to an opportunity posted on grants.gov.

Opportunity Number: 7200AA20RFA00007
Opportunity Title: STOP Spillover
Brief Description: The overall goal of STOP Spillover is to strengthen capacities in high-risk/low-income countries in Africa and Asia to reduce spillover of emerging zoonotic viruses from wildlife to people and reduce amplification and spread of zoonotic viruses in people after they have spilled over from wildlife.

Please see the opportunity on grants.gov.

Note: please route any correspondence to stopspillover@usaid.gov, not to me individually.

Thank You.

--
Anna Nelson
Contracting and Agreement Specialist
United States Agency for International Development
1300 Pennsylvania Avenue, NW
M/OAA/GH, UA, 11.3.2F
Washington, DC 20523
(202) 916-2711

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHPSE)[zud4@cdc.gov]; Zunyou Wu[wuzunyou@chinaaids.cn]; 'wuzy@263.net'[wuzy@263.net]; Baric, Ralph S[rbaric@email.unc.edu]; "Fauci Tony (E-mail)" (afauci@flash.niaid.nih.gov)[afauci@flash.niaid.nih.gov]; Fauci, Anthony (NIH/NIAID) [E][AFAUCI@niaid.nih.gov]
Cc: Schooley, Robert[rschooley@health.ucsd.edu]; Eron, Joseph J Jr[joseph_eron@med.unc.edu]
From: El-Sadr, Wafaa M.[wme1@cumc.columbia.edu]
Sent: Wed 3/11/2020 8:33:08 PM (UTC-04:00)
Subject: RE: Thank you

Adding Tony's correct email address.

Dear Zunyou, John, Ralph and Tony,

Thank you for your superb presentations in the Special COVID-19 Session at the Virtual CROI 2020. As you can imagine, your presentations were very much appreciated by all the audience. There is great thirst for more information at this point in time, which made your presentations particularly timely and impactful.

All the best,
Wafaa

Wafaa El-Sadr, MD, MPH, MPA
Director, ICAP at Columbia University
University Professor of Epidemiology and Medicine
Mathilde Krim-amFAR Professor of Global Health
Tel: 212 342 0505
Fax: 212 342 1824
www.icap.columbia.edu

From: RIVEROS BALTA, Alina Ximena[lauriex@who.int]

Attendees: HENAO RESTREPO, Ana Maria; COSTA, Alejandro Javier; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini

Location: HQ Lower SHOC

Importance: Normal

Subject: WEBEX call - update on COVID vaccines research activities

Start Time: Mon 3/16/2020 8:00:00 AM (UTC-04:00)

End Time: Mon 3/16/2020 9:00:00 AM (UTC-04:00)

Required Attendees: HENAO RESTREPO, Ana Maria; COSTA, Alejandro Javier; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini

Dear all

Following the "2019 novel Coronavirus Global research and innovation forum: towards a research roadmap" last February we will like to provide you with an update on the research activities and to discuss if there is need to update the research plans.

Please join us on Monday 16 March at 13:00 CET

Required Attendees: HENAO RESTREPO, Ana Maria; COSTA, Alejandro Javier; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini

When it's time, join the Webex meeting here.

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Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini

Meeting number (access code): 925 479 510

Meeting password: KGwYntax538

Monday, March 16, 2020

1:00 pm | Europe Time (Paris, GMT+01:00) | 1 hr

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)

41445750282 SWITZERLAND Toll

+1-415-655-0003 US Toll

Global call-in numbers

Join from a video system or application

Dial 925479510@who.webex.com

You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 925479510.who@lync.webex.com

Need help? Go to http://help.webex.com

From: Simon.Funnell@phe.gov.uk[Simon.Funnell@phe.gov.uk]

Attendees: scordo@qb.fcen.uba.ar; Jin.Zhu@health.gov.au; kanta.subbarao@influenzacentre.org; Pearl.Bamford@health.gov.au; Vasan.Vasan@csiro.au; dhoconno@wisc.edu; Gary.Kobinger@crchudequebec.ulaval.ca; Jason.Kindrachuk@umanitoba.ca; AKelvin@dal.ca; paul.hodgson@usask.ca; Volker.gerdts@usask.ca; shanchao@wh.iov.cn; qinchuan@pumc.edu.cn; Marco.Cavaleri@ema.europa.eu; christiane.gerke@pasteur.fr; pauline.maisonnasse@cea.fr; roger.le-grand@cea.fr; Barbara.Schnierle@pei.de; munoz-fontela@bnitm.de; estefania.rodriguez-burgos@leibniz-hpi.de; amy.c.shurtleff@cepi.net; Carolyn Clark; dj56wood@gmail.com; Harry.Kleanthous@gatesfoundation.org; william.dowling@cepi.net; nnagata@niid.go.jp; tksuzuki@nih.go.jp; snumouse@snu.ac.kr; ldenisy@yahoo.com; i.v.krasilnikov@spbniivs.ru; linfa.wang@duke-nus.edu.sg; seungtaek.kim@ip-korea.org; mksong@ivi.int; sekim@krict.re.kr; l.enjuanes@cnb.csic.es; Paul.Lambert@unige.ch; b.rockx@erasmusmc.nl; b.haagmans@erasmusmc.nl; jeroen.kortekaas@wur.nl; nadia.oreshkova@wur.nl; nora.gerhards@wur.nl; JLPRIOR@dstl.gov.uk; Julia Tree; MNELSON@dstl.gov.uk; Miles Carroll; REIRELAND@mail.dstl.gov.uk; Simon Funnell; MSLEVER@dstl.gov.uk; Yper Hall; Adolfo.Garcia-Sastre@mssm.edu; alr2105@columbia.edu; aysegul.nalca.civ@mail.mil; barney.graham@nih.gov; croy@tulane.edu; clint.florence@nih.gov; dbarouch@bidmc.harvard.edu; darryl.falzarano@usask.ca; David.Vaughn@gatesfoundation.org; dsreed@cvr.pitt.edu; emmie.dewit@nih.gov; erik.stemmy@nih.gov; florian.krammer@mssm.edu; Giada.Mattiuzzo@nibsc.org; gustavo.f.palacios.civ@mail.mil; Hana.Golding@fda.hhs.gov; Jacqueline.Kirchner@gatesfoundation.org; James.Little@hhs.gov; John.Treanor@hhs.gov; Karen.Makar@gatesfoundation.org; Karl.Erlandson@hhs.gov; kmodjarrad@eidresearch.org; sktseng@UTMB.EDU; Lakshmi.Jayashankar@hhs.gov; lisa.hensley@nih.gov; margaret.l.pitt.civ@mail.mil; mlewis@bioqual.com; Mark.Page@nibsc.org; Michael.holbrook@nih.gov; MONALISA.CHATTERJI@gatesfoundation.org; nax3@cdc.gov; pduprex@pitt.edu; philip.krause@fda.hhs.gov; Baric, Ralph S; randy.albrecht@mssm.edu; rcarrion@txbiomed.org; robin.levis@fda.hhs.gov; sheri.hild@nih.gov; sinabavari@comcast.net; stanley-perlman@uiowa.edu; thomasf@primate.wisc.edu; tony.wang@fda.hhs.gov; trbrasel@UTMB.EDU; vincent.munster@nih.gov

Location: https://who.webex.com/who/j.php?MTID=mf819d579a5b25232dcf045d72bd360a6

Importance: Normal

Subject: Webex meeting invitation: [COVID-19] Modelling - 4th Telecon details

Start Time: Thur 3/19/2020 9:00:00 AM (UTC-04:00)

End Time: Thur 3/19/2020 10:30:00 AM (UTC-04:00)

Required Attendees: scordo@qb.fcen.uba.ar; Jin.Zhu@health.gov.au; kanta.subbarao@influenzacentre.org; Pearl.Bamford@health.gov.au; Vasan.Vasan@csiro.au; dhoconno@wisc.edu; Gary.Kobinger@crchudequebec.ulaval.ca; Jason.Kindrachuk@umanitoba.ca; AKelvin@dal.ca; paul.hodgson@usask.ca; Volker.gerdts@usask.ca; shanchao@wh.iov.cn; qinchuan@pumc.edu.cn; Marco.Cavaleri@ema.europa.eu; christiane.gerke@pasteur.fr; pauline.maisonnasse@cea.fr; roger.le-grand@cea.fr; Barbara.Schnierle@pei.de; munoz-fontela@bnitm.de; estefania.rodriguez-burgos@leibniz-hpi.de; amy.c.shurtleff@cepi.net; Carolyn Clark; dj56wood@gmail.com; Harry.Kleanthous@gatesfoundation.org; william.dowling@cepi.net; nnagata@niid.go.jp; tksuzuki@nih.go.jp; snumouse@snu.ac.kr; ldenisy@yahoo.com; i.v.krasilnikov@spbniivs.ru; linfa.wang@duke-nus.edu.sg; seungtaek.kim@ip-korea.org; mksong@ivi.int; sekim@krict.re.kr; l.enjuanes@cnb.csic.es; Paul.Lambert@unige.ch; b.rockx@erasmusmc.nl; b.haagmans@erasmusmc.nl; jeroen.kortekaas@wur.nl; nadia.oreshkova@wur.nl; nora.gerhards@wur.nl; JLPRIOR@dstl.gov.uk; Julia Tree; MNELSON@dstl.gov.uk; Miles Carroll; REIRELAND@mail.dstl.gov.uk; Simon Funnell; MSLEVER@dstl.gov.uk; Yper Hall; Adolfo.Garcia-Sastre@mssm.edu; alr2105@columbia.edu; aysegul.nalca.civ@mail.mil; barney.graham@nih.gov; croy@tulane.edu; clint.florence@nih.gov; dbarouch@bidmc.harvard.edu; darryl.falzarano@usask.ca; David.Vaughn@gatesfoundation.org; dsreed@cvr.pitt.edu; emmie.dewit@nih.gov; erik.stemmy@nih.gov; florian.krammer@mssm.edu; Giada.Mattiuzzo@nibsc.org; gustavo.f.palacios.civ@mail.mil; Hana.Golding@fda.hhs.gov; Jacqueline.Kirchner@gatesfoundation.org; James.Little@hhs.gov; John.Treanor@hhs.gov; Karen.Makar@gatesfoundation.org; Karl.Erlandson@hhs.gov; kmodjarrad@eidresearch.org; sktseng@UTMB.EDU; Lakshmi.Jayashankar@hhs.gov; lisa.hensley@nih.gov; margaret.l.pitt.civ@mail.mil; mlewis@bioqual.com; Mark.Page@nibsc.org; Michael.holbrook@nih.gov; MONALISA.CHATTERJI@gatesfoundation.org; nax3@cdc.gov; pduprex@pitt.edu; philip.krause@fda.hhs.gov; Baric, Ralph S; randy.albrecht@mssm.edu; rcarrion@txbiomed.org; robin.levis@fda.hhs.gov; sheri.hild@nih.gov; sinabavari@comcast.net; stanley-perlman@uiowa.edu; thomasf@primate.wisc.edu; tony.wang@fda.hhs.gov; trbrasel@UTMB.EDU; vincent.munster@nih.gov

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Dear COVID-19 modelling group participant, thank you for your continued participation in this growing international collaboration.
Please find attached the Webex dial-in details for our next COVID-19 modelling *ad hoc* experts, regulators and funders telecon.

Our agenda for the 19th March will include;

1. Introduction followed by verbal updates on
    1. Non-human primate studies
    2. Ferret studies
    3. Murine studies
    4. Any other infection modelling studies
1. Update on the current emergency use situation
2. Identification of what we can do now to provide regulators confidence to proceed with Phase 1 vaccine studies

3. Identification of what we can do now to accelerate the identification and use of therapeutics as soon as possible
4. AOB

Please email us slides (no more than 3 for a 5 minute talk) if you have an update you would like to share with us.
We need to hear from all of you if you have live or recently completed studies especially related to disease enhancement if it occurs.

Please note that we intend to keep to a weekly Thursday telecon schedule for the time being
in order to help attendees plan their participation in what we know are challenging circumstances for all.

There are many participants so please mute your microphone unless invited to speak by Pierre to avoid feedback and assist
orderly communication between participants. Please also use a headset where possible as speakerphones tend to be source
of feedback problems.

If you cannot attend this call, please update the growing excel summary table found in the sharepoint drive and view the presentations of this and previous calls.
Access to the sharepoint drive is also included as a reminder;
https://teams.microsoft.com/l/team/19%3a24298ffab829497fb583add36bf4abc9%40thread.tacv2/conversations?groupId=ac72334b-aa32-4a35-8127-80470cd96cf0&tenantId=f610c0b7-bd24-4b39-810b-3dc280afb590
You will also find minutes of our previous calls in the meetings subdirectory.
Your contributions have already led to refinement and continued input will help reduce unnecessary replication of global effort.

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 926 194 548

Meeting password: dQBDfKNg537

Thursday, March 19, 2020

2:00 pm | (UTC+01:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] Animal Models - 4th TC
Location: https://who.webex.com/who/j.php?MTID=mf819d579a5b25232dcf045d72bd360a6
Start Time: 2020-03-19T14:00:00+01:00
End Time: 2020-03-19T15:30:00+01:00
Attendees: Simon.Funnell@phe.gov.uk : Simon.Funnell@phe.gov.uk

When it's time, join the Webex meeting here.

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From: Pierre GSELL[gsellp@who.int]

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Importance: Normal

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Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 926 194 548

Meeting password: dQBDfKNg537

Thursday, March 19, 2020

2:00 pm | (UTC+01:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] Animal Models - 4th TC
Location: https://who.webex.com/who/j.php?MTID=mf819d579a5b25232dcf045d72bd360a6
Start Time: 2020-03-19T14:00:00+01:00
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Attendees: Simon.Funnell@phe.gov.uk : Simon.Funnell@phe.gov.uk

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To: Baric, Ralph S[rbaric@email.unc.edu]; afauci@niaid.nih.gov[afauci@niaid.nih.gov]
From: Sheepcat[Sheepcat@protonmail.com]
Sent: Sun 3/15/2020 11:17:30 PM (UTC-04:00)
Subject: GS-441524 question

Dear Doctors,
I am a Veterinary Researcher. I wanted to know if the Gilead GS-441524 was evaluated, since it had done VERY well both in terms of a cure and in terms of safety in felines.

References:
https://pubmed.ncbi.nlm.nih.gov/30755068-efficacy-and-safety-of-the-nucleoside-analog-gs-441524-for-treatment-of-cats-with-naturally-occurring-feline-infectious-peritonitis/
and:
https://www.mendeley.com/catalogue/5d92d5bb-1cc4-3b70-a8ef-a5b4a115c647/

Thank You,
Allison Rogers, DVM

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

Start Time: Wed 3/18/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 3/18/2020 10:00:00 AM (UTC-04:00)

Required Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu

Hello all

The next meeting will be this Wed at 2 PM CET and the call in information is below. Agenda and draft meeting minutes from the last call will be sent tomorrow.

Thanks

Bill

+41.58.262.0722 / Participant code: 998643.

Organizer: William Dowling[william.dowling@cepi.net]

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Morabito, Kaitlyn (NIH/VRC) [E]

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

Start Time: Wed 3/18/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 3/18/2020 10:00:00 AM (UTC-04:00)

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Optional Attendees: Morabito, Kaitlyn (NIH/VRC) [E]

Hello all

The next meeting will be this Wed at 2 PM CET and the call in information is below. Agenda and draft meeting minutes from the last call will be sent tomorrow.

Thanks

Bill

+41.58.262.0722 / Participant code: 998643.

From: COSTA, Alejandro Javier[costaa@who.int]

Attendees: RIVEROS BALTA, Alina Ximena; HENAO RESTREPO, Ana Maria; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini; rpeto@ndph.ox.ac.uk; Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)

Importance: Normal

Subject: WEBEX call - update on COVID vaccines research activities

Start Time: Mon 3/16/2020 10:00:00 AM (UTC-04:00)

End Time: Mon 3/16/2020 10:30:00 AM (UTC-04:00)

Required Attendees: RIVEROS BALTA, Alina Ximena; HENAO RESTREPO, Ana Maria; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini; rpeto@ndph.ox.ac.uk

Optional Attendees: Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)

I forgot to mention this is the paper mentioned by Simon during the call .

From: COSTA, Alejandro Javier
Sent: 16 March 2020 14:09
To: RIVEROS BALTA, Alina Ximena <lauriex@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; GSELL, Pierre <gsellp@who.int>; William Dowling <william.dowling@cepi.net>; Cesar Munoz-Fontela <munoz-fontela@bnitm.de>; Simon Funnell <simon.funnell@phe.gov.uk>; philip.krause@fda.hhs.gov; Jean-pierre Amorij <jamorij@unicef.org>; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; rbaric <rbaric@email.unc.edu>; bgraham <barney.graham@nih.gov>; Bergquist Charlotta <charlotta.bergquist@lakemedelsverket.se>; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA) <ruben.donis@hhs.gov>; RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham <bgraham@mail.nih.gov>; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee <jeey62@gmail.com>; dkaslow@path.org; (SPmig) Robin Levis <robin.levis@fda.hhs.gov>; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi <madhis@rmpru.co.za>; raburn.mallory@astrazeneca.com; Giada Mattiuzzo <Giada.Mattiuzzo@nibsc.org>; mengwn@sinovac.com; Kayvon Modjarrad <kmodjarrad@eidresearch.org>; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin <stanley.plotkin@vaxconsult.com>; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith <Peter.Smith@lshtm.ac.uk>; jamess@icon.co.za; Julia Tree <Julia.Tree@phe.gov.uk>; linfa.wang <linfa.wang@duke-nus.edu.sg>; xuefeng.yu@cansinotech.com; ilongini <ilongini@ufl.edu>
Cc: Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley <Siobhan.Crowley@pentafoundation.org>;

Laurent Humeau <lhumeau@inovio.com>; Jacqueline Shea <Jacqueline.Shea@inovio.com>; Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>
Subject: RE: WEBEX call - update on COVID vaccines research activities

Effective Treatment of Severe COVID-19 Patients with Tocilizumab

Attached is the paper

Alejandro Costa
Scientist,
R&D Blueprint
Health Emergency Program (WHE)
World Health Organization (WHO)
Office: 1156
Tel: +41 22 791 4965
Mobile: +41 79 217 34 37
Email: costaa@who.int

-----Original Appointment-----
From: RIVEROS BALTA, Alina Ximena
Sent: 13 March 2020 11:51
To: RIVEROS BALTA, Alina Ximena; HENAO RESTREPO, Ana Maria; COSTA, Alejandro Javier; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; rbaric; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini
Cc: Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)
Subject: WEBEX call - update on COVID vaccines research activities
When: 16 March 2020 13:00-14:00 (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna.
Where: HQ Lower SHOC

Dear all

Following the “2019 novel Coronavirus Global research and innovation forum: towards a research roadmap” last February we will like to provide you with an update on the research activities and to discuss if there is need to update the research plans.

Please join us on Monday 16 March at 13:00 CET

When it's time, join the Webex meeting here.

Meeting number (access code): 925 479 510

Meeting password: KGwYntax538

Monday, March 16, 2020

1:00 pm | Europe Time (Paris, GMT+01:00) | 1 hr

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)

41445750282 SWITZERLAND Toll

+1-415-655-0003 US Toll

Global call-in numbers

Join from a video system or application

Dial 925479510@who.webex.com

You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 925479510.who@lync.webex.com

Need help? Go to http://help.webex.com

Organizer: COSTA, Alejandro Javier[costaa@who.int]

From: COSTA, Alejandro Javier[costaa@who.int]

Attendees: RIVEROS BALTA, Alina Ximena; HENAO RESTREPO, Ana Maria; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini; rpeto@ndph.ox.ac.uk; Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)

Importance: Normal

Subject: Canceled: WEBEX call - update on COVID vaccines research activities

Start Time: Mon 3/16/2020 10:00:00 AM (UTC-04:00)

End Time: Mon 3/16/2020 10:30:00 AM (UTC-04:00)

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Optional Attendees: Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)

I forgot to mention this is the paper mentioned by Simon during the call .

From: COSTA, Alejandro Javier
Sent: 16 March 2020 14:09
To: RIVEROS BALTA, Alina Ximena <lauriex@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; GSELL, Pierre <gsellp@who.int>; William Dowling <william.dowling@cepi.net>; Cesar Munoz-Fontela <munoz-fontela@bnitm.de>; Simon Funnell <simon.funnell@phe.gov.uk>; philip.krause@fda.hhs.gov; Jean-pierre Amorij <jamorij@unicef.org>; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; rbaric <rbaric@email.unc.edu>; bgraham <barney.graham@nih.gov>; Bergquist Charlotta <charlotta.bergquist@lakemedelsverket.se>; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA) <ruben.donis@hhs.gov>; RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham <bgraham@mail.nih.gov>; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee <jeey62@gmail.com>; dkaslow@path.org; (SPmig) Robin Levis <robin.levis@fda.hhs.gov>; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi <madhis@rmpru.co.za>; raburn.mallory@astrazeneca.com; Giada Mattiuzzo <Giada.Mattiuzzo@nibsc.org>; mengwn@sinovac.com; Kayvon Modjarrad <kmodjarrad@eidresearch.org>; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin <stanley.plotkin@vaxconsult.com>; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith <Peter.Smith@lshtm.ac.uk>; jamess@icon.co.za; Julia Tree <Julia.Tree@phe.gov.uk>; linfa.wang <linfa.wang@duke-nus.edu.sg>; xuefeng.yu@cansinotech.com; ilongini <ilongini@ufl.edu>

Cc: Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley <Siobhan.Crowley@pentafoundation.org>; Laurent Humeau <lhumeau@inovio.com>; Jacqueline Shea <Jacqueline.Shea@inovio.com>; Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>
Subject: RE: WEBEX call - update on COVID vaccines research activities

Effective Treatment of Severe COVID-19 Patients with Tocilizumab

Attached is the paper

Alejandro Costa
Scientist,
R&D Blueprint
Health Emergency Program (WHE)
World Health Organization (WHO)
Office: 1156
Tel: +41 22 791 4965
Mobile: +41 79 217 34 37
Email: costaa@who.int

-----Original Appointment-----
From: RIVEROS BALTA, Alina Ximena
Sent: 13 March 2020 11:51
To: RIVEROS BALTA, Alina Ximena; HENAO RESTREPO, Ana Maria; COSTA, Alejandro Javier; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; rbaric; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini
Cc: Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)
Subject: WEBEX call - update on COVID vaccines research activities
When: 16 March 2020 13:00-14:00 (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna.
Where: HQ Lower SHOC

Dear all

Following the “2019 novel Coronavirus Global research and innovation forum: towards a research roadmap” last February we will like to provide you with an update on the research activities and to discuss if there is need to update the research plans.

Please join us on Monday 16 March at 13:00 CET

When it's time, join the Webex meeting here.

Meeting number (access code): 925 479 510

Meeting password: KGwYntax538

Monday, March 16, 2020

1:00 pm | Europe Time (Paris, GMT+01:00) | 1 hr

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You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 925479510.who@lync.webex.com

Need help? Go to http://help.webex.com

Organizer: COSTA, Alejandro Javier[costaa@who.int]

From: COSTA, Alejandro Javier[costaa@who.int]

Attendees: RIVEROS BALTA, Alina Ximena; HENAO RESTREPO, Ana Maria; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini; rpeto@ndph.ox.ac.uk; Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)

Importance: High

Subject: Canceled: WEBEX call - update on COVID vaccines research activities

Start Time: Mon 3/16/2020 10:00:00 AM (UTC-04:00)

End Time: Mon 3/16/2020 10:30:00 AM (UTC-04:00)

Required Attendees: RIVEROS BALTA, Alina Ximena; HENAO RESTREPO, Ana Maria; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; Baric, Ralph S; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini; rpeto@ndph.ox.ac.uk

Optional Attendees: Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)

I forgot to mention this is the paper mentioned by Simon during the call .

From: COSTA, Alejandro Javier
Sent: 16 March 2020 14:09
To: RIVEROS BALTA, Alina Ximena <lauriex@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; GSELL, Pierre <gsellp@who.int>; William Dowling <william.dowling@cepi.net>; Cesar Munoz-Fontela <munoz-fontela@bnitm.de>; Simon Funnell <simon.funnell@phe.gov.uk>; philip.krause@fda.hhs.gov; Jean-pierre Amorij <jamorij@unicef.org>; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; rbaric <rbaric@email.unc.edu>; bgraham <barney.graham@nih.gov>; Bergquist Charlotta <charlotta.bergquist@lakemedelsverket.se>; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA) <ruben.donis@hhs.gov>; RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham <bgraham@mail.nih.gov>; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee <jeey62@gmail.com>; dkaslow@path.org; (SPmig) Robin Levis <robin.levis@fda.hhs.gov>; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi <madhis@rmpru.co.za>; raburn.mallory@astrazeneca.com; Giada Mattiuzzo <Giada.Mattiuzzo@nibsc.org>; mengwn@sinovac.com; Kayvon Modjarrad <kmodjarrad@eidresearch.org>; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin <stanley.plotkin@vaxconsult.com>; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith <Peter.Smith@lshtm.ac.uk>; jamess@icon.co.za; Julia Tree <Julia.Tree@phe.gov.uk>; linfa.wang <linfa.wang@duke-nus.edu.sg>; xuefeng.yu@cansinotech.com; ilongini <ilongini@ufl.edu>

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Subject: RE: WEBEX call - update on COVID vaccines research activities

Effective Treatment of Severe COVID-19 Patients with Tocilizumab

Attached is the paper

Alejandro Costa
Scientist,
R&D Blueprint
Health Emergency Program (WHE)
World Health Organization (WHO)
Office: 1156
Tel: +41 22 791 4965
Mobile: +41 79 217 34 37
Email: costaa@who.int

-----Original Appointment-----
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To: RIVEROS BALTA, Alina Ximena; HENAO RESTREPO, Ana Maria; COSTA, Alejandro Javier; GSELL, Pierre; William Dowling; Cesar Munoz-Fontela; Simon Funnell; philip.krause@fda.hhs.gov; Jean-pierre Amorij; Poonepalli_ANURADHA@hsa.gov.sg; ripleyballou@mac.com; rbaric; bgraham; Bergquist Charlotta; gus4tee@yahoo.com; thomas.breuer@gsk.com; kate.broderick@inovio.com; nataliedean@ufl.edu; Donis, Ruben (OS/ASPR/BARDA); RDraghia@ITS.JNJ.com; Anna.DU@gatesfoundation.org; embrya@niaid.nih.gov; Volker.gerdts@usask.ca; prakashghimire@gmail.com; carlo.giaquinto@unipd.it; gglenn@novavax.com; bgraham; guptanivedita.hq@icmr.gov.in; betz@fhcrc.org; Helfand, Rita (CDC/DDID/NCEZID/OD); ziliyasu@gmail.com; hasan.jafri@astrazeneca.com; (SPmig) Youngmee Jee; dkaslow@path.org; (SPmig) Robin Levis; attaya@gmail.com; linjs@sinovac.com; Jyoti.logani@nic.in; ldenisy@yahoo.com; (SPmig) Shabir Madhi; raburn.mallory@astrazeneca.com; Giada Mattiuzzo; mengwn@sinovac.com; Kayvon Modjarrad; lidia.oostvogels@curevac.com; s.pagliusi@dcvmn.net; Stanley Plotkin; Helen.Rees@wits.ac.za; Schmaljohn, Connie (NIH/NIAID) [E]; HSCHUITE@its.jnj.com; mari.v.sergeeva@gmail.com; Peter Smith; jamess@icon.co.za; Julia Tree; linfa.wang; xuefeng.yu@cansinotech.com; ilongini
Cc: Federico.Martinon.Torres@sergas.es; moe.assoum@gmail.com; Siobhan Crowley; Laurent Humeau; Jacqueline Shea; Bresee, Joseph (CDC/DDID/NCIRD/ID)
Subject: WEBEX call - update on COVID vaccines research activities
When: 16 March 2020 13:00-14:00 (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna.
Where: HQ Lower SHOC

Dear all

Following the “2019 novel Coronavirus Global research and innovation forum: towards a research roadmap” last February we will like to provide you with an update on the research activities and to discuss if there is need to update the research plans.

Please join us on Monday 16 March at 13:00 CET

When it's time, join the Webex meeting here.

Meeting number (access code): 925 479 510

Meeting password: KGwYntax538

Monday, March 16, 2020

1:00 pm | Europe Time (Paris, GMT+01:00) | 1 hr

Join meeting

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Organizer: DeStefano, Laura[LDestefano@nas.edu]

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; 'Georges Benjamin'; drnickilurie@gmail.com; Del Rio, Carlos; 'Sharon Inouye'; 'Linda Degutis'; Susan Polan; Ogilvie, Jenna; Kanarek, Morgan; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Overton, Devona; May, David; Kearney, William; Pope, Andrew; Pavlin, Julie; Korsen, Dana; Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen; Paulina Sosa

Location: Zoom - instructions below - see background materials

Importance: Normal

Subject: CONFIRMED - COVID-19 Conversations Webinar Series Advisory Group Meeting

Start Time: Thur 3/19/2020 5:00:00 PM (UTC-04:00)

End Time: Thur 3/19/2020 7:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; 'Georges Benjamin'; drnickilurie@gmail.com; Del Rio, Carlos; 'Sharon Inouye'; 'Linda Degutis'; Susan Polan; Ogilvie, Jenna; Kanarek, Morgan; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Overton, Devona; May, David; Kearney, William; Pope, Andrew; Pavlin, Julie; Korsen, Dana

Optional Attendees: Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen; Paulina Sosa

Background Materials:

Advisory Group Roster
March 19 Call Agenda
COVID-19Conversations.org

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: "COVID-19 Conversations" Webinar Series Advisory Group Call
Time: Mar 19, 2020 05:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/235883148

Or iPhone one-tap :
US: +13126266799,,235883148# or +14702509358,,235883148#
Or Telephone:
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Meeting ID: 235 883 148
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

Organizer:	DeStefano, Laura[LDestefano@nas.edu]
From:	DeStefano, Laura[LDestefano@nas.edu]
Attendees:	'Linda Degutis'; 'Sharon Inouye'; 'ushah@hcphes.org'; 'acasadevall@jhu.edu'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen
Location:	see below
Importance:	Normal
Subject:	"The Science of Social Distancing" - NAM-APHA "COVID-19 Conversations" #1
Start Time:	Wed 3/25/2020 3:00:00 PM (UTC-04:00)
End Time:	Wed 3/25/2020 4:30:00 PM (UTC-04:00)
Required Attendees:	'Linda Degutis'; 'Sharon Inouye'; 'ushah@hcphes.org'; 'acasadevall@jhu.edu'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C
Optional Attendees:	Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen

Hi all, to join tomorrow's webinar, please check your email for personal login instructions from the American Public Health Association.

If you did not receive the email, let me know.

If you would like to register others for the webinar, visit
https://cc.readytalk.com/registration/#/?meeting=mj415bksu3zh&campaign=v693815j1185

Thanks,
Laura

202 334 3268

To: Baric, Ralph S[rbaric@email.unc.edu]
From: Peter Daszak[daszak@ecohealthalliance.org]
Sent: Tue 3/17/2020 10:03:52 AM (UTC-04:00)
Subject: Follow up to the National Academies meeting we did in February
SC on EID and 21st Century Threats - One Pager.pdf
Standing Committee on EIDs and 21st C Health Threats. Details.pdf

Hi Ralph,

Just wanted to let you know that the National Academies did set up a Standing Committee as requested by the OSTP Director, who's on the President's COVID taskforce. It's called the "Standing Committee on Emerging Infectious Diseases & 21st Century Health Threats". The charge to the committee is attached. NASEM put out a call and I was nominated. I got some questions from NAM about my relationship to the Wuhan lab, but I explained that it's purely academic (no funds from China to me), and I offered to recuse myself from any discussions about the conspiracy theories re. lab release or bioengineering. The NASEM staff were ok with that and I joined the Committee. There was a meeting to discuss research agenda for COVID-19 and a doc has been written up on this for the OSTP. The meeting had a public session. I've attached the agenda, and details of who's on the committee (provisional, but we are prob now all approved).

Just wanted to let you know what's happening. I don't think this committee will be getting into the lab release or bioengineering hypothesis again any time soon – White House seems to be satisfied with the earlier meeting, paper in Nature and general comments within scientific community. National Security staff were in the room with OSTP on the first call.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

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Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine will convene a standing committee of experts to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee will include approximately 15 members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee will provide a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

The standing committee will:

- Stand ready to respond on short notice to requests from the federal government to assess and consider the science and policy implications of an emerging infectious disease or significant public health threat;
- Provide a venue to enable science and policy discussions relevant to the federal government on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and objectives;
- Identify opportunities to integrate science into national preparedness and response decision making;
- Explore lessons learned and best practices from previous preparedness and response efforts, and identify opportunities to disseminate that information to a variety of stakeholders;
- Serve as a focal point for national policy discussions by experts and other leaders in the field;
- Consider, identify, and discuss strategies for addressing misinformation; and
- Respond to the federal government's needs for continuing dialog related to strategic planning and program development to address emerging infectious diseases, biosecurity, and public health and medical preparedness.

At the request of the sponsors, the standing committee will be involved in the planning, development, and oversight of related ad hoc activities undertaken by separately appointed committees operating under its auspices.

The standing committee will serve as a focal point for the discussion of scientific, technical, and policy issues relevant to emerging infectious diseases and public health preparedness and response that warrant detailed examination. Topics for discussion with the standing committee may include:

- Technical assistance and/or assessment of response to emerging infectious diseases;
- Availability of and access to information, samples, and other materials to determine the origin and evolution of emerging infectious diseases;
- International coordination and engagement;
- Technical assessment of ecological and evolutionary drivers of disease emergence;
- Approaches to proactive public messaging and strategies to address misinformation;
- Other science and policy issues relevant to emerging infectious diseases and 21st century health threats.

The committee will carry out its charge at its in-person and virtual meetings by gathering evidence from experts, deliberating, and, when necessary, by preparing short reports.

CONTACT INFORMATION

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The National Academies of
SCIENCES • ENGINEERING • MEDICINE

STANDING COMMITTEE ON EMERGING INFECTIOUS DISEASES AND 21ST CENTURY HEALTH THREATS

Health and Medicine Division

Board on Health Sciences Policy
Board on Global Health

Briefing Materials
Meeting 1
March 11, 2020

Virtual Meeting

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

TAB 1

Agenda and Remote Participation Information

First Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Final Agenda

Wednesday, March 11, 2020, 12:00 p.m. – 5:30 p.m. ET
Virtual Zoom Meeting/Keck 201 for Local Participants

Background:
In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine will convene a standing committee of experts to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee will include members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee will provide a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

Meeting Objectives

- Discuss the statement of task (SOT) and role of the standing committee
- Conduct the bias and conflict of interest discussion
- Discuss relevant context and key issues
- Explore potential research priorities arising as a result of the emergence of COVID-19 in the U.S. and globally
- Discuss next steps to move forward on key issues; plan second meeting and identify speakers and topics

Wednesday, March 11, 2020

CLOSED SESSION (COMMITTEE MEMBERS ONLY)

12:00 p.m. **Welcome and Introductions**

- Brief introductions
- Discussion of meeting objectives

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Andrew Pope
Director, Board on Health Sciences Policy
Health and Medicine Division

Julie Pavlin
Director, Board on Global Health
Health and Medicine Division

12:10 p.m. **Role of National Academies Standing Committees**

Andrew Pope
Director, Board on Health Sciences Policy
Health and Medicine Division

12:15 p.m. **Discussion of Bias and Conflict of Interest**

Lauren Shern
Associate Executive Director
Health and Medicine Division

12:30 p.m. **Committee Discussion with Sponsor to Inform Open Session**

Kelvin Droegemeier
Director
White House Office of Science and Technology Policy

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

OPEN SESSION

SESSION I **Welcoming Remarks, Introductions, and Sponsors' Charge to the Committee**

1:30 p.m. **Welcome and Introductions**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Marcia McNutt
President
National Academy of Sciences

Victor Dzau
President
National Academy of Medicine

Gregory Symmes
Chief Program Officer
The National Academies of Sciences, Engineering, and Medicine

1:45 p.m. **Sponsors' Charge to the Committee**

- Discuss the context/purpose for the standing committee
- Review the statement of task

Kelvin Droegemeier
Director
White House Office of Science and Technology Policy

David (Chris) Hassell
Senior Science Advisor
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

2:00 p.m. **Committee Discussion with the Sponsor**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

2:30 p.m. ***BREAK***

SESSION II **Diagnostics and Viral Characterization**

2:45 p.m. **Presentation of the Issues**

Ian Watson
Assistant Director for Biotechnology & Biosecurity
Office of Science & Technology Policy

Paige Waterman
Assistant Director for Biological Threat Defense
Office of Science & Technology Policy

David (Chris) Hassell
Senior Science Advisor
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

3:00 p.m. **Committee Discussion of the Issues**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

SESSION III **Other Selected Topics and Issues**

4:00 p.m. **Discussion of Committee's Selected Topics and Issues**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

CLOSED SESSION (COMMITTEE ONLY)

5:00 p.m. **Committee Debrief, Next Steps, and Potential Future Meeting Topics**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

5:30 p.m. ***ADJOURN MEETING***

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TAB 2

Standing Committee Membership Information

The National Academies of
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Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

INTERNAL COMMITTEE ROSTER

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Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

COMMITTEE MEMBER BIOSKETCHES

Harvey Fineberg, M.D., Ph.D. ***(Chair)***
President
Gordon and Betty Moore Foundation

Harvey Fineberg is president of the Gordon and Betty Moore Foundation. He previously served as president of the Institute of Medicine from 2002 to 2014 and as provost of Harvard University from 1997 to 2001, following 13 years as dean of the Harvard School of Public Health. Fineberg devoted most of his academic career to the fields of health policy and medical decision-making. His past research has focused on the process of policy development and implementation, assessment of medical technology, evaluation and use of vaccines, and dissemination of medical innovations. Fineberg serves on the boards of the Carnegie Endowment for International Peace and the China Medical Board. He helped found and served as president of the Society for Medical Decision Making, previously served on and chaired the board of the William and Flora Hewlett Foundation, and chaired the committee to review the performance of the World Health Organization and the functioning of the International Health Regulations (2005) during the 2009 H1N1 influenza pandemic. Fineberg is co-author of the books *Clinical Decision Analysis*, *Innovators in Physician Education* and *The Epidemic That Never Was*, an analysis of the controversial federal immunization program against swine flu in 1976. He has co-edited several books on such diverse topics as AIDS prevention, vaccine safety, understanding risk in society and global health. He has also authored numerous articles published in professional journals. Fineberg chaired the National Academies committee that produced the 2019 report on *Reproducibility and Replicability in Science*. He earned his bachelor's and doctoral degrees at Harvard and is the recipient of several honorary degrees.

Kristian Andersen, Ph.D.
Associate Professor and Director of Infectious Disease Genomics, Scripps Research Translational Institute
The Scripps Research Institute

Kristian Andersen is an associate professor in the Department of Immunology and Microbiology at Scripps Research, with joint appointments in the Department of Integrative Structural and Computational Biology, and at the Scripps Research Translational Institute. Over the past decade, his research has focused on the complex relationship between host and pathogen. Using a combination of next-generation sequencing, field work, experimentation, and computational biology he has spearheaded large international collaborations investigating the emergence, spread and evolution of deadly pathogens, including SARS-CoV-2, Zika virus, Ebola virus, West Nile virus, and Lassa virus. His work is highly cross-disciplinary and exceptionally collaborative. Kristian earned his doctoral degree from the University of Cambridge and performed postdoctoral work in Pardis Sabeti's group at Harvard University and the Broad Institute.

Mary Bassett, M.D., M.P.H.
Director of the François-Xavier Bagnoud Center for Health and Human Rights
Harvard School of Public Health

Mary Bassett is the Director of the FXB Center for Health and Human Rights at Harvard University, as well as the FXB Professor of the Practice of Health and Human Rights at the Harvard School of Public Health. With more than 30 years of experience in public health, Dr. Mary Travis Bassett has dedicated her career to advancing health equity. Prior to her directorship at the FXB Center, Dr. Bassett served for four years as commissioner of Health for New York City. As commissioner, she worked to ensure that every New York City neighborhood supported the health of its residents, with the goal of closing gaps in population health across the city. Originally from New York City, Dr. Bassett lived in Zimbabwe for nearly 20 years. Previously, she was the Program Director for the African Health Initiative and the Child Well-being Program at the Doris Duke Charitable Foundation. She received her B.A. in History and Science from Harvard University and her M.D. from Columbia University's College of Physicians and Surgeons. She served her medical residency at Harlem Hospital Center, and has a master's degree in Public Health from the University of Washington, where she was a Robert Wood Johnson Clinical Scholar.

Trevor Bedford, Ph.D.
Associate Faculty Member, Vaccine and Infectious Disease Division, Public Health Sciences Division, and Human Biology Division
Fred Hutchinson Cancer Research Center

Trevor Bedford is currently Associate Member of the Vaccine and Infectious Disease Division, the Public Health Sciences Division, and the Human Biology Division at the Fred Hutchinson Cancer Research Center. Dr. Bedford uses powerful computers and complex statistical methods to study the rapid spread and evolution of viruses. Data gathered from these processes help researchers develop successful strategies for monitoring and controlling infectious diseases. His visual representations of viral family trees are used to show how the fate of dangerous outbreaks is often determined by the genetics of the infectious agent, human behavior and geography. Dr. Bedford has applied these techniques to document the worldwide spread of seasonal flu viruses. He is developing models to predict which strains of influenza are likely to be most challenging to humans — data that help inform the crucial early decisions about which strains to include in annual flu shots. He specializes in tracking the evolutionary changes of viruses such as HIV and influenza that use RNA, rather than DNA, to carry their genetic information. RNA viruses are much more prone to rapid mutation, which makes many of them particularly nimble at escaping the human immune system and difficult to stop with vaccines. He is a leading advocate for the immediate release of research analyzing viral evolution during epidemics, fresh information that could make a lifesaving difference. He received his Ph.D. in biology from Harvard University.

Georges Benjamin, M.D.
Executive Director
American Public Health Association

Georges Benjamin is well-known as a health leader, practitioner, and administrator. Dr. Benjamin has served as the executive director of the American Public Health Association, the nation's oldest and largest organization of public health professionals, since December 2002. He is a former secretary of Health for the state of Maryland. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University Of Illinois College Of Medicine. He is board-certified in internal medicine, a Master of the American College of Physicians, a fellow of the National Academy of Public Administration and a fellow emeritus of the American College of Emergency Physicians. He serves on several nonprofit boards such as Research!America, the University of Maryland Medical System and, the Reagan-Udall Foundation. He is a member of the National Academy of Medicine. In April 2016, President Obama appointed Benjamin

to the National Infrastructure Advisory Council, a council that advises the president on how best to assure the security of the nation's critical infrastructure.

Richard Besser, M.D.
President and CEO
Robert Wood Johnson Foundation

Richard Besser is president and CEO of the Robert Wood Johnson Foundation (RWJF), a position he assumed in April 2017. Dr. Besser is the former acting director for the Centers for Disease Control and Prevention (CDC), and ABC News' former chief health and medical editor. At RWJF, Dr. Besser leads the largest private foundation in the country devoted solely to improving the nation's health. RWJF's work is focused on building a comprehensive Culture of Health that provides everyone in America with a fair and just opportunity to live the healthiest life possible. In Dr. Besser's role at ABC News, he provided medical analysis and reports for all ABC News programs and platforms. His weekly health chats on social media reached millions. Before joining ABC News in 2009, Dr. Besser worked as director of the Coordinating Office for Terrorism Preparedness and Emergency Response at the CDC. In that role, he was responsible for all the CDC's public health emergency preparedness and emergency response activities. He also served as acting director of the CDC from January to June 2009, during which time he led the CDC's response to the H1N1 influenza pandemic. He is a member of the National Academy of Medicine. He received the Surgeon General's Medallion for his leadership during the H1N1 response, and in 2011 he accepted the Dean's Medal for his contributions to public health from the Johns Hopkins Bloomberg School of Public Health. Dr. Besser received his Bachelor of Arts degree in economics from Williams College and medical degree from the University of Pennsylvania. He completed a residency and chief residency in pediatrics at Johns Hopkins University Hospital in Baltimore.

Peter Daszak, Ph.D.
President and CEO
EcoHealth Alliance

Peter Daszak is President of EcoHealth Alliance, a US-based organization that conducts research and outreach programs on global health, conservation, and international development. Dr. Daszak's research has been instrumental in identifying and predicting the origins and impact of emerging diseases across the globe. He is one of the founders of the field of Conservation Medicine and has been instrumental in the growth of EcoHealth, One Health, and now Planetary Health. Dr. Daszak is a member of the National Academy of Medicine and Chair of the NASEM's Forum on Microbial Threats. He is a member of the NRC Advisory Committee to the US Global Change Research Program, the Supervisory Board of the One Health Platform, the One Health Commission Council of Advisors, the CEEZAD External Advisory Board, the Cosmos Club, and the Advisory Council of the Bridge Collaborative. He has served on the IOM Committee on global surveillance for emerging zoonoses, the NRC committee on the future of veterinary research, the International Standing Advisory Board of the Australian Biosecurity CRC; and has advised the Director for Medical Preparedness Policy on the White House National Security Staff on global health issues. Dr. Daszak is a regular advisor to WHO on pathogen prioritization for R&D. He received his Ph.D. in parasitic infectious disease from the University of East London.

Ellen Embrey
Managing Partner
Stratitia, Inc.

Ellen Embrey is Managing Partner of Stratitia, Inc., a consulting firm focused on developing meaningful and innovative strategies, and delivering supporting tools and partnerships to bring them successfully to life. Ms. Embrey brings deep expertise in health and medical issues, as well as a wealth of other experience gained during her extensive federal service. In her last federal role, she performed the duties of

the Assistant Secretary of Defense for Health Affairs and the Director, TRICARE Management Activity during the presidential transition period in 2009-2010. From 2002 to 2009, Ms. Embrey was the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, leading significant changes in Department of Defense policies and programs affecting deployment and combat casualty medicine, health promotion and preventive medicine, medical readiness and public health emergency preparedness and response. For 9 months in 2001, Ms. Embrey performed the duties of Assistant Secretary of Defense for Reserve Affairs, shaping policies affecting the readiness and use of the National Guard and Reserve in both federal and state status. From 2000 to 2001, she served as Chief of Staff of that office, and from 1998 to 2001, as Deputy Assistant Secretary of Defense for Military Assistance to Civil Authorities, developing policies that shaped the role of the National Guard and Reserve components in supporting homeland security, disaster preparedness, and national disaster response capabilities, including advising the president on such matters in the days and weeks following September 11, 2001. Between 1978 and 1997, Ms. Embrey served in senior-level policy analyst, budget analyst, program analyst, management analyst, and systems analyst positions in the Office of the Assistant Secretary of Defense for Reserve Affairs, the Defense Contract Audit Agency, and the Office of Personnel Management. Ms. Embrey was recognized with the Secretary of Defense's Distinguished Civilian Service Award in 2001 and 2004, and twice received the Meritorious Executive Presidential Rank Award in 2006 and 2009.

Diane Griffin, M.D., Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health

Diane Griffin is University Distinguished Service Professor and Alfred and Jill Sommer Chair of the W. Harry Feinstone Department of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health. Dr. Griffin is a virologist recognized for her work on the pathogenesis of viral infections. She is known particularly for her studies on measles and alphavirus encephalomyelitis that have delineated the role of the immune response in virus clearance, vaccine-induced protection from infection, tissue damage and immune suppression. Dr. Griffin was born in Iowa City, Iowa, and grew up in Oklahoma City. She graduated from Augustana College, Rock Island, Illinois with a degree in biology and from Stanford University School of Medicine in 1968 with a Ph.D. in immunology and M.D., followed by a residency in internal medicine. She was a postdoctoral fellow in virology and infectious diseases at Johns Hopkins University School of Medicine and joined the faculty in 1974. She has been president of the American Society for Virology and of the American Society for Microbiology and is a member of both the National Academy of Sciences and the National Academy of Medicine.

Margaret Hamburg, M.D.
Foreign Secretary
National Academy of Medicine

Margaret Hamburg is an internationally recognized leader in public health and medicine, and currently serves as foreign secretary of the National Academy of Medicine and chair of the NTI | bio Advisory Group. She is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served for almost six years. As FDA Commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining FDA, Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. She is President-elect of the American Association for the Advancement of Science (AAAS), as well as an elected member of the Council on Foreign Relations and the National Academy of Medicine. Hamburg currently sits on the boards of the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, the Parker Institute for Cancer Immunotherapy and the American Museum

of Natural History. She is chair of the Joint Coordinating Group for the Coalition for Epidemic Preparedness and Innovation, and a member of the Harvard University Global Advisory Council, the Global Health Scientific Advisory Committee for the Gates Foundation, the Harvard Medical School Board of Fellows, and the World Dementia Council. Dr. Hamburg earned her B.A. from Harvard College, her M.D. from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center. She is the recipient of multiple honorary degrees and numerous awards.

John Hick, M.D.
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John L. Hick is a faculty emergency physician at Hennepin Healthcare and a Professor of Emergency Medicine at the University of Minnesota. Dr. Hick serves as the deputy medical director for Hennepin County Emergency Medical Services and Medical Director for Emergency Preparedness at HCMC. He is also the Vice-Chair of the Clinical Council for Life Link III helicopter service and medical director for MN TF-1 state US&R team. He served the Minnesota Department of Health as the medical director for the Office of Emergency Preparedness until becoming an Advisor to the Director of OEM at ASPR/HHS where he is the lead editor for the TRACIE healthcare disaster preparedness website. He is the founder and past chair of the Minneapolis/St. Paul Metropolitan Hospital Compact, a 32-hospital mutual aid and planning group active since 2002. He is a national speaker on hospital preparedness issues and has published numerous papers dealing with hospital preparedness for contaminated casualties, personal protective equipment, crisis standards of care, and surge capacity and was honored to serve the Institute of Medicine on their Crisis Standards of Care projects as well as the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Dr. Hick holds an M.D. from the Mayo Medical School.

Kent E. Kester, M.D.
Vice President and Head, Translational Science and Biomarkers
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Kent Kester is currently Vice President and Head, Translational Science and Biomarkers at Sanofi Pasteur. In this capacity, Dr. Kester leads a team of over 200 research and clinical professionals in the US and France focused on the translational development of new vaccines. During a 24-year career in the US Army, he worked extensively in clinical vaccine development and led multiple research platforms at the Walter Reed Army Institute of Research, the U.S. Department of Defense's largest and most diverse biomedical research laboratory with a major emphasis on emerging infectious diseases, an institution he later led as its Commander/Director. His final military assignment was as the Associate Dean for Clinical Research in the School of Medicine at the Uniformed Services University of the Health Sciences (USUHS). During his military service, Dr. Kester was appointed as the lead policy advisor to the US Army Surgeon General in both Infectious Diseases and in Medical Research & Development. In these capacities, he worked extensively in the interagency environment and developed a variety of Army and DoD medical policies related to infectious diseases, both clinical and research aspects. Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College, completing his internship and residency in internal medicine at the University of Maryland and a research fellowship in infectious diseases at the Walter Reed Army Medical Center. Currently a member of the US Government Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) and the Department of Veterans Affairs Health Services Research & Development Service Merit Review Board, he previously chaired the Steering Committee of the NIAID/USUHS Infectious Disease Clinical Research Program, and has served as a member of the FDA Vaccines & Related Biologics Products Advisory Committee (VRBPAC), the NIAID Advisory Council, and the CDC Office of Infectious Diseases Board of Scientific Counselors. He is the Vice Chair of the National Academy of Medicine Forum on Microbial Threats. Board-certified in both internal medicine and infectious diseases, Dr. Kester

holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Royal College of Physicians of Edinburgh, the Infectious Disease Society of America, and the American Society of Tropical Medicine and Hygiene. He is a member of the clinical faculty at the University of Maryland Shock Trauma Center in Baltimore.

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Patricia King is Professor of Law emeritus at Georgetown University Law Center and an Adjunct Professor in the Department of Health Policy and Management, School of Hygiene and Public Health at Johns Hopkins University. She is the co-author of Cases and Materials on Law, Science and Medicine. She is a member of the National Academy of Medicine, a member of the American Law Institute, a fellow of the Hastings Center and a faculty affiliate of Georgetown's Kennedy Institute of Ethics. Her scholarship focuses on race and genomics, racial disparities in health and reproductive health. Professor King has served on numerous national advisory bodies formed to address the ethical issues generated by developments in science and technology, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), which produced the seminal "Belmont Report," the President's Advisory Committee on Human Radiation Experiments (1994-95), the National Institutes of Health's Embryo Research Panel (co-chair for policy, 1994), the Ethics, Legal and Social Issues Working Group of the NIH's Human Genome Project (1989-95), and the NIH's Recombinant DNA Advisory Committee (1979-81). She has served on numerous boards and Institute of Medicine committees and is currently a member of the Board of Health Sciences Policy of the National Academies. She is also a Director of Mathematica an employee-owned company.She is a graduate of Wheaton College (Massachusetts) and has served as a Trustee and Chair of the Wheaton College Board of Trustees. In 2018 she was designated a Life Trustee by the Wheaton College Board. She graduated from Harvard Law School and is a past member of the Harvard Corporation the governing board of Harvard University. She has received honorary degrees from Wheaton College, Old Dominion University, and Harvard University.

Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
Executive Director, One Health Institute
UC Davis School of Veterinary Medicine

Jonna Mazet is a Professor of Epidemiology and Disease Ecology and Executive Director of the One Health Institute in the UC Davis School of Veterinary Medicine, where she focuses on global health problem solving, especially for emerging infectious disease and conservation challenges. Dr. Mazet is active in international One Health research programs, most notably in relation to disease transmission among wildlife, domestic animals, and people and the ecological drivers of disease emergence. Currently, she is the Global Director of a $175 million viral emergence early warning project, named PREDICT, that has been developed with the US Agency for International Development's (USAID) Emerging Pandemic Threats Program. She was elected to the National Academy of Medicine in 2013 in recognition of her successful and innovative approach to emerging environmental and global health threats and serves on the National Academies' Forum on Microbial Threats, as well as chairs the Academies' One Health Work Group. Jonna joined the UC Global Health Institute Board of Directors as co-vice chair in April 2019. She holds a D.V.M., M.P.V.M., and Ph.D. from UC Davis.

Phyllis Meadows, Ph.D., M.S.N., R.N.
Senior Fellow, Health
The Kresge Foundation

Phyllis Meadows currently serves as the Senior Fellow and Program Advisor for the Kresge Foundation Health Team. In this role, she is responsible for supporting the health team in the development and implementation of investment opportunities within and across the Foundation's various programming areas. Her professional career includes leadership roles in philanthropy, academia, community health and governmental public health. She has previously served in the role of Associate Dean for Public Health Practice and Clinical Professor - Health, Management and Policy with the University of Michigan School of Public Health. She has led several initiatives to expand multi-disciplinary practice in communities, designing the University's first certification program on population health and health equity for medical residents. She is currently a Distinguished Towsley Policy Maker in Residence with the University of Michigan's Gerald Ford School of Public Policy. She has taught and developed graduate level and professional continuing education courses to address emerging health issues, including topics on health policy and public health leadership. Dr. Meadows has extensive experience in public health practice having served in various leadership roles in public health. She has held several official appointments in public health leadership at the state, county and local levels. In her most recent appointment, she served as the Chief Health Officer and Director of Health for the City of Detroit, providing leadership for the department of health, environmental health, infectious diseases, child health, clinical and dental services for the residents of Detroit. Her philanthropic experience includes positions as Program Director for the W.K. Kellogg Foundation - Youth, Education and Higher Education; and advisor for several national initiatives of the Robert Wood Johnson Foundation including the Nurse Executive Leadership Program, Partners in Nursing, and the County Roadmaps project. As a registered nurse, she has worked in both community-based health and hospitals. She currently serves as a Board Member and Advisor for several state level organizations and private foundations focusing on health.

Tara O'Toole, M.D., M.P.H.
Executive Vice President
In-Q-Tel

Tara O'Toole currently serves as Executive Vice President at In-Q-Tel. Dr. O'Toole was confirmed as the Under Secretary for Science and Technology (S&T) at the U.S. Department of Homeland Security (DHS) and served from November 4, 2009 to September 23, 2013. From 2003 to November 2009, Dr. O'Toole was the CEO and Director of the Center for Biosecurity at the University of Pittsburgh Medical Center (UPMC), and Professor of Medicine and of Public Health at the University of Pittsburgh. The Center for Biosecurity of UPMC is an independent organization dedicated to improving the country's resilience to major biological threats. Dr. O'Toole is internationally known for her work on biosecurity and on health and safety issues related to the U.S. nuclear weapons complex. Her publications in the biodefense field include articles on the response to anthrax, smallpox, and plague biological attacks; containment of contagious disease epidemics; biodefense research and development strategies; and hospital preparedness. She is the founding editor of the journal Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. She was a principal author and producer of Dark Winter, an influential exercise conducted in June 2001 to alert national leaders to the dangers of bioterrorist attacks. She was also a principal writer and producer of Atlantic Storm, an international ministerial-level biosecurity exercise held in January 2005. Prior to founding the UPMC in 2003, Dr. O'Toole was one of the original members of the Johns Hopkins Center for Civilian Biodefense Strategies and served as its director from 2001 to 2003. She has served on numerous government and expert advisory committees dealing with biodefense, including panels of the Defense Science Board; the National Academy of Engineering Committee on Combating Terrorism; and the National Academy of Sciences Working Group on Biological Weapons. She served as chair of the Board of the Federation of American Scientists from 2006 to 2007, and in 2006 she was appointed to the board of Google Foundation's International Networked System for Total Early Disease

Detection. From 1993 to 1997, Dr. O'Toole served as Assistant Secretary of Energy for Environment Safety and Health. In this position, she was the principal advisor to the Secretary of Energy on environmental protection and on the health and safety of the approximately 100,000 workers in the U.S. nuclear weapons complex and Department of Energy (DOE) laboratories. She developed the first overall management and safety plan for dealing with the highly enriched uranium, plutonium, spent fuel, and radioactive waste left in place when nuclear weapons production was stopped in the early 1990s. She ran the multi-agency, multimillion-dollar task force that oversaw the government's investigations into human radiation experiments conducted during the Cold War and led the U.S. delegation to Russia to establish the U.S./Russia cooperative effort to study radiationexposure and environmental hazards of the Russian nuclear weapons complex. Prior to her work at DOE, Dr. O'Toole was a senior analyst at the Congressional Office of Technology Assessment, where she directed several projects and studies, including the health impact of pollution resulting from nuclear weapons production. She also served as a consultant to industry and government in matters related to occupational and environmental health; worker participation in workplace safety protection; and organizational change. Dr. O'Toole practiced general internal medicine in community health centers in Baltimore from 1984 to 1988. She is board certified in internal medicine and occupational and environmental health. She has a bachelor's degree from Vassar College, an M.D. from the George Washington University, and a Master of Public Health degree from Johns Hopkins University. She completed internal medicine residency training at Yale University and a fellowship in Occupational and Environmental Medicine at Johns Hopkins University.

Alexandra Phelan, S.J.D., LL.M., LL.B.
Faculty Research Instructor
Center for Global Health Science and Security
Georgetown University

Alexandra Phelan is a member of the Center for Global Health Science and Security and a Faculty Research Instructor in the Department of Microbiology and Immunology at Georgetown University. Dr. Phelan also holds an appointment as Adjunct Professor of Law at Georgetown University Law Center. Dr. Phelan works on legal and policy issues related to infectious diseases, with a particular focus on emerging and reemerging infectious disease outbreaks and international law. She has worked as a consultant for the World Health Organization, the World Bank, and Gavi: the vaccine alliance, and has advised on matters including international law and pathogen sharing, human rights law and Zika, intellectual property law, and contract law. She previously worked for a number of years as a solicitor at a firm in Melbourne, Australia and was admitted to practice to the Supreme Court of Victoria and High Court of Australia in 2010. Dr. Phelan's doctorate examined how overlap between fields of international law – in particular, global health law, international human rights law, and international environmental law – can serve as the catalyst to progressively develop international law to prevent and respond to infectious diseases. She also holds a Master of Laws, specializing in international law, from the Australian National University and a Bachelor of Biomedical Science/Bachelor of Laws (Honours) double degree from Monash University. She also holds a Diploma of Languages (Mandarin Chinese). Dr. Phelan is a General Sir John Monash Scholar and was recognized as an Associate Fellow of the Royal Commonwealth Society in 2015 for her human rights advocacy during the 2013-16 Ebola outbreak.

David Relman, M.D.
Thomas C. and Joan M. Merigan Professor in Medicine, and Chief of Infectious Diseases
Stanford University; VA Palo Alto Health Care System

David Relman is the Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology and Immunology at Stanford University, and Chief of Infectious Diseases at the Veterans Affairs Palo Alto Health Care System. Dr. Relman is also Senior Fellow at the Freeman Spogli Institute for International Studies (FSI), and served as Science Co-Director at the Center for International Security and Cooperation (2013-2017), at Stanford. He is currently director of a new Biosecurity Initiative at FSI. Relman trained at

MIT and then Harvard Medical School, followed by clinical training in internal medicine and infectious diseases at the Massachusetts General Hospital in Boston, and then a postdoctoral fellowship in microbiology at Stanford. His early research focused on molecular methods for pathogen discovery and over the past 20 years, on the human microbiome. He was elected to the National Academy of Medicine in 2011. Dr. Relman served as vice-chair of the National Research Council Committee that reviewed the science performed for the FBI 2001 Anthrax Letters investigation, chair of the Forum on Microbial Threats (2007-2017), and is currently a member of the Intelligence Community Studies Board (2016-) as well as Chair of a Standing Committee tasked with examining the health-related problems of US embassy personnel stationed overseas, all at the U.S. National Academies of Science. He was a founding member of the National Science Advisory Board on Biosecurity (2005-2014), a member of the Working Group on Biodefense for the President's Council of Advisors on Science and Technology (The White House) (2016), and served as President of the Infectious Diseases Society of America (2012-2013). He holds an M.D. from Harvard Medical School.

Mark Smolinski, M.D., M.P.H.
President
Ending Pandemics

Mark Smolinski currently serves as President of Ending Pandemics. Dr. Smolinksi brings 25 years of experience in applying innovative solutions to improve disease prevention, response, and control across the globe. Mark is leading a well-knit team—bringing together technologists; human, animal, and environmental health experts; and key community stakeholders to co-create tools for early detection, advanced warning, and prevention of pandemic threats. Since 2009, Mark has served as the Chief Medical Officer and Director of Global Health at the Skoll Global Threats Fund (SGTF), where he developed the Ending Pandemics in Our Lifetime Initiative in 2012. His work at SGTF created a solid foundation for the work of Ending Pandemics, which branched out as an independent entity on January 1, 2018. Prior to SGTF, Mark developed the Predict and Prevent Initiative at Google.org, as part of the starting team at Google's philanthropic arm. Working with a team of engineers, Google Flu Trends (a project that had tremendous impact on the use of big data for disease surveillance) was created in partnership with the U.S. Centers for Disease Control. Mark has served as Vice President for Biological Programs at the Nuclear Threat Initiative, a public charity directed by CNN founder Ted Turner and former U.S. Senator Sam Nunn. Before NTI, he led an 18-member expert committee of the National Academy of Medicine on the 2003 landmark report "Microbial Threats to Health: Emergence, Detection, and Response." Mark served as the sixth Luther Terry Fellow in Washington, D.C., in the Office of the U.S. Surgeon General and as an Epidemic Intelligence Officer with the U.S. Centers for Disease Control and Prevention. Mark received his B.S. in Biology and M.D. from the University of Michigan in Ann Arbor. He is board-certified in preventive medicine and public health and holds an M.P.H. from the University of Arizona.

David Walt, Ph.D.
Hansjörg Wyss Professor of Biologically Inspired Engineering
Harvard Medical School

David Walt is a member of the faculty at Harvard Medical School in the Department of Pathology, and a Howard Hughes Medical Institute Professor. Dr. Walt pioneered the use of microwell arrays for single-molecule detection and analysis, which has revolutionized the process of genetic and proteomic sequencing, enabling the cost of DNA sequencing and genotyping to plummet nearly a millionfold in the last decade. His current research employs optical fiber microarrays for the detection and analysis of single enzyme molecules to provide mechanistic insight into enzyme mechanisms. In another project, hhe is also investigating the limits of creating high-density sensing arrays containing thousands of microsensors and nanosensors, and are preparing arrays to perform high-density nucleic acid and protein analysis. Dr. Walt is the Scientific Founder of Illumina, Inc. and Quanterix Corp, and has co-founded several other life sciences startups. Previously, he was a University Professor, Professor of Neuroscience, and Professor of

Oral Medicine at Tufts University. He is a member of the National Academy of Engineering, the National Academy of Medicine, a Fellow of the American Academy of Arts and Sciences, a Fellow of the American Institute for Medical and Biological Engineering, and a Fellow of the National Academy of Inventors. He has received numerous awards and honors, including the 2017 American Chemical Society Kathryn C. Hach Award for Entrepreneurial Success, the 2016 Ralph Adams Award in Bioanalytical Chemistry, the 2014 American Chemical Society Gustavus John Esselen Award, the 2013 Analytical Chemistry Spectrochemical Analysis Award, the 2013 Pittsburgh Analytical Chemistry Award, and the 2010 ACS National Award for Creative Invention. He received a B.S. in chemistry from the University of Michigan and a Ph.D. in chemical biology from SUNY at Stony Brook, and did postdoctoral studies at MIT.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

TAB 3

Statement of Task

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine will convene a standing committee of experts to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee will include members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee will provide a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

The standing committee will:

- Stand ready to respond on short notice to requests from the federal government to assess and consider the science and policy implications of an emerging infectious disease or significant public health threat;
- Provide a venue to enable science and policy discussions relevant to the federal government on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and objectives;
- Identify opportunities to integrate science into national preparedness and response decision making;
- Explore lessons learned and best practices from previous preparedness and response efforts, and identify opportunities to disseminate that information to a variety of stakeholders;
- Serve as a focal point for national policy discussions by experts and other leaders in the field;
- Consider, identify, and discuss strategies for addressing misinformation; and
- Respond to the federal government's needs for continuing dialog related to strategic planning and program development to address emerging infectious diseases, biosecurity, and public health and medical preparedness.

At the request of the sponsors, the standing committee will be involved in the planning, development, and oversight of related ad hoc activities undertaken by separately appointed committees operating under its auspices.

The standing committee will serve as a focal point for the discussion of scientific, technical, and policy issues relevant to emerging infectious diseases and public health preparedness and response that warrant detailed examination. Topics for discussion with the standing committee may include:

- Technical assistance and/or assessment of response to emerging infectious diseases;
- Availability of and access to information, samples, and other materials to determine the origin and evolution of emerging infectious diseases;
- International coordination and engagement;
- Technical assessment of ecological and evolutionary drivers of disease emergence;
- Approaches to proactive public messaging and strategies to address misinformation;
- Other science and policy issues relevant to emerging infectious diseases and 21st century health threats.

The committee will carry out its charge at its in-person and virtual meetings by gathering evidence from experts, deliberating, and, when necessary, by preparing short reports.

COMMITTEE SPONSORS

White House Office of Science and Technology Policy and HHS Office of Assistant Secretary for Preparedness and Response

PROVISIONAL COMMITTEE ROSTER

Harvey Fineberg, M.D., Ph.D. ***(Chair)***
President
Gordon and Betty Moore Foundation

Kristian Andersen, Ph.D.
Associate Professor and Director of Infectious Disease Genomics, Scripps Research Translational Institute
The Scripps Research Institute

Mary Bassett, M.D., M.P.H.
Director of the François-Xavier Bagnoud Center for Health and Human Rights
Harvard School of Public Health

Trevor Bedford, Ph.D.
Associate Faculty Member, Vaccine and Infectious Disease Division, Public Health Sciences Division, and Human Biology Division
Fred Hutchinson Cancer Research Center

Georges Benjamin, M.D.
Executive Director
American Public Health Association

Richard Besser, M.D.
President and CEO
Robert Wood Johnson Foundation

Peter Daszak, Ph.D.
President and CEO
EcoHealth Alliance

Ellen Embrey
Managing Partner
Stratitia, Inc.

Diane Griffin, M.D., Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health

Margaret Hamburg, M.D.
Foreign Secretary
National Academy of Medicine

John Hick, M.D.
Associate Medical Director for EMS
Medical Director of Emergency Medicine
Hennepin County Medical Center

Kent E. Kester, M.D.
Vice President and Head, Translational Science and Biomarkers
Sanofi Pasteur

Patricia King, J.D.
Professor Emerita
Georgetown University Law Center

Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
Executive Director, One Health Institute
UC Davis School of Veterinary Medicine

Phyllis Meadows, Ph.D., M.S.N., R.N.
Senior Fellow, Health
The Kresge Foundation

Tara O'Toole, M.D., M.P.H.
Executive Vice President
In-Q-Tel

Alexandra Phelan, S.J.D., LL.M., LL.B.
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Center for Global Health Science and Security
Georgetown University

David Relman, M.D.
Thomas C. and Joan M. Merigan Professor of Medicine, and of Microbiology & Immunology; Chief of Infectious Diseases
Stanford University; VA Palo Alto Health Care System

Mark Smolinski, M.D., M.P.H.
President
Ending Pandemics

David Walt, Ph.D.
Hansjörg Wyss Professor of Biologically Inspired Engineering
Harvard Medical School

CONTACT INFORMATION

Andrew Pope
Director, Board on Health Sciences Policy
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ADDITIONAL INFORMATION

For additional information, please visit http://nationalacademies.org/hmd/Activities/PublicHealth/EmergingInfectiousDiseasesand21stCenturyHealthThreats.aspx

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Health and Medicine Division

Standing Committees: What They Do

Standing committees provide sponsors with an ongoing mechanism to engage the National Academies of Sciences, Engineering, and Medicine, stakeholders, and committee members on specific issues in a variety of ways. They are designed to serve sponsors by helping them address their needs on a continuing basis for short and long-term strategic planning and program development.

Standing committees:

1) Stand ready to respond on short notice to requests and other needs from the sponsor(s);
2) Provide high-level strategic guidance to sponsor(s) on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and activities;
3) Serve as a focal point for national policy discussions by experts and other leaders in the field; and
4) Respond to sponsor(s) needs for continuing advice through planning, strategic thinking, and program development.

As part of the ongoing nature of the activity, the standing committee becomes very familiar with the sponsor(s) program/agency. This understanding and familiarity with the sponsor(s) programs facilitates the standing committee's ability to respond quickly and effectively with in-depth knowledge and insight about the sponsor(s) program.

Standing committee activities may include:

- Meeting periodically with the sponsor(s) and others in information-gathering sessions;
- Inviting experts/guests to provide input on the issues that will serve to inform the sponsor and the standing committee in its strategic planning and program development roles; and
- Conducting public outreach, such as through the development of websites and newsletters from the Academies that provides general information about the standing committee's activities or other related initiatives of the Academies.

Standing committee outputs may include:

Type	Product	Source/Origin	Recipient	Process
1	Immediate, **informal verbal feedback and guidance** provided to sponsors at public meetings	Individual Committee Members during meetings	Sponsors	Public meeting discussions

2	**Meeting "Recap,"** which is a high-level summary of issues discussed at a committee meeting	Staff prepares the recap/summary	Sponsors (and Committee Members)	Internal review by HMD staff
3	**Letter Report,** which is a formal report from the committee, based primarily on information presented and discussed at a committee meeting, that may include findings, conclusions, and recommendations on a specific topic	Committee (with Staff support)	Sponsors and the Public	Formal institutional review process
4	**Consensus Report,** which is a separate Academies report (or workshop) prepared by an ad hoc committee appointed specifically for the identified task	The Standing Committee can identify the need for, and recommend to the Academies that they conduct a study	Sponsors and the Public	Standing committees may also develop 'spin off' ideas for workshops and studies that are conducted via separate ad hoc committees (standing committee members may serve on the committees for these ad hoc workshops and studies along with additional members recruited to address the specific workshop or study charge).

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

February 3, 2020

Dr. Marcia McNutt
President, National Academy of Sciences
2101 Constitution Ave, N.W.
Washington, D.C., U.S. 20418

SUBJECT: Rapid Response Assessment of 2019-nCoV Data Needs

In support of the Office of Science and Technology's (OSTP) National Science and Technology Committee (NSTC) rapid research response work for the 2019-nCoV response, and the Administration's efforts to characterize and provide evidence-based assessments for outbreak response efforts, I am writing to ask the National Academies of Sciences, Engineering, and Medicine (NASEM) to rapidly examine information and identify data requirements that would help determine the origins of 2019-nCoV, specifically from an evolutionary/structural biology standpoint. I also ask NASEM to consider whether this should include more temporally and geographically diverse clinical isolates, sequences, etc.

Although a widely-disputed paper, "Uncanny similarity of unique inserts in the 2019-nCoV spike protein to HIV-1 gp120 and Hag," posted on the pre-print server bioRxiv last week has been withdrawn, the response to that manuscript highlights the need to determine information and data requirements as quickly as possible to better perform and validate such analyses of origin. These questions are important not only for this current situation, but to inform future outbreak preparation and better understand animal/human and environmental transmission aspects of coronaviruses. As part of a broader deliberative process, this review will aid preparedness for future events by establishing a process that quickly assembles subject matter experts for evaluating other potentially threatening organisms.

OSTP requests NASEM convene a meeting of experts, particularly world class geneticists, coronavirus experts, and evolutionary biologists, to assess what data, information, and samples are needed to address the unknowns, in order to understand the evolutionary origins of 2019-nCoV and more effectively respond to both the outbreak and any resulting misinformation. I request a letter statement from the National Academies be prepared and provided in response to this solicitation. A more in-depth examination of the issues will be established as a follow up as needed.

Sincerely,

Kelvin K. Droegemeier
Director

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

February 6, 2020

Kelvin Droegemeier
Director
White House Office of Science and Technology Policy
1650 Pennsylvania Avenue, NW
Washington, D.C. 20504

Dear Dr. Droegemeier:

Thank you for your letter regarding the current outbreak of a new respiratory virus, the 2019 Novel Coronavirus, or 2019-nCoV, which was first detected in Wuhan, China, and has now been reported in a growing number of locations worldwide, including the United States.[1] The request from OSTP is timely given the declaration of a public health emergency and potential for misinformation to confound the response.

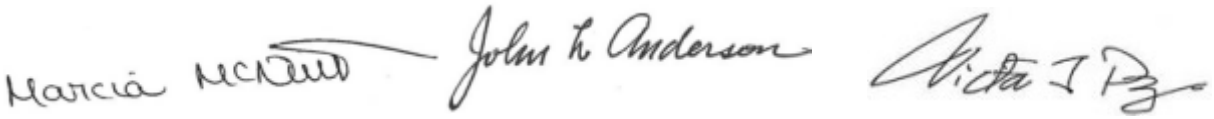
In response to your request, we consulted leading experts[2] in the fields of virology, infectious disease genomics, genome sciences, epidemiology, microbiology, immunobiology, coronaviruses, emerging infections, biosecurity, and global health. We wanted their views about the data needs that could help elucidate the origin and evolution of 2019-nCoV.

Research studies to better understand the origin of 2019-nCoV and how it relates to viruses found in bats and other species are already underway.[3] The closest known relative of 2019-nCoV appears to be a coronavirus identified from bat-derived samples collected in China.[4] The experts informed us that additional genomic sequence data from geographically- and temporally-diverse viral samples are needed to determine the origin and evolution of the virus. Samples collected as early as possible in the outbreak in Wuhan and samples from wildlife would be particularly valuable. Understanding the driving forces behind viral evolution would help facilitate the development of more effective strategies for managing the 2019-nCoV outbreak and for preventing future outbreaks. In this regard, we understand from Chunli Bai, President, Chinese Academy of Sciences, and the Alliance of International Science Organizations (ANSO), that the Wuhan National Biosafety Laboratory of the Chinese Academy of Sciences is willing to share isolates of the 2019-nCoV with the international community and is working with the University of Texas Medical Branch and other international research institutions on the specifics for the sharing and distribution of the isolates. International collaboration of this kind is more important than ever to overcome these types of global challenges.

[1] "2019 Novel Coronavirus (2019-nCoV) Situation Summary." *Centers for Disease Control and Prevention*, 3 Feb. 2020. https://www.cdc.gov/coronavirus/2019-nCoV/summary.html#anchor_1580079137454. Accessed 3 Feb. 2020.
[2] Experts consulted: Kristian G. Andersen (Scripps Research Institute), Ralph Baric (UNC School of Public Health), Trevor Bedford (Fred Hutchinson Cancer Institute), Aravinda Chakravarti (New York University School of Medicine), Peter Daszak (EcoHealth Alliance), Gigi K. Gronvall (Johns Hopkins Bloomberg School of Public Health), Tom Inglesby (Johns Hopkins Center for Health Security), and Stanley Perlman (University of Iowa).
[3] Latinne *et al*. "Origin and cross-species transmission of bat coronaviruses in China." *Nature Communications*, in review.
[4] Zhou *et. al*. "A pneumonia outbreak associated with a new coronavirus of probable bat origin." *Nature*, 2020. https://doi.org/10.1038/s41586-020-2012-7 (2020).

The National Academies stand ready to assemble a committee of experts to examine these issues in more detail and provide evidence-based advice to you in an expedited manner if requested. We appreciate your trust in the National Academies and our efforts to advise the nation and inform public policy decisions.

Sincerely,



Marcia McNutt, President	John L. Anderson., President	Victor J. Dzau, President
National Academy of Sciences	National Academy of Engineering	National Academy of Medicine

cc: Secretary Alex M. Azar, Department of Health and Human Services

EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

WASHINGTON, D.C. 20502

February 26, 2020

Dr. Marcia McNutt
President, National Academy of Sciences
2101 Constitution Ave, N.W.
Washington, D.C., U.S. 20418

SUBJECT: National Academies Standing Committee for Emerging Infectious Disease and 21st Century Health Threats

Dear Dr. McNutt, Marcia

Given the complexities of assessing and responding to emerging infectious diseases and other 21st Century health threats, as demonstrated by the present situation with COVID-19, a need exists to establish an ongoing activity to facilitate rapid access to expert, independent perspectives and insights. A neutral venue is needed through which the U.S. Government can engage subject matter experts from the private sector, non-governmental organizations, the academic community, and other relevant stakeholders involved in topics of emerging infectious disease, biosecurity, and public health and medical preparedness. The purpose is to provide a means for examining critical issues in depth and providing strategic input and guidance, based on the best available information and expertise.

To address this need, and stemming from the offer you extended in your letter to me dated February 6, 2020, the Office of Science and Technology Policy (OSTP) and the Department of Health and Human Services (HHS) have been working with Dr. Andy Pope, and his colleagues from your organization, on a request for the National Academies of Sciences, Engineering, and Medicine (NASEM) to establish a Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. This committee would:

- Stand ready to respond on short notice to requests from the Federal government to assess and consider the science and policy implications of an emerging infectious disease or other significant public health threat;
- Provide a venue to enable science and policy discussions relevant to the Federal government on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and objectives;
- Identify opportunities to integrate science into national preparedness and response decision making;
- Explore lessons learned and best practices from previous preparedness and response efforts, and identify opportunities to disseminate that information to a variety of stakeholders;
- Serve as a focal point for national policy discussions with experts and other leaders in the field;
- Consider, identify and discuss strategies for addressing misinformation; and

- Respond to the Federal government's needs for continuing dialog related to strategic planning and program development to address emerging infectious diseases, biosecurity, and public health and medical preparedness.

I would request that the standing committee serve as a focal point for the discussion of scientific, technical, and policy issues relevant to emerging infectious diseases and public health preparedness and response that warrant detailed examination.

The committee members should include experts in emerging infectious diseases, epidemiology, disease modeling and forecasting, genomics, public health, public health preparedness and response, clinical care and crisis standards of care, risk communication, and regulatory issues. The committee would provide a venue for the exchange of ideas among Federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders such as non-profit/philanthropic organizations.

Topics for discussion with the Committee may include:

- Technical assistance and/or assessment of response to emerging infectious diseases;
- Availability of and access to information, samples, and other materials to determine the origin and evolution of emerging infectious diseases;
- International coordination and engagement;
- Technical assessment of ecological and evolutionary drivers of disease emergence
- Approaches to proactive public messaging and strategies to address misinformation;
- Other science and policy issues relevant to emerging infectious diseases and 21st century health threats.

Thank you for your partnership and willingness to bring scientific expertise to bear on this important issue.

Sincerely,

Kelvin K. Droegemeier
Director

Thank you, Maria!

– Kelvin

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Cc: Fry, Alicia (CDC/DDID/NCIRD/ID)[agf1@CDC.GOV]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@CDC.GOV]; Hall, Aron (CDC/DDID/NCIRD/DVD)[esg3@CDC.GOV]; Post, Diane (NIH/NIAID) [E][postd@niaid.nih.gov]; Embry, Alan (NIH/NIAID) [E][embrya@niaid.nih.gov]; Lampley, Rebecca (NIH/VRC) [F][rebecca.lampley@nih.gov]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; Andy Pekosz[apekosz1@jhu.edu]; Topham, David[David_Topham@URMC.Rochester.edu]; Gerber, Susan I. (CDC/DDID/NCIRD/DVD)[bhx1@cdc.gov]; zhuhuachen@gmail.com[zhuhuachen@gmail.com]; Bozick, Brooke (NIH/OD) [E][brooke.bozick@nih.gov]; martin.linster@duke-nus.edu.sg[martin.linster@duke-nus.edu.sg]
From: Peter Daszak[daszak@ecohealthalliance.org]
Sent: Tue 3/17/2020 10:10:02 AM (UTC-04:00)
Subject: NASEM Standing Committee on EIDs and 21st Century Health Threats
Standing Committee on EIDs and 21st C Health Threats. Details.pdf
SC on EID and 21st Century Threats - One Pager.pdf

Alan, Erik

Here are some details on the NASEM "Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats" – the charge to the committee, and the agenda and membership details from the first call last week. There is a draft doc on research agenda being finalized and sent to OSTP Director also.

This Committee was set up at the request of the OSTP Director, who joined the first call as well as NSC staff, and I'm sure they'll be involved heavily in future calls/reports.

I hope NIH/NIAID can be involved and so you're aware, all of the above info is public domain, and there was a session open to the public for the first meeting.

Cheers,

Peter

Peter Daszak
President

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From: Degrace, Marciela (NIH/NIAID) [E] <marciela.degrace@nih.gov>
Sent: Thursday, February 20, 2020 8:18 AM
To: Mark Denison <mark.denison@vumc.org>; aneesh.mehta@emory.edu; Johnson, Reed (NIH/NIAID) [E] <johnsonreed@niaid.nih.gov>; vincent.munster_nih.gov vincent.munster@nih.gov <vincent.munster@nih.gov>; Leo Poon <llmpoon@hku.hk>; Webby, Richard <Richard.Webby@STJUDE.ORG>; malik <malik@hku.hk>; Ghazi Kayali <ghazi@human-link.org>; Yoshi Kawaoka <kawaokay@vetmed.wisc.edu>; R.A.M. Fouchier <r.fouchier@erasmusmc.nl>; yguan@hku.hk; 'adolfo.garcia-sastre@mssm.edu'; Richard Rothman <rrothma1@jhmi.edu>; Pekosz, Andrew S. <apekosz@jhsph.edu>; Schultz-Cherry, Stacey <Stacey.Schultz-Cherry@STJUDE.ORG>; 'david_topham@urmc.rochester.edu'; Orenstein, Walter <worenst@emory.edu>; Lowen, Anice <anice.lowen@emory.edu>; Baric, Ralph <rbaric@email.unc.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; Peter Daszak <daszak@ecohealthalliance.org>; zhu huachen <zhuhch@hku.hk>; Aubree Gordon <gordonal@umich.edu>; PETERPALESE <peter.palese@mssm.edu>; 'Krammer, Florian' <florian.krammer@mssm.edu>; Ben Cowling <bcowling@hku.hk>; larry.anderson@emory.edu; jwramme@emory.edu; Baric, Toni C <antoinette_baric@med.unc.edu>; MASATO HATTA <masato.hatta@wisc.edu>; Gabriele Neumann (gabriele.neumann@wisc.edu) <gabriele.neumann@wisc.edu>; Subbarao, Kanta <kanta.subbarao@influenzacentre.org>; Mathur, Punam (NIH/NIAID) [E] <mathurpu@niaid.nih.gov>; jmclellan@austin.utexas.edu; MFrieman@som.umaryland.edu; vimenach@UTMB.EDU; Hensley, Lisa (NIH/NIAID) [E] <lisa.hensley@nih.gov>; gavin.smith@duke-nus.edu.sg
Cc: Fry, Alicia (CDC/DDID/NCIRD/ID) <agf1@CDC.GOV>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@CDC.GOV>; Hall, Aron (CDC/DDID/NCIRD/DVD) <esg3@CDC.GOV>; Post, Diane (NIH/NIAID) [E] <postd@niaid.nih.gov>; Embry, Alan (NIH/NIAID) [E] <embrya@niaid.nih.gov>; Lampley, Rebecca (NIH/VRC) [F] <rebecca.lampley@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>; Andy Pekosz <apekosz1@jhu.edu>; Topham, David <David_Topham@URMC.Rochester.edu>; Gerber, Susan I. (CDC/DDID/NCIRD/DVD) <bhx1@cdc.gov>; zhuhuachen@gmail.com; Bozick, Brooke (NIH/OD) [E] <brooke.bozick@nih.gov>; martin.linster@duke-nus.edu.sg
Subject: RE: nCoV weekly investigators meeting

Hello everyone,

As we discussed on the last call, it could be useful to share information certain experimental results, especially animal model work, in as close to real time as possible enable better planning of experiments by the entire group.

During the Zika response, the portal that was used for this was LabKey's Open Research Portal: https://openresearch.labkey.com/project/home/begin.view. This is a fully public portal.

Please consider if this platform might work, and we can discuss on our next call including any logistics and support needed for setting up accounts.

Thank you!

Marciela

-----Original Appointment-----
From: Degrace, Marciela (NIH/NIAID) [E]
Sent: Friday, January 24, 2020 8:08 AM
To: Mark Denison; aneesh.mehta@emory.edu; Johnson, Reed (NIH/NIAID) [E]; Munster, Vincent (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Leo Poon; Webby, Richard; malik; Ghazi Kayali; Yoshi Kawaoka; R.A.M. Fouchier; yguan@hku.hk; 'adolfo.garcia-sastre@mssm.edu'; Richard Rothman; Pekosz, Andrew S.; Schultz-Cherry, Stacey; 'david_topham@urmc.rochester.edu'; Orenstein, Walter; Lowen, Anice; Baric, Ralph; 'Perlman, Stanley'; daszak@ecohealthalliance.org; zhu huachen; Aubree Gordon; PETERPALESE; 'Krammer, Florian'; Ben Cowling; larry.anderson@emory.edu; jwramme@emory.edu; Baric, Toni C; MASATO HATTA; Gabriele Neumann (gabriele.neumann@wisc.edu); Subbarao, Kanta; Mathur, Punam (NIH/NIAID) [E]; jmclellan@austin.utexas.edu; MFrieman@som.umaryland.edu; vimenach@UTMB.EDU; Hensley, Lisa (NIH/NIAID) [E]; gavin.smith@duke-nus.edu.sg
Cc: Fry, Alicia (CDC/DDID/NCIRD/ID); Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Hall, Aron (CDC/DDID/NCIRD/DVD); Post, Diane (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Lampley, Rebecca (NIH/VRC) [F]; Stemmy, Erik (NIH/NIAID) [E]; Andy Pekosz; Topham, David; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); zhuhuachen@gmail.com; Bozick, Brooke (NIH/OD) [E]; martin.linster@duke-nus.edu.sg
Subject: nCoV weekly investigators meeting
When: Tuesday, February 18, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: GoToWebinar

Hi everyone,

Please see updated webinar links below. Hopefully this resolves any issues people had last time with sound.

Hello everyone,

Below please find the registration link for our weekly investigators meeting regarding the nCoV. **Please do not forward**. If you would like anyone else to be added to the invitation, please let me (Marciela.degrace@nih.gov) or Erik (erik.stemmy@nih.gov) know.

Our tentative agendas will be:

- Epi Updates
- NIAID Updates
- Other HHS partner Updates, if applicable
- Investigator research updates
- Discussion and Action Items
-

updated webinar link
https://global.gotomeeting.com/join/888107805

You can also dial in using your phone.
United States: +1 (571) 317-3129

Access Code: 888-107-805

Thank you,

Marciela DeGrace, Ph.D.
Project Officer, CEIRS
NIH/NIAID/DMID/RDB

The National Academies of
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STANDING COMMITTEE ON EMERGING INFECTIOUS DISEASES AND 21ST CENTURY HEALTH THREATS

Health and Medicine Division

Board on Health Sciences Policy
Board on Global Health

Briefing Materials
Meeting 1
March 11, 2020

Virtual Meeting

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

TAB 1

Agenda and Remote Participation Information

First Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Final Agenda

Wednesday, March 11, 2020, 12:00 p.m. – 5:30 p.m. ET
Virtual Zoom Meeting/Keck 201 for Local Participants

Background:
In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine will convene a standing committee of experts to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee will include members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee will provide a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

Meeting Objectives

- Discuss the statement of task (SOT) and role of the standing committee
- Conduct the bias and conflict of interest discussion
- Discuss relevant context and key issues
- Explore potential research priorities arising as a result of the emergence of COVID-19 in the U.S. and globally
- Discuss next steps to move forward on key issues; plan second meeting and identify speakers and topics

Wednesday, March 11, 2020

CLOSED SESSION (COMMITTEE MEMBERS ONLY)

12:00 p.m. **Welcome and Introductions**

- Brief introductions
- Discussion of meeting objectives

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Andrew Pope
Director, Board on Health Sciences Policy
Health and Medicine Division

Julie Pavlin
Director, Board on Global Health
Health and Medicine Division

12:10 p.m. **Role of National Academies Standing Committees**

Andrew Pope
Director, Board on Health Sciences Policy
Health and Medicine Division

12:15 p.m. **Discussion of Bias and Conflict of Interest**

Lauren Shern
Associate Executive Director
Health and Medicine Division

12:30 p.m. **Committee Discussion with Sponsor to Inform Open Session**

Kelvin Droegemeier
Director
White House Office of Science and Technology Policy

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

OPEN SESSION

SESSION I **Welcoming Remarks, Introductions, and Sponsors' Charge to the Committee**

1:30 p.m. **Welcome and Introductions**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Marcia McNutt
President
National Academy of Sciences

Victor Dzau
President
National Academy of Medicine

Gregory Symmes
Chief Program Officer
The National Academies of Sciences, Engineering, and Medicine

1:45 p.m. **Sponsors' Charge to the Committee**

- Discuss the context/purpose for the standing committee
- Review the statement of task

Kelvin Droegemeier
Director
White House Office of Science and Technology Policy

David (Chris) Hassell
Senior Science Advisor
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

2:00 p.m. **Committee Discussion with the Sponsor**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

2:30 p.m. ***BREAK***

SESSION II **Diagnostics and Viral Characterization**

2:45 p.m. **Presentation of the Issues**

Ian Watson
Assistant Director for Biotechnology & Biosecurity
Office of Science & Technology Policy

Paige Waterman
Assistant Director for Biological Threat Defense
Office of Science & Technology Policy

David (Chris) Hassell
Senior Science Advisor
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

3:00 p.m. **Committee Discussion of the Issues**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

SESSION III **Other Selected Topics and Issues**

4:00 p.m. **Discussion of Committee's Selected Topics and Issues**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

CLOSED SESSION (COMMITTEE ONLY)

5:00 p.m. **Committee Debrief, Next Steps, and Potential Future Meeting Topics**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

5:30 p.m. ***ADJOURN MEETING***

The National Academies of
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TAB 2

Standing Committee Membership Information

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

INTERNAL COMMITTEE ROSTER

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The National Academies of
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Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

COMMITTEE MEMBER BIOSKETCHES

Harvey Fineberg, M.D., Ph.D. ***(Chair)***
President
Gordon and Betty Moore Foundation

Harvey Fineberg is president of the Gordon and Betty Moore Foundation. He previously served as president of the Institute of Medicine from 2002 to 2014 and as provost of Harvard University from 1997 to 2001, following 13 years as dean of the Harvard School of Public Health. Fineberg devoted most of his academic career to the fields of health policy and medical decision-making. His past research has focused on the process of policy development and implementation, assessment of medical technology, evaluation and use of vaccines, and dissemination of medical innovations. Fineberg serves on the boards of the Carnegie Endowment for International Peace and the China Medical Board. He helped found and served as president of the Society for Medical Decision Making, previously served on and chaired the board of the William and Flora Hewlett Foundation, and chaired the committee to review the performance of the World Health Organization and the functioning of the International Health Regulations (2005) during the 2009 H1N1 influenza pandemic. Fineberg is co-author of the books *Clinical Decision Analysis*, *Innovators in Physician Education* and *The Epidemic That Never Was*, an analysis of the controversial federal immunization program against swine flu in 1976. He has co-edited several books on such diverse topics as AIDS prevention, vaccine safety, understanding risk in society and global health. He has also authored numerous articles published in professional journals. Fineberg chaired the National Academies committee that produced the 2019 report on *Reproducibility and Replicability in Science*. He earned his bachelor's and doctoral degrees at Harvard and is the recipient of several honorary degrees.

Kristian Andersen, Ph.D.
Associate Professor and Director of Infectious Disease Genomics, Scripps Research Translational Institute
The Scripps Research Institute

Kristian Andersen is an associate professor in the Department of Immunology and Microbiology at Scripps Research, with joint appointments in the Department of Integrative Structural and Computational Biology, and at the Scripps Research Translational Institute. Over the past decade, his research has focused on the complex relationship between host and pathogen. Using a combination of next-generation sequencing, field work, experimentation, and computational biology he has spearheaded large international collaborations investigating the emergence, spread and evolution of deadly pathogens, including SARS-CoV-2, Zika virus, Ebola virus, West Nile virus, and Lassa virus. His work is highly cross-disciplinary and exceptionally collaborative. Kristian earned his doctoral degree from the University of Cambridge and performed postdoctoral work in Pardis Sabeti's group at Harvard University and the Broad Institute.

Mary Bassett, M.D., M.P.H.
Director of the François-Xavier Bagnoud Center for Health and Human Rights
Harvard School of Public Health

Mary Bassett is the Director of the FXB Center for Health and Human Rights at Harvard University, as well as the FXB Professor of the Practice of Health and Human Rights at the Harvard School of Public Health. With more than 30 years of experience in public health, Dr. Mary Travis Bassett has dedicated her career to advancing health equity. Prior to her directorship at the FXB Center, Dr. Bassett served for four years as commissioner of Health for New York City. As commissioner, she worked to ensure that every New York City neighborhood supported the health of its residents, with the goal of closing gaps in population health across the city. Originally from New York City, Dr. Bassett lived in Zimbabwe for nearly 20 years. Previously, she was the Program Director for the African Health Initiative and the Child Well-being Program at the Doris Duke Charitable Foundation. She received her B.A. in History and Science from Harvard University and her M.D. from Columbia University's College of Physicians and Surgeons. She served her medical residency at Harlem Hospital Center, and has a master's degree in Public Health from the University of Washington, where she was a Robert Wood Johnson Clinical Scholar.

Trevor Bedford, Ph.D.
Associate Faculty Member, Vaccine and Infectious Disease Division, Public Health Sciences Division, and Human Biology Division
Fred Hutchinson Cancer Research Center

Trevor Bedford is currently Associate Member of the Vaccine and Infectious Disease Division, the Public Health Sciences Division, and the Human Biology Division at the Fred Hutchinson Cancer Research Center. Dr. Bedford uses powerful computers and complex statistical methods to study the rapid spread and evolution of viruses. Data gathered from these processes help researchers develop successful strategies for monitoring and controlling infectious diseases. His visual representations of viral family trees are used to show how the fate of dangerous outbreaks is often determined by the genetics of the infectious agent, human behavior and geography. Dr. Bedford has applied these techniques to document the worldwide spread of seasonal flu viruses. He is developing models to predict which strains of influenza are likely to be most challenging to humans — data that help inform the crucial early decisions about which strains to include in annual flu shots. He specializes in tracking the evolutionary changes of viruses such as HIV and influenza that use RNA, rather than DNA, to carry their genetic information. RNA viruses are much more prone to rapid mutation, which makes many of them particularly nimble at escaping the human immune system and difficult to stop with vaccines. He is a leading advocate for the immediate release of research analyzing viral evolution during epidemics, fresh information that could make a lifesaving difference. He received his Ph.D. in biology from Harvard University.

Georges Benjamin, M.D.
Executive Director
American Public Health Association

Georges Benjamin is well-known as a health leader, practitioner, and administrator. Dr. Benjamin has served as the executive director of the American Public Health Association, the nation's oldest and largest organization of public health professionals, since December 2002. He is a former secretary of Health for the state of Maryland. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University Of Illinois College Of Medicine. He is board-certified in internal medicine, a Master of the American College of Physicians, a fellow of the National Academy of Public Administration and a fellow emeritus of the American College of Emergency Physicians. He serves on several nonprofit boards such as Research!America, the University of Maryland Medical System and, the Reagan-Udall Foundation. He is a member of the National Academy of Medicine. In April 2016, President Obama appointed Benjamin

to the National Infrastructure Advisory Council, a council that advises the president on how best to assure the security of the nation's critical infrastructure.

Richard Besser, M.D.
President and CEO
Robert Wood Johnson Foundation

Richard Besser is president and CEO of the Robert Wood Johnson Foundation (RWJF), a position he assumed in April 2017. Dr. Besser is the former acting director for the Centers for Disease Control and Prevention (CDC), and ABC News' former chief health and medical editor. At RWJF, Dr. Besser leads the largest private foundation in the country devoted solely to improving the nation's health. RWJF's work is focused on building a comprehensive Culture of Health that provides everyone in America with a fair and just opportunity to live the healthiest life possible. In Dr. Besser's role at ABC News, he provided medical analysis and reports for all ABC News programs and platforms. His weekly health chats on social media reached millions. Before joining ABC News in 2009, Dr. Besser worked as director of the Coordinating Office for Terrorism Preparedness and Emergency Response at the CDC. In that role, he was responsible for all the CDC's public health emergency preparedness and emergency response activities. He also served as acting director of the CDC from January to June 2009, during which time he led the CDC's response to the H1N1 influenza pandemic. He is a member of the National Academy of Medicine. He received the Surgeon General's Medallion for his leadership during the H1N1 response, and in 2011 he accepted the Dean's Medal for his contributions to public health from the Johns Hopkins Bloomberg School of Public Health. Dr. Besser received his Bachelor of Arts degree in economics from Williams College and medical degree from the University of Pennsylvania. He completed a residency and chief residency in pediatrics at Johns Hopkins University Hospital in Baltimore.

Peter Daszak, Ph.D.
President and CEO
EcoHealth Alliance

Peter Daszak is President of EcoHealth Alliance, a US-based organization that conducts research and outreach programs on global health, conservation, and international development. Dr. Daszak's research has been instrumental in identifying and predicting the origins and impact of emerging diseases across the globe. He is one of the founders of the field of Conservation Medicine and has been instrumental in the growth of EcoHealth, One Health, and now Planetary Health. Dr. Daszak is a member of the National Academy of Medicine and Chair of the NASEM's Forum on Microbial Threats. He is a member of the NRC Advisory Committee to the US Global Change Research Program, the Supervisory Board of the One Health Platform, the One Health Commission Council of Advisors, the CEEZAD External Advisory Board, the Cosmos Club, and the Advisory Council of the Bridge Collaborative. He has served on the IOM Committee on global surveillance for emerging zoonoses, the NRC committee on the future of veterinary research, the International Standing Advisory Board of the Australian Biosecurity CRC; and has advised the Director for Medical Preparedness Policy on the White House National Security Staff on global health issues. Dr. Daszak is a regular advisor to WHO on pathogen prioritization for R&D. He received his Ph.D. in parasitic infectious disease from the University of East London.

Ellen Embrey
Managing Partner
Stratitia, Inc.

Ellen Embrey is Managing Partner of Stratitia, Inc., a consulting firm focused on developing meaningful and innovative strategies, and delivering supporting tools and partnerships to bring them successfully to life. Ms. Embrey brings deep expertise in health and medical issues, as well as a wealth of other experience gained during her extensive federal service. In her last federal role, she performed the duties of

the Assistant Secretary of Defense for Health Affairs and the Director, TRICARE Management Activity during the presidential transition period in 2009-2010. From 2002 to 2009, Ms. Embrey was the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, leading significant changes in Department of Defense policies and programs affecting deployment and combat casualty medicine, health promotion and preventive medicine, medical readiness and public health emergency preparedness and response. For 9 months in 2001, Ms. Embrey performed the duties of Assistant Secretary of Defense for Reserve Affairs, shaping policies affecting the readiness and use of the National Guard and Reserve in both federal and state status. From 2000 to 2001, she served as Chief of Staff of that office, and from 1998 to 2001, as Deputy Assistant Secretary of Defense for Military Assistance to Civil Authorities, developing policies that shaped the role of the National Guard and Reserve components in supporting homeland security, disaster preparedness, and national disaster response capabilities, including advising the president on such matters in the days and weeks following September 11, 2001. Between 1978 and 1997, Ms. Embrey served in senior-level policy analyst, budget analyst, program analyst, management analyst, and systems analyst positions in the Office of the Assistant Secretary of Defense for Reserve Affairs, the Defense Contract Audit Agency, and the Office of Personnel Management. Ms. Embrey was recognized with the Secretary of Defense's Distinguished Civilian Service Award in 2001 and 2004, and twice received the Meritorious Executive Presidential Rank Award in 2006 and 2009.

Diane Griffin, M.D., Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health

Diane Griffin is University Distinguished Service Professor and Alfred and Jill Sommer Chair of the W. Harry Feinstone Department of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health. Dr. Griffin is a virologist recognized for her work on the pathogenesis of viral infections. She is known particularly for her studies on measles and alphavirus encephalomyelitis that have delineated the role of the immune response in virus clearance, vaccine-induced protection from infection, tissue damage and immune suppression. Dr. Griffin was born in Iowa City, Iowa, and grew up in Oklahoma City. She graduated from Augustana College, Rock Island, Illinois with a degree in biology and from Stanford University School of Medicine in 1968 with a Ph.D. in immunology and M.D., followed by a residency in internal medicine. She was a postdoctoral fellow in virology and infectious diseases at Johns Hopkins University School of Medicine and joined the faculty in 1974. She has been president of the American Society for Virology and of the American Society for Microbiology and is a member of both the National Academy of Sciences and the National Academy of Medicine.

Margaret Hamburg, M.D.
Foreign Secretary
National Academy of Medicine

Margaret Hamburg is an internationally recognized leader in public health and medicine, and currently serves as foreign secretary of the National Academy of Medicine and chair of the NTI | bio Advisory Group. She is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served for almost six years. As FDA Commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining FDA, Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. She is President-elect of the American Association for the Advancement of Science (AAAS), as well as an elected member of the Council on Foreign Relations and the National Academy of Medicine. Hamburg currently sits on the boards of the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, the Parker Institute for Cancer Immunotherapy and the American Museum

of Natural History. She is chair of the Joint Coordinating Group for the Coalition for Epidemic Preparedness and Innovation, and a member of the Harvard University Global Advisory Council, the Global Health Scientific Advisory Committee for the Gates Foundation, the Harvard Medical School Board of Fellows, and the World Dementia Council. Dr. Hamburg earned her B.A. from Harvard College, her M.D. from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center. She is the recipient of multiple honorary degrees and numerous awards.

John Hick, M.D.
Associate Medical Director for EMS
Medical Director of Emergency Medicine
Hennepin County Medical Center

John L. Hick is a faculty emergency physician at Hennepin Healthcare and a Professor of Emergency Medicine at the University of Minnesota. Dr. Hick serves as the deputy medical director for Hennepin County Emergency Medical Services and Medical Director for Emergency Preparedness at HCMC. He is also the Vice-Chair of the Clinical Council for Life Link III helicopter service and medical director for MN TF-1 state US&R team. He served the Minnesota Department of Health as the medical director for the Office of Emergency Preparedness until becoming an Advisor to the Director of OEM at ASPR/HHS where he is the lead editor for the TRACIE healthcare disaster preparedness website. He is the founder and past chair of the Minneapolis/St. Paul Metropolitan Hospital Compact, a 32-hospital mutual aid and planning group active since 2002. He is a national speaker on hospital preparedness issues and has published numerous papers dealing with hospital preparedness for contaminated casualties, personal protective equipment, crisis standards of care, and surge capacity and was honored to serve the Institute of Medicine on their Crisis Standards of Care projects as well as the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Dr. Hick holds an M.D. from the Mayo Medical School.

Kent E. Kester, M.D.
Vice President and Head, Translational Science and Biomarkers
Sanofi Pasteur

Kent Kester is currently Vice President and Head, Translational Science and Biomarkers at Sanofi Pasteur. In this capacity, Dr. Kester leads a team of over 200 research and clinical professionals in the US and France focused on the translational development of new vaccines. During a 24-year career in the US Army, he worked extensively in clinical vaccine development and led multiple research platforms at the Walter Reed Army Institute of Research, the U.S. Department of Defense's largest and most diverse biomedical research laboratory with a major emphasis on emerging infectious diseases, an institution he later led as its Commander/Director. His final military assignment was as the Associate Dean for Clinical Research in the School of Medicine at the Uniformed Services University of the Health Sciences (USUHS). During his military service, Dr. Kester was appointed as the lead policy advisor to the US Army Surgeon General in both Infectious Diseases and in Medical Research & Development. In these capacities, he worked extensively in the interagency environment and developed a variety of Army and DoD medical policies related to infectious diseases, both clinical and research aspects. Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College, completing his internship and residency in internal medicine at the University of Maryland and a research fellowship in infectious diseases at the Walter Reed Army Medical Center. Currently a member of the US Government Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) and the Department of Veterans Affairs Health Services Research & Development Service Merit Review Board, he previously chaired the Steering Committee of the NIAID/USUHS Infectious Disease Clinical Research Program, and has served as a member of the FDA Vaccines & Related Biologics Products Advisory Committee (VRBPAC), the NIAID Advisory Council, and the CDC Office of Infectious Diseases Board of Scientific Counselors. He is the Vice Chair of the National Academy of Medicine Forum on Microbial Threats. Board-certified in both internal medicine and infectious diseases, Dr. Kester

holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Royal College of Physicians of Edinburgh, the Infectious Disease Society of America, and the American Society of Tropical Medicine and Hygiene. He is a member of the clinical faculty at the University of Maryland Shock Trauma Center in Baltimore.

Patricia King, J.D.
Professor Emerita
Georgetown University Law Center

Patricia King is Professor of Law emeritus at Georgetown University Law Center and an Adjunct Professor in the Department of Health Policy and Management, School of Hygiene and Public Health at Johns Hopkins University. She is the co-author of Cases and Materials on Law, Science and Medicine. She is a member of the National Academy of Medicine, a member of the American Law Institute, a fellow of the Hastings Center and a faculty affiliate of Georgetown's Kennedy Institute of Ethics. Her scholarship focuses on race and genomics, racial disparities in health and reproductive health. Professor King has served on numerous national advisory bodies formed to address the ethical issues generated by developments in science and technology, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), which produced the seminal "Belmont Report," the President's Advisory Committee on Human Radiation Experiments (1994-95), the National Institutes of Health's Embryo Research Panel (co-chair for policy, 1994), the Ethics, Legal and Social Issues Working Group of the NIH's Human Genome Project (1989-95), and the NIH's Recombinant DNA Advisory Committee (1979-81). She has served on numerous boards and Institute of Medicine committees and is currently a member of the Board of Health Sciences Policy of the National Academies. She is also a Director of Mathematica an employee-owned company.She is a graduate of Wheaton College (Massachusetts) and has served as a Trustee and Chair of the Wheaton College Board of Trustees. In 2018 she was designated a Life Trustee by the Wheaton College Board. She graduated from Harvard Law School and is a past member of the Harvard Corporation the governing board of Harvard University. She has received honorary degrees from Wheaton College, Old Dominion University, and Harvard University.

Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
Executive Director, One Health Institute
UC Davis School of Veterinary Medicine

Jonna Mazet is a Professor of Epidemiology and Disease Ecology and Executive Director of the One Health Institute in the UC Davis School of Veterinary Medicine, where she focuses on global health problem solving, especially for emerging infectious disease and conservation challenges. Dr. Mazet is active in international One Health research programs, most notably in relation to disease transmission among wildlife, domestic animals, and people and the ecological drivers of disease emergence. Currently, she is the Global Director of a $175 million viral emergence early warning project, named PREDICT, that has been developed with the US Agency for International Development's (USAID) Emerging Pandemic Threats Program. She was elected to the National Academy of Medicine in 2013 in recognition of her successful and innovative approach to emerging environmental and global health threats and serves on the National Academies' Forum on Microbial Threats, as well as chairs the Academies' One Health Work Group. Jonna joined the UC Global Health Institute Board of Directors as co-vice chair in April 2019. She holds a D.V.M., M.P.V.M., and Ph.D. from UC Davis.

Phyllis Meadows, Ph.D., M.S.N., R.N.
Senior Fellow, Health
The Kresge Foundation

Phyllis Meadows currently serves as the Senior Fellow and Program Advisor for the Kresge Foundation Health Team. In this role, she is responsible for supporting the health team in the development and implementation of investment opportunities within and across the Foundation's various programming areas. Her professional career includes leadership roles in philanthropy, academia, community health and governmental public health. She has previously served in the role of Associate Dean for Public Health Practice and Clinical Professor - Health, Management and Policy with the University of Michigan School of Public Health. She has led several initiatives to expand multi-disciplinary practice in communities, designing the University's first certification program on population health and health equity for medical residents. She is currently a Distinguished Towsley Policy Maker in Residence with the University of Michigan's Gerald Ford School of Public Policy. She has taught and developed graduate level and professional continuing education courses to address emerging health issues, including topics on health policy and public health leadership. Dr. Meadows has extensive experience in public health practice having served in various leadership roles in public health. She has held several official appointments in public health leadership at the state, county and local levels. In her most recent appointment, she served as the Chief Health Officer and Director of Health for the City of Detroit, providing leadership for the department of health, environmental health, infectious diseases, child health, clinical and dental services for the residents of Detroit. Her philanthropic experience includes positions as Program Director for the W.K. Kellogg Foundation - Youth, Education and Higher Education; and advisor for several national initiatives of the Robert Wood Johnson Foundation including the Nurse Executive Leadership Program, Partners in Nursing, and the County Roadmaps project. As a registered nurse, she has worked in both community-based health and hospitals. She currently serves as a Board Member and Advisor for several state level organizations and private foundations focusing on health.

Tara O'Toole, M.D., M.P.H.
Executive Vice President
In-Q-Tel

Tara O'Toole currently serves as Executive Vice President at In-Q-Tel. Dr. O'Toole was confirmed as the Under Secretary for Science and Technology (S&T) at the U.S. Department of Homeland Security (DHS) and served from November 4, 2009 to September 23, 2013. From 2003 to November 2009, Dr. O'Toole was the CEO and Director of the Center for Biosecurity at the University of Pittsburgh Medical Center (UPMC), and Professor of Medicine and of Public Health at the University of Pittsburgh. The Center for Biosecurity of UPMC is an independent organization dedicated to improving the country's resilience to major biological threats. Dr. O'Toole is internationally known for her work on biosecurity and on health and safety issues related to the U.S. nuclear weapons complex. Her publications in the biodefense field include articles on the response to anthrax, smallpox, and plague biological attacks; containment of contagious disease epidemics; biodefense research and development strategies; and hospital preparedness. She is the founding editor of the journal Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. She was a principal author and producer of Dark Winter, an influential exercise conducted in June 2001 to alert national leaders to the dangers of bioterrorist attacks. She was also a principal writer and producer of Atlantic Storm, an international ministerial-level biosecurity exercise held in January 2005. Prior to founding the UPMC in 2003, Dr. O'Toole was one of the original members of the Johns Hopkins Center for Civilian Biodefense Strategies and served as its director from 2001 to 2003. She has served on numerous government and expert advisory committees dealing with biodefense, including panels of the Defense Science Board; the National Academy of Engineering Committee on Combating Terrorism; and the National Academy of Sciences Working Group on Biological Weapons. She served as chair of the Board of the Federation of American Scientists from 2006 to 2007, and in 2006 she was appointed to the board of Google Foundation's International Networked System for Total Early Disease

Detection. From 1993 to 1997, Dr. O'Toole served as Assistant Secretary of Energy for Environment Safety and Health. In this position, she was the principal advisor to the Secretary of Energy on environmental protection and on the health and safety of the approximately 100,000 workers in the U.S. nuclear weapons complex and Department of Energy (DOE) laboratories. She developed the first overall management and safety plan for dealing with the highly enriched uranium, plutonium, spent fuel, and radioactive waste left in place when nuclear weapons production was stopped in the early 1990s. She ran the multi-agency, multimillion-dollar task force that oversaw the government's investigations into human radiation experiments conducted during the Cold War and led the U.S. delegation to Russia to establish the U.S./Russia cooperative effort to study radiationexposure and environmental hazards of the Russian nuclear weapons complex. Prior to her work at DOE, Dr. O'Toole was a senior analyst at the Congressional Office of Technology Assessment, where she directed several projects and studies, including the health impact of pollution resulting from nuclear weapons production. She also served as a consultant to industry and government in matters related to occupational and environmental health; worker participation in workplace safety protection; and organizational change. Dr. O'Toole practiced general internal medicine in community health centers in Baltimore from 1984 to 1988. She is board certified in internal medicine and occupational and environmental health. She has a bachelor's degree from Vassar College, an M.D. from the George Washington University, and a Master of Public Health degree from Johns Hopkins University. She completed internal medicine residency training at Yale University and a fellowship in Occupational and Environmental Medicine at Johns Hopkins University.

Alexandra Phelan, S.J.D., LL.M., LL.B.
Faculty Research Instructor
Center for Global Health Science and Security
Georgetown University

Alexandra Phelan is a member of the Center for Global Health Science and Security and a Faculty Research Instructor in the Department of Microbiology and Immunology at Georgetown University. Dr. Phelan also holds an appointment as Adjunct Professor of Law at Georgetown University Law Center. Dr. Phelan works on legal and policy issues related to infectious diseases, with a particular focus on emerging and reemerging infectious disease outbreaks and international law. She has worked as a consultant for the World Health Organization, the World Bank, and Gavi: the vaccine alliance, and has advised on matters including international law and pathogen sharing, human rights law and Zika, intellectual property law, and contract law. She previously worked for a number of years as a solicitor at a firm in Melbourne, Australia and was admitted to practice to the Supreme Court of Victoria and High Court of Australia in 2010. Dr. Phelan's doctorate examined how overlap between fields of international law – in particular, global health law, international human rights law, and international environmental law – can serve as the catalyst to progressively develop international law to prevent and respond to infectious diseases. She also holds a Master of Laws, specializing in international law, from the Australian National University and a Bachelor of Biomedical Science/Bachelor of Laws (Honours) double degree from Monash University. She also holds a Diploma of Languages (Mandarin Chinese). Dr. Phelan is a General Sir John Monash Scholar and was recognized as an Associate Fellow of the Royal Commonwealth Society in 2015 for her human rights advocacy during the 2013-16 Ebola outbreak.

David Relman, M.D.
Thomas C. and Joan M. Merigan Professor in Medicine, and Chief of Infectious Diseases
Stanford University; VA Palo Alto Health Care System

David Relman is the Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology and Immunology at Stanford University, and Chief of Infectious Diseases at the Veterans Affairs Palo Alto Health Care System. Dr. Relman is also Senior Fellow at the Freeman Spogli Institute for International Studies (FSI), and served as Science Co-Director at the Center for International Security and Cooperation (2013-2017), at Stanford. He is currently director of a new Biosecurity Initiative at FSI. Relman trained at

MIT and then Harvard Medical School, followed by clinical training in internal medicine and infectious diseases at the Massachusetts General Hospital in Boston, and then a postdoctoral fellowship in microbiology at Stanford. His early research focused on molecular methods for pathogen discovery and over the past 20 years, on the human microbiome. He was elected to the National Academy of Medicine in 2011. Dr. Relman served as vice-chair of the National Research Council Committee that reviewed the science performed for the FBI 2001 Anthrax Letters investigation, chair of the Forum on Microbial Threats (2007-2017), and is currently a member of the Intelligence Community Studies Board (2016-) as well as Chair of a Standing Committee tasked with examining the health-related problems of US embassy personnel stationed overseas, all at the U.S. National Academies of Science. He was a founding member of the National Science Advisory Board on Biosecurity (2005-2014), a member of the Working Group on Biodefense for the President's Council of Advisors on Science and Technology (The White House) (2016), and served as President of the Infectious Diseases Society of America (2012-2013). He holds an M.D. from Harvard Medical School.

Mark Smolinski, M.D., M.P.H.
President
Ending Pandemics

Mark Smolinski currently serves as President of Ending Pandemics. Dr. Smolinksi brings 25 years of experience in applying innovative solutions to improve disease prevention, response, and control across the globe. Mark is leading a well-knit team—bringing together technologists; human, animal, and environmental health experts; and key community stakeholders to co-create tools for early detection, advanced warning, and prevention of pandemic threats. Since 2009, Mark has served as the Chief Medical Officer and Director of Global Health at the Skoll Global Threats Fund (SGTF), where he developed the Ending Pandemics in Our Lifetime Initiative in 2012. His work at SGTF created a solid foundation for the work of Ending Pandemics, which branched out as an independent entity on January 1, 2018. Prior to SGTF, Mark developed the Predict and Prevent Initiative at Google.org, as part of the starting team at Google's philanthropic arm. Working with a team of engineers, Google Flu Trends (a project that had tremendous impact on the use of big data for disease surveillance) was created in partnership with the U.S. Centers for Disease Control. Mark has served as Vice President for Biological Programs at the Nuclear Threat Initiative, a public charity directed by CNN founder Ted Turner and former U.S. Senator Sam Nunn. Before NTI, he led an 18-member expert committee of the National Academy of Medicine on the 2003 landmark report "Microbial Threats to Health: Emergence, Detection, and Response." Mark served as the sixth Luther Terry Fellow in Washington, D.C., in the Office of the U.S. Surgeon General and as an Epidemic Intelligence Officer with the U.S. Centers for Disease Control and Prevention. Mark received his B.S. in Biology and M.D. from the University of Michigan in Ann Arbor. He is board-certified in preventive medicine and public health and holds an M.P.H. from the University of Arizona.

David Walt, Ph.D.
Hansjörg Wyss Professor of Biologically Inspired Engineering
Harvard Medical School

David Walt is a member of the faculty at Harvard Medical School in the Department of Pathology, and a Howard Hughes Medical Institute Professor. Dr. Walt pioneered the use of microwell arrays for single-molecule detection and analysis, which has revolutionized the process of genetic and proteomic sequencing, enabling the cost of DNA sequencing and genotyping to plummet nearly a millionfold in the last decade. His current research employs optical fiber microarrays for the detection and analysis of single enzyme molecules to provide mechanistic insight into enzyme mechanisms. In another project, hhe is also investigating the limits of creating high-density sensing arrays containing thousands of microsensors and nanosensors, and are preparing arrays to perform high-density nucleic acid and protein analysis. Dr. Walt is the Scientific Founder of Illumina, Inc. and Quanterix Corp, and has co-founded several other life sciences startups. Previously, he was a University Professor, Professor of Neuroscience, and Professor of

Oral Medicine at Tufts University. He is a member of the National Academy of Engineering, the National Academy of Medicine, a Fellow of the American Academy of Arts and Sciences, a Fellow of the American Institute for Medical and Biological Engineering, and a Fellow of the National Academy of Inventors. He has received numerous awards and honors, including the 2017 American Chemical Society Kathryn C. Hach Award for Entrepreneurial Success, the 2016 Ralph Adams Award in Bioanalytical Chemistry, the 2014 American Chemical Society Gustavus John Esselen Award, the 2013 Analytical Chemistry Spectrochemical Analysis Award, the 2013 Pittsburgh Analytical Chemistry Award, and the 2010 ACS National Award for Creative Invention. He received a B.S. in chemistry from the University of Michigan and a Ph.D. in chemical biology from SUNY at Stony Brook, and did postdoctoral studies at MIT.

The National Academies of
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TAB 3

Statement of Task

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine will convene a standing committee of experts to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee will include members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee will provide a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

The standing committee will:

- Stand ready to respond on short notice to requests from the federal government to assess and consider the science and policy implications of an emerging infectious disease or significant public health threat;
- Provide a venue to enable science and policy discussions relevant to the federal government on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and objectives;
- Identify opportunities to integrate science into national preparedness and response decision making;
- Explore lessons learned and best practices from previous preparedness and response efforts, and identify opportunities to disseminate that information to a variety of stakeholders;
- Serve as a focal point for national policy discussions by experts and other leaders in the field;
- Consider, identify, and discuss strategies for addressing misinformation; and
- Respond to the federal government's needs for continuing dialog related to strategic planning and program development to address emerging infectious diseases, biosecurity, and public health and medical preparedness.

At the request of the sponsors, the standing committee will be involved in the planning, development, and oversight of related ad hoc activities undertaken by separately appointed committees operating under its auspices.

The standing committee will serve as a focal point for the discussion of scientific, technical, and policy issues relevant to emerging infectious diseases and public health preparedness and response that warrant detailed examination. Topics for discussion with the standing committee may include:

- Technical assistance and/or assessment of response to emerging infectious diseases;
- Availability of and access to information, samples, and other materials to determine the origin and evolution of emerging infectious diseases;
- International coordination and engagement;
- Technical assessment of ecological and evolutionary drivers of disease emergence;
- Approaches to proactive public messaging and strategies to address misinformation;
- Other science and policy issues relevant to emerging infectious diseases and 21st century health threats.

The committee will carry out its charge at its in-person and virtual meetings by gathering evidence from experts, deliberating, and, when necessary, by preparing short reports.

COMMITTEE SPONSORS

White House Office of Science and Technology Policy and HHS Office of Assistant Secretary for Preparedness and Response

PROVISIONAL COMMITTEE ROSTER

Harvey Fineberg, M.D., Ph.D. ***(Chair)***
President
Gordon and Betty Moore Foundation

Kristian Andersen, Ph.D.
Associate Professor and Director of Infectious Disease Genomics, Scripps Research Translational Institute
The Scripps Research Institute

Mary Bassett, M.D., M.P.H.
Director of the François-Xavier Bagnoud Center for Health and Human Rights
Harvard School of Public Health

Trevor Bedford, Ph.D.
Associate Faculty Member, Vaccine and Infectious Disease Division, Public Health Sciences Division, and Human Biology Division
Fred Hutchinson Cancer Research Center

Georges Benjamin, M.D.
Executive Director
American Public Health Association

Richard Besser, M.D.
President and CEO
Robert Wood Johnson Foundation

Peter Daszak, Ph.D.
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Diane Griffin, M.D., Ph.D.
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Vice President and Head, Translational Science and Biomarkers
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Patricia King, J.D.
Professor Emerita
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Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
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ADDITIONAL INFORMATION

For additional information, please visit http://nationalacademies.org/hmd/Activities/PublicHealth/EmergingInfectiousDiseasesand21stCenturyHealthThreats.aspx

The National Academies of
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Health and Medicine Division

Standing Committees: What They Do

Standing committees provide sponsors with an ongoing mechanism to engage the National Academies of Sciences, Engineering, and Medicine, stakeholders, and committee members on specific issues in a variety of ways. They are designed to serve sponsors by helping them address their needs on a continuing basis for short and long-term strategic planning and program development.

Standing committees:

1) Stand ready to respond on short notice to requests and other needs from the sponsor(s);
2) Provide high-level strategic guidance to sponsor(s) on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and activities;
3) Serve as a focal point for national policy discussions by experts and other leaders in the field; and
4) Respond to sponsor(s) needs for continuing advice through planning, strategic thinking, and program development.

As part of the ongoing nature of the activity, the standing committee becomes very familiar with the sponsor(s) program/agency. This understanding and familiarity with the sponsor(s) programs facilitates the standing committee's ability to respond quickly and effectively with in-depth knowledge and insight about the sponsor(s) program.

Standing committee activities may include:

- Meeting periodically with the sponsor(s) and others in information-gathering sessions;
- Inviting experts/guests to provide input on the issues that will serve to inform the sponsor and the standing committee in its strategic planning and program development roles; and
- Conducting public outreach, such as through the development of websites and newsletters from the Academies that provides general information about the standing committee's activities or other related initiatives of the Academies.

Standing committee outputs may include:

Type	Product	Source/Origin	Recipient	Process
1	Immediate, **informal verbal feedback and guidance** provided to sponsors at public meetings	Individual Committee Members during meetings	Sponsors	Public meeting discussions

2	**Meeting "Recap,"** which is a high-level summary of issues discussed at a committee meeting	Staff prepares the recap/summary	Sponsors (and Committee Members)	Internal review by HMD staff
3	**Letter Report,** which is a formal report from the committee, based primarily on information presented and discussed at a committee meeting, that may include findings, conclusions, and recommendations on a specific topic	Committee (with Staff support)	Sponsors and the Public	Formal institutional review process
4	**Consensus Report,** which is a separate Academies report (or workshop) prepared by an ad hoc committee appointed specifically for the identified task	The Standing Committee can identify the need for, and recommend to the Academies that they conduct a study	Sponsors and the Public	Standing committees may also develop 'spin off' ideas for workshops and studies that are conducted via separate ad hoc committees (standing committee members may serve on the committees for these ad hoc workshops and studies along with additional members recruited to address the specific workshop or study charge).

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

February 3, 2020

Dr. Marcia McNutt
President, National Academy of Sciences
2101 Constitution Ave, N.W.
Washington, D.C., U.S. 20418

SUBJECT: Rapid Response Assessment of 2019-nCoV Data Needs

In support of the Office of Science and Technology's (OSTP) National Science and Technology Committee (NSTC) rapid research response work for the 2019-nCoV response, and the Administration's efforts to characterize and provide evidence-based assessments for outbreak response efforts, I am writing to ask the National Academies of Sciences, Engineering, and Medicine (NASEM) to rapidly examine information and identify data requirements that would help determine the origins of 2019-nCoV, specifically from an evolutionary/structural biology standpoint. I also ask NASEM to consider whether this should include more temporally and geographically diverse clinical isolates, sequences, etc.

Although a widely-disputed paper, "Uncanny similarity of unique inserts in the 2019-nCoV spike protein to HIV-1 gp120 and Hag," posted on the pre-print server bioRxiv last week has been withdrawn, the response to that manuscript highlights the need to determine information and data requirements as quickly as possible to better perform and validate such analyses of origin. These questions are important not only for this current situation, but to inform future outbreak preparation and better understand animal/human and environmental transmission aspects of coronaviruses. As part of a broader deliberative process, this review will aid preparedness for future events by establishing a process that quickly assembles subject matter experts for evaluating other potentially threatening organisms.

OSTP requests NASEM convene a meeting of experts, particularly world class geneticists, coronavirus experts, and evolutionary biologists, to assess what data, information, and samples are needed to address the unknowns, in order to understand the evolutionary origins of 2019-nCoV and more effectively respond to both the outbreak and any resulting misinformation. I request a letter statement from the National Academies be prepared and provided in response to this solicitation. A more in-depth examination of the issues will be established as a follow up as needed.

Sincerely,

Kelvin K. Droegemeier
Director

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

February 6, 2020

Kelvin Droegemeier
Director
White House Office of Science and Technology Policy
1650 Pennsylvania Avenue, NW
Washington, D.C. 20504

Dear Dr. Droegemeier:

Thank you for your letter regarding the current outbreak of a new respiratory virus, the 2019 Novel Coronavirus, or 2019-nCoV, which was first detected in Wuhan, China, and has now been reported in a growing number of locations worldwide, including the United States.[1] The request from OSTP is timely given the declaration of a public health emergency and potential for misinformation to confound the response.

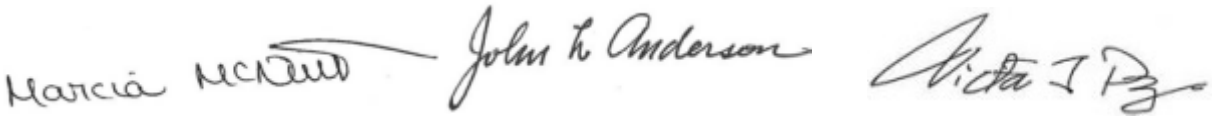
In response to your request, we consulted leading experts[2] in the fields of virology, infectious disease genomics, genome sciences, epidemiology, microbiology, immunobiology, coronaviruses, emerging infections, biosecurity, and global health. We wanted their views about the data needs that could help elucidate the origin and evolution of 2019-nCoV.

Research studies to better understand the origin of 2019-nCoV and how it relates to viruses found in bats and other species are already underway.[3] The closest known relative of 2019-nCoV appears to be a coronavirus identified from bat-derived samples collected in China.[4] The experts informed us that additional genomic sequence data from geographically- and temporally-diverse viral samples are needed to determine the origin and evolution of the virus. Samples collected as early as possible in the outbreak in Wuhan and samples from wildlife would be particularly valuable. Understanding the driving forces behind viral evolution would help facilitate the development of more effective strategies for managing the 2019-nCoV outbreak and for preventing future outbreaks. In this regard, we understand from Chunli Bai, President, Chinese Academy of Sciences, and the Alliance of International Science Organizations (ANSO), that the Wuhan National Biosafety Laboratory of the Chinese Academy of Sciences is willing to share isolates of the 2019-nCoV with the international community and is working with the University of Texas Medical Branch and other international research institutions on the specifics for the sharing and distribution of the isolates. International collaboration of this kind is more important than ever to overcome these types of global challenges.

[1] "2019 Novel Coronavirus (2019-nCoV) Situation Summary." *Centers for Disease Control and Prevention*, 3 Feb. 2020. https://www.cdc.gov/coronavirus/2019-nCoV/summary.html#anchor_1580079137454. Accessed 3 Feb. 2020.
[2] Experts consulted: Kristian G. Andersen (Scripps Research Institute), Ralph Baric (UNC School of Public Health), Trevor Bedford (Fred Hutchinson Cancer Institute), Aravinda Chakravarti (New York University School of Medicine), Peter Daszak (EcoHealth Alliance), Gigi K. Gronvall (Johns Hopkins Bloomberg School of Public Health), Tom Inglesby (Johns Hopkins Center for Health Security), and Stanley Perlman (University of Iowa).
[3] Latinne *et al*. "Origin and cross-species transmission of bat coronaviruses in China." *Nature Communications*, in review.
[4] Zhou *et. al*. "A pneumonia outbreak associated with a new coronavirus of probable bat origin." *Nature*, 2020. https://doi.org/10.1038/s41586-020-2012-7 (2020).

The National Academies stand ready to assemble a committee of experts to examine these issues in more detail and provide evidence-based advice to you in an expedited manner if requested. We appreciate your trust in the National Academies and our efforts to advise the nation and inform public policy decisions.

Sincerely,



Marcia McNutt, President	John L. Anderson., President	Victor J. Dzau, President
National Academy of Sciences	National Academy of Engineering	National Academy of Medicine

cc: Secretary Alex M. Azar, Department of Health and Human Services

EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

WASHINGTON, D.C. 20502

February 26, 2020

Dr. Marcia McNutt
President, National Academy of Sciences
2101 Constitution Ave, N.W.
Washington, D.C., U.S. 20418

SUBJECT: National Academies Standing Committee for Emerging Infectious Disease and 21st Century Health Threats

Dear Dr. McNutt, Marcia

Given the complexities of assessing and responding to emerging infectious diseases and other 21st Century health threats, as demonstrated by the present situation with COVID-19, a need exists to establish an ongoing activity to facilitate rapid access to expert, independent perspectives and insights. A neutral venue is needed through which the U.S. Government can engage subject matter experts from the private sector, non-governmental organizations, the academic community, and other relevant stakeholders involved in topics of emerging infectious disease, biosecurity, and public health and medical preparedness. The purpose is to provide a means for examining critical issues in depth and providing strategic input and guidance, based on the best available information and expertise.

To address this need, and stemming from the offer you extended in your letter to me dated February 6, 2020, the Office of Science and Technology Policy (OSTP) and the Department of Health and Human Services (HHS) have been working with Dr. Andy Pope, and his colleagues from your organization, on a request for the National Academies of Sciences, Engineering, and Medicine (NASEM) to establish a Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. This committee would:

- Stand ready to respond on short notice to requests from the Federal government to assess and consider the science and policy implications of an emerging infectious disease or other significant public health threat;
- Provide a venue to enable science and policy discussions relevant to the Federal government on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and objectives;
- Identify opportunities to integrate science into national preparedness and response decision making;
- Explore lessons learned and best practices from previous preparedness and response efforts, and identify opportunities to disseminate that information to a variety of stakeholders;
- Serve as a focal point for national policy discussions with experts and other leaders in the field;
- Consider, identify and discuss strategies for addressing misinformation; and

- Respond to the Federal government's needs for continuing dialog related to strategic planning and program development to address emerging infectious diseases, biosecurity, and public health and medical preparedness.

I would request that the standing committee serve as a focal point for the discussion of scientific, technical, and policy issues relevant to emerging infectious diseases and public health preparedness and response that warrant detailed examination.

The committee members should include experts in emerging infectious diseases, epidemiology, disease modeling and forecasting, genomics, public health, public health preparedness and response, clinical care and crisis standards of care, risk communication, and regulatory issues. The committee would provide a venue for the exchange of ideas among Federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders such as non-profit/philanthropic organizations.

Topics for discussion with the Committee may include:

- Technical assistance and/or assessment of response to emerging infectious diseases;
- Availability of and access to information, samples, and other materials to determine the origin and evolution of emerging infectious diseases;
- International coordination and engagement;
- Technical assessment of ecological and evolutionary drivers of disease emergence
- Approaches to proactive public messaging and strategies to address misinformation;
- Other science and policy issues relevant to emerging infectious diseases and 21st century health threats.

Thank you for your partnership and willingness to bring scientific expertise to bear on this important issue.

Sincerely,

Kelvin K. Droegemeier
Director

Thank you, Maria!

– Kelvin

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine will convene a standing committee of experts to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee will include approximately 15 members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee will provide a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

The standing committee will:

- Stand ready to respond on short notice to requests from the federal government to assess and consider the science and policy implications of an emerging infectious disease or significant public health threat;
- Provide a venue to enable science and policy discussions relevant to the federal government on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and objectives;
- Identify opportunities to integrate science into national preparedness and response decision making;
- Explore lessons learned and best practices from previous preparedness and response efforts, and identify opportunities to disseminate that information to a variety of stakeholders;
- Serve as a focal point for national policy discussions by experts and other leaders in the field;
- Consider, identify, and discuss strategies for addressing misinformation; and
- Respond to the federal government's needs for continuing dialog related to strategic planning and program development to address emerging infectious diseases, biosecurity, and public health and medical preparedness.

At the request of the sponsors, the standing committee will be involved in the planning, development, and oversight of related ad hoc activities undertaken by separately appointed committees operating under its auspices.

The standing committee will serve as a focal point for the discussion of scientific, technical, and policy issues relevant to emerging infectious diseases and public health preparedness and response that warrant detailed examination. Topics for discussion with the standing committee may include:

- Technical assistance and/or assessment of response to emerging infectious diseases;
- Availability of and access to information, samples, and other materials to determine the origin and evolution of emerging infectious diseases;
- International coordination and engagement;
- Technical assessment of ecological and evolutionary drivers of disease emergence;
- Approaches to proactive public messaging and strategies to address misinformation;
- Other science and policy issues relevant to emerging infectious diseases and 21st century health threats.

The committee will carry out its charge at its in-person and virtual meetings by gathering evidence from experts, deliberating, and, when necessary, by preparing short reports.

CONTACT INFORMATION

Andrew Pope
Director, Board on Health Sciences Policy
202-334-1739 (office)
apope@nas.edu

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; 'Georges Benjamin'; drnickilurie@gmail.com; Del Rio, Carlos; 'Sharon Inouye'; 'Linda Degutis'; Susan Polan; Ogilvie, Jenna; Kanarek, Morgan; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Overton, Devona; May, David; Kearney, William; Pope, Andrew; Pavlin, Julie; Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS)

Location: Zoom - see instructions below

Importance: Normal

Subject: CONFIRMED - COVID-19 Conversations Webinar Series Advisory Group Meeting

Start Time: Thur 3/19/2020 5:00:00 PM (UTC-04:00)

End Time: Thur 3/19/2020 7:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; 'Georges Benjamin'; drnickilurie@gmail.com; Del Rio, Carlos; 'Sharon Inouye'; 'Linda Degutis'; Susan Polan; Ogilvie, Jenna; Kanarek, Morgan; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Overton, Devona; May, David; Kearney, William; Pope, Andrew; Pavlin, Julie

Optional Attendees: Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS)

Note that we will likely not need the full 2 hours.

Agenda and background materials to come ASAP.

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: "COVID-19 Conversations" Webinar Series Advisory Group Call
Time: Mar 19, 2020 05:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/235883148

Or iPhone one-tap :
US: +13126266799,,235883148# or +14702509358,,235883148#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 312 626 6799 or +1 470 250 9358 or +1 470 381 2552 or +1 646 518 9805 or +1 646 558 8656 or +1 786 635 1003 or +1 602 753 0140 or +1 651 372 8299 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 267 831 0333 or +1 301 715 8592 or +1 346 248 7799 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 235 883 148
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

To: 'Tracey McNamara'[tmcNamara@westernu.edu]; 'Carter Mecher'[cmecher@charter.net]; 'Dr. Eva Lee'[eva.evalee.lee64@gmail.com]
Cc: 'Caneva, Duane'[duane.caneva@hq.dhs.gov]; 'McDonald, Eric'[Eric.McDonald@sdcounty.ca.gov]; 'Richard Tubb'[bg.richard.tubb@gmail.com]; 'Rob Darling, MD'[rdarling@patronusmedical.com]; 'William Lang'[wlang@worldclinic.com]; 'Mecher, Carter'[Carter.Mecher@va.gov]; 'Tom Bossert'[tom.bossert@me.com]; 'Richard Hatchett'[richard.hatchett@cepi.net]; 'Lawler, James V'[james.lawler@unmc.edu]; 'Parker Jr, Gerald W'[gparker@cvm.tamu.edu]; 'Hanfling, Dan'[DHanfling@iqt.org]; 'Gruber,David (DSHS)'[David.Gruber@dshs.texas.gov]; 'CHRISTOPHER ALLEN'[chrisallen_10@msn.com]; jamison.day@gmail.com[jamison.day@gmail.com]; 'Borio, Luciana'[LBorio@iqt.org]; Baric, Ralph S[rbaric@email.unc.edu]; 'Hunt, Richard (OS/ASPR/EMMO)'[Richard.Hunt@hhs.gov]; 'WILKINSON, THOMAS'[THOMAS.WILKINSON@hq.dhs.gov]; 'M.D.'[MVCALLAHAN@mgh.harvard.edu]; 'David'[DMarcozzi@som.umaryland.edu]; 'CharitytA@CDPH'[Charity.Dean@cdph.ca.gov]; 'Gregory J'[MartinGJ@state.gov]; 'Walters, William (STATE.GOV)'[walterswa2@state.gov]; 'HAMILTON, CAMERON'[cameron.hamilton@hq.dhs.gov]; 'Dodgen,tDanielt(OS/ASPR/SPPR)'[daniel.dodgen@hhs.gov]; 'DeBord,Kristin (OS/ASPR/SPPR)'[Kristin.DeBord@hhs.gov]; 'Phillips, Sally (OS/ASPR/SPPR)'[Sally.Phillips@hhs.gov]; 'Matthew J CIV USARMY (USA)'[matthew.j.hepburn.civ@mail.mil]; 'Lisa Koonin'[lkoonin1@gmail.com]; 'HARVEY, MELISSA'[melissa.harvey@hq.dhs.gov]; 'WOLFE, HERBERT'[HERBERT.WOLFE@hq.dhs.gov]; 'Eastman, Alexander'[alexander.eastman@hq.dhs.gov]; 'EVANS, MARIEFRED'[mariefred.evans@associates.hq.dhs.gov]; jwleduc@utmb.edu[jwleduc@utmb.edu]; 'Johnson, Robert (OS/ASPR/BARDA)'[Robert.Johnson@hhs.gov]; 'Yeskey, Kevin'[kevin.yeskey@hhs.gov]; 'Disbrow, Gary (OS/ASPR/BARDA)'[Gary.Disbrow@hhs.gov]; 'Redd, John (OS/ASPR/SPPR)'[John.Redd@hhs.gov]; 'Hassell, David (Chris) (OS/ASPR/IO)'[David.Hassell@hhs.gov]; 'Hamel, Joseph (OS/ASPR/IO)'[Joseph.Hamel@hhs.gov]; 'Wade, David'[david.wade@hq.dhs.gov]; 'TARANTINO, DAVID A'[david.a.tarantino@cbp.dhs.gov]; 'KAUSHIK, SANGEETA'[sangeeta.kaushik@hq.dhs.gov]; 'Lee, Scott (OS/ASPR/EMMO)'[Scott.Lee@hhs.gov]; 'Larry G'[PadgetLG@state.gov]; 'Ryan Morhard'[Ryan.Morhard@weforum.org]; 'Steven Jt(tCHFStDPH)'[steven.stack@ky.gov]; 'Adams, Jerome (HHS/OASH)'[Jerome.Adams@hhs.gov]; 'Mansoura, Monique K.'[mmansoura@mitre.org]; 'Fantinato, Jessica (USDA.GOV)'[jessica.fantinato@usda.gov]; 'DC'[michelle.colby@usda.gov]; danny.shiau@usuhs.edu[danny.shiau@usuhs.edu]; 'Cordts, Jerome (CTR)'[jerome.cordts@associates.hq.dhs.gov]; 'Schnitzer, Jay J.'[jschnitzer@mitre.org]; 'Ignacio, Joselito'[joselito.ignacio@fema.dhs.gov]; 'Will Gaskins'[will.gaskins@efiia.com]; 'Kevin Montgomery'[kevin@collaborate.org]; 'Logan, Linda L'[llogan@cvm.tamu.edu]; 'LLogandakar'[llogandakar@gmail.com]; 'Venkayya, Rajeev'[rajeev.venkayya@takeda.com]; 'Ronny Jackson'[ronny.jacksonmd@gmail.com]; 'Brian Benson'[brian.benson@icloud.com]; 'Dr. Eva K Lee'[evalee-gatech@pm.me]
From: 1974usna@gmail.com[1974usna@gmail.com]
Sent: Tue 3/17/2020 1:46:30 PM (UTC-04:00)
Subject: More Social Distancing
Medium- Coronavirus.pdf
joc70085_644_654.pdf

Apparently, my attachments sent last night with my comments on Markel's analysis of 1918 social distancing, etc. did not come through, so I am going to try again.

Coronavirus: Why You Must Act Now

Politicians, Community Leaders and Business Leaders: What Should You Do and When?

Tomas Pueyo
Follow

Mar 10 · 26 min read
Updated on 3/13/2020.

With everything that's happening about the Coronavirus, it might be very hard to make a decision of what to do today. Should you wait for more information? Do something today? What?

Here's what I'm going to cover in this article, with lots of charts, data and models with plenty of sources:

- How many cases of coronavirus will there be in your area?
- What will happen when these cases materialize?
- What should you do?
- When?

When you're done reading the article, this is what you'll take away:

The coronavirus is coming to you.
It's coming at an exponential speed: gradually, and then suddenly.
It's a matter of days. Maybe a week or two.
When it does, your healthcare system will be overwhelmed.
Your fellow citizens will be treated in the hallways.
Exhausted healthcare workers will break down. Some will die.
They will have to decide which patient gets the oxygen and which one dies.
The only way to prevent this is social distancing today. Not tomorrow. Today.
That means keeping as many people home as possible, starting now.

As a politician, community leader or business leader, you have the power and the responsibility to prevent this.

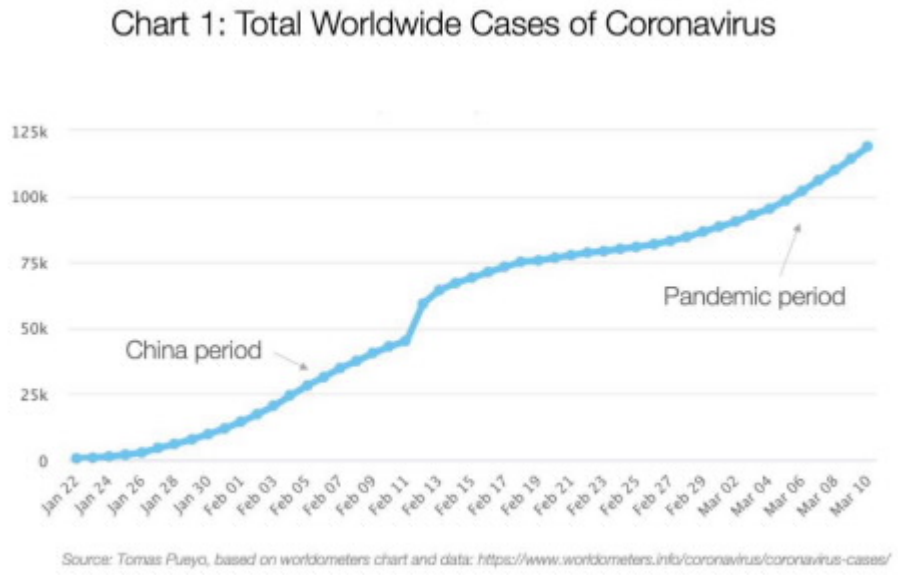
You might have fears today: What if I overreact? Will people laugh at me? Will they be angry at me? Will I look stupid? Won't it be better to wait for others to take steps first?

Will I hurt the economy too much?

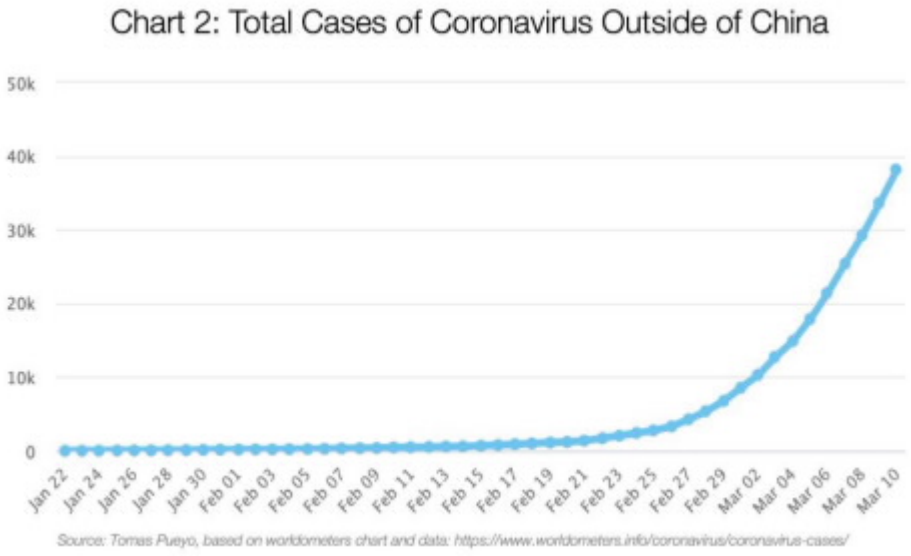
But in 2–4 weeks, when the entire world is in lockdown, when the few precious days of social distancing you will have enabled will have saved lives, people won't criticize you anymore: They will thank you for making the right decision.

Ok, let's do this.

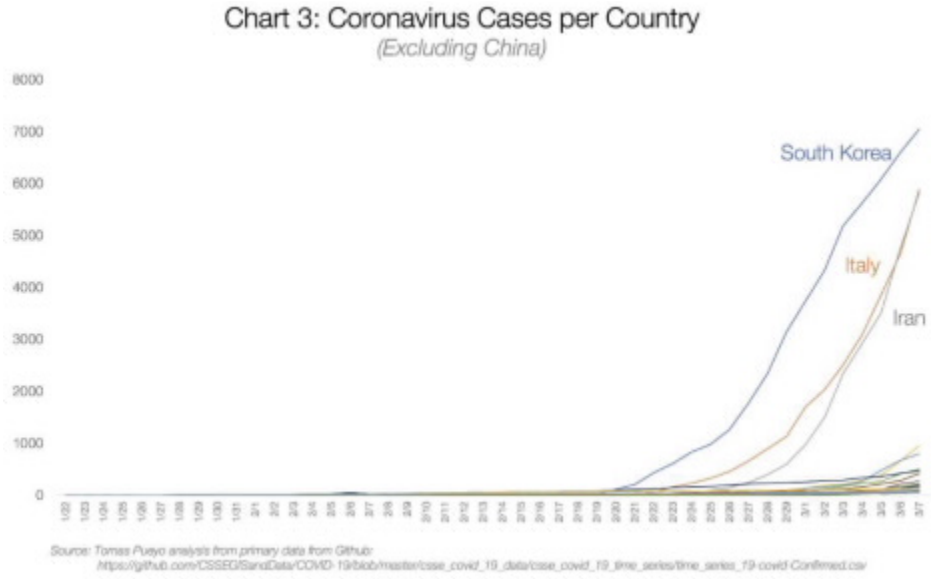
1. How Many Cases of Coronavirus Will There Be in Your Area?
Country Growth



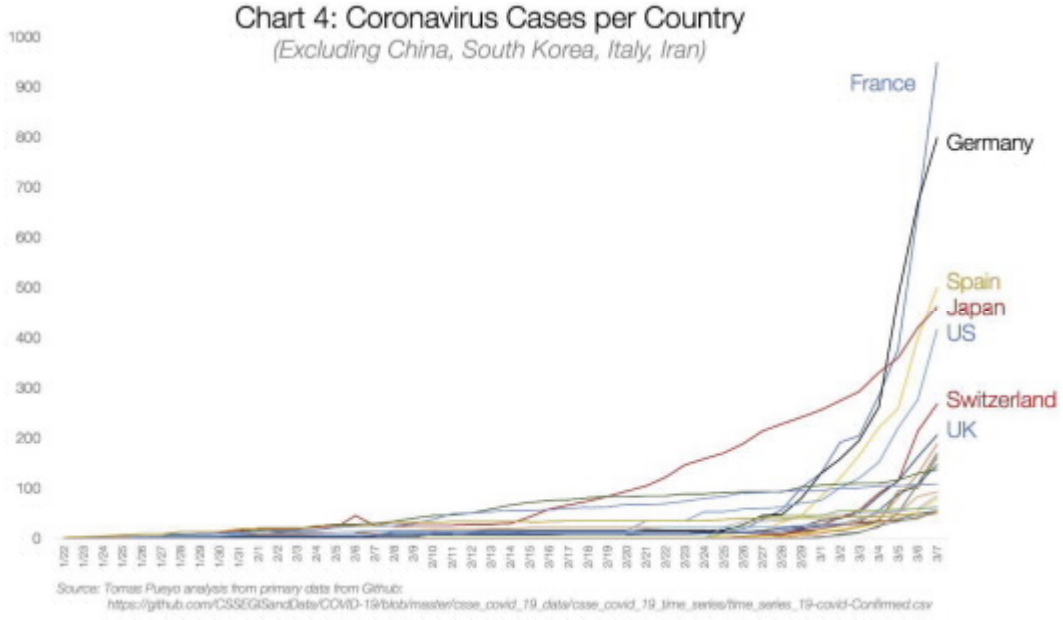
The total number of cases grew exponentially until China contained it. But then, it leaked outside, and now it's a pandemic that nobody can stop.



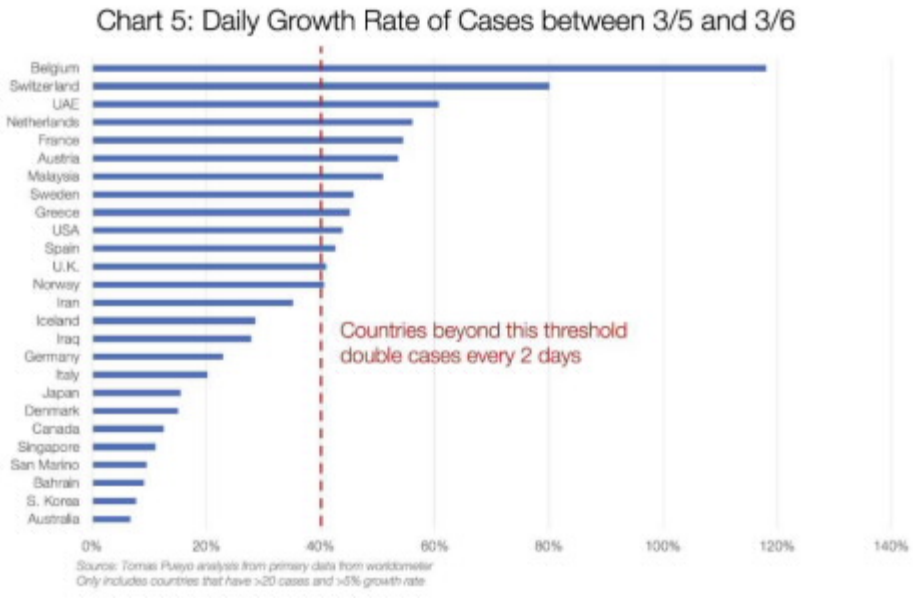
As of today, this is mostly due to Italy, Iran and South Korea:



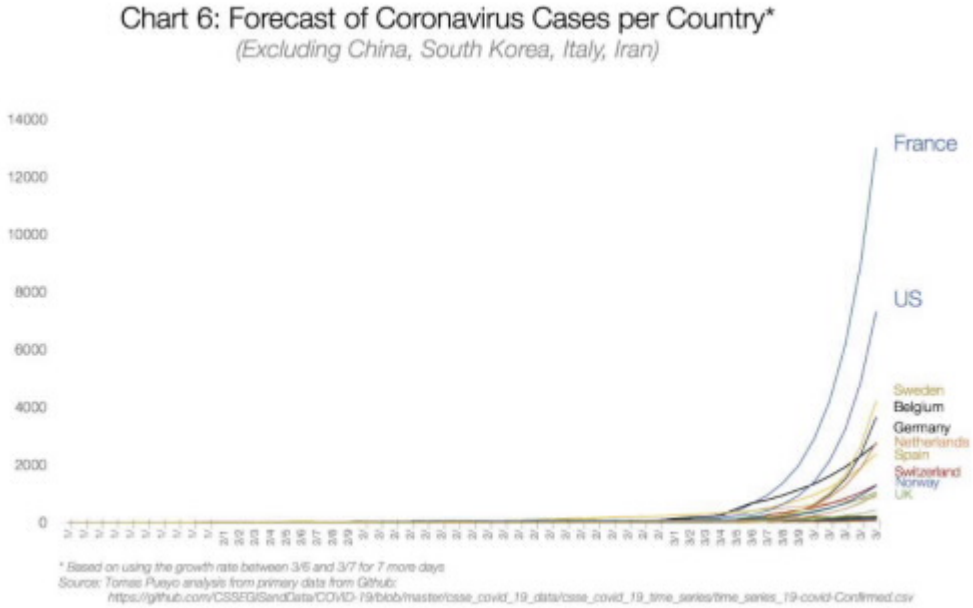
There are so many cases in South Korea, Italy and Iran that it's hard to see the rest of the countries, but let's zoom in on that corner at the bottom right.



There are dozens of countries with exponential growth rates. As of today, most of them are Western.

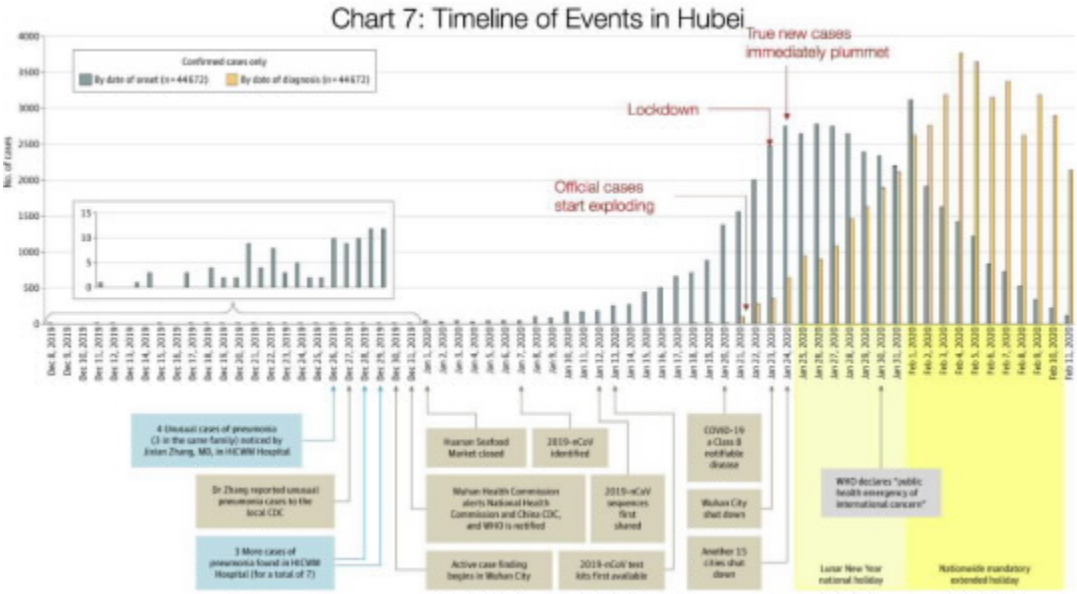


If you keep up with that type of growth rate for just a week, this is what you get:



If you want to understand what will happen, or howto prevent it, you need to look at the cases that have already gone through this: China, Eastern countries with SARS experience, and Italy.

China



Source: Tomas Pueyo analysis over chart from the Journal of the American Medical Association, based on raw case data from the Chinese Center for Disease Control and Prevention

This is one of the most important charts.

It shows in orange bars the daily official number of cases in the Hubei province: How many people were diagnosed that day.

The grey bars show the **true** daily coronavirus cases. The Chinese CDC found these by asking patients during the diagnostic when their symptoms started.

Crucially, these true cases weren't known at the time. We can only figure them out looking backwards: The authorities don't know that somebody just started having symptoms. They know when somebody goes to the doctor and gets diagnosed.

What this means is that the orange bars show you what authorities knew, and the grey ones what was really happening.

On January 21st, the number of new diagnosed cases (orange) is exploding: there are around 100 new cases. In reality, there were 1,500 new cases that day, growing exponentially. But the authorities didn't know that. What they knew was that suddenly there were 100 new cases of this new illness.

Two days later, authorities shut down Wuhan. At that point, the number of diagnosed daily new cases was ~400. Note that number: they made a decision to close the city with just 400 new cases in a day. In reality, there were 2,500 new cases that day, but they didn't know that.

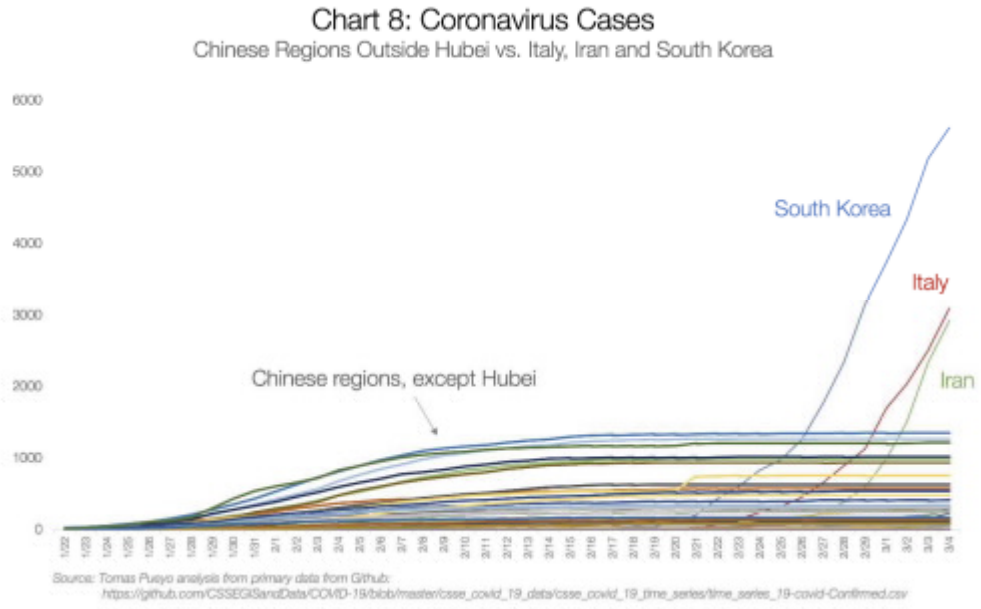
The day after, another 15 cities in Hubei shut down.

Up until Jan 23rd, when Wuhan closes, you can look at the grey graph: it's growing exponentially. True cases were exploding. As soon as Wuhan shuts down, cases slow down. On Jan 24th, when another 15 cities shut down, the number of true cases (again, grey) grinds to a halt. Two days later, the maximum number of true cases was reached, and it has gone down ever since.

Note that the orange (official) cases were still growing exponentially: For 12 more days, it looked like this thing was still exploding. But it wasn't. It's just that the cases were getting stronger symptoms and going to the doctor more, and the system to identify them was stronger.

This concept of official and true cases is important. Let's keep it in mind for later.

The rest of regions in China were well coordinated by the central government, so they took immediate and drastic measures. This is the result:

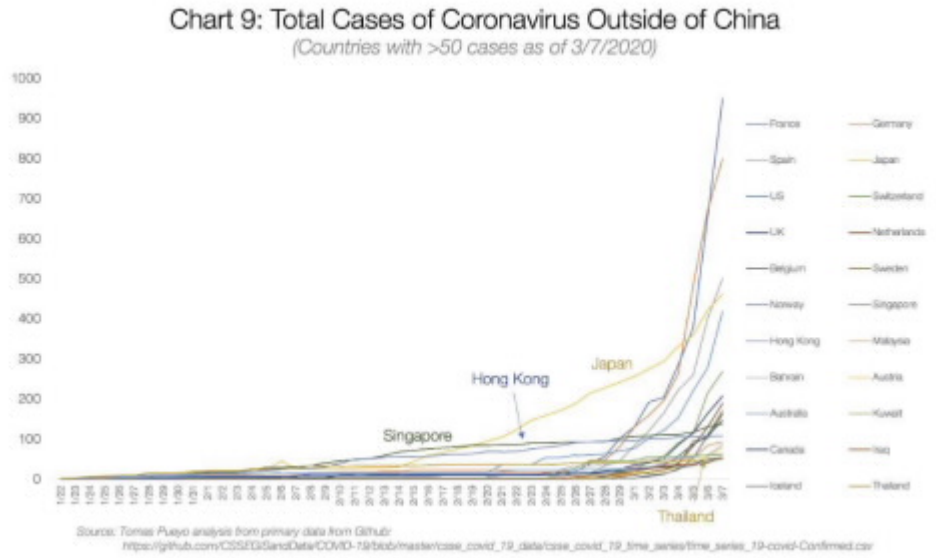


Every flat line is a Chinese region with coronavirus cases. Each one had the potential to become exponential, but thanks to the measures happening just at the end of January, all of them stopped the virus before it could spread.

Meanwhile, South Korea, Italy and Iran had a full month to learn, but didn't. They started the same exponential growth of Hubei and passed every other Chinese region before the end of February.

Eastern Countries

South Korea cases have exploded, but have you wondered why Japan, Taiwan, Singapore, Thailand or Hong Kong haven't?



Taiwan didn't even make it to this graph because it didn't have the 50 cases threshold that I used.

All of them were hit by SARS in 2003, and all of them learned from it. They learned how viral and lethal it could be, so they knew to take it seriously. That's why all of their graphs, despite starting to grow much earlier, still don't look like exponentials.

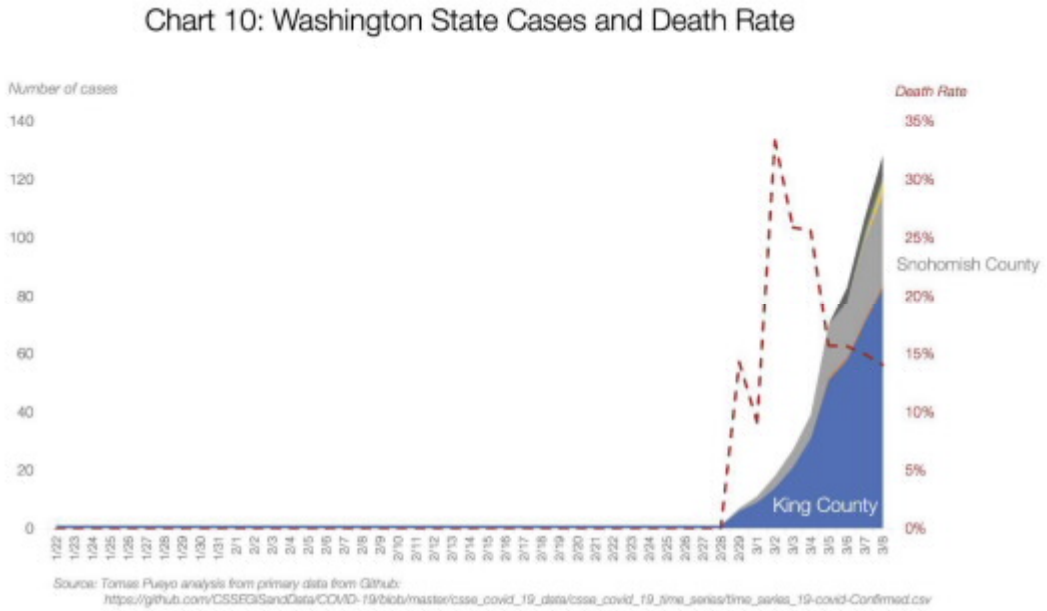
So far, we have stories of coronavirus exploding, governments realizing the threat, and containing them. For the rest of the countries, however, it's a completely different story.

Before I jump to them, a note about South Korea: The country is probably an outlier. The coronavirus was contained for the first 30 cases. Patient 31 was a super-spreader who passed it to thousands of other people. Because the virus spreads before people show symptoms, by the time the authorities realized the issue, the virus was out there. They're now paying the consequences of that one instance. Their containment efforts show, however: Italy has already passed it in numbers of cases, and Iran will pass it tomorrow (3/10/2020).

Washington State

You've already seen the growth in Western countries, and how bad forecasts of just one week look like. Now imagine that containment doesn't happen like in Wuhan or in other Eastern countries, and you get a colossal epidemic.

Let's look at a few cases, such as Washington State, the San Francisco Bay Area, Paris and Madrid.



Washington State is the US's Wuhan. The number of cases there is growing exponentially. It's currently at 140.

But something interesting happened early on. The death rate was through the roof. At some point, the state had 3 cases and one death.

We know from other places that the death rate of the coronavirus is anything between 0.5% and 5% (more on that later). How could the death rate be 33%?

It turned out that the virus had been spreading undetected for weeks. It's not like there were only 3 cases. It's that authorities only knew about 3, and one of them was dead because the more serious the condition, the more likely somebody is to be tested.

This is a bit like the orange and grey bars in China: Here they only knew about the orange bars (official cases) and they looked good: just 3. But in reality, there were hundreds, maybe thousands of true cases.

This is an issue: You only know the official cases, not the true ones. But you need to know the true ones. How can you estimate the true ones? It turns out, there's a couple of ways. And I have a model for both, so you can play with the numbers too (direct link to copy of the model).

First, through deaths. If you have deaths in your region, you can use that to guess the number of true current cases. We know approximately how long it takes for that person to go from catching the virus to dying on average (17.3 days). That means the person who died on 2/29 in Washington State probably got infected around 2/12.

Then, you know the mortality rate. For this scenario, I'm using 1% (we'll discuss later the details). That means that, around 2/12, there were already around ~100 cases in the area (of which only one ended up in death 17.3 days later).

Now, use the average doubling time for the coronavirus (time it takes to double cases, on average). It's 6.2. That means that, in the 17 days it took this person to die, the cases had to multiply by ~8 (=2^(17/6)). That means that, if you are not diagnosing all cases, one death today means 800 true cases today.

Washington state has today 22 deaths. With that quick calculation, you get ~16,000 true coronavirus cases today. *As many as the official cases in Italy and Iran combined.*

If we look into the detail, we realize that 19 of these deaths were from one cluster, which might not have spread the virus widely. So if we consider those 19 deaths as one, the total deaths in the state is four. Updating the model with that number, we still get ~3,000 cases today.

This approach from Trevor Bedford looks at the viruses themselves and their mutations to assess the current case count.

The conclusion is that there are likely ~1,100 cases in Washington state right now. None of these approaches are perfect, but they all point to the same message: We don't know the number of true cases, but it's much higher than the official one. It's not in the hundreds. It's in the thousands, maybe more.

San Francisco Bay Area

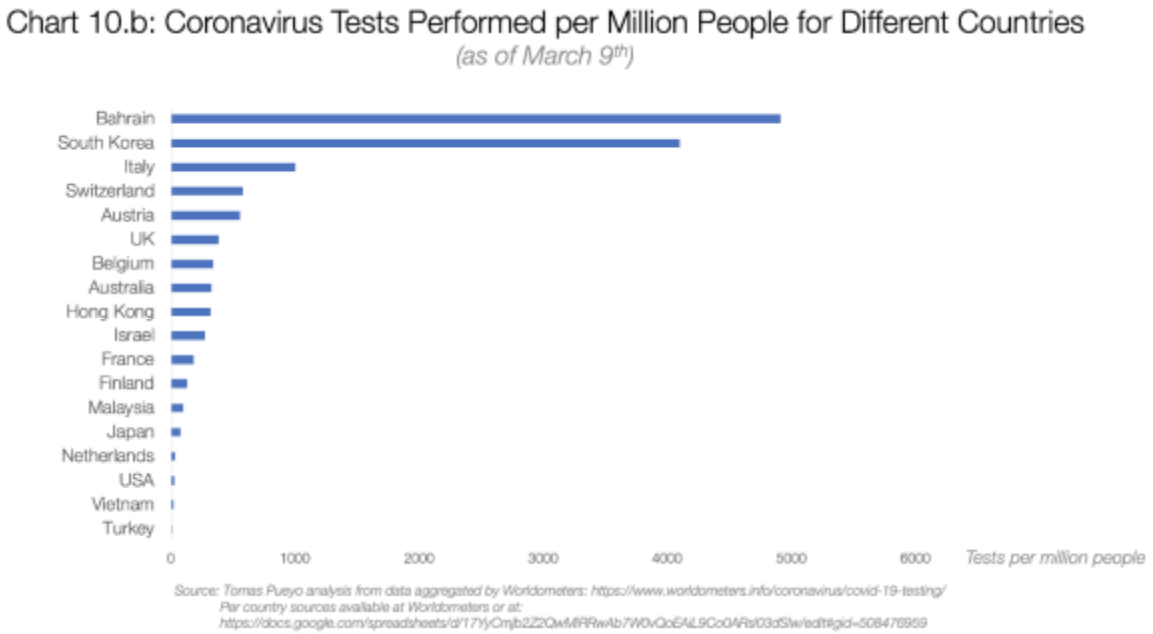
Until 3/8, the Bay Area didn't have any death. That made it hard to know how many true cases there were. Officially, there were 86 cases. But the US is vastly undertesting because it doesn't have enough kits. The country decided to create their own test kit, which turned out not to work.
These were the number of tests carried out in different countries by March 3rd:

Country	Tests Performed	Tests Per Million Citizens	Positive Test Rate
South Korea	109,591	2,138	4.4%
Italy	23,345	386	8.7%
Austria	2,120	235	0.8%
Switzerland	1,850	214	1.6%
UK	13,525	199	0.3%
Finland	130	23	5.4%
Turkey	940	11	0.0%
United States	472	1	21.8%

Source: Tomas Pueyo analysis with data from Worldometer
https://www.worldometers.info/coronavirus/covid-19-testing/

Sources for each number here

Turkey, with no cases of coronavirus, had 10 times the testing per inhabitant than the US. The situation is not much better today, with ~8,000 tests performed in the US, which means ~4,000 people have been tested.



Here, you can just use a share of official cases to true cases. How to decide which one?

For the Bay Area, they were testing everybody who had traveled or was in contact with a traveler, which means that they knew most of the travel-related cases, but none of the community spread cases. By having a sense of community spread vs. travel spread, you can know how many true cases there are.

I looked at that ratio for South Korea, which has great data. By the time they had 86 cases, the % of them from community spread was 86%(86 and 86% are a coincidence).

With that number, you can calculate the number of true cases. If the Bay Area has 86 cases today, it is likely that the true number is ~600.

France and Paris

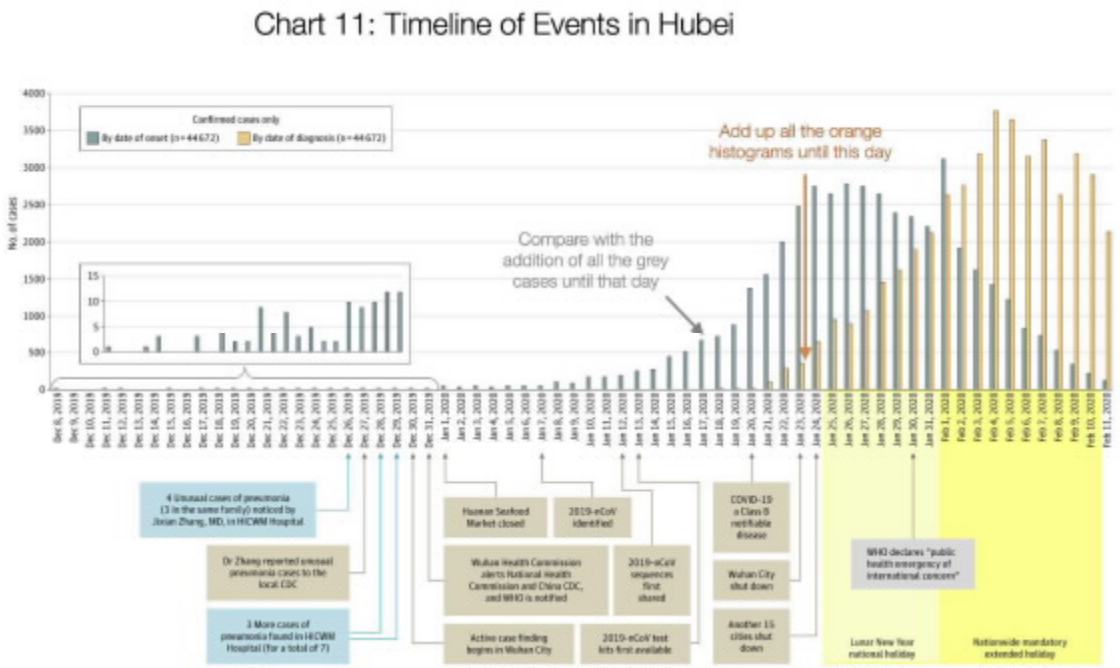
France claims 1,400 cases today and 30 deaths. Using the two methods above, you can have a range of cases: **between 24,000 and 140,000.**

The true number of coronavirus cases in France today is likely to be between 24,000 and

140,000.

Let me repeat that: the number of true cases in France is likely to be between one and two orders or magnitude higher than it is officially reported.

Don't believe me? Let's look at the Wuhan graph again.



Source: Tomas Pueyo analysis over chart and data from the Journal of the American Medical Association

If you stack up the orange bars until 1/22, you get 444 cases. Now add up all the grey bars. They add up to ~12,000 cases. So when Wuhan thought it had 444 cases, it had 27 times more. If France thinks it has 1,400 cases, it might well have tens of thousands

The same math applies to Paris. With ~30 cases inside the city, the true number of cases is likely to be in the hundreds, maybe thousands. With 300 cases in the Ile-de-France region, the total cases in the region might already exceed tens of thousands.

Spain and Madrid

Spain has very similar numbers as France (1,200 cases vs. 1,400, and both have 30 deaths). That means the same rules are valid: Spain has probably upwards of 20k true cases already.
In the Comunidad de Madrid region, with 600 official cases and 17 deaths, the true number of cases is likely between 10,000 and 60,000.

If you read these data and tell yourself: "*Impossible, this can't be true*", just think this: With this number of cases, Wuhan was already in lockdown.

With the number of cases we see today in countries like the US, Spain, France, Iran, Germany, Japan, Netherlands, Denmark, Sweden or Switzerland, Wuhan was already in lockdown.

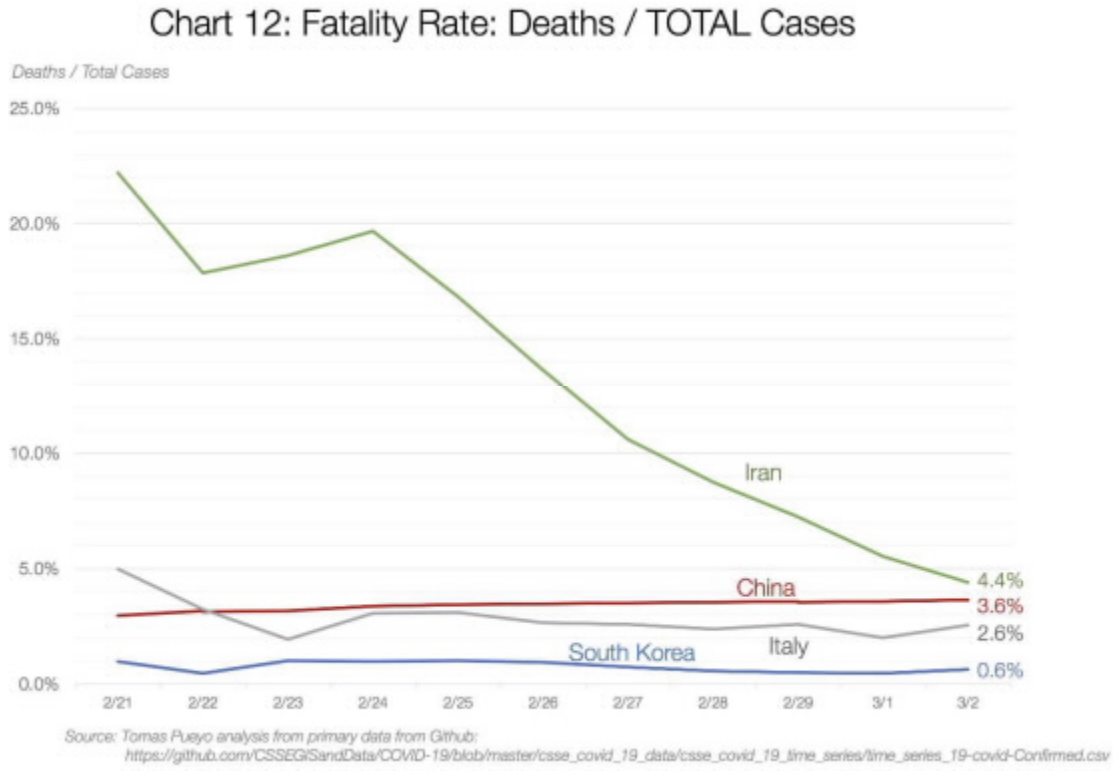
And if you're telling yourself: *"Well, Hubei is just one region"*, let me remind you that it has nearly 60 million people, bigger than Spain and about the size of France.

2. What Will Happen When These Coronavirus Cases Materialize?

So the coronavirus is already here. It's hidden, and it's growing exponentially.
What will happen in our countries when it hits? It's easy to know, because we already have several places where it's happening. The best examples are Hubei and Italy.

Fatality Rates

The World Health Organization (WHO) quotes 3.4% as the fatality rate (% people who contract the coronavirus and then die). This number is out of context so let me explain it.



It really depends on the country and the moment: between 0.6% in South Korea and 4.4% in Iran. So what is it? We can use a trick to figure it out.

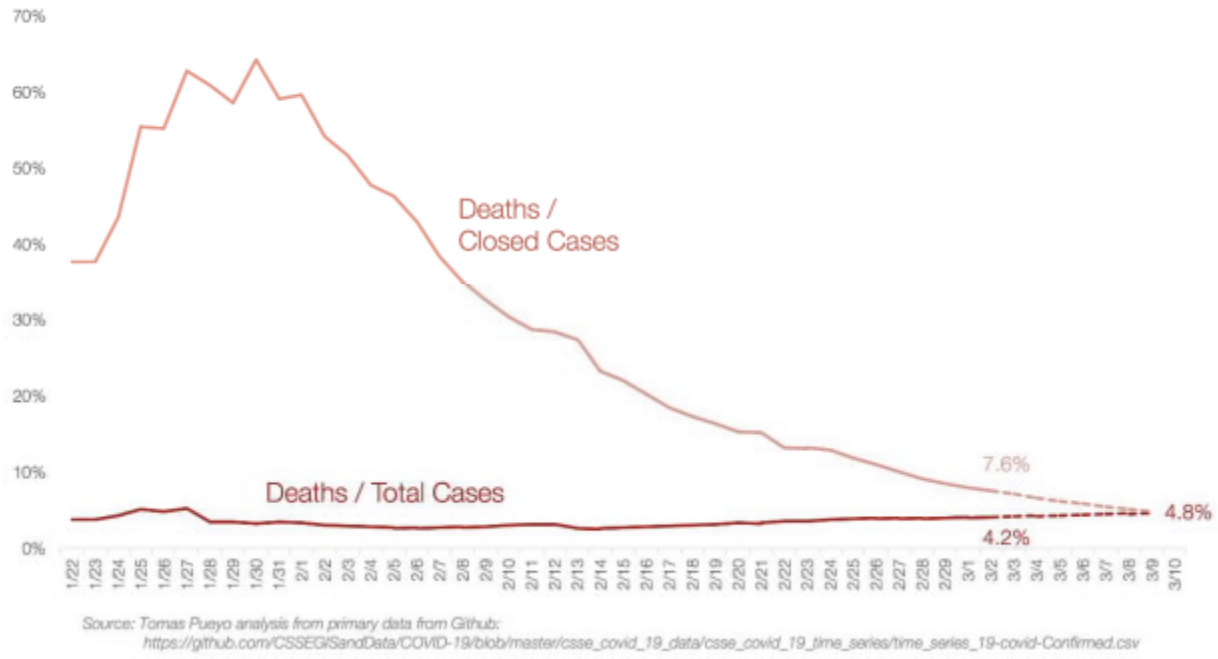
The two ways you can calculate the fatality rate is Deaths/Total Cases and Death/Closed Cases. The first one is likely to be an underestimate, because lots of open cases can still end up in death. The second is an overestimate, because it's likely that deaths are closed quicker than recoveries.

What I did was look at how both evolve over time. Both of these numbers will converge to the same result once all cases are closed, so if you project past trends to the future, you can make a guess on what the final fatality rate will be.

This is what you see in the data. China's fatality rate is now between 3.6% and 6.1%. If you project that in the future, it looks like it converges towards ~3.8%-4%. This is double the current estimate, and 30 times worse than the flu.

It is made up of two completely different realities though: Hubei and the rest of China.

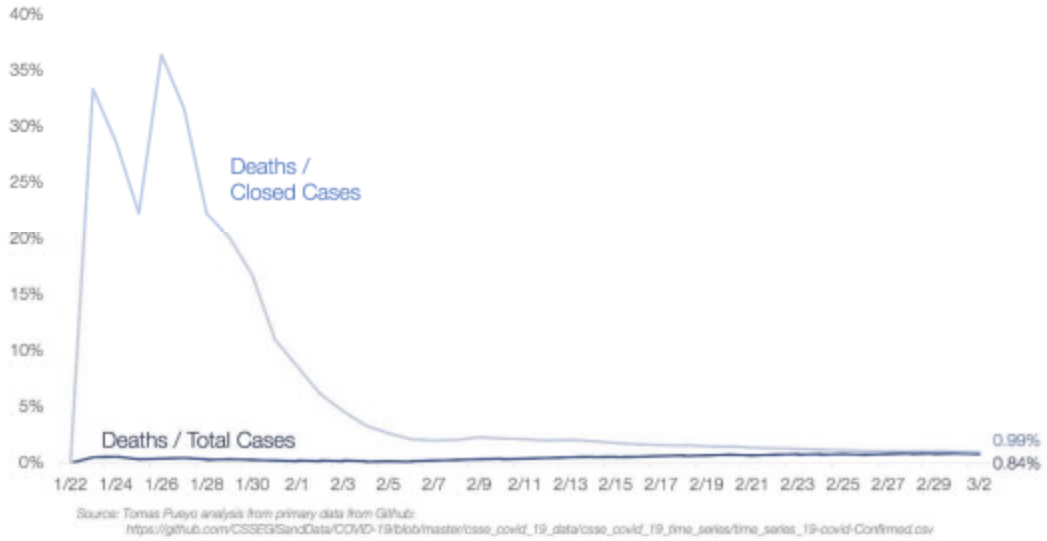
Chart 13: Fatality Rates in Hubei Region, China



Source: Tomas Pueyo analysis from primary data from Github:
https://github.com/CSSEGISandData/COVID-19/blob/master/csse_covid_19_data/csse_covid_19_time_series/time_series_19-covid-Confirmed.csv

Hubei's fatality rate will probably converge towards 4.8%. Meanwhile, for the rest of China, it will likely converge to ~0.9%:

Chart 14: Fatality Rates in China, Excluding Hubei



I also charted the numbers for Iran, Italy and South Korea, the only countries with enough deaths to make this somewhat relevant.

Chart 15: Projection of Coronavirus Fatality Rate in Iran

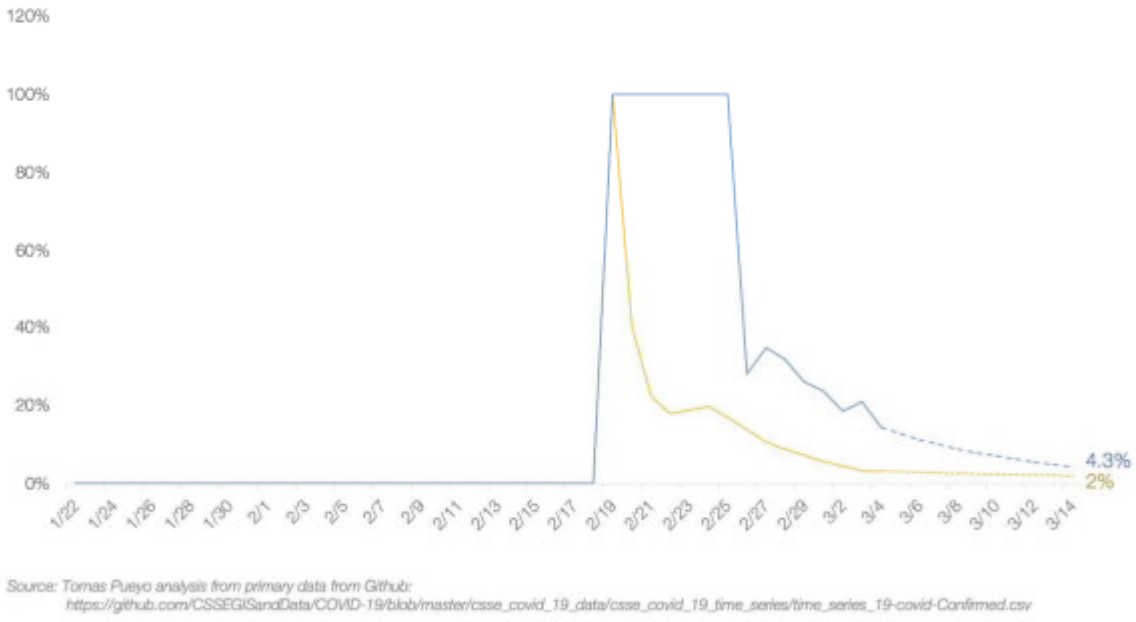


Chart 16: Projection of Coronavirus Fatality Rate in Italy

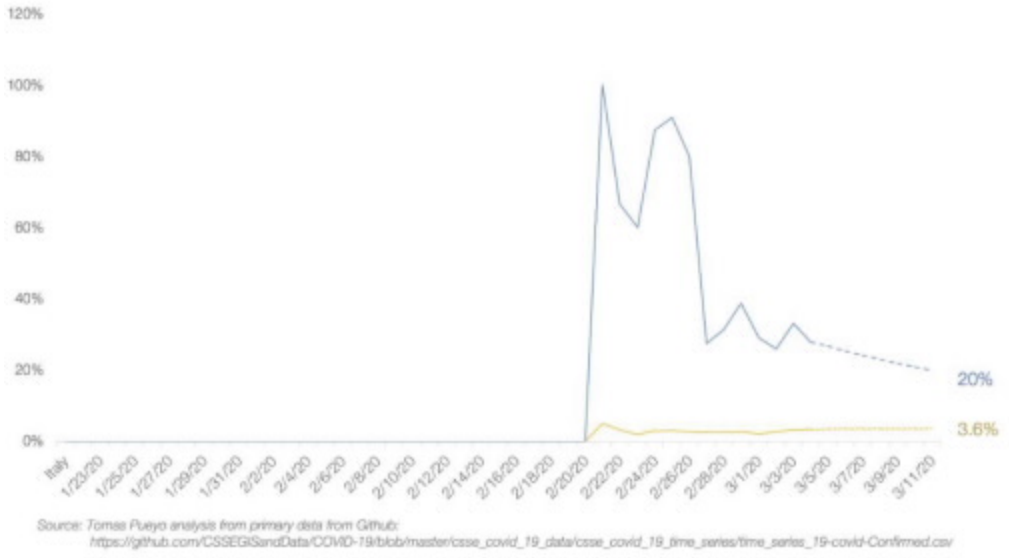
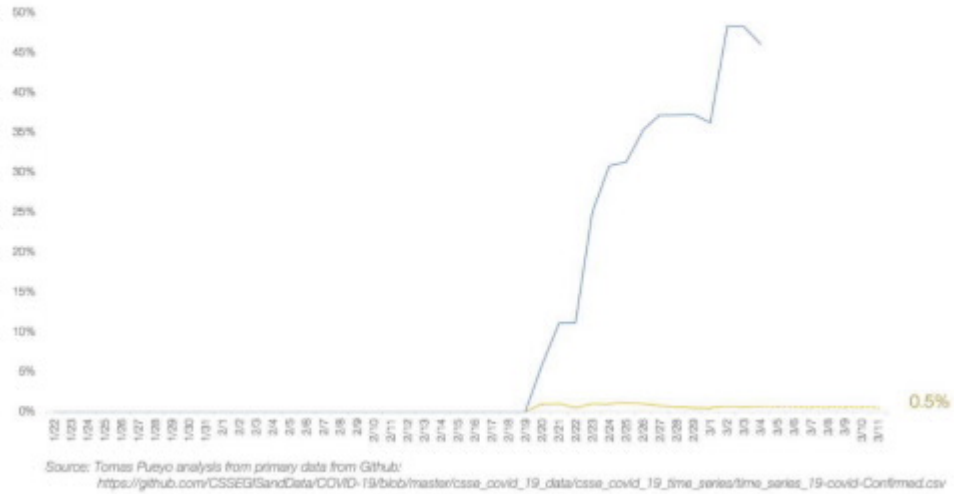
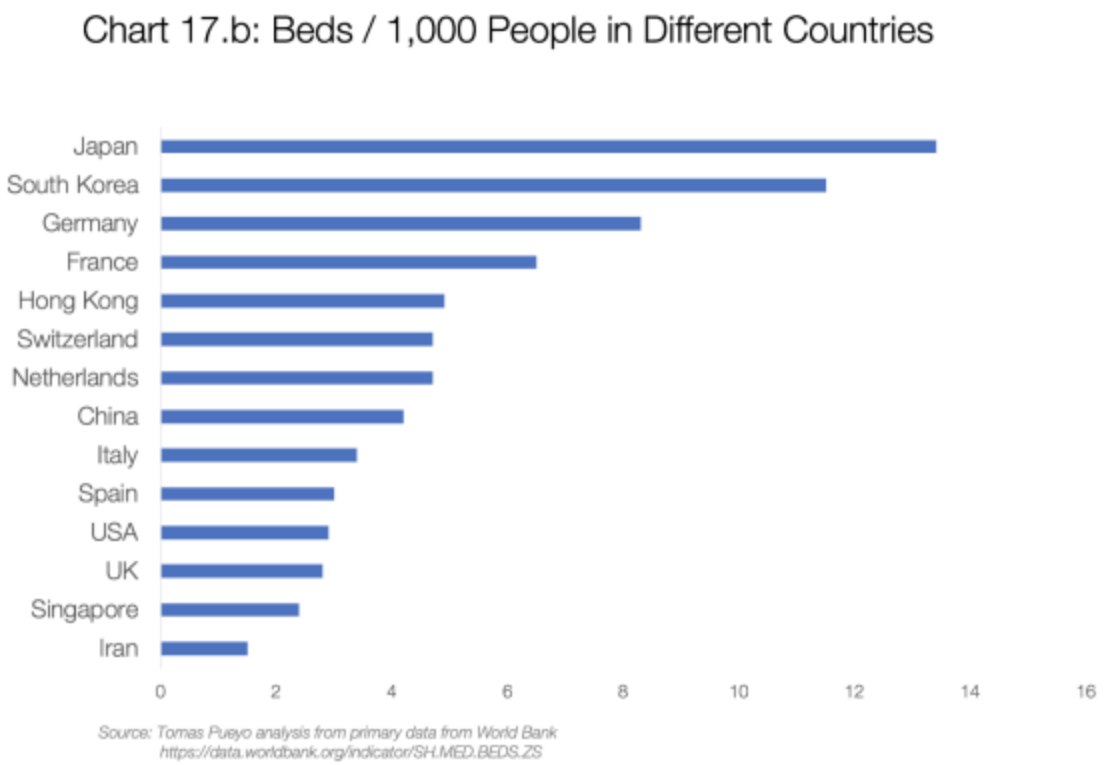


Chart 17: Projection of Coronavirus Fatality Rate in South Korea



Iran's and Italy's Deaths / Total Cases are both converging towards the 3%-4% range. My guess is their numbers will end up around that figure too.



South Korea is the most interesting example, because these 2 numbers are completely disconnected: deaths / total cases is only 0.6%, but deaths / closed cases is a whopping 48%. My take on it is that a few unique things are happening there. First, they're testing everybody (with so many open cases, the death rate seems low), and leaving the cases open for longer (so they close cases quickly when the patient is dead). Second, they have a lot of hospital beds (see chart 17.b). There might also be other reasons we don't know. What is relevant is that deaths/cases has hovered around 0.5% since the beginning, suggesting it will stay there, likely heavily influenced by the healthcare system and crisis management.

The last relevant example is the Diamond Princess cruise: with 706 cases, 6 deaths and 100 recoveries, the fatality rate will be between 1% and 6.5%.

Note that the age distribution in each country will also have an impact: Since mortality is much higher for older people, countries with an aging population like Japan will be harder hit on average than younger countries like Nigeria. There are also weather factors, especially humidity and temperature, but it's still unclear how this will impact transmission and fatality rates.

This is what you can conclude:

- Excluding these, countries that are prepared will see a fatality rate of ~0.5% (South Korea) to 0.9% (rest of China).
- Countries that are overwhelmed will have a fatality rate between ~3%-5%

Put in another way: Countries that act fast can reduce the number of deaths by a factor of ten. And that's just counting the fatality rate. Acting fast also drastically reduces the cases, making this even more of a no-brainer.

Countries that act fast reduce the number of deathsat least by 10x.

So what does a country need to be prepared?

What Will Be the Pressure on the System

Around 20% of cases require hospitalization, 5% ofcases require the Intensive Care Unit (ICU), and around 2.5% require very intensive help, with items such as ventilators or ECMO (extra-corporeal oxygenation).

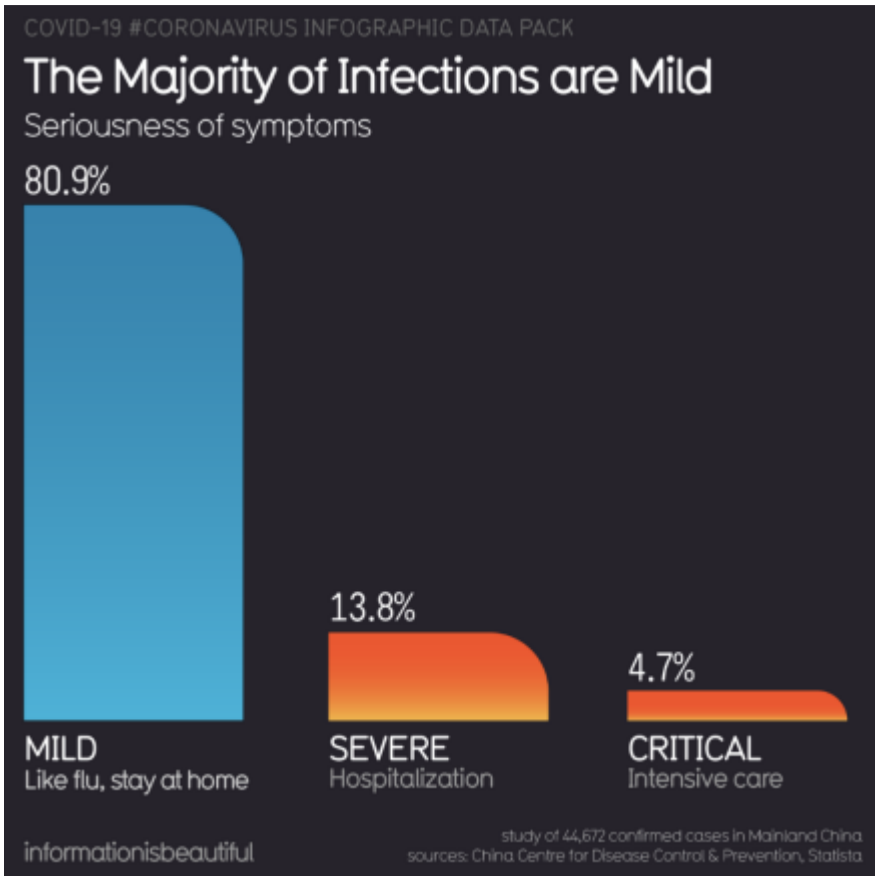
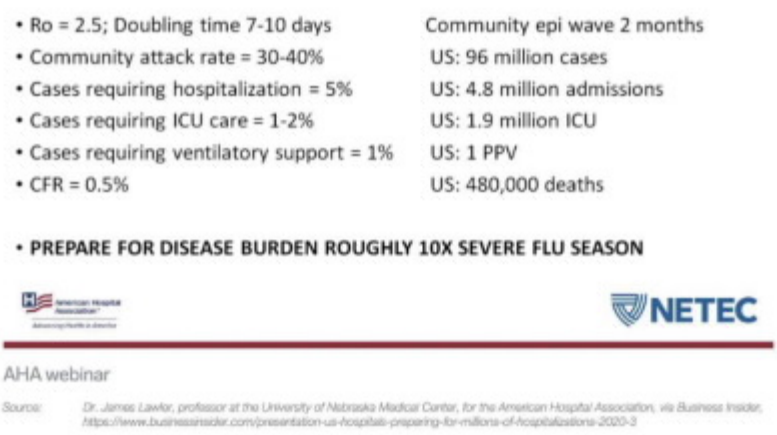


Chart 18: Slide from a Webinar of the American Hospital Association, communicating best guesses on the impact of the Coronavirus in the US healthcare system in 2020



The problem is that items such as ventilators and ECMO can't be produced or bought easily. A few years ago, the US had a total of 250 ECMO machines, for example.

So if you suddenly have 100,000 people infected, many of them will want to go get tested. Around 20,000 will require hospitalization, 5,000 will need the ICU, and 1,000 will need machines that we don't have enough of today. And that's just with 100,000 cases.

That is without taking into account issues such as masks. A country like the US has only 1% of the masks it needs to cover the needs of its healthcare workers (12M N95, 30M surgical vs. 3.5B needed). If a lot of cases appear at once, there will be masks for only 2 weeks.

Countries like Japan, South Korea, Hong Kong or Singapore, as well as Chinese regions outside of Hubei, have been prepared and given the care that patients need.
But the rest of Western countries are rather going in the direction of Hubei and Italy. So what is happening there?

What an Overwhelmed Healthcare System Looks Like

The stories that happened in Hubei and those in Italy are starting to become eerily similar. Hubei built two hospitals in ten days, but even then, it was completely overwhelmed.

Both complained that patients inundated their hospitals. They had to be taken care of anywhere: in hallways, in waiting rooms…

I heavily recommend this short Twitter thread. It paints a pretty stark picture of Italy today

Medico Humanitas su Facebook: "Situazione drammatica, altro che normale influenza"

Pubblichiamo l'intervento sui social di Daniele Macchini, medico alle Cliniche Humanitas Gavazzeni. Una testimonianza...
bergamo.corriere.it

Healthcare workers spend hours in a single piece ofprotective gear, because there's not enough of them. As a result, they can't leave the infected areas for hours. When they do, they crumble, dehydrated and exhausted. Shifts don't exist anymore. People are driven back from retirement to cover needs. People who have no idea about nursing are trained overnight to fulfill critical roles. Everybody is on call, always.

Francesca Mangiatordi, an Italian nurse that crumbled in the middle of the war with the Coronavirus

That is, until they become sick. Which happens a lot, because they're in constant exposure to the virus, without enough protective gear. When that happens, they need to be in quarantine for 14 days, during which they can't help. Best case scenario, 2 weeks are lost. Worst case, they're dead.

The worst is in the ICUs, when patients need to share ventilators or ECMOs. These are in fact impossible to share, so the healthcare workers must determine what patient will use it. That really means, which one lives and which one dies.

Coronavirus: 'We must choose who to treat,' says Italian doctor
An Italian doctor in Lombardy, a region of Italy that has been quarantined due to the new coronavirus (Covid-19)...
www.brusselstimes.com

"After a few days, we have to choose. [...] Not everyone can be intubated. We decide based on age and state of health." —Christian Salaroli, Italian MD.

Medical workers wear protective suits to attend to people sickened by the novel coronavirus, in the intensive care unit of a designated hospital in Wuhan, China, on Feb. 6. (China Daily/Reuters), via Washington Post

All of this is what drives a system to have a fatality rate of ~4% instead of ~0.5%. If you want your city or your country to be part of the 4%, don't do anything today.

Satellite images show Behesht Masoumeh cemetery in the Iranian city of Qom. Photograph: ©2020 Maxar Technologies. Via The Guardian and the The New York Times.

3. What Should You Do?

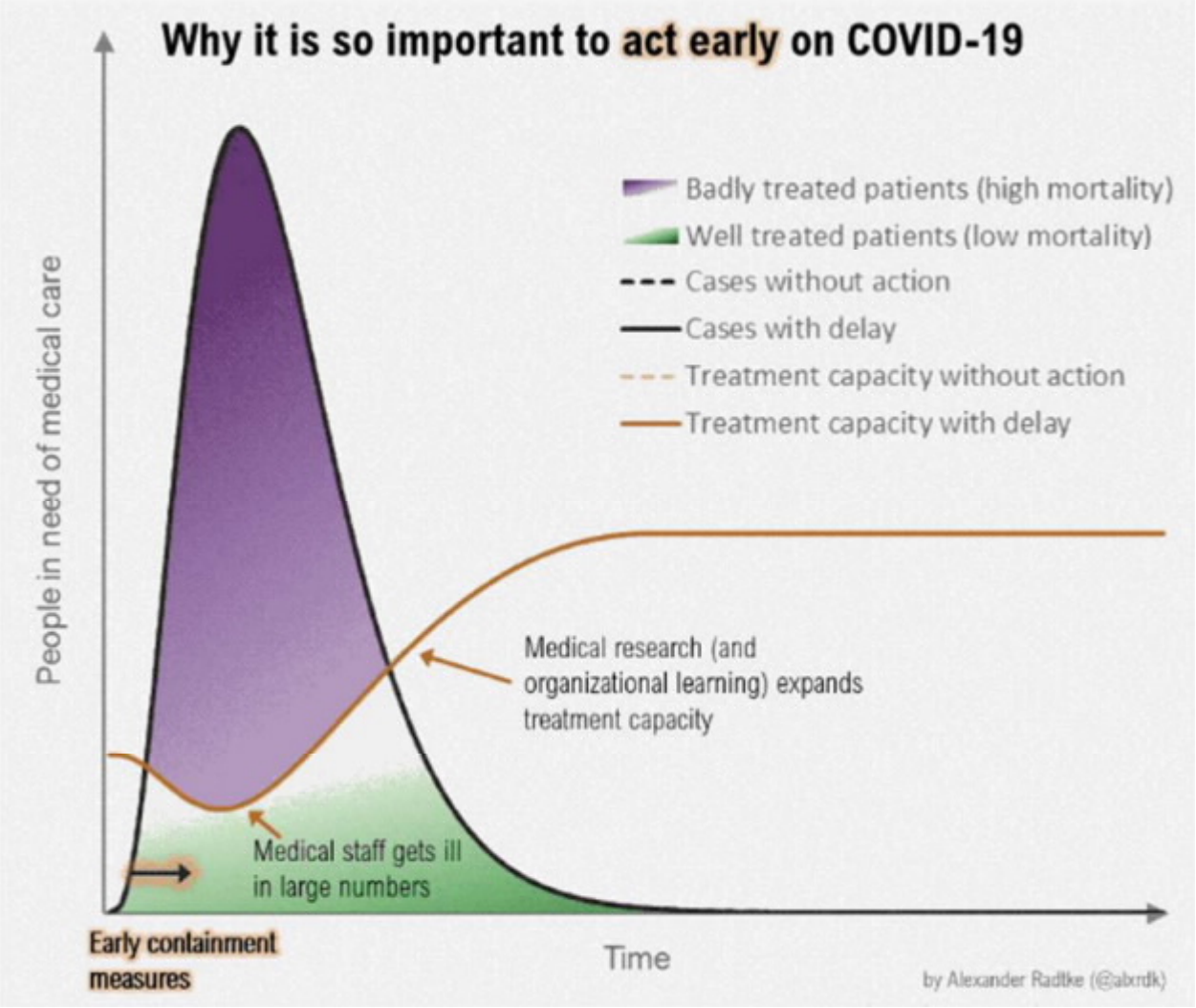
Flatten the Curve

This is a pandemic now. It can't be eliminated. But what we can do is reduce its impact. Some countries have been exemplary at this. The best one is Taiwan, which is extremely connected with China and yet still has as of today fewer than 50 cases. This recent paper explain all the measures they took early on, which were focused on containment.

Response to COVID-19 in Taiwan: Big Data Analytics, New Technology, and Proactive Testing
This Viewpoint describes the outbreak response infrastructure developed by the Taiwanese government following the SARS...
jamanetwork.com

They have been able to contain it, but most countries lacked this expertise and didn't. Now, they're playing a different game: mitigation. They need to make this virus as inoffensive as possible.

If we reduce the infections as much as possible, our healthcare system will be able to handle cases much better, driving the fatality rate down. And, if we spread this over time, we will reach a point where the rest of society can be vaccinated, eliminating the risk altogether. So our goal is not to eliminate coronavirus contagions. It's to postpone them.



Source

The more we postpone cases, the better the healthcare system can function, the lower the mortality rate, and the higher the share of the population that will be vaccinated before it gets infected.

How do we flatten the curve?

Social Distancing

There is one very simple thing that we can do and that works: social distancing.

If you go back to the Wuhan graph, you will remember that as soon as there was a lockdown, cases went down. That's because people didn't interact with each other, and the virus didn't spread.

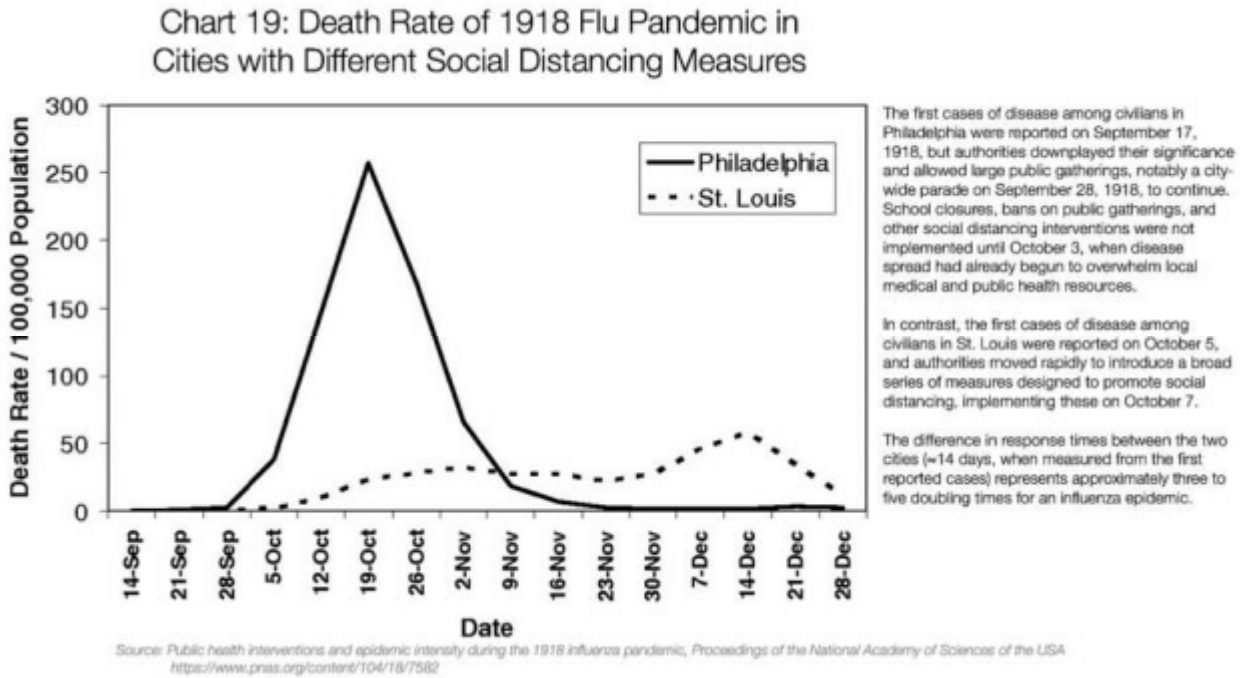
The current scientific consensus is that this virus can be spread within 2 meters (6 feet) if somebody coughs. Otherwise, the droplets fall to the ground and don't infect you.

The worst infection then becomes through surfaces: The virus survives for up to 9 days on different surfaces such as metal, ceramics and plastics. That means things like doorknobs, tables, or elevator buttons can be terrible infection vectors.

The only way to truly reduce that is with social distancing: Keeping people home as much as possible, for as long as possible until this recedes.

This has already been proven in the past. Namely, in the 1918 flu pandemic.

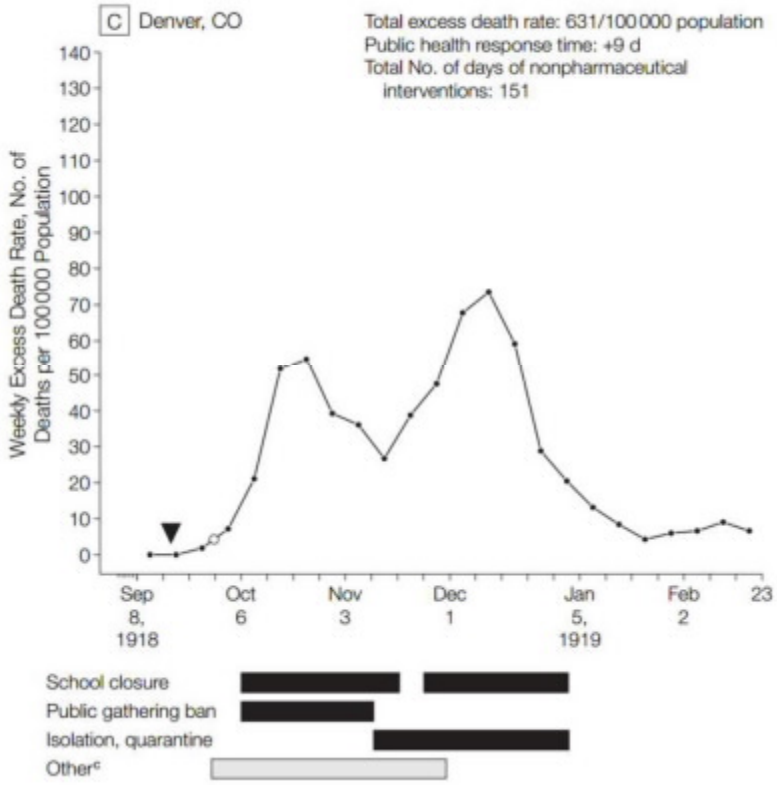
Learnings from the 1918 Flu Pandemic



You can see how Philadelphia didn't act quickly, and had a massive peak in death rates. Compare that with St Louis, which did.

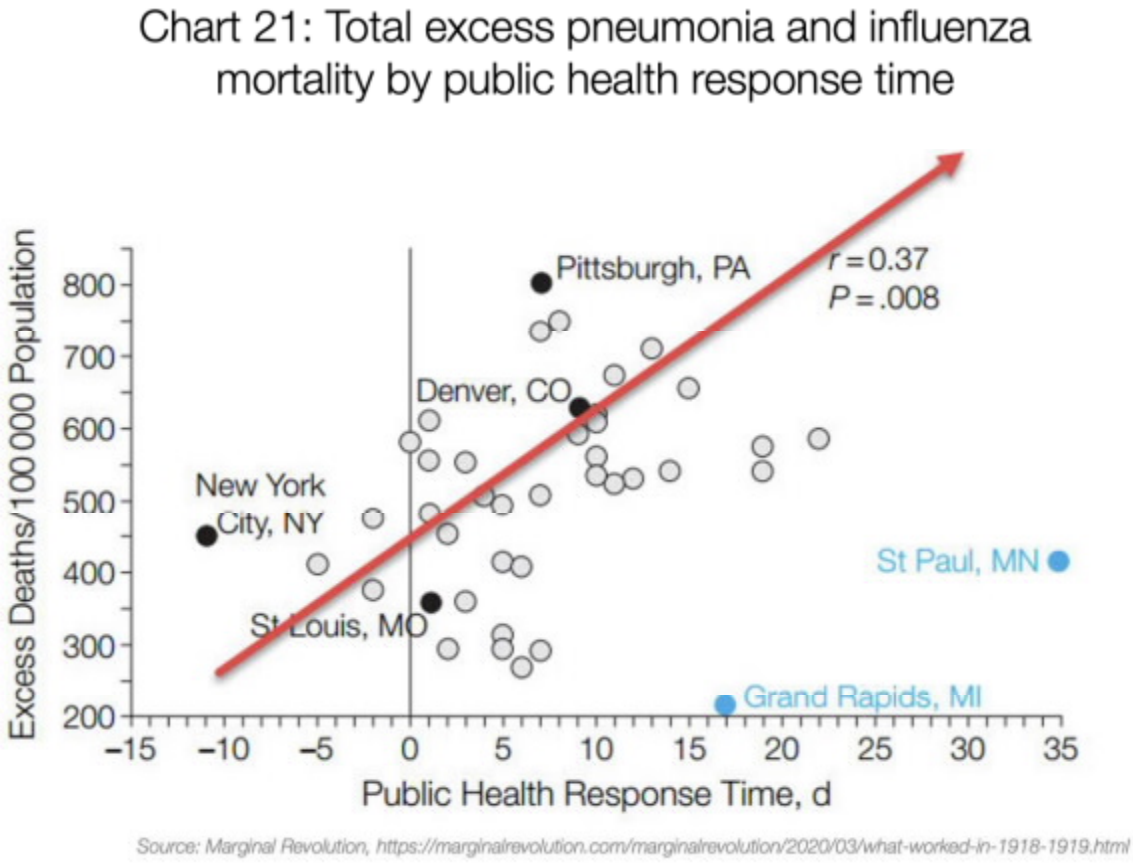
Then look at Denver, which enacted measures and then loosened them. They had a double peak, with the 2nd one higher than the first.

Chart 20: Excess Death in Denver during the 1918 Flu Pandemic



Source: Marginal Revolution, https://marginalrevolution.com/marginalrevolution/2020/03/what-worked-in-1918-1919.html

If you generalize, this is what you find:



This chart shows, for the 1918 flu in the US, how many more deaths there were per city depending on how fast measures were taken. For example, a city like St Louis took measures 6 days before Pittsburgh, and had less than half the deaths per citizen. On average, taking measures 20 days earlier halved the death rate.

Italy has finally figured this out. They first locked down Lombardy on Sunday, and one day later, on Monday, they realized their mistake and decided they had to lock down the entire country.

Hopefully, we will see results in the coming days. However, it will take one to two weeks to see. Remember the Wuhan graph: there was a delay of 12 days between the moment when the lockdown was announced and the moment when official cases (orange) started going down.

How Can Politicians Contribute to Social Distancing?

The question politicians are asking themselves today is not whether they should do something, but rather what's the appropriate action to take.

There are several stages to control an epidemic, starting with anticipation and ending with eradication. But it's too late for most options today. With this level of cases, the two only options politicians have in front of them arecontainment and mitigation.

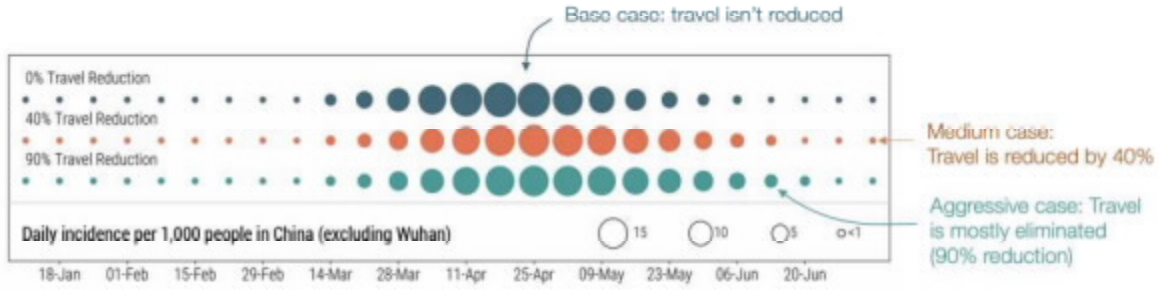
Containment

Containment is making sure all the cases are identified, controlled, and isolated. It's what Singapore, Hong Kong, Japan or Taiwan are doing so well: They very quickly limit people coming in, identify the sick, immediately isolate them, use heavy protective gear to protect their health workers, track all their contacts, quarantine them… This works extremely well when you're prepared and you do it early on, and don't need to grind your economy to a halt to make it happen.

I've already touted Taiwan's approach. But China's is good too. The lengths at which it went to contain the virus are mind-boggling. For example, they had up to 1,800 teams of 5 people each tracking every infected person, everybody they got interacted with, then everybody those people interacted with, and isolating the bunch. That's how they were able to contain the virus across a billion-people country.

This is not what Western countries have done. And now it's too late. The recent US announcement that most travel from Europe was banne is a containment measure for a country that has, as of today, 3 times the cases that Hubei had when it shut down, growing exponentially. How can we know if it's enough? It turns out, we can know by looking at the Wuhan travel ban.

Chart 21.b: Delay in Coronavirus Spread in China, Based on Travel Restrictions



Source: Tomas Pueyo analysis on charts and data from paper: The effect of travel restrictions on the spread of the 2019 novel coronavirus (COVID-19) outbreak, Science Magazine, https://science.sciencemag.org/content/early/2020/03/05/science.aba9757

Link to source

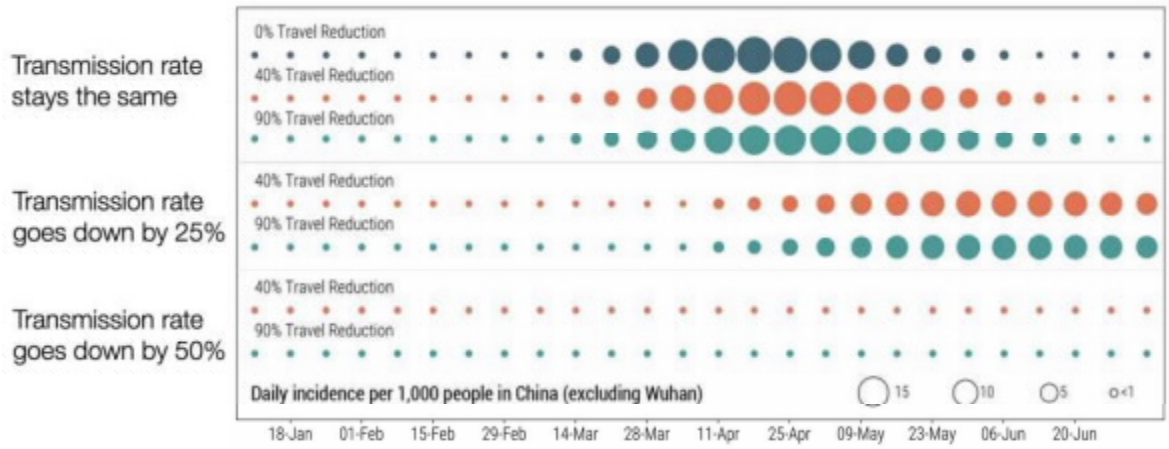
This chart shows the impact that the Wuhan travel ban had delaying the epidemic. The bubble sizes show the number of daily cases. The top line shows the cases if nothing is done. The two other lines show the impact if 40% and 90% of travel is eliminated. This is a model created by epidemiologists, because we can't know for sure.

If you don't see much difference, you're right. It's very hard to see any change in the development of the epidemic.

Researchers estimate that, all in all, the Wuhan travel ban only delayed the spread in China by 3–5 days.

Now what did researchers think the impact of reducing *transmission* would be?

Chart 21.c: Delay in Coronavirus Spread in China, Based on Travel Restrictions and Transmission Rate Reductions



Source: Tomas Pueyo analysis on charts and data from paper: The effect of travel restrictions on the spread of the 2019 novel coronavirus (COVID-19) outbreak, Science Magazine, https://science.sciencemag.org/content/early/2020/03/05/science.aba9757

The top bloc is the same as the one you've seen before. The two other blocks show decreasing transmission rates. If the transmission rate goes down by 25% (through Social Distancing), it flattens the curve and delays the peak by a whole 14 weeks. Lower the transition rate by 50%, and you can't see the epidemic even starting within a quarter.

The US administration's ban on European travel is good: It has probably bought us a few hours, maybe a day or two. But not more. It is not enough. It's containment when what's needed is mitigation.

Once there are hundreds or thousands of cases growing in the population, preventing more from coming, tracking the existing ones and isolating their contacts isn't enough anymore. The next level is mitigation.

Mitigation

Mitigation requires heavy social distancing. People need to stop hanging out to drop the transmission rate (R), from the R=~2–3 that the virus follows without measures, to below 1, so that it eventually dies out.

These measures require closing companies, shops, mass transit, schools, enforcing lockdowns… The worse your situation, the worse the social distancing. The earlier you impose heavy measures, the less time you need to keep them, the easier it is to identify brewing cases, and the fewer people get infected.

This is what Wuhan had to do. This is what Italy was forced to accept. Because when the virus is rampant, the only measure is to lock down all the infected areas to stop spreading it at once.

With thousands of official cases — and tens of thousands of true ones — this is what countries like Iran, France, Spain, Germany, Switzerland or the US need to do.

But they're not doing it.

Some business are working from home, which is fantastic.

Some mass events are being stopped.

Some affected areas are in quarantining themselves.

All these measures will slow down the virus. They will lower the transmission rate from 2.5 to 2.2, maybe 2. But they aren't enough to get us below 1 for a sustained period of time to stop the epidemic. And if we can't do that, we need to get it as close to 1 for as long as possible, to *flatten the curve*.

So the question becomes: What are the tradeoffs we could be making to lower the R? This is the menu that Italy has put in front of all of us:

- Nobody can enter or exit lockdown areas, unless there are proven family or work reasons.
- Movement inside the areas is to be avoided, unless they are justified for urgent personal or work reasons and can't be postponed.
- People with symptoms (respiratory infection and fever) are "highly recommended" to remain home.
- Standard time off for healthcare workers is suspended
- Closure of all educational establishments (schools, universities…), gyms, museums, ski stations, cultural and social centers, swimming pools, and theaters.
- Bars and restaurants have limited opening times from 6am to 6pm, with at least one meter (~3 feet) distance between people.
- All pubs and clubs must close.

- All commercial activity must keep a distance of one meter between customers. Those that can't make it happen must close. Temples can remain open as long as they can guarantee this distance.
- Family and friends hospital visits are limited
- Work meetings must be postponed. Work from home must be encouraged.
- All sports events and competitions, public or private, are canceled. Important events can be held under closed doors.

Then two days later, they added: *No, in fact, you need to close all businesses that aren't crucial. So now we're closing all commercial activities, offices, cafes and shops. Only transportation, pharmacies, groceries will remain open."*

One approach is to gradually increase measures. Unfortunately, that gives precious time for the virus to spread. If you want to be safe, do it Wuhan style. People might complain now, but they'll thank you later.

How Can Business Leaders Contribute to Social Distancing?

If you're a business leader and you want to know what you should do, the best resource for you is Staying Home Club.

Who's staying home because of COVID-19?
A list of all the companies WFH or events changed because of covid-19
stayinghome.club

It is a list of social distancing policies that have been enacted by US tech companies—so far, 328.

They range from allowed to required Work From Home, and restricted visits, travel, or events.

There are more things that every company must determine, such as what to do with hourly workers, whether to keep the office open or not, how to conduct interviews, what to do with the cafeterias… If you want to know how my company, Course Hero, handled some of these, along with a model announcement to your employees, here is the one my company used (view only version here).

4. When?

It is very possible that so far you've agreed with everything I've said, and were just wondering since the beginning when to make each decision. Put in another way, what triggers should we have for each measure.

Risk-Based Model for Triggers

To solve this, I've created a model (direct link to copy).

Coronavirus - When Should You Close Your Office?
How To Use Coronavirus Work From Home Model This model should help you and your company make a decision on whether you...
docs.google.com

It enables you to assess the likely number of cases in your area, the probability that your employees are already infected, how that evolves over time, and how that should tell you whether to remain open.

It tells us things like:

- If your company had 100 employees in the Washington state area, which had 11 coronavirus deaths on 3/8, there was a 25% chance at least one of your employees was infected, and you should have closed immediately.
- If your company had 250 employees mostly in the South Bay (San Mateo and Santa Clara counties, which together had 22 official cases on 3/8 and the true number was probably at least 54), by 3/9 you would have had ~2% chances to have at least one employee infected, and you should have closed your office too.
- *[Updated as of 3/12]* If your company is in Paris (intramuros), and it has 250 employees, today there's a **95% chance that one of your employees has the coronavirus**, and you should close your office by tomorrow.

The model uses labels such as "company" and "employee", but the same model can be used for anything else: schools, mass transit... So if you have only 50 employees in Paris, but all of them are going to take the train, coming across thousands of other people, suddenly the likelihood that at least one of them will get infected is much higher and you should close your office immediately.

If you're still hesitating because nobody is showing symptoms, just realize 26% of contagions happen before there are symptoms.

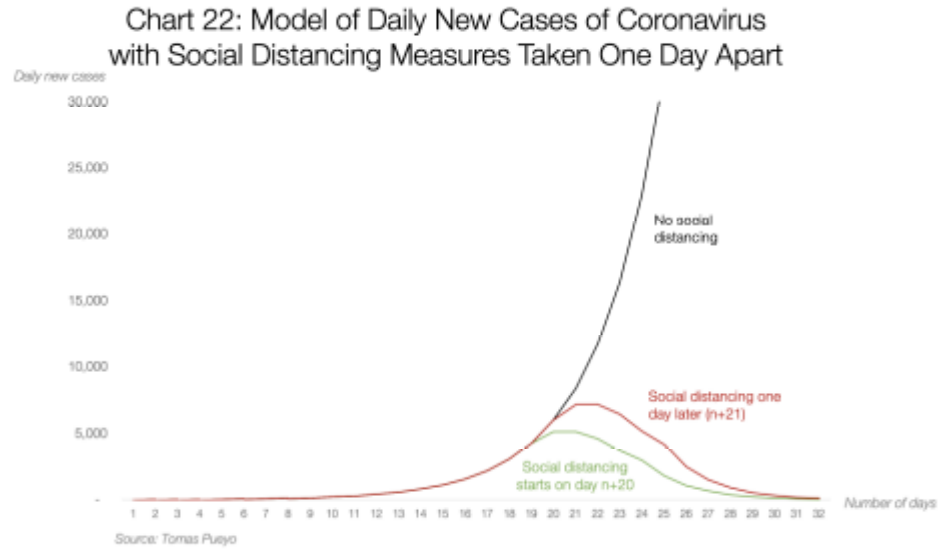
Are You Part of a Group of Leaders?

This math is selfish. It looks at every company's risk individually, taking as much risk as we want until the inevitable hammer of the coronavirus closes our offices.

But if you're part of a league of business leaders or politicians, your calculations are not for just one company, but for the whole. The math becomes: What's the likelihood that any of our companies is infected? If you're a group of 50 companies of 250 employees on average, in the SF Bay Area, there's a 35% chance that at least one of the companies has an employee infected, and 97% chance that will be true next week. I added a tab in the model to play with that.

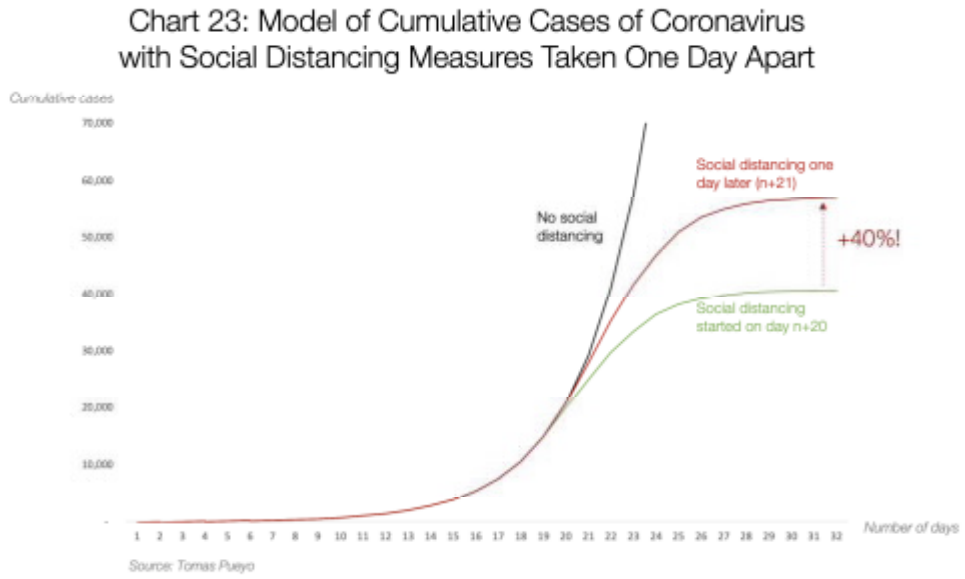
Conclusion: The Cost of Waiting

It might feel scary to make a decision today, but you shouldn't think about it this way.



This theoretical model shows different communities: one doesn't take social distancing measures, one takes them on Day n of an outbreak, the other one on Day n+1. All the numbers are completely fictitious (I chose them to resemble what happened in Hubei, with ~6k daily new cases at the worst). They're just there to illustrate how important a single day can be in something that grows exponentially. You can see that the one-day delay peaks later and higher, but then daily cases converge to zero.

But what about cumulative cases?



In this theoretical model that resembles loosely Hubei, waiting one more day creates 40% more cases! So, maybe, if the Hubei authorities had declared the lockdown on 1/22 instead of 1/23, they might have reduced the number of cases by a staggering 20k.

And remember, these are just cases. Mortality would be much higher, because not only would there be directly 40% more deaths. There would also be a much higher collapse of the healthcare system, leading to a mortality rate up to 10x higher as we saw before. So a one-day difference in social distancing measures can end exploding the number of deaths in your community by multiplying more cases and higher fatality rate.

This is an exponential threat. Every day counts. When you're delaying by a single day a decision, you're not contributing to a few cases maybe. There are probably hundreds or thousands of cases in your community already. Every day that there isn't social distancing, these cases grow exponentially.

Share the Word

This is probably the one time in the last decade that sharing an article might save lives. They need to understand this to avert a catastrophe. The moment to act is now.

https://medium.com/@tomaspueyo/coronavirus-act-today-or-people-will-die-f4d3d9cd99ca

Nonpharmaceutical Interventions Implemented by US Cities During the 1918-1919 Influenza Pandemic

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Context A critical question in pandemic influenza planning is the role nonpharmaceutical interventions might play in delaying the temporal effects of a pandemic, reducing the overall and peak attack rate, and reducing the number of cumulative deaths. Such measures could potentially provide valuable time for pandemic-strain vaccine and antiviral medication production and distribution. Optimally, appropriate implementation of nonpharmaceutical interventions would decrease the burden on health care services and critical infrastructure.

Objectives To examine the implementation of nonpharmaceutical interventions for epidemic mitigation in 43 cities in the continental United States from September 8, 1918, through February 22, 1919, and to determine whether city-to-city variation in mortality was associated with the timing, duration, and combination of nonpharmaceutical interventions; altered population susceptibility associated with prior pandemic waves; age and sex distribution; and population size and density.

Design and Setting Historical archival research, and statistical and epidemiological analyses. Nonpharmaceutical interventions were grouped into 3 major categories: school closure; cancellation of public gatherings; and isolation and quarantine.

Main Outcome Measures Weekly excess death rate (EDR); time from the activation of nonpharmaceutical interventions to the first peak EDR; the first peak weekly EDR; and cumulative EDR during the entire 24-week study period.

Results There were 115 340 excess pneumonia and influenza deaths (EDR, 500/100 000 population) in the 43 cities during the 24 weeks analyzed. Every city adopted at least 1 of the 3 major categories of nonpharmaceutical interventions. School closure and public gathering bans activated concurrently represented the most common combination implemented in 34 cities (79%); this combination had a median duration of 4 weeks (range, 1-10 weeks) and was significantly associated with reductions in weekly EDR. The cities that implemented nonpharmaceutical interventions earlier had greater delays in reaching peak mortality (Spearman $r = -0.74$, P ff .001), lower peak mortality rates (Spearman $r = 0.31$, $P = .02$), and lower total mortality (Spearman $r = 0.37$, $P = .008$). There was a statistically significant association between increased duration of nonpharmaceutical interventions and a reduced total mortality burden (Spearman $r = -0.39$, $P = .005$).

Conclusions These findings demonstrate a strong association between early, sustained, and layered application of nonpharmaceutical interventions and mitigating the consequences of the 1918-1919 influenza pandemic in the United States. In planning for future severe influenza pandemics, nonpharmaceutical interventions should be considered for inclusion as companion measures to developing effective vaccines and medications for prophylaxis and treatment.

JAMA. 2007;298(6):644-654 www.jama.com

THE INFLUENZA PANDEMIC OF 1918-1919 was the most deadly contagious calamity in human history. Approximately 40 million individuals died worldwide, including 550 000 individuals in the United States.[1-4] The historical record demonstrates that when faced with a devastating pandemic, many nations, communities, and individuals adopt what they perceive to be effective social distancing measures or nonpharmaceutical interventions including isolation of those who are ill, quarantine of those suspected of having contact with those who are ill, school and selected business closure, and public gathering cancellations.[5,6] One compelling question emerges: can lessons from the 1918-1919 pandemic be applied to contemporary pandemic planning efforts to maximize public health benefit while minimizing the disruptive social consequences of the pandemic as well as those accompanying public health response measures?[7-10]

Most pandemic influenza policy makers agree that even the most rigorous nonpharmaceutical interventions are unlikely either to prevent a pandemic or change a population's underlying biological susceptibility to the pandemic virus. However, a growing

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body of theoretical modeling research suggests that nonpharmaceutical interventions might play a salubrious role in delaying the temporal effect of a pandemic; reducing the overall and peak attack rate; and reducing the number of cumulative deaths.[11-15] Such measures could potentially provide valuable time for production and distribution of pandemic-strain vaccine and antiviral medication. Optimally, appropriate implementation of nonpharmaceutical interventions would decrease the burden on health care services and critical infrastructure.

The historical record of the 1918-1919 influenza pandemic in the United States constitutes one of the largest recorded experiences with the use of nonpharmaceutical interventions to mitigate an easily spread, high mortality and morbidity influenza virus strain (ie, a category 4-5 pandemic using the Centers for Disease Control and Prevention February 2007 *Interim Pre-Pandemic Planning Guidance*).[16] Our study focused on this data set by assessing the nonpharmaceutical interventions implemented in 43 cities in the continental United States from September 8, 1918, through February 22, 1919, a period that encompasses all of the second pandemic wave (September-December 1918) and the first 2 months of the third wave (January-April 1919) and represents the principal time span of activation and deactivation of nonpharmaceutical interventions. The purpose was to determine whether city-to-city variation in mortality was associated with the timing, duration, and combination (or layering) of nonpharmaceutical interventions; altered population susceptibility associated with prior pandemic waves; age and sex distribution; and population size and density.

METHODS

Data Collection

We combined systematic historical data collection and contemporary epidemiological and statistical analytic tools. Mortality data were obtained from the US Census Bureau's *Weekly Health Index*[17] for 1918-1919, a series of reports listing total deaths and death rates for 43 large US cities. These 43 cities were among the 66 most populous urban centers according to the 1920 census, and all had a population greater than 100 000. Of the 66 most populous cities, the remaining 23 had incomplete archival and mortality records. No city with a comprehensive archival record of nonpharmaceutical interventions was excluded. The *Weekly Health Index* is the most complete extant compilation of weekly pneumonia and influenza mortality data in US urban areas during the 1918-1919 pandemic.

In addition, we captured all of the available public health documents on nonpharmaceutical interventions implemented by these 43 cities during the 1918-1919 pandemic, including municipal public health department annual and monthly reports and weekly bulletins; every state and federal report on the 1918-1919 influenza pandemic published between 1917 and 1922; US Census pneumonia and influenza mortality data from 1910-1920; the corpus of published historical, medical, and public health literature on the 1918-1919 pandemic; 86 different newspapers from the 43 different cities; records of US military installations between 1917-1920; and additional holdings housed in several major libraries and archival repositories (the complete bibliography of the 1144 primary and secondary sources is available as an online supplement at http://www.cdc.gov/ncidod/dq/index.htm).[17-23]

Data Analysis

From the census reports, we extracted the weekly pneumonia and influenza mortality data covering the 24 weeks from September 8, 1918, through February 22, 1919, for the 43 US cities. In 1920, these 43 cities had a combined population of approximately 23 million (22% of the total US population). A small number of missing values (846 [0.6%] of 136 563 deaths) was imputed. Using estimated weekly baseline pneumonia and influenza death rates generated from the 1910-1916 median monthly values found by Collins et al[8], weekly excess death rates (EDR) were computed. Based on available mortality data and epidemiological reports from that era, as well as a recent retrospective statistical analysis, we estimated that those who succumbed to influenza contracted it 10 days earlier.[3,24-27]

The onset of the epidemic in a particular city was estimated as either the day of the first reported pneumonia and influenza case, or the calendar day of the first recorded pneumonia and influenza death minus 10 days, whichever was earlier. Information on nonpharmaceutical interventions was captured by reviewing at least 2 daily, high-circulation newspapers for each city and available municipal or state health reports. Nonpharmaceutical interventions were grouped into 3 major categories: school closure; public gathering bans; and isolation and quarantine. We also considered an additional general category of ancillary nonpharmaceutical interventions (eg, altering work schedules, limited closure or regulations of businesses, transportation restrictions, public risk communications, facemask ordinances).

Nonpharmaceutical interventions were considered either activated ("on") or deactivated ("off"), according to data culled from the historical record and daily newspaper accounts. Specifically, these nonpharmaceutical interventions were legally enforced and affected large segments of the city's population. Isolation of ill persons and quarantine of those suspected of having contact with ill persons refers only to mandatory orders as opposed to voluntary quarantines being discussed in our present era. School closure was considered activated when the city officials closed public schools (grade school through high school); in most, but not all cases, private and parochial schools followed suit. Public gathering bans typically meant the closure of saloons, public entertainment venues, sporting events, and indoor gatherings were banned or moved outdoors; outdoor gatherings were not always canceled during this period (eg, Liberty bond parades); there were no recorded bans on shopping in grocery and drug stores. Based on an estimated 10-day time frame between disease onset and death,

we estimated that the association of nonpharmaceutical interventions with reductions in EDR occurred 10 days after their actual date of implementation.[3,24-27]

To test the association of the layering and timing of nonpharmaceutical interventions with mortality, an analysis of variance (ANOVA) model was constructed with weekly EDR as the dependent variable and epidemiological week, city, and the status (on/off) of every combination of nonpharmaceutical interventions as the independent variables. In the ANOVA model, each possible combination of nonpharmaceutical interventions was treated as an independent variable to test for layering effects. Any factor with a *P* value of less than .10 was included in the model. Because there is ambiguity over the rigor with which the category of ancillary nonpharmaceutical interventions was applied, enforced, and deactivated, we focused primarily on the 3 major categories of nonpharmaceutical interventions discussed above and we included the ancillary nonpharmaceutical interventions in the multivariate model for purposes of completeness.

We defined additional outcome (dependent) variables: (1) the time to first peak as the time in days from the activation of the first major category of nonpharmaceutical interventions to the date of the first peak EDR; (2) the magnitude of the first peak as the first peak weekly EDR; and (3) the mortality burden as the cumulative EDR during the entire 24-week study period.

We also defined the following independent variables. The first was the public health response time (PHRT) as the time in days (either positive or negative) between the date when weekly EDR first exceeds twice the baseline pneumonia and influenza death rate (2 ffi baseline; ie, when the mortality rate begins to accelerate) and the activation of the first major nonpharmaceutical interventions. Interventions that occurred prior to this reference point are recorded as negative PHRT values, indicating that public health officials responded to events prior to the acceleration of weekly death rates. However, most cities had positive PHRT in that they reacted after the 2 ffi baseline mortality threshold, indicating that the epidemic had already entered its acceleration phase. The second independent variable was total days of nonpharmaceutical interventions, which was defined as the total cumulative number of days that nonpharmaceutical interventions from the 3 major categories were activated during the entire 24-week study period.

The ANOVA models were based on the study design of a 43 (city) ffi 24 (week) factorial design without replication. Because there is no replication, the city ffi week interaction term was treated as the error term in the multivariate analysis. We considered 4 different nonpharmaceutical interventions. Hence, there are 15 different combinations of these interventions (excluding the no intervention combination). Each of these 15 combinations was either implemented (on) or not implemented (off) in each city for each week. Thus, the effects of each of these combinations of nonpharmaceutical interventions are included in the city ffi week interaction term. Each of these terms (along with the ffi city and ffi week interaction terms) were extracted from the original city ffi week interaction term. The remaining unexplained variation was used as the error term in the ANOVA model. The remaining error term is likely to be larger than a true error term generated through replication so the analysis of any effects using this error term can be expected to be conservative. Such a factorial model without replication can be used to test hypotheses but the lack of natural error in the model makes estimates or predictions from the model such as effect size measures and confidence intervals nonestimable.

We also generated scatterplots and Spearman rank correlation coefficients to explore the associations between PHRT and each of the 2 additional dependent variables and associations between total days of nonpharmaceutical interventions and mortality burden. We further investigated these associations by using box plots and Wilcoxon rank sum tests to compare the outcomes for the cities above and below the median of each independent variable.

We also generated scatterplots and Spearman rank correlation coefficients to explore other potential or confounding associations (as independent determinants): (1) EDR in the 4 successive waves of the pandemic; (2) city-specific population size vs EDR; (3) city-specific population density vs EDR; (4) city-specific population age distribution vs EDR; and (5) city-specific sex distribution vs EDR. Analyses were performed using SAS statistical software version 9.1 (SAS Institute Inc, Cary, NC).

RESULTS

There were 115 340 excess pneumonia and influenza deaths (EDR, 500/100 000 population) in the 43 cities during the 24 weeks analyzed. **TABLE 1** shows considerable city-to-city variation in mortality profiles and intervention characteristics; lists the earliest reported dates of the first pneumonia and influenza cases by city, mortality acceleration (2 ffi baseline EDR), first implementation of nonpharmaceutical interventions, and first peak EDR; and lists the values for each of the independent and outcome variables described above.

TABLE 2 shows the categories of nonpharmaceutical intervention combinations, the number of cities implementing those combinations, and the median and range of duration of implementation by each of the 43 cities during the study period. Every city adopted at least 1 of the 3 major categories of nonpharmaceutical interventions; 15 applied all 3 categories of nonpharmaceutical interventions concurrently. School closure concurrently combined with public gathering bans represented the most common combination, implemented in 34 cities (79%) for a median duration of 4 weeks (range, 1-10 weeks). School closure was ultimately used in some combination with the other categories of nonpharmaceutical interventions by 40 cities (93%). Three cities never officially closed their schools (New York City, New York, New Haven, Connecticut, and Chicago, Illinois, although the latter reported a student absenteeism

rate of ffl 45% at the peak of its epidemic); 25 cities closed their schools once, 14 closed them twice, and 1 (Kansas City, Missouri) closed its schools 3 times. Schools were officially closed a median of 6 weeks (range, 0-15 weeks). The ANOVA multivariate model had an r^2 of 86.7% (*P* ff .001). Nonpharmaceutical interventions were a significant

Table 1. Characteristics of Influenza Pandemic for 43 US Cities Between September 8, 1918, and February 22, 1919

City	First Case Date	Mortality Acceleration Date[a]	Date of First Nonpharmaceutical Intervention	Public Health Response Time, d[b]	Total No. of Days of Nonpharmaceutical Interventions	Date of Peak Excess Death Rate	Time to Peak, d	Magnitude of First Peak, Excess Deaths/ 100 000 Population[c]	Excess Pneumonia and Influenza Mortality, Deaths/ 100 000 Population[d]
Albany, NY	9/27	10/6	10/9	3	47	10/24	15	161.8	553.2
Baltimore, MD	9/18	9/29	10/9	10	43	10/18	9	182.1	559.3
Birmingham, AL	9/24	9/30	10/9	9	48	10/22	13	70.9	591.8
Boston, MA	9/4	9/12	9/25	13	50	10/3	8	159.9	710.0
Buffalo, NY	9/24	9/28	10/10	12	49	10/22	12	140.9	529.5
Cambridge, MA	9/4	9/11	9/25	14	49	10/3	8	125.5	541.0
Chicago, IL	9/17	9/28	9/26	-2	68	10/21	25	84.8	373.2
Cincinnati, OH	9/24	10/4	10/6	2	123	10/24	18	67.6	451.2
Cleveland, OH	9/20	10/7	10/5	-2	99	10/31	26	83.6	474.0
Columbus, OH	9/20	10/6	10/11	5	147	10/24	13	47.3	311.7
Dayton, OH	9/20	10/5	9/30	-5	156	10/20	20	87.8	410.0
Denver, CO	9/17	9/27	10/6	9	151	10/20	14	55.0	630.9
Fall River, MA	9/9	9/16	9/26	10	60	10/12	16	165.2	621.3
Grand Rapids, MI	9/23	10/2	10/19	17	62	10/25	6	15.0	210.5
Indianapolis, IN	9/22	9/30	10/7	7	82	10/18	11	38.8	290.0
Kansas City, MO	9/20	9/26	9/26	0	170	10/27	31	58.1	579.8
Los Angeles, CA	9/27	10/6	10/11	5	154	10/30	19	64.2	493.8
Louisville, KY	9/13	10/1	10/7	6	145	10/20	13	74.8	406.4
Lowell, MA	9/9	9/16	9/27	11	59	10/10	13	123.1	522.9
Milwaukee, WI	9/14	10/6	10/11	5	132	10/23	12	36.4	291.5
Minneapolis, MN	9/21	10/6	10/12	6	116	10/24	18	37.6	267.1
Nashville, TN	9/21	10/6	10/7	1	55	10/16	9	160.1	610.4
New Haven, CT	9/14	9/23	10/15	22	39	10/24	9	109.5	586.5
New Orleans, LA	9/10	10/1	10/8	7	78	10/20	12	172.9	734.0
New York City, NY	9/5	9/29	9/18	-11	73	10/23	35	90.1	452.3
Newark, NJ	9/6	9/30	10/10	10	33	10/22	12	101.5	533.0
Oakland, CA	10/1	10/8	10/12	4	127	10/30	18	107.0	506.2
Omaha, NE	9/18	10/4	10/5	1	140	10/18	13	81.7	554.0
Philadelphia, PA	8/27	9/25	10/3	8	51	10/16	13	249.7	748.4
Pittsburgh, PA	9/4	9/27	10/4	7	53	11/5	32	130.7	806.8
Portland, OR	10/2	10/7	10/11	4	162	11/2	22	59.4	505.2
Providence, RI	9/8	9/17	10/6	19	42	10/17	11	105.2	574.2
Richmond, VA	9/21	9/29	10/6	7	60	10/16	10	112.2	508.3
Rochester, NY	9/22	10/6	10/9	3	54	10/26	17	70.2	359.1
St Louis, MO	9/23	10/7	10/8	1	143	10/29	21	30.0	358.0
St Paul, MN	9/21	10/2	11/6	35	28	11/12	6	55.6	413.2
San Francisco, CA	9/24	10/7	10/18	11	67	10/29	11	143.0	672.7
Seattle, WA	9/24	10/1	10/6	5	168	10/23	17	49.5	414.1
Spokane, WA	9/28	10/9	10/10	1	164	11/5	26	66.0	481.8
Syracuse, NY	9/12	9/18	10/7	19	39	10/14	7	145.4	541.4
Toledo, OH	9/21	10/13	10/15	2	102	10/25	10	54.8	294.5
Washington, DC	9/11	9/23	10/3	10	64	10/15	12	140.1	607.6
Worcester, MA	9/9	9/12	9/27	15	44	10/7	10	126.1	654.7

[a] Defined as 2 ffi baseline death rate.
[b] Defined as days between 2 ffi baseline death rate and first nonpharmaceutical intervention.
[c] Weekly excess death rate.
[d] Total excess death rate through 24 weeks.

Table 2. Nonpharmaceutical Interventions Implemented in 43 US Cities Between September 8, 1918, and February 22, 1919

Type of Nonpharmaceutical Intervention	No. (%) of Cities Implementing Nonpharmaceutical Intervention for ≥1 wk (N = 43)[a]	Median (Range) Duration of Nonpharmaceutical Intervention, wk
Isolation or quarantine only	15 (35)	1 (1-10)
School closure only	22 (51)	1 (1-7)
Public gathering ban only	6 (14)	1.5 (1-5)
Isolation and quarantine and school closure	2 (5)	5.5 (4-7)
Isolation and quarantine and public gathering ban	4 (9)	4 (2-5)
School closure and public gathering ban	34 (79)	4 (1-10)
Isolation and quarantine, school closure, and public gathering ban	15 (35)	4 (2-6)

[a] Cities often implemented more than 1 nonpharmaceutical intervention combination during the outbreak period, so the total adds to more than 100%. The number of categories of nonpharmaceutical interventions implemented during some part of the outbreak was 1 in 1 city, 2 in 23 cities, and 3 in 19 cities. The total number of weeks that at least 1 nonpharmaceutical intervention was implemented was 4 in 6 cities, 5 in 6 cities, 6 in 8 cities, 7 in 3 cities, 8 in 6 cities, 10 in 5 cities, 11 in 4 cities, 13 in 1 city, 14 in 2 cities, 15 in 1 city, and 16 in 1 city. No cities had at least 1 nonpharmaceutical intervention implemented for durations of 9 and 12 weeks.

source of the variation in the weekly EDRs within and between the cities. The ANOVA results are shown in **TABLE 3**. The multivariate model demonstrates that layered nonpharmaceutical interventions generally had a more significant association with weekly EDR than individual nonpharmaceutical interventions. Specifically, combinations of nonpharmaceutical interventions including school closure and public gathering bans appeared to have the most significant association with weekly EDR (ie, the lowest *P* values, most were *P* ≤ .001). The large number of significant nonpharmaceutical interventions × week interactions in the model confirms that the timing of the implementation of a given combination of nonpharmaceutical interventions was a significant factor in reducing mortality. One caveat is persistent nonpharmaceutical interventions × city interactions, meaning that the success of a strategy of nonpharmaceutical interventions in a particular city does not uniformly translate to all other cities. The 2 outlier cities in our study, Grand Rapids, Michigan, and St Paul, Minnesota, exemplify this point.

The scatterplots in **FIGURE 1**A, Figure 1B, and Figure 1C display the associations between the PHRT and each of the 3 dependent variables. Figure 1A displays the association between PHRT in days and time to first peak EDR; cities that implemented nonpharmaceutical interventions earlier had greater delays in reaching peak mortality (Spearman $r = -0.74$, $P \leq .001$). Figure 1B shows the association between PHRT and the magnitude of the first peak EDR; cities that implemented nonpharmaceutical interventions earlier had lower peak mortality rates (Spearman $r = 0.31$, $P = .02$). Figure 1C depicts the association between PHRT and total mortality burden; cities that implemented nonpharmaceutical interventions earlier experienced a lower total mortality (Spearman $r = 0.37$, $P = .008$). In summary, when comparing the 21 cities with earlier (less than the median) PHRT with the 21 cities with the later (greater than the median) PHRT, there are statistically significant differences for each of the outcome measures ($P < .001$; **TABLE 4**).

Figures 1C and 1D show the association between early, sustained, and layered application of nonpharmaceutical interventions and total excess pneumonia and influenza mortality burden in 43 cities. Figure 1C shows the statistically significant association between PHRT and total mortality burden. Figure 1D shows a statistically significant association between increased duration of nonpharmaceutical interventions and a reduced total mortality burden (Spearman $r = -0.39$, $P = .005$). In summary, the 21 cities that had earlier PHRT (ie, less than the median) and the most sustained and most days of nonpharmaceutical interventions had a statistically significant reduction in excess pneumonia and influenza mortality rates compared with the 21 cities that had later PHRT and fewer days of nonpharmaceutical interventions (Table 4).

FIGURE 2 shows the aggregate city mortality curves by region (East, Midwest and South, and West). **FIGURE 3** displays 4 city-specific mortality curves, including weekly EDR and the nonpharmaceutical interventions implemented as well as their activation and deactivation dates for St Louis, Missouri, New York City, Denver, Colorado, and Pittsburgh, Pennsylvania. These 4 cities were chosen because they indicate the broad spectrum of outcomes seen in the 43 cities studied as well as for their geographical and social diversity. (The mortality curves for all 43 cities are available at http://www.cdc.gov/ncidod/dq/index.htm.) Overall, cities that implemented nonpharmaceutical interventions earlier experienced associated delays in the time to peak mortality, reductions in the magnitude of the peak mortality, and decreases in the total mortality burden.

In exploring alternative and potentially confounding explanations for variation in city-specific EDR, we used a scatterplot to compare the cumulative EDR of the 43 cities during pandemic waves 1 (February-May 1918), 2 (September-December 1918), 3 (January-April 1919), and 4 (January-April 1920).[3,3] We found no statistically significant association of the EDR across the 43 cities when comparing successive waves. Specifically, the severity or occurrence of wave 1 is not associated, either positively or negatively, with the severity of wave 2; the severity of wave 2 is not associated with the severity of wave 3; and the severity of wave 3 is not associated with the severity of wave 4 (figures appear in the online supplement at http://www.cdc.gov/ncidod/dq/index.htm).[28,29]

Published virological evidence for strain variation during wave 2 is limited to a single genotypic variant without evidence for significant phenotypic change in virulence.[30-33] While plausible, no virologi-

cal evidence yet exists to explain the perplexing mortality difference between the spring 1918 wave, which was reportedly milder, and the subsequent fall and winter waves. Additional studies may clarify the understanding of the 1918 pandemic's wave phenomena.

Similarly, scatterplots comparing the cumulative EDR to the city-specific population size and density; sex distribution; and proportion of ages of younger than 1 month to 5 years, 15 to 40 years, and older than 65 years, which corresponded to high reported specific mortality rates in 1918 demonstrated no association. Among the 43 cities we investigated, neither the city's population size, density, sex distribution, nor age distribution accounted for the differences in mortality (figures appear in supplemental at http://www.cdc.gov/ncidod/dq/index.htm).

Table 3. Multivariate Model Showing Effect of Combinations of Nonpharmaceutical Interventions on Weekly Excess Death Rates for 43 US Cities Between September 8, 1918, and February 22, 1919[a]

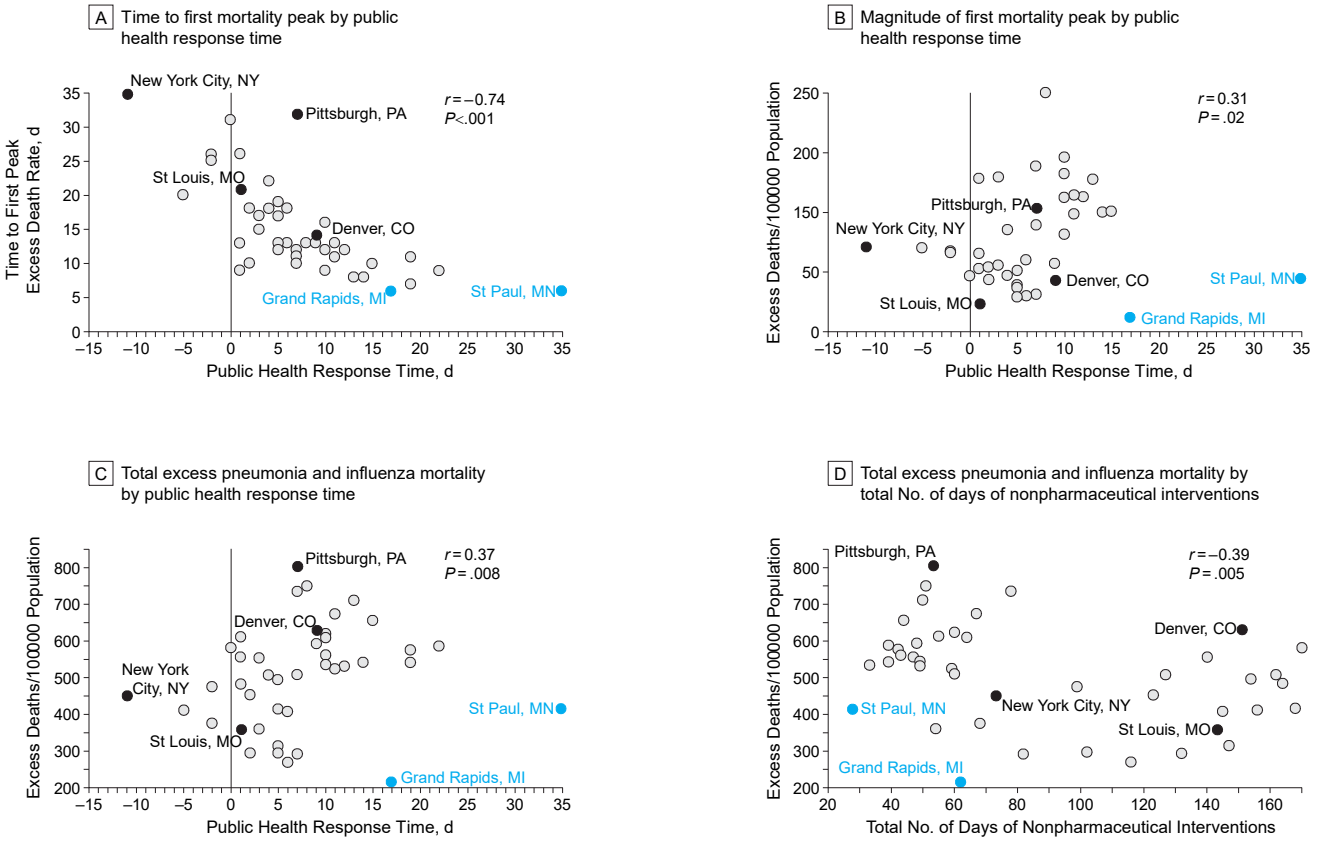
Source of Variation	*df*	Sum of Squares	Mean Square	*F* Score	*P* Value
Type of confounders					
Week	29	75 677.0	2609.6	16.24	ff .001
City	42	65 557.9	1560.9	9.72	ff .001
1 Nonpharmaceutical intervention					
School closure	1	1288.7	1288.7	8.02	.005
ffi Week	8	4551.8	569.0	3.54	ff .001
Banning public gatherings	1	1342.0	1342.0	8.35	.004
Isolation and quarantine	1	911.1	911.1	5.67	.02
ffi City	10	3976.5	397.7	2.48	.006
Ancillary nonpharmaceutical interventions	1	897.3	897.3	5.59	.02
ffi Week	13	6122.4	471.0	2.93	ff .001
ffi City	12	10 257.6	854.8	5.32	ff .001
2 Nonpharmaceutical interventions					
School closure and banning public gatherings	1	681.3	681.3	4.24	.04
ffi Week	9	6497.0	721.9	4.49	ff .001
ffi City	13	6229.9	479.2	2.98	ff .001
School closure and isolation and quarantine	1	2335.3	2335.3	14.54	ff .001
ffi Week	4	2434.2	608.6	3.79	.005
Banning public gatherings and isolation and quarantine	1	292.3	292.3	1.82	.18
ffi Week	1	563.9	563.9	3.51	.06
Banning public gatherings and ancillary nonpharmaceutical interventions	1	272.6	272.6	1.70	.19
ffi Week	4	7444.6	1861.1	11.59	ff .001
ffi City	4	5547.6	1386.9	8.63	ff .001
Isolation and quarantine and ancillary nonpharmaceutical interventions	1	48.1	48.1	0.30	.58
ffi Week	2	1507.6	753.8	4.69	.009
ffi City	2	824.7	412.4	2.57	.08
3 Nonpharmaceutical interventions					
School closure, banning public gatherings, and isolation and quarantine	1	762.4	762.4	4.75	.03
ffi Week	2	2239.3	1119.7	6.97	.001
School closure, banning public gatherings, and ancillary nonpharmaceutical interventions	1	691.6	691.6	4.41	.04
ffi Week	10	12 260.5	1226.0	7.63	ff .001
ffi City	26	51 423.8	1977.8	12.31	ff .001
School closure, isolation and quarantine, and ancillary nonpharmaceutical interventions	1	3451.1	3451.1	21.48	ff .001
ffi Week	4	2493.5	623.4	3.88	.004
Banning public gatherings, isolation and quarantine, and ancillary nonpharmaceutical interventions	1	51.9	51.9	0.32	.57
ffi Week	8	4535.2	566.9	3.53	ff .001
4 Nonpharmaceutical interventions					
School closure, banning public gatherings, isolation and quarantine, and ancillary nonpharmaceutical interventions	1	503.7	503.7	3.14	.08
ffi Week	9	6068.3	674.3	4.20	ff .001
ffi City	13	23 509.7	1808.4	11.26	ff .001
Error	770	123 691.2	160.6		

[a] r^2 = 86.7%

COMMENT

During the 1918-1919 influenza pandemic, all 43 cities eventually implemented nonpharmaceutical interventions but the time of activation, duration, and choice or combination of these nonpharmaceutical interventions appear to have been key factors in their success or failure. In 1918, decisions to activate nonpharmaceutical interventions were typically triggered by excess morbidity, mortality, or both, as well as situational awareness of other communities near and far. Because discerning precisely the first arrival of pandemic virus in a community was difficult, we chose to measure public health response time in reference to excess pneumonia and influenza mortality (ie, when weekly EDR first crossed the threshold of 2ffi the baseline and the mortality rates entered an acceleration phase).

Figure 1. Scatterplot of Public Health Response Time for 43 US Cities From September 8, 1918, Through February 22, 1919



The 4 cities represented by black circles are discussed further in the text. The 2 cities represented by blue circles are outliers chosen to demonstrate that the associations shown are not perfect. The Spearman rank correlation coefficient was used.

Table 4. Implementation Strategy of Nonpharmaceutical Interventions for 21 Cities Between September 8, 1918, and February 22, 1919

Outcome Variable	Public Health Response Time, d: Early (ff 7 d) 25th Percentile	Early (ff 7 d) 50th Percentile	Early (ff 7 d) 75th Percentile	Late (ffl 7 d) 25th Percentile	Late (ffl 7 d) 50th Percentile	Late (ffl 7 d) 75th Percentile	*P* Value
Time to peak, d	13	18	22	9	11	13	ff .001
Magnitude of first peak (weekly EDR)	54.7	67.6	84.8	101.5	125.8	145.4	.001
Excess pneumonia and influenza mortality rate (total EDR)	359.1	451.2	505.2	529.5	580.3	654.7	ff .001
	Total Days of Nonpharmaceutical Interventions						
	Most (ffl 65 d)			**Least (ff 65 d)**			
Excess pneumonia and influenza mortality rate (total EDR)	358.0	451.2	505.2	529.5	559.3	610.4	ff .001

Abbreviation: EDR, excess death rate.

Hence, the difference in time between the first nonpharmaceutical interventions and this excess mortality threshold may be a positive or negative value. For example, in Philadelphia, Pennsylvania, which was affected early and was unprepared to respond, the PHRT was 8 and the EDR was approximately 37/100 000 population at the point of implementing nonpharmaceutical interventions; in contrast, New York City's PHRT was -11 days and the EDR was 0/100 000 population at the point of implementing nonpharmaceutical interventions. New York City responded to its first influenza cases and the perceived severity of the epidemic in nearby cities without waiting for excess deaths to accumulate.

The US Centers for Disease Control and Prevention's newly released interim community mitigation guidance recommends activating nonpharmaceutical interventions when outbreaks due to a pandemic virus strain first are confirmed in a state or metropolitan service region.[16] Several theoretical models suggest that the effect of targeted, layered strategies for nonpharmaceutical interventions may be optimized when community influenza attack rates are 1% or lower.[11-15] Given the exponential growth of an unmitigated influenza pandemic, it is reasonable to expect that the timing of interventions will be among the most critical factors. Such expectations and biological realities are consistent with our observations of the 1918 pandemic, when rapid public health response time was a critical factor in the successful application of nonpharmaceutical interventions.

Late interventions, regardless of their duration or permutation of use, almost always were associated with worse outcomes. However, timing alone was not consistently associated with success. The combination and choice of nonpharmaceutical interventions also appeared to be critical as confirmed by the multivariate model.

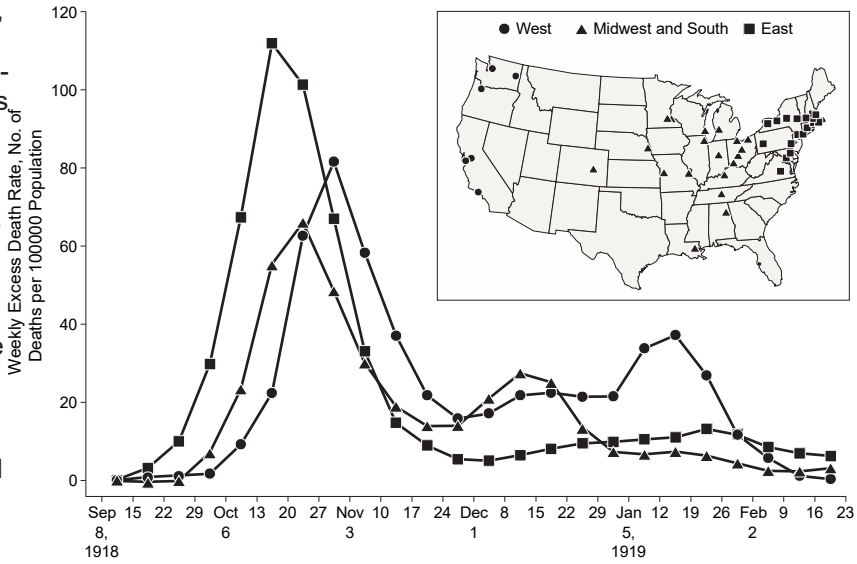
For example, New York City reacted earliest to the gathering influenza crisis, primarily with the sustained (10 weeks beginning September 19, 1918) and rigidly enforced application of compulsory isolation and quarantine procedures, along with an enforced staggered business hour ordinance from October 5 through November 3, 1918.[34] During this era, New York City's health department was renowned internationally for its innovative policies of mandatory case reporting and rigidly enforced isolation and quarantine procedures.[35] Typically, individuals diagnosed with influenza were isolated in hospitals or makeshift facilities, while those suspected to have contact with an ill person (but who were not yet ill themselves) were quarantined in their homes with an official placard declaring that location to be under quarantine. New York City mounted an early and sustained response to the epidemic and experienced the lowest death rate on the Eastern seaboard but it did not layer its response. New York City's cumulative mortality burden, 452/100 000, ranked 15 out of the 43 cities studied.

In contrast, Pittsburgh, under orders from the Pennsylvania health department, executed a public gathering ban on October 4, 1918, but city officials delayed until October 24 before implementing school closure. A week later, on November 2, the state rescinded public gathering bans. The city applied its nonpharmaceutical interventions late and individually rather than combined. Pittsburgh's cumulative excess mortality burden (EDR = 807/100 000) ranked 43 out of 43 cities during the study period.

However, the benefits of these interventions were not equally distributed. Those cities acting in a timely and comprehensive manner appear to have benefited most in terms of reductions in total EDR. For example, St Louis, which implemented a relatively early, layered strategy (school closure and cancellation of public gatherings), and sustained these nonpharmaceutical interventions for about 10 weeks each, did not experience nearly as deleterious an outbreak as 36 other communities in the study (cumulative EDR = 358/100 000 population).

The 1918 experience suggests that sustained nonpharmaceutical interventions are beneficial and need to be "on" throughout the particular peak of a local experience. Many of the 43 cities in the study, particularly in the Midwest and South and West, experienced 2 peaks of excess pneumonia and influenza mortality (eg, Birmingham, Alabama, Cincinnati, Ohio, Columbus, Ohio, Denver, Indianapolis, Indiana, Kansas City,

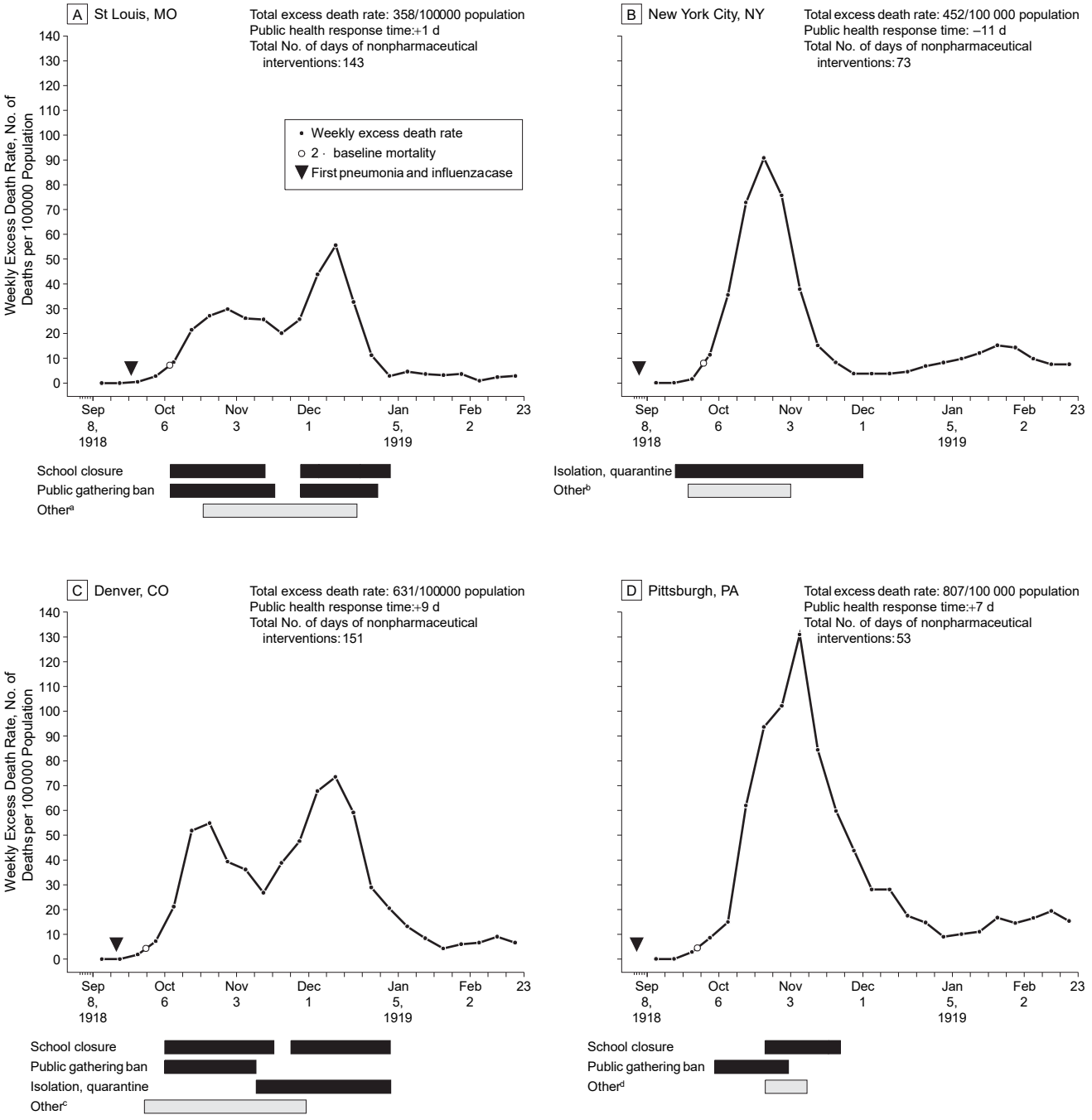
Figure 2. Aggregate Weekly Excess Death Rates for 43 US Cities by Region From September 8, 1918, Through February 22, 1919



The total excess death rate is 555 for the East region; 413 for the Midwest and South region; and 529 for the West region.

Louisville, Kentucky, Milwaukee, Wisconsin, Minneapolis, Minnesota, Oakland, California, Omaha, Nebraska, Portland, Oregon, Rochester, New York, St Louis, San Francisco, California, Seattle, Washington, Spokane, Washington, Toledo, Ohio; see figures in online supplement at http://www.cdc.gov/ncidod/dq/index.htm). These second

Figure 3. Weekly Excess Death Rates From September 8, 1918, Through February 22, 1919



Type and duration of nonpharmaceutical interventions are indicated under each plot. For the specific nonpharmaceutical interventions, black bars indicate activation.
[a] Business hours restricted, streetcars' capacity limited.
[b] Staggered business hours, signs with "cover coughs."
[c] Staggered business hours, warning signs posted in theaters.
[d] School children given information to take home, warned not to gather in groups.

peaks frequently followed the sequential activation, deactivation, and reactivation of nonpharmaceutical interventions, highlighting the transient protective nature of nonpharmaceutical interventions and the need for a sustained response. For example, Denver (cumulative EDR = 631/100 000 population) responded twice with an extensive menu of nonpharmaceutical interventions that included public gathering bans, school closure, isolation and quarantine, and several ancillary nonpharmaceutical interventions and these actions are reflected temporally in its 2-peak mortality curve.

Such dual-peaked cities are of particular interest because of the specificity and temporal associations between excess mortality and the triggers of activation and deactivation of nonpharmaceutical interventions and the implications for a causal relationship. Among the 43 cities, we found no example of a city that had a second peak of influenza while the first set of nonpharmaceutical interventions were still in effect, suggesting that each city with a bimodal pattern served as its own control. In dual-peaked cities, activation of nonpharmaceutical interventions was followed by a diminution of deaths and, typically, when nonpharmaceutical interventions were deactivated, death rates increased.

History is not a predictive science. There exist numerous well-documented and vast differences between US society and public health during the 1918 pandemic compared with the present. We acknowledge the inherent difficulties of interpreting data recorded nearly 90 years ago and contending with the gaps, omissions, and errors that may be included in the extant historical record. The associations observed are not perfect; for example, 2 outlier cities (Grand Rapids and St Paul) experienced better outcomes with less than perfect public health responses. Future work by our research team will explore social, political, and ecological determinants, which may further help to explain some of this variation.

The United States of 1918 had many similar features to the present era: rapid transportation in the form of trains and automobiles; rapid means of communication in the form of the telegraph and telephone; large, heterogeneous populations with substantial urban concentrations (although a much higher percentage of the US population lived in rural areas compared with the present); a news system that was able to circulate information widely during the epidemic, including many daily newspapers and broadsheets distributed in communities; and a wide spectrum of public health agencies at various levels of government.

When examining the 1918 pandemic, however, it is important to recognize the numerous social, cultural, and scientific differences that do exist between that period and the present. For example, the legal understanding of privacy, civil, and constitutional rights as they relate to public health and governmentally directed measures (such as mass vaccination programs) has changed markedly over the past 9 decades. In addition, public support of and trust in these measures, along with trust in the medical profession as a whole, has shifted over time. Finally, other features of the modern era that need to be considered when applying lessons from history to the present era include the increased speed and mode of travel, above all high-volume commercial aviation; instantaneous access to information via the Internet and personal computers; a baseline understanding among the general population that the etiologic agents of infectious diseases are microbial; and advances in medical technology and therapeutics that have expanded considerably the options available for dealing with a pandemic.

Historical contextual issues and statistical limitations aside, the US urban experience with nonpharmaceutical interventions during the 1918-1919 pandemic constitutes one of the largest data sets of its kind ever assembled in the modern, postgerm theory era.

Our findings conform to 8 of A. Bradford Hill's 9 tenets on causal associations in the consideration of disease and the environment.[36] Specifically, during the 1918-1919 pandemic, the relation of early, sustained, and layered nonpharmaceutical interventions to EDR in 43 US cities demonstrates satisfaction of the criteria of *strength* (the magnitude and statistical significance of our findings, which also argue against an association by chance alone), *consistency* (early and combined nonpharmaceutical interventions were consistently associated with reductions in mortality, and our analysis is consistent with 2 recent smaller, preliminary historical epidemiological reports, although these studies look at only 16 US urban centers, do not include actual activation and deactivation time points, duration, or layering of nonpharmaceutical interventions, and rely extensively on secondary historical sources.[37,38]

Further, our retrospective study is consistent with the results from recent theoretical models of the spread of a contemporary pandemic, which highlight the value of early, combined, and sustained nonpharmaceutical interventions to mitigate a pandemic[11-15]), *specificity* (best demonstrated in cities with bimodal mortality peaks when the triggers were activated, deactivated, and reactivated), *temporality* (interventions always preceded the reduction of EDR), *dose-response* (layering and increased duration of the nonpharmaceutical interventions were associated with better outcomes), *biological plausibility* (these interventions reduce person-to-person interactions and biologically would be expected to reduce the spread of a communicable agent such as influenza), *coherence* (our data align with the established body of knowledge on the epidemiology of influenza), and *analogy* (isolation and social distancing have been demonstrated as effective means of preventing person-to-person spread of other respiratory tract diseases, such as rhinovirus, severe acute respiratory syndrome, respiratory syncytial virus, varicella, and seasonal influenza).

The ninth tenet, *experiment*, could not be demonstrated directly because of the paucity of influenza pandemics in the past century, the trend away from such traditional public health mea-

sures for disease control during the past 50 years, and ethical limitations of using population-wide nonpharmaceutical interventions in the absence of a serious threat.

These findings contrast with the conventional wisdom that the 1918 pandemic rapidly spread through each community killing everyone in its path. Although these urban communities had neither effective vaccines nor antivirals, cities that were able to organize and execute a suite of classic public health interventions before the pandemic swept fully through the city appeared to have an associated mitigated epidemic experience. Our study suggests that nonpharmaceutical interventions can play a critical role in mitigating the consequences of future severe influenza pandemics (category 4 and 5) and should be considered for inclusion in contemporary planning efforts as companion measures to developing effective vaccines and medications for prophylaxis and treatment. The history of US epidemics also cautions that the public's acceptance of these health measures is enhanced when guided by ethical and humane principles.[39-41]

Author Contributions Drs Markel and Cetron had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Markel, Lipman, Navarro, Stern, Cetron.
Acquisition of data: Markel, Navarro, Sloan, Michalsen, Stern.
Analysis and interpretation of data: Markel, Lipman, Navarro, Sloan, Michalsen, Stern, Cetron.
Drafting of the manuscript: Markel, Lipman, Navarro, Sloan, Michalsen, Stern, Cetron.
Critical revision of the manuscript for important intellectual content: Markel, Lipman, Navarro, Stern, Cetron.
Statistical analysis: Markel, Lipman, Cetron.
Obtained funding: Markel, Cetron.
Administrative, technical, or material support: Markel, Navarro, Sloan, Michalsen, Cetron.
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Saturated fatty acids increase levels of low-density lipoprotein cholesterol (LDL-C) and HDL-C,[2] whereas *trans*-fatty acids increase LDL-C level but decrease HDL-C level.[2,3] This distinction is important, because *trans*-fatty acids are more strongly associated with the risk of cardiovascular disease than saturated fatty acids due to their undesirable effects on LDL-C and HDL-C levels, endothelial cell function, adipocytes, and inflammatory response.[3,4]

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Financial Disclosures: None reported.

1. Singh IM, Shishehbor MH, Ansell BJ. High-density lipoprotein as a therapeutic target: a systematic review. *JAMA*. 2007;298(7):786-798.
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In Reply: Dr Kim distinguishes the effects of saturated fatty acids and *trans*-fatty acids on lipoproteins. However, reports of the effect of *trans*-fatty acid on HDL-C have been variable, with a large meta-analysis finding a statistically nonsignificant effect on HDL-C.[1] In addition to increasing levels of LDL-C, *trans*-fatty acids promote vascular inflammation and endothelial dysfunction and reduce paraoxonase activity.[2] These lipid and biochemical effects act synergistically to increase cardiovascular disease risk.[2]

The issue is more complex than indicated by HDL-C. Saturated fat rapidly promotes proinflammatory changes in HDL without changing HDL-C level.[3] Thus, as mentioned in our review, dietary intake of both saturated fatty acids and *trans*-fatty acids should be avoided and substituted with intake of monounsaturated and polyunsaturated fatty acids.

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Financial Disclosures: Dr Ansell reported receiving speaking honoraria from AstraZeneca, Kos Pharmaceuticals, Merck, and Pfizer; receiving research medication from Merck and Pfizer in the past; and having equity interest in Bruin Pharma. No other disclosures were reported.

1. Mensink RP, Zock PL, Kester AD, Katan MB. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. *Am J Clin Nutr*. 2003; 77(5):1146-1155.
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3. Nicholls SJ, Lundman P, Harmer JA, et al. Consumption of saturated fat impairs the anti-inflammatory properties of high-density lipoproteins and endothelial function. *J Am Coll Cardiol*. 2006;48(4):715-720.

CORRECTIONS

Data Error: In the Review article entitled "Data Extraction Errors in Meta-analyses That Use Standardized Mean Differences" published in the July 25, 2007, issue of *JAMA* (2007;298:430-437), Figure 4 included incorrect data. The reported point estimate and its 95% confidence interval for the meta-analysis standardized mean differences "-0.74 (-0.98 to -0.49)" for the Edmonds et al article should have read "-0.77 (-1.26 to -0.28)." The error was caused by a wrong label in the Cochrane Library at the time of the study. A meta-analysis was stated to have been done with a random-effects model; however, it was done with a fixed-effect model. The Cochrane Library no longer contains this error.

Typographical Errors in Tables: In the Research Letter entitled "Patterns of Prevalent Major Chronic Disease Among Older Adults in the United States" published in the September 12, 2007, issue of *JAMA* (2007;298[10]:1160-1162), both tables contained typographical errors. In both tables, the column headings of "Estimated Frequency [1000)" and "CVA" were erroneously transposed and the brace under the column head "Disease Pattern, No. of Diseases" should have extended to include the CVA column. Online versions of this article on the *JAMA* Web site were corrected on October 4, 2007.

Unreported Financial Disclosures: In the Original Contribution entitled "Nonpharmaceutical Interventions Implemented by US Cities During the 1918-1919 Influenza Pandemic" published in the August 8, 2007, issue of *JAMA* (2007; 298[6]:644-654), financial disclosures were inadvertently not reported. On page 654, under "Financial Disclosures," the following should appear: "Dr Markel reported having received honoraria for delivering lectures on the social and cultural history of the 1918-1919 influenza pandemic at academic conferences or colloquia presented by Yale University, the US Department of Defense, the RAND Corporation, Columbia University, the US Department of Health and Human Services, the Michigan Society for Infection Control and Prevention, University of Michigan, and Emory University. None of the other authors reported financial disclosures."

Incorrect Affiliation: In the Research Letter entitled "Cardiovascular Response to a Modern Roller Coaster Ride" published in the August 15, 2007, issue of *JAMA* (2007;298[7]:739-741), the affiliations were reversed for 2 authors and 1 author's name was listed out of order. Joachim Brade, MSc, is affiliated with the Department of Medical Statistics and Dariusch Haghi, MD, is affiliated with the 1st Department of Medicine-Cardiology, University Hospital of Mannheim, Mannheim, Germany. The name for Christian Wolpert, MD, should have been placed last among the list of author names.

To: Baric, Ralph S[rbaric@email.unc.edu]
From: William Dowling[william.dowling@cepi.net]
Sent: Wed 3/18/2020 9:09:18 AM (UTC-04:00)
Subject: RE: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

This is all we have Ralph. I am sorry if this is a problem

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From: Baric, Ralph S <rbaric@email.unc.edu>
Sent: Wednesday, March 18, 2020 9:07 AM
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Cc: Morabito, Kaitlyn (NIH/VRC) [E] <kaitlyn.dambach@nih.gov>
Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

Hello all
Attached is an agenda for todays call.
You may have already received this , but below is a link to the sharepoint site.
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Please let me know if there are issues accessing the site.
Right now, there are minutes from each meeting there. There is a new table in a more detailed format that I just began to fill in, but I would appreciate if you could update it as well. We can also add protocols and publications here.
Please keep in mind that you can edit but also delete, so please don't delete anything!

Thanks
Bill

William Dowling, PhD

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Cc: Cesar Munoz-fontela[munoz-fontela@bnitm.de]; COSTA, Alejandro Javier[costaa@who.int]
From: William Dowling[william.dowling@cepi.net]
Sent: Wed 3/18/2020 10:17:07 AM (UTC-04:00)
Subject: WHO International serological survey working group

Hello all
As mentioned on today's call, the WHO is standing up an International serological survey working group. If you are interested in participating , please send an email to myself, Alejandro Costa (costaa@who.int) and Cesar Munoz-fontela (munoz-fontela@bnitm.de) .

Thanks
Bill

William Dowling, PhD (seconded to WHO)

Non-Clinical Vaccine Development Leader

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To: Baric, Ralph S[rbaric@email.unc.edu]
From: William Dowling[william.dowling@cepi.net]
Sent: Wed 3/18/2020 11:42:24 AM (UTC-04:00)
Subject: RE: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

HI Ralph

I am sorry that you had a problem. I think we may need a different platform. Do you have any updates you would like to have added ?

Bill

From: Baric, Ralph S <rbaric@email.unc.edu>
Sent: Wednesday, March 18, 2020 9:07 AM
To: William Dowling <william.dowling@cepi.net>
Subject: RE: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

I have tried to connect but its not letting me through. Ralph

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From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; 'Georges Benjamin'; drnickilurie@gmail.com; Del Rio, Carlos; 'Sharon Inouye'; 'Linda Degutis'; Susan Polan; Ogilvie, Jenna; Kanarek, Morgan; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Overton, Devona; May, David; Kearney, William; Pope, Andrew; Pavlin, Julie; Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen

Location: Zoom - see instructions below

Importance: Normal

Subject: CONFIRMED - COVID-19 Conversations Webinar Series Advisory Group Meeting

Start Time: Thur 3/19/2020 5:00:00 PM (UTC-04:00)

End Time: Thur 3/19/2020 7:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; 'Georges Benjamin'; drnickilurie@gmail.com; Del Rio, Carlos; 'Sharon Inouye'; 'Linda Degutis'; Susan Polan; Ogilvie, Jenna; Kanarek, Morgan; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Overton, Devona; May, David; Kearney, William; Pope, Andrew; Pavlin, Julie

Optional Attendees: Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen

Background Materials:

Advisory Group Roster
March 19 Call Agenda

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: "COVID-19 Conversations" Webinar Series Advisory Group Call
Time: Mar 19, 2020 05:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/235883148

Or iPhone one-tap :
US: +13126266799,,235883148# or +14702509358,,235883148#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 312 626 6799 or +1 470 250 9358 or +1 470 381 2552 or +1 646 518 9805 or +1 646 558 8656 or +1 786 635 1003 or +1 602 753 0140 or +1 651 372 8299 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 267 831 0333 or +1 301 715 8592 or +1 346 248 7799 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 235 883 148
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; 'Georges Benjamin'; drnickilurie@gmail.com; Del Rio, Carlos; 'Sharon Inouye'; 'Linda Degutis'; Susan Polan; Ogilvie, Jenna; Kanarek, Morgan; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Overton, Devona; May, David; Kearney, William; Pope, Andrew; Pavlin, Julie; Korsen, Dana; Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen; Paulina Sosa

Location: Zoom - instructions below - see background materials

Importance: Normal

Subject: CONFIRMED - COVID-19 Conversations Webinar Series Advisory Group Meeting

Start Time: Thur 3/19/2020 5:00:00 PM (UTC-04:00)

End Time: Thur 3/19/2020 7:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; 'Georges Benjamin'; drnickilurie@gmail.com; Del Rio, Carlos; 'Sharon Inouye'; 'Linda Degutis'; Susan Polan; Ogilvie, Jenna; Kanarek, Morgan; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Overton, Devona; May, David; Kearney, William; Pope, Andrew; Pavlin, Julie; Korsen, Dana

Optional Attendees: Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen; Paulina Sosa

Background Materials:

Advisory Group Roster
March 19 Call Agenda
COVID-19Conversations.org

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: "COVID-19 Conversations" Webinar Series Advisory Group Call
Time: Mar 19, 2020 05:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/235883148

Or iPhone one-tap :
US: +13126266799,,235883148# or +14702509358,,235883148#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 312 626 6799 or +1 470 250 9358 or +1 470 381 2552 or +1 646 518 9805 or +1 646 558 8656 or +1 786 635 1003 or +1 602 753 0140 or +1 651 372 8299 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 267 831 0333 or +1 301 715 8592 or +1 346 248 7799 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 235 883 148
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: TBD

Importance: Normal

Subject: TENTATIVE: NAM-APHA Webinar 2 - Additional Considerations for Social Distancing

Start Time: Fri 3/27/2020 3:00:00 PM (UTC-04:00)

End Time: Fri 3/27/2020 4:30:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Organizer:	DeStefano, Laura[LDestefano@nas.edu]
From:	DeStefano, Laura[LDestefano@nas.edu]
Attendees:	Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'
Location:	zoom - see agenda & background materials below
Importance:	Normal
Subject:	CONFIRMED: Second advisory call for COVID-19 webinar series
Start Time:	Fri 3/27/2020 3:00:00 PM (UTC-04:00)
End Time:	Fri 3/27/2020 4:30:00 PM (UTC-04:00)
Required Attendees:	Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Agenda and background materials: https://docs.google.com/document/d/1CK5G6gmaKYaIRvhx8GS7QJGStXXpf0-aT1yGLS-hscw/edit?usp=sharing

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Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: COVID-19 webinar series advisors call
Time: Mar 27, 2020 03:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/797361197

Or iPhone one-tap :
US: +14702509358,,797361197# or +14703812552,,797361197#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 470 250 9358 or +1 470 381 2552 or +1 646 518 9805 or +1 646 558 8656 or +1 786 635 1003 or +1 312 626 6799 or +1 602 753 0140 or +1 651 372 8299 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 267 831 0333 or +1 301 715 8592 or +1 346 248 7799 or 888 475 4499 (Toll Free) or 877 853 5257 (Toll Free)
Meeting ID: 797 361 197
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

Would you like to test your Zoom connection? Please click on the link below.
https://nasem.zoom.us/test

To: DeStefano, Laura[LDestefano@nas.edu]
Cc: Sharon Inouye[SharonInouye@hsl.harvard.edu]; Linda Degutis[lcdegutis@gmail.com]; acasadevall@jhu.edu[acasadevall@jhu.edu]; ushah@hcphes.org[ushah@hcphes.org]; Lawrence Gostin[gostin@georgetown.edu]; Figueroa, Angelica M[amfiguer@email.unc.edu]; Croitoru, Grace Nicole[gracenc@email.unc.edu]; Rimer, Barbara[brimer@unc.edu]; Andy Pavia[Andy.Pavia@hsc.utah.edu]; Shah, Umair MD (PHS)[Umair.Shah@phs.hctx.net]; Arturo Casadevall[acasade1@jhu.edu]; Jha, Ashish[ajha@hsph.harvard.edu]; Gold, Jeffrey P[jeffrey.gold@unmc.edu]; Perez, Elizabeth (PHS)[Elizabeth.Perez@phs.hctx.net]; Castaneda, Tony (PHS)[Tony.Castaneda@phs.hctx.net]; Heidi Larson[Heidi.Larson@lshtm.ac.uk]; Burke, Donald S[donburke@pitt.edu]; Tom Inglesby[tinglesby@jhu.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Maria Jasen[mjasen1@jhu.edu]; Nicole Lurie[drnickilurie@gmail.com]; Del Rio, Carlos[cdelrio@emory.edu]; Dzau, Victor J.[VDzau@nas.edu]; Ogilvie, Jenna[JOgilvie@nas.edu]; Susan Polan[susan.polan@apha.org]; Korsen, Dana[DKorsen@nas.edu]; May, David[DMay@nas.edu]; Overton, Devona[DOverton@nas.edu]; Kearney, William[WKearney@nas.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]; Paulina Sosa[Paulina.Sosa@apha.org]; dhess@emory.edu[dhess@emory.edu]
From: Georges Benjamin[georges.benjamin@apha.org]
Sent: Sun 3/22/2020 2:45:21 PM (UTC-04:00)
Subject: Re: Update & action items - NAM-APHA COVID-19 Webinar Series
image001.png
image001.png

Dr. Sandro Galea I, Dean at BU who has written on the mental health consequences of disasters

Sent from my iPhone
Georges C. Benjamin, MD
APHA
Executive Director

On Mar 22, 2020, at 2:29 PM, DeStefano, Laura <LDestefano@nas.edu> wrote:

Hi there, just a reminder to please send me speaker suggestions ASAP for Webinar 2<https://docs.google.com/document/d/1VU7pMudkTKB5qCzRimeVblvOIq6eXQMrjZ7ZxsvUs-Q/edit?usp=sharing>, which will cover risk/benefit analysis of social distancing strategies, available science to guide eventual relaxation of social distancing measures, and mental health strategies.

Thanks to those who've sent ideas so far!
Laura

Laura DeStefano
Director of Communications
National Academy of Medicine
202-334-3268

From: DeStefano, Laura
Sent: Saturday, March 21, 2020 2:44 PM
To: 'Sharon Inouye' <SharonInouye@hsl.harvard.edu>; 'Linda Degutis' <lcdegutis@gmail.com>; 'acasadevall@jhu.edu' <acasadevall@jhu.edu>; 'ushah@hcphes.org' <ushah@hcphes.org>; 'Lawrence Gostin' <gostin@georgetown.edu>; 'Figueroa, Angelica M' <amfiguer@email.unc.edu>; 'Croitoru, Grace Nicole' <gracenc@email.unc.edu>; 'brimer@unc.edu' <brimer@unc.edu>; 'Andy Pavia' <Andy.Pavia@hsc.utah.edu>; 'Shah, Umair MD (PHS)' <Umair.Shah@phs.hctx.net>; 'Arturo Casadevall' <acasade1@jhu.edu>; 'Jha, Ashish' <ajha@hsph.harvard.edu>; 'Gold, Jeffrey P' <jeffrey.gold@unmc.edu>; 'Perez, Elizabeth (PHS)' <Elizabeth.Perez@phs.hctx.net>; 'Castaneda, Tony

(PHS)' <Tony.Castaneda@phs.hctx.net>; 'Heidi Larson' <Heidi.Larson@LSHTM.ac.uk>; 'Burke, Donald S' <donburke@pitt.edu>; 'Tom Inglesby' <tinglesby@jhu.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'Maria Jasen' <mjasen1@jhu.edu>
Cc: 'Nicole Lurie' <drnickilurie@gmail.com>; 'Del Rio, Carlos' <cdelrio@emory.edu>; 'Georges Benjamin' <georges.benjamin@apha.org>; Dzau, Victor J. <VDzau@nas.edu>; Ogilvie, Jenna <JOgilvie@nas.edu>; 'Susan Polan' <susan.polan@apha.org>; Korsen, Dana <DKorsen@nas.edu>; May, David <DMay@nas.edu>; Overton, Devona <DOverton@nas.edu>; Kearney, William <WKearney@nas.edu>; Pope, Andrew <APope@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; 'Paulina Sosa' <Paulina.Sosa@apha.org>; 'dhess@emory.edu' <dhess@emory.edu>
Subject: RE: Update & action items - NAM-APHA COVID-19 Webinar Series

Hi all, just a heads up that the draft agenda for Webinar 2 has been updated since I got in touch initially. Available at the same link below.

Thanks,
Laura

Laura DeStefano
Director of Communications
National Academy of Medicine
202-334-3268

From: DeStefano, Laura
Sent: Saturday, March 21, 2020 1:30 PM
To: 'Sharon Inouye' <SharonInouye@hsl.harvard.edu<mailto:SharonInouye@hsl.harvard.edu>>; 'Linda Degutis' <lcdegutis@gmail.com<mailto:lcdegutis@gmail.com>>; 'acasadevall@jhu.edu' <acasadevall@jhu.edu<mailto:acasadevall@jhu.edu>>; 'ushah@hcphes.org' <ushah@hcphes.org<mailto:ushah@hcphes.org>>; 'Lawrence Gostin' <gostin@georgetown.edu<mailto:gostin@georgetown.edu>>; Figueroa, Angelica M <amfiguer@email.unc.edu<mailto:amfiguer@email.unc.edu>>; Croitoru, Grace Nicole <gracenc@email.unc.edu<mailto:gracenc@email.unc.edu>>; 'brimer@unc.edu' <brimer@unc.edu<mailto:brimer@unc.edu>>; 'Andy Pavia' <Andy.Pavia@hsc.utah.edu<mailto:Andy.Pavia@hsc.utah.edu>>; Shah, Umair MD (PHS) <Umair.Shah@phs.hctx.net<mailto:Umair.Shah@phs.hctx.net>>; Arturo Casadevall <acasade1@jhu.edu<mailto:acasade1@jhu.edu>>; 'Jha, Ashish' <ajha@hsph.harvard.edu<mailto:ajha@hsph.harvard.edu>>; 'Gold, Jeffrey P' <jeffrey.gold@unmc.edu<mailto:jeffrey.gold@unmc.edu>>; Perez, Elizabeth (PHS) <Elizabeth.Perez@phs.hctx.net<mailto:Elizabeth.Perez@phs.hctx.net>>; Castaneda, Tony (PHS) <Tony.Castaneda@phs.hctx.net<mailto:Tony.Castaneda@phs.hctx.net>>; 'Heidi Larson' <Heidi.Larson@LSHTM.ac.uk<mailto:Heidi.Larson@LSHTM.ac.uk>>; 'Burke, Donald S' <donburke@pitt.edu<mailto:donburke@pitt.edu>>; 'Tom Inglesby' <tinglesby@jhu.edu<mailto:tinglesby@jhu.edu>>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu<mailto:rbaric@email.unc.edu>>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu<mailto:antoinette_baric@med.unc.edu>>; Maria Jasen <mjasen1@jhu.edu<mailto:mjasen1@jhu.edu>>
Cc: 'Nicole Lurie' <drnickilurie@gmail.com<mailto:drnickilurie@gmail.com>>; 'Del Rio, Carlos' <cdelrio@emory.edu<mailto:cdelrio@emory.edu>>; Georges Benjamin <georges.benjamin@apha.org<mailto:georges.benjamin@apha.org>>; Dzau, Victor J. <VDzau@nas.edu<mailto:VDzau@nas.edu>>; Ogilvie, Jenna <JOgilvie@nas.edu<mailto:JOgilvie@nas.edu>>; 'Susan Polan' <susan.polan@apha.org<mailto:susan.polan@apha.org>>; Korsen, Dana <DKorsen@nas.edu<mailto:DKorsen@nas.edu>>; May, David <DMay@nas.edu<mailto:DMay@nas.edu>>; Overton, Devona <DOverton@nas.edu<mailto:DOverton@nas.edu>>; Kearney, William <WKearney@nas.edu<mailto:WKearney@nas.edu>>; Pope, Andrew

<APope@nas.edu<mailto:APope@nas.edu>>; Pavlin, Julie
<JPavlin@nas.edu<mailto:JPavlin@nas.edu>>; Paulina Sosa
<Paulina.Sosa@apha.org<mailto:Paulina.Sosa@apha.org>>; 'dhess@emory.edu'
<dhess@emory.edu<mailto:dhess@emory.edu>>
Subject: Update & action items - NAM-APHA COVID-19 Webinar Series
Importance: High

Hi all,

Thanks very much for taking the time to join the call on Thursday. If you missed the call or would like to revisit the discussion, notes are available here<https://docs.google.com/document/d/15f_py9tmNHrp-vS4ULKRxzAqYTQIV5r5YA7ldiwpLq4/edit?usp=sharing> (special thanks to Jenna Ogilvie).

I'm writing to share an update on Webinar 1 and a few action items.

UPDATE:

Webinar 1 (The Science of Social Distancing) is CONFIRMED for Wednesday, March 25, from 3:00 to 4:30 pm ET. Please see the current agenda here<https://nam.edu/event/webinar-the-science-of-social-distancing-nam-apha-covid-19-conversations-series/>. I will follow up on Monday with promotional materials for you to share with your networks.

ACTION ITEMS:

· Provide feedback & speaker suggestions for Webinar 2 (Anticipating & Mitigating Unintended Consequences of Social Distancing). Pending speaker availability, we have tentatively scheduled this webinar for Friday, March 27, from 3:00 to 4:30 pm ET. A draft agenda is available here<https://docs.google.com/document/d/1VU7pMudkTKB5qCzRimeVblvOIq6eXQMrjZ7ZxsvUs-Q/edit?usp=sharing>. This agenda reflects input from Victor, Georges, Nicki, Sharon, Linda, and Andy but is still preliminary. Suggestions welcome. Please reply to me with feedback/speaker suggestions by the end of the day tomorrow. Don't hesitate to suggest yourself as a speaker, if you're interested!

· Share your availability for our next advisory group call. Please complete this scheduling poll<http://whenisgood.net/i7kka2w> by Wednesday, May 25. Let me know if you have an assistant I should connect with for scheduling.

· Suggest topics and speakers for future webinars. Please enter your ideas and suggestions in this shared Google doc<https://docs.google.com/spreadsheets/d/1OHAxzH0Mspq5en93CVuarXuqTcHpdAnJxSPE18q1NNI/edit?usp=sharing>. Or, feel free to email me and I will add your ideas to the list.

I and my colleagues at NAM and APHA will be in touch regularly as we continue to refine our approach. Please feel free to reach out with questions or suggestions of any kind.

With gratitude for your time and insights,
Laura

Laura DeStefano
Director of Communications
National Academy of Medicine
202-334-3268
nam.edu | @theNAMedicine

[cid:image001.png@01D57D5B.F52A3E60]

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Founded in 1970 as the Institute of Medicine

NATIONAL ACADEMY of MEDICINE

Founded in 1970 as the Institute of Medicine

From: Ángel Honrado[angel.honrado@cepi.net]
Sent: Mon 3/23/2020 3:33:25 AM (UTC-04:00)
Subject: Material from the COVID-19 Enhanced Disease consensus meeting

Dear Colleague,

Thank you for attending the COVID-19 Enhanced Disease consensus meeting hosted by CEPI and the Brighton Collaboration on March 12-13.

We would like to share with you the meeting materials. For that reason, you will receive another email with an invite to access a restricted folder in a secure SharePoint where you can access the full conference pack. After clicking on the link, the system will send you a code to your email you will be requested to insert.

Please, **check your spam folder**, just in case any of both communications have been sent there.

We would like to request that the materials are not shared beyond your organization to limit the chance of misinterpretations that may impact vaccine development programs.

Best regards

Robert Chen
Director of the Brighton Collaboration

SPEAC, a CEPI project

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Morabito, Kaitlyn (NIH/VRC) [E]; Corbett, Kizzmekia (NIH/VRC) [E]

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

Start Time: Wed 3/25/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 3/25/2020 10:00:00 AM (UTC-04:00)

Required Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Morabito, Kaitlyn (NIH/VRC) [E]; Corbett, Kizzmekia (NIH/VRC) [E]

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Thanks
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Organizer: William Dowling[william.dowling@cepi.net]

From: William Dowling[william.dowling@cepi.net]

Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Morabito, Kaitlyn (NIH/VRC) [E]; Corbett, Kizzmekia (NIH/VRC) [E]; N.M.A. Okba; dj56wood@gmail.com

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

Start Time: Wed 3/25/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 3/25/2020 10:00:00 AM (UTC-04:00)

Required Attendees: cheryl@gisaid.org; Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Morabito, Kaitlyn (NIH/VRC) [E]; Corbett, Kizzmekia (NIH/VRC) [E]; N.M.A. Okba

Optional Attendees: dj56wood@gmail.com

Hello all
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Thanks
Bill Dowling

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From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: zoom (see below)

Importance: Normal

Subject: CONFIRMED: Second advisory call for COVID-19 webinar series

Start Time: Fri 3/27/2020 3:00:00 PM (UTC-04:00)

End Time: Fri 3/27/2020 4:30:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

All, since our agenda for webinar 2 is not yet final, we will repurpose this calendar hold to discuss topics for upcoming webinars.

Thank you for your continuing support.

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: COVID-19 webinar series advisors call
Time: Mar 27, 2020 03:00 PM Eastern Time (US and Canada)

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Meeting ID: 797 361 197
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

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To: cheryl@gisaid.org[cheryl@gisaid.org]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; Baric, Ralph S[rbaric@email.unc.edu]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; GSELL, Pierre[gsellp@who.int]; COSTA, Alejandro Javier[costaa@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; vincent.munster@nih.gov[vincent.munster@nih.gov]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; Vasan, Vasan (H&B, Geelong AAHL[Vasan.Vasan@csiro.au]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; jokim@ivi.int[jokim@ivi.int]; mksong@ivi.int[mksong@ivi.int]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; leejooyeon@korea.kr[leejooyeon@korea.kr]; limhy0919@korea.kr[limhy0919@korea.kr]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; christian.brechot[christian.brechot@pasteur.fr]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Mark Page[Mark.Page@nibsc.org]; Graham, Barney (NIH/VRC) [E[bgraham@mail.nih.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; Thue, Tracey[tracey.thue@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Napper, Scott[scott.napper@usask.ca]; Nicola Rose[Nicola.Rose@nibsc.org]; M.P.G. Koopmans[m.koopmans@erasmusmc.nl]; sgerber@cdc.gov[sgerber@cdc.gov]; djernigan@cdc.gov[djernigan@cdc.gov]; Gerber, Susan I. (CDC/DDID/NCIRD/DVD)[bhx1@cdc.gov]; Carroll, Darin (CDC/DDID/NCEZID/OD)[zuz4@cdc.gov]; Watson, John (CDC/DDID/NCIRD/DVD)[acq4@cdc.gov]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; gustavo.f.palacios.civ@mail.mil[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; SPoehlmann@dpz.eu[SPoehlmann@dpz.eu]; mhoffmann@dpz.eu[mhoffmann@dpz.eu]; sylvie.van-der-werf@pasteur.fr[sylvie.van-der-werf@pasteur.fr]; Nelson Michelle[MNELSON@dstl.gov.uk]; Lever Steve[MSLEVER@dstl.gov.uk]; Prior Joann L[JLPRIOR@dstl.gov.uk]; Marston, Hilary (NIH/NIAID) [E][hilary.marston@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; mit666666@pitt.edu[mit666666@pitt.edu]; Mellors, John W[jwm1@pitt.edu]; tlying@fudan.edu.cn[tlying@fudan.edu.cn]; christian.drosten@charite.de[christian.drosten@charite.de]; David Vaughn[David.Vaughn@gatesfoundation.org]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; florian.krammer@mssm.edu[florian.krammer@mssm.edu]; perkinsm@who.int[perkinsm@who.int]; Guthrie, Erica (CDC/DDID/NCIRD/ID)[ilj2@cdc.gov]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; Baric, Toni C[antoinette_baric@med.unc.edu]; SALAMI, Kolawole[salamik@who.int]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Cesar Munoz-fontela[munoz-fontela@bnitm.de]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; Ashley.Smith1@hhs.gov[Ashley.Smith1@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Kovacs, Gerald (OS/ASPR/BARDA) (CTR)[Gerald.Kovacs@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Delgado Vazquez.Rafael[rafael.delgado@salud.madrid.org]; Morabito, Kaitlyn (NIH/VRC) [E][kaitlyn.dambach@nih.gov]; Corbett, Kizzmekia (NIH/VRC) [E][kizzmekia.corbett@nih.gov]; N.M.A. Okba[n.okba@erasmusmc.nl]
Cc: dj56wood@gmail.com[dj56wood@gmail.com]; teresa.lambe@ndm.ox.ac.uk[teresa.lambe@ndm.ox.ac.uk]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; Luc Gagnon[Luc.Gagnon@nexelis.com]; Greg Kulnis[Greg.Kulnis@nexelis.com]
From: William Dowling[william.dowling@cepi.net]
Sent: Tue 3/24/2020 4:57:31 PM (UTC-04:00)
Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 2 PM CET

Hello all

We will have data presentations tomorrow followed by discussion and then updates, as time allows.

- Natalie Thornburg , CDC
- Barney Graham, NIAID
- Bart Haagmans , Erasmus
- Florian Krammer, Mount Sinai

Thanks
Bill

William Dowling, PhD

Non-Clinical Vaccine Development Leader

CEPI New vaccines for a safer world

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From:	DeStefano, Laura[LDestefano@nas.edu]
Attendees:	'Linda Degutis'; 'Sharon Inouye'; 'ushah@hcphes.org'; 'acasadevall@jhu.edu'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen
Location:	see below
Importance:	Normal
Subject:	"The Science of Social Distancing" - NAM-APHA "COVID-19 Conversations" #1
Start Time:	Wed 3/25/2020 3:00:00 PM (UTC-04:00)
End Time:	Wed 3/25/2020 4:30:00 PM (UTC-04:00)
Required Attendees:	'Linda Degutis'; 'Sharon Inouye'; 'ushah@hcphes.org'; 'acasadevall@jhu.edu'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C
Optional Attendees:	Shah, Umair MD (PHS); Arturo Casadevall; Perez, Elizabeth (PHS); Castaneda, Tony (PHS); Maria Jasen

Hi all, to join tomorrow's webinar, please check your email for personal login instructions from the American Public Health Association.

If you did not receive the email, let me know.

If you would like to register others for the webinar, visit
https://cc.readytalk.com/registration/#/?meeting=mj415bksu3zh&campaign=v693815j1185

Thanks,
Laura

202 334 3268

Cc: William Dowling[william.dowling@cepi.net]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Simon Funnell[simon.funnell@phe.gov.uk]
From: GSELL, Pierre[gsellp@who.int]
Sent: Wed 3/25/2020 6:22:02 AM (UTC-04:00)
Subject: [COVID-19 Animal Group] Agenda for tomorrow's call
Draft_WHO COVID-19 Modelling Mar26.docx

Dear all,

Please find attached a draft agenda for our next call. The call is planned tomorrow Thursday 26th at 2PM CET (Geneva time). Please share with us your slides in advance for those who would like to contribute to areas 2 (vaccines), 3 (therapeutics) and 5 (disease enhancement).

Please also note that the ICMRA (International Coalition of Medicines Regulatory Authorities) has just published a summary report on a Global Regulatory Workshop on COVID-19 vaccine development http://www.icmra.info/drupal/sites/default/files/2020-03/First%20regulatory%20COVID-19%20workshop%20-%20meeting%20report_March%202020.pdf
Thank you so much for your contributions, the collaborative spirit of the group and your hard work
Kind regards

Pierre-Stéphane Gsell
Technical Officer
R&D Blueprint | Health Emergencies Programme | 1156
World Health Organization | Avenue Appia 20 | 1211 Geneva 27 | Switzerland
Desk: +41.22.791.50.74 | Mob: +41.79.213.25.30 | gsellp@who.int

WHO *ad hoc* working group on COVID-19 modelling
Agenda for Wednesday 26th MARCH 2020

1. **Area Pathogenesis**

    a. Mount Sinai (Ferrets)
    b. VIDO-Intervac (Ferrets)
    c. Pittsburgh (Ferrets)
    d. RML (NHP)

2. **Area vaccines**
    1. HKU

3. **Area therapeutics**
   Moderated by Marco Cavaleri, EMA

4. **Area disease enhancement**
   All

To: anamin@hs.uci.edu[anamin@hs.uci.edu]; chris.amos@bcm.edu[chris.amos@bcm.edu]; briananderson@mitre.org[briananderson@mitre.org]; ratmar@bcm.edu[ratmar@bcm.edu]; Paul Auwaerter[pauwaert@jhmi.edu]; jeffrey_bailey@brown.edu[jeffrey_bailey@brown.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Baric, Ralph S[rbaric@email.unc.edu]; robert.b.barrow@gmail.com[robert.b.barrow@gmail.com]; Bauer.Philippe@mayo.edu[Bauer.Philippe@mayo.edu]; jbeigel@niaid.nih.gov[jbeigel@niaid.nih.gov]; cbenson@health.ucsd.edu[cbenson@health.ucsd.edu]; Paul Blair[pblair6@jhmi.edu]; Evan Bloch[ebloch2@jhmi.edu]; BOLINP@ecu.edu[BOLINP@ecu.edu]; bottazzi@bcm.edu[bottazzi@bcm.edu]; Anthony Bowen[abowen@jhmi.edu]; m.buchmeier@uci.edu[m.buchmeier@uci.edu]; SGB2C@hscmail.mcc.virginia.edu[SGB2C@hscmail.mcc.virginia.edu]; mbutte@mednet.ucla.edu[mbutte@mednet.ucla.edu]; jcampbel@som.umaryland.edu[jcampbel@som.umaryland.edu]; Arturo Casadevall[acasade1@jhu.edu]; Linzhao Cheng[Lcheng2@jhmi.edu]; david.chesla@spectrumhealth.org[david.chesla@spectrumhealth.org]; 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Cc: Baertlein, Cheryl R. (baertlein.cheryl@mayo.edu)[baertlein.cheryl@mayo.edu]
From: Maryann Smith[maryann.smith@jhu.edu]

Sent: Wed 3/25/2020 1:02:06 PM (UTC-04:00)
Subject: FW:data with CP in COVID-19 paper attached
The feasibility of convalescent plasma therapy in severe COVID19 patients --a pilot study.2020.03.16.20036145v1.full.pdf

Good afternoon,
Please see attached paper and below email.

Best,
Maryann

Maryann K. Smith
Administrative Specialist to Arturo Casadevall, MD, PhD
Professor and Chair
The W. Harry Feinstone Dept. of Molecular Microbiology & Immunology
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From: Morabito, Christopher <Christopher.Morabito@takeda.com>
Sent: Wednesday, March 25, 2020 12:34 PM
To: Arturo Casadevall <acasade1@jhu.edu>
Cc: joyner.michael <joyner.michael@mayo.edu>
Subject: Fwd: You are our inspiration...

Arturo, please distribute this paper to the CP group. Very encouraging data with CP in COVID-19 (but small sample) from China.

C Morabito
Takeda PDT R&D
Begin forwarded message:

> **From:** "Venkayya, Rajeev" <rajeev.venkayya@takeda.com>
> **Date:** March 25, 2020 at 11:48:11 EDT
> **To:** "Haverfield, Sascha" <sascha.haverfield@takeda.com>, "Morabito, Christopher" <Christopher.Morabito@takeda.com>, "Kim, Julie" <Julie.Kim@takeda.com>, "Tsai, Theodore" <Ted.Tsai@Takeda.com>
> **Subject: FW: You are our inspiration...**
>
> All,
>
> China's evaluation of CP just went up on the preprint server and is likely to be published in PNAS or Nature Medicine.
>
> Rajeev

From: Dr. Martin J. Murphy, Jr. <martin.murphy@ceoroundtableoncancer.org>
Sent: 25 March 2020 14:57
To: ZhuChen <zchen@stn.sh.cn>
Cc: sjchen <sjchen@stn.sh.ch>; zhangxinxinrj <zhangxinxinrj@163.com>; yangxiaoming <yangxiaoming@sinopharm.com>; Jeremy Farrar <j.farrar@wellcome.ac.uk>; Dave Reese <dreese@amgen.com>; YuWANG <wangyu@chinacdc.cn>; Bob Bradway <rbradway@amgen.com>; ChrisInglis <inglis6@aol.com>; Ryan Morhard <Ryan.Morhard@weforum.org>; Kevin Si <kevin.si@ceoroundtableoncancer.org>; Richard Hatchett <richard.hatchett@cepi.net>; Kevin Si <kevin.si@ceoroundtableoncancer.org>
Subject: You are our inspiration...

Dear Professor CHEN Zhu,

Congratulations to you and your fellow senior authors, **Professors CHEN Saijuan**, **ZHANG Xinxin** and **YANG Xiaoming**, on the pre-publications of your manuscript, "***The feasibility of convalescent plasma therapy in severe COVID19 patients: a pilot study***," by **DUAN Kai**, *et al.* This is clearly a fundamental advance upon which solid new research may now be built. It give new insights that will lead to genuine new hope ... for all our world.

I have copied key colleagues and have also attached the *medRxiv* that posts your pre-print. In particular we are honored to include **Professor WANG Yu** (*Chairman, CEORT-China & former Director General, China CDC*) **Sir Jeremy Farrar** (*Wellcome Trust*), **Dr. Richard Hatchett** (*CEPI*), along with **Dr. David Reese** (*Amgen*) and our *CEORT-Global Chairman* **Bob Bradway,** all of whom join me in saluting you on this signal achievement.

We and the world anxiously await the results of your *Phase II randomized clinical trial*. Please alert me when it appears on *medRxiv*.

Thank you for remembering February's ***CEORT Airlift*** of PPE supplies for those combating Covid19 at the frontlines in Wuhan. That MD-11 loaded with 153 pallets of supportive gear came from a host of colleagues. These same colleagues are now experiencing the power of this pandemic ... and we hopefully will learn from the advanced experience that China has already shared with the world.

Your recent paper is a perfect example of our global common heritage ... as we truly are all in this together. The saying, "***One for all and all for one***" should become a global motto.

Please stay in good health and in great spirits. You are our inspiration.

Yours,

Marty

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The feasibility of convalescent plasma therapy in severe COVID - 19 patients: a pilot study

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Classification

BIOLOGICAL SCIENCES; Medical Sciences

Keywords

COVID-19, convalescent plasma, treatment outcome, pilot project

Author Contributions

XZ, ZC, and XY contributed to the design of the study. SM, ZW, LL, JZ, WC, YH, SH, LZ, ZZ, ZX, JH, HY, DZ, and DY collected the epidemiological and clinical data. JH, XY, YX, XL, and JZ processed statistical data. KD, BL, CL, HZ, TY, JQ, MZ, ZC and LC drafted the manuscript. ZS, CP, XG, BL, YH, JY, XW, YP, LL, ZZ, YW, KD, QG, WZ, XZ, YL, MY, SC, and DW was responsible for virus detection and summarizing all epidemiological and clinical data. All authors reviewed and approved the final version.

Abstract

Currently, there are no approved specific antiviral agents for 2019 novel coronavirus disease (COVID-19). In this study, ten severe patients confirmed by real-time viral RNA test were enrolled prospectively. One dose of 200 mL convalescent plasma (CP) derived from recently recovered donors with the neutralizing antibody titers above 1:640 was transfused to the patients as an addition to maximal supportive care and antiviral agents. The primary endpoint was the safety of CP transfusion. The second endpoints were the improvement of clinical symptoms and laboratory parameters within 3 days after CP transfusion. The median time from onset of illness to CP transfusion was 16.5 days. After CP transfusion, the level of neutralizing antibody increased rapidly up to 1:640 in five cases, while that of the other four cases maintained ata high level (1:640). The clinical symptoms were significantly improved along with increase of oxyhemoglobin saturation within 3 days. Several parameters tended to improve as compared to pre-transfusion, including increased lymphocyte counts (0.65×10^9/L vs. 0.76×10^9/L) and decreased C-reactive protein (55.98 mg/L vs. 18.13 mg/L). Radiological examinations showed varying degrees of absorption of lung lesionswithin 7 days. The viral load was undetectable after transfusion in seven patients who had previous viremia. No severe adverse effects were observed. This study showed CP therapy was welltolerated and could potentially improve the clinical outcomes through neutralizing viremia in severe COVID-19 cases. The optimal dose and time point, as well as the clinical benefit of CP therapy, needs further investigation in larger well-controlled trials.

Significance Statement

COVID-19is currently a big threat to global health. However, no specific antiviral agents are available for its treatment. In this work, we explored the feasibility of convalescent plasma (CP) transfusion to rescue severe patients. The results from 10 severe adult cases showed that one dose (200 mL) of CP was welltolerated and could significantly increase or maintain the neutralizing antibodies at a high level, leading to disappearance of viremia in 7 days. Meanwhile, clinical symptoms and paraclinical criteria rapidly improved within 3 days. Radiological examination

showed varying degrees of absorption of lung lesions within 7 days. These results indicate that CP can serve as a promising rescue option for severe COVID-19 while the randomized trial is warranted.

Main Text

Introduction

Since December 2019, a pneumonia associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), named as 2019 novel coronavirus disease (COVID-19) by World Health Organization (WHO), emerged in Wuhan, China (1-3). The epidemic spread rapidly worldwidewithin three months and was characterized as a pandemicby WHO on March 11,2020.As of March 12, 2020, a total of80,980confirmed cases and 3,173deaths had been reported in China. Meanwhile, a total of 44,377 confirmed cases and 1,446 deaths was reported in other 108 countries or regions.Currently, there are no approved specific antiviral agents targeting the novel virus, while some drugs are still under investigation, including remdesivir and lopinavir/ritonavir (4, 5). Although remdesivirwas reported to possess potential antiviral effectin one COVID-19 patient from the U.S., randomized controlled trials of this drug are ongoing to determine its safety and efficacy (6). Moreover, the corticosteroid treatment for COVID -19 lung injury remains controversial, due to delayed clearance of viral infection and complications(7,8). Since the effective vaccine and specific antiviral medicines are unavailable, it is an urgent need to look for an alternative strategy for COVID-19 treatment, especially amongsevere patients.

Convalescent plasma (CP) therapy, a classic adaptiveimmunotherapy, has been applied to the prevention and treatment of many infectious diseases for more than one century. Over the past two decades,CP therapy was successfully used in the treatment of SARS, MERS, and 2009 H1N1 pandemic with satisfactory efficacy and safety (9-12). A meta-analysis from 32 studies of SARS coronavirus infection and severe influenza showed a statistically significant reduction in the pooled odds of mortality following CP therapy, compared with placebo or no therapy (odds ratio, 0.25; 95% confidence interval, 0.14-0.45) (13). However, the CP therapy was unable to significantly improve the survival in the Ebola virus disease, probably due to the absence of data of neutralizing antibodytitrationfor stratified analysis (14). Since the virological and clinical characteristics share similarity among SARS, MERS, and COVID-19 (15), CP therapy might be a promising treatment option for COVID-19 rescue(16). Patients who have recovered from COVID-19 with a high neutralizing antibody titermay bea valuable donor source of CP. Nevertheless, the potential clinical benefit and risk of convalescent blood products in COVID-19 remains uncertain. Hence, we performed this pilot study in three participated hospitals to explore the feasibility ofCPtreatment in 10 severe COVID-19 patients.

Results

Neutralizing activity of CP against SARS-CoV-2

The neutralizing activity against SARS-CoV-2 was evaluated by classical plaque reduction test using a recently isolated viral strain (1). Among the first batch of CP samples from 40 recovered COVID-19 patients, 39 showed high antibody titers of at least 1:160 whereas only one had a antibody titer of 1:32. This result laid the basis for our pilot clinical trial using CP in severe patients.

General characteristics of Patients in the trial

From January 23, 2020, to February 19, 2020, ten severe COVID-19 patients (six males and four females) were enrolled and received CP transfusion. The median age was 52.5 years (IQR, 45.0–59.5 years) (Table 1). None of the patients had direct exposure to Huanan Seafood Wholesale Market. The median time from onset of symptoms to hospital admission and CP transfusion was 6 days (IQR, 2.5–8.5 days) and 16.5 days (IQR11.0–19.3 days), respectively. Three patients were affected by clustering infection. The most common symptoms at disease onset were fever (seven of ten patients), cough (eight cases), and shortness of breath (eight cases), while less common symptoms included sputum production (five cases), chest pain (two cases), diarrhea (two cases), nausea and vomiting (two cases), headache (one case), and sore throat (one case). Four patients had underlying chronic diseases, including cardiovascular and/or cerebrovascular diseases and essential hypertension. Nine patients received arbidolmonotherapy or combination therapy with remdesivir (in one case not included in the current clinical trial) or ribavirin, or peramivir, while one patient received ribavirin monotherapy(Table 2). Antibacterial or antifungal treatment was used when patients had co-infection. Six patients received intravenous methylprednisolone (20 mg every 24 hrs).

On computer-assisted tomography (CT), all patients presented bilateral ground-glass opacity and/or pulmonary parenchymal consolidation with predominantly subpleural and bronchovascular bundles distribution in the lungs. Seven patients had multiple lobe involvement and four patients had interlobular septal thickening.

Effects of CP transfusion

Improvement of clinical symptoms All symptoms in the 10 patients, especially fever, cough, shortness of breath and chest pain, disappeared or largely improved within 3 days upon CP transfusion. Prior to CP treatment, three patients received mechanical ventilation, three received

high-flow nasal cannula oxygenation, and two received conventional low-flow nasal cannula oxygenation. After treatment with CP, two patients were weaned from mechanical ventilation to high-flow nasal cannula and one patient discontinued high flow nasal cannula. Besides, in one patient treated with conventional nasal cannula oxygenation, continuous oxygenation was shifted to intermittent one (Table 2).

Reduction of pulmonary lesions on chest CT examinations. According to chest CTs, all patients showed different degrees of absorption of pulmonary lesions after CP transfusion. Representative chest CT images of patient 9 and patient 10 were shown on Fig. 1. Patient 9, a 49-year-old female admitted on 1 day post onset of illness (dpoi), showed the most obvious pulmonary image improvement. On 10 dpoi, one dose of 200 mL transfusion of CP was given. The SARS-CoV-2 RNA converted to negative on 12 dpoi. Compared with the result on 7 dpoi, massive infiltration and ground-glass attenuation disappeared on CT image performed on 13 dpoi, accompanied by a much better pulmonary function. Patient 10, a 50-year-old male, was admitted on 3 dpoi and was given a 200 mL transfusion of CP on 20 dpoi. His chest CT presented massive infiltration and widespread ground-glass attenuation on admission and started to show a gradual absorption of lung lesions 5 days after CP transfusion. The SARS-CoV-2 RNA became negative on 25 dpoi.

Amelioration of routine laboratory criteria and pulmonary function. Lymphocytopenia, an important index for prognosis in COVID-19 (2), tended to be improved after CP transfusion (median: 0.65×10^9 per L vs. 0.76×10^9 per L), seven out of ten patients showing an increase of lymphocyte counts (Fig. 2). Concerning other laboratory tests, we observed a tendency of decrement of parameters indicative of inflammation and/or liver dysfunction as compared to the status before CP therapy. These included C-reactive protein (CRP) (median: 55.98 mg/L vs. 18.13 mg/L), alanine aminotransferase (median: 42.00 U/L vs. 34.30 U/L) and aspartate aminotransferase (median: 38.10 U/L vs. 30.30 U/L) (Table 3). The total bilirubin (median: 12.40 μmol/L vs. 13.98 μmol/L) remained unchanged except an obvious increment in patient 1 (Fig. 2). An increase of SaO_2 (median: 93.00% vs. 96.00%), a measurement constantly performed in most patients in our trial, was found, which could indicate recovering lung function. This temporal relationship was notable despite the provision of maximal supportive care and antiviral agents.

Remarkably, patient 1, a 46-year-old male admitted on 8 dpoi, had a very quick recovery with much improved result of laboratory tests. He received antiviral drugs (arbidol and ribavirin) treatment and high flow nasal cannula on admission. Mechanical ventilation was given on 10 dpoi for critical care support. CP transfusion was performed on 11 dpoi. On 12 dpoi, the SARS-CoV-2 test turned to negative, with a sharp decrease of CRP from 65.04 mg/L to 23.57 mg/L and increment of SaO_2 from 86% to 90% (Fig. 3). The mechanical ventilation was successfully weaned off 2 days after CP

transfusion. On 15 dpoi, a steady elevation oflymphocyte count and a drop ofaminopherase levelwere observed, indicating improvement ofimmunological and hepatic function.

Increase of neutralizing antibody titers and disappearanceof SARS-CoV-2 RNA We determined neutralizing antibody titers before and after CP transfusion in all patients except one (patient2) (Table 4). The neutralizing antibody titers of five patients increased and four patients remained atthe same level after CP transfusion.SARS-CoV-2 RNA, assayed by reverse transcriptase-polymerase chain reaction (RT-PCR), was positive in seven patients and negative in three cases before CP transfusion. Of note, SARS-CoV-2 RNA was decreased to anundetectable level in 3 patients on day 2, 3 patients on day 3 and 1 patients on day 6 after CP therapy.These results were in support of anneutralizing effectof CP on serum SARS-CoV-2.

Outcome of patients treated with CP as compared to a recent historic control groupA historic control group was formed by random selection of10 patients from the cohort treated in the same hospitals andmatched by age, gender and severity of the diseases to the 10 cases in our trial. Baseline characteristics of patients between CP treatment group and control group showed no significant differences, while clinical outcomesof these two groups weredifferent: 3 cases dischargedwhile 7 cases in much improved status and ready for discharge in CP group, as compared to 3 deaths, 6 cases in stabIzed status and one case in improvementin the control group ($p<0.001$, Supplementary table 1).

Adverse effects of CP transfusions

Patient 2 showed an evanescent facial red spot. No serious adverse reactions or safety events were recorded after CP transfusion.

Discussion

To our knowledge, this is the first study to explore the feasibility of CP therapy in COVID -19. All enrolled severe COVID-19 patients achieved primary and secondary outcomes.One dose of 200 mL CP transfusion was welltolerated, while the clinical symptoms significantly improved with the increase of oxyhemoglobin saturation within 3 days, accompanied by rapid neutralization of viremia. Severe pneumonia caused by human coronaviru s was characterized by rapid viral replication, massive inflammatory cell infiltration, and elevated proinflammatory cytokines or even cytokine storm in alveoli of lungs, resulting in acute pulmonary injury and acute respiratory distress

syndrome (ARDS) (17). Recent studies on COVID-19 demonstrated that the lymphocyte counts in the peripheral blood were remarkably decreased and the levels of cytokines in the plasma from patients requiring ICU support, including IL-6, IL-10, TNF-α, GM-CSF, were significantly higher than those who did not require ICU conditions (2, 18). CP, obtained from recovered COVID-19 patients who had established humoral immunity against the virus, contains a large quantity of neutralizing antibodies capable of neutralizing SARS-CoV-2 and eradicating the pathogen from blood circulation and pulmonary tissues (19). In the present study, all investigated patients achieved serum SARS-CoV-2 RNA negativity after CP transfusion, accompanied by the increase of oxygen saturation and lymphocyte counts, and the improvement of liver function and C-reactive protein. The results suggested that the inflammation and overreaction of the immune system were alleviated by antibodies contained in CP. The case-fatality rates (CFRs) in the present study were 0% (0/10), which was comparable to the CFRs in SARS which varied from 0% (0/10) to 12.5% (10/80) in four non-comparative studies using CP treatment (9, 20-22). Based on our preliminary results, CP therapy can be an easy-accessible, promising and safe rescue option for severe COVID-19 patients. It is nevertheless worth mentioning that the absorption of pulmonary lesions was often behind the improvement of clinical symptoms, as shown in patients 9 and 10 in this trial.

The first key factor associated with CP therapy is the neutralizing antibody titer. A small sample study in MERS-CoV infection showed that the neutralizing antibody titer should exceed 1:80 to achieve effective CP therapy (12). To find eligible donors who have high levels of neutralizing antibody is a prerequisite. Cao (23) et al showed that the level of specific neutralizing antibody to SARS-CoV decreased gradually 4 months after the disease process, reaching undetectable levels in 25.6% (IgG) and 16.1% (neutralizing antibodies) of patients at 36 months after disease status. A study from the MERS-CoV infected patients and the exposed healthcare workers showed that the prevalence of MERS-CoV IgG seroreactivity was very low (2.7%), and the antibodies titer decreased rapidly within 3 months (24). These studies suggested that the neutralizing antibodies represented short-lasting humoral immune response and plasma from recently recovered patients should be more effective. In the present study, recently recovered COVID-19 patients, who were infected by SARS-CoV-2 with neutralizing antibody titer above 1:640 and recruited from local hospitals should be considered as suitable donors. The median age of donors was lower than that of recipients (42.0 vs. 52.5 years). Among the nine cases investigated, the neutralizing antibody titers of five patients increased while four patients kept the same level to 1:640 within two days. The antibody titers in CP in COVID-19 seem thus higher than those used in the treatment of MERS patient (1:80) (12).

The second key factor associated with efficacy is the treatment time point. A better treatment outcome was observed among SARS patients who were given CP before 14 dpoi (58.3% vs 15.6%; $P < 0.01$), highlighting the importance of timely rescue therapy (9). The mean time from onset of illness to CP transfusion was 16.5 days. Consistent with previous research, all three patients

receiving plasma transfusion given before 14 dpoi (patients 1, 2 and 9) in our study showed a rapid increase of lymphocyte counts and a decrease of CRP, with remarkable absorption of lung lesions in CT. Notably, patients who received CP transfusion after 14 dpoi showed much less significant improvement, such as patient 10. However, the dynamics of the viremia of SARS-CoV-2 was unclear, so the optimal transfusion time point needs to be determined in the future.

In the present study, no severe adverse effects were observed. One of the risks of plasma transfusion is the transmission of the potential pathogen. Methylene blue photochemistry was applied in this study to inactivate the potential residual virus and to maintain the activity of neutralizing antibodies as much as possible, a method known to be much better than ultraviolet C light (25). No specific virus was detected before transfusion. Transfusion-related acute lung injury (TRALI) was reported in an Ebola virus disease woman who received CP therapy (26). Although uncommon in the general population receiving plasma transfusion, this specific adverse reaction is worth noting, especially among critically ill patients experiencing significant pulmonary injury (27). Another rare risk worth mentioning during CP therapy is antibody-dependent infection enhancement, occurring at sub-neutralizing concentrations, which could suppress innate antiviral systems and thus could allow logarithmic intracellular growth of the virus (28). The special immune enhancement was reportedly more common in Dengue fever, but also could be found in SARS-CoV infection *in vitro* (29). No such pulmonary injury and infection enhancement were observed in our patients, probably owing to high levels of neutralizing antibodies, timely transfusion, and appropriate plasma volume.

There were some limitations to the present study. First, except for CP transfusion, the patients received other standard cares. All patients received antiviral treatment despite the uncertainty of the efficacy of drugs used. As a result, the possibility that these antiviral agents could contribute to the recovery of patients, or synergize with the therapeutic effect of CP, could not be ruled out. Furthermore, some patients received glucocorticoid therapy, which might interfere with immune response and delay virus clearance. Second, the median time from onset of symptoms to CP transfusion was 16.5 days (IQR 11.0-19.3 days). Although the kinetics of viremia during natural history remains unclear, the relationship between SARS-CoV-2 RNA reduction and CP therapy, as well as the optimal concentration of neutralizing antibodies and treatment schedule, should be further clarified. Third, the dynamic changes of cytokines during treatment were not investigated. Nevertheless, the preliminary results of this trial seem promising, justifying a randomized controlled clinical trial in a larger patient cohort.

In conclusion, this pilot study on CP therapy showed a potential therapeutic effect and low risk in the treatment of severe COVID-19 patients. One dose of CP with high concentration of neutralizing

antibodies can rapidly reduce the viral load and tends to improve clinical outcomes. The optimal dose and treatment time point, as well as the definite clinical benefits of CP therapy, need to be further investigated in randomized clinical studies.

Materials and Methods

Patients

From January 23, 2020, to February 19, 2020, ten patients in three participating hospitals (Wuhan Jinyintan Hospital, the Jiangxia District Hospital of Integrative Traditional Chinese and Western Medicine, Wuhan, and the First People's Hospital of Jiangxia District, Wuhan) were recruited in this pilot study. All patients were diagnosed as having severe COVID-19 according to the WHO Interim Guidance (30) and the Guideline of Diagnosis and Treatment of COVID-19 of National Health Commission of China (version 5.0) (31), with confirmation by real-time RT-PCR assay. The enrollment criteria were one of the conditions (2 to 4) plus condition (1): 1). Age ≥18 years; 2).Respiratory distress, RR ≥30 beats/min; 3).Oxygen saturation level less than 93% in resting state; 4). Partial pressure of oxygen (PaO_2)/oxygen concentration (FiO_2) ≤300 mmHg (1 mmHg=0.133 kPa). The exclusion criteria were as follows: 1). Previous allergic history to plasma or ingredients (Sodium Citrate); 2). Cases with serious general conditions, such as severe organ dysfunction, who were not suitable for CP transfusion; Written informed consent according to the Declaration of Helsinki was obtained from each patient or legal relatives. This study was approved by the Ethics Committee of the China National Biotec Group Co., Ltd. (Approval number:2020-0001). The registration number of this trial was ChiCTR2000030048.

Donors for convalescent plasma transfusion

Tendonor patients who recovered from COVID-19 were recruited from three participating hospitals. The recovery criteria were as follows: 1). Normality of body temperature for more than 3 days; 2). Resolution of respiratory tract symptoms; 3). Two consecutively negative results of sputum SARS-CoV-2 of real-time reverse transcriptase-polymerase chain reaction (RT-PCR) assay (one-day sampling interval). The donor's blood was collected after three weeks post-onset of illness and 4 days post-discharge. Written informed consent was obtained from each patient.

Plasma preparation procedure and quality control

Apheresis was performed using a Baxter CS 300 cell separator (Baxter, Deerfield, IL, USA). Convalescence plasma for treatment was colle cted from 40donors. The median age was 42.0 years (IQR, 32.5–49 years). A 400–600 mL ABO-compatible plasma sample was harvested from each

donor depending on the age and body weight, and each sample was divided and stored as 200mL aliquots at 4℃ without any detergent or heat treatment. The CP was then treated with methylene blue and light treatment for 30 minutes in the medical plasma virus inactivation cabinet (Shandong Zhongbaokang Medical Appliance Co., Ltd).

Serology test and real-time RT–PCR detection of SARS-CoV-2 and other pathogens

The neutralized activity of plasma was determined by p laque reduction neutralization test using SARS-CoV-2 virusin the high biosafy level (BSL-4) laboratory of Wuhan Institute of Virology, Chinese Academy of Sciences.Neutralization titer was defined as the highest serum dilution with 50 % reduction in the number of plaques, as compared with the number of plaques in wells in the absence of novel coronavirus antibody as blank control.The neutralization activity of the receptor-binding domain (RBD) of antibody in theCP was detected by a sandwich ELISA.SARS-CoV-2-IgG antibody titer was tested by enzyme-linked immunosorbent assay. SARS-CoV-2 RNA was detected by RT-PCR assay and the result was presented as cycle threshold (Ct) value (Shanghai BioGerm Medical Biotechnology Co., Ltd). Methylene blue residue was detected by the verified ultraviolet method. The serology screening for hepatitis B and C virus, human immunodeficiency virus, and syphilis spirochete was negative. The protocols for SARS-CoV-2 serology and RNAtest are presented in the supplementary materials.

Treatment

All patients were admitted to the intensive care unit (ICU) and received antiviral therapy and other supportive care, while somepatients received antibiotic treatment, antifungal treatment, glucocorticoid and oxygen support at the appropriate situation. One dose of 200mL inactivated CP with neutralization activity >1: 640 was transfused into the patients within 4 hours following the WHO blood transfusion protocol.

Data collection

Clinical information of all enrolled patients was retrieved from the hospital electronic history system, including the baseline demographic data, days of illness duration, presenting symptoms, different kinds of examination and methods of treatment. Bacterial co-infection was identified by a positive culture from respiratory, urinary or blood culture within 48h of hospital admission. Complications including acute renal failure, acute coronary syndrome, myocarditis, acute respiratory distress syndrome, and nosocomial infection were recorded. The applications of assisted mechanical ventilation, intranasal oxygen inhalation, and medication regimen were recorded. The SARS-CoV-2 RNA from the serum sample was monitored during treatment.

Outcome Measures and Definitions

The clinical symptoms were recorded by attending physicians daily. The blood test and biochemical tests were carried out every 1-2 days. SARS-CoV-2 RNA was detected every 2-3 days. CT scan was repeated every 3-5 days. The primary endpoint was the safety of CP transfusion. The second endpoints were the improvement of clinical symptoms, laboratory and radiological parameters within 3 days after CP transfusion. The clinical symptoms improvement was defined as temperature normalization, relief of dyspnea, and oxygen saturation normalization, and the radiological improvement was defined as different degrees of absorption of lung lesions.

Statistical analysis

Continuous variables were presented as the median and interquartile range (IQR). Graphs were plotted using GraphPad Prism 7.0. Statistical software used included SPSS 24.0.

Data Availability statement

The data that support the findings of this study are a vailable from the corresponding author on reasonable request. Participant data without names and identifiers will be made available after approval from the corresponding author. After publication of study findings, the data will be available for others to request. The research team will provide an email address for communication once the data are approved to be shared with others. The proposal with detailed description of study objectives and statistical analysis plan will be needed for evaluation of the reasonability to request for our data. The corresponding author will make decision based on these materials. Additional materials may also be required during the process.

Acknowledgments

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Figures and Tables

Figure 1. Chest CTs of two patients

(*A*) Chest CT of patient 9 obtained on Feb 9 (7 dpoi) beforeconvalescent plasma transfusion (10 dpoi)showed ground glass opacity with uneven density involving the multilobal segments of both lungs. The heart shadow outline was not clear. The lesion was close to the pleura. (*B*) CT Image of patient 9 taken on Feb 15(13 dpoi) showed the absorption of bilateral ground glassopacity after convalescent plasma transfusion. (*C*)Chest CT of patient 10 was obtained on Feb 8 (19 dpoi) before convalescent plasma transfusion (20 dpoi). The brightness of both lungs was diffusely decreased and multiple shadows of high density in both lungs were observed.(*D*) Chest CTof patient 10 on Feb 18 (29dpoi) showed those lesions improvedafter convalescent plasma transfusion.

Figure 2. Dynamic changes of laboratory parameters in all patients.

The dotted horizontal line represents the reference value range. CP=convalescent plasma. CRP=C-reactive protein. SaO_2=oxyhemoglobin saturation. TBIL=total bilirubin. ALT=alanine aminotransferase. AST=aspartate aminotransferase.

Figure 3. Change of laboratory parameters in patient 1

X-axis represents the day post convalescent plasma transfusion.The dotted horizontal line represents the reference value range. CP=convalescent plasma. CRP=C -reactive protein. SaO_2=oxyhemoglobin saturation. TBIL=total bilirubin. ALT=alanine aminotransferase. AST=aspartate aminotransferase.

Table 1. Clinical characteristics of patients receiving convalescent plasma transfusion.

No.	Sex	Age	Clinical classification	Days of admission from symptom onset	Days of convalescent plasma therapy from symptom onset	Clustering infection	Principal symptoms	Comorbidity
1	M	46	Severe	8	11	No	Fever, cough, sputum production, shortness of breath, chest pain	Hypertension
2	F	34	Severe	0	11	Yes	Cough, shortness of breath, chest pain, nausea and vomiting	None
3	M	42	Severe	8	19	Yes	Fever, cough, sputum production, shortness of breath, sore throat, diarrhea	Hypertension
4	F	55	Severe	10	19	No	Fever, cough, sputum production, shortness of breath	None
5	M	57	Severe	4	14	No	Fever, shortness of breath	None
6	F	78	Severe	8	17	Yes	Fever, cough, sputum production, shortness of breath, muscle ache	None
7	M	56	Severe	4	16	No	Fever, cough, sputum production, arthralgia	None
8	M	67	Severe	10	20	No	Fever, cough, headache, diarrhea, vomiting	Cardiovascular andcerebrovascular diseases
9	F	49	Severe	1	10	No	Cough, shortness of breath	None
10	M	50	Severe	3	20	No	Shortness of breath	Hypertension

M=male. F=female.

Table 2. Other treatments of ten patients receiving convalescent plasma transfusion.

No.	Drugs administered			Oxygen support	
	Antiviral treatment	Antibiotic or antifungal treatment	Corticosteroids treatment	Before convalescent plasma therapy	After convalescent plasma therapy
1	Arbidol0.2g q8h po. Ribavirin 0.5g qdi.v.	Cefoperazone Sodium i.v.	None	High-flow nasal cannula, mechanical ventilation	Mechanical ventilation
2	Arbidol0.2g q8hpo.	Cefoperazone Sodium i.v.	None	None	None
3	Arbidol0.2g q8hpo.	Moxifloxacini.v.	Methylprednisolone i.v.	High-flow nasal cannula, mechanical ventilation	High-flow nasal cannula
4	Ribavirin 0.5g qdi.v.	Linezolid i.v.Imipenem - Sitastatin Sodium i.v.	Methylprednisolone i.v.	Mechanical ventilation	High-flow nasal cannula
5	Arbidol0.2g q8hpo. Remdesivir0.2gqdi.v. Interferon-α 500MIUqdinh.	Moxifloxacini.v.Cefoperagone Sodium and Tazobactam Sodium i.v.	Methylprednisolone i.v.	Low-flow nasal cannula	Low-flow nasal cannula
6	Arbidol0.2g q8h po.	Cefoperazone Sodium i.v. Levofloxacin i.v.	Methylprednisolone i.v.	High-flow nasal cannula	High-flow nasal cannula
7	Arbidol0.2g q8h po.	Cefoperagone Sodium and Tazobactam Sodium i.v. Fluconazole i.v.	Methylprednisolone i.v.	High-flow nasal cannula	none
8	Arbidol0.2g q8h po. Ribavirin 0.5g qdi.v.	None	None	None	None
9	Arbidol0.2g q8h po. Oseltamivir75mg q12h po. Peramivir0.3gqdi.v.	None	None	Low-flow nasal cannula	Low-flow nasal cannula (Intermittent)
10	Arbidol0.2g q8h po. Interferon-α 500MIU qdinh.	Cefoperazone Sodium i.v.Caspofungini.v.	Methylprednisolone i.v.	High-flow nasal cannula	High-flow nasal cannula

po.=peros. i.v.=intravenous injection. inh.=inhalation.

Table 3. Comparison of laboratory parameters before and after convalescent plasma transfusion

Clinical Factors	BeforeCP transfusion	After CPtransfusion
C-reactive protein (mg/L, normal range 0-6)	55.98 (15.57-66.67)	18.13 (10.92-71.44)
Lymphocyte (10^9 per L, normal range 1.1-3.2)	0.65 (0.53-0.90)	0.76 (0.52-1.43)
Alanine aminotransferase (U/L, normal range 9-50)	42.00 (28.25-61.85)	34.30 (25.75-53.90)
Aspartate aminotransferase (U/L, normal range 15-40)	38.10 (28.50-44.00)	30.30 (17.30-38.10)
Total bilirubin (μmol/L, normal range 0-26)	12.40 (11.71-22.05)	13.98 (12.20-20.80)
SaO_2 (%, normal range ≥95)	93.00 (89.00-96.50)	96.00 (95.00-96.50)

SaO_2=oxyhemoglobin saturation.

Table 4. Comparison of serum neutralizing antibody tit ers and SARS-CoV-2 RNA load before and after convalescent plasma therapy

patient No.	CP transfusionDate	Before CP transfusion			After CP transfusion		
		Date	Serum neutralizing antibody titres	Serum SARS-CoV-2 RNA load (Ct value)	Date	Serum neutralizing antibody titres	Serum SARS-CoV-2 RNA load (Ct value)
1	February 9	February 8	1:160	37.25	February 10	1:640	negative
2	February 9	February 8	Unavailable	35.08	February 11	Unavailable	negative
3	February 13	February 12	1:320	38.07	February 14	1:640	negative
4	February 13	February 12	1:160	37.68	February 14	1:640	negative
5	February 12	February 11	1:640	negative	February 14	1:640	negative
6	February 12	February 11	1:640	negative	February 14	1:640	negative
7	February 12	February 11	1:320	34.64	February 14	1:640	negative
8	February 12	February 11	1:640	35.45	February 14	1:640	negative
9	February 12	February 11	1:160	negative	February 14	1:640	negative
10	February 9	February 8	1:640	38.19	February 14	1:640	negative

Figure 1:

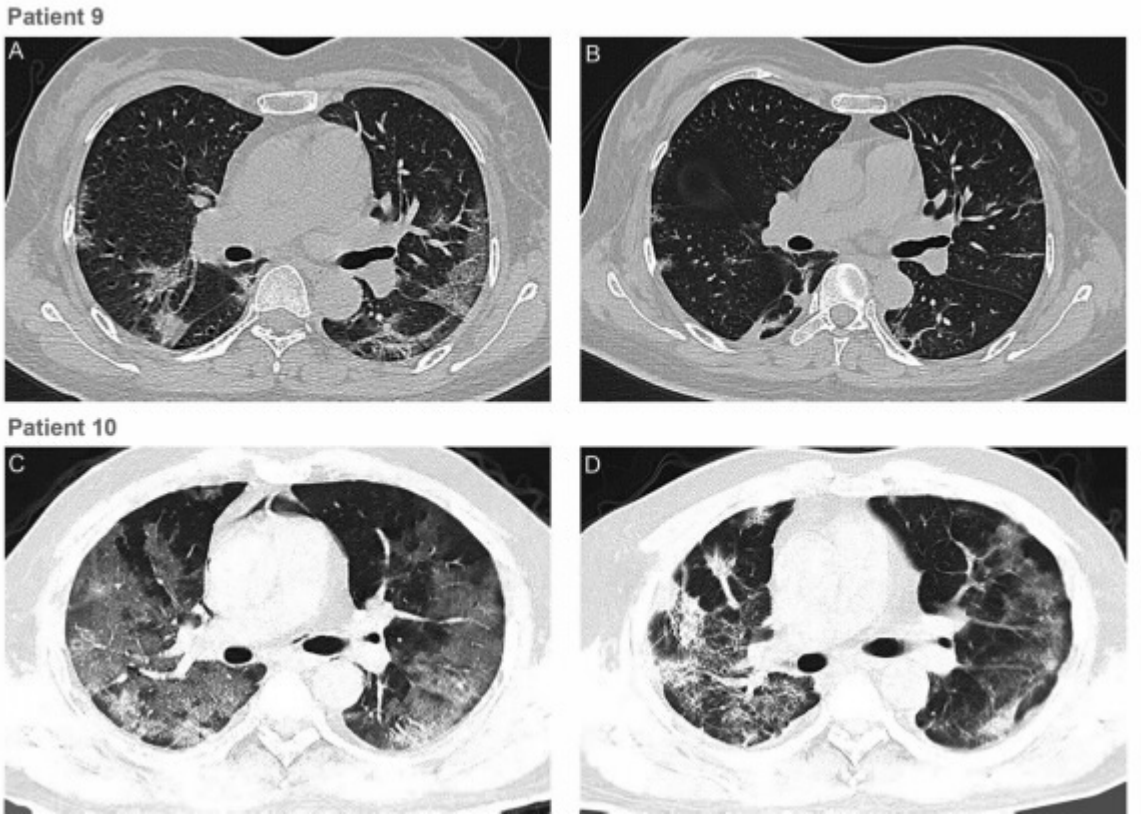


Figure 2:

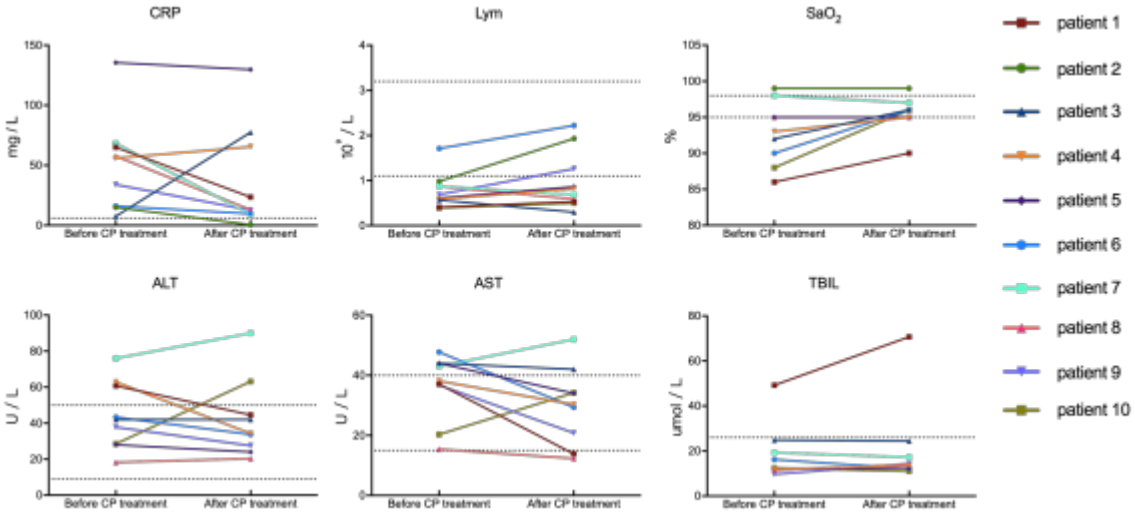
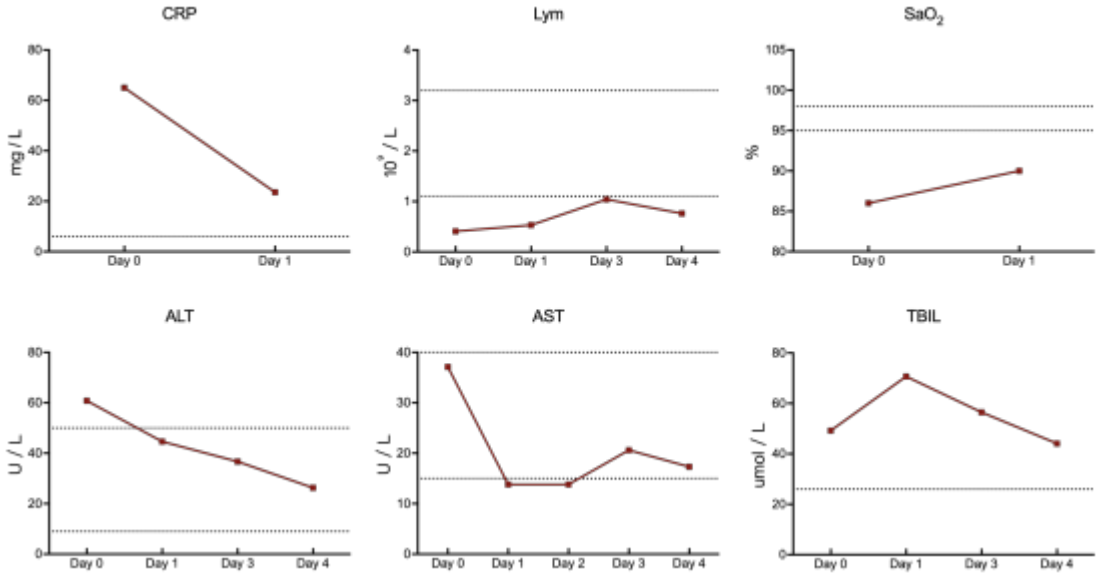


Figure 3:



From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: zoom - see agenda & background materials below

Importance: Normal

Subject: CONFIRMED: Second advisory call for COVID-19 webinar series

Start Time: Fri 3/27/2020 3:00:00 PM (UTC-04:00)

End Time: Fri 3/27/2020 4:30:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Agenda and background materials: https://docs.google.com/document/d/1CK5G6gmaKYaIRvhx8GS7QJGStXXpf0-aT1yGLS-hscw/edit?usp=sharing

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Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: COVID-19 webinar series advisors call
Time: Mar 27, 2020 03:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/797361197

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From: 罗波[luob041@nenu.edu.cn]
Sent: Fri 3/27/2020 11:34:22 AM (UTC-04:00)
Subject: 'Survey to help preserve Chinese bats: bat researcher, please help'

Dear Bat Researchers,
Good day! More than 130 bat species have been recorded in China. None of them are included in the List of Chinese State Key Protected Wildlife, although some bat species are in rapid decline in recent decades. Many Chinese people experience intense panic at the thought of bats and some even propose to kill bats since the outbreak of novel coronavirus (COVID-19). In this case, we are dedicated to gathering researchers' opinions on the major threats and conservation strategies of bats in China. We restricted the population surveyed to researchers and students worldwide that have research experience on bats. Through this brief survey, your answers may be helpful in improving the conservation status of bats in China. There is no right or wrong answer to the question. Your response will only be used for survey purposes. Thank you very much for your valuable time and suggestions! Could you please also send this email to your colleagues and students? If you have already received my e-mail please disregard.

Here is the network link of our self-designed questionnaire: https://www.wjx.cn/jq/66714439.aspx

Best,

Bo Luo, PhD
Key Laboratory of Southwest China Wildlife Resources Conservation (Ministry of Education), China West Normal University 1# Shida Road, Nanchong 637002, ChinaJilin Provincial Key Laboratory of Animal Resource Conservation and Utilization, Northeast Normal University, 2555 Jingyue Street, Changchun 130117, China

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To: Wade, David[david.wade@hq.dhs.gov]
From: Mark Keim[mark@disasterdoc.org]
Sent: Sun 3/29/2020 6:43:58 PM (UTC-04:00)
Subject: Re: Masks

All
These discussions remind me of the response to our early concern regarding the lack of PPE being worn at the WTC response.
The time weighted averages of millions of worker hours have borne out the effectiveness of N95 used entire work shifts by multiple sectors. Contrary to some public advisories, they are very effective in preventing both droplet and airborne infections.

I understand the current implications of the PPE market, but I also understand the need for an informed consent among the public that will seek to find the evidence behind such decisions. No one ever thanks us for making “paternal” decisions when things go wrong. WTC, anthrax, Flint...people want us to communicate their risk and allow them to make their own decisions regarding acceptable risk - risk communication 101.

Perhaps (more than likely) I’m too far out of the loop, but I’m unaware of a data-driven profile that places public mask wearing as a higher risk than benefit. I personally don’t understand why we would tell the public that they are not effective. However, I am aware of the Los Alamos model for Influenza that estimated a 20% drop in flu cases for 10% of the population wearing masks. Did I miss something since then?

How does the fact that we are not a mask wearing culture (like S Korea and Japan where the epi curves also happen to be less steep) impact community transmission?. As far as I know, the answer remains unknown as of date. Is there evidence to support the use of masks by infected symptomatic and asymptomatic) individuals?

I join Jerry in wondering why we would willingly give up on pilot implementation and study of any potential impact.

All my best,

Mark

On Mar 29, 2020, at 4:30 PM, Wade, David <david.wade@hq.dhs.gov> wrote:

As the surgeon in the crowd, I'll add my two cents.

We probably all had the unpleasant and embarrassing experience of contaminating ourselves (usually by touching our face while scrubbed-in), or even worse, then contaminating the surgical field. After the requisite berating by the attending surgeon, we got to scrub-out and re-scrub to rejoin the case. That was a Learning Experience that seldom required repeat lessons.

But above and beyond remembrances of 3rd year medical school rotations, when wearing a mask, you actually do learn to NOT touch your face. It eventually becomes something you don't even think about.

So, I concur with Jerry's idea. If nothing else, it provides constant reminders that we need to not touch our face. The cloth face mask are probably less likely to need adjustment.

Dave

From: Martin, Gregory J <MartinGJ@state.gov>
Sent: Sunday, March 29, 2020 12:44 PM
To: McDonald, Eric <Eric.McDonald@sdcounty.ca.gov>; jmothershead@patronusmedical.com
Cc: Dr. Eva Lee <eva.evalee.lee64@gmail.com>; Carter Mecher <cmecher@charter.net>; 1974usna@gmail.com; TARANTINO, DAVID A <david.a.tarantino@cbp.dhs.gov>; Caneva, Duane <duane.caneva@hq.dhs.gov>; Dr. Eva K Lee <evalee-gatech@pm.me>; Lawler, James V <james.lawler@unmc.edu>; Ciottone,Gregory (HMFP - Emergency Medicine) <gciotton@bidmc.harvard.edu>; Richard Tubb <bg.richard.tubb@gmail.com>; reddawn@mphise.us; Arthur Kellermann <arthur.kellermann@usuhs.edu>; William Lang <wlang@worldclinic.com>; Rob Darling, MD <rdarling@patronusmedical.com>; Mecher, Carter <Carter.Mecher@va.gov>; Jamison Day <jamison.day@gmail.com>; Logan, Linda L <llogan@cvm.tamu.edu>; Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@hhs.gov>; Venkayya, Rajeev <rajeev.venkayya@takeda.com>; Ronny Jackson <ronny.jacksonmd@gmail.com>; Eastman, Alexander <alexander.eastman@hq.dhs.gov>; Mansoura, Monique K. <mmansoura@mitre.org>; LLogandakar <llogandakar@gmail.com>; Walters, William <WaltersWA2@state.gov>; Parker Jr, Gerald W <gparker@cvm.tamu.edu>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>; EVANS, MARIEFRED <mariefred.evans@associates.hq.dhs.gov>; Kevin Montgomery <kevin@collaborate.org>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; DC <michelle.colby@usda.gov>; Matthew JtCIVtUSARMY (USA) <matthew.j.hepburn.civ@mail.mil>; Andy Desjardins, MD <adesjardins@patronusmedical.com>; Fantinato, Jessica (USDA.GOV) <jessica.fantinato@usda.gov>; Yeskey, Kevin <kevin.yeskey@hhs.gov>; Danny Shiau <danny.shiau@usuhs.edu>; Ryan Morhard <Ryan.Morhard@weforum.org>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Borio, Luciana <LBorio@iqt.org>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; KAUSHIK, SANGEETA <sangeeta.kaushik@hq.dhs.gov>; CHRISTOPHER ALLEN <chrisallen_10@msn.com>; Cordts, Jerome (CTR) <jerome.cordts@associates.hq.dhs.gov>; Baric, Ralph S <rbaric@email.unc.edu>; Schnitzer, Jay J. <jschnitzer@mitre.org>; jwleduc@utmb.edu; HARVEY, MELISSA <melissa.harvey@hq.dhs.gov>; Lisa Koonin <lkoonin1@gmail.com>; Padget, Larry G <PadgetLG@state.gov>; M.D. <MVCALLAHAN@mgh.harvard.edu>; Ignacio, Joselito <joselito.ignacio@fema.dhs.gov>; David <DMarcozzi@som.umaryland.edu>; Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Hanfling, Dan <DHanfling@iqt.org>; Will Gaskins <will.gaskins@efiia.com>; Lee, Scott <Scott.Lee@hhs.gov>; Lauren Johnston <ljohnston@patronusmedical.com>; Steven Jt(tCHFStDPH) <steven.stack@ky.gov>; Tom Bossert <tom.bossert@me.com>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; HAMILTON, CAMERON <cameron.hamilton@hq.dhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; David Gruber <david.gruber@dshs.texas.gov>; Wade, David <david.wade@hq.dhs.gov>; Lewis Hofmann <lewhof@mac.com>; WILKINSON, THOMAS <THOMAS.WILKINSON@hq.dhs.gov>; WOLFE, HERBERT <HERBERT.WOLFE@hq.dhs.gov>; CharitytA@CDPH <Charity.Dean@cdph.ca.gov>; Taylor, Justin (CTR) <justin.taylor@associates.hq.dhs.gov>; Marinissen, Maria <Maria.Marinissen@hhs.gov>; Sutter, Mark <mark.sutter@hq.dhs.gov>; Mark Keim, MD MBA <mark@disasterdoc.org>; Richard Hatchett

<richard.hatchett@cepi.net>; McLeod James <jmcleod@patronusmedical.com>; Wine G.C. <gcwine@patronusmedical.com>; Dan Carlin <dcarlin@worldclinic.com>; Krohmer, Jon (NHTSA) <jon.krohmer@dot.gov>; Jolly, Brantley (OS/ASPR/EMMO) (CTR) <Brantley.Jolly@hhs.gov>; Hart,Alexander (APHMFP - Emergency Medicine) <ahart1@bidmc.harvard.edu>
Subject: RE: Masks

I spent a couple weeks at our embassy in Beijing in February and as we all know the Chinese govt required masks to be worn by everyone out on the street.
I agree with Jerry that masks do give you constant awareness that things are not usual and you should avoid touching your mouth or nostrils. However, I also found that as I watched others, and myself, the constant need to adjust your mask, stop the mask from riding down or up on your nose, clear your glasses from fogging… actually makes people more likely to be touching your face.
Greg

From: McDonald, Eric <Eric.McDonald@sdcounty.ca.gov>
Sent: Sunday, 29 March, 2020 12:16
To: jmothershead@patronusmedical.com
Cc: Dr. Eva Lee <eva.evalee.lee64@gmail.com>; Carter Mecher <cmecher@charter.net>; 1974usna@gmail.com; TARANTINO, DAVID A <david.a.tarantino@cbp.dhs.gov>; Caneva, Duane <duane.caneva@hq.dhs.gov>; Dr. Eva K Lee <evalee-gatech@pm.me>; Lawler, James V <james.lawler@unmc.edu>; Ciottone,Gregory (HMFP - Emergency Medicine) <gciotton@bidmc.harvard.edu>; Richard Tubb <bg.richard.tubb@gmail.com>; reddawn@mphise.us; Arthur Kellermann <arthur.kellermann@usuhs.edu>; William Lang <wlang@worldclinic.com>; Rob Darling, MD <rdarling@patronusmedical.com>; Mecher, Carter <Carter.Mecher@va.gov>; Jamison Day <jamison.day@gmail.com>; Logan, Linda L <llogan@cvm.tamu.edu>; Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@hhs.gov>; Venkayya, Rajeev <rajeev.venkayya@takeda.com>; Ronny Jackson <ronny.jacksonmd@gmail.com>; Eastman, Alexander <alexander.eastman@hq.dhs.gov>; Mansoura, Monique K. <mmansoura@mitre.org>; LLogandakar <llogandakar@gmail.com>; Walters, William <WaltersWA2@state.gov>; Parker Jr, Gerald W <gparker@cvm.tamu.edu>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>; EVANS, MARIEFRED <mariefred.evans@associates.hq.dhs.gov>; Kevin Montgomery <kevin@collaborate.org>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; DC <michelle.colby@usda.gov>; Matthew JtCIVtUSARMY (USA) <matthew.j.hepburn.civ@mail.mil>; Andy Desjardins, MD <adesjardins@patronusmedical.com>; Fantinato, Jessica (USDA.GOV) <jessica.fantinato@usda.gov>; Yeskey, Kevin <kevin.yeskey@hhs.gov>; Danny Shiau <danny.shiau@usuhs.edu>; Martin, Gregory J <MartinGJ@state.gov>; Ryan Morhard <Ryan.Morhard@weforum.org>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Borio, Luciana <LBorio@iqt.org>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; KAUSHIK, SANGEETA <sangeeta.kaushik@hq.dhs.gov>; CHRISTOPHER ALLEN <chrisallen_10@msn.com>; Cordts, Jerome (CTR) <jerome.cordts@associates.hq.dhs.gov>; Baric, Ralph S <rbaric@email.unc.edu>; Schnitzer, Jay J. <jschnitzer@mitre.org>; jwleduc@utmb.edu; HARVEY, MELISSA <melissa.harvey@hq.dhs.gov>; Lisa Koonin <lkoonin1@gmail.com>; Padget, Larry G <PadgetLG@state.gov>; M.D. <MVCALLAHAN@mgh.harvard.edu>; Ignacio, Joselito <joselito.ignacio@fema.dhs.gov>; David <DMarcozzi@som.umaryland.edu>; Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Hanfling, Dan <DHanfling@iqt.org>; Will Gaskins <will.gaskins@efiia.com>; Lee, Scott <Scott.Lee@hhs.gov>; Lauren Johnston <ljohnston@patronusmedical.com>; Steven Jt(tCHFStDPH) <steven.stack@ky.gov>; Tom Bossert <tom.bossert@me.com>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; HAMILTON, CAMERON <cameron.hamilton@hq.dhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; David Gruber <david.gruber@dshs.texas.gov>; Wade, David <David.Wade@hq.dhs.gov>; Lewis Hofmann <lewhof@mac.com>; WILKINSON, THOMAS <THOMAS.WILKINSON@hq.dhs.gov>; WOLFE, HERBERT <HERBERT.WOLFE@hq.dhs.gov>; CharitytA@CDPH <Charity.Dean@cdph.ca.gov>; Taylor, Justin (CTR) <justin.taylor@associates.hq.dhs.gov>; Marinissen, Maria <Maria.Marinissen@hhs.gov>; Sutter, Mark <mark.sutter@hq.dhs.gov>; Mark Keim, MD MBA <mark@disasterdoc.org>; Richard Hatchett <richard.hatchett@cepi.net>; McLeod James <jmcleod@patronusmedical.com>; Wine G.C. <gcwine@patronusmedical.com>; Dan Carlin <dcarlin@worldclinic.com>; Krohmer, Jon (NHTSA) <jon.krohmer@dot.gov>; Jolly, Brantley (OS/ASPR/EMMO) (CTR) <Brantley.Jolly@hhs.gov>; Hart,Alexander (APHMFP - Emergency Medicine) <ahart1@bidmc.harvard.edu>
Subject: Re: Masks

I think if the general public is wearing bandanas and washable, reusable personal masks (which can be made or bought) then the general public goal is met while preserving masks for HCW. My teenage son has six or seven bands as in our house. This is not a hard item to locate/find/make. I think this should be a wide recommendation for now.

Sent from my iPhone

> On Mar 29, 2020, at 9:11 AM, "jmothershead@patronusmedical.com" <jmothershead@patronusmedical.com> wrote:
>
> I am going to float an idea, and would appreciate any contrarian thoughts.
>
> From day one of the outbreak, we have all (myself included) put out there that surgical masks really do not protect you from COVID, what hey do is reduce someone with COVID from spewing droplets everywhere.
>
> I still believe that, BUT, we (at least I) was thinking about the lack of protection from airborne spread.
>
> I now am coming to believe that there MAY be a role for wearing masks of some sort, even for people who have no symptoms whatsoever, at least out in public. Why? Because of two things…wearing a mask is radically different that what we normally do, it would be a constant reminder to people to be diligent in social distancing and hygiene practices. But perhaps more importantly, I have read varying numbers, but I have seen that people touch their faces between 30-90 times/day, and it usually totally subconsciously. THAT is a hard habit to break.
>
> So, if I wear a mask, while away from home, I am not going to be directly touching my mouth or nose. Even if I have virus on my hand, it shouldn't be able to get to my mouth or nose. If I immediately remove the mask, throw it away or toss it in a bucket, then wash my face and hands, I have likely reduced the probability of getting infected through fomite spread. In China, 100% of the population had to wear masks when away from home, and if we are to believe their numbers (even if twice what they actually reported and are reporting), they have actually gotten a pretty good handle on the spread of disease. Could this have been partially responsible for it?
>
> I am not talking about taking surgical masks from the hospitals. There have been a bunch of local drives to have citizens make cloth masks, only to find that the hospitals won't accept them.
>
> In risk management, we often talk about engineering controls and administrative controls. Telling people not to touch their not to touch their faces is an admin control, wearing a mask in public is an engineering control. When we first mandated seat belts (an admin control), there was a lot of non-compliance, primarily because it was not in peoples' habit patterns. Then, the auto manufacturers started putting bells and buzzers that would go off incessantly until you put on your seat belt…so compliance went way up because of the noise.
>
> Would there be any down side to this? Are my assumptions wrong?
>
> **From:** Dr. Eva Lee <eva.evalee.lee64@gmail.com>
> **Sent:** Sunday, March 29, 2020 11:32 AM
> **To:** Carter Mecher <cmecher@charter.net>
> **Cc:** 1974usna@gmail.com; TARANTINO, DAVID A <david.a.tarantino@cbp.dhs.gov>; Caneva, Duane <Duane.Caneva@hq.dhs.gov>; Dr. Eva K Lee <evalee-gatech@pm.me>; Lawler, James V <james.lawler@unmc.edu>; Ciottone,Gregory (HMFP - Emergency Medicine) <gciotton@bidmc.harvard.edu>; Richard Tubb <bg.richard.tubb@gmail.com>; reddawn@mphise.us; Arthur Kellermann <arthur.kellermann@usuhs.edu>; William Lang <wlang@worldclinic.com>; Rob Darling, MD <rdarling@patronusmedical.com>; Mecher, Carter <Carter.Mecher@va.gov>; Jamison Day <jamison.day@gmail.com>; Logan, Linda L <llogan@cvm.tamu.edu>; Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@hhs.gov>; Venkayya, Rajeev <rajeev.venkayya@takeda.com>; Ronny Jackson

<ronny.jacksonmd@gmail.com>; Eastman, Alexander <Alexander.Eastman@hq.dhs.gov>; Mansoura, Monique K. <mmansoura@mitre.org>; LLogandakar <llogandakar@gmail.com>; Walters, William (STATE.GOV) <walterswa2@state.gov>; Parker Jr, Gerald W <gparker@cvm.tamu.edu>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>; EVANS, MARIEFRED <mariefred.evans@associates.hq.dhs.gov>; Kevin Montgomery <kevin@collaborate.org>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; DC <michelle.colby@usda.gov>; Matthew JtCIVtUSARMY (USA) <matthew.j.hepburn.civ@mail.mil>; Andy Desjardins, MD <adesjardins@patronusmedical.com>; Fantinato, Jessica (USDA.GOV) <jessica.fantinato@usda.gov>; Yeskey, Kevin <kevin.yeskey@hhs.gov>; Danny Shiau <danny.shiau@usuhs.edu>; Martin, Greg (state.gov) <MartinGJ@state.gov>; Ryan Morhard <Ryan.Morhard@weforum.org>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Borio, Luciana <LBorio@iqt.org>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; KAUSHIK, SANGEETA <SANGEETA.KAUSHIK@hq.dhs.gov>; Eric (San Diego County) <eric.mcdonald@sdcounty.ca.gov>; CHRISTOPHER ALLEN <CHRISALLEN_10@msn.com>; Cordts, Jerome (CTR) <jerome.cordts@associates.hq.dhs.gov>; Baric, Ralph S <rbaric@email.unc.edu>; Schnitzer, Jay J. <Jschnitzer@mitre.org>; jwleduc@utmb.edu; HARVEY, MELISSA <MELISSA.HARVEY@hq.dhs.gov>; Lisa Koonin <lkoonin1@gmail.com>; Larry G <PadgetLG@state.gov>; M.D. <MVCALLAHAN@mgh.harvard.edu>; Ignacio, Joselito <joselito.ignacio@fema.dhs.gov>; David <DMarcozzi@som.umaryland.edu>; Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Hanfling, Dan <DHanfling@iqt.org>; Will Gaskins <will.gaskins@efiia.com>; Lee, Scott (OS/ASPR/EMMO) <Scott.Lee@hhs.gov>; Lauren Johnston <ljohnston@patronusmedical.com>; Steven Jt(tCHFStDPH) <steven.stack@ky.gov>; Tom Bossert <tom.bossert@me.com>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; HAMILTON, CAMERON <CAMERON.HAMILTON@hq.dhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; David Gruber <david.gruber@dshs.texas.gov>; Wade, David <David.Wade@hq.dhs.gov>; Lewis Hofmann <lewhof@mac.com>; WILKINSON, THOMAS <THOMAS.WILKINSON@hq.dhs.gov>; WOLFE, HERBERT <HERBERT.WOLFE@hq.dhs.gov>; CharitytA@CDPH <Charity.Dean@cdph.ca.gov>; Taylor, Justin (CTR) <justin.taylor@associates.hq.dhs.gov>; Marinissen, Maria (HHS/OS/OGA) <Maria.Marinissen@hhs.gov>; Sutter, Mark <Mark.Sutter@hq.dhs.gov>; Mark Keim, MD MBA <mark@disasterdoc.org>; Richard Hatchett <richard.hatchett@cepi.net>; McLeod James <jmcleod@patronusmedical.com>; Wine G.C. <gcwine@patronusmedical.com>; Dan Carlin <dcarlin@worldclinic.com>; Jerry Mothershead <jmothershead@patronusmedical.com>; Krohmer, Jon (NHTSA) <jon.krohmer@dot.gov>; Jolly, Brantley (OS/ASPR/EMMO) (CTR) <Brantley.Jolly@hhs.gov>; Hart,Alexander (APHMFP - Emergency Medicine) <ahart1@bidmc.harvard.edu>
Subject: Re: Red Dawn Pondering, Start Mar 27, 15:45

Please see attached an updated slides for NYC on bed surge.Sorry, I forgot to include the finding slide. You can see the drastic reduction in overall infection and mortality if NYC receives medical surge on April 1 -- over 88% reduction in both. NYC is the heartbeat of US and if NYC falls, it will affect the morale of every single frontline worker throughout the US. So we must work very hard to make sure NYC win!!

In the meantime, I should determine/optimize the surge to so many other at-risk cities. I will get back to the analysis.

And keep in mind all the neighbouring effect (and inter-dependency and cascading effects) as you implement your plans.

On Sun, Mar 29, 2020 at 8:19 AM Dr. Eva Lee <eva.evalee.lee64@gmail.com> wrote:

Three items: **cities at risks, bed surge and results, and update from NYP**

1. Cities/Counties at Risks:
We have many fires -- it's spreading rapidly. Sorry a very long list here. Please take action. Cook (IL), Oakland+Wayne (MI), New Orleans (LA), Palm Beach+Miami (FL), King+two neighours (WA), Santa Clara+neighbors, Los Angels+neighbors (CA) Fulton+DeKalb (GA) NJ,CT, Clark (NV),

2. Here's the New York City with 10,000 beds and 5,000. You can see we can blunt the total

infection with 10,000 bed surge and 5,000 the low-acuity units. The results for NYC can be drastic. I take that NYC was 4 weeks late in closing schools, Recall Feb 20 is the Day 1 on these curves. NY City finishes school closing and tele-work on March 23.
In am include closing in Week 3 just to show the contrast. Please get NYC the beds it needs.

3. Here's the number of hospitalization for the last 7 days:
598 654 722 >1000 1100 1229 1323, About 20% of covid-19 patients need ICU care (virtually all nee ventilators). There are also ED covid-19 patients who are waiting for beds (surge can help here).

Please keep in mind these are just snapshots, probably in the morning. But you can see number of admitted outpaces the discharged ones.

On Sun, Mar 29, 2020 at 6:56 AM Carter Mecher <cmecher@charter.net> wrote:
Sorry, use this table (had the wrong dates for China.

Comparison of COVID-19 Cumulative Deaths									
France Date	France (65M)	Spain Date	Spain (47M)	Italy Date	Italy (60M)	US Date	US (330M)	UK Date	UK
						20-Feb	0.0		
						21-Feb	0.0		
						22-Feb	0.0		
						23-Feb	0.0		
						24-Feb	0.0		
						25-Feb	0.0	20-Feb	
						26-Feb	0.0	21-Feb	
						27-Feb	0.0	22-Feb	
20-Feb	0.0					28-Feb	0.0	23-Feb	
21-Feb	0.0					29-Feb	0.0	24-Feb	
22-Feb	0.0					1-Mar	0.0	25-Feb	
23-Feb	0.0	20-Feb	0.0			2-Mar	0.0	26-Feb	
24-Feb	0.0	21-Feb	0.0			3-Mar	0.0	27-Feb	
25-Feb	0.0	22-Feb	0.0			4-Mar	0.0	28-Feb	
26-Feb	0.0	23-Feb	0.0			5-Mar	0.0	29-Feb	
27-Feb	0.0	24-Feb	0.0			6-Mar	0.0	1-Mar	
28-Feb	0.0	25-Feb	0.0			7-Mar	0.1	2-Mar	

29-Feb	0.0	26-Feb	0.0			8-Mar	0.1	3-Mar	
1-Mar	0.0	27-Feb	0.0			9-Mar	0.1	4-Mar	
2-Mar	0.0	28-Feb	0.0	20-Feb	0.0	10-Mar	0.1	5-Mar	
3-Mar	0.1	29-Feb	0.0	21-Feb	0.0	11-Mar	0.1	6-Mar	
4-Mar	0.1	1-Mar	0.0	22-Feb	0.0	12-Mar	0.1	7-Mar	
5-Mar	0.1	2-Mar	0.0	23-Feb	0.1	13-Mar	0.1	8-Mar	
6-Mar	0.1	3-Mar	0.0	24-Feb	0.1	14-Mar	0.2	9-Mar	
7-Mar	0.2	4-Mar	0.0	25-Feb	0.2	15-Mar	0.2	10-Mar	
8-Mar	0.3	5-Mar	0.0	26-Feb	0.2	16-Mar	0.3	11-Mar	
9-Mar	0.5	6-Mar	0.2	27-Feb	0.3	17-Mar	0.3	12-Mar	
10-Mar	0.5	7-Mar	0.4	28-Feb	0.4	18-Mar	0.5	13-Mar	
11-Mar	0.8	8-Mar	0.5	29-Feb	0.5	19-Mar	0.6	14-Mar	
12-Mar	0.9	9-Mar	0.6	1-Mar	0.6	20-Mar	0.8	15-Mar	
13-Mar	1.2	10-Mar	0.7	2-Mar	0.9	21-Mar	1.0	16-Mar	
14-Mar	1.4	11-Mar	1.2	3-Mar	1.3	22-Mar	1.4	17-Mar	
15-Mar	2.0	12-Mar	1.8	4-Mar	1.8	23-Mar	1.8	18-Mar	
16-Mar	2.3	13-Mar	2.6	5-Mar	2.5	24-Mar	2.3	19-Mar	
17-Mar	2.7	14-Mar	4.1	6-Mar	3.3	25-Mar	3.1	20-Mar	
18-Mar	3.8	15-Mar	6.1	7-Mar	3.9	26-Mar	3.9	21-Mar	
19-Mar	5.7	16-Mar	7.3	8-Mar	6.1	27-Mar	5.2	22-Mar	
20-Mar	6.9	17-Mar	10.9	9-Mar	7.7	28-Mar	6.7	23-Mar	
21-Mar	8.6	18-Mar	11.3	10-Mar	10.5			24-Mar	
22-Mar	10.4	19-Mar	17.1	11-Mar	13.8			25-Mar	
23-Mar	13.2	20-Mar	21.3	12-Mar	16.9			26-Mar	
24-Mar	16.9	21-Mar	28.2	13-Mar	21.1			27-Mar	
25-Mar	20.5	22-Mar	37.4	14-Mar	24.0			28-Mar	
26-Mar	24.6	23-Mar	46.4	15-Mar	30.2				

27-Mar	30.7	24-Mar	57.4	16-Mar	36.0
28-Mar	35.6	25-Mar	73.1	17-Mar	41.7
		26-Mar	87.0	18-Mar	49.6
		27-Mar	103.4	19-Mar	56.8
		28-Mar	121.1	20-Mar	67.2
				21-Mar	80.4
				22-Mar	91.3
				23-Mar	101.3
				24-Mar	113.7
				25-Mar	125.1
				26-Mar	136.1
				27-Mar	152.2
				28-Mar	167.1

Sent from Mail for Windows 10

From: Carter Mecher
Sent: Sunday, March 29, 2020 6:48 AM
To: 1974usna@gmail.com; 'TARANTINO, DAVID A'; 'Dr. Eva Lee'; 'Caneva, Duane'
Cc: 'Dr. Eva K Lee'; 'Lawler, James V'; 'Ciottone,Gregory (HMFP - Emergency Medicine)'; 'Richard Tubb'; reddawn@mphise.us; 'Arthur Kellermann'; 'William Lang'; 'Rob Darling, MD'; 'Mecher, Carter'; 'Jamison Day'; 'Logan, Linda L'; 'Dodgen, Daniel (OS/ASPR/SPPR)'; 'Venkayya, Rajeev'; 'Ronny Jackson'; 'Eastman, Alexander'; 'Mansoura, Monique K.'; 'LLogandakar'; 'Walters, William (STATE.GOV)'; 'Parker Jr, Gerald W'; 'DeBord, Kristin (OS/ASPR/SPPR)'; 'EVANS, MARIEFRED'; 'Kevin Montgomery'; 'Phillips, Sally (OS/ASPR/SPPR)'; 'DC'; 'Matthew JtCIVtUSARMY (USA)'; 'Andy Desjardins, MD'; 'Fantinato, Jessica (USDA.GOV)'; 'Yeskey, Kevin'; 'Danny Shiau'; 'Martin, Greg (state.gov)'; 'Ryan Morhard'; 'Disbrow, Gary (OS/ASPR/BARDA)'; 'Borio, Luciana'; 'Redd, John (OS/ASPR/SPPR)'; 'KAUSHIK, SANGEETA'; 'Eric (San Diego County)'; 'CHRISTOPHER ALLEN'; 'Cordts, Jerome (CTR)'; 'Baric, Ralph S'; 'Schnitzer, Jay J.'; jwleduc@utmb.edu; 'HARVEY, MELISSA'; 'Lisa Koonin'; 'Larry G'; 'M.D.'; 'Ignacio, Joselito'; 'David'; 'Hassell, David (Chris) (OS/ASPR/IO)'; 'Hanfling, Dan'; 'Will Gaskins'; 'Lee, Scott (OS/ASPR/EMMO)'; 'Lauren Johnston'; 'Steven Jt(tCHFStDPH)'; 'Tom Bossert'; 'Johnson, Robert (OS/ASPR/BARDA)'; 'HAMILTON, CAMERON'; 'Adams, Jerome (HHS/OASH)'; 'David Gruber'; 'Wade, David'; 'Lewis Hofmann'; 'WILKINSON, THOMAS'; 'WOLFE, HERBERT'; 'CharitytA@CDPH'; 'Taylor, Justin (CTR)'; 'Marinissen, Maria (HHS/OS/OGA)'; 'Sutter, Mark'; 'Mark Keim, MD MBA'; 'Richard Hatchett'; 'McLeod James'; 'Wine G.C.'; 'Dan Carlin'; 'Jerry Mothershead'; 'Krohmer, Jon (NHTSA)'; 'Jolly, Brantley (OS/ASPR/EMMO) (CTR)'; 'Hart,Alexander (APHMFP - Emergency Medicine)'
Subject: RE: Red Dawn Pondering, Start Mar 27, 15:45

A way of directly comparing the trajectories of the US, Europe (France, Spain, Italy, UK, Germany), and China (Hubei ad Wuhan) and getting a better sense of relative timing of each outbreak.

Comparison of COVID-19 Cumulative Deaths									
France Date	France (65M)	Spain Date	Spain (47M)	Italy Date	Italy (60M)	US Date	US (330M)	UK Date	UK
						20-Feb	0.0		
						21-Feb	0.0		
						22-Feb	0.0		
						23-Feb	0.0		
						24-Feb	0.0		
						25-Feb	0.0	20-Feb	
						26-Feb	0.0	21-Feb	
						27-Feb	0.0	22-Feb	
20-Feb	0.0					28-Feb	0.0	23-Feb	
21-Feb	0.0					29-Feb	0.0	24-Feb	
22-Feb	0.0					1-Mar	0.0	25-Feb	
23-Feb	0.0	20-Feb	0.0			2-Mar	0.0	26-Feb	

24-Feb	0.0	21-Feb	0.0			3-Mar	0.0	27-Feb	
25-Feb	0.0	22-Feb	0.0			4-Mar	0.0	28-Feb	
26-Feb	0.0	23-Feb	0.0			5-Mar	0.0	29-Feb	
27-Feb	0.0	24-Feb	0.0			6-Mar	0.0	1-Mar	
28-Feb	0.0	25-Feb	0.0			7-Mar	0.1	2-Mar	
29-Feb	0.0	26-Feb	0.0			8-Mar	0.1	3-Mar	
1-Mar	0.0	27-Feb	0.0			9-Mar	0.1	4-Mar	
2-Mar	0.0	28-Feb	0.0	20-Feb	0.0	10-Mar	0.1	5-Mar	
3-Mar	0.1	29-Feb	0.0	21-Feb	0.0	11-Mar	0.1	6-Mar	
4-Mar	0.1	1-Mar	0.0	22-Feb	0.0	12-Mar	0.1	7-Mar	
5-Mar	0.1	2-Mar	0.0	23-Feb	0.1	13-Mar	0.1	8-Mar	
6-Mar	0.1	3-Mar	0.0	24-Feb	0.1	14-Mar	0.2	9-Mar	
7-Mar	0.2	4-Mar	0.0	25-Feb	0.2	15-Mar	0.2	10-Mar	
8-Mar	0.3	5-Mar	0.0	26-Feb	0.2	16-Mar	0.3	11-Mar	
9-Mar	0.5	6-Mar	0.2	27-Feb	0.3	17-Mar	0.3	12-Mar	
10-Mar	0.5	7-Mar	0.4	28-Feb	0.4	18-Mar	0.5	13-Mar	
11-Mar	0.8	8-Mar	0.5	29-Feb	0.5	19-Mar	0.6	14-Mar	
12-Mar	0.9	9-Mar	0.6	1-Mar	0.6	20-Mar	0.8	15-Mar	
13-Mar	1.2	10-Mar	0.7	2-Mar	0.9	21-Mar	1.0	16-Mar	
14-Mar	1.4	11-Mar	1.2	3-Mar	1.3	22-Mar	1.4	17-Mar	
15-Mar	2.0	12-Mar	1.8	4-Mar	1.8	23-Mar	1.8	18-Mar	
16-Mar	2.3	13-Mar	2.6	5-Mar	2.5	24-Mar	2.3	19-Mar	
17-Mar	2.7	14-Mar	4.1	6-Mar	3.3	25-Mar	3.1	20-Mar	
18-Mar	3.8	15-Mar	6.1	7-Mar	3.9	26-Mar	3.9	21-Mar	
19-Mar	5.7	16-Mar	7.3	8-Mar	6.1	27-Mar	5.2	22-Mar	
20-Mar	6.9	17-Mar	10.9	9-Mar	7.7	28-Mar	6.7	23-Mar	
21-Mar	8.6	18-Mar	11.3	10-Mar	10.5			24-Mar	

22-Mar	10.4	19-Mar	17.1	11-Mar	13.8
23-Mar	13.2	20-Mar	21.3	12-Mar	16.9
24-Mar	16.9	21-Mar	28.2	13-Mar	21.1
25-Mar	20.5	22-Mar	37.4	14-Mar	24.0
26-Mar	24.6	23-Mar	46.4	15-Mar	30.2
27-Mar	30.7	24-Mar	57.4	16-Mar	36.0
28-Mar	35.6	25-Mar	73.1	17-Mar	41.7
		26-Mar	87.0	18-Mar	49.6
		27-Mar	103.4	19-Mar	56.8
		28-Mar	121.1	20-Mar	67.2
				21-Mar	80.4
				22-Mar	91.3
				23-Mar	101.3
				24-Mar	113.7
				25-Mar	125.1
				26-Mar	136.1
				27-Mar	152.2
				28-Mar	167.1

25-Mar	
26-Mar	
27-Mar	
28-Mar	

Sent from Mail for Windows 10

From: 1974usna@gmail.com
Sent: Saturday, March 28, 2020 10:05 PM
To: 'Carter Mecher'; 'TARANTINO, DAVID A'; 'Dr. Eva Lee'; 'Caneva, Duane'
Cc: 'Dr. Eva K Lee'; 'Lawler, James V'; 'Ciottone,Gregory (HMFP - Emergency Medicine)'; 'Richard Tubb'; reddawn@mphise.us; 'Arthur Kellermann'; 'William Lang'; 'Rob Darling, MD'; 'Mecher, Carter'; 'Jamison Day'; 'Logan, Linda L'; 'Dodgen, Daniel (OS/ASPR/SPPR)'; 'Venkayya, Rajeev'; 'Ronny Jackson'; 'Eastman, Alexander'; 'Mansoura, Monique K.'; 'LLogandakar'; 'Walters, William (STATE.GOV)'; 'Parker Jr, Gerald W'; 'DeBord, Kristin (OS/ASPR/SPPR)'; 'EVANS, MARIEFRED'; 'Kevin Montgomery'; 'Phillips, Sally (OS/ASPR/SPPR)'; 'DC'; 'Matthew JtCIVtUSARMY (USA)'; 'Andy Desjardins, MD'; 'Fantinato, Jessica (USDA.GOV)'; 'Yeskey, Kevin'; 'Danny Shiau'; 'Martin, Greg (state.gov)'; 'Ryan Morhard'; 'Disbrow, Gary (OS/ASPR/BARDA)'; 'Borio, Luciana'; 'Redd, John (OS/ASPR/SPPR)'; 'KAUSHIK, SANGEETA'; 'Eric (San Diego County)'; 'CHRISTOPHER ALLEN'; 'Cordts, Jerome (CTR)'; 'Baric, Ralph S'; 'Schnitzer, Jay J.'; jwleduc@utmb.edu; 'HARVEY, MELISSA'; 'Lisa Koonin'; 'Larry G'; 'M.D.'; 'Ignacio, Joselito'; 'David'; 'Hassell, David (Chris) (OS/ASPR/IO)'; 'Hanfling, Dan'; 'Will Gaskins'; 'Lee, Scott (OS/ASPR/EMMO)'; 'Lauren Johnston'; 'Steven Jt(tCHFStDPH)'; 'Tom Bossert'; 'Johnson, Robert (OS/ASPR/BARDA)'; 'HAMILTON, CAMERON'; 'Adams, Jerome (HHS/OASH)'; 'David Gruber'; 'Wade, David'; 'Lewis Hofmann'; 'WILKINSON, THOMAS'; 'WOLFE, HERBERT'; 'CharitytA@CDPH'; 'Taylor, Justin (CTR)'; 'Marinissen, Maria (HHS/OS/OGA)'; 'Sutter, Mark'; 'Mark Keim, MD MBA'; 'Richard Hatchett'; 'McLeod James'; 'Wine G.C.'; 'Dan Carlin'; 'Jerry Mothershead'; 'Krohmer, Jon (NHTSA)'; 'Jolly, Brantley (OS/ASPR/EMMO) (CTR)'; 'Hart,Alexander (APHMFP - Emergency Medicine)'
Subject: RE: Red Dawn Pondering, Start Mar 27, 15:45

Excellent educational video for the masses on the importance of social distancing, avoiding mass gatherings, etc.
https://www.youtube.com/watch?v=gxAaO2rsdIs&feature=emb_logo

From: Ignacio, Joselito[joselito.ignacio@fema.dhs.gov]

Attendees: 1974usna@gmail.com; TARANTINO, DAVID A; Dr. Eva K Lee; Lawler, James V; Ciottone,Gregory (HMFP - Emergency Medicine); Richard Tubb; reddawn@mphise.us; Arthur Kellermann; William Lang; Rob Darling, MD; Mecher, Carter; Jamison Day; Logan, Linda L; Dodgen, Daniel (OS/ASPR/SPPR); Venkayya, Rajeev; Ronny Jackson; Eastman, Alexander; Mansoura, Monique K.; LLogandakar; Walters, William (STATE.GOV); Parker Jr, Gerald W; DeBord, Kristin (OS/ASPR/SPPR); EVANS, MARIEFRED; Kevin Montgomery; Phillips, Sally (OS/ASPR/SPPR); DC; Matthew JtCIVtUSARMY (USA); Andy Desjardins, MD; Fantinato, Jessica (USDA.GOV); Yeskey, Kevin; Danny Shiau; Martin, Greg (state.gov); Ryan Morhard; Disbrow, Gary (OS/ASPR/BARDA); Borio, Luciana; Redd, John (Capt); KAUSHIK, SANGEETA; Eric (San Diego County); CHRISTOPHER ALLEN; Cordts, Jerome (CTR); Baric, Ralph S; Schnitzer, Jay J.; jwleduc@utmb.edu; HARVEY, MELISSA; Lisa Koonin; Larry G; M.D.; David; Hassell, David (Chris) (OS/ASPR/IO); Hanfling, Dan; Will Gaskins; Lee, Scott (OS/ASPR/EMMO); Lauren Johnston; Steven Jt(tCHFStDPH); Tom Bossert; Johnson, Robert (OS/ASPR/BARDA); HAMILTON, CAMERON; Adams, Jerome (HHS/OASH); David Gruber; Wade, David; Lewis Hofmann; WILKINSON, THOMAS; WOLFE, HERBERT; CharitytA@CDPH; Taylor, Justin (CTR); Marinissen, Maria (HHS/OS/OGA); Sutter, Mark; Mark Keim, MD MBA; Richard Hatchett; McLeod James; Wine G.C.; Dan Carlin; Jerry Mothershead; Krohmer, Jon (OGA); Jolly, Brantley (OS/ASPR/EMMO) (CTR); Hart,Alexander (APHMFP - Emergency Medicine)

Location: 1(888)270-9936; Access Code: 6490634#; https://fema.connectsolutions.com/supplychaintfcovid-19/

Importance: Normal

Subject: FW: Preservation Series Technical Webinar: The CALM System - A Product to Potentially Increase COVID-19 Testing Site Efficiency and Less Healthcare Provider Time

Start Time: Tue 3/31/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 3/31/2020 2:45:00 PM (UTC-04:00)

Required Attendees: 1974usna@gmail.com; TARANTINO, DAVID A; Dr. Eva K Lee; Lawler, James V; Ciottone,Gregory (HMFP - Emergency Medicine); Richard Tubb; reddawn@mphise.us; Arthur Kellermann; William Lang; Rob Darling, MD; Mecher, Carter; Jamison Day; Logan, Linda L; Dodgen, Daniel (OS/ASPR/SPPR); Venkayya, Rajeev; Ronny Jackson; Eastman, Alexander; Mansoura, Monique K.; LLogandakar; Walters, William (STATE.GOV); Parker Jr, Gerald W; DeBord, Kristin (OS/ASPR/SPPR); EVANS, MARIEFRED; Kevin Montgomery; Phillips, Sally (OS/ASPR/SPPR); DC; Matthew JtCIVtUSARMY (USA); Andy Desjardins, MD; Fantinato, Jessica (USDA.GOV); Yeskey, Kevin; Danny Shiau; Martin, Greg (state.gov); Ryan Morhard; Disbrow, Gary (OS/ASPR/BARDA); Borio, Luciana; Redd, John (Capt); KAUSHIK, SANGEETA; Eric (San Diego County); CHRISTOPHER ALLEN; Cordts, Jerome (CTR); Baric, Ralph S; Schnitzer, Jay J.; jwleduc@utmb.edu; HARVEY, MELISSA; Lisa Koonin; Larry G; M.D.; David; Hassell, David (Chris) (OS/ASPR/IO); Hanfling, Dan; Will Gaskins; Lee, Scott (OS/ASPR/EMMO); Lauren Johnston; Steven Jt(tCHFStDPH); Tom Bossert; Johnson, Robert (OS/ASPR/BARDA); HAMILTON, CAMERON; Adams, Jerome (HHS/OASH); David Gruber; Wade, David; Lewis Hofmann; WILKINSON, THOMAS; WOLFE, HERBERT; CharitytA@CDPH; Taylor, Justin (CTR); Marinissen, Maria (HHS/OS/OGA); Sutter, Mark; Mark Keim, MD MBA; Richard Hatchett; McLeod James; Wine G.C.; Dan Carlin; Jerry Mothershead; Krohmer, Jon (OGA); Jolly, Brantley (OS/ASPR/EMMO) (CTR); Hart,Alexander (APHMFP - Emergency Medicine)

CALM Info.pdf

Please pass the word on this Technical Webinar, under the Preservation Line of Effort for the FEMA Supply Chain Task Force, on the CALM System.

Thank you.
V/r

Joselito Ignacio

Joselito Ignacio, MA, MPH, CIH, CSP, REHS
Captain, U.S. Public Health Service
Planning Specialist, Preservation Line of Effort
HHS/FEMA Supply Chain Stabilization Task Force
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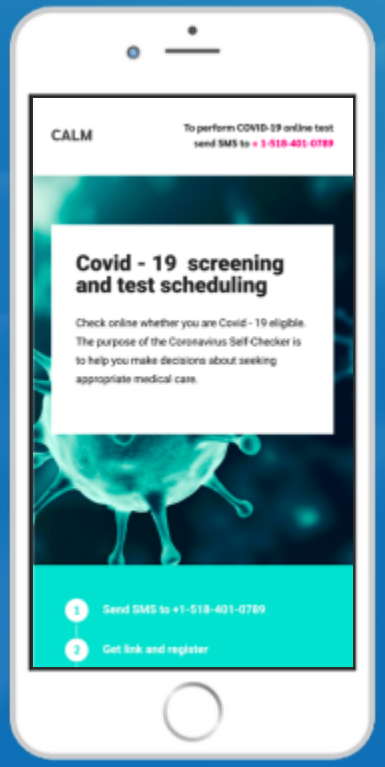
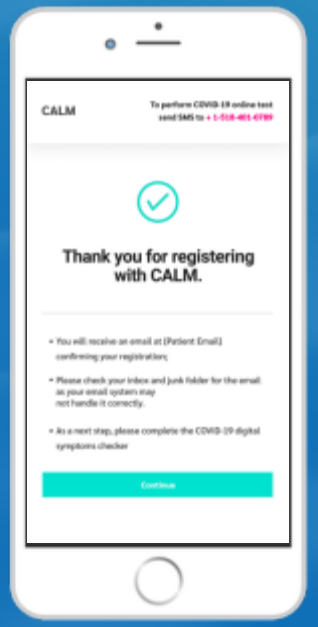


Introducing CALM.

It’s the one tool you need to free up healthcare workers and increase throughput at COVID -19 testing sites.

by NOVOSI

THE CALM SYSTEM



REGISTRATION

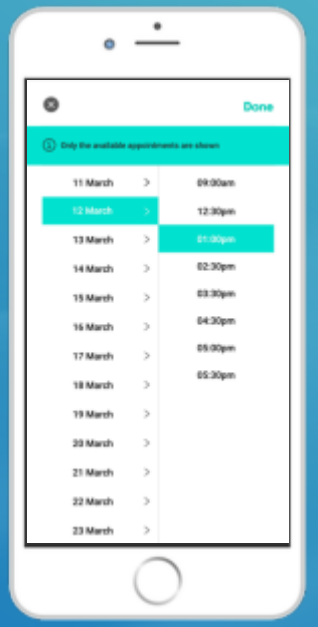
Capture patient and insurance information.

Frees up staff from data entry.

TRIAGE

Digital screening and if warranted, screening by a registered nurse.

Frees up frontline workers.



SCHEDULING

Schedules time at a testing facility, based on availability.

Ends bottlenecks at testing sites.

VERIFICATION

One-step verification of patient information.

Increases throughput at testing sites.

Organizer: Ignacio, Joselito[joselito.ignacio@fema.dhs.gov]

From: Ignacio, Joselito[joselito.ignacio@fema.dhs.gov]

Attendees: Cheryl Holloman; drollins@objectsystems.com; FEMA-NRCC-NBEOC,; Vineyard, Micheal; MacIntyre, Anthony (OGA); Macintyre, Anthony; Vineyard, Micheal; Macintyre, Anthony; 1974usna@gmail.com; TARANTINO, DAVID A; Dr. Eva K Lee; Lawler, James V; Ciottone,Gregory (HMFP - Emergency Medicine); Richard Tubb; reddawn@mphise.us; Arthur Kellermann; William Lang; Rob Darling, MD; Mecher, Carter; Jamison Day; Dodgen, Daniel (OS/ASPR/SPPR); Ronny Jackson; Mansoura, Monique K.; LLogandakar; Walters, William (STATE.GOV); Parker Jr, Gerald W; DeBord, Kristin (OS/ASPR/SPPR); EVANS, MARIEFRED; Kevin Montgomery; Phillips, Sally (OS/ASPR/SPPR); DC; Matthew JtCIVtUSARMY (USA); Andy Desjardins, MD; Fantinato, Jessica (USDA.GOV); Danny Shiau; Martin, Greg (state.gov); Ryan Morhard; Disbrow, Gary (OS/ASPR/BARDA); Borio, Luciana; Redd, John (Capt); KAUSHIK, SANGEETA; Eric (San Diego County); CHRISTOPHER ALLEN; Cordts, Jerome (CTR); Baric, Ralph S; jwleduc@utmb.edu; Lisa Koonin; Larry G; M.D.; Hassell, David (Chris) (OS/ASPR/IO); Hanfling, Dan; Will Gaskins; Lee, Scott (OS/ASPR/EMMO); Lauren Johnston; Steven Jt(tCHFStDPH); Tom Bossert; Johnson, Robert (OS/ASPR/BARDA); HAMILTON, CAMERON; Adams, Jerome (HHS/OASH); David Gruber; Lewis Hofmann; WILKINSON, THOMAS; CharitytA@CDPH; Taylor, Justin (CTR); Marinissen, Maria (HHS/OS/OGA); Sutter, Mark; Mark Keim, MD MBA; Richard Hatchett; Wine G.C.; Dan Carlin; Jerry Mothershead; Krohmer, Jon (OGA); Hart,Alexander (APHMFP - Emergency Medicine); McKay, Samuel; Bowers, Christopher O (MIL); Nelms, Jordan; Crawford, Sean; alerts@healthcareready.org; 'Sarah Baker'; Brodoff, Bruce; Cappannari, Michael L; Cesar, Fritzmarie; Cummings, Michael; Epstein, Corinne; Fox, Shyrlee; Holt, Brett; Manfield, Craig; Messer, Margaret; Phan, Minh; Phillips, Kimberly; Sanford, Kristiana; Swoopes, Karyn; Seiler, Brittney (OS/ASPR/SIIM); Magill, Stephanie C. (CMS/CISP); Georgi Kremenliev; Matt Landheim; Benjamin Toronto; Dave Smith; Brannman, Shayne (OS/ASPR/EMMO); Shane Nielsen; Marcozzi, David; Yeskey, Kevin; WOLFE, HERBERT; Jolly, Brantley (OS/ASPR/EMMO) (CTR); eva.evalee.lee64@gmail.com; Eastman, Alexander; Logan, Linda L; HARVEY, MELISSA; DeBord, Kristin (OS/ASPR/SPPR); Venkayya, Rajeev; Wade, David

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CALM Info.pdf

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Joselito Ignacio, MA, MPH, CIH, CSP, REHS
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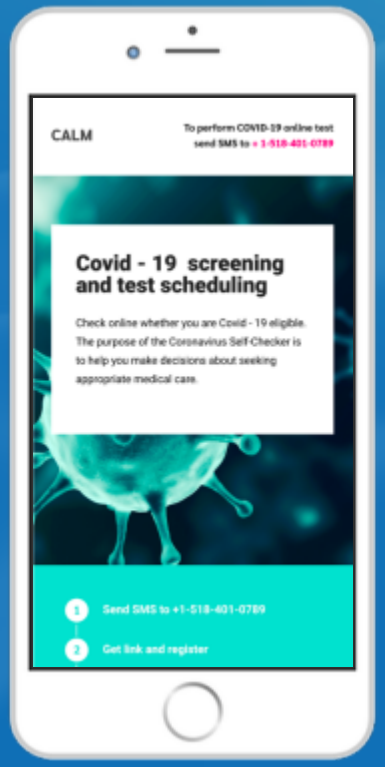

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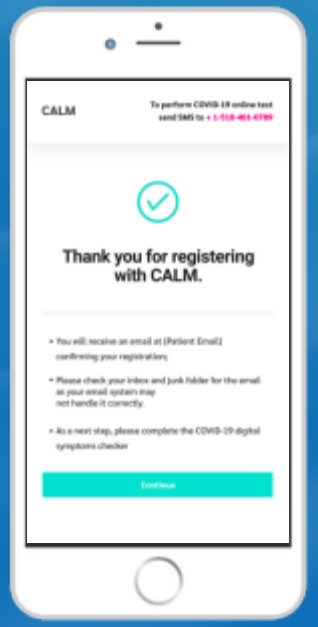

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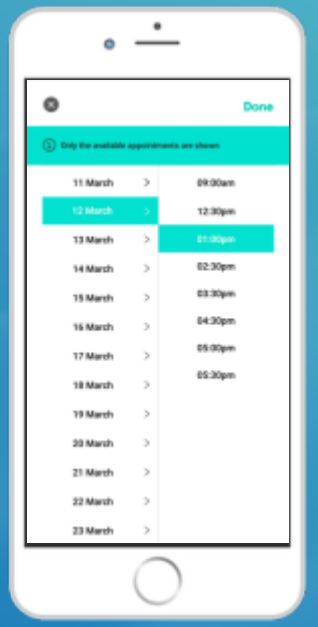

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Increases throughput at testing sites.

From: William Dowling[william.dowling@cepi.net]

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Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 3 PM CET

Start Time: Wed 4/1/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/1/2020 9:30:00 AM (UTC-04:00)

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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 4/1/2020 6:35:51 AM (UTC-04:00)
Subject: Statement of collaboration towards a COVID-19 vaccine

Dear colleagues,

During a recent meeting with vaccine manufacturers and funders there was a suggestion to have a statement to support the RD of a vaccine against COVID-19. WHO would like to extend this invitation to all groups working on vaccine development, which of course includes the *ad hoc* expert groups for development of COVID-19 animal models as well as assays and reagents. If you support the statement below and are willing to sign it please acknowledge it by emailing Ximena Riveros at lauriex@who.int.

Thank you all very much for your continued support

César Muñoz-Fontela, Simon Funnell and William Dowling (seconded to WHO).

We are scientists, physicians, funders, and manufacturers who have come together as part of an international collaboration, coordinated by WHO, to help speed the availability of a vaccine against COVID-19. While a vaccine for general use will not be available quickly, a vaccine may ultimately be instrumental in controlling this worldwide pandemic. In the interim, we applaud the implementation of measures that reduce spread of the virus and protect vulnerable populations, and pledge to use the time gained by use of such measures to develop a vaccine as efficiently as possible. We will continue and strengthen the unprecedented world-wide collaboration, cooperation and sharing of data already underway to reduce inefficiencies and duplication of effort, working tenaciously to increase the likelihood that one or more safe and effective vaccines will soon be made available to all whose health would benefit.

To: Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; Baric, Ralph S[rbaric@email.unc.edu]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; GSELL, Pierre[gsellp@who.int]; COSTA, Alejandro Javier[costaa@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; vincent.munster@nih.gov[vincent.munster@nih.gov]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; Vasan, Vasan (H&B, Geelong AAHL[Vasan.Vasan@csiro.au]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; jokim@ivi.int[jokim@ivi.int]; mksong@ivi.int[mksong@ivi.int]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; leejooyeon@korea.kr[leejooyeon@korea.kr]; limhy0919@korea.kr[limhy0919@korea.kr]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; christian.brechot[christian.brechot@pasteur.fr]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Mark Page[Mark.Page@nibsc.org]; Graham, Barney (NIH/VRC) [E[bgraham@mail.nih.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; Thue, Tracey[tracey.thue@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Napper, Scott[scott.napper@usask.ca]; Nicola Rose[Nicola.Rose@nibsc.org]; M.P.G. Koopmans[m.koopmans@erasmusmc.nl]; sgerber@cdc.gov[sgerber@cdc.gov]; djernigan@cdc.gov[djernigan@cdc.gov]; Gerber, Susan I. (CDC/DDID/NCIRD/DVD)[bhx1@cdc.gov]; Carroll, Darin (CDC/DDID/NCEZID/OD)[zuz4@cdc.gov]; Watson, John (CDC/DDID/NCIRD/DVD)[acq4@cdc.gov]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; gustavo.f.palacios.civ@mail.mil[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; SPoehlmann@dpz.eu[SPoehlmann@dpz.eu]; mhoffmann@dpz.eu[mhoffmann@dpz.eu]; sylvie.van-der-werf@pasteur.fr[sylvie.van-der-werf@pasteur.fr]; Nelson Michelle[MNELSON@dstl.gov.uk]; Lever Steve[MSLEVER@dstl.gov.uk]; Prior Joann L[JLPRIOR@dstl.gov.uk]; Marston, Hilary (NIH/NIAID) [E][hilary.marston@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; mit666666@pitt.edu[mit666666@pitt.edu]; Mellors, John W[jwm1@pitt.edu]; tlying@fudan.edu.cn[tlying@fudan.edu.cn]; christian.drosten@charite.de[christian.drosten@charite.de]; David Vaughn[David.Vaughn@gatesfoundation.org]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; florian.krammer@mssm.edu[florian.krammer@mssm.edu]; perkinsm@who.int[perkinsm@who.int]; Guthrie, Erica (CDC/DDID/NCIRD/ID)[ilj2@cdc.gov]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; Baric, Toni C[antoinette_baric@med.unc.edu]; SALAMI, Kolawole[salamik@who.int]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Cesar Munoz-fontela[munoz-fontela@bnitm.de]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; Ashley.Smith1@hhs.gov[Ashley.Smith1@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Kovacs, Gerald (OS/ASPR/BARDA) (CTR)[Gerald.Kovacs@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Delgado Vazquez.Rafael[rafael.delgado@salud.madrid.org]; Morabito, Kaitlyn (NIH/VRC) [E][kaitlyn.dambach@nih.gov]; Corbett, Kizzmekia (NIH/VRC) [E][kizzmekia.corbett@nih.gov]; N.M.A. Okba[n.okba@erasmusmc.nl]
Cc: dj56wood@gmail.com[dj56wood@gmail.com]; teresa.lambe@ndm.ox.ac.uk[teresa.lambe@ndm.ox.ac.uk]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; Luc Gagnon[Luc.Gagnon@nexelis.com]; Greg Kulnis[Greg.Kulnis@nexelis.com]; Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA)[aysegul.nalca.civ@mail.mil]; SWAMINATHAN, Soumya[swaminathans@who.int]; MORGAN, Oliver[omorgan@who.int]
From: William Dowling[william.dowling@cepi.net]
Sent: Wed 4/1/2020 7:27:10 AM (UTC-04:00)
Subject: Agenda for Today's call -- WHO Consultation on SARS-CoV -2 Reagents, Cross reactivity and immune Assays - Wed 3 PM CET -

1. Virus updates
2. Recombinant proteins
    a. Needs for use in vaccine development and Serosurveys
    b. Sources of protein – NIH and Gates funded efforts, others
    c. Protein quality – data from PHE
3. COVID-19 human Sera Collection and distribution
    a. NIBSC
    b. Other efforts – US, France, others?
4. Neutralization assays
    a. live virus comparison to pseudovirions
    b. Pseudovirion availability – NIBSC, BEI, others
5. Protocol sharing
6. WHO statement
7. Meeting with Vaccine Developers
8. Other updates

William Dowling, PhD

Non-Clinical Vaccine Development Leader

CEPI New vaccines for a safer world

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Cc: William Dowling[william.dowling@cepi.net]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Simon Funnell[simon.funnell@phe.gov.uk]
From: GSELL, Pierre[gsellp@who.int]
Sent: Thur 4/2/2020 8:33:11 AM (UTC-04:00)
Subject: RE: [COVID-19 Animal Group] Agenda for today's call

Dear all

Please see below the agenda items for this call.

1.UTMB
2.IRF (verbal update)
Any Other Verbal Update
3.Human in vitro – EmulateBio

4.CMF on mice model
5.Discussion about having developers in the calls once a month

Please note that the presentations section is reduced today. We would encourage you all of you to reflect on and synthetize the large and important piece of evidence provided so far to accelerate vaccine and treatment development and highlight the critical gaps that some of you have encountered or may face in the near term.

Kind regards
Pierre

From: GSELL, Pierre
Sent: 25 March 2020 11:22
Cc: William Dowling <william.dowling@cepi.net>; munoz-fontela@bnitm.de; Simon Funnell <simon.funnell@phe.gov.uk>
Subject: [COVID-19 Animal Group] Agenda for tomorrow's call

Dear all,

Please find attached a draft agenda for our next call. The call is planned tomorrow Thursday 26th at 2PM CET (Geneva time). Please share with us your slides in advance for those who would like to contribute to areas 2 (vaccines), 3 (therapeutics) and 5 (disease enhancement).

Please also note that the ICMRA (International Coalition of Medicines Regulatory Authorities) has just published a summary report on a Global Regulatory Workshop on COVID-19 vaccine development http://www.icmra.info/drupal/sites/default/files/2020-03/First%20regulatory%20COVID-19%20workshop%20-%20meeting%20report_March%202020.pdf

Thank you so much for your contributions, the collaborative spirit of the group and your hard work
Kind regards

Pierre-Stéphane Gsell
Technical Officer
R&D Blueprint | Health Emergencies Programme | 1156
World Health Organization | Avenue Appia 20 | 1211 Geneva 27 | Switzerland
Desk: +41.22.791.50.74 | Mob: +41.79.213.25.30 | gsellp@who.int

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: zoom (see below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 4/10/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 4/10/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

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Topic: Advisory Group Call: NAM-APHA COVID-19 Webinar Series
Time: Apr 10, 2020 02:00 PM Eastern Time (US and Canada)

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Organizer: DeStefano, Laura[LDestefano@nas.edu]

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: https://nasem.zoom.us/j/303389840 (see agenda below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 4/10/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 4/10/2020 3:00:00 PM (UTC-04:00)

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Agenda

- Debrief from webinars 1-3 and update on webinar 4
- Discussion and prioritization of possible upcoming topics
  - Testing protocols and options
  - COVID-19 and equity
  - Health and essential workforce impacts
  - Planning for recovery
  - Lessons for building a more resilient public health and health care system
  - Updates on treatment and vaccine development
  - New information on characteristics of the virus and variations in the disease state
  - Best practices from US states and other countries

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Location: zoom (see below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 4/24/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 4/24/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

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Topic: Advisory Group Call: NAM-APHA COVID-19 Webinar Series
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Organizer: DeStefano, Laura[LDestefano@nas.edu]

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: https://nasem.zoom.us/j/186433432 (call-in information below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 4/24/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 4/24/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Our two main points of discussion will be prioritizing the topics of upcoming webinars and discussing the ideal duration/frequency of the series long-term.

As background for our conversation, please see:

- A table of potential future topics
- Attendee surveys from Webinar 4 (crisis standards of care) and Webinar 3 (spread & treatment)

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Topic: Advisory Group Call: NAM-APHA COVID-19 Webinar Series
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From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: zoom (see below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 5/8/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 5/8/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

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Organizer: DeStefano, Laura[LDestefano@nas.edu]

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Location: zoom (see below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 5/8/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 5/8/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Calendar Exception: Untitled

Calendar Exception: Untitled

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Meeting: NAM-APHA COVID-19 Webinar Series
Time: May 8, 2020 02:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/526660780

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Organizer: DeStefano, Laura[LDestefano@nas.edu]

Importance: Normal

Subject: Canceled: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 6/19/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 6/19/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

We are canceling this meeting because the group is fairly caught up at the moment – we will keep in touch by email.

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Meeting: NAM-APHA COVID-19 Webinar Series
Time: May 8, 2020 02:00 PM Eastern Time (US and Canada)

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Meeting ID: 526 660 780
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

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Organizer: DeStefano, Laura[LDestefano@nas.edu]

Location: RESCHEDULED due to holiday - please reply if you can attend

Subject: Canceled: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Tue 6/30/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 6/30/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Thanks to those of you who responded and held time on your calendars. We are canceling this instance and will follow up to seek feedback by email. Best wishes for an enjoyable holiday week.

From: William Dowling[william.dowling@cepi.net]

Attendees: Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Morabito, Kaitlyn (NIH/VRC) [E]; Corbett, Kizzmekia (NIH/VRC) [E]; N.M.A. Okba; dj56wood@gmail.com; teresa.lambe@ndm.ox.ac.uk; brooke.bozick@nih.gov; Luc Gagnon; Greg Kulnis; Schmaljohn, Connie (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); SWAMINATHAN, Soumya; MORGAN, Oliver; Ragini.Shivji@ema.europa.eu; Phil Krause; PScott@eidresearch.org; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Sarah Mudrak, Ph.D.; Georgia Tomaras, Ph.D.; Solomon Abebe Yimer; schendel@lji.org; sunL@antibodychina.com; 93353503@qq.com; Erica Ollmann Saphire; Chu, May; Leader, Troy; Cassandra.Kelly@finddx.org

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3 PM CET

Start Time: Wed 4/8/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/8/2020 10:00:00 AM (UTC-04:00)

Required Attendees: Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; linfa.wang@duke-nus.edu.sg; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Thue, Tracey; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; SATHIYAMOORTHY, Vaseeharan; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Morabito, Kaitlyn (NIH/VRC) [E]; Corbett, Kizzmekia (NIH/VRC) [E]; N.M.A. Okba

Optional Attendees: dj56wood@gmail.com; teresa.lambe@ndm.ox.ac.uk; brooke.bozick@nih.gov; Luc Gagnon; Greg Kulnis; Schmaljohn, Connie (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); SWAMINATHAN, Soumya; MORGAN, Oliver; Ragini.Shivji@ema.europa.eu; Phil Krause; PScott@eidresearch.org; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Sarah Mudrak, Ph.D.; Georgia Tomaras, Ph.D.; Solomon Abebe Yimer; schendel@lji.org; sunL@antibodychina.com; 93353503@qq.com; Erica Ollmann Saphire; Chu, May; Leader, Troy; Cassandra.Kelly@finddx.org

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Organizer: William Dowling[william.dowling@cepi.net]

From: William Dowling[william.dowling@cepi.net]

Attendees: Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Morabito, Kaitlyn (NIH/VRC) [E]; Corbett, Kizzmekia (NIH/VRC) [E]; N.M.A. Okba; dj56wood@gmail.com; teresa.lambe@ndm.ox.ac.uk; brooke.bozick@nih.gov; Luc Gagnon; Greg Kulnis; Schmaljohn, Connie (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); MORGAN, Oliver; Ragini.Shivji@ema.europa.eu; Phil Krause; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Sarah Mudrak, Ph.D.; Georgia Tomaras, Ph.D.; Solomon Abebe Yimer; schendel@lji.org; sunL@antibodychina.com; 93353503@qq.com; Erica Ollmann Saphire; Chu, May; Leader, Troy; Cassandra.Kelly@finddx.org; Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); Boyle, David; McDermott, Adrian (NIH/VRC) [E]; sysun@anygotech.com; Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP)

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3 PM CET

Start Time: Wed 4/8/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/8/2020 10:00:00 AM (UTC-04:00)

Required Attendees: Michael.holbrook@nih.gov; lisa.hensley@nih.gov; Baric, Ralph S; HENAO RESTREPO, Ana Maria; GSELL, Pierre; COSTA, Alejandro Javier; RIVEROS BALTA, Alina Ximena; vincent.munster@nih.gov; daszak@ecohealthalliance.org; b.haagmans@erasmusmc.nl; Vasan, Vasan (H&B, Geelong AAHL; jokim@ivi.int; mksong@ivi.int; Volker.gerdts@usask.ca; Giada.Mattiuzzo@nibsc.org; zlshi@wh.iov.cn; Barbara.Schnierle@pei.de; leejooyeon@korea.kr; limhy0919@korea.kr; Damon, Inger K. (CDC/OID/NCEZID); christian.brechot; Kayvon Modjarrad; Amy C. Shurtleff; erik.stemmy@nih.gov; Julia.Tree@phe.gov.uk; Mark Page; Graham, Barney (NIH/VRC) [E; Falzarano, Darryl; Hodgson, Paul; Napper, Scott; Nicola Rose; M.P.G. Koopmans; sgerber@cdc.gov; djernigan@cdc.gov; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Carroll, Darin (CDC/DDID/NCEZID/OD); Watson, John (CDC/DDID/NCIRD/DVD); Lathey, Janet (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); MFrieman@som.umaryland.edu; REIRELAND@mail.dstl.gov.uk; SPoehlmann@dpz.eu; mhoffmann@dpz.eu; sylvie.van-der-werf@pasteur.fr; Nelson Michelle; Lever Steve; Prior Joann L; Marston, Hilary (NIH/NIAID) [E]; De wit, Emmie (NIH/NIAID) [E]; mit666666@pitt.edu; Mellors, John W; tlying@fudan.edu.cn; christian.drosten@charite.de; David Vaughn; Jacqueline Kirchner; Karen Makar; florian.krammer@mssm.edu; perkinsm@who.int; Guthrie, Erica (CDC/DDID/NCIRD/ID); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Baric, Toni C; SALAMI, Kolawole; Simon Funnell; Cesar Munoz-fontela; Monalisa Chatterji; Ashley.Smith1@hhs.gov; Karl.Erlandson@hhs.gov; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Little, James (OS/ASPR/BARDA); Lakshmi.Jayashankar@hhs.gov; wilsonp@uchicago.edu; Florence, Clint (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Morabito, Kaitlyn (NIH/VRC) [E]; Corbett, Kizzmekia (NIH/VRC) [E]; N.M.A. Okba

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Cc: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; GSELL, Pierre[gsellp@who.int]; Simon Funnell[Simon.Funnell@phe.gov.uk]; William Dowling[william.dowling@cepi.net]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; COSTA, Alejandro Javier[costaa@who.int]
To: sandra cordo[scordo@qb.fcen.uba.ar]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Vasan, Vasan (H&B, Geelong AAHL)[Vasan.Vasan@csiro.au]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; Alyson Kelvin[AKelvin@dal.ca]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; dhoconno@wisc.edu[dhoconno@wisc.edu]; paul.hodgson@usask.ca[paul.hodgson@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; 秦川[qinchuan@pumc.edu.cn]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; pauline.maisonnasse@cea.fr[pauline.maisonnasse@cea.fr]; roger.le-grand@cea.fr[roger.le-grand@cea.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; sandrine.lesellier@anses.fr[sandrine.lesellier@anses.fr]; Rodriguez-Burgos, Estefania[estefania.rodriguez-burgos@leibniz-hpi.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; amy.c.shurtleff@cepi.net[amy.c.shurtleff@cepi.net]; Carolyn Clark[carolyn.clark@cepi.net]; woodd@who.int[woodd@who.int]; hlchen@hku.hk[hlchen@hku.hk]; jfwchan@hku.hk[jfwchan@hku.hk]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; ldenisy@yahoo.com[ldenisy@yahoo.com]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; sekim@krict.re.kr[sekim@krict.re.kr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; b.rockx@erasmusmc.nl[b.rockx@erasmusmc.nl]; B.L. Haagmans[b.haagmans@erasmusmc.nl]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; jeroen.kortekaas@wur.nl[jeroen.kortekaas@wur.nl]; nadia.oreshkova@wur.nl[nadia.oreshkova@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; Neil.Berry@nibsc.org[Neil.Berry@nibsc.org]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Yper.Hall@phe.gov.uk[Yper.Hall@phe.gov.uk]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; nax3@cdc.gov[nax3@cdc.gov]; alr2105@columbia.edu[alr2105@columbia.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; Duprex, Paul[pduprex@pitt.edu]; geraldine.hamilton@emulatebio.com[geraldine.hamilton@emulatebio.com]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; tony.wang@fda.hhs.gov[tony.wang@fda.hhs.gov]; Tracy.MacGill@fda.hhs.gov[Tracy.MacGill@fda.hhs.gov]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Dan Barouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; Krammer, Florian[florian.krammer@mssm.edu]; Juergen Richt[jricht@vet.k-state.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Albrecht, Randy[randy.albrecht@mssm.edu]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark.Page@nibsc.org[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; connie.schmaljohn@nih.gov[connie.schmaljohn@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Ian Crozier[ian.crozier@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; Spergel, Jonathan[SPERGEL@email.chop.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; rcarrion@txbiomed.org[rcarrion@txbiomed.org]; Roy, Chad J[croy@tulane.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gustavo.palacios@gmail.com[Gustavo.palacios@gmail.com]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; sktseng@utmb.edu[sktseng@UTMB.EDU]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; darryl.falzarano@usask.ca[darryl.falzarano@usask.ca]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Dohm, Erik Daniel[edohm@uab.edu]; Chi Van Dang[cdang@lcr.org]; fcassels@path.org[fcassels@path.org]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; snumouse@snu.ac.kr[snumouse@snu.ac.kr]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 4/9/2020 5:46:31 AM (UTC-04:00)
Subject: Agenda: WHO Ad hoc group Animal Models Call
Mail Attachment.ics
Webex_Meeting.ics

Dear all,

Please find below the agenda for today's call as well as a Webex invite.

Best regards

César, Bill, Simon and Pierre.

Area Therapeutics

(1) Ludwig Institute
(2) PUMC

Area Pathogenesis

(1) PHE
(2) U Pittsburgh
(3) CEA
(4) Open question to the group: Should we start modeling co-morbidities (e. g. diabetes, immunosupression, inflammation, ageing)?

Additional topics and open group discussion

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 491 111 336

Meeting password: PKwirBMp263

Thursday, April 9, 2020

3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Organizer:	GSELL, Pierre **:** gsellp@who.int
Subject:	FW: Webex meeting invitation: [COVID-19] 7th TC Animal Models Expert Group
Location:	https://who.webex.com/who/j.php?MTID=mf265d0e955bb53a6536d4ad55e27f29c
Start Time:	2020-04-09T15:00:00+02:00
End Time:	2020-04-09T16:30:00+02:00
Attendees:	Cesar Munoz-Fontela **:** munoz-fontela@bnitm.de

CID:18B5014D83125C48928BAEFDBE0F0C5E@eurprd01.prod.exchangelabs.com

-----Original Appointment-----
From: Pierre GSELL <gsellp@who.int>
Sent: 04 April 2020 15:08
To: Pierre GSELL
Subject: Webex meeting invitation: [COVID-19] 7th TC Animal Models Expert Group
When: 09 April 2020 15:00-16:30 Europe/Paris.
Where: https://who.webex.com/who/j.php?MTID=mf265d0e955bb53a6536d4ad55e27f29c

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 491 111 336

Meeting password: PKwirBMp263

Thursday, April 9, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting<https://who.webex.com/who/j.php?MTID=mf265d0e955bb53a6536d4ad55e27f29c>

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numbers<https://who.webex.com/who/globalcallin.php?MTID=m2a26513660b8f52a57150dd5e5698e6b>

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Dial 491111336@who.webex.com<%20sip:491111336@who.webex.com>
You can also dial 173.243.2.68 and enter your meeting number.

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 7th TC Animal Models Expert Group
Location: https://who.webex.com/who/j.php?MTID=mf265d0e955bb53a6536d4ad55e27f29c
Start Time: 2020-04-09T15:00:00+02:00
End Time: 2020-04-09T16:30:00+02:00
Attendees: Pierre GSELL : gsellp@who.int

When it's time, join the Webex meeting here.

Meeting number (access code): 491 111 336
Meeting password:PKwirBMp263

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From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: https://nasem.zoom.us/j/303389840 (see agenda below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 4/10/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 4/10/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Agenda

- Debrief from webinars 1-3 and update on webinar 4
- Discussion and prioritization of possible upcoming topics
  - Testing protocols and options
  - COVID-19 and equity
  - Health and essential workforce impacts
  - Planning for recovery
  - Lessons for building a more resilient public health and health care system
  - Updates on treatment and vaccine development
  - New information on characteristics of the virus and variations in the disease state
  - Best practices from US states and other countries

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Call: NAM-APHA COVID-19 Webinar Series
Time: Apr 10, 2020 02:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/303389840

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Meeting ID: 303 389 840
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

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consent to the foregoing, please do not join the session.

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan

Location: https://zoom.us/j/843219964?pwd=KzdYZzMwem1CQ0FTaWtvUWJMMmx1UT09

Importance: Normal

Subject: COVID Preclinical working group (meeting # 1)

Start Time: Tue 4/14/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 4/14/2020 3:30:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan

Dear preclinical working group members,

Thank you for agreeing to participate in this working group to help guide the COVID partnership effort. We are looking forward to working with you. We understand that time is of the essence and that many of you are occupied with other activities that address the COVID-19 pandemic. However, we ask for your flexibility and patience as we begin to schedule these meetings. We will do out best to ensure that all can attend and participate.

We will be sending additional materials in the next day or so for you to prepare for this meeting. This will let us get to the important discussions and decisions that we need to make to move the process forward rapidly.

Thank you again for your willingness to participate.

Sincerely,

Joe Menetski, for COVID preclinical working group

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://zoom.us/j/843219964?pwd=KzdYZzMwem1CQ0FTaWtvUWJMMmx1UT09

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Password: 572840
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+1 669 900 6833 US (San Jose)
+1 253 215 8782 US
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Password: 572840
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Cc: William Dowling[william.dowling@cepi.net]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Simon Funnell[simon.funnell@phe.gov.uk]
From: GSELL, Pierre[gsellp@who.int]
Sent: Sat 4/11/2020 12:13:53 PM (UTC-04:00)
Subject: in prep of next WHO covid animal model call

Dear participant of the WHO COVID animal model group of experts

Many thanks for your continuous effort and participation in these calls.
As discussed during the last call, please

- Update the mapping of studies in the Animal Group sharepoint. It will take 5 minutes and it is very helpful.
- Contact Bill, Cesar and Simon back on any important update you would like to provide at the next call.
- Contact Bill, Cesar and Simon back to suggest your approach and contribution to the preclinical screening of investigational therapeutics to be considered for the global SOLIDARITY trial.

Please do not hesitate to share any feedback with us.
Happy Easter all.

Kind regards

Pierre-Stéphane Gsell
Technical Officer
R&D Blueprint | Health Emergencies Programme | 1156
World Health Organization | Avenue Appia 20 | 1211 Geneva 27 | Switzerland
Desk: +41.22.791.50.74 | Mob: +41.79.213.25.30 | gsellp@who.int

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Jonson, Samantha (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]

Location: https://zoom.us/j/98359338682?pwd=dGpHY2FoWElUMmlmT2U3NEJCdG5mQT09

Importance: Normal

Subject: COVID Preclinical Working group Meeting #2

Start Time: Fri 4/17/2020 11:00:00 AM (UTC-04:00)

End Time: Fri 4/17/2020 12:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Jonson, Samantha (NIH/NCATS) [E]

Optional Attendees: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]

Saving time on the calendar.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer:	Grant, Evan H[ehgrant@usgs.gov]
From:	Grant, Evan H[ehgrant@usgs.gov]
Attendees:	Daniel Streicker; dreeder@bucknell.edu; jit8@cdc.gov; raina.plowright@montana.edu; Rebekah.Kading@colostate.edu; wfrick@batcon.org; a.peel@griffith.edu.au; Amy.T.Gilbert@aphis.usda.gov; castlekt@gmail.com; ckjohnson@UCDAVIS.EDU; epstein@ecohealthalliance.org; kate.e.jones@ucl.ac.uk; linfa.wang@duke-nus.edu.sg; O'Shea, Thomas; Baric, Ralph S; sja2127@cumc.columbia.edu
Location:	Microsoft Teams Meeting
Importance:	Normal
Subject:	SARS-expert judgment - initial response and share insights
Start Time:	Wed 4/15/2020 11:00:00 AM (UTC-04:00)
End Time:	Wed 4/15/2020 1:00:00 PM (UTC-04:00)
Required Attendees:	Daniel Streicker; dreeder@bucknell.edu; jit8@cdc.gov; raina.plowright@montana.edu; Rebekah.Kading@colostate.edu; wfrick@batcon.org; a.peel@griffith.edu.au; Amy.T.Gilbert@aphis.usda.gov; castlekt@gmail.com; ckjohnson@UCDAVIS.EDU; epstein@ecohealthalliance.org; kate.e.jones@ucl.ac.uk; linfa.wang@duke-nus.edu.sg; O'Shea, Thomas; Baric, Ralph S; sja2127@cumc.columbia.edu

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To: Alexandra Phelan (alp81@georgetown.edu)[alp81@georgetown.edu]; David A Relman (relman@stanford.edu)[relman@stanford.edu]; David Walt (dwalt@bwh.harvard.edu)[dwalt@bwh.harvard.edu]; Diane Griffin (dgriffi6@jhmi.edu)[dgriffi6@jhmi.edu]; Embrey, Ellen (eembrey@stratitia.com)[eembrey@stratitia.com]; Georges Benjamin (georges.benjamin@apha.org)[georges.benjamin@apha.org]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; John Hick (hick.john@gmail.com)[hick.john@gmail.com]; Jonna Mazet (jkmazet@ucdavis.edu)[jkmazet@ucdavis.edu]; Kent Kester (Kent.Kester@sanofi.com)[Kent.Kester@sanofi.com]; Kristian G. Andersen (kga1978@gmail.com)[kga1978@gmail.com]; Mark Smolinski (mark@endingpandemics.org)[mark@endingpandemics.org]; Mary Travis Bassett (mbassett@hsph.harvard.edu)[mbassett@hsph.harvard.edu]; Patricia King (patricia.king1@gmail.com)[patricia.king1@gmail.com]; Peggy Hamburg (peggy@hbfam.net)[peggy@hbfam.net]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; Phyllis D. Meadows (PDMeadows@kresge.org)[PDMeadows@kresge.org]; Richard Besser (rbesser@rwjf.org)[rbesser@rwjf.org]; Tara O'Toole (totoole@iqt.org)[totoole@iqt.org]; Trevor Bedford (trevor@bedford.io)[trevor@bedford.io]; Baric, Ralph S[rbaric@email.unc.edu]; Donald Berwick[donberwick@gmail.com]; alta.charo@wisc.edu[alta.charo@wisc.edu]; Jeff.Duchin@kingcounty.gov[Jeff.Duchin@kingcounty.gov]; Baruch Fischhoff[baruch@cmu.edu]; DHanfling@iqt.org[DHanfling@iqt.org]; bgroves@georgetown.edu[bgroves@georgetown.edu]
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; mnavish@iqt.org[mnavish@iqt.org]; andre@ecohealthalliance.org[andre@ecohealthalliance.org]; Peisch, Samuel Francis[speisch@hsph.harvard.edu]; jbaker@rwjf.org[jbaker@rwjf.org]; Baric, Toni C[antoinette_baric@med.unc.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]; Feit, Monica[MFeit@nas.edu]; Shore, Carolyn[CShore@nas.edu]; Wollek, Scott[SWollek@nas.edu]; Downey, Autumn[ADowney@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Tue 4/14/2020 2:43:27 PM (UTC-04:00)
Subject: Note from Harvey - Working Groups for the Standing Committee on Emerging Infectious Diseases
SCEID Working Group Topics and Questions w Leads_v2.docx

Dear Members of the Standing Committee,

It is little over a month since we convened our first standing committee meeting, and I thank you for your willing participation in responding to many critical requests from OSTP and ASPR. As we look beyond the first 30 days, I would like to provide you with an update about next steps.

The Committee will likely pivot away from drafting written rapid expert consultations and move towards rapid telephonic consultations between members and sponsors. The time-constant for issues of concern to the sponsors can be measured in hours to a day or two, and even our rapid, written responses may take too long. We conducted our first telephonic consultation on the role of academic labs in sero-prevalence surveillance on April 6th.

In the next phase of our work, I expect the Committee will also have the opportunity to focus on more intermediate to long-term topics, measured in turn-around time of weeks to months. Some of these may be at the request of our sponsors, and some could be initiated by the committee in accordance with the usual National Academy procedures for self-initiated projects.

Based on your earlier feedback to the idea of working groups, the staff have been working diligently to help me define a small number of working groups to better manage incoming requests; tackle immediate, medium-term and longer-term scientific assessments; and allow us to call upon a more comprehensive network of subject-specific experts. We have simplified the proposed working groups into four domains: viral characteristics; patient care and medical countermeasures; community engagement and population health; and, cross-cutting issues (please see attached). We have identified and confirmed leads for each working group, and I have provisionally identified members for each working group based on your initial expressions of interest. Please review your working group and confirm whether you agree with your assignment or if you would prefer to participate in a different working group. Also, if you are interested and willing to participate in a second working group, please let me know (several members are already in two working groups). **Please provide this feedback to Lisa Brown (lbrown@nas.edu) by COB Wednesday, April 15th.** Once I have received confirmation on the working group assignments, the working groups can move forward with revisiting and prioritizing topics/questions for the sponsor to consider and potentially for our own, self-initiated activity.

At this time, to round out our capacities, the presidents of the Academies are adding several new members to the Committee. Please join me in welcoming Ralph Baric, Don Berwick, Alta Charo, Jeff Duchin, Baruch Fischhoff, Robert Groves, and Dan Hanfling. Staff will provide a revised roster and biosketches in the coming days.

We are in the process of organizing our second committee meeting (likely a two-hour call) for some time next week.

Please stay tuned for additional details.

Please let Andy, Lisa, or me know if you have any questions. We look forward to your feedback.

Warm regards,

Harvey

Harvey V. Fineberg, MD, PhD
President
Gordon and Betty Moore Foundation

1661 Page Mill Rd
Palo Alto CA 94304

T: 650.213.3100

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Topics for Consideration

**Note: Underlined names indicate that formal committee appointment is pending.

Group A – Viral Characteristics (SC Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
One Health

Viral characterization (virus genetics, origin, and evolution of SARS-CoV-2)

Examples of short-term research needs

- Biological/molecular characteristics of SARS-CoV-2
- Real-time tracking of whole genomes and a mechanism for coordinating the rapid dissemination of that information to inform the development of diagnostics and therapeutics and to track variations of the virus over time.
- Access to geographic and temporal diverse sample sets to understand geographic distribution and genomic differences, and determine whether there is more than one strain in circulation. Multi-lateral agreements such as the Nagoya Protocol could be leveraged.

Transmission, incubation, and environmental stability

Examples of short-term research needs

- Physical science of the coronavirus (e.g., charge distribution, adhesion to hydrophilic/phobic surfaces, environmental survival to inform decontamination efforts for affected areas and provide information about viral shedding).
- Persistence and stability on a multitude of substrates and sources (e.g., nasal discharge, sputum, urine, fecal matter, blood).
- Persistence of virus on surfaces of different materials (e,g., copper, stainless steel, plastic).
- Effective decontamination protocols

- Range of incubation periods for the disease in humans (and how this varies across age and health status) and how long individuals are contagious, even after recovery.
- Prevalence of asymptomatic shedding and transmission (e.g., particularly children).
- Seasonality of transmission.
- Correlates of immunity- and whether immunity occurs and duration.
- Resistance of previously infected people to mutated strains.

One Health

Examples of long-term research needs

- Enhance capacity (people, technology, data) for sequencing with advanced analytics for unknown pathogens, and explore capabilities for distinguishing naturally-occurring pathogens from intentional.
- One Health surveillance of humans and potential sources of future spillover or ongoing exposure for this organism and future pathogens, including both evolutionary hosts (e.g., bats) and transmission hosts (e.g., heavily trafficked and farmed wildlife and domestic food and companion species), inclusive of environmental, demographic, and occupational risk factors.
- Evidence that livestock could be infected (e.g., field surveillance, genetic sequencing, receptor binding) and serve as a reservoir after the epidemic appears to be over.
  - Evidence of whether farmers are infected, and whether farmers could have played a role in the origin.
  - Surveillance of mixed wildlife- livestock farmsfor SARS-CoV-2 and other coronaviruses in Southeast Asia.
  - Experimental infections to test host range for this pathogen.

Group B – Patient Care and Medical Countermeasures (MCM) (SC Leads: Don Berwick, Co-Lead TBD)

Staff Leads: Lisa Brown and Scott Wollek

Members: Kristian Andersen
Rich Besser
Diane Griffin
Margaret Hamburg
John Hick
Kent Kester
Tara O'Toole
David Relman
David Walt
Dan Hanfling

Topics: Vaccines and therapeutics
Diagnostics

Patient care (including personal protective equipment, crisis standards of care, and quality)

Vaccines and therapeutics

- Need for an end-to-end process for getting promising products to the people who need them (e.g. small biotechs may not have developed a vaccine before and may lack scale-up manufacturing and/or support for larger studies)
- Research and development and evaluation efforts
  Examples of short-term research needs
    - Evaluate/investigate effectiveness of drugs and antivirals being developed and tried to treat COVID-19 patients.
        - E.g., Would it be beneficial to give IL6 receptor antibodies therapy prior to admission to the ICU; use of monoclonal antibodies.
    - Clinical and bench trials to investigate less common viral inhibitors against COVID-19 such as naproxen, clarithromycin, and minocyclinethat that may exert effects on viral replication.
    - Methods to evaluate potential complication of Antibody-Dependent Enhancement (ADE) in vaccine recipients.
    - From a clinical development perspective, explore use of best animal models and their predictive value for a human vaccine.
    - Capabilities to discover a therapeutic (not vaccine) for the disease, and clinical effectiveness studies to discover therapeutics, to include antiviral agents.
    - Alternative models to aid decision makers in determining how to prioritize and distribute scarce, newly proven therapeutics as production ramps up. This could include identifying approaches for expanding production capacity to ensure equitable and timely distribution to populations in need.

  Example of long-term research needs
    - Efforts targeted at a universal coronavirus vaccine.

Diagnostics

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes)
  Examples of short-term research needs
    - Evaluate how widespread current exposure is to be able to make immediate policy recommendations on mitigation measures. Denominators for testing and a mechanism for rapidly sharing that information, including demographics, to the extent possible. Sampling methods to determine asymptomatic disease (e.g., use of serosurveys (such as convalescent samples) and early detection of disease (e.g., use of screening of neutralizing antibodies such as ELISAs),
    - Efforts to increase capacity on existing diagnostic platforms and tap into existing surveillance platforms.

- Development of a rapid, point-of-care test (like a rapid influenza test; home tests;) and rapid bed-side tests, recognizing the tradeoffs between speed, accessibility, and accuracy.
- Best tests to look at IgM and IgG antibodies and how best to scale up and create a rapid test.
- Rapid design and execution of targeted surveillance experiments calling for all potential testers using PCR in a defined area to start testing and report to a specific entity. These experiments could aid in collecting longitudinal samples, which are critical to understanding the impact of ad hoc local interventions (which also need to be recorded).
- Separation of assay development issues from instruments, and the role of the private sector to help quickly migrate assays onto those devices.
- Establish efforts to track the evolution of the virus (i.e., genetic drift or mutations) and avoid locking into specific reagents and surveillance/detection schemes.
- Latency issues and when there is sufficient viral load to detect the pathogen, and understanding of what is needed in terms of biological and environmental sampling.
- Use of diagnostics such as host response markers (e.g., cytokines) to detect early disease or predict severe disease progression, which would be important to understanding best clinical practice and efficacy of therapeutic interventions.
- Policies and protocols for screening and testing.
- Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.

Examples of long-term research needs

- Technology roadmap for diagnostics.
- Barriers to developing and scaling up new diagnostic tests (e.g., market forces), how future coalition and accelerator models (e.g., Coalition for Epidemic Preparedness Innovations) could provide critical funding for diagnostics, and opportunities for a streamlined regulatory environment.
- New platforms and technology (e.g., CRISPR) to improve response times and employ more holistic approaches to COVID-19 and future diseases.
- Coupling genomics and diagnostic testing on a large scale.
- Enhance capabilities for rapid sequencing and bioinformatics to target regions of the genome that will allow specificity for a particular variant.

Patient care

- Risk factors

  Examples of short-term research needs

  - Data on potential risks factors
    - Smoking, pre-existing pulmonary disease
    - Co-infections (determine whether co-existing respiratory/viral infections make the virus more transmissible or virulent) and other co-morbidities

  - Differences in respiratory/viral infections for neonates and pregnant women
  - Socio-economic and behavioral factors to understand the economic impact of the virus and whether there were differences.
  - Pediatrics – Innate immune system of children vs adaptive immune system response of adults (e.g., cross reactivity between some routine childhood vaccination that is providing protection to the youngest in the population).
- Surge capacity and nursing homes
  Examples of short-term research needs
  - Resources to support skilled nursing facilities and long term care facilities.
  - Mobilization of surge medical staff to address shortages in overwhelmed communities.
- Efforts to inform allocation of scarce resources
  Examples of short-term research needs
  - Age-adjusted mortality data for Acute Respiratory Distress Syndrome (ARDS) with/without other organ failure – particularly for viral etiologies
  - Extracorporeal membrane oxygenation (ECMO) outcomes data of COVID-19 patients; and,
  - Outcomes data for COVID-19 after mechanical ventilation adjusted for age.
  - Knowledge of the frequency, manifestations, and course of extrapulmonary manifestations of COVID-19, including, but not limited to, possible cardiomyopathy and cardiac arrest.
  - Application of regulatory standards (e.g., EUA, CLIA) and ability to adapt care to crisis standards of care level.
- Personal protective equipment
  Example of short-term research needs
  - Approaches for encouraging and facilitating the production of elastomeric respirators, which can save thousands of N95 masks.
- Alternative methods to advise on disease management
  Examples of short-term research needs
  - Best telemedicine practices, barriers and facilitators, and specific actions to remove/expand them within and across state boundaries.
  - Guidance on the simple things people can do at home to take care of sick people and manage disease.
  - Oral medications that might potentially work.

  Example of long-term research needs
  - Use of AI in real-time health care delivery to evaluate interventions, risk factors, and outcomes in a way that could not be done manually.
- Processes of care
  Example of short-term research needs
  - Best practices and critical challenges and innovative solutions and technologies in hospital flow and organization, workforce protection, workforce allocation,

community-based support resources, payment, and supply chain management to enhance capacity, efficiency, and outcomes.

Group C – Community Engagement and Population Health (SC Leads: Mary Travis Bassett, Robert Groves)

Staff Leads: Julie Pavlin and Monica Feit (DBASSE)

Members: Georges Benjamin
Rich Besser
Peter Daszak
Phyllis Meadows
Mark Smolinski
Jeff Duchin
Baruch Fischhoff
(SBS WG, membership TBD)

Topics: Epidemiology and population surveillance
Social and public health interventions
Public communication and understanding

Epidemiology and population surveillance

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes and for understanding/guidance to be implemented).

  Examples of short-term research needs
  - Plans for serosurveys of previously exposed/immune individuals. Evaluation of background level of people with Covid19 antibodies in the community.
  - Policies and protocols for screening and testing (e.g. screening/testing schedule for post-exposure).
  - Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.
  - Recruitment, support, and coordination of local expertise and capacity (public, private—commercial, and non-profit, including academic), including legal, ethical, communications, and operational issues.
  - National guidance and guidelines about best practices to states (e.g., how states might leverage universities and private laboratories for testing purposes, communications to public health officials and the public).
  - Validation and sharing (and effectively using) modeling outputs.

  Examples of long-term research needs
  - Technology roadmap for diagnostics.
  - Barriers to developing and scaling up new diagnostic tests (e.g., market forces), how future coalition and accelerator models (e.g., Coalition for Epidemic Preparedness

Innovations) could provide critical funding for diagnostics, and opportunities for a streamlined regulatory environment.
- New platforms and technology (e.g., CRISPR) to improve response times and employ more holistic approaches to COVID-19 and future diseases.
- Coupling genomics and diagnostic testing on a large scale (intersection with Group A).

Social and public health interventions

Example of short-term research needs

- Effectiveness of non-therapeutic public health measures (e.g. patient contact tracing, social distancing strategies, school closings, telework). Rapid design and execution of experiments to examine and compare NPIs currently being implemented.
    - Risk/benefit of various social distancing measures
        - Optimal timing of social distancing (what are the triggers to start, when is it too late)
        - Importance of herd immunity
        - Avoiding the second wave
- Guidance on ways to scale up NPIs in a more coordinated way (e.g., establish funding, infrastructure and authorities to support real time, authoritative (qualified participants) collaboration with all states to gain consensus on consistent guidance and to mobilize resources to geographic areas where critical shortfalls are identified) to give us time to enhance our health care delivery system capacity to respond to an increase in cases.
- Methods to control the spread in communities, barriers to compliance and how these vary among different populations.

Examples of long-term research needs

- Models of potential interventions to predict costs and benefits that take account of such factors as race, income, disability, age, geographic location, immigration status, housing status, employment status, and health insurance status.
- Policy changes necessary to enable the compliance of individuals with limited resources and the underserved with NPIs. Research on why people fail to comply with public health advice, even if they want to do so (e.g., social or financial costs may be too high).
- Research on the economic impact of this or any pandemic. This would include identifying policy and programmatic alternatives that lessen/mitigate risks to critical government services, food distribution and supplies, access to critical household supplies, and access to health diagnoses, treatment, and needed care, regardless of ability to pay.

Public communication and understanding

- Messaging to the public, health professionals, civic leaders, etc.
- Communicating with high-risk populations

  Examples of short-term research needs
  - Modes of communicating with target high-risk populations (elderly, health care workers).
  - Risk communication and guidelines that are easy to understand and follow (include targeting at risk populations' families too).
  - Communication that indicates potential risk of disease to all population groups.
  - Clarify community measures
  - Clarify misunderstanding around containment and mitigation

Group D – Cross-cutting Issues (SC Leads: Tara O'Toole, Alta Charo)

Staff Leads: Andy Pope and Lisa Brown
Members: Ellen Embry
Patricia King
Phyllis Meadows
Alexandra Phelan
Topics: Ethics, equity, and law
International relations and cooperation
Innovative solutions across the public and private sectors
Lessons learned/future outbreaks

Ethics, equity, and law

- Consideration of the health needs and wellbeing of underserved/disinfranchised populations

  Examples of short-term research needs
  - Action plan to mitigate gaps and problems of inequity in the Nation's public health capability, capacity, and funding to ensure all citizens in need are supported and can access information, surveillance, and treatment.
  - Measures to reach marginalized and disadvantaged populations.
  - Data systems and research priorities and agendas incorporate attention to the needs and circumstances of disadvantaged populations and underrepresented minorities.
  - Understand and mitigate threats to incarcerated people from COVID-19, assuring access to information, prevention, diagnosis, and treatment.
  - Understand coverage policies (barriers and opportunities) related to testing, treatment, and care

International relations and cooperation

- The role of international regulatory organizations, WHO, etc

- Reliance and mutual recognition agreements (see NASEM study: Mutual Recognition Agreements in the Regulation of Medicines https://www.nationalacademies.org/our-work/mutual-recognition-agreements-in-the-regulation-of-medicines)
- Data standards and nomenclature:
    - Methods for coordinating data-gathering with standardized nomenclature.
    - Consistent platform for sharing response information among planners, providers, and others.
    - Understand and mitigate barriers to information-sharing.

Innovative solutions across public and private sectors

- Governmental public health

  Example of short-term research needs
    - Determine how to recruit, support, and coordinate local (non-Federal) expertise and capacity relevant to public health emergency response (public, private—commercial and non-profit, including academic).

  Examples of long-term research needs
    - Better integration of federal/state/local public health surveillance systems.
    - Value of investments in baseline public health response infrastructure preparedness capacity and capability.

Lessons learned/Future outbreaks

- Research needs to improve our understanding of the viral diversity and risk factors for viruses that are not yet known to medicine but exist and are available to infect humans and present epidemic and pandemic threats.
- Research needs and evaluation metrics to inform the immediate response and future outbreak response.

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D

Location: https://zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: COVID Preclinical working group (Tuesday meeting)

Start Time: Tue 4/21/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 5/26/2020 3:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D

Holding time

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical full working group

Start Time: Wed 4/22/2020 10:00:00 AM (UTC-04:00)

End Time: Wed 4/22/2020 11:00:00 AM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Calendar Exception: Untitled

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Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Annaliesa.Anderson@pfizer.com; Cat.Lutz@jax.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Santos, Michael (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Diamond, Michael; Jonson, Samantha (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C
Importance:	Normal
Start Time:	Tue 4/21/2020 2:00:00 PM (UTC-04:00)
End Time:	Tue 4/21/2020 3:00:00 PM (UTC-04:00)
Required Attendees:	Annaliesa.Anderson@pfizer.com; Cat.Lutz@jax.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)
Optional Attendees:	Santos, Michael (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Diamond, Michael; Jonson, Samantha (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 4/28/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 4/28/2020 3:00:00 PM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; ken.duncan@gatesfoundation.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Lowy, Douglas (NIH/NCI) [E]; Diamond, Michael; Rodriguez, Robin D; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C

We are planning several smaller individual workstream meetings instead of the full working group. We will provide updates from the individual workstreams the next full Working group meeting (Thursday, 11-12 Eastern time).

Joe

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 5/5/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 5/5/2020 3:00:00 PM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Florence, Clint (NIH/NIAID) [E]; Diamond, Michael; Gonzalez, Nina; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]

Cancelling due to the NPRC director's meeting.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Importance:	Normal
Start Time:	Wed 7/29/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 7/29/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Optional Attendees:	Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
Importance:	Normal
Start Time:	Wed 6/17/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 6/17/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Optional Attendees:	Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Importance:	Normal
Start Time:	Wed 6/24/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 6/24/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
Optional Attendees:	Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com

Importance: Normal

Start Time: Wed 9/23/2020 10:30:00 AM (UTC-04:00)

End Time: Wed 9/23/2020 11:30:00 AM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com

Changing time for this meeting at the request of the cochair.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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+1 346 248 7799 US (Houston)
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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical full working group

Start Time: Wed 1/13/2021 11:00:00 AM (UTC-04:00)

End Time: Wed 1/13/2021 12:00:00 PM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net

Optional Attendees: Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Calendar Exception: Untitled

Calendar Exception: Untitled

Calendar Exception: Untitled

Calendar Exception: Untitled

Calendar Exception: Untitled

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Calendar Exception: Untitled

Changing time for preclinical WG

Joe Menetski (he/him/his) is inviting you to a scheduled Zoom meeting.

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- +1 669 900 6833 US (San Jose)
- +1 253 215 8782 US (Tacoma)
- +1 346 248 7799 US (Houston)

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Passcode: 124630
Find your local number: https://fnih.zoom.us/u/acVE1R8lN

Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Annaliesa.Anderson@pfizer.com; Cat.Lutz@jax.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Santos, Michael (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Diamond, Michael; Jonson, Samantha (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C
Importance:	Normal
Start Time:	Tue 4/21/2020 2:00:00 PM (UTC-04:00)
End Time:	Tue 4/21/2020 3:00:00 PM (UTC-04:00)
Required Attendees:	Annaliesa.Anderson@pfizer.com; Cat.Lutz@jax.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)
Optional Attendees:	Santos, Michael (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Diamond, Michael; Jonson, Samantha (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: High

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 4/28/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 4/28/2020 3:00:00 PM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; ken.duncan@gatesfoundation.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Lowy, Douglas (NIH/NCI) [E]; Diamond, Michael; Rodriguez, Robin D; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C

We are planning several smaller individual workstream meetings instead of the full working group. We will provide updates from the individual workstreams the next full Working group meeting (Thursday, 11-12 Eastern time).

Joe

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: High

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 5/5/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 5/5/2020 3:00:00 PM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Florence, Clint (NIH/NIAID) [E]; Diamond, Michael; Gonzalez, Nina; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]

Cancelling due to the NPRC director's meeting.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Importance:	Normal
Start Time:	Wed 7/29/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 7/29/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Optional Attendees:	Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
Importance:	Normal
Start Time:	Wed 6/17/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 6/17/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Optional Attendees:	Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Importance:	Normal
Start Time:	Wed 6/24/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 6/24/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
Optional Attendees:	Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com

Importance: Normal

Start Time: Wed 9/23/2020 10:30:00 AM (UTC-04:00)

End Time: Wed 9/23/2020 11:30:00 AM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com

Changing time for this meeting at the request of the cochair.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; caroline.sferrazza@roseliassociates.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

Importance: High

Subject: Canceled: ACTIV Preclinical full working group

Start Time: Thur 10/8/2020 9:00:00 AM (UTC-04:00)

End Time: Thur 10/8/2020 10:00:00 AM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com

Optional Attendees: caroline.sferrazza@roseliassociates.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

Move due to conflict with the ACTIV executive Committee meeting

Changing time for preclinical WG

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Passcode: 124630
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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	john.young.jy3@roche.com; kara.carter@evotec.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; caroline.sferrazza@roseliassociates.com; RZahn@its.jnj.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah
Importance:	Normal
Start Time:	Wed 10/21/2020 10:15:00 AM (UTC-04:00)
End Time:	Wed 10/21/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	fstegmeier@ksqtx.comjohn.young.jy3@roche.com; kara.carter@evotec.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com
Optional Attendees:	caroline.sferrazza@roseliassociates.com; RZahn@its.jnj.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison;

Mason, Stephen; Connelly, Sarah

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: john.young.jy3@roche.com; Baric, Ralph S; Colvis, Christine (NIH/NCATS) [E]; diamond@wusm.wustl.edu; ken.duncan@gatesfoundation.org; Tomas Cihlar; Melencio, Cheryl (FNIH) [T]; Diamond, Michael; Rose Li; Dana Carluccio; Baric, Toni C; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; Gadbois, Ellen (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Ottinger, Elizabeth (NIH/NCATS [E]

Location: Zoom Meeting

Importance: Normal

Subject: Subgroup discussion of prediction of therapy resistance from emerging viral sequence data

Start Time: Wed 11/18/2020 11:00:00 AM (UTC-04:00)

End Time: Wed 11/18/2020 12:00:00 PM (UTC-04:00)

Required Attendees: Isis.Kanevsky@pfizer.com; Fessel, Josh (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Punturieri, Antonello (NIH/NHLBI) [E]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Rao, Srinivas; Adams, Peter (OS/ASPR/BARDA); Collins, Francis (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Frank.Nestle@sanofi.com; Cat.Lutz@jax.org; Deming, Damon (FDA/CDER); Hewitt, Judith (NIH/NIAID) [E]; prabha.fernandes@gmail.com; ggatto@rti.org; jay_grobler@merck.com; kara.carter@evotec.com; jrappaport@tulane.edu; Anderson, Annaliesa; fstegmeier@ksqtx.com; david.j.payne@gsk.com; Hild, Sheri (NIH/OD) [E]john.young.jy3@roche.com; Baric, Ralph S; Colvis, Christine (NIH/NCATS) [E]; diamond@wusm.wustl.edu; ken.duncan@gatesfoundation.org; Tomas Cihlar

Optional Attendees: Anderson, James (NIH/OD) [E]; Stratton, Benjamin; Nancy Haigwood; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]; Dave Frankowski; Rodriguez, Robin D; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Gonzalez, Nina; Jonson, Samantha (NIH/NCATS) [E]; Lagos, Enrique (NIH/NCATS) [E]; Prabhavathi Fernandes; Wachtel, Jonathan; Tolman, Brett; Kim, Elizabeth; Alvarez, Rosa Maria; James, Stephanie (FNIH) [T]; Adam, Stacey (FNIH) [T]; Santos, Michael (FNIH) [T]; Tountas, Karen (FNIH) [T]; Read, Sarah (NIH/NIAID) [E]; Lowy, Douglas (NCI); Kurilla, Michael (NIH/NCATS) [E]; Jansen, Kathrin; Hughes, Eric; Desrosiers, Betsy; Austin, Christopher (NIH/NCATS) [E]; Wholley, David (FNIH) [T]Melencio, Cheryl (FNIH) [T]; Diamond, Michael; Rose Li; Dana Carluccio; Baric, Toni C; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; Gadbois, Ellen (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Ottinger, Elizabeth (NIH/NCATS [E]

Changing to a discussion of sequence variation and therapy/vaccine escape

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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; caroline.sferrazza@roseliassociates.com; kcarter@dewpointx.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd
Importance:	Normal
Start Time:	Fri 12/18/2020 9:00:00 AM (UTC-04:00)
End Time:	Fri 12/18/2020 10:00:00 AM (UTC-04:00)
Required Attendees:	Collins, Francis (NIH/OD) [E]; kara.carter@evotec.com; fstegmeier@ksqtx.comHild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net
Optional Attendees:	caroline.sferrazza@roseliassociates.com; kcarter@dewpointx.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton,

Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Importance: High

Subject: Canceled: ACTIV Preclinical full working group

Start Time: Wed 12/23/2020 11:00:00 AM (UTC-04:00)

End Time: Wed 12/23/2020 12:00:00 PM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com

Changing time for preclinical WG

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Importance: High

Subject: Canceled: ACTIV Preclinical full working group

Start Time: Wed 12/30/2020 11:00:00 AM (UTC-04:00)

End Time: Wed 12/30/2020 12:00:00 PM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com

Changing time for preclinical WG

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Importance: High
Subject: Canceled: ACTIV Preclinical full working group
Start Time: Wed 3/3/2021 11:00:00 AM (UTC-04:00)
End Time: Wed 3/3/2021 12:00:00 PM (UTC-04:00)
Required Attendees: Cat.Lutz@jax.org; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net
Optional Attendees: Lerner, Andrea (NIH/NIAID) [E]; Gonzalez, Nina; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]

The cochairs would like to cancel today and encourage you to join the WHO meeting below.
WHO will host a **Global consultation on COVID-19 therapeutics** to discuss knowledge gaps and research priorities, with the following objectives to outline:

- the main priority research questions of importance to public health and a targeted research agenda for 2021 that identifies knowledge gaps and prioritization pathways for therapeutics in clinical development phase and those being repurposed, including combinations, and research priorities for new COVID therapeutics; and
- additional steps to ensure further international collaboration supports the coordinated implementation of key research.

The webinar will be convened on **Wednesday, 3 March 2021, 13:30 – 18:30 Central European Time (CET)**. The proposed agenda will be provided in advance.

Please register on the link below to receive your connection details.
https://who-e.zoom.us/webinar/register/WN_CNfywAEiTEWgqA_nEcjeow

Changing time for preclinical WG

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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda
Start Time:	Wed 8/11/2021 10:00:00 AM (UTC-04:00)
End Time:	Wed 8/11/2021 11:00:00 AM (UTC-04:00)
Required Attendees:	Anderson, AnnaliesaHild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net
Optional Attendees:	Mason, Stephen; Baric, Toni C; Diamond, MichaelWholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; Cat.Lutz@jax.org; john.young.jy3@roche.com; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Importance: High

Subject: Canceled: ACTIV Preclinical full working group

Start Time: Wed 6/9/2021 10:00:00 AM (UTC-04:00)

End Time: Wed 6/9/2021 11:00:00 AM (UTC-04:00)

Required Attendees: ggatto@rti.orgCat.Lutz@jax.org; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net

Optional Attendees: Mason, StephenHughes, Eric; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Canceling the preclinical working group meeting for this week. Please let me know if you have anything that we need to address in future meetings.

Best regards,
Joe

Joe Menetski (he/him/his) is inviting you to a scheduled Zoom meeting.

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical full working group

Start Time: Wed 1/13/2021 11:00:00 AM (UTC-04:00)

End Time: Wed 1/13/2021 12:00:00 PM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net

Optional Attendees: Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Calendar Exception: Untitled

Calendar Exception: Untitled

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- +1 408 638 0968 US (San Jose)
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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Annaliesa.Anderson@pfizer.com; Cat.Lutz@jax.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Santos, Michael (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Diamond, Michael; Jonson, Samantha (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C
Importance:	Normal
Start Time:	Tue 4/21/2020 2:00:00 PM (UTC-04:00)
End Time:	Tue 4/21/2020 3:00:00 PM (UTC-04:00)
Required Attendees:	Annaliesa.Anderson@pfizer.com; Cat.Lutz@jax.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)
Optional Attendees:	Santos, Michael (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Diamond, Michael; Jonson, Samantha (NIH/NCATS) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: High

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 4/28/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 4/28/2020 3:00:00 PM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; ken.duncan@gatesfoundation.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Lowy, Douglas (NIH/NCI) [E]; Diamond, Michael; Rodriguez, Robin D; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C

We are planning several smaller individual workstream meetings instead of the full working group. We will provide updates from the individual workstreams the next full Working group meeting (Thursday, 11-12 Eastern time).

Joe

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: High

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 5/5/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 5/5/2020 3:00:00 PM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Florence, Clint (NIH/NIAID) [E]; Diamond, Michael; Gonzalez, Nina; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]

Cancelling due to the NPRC director's meeting.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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+1 253 215 8782 US
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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Importance:	Normal
Start Time:	Wed 7/29/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 7/29/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Optional Attendees:	Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
Importance:	Normal
Start Time:	Wed 6/17/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 6/17/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Optional Attendees:	Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Importance:	Normal
Start Time:	Wed 6/24/2020 10:00:00 AM (UTC-04:00)
End Time:	Wed 6/24/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
Optional Attendees:	Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com

Importance: Normal

Start Time: Wed 9/23/2020 10:30:00 AM (UTC-04:00)

End Time: Wed 9/23/2020 11:30:00 AM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com

Changing time for this meeting at the request of the cochair.

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; caroline.sferrazza@roseliassociates.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

Importance: High

Subject: Canceled: ACTIV Preclinical full working group

Start Time: Thur 10/8/2020 9:00:00 AM (UTC-04:00)

End Time: Thur 10/8/2020 10:00:00 AM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com

Optional Attendees: caroline.sferrazza@roseliassociates.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

Move due to conflict with the ACTIV executive Committee meeting

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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+1 346 248 7799 US (Houston)
Meeting ID: 960 4240 3854
Passcode: 124630
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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	john.young.jy3@roche.com; kara.carter@evotec.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; caroline.sferrazza@roseliassociates.com; RZahn@its.jnj.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah
Importance:	Normal
Start Time:	Wed 10/21/2020 10:15:00 AM (UTC-04:00)
End Time:	Wed 10/21/2020 11:00:00 AM (UTC-04:00)
Required Attendees:	fstegmeier@ksqtx.comjohn.young.jy3@roche.com; kara.carter@evotec.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com
Optional Attendees:	caroline.sferrazza@roseliassociates.com; RZahn@its.jnj.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison;

Mason, Stephen; Connelly, Sarah

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: john.young.jy3@roche.com; Baric, Ralph S; Colvis, Christine (NIH/NCATS) [E]; diamond@wusm.wustl.edu; ken.duncan@gatesfoundation.org; Tomas Cihlar; Melencio, Cheryl (FNIH) [T]; Diamond, Michael; Rose Li; Dana Carluccio; Baric, Toni C; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; Gadbois, Ellen (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Ottinger, Elizabeth (NIH/NCATS [E]

Location: Zoom Meeting

Importance: Normal

Subject: Subgroup discussion of prediction of therapy resistance from emerging viral sequence data

Start Time: Wed 11/18/2020 11:00:00 AM (UTC-04:00)

End Time: Wed 11/18/2020 12:00:00 PM (UTC-04:00)

Required Attendees: Isis.Kanevsky@pfizer.com; Fessel, Josh (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Punturieri, Antonello (NIH/NHLBI) [E]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Rao, Srinivas; Adams, Peter (OS/ASPR/BARDA); Collins, Francis (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Frank.Nestle@sanofi.com; Cat.Lutz@jax.org; Deming, Damon (FDA/CDER); Hewitt, Judith (NIH/NIAID) [E]; prabha.fernandes@gmail.com; ggatto@rti.org; jay_grobler@merck.com; kara.carter@evotec.com; jrappaport@tulane.edu; Anderson, Annaliesa; fstegmeier@ksqtx.com; david.j.payne@gsk.com; Hild, Sheri (NIH/OD) [E]john.young.jy3@roche.com; Baric, Ralph S; Colvis, Christine (NIH/NCATS) [E]; diamond@wusm.wustl.edu; ken.duncan@gatesfoundation.org; Tomas Cihlar

Optional Attendees: Anderson, James (NIH/OD) [E]; Stratton, Benjamin; Nancy Haigwood; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]; Dave Frankowski; Rodriguez, Robin D; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Gonzalez, Nina; Jonson, Samantha (NIH/NCATS) [E]; Lagos, Enrique (NIH/NCATS) [E]; Prabhavathi Fernandes; Wachtel, Jonathan; Tolman, Brett; Kim, Elizabeth; Alvarez, Rosa Maria; James, Stephanie (FNIH) [T]; Adam, Stacey (FNIH) [T]; Santos, Michael (FNIH) [T]; Tountas, Karen (FNIH) [T]; Read, Sarah (NIH/NIAID) [E]; Lowy, Douglas (NCI); Kurilla, Michael (NIH/NCATS) [E]; Jansen, Kathrin; Hughes, Eric; Desrosiers, Betsy; Austin, Christopher (NIH/NCATS) [E]; Wholley, David (FNIH) [T]Melencio, Cheryl (FNIH) [T]; Diamond, Michael; Rose Li; Dana Carluccio; Baric, Toni C; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; Gadbois, Ellen (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Ottinger, Elizabeth (NIH/NCATS [E]

Changing to a discussion of sequence variation and therapy/vaccine escape

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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; caroline.sferrazza@roseliassociates.com; kcarter@dewpointx.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; btolman; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd
Importance:	Normal
Start Time:	Fri 12/18/2020 9:00:00 AM (UTC-04:00)
End Time:	Fri 12/18/2020 10:00:00 AM (UTC-04:00)
Required Attendees:	Collins, Francis (NIH/OD) [E]; kara.carter@evotec.com; fstegmeier@ksqtx.comHild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net
Optional Attendees:	caroline.sferrazza@roseliassociates.com; kcarter@dewpointx.com; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton,

Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Importance: High

Subject: Canceled: ACTIV Preclinical full working group

Start Time: Wed 12/23/2020 11:00:00 AM (UTC-04:00)

End Time: Wed 12/23/2020 12:00:00 PM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Importance: High

Subject: Canceled: ACTIV Preclinical full working group

Start Time: Wed 12/30/2020 11:00:00 AM (UTC-04:00)

End Time: Wed 12/30/2020 12:00:00 PM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Importance: High
Subject: Canceled: ACTIV Preclinical full working group
Start Time: Wed 3/3/2021 11:00:00 AM (UTC-04:00)
End Time: Wed 3/3/2021 12:00:00 PM (UTC-04:00)
Required Attendees: Cat.Lutz@jax.org; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net
Optional Attendees: Lerner, Andrea (NIH/NIAID) [E]; Gonzalez, Nina; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]

The cochairs would like to cancel today and encourage you to join the WHO meeting below.
WHO will host a **Global consultation on COVID-19 therapeutics** to discuss knowledge gaps and research priorities, with the following objectives to outline:

- the main priority research questions of importance to public health and a targeted research agenda for 2021 that identifies knowledge gaps and prioritization pathways for therapeutics in clinical development phase and those being repurposed, including combinations, and research priorities for new COVID therapeutics; and
- additional steps to ensure further international collaboration supports the coordinated implementation of key research.

The webinar will be convened on **Wednesday, 3 March 2021, 13:30 – 18:30 Central European Time (CET)**. The proposed agenda will be provided in advance.

Please register on the link below to receive your connection details.
https://who-e.zoom.us/webinar/register/WN_CNfywAEiTEWgqA_nEcjeow

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda
Start Time:	Wed 8/11/2021 10:00:00 AM (UTC-04:00)
End Time:	Wed 8/11/2021 11:00:00 AM (UTC-04:00)
Required Attendees:	Anderson, AnnaliesaHild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net
Optional Attendees:	Mason, Stephen; Baric, Toni C; Diamond, MichaelWholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; Cat.Lutz@jax.org; john.young.jy3@roche.com; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Importance: High

Subject: Canceled: ACTIV Preclinical full working group

Start Time: Wed 6/9/2021 10:00:00 AM (UTC-04:00)

End Time: Wed 6/9/2021 11:00:00 AM (UTC-04:00)

Required Attendees: ggatto@rti.orgCat.Lutz@jax.org; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; Anderson, Annaliesa; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net

Optional Attendees: Mason, StephenHughes, Eric; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

Canceling the preclinical working group meeting for this week. Please let me know if you have anything that we need to address in future meetings.

Best regards,
Joe

Joe Menetski (he/him/his) is inviting you to a scheduled Zoom meeting.

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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda
Start Time:	Wed 7/14/2021 10:00:00 AM (UTC-04:00)
End Time:	Wed 7/14/2021 11:00:00 AM (UTC-04:00)
Required Attendees:	john.young.jy3@roche.comHild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Isis.Kanevsky@pfizer.com; kara.carter01@comcast.net
Optional Attendees:	Hughes, EricWholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; caroline.sferrazza@roseliassociates.com; Connelly, Sarah; RZahn@its.jnj.com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kcarter@dewpointx.com; Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]; Cardin, Rhonda

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D

Location: https://zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: COVID Preclinical working group (Tuesday meeting)

Start Time: Tue 4/21/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 4/21/2020 3:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D

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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D

Location: https://zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Importance: Normal

Subject: COVID Preclinical working group (Thursday meeting)

Start Time: Fri 4/24/2020 11:00:00 AM (UTC-04:00)

End Time: Fri 4/24/2020 12:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D

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Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt (louise.pitt@us.army.mil); Nancy Haigwood; Hild, Sheri (NIH/OD) [E]

Location: https://fnih.zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Importance: Normal

Subject: ACTIV Preclinical working group (Friday meeting)

Start Time: Fri 4/24/2020 11:00:00 AM (UTC-04:00)

End Time: Fri 4/24/2020 12:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt (louise.pitt@us.army.mil); Nancy Haigwood; Hild, Sheri (NIH/OD) [E]

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+1 669 900 6833 US (San Jose)
Meeting ID: 930 2871 7745
Password: 920539
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Organizer:	Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Attendees:	david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski
Start Time:	Fri 4/24/2020 11:00:00 AM (UTC-04:00)
End Time:	Fri 4/24/2020 12:00:00 PM (UTC-04:00)
Required Attendees:	david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)
Optional Attendees:	Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski

Organizer: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Qashu, Felicia (NIH/OD) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]

Location: https://fnih.zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Start Time: Thur 4/30/2020 11:00:00 AM (UTC-04:00)

End Time: Thur 4/30/2020 12:30:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Qashu, Felicia (NIH/OD) [E]

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]

Request to move due to holiday and extended by 30min

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Cc: Simon Funnell[Simon.Funnell@phe.gov.uk]; William Dowling[william.dowling@cepi.net]; GSELL, Pierre[gsellp@who.int]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: sandra cordo[scordo@qb.fcen.uba.ar]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Vasan, Vasan (H&B, Geelong AAHL)[Vasan.Vasan@csiro.au]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; Alyson Kelvin[AKelvin@dal.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; dhoconno@wisc.edu[dhoconno@wisc.edu]; paul.hodgson@usask.ca[paul.hodgson@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; 秦川[qinchuan@pumc.edu.cn]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; romain.volmer@envt.fr[romain.volmer@envt.fr]; sandrine.lesellier@anses.fr[sandrine.lesellier@anses.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; pauline.maisonnasse@cea.fr[pauline.maisonnasse@cea.fr]; roger.le-grand@cea.fr[roger.le-grand@cea.fr]; Rodriguez-Burgos, Estefania[estefania.rodriguez-burgos@leibniz-hpi.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; amy.c.shurtleff@cepi.net[amy.c.shurtleff@cepi.net]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; woodd@who.int[woodd@who.int]; hlchen@hku.hk[hlchen@hku.hk]; jfwchan@hku.hk[jfwchan@hku.hk]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; ldenisy@yahoo.com[ldenisy@yahoo.com]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; sekim@krict.re.kr[sekim@krict.re.kr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; snumouse@snu.ac.kr[snumouse@snu.ac.kr]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; b.rockx@erasmusmc.nl[b.rockx@erasmusmc.nl]; B.L. Haagmans[b.haagmans@erasmusmc.nl]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; jeroen.kortekaas@wur.nl[jeroen.kortekaas@wur.nl]; nadia.oreshkova@wur.nl[nadia.oreshkova@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; Neil.Berry@nibsc.org[Neil.Berry@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Yper.Hall@phe.gov.uk[Yper.Hall@phe.gov.uk]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; Griffiths, Anthony[ahgriff@bu.edu]; nax3@cdc.gov[nax3@cdc.gov]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; alr2105@columbia.edu[alr2105@columbia.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; geraldine.hamilton@emulatebio.com[geraldine.hamilton@emulatebio.com]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; tony.wang@fda.hhs.gov[tony.wang@fda.hhs.gov]; Tracy.MacGill@fda.hhs.gov[Tracy.MacGill@fda.hhs.gov]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Dan Barouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; Krammer, Florian[florian.krammer@mssm.edu]; Juergen Richt[jricht@vet.k-state.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Albrecht, Randy[randy.albrecht@mssm.edu]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark.Page@nibsc.org[Mark.Page@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; connie.schmaljohn@nih.gov[connie.schmaljohn@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Ian Crozier[ian.crozier@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Spergel, Jonathan[SPERGEL@email.chop.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; rcarrion@txbiomed.org[rcarrion@txbiomed.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Roy, Chad J[croy@tulane.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gustavo.palacios@gmail.com[Gustavo.palacios@gmail.com]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Dohm, Erik Daniel[edohm@uab.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; sktseng@utmb.edu[sktseng@UTMB.EDU]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; darryl.falzarano@usask.ca[darryl.falzarano@usask.ca]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Padmini Salgame[salgampa@njms.rutgers.edu]; Amelia Karlsson[amelia.karlsson@duke.edu]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 4/16/2020 6:13:42 AM (UTC-04:00)
Subject: Agenda and invitation WHO COVID-19 Animal Models Group
Mail Attachment.ics

Webex_Meeting.ics

Dear all,

Please find below the agenda for today's call as well as a Webex invite.

Best regards

César, Bill, Simon and Pierre.

Pathogenesis

(1) BIDMC-Bioqual

(2) Tulane

(3) PUMC (transmission studies in hACE2 tg mice)

(4) Wageningen Bioveterinary Research

WHO Vaccine Assesment Acceleration Plan

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 925 543 184
Meeting password: ApGwNYs5m89

Thursday, April 16, 2020
12:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr

Join meeting

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Organizer: Pierre GSELL : gsellp@who.int
Subject: FU discussion - screening vaccines - animal models
Location: https://who.webex.com/who/j.php?MTID=mbb01177bc6552d471275d8c48d4ad90b
Start Time: 2020-04-16T12:00:00+02:00
End Time: 2020-04-16T13:00:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

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Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Cc: Simon Funnell[Simon.Funnell@phe.gov.uk]; GSELL, Pierre[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: sandra cordo[scordo@qb.fcen.uba.ar]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Vasan, Vasan (H&B, Geelong AAHL)[Vasan.Vasan@csiro.au]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; Alyson Kelvin[AKelvin@dal.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; dhoconno@wisc.edu[dhoconno@wisc.edu]; paul.hodgson@usask.ca[paul.hodgson@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; 秦川[qinchuan@pumc.edu.cn]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; romain.volmer@envt.fr[romain.volmer@envt.fr]; sandrine.lesellier@anses.fr[sandrine.lesellier@anses.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; pauline.maisonnasse@cea.fr[pauline.maisonnasse@cea.fr]; roger.le-grand@cea.fr[roger.le-grand@cea.fr]; Rodriguez-Burgos, Estefania[estefania.rodriguez-burgos@leibniz-hpi.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; amy.c.shurtleff@cepi.net[amy.c.shurtleff@cepi.net]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; woodd@who.int[woodd@who.int]; hlchen@hku.hk[hlchen@hku.hk]; jfwchan@hku.hk[jfwchan@hku.hk]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; ldenisy@yahoo.com[ldenisy@yahoo.com]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; sekim@krict.re.kr[sekim@krict.re.kr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; snumouse@snu.ac.kr[snumouse@snu.ac.kr]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; b.rockx@erasmusmc.nl[b.rockx@erasmusmc.nl]; B.L. Haagmans[b.haagmans@erasmusmc.nl]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; jeroen.kortekaas@wur.nl[jeroen.kortekaas@wur.nl]; nadia.oreshkova@wur.nl[nadia.oreshkova@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; Neil.Berry@nibsc.org[Neil.Berry@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Yper.Hall@phe.gov.uk[Yper.Hall@phe.gov.uk]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; Griffiths, Anthony[ahgriff@bu.edu]; nax3@cdc.gov[nax3@cdc.gov]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; alr2105@columbia.edu[alr2105@columbia.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; geraldine.hamilton@emulatebio.com[geraldine.hamilton@emulatebio.com]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; tony.wang@fda.hhs.gov[tony.wang@fda.hhs.gov]; Tracy.MacGill@fda.hhs.gov[Tracy.MacGill@fda.hhs.gov]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Dan Barouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; Krammer, Florian[florian.krammer@mssm.edu]; Juergen Richt[jricht@vet.k-state.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Albrecht, Randy[randy.albrecht@mssm.edu]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark.Page@nibsc.org[Mark.Page@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; connie.schmaljohn@nih.gov[connie.schmaljohn@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Ian Crozier[ian.crozier@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Spergel, Jonathan[SPERGEL@email.chop.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; rcarrion@txbiomed.org[rcarrion@txbiomed.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Roy, Chad J[croy@tulane.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gustavo.palacios@gmail.com[Gustavo.palacios@gmail.com]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Dohm, Erik Daniel[edohm@uab.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; sktseng@utmb.edu[sktseng@UTMB.EDU]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; darryl.falzarano@usask.ca[darryl.falzarano@usask.ca]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Padmini Salgame[salgampa@njms.rutgers.edu]; Amelia Karlsson[amelia.karlsson@duke.edu]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 4/16/2020 7:44:10 AM (UTC-04:00)
Subject: CORRECTION!: Agenda and invitation WHO COVID-19 Animal Models Group
Mail Attachment.ics
Webex_Meeting.ics

Dear all,
There was a mistake in the previous webex invite. As usual the meeting will take place at 3PM CET (Geneva time). Please find below the correct invite

Sorry for the confusion

César

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 925 215 374
Meeting password: mcQz6huvk96

Thursday, April 16, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)

41445750282 SWITZERLAND Toll

+1-415-655-0003 US Toll

Global call-in numbers

Join from a video system or application

Dial 925215374@who.webex.com

You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 925215374.who@lync.webex.com

Need help? Go to http://help.webex.com

Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 8th TC Animal Models Expert Group
Location: https://who.webex.com/who/j.php?MTID=m8f437c28167647f8fb32c24cf8049a74
Start Time: 2020-04-16T15:00:00+02:00
End Time: 2020-04-16T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

Meeting number (access code): 925 215 374
Meeting password:mcQz6huvk96

Join meeting

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 8th TC Animal Models Expert Group
Location: https://who.webex.com/who/j.php?MTID=m8f437c28167647f8fb32c24cf8049a74
Start Time: 2020-04-16T15:00:00+02:00
End Time: 2020-04-16T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

Meeting number (access code): 925 215 374
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You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 925215374.who@lync.webex.com

Need help? Go to http://help.webex.com

To: Baric, Ralph S[rbaric@email.unc.edu]
From: Fang Li[lifang@umn.edu]
Sent: Thur 4/16/2020 9:59:12 AM (UTC-04:00)
Subject: talk on the phone?

Hi Ralph,
Will you be available to talk on the phone today? I will need to discuss with you a few things related to SARS-CoV-2.

Thanks,
Fang
--
****
Fang Li, Ph.D.
Associate Professor
Department of Veterinary and Biomedical Sciences
University of Minnesota Twin Cities
612-625-6149, lifang@umn.edu
http://www.msi.umn.edu/~lifang
****

To: Alexandra Phelan (alp81@georgetown.edu)[alp81@georgetown.edu]; David A Relman (relman@stanford.edu)[relman@stanford.edu]; David Walt (dwalt@bwh.harvard.edu)[dwalt@bwh.harvard.edu]; Diane Griffin (dgriffi6@jhmi.edu)[dgriffi6@jhmi.edu]; Embrey, Ellen (eembrey@stratitia.com)[eembrey@stratitia.com]; Georges Benjamin (georges.benjamin@apha.org)[georges.benjamin@apha.org]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; John Hick (hick.john@gmail.com)[hick.john@gmail.com]; Jonna Mazet (jkmazet@ucdavis.edu)[jkmazet@ucdavis.edu]; Kent Kester (Kent.Kester@sanofi.com)[Kent.Kester@sanofi.com]; Kristian G. Andersen (kga1978@gmail.com)[kga1978@gmail.com]; Mark Smolinski (mark@endingpandemics.org)[mark@endingpandemics.org]; Mary Travis Bassett (mbassett@hsph.harvard.edu)[mbassett@hsph.harvard.edu]; Patricia King (patricia.king1@gmail.com)[patricia.king1@gmail.com]; Peggy Hamburg (peggy@hbfam.net)[peggy@hbfam.net]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; Phyllis D. Meadows (PDMeadows@kresge.org)[PDMeadows@kresge.org]; Richard Besser (rbesser@rwjf.org)[rbesser@rwjf.org]; Tara O'Toole (totoole@iqt.org)[totoole@iqt.org]; Trevor Bedford (trevor@bedford.io)[trevor@bedford.io]; Baric, Ralph S[rbaric@email.unc.edu]; Donald Berwick[donberwick@gmail.com]; alta.charo@wisc.edu[alta.charo@wisc.edu]; Jeff.Duchin@kingcounty.gov[Jeff.Duchin@kingcounty.gov]; Baruch Fischhoff[baruch@cmu.edu]; DHanfling@iqt.org[DHanfling@iqt.org]; bgroves@georgetown.edu[bgroves@georgetown.edu]
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; mnavish@iqt.org[mnavish@iqt.org]; andre@ecohealthalliance.org[andre@ecohealthalliance.org]; Peisch, Samuel Francis[speisch@hsph.harvard.edu]; jbaker@rwjf.org[jbaker@rwjf.org]; Baric, Toni C[antoinette_baric@med.unc.edu]; Mary Radford[maradford@ucdavis.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]; Feit, Monica[MFeit@nas.edu]; Shore, Carolyn[CShore@nas.edu]; Wollek, Scott[SWollek@nas.edu]; Downey, Autumn[ADowney@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Thur 4/16/2020 3:48:37 PM (UTC-04:00)
Subject: Next Steps - Working Groups for the Standing Committee on Emerging Infectious Diseases
SCEID Working Group Topics and Questions w Leads_v3.docx
SCEID Working Group Responsibilities_v3.docx

Dear Members of the Standing Committee,

Thank you for your quick responses in confirming your working groups (WGs). The attached list should reflect all of the changes that you provided us, and it also includes an updated list of preliminary topics for each WG.

Also attached is a description of the roles and responsibilities of the these working groups. In summary, the working groups will:

- Provide a locus for consideration of a defined area of issues and topics;
- Identify priorities within its respective area of emphasis for consideration as action items by the sponsors and full Standing Committee; and,
- Assist in the development of useful and timely responses, e.g., in defining clear and specific task statements and identifying subject matter experts who might join the response team.

Next Steps:
Staff will be following up with each of the working groups separately in order to move forward with identifying and prioritizing at least one topic/question from each working group for further consideration. We will also be organizing a meeting of the WG leads to facilitate this process.

Please note that the topics included in the attached document were identified at the first committee meeting. These are meant to be a starting point and not meant to be entirely comprehensive.

Next SC Meeting:
We would like to organize a meeting of the full SC before the end of the month, if possible. At that meeting, we will spend most of the time discussing topics and issues that have been identified by the WGs. To that end, **would you please let us know your availability for a 2-hour (virtual) committee meeting during the below options as soon as possible?**

- **Weds, April 22, sometime between 11 a.m. – 2 p.m. ET**
- **Thurs, April 23, Noon – 2 p.m. ET**
- **Fri, April 24, 1 p.m. – 3 p.m. ET**
- **Thurs, April 30, sometime between 11 a.m. – 3 p.m. ET**

Please let us know if you have any questions.

Many thanks,
Lisa

Lisa Brown, MPH
Senior Program Officer
Board on Health Sciences Policy
Health and Medicine Division
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW, Washington, DC 20001
202-334-2487 (office)
lbrown@nas.edu

From: Brown, Lisa
Sent: Tuesday, April 14, 2020 2:43 PM
To: Alexandra Phelan (alp81@georgetown.edu) <alp81@georgetown.edu>; David A Relman (relman@stanford.edu) <relman@stanford.edu>; David Walt (dwalt@bwh.harvard.edu) <dwalt@bwh.harvard.edu>; Diane Griffin (dgriffi6@jhmi.edu) <dgriffi6@jhmi.edu>; Embrey, Ellen (eembrey@stratitia.com) <eembrey@stratitia.com>; Georges Benjamin (georges.benjamin@apha.org) <georges.benjamin@apha.org>; Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; John Hick (hick.john@gmail.com) <hick.john@gmail.com>; Jonna Mazet (jkmazet@ucdavis.edu) <jkmazet@ucdavis.edu>; Kent Kester (Kent.Kester@sanofi.com) <Kent.Kester@sanofi.com>; Kristian G. Andersen (kga1978@gmail.com) <kga1978@gmail.com>; Mark Smolinski (mark@endingpandemics.org) <mark@endingpandemics.org>; Mary Travis Bassett (mbassett@hsph.harvard.edu) <mbassett@hsph.harvard.edu>; Patricia King (patricia.king1@gmail.com) <patricia.king1@gmail.com>; Peggy Hamburg (peggy@hbfam.net) <peggy@hbfam.net>; Peter Daszak (daszak@ecohealthalliance.org) <daszak@ecohealthalliance.org>; Phyllis D. Meadows (PDMeadows@kresge.org) <PDMeadows@kresge.org>; Richard Besser (rbesser@rwjf.org) <rbesser@rwjf.org>; Tara O'Toole (totoole@iqt.org) <totoole@iqt.org>; Trevor Bedford (trevor@bedford.io) <trevor@bedford.io>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'Donald Berwick' <donberwick@gmail.com>; 'alta.charo@wisc.edu' <alta.charo@wisc.edu>; 'Jeff.Duchin@kingcounty.gov' <Jeff.Duchin@kingcounty.gov>; 'Baruch Fischhoff' <baruch@cmu.edu>; DHanfling@iqt.org; 'bgroves@georgetown.edu' <bgroves@georgetown.edu>
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; 'mnavish@iqt.org' <mnavish@iqt.org>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; Peisch, Samuel Francis <speisch@hsph.harvard.edu>; 'jbaker@rwjf.org' <jbaker@rwjf.org>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; Pope, Andrew <APope@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; Feit, Monica <MFeit@nas.edu>; Shore, Carolyn <CShore@nas.edu>; Wollek, Scott <SWollek@nas.edu>; Downey, Autumn <ADowney@nas.edu>
Subject: Note from Harvey - Working Groups for the Standing Committee on Emerging Infectious Diseases
Importance: High

Dear Members of the Standing Committee,

It is little over a month since we convened our first standing committee meeting, and I thank you for your willing participation in responding to many critical requests from OSTP and ASPR. As we look beyond the first 30 days, I would like to provide you with an update about next steps.

The Committee will likely pivot away from drafting written rapid expert consultations and move towards rapid telephonic consultations between members and sponsors. The time-constant for issues of concern to the sponsors can be measured in hours to a day or two, and even our rapid, written responses may take too long. We conducted our first telephonic consultation on the role of academic labs in sero-prevalence surveillance on April 6th.

In the next phase of our work, I expect the Committee will also have the opportunity to focus on more intermediate to long-term topics, measured in turn-around time of weeks to months. Some of these may be at the request of our

sponsors, and some could be initiated by the committee in accordance with the usual National Academy procedures for self-initiated projects.

Based on your earlier feedback to the idea of working groups, the staff have been working diligently to help me define a small number of working groups to better manage incoming requests; tackle immediate, medium-term and longer-term scientific assessments; and allow us to call upon a more comprehensive network of subject-specific experts. We have simplified the proposed working groups into four domains: viral characteristics; patient care and medical countermeasures; community engagement and population health; and, cross-cutting issues (please see attached). We have identified and confirmed leads for each working group, and I have provisionally identified members for each working group based on your initial expressions of interest. Please review your working group and confirm whether you agree with your assignment or if you would prefer to participate in a different working group. Also, if you are interested and willing to participate in a second working group, please let me know (several members are already in two working groups). **Please provide this feedback to Lisa Brown (lbrown@nas.edu) by COB Wednesday, April 15th.** Once I have received confirmation on the working group assignments, the working groups can move forward with revisiting and prioritizing topics/questions for the sponsor to consider and potentially for our own, self-initiated activity.

At this time, to round out our capacities, the presidents of the Academies are adding several new members to the Committee. Please join me in welcoming Ralph Baric, Don Berwick, Alta Charo, Jeff Duchin, Baruch Fischhoff, Robert Groves, and Dan Hanfling. Staff will provide a revised roster and biosketches in the coming days.

We are in the process of organizing our second committee meeting (likely a two-hour call) for some time next week. Please stay tuned for additional details.

Please let Andy, Lisa, or me know if you have any questions. We look forward to your feedback.

Warm regards,

Harvey

Harvey V. Fineberg, MD, PhD
President
Gordon and Betty Moore Foundation

1661 Page Mill Rd
Palo Alto CA 94304

T: 650.213.3100

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Topics for Consideration

**Note: Underlined names indicate that formal committee appointment is pending.

Group A – Viral Characteristics (SC Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
One Health

Viral characterization (virus genetics, origin, and evolution of SARS-CoV-2)

Examples of short-term research needs

- Biological/molecular characteristics of SARS-CoV-2
- Real-time tracking of whole genomes and a mechanism for coordinating the rapid dissemination of that information to inform the development of diagnostics and therapeutics and to track variations of the virus over time.
- Access to geographic and temporal diverse sample sets to understand geographic distribution and genomic differences, and determine whether there is more than one strain in circulation. Multi-lateral agreements such as the Nagoya Protocol could be leveraged.

Transmission, incubation, and environmental stability

Examples of short-term research needs

- Physical science of the coronavirus (e.g., charge distribution, adhesion to hydrophilic/phobic surfaces, environmental survival to inform decontamination efforts for affected areas and provide information about viral shedding).
- Persistence and stability on a multitude of substrates and sources (e.g., nasal discharge, sputum, urine, fecal matter, blood).
- Persistence of virus on surfaces of different materials (e,g., copper, stainless steel, plastic).
- Effective decontamination protocols

- Range of incubation periods for the disease in humans (and how this varies across age and health status) and how long individuals are contagious, even after recovery.
- Prevalence of asymptomatic shedding and transmission (e.g., particularly children).
- Seasonality of transmission.
- Correlates of immunity- and whether immunity occurs and duration.
- Resistance of previously infected people to mutated strains.

One Health

Examples of long-term research needs

- Enhance capacity (people, technology, data) for sequencing with advanced analytics for unknown pathogens, and explore capabilities for distinguishing naturally-occurring pathogens from intentional.
- One Health surveillance of humans and potential sources of future spillover or ongoing exposure for this organism and future pathogens, including both evolutionary hosts (e.g., bats) and transmission hosts (e.g., heavily trafficked and farmed wildlife and domestic food and companion species), inclusive of environmental, demographic, and occupational risk factors.
- Evidence that livestock could be infected (e.g., field surveillance, genetic sequencing, receptor binding) and serve as a reservoir after the epidemic appears to be over.
  - Evidence of whether farmers are infected, and whether farmers could have played a role in the origin.
  - Surveillance of mixed wildlife- livestock farms for SARS-CoV-2 and other coronaviruses in Southeast Asia.
  - Experimental infections to test host range for this pathogen.

Group B – Patient Care and Medical Countermeasures (MCM) (SC Leads: Don Berwick, Co-Lead TBD)

Staff Leads: Lisa Brown and Scott Wollek

Members: Kristian Andersen
Diane Griffin
Margaret Hamburg
John Hick
Kent Kester
Tara O'Toole
David Relman
David Walt
Dan Hanfling

Topics: Vaccines and therapeutics
Diagnostics

Patient care (including personal protective equipment, crisis standards of care, and quality)

Vaccines and therapeutics

- How to expedite development, manufacturing, distribution of a safe, effective vaccine.
- Need for an end-to-end process for getting promising products to the people who need them (e.g. small biotechs may not have developed a vaccine before and may lack scale-up manufacturing and/or support for larger studies)
- Research and development and evaluation efforts
  Examples of short-term research needs
    - Evaluate/investigate effectiveness of drugs and antivirals being developed and tried to treat COVID-19 patients.
        - E.g., Would it be beneficial to give IL6 receptor antibodies therapy prior to admission to the ICU; use of monoclonal antibodies.
    - Clinical and bench trials to investigate less common viral inhibitors against COVID-19 such as naproxen, clarithromycin, and minocycline that may exert effects on viral replication.
    - Methods to evaluate potential complication of Antibody-Dependent Enhancement (ADE) in vaccine recipients.
    - From a clinical development perspective, explore use of best animal models and their predictive value for a human vaccine.
    - Capabilities to discover a therapeutic (not vaccine) for the disease, and clinical effectiveness studies to discover therapeutics, to include antiviral agents.
    - Alternative models to aid decision makers in determining how to prioritize and distribute scarce, newly proven therapeutics as production ramps up. This could include identifying approaches for expanding production capacity to ensure equitable and timely distribution to populations in need.

  Example of long-term research needs
    - Efforts targeted at a universal coronavirus vaccine.

Diagnostics

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes)
  Examples of short-term research needs
    - Evaluate how widespread current exposure is to be able to make immediate policy recommendations on mitigation measures. Denominators for testing and a mechanism for rapidly sharing that information, including demographics, to the extent possible. Sampling methods to determine asymptomatic disease (e.g., use of serosurveys (such as convalescent samples) and early detection of disease (e.g., use of screening of neutralizing antibodies such as ELISAs),

- Efforts to increase capacity on existing diagnostic platforms and tap into existing surveillance platforms.
- Development of a rapid, point-of-care test (like a rapid influenza test; home tests;) and rapid bed-side tests, recognizing the tradeoffs between speed, accessibility, and accuracy.
- Best tests to look at IgM and IgG antibodies and how best to scale up and create a rapid test.
- Rapid design and execution of targeted surveillance experiments calling for all potential testers using PCR in a defined area to start testing and report to a specific entity. These experiments could aid in collecting longitudinal samples, which are critical to understanding the impact of ad hoc local interventions (which also need to be recorded).
- Separation of assay development issues from instruments, and the role of the private sector to help quickly migrate assays onto those devices.
- Establish efforts to track the evolution of the virus (i.e., genetic drift or mutations) and avoid locking into specific reagents and surveillance/detection schemes.
- Latency issues and when there is sufficient viral load to detect the pathogen, and understanding of what is needed in terms of biological and environmental sampling.
- Use of diagnostics such as host response markers (e.g., cytokines) to detect early disease or predict severe disease progression, which would be important to understanding best clinical practice and efficacy of therapeutic interventions.
- Policies and protocols for screening and testing.
- Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.

Examples of long-term research needs

- Technology roadmap for diagnostics.
- Barriers to developing and scaling up new diagnostic tests (e.g., market forces), how future coalition and accelerator models (e.g., Coalition for Epidemic Preparedness Innovations) could provide critical funding for diagnostics, and opportunities for a streamlined regulatory environment.
- New platforms and technology (e.g., CRISPR) to improve response times and employ more holistic approaches to COVID-19 and future diseases.
- Coupling genomics and diagnostic testing on a large scale.
- Enhance capabilities for rapid sequencing and bioinformatics to target regions of the genome that will indicate specificity for a particular variant.

Patient care

- Risk factors

  Examples of short-term research needs

  - Data on potential risks factors
    - Smoking, pre-existing pulmonary disease

        - Co-infections (determine whether co-existing respiratory/viral infections make the virus more transmissible or virulent) and other co-morbidities
    - Differences in respiratory/viral infections for neonates and pregnant women
    - Socio-economic and behavioral factors to understand the economic impact of the virus and whether there were differences.
    - Pediatrics – Innate immune system of children vs adaptive immune system response of adults (e.g., cross reactivity between some routine childhood vaccinations that is providing protection to the youngest in the population).
- Surge capacity and nursing homes
  Examples of short-term research needs
    - Resources to support skilled nursing facilities and long term care facilities.
    - Mobilization of surge medical staff to address shortages in overwhelmed communities.
- Efforts to inform allocation of scarce resources
  Examples of short-term research needs
    - Age-adjusted mortality data for Acute Respiratory Distress Syndrome (ARDS) with/without other organ failure – particularly for viral etiologies
    - Extracorporeal membrane oxygenation (ECMO) outcomes data of COVID-19 patients; and,
    - Outcomes data for COVID-19 after mechanical ventilation adjusted for age.
    - Knowledge of the frequency, manifestations, and course of extra-pulmonary manifestations of COVID-19, including, but not limited to, possible cardiomyopathy and cardiac arrest.
    - Application of regulatory standards (e.g., EUA, CLIA) and ability to adapt care to crisis standards of care level.
- Personal protective equipment
  Example of short-term research needs
    - Approaches for encouraging and facilitating the production of elastomeric respirators, which can save thousands of N95 masks.
    - Efficacy of cloth face coverings.
- Alternative methods to advise on disease management
  Examples of short-term research needs
    - Best telemedicine practices, barriers and facilitators, and specific actions to remove/expand them within and across state boundaries.
    - Guidance on the simple things people can do at home to take care of sick people and manage disease.
    - OTC oral medications that might potentially work.

  Example of long-term research needs
    - Use of AI in real-time health care delivery to evaluate interventions, risk factors, and outcomes in a way that could not be done manually.
- Processes of care

Example of short-term research needs

- Best practices and critical challenges and innovative solutions and technologies in hospital flow and organization, workforce protection, workforce allocation, community-based support resources, payment, and supply chain management to enhance capacity, efficiency, and outcomes.

Group C – Community Engagement and Population Health (SC Leads: Mary Travis Bassett, Robert Groves)

Staff Leads: Julie Pavlin and Monica Feit (DBASSE)

Members: Georges Benjamin
Rich Besser
Peter Daszak
Phyllis Meadows
Alexandra Phelan
Mark Smolinski
Jeff Duchin
Baruch Fischhoff
(SBS WG, membership TBD)

Topics: Epidemiology and population surveillance
Social and public health interventions
Public communication and understanding
Occupational safety and health

Epidemiology and population surveillance

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes and for understanding/guidance to be implemented).

  Examples of short-term research needs

  - Plans for sero-surveys of previously exposed/immune individuals. Evaluation of background level of people with Covid19 antibodies in the community.
  - Policies and protocols for screening and testing (e.g. screening/testing schedule for post-exposure).
  - Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.
  - Recruitment, support, and coordination of local expertise and capacity (public, private—commercial, and non-profit, including academic), including legal, ethical, communications, and operational issues.
  - National guidance and guidelines about best practices to states (e.g., how states might leverage universities and private laboratories for testing purposes, communications to public health officials and the public).
  - Validation and sharing (and effectively using) modeling outputs.

Social and public health interventions

Example of short-term research needs

- Effectiveness of non-therapeutic public health measures (e.g. patient contact tracing, social distancing strategies, school closings, telework). Rapid design and execution of experiments to examine and compare NPIs currently being implemented.
    - Risk/benefit of various social distancing measures
        - Optimal timing of social distancing (what are the triggers to start, when is it too late)
        - Importance of herd immunity
        - Avoiding the second wave
- Guidance on ways to scale up NPIs in a more coordinated way to give us time to enhance our health care delivery system capacity to respond to an increase in cases.
- Methods to control the spread in communities, barriers to compliance, and how these vary among different populations.

Examples of long-term research needs

- Models of potential interventions to predict costs and benefits that take account of such factors as race, income, disability, age, geographic location, immigration status, housing status, employment status, and health insurance status.
- Policy changes necessary to enable the compliance of individuals with limited resources and the underserved with NPIs. Research on why people fail to comply with public health advice, even if they want to do so (e.g., social or financial costs may be too high).
- Research on the economic impact of this or any pandemic. This would include identifying policy and programmatic alternatives that lessen/mitigate risks to critical government services, food distribution and supplies, access to critical household supplies, and access to health diagnoses, treatment, and needed care, regardless of ability to pay.

Public communication and understanding

- Messaging to the public, health professionals, civic leaders, etc.
- Communicating with high-risk populations

Examples of short-term research needs

- Modes of communicating with target high-risk populations (elderly, health care workers, first responders).
- Risk communication and guidelines that are easy to understand and follow (include targeting at risk populations' families too).
- Communication that indicates potential risk of disease to all population groups.
- Clarify community measures
- Clarify misunderstanding around containment and mitigation

Group D – Cross-Cutting Issues (SC Leads: Tara O'Toole, Alta Charo)

Staff Leads: Andy Pope and Lisa Brown

Members: Rich Besser
Ellen Embry
Patricia King
Jonna Mazet
Phyllis Meadows
Alexandra Phelan
Don Berwick

Topics: Ethics, equity, and law
International relations and cooperation
Innovative solutions across the public and private sectors
Lessons learned/future outbreaks

Ethics, equity, and law

- Consideration of the health needs and wellbeing of underserved/disinfranchised populations

  Examples of short-term research needs
  - Action plan to mitigate gaps and problems of inequity in the Nation's public health capability, capacity, and funding to ensure all citizens in need are supported and can access information, surveillance, and treatment.
  - Measures to reach marginalized and disadvantaged populations.
  - Data systems and research priorities and agendas incorporate attention to the needs and circumstances of disadvantaged populations and underrepresented minorities.
  - Understand and mitigate threats to incarcerated people from COVID-19, assuring access to information, prevention, diagnosis, and treatment.
  - Understand coverage policies (barriers and opportunities) related to testing, treatment, and care

International relations and cooperation

- The role of international regulatory organizations, WHO, etc
- Reliance and mutual recognition agreements (see NASEM study: Mutual Recognition Agreements in the Regulation of Medicines https://www.nationalacademies.org/our-work/mutual-recognition-agreements-in-the-regulation-of-medicines)
- Data standards and nomenclature:
  - Methods for coordinating data-gathering with standardized nomenclature.
  - Consistent platform for sharing response information among planners, providers, and others.

- Understand and mitigate barriers to information-sharing.

Innovative solutions across public and private sectors

- Governmental public health

  Example of short-term research needs
  - Determine how to recruit, support, and coordinate local (non-Federal) expertise and capacity relevant to public health emergency response (public, private—commercial and non-profit, including academic).

  Examples of long-term research needs
  - Better integration of federal/state/local public health surveillance systems.
  - Value of investments in baseline public health response infrastructure, preparedness capacity, and capability.

Lessons learned/Future outbreaks

- Research needs to improve our understanding of the viral diversity and risk factors for viruses that are not yet known to medicine, but exist and are available to infect humans and present epidemic and pandemic threats.
- Research needs and evaluation metrics to inform the immediate response and future outbreak response.

V3_April 15, 2020

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Responsibilities

The Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats stands ready to respond to urgent requests from the sponsors (OSTP and HHS/ASPR) through the assembly of ad hoc response teams consisting of committee members and other subject matter experts. The standing committee also has the responsibility to be proactive in identifying topics and issues for consideration and attention. The standing committee has established four working groups to ensure adequate attention to a broad range of relevant issues and topics, and to propose priorities for consideration and responding to the needs of the sponsors. The working groups focus on the following domains:

- Viral characteristics
- Patient care and medical countermeasures
- Community engagement and population health
- Cross-cutting issues

Working Group Responsibilities

The working group responsibilities include:

- Provide a locus for consideration of a defined area of issues and topics;
- Identify priorities within its respective area of emphasis for consideration as action items by the sponsors and full Standing Committee; and,
- Assist in the development of useful and timely responses, e.g., in defining clear and specific task statements and identifying subject matter experts who might join the response team.

When describing topics for priority consideration, the working groups will specify:

1) Question, topic or task, with clear objectives and rationale
2) Suitable type of product (telephonic consultation, rapid expert consultation, letter report, or consensus report)
3) Primary audience for the assessment
4) Anticipated time-frame for completion
5) Volunteers from the standing committee and working groups, and suggestions for additional experts to serve on the response team

Working Group Leads Meetings. The standing committee chair will periodically convene the leads of the four working groups to discuss operational issues, coordinate assessments, identify cross-cutting interests, and establish priorities for consideration by the standing committee and sponsors.

Response Teams. For each topic that is identified for attention, there may be an ad hoc "response team." The response team may include members of the standing committee and other subject matter experts as appropriate and necessary.

To: Fang Li[lifang@umn.edu]
From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]
Sent: Fri 4/17/2020 1:07:53 PM (UTC-04:00)
Subject: RE: talk on the phone?

9:30AM?

From: Fang Li <lifang@umn.edu>
Sent: Friday, April 17, 2020 12:03 PM
To: Baric, Ralph S <rbaric@email.unc.edu>
Subject: Re: talk on the phone?

Sure. What time on Saturday?

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http://www.msi.umn.edu/~lifang
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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski

Location: https://zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Importance: Normal

Subject: ACTIV Preclinical working group (Friday meeting)

Start Time: Fri 4/24/2020 11:00:00 AM (UTC-04:00)

End Time: Fri 4/24/2020 12:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski

Holding time

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Meeting ID: 930 2871 7745
Password: 920539
One tap mobile
+16468769923,,93028717745#,,#,920539# US (New York)
+13126266799,,93028717745#,,#,920539# US (Chicago)

Dial by your location
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+1 301 715 8592 US
+1 346 248 7799 US (Houston)
+1 408 638 0968 US (San Jose)
+1 669 900 6833 US (San Jose)
Meeting ID: 930 2871 7745
Password: 920539
Find your local number: https://zoom.us/u/acEhhKOsw5

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C

Location: https://zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 4/21/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 4/21/2020 3:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA)

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Holding time

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Join Zoom Meeting
https://zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Meeting ID: 960 4240 3854
Password: 124630
One tap mobile
+13126266799,,96042403854#,,#,124630# US (Chicago)
+16468769923,,96042403854#,,#,124630# US (New York)

Dial by your location
+1 312 626 6799 US (Chicago)
+1 646 876 9923 US (New York)
+1 301 715 8592 US
+1 346 248 7799 US (Houston)
+1 408 638 0968 US (San Jose)
+1 669 900 6833 US (San Jose)
+1 253 215 8782 US
Meeting ID: 960 4240 3854
Password: 124630
Find your local number: https://zoom.us/u/acEhhKOsw5

To: Fang Li[lifang@umn.edu]
From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]
Sent: Sat 4/18/2020 9:02:49 AM (UTC-04:00)
Subject: RE: talk on the phone?

4PM? Number?

From: Fang Li <lifang@umn.edu>
Sent: Friday, April 17, 2020 4:36 PM
To: Baric, Ralph S <rbaric@email.unc.edu>
Subject: Re: talk on the phone?

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On Fri, Apr 17, 2020 at 12:07 PM Baric, Ralph S <rbaric@email.unc.edu> wrote:
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To: Baric, Ralph S[rbaric@email.unc.edu]
From: Fang Li[lifang@umn.edu]
Sent: Sat 4/18/2020 11:24:26 AM (UTC-04:00)
Subject: Re: talk on the phone?

Sure. You can call 612-501-7893.

On Sat, Apr 18, 2020 at 8:02 AM Baric, Ralph S <rbaric@email.unc.edu> wrote:

> 4PM? Number?
>
> **From:** Fang Li <lifang@umn.edu>
> **Sent:** Friday, April 17, 2020 4:36 PM
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> > > **Sent:** Thursday, April 16, 2020 9:59 AM
> > > **To:** Baric, Ralph S <rbaric@email.unc.edu>
> > > **Subject:** talk on the phone?
> > >
> > > Hi Ralph,
> > >
> > > Will you be available to talk on the phone today? I will need to discuss with you a few things related to SARS-CoV-2.

Thanks,

Fang

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****
Fang Li, Ph.D.
Associate Professor
Department of Veterinary and Biomedical Sciences
University of Minnesota Twin Cities
612-625-6149, lifang@umn.edu
http://www.msi.umn.edu/~lifang
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To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Kirby, Donna[donna.kirby@pfizer.com]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Moore, Debra[debra.l.moore@gsk.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Sun 4/19/2020 2:34:38 PM (UTC-04:00)
Subject: FNIH wishes to disclose who is on each COVID working group

Dear Preclinical Working Group Members,

I hope this message finds you well. I am writing to seek your approval to publicly list your name in association with this ACTIV working group. FNIH has been asked for the names of the working group members, and we would like to point them to a listing of these names on the FNIH website, once you have provided clearance for this.

The FNIH's Vice President of Communications and Events, Abbey Meltzer, will be tracking these approvals, so please send your approval to her at ameltzer@fnih.org. If you have any questions, please do not hesitate to reach out to Abbey.

Best regards,
Joe

Joseph P. Menetski, Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6596
fnih.org
11400 Rockville Pike Suite 600 North Bethesda MD 20852

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Kirby, Donna[donna.kirby@pfizer.com]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Moore, Debra[debra.l.moore@gsk.com]
From: Rappaport, Jay[jrappaport@tulane.edu]
Sent: Sun 4/19/2020 3:43:56 PM (UTC-04:00)
Subject: Re: FNIH wishes to disclose who is on each COVID working group

Joe,
Please feel free to list my name. Its an honor to be part of this team and effort.
Best regards,
Jay

Get Outlook for iOS

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Sunday, April 19, 2020 1:34:38 PM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Cc: Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kirby, Donna <donna.kirby@pfizer.com>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Moore, Debra <debra.l.moore@gsk.com>
Subject: FNIH wishes to disclose who is on each COVID working group

> External Sender. Be aware of links, attachments and requests.

Dear Preclinical Working Group Members,

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Joseph P. Menetski, Ph.D.
Associate Vice President, Research Partnerships
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fnih.org
11400 Rockville Pike Suite 600 North Bethesda MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Brown, Lisa[LBrown@nas.edu]

Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; jbaker@rwjf.org; Baric, Toni C; Mary Radford; Pope, Andrew; Pavlin, Julie; Feit, Monica; Shore, Carolyn; Wollek, Scott; Downey, Autumn; Motrya Calafiura; rhock@ihi.org; Fine, Emma; Shin, Rebecca; Attal-Juncqua, Aurelia; Borel, Bridget

Location: Zoom Information Forthcoming

Importance: Normal

Subject: Second Virtual Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Start Time: Thur 4/30/2020 11:00:00 AM (UTC-04:00)

End Time: Thur 4/30/2020 1:30:00 PM (UTC-04:00)

Required Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; jbaker@rwjf.org; Baric, Toni C; Mary Radford; Pope, Andrew; Pavlin, Julie; Feit, Monica; Shore, Carolyn; Wollek, Scott; Downey, Autumn; Motrya Calafiura; rhock@ihi.org; Fine, Emma; Shin, Rebecca; Attal-Juncqua, Aurelia; Borel, Bridget

Greetings,

Please hold Thursday, April 30th from 11:00 a.m. – 1:30 p.m. ET for the second virtual meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. This is the time frame that worked best for the majority of the committee. Remote participation information, an agenda, and additional materials will be shared in the coming days.

Please let me know if you have any questions.

Best,
Lisa

Lisa Brown, MPH
Senior Program Officer
Board on Health Sciences Policy
Health and Medicine Division
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW, Washington, DC 20001
202-334-2487 (office)
lbrown@nas.edu

Organizer: Brown, Lisa[LBrown@nas.edu]

From: Brown, Lisa[LBrown@nas.edu]

Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; jbaker@rwjf.org; Baric, Toni C; Mary Radford; Pope, Andrew; Pavlin, Julie; Feit, Monica; Shore, Carolyn; Wollek, Scott; Downey, Autumn; Motrya Calafiura; rhock@ihi.org; Fine, Emma; Shin, Rebecca; Attal-Juncqua, Aurelia; Borel, Bridget; jonna.mazet@gmail.com; Logan, Kendall

Location: https://nasem.zoom.us/j/91377677378

Importance: Normal

Subject: Second Virtual Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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Optional Attendees: jonna.mazet@gmail.com; Logan, Kendall

FINAL Agenda_Virtual Meeting 2_ SC on EID and 21st Century Threats.pdf

SCEID Working Group Priority Issues_v1_42920.docx

ASPR COVID Strategic Operational Priorities.docx

SCEID Working Group Membership.docx

Committee Membership Roster - SC on EID and 21st Century Threats.pdf

Committee Internal Roster - SC on EID and 21st Century Threats.pdf

Committee Member Biosketches - SC on EID and 21st Century Threats.pdf

Updated with Zoom information, the agenda, and meeting materials

Zoom Call-In Information
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378
Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Greetings,

Please hold Thursday, April 30th from 11:00 a.m. – 1:30 p.m. ET for the second virtual meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. This is the time frame that worked best for the majority of the committee. Remote participation information, an agenda, and additional materials will be shared in the coming days.

Please let me know if you have any questions.

Best,
Lisa

Lisa Brown, MPH
Senior Program Officer
Board on Health Sciences Policy
Health and Medicine Division
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW, Washington, DC 20001
202-334-2487 (office)
lbrown@nas.edu

Second Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Final Agenda
Thursday, April 30, 2020 11:00 a.m. – 1:00 p.m. ET

Zoom Information

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378

Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Background: In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine established the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. The Standing Committee's purpose is to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee includes members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee provides a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

Meeting Objectives

- Discuss the status and progress of the work of the standing committee with the sponsors
- Discuss the priorities of each working group: viral characteristics; patient care and medical countermeasures; community engagement and population health; and, cross-cutting issues
- Discuss and plan priorities, strategies, and next steps

THURSDAY, APRIL 30, 2020

CLOSED SESSION

SESSION I **Welcoming Remarks and Sponsors' Reflections on Status and Progress since the First Standing Committee Meeting**

11:00 a.m. **Welcoming Remarks and Introduction of New Members**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Victor Dzau
President
National Academy of Medicine

Gregory Symmes
Chief Program Officer
The National Academies of Sciences, Engineering, and Medicine

11:15 a.m. **Sponsor's Remarks and Update on COVID-19 Response**

David (Chris) Hassell
Senior Science Advisor
The Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

SESSION II **Working Group Discussions**

11:25 a.m. **Group A: Viral Characteristics Working Group**

David Relman, *Committee Member*

Jonna Mazet, *Committee Member*

11:35 a.m. **Group B: Patient Care and Medical Countermeasures Working Group**

Donald Berwick, *Committee Member*

Margaret Hamburg, *Committee Member*

11:45 a.m. **Group C: Community Engagement and Population Health Working Group**

Mary Travis Bassett, *Committee Member*

Robert Groves, *Committee Member*

11:55 a.m. **Group D: Cross-Cutting Issues Working Group**

Alta Charo, *Committee Member*

Tara O'Toole, *Committee Member*

12:05 p.m. **Discussion of the Issues and Next Steps with the Sponsors**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:30 p.m. ***ADJOURN***

CLOSED SESSION (COMMITTEE ONLY)

12:35 p.m. **Committee Debrief, Next Steps, and Potential Future Meeting Topics**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:40 p.m. **Office of News and Public Information Briefing**

Dana Korsen
Media Relations Manager
Office of News and Public Information
The National Academies of Sciences, Engineering, and Medicine

12:45 p.m. **Discussion of Bias and Conflict of Interest**

Lauren Shern
Associate Executive Director
Health and Medicine Division

1:00 p.m. ***ADJOURN MEETING***

April 29, 2020

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Priority Topics

The standing committee has established four working groups to ensure adequate attention to a broad range of relevant issues and topics, and to propose priorities for consideration and responding to the needs of the sponsors.

The working groups focus on the following domains:

- Viral characteristics
- Patient care and medical countermeasures
- Community engagement and population health
- Cross-cutting issues

This document is a preliminary list of topics discussed by each working group. Of these topics, each working group has identified their top three priority topics (indicated by **priority**).

Summary Table: Top Three Priority Topics of Each Working Group

Working Group Topics	Informal Feedback (Telephonic Consultation)	Written Rapid Expert Consultation	Letter Report	Consensus Report
WG A: Viral Characterization				
Topic A-1: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement)	X	X	X	
Topic A-2: Viral evolution (tracking viral genome evolution, and correlation of genotype with in vitro phenotypes and in vivo host phenotypes)	X		X	
Topic A-3: Transmission and Spread	X			
WG B: Patient Care and MCM				
Topic B-1: Diagnostics roadmap			X	X
Topic B-2: Research agenda to understand pathogenesis, risk factors, and protective factors			X	
Topic B-3: Assessment of preparedness efforts				X
WG C: Community Engagement and Population Health				
Topic C-1: Data needs for decision making		X	X	X
Topic C-2: Specific data need and analysis to determine the role of children in disease transmission		X		
Topic C-3: Defining needs for successful response to COVID-19 among minority and disenfranchised populations		X	X	X
WG D: Cross-Cutting Issues				
Topic D-1: COVID-19 and racial and ethnic disparities		X	X	
Topic D-2: Workplace and school re-opening			X	
Topic D-3: Redefining the public health system for future pandemics				X

Group A: Viral Characterization Working Group

Topic A-1: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement) Priority

Analyses to better understand the role of antibodies and cellular immune responses in protection, and the development/durability of protective immunity:

- Characterization of the immune response and implications for disease severity and for short- and long-term protection from re-infection?
- How does viral clearance occur and what are the likelihoods of, and the risk factors for intermittent and long-term virus shedding?
- How long do neutralizing and non-neutralizing antibodies last?
- Does the presence of antibodies convey protective immunity, and if so, what kinds of antibodies, in what quantities, and for how long?
- What is the likelihood of herd immunity in the US and how will it vary by regional and local demographic factors?
- What is the role of pre-existing antibody (to other coronavirus strains, and potentially to other infectious agents) in the development of a protective immune response to SARS-CoV-2? Does antibody-mediated disease enhancement occur in humans infected by SARS-CoV-2?

JUSTIFICATION: Critical for vaccine, but also for national strategy going forward. If durable immunity doesn't exist, suppression is much more desirable than otherwise.

TIMELINE: Short- to medium-term

PRODUCT TYPE(S): Informal discussions, rapid expert consultation, letter report

PRIMARY AUDIENCE: Policymakers, researchers, funders & lay public

Topic A-2: Viral evolution (tracking viral genome evolution, and correlation of genotype with *in vitro* phenotypes and *in vivo* host phenotypes) Priority

Analyses to track/correlate viral genome sequence features with viral phenotypes *in vitro* and *in vivo* in host/s) as they relate to receptor recognition, growth, host responses and pathogenic mechanisms, and/or selective pressures in the host or environment. Examples of questions to be addressed:

- What are rates and mechanisms of genome evolution as a function of geography, time since introduction into human population, and host features such as immune status?
- How does viral genotype correlate with clinical outcomes?
- Are variant viral sequence features correlated with viral escape from host immune recognition or vaccine-induced immunity, therapeutic beneficial effects, or detection by currently deployed methods?
- How should features of viral genome evolution be used to help optimize the design and development of therapeutics and vaccines? Note: current features of genome evolution may not be a good indicator of genome evolution under the selective pressure of therapeutics, naturally-induced immunity, or vaccine-induced immunity.

JUSTIFICATION: Not expecting significant changes in phenotype, but it's important to do this research now to be sure. Correlation with clinical outcomes critical; it will be critical to make sure that detection/diagnosis and counter-measure efforts are informed about viral evolution.

TIMELINE: Short to medium-term. We need time to observe viral evolution and measure concurrent host phenotypes.

PRODUCT TYPE(S): An early discussion could help with development and deployment of infrastructure for properly capturing, assessing and sharing viral genome and associated host data, then letter report for disseminating results.

PRIMARY AUDIENCE: Policymakers, researchers, lay public

Topic A-3: Transmission and Spread Priority

An analysis to consider the key drivers/determinants and mechanisms of transmission and spread:

- What are the key drivers/determinants of viral spread and cycles of infection and illness?
- Are cycles of infection likely to result from environmental (e.g., temperature, humidity) or social (e.g., school openings/closings) factors?
- What are the mechanisms of transmission and spread?
    - Role of airborne particles of various sizes, fomites, respiratory versus fecal-oral
    - Identification and characterization of super spreaders?
    - Can risk factors for asymptomatic transmission be identified, especially long-term shedding?
    - Note: this work would impact case-based interventions, contact tracing, quarantine measures
- What is the duration of shedding of infectious virus by patients and the relationship to detection of viral RNA? Note: relevant for understanding recovery and when it is ok for people to leave isolation
- Is presence/shedding of viral RNA indicative of transmission risk (i.e., contagiousness)?

JUSTIFICATION: We still don't understand enough about transmission to be making clear policy judgements (aka should city parks stay open?, etc...); Issues are critical for understanding ongoing disease spread and design of interventions.

TIMELINE: Short to medium-term

PRODUCT TYPE(S): Early discussion to promote optimal approaches for data collection and experimental design. Letter report for findings.

PRIMARY AUDIENCE: Policymakers, funders, lay public

Topic A-4: Mechanisms of pathogenesis (host susceptibility, dynamics of the virus in the host, shedding, organ tropism, host response)

Analysis to better understand the "choreography" between the virus and host, including host molecular pathways and/or host response features during the course of infection:

- What are the mechanisms of pathogenesis and the factors contributing to variability in disease severity and outcome (consider relative contribution of viral versus host characteristics)?
- What is the natural history of the virus in humans (where, when)?
- What are the mechanisms of organ damage?
- What are the implications for development and use of therapeutics and other interventions? (Note: possible overlap with patient management group)
- What are the tools (e.g. animal models of disease, susceptibility, and early biomarkers) needed to understand the mechanisms of pathogenesis and the range of disease phenotypes?

TIMELINE: Short- medium- and long-term

PRODUCT TYPE(S): This would be a research agenda-setting exercise—where the early phase might involve discussions, then mid-term with a rapid consultation to promote the agenda, then Letter report later with early research findings of particular relevance to countermeasure development.

PRIMARY AUDIENCE: Researchers, funders, policy-makers

Topic A-5: SARS-COV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

A more substantive analysis of current and future issues of immediate critical need regarding viral emergence and host range:

- What are the host and transmission circumstances that could inform on origins and future spillovers for this pathogen?
- What are the natural hosts/animal reservoirs for this pathogen? What is the potential for domesticated livestock to serve as a reservoir and what are the implications for food security?
- What is the potential for future outbreaks from re-emergence from the human population, additional spillovers from existing hosts, and exposures from new hosts resulting from spillback events from humans into susceptible animals, especially pets and food animals?
- What is the host range for this virus (e.g., what is the current risk to and from companion animals)?

TIMELINE: Long-term

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: Policymakers, researchers, funders

Topic A-6: Development and recommendation of a research agenda

To include:

- Topic 1: Viral evolution (tracking viral genome evolution, and correlation of genotype with in vitro phenotypes and pathogenesis (hypothesis)
- Topic 3: Mechanisms of pathogenesis (hypothesis)
- Topic 5: SARS-CoV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

TIMELINE: Long-term

PRODUCT TYPE(S): Letter report/Consensus study

PRIMARY AUDIENCE: Policymakers, researchers, funders, lay public

Group B: Patient Care and Medical Countermeasures Working Group

Topic B-1: Diagnostics roadmap Priority _

Develop a comprehensive framework for diagnostic test development, deployment, and implementation, as well as analysis of diagnostic data, to ensure a robust testing system for the COVID-19 and future pandemics (both for public health surveillance/control measures and clinical management needs).

- Review the factors that led to shortcomings in current diagnostic development and availability.
- Examine the technological, procedural, and regulatory challenges, as well as the policies, strategies, and practices needed.
    - How can existing/advancing technologies be more effectively harnessed to develop appropriate diagnostics?
    - What factors create barriers and facilitators to successful public-private-academic partnerships for diagnostic development?
    - What kinds of diagnostics are required for different settings?
- Propose a roadmap for successful diagnostic development and testing systems for COVID-19 and future epidemic threats.

TIMELINE: Short-term (1 -2 months) and long-term (12 months)

PRODUCT TYPE(S): Letter report/Consensus report

PRIMARY AUDIENCE: HHS; State and local governments

Topic B-2: Research agenda to understand pathogenesis, risk factors, and protective factors Priority _

Review existing research on mechanisms of pathogenesis and risk and protective factors to inform patient care and extend understanding of how virus causes disease and the fuller elucidation of manifestations of disease.

- Enhance understanding of which patients' may be at especially high risk of serious disease and why.
- Develop more accurate predictive models for disease management and individual risk.
- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS; Medical community

Topic B-3: Assessment of preparedness efforts Priority ___

Examine the role of PHEP/HPP programs for public health and healthcare in preparing for and responding to COVID-19.

- Identify factors related to PHEP/HPP programs that create barriers to and facilitators of effective preparedness and response.
- Examine preparedness elements prior to the COVID-19 pandemic, and determine the actual value and needed improvements for the future.
- Propose recommendations to improve the nation's public health and healthcare preparedness and response programs.

TIMELINE: Long-term (12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

Topic B-4: Research agenda to understand the nature of immune response and protection

Review existing information concerning immune response to SARS-CoV-2 infection to inform key aspects of immune protection for individuals and for vaccine development. Undertake efforts to determine the duration and degree of protectiveness of immunologic responses. (Collaborate with Working Group 1.)

- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS

Topic B-5: Addressing global vaccine needs

Examine adequacy of current efforts for large-scale, coordinated and international research and development initiatives, including scientific collaboration, governance and funding of vaccine-related research projects for COVID-19 and future pandemics.

- Draw on best practices and work already supported by many governments and independent organizations like the Coalition for Epidemic Preparedness Innovations.
- Assess the current status and needed changes in international coordination of vaccine development and production.
- Consider needs/benefits of a strengthened USG engagement

TIMELINE: Medium-term (6-8 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS; Vaccine developers; WHO

Topic B-6: Leveraging real-world data to inform patient care

Identify and examine mechanisms to use real-world data, such as electronic health records, patient and clinician surveys, and semi-structured interviews, to better understand patient outcomes and to inform patient care.

- Explore ways to leverage data mining/analytics to improve patient care processes during COVID-19, including ways to standardize data collection and assemble information from electronic medical records to better inform patient care and outcomes.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS

Topic B-7: Risk analysis of healthcare and economic recovery requirements

Develop a risk analysis framework to examine the balance between healthcare recovery requirements and economic recovery requirements and consider relevant policy implications.

TIMELINE: Medium-term (6-8 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS; DOL; Others

Topic B-8: Rapid learning cycle capacities for health system adaptations and improvement

Explore concepts and methods of learning health systems to understand public health and healthcare system adaptations in response to COVID-19 (e.g., what were your system's expectations and planning assumptions, what was the reality, and how did your system adapt).

- How can we embed research/data collection into ongoing activities to enhance understanding and inform future approaches? How can we "learn as we go" more efficiently and effectively?

TIMELINE: Long-term (12 months)

PRODUCT TYPE(S): Consensus Study

PRIMARY AUDIENCE: HHS

Topic B-9: Understanding pediatric COVID-19 cases

Review existing research on pediatric COVID-19 cases to understand which children might be at highest risk for severe COVID-19 illness and to understand the role children with asymptomatic and mild disease are playing in transmission and spread of COVID-19 in the community.

- Examine policy implications (especially regarding school re-openings) related to the findings.
- Identify implications for pediatric care/hospital management needs
- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Rapid expert consultation; Letter report

PRIMARY AUDIENCE: HHS; state governments; municipal governments; medical community

Group C: Community Engagement and Population Health Working Group

Topic C-1: Data needs for decision making Priority

Determine minimum datasets jurisdictions should collect, how the data should be collected, and justification for collection, in order to develop public health strategies based on evidence.

- Obtain evidence for the effectiveness of non-pharmaceutical interventions to justify epidemiologic data collection (to include serology and other testing) and resultant public health interventions such as social distancing, business and school closures, and travel and trade restrictions.

- Determine a "minimum data set" for population surveillance, including demographic components (e.g., geographic location, age, race, gender, disability, immigration status, socio-economic status, underlying health issues) that is necessary to make public health decisions.
- Determine how to ensure high priority populations are included in surveillance to include health workers, disadvantaged (nursing home populations, homeless, prisoners, etc.), and racial and ethnic minorities.
- Determine what outcome measures for each of the above are needed (e.g., who gets tested, who gets treated, who is in isolation, health outcome).
- Review the utility of non-traditional data sources such as participatory surveillance, and innovative methods for contact tracing. Evaluate new data sources and alternative methods for analysis so that all jurisdictions in the US and internationally can best evaluate utility of data.
- Determine how to best incorporate modeling into real-time decision-making and what data are most useful for the models.

TIMELINE: Short for evaluating alternative methods, L for modeling and retrospective analyses

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, state and local PH

VOLUNTEERS/COLLABORATION: SEAN, modelers

Topic C-2: Specific data need and analysis to determine the role of children in disease transmission Priority

Summarize what is known about the contribution of school-age children to disease transmission and recommend studies that can address gaps in this knowledge.

- Can provide critical information for re-opening the economy.

TIMELINE: Short

PRODUCT TYPE(S): Rapid expert consultation

PRIMARY AUDIENCE: HHS, OSTP, local governments

VOLUNTEERS/COLLABORATION: SEAN

Topic C-3: Defining needs for successful response to COVID-19 among minority and disenfranchised populations Priority

Review the issues faced by disenfranchised and minority populations to ensure they are protected and to improve overall effectiveness of mitigation methods.

- Determine ability of disenfranchised populations to comply with social distancing, isolation and quarantine, and impact of inability to comply on overall mitigation efforts.

- Evaluation of access to testing, healthcare and available countermeasures by demographics and methods to ensure equity.
- Review the ethical implications of crisis standards of care prioritization and appropriate guidance for triage of life-sustaining resources.
- Determine methods to provide appropriate communications in both low English proficiency populations and in different cultural and ethnic groups.

TIMELINE: Medium-term for synthesis of current data. Long-term when more data becomes available

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, state and local PH

VOLUNTEERS/COLLABORATION: Minority focused and community based organizations

Topic C-4: Determine risk assessments for population activities

Provide risk assessments to determine the appropriate decisions regarding opening of schools and businesses, indoor and outdoor activities, and mitigation efforts at facilities and events.

- Determine testing needs for school and workplace openings.
- Determine parameters to guide assessment of Covid19 resurgence.
- Provide occupational safety and health standards to include distancing between workers, use of barriers (to include masks), and tracking potentially infectious states.
- Evaluate the risk of indoor and outdoor settings with regard to effects on the virus (heat/humidity/sunlight) and appropriate public health measures.
- Determine responsibility to disadvantaged communities to include nursing homes and prisons. Provide models for each to determine reasonable risk-based standards to open locations in a reasonable way.

TIMELINE: Short for framework, long for reopening evaluations

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, local and state PH

VOLUNTEERS/COLLABORATION: SEAN

Topic C-5: Adverse impacts of NPI

Measure and find ways to mitigate the unintended adverse health consequences of social distancing measures on individuals, families and societal groups.

TIMELINE: Medium-term to long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: HHS and state and local PH

VOLUNTEERS/COLLABORATION: Chamber of commerce, NGA, US conference of Mayors

Topic C-6: Future impact of COVID-19

Given known epidemiology of the virus, what can we predict will be its future impact and how can we best prepare.

- Predict changes in virus transmission given seasonality and contribution of social changes such as school openings.
- Understand disease progression and health needs in developing countries and how we can mitigate impact internationally and on US populations.

TIMELINE: Medium-term to long-term

PRODUCT TYPE(S): Consensus

PRIMARY AUDIENCE: Federal, state and local PH

Topic C-7: Develop best communication techniques for clarity

Identify and disseminate best practices for communications that can be used by public health, and the public in general, in a practical way.

- Determine best ways to have culturally-competent communications with sensitivity to the audience.
    - What are some innovative and non-traditional communication mechanisms that can support disease control activities?
- Find ways to maintain clarity of messages and have coherent community-focused communications.
- Determine how to ensure communication continues on the downslope of the epi curve – need to encourage vigilance and understanding of seasonality.
- Develop key messages that are important to relay at various points in time (crisis, recovery, etc.)

TIMELINE: Medium-term for synthesis, long-term for better data

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: Standing committee on science communication, SEAN, media

Topic C-8: Role of One Health

Determine the role of domestic pets and livestock in virus transmission and risk (to them and to people). Need good epidemiology and appropriate communication to decrease panic.

TIMELINE: Long-term

PRODUCT TYPE(S): Letter/consensus report

Topics C-9: Evaluation of products

Find methods to evaluate new and innovative products that could be useful but may overwhelm public health departments.

TIMELINE: Medium- to long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: FEMA

Topic C-10: Healthcare system preparedness

Develop metrics for healthcare system preparedness.

TIMELINE: Long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: Tech industry, Mitre, Rand

Group D: Cross-Cutting Issues Working Group

Topic D-1: COVID-19 and racial and ethnic disparities Priority

Understand how COVID-19 is disproportionally affecting communities in order to shape and target immediate response efforts.

- Examine the patterns of COVID-19 related morbidity and mortality across racial and ethnic groups.
- Understand (clearly articulate and disseminate) the underlying causes and existing systemic issues leading to these disparities.
- Propose short-term recommendations to reduce the impact of COVID-19 on the health of racial and ethnic minorities on, but not limited, to the following:
    - Structural elements of access and equitable public health information, screening, testing, treatment, and follow-up.
    - Clinical management of patients and equitable allocation of resources.

- Appropriate strategies to assure appropriate and safe levels of quarantine and/or isolation, for those in more highly concentrated communities and housing situations.
- Occupational health and safety, including disparate impacts on current workers in essential businesses and on workers as new businesses re-open.
- Data systems to monitor and track disparities among racial and ethnic groups.

TIMELINE): Short-term (1 -2 months). *(Note: This topic has priority has both immediate and longer-term implications. The items above, are consistent with increasing awareness of the impact of the virus. Over the long-term, there needs to be efforts to define the range of solutions that can be applied to address the underlying factors that contribute to the disparate impacts. We would be missing a critical opportunity, if we only focus on the data (which is empirically known), versus organizing the systems to more effectively respond to the different experiences and life-circumstances of certain populations who are likely to require modified approaches to yield positive results.)*

PRODUCT TYPE(S): Rapid expert consultation, letter report

PRIMARY AUDIENCE: HHS

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health

Topic D-2: Workplace and school re-opening Priority

Identify and disseminate best practices for re-opening businesses and schools

- Integrate demands for testing (active infection and immunity) with management of physical space and use of protective equipment. To include periodic testing standards, workplace policies, preventing and managing future surges or infectious threats.
- Identify and mitigate measures with unintended deleterious impact on sub-populations (age, disability, pregnancy, co-morbidities).
- Anticipate accommodations needed to comply with ADA.
- Examine the role of school based health centers, school health.

TIMELINE: Medium-term (3-6 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS, DOE, DOL

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health, National Alliance for School Based Health

Topic D-3: Redefining the public health system for future pandemics Priority

A comprehensive effort to redefine the nation's public health system to accommodate emerging infectious diseases, and manage and prevent other diseases and underlying conditions (health and

social) that can influence health outcomes and expand the scope of national security to include public health.

- Examine the public health system infrastructure challenges that are arising in response to COVID-19.
- Map how public-private partnerships are currently being leveraged in the public health system in the COVID-19 pandemic (e.g., private sector augmenting public health departments and aiding in contract tracing), and identify best practices.
- Map how technology is currently being leveraged in the public health system in the COVID-19 pandemic, and identify best practices.
- Clarify ambiguities or fill gaps in policy and law governing federal vs state and local authorities
- Identify obstacles to better coordination with public health authorities domestically and abroad
- Propose a framework and recommendations to redefine the nation's public health system to include creating a system that addresses inequities in policies and practices that result in adverse experiences and outcomes for racial, ethnic and marginalized populations.

TIMELINE: Long-term (6-12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health, National Association of City and County Health Officials, Association of State and Territorial Health Officers, Trust for America's Health

Topic D-4: Learning health system for pandemics

Examine concepts and methods of learning health systems related the COVID-19 pandemic and future pandemics.

- Examine how the components of a learning health system are currently being implemented in the COVID-19 pandemic and identify best practices.
- Identify components of a learning health system that could be implemented in the immediate COVID-19 response.
- Develop a framework and propose recommendations related to the key components of a learning health system to optimize care of individuals in a pandemic.

TIMELINE: Long-term (6-12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

ASPR COVID-19 Strategic Operational Priorities

SHIELD the vulnerable who have greatest risk of morbidity & mortality

- Skilled Nursing Facilities
- Elder Care Facilities
- Dialysis Clinics
- Other: Cancer Treatment Centers

SHELTER the susceptible: Decrease community transmission

- Non-pharmaceutical interventions: school closures, mass gathering cancellations

SAVE the sick: preserve the integrity & capacity of the health care system

- Segregate the care of COVID-19patients
- Preserve the care of routine & emergency care

SUSTAIN supplies

- Increase the supply
- Extend the use
- Innovate new sources or approaches

SCIENCE

- Vaccines
- Therapeutics
- Diagnostics

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Membership

Group A – Viral Characteristics (WG Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
Mechanisms for pathogenesis
One Health

Group B – Patient Care and Medical Countermeasures (MCM) (WG Leads: Don Berwick, Margaret Hamburg)

Staff Leads: Lisa Brown and Scott Wollek

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Topics: Vaccines and therapeutics
Diagnostics
Patient care (including personal protective equipment, crisis standards of care, and quality)

Group C – Community Engagement and Population Health (WG Leads: Mary Travis Bassett, Robert Groves)

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Peter Daszak
Phyllis Meadows

	Alexandra Phelan
	Mark Smolinski
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Topics:	Epidemiology and population surveillance
	Social and public health interventions
	Public communication and understanding
	Occupational safety and health

<u>Group D – Cross-Cutting Issues</u> (WG Leads: Tara O'Toole, Alta Charo)

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Topics:	Ethics, equity, and law
	International relations and cooperation
	Innovative solutions across the public and private sectors
	Lessons learned/future outbreaks

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Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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The National Academies of
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Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

COMMITTEE MEMBER BIOSKETCHES

Harvey Fineberg, M.D., Ph.D. ***(Chair)***
President
Gordon and Betty Moore Foundation

Harvey Fineberg is president of the Gordon and Betty Moore Foundation. He previously served as president of the Institute of Medicine from 2002 to 2014 and as provost of Harvard University from 1997 to 2001, following 13 years as dean of the Harvard School of Public Health. Fineberg devoted most of his academic career to the fields of health policy and medical decision-making. His past research has focused on the process of policy development and implementation, assessment of medical technology, evaluation and use of vaccines, and dissemination of medical innovations. Fineberg serves on the boards of the Carnegie Endowment for International Peace and the China Medical Board. He helped found and served as president of the Society for Medical Decision Making, previously served on and chaired the board of the William and Flora Hewlett Foundation, and chaired the committee to review the performance of the World Health Organization and the functioning of the International Health Regulations (2005) during the 2009 H1N1 influenza pandemic. Fineberg is co-author of the books *Clinical Decision Analysis*, *Innovators in Physician Education* and *The Epidemic That Never Was*, an analysis of the controversial federal immunization program against swine flu in 1976. He has co-edited several books on such diverse topics as AIDS prevention, vaccine safety, understanding risk in society and global health. He has also authored numerous articles published in professional journals. Fineberg chaired the National Academies committee that produced the 2019 report on *Reproducibility and Replicability in Science*. He earned his bachelor's and doctoral degrees at Harvard and is the recipient of several honorary degrees.

Kristian Andersen, Ph.D.
Associate Professor and Director of Infectious Disease Genomics, Scripps Research Translational Institute
The Scripps Research Institute

Kristian Andersen is an associate professor in the Department of Immunology and Microbiology at Scripps Research, with joint appointments in the Department of Integrative Structural and Computational Biology, and at the Scripps Research Translational Institute. Over the past decade, his research has focused on the complex relationship between host and pathogen. Using a combination of next-generation sequencing, field work, experimentation, and computational biology he has spearheaded large international collaborations investigating the emergence, spread and evolution of deadly pathogens, including SARS-CoV-2, Zika virus, Ebola virus, West Nile virus, and Lassa virus. His work is highly cross-disciplinary and exceptionally collaborative. Kristian earned his doctoral degree from the University of Cambridge and performed postdoctoral work in Pardis Sabeti's group at Harvard University and the Broad Institute.

Ralph Baric, Ph.D.
William R. Kenan, Jr. Distinguished Professor
The University of North Carolina at Chapel Hill

Ralph Baric is a William R. Kenan, Jr. Distinguished Professor in the Department of Epidemiology at the University of North Carolina. He obtained a Bachelor of Science Degree in Zoology from North Carolina State University in 1977 and a PhD in Microbiology and Immunology from North Carolina State University in 1983. He conducted postgraduate research at the University of Southern California School of Medicine in the department of Microbiology and Immunology between 1983-1986. He is a Harvey Weaver Scholar from the National Multiple Sclerosis Society and an Established Investigator Awardee from the American Heart Association. In addition, he is a World Technology Award Finalist, a fellow of the American Association for Microbiology, a senior editor of PloS Patho gen, and a member of the editorial board of several other specialty journals. He was a member of the National Academy Sciences Working Groups that focused on Gene Sequence Methods for Classification of Select Agents and the Risks and Benefits of Gain of Function Research, an invited speaker to the Institute of Medicine Forum on Emerging Infectious Diseases and an invited panelist for the MERS-CoV Stakeholders Workshop. His group has published over 300 papers, many in highly visible journals like PNAS, Natur e Medicine, Science, PloS Medicine and PloS Pathogens. The Baric laboratory uses genetic, immunologic, molecular and biochemical approaches to study the molecular mechanisms regulating virus replication, pathogenesis, molecular evolution and cross species transmission using emerging coronaviruses, flaviviruses (Dengue) and noroviruses as model systems. We have pioneered new strategies for developing reverse genetic approaches for manipulating the SARS-CoV, SAR-CoV-2 and MERS-CoV genomes and are actively studying the role of multiple genes that function in cross species transmission, virulence, pathogenesis, viral transcription and RNA fidelity. The Baric laboratory is also identifying key neutralizing epitopes in emerging coronaviruses, dengue and noroviruse s using human monoclonal antibodies and structure guided immunogen design to develop broadly active vaccines and immunotherapuetics against these pathogens. Finally, his group has developed novel animal models of human disease and identified dozens of host susceptibility loci that regulate emerging CoV pathogenesis.

Mary Bassett, M.D., M.P.H.
Director of the François-Xavier Bagnoud Center for Health and Human Rights
Harvard School of Public Health

Mary Bassett is the Director of the FXB Center for Health and Human Rights at Harvard University, as well as the FXB Professor of the Practice of Health and Human Rights at the Harvard School of Public Health. With more than 30 years of experience in public health, Dr. Mary Travis Bassett has dedicated her career to advancing health equity. Prior to her directorship at the FXB Center, Dr. Bassett served for four years as commissioner of Health for New York City. As commissioner, she worked to ensure that every New York City neighborhood supported the health of its residents, with the goal of closing gaps in population health across the city. Originally from New York City, Dr. Bassett lived in Zimbabwe for nearly 20 years. Previously, she was the Program Director for the African Health Initiative and the Child Well-being Program at the Doris Duke Charitable Foundation. She received her B.A. in History and Science from Harvard University and her M.D. from Columbia University's College of Physicians and Surgeons. She served her medical residency at Harlem Hospital Cen ter, and has a master's degree in Public Health from the University of Washington, where she was a Robert Wood Johnson Clinical Scholar.

Trevor Bedford, Ph.D.
Associate Faculty Member, Vaccine and Infectious Disease Division, Public Health Sciences Division, and Human Biology Division
Fred Hutchinson Cancer Research Center

Trevor Bedford is currently Associate Member of the Vaccine and Infectious Disease Division, the Public Health Sciences Division, and the Human Biology Division at the Fred Hutchinson Cancer Research Center. Dr. Bedford uses powerful computers and complex statistical methods to study the rapid spread and evolution of viruses. Data gathered from these processes help researchers develop successful strategies for monitoring and controlling infectious diseases. His visual representations of viral family trees are used to show how the fate of dangerous outbreaks is often determined by the genetics of the infectious agent, human behavior and geography. Dr. Bedford has applied these techniques to document the worldwide spread of seasonal flu viruses. He is developing models to predict which strains of influenza are likely to be most challenging to humans — data that help inform the crucial early decisions about which strains to include in annual flu shots. He specializes in tracking the evolutionary changes of viruses such as HIV and influenza that use RNA, rather than DNA, to carry their genetic information. RNA viruses are much more prone to rapid mutation, which makes many of them particularly nimble at escaping the human immune system and difficult to stop with vaccines. He is a leading advocate for the immediate release of research analyzing viral evolution during epidemics, fresh information that could make a lifesaving difference. He received his Ph.D. in biology from Harvard University.

Georges Benjamin, M.D.
Executive Director
American Public Health Association

Georges Benjamin is well-known as a health leader, practitioner, and administrator. Dr. Benjamin has served as the executive director of the American Public Health Association, the nation's oldest and largest organization of public health professionals, since December 2002. He is a former secretary of Health for the state of Maryland. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University Of Illinois College Of Medicine. He is board-certified in internal medicine, a Master of the American College of Physicians, a fellow of the National Academy of Public Administration and a fellow emeritus of the American College of Emergency Physicians. He serves on several nonprofit boards such as Research!America, the University of Maryland Medical System and, the Reagan-Udall Foundation. He is a member of the National Academy of Medicine. In April 2016, President Obama appointed Benjamin to the National Infrastructure Advisory Council, a council that advises the president on how best to assure the security of the nation's critical infrastructure.

Donald Berwick, M.D., M.P.P., F.R.C.P., KBE
Lecturer of Health Care Policy
Harvard Medical School

Donald Berwick is president emeritus and senior fellow at the Institute for Healthcare Improvement and former administrator of the Centers for Medicare & Medicaid Services. A pediatrician by background, Dr. Berwick has served on the faculty of the Harvard Medical School and Harvard School of Public Health, and on the staffs of Boston's Children's Hospital Medical Center, Massachusetts General Hospital, and the Brigham and Women's Hospital. He has also served as vice chair of the US Preventive Services Task Force, the first "independent member" of the American Hospital Association Board of Trustees, and chair of the National Advisory Council of the Agency for Healthcare Research and Quality. He served two terms on the Institute of Medicine's (IOM's) Governing Council, was a member of the IOM's Global Health Board, and served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. Recognized as a leading authority on health care quality and improvement, Dr. Berwick has received numerous awards for his contributions. In 2005, he was

appointed "Honorary Knight Commander of the British Empire" by Her Majesty, Queen Elizabeth II in recognition of his work with the British National Health Service. Dr. Berwick is the author or co -author of over 160 scientific articles and six books. He currently serves as lecturer in the Department of Health Care Policy at Harvard Medical School.

Richard Besser, M.D.
President and CEO
Robert Wood Johnson Foundation

Richard Besser is president and CEO of the Robert Wood Johnson Foundation (RWJF), a position he assumed in April 2017. Dr. Besser is the former acting director for the Centers for Disease Control and Prevention (CDC), and ABC News' former chief health and medical editor. At RWJF, Dr. Bes ser leads the largest private foundation in the country devoted solely to improving the nation's health. RWJF's work is focused on building a comprehensive Culture of Health that provides everyone in America with a fair and just opportunity to live the hea lthiest life possible. In Dr. Besser's role at ABC News, he provided medical analysis and reports for all ABC News programs and platforms. His weekly health chats on social media reached millions. Before joining ABC News in 2009, Dr. Besser worked as direc tor of the Coordinating Office for Terrorism Preparedness and Emergency Response at the CDC. In that role, he was responsible for all the CDC's public health emergency preparedness and emergency response activities. He also served as acting director of the CDC from January to June 2009, during which time he led the CDC's response to the H1N1 influenza pandemic. He is a member of the National Academy of Medicine. He received the Surgeon General's Medallion for his leadership during the H1N1 response, and in 2011 he accepted the Dean's Medal for his contributions to public health from the Johns Hopkins Bloomberg School of Public Health. Dr. Besser received his Bachelor of Arts degree in economics from Williams College and medical degree from the University of Pennsylvania. He completed a residency and chief residency in pediatrics at Johns Hopkins University Hospital in Baltimore.

R. Alta Charo, J.D.
Warren P. Knowles Professor of Law and Bioethics
University of Wisconsin at Madison

R. Alta Charo is a member of the National Academy of Medicine and is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison (UW), where she is on the faculties of the law and medical schools. She teaches in the areas of bioethics, public health law and biotechnology policy and has served on UW's clinical ethics and research oversight committees. Professor Charo was a member of President Obama's transition team, focusing her attention particularly on transition issues related to NIH, FDA, stem cell policy, and women's reproductive health. From 2009 to 2011 she was on leave to serve as a senior policy advisor on emerging technology issues in the Office of the Commissioner at FDA. Her federal advisory committee service includes the 1994 NIH Human Embryo Research Panel and President Clinton's National Bioethics Advisory Commission (1996 to 2001). At the National Academies she co-chaired (with Richard Hynes) the committee on guidelines for embryonic stem cell research, and has been a member of its Board on Life Sciences, Board on Population Health and Public Health Practice, and Board on Health Sciences Policy.

Peter Daszak, Ph.D.
President and CEO
EcoHealth Alliance

Peter Daszak is President of EcoHealth Alliance, a US-based organization that conducts research and outreach programs on global health, conservation, and international development. Dr. Daszak's research has been instrumental in identifying and predicting the origins and impact of emerging diseases across the globe. He is one of the founders of the field of Conservation Medicine and has been instrumental in the

growth of EcoHealth, One Health, and now Planetary Health. Dr. Daszak is a member of the National Academy of Medicine and Chair of the NASEM's Forum on Microbial Threats. He is a me mber of the NRC Advisory Committee to the US Global Change Research Program, the Supervisory Board of the One Health Platform, the One Health Commission Council of Advisors, the CEEZAD External Advisory Board, the Cosmos Club, and the Advisory Council of the Bridge Collaborative. He has served on the IOM Committee on global surveillance for emerging zoonoses, the NRC committee on the future of veterinary research, the International Standing Advisory Board of the Australian Biosecurity CRC; and has advised the Director for Medical Preparedness Policy on the White House National Security Staff on global health issues. Dr. Daszak is a regular advisor to WHO on pathogen prioritization for R&D. He received his Ph.D. in parasitic infectious disease from the Univer sity of East London.

Jeffrey S. Duchin, M.D.
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section and Professor in Medicine
Public Health – Seattle & King County, WA and University of Washington, Seattle

Jeffrey Duchin is the Health Officer and the Chief of the Communicable Disease Epidemiology & Immunization Section for Public Health–Seattle & King County, Professor of Medicine in the Division of Infectious Diseases, and Adjunct Professor in the School of Public Health at the University of Washington, Seattle. Jeff currently serves on the Centers for Disease Control & Prevention's (CDC) Board of Scientific Counselors (Office of Infectious Diseases), the CDC's Advisory Committee on Immunization Practices and the Board of Directors for the Infectious Disease Society of America. Jeff has previously been a member of the National Academy of Medicine's (NAM) Forum on Microbial Threats and Forum on Medical and Public Health Preparedness, and the National Quality Forum's Adult Immunization Committee. Jeff received his medical degree from Rutgers Medical School and trained in internal medicine at Thomas Jefferson University Hospital, completed a fellowship in general internal medicine and emergency medicine at the Hospital of the Univ ersity of Pennsylvania, and did his infectious disease subspecialty training at the University of Washington in Seattle. Jeff is a graduate of the CDC's Epidemic Intelligence Service (EIS) Officer training where he was assigned to the National Center for Infectious Diseases where he also completed the CDC's Preventive Medicine Residency program. Jeff worked for CDC as a medical epidemiologist in the Divisions of Tuberculosis Elimination and HIV/AIDS Special Studies Branch before assuming his current positio n. His peer review publications and research interests focus on communicable diseases of public health significance. For a complete listing of publications, please see PubMED.

Ellen Embrey
Managing Partner
Stratitia, Inc.

Ellen Embrey is Managing Partner of Stratitia, Inc., a consulting firm focused on developing meaningful and innovative strategies, and delivering supporting tools and partnerships to bring them successfully to life. Ms. Embrey brings deep expertise in health and medic al issues, as well as a wealth of other experience gained during her extensive federal service. In her last federal role, she performed the duties of the Assistant Secretary of Defense for Health Affairs and the Director, TRICARE Management Activity during the presidential transition period in 2009-2010. From 2002 to 2009, Ms. Embrey was the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, leading significant changes in Department of Defense policies and programs affecting deployment and combat casualty medicine, health promotion and preventive medicine, medical readiness and public health emergency preparedness and response. For 9 months in 2001, Ms. Embrey performed the duties of Assistant Secretary of Defense for Reserve Affairs, shaping policies affecting the readiness and use of the National Guard and Reserve in both federal and state status. From 2000 to 2001, she served as Chief of Staff of that office, and from 1998 to 2001, as Deputy Assistant Secretary of Defense for Military Assistance to Civil Authorities,

developing policies that shaped the role of the National Guard and Reserve components in supporting homeland security, disaster preparedness, and national disaster response capabilities, including advising the president on such matters in the days and weeks following September 11, 2001. Between 1978 and 1997, Ms. Embrey served in senior-level policy analyst, budget analyst, program analyst, management analyst, and systems analyst positions in the Office of the Assistant Secretary of Defense for Reserve Affairs, the Defense Contract Audit Agency, and the Office of Personnel Management. Ms. Embrey was recognized with the Secretary of Defense's Distinguished Civilian Service Award in 2001 and 2004, and twice received the Meritorious Executive Presidential Rank Award in 2006 and 2009.

Baruch Fischhoff, Ph.D.
Howard Heinz University Professor, Department of Engineering and Public Policy
Carnegie Mellon University

Baruch Fischhoff is Howard Heinz University Professor, Department of Engineering and Public Policy and Institute for Politics and Strategy, Carnegie Mellon University (CMU). A graduate of the Detroit Public Schools, he holds a BS (mathematics, psychology) from Wayne State University and a PhD (psychology) from the Hebrew University of Jerusalem. He is a member of the National Academy of Sciences and of the National Academy of Medicine. He is past President of the Society for Judgment and Decision Making and of the Society for Risk Analysis. He has chaired the Food and Drug Administration Risk Communication Advisory Committee and been a member of the Eugene (Oregon) Commission on the Rights of Women, the Department of Homeland Security Science and Technology Advisory Committee and the Environmental Protection Agency Scientific Advisory Board, where he chaired the Homeland Security Advisory Committee. He has received the American Psychological Association (APA) Award for Distinguished Contribution to Psychology, CMU's Ryan Award for Teaching, an honorary Doctorate of Humanities from Lund University, and an Andrew Carnegie Fellowship. He is a Fellow of APA, the Association for Psychological Science, Society of Experimental Psychologists, and Society for Risk Analysis. His books include Acceptable Risk, Risk: A Very Short Introduction, Judgment and Decision Making, A Two-State Solution in the Middle East, Counting Civilian Casualties, and Communicating Risks and Benefits. He has co-chaired three National Academy Colloquia on the Science of Science Communication, as well as its committees on applying decision science to intelligence analysis and its committee on foundational science for cybersecurity.

Diane Griffin, M.D., Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health

Diane Griffin is University Distinguished Service Professor and Alfred and Jill Sommer Chair of the W. Harry Feinstone Department of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health. Dr. Griffin is a virologist recognized for her work on the pathogenesis of viral infections. She is known particularly for her studies on measles and alphavirus encephalomyelitis that have delineated the role of the immune response in virus clearance, vaccine-induced protection from infection, tissue damage and immune suppression. Dr. Griffin was born in Iowa City, Iowa, and grew up in Oklahoma City. She graduated from Augustana College, Rock Island, Illinois with a degree in biology and from Stanford University School of Medicine in 1968 with a Ph.D. in immunology and M.D., followed by a residency in internal medicine. She was a postdoctoral fellow in virology and infectious diseases at Johns Hopkins University School of Medicine and joined the faculty in 1974. She has been president of the American Society for Virology and of the American Society for Microbiology and is a member of both the National Academy of Sciences and the National Academy of Medicine.

Robert Groves
Executive Vice President and Provost
Gerard J. Campbell, S.J. Professor, Math and Statistics Department & Sociology Department
Georgetown University

Robert Groves is the Gerard J. Campbell, S.J. Professor in the Math and Statistics Department as well as the Sociology Department at Georgetown University where he has served as the Executive Vice President and Provost since 2012. Groves is a Social Statistician, who studies the Impact of Social Cognitive and Behavioral Influences on the quality of Statistical Information. His research has focused on the impact of mode of data collection on responses in sample surveys, the social and political influences on survey participation, the use of adaptive research designs to improve the cost and error properties of statistics, and public concerns about privacy affecting attitudes toward statistical agencies. He has authored or co-authored seven books and scores of peer-reviewed articles. His 1989 book, Survey Errors and Survey Costs, was named one of the 50 most influential books in survey research by the American Association of Public Opinion Research. His book, Nonresponse in Household Interview Surveys, with Mick Couper, received the 2008 AAPOR Book Award. His co-authored book, Survey Nonresponse, received the 2011 AAPOR Book Award. He served as the Director of the US Census Bureau between 2009-2012. Groves serves on several boards and advisory committees including the National Research Council Committee on National Statistics, Pew Research Center Board, the National Science Board, and the Federal Economic Statistics Advisory Committee. He is an elected member of the US National Academy of Sciences, of the National Academy of Medicine, of the American Academy of Arts and Sciences, and of the International Statistical Institute.

Margaret Hamburg, M.D.
Foreign Secretary
National Academy of Medicine

Margaret Hamburg is an internationally recognized leader in public health and medicine, and currently serves as foreign secretary of the National Academy of Medicine and chair of the NTI | bio Advisory Group. She is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served for almost six years. As FDA Commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining FDA, Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. She is President-elect of the American Association for the Advancement of Science (AAAS), as well as an elected member of the Council on Foreign Relations and the National Academy of Medicine. Hamburg currently sits on the boards of the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, the Parker Institute for Cancer Immunotherapy and the American Museum of Natural History. She is chair of the Joint Coordinating Group for the Coalition for Epidemic Preparedness and Innovation, and a member of the Harvard University Global Advisory Council, the Global Health Scientific Advisory Committee for the Gates Foundation, the Harvard Medical School Board of Fellows, and the World Dementia Council. Dr. Hamburg earned her B.A. from Harvard College, her M.D. from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center. She is the recipient of multiple honorary degrees and numerous awards.

Dan Hanfling, M.D.
Vice President, Technical Staff
In-Q-Tel

Dan Hanfling is Vice President on the Technical Staff at In-Q-Tel, a non-governmental not-for-profit strategic investor focused on enabling technologies to support national security requirements. He is a board-certified emergency physician practicing at Inova Fairfax Hospital, northern Virginia's Level I trauma center, where he led emergency preparedness response efforts in the aftermath of the 9-11 attacks and the anthrax mailings. He participates as a Medical Team Manager for Virginia Task Force One, a FEMA- and USAID-sanctioned international urban search and rescue team and has deployed to numerous catastrophic disaster events, both domestic and international. Dr. Hanfling currently serves as the co-chair of the National Academies Forum on Medical and Public Health Preparedness and co-chaired the Institute of Medicine committees responsible for developing the work on "crisis standards of care". Dr. Hanfling is Clinical Professor of Emergency Medicine at George Washington University. He received an AB in political science from Duke University and was awarded his medical degree from Brown University. He completed an internship in internal medicine at the Miriam Hospital in Providence, Rhode Island, and an emergency medicine residency at George Washington/Georgetown University Hospitals.

John Hick, M.D.
Associate Medical Director for EMS
Medical Director of Emergency Medicine
Hennepin County Medical Center

John Hick is a faculty emergency physician at Hennepin Healthcare and a Professor of Emergency Medicine at the University of Minnesota. Dr. Hick serves as the deputy medical director for Hennepin County Emergency Medical Services and Medical Director for Emergency Preparedness at HCMC. He is also the Vice-Chair of the Clinical Council for Life Link III helicopter service and me dical director for MN TF-1 state US&R team. He served the Minnesota Department of Health as the medical director for the Office of Emergency Preparedness until becoming an Advisor to the Director of OEM at ASPR/HHS where he is the lead editor for the TRACIE healthcare disaster preparedness website. He is the founder and past chair of the Minneapolis/St. Paul Metropolitan Hospital Compact, a 32-hospital mutual aid and planning group active since 2002. He is a national speaker on hospital preparedness issues and has published numerous papers dealing with hospital preparedness for contaminated casualties, personal protective equipment, crisis standards of care, and surge capacity and was honored to serve the Institute of Medicine on their Crisis Standards of Care projects as well as the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Dr. Hick holds an M.D. from the Mayo Medical School.

Kent E. Kester, M.D.
Vice President and Head, Translational Science and Biomarkers
Sanofi Pasteur

Kent Kester is currently Vice President and Head, Translational Science and Biomarkers at Sanofi Pasteur. In this capacity, Dr. Kester leads a team of over 200 research and clinical professionals in the US and France focused on the translational development of new vaccines. During a 24-year career in the US Army, he worked extensively in clinical vaccine development and led multiple research platforms at the Walter Reed Army Institute of Research, the U.S. Department of Defense's largest and most diverse biomedical research laboratory with a major emphasis on emerging infectious diseases, an institution he later led as its Commander/Director. His final military assignment was as the Associate Dean for Clinical Research in the School of Medicine at the Uniformed Services University of the Health Sciences (USUHS). During his military service, Dr. Kester was appointed as the lead policy advisor to the US Army Surgeon General in both Infectious Diseases and in Medical Research & Development. In these

capacities, he worked extensively in the interagency environment and developed a variety of Army and DoD medical policies related to infectious diseases, both clinical and research aspects. Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College, completing his internship and residency in internal medicine at the University of Maryland and a research fellowship in infectious diseases at the Walter Reed Army Medical Center. Currently a member of the US Government Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) and the Department of Veterans Affairs Health Services Research & Development Service Merit Review Board, he previously chaired the Steering Committee of the NIAID/USUHS Infectious Disease Clinical Research Program, and has served as a member of the FDA Vaccines & Related Biologics Products Advisory Committee (VRBPAC), the NIAID Advisory Council, and the CDC Office of Infectious Diseases Board of Scientific Counselors. He is the Vice Chair of the National Academy of Medicine Forum on Microbial Threats. Board-certified in both internal medicine and infectious diseases, Dr. Kester holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Royal College of Physicians of Edinburgh, the Infectious Disease Society of America, and the American Society of Tropical Medicine and Hygiene. He is a member of the clinical faculty at the University of Maryland Shock Trauma Center in Baltimore.

Patricia King, J.D.
Professor Emerita
Georgetown University Law Center

Patricia King is Professor of Law emeritus at Georgetown University Law Center and an Adjunct Professor in the Department of Health Policy and Management, School of Hygiene and Public Health at Johns Hopkins University. She is the co-author of Cases and Materials on Law, Science and Medicine. She is a member of the National Academy of Medicine, a member of the American Law Institute, a fellow of the Hastings Center and a faculty affiliate of Georgetown's Kennedy Institute of Ethics. Her scholarship focuses on race and genomics, racial disparities in health and reproductive health. Professor King has served on numerous national advisory bodies formed to address the ethical issues generated by developments in science and technology, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), which produced the seminal "Belmont Report," the President's Advisory Committee on Human Radiation Experiments (1994-95), the National Institutes of Health's Embryo Research Panel (co-chair for policy, 1994), the Ethics, Legal and Social Issues Working Group of the NIH's Human Genome Project (1989-95), and the NIH's Recombinant DNA Advisory Committee (1979-81). She has served on numerous boards and Institute of Medicine committees and is currently a member of the Board of Health Sciences Policy of the National Academies. She is also a Director of Mathematica an employee-owned company.She is a graduate of Wheaton College (Massachusetts) and has served as a Trustee and Chair of the Wheaton College Board of Trustees. In 2018 she was designated a Life Trustee by the Wheaton College Board. She graduated from Harvard Law School and is a past member of the Harvard Corporation the governing board of Harvard University. She has received honorary degrees from Wheaton College, Old Dominion University, and Harvard University.

Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
Executive Director, One Health Institute
UC Davis School of Veterinary Medicine

Jonna Mazet, D.V.M, M.P.V.M., Ph.D., is a Professor of Epidemiology and Disease Ecology at the UC Davis School of Veterinary Medicine and Executive Director of the UC Davis One Health Institute. Her work focuses on global health problem solving for emerging infectious diseases and conservation challenges. She is active in international One Health education, service, and research programs, most notably in relation to disease transmission among wildlife, domestic animals, and people and the ecological drivers of disease emergence. Currently, Dr. Mazet is the Co-Director of the US Agency for

International Development's One Health Workforce – Next Generation, an $85 million educational strengthening project to empower professionals in Central/East Africa and Southeast Asia to address complex health threats, including antimicrobial resistance and zoonotic diseases. She recently served as the Global Director of PREDICT Project, a greater than $200 million viral emergence early warning project under USAID's Emerging Pandemic Threats Division. She was elected to the US National Academy of Medicine in 2013 in recognition of her successful and innovative approach to emerging environmental and global health threats and serves on the National Academies of Science, Engineering, and Medicine's Forum on Microbial Threats and chairs the Academies' One Health Action Collaborative.

Phyllis Meadows, Ph.D., M.S.N., R.N.
Senior Fellow, Health
The Kresge Foundation

Phyllis Meadows currently serves as the Senior Fellow and Program Advisor for the Kresge Foundation Health Team. In this role, she is responsible for supporting the health team in the development and implementation of investment opportunities within and across the Foundation's various programming areas. Her professional career includes leadership roles in philanthropy, academia, community health and governmental public health. She has previously served in the role of Associate Dean for Public Health Practice and Clinical Professor - Health, Management and Policy with the University of Michigan School of Public Health. She has led several initiatives to expand multi-disciplinary practice in communities, designing the University's first certification program on population health and health equity for medical residents. She is currently a Distinguished Towsley Policy Maker in Residence with the University of Michigan's Gerald Ford School of Public Policy. She has taught and developed graduate level and professional continuing education courses to address emerging health issues, including topics on health policy and public health leadership. Dr. Meadows has extensive experience in public health practice having served in various leadership roles in public health. She has held several official appointments in public health leadership at the state, county and local levels. In her most recent appointment, she served as the Chief Health Officer and Director of Health for the City of Detroit, providing leadership for the department of health, environmental health, infectious disea ses, child health, clinical and dental services for the residents of Detroit. Her philanthropic experience includes positions as Program Director for the W.K. Kellogg Foundation - Youth, Education and Higher Education; and advisor for several national initiatives of the Robert Wood Johnson Foundation including the Nurse Executive Leadership Program, Partners in Nursing, and the County Roadmaps project. As a registered nurse, she has worked in both community-based health and hospitals. She currently serves as a Board Member and Advisor for several state level organizations and private foundations focusing on health.

Tara O'Toole, M.D., M.P.H.
Executive Vice President
In-Q-Tel

Tara O'Toole currently serves as Executive Vice President at In-Q-Tel. Dr. O'Toole was confirmed as the Under Secretary for Science and Technology (S&T) at the U.S. Department of Homeland Security (DHS) and served from November 4, 2009 to September 23, 2013. From 2003 to November 2009, Dr. O'Toole was the CEO and Director of the Center for Biosecurity at the University of Pittsburgh Medical Center (UPMC), and Professor of Medicine and of Public Health at the University of Pittsburgh. The Center for Biosecurity of UPMC is an independent organization dedicated to improving the country's resilience to major biological threats. Dr. O'Toole is internationally known for her work on biosecurity and on health and safety issues related to the U.S. nuclear weapons complex. Her publications in the biodefense field include articles on the response to anthrax, smallpox, and plague biological attacks; containment of contagious disease epidemics; biodefense research and development strategies; and hospital preparedness. She is the founding editor of the journal Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. She was a principal author and producer of Dark Winter, an influential exercise conducted in

June 2001 to alert national leaders to the dangers of bioterrorist attacks. She was also a principal writer and producer of Atlantic Storm, an international ministerial-level biosecurity exercise held in January 2005. Prior to founding the UPMC in 2003, Dr. O'Toole was one of the original members of the J ohns Hopkins Center for Civilian Biodefense Strategies and served as its director from 2001 to 2003. She has served on numerous government and expert advisory committees dealing with biodefense, including panels of the Defense Science Board; the National Academy of Engineering Committee on Combating Terrorism; and the National Academy of Sciences Working Group on Biological Weapons. She served as chair of the Board of the Federation of American Scientists from 2006 to 2007, and in 2006 she was appointed to the board of Google Foundation's International Networked System for Total Early Disease Detection. From 1993 to 1997, Dr. O'Toole served as Assistant Secretary of Energy for Environment Safety and Health. In this position, she was the principal advisor to the Secretary of Energy on environmental protection and on the health and safety of the approximately 100,000 workers in the U.S. nuclear weapons complex and Department of Energy (DOE) laboratories. She developed the first overall management and safety plan for dealing with the highly enriched uranium, plutonium, spent fuel, and radioactive waste left in place when nuclear weapons production was stopped in the early 1990s. She ran the multi-agency, multimillion-dollar task force that oversaw the government's investigations into human radiation experiments conducted during the Cold War and led the U.S. delegation to Russia to establish the U.S./Russia cooperative effort to study radiation exposure and environmental hazards of the Russian nuclear weapons complex. Prior to her work at DOE, Dr. O'Toole was a senior analyst at the Congressional Office of Technology Assessment, where she directed several projects and studies, including the health impact of pollution resulting from nuclear weapons production. She al so served as a consultant to industry and government in matters related to occupational and environmental health; worker participation in workplace safety protection; and organizational change. Dr. O'Toole practiced general internal medicine in community health centers in Baltimore from 1984 to 1988. She is board certified in internal medicine and occupational and environmental health. She has a bachelor's degree from Vassar College, an M.D. from the George Washington University, and a Master of Public Heal th degree from Johns Hopkins University. She completed internal medicine residency training at Yale University and a fellowship in Occupational and Environmental Medicine at Johns Hopkins University.

Alexandra Phelan, S.J.D., LL.M., LL.B.
Assistant Professor
Center for Global Health Science and Security
Georgetown University

Alexandra Phelan is an Assistant Professor at the Center for Global Health Science and Security in the Department of Microbiology and Immunology at Georgetown University School of Medicine. Dr. Phelan also holds an appointment as Adjunct Professor of Law at Georgetown University Law Center. Dr. Phelan works on legal and policy issues related to infectious diseases, with a particular focus on emerging and reemerging infectious disease outbreaks and international law. She has worked as a consultant for the World Health Organization, the World Bank, and Gavi: the vaccine alliance, and has advised on matters including international law and pathogen sharing, human rights law and Zika, int ellectual property law, and contract law. She previously worked for a number of years as a solicitor at a firm in Melbourne, Australia and was admitted to practice to the Supreme Court of Victoria and High Court of Australia in 2010. Dr. Phelan's doctorate examined how overlap between fields of international law – in particular, global health law, international human rights law, and international environmental law – can serve as the catalyst to progressively develop international law to prevent and respond to infectious diseases. She also holds a Master of Laws, specializing in international law, from the Australian National University and a Bachelor of Biomedical Science/Bachelor of Laws (Honours) double degree from Monash University. She also holds a Diploma of Languages (Mandarin Chinese). Dr. Phelan is a General Sir John Monash Scholar and was recognized as an Associate Fellow of the Royal Commonwealth Society in 2015 for her human rights advocacy during the 2013-16 Ebola outbreak.

David Relman, M.D.
Thomas C. and Joan M. Merigan Professor in Medicine, and Chief of Infectious Diseases
Stanford University; VA Palo Alto Health Care System

David Relman is the Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology and Immunology at Stanford University, and Chief of Infectious Diseases at the Veterans Affairs Palo Alto Health Care System. Dr. Relman is also Senior Fellow at the Freeman Spogli Institute for International Studies (FSI), and served as Science Co-Director at the Center for International Security and Cooperation (2013-2017), at Stanford. He is currently director of a new Biosecurity Initiative at FSI. Relman trained at MIT and then Harvard Medical School, followed by clinical training in internal medicine and infectious diseases at the Massachusetts General Hospital in Boston, and then a postdoctoral fellowship in microbiology at Stanford. His early research focused on molecular methods for pathogen discovery and over the past 20 years, on the human microbiome. He was elected to the National Academy of Medicine in 2011. Dr. Relman served as vice-chair of the National Research Council Committee that reviewed the science performed for the FBI 2001 Anthrax Letters investigation, chair of the Forum on Microbial Threats (2007-2017), and is currently a member of the Intelligence Community Studies Board (2016-) as well as Chair of a Standing Committee tasked with examining the health-related problems of US embassy personnel stationed overseas, all at the U.S. National Academies of Science. He was a founding member of the National Science Advisory Board on Biosecurity (2005-2014), a member of the Working Group on Biodefense for the President's Council of Advisors on Science and Technology (The White House) (2016), and served as President of the Infectious Diseases Society of America (2012-2013). He holds an M.D. from Harvard Medical School.

Mark Smolinski, M.D., M.P.H.
President
Ending Pandemics

Mark Smolinski currently serves as President of Ending Pandemics. Dr. Smolinksi brings 25 years of experience in applying innovative solutions to improve disease prevention, response, and control across the globe. Mark is leading a well-knit team—bringing together technologists; human, animal, and environmental health experts; and key community stakeholders to co-create tools for early detection, advanced warning, and prevention of pandemic threats. Since 2009, Mark has served as the Chief Medical Officer and Director of Global Health at the Skoll Global Threats Fund (SGTF), where he developed the Ending Pandemics in Our Lifetime Initiative in 2012. His work at SGTF created a solid foundation for the work of Ending Pandemics, which branched out as an independent entity on January 1, 2018. Prior to SGTF, Mark developed the Predict and Prevent Initiative at Google.org, as part of the starting team at Google's philanthropic arm. Working with a team of engineers, Google Flu Trends (a project that had tremendous impact on the use of big data for disease surveillance) was created in partnership with the U.S. Centers for Disease Control. Mark has served as Vice President for Biological Programs at the Nuclear Threat Initiative, a public charity directed by CNN founder Ted Turner and former U.S. Senator Sam Nunn. Before NTI, he led an 18-member expert committee of the National Academy of Medicine on the 2003 landmark report "Microbial Threats to Health: Emergence, Detection, and Response." Mark served as the sixth Luther Terry Fellow in Washington, D.C., in the Office of the U.S. Surgeon General and as an Epidemic Intelligence Officer with the U.S. Centers for Disease Control and Prevention. Mark received his B.S. in Biology and M.D. from the University of Michigan in Ann Arbor. He is board-certified in preventive medicine and public health and holds an M.P.H. from the University of Arizona.

David Walt, Ph.D.
Hansjörg Wyss Professor of Biologically Inspired Engineering
Harvard Medical School

David R. Walt is the Hansjörg Wyss Professor of Bioinspired Engineering at Harvard Medical School and Professor of Pathology at Harvard Medical School and Brigham and Women's Hospital, is a Core Faculty Member of the Wyss Institute at Harvard University and is a Howard Hughes Medical Institute Professor. Previously, he was University Professor at Tufts University. His laboratory pioneered the development of microwell arrays, which revolutionized the field of genetic analysis. Dr. Walt's laboratory also introduced the idea of digital protein detection by developing a high throughput technology for performing single molecule analysis. Dr. Walt's research is aimed at applying new technologies to address unmet clinical diagnostics needs. Dr. Walt is the Scientific Founder of Illumina Inc., Quanterix Corp., and has co-founded several other life sciences startups including Ultivue, Inc., Arbor Biotechnologies, Sherlock Biosciences, and Vizgen, Inc. He has received numerous national and international awards and honors for his fundamental and applied work in the field of optical microwell arrays and single molecules. He is a member of the National Academy of Engineering, the National Academy of Medicine, a Fellow of the American Academy of Arts and Sciences, a Fellow of the American Institute for Medical and Biological Engineering, a Fellow of the National Academy of Inventors, and is inducted in the US National Inventors Hall of Fame.

Organizer: Brown, Lisa[LBrown@nas.edu]

From: Brown, Lisa[LBrown@nas.edu]

Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; jbaker@rwjf.org; Baric, Toni C; Mary Radford; Pope, Andrew; Pavlin, Julie; Feit, Monica; Shore, Carolyn; Wollek, Scott; Downey, Autumn; Motrya Calafiura; rhock@ihi.org; Fine, Emma; Shin, Rebecca; Attal-Juncqua, Aurelia; Borel, Bridget; jonna.mazet@gmail.com; Logan, Kendall

Location: https://nasem.zoom.us/j/91377677378

Importance: High

Subject: Second Virtual Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Start Time: Thur 4/30/2020 11:00:00 AM (UTC-04:00)

End Time: Thur 4/30/2020 1:30:00 PM (UTC-04:00)

Required Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; jbaker@rwjf.org; Baric, Toni C; Mary Radford; Pope, Andrew; Pavlin, Julie; Feit, Monica; Shore, Carolyn; Wollek, Scott; Downey, Autumn; Motrya Calafiura; rhock@ihi.org; Fine, Emma; Shin, Rebecca; Attal-Juncqua, Aurelia; Borel, Bridget

Optional Attendees: jonna.mazet@gmail.com; Logan, Kendall

FINAL Agenda_Virtual Meeting 2_ SC on EID and 21st Century Threats.pdf

SCEID Working Group Priority Issues_v1_42920.docx

ASPR COVID Strategic Operational Priorities.docx

SCEID Working Group Membership.docx

Committee Membership Roster - SC on EID and 21st Century Threats.pdf

Committee Internal Roster - SC on EID and 21st Century Threats.pdf

Committee Member Biosketches - SC on EID and 21st Century Threats.pdf

Updated with Zoom information, the agenda, and meeting materials

Zoom Call-In Information
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378
Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Greetings,

Please hold Thursday, April 30th from 11:00 a.m. – 1:30 p.m. ET for the second virtual meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. This is the time frame that worked best for the majority of the committee. Remote participation information, an agenda, and additional materials will be shared in the coming days.

Please let me know if you have any questions.

Best,
Lisa

Lisa Brown, MPH
Senior Program Officer
Board on Health Sciences Policy
Health and Medicine Division
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Second Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Final Agenda
Thursday, April 30, 2020 11:00 a.m. – 1:00 p.m. ET

Zoom Information

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378

Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Background: In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine established the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. The Standing Committee's purpose is to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee includes members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee provides a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

Meeting Objectives

- Discuss the status and progress of the work of the standing committee with the sponsors
- Discuss the priorities of each working group: viral characteristics; patient care and medical countermeasures; community engagement and population health; and, cross-cutting issues
- Discuss and plan priorities, strategies, and next steps

THURSDAY, APRIL 30, 2020

CLOSED SESSION

SESSION I **Welcoming Remarks and Sponsors' Reflections on Status and Progress since the First Standing Committee Meeting**

11:00 a.m. **Welcoming Remarks and Introduction of New Members**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Victor Dzau
President
National Academy of Medicine

Gregory Symmes
Chief Program Officer
The National Academies of Sciences, Engineering, and Medicine

11:15 a.m. **Sponsor's Remarks and Update on COVID-19 Response**

David (Chris) Hassell
Senior Science Advisor
The Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

SESSION II **Working Group Discussions**

11:25 a.m. **Group A: Viral Characteristics Working Group**

David Relman, *Committee Member*

Jonna Mazet, *Committee Member*

11:35 a.m. **Group B: Patient Care and Medical Countermeasures Working Group**

Donald Berwick, *Committee Member*

Margaret Hamburg, *Committee Member*

11:45 a.m. **Group C: Community Engagement and Population Health Working Group**

Mary Travis Bassett, *Committee Member*

Robert Groves, *Committee Member*

11:55 a.m. **Group D: Cross-Cutting Issues Working Group**

Alta Charo, *Committee Member*

Tara O'Toole, *Committee Member*

12:05 p.m. **Discussion of the Issues and Next Steps with the Sponsors**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:30 p.m. ***ADJOURN***

CLOSED SESSION (COMMITTEE ONLY)

12:35 p.m. **Committee Debrief, Next Steps, and Potential Future Meeting Topics**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:40 p.m. **Office of News and Public Information Briefing**

Dana Korsen
Media Relations Manager
Office of News and Public Information
The National Academies of Sciences, Engineering, and Medicine

12:45 p.m. **Discussion of Bias and Conflict of Interest**

Lauren Shern
Associate Executive Director
Health and Medicine Division

1:00 p.m. ***ADJOURN MEETING***

April 29, 2020

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Priority Topics

The standing committee has established four working groups to ensure adequate attention to a broad range of relevant issues and topics, and to propose priorities for consideration and responding to the needs of the sponsors.

The working groups focus on the following domains:

- Viral characteristics
- Patient care and medical countermeasures
- Community engagement and population health
- Cross-cutting issues

This document is a preliminary list of topics discussed by each working group. Of these topics, each working group has identified their top three priority topics (indicated by **priority**).

Summary Table: Top Three Priority Topics of Each Working Group

Working Group Topics	Informal Feedback (Telephonic Consultation)	Written Rapid Expert Consultation	Letter Report	Consensus Report
WG A: Viral Characterization				
Topic A-1: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement)	X	X	X	
Topic A-2: Viral evolution (tracking viral genome evolution, and correlation of genotype with in vitro phenotypes and in vivo host phenotypes)	X		X	
Topic A-3: Transmission and Spread	X			
WG B: Patient Care and MCM				
Topic B-1: Diagnostics roadmap			X	X
Topic B-2: Research agenda to understand pathogenesis, risk factors, and protective factors			X	
Topic B-3: Assessment of preparedness efforts				X
WG C: Community Engagement and Population Health				
Topic C-1: Data needs for decision making		X	X	X
Topic C-2: Specific data need and analysis to determine the role of children in disease transmission		X		
Topic C-3: Defining needs for successful response to COVID-19 among minority and disenfranchised populations		X	X	X
WG D: Cross-Cutting Issues				
Topic D-1: COVID-19 and racial and ethnic disparities		X	X	
Topic D-2: Workplace and school re-opening			X	
Topic D-3: Redefining the public health system for future pandemics				X

Group A: Viral Characterization Working Group

Topic A-1: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement) Priority

Analyses to better understand the role of antibodies and cellular immune responses in protection, and the development/durability of protective immunity:

- Characterization of the immune response and implications for disease severity and for short- and long-term protection from re-infection?
- How does viral clearance occur and what are the likelihoods of, and the risk factors for intermittent and long-term virus shedding?
- How long do neutralizing and non-neutralizing antibodies last?
- Does the presence of antibodies convey protective immunity, and if so, what kinds of antibodies, in what quantities, and for how long?
- What is the likelihood of herd immunity in the US and how will it vary by regional and local demographic factors?
- What is the role of pre-existing antibody (to other coronavirus strains, and potentially to other infectious agents) in the development of a protective immune response to SARS-CoV-2? Does antibody-mediated disease enhancement occur in humans infected by SARS-CoV-2?

JUSTIFICATION: Critical for vaccine, but also for national strategy going forward. If durable immunity doesn't exist, suppression is much more desirable than otherwise.

TIMELINE: Short- to medium-term

PRODUCT TYPE(S): Informal discussions, rapid expert consultation, letter report

PRIMARY AUDIENCE: Policymakers, researchers, funders & lay public

Topic A-2: Viral evolution (tracking viral genome evolution, and correlation of genotype with *in vitro* phenotypes and *in vivo* host phenotypes) Priority

Analyses to track/correlate viral genome sequence features with viral phenotypes *in vitro* and *in vivo* in host/s) as they relate to receptor recognition, growth, host responses and pathogenic mechanisms, and/or selective pressures in the host or environment. Examples of questions to be addressed:

- What are rates and mechanisms of genome evolution as a function of geography, time since introduction into human population, and host features such as immune status?
- How does viral genotype correlate with clinical outcomes?
- Are variant viral sequence features correlated with viral escape from host immune recognition or vaccine-induced immunity, therapeutic beneficial effects, or detection by currently deployed methods?
- How should features of viral genome evolution be used to help optimize the design and development of therapeutics and vaccines? Note: current features of genome evolution may not be a good indicator of genome evolution under the selective pressure of therapeutics, naturally-induced immunity, or vaccine-induced immunity.

JUSTIFICATION: Not expecting significant changes in phenotype, but it's important to do this research now to be sure. Correlation with clinical outcomes critical; it will be critical to make sure that detection/diagnosis and counter-measure efforts are informed about viral evolution.

TIMELINE: Short to medium-term. We need time to observe viral evolution and measure concurrent host phenotypes.

PRODUCT TYPE(S): An early discussion could help with development and deployment of infrastructure for properly capturing, assessing and sharing viral genome and associated host data, then letter report for disseminating results.

PRIMARY AUDIENCE: Policymakers, researchers, lay public

Topic A-3: Transmission and Spread Priority

An analysis to consider the key drivers/determinants and mechanisms of transmission and spread:

- What are the key drivers/determinants of viral spread and cycles of infection and illness?
- Are cycles of infection likely to result from environmental (e.g., temperature, humidity) or social (e.g., school openings/closings) factors?
- What are the mechanisms of transmission and spread?
    - Role of airborne particles of various sizes, fomites, respiratory versus fecal-oral
    - Identification and characterization of super spreaders?
    - Can risk factors for asymptomatic transmission be identified, especially long-term shedding?
    - Note: this work would impact case-based interventions, contact tracing, quarantine measures
- What is the duration of shedding of infectious virus by patients and the relationship to detection of viral RNA? Note: relevant for understanding recovery and when it is ok for people to leave isolation
- Is presence/shedding of viral RNA indicative of transmission risk (i.e., contagiousness)?

JUSTIFICATION: We still don't understand enough about transmission to be making clear policy judgements (aka should city parks stay open?, etc...); Issues are critical for understanding ongoing disease spread and design of interventions.

TIMELINE: Short to medium-term

PRODUCT TYPE(S): Early discussion to promote optimal approaches for data collection and experimental design. Letter report for findings.

PRIMARY AUDIENCE: Policymakers, funders, lay public

Topic A-4: Mechanisms of pathogenesis (host susceptibility, dynamics of the virus in the host, shedding, organ tropism, host response)

Analysis to better understand the "choreography" between the virus and host, including host molecular pathways and/or host response features during the course of infection:

- What are the mechanisms of pathogenesis and the factors contributing to variability in disease severity and outcome (consider relative contribution of viral versus host characteristics)?
- What is the natural history of the virus in humans (where, when)?
- What are the mechanisms of organ damage?
- What are the implications for development and use of therapeutics and other interventions? (Note: possible overlap with patient management group)
- What are the tools (e.g. animal models of disease, susceptibility, and early biomarkers) needed to understand the mechanisms of pathogenesis and the range of disease phenotypes?

TIMELINE: Short- medium- and long-term

PRODUCT TYPE(S): This would be a research agenda-setting exercise—where the early phase might involve discussions, then mid-term with a rapid consultation to promote the agenda, then Letter report later with early research findings of particular relevance to countermeasure development.

PRIMARY AUDIENCE: Researchers, funders, policy-makers

Topic A-5: SARS-COV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

A more substantive analysis of current and future issues of immediate critical need regarding viral emergence and host range:

- What are the host and transmission circumstances that could inform on origins and future spillovers for this pathogen?
- What are the natural hosts/animal reservoirs for this pathogen? What is the potential for domesticated livestock to serve as a reservoir and what are the implications for food security?
- What is the potential for future outbreaks from re-emergence from the human population, additional spillovers from existing hosts, and exposures from new hosts resulting from spillback events from humans into susceptible animals, especially pets and food animals?
- What is the host range for this virus (e.g., what is the current risk to and from companion animals)?

TIMELINE: Long-term

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: Policymakers, researchers, funders

Topic A-6: Development and recommendation of a research agenda

To include:

- Topic 1: Viral evolution (tracking viral genome evolution, and correlation of genotype with in vitro phenotypes and pathogenesis (hypothesis)
- Topic 3: Mechanisms of pathogenesis (hypothesis)
- Topic 5: SARS-CoV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

TIMELINE: Long-term

PRODUCT TYPE(S): Letter report/Consensus study

PRIMARY AUDIENCE: Policymakers, researchers, funders, lay public

Group B: Patient Care and Medical Countermeasures Working Group

Topic B-1: Diagnostics roadmap Priority _

Develop a comprehensive framework for diagnostic test development, deployment, and implementation, as well as analysis of diagnostic data, to ensure a robust testing system for the COVID-19 and future pandemics (both for public health surveillance/control measures and clinical management needs).

- Review the factors that led to shortcomings in current diagnostic development and availability.
- Examine the technological, procedural, and regulatory challenges, as well as the policies, strategies, and practices needed.
    - How can existing/advancing technologies be more effectively harnessed to develop appropriate diagnostics?
    - What factors create barriers and facilitators to successful public-private-academic partnerships for diagnostic development?
    - What kinds of diagnostics are required for different settings?
- Propose a roadmap for successful diagnostic development and testing systems for COVID-19 and future epidemic threats.

TIMELINE: Short-term (1 -2 months) and long-term (12 months)

PRODUCT TYPE(S): Letter report/Consensus report

PRIMARY AUDIENCE: HHS; State and local governments

Topic B-2: Research agenda to understand pathogenesis, risk factors, and protective factors Priority _

Review existing research on mechanisms of pathogenesis and risk and protective factors to inform patient care and extend understanding of how virus causes disease and the fuller elucidation of manifestations of disease.

- Enhance understanding of which patients' may be at especially high risk of serious disease and why.
- Develop more accurate predictive models for disease management and individual risk.
- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS; Medical community

Topic B-3: Assessment of preparedness efforts Priority ___

Examine the role of PHEP/HPP programs for public health and healthcare in preparing for and responding to COVID-19.

- Identify factors related to PHEP/HPP programs that create barriers to and facilitators of effective preparedness and response.
- Examine preparedness elements prior to the COVID-19 pandemic, and determine the actual value and needed improvements for the future.
- Propose recommendations to improve the nation's public health and healthcare preparedness and response programs.

TIMELINE: Long-term (12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

Topic B-4: Research agenda to understand the nature of immune response and protection

Review existing information concerning immune response to SARS-CoV-2 infection to inform key aspects of immune protection for individuals and for vaccine development. Undertake efforts to determine the duration and degree of protectiveness of immunologic responses. (Collaborate with Working Group 1.)

- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS

Topic B-5: Addressing global vaccine needs

Examine adequacy of current efforts for large-scale, coordinated and international research and development initiatives, including scientific collaboration, governance and funding of vaccine-related research projects for COVID-19 and future pandemics.

- Draw on best practices and work already supported by many governments and independent organizations like the Coalition for Epidemic Preparedness Innovations.
- Assess the current status and needed changes in international coordination of vaccine development and production.
- Consider needs/benefits of a strengthened USG engagement

TIMELINE: Medium-term (6-8 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS; Vaccine developers; WHO

Topic B-6: Leveraging real-world data to inform patient care

Identify and examine mechanisms to use real-world data, such as electronic health records, patient and clinician surveys, and semi-structured interviews, to better understand patient outcomes and to inform patient care.

- Explore ways to leverage data mining/analytics to improve patient care processes during COVID-19, including ways to standardize data collection and assemble information from electronic medical records to better inform patient care and outcomes.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS

Topic B-7: Risk analysis of healthcare and economic recovery requirements

Develop a risk analysis framework to examine the balance between healthcare recovery requirements and economic recovery requirements and consider relevant policy implications.

TIMELINE: Medium-term (6-8 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS; DOL; Others

Topic B-8: Rapid learning cycle capacities for health system adaptations and improvement

Explore concepts and methods of learning health systems to understand public health and healthcare system adaptations in response to COVID-19 (e.g., what were your system's expectations and planning assumptions, what was the reality, and how did your system adapt).

- How can we embed research/data collection into ongoing activities to enhance understanding and inform future approaches? How can we "learn as we go" more efficiently and effectively?

TIMELINE: Long-term (12 months)

PRODUCT TYPE(S): Consensus Study

PRIMARY AUDIENCE: HHS

Topic B-9: Understanding pediatric COVID-19 cases

Review existing research on pediatric COVID-19 cases to understand which children might be at highest risk for severe COVID-19 illness and to understand the role children with asymptomatic and mild disease are playing in transmission and spread of COVID-19 in the community.

- Examine policy implications (especially regarding school re-openings) related to the findings.
- Identify implications for pediatric care/hospital management needs
- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Rapid expert consultation; Letter report

PRIMARY AUDIENCE: HHS; state governments; municipal governments; medical community

Group C: Community Engagement and Population Health Working Group

Topic C-1: Data needs for decision making Priority

Determine minimum datasets jurisdictions should collect, how the data should be collected, and justification for collection, in order to develop public health strategies based on evidence.

- Obtain evidence for the effectiveness of non-pharmaceutical interventions to justify epidemiologic data collection (to include serology and other testing) and resultant public health interventions such as social distancing, business and school closures, and travel and trade restrictions.

- Determine a "minimum data set" for population surveillance, including demographic components (e.g., geographic location, age, race, gender, disability, immigration status, socio-economic status, underlying health issues) that is necessary to make public health decisions.
- Determine how to ensure high priority populations are included in surveillance to include health workers, disadvantaged (nursing home populations, homeless, prisoners, etc.), and racial and ethnic minorities.
- Determine what outcome measures for each of the above are needed (e.g., who gets tested, who gets treated, who is in isolation, health outcome).
- Review the utility of non-traditional data sources such as participatory surveillance, and innovative methods for contact tracing. Evaluate new data sources and alternative methods for analysis so that all jurisdictions in the US and internationally can best evaluate utility of data.
- Determine how to best incorporate modeling into real-time decision-making and what data are most useful for the models.

TIMELINE: Short for evaluating alternative methods, L for modeling and retrospective analyses

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, state and local PH

VOLUNTEERS/COLLABORATION: SEAN, modelers

Topic C-2: Specific data need and analysis to determine the role of children in disease transmission Priority

Summarize what is known about the contribution of school-age children to disease transmission and recommend studies that can address gaps in this knowledge.

- Can provide critical information for re-opening the economy.

TIMELINE: Short

PRODUCT TYPE(S): Rapid expert consultation

PRIMARY AUDIENCE: HHS, OSTP, local governments

VOLUNTEERS/COLLABORATION: SEAN

Topic C-3: Defining needs for successful response to COVID-19 among minority and disenfranchised populations Priority

Review the issues faced by disenfranchised and minority populations to ensure they are protected and to improve overall effectiveness of mitigation methods.

- Determine ability of disenfranchised populations to comply with social distancing, isolation and quarantine, and impact of inability to comply on overall mitigation efforts.

- Evaluation of access to testing, healthcare and available countermeasures by demographics and methods to ensure equity.
- Review the ethical implications of crisis standards of care prioritization and appropriate guidance for triage of life-sustaining resources.
- Determine methods to provide appropriate communications in both low English proficiency populations and in different cultural and ethnic groups.

TIMELINE: Medium-term for synthesis of current data. Long-term when more data becomes available

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, state and local PH

VOLUNTEERS/COLLABORATION: Minority focused and community based organizations

Topic C-4: Determine risk assessments for population activities

Provide risk assessments to determine the appropriate decisions regarding opening of schools and businesses, indoor and outdoor activities, and mitigation efforts at facilities and events.

- Determine testing needs for school and workplace openings.
- Determine parameters to guide assessment of Covid19 resurgence.
- Provide occupational safety and health standards to include distancing between workers, use of barriers (to include masks), and tracking potentially infectious states.
- Evaluate the risk of indoor and outdoor settings with regard to effects on the virus (heat/humidity/sunlight) and appropriate public health measures.
- Determine responsibility to disadvantaged communities to include nursing homes and prisons. Provide models for each to determine reasonable risk-based standards to open locations in a reasonable way.

TIMELINE: Short for framework, long for reopening evaluations

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, local and state PH

VOLUNTEERS/COLLABORATION: SEAN

Topic C-5: Adverse impacts of NPI

Measure and find ways to mitigate the unintended adverse health consequences of social distancing measures on individuals, families and societal groups.

TIMELINE: Medium-term to long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: HHS and state and local PH

VOLUNTEERS/COLLABORATION: Chamber of commerce, NGA, US conference of Mayors

Topic C-6: Future impact of COVID-19

Given known epidemiology of the virus, what can we predict will be its future impact and how can we best prepare.

- Predict changes in virus transmission given seasonality and contribution of social changes such as school openings.
- Understand disease progression and health needs in developing countries and how we can mitigate impact internationally and on US populations.

TIMELINE: Medium-term to long-term

PRODUCT TYPE(S): Consensus

PRIMARY AUDIENCE: Federal, state and local PH

Topic C-7: Develop best communication techniques for clarity

Identify and disseminate best practices for communications that can be used by public health, and the public in general, in a practical way.

- Determine best ways to have culturally-competent communications with sensitivity to the audience.
    - What are some innovative and non-traditional communication mechanisms that can support disease control activities?
- Find ways to maintain clarity of messages and have coherent community-focused communications.
- Determine how to ensure communication continues on the downslope of the epi curve – need to encourage vigilance and understanding of seasonality.
- Develop key messages that are important to relay at various points in time (crisis, recovery, etc.)

TIMELINE: Medium-term for synthesis, long-term for better data

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: Standing committee on science communication, SEAN, media

Topic C-8: Role of One Health

Determine the role of domestic pets and livestock in virus transmission and risk (to them and to people). Need good epidemiology and appropriate communication to decrease panic.

TIMELINE: Long-term

PRODUCT TYPE(S): Letter/consensus report

Topics C-9: Evaluation of products

Find methods to evaluate new and innovative products that could be useful but may overwhelm public health departments.

TIMELINE: Medium- to long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: FEMA

Topic C-10: Healthcare system preparedness

Develop metrics for healthcare system preparedness.

TIMELINE: Long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: Tech industry, Mitre, Rand

Group D: Cross-Cutting Issues Working Group

Topic D-1: COVID-19 and racial and ethnic disparities Priority

Understand how COVID-19 is disproportionally affecting communities in order to shape and target immediate response efforts.

- Examine the patterns of COVID-19 related morbidity and mortality across racial and ethnic groups.
- Understand (clearly articulate and disseminate) the underlying causes and existing systemic issues leading to these disparities.
- Propose short-term recommendations to reduce the impact of COVID-19 on the health of racial and ethnic minorities on, but not limited, to the following:
    - Structural elements of access and equitable public health information, screening, testing, treatment, and follow-up.
    - Clinical management of patients and equitable allocation of resources.

- Appropriate strategies to assure appropriate and safe levels of quarantine and/or isolation, for those in more highly concentrated communities and housing situations.
- Occupational health and safety, including disparate impacts on current workers in essential businesses and on workers as new businesses re-open.
- Data systems to monitor and track disparities among racial and ethnic groups.

TIMELINE): Short-term (1 -2 months). *(Note: This topic has priority has both immediate and longer-term implications. The items above, are consistent with increasing awareness of the impact of the virus. Over the long-term, there needs to be efforts to define the range of solutions that can be applied to address the underlying factors that contribute to the disparate impacts. We would be missing a critical opportunity, if we only focus on the data (which is empirically known), versus organizing the systems to more effectively respond to the different experiences and life-circumstances of certain populations who are likely to require modified approaches to yield positive results.)*

PRODUCT TYPE(S): Rapid expert consultation, letter report

PRIMARY AUDIENCE: HHS

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health

Topic D-2: Workplace and school re-opening Priority

Identify and disseminate best practices for re-opening businesses and schools

- Integrate demands for testing (active infection and immunity) with management of physical space and use of protective equipment. To include periodic testing standards, workplace policies, preventing and managing future surges or infectious threats.
- Identify and mitigate measures with unintended deleterious impact on sub-populations (age, disability, pregnancy, co-morbidities).
- Anticipate accommodations needed to comply with ADA.
- Examine the role of school based health centers, school health.

TIMELINE: Medium-term (3-6 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS, DOE, DOL

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health, National Alliance for School Based Health

Topic D-3: Redefining the public health system for future pandemics Priority

A comprehensive effort to redefine the nation's public health system to accommodate emerging infectious diseases, and manage and prevent other diseases and underlying conditions (health and

social) that can influence health outcomes and expand the scope of national security to include public health.

- Examine the public health system infrastructure challenges that are arising in response to COVID-19.
- Map how public-private partnerships are currently being leveraged in the public health system in the COVID-19 pandemic (e.g., private sector augmenting public health departments and aiding in contract tracing), and identify best practices.
- Map how technology is currently being leveraged in the public health system in the COVID-19 pandemic, and identify best practices.
- Clarify ambiguities or fill gaps in policy and law governing federal vs state and local authorities
- Identify obstacles to better coordination with public health authorities domestically and abroad
- Propose a framework and recommendations to redefine the nation's public health system to include creating a system that addresses inequities in policies and practices that result in adverse experiences and outcomes for racial, ethnic and marginalized populations.

TIMELINE: Long-term (6-12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health, National Association of City and County Health Officials, Association of State and Territorial Health Officers, Trust for America's Health

Topic D-4: Learning health system for pandemics

Examine concepts and methods of learning health systems related the COVID-19 pandemic and future pandemics.

- Examine how the components of a learning health system are currently being implemented in the COVID-19 pandemic and identify best practices.
- Identify components of a learning health system that could be implemented in the immediate COVID-19 response.
- Develop a framework and propose recommendations related to the key components of a learning health system to optimize care of individuals in a pandemic.

TIMELINE: Long-term (6-12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

ASPR COVID-19 Strategic Operational Priorities

SHIELD the vulnerable who have greatest risk of morbidity & mortality

- Skilled Nursing Facilities
- Elder Care Facilities
- Dialysis Clinics
- Other: Cancer Treatment Centers

SHELTER the susceptible: Decrease community transmission

- Non-pharmaceutical interventions: school closures, mass gathering cancellations

SAVE the sick: preserve the integrity & capacity of the health care system

- Segregate the care of COVID-19patients
- Preserve the care of routine & emergency care

SUSTAIN supplies

- Increase the supply
- Extend the use
- Innovate new sources or approaches

SCIENCE

- Vaccines
- Therapeutics
- Diagnostics

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Membership

Group A – Viral Characteristics (WG Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
Mechanisms for pathogenesis
One Health

Group B – Patient Care and Medical Countermeasures (MCM) (WG Leads: Don Berwick, Margaret Hamburg)

Staff Leads: Lisa Brown and Scott Wollek

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Tara O'Toole
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Topics: Vaccines and therapeutics
Diagnostics
Patient care (including personal protective equipment, crisis standards of care, and quality)

Group C – Community Engagement and Population Health (WG Leads: Mary Travis Bassett, Robert Groves)

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Rich Besser
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Phyllis Meadows

	Alexandra Phelan
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	Social and public health interventions
	Public communication and understanding
	Occupational safety and health

<u>Group D – Cross-Cutting Issues</u> (WG Leads: Tara O'Toole, Alta Charo)

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	International relations and cooperation
	Innovative solutions across the public and private sectors
	Lessons learned/future outbreaks

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Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

COMMITTEE MEMBER BIOSKETCHES

Harvey Fineberg, M.D., Ph.D. ***(Chair)***
President
Gordon and Betty Moore Foundation

Harvey Fineberg is president of the Gordon and Betty Moore Foundation. He previously served as president of the Institute of Medicine from 2002 to 2014 and as provost of Harvard University from 1997 to 2001, following 13 years as dean of the Harvard School of Public Health. Fineberg devoted most of his academic career to the fields of health policy and medical decision-making. His past research has focused on the process of policy development and implementation, assessment of medical technology, evaluation and use of vaccines, and dissemination of medical innovations. Fineberg serves on the boards of the Carnegie Endowment for International Peace and the China Medical Board. He helped found and served as president of the Society for Medical Decision Making, previously served on and chaired the board of the William and Flora Hewlett Foundation, and chaired the committee to review the performance of the World Health Organization and the functioning of the International Health Regulations (2005) during the 2009 H1N1 influenza pandemic. Fineberg is co-author of the books *Clinical Decision Analysis*, *Innovators in Physician Education* and *The Epidemic That Never Was*, an analysis of the controversial federal immunization program against swine flu in 1976. He has co-edited several books on such diverse topics as AIDS prevention, vaccine safety, understanding risk in society and global health. He has also authored numerous articles published in professional journals. Fineberg chaired the National Academies committee that produced the 2019 report on *Reproducibility and Replicability in Science*. He earned his bachelor's and doctoral degrees at Harvard and is the recipient of several honorary degrees.

Kristian Andersen, Ph.D.
Associate Professor and Director of Infectious Disease Genomics, Scripps Research Translational Institute
The Scripps Research Institute

Kristian Andersen is an associate professor in the Department of Immunology and Microbiology at Scripps Research, with joint appointments in the Department of Integrative Structural and Computational Biology, and at the Scripps Research Translational Institute. Over the past decade, his research has focused on the complex relationship between host and pathogen. Using a combination of next-generation sequencing, field work, experimentation, and computational biology he has spearheaded large international collaborations investigating the emergence, spread and evolution of deadly pathogens, including SARS-CoV-2, Zika virus, Ebola virus, West Nile virus, and Lassa virus. His work is highly cross-disciplinary and exceptionally collaborative. Kristian earned his doctoral degree from the University of Cambridge and performed postdoctoral work in Pardis Sabeti's group at Harvard University and the Broad Institute.

Ralph Baric, Ph.D.
William R. Kenan, Jr. Distinguished Professor
The University of North Carolina at Chapel Hill

Ralph Baric is a William R. Kenan, Jr. Distinguished Professor in the Department of Epidemiology at the University of North Carolina. He obtained a Bachelor of Science Degree in Zoology from North Carolina State University in 1977 and a PhD in Microbiology and Immunology from North Carolina State University in 1983. He conducted postgraduate research at the University of Southern California School of Medicine in the department of Microbiology and Immunology between 1983-1986. He is a Harvey Weaver Scholar from the National Multiple Sclerosis Society and an Established Investigator Awardee from the American Heart Association. In addition, he is a World Technology Award Finalist, a fellow of the American Association for Microbiology, a senior editor of PloS Patho gen, and a member of the editorial board of several other specialty journals. He was a member of the National Academy Sciences Working Groups that focused on Gene Sequence Methods for Classification of Select Agents and the Risks and Benefits of Gain of Function Research, an invited speaker to the Institute of Medicine Forum on Emerging Infectious Diseases and an invited panelist for the MERS-CoV Stakeholders Workshop. His group has published over 300 papers, many in highly visible journals like PNAS, Natur e Medicine, Science, PloS Medicine and PloS Pathogens. The Baric laboratory uses genetic, immunologic, molecular and biochemical approaches to study the molecular mechanisms regulating virus replication, pathogenesis, molecular evolution and cross species transmission using emerging coronaviruses, flaviviruses (Dengue) and noroviruses as model systems. We have pioneered new strategies for developing reverse genetic approaches for manipulating the SARS-CoV, SAR-CoV-2 and MERS-CoV genomes and are actively studying the role of multiple genes that function in cross species transmission, virulence, pathogenesis, viral transcription and RNA fidelity. The Baric laboratory is also identifying key neutralizing epitopes in emerging coronaviruses, dengue and noroviruse s using human monoclonal antibodies and structure guided immunogen design to develop broadly active vaccines and immunotherapuetics against these pathogens. Finally, his group has developed novel animal models of human disease and identified dozens of host susceptibility loci that regulate emerging CoV pathogenesis.

Mary Bassett, M.D., M.P.H.
Director of the François-Xavier Bagnoud Center for Health and Human Rights
Harvard School of Public Health

Mary Bassett is the Director of the FXB Center for Health and Human Rights at Harvard University, as well as the FXB Professor of the Practice of Health and Human Rights at the Harvard School of Public Health. With more than 30 years of experience in public health, Dr. Mary Travis Bassett has dedicated her career to advancing health equity. Prior to her directorship at the FXB Center, Dr. Bassett served for four years as commissioner of Health for New York City. As commissioner, she worked to ensure that every New York City neighborhood supported the health of its residents, with the goal of closing gaps in population health across the city. Originally from New York City, Dr. Bassett lived in Zimbabwe for nearly 20 years. Previously, she was the Program Director for the African Health Initiative and the Child Well-being Program at the Doris Duke Charitable Foundation. She received her B.A. in History and Science from Harvard University and her M.D. from Columbia University's College of Physicians and Surgeons. She served her medical residency at Harlem Hospital Cen ter, and has a master's degree in Public Health from the University of Washington, where she was a Robert Wood Johnson Clinical Scholar.

Trevor Bedford, Ph.D.
Associate Faculty Member, Vaccine and Infectious Disease Division, Public Health Sciences Division, and Human Biology Division
Fred Hutchinson Cancer Research Center

Trevor Bedford is currently Associate Member of the Vaccine and Infectious Disease Division, the Public Health Sciences Division, and the Human Biology Division at the Fred Hutchinson Cancer Research Center. Dr. Bedford uses powerful computers and complex statistical methods to study the rapid spread and evolution of viruses. Data gathered from these processes help researchers develop successful strategies for monitoring and controlling infectious diseases. His visual representations of viral family trees are used to show how the fate of dangerous outbreaks is often determined by the genetics of the infectious agent, human behavior and geography. Dr. Bedford has applied these techniques to document the worldwide spread of seasonal flu viruses. He is developing models to predict which strains of influenza are likely to be most challenging to humans — data that help inform the crucial early decisions about which strains to include in annual flu shots. He specializes in tracking the evolutionary changes of viruses such as HIV and influenza that use RNA, rather than DNA, to carry their genetic information. RNA viruses are much more prone to rapid mutation, which makes many of them particularly nimble at escaping the human immune system and difficult to stop with vaccines. He is a leading advocate for the immediate release of research analyzing viral evolution during epidemics, fresh information that could make a lifesaving difference. He received his Ph.D. in biology from Harvard University.

Georges Benjamin, M.D.
Executive Director
American Public Health Association

Georges Benjamin is well-known as a health leader, practitioner, and administrator. Dr. Benjamin has served as the executive director of the American Public Health Association, the nation's oldest and largest organization of public health professionals, since December 2002. He is a former secretary of Health for the state of Maryland. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University Of Illinois College Of Medicine. He is board-certified in internal medicine, a Master of the American College of Physicians, a fellow of the National Academy of Public Administration and a fellow emeritus of the American College of Emergency Physicians. He serves on several nonprofit boards such as Research!America, the University of Maryland Medical System and, the Reagan-Udall Foundation. He is a member of the National Academy of Medicine. In April 2016, President Obama appointed Benjamin to the National Infrastructure Advisory Council, a council that advises the president on how best to assure the security of the nation's critical infrastructure.

Donald Berwick, M.D., M.P.P., F.R.C.P., KBE
Lecturer of Health Care Policy
Harvard Medical School

Donald Berwick is president emeritus and senior fellow at the Institute for Healthcare Improvement and former administrator of the Centers for Medicare & Medicaid Services. A pediatrician by background, Dr. Berwick has served on the faculty of the Harvard Medical School and Harvard School of Public Health, and on the staffs of Boston's Children's Hospital Medical Center, Massachusetts General Hospital, and the Brigham and Women's Hospital. He has also served as vice chair of the US Preventive Services Task Force, the first "independent member" of the American Hospital Association Board of Trustees, and chair of the National Advisory Council of the Agency for Healthcare Research and Quality. He served two terms on the Institute of Medicine's (IOM's) Governing Council, was a member of the IOM's Global Health Board, and served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. Recognized as a leading authority on health care quality and improvement, Dr. Berwick has received numerous awards for his contributions. In 2005, he was

appointed "Honorary Knight Commander of the British Empire" by Her Majesty, Queen Elizabeth II in recognition of his work with the British National Health Service. Dr. Berwick is the author or co -author of over 160 scientific articles and six books. He currently serves as lecturer in the Department of Health Care Policy at Harvard Medical School.

Richard Besser, M.D.
President and CEO
Robert Wood Johnson Foundation

Richard Besser is president and CEO of the Robert Wood Johnson Foundation (RWJF), a position he assumed in April 2017. Dr. Besser is the former acting director for the Centers for Disease Control and Prevention (CDC), and ABC News' former chief health and medical editor. At RWJF, Dr. Bes ser leads the largest private foundation in the country devoted solely to improving the nation's health. RWJF's work is focused on building a comprehensive Culture of Health that provides everyone in America with a fair and just opportunity to live the hea lthiest life possible. In Dr. Besser's role at ABC News, he provided medical analysis and reports for all ABC News programs and platforms. His weekly health chats on social media reached millions. Before joining ABC News in 2009, Dr. Besser worked as direc tor of the Coordinating Office for Terrorism Preparedness and Emergency Response at the CDC. In that role, he was responsible for all the CDC's public health emergency preparedness and emergency response activities. He also served as acting director of the CDC from January to June 2009, during which time he led the CDC's response to the H1N1 influenza pandemic. He is a member of the National Academy of Medicine. He received the Surgeon General's Medallion for his leadership during the H1N1 response, and in 2011 he accepted the Dean's Medal for his contributions to public health from the Johns Hopkins Bloomberg School of Public Health. Dr. Besser received his Bachelor of Arts degree in economics from Williams College and medical degree from the University of Pennsylvania. He completed a residency and chief residency in pediatrics at Johns Hopkins University Hospital in Baltimore.

R. Alta Charo, J.D.
Warren P. Knowles Professor of Law and Bioethics
University of Wisconsin at Madison

R. Alta Charo is a member of the National Academy of Medicine and is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison (UW), where she is on the faculties of the law and medical schools. She teaches in the areas of bioethics, public health law and biotechnology policy and has served on UW's clinical ethics and research oversight committees. Professor Charo was a member of President Obama's transition team, focusing her attention particularly on transition issues related to NIH, FDA, stem cell policy, and women's reproductive health. From 2009 to 2011 she was on leave to serve as a senior policy advisor on emerging technology issues in the Office of the Commissioner at FDA. Her federal advisory committee service includes the 1994 NIH Human Embryo Research Panel and President Clinton's National Bioethics Advisory Commission (1996 to 2001). At the National Academies she co-chaired (with Richard Hynes) the committee on guidelines for embryonic stem cell research, and has been a member of its Board on Life Sciences, Board on Population Health and Public Health Practice, and Board on Health Sciences Policy.

Peter Daszak, Ph.D.
President and CEO
EcoHealth Alliance

Peter Daszak is President of EcoHealth Alliance, a US-based organization that conducts research and outreach programs on global health, conservation, and international development. Dr. Daszak's research has been instrumental in identifying and predicting the origins and impact of emerging diseases across the globe. He is one of the founders of the field of Conservation Medicine and has been instrumental in the

growth of EcoHealth, One Health, and now Planetary Health. Dr. Daszak is a member of the National Academy of Medicine and Chair of the NASEM's Forum on Microbial Threats. He is a me mber of the NRC Advisory Committee to the US Global Change Research Program, the Supervisory Board of the One Health Platform, the One Health Commission Council of Advisors, the CEEZAD External Advisory Board, the Cosmos Club, and the Advisory Council of the Bridge Collaborative. He has served on the IOM Committee on global surveillance for emerging zoonoses, the NRC committee on the future of veterinary research, the International Standing Advisory Board of the Australian Biosecurity CRC; and has advised the Director for Medical Preparedness Policy on the White House National Security Staff on global health issues. Dr. Daszak is a regular advisor to WHO on pathogen prioritization for R&D. He received his Ph.D. in parasitic infectious disease from the Univer sity of East London.

Jeffrey S. Duchin, M.D.
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section and Professor in Medicine
Public Health – Seattle & King County, WA and University of Washington, Seattle

Jeffrey Duchin is the Health Officer and the Chief of the Communicable Disease Epidemiology & Immunization Section for Public Health–Seattle & King County, Professor of Medicine in the Division of Infectious Diseases, and Adjunct Professor in the School of Public Health at the University of Washington, Seattle. Jeff currently serves on the Centers for Disease Control & Prevention's (CDC) Board of Scientific Counselors (Office of Infectious Diseases), the CDC's Advisory Committee on Immunization Practices and the Board of Directors for the Infectious Disease Society of America. Jeff has previously been a member of the National Academy of Medicine's (NAM) Forum on Microbial Threats and Forum on Medical and Public Health Preparedness, and the National Quality Forum's Adult Immunization Committee. Jeff received his medical degree from Rutgers Medical School and trained in internal medicine at Thomas Jefferson University Hospital, completed a fellowship in general internal medicine and emergency medicine at the Hospital of the Univ ersity of Pennsylvania, and did his infectious disease subspecialty training at the University of Washington in Seattle. Jeff is a graduate of the CDC's Epidemic Intelligence Service (EIS) Officer training where he was assigned to the National Center for Infectious Diseases where he also completed the CDC's Preventive Medicine Residency program. Jeff worked for CDC as a medical epidemiologist in the Divisions of Tuberculosis Elimination and HIV/AIDS Special Studies Branch before assuming his current positio n. His peer review publications and research interests focus on communicable diseases of public health significance. For a complete listing of publications, please see PubMED.

Ellen Embrey
Managing Partner
Stratitia, Inc.

Ellen Embrey is Managing Partner of Stratitia, Inc., a consulting firm focused on developing meaningful and innovative strategies, and delivering supporting tools and partnerships to bring them successfully to life. Ms. Embrey brings deep expertise in health and medic al issues, as well as a wealth of other experience gained during her extensive federal service. In her last federal role, she performed the duties of the Assistant Secretary of Defense for Health Affairs and the Director, TRICARE Management Activity during the presidential transition period in 2009-2010. From 2002 to 2009, Ms. Embrey was the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, leading significant changes in Department of Defense policies and programs affecting deployment and combat casualty medicine, health promotion and preventive medicine, medical readiness and public health emergency preparedness and response. For 9 months in 2001, Ms. Embrey performed the duties of Assistant Secretary of Defense for Reserve Affairs, shaping policies affecting the readiness and use of the National Guard and Reserve in both federal and state status. From 2000 to 2001, she served as Chief of Staff of that office, and from 1998 to 2001, as Deputy Assistant Secretary of Defense for Military Assistance to Civil Authorities,

developing policies that shaped the role of the National Guard and Reserve components in supporting homeland security, disaster preparedness, and national disaster response capabilities, including advising the president on such matters in the days and weeks following September 11, 2001. Between 1978 and 1997, Ms. Embrey served in senior-level policy analyst, budget analyst, program analyst, management analyst, and systems analyst positions in the Office of the Assistant Secretary of Defense for Reserve Affairs, the Defense Contract Audit Agency, and the Office of Personnel Management. Ms. Embrey was recognized with the Secretary of Defense's Distinguished Civilian Service Award in 2001 and 2004, and twice received the Meritorious Executive Presidential Rank Award in 2006 and 2009.

Baruch Fischhoff, Ph.D.
Howard Heinz University Professor, Department of Engineering and Public Policy
Carnegie Mellon University

Baruch Fischhoff is Howard Heinz University Professor, Department of Engineering and Public Policy and Institute for Politics and Strategy, Carnegie Mellon University (CMU). A graduate of the Detroit Public Schools, he holds a BS (mathematics, psychology) from Wayne State University and a PhD (psychology) from the Hebrew University of Jerusalem. He is a member of the National Academy of Sciences and of the National Academy of Medicine. He is past President of the Society for Judgment and Decision Making and of the Society for Risk Analysis. He has chaired the Food and Drug Administration Risk Communication Advisory Committee and been a member of the Eugene (Oregon) Commission on the Rights of Women, the Department of Homeland Security Science and Technology Advisory Committee and the Environmental Protection Agency Scientific Advisory Board, where he chaired the Homeland Security Advisory Committee. He has received the American Psychological Association (APA) Award for Distinguished Contribution to Psychology, CMU's Ryan Award for Teaching, an honorary Doctorate of Humanities from Lund University, and an Andrew Carnegie Fellowship. He is a Fellow of APA, the Association for Psychological Science, Society of Experimental Psychologists, and Society for Risk Analysis. His books include Acceptable Risk, Risk: A Very Short Introduction, Judgment and Decision Making, A Two-State Solution in the Middle East, Counting Civilian Casualties, and Communicating Risks and Benefits. He has co-chaired three National Academy Colloquia on the Science of Science Communication, as well as its committees on applying decision science to intelligence analysis and its committee on foundational science for cybersecurity.

Diane Griffin, M.D., Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health

Diane Griffin is University Distinguished Service Professor and Alfred and Jill Sommer Chair of the W. Harry Feinstone Department of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health. Dr. Griffin is a virologist recognized for her work on the pathogenesis of viral infections. She is known particularly for her studies on measles and alphavirus encephalomyelitis that have delineated the role of the immune response in virus clearance, vaccine-induced protection from infection, tissue damage and immune suppression. Dr. Griffin was born in Iowa City, Iowa, and grew up in Oklahoma City. She graduated from Augustana College, Rock Island, Illinois with a degree in biology and from Stanford University School of Medicine in 1968 with a Ph.D. in immunology and M.D., followed by a residency in internal medicine. She was a postdoctoral fellow in virology and infectious diseases at Johns Hopkins University School of Medicine and joined the faculty in 1974. She has been president of the American Society for Virology and of the American Society for Microbiology and is a member of both the National Academy of Sciences and the National Academy of Medicine.

Robert Groves
Executive Vice President and Provost
Gerard J. Campbell, S.J. Professor, Math and Statistics Department & Sociology Department
Georgetown University

Robert Groves is the Gerard J. Campbell, S.J. Professor in the Math and Statistics Department as well as the Sociology Department at Georgetown University where he has served as the Executive Vice President and Provost since 2012. Groves is a Social Statistician, who studies the Impact of Social Cognitive and Behavioral Influences on the quality of Statistical Information. His research has focused on the impact of mode of data collection on responses in sample surveys, the social and political influences on survey participation, the use of adaptive research designs to improve the cost and error properties of statistics, and public concerns about privacy affecting attitudes toward statistical agencies. He has authored or co-authored seven books and scores of peer-reviewed articles. His 1989 book, Survey Errors and Survey Costs, was named one of the 50 most influential books in survey research by the American Association of Public Opinion Research. His book, Nonresponse in Household Interview Surveys, with Mick Couper, received the 2008 AAPOR Book Award. His co-authored book, Survey Nonresponse, received the 2011 AAPOR Book Award. He served as the Director of the US Census Bureau between 2009-2012. Groves serves on several boards and advisory committees including the National Research Council Committee on National Statistics, Pew Research Center Board, the National Science Board, and the Federal Economic Statistics Advisory Committee. He is an elected member of the US National Academy of Sciences, of the National Academy of Medicine, of the American Academy of Arts and Sciences, and of the International Statistical Institute.

Margaret Hamburg, M.D.
Foreign Secretary
National Academy of Medicine

Margaret Hamburg is an internationally recognized leader in public health and medicine, and currently serves as foreign secretary of the National Academy of Medicine and chair of the NTI | bio Advisory Group. She is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served for almost six years. As FDA Commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining FDA, Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. She is President-elect of the American Association for the Advancement of Science (AAAS), as well as an elected member of the Council on Foreign Relations and the National Academy of Medicine. Hamburg currently sits on the boards of the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, the Parker Institute for Cancer Immunotherapy and the American Museum of Natural History. She is chair of the Joint Coordinating Group for the Coalition for Epidemic Preparedness and Innovation, and a member of the Harvard University Global Advisory Council, the Global Health Scientific Advisory Committee for the Gates Foundation, the Harvard Medical School Board of Fellows, and the World Dementia Council. Dr. Hamburg earned her B.A. from Harvard College, her M.D. from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center. She is the recipient of multiple honorary degrees and numerous awards.

Dan Hanfling, M.D.
Vice President, Technical Staff
In-Q-Tel

Dan Hanfling is Vice President on the Technical Staff at In-Q-Tel, a non-governmental not-for-profit strategic investor focused on enabling technologies to support national security requirements. He is a board-certified emergency physician practicing at Inova Fairfax Hospital, northern Virginia's Level I trauma center, where he led emergency preparedness response efforts in the aftermath of the 9-11 attacks and the anthrax mailings. He participates as a Medical Team Manager for Virginia Task Force One, a FEMA- and USAID-sanctioned international urban search and rescue team and has deployed to numerous catastrophic disaster events, both domestic and international. Dr. Hanfling currently serves as the co-chair of the National Academies Forum on Medical and Public Health Preparedness and co-chaired the Institute of Medicine committees responsible for developing the work on "crisis standards of care". Dr. Hanfling is Clinical Professor of Emergency Medicine at George Washington University. He received an AB in political science from Duke University and was awarded his medical degree from Brown University. He completed an internship in internal medicine at the Miriam Hospital in Providence, Rhode Island, and an emergency medicine residency at George Washington/Georgetown University Hospitals.

John Hick, M.D.
Associate Medical Director for EMS
Medical Director of Emergency Medicine
Hennepin County Medical Center

John Hick is a faculty emergency physician at Hennepin Healthcare and a Professor of Emergency Medicine at the University of Minnesota. Dr. Hick serves as the deputy medical director for Hennepin County Emergency Medical Services and Medical Director for Emergency Preparedness at HCMC. He is also the Vice-Chair of the Clinical Council for Life Link III helicopter service and me dical director for MN TF-1 state US&R team. He served the Minnesota Department of Health as the medical director for the Office of Emergency Preparedness until becoming an Advisor to the Director of OEM at ASPR/HHS where he is the lead editor for the TRACIE healthcare disaster preparedness website. He is the founder and past chair of the Minneapolis/St. Paul Metropolitan Hospital Compact, a 32-hospital mutual aid and planning group active since 2002. He is a national speaker on hospital preparedness issues and has published numerous papers dealing with hospital preparedness for contaminated casualties, personal protective equipment, crisis standards of care, and surge capacity and was honored to serve the Institute of Medicine on their Crisis Standards of Care projects as well as the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Dr. Hick holds an M.D. from the Mayo Medical School.

Kent E. Kester, M.D.
Vice President and Head, Translational Science and Biomarkers
Sanofi Pasteur

Kent Kester is currently Vice President and Head, Translational Science and Biomarkers at Sanofi Pasteur. In this capacity, Dr. Kester leads a team of over 200 research and clinical professionals in the US and France focused on the translational development of new vaccines. During a 24-year career in the US Army, he worked extensively in clinical vaccine development and led multiple research platforms at the Walter Reed Army Institute of Research, the U.S. Department of Defense's largest and most diverse biomedical research laboratory with a major emphasis on emerging infectious diseases, an institution he later led as its Commander/Director. His final military assignment was as the Associate Dean for Clinical Research in the School of Medicine at the Uniformed Services University of the Health Sciences (USUHS). During his military service, Dr. Kester was appointed as the lead policy advisor to the US Army Surgeon General in both Infectious Diseases and in Medical Research & Development. In these

capacities, he worked extensively in the interagency environment and developed a variety of Army and DoD medical policies related to infectious diseases, both clinical and research aspects. Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College, completing his internship and residency in internal medicine at the University of Maryland and a research fellowship in infectious diseases at the Walter Reed Army Medical Center. Currently a member of the US Government Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) and the Department of Veterans Affairs Health Services Research & Development Service Merit Review Board, he previously chaired the Steering Committee of the NIAID/USUHS Infectious Disease Clinical Research Program, and has served as a member of the FDA Vaccines & Related Biologics Products Advisory Committee (VRBPAC), the NIAID Advisory Council, and the CDC Office of Infectious Diseases Board of Scientific Counselors. He is the Vice Chair of the National Academy of Medicine Forum on Microbial Threats. Board-certified in both internal medicine and infectious diseases, Dr. Kester holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Royal College of Physicians of Edinburgh, the Infectious Disease Society of America, and the American Society of Tropical Medicine and Hygiene. He is a member of the clinical faculty at the University of Maryland Shock Trauma Center in Baltimore.

Patricia King, J.D.
Professor Emerita
Georgetown University Law Center

Patricia King is Professor of Law emeritus at Georgetown University Law Center and an Adjunct Professor in the Department of Health Policy and Management, School of Hygiene and Public Health at Johns Hopkins University. She is the co-author of Cases and Materials on Law, Science and Medicine. She is a member of the National Academy of Medicine, a member of the American Law Institute, a fellow of the Hastings Center and a faculty affiliate of Georgetown's Kennedy Institute of Ethics. Her scholarship focuses on race and genomics, racial disparities in health and reproductive health. Professor King has served on numerous national advisory bodies formed to address the ethical issues generated by developments in science and technology, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), which produced the seminal "Belmont Report," the President's Advisory Committee on Human Radiation Experiments (1994-95), the National Institutes of Health's Embryo Research Panel (co-chair for policy, 1994), the Ethics, Legal and Social Issues Working Group of the NIH's Human Genome Project (1989-95), and the NIH's Recombinant DNA Advisory Committee (1979-81). She has served on numerous boards and Institute of Medicine committees and is currently a member of the Board of Health Sciences Policy of the National Academies. She is also a Director of Mathematica an employee-owned company.She is a graduate of Wheaton College (Massachusetts) and has served as a Trustee and Chair of the Wheaton College Board of Trustees. In 2018 she was designated a Life Trustee by the Wheaton College Board. She graduated from Harvard Law School and is a past member of the Harvard Corporation the governing board of Harvard University. She has received honorary degrees from Wheaton College, Old Dominion University, and Harvard University.

Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
Executive Director, One Health Institute
UC Davis School of Veterinary Medicine

Jonna Mazet, D.V.M, M.P.V.M., Ph.D., is a Professor of Epidemiology and Disease Ecology at the UC Davis School of Veterinary Medicine and Executive Director of the UC Davis One Health Institute. Her work focuses on global health problem solving for emerging infectious diseases and conservation challenges. She is active in international One Health education, service, and research programs, most notably in relation to disease transmission among wildlife, domestic animals, and people and the ecological drivers of disease emergence. Currently, Dr. Mazet is the Co-Director of the US Agency for

International Development's One Health Workforce – Next Generation, an $85 million educational strengthening project to empower professionals in Central/East Africa and Southeast Asia to address complex health threats, including antimicrobial resistance and zoonotic diseases. She recently served as the Global Director of PREDICT Project, a greater than $200 million viral emergence early warning project under USAID's Emerging Pandemic Threats Division. She was elected to the US National Academy of Medicine in 2013 in recognition of her successful and innovative approach to emerging environmental and global health threats and serves on the National Academies of Science, Engineering, and Medicine's Forum on Microbial Threats and chairs the Academies' One Health Action Collaborative.

Phyllis Meadows, Ph.D., M.S.N., R.N.
Senior Fellow, Health
The Kresge Foundation

Phyllis Meadows currently serves as the Senior Fellow and Program Advisor for the Kresge Foundation Health Team. In this role, she is responsible for supporting the health team in the development and implementation of investment opportunities within and across the Foundation's various programming areas. Her professional career includes leadership roles in philanthropy, academia, community health and governmental public health. She has previously served in the role of Associate Dean for Public Health Practice and Clinical Professor - Health, Management and Policy with the University of Michigan School of Public Health. She has led several initiatives to expand multi-disciplinary practice in communities, designing the University's first certification program on population health and health equity for medical residents. She is currently a Distinguished Towsley Policy Maker in Residence with the University of Michigan's Gerald Ford School of Public Policy. She has taught and developed graduate level and professional continuing education courses to address emerging health issues, including topics on health policy and public health leadership. Dr. Meadows has extensive experience in public health practice having served in various leadership roles in public health. She has held several official appointments in public health leadership at the state, county and local levels. In her most recent appointment, she served as the Chief Health Officer and Director of Health for the City of Detroit, providing leadership for the department of health, environmental health, infectious disea ses, child health, clinical and dental services for the residents of Detroit. Her philanthropic experience includes positions as Program Director for the W.K. Kellogg Foundation - Youth, Education and Higher Education; and advisor for several national initiatives of the Robert Wood Johnson Foundation including the Nurse Executive Leadership Program, Partners in Nursing, and the County Roadmaps project. As a registered nurse, she has worked in both community-based health and hospitals. She currently serves as a Board Member and Advisor for several state level organizations and private foundations focusing on health.

Tara O'Toole, M.D., M.P.H.
Executive Vice President
In-Q-Tel

Tara O'Toole currently serves as Executive Vice President at In-Q-Tel. Dr. O'Toole was confirmed as the Under Secretary for Science and Technology (S&T) at the U.S. Department of Homeland Security (DHS) and served from November 4, 2009 to September 23, 2013. From 2003 to November 2009, Dr. O'Toole was the CEO and Director of the Center for Biosecurity at the University of Pittsburgh Medical Center (UPMC), and Professor of Medicine and of Public Health at the University of Pittsburgh. The Center for Biosecurity of UPMC is an independent organization dedicated to improving the country's resilience to major biological threats. Dr. O'Toole is internationally known for her work on biosecurity and on health and safety issues related to the U.S. nuclear weapons complex. Her publications in the biodefense field include articles on the response to anthrax, smallpox, and plague biological attacks; containment of contagious disease epidemics; biodefense research and development strategies; and hospital preparedness. She is the founding editor of the journal Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. She was a principal author and producer of Dark Winter, an influential exercise conducted in

June 2001 to alert national leaders to the dangers of bioterrorist attacks. She was also a principal writer and producer of Atlantic Storm, an international ministerial-level biosecurity exercise held in January 2005. Prior to founding the UPMC in 2003, Dr. O'Toole was one of the original members of the J ohns Hopkins Center for Civilian Biodefense Strategies and served as its director from 2001 to 2003. She has served on numerous government and expert advisory committees dealing with biodefense, including panels of the Defense Science Board; the National Academy of Engineering Committee on Combating Terrorism; and the National Academy of Sciences Working Group on Biological Weapons. She served as chair of the Board of the Federation of American Scientists from 2006 to 2007, and in 2006 she was appointed to the board of Google Foundation's International Networked System for Total Early Disease Detection. From 1993 to 1997, Dr. O'Toole served as Assistant Secretary of Energy for Environment Safety and Health. In this position, she was the principal advisor to the Secretary of Energy on environmental protection and on the health and safety of the approximately 100,000 workers in the U.S. nuclear weapons complex and Department of Energy (DOE) laboratories. She developed the first overall management and safety plan for dealing with the highly enriched uranium, plutonium, spent fuel, and radioactive waste left in place when nuclear weapons production was stopped in the early 1990s. She ran the multi-agency, multimillion-dollar task force that oversaw the government's investigations into human radiation experiments conducted during the Cold War and led the U.S. delegation to Russia to establish the U.S./Russia cooperative effort to study radiation exposure and environmental hazards of the Russian nuclear weapons complex. Prior to her work at DOE, Dr. O'Toole was a senior analyst at the Congressional Office of Technology Assessment, where she directed several projects and studies, including the health impact of pollution resulting from nuclear weapons production. She al so served as a consultant to industry and government in matters related to occupational and environmental health; worker participation in workplace safety protection; and organizational change. Dr. O'Toole practiced general internal medicine in community health centers in Baltimore from 1984 to 1988. She is board certified in internal medicine and occupational and environmental health. She has a bachelor's degree from Vassar College, an M.D. from the George Washington University, and a Master of Public Heal th degree from Johns Hopkins University. She completed internal medicine residency training at Yale University and a fellowship in Occupational and Environmental Medicine at Johns Hopkins University.

Alexandra Phelan, S.J.D., LL.M., LL.B.
Assistant Professor
Center for Global Health Science and Security
Georgetown University

Alexandra Phelan is an Assistant Professor at the Center for Global Health Science and Security in the Department of Microbiology and Immunology at Georgetown University School of Medicine. Dr. Phelan also holds an appointment as Adjunct Professor of Law at Georgetown University Law Center. Dr. Phelan works on legal and policy issues related to infectious diseases, with a particular focus on emerging and reemerging infectious disease outbreaks and international law. She has worked as a consultant for the World Health Organization, the World Bank, and Gavi: the vaccine alliance, and has advised on matters including international law and pathogen sharing, human rights law and Zika, int ellectual property law, and contract law. She previously worked for a number of years as a solicitor at a firm in Melbourne, Australia and was admitted to practice to the Supreme Court of Victoria and High Court of Australia in 2010. Dr. Phelan's doctorate examined how overlap between fields of international law – in particular, global health law, international human rights law, and international environmental law – can serve as the catalyst to progressively develop international law to prevent and respond to infectious diseases. She also holds a Master of Laws, specializing in international law, from the Australian National University and a Bachelor of Biomedical Science/Bachelor of Laws (Honours) double degree from Monash University. She also holds a Diploma of Languages (Mandarin Chinese). Dr. Phelan is a General Sir John Monash Scholar and was recognized as an Associate Fellow of the Royal Commonwealth Society in 2015 for her human rights advocacy during the 2013-16 Ebola outbreak.

David Relman, M.D.
Thomas C. and Joan M. Merigan Professor in Medicine, and Chief of Infectious Diseases
Stanford University; VA Palo Alto Health Care System

David Relman is the Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology and Immunology at Stanford University, and Chief of Infectious Diseases at the Veterans Affairs Palo Alto Health Care System. Dr. Relman is also Senior Fellow at the Freeman Spogli Institute for International Studies (FSI), and served as Science Co-Director at the Center for International Security and Cooperation (2013-2017), at Stanford. He is currently director of a new Biosecurity Initiative at FSI. Relman trained at MIT and then Harvard Medical School, followed by clinical training in internal medicine and infectious diseases at the Massachusetts General Hospital in Boston, and then a postdoctoral fellowship in microbiology at Stanford. His early research focused on molecular methods for pathogen discovery and over the past 20 years, on the human microbiome. He was elected to the National Academy of Medicine in 2011. Dr. Relman served as vice-chair of the National Research Council Committee that reviewed the science performed for the FBI 2001 Anthrax Letters investigation, chair of the Forum on Microbial Threats (2007-2017), and is currently a member of the Intelligence Community Studies Board (2016-) as well as Chair of a Standing Committee tasked with examining the health-related problems of US embassy personnel stationed overseas, all at the U.S. National Academies of Science. He was a founding member of the National Science Advisory Board on Biosecurity (2005-2014), a member of the Working Group on Biodefense for the President's Council of Advisors on Science and Technology (The White House) (2016), and served as President of the Infectious Diseases Society of America (2012-2013). He holds an M.D. from Harvard Medical School.

Mark Smolinski, M.D., M.P.H.
President
Ending Pandemics

Mark Smolinski currently serves as President of Ending Pandemics. Dr. Smolinksi brings 25 years of experience in applying innovative solutions to improve disease prevention, response, and control across the globe. Mark is leading a well-knit team—bringing together technologists; human, animal, and environmental health experts; and key community stakeholders to co-create tools for early detection, advanced warning, and prevention of pandemic threats. Since 2009, Mark has served as the Chief Medical Officer and Director of Global Health at the Skoll Global Threats Fund (SGTF), where he developed the Ending Pandemics in Our Lifetime Initiative in 2012. His work at SGTF created a solid foundation for the work of Ending Pandemics, which branched out as an independent entity on January 1, 2018. Prior to SGTF, Mark developed the Predict and Prevent Initiative at Google.org, as part of the starting team at Google's philanthropic arm. Working with a team of engineers, Google Flu Trends (a project that had tremendous impact on the use of big data for disease surveillance) was created in partnership with the U.S. Centers for Disease Control. Mark has served as Vice President for Biological Programs at the Nuclear Threat Initiative, a public charity directed by CNN founder Ted Turner and former U.S. Senator Sam Nunn. Before NTI, he led an 18-member expert committee of the National Academy of Medicine on the 2003 landmark report "Microbial Threats to Health: Emergence, Detection, and Response." Mark served as the sixth Luther Terry Fellow in Washington, D.C., in the Office of the U.S. Surgeon General and as an Epidemic Intelligence Officer with the U.S. Centers for Disease Control and Prevention. Mark received his B.S. in Biology and M.D. from the University of Michigan in Ann Arbor. He is board-certified in preventive medicine and public health and holds an M.P.H. from the University of Arizona.

David Walt, Ph.D.
Hansjörg Wyss Professor of Biologically Inspired Engineering
Harvard Medical School

David R. Walt is the Hansjörg Wyss Professor of Bioinspired Engineering at Harvard Medical School and Professor of Pathology at Harvard Medical School and Brigham and Women's Hospital, is a Core Faculty Member of the Wyss Institute at Harvard University and is a Howard Hughes Medical Institute Professor. Previously, he was University Professor at Tufts University. His laboratory pioneered the development of microwell arrays, which revolutionized the field of genetic analysis. Dr. Walt's laboratory also introduced the idea of digital protein detection by developing a high throughput technology for performing single molecule analysis. Dr. Walt's research is aimed at applying new technologies to address unmet clinical diagnostics needs. Dr. Walt is the Scientific Founder of Illumina Inc., Quanterix Corp., and has co-founded several other life sciences startups including Ultivue, Inc., Arbor Biotechnologies, Sherlock Biosciences, and Vizgen, Inc. He has received numerous national and international awards and honors for his fundamental and applied work in the field of optical microwell arrays and single molecules. He is a member of the National Academy of Engineering, the National Academy of Medicine, a Fellow of the American Academy of Arts and Sciences, a Fellow of the American Institute for Medical and Biological Engineering, a Fellow of the National Academy of Inventors, and is inducted in the US National Inventors Hall of Fame.

From: William Dowling[william.dowling@cepi.net]

Attendees: Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

Location: Skype Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 4/22/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/22/2020 10:00:00 AM (UTC-04:00)

Required Attendees: Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

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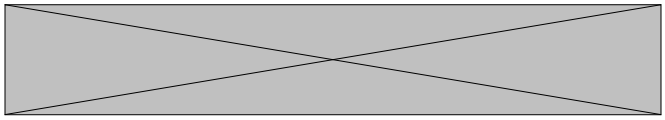

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Location: Microsoft Teams Meeting

Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 4/22/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/22/2020 10:00:00 AM (UTC-04:00)

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Organizer: William Dowling[william.dowling@cepi.net]

Attendees: GSELL, Pierre; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn; Graham, Barney (NIH/VRC) [E]; Trefry, John C CIV (USA)

Start Time: Wed 4/22/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/22/2020 10:00:00 AM (UTC-04:00)

Required Attendees: GSELL, Pierre; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul

Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

Organizer: William Dowling[william.dowling@cepi.net]

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Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 4/29/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/29/2020 10:00:00 AM (UTC-04:00)

Required Attendees: M.P.G. Koopmans; Carolyn Clark; Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

Optional Attendees: KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)

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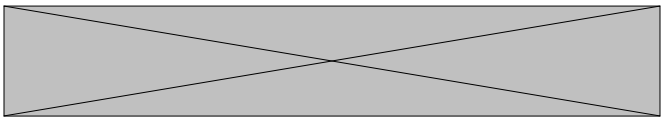

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Organizer: William Dowling[william.dowling@cepi.net]

Attendees: Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD); KNEZEVIC, Ivana

Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 5/6/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 5/6/2020 10:00:00 AM (UTC-04:00)

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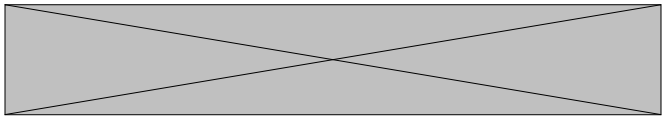

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Organizer: William Dowling[william.dowling@cepi.net]

Attendees: Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Drosten, Christian; Karl.Erlandson@hhs.gov; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Cassandra.Kelly@finddx.org; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn; David Vaughn; Falzarano, Darryl; Holbrook, Michael (NIH/NIAID) [C]; mit666666@pitt.edu; Erica Ollmann Saphire; Jacqueline Kirchner; Johnson, Reed (NIH/NIAID) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD); KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]

Location: Microsoft Teams Meeting

Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 5/20/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 5/20/2020 10:00:00 AM (UTC-04:00)

Required Attendees: Baric, Toni CDavid Vaughn; Falzarano, Darryl; Holbrook, Michael (NIH/NIAID) [C]; mit666666@pitt.edu; Erica Ollmann Saphire; Jacqueline Kirchner; Johnson, Reed (NIH/NIAID) [E]; Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Drosten, Christian; Karl.Erlandson@hhs.gov; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Cassandra.Kelly@finddx.org; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer;

tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

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Organizer: William Dowling[william.dowling@cepi.net]

Attendees: Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Drosten, Christian; Karl.Erlandson@hhs.gov; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Cassandra.Kelly@finddx.org; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; SATHIYAMOORTHY, Vaseeharan; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); linfa.wang@duke-nus.edu.sg; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn; wilsonp@uchicago.edu; David Vaughn; Falzarano, Darryl; Holbrook, Michael (NIH/NIAID) [C]; mit666666@pitt.edu; schendel@lji.org; Erica Ollmann Saphire; Jacqueline Kirchner; Johnson, Reed (NIH/NIAID) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD); KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]

Start Time: Wed 5/13/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 5/13/2020 10:00:00 AM (UTC-04:00)

Required Attendees: wilsonp@uchicago.edu; David Vaughn; Falzarano, Darryl; Holbrook, Michael (NIH/NIAID) [C]; mit666666@pitt.edu; schendel@lji.org; Erica Ollmann Saphire; Jacqueline Kirchner; Johnson, Reed (NIH/NIAID) [E]; Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Drosten, Christian; Karl.Erlandson@hhs.gov; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Cassandra.Kelly@finddx.org; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; SATHIYAMOORTHY, Vaseeharan; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); linfa.wang@duke-nus.edu.sg; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

Optional Attendees: KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)

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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski

Location: https://fnih.zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Importance: Normal

Subject: ACTIV Preclinical working group (Friday meeting)

Start Time: Thur 4/30/2020 11:00:00 AM (UTC-04:00)

End Time: Thur 4/30/2020 12:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski

Request to move due to holiday

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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To: Jonna Mazet[jkmazet@ucdavis.edu]; 'David A Relman'[relman@stanford.edu]; 'andersen@scripps.edu'[andersen@scripps.edu]; 'trevor@bedford.io'[trevor@bedford.io]; 'dgriffi6@jhu.edu'[dgriffi6@jhu.edu]; 'daszak@ecohealthalliance.org'[daszak@ecohealthalliance.org]; Baric, Ralph S[rbaric@email.unc.edu]
Cc: Shore, Carolyn[CShore@nas.edu]; 'andre@ecohealthalliance.org'[andre@ecohealthalliance.org]; 'Mary Radford'[maradford@ucdavis.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Brown, Lisa[LBrown@nas.edu]; Pope, Andrew[APope@nas.edu]
From: Downey, Autumn[ADowney@nas.edu]
Sent: Tue 4/21/2020 5:29:41 PM (UTC-04:00)
Subject: Next Steps - Viral Characteristics Working Group for the Standing Committee on Emerging Infectious Diseases
SCEID Working Group Topics and Questions w Leads_v5.docx

Dear Members of the Viral Characteristics Working Group,

We are writing to initiate next steps with your respective working group (WG). David Relman and Jonna Mazet have graciously volunteered to be the co-leads of your WG.

In preparation for the second virtual committee meeting (scheduled for Thursday, April 30th from 11:00 a.m. – 1:30 p.m. ET), Harvey is asking each WG to identify the most important intermediate range topic (to be addressed in weeks to months) within your WG domain (see attached list of topics). The WG is more than welcome to identify more than one priority; and, in the event the WG identifies more than one priority, the WG should designate the one priority at the top of the list. The goal will be to briefly present and discuss these priorities during the second committee meeting.

When describing topics for priority consideration, we are asking each WG to specify the following:

1) Question, topic or task, with clear objectives and rationale
2) Suitable type of product (telephonic consultation, rapid expert consultation, letter report, or consensus report)
3) Primary audience for the assessment
4) Anticipated time-frame for completion
5) Volunteers from the standing committee and working groups, and suggestions for additional experts to serve on the response team

We are asking David and Jonna as the co-leads of this WG to take the lead and initiate discussions within this email chain. In the meantime, we would also like to convene at least one meeting of the WG before the second virtual committee meeting. Please let us know by COB tomorrow if possible (via email response) if you can be available for a 1-hour call during any of the following dates/times:

- 4/23: 5-6pm ET/2-3pm PT
- 4/27: 12-1pm ET/9-10am PT
- 4/27: 1-2pm ET/10-11am PT
- 4/28: 1-2pm ET/10-11am PT
- 4/28: 4-5pm ET/1-2pm PT
- 4/28: 5-6pm ET/2-3pm PT

Very best,
Autumn and Carolyn

Autumn Downey, Ph.D.
Senior Program Officer
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The National Academies of Sciences, Engineering, and Medicine
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Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Topics for Consideration

**Note: Underlined names indicate that formal committee appointment is pending.

Group A – Viral Characteristics (SC Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
Mechanisms for pathogenesis
One Health

Viral characterization (virus genetics, origin, and evolution of SARS-CoV-2)

Examples of short-term research needs

- Biological/molecular characteristics of SARS-CoV-2
- Real-time tracking of whole genomes and a mechanism for coordinating the rapid dissemination of that information to inform the development of diagnostics and therapeutics and to track variations of the virus over time.
- Access to geographic and temporal diverse sample sets to understand geographic distribution and genomic differences, and determine whether there is more than one strain in circulation. Multi-lateral agreements such as the Nagoya Protocol could be leveraged.

Transmission, incubation, and environmental stability

Examples of short-term research needs

- Physical science of the coronavirus (e.g., charge distribution, adhesion to hydrophilic/phobic surfaces, environmental survival to inform decontamination efforts for affected areas and provide information about viral shedding).
- Persistence and stability on a multitude of substrates and sources (e.g., nasal discharge, sputum, urine, fecal matter, blood).
- Persistence of virus on surfaces of different materials (e,g., copper, stainless steel, plastic).
- Effective decontamination protocols

- Range of incubation periods for the disease in humans (and how this varies across age and health status) and how long individuals are contagious, even after recovery.
- Prevalence of asymptomatic shedding and transmission (e.g., particularly children).
- Seasonality of transmission.
- Correlates of immunity- and whether immunity occurs and duration.
- Resistance of previously infected people to mutated strains.

One Health

Examples of long-term research needs

- Enhance capacity (people, technology, data) for sequencing with advanced analytics for unknown pathogens, and explore capabilities for distinguishing naturally-occurring pathogens from intentional.
- One Health surveillance of humans and potential sources of future spillover or ongoing exposure for this organism and future pathogens, including both evolutionary hosts (e.g., bats) and transmission hosts (e.g., heavily trafficked and farmed wildlife and domestic food and companion species), inclusive of environmental, demographic, and occupational risk factors.
- Evidence that livestock could be infected (e.g., field surveillance, genetic sequencing, receptor binding) and serve as a reservoir after the epidemic appears to be over.
  - Evidence of whether farmers are infected, and whether farmers could have played a role in the origin.
  - Surveillance of mixed wildlife- livestock farms for SARS-CoV-2 and other coronaviruses in Southeast Asia.
  - Experimental infections to test host range for this pathogen.

Group B – Patient Care and Medical Countermeasures (MCM) (SC Leads: Don Berwick, Margaret Hamburg)

Staff Leads: Lisa Brown and Scott Wollek

Members: Kristian Andersen
Diane Griffin
John Hick
Kent Kester
Tara O'Toole
David Relman
David Walt
Dan Hanfling

Topics: Vaccines and therapeutics
Diagnostics
Patient care (including personal protective equipment, crisis standards of care, and quality)

Vaccines and therapeutics

- How to expedite development, manufacturing, distribution of a safe, effective vaccine.
- Need for an end-to-end process for getting promising products to the people who need them (e.g. small biotechs may not have developed a vaccine before and may lack scale-up manufacturing and/or support for larger studies)
- Research and development and evaluation efforts
  Examples of short-term research needs
    - Evaluate/investigate effectiveness of drugs and antivirals being developed and tried to treat COVID-19 patients.
        - E.g., Would it be beneficial to give IL6 receptor antibodies therapy prior to admission to the ICU; use of monoclonal antibodies.
    - Clinical and bench trials to investigate less common viral inhibitors against COVID-19 such as naproxen, clarithromycin, and minocycline that may exert effects on viral replication.
    - Methods to evaluate potential complication of Antibody-Dependent Enhancement (ADE) in vaccine recipients.
    - From a clinical development perspective, explore use of best animal models and their predictive value for a human vaccine.
    - Capabilities to discover a therapeutic (not vaccine) for the disease, and clinical effectiveness studies to discover therapeutics, to include antiviral agents.
    - Alternative models to aid decision makers in determining how to prioritize and distribute scarce, newly proven therapeutics as production ramps up. This could include identifying approaches for expanding production capacity to ensure equitable and timely distribution to populations in need.

  Example of long-term research needs
    - Efforts targeted at a universal coronavirus vaccine.

Diagnostics

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes)
  Examples of short-term research needs
    - Evaluate how widespread current exposure is to be able to make immediate policy recommendations on mitigation measures. Denominators for testing and a mechanism for rapidly sharing that information, including demographics, to the extent possible. Sampling methods to determine asymptomatic disease (e.g., use of serosurveys (such as convalescent samples) and early detection of disease (e.g., use of screening of neutralizing antibodies such as ELISAs),
    - Efforts to increase capacity on existing diagnostic platforms and tap into existing surveillance platforms.

- Development of a rapid, point-of-care test (like a rapid influenza test; home tests;) and rapid bed-side tests, recognizing the tradeoffs between speed, accessibility, and accuracy.
- Best tests to look at IgM and IgG antibodies and how best to scale up and create a rapid test.
- Rapid design and execution of targeted surveillance experiments calling for all potential testers using PCR in a defined area to start testing and report to a specific entity. These experiments could aid in collecting longitudinal samples, which are critical to understanding the impact of ad hoc local interventions (which also need to be recorded).
- Separation of assay development issues from instruments, and the role of the private sector to help quickly migrate assays onto those devices.
- Establish efforts to track the evolution of the virus (i.e., genetic drift or mutations) and avoid locking into specific reagents and surveillance/detection schemes.
- Latency issues and when there is sufficient viral load to detect the pathogen, and understanding of what is needed in terms of biological and environmental sampling.
- Use of diagnostics such as host response markers (e.g., cytokines) to detect early disease or predict severe disease progression, which would be important to understanding best clinical practice and efficacy of therapeutic interventions.
- Policies and protocols for screening and testing.
- Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.

Examples of long-term research needs

- Technology roadmap for diagnostics.
- Barriers to developing and scaling up new diagnostic tests (e.g., market forces), how future coalition and accelerator models (e.g., Coalition for Epidemic Preparedness Innovations) could provide critical funding for diagnostics, and opportunities for a streamlined regulatory environment.
- New platforms and technology (e.g., CRISPR) to improve response times and employ more holistic approaches to COVID-19 and future diseases.
- Coupling genomics and diagnostic testing on a large scale.
- Enhance capabilities for rapid sequencing and bioinformatics to target regions of the genome that will indicate specificity for a particular variant.

Patient care

- Risk factors

  Examples of short-term research needs

  - Data on potential risks factors
    - Smoking, pre-existing pulmonary disease
    - Co-infections (determine whether co-existing respiratory/viral infections make the virus more transmissible or virulent) and other co-morbidities

    - Differences in respiratory/viral infections for neonates and pregnant women
    - Socio-economic and behavioral factors to understand the economic impact of the virus and whether there were differences.
    - Pediatrics – Innate immune system of children vs adaptive immune system response of adults (e.g., cross reactivity between some routine childhood vaccinations that is providing protection to the youngest in the population).
- Surge capacity and nursing homes
  Examples of short-term research needs
    - Resources to support skilled nursing facilities and long term care facilities.
    - Mobilization of surge medical staff to address shortages in overwhelmed communities.
- Efforts to inform allocation of scarce resources
  Examples of short-term research needs
    - Age-adjusted mortality data for Acute Respiratory Distress Syndrome (ARDS) with/without other organ failure – particularly for viral etiologies
    - Extracorporeal membrane oxygenation (ECMO) outcomes data of COVID-19 patients; and,
    - Outcomes data for COVID-19 after mechanical ventilation adjusted for age.
    - Knowledge of the frequency, manifestations, and course of extra-pulmonary manifestations of COVID-19, including, but not limited to, possible cardiomyopathy and cardiac arrest.
    - Application of regulatory standards (e.g., EUA, CLIA) and ability to adapt care to crisis standards of care level.
- Personal protective equipment
  Example of short-term research needs
    - Approaches for encouraging and facilitating the production of elastomeric respirators, which can save thousands of N95 masks.
    - Efficacy of cloth face coverings.
- Alternative methods to advise on disease management
  Examples of short-term research needs
    - Best telemedicine practices, barriers and facilitators, and specific actions to remove/expand them within and across state boundaries.
    - Guidance on the simple things people can do at home to take care of sick people and manage disease.
    - OTC oral medications that might potentially work.

  Example of long-term research needs
    - Use of AI in real-time health care delivery to evaluate interventions, risk factors, and outcomes in a way that could not be done manually.
- Processes of care
  Example of short-term research needs

- Best practices and critical challenges and innovative solutions and technologies in hospital flow and organization, workforce protection, workforce allocation, community-based support resources, payment, and supply chain management to enhance capacity, efficiency, and outcomes.

Group C – Community Engagement and Population Health (SC Leads: Mary Travis Bassett, Robert Groves)

Staff Leads: Julie Pavlin and Monica Feit (DBASSE)

Members: Georges Benjamin
Rich Besser
Peter Daszak
Phyllis Meadows
Alexandra Phelan
Mark Smolinski
Jeff Duchin
Baruch Fischhoff
(SBS WG, membership TBD)

Topics: Epidemiology and population surveillance
Social and public health interventions
Public communication and understanding
Occupational safety and health

Epidemiology and population surveillance

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes and for understanding/guidance to be implemented).
  Examples of short-term research needs
  - Plans for sero-surveys of previously exposed/immune individuals. Evaluation of background level of people with Covid19 antibodies in the community.
  - Policies and protocols for screening and testing (e.g. screening/testing schedule for post-exposure).
  - Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.
  - Recruitment, support, and coordination of local expertise and capacity (public, private—commercial, and non-profit, including academic), including legal, ethical, communications, and operational issues.
  - National guidance and guidelines about best practices to states (e.g., how states might leverage universities and private laboratories for testing purposes, communications to public health officials and the public).
  - Validation and sharing (and effectively using) modeling outputs.

Social and public health interventions

Example of short-term research needs

- Effectiveness of non-therapeutic public health measures (e.g. patient contact tracing, social distancing strategies, school closings, telework). Rapid design and execution of experiments to examine and compare NPIs currently being implemented.
    - Risk/benefit of various social distancing measures
        - Optimal timing of social distancing (what are the triggers to start, when is it too late)
        - Importance of herd immunity
        - Avoiding the second wave
- Guidance on ways to scale up NPIs in a more coordinated way to give us time to enhance our health care delivery system capacity to respond to an increase in cases.
- Methods to control the spread in communities, barriers to compliance, and how these vary among different populations.

Examples of long-term research needs

- Models of potential interventions to predict costs and benefits that take account of such factors as race, income, disability, age, geographic location, immigration status, housing status, employment status, and health insurance status.
- Policy changes necessary to enable the compliance of individuals with limited resources and the underserved with NPIs. Research on why people fail to comply with public health advice, even if they want to do so (e.g., social or financial costs may be too high).
- Research on the economic impact of this or any pandemic. This would include identifying policy and programmatic alternatives that lessen/mitigate risks to critical government services, food distribution and supplies, access to critical household supplies, and access to health diagnoses, treatment, and needed care, regardless of ability to pay.

Public communication and understanding

- Messaging to the public, health professionals, civic leaders, etc.
- Communicating with high-risk populations

Examples of short-term research needs

- Modes of communicating with target high-risk populations (elderly, health care workers, first responders).
- Risk communication and guidelines that are easy to understand and follow (include targeting at risk populations' families too).
- Communication that indicates potential risk of disease to all population groups.
- Clarify community measures
- Clarify misunderstanding around containment and mitigation

Group D – Cross-Cutting Issues (SC Leads: Tara O'Toole, Alta Charo)

Staff Leads: Andy Pope and Lisa Brown

Members: Rich Besser
Ellen Embry
Patricia King
Jonna Mazet
Phyllis Meadows
Alexandra Phelan
Don Berwick

Topics: Ethics, equity, and law
International relations and cooperation
Innovative solutions across the public and private sectors
Lessons learned/future outbreaks

Ethics, equity, and law

- Consideration of the health needs and wellbeing of underserved/disinfranchised populations

  Examples of short-term research needs
  - Action plan to mitigate gaps and problems of inequity in the Nation's public health capability, capacity, and funding to ensure all citizens in need are supported and can access information, surveillance, and treatment.
  - Measures to reach marginalized and disadvantaged populations.
  - Data systems and research priorities and agendas incorporate attention to the needs and circumstances of disadvantaged populations and underrepresented minorities.
  - Understand and mitigate threats to incarcerated people from COVID-19, assuring access to information, prevention, diagnosis, and treatment.
  - Understand coverage policies (barriers and opportunities) related to testing, treatment, and care

International relations and cooperation

- The role of international regulatory organizations, WHO, etc
- Reliance and mutual recognition agreements (see NASEM study: Mutual Recognition Agreements in the Regulation of Medicines https://www.nationalacademies.org/our-work/mutual-recognition-agreements-in-the-regulation-of-medicines)
- Data standards and nomenclature:
  - Methods for coordinating data-gathering with standardized nomenclature.
  - Consistent platform for sharing response information among planners, providers, and others.
  - Understand and mitigate barriers to information-sharing.

Innovative solutions across public and private sectors

- Governmental public health

  Example of short-term research needs

  - Determine how to recruit, support, and coordinate local (non-Federal) expertise and capacity relevant to public health emergency response (public, private—commercial and non-profit, including academic).

  Examples of long-term research needs

  - Better integration of federal/state/local public health surveillance systems.
  - Value of investments in baseline public health response infrastructure, preparedness capacity, and capability.

Lessons learned/Future outbreaks

- Research needs to improve our understanding of the viral diversity and risk factors for viruses that are not yet known to medicine, but exist and are available to infect humans and present epidemic and pandemic threats.
- Research needs and evaluation metrics to inform the immediate response and future outbreak response.

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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Wed 4/22/2020 7:52:41 AM (UTC-04:00)
Subject: FW: Drug repurposing screen paper
A Large-scale Drug Repositioning Survey for SARS-CoV-2 Antivirals.pdf

Fyi, may be of interest for discussion.

From: Young, John <john.young.jy3@roche.com>
Sent: Wednesday, April 22, 2020 2:24 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>
Subject: Drug repurposing screen paper

Dear Joe

Please share this paper with the members of the working group.

Thanks

John

--
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A Large-scale Drug Repositioning Survey for SARS-CoV-2 Antivirals

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Abstract

The emergence of novel SARS coronavirus 2 (SARS-CoV-2) in 2019 has triggered an ongoing global pandemic of severe pneumonia-like disease designated as coronavirus disease 2019 (COVID-19). To date, more than 2.1 million confirmed cases and 139,500 deaths have been reported worldwide, and there are currently no medical countermeasures available to prevent or treat the disease. As the development of a vaccine could require at least 12-18 months, and the typical timeline from hit finding to drug registration of an antiviral is >10 years, repositioning of known drugs can significantly accelerate the development and deployment of therapies for COVID-19. To identify therapeutics that can be repurposed as SARS-CoV-2 antivirals, we profiled a library of known drugs encompassing approximately 12,000 clinical-stage or FDA-approved small molecules. Here, we report the identification of 30 known drugs that inhibit viral replication. Of these, six were characterized for cellular dose-activity relationships, and showed effective concentrations likely to be commensurate with therapeutic doses in patients. These include the PIKfyve kinase inhibitor Apilimod, cysteine protease inhibitors MDL-28170, Z LVG CHN2, VBY-825, and ONO 5334, and the CCR1 antagonist MLN-3897. Since many of these molecules have advanced into the clinic, the known pharmacological and human safety profiles of these compounds will accelerate their preclinical and clinical evaluation for COVID-19 treatment.

Introduction

In December 2019, the novel SARS coronavirus 2 (SARS-CoV-2) was identified as the causative agent of a severe pneumonia-like coronavirus disease (COVID-19) outbreak in Wuhan in the Hubei province of China[1]. SARS-CoV-2 is an enveloped, positive-sense, single-stranded RNA betacoronavirus, related to the viruses that caused severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) in 2002-2004 and 2012-present, respectively. The World Health Organization (WHO) declared the rapidly spreading disease a pandemic on March 11th, 2020, and, as of April 16th, more than 2.1 million confirmed cases and 139,500 deaths have been recorded worldwide in 213 countries[2]. The WHO estimates the global case fatality rate (CFR) at 3.4% of those infected, though the number of actual infections is likely much higher than the number of reported cases[3,4]. Typical COVID-19 symptoms include fever, cough, anosmia, headache, anorexia, myalgia, and, in the most severe cases, viral-induced pneumonia accompanied by prolonged and systemic cytokine release[5,6]. Notably, the levels of IL-6 have been reported to correlate with respiratory failure, and inhibitors are currently being pursued in clinical studies for the amelioration of virus-induced inflammatory responses[7]. Patients with pre-existing chronic conditions such as hypertension, diabetes, and asthma, as well as those 65 years or older, are at a higher risk of severe disease outcome[8]. The underlying basis for these differential outcomes is yet unknown. Together, the still accelerating rate of community transmission and severity of the symptoms have placed an unprecedented burden on the medical supply chain and health care system in Italy, Spain, and the U.S.[9-11], with similar scenarios playing out or anticipated in other countries.

While the FDA has recently granted the antimalarial drug hydroxychloroquine sulfate (also known as hydroxychloroquine) emergency use authorization (EUA) for COVID-19 treatment, at present, there is no vaccine or approved antiviral therapeutic agent available[12]. Thus, there is an urgent and critical need to identify novel medical countermeasures both for prophylactic and treatment use. Since the production of a vaccine could take 12-18 months[13], and *de novo* development of therapies usually requires 10-17 years[14], repositioning clinically evaluated drugs represents one of the

most practicable strategies for the rapid identification and deployment of treatments for emerging infectious diseases such as COVID-19.

Toward this end, in addition to many anti-immune treatments not addressed in this paper, many investigational clinical trials using repurposed drugs for evaluation of direct antiviral activity have already been launched. Those include multiple antiviral and antimalarial medicines. Early results of a multicenter trial in China suggested that the antimalarial drug, chloroquine, may limit exacerbation of pneumonia and shorten viral replication and course of disease[15]. A French study that used hydroxychloroquine together with azithromycin reported a significant reduction in viral load in COVID-19 patients when used in combination[16]. However, a sufficiently powered case-control study has not yet been reported, and thus it is unclear if there are therapeutic benefits of chloroquine administration to SARS-CoV-2-infected patients, although several concerns are being raised recently, due to the severe cardiac complications potentially resulting from the use of this treatment in COVID-19 patients[17,18].

The repurposing of several approved antiviral therapies have all been the focus of clinical investigations, including HIV-1 protease inhibitors lopinavir/ritonavir (Kaletra, Aluvia by AbbVie)[19], hepatitis C virus protease inhibitor danoprevir (Ganovo, Ascletis Pharma)[20], and the influenza antiviral favipiravir (T-705, Avigan)[21]. Most notably, ten clinical trials at more than 50 global sites are underway to investigate remdesivir (GS-5734), an investigational antiviral originally developed by Gilead Sciences to treat Ebola virus infection[22]. Remdesivir, an adenosine analogue, is a viral RNA polymerase inhibitor that causes premature termination of transcription when incorporated into nascent viral RNA[23]. The drug has demonstrated *in vitro* and *in vivo* activity in animal models against both MERS and SARS[24,25], as well as potent antiviral activity in Vero E6 against a clinical isolate of SARS-CoV-2[26]. Pending results of several randomized (n = 308) clinical trials are expected to provide definitive insight into the efficacy of remdesivir as a therapeutic solution for the treatment of COVID-19. However, a well-powered randomized controlled trial has yet to demonstrate definitive evidence of antiviral efficacy for remdesivir or any other potential therapeutic.

While these targeted repurposing strategies provide potentially rapid trajectories toward an approved treatment, an unbiased large-scale evaluation of known drugs and

clinical candidates can identify additional unanticipated therapeutic options with accelerated evaluation for the treatment of COVID-19 disease. Here, we describe a high-throughput repositioning screen using the commercial library of 1,280 pharmacologically active compounds LOPAC®1280 and the ReFRAME (Repurposing, Focused Rescue, and Accelerated Medchem) drug collection, a comprehensive open-access library of ~12,000 clinical-staged or approved small molecules respectively, to identify existing drugs that harbor antiviral activity against SARS-CoV-2 in a cell-based assay[27,28]. The ReFRAME library has previously been used to successfully identify the anti-inflammatory auranofin as a potential therapy for tuberculosis[29], the approved drug clofazimine as a potent antiparasitic compound that is now being tested for efficacy against *Cryptosporidium*[30], and has also been used to identify and optimize the FDA-approved antifungal drug itraconazole as a novel efficacious molecule suitable for chronic administration as an anti-fibrotic[31]. Importantly, the ReFRAME library is unique in that it is the only repurposing collection we are aware of where nearly 50% of the library was derived from custom synthesis, as commercially available sources of these clinical molecules were not available[32]. Each of the molecules in this collection has been previously optimized for efficacy, safety, and bioavailability. Therefore, this enables leveraging of the considerable investment in research and development to compress the timeline required for drug discovery and development[33]. For example, repositioning is estimated to reduce the typical 10-17 year development process to 3-12 years[34], and under emergency use authorization (EUA) for chemical, biological, radiological, and nuclear (CBRN) threats during public health emergencies, such as the SARS-CoV-2 pandemic, this may be abbreviated to a <6-month time frame.

Here, we describe a high-throughput analysis of the ReFRAME library to identify inhibitors of SARS-CoV-2 replication in mammalian cells, and identified several targets and mechanistic classes that were highly enriched, including aldose reductase inhibitors, retinoic acid receptor antagonists, benzodiazepine receptor agonists, regulators of cholesterol homeostasis and antimalarial compounds. Validation studies further confirmed 30 known drugs to inhibit viral replication, including four molecules previously approved by the FDA (clofazimine, acitretin, tretinoin, and astemizole) or registered outside the US (tamibarotene). Dose response studies have thus far

characterized 7 compounds that exhibit a range of effective concentrations (EC_{50}) that are consistent with potential clinical efficacy. These include a PIKfyve kinase inhibitor that has reached Phase II clinical trials (Apilimod), and cysteine protease inhibitors (MDL-28170, Z LVG CHN2, VBY-825, and ONO 5334) that are in various phases of preclinical and clinical development. In addition, the preclinical ion channel blocker AMG-2674 and the ion channer blocker and antimalarial drug hanfangchin A, the phase I proton pump inhibitor YH-1238, as well as the G-protein receptor antagonists MLN-3897 and SDZ-62-434[35], which are in phase II and phase I clinical evaluation respectively, were also found to possess antiviral activity against SARS-CoV-2. Rapid experimental and clinical evaluation of these therapeutics for *in vivo* antiviral efficacy and amelioration of disease-associated pathologies can provide an important opportunity for the accelerated development of potential therapies for COVID-19 treatment.

Materials and Methods

Cells and Viruses

SARS-CoV-2 HKU-001a strain was isolated from the nasopharyngeal aspirate specimen of a laboratory-confirmed COVID-19 patient in Hong Kong[36]. SARS-CoV-2 USA-WA1/2020 strain, isolated from an oropharyngeal swab from a patient with a respiratory illness who developed clinical disease (COVID-19) in January 2020 in Washington, USA, was obtained from BEI Resources (NR-52281). The virus was propagated in Vero E6 (ATCC® CRL-1586™) cells transfected with exogenous human ACE2 and TMPRSS2 and stored at −80 °C in aliquots. Plaque forming unit (PFU) and $TCID_{50}$ assays were performed to titrate the cultured virus. Vero E6 and Huh-7 cells (Apath LLC, Brooklyn) were maintained in Dulbecco's modified eagle medium (DMEM, Gibco) supplemented with 10 % heat-inactivated fetal bovine serum (FBS, Gibco), 50 U/mL penicillin, 50 µg/mL streptomycin, 1 mM sodium pyruvate (Gibco), 10 mM HEPES (Gibco), and 1X MEM non-essential amino acids solution (Gibco). Huh-7 cells were transfected with PLVX-ACE2 and PLX304-TMPRSS2 prior to infection. All experiments involving live SARS-CoV-2 followed the approved standard operating

procedures of the Biosafety Level 3 facility at the University of Hong Kong[37] and Sanford Burnham Prebys Medical Discovery Institute.

Chemical libraries

The LOPAC®1280 library is a collection of 1,280 pharmacologically active compounds, covering all the major target classes, including kinases, GPCRs, neurotransmission and gene regulation (Sigma). The ReFRAME (Repurposing, Focused Rescue, and Accelerated Medchem) library, built at the California Institute for Biomedical Research (Calibr)[27], contains approximately 12,000 high-value molecules assembled by combining three databases (Clarivate Integrity, GVK Excelra GoStar and Citeline Pharmaprojects) for fast-track drug discovery. This library contains US Food and Drug Administration (FDA)-approved/registered drugs (~35 %), investigational new drugs (~58 %), and preclinical compounds (~3 %).

Drug screening

Compounds from the LOPAC®1280 and ReFRAME library were transferred into F-BOTTOM, µCLEAR®, BLACK 384-well plates (Greiner) using an Echo 550 Liquid Handler (Labcyte). All compounds were diluted in culture media to a final concentration of 5 µM during screening. Briefly, Vero E6 cells were seeded in 384-well plates, on top of pre-spotted compounds, at a density of 3,000 cells per well in 40 µl using a microFlo™ select dispenser (BioTek Instruments). Sixteen hours post-seeding, the cells were infected by adding 10 µl of SARS-CoV-2 per well at an MOI of 0.01. Cytopathic effect (CPE) was indirectly quantified as the presence of ATP in live cells by using the CellTiter-Glo (Promega) luminescent cell viability assay at 72 hours post-infection. Data were normalized to the median of each plate. For the ReFRAME library, the Z-score was calculated based on the log2FC with the average and standard deviation of each plate. The screen was performed in duplicate by running the assay in parallel for the LOPAC®1280 library or as two independent experiments for the ReFRAME collection. Twenty-eight compounds from the LOPAC®1280 were selected according to the cutoff of >5*Stdev Log2FC and included in a dose-response confirmation assay. Compounds

from the ReFRAME collection were ranked according to their Z-score. The top 100 hits from each replicate were selected (25 overlapping). Seventy-five additional hits were chosen according to their ranking based on the average Z-score. The last 48 hits were selected according to drug target and pathway enrichment analysis. The 298 prioritized hits were included in a dose-response confirmation assay.

Dose Response Curves, EC_{50} Calculations, and Orthogonal Validation

The selected hits were further validated by immunofluorescence in an 8-point dose response experiment to determine EC_{50} and CC_{50} through a cell-based high-content imaging assay, labeling the viral nucleoproteins within infected cells. Three thousand Vero E6 cells were added into 384-well plates pre-spotted with compounds, in a volume of 40 µl. The final concentration of compound ranged from 1.1 nM to 2.5 µM. Sixteen hours post-seeding, 10 µl of SARS-CoV-2 USA-WA1/2020 were added to each well, at an MOI of 0.75. Twenty-four hours post-infection, cells were fixed with 5 % paraformaldehyde for 4 hours and permeabilized with 0.5 % Triton X-100 for 5 min. After blocking with 3 % bovine serum albumin (BSA) for 30 min, the cells were incubated for 1 hour at room temperature with rabbit-anti-SARS-CoV-1 nucleoprotein serum, which exhibits strong cross-reactivity with SARS-CoV-2. After two washes with phosphate-buffered saline (PBS), the cells were incubated with Alexa Fluor 488-conjugated goat-anti-rabbit IgG (Thermo Fisher Scientific, USA) for 1 hour at room temperature. After two additional washes, PBS supplemented with 0.1 µg/ml antifade-4 6-diamidino-2-phenylindole (DAPI) (BioLegend, USA) was added to the cells for at least 30 min before imaging. Images were acquired using the Celigo Image Cytometer (Nexcelom). The assay results and data analysis enabled us to determine infectivity and viability/cytotoxicity. Based on all infectivity and cytotoxicity values, a 4-parameter logistic non-linear regression model was used to calculate EC_{50} and CC_{50} concentration values.

Enrichment analysis

Compounds were annotated in the three databases used to assemble the ReFRAME library (Clarivate Integrity, GVK Excelra GoStar and Citeline Pharmaprojects) according

to a variety of properties, including targets, pathways, indications, and mechanisms of actions (MOA). Each annotation property was tested for enrichment among the screening hits using the GSEA software[38,39]. The compounds annotated for each property were treated as a "gene set". For each set of vendor annotations, the background compound set was defined as the set of compounds annotated for any property by that vendor. Enrichment results at $p < 0.05$ and FDR q-value < 0.25 were defined as significant. Additional enrichment analyses were performed using the free online meta-analysis tool Metascape[40].

Expression analysis

Gene expression analysis was conducted using single-cell RNA profiling data of samples from four macro-anatomical locations of human airway epithelium in healthy living volunteers[41]. For each gene, the fraction of cells with non-zero expression values was calculated in nasal, tracheal, intermediate, and distal samples from multiple donors. Values for each sampling location were averaged across donors. To analyze gene expression levels in different cell types, the fractions of cells with non-zero expression values were determined in all cells of a given cell type across samples. Cell types with a total of less than 250 cells detected were excluded from analysis. Clustered heat maps were generated in R using the pheatmap and viridis packages.

Results

Optimization of a high-throughput screen for inhibitors of SARS-CoV-2 Replication. One of the most efficient ways to identify antiviral candidates against an emergent virus, such as SARS-CoV-2, that can be rapidly evaluated in clinical trials is to repurpose clinically assessed drugs. Given the urgent need for therapeutics to treat SARS-CoV-2 infection, we developed a high-throughput assay to screen a comprehensive repurposing library. Vero E6 cells, kidney epithelial cells derived from an African green monkey, have been shown to be highly permissive to SARS-CoV-2 infection[42] and viral replication can be assessed through measurement of viral-induced cytopathic effects (CPE)[43]. A clinical isolate of the SARS-CoV-2 virus (SARS-CoV-2

HKU-001a)[36] was utilized for assay development and screening. The assay parameters, including cell seeding density, multiplicity of infection (MOI), and timepoints, were optimized in Vero E6 cells by measuring virus-induced CPE using CellTiter-glo, which quantifies cellular ATP levels, in a 384-well format. Maximal dynamic range and reproducibility were found at conditions of 3,000 cells/well, infection at an MOI of 0.01, and CPE measurement at 72 hours post-infection (**Figure 1A**; data not shown).

In an effort to assess robustness and reproducibility of the optimized assay in a high-throughput screening (HTS) configuration, we initially evaluated the assay utilizing the collection of 1,280 known bioactive molecules LOPAC®1280. Upon initiation of the screening effort, a compound with activity against SARS-CoV-2 in Vero E6 cells had not been reported. Based on studies that indicate that inhibition of the PIKfyve kinase inhibits low pH-dependent entry of viruses such as Ebola[44,45], we evaluated the potential antiviral activity of the PIKfyve kinase inhibitor APY0201 against SARS-CoV-2. Compared to vehicle (DMSO), cells dosed with 1 μM APY0201 harbored a 2.5X increase in cell viability, reflecting reduced CPE after viral challenge, which was comparable to the non-infected control (**Figure 1B, left panel**). These data confirmed the antiviral activity of APY0201 against SARS-CoV-2 and enabled us to establish a reliable dynamic range based on the activity of a positive control. Vero E6 cells were seeded in 384-well plates with pre-spotted compounds from the LOPAC®1280 library at a 5 μM (final) concentration. After 16 hours, cells were infected with SARS-CoV-2 (MOI = 0.01) in the presence of compound, and at 72 hours post-infection CPE induced by the virus was quantified through previously described measurement of cell viability. Duplicates of each plate were run in parallel and the value corresponding to each well was normalized to the median of each plate and used to calculate the log base 2 of the fold change (Log2FC). Based on the activity of APY0201, the average Z' factor for the 5 plates in duplicate was 0.4, and the correlation coefficient for the duplicates (R^2) was 0.81 (**Figure 1B**), although an usual distribution of the positive controls in the correlation plot was observed. Twenty-eight compounds were selected for further study based on activities in both screens. These included the HIV protease inhibitor nelfinavir mesylate hydrate, the calpain and cathepsin B inhibitor MDL28170 and the antagonist of the serotonin receptors 5-HT1B and 5-HT1D GR 127935 hydrochloride hydrate, which have

all been shown to efficiently block either SARS-CoV-1 or 2 infection *in vitro* or *in vivo*[46-50], thus assessing the sensitivity of our screening conditions in identifying compounds with known antiviral activity (**Figure 1B, top right middle panel)**.

Repositioning analysis of the ReFRAME Drug Repurposing Library. Since the results of the LOPAC®1280 HTS analysis indicated that these assay conditions were suitable to progress to a large-scale screen, we used this experimental design to screen the comprehensive ReFRAME drug repurposing collection. This library is an inclusive collection of nearly 12,000 chemical compounds, that have been either FDA-approved or registered outside the US, entered clinical trials, or undergone significant pre-clinical characterization[27]. Specifically, 11,987 compounds were arrayed in 384-well plates at a final concentration of 5 µM. As with the previous assay, Vero E6 cells were seeded into each well pre-spotted with compound, infected 16 h later with SARS-CoV-2 (MOI = 0.01) and at 72 hours post-infection, CPE was determined. Analysis of the average Z' factor calculated on the activity of APY0201 was determined to be 0.51, reflecting an acceptable assay dynamic range (**Figure 1C, left panel**). The screen was then repeated as an independent replicate and the correlation coefficient (R^2) for the two replicates was determined to be 0.68 (**Figure 1C, middle panel**). Data were normalized to the median of each plate and used to calculate the Log2FC. The distribution of the compounds based on the average of their Log2FC calculated within the replicates is shown in **Figure 1C** (**right panel**). Z-scores were then calculated per plate, based on the Log2FC values (**Figure S1**).

To elucidate targets, pathways, indications, and mechanisms of actions (MOA) enriched among hits in the primary screen, compounds in the collection were classified based on their reported target annotation. Gene Set Enrichment Analysis (GSEA) was used to assess the distribution of molecules with similar targets, functional categories or MOA across the screen[51,52]. We next examined whether any target, pathway, indication, or MOAs was enriched across the entire dataset. Compounds in the collection were classified based on their reported annotations from three commercial vendors, and each annotation group was tested for enrichment among hits using the GSEA software[38,39]. Based on a nominal P-value cutoff of 0.05 and FDR q-value < 0.25, we found that

15 target sets were enriched in our ranked hit list (**Figure 2A and Figure S2**). These enriched targets and biological processes include allosteric modulators of the benzodiazepine and retinoic receptors, cytosolic NADPH-dependent oxidoreductase aldose reductase, potassium channels, cholesterol homeostasis, and serine proteases. Antimalarials including chloroquine derivatives (i.e. Amopyroquine and AQ-13) were also enriched, although the FDR q-value was below the established threshold (0.33) (**Figure 2A; Figure S2 and Table S2**).

SARS-CoV-2 primarily infects the epithelial cells in the respiratory tract[53]. To elucidate the expression pattern of the genes that have been annotated to be targeted by putative antiviral compounds, we compared the expression of drug target genes enriched in the compound screen across cell types within the respiratory tract[41]. Although both the entry receptor for SARS-CoV-2, ACE2, and the priming protease TMPRSS2, were found to be expressed within specific anatomical sampling locations in the respiratory tract (**Figure 2B, left heatmap**), ACE2 expression was found to be restricted to epithelial cell types including multiciliated, nasal, deuterosomal, secretory, and basal cells (**Figure 2B, right heatmap**). Nonetheless, ACE2 expression has been reported to be induced by type-I interferon[90]. Notably, a majority of the mapped targets of active compounds also harbored expression in relevant respiratory epithelial cells, suggesting these may be physiologically relevant drug targets (**Figure 2B**). Further pathway analyses of these enriched MOAs and targets revealed enrichment in genes involved in nuclear receptor pathways, GPCR ligand binding and signaling, and calcium signaling (**Figure S3**), underscoring the potential critical role of these molecular circuits in cellular control of the SARS-CoV-2 life cycle[40].

Orthogonal validation of selected anti-SARS-CoV-2 compounds. To select candidates for validation studies, compounds were ranked according to their Z-score in the primary screen (Figure S1), and 100 compounds from replicate 1 were prioritized based on this ranking, and an additional 75 molecules were selected that were only found in replicate 2. 75 compounds were also selected according to their ranking calculated based on the average Z-score between the replicates, and an additional 48

hits were chosen because they were classified within an enriched drug target and pathway class (see above).

We initially assessed the activity of hits at half the original screening concentration (2.5 μM) using an orthogonal assay readout. Specifically, Vero E6 cells were pre-incubated with each compound dilution for 16 hours, followed by infection with an independent SARS-CoV-2 isolate (SARS-CoV-2 USA-WA1/2020) (MOI = 0.75). 24 hours post-infection, cells were fixed and immunostained for the CoV nucleoprotein (NP). Cellular nuclei were stained with DAPI, prior to automated imaging and analysis. The percentage of infection for each well was calculated as the ratio of infected cells stained with NP antibody, over the total number of cells. Each of these values was normalized to the average of the DMSO control wells in each plate. Twenty-seven percent of compounds (89 compounds) were found to reduce viral replication by at least 40 % at 2.5 μM (data not shown) when averaging data from at least two replicates. These include compounds that were found to belong to enriched target classes (**Figure 2A**), including retinoic acid receptor agonists (LGD-1550, tretinoin, tamibarotene, acitretin, tazarotene, RBAD), the aldose reductase inhibitor AL 3152, benzodiazepine receptor agonists (ZK-93426, zaleplon GR, pagoclone) and antimalarial drugs (AQ-13 and hanfangchin A), as well as the FDA-approved anti-mycobacterial clofazimine.

Dose response analysis.

Although specific for each compound, therapeutic dose ranges are typically expected to track to cellular EC_{50}s well below 1 μM concentrations. Therefore, we conducted a dose response analysis to determine the relationship between compound concentration and antiviral activity. Compound concentrations tested ranged from 1.1 nM to 2.5 μM in the immunofluorescence assay described previously. Total cell counts were used to assess compound cytotoxicity (**Figure S4**). In addition to remdesivir, treatment with 17 compounds resulted in discernable dose-dependent antiviral activities, most of which could be segregated based on broad functional, structural, or target-based classes (**Figure 3A**). 10 of these known drugs have EC_{50}s > 750 nM or values that could not be exactly extrapolated (**Figures 3A and Figure S5**), while 7 compounds harbored EC_{50}s < 500 nM (6 of which reached > 80%

inhibiton of the infection at the highest concentration (**Figure 3B-C**)), suggesting that effective antiviral potency could likely be achieved during therapeutic dosing of a COVID-19 patient. Data are also available at reframedb.org.

To enable prioritization of known drugs for preclinical and clinical evaluation for the treatment of SARS-CoV-2, a summary of the publicly disclosed and relevant preclinical and clinical properties of the most advanced among these molecules are annotated in Table 1 (information retrieved from CortellisTM (Clarivate Analytics) and drugs.com).

Discussion

Since the beginning of January 2020, an extraordinary number of investigational programs and clinical trials has been initiated in a concerted effort to identify therapeutics against the rapidly growing COVID-19 pandemic. Clinical trials using repurposed clinical-stage or approved drugs such as remdesivir, favipiravir, lopinavir/ritonavir, hydroxychloroquine and others have been under investigation for treating COVID-19 patients[15,16,20,54-59]. Some other therapies, such as treatment with antibodies from seroconverted idividuals, are also being investigated. However, most of the reported studies have been conducted in small cohorts and thus should be considered preliminary, with larger case-control clinical evaluations still pending[15-16,19-22]

The elucidation of additional candidate therapies would greatly enhance the probability of rapidly identifying safe and efficacious treatment options, and would also enable the development of combinatorial regimens (“cocktails”), which reflects the current treatment strategies for HIV-1 and hepatitis C virus (HCV)[60-62].

Large-scale surveys of existing drugs that may harbor antiviral activities can significantly facilitate such repositioning efforts. A recently reported SARS-CoV-2-human protein-protein interaction (PPI) analysis identified 332 viral-host interactions, 66 of which are potential druggable human host factors targeted by 69 known drugs that have FDA approval, however activities on SARS-CoV-2 replication have not yet been reported[63]. An additional study that tested a focused panel of 48 FDA-approved drugs, previously shown to have antiviral activity against both SARS-CoV and MERS-CoV,

also demonstrated that several known drugs harbor potent antiviral activities against SARS-CoV-2[64].

Here, we report the high-throughput analysis of approximately 12,000 known drugs evaluated for activity against SARS-CoV-2 replication. The assay, conducted in Vero E6 cells was designed to capture multicycle replication, based upon low viral input (MOI = 0.01) and an extended endpoint measurement (72 hours post-infection). Although cell-based assays can be biased towards capturing inhibitors of viral entry, the assay was constructed to interrogate each step of the viral life cycle. Of note, one potential limitation of Vero cells is that, due to species differences, pro-drugs that require the human host cell machinery for processing into their active form, such as some nucleoside inhibitors, may not harbor the same potency as in human cells. Consistently, we found that remdesivir inhibits SARS-CoV-2 replication ~60-fold more potently in human cells in comparison to Vero E6 cells (**Figure 3A and Figure S5; data not shown**).

The dynamic range of the viral-induced CPE in the assay was small (~2-2.5 fold), but robust and reproducible (**Figure 1B**). Both the optimization using the LOPAC® 1280library and the first ReFRAME collection screen displayed acceptable Z' factors (0.4 and 0.51, respectively). The duplicate ReFRAME screen, had a reduced dynamic range (1.5-fold) and corresponding Z' factor (0.19). Although the correlation between the two ReFRAME replications was high (R^2=0.68), there were compounds that were found active in replicate 1, but not replicate 2 (**Figure 1C, bottom right of middle panel**). While we leveraged all datasets to select molecules for further validation, compound selection was weighted for replicate 1. Specifically, in addition to 28 molecules from the LOPAC®1280 library, 250 drugs were selected based on their activity. 48 additional ones, belonging to enriched target/MOA sets based on GSEA analysis, were also included.

These selected compounds were tested in an orthogonal assay that directly measures viral replication, in contrast to the indirect measurement of replication assessed by CPE. Here, we took advantage of a high-throughput immunofluorescence assay that monitors infection levels as reflected by SARS-CoV-2 N protein expression at a single cell resolution. Importantly, this validation step enables the separation of

molecules that function to block CPE (i.e. cell death), instead of direct effects on replication. This assay was found to be most robust at a 24-hour timepoint using an MOI of 0.75, thus, the antiviral activities of compounds were not interrogated under the original MOI or 72-hour timepoint conditions. Both the earlier timepoint and higher MOI likely biased the validation screen towards the confirmation of early stage inhibitors. Consistent with this hypothesis, we found that several molecules with potent EC_{50}s were only able to inhibit replication to approximately 50-60 % at multiple high concentrations, including MLN-3897, YH-1238 and SL-11128 (**Figure 3A and Figure S5**). While this may represent the maximal ability of these molecules to suppress viral replication, alternatively, analysis of these molecules utilizing lower MOIs at later timepoint may reveal greater inhibition of infection. In addition, validation assays were conducted employing drug concentrations that were half of what was utilized in the screen (2.5 ∝M versus 5 ∝M) and using a second isolate of SARS-CoV-2. The introduction of these stringencies during the validation step, as well as false positive activities from the HTS assay, likely account for ~30 % confirmation rate observed at this step of the analysis.

Tretinoin, clofazimine, acitretin were amongst the notable validated compounds, since they have been approved by the FDA. Clofazimine is a lipophilic riminophenazine antibiotic, with described antimycobacterial and anti-inflammatory activity[65] used for the treatment of leprosy. Main adverse effects include changes in skin pigmentation, nausea and vomiting. The antibacterial activity of clofazimine is described to be related to its ability to bind to the bacterial DNA. Interestingly, this compound was also identified as a potent antiparasitic drug active against *Cryptosporidium*, during a repurposing screen of the ReFRAME library[30]. Further studies are required to understand the mechanism by which this molecule blocks the replication of this positive-strand RNA virus, and determination of the dose-response relationship for clofazimine will enable assessment of whether antiviral efficacy can be achieved at therapeutic doses. Acitretin is an approved orally bioavailable retinoid used for the treatment of psoriasis[66]. Tretinoin, together with tamibarotene, which is registered in Japan, as well as LGD-155, tamibarotene, tazarotene and RBAD, were all validated compounds belonging to the enriched GSEA class of class of retinoic acid agonists highly enriched in the GSEA analysis (**Figure 2A**). It is currently unclear how the activation of the transcriptional

program governed by retinoic acid receptors may impinge upon SARS-CoV-2 replication.

Six additional compounds which confirmed in our validation studies also modulate targets that were enriched in the high-throughput screen. Those include aldose reductase inhibitor AL 3151, the benzodiazepine receptor agonists ZK-93426, zaleplon GR and pagoclone, and the two antimalarial drugs AQ-13 and hanfangchin A. Antimalarial drugs have been reported to effectively block several viral infections[67], including SARS-CoV-2[26]. However, the activities of many of these, in particular chloroquine derivatives, have not been recapitulated in clinical trials[17,18]. Drugs belonging to this class are generally reported to be less effective in blocking viral infections compared to their anti-malarial activity, with EC_{50} generally in a ∝M range[67]. The concentration required for their antiviral activity could thus likely be difficult to reach in humans, without causing adverse effects. Taken together, confirmation of compounds with membership in enriched target classes underscore the importance of these molecular circuits in the regulation of SARS-CoV-2 replication and support the evaluation of additional preclinical and clinical stage molecules that target over-represented mechanisms.

Among the 17 compounds validated to show a dose-response relationship in our orthogonal assay, 10 compounds harbored EC_{50} antiviral activities >750 nM, suggesting that additional preclinical studies will likely be required to determine whether administration of these compounds can achieve sufficient systemic exposure to enable antiviral activity (**Figure S5**). Seven molecules were found to inhibit viral replication at EC_{50} concentration <500 nM. These include Z LVG CHN2, a preclinical tripeptide derivative that displays a broad-spectrum bactericidal activity. Specifically, this molecule has been previously shown to suppress herpes simplex virus (HSV) replication by inhibiting the enzymatic activity of HSV-encoded cysteine protease[68], which may indicate that the antiviral function of Z LVG CHN2 occurs through inhibition of SARS-COV-2 3CLpro protease. Another preclinical molecule that exhibits strong antiviral activity, MDL 28170, is a potent cell permeable calpain I and II inhibitor. Interestingly, MDL 28170 was previously found to impair infection by SARS-COV-1 and Ebola virus (EBOV)[50,69]. Additionally, astemizole a registered anti-histamine H1 receptor antagonist

that also reported to have anti-malarial properties[70], inhibited replication at an EC_{50} concentration of ~1.1 ∝M. Due to fatal arrhythmias when given in high doses or in combination with certain other common drugs, astemizole has been withdrawn in many countries[71]. Therefore, thorough safety studies are required to determine if there exists a sufficient therapeutic index for the acute treatment of SARS-CoV-2 infection.

MLN-3897 (AVE-9897) is an orally active chemokine CCR1 antagonist and was evaluated in phase II clinical studies for the treatment of rheumatoid arthritis (RA) and multiple sclerosis (MS)[72], showing a dose of 10 mg once daily was well tolerated[73]. It was determined to inhibit SARS-CoV-2 replication at an estimated EC_{50} concentration of 140 nM (**Figure 2**), and the C_{max} of the compound has been reported at 9.0 nM (10 mg QD). Therefore, additional *in vivo* studies will be required to determine if sufficient systemic concentrations can be reached to promote antiviral activities. The mechanism by which CCR1 antagonism inhibits SARS-CoV-2 infection requires further investigation. However, it has been reported that CCR1 inhibition with MLN-3897 potentially blocks ERK phosphorylation, leading to suppression of the mitogen-activated protein kinase (Raf/MEK/ERK) signal transduction pathway[74]. Interestingly, Raf/MEK/ERK signaling pathways are employed by SARS-CoV-1 to support its replication via multiple well-documented mechanisms[75,76], and thus this signaling axis may also represent a critical therapeutic target for host-directed SARS-CoV-2 antivirals.

Human cysteinyl cathepsins, including cathepsin B, cathepsin L, and cathepsin K, are required for the proteolytic processing of virally encoded proteins during infection[77-79]. Cathepsin activity seems to be required for proper processing of the SARS-CoV-1 S protein within the endosome in order to activate its fusogenic acitivity[78]. Inhibition of cathepsin L activity has been previously shown to efficiently suppress SARS-CoV-1 infection[78]. We found ONO 5334 (a cathepsin K inhibitor) and VBY-825 (a reversible cathepsin protease inhibitor) to inhibit SARS-CoV-2 infection in a dose-dependent manner, however additional studies will be required to determine if their antiviral activities are due to inhibiting proteolysis of viral or host cellular proteins. ONO 5334 harbored an antiviral EC50 of ~500 nM, which is in range of a previously reported 85 % activity observed at 100 nM in an osteoclast-mediated bone resorption assay[80]. Importantly, the Cmax of this compound is 1.6 ∝M (300 mg QD), and treatment with

ONO-5334 was well tolerated up to daily doses of 300 mg and for up to 12 months without any clinically relevant safety concerns. ONO5334 reached phase II clinical trials for the treatment of osteoporosis in postmenopausal women, but development was discontinued due to an unfavorable competitive landscape[81,82]. VBY-825, which is in preclinical development, is another cathepsin inhibitor harboring potential antiviral activities against SARS-CoV-2 with an EC50 of ~300 nM, and it shows high potency against cathepsins B, L, S and V *in vitro*[83]. Overall, the identification of VBY-825 and ONO 5334 as effective antiviral molecules against SAR-COV-2 supports the repositioning of these, and potentially additional protease inhibitors, for the treatment of COVID-19 disease.

Finally, apilimod, a specific PIKfyve kinase inhibitor, was found to inhibit SARS-CoV-2 replication at an EC_{50} concentration of 23 nM (**Figure 3**). Importantly, apilimod is found to be well tolerated in humans showing a desirable safety profile at doses of ≤ 125 mg BID, and the Cmax of this compound is 0.265 +/- 0.183 ∝M (70 mg QD)[84,85]. These data indicate that therapeutic dosing of apilimod in patients can achieve concentrations that are likely to promote antiviral activity. Apilimod has been evaluated in phase II clinical trials for the treatment of active Crohn's disease and rheumatoid arthritis (RA)[86], and in additional phase II trials for the oral treatment of common variable immunodeficiency (CVID), but did not show efficacy for these indications[85,87]. In 2019, orphan drug designation was granted to apilimod in the U.S. for the treatment of follicular lymphoma[88], with phase I clinical trials ongoing. Notably, it has been reported that apilimod efficiently inhibits EBOV, Lassa virus (LASV), and Marburg virus (MARV) in human cell lines, underscoring its potential broad-spectrum antiviral activity[44,89]. The underlying mechanism for the inhibition of SARS-CoV-2 infection by apilimod is currently not known. However, since PIKfyve predominately resides in early endosomes and plays an essential role in maintenance of endomembrane homeostasis, apilimod likely blocks viral low pH-dependent entry through inhibition of the lipid kinase activity of PIKfyve.

Taken together, this study has illuminated a compendium of druggable targets, pathways, biological processes and small molecules that modulate the SARS-CoV-2 replication cycle. These data can be leveraged to focus studies aimed at deciphering

the biology of this coronavirus, and to guide additional directed repurposing studies, particularly of existing late-stage preclinical assets. Critically, this campaign led to the identification and validation of 30 molecules with antiviral activities against SARS-CoV-2, including four FDA-approved compounds, one drug registered in Japan, and 11 molecules that have entered clinical trials. The availability of human safety and pharmacological data of these molecules is expected to enable rapid preclinical and clinical assessment of these compounds. However, expedited regulatory review under EUA guidelines also provides a rationale for the development of earlier stage candidate molecules that can be deployed for use during this current pandemic outbreak. It is critical that multiple therapeutic options that demonstrate efficacy against SARS-CoV-2 are available to mitigate potential emergence of drug resistance, as well as enable the evaluation of optimal therapeutic cocktails that are broadly curative for COVID-19 disease.

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Figure 1.

A) Screen schematic. Distribution of the approximately 12,000 compounds in the ReFRAME collection across different stages of clinical development. Compounds were pre-spotted in 384-well plates at a final concentration of 5 μM. 3,000 Vero E6 cells were added to each well and pre-incubated with each compound for 16 h, followed by infection with a clinical isolate of SARS-CoV-2 (HKU-001a) at an MOI of 0.01. ATP levels in each well were measured 72 h post-infection by the Cell Titer Glo viability assay, as a readout of the cytopathic effect (CPE) induced by the virus. B) LOPAC®1280 library primary screen. The left graph shows the Log2 fold change (Log2FC) of ATP levels after normalization to the median of each plate for all positive (APY0201) and negative (DMSO) controls as well as for non-infected cells, across all screening plates. The correlation plot in the middle panel indicates the Log2FC of each compound in the two replicates. The distribution of each compound according to the average of the log2C of each replicate (right panel) is also represented. Each dot indicates the log2FC of each drug in each replicate of the screen (black dots). Values corresponding to DMSO (orange dots), APY0201 (cyan dots) and non-infected cells (purple dots) are also represented. R squared indicates the correlation coefficient for the replicates. C) ReFRAME collection primary screen. The left graph represents the Log2 fold change (Log2FC) of ATP levels after normalization to the median of each plate for all positive (APY0201) and negative (DMSO) controls as well as for non-infected cells, across all screening plates. The correlation plot in the middle panel indicates the Log2FC of each compound in the two replicates. The distribution of each compound according to the average of the log2C of each replicate (right panel) is also represented. Each dot indicates the log2FC of each drug in each replicate of the screen (black dots). Values corresponding to DMSO (orange dots), APY0201 (cyan dots) and non-infected cells (purple dots) are also represented. R squared indicates the correlation coefficient for the replicates.

Figure 2.

A) Gene set enrichment analysis (GSEA) of primary screening data according to the average Z′ factor. GSEA enrichment plots of five target clusters that are enriched were represented including retinoic acid receptor agonist, benzodiazepine receptor inhibitor,

aldose reductase agonist, potassium channel agonist, cholesterol inhibitor, and antimalarial (P-value < 0.05, FDR q-value < 0.25). Antimalarials, enriched althought not significantly (FDR q-value 0.33), were also included as relevant class. B) Expression of ACE2, TMPRSS2, and select target genes was analyzed using single-cell RNA profiling data from human airway samples of healthy donors. Clustered heat maps show the fraction of gene-expressing cells separated by sampling locations (left panel) or cell type (right panel).

Figure 3:

A-C) Vero E6 cells were pre-treated for 16 h with increasing concentrations of the indicated compound and then infected with SARS-CoV-2 at an MOI = 0.75 always in the presence of the compound. 24 h post-infection, cells were fixed and an immunofluorescence was performed, followed by imaging. For each condition, the percentage of infection was calculated as the ratio between the number of infected cells stained for CoV NP and the total amount of cells stained with DAPI. Compound concentrations range between 1 nM and 2.5 µM with 3-fold dilutions. A) Heatmap representing normalized infection of the indicated 17 compounds in dose-response, on a scale from 0 to 1, on the average of three independent experiments. Compounds are associated in clusters, based on their classification category. Concentrations are rounded. # Indicated compounds were evaluated at a concentration of 0.85 µM instead of 1 µM. B) Dose-response curves for both infectivity (black) and cell number (red) are shown. Data are normalized to the average of DMSO-treated wells and represent mean ± SEM for n=3. EC50 for the * indicated compounds was calculated as relative to top concentration. C) Representative immunofluorescence images corresponding to one of the three dose-responses in B are shown. For each condition, the corresponding entire well is shown (4x objective).

Figure S1.

A) Z-scores for ReFRAME collection primary screen. The left graph represents the Z-score of ATP levesl after normalization to the median of each plate for all positive (APY0201) and negative (DMSO) controls as well as for non-infected cells, across all the screening plates. The correlation plot in the middle panel indicates the Z-score of each compound in the two replicates. The distribution of each compound according to the average of the Z-score of each replicate (right panel) is also represented. Each dot indicates the Z-score of each drug in each replicate of the screen (black dots). Values corresponding to DMSO (orange dots), APY0201 (cyan dots) and non-infected cells (purple dots) are also represented. R squared indicates the correlation coefficient for the replicates.

Figure S2.

Gene set enrichment analysis (GSEA) of primary screening data according to the average Z′ factor. GSEA enrichment plots of additional ten target clusters that are enriched were represented including beta adrenoreceptor antagonist, platelet aggregation inhibitor, progesterone receptor agonist, protein synthesis inhibitor, phosphodiesterase inhibitor, angiotensin II 1 antagonist, GPIIB IIIA receptor antagonist, thromboxane A2 receptor antagonist, leucotriene B4 antagonist, serine protease inhibitor (P-value < 0.05, FDR q-value < 0.25).

Figure S3.

Bar plot of enriched terms across the enriched genes targeted by the compounds. The x-axis corresponds to -log10(p value) while the y-axis indicates the enriched terms. The analysis was performed using Metascape[40].

Figure S4.

Vero E6 cells were pre-treated for 16 h with increasing concentrations of the indicated compound and then infected with SARS-CoV-2 at an MOI = 0.75 always in the presence of the compound. 24 h post-infection, cells were fixed and an immunofluorescence was performed, followed by imaging. For each condition, the total

amount of cells stained with DAPI was calculated. Data are normalized to the average of DMSO-treated wells. The heatmap represents the normalized cell number of the indicated 17 compounds in dose-response, on a scale from 0 to 1, on the average of three independent experiments. Compounds are associated in clusters, based on their classification category. Concentrations are rounded. # Indicated compounds were evaluated at a concentration of 0.85 µM instead of 1 µM.

Figure S5.

Vero E6 cells were pre-treated for 16 h with increasing concentrations of the indicated compound and then infected with SARS-CoV-2 at an MOI = 0.75 always in the presence of the compound. 24 h post-infection, cells were fixed and an immunofluorescence was performed. For each condition, the percentage of infection was calculated as the ratio between the number of infected cells stained for CoV NP and the total amount of cells stained with DAPI. Dose-response curves for both infectivity (black) and cell number (red) are shown. Data are normalized to the average of DMSO-treated wells and represent mean ± SEM for n=3. EC50 for the * indicated compounds was calculated as relative to top concentration.

Table 1

Activity and clinical profiles of compounds with confirmed dose-activity relationships that have entered into clinical evaluation.

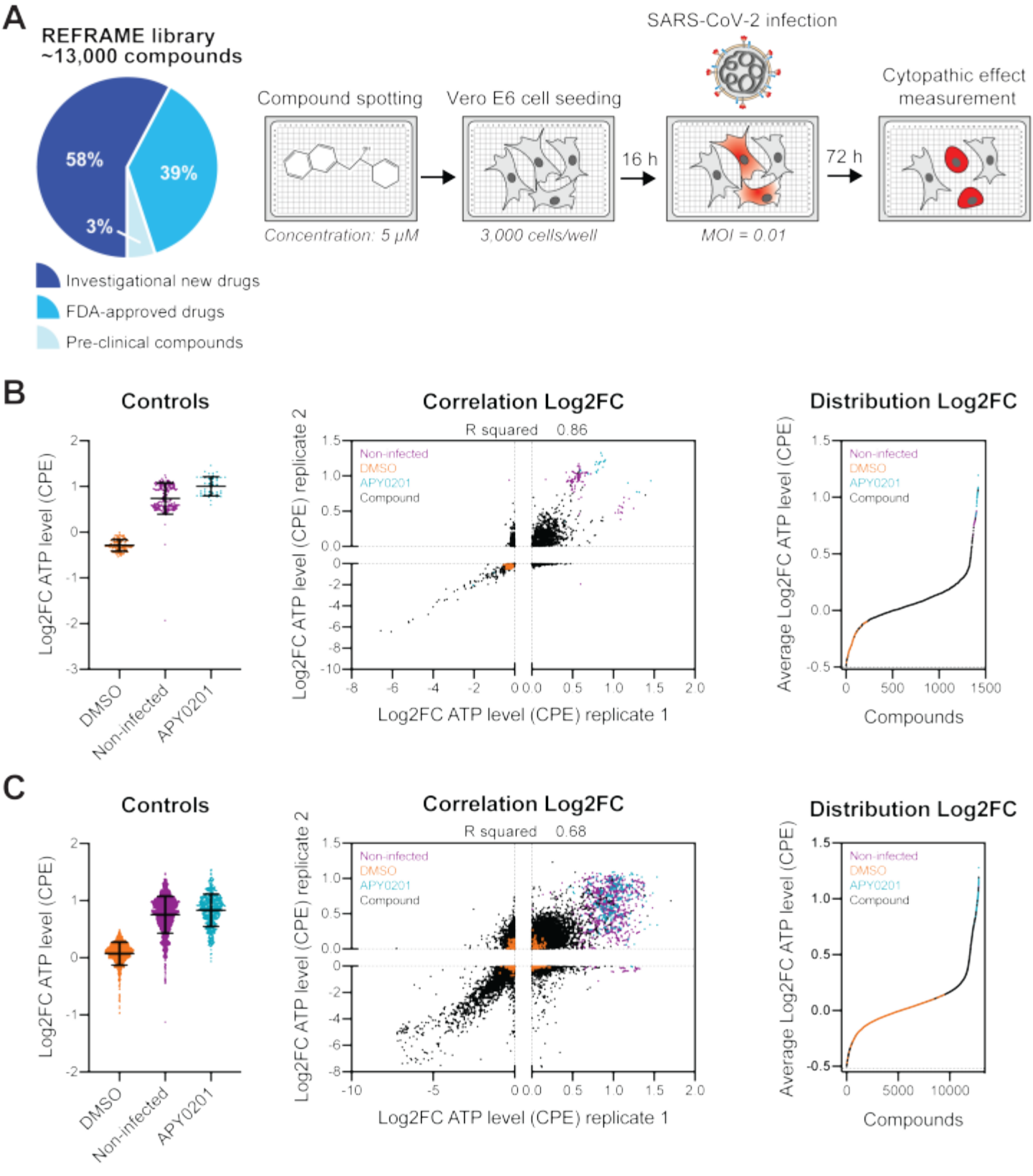
Table S1

Drug targets enriched in GSEA analysis of HTS data.

Table S2

FDA-approved or GSEA-enriched compounds.

Figure 1


A
REFRAME library
~13,000 compounds
58%
39%
3%
Investigational new drugs
FDA-approved drugs
Pre-clinical compounds
Compound spotting
Vero E6 cell seeding
SARS-CoV-2 infection
16 h
72 h
Cytopathic effect measurement
Concentration: 5 µM
3,000 cells/well
MOI = 0.01
B
Controls
Log2FC ATP level (CPE)
DMSO
Non-infected
APY0201
Correlation Log2FC
R squared 0.86
Non-infected
DMSO
APY0201
Compound
Log2FC ATP level (CPE) replicate 2
Log2FC ATP level (CPE) replicate 1
Distribution Log2FC
Average Log2FC ATP level (CPE)
Compounds
C
Controls
Log2FC ATP level (CPE)
DMSO
Non-infected
APY0201
Correlation Log2FC
R squared 0.68
Non-infected
DMSO
APY0201
Compound
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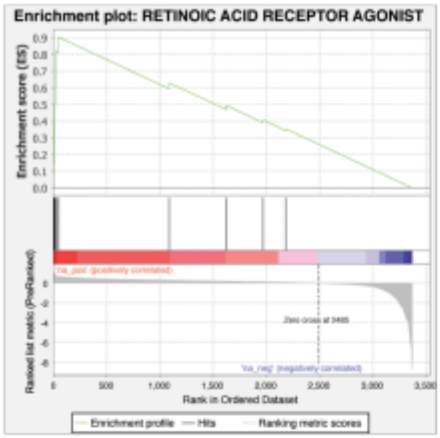
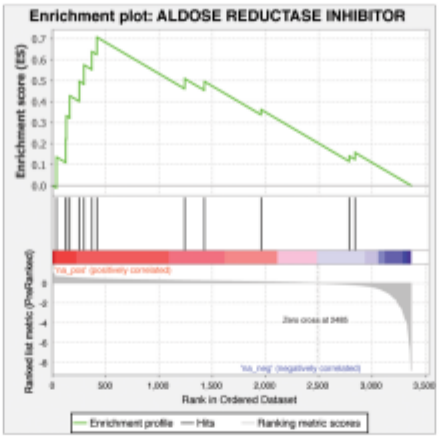
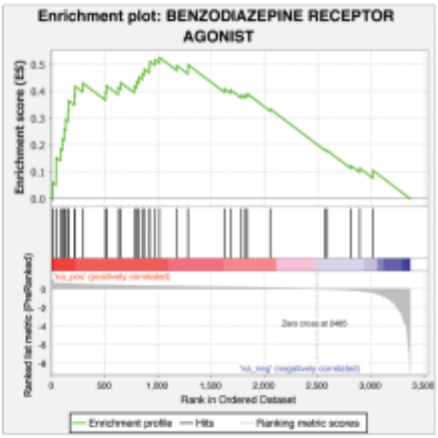
Log2FC ATP level (CPE) replicate 1
Distribution Log2FC
Average Log2FC ATP level (CPE)
Compounds

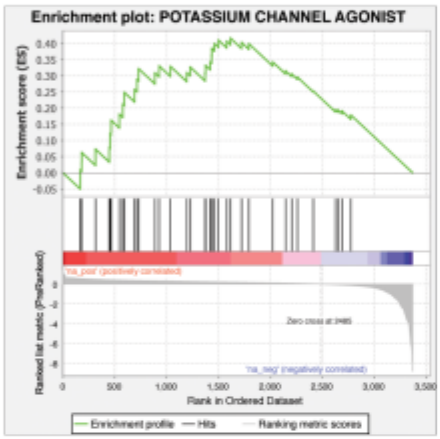
Figure 2

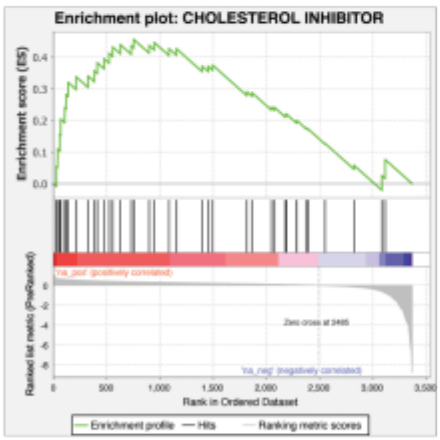
A

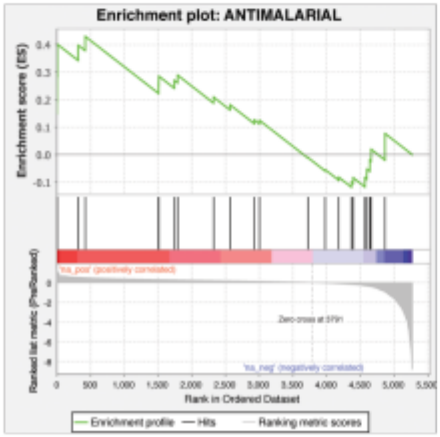

Enrichment plot: RETINOIC ACID RECEPTOR AGONIST
Enrichment score (ES)
Ranked list metric (PreRanked)
Rank in Ordered Dataset
Enrichment profile
Hits
Ranking metric scores


Enrichment plot: ALDOSE REDUCTASE INHIBITOR
Enrichment score (ES)
Ranked list metric (PreRanked)
Rank in Ordered Dataset
Enrichment profile
Hits
Ranking metric scores


Enrichment plot: BENZODIAZEPINE RECEPTOR AGONIST
Enrichment score (ES)
Ranked list metric (PreRanked)
Rank in Ordered Dataset
Enrichment profile
Hits
Ranking metric scores


Enrichment plot: POTASSIUM CHANNEL AGONIST
Enrichment score (ES)
Ranked list metric (PreRanked)
Rank in Ordered Dataset
Enrichment profile
Hits
Ranking metric scores


Enrichment plot: CHOLESTEROL INHIBITOR
Enrichment score (ES)
Ranked list metric (PreRanked)
Rank in Ordered Dataset
Enrichment profile
Hits
Ranking metric scores


Enrichment plot: ANTIMALARIAL
Enrichment score (ES)
Ranked list metric (PreRanked)
Rank in Ordered Dataset
Enrichment profile
Hits
Ranking metric scores

B

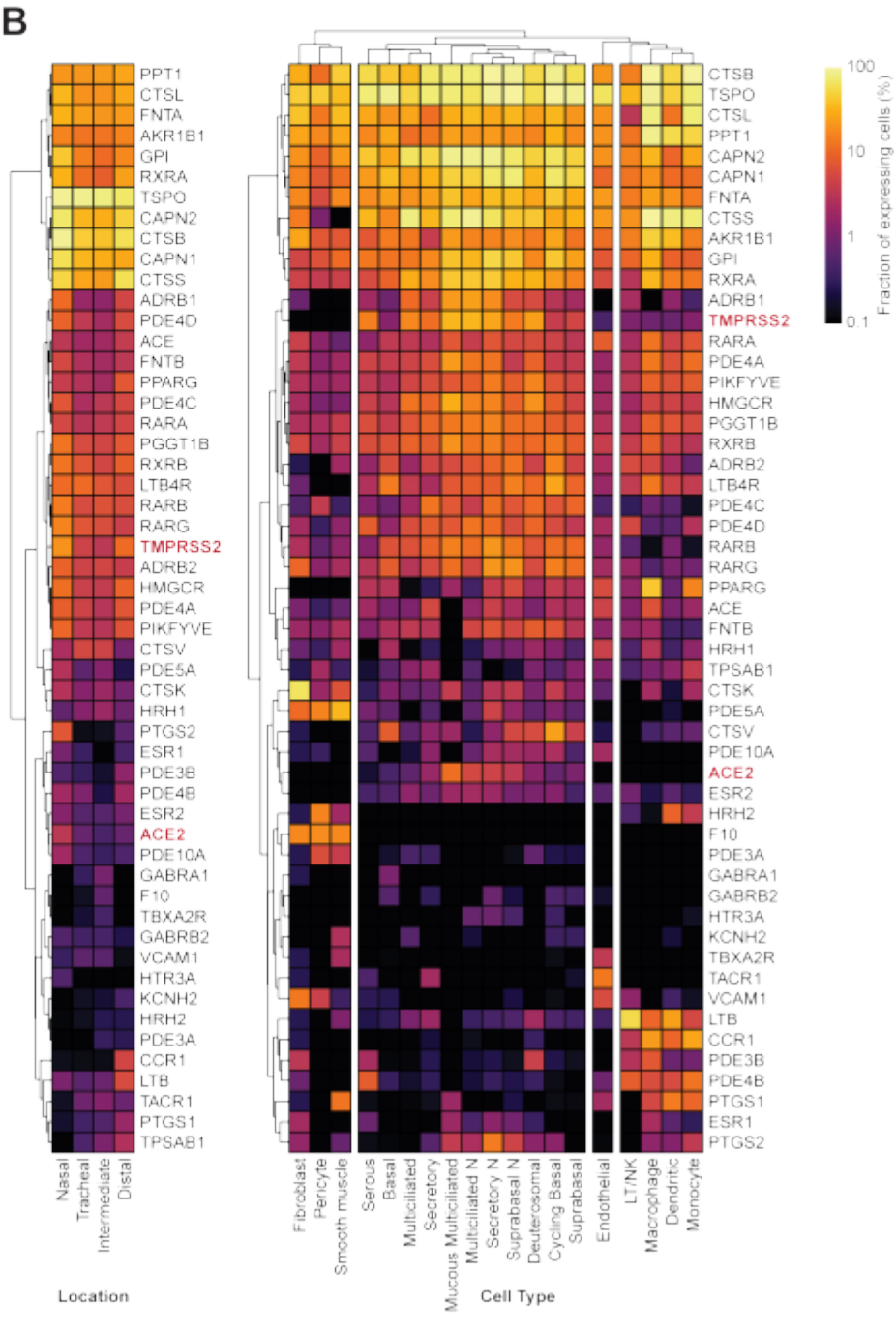

PPT1
CTSL
FNTA
AKR1B1
GPI
RXRA
TSPO
CAPN2
CTSB
CAPN1
CTSS
ADRB1
PDE4D
ACE
FNTB
PPARG
PDE4C
RARA
PGGT1B
RXRB
LTB4R
RARB
RARG
TMPRSS2
ADRB2
HMGCR
PDE4A
PIKFYVE
CTSV
PDE5A
CTSK
HRH1
PTGS2
ESR1
PDE3B
PDE4B
ESR2
ACE2
PDE10A
GABRA1
F10
TBXA2R
GABRB2
VCAM1
HTR3A
KCNH2
HRH2
PDE3A
CCR1
LTB
TACR1
PTGS1
TPSAB1
Nasal
Tracheal
Intermediate
Distal
Location
CTSB
TSPO
CTSL
PPT1
CAPN2
CAPN1
FNTA
CTSS
AKR1B1
GPI
RXRA
ADRB1
TMPRSS2
RARA
PDE4A
PIKFYVE
HMGCR
PGGT1B
RXRB
ADRB2
LTB4R
PDE4C
PDE4D
RARB
RARG
PPARG
ACE
FNTB
HRH1
TPSAB1
CTSK
PDE5A
CTSV
PDE10A
ACE2
ESR2
HRH2
F10
PDE3A
GABRA1
GABRB2
HTR3A
KCNH2
TBXA2R
TACR1
VCAM1
LTB
CCR1
PDE3B
PDE4B
PTGS1
ESR1
PTGS2
Fibroblast
Pericyte
Smooth muscle
Serous
Basal
Multiciliated
Secretory
Mucous Multiciliated
Multiciliated N
Secretory N
Suprabasal N
Deuterosomal
Cycling Basal
Suprabasal
Endothelial
LT/NK
Macrophage
Dendritic
Monocyte
Cell Type
100
10
1
0.1
Fraction of expressing cells (%)

Figure 3

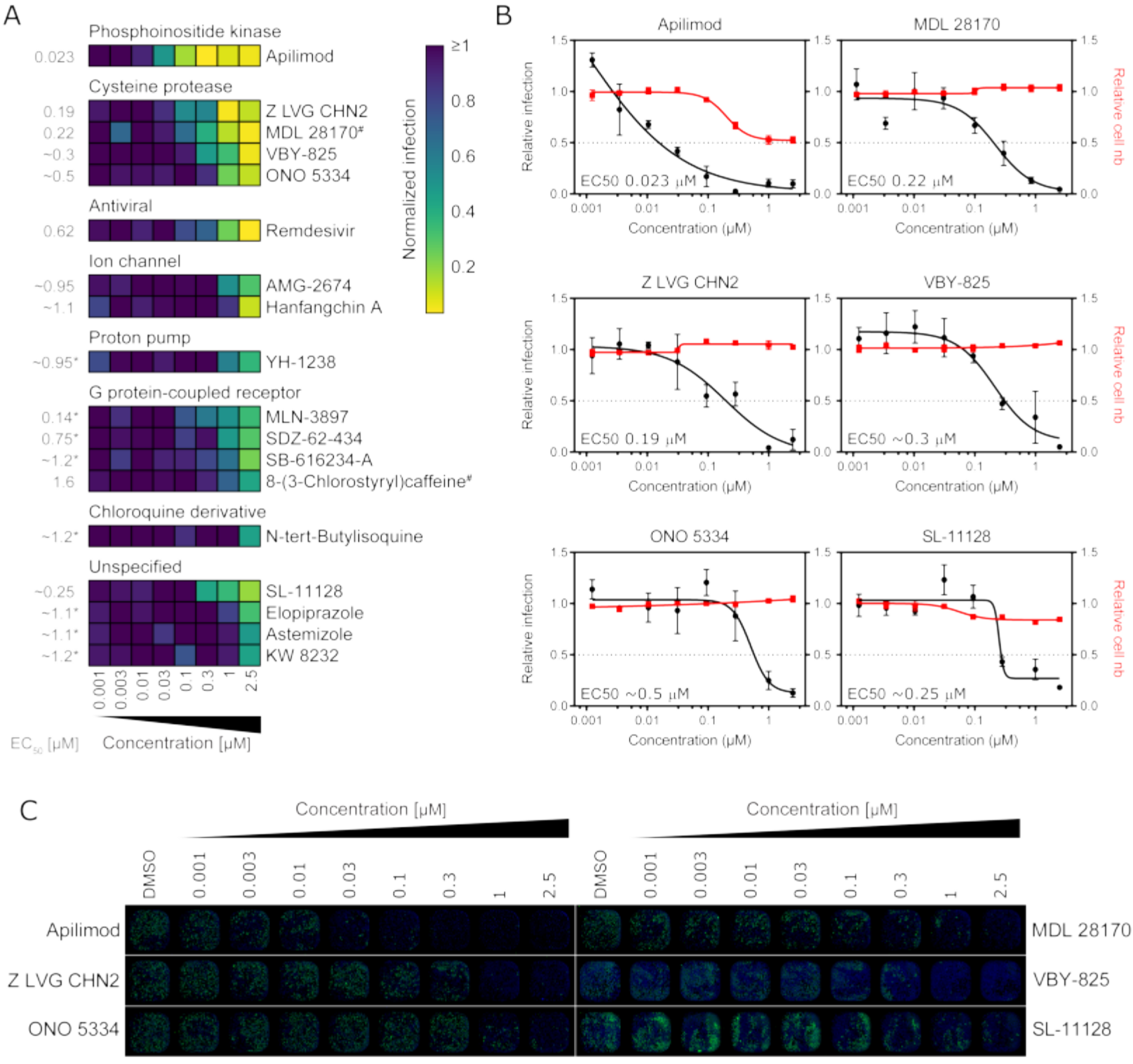

A
Phosphoinositide kinase
0.023 Apilimod
Cysteine protease
0.19 Z LVG CHN2
0.22 MDL 28170#
~0.3 VBY-825
~0.5 ONO 5334
Antiviral
0.62 Remdesivir
Ion channel
~0.95 AMG-2674
~1.1 Hanfangchin A
Proton pump
~0.95* YH-1238
G protein-coupled receptor
0.14* MLN-3897
0.75* SDZ-62-434
~1.2* SB-616234-A
1.6 8-(3-Chlorostyryl)caffeine#
Chloroquine derivative
~1.2* N-tert-Butylisoquine
Unspecified
~0.25 SL-11128
~1.1* Elopiprazole
~1.1* Astemizole
~1.2* KW 8232
Normalized infection
≥1
0.8
0.6
0.4
0.2
0.001 0.003 0.01 0.03 0.1 0.3 1 2.5
EC50 [μM]
Concentration [μM]
B
Apilimod
MDL 28170
Z LVG CHN2
VBY-825
ONO 5334
SL-11128
Relative infection
Relative cell nb
EC50 0.023 μM
EC50 0.22 μM
EC50 0.19 μM
EC50 ~0.3 μM
EC50 ~0.5 μM
EC50 ~0.25 μM
Concentration (μM)
C
Concentration [μM]
DMSO 0.001 0.003 0.01 0.03 0.1 0.3 1 2.5
Apilimod
Z LVG CHN2
ONO 5334
MDL 28170
VBY-825
SL-11128

Figure S1

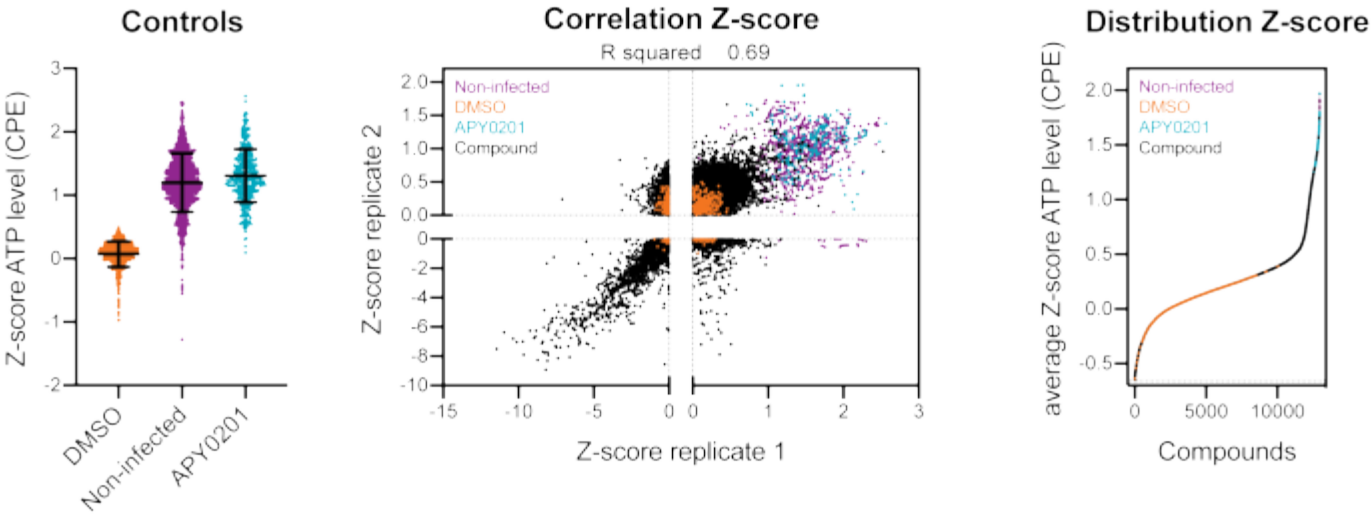
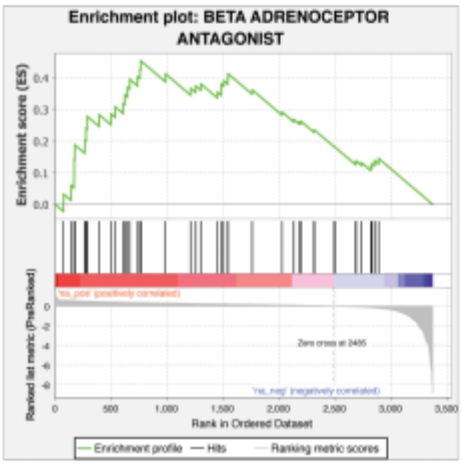
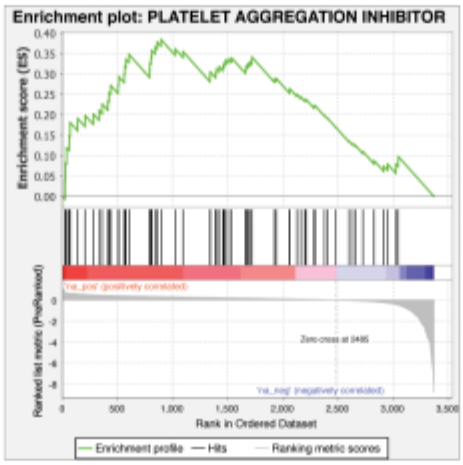
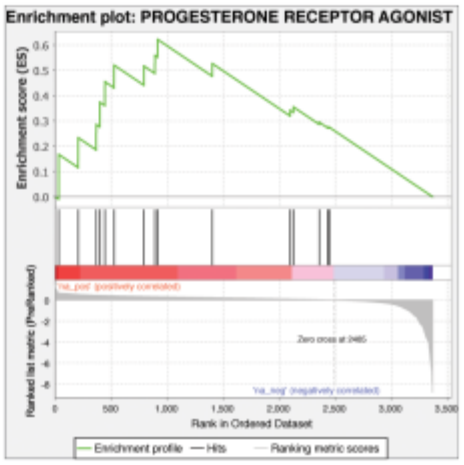
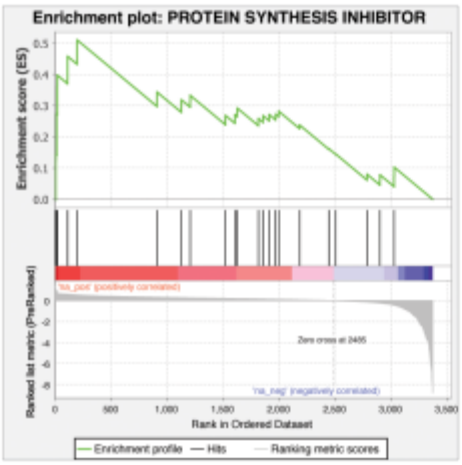

Controls
Z-score ATP level (CPE)
DMSO
Non-infected
APY0201
Correlation Z-score
R squared 0.69
Non-infected
DMSO
APY0201
Compound
Z-score replicate 2
Z-score replicate 1
Distribution Z-score
average Z-score ATP level (CPE)
Compounds

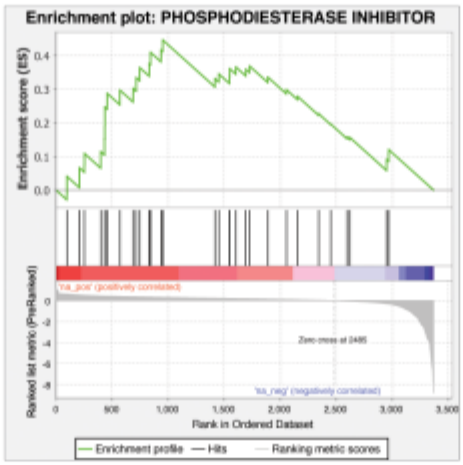
Figure S2

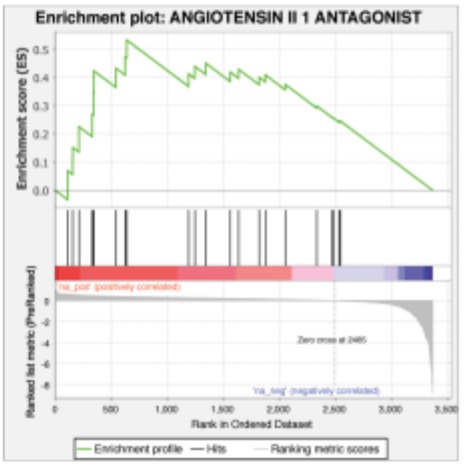


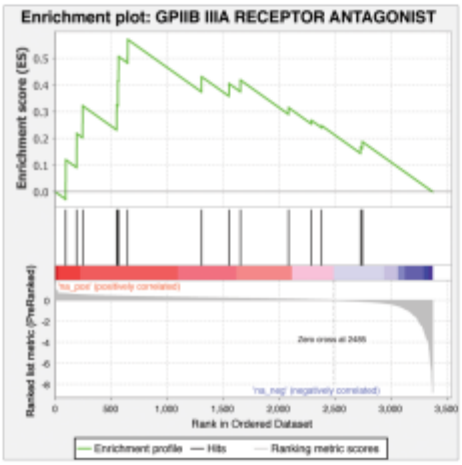


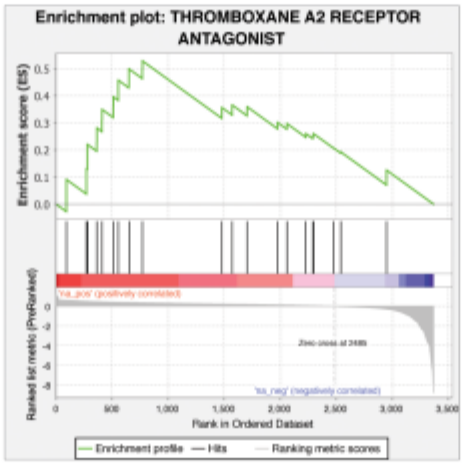


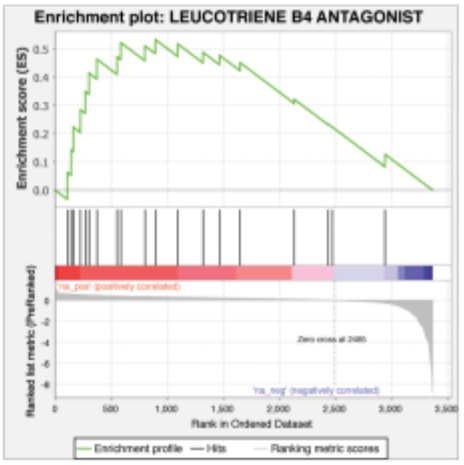












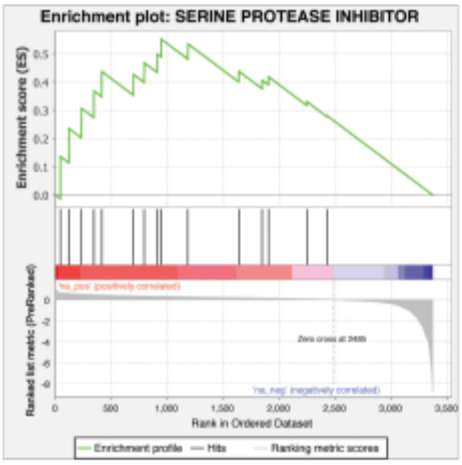


Figure S3

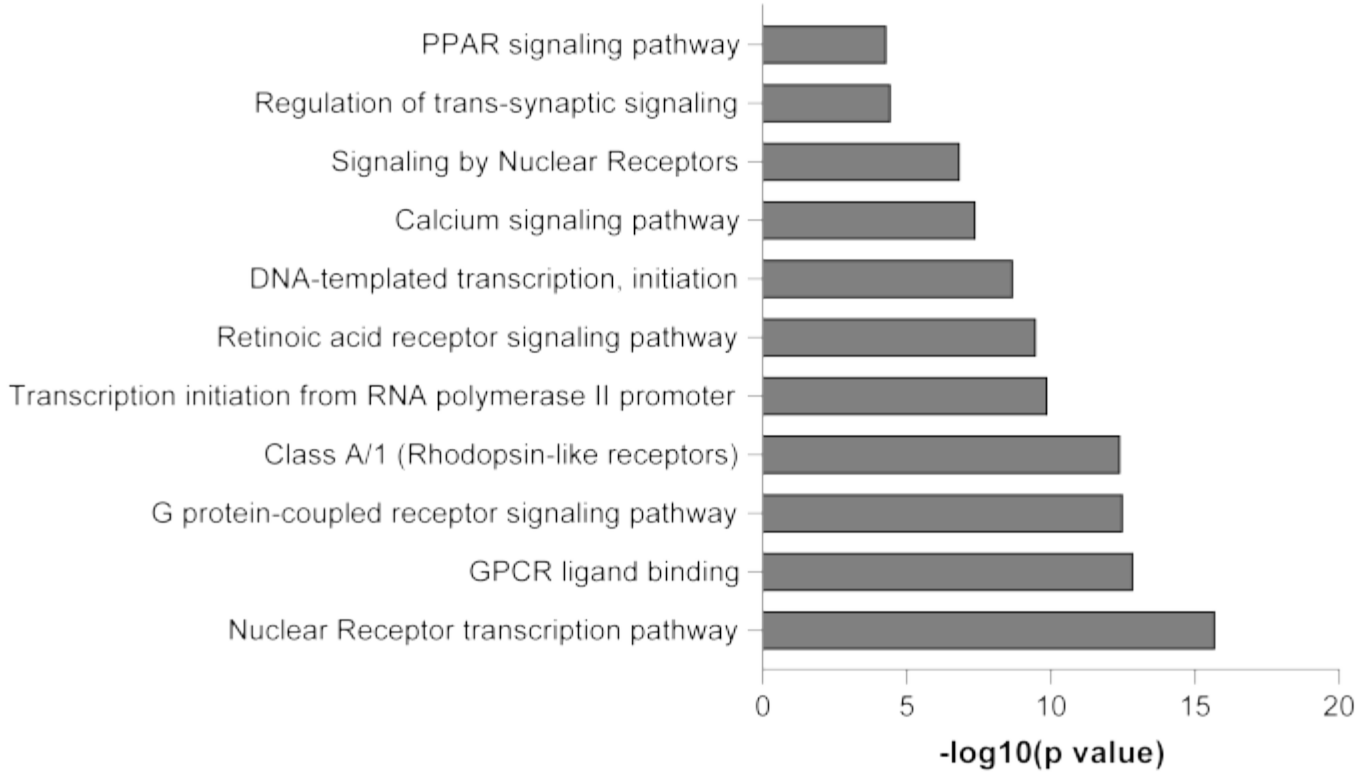

PPAR signaling pathway
Regulation of trans-synaptic signaling
Signaling by Nuclear Receptors
Calcium signaling pathway
DNA-templated transcription, initiation
Retinoic acid receptor signaling pathway
Transcription initiation from RNA polymerase II promoter
Class A/1 (Rhodopsin-like receptors)
G protein-coupled receptor signaling pathway
GPCR ligand binding
Nuclear Receptor transcription pathway
0
5
10
15
20
-log10(p value)

Figure S4

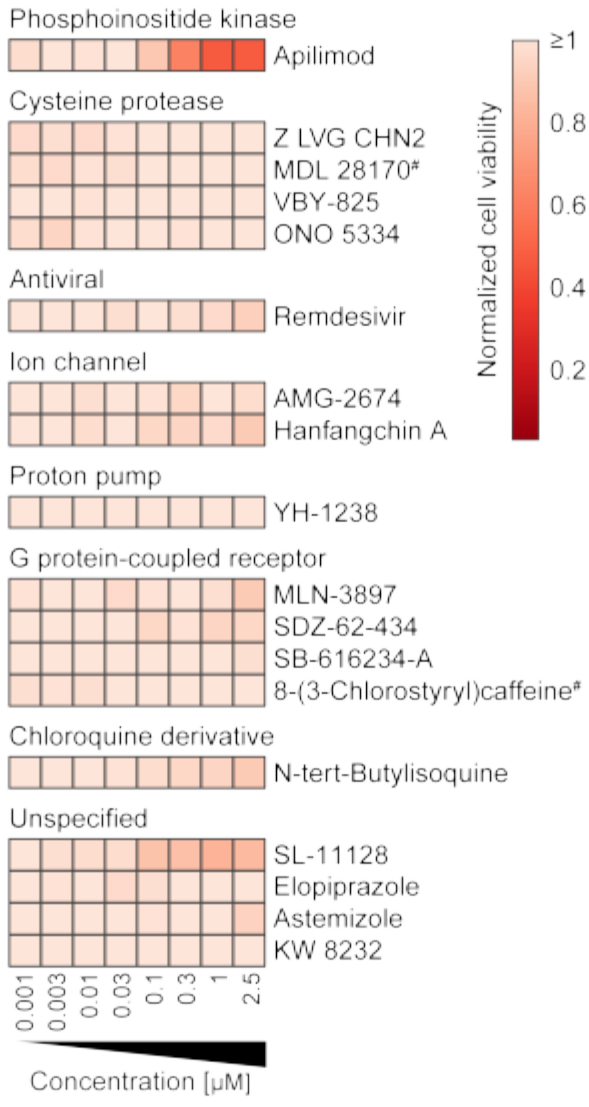
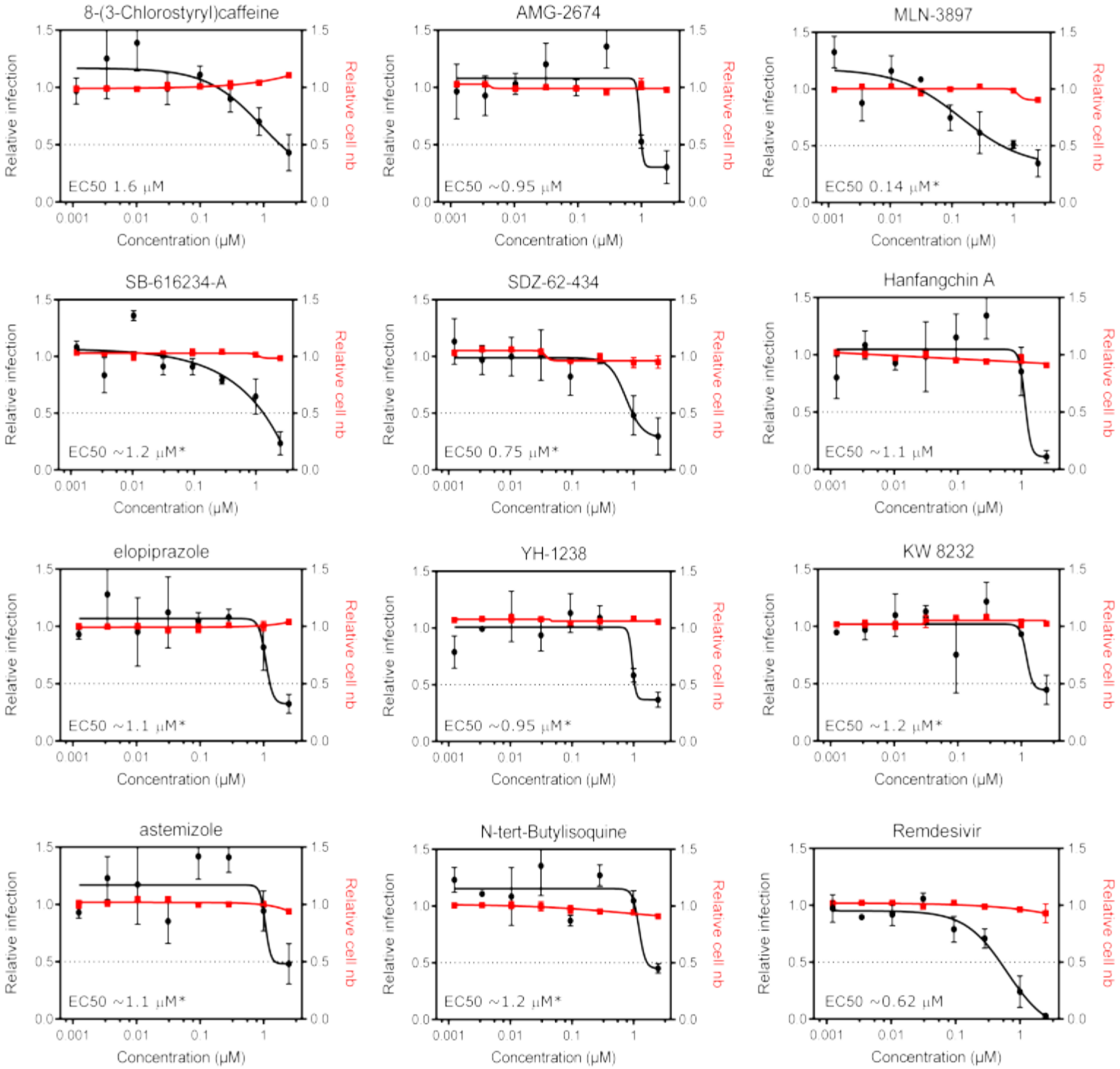

Phosphoinositide kinase
Apilimod
Cysteine protease
Z LVG CHN2
MDL 28170#
VBY-825
ONO 5334
Antiviral
Remdesivir
Ion channel
AMG-2674
Hanfangchin A
Proton pump
YH-1238
G protein-coupled receptor
MLN-3897
SDZ-62-434
SB-616234-A
8-(3-Chlorostyryl)caffeine#
Chloroquine derivative
N-tert-Butylisoquine
Unspecified
SL-11128
Elopiprazole
Astemizole
KW 8232
0.001
0.003
0.01
0.03
0.1
0.3
1
2.5
Concentration [μM]
Normalized cell viability
≥1
0.8
0.6
0.4
0.2

Figure S5


8-(3-Chlorostyryl)caffeine
EC50 1.6 μM
AMG-2674
EC50 ~0.95 μM
MLN-3897
EC50 0.14 μM*
SB-616234-A
EC50 ~1.2 μM*
SDZ-62-434
EC50 0.75 μM*
Hanfangchin A
EC50 ~1.1 μM
elopiprazole
EC50 ~1.1 μM*
YH-1238
EC50 ~0.95 μM*
KW 8232
EC50 ~1.2 μM*
astemizole
EC50 ~1.1 μM*
N-tert-Butylisoquine
EC50 ~1.2 μM*
Remdesivir
EC50 ~0.62 μM
Relative infection
Relative cell nb
Concentration (μM)
0.001
0.01
0.1
1
0.0
0.5
1.0
1.5

Name	IC50 range (µM)	Reported cellular IC50	Original indication	Highest phase	smiles	MOAs	Known targets	Cmax in humans	Category	Reference
Apilimod	0.033	IC51 nM	Autoimmune disease, Cancer	Phase 2 Clinical	Cc1cccc(c1)C(=O)Nc1cc(OCc2ccccn2)ccc1N1CCOCC1	A PIKfyve-dependent PtdIns4P synthesis inhibitors (Blocking the endocytosis)	PIKfyve	Cmax 0.295+/-0.163 uM (70 mg QD)	phosphoinositide kinase	[64]
VBY-825	~ 0.3	NA	Bone cancer, NASH, PBC	Phase II	CC[C@@H]([C+](O)[O-])NC1CC1(NC(=O)[C@@H]([C@+](O)(O)CC1CC1)NC(=O)[C@@H](CF)F)c1ccccc1F	A reversible cathepsin protease inhibitor	Cathepsins B, L, S and V	NA	Cysteine protease	
ONO-5334	~ 0.5	80% reduction at 0.1 µM (human osteoclast-mediated bone resorption assay)	Osteoporosis	Phase 2 Clinical	O=[C@]1CCCCCC1(N[C@@H]([C+](O)[O-])NC(=O)[C@@H](NC(=O)C[C@H](O)CC)C(C)C)CCCCC1	A cathepsin K inhibitor	Cathepsin K	Cmax 1.6uM (200 mg QD)	Cysteine protease	[57,62]
MLN-3897	0.14*	60 - 80% inhibition at 0.01 uM (osteoclast formation assay)	Bone disease, Inflammatory disease	Phase 2 clinical	ClC1cccc(c1)C1(O)CCN(C1)C(=O)CCc1cc2cc(ccc2[C@]2(N)CC2)[C+](O)[O-]	A specific antagonist of CCR1	C-C Motif Chemokine Receptor 1 (CCR1)	Cmax 9.0 nM (10 mg QD)	Gprotein-coupled receptor	[72]
BGZ-62-434	0.75*	5 uM - 111 uM (MTT cytotoxic assay)	Cancer	Phase 1 Clinical	C1CCN(CC1)Cc1nc(cs1)c1ccc(cc2nNCC)c12	A platelet-activating factor (PAF) antagonist, may have anti-inflammatory features derived from PI3K/Akt/NF-kappaB inhibitory activity	PAF /PI3K/Akt/NF-kappaB pathway	NA	Gprotein-coupled receptor	[58]
YH-1238	~ 0.697	NA	Stomach ulcer	Phase 1 Clinical	CCc1ccc(s1)c1nc(Nc1ccc(cc1C(F)(F)F)c2ncn[nH]2)C1CCccc2	Potassium-competitive acid antagonist	H^+, K^+-ATPase enzyme	NA	Proton Pump	
Bisopiprazole	~ 1.1*	NA	Psychotic disorder	Phase 1 Clinical	Fc1ccc(cc1)c1ccc([nH]1)C(=O)N[C@H]1CN1CCN(CC1)c1ccccc2c1ncc2	An antipsychotic drug of the phenylpiperazine class, an antagonist at dopamine D2 and D3 receptors and an agonist at serotonin 5A receptors.	D2, D3, 5-HT1A receptor	NA	Unspecified	
zolenicotine	~ 1.1*	0.08 uM (HERG K+ channel); 0.089-0.37 uM (antiplasmodium activity)	Allergies	Registered and withdrawn	CCc1ccc(s1)C(N1CCCC(C1)Nc1ncc2c(n1)CCN(c1ccccc1)F)ccc2	A histamine H1-receptor antagonist, KCNH voltage-gated potassium channel-1 inhibitor; Unspecified ion channel modulator	Histamine H1 receptor	NA	Unspecified	[70]

To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Wed 4/22/2020 8:55:24 AM (UTC-04:00)
Subject: FW: interesting paper

Thought you might be interested.

Complex Immune Dysregulation in COVID-19 Patients with Severe Respiratory Failure

Evangelos J. Giamarellos-Bourboulis, Mihai G. Netea, Nikoletta Rovina, Karolina Akinosoglou, Anastasia Antoniadou, Nikolaos Antonakos, Georgia Damoraki, Theologia Gkavogianni, Maria-Evangelia Adami, Paraskevi Katsaounou, Maria Ntaganou, Magdalini Kyriakopoulou, George Dimopoulos, Ioannis Koutsodimitropoulos, Dimitrios Velissaris, Panagiotis Koufargyris, Athanassios Karageorgos, Konstantina Katrini, Vasileios Lekakis, Mihaela Lupse, Antigone Kotsaki, George Renieris, Danai Theodoulou, Vassiliki Panou, Evangelia Koukaki, Nikolaos Koulouris, Charalambos Gogos, Antonia Koutsoukou

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To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Rappaport, Jay[jrappaport@tulane.edu]
Sent: Wed 4/22/2020 10:32:26 AM (UTC-04:00)
Subject: Re: interesting paper

Joe,
Thanks, this is very intetesting . The effect of plasma on HLADR expression is concerning and the immune dysregulatiom observed may provide biomarkers for enhancement.
Im sure you are thinking the same.
Best regards,
Jay

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From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Wednesday, April 22, 2020 7:55:24 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
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Senior Investigator
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National Institute of Allergy and Infectious Diseases

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National Institutes of Health
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Office: 240-669-5598
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To: 'Jonna Mazet'[jkmazet@ucdavis.edu]; 'David A Relman'[relman@stanford.edu]; 'andersen@scripps.edu'[andersen@scripps.edu]; 'trevor@bedford.io'[trevor@bedford.io]; 'dgriffi6@jhu.edu'[dgriffi6@jhu.edu]; 'daszak@ecohealthalliance.org'[daszak@ecohealthalliance.org]; Baric, Ralph S[rbaric@email.unc.edu]
Cc: Shore, Carolyn[CShore@nas.edu]; 'andre@ecohealthalliance.org'[andre@ecohealthalliance.org]; 'Mary Radford'[maradford@ucdavis.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Brown, Lisa[LBrown@nas.edu]; Pope, Andrew[APope@nas.edu]
From: Downey, Autumn[ADowney@nas.edu]
Sent: Wed 4/22/2020 3:47:32 PM (UTC-04:00)
Subject: RE: Next Steps - Viral Characteristics Working Group for the Standing Committee on Emerging Infectious Diseases

Dear Viral Characteristics Work Group members,

As a gentle reminder, please try to send your availability for a 1-hour Working Group call by COB today if you have not already done so. The date/time options under consideration are:

- 4/23: 5-6pm ET/2-3pm PT
- 4/27: 12-1pm ET/9-10am PT
- 4/27: 1-2pm ET/10-11am PT
- 4/28: 1-2pm ET/10-11am PT
- 4/28: 4-5pm ET/1-2pm PT
- 4/28: 5-6pm ET/2-3pm PT

Best,

Autumn and Carolyn

From: Downey, Autumn
Sent: Tuesday, April 21, 2020 5:30 PM
To: Jonna Mazet <jkmazet@ucdavis.edu>; 'David A Relman' <relman@stanford.edu>; 'andersen@scripps.edu' <andersen@scripps.edu>; 'trevor@bedford.io' <trevor@bedford.io>; 'dgriffi6@jhu.edu' <dgriffi6@jhu.edu>; 'daszak@ecohealthalliance.org' <daszak@ecohealthalliance.org>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>
Cc: Shore, Carolyn <CShore@nas.edu>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'Mary Radford' <maradford@ucdavis.edu>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; Brown, Lisa <LBrown@nas.edu>; Pope, Andrew <APope@nas.edu>
Subject: Next Steps - Viral Characteristics Working Group for the Standing Committee on Emerging Infectious Diseases

Dear Members of the Viral Characteristics Working Group,

We are writing to initiate next steps with your respective working group (WG). David Relman and Jonna Mazet have graciously volunteered to be the co-leads of your WG.

In preparation for the second virtual committee meeting (scheduled for Thursday, April 30th from 11:00 a.m. – 1:30 p.m. ET), Harvey is asking each WG to identify the most important intermediate range topic (to be addressed in weeks to months) within your WG domain (see attached list of topics). The WG is more than welcome to identify more than one priority; and, in the event the WG identifies more than one priority, the WG should designate the one priority at the top of the list. The goal will be to briefly present and discuss these priorities during the second committee meeting.

When describing topics for priority consideration, we are asking each WG to specify the following:

1) Question, topic or task, with clear objectives and rationale
2) Suitable type of product (telephonic consultation, rapid expert consultation, letter report, or consensus report)
3) Primary audience for the assessment
4) Anticipated time-frame for completion
5) Volunteers from the standing committee and working groups, and suggestions for additional experts to serve on the response team

We are asking David and Jonna as the co-leads of this WG to take the lead and initiate discussions within this email chain. In the meantime, we would also like to convene at least one meeting of the WG before the second virtual committee meeting. Please let

us know by COB tomorrow if possible (via email response) if you can be available for a 1-hour call during any of the following dates/times:

- 4/23: 5-6pm ET/2-3pm PT
- 4/27: 12-1pm ET/9-10am PT
- 4/27: 1-2pm ET/10-11am PT
- 4/28: 1-2pm ET/10-11am PT
- 4/28: 4-5pm ET/1-2pm PT
- 4/28: 5-6pm ET/2-3pm PT

Very best,
Autumn and Carolyn

Autumn Downey, Ph.D.
Senior Program Officer
Health and Medicine Division | Find us at nationalacademies.org/HMD
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW
Washington, DC 20001
Phone: 202-334-2046
Follow Us

From: Downey, Autumn[ADowney@nas.edu]

Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew

Location: Zoom information to follow

Importance: Normal

Subject: HOLD - Viral Characteristics WG Discussion

Start Time: Thur 4/23/2020 5:00:00 PM (UTC-04:00)

End Time: Thur 4/23/2020 6:00:00 PM (UTC-04:00)

Required Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew

Dear working group members,

We've narrowed the WG call to two possible dates and are sending a hold for both pending receipt of availability information from the remaining members. Since one of the options is tomorrow afternoon/evening, we'll confirm no later than tomorrow morning.

Best,
Autumn and Carolyn

Organizer: Downey, Autumn[ADowney@nas.edu]

From: Downey, Autumn[ADowney@nas.edu]

Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew; Harvey V. Fineberg; 'jennifer.ryan@moore.org'; Pavlin, Julie; kga1978@gmail.com

Location: https://nasem.zoom.us/j/98223865986

Importance: Normal

Subject: CONFIRMED - Viral Characteristics WG Discussion

Start Time: Thur 4/23/2020 5:00:00 PM (UTC-04:00)

End Time: Thur 4/23/2020 6:00:00 PM (UTC-04:00)

Required Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew; Harvey V. Fineberg; 'jennifer.ryan@moore.org'; Pavlin, Julie

Optional Attendees: kga1978@gmail.com

SCEID Working Group Topics and Questions w Leads_v5.docx

Updated with Zoom Information

Dear working group members,

It appears nearly everyone is available tomorrow afternoon/evening so we are confirming the WG call for 5-6pm ET/2-3pm PT for April 23. The Zoom information is below and the topic list for prioritization is attached. Please let us know if you have any questions or concerns. We look forward to talking tomorrow!

Best,
Autumn and Carolyn

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/98223865986

Or iPhone one-tap :
US: +16465189805,,98223865986# or +16465588656,,98223865986#
Or Telephone:
Dial(for higher quality, dial a number based on your current location):
US: +1 646 518 9805 or +1 646 558 8656 or +1 312 626 6799 or +1 470 250 9358 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 301 715 8592 or +1 602 753 0140 or +1 651 372 8299 or +1 669 219 2599 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 982 2386 5986
International numbers available: https://nasem.zoom.us/u/aoQzNPqzu

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Topics for Consideration

**Note: Underlined names indicate that formal committee appointment is pending.

Group A – Viral Characteristics (SC Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
Mechanisms for pathogenesis
One Health

Viral characterization (virus genetics, origin, and evolution of SARS-CoV-2)

Examples of short-term research needs

- Biological/molecular characteristics of SARS-CoV-2
- Real-time tracking of whole genomes and a mechanism for coordinating the rapid dissemination of that information to inform the development of diagnostics and therapeutics and to track variations of the virus over time.
- Access to geographic and temporal diverse sample sets to understand geographic distribution and genomic differences, and determine whether there is more than one strain in circulation. Multi-lateral agreements such as the Nagoya Protocol could be leveraged.

Transmission, incubation, and environmental stability

Examples of short-term research needs

- Physical science of the coronavirus (e.g., charge distribution, adhesion to hydrophilic/phobic surfaces, environmental survival to inform decontamination efforts for affected areas and provide information about viral shedding).
- Persistence and stability on a multitude of substrates and sources (e.g., nasal discharge, sputum, urine, fecal matter, blood).
- Persistence of virus on surfaces of different materials (e,g., copper, stainless steel, plastic).
- Effective decontamination protocols

- Range of incubation periods for the disease in humans (and how this varies across age and health status) and how long individuals are contagious, even after recovery.
- Prevalence of asymptomatic shedding and transmission (e.g., particularly children).
- Seasonality of transmission.
- Correlates of immunity- and whether immunity occurs and duration.
- Resistance of previously infected people to mutated strains.

One Health

Examples of long-term research needs

- Enhance capacity (people, technology, data) for sequencing with advanced analytics for unknown pathogens, and explore capabilities for distinguishing naturally-occurring pathogens from intentional.
- One Health surveillance of humans and potential sources of future spillover or ongoing exposure for this organism and future pathogens, including both evolutionary hosts (e.g., bats) and transmission hosts (e.g., heavily trafficked and farmed wildlife and domestic food and companion species), inclusive of environmental, demographic, and occupational risk factors.
- Evidence that livestock could be infected (e.g., field surveillance, genetic sequencing, receptor binding) and serve as a reservoir after the epidemic appears to be over.
  - Evidence of whether farmers are infected, and whether farmers could have played a role in the origin.
  - Surveillance of mixed wildlife- livestock farms for SARS-CoV-2 and other coronaviruses in Southeast Asia.
  - Experimental infections to test host range for this pathogen.

Group B – Patient Care and Medical Countermeasures (MCM) (SC Leads: Don Berwick, Margaret Hamburg)

Staff Leads: Lisa Brown and Scott Wollek

Members: Kristian Andersen
Diane Griffin
John Hick
Kent Kester
Tara O'Toole
David Relman
David Walt
Dan Hanfling

Topics: Vaccines and therapeutics
Diagnostics
Patient care (including personal protective equipment, crisis standards of care, and quality)

Vaccines and therapeutics

- How to expedite development, manufacturing, distribution of a safe, effective vaccine.
- Need for an end-to-end process for getting promising products to the people who need them (e.g. small biotechs may not have developed a vaccine before and may lack scale-up manufacturing and/or support for larger studies)
- Research and development and evaluation efforts
  Examples of short-term research needs
    - Evaluate/investigate effectiveness of drugs and antivirals being developed and tried to treat COVID-19 patients.
        - E.g., Would it be beneficial to give IL6 receptor antibodies therapy prior to admission to the ICU; use of monoclonal antibodies.
    - Clinical and bench trials to investigate less common viral inhibitors against COVID-19 such as naproxen, clarithromycin, and minocycline that may exert effects on viral replication.
    - Methods to evaluate potential complication of Antibody-Dependent Enhancement (ADE) in vaccine recipients.
    - From a clinical development perspective, explore use of best animal models and their predictive value for a human vaccine.
    - Capabilities to discover a therapeutic (not vaccine) for the disease, and clinical effectiveness studies to discover therapeutics, to include antiviral agents.
    - Alternative models to aid decision makers in determining how to prioritize and distribute scarce, newly proven therapeutics as production ramps up. This could include identifying approaches for expanding production capacity to ensure equitable and timely distribution to populations in need.

  Example of long-term research needs
    - Efforts targeted at a universal coronavirus vaccine.

Diagnostics

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes)
  Examples of short-term research needs
    - Evaluate how widespread current exposure is to be able to make immediate policy recommendations on mitigation measures. Denominators for testing and a mechanism for rapidly sharing that information, including demographics, to the extent possible. Sampling methods to determine asymptomatic disease (e.g., use of serosurveys (such as convalescent samples) and early detection of disease (e.g., use of screening of neutralizing antibodies such as ELISAs),
    - Efforts to increase capacity on existing diagnostic platforms and tap into existing surveillance platforms.

- Development of a rapid, point-of-care test (like a rapid influenza test; home tests;) and rapid bed-side tests, recognizing the tradeoffs between speed, accessibility, and accuracy.
- Best tests to look at IgM and IgG antibodies and how best to scale up and create a rapid test.
- Rapid design and execution of targeted surveillance experiments calling for all potential testers using PCR in a defined area to start testing and report to a specific entity. These experiments could aid in collecting longitudinal samples, which are critical to understanding the impact of ad hoc local interventions (which also need to be recorded).
- Separation of assay development issues from instruments, and the role of the private sector to help quickly migrate assays onto those devices.
- Establish efforts to track the evolution of the virus (i.e., genetic drift or mutations) and avoid locking into specific reagents and surveillance/detection schemes.
- Latency issues and when there is sufficient viral load to detect the pathogen, and understanding of what is needed in terms of biological and environmental sampling.
- Use of diagnostics such as host response markers (e.g., cytokines) to detect early disease or predict severe disease progression, which would be important to understanding best clinical practice and efficacy of therapeutic interventions.
- Policies and protocols for screening and testing.
- Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.

Examples of long-term research needs

- Technology roadmap for diagnostics.
- Barriers to developing and scaling up new diagnostic tests (e.g., market forces), how future coalition and accelerator models (e.g., Coalition for Epidemic Preparedness Innovations) could provide critical funding for diagnostics, and opportunities for a streamlined regulatory environment.
- New platforms and technology (e.g., CRISPR) to improve response times and employ more holistic approaches to COVID-19 and future diseases.
- Coupling genomics and diagnostic testing on a large scale.
- Enhance capabilities for rapid sequencing and bioinformatics to target regions of the genome that will indicate specificity for a particular variant.

Patient care

- Risk factors

  Examples of short-term research needs

  - Data on potential risks factors
    - Smoking, pre-existing pulmonary disease
    - Co-infections (determine whether co-existing respiratory/viral infections make the virus more transmissible or virulent) and other co-morbidities

    - Differences in respiratory/viral infections for neonates and pregnant women
    - Socio-economic and behavioral factors to understand the economic impact of the virus and whether there were differences.
    - Pediatrics – Innate immune system of children vs adaptive immune system response of adults (e.g., cross reactivity between some routine childhood vaccinations that is providing protection to the youngest in the population).
- Surge capacity and nursing homes
  Examples of short-term research needs
    - Resources to support skilled nursing facilities and long term care facilities.
    - Mobilization of surge medical staff to address shortages in overwhelmed communities.
- Efforts to inform allocation of scarce resources
  Examples of short-term research needs
    - Age-adjusted mortality data for Acute Respiratory Distress Syndrome (ARDS) with/without other organ failure – particularly for viral etiologies
    - Extracorporeal membrane oxygenation (ECMO) outcomes data of COVID-19 patients; and,
    - Outcomes data for COVID-19 after mechanical ventilation adjusted for age.
    - Knowledge of the frequency, manifestations, and course of extra-pulmonary manifestations of COVID-19, including, but not limited to, possible cardiomyopathy and cardiac arrest.
    - Application of regulatory standards (e.g., EUA, CLIA) and ability to adapt care to crisis standards of care level.
- Personal protective equipment
  Example of short-term research needs
    - Approaches for encouraging and facilitating the production of elastomeric respirators, which can save thousands of N95 masks.
    - Efficacy of cloth face coverings.
- Alternative methods to advise on disease management
  Examples of short-term research needs
    - Best telemedicine practices, barriers and facilitators, and specific actions to remove/expand them within and across state boundaries.
    - Guidance on the simple things people can do at home to take care of sick people and manage disease.
    - OTC oral medications that might potentially work.

  Example of long-term research needs
    - Use of AI in real-time health care delivery to evaluate interventions, risk factors, and outcomes in a way that could not be done manually.
- Processes of care
  Example of short-term research needs

- Best practices and critical challenges and innovative solutions and technologies in hospital flow and organization, workforce protection, workforce allocation, community-based support resources, payment, and supply chain management to enhance capacity, efficiency, and outcomes.

Group C – Community Engagement and Population Health (SC Leads: Mary Travis Bassett, Robert Groves)

Staff Leads: Julie Pavlin and Monica Feit (DBASSE)

Members: Georges Benjamin
Rich Besser
Peter Daszak
Phyllis Meadows
Alexandra Phelan
Mark Smolinski
Jeff Duchin
Baruch Fischhoff
(SBS WG, membership TBD)

Topics: Epidemiology and population surveillance
Social and public health interventions
Public communication and understanding
Occupational safety and health

Epidemiology and population surveillance

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes and for understanding/guidance to be implemented).
  Examples of short-term research needs
  - Plans for sero-surveys of previously exposed/immune individuals. Evaluation of background level of people with Covid19 antibodies in the community.
  - Policies and protocols for screening and testing (e.g. screening/testing schedule for post-exposure).
  - Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.
  - Recruitment, support, and coordination of local expertise and capacity (public, private—commercial, and non-profit, including academic), including legal, ethical, communications, and operational issues.
  - National guidance and guidelines about best practices to states (e.g., how states might leverage universities and private laboratories for testing purposes, communications to public health officials and the public).
  - Validation and sharing (and effectively using) modeling outputs.

Social and public health interventions

Example of short-term research needs

- Effectiveness of non-therapeutic public health measures (e.g. patient contact tracing, social distancing strategies, school closings, telework). Rapid design and execution of experiments to examine and compare NPIs currently being implemented.
    - Risk/benefit of various social distancing measures
        - Optimal timing of social distancing (what are the triggers to start, when is it too late)
        - Importance of herd immunity
        - Avoiding the second wave
- Guidance on ways to scale up NPIs in a more coordinated way to give us time to enhance our health care delivery system capacity to respond to an increase in cases.
- Methods to control the spread in communities, barriers to compliance, and how these vary among different populations.

Examples of long-term research needs

- Models of potential interventions to predict costs and benefits that take account of such factors as race, income, disability, age, geographic location, immigration status, housing status, employment status, and health insurance status.
- Policy changes necessary to enable the compliance of individuals with limited resources and the underserved with NPIs. Research on why people fail to comply with public health advice, even if they want to do so (e.g., social or financial costs may be too high).
- Research on the economic impact of this or any pandemic. This would include identifying policy and programmatic alternatives that lessen/mitigate risks to critical government services, food distribution and supplies, access to critical household supplies, and access to health diagnoses, treatment, and needed care, regardless of ability to pay.

Public communication and understanding

- Messaging to the public, health professionals, civic leaders, etc.
- Communicating with high-risk populations

Examples of short-term research needs

- Modes of communicating with target high-risk populations (elderly, health care workers, first responders).
- Risk communication and guidelines that are easy to understand and follow (include targeting at risk populations' families too).
- Communication that indicates potential risk of disease to all population groups.
- Clarify community measures
- Clarify misunderstanding around containment and mitigation

Group D – Cross-Cutting Issues (SC Leads: Tara O'Toole, Alta Charo)

Staff Leads: Andy Pope and Lisa Brown

Members: Rich Besser
Ellen Embry
Patricia King
Jonna Mazet
Phyllis Meadows
Alexandra Phelan
Don Berwick

Topics: Ethics, equity, and law
International relations and cooperation
Innovative solutions across the public and private sectors
Lessons learned/future outbreaks

Ethics, equity, and law

- Consideration of the health needs and wellbeing of underserved/disinfranchised populations

  Examples of short-term research needs
  - Action plan to mitigate gaps and problems of inequity in the Nation's public health capability, capacity, and funding to ensure all citizens in need are supported and can access information, surveillance, and treatment.
  - Measures to reach marginalized and disadvantaged populations.
  - Data systems and research priorities and agendas incorporate attention to the needs and circumstances of disadvantaged populations and underrepresented minorities.
  - Understand and mitigate threats to incarcerated people from COVID-19, assuring access to information, prevention, diagnosis, and treatment.
  - Understand coverage policies (barriers and opportunities) related to testing, treatment, and care

International relations and cooperation

- The role of international regulatory organizations, WHO, etc
- Reliance and mutual recognition agreements (see NASEM study: Mutual Recognition Agreements in the Regulation of Medicines https://www.nationalacademies.org/our-work/mutual-recognition-agreements-in-the-regulation-of-medicines)
- Data standards and nomenclature:
  - Methods for coordinating data-gathering with standardized nomenclature.
  - Consistent platform for sharing response information among planners, providers, and others.
  - Understand and mitigate barriers to information-sharing.

Innovative solutions across public and private sectors

- Governmental public health

  Example of short-term research needs

  - Determine how to recruit, support, and coordinate local (non-Federal) expertise and capacity relevant to public health emergency response (public, private—commercial and non-profit, including academic).

  Examples of long-term research needs

  - Better integration of federal/state/local public health surveillance systems.
  - Value of investments in baseline public health response infrastructure, preparedness capacity, and capability.

Lessons learned/Future outbreaks

- Research needs to improve our understanding of the viral diversity and risk factors for viruses that are not yet known to medicine, but exist and are available to infect humans and present epidemic and pandemic threats.
- Research needs and evaluation metrics to inform the immediate response and future outbreak response.

From: Downey, Autumn[ADowney@nas.edu]

Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew

Location: Zoom information to follow

Importance: Normal

Subject: HOLD - Viral Characteristics WG Discussion

Start Time: Tue 4/28/2020 5:00:00 PM (UTC-04:00)

End Time: Tue 4/28/2020 6:00:00 PM (UTC-04:00)

Required Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew

Dear working group members,

We've narrowed the WG call to two possible dates and are sending a hold for both pending receipt of availability information from the remaining members. Since one of the options is tomorrow afternoon/evening, we'll confirm no later than tomorrow morning.

Best,
Autumn and Carolyn

Organizer:	Downey, Autumn[ADowney@nas.edu]
From:	Downey, Autumn[ADowney@nas.edu]
Attendees:	'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew
Location:	Zoom information to follow
Importance:	Normal
Subject:	Canceled: HOLD - Viral Characteristics WG Discussion
Start Time:	Tue 4/28/2020 5:00:00 PM (UTC-04:00)
End Time:	Tue 4/28/2020 6:00:00 PM (UTC-04:00)
Required Attendees:	'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew
Optional Attendees:	kga1978@gmail.com

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Importance:	High
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Optional Attendees:	kga1978@gmail.com

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Autumn and Carolyn

To: zlshi@wh.iov.cn[zlshi@wh.iov.cn]; virologica@wh.iov.cn[virologica@wh.iov.cn]
Cc: Baric, Ralph S[rbaric@email.unc.edu]; johan.neyts@kuleuven.be[johan.neyts@kuleuven.be]
From: Glenn Diamond[glenn.evan.diamond@gmail.com]
Sent: Wed 4/22/2020 8:50:59 PM (UTC-04:00)
Subject: Duplicate - Letter to the Editor of Virologica Sinica

Duplicate

Professor Shi Zhengli, distinguished editor of Virologica Sinica
Copy Professor Ralph Baric, legendary American coronavirus expert
Copy Professor Johan Neyts, president of the International Society for Antiviral Research

Letter to the Editor

Respectfully Submitted by Glenn Diamond, Founder and Chief Virologist, United States Antivirals, an emergency antiviral medicines company, Los Angeles, California

April 22nd, 2020
Dear Editor,
The world is shut down by a virus, a coronavirus gone rogue called SARS-CoV-2, who would have imagined that that could ever really happen?
Sure, we warned all who would listen about the possible pandemic threat in many of our publications and lectures, but, surely, we all felt confident in our heart of hearts that that could never happen on our watch.
Yet, SARS-CoV-2 has ambushed the world, and, surely, it has surprised most of us in the virology field.
Well, here we are, this is a very very very bad situation, and, now, we need to get serious, all politics and national boundaries aside, and, all business aside, too, because, my fellow virologists, we are dealing with an ongoing catastrophe, in virus time, in viral reality, and not a one of us wants to see the world collectively snap.
Being a can do person, of the last of the proteges of Bob Swanson, who founded the legendary biotechnology company Genentech and with that the world biotechnology industry, I am already far along in my strategy and the associated biomolecular weaponry against this nemesis, once my emergency company is funded it will probably be game over for SARS-CoV-2.
But, still, for me and the other applied virologists in science and industry whom we all are depending on to wind down this mostly man made calamity, it would be helpful if we had a perfectly complete picture of this virus, all aspects of its existence and its materiality, because, time matters, our twenty first century civilization and our tightly interwoven global economy cannot handle for long the necessary mitigation measures, the speeches and declarations of our government officials notwithstanding.
So, yes, even amongst those of us all across our besieged planet who are most learned in and innovative with the most advanced knowledge and methodologies of our beloved virology field, our endeavors are constrained by a less than perfect picture of all of the specifics about the SARS-CoV-2 virus itself.
Of course, we know its sequence and we know its virionics and we know its devastating effects, but we need to know everything, absolutely everything, about this nemesis.
Because now SARS-CoV-2 is loose and it is beginning to up its game, and people everywhere in the world are not only highly inconvenienced but also very afraid.
So, this humble letter is a clarion call for any and all amongst us men and women of science and medicine in this honorable global virology community to hasten, in virus time, to provide any and all information, both information that there is and information that may exist but is not supposed to exist, because, no one can be certain in advance which piece of information is that key missing piece of the puzzle once solved that prompts the beginning of the end of the reign of terror of SARS-CoV-2.
I do not mention governments or other political entities in this humble letter of mine, because, frankly, this is a matter for our civilization as a whole, and the parochial priorities and designs of our various governments do not matter any more.
As to the mechanics of the creation and the structure of the SARS-CoV-2 information clearinghouse that I am proposing here, I respectfully suggest that we leave that up to Professor Shi Zhengli of China and Professor Ralph Baric of the United States, probably the two most outstanding coronavirus minds in our worldwide virology community, to put their heads together and rapidly organize that for our International Society for Antiviral Research to field and maintain through the duration of this crisis that is unparalleled in modern human history.
My fellow virologists, SARS-CoV-2 is our responsibility, therefore, let us take responsibility, immediately.
Respectfully submitted,

Glenn Diamond
Founder and Chief Virologist
United States Antivirals
An Emergency Antiviral Medicines Company
Los Angeles, California

Duplicate

From: Downey, Autumn[ADowney@nas.edu]

Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew; Harvey V. Fineberg; 'jennifer.ryan@moore.org'; Pavlin, Julie; kga1978@gmail.com

Location: https://nasem.zoom.us/j/98223865986

Importance: Normal

Subject: CONFIRMED - Viral Characteristics WG Discussion

Start Time: Thur 4/23/2020 5:00:00 PM (UTC-04:00)

End Time: Thur 4/23/2020 6:00:00 PM (UTC-04:00)

Required Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew; Harvey V. Fineberg; 'jennifer.ryan@moore.org'; Pavlin, Julie

Optional Attendees: kga1978@gmail.com

SCEID Working Group Topics and Questions w Leads_v5.docx

Updated with Zoom Information

Dear working group members,

It appears nearly everyone is available tomorrow afternoon/evening so we are confirming the WG call for 5-6pm ET/2-3pm PT for April 23. The Zoom information is below and the topic list for prioritization is attached. Please let us know if you have any questions or concerns. We look forward to talking tomorrow!

Best,
Autumn and Carolyn

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/98223865986

Or iPhone one-tap :
US: +16465189805,,98223865986# or +16465588656,,98223865986#
Or Telephone:
Dial(for higher quality, dial a number based on your current location):
US: +1 646 518 9805 or +1 646 558 8656 or +1 312 626 6799 or +1 470 250 9358 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 301 715 8592 or +1 602 753 0140 or +1 651 372 8299 or +1 669 219 2599 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 982 2386 5986
International numbers available: https://nasem.zoom.us/u/aoQzNPqzu

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Topics for Consideration

**Note: Underlined names indicate that formal committee appointment is pending.

Group A – Viral Characteristics (SC Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
Mechanisms for pathogenesis
One Health

Viral characterization (virus genetics, origin, and evolution of SARS-CoV-2)

Examples of short-term research needs

- Biological/molecular characteristics of SARS-CoV-2
- Real-time tracking of whole genomes and a mechanism for coordinating the rapid dissemination of that information to inform the development of diagnostics and therapeutics and to track variations of the virus over time.
- Access to geographic and temporal diverse sample sets to understand geographic distribution and genomic differences, and determine whether there is more than one strain in circulation. Multi-lateral agreements such as the Nagoya Protocol could be leveraged.

Transmission, incubation, and environmental stability

Examples of short-term research needs

- Physical science of the coronavirus (e.g., charge distribution, adhesion to hydrophilic/phobic surfaces, environmental survival to inform decontamination efforts for affected areas and provide information about viral shedding).
- Persistence and stability on a multitude of substrates and sources (e.g., nasal discharge, sputum, urine, fecal matter, blood).
- Persistence of virus on surfaces of different materials (e,g., copper, stainless steel, plastic).
- Effective decontamination protocols

- Range of incubation periods for the disease in humans (and how this varies across age and health status) and how long individuals are contagious, even after recovery.
- Prevalence of asymptomatic shedding and transmission (e.g., particularly children).
- Seasonality of transmission.
- Correlates of immunity- and whether immunity occurs and duration.
- Resistance of previously infected people to mutated strains.

One Health

Examples of long-term research needs

- Enhance capacity (people, technology, data) for sequencing with advanced analytics for unknown pathogens, and explore capabilities for distinguishing naturally-occurring pathogens from intentional.
- One Health surveillance of humans and potential sources of future spillover or ongoing exposure for this organism and future pathogens, including both evolutionary hosts (e.g., bats) and transmission hosts (e.g., heavily trafficked and farmed wildlife and domestic food and companion species), inclusive of environmental, demographic, and occupational risk factors.
- Evidence that livestock could be infected (e.g., field surveillance, genetic sequencing, receptor binding) and serve as a reservoir after the epidemic appears to be over.
  - Evidence of whether farmers are infected, and whether farmers could have played a role in the origin.
  - Surveillance of mixed wildlife- livestock farms for SARS-CoV-2 and other coronaviruses in Southeast Asia.
  - Experimental infections to test host range for this pathogen.

Group B – Patient Care and Medical Countermeasures (MCM) (SC Leads: Don Berwick, Margaret Hamburg)

Staff Leads: Lisa Brown and Scott Wollek

Members: Kristian Andersen
Diane Griffin
John Hick
Kent Kester
Tara O'Toole
David Relman
David Walt
Dan Hanfling

Topics: Vaccines and therapeutics
Diagnostics
Patient care (including personal protective equipment, crisis standards of care, and quality)

Vaccines and therapeutics

- How to expedite development, manufacturing, distribution of a safe, effective vaccine.
- Need for an end-to-end process for getting promising products to the people who need them (e.g. small biotechs may not have developed a vaccine before and may lack scale-up manufacturing and/or support for larger studies)
- Research and development and evaluation efforts
  Examples of short-term research needs
    - Evaluate/investigate effectiveness of drugs and antivirals being developed and tried to treat COVID-19 patients.
        - E.g., Would it be beneficial to give IL6 receptor antibodies therapy prior to admission to the ICU; use of monoclonal antibodies.
    - Clinical and bench trials to investigate less common viral inhibitors against COVID-19 such as naproxen, clarithromycin, and minocycline that may exert effects on viral replication.
    - Methods to evaluate potential complication of Antibody-Dependent Enhancement (ADE) in vaccine recipients.
    - From a clinical development perspective, explore use of best animal models and their predictive value for a human vaccine.
    - Capabilities to discover a therapeutic (not vaccine) for the disease, and clinical effectiveness studies to discover therapeutics, to include antiviral agents.
    - Alternative models to aid decision makers in determining how to prioritize and distribute scarce, newly proven therapeutics as production ramps up. This could include identifying approaches for expanding production capacity to ensure equitable and timely distribution to populations in need.

  Example of long-term research needs
    - Efforts targeted at a universal coronavirus vaccine.

Diagnostics

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes)
  Examples of short-term research needs
    - Evaluate how widespread current exposure is to be able to make immediate policy recommendations on mitigation measures. Denominators for testing and a mechanism for rapidly sharing that information, including demographics, to the extent possible. Sampling methods to determine asymptomatic disease (e.g., use of serosurveys (such as convalescent samples) and early detection of disease (e.g., use of screening of neutralizing antibodies such as ELISAs),
    - Efforts to increase capacity on existing diagnostic platforms and tap into existing surveillance platforms.

- Development of a rapid, point-of-care test (like a rapid influenza test; home tests;) and rapid bed-side tests, recognizing the tradeoffs between speed, accessibility, and accuracy.
- Best tests to look at IgM and IgG antibodies and how best to scale up and create a rapid test.
- Rapid design and execution of targeted surveillance experiments calling for all potential testers using PCR in a defined area to start testing and report to a specific entity. These experiments could aid in collecting longitudinal samples, which are critical to understanding the impact of ad hoc local interventions (which also need to be recorded).
- Separation of assay development issues from instruments, and the role of the private sector to help quickly migrate assays onto those devices.
- Establish efforts to track the evolution of the virus (i.e., genetic drift or mutations) and avoid locking into specific reagents and surveillance/detection schemes.
- Latency issues and when there is sufficient viral load to detect the pathogen, and understanding of what is needed in terms of biological and environmental sampling.
- Use of diagnostics such as host response markers (e.g., cytokines) to detect early disease or predict severe disease progression, which would be important to understanding best clinical practice and efficacy of therapeutic interventions.
- Policies and protocols for screening and testing.
- Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.

Examples of long-term research needs

- Technology roadmap for diagnostics.
- Barriers to developing and scaling up new diagnostic tests (e.g., market forces), how future coalition and accelerator models (e.g., Coalition for Epidemic Preparedness Innovations) could provide critical funding for diagnostics, and opportunities for a streamlined regulatory environment.
- New platforms and technology (e.g., CRISPR) to improve response times and employ more holistic approaches to COVID-19 and future diseases.
- Coupling genomics and diagnostic testing on a large scale.
- Enhance capabilities for rapid sequencing and bioinformatics to target regions of the genome that will indicate specificity for a particular variant.

Patient care

- Risk factors

  Examples of short-term research needs

  - Data on potential risks factors
    - Smoking, pre-existing pulmonary disease
    - Co-infections (determine whether co-existing respiratory/viral infections make the virus more transmissible or virulent) and other co-morbidities

    - Differences in respiratory/viral infections for neonates and pregnant women
    - Socio-economic and behavioral factors to understand the economic impact of the virus and whether there were differences.
    - Pediatrics – Innate immune system of children vs adaptive immune system response of adults (e.g., cross reactivity between some routine childhood vaccinations that is providing protection to the youngest in the population).
- Surge capacity and nursing homes
  Examples of short-term research needs
    - Resources to support skilled nursing facilities and long term care facilities.
    - Mobilization of surge medical staff to address shortages in overwhelmed communities.
- Efforts to inform allocation of scarce resources
  Examples of short-term research needs
    - Age-adjusted mortality data for Acute Respiratory Distress Syndrome (ARDS) with/without other organ failure – particularly for viral etiologies
    - Extracorporeal membrane oxygenation (ECMO) outcomes data of COVID-19 patients; and,
    - Outcomes data for COVID-19 after mechanical ventilation adjusted for age.
    - Knowledge of the frequency, manifestations, and course of extra-pulmonary manifestations of COVID-19, including, but not limited to, possible cardiomyopathy and cardiac arrest.
    - Application of regulatory standards (e.g., EUA, CLIA) and ability to adapt care to crisis standards of care level.
- Personal protective equipment
  Example of short-term research needs
    - Approaches for encouraging and facilitating the production of elastomeric respirators, which can save thousands of N95 masks.
    - Efficacy of cloth face coverings.
- Alternative methods to advise on disease management
  Examples of short-term research needs
    - Best telemedicine practices, barriers and facilitators, and specific actions to remove/expand them within and across state boundaries.
    - Guidance on the simple things people can do at home to take care of sick people and manage disease.
    - OTC oral medications that might potentially work.

  Example of long-term research needs
    - Use of AI in real-time health care delivery to evaluate interventions, risk factors, and outcomes in a way that could not be done manually.
- Processes of care
  Example of short-term research needs

- Best practices and critical challenges and innovative solutions and technologies in hospital flow and organization, workforce protection, workforce allocation, community-based support resources, payment, and supply chain management to enhance capacity, efficiency, and outcomes.

Group C – Community Engagement and Population Health (SC Leads: Mary Travis Bassett, Robert Groves)

Staff Leads: Julie Pavlin and Monica Feit (DBASSE)

Members: Georges Benjamin
Rich Besser
Peter Daszak
Phyllis Meadows
Alexandra Phelan
Mark Smolinski
Jeff Duchin
Baruch Fischhoff
(SBS WG, membership TBD)

Topics: Epidemiology and population surveillance
Social and public health interventions
Public communication and understanding
Occupational safety and health

Epidemiology and population surveillance

- Systematic, holistic approach to diagnostics (from the public health surveillance perspective to being able to predict clinical outcomes and for understanding/guidance to be implemented).
  Examples of short-term research needs
  - Plans for sero-surveys of previously exposed/immune individuals. Evaluation of background level of people with Covid19 antibodies in the community.
  - Policies and protocols for screening and testing (e.g. screening/testing schedule for post-exposure).
  - Policies to mitigate the effects on supplies associated with mass testing, including swabs and reagents.
  - Recruitment, support, and coordination of local expertise and capacity (public, private—commercial, and non-profit, including academic), including legal, ethical, communications, and operational issues.
  - National guidance and guidelines about best practices to states (e.g., how states might leverage universities and private laboratories for testing purposes, communications to public health officials and the public).
  - Validation and sharing (and effectively using) modeling outputs.

Social and public health interventions

Example of short-term research needs

- Effectiveness of non-therapeutic public health measures (e.g. patient contact tracing, social distancing strategies, school closings, telework). Rapid design and execution of experiments to examine and compare NPIs currently being implemented.
    - Risk/benefit of various social distancing measures
        - Optimal timing of social distancing (what are the triggers to start, when is it too late)
        - Importance of herd immunity
        - Avoiding the second wave
- Guidance on ways to scale up NPIs in a more coordinated way to give us time to enhance our health care delivery system capacity to respond to an increase in cases.
- Methods to control the spread in communities, barriers to compliance, and how these vary among different populations.

Examples of long-term research needs

- Models of potential interventions to predict costs and benefits that take account of such factors as race, income, disability, age, geographic location, immigration status, housing status, employment status, and health insurance status.
- Policy changes necessary to enable the compliance of individuals with limited resources and the underserved with NPIs. Research on why people fail to comply with public health advice, even if they want to do so (e.g., social or financial costs may be too high).
- Research on the economic impact of this or any pandemic. This would include identifying policy and programmatic alternatives that lessen/mitigate risks to critical government services, food distribution and supplies, access to critical household supplies, and access to health diagnoses, treatment, and needed care, regardless of ability to pay.

Public communication and understanding

- Messaging to the public, health professionals, civic leaders, etc.
- Communicating with high-risk populations

Examples of short-term research needs

- Modes of communicating with target high-risk populations (elderly, health care workers, first responders).
- Risk communication and guidelines that are easy to understand and follow (include targeting at risk populations' families too).
- Communication that indicates potential risk of disease to all population groups.
- Clarify community measures
- Clarify misunderstanding around containment and mitigation

Group D – Cross-Cutting Issues (SC Leads: Tara O'Toole, Alta Charo)

Staff Leads: Andy Pope and Lisa Brown

Members: Rich Besser
Ellen Embry
Patricia King
Jonna Mazet
Phyllis Meadows
Alexandra Phelan
Don Berwick

Topics: Ethics, equity, and law
International relations and cooperation
Innovative solutions across the public and private sectors
Lessons learned/future outbreaks

Ethics, equity, and law

- Consideration of the health needs and wellbeing of underserved/disinfranchised populations

  Examples of short-term research needs
  - Action plan to mitigate gaps and problems of inequity in the Nation's public health capability, capacity, and funding to ensure all citizens in need are supported and can access information, surveillance, and treatment.
  - Measures to reach marginalized and disadvantaged populations.
  - Data systems and research priorities and agendas incorporate attention to the needs and circumstances of disadvantaged populations and underrepresented minorities.
  - Understand and mitigate threats to incarcerated people from COVID-19, assuring access to information, prevention, diagnosis, and treatment.
  - Understand coverage policies (barriers and opportunities) related to testing, treatment, and care

International relations and cooperation

- The role of international regulatory organizations, WHO, etc
- Reliance and mutual recognition agreements (see NASEM study: Mutual Recognition Agreements in the Regulation of Medicines https://www.nationalacademies.org/our-work/mutual-recognition-agreements-in-the-regulation-of-medicines)
- Data standards and nomenclature:
  - Methods for coordinating data-gathering with standardized nomenclature.
  - Consistent platform for sharing response information among planners, providers, and others.
  - Understand and mitigate barriers to information-sharing.

Innovative solutions across public and private sectors

- Governmental public health

  Example of short-term research needs

  - Determine how to recruit, support, and coordinate local (non-Federal) expertise and capacity relevant to public health emergency response (public, private—commercial and non-profit, including academic).

  Examples of long-term research needs

  - Better integration of federal/state/local public health surveillance systems.
  - Value of investments in baseline public health response infrastructure, preparedness capacity, and capability.

Lessons learned/Future outbreaks

- Research needs to improve our understanding of the viral diversity and risk factors for viruses that are not yet known to medicine, but exist and are available to infect humans and present epidemic and pandemic threats.
- Research needs and evaluation metrics to inform the immediate response and future outbreak response.

From: Downey, Autumn[ADowney@nas.edu]

Location: Zoom information to follow

Importance: Normal

Subject: Canceled: HOLD - Viral Characteristics WG Discussion

Start Time: Tue 4/28/2020 5:00:00 PM (UTC-04:00)

End Time: Tue 4/28/2020 6:00:00 PM (UTC-04:00)

Required Attendees: 'Jonna Mazet'; 'David A Relman'; 'andersen@scripps.edu'; 'trevor@bedford.io'; 'dgriffi6@jhu.edu'; 'daszak@ecohealthalliance.org'; Baric, Ralph S; Shore, Carolyn; 'andre@ecohealthalliance.org'; 'Mary Radford'; Baric, Toni C; Brown, Lisa; Pope, Andrew

Optional Attendees: kga1978@gmail.com

Dear working group members,

We've narrowed the WG call to two possible dates and are sending a hold for both pending receipt of availability information from the remaining members. Since one of the options is tomorrow afternoon/evening, we'll confirm no later than tomorrow morning.

Best,
Autumn and Carolyn

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; GSELL, Pierre[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]
To: sandra cordo[scordo@qb.fcen.uba.ar]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Vasan, Vasan (H&B, Geelong AAHL)[Vasan.Vasan@csiro.au]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; Alyson Kelvin[AKelvin@dal.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; dhoconno@wisc.edu[dhoconno@wisc.edu]; paul.hodgson@usask.ca[paul.hodgson@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; 秦川[qinchuan@pumc.edu.cn]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; romain.volmer@envt.fr[romain.volmer@envt.fr]; sandrine.lesellier@anses.fr[sandrine.lesellier@anses.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; pauline.maisonnasse@cea.fr[pauline.maisonnasse@cea.fr]; roger.le-grand@cea.fr[roger.le-grand@cea.fr]; Rodriguez-Burgos, Estefania[estefania.rodriguez-burgos@leibniz-hpi.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; amy.c.shurtleff@cepi.net[amy.c.shurtleff@cepi.net]; Carolyn Clark[carolyn.clark@cepi.net]; Alejandro Javier COSTA[costaa@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; knezevici@who.int[knezevici@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; moorthyv@who.int[moorthyv@who.int]; preziosim@who.int[preziosim@who.int]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; hlchen@hku.hk[hlchen@hku.hk]; jfwchan@hku.hk[jfwchan@hku.hk]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; ldenisy@yahoo.com[ldenisy@yahoo.com]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; sekim@krict.re.kr[sekim@krict.re.kr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; snumouse@snu.ac.kr[snumouse@snu.ac.kr]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; B. 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Haagmans[b.haagmans@erasmusmc.nl]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; jeroen.kortekaas@wur.nl[jeroen.kortekaas@wur.nl]; nadia.oreshkova@wur.nl[nadia.oreshkova@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; Neil.Berry@nibsc.org[Neil.Berry@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Yper.Hall@phe.gov.uk[Yper.Hall@phe.gov.uk]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; Griffiths, Anthony[ahgriff@bu.edu]; nax3@cdc.gov[nax3@cdc.gov]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; alr2105@columbia.edu[alr2105@columbia.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; White, Alexander G[agw13@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; Duprex, Paul[pduprex@pitt.edu]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; Amelia Karlsson[amelia.karlsson@duke.edu]; geraldine.hamilton@emulatebio.com[geraldine.hamilton@emulatebio.com]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; tony.wang@fda.hhs.gov[tony.wang@fda.hhs.gov]; Tracy.MacGill@fda.hhs.gov[Tracy.MacGill@fda.hhs.gov]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Dan Barouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; Krammer, Florian[florian.krammer@mssm.edu]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Juergen Richt[jricht@vet.k-state.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Albrecht, Randy[randy.albrecht@mssm.edu]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark.Page@nibsc.org[Mark.Page@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; connie.schmaljohn@nih.gov[connie.schmaljohn@nih.gov]; Ian Crozier[ian.crozier@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Spergel, Jonathan[SPERGEL@email.chop.edu]; Padmini Salgame[salgampa@njms.rutgers.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; rcarrion@txbiomed.org[rcarrion@txbiomed.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Roy, Chad J[croy@tulane.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gustavo.palacios@gmail.com[Gustavo.palacios@gmail.com]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Dohm, Erik Daniel[edohm@uab.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; sktseng@utmb.edu[sktseng@UTMB.EDU]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; darryl.falzarano@usask.ca[darryl.falzarano@usask.ca]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Gralinski, Lisa E[lgralins@email.unc.edu]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 4/23/2020 6:02:07 AM (UTC-04:00)
Subject: WHO Animal Models Group Call Apr 23
Mail Attachment.ics
Webex_Meeting.ics

Dear colleagues,

Please find below the agenda for today's call as well as the webex link to join.

Very best

Simon, Bill and César.

AGENDA

Pathogenesis
1- Koert Stittelar: Viroclinics

2- Stanley Perlman: University of Iowa

3- Bart Haagmans: Erasmus

4- Yuri Vasiliev: SPbSRIVS

Therapeutics

Updates and open discussion

Vaccines

5- SINOVAC

Update and discussion

Simon Funnell: PHE. Role of ACE2 in pathogenesis.

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 927 784 731
Meeting password: znX83pvBcT3

Thursday, April 23, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)
41445750282 SWITZERLAND Toll
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You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 927784731.who@lync.webex.com

Need help? Go to http://help.webex.com

Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 9th Animal Models TC
Location: https://who.webex.com/who/j.php?MTID=mc579b920aca9493ede5d9bb8e311532f
Start Time: 2020-04-23T15:00:00+02:00
End Time: 2020-04-23T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

Meeting number (access code): 927 784 731
Meeting password:znX83pvBcT3

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Start Time: 2020-04-23T15:00:00+02:00
End Time: 2020-04-23T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Dial 927784731.who@lync.webex.com

Need help? Go to http://help.webex.com

To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Alvarez, Rosa Maria[rosalvarez@deloitte.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Thur 4/23/2020 10:30:00 AM (UTC-04:00)
Subject: FW: New paper

Important for preclinical testing?

Joe

From: Little, Roger (NIH/NIDA) [E] <alittle@mail.nih.gov>
Sent: Thursday, April 23, 2020 9:36 AM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: New paper

Just in case some of you have not yet seen this paper.

. Ziegler et al. **SARS-CoV-2 receptor ACE2 is an interferon-stimulated gene in human airway epithelial cells and is detected in specific cell subsets across tissues**. *Cell*, April 22, 2020; DOI: 10.1016/j.cell.2020.04.035

Roger Little Ph.D.
Deputy Director
Divison of Neuroscience and Behavior
National Institute on Drug Abuse/NIH
301 435 1316

FAQs - NOT-DA-20-047: Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus

NIH Neurobiobank https://neurobiobank.nih.gov

Genotype-Tissue Expression Project GTEx
https://commonfund.nih.gov/gtex
www.GTExPortal.org
https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000424.v7.p2

To: 'Jonna Mazet'[jkmazet@ucdavis.edu]; 'David A Relman'[relman@stanford.edu]; 'andersen@scripps.edu'[andersen@scripps.edu]; 'trevor@bedford.io'[trevor@bedford.io]; 'dgriffi6@jhu.edu'[dgriffi6@jhu.edu]; 'daszak@ecohealthalliance.org'[daszak@ecohealthalliance.org]; Baric, Ralph S[rbaric@email.unc.edu]
Cc: Shore, Carolyn[CShore@nas.edu]; 'andre@ecohealthalliance.org'[andre@ecohealthalliance.org]; 'Mary Radford'[maradford@ucdavis.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Brown, Lisa[LBrown@nas.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]
From: Downey, Autumn[ADowney@nas.edu]
Sent: Thur 4/23/2020 11:59:26 AM (UTC-04:00)
Subject: Materials for today's call - Viral Characteristics Working Group
April 23 Viral Characteristics WG Call Agenda.docx
Two Pager for WG Call_Viral Characteristics.docx
Standing Committees-What They Do_March 2020.docx

Dear Members of the Viral Characteristics Working Group,

In preparation for the WG call this afternoon/evening (5-6pm ET/2-3pm PT), please find attached the following materials that we'll be going over:

- Call Agenda
- 2-pager with the WG responsibilities, call objectives, and topics for prioritization
- A document describing what standing committees do and the kinds of products that could be considered for the prioritized topic

The Zoom information is below and also on the calendar invite. Please let us know if you have any questions/concerns or if something comes up and you are unable to make the call.

We look forward to talking later today!

Very best,
Autumn and Carolyn

Zoom information

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/98223865986

Or iPhone one-tap :

US: +16465588656,,98223865986#

Or Telephone:

US: 888 475 4499 (Toll Free)

Meeting ID: 982 2386 5986

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Viral Characteristics Work Group Call
Thursday, April 23, 2020 5-6pm ET

Call info
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/98223865986

Or iPhone one-tap :
US: +16465588656,,98223865986#

Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 982 2386 5986

Call agenda

- Roll call – *5 mins* (staff)
- Discuss prioritization process for identifying topics for discussion with the sponsor next week and types of products that can be considered – *5 mins* (staff)
- Identify priority question, topic or task, with clear objectives and rationale – *25 mins* (David)
- Discuss the following criteria – *20 mins* (Jonna)
    - Suitable type of product (telephonic consultation, rapid expert consultation, letter report, or consensus report)
    - Primary audience for the assessment
    - Anticipated time-frame for completion
    - Volunteers from the standing committee and working groups, and suggestions for additional experts to serve on the response team
- Next steps – *5 mins* (staff)

Work Group Participants

- Jonna Mazet and David Relman (Work Group Leads)
- Kristian Andersen
- Trevor Bedford
- Peter Daszak
- Diane Griffin
- Ralph Baric

NASEM Staff Leads

- Autumn Downey
- Carolyn Shore

April 23, 2020

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Group A – Viral Characteristics (SC Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
Mechanisms for pathogenesis
One Health

Working Group Responsibilities

The working group responsibilities include:

- Provide a locus for consideration of a defined area of issues and topics;
- Identify priorities within its respective area of emphasis for consideration as action items by the sponsors and full Standing Committee; and,
- Assist in the development of useful and timely responses, e.g., in defining clear and specific task statements and identifying subject matter experts who might join the response team.

When describing topics for priority consideration (for discussion at next week's meeting), the working groups will specify:

1) Question, topic or task, with clear objectives and rationale
2) Suitable type of product (telephonic consultation, rapid expert consultation, letter report, or consensus report)
3) Primary audience for the assessment
4) Anticipated time-frame for completion
5) Volunteers from the standing committee and working groups, and suggestions for additional experts to serve on the response team

Additional questions:

1. Identifying some of the most important "known unknowns" required for decision-makers
2. Get consensus on the study designs and analysis plans that are likely to provide robust answers

Viral characterization (virus genetics, origin, and evolution of SARS-CoV-2)

Examples of short-term research needs

- Biological/molecular characteristics of SARS-CoV-2
- Real-time tracking of whole genomes and a mechanism for coordinating the rapid dissemination of that information to inform the development of diagnostics and therapeutics and to track variations of the virus over time.
- Access to geographic and temporal diverse sample sets to understand geographic distribution and genomic differences, and determine whether there is more than one strain in circulation. Multi-lateral agreements such as the Nagoya Protocol could be leveraged.

Transmission, incubation, and environmental stability

Examples of short-term research needs

- Physical science of the coronavirus (e.g., charge distribution, adhesion to hydrophilic/phobic surfaces, environmental survival to inform decontamination efforts for affected areas and provide information about viral shedding).
- Persistence and stability on a multitude of substrates and sources (e.g., nasal discharge, sputum, urine, fecal matter, blood).
- Persistence of virus on surfaces of different materials (e,g., copper, stainless steel, plastic).
- Effective decontamination protocols
- Range of incubation periods for the disease in humans (and how this varies across age and health status) and how long individuals are contagious, even after recovery.
- Prevalence of asymptomatic shedding and transmission (e.g., particularly children).
- Seasonality of transmission.
- Correlates of immunity- and whether immunity occurs and duration.
- Resistance of previously infected people to mutated strains.

One Health

Examples of long-term research needs

- Enhance capacity (people, technology, data) for sequencing with advanced analytics for unknown pathogens, and explore capabilities for distinguishing naturally-occurring pathogens from intentional.
- One Health surveillance of humans and potential sources of future spillover or ongoing exposure for this organism and future pathogens, including both evolutionary hosts (e.g., bats) and transmission hosts (e.g., heavily trafficked and farmed wildlife and domestic food and companion species), inclusive of environmental, demographic, and occupational risk factors.
- Evidence that livestock could be infected (e.g., field surveillance, genetic sequencing, receptor binding) and serve as a reservoir after the epidemic appears to be over.
    - Evidence of whether farmers are infected, and whether farmers could have played a role in the origin.
    - Surveillance of mixed wildlife- livestock farms for SARS-CoV-2 and other coronaviruses in Southeast Asia.
    - Experimental infections to test host range for this pathogen.

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Health and Medicine Division

Standing Committees: What They Do

Standing committees provide sponsors with an ongoing mechanism to engage the National Academies of Sciences, Engineering, and Medicine, stakeholders, and committee members on specific issues in a variety of ways. They are designed to serve sponsors by helping them address their needs on a continuing basis for short and long-term strategic planning and program development.

Standing committees:

1) Stand ready to respond on short notice to requests and other needs from the sponsor(s);
2) Provide high-level strategic guidance to sponsor(s) on emerging issues, research, and activities through in-depth knowledge of the sponsor's programs, goals, and activities;
3) Serve as a focal point for national policy discussions by experts and other leaders in the field; and
4) Respond to sponsor(s) needs for continuing advice through planning, strategic thinking, and program development.

As part of the ongoing nature of the activity, the standing committee becomes very familiar with the sponsor(s) program/agency. This understanding and familiarity with the sponsor(s) programs facilitates the standing committee's ability to respond quickly and effectively with in-depth knowledge and insight about the sponsor(s) program.

Standing committee activities may include:

- Meeting periodically with the sponsor(s) and others in information-gathering sessions;
- Inviting experts/guests to provide input on the issues that will serve to inform the sponsor and the standing committee in its strategic planning and program development roles; and
- Conducting public outreach, such as through the development of websites and newsletters from the Academies that provides general information about the standing committee's activities or other related initiatives of the Academies.

Standing committee outputs may include:

Type	Product	Source/Origin	Recipient	Process
1	Immediate, **informal verbal feedback and guidance** provided to sponsors at public meetings	Individual Committee Members during meetings	Sponsors	Public meeting discussions

	a) **Science diplomacy,** which involves outreach to international scientific communities and colleagues with specific requests b) **Technical experts group,** which includes creating a large group of experts with relevant expertise to the kinds of issues the committee may address who would formally agree to be "on call" for quick responses c) **Letters and outreach to the scientific community,** which involves outreach to the domestic scientific community with specific requests			
2	**Meeting "Recap,"** which is a high-level summary of issues discussed at a committee meeting	Staff prepares the recap/summary	Sponsors (and Committee Members)	Internal review by HMD staff
3	**Rapid Expert Consultation (*NEW*),** which is a formal response from subject matter experts to urgent technical questions with a narrow focus that can be supported by a body of evidence.	Committee (with Staff support)	Sponsors and the Public	Expedited institutional review process
4	**Letter Report,** which is a formal report from the committee, based primarily on information presented and discussed at a committee meeting, that may include findings, conclusions, and recommendations on a specific topic	Committee (with Staff support)	Sponsors and the Public	Formal institutional review process
5	**Consensus Report,** which is	The Standing	Sponsors	Standing committees may

	a separate Academies report (or workshop) prepared by an ad hoc committee appointed specifically for the identified task	Committee can identify the need for, and recommend to the Academies that they conduct a study	and the Public	also develop 'spin off' ideas for workshops and studies that are conducted via separate ad hoc committees (standing committee members may serve on the committees for these ad hoc workshops and studies along with additional members recruited to address the specific workshop or study charge).
6	**Other products,** depending on the sponsors' needs, as well as the committee's			

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Location: https://nasem.zoom.us/j/186433432 (call-in information below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 4/24/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 4/24/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'

Our two main points of discussion will be prioritizing the topics of upcoming webinars and discussing the ideal duration/frequency of the series long-term.

As background for our conversation, please see:

- A table of potential future topics
- Attendee surveys from Webinar 4 (crisis standards of care) and Webinar 3 (spread & treatment)

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Call: NAM-APHA COVID-19 Webinar Series
Time: Apr 24, 2020 02:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/186433432

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Meeting ID: 186 433 432
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

Would you like to test your Zoom connection? Please click on the link below.
https://nasem.zoom.us/test

To: 'DeStefano, Laura'[LDestefano@nas.edu]; 'Sharon Inouye'[SharonInouye@hsl.harvard.edu]; 'Linda Degutis'[lcdegutis@gmail.com]; 'acasadevall@jhu.edu'[acasadevall@jhu.edu]; 'ushah@hcphes.org'[ushah@hcphes.org]; 'Lawrence Gostin'[gostin@georgetown.edu]; Figueroa, Angelica M[amfiguer@email.unc.edu]; Croitoru, Grace Nicole[gracenc@email.unc.edu]; Rimer, Barbara[brimer@unc.edu]; 'Andy Pavia'[Andy.Pavia@hsc.utah.edu]; 'Shah, Umair MD (PHS)'[Umair.Shah@phs.hctx.net]; 'Arturo Casadevall'[acasade1@jhu.edu]; 'Jha, Ashish'[ajha@hsph.harvard.edu]; 'Gold, Jeffrey P'[jeffrey.gold@unmc.edu]; 'Perez, Elizabeth (PHS)'[Elizabeth.Perez@phs.hctx.net]; 'Castaneda, Tony (PHS)'[Tony.Castaneda@phs.hctx.net]; 'Heidi Larson'[Heidi.Larson@LSHTM.ac.uk]; 'Burke, Donald S'[donburke@pitt.edu]; 'Tom Inglesby'[tinglesby@jhu.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'Maria Jasen'[mjasen1@jhu.edu]; 'mvnovotny@unmc.edu'[mvnovotny@unmc.edu]
Cc: Dzau, Victor J.[VDzau@nas.edu]; Georges Benjamin[georges.benjamin@apha.org]; Ogilvie, Jenna[JOgilvie@nas.edu]; 'Nicole Lurie'[drnickilurie@gmail.com]; Del Rio, Carlos[cdelrio@emory.edu]
From: Susan Polan[susan.polan@apha.org]
Sent: Fri 4/24/2020 12:26:43 PM (UTC-04:00)
Subject: RE: background for NAM-APHA advisory group call tomorrow

Good afternoon,

FYI – here is the agenda and final speaker list for the April 29 webinar entitled COVID-19 and Health Equity — Exploring Disparities and Long-Term Health Impacts. All the speakers have accepted so we are working on the background materials now.

Susan

Susan L. Polan, PhD
Associate Executive Director, Public Affairs and Advocacy
American Public Health Association
800 I Street, NW
Washington, DC 20001
www.apha.org

202/777-2510 (o)
@SLP4publichlth

Help us counteract the 'infodemic' of COVID-19 misinformation and rumors. Share our most up-to-date COVID-19 resources and information.

From: DeStefano, Laura [mailto:LDestefano@nas.edu]
Sent: Thursday, April 23, 2020 7:08 PM
To: 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; 'Figueroa, Angelica M'; 'Croitoru, Grace Nicole'; 'brimer@unc.edu'; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; 'rbaric@email.unc.edu'; 'antoinette_baric@med.unc.edu'; 'Maria Jasen'; 'mvnovotny@unmc.edu'
Cc: Dzau, Victor J.; Georges Benjamin; Susan Polan; Ogilvie, Jenna; 'Nicole Lurie'; Del Rio, Carlos
Subject: background for NAM-APHA advisory group call tomorrow

Good evening, I hope this message finds you safe and well.

We look forward to speaking with you tomorrow at 2 pm ET.

Our two main points of discussion will be prioritizing the topics of upcoming webinars and discussing the ideal duration/frequency of the series long-term.

As background for our conversation, please see:

- A table of potential future topics
- Attendee surveys from Webinar 4 (crisis standards of care) and Webinar 3 (spread & treatment)

Thanks,
Laura

Laura DeStefano
Director of Communications
National Academy of Medicine
202-334-3268
nam.edu | @theNAMedicine

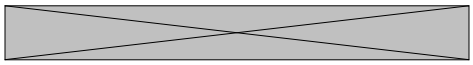
To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Mon 4/27/2020 9:25:42 AM (UTC-04:00)
Subject: FW: Register Now! Webinar on Can old drugs take down a new coronavirus? The state of COVID-19 drug repurposing efforts

FYI from Prabha.

From: Prabha Fernandes <prabha.fernandes@gmail.com>
Sent: Monday, April 27, 2020 9:23 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: FW: Register Now! Webinar on Can old drugs take down a new coronavirus? The state of COVID-19 drug repurposing efforts

Dear Joe,
I signed up for this ACS webinar held by a screening company. They are talking about Mpro and some newer targets for SARS-CoV2. In case someone else would like to hear in our group am sending on to you.
Best,
Prabha

From: C&EN Webinars <cenwebinar@acs.org>
Sent: Monday, April 27, 2020 9:04 AM
To: prabha.fernandes@gmail.com
Subject: Register Now! Webinar on Can old drugs take down a new coronavirus? The state of COVID-19 drug repurposing efforts



Can old drugs take down a new coronavirus? The state of COVID-19 drug repurposing efforts

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REGISTER NOW

May 6, 2020

8:00 a.m. PDT, 11:00 a.m. EDT, 16:00 BST, 17:00 CEST

Speakers

Matthew D. Hall
Acting Director and Biology Group Leader, Early Translation Branch, NIH

Derek Lowe
Medicinal chemist and author of Science Translational Medicine's In the Pipeline blog

Lisa Jarvis
Senior correspondent and pharmaceuticals editor, C&EN

Overview

When any new virus emerges, drug and vaccine developers spring into action, searching for products to stop it in its tracks. Drug discovery campaigns launch, vaccine development efforts ramp up, and everyone mobilizes to get it all into the clinic as quickly as possible. The current COVID-19 pandemic, driven by a coronavirus known as SARS-CoV-2, is no different. Vaccine candidates have already started entering the clinic. But even if they work, the most optimistic timelines put a vaccine a year to 18 months away. The more immediate approach to an outbreak is to scour the medicine cabinet for existing molecules that could be repurposed against a

new virus. In this roundtable discussion, drug industry experts will review the state of drug repurposing efforts for COVID-19, including what we've learned so far, and take your questions.

Read More

Sponsored by:

Key Learning Objectives

- What scientists have learned over the years about best practices in drug repurposing and how those are being applied to COVID-19
- How researchers think about prioritizing approved drugs or drug classes to test--and try to understand these drugs' potential liabilities for COVID-19
- What we've learned so far both in the labs and in humans about what might work
- How academia, industry, and government labs can collaborate on drug repurposing amid this outbreak

Who Should Attend

- M.S. practitioners
- Researchers/ R& Managers
- Laboratory Managers/ Directors / Supervisors

Laboratory Technicians / Operators

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To: M.P.G. Koopmans[m.koopmans@erasmusmc.nl]; Carolyn Clark[carolyn.clark@cepi.net]; Baric, Toni C[antoinette_baric@med.unc.edu]; Baric, Ralph S[rbaric@email.unc.edu]; cheryl@gisaid.org[cheryl@gisaid.org]; Bok, Karin (NIH/VRC) [E][karin.bok@nih.gov]; Boyle, David[dboyle@path.org]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; christian.brechot[christian.brechot@pasteur.fr]; Christine.bruce@phe.gov.uk[Christine.bruce@phe.gov.uk]; Carroll, Darin (CDC/DDID/NCEZID/OD)[zuz4@cdc.gov]; Miles.Carroll[Miles.Carroll@phe.gov.uk]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; Chu, May[MAY.CHU@CUANSCHUTZ.EDU]; Corbett, Kizzmekia (NIH/VRC) [E][kizzmekia.corbett@nih.gov]; Alejandro Javier COSTA[costaa@who.int]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Damon, Inger K. 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(CDC/DDID/NCIRD/DVD)[map1@cdc.gov]; Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP)[xdv3@cdc.gov]; Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA)[sheila.a.peel2.civ@mail.mil]; PERKINS, Mark[perkinsm@who.int]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Prior Joann L[JLPRIOR@dstl.gov.uk]; Alina Ximena Riveros Balta[lauriex@who.int]; Nicola Rose[Nicola.Rose@nibsc.org]; Erica Ollmann Saphire[erica@lji.org]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; schendel@lji.org[schendel@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Schnierle, Barbara[Barbara.Schnierle@pei.de]; Paul Scott[PScott@eidresearch.org]; Shivji Ragini[Ragini.Shivji@ema.europa.eu]; Amy C. 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Cc: KNEZEVIC, Ivana[knezevici@who.int]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)[htq4@cdc.gov]
From: William Dowling[william.dowling@cepi.net]
Sent: Mon 4/27/2020 10:28:01 AM (UTC-04:00)
Subject: RE: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Hello all
This week , we will use a Webex platform. A new invite has been sent. If any do not receive it, please let me know.
Thanks
Bill

-----Original Appointment-----
From: William Dowling
Sent: Tuesday, April 21, 2020 2:44 PM
To: M.P.G. Koopmans; Carolyn Clark; William Dowling; Baric, Toni C; Baric, Ralph; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E];

Boyle, David; brooke.bozick@nih.gov; christian.brechot@pasteur.fr; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/DDID/NCEZID/DHCPP); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); Pierre Gsell; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn
Cc: KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)
Subject: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET
When: Wednesday, April 29, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Skype Meeting

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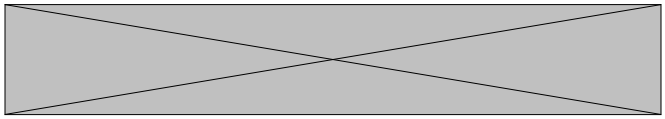

Click "Help" for more ways to join the Meeting

From: William Dowling[william.dowling@cepi.net]

Location: Skype Meeting

Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 4/29/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/29/2020 10:00:00 AM (UTC-04:00)

Required Attendees: M.P.G. Koopmans; Carolyn Clark; Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

Optional Attendees: KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)

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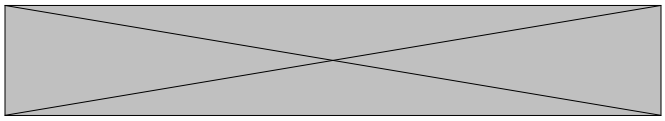

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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 4/28/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 4/28/2020 3:00:00 PM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; ken.duncan@gatesfoundation.org; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Lowy, Douglas (NIH/NCI) [E]; Diamond, Michael; Rodriguez, Robin D; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C

We are planning several smaller individual workstream meetings instead of the full working group. We will provide updates from the individual workstreams the next full Working group meeting (Thursday, 11-12 Eastern time).

Joe

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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To: Embry, Alan (NIH/NIAID) [E][embrya@niaid.nih.gov]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; Leo Poon[llmpoon@hku.hk]; Webby, Richard[Richard.Webby@STJUDE.ORG]; malik[malik@hku.hk]; Ghazi Kayali[ghazi@human-link.org]; Yoshi Kawaoka[kawaokay@vetmed.wisc.edu]; R.A.M. Fouchier[r.fouchier@erasmusmc.nl]; yguan@hku.hk[yguan@hku.hk]; Richard Rothman[rrothma1@jhmi.edu]; Pekosz, Andrew S.[apekosz@jhsph.edu]; Schultz-Cherry, Stacey[Stacey.Schultz-Cherry@STJUDE.ORG]; Orenstein, Walter[worenst@emory.edu]; Lowen, Anice[anice.lowen@emory.edu]; Baric, Ralph S[rbaric@email.unc.edu]; 'Perlman, Stanley'[stanley-perlman@uiowa.edu]; zhu huachen[zhuhch@hku.hk]; Aubree Gordon[gordonal@umich.edu]; vincent.munster_nih.gov vincent.munster@nih.gov[vincent.munster@nih.gov]; PETERPALESE[peter.palese@mssm.edu]; 'Krammer, Florian'[florian.krammer@mssm.edu]; Ben Cowling[bcowling@hku.hk]; larry.anderson@emory.edu[larry.anderson@emory.edu]; jwramme@emory.edu[jwramme@emory.edu]; aneesh.mehta@emory.edu[aneesh.mehta@emory.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; MASATO HATTA[masato.hatta@wisc.edu]; Gabriele Neumann (gabriele.neumann@wisc.edu)[gabriele.neumann@wisc.edu]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; Mathur, Punam (NIH/NIAID) [E][mathurpu@niaid.nih.gov]; Mark Denison[mark.denison@vumc.org]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; vimenach@UTMB.EDU[vimenach@UTMB.EDU]; Johnson, Reed (NIH/NIAID) [E][johnsonreed@niaid.nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; gavin.smith@duke-nus.edu.sg[gavin.smith@duke-nus.edu.sg]; Stemple, Kimberly (NIH/NIAID) [E][kstemple@niaid.nih.gov]; Sutton, Troy Clavell[tcs38@psu.edu]; marlene.espinozamoraga@mssm.edu[marlene.espinozamoraga@mssm.edu]; Simon, Viviana[viviana.simon@mssm.edu]; Van bakel, Harm[harm.vanbakel@mssm.edu]; McKenzie, Pamela[Pamela.McKenzie@STJUDE.ORG]; Deckhut, Alison (NIH/NIAID) [E][augustine@niaid.nih.gov]; Donald K. Milton[dmilton@umd.edu]; jmclellan@austin.utexas.edu[jmclellan@austin.utexas.edu]
Cc: Fry, Alicia (CDC/DDID/NCIRD/ID)[agf1@CDC.GOV]; Pallansch, Mark A. (CDC/DDID/NCIRD/OD)[map1@CDC.GOV]; Hall, Aron (CDC/DDID/NCIRD/DVD)[esg3@CDC.GOV]; Post, Diane (NIH/NIAID) [E][postd@niaid.nih.gov]; Lampley, Rebecca (NIH/NIAID) [C][rebecca.lampley@nih.gov]; Andy Pekosz[apekosz1@jhu.edu]; Topham, David[David_Topham@URMC.Rochester.edu]; Gerber, Susan I. (CDC/DDID/NCIRD/DVD)[bhx1@cdc.gov]; zhuhuachen@gmail.com[zhuhuachen@gmail.com]; Bozick, Brooke (NIH/OD) [E][brooke.bozick@nih.gov]; martin.linster@duke-nus.edu.sg[martin.linster@duke-nus.edu.sg]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Wentworth, David E. (CDC/DDID/NCIRD/ID)[gll9@cdc.gov]; Russell, Charles[Charles.Russell@STJUDE.ORG]; Cooper, Michael (NIH/NIAID) [E][michael.cooper3@nih.gov]; Weiss, Susan[weisssr@pennmedicine.upenn.edu]; bushman@pennmedicine.upenn.edu[bushman@pennmedicine.upenn.edu]; bencowling88@gmail.com[bencowling88@gmail.com]; Sun, Weina[weina.sun@mssm.edu]; Roberts, Chris (NIH/NIAID) [E][paul.roberts@nih.gov]; Stephen M Tompkins[smt@uga.edu]; Uccellini, Melissa[melissa.uccellini@mssm.edu]; Thomas, Paul[Paul.Thomas@STJUDE.ORG]; B.H.G. Rockx[b.rockx@erasmusmc.nl]; Michael Chan[mchan@hku.hk]; S. Herfst[s.herfst@erasmusmc.nl]; Lane, Chelsea (NIH/NIAID) [E][mary.lane@nih.gov]; Park, Eun-Chung (NIH/NIAID) [E][epark@niaid.nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; andrea_sant@urmc.rochester.edu[andrea_sant@urmc.rochester.edu]; Ellebedy, Ali[ellebedy@wustl.edu]; maureen.Mcgargill@stjude.org[maureen.Mcgargill@stjude.org]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Finzi, Diana (NIH/NIAID) [E][dfinzi@niaid.nih.gov]; Turpin, Jim (NIH/NIAID) [E][jturpin@niaid.nih.gov]; jae jung (jaeujung@med.usc.edu)[jaeujung@med.usc.edu]; SAMANTHA LOEBER[sloeber@wisc.edu]; Cherry, Sara[cherrys@pennmedicine.upenn.edu]; akuki@trudeauinstitute.org[akuki@trudeauinstitute.org]; Hui-Ling Yen[hyen@hku.hk]; Andrew Mesecar[amesecar@purdue.edu]; Jonsson, Colleen Beth[cjonsson@uthsc.edu]; Strome, Scott Eric[sstrome@uthsc.edu]; Fitzpatrick, Elizabeth A[efitzpat@uthsc.edu]; Aleksei Chmura[chmura@ecohealthalliance.org]
From: Peter Daszak[daszak@ecohealthalliance.org]
Sent: Wed 4/29/2020 3:08:25 AM (UTC-04:00)
Subject: RE: Termination of our Coronavirus work by NIH last Friday.

Thank you very much Alan,

At this moment, this means a great deal indeed. I'm very conscious of the fact that our 'termination' letter came directly from NIH building 1, completely bypassing NIAID, and all of the program staff at NIAID have been very supportive of our efforts to find out more about the rationale behind it, and hopefully find ways to rescind this decision.

In the meantime I look forward to continuing to join the calls, and we are rapidly working on a new application to NIAID for coronavirus work right now.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
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New York, NY 10001
USA

Tel.: +1-212-380-4474
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Embry, Alan (NIH/NIAID) [E] <embrya@niaid.nih.gov>
Sent: Tuesday, April 28, 2020 8:43 AM
To: Peter Daszak <daszak@ecohealthalliance.org>; Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>; Degrace, Marciela (NIH/NIAID) [E] <marciela.degrace@nih.gov>; Leo Poon <llmpoon@hku.hk>; Webby, Richard <Richard.Webby@STJUDE.ORG>; malik <malik@hku.hk>; Ghazi Kayali <ghazi@human-link.org>; Yoshi Kawaoka <kawaokay@vetmed.wisc.edu>; R.A.M. Fouchier <r.fouchier@erasmusmc.nl>; yguan@hku.hk; Richard Rothman <rrothma1@jhmi.edu>; Pekosz, Andrew S. <apekosz@jhsph.edu>; Schultz-Cherry, Stacey <Stacey.Schultz-Cherry@STJUDE.ORG>; Orenstein, Walter <worenst@emory.edu>; Lowen, Anice <anice.lowen@emory.edu>; Baric, Ralph <rbaric@email.unc.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; zhu huachen <zhuhch@hku.hk>; Aubree Gordon <gordonal@umich.edu>; vincent.munster_nih.gov vincent.munster@nih.gov <vincent.munster@nih.gov>; PETERPALESE <peter.palese@mssm.edu>; 'Krammer, Florian' <florian.krammer@mssm.edu>; Ben Cowling <bcowling@hku.hk>; larry.anderson@emory.edu; jwramme@emory.edu; aneesh.mehta@emory.edu; Baric, Toni C <antoinette_baric@med.unc.edu>; MASATO HATTA <masato.hatta@wisc.edu>; Gabriele Neumann (gabriele.neumann@wisc.edu) <gabriele.neumann@wisc.edu>; Subbarao, Kanta <kanta.subbarao@influenzacentre.org>; Mathur, Punam (NIH/NIAID) [E] <mathurpu@niaid.nih.gov>; Mark Denison <mark.denison@vumc.org>; MFrieman@som.umaryland.edu; vimenach@UTMB.EDU; Johnson, Reed (NIH/NIAID) [E] <johnsonreed@niaid.nih.gov>; Hensley, Lisa (NIH/NIAID) [E] <lisa.hensley@nih.gov>; gavin.smith@duke-nus.edu.sg; Stemple, Kimberly (NIH/NIAID) [E] <kstemple@niaid.nih.gov>; Sutton, Troy Clavell <tcs38@psu.edu>; marlene.espinozamoraga@mssm.edu; Simon, Viviana <viviana.simon@mssm.edu>; Van bakel, Harm <harm.vanbakel@mssm.edu>; McKenzie, Pamela <Pamela.McKenzie@STJUDE.ORG>; Deckhut, Alison (NIH/NIAID) [E] <augustine@niaid.nih.gov>; Donald K. Milton <dmilton@umd.edu>; jmclellan@austin.utexas.edu
Cc: Fry, Alicia (CDC/DDID/NCIRD/ID) <agf1@CDC.GOV>; Pallansch, Mark A. (CDC/DDID/NCIRD/OD) <map1@CDC.GOV>; Hall, Aron (CDC/DDID/NCIRD/DVD) <esg3@CDC.GOV>; Post, Diane (NIH/NIAID) [E] <postd@niaid.nih.gov>; Lampley, Rebecca (NIH/NIAID) [C] <rebecca.lampley@nih.gov>; Andy Pekosz <apekosz1@jhu.edu>; Topham, David <David_Topham@URMC.Rochester.edu>; Gerber, Susan I. (CDC/DDID/NCIRD/DVD) <bhx1@cdc.gov>; zhuhuachen@gmail.com; Bozick, Brooke (NIH/OD) [E] <brooke.bozick@nih.gov>; martin.linster@duke-nus.edu.sg; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; Wentworth, David E. (CDC/DDID/NCIRD/ID) <gll9@cdc.gov>; Russell, Charles <Charles.Russell@STJUDE.ORG>; Cooper, Michael (NIH/NIAID) [E] <michael.cooper3@nih.gov>; Weiss, Susan <weisssr@pennmedicine.upenn.edu>; bushman@pennmedicine.upenn.edu; bencowling88@gmail.com; Sun, Weina <weina.sun@mssm.edu>; Roberts, Chris (NIH/NIAID) [E] <paul.roberts@nih.gov>; Stephen M Tompkins <smt@uga.edu>; Uccellini, Melissa <melissa.uccellini@mssm.edu>; Thomas, Paul <Paul.Thomas@STJUDE.ORG>; B.H.G. Rockx <b.rockx@erasmusmc.nl>; Michael Chan <mchan@hku.hk>; S. Herfst <s.herfst@erasmusmc.nl>; Lane, Chelsea (NIH/NIAID) [E] <mary.lane@nih.gov>; Park, Eun-Chung (NIH/NIAID) [E] <epark@niaid.nih.gov>; Crozier, Ian (NIH) [C] <ian.crozier@nih.gov>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; andrea_sant@urmc.rochester.edu; Ellebedy, Ali <ellebedy@wustl.edu>; maureen.Mcgargill@stjude.org; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Finzi, Diana (NIH/NIAID) [E] <dfinzi@niaid.nih.gov>; Turpin, Jim (NIH/NIAID) [E] <jturpin@niaid.nih.gov>; jae jung (jaeujung@med.usc.edu) <jaeujung@med.usc.edu>; SAMANTHA LOEBER <sloeber@wisc.edu>; Cherry, Sara <cherrys@pennmedicine.upenn.edu>; akuki@trudeauinstitute.org; Hui-Ling Yen <hyen@hku.hk>; Andrew Mesecar <amesecar@purdue.edu>; Jonsson, Colleen Beth <cjonsson@uthsc.edu>; Strome, Scott Eric <sstrome@uthsc.edu>; Fitzpatrick, Elizabeth A <efitzpat@uthsc.edu>
Subject: RE: Termination of our Coronavirus work by NIH last Friday.

Peter,

We would very much appreciate it if you would still be willing to join these meetings. Your expertise is greatly appreciated.

Alan

Alan Embry, Ph.D.
Chief, Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases, NIAID, NIH
5601 Fishers Lane, Room 8E31
Rockville, MD 20892
301-435-3751
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From: Peter Daszak <daszak@ecohealthalliance.org>
Sent: Tuesday, April 28, 2020 8:38 AM
To: Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>; Degrace, Marciela (NIH/NIAID) [E] <marciela.degrace@nih.gov>; Leo Poon <llmpoon@hku.hk>; Webby, Richard <Richard.Webby@STJUDE.ORG>; malik <malik@hku.hk>; Ghazi Kayali <ghazi@human-link.org>; Yoshi Kawaoka <kawaokay@vetmed.wisc.edu>; R.A.M. Fouchier <r.fouchier@erasmusmc.nl>; yguan@hku.hk; Richard Rothman <rrothma1@jhmi.edu>; Pekosz, Andrew S. <apekosz@jhsph.edu>; Schultz-Cherry, Stacey <Stacey.Schultz-Cherry@STJUDE.ORG>; Orenstein, Walter <worenst@emory.edu>; Lowen, Anice <anice.lowen@emory.edu>; Baric, Ralph <rbaric@email.unc.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; zhu huachen <zhuhch@hku.hk>; Aubree Gordon <gordonal@umich.edu>; Munster, Vincent (NIH/NIAID) [E] <vincent.munster@nih.gov>; PETERPALESE <peter.palese@mssm.edu>; 'Krammer, Florian' <florian.krammer@mssm.edu>; Ben Cowling <bcowling@hku.hk>; larry.anderson@emory.edu; jwramme@emory.edu; aneesh.mehta@emory.edu; Baric, Toni C <antoinette_baric@med.unc.edu>; MASATO HATTA <masato.hatta@wisc.edu>; Gabriele Neumann (gabriele.neumann@wisc.edu) <gabriele.neumann@wisc.edu>; Subbarao, Kanta <kanta.subbarao@influenzacentre.org>; Mathur, Punam (NIH/NIAID) [E] <mathurpu@niaid.nih.gov>; Mark Denison <mark.denison@vumc.org>; MFrieman@som.umaryland.edu; vimenach@UTMB.EDU; Johnson, Reed (NIH/NIAID) [E] <johnsonreed@niaid.nih.gov>; Hensley, Lisa (NIH/NIAID) [E] <lisa.hensley@nih.gov>; gavin.smith@duke-nus.edu.sg; Stemple, Kimberly (NIH/NIAID) [E] <kstemple@niaid.nih.gov>; Sutton, Troy Clavell <tcs38@psu.edu>; marlene.espinozamoraga@mssm.edu; Simon, Viviana <viviana.simon@mssm.edu>; Van bakel, Harm <harm.vanbakel@mssm.edu>; McKenzie, Pamela <Pamela.McKenzie@STJUDE.ORG>; Deckhut, Alison (NIH/NIAID) [E] <augustine@niaid.nih.gov>; Donald K. Milton <dmilton@umd.edu>; jmclellan@austin.utexas.edu
Cc: Fry, Alicia (CDC/DDID/NCIRD/ID) <agf1@CDC.GOV>; Pallansch, Mark A. (CDC/DDID/NCIRD/OD) <map1@CDC.GOV>; Hall, Aron (CDC/DDID/NCIRD/DVD) <esg3@CDC.GOV>; Post, Diane (NIH/NIAID) [E] <postd@niaid.nih.gov>; Embry, Alan (NIH/NIAID) [E] <embrya@niaid.nih.gov>; Lampley, Rebecca (NIH/NIAID) [C] <rebecca.lampley@nih.gov>; Andy Pekosz <apekosz1@jhu.edu>; Topham, David <David_Topham@URMC.Rochester.edu>; Gerber, Susan I. (CDC/DDID/NCIRD/DVD) <bhx1@cdc.gov>; zhuhuachen@gmail.com; Bozick, Brooke (NIH/OD) [E] <brooke.bozick@nih.gov>; martin.linster@duke-nus.edu.sg; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; Wentworth, David E. (CDC/DDID/NCIRD/ID) <gll9@cdc.gov>; Russell, Charles <Charles.Russell@STJUDE.ORG>; Cooper, Michael (NIH/NIAID) [E] <michael.cooper3@nih.gov>; Weiss, Susan <weisssr@pennmedicine.upenn.edu>; bushman@pennmedicine.upenn.edu; bencowling88@gmail.com; Sun, Weina <weina.sun@mssm.edu>; Roberts, Chris (NIH/NIAID) [E] <paul.roberts@nih.gov>; Stephen M Tompkins <smt@uga.edu>; Uccellini, Melissa <melissa.uccellini@mssm.edu>; Thomas, Paul <Paul.Thomas@STJUDE.ORG>; B.H.G. Rockx <b.rockx@erasmusmc.nl>; Michael Chan <mchan@hku.hk>; S. Herfst <s.herfst@erasmusmc.nl>; Lane, Chelsea (NIH/NIAID) [E] <mary.lane@nih.gov>; Park, Eun-Chung (NIH/NIAID) [E] <epark@niaid.nih.gov>; Crozier, Ian (NIH) [C] <ian.crozier@nih.gov>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; andrea_sant@urmc.rochester.edu; Ellebedy, Ali <ellebedy@wustl.edu>; maureen.Mcgargill@stjude.org; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Finzi, Diana (NIH/NIAID) [E] <dfinzi@niaid.nih.gov>; Turpin, Jim (NIH/NIAID) [E] <jturpin@niaid.nih.gov>; jae jung (jaeujung@med.usc.edu) <jaeujung@med.usc.edu>; SAMANTHA LOEBER <sloeber@wisc.edu>; Cherry, Sara <cherrys@pennmedicine.upenn.edu>; akuki@trudeauinstitute.org; Hui-Ling Yen <hyen@hku.hk>; Andrew Mesecar <amesecar@purdue.edu>; Jonsson, Colleen Beth <cjonsson@uthsc.edu>; Strome, Scott Eric <sstrome@uthsc.edu>; Fitzpatrick, Elizabeth A <efitzpat@uthsc.edu>

Subject: Termination of our Coronavirus work by NIH last Friday.
Importance: High

Dear All,

Just so we don't get waylaid by this – I want to let you all know that NIH (not NIAID) wrote to us last week to abruptly terminate our R01, 'for convenience'.

There is a Politico story about this here:
https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076

And we have put out a statement here:
https://www.ecohealthalliance.org/2020/04/regarding-nih-termination-of-coronavirus-research-funding

My plan is to continue this work, unfunded for now, and to attend these meetings if you will all have me.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

Tel.: +1-212-380-4474
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>
Sent: Monday, April 27, 2020 3:49 PM
To: Degrace, Marciela (NIH/NIAID) [E] <marciela.degrace@nih.gov>; Leo Poon <llmpoon@hku.hk>; Webby, Richard <Richard.Webby@STJUDE.ORG>; malik <malik@hku.hk>; Ghazi Kayali <ghazi@human-link.org>; Yoshi Kawaoka <kawaokay@vetmed.wisc.edu>; R.A.M. Fouchier <r.fouchier@erasmusmc.nl>; yguan@hku.hk; Richard Rothman <rrothma1@jhmi.edu>; Pekosz, Andrew S. <apekosz@jhsph.edu>; Schultz-Cherry, Stacey <Stacey.Schultz-Cherry@STJUDE.ORG>; Orenstein, Walter <worenst@emory.edu>; Lowen, Anice <anice.lowen@emory.edu>; Baric, Ralph <rbaric@email.unc.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; Peter Daszak <daszak@ecohealthalliance.org>; zhu huachen <zhuhch@hku.hk>; Aubree Gordon <gordonal@umich.edu>; vincent.munster_nih.gov vincent.munster@nih.gov <vincent.munster@nih.gov>; PETERPALESE <peter.palese@mssm.edu>; 'Krammer, Florian' <florian.krammer@mssm.edu>; Ben Cowling <bcowling@hku.hk>; larry.anderson@emory.edu; jwramme@emory.edu; aneesh.mehta@emory.edu; Baric, Toni C <antoinette_baric@med.unc.edu>; MASATO HATTA <masato.hatta@wisc.edu>; Gabriele Neumann (gabriele.neumann@wisc.edu) <gabriele.neumann@wisc.edu>; Subbarao, Kanta <kanta.subbarao@influenzacentre.org>; Mathur, Punam (NIH/NIAID) [E] <mathurpu@niaid.nih.gov>; Mark Denison <mark.denison@vumc.org>; MFrieman@som.umaryland.edu; vimenach@UTMB.EDU; Johnson, Reed (NIH/NIAID) [E] <johnsonreed@niaid.nih.gov>; Hensley, Lisa (NIH/NIAID) [E] <lisa.hensley@nih.gov>; gavin.smith@duke-nus.edu.sg; Stemple, Kimberly (NIH/NIAID) [E] <kstemple@niaid.nih.gov>; Sutton, Troy Clavell <tcs38@psu.edu>; marlene.espinozamoraga@mssm.edu; Simon, Viviana <viviana.simon@mssm.edu>; Van bakel, Harm <harm.vanbakel@mssm.edu>; McKenzie, Pamela <Pamela.McKenzie@STJUDE.ORG>; Deckhut, Alison (NIH/NIAID) [E] <augustine@niaid.nih.gov>; Donald K. Milton <dmilton@umd.edu>; jmclellan@austin.utexas.edu

Cc: Fry, Alicia (CDC/DDID/NCIRD/ID) <agf1@CDC.GOV>; Pallansch, Mark A. (CDC/DDID/NCIRD/OD) <map1@CDC.GOV>; Hall, Aron (CDC/DDID/NCIRD/DVD) <esg3@CDC.GOV>; Post, Diane (NIH/NIAID) [E] <postd@niaid.nih.gov>; Embry, Alan (NIH/NIAID) [E] <embrya@niaid.nih.gov>; Lampley, Rebecca (NIH/NIAID) [C] <rebecca.lampley@nih.gov>; Andy Pekosz <apekosz1@jhu.edu>; Topham, David <David_Topham@URMC.Rochester.edu>; Gerber, Susan I. (CDC/DDID/NCIRD/DVD) <bhx1@cdc.gov>; zhuhuachen@gmail.com; Bozick, Brooke (NIH/OD) [E] <brooke.bozick@nih.gov>; martin.linster@duke-nus.edu.sg; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; Wentworth, David E. (CDC/DDID/NCIRD/ID) <gll9@cdc.gov>; Russell, Charles <Charles.Russell@STJUDE.ORG>; Cooper, Michael (NIH/NIAID) [E] <michael.cooper3@nih.gov>; Weiss, Susan <weisssr@pennmedicine.upenn.edu>; bushman@pennmedicine.upenn.edu; bencowling88@gmail.com; Sun, Weina <weina.sun@mssm.edu>; Roberts, Chris (NIH/NIAID) [E] <paul.roberts@nih.gov>; Stephen M Tompkins <smt@uga.edu>; Uccellini, Melissa <melissa.uccellini@mssm.edu>; Thomas, Paul <Paul.Thomas@STJUDE.ORG>; B.H.G. Rockx <b.rockx@erasmusmc.nl>; Michael Chan <mchan@hku.hk>; S. Herfst <s.herfst@erasmusmc.nl>; Lane, Chelsea (NIH/NIAID) [E] <mary.lane@nih.gov>; Park, Eun-Chung (NIH/NIAID) [E] <epark@niaid.nih.gov>; Crozier, Ian (NIH) [C] <ian.crozier@nih.gov>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; andrea_sant@urmc.rochester.edu; Ellebedy, Ali <ellebedy@wustl.edu>; maureen.Mcgargill@stjude.org; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Finzi, Diana (NIH/NIAID) [E] <dfinzi@niaid.nih.gov>; Turpin, Jim (NIH/NIAID) [E] <jturpin@niaid.nih.gov>; jae jung (jaeujung@med.usc.edu) <jaeujung@med.usc.edu>; SAMANTHA LOEBER <sloeber@wisc.edu>; Cherry, Sara <cherrys@pennmedicine.upenn.edu>; akuki@trudeauinstitute.org; Hui-Ling Yen <hyen@hku.hk>; Andrew Mesecar <amesecar@purdue.edu>; Jonsson, Colleen Beth <cjonsson@uthsc.edu>; Strome, Scott Eric <sstrome@uthsc.edu>; Fitzpatrick, Elizabeth A <efitzpat@uthsc.edu>
Subject: COVID-19 Weekly Investigator Call April 28th

Hi Everyone,
On this week's call we'll have highlights from Sue Gerber from CDC and Yoshi Kawaoka from the Univ of Wisconsin. Please see below for last week's attendees. As usual, if you just dialed in via phone the system recorded you as Caller X, so please let me and Rebecca Lampley know if your name should be added.

Please also let us know if you would like to present on May 12th or 19th.
Erik

Attendees 4/21
Erik Stemmy

Marciela DeGrace

Rebecca Lampley

Adolfo Garcia-Sastre

Alan Embry

Ali Ellebedy

Andrea Sant

Andrew Pekosz

Annice Lowen

Brooke Bozick

Charles Russell

Chris Roberts

Connie

David Topham

David Wentworth

Diane Post

Donna Neu

Eunchung Park

Florian Krammer

Gabriele Neumann

Ghazi Kayali

Harm van Bakel

Ian Crozier

James Kobie

Jim Chappell

Juergen Richt

Kanta Subbarao

Katy Shaw-Saliba

Kimberly Stemple

Larry Anderson

Lisa Hensley

Mark Denison

Mark Sangster

Marlene Espinoza

Masato Hatta (UW)

Matt Frieman

Maureen McGargill

Melissa Uccellini

Pamela McKenzie

Paul Thomas

Peter Daszak

Peter Palese

Punam Mathur

Ralph Baric

Reed Johnson

Richard Rothman

Ron Fouchier

Sander Herfst

Simon Anthony

Stacey Schultz-Cherry

Stanley Perlman

Stephen Tompkins

Susan Gerber

Susan Weiss

Troy Sutton

Tom Fabrizio

Vineet Menachery

Vivanna

Walt Orenstein

Weina Sun

Yoshihiro Kawaoka

To: Baric, Ralph S[rbaric@email.unc.edu]
From: 石正丽[zlshi@wh.iov.cn]
Sent: Wed 4/29/2020 5:06:34 AM (UTC-04:00)
Subject: conspiracy information

Dear Ralph,

Have you read this information? https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503。

I found several points misleading the readers:

1. Regarding our joint publication in *Nature Medicine* in 2015, the experiment was conducted in your lab. But according to this news, it was assumed that it was conducted in my lab. In fact I have been blamed by the peoples from the beginning of the outbreak because of this paper.

2.The above chimieric virus is to study a bat coronavirus with unknown function, which is not related to GOF.

3. The phrase "Wuhan would probably have had to start with a virus closer to SARS-CoV-2 than RATG13, which is within the realm of possibilities" immdieatly follows your words and make people think it's your comments.

4. In the last paragraph, I don't agree with you on the origin of the virus. Ian Lipkin has a very close collaboration with a lab in Guandong province. My lab is transparent and open in bat coronavirus research because I have several long-term international collaborators. Each time I had a meeting with our colleagues within and outside of China, I reported some novel and unpublished results. We have nothing to conceal.

It's a pity that our science is involved in politic conflict.

Best regards,

Zhengli,

To: Rappaport, Jay[jrappaport@tulane.edu]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Stegmeier, Frank[fstegmeier@ksqtx.com]
From: Young, John[john.young.jy3@roche.com]
Sent: Wed 4/29/2020 8:51:54 AM (UTC-04:00)
Subject: Re: Direct observation of repeated infections with endemic coronaviruses

Yikes!
John

On Wed, Apr 29, 2020 at 2:08 PM Rappaport, Jay <jrappaport@tulane.edu> wrote:

Very interesting,
Joe, thanks!

Get Outlook for iOS

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Wednesday, April 29, 2020 7:03:42 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Subject: FW: Direct observation of repeated infections with endemic coronaviruses

> External Sender. Be aware of links, attachments and requests.

The note below reinforces the need to do some WGS in NHP and humans.

From: Hall, Matthew (NIH/NCATS) [E] <hallma@mail.nih.gov>
Sent: Tuesday, April 28, 2020 10:32 PM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: Direct observation of repeated infections with endemic coronaviruses

Here's a pre-print from Columbia that my colleague Mike Kurilla passed along to me, which might impact how well you sleep tonight:

Direct observation of repeated infections with endemic coronaviruses

http://www.columbia.edu/~jls106/galanti_shaman_ms_supp.pdf

“Findings

During the study, 12 individuals tested positive multiple times for the same coronavirus. We found no significant difference between the probability of testing positive at least once and the probability of a recurrence for the beta-coronaviruses HKU1 and OC43 at 34 weeks after enrollment/first infection. We also found no significant association between repeat infections and symptom severity **but strong association between symptom severity and belonging to the same family**”

“Interpretation

This study provides evidence that **re-infections with the same endemic coronavirus are not atypical in a time window shorter than 1 year** and that the **genetic basis of innate immune response may be a greater determinant of infection severity** than immune memory acquired after a previous infection.”

Matthew D. Hall

Acting Branch Chief, Early Translation Branch

Group Leader, Biology

National Center for Advancing Translational Sciences (NCATS)

National Institutes of Health

9800 Medical Center Drive

Rockville, MD 20850

Office: 301-480-9928

https://ncats.nih.gov/staff/hallma

@cispt2

NCATS Website: http://ncats.nih.gov

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

http://list.nih.gov/cgi-bin/wa.exe?SUBED1=COVID19RESEARCH&A=1

--

John A.T. Young, PhD
VP and Global Head Infectious Diseases
Immunology, Infectious Diseases and Ophthalmology (I2O) Discovery and Translational Area
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Roche Innovation Center Basel

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Assistant:
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To: 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Alvarez, Rosa'[rosalvarez@deloitte.com]; 'Anderson, Annaliesa'[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; 'Carter, Kara'[kara.carter@evotec.com]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; 'Diamond, Michael'[diamond@wusm.wustl.edu]; 'Duncan, Ken'[ken.duncan@gatesfoundation.org]; 'Gatto, Greg'[ggatto@rti.org]; 'Grobler, Jay'[jay_grobler@merck.com]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Jonson, Samantha (NIH/NCATS) [E]'[samantha.jonson@nih.gov]; 'Lutz, Cat'[Cat.Lutz@jax.org]; 'Nestle, Frank'[Frank.Nestle@sanofi.com]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; 'Payne, David'[david.j.payne@gsk.com]; 'Rao, Srinivas'[Srinivas.Rao@sanofi.com]; 'Rappaport, Jay'[jrappaport@tulane.edu]; 'Stegmeier, Frank'[fstegmeier@ksqtx.com]; 'Young, John'[john.young.jy3@roche.com]
From: Prabha Fernandes[prabha.fernandes@gmail.com]
Sent: Wed 4/29/2020 9:06:25 AM (UTC-04:00)
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

Thank you for sharing, Joe. I am not an immunologist.. and was wondering if anyone knows what the profile looks like in Influenza pneumonia ? (or other viral pneumonia. The control are normal subjects..and I was wondering what Covid-19 differences were from other pneumonias also.
Although pretty scary that patients need to be followed 7days after being DISCHARGED.
On the vaccine front, some good hints of which antibodies to look for with some translation to Ebola vaccine work. All very educational!

Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Wednesday, April 29, 2020 8:04 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
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“Interpretation
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Matthew D. Hall
Acting Branch Chief, Early Translation Branch
Group Leader, Biology

National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health
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To: Young, John[john.young.jy3@roche.com]; Rappaport, Jay[jrappaport@tulane.edu]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Stegmeier, Frank[fstegmeier@ksqtx.com]
From: Grobler, Jay A[jay_grobler@merck.com]
Sent: Wed 4/29/2020 9:32:03 AM (UTC-04:00)
Subject: RE: Direct observation of repeated infections with endemic coronaviruses
96-2-94.pdf

Scary indeed! See attached from 1972. From the attached article:

"Reinfection with 229E appeared to be commonplace and pre-infection neutralizing antibody did not diminish (or increase) the frequency of illness with infection."

From: Young, John <john.young.jy3@roche.com>
Sent: Wednesday, April 29, 2020 8:52 AM
To: Rappaport, Jay <jrappaport@tulane.edu>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay A <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Stegmeier, Frank <fstegmeier@ksqtx.com>
Subject: Re: Direct observation of repeated infections with endemic coronaviruses

EXTERNAL EMAIL – Use caution with any links or file attachments.
Yikes!

John

On Wed, Apr 29, 2020 at 2:08 PM Rappaport, Jay <jrappaport@tulane.edu> wrote:
Very interesting,
Joe, thanks!

Get Outlook for iOS

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Wednesday, April 29, 2020 7:03:42 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Subject: FW: Direct observation of repeated infections with endemic coronaviruses

The note below reinforces the need to do some WGS in NHP and humans.

From: Hall, Matthew (NIH/NCATS) [E] <hallma@mail.nih.gov>
Sent: Tuesday, April 28, 2020 10:32 PM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: Direct observation of repeated infections with endemic coronaviruses

Here's a pre-print from Columbia that my colleague Mike Kurilla passed along to me, which might impact how well you sleep tonight:

Direct observation of repeated infections with endemic coronaviruses

http://www.columbia.edu/~jls106/galanti_shaman_ms_supp.pdf

"Findings

During the study, 12 individuals tested positive multiple times for the same coronavirus. We found no significant difference between the probability of testing positive at least once and the probability of a recurrence for the beta-coronaviruses HKU1 and OC43 at 34 weeks after enrollment/first infection. We also found no significant association between repeat infections and symptom severity **but strong association between symptom severity and belonging to the same family**"

"Interpretation

This study provides evidence that **re-infections with the same endemic coronavirus are not atypical in a time window shorter than 1 year** and that the **genetic basis of innate immune response may be a greater determinant of infection severity** than immune memory acquired after a previous infection."

Matthew D. Hall

Acting Branch Chief, Early Translation Branch

Group Leader, Biology

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VIROLOGIC STUDIES OF ACUTE RESPIRATORY DISEASE IN YOUNG ADULTS

V. CORONAVIRUS 229E INFECTIONS DURING SIX YEARS OF SURVEILLANCE

DOROTHY HAMRE AND MARC BEEM[1]

(Received for publication November 24, 1971)

Hamre, D. and M. Beem (Dept. Pediatrics, Univ. of Chicago, Chicago, Ill. 60637). Virologic studies of acute respiratory disease in young adults. V. Coronavirus 229E infections during six years of surveillance. *Am J Epidemiol* 96: 94–106, 1972.—In a surveillance study of acute respiratory disease in medical students that spanned six consecutive seasons between 1961 and 1968 and encompassed 937 student years of observation, infection with coronavirus 229E was identified by virus isolation and serologic studies. Virus isolation identified 12 infections, 8 in one season, 4 in another. Complement fixing (CF) antibody titer rises identified 133 infections that occurred in all six seasons of surveillance, involving from 15 to 35% of students in three seasons of "high" prevalence, and 1 to 5% in intervening seasons of "low" prevalence. Infection occurred in a winter-spring seasonal pattern and was associated with acute respiratory illness that was not clinically distinctive. Neutralizing antibody to 229E was commonly present in the sera of the students. The level of this did not appear to influence the occurrence of, or likelihood of illness with, reinfection as judged by CF seroconversion; however, the frequency of significant rise in neutralizing antibody titer with reinfection was inversely related to pre-infection levels of this antibody. Infection with other common respiratory viruses did not stimulate significant CF or neutralizing antibody titer rises to 229E.

coronaviruses; respiratory tract infections; serology; viruses

INTRODUCTION

The isolation in cell culture and characterization of a new respiratory virus designated "229E" has previously been reported from this laboratory (1). It has subsequently been shown that this ether and acid labile RNA virus shares morphologic and biophysical characteristics with other human respiratory viruses that can be isolated only in organ culture of human respiratory epithelium (2, 3) and that these human respiratory viruses, in turn, are morphologically similar to avian infectious bronchitis virus (IBV) and mouse hepatitis virus (MHV) (3–5). The term "coronavi-

Abbreviations: CF, complement fixing; CPE, cytopathic changes; HDF, human diploid fibroblasts; HI, hemagglutination inhibition; HK, human kidney; IBV, infectious bronchitis virus; MHV, mouse hepatitis virus; MK, monkey kidney; RS, respiratory syncytial.

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This investigation was supported by Public Health Service Grant NIH-5-RO1-AI-03292, contract number PH-43-63-564 from the Vaccine Development Branch, National Institutes of Allergy and Infectious Diseases, General Research Support Grant PHS FR-5367, and the Children's Research Foundation, Western Springs, Ill.

The authors gratefully acknowledge the technical assistance of Evelyn Saxon.

rus" has been proposed for this group of viruses (6).

Definition of the antigenic composition of the human coronaviruses has been limited by the small number of isolations so far reported (14 in tissue culture, nine in organ culture) and the inability to adapt most of the organ culture strains to more practical laboratory systems. At least two immunotypes have so far been distinguished: one consisting of 229E and all of the other strains derived from primary isolation in cell culture, and the other of organ culture strains OC 38 and 43 (7). The number of additional immunotypes represented by the remaining organ culture strains is as yet uncertain.

That human respiratory coronaviruses have the potential to be respiratory pathogens has been demonstrated in artificial challenge studies: common colds have developed in significant numbers of volunteers inoculated with coronavirus strains B814 and 229E (2, 8). However, little is known about the extent and significance of infection with these viruses in naturally occurring acute respiratory illnesses. The relatively complex methodology of organ culture systems limits the applicability of this technique to etiologic studies, and, although the primary isolation of 229E-like strains can be accomplished in cell culture, this is usually quite difficult to do. Even so, the isolation of multiple 229E-like strains from adults with acute respiratory illness has previously been reported on two occasions (1, 9), and a third is described below.

The application of serologic techniques to the question of prevalence and significance of human respiratory coronavirus infections has been circumscribed by incomplete knowledge of the serologic interrelations of the group and the restriction of laboratory methods suitable for such studies to tissue culture strain 229E and organ culture strain OC 38/43. Antibody prevalence surveys indicate human infection with these and/or related coronaviruses may be quite common (8, 10, 11), and serologic studies have suggested an etiologic role for both 229E (9, 10) and OC 38/43 (9, 12) in acute respiratory illness that was not selected on the basis of severity. However, in a study of acute lower respiratory disease of infants and children that necessitated hospitalization, there was no complement fixing (CF) antibody evidence that infections with these viruses played a significant role (11).

The following report of serologic and epidemiologic studies of 229E virus is based upon observations made in the course of a continuous surveillance of respiratory disease among medical students at the University of Chicago during a six-year period between 1961 and 1968. It includes observations on 1) CF and neutralizing antibody responses to 229E of eight previously reported (1) and four additional individuals from whom 229E virus was isolated, 2) the persistence of neutralizing and CF antibody in 12 other individuals in whom infection with this virus was diagnosed serologically, 3) the occurrence of neutralizing and/or CF antibody responses to 229E virus in the course of infection with other respiratory viruses, 4) the overall occurrence during the six years of respiratory disease surveillance of CF antibody rises to 229E, 5) the relationship between neutralizing and CF antibody rises to 229E in 189 of the students under surveillance during the 1966–1967 season, and 6) the relation between 229E virus infection and acute respiratory illness.

Materials and methods

The methods employed for surveillance of the medical students and isolation and identification of respiratory viruses have been reported in detail previously (13, 14). They were briefly as follows:

Medical student surveillance. Medical students participated in the program on a voluntary basis. Only students in the first two years of school were included during 1961 through 1963. After that students in their third and fourth years, as well as a few who had gone on to internship and residency were included. Students reported to

the laboratory at the first sign of an acute illness and secretions from the nose and throat were obtained on cotton swabs which were subsequently placed in collecting medium. The first of two "illness" blood specimens were obtained at the time of the original visit and the second two to five weeks later. At this time a brief form describing the symptoms and duration of illness was completed. Additional blood specimens and cultures were obtained from all participants at six-week intervals on a routine basis.

Virus isolation. Over the several years of the study there were minor variations in the media and cell cultures employed for virus isolation. Throughout the study all specimens were inoculated into cell cultures of rhesus monkey kidney (MK) and HEp-2. Human kidney (HK) cell cultures were also employed routinely in 1961–1962. After this time, human diploid fibroblasts (HDF), WI-38, or HEL-1 (a University of Chicago strain), were routinely employed and HK was only used periodically.

Cell cultures inoculated with specimens, and an appropriate number of controls, were incubated at 36 C (MK, HEp-2) or 33 C (HK, HDF), stationary (MK, HEp-2), or rolling (HK, HDF) and observed at regular intervals over a 20-day period for the development of cytopathic changes (CPE); MK cultures were also tested for hemadsorption.

Virus isolates were identified by neutralization of infectivity or hemadsorption inhibition employing appropriate antisera.

CF test. Bottles containing confluent HDF monolayers were drained of medium and inoculated with enough 229E virus to provide about one plaque forming unit per cell. After a one hour absorption at 33 C, enough maintenance medium (Eagle's Minimal Essential Medium with 1 per cent fetal calf serum) was added to cover the monolayer and the bottles incubated until the first appearance of CPE could be detected (about 36 to 48 hours later). The bottles were then frozen and thawed three times and the debris removed by centrifugation. The supernate was divided into small aliquots and refrozen for use as CF antigen.

The CF test was performed in microtiter plates essentially using the method of Sever (15). Antigen was titrated by the checkerboard method, employing acute and convalescent sera of a student from whom the virus was isolated in 1961. Two units of antigen were employed in the test, along with two exact units of complement which had been titrated in the presence of antigen. After overnight fixation at 4 C, the hemolytic system was added and the plates incubated at 37 C for 30 minutes. Readings were made after the cells had settled in the refrigerator for three to four hours. Titers represent the highest dilution showing 3+ to 4+ fixation.

Neutralization tests. Twofold dilutions of heat inactivated serum (56 C for 30 minutes) were made in beef heart infusion broth and mixed with an equal volume of virus diluted to give 5–50 $TCID_{50}$ of virus per 0.2 ml of virus-serum mixture. After incubation at room temperature for two hours, three tubes of HDF were inoculated with 0.2 ml of each virus-serum mixture. Appropriate virus controls and titrations were included in each test to provide a concurrent determination of the actual $TCID_{50}$ of virus used in the test. Final readings were made after three to five days of incubation on roller drums at 33 C, when virus control tubes showed 3+ to 4+ CPE. Tubes showing any degree of CPE were considered positive and endpoint titers represent the highest dilution of serum neutralizing the virus dose (indicated in parentheses in table 1) in at least two of the three inoculated cell cultures.

Serologic observations on students from whom 229E was isolated

Twelve 229E infections were identified by virus isolation in the six-year surveillance period and the serum neutralizing and CF

antibody responses to 229E that occurred following these infections are presented in table 1.

Neutralizing antibody was present in the pre-infection sera of eight of 12 students at titers of 1:2 to 1:16. Of the four students "without" pre-infection antibody, three had titers <1:8 and one was <1:4. Post-infection, eight of the 12 developed fourfold rises in titer, with 1:64 the peak titer observed. CF antibody was absent (<1:4) from all pre-infection sera. Post-infection sera showed fourfold or better rises in seven of the 12 and an additional student had a two-fold titer rise.

Thus, in this small experience, two thirds of individuals with virus-shedding infections developed significant rises in either CF or neutralizing serum antibody titer. The majority of the negative serologic responses of infection were contributed by three students who failed to develop either neutralizing or CF antibody titer rises and were alike in the additional respect that all were "without" pre-infection neutralizing antibody. It was not possible to reconfirm these isolations because material was not available for reisolation attempts, but it was determined that the strains of virus isolated from these students were antigenically similar to the prototype to the extent that they and the prototype strain were neutralized with equal efficiency by 229E hyperimmune guinea pig serum. It was also determined that these students failed to develop a neutralizing antibody response to their own as well as the prototype strain of 229E.

TABLE 1

Serum CF and neutralizing antibody response to 229E virus: 12 students from whom this virus was isolated

Student identification	Antibody titer to 229E*			
	Neutralizing		Complement fixing	
	Pre	Post	Pre	Post
220	*8*	***32*** (5)†	*<4*	*16*
227	*<8*	***32*** (5)	*<2*	*4*
229	*2*	***32*** (30)	*<4*	*8*
241	*4*	***32*** (50)	<4	<4
243	*8*	***32*** (50)	*<4*	*16*
276	*4*	*≥**32*** (50)	*<4*	*8*
297	<8	8 (5)	<4	<4
299	16	32 (30)	*<4*	*8*
0661‡	<8	<8 (30)	<4	<4
0744‡	*16*	*64* (30)	*<4*	*16*
0765‡	*8*	***32*** (60)	*<4*	*4*
0312‡	<4	<4 (60)	<4	<4

* Reciprocal of initial serum dilution; significant rises italicized.

† $TCID_{50}$ of virus used in test.

‡ These 229E virus isolations not previously reported.

PERSISTENCE OF CF AND NEUTRALIZING ANTIBODY

In 12 other medical students, 229E infection was identified by CF and neutralizing antibody seroconversion early in the course of their participation in this surveillance study. Serial serum specimens were available from them that extended over a two- to four-year period. The persistence of antibody observed in these students is summarized in table 2. Considering neutralizing antibody first, three of the 12 "lacked" antibody to 229E virus in the pre-rise serum while the remainder had titers ranging from 1:4 to 1:16. Peak titers ranged from 1:16 to ≥1:128 and 22 to 28 months later titers were still significantly higher than pre-rise levels in seven of the 12 students. In contrast, CF antibody titers were <1:4 in the initial sera of all 12 students, rose to peak values of 1:4 to ≥1:16 and in all cases returned to <1:4 within one to nine months following peak values. The persistence of neutralizing and evanescence of CF antibody to 229E implied by the common occurrence of neutralizing but not CF antibody in pre-infection sera of students, is demonstrated in these data. Also, the presence of neutralizing antibody in the pre-infection sera of nine of these 12 students with seroconversion to 229E, as well as eight of the 12 from whom virus was iso-

TABLE 2

*Persistence of CF and neutralizing antibody following 229E virus infection**

Student identification	Antibody titer to 229E†							
	Neutralizing				Complement fixing			
	Pre-rise	Peak	Final	Time interval—peak to final	Pre-rise	Peak	Final	Time interval—peak to <4
0237	<4	128	>32	3 yrs 2 mos	<4	≥16	<4	6 mos
0531	<4	16	8	3 yrs	<4	8	<4	8 mos
0503	<8	32	16	3 yrs 2 mos	<4	8	<4	2 mos
0459	16	64	32	1 yr 10 mos	<4	8	<4	3 mos
0516	8	≥128	≥64	3 yrs 5 mos	<4	8	<4	6 wks
0535	16	≥128	32	2 yrs 2 mos	<4	16	<4	3 mos
0532	4	32	16	3 yrs 3 mos	<4	16	<4	9 mos
0505	8	≥128	8	3 yrs 11 mos	<4	16	<4	8 mos
0515	16	≥128	≥64	3 yrs	<4	4	<4	6 wks
0453	8	≥64	16	2 yrs 2 mos	<4	8	<4	6 wks
0486	4	16	16	4 yrs	<4	4	<4	4 wks
0498	8	32	16	2 yrs 9 mos	<4	8	<4	5 mos

* Infection identified by 4-fold or greater rise in neutralizing and 2-fold or greater rise in CF antibody titer.

† Reciprocal of initial serum dilution.

lated, underscores the natural occurrence of reinfection with this virus.

SPECIFICITY OF SEROLOGIC RESPONSE TO 229E VIRUS

Information concerning the specificity of the serologic responses to 229E virus was sought by examining pre- and post-infection sera of students with virus shedding respiratory infections caused by other viruses. CF and neutralizing antibody responses to 229E virus were determined following infection with rhinovirus (82 students), herpesvirus (12 students), respiratory syncytial (RS) virus (16 students), influenza virus (A_2—two students, B—10 students), parainfluenza virus (type 1—four students, type 2—five students, type 3—six students), and adenovirus type 1 (one student). Four increases of 229E CF antibody titer were observed: two followed rhinovirus infections and one each infection with herpesvirus and adenovirus. With two of the CF rises (herpesvirus—one, rhinovirus —one), there were concomitant increases in the titer of neutralizing antibody to 229E. All rises took place during time periods of known 229E prevalence. Since these CF titer rises were few in number, accompanied in two of the four instances by rises in neutralizing antibody titer, and occurred during times when concomitant infection with 229E was possible, these data are interpreted as showing little, if any, evidence of heterologous responses to 229E in the course of infection with the indicated respiratory viruses.

CF ANTIBODY SEROLOGIC SURVEY— ALL SURVEILLANCE YEARS

Because the cytopathic changes of 229E in human diploid cell cultures are difficult to detect, it seemed probable that a serologic test would better estimate the true incidence of infection in the medical student group. For this, CF tests were performed on all sera collected between November 1961 and May 1968, including both "routine" specimens collected at six-week intervals and acute and convalescent "illness" specimens. In doing the CF tests, it was found that almost all sera were completely nega-

TABLE 3

229E virus isolations and antibody rises among medical students by surveillance year

No(s). of students	Surveillance year						Total
	1961–62	1962–63	1963–64	1964–65	1965–66	1966–67	
Under surveillance	110	116	137	182	201	191	937
With 229E virus isolation	8					4	12
With CF antibody rises*	34 (31%)	6 (5%)	21 (15%)	1 (1%)	5 (3%)	66 (35%)	133 (15%)
With neutralizing antibody rises†	20	0	14	1	2	29	66

* CF rises included seroconversions (<4 to 4) confirmed by retesting as well as instances of fourfold or greater rises (see text).

†Neutralization tests performed only on students with CF rises.

tive for complement fixation at the initial 1:4 dilution. When, in a series of specimens from one student, a positive reaction was found at but not beyond this 1:4 dilution, the immediately following sera also showed complement fixation that was at the same level or progressively declined through 2+ or 1+ and then became, and remained, completely negative. It was decided, therefore, that CF titer changes from <1:4 to ⩾1:4 that could be confirmed on repeat testing were serologically significant.

CF antibody titer rises and 229E isolations found in the entire group of students together with neutralizing antibody titer rises of students with CF seroconversions are presented in table 3. In the overall experience, which encompassed 937 "student years" of observation, 133 students with CF antibody titer rises were identified. One or more students developed rises in each of the six seasons and the frequency of rises in any one season appeared to fall into one of two patterns, "high" or "low". Thus, there were three "high" seasons with 15 to 35 per cent of students showing rises (1961–1962—31 per cent, 1963–1964—15 per cent, 1966–1967—35 per cent) and three "low" seasons with 1 to 5 per cent showing rises (1962–1963—5 per cent, 1964–1965—1 per cent, 1965–1966—3 per cent). The high frequency seasons did not occur consecutively but were separated by one or two low frequency seasons.

High and low frequency seasons also differed in respect to the portion of the observed CF rises that were "2×" (<1:4 to 1:4) and "⩾4×" (<1:4 to ⩾1:8). In high frequency seasons, both 2× and ⩾4× rises occurred, with the latter comprising 76, 48 and 74 per cent of CF rises in the 1961–1962, 1963–1964 and 1966–1967 seasons, respectively, and 64 per cent (85/133) of all CF rises observed. In low frequency seasons, only 2× rises were seen and in this respect low frequency seasons differed significantly from high frequency seasons ($p < .001$).

NEUTRALIZING ANTIBODY RISES TO 229E

Although CF cross-reactions between 229E and other viruses have not been described, the specificity of this test is uncertain. Therefore, neutralization tests were also done on the sera of students with CF rises. Of the 133 students with CF rises, 66 (50 per cent) had concomitant neutralizing antibody rises. The portion of students with neutralizing antibody rises showed a direct relation to the extent of CF antibody rise (table 4), being 35 per cent of 48 students with 2× CF rises, 45 per cent for 53 students with 4× rises and 78 per cent of 32 students with ⩾8× rises. Among students with 2× CF rises, concomitant neutralizing antibody rises occurred less often in low than in high frequency years (3/12 vs 14/36) but

TABLE 4

Neutralizing antibody titer rises in students with CF antibody titer rises according to extent of CF rise*

Season	Fold increase in CF titer					Totals
	<2×†	2×	4×	8×	≥16	
1961–62	ND‡	4/8§	9/18	3/4	4/4	20/34
1962–63	ND	0/6				0/6
1963–64	ND	4/11	6/6	4/4		14/21
1964–65	ND	1/1				1/1
1965–66	ND	2/5				2/5
1966–67	(4/123)¶	6/17	9/29	11/15	3/5	29/66
Totals		17/48	24/53	18/23	7/9	66/133

* ≥4-fold increases in titer.

† <4 − 4 = 2×; <4 − 8 = 4×, etc.

‡ Not done.

§ No. with neutralizing antibody titer rise/no. with this extent of CF antibody titer rise.

¶ Not included in totals.

this difference did not appear to be significant ($p = .5$). One or more neutralizing antibody titer rises occurred in all except one season, 1962–1963.

COMPARISON OF CF AND NEUTRALIZING ANTIBODY SEROCONVERSION RATES AND PREVALENCE IN 1966–1967

To further compare the CF and neutralization tests, neutralizing antibody titers were determined in the November, January and May sera of all but two of the students under surveillance in the 1966–1967 season (table 5). Of the 189 students with sera surveyed by both tests, significant rises in neutralizing antibody titer occurred in 33 (17 per cent) while 66 (35 per cent) developed CF rises. Four students showed seroconversion by neutralization test only and 37 by CF test only. Thus, CF seroconversion to 229E occurred twice as often as neutralizing antibody seroconversion and the CF test alone identified 66 (94 per cent) of the 70 students with seroconversion to 229E that were found when both tests were used. In the November sera of these students, CF antibody titers were uniformly <1:4, while 169 (89 per cent) of the 189 students had neutralizing antibody at titers ≥1:4.

RELATION OF PRE-INFECTION SERUM NEUTRALIZING ANTIBODY LEVEL TO CF AND NEUTRALIZING ANTIBODY SEROCONVERSION

The serologic findings in the students from whom 229E virus was isolated indicated that the immune state characterized by serum neutralizing antibody to this virus did not preclude natural reinfection. Other serologic evidence supported this. In the 1966–1967 season, pre-infection neutralizing antibody titers ≥1:4 were found in 62 (94 per cent) of 66 students with CF seroconversion and in 28 (85 per cent) of 33 students with neutralizing antibody seroconversion; in the other five seasons of surveillance, of 67 students with CF seroconversion, 46 (69 per cent) had pre-rise neutralizing antibody titers ≥1:8.

To determine how reinfection was related to the level of neutralizing antibody, neutralizing and CF antibody seroconversion rates were determined for the 189 students of the 1966–1967 season according to the level of neutralizing antibody found in their November 1966 serum specimen (table 6). A distinctly different relationship was found between the preinfection neutralizing antibody level and the frequency of seroconversion as determined by the two tests. The frequency of neutralizing antibody seroconversion was inversely related to the

TABLE 5

Serum neutralizing and CF antibody rises to 229E among 189 students in the 1966–67 surveillance year

Neutralizing antibody titer rise*	Complement fixing antibody titer rise†		Total with indicated neutralizing antibody response
	Yes	No	
Yes	29	4	33
No	37	119	156
Total with indicated CF antibody response	66	123	189

* ≥4-fold rise in titer between November 1966 and May 1967.

† Titer increase from <1:4 to ≥1:4.

TABLE 6

Neutralizing and CF antibody seroconversions to 229E according to initial neutralizing antibody titer (1966–67 surveillance year, 189 students)*

Initial neutralizing antibody titer†	Students				
	No.	Neutralizing antibody seroconversion		CF antibody seroconversion	
		No.	%	*No.*	%
<4	20	5	25	4	20
4	56	15	27	25	45
8	53	9	17	15	28
16	44	4	9	16	36
≥32	16	0	0	6	38

* CF = <1:4 → ≥1:4; neutralization ≥4-fold.
† Reciprocal, initial serum dilution.

level of neutralizing antibody in the November serum ($p = 0.05$), while CF seroconversion occurred with similar frequency irrespective of neutralizing antibody in the November serum.

Strictly comparable data were not available for other years of the study when neutralization tests were only done on sera of students with CF titer rises. However, among those students with CF seroconversion, a significant ($p < .01$) inverse relation between initial neutralizing antibody titer and frequency of significant rise of neutralizing antibody was again seen (table 7).

CLINICAL MANIFESTATIONS OF 229E VIRUS INFECTION

Since students were sampled by culture and serology during periods of good health as well as periods of illness, a controlled estimate could be made of the relation of 229E infection to acute respiratory illness. Briefly, infection, whether determined by virus isolation or CF antibody seroconversion, showed a significant relationship to acute respiratory illness.

Of 12 virus isolations made in the 1961–1962 and 1966–1967 seasons, 11 were from 521 cultures taken during respiratory illness while one came from 1,927 cultures taken during times of good health ($p < .001$).

The multiple serum specimens from the 133 students with CF seroconversions spanned a total of 909 time periods of known health status that could be divided, according to the presence or absence of acute respiratory illness, into "illness periods" and "wellness periods." CF seroconversion to 229E occurred with a significantly greater frequency during "illness periods" than during "wellness periods" (75 seroconversions/245 "illness periods" vs 58/664 "wellness periods" ($p < .001$)).

As cited above, CF seroconversion rates to 229E were not related to presence or absence of homologous neutralizing antibody in sera obtained prior to the time of the CF antibody titer rise. It was also found that the level of neutralizing antibody did not clearly influence the likelihood that illness would accompany CF seroconversion. There was illness during the period of CF seroconversion in 67 per cent of 49 students with initial neutralizing antibody titers <1:8 as compared to 50 per cent of 84 students with initial neutralizing antibody titers ≥1:8 ($p > .05 < .10$). Also, CF seroconversions were illness associated with equal frequency among students with and without concomitant neutralizing antibody titer rises: 60 per cent vs 52 per cent ($p > .3 < .5$).

The clinical characteristics of these respiratory illnesses were not distinctive. Symptoms reported by students during illnesses

TABLE 7

Neutralizing antibody seroconversion to 229E according to pre-rise neutralizing antibody titer: 67 students with CF antibody seroconversions† (Sept. 1961–Sept. 1966)*

Initial neutralizing antibody titer‡	Students		
	No.	Neutralizing antibody titer rise	
		No.	%
<8	19	12	63
8	26	19	73
16	15	5	33
32	7	0	0

* ≥4-fold rise in titer.
† <1:4 → ≥1:4.
‡ Reciprocal, initial serum dilution.

TABLE 8

Seasonal pattern of 229E infections

Surveillance year	No. of students with CF antibody rise* and/or virus isolation†											
	Sept.	Oct.	Nov.	Dec.	Jan.	Feb.	March	April	May	June	July	Aug.
1961–62					(2)†	11, (5)	13, (1)	7	3			
1962–63					2	2		2				
1963–64					5	7	1	6	2			
1964–65								1				
1965–66		1	1		1		1	2	1			
1966–67					7	11	18, (3)	24, (1)	2	2		

* $<1{:}4 \rightarrow \geq 1{:}4$.

† Virus isolations in parentheses.

associated with CF antibody titer rises to this virus were those of undifferentiated acute respiratory infections and did not differ significantly from those reported by these and other students during respiratory infections caused by rhino, RS or parainfluenza viruses.

SEASONAL PATTERN OF 229E INFECTIONS

The seasonal pattern of 229E infections, as evidenced by virus isolation and CF antibody titer rises, is presented in table 8. In each of the six seasons of surveillance, virus isolations and CF seroconversions occurred almost exclusively in the winter and spring months, the exception being 1966–1967 when CF rises were seen in October, November and June. If allowance is made for the time interval by which positive serum specimens post dated the time of infection (two weeks with "illness" specimens and longer with "routine" specimens) most infections occurred during the months of December through April.

DISCUSSION

Certain conclusions seem clear from the observations based on virus isolation and neutralizing antibody seroconversion. Infection with 229E virus was far from uncommon and significantly related to acute respiratory illness. Infection occurred in a winter-spring seasonal pattern similar to that reported previously (9, 11) while the pattern of prevalence over successive years suggested this agent might circulate annually in urban populations with seasons of accentuated prevalence at two- to three-year intervals. Infection was associated with acute respiratory illness clinically indistinguishable from that caused by other common respiratory viruses, and serologically followed by persistently elevated neutralizing and transiently elevated CF antibody titers. Reinfection with 229E appeared to be commonplace and pre-infection neutralizing antibody did not diminish (or increase) the frequency of illness with infection.

Other interpretations of the data must remain tentative to the extent that the specificity of the CF test is not yet clearly defined. Present information concerning this may be summarized as follows. A serologic relation of 229E to viruses of other common groups has not been found in previous or the present studies (1, 7). However, within the coronavirus group, neither the number of human respiratory immunotypes nor the extent of their serologic cross-reactivity are fully known. An antigenic relationship has been demonstrated by CF and HI tests between certain members such as OC 38/43 and MHV, and other less well defined CF cross-reactions may exist within the group (7, 17). However, a common group antigen such as is found in the adeno and influenza viruses has not been demonstrated. In the case of 229E, studies with hyperimmune an-

imal sera have revealed no clear evidence of CF cross-reactions between this virus and MHV, IBV and OC 38/43 (7, 17). Furthermore, sera of human subjects with presumed or known infections with other respiratory coronaviruses have only occasionally shown heterotypic responses to 229E (7, 11, 17). However, even though these studies have not demonstrated extensive CF cross-relations between 229E and presently recognized coronaviruses, the observations are relatively few in number, do reveal some degree of cross-reactivity and do not preclude the possibility that this may exist to an even greater extent with other as yet unrecognized coronaviruses.

Seroconversion to 229E was found more commonly by the CF than the neutralizing antibody test. This was clearly seen in 1966–1967 when both tests were used to follow all students: CF seroconversion occurred in virtually all students with neutralizing seroconversion (29 of 33); and an additional 37 students showed seroconversion by CF test only. In other years of the study when neutralizing antibody tests were only done on students with CF seroconversion, only half of these showed significant rises of neutralizing antibody titer. If it is assumed that in these other years, as in 1966–1967, CF seroconversion identified most of the students with neutralizing antibody titer rises, it was the overall experience that seroconversion to 229E occurred twice as often by the CF as by the neutralizing antibody test.

This difference in CF and neutralizing antibody seroconversion rates could not be entirely accounted for by the decision that 2× CF rises were significant. Although students with 2× CF titer rises showed concomitant neutralizing antibody seroconversion less frequently than those with ⩾4× CF titer rises, 2× reactors appeared to relate to ⩾4× reactors as the lower end of a continuum in which the frequency of neutralizing antibody seroconversion was directly related to the extent of CF antibody titer rise. This was true in each of the high prevalence seasons, and in the overall experience the portion of CF reactors with concomitant neutralizing antibody rises was 35, 45 and 78 per cent of students with 2×, 4× and ⩾8× CF rises, respectively. It should also be noted that 2× and ⩾4× rises were similar in respect to seasonal distribution and the relation of seroconversion to illness.

Thus, either (or both) lesser specificity or greater sensitivity of the CF test also contributed to the difference in CF and neutralizing antibody seroconversion rates. The observations made in these studies do not provide the basis for a clear choice between these alternatives. Infection with other virus(es) cross-reacting with 229E by CF at low titer could be postulated as the origin of the small number of exclusively 2× CF rises that were seen in low frequency seasons, but this would not account for the observation that three of 12 students with CF rises under these circumstances had concomitant neutralizing antibody titer rises to 229E. A similar explanation could be proposed for the finding that pre-existing neutralizing antibody was associated with a diminished frequency of seroconversion by the neutralization test but did not influence the frequency of seroconversion by the CF test. However, if the CF seroconversions in students with high levels of 229E neutralizing antibody in their pre-infection serum were due to infection with one or more other viruses having CF cross-reactivity with 229E, it must be further assumed that something acted to restrict infection rates with the same agents in students with low levels of 229E neutralizing antibody. Otherwise, it might be expected that the latter group of students, subject to infection with 229E as well as the hypothesized cross-reacting agents, would have shown higher CF seroconversion rates than the students subject to infection only by the cross-reacting viruses. The CF seroconversion rates observed were, if anything, lower in students with low levels of pre-infection neutralizing antibody. That different agents would show

such nicely reciprocal infection rates seems somewhat improbable.

It is, however, also possible that the CF test is almost or indeed as specific as the neutralizing antibody test and, where serum specimens are closely spaced, considerably more sensitive. Immunologic factors related to the transient elevation of CF antibody and persistent elevation of neutralizing antibody following infection could play a role in this. The adverse effect of high levels of pre-infection antibody on the serodiagnosis of streptococcal and poliovirus infection has previously been commented upon (18–20). In the case of 229E, long persisting neutralizing antibody may diminish the likelihood that the antigenic stimulus of reinfection will evoke a measureable rise in titer of this antibody while this would not be the case with the CF antibody response. Indeed, if it is assumed that at least a portion of the antibody reacting in the CF test is produced by a segment of the immune system that can develop persisting sensitization, past infection would actually serve to enhance the frequency of measureable CF response to reinfection.

There is not yet sufficient information about the human respiratory coronaviruses to determine the extent to which sensitivity, specificity or both factors account for the observed differences in neutralizing and CF antibody seroconversion rates. Even so certain conclusions can be drawn from the results of the CF survey about the overall role of these viruses in acute respiratory illnesses of humans. Whether in response to infection with only 229E or infection with one or more other serotypes of coronaviruses, CF antibody titer rises to 229E occurred in all six seasons of these studies and were significantly related to acute respiratory illnesses.

If the twofold greater CF than neutralizing antibody seroconversion rate is to be attributable to lesser specificity of the CF test, then among the human respiratory coronaviruses yet to be discovered there must be one or more that circulate widely and share CF antigens with 229E. However, if the difference in seroconversion rates is to be attributed to the factor of sensitivity, several other interesting considerations follow. First, in respect to reinfection, the nearly uniform rate of CF antibody seroconversion to 229E observed among individuals with high as well as low levels of pre-infection neutralizing antibody describes a dissociation between naturally acquired serum antibody and resistance to reinfection (under conditions of natural challenge) that is unusual. Although it has been shown that naturally acquired local respiratory tract antibody is a better predictor than serum antibody, of resistance to reinfection with parainfluenza (21, 22) and RS (23) viruses, a correlation has nevertheless been demonstrable between naturally acquired serum antibody and resistance to reinfection with influenza (24), parainfluenza (21, 22, 25) and rhinoviruses (26). While the apparent dissociation of prechallenge neutralizing antibody and reinfection with 229E as measured by CF antibody seroconversion may simply be an extreme example of the fact that circulating antibody is only an indirect indicator of surface immunity, it could also be interpreted as suggesting that resistance to reinfection is particularly evanescent in the case of the human respiratory coronavirus. That many of the 229E infections were indeed reinfections was clear from both the virus isolation and the neutralizing antibody seroconversion data. Similar findings in respect to OC 43 have been described by Kaye et al. (12) who found that almost 50 per cent of children aged 10–14 years who developed HI seroconversions to OC 43 had pre-existing antibody titers of 1:10 or greater. It might also be emphasized here that not only seroconversion rates but also the frequency with which such seroconversions were illness associated were unaffected by the presence of pre-infection antibody in both the

present studies of 229E and those of OC 43 (12).

An unusual aspect of the seroepidemiology of 229E, referred to above (11), might also be explained on the basis of transience of CF antibody and the enhancement of this antibody response after reinfection. This is the failure to find CF antibody in the acute or convalescent serum specimens of either children hospitalized with lower respiratory tract illness, or those hospitalized for nonrespiratory tract disease, although such antibody was found in sera collected from adults with acute respiratory illness from the same general (but different specific) locale and time period. This could reflect the fact that 229E infections of young children are unusual, or at least seldom of severity that requires hospitalization. However, the experience with other viruses that cause acute respiratory disease in the general population such as influenza, parainfluenza, rhino and RS viruses is that they circulate among children as well as or to a greater extent than among adults (27, 28). Suggesting that this may indeed also be true of 229E virus is the finding by Bradburne (8) of neutralizing antibody to this virus in the sera of eight of 32 children aged 0–5 years and serologic studies in this laboratory indicating a similar prevalence of 229E in the pre-school age group (29). Therefore, lessened serologic responsiveness rather than lower infection rates in this age group must be entertained as a possible explanation of the paucity of CF antibody to 229E observed in the sera of infants and young children.

Finally, this possible enhancement of CF and diminution of neutralizing antibody responsiveness with reinfection could have an important bearing on the procedure of choice for serologic diagnosis of 229E infection in subjects of different ages. Thus, the neutralization test would be the procedure of choice for infants and young children, and the CF test the most sensitive procedure (provided serum specimens are closely spaced) for older children and adults.

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From: Nestle, Frank /US[Frank.Nestle@sanofi.com]
Sent: Wed 4/29/2020 9:34:31 AM (UTC-04:00)
Subject: Re: Direct observation of repeated infections with endemic coronaviruses
Innate IFN down Inflammatory IL6 Lung transcriptome Serum up Blanco-Melo Cell 2020.pdf

Hypothesis: Defective Type I/III IFN response (due to IFN antagonists?) with consequent suboptimal T cell priming/Ab production…

Best regards,

Frank

From: Young, John <john.young.jy3@roche.com>
Sent: Wednesday, April 29, 2020 8:52 AM
To: Rappaport, Jay <jrappaport@tulane.edu>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter Kara <Kara.Carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank /US <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas /US <Srinivas.Rao@sanofi.com>; Stegmeier, Frank <fstegmeier@ksqtx.com>
Subject: [EXTERNAL] Re: Direct observation of repeated infections with endemic coronaviruses

EXTERNAL : Real sender is john.young.jy3@roche.com

Yikes!

John

On Wed, Apr 29, 2020 at 2:08 PM Rappaport, Jay <jrappaport@tulane.edu> wrote:
Very interesting,
Joe, thanks!

Get Outlook for iOS

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Wednesday, April 29, 2020 7:03:42 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank

<fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Subject: FW: Direct observation of repeated infections with endemic coronaviruses

> External Sender. Be aware of links, attachments and requests.

The note below reinforces the need to do some WGS in NHP and humans.

From: Hall, Matthew (NIH/NCATS) [E] <hallma@mail.nih.gov>
Sent: Tuesday, April 28, 2020 10:32 PM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: Direct observation of repeated infections with endemic coronaviruses

Here's a pre-print from Columbia that my colleague Mike Kurilla passed along to me, which might impact how well you sleep tonight:

Direct observation of repeated infections with endemic coronaviruses

http://www.columbia.edu/~jls106/galanti_shaman_ms_supp.pdf

"Findings

During the study, 12 individuals tested positive multiple times for the same coronavirus. We found no significant difference between the probability of testing positive at least once and the probability of a recurrence for the beta-coronaviruses HKU1 and OC43 at 34 weeks after enrollment/first infection. We also found no significant association between repeat infections and symptom severity **but strong association between symptom severity and belonging to the same family**"

"Interpretation

This study provides evidence that **re-infections with the same endemic coronavirus are not atypical in a time window shorter than 1 year** and that the **genetic basis of innate immune response may be a greater determinant of infection severity** than immune memory acquired after a previous infection."

Matthew D. Hall

Acting Branch Chief, Early Translation Branch

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Imbalanced host response to SARS-CoV-2 drives development of COVID-19

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SUMMARY

Viral pandemics, such as the one caused by SARS-CoV-2, pose an imminent threat to humanity. Because of its recent emergence, there is a paucity of information regarding viral behavior and host response following SARS-CoV-2 infection. Here, we offer an in-depth analysis of the transcriptional response to SARS-CoV-2 as it compares to other respiratory viruses. Cell and animal models of SARS-CoV-2 infections, in addition to transcriptional and serum profiling of COVID-19 patients, consistently revealed a unique and inappropriate inflammatory response. This response is defined by low levels of Type I and III interferons juxtaposed to elevated chemokines and high expression of IL-6. Taken together, we propose that reduced innate antiviral defenses coupled with exuberant inflammatory cytokine production are the defining and driving feature of COVID-19.

INTRODUCTION

Coronaviruses are a diverse group of single-stranded positive-sense RNA viruses with a wide range of vertebrate hosts (Cui et al., 2019). Four common coronavirus genera (alpha, beta, gamma, and delta) circulate among vertebrates and cause mild upper respiratory tract illnesses in humans and gastroenteritis in animals (Weiss and Navas-Martin, 2005). However, in the past two decades, three highly pathogenic human betacoronaviruses have emerged from zoonotic events (Amanat and Krammer, 2020). In 2002-2003, severe acute respiratory syndrome-related coronavirus (SARS-CoV-1) infected ~8,000 people worldwide with a case-fatality rate of ~10%, followed by Middle East respiratory syndrome-related coronavirus (MERS-CoV) that has infected ~2,500 people with a case-fatality rate of ~36% since 2012 (de Wit et al., 2016). At present, the world is suffering from a pandemic of severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), which causes Coronavirus Disease-2019 (COVID-19) and has a global mortality rate that remains to be determined (Wu et al., 2020; Zhu et al., 2020). SARS-CoV-2 infection is characterized by a range of symptoms including fever, cough, and general malaise in the majority of cases (Chen et al., 2020). More severe cases of COVID-19 show development of acute respiratory distress syndrome and acute lung injury, leading to morbidity and mortality caused by damage to the alveolar lumen leading to inflammation and pneumonia (Wolfel et al., 2020; Xu et al., 2020).

The physiological response to virus infection is generally initiated at the cellular level following replication (tenOever, 2016). After virus entry, the infected cell detects the presence of virus replication through use of any one of a number of pattern recognition receptors (PRRs) (Janeway and Medzhitov, 2002). These receptors serve as sentinels for a variety of microbes both inside and outside of the cell by physically engaging distinct structures that are shared amongst different pathogens. In the case of virus infection, cellular detection of replication is largely mediated by a family of intracellular PRRs that sense aberrant RNA structures that often form during virus replication (Janeway and Medzhitov, 2002). Engagement of virus-specific RNA structures

culminates in the oligomerization of these receptors and the activation of downstream transcription factors, most notably the interferon regulator factors (IRFs) and Nuclear Factor (NF) κB (Hur, 2019). Transcriptional activation of IRFs and NFκB results in the launching of two general antiviral programs. The first is the engagement of cellular antiviral defenses, which is mediated by the transcriptional induction of Type I and III interferons (IFN-I and IFN-III) and the subsequent upregulation of interferon stimulated genes (ISGs) (Lazear et al., 2019). The second arm of the antiviral response involves the recruitment and coordination of specific subsets of leukocytes, which is orchestrated primarily by chemokine secretion (Proudfoot, 2002; Sokol and Luster, 2015).

This broad antiviral response puts a selective pressure on viruses and has resulted in the evolution of countless viral countermeasures (Garcia-Sastre, 2017). Therefore, the host response to virus is generally not uniform, and infections can inflict different degrees of morbidity and mortality. The current pandemic of COVID-19 represents an acute and rapidly developing global health crisis. In an effort to better understand the molecular basis of the disease, we sought to characterize the transcriptional response to infection in a variety of model systems including *in vitro* tissue culture, *ex vivo* infection of primary cells, and *in vivo* samples derived from both COVID-19 patients and animals. We chose to characterize the transcriptional response to SARS-CoV-2 and determine how it compares to common respiratory viruses, including influenza A virus (IAV). These two respiratory viruses both encode a variety of different antagonists to the IFN-I/-III response (Frieman and Baric, 2008; Garcia-Sastre, 2017). For the closely related SARS-CoV-1, IFN antagonism has been attributed to ORF3B, ORF6, and the nucleoprotein (N) gene products (Frieman et al., 2010; Kopecky-Bromberg et al., 2007). SARS-CoV-1 also encodes nsp1, a nuclease that has been implicated in cleaving host mRNA to prevent ribosomal loading and causing host shut-off (Kamitani et al., 2006). Similar to SARS-CoV-1, IAV also encodes the IFN-I/-III antagonist, nonstructural protein 1 (NS1), that blocks initial detection by the PRR through binding and masking aberrant RNA produced during infection (Garcia-Sastre et al., 1998).

Here, we compare the transcriptional response of SARS-CoV-2 to other respiratory viruses to identify transcriptional signatures that may underlie COVID-19 biology. In all, these data demonstrate that the overall transcriptional induction to SARS-CoV-2 is aberrant. Despite virus replication, the host response to SARS-CoV-2 fails to launch a robust IFN-I/-III response, while simultaneously inducing high levels of chemokines needed to recruit effector cells. As a waning immune response would enable sustained viral replication, these findings may explain why serious cases of COVID-19 are more frequently observed in individuals with comorbidities.

RESULTS

Defining the transcriptional response to SARS-CoV-2 relative to other respiratory viruses.

In an effort to compare the transcriptional response of SARS-CoV-2 to other respiratory viruses, including MERS-CoV, SARS-CoV-1, human parainfluenza virus 3 (HPIV3), respiratory syncytial virus (RSV), and IAV, we first chose to focus on infections in a variety of respiratory cell lines (Figure 1). To this end, we collected polyA RNA from infected cells and performed RNA-Seq to estimate viral load. These data show that virus infection levels ranged from 0.1 to > 50% of total RNA reads (Figure 1A). In agreement with others (Harcourt et al, 2020), we find A549 lung alveolar cells to be relatively non-permissive to SARS-CoV-2 replication in contrast to Calu-3 cells (0.1% vs. 15% total reads, respectively). The low rate of infection in A549 cells is postulated to be the result of low expression of the viral receptor, ACE2 (Harcourt et al, 2020; Hoffman et al. 2020). In an effort to bypass this restriction, we supplemented A549 cells with a vector expressing either mCherry or ACE2 (Figure 1B-D). In low MOI infections (MOI: 0.2), exogenous expression of ACE2 enabled SARS-CoV-2 to replicate and comprise ~54% of the total reads mapping greater than 300X coverage across the ~30kB genome (Figure 1A-B). Western blot analyses corroborated these RNA-Seq data showing Nucleocapsid (N) expression only in cells supplemented with ACE2 (Figure 1C). Furthermore, qPCR analyses of these cells demonstrated levels of Envelope (E) and non-structural protein 14 (nsp14) were more than three orders of magnitude higher in the presence of ACE2 (Figure 1D). It is noteworthy that despite

this dramatic increase in viral load, we observed no activation of TBK1, the kinase responsible for IFN-I and IFN-III expression, nor the induction of STAT1 and MX1, IFN-I stimulated genes (Figure S1A) (Sharma et al. 2003). The lack of IFN-I/-III engagement in ACE2-expressing A549 cells could however be overcome by using a ten-fold increase in virus (MOI: 2) despite the fact that total viral reads after 24 hrs of replication where comparable to low MOI conditions (Figure 1A-B and 1F).

To determine if SARS-CoV-2 was sensitive to IFN-I, we next treated cells with universal IFNβ and assessed viral levels at both an RNA and protein level (Figure S1B-1C). These data demonstrate that the addition of IFN-I resulted in a dramatic reduction of virus replication in agreement with the findings of others (Lokugamage et al., 2020). We also observed no increase in viral Spike levels (nor a considerable impact in viral reads) when IFN-I signaling was blocked by the addition of Ruxolitinib, a JAK1/2 kinase inhibitor, despite significantly preventing the induction of ISGs (Figure S1D-H). In contrast, Ruxolitinib treatment had a minimal effect on the induction of cytokines and chemokines, indicating that the high induction of these genes in SARS-CoV-2 infection is independent of IFN-I/-III signaling (Figure S1G).

To next determine how each of these *in vitro* infections alter the host transcriptional landscape, we first performed differential expression analysis comparing infected cell conditions to their respective mock conditions. These analyses indicate that the transcriptional response in cells that allows high replication of SARS-CoV-2 are significantly different to the host response of all other viruses tested (Figure 1E). Moreover, SARS-CoV-2 infection in unmodified A549 cells shows a unique response as compared to SARS-CoV-1 despite comparable levels of viral load (Figure 1A and E). Lastly, MERS-CoV infection, which approaches ~50% of total reads at 24hpi clusters together with SARS-CoV-1 and IAV, reflecting an overall repression of the host antiviral response (Figure 1E-F). Conversely, HPIV3 and RSV comprise a unique cluster denoted by the high expression of IFNs and IFN-stimulated genes (ISGs) (Figure 1E-F). Interestingly, low MOI SARS-CoV-2-infected A549 cells expressing ACE2 (A549-ACE2*), show no significant IFN-I or IFN-III expression, but instead display moderate

levels of a subset of ISGs and a unique proinflammatory cytokine signature (Figure 1F). This signature is also present in high MOI infections of SARS-CoV-2 in A549-ACE2 and Calu-3 cells, together with > 6000 other differentially expressed genes – further explaining their extreme coordinates on the principle component analysis (PCA) (Figure 1E-F and Table S1). Furthermore, high MOI infections in these cells also led to the high induction of IFNs and ISGs observed for HPIV3 and RSV, despite remarkable differences in viral replication (~60% total reads in A549-ACE2 cells, compared to ~15% in Calu-3) (Figure 1A and 1F). The discrepancy between the levels of viral replication and IFN production/signaling suggests that although SARS-CoV-2 is capable of engaging the IFN-I and IFN-III systems, this response is prevented by an antagonist that is rendered ineffective under high MOI conditions. Alternatively, these data may instead indicate that high MOI conditions in cell culture results in the formation of PAMPs which may or may not reflect physiological conditions *in vivo*.

SARS-CoV-2 in primary cells induces a limited IFN-I and -III response.

Given the disparate results of our *in vitro* cell culture systems, we next sought to determine how normal human bronchial epithelial (NHBE) cells respond to SARS-CoV-2 infection, in contrast to treatment with IFN-I alone or infection with either wild type (WT) IAV, or a mutant IAV lacking its antiviral antagonist (IAVΔNS1) (Figure 2). Treatment of NHBE cells with IFN-I resulted in significant induction of 381 genes, most of these also differentially expressed in IAVΔNS1 infection, together outlining a robust innate immune response in these cells (Figure 2A). In contrast, and despite different levels of replication, the transcriptional response to infection with SARS-CoV-2 and WT IAV are similar in magnitude but different in nature with only 8 shared significantly induced genes, including IL-6, IRF9, ICAM1, and TNF (Figure 2A and Figure S2A). To further understand the global host response as it pertained to each of these conditions, we grouped these samples in a PCA space (Figure 2B). This analysis shows progressive transcriptional perturbations along principle component one, which accounts for more than 60% of sample variation. In this space, SARS-CoV-2 elicits the most modest transcriptional changes, followed by IAV, IFNβ treatment, and lastly IAVΔNS1 (Figure 2B).

Gene enrichment analyses on differentially expressed transcripts illustrate a diminished IFN-I signaling biology for both SARS-CoV-2 and IAV infections (Figure 2C-D). In both examples, IFN-I and IFN-III are undetectable, but a very small subset of ISGs are induced (Figure 2C-D, Figure S2B and Table S2). In the case of IAV, this diminished antiviral response is mediated by the expression of NS1, as IAVΔNS1 infections result in robust IFNB and IFNL1-3 induction (Figure 2C-D, Figure S2B and Table S2). Despite a complete lack of IFN expression, the response to SARS-CoV-2 in NHBE cells still elicited a strong chemotactic and inflammatory response, indicated by the expression of CCL20, CXCL1, IL-1B, IL-6, CXCL3, CXCL5, CXCL6, CXCL2, CXCL16, and TNF, (Figure 2C, 2E and Table S2). In addition to the modest IFN-I response, SARS-CoV-2 in NHBE cells also triggers some unique pathways, including a response to IFN-II (which is also observed in response to IAVΔNS1), and a significant enrichment in chemokine signaling (Figure 2C).

Longitudinal ferret studies mirror the imbalanced in vitro response to SARS-CoV-2.

To determine whether the limited response to SARS-CoV-2 observed thus far was a by-product of cell culture, we next pursued an *in vivo* longitudinal study in animals. To this end, we chose to perform SARS-CoV-2 infections in ferrets as this has been described as an appropriate animal model (Kim et al., 2020). Ferrets were infected intranasally with SARS-CoV-2 or influenza A/California/04/2009 and monitored by nasal wash, which generates a small pellet of cells from the upper respiratory tract. RNA-Seq was performed on these cells enabling us to quantify viral load over time. Reads from nasal wash one-day post infection revealed a low level of virus replication comprising 0.006% of total reads (Figure 3A). At three days post infection, virus replication peaks at 1.2% of the total sequencing reads before decreasing to 0.05% of total reads on day 7 and completely clearing the virus by day 14 (Figure 3A). As a comparison, a sublethal infection of IAV comprises less than 0.03% of total reads on day 7 from the same sample type (Figure S3A). The presence of virus in the nasal passage would further

suggest that these ferrets had the potential to transmit virus in agreement with the findings of others (Kim et al., 2020; Varble et al., 2014).

To characterize the response to SARS-CoV-2 over time, upper respiratory cell populations were compared to mock-treated ferrets. On day one post infection, we observe very little transcriptional difference correlating to the amount of virus detection at this time (Figure 3B). By day three, we observe the beginning of a cytokine response marked by CCL8 and CXCL9, consistent with what was observed in cell culture. By day seven, despite waning levels of virus, the cytokine response continued to expand and included CCL2, CCL8, and CXCL9 amongst others (Figure 3B and Table S3). Moreover, we note evidence for mixed leukocyte infiltration with significant up-regulation in CD163, CD226, CCR5, CCR6, CXCR1, CXCR2 and CXCR7 (Figure 3C). Overall the magnitude of this transcriptional response in the upper respiratory tract was significantly lower as compared to a comparable IAV infection (Figure S3B). However, while IAV induces a greater number of genes, SARS-CoV-2 generates a unique gene signature enriched for cell death and leukocyte activation including transcripts such as IL1A and CXCL8 (GO: 0008219 and GO: 0045431, Table S3). In contrast, the transcriptional footprint of IAV as it pertains to the cellular antiviral response was strikingly greater in magnitude than that observed for SARS-CoV-2 and included the interferon signature genes: MX1, ISG20, OASL, and Tetherin (Figure S3B and Table S3). By day fourteen, we detect no viral reads for SARS-CoV-2 and the observed cytokines return to baseline with the exception of IL-6 and IL1RN/IL1RA, which remain elevated similar to results observed with MERS (Pascal et al. 2015)(Figure 3B-C).

Lastly, to investigate how the host response to SARS-CoV-2 and IAV impacted the respiratory tract, we next performed parallel infections and examined the trachea at day three. In both infections, we observed very low levels of virus but a robust transcriptional response (Table S3). Gene enrichment analysis of differentially expressed transcripts implicated two populations of immune cell signatures (Figure 3D). The first population included common markers for both monocytes and lymphocytes and the induction of these genes were comparable between SARS-CoV-2 and IAV

(Figure 3D and Figure S3C). Intriguingly, unique gene signatures from SARS-CoV-2-infected trachea that were largely absent in response to IAV align with those of progenitor cells from the hematopoietic lineage, suggesting that infection may be inducing hematopoiesis (Figure 3D and Figure S3C) (Lefrancais et al., 2017; Yoshida et al., 2019). Additional research in this area will be required to ascertain whether this is a contributing factor towards the development of COVID-19.

COVID-19 patients present low IFN-I/-III and high chemokine signatures.
Following the characterization of SARS-CoV-2 infection in ferrets, we next sought to correlate these results with natural human infections. To this end, we first compared post mortem lung samples from COVID-19 positive patients to biopsied healthy lung tissue from uninfected individuals. Transcriptional profiling of these samples, all derived from males greater than 60 years of age (n=2 for each group), demonstrated ~2000 differentially expressed genes with enrichment for both the innate and humoral responses (Figure 4A and S4A). Genes significantly induced in response to SARS-CoV-2 included a subset of ISGs with no IFN-I or IFN-III detected by either RNA-Seq or semi-quantitative PCR (Figure S4B and Table S4). In addition to genes implicated in innate antiviral immunity, SARS-CoV-2 also induced robust levels of chemokines, including CCL2, CCL8, and CCL11 (Figure 4A). Despite the limited number of patients analyzed, these data corroborate our findings in both NHBE and ferrets (Figure S4A).

Next, we wished to further validate our findings with a larger cohort of patients through the direct detection of circulating cytokines induced by SARS-CoV-2 infection. To this end, we obtained serum from two cohorts of individuals from the Kaiser Santa Clara testing facility (Santa Clara, CA). These two cohorts either tested positive for SARS-CoV-2 by nasopharyngeal swabs or were admitted to the hospital for non-COVID-19–related respiratory issues (n=24 for each group). Initial analyses of these serum samples consistently tested negative for both IFNβ and the IFNλ family of interferons (Figure 4B). Moreover, analyses of cytokines and chemokines quantified in individual serum samples revealed an enhancement of generalized inflammation amongst the COVID-19 patients, marked by a significant increase in circulating IL-6, IL-1β, IL1RA,

CCL2, CCL8 CXCL2, CXCL8, CXCL9, and CXCL16 levels (Figure 4C). Significant elevation of CXCL9 and CXCL16, chemoattractants of T or NK cells, CCL8 and CCL2, which recruit monocytes/macrophages, and CXCL8, a classic neutrophil chemoattractant, suggest that the presence of these cells may be a primary driver of the signature pathology observed in COVID-19 patients (Proudfoot, 2002). While this sample size is not necessarily representative of the whole population of infected COVID-19 patients, our data is consistent with what we observe using our other model systems. Additional sampling will be required to validate these findings.

DISCUSSION

In the present study, we focus on defining the host response to SARS-CoV-2 and other human respiratory viruses in cell lines, primary cell cultures, ferrets and COVID-19 patients. In general, our data show that the overall transcriptional footprint to SARS-CoV-2 infection was distinct in comparison to other highly pathogenic coronaviruses, and common respiratory viruses such as IAV, HPIV3 and RSV. It is noteworthy that despite a reduced IFN-I/-III response to SARS-CoV-2, we observed a consistent chemokine signature. One exception to this observation is the response to high MOI infections in A549-ACE2 and Calu-3 cells where replication was robust and an IFN-I and –III signature could be observed. In both of these examples, cells were infected at a rate to theoretically deliver two functional virions per cell in addition to any defective interfering particles within the virus stock that were not accounted for by plaque assay. Under these conditions, the threshold for PAMP may be achieved prior to the ability of the virus to evade detection through the production of a viral antagonist. Alternatively, the addition of multiple genomes to a single cell may disrupt the stoichiometry of viral components which, in turn, may itself generate PAMPs that would not otherwise form. These ideas are supported by the fact that at a low MOI infection in A549-ACE2 cells, high levels of replication could also be achieved but in the absence of IFN-I/-III induction. Taken together, these data would suggest that at low MOIs, the virus is not a strong inducer of the IFN-I/-III system, opposed to conditions where the MOI is high. These dynamics are also likely to contribute to the development of COVID-19 during the course of infection (Wolfel et al., 2020).

A recurrent observation in each of our systems is the robust production of cytokines and its subsequent transcriptional response. According to our longitudinal *in vivo* data, this response starts as early as three days post infection and continues beyond the clearance of the virus. A recent study analyzing severe versus mild cases of COVID-19 showed that peripherally-derived macrophages predominated in the lungs of severe cases (Liao et al., 2020). Consistent with this, we found in all of our systems a significant induction of monocyte-associated chemokines, such as CCL2 and CCL8. In addition, our data suggest that neutrophils could also contribute to the disease observed in COVID-19 patients as demonstrated by CXCL2 and CXCL8 induction. This is consistent with data showing elevated circulating neutrophil levels among COVID-19 patients (Chen et al., 2020; Qin et al., 2020), which may have prognostic value in identifying individuals at risk for developing severe disease. It is also noteworthy, that two of the cytokines uniquely elevated in response to SARS-CoV-2 are IL-6 and IL1RA, suggesting that there might be a parallel between COVID-19 and cytokine-release syndrome (CRS), a complication commonly seen following CAR-T treatment (Giavridis et al., 2018). Should this be true, drugs such as tocilizumab and anakinra may prove beneficial for the treatment of COVID-19 (Norelli et al., 2018). Future studies will be needed to address this formally.

Like SARS-CoV-2, the clinical manifestation of SARS-CoV-1 has been proposed to stem from a dysregulated immune response in patients and delayed expression of IFN-I (Channappanavar et al., 2016; Law et al., 2005; Menachery et al., 2014). Based on animal models, SARS-CoV-1 was found to induce a robust cytokine response that generally showed a delay in IFN-I, culminating in the improper recruitment of inflammatory monocyte-macrophage populations (Channappanavar et al., 2016). This dynamic seems in line with what we observe with SARS-CoV-2 as low levels of IFN-I and –III are likely produced in response to infection. Given the moderate viral replication levels observed *in vivo*, one explanation for the low IFN expression could be that a small subset of cells are refractory to the antagonistic mechanism of SARS-CoV-

2 (similar to infected Calu-3 cells), producing sufficient amounts of IFN-I and/or IFN-III to guide immune cell activation and ISG induction.

What makes SARS-CoV-2 distinct from other viruses used in this study is the propensity to selectively induce morbidity and mortality in older populations (Novel Coronavirus Pneumonia Emergency Response Epidemiology, 2020). The physiological basis for this morbidity is believed to be the selective death of Type II pneumocytes that results in both loss of air exchange and fluid leakage into the lungs (Qian et al., 2013; Xu et al., 2020). While it remains to be determined whether the inappropriate inflammatory response to SARS-CoV-2 is responsible for the abnormally high lethality in the older populations, it does explain why the virus is generally asymptomatic in young people with healthy and robust immune systems (Lu et al., 2020). Given the results here, it is tempting to speculate that an already restricted immune response in the aging population prevents successful inhibition of viral spread at early stages of infection, further exacerbating the morbidity and mortality observed for this age group (Jing et al., 2009; Montecino-Rodriguez et al., 2013).

Taken together, these data presented here suggest that the response to SARS-CoV-2 is imbalanced with regards to controlling virus replication versus activation of the adaptive immune response. Given this dynamic, treatments for COVID-19 have less to do with the IFN response and more to do with controlling inflammation. As our data suggests that numerous chemokines and interleukins are elevated in COVID-19 patients, future efforts should focus on FDA-approved drugs that can be rapidly deployed and have immunomodulating properties.

AUTHOR CONTRIBUTIONS

Conceptualization, DBM, BENP, and BRT; Methodology, DBM, BENP, WCL, JKL, RAA, and BRT; Software, DBM and DS; Validation, BENP, SU, DH, and JKL; Formal Analysis, DBM, DS, and BRT; Investigation, BENP, WCL, SU, DH, RM, TXJ, KO, MP, DS, JKL, and RAA; Resources, WCL, TTW, RES, JKL, RAA; Data Curation, DBM; Writing – Original Draft, DBM, BENP, BTO; Writing – Review & Editing, DBM, BENP,

JKL, and BRT; Visualization: DBM, DS, BENP, SU, DH, and BRT; Supervision, RAA and BRT; Project Administration, RAA and BRT; Funding, BRT.

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The authors declare no competing interests.

FIGURE LEGENDS

Figure 1. Host Transcriptional response to respiratory infections in human lung epithelial-derived cell lines. (**A**) Virus replication levels in infected cells. RNA-seq was performed on polyA enriched total RNA and the percentage of virus-aligned reads (over

total reads) is indicated for each sample. Error bars represent standard deviation from three independent biological replicates (except for IAV infection where data is representative of independent biological duplicates). The cell types used for each infection is indicated (+) at the bottom of the figure. All infections were performed at a high MOI (MOI: 2-5), except for (*) that indicates an MOI: 0.2 (**B**) Read coverage along the SARS-CoV-2 genome for mCherry or ACE2 expressing A549 cells. Graph indicates the number of viral reads per each position of the virus genome in A549 cells transduced with AdV-based vectors expressing mCherry (MOI: 0.2, light blue) or ACE2 (MOI: 0.2, salmon (*) and MOI: 2, dark red). Scaled model of SARS-CoV-2 genome and its genes is depicted below (generated in BioRender). (**C**) Western blot analysis of mCherry or ACE2 expressing A549 cells infected with SARS-CoV-2. Whole cell lysates were analyzed by SDS-PAGE and blotted for ACE2, SARS-CoV-2 nucleocapsid (N) and actin. (**D**) qRT-PCR analysis of mCherry or ACE2 expressing A549 cells infected with SARS-CoV-2 (MOI: 0.2). The graph depicts the relative amount of SARS-CoV-2 envelope (E), non-structural protein 14 (nsp14) and human IFNB transcripts normalized to human α-Tubulin. Error bars represent the standard deviation of the mean $\log_2$(Fold Change) of three independent biological replicates. (**E**) Principal component analysis (PCA) for the global transcriptional response to respiratory viruses. Sparse PCA depict global transcriptome profiles of samples in (A). Cell types used for infection are represented by different shapes (Circle: A549, Square: A549-ACE, Diamond: Calu-3, Triangle: MRC5). (**F**) Heatmap depicting the expression levels of differentially expressed genes (DEGs) of samples in (A) belonging to the GO biological processes indicated (GO:0034097, GO:0045087, GO:0009615, GO:0006954). The graph depicts the $\log_2$(Fold Change) of DEGs of infected compared to mock-treated cells. Genes included have a $\log_2$(Fold Change) > 2 and a p-adjusted value < 0.05. Data from SARS-CoV-1 and MERS-CoV infections correspond to GEO entry: GSE56192.

Figure 2. Host Transcriptional response to IAV and SARS-CoV-2 in primary human bronchial epithelial cells. (**A**) Shared DEGs in IFNβ-treated, SARS-CoV-2 or IAV infected NHBE cells. Venn diagram depicts genes shared and/or unique between each comparison. (**B**) Sparse PCA depicting global transcriptional profiles of samples in

(A). (**C**) Dotplot visualization of enriched GO terms in NHBE cells. Gene enrichment analyses were performed using STRING against the GO dataset for biological processes. The color of the dots represents the false discovery rate (FDR) value for each enriched GO term and its size represents the percentage of genes enriched in the total gene set. (**D**) Heatmap indicating the expression levels of DEGs involved in type-I IFN responses. (**E**) Heatmap as in (D) for genes belonging to GO annotations for cytokine activity and chemokine activity (GO:0005125, GO:0008009). The graphs depict the log_2(Fold Change) of DEGs of infected compared to mock-treated cells. Genes included have a log_2(Fold Change) > 1 and a p-adjusted value < 0.05.

Figure 3. Longitudinal analysis of the host response to SARS-CoV-2 in ferrets. (**A**) Read coverage along the SARS-CoV-2 genome. Graph indicates the number of viral reads per each position of the virus genome identified in RNA extracted from nasal washes of ferrets at 1 (gray), 3 (red), 7 (blue) and 14 (green) days post infection. (**B**) Volcano plots indicating differentially expressed genes of ferrets along the course of a SARS-CoV-2 infection as in (A). Differentially expressed genes (p-adjusted value < 0.05) with a |Log_2(Fold Change)| > 2 are indicated in red. Non-significant differentially expressed Genes with a |Log_2(Fold Change)| > 2 are indicated in green. (**C**) Heatmap depicting the expression levels of a subset of cytokines differentially expressed in nasal washes collected from ferrets infected with the indicated viruses at specific times. (**D**) Heatmap depicting the expression levels of Lymphoblast-related genes differentially expressed in trachea samples collected from ferrets infected with the indicated viruses after 3 days. The graphs shows the log_2(Fold Change) of DEGs of infected compared to mock-infected animals. Genes included have a log_2(Fold Change) > 2 and a p-adjusted value < 0.05. Ferrets were randomly assigned to the different treatment groups (naïve, *n* = 2; SARS-CoV-2 infection, *n* = 6; influenza A virus (pH1N1) infection, *n* = 2; influenza A virus (H3N2) infection, *n* = 2).

Figure 4. Transcriptional and serological profile of clinical COVID-19 patients. (**A**) Volcano plot depicting differentially expressed genes in post-mortem lung samples of

two COVID-19 patients compared to healthy lung biopsies. Differentially expressed genes (p-adjusted value < 0.05) with a $|Log_2(Fold\ Change)| > 2$ are indicated in red. Non-significant differentially expressed Genes with a $|Log_2(Fold\ Change)| > 2$ are indicated in green. (**B**-**C**) Cytokine profiles of COVID-19 patients. Sera of 24 COVID-19 patients and 24 SARS-CoV-2 negative controls were analyzed by ELISA for the protein levels of (B) Interferon type I and III, or (C) a broad panel of cytokines. Statistical significance calculated by Mann-Whitney non-parametric t test. NS: non-significant, (*): p-value < 0.05, (**): p-value < 0.005, (*): p-value < 0.0001.

Figure S1. Role of interferon response in infections with SARS-CoV-2, related to Figure 1. (**A**) Western blot analysis of WT or ACE2-expressing A549 cells mock-treated or infected with SARS-CoV-2 or Sendai virus. Whole cell lysates were analyzed by SDS-PAGE and blotted for SARS-CoV-2 spike, phospho-TBK1, MX1, STAT1 and actin. (**B**) qRT-PCR analysis of Vero E6 cells infected with SARS-CoV-2 and treated with IFNβ two hours post infection as indicated. The graph depicts the relative amount of SARS-CoV-2 envelope (E) and non-structural protein 14 (nsp14) normalized to human α-Tubulin. Error bars represent the standard deviation of the mean fold change of three independent biological replicates. Statistical significance calculated by Student-t test corrected for multiple comparisons using Holm-Sidak method (***) p-value < 0.001. (**C**) Western blot analysis of conditions as in (B). Whole cell lysates were analyzed by SDS-PAGE and blotted for SARS-CoV-2 spike and GAPDH. (**D**) Western blot analysis of ACE2-expressing A549 cells infected with SARS-CoV-2 with or without Ruxolitinib. Whole cell lysates were analyzed by SDS-PAGE and blotted for SARS-CoV-2 spike and GAPDH. (**E**) Virus replication levels in SARS-CoV-2-infected A549-ACE2 cells treated with or without Ruxolitinib. RNA-seq was performed on polyA enriched total RNA and the percentage of virus-aligned reads (over total reads) is indicated for each sample. Error bars represent standard deviation from three independent biological replicates. Infections were preformed at high MOI (MOI: 2). (**F-G**) Expression levels of (F) ISGs or (G) cytokines and chemokines in conditions as in (E). Scatterplot of the $log_2(Fold\ Change)$ of individual genes in SARS-CoV-2-infected A549-ACE2 cells treated with or

without Ruxolitinib. Linear regression line and confidence interval (0.95) is shown as a red line and gray shaded area, respectively. Dotted diagonal represent no changes between conditions. (**G**). Heatmap depicting the expression levels of ISGs as in (F).

Figure S2. Infectivity and host response to SARS-CoV-2 infection in NHBE cells, related to Figure 2. (**A**) Virus replication levels in infected cells. RNA-seq was performed on polyA enriched total RNA and the percentage of virus-aligned reads (over total reads) is indicated for each sample. Error bars represent standard deviation from four independent biological replicates (except for SARS-CoV-2 infection where data is representative of independent biological triplicates). (**B**) Heatmap depicting the expression levels of Interferon transcripts in the indicated conditions. Colors representing transcripts per million (TPMs) in RNA-seq experiments.

Figure S3. Transcriptional response to SARS-CoV-2 and IAV in ferrets, related to Figure 3. (**A**) Read coverage along the IAV genome. Graph indicates the number of viral reads per each position of the IAV virus genome identified in RNA extracted from nasal washes of ferrets at 7 days post infection. Scaled model of the concatenated IAV segments is depicted below. (**B**) Volcano plots indicating differentially expressed genes of ferrets infected with SARS-CoV-2 or IAV for 7 days. Differentially expressed genes (p-adjusted value < 0.05) with a $|Log_2(\text{Fold Change})| > 2$ are indicated in red. Non-significant differentially expressed Genes with a $|Log_2(\text{Fold Change})| > 2$ are indicated in green. (**C**) Cellular profiling from a subset of genes selectively enriched in response to SARS-CoV-2 compared to IAV, as determined by the Immunological Genome Project.

Figure S4. Unique and shared biological processes between different models of SARS-CoV-2 infections, related to Figure 4. (**A**) Dotplot visualization of enriched GO terms in NHBE cells, ferrets and COVID-19 patients. Gene enrichment analyses were performed using STRING against the GO dataset for biological processes. The color of the dots represents the false discovery rate (FDR) value for each enriched GO term and its size represents the percentage of genes enriched in the total gene set. (**B**) Semi-

quantitative PCR analysis of healthy and COVID-19 derived lung tissues. Image indicates the relative expression of SARS-CoV-2 nsp14, IFNB and tubulin transcripts in healthy human biopsies and biological replicates of lung tissue from COVID-19 patients. Additionally cDNA of A549 cells infected with IAVΔNS1 are included as controls.

STAR★ METHODS

RESOURCE AVAILABILITY

Lead Contact

Further information and requests for resources and reagents should be directed to and will be fulfilled by the Lead Contact, Benjamin tenOever (benjamin.tenoever@mssm.edu).

Materials Availability

All materials and reagents will be made available upon instalment of a material transfer agreement (MTA).

Data and Code Availability

The raw sequencing datasets generated during this study are were deposited on the NCBI Gene Expression Omnibus (GEO) server under the accession number GSE147507. The original sequencing datasets for SARS-CoV-1 and MERS-CoV infections can be found on the NCBI Gene Expression Omnibus (GEO) server under the accession number GSE56192.

EXPERIMENTAL MODEL AND SUBJECT AVAILABILITY

Cell cultures and primary cells

Human adenocarcinomic alveolar basal epithelial (A549) cells (ATCC, CCL-185), human adenocarcinomic lung epithelial (Calu-3) cells (ATCC, HTB-55), human HEp-2 cells (ATCC, CCL-23), Madin-Darby Canine Kidney (MDCK) cells (ATCC, CCL-34), MDCK-NS1 cells (Garcia-Sastre et al., 1998) and African green monkey kidney epithelial Vero E6 cells (ATCC, CRL-1586) were maintained at 37°C and 5% CO_2 in Dulbecco's Modified Eagle Medium (DMEM, Gibco) supplemented with 10% Fetal Bovine Serum (FBS, Corning). Undifferentiated normal human bronchial epithelial (NHBE) cells (Lonza, CC-2540 Lot# 580580) were isolated from a 79-year-old

Caucasian female and were maintained in bronchial epithelial growth media (Lonza, CC-3171) supplemented with BEGM SingleQuots as per the manufacturer's instructions (Lonza, CC-4175) at 37°C and 5% CO_2.

Animal studies

Outbred 4-month old castrated male Fitch ferrets were purchased from Triple F. Farm (North Rose, NY). All animals were confirmed to be seronegative for circulating influenza A (H1N1) viruses, influenza A (H3N2) viruses and influenza B viruses prior to purchase. Ferrets were housed in cages in the enhanced BSL-3 facility of the Emerging Pathogens Institute at the Icahn School of Medicine at Mount Sinai. All animal experiments were performed according to protocols approved by the Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety Committee of the Icahn School of Medicine at Mount Sinai (NY, USA). Ferrets were randomly assigned to the different experimental groups.

Human studies

For RNA analysis, two COVID19 human subjects were deceased upon tissue acquisition and were provided from Weill Cornell Medicine as fixed samples. For semi-quantitative PCR analyses, two additional lung samples were derived post-mortem from males over 60 years of age. The uninfected human lung samples (n=2) were obtained post surgery through the Mount Sinai Institutional Biorepository and Molecular Pathology Shared Resource Facility (SRF) in the Department of Pathology. The Biorepository operates under a Mount Sinai Institutional Review Board (IRB) approved protocol and follows guidelines set by HIPAA. Sera were obtained from the Kaiser Santa Clara testing facility (Santa Clara, CA). Sera were from subjects with a CoV PCR+ nasopharyngeal swab (n=24) or from subjects who were not being tested for CoV infection (n=24). The study was reviewed and approved by the Stanford University institutional review board (PI TTW). Experiments using samples from human subjects were conducted in accordance with local regulations and with the approval of the institutional review board at the Icahn School of Medicine at Mount Sinai under protocol HS#12-00145.

Viruses

Influenza A/Puerto Rico/8/1934 (H1N1) virus (NCBI:txid183764), influenza A/California/04/2009 (pH1N1) virus and influenza A/Texas/71/2017 (H3N2) virus were grown in MDCK cells (Langlois et al., 2013). Influenza A/Puerto Rico/8/1934 (H1N1) virus lacking the NS1 gene (IAVΔNS1, (Garcia-Sastre et al., 1998)) was grown in MDCK-NS1 cells. Influenza viruses were grown in EMEM supplemented with 0.35% bovine serum albumin (BSA, MP Biomedicals), 4 mM L-glutamine, 10 mM HEPES, 0.15% $NaHCO_3$ and 1 µg/ml TPCK-trypsin (Sigma-Aldrich). Infectious titers of influenza A viruses were determined by plaque assay in MDCK or MDCK-NS1 cells, accordingly. Recombinant GFP-expressing human respiratory syncytial virus (RSV), strain A2 (§) was generously provided by Dr. M. Peeples (OSU) and was described previously (Hallak et al., 2000). rgRSV[224] was grown in HEp-2 cells in in DMEM supplemented with 2% FBS, 4.5 g/L D-glucose and 4 mM L-glutamine. SARS-related coronavirus 2 (SARS-CoV-2), Isolate USA-WA1/2020 (NR-52281) was deposited by the Center for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH. SARS-CoV-2 was propagated in Vero E6 cells in DMEM supplemented with 2% FBS, 4.5 g/L D-glucose, 4 mM L-glutamine, 10 mM Non-Essential Amino Acids, 1 mM Sodium Pyruvate and 10 mM HEPES. Infectious titers of SARS-CoV-2 were determined by plaque assay in Vero E6 cells in Minimum Essential Media supplemented with 2% FBS, 4 mM L-glutamine, 0.2% BSA, 10 mM HEPES and 0.12% $NaHCO_3$ and 0.7% agar. eGFP/ GLuc-expressing human parainfluenza virus 3, strain JS (rHPIV3JS-GlucP2AeGFP) was described previously (Blanco-Melo et al., 2020). HPIV3-eGFP/GLuc was grown in HeLa cells at 32ºC in DMEM supplemented with 10% FBS and 1ug/mL TPCK-trypsin (Millipore Sigma, Burlington MA, USA) and titers in Vero E6 cells as previously described. All work involving live SARS-CoV-2 was performed in the CDC/USDA-approved BSL-3 facility of the Icahn School of Medicine at Mount Sinai in accordance with institutional biosafety requirements.

METHOD DETAILS

RNA-Seq of viral infections

Approximately 5 × 10^5 A549 or Calu-3 cells were infected with influenza A/Puerto Rico/8/1934 (H1N1) virus (IAV), human respiratory syncytial virus (RSV), human parainfluenza virus 3 (HPIV3) or SARS-CoV-2 as indicated. Infections with IAV were performed at a multiplicity of infection of 5 for 9 h in DMEM supplemented with 0.3% BSA, 4.5 g/L D-glucose, 4 mM L-glutamine and 1 µg/ml TPCK-trypsin. Infections with RSV and HPIV3 were performed at an MOI of 2 for 24 h in DMEM supplemented with 2% FBS, 4.5 g/L D-glucose and 4 mM L-glutamine. Infections with SARS-CoV-2 were performed at an MOI of 2 for 24 h in DMEM supplemented with 2% FBS, 4.5 g/L D-glucose, 4 mM L-glutamine, 10 mM Non-Essential Amino Acids, 1 mM Sodium Pyruvate and 10 mM HEPES. Approximately 5 × 10^5 NHBE cells were infected with either SARS-CoV-2 at an MOI of 2 for 24 h or influenza A/Puerto Rico/8/1934 (H1N1) virus or influenza A/Puerto Rico/8/1934 (H1N1) virus lacking the NS1 gene at an MOI of 3 for 12 h in bronchial epithelial growth media supplemented with BEGM SingleQuots. As a comparison to viral infection, NHBE cells were treated with 100 units / ml of IFNβ for 4 – 12 h. Total RNA from infected and mock infected cells was lysed in TRIzol (Invitrogen) and extracted and DNase I treated using Direct-zol RNA Miniprep kit (Zymo Research) according to the manufacturer's instructions. RNA-seq libraries of polyadenylated RNA were prepared using the TruSeq RNA Library Prep Kit v2 (Illumina) or TruSeq Stranded mRNA Library Prep Kit (Illumina) according to the manufacturer's instructions. Sequencing libraries were sequenced on an Illumina NextSeq 500 platform.

Adenovector transductions

Approximately 5 × 10^5 A549 cells were transduced with Adenovectors purchased from Vector Biolabs at an MOI of 500 to induce expression of mCherry (Ad(RDG)-mCherry) and human ACE2 (Ad-eGFP-h-ACE2). 48 h post-transduction, efficient gene expression of delivered fluorescent proteins was confirmed by fluorescent microscopy using an EVOS M5000 Imaging System.

Drug treatments

Approximately 5 × 10^5 Vero E6 cells were infected with SARS-CoV-2 at an MOI of 0.05 in DMEM supplemented with 2% FBS, 4.5 g/L D-glucose, 4 mM L-glutamine, 10 mM

Non-Essential Amino Acids, 1 mM Sodium Pyruvate and 10 mM HEPES. Vero E6 cells were treated with 100 units of universal Type-I IFNB 2 hours post-infection. NHBE cells were treated with 100 units of human IFNβ as indicated. Cells were harvested for RNA and protein analysis 24 hpi as described below. Approximately 2.5×10^5 A549 cells transduced with an ACE2 Adenovector were pre-treated with 500 nM Ruxolitinib or DMSO control for 1 h in infection media before infection with SARS-CoV-2 at an MOI of 2 for 24 h. Cells were harvested for protein analysis as described below.

Western blot

Protein was extracted from cells in Radioimmunoprecipitation assay (RIPA) lysis buffer containing 1X cOmplete Protease Inhibitor Cocktail (Roche) and 1X Phenylmethylsulfonyl fluoride (Sigma Aldrich) prior to safe removal from the BSL-3 facility. Samples were analysed by SDS-PAGE and transferred onto nitrocellulose membranes. Proteins were detected using mouse monoclonal anti-Actin (Thermo Scientific, MS-2295), rabbit monoclonal anti-GAPDH (Cell Signaling, 2118), rabbit monoclonal anti-ACE2 (Abcam, ab239924), rabbit monoclonal phospho-TBK1(Ser172) (Cell Signaling, D52C2), mouse monoclonal STAT1 (BD Biosciences, 558537), rabbit polyclonal MX1 (Abcam, ab207414), as well as mouse monoclonal anti-SARS-CoV-2 Nucleocapsid [1C7] and Spike [2B3E5] protein (a kind gift by Dr. T. Moran, Center for Therapeutic Antibody Discovery at the Icahn School of Medicine at Mount Sinai). Primary antibodies were detected using Fluorophore-conjugated secondary goat anti-mouse (IRDye 680RD, 926-68070; IRDye 800CW, 926-32210) and goat anti-rabbit (IRDye 680RD, 926-68071; IRDye 800CW, 926-32211) antibodies. Fluorescent signal was detected using a LI-COR Odyssey CLx imaging system and analysed by Image Studio software (LI-COR).

Quantitative real-time and semi-quantitative PCR analysis

RNA was reverse transcribed into cDNA using oligo d(T) primers using SuperScript II Reverse Transcriptase (Thermo Fisher). Quantitative real-time PCR was performed on a LightCycler 480 Instrument II (Roche) using KAPA SYBR FAST qPCR Master Mix Kit (Kapa Biosystems) and primers specific for SARS-CoV-2 E and nsp14 transcripts as

described previously (Chu et al., 2020; Corman et al., 2020) as well as human IFNB and α-Tubulin transcripts (Table S6). Delta-delta-cycle threshold (ΔΔCT) was determined relative to mock infected samples. Viral RNA levels were normalized to α-Tubulin and depicted as fold change over mock infected samples. Error bars indicate the standard deviation from three biological replicates. Semi-quantitative PCR analysis of cDNA was performed using GoTaq Green MasterMix (Promega) and analysed by 1.5% agarose gel electrophoresis in TAE buffer.

Cytokine and Chemokine Protein Analysis

Serum levels of IFNβ were measured using the VeriKine-HS human IFN-β serum ELISA kit (PBL Interferon Source, NJ). Serum levels of IFNλ were measured using the IFNλ ELISA kit (PBL Interferon Source, NJ). The following cytokines/chemokines were evaluated using multiplex ELISA: CCL2/monocyte chemoattractant protein (MCP-1), CCL8/MCP-2, CXCL8/interleukin 8 (IL-8), CXCL9/monokine induced by IFN-γ (MIG), CXCL16, interleukin 1β (IL-1β), interleukin 1 receptor antagonist (IL-1RA), interleukin 4, and interleukin 6 (IL-6). All antibodies and cytokine standards were purchased as antibody pairs from R&D Systems (Minneapolis, Minnesota) or Peprotech (Rocky Hill, New Jersey). Individual magnetic Luminex bead sets (Luminex Corp, CA) were coupled to cytokine-specific capture antibodies according to the manufacturer's recommendations. The assays were read on a MAGPIX platform. The median fluorescence intensity of these beads was recorded for each bead and was used for analysis using a custom R script and a 5P regression algorithm.

Ferret infections

All procedures are described in our previous study (Liu et al., 2019). Ferrets were randomly assigned to the different treatment groups (naïve, *n* = 2; SARS-CoV-2 infection, *n* = 6; influenza A virus (pH1N1) infection, *n* = 2; influenza A virus (H3N2) infection, *n* = 2). Both influenza A virus and SARS-CoV-2 infections of ferrets were performed simultaneously in the BSL-3 facility. For influenza A virus infections, all naïve ferrets were infected intranasally with 10^5 PFU of influenza A/California/04/2009

(pH1N1) virus or 10^6 PFU of influenza A/Texas/71/2017 (H3N2) virus. Nasal washes were collected from anesthetized ferrets challenged with influenza A/California/04/2009 (pH1N1) virus on day 7 post infection and preserved at -80°C. Trachea were collected from euthanized ferrets challenged with influenza A/Texas/71/2017 (H3N2) virus on day 3 post infection and preserved at -80°C. For SARS-CoV-2 virus infections, all naïve ferrets were infected with 5×10^4 PFU of SARS-CoV-2 isolate USA-WA1/2020. Nasal washes were collected from anesthetized ferrets on days 1, 3, 7 and 14 post-infection and trachea were collected from euthanized ferrets on day 3 post infection and preserved at -80°C. At the end of the study, anesthetized ferrets were euthanized by exsanguination followed by intracardiac injection of euthanasia solution (Sodium Pentobarbital). Total RNA from nasal washes and trachea was extracted using TRIzol (Invitrogen) and analyzed by RNA-Seq as described above.

QUANTIFICATION AND STATISTICAL ANALYSIS

Bioinformatic analyses

Raw reads were aligned to the human genome (hg19) using the RNA-Seq Aligment App on Basespace (Illumina, CA), following differential expression analysis using DESeq2 (Love et al., 2014). To diminish the noise introduced by variables inherent to the use of different cell types and systems, our differential expression analyses were always performed by matching each experimental condition with a corresponding mock treated sample that counted for the cell type, collection time, concurrent animal controls, etc. The raw sequencing data (fastq files) for the SARS-CoV-1 and MERS infections was downloaded from GEO (GSE56192, including their corresponding mock-treated controls) and processed in the same way as the rest of our experimental conditions. In order to capture the whole breadth of the response to IFNβ treatment we pooled samples from 4, 6 and 12 hrs post treatment and compare them together to mock treated cells. Differentially expressed genes (DEGs) were characterized for each sample ($|L2FC| > 1$p adjusted-value < 0.05) and were used as query to search for enriched biological processes (Gene ontology BP) and network analysis of protein interactions using STRING (Szklarczyk et al., 2019). Heatmaps of gene expression

levels were constructing using heatmap.2 from the gplot package in R (https://cran.r-project.org/web/packages/gplots/index.html). Sparse principal component analysis (sPCA) was performed on Log_2(Fold Change) values using SPC from the PMA package in R (Witten et al., 2009). Volcano plots, dot plots, scatter plots and linear regressions were constructed using ggplot2 (Wickham and SpringerLink (Online service), 2016) and custom scripts in R. Heatmap of Type-I IFN responses was constructed on DEGs belonging to the following GO annotations: GO:0035457, GO:0035458, GO:0035455, GO:0035456, GO:0034340. Alignments to viral genomes was performed using bowtie2 (Langmead and Salzberg, 2012). Cell lineage profiling from SARS-CoV-2 unique gene signatures was generated using the Immunological Genome Project (ImmGen.org) (Yoshida et al., 2019). The genomes used for this study were: SARS-CoV-2 (NC_045512.2), SARS-CoV-1 (NC_004718.3), MERS-CoV (NC_038294.1), HPIV3 (Z11575.1), RSV (NC_001803.1), IAV PR8 (AF389115.1, AF389116.1, AF389117.1, AF389118.1, AF389119.1, AF389120.1, AF389121.1, AF389122.1) and IAV A/California/VRDL6/2010(H1N1) (CY064994, CY064993, CY064992, CY064987, CY064990, CY064989, CY064988, CY064991). All RNA-Seq data performed in this paper can be found on the NCBI Gene Expression Omnibus (GEO) under accession number GSE147507. All non-RNA-seq statistical analyses were performed as indicted in figure legends using prism 8 (GraphPad Software, San Diego, California USA, www.graphpad.com).

SUPPLEMENTAL TABLES

Table S1. Differential gene expression analysis of respiratory virus infections in cell lines. Related to Figure 1.
Table S2. Differential gene expression analysis of experiments performed in NHBE cells. Related to Figure 2.
Table S3. Differential gene expression analysis of longitudinal ferret experiments. Related to Figure 3.
Table S4. Differential gene expression analysis of COVID-19 patients. Related to Figure 4.
Table S5. qPCR primer sequences. Related to Figure 1 and 4.

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KEY RESOURCES TABLE

The table highlights the genetically modified organisms and strains, cell lines, reagents, software, and source data **essential** to reproduce results presented in the manuscript. Depending on the nature of the study, this may include standard laboratory materials (i.e., food chow for metabolism studies), but the Table is **not** meant to be comprehensive list of all materials and resources used (e.g., essential chemicals such as SDS, sucrose, or standard culture media don't need to be listed in the Table). **Items in the Table must also be reported in the Method Details section within the context of their use.** The number of **primers and RNA sequences** that may be listed in the Table is restricted to no more than ten each. If there are more than ten primers or RNA sequences to report, please provide this information as a supplementary document and reference this file (e.g., See Table S1 for XX) in the Key Resources Table.

Please note that ALL references cited in the Key Resources Table must be included in the References list. Please report the information as follows:

- **REAGENT or RESOURCE:** Provide full descriptive name of the item so that it can be identified and linked with its description in the manuscript (e.g., provide version number for software, host source for antibody, strain name). In the Experimental Models section, please include all models used in the paper and describe each line/strain as: model organism: name used for strain/line in paper: genotype. (i.e., Mouse: OXTR$^{fl/fl}$: B6.129(SJL)-Oxtr$^{tm1.1Wsy/J}$). In the Biological Samples section, please list all samples obtained from commercial sources or biological repositories. Please note that software mentioned in the Methods Details or Data and Software Availability section needs to be also included in the table. See the sample Table at the end of this document for examples of how to report reagents.

- **SOURCE:** Report the company, manufacturer, or individual that provided the item or where the item can obtained (e.g., stock center or repository). For materials distributed by Addgene, please cite the article describing the plasmid and include "Addgene" as part of the identifier. If an item is from another lab, please include the name of the principal investigator and a citation if it has been previously published. If the material is being reported for the first time in the current paper, please indicate as "this paper." For software, please provide the company name if it is commercially available or cite the paper in which it has been initially described.

- **IDENTIFIER:** Include catalog numbers (entered in the column as "Cat#" followed by the number, e.g., Cat#3879S). Where available, please include unique entities such as RRIDs, Model Organism Database numbers, accession numbers, and PDB or CAS IDs. For antibodies, if applicable and available, please also include the lot number or clone identity. For software or data resources, please include the URL where the resource can be downloaded. Please ensure accuracy of the identifiers, as they are essential for generation of hyperlinks to external sources when available. Please see the Elsevier list of Data Repositories with automated bidirectional linking for details. When listing more than one identifier for the same item, use semicolons to separate them (e.g. Cat#3879S; RRID: AB_2255011). If an identifier is not available, please enter "N/A" in the column.
    - ***A NOTE ABOUT RRIDs:*** We highly recommend using RRIDs as the identifier (in particular for antibodies and organisms, but also for software tools and databases). For more details on how to obtain or generate an RRID for existing or newly generated resources, please visit the RII or search for RRIDs.

Please use the empty table that follows to organize the information in the sections defined by the subheading, skipping sections not relevant to your study. Please do not add subheadings. To add a row, place the cursor at the end of the row above where you would like to add the row, just outside the right border of the table. Then press the ENTER key to add the row. Please delete empty rows. Each entry must be on a separate row; do not list multiple items in a single table cell. Please see the sample table at the end of this document for examples of how reagents should be cited.

TABLE FOR AUTHOR TO COMPLETE

Please upload the completed table as a separate document. ***Please do not add subheadings to the Key Resources Table.*** *If you wish to make an entry that does not fall into one of the subheadings below, please contact your handling editor. (**NOTE:** For authors publishing in Current Biology, please note that references within the KRT should be in numbered style, rather than Harvard.)*

KEY RESOURCES TABLE

REAGENT or RESOURCE	SOURCE	IDENTIFIER
Antibodies		
Mouse monoclonal anti-Actin	Thermo Scientific	MS-2295
Rabbit monoclonal anti-GAPDH	Cell Signaling Technologies	2118
Rabbit monoclonal anti-ACE2	Abcam	ab239924
Rabbit monoclonal anti-Phospho-TBK1(Ser172)	Cell Signaling Technologies	D52C2
Mouse monoclonal anti-STAT1	BD Biosciences	558537
Rabbit polyclonal anti-MX1	Abcam	ab207414
Mouse monoclonal anti-SARS-CoV-2 Spike [2B3E5]	Center for Therapeutic Antibody Discovery at the Icahn School of Medicine at Mount Sinai	
Mouse monoclonal anti-SARS-CoV-2 Nucleocapsid [2B3E5]	Center for Therapeutic Antibody Discovery at the Icahn School of Medicine at Mount Sinai	
IRDye 680RD Goat anti-Rabbit IgG	LI-COR	926-68071
IRDye 680RD Goat anti-Mouse IgG	LI-COR	926-68070
IRDye 800CW Goat anti-Rabbit IgG	LI-COR	926-32211
IRDye 800CW Goat anti-Mouse IgG	LI-COR	926-32210
Bacterial and Virus Strains		
Ad-mCherry	Vector Biolabs	1767
Ad-h-ACE2	Vector Biolabs	ADV-200183
SARS-CoV-2 Isolate USA-WA1/2020	BEI Resources	NR-52281
Influenza A/Puerto Rico/8/1934 (H1N1) virus	Langlois et al., 2013	PR8
Influenza A/California/04/2009 (pH1N1) virus	Langlois et al., 2013	Cal04
Influenza A/Texas/71/2017 (H3N2) virus	Langlois et al., 2013	Texas71
Influenza A/Puerto Rico/8/1934-ΔNS1 (H1N1) virus	Garcia-Sastre et al., 1998	IAVΔNS1
rgRSV[224] (strain A2)	Hallak et al., 2000	
rHPIV3JS-GlucP2AeGFP	Blanco-Melo et al., 2020	
Biological Samples		
Healthy human lung tissue	Mount Sinai Institutional Biorepository and Molecular Pathology Shared Resource Facility	
COVID-19 human lung tissue	Weill Cornell Medicine	
Human patient sera	Kaiser Santa Clara testing facility	
Chemicals, Peptides, and Recombinant Proteins		
Ruxolitnib	ACT Chemical	ACT06813
Universal Type I IFN	R&D Systems	11200-2
Human IFNβ	BEI Resources	NR-3080

TRIzol Reagent	Thermo Scientific	15596026
Critical Commercial Assays		
Direct-zol RNA MiniPrep kit	Zymo Research	R2051
TruSeq RNA Library Prep Kit v2	Illumina	RS-122-2001
TruSeq Stranded mRNA Library Prep Kit	Illumina	20020594
KAPA SYBR FAST qPCR Master Mix Kit Universal	Kapa Biosystems	KK4601
VeriKine-HS human IFN-β serum ELISA kit	PBL Interferon Source	41415-1
VeriKine-HS human IFN-λ serum ELISA kit	PBL Interferon Source	61840-1
Deposited Data		
Raw and analysed data	This paper	GEO: GSE147507
SARS-CoV-1 and MERS-CoV data	NCBI GEO	GEO: GSE56192
Experimental Models: Cell Lines		
A549	ATCC	CCL-185
Calu-3	ATCC	HTB-55
Hep-2	ATCC	CCL-23
MDCK	ATCC	CCL-34
MDCK-NS1	Garcia-Sastre et al., 1998	MDCK-NS1
Vero E6	ATCC	CRL-1586
NHBE	Lonza	CC-2540, #580580
Experimental Models: Organisms/Strains		
Ferrets	Triple F. Farm	Fitch ferrets
Oligonucleotides		
h-aTubulin_F: GCCTGGACCACAAGTTTGAC	This paper	
h-aTubulin_R: TGAAATTCTGGGAGCATGAC	This paper	
h-IFNb_F: GTCAGAGTGGAAATCCTAAG	This paper	
h-IFNb_R: ACAGCATCTGCTGGTTGAAG	This paper	
SARSCoV2-nsp14_F: TGGGGYTTTACRGGTAACCT	Chu et al, 2020	
SARSCoV2-nsp14_R: AACRCGCTTAACAAAGCACTC	Chu et al, 2020	
SARSCoV2-E_F: ACAGGTACGTTAATAGTTAATAGCGT	Corman et al, 2020	
SARSCoV2-E_R: ATATTGCAGCAGTACGCACACA	Corman et al, 2020	
Recombinant DNA		

Software and Algorithms		
Prism8	GraphPad	http://www.graphpad .com
ImageStudio	LI-COR	https://www.licor.com/bio/image-studio/
BaseSpace	Ilumina	https://basespace.illumina.com/
RNA-Seq Aligment App v2.0.2	Ilumina	https://basespace.illumina.com/
RNA-Express v1.1.10	Ilumina	https://basespace.illumina.com/
DESeq2	Love, et al. 2014	https://bioconductor.org/packages/release/bioc/html/DESeq2.html
STRING	Szklarczyk et al., 2019	https://string-db.org/
gplots	CRAN	https://cran.r-project.org/web/packages/gplots/index.html
PMA	Witten et al., 2009	https://cran.r-project.org/web/packages/PMA/index.html
ggplot2	Tidyverse	https://ggplot2.tidyverse.org/
Bowtie2	Langmead and Salzberg, 2012	http://bowtie-bio.sourceforge.net/bowtie2/index.shtml
ImmGen	Yoshida et al., 2019	http://www.immgen.org/
Other		

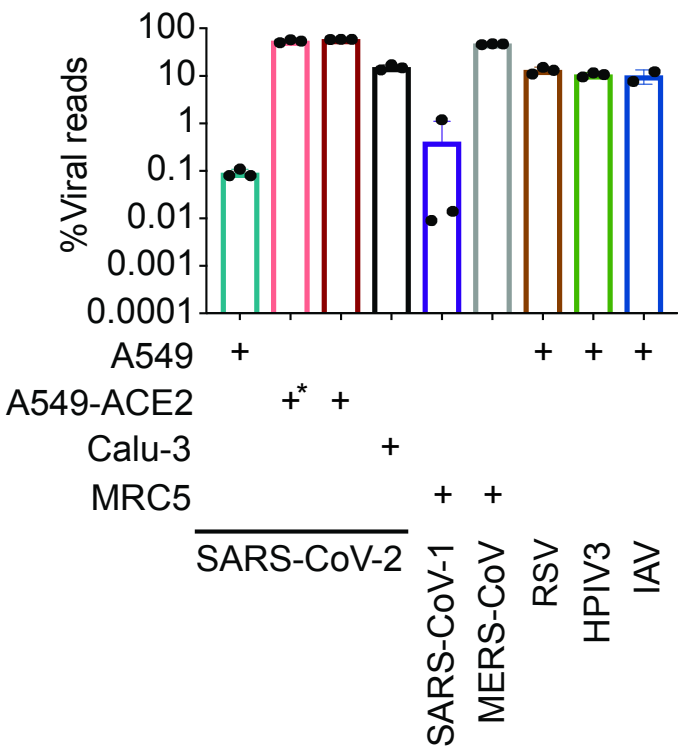
TABLE WITH EXAMPLES FOR AUTHOR REFERENCE

REAGENT or RESOURCE	SOURCE	IDENTIFIER
Antibodies		
Rabbit monoclonal anti-Snail	Cell Signaling Technology	Cat#3879S; RRID: AB_2255011
Mouse monoclonal anti-Tubulin (clone DM1A)	Sigma-Aldrich	Cat#T9026; RRID: AB_477593
Rabbit polyclonal anti-BMAL1	This paper	N/A
Bacterial and Virus Strains		
pAAV-hSyn-DIO-hM3D(Gq)-mCherry	Krashes et al., 2011	Addgene AAV5; 44361-AAV5
AAV5-EF1a-DIO-hChR2(H134R)-EYFP	Hope Center Viral Vectors Core	N/A
Cowpox virus Brighton Red	BEI Resources	NR-88
Zika-SMGC-1, GENBANK: KX266255	Isolated from patient (Wang et al., 2016)	N/A
Staphylococcus aureus	ATCC	ATCC 29213
Streptococcus pyogenes: M1 serotype strain: strain SF370; M1 GAS	ATCC	ATCC 700294
Biological Samples		
Healthy adult BA9 brain tissue	University of Maryland Brain & Tissue Bank; http://medschool.umaryland.edu/btbank/	Cat#UMB1455
Human hippocampal brain blocks	New York Brain Bank	http://nybb.hs.columbia.edu/
Patient-derived xenografts (PDX)	Children's Oncology Group Cell Culture and Xenograft Repository	http://cogcell.org/
Chemicals, Peptides, and Recombinant Proteins		
MK-2206 AKT inhibitor	Selleck Chemicals	S1078; CAS: 1032350-13-2
SB-505124	Sigma-Aldrich	S4696; CAS: 694433-59-5 (free base)
Picrotoxin	Sigma-Aldrich	P1675; CAS: 124-87-8
Human TGF-β	R&D	240-B; GenPept: P01137
Activated S6K1	Millipore	Cat#14-486
GST-BMAL1	Novus	Cat#H00000406-P01
Critical Commercial Assays		
EasyTag EXPRESS 35S Protein Labeling Kit	Perkin-Elmer	NEG772014MC
CaspaseGlo 3/7	Promega	G8090

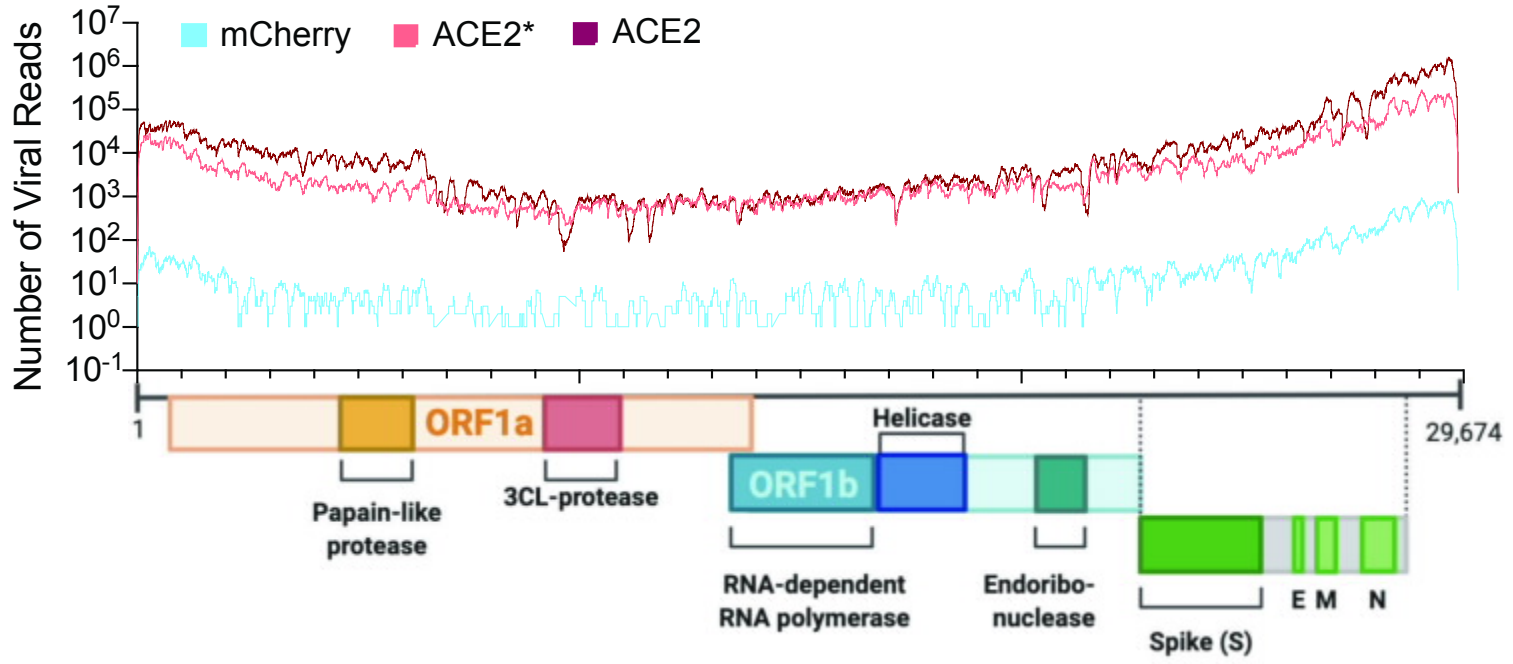
TruSeq ChIP Sample Prep Kit	Illumina	IP-202-1012
Deposited Data		
Raw and analyzed data	This paper	GEO: GSE63473
B-RAF RBD (apo) structure	This paper	PDB: 5J17
Human reference genome NCBI build 37, GRCh37	Genome Reference Consortium	http://www.ncbi.nlm.nih.gov/projects/genome/assembly/grc/human/
Nanog STILT inference	This paper; Mendeley Data	http://dx.doi.org/10.17632/wx6s4mj7s8.2
Affinity-based mass spectrometry performed with 57 genes	This paper; and Mendeley Data	Table S8; http://dx.doi.org/10.17632/5hvpvspw82.1
Experimental Models: Cell Lines		
Hamster: CHO cells	ATCC	CRL-11268
D. melanogaster: Cell line S2: S2-DRSC	Laboratory of Norbert Perrimon	FlyBase: FBtc0000181
Human: Passage 40 H9 ES cells	MSKCC stem cell core facility	N/A
Human: HUES 8 hESC line (NIH approval number NIHhESC-09-0021)	HSCI iPS Core	hES Cell Line: HUES-8
Experimental Models: Organisms/Strains		
C. elegans: Strain BC4011: srl-1(s2500) II; dpy-18(e364) III; unc-46(e177)rol-3(s1040) V.	Caenorhabditis Genetics Center	WB Strain: BC4011; WormBase: WBVar00241916
D. melanogaster: RNAi of Sxl: y[1] sc[*] v[1]; P{TRiP.HMS00609}attP2	Bloomington Drosophila Stock Center	BDSC:34393; FlyBase: FBtp0064874
S. cerevisiae: Strain background: W303	ATCC	ATTC: 208353
Mouse: R6/2: B6CBA-Tg(HDexon1)62Gpb/3J	The Jackson Laboratory	JAX: 006494
Mouse: OXTRfl/fl: B6.129(SJL)-Oxtr$^{tm1.1Wsy}$/J	The Jackson Laboratory	RRID: IMSR_JAX:008471
Zebrafish: Tg(Shha:GFP)t10: t10Tg	Neumann and Nuesslein-Volhard, 2000	ZFIN: ZDB-GENO-060207-1
Arabidopsis: 35S::PIF4-YFP, BZR1-CFP	Wang et al., 2012	N/A
Arabidopsis: JYB1021.2: pS24(AT5G58010)::cS24:GFP(-G):NOS #1	NASC	NASC ID: N70450
Oligonucleotides		
siRNA targeting sequence: PIP5K I alpha #1: ACACAGUACUCAGUUGAUA	This paper	N/A
Primers for XX, see Table SX	This paper	N/A
Primer: GFP/YFP/CFP Forward: GCACGACTTCTTCAAGTCCGCCATGCC	This paper	N/A
Morpholino: MO-pax2a GGTCTGCTTTGCAGTGAATATCCAT	Gene Tools	ZFIN: ZDB-MRPHLNO-061106-5
ACTB (hs01060665_g1)	Life Technologies	Cat#4331182

RNA sequence: hnRNPA1_ligand: UAGGGACUUAGGGUUCUCUCUAGGGACUUAGGGUUCUCUCUAGGGA	This paper	N/A
Recombinant DNA		
pLVX-Tight-Puro (TetOn)	Clonetech	Cat#632162
Plasmid: GFP-Nito	This paper	N/A
cDNA GH111110	Drosophila Genomics Resource Center	DGRC:5666; FlyBase:FBcl0130415
AAV2/1-hsyn-GCaMP6- WPRE	Chen et al., 2013	N/A
Mouse raptor: pLKO mouse shRNA 1 raptor	Thoreen et al., 2009	Addgene Plasmid #21339
Software and Algorithms		
ImageJ	Schneider et al., 2012	https://imagej.nih.gov/ij/
Bowtie2	Langmead and Salzberg, 2012	http://bowtie-bio.sourceforge.net/bowtie2/index.shtml
Samtools	Li et al., 2009	http://samtools.sourceforge.net/
Weighted Maximal Information Component Analysis v0.9	Rau et al., 2013	https://github.com/ChristophRau/wMICA
ICS algorithm	This paper; Mendeley Data	http://dx.doi.org/10.17632/5hvpvspw82.1
Other		
Sequence data, analyses, and resources related to the ultra-deep sequencing of the AML31 tumor, relapse, and matched normal.	This paper	http://aml31.genome.wustl.edu
Resource website for the AML31 publication	This paper	https://github.com/chrisamiller/aml31SuppSite

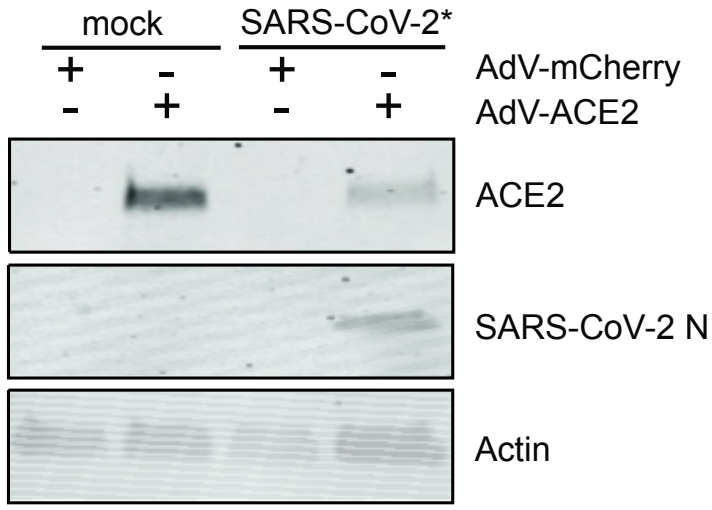
A


%Viral reads
100
10
1
0.1
0.01
0.001
0.0001
A549
A549-ACE2
Calu-3
MRC5
SARS-CoV-2
SARS-CoV-1
MERS-CoV
RSV
HPIV3
IAV

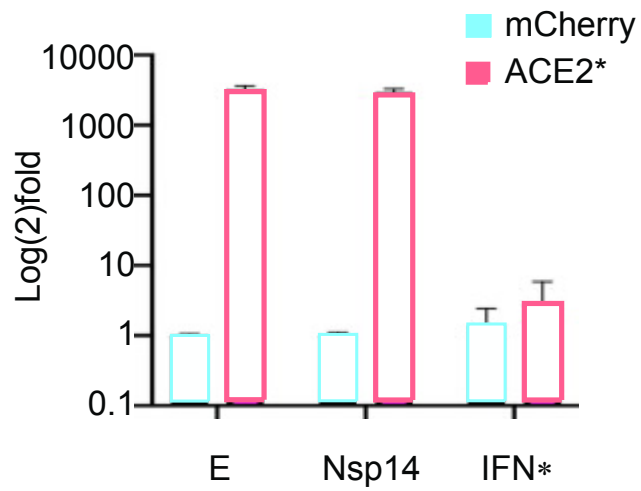
B


Number of Viral Reads
mCherry
ACE2*
ACE2
1
29,674
ORF1a
ORF1b
Helicase
Papain-like protease
3CL-protease
RNA-dependent RNA polymerase
Endoribo-nuclease
Spike (S)
E
M
N

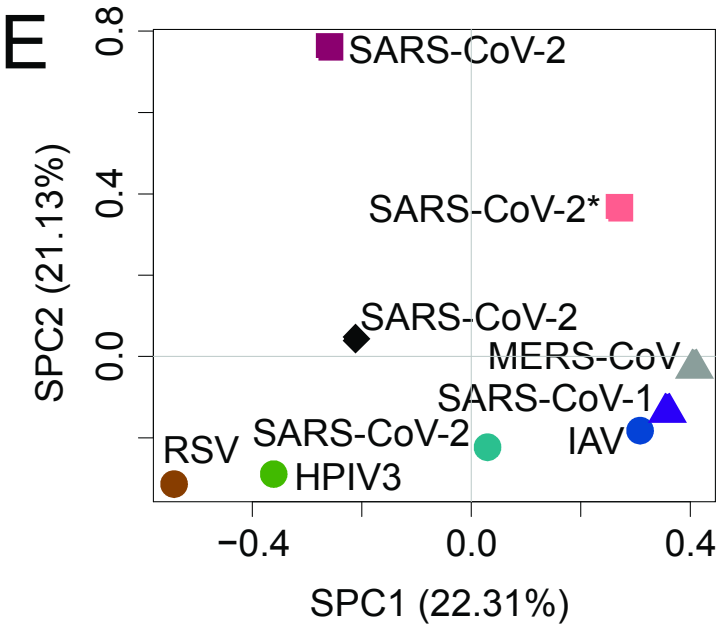
C


mock
SARS-CoV-2*
AdV-mCherry
AdV-ACE2
ACE2
SARS-CoV-2 N
Actin

D


mCherry
ACE2*
Log(2)fold
E
Nsp14
IFN*

E


SARS-CoV-2
SARS-CoV-2*
SARS-CoV-2
MERS-CoV
SARS-CoV-1
IAV
RSV
HPIV3
SPC2 (21.13%)
SPC1 (22.31%)

F

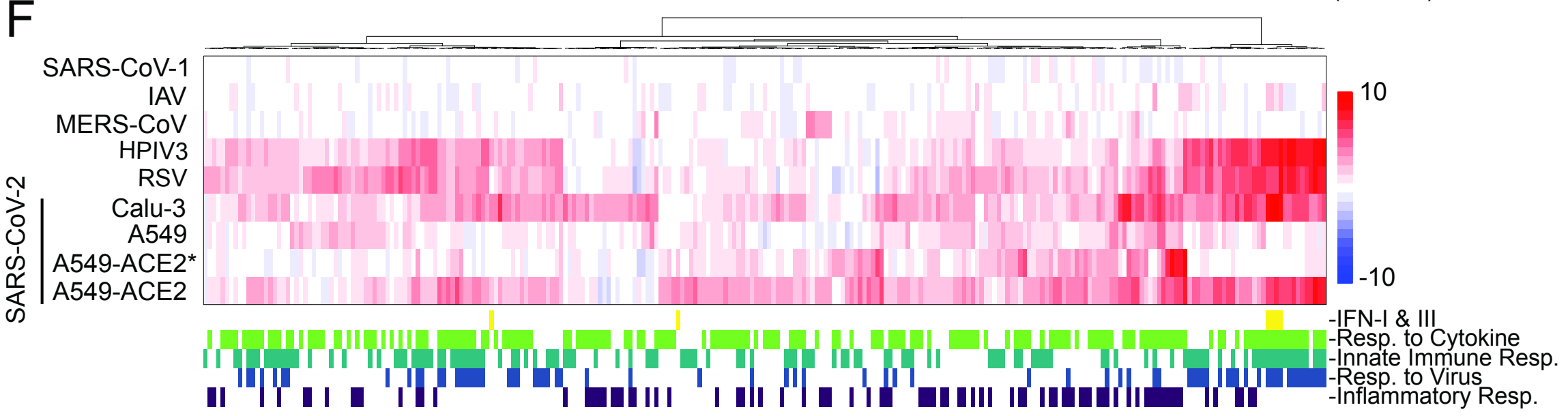
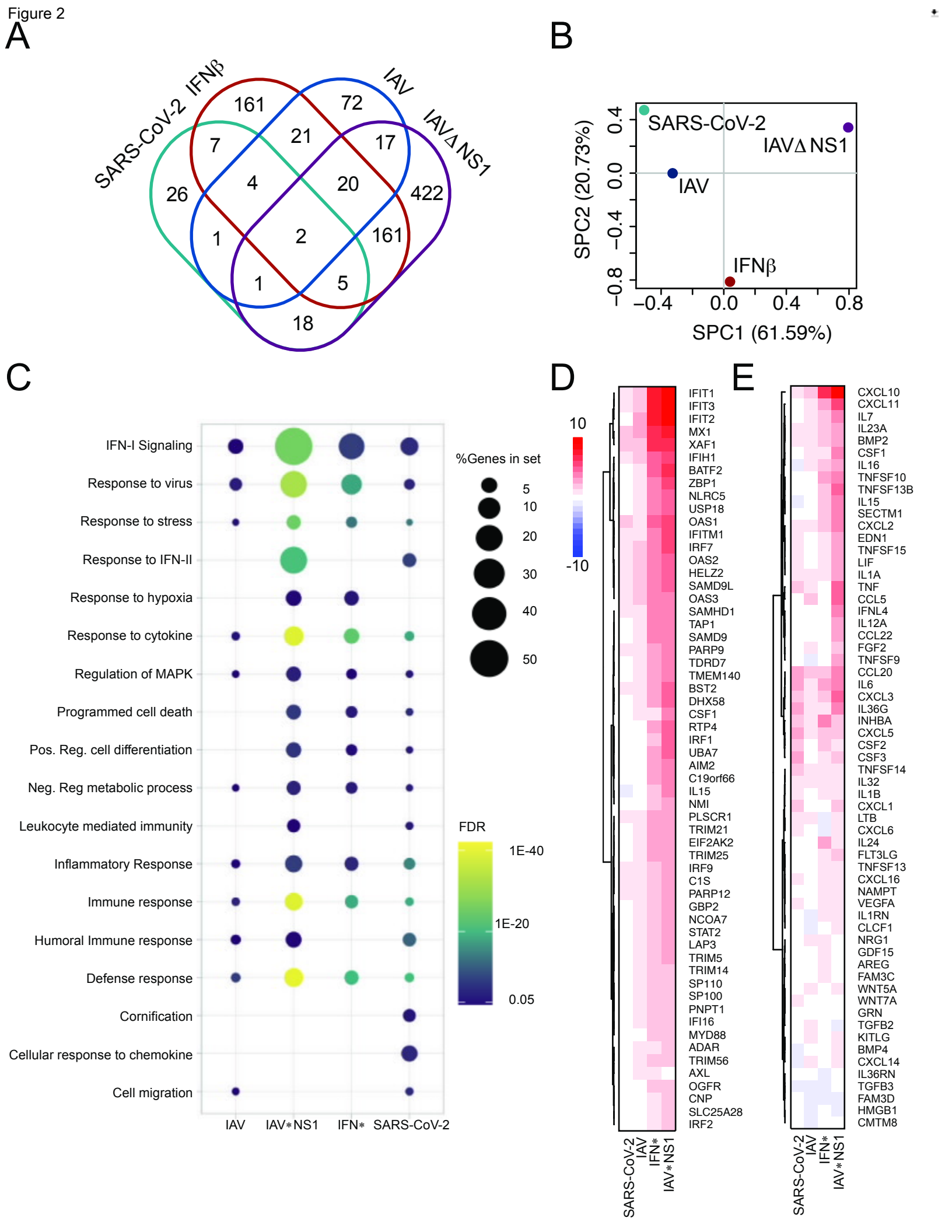
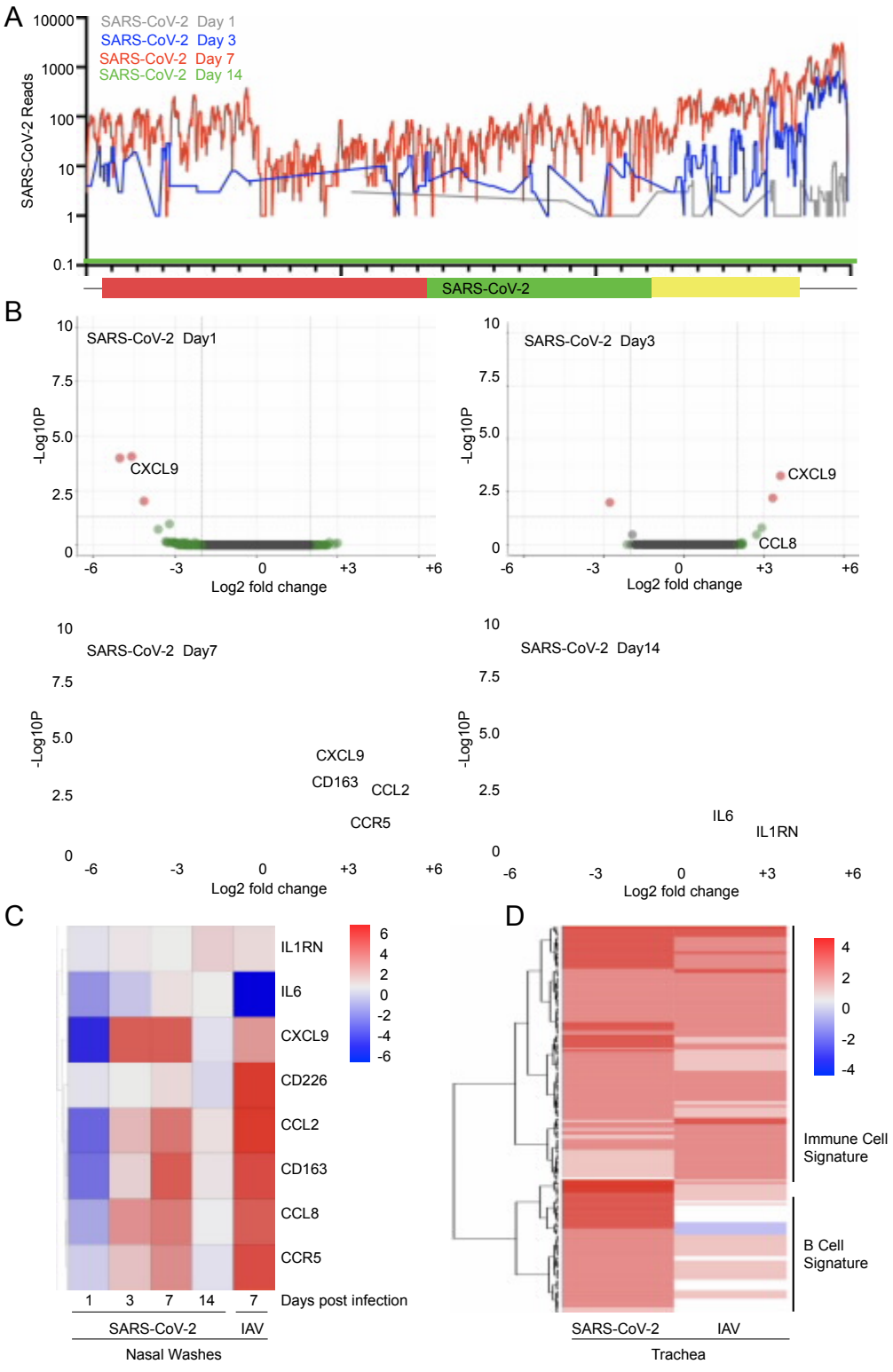
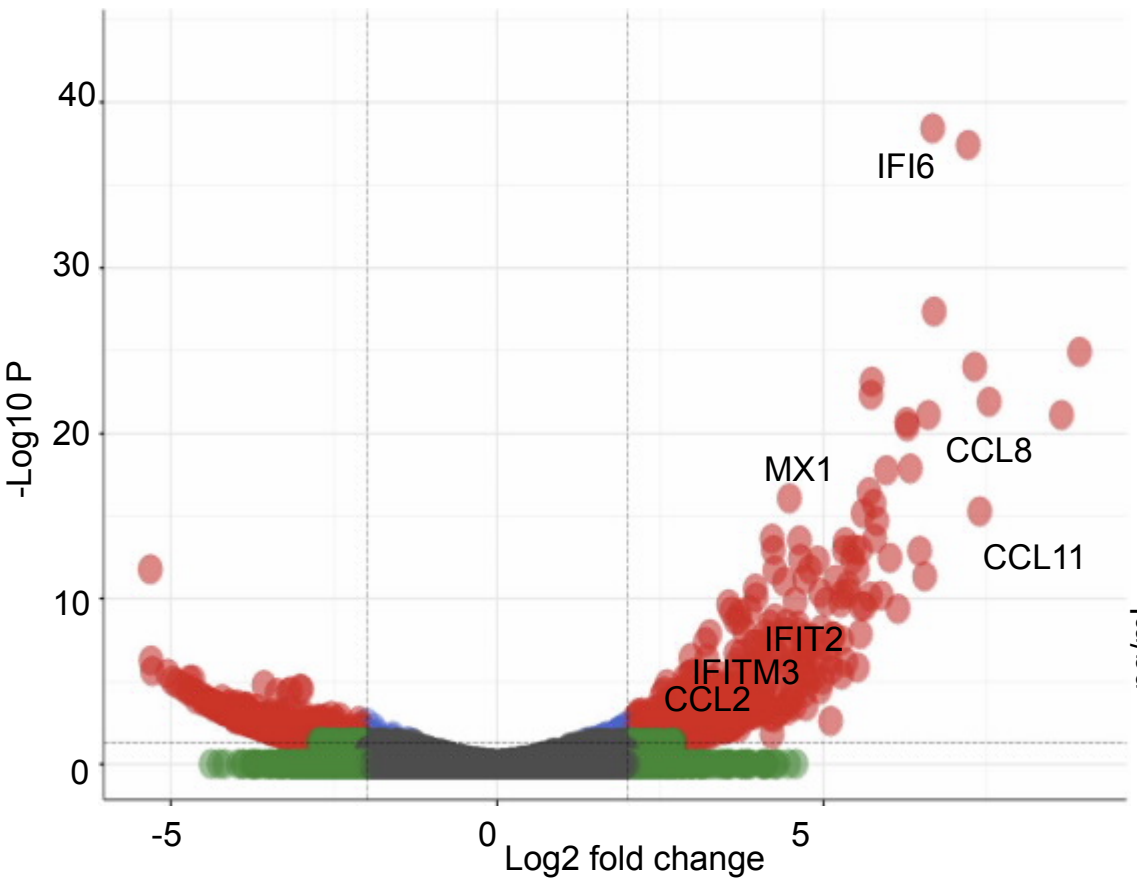

SARS-CoV-1
IAV
MERS-CoV
HPIV3
RSV
SARS-CoV-2
Calu-3
A549
A549-ACE2*
A549-ACE2
-IFN-I & III
-Resp. to Cytokine
-Innate Immune Resp.
-Resp. to Virus
-Inflammatory Resp.

Figure 2

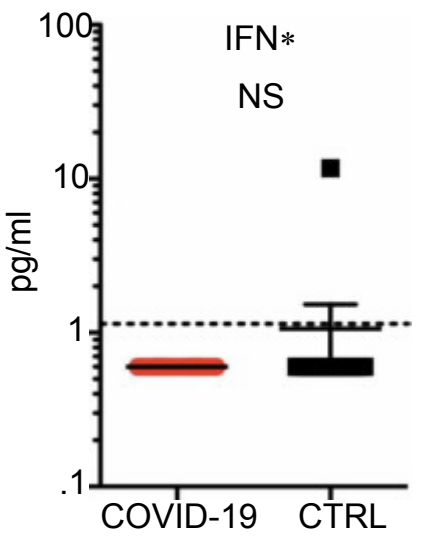

A
SARS-CoV-2
IFNβ
IAV
IAVΔNS1
161
72
7
21
17
26
4
20
422
1
2
161
1
5
18
B
SARS-CoV-2
IAVΔNS1
IAV
IFNβ
SPC2 (20.73%)
SPC1 (61.59%)
0.4
0.0
−0.4
−0.8
−0.4
0.0
0.4
0.8
C
IFN-I Signaling
Response to virus
Response to stress
Response to IFN-II
Response to hypoxia
Response to cytokine
Regulation of MAPK
Programmed cell death
Pos. Reg. cell differentiation
Neg. Reg metabolic process
Leukocyte mediated immunity
Inflammatory Response
Immune response
Humoral Immune response
Defense response
Cornification
Cellular response to chemokine
Cell migration
IAV
IAV∗NS1
IFN∗
SARS-CoV-2
%Genes in set
5
10
20
30
40
50
FDR
1E-40
1E-20
0.05
D
10
-10
IFIT1
IFIT3
IFIT2
MX1
XAF1
IFIH1
BATF2
ZBP1
NLRC5
USP18
OAS1
IFITM1
IRF7
OAS2
HELZ2
SAMD9L
OAS3
SAMHD1
TAP1
SAMD9
PARP9
TDRD7
TMEM140
BST2
DHX58
CSF1
RTP4
IRF1
UBA7
AIM2
C19orf66
IL15
NMI
PLSCR1
TRIM21
EIF2AK2
TRIM25
IRF9
C1S
PARP12
GBP2
NCOA7
STAT2
LAP3
TRIM5
TRIM14
SP110
SP100
PNPT1
IFI16
MYD88
ADAR
TRIM56
AXL
OGFR
CNP
SLC25A28
IRF2
SARS-CoV-2
IAV
IFN∗
IAV∗NS1
E
CXCL10
CXCL11
IL7
IL23A
BMP2
CSF1
IL16
TNFSF10
TNFSF13B
IL15
SECTM1
CXCL2
EDN1
TNFSF15
LIF
IL1A
TNF
CCL5
IFNL4
IL12A
CCL22
FGF2
TNFSF9
CCL20
IL6
CXCL3
IL36G
INHBA
CXCL5
CSF2
CSF3
TNFSF14
IL32
IL1B
CXCL1
LTB
CXCL6
IL24
FLT3LG
TNFSF13
CXCL16
NAMPT
VEGFA
IL1RN
CLCF1
NRG1
GDF15
AREG
FAM3C
WNT5A
WNT7A
GRN
TGFB2
KITLG
BMP4
CXCL14
IL36RN
TGFB3
FAM3D
HMGB1
CMTM8
SARS-CoV-2
IAV
IFN∗
IAV∗NS1

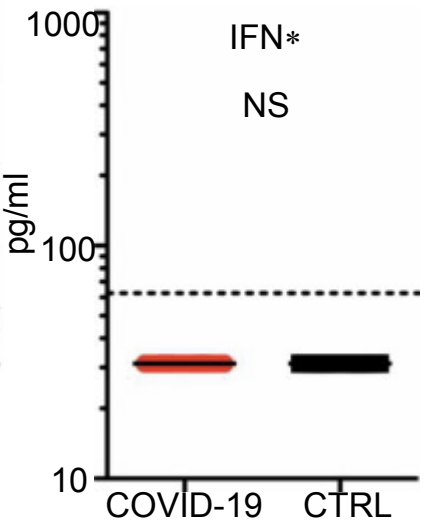

A
SARS-CoV-2 Day 1
SARS-CoV-2 Day 3
SARS-CoV-2 Day 7
SARS-CoV-2 Day 14
SARS-CoV-2 Reads
10000
1000
100
10
1
0.1
SARS-CoV-2
B
SARS-CoV-2 Day1
CXCL9
SARS-CoV-2 Day3
CXCL9
CCL8
SARS-CoV-2 Day7
CXCL9
CD163
CCL2
CCR5
SARS-CoV-2 Day14
IL6
IL1RN
-Log10P
Log2 fold change
C
IL1RN
IL6
CXCL9
CD226
CCL2
CD163
CCL8
CCR5
Days post infection
SARS-CoV-2
IAV
Nasal Washes
D
Immune Cell Signature
B Cell Signature
SARS-CoV-2
IAV
Trachea

A

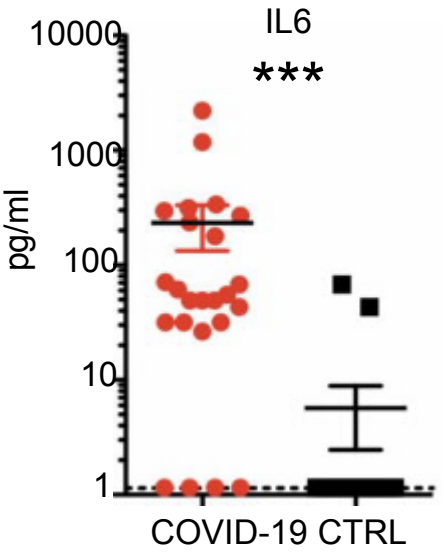

-Log10 P
40
30
20
10
0
-5
0
5
Log2 fold change
IFI6
MX1
CCL8
CCL11
IFIT2
IFITM3
CCL2

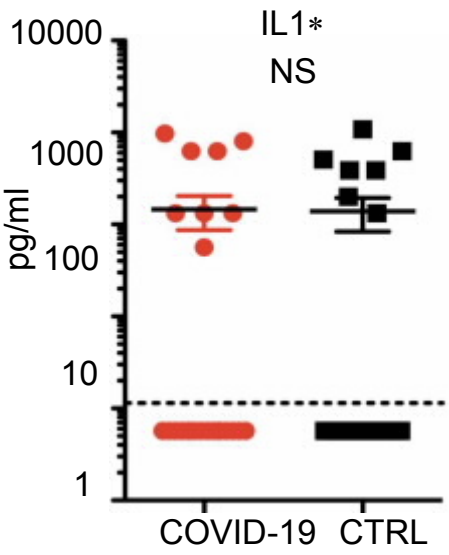
B

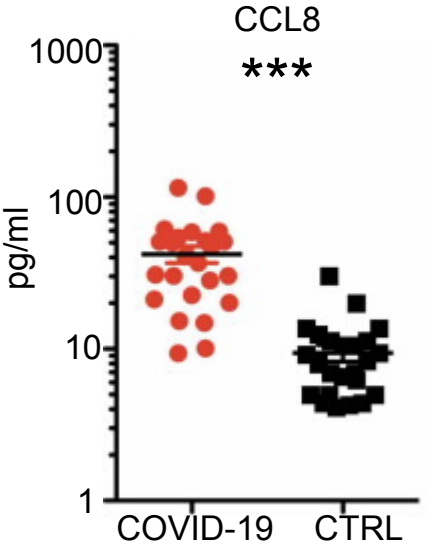

IFN*
NS
pg/ml
100
10
1
.1
COVID-19
CTRL

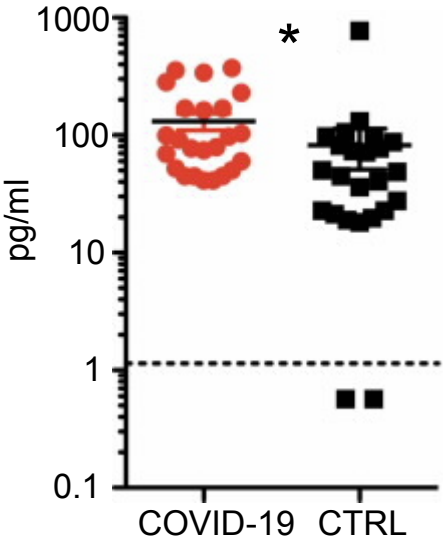

IFN*
NS
pg/ml
1000
100
10
COVID-19
CTRL

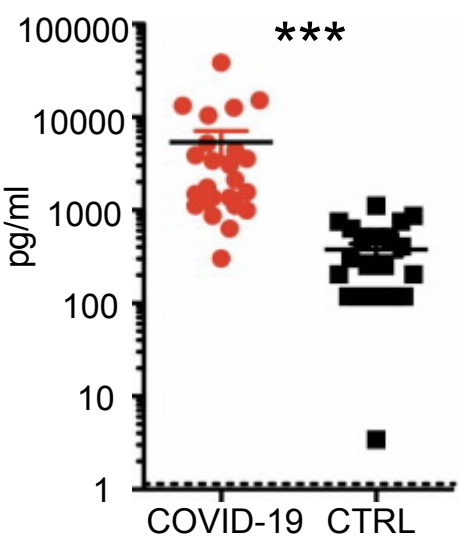
C

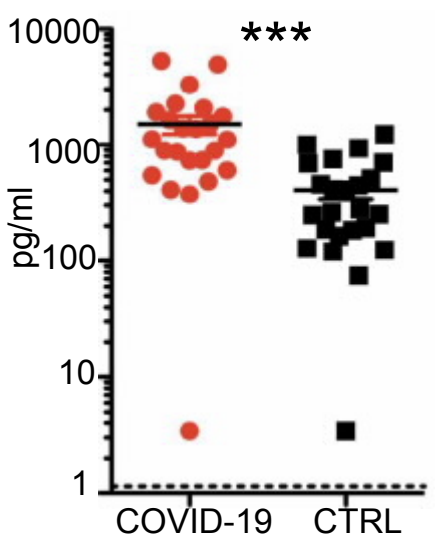

IL6
***
pg/ml
10000
1000
100
10
1
COVID-19
CTRL

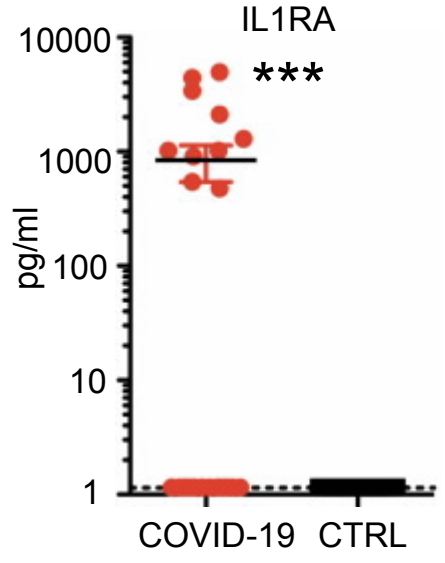

IL1*
NS
pg/ml
10000
1000
100
10
1
COVID-19
CTRL

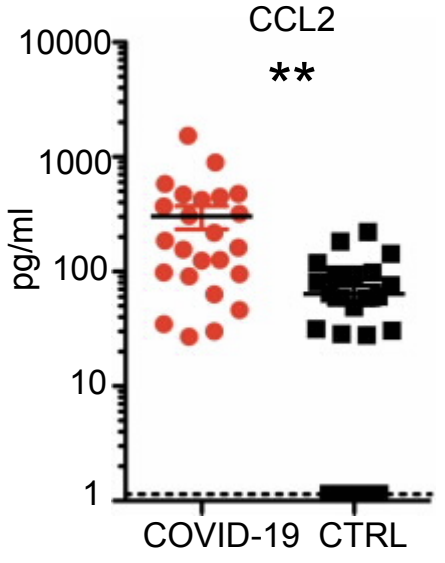

CCL8
***
pg/ml
1000
100
10
1
COVID-19
CTRL

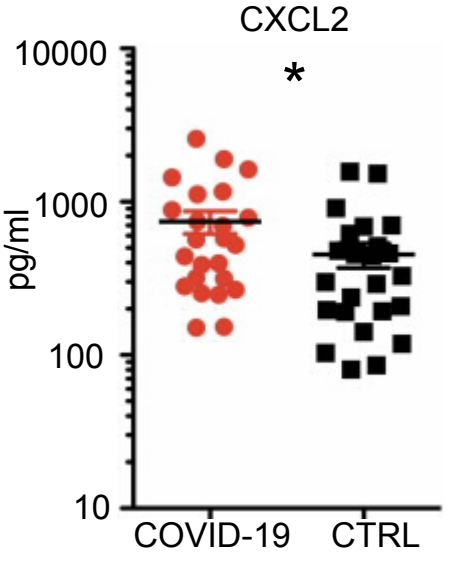

CXCL8
*
pg/ml
1000
100
10
1
0.1
COVID-19
CTRL

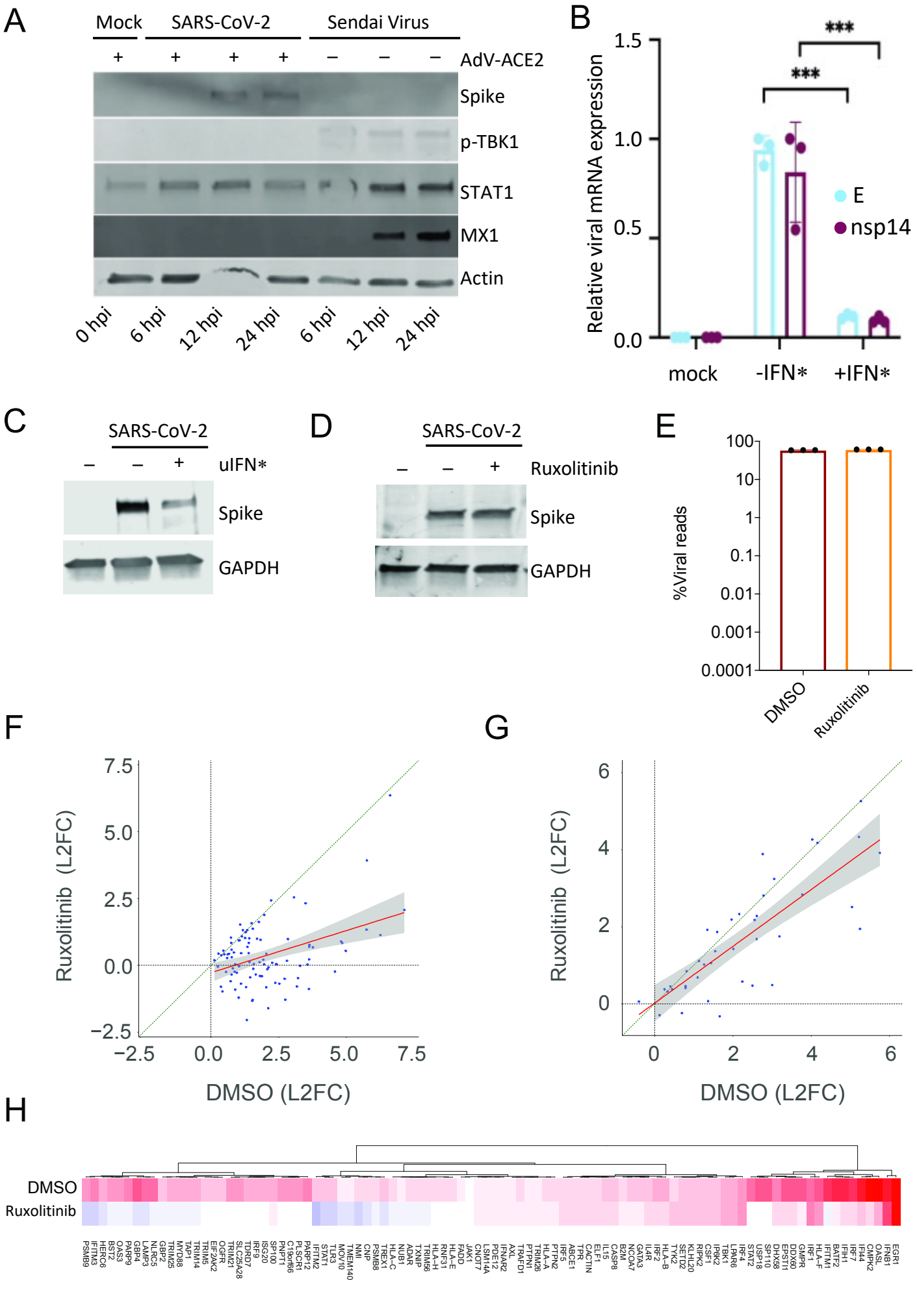

CXCL9
***
pg/ml
100000
10000
1000
100
10
1
COVID-19
CTRL


CXCL16
***
pg/ml
10000
1000
100
10
1
COVID-19
CTRL

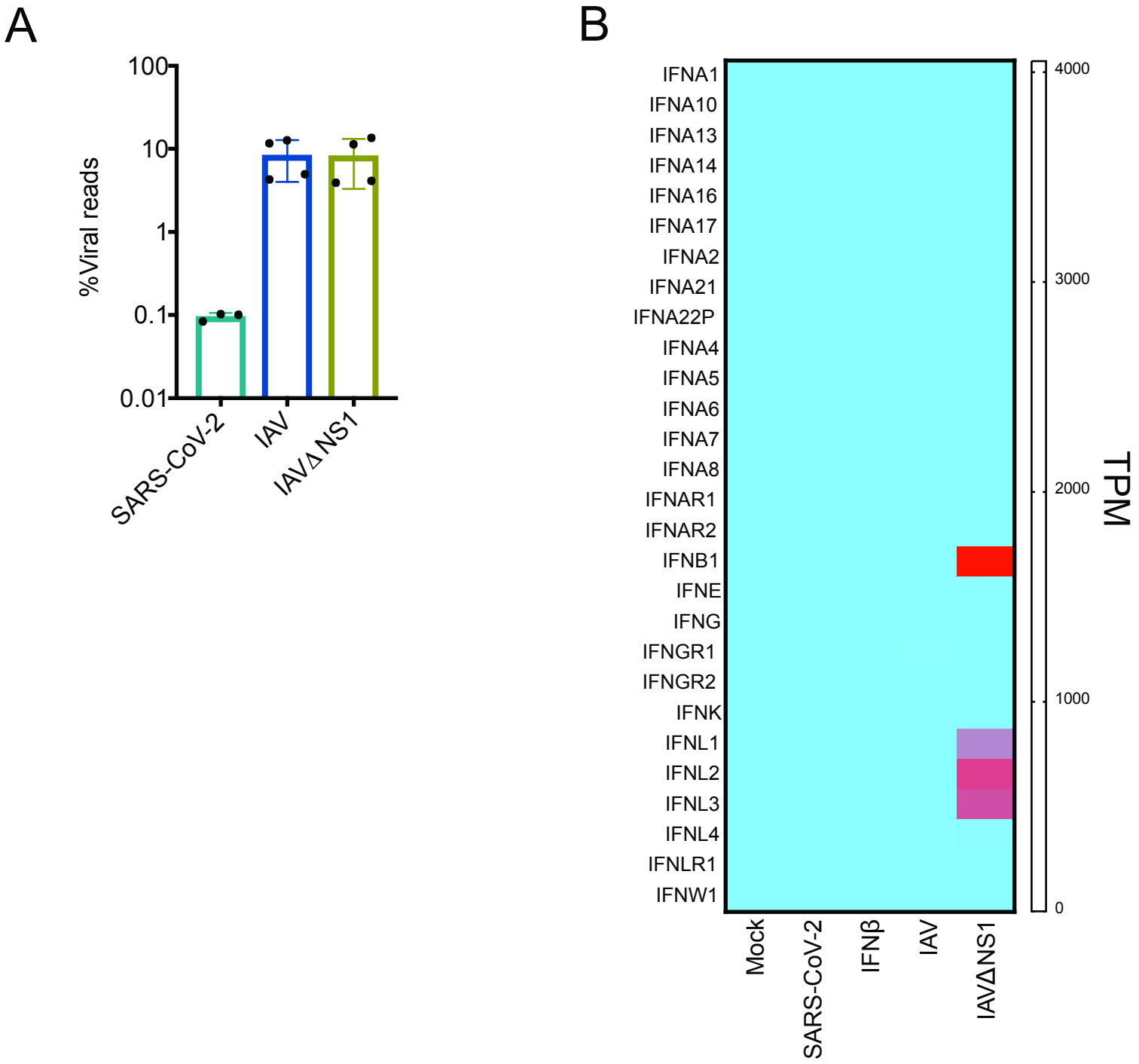

IL1RA
***
pg/ml
10000
1000
100
10
1
COVID-19
CTRL

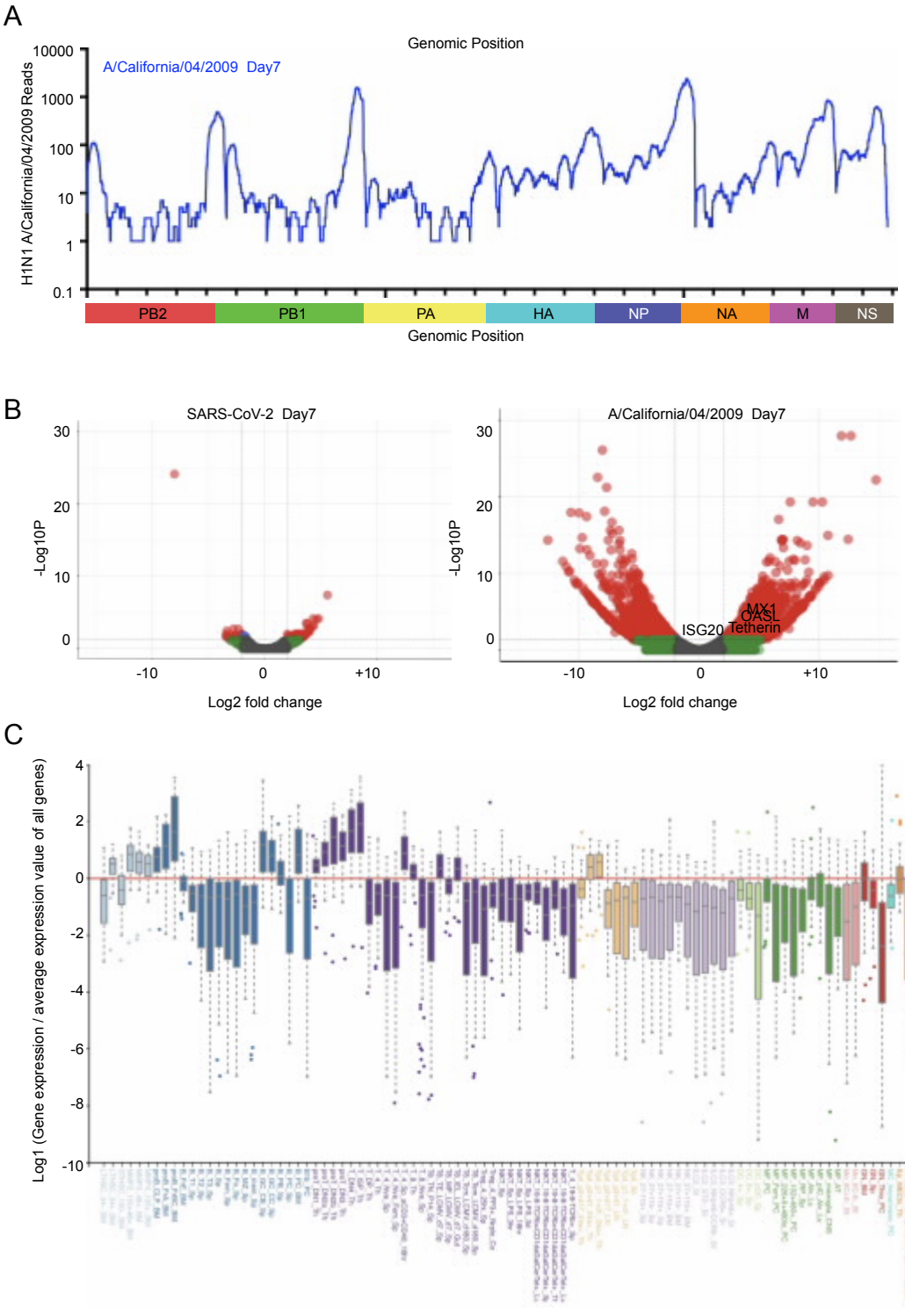

CCL2
**
pg/ml
10000
1000
100
10
1
COVID-19
CTRL


CXCL2
*
pg/ml
10000
1000
100
10
COVID-19
CTRL

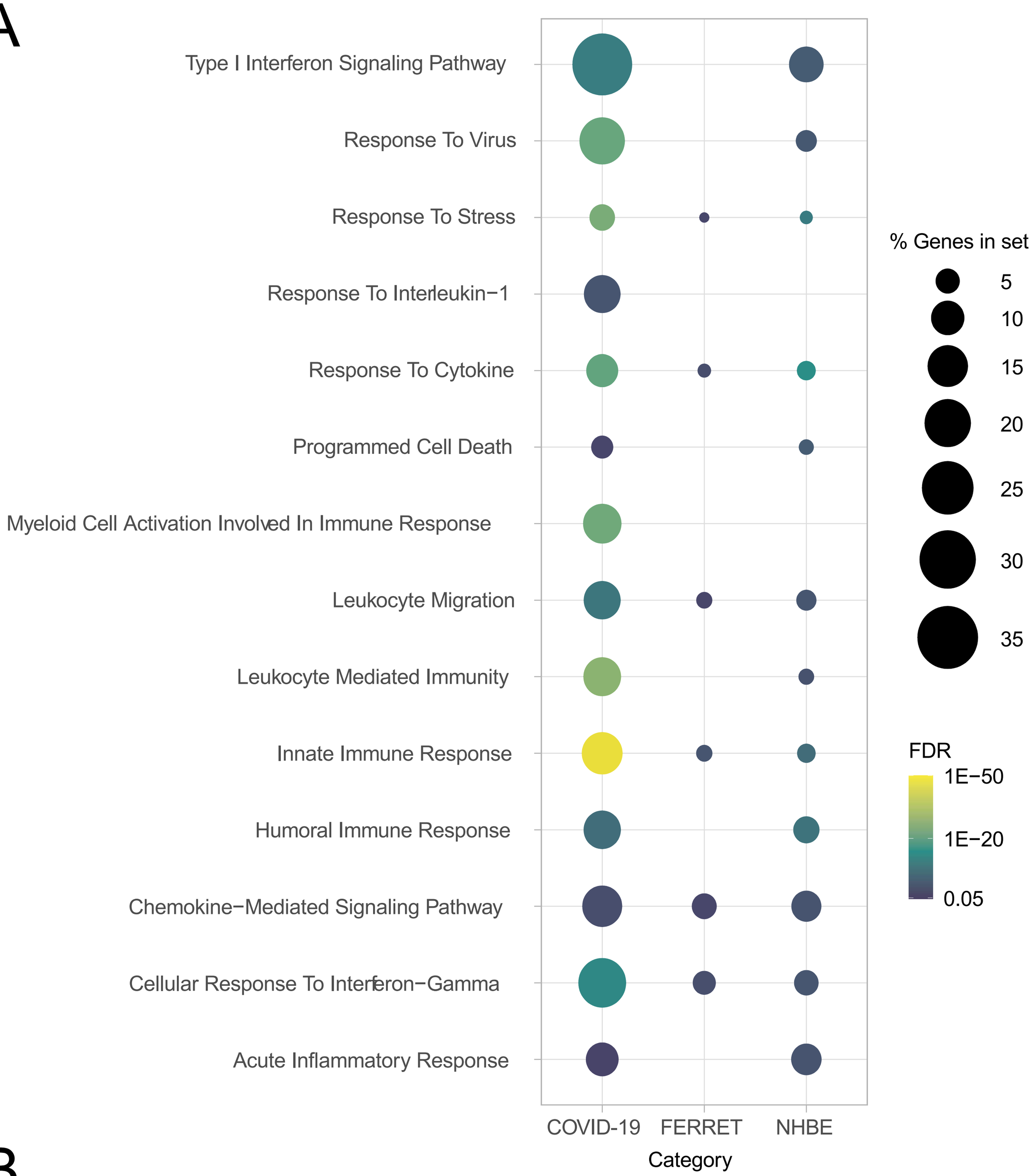

A
Mock
SARS-CoV-2
Sendai Virus
+ + + + – – – AdV-ACE2
Spike
p-TBK1
STAT1
MX1
Actin
0 hpi
6 hpi
12 hpi
24 hpi
6 hpi
12 hpi
24 hpi
B
Relative viral mRNA expression
1.5
1.0
0.5
0.0
***
***
E
nsp14
mock
-IFN*
+IFN*
C
SARS-CoV-2
– – + uIFN*
Spike
GAPDH
D
SARS-CoV-2
– – + Ruxolitinib
Spike
GAPDH
E
%Viral reads
100
10
1
0.1
0.01
0.001
0.0001
DMSO
Ruxolitinib
F
Ruxolitinib (L2FC)
7.5
5.0
2.5
0.0
−2.5
−2.5
0.0
2.5
5.0
7.5
DMSO (L2FC)
G
Ruxolitinib (L2FC)
6
4
2
0
0
2
4
6
DMSO (L2FC)
H
DMSO
Ruxolitinib
10
-10
PSMB9 IFITM3 HERC6 BST2 OAS3 PARP9 GBP4 LAMP3 NLRC5 GBP2 TRIM25 MYD88 TAP1 TRIM14 TRIM5 EIF2AK2 OGFR TRIM21 SLC25A28 IRF9 TDRD7 ISG20 SP100 PNPT1 C19orf66 PLSCR1 PARP12 IFITM2 STAT1 TLR3 MOV10 TMEM140 CNP NMI PSMB8 TREX1 HLA-C NUB1 ADAR TXNIP TRIM56 HLA-H RNF31 HLA-E JAK1 RAD51 CNOT7 LSM14A PDE12 IFNAR2 AXL TRAFD1 PTPN1 TRIM26 HLA-A PTPN2 IRF5 ABCE1 TPR CACTIN ELF1 CASP8 B2M NCOA7 GATA3 IL4R IRF2 HLA-B TYK2 SETD2 KLHL20 RIPK2 CSF1 IPPK2 TBK1 LIMK2 IRF4 STAT2 USP18 SP110 DHX58 EPSTI1 DDX60 GMPR IRF1 HLA-F IFITM1 BATF2 IFIH1 IRF7 IFI44 CMPK2 OASL IFNB1 EGR1

Supplemental Figure 2

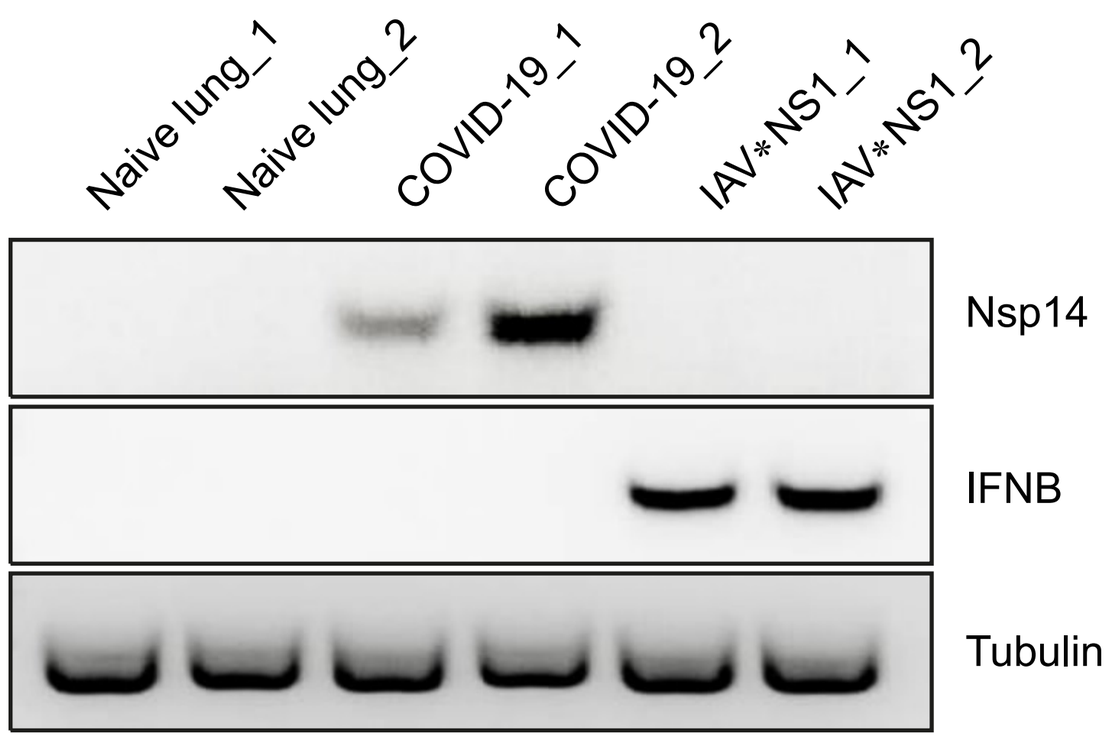



A
Genomic Position
A/California/04/2009 Day7
H1N1 A/California/04/2009 Reads
10000
1000
100
10
1
0.1
PB2
PB1
PA
HA
NP
NA
M
NS
Genomic Position
B
SARS-CoV-2 Day7
A/California/04/2009 Day7
-Log10P
30
20
10
0
-10
0
+10
Log2 fold change
MX1
OASL
ISG20
Tetherin
C
Log1 (Gene expression / average expression value of all genes)
4
2
0
-2
-4
-6
-8
-10

A


Type I Interferon Signaling Pathway
Response To Virus
Response To Stress
Response To Interleukin−1
Response To Cytokine
Programmed Cell Death
Myeloid Cell Activation Involved In Immune Response
Leukocyte Migration
Leukocyte Mediated Immunity
Innate Immune Response
Humoral Immune Response
Chemokine−Mediated Signaling Pathway
Cellular Response To Interferon−Gamma
Acute Inflammatory Response
COVID-19
FERRET
NHBE
Category
% Genes in set
5
10
15
20
25
30
35
FDR
1E−50
1E−20
0.05

B


Naive lung_1
Naive lung_2
COVID-19_1
COVID-19_2
IAV*NS1_1
IAV*NS1_2
Nsp14
IFNB
Tubulin

To: Prabha Fernandes[prabha.fernandes@gmail.com]; 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Alvarez, Rosa'[rosalvarez@deloitte.com]; 'Anderson, Annaliesa'[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; 'Diamond, Michael'[diamond@wusm.wustl.edu]; 'Duncan, Ken'[ken.duncan@gatesfoundation.org]; 'Gatto, Greg'[ggatto@rti.org]; 'Grobler, Jay'[jay_grobler@merck.com]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Jonson, Samantha (NIH/NCATS) [E]'[samantha.jonson@nih.gov]; 'Lutz, Cat'[Cat.Lutz@jax.org]; 'Nestle, Frank'[Frank.Nestle@sanofi.com]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; 'Payne, David'[david.j.payne@gsk.com]; 'Rao, Srinivas'[Srinivas.Rao@sanofi.com]; 'Rappaport, Jay'[jrappaport@tulane.edu]; 'Stegmeier, Frank'[fstegmeier@ksqtx.com]; 'Young, John'[john.young.jy3@roche.com]
From: Kara Carter[Kara.Carter@evotec.com]
Sent: Wed 4/29/2020 9:37:56 AM (UTC-04:00)
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

Joe,

Thanks for sharing this. It would be particularly interesting to know if these same patients have COVID-19 histories and how they track. If a person is predisposed to have symptoms to OC43 or other endemic coronaviruses, do they also have more severe disease with SARS-CoV-2 infection. Since these patients are from NYC, I think there is good chance that many of them were tested for SARS-CoV-2. Of course, there is likely not continued surveillance of these folks for SARS-CoV-2. It may be just that those with severe disease are noted and it would be interesting to know if those same patients also had symptoms for endemic coronaviruses.

Also, I am a bit encouraged to see that there is not any strong evidence for ADE for the endemic coronaviruses (I am also surprised there was no discussion of ADE potential in the paper), which is something I am tracking in the literature as it would have major implications for the pandemic and also vaccine development. Could there be ADE for SARS-CoV-2 after endemic coronavirus exposure?

Kara

evotec

Kara Carter, PhD
Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
kara.carter@evotec.com
www.evotec.com

From: Prabha Fernandes <prabha.fernandes@gmail.com>
Sent: Wednesday, April 29, 2020 9:06 AM
To: 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; 'Adams, Peter (OS/ASPR/BARDA)' <Peter.Adams@hhs.gov>; 'Alvarez, Rosa' <rosalvarez@deloitte.com>; 'Anderson, Annaliesa' <Annaliesa.Anderson@pfizer.com>; 'Baric, Ralph' <rbaric@email.unc.edu>; Kara Carter <Kara.Carter@evotec.com>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Deming, Damon (FDA/CDER)' <damon.deming@fda.hhs.gov>; 'Diamond, Michael' <diamond@wusm.wustl.edu>; 'Duncan, Ken' <ken.duncan@gatesfoundation.org>; 'Gatto, Greg' <ggatto@rti.org>; 'Grobler, Jay' <jay_grobler@merck.com>; 'Hewitt, Judith (NIH/NIAID) [E]' <jhewitt@niaid.nih.gov>; 'Jonson, Samantha (NIH/NCATS) [E]' <samantha.jonson@nih.gov>; 'Lutz, Cat' <Cat.Lutz@jax.org>; 'Nestle, Frank' <Frank.Nestle@sanofi.com>; 'Ottinger, Elizabeth (NIH/NCATS [E]' <elizabeth.ottinger@nih.gov>; 'Parker, Ashley (NIH/OD) [E]' <ashley.parker@nih.gov>; 'Payne, David' <david.j.payne@gsk.com>; 'Rao, Srinivas' <Srinivas.Rao@sanofi.com>; 'Rappaport, Jay' <jrappaport@tulane.edu>; 'Stegmeier, Frank' <fstegmeier@ksqtx.com>; 'Young, John' <john.young.jy3@roche.com>
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

[EXTERNAL]

Thank you for sharing, Joe. I am not an immunologist.. and was wondering if anyone knows what the profile looks like in Influenza pneumonia ? (or other viral pneumonia. The control are normal subjects..and I was wondering what Covid-19 differences were from other pneumonias also.

Although pretty scary that patients need to be followed 7days after being DISCHARGED.
On the vaccine front, some good hints of which antibodies to look for with some translation to Ebola vaccine work. All very educational!

Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Wednesday, April 29, 2020 8:04 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Subject: FW: Direct observation of repeated infections with endemic coronaviruses

The note below reinforces the need to do some WGS in NHP and humans.

From: Hall, Matthew (NIH/NCATS) [E] <hallma@mail.nih.gov>
Sent: Tuesday, April 28, 2020 10:32 PM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: Direct observation of repeated infections with endemic coronaviruses

Here's a pre-print from Columbia that my colleague Mike Kurilla passed along to me, which might impact how well you sleep tonight:

Direct observation of repeated infections with endemic coronaviruses
http://www.columbia.edu/~jls106/galanti_shaman_ms_supp.pdf

"Findings
During the study, 12 individuals tested positive multiple times for the same coronavirus. We found no significant difference between the probability of testing positive at least once and the probability of a recurrence for the beta-coronaviruses HKU1 and OC43 at 34 weeks after enrollment/first infection. We also found no significant association between repeat infections and symptom severity **but strong association between symptom severity and belonging to the same family**"

"Interpretation
This study provides evidence that **re-infections with the same endemic coronavirus are not atypical in a time window shorter than 1 year** and that the **genetic basis of innate immune response may be a greater determinant of infection severity** than immune memory acquired after a previous infection."

Matthew D. Hall
Acting Branch Chief, Early Translation Branch
Group Leader, Biology

National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health
9800 Medical Center Drive
Rockville, MD 20850
Office: 301-480-9928
https://ncats.nih.gov/staff/hallma

@cispt2

NCATS Website: http://ncats.nih.gov

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

To: 'Grobler, Jay A'[jay_grobler@merck.com]; 'Young, John'[john.young.jy3@roche.com]; 'Rappaport, Jay'[jrappaport@tulane.edu]
Cc: 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Alvarez, Rosa'[rosalvarez@deloitte.com]; 'Anderson, Annaliesa'[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; 'Carter, Kara'[kara.carter@evotec.com]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; 'Diamond, Michael'[diamond@wusm.wustl.edu]; 'Duncan, Ken'[ken.duncan@gatesfoundation.org]; 'Gatto, Greg'[ggatto@rti.org]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Jonson, Samantha (NIH/NCATS) [E]'[samantha.jonson@nih.gov]; 'Lutz, Cat'[Cat.Lutz@jax.org]; 'Nestle, Frank'[Frank.Nestle@sanofi.com]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; 'Payne, David'[david.j.payne@gsk.com]; 'Rao, Srinivas'[Srinivas.Rao@sanofi.com]; 'Stegmeier, Frank'[fstegmeier@ksqtx.com]
From: Prabha Fernandes[prabha.fernandes@gmail.com]
Sent: Wed 4/29/2020 9:51:29 AM (UTC-04:00)
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

Thanks Jay for sharing. Very interesting and their expertise from other CoV's can help.
Prabha

From: Grobler, Jay A <jay_grobler@merck.com>
Sent: Wednesday, April 29, 2020 9:32 AM
To: Young, John <john.young.jy3@roche.com>; Rappaport, Jay <jrappaport@tulane.edu>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Stegmeier, Frank <fstegmeier@ksqtx.com>
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

Scary indeed! See attached from 1972. From the attached article:

"Reinfection with 229E appeared to be commonplace and pre-infection neutralizing antibody did not diminish (or increase) the frequency of illness with infection."

From: Young, John <john.young.jy3@roche.com>
Sent: Wednesday, April 29, 2020 8:52 AM
To: Rappaport, Jay <jrappaport@tulane.edu>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay A <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Stegmeier, Frank <fstegmeier@ksqtx.com>
Subject: Re: Direct observation of repeated infections with endemic coronaviruses

EXTERNAL EMAIL – Use caution with any links or file attachments.
Yikes!

John

On Wed, Apr 29, 2020 at 2:08 PM Rappaport, Jay <jrappaport@tulane.edu> wrote:
Very interesting,
Joe, thanks!

Get Outlook for iOS

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Wednesday, April 29, 2020 7:03:42 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Subject: FW: Direct observation of repeated infections with endemic coronaviruses

The note below reinforces the need to do some WGS in NHP and humans.

From: Hall, Matthew (NIH/NCATS) [E] <hallma@mail.nih.gov>
Sent: Tuesday, April 28, 2020 10:32 PM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: Direct observation of repeated infections with endemic coronaviruses

Here's a pre-print from Columbia that my colleague Mike Kurilla passed along to me, which might impact how well you sleep tonight:

Direct observation of repeated infections with endemic coronaviruses

http://www.columbia.edu/~jls106/galanti_shaman_ms_supp.pdf

"Findings

During the study, 12 individuals tested positive multiple times for the same coronavirus. We found no significant difference between the probability of testing positive at least once and the probability of a recurrence for the beta-coronaviruses HKU1 and OC43 at 34 weeks after enrollment/first infection. We also found no significant association between repeat infections and symptom severity **but strong association between symptom severity and belonging to the same family**"

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This study provides evidence that **re-infections with the same endemic coronavirus are not atypical in a time window shorter than 1 year** and that the **genetic basis of innate immune response may be a greater determinant of infection severity** than immune memory acquired after a previous infection."

Matthew D. Hall

Acting Branch Chief, Early Translation Branch

Group Leader, Biology

National Center for Advancing Translational Sciences (NCATS)

National Institutes of Health

9800 Medical Center Drive

Rockville, MD 20850

Office: 301-480-9928

https://ncats.nih.gov/staff/hallma

@cispt2

NCATS Website: http://ncats.nih.gov

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

--
John A.T. Young, PhD
VP and Global Head Infectious Diseases
Immunology, Infectious Diseases and Ophthalmology (I2O) Discovery and Translational Area
Roche Pharma Research & Early Development

Roche Innovation Center Basel

F.Hoffmann-La Roche Ltd
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Nuran Aktas-Ibis

Phone +41 61 68 79502
Mobile +41 79 861 88 53
Mail to: nuran.aktas-ibis@roche.com

To: Kara Carter[kara.carter@evotec.com]; Prabha Fernandes[prabha.fernandes@gmail.com]; 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Alvarez, Rosa'[rosalvarez@deloitte.com]; 'Anderson, Annaliesa'[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; 'Diamond, Michael'[diamond@wusm.wustl.edu]; 'Duncan, Ken'[ken.duncan@gatesfoundation.org]; 'Gatto, Greg'[ggatto@rti.org]; 'Grobler, Jay'[jay_grobler@merck.com]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Jonson, Samantha (NIH/NCATS) [E]'[samantha.jonson@nih.gov]; 'Lutz, Cat'[Cat.Lutz@jax.org]; 'Nestle, Frank'[Frank.Nestle@sanofi.com]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; 'Payne, David'[david.j.payne@gsk.com]; 'Rao, Srinivas'[Srinivas.Rao@sanofi.com]; 'Stegmeier, Frank'[fstegmeier@ksqtx.com]; 'Young, John'[john.young.jy3@roche.com]
From: Rappaport, Jay[jrappaport@tulane.edu]
Sent: Wed 4/29/2020 10:57:59 AM (UTC-04:00)
Subject: Re: Direct observation of repeated infections with endemic coronaviruses

Regarding ADE, The reference to Callow #13 in the Galanti paper shows experimentally infected humans that were then rechallenged. While the subjects were not necessarily protected from reinfection, they seemed to be resistant to disease, which is encouraging.
Jay

From: Kara Carter <kara.carter@evotec.com>
Date: Wednesday, April 29, 2020 at 8:38 AM
To: Prabha Fernandes <prabha.fernandes@gmail.com>, "'Menetski, Joseph (FNIH) [T]'" <jmenetski@fnih.org>, "'Adams, Peter (OS/ASPR/BARDA)'" <Peter.Adams@hhs.gov>, "'Alvarez, Rosa'" <rosalvarez@deloitte.com>, "'Anderson, Annaliesa'" <Annaliesa.Anderson@pfizer.com>, "'Baric, Ralph'" <rbaric@email.unc.edu>, "'Colvis, Christine (NIH/NCATS) [E]'" <christine.colvis@nih.gov>, "'Deming, Damon (FDA/CDER)'" <damon.deming@fda.hhs.gov>, "'Diamond, Michael'" <diamond@wusm.wustl.edu>, "'Duncan, Ken'" <ken.duncan@gatesfoundation.org>, "'Gatto, Greg'" <ggatto@rti.org>, "'Grobler, Jay'" <jay_grobler@merck.com>, "'Hewitt, Judith (NIH/NIAID) [E]'" <jhewitt@niaid.nih.gov>, "'Jonson, Samantha (NIH/NCATS) [E]'" <samantha.jonson@nih.gov>, "'Lutz, Cat'" <Cat.Lutz@jax.org>, "'Nestle, Frank'" <Frank.Nestle@sanofi.com>, "'Ottinger, Elizabeth (NIH/NCATS [E]'" <elizabeth.ottinger@nih.gov>, "'Parker, Ashley (NIH/OD) [E]'" <ashley.parker@nih.gov>, "'Payne, David'" <david.j.payne@gsk.com>, "'Rao, Srinivas'" <Srinivas.Rao@sanofi.com>, "Rappaport, Jay" <jrappaport@tulane.edu>, "'Stegmeier, Frank'" <fstegmeier@ksqtx.com>, "'Young, John'" <john.young.jy3@roche.com>
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

Joe,

Thanks for sharing this. It would be particularly interesting to know if these same patients have COVID-19 histories and how they track. If a person is predisposed to have symptoms to OC43 or other endemic coronaviruses, do they also have more severe disease with SARS-CoV-2 infection. Since these patients are from NYC, I think there is good chance that many of them were tested for SARS-CoV-2. Of course, there is likely not continued surveillance of these folks for SARS-CoV-2. It may be just that those with severe disease are noted and it would be interesting to know if those same patients also had symptoms for endemic coronaviruses.

Also, I am a bit encouraged to see that there is not any strong evidence for ADE for the endemic coronaviruses (I am also surprised there was no discussion of ADE potential in the paper), which is something I am tracking in the literature as it would have major implications for the pandemic and also vaccine development. Could there be ADE for SARS-CoV-2 after endemic coronavirus exposure?

Kara

evotec

Kara Carter, PhD
Executive Vice President Infectious Disease

+1-617-763-6855 (Mobile)
kara.carter@evotec.com
www.evotec.com

From: Prabha Fernandes <prabha.fernandes@gmail.com>
Sent: Wednesday, April 29, 2020 9:06 AM
To: 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; 'Adams, Peter (OS/ASPR/BARDA)' <Peter.Adams@hhs.gov>; 'Alvarez, Rosa' <rosalvarez@deloitte.com>; 'Anderson, Annaliesa' <Annaliesa.Anderson@pfizer.com>; 'Baric, Ralph' <rbaric@email.unc.edu>; Kara Carter <Kara.Carter@evotec.com>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Deming, Damon (FDA/CDER)' <damon.deming@fda.hhs.gov>; 'Diamond, Michael' <diamond@wusm.wustl.edu>; 'Duncan, Ken' <ken.duncan@gatesfoundation.org>; 'Gatto, Greg' <ggatto@rti.org>; 'Grobler, Jay' <jay_grobler@merck.com>; 'Hewitt, Judith (NIH/NIAID) [E]' <jhewitt@niaid.nih.gov>; 'Jonson, Samantha (NIH/NCATS) [E]' <samantha.jonson@nih.gov>; 'Lutz, Cat' <Cat.Lutz@jax.org>; 'Nestle, Frank' <Frank.Nestle@sanofi.com>; 'Ottinger, Elizabeth (NIH/NCATS [E]' <elizabeth.ottinger@nih.gov>; 'Parker, Ashley (NIH/OD) [E]' <ashley.parker@nih.gov>; 'Payne, David' <david.j.payne@gsk.com>; 'Rao, Srinivas' <Srinivas.Rao@sanofi.com>; 'Rappaport, Jay' <jrappaport@tulane.edu>; 'Stegmeier, Frank' <fstegmeier@ksqtx.com>; 'Young, John' <john.young.jy3@roche.com>
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

[EXTERNAL]

Thank you for sharing, Joe. I am not an immunologist.. and was wondering if anyone knows what the profile looks like in Influenza pneumonia ? (or other viral pneumonia. The control are normal subjects..and I was wondering what Covid-19 differences were from other pneumonias also.
Although pretty scary that patients need to be followed 7days after being DISCHARGED.
On the vaccine front, some good hints of which antibodies to look for with some translation to Ebola vaccine work. All very educational!

Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Wednesday, April 29, 2020 8:04 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Subject: FW: Direct observation of repeated infections with endemic coronaviruses

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From: Hall, Matthew (NIH/NCATS) [E] <hallma@mail.nih.gov>
Sent: Tuesday, April 28, 2020 10:32 PM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: Direct observation of repeated infections with endemic coronaviruses

Here's a pre-print from Columbia that my colleague Mike Kurilla passed along to me, which might impact how well you sleep tonight:

Direct observation of repeated infections with endemic coronaviruses

http://www.columbia.edu/~jls106/galanti_shaman_ms_supp.pdf

"Findings
During the study, 12 individuals tested positive multiple times for the same coronavirus. We found no significant difference between the probability of testing positive at least once and the probability of a recurrence for the beta-coronaviruses HKU1 and OC43 at 34 weeks after enrollment/first infection. We also found no significant association between repeat infections and symptom severity **but strong association between symptom severity and belonging to the same family**"

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This study provides evidence that **re-infections with the same endemic coronavirus are not atypical in a time window shorter than 1 year** and that the **genetic basis of innate immune response may be a greater determinant of infection severity** than immune memory acquired after a previous infection."

Matthew D. Hall
Acting Branch Chief, Early Translation Branch
Group Leader, Biology

National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health
9800 Medical Center Drive
Rockville, MD 20850
Office: 301-480-9928
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NCATS Website: http://ncats.nih.gov

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

To: Alexandra Phelan (alp81@georgetown.edu)[alp81@georgetown.edu]; David A Relman (relman@stanford.edu)[relman@stanford.edu]; David Walt (dwalt@bwh.harvard.edu)[dwalt@bwh.harvard.edu]; Diane Griffin (dgriffi6@jhmi.edu)[dgriffi6@jhmi.edu]; Embrey, Ellen (eembrey@stratitia.com)[eembrey@stratitia.com]; Georges Benjamin (georges.benjamin@apha.org)[georges.benjamin@apha.org]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; John Hick (hick.john@gmail.com)[hick.john@gmail.com]; Jonna Mazet (jkmazet@ucdavis.edu)[jkmazet@ucdavis.edu]; Kent Kester (Kent.Kester@sanofi.com)[Kent.Kester@sanofi.com]; Kristian G. Andersen (kga1978@gmail.com)[kga1978@gmail.com]; Mark Smolinski (mark@endingpandemics.org)[mark@endingpandemics.org]; Mary Travis Bassett (mbassett@hsph.harvard.edu)[mbassett@hsph.harvard.edu]; Patricia King (patricia.king1@gmail.com)[patricia.king1@gmail.com]; Peggy Hamburg (peggy@hbfam.net)[peggy@hbfam.net]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; Phyllis D. Meadows (PDMeadows@kresge.org)[PDMeadows@kresge.org]; Richard Besser (rbesser@rwjf.org)[rbesser@rwjf.org]; Tara O'Toole (totoole@iqt.org)[totoole@iqt.org]; Trevor Bedford (trevor@bedford.io)[trevor@bedford.io]; Baric, Ralph S[rbaric@email.unc.edu]; Donald Berwick[donberwick@gmail.com]; alta.charo@wisc.edu[alta.charo@wisc.edu]; Jeff.Duchin@kingcounty.gov[Jeff.Duchin@kingcounty.gov]; Baruch Fischhoff[baruch@cmu.edu]; DHanfling@iqt.org[DHanfling@iqt.org]; bgroves@georgetown.edu[bgroves@georgetown.edu]
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; mnavish@iqt.org[mnavish@iqt.org]; andre@ecohealthalliance.org[andre@ecohealthalliance.org]; Peisch, Samuel Francis[speisch@hsph.harvard.edu]; jbaker@rwjf.org[jbaker@rwjf.org]; Baric, Toni C[antoinette_baric@med.unc.edu]; Mary Radford[maradford@ucdavis.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]; Feit, Monica[MFeit@nas.edu]; Shore, Carolyn[CShore@nas.edu]; Wollek, Scott[SWollek@nas.edu]; Downey, Autumn[ADowney@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Wed 4/29/2020 11:15:38 AM (UTC-04:00)
Subject: Agenda and Zoom Information for Second Virtual Meeting of the Standing Committee 4/30
FINAL Agenda_Virtual Meeting 2_ SC on EID and 21st Century Threats.pdf
Committee Member Biosketches - SC on EID and 21st Century Threats.pdf
Committee Internal Roster - SC on EID and 21st Century Threats.pdf
Committee Membership Roster - SC on EID and 21st Century Threats.pdf

Dear Members of the Standing Committee,

We are looking forward to the second virtual meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats taking place tomorrow, April 30th, from 11:00 a.m. – 1:00 p.m. ET. Please find attached the final agenda, and the Zoom information is below. The primary objective of tomorrow's call is to discuss the priorities that were raised on each of the four working group calls with the sponsors and the full committee. This is the first full committee meeting for the new members; therefore, we are also attaching updated bios and rosters of the full committee for your reference.

Please note that later today, we will be disseminating a compilation of the priority topics to the full committee. Several of the working groups met yesterday, so we are in the process of revising and compiling those priorities.

Zoom Call-In Information
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378
Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Please let us know if you have any questions.

Many thanks,
Lisa

Lisa Brown, MPH
Senior Program Officer
Board on Health Sciences Policy
Health and Medicine Division
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW, Washington, DC 20001

202-334-2487 (office)
lbrown@nas.edu

Second Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Final Agenda
Thursday, April 30, 2020 11:00 a.m. – 1:00 p.m. ET

Zoom Information

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378

Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Background: In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine established the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. The Standing Committee's purpose is to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee includes members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee provides a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

Meeting Objectives

- Discuss the status and progress of the work of the standing committee with the sponsors
- Discuss the priorities of each working group: viral characteristics; patient care and medical countermeasures; community engagement and population health; and, cross-cutting issues
- Discuss and plan priorities, strategies, and next steps

THURSDAY, APRIL 30, 2020

CLOSED SESSION

SESSION I **Welcoming Remarks and Sponsors' Reflections on Status and Progress since the First Standing Committee Meeting**

11:00 a.m. **Welcoming Remarks and Introduction of New Members**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Victor Dzau
President
National Academy of Medicine

Gregory Symmes
Chief Program Officer
The National Academies of Sciences, Engineering, and Medicine

11:15 a.m. **Sponsor's Remarks and Update on COVID-19 Response**

David (Chris) Hassell
Senior Science Advisor
The Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

SESSION II **Working Group Discussions**

11:25 a.m. **Group A: Viral Characteristics Working Group**

David Relman, *Committee Member*

Jonna Mazet, *Committee Member*

11:35 a.m. **Group B: Patient Care and Medical Countermeasures Working Group**

Donald Berwick, *Committee Member*

Margaret Hamburg, *Committee Member*

11:45 a.m. **Group C: Community Engagement and Population Health Working Group**

Mary Travis Bassett, *Committee Member*

Robert Groves, *Committee Member*

11:55 a.m. **Group D: Cross-Cutting Issues Working Group**

Alta Charo, *Committee Member*

Tara O'Toole, *Committee Member*

12:05 p.m. **Discussion of the Issues and Next Steps with the Sponsors**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:30 p.m. ***ADJOURN***

CLOSED SESSION (COMMITTEE ONLY)

12:35 p.m. **Committee Debrief, Next Steps, and Potential Future Meeting Topics**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:40 p.m. **Office of News and Public Information Briefing**

Dana Korsen
Media Relations Manager
Office of News and Public Information
The National Academies of Sciences, Engineering, and Medicine

12:45 p.m. **Discussion of Bias and Conflict of Interest**

Lauren Shern
Associate Executive Director
Health and Medicine Division

1:00 p.m. ***ADJOURN MEETING***

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

COMMITTEE MEMBER BIOSKETCHES

Harvey Fineberg, M.D., Ph.D. ***(Chair)***
President
Gordon and Betty Moore Foundation

Harvey Fineberg is president of the Gordon and Betty Moore Foundation. He previously served as president of the Institute of Medicine from 2002 to 2014 and as provost of Harvard University from 1997 to 2001, following 13 years as dean of the Harvard School of Public Health. Fineberg devoted most of his academic career to the fields of health policy and medical decision-making. His past research has focused on the process of policy development and implementation, assessment of medical technology, evaluation and use of vaccines, and dissemination of medical innovations. Fineberg serves on the boards of the Carnegie Endowment for International Peace and the China Medical Board. He helped found and served as president of the Society for Medical Decision Making, previously served on and chaired the board of the William and Flora Hewlett Foundation, and chaired the committee to review the performance of the World Health Organization and the functioning of the International Health Regulations (2005) during the 2009 H1N1 influenza pandemic. Fineberg is co-author of the books *Clinical Decision Analysis*, *Innovators in Physician Education* and *The Epidemic That Never Was*, an analysis of the controversial federal immunization program against swine flu in 1976. He has co-edited several books on such diverse topics as AIDS prevention, vaccine safety, understanding risk in society and global health. He has also authored numerous articles published in professional journals. Fineberg chaired the National Academies committee that produced the 2019 report on *Reproducibility and Replicability in Science*. He earned his bachelor's and doctoral degrees at Harvard and is the recipient of several honorary degrees.

Kristian Andersen, Ph.D.
Associate Professor and Director of Infectious Disease Genomics, Scripps Research Translational Institute
The Scripps Research Institute

Kristian Andersen is an associate professor in the Department of Immunology and Microbiology at Scripps Research, with joint appointments in the Department of Integrative Structural and Computational Biology, and at the Scripps Research Translational Institute. Over the past decade, his research has focused on the complex relationship between host and pathogen. Using a combination of next-generation sequencing, field work, experimentation, and computational biology he has spearheaded large international collaborations investigating the emergence, spread and evolution of deadly pathogens, including SARS-CoV-2, Zika virus, Ebola virus, West Nile virus, and Lassa virus. His work is highly cross-disciplinary and exceptionally collaborative. Kristian earned his doctoral degree from the University of Cambridge and performed postdoctoral work in Pardis Sabeti's group at Harvard University and the Broad Institute.

Ralph Baric, Ph.D.
William R. Kenan, Jr. Distinguished Professor
The University of North Carolina at Chapel Hill

Ralph Baric is a William R. Kenan, Jr. Distinguished Professor in the Department of Epidemiology at the University of North Carolina. He obtained a Bachelor of Science Degree in Zoology from North Carolina State University in 1977 and a PhD in Microbiology and Immunology from North Carolina State University in 1983. He conducted postgraduate research at the University of Southern California School of Medicine in the department of Microbiology and Immunology between 1983-1986. He is a Harvey Weaver Scholar from the National Multiple Sclerosis Society and an Established Investigator Awardee from the American Heart Association. In addition, he is a World Technology Award Finalist, a fellow of the American Association for Microbiology, a senior editor of PloS Pathogen, and a member of the editorial board of several other specialty journals. He was a member of the National Academy Sciences Working Groups that focused on Gene Sequence Methods for Classification of Select Agents and the Risks and Benefits of Gain of Function Research, an invited speaker to the Institute of Medicine Forum on Emerging Infectious Diseases and an invited panelist for the MERS-CoV Stakeholders Workshop. His group has published over 300 papers, many in highly visible journals like PNAS, Nature Medicine, Science, PloS Medicine and PloS Pathogens. The Baric laboratory uses genetic, immunologic, molecular and biochemical approaches to study the molecular mechanisms regulating virus replication, pathogenesis, molecular evolution and cross species transmission using emerging coronaviruses, flaviviruses (Dengue) and noroviruses as model systems. We have pioneered new strategies for developing reverse genetic approaches for manipulating the SARS-CoV, SAR-CoV-2 and MERS-CoV genomes and are actively studying the role of multiple genes that function in cross species transmission, virulence, pathogenesis, viral transcription and RNA fidelity. The Baric laboratory is also identifying key neutralizing epitopes in emerging coronaviruses, dengue and noroviruses using human monoclonal antibodies and structure guided immunogen design to develop broadly active vaccines and immunotherapuetics against these pathogens. Finally, his group has developed novel animal models of human disease and identified dozens of host susceptibility loci that regulate emerging CoV pathogenesis.

Mary Bassett, M.D., M.P.H.
Director of the François-Xavier Bagnoud Center for Health and Human Rights
Harvard School of Public Health

Mary Bassett is the Director of the FXB Center for Health and Human Rights at Harvard University, as well as the FXB Professor of the Practice of Health and Human Rights at the Harvard School of Public Health. With more than 30 years of experience in public health, Dr. Mary Travis Bassett has dedicated her career to advancing health equity. Prior to her directorship at the FXB Center, Dr. Bassett served for four years as commissioner of Health for New York City. As commissioner, she worked to ensure that every New York City neighborhood supported the health of its residents, with the goal of closing gaps in population health across the city. Originally from New York City, Dr. Bassett lived in Zimbabwe for nearly 20 years. Previously, she was the Program Director for the African Health Initiative and the Child Well-being Program at the Doris Duke Charitable Foundation. She received her B.A. in History and Science from Harvard University and her M.D. from Columbia University's College of Physicians and Surgeons. She served her medical residency at Harlem Hospital Center, and has a master's degree in Public Health from the University of Washington, where she was a Robert Wood Johnson Clinical Scholar.

Trevor Bedford, Ph.D.
Associate Faculty Member, Vaccine and Infectious Disease Division, Public Health Sciences Division, and Human Biology Division
Fred Hutchinson Cancer Research Center

Trevor Bedford is currently Associate Member of the Vaccine and Infectious Disease Division, the Public Health Sciences Division, and the Human Biology Division at the Fred Hutchinson Cancer Research Center. Dr. Bedford uses powerful computers and complex statistical methods to study the rapid spread and evolution of viruses. Data gathered from these processes help researchers develop successful strategies for monitoring and controlling infectious diseases. His visual representations of viral family trees are used to show how the fate of dangerous outbreaks is often determined by the genetics of the infectious agent, human behavior and geography. Dr. Bedford has applied these techniques to document the worldwide spread of seasonal flu viruses. He is developing models to predict which strains of influenza are likely to be most challenging to humans — data that help inform the crucial early decisions about which strains to include in annual flu shots. He specializes in tracking the evolutionary changes of viruses such as HIV and influenza that use RNA, rather than DNA, to carry their genetic information. RNA viruses are much more prone to rapid mutation, which makes many of them particularly nimble at escaping the human immune system and difficult to stop with vaccines. He is a leading advocate for the immediate release of research analyzing viral evolution during epidemics, fresh information that could make a lifesaving difference. He received his Ph.D. in biology from Harvard University.

Georges Benjamin, M.D.
Executive Director
American Public Health Association

Georges Benjamin is well-known as a health leader, practitioner, and administrator. Dr. Benjamin has served as the executive director of the American Public Health Association, the nation's oldest and largest organization of public health professionals, since December 2002. He is a former secretary of Health for the state of Maryland. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University Of Illinois College Of Medicine. He is board-certified in internal medicine, a Master of the American College of Physicians, a fellow of the National Academy of Public Administration and a fellow emeritus of the American College of Emergency Physicians. He serves on several nonprofit boards such as Research!America, the University of Maryland Medical System and, the Reagan-Udall Foundation. He is a member of the National Academy of Medicine. In April 2016, President Obama appointed Benjamin to the National Infrastructure Advisory Council, a council that advises the president on how best to assure the security of the nation's critical infrastructure.

Donald Berwick, M.D., M.P.P., F.R.C.P., KBE
Lecturer of Health Care Policy
Harvard Medical School

Donald Berwick is president emeritus and senior fellow at the Institute for Healthcare Improvement and former administrator of the Centers for Medicare & Medicaid Services. A pediatrician by background, Dr. Berwick has served on the faculty of the Harvard Medical School and Harvard School of Public Health, and on the staffs of Boston's Children's Hospital Medical Center, Massachusetts General Hospital, and the Brigham and Women's Hospital. He has also served as vice chair of the US Preventive Services Task Force, the first "independent member" of the American Hospital Association Board of Trustees, and chair of the National Advisory Council of the Agency for Healthcare Research and Quality. He served two terms on the Institute of Medicine's (IOM's) Governing Council, was a member of the IOM's Global Health Board, and served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. Recognized as a leading authority on health care quality and improvement, Dr. Berwick has received numerous awards for his contributions. In 2005, he was

appointed "Honorary Knight Commander of the British Empire" by Her Majesty, Queen Elizabeth II in recognition of his work with the British National Health Service. Dr. Berwick is the author or co-author of over 160 scientific articles and six books. He currently serves as lecturer in the Department of Health Care Policy at Harvard Medical School.

Richard Besser, M.D.
President and CEO
Robert Wood Johnson Foundation

Richard Besser is president and CEO of the Robert Wood Johnson Foundation (RWJF), a position he assumed in April 2017. Dr. Besser is the former acting director for the Centers for Disease Control and Prevention (CDC), and ABC News' former chief health and medical editor. At RWJF, Dr. Besser leads the largest private foundation in the country devoted solely to improving the nation's health. RWJF's work is focused on building a comprehensive Culture of Health that provides everyone in America with a fair and just opportunity to live the healthiest life possible. In Dr. Besser's role at ABC News, he provided medical analysis and reports for all ABC News programs and platforms. His weekly health chats on social media reached millions. Before joining ABC News in 2009, Dr. Besser worked as director of the Coordinating Office for Terrorism Preparedness and Emergency Response at the CDC. In that role, he was responsible for all the CDC's public health emergency preparedness and emergency response activities. He also served as acting director of the CDC from January to June 2009, during which time he led the CDC's response to the H1N1 influenza pandemic. He is a member of the National Academy of Medicine. He received the Surgeon General's Medallion for his leadership during the H1N1 response, and in 2011 he accepted the Dean's Medal for his contributions to public health from the Johns Hopkins Bloomberg School of Public Health. Dr. Besser received his Bachelor of Arts degree in economics from Williams College and medical degree from the University of Pennsylvania. He completed a residency and chief residency in pediatrics at Johns Hopkins University Hospital in Baltimore.

R. Alta Charo, J.D.
Warren P. Knowles Professor of Law and Bioethics
University of Wisconsin at Madison

R. Alta Charo is a member of the National Academy of Medicine and is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison (UW), where she is on the faculties of the law and medical schools. She teaches in the areas of bioethics, public health law and biotechnology policy and has served on UW's clinical ethics and research oversight committees. Professor Charo was a member of President Obama's transition team, focusing her attention particularly on transition issues related to NIH, FDA, stem cell policy, and women's reproductive health. From 2009 to 2011 she was on leave to serve as a senior policy advisor on emerging technology issues in the Office of the Commissioner at FDA. Her federal advisory committee service includes the 1994 NIH Human Embryo Research Panel and President Clinton's National Bioethics Advisory Commission (1996 to 2001). At the National Academies she co-chaired (with Richard Hynes) the committee on guidelines for embryonic stem cell research, and has been a member of its Board on Life Sciences, Board on Population Health and Public Health Practice, and Board on Health Sciences Policy.

Peter Daszak, Ph.D.
President and CEO
EcoHealth Alliance

Peter Daszak is President of EcoHealth Alliance, a US-based organization that conducts research and outreach programs on global health, conservation, and international development. Dr. Daszak's research has been instrumental in identifying and predicting the origins and impact of emerging diseases across the globe. He is one of the founders of the field of Conservation Medicine and has been instrumental in the

growth of EcoHealth, One Health, and now Planetary Health. Dr. Daszak is a member of the National Academy of Medicine and Chair of the NASEM's Forum on Microbial Threats. He is a member of the NRC Advisory Committee to the US Global Change Research Program, the Supervisory Board of the One Health Platform, the One Health Commission Council of Advisors, the CEEZAD External Advisory Board, the Cosmos Club, and the Advisory Council of the Bridge Collaborative. He has served on the IOM Committee on global surveillance for emerging zoonoses, the NRC committee on the future of veterinary research, the International Standing Advisory Board of the Australian Biosecurity CRC; and has advised the Director for Medical Preparedness Policy on the White House National Security Staff on global health issues. Dr. Daszak is a regular advisor to WHO on pathogen prioritization for R&D. He received his Ph.D. in parasitic infectious disease from the University of East London.

Jeffrey S. Duchin, M.D.
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section and Professor in Medicine
Public Health – Seattle & King County, WA and University of Washington, Seattle

Jeffrey Duchin is the Health Officer and the Chief of the Communicable Disease Epidemiology & Immunization Section for Public Health–Seattle & King County, Professor of Medicine in the Division of Infectious Diseases, and Adjunct Professor in the School of Public Health at the University of Washington, Seattle. Jeff currently serves on the Centers for Disease Control & Prevention's (CDC) Board of Scientific Counselors (Office of Infectious Diseases), the CDC's Advisory Committee on Immunization Practices and the Board of Directors for the Infectious Disease Society of America. Jeff has previously been a member of the National Academy of Medicine's (NAM) Forum on Microbial Threats and Forum on Medical and Public Health Preparedness, and the National Quality Forum's Adult Immunization Committee. Jeff received his medical degree from Rutgers Medical School and trained in internal medicine at Thomas Jefferson University Hospital, completed a fellowship in general internal medicine and emergency medicine at the Hospital of the University of Pennsylvania, and did his infectious disease subspecialty training at the University of Washington in Seattle. Jeff is a graduate of the CDC's Epidemic Intelligence Service (EIS) Officer training where he was assigned to the National Center for Infectious Diseases where he also completed the CDC's Preventive Medicine Residency program. Jeff worked for CDC as a medical epidemiologist in the Divisions of Tuberculosis Elimination and HIV/AIDS Special Studies Branch before assuming his current position. His peer review publications and research interests focus on communicable diseases of public health significance. For a complete listing of publications, please see PubMED.

Ellen Embrey
Managing Partner
Stratitia, Inc.

Ellen Embrey is Managing Partner of Stratitia, Inc., a consulting firm focused on developing meaningful and innovative strategies, and delivering supporting tools and partnerships to bring them successfully to life. Ms. Embrey brings deep expertise in health and medical issues, as well as a wealth of other experience gained during her extensive federal service. In her last federal role, she performed the duties of the Assistant Secretary of Defense for Health Affairs and the Director, TRICARE Management Activity during the presidential transition period in 2009-2010. From 2002 to 2009, Ms. Embrey was the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, leading significant changes in Department of Defense policies and programs affecting deployment and combat casualty medicine, health promotion and preventive medicine, medical readiness and public health emergency preparedness and response. For 9 months in 2001, Ms. Embrey performed the duties of Assistant Secretary of Defense for Reserve Affairs, shaping policies affecting the readiness and use of the National Guard and Reserve in both federal and state status. From 2000 to 2001, she served as Chief of Staff of that office, and from 1998 to 2001, as Deputy Assistant Secretary of Defense for Military Assistance to Civil Authorities,

developing policies that shaped the role of the National Guard and Reserve components in supporting homeland security, disaster preparedness, and national disaster response capabilities, including advising the president on such matters in the days and weeks following September 11, 2001. Between 1978 and 1997, Ms. Embrey served in senior-level policy analyst, budget analyst, program analyst, management analyst, and systems analyst positions in the Office of the Assistant Secretary of Defense for Reserve Affairs, the Defense Contract Audit Agency, and the Office of Personnel Management. Ms. Embrey was recognized with the Secretary of Defense's Distinguished Civilian Service Award in 2001 and 2004, and twice received the Meritorious Executive Presidential Rank Award in 2006 and 2009.

Baruch Fischhoff, Ph.D.
Howard Heinz University Professor, Department of Engineering and Public Policy
Carnegie Mellon University

Baruch Fischhoff is Howard Heinz University Professor, Department of Engineering and Public Policy and Institute for Politics and Strategy, Carnegie Mellon University (CMU). A graduate of the Detroit Public Schools, he holds a BS (mathematics, psychology) from Wayne State University and a PhD (psychology) from the Hebrew University of Jerusalem. He is a member of the National Academy of Sciences and of the National Academy of Medicine. He is past President of the Society for Judgment and Decision Making and of the Society for Risk Analysis. He has chaired the Food and Drug Administration Risk Communication Advisory Committee and been a member of the Eugene (Oregon) Commission on the Rights of Women, the Department of Homeland Security Science and Technology Advisory Committee and the Environmental Protection Agency Scientific Advisory Board, where he chaired the Homeland Security Advisory Committee. He has received the American Psychological Association (APA) Award for Distinguished Contribution to Psychology, CMU's Ryan Award for Teaching, an honorary Doctorate of Humanities from Lund University, and an Andrew Carnegie Fellowship. He is a Fellow of APA, the Association for Psychological Science, Society of Experimental Psychologists, and Society for Risk Analysis. His books include Acceptable Risk, Risk: A Very Short Introduction, Judgment and Decision Making, A Two-State Solution in the Middle East, Counting Civilian Casualties, and Communicating Risks and Benefits. He has co-chaired three National Academy Colloquia on the Science of Science Communication, as well as its committees on applying decision science to intelligence analysis and its committee on foundational science for cybersecurity.

Diane Griffin, M.D., Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health

Diane Griffin is University Distinguished Service Professor and Alfred and Jill Sommer Chair of the W. Harry Feinstone Department of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health. Dr. Griffin is a virologist recognized for her work on the pathogenesis of viral infections. She is known particularly for her studies on measles and alphavirus encephalomyelitis that have delineated the role of the immune response in virus clearance, vaccine-induced protection from infection, tissue damage and immune suppression. Dr. Griffin was born in Iowa City, Iowa, and grew up in Oklahoma City. She graduated from Augustana College, Rock Island, Illinois with a degree in biology and from Stanford University School of Medicine in 1968 with a Ph.D. in immunology and M.D., followed by a residency in internal medicine. She was a postdoctoral fellow in virology and infectious diseases at Johns Hopkins University School of Medicine and joined the faculty in 1974. She has been president of the American Society for Virology and of the American Society for Microbiology and is a member of both the National Academy of Sciences and the National Academy of Medicine.

Robert Groves
Executive Vice President and Provost
Gerard J. Campbell, S.J. Professor, Math and Statistics Department & Sociology Department
Georgetown University

Robert Groves is the Gerard J. Campbell, S.J. Professor in the Math and Statistics Department as well as the Sociology Department at Georgetown University where he has served as the Executive Vice President and Provost since 2012. Groves is a Social Statistician, who studies the Impact of Social Cognitive and Behavioral Influences on the quality of Statistical Information. His research has focused on the impact of mode of data collection on responses in sample surveys, the social and political influences on survey participation, the use of adaptive research designs to improve the cost and error properties of statistics, and public concerns about privacy affecting attitudes toward statistical agencies. He has authored or co-authored seven books and scores of peer-reviewed articles. His 1989 book, Survey Errors and Survey Costs, was named one of the 50 most influential books in survey research by the American Association of Public Opinion Research. His book, Nonresponse in Household Interview Surveys, with Mick Couper, received the 2008 AAPOR Book Award. His co-authored book, Survey Nonresponse, received the 2011 AAPOR Book Award. He served as the Director of the US Census Bureau between 2009-2012. Groves serves on several boards and advisory committees including the National Research Council Committee on National Statistics, Pew Research Center Board, the National Science Board, and the Federal Economic Statistics Advisory Committee. He is an elected member of the US National Academy of Sciences, of the National Academy of Medicine, of the American Academy of Arts and Sciences, and of the International Statistical Institute.

Margaret Hamburg, M.D.
Foreign Secretary
National Academy of Medicine

Margaret Hamburg is an internationally recognized leader in public health and medicine, and currently serves as foreign secretary of the National Academy of Medicine and chair of the NTI | bio Advisory Group. She is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served for almost six years. As FDA Commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining FDA, Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. She is President-elect of the American Association for the Advancement of Science (AAAS), as well as an elected member of the Council on Foreign Relations and the National Academy of Medicine. Hamburg currently sits on the boards of the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, the Parker Institute for Cancer Immunotherapy and the American Museum of Natural History. She is chair of the Joint Coordinating Group for the Coalition for Epidemic Preparedness and Innovation, and a member of the Harvard University Global Advisory Council, the Global Health Scientific Advisory Committee for the Gates Foundation, the Harvard Medical School Board of Fellows, and the World Dementia Council. Dr. Hamburg earned her B.A. from Harvard College, her M.D. from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center. She is the recipient of multiple honorary degrees and numerous awards.

Dan Hanfling, M.D.
Vice President, Technical Staff
In-Q-Tel

Dan Hanfling is Vice President, Technical Staff at In-Q-Tel and a Contributing Scholar at the Johns Hopkins Center for Health Secutiry. He is also Special Advisor to the Inova Health System in Falls Church, Virginia, on matters related to emergency preparedness and disaster response. He is a board-certified emergency physician practicing at Inova Fairfax Hospital, northern Virginia's Level I trauma center. He has responsibilities as Operational Medical Director for PHI Air Medical Group—Virginia, the largest private rotor-wing air medevac service in the Commonwealth of Virginia, and as a Medical Team Manager for Virginia Task Force One, a FEMA- and USAID-sanctioned international urban search and rescue team. Dr. Hanfling has been involved in the responses to international and domestic disaster events, including the Izmit, Turkey, earthquake in 1999; the attack on the Pentagon in September 2001; Hurricanes Rita and Katrina in 2005; Hurricanes Gustav and Ike in 2008; and the response to the Port au Prince, Haiti, earthquake in January 2010. He was integrally involved in the management of the response to the anthrax bioterror mailings in fall 2001, when 2 cases of inhalational anthrax were successfully diagnosed and managed at Inova Fairfax Hospital. Dr. Hanfling is Clinical Professor of Emergency Medicine at George Washington University and an invited member of the George Mason University School of Public Policy Advisory Board. He received an AB in political science from Duke University and was awarded his medical degree from Brown University. He completed an internship in internal medicine at the Miriam Hospital in Providence, Rhode Island, and an emergency medicine residency at George Washington/Georgetown University Hospitals.

John Hick, M.D.
Associate Medical Director for EMS
Medical Director of Emergency Medicine
Hennepin County Medical Center

John Hick is a faculty emergency physician at Hennepin Healthcare and a Professor of Emergency Medicine at the University of Minnesota. Dr. Hick serves as the deputy medical director for Hennepin County Emergency Medical Services and Medical Director for Emergency Preparedness at HCMC. He is also the Vice-Chair of the Clinical Council for Life Link III helicopter service and medical director for MN TF-1 state US&R team. He served the Minnesota Department of Health as the medical director for the Office of Emergency Preparedness until becoming an Advisor to the Director of OEM at ASPR/HHS where he is the lead editor for the TRACIE healthcare disaster preparedness website. He is the founder and past chair of the Minneapolis/St. Paul Metropolitan Hospital Compact, a 32-hospital mutual aid and planning group active since 2002. He is a national speaker on hospital preparedness issues and has published numerous papers dealing with hospital preparedness for contaminated casualties, personal protective equipment, crisis standards of care, and surge capacity and was honored to serve the Institute of Medicine on their Crisis Standards of Care projects as well as the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Dr. Hick holds an M.D. from the Mayo Medical School.

Kent E. Kester, M.D.
Vice President and Head, Translational Science and Biomarkers
Sanofi Pasteur

Kent Kester is currently Vice President and Head, Translational Science and Biomarkers at Sanofi Pasteur. In this capacity, Dr. Kester leads a team of over 200 research and clinical professionals in the US and France focused on the translational development of new vaccines. During a 24-year career in the US Army, he worked extensively in clinical vaccine development and led multiple research platforms at the Walter Reed Army Institute of Research, the U.S. Department of Defense's largest and most diverse biomedical research laboratory with a major emphasis on emerging infectious diseases, an institution he

later led as its Commander/Director. His final military assignment was as the Associate Dean for Clinical Research in the School of Medicine at the Uniformed Services University of the Health Sciences (USUHS). During his military service, Dr. Kester was appointed as the lead policy advisor to the US Army Surgeon General in both Infectious Diseases and in Medical Research & Development. In these capacities, he worked extensively in the interagency environment and developed a variety of Army and DoD medical policies related to infectious diseases, both clinical and research aspects. Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College, completing his internship and residency in internal medicine at the University of Maryland and a research fellowship in infectious diseases at the Walter Reed Army Medical Center. Currently a member of the US Government Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) and the Department of Veterans Affairs Health Services Research & Development Service Merit Review Board, he previously chaired the Steering Committee of the NIAID/USUHS Infectious Disease Clinical Research Program, and has served as a member of the FDA Vaccines & Related Biologics Products Advisory Committee (VRBPAC), the NIAID Advisory Council, and the CDC Office of Infectious Diseases Board of Scientific Counselors. He is the Vice Chair of the National Academy of Medicine Forum on Microbial Threats. Board-certified in both internal medicine and infectious diseases, Dr. Kester holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Royal College of Physicians of Edinburgh, the Infectious Disease Society of America, and the American Society of Tropical Medicine and Hygiene. He is a member of the clinical faculty at the University of Maryland Shock Trauma Center in Baltimore.

Patricia King, J.D.
Professor Emerita
Georgetown University Law Center

Patricia King is Professor of Law emeritus at Georgetown University Law Center and an Adjunct Professor in the Department of Health Policy and Management, School of Hygiene and Public Health at Johns Hopkins University. She is the co-author of Cases and Materials on Law, Science and Medicine. She is a member of the National Academy of Medicine, a member of the American Law Institute, a fellow of the Hastings Center and a faculty affiliate of Georgetown's Kennedy Institute of Ethics. Her scholarship focuses on race and genomics, racial disparities in health and reproductive health. Professor King has served on numerous national advisory bodies formed to address the ethical issues generated by developments in science and technology, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), which produced the seminal "Belmont Report," the President's Advisory Committee on Human Radiation Experiments (1994-95), the National Institutes of Health's Embryo Research Panel (co-chair for policy, 1994), the Ethics, Legal and Social Issues Working Group of the NIH's Human Genome Project (1989-95), and the NIH's Recombinant DNA Advisory Committee (1979-81). She has served on numerous boards and Institute of Medicine committees and is currently a member of the Board of Health Sciences Policy of the National Academies. She is also a Director of Mathematica an employee-owned company.She is a graduate of Wheaton College (Massachusetts) and has served as a Trustee and Chair of the Wheaton College Board of Trustees. In 2018 she was designated a Life Trustee by the Wheaton College Board. She graduated from Harvard Law School and is a past member of the Harvard Corporation the governing board of Harvard University. She has received honorary degrees from Wheaton College, Old Dominion University, and Harvard University.

Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
Executive Director, One Health Institute
UC Davis School of Veterinary Medicine

Jonna Mazet, D.V.M, M.P.V.M., Ph.D., is a Professor of Epidemiology and Disease Ecology at the UC Davis School of Veterinary Medicine and Executive Director of the UC Davis One Health Institute. Her

work focuses on global health problem solving for emerging infectious diseases and conservation challenges. She is active in international One Health education, service, and research programs, most notably in relation to disease transmission among wildlife, domestic animals, and people and the ecological drivers of disease emergence. Currently, Dr. Mazet is the Co-Director of the US Agency for International Development's One Health Workforce – Next Generation, an $85 million educational strengthening project to empower professionals in Central/East Africa and Southeast Asia to address complex health threats, including antimicrobial resistance and zoonotic diseases. She recently served as the Global Director of PREDICT Project, a greater than $200 million viral emergence early warning project under USAID's Emerging Pandemic Threats Division. She was elected to the US National Academy of Medicine in 2013 in recognition of her successful and innovative approach to emerging environmental and global health threats and serves on the National Academies of Science, Engineering, and Medicine's Forum on Microbial Threats and chairs the Academies' One Health Action Collaborative.

Phyllis Meadows, Ph.D., M.S.N., R.N.
Senior Fellow, Health
The Kresge Foundation

Phyllis Meadows currently serves as the Senior Fellow and Program Advisor for the Kresge Foundation Health Team. In this role, she is responsible for supporting the health team in the development and implementation of investment opportunities within and across the Foundation's various programming areas. Her professional career includes leadership roles in philanthropy, academia, community health and governmental public health. She has previously served in the role of Associate Dean for Public Health Practice and Clinical Professor - Health, Management and Policy with the University of Michigan School of Public Health. She has led several initiatives to expand multi-disciplinary practice in communities, designing the University's first certification program on population health and health equity for medical residents. She is currently a Distinguished Towsley Policy Maker in Residence with the University of Michigan's Gerald Ford School of Public Policy. She has taught and developed graduate level and professional continuing education courses to address emerging health issues, including topics on health policy and public health leadership. Dr. Meadows has extensive experience in public health practice having served in various leadership roles in public health. She has held several official appointments in public health leadership at the state, county and local levels. In her most recent appointment, she served as the Chief Health Officer and Director of Health for the City of Detroit, providing leadership for the department of health, environmental health, infectious diseases, child health, clinical and dental services for the residents of Detroit. Her philanthropic experience includes positions as Program Director for the W.K. Kellogg Foundation - Youth, Education and Higher Education; and advisor for several national initiatives of the Robert Wood Johnson Foundation including the Nurse Executive Leadership Program, Partners in Nursing, and the County Roadmaps project. As a registered nurse, she has worked in both community-based health and hospitals. She currently serves as a Board Member and Advisor for several state level organizations and private foundations focusing on health.

Tara O'Toole, M.D., M.P.H.
Executive Vice President
In-Q-Tel

Tara O'Toole currently serves as Executive Vice President at In-Q-Tel. Dr. O'Toole was confirmed as the Under Secretary for Science and Technology (S&T) at the U.S. Department of Homeland Security (DHS) and served from November 4, 2009 to September 23, 2013. From 2003 to November 2009, Dr. O'Toole was the CEO and Director of the Center for Biosecurity at the University of Pittsburgh Medical Center (UPMC), and Professor of Medicine and of Public Health at the University of Pittsburgh. The Center for Biosecurity of UPMC is an independent organization dedicated to improving the country's resilience to major biological threats. Dr. O'Toole is internationally known for her work on biosecurity and on health and safety issues related to the U.S. nuclear weapons complex. Her publications in the biodefense field

include articles on the response to anthrax, smallpox, and plague biological attacks; containment of contagious disease epidemics; biodefense research and development strategies; and hospital preparedness. She is the founding editor of the journal Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. She was a principal author and producer of Dark Winter, an influential exercise conducted in June 2001 to alert national leaders to the dangers of bioterrorist attacks. She was also a principal writer and producer of Atlantic Storm, an international ministerial-level biosecurity exercise held in January 2005. Prior to founding the UPMC in 2003, Dr. O'Toole was one of the original members of the Johns Hopkins Center for Civilian Biodefense Strategies and served as its director from 2001 to 2003. She has served on numerous government and expert advisory committees dealing with biodefense, including panels of the Defense Science Board; the National Academy of Engineering Committee on Combating Terrorism; and the National Academy of Sciences Working Group on Biological Weapons. She served as chair of the Board of the Federation of American Scientists from 2006 to 2007, and in 2006 she was appointed to the board of Google Foundation's International Networked System for Total Early Disease Detection. From 1993 to 1997, Dr. O'Toole served as Assistant Secretary of Energy for Environment Safety and Health. In this position, she was the principal advisor to the Secretary of Energy on environmental protection and on the health and safety of the approximately 100,000 workers in the U.S. nuclear weapons complex and Department of Energy (DOE) laboratories. She developed the first overall management and safety plan for dealing with the highly enriched uranium, plutonium, spent fuel, and radioactive waste left in place when nuclear weapons production was stopped in the early 1990s. She ran the multi-agency, multimillion-dollar task force that oversaw the government's investigations into human radiation experiments conducted during the Cold War and led the U.S. delegation to Russia to establish the U.S./Russia cooperative effort to study radiation exposure and environmental hazards of the Russian nuclear weapons complex. Prior to her work at DOE, Dr. O'Toole was a senior analyst at the Congressional Office of Technology Assessment, where she directed several projects and studies, including the health impact of pollution resulting from nuclear weapons production. She also served as a consultant to industry and government in matters related to occupational and environmental health; worker participation in workplace safety protection; and organizational change. Dr. O'Toole practiced general internal medicine in community health centers in Baltimore from 1984 to 1988. She is board certified in internal medicine and occupational and environmental health. She has a bachelor's degree from Vassar College, an M.D. from the George Washington University, and a Master of Public Health degree from Johns Hopkins University. She completed internal medicine residency training at Yale University and a fellowship in Occupational and Environmental Medicine at Johns Hopkins University.

Alexandra Phelan, S.J.D., LL.M., LL.B.
Assistant Professor
Center for Global Health Science and Security
Georgetown University

Alexandra Phelan is an Assistant Professor at the Center for Global Health Science and Security in the Department of Microbiology and Immunology at Georgetown University School of Medicine. Dr. Phelan also holds an appointment as Adjunct Professor of Law at Georgetown University Law Center. Dr. Phelan works on legal and policy issues related to infectious diseases, with a particular focus on emerging and reemerging infectious disease outbreaks and international law. She has worked as a consultant for the World Health Organization, the World Bank, and Gavi: the vaccine alliance, and has advised on matters including international law and pathogen sharing, human rights law and Zika, intellectual property law, and contract law. She previously worked for a number of years as a solicitor at a firm in Melbourne, Australia and was admitted to practice to the Supreme Court of Victoria and High Court of Australia in 2010. Dr. Phelan's doctorate examined how overlap between fields of international law – in particular, global health law, international human rights law, and international environmental law – can serve as the catalyst to progressively develop international law to prevent and respond to infectious diseases. She also holds a Master of Laws, specializing in international law, from the Australian National University and a Bachelor of Biomedical Science/Bachelor of Laws (Honours) double degree from Monash University.

She also holds a Diploma of Languages (Mandarin Chinese). Dr. Phelan is a General Sir John Monash Scholar and was recognized as an Associate Fellow of the Royal Commonwealth Society in 2015 for her human rights advocacy during the 2013-16 Ebola outbreak.

David Relman, M.D.
Thomas C. and Joan M. Merigan Professor in Medicine, and Chief of Infectious Diseases
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David Relman is the Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology and Immunology at Stanford University, and Chief of Infectious Diseases at the Veterans Affairs Palo Alto Health Care System. Dr. Relman is also Senior Fellow at the Freeman Spogli Institute for International Studies (FSI), and served as Science Co-Director at the Center for International Security and Cooperation (2013-2017), at Stanford. He is currently director of a new Biosecurity Initiative at FSI. Relman trained at MIT and then Harvard Medical School, followed by clinical training in internal medicine and infectious diseases at the Massachusetts General Hospital in Boston, and then a postdoctoral fellowship in microbiology at Stanford. His early research focused on molecular methods for pathogen discovery and over the past 20 years, on the human microbiome. He was elected to the National Academy of Medicine in 2011. Dr. Relman served as vice-chair of the National Research Council Committee that reviewed the science performed for the FBI 2001 Anthrax Letters investigation, chair of the Forum on Microbial Threats (2007-2017), and is currently a member of the Intelligence Community Studies Board (2016-) as well as Chair of a Standing Committee tasked with examining the health-related problems of US embassy personnel stationed overseas, all at the U.S. National Academies of Science. He was a founding member of the National Science Advisory Board on Biosecurity (2005-2014), a member of the Working Group on Biodefense for the President's Council of Advisors on Science and Technology (The White House) (2016), and served as President of the Infectious Diseases Society of America (2012-2013). He holds an M.D. from Harvard Medical School.

Mark Smolinski, M.D., M.P.H.
President
Ending Pandemics

Mark Smolinski currently serves as President of Ending Pandemics. Dr. Smolinksi brings 25 years of experience in applying innovative solutions to improve disease prevention, response, and control across the globe. Mark is leading a well-knit team—bringing together technologists; human, animal, and environmental health experts; and key community stakeholders to co-create tools for early detection, advanced warning, and prevention of pandemic threats. Since 2009, Mark has served as the Chief Medical Officer and Director of Global Health at the Skoll Global Threats Fund (SGTF), where he developed the Ending Pandemics in Our Lifetime Initiative in 2012. His work at SGTF created a solid foundation for the work of Ending Pandemics, which branched out as an independent entity on January 1, 2018. Prior to SGTF, Mark developed the Predict and Prevent Initiative at Google.org, as part of the starting team at Google's philanthropic arm. Working with a team of engineers, Google Flu Trends (a project that had tremendous impact on the use of big data for disease surveillance) was created in partnership with the U.S. Centers for Disease Control. Mark has served as Vice President for Biological Programs at the Nuclear Threat Initiative, a public charity directed by CNN founder Ted Turner and former U.S. Senator Sam Nunn. Before NTI, he led an 18-member expert committee of the National Academy of Medicine on the 2003 landmark report "Microbial Threats to Health: Emergence, Detection, and Response." Mark served as the sixth Luther Terry Fellow in Washington, D.C., in the Office of the U.S. Surgeon General and as an Epidemic Intelligence Officer with the U.S. Centers for Disease Control and Prevention. Mark received his B.S. in Biology and M.D. from the University of Michigan in Ann Arbor. He is board-certified in preventive medicine and public health and holds an M.P.H. from the University of Arizona.

David Walt, Ph.D.
Hansjörg Wyss Professor of Biologically Inspired Engineering
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David R. Walt is the Hansjörg Wyss Professor of Bioinspired Engineering at Harvard Medical School and Professor of Pathology at Harvard Medical School and Brigham and Women's Hospital, is a Core Faculty Member of the Wyss Institute at Harvard University and is a Howard Hughes Medical Institute Professor. Previously, he was University Professor at Tufts University. His laboratory pioneered the development of microwell arrays, which revolutionized the field of genetic analysis. Dr. Walt's laboratory also introduced the idea of digital protein detection by developing a high throughput technology for performing single molecule analysis. Dr. Walt's research is aimed at applying new technologies to address unmet clinical diagnostics needs. Dr. Walt is the Scientific Founder of Illumina Inc., Quanterix Corp., and has co-founded several other life sciences startups including Ultivue, Inc., Arbor Biotechnologies, Sherlock Biosciences, and Vizgen, Inc. He has received numerous national and international awards and honors for his fundamental and applied work in the field of optical microwell arrays and single molecules. He is a member of the National Academy of Engineering, the National Academy of Medicine, a Fellow of the American Academy of Arts and Sciences, a Fellow of the American Institute for Medical and Biological Engineering, a Fellow of the National Academy of Inventors, and is inducted in the US National Inventors Hall of Fame.

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Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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From: Kara Carter[Kara.Carter@evotec.com]
Sent: Wed 4/29/2020 11:19:25 AM (UTC-04:00)
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

That is encouraging. Past experience with FIPV in cats has led to ADE after challenge with the same virus and that ADE was shown in vitro with antibodies from both vaccinated and naturally infected cats. Something to watch for.

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From: Rappaport, Jay <jrappaport@tulane.edu>
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[EXTERNAL]

Regarding ADE, The reference to Callow #13 in the Galanti paper shows experimentally infected humans that were then rechallenged. While the subjects were not necessarily protected from reinfection, they seemed to be resistant to disease, which is encouraging.
Jay

From: Kara Carter <kara.carter@evotec.com>
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> External Sender. Be aware of links, attachments and requests.

Joe,

Thanks for sharing this. It would be particularly interesting to know if these same patients have COVID-19 histories and how they track. If a person is predisposed to have symptoms to OC43 or other endemic coronaviruses, do they also have more severe disease with SARS-CoV-2 infection. Since these patients are from NYC, I think there is good chance that many of them were tested for SARS-CoV-2. Of course, there is likely not continued surveillance of these folks for SARS-CoV-2. It may be just that those with severe disease are noted and it would be interesting to know if those same patients also had symptoms for endemic coronaviruses.

Also, I am a bit encouraged to see that there is not any strong evidence for ADE for the endemic coronaviruses (I am also surprised there was no discussion of ADE potential in the paper), which is something I am tracking in the literature as it would have major implications for the pandemic and also vaccine development. Could there be ADE for SARS-CoV-2 after endemic coronavirus exposure?

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To: 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; 'Adams, Peter (OS/ASPR/BARDA)' <Peter.Adams@hhs.gov>; 'Alvarez, Rosa' <rosalvarez@deloitte.com>; 'Anderson, Annaliesa' <Annaliesa.Anderson@pfizer.com>; 'Baric, Ralph' <rbaric@email.unc.edu>; Kara Carter <Kara.Carter@evotec.com>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Deming, Damon (FDA/CDER)' <damon.deming@fda.hhs.gov>; 'Diamond, Michael' <diamond@wusm.wustl.edu>; 'Duncan, Ken' <ken.duncan@gatesfoundation.org>; 'Gatto, Greg' <ggatto@rti.org>; 'Grobler, Jay' <jay_grobler@merck.com>; 'Hewitt, Judith (NIH/NIAID) [E]' <jhewitt@niaid.nih.gov>; 'Jonson, Samantha (NIH/NCATS) [E]' <samantha.jonson@nih.gov>; 'Lutz, Cat' <Cat.Lutz@jax.org>; 'Nestle, Frank' <Frank.Nestle@sanofi.com>; 'Ottinger, Elizabeth (NIH/NCATS [E]' <elizabeth.ottinger@nih.gov>; 'Parker, Ashley (NIH/OD) [E]' <ashley.parker@nih.gov>; 'Payne, David' <david.j.payne@gsk.com>; 'Rao, Srinivas' <Srinivas.Rao@sanofi.com>; 'Rappaport, Jay' <jrappaport@tulane.edu>; 'Stegmeier, Frank' <fstegmeier@ksqtx.com>; 'Young, John' <john.young.jy3@roche.com>
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

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Subject: FW: Direct observation of repeated infections with endemic coronaviruses

The note below reinforces the need to do some WGS in NHP and humans.

From: Hall, Matthew (NIH/NCATS) [E] <hallma@mail.nih.gov>
Sent: Tuesday, April 28, 2020 10:32 PM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: Direct observation of repeated infections with endemic coronaviruses

Here's a pre-print from Columbia that my colleague Mike Kurilla passed along to me, which might impact how well you sleep tonight:

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http://www.columbia.edu/~jls106/galanti_shaman_ms_supp.pdf

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This study provides evidence that **re-infections with the same endemic coronavirus are not atypical in a time window shorter than 1 year** and that the **genetic basis of innate immune response may be a greater determinant of infection severity** than immune memory acquired after a previous infection."

Matthew D. Hall
Acting Branch Chief, Early Translation Branch
Group Leader, Biology

National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health
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If received in error, please notify us immediately by reply email and then delete this email and any attachments from your system. Thank you!

Please find our information on data protection here.

To: 'Kara Carter'[Kara.Carter@evotec.com]; 'Rappaport, Jay'[jrappaport@tulane.edu]; 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Alvarez, Rosa'[rosalvarez@deloitte.com]; 'Anderson, Annaliesa'[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; 'Diamond, Michael'[diamond@wusm.wustl.edu]; 'Duncan, Ken'[ken.duncan@gatesfoundation.org]; 'Gatto, Greg'[ggatto@rti.org]; 'Grobler, Jay'[jay_grobler@merck.com]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Jonson, Samantha (NIH/NCATS) [E]'[samantha.jonson@nih.gov]; 'Lutz, Cat'[Cat.Lutz@jax.org]; 'Nestle, Frank'[Frank.Nestle@sanofi.com]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; 'Payne, David'[david.j.payne@gsk.com]; 'Rao, Srinivas'[Srinivas.Rao@sanofi.com]; 'Stegmeier, Frank'[fstegmeier@ksqtx.com]; 'Young, John'[john.young.jy3@roche.com]
From: Prabha Fernandes[prabha.fernandes@gmail.com]
Sent: Wed 4/29/2020 11:21:31 AM (UTC-04:00)
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

Hello Kara,
Good information and something to watch for.
I know the issues with the Dengue vaccine and children who died
Regards,
prabha

From: Kara Carter <Kara.Carter@evotec.com>
Sent: Wednesday, April 29, 2020 11:19 AM
To: Rappaport, Jay <jrappaport@tulane.edu>; Prabha Fernandes <prabha.fernandes@gmail.com>; 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; 'Adams, Peter (OS/ASPR/BARDA)' <Peter.Adams@hhs.gov>; 'Alvarez, Rosa' <rosalvarez@deloitte.com>; 'Anderson, Annaliesa' <Annaliesa.Anderson@pfizer.com>; 'Baric, Ralph' <rbaric@email.unc.edu>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Deming, Damon (FDA/CDER)' <damon.deming@fda.hhs.gov>; 'Diamond, Michael' <diamond@wusm.wustl.edu>; 'Duncan, Ken' <ken.duncan@gatesfoundation.org>; 'Gatto, Greg' <ggatto@rti.org>; 'Grobler, Jay' <jay_grobler@merck.com>; 'Hewitt, Judith (NIH/NIAID) [E]' <jhewitt@niaid.nih.gov>; 'Jonson, Samantha (NIH/NCATS) [E]' <samantha.jonson@nih.gov>; 'Lutz, Cat' <Cat.Lutz@jax.org>; 'Nestle, Frank' <Frank.Nestle@sanofi.com>; 'Ottinger, Elizabeth (NIH/NCATS [E]' <elizabeth.ottinger@nih.gov>; 'Parker, Ashley (NIH/OD) [E]' <ashley.parker@nih.gov>; 'Payne, David' <david.j.payne@gsk.com>; 'Rao, Srinivas' <Srinivas.Rao@sanofi.com>; 'Stegmeier, Frank' <fstegmeier@ksqtx.com>; 'Young, John' <john.young.jy3@roche.com>
Subject: RE: Direct observation of repeated infections with endemic coronaviruses

That is encouraging. Past experience with FIPV in cats has led to ADE after challenge with the same virus and that ADE was shown in vitro with antibodies from both vaccinated and naturally infected cats. Something to watch for.

evotec

Kara Carter, PhD
Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
kara.carter@evotec.com
www.evotec.com

From: Rappaport, Jay <jrappaport@tulane.edu>
Sent: Wednesday, April 29, 2020 10:58 AM
To: Kara Carter <Kara.Carter@evotec.com>; Prabha Fernandes <prabha.fernandes@gmail.com>; 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; 'Adams, Peter (OS/ASPR/BARDA)' <Peter.Adams@hhs.gov>; 'Alvarez, Rosa' <rosalvarez@deloitte.com>; 'Anderson, Annaliesa' <Annaliesa.Anderson@pfizer.com>; 'Baric, Ralph' <rbaric@email.unc.edu>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Deming, Damon (FDA/CDER)' <damon.deming@fda.hhs.gov>; 'Diamond, Michael' <diamond@wusm.wustl.edu>; 'Duncan, Ken' <ken.duncan@gatesfoundation.org>; 'Gatto, Greg' <ggatto@rti.org>; 'Grobler, Jay' <jay_grobler@merck.com>; 'Hewitt, Judith (NIH/NIAID) [E]' <jhewitt@niaid.nih.gov>; 'Jonson, Samantha (NIH/NCATS) [E]' <samantha.jonson@nih.gov>; 'Lutz, Cat' <Cat.Lutz@jax.org>; 'Nestle, Frank' <Frank.Nestle@sanofi.com>; 'Ottinger, Elizabeth (NIH/NCATS [E]' <elizabeth.ottinger@nih.gov>; 'Parker, Ashley (NIH/OD) [E]' <ashley.parker@nih.gov>; 'Payne, David' <david.j.payne@gsk.com>; 'Rao, Srinivas' <Srinivas.Rao@sanofi.com>; 'Stegmeier, Frank' <fstegmeier@ksqtx.com>; 'Young, John' <john.young.jy3@roche.com>

Subject: Re: Direct observation of repeated infections with endemic coronaviruses

[EXTERNAL]

Regarding ADE, The reference to Callow #13 in the Galanti paper shows experimentally infected humans that were then rechallenged. While the subjects were not necessarily protected from reinfection, they seemed to be resistant to disease, which is encouraging.
Jay

From: Kara Carter <kara.carter@evotec.com>
Date: Wednesday, April 29, 2020 at 8:38 AM
To: Prabha Fernandes <prabha.fernandes@gmail.com>, "'Menetski, Joseph (FNIH) [T]'" <jmenetski@fnih.org>, "'Adams, Peter (OS/ASPR/BARDA)'" <Peter.Adams@hhs.gov>, "'Alvarez, Rosa'" <rosalvarez@deloitte.com>, "'Anderson, Annaliesa'" <Annaliesa.Anderson@pfizer.com>, "'Baric, Ralph'" <rbaric@email.unc.edu>, "'Colvis, Christine (NIH/NCATS) [E]'" <christine.colvis@nih.gov>, "'Deming, Damon (FDA/CDER)'" <damon.deming@fda.hhs.gov>, "'Diamond, Michael'" <diamond@wusm.wustl.edu>, "'Duncan, Ken'" <ken.duncan@gatesfoundation.org>, "'Gatto, Greg'" <ggatto@rti.org>, "'Grobler, Jay'" <jay_grobler@merck.com>, "'Hewitt, Judith (NIH/NIAID) [E]'" <jhewitt@niaid.nih.gov>, "'Jonson, Samantha (NIH/NCATS) [E]'" <samantha.jonson@nih.gov>, "'Lutz, Cat'" <Cat.Lutz@jax.org>, "'Nestle, Frank'" <Frank.Nestle@sanofi.com>, "'Ottinger, Elizabeth (NIH/NCATS [E]'" <elizabeth.ottinger@nih.gov>, "'Parker, Ashley (NIH/OD) [E]'" <ashley.parker@nih.gov>, "'Payne, David'" <david.j.payne@gsk.com>, "'Rao, Srinivas'" <Srinivas.Rao@sanofi.com>, "Rappaport, Jay" <jrappaport@tulane.edu>, "'Stegmeier, Frank'" <fstegmeier@ksqtx.com>, "'Young, John'" <john.young.jy3@roche.com>
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> External Sender. Be aware of links, attachments and requests.

Joe,

Thanks for sharing this. It would be particularly interesting to know if these same patients have COVID-19 histories and how they track. If a person is predisposed to have symptoms to OC43 or other endemic coronaviruses, do they also have more severe disease with SARS-CoV-2 infection. Since these patients are from NYC, I think there is good chance that many of them were tested for SARS-CoV-2. Of course, there is likely not continued surveillance of these folks for SARS-CoV-2. It may be just that those with severe disease are noted and it would be interesting to know if those same patients also had symptoms for endemic coronaviruses.

Also, I am a bit encouraged to see that there is not any strong evidence for ADE for the endemic coronaviruses (I am also surprised there was no discussion of ADE potential in the paper), which is something I am tracking in the literature as it would have major implications for the pandemic and also vaccine development. Could there be ADE for SARS-CoV-2 after endemic coronavirus exposure?

Kara

evotec

Kara Carter, PhD
Executive Vice President Infectious Disease
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On the vaccine front, some good hints of which antibodies to look for with some translation to Ebola vaccine work. All very educational!

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Sent: Tuesday, April 28, 2020 10:32 PM
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Matthew D. Hall
Acting Branch Chief, Early Translation Branch
Group Leader, Biology

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To: 'Jonna Mazet'[jkmazet@ucdavis.edu]; 'David A Relman'[relman@stanford.edu]; andersen@scripps.edu[andersen@scripps.edu]; trevor@bedford.io[trevor@bedford.io]; dgriffi6@jhu.edu[dgriffi6@jhu.edu]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; Baric, Ralph S[rbaric@email.unc.edu]
Cc: Downey, Autumn[ADowney@nas.edu]; Brown, Lisa[LBrown@nas.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]
From: Shore, Carolyn[CShore@nas.edu]
Sent: Wed 4/29/2020 3:42:46 PM (UTC-04:00)
Subject: RE: FOR WORKING GROUP REVIEW - Topic List RE: Viral Characteristics
Viral Characteristics - Topics.docx

Many thanks to those of you who have already submitted your top three priority topics. For those who haven't yet responded – we welcome your input by COB today.

We'll be finalizing the list to go to the standing committee sponsors later tonight and look forward to the meeting tomorrow.

Best,
Carolyn & Autumn

From: Shore, Carolyn
Sent: Monday, April 27, 2020 4:13 PM
To: 'Jonna Mazet' <jkmazet@ucdavis.edu>; 'David A Relman' <relman@stanford.edu>; ' <andersen@scripps.edu>; 'trevor@bedford.io' <trevor@bedford.io>; 'dgriffi6@jhu.edu' <dgriffi6@jhu.edu>; 'daszak@ecohealthalliance.org' <daszak@ecohealthalliance.org>; ' <rbaric@email.unc.edu>
Cc: Downey, Autumn <ADowney@nas.edu>; Brown, Lisa <LBrown@nas.edu>; Pope, Andrew <APope@nas.edu>; Harvey V. Fineberg <harvey.fineberg@moore.org>; Pavlin, Julie <JPavlin@nas.edu>
Subject: FOR WORKING GROUP REVIEW - Topic List RE: Viral Characteristics

Dear all,

Many thanks for your time and thoughtful input on the working group call last week.

For your review/input, please find attached a list of topics raised during the working group call on viral characteristics. We've bucketed the questions by topic and highlighted sections in yellow specific questions that we would welcome your input on. More specifically, we are asking each of you to:

- Please rank your top three topics based on what you consider highest priority for consideration by the full standing committee and sponsors, and indicate for each your preferred timeline and product type (please read through all five topics and the research option before making selections).
- Provide a brief justification for your priority selections.

If possible, we would welcome your feedback by **Wednesday 4/29 noon** so that staff have time to compile your responses and circulate ahead of the standing committee meeting on Thursday of this week.

Thank you again!

Best,
Carolyn

_____
Carolyn Shore, PhD
Director, Forum on Drug Discovery, Development, and Translation
Senior Program Officer, Board on Health Sciences Policy
Health and Medicine Division | Find us at nationalacademies.org/DRUGFORUM
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500 Fifth Street, NW
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April 27, 2020

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Viral Characteristics Work Group

Goal: Narrow down the list of proposed topics (see below) to 1-2 priorities to discuss with the full standing committee and sponsors on Thursday, April 30, 2020 (note: each work group will have ~15 mins to present). For each priority, provide the following information:

1. Question, topic or task, with clear objectives and rationale
2. Suitable type of product (telephonic consultation, rapid expert consultation, letter report, or consensus report)
3. Primary audience for the assessment
4. Anticipated time-frame for completion
5. Volunteers from the standing committee and working groups, and suggestions for additional experts to serve on the response team

When narrowing down the list of proposed topics, the work group might consider the following:

- Is the topic timely (consider fast moving issues as well as longer term questions)?
- Does the topic address a profound knowledge gap (e.g., consider what can be done given incomplete information and the rapidly changing data landscape)?
- Is the topic something that others have missed (i.e. is there unique perspective/analysis that the standing committee could provide)?
- What are the most important "known unknowns" required for decision-makers?
- Does the topic overlap with the other working group issue areas?
- Is there a clear path/mechanism (i.e. informal discussion, rapid expert consultation, letter report, or consensus study) for providing robust answers to key questions?

Please rank your top three topics based on what you consider highest priority for consideration by the full standing committee and sponsors, and indicate for each your preferred timeline and product type (please read through the five topics and the research agenda option, and then rank your top three selections among the six: 1 = first choice, 2 = second choice, 3 = third choice).

☐ **Topic 1: Viral evolution (tracking viral genome evolution, and correlation of genotype with *in vitro* phenotypes and *in vivo* host phenotypes)**
☐ **Topic 2: Viral transmission and spread**
☐ **Topic 3: Mechanisms of pathogenesis (host susceptibility, dynamics of the virus in the host, shedding, organ tropism, host response)**
☐ **Topic 4: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement)**
☐ **Topic 5: SARS-COV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)**
☐ **Topic 6: Development and recommendation of a research agenda, for any or all of the 5 other topics**

Brief justification for priority selections:

Topic 1: Viral evolution (tracking viral genome evolution, and correlation of genotype with *in vitro* phenotypes and *in vivo* host phenotypes)

Analyses to track/correlate viral genome sequence features with viral phenotypes *in vitro* and *in vivo* in host/s) as they relate to receptor recognition, growth, host responses and pathogenic mechanisms, and/or selective pressures in the host or environment. Examples of questions to be addressed:

- What are rates and mechanisms of genome evolution as a function of geography, time since introduction into human population, and host features such as immune status?
- How does viral genotype correlate with clinical outcomes?
- Are variant viral sequence features correlated with viral escape from host immune recognition or vaccine-induced immunity, therapeutic beneficial effects, or detection by currently deployed methods?
- How should features of viral genome evolution be used to help optimize the design and development of therapeutics and vaccines? Note: current features of genome evolution may not be a good indicator of genome evolution under the selective pressure of therapeutics, naturally-induced immunity, or vaccine-induced immunity.

TIMELINE (short-, medium-, long-term):

PRIMARY AUDIENCE (e.g. policy makers, researchers, funders, lay public):

PRODUCT TYPE(S) (informal discussion, rapid expert consultation, letter report, or consensus study):

Topic 2: Transmission and Spread

An analysis to consider the key drivers/determinants and mechanisms of transmission and spread:

- What are the key drivers/determinants of viral spread and cycles of infection and illness?
- Are cycles of infection likely to result from environmental (e.g., temperature, humidity) or social (e.g., school openings/closings) factors?
- What are the mechanisms of transmission and spread?
    - Role of airborne particles of various sizes, fomites, respiratory versus fecal-oral
    - Identification and characterization of super spreaders?
    - Can risk factors for asymptomatic transmission be identified, especially long-term shedding?
    - Note: this work would impact case-based interventions, contact tracing, quarantine measures
- What is the duration of shedding of infectious virus by patients and the relationship to detection of viral RNA? Note: relevant for understanding recovery and when it is ok for people to leave isolation
- Is presence/shedding of viral RNA indicative of transmission risk (i.e., contagiousness)?

TIMELINE (short-, medium-, long-term):

PRIMARY AUDIENCE (e.g. policy makers, researchers, funders, lay public):

PRODUCT TYPE(S) (informal discussion, rapid expert consultation, letter report, or consensus study):

Topic 3: Mechanisms of pathogenesis (host susceptibility, dynamics of the virus in the host, shedding, organ tropism, host response)

Analysis to better understand the "choreography" between the virus and host, including host molecular pathways and/or host response features during the course of infection:

- What are the mechanisms of pathogenesis and the factors contributing to variability in disease severity and outcome (consider relative contribution of viral versus host characteristics)?
- What is the natural history of the virus in humans (where, when)?
- What are the mechanisms of organ damage?
- What are the implications for development and use of therapeutics and other interventions? (Note: possible overlap with patient management group)
- What are the tools (e.g. animal models of disease, susceptibility, and early biomarkers) needed to understand the mechanisms of pathogenesis and the range of disease phenotypes?

TIMELINE (short-, medium-, long-term):

PRIMARY AUDIENCE (e.g. policy makers, researchers, funders, lay public):

PRODUCT TYPE(S) (informal discussion, rapid expert consultation, letter report, or consensus study):

Topic 4: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement)

Analyses to better understand the role of antibodies and cellular immune responses in protection, and the development/durability of protective immunity:

- Characterization of the immune response and implications for disease severity and for short- and long-term protection from re-infection?
- How does viral clearance occur and what are the likelihoods of, and the risk factors for intermittent and long-term virus shedding?
- How long do neutralizing and non-neutralizing antibodies last?
- Does the presence of antibodies convey protective immunity, and if so, what kinds of antibodies, in what quantities, and for how long?
- What is the likelihood of herd immunity in the US and how will it vary by regional and local demographic factors?
- What is the role of pre-existing antibody (to other coronavirus strains, and potentially to other infectious agents) in the development of a protective immune response to SARS-CoV-2? Does antibody-mediated disease enhancement occur in humans infected by SARS-CoV-2?

TIMELINE (short-, medium-, long-term): short- and/or medium-term

PRIMARY AUDIENCE (e.g. policy makers, researchers, funders, lay public):

PRODUCT TYPE(S) (informal discussion, rapid expert consultation, letter report, or consensus study): informal discussions, REC, letter report

Topic 5: SARS-COV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

A more substantive analysis of current and future issues of immediate critical need regarding viral emergence and host range:

- What are the host and transmission circumstances that could inform on origins and future spillovers for this pathogen?
- What are the natural hosts/animal reservoirs for this pathogen? What is the potential for domesticated livestock to serve as a reservoir and what are the implications for food security?
- What is the potential for future outbreaks from re-emergence from the human population, additional spillovers from existing hosts, and exposures from new hosts resulting from spillback events from humans into susceptible animals, especially pets and food animals?
- What is the host range for this virus (e.g., what is the current risk to and from companion animals)?

TIMELINE (short-, medium-, long-term): Long-term

PRIMARY AUDIENCE (e.g. policy makers, researchers, funders, lay public):

PRODUCT TYPE(S) (informal discussion, rapid expert consultation, letter report, or consensus study): Consensus study

Topic 6: Development and recommendation of a research agenda, for any or all of the five topics listed above. Please indicate whether the formulation of a research agenda for one or some combination of the topics above should be a priority—and, if so, indicate which topic(s) should be included.

TIMELINE (short-, medium-, long-term): Long-term

PRIMARY AUDIENCE (e.g. policy makers, researchers, funders, lay public):

PRODUCT TYPE(S) (informal discussion, rapid expert consultation, letter report, or consensus study): Consensus study

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; david.j.payne@gsk.com[david.j.payne@gsk.com]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Annaliesa.Anderson@pfizer.com[Annaliesa.Anderson@pfizer.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; kara.carter@evotec.com[kara.carter@evotec.com]; john.young.jy3@roche.com[john.young.jy3@roche.com]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Collins, Francis (NIH/OD) [E][collinsf@od.nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Rao, Srinivas /US[Srinivas.Rao@sanofi.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]
Cc: Wholley, David (FNIH) [T][dwholley@fnih.org]; Austin, Christopher (NIH/NCATS) [E][austinc@mail.nih.gov]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Desrosiers, Betsy[elizabeth_desrosiers@merck.com]; Hughes, Eric[eric.hughes@novartis.com]; Jansen, Kathrin[kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E][michael.kurilla@nih.gov]; Lowy, Douglas (NCI)[dl60z@nih.gov]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; James, Stephanie (FNIH) [T][sjames@fnih.org]; Kim, Elizabeth[elkim@deloitte.com]; Tolman, Brett[btolman@deloitte.com]; Wachtel, Jonathan[jwachtel@DELOITTE.com]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Diamond, Michael[mdiamond@wustl.edu]; Rose Li[rose.li@roseliassociates.com]; Dana Carluccio[dana.carluccio@roseliassociates.com]; Lagos, Enrique (NIH/NCATS) [E][enrique.lagos@nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Gonzalez, Nina[ningonzalez@deloitte.com]; Simon, Dina (NIH/OD) [C][dina.simon@nih.gov]; Burrus-Shaw, Cyndi (NIH/OD) [E][cyndi.burrus-shaw@nih.gov]; Rodriguez, Robin D[rmdaigle@tulane.edu]; Dave Frankowski[david.frankowski@roseliassociates.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Wed 4/29/2020 6:33:44 PM (UTC-04:00)
Subject: RE: ACTIV Preclinical working group (Friday meeting)

Hi all,

Please find below our agenda for tomorrow's WG meeting. We have a few topics that we want to discuss and get feedback from the entire WG before going our presentation to the ACTIV leadership next week. Please note that we are extending our meeting until 12:30pm.

Agenda Topic	Duration	Facilitator
Provide overview of agenda topics	5 mins	Christine Colvis, John Young
Discuss prioritization filter scheme for antiviral molecules	25 mins	Kara Carter, Jay Grobler
Discuss NHP Strategy Framework	25 mins	Jay Rappaport
Discuss pending cross-subgroup questions/decisions • E.g. Better understand the use of adaptive viruses in small animal model studies	20 mins	Cat Lutz, Mike Diamond
Align on next steps	10 mins	Joe Menetski, Rosa Alvarez

Sincerely,

Joseph Menetski

-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Tuesday, April 14, 2020 6:49 PM
To: Menetski, Joseph (FNIH) [T]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski
Subject: ACTIV Preclinical working group (Friday meeting)
When: Thursday, April 30, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Request to move due to holiday

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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+1 646 876 9923 US (New York)
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+1 253 215 8782 US
+1 301 715 8592 US
+1 346 248 7799 US (Houston)
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+1 669 900 6833 US (San Jose)
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Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
301 594-6596 | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852


FNIH PANDEMIC
RESPONSE FUND

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Qashu, Felicia (NIH/OD) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]

Location: https://fnih.zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Importance: Normal

Subject: ACTIV Preclinical working group (Friday meeting)

Start Time: Thur 4/30/2020 11:00:00 AM (UTC-04:00)

End Time: Thur 4/30/2020 12:30:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Qashu, Felicia (NIH/OD) [E]

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]

Request to move due to holiday and extended by 30min

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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+1 301 715 8592 US
+1 346 248 7799 US (Houston)
+1 408 638 0968 US (San Jose)
+1 669 900 6833 US (San Jose)
Meeting ID: 930 2871 7745
Password: 920539
Find your local number: https://fnih.zoom.us/u/ackW4UiLB0

To: Alexandra Phelan (alp81@georgetown.edu)[alp81@georgetown.edu]; David A Relman (relman@stanford.edu)[relman@stanford.edu]; David Walt (dwalt@bwh.harvard.edu)[dwalt@bwh.harvard.edu]; Diane Griffin (dgriffi6@jhmi.edu)[dgriffi6@jhmi.edu]; Embrey, Ellen (eembrey@stratitia.com)[eembrey@stratitia.com]; Georges Benjamin (georges.benjamin@apha.org)[georges.benjamin@apha.org]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; John Hick (hick.john@gmail.com)[hick.john@gmail.com]; Jonna Mazet (jkmazet@ucdavis.edu)[jkmazet@ucdavis.edu]; Kent Kester (Kent.Kester@sanofi.com)[Kent.Kester@sanofi.com]; Kristian G. Andersen (kga1978@gmail.com)[kga1978@gmail.com]; Mark Smolinski (mark@endingpandemics.org)[mark@endingpandemics.org]; Mary Travis Bassett (mbassett@hsph.harvard.edu)[mbassett@hsph.harvard.edu]; Patricia King (patricia.king1@gmail.com)[patricia.king1@gmail.com]; Peggy Hamburg (peggy@hbfam.net)[peggy@hbfam.net]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; Phyllis D. Meadows (PDMeadows@kresge.org)[PDMeadows@kresge.org]; Richard Besser (rbesser@rwjf.org)[rbesser@rwjf.org]; Tara O'Toole (totoole@iqt.org)[totoole@iqt.org]; Trevor Bedford (trevor@bedford.io)[trevor@bedford.io]; Baric, Ralph S[rbaric@email.unc.edu]; Donald Berwick[donberwick@gmail.com]; alta.charo@wisc.edu[alta.charo@wisc.edu]; Jeff.Duchin@kingcounty.gov[Jeff.Duchin@kingcounty.gov]; Baruch Fischhoff[baruch@cmu.edu]; DHanfling@iqt.org[DHanfling@iqt.org]; bgroves@georgetown.edu[bgroves@georgetown.edu]
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; mnavish@iqt.org[mnavish@iqt.org]; andre@ecohealthalliance.org[andre@ecohealthalliance.org]; Peisch, Samuel Francis[speisch@hsph.harvard.edu]; jbaker@rwjf.org[jbaker@rwjf.org]; Baric, Toni C[antoinette_baric@med.unc.edu]; Mary Radford[maradford@ucdavis.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]; Feit, Monica[MFeit@nas.edu]; Shore, Carolyn[CShore@nas.edu]; Wollek, Scott[SWollek@nas.edu]; Downey, Autumn[ADowney@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Wed 4/29/2020 6:56:19 PM (UTC-04:00)
Subject: Additional Materials RE: Agenda and Zoom Information for Second Virtual Meeting of the Standing Committee 4/30
SCEID Working Group Priority Issues_v1_42920.docx
SCEID Working Group Membership.docx
ASPR COVID Strategic Operational Priorities.docx
FINAL Agenda_Virtual Meeting 2_ SC on EID and 21st Century Threats.pdf

Dear Members of the Standing Committee,

As promised, please find attached a compilation of the priority topics discussed by each working group. Please refer to this document for our working group discussions during tomorrow's meeting. Please note that the numbering of the topics may differ than earlier versions of these lists because this list now reflects the prioritization process. Each working group has identified three priorities. For reference, we are also attaching a document listing the working group membership.

Furthermore, for tomorrow's meeting please find attached ASPR's list of strategic operational priorities. Chris Hassle will be presenting these priorities to the standing committee.

Lastly, we are re-attaching the agenda, and we will update the calendar invite with all of these materials and Zoom information.

Please let us know if you have any questions.

We are looking forward to tomorrow's discussions!!

Very best,
Lisa

Lisa Brown, MPH
Senior Program Officer
Board on Health Sciences Policy
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From: Brown, Lisa
Sent: Wednesday, April 29, 2020 11:16 AM
To: Alexandra Phelan (alp81@georgetown.edu) <alp81@georgetown.edu>; David A Relman (relman@stanford.edu) <relman@stanford.edu>; David Walt (dwalt@bwh.harvard.edu) <dwalt@bwh.harvard.edu>; Diane Griffin (dgriffi6@jhmi.edu) <dgriffi6@jhmi.edu>; Embrey, Ellen (eembrey@stratitia.com) <eembrey@stratitia.com>; Georges Benjamin (georges.benjamin@apha.org) <georges.benjamin@apha.org>; Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; John Hick (hick.john@gmail.com) <hick.john@gmail.com>; Jonna Mazet (jkmazet@ucdavis.edu) <jkmazet@ucdavis.edu>; Kent Kester (Kent.Kester@sanofi.com) <Kent.Kester@sanofi.com>; Kristian G. Andersen (kga1978@gmail.com) <kga1978@gmail.com>; Mark Smolinski (mark@endingpandemics.org) <mark@endingpandemics.org>; Mary Travis Bassett (mbassett@hsph.harvard.edu) <mbassett@hsph.harvard.edu>; Patricia King (patricia.king1@gmail.com) <patricia.king1@gmail.com>; Peggy Hamburg (peggy@hbfam.net) <peggy@hbfam.net>; Peter Daszak (daszak@ecohealthalliance.org) <daszak@ecohealthalliance.org>; Phyllis D. Meadows (PDMeadows@kresge.org) <PDMeadows@kresge.org>; Richard Besser (rbesser@rwjf.org) <rbesser@rwjf.org>; Tara O'Toole (totoole@iqt.org) <totoole@iqt.org>; Trevor Bedford (trevor@bedford.io) <trevor@bedford.io>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'Donald Berwick' <donberwick@gmail.com>; 'alta.charo@wisc.edu' <alta.charo@wisc.edu>; 'Jeff.Duchin@kingcounty.gov' <Jeff.Duchin@kingcounty.gov>; 'Baruch Fischhoff' <baruch@cmu.edu>; 'DHanfling@iqt.org' <DHanfling@iqt.org>; 'bgroves@georgetown.edu' <bgroves@georgetown.edu>
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; 'mnavish@iqt.org' <mnavish@iqt.org>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'Peisch, Samuel Francis' <speisch@hsph.harvard.edu>; 'jbaker@rwjf.org' <jbaker@rwjf.org>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'Mary Radford' <maradford@ucdavis.edu>; Pope, Andrew <APope@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; Feit, Monica <MFeit@nas.edu>; Shore, Carolyn <CShore@nas.edu>; Wollek, Scott <SWollek@nas.edu>; Downey, Autumn <ADowney@nas.edu>
Subject: Agenda and Zoom Information for Second Virtual Meeting of the Standing Committee 4/30
Importance: High

Dear Members of the Standing Committee,

We are looking forward to the second virtual meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats taking place tomorrow, April 30th, from 11:00 a.m. – 1:00 p.m. ET. Please find attached the final agenda, and the Zoom information is below. The primary objective of tomorrow's call is to discuss the priorities that were raised on each of the four working group calls with the sponsors and the full committee. This is the first full committee meeting for the new members; therefore, we are also attaching updated bios and rosters of the full committee for your reference.

Please note that later today, we will be disseminating a compilation of the priority topics to the full committee. Several of the working groups met yesterday, so we are in the process of revising and compiling those priorities.

Zoom Call-In Information
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378
Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Please let us know if you have any questions.

Many thanks,
Lisa

Lisa Brown, MPH
Senior Program Officer

Board on Health Sciences Policy
Health and Medicine Division
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW, Washington, DC 20001
202-334-2487 (office)
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April 29, 2020

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Priority Topics

The standing committee has established four working groups to ensure adequate attention to a broad range of relevant issues and topics, and to propose priorities for consideration and responding to the needs of the sponsors.

The working groups focus on the following domains:

- Viral characteristics
- Patient care and medical countermeasures
- Community engagement and population health
- Cross-cutting issues

This document is a preliminary list of topics discussed by each working group. Of these topics, each working group has identified their top three priority topics (indicated by **priority**).

Summary Table: Top Three Priority Topics of Each Working Group

Working Group Topics	Informal Feedback (Telephonic Consultation)	Written Rapid Expert Consultation	Letter Report	Consensus Report
WG A: Viral Characterization				
Topic A-1: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement)	X	X	X	
Topic A-2: Viral evolution (tracking viral genome evolution, and correlation of genotype with in vitro phenotypes and in vivo host phenotypes)	X		X	
Topic A-3: Transmission and Spread	X			
WG B: Patient Care and MCM				
Topic B-1: Diagnostics roadmap			X	X
Topic B-2: Research agenda to understand pathogenesis, risk factors, and protective factors			X	
Topic B-3: Assessment of preparedness efforts				X
WG C: Community Engagement and Population Health				
Topic C-1: Data needs for decision making		X	X	X
Topic C-2: Specific data need and analysis to determine the role of children in disease transmission		X		
Topic C-3: Defining needs for successful response to COVID-19 among minority and disenfranchised populations		X	X	X
WG D: Cross-Cutting Issues				
Topic D-1: COVID-19 and racial and ethnic disparities		X	X	
Topic D-2: Workplace and school re-opening			X	
Topic D-3: Redefining the public health system for future pandemics				X

Group A: Viral Characterization Working Group

Topic A-1: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement) Priority

Analyses to better understand the role of antibodies and cellular immune responses in protection, and the development/durability of protective immunity:

- Characterization of the immune response and implications for disease severity and for short- and long-term protection from re-infection?
- How does viral clearance occur and what are the likelihoods of, and the risk factors for intermittent and long-term virus shedding?
- How long do neutralizing and non-neutralizing antibodies last?
- Does the presence of antibodies convey protective immunity, and if so, what kinds of antibodies, in what quantities, and for how long?
- What is the likelihood of herd immunity in the US and how will it vary by regional and local demographic factors?
- What is the role of pre-existing antibody (to other coronavirus strains, and potentially to other infectious agents) in the development of a protective immune response to SARS-CoV-2? Does antibody-mediated disease enhancement occur in humans infected by SARS-CoV-2?

JUSTIFICATION: Critical for vaccine, but also for national strategy going forward. If durable immunity doesn't exist, suppression is much more desirable than otherwise.

TIMELINE: Short- to medium-term

PRODUCT TYPE(S): Informal discussions, rapid expert consultation, letter report

PRIMARY AUDIENCE: Policymakers, researchers, funders & lay public

Topic A-2: Viral evolution (tracking viral genome evolution, and correlation of genotype with *in vitro* phenotypes and *in vivo* host phenotypes) Priority

Analyses to track/correlate viral genome sequence features with viral phenotypes *in vitro* and *in vivo* in host/s) as they relate to receptor recognition, growth, host responses and pathogenic mechanisms, and/or selective pressures in the host or environment. Examples of questions to be addressed:

- What are rates and mechanisms of genome evolution as a function of geography, time since introduction into human population, and host features such as immune status?
- How does viral genotype correlate with clinical outcomes?
- Are variant viral sequence features correlated with viral escape from host immune recognition or vaccine-induced immunity, therapeutic beneficial effects, or detection by currently deployed methods?
- How should features of viral genome evolution be used to help optimize the design and development of therapeutics and vaccines? Note: current features of genome evolution may not be a good indicator of genome evolution under the selective pressure of therapeutics, naturally-induced immunity, or vaccine-induced immunity.

JUSTIFICATION: Not expecting significant changes in phenotype, but it's important to do this research now to be sure. Correlation with clinical outcomes critical; it will be critical to make sure that detection/diagnosis and counter-measure efforts are informed about viral evolution.

TIMELINE: Short to medium-term. We need time to observe viral evolution and measure concurrent host phenotypes.

PRODUCT TYPE(S): An early discussion could help with development and deployment of infrastructure for properly capturing, assessing and sharing viral genome and associated host data, then letter report for disseminating results.

PRIMARY AUDIENCE: Policymakers, researchers, lay public

Topic A-3: Transmission and Spread Priority

An analysis to consider the key drivers/determinants and mechanisms of transmission and spread:

- What are the key drivers/determinants of viral spread and cycles of infection and illness?
- Are cycles of infection likely to result from environmental (e.g., temperature, humidity) or social (e.g., school openings/closings) factors?
- What are the mechanisms of transmission and spread?
    - Role of airborne particles of various sizes, fomites, respiratory versus fecal-oral
    - Identification and characterization of super spreaders?
    - Can risk factors for asymptomatic transmission be identified, especially long-term shedding?
    - Note: this work would impact case-based interventions, contact tracing, quarantine measures
- What is the duration of shedding of infectious virus by patients and the relationship to detection of viral RNA? Note: relevant for understanding recovery and when it is ok for people to leave isolation
- Is presence/shedding of viral RNA indicative of transmission risk (i.e., contagiousness)?

JUSTIFICATION: We still don't understand enough about transmission to be making clear policy judgements (aka should city parks stay open?, etc...); Issues are critical for understanding ongoing disease spread and design of interventions.

TIMELINE: Short to medium-term

PRODUCT TYPE(S): Early discussion to promote optimal approaches for data collection and experimental design. Letter report for findings.

PRIMARY AUDIENCE: Policymakers, funders, lay public

Topic A-4: Mechanisms of pathogenesis (host susceptibility, dynamics of the virus in the host, shedding, organ tropism, host response)

Analysis to better understand the "choreography" between the virus and host, including host molecular pathways and/or host response features during the course of infection:

- What are the mechanisms of pathogenesis and the factors contributing to variability in disease severity and outcome (consider relative contribution of viral versus host characteristics)?
- What is the natural history of the virus in humans (where, when)?
- What are the mechanisms of organ damage?
- What are the implications for development and use of therapeutics and other interventions? (Note: possible overlap with patient management group)
- What are the tools (e.g. animal models of disease, susceptibility, and early biomarkers) needed to understand the mechanisms of pathogenesis and the range of disease phenotypes?

TIMELINE: Short- medium- and long-term

PRODUCT TYPE(S): This would be a research agenda-setting exercise—where the early phase might involve discussions, then mid-term with a rapid consultation to promote the agenda, then Letter report later with early research findings of particular relevance to countermeasure development.

PRIMARY AUDIENCE: Researchers, funders, policy-makers

Topic A-5: SARS-COV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

A more substantive analysis of current and future issues of immediate critical need regarding viral emergence and host range:

- What are the host and transmission circumstances that could inform on origins and future spillovers for this pathogen?
- What are the natural hosts/animal reservoirs for this pathogen? What is the potential for domesticated livestock to serve as a reservoir and what are the implications for food security?
- What is the potential for future outbreaks from re-emergence from the human population, additional spillovers from existing hosts, and exposures from new hosts resulting from spillback events from humans into susceptible animals, especially pets and food animals?
- What is the host range for this virus (e.g., what is the current risk to and from companion animals)?

TIMELINE: Long-term

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: Policymakers, researchers, funders

Topic A-6: Development and recommendation of a research agenda

To include:

- Topic 1: Viral evolution (tracking viral genome evolution, and correlation of genotype with in vitro phenotypes and pathogenesis (hypothesis)
- Topic 3: Mechanisms of pathogenesis (hypothesis)
- Topic 5: SARS-CoV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

TIMELINE: Long-term

PRODUCT TYPE(S): Letter report/Consensus study

PRIMARY AUDIENCE: Policymakers, researchers, funders, lay public

Group B: Patient Care and Medical Countermeasures Working Group

Topic B-1: Diagnostics roadmap Priority _

Develop a comprehensive framework for diagnostic test development, deployment, and implementation, as well as analysis of diagnostic data, to ensure a robust testing system for the COVID-19 and future pandemics (both for public health surveillance/control measures and clinical management needs).

- Review the factors that led to shortcomings in current diagnostic development and availability.
- Examine the technological, procedural, and regulatory challenges, as well as the policies, strategies, and practices needed.
    - How can existing/advancing technologies be more effectively harnessed to develop appropriate diagnostics?
    - What factors create barriers and facilitators to successful public-private-academic partnerships for diagnostic development?
    - What kinds of diagnostics are required for different settings?
- Propose a roadmap for successful diagnostic development and testing systems for COVID-19 and future epidemic threats.

TIMELINE: Short-term (1 -2 months) and long-term (12 months)

PRODUCT TYPE(S): Letter report/Consensus report

PRIMARY AUDIENCE: HHS; State and local governments

Topic B-2: Research agenda to understand pathogenesis, risk factors, and protective factors Priority _

Review existing research on mechanisms of pathogenesis and risk and protective factors to inform patient care and extend understanding of how virus causes disease and the fuller elucidation of manifestations of disease.

- Enhance understanding of which patients' may be at especially high risk of serious disease and why.
- Develop more accurate predictive models for disease management and individual risk.
- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS; Medical community

Topic B-3: Assessment of preparedness efforts Priority ___

Examine the role of PHEP/HPP programs for public health and healthcare in preparing for and responding to COVID-19.

- Identify factors related to PHEP/HPP programs that create barriers to and facilitators of effective preparedness and response.
- Examine preparedness elements prior to the COVID-19 pandemic, and determine the actual value and needed improvements for the future.
- Propose recommendations to improve the nation's public health and healthcare preparedness and response programs.

TIMELINE: Long-term (12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

Topic B-4: Research agenda to understand the nature of immune response and protection

Review existing information concerning immune response to SARS-CoV-2 infection to inform key aspects of immune protection for individuals and for vaccine development. Undertake efforts to determine the duration and degree of protectiveness of immunologic responses. (Collaborate with Working Group 1.)

- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS

Topic B-5: Addressing global vaccine needs

Examine adequacy of current efforts for large-scale, coordinated and international research and development initiatives, including scientific collaboration, governance and funding of vaccine-related research projects for COVID-19 and future pandemics.

- Draw on best practices and work already supported by many governments and independent organizations like the Coalition for Epidemic Preparedness Innovations.
- Assess the current status and needed changes in international coordination of vaccine development and production.
- Consider needs/benefits of a strengthened USG engagement

TIMELINE: Medium-term (6-8 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS; Vaccine developers; WHO

Topic B-6: Leveraging real-world data to inform patient care

Identify and examine mechanisms to use real-world data, such as electronic health records, patient and clinician surveys, and semi-structured interviews, to better understand patient outcomes and to inform patient care.

- Explore ways to leverage data mining/analytics to improve patient care processes during COVID-19, including ways to standardize data collection and assemble information from electronic medical records to better inform patient care and outcomes.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS

Topic B-7: Risk analysis of healthcare and economic recovery requirements

Develop a risk analysis framework to examine the balance between healthcare recovery requirements and economic recovery requirements and consider relevant policy implications.

TIMELINE: Medium-term (6-8 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS; DOL; Others

Topic B-8: Rapid learning cycle capacities for health system adaptations and improvement

Explore concepts and methods of learning health systems to understand public health and healthcare system adaptations in response to COVID-19 (e.g., what were your system's expectations and planning assumptions, what was the reality, and how did your system adapt).

- How can we embed research/data collection into ongoing activities to enhance understanding and inform future approaches? How can we "learn as we go" more efficiently and effectively?

TIMELINE: Long-term (12 months)

PRODUCT TYPE(S): Consensus Study

PRIMARY AUDIENCE: HHS

Topic B-9: Understanding pediatric COVID-19 cases

Review existing research on pediatric COVID-19 cases to understand which children might be at highest risk for severe COVID-19 illness and to understand the role children with asymptomatic and mild disease are playing in transmission and spread of COVID-19 in the community.

- Examine policy implications (especially regarding school re-openings) related to the findings.
- Identify implications for pediatric care/hospital management needs
- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Rapid expert consultation; Letter report

PRIMARY AUDIENCE: HHS; state governments; municipal governments; medical community

Group C: Community Engagement and Population Health Working Group

Topic C-1: Data needs for decision making Priority

Determine minimum datasets jurisdictions should collect, how the data should be collected, and justification for collection, in order to develop public health strategies based on evidence.

- Obtain evidence for the effectiveness of non-pharmaceutical interventions to justify epidemiologic data collection (to include serology and other testing) and resultant public health interventions such as social distancing, business and school closures, and travel and trade restrictions.

- Determine a "minimum data set" for population surveillance, including demographic components (e.g., geographic location, age, race, gender, disability, immigration status, socio-economic status, underlying health issues) that is necessary to make public health decisions.
- Determine how to ensure high priority populations are included in surveillance to include health workers, disadvantaged (nursing home populations, homeless, prisoners, etc.), and racial and ethnic minorities.
- Determine what outcome measures for each of the above are needed (e.g., who gets tested, who gets treated, who is in isolation, health outcome).
- Review the utility of non-traditional data sources such as participatory surveillance, and innovative methods for contact tracing. Evaluate new data sources and alternative methods for analysis so that all jurisdictions in the US and internationally can best evaluate utility of data.
- Determine how to best incorporate modeling into real-time decision-making and what data are most useful for the models.

TIMELINE: Short for evaluating alternative methods, L for modeling and retrospective analyses

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, state and local PH

VOLUNTEERS/COLLABORATION: SEAN, modelers

Topic C-2: Specific data need and analysis to determine the role of children in disease transmission Priority

Summarize what is known about the contribution of school-age children to disease transmission and recommend studies that can address gaps in this knowledge.

- Can provide critical information for re-opening the economy.

TIMELINE: Short

PRODUCT TYPE(S): Rapid expert consultation

PRIMARY AUDIENCE: HHS, OSTP, local governments

VOLUNTEERS/COLLABORATION: SEAN

Topic C-3: Defining needs for successful response to COVID-19 among minority and disenfranchised populations Priority

Review the issues faced by disenfranchised and minority populations to ensure they are protected and to improve overall effectiveness of mitigation methods.

- Determine ability of disenfranchised populations to comply with social distancing, isolation and quarantine, and impact of inability to comply on overall mitigation efforts.

- Evaluation of access to testing, healthcare and available countermeasures by demographics and methods to ensure equity.
- Review the ethical implications of crisis standards of care prioritization and appropriate guidance for triage of life-sustaining resources.
- Determine methods to provide appropriate communications in both low English proficiency populations and in different cultural and ethnic groups.

TIMELINE: Medium-term for synthesis of current data. Long-term when more data becomes available

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, state and local PH

VOLUNTEERS/COLLABORATION: Minority focused and community based organizations

Topic C-4: Determine risk assessments for population activities

Provide risk assessments to determine the appropriate decisions regarding opening of schools and businesses, indoor and outdoor activities, and mitigation efforts at facilities and events.

- Determine testing needs for school and workplace openings.
- Determine parameters to guide assessment of Covid19 resurgence.
- Provide occupational safety and health standards to include distancing between workers, use of barriers (to include masks), and tracking potentially infectious states.
- Evaluate the risk of indoor and outdoor settings with regard to effects on the virus (heat/humidity/sunlight) and appropriate public health measures.
- Determine responsibility to disadvantaged communities to include nursing homes and prisons. Provide models for each to determine reasonable risk-based standards to open locations in a reasonable way.

TIMELINE: Short for framework, long for reopening evaluations

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, local and state PH

VOLUNTEERS/COLLABORATION: SEAN

Topic C-5: Adverse impacts of NPI

Measure and find ways to mitigate the unintended adverse health consequences of social distancing measures on individuals, families and societal groups.

TIMELINE: Medium-term to long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: HHS and state and local PH

VOLUNTEERS/COLLABORATION: Chamber of commerce, NGA, US conference of Mayors

Topic C-6: Future impact of COVID-19

Given known epidemiology of the virus, what can we predict will be its future impact and how can we best prepare.

- Predict changes in virus transmission given seasonality and contribution of social changes such as school openings.
- Understand disease progression and health needs in developing countries and how we can mitigate impact internationally and on US populations.

TIMELINE: Medium-term to long-term

PRODUCT TYPE(S): Consensus

PRIMARY AUDIENCE: Federal, state and local PH

Topic C-7: Develop best communication techniques for clarity

Identify and disseminate best practices for communications that can be used by public health, and the public in general, in a practical way.

- Determine best ways to have culturally-competent communications with sensitivity to the audience.
    - What are some innovative and non-traditional communication mechanisms that can support disease control activities?
- Find ways to maintain clarity of messages and have coherent community-focused communications.
- Determine how to ensure communication continues on the downslope of the epi curve – need to encourage vigilance and understanding of seasonality.
- Develop key messages that are important to relay at various points in time (crisis, recovery, etc.)

TIMELINE: Medium-term for synthesis, long-term for better data

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: Standing committee on science communication, SEAN, media

Topic C-8: Role of One Health

Determine the role of domestic pets and livestock in virus transmission and risk (to them and to people). Need good epidemiology and appropriate communication to decrease panic.

TIMELINE: Long-term

PRODUCT TYPE(S): Letter/consensus report

Topics C-9: Evaluation of products

Find methods to evaluate new and innovative products that could be useful but may overwhelm public health departments.

TIMELINE: Medium- to long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: FEMA

Topic C-10: Healthcare system preparedness

Develop metrics for healthcare system preparedness.

TIMELINE: Long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: Tech industry, Mitre, Rand

Group D: Cross-Cutting Issues Working Group

Topic D-1: COVID-19 and racial and ethnic disparities Priority

Understand how COVID-19 is disproportionally affecting communities in order to shape and target immediate response efforts.

- Examine the patterns of COVID-19 related morbidity and mortality across racial and ethnic groups.
- Understand (clearly articulate and disseminate) the underlying causes and existing systemic issues leading to these disparities.
- Propose short-term recommendations to reduce the impact of COVID-19 on the health of racial and ethnic minorities on, but not limited, to the following:
    - Structural elements of access and equitable public health information, screening, testing, treatment, and follow-up.
    - Clinical management of patients and equitable allocation of resources.

- Appropriate strategies to assure appropriate and safe levels of quarantine and/or isolation, for those in more highly concentrated communities and housing situations.
- Occupational health and safety, including disparate impacts on current workers in essential businesses and on workers as new businesses re-open.
- Data systems to monitor and track disparities among racial and ethnic groups.

TIMELINE): Short-term (1 -2 months). *(Note: This topic has priority has both immediate and longer-term implications. The items above, are consistent with increasing awareness of the impact of the virus. Over the long-term, there needs to be efforts to define the range of solutions that can be applied to address the underlying factors that contribute to the disparate impacts. We would be missing a critical opportunity, if we only focus on the data (which is empirically known), versus organizing the systems to more effectively respond to the different experiences and life-circumstances of certain populations who are likely to require modified approaches to yield positive results.)*

PRODUCT TYPE(S): Rapid expert consultation, letter report

PRIMARY AUDIENCE: HHS

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health

Topic D-2: Workplace and school re-opening Priority

Identify and disseminate best practices for re-opening businesses and schools

- Integrate demands for testing (active infection and immunity) with management of physical space and use of protective equipment. To include periodic testing standards, workplace policies, preventing and managing future surges or infectious threats.
- Identify and mitigate measures with unintended deleterious impact on sub-populations (age, disability, pregnancy, co-morbidities).
- Anticipate accommodations needed to comply with ADA.
- Examine the role of school based health centers, school health.

TIMELINE: Medium-term (3-6 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS, DOE, DOL

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health, National Alliance for School Based Health

Topic D-3: Redefining the public health system for future pandemics Priority

A comprehensive effort to redefine the nation's public health system to accommodate emerging infectious diseases, and manage and prevent other diseases and underlying conditions (health and

social) that can influence health outcomes and expand the scope of national security to include public health.

- Examine the public health system infrastructure challenges that are arising in response to COVID-19.
- Map how public-private partnerships are currently being leveraged in the public health system in the COVID-19 pandemic (e.g., private sector augmenting public health departments and aiding in contract tracing), and identify best practices.
- Map how technology is currently being leveraged in the public health system in the COVID-19 pandemic, and identify best practices.
- Clarify ambiguities or fill gaps in policy and law governing federal vs state and local authorities
- Identify obstacles to better coordination with public health authorities domestically and abroad
- Propose a framework and recommendations to redefine the nation's public health system to include creating a system that addresses inequities in policies and practices that result in adverse experiences and outcomes for racial, ethnic and marginalized populations.

TIMELINE: Long-term (6-12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health, National Association of City and County Health Officials, Association of State and Territorial Health Officers, Trust for America's Health

Topic D-4: Learning health system for pandemics

Examine concepts and methods of learning health systems related the COVID-19 pandemic and future pandemics.

- Examine how the components of a learning health system are currently being implemented in the COVID-19 pandemic and identify best practices.
- Identify components of a learning health system that could be implemented in the immediate COVID-19 response.
- Develop a framework and propose recommendations related to the key components of a learning health system to optimize care of individuals in a pandemic.

TIMELINE: Long-term (6-12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Membership

Group A – Viral Characteristics (WG Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
Mechanisms for pathogenesis
One Health

Group B – Patient Care and Medical Countermeasures (MCM) (WG Leads: Don Berwick, Margaret Hamburg)

Staff Leads: Lisa Brown and Scott Wollek

Members: Kristian Andersen
Diane Griffin
John Hick
Kent Kester
Tara O'Toole
David Relman
David Walt
Dan Hanfling

Topics: Vaccines and therapeutics
Diagnostics
Patient care (including personal protective equipment, crisis standards of care, and quality)

Group C – Community Engagement and Population Health (WG Leads: Mary Travis Bassett, Robert Groves)

Staff Leads: Julie Pavlin and Monica Feit (DBASSE)

Members: Georges Benjamin
Rich Besser
Peter Daszak
Phyllis Meadows

	Alexandra Phelan
	Mark Smolinski
	Jeff Duchin
	Baruch Fischhoff
Topics:	Epidemiology and population surveillance
	Social and public health interventions
	Public communication and understanding
	Occupational safety and health

<u>Group D – Cross-Cutting Issues</u> (WG Leads: Tara O'Toole, Alta Charo)

Staff Leads:	Andy Pope and Lisa Brown
Members:	Rich Besser
	Ellen Embry
	Patricia King
	Jonna Mazet
	Phyllis Meadows
	Alexandra Phelan
	Don Berwick
Topics:	Ethics, equity, and law
	International relations and cooperation
	Innovative solutions across the public and private sectors
	Lessons learned/future outbreaks

ASPR COVID-19 Strategic Operational Priorities

SHIELD the vulnerable who have greatest risk of morbidity & mortality

- Skilled Nursing Facilities
- Elder Care Facilities
- Dialysis Clinics
- Other: Cancer Treatment Centers

SHELTER the susceptible: Decrease community transmission

- Non-pharmaceutical interventions: school closures, mass gathering cancellations

SAVE the sick: preserve the integrity & capacity of the health care system

- Segregate the care of COVID-19patients
- Preserve the care of routine & emergency care

SUSTAIN supplies

- Increase the supply
- Extend the use
- Innovate new sources or approaches

SCIENCE

- Vaccines
- Therapeutics
- Diagnostics

Second Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Final Agenda
Thursday, April 30, 2020 11:00 a.m. – 1:00 p.m. ET

Zoom Information

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378

Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Background: In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine established the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. The Standing Committee's purpose is to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee includes members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee provides a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

Meeting Objectives

- Discuss the status and progress of the work of the standing committee with the sponsors
- Discuss the priorities of each working group: viral characteristics; patient care and medical countermeasures; community engagement and population health; and, cross-cutting issues
- Discuss and plan priorities, strategies, and next steps

THURSDAY, APRIL 30, 2020

CLOSED SESSION

SESSION I **Welcoming Remarks and Sponsors' Reflections on Status and Progress since the First Standing Committee Meeting**

11:00 a.m. **Welcoming Remarks and Introduction of New Members**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Victor Dzau
President
National Academy of Medicine

Gregory Symmes
Chief Program Officer
The National Academies of Sciences, Engineering, and Medicine

11:15 a.m. **Sponsor's Remarks and Update on COVID-19 Response**

David (Chris) Hassell
Senior Science Advisor
The Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

SESSION II **Working Group Discussions**

11:25 a.m. **Group A: Viral Characteristics Working Group**

David Relman, *Committee Member*

Jonna Mazet, *Committee Member*

11:35 a.m. **Group B: Patient Care and Medical Countermeasures Working Group**

Donald Berwick, *Committee Member*

Margaret Hamburg, *Committee Member*

11:45 a.m. **Group C: Community Engagement and Population Health Working Group**

Mary Travis Bassett, *Committee Member*

Robert Groves, *Committee Member*

11:55 a.m. **Group D: Cross-Cutting Issues Working Group**

Alta Charo, *Committee Member*

Tara O'Toole, *Committee Member*

12:05 p.m. **Discussion of the Issues and Next Steps with the Sponsors**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:30 p.m. ***ADJOURN***

CLOSED SESSION (COMMITTEE ONLY)

12:35 p.m. **Committee Debrief, Next Steps, and Potential Future Meeting Topics**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:40 p.m. **Office of News and Public Information Briefing**

Dana Korsen
Media Relations Manager
Office of News and Public Information
The National Academies of Sciences, Engineering, and Medicine

12:45 p.m. **Discussion of Bias and Conflict of Interest**

Lauren Shern
Associate Executive Director
Health and Medicine Division

1:00 p.m. ***ADJOURN MEETING***

From: Brown, Lisa[LBrown@nas.edu]

Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; jbaker@rwjf.org; Baric, Toni C; Mary Radford; Pope, Andrew; Pavlin, Julie; Feit, Monica; Shore, Carolyn; Wollek, Scott; Downey, Autumn; Motrya Calafiura; rhock@ihi.org; Fine, Emma; Shin, Rebecca; Attal-Juncqua, Aurelia; Borel, Bridget; jonna.mazet@gmail.com; Logan, Kendall

Location: https://nasem.zoom.us/j/91377677378

Importance: Normal

Subject: Second Virtual Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Start Time: Thur 4/30/2020 11:00:00 AM (UTC-04:00)

End Time: Thur 4/30/2020 1:30:00 PM (UTC-04:00)

Required Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; jbaker@rwjf.org; Baric, Toni C; Mary Radford; Pope, Andrew; Pavlin, Julie; Feit, Monica; Shore, Carolyn; Wollek, Scott; Downey, Autumn; Motrya Calafiura; rhock@ihi.org; Fine, Emma; Shin, Rebecca; Attal-Juncqua, Aurelia; Borel, Bridget

Optional Attendees: jonna.mazet@gmail.com; Logan, Kendall

FINAL Agenda_Virtual Meeting 2_ SC on EID and 21st Century Threats.pdf

SCEID Working Group Priority Issues_v1_42920.docx

ASPR COVID Strategic Operational Priorities.docx

SCEID Working Group Membership.docx

Committee Membership Roster - SC on EID and 21st Century Threats.pdf

Committee Internal Roster - SC on EID and 21st Century Threats.pdf

Committee Member Biosketches - SC on EID and 21st Century Threats.pdf

Updated with Zoom information, the agenda, and meeting materials

Zoom Call-In Information
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378
Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Greetings,

Please hold Thursday, April 30th from 11:00 a.m. – 1:30 p.m. ET for the second virtual meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. This is the time frame that worked best for the majority of the committee. Remote participation information, an agenda, and additional materials will be shared in the coming days.

Please let me know if you have any questions.

Best,
Lisa

Lisa Brown, MPH
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Board on Health Sciences Policy
Health and Medicine Division
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Second Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Final Agenda
Thursday, April 30, 2020 11:00 a.m. – 1:00 p.m. ET

Zoom Information

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378

Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Background: In response to a request from the Office of Science and Technology Policy (OSTP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR), the National Academies of Sciences, Engineering, and Medicine established the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. The Standing Committee's purpose is to help inform the federal government on critical science and policy issues related to emerging infectious diseases and other 21st century health threats. The standing committee includes members with expertise in emerging infectious diseases, public health, public health preparedness and response, biological sciences, clinical care and crisis standards of care, risk communication, epidemiology, and regulatory issues, as well as veterinary science, One Health, ethics, and community engagement. The standing committee provides a venue for the exchange of ideas among federal government agencies, the private sector, and the academic community, as well as other relevant stakeholders.

Meeting Objectives

- Discuss the status and progress of the work of the standing committee with the sponsors
- Discuss the priorities of each working group: viral characteristics; patient care and medical countermeasures; community engagement and population health; and, cross-cutting issues
- Discuss and plan priorities, strategies, and next steps

THURSDAY, APRIL 30, 2020

CLOSED SESSION

SESSION I **Welcoming Remarks and Sponsors' Reflections on Status and Progress since the First Standing Committee Meeting**

11:00 a.m. **Welcoming Remarks and Introduction of New Members**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

Victor Dzau
President
National Academy of Medicine

Gregory Symmes
Chief Program Officer
The National Academies of Sciences, Engineering, and Medicine

11:15 a.m. **Sponsor's Remarks and Update on COVID-19 Response**

David (Chris) Hassell
Senior Science Advisor
The Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

SESSION II **Working Group Discussions**

11:25 a.m. **Group A: Viral Characteristics Working Group**

David Relman, *Committee Member*

Jonna Mazet, *Committee Member*

11:35 a.m. **Group B: Patient Care and Medical Countermeasures Working Group**

Donald Berwick, *Committee Member*

Margaret Hamburg, *Committee Member*

11:45 a.m. **Group C: Community Engagement and Population Health Working Group**

Mary Travis Bassett, *Committee Member*

Robert Groves, *Committee Member*

11:55 a.m. **Group D: Cross-Cutting Issues Working Group**

Alta Charo, *Committee Member*

Tara O'Toole, *Committee Member*

12:05 p.m. **Discussion of the Issues and Next Steps with the Sponsors**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:30 p.m. ***ADJOURN***

CLOSED SESSION (COMMITTEE ONLY)

12:35 p.m. **Committee Debrief, Next Steps, and Potential Future Meeting Topics**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

12:40 p.m. **Office of News and Public Information Briefing**

Dana Korsen
Media Relations Manager
Office of News and Public Information
The National Academies of Sciences, Engineering, and Medicine

12:45 p.m. **Discussion of Bias and Conflict of Interest**

Lauren Shern
Associate Executive Director
Health and Medicine Division

1:00 p.m. ***ADJOURN MEETING***

April 29, 2020

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Priority Topics

The standing committee has established four working groups to ensure adequate attention to a broad range of relevant issues and topics, and to propose priorities for consideration and responding to the needs of the sponsors.

The working groups focus on the following domains:

- Viral characteristics
- Patient care and medical countermeasures
- Community engagement and population health
- Cross-cutting issues

This document is a preliminary list of topics discussed by each working group. Of these topics, each working group has identified their top three priority topics (indicated by **priority**).

Summary Table: Top Three Priority Topics of Each Working Group

Working Group Topics	Informal Feedback (Telephonic Consultation)	Written Rapid Expert Consultation	Letter Report	Consensus Report
WG A: Viral Characterization				
Topic A-1: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement)	X	X	X	
Topic A-2: Viral evolution (tracking viral genome evolution, and correlation of genotype with in vitro phenotypes and in vivo host phenotypes)	X		X	
Topic A-3: Transmission and Spread	X			
WG B: Patient Care and MCM				
Topic B-1: Diagnostics roadmap			X	X
Topic B-2: Research agenda to understand pathogenesis, risk factors, and protective factors			X	
Topic B-3: Assessment of preparedness efforts				X
WG C: Community Engagement and Population Health				
Topic C-1: Data needs for decision making		X	X	X
Topic C-2: Specific data need and analysis to determine the role of children in disease transmission		X		
Topic C-3: Defining needs for successful response to COVID-19 among minority and disenfranchised populations		X	X	X
WG D: Cross-Cutting Issues				
Topic D-1: COVID-19 and racial and ethnic disparities		X	X	
Topic D-2: Workplace and school re-opening			X	
Topic D-3: Redefining the public health system for future pandemics				X

Group A: Viral Characterization Working Group

Topic A-1: Immunity (basis for protection, durability of response, role of prior history of exposures, possibility of disease enhancement) Priority

Analyses to better understand the role of antibodies and cellular immune responses in protection, and the development/durability of protective immunity:

- Characterization of the immune response and implications for disease severity and for short- and long-term protection from re-infection?
- How does viral clearance occur and what are the likelihoods of, and the risk factors for intermittent and long-term virus shedding?
- How long do neutralizing and non-neutralizing antibodies last?
- Does the presence of antibodies convey protective immunity, and if so, what kinds of antibodies, in what quantities, and for how long?
- What is the likelihood of herd immunity in the US and how will it vary by regional and local demographic factors?
- What is the role of pre-existing antibody (to other coronavirus strains, and potentially to other infectious agents) in the development of a protective immune response to SARS-CoV-2? Does antibody-mediated disease enhancement occur in humans infected by SARS-CoV-2?

JUSTIFICATION: Critical for vaccine, but also for national strategy going forward. If durable immunity doesn't exist, suppression is much more desirable than otherwise.

TIMELINE: Short- to medium-term

PRODUCT TYPE(S): Informal discussions, rapid expert consultation, letter report

PRIMARY AUDIENCE: Policymakers, researchers, funders & lay public

Topic A-2: Viral evolution (tracking viral genome evolution, and correlation of genotype with *in vitro* phenotypes and *in vivo* host phenotypes) Priority

Analyses to track/correlate viral genome sequence features with viral phenotypes *in vitro* and *in vivo* in host/s) as they relate to receptor recognition, growth, host responses and pathogenic mechanisms, and/or selective pressures in the host or environment. Examples of questions to be addressed:

- What are rates and mechanisms of genome evolution as a function of geography, time since introduction into human population, and host features such as immune status?
- How does viral genotype correlate with clinical outcomes?
- Are variant viral sequence features correlated with viral escape from host immune recognition or vaccine-induced immunity, therapeutic beneficial effects, or detection by currently deployed methods?
- How should features of viral genome evolution be used to help optimize the design and development of therapeutics and vaccines? Note: current features of genome evolution may not be a good indicator of genome evolution under the selective pressure of therapeutics, naturally-induced immunity, or vaccine-induced immunity.

JUSTIFICATION: Not expecting significant changes in phenotype, but it's important to do this research now to be sure. Correlation with clinical outcomes critical; it will be critical to make sure that detection/diagnosis and counter-measure efforts are informed about viral evolution.

TIMELINE: Short to medium-term. We need time to observe viral evolution and measure concurrent host phenotypes.

PRODUCT TYPE(S): An early discussion could help with development and deployment of infrastructure for properly capturing, assessing and sharing viral genome and associated host data, then letter report for disseminating results.

PRIMARY AUDIENCE: Policymakers, researchers, lay public

Topic A-3: Transmission and Spread Priority

An analysis to consider the key drivers/determinants and mechanisms of transmission and spread:

- What are the key drivers/determinants of viral spread and cycles of infection and illness?
- Are cycles of infection likely to result from environmental (e.g., temperature, humidity) or social (e.g., school openings/closings) factors?
- What are the mechanisms of transmission and spread?
    - Role of airborne particles of various sizes, fomites, respiratory versus fecal-oral
    - Identification and characterization of super spreaders?
    - Can risk factors for asymptomatic transmission be identified, especially long-term shedding?
    - Note: this work would impact case-based interventions, contact tracing, quarantine measures
- What is the duration of shedding of infectious virus by patients and the relationship to detection of viral RNA? Note: relevant for understanding recovery and when it is ok for people to leave isolation
- Is presence/shedding of viral RNA indicative of transmission risk (i.e., contagiousness)?

JUSTIFICATION: We still don't understand enough about transmission to be making clear policy judgements (aka should city parks stay open?, etc...); Issues are critical for understanding ongoing disease spread and design of interventions.

TIMELINE: Short to medium-term

PRODUCT TYPE(S): Early discussion to promote optimal approaches for data collection and experimental design. Letter report for findings.

PRIMARY AUDIENCE: Policymakers, funders, lay public

Topic A-4: Mechanisms of pathogenesis (host susceptibility, dynamics of the virus in the host, shedding, organ tropism, host response)

Analysis to better understand the "choreography" between the virus and host, including host molecular pathways and/or host response features during the course of infection:

- What are the mechanisms of pathogenesis and the factors contributing to variability in disease severity and outcome (consider relative contribution of viral versus host characteristics)?
- What is the natural history of the virus in humans (where, when)?
- What are the mechanisms of organ damage?
- What are the implications for development and use of therapeutics and other interventions? (Note: possible overlap with patient management group)
- What are the tools (e.g. animal models of disease, susceptibility, and early biomarkers) needed to understand the mechanisms of pathogenesis and the range of disease phenotypes?

TIMELINE: Short- medium- and long-term

PRODUCT TYPE(S): This would be a research agenda-setting exercise—where the early phase might involve discussions, then mid-term with a rapid consultation to promote the agenda, then Letter report later with early research findings of particular relevance to countermeasure development.

PRIMARY AUDIENCE: Researchers, funders, policy-makers

Topic A-5: SARS-COV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

A more substantive analysis of current and future issues of immediate critical need regarding viral emergence and host range:

- What are the host and transmission circumstances that could inform on origins and future spillovers for this pathogen?
- What are the natural hosts/animal reservoirs for this pathogen? What is the potential for domesticated livestock to serve as a reservoir and what are the implications for food security?
- What is the potential for future outbreaks from re-emergence from the human population, additional spillovers from existing hosts, and exposures from new hosts resulting from spillback events from humans into susceptible animals, especially pets and food animals?
- What is the host range for this virus (e.g., what is the current risk to and from companion animals)?

TIMELINE: Long-term

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: Policymakers, researchers, funders

Topic A-6: Development and recommendation of a research agenda

To include:

- Topic 1: Viral evolution (tracking viral genome evolution, and correlation of genotype with in vitro phenotypes and pathogenesis (hypothesis)
- Topic 3: Mechanisms of pathogenesis (hypothesis)
- Topic 5: SARS-CoV-2 emergence and host range (origins of virus/natural reservoirs, basis for host range, One Health approach to identifying risks of recurring spillover and spillback)

TIMELINE: Long-term

PRODUCT TYPE(S): Letter report/Consensus study

PRIMARY AUDIENCE: Policymakers, researchers, funders, lay public

Group B: Patient Care and Medical Countermeasures Working Group

Topic B-1: Diagnostics roadmap Priority _

Develop a comprehensive framework for diagnostic test development, deployment, and implementation, as well as analysis of diagnostic data, to ensure a robust testing system for the COVID-19 and future pandemics (both for public health surveillance/control measures and clinical management needs).

- Review the factors that led to shortcomings in current diagnostic development and availability.
- Examine the technological, procedural, and regulatory challenges, as well as the policies, strategies, and practices needed.
    - How can existing/advancing technologies be more effectively harnessed to develop appropriate diagnostics?
    - What factors create barriers and facilitators to successful public-private-academic partnerships for diagnostic development?
    - What kinds of diagnostics are required for different settings?
- Propose a roadmap for successful diagnostic development and testing systems for COVID-19 and future epidemic threats.

TIMELINE: Short-term (1 -2 months) and long-term (12 months)

PRODUCT TYPE(S): Letter report/Consensus report

PRIMARY AUDIENCE: HHS; State and local governments

Topic B-2: Research agenda to understand pathogenesis, risk factors, and protective factors Priority _

Review existing research on mechanisms of pathogenesis and risk and protective factors to inform patient care and extend understanding of how virus causes disease and the fuller elucidation of manifestations of disease.

- Enhance understanding of which patients' may be at especially high risk of serious disease and why.
- Develop more accurate predictive models for disease management and individual risk.
- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS; Medical community

Topic B-3: Assessment of preparedness efforts Priority ___

Examine the role of PHEP/HPP programs for public health and healthcare in preparing for and responding to COVID-19.

- Identify factors related to PHEP/HPP programs that create barriers to and facilitators of effective preparedness and response.
- Examine preparedness elements prior to the COVID-19 pandemic, and determine the actual value and needed improvements for the future.
- Propose recommendations to improve the nation's public health and healthcare preparedness and response programs.

TIMELINE: Long-term (12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

Topic B-4: Research agenda to understand the nature of immune response and protection

Review existing information concerning immune response to SARS-CoV-2 infection to inform key aspects of immune protection for individuals and for vaccine development. Undertake efforts to determine the duration and degree of protectiveness of immunologic responses. (Collaborate with Working Group 1.)

- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS

Topic B-5: Addressing global vaccine needs

Examine adequacy of current efforts for large-scale, coordinated and international research and development initiatives, including scientific collaboration, governance and funding of vaccine-related research projects for COVID-19 and future pandemics.

- Draw on best practices and work already supported by many governments and independent organizations like the Coalition for Epidemic Preparedness Innovations.
- Assess the current status and needed changes in international coordination of vaccine development and production.
- Consider needs/benefits of a strengthened USG engagement

TIMELINE: Medium-term (6-8 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS; Vaccine developers; WHO

Topic B-6: Leveraging real-world data to inform patient care

Identify and examine mechanisms to use real-world data, such as electronic health records, patient and clinician surveys, and semi-structured interviews, to better understand patient outcomes and to inform patient care.

- Explore ways to leverage data mining/analytics to improve patient care processes during COVID-19, including ways to standardize data collection and assemble information from electronic medical records to better inform patient care and outcomes.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS

Topic B-7: Risk analysis of healthcare and economic recovery requirements

Develop a risk analysis framework to examine the balance between healthcare recovery requirements and economic recovery requirements and consider relevant policy implications.

TIMELINE: Medium-term (6-8 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS; DOL; Others

Topic B-8: Rapid learning cycle capacities for health system adaptations and improvement

Explore concepts and methods of learning health systems to understand public health and healthcare system adaptations in response to COVID-19 (e.g., what were your system's expectations and planning assumptions, what was the reality, and how did your system adapt).

- How can we embed research/data collection into ongoing activities to enhance understanding and inform future approaches? How can we "learn as we go" more efficiently and effectively?

TIMELINE: Long-term (12 months)

PRODUCT TYPE(S): Consensus Study

PRIMARY AUDIENCE: HHS

Topic B-9: Understanding pediatric COVID-19 cases

Review existing research on pediatric COVID-19 cases to understand which children might be at highest risk for severe COVID-19 illness and to understand the role children with asymptomatic and mild disease are playing in transmission and spread of COVID-19 in the community.

- Examine policy implications (especially regarding school re-openings) related to the findings.
- Identify implications for pediatric care/hospital management needs
- Recommend a future research agenda.

TIMELINE: Short-term (1-2 months)

PRODUCT TYPE(S): Rapid expert consultation; Letter report

PRIMARY AUDIENCE: HHS; state governments; municipal governments; medical community

Group C: Community Engagement and Population Health Working Group

Topic C-1: Data needs for decision making Priority

Determine minimum datasets jurisdictions should collect, how the data should be collected, and justification for collection, in order to develop public health strategies based on evidence.

- Obtain evidence for the effectiveness of non-pharmaceutical interventions to justify epidemiologic data collection (to include serology and other testing) and resultant public health interventions such as social distancing, business and school closures, and travel and trade restrictions.

- Determine a "minimum data set" for population surveillance, including demographic components (e.g., geographic location, age, race, gender, disability, immigration status, socio-economic status, underlying health issues) that is necessary to make public health decisions.
- Determine how to ensure high priority populations are included in surveillance to include health workers, disadvantaged (nursing home populations, homeless, prisoners, etc.), and racial and ethnic minorities.
- Determine what outcome measures for each of the above are needed (e.g., who gets tested, who gets treated, who is in isolation, health outcome).
- Review the utility of non-traditional data sources such as participatory surveillance, and innovative methods for contact tracing. Evaluate new data sources and alternative methods for analysis so that all jurisdictions in the US and internationally can best evaluate utility of data.
- Determine how to best incorporate modeling into real-time decision-making and what data are most useful for the models.

TIMELINE: Short for evaluating alternative methods, L for modeling and retrospective analyses

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, state and local PH

VOLUNTEERS/COLLABORATION: SEAN, modelers

Topic C-2: Specific data need and analysis to determine the role of children in disease transmission Priority

Summarize what is known about the contribution of school-age children to disease transmission and recommend studies that can address gaps in this knowledge.

- Can provide critical information for re-opening the economy.

TIMELINE: Short

PRODUCT TYPE(S): Rapid expert consultation

PRIMARY AUDIENCE: HHS, OSTP, local governments

VOLUNTEERS/COLLABORATION: SEAN

Topic C-3: Defining needs for successful response to COVID-19 among minority and disenfranchised populations Priority

Review the issues faced by disenfranchised and minority populations to ensure they are protected and to improve overall effectiveness of mitigation methods.

- Determine ability of disenfranchised populations to comply with social distancing, isolation and quarantine, and impact of inability to comply on overall mitigation efforts.

- Evaluation of access to testing, healthcare and available countermeasures by demographics and methods to ensure equity.
- Review the ethical implications of crisis standards of care prioritization and appropriate guidance for triage of life-sustaining resources.
- Determine methods to provide appropriate communications in both low English proficiency populations and in different cultural and ethnic groups.

TIMELINE: Medium-term for synthesis of current data. Long-term when more data becomes available

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, state and local PH

VOLUNTEERS/COLLABORATION: Minority focused and community based organizations

Topic C-4: Determine risk assessments for population activities

Provide risk assessments to determine the appropriate decisions regarding opening of schools and businesses, indoor and outdoor activities, and mitigation efforts at facilities and events.

- Determine testing needs for school and workplace openings.
- Determine parameters to guide assessment of Covid19 resurgence.
- Provide occupational safety and health standards to include distancing between workers, use of barriers (to include masks), and tracking potentially infectious states.
- Evaluate the risk of indoor and outdoor settings with regard to effects on the virus (heat/humidity/sunlight) and appropriate public health measures.
- Determine responsibility to disadvantaged communities to include nursing homes and prisons. Provide models for each to determine reasonable risk-based standards to open locations in a reasonable way.

TIMELINE: Short for framework, long for reopening evaluations

PRODUCT TYPE(S): Rapid expert consultation, letter/consensus report

PRIMARY AUDIENCE: HHS, local and state PH

VOLUNTEERS/COLLABORATION: SEAN

Topic C-5: Adverse impacts of NPI

Measure and find ways to mitigate the unintended adverse health consequences of social distancing measures on individuals, families and societal groups.

TIMELINE: Medium-term to long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: HHS and state and local PH

VOLUNTEERS/COLLABORATION: Chamber of commerce, NGA, US conference of Mayors

Topic C-6: Future impact of COVID-19

Given known epidemiology of the virus, what can we predict will be its future impact and how can we best prepare.

- Predict changes in virus transmission given seasonality and contribution of social changes such as school openings.
- Understand disease progression and health needs in developing countries and how we can mitigate impact internationally and on US populations.

TIMELINE: Medium-term to long-term

PRODUCT TYPE(S): Consensus

PRIMARY AUDIENCE: Federal, state and local PH

Topic C-7: Develop best communication techniques for clarity

Identify and disseminate best practices for communications that can be used by public health, and the public in general, in a practical way.

- Determine best ways to have culturally-competent communications with sensitivity to the audience.
    - What are some innovative and non-traditional communication mechanisms that can support disease control activities?
- Find ways to maintain clarity of messages and have coherent community-focused communications.
- Determine how to ensure communication continues on the downslope of the epi curve – need to encourage vigilance and understanding of seasonality.
- Develop key messages that are important to relay at various points in time (crisis, recovery, etc.)

TIMELINE: Medium-term for synthesis, long-term for better data

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: Standing committee on science communication, SEAN, media

Topic C-8: Role of One Health

Determine the role of domestic pets and livestock in virus transmission and risk (to them and to people). Need good epidemiology and appropriate communication to decrease panic.

TIMELINE: Long-term

PRODUCT TYPE(S): Letter/consensus report

Topics C-9: Evaluation of products

Find methods to evaluate new and innovative products that could be useful but may overwhelm public health departments.

TIMELINE: Medium- to long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: FEMA

Topic C-10: Healthcare system preparedness

Develop metrics for healthcare system preparedness.

TIMELINE: Long-term

PRODUCT TYPE(S): Letter/consensus report

PRIMARY AUDIENCE: Federal, state and local PH

VOLUNTEERS/COLLABORATION: Tech industry, Mitre, Rand

Group D: Cross-Cutting Issues Working Group

Topic D-1: COVID-19 and racial and ethnic disparities Priority

Understand how COVID-19 is disproportionally affecting communities in order to shape and target immediate response efforts.

- Examine the patterns of COVID-19 related morbidity and mortality across racial and ethnic groups.
- Understand (clearly articulate and disseminate) the underlying causes and existing systemic issues leading to these disparities.
- Propose short-term recommendations to reduce the impact of COVID-19 on the health of racial and ethnic minorities on, but not limited, to the following:
    - Structural elements of access and equitable public health information, screening, testing, treatment, and follow-up.
    - Clinical management of patients and equitable allocation of resources.

- Appropriate strategies to assure appropriate and safe levels of quarantine and/or isolation, for those in more highly concentrated communities and housing situations.
- Occupational health and safety, including disparate impacts on current workers in essential businesses and on workers as new businesses re-open.
- Data systems to monitor and track disparities among racial and ethnic groups.

TIMELINE): Short-term (1 -2 months). *(Note: This topic has priority has both immediate and longer-term implications. The items above, are consistent with increasing awareness of the impact of the virus. Over the long-term, there needs to be efforts to define the range of solutions that can be applied to address the underlying factors that contribute to the disparate impacts. We would be missing a critical opportunity, if we only focus on the data (which is empirically known), versus organizing the systems to more effectively respond to the different experiences and life-circumstances of certain populations who are likely to require modified approaches to yield positive results.)*

PRODUCT TYPE(S): Rapid expert consultation, letter report

PRIMARY AUDIENCE: HHS

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health

Topic D-2: Workplace and school re-opening Priority

Identify and disseminate best practices for re-opening businesses and schools

- Integrate demands for testing (active infection and immunity) with management of physical space and use of protective equipment. To include periodic testing standards, workplace policies, preventing and managing future surges or infectious threats.
- Identify and mitigate measures with unintended deleterious impact on sub-populations (age, disability, pregnancy, co-morbidities).
- Anticipate accommodations needed to comply with ADA.
- Examine the role of school based health centers, school health.

TIMELINE: Medium-term (3-6 months)

PRODUCT TYPE(S): Letter report

PRIMARY AUDIENCE: HHS, DOE, DOL

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health, National Alliance for School Based Health

Topic D-3: Redefining the public health system for future pandemics Priority

A comprehensive effort to redefine the nation's public health system to accommodate emerging infectious diseases, and manage and prevent other diseases and underlying conditions (health and

social) that can influence health outcomes and expand the scope of national security to include public health.

- Examine the public health system infrastructure challenges that are arising in response to COVID-19.
- Map how public-private partnerships are currently being leveraged in the public health system in the COVID-19 pandemic (e.g., private sector augmenting public health departments and aiding in contract tracing), and identify best practices.
- Map how technology is currently being leveraged in the public health system in the COVID-19 pandemic, and identify best practices.
- Clarify ambiguities or fill gaps in policy and law governing federal vs state and local authorities
- Identify obstacles to better coordination with public health authorities domestically and abroad
- Propose a framework and recommendations to redefine the nation's public health system to include creating a system that addresses inequities in policies and practices that result in adverse experiences and outcomes for racial, ethnic and marginalized populations.

TIMELINE: Long-term (6-12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

VOLUNTEERS/COLLABORATION: Collaboration with the Board on Population Health, National Association of City and County Health Officials, Association of State and Territorial Health Officers, Trust for America's Health

Topic D-4: Learning health system for pandemics

Examine concepts and methods of learning health systems related the COVID-19 pandemic and future pandemics.

- Examine how the components of a learning health system are currently being implemented in the COVID-19 pandemic and identify best practices.
- Identify components of a learning health system that could be implemented in the immediate COVID-19 response.
- Develop a framework and propose recommendations related to the key components of a learning health system to optimize care of individuals in a pandemic.

TIMELINE: Long-term (6-12 months)

PRODUCT TYPE(S): Consensus study

PRIMARY AUDIENCE: HHS

ASPR COVID-19 Strategic Operational Priorities

SHIELD the vulnerable who have greatest risk of morbidity & mortality

- Skilled Nursing Facilities
- Elder Care Facilities
- Dialysis Clinics
- Other: Cancer Treatment Centers

SHELTER the susceptible: Decrease community transmission

- Non-pharmaceutical interventions: school closures, mass gathering cancellations

SAVE the sick: preserve the integrity & capacity of the health care system

- Segregate the care of COVID-19patients
- Preserve the care of routine & emergency care

SUSTAIN supplies

- Increase the supply
- Extend the use
- Innovate new sources or approaches

SCIENCE

- Vaccines
- Therapeutics
- Diagnostics

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Working Group Membership

Group A – Viral Characteristics (WG Leads: David Relman, Jonna Mazet)

Staff Leads: Autumn Downey and Carolyn Shore

Members: Kristian Andersen
Trevor Bedford
Peter Daszak
Diane Griffin
Ralph Baric

Topics: Viral characterization (including genomic surveillance)
Transmission, incubation, and environmental stability
Mechanisms for pathogenesis
One Health

Group B – Patient Care and Medical Countermeasures (MCM) (WG Leads: Don Berwick, Margaret Hamburg)

Staff Leads: Lisa Brown and Scott Wollek

Members: Kristian Andersen
Diane Griffin
John Hick
Kent Kester
Tara O'Toole
David Relman
David Walt
Dan Hanfling

Topics: Vaccines and therapeutics
Diagnostics
Patient care (including personal protective equipment, crisis standards of care, and quality)

Group C – Community Engagement and Population Health (WG Leads: Mary Travis Bassett, Robert Groves)

Staff Leads: Julie Pavlin and Monica Feit (DBASSE)

Members: Georges Benjamin
Rich Besser
Peter Daszak
Phyllis Meadows

	Alexandra Phelan
	Mark Smolinski
	Jeff Duchin
	Baruch Fischhoff
Topics:	Epidemiology and population surveillance
	Social and public health interventions
	Public communication and understanding
	Occupational safety and health

<u>Group D – Cross-Cutting Issues</u> (WG Leads: Tara O'Toole, Alta Charo)

Staff Leads:	Andy Pope and Lisa Brown
Members:	Rich Besser
	Ellen Embry
	Patricia King
	Jonna Mazet
	Phyllis Meadows
	Alexandra Phelan
	Don Berwick
Topics:	Ethics, equity, and law
	International relations and cooperation
	Innovative solutions across the public and private sectors
	Lessons learned/future outbreaks

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Health and Medicine Division

Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

COMMITTEE MEMBER BIOSKETCHES

Harvey Fineberg, M.D., Ph.D. ***(Chair)***
President
Gordon and Betty Moore Foundation

Harvey Fineberg is president of the Gordon and Betty Moore Foundation. He previously served as president of the Institute of Medicine from 2002 to 2014 and as provost of Harvard University from 1997 to 2001, following 13 years as dean of the Harvard School of Public Health. Fineberg devoted most of his academic career to the fields of health policy and medical decision-making. His past research has focused on the process of policy development and implementation, assessment of medical technology, evaluation and use of vaccines, and dissemination of medical innovations. Fineberg serves on the boards of the Carnegie Endowment for International Peace and the China Medical Board. He helped found and served as president of the Society for Medical Decision Making, previously served on and chaired the board of the William and Flora Hewlett Foundation, and chaired the committee to review the performance of the World Health Organization and the functioning of the International Health Regulations (2005) during the 2009 H1N1 influenza pandemic. Fineberg is co-author of the books *Clinical Decision Analysis*, *Innovators in Physician Education* and *The Epidemic That Never Was*, an analysis of the controversial federal immunization program against swine flu in 1976. He has co-edited several books on such diverse topics as AIDS prevention, vaccine safety, understanding risk in society and global health. He has also authored numerous articles published in professional journals. Fineberg chaired the National Academies committee that produced the 2019 report on *Reproducibility and Replicability in Science*. He earned his bachelor's and doctoral degrees at Harvard and is the recipient of several honorary degrees.

Kristian Andersen, Ph.D.
Associate Professor and Director of Infectious Disease Genomics, Scripps Research Translational Institute
The Scripps Research Institute

Kristian Andersen is an associate professor in the Department of Immunology and Microbiology at Scripps Research, with joint appointments in the Department of Integrative Structural and Computational Biology, and at the Scripps Research Translational Institute. Over the past decade, his research has focused on the complex relationship between host and pathogen. Using a combination of next-generation sequencing, field work, experimentation, and computational biology he has spearheaded large international collaborations investigating the emergence, spread and evolution of deadly pathogens, including SARS-CoV-2, Zika virus, Ebola virus, West Nile virus, and Lassa virus. His work is highly cross-disciplinary and exceptionally collaborative. Kristian earned his doctoral degree from the University of Cambridge and performed postdoctoral work in Pardis Sabeti's group at Harvard University and the Broad Institute.

Ralph Baric, Ph.D.
William R. Kenan, Jr. Distinguished Professor
The University of North Carolina at Chapel Hill

Ralph Baric is a William R. Kenan, Jr. Distinguished Professor in the Department of Epidemiology at the University of North Carolina. He obtained a Bachelor of Science Degree in Zoology from North Carolina State University in 1977 and a PhD in Microbiology and Immunology from North Carolina State University in 1983. He conducted postgraduate research at the University of Southern California School of Medicine in the department of Microbiology and Immunology between 1983-1986. He is a Harvey Weaver Scholar from the National Multiple Sclerosis Society and an Established Investigator Awardee from the American Heart Association. In addition, he is a World Technology Award Finalist, a fellow of the American Association for Microbiology, a senior editor of PloS Patho gen, and a member of the editorial board of several other specialty journals. He was a member of the National Academy Sciences Working Groups that focused on Gene Sequence Methods for Classification of Select Agents and the Risks and Benefits of Gain of Function Research, an invited speaker to the Institute of Medicine Forum on Emerging Infectious Diseases and an invited panelist for the MERS-CoV Stakeholders Workshop. His group has published over 300 papers, many in highly visible journals like PNAS, Natur e Medicine, Science, PloS Medicine and PloS Pathogens. The Baric laboratory uses genetic, immunologic, molecular and biochemical approaches to study the molecular mechanisms regulating virus replication, pathogenesis, molecular evolution and cross species transmission using emerging coronaviruses, flaviviruses (Dengue) and noroviruses as model systems. We have pioneered new strategies for developing reverse genetic approaches for manipulating the SARS-CoV, SAR-CoV-2 and MERS-CoV genomes and are actively studying the role of multiple genes that function in cross species transmission, virulence, pathogenesis, viral transcription and RNA fidelity. The Baric laboratory is also identifying key neutralizing epitopes in emerging coronaviruses, dengue and noroviruse s using human monoclonal antibodies and structure guided immunogen design to develop broadly active vaccines and immunotherapuetics against these pathogens. Finally, his group has developed novel animal models of human disease and identified dozens of host susceptibility loci that regulate emerging CoV pathogenesis.

Mary Bassett, M.D., M.P.H.
Director of the François-Xavier Bagnoud Center for Health and Human Rights
Harvard School of Public Health

Mary Bassett is the Director of the FXB Center for Health and Human Rights at Harvard University, as well as the FXB Professor of the Practice of Health and Human Rights at the Harvard School of Public Health. With more than 30 years of experience in public health, Dr. Mary Travis Bassett has dedicated her career to advancing health equity. Prior to her directorship at the FXB Center, Dr. Bassett served for four years as commissioner of Health for New York City. As commissioner, she worked to ensure that every New York City neighborhood supported the health of its residents, with the goal of closing gaps in population health across the city. Originally from New York City, Dr. Bassett lived in Zimbabwe for nearly 20 years. Previously, she was the Program Director for the African Health Initiative and the Child Well-being Program at the Doris Duke Charitable Foundation. She received her B.A. in History and Science from Harvard University and her M.D. from Columbia University's College of Physicians and Surgeons. She served her medical residency at Harlem Hospital Cen ter, and has a master's degree in Public Health from the University of Washington, where she was a Robert Wood Johnson Clinical Scholar.

Trevor Bedford, Ph.D.
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Trevor Bedford is currently Associate Member of the Vaccine and Infectious Disease Division, the Public Health Sciences Division, and the Human Biology Division at the Fred Hutchinson Cancer Research Center. Dr. Bedford uses powerful computers and complex statistical methods to study the rapid spread and evolution of viruses. Data gathered from these processes help researchers develop successful strategies for monitoring and controlling infectious diseases. His visual representations of viral family trees are used to show how the fate of dangerous outbreaks is often determined by the genetics of the infectious agent, human behavior and geography. Dr. Bedford has applied these techniques to document the worldwide spread of seasonal flu viruses. He is developing models to predict which strains of influenza are likely to be most challenging to humans — data that help inform the crucial early decisions about which strains to include in annual flu shots. He specializes in tracking the evolutionary changes of viruses such as HIV and influenza that use RNA, rather than DNA, to carry their genetic information. RNA viruses are much more prone to rapid mutation, which makes many of them particularly nimble at escaping the human immune system and difficult to stop with vaccines. He is a leading advocate for the immediate release of research analyzing viral evolution during epidemics, fresh information that could make a lifesaving difference. He received his Ph.D. in biology from Harvard University.

Georges Benjamin, M.D.
Executive Director
American Public Health Association

Georges Benjamin is well-known as a health leader, practitioner, and administrator. Dr. Benjamin has served as the executive director of the American Public Health Association, the nation's oldest and largest organization of public health professionals, since December 2002. He is a former secretary of Health for the state of Maryland. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University Of Illinois College Of Medicine. He is board-certified in internal medicine, a Master of the American College of Physicians, a fellow of the National Academy of Public Administration and a fellow emeritus of the American College of Emergency Physicians. He serves on several nonprofit boards such as Research!America, the University of Maryland Medical System and, the Reagan-Udall Foundation. He is a member of the National Academy of Medicine. In April 2016, President Obama appointed Benjamin to the National Infrastructure Advisory Council, a council that advises the president on how best to assure the security of the nation's critical infrastructure.

Donald Berwick, M.D., M.P.P., F.R.C.P., KBE
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Donald Berwick is president emeritus and senior fellow at the Institute for Healthcare Improvement and former administrator of the Centers for Medicare & Medicaid Services. A pediatrician by background, Dr. Berwick has served on the faculty of the Harvard Medical School and Harvard School of Public Health, and on the staffs of Boston's Children's Hospital Medical Center, Massachusetts General Hospital, and the Brigham and Women's Hospital. He has also served as vice chair of the US Preventive Services Task Force, the first "independent member" of the American Hospital Association Board of Trustees, and chair of the National Advisory Council of the Agency for Healthcare Research and Quality. He served two terms on the Institute of Medicine's (IOM's) Governing Council, was a member of the IOM's Global Health Board, and served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. Recognized as a leading authority on health care quality and improvement, Dr. Berwick has received numerous awards for his contributions. In 2005, he was

appointed "Honorary Knight Commander of the British Empire" by Her Majesty, Queen Elizabeth II in recognition of his work with the British National Health Service. Dr. Berwick is the author or co -author of over 160 scientific articles and six books. He currently serves as lecturer in the Department of Health Care Policy at Harvard Medical School.

Richard Besser, M.D.
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Richard Besser is president and CEO of the Robert Wood Johnson Foundation (RWJF), a position he assumed in April 2017. Dr. Besser is the former acting director for the Centers for Disease Control and Prevention (CDC), and ABC News' former chief health and medical editor. At RWJF, Dr. Bes ser leads the largest private foundation in the country devoted solely to improving the nation's health. RWJF's work is focused on building a comprehensive Culture of Health that provides everyone in America with a fair and just opportunity to live the hea lthiest life possible. In Dr. Besser's role at ABC News, he provided medical analysis and reports for all ABC News programs and platforms. His weekly health chats on social media reached millions. Before joining ABC News in 2009, Dr. Besser worked as direc tor of the Coordinating Office for Terrorism Preparedness and Emergency Response at the CDC. In that role, he was responsible for all the CDC's public health emergency preparedness and emergency response activities. He also served as acting director of the CDC from January to June 2009, during which time he led the CDC's response to the H1N1 influenza pandemic. He is a member of the National Academy of Medicine. He received the Surgeon General's Medallion for his leadership during the H1N1 response, and in 2011 he accepted the Dean's Medal for his contributions to public health from the Johns Hopkins Bloomberg School of Public Health. Dr. Besser received his Bachelor of Arts degree in economics from Williams College and medical degree from the University of Pennsylvania. He completed a residency and chief residency in pediatrics at Johns Hopkins University Hospital in Baltimore.

R. Alta Charo, J.D.
Warren P. Knowles Professor of Law and Bioethics
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R. Alta Charo is a member of the National Academy of Medicine and is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison (UW), where she is on the faculties of the law and medical schools. She teaches in the areas of bioethics, public health law and biotechnology policy and has served on UW's clinical ethics and research oversight committees. Professor Charo was a member of President Obama's transition team, focusing her attention particularly on transition issues related to NIH, FDA, stem cell policy, and women's reproductive health. From 2009 to 2011 she was on leave to serve as a senior policy advisor on emerging technology issues in the Office of the Commissioner at FDA. Her federal advisory committee service includes the 1994 NIH Human Embryo Research Panel and President Clinton's National Bioethics Advisory Commission (1996 to 2001). At the National Academies she co-chaired (with Richard Hynes) the committee on guidelines for embryonic stem cell research, and has been a member of its Board on Life Sciences, Board on Population Health and Public Health Practice, and Board on Health Sciences Policy.

Peter Daszak, Ph.D.
President and CEO
EcoHealth Alliance

Peter Daszak is President of EcoHealth Alliance, a US-based organization that conducts research and outreach programs on global health, conservation, and international development. Dr. Daszak's research has been instrumental in identifying and predicting the origins and impact of emerging diseases across the globe. He is one of the founders of the field of Conservation Medicine and has been instrumental in the

growth of EcoHealth, One Health, and now Planetary Health. Dr. Daszak is a member of the National Academy of Medicine and Chair of the NASEM's Forum on Microbial Threats. He is a me mber of the NRC Advisory Committee to the US Global Change Research Program, the Supervisory Board of the One Health Platform, the One Health Commission Council of Advisors, the CEEZAD External Advisory Board, the Cosmos Club, and the Advisory Council of the Bridge Collaborative. He has served on the IOM Committee on global surveillance for emerging zoonoses, the NRC committee on the future of veterinary research, the International Standing Advisory Board of the Australian Biosecurity CRC; and has advised the Director for Medical Preparedness Policy on the White House National Security Staff on global health issues. Dr. Daszak is a regular advisor to WHO on pathogen prioritization for R&D. He received his Ph.D. in parasitic infectious disease from the Univer sity of East London.

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Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section and Professor in Medicine
Public Health – Seattle & King County, WA and University of Washington, Seattle

Jeffrey Duchin is the Health Officer and the Chief of the Communicable Disease Epidemiology & Immunization Section for Public Health–Seattle & King County, Professor of Medicine in the Division of Infectious Diseases, and Adjunct Professor in the School of Public Health at the University of Washington, Seattle. Jeff currently serves on the Centers for Disease Control & Prevention's (CDC) Board of Scientific Counselors (Office of Infectious Diseases), the CDC's Advisory Committee on Immunization Practices and the Board of Directors for the Infectious Disease Society of America. Jeff has previously been a member of the National Academy of Medicine's (NAM) Forum on Microbial Threats and Forum on Medical and Public Health Preparedness, and the National Quality Forum's Adult Immunization Committee. Jeff received his medical degree from Rutgers Medical School and trained in internal medicine at Thomas Jefferson University Hospital, completed a fellowship in general internal medicine and emergency medicine at the Hospital of the Univ ersity of Pennsylvania, and did his infectious disease subspecialty training at the University of Washington in Seattle. Jeff is a graduate of the CDC's Epidemic Intelligence Service (EIS) Officer training where he was assigned to the National Center for Infectious Diseases where he also completed the CDC's Preventive Medicine Residency program. Jeff worked for CDC as a medical epidemiologist in the Divisions of Tuberculosis Elimination and HIV/AIDS Special Studies Branch before assuming his current positio n. His peer review publications and research interests focus on communicable diseases of public health significance. For a complete listing of publications, please see PubMED.

Ellen Embrey
Managing Partner
Stratitia, Inc.

Ellen Embrey is Managing Partner of Stratitia, Inc., a consulting firm focused on developing meaningful and innovative strategies, and delivering supporting tools and partnerships to bring them successfully to life. Ms. Embrey brings deep expertise in health and medic al issues, as well as a wealth of other experience gained during her extensive federal service. In her last federal role, she performed the duties of the Assistant Secretary of Defense for Health Affairs and the Director, TRICARE Management Activity during the presidential transition period in 2009-2010. From 2002 to 2009, Ms. Embrey was the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, leading significant changes in Department of Defense policies and programs affecting deployment and combat casualty medicine, health promotion and preventive medicine, medical readiness and public health emergency preparedness and response. For 9 months in 2001, Ms. Embrey performed the duties of Assistant Secretary of Defense for Reserve Affairs, shaping policies affecting the readiness and use of the National Guard and Reserve in both federal and state status. From 2000 to 2001, she served as Chief of Staff of that office, and from 1998 to 2001, as Deputy Assistant Secretary of Defense for Military Assistance to Civil Authorities,

developing policies that shaped the role of the National Guard and Reserve components in supporting homeland security, disaster preparedness, and national disaster response capabilities, including advising the president on such matters in the days and weeks following September 11, 2001. Between 1978 and 1997, Ms. Embrey served in senior-level policy analyst, budget analyst, program analyst, management analyst, and systems analyst positions in the Office of the Assistant Secretary of Defense for Reserve Affairs, the Defense Contract Audit Agency, and the Office of Personnel Management. Ms. Embrey was recognized with the Secretary of Defense's Distinguished Civilian Service Award in 2001 and 2004, and twice received the Meritorious Executive Presidential Rank Award in 2006 and 2009.

Baruch Fischhoff, Ph.D.
Howard Heinz University Professor, Department of Engineering and Public Policy
Carnegie Mellon University

Baruch Fischhoff is Howard Heinz University Professor, Department of Engineering and Public Policy and Institute for Politics and Strategy, Carnegie Mellon University (CMU). A graduate of the Detroit Public Schools, he holds a BS (mathematics, psychology) from Wayne State University and a PhD (psychology) from the Hebrew University of Jerusalem. He is a member of the National Academy of Sciences and of the National Academy of Medicine. He is past President of the Society for Judgment and Decision Making and of the Society for Risk Analysis. He has chaired the Food and Drug Administration Risk Communication Advisory Committee and been a member of the Eugene (Oregon) Commission on the Rights of Women, the Department of Homeland Security Science and Technology Advisory Committee and the Environmental Protection Agency Scientific Advisory Board, where he chaired the Homeland Security Advisory Committee. He has received the American Psychological Association (APA) Award for Distinguished Contribution to Psychology, CMU's Ryan Award for Teaching, an honorary Doctorate of Humanities from Lund University, and an Andrew Carnegie Fellowship. He is a Fellow of APA, the Association for Psychological Science, Society of Experimental Psychologists, and Society for Risk Analysis. His books include Acceptable Risk, Risk: A Very Short Introduction, Judgment and Decision Making, A Two-State Solution in the Middle East, Counting Civilian Casualties, and Communicating Risks and Benefits. He has co-chaired three National Academy Colloquia on the Science of Science Communication, as well as its committees on applying decision science to intelligence analysis and its committee on foundational science for cybersecurity.

Diane Griffin, M.D., Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health

Diane Griffin is University Distinguished Service Professor and Alfred and Jill Sommer Chair of the W. Harry Feinstone Department of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health. Dr. Griffin is a virologist recognized for her work on the pathogenesis of viral infections. She is known particularly for her studies on measles and alphavirus encephalomyelitis that have delineated the role of the immune response in virus clearance, vaccine-induced protection from infection, tissue damage and immune suppression. Dr. Griffin was born in Iowa City, Iowa, and grew up in Oklahoma City. She graduated from Augustana College, Rock Island, Illinois with a degree in biology and from Stanford University School of Medicine in 1968 with a Ph.D. in immunology and M.D., followed by a residency in internal medicine. She was a postdoctoral fellow in virology and infectious diseases at Johns Hopkins University School of Medicine and joined the faculty in 1974. She has been president of the American Society for Virology and of the American Society for Microbiology and is a member of both the National Academy of Sciences and the National Academy of Medicine.

Robert Groves
Executive Vice President and Provost
Gerard J. Campbell, S.J. Professor, Math and Statistics Department & Sociology Department
Georgetown University

Robert Groves is the Gerard J. Campbell, S.J. Professor in the Math and Statistics Department as well as the Sociology Department at Georgetown University where he has served as the Executive Vice President and Provost since 2012. Groves is a Social Statistician, who studies the Impact of Social Cognitive and Behavioral Influences on the quality of Statistical Information. His research has focused on the impact of mode of data collection on responses in sample surveys, the social and political influences on survey participation, the use of adaptive research designs to improve the cost and error properties of statistics, and public concerns about privacy affecting attitudes toward statistical agencies. He has authored or co-authored seven books and scores of peer-reviewed articles. His 1989 book, Survey Errors and Survey Costs, was named one of the 50 most influential books in survey research by the American Association of Public Opinion Research. His book, Nonresponse in Household Interview Surveys, with Mick Couper, received the 2008 AAPOR Book Award. His co-authored book, Survey Nonresponse, received the 2011 AAPOR Book Award. He served as the Director of the US Census Bureau between 2009-2012. Groves serves on several boards and advisory committees including the National Research Council Committee on National Statistics, Pew Research Center Board, the National Science Board, and the Federal Economic Statistics Advisory Committee. He is an elected member of the US National Academy of Sciences, of the National Academy of Medicine, of the American Academy of Arts and Sciences, and of the International Statistical Institute.

Margaret Hamburg, M.D.
Foreign Secretary
National Academy of Medicine

Margaret Hamburg is an internationally recognized leader in public health and medicine, and currently serves as foreign secretary of the National Academy of Medicine and chair of the NTI | bio Advisory Group. She is a former Commissioner of the U.S. Food and Drug Administration (FDA), having served for almost six years. As FDA Commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining FDA, Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative. Previous government positions include Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. She is President-elect of the American Association for the Advancement of Science (AAAS), as well as an elected member of the Council on Foreign Relations and the National Academy of Medicine. Hamburg currently sits on the boards of the Commonwealth Fund, the Simons Foundation, the Urban Institute, the Global Alliance for Vaccines and Immunization, the Parker Institute for Cancer Immunotherapy and the American Museum of Natural History. She is chair of the Joint Coordinating Group for the Coalition for Epidemic Preparedness and Innovation, and a member of the Harvard University Global Advisory Council, the Global Health Scientific Advisory Committee for the Gates Foundation, the Harvard Medical School Board of Fellows, and the World Dementia Council. Dr. Hamburg earned her B.A. from Harvard College, her M.D. from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center. She is the recipient of multiple honorary degrees and numerous awards.

Dan Hanfling, M.D.
Vice President, Technical Staff
In-Q-Tel

Dan Hanfling is Vice President on the Technical Staff at In-Q-Tel, a non-governmental not-for-profit strategic investor focused on enabling technologies to support national security requirements. He is a board-certified emergency physician practicing at Inova Fairfax Hospital, northern Virginia's Level I trauma center, where he led emergency preparedness response efforts in the aftermath of the 9-11 attacks and the anthrax mailings. He participates as a Medical Team Manager for Virginia Task Force One, a FEMA- and USAID-sanctioned international urban search and rescue team and has deployed to numerous catastrophic disaster events, both domestic and international. Dr. Hanfling currently serves as the co-chair of the National Academies Forum on Medical and Public Health Preparedness and co-chaired the Institute of Medicine committees responsible for developing the work on "crisis standards of care". Dr. Hanfling is Clinical Professor of Emergency Medicine at George Washington University. He received an AB in political science from Duke University and was awarded his medical degree from Brown University. He completed an internship in internal medicine at the Miriam Hospital in Providence, Rhode Island, and an emergency medicine residency at George Washington/Georgetown University Hospitals.

John Hick, M.D.
Associate Medical Director for EMS
Medical Director of Emergency Medicine
Hennepin County Medical Center

John Hick is a faculty emergency physician at Hennepin Healthcare and a Professor of Emergency Medicine at the University of Minnesota. Dr. Hick serves as the deputy medical director for Hennepin County Emergency Medical Services and Medical Director for Emergency Preparedness at HCMC. He is also the Vice-Chair of the Clinical Council for Life Link III helicopter service and me dical director for MN TF-1 state US&R team. He served the Minnesota Department of Health as the medical director for the Office of Emergency Preparedness until becoming an Advisor to the Director of OEM at ASPR/HHS where he is the lead editor for the TRACIE healthcare disaster preparedness website. He is the founder and past chair of the Minneapolis/St. Paul Metropolitan Hospital Compact, a 32-hospital mutual aid and planning group active since 2002. He is a national speaker on hospital preparedness issues and has published numerous papers dealing with hospital preparedness for contaminated casualties, personal protective equipment, crisis standards of care, and surge capacity and was honored to serve the Institute of Medicine on their Crisis Standards of Care projects as well as the Forum on Medical and Public Health Preparedness for Disasters and Emergencies. Dr. Hick holds an M.D. from the Mayo Medical School.

Kent E. Kester, M.D.
Vice President and Head, Translational Science and Biomarkers
Sanofi Pasteur

Kent Kester is currently Vice President and Head, Translational Science and Biomarkers at Sanofi Pasteur. In this capacity, Dr. Kester leads a team of over 200 research and clinical professionals in the US and France focused on the translational development of new vaccines. During a 24-year career in the US Army, he worked extensively in clinical vaccine development and led multiple research platforms at the Walter Reed Army Institute of Research, the U.S. Department of Defense's largest and most diverse biomedical research laboratory with a major emphasis on emerging infectious diseases, an institution he later led as its Commander/Director. His final military assignment was as the Associate Dean for Clinical Research in the School of Medicine at the Uniformed Services University of the Health Sciences (USUHS). During his military service, Dr. Kester was appointed as the lead policy advisor to the US Army Surgeon General in both Infectious Diseases and in Medical Research & Development. In these

capacities, he worked extensively in the interagency environment and developed a variety of Army and DoD medical policies related to infectious diseases, both clinical and research aspects. Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College, completing his internship and residency in internal medicine at the University of Maryland and a research fellowship in infectious diseases at the Walter Reed Army Medical Center. Currently a member of the US Government Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) and the Department of Veterans Affairs Health Services Research & Development Service Merit Review Board, he previously chaired the Steering Committee of the NIAID/USUHS Infectious Disease Clinical Research Program, and has served as a member of the FDA Vaccines & Related Biologics Products Advisory Committee (VRBPAC), the NIAID Advisory Council, and the CDC Office of Infectious Diseases Board of Scientific Counselors. He is the Vice Chair of the National Academy of Medicine Forum on Microbial Threats. Board-certified in both internal medicine and infectious diseases, Dr. Kester holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Royal College of Physicians of Edinburgh, the Infectious Disease Society of America, and the American Society of Tropical Medicine and Hygiene. He is a member of the clinical faculty at the University of Maryland Shock Trauma Center in Baltimore.

Patricia King, J.D.
Professor Emerita
Georgetown University Law Center

Patricia King is Professor of Law emeritus at Georgetown University Law Center and an Adjunct Professor in the Department of Health Policy and Management, School of Hygiene and Public Health at Johns Hopkins University. She is the co-author of Cases and Materials on Law, Science and Medicine. She is a member of the National Academy of Medicine, a member of the American Law Institute, a fellow of the Hastings Center and a faculty affiliate of Georgetown's Kennedy Institute of Ethics. Her scholarship focuses on race and genomics, racial disparities in health and reproductive health. Professor King has served on numerous national advisory bodies formed to address the ethical issues generated by developments in science and technology, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), which produced the seminal "Belmont Report," the President's Advisory Committee on Human Radiation Experiments (1994-95), the National Institutes of Health's Embryo Research Panel (co-chair for policy, 1994), the Ethics, Legal and Social Issues Working Group of the NIH's Human Genome Project (1989-95), and the NIH's Recombinant DNA Advisory Committee (1979-81). She has served on numerous boards and Institute of Medicine committees and is currently a member of the Board of Health Sciences Policy of the National Academies. She is also a Director of Mathematica an employee-owned company.She is a graduate of Wheaton College (Massachusetts) and has served as a Trustee and Chair of the Wheaton College Board of Trustees. In 2018 she was designated a Life Trustee by the Wheaton College Board. She graduated from Harvard Law School and is a past member of the Harvard Corporation the governing board of Harvard University. She has received honorary degrees from Wheaton College, Old Dominion University, and Harvard University.

Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
Executive Director, One Health Institute
UC Davis School of Veterinary Medicine

Jonna Mazet, D.V.M, M.P.V.M., Ph.D., is a Professor of Epidemiology and Disease Ecology at the UC Davis School of Veterinary Medicine and Executive Director of the UC Davis One Health Institute. Her work focuses on global health problem solving for emerging infectious diseases and conservation challenges. She is active in international One Health education, service, and research programs, most notably in relation to disease transmission among wildlife, domestic animals, and people and the ecological drivers of disease emergence. Currently, Dr. Mazet is the Co-Director of the US Agency for

International Development's One Health Workforce – Next Generation, an $85 million educational strengthening project to empower professionals in Central/East Africa and Southeast Asia to address complex health threats, including antimicrobial resistance and zoonotic diseases. She recently served as the Global Director of PREDICT Project, a greater than $200 million viral emergence early warning project under USAID's Emerging Pandemic Threats Division. She was elected to the US National Academy of Medicine in 2013 in recognition of her successful and innovative approach to emerging environmental and global health threats and serves on the National Academies of Science, Engineering, and Medicine's Forum on Microbial Threats and chairs the Academies' One Health Action Collaborative.

Phyllis Meadows, Ph.D., M.S.N., R.N.
Senior Fellow, Health
The Kresge Foundation

Phyllis Meadows currently serves as the Senior Fellow and Program Advisor for the Kresge Foundation Health Team. In this role, she is responsible for supporting the health team in the development and implementation of investment opportunities within and across the Foundation's various programming areas. Her professional career includes leadership roles in philanthropy, academia, community health and governmental public health. She has previously served in the role of Associate Dean for Public Health Practice and Clinical Professor - Health, Management and Policy with the University of Michigan School of Public Health. She has led several initiatives to expand multi-disciplinary practice in communities, designing the University's first certification program on population health and health equity for medical residents. She is currently a Distinguished Towsley Policy Maker in Residence with the University of Michigan's Gerald Ford School of Public Policy. She has taught and developed graduate level and professional continuing education courses to address emerging health issues, including topics on health policy and public health leadership. Dr. Meadows has extensive experience in public health practice having served in various leadership roles in public health. She has held several official appointments in public health leadership at the state, county and local levels. In her most recent appointment, she served as the Chief Health Officer and Director of Health for the City of Detroit, providing leadership for the department of health, environmental health, infectious disea ses, child health, clinical and dental services for the residents of Detroit. Her philanthropic experience includes positions as Program Director for the W.K. Kellogg Foundation - Youth, Education and Higher Education; and advisor for several national initiatives of the Robert Wood Johnson Foundation including the Nurse Executive Leadership Program, Partners in Nursing, and the County Roadmaps project. As a registered nurse, she has worked in both community-based health and hospitals. She currently serves as a Board Member and Advisor for several state level organizations and private foundations focusing on health.

Tara O'Toole, M.D., M.P.H.
Executive Vice President
In-Q-Tel

Tara O'Toole currently serves as Executive Vice President at In-Q-Tel. Dr. O'Toole was confirmed as the Under Secretary for Science and Technology (S&T) at the U.S. Department of Homeland Security (DHS) and served from November 4, 2009 to September 23, 2013. From 2003 to November 2009, Dr. O'Toole was the CEO and Director of the Center for Biosecurity at the University of Pittsburgh Medical Center (UPMC), and Professor of Medicine and of Public Health at the University of Pittsburgh. The Center for Biosecurity of UPMC is an independent organization dedicated to improving the country's resilience to major biological threats. Dr. O'Toole is internationally known for her work on biosecurity and on health and safety issues related to the U.S. nuclear weapons complex. Her publications in the biodefense field include articles on the response to anthrax, smallpox, and plague biological attacks; containment of contagious disease epidemics; biodefense research and development strategies; and hospital preparedness. She is the founding editor of the journal Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. She was a principal author and producer of Dark Winter, an influential exercise conducted in

June 2001 to alert national leaders to the dangers of bioterrorist attacks. She was also a principal writer and producer of Atlantic Storm, an international ministerial-level biosecurity exercise held in January 2005. Prior to founding the UPMC in 2003, Dr. O'Toole was one of the original members of the J ohns Hopkins Center for Civilian Biodefense Strategies and served as its director from 2001 to 2003. She has served on numerous government and expert advisory committees dealing with biodefense, including panels of the Defense Science Board; the National Academy of Engineering Committee on Combating Terrorism; and the National Academy of Sciences Working Group on Biological Weapons. She served as chair of the Board of the Federation of American Scientists from 2006 to 2007, and in 2006 she was appointed to the board of Google Foundation's International Networked System for Total Early Disease Detection. From 1993 to 1997, Dr. O'Toole served as Assistant Secretary of Energy for Environment Safety and Health. In this position, she was the principal advisor to the Secretary of Energy on environmental protection and on the health and safety of the approximately 100,000 workers in the U.S. nuclear weapons complex and Department of Energy (DOE) laboratories. She developed the first overall management and safety plan for dealing with the highly enriched uranium, plutonium, spent fuel, and radioactive waste left in place when nuclear weapons production was stopped in the early 1990s. She ran the multi-agency, multimillion-dollar task force that oversaw the government's investigations into human radiation experiments conducted during the Cold War and led the U.S. delegation to Russia to establish the U.S./Russia cooperative effort to study radiation exposure and environmental hazards of the Russian nuclear weapons complex. Prior to her work at DOE, Dr. O'Toole was a senior analyst at the Congressional Office of Technology Assessment, where she directed several projects and studies, including the health impact of pollution resulting from nuclear weapons production. She al so served as a consultant to industry and government in matters related to occupational and environmental health; worker participation in workplace safety protection; and organizational change. Dr. O'Toole practiced general internal medicine in community health centers in Baltimore from 1984 to 1988. She is board certified in internal medicine and occupational and environmental health. She has a bachelor's degree from Vassar College, an M.D. from the George Washington University, and a Master of Public Heal th degree from Johns Hopkins University. She completed internal medicine residency training at Yale University and a fellowship in Occupational and Environmental Medicine at Johns Hopkins University.

Alexandra Phelan, S.J.D., LL.M., LL.B.
Assistant Professor
Center for Global Health Science and Security
Georgetown University

Alexandra Phelan is an Assistant Professor at the Center for Global Health Science and Security in the Department of Microbiology and Immunology at Georgetown University School of Medicine. Dr. Phelan also holds an appointment as Adjunct Professor of Law at Georgetown University Law Center. Dr. Phelan works on legal and policy issues related to infectious diseases, with a particular focus on emerging and reemerging infectious disease outbreaks and international law. She has worked as a consultant for the World Health Organization, the World Bank, and Gavi: the vaccine alliance, and has advised on matters including international law and pathogen sharing, human rights law and Zika, int ellectual property law, and contract law. She previously worked for a number of years as a solicitor at a firm in Melbourne, Australia and was admitted to practice to the Supreme Court of Victoria and High Court of Australia in 2010. Dr. Phelan's doctorate examined how overlap between fields of international law – in particular, global health law, international human rights law, and international environmental law – can serve as the catalyst to progressively develop international law to prevent and respond to infectious diseases. She also holds a Master of Laws, specializing in international law, from the Australian National University and a Bachelor of Biomedical Science/Bachelor of Laws (Honours) double degree from Monash University. She also holds a Diploma of Languages (Mandarin Chinese). Dr. Phelan is a General Sir John Monash Scholar and was recognized as an Associate Fellow of the Royal Commonwealth Society in 2015 for her human rights advocacy during the 2013-16 Ebola outbreak.

David Relman, M.D.
Thomas C. and Joan M. Merigan Professor in Medicine, and Chief of Infectious Diseases
Stanford University; VA Palo Alto Health Care System

David Relman is the Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology and Immunology at Stanford University, and Chief of Infectious Diseases at the Veterans Affairs Palo Alto Health Care System. Dr. Relman is also Senior Fellow at the Freeman Spogli Institute for International Studies (FSI), and served as Science Co-Director at the Center for International Security and Cooperation (2013-2017), at Stanford. He is currently director of a new Biosecurity Initiative at FSI. Relman trained at MIT and then Harvard Medical School, followed by clinical training in internal medicine and infectious diseases at the Massachusetts General Hospital in Boston, and then a postdoctoral fellowship in microbiology at Stanford. His early research focused on molecular methods for pathogen discovery and over the past 20 years, on the human microbiome. He was elected to the National Academy of Medicine in 2011. Dr. Relman served as vice-chair of the National Research Council Committee that reviewed the science performed for the FBI 2001 Anthrax Letters investigation, chair of the Forum on Microbial Threats (2007-2017), and is currently a member of the Intelligence Community Studies Board (2016-) as well as Chair of a Standing Committee tasked with examining the health-related problems of US embassy personnel stationed overseas, all at the U.S. National Academies of Science. He was a founding member of the National Science Advisory Board on Biosecurity (2005-2014), a member of the Working Group on Biodefense for the President's Council of Advisors on Science and Technology (The White House) (2016), and served as President of the Infectious Diseases Society of America (2012-2013). He holds an M.D. from Harvard Medical School.

Mark Smolinski, M.D., M.P.H.
President
Ending Pandemics

Mark Smolinski currently serves as President of Ending Pandemics. Dr. Smolinksi brings 25 years of experience in applying innovative solutions to improve disease prevention, response, and control across the globe. Mark is leading a well-knit team—bringing together technologists; human, animal, and environmental health experts; and key community stakeholders to co-create tools for early detection, advanced warning, and prevention of pandemic threats. Since 2009, Mark has served as the Chief Medical Officer and Director of Global Health at the Skoll Global Threats Fund (SGTF), where he developed the Ending Pandemics in Our Lifetime Initiative in 2012. His work at SGTF created a solid foundation for the work of Ending Pandemics, which branched out as an independent entity on January 1, 2018. Prior to SGTF, Mark developed the Predict and Prevent Initiative at Google.org, as part of the starting team at Google's philanthropic arm. Working with a team of engineers, Google Flu Trends (a project that had tremendous impact on the use of big data for disease surveillance) was created in partnership with the U.S. Centers for Disease Control. Mark has served as Vice President for Biological Programs at the Nuclear Threat Initiative, a public charity directed by CNN founder Ted Turner and former U.S. Senator Sam Nunn. Before NTI, he led an 18-member expert committee of the National Academy of Medicine on the 2003 landmark report "Microbial Threats to Health: Emergence, Detection, and Response." Mark served as the sixth Luther Terry Fellow in Washington, D.C., in the Office of the U.S. Surgeon General and as an Epidemic Intelligence Officer with the U.S. Centers for Disease Control and Prevention. Mark received his B.S. in Biology and M.D. from the University of Michigan in Ann Arbor. He is board-certified in preventive medicine and public health and holds an M.P.H. from the University of Arizona.

David Walt, Ph.D.
Hansjörg Wyss Professor of Biologically Inspired Engineering
Harvard Medical School

David R. Walt is the Hansjörg Wyss Professor of Bioinspired Engineering at Harvard Medical School and Professor of Pathology at Harvard Medical School and Brigham and Women's Hospital, is a Core Faculty Member of the Wyss Institute at Harvard University and is a Howard Hughes Medical Institute Professor. Previously, he was University Professor at Tufts University. His laboratory pioneered the development of microwell arrays, which revolutionized the field of genetic analysis. Dr. Walt's laboratory also introduced the idea of digital protein detection by developing a high throughput technology for performing single molecule analysis. Dr. Walt's research is aimed at applying new technologies to address unmet clinical diagnostics needs. Dr. Walt is the Scientific Founder of Illumina Inc., Quanterix Corp., and has co-founded several other life sciences startups including Ultivue, Inc., Arbor Biotechnologies, Sherlock Biosciences, and Vizgen, Inc. He has received numerous national and international awards and honors for his fundamental and applied work in the field of optical microwell arrays and single molecules. He is a member of the National Academy of Engineering, the National Academy of Medicine, a Fellow of the American Academy of Arts and Sciences, a Fellow of the American Institute for Medical and Biological Engineering, a Fellow of the National Academy of Inventors, and is inducted in the US National Inventors Hall of Fame.

To: Baric, Toni C[antoinette_baric@med.unc.edu]
Cc: Baric, Ralph S[rbaric@email.unc.edu]; Aleksei Chmura[chmura@ecohealthalliance.org]
From: Peter Daszak[daszak@ecohealthalliance.org]
Sent: Wed 4/29/2020 10:46:53 PM (UTC-04:00)
Subject: RE: Got the remdesivir bat cov paper

Just watched Ralph on The Don Lemon Show. Tell him 'welcome to the Resistance' from me…

He did a great job – just perfect, and this is a great breakthrough, and such an affirmation at a time when the Luddites are shouting loudly. Perfect timing for us also..

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
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USA

Tel.: +1-212-380-4474
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Baric, Toni C <antoinette_baric@med.unc.edu>
Sent: Wednesday, April 29, 2020 6:04 PM
To: Peter Daszak <daszak@ecohealthalliance.org>
Subject: RE: Got the remdesivir bat cov paper

HI Peter,
Did Ralph send you an email? He sent it, but not sure you got it. He will be off the calls at 7 then Don Lemon at 10:15.
Toni

From: Peter Daszak <daszak@ecohealthalliance.org>
Sent: Wednesday, April 29, 2020 6:02 PM
To: Baric, Toni C <antoinette_baric@med.unc.edu>
Subject: Got the remdesivir bat cov paper

Thanks Toni and please tell Ralph I have the paper it's 2017 sheahan

Congratulations on this work

Cheers,

Peter

Peter Daszak
(Sent from my iPhone)

President
EcoHealth Alliance

460 West 34th Street, New York, NY10001, USA

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On Apr 27, 2020, at 7:54 AM, Baric, Toni C <antoinette_baric@med.unc.edu> wrote:

Hi Peter
Just read a very positive article about your work from CNN. It was very interesting and so glad you are getting national recognition for the good work you do. Hang in there and know that you can always call on us. We are kindred souls in this mess
Best always
Toni

Sent from Outlook Mobile

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; GSELL, Pierre[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; Alejandro Javier COSTA[costaa@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
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Sent: Thur 4/30/2020 5:27:26 AM (UTC-04:00)
Subject: WHO Animal Models Call-Agenda
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Dear Colleagues,
Please find below the agenda for today's group call. Please note that in the context of the WHO Vaccine acceleration plan we would like to foster interactions between vaccine developers and laboratories that are working on COVID-19 animal models. Therefore today we will have short presentations from vaccine developers. We intend to have this interaction with developers once a month.

Below you can also find the Webex link to join the call.

See you all later

César, Bill and Simon.

Agenda (In alphabetical order)

1- High-level summary of previous deliberations (co-chairs)
2- BIOCAD, Anton Seleznev
3- Bio-Net Asia, Wassana Wijagkanalan (verbal update)
4- BioNTech, Ugur Sahin (verbal update)
5- CNBG (Sinopharm), multiple reps (verbal update)
6-Curevac, Susanne Rauch (verbal update)
7-Flow Pharma, Trevor Brasel
8-GSK, Robbert Van der Most
9-IMBCAMS, Shaozong Dong
10-IMV, Marianne Stanford
11-J&J, Roland Zahn
12-Inovio, Trevor Smith
13-Novavax, Gale Smith
14-Moderna, Darin Edwards
15-Univ. of Oxford, Teresa Lambe
16-Saiba, Mona Mohsen
17-Sanofi Pasteur, Fu Tong-Ming
18-UQ, Keith Chappell
19-Vabiotech, Do Tuan Dat
20-General discussion

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Start Time: 2020-04-30T15:00:00+02:00
End Time: 2020-04-30T16:30:00+02:00
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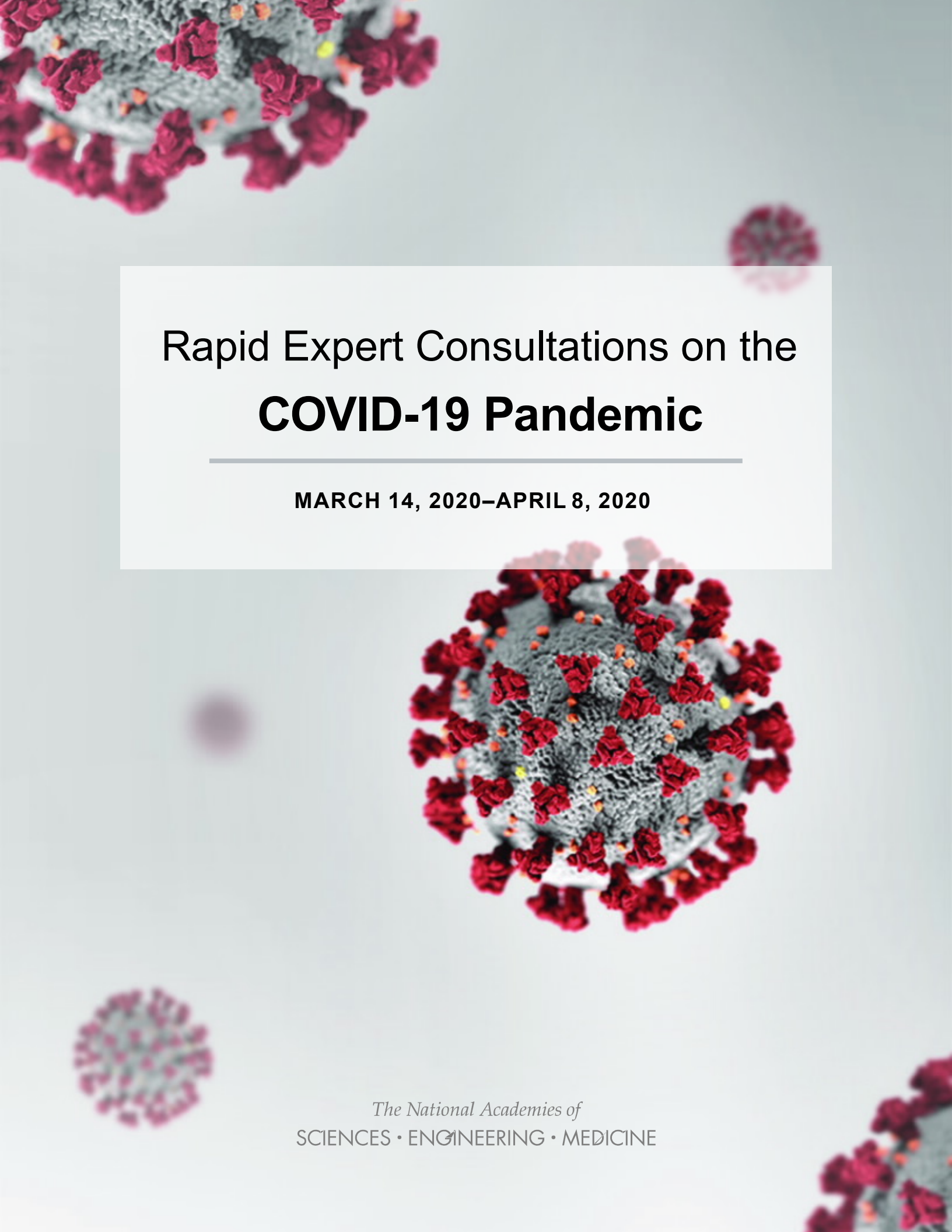

Rapid Expert Consultations on the

COVID-19 Pandemic

MARCH 14, 2020–APRIL 8, 2020

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Contents

Preface

The National Academies are a unique national resource. Their members represent the best in American science, engineering, and medicine. For more than a century, the National Academies have called upon their members and other experts to lend their knowledge and experience as volunteers in service to the nation. The National Academies have rightly been called objective, evidence-based, influential, and authoritative. In this instance, they have also proved to be quick.

The COVID-19 pandemic has demanded exceptional responses from many institutions, domestic and international, public and private. As the pandemic began to take hold in the United States, the White House Office of Science and Technology Policy, led by Dr. Kelvin Droegemeier, and the U.S. Department of Health and Human Services, in the person of Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, turned to the National Academies for expert advice. Presidents Marcia McNutt, John Anderson, and Victor Dzau responded by setting up the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats.

The standing committee held its first organizational meeting on Wednesday, March 11, 2020, and in consultation with the sponsors, prepared an initial list of scientific and technical questions that the COVID-19 pandemic posed. Sponsor assignments cascaded onto the committee, and the staff, members, and other experts responded with alacrity. The main work product in this phase has been the "rapid expert consultation," a written product prepared by the committee and subject to accelerated review by the quality assurance arm of the National Academies, its Report Review Committee.

As I write this, just 1 month after the initial, organizing meeting, the standing committee has produced 11 rapid expert consultations in addition to the initial listing of important issues, and it has organized one informal telephone consultation on behalf of the sponsors, a mechanism that allows government officials to tap even more rapidly into the expertise of the standing committee members and others. As we look ahead, we anticipate that the committee will begin to focus on intermediate-term questions, where

the answers have a time constant measured in weeks to months rather than hours to days. We also expect to turn more regularly to the informal, telephonic consultations in which the sponsors can obtain expert input in a timely way and experts can be directly responsive to the most pressing questions.

With this expected transition in emphasis, this seems like an appropriate moment to collect the set of completed rapid expert consultations, assembled here. In this rapidly evolving pandemic, new knowledge emerges by the day, and these statements each represent a snapshot of what was known at a particular moment in time. While they were rapidly prepared, we also hope they represent sound, thoughtful, timely, and useful information for the decision makers who are shaping the nation's response to COVID-19.

I would like to express my appreciation to Drs. Droegemeier and Kadlec who placed their confidence in the National Academies, to the Academy presidents who established the standing committee, to the members of the committee and other experts who stepped up whenever asked, to the outside reviewers and Report Review Committee staff and leaders who moved briskly to improve the final products, and above all, to the exceptional standing committee staff who labored literally day and night to produce these documents.

As the National Academies contribute to policy decisions with objective, scientific, evidence-based guidance, these rapid expert consultations stand as testimony to an additional capability of the National Academies to act as swiftly as the current crisis demands.

Harvey V. Fineberg, M.D., Ph.D.
Chair
National Academies of Sciences, Engineering, and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Rapid Expert Consultation on Severe Illness in Young Adults for the COVID-19 Pandemic (March 14, 2020)

March 14, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
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Washington, DC 20504

Robert Kadlec, M.D.
Assistant Secretary for Preparedness and Response
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Dear Drs. Droegemeier and Kadlec:

Attached is a brief response to your question on whether reports of severe illness in younger adults in Italy may represent a genetic change to the virus. As explained in the note, the reports from Italy of severe illness in young adults may not represent a change in the pattern of susceptibility, as even the earliest reports from China indicated severe illness among young adults, though at a lower frequency than among older persons. At the present time, the genetic make up of the virus circulating in Italy appears to be the same as that found in other countries of Europe.

The enclosed document was prepared by staff of the National Academies of Sciences, Engineering, and Medicine based on input from Trevor Bedford, David Walt, and me.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Recent reports from Italy describe severe illness requiring ventilatory support in younger adults without underlying comorbidities. At this time, there are not enough data to indicate whether these cases are a small fraction of a large number of infected young adults or represent a shift in the severity spectrum toward more severe disease in younger adults. Of note, China reported 12.0% (67/557) of patients 15-49 years of age developed severe illness (compared to 28.8% [44/153] in those ≥65 years),[1] so severe illness in young adults has not been an uncommon occurrence from the start of the pandemic.[2] Unofficial reports from the outbreak in the state of Washington similarly note the occurrence of severe illness in young adults.

A determination of any change in the incidence or severity spectrum of illness in different segments of the population requires a systematic analysis of longitudinal data, currently unavailable. Obtaining these data through the tracking of natural patient histories and outcomes is an important component of managing the epidemic. This analysis would produce updated calculations of risk factors by age group and tracking of any changes over time. We need to be prepared to routinely collect and share these data as the epidemic progresses in the United States.

If changes in risk factor by age group were to occur, this could potentially be a result of mutations in the circulating virus. On genomic epidemiologic analysis, the Italian outbreak is primarily driven by the "Lombardy clade" or "A2."[3] This clade has a P314L mutation in ORF1b and also R203K and G204R in N. However, this same virus is distributed widely throughout Europe, and there are not enough data reported from other European countries to conclude whether the Italian experience is atypical. The epidemic expanded rapidly in Italy prior to an increase in cases in other European countries. If Italy is reporting an increase in severity and deaths among young adults compared to other European countries, this could be due to the stage of the epidemic, health system shortcomings, or different reporting methods rather than virus evolution.

[1] Guan et al. 2020. Clinical characteristics of coronavirus disease 2019 in China. *New England Journal of Medicine*. DOI: 10.1056/NEJMoa2002032.

[2] The manuscript defines "severe" as per the American Thoracic Society guidelines and not all severe cases may have required mechanical ventilation. In addition, the manuscript does not delineate by age group how many severe cases had underlying illnesses (38.7% of severe cases overall had a coexisting disorder). Metlay et al. 2019. Diagnosis and treatment of adults with community-acquired pneumonia: An official clinical practice guideline of the American Thoracic Society and Infectious Diseases Society of America. *American Journal of Respiratory and Critical Care Medicine* 200(7):e45-e67. DOI: 10.1164/rccm.201908-1581ST.

[3] See https://nextstrain.org/ncov?branchLabel=aa&label=clade:A2&m=div.

Although COVID-19 typically has caused higher rates of severe illness and mortality in older populations and those with underlying illnesses, it is important not to downplay the potential seriousness of this infection in younger age groups. While data are gathered and analyzed, messaging should stress that everyone should be concerned about COVID-19 and take appropriate steps to protect their health, the health of their loved ones and neighbors, and the health of the public at large.

Rapid Expert Consultation on SARS-CoV-2 Surface Stability and Incubation for the COVID-19 Pandemic (March 15, 2020)

March 15, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
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Dear Dr. Droegemeier:

You requested immediate feedback on two crucial questions. The following expert members of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats were involved in preparing this document: Kent Kester, David Relman, David Walt, and me. Ellen Wright Clayton, Vanderbilt University, reviewed this document.

Question 1: Survival of virus on surfaces. One of the most thorough and informative studies is just now under consideration for publication and has not undergone full peer review. The investigators are a highly reputable group, and we can expect that their study was carefully conducted. They tested both the current coronavirus (SARS-CoV-2) and the original SARS virus (SARS-CoV-1). Results were similar for both viruses. They tested the viability (survival) of both viruses after controlled aerosolization and on a variety of surfaces. The aerosol (particles smaller than 5 microns that can float in the air) showed viral detection up to 3 hours post aerosolization. Following surface contamination, SARS-CoV-2 could be detected up to 4 hours on copper, up to 24 hours on cardboard and up to 2-3 days on plastic and on stainless steel. These results are

consistent with the plausibility of both aerosol and surface (fomite) transmission of SARS-CoV-2. The difference in survival on copper (4 hours) and on stainless steel (2-3 days) is noteworthy. Note that this study excludes what is probably the most common route of spread, direct droplet transmission by cough or sneeze, or even exhalation by an infected person. Additionally, the members of the standing committee identified above note that the National Biodefense Analysis and Countermeasures Center (NBACC) is conducting environmental survival studies of SARS-CoV-2 and their results should be taken into account.

Question 2: Incubation period (time between exposure and onset of symptoms). Note that it is possible for viral shedding to begin prior to the onset of symptoms. Also, we are not considering here the question of how long viral shedding can continue in someone who has been infected. Rather, as we understand it, the question here pertains to the appropriate period of quarantine for an exposed individual. One of the more informative reports on incubation period studied 181 patients in China who had identifiable dates of exposure and of symptom onset.[1] In this study, the mean incubation period was estimated to be 5.1 days (95% confidence interval 4.5 to 5.8 days) and 97.5% of those who develop symptoms will do so within 11.5 days (95% confidence interval 8.2 to 15.6 days) of exposure. These estimates imply that only about 1% of cases (101/10,000) will develop symptoms following 14 days after exposure. Shortening quarantine to fewer than 14 days would increase the fraction who were still to develop symptoms. Note that Lauer et al. acknowledged that publicly reported cases may overrepresent severe cases, the incubation period for which may differ from that of mild cases.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

[1] Lauer et al. 2020. The incubation period of coronavirus disease 2019 (COVID-19) from publicly reported confirmed cases: Estimation and application free. *Annals of Internal Medicine*. DOI: 10.7326/M20-0504.

Rapid Expert Consultation on Social Distancing for the COVID-19 Pandemic (March 19, 2020)

March 19, 2020

Kelvin Droegemeier, Ph.D.
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Dear Dr. Droegemeier:

This letter responds to your question about evidence on the effectiveness and costs of social distancing measures in contending with COVID-19.

Respiratory viruses are transmitted from person to person via air droplet (talk, sneeze, cough), suspended droplet nuclei (<5 microns diameter; sneeze, cough), and surface fomites (touch contaminated surface and then touch mucous membrane in eye, nose, mouth). Social distancing measures are based on the idea of interrupting these forms of transmission by separating infected and uninfected persons. In the absence of a vaccine or effective prophylactic agents, social distancing is the principal tool available to blunt the force of an epidemic.[1]

[1] Qualls et al. 2017. Community mitigation guidelines to prevent pandemic influenza—United States, 2017. *Morbidity and Mortality Weekly Report—Recommendations and Reports* 66(1):1-32. DOI: 10.15585/mmwr.rr6601a1.

This response was prepared by staff of the National Academies of Sciences, Engineering, and Medicine based on input from Alexandra Phelan and me. Ned Calonge, The Colorado Trust; Sue Curry, University of Iowa; and Steven Teutsch, University of California, Los Angeles, reviewed this document, and Ellen Wright Clayton, Vanderbilt University, approved the document on behalf of the Report Review Committee. The attached materials summarize evidence bearing on the effectiveness of social distancing measures, and they demonstrate that social distancing measures are effective. However, their effectiveness depends on such factors as early implementation and compliance.

Most of these studies are based on past experience with influenza. Some are empirical studies of the experience in different places that employed varying degrees of social separation during the great influenza pandemic of 1918-1919. Others are modeling exercises using available data and certain assumptions about relevant characteristics of an infection, such as the basic reproductive number, degree of mixing, and fraction of susceptible individuals. In general, these studies support the value of social distancing in reducing the amount of illness and death and in spreading the onset of illness over a longer time period ("flattening the curve"), which makes clinical management more feasible. For example, one study of 34 U.S. cities during the 1918-1919 influenza pandemic found that those communities that implemented social distancing measures earlier experienced greater delays in reaching peak mortality, lower peak mortality rates, and lower total mortality.[2]

In interpreting these data, it is important to note that "social distancing" can cover a wide range of community-based interventions, from closing schools and workplaces to eliminating mass public events to wearing face masks, and it is not always clear exactly which intervention is contributing what degree to the differential outcomes. Also important in the current context are differences between influenza and SARS-CoV-2 in such key attributes as transmission rate, incubation period, uncertainty regarding children as vectors, and pre-existing immunity in the population.

In general, studies based on historical data and on modeling both indicate that social distancing interventions are more effective when instituted early in the course of an epidemic.[3,4]

Only a handful of studies consider cost-effectiveness of this class of interventions, and many of them include consideration of pharmaceutical interventions such as antiviral treatments and vaccination strategies that are not currently available for this

[2] Markel et al. 2007. Nonpharmaceutical interventions implemented by US cities during the 1918-1919 influenza pandemic. *JAMA* 298(6):644-654. DOI: 10.1001/jama.298.6.644.

[3] Hatchett et al. 2007. Public health interventions and epidemic intensity during the 1918 influenza pandemic. *PNAS* 104(18):7582-7587. https://doi.org/10.1073/pnas.0610941104.

[4] Halloran et al. 2008. Modeling targeted layered containment of an influenza pandemic in the United States. *PNAS* 105(12):4639-4644. DOI: 10.1073/pnas.0706849105.

pandemic.[5,6,7,8] In general, these studies do not fully incorporate all social and economic costs that attend to such interventions as the cancellation of travel and the suspension of many businesses. They are not updated to today's economic and social circumstances, and the comparison to "benefits" relate to the burden of influenza, not SARS-CoV-2. Therefore, they do not have much to reveal about the cost or cost-effectiveness of today's interventions in the current pandemic.

More pertinent to decision making today about COVID-19 is the experience of other countries where the pandemic preceded outbreaks in the United States.

In an informative analysis, for example, Wang et al. evaluated the impact of social distancing and case finding and isolation of patients over three phases of the epidemic in Wuhan, China.[9] Prior to introducing any of these measures, the basic reproductive number was estimated to be 3.86 (95% credible interval 3.74 to 3.97). This period, from December 8, 2019, to January 23, 2020, was marked by an exponential growth in new cases. From January 23, 2020, to February 2, 2020, the following social distancing measures were implemented: home quarantine for suspected cases, cordon sanitaire, suspension of public transportation, closure of entertainment venues and public spaces, compulsory wearing of face masks, mandated personal hygiene, and body temperature self-monitoring. During this period, the reproductive number fell to 1.26, a substantial improvement, but still above the level of 1.0 that sustains spread. From February 2, 2020, and on, cordon sanitaire, suspension of public transportation, closure of entertainment venues and public spaces continued, and the following measures were also implemented: centralized isolation in designated hospitals for cases; mobile-cabin hospitals, schools, and hotels for exposed and possible cases; universal and strict stay-at-home policy for all residents unless permitted; widespread temperature and symptom monitoring; and universal screening and reporting. With these added measures the basic reproductive number fell to 0.32, and the epidemic subsided. The interventions were estimated to prevent 94.5% (93.7 to 95.2%) of infections until February 18.

A recent modeling exercise reported from Imperial College London[10] examined the effectiveness of different social distancing strategies to mitigate or suppress the force of the epidemic in the United Kingdom and the United States. The overall conclusion is that population-wide social distancing in combination with home isolation of cases, quarantine of exposed individuals, and school and university closure could reduce the

[5] Milne et al. 2013. The cost effectiveness of pandemic influenza interventions: A pandemic severity based analysis. *PLOS ONE* 8(4):e61504. DOI: 10.1371/journal.pone.0061504.

[6] Pasquini-Descomps et al. 2017. Value for money in H1N1 influenza: A systematic review of the cost-effectiveness of pandemic interventions. *Value in Health* 20(6):819-827. DOI: 10.1016/j.jval.2016.05.005.

[7] Pérez Velasco et al. 2017. Systematic review of economic evaluations of preparedness strategies and interventions against influenza pandemics. *PLOS ONE* 7(2):e30333. DOI: 10.1371/journal.pone.0030333.

[8] Perlroth et al. 2010. Health outcomes and costs of community mitigation strategies for an influenza pandemic in the United States. *Clinical Infectious Diseases* 50(2):165-174. DOI: 10.1086/649867.

[9] Wang et al. 2020. Evolving epidemiology and impact of non-pharmaceutical interventions on the outbreak of coronavirus disease 2019 in Wuhan, China. *medRxiv*. https://doi.org/10.1101/2020.03.03.20030593.

[10] Ferguson et al. 2020. Impact of non-pharmaceutical interventions (NPIs) to reduce COVID-19 mortality and healthcare demand. Imperial College London (16-03-2020). DOI: https://doi.org/10.25561/77482.

incidence of new cases (suppress) and not merely slow the rise (mitigate). However, to avoid the re-emergence of the disease, their models indicate these interventions would need to be maintained until an effective vaccine is developed and deployed, and this could take 18 months or longer. The authors stress uncertainty in estimates of transmissibility and effectiveness of interventions. They acknowledge the practical possibility of shorter-term interventions and variation across geographies depending on the local stage of the outbreak. Their analysis suggests that a 3-month period of intervention, stressing social distancing of vulnerable (older or chronically ill) populations in combination with other measures could reduce deaths in half and peak health care demand by two-thirds. At the same time, half-measures, such as case isolation and social distancing of the elderly only (rather than the entire population), could lead to an epidemic that overwhelms hospital surge capacity and, they project, could cause more than 1 million deaths in the United States.

Anecdotally, Singapore, which after the experience of the SARS outbreak in 2002 refined its capacity for intensive detection, isolation of cases, contact tracing, and quarantine of exposed individuals, has managed to suppress the SARS-CoV-2 epidemic without resorting as yet to closing schools and workplaces. These results are possible only with the availability of widespread diagnostic testing. The continued influx of new cases, probably related to travel, creates an ongoing challenge for the public health authorities there.

In the United States, we are embarked on a natural experiment where different communities will likely enact different levels and timing of social distancing relative to the local phase of the epidemic. Experience in other countries during the current COVID-19 pandemic shows the value of widely available diagnostic testing to guide the response. If our nation mounts a coordinated effort to detect and monitor disease incidence and tracks the control measures that are being implemented in each community, compliance rates, and other relevant data, we can better inform decisions about when social distancing measures may be withdrawn and in what circumstances they may need to be reinstated or enlarged. Judgments about when to suspend which social distancing measures will be critical and should involve discussions with public health experts, mathematical modelers, economists, and social and behavioral scientists. Decision makers will be greatly aided by ongoing data collection and disease monitoring.

My colleagues and I hope this rapid expert consultation is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Rapid Expert Consultation on Data Elements and Systems Design for Modeling and Decision Making for the COVID-19 Pandemic (March 21, 2020)

March 21, 2020

Kelvin Droegemeier, Ph.D.
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Dear Dr. Droegemeier:

This letter responds to your question about necessary data elements, sources of data, gaps in collection, and suggestions for data system design and integration to improve modeling and decision making for COVID-19.

We enumerate eight basic points of perspective on the question you posed.

1. Utilizing existing databases and focusing on accessibility, usability, interoperability, and scalability will lead more rapidly to functional data systems than attempting to build systems from scratch.
2. It is better to start with basic functions that cover only the fundamental needs for viral tracking, epidemic monitoring and modeling, clinical management, resource deployment, and public communication.
3. Depending on the intended range of users and uses, the relevant data may include disease surveillance, longitudinal clinical health information, human genomic data, viral genomic data, medical supplies and logistics, and sociodemographic and behavioral data.

4. Choices about system architecture, design elements, and desired outputs are best made in concert with choices of software and system platforms.
5. Integration will be a challenge across public and private sources; clinical care and public health; and local, state, and national levels.
6. Anticipate the need to fill gaps in currently available data systems, including in public health information currently collected by individual states and local authorities.[1]
7. Attempt to design so as to reduce tradeoffs across accessibility and security, ease of use and comprehensiveness, and local utility and scalability.
8. Clarity about the prospective users and purposes of the system will greatly aid making sensible design choices and tradeoffs. A data system intended to serve all needs for everyone is liable to end up satisfying no one's basic needs.

We can use data systems to (1) determine community spread and impact; (2) monitor the clinical spectrum of illness to include response to treatment; and (3) provide accurate, up-to-date information to feed into models to forecast disease rates and subsequent clinical and logistical needs and the effectiveness of mitigation plans. All three contribute to the public health and clinical and logistical response to an epidemic.

Useful community patient data precede specific diagnoses of a COVID-19 infection. Available systems illustrate the richness of current data gathering and the opportunity for integration and interoperability. At a syndromic level (symptoms and signs prior to a final diagnosis), the Centers for Disease Control and Prevention's (CDC's) National Syndromic Surveillance Program (NSSP) collects emergency room visit data across the United States, including the reason for the visit and, as appropriate, a diagnosis.[2] Collaborating commercial laboratories are providing SARS-CoV-2 testing and results into the NSSP in a near-real-time basis. In addition, using traditional influenza surveillance programs that track influenza-like symptoms along with confirmed laboratory tests (CDC's FluView), the NSSP is comparing emergency room symptoms with test results to assess divergence, which could indicate COVID-19 infections in those communities. The Flu Near You program out of HealthMap and the American Public Health Association is a participatory surveillance program that allows the public to report symptoms by geographic location. This program is being relaunched as a COVID Near You program that can also evaluate human behaviors along with health status. These programs illustrate the richness of existing data-gathering systems, to include smartphone technology and social media outreach, and an opportunity to take fuller advantage of the complementary information they provide.

Complete and accurate clinical data may include exposure information, reliable markers of disease progression and severity, important comorbidities such as diabetes and heart and lung disease, relevant conditions such as pregnancy (and obstetric outcomes), treatment protocols, geo-locations, and mortality. These data ideally will come from trusted sources. Most hospitals use electronic data records that can differ across

[1] Local public health authorities can invoke section 45 CFR 164.512(b) of the Health Insurance Portability and Accountability Act (HIPAA) to obtain protected health information without authorization in order to prevent or control COVID-19.

[2] For additional information on the NSSP, see https://www.cdc.gov/nssp/images/nsspinfo/Final_NSSP-Infographic.pdf.

institutions, localities, and states. Deploying a system of systems, it may be possible to consolidate clinical data and augment these programs to include additional elements. The use of natural language processing on narrative notes and sharing the analysis through a distributed query architecture has been accomplished regionally for clinical research and could be expanded. Programs such as the Shared Health Research Information Network,[3] the Patient-Centered Outcomes Research Institute's Clinical Data Research Network[4] and the Observational Health Data Sciences and Informatics' Observational Medical Outcomes Partnership Common Data Model[5] all support interoperability of core datasets. Starting with basic descriptive statistics of patients and expanding as more data and techniques are available can assist with triage and identify important biological themes.

Whether for a known infectious pathogen or a novel one, the ability to model the pathogenesis, transmission, effective control strategies, and spread of a disease can provide crucial information to those needing to make decisions about the distribution of limited resources. An example of a successful collaborative effort is the Models of Infectious Disease Agent Study (MIDAS).[6] This effort, funded by the National Institute of General Medical Sciences at the National Institutes of Health, is a global network of research scientists and practitioners who develop and use computational, statistical, and mathematical models to understand infectious disease dynamics. MIDAS has an online portal to share data and information regarding the COVID-19 pandemic and could be used as a resource for decision makers. To assist with forecasting disease progression and identifying important clinical markers before we obtain more data on COVID-19 in the United States, data from other countries, such as the daily number of hospitalizations, intensive care admissions, ventilator use, and deaths, can be used in forecasting expected epidemic progression and assist with clinical care decisions.

Assessing the capacity of medical facilities to provide intensive care to those in need will facilitate the allocation of ICU beds and ventilators. Programs at local and regional levels currently monitor the availability of hospital beds and other resources, and expanding these programs would provide a national view of areas most in need. Tracking mortality from disease in relation to resources can aid in the interpretation of fatality rates and inform future pandemic preparedness.

Current estimates surrounding the use of social interventions can be examined, evaluated, and adjusted using social data. The number of contacts being isolated and monitored and facility closings by state and region can be monitored along with de-identified social media postings that correlate with behaviors. Some insight into the impact of isolation and closings of schools, worksites, and volunteer programs can also be monitored through social media and voluntary reporting.

Knowing how a virus mutates as it moves through a population is vital to understanding possible changes in disease severity or transmissibility, amenity to diagnosis, and responsiveness to vaccine. This is an issue of global interest and will involve

[3] McMurry et al. 2013. SHRINE: Enabling nationally scalable multi-site disease studies. *PLOS ONE* 8(3):e55811. DOI: 10.1371/journal.pone.0055811.

[4] See https://www.pcori.org/research-results/pcornet%C2%AE-national-patient-centered-clinical-research-network.

[5] See https://www.ohdsi.org/data-standardization/the-common-data-model.

[6] See https://midasnetwork.us.

scientists from many parts of the world. International data sharing and enlisting tech companies that have the ability to provide data acquisition and processing would be important components of a comprehensive data system.

Moving forward, data collection tools can be designed to improve consolidation and sharing. For basic public health data, working with organizations that bring together local and state health departments (such as the Association of State and Territorial Health Officials [ASTHO], the National Association of County & City Health Officials [NACCHO], and the Council of State and Territorial Epidemiologists [CSTE]) would be a good starting point to ensure participation from across the public health community.

By following these principles, we believe it will be possible to rapidly assemble data systems that can inform decisions on managing the epidemic.

This response was prepared by staff of the National Academies of Sciences, Engineering, and Medicine based on input from Georges Benjamin, Ellen Embrey, Peggy Hamburg, Kent Kester, Patricia King, Jonna Mazet, Alexandra Phelan, Mark Smolinksi, David Walt, and me. Ned Calonge, The Colorado Trust; Marie Griffin and Kevin Johnson, Vanderbilt University Medical Center; Sandro Galea, Boston University; and Isaac Kohane, Harvard Medical School, reviewed this document, and Ellen Wright Clayton, Vanderbilt University, approved the document as monitor on behalf of the Report Review Committee.

Should you desire more substantive and detailed recommendations on system design and content, we would be happy to take this up over a suitable time frame. My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Rapid Expert Consultation Update on SARS-CoV-2 Surface Stability and Incubation for the COVID-19 Pandemic (March 27, 2020)

March 27, 2020

Kelvin Droegemeier, Ph.D.
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Dear Dr. Droegemeier:

You requested an update and elaboration on our previous rapid expert consultation dated March 15, concerning issues of virus survival on surfaces and in the air, and virus/disease incubation period. Here, we provide an update and elaboration on these issues, as well as some caveats about the work performed so far and as yet unmet needs. As with other questions and issues related to SARS-CoV-2 and COVID-19, work on these two topics is proceeding at a rapid pace at many locations across the globe. Consequently, aspects of this update may rapidly be superseded by new data.

This rapid expert consultation is organized by question and summarizes published and unpublished studies that were deemed most useful, as well as personal communications with experts (cited below). We have selected studies that are most relevant and critical, rather than attempting to be comprehensive. For each of the questions, data are presented for experimental studies and natural history studies, followed by comments on caveats and unmet needs.

This document was prepared by me with support from staff of the National Academies of Sciences, Engineering, and Medicine. Harvey Fineberg approved this document

as chair of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. The following individuals served as reviewers: Kathryn Edwards, Vanderbilt University Medical Center; James LeDuc, University of Texas Medical Branch; and Linsey Marr, Virginia Tech. Ellen Wright Clayton, Vanderbilt University, and Susan Curry, University of Iowa, served as arbiters of this review on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

QUESTION 1: ENVIRONMENTAL SURVIVAL

In general, there are two basic approaches to study this issue: (A) experimental studies, typically involving the deliberate dissemination of a laboratory-propagated virus under controlled environmental conditions and subsequent sampling; and (B) natural history studies, typically involving the characterization of environments naturally contaminated by a virus, such as hospital rooms recently occupied by patients. Each approach has strengths and weaknesses: with experimental studies there is control over important parameters, but almost always the conditions fail to adequately mimic those of the natural setting; with natural history studies, the conditions are relevant and reflect the real world, but there is typically little control of environmental conditions and potentially confounding factors. Since March 15, there have been advances with studies of each type.

A. Experimental Studies

In a recent study from Hong Kong, Chin et al. examined the stability (using viral culture) of SARS-CoV-2 as a function of temperature, type of surface, and following the use of disinfectants.[1] With respect to temperature, using a starting suspension of 6.7 log $TCID_{50}$/ml in virus transport medium,[2] at 4°C there was only a 0.6-log unit reduction at the end of 14 days of incubation in this medium; at 22°C, a 3-log unit reduction after 7 days, and no detection at 14 days; and at 37°C, a 3-log unit reduction after 1 day and no virus detected afterward. No virus was detected after 30 minutes at 56°C or after 5 minutes at 70°C. With respect to survival on surfaces using a 5 μL droplet of virus culture at 7.8 log $TCID_{50}$/ml, no infectious virus was recovered from printing and tissue paper after 3 hours; no infectious virus was detected on cloth after 2 days or on stainless steel after 7 days. However, on the outside of a surgical mask, 0.1% of the original inoculum was detected on day 7. The persistence of infectious virus on personal protective equipment (PPE) is concerning and warrants additional study to inform guidance for health care workers. Such studies should also examine the effects of various treatments that might be used to disinfect PPE when they cannot be discarded after single use.

Chad Roy from the Tulane University National Primate Research Center shared via telephone some preliminary results of dynamic aerosol stability experiments with SARS-CoV-2 conducted over the past several weeks at the Infectious Disease

[1] Chin et al. 2020. Stability of SARS-CoV-2 in different environmental conditions. https://www.medrxiv.org/content/10.1101/2020.03.15.20036673v1.full.pdf (accessed March 24, 2020).

[2] $TCID_{50}$ is the Median Tissue Culture Infectious Dose.

Aerobiology Core program at Tulane.[3] His group generated an aerosol with a fairly uniform distribution of 2 micron particles, using virus grown in DMEM tissue culture (TC) medium and suspended in a rotating drum at an ambient temperature of ~23 ^{o}C and ~50% humidity. The aerosol was sampled longitudinally for up to 16 hours, and the virus was assessed for viability by growth (enumeration of plaque forming units [PFUs]) and morphology (electron microscopy). He reports surprisingly that SARS-CoV-2 has a longer half-life under these conditions than influenza virus, SARS-CoV-1, monkeypox virus, and *Mycobacterium tuberculosis*. He is still waiting for some growth results, but expects to post a manuscript describing these findings to bioRxiv on March 27. This result is also concerning, but is quite preliminary; importantly, the details have not yet been shared.

George Korch and Mike Hevey from the National Biodefense Analysis and Countermeasures Center (NBACC), which was created by the U.S. Department of Homeland Security, shared their plans for an extensive series of experiments on SARS-CoV-2 environmental survival.[4] Because they have shared these plans with the White House Coronavirus Task Force, only a few observations are provided here. The NBACC is well suited for the kinds of studies it has planned, and the scope and relevance are noteworthy. In particular, it plans to create simulated infected body fluids, including saliva and lower respiratory secretions. It plans to test simulated solar radiation on virus survival, which is important. It also has already examined a wider range of relative humidity and temperature than some other groups, which is again, important. And they will compare RNA semi-quantitative measurements with viral growth (PFUs) on samples from all conditions, which is critical.

At Rocky Mountain Laboratories (RML), part of the National Institutes of Health, current studies include the effect of temperature and humidity on virus stability; virus stability in human body fluids, including urine and feces; and the effectiveness of decontamination procedures for PPE, including N95 respirators.[5]

As follow-up, the study by van Doremalen et al. mentioned in our rapid expert consultation on March 15, which was at that time an unpublished preprint, has since been published by the *New England Journal of Medicine*.[6]

B. Natural History Studies

In a recent published study from Singapore, Ong et al. sampled environmental surfaces at 26 sites in each of 3 SARS-CoV-2 patient isolation rooms, as well as PPE worn by physicians exiting patient rooms and air in the patient rooms and anterooms.[7] All samples were tested using reverse transcriptase-polymerase chain reaction (RT-PCR).

[3] Personal communication, Chad Roy, Tulane University National Primate Research Center, March 24, 2020.

[4] Personal communication, George Korch and Mike Hevey, National Biodefense Analysis and Countermeasures Center, March 24, 2020.

[5] Personal communication, Vincent Munster, Rocky Mountain Laboratories, March 24, 2020.

[6] van Doremalen et al. 2020. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. *New England Journal of Medicine*. DOI: 10.1056/NEJMc2004973.

[7] Ong et al. 2020. Air, surface environmental, and personal protective equipment contaminated by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from a symptomatic patient. *JAMA*. https://jamanetwork.com/journals/jama/fullarticle/2762692 (accessed March 24, 2020).

There were no efforts to assess virus viability. Patient A's room was sampled on days 4 and 10 of illness while the patient was still symptomatic after routine cleaning. All samples were negative. Patient B was symptomatic on day 8 and asymptomatic on day 11 of illness; samples taken on these 2 days after routine cleaning were negative. Samples collected from Patient C's room before routine cleaning had positive results at 13 (87%) of 15 room sites (including air outlet fans) and 3 (60%) of 5 toilet sites (toilet bowl, sink, and door handle). Anteroom and corridor samples were negative. Patient C had upper respiratory tract involvement with no pneumonia and had 2 positive stool samples for SARS-CoV-2 on RT-PCR, despite not having diarrhea. Only 1 PPE swab, from the surface of a shoe front, was positive. All other PPE swabs were negative. All air samples were negative. However, the lack of detection of the virus in air samples does not necessarily contradict the finding of the virus on the air outlet fan in Patient C's room, which presumably deposited from air onto the surface of the fan. There are at least three explanations for the negative findings in air: (1) a high ventilation rate of the room would dilute concentrations to a level that would be difficult to detect except with a large volume of air; (2) the sample volume was only a fraction of the total room volume; and (3) the air outlets were located above the head of the bed, and it is likely that any virus released into air would be transported directly upward to the outlet, so an air sampler would need to intersect this pathway to optimize chances of detection. Again, it is important to underscore that samples from the two surface-negative rooms were collected after the rooms had been cleaned.

In a recent unpublished study from Changchun, China, Jiang et al. collected 158 environmental surface and air samples from inside and near isolation wards where persons under investigation (PUIs) and known infected patients were housed.[8] Samples were collected just before daily cleaning procedures. Only 2 of the 158 samples were RT-PCR-positive: one from surfaces at a nursing station, and the other from an air sample from the room of an intensive care patient.

The Centers for Disease Control and Prevention (CDC) Cruise Ship Environmental Investigation Team mentioned in the CDC's *Morbidity and Mortality Weekly Report* (*MMWR*) on March 23, 2020, the results of environmental sample analysis from the Diamond Princess cruise ship.[9] In total, 601 samples were collected and tested, of which 58 were positive (9.7%) by RT-PCR. According to the Discussion, "SARS-CoV-2 RNA was identified on a variety of surfaces in cabins of both symptomatic and asymptomatic infected passengers up to 17 days after cabins were vacated on the Diamond Princess but before disinfection procedures had been conducted (Takuya Yamagishi, National Institute of Infectious Diseases, personal communication, 2020). Although these data cannot be used to determine whether transmission occurred from contaminated surfaces, further study of fomite transmission of SARS-CoV-2 aboard cruise ships is warranted."

Santarpia et al. recently completed a study (as yet unpublished and not yet posted on a preprint server) of air and surface samples from 11 isolation rooms at the University

[8] Jiang et al. 2020. Clinical data on hospital environmental hygiene monitoring and medical staffs protection during the coronavirus disease 2019 outbreak. https://www.medrxiv.org/content/10.1101/2020.02.25.20028043v2.full.pdf (accessed March 25, 2020).

[9] Moriarty et al. 2020. Public health responses to COVID-19 outbreaks on cruise ships—worldwide, February–March 2020. *Morbidity and Mortality Weekly Report* 69(12):347-352. http://dx.doi.org/10.15585/mmwr.mm6912e3.

of Nebraska Medical Center that were used to care for SARS-CoV-2 patients.[10] Samples were collected from common room surfaces, personal items, and toilets, as well as high volume air samples and low volume personal air samples. Many commonly used items, toilet facilities, and air samples had evidence of viral contamination: 76.5% of all personal items and 80.4% of all room surfaces were positive for SARS-CoV-2 by RT-PCR (0.22-0.82 gene copies/microliter of swab resuspension); 63% of room air samples were positive (mean 2.86 copies/L of air); 81% of toilet samples were positive. The percentage of positive samples from each room ranged from 50% to 100%. There was no clear correlation between severity of illness, cough or fever, and the prevalence of viral RNA. Of note, air collectors positioned more than 6 feet from each of two patients yielded positive samples, as did air samplers placed outside patient rooms in the hallways. Although the results are preliminary, it appears that some samples are positive for infectious virus, including an air sample collected well more than 6 feet from a patient.[11] These results require urgent confirmation under a variety of conditions as they have significant implications for current public health messaging regarding necessary distancing between nearby individuals to prevent virus transmission. In addition, and in this case anecdotal, the highest airborne RNA concentrations were recorded by personal samplers while a patient was receiving oxygen through a nasal cannula (19.17 and 48.21 copies/L). The possibility of aerosol generation by oxygen delivery via nasal cannula and other mechanisms is currently being explored. Overall, these data support the possibilities of both direct (droplet and person-to-person) and indirect (contaminated objects, airborne) forms of transmission.

A recent study by Liu et al. provides additional information regarding aerodynamics, concentrations, and distribution of aerosols containing SARS-CoV-2.[12] A total of 35 aerosol samples (30 samples with total suspended particles, 3 samples with size-segregated particles, and 2 aerosol deposition samples) were collected in two hospitals and public areas in Wuhan, including patient areas, ICUs, medical staff areas, and toilet areas. In regard to patient areas, the highest concentrations of airborne SARS-CoV-2 were observed inside the patient mobile toilet room (19 copies m^{-3}), suggesting the importance of frequent disinfection of patient toilets. In regard to medical staff areas, the protective apparel removal rooms had the highest airborne virus concentrations (18 to 42 copies m^{-3}). In regard to public areas, airborne concentrations were generally below 3 copies m^{-3}, except for a crowded site near the entrance to a department store and a busy site next to a hospital. The peak concentrations of SARS-CoV-2 aerosols appear to exist in two distinct size ranges: 0.25 to 1.0 μm and those larger than 2.5 μm. Aerosols smaller than 2.5 μm can remain suspended in the air for many hours. The study observed that the negative pressure ventilation and high air exchange rate inside some locations were effective in minimizing airborne SARS-CoV-2. Additional findings suggest that virus-laden aerosol deposition may play a role in surface contamination and thus subsequent human infection. The authors believe that a direct source of SARS-CoV-2 may be due

[10] Santarpia et al. In preparation. Transmission potential of SARS-CoV-2 in viral shedding observed at the University of Nebraska Medical Center. Soon at *medRxiv*.

[11] Personal communication, Josh Santarpia, University of Nebraska Medical Center, March 25, 2020.

[12] Liu et al. 2020. Aerodynamic characteristics and RNA concentration of SARS-CoV-2 aerosol in Wuhan hospitals during COVID-19 outbreak. https://www.biorxiv.org/content/10.1101/2020.03.08.982637v1 (accessed March 26, 2020).

to a resuspension of virus-laden aerosol from the surface of medical staff protective apparel during removal, which may come from direct deposition of respiratory droplets while medical staff are working. Floor dust aerosol containing the virus is also subject to resuspension—meaning that virus-laden aerosols could first deposit on the surface of protective gear and then fall to the floor to be resuspended by medical staff movement. Outside of the hospital, only 2 crowd gathering sites (of 11 sites sampled) had detectable concentrations of SARS-CoV-2 aerosol, which may contribute to sources of virus-laden aerosol during sampling. It is important to note that the sample size for the aerosol samples, and notably the size-segregated samples (3) and aerosol deposition samples (2), were small—a limitation of this study. Furthermore, TRIzol LS Reagent (Invitrogen) was added to inactivate SARS-CoV-2 to extract the RNA, which should be noted as a limitation to the study because the authors measured viral RNA, not infectious virus.

There are a number of published studies that examine the relationship between the geographic incidence of COVID-19 cases and ambient temperature and humidity. Some suggest possible but modest correlations between geographies with higher temperature or humidity, and lower rates of disease; however, there are a number of confounding factors, including disease reporting practices and quality of and access to health care. We did not scrutinize these studies carefully nor perform an extensive search for related studies.

C. Caveats, Needs

A notable limitation of most of the natural history studies described above is a reliance on RT-PCR to assess the presence of SARS-CoV-2 on surfaces and air. Although viral RNA was detected in many environmental samples across the various studies, infectivity is not known. It is important to note that there are no available data to our knowledge that speak to the possible linkage between the presence of environmental viral RNA or even infectious virus and the risk of transmission from these environmental sites to humans. This is a key issue, and relates in part to another major issue and unanswered question: What is the infectious dose of SARS-CoV-2 for humans? Studies to address this question are planned, and in fact may be under way with non-human primates at several laboratories, but these studies will be limited by the relevance of non-human primate susceptibility to human susceptibility. The use of other laboratory animals will provide even less relevant information on incubation time.

Questions have been (appropriately) raised about whether there are relatively easy-to-perform, quick, and safe measurements one might undertake on environmental samples for predicting the presence of viable virus, rather than reliance on cultivation (PFU) assays. One idea recently discussed by Wölfel et al.[13] is to look for subgenomic mRNAs made by the virus during its life cycle in a human cell but not packaged into mature virions. These subgenomic mRNAs, if detected directly in a clinical sample, signify that the virus has been actively replicating in host cells in the sample at the time the sample was expelled from the body. This approach was used by Wölfel et al. to argue for active SARS-CoV-2 replication in the throat of COVID-19 patients during

[13] Wölfel et al. 2020. Virological assessment of hospitalized cases of coronavirus disease 2019. https://www.medrxiv.org/content/10.1101/2020.03.05.20030502v1.full.pdf (accessed March 25, 2020).

the first 5 days after symptoms onset. This approach could conceivably be used to assess the possibility of recent active viral replication in environmental swab samples.

An important caveat regarding the results from experimental studies relates to their relevance to real-world conditions. For example, many of the experimental environmental survival studies have used virus grown in TC media. It is quite possible that virus from naturally infected humans when directly disseminated to the nearby environment has different survival properties than virus grown in TC media, even when the latter is purified and spiked into a relevant human body fluid such as saliva. However, environmental dissemination of clinically relevant human fluids spiked with TC-grown virus will be more predictive of real-world environmental survival than environmental dissemination of TC-grown virus in TC media. Important human clinical matrices into which virus should be spiked include saliva, respiratory (including nasal) mucus and lower respiratory tract airway secretions, urine, blood, and stool. In addition, nebulized saline should be spiked and studied. Another issue related to experimental conditions is the effect of humidity on viral stability. Aerosol studies to date have tended to use humidity levels for culture media that are more favorable for viral decay (e.g., 50-65% relative humidity). Real respiratory fluid is likely to be more protective of infectivity, and indoor relative humidity in wintertime in temperate regions is usually 20-40%, a range that is more favorable for virus survival. Consequently, the half-lives reported to date may represent the lower end of the range. Differences in experimental conditions across studies (e.g., viral growth media, viral titer determination methods, infectivity of the inoculum) would be expected to contribute to variation in study results.

Before too many public health decisions are made on the basis of experimental or natural history studies using just one virus strain, some attention should be paid to the possibility of variation among different SARS-CoV-2 strains in their environmental survival properties. Different isolates from early and late in the pandemic, and from different geographic regions, should be studied and compared.

Registries of patient data and patient samples (e.g., nasopharyngeal, sera, urine, stool) are being created and can be used in future studies examining environmental persistence of the virus. For example, such samples could be used as clinical matrices to look at SARS-CoV-2 persistence on surfaces.

QUESTION 2: INCUBATION PERIOD

We approach this question in a similar way, examining first experimental studies and then natural history studies: (A) experimental studies, typically involving the inoculation of animals in the laboratory using a laboratory-propagated virus under controlled conditions and subsequent monitoring for onset of viral shedding, signs of disease, or other physiological responses; and (B) natural history studies, typically involving longitudinal or cross-sectional studies of naturally exposed humans and the collection of data on time of exposure and time of onset of signs, symptoms, and virological and molecular features of infection and disease. Each approach has strengths and weaknesses: with experimental studies there is control over time of exposure and various features of the inoculum, but non-human animals to varying degrees fail to reflect the natural history of infection in humans; with natural history studies, the host

is relevant, but the time and nature of the exposure is less well understood and sample availability is uncertain.

A. Experimental Studies

As mentioned above, experimental infections in non-human primates are planned or are under way at several sites in the United States, including the Tulane University National Primate Research Center and RML,[14] and presumably in other countries. While animal models are very important for understanding pathogenesis and responses to therapeutic and vaccine candidates, they are not as helpful with the incubation period studies given physiological differences across species.

B. Natural History Studies

In a recent preprint from Shaanxi, China, and New York, Men et al. examined confirmed cases of COVID-19 from 10 regions in China, other than Hubei province, for whom there were data on time of exposure and time of disease onset.[15] A Monte Carlo simulation was employed to estimate incubation period, along with additional statistical analysis to assess relationships between different age and gender groups. In this study, the mean and median incubation periods were estimated to be 5.84 and 5.0 days, respectively. Patients 40 years or older had a longer incubation period and larger variance than did patients younger than 40 years. There was no statistically significant difference in incubation period based on gender. These findings suggest that different periods of quarantine may be advisable based on age. However, these results need to be confirmed through additional studies and with further stratification of incubation period results by age group.

In a recent preprint from the National Institute of Allergy and Infectious Diseases, Peking University, and the Chinese Center for Disease Control and Prevention, Qin et al. identified asymptomatic individuals at their time of departure from Wuhan and followed them until symptoms arose.[16] This method was reported to offer enhanced accuracy by reducing recall bias and by utilizing forward time data. More than 1,000 cases were collected from publicly available data. They found that the estimated median incubation period was 8.13 days, the mean was 8.62 days, the 90th percentile was 14.65 days, and the 99th percentile 20.59 days. Compared to other studies, this incubation period is longer. They conclude that ~10% of patients with COVID-19 do not develop symptoms until 14 days after infection.

In a recent preprint from Guangzhou and Hong Kong, He et al. reported on temporal patterns of viral shedding in 94 laboratory-confirmed COVID-19 patients and modeled COVID-19 infectiousness from a separate sample of 77 infector-infectee

[14] Personal communication, Chad Roy, Tulane University National Primate Research Center, March 24, 2020.

[15] Men et al. 2020. Estimate the incubation period of coronavirus 2019 (COVID-19). https://www.medrxiv.org/content/10.1101/2020.02.24.20027474v1.full.pdf (accessed March 25, 2020).

[16] Qin et al. 2020. Estimation of incubation period distribution of COVID-19 using disease onset forward time: A novel cross-sectional and forward follow-up study. https://www.medrxiv.org/content/10.1101/2020.03.06.20032417v1.full.pdf (accessed March 25, 2020).

transmission pairs.[17] They observed the highest viral load in throat swabs at the time of symptom onset, and inferred that infectiousness peaked on or before symptom onset. They estimated that 44% of transmissions may occur before the first symptoms of the index case.

C. Caveats, Needs

Robust estimates of the distribution of the incubation period and the period of infectiousness for SARS-CoV-2 are critically important to inform public health messaging. Differences in incubation period findings among existing studies may relate to methodological differences, limited sample sizes, recall bias, or inadequate follow-up (potentially missing people who have longer incubation periods). Given the small number of human studies evaluating these disease characteristics for COVID-19, additional studies to confirm incubation period estimates and infectiousness prior to symptom onset are urgently needed. For public health management, it makes a great deal of difference whether 1% of patients will develop the disease after 14 days (if the mean incubation is approximately 5 days) or whether the fraction is 10% of patients (if the mean incubation period is approximately 8 days). Additional studies should examine variables that may have an impact on incubation period, which, besides age (see Men et al. above), may include inoculum size, immune competency of host, co-infecting agents, and underlying morbid conditions. Prospective longitudinal studies are most effective for addressing this issue. An obvious challenge is precise identification and timing of natural exposures. Additionally, as mentioned above, it is conceivable that the evolution of new SARS-CoV-2 strain variants will be accompanied by different properties, including incubation period. Prior to changing current public health guidance, it may be prudent to compare observed incubation periods among different SARS-CoV-2 strains. Future studies related to incubation period and viral loads in asymptomatic patients may help to inform pressing questions related to, for example, the role of super spreaders and children in transmission.

Respectfully,
David A. Relman, M.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

[17] He et al. 2020. Temporal dynamics in viral shedding and transmissibility of COVID-19. https://www.medrxiv.org/content/10.1101/2020.03.15.20036707v2.full.pdf (accessed March 25, 2020).

Rapid Expert Consultation on Crisis Standards of Care for the COVID-19 Pandemic (March 28, 2020)

March 28, 2020

ADM Brett Giroir, M.D.
Assistant Secretary for Health
200 Independence Avenue, SW
Washington, DC 20201

Robert Kadlec, M.D.
Assistant Secretary for Preparedness and Response
200 Independence Avenue, SW
Washington, DC 20201

Dear ADM Giroir and Dr. Kadlec:

Attached please find a rapid expert consultation that was prepared by the co-conveners of the Crisis Standards of Care working group, John Hick and Dan Hanfling, with input from others listed in the attachment, and conducted under the auspices of the National Academies of Sciences, Engineering, and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats.

Building on the previous decade of National Academies reports, the aim of this rapid expert consultation is to articulate the guiding principles, key elements, and core messages that undergird Crisis Standards of Care decision making at all levels. It does not, and in our opinion should not, attempt to dictate exactly what choice should be made under exactly what circumstance, as that depends on the specific circumstances of

the case at hand, and these must be left to the judgment of the professional, institutional, community, and civic leaders who are best situated to understand the local reality.

In my opinion, one of the most important components of the rapid expert consultation is the core principle derived from earlier reports, namely, that Crisis Standards of Care compel thinking in terms of what is best for an entire group of patients, on the principle of saving the most lives (or achieving the best outcome for the group of patients) rather than focusing only on an individual patient under your care. When equipment, staffing, and material are sufficient, focusing only on what is best for each individual patient is tantamount to the best outcome for the collection of patients because the group outcome is simply the sum of the individual outcomes. Under conditions that compel Crisis Standards of Care, this identity of outcomes for the individual and group breaks down, and the decision makers cannot avoid the hard choices before them. We hope these principles, elements, and messages can assist in discussing and making these difficult, heart-rending decisions.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

This rapid expert consultation responds to your March 25 request to provide a rationale for the implementation of crisis standards of care (CSC) in response to the COVID-19 outbreak. Also discussed are the broad principles and core elements of CSC planning and implementation. This discussion builds on a 10-year foundation of three seminal reports on CSC issued in 2009, 2012, and 2013 by the Institute of Medicine (IOM), which are described in Appendix A at the end of this document.

This document is meant to provide principles and guidance. It is neither appropriate nor feasible for us to detail actual choices and preferences that apply to specific situations, each of which depends on the exigencies of the epidemic relative to locally available facilities, equipment, personnel, and other needed resources. Rather, this document describes the basis upon which to carry out such decision making whenever it has to happen.

Catastrophic emergencies are by their very nature disruptive and life altering. They can have far-reaching societal impacts, even challenging fundamental assumptions about how we live and what we take for granted. Nowhere is this more evident than when medical facilities cannot deliver the usual level of care to all those who need medical attention. This is the current and likely future reality for many institutions caring for the growing numbers of patients with SARS-CoV-2 infection.

CRISIS STANDARDS OF CARE DEFINITION, GUIDING PRINCIPLES, AND KEY ELEMENTS OF PLANNING

Crisis standards of care are applied when a pervasive or catastrophic disaster make it impossible to meet usual health care standards.

GUIDING PRINCIPLES

- Health care planning must do everything possible never to need CSC.
- CSC have the joint goals of extending the availability of key resources and minimizing the impact of shortages on clinical care.
- CSC strive to save the most lives possible, recognizing that some individual patients will die, who would survive under usual care.
- Implementation of CSC will require facility-specific decisions regarding the allocation of limited resources, including how patients will be triaged to receive life-saving care.

KEY ELEMENTS OF CSC PLANNING

Ethical Grounding

- During a catastrophic crisis, it is vitally important to uphold the core ethical principles of fairness, duty to care, duty to steward resources, transparency in decision making, consistency, proportionality, and accountability.
- When resource scarcity reaches catastrophic levels, clinicians are ethically justified—and, indeed, are ethically obligated—to use the available resources to sustain life and well-being to the greatest extent possible.

Engagement, Education, and Communication

- CSC planning must involve both providers and the public in order to ensure the legitimacy of the process and the standards.
- These CSC planning processes must be proactive, honest, transparent, and accountable regarding the state of the U.S. health care system as COVID-19 cases increase, in order to warrant the public's trust.
- Senior leadership must prepare health care workers for the possible need for CSC and support them as they face the decisions that violate usual care standards.

continued

Legal Considerations

- Health care workers who must make difficult decisions implementing CSC must have adequate guidance and legal protections.
- Under disaster conditions, adherence to core constitutional principles remains a constant, but other statutory or regulatory provisions can be altered as necessary in real time.

Indicators, Triggers, and Responsibility

(Examples of hospital indicators, triggers, and tactics for transitions along the continuum of care are outlined in Appendix A.)

- Institutions must be alert to indicators that signal a shift to CSC levels of care.
- Observation of those indicators should trigger plans for initiating the contingency or crisis care standards.

Evidence-Based Clinical Operations

- Decisions made at the bedside should be evidence-based.
- Current predictive scoring systems of patient outcomes have unclear value in the COVID-19 context.
- Evidence-based care guidelines may emerge over the course of the pandemic, and with them, CSC guidelines should also evolve, if feasible.

Shifting to CSC is the only ethically tenable approach to shortages of health care resources. Ultimately, this shift represents not a rejection of ethical principles but their embodiment.

THE CONTINUUM OF CARE

Standards of care fall along a continuum of three levels, reflecting the incremental surge in demand relative to available health care resources:

- *Conventional care* is everyday health care services.
- *Contingency care* arises when demand for medical staff, equipment, or pharmaceuticals begins to exceed supply. Contingency care seeks functionally equivalent care, recognizing that some adjustments to usual care are necessary.
- *Crisis care* occurs when resources are so depleted that functionally equivalent care is no longer possible.

Appendix A provides examples of the kinds of shortages that can trigger CSC.

THE GOAL OF CSC PLANNING

The transition from conventional to contingency to crisis care comes with a concomitant increase in morbidity and mortality. Thus, it is crucial that planning ensure that

CSC is never needed, proactively moving resources ahead of when they are needed. When the system is at risk of becoming overwhelmed, the goal then becomes to conserve, substitute, adapt, and reuse, so that, only in the most extreme of circumstances, are CSC needed.

THE KEY ELEMENTS OF CSC PLANNING

Here, we elaborate briefly on the five key elements of CSC planning:

- A strong ethical grounding;
- Integrated, continuing community and provider engagement, education, and communication;
- Assurances regarding legal authority and environment;
- Clear indicators, triggers, and lines of responsibility; and
- Evidence-based clinical processes and operations.

Ethical Grounding. During a crisis, it is vitally important to adhere to core ethical principles: fairness, the duty to care, the duty to steward resources, transparency in decision making, consistency, proportionality, and accountability. Medical decisions informed by these ethical principles may allow for actions that would be unacceptable under ordinary circumstances, such as not providing some patients with resources when other patients would derive greater benefit from them. When resource scarcity reaches catastrophic levels, clinicians are ethically justified—and indeed are ethically obligated—to use the available resources to sustain life and well-being to the greatest extent possible.

Engagement, Education, and Communication. Both providers and the public must be engaged in CSC planning both to ensure the legitimacy of the process and the resulting standards and to achieve the best possible result. Both the public and health care providers must understand these difficult choices and be engaged in developing the criteria for making them. Those criteria must then be clear enough that practitioners can apply them when making decisions at the bedside, especially when the stewarding of scarce resources means withholding or withdrawing critical care services. Those criteria must reflect the values, wishes, and interests of all patients, especially the most vulnerable.

In the current pandemic, public trust is essential. To this end, health care leaders must be proactive, honest, transparent, and accountable when communicating the state of their institutions and the system as a whole. Given the resources available at the start of the crisis and expected during the immediate period, demand for health care services, especially in critical care, will soon outstrip health care providers' ability to deliver usual care in many communities, as has already occurred in several metropolitan areas. Reports on extreme conditions elsewhere may not prepare the public for the shift to CSC in their own hometowns. Health care and political leaders have a duty to forewarn the public about what is coming, and the implications of CSC.

Senior leaders must also provide material and moral support to health care workers, who will bear the physical, health, and psychological burdens of working under CSC

conditions. Providing that support will require careful, consistent messaging; ongoing two-way communication; and attention to the needs created by grueling, stressful work.

Legal Considerations. The law must inform CSC and create incentives for protecting the public's health and respecting individual rights. Extreme scarcity can necessitate difficult life-and-death decisions. Health care workers who will have to make them must have adequate guidance and legal protections. They must be able to follow the rule of law, even under disaster conditions.

At the same time, health care workers must be continually and clearly informed about all relevant changes in statutory or regulatory provisions. These legal issues may affect (1) the organization of key personnel, (2) fair access to treatment, (3) coordination of services within and across health systems, (4) assurance of patients' interests, (5) allocation of scarce resources, (6) protection of health care workers and volunteers from unwarranted liability claims, (7) reimbursement of costs incurred when protecting the public's health, and (8) interjurisdictional cooperation and coordination.

Indicators, Triggers, and Responsibility. Communities must be alert to indicators that signal a shift in the level of care that can be delivered. Under pandemic conditions, changes can occur rapidly. Being as prepared as possible requires situational awareness, open lines of practical and risk communication, and clear lines of authority and responsibility. Appendix A provides examples of such signals.

Evidence-Based Clinical Operations (Making Clinical Decisions Under Crisis Conditions). Bedside decisions should be evidence-based, drawing on clinical research and experience as consistently and transparently as possible. These should evolve as evidence accrues. For the current situation, existing prospective tools are insufficient for decision making. For example, Sequential Organ Failure Assessment (SOFA) scores have proven to be poor predictors of individual patients' survival, particularly for those with primary respiratory failure. Hence, at their current state of development, these scores are not suitable for excluding patients with respiratory failure from SARS-CoV-2 from receiving critical care. Similar reservations apply to other currently available decision support tools, although their value may improve as experience accumulates with patients having SARS-CoV-2 infection. Even in the face of imperfect data, decision making will be needed at multiple levels. Governments and institutions should consider these criteria proactively, and disseminate them publicly and transparently. This will permit public input and enable better response to evolving science and local circumstances. A useful summary of ethical guidelines and list of resources has been compiled by The Hastings Center.[1]

It is important to separate triage at each level of care from care provided at the bedside. This enables caregivers to better fulfill their ethical obligations to individual patients, while other decision-making processes ensure care provides the greatest good for the greatest number. Governments at all levels, institutions, and frontline caregivers

[1] Berlinger et al. 2020. Ethical framework for health care institutions & guidelines for institutional ethics services responding to the coronavirus pandemic: Managing uncertainty, safeguarding communities, guiding practice. The Hastings Center. https://www.thehastingscenter.org/ethicalframeworkcovid19 .

should recognize that these decisions are difficult and inherently involve ethical concerns. Ongoing peer and psychological support for those involved will be essential for them to continue their work.

THE BOTTOM LINE

Despite efforts to forestall the spread of SARS-CoV-2 to date, it appears that the COVID-19 outbreak will continue expanding across the United States. We can, therefore, anticipate that a growing number of hospitals will face medical needs that outpace the existing supply of ventilators, protective equipment, and other essentials, as well as the rate that enhanced supply can be produced, acquired, and put into place. These circumstances will require a shift to CSC.

Preparing for CSC means taking all feasible measures—including reuse, substitution, conservation, and administrative controls—to prevent or delay the need for CSC as long as possible. These measures must be taken at all levels of government, the health care system, and society. There is also an imminent need to prepare for difficult decisions about allocating limited resources, triaging patients to receive life-saving care, and minimizing the negative impacts of delivering care under crisis conditions. These preparations and the decisions that arise from them should be transparent and shared with the public. We hope the principles and elements of CSC planning outlined here will help decision makers at all levels.

Preparations for CSC include trustworthy communication with all stakeholders. Both the content and the process of those communications must convey the messages in the box below, which summarize the principles in the three seminal IOM reports on CSC. Failure to communicate regarding the shift to CSC will diminish public trust in health care providers and systems, as well as in government leadership. Without clear, consistent, candid communication, lost faith in institutions could become one more victim of COVID-19.

KEY MESSAGES AND PRINCIPLES

The following key messages and principles drawn from the three seminal Institute of Medicine (IOM) reports, described in Appendix A, can serve as a starting point for introducing the commitments of those responsible for the shift to CSC in response to COVID-19:

- **We, the health care community, are doing everything possible to prevent and avoid crisis conditions and maintain conventional standards of care.** We are partners with the rest of society in slowing the spread of disease to decrease the number of people who may need critical care at the same time.

continued

- **We recognize that the principal goal of implementing CSC is to maximize benefits to society, which includes saving as many lives—patients, health care workers, and front-line first responders—as possible.** CSC decisions allocate scarce treatment resources to those patients who are most likely to benefit, consistent with community values as articulated by bodies convened for this purpose (see Appendix A). Applying this overarching principle requires wise stewardship of medical resources, so that health care workers can help as many patients as possible. They need government, business, and health care systems to increase the supply and timely delivery of needed resources.
- **We are committed to creating CSC strategies that are fair, equitable, and responsive in order to maximize the safety of providers and patients.** Fairness is of paramount importance in the allocation of scarce life-saving medical resources.
- **We will communicate CSC in clear, consistent terms, through channels relevant to diverse stakeholder audiences.** We will speak with one voice to convey governmental commitment to a deliberate, thoughtful process on making these decisions of grave importance. We will draw on relevant research and community experience.
- **We anticipate that conditions will change as the pandemic spreads nationally, leading to dynamic shifts in standards of care, across communities and facilities.** We will apply the best available science to forecast those needs, address them equitably, and communicate the rationale for our actions.
- **We will consider patient and family preferences insofar as possible, within the constraint of allocating resources with the goal of saving the most patient and provider lives.** We will respect patients' dignity and preserve their comfort in all instances.
- **We will prepare adequately for the emotional impacts of CSC on health care workers, patients, their loved ones, and the public as a whole.** We will address the behavioral health needs of health care workers, patients, and their families, knowing the distress that CSC decisions will bring. We will explain these decisions and demonstrate empathy with the distress and losses.

Respectfully,
John Hick, M.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Dan Hanfling, M.D.
Co-Chair
2009, 2012, and 2013 Institute of Medicine Crisis Standards of Care committees

APPENDIX A

Foundational Work of the Institute of Medicine

A decade ago, during the period between the first and second waves of the H1N1 pandemic, the Institute of Medicine (IOM) convened a committee to address the following fundamental questions related to crisis standards of care (CSC):

- Who should receive care when not all who need it can be attended to?
- How should decisions be made about who gets access to care?
- Should the standard of care change to reflect the care that can be delivered under such circumstances?

The answers to these core questions formed the basis for the recommendations in the IOM's 2009 Letter Report.[2] One of those recommendations was to "enable specific legal/regulatory powers and protections for health care providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facilities" in the response to such events. The Letter Report also emphasized that CSC should be "formally declared by a state government" in recognition that crisis care operations "will be in place for a sustained period of time."

Building on this work, the IOM in 2012 issued a report[3] articulating a systems framework for catastrophic disaster planning and response, highlighting specific steps that key stakeholders—hospitals and health systems, public health and public safety agencies, emergency medical services, and providers of outpatient medical services—would need to take to prepare for health care delivery under crisis conditions. The third report, published in 2013,[4] focused on the development of a toolkit identifying the indicators, triggers, and tactics needed to transition from conventional care to CSC.

These reports are as timely and relevant today as they were the day they were released. The conditions under which CSC must be considered as a possibility clearly exist today, given the rapid spread of COVID-19 in communities across the United States and the resulting declarations of a public health emergency by U.S. Department of Health and Human Services Secretary Azar; a national emergency by President Trump; and emergency declarations by every U.S. state and territory, as well as hundreds of municipalities.[5]

All decision makers engaged in the response to the COVID-19 outbreak will be challenged to answer crucial, complex questions reflecting the ethical, legal, clinical, political, and societal dimensions of this crisis. They will need to make difficult decisions about the allocation of resources, decisions with life-and-death consequences. The

[2] Institute of Medicine. 2009. *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report*. Washington, DC: The National Academies Press. https://doi.org/10.17226/12749.

[3] Institute of Medicine. 2012. *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response: Volume 1: Introduction and CSC Framework*. Washington, DC: The National Academies Press. https://doi.org/10.17226/13351.

[4] Institute of Medicine. 2013. *Crisis Standards of Care: A Toolkit for Indicators and Triggers*. Washington, DC: The National Academies Press. https://doi.org/10.17226/18338.

[5] Descriptions of the emergency, disaster, and public health emergency categories can be found at https://www.networkforphl.org/resources/emergency-legal-preparedness-covid19.

CSC framework, expressed in the recommendations and guidance of the IOM reports constitute the foundation for this rapid expert consultation and can guide our nation's response.

APPENDIX B

Authors and Reviewers of This Rapid Expert Consultation

This rapid expert consultation was prepared by Dan Hanfling, In-Q-Tel, and John Hick, Hennepin County Medical Center, as the co-conveners of the CSC working group under the auspices of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. The working group for this document included the following individuals: Donald Berwick, Institute for Healthcare Improvement; Richard Besser, Robert Wood Johnson Foundation; Carlos del Rio, Emory Vaccine Center; James Hodge, Arizona State University; Kent Kester, Sanofi Pasteur; Jennifer Nuzzo, Johns Hopkins Bloomberg School of Public Health; Tara O'Toole, In-Q-Tel; Richard Serino, Harvard T.H. Chan School of Public Health; Beth Weaver, RESOLVE; and Matthew Wynia, University of Colorado Center for Bioethics and Humanities.

Harvey Fineberg, chair of the Standing Committee, approved this document. The following individuals served as reviewers: Baruch Fischhoff, Carnegie Mellon University; Bernard Lo, The Greenwall Foundation; Nicole Lurie, Coalition for Epidemic Preparedness Innovations and Harvard University; and Monica Schoch-Spana, Johns Hopkins Bloomberg School of Public Health. Ellen Wright Clayton, Vanderbilt University Medical University, and Susan Curry, University of Iowa, served as arbiters of this review on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

Rapid Expert Consultation on the Possibility of Bioaerosol Spread of SARS-CoV-2 for the COVID-19 Pandemic (April 1, 2020)

April 1, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Dr. Droegemeier:

This letter responds to your question concerning the possibility that SARS-CoV-2 could be spread by conversation, in addition to sneeze/cough-induced droplets.

Currently available research supports the possibility that SARS-CoV-2 could be spread via bioaerosols generated directly by patients' exhalation. One must be cautious in imputing the findings with one respiratory virus to another respiratory virus, as each virus may have its own effective infectious inoculum and distinct aerosolization characteristics. Studies that rely on polymerase chain reaction (PCR) to detect the presence of viral RNA may not represent viable virus in sufficient amounts to produce infection. Nevertheless, the presence of viral RNA in air droplets and aerosols indicates the possibility of viral transmission via these routes.

A recent study of SARS-CoV-2 aerosolization at the University of Nebraska Medical Center showed widespread presence of viral RNA in isolation rooms where patients with SARS-CoV-2 were receiving care. Santarpia et al. collected air and surface samples from 11 isolation rooms that were used to care for patients infected with SARS-CoV-2. Included in that study were both high volume air samples and low volume personal air samples. Of note, air collectors positioned more than 6 feet from each of two patients

yielded samples positive for viral RNA when evaluated using reverse-transcriptase PCR (RT-PCR), as did air samplers placed outside patient rooms in the hallways. Personal collectors worn by samplers also were positive even though patients were not coughing while samplers were present. Anecdotally, the highest airborne RNA concentrations were recorded by personal samplers while a patient was receiving oxygen through a nasal cannula (19.17 and 48.21 copies/L). While this research indicates that viral particles can be spread via bioaerosols, the authors stated that finding infectious virus has proved elusive and experiments are ongoing to determine viral activity in the collected samples.[1]

An airflow modeling study following the SARS-CoV-1 outbreak in Hong Kong in the early 2000s supports the potential for transmission via bioaerosols. In that study, the significantly increased risk of infection to residents on higher floors of a building that was home to an infected individual indicated to the researchers a pattern of infection consistent with a rising plume of contaminated warm air.[2]

In a recent study conducted at the University of Hong Kong, not yet subject to peer review, Leung et al collected respiratory droplets and aerosols from children and adults with acute respiratory illnesses with and without surgical masks. The investigators found human coronaviruses [other than SARS-CoV-2], influenza virus, and rhinovirus from both aerosols and respiratory droplets. Surgical masks reduced detection of coronavirus RNA in both respiratory droplets and aerosols, but only respiratory droplets and not aerosols for influenza virus RNA. These findings suggest that surgical face masks could reduce the transmission of human coronavirus and influenza infections if worn by infected individuals capable of transmitting the infection.[3]

A study of SARS-CoV-2 raises concerns about transmission via aerosols generated from droplet contaminated surfaces. Liu et al. collected 35 aerosol samples in 2 hospitals and public areas in Wuhan. From samples collected in patient care areas the highest concentration of the virus was found in toilet facilities (19 copies m^{-3}), and in medical staff areas the highest concentrations were identified in personal protective equipment (PPE) removal rooms (18-42 copies m^{-3}). By comparison, in all but two crowded sites, the concentrations of the virus found in public areas was below 3 copies m^{-3}. The authors conclude that a direct source of SARS-CoV-2 may be a virus-laden aerosol resuspended by the doffing of PPE, the cleaning of floors, or the movement of staff.[4] It may be difficult to resuspend particles of a respirable size. However, fomites could be transmitted to the hands, mouth, nose, or eyes without requiring direct respiration into the lungs.

[1] Santarpia et al. 2020. Transmission potential of SARS-CoV-2 in viral shedding observed at the University of Nebraska Medical Center. https://www.medrxiv.org/content/10.1101/2020.03.23.20039446v2.

[2] Yu et al. 2004. Evidence of airborne transmission of the severe acute respiratory syndrome virus. *New England Journal of Medicine* 350:1731-1739. DOI: 10.1056/NEJMoa032867.

[3] Leung et al. 2020. Respiratory virus shedding in exhaled breath and efficacy of face masks. Under review. DOI: 10.21203/rs.3.rs-16836/v1.

[4] Liu et al. 2020. Aerodynamic characteristics and RNA concentration of SARS-CoV-2 aerosol in Wuhan hospitals during COVID-19 outbreak. https://www.biorxiv.org/content/10.1101/2020.03.08.982637v1.

Individuals vary in the degree to which they produce bioaerosols through normal breathing.[5] This may have a bearing on efficiency of transmission of SARS-CoV-2 by different infected but asymptomatic individuals.

Additional research specific to the aerosolization of SARS-CoV-2 during breathing and speech, the behavior of SARS-CoV-2 containing aerosols in the environment, both from laboratory studies and clinical experience, and the infectivity of bioaerosols containing SARS-CoV-2, would provide a more complete understanding of the level of risk of transmission of SARS-CoV-2 via bioaerosols spread by exhalation and normal speech. However, for no respiratory virus is the exact proportion of infections due to air droplet, aerosol, or fomite transmission fully established, and many individual factors and situations may contribute to the importance of each route of transmission.

While the current SARS-CoV-2 specific research is limited, the results of available studies are consistent with aerosolization of virus from normal breathing.

This response was prepared by staff of the National Academies of Sciences, Engineering, and Medicine based on a rapid review of the available literature and input from me. Georges Benjamin, American Public Health Association, and Ed Nardell, Harvard University, contributed to this response. Bobbie Berkowitz, Columbia University School of Nursing, and Ellen Wright Clayton, Vanderbilt University Medical University, reviewed and approved this document on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

[5] Edwards et al. 2004. Inhaling to mitigate exhaled bioaerosols. *PNAS* 101(50):17383-17388. DOI: 10.1073/pnas.0408159101.

Rapid Expert Consultation on SARS-CoV-2 Survival in Relation to Temperature and Humidity and Potential for Seasonality for the COVID-19 Pandemic (April 7, 2020)

April 7, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Dr. Droegemeier:

Attached please find a rapid expert consultation on the topics of virus survival in relation to temperature and humidity and potential for seasonal reduction and resurgence of cases. This assessment was prepared by members of the National Academies of Sciences, Engineering, and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats.

The aim of this rapid expert consultation is to provide scientifically grounded principles that are relevant to decision making about the potential for seasonal variation of SARS-CoV-2.

We hope this document proves useful to you and your colleagues.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

This rapid expert consultation responds to your request concerning (1) survival of SARS-CoV-2 in relation to temperature and humidity; and (2) potential for seasonal reduction and resurgence in cases.[1]

In general, a common approach to issue 1 is with experimental studies in the laboratory, typically involving the deliberate dissemination of a laboratory-propagated virus under controlled environmental conditions with subsequent sampling. The most common approach to issue 2 is with natural history studies that observe disease transmission in different locations and times of year and seek correlations with environmental conditions such as temperature and humidity. Each approach has strengths and weaknesses: with experimental studies, environmental conditions can be controlled, but almost always the conditions fail to adequately mimic those of the natural setting; with natural history studies, the conditions are relevant and reflect the real world, but there is typically little control of environmental conditions and there are many confounding factors. Because the two approaches are so distinct, it is often difficult to harmonize the findings from the two, and relate the findings from one to the other.

LABORATORY STUDIES

In the *Rapid Expert Consultation Update on SARS-CoV-2 Surface Stability and Incubation for the COVID-19 Pandemic (March 27, 2020)* we reviewed laboratory studies of SARS-CoV-2 survival under controlled environmental conditions. We provide a slightly updated version of that review here. We note that since the March 27 rapid expert consultation, there is minimal new information published on this topic (e.g., one preprint is now published). Work is ongoing, but no results have been made available.

The laboratory data available so far indicate reduced survival of SARS-CoV-2 at elevated temperatures and variation in temperature sensitivity as a function of the type of surface on which the virus is placed. However, the number of well-controlled studies on the topic available at this time remains small. We anticipate new, relevant data within the next week or two, and in particular, data on surface survival of the virus under different levels of humidity, and aerosol survival with and without exposure to natural levels of ultraviolet (UV) radiation.

In a now published report from Hong Kong, Chin et al. examined the stability (using viral culture) of SARS-CoV-2 as a function of temperature, type of surface, and following the use of disinfectants.[2] With respect to temperature, using a starting suspension of 6.7 log $TCID_{50}$/ml in virus transport medium,[3] at 4°C there was only a 0.6-log unit reduction at the end of 14 days of incubation in this medium; at 22°C, a 3-log unit reduction after 7 days, and no detection at 14 days; and at 37°C, a 3-log unit reduction after 1 day and no virus detected afterward. No virus was detected after 30 minutes at 56°C or after 5 minutes at 70°C. With respect to survival on surfaces using a 5 μL droplet of virus culture at 7.8 log $TCID_{50}$/ml, no infectious virus was recovered from printing and tissue paper after 3 hours; no infectious virus was detected on cloth after

[1] A previous iteration of this rapid expert consultation is available upon request from SCEID@nas.edu. The previous iteration did not include the discussion on laboratory studies.

[2] Chin et al. Stability of SARS-CoV-2 in different environmental conditions. Lancet Microbe 2020. https://doi.org/10.1016/S2666-5247(20)30003-3.

[3] $TCID_{50}$ is the Median Tissue Culture Infectious Dose.

2 days or on stainless steel after 7 days. However, on the outside of a surgical mask, 0.1% of the original inoculum was detected on day 7. The persistence of infectious virus on personal protective equipment (PPE) is concerning and warrants additional study to inform guidance for health care workers. Such studies should also examine the effects of various treatments that might be used to disinfect PPE when they cannot be discarded after single use.

Chad Roy from the Tulane University National Primate Research Center shared via telephone some preliminary results of dynamic aerosol stability experiments with SARS-CoV-2 conducted over the past several weeks at the Infectious Disease Aerobiology Core program at Tulane.[4] His group generated an aerosol with a fairly uniform distribution of 2 micron particles, using virus grown in DMEM tissue culture (TC) medium and suspended in a rotating drum at an ambient temperature of ~23 °C and ~50% humidity. The aerosol was sampled longitudinally for up to 16 hours, and the virus was assessed for viability by growth (enumeration of plaque forming units [PFUs]) and morphology (electron microscopy). He reports surprisingly that SARS-CoV-2 has a longer half-life under these conditions than influenza virus, SARS-CoV-1, monkeypox virus, and *Mycobacterium tuberculosis*. As of March 24, he was waiting for some growth results, but expected to post a manuscript describing these findings to bioRxiv soon. This result is also concerning, but is quite preliminary; importantly, the details have not yet been shared.

George Korch and Mike Hevey from the National Biodefense Analysis and Countermeasures Center (NBACC), which was created by the U.S. Department of Homeland Security, shared their plans for an extensive series of experiments on SARS-CoV-2 environmental survival.[5] Because they share their plans with the White House Coronavirus Task Force, only a few observations are provided here. The NBACC is well suited for the kinds of studies it has planned, and the scope and relevance are noteworthy. In particular, it plans to create simulated infected body fluids, including saliva and lower respiratory secretions. It plans to test simulated solar radiation on virus survival, which is important. It also has already examined a wider range of relative humidity and temperature than some other groups, which is again, important. And it will compare RNA semi-quantitative measurements with viral growth (PFUs) on samples from all conditions, which is critical.

At Rocky Mountain Laboratories (RML), part of the National Institutes of Health, current studies include the effect of temperature and humidity on virus stability; virus stability in human body fluids, including urine and feces; and the effectiveness of decontamination procedures for PPE, including N95 respirators.[6]

There are important caveats regarding the results from experimental studies. The first caveat concerns the relevance of laboratory conditions to real-world conditions. For example, many of the experimental survival studies have used virus grown in TC media. One expects that virus from naturally infected humans when directly disseminated to the nearby environment has different survival properties than virus grown

[4] Personal communication, Chad Roy, Tulane University National Primate Research Center, March 24, 2020.

[5] Personal communication, George Korch and Mike Hevey, National Biodefense Analysis and Countermeasures Center, March 24, 2020.

[6] Personal communication, Vincent Munster, Rocky Mountain Laboratories, March 24, 2020.

in TC media, even when the latter is purified and spiked into a relevant human body fluid such as saliva. Having said this, environmental dissemination of clinically relevant human fluids spiked with TC-grown virus will be more predictive of real-world virus survival than environmental dissemination of TC-grown virus in TC media. Important human clinical matrices into which virus should be spiked include saliva, respiratory (including nasal) mucus and lower respiratory tract airway secretions, urine, blood, and stool. In addition, nebulized saline should be spiked and studied.

Another issue is humidity and the failure or inability of some laboratories to control and vary relative humidity for their experiments. For example, the Tulane Infectious Disease Aerobiology Core lab cannot vary humidity in a controlled fashion; whereas the NBACC is able to do so. Aerosol studies to date have typically used TC-grown virus and have therefore used humidity levels that are more favorable for viral decay (e.g., 50-65% relative humidity). Real respiratory fluid is likely to be more protective of infectivity, and indoor relative humidity in wintertime in temperate regions is usually 20-40%, a range that is more favorable for virus survival. Consequently, the half-lives reported to date under these conditions may represent the lower end of the range. Differences in experimental conditions across studies (e.g., viral growth media, viral titer determination methods, infectivity of the inoculum) would be expected to contribute to variation in study results.

Finally, attention should be paid to the possibility of variation in environmental survival among different SARS-CoV-2 strains. Isolates from early and late in the pandemic and from different geographic regions should be studied and compared.

NATURAL HISTORY STUDIES

Studies published so far have conflicting results regarding potential seasonal effects and are hampered by poor data quality, confounding factors, and insufficient time since the beginning of the pandemic from which to draw conclusions. There is some evidence to suggest that SARS-CoV-2 may transmit less efficiently in environments with higher ambient temperature and humidity; however, given the lack of host immunity globally, this reduction in transmission efficiency may not lead to a significant reduction in disease spread without the concomitant adoption of major public health interventions. Furthermore, the other coronaviruses causing potentially serious human illness, including both SARS-CoV and MERS-CoV, have not demonstrated any evidence of seasonality following their emergence.

The current pandemic started in the winter season mostly in northern latitudes, and less than 4 months ago, making it difficult to ascertain differences within a localized geographic region with changing seasons. Some analyses of variability across different geographic regions based on humidity and temperature are available. A study from China in the early part of the pandemic suggested that every 1°C elevation in ambient temperature led to a decrease in daily confirmed cases by 36-57% when relative humidity was between 67% to 85.5%, and every 1% increase in relative humidity decreased the daily confirmed cases by 11-22% when the average temperature was between 5.04°C and 8.2°C, but these findings were not consistent across mainland

China.[7] Another study in China concluded that increases in temperature and relative humidity can lower the reproductive rate, but the average R_0 was still close to 2 at maximum temperatures and humidity in their dataset, suggesting that the virus will still spread exponentially at higher temperatures and humidity.[8] Outside of China, a study looking at daily case growth rates in 121 countries or regions found the highest rates in temperate regions.[9] They found growth rates peaked in regions with a mean temperature of 5°C and decreased in warmer and colder climates. Temperature was the variable with the highest relative importance in explaining variations in growth rates although they did see fast growth rates in warmer climates and huge variations in regions with similar climates, suggesting that many factors contribute to transmission. Another study in 310 geographic regions across 116 countries also found an inverse relationship between temperature and humidity and incidence of COVID-19.[10] One study examined cities with significant community spread compared to those without spread and found greater disease rates in cities and regions along a narrow distribution within the 30-50° N' corridor (areas of lower average temperature and humidity), which is consistent with the behavior of seasonal respiratory viruses.[11] A study in countries that had at least 12 days of data found an increase in doubling time of virus transmission at warmer temperatures (average of 9.5°C versus 26.5°C), suggesting a slowing of disease spread at warmer temperatures.[12]

The results of these studies should be interpreted with caution, in the context of the limited time during which natural experiments have taken place in different locations. There are significant caveats in all of the studies presented, mostly related to data quality and the limitation in time and location, with the pandemic mostly in temperate regions during the winter months. Issues with data quality include the estimates of reproductive rate, assumptions about infectivity period, and short observational time windows. There are also important confounding factors associated with geography and hence, with temperature and humidity: access to and quality of public health and health care systems, per capita income, human behavioral patterns, and the availability of diagnostics. As a reflection of these confounding factors, those studies that show a significant correlation between temperature and humidity and disease transmission, also show that the two factors explain only a small fraction of the overall variation in transmission rates. Of note, a study by Luo et al. showed sustained transmission despite changes in weather in various parts of China that ranged from cold and dry to tropical arguing against any seasonal differences, although issues with data collection and

[7] Qi et al. 2020. COVID-19 transmission in Mainland China is associated with temperature and humidity: A time-series analysis. https://doi.org/10.1101/2020.03.30.20044099.

[8] Wang et al. 2020. High temperature and high humidity reduce the transmission of COVID-19. http://dx.doi.org/10.2139/ssrn.3551767.

[9] Ficetola and Rubolini. 2020. Climate affects global patterns of COVID-19 early outbreak dynamics. https://doi.org/10.1101/2020.03.23.20040501.

[10] Islam et al. 2020. Temperature, humidity, and wind speed are associated with lower COVID-19 incidence. https://doi.org/10.1101/2020.03.27.20045658.

[11] Sajadi et al. 2020. Temperature, humidity and latitude analysis to predict potential spread and seasonality for COVID-19. http://dx.doi.org/10.2139/ssrn.3550308.

[12] Notari. 2020. Temperature dependence of COVID-19 transmission. https://doi.org/10.1101/2020.03.26.20044529.

reporting, as with all of the studies, makes this analysis limited.[13] This study concludes that changes in weather alone will not necessarily lead to declines in cases without extensive public health interventions.

Some limited data support a potential waning of cases in warmer and more humid seasons, yet none are without major limitations. Given that countries currently in "summer" climates, such as Australia and Iran, are experiencing rapid virus spread, a decrease in cases with increases in humidity and temperature elsewhere should not be assumed. Given the lack of immunity to SARS-CoV-2 across the world, if there is an effect of temperature and humidity on transmission, it may not be as apparent as with other respiratory viruses for which there is at least some pre-existing partial immunity. It is useful to note that pandemic influenza strains have not exhibited the typical seasonal pattern of endemic/epidemic strains. There have been 10 influenza pandemics in the past 250-plus years—two started in the northern hemisphere winter, three in the spring, two in the summer, and three in the fall. All had a peak second wave approximately 6 months after emergence of the virus in the human population, regardless of when the initial introduction occurred.

Additional studies as the SARS-CoV-2 pandemic unfolds could shed more light on the effects of climate on transmission.

In summary, although experimental studies show a relationship between higher temperatures and humidity levels, and reduced survival of SARS-CoV-2 in the laboratory, there are many other factors besides environmental temperature, humidity, and survival of the virus outside of the host, that influence and determine transmission rates among humans in the "real world."

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
David A. Relman, M.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

APPENDIX

Authors and Reviewers of This Rapid Expert Consultation

This rapid expert consultation was prepared by staff of the National Academies of Sciences, Engineering, and Medicine, and members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats:

[13] Luo et al. 2020. The role of absolute humidity on transmission rates of the COVID-19 outbreak. https://doi.org/10.1101/2020.02.12.20022467.

Kristian Andersen, The Scripps Research Institute; David Relman, Stanford University; and David Walt, Brigham and Women's Hospital and Harvard Medical School.

Harvey Fineberg, chair of the Standing Committee, approved this document. The following individuals served as reviewers: Jim Chappell, Vanderbilt University Medical Center; Mark Denison, Vanderbilt University Medical Center; Michael Diamond, Washington University; Matthew Frieman, University of Maryland School of Medicine; Linsey Marr, Virginia Tech; Michael Osterholm, University of Minnesota; and Stanley Perlman, University of Iowa. Ellen Wright Clayton, Vanderbilt University Medical Center, and Susan Curry, University of Iowa, served as arbiters of this review on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic (April 8, 2020)

April 8, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Dr. Droegemeier:

Attached please find a rapid expert consultation on the uses, interpretation, and future directions of laboratory tests that was prepared by David Relman, David Walt, and Kristian Andersen, members of the National Academies of Sciences, Engineering, and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. Details on the authors and reviewers of this rapid expert consultation can be found in the Appendix.

The aim of this rapid expert consultation is to provide scientifically grounded principles that are relevant to decision making about the interpretation of laboratory tests.

This rapid expert consultation covers the current, pertinent studies and points the way to specific research needs in the days and months ahead. We hope this document proves useful to you and your colleagues.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

This rapid expert consultation responds to your request for information on the interpretation of laboratory tests, future developments, and research needs.

Laboratory confirmation with reliable, standardized testing is the gold standard for determining disease rates. However, especially early after recognition of a new infectious disease, tests with high sensitivity[1] and specificity[2] may not be available that can accurately and consistently separate individuals with the infection from individuals without the infection. It is important to note that clinical judgment, which usually takes into account the probability of infection based on exposure risk and a review of clinical signs and symptoms, is crucial in understanding an infectious disease such as COVID-19 and who may have it.

There are two general types of infectious disease tests—those that detect the disease agent directly (e.g., PCR tests for viral RNA) and those that detect a host response to the disease agent (e.g., serology tests that detect specific antibodies). An increasing number of purveyors now offer COVID-19 tests of each type.

DETECTION OF VIRAL RNA

Most COVID-19 tests in current use detect the disease agent directly and measure viral RNA. Viral RNA indicates current infection and suggests infectivity and transmission risk for others; however, the presence of viral RNA in an individual, especially late in infection, may represent viral remnants rather than intact virus particles capable of transmission. Additional studies on the temporal dynamics of viral RNA in infected persons, across body sites and fluids, and correlations of these measurements with risk of transmission to other individuals, are sorely needed—as is a much greater capacity to perform these tests nationwide.

Current clinical tests for SARS-CoV-2 rely on the detection of viral RNA, using reverse-transcriptase polymerase chain reaction (RT-PCR) or loop-mediated isothermal amplification (LAMP) in nasopharyngeal (NP), oropharyngeal (OP), sputum, or saliva samples. RT-PCR tests have been widely used for the diagnosis of COVID-19. A retrospective study suggested that these tests may be less sensitive in identifying the early phases of disease than computed tomography (CT) scans of the chest, and other clinical and laboratory findings.[3] One study of 51 patients with COVID-19, diagnosed on the basis of a positive RT-PCR at any time during the course of their illness, found that only 35 of the 51 had a positive RT-PCR at the time of clinical presentation, while 50 of the 51 had abnormal CT findings at the time of presentation.[4] Neither this nor other studies we have found pinpoint the reasons for false negative results on initial PCR tests, but the reasons may include stage of illness, lower amounts of virus in certain anatomic sites and in certain patients, and suboptimal sample collection methods.

[1] Sensitivity: The probability of a positive test result in a patient who has the disease. An error in sensitivity produces a false negative result.

[2] Specificity: The probability of a negative test result in a patient who does not have the disease. An error in specificity produces a false positive result.

[3] Xu et al. 2020. Analysis and prediction of false negative results for SARS-CoV-2 detection with pharyngeal swab specimen in COVID-19 patients: A retrospective study. https://doi.org/10.1101/2020.03.26.20043042.

[4] Fang et al. 2020. Sensitivity of chest CT for COVID-19: Comparison to RT-PCR. *Radiology*. https://doi.org/10.1148/radiol.2020200432.

LAMP testing methods developed for SARS-CoV in 2004 were found to be more rapid, more simple to perform, and cheaper than conventional methods.[5] LAMP also appears to be sensitive and specific for SARS-CoV-2 when compared to RT-PCR, using spiked non-patient samples.[6] Large cohort studies are now under way to test whether these advantages hold up.

Rapid tests that detect viral RNA include Cepheid's SARS-CoV-2 cartridge[7] for use on its rapid PCR Xpert platform with a 45-minute turn-around, and Abbott's ID NOW COVID-19 isothermal amplification test[8] for use on its ID NOW platform with results in less than 15 minutes. Both of these tests are helpful toward building local capacity, but at the time of this rapid expert consultation (April 8), neither had achieved levels of production that come close to meeting national needs. Their use will be limited to sites that have invested in those instrument platforms; in addition, the robustness of their supply chains has not been adequately confirmed. Rapid tests like these will be most valuable in assessing patients for whom emergency procedures such as surgery, if undertaken without a test result, might pose a high risk of disease transmission.

Although not yet in the clinical workplace, a CRISPR-Cas12 or -Cas13 based diagnostic test for SARS-CoV-2 might offer advantages over current technologies. CRISPR-Cas12 and -Cas13 provide for high sensitivity (can detect as few as 10 gene copies), specificity, portability, easy read-out (e.g., colorimetric with paper strips), speed (~45 minutes), and low cost (few dollars per sample).[9,10,11]

A recent report indicates that viral RNA can be detected by RT-PCR directly in NP swab samples without the need for an RNA extraction step, presumably due to the high burden of infection at this body site and the shedding of viral RNA from dead and lysed host cells.[12] In this report, there was only a 20-fold decrease in sensitivity of viral detection; other reports suggest ~100-fold loss in sensitivity. This is an important finding in the event that current shortages of RNA extraction kits continue or worsen.

One approach for increasing the scale of PCR testing relies on pooling samples for initial screening, with follow-up testing of subsets of the original pool if the initial screen produces a positive result.[13] While early tests of this approach are promising and this

[5] Thai et al. 2004. Development and evaluation of a novel loop-mediated isothermal amplification method for rapid detection of severe acute respiratory syndrome coronavirus. *Journal of Clinical Microbioliogy* 42(5):1956-1961.

[6] Lamb et al. 2020. Rapid detection of novel coronavirus (COVID-19) by reverse transcription-loop-mediated isothermal amplification. https://doi.org/10.1101/2020.02.19.20025155.

[7] Cepheid. 2020. Xpert Xpress SARS-CoV-2 has received FDA Emergency Use Authorization. https://www.cepheid.com/coronavirus (accessed April 2, 2020).

[8] Abbott. 2020. Detect COVID-19 in as little as 5 minutes. https://www.abbott.com/corpnewsroom/product-and-innovation/detect-covid-19-in-as-little-as-5-minutes.html (accessed April 2, 2020).

[9] Kellner et al. 2019. SHERLOCK: Nucleic acid detection with CRISPR nucleases. *Nature Protocols* 14:2986-3012.

[10] Lucia et al. 2020. An ultrasenstitive, rapid, and portable coronavirus SARS-CoV-2 sequence detection method based on CRISPR-Cas12. https://doi.org/10.1101/2020.02.29.971127.

[11] Metsky et al. 2020. CRISPR-based surveillance for COVID-19 using genomically-comprehensive machine learning design. https://doi.org/10.1101/2020.02.26.967026.

[12] Bruce et al. 2020. RT-qPCR detection of SARS-CoV-2 RNA from patient nasopharyngeal swab using Qiagen RNeasy kits or directly via omission of an RNA extraction step. https://biorxiv.org/content/10.1101/2020.03.20.001008v1 (accessed April 2, 2020).

[13] Yelin et al. 2020. Evaluation of COVID-19 RT-zPCR test in multi-sample pools. https://doi.org/10.1101/2020.03.26.20039438.

type of multiplexing strategy has worked in other disease screening scenarios, it will require further validation. If pooled samples prove feasible, pooling could multiply the throughput of test facilities by 5- or 10-fold, depending on the prevalence of positive results in the sampled population.

DETECTION OF HOST IMMUNE RESPONSE

Tests of the second type (i.e., those that detect a host response to the disease agent) typically measure specific antibodies to the agent, and a number of these so-called serological tests for SARS-CoV-2 are coming online as well. These tests also offer useful information, but the utility and meaning of serological information are quite distinct from the utility and meaning of viral RNA diagnostic test results. Serological tests measure whether an individual has been previously exposed to the agent; however, they have also been used to complement RT-PCR results in establishing a diagnosis later in the course of illness (see also *Rapid Expert Consultation on Viral Shedding and Antibody Response (April 8, 2020)*). IgM antibodies typically appear within days to about a week after the onset of symptoms, and persist for weeks to a month or two. They appear earlier than IgG antibodies but are less specific. IgG antibodies typically first appear in the bloodstream 2 weeks after infection and last for months and in some cases, years. Anti-SARS-CoV-2 antibodies of various types have been detected in COVID-19 patients a median of 5 to 14 days following symptom onset (see also *Rapid Expert Consultation on Viral Shedding and Antibody Response (April 8, 2020)*). Within a few weeks of infection, SARS-CoV-2 antibodies and viral RNA can both be present in the same individual. In general, serological results, especially IgM measurement, may be less specific than molecular tests. All SARS-CoV-2 serological study results should be viewed as suspect until rigorous controls are performed and performance characteristics described, as antibody detection methods can vary considerably, and most so far have not described well-standardized controls. Samples from patients with seasonal (non-SARS-CoV-2) coronavirus infections are especially important as negative controls (see below).

The presence of antibodies against an infectious agent can be a valuable marker for past infection in population-based epidemiologic studies, and they enable assessments of the efficacy of various public interventions in preventing disease spread. Antibodies can also indicate host immunity against the agent. However, in the case of SARS-CoV-2, it is not known whether the presence of antibodies indicates protection from illness.

A consideration of the human immune response to the four seasonal coronaviruses, and to previous emerging coronaviruses, is important to note here. By adulthood, almost everyone has antibodies against common viruses (hCoV-OC43, hCoV-229E, hCoV-HKU1, and hCoV-NL63); however, people still get infected with these viruses each winter. There are limited data on how this happens, what the antibodies in our blood actually recognize on these viruses, why naturally occurring antibodies do not protect us, how the seasonal coronaviruses mutate each year, and why we see them in the winter but not in the summer.

In analyses of antibody responses in individuals exposed to MERS-CoV, commercial ELISA kits in general exhibited good specificity but poor sensitivity compared to

a plaque reduction/neutralization titer assay used in a research laboratory.[14] Establishing standards with high sensitivity and specificity that are accepted and followed by all laboratories will be key to determining true exposure to SARS-CoV-2 and potential immunity and for obtaining validated results. In addition, in the case of MERS, as with SARS-CoV-2 (see above), high levels of antibody and of virus are often found in the same patient.[15] Measurements of T cell responses to SARS-CoV-2 may be useful as a complement to antibody assays, in the same fashion as with MERS-CoV.[16]

DETERMINATION OF INFECTIVITY

Current molecular tests for RNA do not determine whether there is viable virus in the specimen. For example, high levels of viral RNA can be found in stool samples, but infectious virus is typically not isolated from these samples.[17] Some types of viral RNA intermediates may be indicative of active replication in, or proximal to, the specimen. These RNAs are produced during the viral life cycle in a human cell but are not incorporated into the mature virus particle; thus, the presence of these RNAs indicates active replication, rather than previously assembled viable virus. The identification and development of assays for these non-packaged replicative RNA intermediates may have clinical utility in predicting an increased likelihood of the presence of infectious virus. Protein-based tests for virus are more likely to be superior in detecting infectivity than genomic tests as proteins are degraded more rapidly than viral RNA.

RESEARCH NEEDS

There are several important unmet needs, some of which are now the subject of ongoing research.

It would be quite helpful to have a test that identifies infected individuals before they are symptomatic and before they shed the virus and become infectious for others. One promising approach is to identify human genes that are expressed early in infection, perhaps in blood or saliva, with some specificity for the infection of interest. Work on broad classes of viral and bacterial infections suggests that this may be possible,[18,19] and groundwork on SARS-CoV-2 has begun.[20]

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[14] Alshukairi et al. 2018. High prevalence of MERS-CoV infection in camel workers in Saudi Arabia. *mBio* 9(5):e01985-18. DOI: 10.1128/mBio.01985-18.

[15] Corman et al. 2016. Viral shedding and antibody response in 37 patients with Middle East respiratory syndrome coronavirus infection. *Clinical Infectious Diseases* 62(4):477-483. DOI: 10.1093/cid/civ951.

[16] Zhao et al. 2017. Recovery from the Middle East respiratory syndrome is associated with antibody and T cell responses. *Science Immunology* 2:eaan5393. DOI: 10.1126/sciimmunol.aan5393.

[17] Wölfel et al. 2020. Virological assessment of hospitalized patients with COVID-2019. *Nature.* https://doi.org/10.1038/s41586-020-2196-x .

[18] Mayhew et al. 2020. A generalizable 29-mRNA neural-network classifier for acute bacterial and viral infections. *Nature Communications* 11:1177. https://www.nature.com/articles/s41467-020-14975-w (accessed April 4, 2020).

[19] Warsinske et al. 2019. Host-response-based gene signatures for tuberculosis diagnosis: A systematic comparison of 16 signatures. *PLOS Medicine* 16(4):e1002786. DOI: 10.1371/journal.pmed.1002786.

[20] Blanco-Melo et al. 2020. SARS-CoV-2 launches a unique transcriptional signature from in vitro, ex vivo, and in vivo systems. https://doi.org/10.1101/2020.03.24.004655.

A comprehensive mapping of antibody specificity during the course of SARS-CoV-2 infection (i.e., a survey of antibody reactivity and function) would greatly help in understanding variability in the outcome of infection in different individuals, risk stratification, the relationship of pre-existing antibody profiles with SARS-CoV-2 outcome, and the identification of optimal vaccine antigens. An interesting preprint by Khan et al. describes the creation of a microarray with 67 antigens from all known coronaviruses and other known respiratory viruses that will help elucidate whether baseline anti-coronavirus antibodies might influence the clinical course of COVID-19 and help to describe the evolution of the immune response during the course of SARS-CoV-2 infection.[21] Other, more comprehensive antibody profiling technology already exists, and awaits application to COVID-19 patient serum samples.[22]

Well-controlled longitudinal studies are critically needed as they can determine the relationship between different types of SARS-CoV-2-specific antibodies and the likelihood of an individual becoming re-infected. A critical goal is identification of antibodies that neutralize and block SARS-CoV-2 viral infection, as well as the determination of how much neutralizing antibody is needed for protection. As a technical note, proper identification of neutralizing antibodies will require not only pseudotyped virus with the appropriate epitopes, but fresh clinical isolates of SARS-CoV-2 as well.

SUMMARY

The two general classes of diagnostic tests, one to detect viral RNA and the other to detect human antibodies directed against the virus, each provide a distinct set of benefits and weaknesses. Detection of viral RNA generally indicates active, ongoing infection and suggests infectiousness for others, especially early in the course of infection, although the persistence of detectable viral RNA weeks after infection may no longer be synonymous with a virus capable of causing infection. Antibody tests provide evidence of past exposure and possible immunity; however, the relationship between antibody and protection has not been established for this virus. Both types of tests will require proper validation and new longitudinal studies of infected individuals before they can be properly interpreted.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
David A. Relman, M.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

[21] Khan et al. 2020. Analysis of serological cross-reactivity between common human coronaviruses and SARS-CoV-2 using coronavirus antigen microarray. https://doi.org/10.1101/2020.03.24.006544.

[22] Xu et al. 2015. Comprehensive serological profiling of human populations using a synthetic human virome. *Science* 348(6239):aaa0698. DOI: 10.1126/science.aaa0698.

APPENDIX

Authors and Reviewers of This Rapid Expert Consultation

This rapid expert consultation was prepared by staff of the National Academies of Sciences, Engineering, and Medicine, and members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats: Kristian Andersen, The Scripps Research Institute; David Relman, Stanford University; and David Walt, Brigham and Women's Hospital and Harvard Medical School.

Harvey Fineberg, chair of the Standing Committee, approved this document. The following individuals served as reviewers: Jim Chappell, Vanderbilt University Medical Center; Mark Denison, Vanderbilt University Medical Center; Michael Diamond, Washington University; Matthew Frieman, University of Maryland School of Medicine; Linsey Marr, Virginia Tech; Michael Osterholm, University of Minnesota; and Stanley Perlman, University of Iowa. Ellen Wright Clayton, Vanderbilt University Medical Center, and Susan Curry, University of Iowa, served as arbiters of this review on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

Rapid Expert Consultation on the Effectiveness of Fabric Masks for the COVID-19 Pandemic (April 8, 2020)

April 8, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Dr. Droegemeier:

Attached please find a rapid expert consultation that was prepared by Rich Besser and Baruch Fischhoff, members of the National Academies of Sciences, Engineering, and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, with input from Sundaresan Jayaraman and Michael Osterholm. Details on the authors and reviewers of this rapid expert consultation can be found in the Appendix.

The aim of this rapid expert consultation is to respond to your request concerning the effectiveness of homemade fabric masks worn by the general public to protect others, as distinct from protecting the wearer. The request stems from an interest in reducing transmission within the community by individuals who are infected, potentially contagious, but asymptomatic.

Overall, the available evidence is inconclusive about the degree to which homemade fabric masks may suppress the spread of infection from the wearer to others. For as long as homemade fabric masks are in use by the public, the investigations outlined at the end of the rapid expert consultation could reduce uncertainty about the effectiveness of these masks.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

This rapid expert consultation responds to your request concerning the effectiveness of homemade fabric masks worn by the general public to protect others, as distinct from protecting the wearer. The request stems from an interest in reducing transmission within the community by individuals who are infected, potentially contagious, but asymptomatic or presymptomatic. As discussed below, the answer depends on both the masks themselves and how infected individuals use them.

The following analysis is restricted to the effectiveness of homemade fabric masks, of the sort illustrated in recommendations[1] directed at the general public, in terms of their ability to reduce viral spread during the asymptomatic or presymptomatic period. It does not apply to either N95 respirators or medical masks.

In considering the evidence about the potential effectiveness of homemade fabric masks, it is important to bear in mind how a respiratory virus such as SARS-CoV-2 spreads from person to person. Current research supports the possibility that, in addition to being spread by respiratory droplets that one can see and feel, SARS-CoV-2 can also be spread by invisible droplets, as small as 5 microns (or micrometers), and by even smaller bioaerosol particles.[2] Such tiny bioaerosol particles may be found in an infected person's normal exhalation.[3] The relative contribution of each particle size in disease transmission is unknown.

There is limited research on the efficacy of fabric masks for influenza and specifically for SARS-CoV-2. As we describe below, the few available experimental studies

[1] Centers for Disease Control and Prevention (CDC) Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission in response to COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html.

[2] Gralton et al. (2011) noted the following in regard to particulate size and the importance of airborne precautions whenever there is a risk of both droplet and aerosol transmission: "Regardless of the complexities and limitations of sizing particles and the contention of size cut-offs, it remains that particles have been observed to occupy a size range between 0.05 and 500 microns. Even using the conservative cut-off of 10 microns, rather than the 5 micron to define between airborne and droplet transmission, this size range indicates that particles do not exclusively disperse by airborne transmission or via droplet transmission but rather avail of both methods simultaneously. This suggestion is further supported by the simultaneous detection of both large and small particles. In line with these observations and logic, current dichotomous infection control precautions should be updated to include measures to contain both modes of aerosolised transmission. This may require airborne precautions to be used when at risk of any aerosolized infection, as airborne precautions are considered as a step-up from droplet precautions." Gralton et al. 2011. The role of particle size in aerosolised pathogen transmission: A review. *Journal of Infection* 62(1):1-13. DOI: 10.1016/j.jinf.2010.11.010.

[3] National Academies of Sciences, Engineering, and Medicine. 2020. *Rapid Expert Consultation on the Possibility of Bioaerosol Spread of SARS-CoV-2 for the COVID-19 Pandemic (April 1, 2020).* Washington, DC: The National Academies Press. https://doi.org/10.17226/25769.

have important limitations in their relevance and methods. Any type of mask will have its own capacity to arrest particles of different sizes. Even if the filtering capacity of a mask were well understood, however, the degree to which it could in practice reduce disease spread depends on the unknown role of each particle size in transmission.

Asymptomatic but infected individuals are of special concern, and the particles they would emit from breathing are predominantly bioaerosols. To complicate matters further, different individuals vary in the extent to which they emit bioaerosols while breathing. Because of the concern with spread from asymptomatic individuals, who, unlike symptomatic persons, may be out and about, this rapid expert consultation includes the effects of fabric masks on bioaerosol transmission.

IMPACT OF MASK DESIGN AND FABRICATION ON PERFORMANCE

Any effects of fabric masks will depend on how and how well they are made. In an unpublished study whose raw data are not currently available, Jayaraman et al.[4] examined a range of fabric-based filtration systems, in terms of how well they stopped particles (filtration efficiency) and how much they impeded breathing (differential pressure, Delta-P, the measured pressure drop across the material, which determines the resistance of the material to air flow).[5] The study varied fabric type (woven, woven brushed, knitted, knitted brushed, knitted pile), material type (cotton, polyester, polypropylene, silk), fabric parameters (fabric areal density, yarn linear density, fabric weight), and construction type (number of layers, orientation of the layers). The study found wide variation in filtration efficiency. A mask made from a four-layer woven handkerchief fabric, of a sort that might be found in many homes, had 0.7% filtration efficiency for 0.3 micron size particles and a Delta-P of 0.1". Much higher filtration efficiency was observed with filters created specifically for the research from a five-layer woven brushed fabric (35.3% of the particles were trapped) and from four layers of polyester knitted cut-pile fabric (50% of the particles were trapped with a Delta-P of 0.2").

The greater a mask's breathing resistance, which is reflected in a higher Delta-P, the more difficult it is for users to wear it consistently, and the more likely they are to experience breathing difficulties when they do.[6] Although Jayaraman et al. did not measure breathing resistance directly, almost all of the masks they tested would be expected to have breathing resistance within the range of commercial N95 respirators. One mask that used 16 layers of the handkerchief fabric, in order to increase filtration efficiency (63% efficiency with a Delta-P of 0.425"), had breathing resistance greater

[4] Jayaraman et al. *Pandemic Flu—Textile Solutions Pilot: Design and Development of Innovative Medical Masks*, Final Technical Report, Georgia Institute of Technology, Atlanta, Georgia, submitted to CDC, February 14, 2012.

[5] The tests were conducted according to ASTM F2299-3 test method using poly-dispersed sodium chloride aerosol particles with an airflow rate of 30L/min and airflow velocity of 11 cm/s. Aerosol sizes measured: 0.1, 0.2, 0.3, 0.4, 0.5, 0.7, 1, and 2 microns.

[6] 3M™ Health Care Particulate Respirator and Surgical Masks, Healthcare Respirator Brochure, 3M Company, Minnesota.

than that of commercial N95 respirators, which would cause great discomfort to many wearers and cause some to pass out.

An additional consideration in the effectiveness of any mask is how well it fits the user.[7] Even with the best material, if a mask does not fit, virus-containing particles can escape through creases and gaps between the mask and face. Leakage can also occur if the holding mechanism (e.g., straps, Velcro®) is weak. We found no studies of non-expert individuals' ability to produce properly fitting masks. Nor did we find any studies of the effectiveness of masks produced by professionals, when following instructions available to the general public (e.g., online). Given the current Centers for Disease Control and Prevention (CDC) recommendation to wear cloth face coverings in public settings in areas of significant community-based transmission, additional research should examine the ability of the general public to produce properly fitted fabric masks when following communications and instructions.

ROLE OF THE WEARER

The effectiveness of homemade fabric masks will also depend on the wearer's behavior. Even if a mask could fit well, its effectiveness still depends on how well the wearer puts it on and keeps it in place. As mentioned, breathing difficulty can impede effective use (e.g., pulling a mask down), as can moisture from the wearer's breath. Moisture saturation is inevitable with fabrics available in most homes. Moreover, moisture can trap the virus and become a potential contamination source for others after a mask is removed.

EFFECTIVENESS OF HOMEMADE FABRIC MASKS IN PROTECTING OTHERS

Several experimental studies have examined the effects of fabric masks on the transmission of droplets of various sizes.

Anfinrud et al.[8] shared via email that they used sensitive laser light-scattering procedures to detect droplet emission while people were speaking. The authors found that "a damp homemade cloth facemask" reduced droplet emission to background levels (when users said "Stay Healthy" three times). However, when a fabric is dampened, the yarns can swell over time, potentially altering its filtering performance. That swelling will depend on the fabric: cotton swells readily, synthetics less so. In an unpublished follow-up experiment, Anfinrud et al. repeated their study with a variety of dry (not moistened) cloths, including a standard workers dust mask (not certified N95) and a

[7] Davies et al. (2013) noted that, "Although any material may provide a physical barrier to an infection, if as a mask it does not fit well around the nose and mouth, or the material freely allows infectious aerosols to pass through it, then it will be of no benefit." Davies et al. 2013. Testing the efficacy of homemade masks: Would they protect in an influenza pandemic? *Disaster Medicine and Public Health Preparedness* 7(4):413-418. DOI: 10.1017/dmp.2013.43.

[8] Anfinrud et al. In Press. Could SARS-CoV-2 be transmitted via speech droplets? *New England Journal of Medicine*. https://doi.org/10.1101/2020.04.02.20051177.

mask rigged from an airline eye covering. They found that all of these masks reduced droplet emission generated by speech to background level.[9]

Bae et al. (2020) evaluated the effectiveness of surgical and cotton masks in filtering SARS-CoV-2.[10] They found that neither kind of mask reduced the dissemination of SARS-CoV-2 from the coughs of four symptomatic patients with COVID-19 to the environment and external mask surface. The study used disposable surgical masks (180 mm × 90 mm, 3 layers [inner surface mixed with polypropylene and polyethylene, polypropylene filter, and polypropylene outer surface], pleated, bulk packaged in cardboard; KM Dental Mask, KM Healthcare Corp) and reusable 100% cotton masks (160 mm × 135 mm, 2 layers, individually packaged in plastic; Seoulsa). The median viral loads of nasopharyngeal and saliva samples from the four participants were 5.66 log copies/mL and 4.00 log copies/mL, respectively. The median viral loads after coughs without a mask, with a surgical mask, and with a cotton mask were similar: 2.56 log copies/mL, 2.42 log copies/mL, and 1.85 log copies/mL, respectively. All swabs from the outer mask surfaces of the masks were positive for SARS-CoV-2, whereas swabs from three out of the four symptomatic patients from the inner mask surfaces were negative. Note that this study focused on symptomatic patients who coughed.

Rengasamy et al. (2010)[11] tested the filtration performance of five common household fabric materials: sweatshirts, T-shirts, towels, scarves, and cloth masks (of unknown material) in a laboratory setting. These fabric materials were tested for sprays having both similar and diverse particle sizes (monodisperse and polydisperse). The range of sizes used in the study (0.02-1 micron) includes that of potential virus-containing droplets.[12] The study projected the particles at face velocities, typical of breathing at rest and during exertion (5.5 and 16.5 cm/s). The test also examined N95 respirator filter media. At the lower velocity, 0.12% of particles penetrated the N95 respirator material; at the higher velocity, penetration was less than 5%. For the five common household fabric materials, across the tests, penetration ranged from about 40-90%, indicating a 10-60% reduction. The authors concluded that common fabric materials may provide a low level of protection against nanoparticles, including those in the size ranges of virus-containing particles in exhaled breath (0.02-1 micron). However, Gralton et al. (2011) found particles generated from respiratory activities range from 0.01 up to 500 microns, with a particle size range of 0.05 to 500 microns associated with infection. They stress the need for airborne precautions to be used when at risk of any aerosolized infection, as airborne precautions are considered as a step-up from droplet precautions.

[9] Personal communication, Adriaan Bax, National Institutes of Health, April 4, 2020.

[10] Bae et al. 2020. Effectiveness of surgical and cotton masks in blocking SARS-CoV-2: A controlled comparison in 4 patients. *Annals of Internal Medicine*. DOI: 10.7326/M20-1342.

[11] Rengasamy et al. 2010. Simple respiratory protection—evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles. *Annals of Occupational Hygiene* 54(7):789-798. https://doi.org/10.1093/annhyg/meq044.

[12] According to Gralton et al. (2011), particles generated from respiratory activities range from 0.01 up to 500 microns, with a particle size range of 0.05 to 500 microns associated with infection. Gralton et al. 2011. The role of particle size in aerosolised pathogen transmission: A review. *Journal of Infection* 62:1-13. DOI: 10.1016/j.jinf.2010.11.010.

Davies et al. (2013)[13] had 21 healthy volunteers make their own face masks from fresh, unworn cotton t-shirts. This is the only study we found with user-made masks. Participants then coughed into a box, when wearing their own mask, a surgical mask, or no mask. They received no help or guidance from the researcher in making or fitting their masks. The researchers took samples of particles settling onto agar plates and a Casella slit sampler in the box. Under the baseline conditions of no mask, only a small number of colony-forming units (indicative of bacteria) were detected, limiting the opportunity to demonstrate reductions. Still, the investigators reported that both homemade and surgical masks reduced the number of large-sized microorganisms expelled by volunteers, with the surgical mask being more effective.

van der Sande et al. (2008)[14] examined the extent to which respirator masks, surgical masks, and tea-cloth masks made by the researchers would reduce tiny (0.02-1 micron) particle counts on one side of the mask compared to the other. They used burning candles in a test room to generate particles. Two of the study's three experiments examined the protection afforded the wearer (reduced particle counts inside the masks compared to outside). Although not directly germane to the question of protecting others, the study found a modest degree of protection for the wearer from cloth masks, an intermediate degree from surgical masks, and a marked degree with the equivalent of N95 masks. For example, among adults, N95 masks provided 25 times the protection of surgical masks and 50 times the protection of cloth masks. The study's third experiment tested the effectiveness of the three masks at reducing emissions from a simulation dummy head that produced uniform "exhalations." It found that cloth masks reduced emitted particles (leakage) by one-fifth, surgical masks reduced it by one-half, and N95-equivalent masks reduced it by two-thirds.

MacIntyre et al. (2015)[15] conducted a randomized controlled trial comparing infection rates of 1,607 hospital health care workers wearing cloth (two layers, made of cotton) or medical masks (three layers, made of non-woven material) while performing their normal tasks. Workers who used cloth masks experienced much higher rates of influenza-like illness (relative risk = 13.00, 95% confidence interval 1.59 to 100.07). This study measured the protective effect for the wearer, rather than the protection of others from the wearer, and did not include a condition with individuals wearing no masks.

EFFECT ON USERS' RISK BEHAVIOR

In our rapid review, we found no studies of the effects of wearing masks on users' behavior. Speculatively, for some users, masks could provide a constant reminder of the importance of social distancing, as well as signal its importance to others, strengthening the social norm of social distancing. Conversely, for some users, masks might "crowd out" other precautionary behaviors, giving them a feeling that they have done enough to protect themselves and others. Prior research, conducted in less intense settings,

[13] Davies et al. 2013. Testing the efficacy of homemade masks: Would they protect in an influenza pandemic? *Disaster Medicine and Public Health Preparedness* 7(4):413-418. DOI: 10.1017/dmp.2013.43.

[14] van der Sande et al. 2008. Professional and home-made face masks reduce exposure to respiratory infections among the general population. *PLOS ONE* 3(7):e2618. DOI: 10.1371/journal.pone.0002618.

[15] MacIntyre et al. 2015. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. *BMJ Open* 5(4):e006577. DOI: 10.1136/bmjopen-2014-006577.

could support either speculation. Focused research could help determine when precautionary behaviors reinforce or displace one another.

It is critically important that any discussion of homemade fabric masks reinforce the central importance of physical distancing and personal hygiene (frequent handwashing) in reducing spread of infection.

CONCLUSIONS

There are no studies of individuals wearing homemade fabric masks in the course of their typical activities. Therefore, we have only limited, indirect evidence regarding the effectiveness of such masks for protecting others, when made and worn by the general public on a regular basis. That evidence comes primarily from laboratory studies testing the effectiveness of different materials at capturing particles of different sizes.

The evidence from these laboratory filtration studies suggests that such fabric masks may reduce the transmission of larger respiratory droplets. There is little evidence regarding the transmission of small aerosolized particulates of the size potentially exhaled by asymptomatic or presymptomatic individuals with COVID-19. The extent of any protection will depend on how the masks are made and used. It will also depend on how mask use affects users' other precautionary behaviors, including their use of better masks, when those become widely available. Those behavioral effects may undermine or enhance homemade fabric masks' overall effect on public health. The current level of benefit, if any, is not possible to assess.

Research could provide firmer answers by assessing the effectiveness of such fabric masks, as made and used by the general public. That research would have the goals of providing the public with (1) usable instructions on how to make, fit, use, and clean homemade fabric masks; (2) estimates of the protection that such masks afford users and others in different environments (e.g., where the likelihood of contact is higher, like grocery stores, compared to wearing masks all of the time); and (3) effective reinforcement of other precautionary behaviors. That research could provide policy makers with estimates of the net effect of encouraging the use of homemade fabric masks on public health, with realistic estimates of how such masks will be made and used, as well as how they will affect other precautionary behaviors of users and others who observe and interact with them.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
Richard Besser, M.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Baruch Fischhoff, Ph.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

APPENDIX

Authors and Reviewers of This Rapid Expert Consultation

This rapid expert consultation was prepared by staff of the National Academies of Sciences, Engineering, and Medicine, and members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats: Richard Besser, Robert Wood Johnson Foundation, and Baruch Fischhoff, Carnegie Mellon University. The following subject-matter experts also provided input: Sundaresan Jayaraman, Georgia Tech, and Michael Osterholm, University of Minnesota.

Harvey Fineberg, chair of the Standing Committee, approved this document. The following individuals served as reviewers: Ned Calonge, The Colorado Trust; Robert Hornik, University of Pennsylvania; Thomas Inglesby, Johns Hopkins Bloomberg School of Public Health Center for Health Security; and Grace Lee, Stanford University. Bobbie A. Berkowitz, Columbia University School of Nursing; Ellen Wright Clayton, Vanderbilt University Medical Center; and Susan Curry, University of Iowa, served as arbiters of this review on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

Rapid Expert Consultation on SARS-CoV-2 Viral Shedding and Antibody Response for the COVID-19 Pandemic (April 8, 2020)

April 8, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Dr. Droegemeier:

Attached please find a rapid expert consultation in response to your request concerning (1) the duration of viral shedding by stage of infection, clinical signs and symptoms, and patient attributes; (2) the levels and duration of antibody response and related resistance to illness; and (3) the optimal duration of isolation of cases.

Members of the National Academies of Sciences, Engineering, and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats who were instrumental in preparing this response include Peter Daszak, EcoHealth Alliance; Diane E. Griffin, Johns Hopkins Bloomberg School of Public Health; Kent E. Kester, Sanofi Pasteur; and Mark S. Smolinski, Ending Pandemics.

This document stresses what is known and what are the most salient questions yet to be answered to guide critical decisions related to the duration of isolation of infected patients, the potential effectiveness of a vaccine, and when we can be confident that previously infected patients are resistant to re-infection.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

This rapid expert consultation responds to your request concerning (1) the duration of viral shedding by stage of infection, clinical signs and symptoms, and patient attributes; (2) the levels and duration of antibody response and related resistance to illness; and (3) the optimal duration of isolation of cases.

Our intent is to answer three questions in response to each issue:

- What is the relevant scientific evidence and state of current scientific knowledge?
- Who is doing the best work in the area and what new results can we anticipate?
- Gaps in knowledge: What investigations should be initiated or extended to provide a more complete answer?

Shedding of infectious virus from the respiratory tract tends to be highest early in disease. This is followed by a prolonged period of viral RNA shedding, but the extent to which this represents infectious virus is uncertain.[1] In addition, the role of shedding from the gastrointestinal tract in transmission is unclear. Antibody responses begin to appear over a period of days to weeks after infection. Studies of SARS and MERS survivors suggest that antibody responses for SARS-CoV-1 and MERS-CoV are not durable.[2,3,4] Further investigation is needed to understand the duration of protective immunity for SARS-CoV-2. The groups referenced in this rapid expert consultation are continuing to produce work in these areas. We anticipate that additional studies based on cases coming out of the United States and Europe will provide further information on these critical topics.

(1) The duration of viral shedding by stage of infection, clinical signs and symptoms, and patient attributes.

Viral shedding has been assessed and detected by culture, but most often by reverse-transcriptase polymerase chain reaction (RT-PCR) for viral RNA.[5] RNA can be detected from infectious virus or from remnants of virus that are no longer infectious. In a patient recovering from an illness who was previously PCR positive, at least two sequential

[1] Joynt and Wu. 2020. Understanding COVID-19: What does viral RNA load really mean? *The Lancet Infectious Diseases.* https://doi.org/10.1016/S1473-3099(20)30237-1.

[2] Alshukairi et al. 2016. Antibody response and disease severity in healthcare worker MERS survivors. *Emerging Infectious Diseases* 22(6):1113-1115. https://dx.doi.org/10.3201/eid2206.160010.

[3] Liu et al. 2006. Two-year prospective study of the humoral immune response of patients with severe acute respiratory syndrome. *The Journal of Infectious Diseases* 193(6):792-795.

[4] Wu et al. 2007. Duration of antibody responses after severe acute respiratory syndrome. *Emerging Infectious Diseases* 13(10):1562-1564. DOI: 10.3201/eid1310.070576.

[5] Wölfel et al. 2020. Virological assessment of hospitalized patients with COVID-2019. *Nature.* https://doi.org/10.1038/s41586-020-2196-x.

negative tests for viral RNA is a reasonable indicator of when infectious virus is no longer being shed. Most studies have analyzed respiratory secretions (throat and/or nasopharyngeal samples), but stool samples are also often positive for RNA later in the course of the infection while other sites (e.g., blood, urine, tears, vaginal secretions) are usually negative. These data are likely to be important for the understanding of routes and periods of transmission.

It is not uncommon for viral shedding in respiratory secretions to occur 2-3 days prior to first symptoms.[6,7,8] Higher amounts of virus and viral RNA are seen early in infection independent of severity of symptoms with sputum and nasopharyngeal samples more likely to be positive than throat swab samples.[9,10,11,12,13] More severe clinical disease is associated with longer persistence of viral RNA shedding and may represent a significant occupational transmission risk for health care workers.[14,15] Viral RNA shedding for up to a week after the resolution of symptoms is common and in one case has been documented to continue for as long as 49 days although this viral RNA may not represent infectious virus.[16,17,18,19] No differences in these parameters have been detected based on age or sex.

In addition, gastrointestinal symptoms may be common and viral RNA is frequently detected in stool. Viral RNA persists in stool after symptoms have subsided for longer

[6] He. 2020. Temporal dynamics in viral shedding and transmissibility of COVID-19. *medRxiv.*

[7] Kimball et al. 2020. Asymptomatic and presymptomatic SARS-CoV-2 infections in residents of a long-term care skilled nursing facility—King County, Washington, March 2020. *Morbidity and Mortality Weekly Report* 69(13):377-381. http://dx.doi.org/10.15585/mmwr.mm6913e1.

[8] Li et al. 2020. Asymptomatic and human-to-human transmission of SARS-CoV-2 in a 2-family cluster, Xuzhou, China. *Emerging Infectious Diseases* 26(7). https://doi.org/10.3201/eid2607.200718.

[9] Wölfel et al. 2020. Virological assessment of hospitalized patients with COVID-2019. *Nature.* https://doi.org/10.1038/s41586-020-2196-x.

[10] He. 2020. Temporal dynamics in viral shedding and transmissibility of COVID-19. *medRxiv.*

[11] Yu et al. 2020. Quantitative detection and viral load analysis of SARS-CoV-2 in infected patients. *Clinical Infectious Diseases.* https://doi.org/10.1093/cid/ciaa345.

[12] Zou et al. 2020. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. *New England Journal of Medicine* 382(12):1177-1179. DOI: 10.1056/NEJMc2001737.

[13] Cereda et al. 2020. The early phase of the COVID-19 outbreak in Lombardy, Italy. *medRxiv.*

[14] Liu et al. 2020. Viral dynamics in mild and severe cases of COVID-19. *The Lancet Infectious Diseases.* https://doi.org/10.1016/S1473-3099(20)30232-2.

[15] Lescure et al. 2020. Clinical and virological data of the first cases of COVID-19 in Europe: A case series. *The Lancet Infectious Diseases.* https://doi.org/10.1016/S1473-3099(20)30200-0.

[16] Wölfel et al. 2020. Virological assessment of hospitalized patients with COVID-2019. *Nature.* https://doi.org/10.1038/s41586-020-2196-x.

[17] Zhou et al. 2020. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: A retrospective cohort study. *The Lancet* 395(10229):1054-1062. https://doi.org/10.1016/S0140-6736(20)30566-3.

[18] Tan. 2020. Viral kinetics and antibody responses in patients with COVID-19. *medRxiv.*

[19] Young et al. 2020. Epidemiologic features and clinical course of patients infected with SARS-CoV-2 in Singapore. *JAMA* 323(15):1488-1494. DOI: 10.1001/jama.2020.3204.

than in samples from the respiratory tract, but a role in transmission is unclear.[20,21,22,23,24] In a recent report infectious virus was readily isolated from respiratory samples, but not from stool samples.[25]

Gaps in knowledge:

- Effect of various treatments on length of shedding.
- Epidemiologic evidence of transmission while RT-PCR positive after recovery.
- Significance of viral RNA shedding after resolution of symptoms.
- Importance of shedding from non-respiratory sites.
- Innovative assays to determine if the virus is infectious.

(2) Levels and duration of antibody response and related resistance to illness.

The time of antibody detection after infection is dependent on the sensitivity of the assay and the viral protein used as antigen. IgM can be detected by enzyme immunoassay to nucleoprotein 3-6 (median 5) days after onset of symptoms and has been used to complement RT-PCR for diagnosis of COVID-19.[26,27] IgG to the same protein is detected 10-18 (median 14) days after the onset of symptoms.[28] Anti-nucleoprotein antibody did not correlate with virus clearance[29] and a higher antibody titer was independently associated with more severe disease.[30] Antibody to the receptor-binding domain of the

[20] Zhang et al. 2020. Molecular and serological investigation of 2019-nCoV infected patients: Implication of multiple shedding routes. *Emerging Microbes & Infections* 9(1):386-389. DOI: 10.1080/22221751.2020.1729071.

[21] Lo et al. 2020. Evaluation of SARS-CoV-2 RNA shedding in clinical specimens and clinical characteristics of 10 patients with COVID-19 in Macau. *International Journal of Biological Sciences* 16(10):1698-1707. DOI: 10.7150/ijbs.45357.

[22] Ling et al. 2020. Persistence and clearance of viral RNA in 2019 novel coronavirus disease rehabilitation patients. *Chinese Medical Journal (English).* DOI: 10.1097/CM9.0000000000000774.

[23] Xu. 2020. Characteristics of pediatric SARS-CoV-2 infection and potential evidence for persistent fecal viral shedding. *Nature Medicine* 26:502-505. https://doi.org/10.1038/s41591-020-0817-4.

[24] During the SARS epidemic in Hong Kong in 2003, the virus was spread in an apartment complex (Amoy Gardens) due to aerosolized waste flushed from toilets that found its way into the air of other apartments through poorly designed bathroom floor drains.

[25] Wölfel et al. 2020. Virological assessment of hospitalized patients with COVID-2019. *Nature.* https://doi.org/10.1038/s41586-020-2196-x.

[26] Guo et al. 2020. Profiling early humoral response to diagnose novel coronavirus disease (COVID-19). *Clinical Infectious Diseases.* https://doi.org/10.1093/cid/ciaa310.

[27] Zhao et al. 2020. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clinical Infectious Diseases.* DOI: 10.1093/cid/ciaa344.

[28] Guo et al. 2020. Profiling early humoral response to diagnose novel coronavirus disease (COVID-19). *Clinical Infectious Diseases.* https://doi.org/10.1093/cid/ciaa310.

[29] Tan. 2020. Viral kinetics and antibody responses in patients with COVID-19. *medRxiv.*

[30] Guo et al. 2020. Profiling early humoral response to diagnose novel coronavirus disease (COVID-19). *Clinical Infectious Diseases.* https://doi.org/10.1093/cid/ciaa310.

spike protein was detected a median of 11 days after the onset of symptoms, but the timing of seroconversion did not correlate with clinical course.[31,32]

The duration of the antibody response and acquired immunity to re-infection will be critical to understanding (1) how effective vaccination is likely to be; (2) how durable immunity is; (3) whether it is possible to achieve herd immunity against COVID-19; and (4) how safe it is for people who are positive in a serology test to return to work. One key uncertainty arises from the fact that we are early in the outbreak and survivors from the first weeks of infection in China are, at most, only 3 months since recovery. Some lessons may be gleaned from evidence about the duration of antibody responses to SARS-CoV and MERS-CoV, which are related viruses. Studies of patients who recovered from the SARS outbreak in 2003 show a steady decrease in amounts of antiviral binding IgG over time with 12% negative at 2 years and 50% at 3 years.[33,34] Similarly, health care workers with mild to moderate MERS-CoV infection had no detectable antiviral binding IgG 18 months after recovery.[35] The response to SARS-CoV-2 is likely to be similar to this closely related virus. Longitudinal data from the large numbers of recovered cases in China from earlier in the outbreak may give us insight into the temporal dynamics of antibody titers to this virus.

Gaps in knowledge:

- Evaluation of whether the presence of antibodies confers protection from illness due to re-infection, and if so, what levels of antibodies are needed.
- A better understanding of the role of specific antibodies will inform possible therapy with immune plasma and the development of monoclonal antibodies for potential treatment, as well as vaccine design.
- Following antibody titers in cohorts of patients with mild, moderate, severe, and critical COVID-19 disease will be revealing. This would best be done in multiple geographies, with diverse age classes, ethnic background, etc.
- Evidence of waning antibody titer can be anticipated after 2 years, but any indication of earlier significant drop in titers per age class or other grouping would be very important to identify because it might affect vaccine efficacy, the ability of these people to be re-infected and the potential for disease attenuation with an anamnestic response.

[31] Wölfel et al. 2020. Virological assessment of hospitalized patients with COVID-2019. *Nature.* https://doi.org/10.1038/s41586-020-2196-x.

[32] Zhao et al. 2020. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clinical Infectious Diseases.* DOI: 10.1093/cid/ciaa344.

[33] Liu et al. 2006. Two-year prospective study of the humoral immune response of patients with severe acute respiratory syndrome. *The Journal of Infectious Diseases* 193(6):792-795.

[34] Wu et al. 2007. Duration of antibody responses after severe acute respiratory syndrome. *Emerging Infectious Diseases* 13(10):1562-1564. DOI: 10.3201/eid1310.070576.

[35] Alshukairi et al. 2016. Antibody response and disease severity in healthcare worker MERS survivors. *Emerging Infectious Diseases* 22(6):1113-1115. https://dx.doi.org/10.3201/eid2206.160010.

(3) Optimal duration of isolation of cases.

Because many patients continue to be RT-PCR positive for viral RNA in both respiratory secretions and stool, this is a difficult question that will best be informed by observational studies of transmission from discharged patients with known status for viral RNA by RT-PCR. Waiting for all tests to be repeatedly negative is the most conservative approach, but may result in prolonged unnecessary isolation. Assessment of humoral and cellular immune response may also be informative. Current Centers for Disease Control and Prevention recommendations are that patients are no longer infectious after 7 days of illness and 3 days without symptoms.

Gaps in knowledge:

- Duration of shedding of infectious virus by recovered patients and the relationship to the detection of viral RNA.
- Knowledge of immune mechanisms responsible for virus clearance that might predict recovery and help determine when patients are no longer infectious.
- Immune correlates of protection.
- Duration of protective immunity.

APPENDIX

Authors and Reviewers of This Rapid Expert Consultation

This rapid expert consultation was prepared by staff of the National Academies of Sciences, Engineering, and Medicine, and members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats: Peter Daszak, EcoHealth Alliance; Diane E. Griffin, Johns Hopkins Bloomberg School of Public Health; Kent E. Kester, Sanofi Pasteur; and Mark S. Smolinski, Ending Pandemics.

Harvey Fineberg, chair of the Standing Committee, approved this document. The following individuals served as reviewers: Kathryn M. Edwards, Vanderbilt University School of Medicine; James W. LeDuc, Galveston National Laboratory; and Steven M. Teutsch, University of California, Los Angeles. Bobbie A. Berkowitz, Columbia University School of Nursing, and Ellen Wright Clayton, Vanderbilt University Medical University, served as arbiters of this review on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

To: Pope, Andrew[apope@nas.edu]
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From: Peggy Hamburg[peggy@hbfam.net]
Sent: Thur 4/30/2020 1:03:13 PM (UTC-04:00)
Subject: Re: Just in: Compilation of RECs

Very classy! Thanks.
Peggy

Sent from my iPhone

> On Apr 30, 2020, at 12:51 PM, Pope, Andrew <apope@nas.edu> wrote:
>
> We just received this from the National Academies Press!
> <Final PDF with cover for RECs for the COVID-19 Pandemic.pdf>

To: Brown, Lisa[LBrown@nas.edu]; Alexandra Phelan (alp81@georgetown.edu)[alp81@georgetown.edu]; David A Relman (relman@stanford.edu)[relman@stanford.edu]; David Walt (dwalt@bwh.harvard.edu)[dwalt@bwh.harvard.edu]; Diane Griffin (dgriffi6@jhmi.edu)[dgriffi6@jhmi.edu]; Embrey, Ellen (eembrey@stratitia.com)[eembrey@stratitia.com]; Georges Benjamin (georges.benjamin@apha.org)[georges.benjamin@apha.org]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; John Hick (hick.john@gmail.com)[hick.john@gmail.com]; Jonna Mazet (jkmazet@ucdavis.edu)[jkmazet@ucdavis.edu]; Kent Kester (Kent.Kester@sanofi.com)[Kent.Kester@sanofi.com]; Kristian G. Andersen (kga1978@gmail.com)[kga1978@gmail.com]; Mark Smolinski (mark@endingpandemics.org)[mark@endingpandemics.org]; Mary Travis Bassett (mbassett@hsph.harvard.edu)[mbassett@hsph.harvard.edu]; Patricia King (patricia.king1@gmail.com)[patricia.king1@gmail.com]; Peggy Hamburg (peggy@hbfam.net)[peggy@hbfam.net]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; Phyllis D. Meadows (PDMeadows@kresge.org)[PDMeadows@kresge.org]; Richard Besser (rbesser@rwjf.org)[rbesser@rwjf.org]; Tara O'Toole (totoole@iqt.org)[totoole@iqt.org]; Trevor Bedford (trevor@bedford.io)[trevor@bedford.io]; Baric, Ralph S[rbaric@email.unc.edu]; Donald Berwick[donberwick@gmail.com]; Jeff.Duchin@kingcounty.gov[Jeff.Duchin@kingcounty.gov]; Baruch Fischhoff[baruch@cmu.edu]; DHanfling@iqt.org[DHanfling@iqt.org]; bgroves@georgetown.edu[bgroves@georgetown.edu]; mnavish@iqt.org[mnavish@iqt.org]; andre@ecohealthalliance.org[andre@ecohealthalliance.org]; Peisch, Samuel Francis[speisch@hsph.harvard.edu]; jbaker@rwjf.org[jbaker@rwjf.org]; Baric, Toni C[antoinette_baric@med.unc.edu]; Mary Radford[maradford@ucdavis.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]; Feit, Monica[MFeit@nas.edu]; Shore, Carolyn[CShore@nas.edu]; Wollek, Scott[SWollek@nas.edu]; Downey, Autumn[ADowney@nas.edu]; Motrya Calafiura[Motrya.Calafiura@georgetown.edu]; rhock@ihi.org[rhock@ihi.org]; Fine, Emma[EFine@nas.edu]; Shin, Rebecca[rebeccashin@hsph.harvard.edu]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Borel, Bridget[BBorel@nas.edu]
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From: Alta CHARO[alta.charo@wisc.edu]
Sent: Thur 4/30/2020 1:27:36 PM (UTC-04:00)
Subject: apropos "warp speed" vaccine development

This popped in:

https://www.bloomberg.com/news/articles/2020-04-29/trump-s-operation-warp-speed-aims-to-rush-coronavirus-vaccine

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To the wrongs that need resistance, To the right that needs assistance,
To the future in the distance, Give yourselves.
--- Carrie Chapman Catt

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From: Brown, Lisa[LBrown@nas.edu]
Sent: Thur 4/30/2020 5:10:19 PM (UTC-04:00)
Subject: RE: Additional Materials RE: Agenda and Zoom Information for Second Virtual Meeting of the Standing Committee 4/30
SPP 2020.2097COVID-19 Global Preparedness Pledging infographic proof7_29APRIL.pdf
Coronavirus Global Response.docx
access-to-covid-19-tools-(act)-accelerator-call-to-action-24april2020.pdf
Global leaders unite to ensure everyone everywhere can access new vaccines, tests and treatments for COVID-19.pdf

Dear all,

I am forwarding a note and materials by Dr. Dzau.

Dear committee members,

In view of the significant interest of global effort on vaccine in today's discussion, I am sending you several attachments for your consideration in your discussion. I am happy to provide more background information. Indeed we need to engage US more actively in this effort.

Victor

From: Brown, Lisa
Sent: Wednesday, April 29, 2020 6:56 PM
To: Alexandra Phelan (alp81@georgetown.edu) <alp81@georgetown.edu>; David A Relman (relman@stanford.edu) <relman@stanford.edu>; David Walt (dwalt@bwh.harvard.edu) <dwalt@bwh.harvard.edu>; Diane Griffin (dgriffi6@jhmi.edu) <dgriffi6@jhmi.edu>; Embrey, Ellen (eembrey@stratitia.com) <eembrey@stratitia.com>; Georges Benjamin (georges.benjamin@apha.org) <georges.benjamin@apha.org>; Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; John Hick (hick.john@gmail.com) <hick.john@gmail.com>; Jonna Mazet (jkmazet@ucdavis.edu) <jkmazet@ucdavis.edu>; Kent Kester (Kent.Kester@sanofi.com) <Kent.Kester@sanofi.com>; Kristian G. Andersen (kga1978@gmail.com) <kga1978@gmail.com>; Mark Smolinski (mark@endingpandemics.org) <mark@endingpandemics.org>; Mary Travis Bassett (mbassett@hsph.harvard.edu) <mbassett@hsph.harvard.edu>; Patricia King (patricia.king1@gmail.com) <patricia.king1@gmail.com>; Peggy Hamburg (peggy@hbfam.net) <peggy@hbfam.net>; Peter Daszak (daszak@ecohealthalliance.org) <daszak@ecohealthalliance.org>; Phyllis D. Meadows (PDMeadows@kresge.org) <PDMeadows@kresge.org>; Richard Besser (rbesser@rwjf.org) <rbesser@rwjf.org>; Tara O'Toole (totoole@iqt.org) <totoole@iqt.org>; Trevor Bedford (trevor@bedford.io) <trevor@bedford.io>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'Donald Berwick' <donberwick@gmail.com>; 'alta.charo@wisc.edu' <alta.charo@wisc.edu>; 'Jeff.Duchin@kingcounty.gov' <Jeff.Duchin@kingcounty.gov>; 'Baruch Fischhoff' <baruch@cmu.edu>; 'DHanfling@iqt.org' <DHanfling@iqt.org>; 'bgroves@georgetown.edu' <bgroves@georgetown.edu>
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; 'mnavish@iqt.org' <mnavish@iqt.org>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'Peisch, Samuel Francis' <speisch@hsph.harvard.edu>;

'jbaker@rwjf.org' <jbaker@rwjf.org>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'Mary Radford' <maradford@ucdavis.edu>; Pope, Andrew <APope@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; Feit, Monica <MFeit@nas.edu>; Shore, Carolyn <CShore@nas.edu>; Wollek, Scott <SWollek@nas.edu>; Downey, Autumn <ADowney@nas.edu>
Subject: Additional Materials RE: Agenda and Zoom Information for Second Virtual Meeting of the Standing Committee 4/30
Importance: High

Dear Members of the Standing Committee,

As promised, please find attached a compilation of the priority topics discussed by each working group. Please refer to this document for our working group discussions during tomorrow's meeting. Please note that the numbering of the topics may differ than earlier versions of these lists because this list now reflects the prioritization process. Each working group has identified three priorities. For reference, we are also attaching a document listing the working group membership.

Furthermore, for tomorrow's meeting please find attached ASPR's list of strategic operational priorities. Chris Hassle will be presenting these priorities to the standing committee.

Lastly, we are re-attaching the agenda, and we will update the calendar invite with all of these materials and Zoom information.

Please let us know if you have any questions.

We are looking forward to tomorrow's discussions!!

Very best,
Lisa

Lisa Brown, MPH
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Board on Health Sciences Policy
Health and Medicine Division
The National Academies of Sciences, Engineering, and Medicine
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202-334-2487 (office)
lbrown@nas.edu

From: Brown, Lisa
Sent: Wednesday, April 29, 2020 11:16 AM
To: Alexandra Phelan (alp81@georgetown.edu) <alp81@georgetown.edu>; David A Relman (relman@stanford.edu) <relman@stanford.edu>; David Walt (dwalt@bwh.harvard.edu) <dwalt@bwh.harvard.edu>; Diane Griffin (dgriffi6@jhmi.edu) <dgriffi6@jhmi.edu>; Embrey, Ellen (eembrey@stratitia.com) <eembrey@stratitia.com>; Georges Benjamin (georges.benjamin@apha.org) <georges.benjamin@apha.org>; Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; John Hick (hick.john@gmail.com) <hick.john@gmail.com>; Jonna Mazet (jkmazet@ucdavis.edu) <jkmazet@ucdavis.edu>; Kent Kester (Kent.Kester@sanofi.com) <Kent.Kester@sanofi.com>; Kristian G. Andersen (kga1978@gmail.com) <kga1978@gmail.com>; Mark Smolinski (mark@endingpandemics.org) <mark@endingpandemics.org>; Mary Travis Bassett (mbassett@hsph.harvard.edu) <mbassett@hsph.harvard.edu>; Patricia King (patricia.king1@gmail.com) <patricia.king1@gmail.com>; Peggy Hamburg (peggy@hbfam.net) <peggy@hbfam.net>; Peter Daszak (daszak@ecohealthalliance.org) <daszak@ecohealthalliance.org>; Phyllis D. Meadows (PDMeadows@kresge.org) <PDMeadows@kresge.org>; Richard Besser (rbesser@rwjf.org) <rbesser@rwjf.org>; Tara O'Toole (totoole@iqt.org) <totoole@iqt.org>; Trevor Bedford (trevor@bedford.io) <trevor@bedford.io>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>;

'Donald Berwick' <donberwick@gmail.com>; 'alta.charo@wisc.edu' <alta.charo@wisc.edu>; 'Jeff.Duchin@kingcounty.gov' <Jeff.Duchin@kingcounty.gov>; 'Baruch Fischhoff' <baruch@cmu.edu>; 'DHanfling@iqt.org' <DHanfling@iqt.org>; 'bgroves@georgetown.edu' <bgroves@georgetown.edu>
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; 'mnavish@iqt.org' <mnavish@iqt.org>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'Peisch, Samuel Francis' <speisch@hsph.harvard.edu>; 'jbaker@rwjf.org' <jbaker@rwjf.org>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'Mary Radford' <maradford@ucdavis.edu>; Pope, Andrew <APope@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; Feit, Monica <MFeit@nas.edu>; Shore, Carolyn <CShore@nas.edu>; Wollek, Scott <SWollek@nas.edu>; Downey, Autumn <ADowney@nas.edu>
Subject: Agenda and Zoom Information for Second Virtual Meeting of the Standing Committee 4/30
Importance: High

Dear Members of the Standing Committee,

We are looking forward to the second virtual meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats taking place tomorrow, April 30th, from 11:00 a.m. – 1:00 p.m. ET. Please find attached the final agenda, and the Zoom information is below. The primary objective of tomorrow's call is to discuss the priorities that were raised on each of the four working group calls with the sponsors and the full committee. This is the first full committee meeting for the new members; therefore, we are also attaching updated bios and rosters of the full committee for your reference.

Please note that later today, we will be disseminating a compilation of the priority topics to the full committee. Several of the working groups met yesterday, so we are in the process of revising and compiling those priorities.

Zoom Call-In Information
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91377677378
Or iPhone one-tap:
US: +16465189805,,91377677378#
Or Telephone:
US: 888 475 4499 (Toll Free)
Meeting ID: 913 7767 7378
International numbers available: https://nasem.zoom.us/u/abTf8M7RWN

Please let us know if you have any questions.

Many thanks,
Lisa

Lisa Brown, MPH
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ACT- ACCELERATOR GLOBAL RESPONSE TO COVID-19

European Commission

29 April 2020
Draft - Work in progress

G20 + AU + APEC + WHO + World Bank

Global Stewardship with 2 High Level Personalities (North and South)
Supported by pledging co-leads (EU, France, Germany, Norway, Saudi Arabia, UK, ...)
and consortium of partners (WHO, BMGF, WEF, Wellcome Trust), co-ordination hub from WHO

R&D

MANUFACTURING

PROCUREMENT

DEPLOYMENT

(lead actor)

VACCINE PARTNERSHIP

CEPI (lead actor)

WHO
Research
Industry
Foundations
Funders
International organisations
Regulators

GAVI (lead actor)

THERAPEUTIC PARTNERSHIP

Therapeutics Accelerator (lead actor)

WHO
Research
Funders
Industry
International organisations
Regulators

DIAGNOSTICS PARTNERSHIP

FIND (lead actor)

WHO
Research
Funders
Industry
International organisations
Regulators

Global Fund (lead actor)

HEALTH SYTEMS AND CROSSCUTTING ISSUES

Coronavirus Global Response

Joining Forces to Accelerate the Development, Production and Equitable Access to COVID Vaccines, Diagnostics and Therapeutics

Press Conference - On-line Pledging Event

3 pm CET/9 am EST – 5 pm CET/10 am EST

Moderator: President von der Leyen, European Commission, Brussels

Welcome and pledges by co-hosts (2 minutes each)

1. President Ursula von der Leyen, European Commission
2. Dr Tedros, Director General of the WHO
3. [title, name], Saudi Arabia, G20 President
4. Prime Minister Conte, Italy, Future G20 President
5. President Emmanuel Macron, France
6. Chancellor Angela Merkel, Germany
7. Prime Minister Boris Johnson, The United Kingdom
8. *Prime Minister Justin Trudeau, Canada - tbc*
9. *Prime Minister Shinzo Abe, Japan - tbc*
10. Prime Minister Erna Solberg, Norway

Special Remarks (2 minutes each)

1. GPMB – Dr Victor Dzau
2. The Bill and Melinda Gates Foundation – Bill Gates
3. Wellcome Trust – Jeremy Farrar

Special Remarks by the Secretary General of the United Nations (2 minutes)

Governments – announcements of pledge (2 minutes each)

1. South Africa - tbc
2. South Korea - tbc
3. Israel - tbc
4. Australia - tbc
5. New Zealand - tbc
6. […]

Commitments and Pledges by Industry (2 minutes each)

1. IFPMA - Dave Ricks, Chairman
2. The World Economic Forum - tbc

Commitments and Expressions of Support by Partner Organisations

1. CEPI
2. GAVI
3. Therapeutics Accelerator
4. FIND
5. […]

Concluding Remarks by President Ursula von der Leyen (2 minutes)

1. Announcement of total amount pledged
2. Announcement of 23 May 2020 culminating event

ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR

A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 diagnostics, therapeutics and vaccines

24 April 2020

COMMITMENT and CALL TO ACTION

Our Vision and Mission

Grounded in a vision of a planet protected from human suffering and the devastating social and economic consequences of COVID-19, we, an initial group of global health actors (BMGF, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust, WHO) and private sector partners and other stakeholders, are launching a landmark, global and time-limited collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.

We know that as long as anyone is at risk from this virus, the entire world is at risk – every single person on the planet needs to be protected from this disease.

We agree that alongside evidence-based public health measures, innovative COVID-19 diagnostics, therapeutics and vaccines are needed – in record time and at record scale and access – to save millions of lives and countless trillions of dollars, and to return the world to a sense of 'normalcy'.

We recognize the significant amount of critical work, investment and initiatives already ongoing around the world to expedite the development and deployment of innovative COVID-19 related products and interventions.

We appreciate that while development and deployment of innovative products is essential, it will not be enough. We must simultaneously and urgently accelerate the strengthening of sustainable health systems and capacities to enable delivery of the new COVID-19 tools to those who need them and to mitigate the knock-on impact on other diseases.

We remember lessons from the past, which have shown that even when effective tools are available to the world, too often some are protected, while others are not. This inequity is unacceptable – all tools to address COVID-19 must be available to all. In the fight against COVID-19, no one should be left behind.

We understand we cannot do this alone, and that we need to work together in unprecedented and inclusive partnership with all stakeholders – political leaders, public and private sector partners, civil society, academia, and all other stakeholders across society – jointly leveraging our comparative strengths and respective voices to drive towards collective solutions, an accelerated path, and access for all. We are stronger, faster and more effective working together.

Our Mission is not only accelerated development and availability of new COVID-19 tools – it is to accelerate equitable global access to safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines, and thus to ensure that in the fight against COVID-19, no one is left behind.

Our Commitment

1. We commit to the shared aim of equitable global access to innovative tools for COVID-19 for all.
2. We commit to an unprecedented level of partnership – proactively engaging stakeholders, aligning and coordinating efforts, building on existing collaborations, collectively devising solutions, and grounding our partnership in transparency, and science.
3. We commit to create a strong unified voice to maximize impact, recognizing this is not about singular decision-making authority, but rather collective problem-solving, interconnectedness and inclusivity, where all stakeholders can connect and benefit from the expertise, knowledge and activities of this shared action-oriented platform.
4. We commit to build on past experiences towards achieving this objective, including ensuring that every activity we undertake is executed through the lens of equitable global access, and that the voices of the communities most affected are heard.
5. We commit to be accountable to the world, to communities, and to one another. We are coming together in the spirit of solidarity, and in the service of humanity, to achieve our mission and vision.

Our Call

We ask the global community and political leaders to support this landmark collaboration, and for donors to provide the necessary resources to accelerate achievement of the objectives of this global collaboration, capitalizing on the opportunity provided by the rolling pledging campaign that will start on 4 May 2020.

Bill & Melinda Gates foundation · dcvmn Developing Countries Vaccine Manufacturers Network · The Global Fund · IGBA · wellcome

CEPI · Gavi The Vaccine Alliance · IFPMA International Federation of Pharmaceutical Manufacturers & Associations · Unitaid Innovation in Global Health · World Health Organization

World Health Organization

Global leaders unite to ensure everyone everywhere can access new vaccines, tests and treatments for COVID-19

Unprecedented gathering of heads of government, institutions and industry cements commitment to accelerate development and delivery for all populations

24 April 2020| News release

GENEVA - Heads of state and global health leaders today made an unprecedented commitment to work together to accelerate the development and production of new vaccines, tests and treatments for COVID-19 and assure equitable access worldwide.

The COVID-19 pandemic has already affected more than 2.4 million people, killing over 160,000. It is taking a huge toll on families, societies, health systems and economies around the world, and for as long as this virus threatens any country, the entire world is at risk.

There is an urgent need, therefore, while following existing measures to keep people physically distanced and to test and track all contacts of people who test positive, for innovative COVID-19 vaccines, diagnostics and treatments.

“We will only halt COVID-19 through solidarity,” said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. “Countries, health partners, manufacturers, and the private sector must act together and ensure that the fruits of science and research can benefit everybody.”

Work has already started. Since January, WHO has been working with researchers from hundreds of institutions to develop and test vaccines, standardize assays and standardize regulatory approaches on innovative trial designs and define criteria to prioritize vaccine candidates. The Organization has prequalified diagnostics that are being used all over the world, and more are in the pipeline. And it is coordinating a global trial to assess the safety and efficacy of four therapeutics against COVID-19.

The challenge is to speed up and harmonize processes to ensure that once products are deemed safe and effective, they can be brought to the billions of people in the world who need them. Past experience, in the early days of HIV treatment, for example, and in the deployment of vaccines against the H1N1 outbreak in 2009, shows that even when tools are available, they have not been equally available to all.

So today leaders came together at a virtual event, co-hosted by the World Health Organization, the President of France, the President of the European Commission, and the Bill & Melinda Gates Foundation. The event was joined by the UN Secretary General, the AU Commission Chairperson, the G20 President, heads of state of France, South Africa, Germany, Vietnam, Costa Rica, Italy, Rwanda, Norway, Spain, Malaysia and the UK (represented by the First Secretary of State).

Health leaders from the Coalition for Epidemic Preparedness Innovations (CEPI), GAVI-the Vaccine Alliance, the Global Fund, UNITAID, the Wellcome Trust, the International Red Cross and Red Crescent Movement (IFRC), the International Federation of Pharmaceutical Manufacturers (IFPMA), the Developing Countries Vaccine Manufacturers’ Network (DCVMN), and the International Generic and Biosimilar Medicines Association (IGBA) committed to come together, guided by a common vision of a planet protected from human suffering and the devastating social and economic consequences of COVID-19, to launch this groundbreaking collaboration. They are joined by two Special Envoys: Ngozi Okonjo-Iweala, Gavi Board Chair and Sir Andrew Witty, former CEO of GlaxoSmithKline.

They pledged to work towards equitable global access based on an unprecedented level of partnership. They agreed to create a strong unified voice, to build on past experience and to be accountable to the world, to communities and to one another.

“Our shared commitment is to ensure all people have access to all the tools to prevent, detect, treat and defeat COVID-19,” said Dr Tedros. “No country and no organization can do this alone. The Access to COVID-19 Tools Accelerator brings together the combined power of several organizations

to work with speed and scale.”

Health leaders called on the global community and political leaders to support this landmark collaboration and for donors to provide the necessary resources to accelerate achievement of its objectives, capitalizing on the opportunity provided by a forthcoming pledging initiative that starts on 4 May 2020. This initiative, spearheaded by the European Union, aims to mobilize the significant resources needed to accelerate the work towards protecting the world from COVID-19.

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Location: zoom (see below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 5/8/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 5/8/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Meeting: NAM-APHA COVID-19 Webinar Series
Time: May 8, 2020 02:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/526660780

Or iPhone one-tap :
US: +13126266799,,526660780# or +14702509358,,526660780#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 312 626 6799 or +1 470 250 9358 or +1 646 518 9805 or +1 646 558 8656 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 301 715 8592 or +1 602 753 0140 or +1 651 372 8299 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 526 660 780
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

Would you like to test your Zoom connection? Please click on the link below.
https://nasem.zoom.us/test

To: Carter Mecher[cmecher@charter.net]; to: Dr. Eva Lee[eva.evalee.lee64@gmail.com]; William Lang[wlang@worldclinic.com]; cc: Jerry Mothershead[jmothershead@patronusmedical.com]; Richard Hatchett[richard.hatchett@cepi.net]; Richard Tubb[bg.richard.tubb@gmail.com]; Dr. Eva K Lee[evalee-gatech@pm.me]; McDonald, Eric[Eric.McDonald@sdcounty.ca.gov]; Caneva, Duane[duane.caneva@hq.dhs.gov]; Mark Keim, MD MBA[mark@disasterdoc.org]; Jerry Mothershead[1974usna@gmail.com]; Tom Bossert[tom.bossert@me.com]; Rob Darling, MD[rdarling@patronusmedical.com]; Callahan, Michael V.,M.D.[MVCALLAHAN@mgh.harvard.edu]; Madad, Syra[syra.madad@nychhc.org]; Baric, Ralph S[rbaric@email.unc.edu]; Hanfling, Dan[DHanfling@iqt.org]; McGinn, Tom[Tom.McGinn@hq.dhs.gov]; Gruber,David (DSHS)[David.Gruber@dshs.texas.gov]; Ciottone,Gregory (HMFP - Emergency Medicine)[gciotton@bidmc.harvard.edu]; reddawn@mphise.us[reddawn@mphise.us]; Arthur Kellermann[arthur.kellermann@usuhs.edu]; Jamison Day[jamison.day@gmail.com]; Logan, Linda L[llogan@cvm.tamu.edu]; Venkayya, Rajeev[rajeev.venkayya@takeda.com]; Eastman, Alexander[alexander.eastman@hq.dhs.gov]; Mansoura, Monique K.[mmansoura@mitre.org]; James Lawler[jvlawler92@gmail.com]; LLogandakar[llogandakar@gmail.com]; Walters, William (STATE.GOV)[walterswa2@state.gov]; Parker Jr, Gerald W[gparker@cvm.tamu.edu]; Kevin Montgomery[kevin@collaborate.org]; DC[michelle.colby@usda.gov]; Matthew JtCIVtUSARMY (USA)[matthew.j.hepburn.civ@mail.mil]; Andy Desjardins, MD[adesjardins@patronusmedical.com]; Fantinato, Jessica (USDA.GOV)[jessica.fantinato@usda.gov]; Martin, Greg (state.gov)[MartinGJ@state.gov]; Ryan Morhard[Ryan.Morhard@weforum.org]; Borio, Luciana[LBorio@iqt.org]; KAUSHIK, SANGEETA[sangeeta.kaushik@hq.dhs.gov]; CHRISTOPHER ALLEN[chrisallen_10@msn.com]; Cordts, Jerome (CTR)[jerome.cordts@associates.hq.dhs.gov]; Schnitzer, Jay J.[jschnitzer@mitre.org]; jwleduc@utmb.edu[jwleduc@utmb.edu]; HARVEY, MELISSA[melissa.harvey@hq.dhs.gov]; Larry G[PadgetLG@state.gov]; Ignacio, Joselito[joselito.ignacio@fema.dhs.gov]; David[DMarcozzi@som.umaryland.edu]; Hassell, David (Chris) (OS/ASPR/IO)[David.Hassell@hhs.gov]; Will Gaskins[will.gaskins@efiia.com]; Lauren Johnston[ljohnston@patronusmedical.com]; Steven Jt(tCHFStDPH)[steven.stack@ky.gov]; HAMILTON, CAMERON[cameron.hamilton@hq.dhs.gov]; Wade, David[david.wade@hq.dhs.gov]; Lewis Hofmann[lewhof@mac.com]; WILKINSON, THOMAS[THOMAS.WILKINSON@hq.dhs.gov]; WOLFE, HERBERT[HERBERT.WOLFE@hq.dhs.gov]; CharitytA@CDPH[Charity.Dean@cdph.ca.gov]; Marinissen, Maria (HHS/OS/OGA)[Maria.Marinissen@hhs.gov]; Sutter, Mark[mark.sutter@hq.dhs.gov]; McLeod James[jmcleod@patronusmedical.com]; Wine G.C.[gcwine@patronusmedical.com]; Dan Carlin[dcarlin@worldclinic.com]; Krohmer, Jon (NHTSA)[jon.krohmer@dot.gov]; Hart,Alexander (APHMFP - Emergency Medicine)[ahart1@bidmc.harvard.edu]; You, Edward H. (WMD) (FBI)[ehyou@fbi.gov]
From: Richard Tubb[bg.richard.tubb@gmail.com]
Sent: Sat 5/2/2020 8:36:43 AM (UTC-04:00)
Subject: Fwd: COVOD G6PD deficiency and oxidative stress—an endothelial basis for disease...and treatment
image0.jpeg
image0.jpeg
62b17ae0-3c76-456b-9238-8818d3908773.png
G6PDd and COVID Observations-4.13.pdf

---------- Forwarded message ---------
From: **Richard Tubb** <bg.richard.tubb@gmail.com>
Date: Sat, May 2, 2020 at 8:34 AM
Subject: Fwd: COVOD G6PD deficiency and oxidative stress—an endothelial basis for disease...and treatment
To: bg.richard.tubb <bg.richard.tubb@gmail.com>

All,(Long note of pieced together forward emails regarding theory of COVID as an endothelial disease initiated by oxidative stress with significant hat tip to Dr. Seheult of Medcram.com .)
Again, no need to respond. If nothing else, just look at the screen shot that follows.

> A follow up on my G6PD deficiency observation in COVID. Have added a few people but moved everybody to bcc since I didn't ask your permission. That said, feel free to forward as you see fit.
>
> (Briefly, for those new to this, a while back I raised the question as to whether people with G6PD deficiency were at increased risk of the worst manifestations of COVID 19, and if so did it suggest a final common pathway to destruction, or even a common beginning. I won't belabor it beyond that, but if you want me to forward the earlier email, I will do so.)
>
> For now, if you're wondering whether to read the rest of this, look at the screenshot first then decide.). I welcome your thoughts.
>
> Increasingly I believe some of the worst manifestations of COVID are best explained by endothelial disorder brought about by oxidative stress via reactive oxygen species.

If that is the case, it might explain what the intensivists have noted about managing what often looks like ARDS but all too often doesn't behave like ARDS.

Epidemiologically (and by observation) it might also explain why the Comorbid conditions Presenting the greatest risks for the worst outcome—obesity, obesity, obesity, diabetes, hypertension, and coronary artery disease (and I believe if it was looked for, we would also add NAFLD/NASH)—all conditions thought to be associated with oxidative stress. What we don't see as clear of an association, for a presumed respiratory disease, is COPD, RAD, or tobacco use .

With that foundation, if you quickly review the highlighted sections in the attached screenshot of a dated paper, you will find a possible pathophysiological explanation for an apparent association between COVID19 and G6PD deficiency—increased oxidative stress and inactivated nitric oxide resulting in endothelial disease.

(Although he hasn't yet drawn the link between COVID and G6PDd, an internet doctor MedCram.com is speaking to the endothelial hypothesis, and is the origin of the screen shot as noted). Dr. Seheult view episodes 61, 63, 65 (as of this date 5/2; more to follow i am certain)

Again, no need to reply. Somebody smarter than me is undoubtedly working on it (maybe the medcram doctor will talk about it in next episode).

Thank you for all that you all do.

V/R

Dick Tubb

PS

PS—it would be easy epidemiologically and then by rapid diagnostic test or central lab test to identify those with G6PD deficiency.

Why is it IMPORTANT?

Doing so might help validate an endothelial basis for what I call a COVID crisis (ala cytokine Storm, ARDS, and respiratory, circulatory, and thrombotic collapse)...and there bye direct a treatment.

If validated, it would help to alert at risk communities, a focus of the President—e.g. African American, African-Caribbean-American, and Mediterranean Americans, and those known to be G6PD deficient—both for the ravages of COVID (and the need to reprioritize self isolation), and if ever treated with chloroquine.

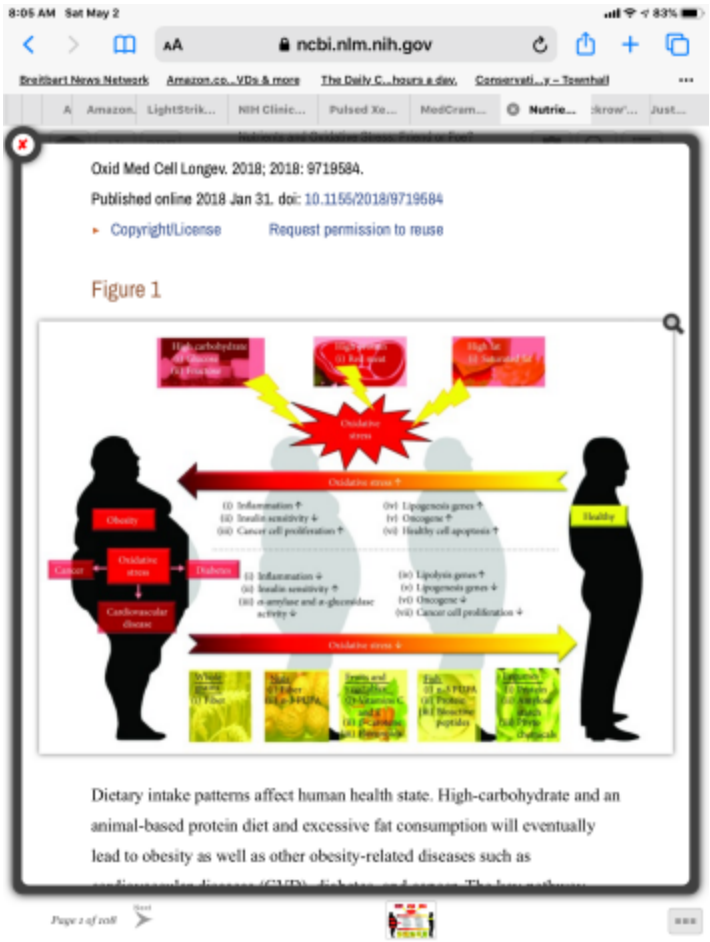
It would also identify individuals with oxidative stress mediated disease to redouble their remedial efforts.

PSS

I would strongly encourage you to look at the 15' video below (and ideally the two related episodes preceding it—you have to register but it's free and they don't send you stuff). It's pretty thick pchem but it all makes total sense to me,

explains many things heretofore unexplained about COVID (and your work with HCQ), identifies those at risk, and points the way to a treatment (??? ACE, NAD+, niacinamide/nicotine, certain diets, nitric oxide active medications, etc).

https://www.medcram.com/courses/take/coronavirus-outbreak-symptoms-treatment/lessons/12463438-update-65-covid-19-and-oxidative-stress-prevention-risk-factors



Sent from my iPad

--
Richard J. Tubb, MD
Brigadier General (retired)
White House Physician Emeritus

Format: Abstract Send to

Pathophysiol Haemost Thromb. 2002 Sep-Dec;32(5-6):359-60.

Oxidative stress in endothelial cell dysfunction and thrombosis.

Loscalzo J[1].

Author information

Abstract

Endothelial dysfunction (ECD) is the earliest phenotypic change in the vasculature following exposure to atherothrombotic risk factors. ECD is associated with decreased synthesis and increased oxidative inactivation of nitric oxide (NO). Critical antioxidant enzymes essential for eliminating reactive oxygen species that can inactivate NO include the superoxide dismutases, the glutathione peroxidases, catalase, and glucose-6-phosphate dehydrogenase. Deficiencies of these enzymes increase oxidative stress and NO inactivation and, as such, can either lead to ECD or account for the underlying mechanism of ECD associated with a given atherothrombotic risk factor. Selected antioxidants improve intracellular redox state and reverse ECD by improving the bioavailability of NO. These observations provide mechanistic insights into the molecular basis of ECD in vascular disease and its treatment.

PMID: 13679676 DOI: 10.1159/000073600

[Indexed for MEDLINE] Free full text

Format: Abstract Send to

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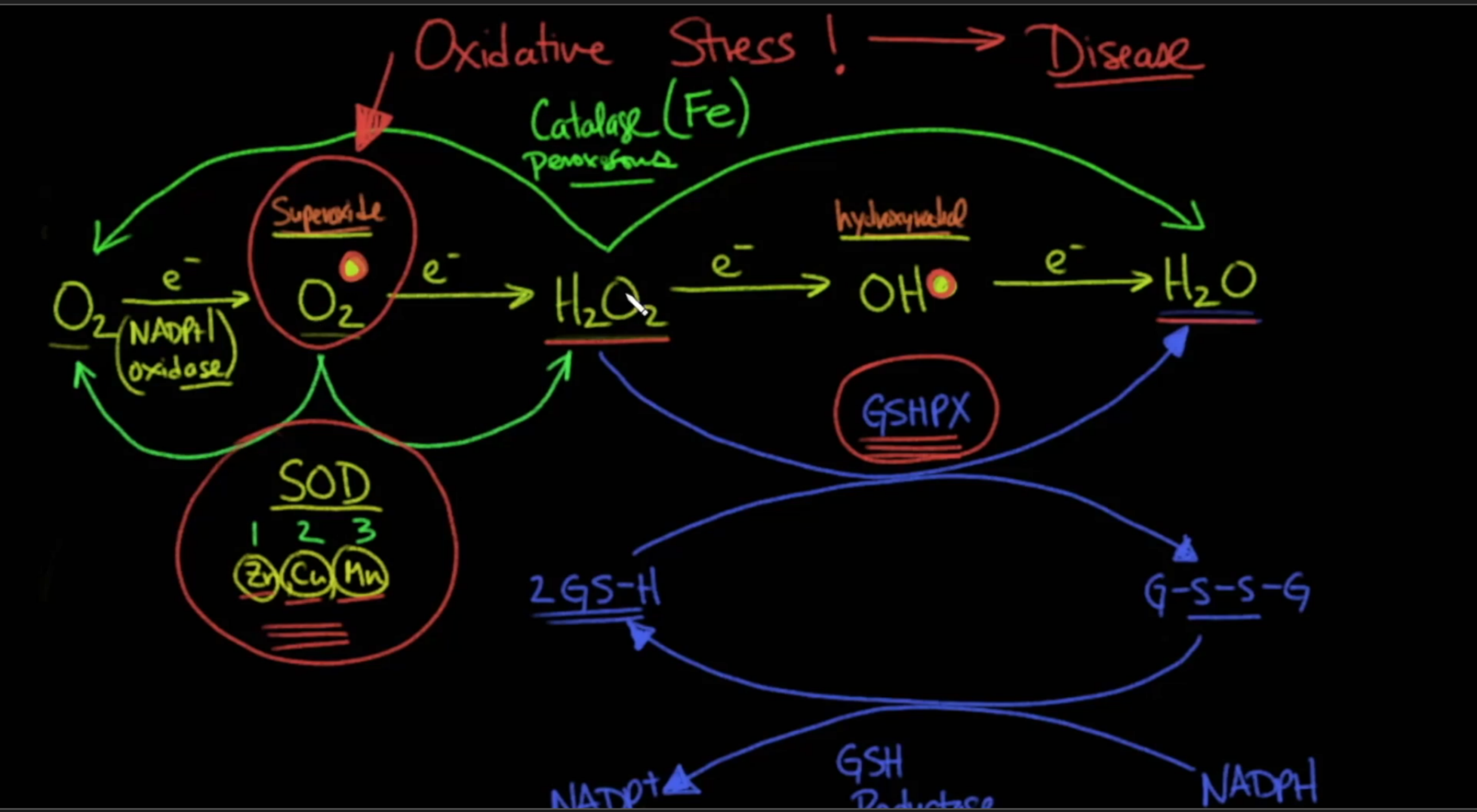
[Indexed for MEDLINE] Free full text

Update 65: COVID-19 and Oxidative Stress (Prevention & Risk Factors)



Richard Tubb, MD
Brigadier General (retired)
White House Physician, Emeritus

Is there a Correlation Between G6PD Deficiency and "COVID Crisis"?

Observation

Many of the communities that have suffered from the most severe manifestations of COVID-19 are also those who might also be expected to have the highest prevalence of G6PD deficiency (G6PDd) and its comorbidities.

Questions

1. Is there a correlation between G6PD deficiency and COVID-infected patients who experience "cytokine storm," ARDS, rapid clinical decompensation, and/or death?
2. Is G6PDd a possible marker for individuals who might be at increased risk for the same?
3. Is there a direct causal relationship between G6PDd and the above-mentioned complications?
4. Is there an indirect causal relationship between G6PDd and the above-mentioned complications?

Background

It has been impossible to miss the disproportionate burden of suffering born by the population of Italy, particularly of Lombardy, imposed by the coronavirus, COVID-19 (even more so, in some respects, than by Wuhan, Hubei, and China). That burden, itself, has been disproportionately carried by older men with underlying diseases to include hypertension, diabetes mellitus, obesity, coronary heart disease, cerebrovascular disease, immune suppression, and the treatments of the same. It has also been noted that individuals who are eventually admitted to the hospital will experience a period of transient clinical improvement followed by a sudden need for respiratory support, radiographs or CT with a "ground glass" appearance consistent with bilateral pneumonia, (often preceded by a strikingly low oxygen saturation out of proportion to the patient's clinical appearance), intubation, "cytokine storm," apparent "ARDS," and death. Questions have been raised as to the utility, even futility, of traditional ventilatory support as might be traditionally offered in ARDS; the utility of "proning;" the adverse contributions of an inflammatory response, exaggerated immune response, or even an autoimmune response; the possible presence of a hemoglobinopathy; the role, if any, and mechanism of action of hydroxychloroquine (HCQ), ivermectin, and anti-psoriatic medications.

Commented [LH1]: Do you need to explain this, or am I the only one too dumb to know?

In explaining the disproportionate burden born by Italy, observers have suggested the following:

Commented [LH2]: Added the r to observers

- "The 'old man' of Europe." i.e., a disproportionately elderly population.
- "The 'sick man' of Europe." i.e., a disproportionately sick population.
- A Country bound by the sea and the mountains.

- High population density.
- A highly social and physically expressive culture that encourages close contact.
- A recent influx of immigrants and business from Mainland China.

To help assess these observations, it may also help to note that two other Mediterranean European countries, Spain and France, are second and third, respectively in the disease burden. This contrasts with the disease burden and especially the case fatality rate (CFR) born by Germany and the Nordic countries of Europe. Perhaps the region most severely impacted outside of Italy (and soon to surpass in total number of deaths) is the New York City Metropolitan area.

The impact on both regions can't help but lead to the search for common threads, not shared by other dense metropolitan areas in Europe or in the United States. A possible commonality might be a shared European, even Mediterranean ethnic heritage, i.e. Mediterranean Italian, or Spanish (or French). A point of investigation might be to examine the ethnic heritage and demographics of those who suffered from cytokine storm, ARDS, sudden respiratory collapse and death (aka "COVID crisis") in the New York City metro area compared with the metropolitan areas of the West Coast of the United States. Possible pertinent questions regarding the victims might include:

- Age
- Sex
- Comorbidities
- Ethnic heritage

Or, as we did in Europe, it might be helpful to analyze the impact of "COVID crisis" on Italian-American, Spanish-American, and other Mediterranean-American communities in urban areas of the US Eastern seaboard based on the above demographic descriptors.

Following a different potential lead, when I hear about "inflammatory reactions," "exaggerated immunologic responses," and "autoimmune disease," disproportionately distributed within a particular ethnic population, I begin to think of genetic predispositions. In this particular case, one that jumps out at me from my medical school days is G6PD deficiency (aka G6PDd). G6PDd is a recessive x-linked inborn error in metabolism necessary for the proper functioning of red blood cells, the hemoglobin containing, oxygen carrying entity for the body. (without G6PD, when the RBC is subjected to "oxidative stress," e.g. certain medications, especially antimalarial, sulfa and nonsteroidal anti-inflammatory drugs, the red cell "self-destructs" in a "hemolytic crisis.") Two variants of G6PDd are especially prevalent: G6PD A- in Africans and African Americans/Caribbean; and G6PD Mediterranean predominantly in Spaniards, Italians, Greeks, Armenians, and Semitic peoples. (another variant, G6PD Canton is seen especially in South/Southeast Asians.) Both deficiency (and perhaps others) are thought to be evolutionary developments providing protection against malaria.

If we were to propose a correlation between G6PDd and COVID crisis, we would expect to find it in other "at-risk" populations. One such population that in the past two weeks has received substantial attention from the White House has been the African American community. The Task Force has been deliberate and precise in noting that the African American community is

NOT more susceptible to the coronavirus; rather, it is more susceptible to the devastating harms of the disease. The data to date suggests that to be true due to the high prevalence of "co-morbidities" within the African American community that predispose any patient to the risk and consequences of COVID crisis. Just as in Italy, and in New York, those comorbidities include: hypertension, diabetes mellitus, obesity, coronary artery disease, cerebrovascular disease, chronic kidney disease, immunosuppression, and the therapies directed against those diseases. While the scientists are correct in noting that most of those comorbidities are associated with unhealthy lifestyles, what is not mentioned is that they are also known to be more prevalent within populations (especially African-American-Caribbean) that are G6PD deficient (especially hypertension and diabetes, which are, in turn, associated with many/most of the others).

Lastly, having raised the question of the role G6PDd might play in COVID crisis, we can now ask the question that if G6PDd is involved, what other conditions might reasonably be observed? The following have already been noted:

- Italians, Spaniards, and other Mediterranean peoples
- Their descendants in America
- Africans and their descendants in America and the Caribbean
- Males
- Persons with the comorbidities noted above
- Persons with less physiological reserves (older people)

Other conditions known to impact G6PDd that might be observed in COVID crisis:

- Medications known to precipitate a hemolytic crisis in patients with G6PDd:
  - The Antimalarials, quinine, primaquine, and to a lesser extent hydroxychloroquine
  - NSAIDs (nonsteroidal anti-inflammatory drugs)
  - High dose vitamin C (+/-)
- G6PDd is known to augment cytokine response (IL8) and hyperinflammatory response in the face of endotoxemia and severe polymicrobial sepsis (there is also some suggestion that COVID may respond to anti-psoriatic drugs directed toward IL6 and IL8)
- G6PD deficient cells are known to be more susceptible to viral infections (and especially to human coronaviruses such as HCoV229E) and to subsequent oxidative stress.
- Proteins associated with COVID infections (e.g., orf1ab, ORF10, ORF3a) are postulated to attack the beta chain of hemoglobin, negatively impacting carriage of oxygen and carbon dioxide, producing an inflammatory response, and the ground glass appearance of COVID-infected lungs on radiographs. The hemoglobin of diabetics is especially affected. (this process may be where chloroquine and favipiravir work).

If G6PD deficiency evolved to provide a protective effect (or perhaps more precisely, selected for those populations with a protective enzyme deficiency) did a similar process occur in Asian populations leading to G6PD (Canton)? If so, how prevalent is such an enzyme deficiency and where in Asia is it most prevalent? How prevalent is G6PDd in Wuhan? Other large Chinese cities (e.g., Beijing)? Singapore? Hong Kong? Seoul? Tokyo? Contrary to the European and American experience, can the prevalence of G6PDd explain why such metropolitan areas were spared, or had such impressive success in responding to the virus? Could it also possibly explain the epi curve in Wuhan and Hubei, or in their ability to relatively rapidly and successfully return

to work? Did the suspected bat virus and its human neighbors induce other "evolutionary advantages"? Do the various viral claves suggest recent migration from Wuhan to Italy, then throughout Europe, and the United States to populations that hadn't "profited" from such evolutionary advantages?

Conclusion

I now return full circle to the four questions I posed at the beginning. I am certain that if there is any "there there," this will simply serve as a springboard to many more questions, and hopefully many, many more answers, and some solutions. I would be happy to discuss, elaborate, and provide citations at your convenience.

Richard Tubb, MD
Brigadier General (retired)
White House Physician, Emeritus

To: 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; david.j.payne@gsk.com[david.j.payne@gsk.com]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Annaliesa.Anderson@pfizer.com[Annaliesa.Anderson@pfizer.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; kara.carter@evotec.com[kara.carter@evotec.com]; john.young.jy3@roche.com[john.young.jy3@roche.com]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; 'Collins, Francis (NIH/OD) [E]'[collinsf@od.nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Rao, Srinivas /US'[Srinivas.Rao@sanofi.com]; 'Qashu, Felicia (NIH/OD) [E]'[felicia.qashu@nih.gov]
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From: Prabha Fernandes[prabha.fernandes@gmail.com]
Sent: Sun 5/3/2020 11:48:55 AM (UTC-04:00)
Subject: RE: April 30 Preclinical meeting minutes

Thank you, Joe!
Prabha

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Sunday, May 03, 2020 10:16 AM
To: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph <rbaric@email.unc.edu>; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Rao, Srinivas /US <Srinivas.Rao@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Austin, Christopher (NIH/NCATS) [E] <austinc@mail.nih.gov>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Desrosiers, Betsy <elizabeth_desrosiers@merck.com>; Hughes, Eric <eric.hughes@novartis.com>; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Kurilla, Michael (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas (NCI) <dl60z@nih.gov>; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Tountas, Karen (FNIH) [T] <ktountas@fnih.org>; Santos, Michael (FNIH) [T] <msantos@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; James, Stephanie (FNIH) [T] <sjames@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kim, Elizabeth <elkim@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes <prabha.fernandes@outlook.com>; Diamond, Michael <mdiamond@wustl.edu>; Rose Li <rose.li@roseliassociates.com>; Dana Carluccio <dana.carluccio@roseliassociates.com>; Lagos, Enrique (NIH/NCATS) [E] <enrique.lagos@nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Gonzalez, Nina <ningonzalez@deloitte.com>; Simon, Dina (NIH/OD) [C] <dina.simon@nih.gov>; Burrus-Shaw, Cyndi (NIH/OD) [E] <cyndi.burrus-shaw@nih.gov>; Rodriguez, Robin D <rmdaigle@tulane.edu>; Dave Frankowski <david.frankowski@roseliassociates.com>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Lowy, Douglas (NIH/NCI) [E] <lowyd@mail.nih.gov>
Subject: April 30 Preclinical meeting minutes

Dear Preclinical working group participants,

Please find the minutes from the meeting on April 30th. For ease of review, I have pasted the action items below. In addition, Mike Diamond and Prabha Fernandes have collected potential members of an expert panel for preclinical asset prioritization. The bios for this group have been attached for your review.

Action Items:

- Revise the slides for presentation at the Leadership Meeting. Joe and Rosa to revise, John and Christine to review.
- Prepare slides to describe the proposed NHP strategy for discussion with the NPRC directors on Tuesday, May 5th.
- Small animal team to complete the Table of small animal models and their preferred use for prioritization and presentation to this team next week.
- Send list of Bios for the In Vitro expert panel for review to the full working group, before sending meeting requests from FNIH and Co-chairs. [document included with these minutes, thank you Michael and Prabha for putting this together].

Thank you all for a very interesting and productive meeting. Please provide any comments and suggested modifications to Joe and Rosa.

Sincerely,
Joe and Rosa

From: William Dowling[william.dowling@cepi.net]

Location: Skype Meeting

Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 5/6/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 5/6/2020 10:00:00 AM (UTC-04:00)

Required Attendees: Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

Optional Attendees: KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)

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US2 +13479604639,,54253499# (Intility)	English (United Kingdom)
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France +33975183429,,54253499# (Intility)	English (United Kingdom)
Netherlands +31858887765,,54253499# (Intility)	English (United Kingdom)
South Africa +27875509230,,54253499# (Intility)	English (United Kingdom)
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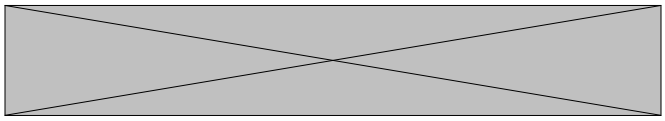

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.....

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Tue 5/5/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 5/5/2020 3:00:00 PM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas

Optional Attendees: Florence, Clint (NIH/NIAID) [E]; Diamond, Michael; Gonzalez, Nina; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]

Cancelling due to the NPRC director's meeting.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

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+1 253 215 8782 US
Meeting ID: 960 4240 3854
Password: 124630
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To: Baric, Ralph S[rbaric@email.unc.edu]
Cc: Aleksei Chmura[chmura@ecohealthalliance.org]
From: Peter Daszak[daszak@ecohealthalliance.org]
Sent: Wed 5/6/2020 7:16:01 PM (UTC-04:00)
Subject: FW: Washington Post story on bat CoVs etc.

Here's what I said to the Washington Post reporter. Hope that works. If he asks you about GoF I strongly recommend you just come back with the comments:

- Well that's already been debated extensively and decided on by NIH
- The origin of COVID-19 doesn't have anything to do with this because a NASEM committee and a paper in Nat. Med clearly show the virus has a natural origin, no evidence of manipulation

I practice lines like that and ways to get it back onto the real issue of either the importance of Remdesivir, or the massive interface in rural China (1-7 million people per year infected by bat CoVs from our serology study), or the greater issue of needing broad based drugs and vaccines. They will eventually move on to that topic…

I will from now on make everything extremely clear to reporters about the way this all happens…

Cheers,

Peter

Peter Daszak
President

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USA

Tel.: +1-212-380-4474
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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From: Peter Daszak <daszak@ecohealthalliance.org>
Sent: Wednesday, May 6, 2020 5:41 PM
To: Sonne, Paul <Paul.Sonne@washpost.com>
Cc: Robert Kessler <kessler@ecohealthalliance.org>; Aleksei Chmura <chmura@ecohealthalliance.org>
Subject: Re: Washington Post story on bat CoVs etc.
Importance: High

Hi Paul – I was just talking with Ralph Baric at UNC about the work in China and he mentioned that you were likely running with the story. Glad to hear that. Let me know if there's anything you might need fact-checking – I'm available and will respond rapidly.

He mentioned the link between our work sampling bats in China and the breakthrough drug Remdesivir. It's a

complicated chain, and to be honest one that I only realized recently, but the genetic sequences of the bat viruses that we discovered in China are put online (Genbank, GISAID) and have been used to help test how effective the drug Remdesivir would be against not only SARS-CoV, but also MERS, and 'other potentially zoonotic, or pre-pandemic bat-CoVs'. This is all done without even the need for culture of virus, or shipping viruses internationally, despite what has been said by some conspiracy theorists. I have articles to support that if you need to cross-reference.

Hope that helps, and please don't hesitate if any other comments/quotes need to be checked or supported by data/publications.

Cheers,

Peter

Peter Daszak
President

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EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

From: Sonne, Paul <Paul.Sonne@washpost.com>
Sent: Monday, April 27, 2020 12:40 PM
To: Peter Daszak
Subject: Washington Post Interview

Hi Dr. Daszak,

I cover national security for The Washington Post out of our office in Washington DC.

I'm wondering if you would have some time for a phone interview, as I'm interested in writing a story about US-funded research into novel bat coronaviruses over the years, and I see that your organization has been one of the main drivers in this space. (I cover the military and noticed in particular the funding stream from DTRA).

I've read a number of stories covering the alliance's work, and was hoping you might be able to walk me through a few things. Thanks very much.

All the best,
Paul

--
Paul Sonne
The Washington Post
+1 202 412 1708
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Cc: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; GSELL, Pierre[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 5/7/2020 6:00:53 AM (UTC-04:00)
Subject: Webex Meeting invitation and Agenda WHO Animal Models group call_May 7 2020
Mail Attachment.ics
Webex_Meeting.ics

Dear all,
Please find below the agenda for today's call and the webex invite.

Best regards

César, Bill and Simon.

Agenda: COVID-19 Animal Models Expert Group call (7 MAY 2020 3PM CET)

Introductory remarks (Cesar)

1- Update on VAAP

2- Laboratory landscape questionnaire

3- Review of the state of the art

Pathogenesis

1- Stanford University (Garry Nolan)

2- HKU (Honglin Chen: High level summary https://www.tandfonline.com/doi/full/10.1080/22221751.2020.1756700)

Therapeutics (Focus on chloroquine/hydroxichloroquine)

1- RML (Heinz Feldmann)

2- CEA (Roger LeGrand) https://www.researchsquare.com/article/rs-27223/v1

3-Emulate Bio (Geraldine Hamilton)

4- Concluding remarks (Pierre Gsell and Simon Funnell)

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 924 180 666
Meeting password: Bq2KPwxQD63

Thursday, May 7, 2020

3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] Animal Models Expert Group - 11th TC
Location: https://who.webex.com/who/j.php?MTID=m452d8c76b3d7eb3966436972bcd1cc99
Start Time: 2020-05-07T15:00:00+02:00
End Time: 2020-05-07T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

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Location: https://who.webex.com/who/j.php?MTID=m452d8c76b3d7eb3966436972bcd1cc99
Start Time: 2020-05-07T15:00:00+02:00
End Time: 2020-05-07T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 5/7/2020 10:54:01 AM (UTC-04:00)
Subject: Laboratory Landscape Survey

Dear all,
As we just mentioned in the call, please find below the link to access the Laboratory Lanscape Survey questionnaire. We know you all are very busy but it will take 5 min of your time and it will be extremely helpful for us. The link to the survey will be also posted at the WHO R&D Blueprint website

https://enketo.lshtm.ac.uk/::SVcm9oTW

Thank you all very much for your support

César, Simon and Bill.

From: William Dowling[william.dowling@cepi.net]

Attendees: Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD); KNEZEVIC, Ivana

Location: Microsoft Teams Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 5/13/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 5/13/2020 10:00:00 AM (UTC-04:00)

Required Attendees: Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer;

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From: William Dowling[william.dowling@cepi.net]

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Location: Microsoft Teams Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 4/22/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/22/2020 10:00:00 AM (UTC-04:00)

Required Attendees: Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; mit666666@pitt.edu; Drosten, Christian; Karl.Erlandson@hhs.gov; Falzarano, Darryl; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; Holbrook, Michael (NIH/NIAID) [C]; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Johnson, Reed (NIH/NIAID) [E]; Cassandra.Kelly@finddx.org; Jacqueline Kirchner; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; Erica Ollmann Saphire; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); David Vaughn; linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer;

tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

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From: William Dowling[william.dowling@cepi.net]

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Location: Microsoft Teams Meeting

Importance: Normal

Subject: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 5/20/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 5/20/2020 10:00:00 AM (UTC-04:00)

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Cc: KNEZEVIC, Ivana[knezevici@who.int]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)[htq4@cdc.gov]
From: William Dowling[william.dowling@cepi.net]
Sent: Sat 5/9/2020 7:56:32 AM (UTC-04:00)
Subject: WHO SARS-COV-2 assays call - new invite

Hello all

I had sent a recurring Outlook invite for the meeting with a Skype number (now transitioned to Teams by my organization). But going forward, you will receive a new Webex invite each week from Pierre Gsell at WHO. I am going to cancel my invite, and wanted to make sure there was not confusion – there will be a meeting this week.

Thanks
Bill

William Dowling, PhD

Non-Clinical Vaccine Development Leader

CEPI New vaccines for a safer world

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From: William Dowling[william.dowling@cepi.net]

Location: Microsoft Teams Meeting

Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 4/22/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 4/22/2020 10:00:00 AM (UTC-04:00)

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Optional Attendees: Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)

This meeting will still occur every Wed, but there will be a Webex invitation from WHO each week to replace this one.

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From: William Dowling[william.dowling@cepi.net]

Location: Microsoft Teams Meeting

Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 5/20/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 5/20/2020 10:00:00 AM (UTC-04:00)

Required Attendees: David Vaughn; Falzarano, Darryl; Holbrook, Michael (NIH/NIAID) [C]; mit666666@pitt.edu; Erica Ollmann Saphire; Jacqueline Kirchner; Johnson, Reed (NIH/NIAID) [E]; Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Drosten, Christian; Karl.Erlandson@hhs.gov; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Cassandra.Kelly@finddx.org; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); linfa.wang@duke-nus.edu.sg; wilsonp@uchicago.edu; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

Optional Attendees: KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)

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From: William Dowling[william.dowling@cepi.net]

Location: Microsoft Teams Meeting

Importance: Normal

Subject: Canceled: WHO Consultation on SARS-CoV -2 Viruses, Reagents and immune Assays - Wed 3:00 PM CET

Start Time: Wed 5/13/2020 9:00:00 AM (UTC-04:00)

End Time: Wed 5/13/2020 10:00:00 AM (UTC-04:00)

Required Attendees: wilsonp@uchicago.edu; David Vaughn; Falzarano, Darryl; Holbrook, Michael (NIH/NIAID) [C]; mit666666@pitt.edu; schendel@lji.org; Erica Ollmann Saphire; Jacqueline Kirchner; Johnson, Reed (NIH/NIAID) [E]; Baric, Toni C; Baric, Ralph S; cheryl@gisaid.org; Bok, Karin (NIH/VRC) [E]; Boyle, David; brooke.bozick@nih.gov; christian.brechot; Christine.bruce@phe.gov.uk; Carroll, Darin (CDC/DDID/NCEZID/OD); Miles.Carroll; Marco.Cavaleri@ema.europa.eu; Monalisa Chatterji; Chu, May; Carolyn Clark; Corbett, Kizzmekia (NIH/VRC) [E]; Alejandro Javier COSTA; Crozier, Ian (NIH) [C]; Damon, Inger K. (CDC/OID/NCEZID); daszak@ecohealthalliance.org; De wit, Emmie (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Delgado Vazquez.Rafael; Drosten, Christian; Karl.Erlandson@hhs.gov; Florence, Clint (NIH/NIAID) [E]; MFrieman@som.umaryland.edu; Simon Funnell; Luc Gagnon; Gerber, Susan I. (CDC/DDID/NCIRD/DVD); Volker.gerdts@usask.ca; Raul Gomez Roman; barney.graham@nih.gov; Gromowski, Gregory D CIV USARMY MEDCOM WRAIR (USA); GSELL, Pierre; Guthrie, Erica (CDC/DDID/NCIRD/ID); b.haagmans@erasmusmc.nl; HENAO RESTREPO, Ana Maria; Hensley, Lisa (NIH/NIAID) [E]; Hodgson, Paul; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; Cassandra.Kelly@finddx.org; M.P.G. Koopmans; Kovacs, Gerald (OS/ASPR/BARDA) (CTR); Krammer, Florian; Shelly Krebs; Greg Kulnis; Arun Kumar; teresa.lambe@ndm.ox.ac.uk; Lathey, Janet (NIH/NIAID) [E]; Leader, Troy; leejooyeon@korea.kr; Lever Steve; limhy0919@korea.kr; Little, James (OS/ASPR/BARDA); Karen Makar; Giada Mattiuzzo; McDermott, Adrian (NIH/VRC) [E]; jmcelrat@fredhutch.org; Mellors, John W; Kayvon Modjarrad; Morabito, Kaitlyn (NIH/VRC) [E]; MORGAN, Oliver; Sarah Mudrak, Ph.D.; Cesar Munoz-fontela; Munster, Vincent (NIH/NIAID) [E]; Nalca, Aysegul CIV USARMY MEDCOM USAMRIID (USA); Napper, Scott; Nelson Michelle; N.M.A. Okba; jokim@ivi.int; Mark Page; gustavo.f.palacios.civ@mail.mil; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP); Peel, Sheila A CIV USARMY MEDCOM WRAIR (USA); PERKINS, Mark; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Prior Joann L; Alina Ximena Riveros Balta; Nicola Rose; SATHIYAMOORTHY, Vaseeharan; Schmaljohn, Connie (NIH/NIAID) [E]; Schnierle, Barbara; Paul Scott; Shivji Ragini; Amy C. Shurtleff; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SWAMINATHAN, Soumya; Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Thue, Tracey; Georgia Tomaras, Ph.D.; Julia.Tree@phe.gov.uk; Sylvie VAN DER WERF; Vasan, Vasan (H&B, Geelong AAHL); linfa.wang@duke-nus.edu.sg; Wolfraim, Larry (NIH/NIAID) [E]; (SPmig) David Wood; Solomon Abebe Yimer; tlying@fudan.edu.cn; Vidadi Yusibov; zlshi@wh.iov.cn

Optional Attendees: KNEZEVIC, Ivana; Graham, Barney (NIH/VRC) [E]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)

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To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Sun 5/10/2020 8:28:18 PM (UTC-04:00)
Subject: Public preclinical compounds to assess for initial prioritization scheme
Preclinical Asset filter strategy.pptx
Preclinical assets from public databases.xlsx

Dear All,

I have spent a little time with the list of therapies that Deloitte has collected by scraping several public databases. I have done an initial filtering exercise and thought you might like to see the initial list. We may use this as a test for how we might prioritize therapies as we get into this more.

I have included an excel sheet based on slide 7 and shown graphically on slides 8 and 9.

We can discuss more on Monday.

Best regards,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
301 594-6596 | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

ACTIV

THERAPEUTICS PRECLINICAL WORKING GROUP

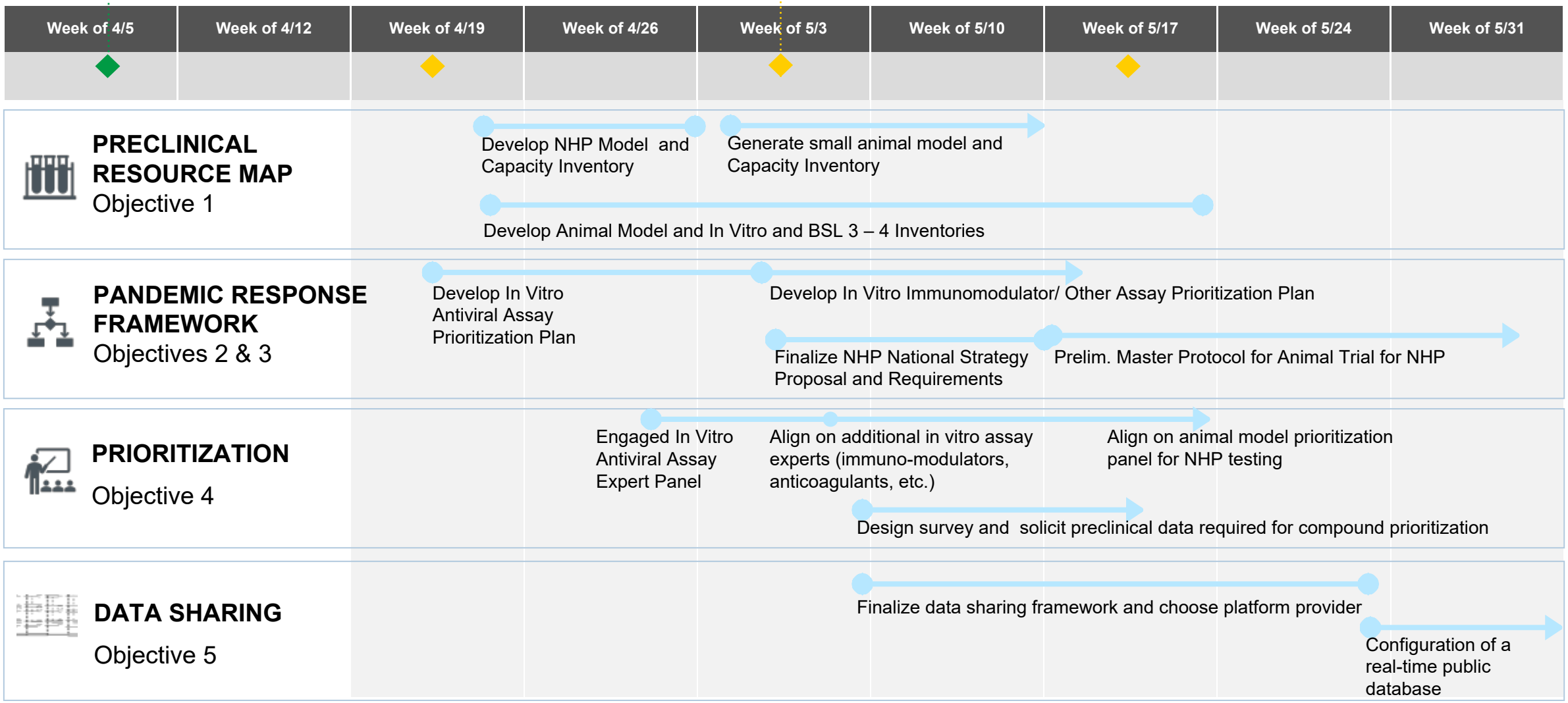
John Young, Roche
Christine Colvis, NCATS

Therapeutics Preclinical Working Group and Timeline

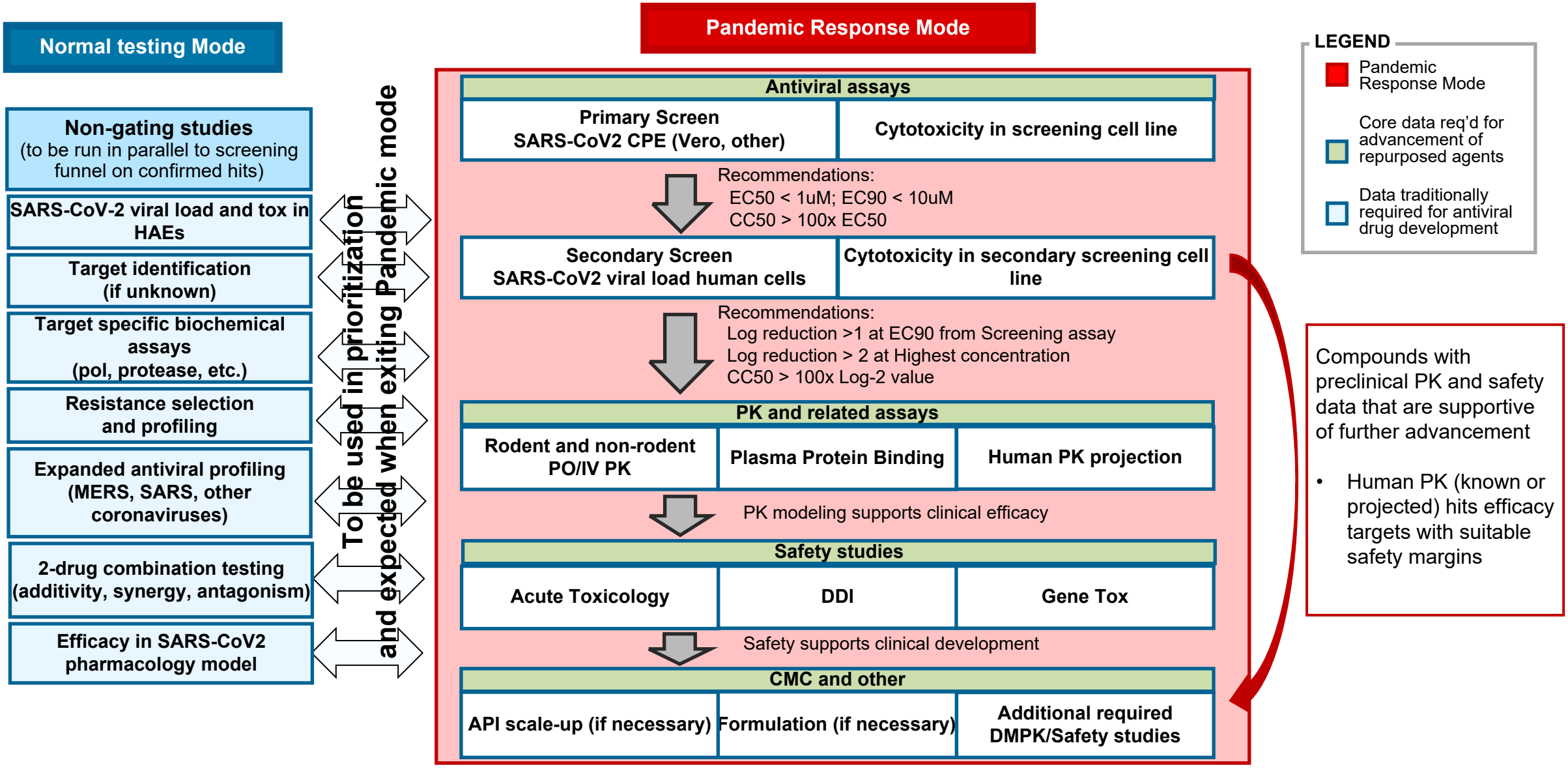
ACTIV WORKING GROUP KICKOFF

We Are Here

ACTIV Leadership Meeting



SOP for accelerating preclinical screening during pandemic response

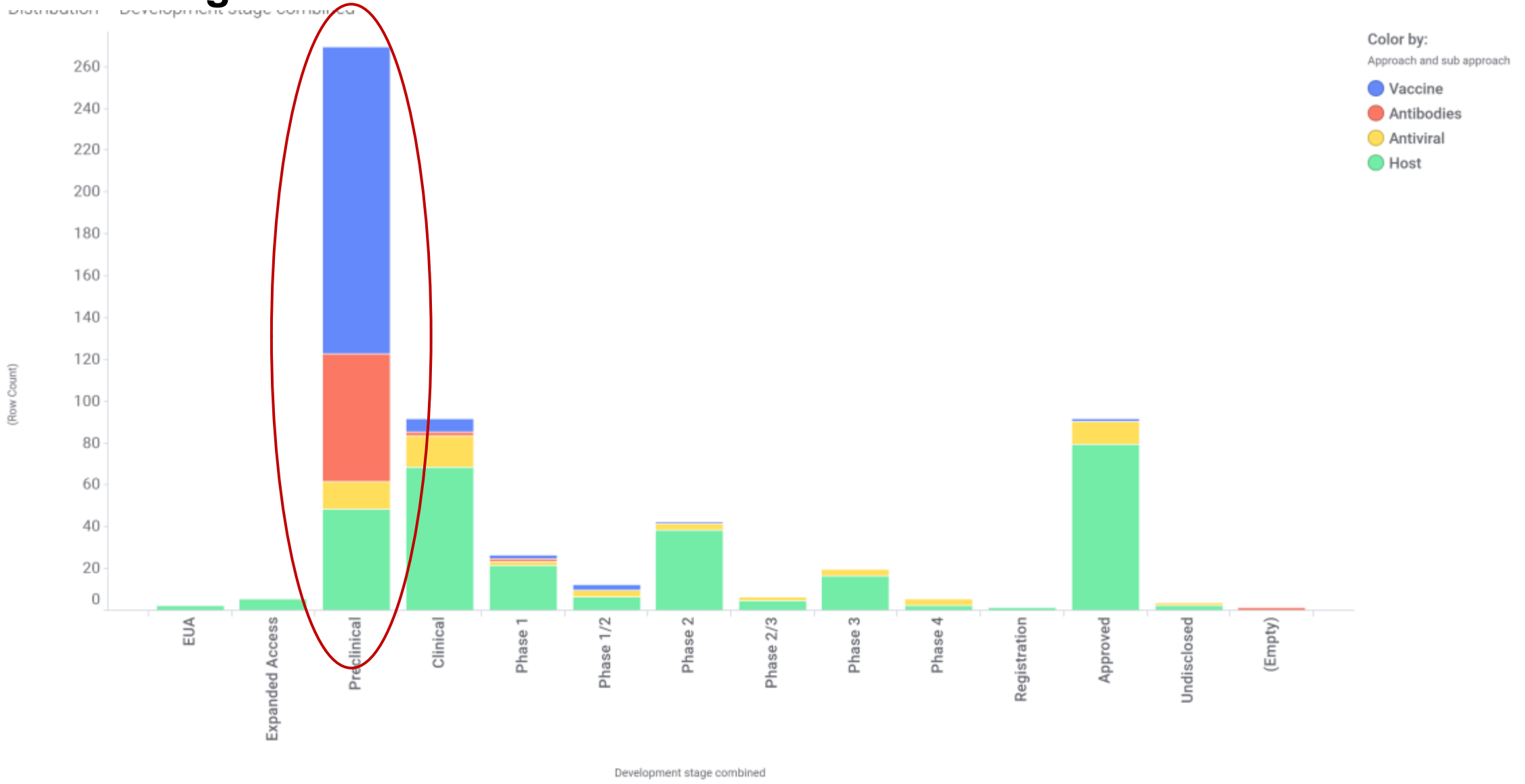


Analysis of therapeutic data from public databases

- Databases scraped
  - Biocentury
  - FasterCures
  - BIO
- Characterized for therapeutic type
  - Vaccine
  - Neutralizing Antibody
  - Host target
  - Viral Target
- Development stage
  - Overall
  - For Covid-19

FNIH

Most of the entries are in preclinical and predominantly vaccines and neutralizing antibodies

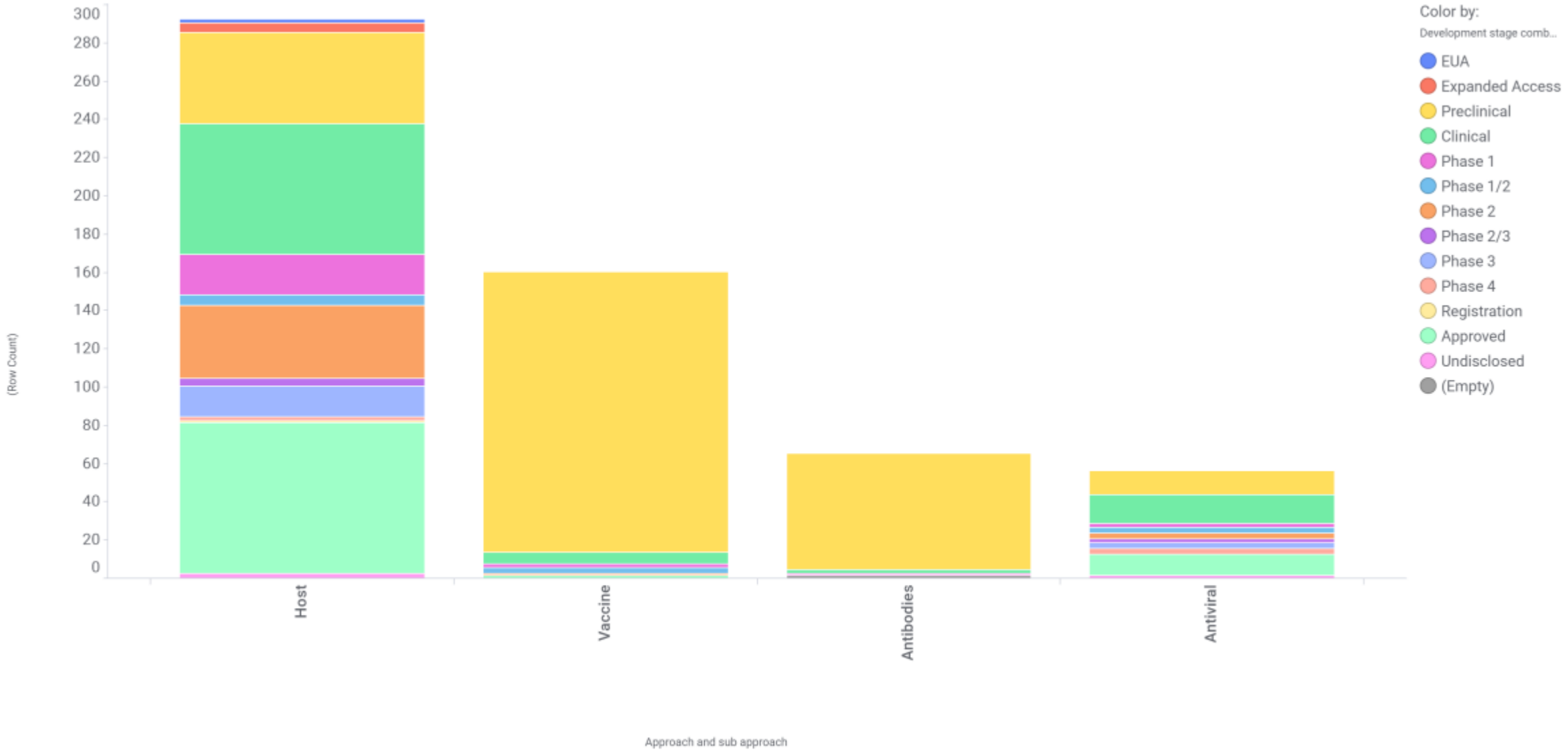


Slide 5 Notes

Filter Settings

- Data Source: (biocentury_clinical, biocentury_preclinical, milkeninstitute, C-19 pipeline by BIO IA 2020-04-19, Source 1)
- Approach and sub approach: (Vaccine, Antibodies, Antiviral, Host)

Most of the therapeutics overall are directed to host targets and are in some stage of clinical development



Slide 6 Notes

Filter Settings

- Data Source: (biocentury_clinical, biocentury_preclinical, milkeninstitute, C-19 pipeline by BIO IA 2020-04-19, Source 1)
- Approach and sub approach: (Vaccine, Antibodies, Antiviral, Host)

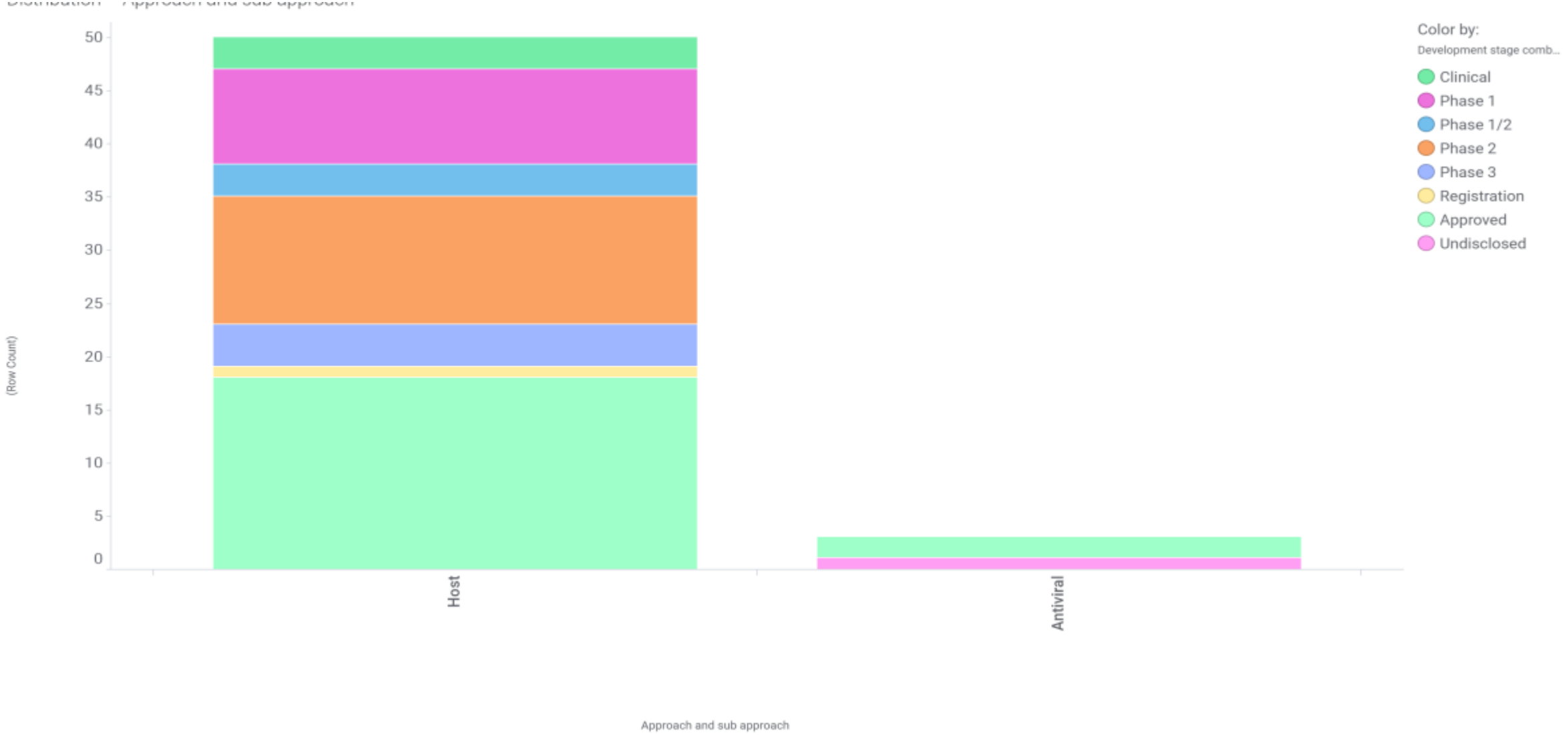
Filtering Strategy for looking at therapies that have potential for repurposing but need COVID preclinical work completed.

- Remove the therapies that are in preclinical overall
- Focus on compounds that have some information about their clinical use (Label)
- Select therapies that have been identified as in COVID Preclinical

- Total starting items – 573
- After filtering as above -53
  - 50 host targeted therapies
  - 3 viral targeted therapies

FNIH

Host and viral targets after initial filtering

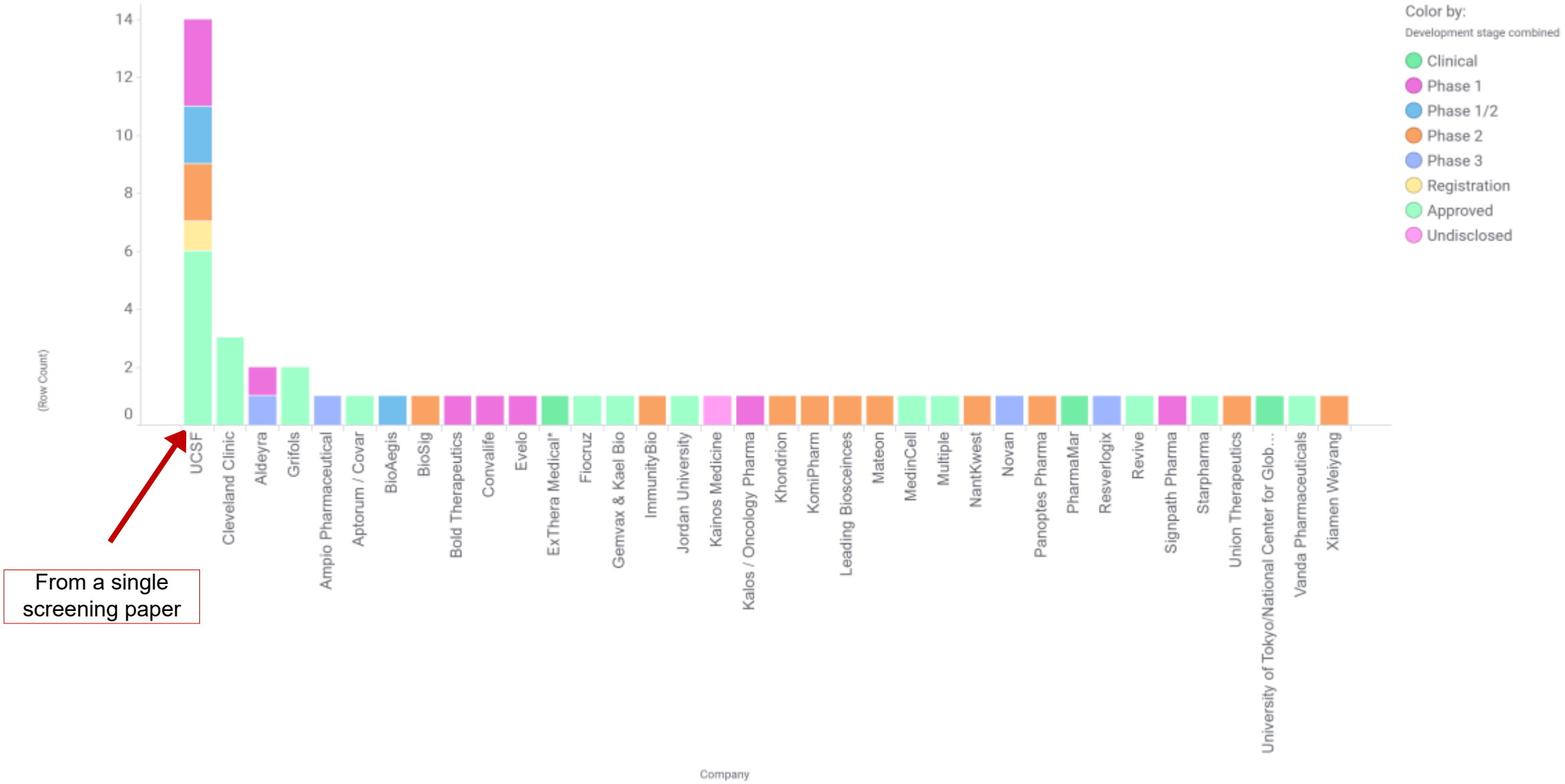


Slide 8 Notes

Filter Settings

- Data Source: (biocentury_clinical, biocentury_preclinical, milkeninstitute, C-19 pipeline by BIO IA 2020-04-19, Source 1)
- Label/IB: (Acute coronary syndrome, Acute respiratory distress syndrom (ARDS), Acute respiratory distress syndrome (ARDS), Acute respiratory distress syndrome; others, Adjunct to stem cell transplant in hematological cancers, Alpha-1 antitrypsin deficiency, Amyotrophic Lateral Sclerosis, approved in Australia to treat multiple myeloma, approved in Japan to treat multiple conditions including pancreatitis, approved in Japan to treat pancreatitis and other diseases, approved in the EU for pathogen reduction*, Asthma, Atopic dermatitis, Autoimmune diseases, Autoimmune disorders, Bacterial infections, Bacterial vaginosis, Bladder cancer, Brain cancer, Cancer, Cancer, autoimmune disorders, Cardiovascular disease, Cerebrovascular disorders, Chest congestion and cough, Community-acquired pneumonia, COPD, Asthma, COVID-19, Critical limb ischemia, Cystic fibrosis, Cytokine release syndrome (CRS), Diabetes; Alopecia, Diabetic cardiomyopathy, Diarrhea (infectious), Ebola, Eczema, Pruritus, Gastroparesis, Chronic Pruritus, and Atopic Dermatitis, Erectile dysfunction, Familial adenomatous polyposis (FAP); Ulcerative colitis (UC), Gastroesophageal reflux disease (GERD), Gastrointestinal cancer, Gout, Graft-versus-host disease, Graft-versus-host disease (GVHD), HCV, HCV; influenza, Hematological cancers, Hemophagocytic lymphohistiocytosis, Hemorrhagic fevers, Hepatic veno-occlusive disease, Hepatitis delta virus (HDV), HIV, HIV-1 Infection, HIV; breast cancer, Hookworm infection, Hypercholesterolemia, Hyperlipidemia, Hypertension, Hypotension, Hypoxic respiratory failure in neonates, Idiopathic multicentric Castleman disease, Idiopathic pulmonary fibrosis (IPF), Idiopathic pulmonary fibrosis (IPF); Systemic sclerosis-associated interstitial lung disease (SSc-ILD), Idiopathic pulmonary fibrosis; Pulmonary fibrosis in systemic sclerosis, Immunodeficiencies, Inflammation, Inflammatory conditions, Influenza, Influenza, Parkinson's disease, Iron overload, Knee osteoarthritis, licensed in China for Hepatitis B, licensed in Russia and China for treatment of respiratory viral infections, Malaria, Melanoma, Migraine, Mitochondrial disease, Molluscum contagiosum; Acne, Multiple, Multiple infectious and pulmonary diseases, Multiple myeloma, others, Multiple sclerosis, Muscular dystrophy, Muscular dystrophy, myocardial infarction, Myelodysplastic syndromes, Myelofibrosis, Myelofibrosis; Polycythemia vera; Graft-versus-host disease (GvHD), Myocardial reperfusion injury, N/A, Neurological disorders, Ocular inflammation, Pain, Pain; Fever, Pancreatitis, Parainfluenza, Parasitic infections, Paroxysmal nocturnal hemoglobinuria (PNH), Pneumocystis carinii pneumonia, Pneumocystis pneumonia, Post-operative ileus, Prevent blood clots, Prevent transplant rejection, other, Prevents pulmonary infection, Psoriasis, atopic dermatitis, Pulmonary hypertension, Respiratory distress syndrome in premature infants, Respiratory infections, Respiratory syncytial virus (RSV), Rheumatoid arthritis, Rheumatoid arthritis, neonatal-onset multisystem inflammatory disease, Same platform as vaccine candidates for EBOV, Same platform as vaccine candidates for influenza, TB, Chikungunya, Zika, MenB, plague, Same platform as vaccine candidates for Lassa, Nipah, HIV, Filovirus, HPV, cancer indications, Zika, and Hepatitis B, Same platform as vaccine candidates for multiple candidates, Sinusitis, Tapeworms, Transplant rejection, Tuberculosis, Type II diabetes, Undisclosed, Uveitis, Viral infections, Wounds, Yellow fever)
- Current COVID19 clinical trials: (Clinical trial planned, Preclin, Preclin; Expanded access planned, Preclin; IND planned, Preclin; Ph II planned, (Empty))
- Approach and sub approach: (Vaccine, Antibodies, Antiviral, Host)
- Development stage combined: (EUA, Expanded Access, Clinical, Phase 1, Phase 1/2, Phase 2, Phase 2/3, Phase 3, Phase 4, Registration, Approved, Undisclosed, (Empty))

The organizations associated with the therapies are diverse



From a single screening paper

Slide 9 Notes

Filter Settings

- Data Source: (biocentury_clinical, biocentury_preclinical, milkeninstitute, C-19 pipeline by BIO IA 2020-04-19, Source 1)
- Label/IB: (Acute coronary syndrome, Acute respiratory distress syndrom (ARDS), Acute respiratory distress syndrome (ARDS), Acute respiratory distress syndrome; others, Adjunct to stem cell transplant in hematological cancers, Alpha-1 antitrypsin deficiency, Amyotrophic Lateral Sclerosis, approved in Australia to treat multiple myeloma, approved in Japan to treat multiple conditions including pancreatitis, approved in Japan to treat pancreatitis and other diseases, approved in the EU for pathogen reduction*, Asthma, Atopic dermatitis, Autoimmune diseases, Autoimmune disorders, Bacterial infections, Bacterial vaginosis, Bladder cancer, Brain cancer, Cancer, Cancer, autoimmune disorders, Cardiovascular disease, Cerebrovascular disorders, Chest congestion and cough, Community-acquired pneumonia, COPD, Asthma, COVID-19, Critical limb ischemia, Cystic fibrosis, Cytokine release syndrome (CRS), Diabetes; Alopecia, Diabetic cardiomyopathy, Diarrhea (infectious), Ebola, Eczema, Pruritus, Gastroparesis, Chronic Pruritus, and Atopic Dermatitis, Erectile dysfunction, Familial adenomatous polyposis (FAP); Ulcerative colitis (UC), Gastroesophageal reflux disease (GERD), Gastrointestinal cancer, Gout, Graft-versus-host disease, Graft-versus-host disease (GVHD), HCV, HCV; influenza, Hematological cancers, Hemophagocytic lymphohistiocytosis, Hemorrhagic fevers, Hepatic veno-occlusive disease, Hepatitis delta virus (HDV), HIV, HIV-1 Infection, HIV; breast cancer, Hookworm infection, Hypercholesterolemia, Hyperlipidemia, Hypertension, Hypotension, Hypoxic respiratory failure in neonates, Idiopathic multicentric Castleman disease, Idiopathic pulmonary fibrosis (IPF), Idiopathic pulmonary fibrosis (IPF); Systemic sclerosis-associated interstitial lung disease (SSc-ILD), Idiopathic pulmonary fibrosis; Pulmonary fibrosis in systemic sclerosis, Immunodeficiencies, Inflammation, Inflammatory conditions, Influenza, Influenza, Parkinson's disease, Iron overload, Knee osteoarthritis, licensed in China for Hepatitis B, licensed in Russia and China for treatment of respiratory viral infections, Malaria, Melanoma, Migraine, Mitochondrial disease, Molluscum contagiosum; Acne, Multiple, Multiple infectious and pulmonary diseases, Multiple myeloma, others, Multiple sclerosis, Muscular dystrophy, Muscular dystrophy, myocardial infarction, Myelodysplastic syndromes, Myelofibrosis, Myelofibrosis; Polycythemia vera; Graft-versus-host disease (GvHD), Myocardial reperfusion injury, N/A, Neurological disorders, Ocular inflammation, Pain, Pain; Fever, Pancreatitis, Parainfluenza, Parasitic infections, Paroxysmal nocturnal hemoglobinuria (PNH), Pneumocystis carinii pneumonia, Pneumocystis pneumonia, Post-operative ileus, Prevent blood clots, Prevent transplant rejection, other, Prevents pulmonary infection, Psoriasis, atopic dermatitis, Pulmonary hypertension, Respiratory distress syndrome in premature infants, Respiratory infections, Respiratory syncytial virus (RSV), Rheumatoid arthritis, Rheumatoid arthritis, neonatal-onset multisystem inflammatory disease, Same platform as vaccine candidates for EBOV, Same platform as vaccine candidates for influenza, TB, Chikungunya, Zika, MenB, plague, Same platform as vaccine candidates for Lassa, Nipah, HIV, Filovirus, HPV, cancer indications, Zika, and Hepatitis B, Same platform as vaccine candidates for multiple candidates, Sinusitis, Tapeworms, Transplant rejection, Tuberculosis, Type II diabetes, Undisclosed, Uveitis, Viral infections, Wounds, Yellow fever)
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- Approach and sub approach: (Vaccine, Antibodies, Antiviral, Host)
- Development stage combined: (EUA, Expanded Access, Clinical, Phase 1, Phase 1/2, Phase 2, Phase 2/3, Phase 3, Phase 4, Registration, Approved, Undisclosed, (Empty))

Development stage combined	Developmental stage	Current COVID19 clinical trials	Label/IB	Therapeutic Type	Therapeutic Name	Therapeutic Name Extract	Company	Mechanism of Action/rationale	Therapeutic Name Mechanism Extract	Sources	Source hyperlinks	Preclinical data (SARS-COV2)	Clinical data (SARS-COV2)	PK/PD	Safety	Safety database size (<100, 100-1000, 1000-10,000, >10,000)	Regimen/route	DrugDrugInteractions	Manufacturability	Availability/ cost	Unintended consequences	MOA provided?	Stage condense	COVID Stage	Mechanism combined	Approach and sub approach
Approved	Approved globally	Preclin	Hypertension	Small molecule	Captopril	Captopril	UCSF	Angiotensin-converting enzyme (ACE)		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.who.int/blueprint/priority-diseases/key-action/Table_of_therapeutics_Appendix_17022020.pdf?ua=1											Yes	Approved	Preclinical	Angiotensin-converting enzyme (ACE)	Host
Approved	Approved globally	Preclin	Hypertension	Small molecule	Lisonopril	Lisonopril	UCSF	Angiotensin-converting enzyme (ACE)		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.who.int/blueprint/priority-diseases/key-action/Novel-Coronavirus_Landscape_nCoV-4april2020.pdf											Yes	Approved	Preclinical	Angiotensin-converting enzyme (ACE)	Host
Phase 3	Phase III	Preclin	Cardiovascular disease	Small molecule	Apabetalone	Apabetalone	Resverlogix	BET bromodomain proteins		https://www.resverlogix.com/investors/news?article=661	https://www.who.int/blueprint/priority-diseases/key-action/Table_of_therapeutics_Appendix_17022020.pdf?ua=1											Yes	Phase 3	Preclinical	BET bromodomain proteins	Host
Approved	Approved in U.S., EU, Japan, others	Preclin	Melanoma	Small molecule	Trafinlar dabrafenib	Trafinlar dabrafenib	UCSF	BRAF		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://investor.theravance.com/news-releases/news-release-details/theravance-biopharma-responds-covid-19-pandemic-advancing-td											Yes	Approved	Preclinical	BRAF	Host
Phase 1	Phase I	Preclin	Cancer	Small molecule	ABBV-744	ABBV-744	UCSF	Bromodomain containing 2 (BRD2); BRD4		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.businesswire.com/news/home/20200413005181/en/%C2%A0Celltrion-Completes-Neutralisation-Test-Candidate-Monoclonal-Antibodies											Yes	Phase 1	Preclinical	Bromodomain containing 2 (BRD2); BRD4	Host
Phase 1/2	Phase I/II	Preclin	Myelofibrosis	Small molecule	CPI-0610	CPI-0610	UCSF	Bromodomain containing 2 (BRD2); BRD4		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://investor.lilly.com/news-releases/news-release-details/lilly-begins-clinical-testing-therapies-covid-19											Yes	Phase 1/2	Preclinical	Bromodomain containing 2 (BRD2); BRD4	Host
Phase 2	Phase II	Clinical trial planned	Uveitis	Small molecule	PP-001	PP-001	Panoptes Pharma	Dihydroorotate dehydrogenase (Quinone) (DHODH)		http://www.panoptes-pharma.com/wp-content/uploads/2020/03/Pressemitteilung-Panoptes-COVID-19.pdf	https://www.remapcap.org/ https://www.faron.com/news-events/news-and-press-releases?rnsid=1383488&cid=2223 https://clinicaltrials.gov/ct2/show/NCT02735707?term=remap-cap&draw=2&rank=1											Yes	Phase 2	Preclinical	Dihydroorotate dehydrogenase (Quinone) (DHODH)	Host
Approved	Approved globally	Preclin	Cancer	Small molecule	Toremifene	Toremifene	Cleveland Clinic	Estrogen receptor 1 (ER1)		https://www.nature.com/articles/s41421-020-0153-3	https://www.primmunerx.com/press-releases/primmune-therapeutics-announces-the-selection-of-prtx007-as-its-clinical-development-candidate-for-covid-19-and-oncology-indications/											Yes	Approved	Preclinical	Estrogen receptor 1 (ER1)	Host
Phase 1/2	Phase I/II	Preclin	Cancer	Small molecule	Zotatifin	Zotatifin	UCSF	Eukaryotic translation initiation factor 4A1 (EIF4A1; EIF4A)		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://immunitybio.com/nantkwest-and-immunitybio-announce-therapeutics-and-vaccines-for-combatting-covid-19-clinical-trials-anticipated-to-begin-this-quarter/											Yes	Phase 1/2	Preclinical	Eukaryotic translation initiation factor 4A1 (EIF4A1; EIF4A)	Host
Phase 1	Phase I	Preclin	Viral infections	Small molecule	Verdinexor	Verdinexor	UCSF	Exportin 1 (XPO1; CRM1)		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://cepi.net/news_cepi/cepi-partners-with-university-of-hong-kong-to-develop-covid-19-vaccine/											Yes	Phase 1	Preclinical	Exportin 1 (XPO1; CRM1)	Host
Approved	Approved globally	Preclin	Parasitic infections	Small molecule	LAI ivermectin	LAI ivermectin	MedinCell	Glutamate decarboxylase 2 (GAD2; GAD65)		https://invest.medincell.com/wp-content/uploads/2020/04/PR_MedinCell-Covid19-EN.pdf	https://smartpharmtx.com/sorrento-therapeutics-and-smartpharm-therapeutics-announce-intention-to-collaborate-to-develop-novel-gene-encoded-antibody-vaccine-intended-for-covid-19/											Yes	Approved	Preclinical	Glutamate decarboxylase 2 (GAD2; GAD65)	Host
Phase 1	Phase I	Preclin	Gastrointestinal cancer	Small molecule	BOLD-100	BOLD-100	Bold Therapeutics	Heat shock 70 kDa protein 5 (glucose-regulated protein, 78kDa; GRP78; HspA5)		https://www.bold-therapeutics.com/news-post?Bold+Therapeutics+and+the+University+of+Ottawa+Initiate+Research+Partnership+to+Study+BOLD-100+in+the+Treatment+of+COVID-19	https://www.wsj.com/articles/u-s-drugmakers-ship-therapies-to-china-seeking-to-treat-coronavirus-11580166592?mod=article_inline											Yes	Phase 1	Preclinical	Heat shock 70 kDa protein 5 (glucose-regulated protein, 78kDa; GRP78; HspA5)	Host
Phase 1	Phase I	Preclin	Hemorrhagic fevers	Small molecule	IHVR-19029	IHVR-19029	UCSF	Î±-glucosidases		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.who.int/blueprint/priority-diseases/key-action/Novel-Coronavirus_Landscape_nCoV-4april2020.pdf											Yes	Phase 1	Preclinical	Î±-glucosidases	Host
Phase 2	Phase II	Preclin	Multiple infectious and pulmonary diseases	Protein	Low-dose oral interferon-Î±	Low-dose oral interferon-Î±	Xiamen Weiyang	IFN receptor		https://www.globenewswire.com/news-release/2020/02/13/1984821/0/en/Amarillo-Biosciences-to-Explore-Low-Dose-Oral-Interferon-Therapeutics-in-China-as-a-Line-of-Defense-Against-Coronavirus-and-Other-Viral-Indications.html http://www.wypharm.com/en/content/?193.html	https://www.remapcap.org/ https://clinicaltrials.gov/ct2/show/NCT02735707											Yes	Phase 2	Preclinical	IFN receptor	Host
Phase 2	Phase II	Preclin	HCV	Small molecule	Vicromax merimepodib	Vicromax merimepodib	BioSig	Inosine monophosphate dehydrogenase (IMPDH)		https://www.biorxiv.org/content/10.1101/2020.04.07.028589v1 https://www.biosig.com/news-media/press-releases/detail/184/biosig-subsidiary-neuroclear-acquires-license-for-a	http://www.biokangtai.com/news/133.html											Yes	Phase 2	Preclinical	Inosine monophosphate dehydrogenase (IMPDH)	Host
Phase 2	Phase II	Preclin	Pain	Small molecule	Panaphix	Panaphix	KomiPharm	Interleukin-1 (IL-1) beta; Interleukin-18 (IL-18)		https://novotech-cro.com/news/novotech-wins-cro-contract-komipharm-coronavirus-covid-19-clinical-trial-south-korea	https://www.kerecis.com/2020/04/09/kerecis-begins-omega3-viruxide-covid-19-trial-at-the-national-hospital-of-iceland											Yes	Phase 2	Preclinical	Interleukin-1 (IL-1) beta; Interleukin-18 (IL-18)	Host
Phase 2	Phase II	Preclin	Bladder cancer	Fusion protein	N-803	N-803	ImmunityBio	Interleukin-15 (IL-15) receptor alpha chain (IL-15RA)		https://immunitybio.com/nantkwest-and-immunitybio-announce-therapeutics-and-vaccines-for-combatting-covid-19-clinical-trials-anticipated-to-begin-this-quarter/	https://clinicaltrials.gov/ct2/show/NCT04333550											Yes	Phase 2	Preclinical	Interleukin-15 (IL-15) receptor alpha chain (IL-15RA)	Host
Phase 2	Phase II	Preclin	Cancer	Small molecule	Sapanisertib (TAK-228)	Sapanisertib (TAK-228)	UCSF	Mammalian target of rapamycin (mTOR; FRAP; RAFT1)		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full												Yes	Phase 2	Preclinical	Mammalian target of rapamycin (mTOR; FRAP; RAFT1)	Host
Phase 2	Phase II	Preclin	Cancer	Small molecule	Tomivosertib	Tomivosertib	UCSF	MAP kinase interacting serine-threonine kinase 1 (MKNK1; MNK1); MKNK2		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.noxopharm.com/site/PDF/6ddda156-2885-4417-ba1f-9e520f1cb085/NoxopharmInvestigatingPotentialCOVID19Treatment											Yes	Phase 2	Preclinical	MAP kinase interacting serine-threonine kinase 1 (MKNK1; MNK1); MKNK2	Host
Phase 1	Phase I	Preclin	Cancer	Peptide	KTH-222	KTH-222	Kalos / Oncology Pharma	MAP kinases		http://www.globenewswire.com/news-release/2020/04/06/2012081/0/en/Oncology-Pharma-and-Kalos-Therapeutics-Expand-Licensing-Agreement-for-Exploring-Kalos-s-Anti-Cancer-Lead-Drug-in-Treating-COVID-19.html	https://www.who.int/blueprint/priority-diseases/key-action/Novel-Coronavirus_Landscape_nCoV-4april2020.pdf											Yes	Phase 1	Preclinical	MAP kinases	Host
Phase 2	Phase II	Preclin	Mitochondrial disease	Small molecule	Sonlicromanol (KH176)	Sonlicromanol (KH176)	Khondrion	Microsomal prostaglandin E synthase-1 (PTGES; mPGES-1)		https://www.khondrion.com/potential-role-of-inflammatory-lipid-modulator-prostaglandin-e2-in-covid-19-disease/	https://clinicaltrials.gov/ct2/show/NCT04276896											Yes	Phase 2	Preclinical	Microsomal prostaglandin E synthase-1 (PTGES; mPGES-1)	Host
Approved	Approved globally	Preclin	Alpha-1 antitrypsin deficiency	Protein	Alpha-1 antitrypsin	Alpha-1 antitrypsin	Grifols	N/A		https://intranet.grifols.com/documents/38081080/1023350216/np-20200325-en.pdf/4118c237-8aa2-4474-95df-dbecaed9e94c https://www.grifols.com/en/view-news/-/news/grifols-reinforces-its-commitment-to-all-stakeholders-as-a-response-to-the-covid-19-outbreak	https://www.bioworld.com/articles/433890-humanigen-preps-lenzilumab-for-potential-battle-with-deadly-covid-19-symptom											Undisclosed	Approved	Preclinical	N/A	Host
Approved	Approved in Japan, South Korea	Preclin; Ph II planned	Rheumatoid arthritis	Small molecule	Bucillamine	Bucillamine	Revive	N/A		https://www.globenewswire.com/news-release/2020/04/03/2011529/0/en/Revive-Therapeutics-Announces-Filing-of-FDA-Pre-IND-Meeting.html	https://www.gov.uk/government/news/vaccine-trials-among-recipients-of-20-million-coronavirus-research-investment											Undisclosed	Approved	Preclinical	N/A	Host
Phase 1	Phase I	Preclin	Psoriasis, atopic dermatitis	Bacteria	EDP1815	EDP1815	Evelo	N/A			https://www.biocentury.com/article/304658											Undisclosed	Phase 1	Preclinical	N/A	Host
Phase 2	Phase II	Clinical trial planned	Cancer	Cell therapy	haNK	haNK	NantKwest	N/A		https://nantkwest.com/nantkwest-and-immunitybio-announce-therapeutics-and-vaccines-for-combatting-covid-19-clinical-trials-anticipated-to-begin-this-quarter/	https://www.eurekalert.org/pub_releases/2020-04/fu-cio040220.php											Undisclosed	Phase 2	Preclinical	N/A	Host
Phase 1	Phase I	Preclin	Cancer	Small molecule	LipoCurc (IV liposomal curcumin)	LipoCurc (IV liposomal curcumin)	Signpath Pharma	N/A		http://signpathpharma.com/wp-content/uploads/2018/02/8-InVivoJan15.pdf	https://www.who.int/blueprint/priority-diseases/key-action/Novel-Coronavirus_Landscape_nCoV-4april2020.pdf											Undisclosed	Phase 1	Preclinical	N/A	Host
Phase 1/2	Phase I/II	Preclin	Community-acquired pneumonia	Protein	Recombinant human plasma gelsolin therapy (rhu pGSN)	Recombinant human plasma gelsolin therapy (rhu-pGSN)	BioAegis	N/A		https://www.bioaegistherapeutics.com/covid19/plasma-gelsolin-to-protect-tissue-organs-in-severe-coronavirus-infection-without-compromising-pathogen-response/	https://izanabio.com/initiation-of-two-centre-compassionate-use-study-involving-namilumab-in-the-treatment-of-individual-patients-with-rapidly-worsening-covid-19-infection-in-italy/											Undisclosed	Phase 1/2	Preclinical	N/A	Host
Registration	Registration	Preclin	Myelodysplastic syndromes	Small molecule	Pevonedistat	Pevonedistat	UCSF	NEDD8 activating enzyme (NAE)		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full https://www.u-tokyo.ac.jp/focus/en/articles/z0508_00083.html											Yes	Registration	Preclinical	NEDD8 activating enzyme (NAE)	Host
Approved	Approved globally	Preclin	Influenza, Parkinson's disease	Small molecule	Amantadine	Amantadine	Vanda Pharmaceuticals	Not determined		https://www.biorxiv.org/content/10.1101/2020.04.05.026187v2	https://ir.alexion.com/news-releases/news-release-details/alexion-statement-solirisr-eculizumab-and-covid-19											Yes	Approved	Preclinical	Not determined	Host
Phase 3	Phase III	Preclin	Molluscum contagiosum; Acne	Macromolecule	Berdazimer sodium (NVN1000)	Berdazimer sodium (NVN1000)	Novan	Not determined		https://novan.gcs-web.com/news-releases/news-release-details/novan-announces-data-b-simple-week-24-safety-evaluation-and	https://finance.yahoo.com/news/aim-immunotech-drug-ampligen-tested-103000673.html											Yes	Phase 3	Preclinical	Not determined	Host
Approved	Approved globally	Preclin	Cancer	Peptide	Dactinomycin	Dactinomycin	Cleveland Clinic	Not determined		https://www.nature.com/articles/s41421-020-0153-3												Yes	Approved	Preclinical	Not determined	Host
Approved	Approved globally	Preclin	Cancer, autoimmune disorders	Small molecule	Mercaptopurine	Mercaptopurine	Cleveland Clinic	Not determined		https://www.nature.com/articles/s41421-020-0153-3	https://clinicaltrials.gov/ct2/results?cond=COVID-19&term=Baricitinib&cntry=&state=&city=&dist=&Search=Search											Yes	Approved	Preclinical	Not determined	Host
Phase 2	Phase II	Preclin	Atopic dermatitis	Small molecule	Niclosamide	Niclosamide	Union Therapeutics	Not determined		https://www.newswire.com/news/union-therapeutics-launches-covid-19-program-in-collaboration-with-21127619												Yes	Phase 2	Preclinical	Not determined	Host
Approved	Approved in EU, Japan, Canada, others	Preclin	Bacterial vaginosis	Small molecule	VivaGel	VivaGel	Starpharma	Not determined		https://starpharma.com/news/473	https://www.bat.com/group/sites/UK__9D9KCY.nsf/vwPagesWebLive/DOBN8QNL											Yes	Approved	Preclinical	Not determined	Host
Phase 1	Phase I	Preclin	Cancer	Small molecule	CVL218	CVL218	Convalife	Poly(ADP-ribose) polymerase 1 (PARP-1)		https://www.biorxiv.org/content/10.1101/2020.03.11.986836v1	https://nationalpost.com/news/can-a-cheap-gout-drug-slash-covid-19-deaths											Yes	Phase 1	Preclinical	Poly(ADP-ribose) polymerase-1 (PARP-1)	Host
Phase 1	Phase I	Preclin	Autoimmune disorders	Small molecule	ADX-629	ADX-629	Aldeyra	Reactive aldehyde species		https://ir.aldeyra.com/news-releases/news-release-details/aldeyra-screen-clinical-stage-compounds-activity-covid-19	https://www.hrs.com.cn/hren/products_pipeline_oncology.html											Yes	Phase 1	Preclinical	Reactive aldehyde species	Host
Phase 3	Phase III	Preclin	Ocular inflammation	Small molecule	Reproxalap	Reproxalap	Aldeyra	Reactive aldehyde species		https://ir.aldeyra.com/news-releases/news-release-details/aldeyra-screen-clinical-stage-compounds-activity-covid-19	https://immunitybio.com/nantkwest-and-immunitybio-announce-therapeutics-and-vaccines-for-combatting-covid-19-clinical-trials-anticipated-to-begin-this-quarter/											Yes	Phase 3	Preclinical	Reactive aldehyde species	Host
Approved	Approved globally	Preclin	Bacterial infections	Small molecule	Tigecycline	Tigecycline	UCSF	Ribosomal 30S subunit		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full											Yes	Approved	Preclinical	Ribosomal 30S subunit	Host
Approved	Approved globally	Preclin	Bacterial infections	Small molecule	Chloramphenicol	Chloramphenicol	UCSF	Ribosomal 50S subunit		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.clinicaltrialsarena.com/analysis/coronavirus-mers-cov-drugs/											Yes	Approved	Preclinical	Ribosomal 50S subunit	Host
Approved	Approved globally	Preclin	Bacterial infections	Small molecule	Linezolid	Linezolid	UCSF	Ribosomal 50S subunit		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full	https://www.bat.com/group/sites/UK__9D9KCY.nsf/vwPagesWebLive/DOBN8QNL											Yes	Approved	Preclinical	Ribosomal 50S subunit	Host
Phase 2	Phase II	Preclin	Post-operative ileus	Small molecule	LB1148	LB1148	Leading Bioscеinces	Serine protease		https://leadingbiosciences.com/lb1148-for-the-treatment-of-covid-19/	https://www.nature.com/articles/d41573-020-00073-5											Yes	Phase 2	Preclinical	Serine protease	Host
Approved	Approved in Japan	Preclin	Pancreatitis	Small molecule	Nafamostat	Nafamostat	Multiple	Serine protease		https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full https://www.u-tokyo.ac.jp/focus/en/articles/z0508_00083.html	https://clinicaltrials.gov/ct2/show/NCT04333407											Yes	Approved	Preclinical	Serine protease	Host
Approved	Approved in South Korea	Preclin	Cancer	Peptide	Riavax tertomotide HCl (GV1001)	Riavax tertomotide HCl (GV1001)	Gemvax & Kael Bio	Telomerase reverse transcriptase (TERT)		https://nedrug.mfds.go.kr/pbp/CCBBQ01/getList?totalPages=271&page=1&limit=10&sort=&sortOrder=&searchYn=true&clinicFlagName=&approvalDtStart=&approvalDtEnd=&applyEntpName=&targetDisease=&prductName=GV1001&genName=&btnSearch=	https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full											Yes	Approved	Preclinical	Telomerase reverse transcriptase (TERT)	Host
Phase 2	Phase II	Preclin; IND planned	Cancer	Antisense oligonucleotide	OT-101	OT-101	Mateon	Transforming growth factor (TGF) beta 2 (TGFB2)		http://investor.mateon.com/news-releases/news-release-details/mateon-expands-its-covid-19-therapeutic-program-include	https://www.vero-biotech.com/news-2/											Yes	Phase 2	Preclinical	Transforming growth factor (TGF) beta 2 (TGFB2)	Host
Approved	Approved globally	Preclin	Pneumocystis pneumonia	Small molecule	Inhaled pentamidine	Inhaled pentamidine	Jordan University	Transmembrane protease serine 2 (TMPRSS2)			https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus-landscape-ncov.pdf?ua=1											Yes	Approved	Preclinical	Transmembrane protease serine 2 (TMPRSS2)	Host
Phase 3	Phase III	Preclin; Expanded access planned	Knee osteoarthritis	Peptide	Ampion	Ampion	Ampio Pharmaceutical	Undisclosed		https://ampiopharma.com/news/ampio-is-preparing-an-expanded-access-fda-protocol-to-study-nebulized-ampion-as-a-treatment-for-moderate-to-severe-acute-respiratory-distress-syndrome-associated-with-covid-19/												Undisclosed	Phase 3	Preclinical	Undisclosed	Host
Approved	Approved globally	Preclin	Immunodeficiencies	Protein	Intravenous immunoglobulin	Intravenous immunoglobulin	Grifols	Undisclosed		https://intranet.grifols.com/documents/38081080/1023350216/np-20200325-en.pdf/4118c237-8aa2-4474-95df-dbecaed9e94c https://www.grifols.com/en/view-news/-/news/grifols-reinforces-its-commitment-to-all-stakeholders-as-a-response-to-the-covid-19-outbreak	https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus-landscape-ncov.pdf?ua=1											Undisclosed	Approved	Preclinical	Undisclosed	Host
Clinical	Clinical		approved in Australia to treat multiple myeloma	OTHERS	Aplidin (plitidepsin), approved in Australia to treat multiple myeloma	Aplidin (plitidepsin),	PharmaMar			http://pharmamar.com/wp-content/uploads/2020/04/PR_clinical_trial_plitidepsin_covid19_DEF.pdf	https://uk.reuters.com/article/uk-china-health-treatments-factbox/factbox-global-efforts-to-develop-vaccines-drugs-to-fight-the-coronavirus-idUKKBN20D2MD?rpc=401											No	Clinical		not provided	Host
Clinical	Clinical		approved in Japan to treat pancreatitis and other diseases	OTHERS	nafamostat, approved in Japan to treat pancreatitis and other diseases	nafamostat,	University of Tokyo/National Center for Global Health and Medicine/ Ensysce Biosciences*			http://bnnbloomberg.ca/japanese-researchers-to-test-blood-thinner-for-virus-treatment-1.1407980	https://clinicaltrials.gov/ct2/show/NCT04333407											No	Clinical		not provided	Host
Clinical	Clincal*		approved in the EU for pathogen reduction*	DEVICES	Seraph100MicrobindAffinity Blood Filter (Seraphy 100), approved in the EU for pathogen reduction*	Seraph100MicrobindAffinity Blood Filter (Seraphy 100)	ExThera Medical*			https://www.businesswire.com/news/home/20200326005174/en/ExThera%E2%80%99s-Affinity-Blood-Filter-Treat-COVID-19-Patients	https://www.biorxiv.org/content/10.1101/2020.03.22.002386v1.full											No	Clinical		not provided	Host

Development stage combined	Developmental stage	Current COVID19 clinical info	LatestTB	Therapeutic Type	Therapeutic Name	Therapeutic Name Extract	Company	Mechanism of Action/rationale	Therapeutic Science Mechanism Extract	Sources	Source hyperlinks	Preclinical data (SARS-COV2)	Clinical data (SARS-COV2)	PK/PD	Safety	Safety database(s) (eg: LOVD, GEN-SNP, GWAS, SECRET, ICLOPUS)	Regimens/route	DrugDrugInteraction	Manufacturability	Availability/ cost	Nominated Investigator(s)	WHO promoted?	Stage combined	COVID Stage	Mechanism combined	Approach and sub approach
Approved	Approved globally	Predin	HIV	Small molecule	Atazanavir	Atazanavir	Fiocruz	HIV protease		https://www.biomin.org/content/10.1101/2020.04.06.028092v1.full	https://www.promeraware.com/news-release/nitgenbach-biotherapeutics-and-drug-innovation-announce-strategic-partnership-to-develop-first-oral-drugs-innovative-treatment-for-covid-19/											Yes	Approved	Preclinical	HIV protease	Antiviral
Undisclosed	Undisclosed	Predin	Undisclosed	Small molecule	Kaletra: small molecule antivirals	Kaletra: small molecule antivirals	Kaletra: Medicine	Undisclosed		https://clinicaltrialsfeed.com/?s=covid&latest-result=1#:~:text=no%20clinical%20trial%20results%20for%20this%20drug%20or%20condition%20have%20been%20posted%20to%20clinicaltrials.gov%20yet.	https://www.fiercebiotech.com/biotech/aurinia-to-get-lw-covid-19-second-trial-biomarin-heads-170m-deal-and-advancers-affairs-talks										Undisclosed	Undisclosed	Preclinical	Undisclosed	Antiviral
Approved	Approved in undisclosed territories.	Predin	Undisclosed	Small molecule	SACT-COVID (5 undisclosed repurposed drugs)	SACT-COVID (5 undisclosed repurposed drugs)	Aptorum / Covar	SARS-CoV-2 3CL-Protease; Viral RNA-dependent RNA polymerase; undisclosed		https://clinicaltrials.gov/ct2/show/results/nct04308668?cond=%22Coronavirus%22&draw=2&rank=1&view=results#:~:text=Aptorum%20Group%20Limited%20%28Nasdaq%3A%20APM%29%20announced%20that%20the%20Company%27s%20SACT%2DCOVID%20clinical%20trial%20has%20been%20approved%20by%20the%20Australian%20Human%20Research%20Ethics%20Committee%20%28HREC%29%20and%20the%20Australian%20Department%20of%20Health%27s%20Therapeutic%20Goods%20Administration%20%28TGA%29%20to%20commence%20in%20Australia.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7523836/ http://t-bioscript.com/news-releases/news-release-details/bioscryptannounces-clinical-trial-guidelines-treatment-patients										Undisclosed	Approved	Preclinical	SARS-CoV-2 3CL-Protease; Viral RNA-dependent RNA polymerase; undisclosed	Antiviral

To: 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Alvarez, Rosa'[rosalvarez@deloitte.com]; 'Anderson, Annaliesa'[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; 'Carter, Kara'[kara.carter@evotec.com]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; 'Diamond, Michael'[diamond@wusm.wustl.edu]; 'Duncan, Ken'[ken.duncan@gatesfoundation.org]; 'Gatto, Greg'[ggatto@rti.org]; 'Grobler, Jay'[jay_grobler@merck.com]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Jonson, Samantha (NIH/NCATS) [E]'[samantha.jonson@nih.gov]; 'Lutz, Cat'[Cat.Lutz@jax.org]; 'Nestle, Frank'[Frank.Nestle@sanofi.com]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; 'Payne, David'[david.j.payne@gsk.com]; 'Qashu, Felicia (NIH/OD) [E]'[felicia.qashu@nih.gov]; 'Rao, Srinivas'[Srinivas.Rao@sanofi.com]; 'Rappaport, Jay'[jrappaport@tulane.edu]; 'Stegmeier, Frank'[fstegmeier@ksqtx.com]; 'Young, John'[john.young.jy3@roche.com]
From: Prabha Fernandes[prabha.fernandes@gmail.com]
Sent: Mon 5/11/2020 9:13:38 AM (UTC-04:00)
Subject: RE: Request for change: ACTIV Preclinical working group (Tuesday meeting)

Hello Joe,
This week I cannot do it but from next week I can.
Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Monday, May 11, 2020 9:00 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Request for change: ACTIV Preclinical working group (Tuesday meeting)

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Sincerely,

Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
301 594-6596 | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852


FNIH PANDEMIC
RESPONSE FUND

To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Mon 5/11/2020 9:21:44 AM (UTC-04:00)
Subject: RE: Request for change: ACTIV Preclinical working group (Tuesday meeting)

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Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
From: Rappaport, Jay[jrappaport@tulane.edu]
Sent: Mon 5/11/2020 9:50:59 AM (UTC-04:00)
Subject: Re: Request for change: ACTIV Preclinical working group (Tuesday meeting)

DearJoe and All,
This would be great for me and and allow me and other NPRC Directors, to attend both ACTIV and NPRCs meetings.
Thank you for making this change.
Best regards,
Jay

Get Outlook for iOS

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Sent: Monday, May 11, 2020 8:21:44 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
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> External Sender. Be aware of links, attachments and requests.

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From: Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]
Sent: Mon 5/11/2020 10:49:01 AM (UTC-04:00)
Subject: RE: Public preclinical compounds to assess for initial prioritization scheme
Should we stimulate or suppress immune responses in COVID-19.pdf

This review paper on immunomodulation might also be of interest as the group starts to think about prioritization of possible therapies.
Best,
Liz

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Sunday, May 10, 2020 8:28 PM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Subject: Public preclinical compounds to assess for initial prioritization scheme

Dear All,

I have spent a little time with the list of therapies that Deloitte has collected by scraping several public databases. I have done an initial filtering exercise and thought you might like to see the initial list. We may use this as a test for how we might prioritize therapies as we get into this more.

I have included an excel sheet based on slide 7 and shown graphically on slides 8 and 9.

We can discuss more on Monday.

Best regards,
Joe

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Autoimmunity Reviews xxx (xxxx) xxxx

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Autoimmunity Reviews

journal homepage: www.elsevier.com/locate/autrev

Should we stimulate or suppress immune responses in COVID-19? Cytokine and anti-cytokine interventions

Yvan Jamilloux [a,b,*], Thomas Henry [b], Alexandre Belot [b,c,f], Sébastien Viel [b,d,f], Maxime Fauter [a,b], Thomas El Jammal [a], Thierry Walzer [b], Bruno François [e], Pascal Sève [a]

[a] Department of Internal Medicine, Lyon University Hospital, Lyon, France
[b] Centre International de Recherche en Infectiologie (CIRI), Inserm U1111, CNRS, UMR5308, Ecole Normale Supérieure de Lyon, Université Claude Bernard-Lyon1, Lyon, France
[c] Department of Pediatric rheumatology, nephrology, and dermatology, Lyon University Hospital, Lyon, France
[d] Service d'Immunologie Biologique, Centre, Hospitalier Lyon Sud, Hospices Civils de Lyon, Pierre-Bénite France
[e] Intensive care unit & Inserm CIC 1435 & Inserm UMR 1092, Dupuytren University Hospital, Limoges, France
[f] National Referee Centre for Rheumatic and AutoImmune and Systemic diseases in childrEn (RAISE), Lyon, France

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Sars-CoV2
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Type-I interferon
IL-6
IL-1

ABSTRACT

The coronavirus disease-19 pandemic (COVID-19), which appeared in China in December 2019 and rapidly spread throughout the world, has forced clinicians and scientists to take up extraordinary challenges. This unprecedented situation led to the inception of numerous fundamental research protocols and many clinical trials. It quickly became apparent that although COVID-19, in the vast majority of cases, was a benign disease, it could also develop a severe form with sometimes fatal outcomes. Cytokines are central to the pathophysiology of COVID-19; while some of them are beneficial (type-I interferon, interleukin-7), others appear detrimental (interleukin-1β, -6, and TNF-α) particularly in the context of the so-called cytokine storm. Yet another characteristic of the disease has emerged: concomitant immunodeficiency, notably involving impaired type-I interferon response, and lymphopenia. This review provides an overview of current knowledge on COVID-19 immunopathology. We discuss the defective type-I IFN response, the theoretical role of IL-7 to restore lymphocyte repertoire, as well as we mention the two patterns observed in severe COVID-19 (i.e. interleukin-1β-driven macrophage activation syndrome vs. interleukin-6-driven immune dysregulation). Next, reviewing current evidence drawn from clinical trials, we examine a number of cytokine and anti-cytokine therapies, including interleukin-1, -6, and TNF inhibitors, as well as less targeted therapies, such as corticosteroids, chloroquine, or JAK inhibitors.

1. Introduction

Severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) is a new β-coronavirus responsible for the pandemic viral pneumonia known as COVID-19. The disease started in Wuhan, China in December 2019 and has rapidly spread throughout the world [1]. As of April 24, 2020, the overall outbreak had caused over 191,000 deaths and approximately 2,700,000 infections. SARS-CoV-2 shares genomic similarities with two human coronaviruses, SARS-CoV and MERS-CoV (about 80% and 50%, respectively), which have caused fatal infections in the past 20 years [2]. COVID-19 causes a wide spectrum of clinical manifestations, ranging from asymptomatic or paucisymptomatic forms (with cough, fever, myalgia, and malaise) to full-blown viral pneumonia, which can lead to acute respiratory distress syndrome (ARDS) [3,4]. Currently, three phenotypes are observed in COVID-19 patients, indicating three stages of the infection's progression and extent: (i) "mild" (benign infection: 80%) in patients with minor and nonspecific symptoms who will not progress to a more severe disease; (ii) "moderate" (overt pneumonia with or without hypoxia and localized inflammation: 15%) in patients requiring hospitalization; and (iii) "severe" (systemic hyperinflammation and ARDS: 5%) in patients who require critical care management and at risk of fatal outcome (1-2%) [5,6]. Despite multiple targeted and non-targeted interventions, no treatment has yet proven effective in treating COVID-19. Numerous clinical trials are ongoing.

As the pandemic progresses, the pathophysiology of COVID-19 is becoming clearer and the potential of multiple cytokine and/or anti-cytokine interventions is raised. Indeed, it has been reported that

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Received 26 April 2020; Accepted 28 April 2020

COVID-19 associates states of both immunodeficiency and hyperinflammation, with the latter being manifested by a cytokine storm.

In this paper, we summarize today's principal findings and attempt to establish a more definitive view of COVID-19 pathophysiology, focusing on one key question: "*How can antiviral immunity be reinforced and hyperinflammatory damages be avoided?*" In the second half of this paper, we will describe the early results of clinical investigations which have assessed targeted and non-targeted therapies.

In this review, we will not discuss antiviral strategies used to treat COVID-19, nor will we discuss how to manage the wide spectrum of SARS-CoV2 infection-related complications, such as thromboembolism, vasculitis (chilblains), acute kidney injury or neurologic involvements.

2. Overview of COVID-19 immunopathology

2.1. Act 1: the virus entry

SARS-CoV-2 is a zoonotic β-coronavirus, which infects human airways and enters cells by binding its S (spike) protein envelope to the human angiotensin-converting enzyme 2 (hACE2) after S protein priming by host serine protease TMPRSS2 [7]. hACE2 is present in type II alveolar cells (representing about 80% of all hACE2-expressing cells), nasal mucosa, upper respiratory tract, endothelium, heart, kidney, and intestine cells [8]. It has been reported that patients with diabetes, hypertension, or patients treated with ibuprofen are at higher risk of contracting severe COVID-19 [9–11]. In these patients, because there is increased expression of hACE2 on lung epithelial cells, some authors have postulated a connection between these points [12]. Of note, another receptor, CD147, has been implicated in mediating host cell invasion by SARS-CoV-2 [13]. After binding to its receptor, the virus enters the cells through endocytosis, viral RNA is released into the cytosol, the virus exploits the cell machinery to replicate, and it is further excreted from the cell by exocytosis [14].

Lung injury directly induced by the virus remains poorly explained. Patients with high viral loads and long virus-shedding periods are at higher risk of severe COVID-19 [15]. The early onset of rapid viral replication may cause massive epithelial and endothelial cell apoptosis, vascular leakage, as well as pro-inflammatory mediator release [16]. Furthermore, hACE2 downregulation and shedding by viral S protein can cause dysfunction of the renin-angiotensin system and exacerbate inflammation and vascular permeability leading to acute lung injury [17,18]. Finally, recent data have suggested that SARS-CoV-2 can directly infect T cells through receptor-dependent, S protein-mediated membrane fusion [19]. Nevertheless, T cells have a very low expression level of hACE2, suggesting either an alternative receptor or high S protein affinity for hACE2. T cell infection is abortive, meaning that SARS-CoV-2 cannot replicate within T cells but rather induces cell death [19]. In SARS-CoV infection, the modulation of TNF-α-converting enzyme (TACE or ADAM17) by the spike protein of SARS-CoV and hACE2 induces TNF-α production which may accentuate T cell apoptosis [20,21]. In this vein, Xiong et al. reported upregulation of apoptosis, autophagy, and p53 pathways in PBMCs from COVID-19 patients, when compared to healthy controls [22].

2.2. Act 2: the innate immune response first cytokine wave

Epidemiological studies have demonstrated an elevation of acute phase reactants in patients with COVID-19, including ESR, C-reactive protein (CRP), serum amyloid A, and ferritin, suggesting a rapid activation of the innate immune response [3,23–25]. Accordingly, COVID-19 patients have high levels of circulating TNF-α, IL-1β, IL-1Ra, sIL-2Rα, IL-6, IL-10, IL-17, IL-18, IFN-γ, MCP-3, M-CSF, MIP-1a, G-CSF, IP-10 and MCP-1 [23,26].

These results are suggestive of hypercytokinemia, which is a hallmark of COVID-19. Nevertheless, only the serum concentrations of certain of these cytokines make it possible to discriminate between mild, moderate, and severe cases (mainly IL-1 β, IL-1Ra, IL-6, IL-7, IL-10, IP-10, and TNF-α) [26]. In addition, the levels of these cytokines in mild/moderate cases are generally below levels observed in usual macrophage activation syndrome/reactive hemophagocytic lymphohistiocytosis (MAS/reHLH) or in severe cytokine release syndrome (CRS) [27,28]. Thus, hypercytokinemia should be regarded as a general marker of SARS-CoV-2, while the term 'cytokine storm' should be kept for those situations of overly exuberant inflammation leading to critical conditions, such as ARDS, disseminated intravascular coagulation or multiple organ failure.

Within cells, RNA viruses are sensed by the innate immune system through three major classes of pattern recognition receptors (PRRs): toll-like receptors (i.e. TLR-3, -7, -8), RIG-I-like receptors (RLRs), and NOD-like receptors (NLRs) [29]. Among TLRs, only TLR-7 and -8 recognize single stranded viral genomic RNA. Nonetheless, other cytosolic sensors such as TLR-3 and RIG-I/MDA5 may detect the virus intermediates during intracellular replication, including double stranded RNA [30]. These recognitions then activate downstream signaling effectors, i.e. NF-κB and IRF3/7. NF-κB promotes the transcription of proinflammatory cytokines, such as TNF-α, IL-1β, and IL-6, further triggering Th1 and Th17 inflammatory responses with subsequent secretion of IFN-γ and IL-17. IRF3/7 promote type-I IFN production, which in turn activates the JAK1/TYK2-STAT1/2 pathway. STAT1 and STAT2 form a complex with IRF9 that translocates into the nucleus where it initiates the transcription of hundreds of genes called IFN-stimulated genes (ISGs). An early and robust type-I IFN response is required as the very first line of defense to suppress viral replication and spread.

Early NLR engagement has also been postulated during the innate immune response against coronaviruses [16]. Evidence of NLRs directly recognizing viral RNA is scant [31], however, NLRs are more possibly involved in detecting intracellular homeostasis perturbations or danger signals, such as ROS production [32,33]. Evidence of their involvement can be found in the observation of high levels of circulating IL-1β, IL1-Ra, and IL-18 [23,26] and synergistic upregulation of *IL1* and *IL1RN* genes in the lung [34]. Indeed, some NLRs are able to assemble a multimolecular platform termed inflammasome (via recruiting the adaptor ASC, *apoptosis-associated speck-like protein containing a CARD*), which in turn activates the proinflammatory caspase-1. Caspase-1 cleaves and activates IL-1β and IL-18, and induces a hyperinflammatory form of cell death, termed pyroptosis, through the cleavage of the pore-forming gasdermin-D [32,35]. IL-1 family cytokines include IL-1α, IL-1β, IL-18 and their bioavailability is regulated by soluble antagonists (IL-1Ra, IL-18BP) of either endogenous origin or resulting from therapeutic intervention [36,37]. The most frequently studied inflammasome sensor, NLRP3, drives inflammation during SARS-CoV infection through several activating pathways [38–41]. Given the similarities between SARS-CoV and SARS-CoV-2, comparable mechanisms likely intervene during the acute phase of COVID-19.

Of note, the cytosolic sensor RIG-I can also associate with ASC to form a non-canonical inflammasome inducing caspase-1 activation and subsequent IL1-β/IL-18 secretion and pyroptosis [42]. IL-1β secretion may itself contribute to hypercytokinemia since IL-1β further induces the expression of other proinflammatory cytokines such as TNF-α and IL-6.

Lastly, high levels of chemokines and their coupled receptors have been observed in COVID-19 patients [22,23,26]. Accordingly, analysis of the molecular signature within the BALFs of patients revealed a plethora of upregulated chemokine transcripts, including neutrophil-recruiting mediators (CXCL8, CXCL1, CXCL2, CXCL10, CCL2, CCL7) and other attractants of monocytes and immune cells (CXCL6, CXCL11, CCL2, CCL3, CCL4, CCL7, CCL8, CCL20) [34]. These results are consistent with pathological findings attesting to lung infiltration by monocytes, macrophages and neutrophils, in contrast with lower amounts of lymphocytes [43]. This hyperactivated chemotaxis may play a major role in developing a pulmonary-centric disease by driving accumulated immune cells into the lungs and restricting the immune response to this particular organ.

2.3. Act 3: the immunodeficient state

As stated above, type-I IFN is critical for protecting against viral infections, since it promotes intracellular RNA degradation and virus clearance, induces tissue repair, and triggers a prolonged adaptive immune response [44–46]. Type-I IFN is mainly produced by plasmacytoid dendritic cells (pDCs), which are less sensitive to productive viral infection and/or virus-mediated cytotoxicity and can produce other inflammatory cytokines, such as TNF-α and IL-6 or control T cell response [47,48]. pDCs are circulating immune cells, which act as sentinels and are activated after physical contact with virally-infected cells and transfer of PAMPs to the TLR7 sensors in pDCs, part of a process termed *interferogenic synapse* [49]. This synapse enables robust type-I IFN production at the infected site, thereby possibly limiting viral replication and systemic deleterious response. Data derived from the SARS-CoV and MERS-CoV outbreaks have revealed that coronaviruses suppress type-I IFN response by interfering with PRRs or type-I IFN receptor-signaling pathways. For instance, SARS-CoV induces the degradation of RNA sensor adaptor molecules, MAVS and TRAF3/6, thus inhibiting IRF3 translocation into the nucleus. MERS-CoV employs additional strategies, such as repression of histone modifications. Both viruses inhibit JAK/STAT signaling by decreasing STAT1 phosphorylation.

Considering the 80% overlap between SARS-CoV and SARS-CoV-2, it has been speculated that the latter uses similar strategies to dampen innate immune response. Nevertheless, SARS-CoV2 appears to have lower pathogenicity than SARS-CoV (with about a 10%-fatality rate) suggesting a lesser IFN antagonism [50]. On the other hand, exceptional genetic defects or immunosenescence may account for a reduced type-I IFN response and greater severity of COVID-19. Accordingly increased age is associated with a poorer outcome [3,6,23,51].

In mouse models of SARS-CoV and MERS-CoV infections, a delayed type-I IFN response may explain more severe disease, with compromised virus control and paradoxical hyperinflammation induced by type-I IFN itself [52]. This leads to an influx of neutrophils and monocytes-macrophages (the major sources of pro-inflammatory cytokines) and further apoptosis of T cells, epithelial and endothelial cells [52–55]. These acute inflammatory mechanisms damage the pulmonary microvascular and alveolar barrier and cause vascular leakage and alveolar edema, converging to ARDS. Therefore, not only the strength of the response but also its timing would appear to play a critical role in coronavirus infection (Fig. 1).

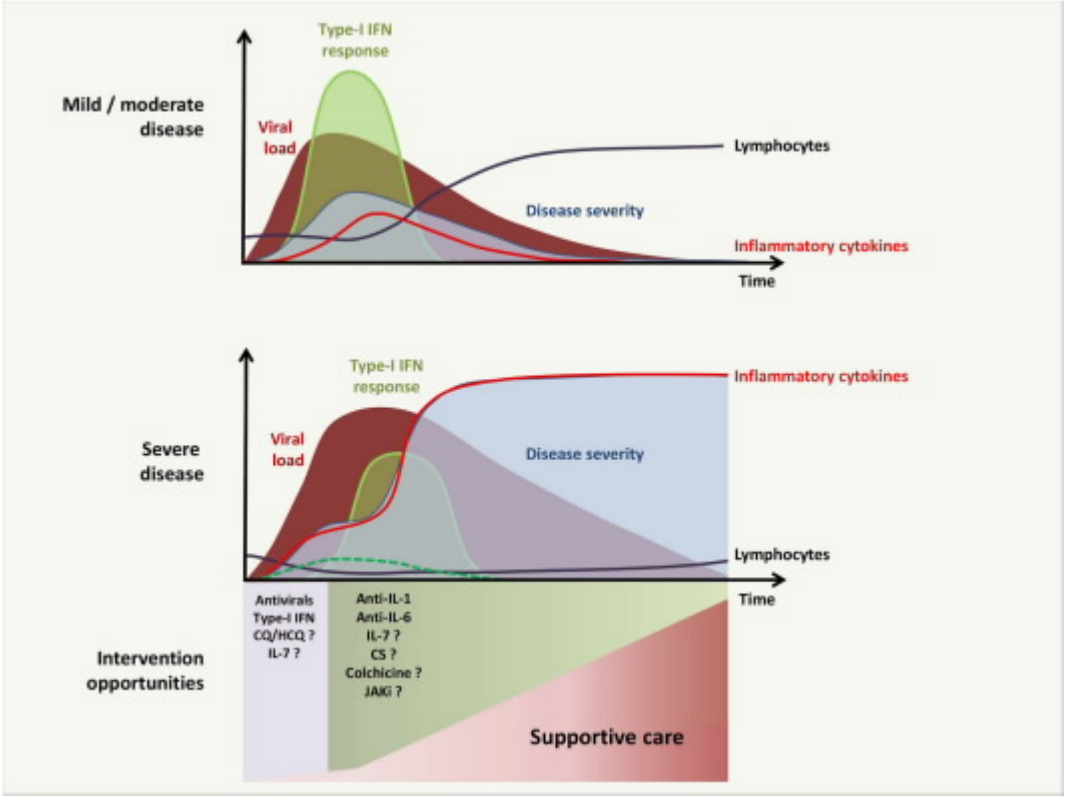

Fig. 1. Kinetics and intensity of the antiviral response are decisive in COVID-19 outcome. In mild to moderate COVID-19, the early antiviral response, mostly type-I interferon (IFN), allows the rapid reduction of viral load and prevents T-cell depletion and hypercytokinemia. In severe COVID-19, delayed (solid green line) or low (dotted green line) antiviral responses results in elevated lung cytokine/chemokine levels, impaired virus-specific T-cell responses, and acute clinical deterioration. Optimal times for therapeutic interventions are proposed. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

In vitro, SARS-COV-2 displays a greater sensitivity to type-I IFN than SARS-COV[56]. Furthermore, SARS-CoV-2 does not impair STAT1 phosphorylation. Interestingly, mild/moderate infection by SARS-CoV-2 is associated with a potent type-I IFN response, characterized by the robust expression of ISGs in patients' BALFs [34]. Moreover, preliminary results have revealed early IFN production in peripheral blood from patients with mild/moderate to severe forms during the first week of COVID-19 ([203]). In contrast, about 20% displayed no IFN production. Another study found the type-I IFN response to be high (between days 8-12) in mild-to-moderate patients while reduced in more severe patients who had a striking downregulation of IFN-stimulated genes [57]. These results are in line with previous conclusions and would indicate that the characteristics of type-I IFN response - both in terms of kinetics and intensity - could be linked to clinical outcome [52]. How exactly SARS-CoV-2 escapes type-I IFN in some patients remains to be elucidated.

Lymphopenia is one of the most prominent markers of COVID-19 and has been observed in over 80% of patients [23,58,59]. Analyses have shown that all subsets of lymphocytes were decreased, including CD4+ and CD8+ cytotoxic T cells [57,60], natural killer (NK) cells, memory and regulatory T cells [61] along with B cells [62]. Lower lymphocyte counts are closely linked to severe disease [61,62]. In addition to being quantitatively decreased, T cells exhibit elevated exhaustion levels and reduced functional diversity [60,63]. T cell numbers are negatively correlated with serum IL-6, IL-10 and TNF-α and with higher levels of exhaustion markers, such as PD-1 or Tim-3 [57,60,64]. Patients with severe form of COVID-19 have less multifunctional and more non-functional CD4+ T cells, as well as fewer non-exhausted CD8+ T cells than patients with mild COVID-19 [63].

Several explanations are posited to explain this SARS-CoV-2-induced lymphopenia.

First, the virus can directly infect T cells but cannot replicate within the cells [19]. T cell infection may thus result in cell death by apoptosis, necrosis, or pyroptosis [19,65,66].

Second, a number of inhibitory cytokines are released by infected lung macrophages or epithelial cells (first wave of hypercytokinemia), including TNF-α which causes T cell apoptosis [21], IL-10 which is known to prevent T cell proliferation [67], and type-I IFN which regulates lymphocyte recirculation [68]. T cell exhaustion, characterizing severe COVID-19, may stem from increased PD-1 or Tim-3 expression, from elevated levels of inhibitory IL-10 [60] or from increased IL-6-induced expression of SOCS3 [69–71]. Interestingly, IL-2 and IL-7, the cytokines responsible for expansion and differentiation of various T cell subsets are increased in the sera of patients having either mild/moderate or severe forms of COVID-19 [23]. Nevertheless, these increased levels most likely represent attempts by the immune system to reverse lymphopenia and T cell exhaustion.

Lastly, lymphopenia has been thought to be the result of immune cells redistribution, with accumulation of lymphocytes in the lungs or lymphoid organs [72]. However, though pathological results are scarce and contradictory, it would seem that alveolar or interstitial tissues are not invaded by lymphocytes but rather by monocytes, macrophages and moderate numbers of multinucleated giant cells [43]. More intriguingly, autopsies have revealed that secondary lymphoid tissues had been destroyed with atrophied spleen and decreased lymphocyte numbers, accompanied by significant cell degeneration, focal hemorrhagic necrosis, plus macrophage proliferation and phagocytosis. Lymph nodes were atrophied and their number decreased, with signs of necrosis. Immunohistochemical staining demonstrated decreased rates of CD4+ and CD8+ T cells in the spleen and lymph nodes [61].

2.4. Act 4: the cytokine storm, a lethal second wave

Sudden and rapidly progressing clinical deterioration has been widely mentioned in late stages of COVID-19 (around 7-10 days). This often manifests as an unexpected aggravation of symptoms (fever, dyspnea) and is correlated with increased levels of acute phase reactants (ESR, CRP, ferritin), coagulopathy (elevated titers of d-dimers, disseminated intravascular coagulation), and cell lysis (CK, LDH) [3,4,11,23,59]. In the most severe patients, clinical and laboratory parameters correlated with increased levels of proinflammatory cytokines (IL-1β, IL-1Ra, IL-6, TNF-α, and sIL2-Rα), evocative of a cytokine storm [3,73–75]. Interestingly, ARDS occurs in SARS-CoV patients despite a diminishing viral load, suggesting that exuberant host immune response may be responsible for this outcome rather than viral virulence. Such a cytokine profile is strongly reminiscent of both Cytokine Release Syndrome (CRS, seen in CAR T cell therapy) and hemophagocytic lymphohistiocytosis (HLH) [76,77]. Numerous authors have paralleled the COVID-19 cytokine storm to either primary or reactive HLH (reHLH) because of its close resemblance, including high fever, cytopenia, hyperferritinemia, abnormal liver tests, coagulopathy, and pulmonary involvement (including ARDS), occurring in approximately 50% of patients with reHLH [73,74,78]. In adults, reHLH is most often triggered by viral infections and is observed in 3 - 4% of sepsis cases [79]. Herpesviridae (e.g. Epstein-Barr virus) and influenza are major triggers of such cytokine storms [77]. Systemic diseases, like systemic lupus erythematosus, or the autoinflammatory adult-onset Still's disease and its pediatric counterpart, can also be complicated by cytokine storm, known as the macrophage activation syndrome (identical to reHLH) [80–82]. In all these conditions, IL-1β, IL-18, IFN-γ, and IL-6 are key mediators of hyperinflammation.

Similar to what is observed in SARS-CoV-2 infection, the immunodeficiency linked to abnormal T cell number or function (genetically determined in primary HLH) appears to be the *primum mobile* of most cytokine storms [83–87]. Although an alternative pathway of primary hyperactivated innate immunity is possible, it is more likely that this cytokine storm occurs due to the combination of a defective (or delayed) first line of defense, followed by persistent hypercytokinemia (IL-6, IL-1β, and TNF-α), and dysfunctional T cell response (generally cytotoxicity). This results in an impaired clearance of apoptic cells or infected/activated macrophages, an increase in viral replication and dissemination, followed by an IL-18/IFN-γ feedforward loop activating macrophages, culminating in multiple cytokine release, hemophagocytosis, coagulopathy, and ARDS (Fig. 2) [85,88,89]. Some of these mediators may further fuel this vicious cycle, including NK cell function impairment by IL-6 [71] or macrophage activation by the H-chain of ferritin [90–92]. Quite importantly, hemophagocytosis has been reported in lung tissues from patients who succumbed to SARS-CoV infection [93].

Thus, in COVID-19, the onset of ARDS may be the consequence of a HLH-like syndrome, after a first period of lung damage, mainly localized within the lungs due to a prior accumulation of large amounts of innate immune cells. Systemic features of HLH are lacking (such as extremely high titers of ferritinemia, organomegaly, and severe end-organ disease) but this is most probably the consequence of lymphoid organ immune cell depopulation of [43].

Analysing more precisely the immunopathology of SARS-CoV2-related ARDS, Giamarellos-Bourboulis *et al.* have come to the conclusion that two patterns of immune dysfunction exist in worsening COVID-19: (i) one pattern highly suggestive of macrophage activation syndrome (hyperferritinemia and elevated H score : 25% of patients), which is driven by IL-1β; and (ii) one pattern with immune dysregulation driven by IL-6 [71]. The latter was characterized by a combination of hypercytokinemia, immunoparalysis (as indicated by decreased HLA-DR molecules on CD14 monocytes), and global lymphopenia (including CD4+ and NK cells). Interestingly, IL-6 blockade with tocilizumab partially restored HLA-DR expression on CD14 monocytes and increased the circulating lymphocyte count.

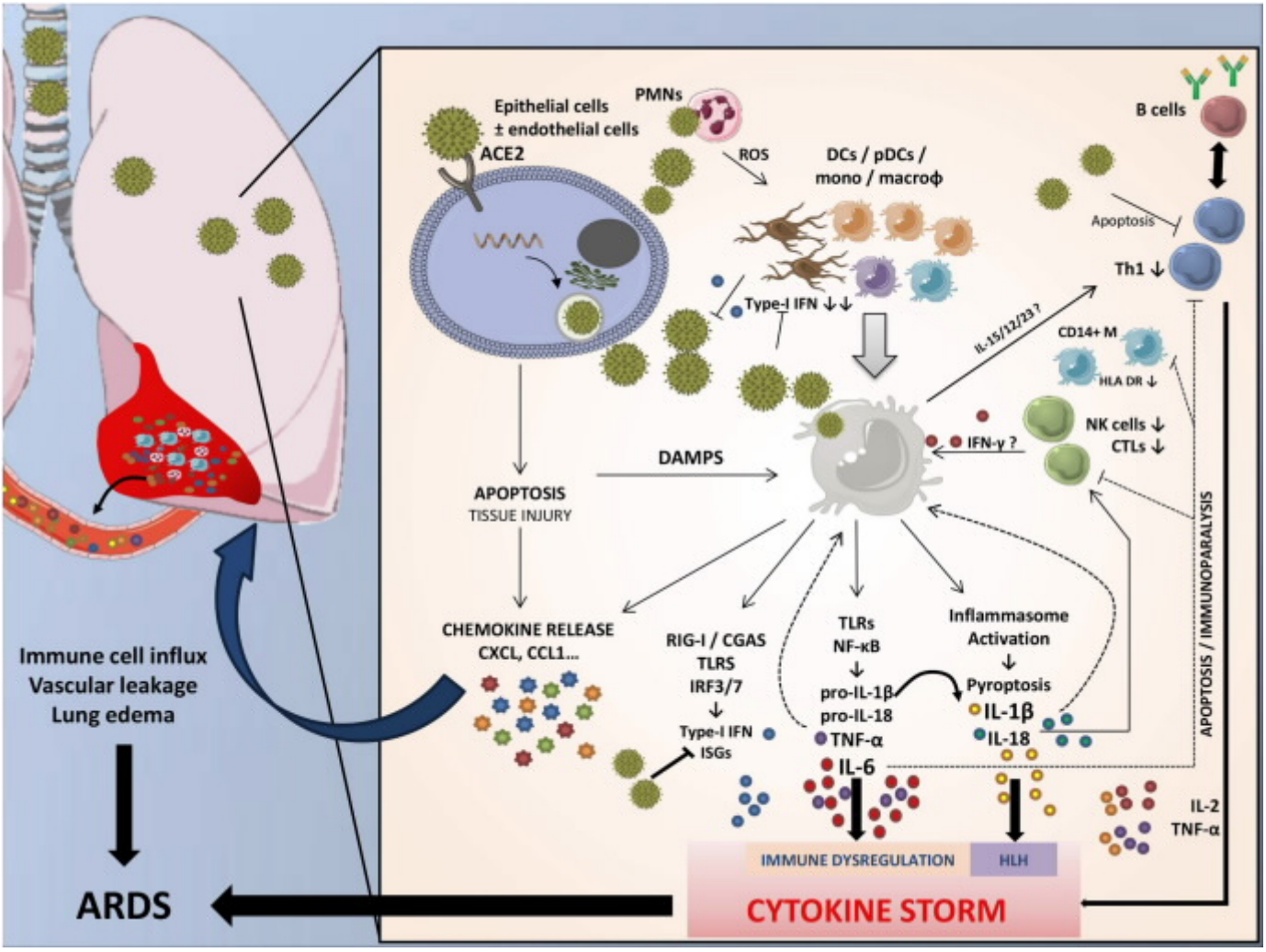

Fig. 2. The immunopathology of COVID-19.
The entry of SARS-CoV-2 in epithelial/endothelial cells, via binding to ACE2 (and CD147), induces apoptotic and necroptotic pathways resulting in lung injury and release of numerous chemokines driving the recruitment of large amounts of immune cells within the lungs. Dendritic cells (DCs) and plasmacytoid DCs (pDCs, the main source of type-I interferon (IFN)), along with alveolar macrophages and neutrophils, promote the innate immune response by secreting alarmins and antiviral or proinflammatory cytokines, plus presenting the antigen to adaptive immune cells. SARS-CoV-2 may have evolved strategies to downregulate the type-I IFN response and induce T cell apoptosis. The recognition of molecular patterns (viral RNA, particles, or danger signals) by various Toll-like receptors (TLRs), NOD-like receptors (NLRs) or RIG-I like receptors (RLRs) activates the transcription and release of proinflammatory mediators, such as interleukin (IL)-1β, -6, -18, and tumor necrosis factor (TNF)-α. These mediators further skew naïve T-cells to Th1 or cytotoxic lymphocytes (CTLs or CD8+), which in turn secrete amounts of cytokines. A pro-inflammatory feedforward loop of cytokines on innate immune cells results in cytokine storm, coagulopathy, and acute respiratory distress syndrome (ARDS). COVID-19 cytokine storm may intertwine two mechanisms; one highly suggestive of macrophage activation syndrome (hemophagocytic lymphohistiocytosis, HLH) driven by IL-1β, and another pattern characterized by immune dysregulation driven by IL-6, which triggers immunoparalysis (decreased HLA-DR on CD14 monocytes) and global lymphopenia.

A number of key points stand out in this overview of the immunopathology of SARS-CoV-2 infection:

1) While the virus induces both impairment and hyperactivation of the immune system, these are sequential, and the latter seems to ensue from the former, at least partially;
2) An early viral clearance by type-I IFN is a key to preventing further viral replication, T cell exhaustion, and subsequent cytokine storm;
3) Therapies (when applicable) should be administered with the right timing; i.e. antivirals and immune boosters should be initiated promptly after symptom onset, whereas immunosuppressants should be administered at the very start of the cytokine storm (Fig. 1);
4) Given the great frequency of non-severe presentations, therapeutic interventions should be kept for selected patients (i.e. those with risk factors or worsening diseases). Nonetheless, except for advanced age, elevated body mass index, and comorbid conditions, there is still a lack of robust prognostic factors [3,23,24,75].

Routine and non-routine markers can be monitored to help evaluate the risk of developing cytokine storm. However, at present, no cut-off value has yet been proposed for any of these markers. It would be of great benefit to analyze their trends in depth, along with daily clinical evaluation.

3. Cytokine-based interventions

3.1. Type-I interferon

Since type-I IFN's key role in antiviral response and low or delayed IFN response has been associated with poor outcome, IFN-α and IFN-β have emerged as potentially effective drugs against SARS-CoV-2

[52,94]. Evidence is mainly derived from experience with SARS-CoV and MERS-CoV infections [95]. *In vivo*, type-I is most often used in combination with other antiviral drugs, such as lopinavir/ritonavir [96–99] or ribavirin [100–102]. *In vitro*, IFN-α and -β have very systematically demonstrated robust efficacy against coronaviruses, but proved disappointing when transposed to human diseases [95,96,100,103]. Multiple biases in these trials have prevented drawing conclusions from them. These biases include: coronavirus escape strategies to type-I IFN, limited sample sizes, heterogeneous experimental designs/clinical conditions, the nature of IFN isoform, administration route, plus difficulties in assessing whether disease outcome was linked to type-I IFN or to the drugs used in combination. Key points which have emerged from these studies are: (i) IFN-β1b and IFN-β1a are the most potent subtypes for SARS-CoV inhibition (probably even more for SARS-CoV-2) [56,104,105]; (ii) type-I IFN must be administered as soon as possible after infection (ideally before symptom onset) although not in the late phase, because of possible tissue damage [5,52,106,107]; and (iii) although IFN-α inhalation can lower SARS-CoV-2 infection rate and serve in prophylaxis or treatment (Chinese guidelines) [108], the preferred solutions remain the better-evaluated, safer intravenous and subcutaneous routes [94,109].

Even though type-I IFN is being evaluated in several clinical trials, either alone (NCT04293887, NCT04320238, ChiCTR2000029989) or in combination (NCT04254874, NCT04276688, NCT04273763, NCT04315948, NCT04350684, NCT04350281, NCT04343768, NCT04350671), only one single retrospective study is currently available [110]. Zhou et al. compared 77 adults with laboratory-confirmed COVID-19 who were treated with either nebulized IFN-α2b (5 mU b.i.d.), oral umifenovir (200 mg t.i.d.), or a combination of both [110]. The authors found that treatment with IFN-α2b - with or without umifenovir - significantly reduced the duration of detectable virus in the upper respiratory tract and reduced the duration of elevated inflammatory markers (IL-6 and CRP). Unfortunately, this study has major flaws: (i) the study did not include a control group; (ii) only moderate forms of COVID-19 were included, with a median time from symptom onset to treatment of 11 days (range, 5 -22); (iii) patients in the IFN-α-treated group were significantly younger and had fewer comorbidities; (iv) the only patients treated with IFN-α2b alone were women; and (v) treatment regimens were quite heterogeneous since, in the combination group, 34% of patients received IFN-α2b as add-on to umifenovir and 52% started IFN-α2b after umifenovir had been stopped. None of the patients developed end organ dysfunction, nor respiratory failure requiring oxygen or critical care management. Interestingly, another study prospectively evaluated IFN-α1b nasal drops to prevent medical staff SARS-CoV-2 infection [111]. 2,944 medical staff members were allocated to either a low-risk group (n=2,415, 4-6 drops q.i.d. for 28 days) or a high-risk group (nasal drops + subcutaneous thymosin-α1 every week) depending on their exposure to the coronavirus. The control group consisted of medical staff in the same areas of Hubei Province, China. The 28-day incidence of COVID-19 amounted to zero for both groups, whereas over 2,000 new COVID-19 cases were diagnosed among medical personnel over the same period. Despite problems of major bias, this study suggests that IFN-α1b could serve as an efficient prophylactic against COVID-19.

Additional well-designed studies involving timely administration of IFN-α are thus eagerly awaited.

3.2. Interleukin-7

Lymphopenia and lymphocyte exhaustion are hallmarks of COVID-19 and are possibly responsible for the cytokine storm due to defective clearance of both virus and infected cells. It is thus tempting to speculate that IL-7 - the major cytokine promoting lymphocyte expansion and possibly reversal of T cell exhaustion - may be useful in restoring immune system homeostasis. IL-7 exerts anti-apoptotic properties and induces potent proliferation of naive and memory T cells leading to replenishment of the circulating pool (CD4+ and CD8+) [112,113]. IL-7 also increases T cell receptor repertoire diversity [114] and promote the expression of cell adhesion molecules, improving the capacity of T cells to traffic to infection sites [115]. More importantly, the administration of recombinant IL-7 (rIL-7) does not induce hyperinflammatory response through stimulating adaptive immunity. Indeed, rIL-7 has been successfully used to treat T cell exhaustion following septic shock and restore CD4+ T cells in HIV patients, with no evidence of clinical deterioration nor proinflammatory marker exacerbation (TNF-α, IL-6, CRP)[116,117]. Surprisingly, at the time of writing this review, there is no trial registered yet to evaluate this strategy. If such a study were to be launched, the perfect timing for lymphocyte restoration would need to be strictly determined.

4. Anti-cytokine interventions

4.1. Interleukin-6 inhibition

Not only is IL-6 a major mediator within the cytokine storm, its levels have been closely correlated with ARDS severity and outcome, along with blood SARS-CoV-2 viral load [71,74,118]. A recent meta-analysis reported 2.9-fold higher serum levels in patients with complicated COVID-19 compared to patients with non-complicated disease [119]. Inhibitors of IL-6 or its receptor have been successful in treating other cytokine storm syndromes, such as reHLH associated with adult-onset Still's disease [120], or CRS secondary to CAR T cell therapies [28,121]. Several drugs are available, including IL-6 receptor inhibitors (tocilizumab, sarilumab) and IL-6 inhibitors (siltuximab, clazakizumab, sirukumab) [122].

To date, only four studies and case reports are available [123–127].

Xu et al. have reported on 21 severe or critical patients treated with tocilizumab although there was no control group [123]. This first study demonstrated decreased oxygen requirements (75%), resolution of CT-scan abnormalities (90.5%), and clinical improvement (100%). No adverse events or deaths were reported. To estimate the results of a potential control group not administered tocilizumab, Xu *et al.* referred to the results of a previous study which found a baseline mortality rate of 60% in critical patients and 11% in severe patients admitted to one ICU [9].

The second study, from China, retrospectively analyzed 15 patients (median age, 73 years) with moderate (n=2), severe (n=6), and critical (n=7) forms of COVID-19 [124]. Eight patients received concurrent methylprednisolone. Three patients died (all from the critical group), 1 patient improved, 9 were clinically stabilized and 2 experienced disease worsening. A persistent increase of serum IL-6 was observed in 4 (out of 5) patients resulting in either aggravation or fatal outcome.

The third study, performed in Italy, analyzed 21 patients with COVID-19 who developed ARDS and were enrolled into a compassionate-use program [125]. All patients received siltuximab at doses ranging from 700 to 1,200 mg. Clinical improvement was observed in 33% of patients, 43% stabilized as evidenced by absence of clinically-relevant change in condition, and 24% experienced a worsened condition. One patient died, and one patient suffered a cerebrovascular event. The absence of control group precludes final conclusions, basically because the mortality rate for patients undergoing standard of care was not mentioned.

Finally, Roumier et al. reported their experience regarding tocilizumab in 30 selected patients (23% in ICU) [127]. Patients were aged < 80, with > 5-days disease duration, and with severe pneumonia (i.e. requiring > 6L/min of oxygen) and rapidly deteriorating (i.e. increase by more than 3L/min of oxygen flow within the previous 12 hours). The control group (standard of care) included patients matched for age, gender, and disease severity. Patients were followed-up for a median of 8 days. Tocilizumab significantly reduced mechanical ventilation requirement (OR: 0.42; p=0.025) and risk of subsequent ICU

admission (OR: 0.17; p=0.001). There was a trend, though no statistical difference, toward lower mortality. Tocilizumab was well-tolerated, yet the author reported two mild liver test disturbances, and one ventilator-acquired pneumonia.

These mixed results must be further clarified. Most notably, since experimental models have shown that IL-6 can either suppress or facilitate viral replication [128], one crucial remaining question to answer will be the optimal timing for anti-IL6 administration. If too early, the drugs may adversely affect viral clearance. If too late, the drugs may not be effective enough. The perfect timing of this must be assessed in trials. At present, several clinical trials are under way to evaluate the safety and efficacy of IL-6 inhibitors, with various protocols and comparators (clinicaltrials.gov identifiers: NCT04332913, NCT04322773, NCT04317092, NCT04320615, NCT04306705, NCT04324073, NCT04315298, NCT04315480, NCT04321993, NCT04335071, NCT04348500, NCT04329650, NCT04330638, NCT04345289, NCT04327388, NCT04341870). In China, tocilizumab is also being evaluated either alone or in combination (identifiers: ChiCTR-2000029765, ChiCTR2000030796, ChiCTR2000030442, ChiCTR20-00030894).

It is noteworthy that since March 2020 tocilizumab has been formally included in the National Health Commission of China's COVID-19 diagnosis and treatment program (7th edition): "Tocilizumab can be used in patients with extensive bilateral lung lesions opacity or in severe or critical patients, who have elevated laboratory detected IL-6 levels". More recently, the Infectious Diseases Society of America (IDSA) has published guidelines and recommends that, for patients who have been admitted to the hospital with COVID-19, tocilizumab should be used only in the context of a clinical trial, due to "knowledge gap" [129].

4.2. Interleukin-1 family: IL-1 and IL-18 blockade

IL-1β and its natural antagonist (i.e. IL-1Ra) have been observed in the peripheral blood and BALF of patients with COVID-19-induced pneumonia [22,23,26,71]. This is a striking result since IL-1β has a short half-life in serum and is rarely isolated in peripheral blood. This finding suggests high levels of IL-1β production, reinforced by reports indicating *IL1B* and *IL1R1* gene upregulations [57].

IL-1β is a proinflammatory cytokine that is activated and secreted upon activation of the inflammasome [32]. NLRP3, the most-frequently studied inflammasome, is activated by danger signals, which have been suggested to be viroporin A, E protein, or ORF3 proteins from SARS-CoV and MERS-CoV[38,40,130]. Pyroptosis has also been associated with coronavirus infection [16,131]. Elevated IL-1β is central to ARDS [132] and HLH [89,133]. Indeed, HLH is a well-known and frequent complication in about 10% of juvenile and adult-onset Still's disease, whith pathophysiology marked by very high levels of IL-1β [81,134]. Anakinra, a recombinant IL-1Ra, has proved effective in treating HLH (via continuous intravenous infusion) [135,136], and it is currently used in IL-1-induced autoinflammatory diseases, including cryopyrinopathies (dominant NLRP3 gain-of-function) [137], familial Mediterranean fever (pyrin inflammasome deregulation) [138], PFAPA [139], and Still's disease[140]. In a reanalysis of data from a phase-III randomized trial, anakinra was associated with significant survival improvement in patients with severe sepsis and features of reHLH, without triggering any serious adverse events [141]. Today, anakinra is being evaluated in this context in the PROVIDE study (NCT03332225). Often efficacious within hours, anakinra has a short half-life and is considered safe. It may thus constitute a drug of choice for certain selected COVID-19 patients presenting signs of imminent cytokine storm. So far, no clinical data are available but clinical trials are ongoing to test anakinra in COVID-19 (NCT04330638, NCT04341584, NCT04339712, NCT04324021).

Canakinumab, a monoclonal antibody targeting IL-1β, is also being investigated in a single-arm observational study (NCT04348448); however its longer half-life (26 days) may be problematic for infected patients.

IL-18 is mainly produced by macrophages as an inactive precursor which is processed by inflammasome-activated caspase-1, like IL-1β [32,142]. By binding to IL-18R, IL-18 (in combination with IL-12/-15) acts on CD4+, CD8+ T cells, and NK cells to induce IFN-γ, the major driver of macrophage activation syndrome (i.e. HLH) [85,86,89,143]. IL-18 is one of the upregulated cytokines in sera and BALF from COVID-19 patients [26,144]. In addition, IL-18 has been reported as a biomarker of Still's disease, its levels being correlated with disease activity [145]. High levels of serum IL-18 have also been reported in patients with a newly-described autoinflammatory disease associating pulmonary alveolar proteinosis and recurrent macrophage activation syndrome (IL18PAP-MAS) [146]. Tadekinig alfa is a recombinant IL-18 binding protein (IL-18BP, a naturally-occurring inhibitor of IL-18) which has shown encouraging results in Still's disease [135,136]. Interestingly, rIL-18BP was uused to successfully treat a 6-week old girl with life-threatening NLRC4-associated hyperinflammation (HLH), which was refractory to corticosteroids, IL-1 blockade, anti-TNF, cyclosporine, and vedolizumab [147]. Although blocking IL-18 could be of interest in COVID-19, there is no clinical evidence, nor any registered RCT assessing the safety and efficacy of rIL-18BP in this framework.

4.3. Interferon-γ inhibition

Intriguingly, while being central to cytokine storm occurrence in SARS-CoV infection [148], IFN-γ was not found to be elevated in the sera or BALFs of patients with severe forms of COVID-19 [22,23,26,149]. Actually, there are even conflicting results showing a mild elevation in the sera of non-severe patients [23,26,75,150]. However, one meta-analysis has shown a link between high IL-6/IFN-γ ratio and disease severity, thereby indicating that lower levels of IFN-γ should rather predict poorer outcomes [151]. Emapalumab, a monoclonal antibody directed against IFN-γ is approved for treating pediatric and adult primary HLH patients with refractory, recurrent, or progressive disease or intolerance to conventional therapy (despite a lack of clinical trial data in adults) [152,153]. However, in the single RCT on 34 patients, serious adverse reactions occurred in 53% of the recipients, including (bacterial, viral, and opportunistic) infections and multiple organ dysfunction syndrome. In addition, data from mouse models suggest that simultaneously inhibiting multiple cytokine-signaling pathways (such as with JAK inhibitors) may be more effective than targeting IFN-γ alone [154,155]. RCTs are now ongoing to evaluate emapalumab in HLH (either primary or reactive: NCT01818492, NCT0331275, NCT03985423, NCT03311854) and in COVID-19 (NCT04324021).

4.4. Tumor necrosis factor-α inhibition

TNF is present in COVID-19 patients' blood and diseased tissues and its levels are even higher in patients with severe disease [23,61,75,156]. Since TNF inhibitors are readily available and well-evaluated drugs, some authors postulate that there is sufficient evidence to conduct clinical trials in COVID-19 [157]. Nevertheless, the literature remains very scanty when exploring possible treatments for cytokine storm or HLH. Indeed, while a few case reports described the benefits of etanercept [158–160], other studies have shown that it may trigger or worsen disease progression [161–163]. However, some cases argue for TNF inhibitors use in COVID-19: (i) TNF neutralization provides protection against SARS-CoV infection in animal models [164]; (ii) anti-TNF induce a rapid decrease of IL-6 and IL-1 concentrations in patients with active rheumatoid arthritis [165]; (iii) anti-TNF trigger a reduction of adhesion molecules and vascular endothelial growth factor, which is partly responsible for capillary leak [166,167]; and (iv) anti-TNF lead to less leucocyte traffick to inflamed tissues due to reduced adhesion molecules and chemokines with subsequent reduction

of cell content and exudate [168]. It is suggested that initial assessments of TNF inhibitors should be done in patients with moderate disease, as soon as possible after their admission to hospital [157]. To date, only a single RCT evaluating adalimumab in COVID-19 has been registered (ChiCTR2000030089).

4.5. Non-targeted therapies

4.5.1. Corticosteroids

Corticosteroids are potent cytokine inhibitors working through several mechanisms but mainly by inhibiting the NF-κB transcription factor. They are the cornerstone of treatments for cytokine storms and HLH associated with autoimmune/autoinflammatory diseases. However, their use in managing SARS-CoV-2 patients is currently highly contested [169–171]. Indeed, a systematic review of observational studies on corticosteroids administered to SARS-CoV infected patients reported no survival benefit, plus potential harm (although mostly inconclusive) [95]. Similarly, a systematic review of observational studies in influenza found a higher risk of mortality and secondary infections with (high-dose) corticosteroids [172]. Further, a study of patients given corticosteroids for MERS-CoV infection revealed delayed clearance of the virus and zero effect of corticosteroids on mortality [173]. Finally, while most previous guidelines did not recommend corticosteroid use for treating sepsis in the absence of refractory shock, a recent statement (triggered by the analysis of two RCTs) made a weak recommendation to use corticosteroids in sepsis patients [174]. Altogether, it has become apparent that corticosteroids may be more detrimental than beneficial in COVID-19 and the WHO (as well as IDSA) recommends that they not be used outside of clinical trials [175]. However, given that these data are derived from previous infections, corticosteroids have been recommended as adjuvant therapy by China's National Health Commission. In particular, one study of 201 patients has found that, among patients who developed ARDS (n=84, 41.8%), treatment with methylprednisolone decreased the risk of death (HR, 0.38; 95% CI, 0.20-0.72, p=0.003) [24]. Nevertheless, in a recent meta-analysis of 15 studies on COVID-19, corticosteroids were associated with significantly higher mortality (RR=2.11, p=0.019), longer length-of-stay ($P < 0.001$), and higher rates of bacterial infection (RR=2.08, $P < 0.001$) [176].

Such conflicting findings are most likely linked to the heterogeneity of protocols and clinical conditions and, above all, to different timings of in corticosteroid administration. Thus, there is no doubt that the main challenge of up-coming RCTs will be to define the precise moment and best dosages for preventing hyperinflammation, while lessening the risks of prolonged viral shedding and secondary bacterial infections.

4.5.2. Chloroquine and hydroxychloroquine

There has been tremendous debate about chloroquine or its derivative, hydroxychloroquine, as potentially effective treatments in COVID-19. Although these drugs have *in vitro* antiviral properties [177–179], including on SARS-CoV-2 [180], studies have systematically failed to demonstrate positive effects in human viral diseases. Both drugs can prevent the virus' binding to hACE2 *in vitro*, or inhibit viral cycle [181]. In addition, they are used in autoimmune and inflammatory diseases (mainly systemic lupus erythematosus) for their immunomodulating properties. It is hypothesized that their action is tied to their ability to accumulate in lysosomes where they raise pH and interfere with antigen degradation and presentation to CD4+ T cells [182,183]. Data also indicate that they reduce proinflammatory IL-6, IL-18, and TNF-α [184,185]. Lastly, they inhibit endosomal TLRs and have anti-inflammatory effects, such inhibiting prostaglandin synthesis or lipid peroxidation [186–188].

Altogether, chloroquine and hydroxychloroquine are thought to be able to reduce viral load and prevent cytokine storm. At the time of writing this review, seven articles are reporting clinical data (observational studies or clinical trials), with either positive (n=4) [189–192] or negative (n=5) results [193–196], but no definitive conclusions can currently be drawn because of major biases in all of the studies [197]. Several RCTs are also ongoing to evaluate these drugs in the context of COVID-19 (n=32 registered with www.clinicaltrials.gov; n=16 with the Chinese clinical trial registry).

In conclusion, it is noteworthy that several national guidelines already include chloroquine or hydroxychloroquine whereas the IDSA recommends reserving its use (in combination with azithromycin or not) for clinical trials.

4.5.3. JAK inhibitors and colchicine

Other drugs are currently being investigated, such as the JAK inhibitors (i.e. tofacitinib, NCT04332042; baricitinib, NCT04321993, NCT04345289, NCT04320277, NCT04346147, NCT04340232; ruxolitinib, NCT04348695, NCT04331665, NCT04337359, NCT04338958, NCT04334044, NCT04348071) or colchicine. The JAK/STAT pathway lies downstream of several cytokines which are increased in HLH and thus it is an attractive target to abrogate the signaling of multiple cytokine pathways [198]. However, caution should be applied in using JAK inhibitors because: (i) COVID-19 can be complicated by coagulopathy with increased frequency of thromboembolic events, and the FDA has recently warned clinicians about increased thromboembolism risk with some JAK inhibitors [199]; ii) treatment with JAK inhibitors is associated with increased frequency of herpes zoster virus reactivation; and (iii) pan-JAK inhibitors may repress some cytokines required for antiviral defense (type-I IFN) or for immune restoration (IL-2, IL-7) [200,201].

Colchicine is a long-established drug with anti-inflammatory properties used to treat patients with Behçet's disease or familial Mediterranean fever. Colchicine inhibits IL-1β and its subsequent inflammatory cascade principally by blocking pyrin and (to a lesser extent) NLRP3 inflammasome activation. Until now, there has been no data indicating that pyrin is activated upon SARS-CoV-2 infection and this would appear rather unlikely. On the other hand, NLRP3 is likely to be activated following virus entry into the cell [38–40,65,130]. Nevertheless, the inhibition of NLRP3 inflammasome by colchicine has not been firmly demonstrated since *in vitro* it does not prevent IL-1β secretion induced by typical NLRP3 stimuli (i.e. ATP, nigericin) [202]. Five RCTs are currently under way to test the efficacy of colchicine in COVID-19 patients (NCT04322682, NCT04322565, NCT04328480, NCT04326790, NCT04350320).

5. Conclusion

The rapid diffusion of COVID-19 drives an urgent search for effective treatments, mainly for its severe forms. The disease is polyphasic in nature, with secondary cytokine storm and ARDS resulting in poor outcomes, plus overwhelmed intensive care units and hospitals. In the very early stages of the disease, treatment should focus on reducing viral load either by specific antivirals or by stimulating type-I IFN. Later on, in selected patients, therapies targeting proinflammatory cytokines could suppress hyperinflammation, while some cytokines (IL-7) could theoretically trigger immune restoration. In clinical practice, unfortunately, patients are unlikely to be detected early enough (i.e. before/at symptom onset) to benefit from antiviral strategies. Therefore, factors to predict progression toward severe forms of the disease are, at present, the most urgently needed and awaited determinants. A highly-structured approach, which includes immune monitoring, would thus be of utmost importance.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Location: zoom (see below)

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Fri 5/8/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 5/8/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Meeting: NAM-APHA COVID-19 Webinar Series
Time: May 8, 2020 02:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/526660780

Or iPhone one-tap :
US: +13126266799,,526660780# or +14702509358,,526660780#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 312 626 6799 or +1 470 250 9358 or +1 646 518 9805 or +1 646 558 8656 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 301 715 8592 or +1 602 753 0140 or +1 651 372 8299 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 526 660 780
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

Would you like to test your Zoom connection? Please click on the link below.
https://nasem.zoom.us/test

To: 'David A Relman'[relman@stanford.edu]; Baric, Ralph S[rbaric@email.unc.edu]; 'Saif, Linda'[saif.2@osu.edu]; 'Perlman, Stanley'[stanley-perlman@uiowa.edu]; 'Peter Daszak'[daszak@ecohealthalliance.org]; 'Harvey V. Fineberg'[harvey.fineberg@moore.org]; 'Diane Griffin'[dgriffi6@jhmi.edu]; 'Peggy Hamburg'[peggy@hbfam.net]; 'jwleduc@UTMB.EDU'[jwleduc@UTMB.EDU]; 'Dave Franz (davidrfranz@gmail.com)'[davidrfranz@gmail.com]; 'Shi, Pei yong (peshi@UTMB.EDU)'[peshi@UTMB.EDU]; Dzau, Victor J.[VDzau@nas.edu]
Cc: 'Frances Sharples'[fsharples_3@hotmail.com]; Lowenthal, Micah[mlowenth@nas.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'Alison Andre'[andre@ecohealthalliance.org]; 'Jennifer Ryan'[jennifer.ryan@moore.org]; Bowman, Katherine[KBowman@nas.edu]; Hare, Hope[HHare@nas.edu]; Kanarek, Morgan[MKanarek@nas.edu]; Clark, David[DClark@nas.edu]
From: Rusek, Benjamin[BRusek@nas.edu]
Sent: Tue 5/12/2020 4:10:07 PM (UTC-04:00)
Subject: RE: Virtual U.S. China dialogue meeting on COVID-19: Zoom link for Wednesday May 13 call 9pm et
Topics for future collaborations between the NAS and CAS on COVID-draft 1.docx

Greetings,

Thank you for participating in and asking thoughtful questions during the Zoom call last night. Thanks especially to Diane Griffin for outstanding moderating, to Harvey Fineberg for giving a clear and concise overview of the U.S. situation and to Jim Le Duc for drafting a list (see attachment) of possible future areas of collaboration that came up during the discussion.

Although Zoom seemed to work well for most of the participants I asked CAS staff to help the group move on quickly if a Chinese speaker's audio is malfunctioning. I let CAS know that during the next session we want to start discussing the agenda / remaining list of questions right away. I reiterated that we find a discussion format to be the most useful and asked that they send any slide presentations to me in advance of the call (so I can send them to you). I also asked CAS for copies of the PPT slides that were shared with the group last night. Please let me know if you have any thoughts on how to make the Zoom session tomorrow night more productive.

Here is the Zoom link for the next session
Meeting Time: **Wednesday, May 13, 2020 9:00 -11:00 PM (ET)**
Meeting link: https://nasem.zoom.us/j/98730322332?pwd=d2RpdUlYVVZpT1pTZ1dHVFdKL1QyQT09
Meeting ID: 987 3032 2332
Meeting Password: 569674

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, May 11, 2020 6:13 PM
To: 'David A Relman' <relman@stanford.edu>; 'Baric, Ralph S' <rbaric@email.unc.edu>; 'Saif, Linda' <saif.2@osu.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; 'Peter Daszak' <daszak@ecohealthalliance.org>; 'Harvey V. Fineberg' <harvey.fineberg@moore.org>; 'Diane Griffin' <dgriffi6@jhmi.edu>; 'Peggy Hamburg' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>; 'Shi, Pei yong (peshi@UTMB.EDU)' <peshi@UTMB.EDU>; Dzau, Victor J. <VDzau@nas.edu>
Cc: 'Frances Sharples' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; ''Baric, Toni C' (antoinette_baric@med.unc.edu)' <antoinette_baric@med.unc.edu>; 'Alison Andre' <andre@ecohealthalliance.org>; 'Jennifer Ryan' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>; Hare, Hope <HHare@nas.edu>; Kanarek, Morgan <MKanarek@nas.edu>; Clark, David <DClark@nas.edu>
Subject: Virtual U.S. China dialogue meeting on COVID-19: final docs, Zoom link (and back up phone number)
Importance: High

Greetings,

I have attached all the documents that you need for **the first U.S. China dialogue Zoom call tonight [Monday, May 11 from 9:00 PM – 11:00 PM (ET)]** so you have them all in one place. They are 1) the slightly updated Chinese participant list (availability is Beijing time) 2) the American participant list and 3) the American version of the agenda. Please remember that because we want the Chinese participants to lead the discussion their version of the agenda does not include your names after the questions.

At the beginning of the call Diane Griffin will ask each person to introduce themselves briefly (just say your name and affiliations). **Please do this in the order that you appear on the American participant list. (**FYI Peter Daszak and Victor Dzau will join the call later.) George Gao and then Harvey Fineberg will give the brief overviews and then we will discuss the Day 1 questions. Re this discussion, please try and prompt the Chinese participants to answer and address the questions and issues on the agenda, we will also need to mind the time closely if we are going to get through the entire Day 1 question list.

The Zoom link is here again:
Time: Monday, May 11, 2020 9:00 PM (ET)
Meeting Link: https://nasem.zoom.us/j/94861525373?pwd=RG9LNTRRRjQrY3ZqTy9SclR5K05SQT09
(Password: 613725, Meeting ID: 948 6152 5373, but you should not need it, it's in the link)

Re logistics, CAS agreed to allow us to use the Zoom record feature to produce a transcript of the call. I will have host access to Zoom and there will be an NAS IT professional (David Clark) in the Zoom call in case there is a problem. If for some reason we need to abandon the Zoom call and reconvene over the phone we have set up an alternative conference call in line (with Conference America). That number is 1-888-537-7715 (and then enter 12223052#), CAS will also be able to access the line via a toll free Chinese phone number. We will only activate this line if we decide to abandon the Zoom call.

If you have any final questions or concerns please feel free to email or call me (at the number below) before the meeting. Thank you again for agreeing to participate in the virtual dialogue, I looks forward to seeing and hearing you all later this evening.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, May 11, 2020 12:06 AM
To: 'David A Relman' <relman@stanford.edu>; 'Baric, Ralph S' <rbaric@email.unc.edu>; 'Saif, Linda' <saif.2@osu.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; 'Peter Daszak' <daszak@ecohealthalliance.org>; 'Harvey V. Fineberg' <harvey.fineberg@moore.org>; 'Diane Griffin' <dgriffi6@jhmi.edu>; 'Peggy Hamburg' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>; 'Shi, Pei yong (peshi@UTMB.EDU)' <peshi@UTMB.EDU>
Cc: 'Frances Sharples' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; ''Baric, Toni C' (antoinette_baric@med.unc.edu)' <antoinette_baric@med.unc.edu>; 'Alison Andre' <andre@ecohealthalliance.org>; 'Jennifer Ryan' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>; Hare, Hope <HHare@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting on COVID-19: ZOOM link for first call

And here is the Zoom link for the call on Monday night.

Time: Monday, May 11, 2020 9:00 PM (ET)
Meeting Link: https://nasem.zoom.us/j/94861525373?pwd=RG9LNTRRRjQrY3ZqTy9SclR5K05SQT09
Password: 613725

PS I tested Zoom with CAS and many of the Chinese group members earlier tonight, the video was clear and I could hear everyone well. Hopefully it will work well when we are all connected.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Sunday, May 10, 2020 12:15 PM
To: 'David A Relman' <relman@stanford.edu>; 'Baric, Ralph S' <rbaric@email.unc.edu>; 'Saif, Linda' <saif.2@osu.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; 'Peter Daszak' <daszak@ecohealthalliance.org>; 'Harvey V. Fineberg' <harvey.fineberg@moore.org>; 'Diane Griffin' <dgriffi6@jhmi.edu>; 'Peggy Hamburg' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>; 'Shi, Pei yong (peshi@UTMB.EDU)' <peshi@UTMB.EDU>
Cc: 'Frances Sharples' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; ''Baric, Toni C' (antoinette_baric@med.unc.edu)' <antoinette_baric@med.unc.edu>; 'Alison Andre' <andre@ecohealthalliance.org>; 'Jennifer Ryan' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting on COVID-19: planning discussion on May 7
Importance: High

The list of Chinese participants is attached.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Saturday, May 9, 2020 11:24 PM
To: 'David A Relman' <relman@stanford.edu>; 'Baric, Ralph S' <rbaric@email.unc.edu>; 'Saif, Linda' <saif.2@osu.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; 'Peter Daszak' <daszak@ecohealthalliance.org>; 'Harvey V. Fineberg' <harvey.fineberg@moore.org>; 'Diane Griffin' <dgriffi6@jhmi.edu>; 'Peggy Hamburg' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>; 'Shi, Pei yong (peshi@UTMB.EDU)' <peshi@UTMB.EDU>
Cc: 'Frances Sharples' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; ''Baric, Toni C' (antoinette_baric@med.unc.edu)' <antoinette_baric@med.unc.edu>; 'Alison Andre' <andre@ecohealthalliance.org>; 'Jennifer Ryan' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting on COVID-19: planning discussion on May 7

Greetings,

We have created a proposed draft agenda (with topics slightly rearranged) that, as we discussed during the call on Thursday, starts with a brief introduction of the situation in China and the U.S. We hope that Harvey Fineberg can give a (very) brief overview of the situation in the U.S.

To ensure that each question is addressed during the discussion, we have listed the names of American delegation member after each question. We have asked and expect the Chinese group to take the lead but we hope that those listed can ensure that each question is covered. (FYI this version is for your information only, we will send an agenda without the names listed after the questions to the Chinese.) Please let me know if you have thoughts or concerns about this plan.

FYI I plan to send a new version of the agenda to CAS and George Gao on Sunday evening (before I test the Zoom connection with CAS at 9:00 PM ET).

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin

Sent: Friday, May 8, 2020 2:31 PM
To: 'David A Relman' <relman@stanford.edu>; 'Baric, Ralph S' <rbaric@email.unc.edu>; 'Saif, Linda' <saif.2@osu.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; 'Peter Daszak' <daszak@ecohealthalliance.org>; 'Harvey V. Fineberg' <harvey.fineberg@moore.org>; 'Diane Griffin' <dgriffi6@jhmi.edu>; 'Peggy Hamburg' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>; 'Shi, Pei yong (peshi@UTMB.EDU)' <peshi@UTMB.EDU>
Cc: 'Frances Sharples' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; ''Baric, Toni C' (antoinette_baric@med.unc.edu)' <antoinette_baric@med.unc.edu>; 'Alison Andre' <andre@ecohealthalliance.org>; 'Jennifer Ryan' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting on COVID-19: planning discussion on May 7
Importance: High

Greetings,

Thanks for joining the call last night. We received good news from CAS this morning. They agreed to hold the two sessions as we requested. However because George Gao is not available on the second day they want to push the second session back by one day. That's not bad because as I noted on the call, Jim Le Duc and Harvey Fineberg were not available at that time anyway.

So for the Americans we will keep the time on Monday, May 11 (from 9-11:00 PM ET) as planned but move the second session back one day to Wednesday, May 13th (from 9-11:00 PM ET). I hope the new time for the second session works for most of you.

In addition they said that the topical agenda (topic list we sent) looks fine and that there would about a dozen Chinese experts (said no more than 13) on the call on their side.

I will send you more info later today.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Thursday, May 7, 2020 4:58 PM
To: 'David A Relman' <relman@stanford.edu>; 'Baric, Ralph S' <rbaric@email.unc.edu>; 'Saif, Linda' <saif.2@osu.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; 'Peter Daszak' <daszak@ecohealthalliance.org>; 'Harvey V. Fineberg' <harvey.fineberg@moore.org>; 'Diane Griffin' <dgriffi6@jhmi.edu>; 'Peggy Hamburg' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>; 'Shi, Pei yong (peshi@UTMB.EDU)' <peshi@UTMB.EDU>
Cc: 'Frances Sharples' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; ''Baric, Toni C' (antoinette_baric@med.unc.edu)' <antoinette_baric@med.unc.edu>; 'Alison Andre' <andre@ecohealthalliance.org>; 'Jennifer Ryan' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting on COVID-19: planning discussion on May 7
Importance: High

Greetings,

Below you will find an agenda for tonight's **(8:00 PM ET)** call. Diane is the U.S. chair so will lead the call (with input from others).

1) Introductions (Diane, Ben, group)
2) The China bio dialogue: brief background, previous meetings and key Chinese participants (Jim, Dave, Diane, Peggy, Pei-yong, Ben, others)
3) Recent work (2020) to set up the virtual dialogue sessions, purpose of the call and issues we should probably avoid (Diane, Ben, others)
4) Discussion topics/questions (see attachment), assign discussion leaders for each question (Diane, others)
5) Call logistics (best way to interact on the Zoom call, recording the sessions, plan between calls, etc.) (Ben, Micah, Diane)

6) Other questions or concerns (group)

I have re attached the “agenda” (list of topics/questions) for the dialogue meetings next week for your information. Also the Zoom call in information is below:

https://nasem.zoom.us/j/93418637725?pwd=OHBnamM1cWs5MUl1TWFiNmlNdGMwQT09
Meeting ID: 934 1863 7725
Password: 662746

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Wednesday, May 6, 2020 5:42 PM
To: 'David A Relman' <relman@stanford.edu>; 'Baric, Ralph S' <rbaric@email.unc.edu>; 'Saif, Linda' <saif.2@osu.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; 'Peter Daszak' <daszak@ecohealthalliance.org>; 'Harvey V. Fineberg' <harvey.fineberg@moore.org>; 'Diane Griffin' <dgriffi6@jhmi.edu>; 'Peggy Hamburg' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>; 'Shi, Pei yong (peshi@UTMB.EDU)' <peshi@UTMB.EDU>
Cc: 'Frances Sharples' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; ''Baric, Toni C' (antoinette_baric@med.unc.edu)' <antoinette_baric@med.unc.edu>; 'Alison Andre' <andre@ecohealthalliance.org>; 'Jennifer Ryan' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting on COVID-19: planning discussion on May 7
Importance: High

Greetings,

Information on how to join the planning call **at 8:00 PM ET, Thursday, May 7 is below:**

Zoom link: https://nasem.zoom.us/j/93418637725?pwd=OHBnamM1cWs5MUl1TWFiNmlNdGMwQT09
Meeting ID: 934 1863 7725
Password: 662746

Please join by Zoom (but the call in phone number is below my email signature if you need it). Thank you again for agreeing to participate in the planned virtual dialogue meeting next week.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Benjamin Rusek is inviting you to a scheduled Zoom meeting.

Topic: Zoom meeting to discuss U.S. China dialogue
Time: May 7, 2020 08:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android:
https://nasem.zoom.us/j/93418637725?pwd=OHBnamM1cWs5MUl1TWFiNmlNdGMwQT09

Password: 662746

Or iPhone one-tap :
US: +16513728299,,93418637725# or +13017158592,,93418637725#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 651 372 8299 or +1 301 715 8592 or +1 312 626 6799 or +1 470 250 9358 or +1 646 518 9805 or +1 646 558 8656 or +1 213 338 8477 or +1 253 215 8782 or +1 602 753 0140 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or 888 475 4499 (Toll Free) or 877 853 5257 (Toll Free)
Meeting ID: 934 1863 7725
Password: 662746
International numbers available: https://nasem.zoom.us/u/a5XnNJEND

Would you like to test your Zoom connection? Please click on the link below.
https://nasem.zoom.us/test

From: Rusek, Benjamin
Sent: Monday, May 4, 2020 6:15 PM
To: 'David A Relman' <relman@stanford.edu>; 'Baric, Ralph S' <rbaric@email.unc.edu>; 'Saif, Linda' <saif.2@osu.edu>; 'Perlman, Stanley' <stanley-perlman@uiowa.edu>; 'Peter Daszak' <daszak@ecohealthalliance.org>; Harvey V. Fineberg <harvey.fineberg@moore.org>; 'Diane Griffin' <dgriffi6@jhmi.edu>; 'Peggy Hamburg' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>; Shi, Pei yong (peshi@UTMB.EDU) <peshi@UTMB.EDU>
Cc: 'Frances Sharples' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; 'Baric, Toni C' (antoinette_baric@med.unc.edu) <antoinette_baric@med.unc.edu>; Alison Andre <andre@ecohealthalliance.org>; Jennifer Ryan <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>
Subject: Virtual U.S. China dialogue meeting on COVID-19: planning discussion on May 7
Importance: High

Greetings,

Thank you for agreeing to participate in a virtual bilateral dialogue meeting between Chinese and American experts studying and fighting the COVID-19 pandemic. I am reaching out to you now so 1) the group is connected by email and 2) to organize the planning teleconference for the American participants on May 7. The purpose of the May 7 discussion is to fill you in on the dialogue background, discuss the topics/questions (list in your invitation letter and attached) and issues we should probably avoid (origin questions, politics), logistics, and address any other questions or concerns you may have.

We are proposing that this ~1 hour discussion take place over Zoom at 8:00 PM ET on Thursday, May 7. If this time does not work for someone we could push the time up or back slightly. Please let me know. Also if Thursday evening is impossible I can brief you on the discussion over the phone sometime on Friday.

Re the actually dialogue meeting with the Chinese group, as your invitation letter notes we have proposed that the dialogue meeting take place on the evenings of Monday, May 11th (to address the first set of bullet points) and Tuesday, May 12th (to ask/answer follow-up questions and address the second set of bullet points), at 9:00 PM ET for the Americans. George Gao has not yet let us know if these exact times work but we should hear back from him soon (the Chinese May day holidays end on the 5th).

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

Topics for future collaborations between the NAS and CAS on COVID-19, Day 1.

1. Natural experiment underway in the USA as states implement various strategies of public health response to address COVID-19 and resume normal activities
2. Clinical Disease—Acute and Convalescence
    a. Early predictors of severe disease/cytokine storm
    b. Long-term sequela seen in survivors
    c. Better understanding/recognition of Pediatric Inflammatory Syndrome of COVID
3. Pathogenesis and Treatment options
    a. Antiviral drug targets and development (not really discussed but important for future dialogue)
    b. Monoclonal antibody therapies (anti-IL-6 monoclonal antibody treatment; “balance” with coagulation dysfunction)
    c. Clinical trial of chloroquine treatment (preliminary results shared)
4. Prophylactics and Preventatives
    a. Passive antibody therapy (raised question but not really discussed)
    b. Vaccine development
        i. Various techniques under development (not discussed)
        ii. Animal models (mentioned but details not shared)
        iii. Clinical testing (not discussed)
        iv. Production capacity (not discussed)
        v. Ethics considerations (not discussed)
    c. Isolation of contacts (Wuhan lock-down)
    d. Educational tools for communications with populations at risk

To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Alvarez, Rosa Maria[rosalvarez@deloitte.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Tue 5/12/2020 5:27:44 PM (UTC-04:00)
Subject: RE: Slides and document from our meeting
DPI CoV-2 ACTIVE slides May 2020_KRB2.pptx

One more file from today. Here are Matt's slides about the Open Science Portal.

Best,
Joe

From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, May 12, 2020 3:44 PM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine <ccolvis@mail.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith <jh18v@nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Liz <ottingerea@mail.nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Cc: Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Slides and document from our meeting

Dear Preclinical Working group,

Thank you for another terrific call. I am attaching the slides we showed that contain the future state strategy slide. Also, I have attached the Request for information/Information for prioritization form. As discussed, please make suggestions and modifications. The questions about "what is the metric?" are to you, please suggest the appropriate metric for that category.

Please try to have your responses to me by COB tomorrow and we will be able to review on Friday.

Sincerely,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
301 594-6596 | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852


FNIH PANDEMIC
RESPONSE FUND

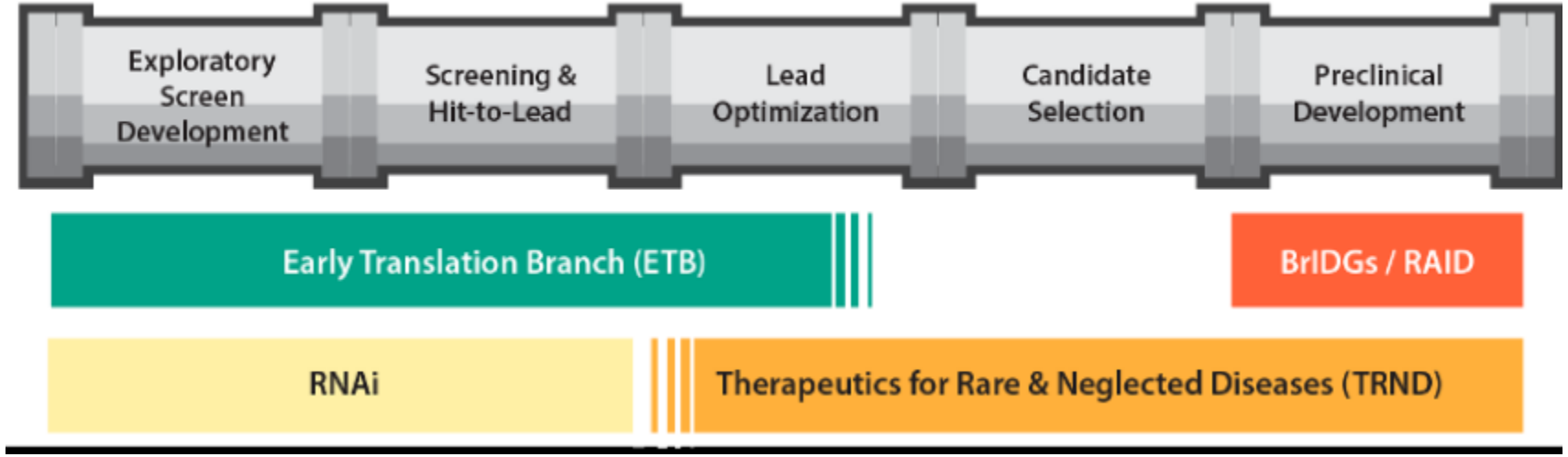
The NCATS Division of Preclinical Innovation COVID-19 Response & Open Science Data Portal

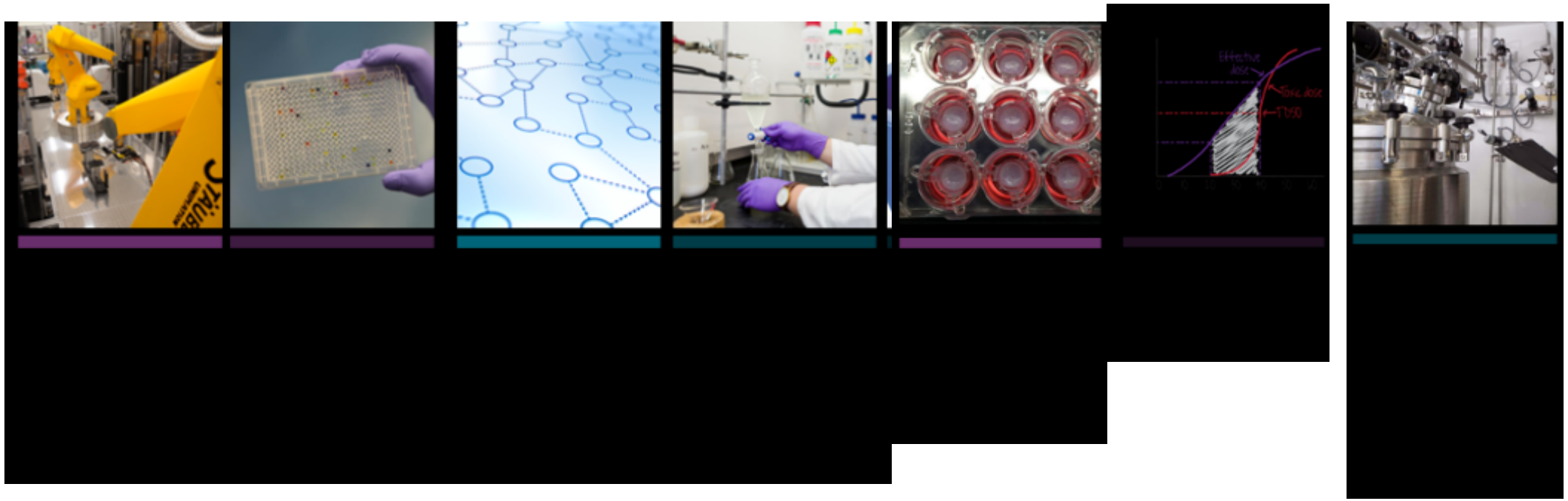
Matthew D. Hall, Ph.D.
Acting Branch Chief
Early Translation Branch

On behalf of:
The DPI COVID Team, including
Kyle Brimacombe
Tongan Zhao
Min Shen
Richard Eastman
Xin Hu
Don Lo (Director, Therapeutics Development Branch)
Ewy Mathe (Director, Preclinical Informatics)
Anton Simeonov (Scientific Director)

NIH ACTIV meeting
12th May 2020

NCATS: An integrated pipeline for discovery

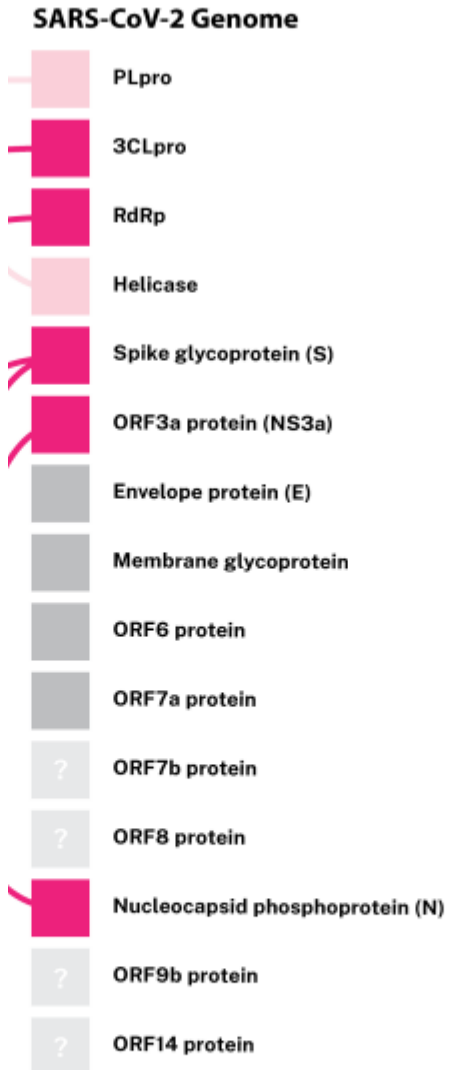


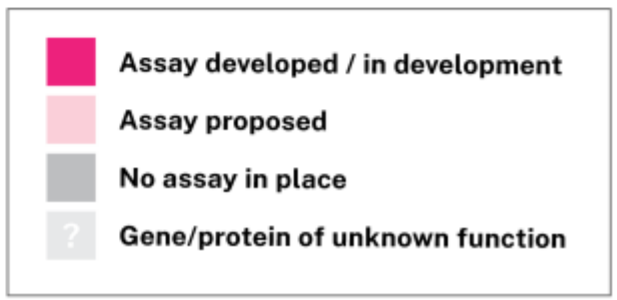


Slide 2 Notes

We are made up of a different groups that create an integrated pipeline allowing for multiple project entry point ranging from target validation through preclinical studies.
We offer a very rich environment merging automation with biology, chemistry, and informatics

SARS-CoV-2 genome





SARS-CoV-2 genome + NCATS assay coverage

Problem

SARS-CoV-2 drug repurposing data is being generated by numerous labs in parallel, but the data and assay protocols are siloed and inaccessible to the scientific community, **severely limiting the impact of this data and delaying translation to the clinic**

SARS-CoV-2 Open Science Data Portal

Vision

We’re creating an open portal for NCATS-validated assays and drug repurposing data across the breadth of CoV-2 biology, **so that the scientific community can immediately access it to inform their own CoV-2 therapeutic hypotheses, and prioritize new research directions**

SARS-CoV-2 Open Science Data Portal

NCATS is generating a collection of datasets by screening a panel of SARS-CoV-2-related assays against all approved drugs

These datasets, as well as the assay protocols used to generate them, are being made immediately available to the scientific community on this site as these screens are completed

New dataset added! Spike-ACE2 protein-protein interaction (AlphaLISA)
05.07.2020

Screening data for the **Spike-ACE2 protein-protein interaction assay** has been processed and uploaded – access it here. This assay measures the ability of compounds to disrupt binding between the SARS-CoV-2 Spike protein and human ACE2 receptor. This interaction is required for SARS-CoV-2 binding to host cells, so compounds which interfere may inhibit entry of the virus.

NIH National Center for Advancing Translational Sciences

SARS-CoV-2 Open Science Data Portal

SARS-CoV-2 Assays

The assays below have been developed to cover a wide spectrum of the SARS-CoV-2 life cycle, including both viral and human (host) targets. This list will be updated continuously as more assays are developed and screened, and all protocols and screening datasets will be made freely available below.

Assay Name	Assay Type	Target Category	Detection Type	Cell Line	Status	Data
Spike-ACE2 protein-protein interaction (AlphaLISA)	Proximity	Viral Entry	Fluorescence		Screening complete	
Spike-ACE2 protein-protein interaction (TruHit Counterscreen)	Proximity	Viral Entry	Fluorescence		Screening complete	
Spike-ACE2 protein-protein interaction (QD)	Proximity	Viral Entry	Fluorescence		In development	
Spike-ACE2 binding	Biophysical	Viral Entry	Label-free		Development complete	
ACE2 binding	Biophysical	Viral Entry	Label-free		Development complete	
ACE2 enzymatic activity	Biochemical	Viral Entry	Fluorescence		In development	

Spike-ACE2 protein-protein interaction (AlphaLISA)

Screening complete

Background Screening Data

Target Category	Viral Entry
Target	Human ACE2 receptor protein
Assay Type	Proximity
Cell Line	N/A
Detection Type	Fluorescence
Date Screened	2020-05-05
Throughput	1536-well
Status	Screening complete

DOWNLOAD ASSAY PROTOCOL

EXPORT SCREENING DATA

Assay Overview

Surface ACE2 receptor protein has been shown to be the primary host factor recognized and targeted by SARS-CoV-2 virions. This binding event between SARS-CoV-2 Spike protein and host ACE2 initiates binding of the viral capsid and eventually leads to viral entry in host cells.

The primary function of ACE2 is to act as a counter-balance to ACE, which cleaves angiotensin I hormone into the vasoconstricting angiotensin II. ACE2 in turn cleaves the carboxyl-terminal amino acid phenylalanine from angiotensin II and hydrolyzes it into the vasodilator angiotensin.

Though disruption of this Spike:ACE2 interaction may inhibit SARS-CoV-2 entry, off-target effects on endogenous ACE2 function could result in disruption of critical vasodilation pathways. This ACE2 enzymatic assay serves to measure inhibition of human ACE2 to identify compounds with the potential to disrupt endogenous enzyme function

Slide 9 Notes

Category for broad MOA, and source
Test data set: CALIBR - test set with active data

U.S. Department of Health and Human Services › National Institutes of Health › National Center for Advancing Translational Sciences

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SARS-CoV-2 Open Science Data Portal

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MOA, sample name, drug name or gene

Drug Information		Viral Entry				Viral replication		In vitro infectivity		Live virus infectivity			
Drug Name △▽	Primary MOA △▽	Biophysical (SPR) Spike:ACE2 binding	Biophysical (MST) Spike:ACE2 binding	Enzymatic assay ACE2 inhibition	Cell-based assay ACE2 internalization	Enzymatic assay CL3 Protease inhibition	Enzymatic assay RdRp inhibition	Cell-based assay CoV-2 Pseudovirus	Cell-based assay CoV-2 VLP Entry	Live virus assay CoV-2 Cytopathic Effect #1 (CPE)	Live virus assay CoV-2 Vero Tox Counter #1	Live virus assay CoV-2 Cytopathic Effect #1 (CPE)	Live virus assay CoV-2 Cytopathic Effect #2 (CPE)
Malachite green oxalate													
trans-Aconitic acid	Cytoplasmic aconitate hydratas...												
Geraniol	Trichomonas vaginalis Inhibito...												
Phenol red	amyloid fibril formation Inhib...												
Aminoquinuride dihydrochloride													
Trifluoperazine hydrochloride	CaMK-II Inhibitor												
Pyridoxamine dihydrochloride	reactive oxygen species metabo...												
Carzenide													

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SARS-CoV-2 Open Science Data Portal

Chloroquine

Drug Information		Viral Entry				Viral replication		In vitro infectivity		Live virus infectivity			
Drug Name △▽	Primary MOA △▽	Biophysical (SPR) Spike:ACE2 binding	Biophysical (MST) Spike:ACE2 binding	Enzymatic assay ACE2 inhibition	Cell-based assay ACE2 internalization	Enzymatic assay CL3 Protease inhibition	Enzymatic assay RdRp inhibition	Cell-based assay CoV-2 Pseudovirus	Cell-based assay CoV-2 VLP Entry	Live virus assay CoV-2 Cytopathic Effect #1 (CPE)	Live virus assay CoV-2 Vero Tox Counter #1	Live virus assay CoV-2 Cytopathic Effect #1 (CPE)	Live virus assay CoV-2 Cytopathic Effect #2 (CPE)
Chloroquine	antimalarial agents												
Chloroquine	antimalarial agents												
Hydroxychloroquine sulfate	Autophagy Inhibitor												
Hydroxychloroquine sulfate	Autophagy Inhibitor												

<< browse data

SARS-CoV-2 Open Science Data Portal

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Sample ID : NCGC00015256-13

Sample Name : Chloroquine

Assay Name : pcdr-MG636TG-NPC-MIPE4.0-cellviability

AC50 : 11.7703820755

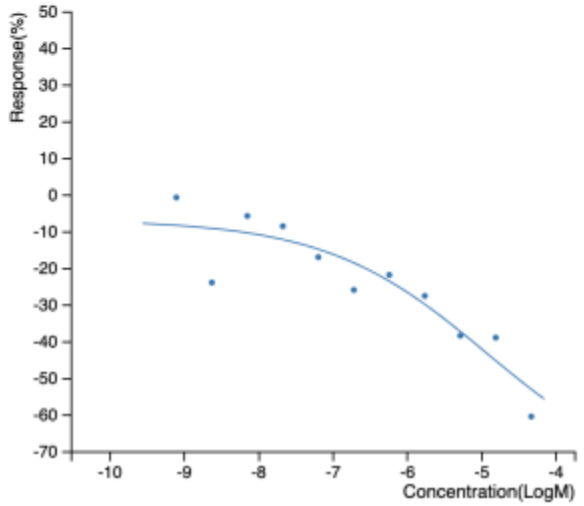
CurveClass2: -2.2

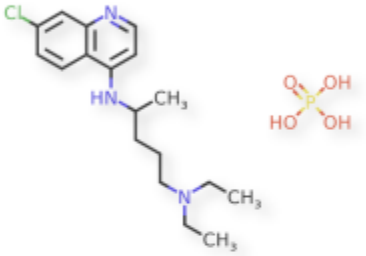
Efficacy : -72.968739387

Primary MOA : antimalarial agents

SMILES : CCN(CC)CCCC(C)NC1=CC=NC2=C1C=CC(=C2)Cl

Curve:





Slide 12 Notes

INXIGHT linkout

NIH National Center for Advancing Translational Sciences

SARS-CoV-2 Open Science Data Portal

HDAC

Drug Information		Viral Entry				Viral replication		In vitro infectivity		Live virus infectivity			
Drug Name △▽	Primary MOA △▽	Biophysical (SPR) Spike:ACE2 binding	Biophysical (MST) Spike:ACE2 binding	Enzymatic assay ACE2 inhibition	Cell-based assay ACE2 internalization	Enzymatic assay CL3 Protease inhibition	Enzymatic assay RdRp inhibition	Cell-based assay CoV-2 Pseudovirus	Cell-based assay CoV-2 VLP Entry	Live virus assay CoV-2 Cytopathic Effect #1 (CPE)	Live virus assay CoV-2 Vero Tox Counter #1	Live virus assay CoV-2 Cytopathic Effect #1 (CPE)	Live virus assay CoV-2 Cytopathic Effect #2 (CPE)
Droxinostat	HDAC Inhibitor												
Trichostatin A	HDAC Inhibitor												
Entinostat	HDAC Inhibitor												
Vorinostat (SAHA)	HDAC Inhibitor												
Vorinostat (SAHA)	HDAC Inhibitor												
ISOX	HDAC Inhibitor												
Panobinostat	HDAC Inhibitor												
Pracinostat	HDAC Inhibitor												

1. A Large-scale Drug Reposit
Journal: BioRxiv (4/17/2020)
Author(s): LauraRiva et al. (Sanfo
Compound library: LOPAC (1280)
Assay: SARS-CoV-2 infection cell-
dataset1 dataset2

2. In vitro screening of a FDA ... oV-2 replication
Journal: BioRxiv (4/5/2020)
Author(s): Franck Touret et al. (U
Compound library: Prestwick drug
Assay: SARS-CoV-2 infection cell-
dataset

3. Identification of inhibitors ... ing a large scale drug repurposing collection
Journal: Research Square (4/20/2020)
Author(s): Sandra Ciesek et al. (Fraunhofer Institute, German)
Compound library: Drug collection (5632)
Assay: SARS-CoV-2 infection cell-based assay (human epithelial Caco-2 cell)

Contact Us

Your Full Name:

Your E-mail:

Subject:

Message:

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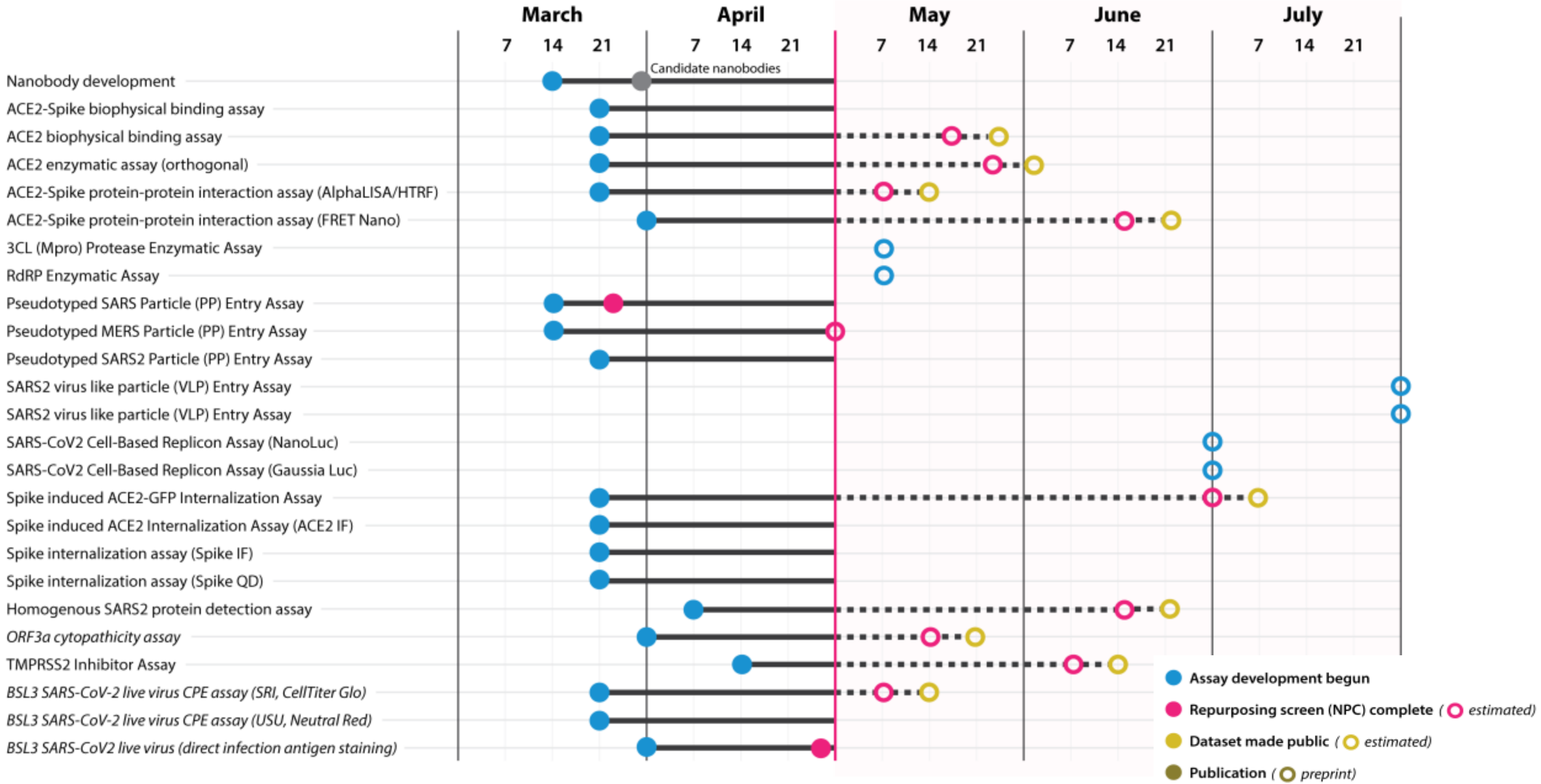
SEND

CANCEL

NCATS SARS-CoV-2 assays and repurposing work



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Cc: William Dowling[william.dowling@cepi.net]; Mark Page[Mark.Page@nibsc.org]
From: GSELL, Pierre[gsellp@who.int]
Sent: Wed 5/13/2020 6:14:52 AM (UTC-04:00)
Subject: [COVID-19] 12th Assay call - today's agenda -

Dear All,

Please find below today's agenda –

1. Miao XU, Deputy Director, Institute for Biological Products Control, National Institutes for Food and Drug Control(NIFDC) – Establishment and Validation of a pseudovirus neutralization assay and development of national antibody standard
2. Kathy Rowlen, CEO&CSO, InDevR, Establishment and Validation of a Multiplex CoV serology assay

3. And other Updates and general discussion

Thanks for your continuous support all.
Kind regards
Pierre-Stéphane Gsell
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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 5/14/2020 7:05:26 AM (UTC-04:00)
Subject: Agenda and Webex Invite-WHO ad hoc group on Animal Models
Mail Attachment.ics
Webex_Meeting.ics

Dear colleagues,
Please find below the agenda for today's call, which as usual will take place at 3PM CET (Geneva). A webex link to dial in is also at the end of this email.

Very best

César, Simon and Bill.

WHO ad hoc group on COVID-19 Animal Models

Agenda May 14 2020

Reminder: Laboratory Landscape Questionnaire/Manuscript

HCQ paper (Simon Funnell)

Vaccines/Immunization

(1) BIDMC-Bioqual (Dan Barouch)

(2) RML (Vincent Munster)

(3)Scripps (Thomas Rogers)

(4) PHE (Miles Carroll)

Pathogenesis

(1) Tulane (Chad Roy)

State of the art: Animal Models for COVID-19

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 923 191 539
Meeting password: 7PmvJ2npig6

Thursday, May 14, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)

41445750282 SWITZERLAND Toll

+1-415-655-0003 US Toll

Global call-in numbers

Join from a video system or application

Dial 923191539@who.webex.com

You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 923191539.who@lync.webex.com

Need help? Go to http://help.webex.com

Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] Animal Models - WHO Expert Group - 12th TC
Location: https://who.webex.com/who/j.php?MTID=me061dd17a1950c473605e88ea0b15dab
Start Time: 2020-05-14T15:00:00+02:00
End Time: 2020-05-14T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

Meeting number (access code): 923 191 539
Meeting password:7PmvJ2npig6

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] Animal Models - WHO Expert Group - 12th TC
Location: https://who.webex.com/who/j.php?MTID=me061dd17a1950c473605e88ea0b15dab
Start Time: 2020-05-14T15:00:00+02:00
End Time: 2020-05-14T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

Meeting number (access code): 923 191 539
Meeting password:7PmvJ2npig6

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To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Kirby, Donna[donna.kirby@pfizer.com]; Lombardo, John[John.Lombardo@sanofi.com]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Moore, Debra[debra.l.moore@gsk.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Fri 5/15/2020 8:11:46 AM (UTC-04:00)
Subject: Survey for new time for Preclinical group meeting

Dear Team,

We need to move our normally scheduled Tuesday Meeting to Wednesday. It would be better to have this meeting in the late morning and before 3pm for those on other time zones. I will try to get everyone, but with schedules as the are, I will do my best. Please indicate your availability in the grid below.

Thank you for all of your help AND your flexibility as we try to find a time to meet that suits the majority of the group.

Times are for Wednesdays for the next month or two.

Start Time	End time	Available?
10:00 AM	11:00 AM	
10:30 AM	11:30 AM	
11:00 AM	12:00 PM	
11:30 AM	12:30 PM	
12:00 PM	1:00 PM	
12:30 PM	1:30 PM	
1:00 PM	2:00 PM	
1:30 PM	2:30 PM	
2:00 PM	3:00 PM	
2:30 PM	3:30 PM	
3:00 PM	4:00 PM	

Best regards,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships

Foundation for the National Institutes of Health
301 594-6596 | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Sat 5/16/2020 11:19:31 AM (UTC-04:00)
Subject: FW: Questionnaire -

Dear WG,

Please see the links below forwarded from Hilary Marston (NIAID). As she suggests, distribute as you see appropriate.

Joe

From: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Sent: Friday, May 15, 2020 3:54 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Steven T. Smith <smithst1@state.gov>
Subject: FW: Questionnaire -

David -

A number of staff at NIAID received these requests for information from WHO. While we are trying to be response to WHO in an effort to continue technical engagement, we also understand that much of this information is already being collected under other initiatives, including ACTIV.

The first survey is related to expressing interest in the WHO Solidarity vaccine trial. We've already informed WHO that we cannot propose clinical sites for their vaccine trial, as our sites are autonomous and will need to determine which trials that they will participate in (though NIAID funding will go to support our trials, and likely would not be available for Solidarity site support).

The second survey is requesting information on laboratory animal capacity. We think this may be information that NIH could share. I am of course aware that ACTIV the preclinical WG has collected similar information. Given this, would it be more efficient to direct that portion to FNIH for response?

Many thanks for considering,

Hilary

From: "GSELL, Pierre" <gsellp@who.int>
Date: Sunday, May 10, 2020 at 5:21 AM
Subject: Questionnaire -

Dear all,

We are pleased to invite you to answer to the 2 following call for interests -

- Call for interest in engagement of vaccine trial sites in evaluation of COVID19 vaccines in adaptive multi-country global

Solidarity Vaccine Trial - https://www.who.int/news-room/articles-detail/call-for-interest-in-engagement-of-vaccine-trial-sites-in-evaluation-of-covid19-vaccines-in-adaptive-multi-country-global-solidarity-vaccine-trial
Access to survey - https://enketo.lshtm.ac.uk/::5qVzS2ez

- Mapping animal lab capacity to accelerate COVID-19 vaccine and therapeutic development

Access to survey - https://enketo.lshtm.ac.uk/::SVcm9oTW

Please disseminate the links extensively.
Kind regards.

Pierre on behalf of the R&D Blueprint team.

From: GSELL, Pierre
Sent: 26 March 2020 10:44
Subject: RE: COVID-19 – GCM/SAG TC - Thursday 26 March - 12pm Geneva time

KIND REMINDER, call in about 1 hour + attaching global call codes

Dear all,

We are pleased to invite you to a follow-up 1 hour TC on COVID-19 research activities.

Agenda items:

- Update on the progress in the Forum Research and Innovation thematic areas (WHO focal points and/or chairs)
- Update on research activities from partners

Dial-in details:
Thursday 26 March – 12pm Geneva time
+41.58.26.20722 / Participant code: 998624

Kind regards
Pierre on behalf of Blueprint team

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical working group (Tuesday meeting)

Start Time: Wed 4/22/2020 10:00:00 AM (UTC-04:00)

End Time: Wed 4/22/2020 11:00:00 AM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

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+1 346 248 7799 US (Houston)
Meeting ID: 960 4240 3854
Password: 124630

Find your local number: https://fnih.zoom.us/u/aemFGSQrl

To: Hare, Hope[HHare@nas.edu]; 'relman@stanford.edu'[relman@stanford.edu]; Baric, Ralph S[rbaric@email.unc.edu]; 'saif.2@osu.edu'[saif.2@osu.edu]; 'stanley-perlman@uiowa.edu'[stanley-perlman@uiowa.edu]; 'daszak@ecohealthalliance.org'[daszak@ecohealthalliance.org]; 'harvey.fineberg@moore.org'[harvey.fineberg@moore.org]; 'dgriffi6@jhmi.edu'[dgriffi6@jhmi.edu]; 'peggy@hbfam.net'[peggy@hbfam.net]; 'jwleduc@UTMB.EDU'[jwleduc@UTMB.EDU]; 'davidrfranz@gmail.com'[davidrfranz@gmail.com]; 'peshi@UTMB.EDU'[peshi@UTMB.EDU]; Dzau, Victor J.[VDzau@nas.edu]; 'fsharples_3@hotmail.com'[fsharples_3@hotmail.com]; Lowenthal, Micah[mlowenth@nas.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'andre@ecohealthalliance.org'[andre@ecohealthalliance.org]; 'jennifer.ryan@moore.org'[jennifer.ryan@moore.org]; Bowman, Katherine[KBowman@nas.edu]; Kanarek, Morgan[MKanarek@nas.edu]; 'Raymond JEANLOZ'[jeanloz@berkeley.edu]
From: Rusek, Benjamin[BRusek@nas.edu]
Sent: Mon 5/18/2020 10:18:02 AM (UTC-04:00)
Subject: RE: Follow up Meeting to Discuss Results of the Virtual U.S. China dialogue meeting on COVID-19
Draft Covid-19 US-China dialogue agenda v4.docx
Topics for future collaborations between the NAS and CAS on COVID-draft 1 Day 1 and 2.docx

Greetings,

Thought it would be helpful to send you a basic outline for the follow up call (**at 11:30 ET today**).

1) Intro
2) Comments on the Day 1 and Day 2 discussion
3) Ideas for topics (and additional American experts) for future virtual dialogue sessions
4) Discussion of George Gao's joint statement idea
5) CAS idea to post a blurb about the meetings on the CAS website
6) Other issues, concerns

I have attached the dialogue agenda (American version) for reference along with Jim's summaries of future collaboration ideas from the sessions.

I know a few people can't make it but I would be happy to follow up with you individually over the phone or email.

I look forward to talking to the group soon.
Zoom link: https://nasem.zoom.us/j/99353621870?pwd=cDM4WVE3YzFESDF4WGtKY0llVkFuZz09

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Hare, Hope <HHare@nas.edu>
Sent: Friday, May 15, 2020 4:26 PM
To: 'relman@stanford.edu' <relman@stanford.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'saif.2@osu.edu' <saif.2@osu.edu>; 'stanley-perlman@uiowa.edu' <stanley-perlman@uiowa.edu>; 'daszak@ecohealthalliance.org' <daszak@ecohealthalliance.org>; 'harvey.fineberg@moore.org' <harvey.fineberg@moore.org>; 'dgriffi6@jhmi.edu' <dgriffi6@jhmi.edu>; 'peggy@hbfam.net' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'davidrfranz@gmail.com' <davidrfranz@gmail.com>; 'peshi@UTMB.EDU' <peshi@UTMB.EDU>; Dzau, Victor J. <VDzau@nas.edu>; 'fsharples_3@hotmail.com' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'jennifer.ryan@moore.org' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>; Kanarek, Morgan <MKanarek@nas.edu>; 'Raymond JEANLOZ' <jeanloz@berkeley.edu>
Cc: Rusek, Benjamin <BRusek@nas.edu>
Subject: RE: Follow up Meeting to Discuss Results of the Virtual U.S. China dialogue meeting on COVID-19

It is very difficult to find a time suitable for all—we apologize, but the one time that seemed to work is Monday, May 18th, at 11:30 AM. We understand that not all of you will be able to participate.
Here is the Zoom link for this meeting: https://nasem.zoom.us/j/99353621870?pwd=cDM4WVE3YzFESDF4WGtKY0llVkFuZz09
We look forward to seeing you on Monday at 11:30 am.

Best wishes,
Hope

From: Hare, Hope
Sent: Thursday, May 14, 2020 3:16 PM
Subject: Follow up Meeting to Discuss Results of the Virtual U.S. China dialogue meeting on COVID-19

Ben has asked me to contact you to schedule a time for the follow up call. We need to do this early next week, as there was not a time that worked well for everyone this week. Please send me your availability for a one hour Zoom meeting between 9AM - 6PM ET, Monday - Wednesday next week.

Thank you and best wishes,

Hope Hare
Administrative Assistant
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW
Washington, DC 20001
Phone: 202-334-3435

Day 1

Introductory remarks and group introductions: **George Gao** and **Diane Griffin**

China situational overview: **George Gao** (5 mins)

U.S. situational overview: **Harvey Fineberg** (5 mins)

Clinical Issues Related to Treatment and Management of Patients

- **Clinical manifestations of COVID-19 disease:** What range of clinical, end-organ, organ, and other body system manifestations of disease has been documented in China? (Relman or Dzau)
- **Influence of Patient Characteristics:** How did patient age, gender, general health condition, or other characteristics influence the efficacy of drugs, NPIs, or best practices? How was this determined? (Relman or Dzau or Perlman)
- **Protection of Medical Personnel**: What measures have proven most effective in preventing infection of medical personnel? (Le Duc)
- **Drug Treatments:** What has been the Chinese experience with developing drug treatments or using existing drugs in treatment of patients, from prophylaxis to pre-symptomatic patients to patients with severe symptoms? (Hamburg)
- **Non-pharmaceutical Interventions**: Were effective non-pharmaceutical interventions (NPIs) for patient care identified? Were there other best practices for management of COVID-19 patients that emerged from the pandemic experience? (Hamburg)
- **Immune plasma:** What is China's experience in using immune plasma or other antibody-based therapies in the treatment of COVID-19 patients or prevention of further spread of disease? (Hamburg)
- **Lessons Learned:** Were other lessons learned from China's pandemic experience that should be applied to future staffing and equipping of hospitals or other patient care facilities? (Dzau or Griffin)
- **Future Collaboration**: What are the most fruitful areas of future scientific collaborations between our countries in this area? (Le Duc)

Day 2

Limiting the Spread of COVID-19 and Steps Toward Restarting Society

- **Incubation period:** Has the incubation period of the virus in humans been determined? What variability may exist and can factors be identified that may influence such variability? (Baric)
- **Viral Load**: What is known about magnitude of viral load required to initiate infection? Has it been determined at what point a patient is most infectious? (Baric)

- **Viral shedding**: What is the degree of shedding among pre-symptomatic/asymptomatic individuals? Do "recovered" patients continue to shed infectious virus? If yes, for how long? Has post-infection viral shedding been demonstrated to result in new infections? Has an explanation regarding pathogenesis leading to apparent recrudescence of disease in previously positive, then negative patients been arrived at? (Shi)
- **Immune response**: How is immune response being measured? Is it via binding assays versus neutralization tests; use of antibody assays in diagnosis of acute disease and as an indicator of protection? Was there standardization of your testing tools? (Saif)
- **Immunity**: After recovery, do patients have immunity? How protective is this immunity? Is there indication of persistence of such immunity? (Saif)
- **Vaccines:** Has the Chinese research community made progress in the development of COVID-19 vaccines? (Perlman or Baric)
- **Exposure routes:** Has progress been made in understanding the routes of exposure to COVID-19—air, water, and surfaces, both indoors and outdoors? (Fineberg)
- **Contact with Animals:** Would increased surveillance of or interventions to reduce contact with pets, wild, or livestock animal species help limit the future spread of COVID-19 or other coronaviruses? (Daszak)
- **Halting Spread:** What measures have proven most effective in halting viral spread in China? (Fineberg)
- **Preventing a Fall Resurgence:** What steps should be taken in anticipation of a fall resurgence in transmission? (Fineberg)
- **Reestablishing Normality:** What lessons has China learned about returning society and the economy to a "normal" state? (Fineberg)
- **Future Collaboration**: What are the most fruitful areas of future scientific collaborations between our countries in this area? (Franz)

Topics for future collaborations between the NAS and CAS on COVID-19, Day 1 (11 May 2020)

1. Natural experiment underway in the USA as states implement various strategies of public health response to address COVID-19 and resume normal activities
2. Clinical Disease—Acute and Convalescence
    a. Early predictors of severe disease/cytokine storm
    b. Long-term sequela seen in survivors
    c. Better understanding/recognition of Pediatric Inflammatory Syndrome of COVID
3. Pathogenesis and Treatment options
    a. Antiviral drug targets and development (not really discussed but important for future dialogue)
    b. Monoclonal antibody therapies (anti-IL-6 monoclonal antibody treatment; “balance” with coagulation dysfunction)
    c. Clinical trial of chloroquine treatment (preliminary results shared)
4. Prophylactics and Preventatives
    a. Passive antibody therapy (raised question but not really discussed)
    b. Vaccine development
        i. Various techniques under development (not discussed)
        ii. Animal models (mentioned but details not shared)
        iii. Clinical testing (not discussed)
        iv. Production capacity (not discussed)
        v. Ethics considerations (not discussed)
    c. Isolation of contacts (Wuhan lock-down)
    d. Educational tools for communications with populations at risk

NASEM-CAS Topics for Future Collaborations on COVID-19, Day 2 (13 May 2020)

1. Viral shedding
    a. Duration of shedding
    b. Does PCR positive result correspond to infectious virus shedding, especially among specimens drawn late in disease or in convalescence?
    c. Role of children in transmission of SARS CoV-2 transmission, especially as we consider reopening schools
2. Immunity
    a. Characterization of the humoral immune response
    b. Characterization of cellular immune response
    c. Durability of neutralizing antibody
    d. Is there reactivation of latent virus or re-infection among survivors?
3. Immunotherapy
    a. Discussion of human monoclonal antibodies for treatment (and prevention?)
    b. Efficacy of immune plasma for the treatment of severely ill patients (not discussed but relevant with clinical trials underway)
4. Vaccines
    a. Various candidate vaccines are in development, some of which are already into human phase 1 or phase 2 clinical trials.
    b. Strategies for accelerated efficacy testing of vaccines
    c. Strategies to detect adverse impact of vaccination on the course of disease

5. Animal models
    a. Small animal models (mice; transgenic mice; others not discusses such as hamsters, ferrets)
    b. Non-human primates
6. Animals as possible novel reservoir hosts for SARS CoV-2 virus in nature
    a. Felines
    b. Mink in Netherlands
7. Virus evolution
    a. Genomic mutations and their possible association with resulting clinical disease and/or transmission characteristics

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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 5/20/2020 11:06:19 AM (UTC-04:00)
Subject: Webex Invite and Agenda-WHO ad hoc expert group on animal models weekly call
Mail Attachment.ics
Webex_Meeting.ics

Dear colleagues,

Please find below the agenda and webex invite for our next call on Thursday 21st at 3PM CET.

There is an open discussion slot at the end of the call this week so please send us an email if you would like to bring forward a specific topic.

Best regards

César, Simon and Bill

Agenda May 21st

1- Update on COVID-19 mouse models

Stephanie Dion (Jackson Laboratories)

Donna Gulezian (Taconic Biosciences)

2- Vaccines

Mark Lewis (Bioqual)

Dan Barouch (BIDMC)

3- Pathogenesis

Garry Nolan (Stanford University)

4- Open discussion

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 921 838 210
Meeting password: yNWpjPKf493

Thursday, May 21, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] Animal Models Expert Group - 13th TC
Location: https://who.webex.com/who/j.php?MTID=mf1dde8640dc8e9f76621c680675e6495
Start Time: 2020-05-21T15:00:00+02:00
End Time: 2020-05-21T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; preziosim@who.int[preziosim@who.int]; woodd@who.int[woodd@who.int]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; Randy Albrecht[randy.albrecht@mssm.edu]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; nnagata@niid.go.jp[nnagata@niid.go.jp]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; Duprex, Paul[pduprex@pitt.edu]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; Gralinski, Lisa E[lgralins@email.unc.edu]; Alyson Kelvin[AKelvin@dal.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Javier Salguero[Javier.Salguero@phe.gov.uk]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Spergel, Jonathan[SPERGEL@email.chop.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 5/27/2020 12:05:07 PM (UTC-04:00)
Subject: Agenda and Webex Invite-WHO Animal Models Call-May 28
Mail Attachment.ics
Webex_Meeting.ics

Dear colleagues,

Please find below the agenda and webex invite for our call tomorrow. As usual it will be at 3PM CET. Also, if there are any open questions for the group that you'd like to send us in advance please do so.

Best regards to all

César, Bill and Simon.

Agenda May28

Pathogenesis

Bioqual: Mark Lewis

Sinai: Michael Shotsaert

Sinai: Claire Liu

Vaccines and therapeutics

Pittsburgh: Dimiter Dimitrov

KU-Leuven: Kai Dallmeier

Enhanced disease

PHE: Miles Carroll (verbal update)

Open questions

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 925 342 789
Meeting password: NYkR2eKh9p5

Thursday, May 28, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)

41445750282 SWITZERLAND Toll

+1-415-655-0003 US Toll

Global call-in numbers

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You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 925342789.who@lync.webex.com

Need help? Go to http://help.webex.com

Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 14th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=mc67d35178dadc450697801f003c75bdd
Start Time: 2020-05-28T15:00:00+02:00
End Time: 2020-05-28T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

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Start Time: 2020-05-28T15:00:00+02:00
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Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Fri 5/29/2020 9:06:00 AM (UTC-04:00)
Subject: FW: REDCap Survey Emails

Dear Preclinical group,

Please see below the link to the current version of the survey portal. Please take a look and reply with any concerns. Otherwise, we would like to get this finalized today, for immediate use.

There are now mandatory fields, so you will not be able to proceed without something in those areas. Right now this is still in test mode, so the input will not be stored.

Best regards,
Joe

Subject: RE: REDCap Survey Emails

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https://redcap.ncats.nih.gov/redcap/surveys/index.php?s=DAE87WPTE7&

Thanks
Ben

To: Young, John[john.young.jy3@roche.com]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Cc: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter Kara[Kara.Carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank /US[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Adam, Stacey (FNIH) [T][sadam@fnih.org]
From: Rao, Srinivas /US[Srinivas.Rao@sanofi.com]
Sent: Fri 5/29/2020 9:54:08 AM (UTC-04:00)
Subject: Re: FW: REDCap Survey Emails

John, following your prompt, I did the same. Impressive
Srini

From: Young, John <john.young.jy3@roche.com>
Sent: Friday, May 29, 2020 9:46 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Cc: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter Kara <Kara.Carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank /US <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas /US <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: [EXTERNAL] Re: FW: REDCap Survey Emails

EXTERNAL : Real sender is john.young.jy3@roche.com

Thanks Joe. I just ran through the entire survey with dummy entries. It is very intuitive and user-friendly. Also the information fields can be filled in very quickly.
In short, it is super and good to go as far as I am concerned.
Best regards
John

On Fri, May 29, 2020 at 3:06 PM Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org> wrote:
Dear Preclinical group,

Please see below the link to the current version of the survey portal. Please take a look and reply with any concerns. Otherwise, we would like to get this finalized today, for immediate use.

There are now mandatory fields, so you will not be able to proceed without something in those areas. Right now this is still in test mode, so the input will not be stored.

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https://redcap.ncats.nih.gov/redcap/surveys/index.php?s=DAE87WPTE7&

Thanks
Ben

--
John A.T. Young, PhD
VP and Global Head Infectious Diseases
Immunology, Infectious Diseases and Ophthalmology (I2O) Discovery and Translational Area
Roche Pharma Research & Early Development

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Mail to: nuran.aktas-ibis@roche.com

To: Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Young, John[john.young.jy3@roche.com]
Cc: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Adam, Stacey (FNIH) [T][sadam@fnih.org]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Fri 5/29/2020 12:05:53 PM (UTC-04:00)
Subject: RE: FW: REDCap Survey Emails

This form is exclusively for therapeutics, there is a different one for models and assays.

From: Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>
Sent: Friday, May 29, 2020 11:11 AM
To: Young, John <john.young.jy3@roche.com>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Cc: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: RE: FW: REDCap Survey Emails

I agree with John, but if you had an interesting assay, and not a drug candidate, you would have put in a lot of dummy info to get to the assay page.

Best,

Marc Charette, Ph.D.
Program Director
Vascular Biology and Hypertension Branch
Division of Cardiovascular Sciences

Director
Vascular Interventions/Innovations and Therapeutic Advances (VITA) Program

NIH National Heart, Lung, and Blood Institute

6705 Rockledge Drive
Rockledge Center One, workspace 313M
Bethesda, MD 20892
301-435-0527
marc.charette@nih.gov

From: Young, John <john.young.jy3@roche.com>
Sent: Friday, May 29, 2020 9:46 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Cc: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Re: FW: REDCap Survey Emails

Thanks Joe. I just ran through the entire survey with dummy entries. It is very intuitive and user-friendly. Also the information fields can be filled in very quickly.
In short, it is super and good to go as far as I am concerned.
Best regards
John

On Fri, May 29, 2020 at 3:06 PM Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org> wrote:

> Dear Preclinical group,
>
> Please see below the link to the current version of the survey portal. Please take a look and reply with any concerns. Otherwise, we would like to get this finalized today, for immediate use.
>
> There are now mandatory fields, so you will not be able to proceed without something in those areas. Right now this is still in test mode, so the input will not be stored.
>
> Best regards,
> Joe
>
> ---
>
> **Subject:** RE: REDCap Survey Emails
>
> Hi All,
>
> The survey is in a place now where we can get feedback from the working groups. Please share the below link with them and ask for any feedback they have. Of note, I need to put together the additional introductory paragraph that summarizes each of the question pages that the respondents need to fill out. I wanted to get this out to everyone for review now and that is a conceptually simple thing that we need to just drop in. Please have anyone send me their comments or edits!
>
> https://redcap.ncats.nih.gov/redcap/surveys/index.php?s=DAE87WPTE7&
>
> Thanks
> Ben

--
John A.T. Young, PhD
VP and Global Head Infectious Diseases
Immunology, Infectious Diseases and Ophthalmology (I2O) Discovery and Translational Area
Roche Pharma Research & Early Development

Roche Innovation Center Basel

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To: 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; jrappaport@tulane.edu[jrappaport@tulane.edu]; john.young.jy3@roche.com[john.young.jy3@roche.com]; david.j.payne@gsk.com[david.j.payne@gsk.com]; 'Hild, Sheri (NIH/OD) [E]'[sheri.hild@nih.gov]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; kara.carter@evotec.com[kara.carter@evotec.com]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Rao, Srinivas'[Srinivas.Rao@sanofi.com]; 'Qashu, Felicia (NIH/OD) [E]'[felicia.qashu@nih.gov]; 'Tomas Cihlar'[Tomas.Cihlar@gilead.com]; 'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)'[margaret.l.pitt.civ@mail.mil]
Cc: 'Gadbois, Ellen (NIH/OD) [E]'[gadboisel@od.nih.gov]; 'Hughes, Eric'[eric.hughes@novartis.com]; 'Gonzalez, Nina'[ningonzalez@deloitte.com]; 'Cutillo, Christine (NIH/NCATS) [E]'[cutilloc@mail.nih.gov]; 'Simon, Dina (NIH/OD) [C]'[dina.simon@nih.gov]; 'Wholley, David (FNIH) [T]'[dwholley@fnih.org]; 'Austin, Christopher (NIH/NCATS) [E]'[austinc@mail.nih.gov]; 'Melencio, Cheryl (FNIH) [T]'[cmelencio@fnih.org]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Desrosiers, Betsy'[elizabeth_desrosiers@merck.com]; 'Jansen, Kathrin'[kathrin.jansen@pfizer.com]; 'Kurilla, Michael (NIH/NCATS) [E]'[michael.kurilla@nih.gov]; 'Lowy, Douglas (NCI)'[dl60z@nih.gov]; 'Read, Sarah (NIH/NIAID) [E]'[readsa@niaid.nih.gov]; 'Tountas, Karen (FNIH) [T]'[ktountas@fnih.org]; 'Santos, Michael (FNIH) [T]'[msantos@fnih.org]; 'Adam, Stacey (FNIH) [T]'[sadam@fnih.org]; 'James, Stephanie (FNIH) [T]'[sjames@fnih.org]; 'Alvarez, Rosa Maria'[rosalvarez@deloitte.com]; 'Kim, Elizabeth'[elkim@deloitte.com]; 'Tolman, Brett'[btolman@deloitte.com]; 'Wachtel, Jonathan'[jwachtel@deloitte.com]; 'Prabhavathi Fernandes'[prabha.fernandes@outlook.com]; 'Diamond, Michael'[mdiamond@wustl.edu]; 'Rose Li'[rose.li@roseliassociates.com]; 'Dana Carluccio'[dana.carluccio@roseliassociates.com]; 'Lagos, Enrique (NIH/NCATS) [E]'[enrique.lagos@nih.gov]; 'Jonson, Samantha (NIH/NCATS) [E]'[samantha.jonson@nih.gov]; 'Burrus-Shaw, Cyndi (NIH/OD) [E]'[cyndi.burrus-shaw@nih.gov]; 'Rodriguez, Robin D'[rmdaigle@tulane.edu]; 'Dave Frankowski'[david.frankowski@roseliassociates.com]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'Lowy, Douglas (NIH/NCI) [E]'[lowyd@mail.nih.gov]; 'Florence, Clint (NIH/NIAID) [E]'[clint.florence@nih.gov]; 'Nancy Haigwood'[haigwoon@ohsu.edu]; 'Stratton, Benjamin'[bstratton@DELOITTE.com]
From: Prabha Fernandes[prabha.fernandes@gmail.com]
Sent: Fri 5/29/2020 3:31:05 PM (UTC-04:00)
Subject: RE: ACTIV Preclinical working group (Tuesday meeting)
GC376 A vet feline infectious peritontis_Anivvive .pdf
GC376 JJ Viology 2015-Kim-feline coronavirusl - Copy.pdf

Hi Joe,
When we prioritize re-purposed drugs..
Should we should include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.
Oral product.
Selectivity index is great..

Attached FYI in case you have not seen.

Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Friday, May 29, 2020 3:25 PM
To: jrappaport@tulane.edu; john.young.jy3@roche.com; david.j.payne@gsk.com; Hild, Sheri (NIH/OD) [E] <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph <rbaric@email.unc.edu>; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Tomas Cihlar <Tomas.Cihlar@gilead.com>; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) <margaret.l.pitt.civ@mail.mil>
Cc: Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Hughes, Eric <eric.hughes@novartis.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; Cutillo, Christine (NIH/NCATS) [E] <cutilloc@mail.nih.gov>; Simon, Dina (NIH/OD) [C] <dina.simon@nih.gov>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Austin, Christopher (NIH/NCATS) [E] <austinc@mail.nih.gov>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Desrosiers, Betsy <elizabeth_desrosiers@merck.com>; Jansen, Kathrin <kathrin.jansen@pfizer.com>;

Kurilla, Michael (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas (NCI) <dl60z@nih.gov>; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Tountas, Karen (FNIH) [T] <ktountas@fnih.org>; Santos, Michael (FNIH) [T] <msantos@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; James, Stephanie (FNIH) [T] <sjames@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kim, Elizabeth <elkim@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes <prabha.fernandes@outlook.com>; Diamond, Michael <mdiamond@wustl.edu>; Rose Li <rose.li@roseliassociates.com>; Dana Carluccio <dana.carluccio@roseliassociates.com>; Lagos, Enrique (NIH/NCATS) [E] <enrique.lagos@nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Burrus-Shaw, Cyndi (NIH/OD) [E] <cyndi.burrus-shaw@nih.gov>; Rodriguez, Robin D <rmdaigle@tulane.edu>; Dave Frankowski <david.frankowski@roseliassociates.com>; Baric, Toni C <antoinette_baric@med.unc.edu>; Lowy, Douglas (NIH/NCI) [E] <lowyd@mail.nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Nancy Haigwood <haigwoon@ohsu.edu>; Stratton, Benjamin <bstratton@DELOITTE.com>
Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, April 14, 2020 6:43 PM
To: jrappaport@tulane.edu; john.young.jy3@roche.com; david.j.payne@gsk.com; Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; rbaric@email.unc.edu; prabha.fernandes@gmail.com; ottingerea@mail.nih.gov; ccolvis@mail.nih.gov; jh18v@nih.gov; Damon.Deming@fda.hhs.gov; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
Subject: ACTIV Preclinical working group (Tuesday meeting)
When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Meeting ID: 960 4240 3854
Password: 124630
One tap mobile
+13017158592,,96042403854#,,1#,124630# US (Germantown)
+13126266799,,96042403854#,,1#,124630# US (Chicago)

Dial by your location
+1 301 715 8592 US (Germantown)
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+1 646 876 9923 US (New York)

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+1 669 900 6833 US (San Jose)
+1 253 215 8782 US (Tacoma)
+1 346 248 7799 US (Houston)
Meeting ID: 960 4240 3854
Password: 124630
Find your local number: https://fnih.zoom.us/u/aemFGSQrl

American Pharmaceutical Review™

Anivive Repurposes Veterinary Drug for COVID-19, Submits Pre-IND

Thursday, May 28, 2020

Anivive Lifesciences has filed a pre-Investigational New Drug (pIND) request with the Food and Drug Administration (FDA) for GC376, a candidate for the treatment of COVID-19 in humans.

"Published data shows that GC376 demonstrates in vitro and in vivo activity against many animal and human coronaviruses including SARS, MERS and most recently SARS-CoV-2," said Anivive Chief Medical Officer David Bruyette, DVM, DACVIM. "GC376 has shown strong activity against both the main protease (3CLpro) as well as SARS-CoV-2 in cell lines and has a CC50 of > 200 resulting in a high therapeutic index".

Since 2018 Anivive has been developing GC376 to treat the leading cause of death in kittens and young cats, Feline Infectious Peritonitis (FIP), a disease caused by a coronavirus. GC376 was identified as a promising therapeutic candidate by AniviveSELECT, Anivive's AI-powered software that accelerates the drug discovery process by analyzing and learning from a massive collection of drug data compiled from over 300 sources.

"We look forward to our discussions with the FDA and advancing toward a clinical trial," says Anivive CEO and Founder Dylan Balsz. "Our research over the past few months and our experience with GC376 support the exploration of the drug as an adjunct therapy to standard of care for COVID-19 patients or for patients where standard of care may be contraindicated."

GC376 is a protease inhibitor. Like all coronaviruses, FIP and SARS-CoV-2 contain a protease which is responsible for replication of the virus. GC376 successfully blocks the replication process. Internal and third-party research suggests that GC376 is also highly active against the protease in SARS-CoV-2, 3CLpro, that causes COVID-19. Prior to the COVID-19 pandemic, Anivive was working with their existing GMP manufacturers to meet regulatory requirements and have since accelerated production to provide GC376 for human clinical trials.

Anivive remains dedicated to developing GC376 for veterinary patients but, given the current pandemic and scarcity of effective therapies, is also exploring the use of GC376 in humans to help combat COVID-19.

The FDA will guide Anivive on the proposed clinical study protocol. Anivive then plans to submit an IND application for GC376 to be evaluated as a potential addition to the current standard of care treatment for COVID-19.

GC376 is a novel, first-in-class, small molecule protease inhibitor with a favorable therapeutic index demonstrated in preclinical studies. A common feature of viruses in the picornavirus-like supercluster (including coronaviruses) is a 3C or 3C-like protease (3Cpro or 3CLpro, respectively) responsible for viral replication. Viruses in this family include human coronavirus 229E, transmissible gastroenteritis virus of swine (TGEV), murine hepatitis virus (MHV), bovine coronavirus (BCV), feline infectious peritonitis virus (FIPV), severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East Respiratory Syndrome (MERS) and COVID-19 (SARS-CoV-2). GC376 has been shown to be a potent inhibitor of this protease across all coronaviruses with a high therapeutic index.

- **Formulation Development »**

JVI Journals.ASM.org

Broad-Spectrum Inhibitors against 3C-Like Proteases of Feline Coronaviruses and Feline Caliciviruses

Yunjeong Kim,[a] Vinay Shivanna,[a] Sanjeev Narayanan,[a] Allan M. Prior,[b]* Sahani Weerasekara,[b] Duy H. Hua,[b] Anushka C. Galasiti Kankanamalage,[c] William C. Groutas,[c] Kyeong-Ok Chang[a]

Department of Diagnostic Medicine and Pathobiology, College of Veterinary Medicine, Kansas State University, Manhattan, Kansas, USA[a]; Department of Chemistry, Kansas State University, Manhattan, Kansas, USA[b]; Department of Chemistry, Wichita State University, Wichita, Kansas, USA[c]

ABSTRACT

Feline infectious peritonitis and virulent, systemic calicivirus infection are caused by certain types of feline coronaviruses (FCoVs) and feline caliciviruses (FCVs), respectively, and are important infectious diseases with high fatality rates in members of the Felidae family. While FCoV and FCV belong to two distinct virus families, the *Coronaviridae* and the *Caliciviridae*, respectively, they share a dependence on viral 3C-like protease (3CL^{pro}) for their replication. Since 3CL^{pro} is functionally and structurally conserved among these viruses and essential for viral replication, 3CL^{pro} is considered a potential target for the design of antiviral drugs with broad-spectrum activities against these distinct and highly important viral infections. However, small-molecule inhibitors against the 3CL^{pro} enzymes of FCoV and FCV have not been previously identified. In this study, derivatives of peptidyl compounds targeting 3CL^{pro} were synthesized and evaluated for their activities against FCoV and FCV. The structures of compounds that showed potent dual antiviral activities with a wide margin of safety were identified and are discussed. Furthermore, the *in vivo* efficacy of 3CL^{pro} inhibitors was evaluated using a mouse model of coronavirus infection. Intraperitoneal administration of two 3CL^{pro} inhibitors in mice infected with murine hepatitis virus A59, a hepatotropic coronavirus, resulted in significant reductions in virus titers and pathological lesions in the liver compared to the findings for the controls. These results suggest that the series of 3CL^{pro} inhibitors described here may have the potential to be further developed as therapeutic agents against these important viruses in domestic and wild cats. This study provides important insights into the structure and function relationships of 3CL^{pro} for the design of antiviral drugs with broader antiviral activities.

IMPORTANCE

Feline infectious peritonitis virus (FIPV) is the leading cause of death in young cats, and virulent, systemic feline calicivirus (vs-FCV) causes a highly fatal disease in cats for which no preventive or therapeutic measures is available. The genomes of these distinct viruses, which belong to different virus families, encode a structurally and functionally conserved 3C-like protease (3CL-pro) which is a potential target for broad-spectrum antiviral drug development. However, no studies have previously reported a structural platform for the design of antiviral drugs with activities against these viruses or on the efficacy of 3CL^{pro} inhibitors against coronavirus infection in experimental animals. In this study, we explored the structure-activity relationship of the derivatives of 3CL^{pro} inhibitors and identified inhibitors with potent dual activities against these viruses. In addition, the efficacy of the 3CL^{pro} inhibitors was demonstrated in mice infected with a murine coronavirus. Overall, our study provides the first insight into a structural platform for anti-FIPV and anti-FCV drug development.

Feline coronaviruses (FCoVs) and feline caliciviruses (FCVs) are important pathogens of cats and generally cause mild, self-limiting localized infection in the intestinal tract or oral cavity and upper respiratory tract, respectively. However, these viruses can also cause a life-threatening systemic illness with a high fatality rate in cats. FCoV associated with a fatal disease in cats, feline infectious peritonitis (FIP), causes systemic pyogranulomatous inflammation in various organs, which subsequently progresses to fluid accumulation in the abdominal cavity and death. In contrast to the more common asymptomatic or mild enteritis caused by feline enteric coronavirus, the enteric biotype of FCoV, FIP is relatively uncommon in the general cat population, but it is the leading cause of death in young cats (1–3). In addition to the two biotypes of feline enteric coronavirus and FIP coronavirus, FCoVs are also classified into two serotypes, I and II. FCoV serotype I is more prevalent than serotype II, which appears to be derived from recombination with canine coronavirus in the spike (S) protein (4–8). Both serotypes can cause enteritis or FIP in domestic and wild feline populations, including wildcats, cheetahs, mountain lions, and leopards (9–11). Virulent, systemic FCV (vs-FCV) is associated with systemic infection with a mortality rate as high as 67% (12–16). Unlike FCV associated with acute upper respiratory tract infection and oral ulceration, vs-FCV infection is characterized by an expanded tissue tropism, causing facial and limb

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edema, vasculitis, and dysfunctions in multiple organs (12–16). Despite the importance of these virus infections in cats, no effective preventive measure is currently available (reviewed in reference 17), and treatment options for FIP and vs-FCV infections are limited to supportive therapy, due to the lack of specific antiviral drugs. Therefore, effective therapeutic measures, such as antiviral drugs, are direly needed to combat these viral infections in cats.

FCoV is an enveloped, single-stranded positive-sense RNA virus that is a member of the *Coronaviridae* family. FCV is a nonenveloped, single-stranded positive-sense RNA virus that belongs to the *Caliciviridae* family. During replication, these viruses produce one (calicivirus) or multiple (coronavirus) viral polyproteins that are cleaved into functional structural or nonstructural virus proteins by virus genome-encoded proteases (reviewed in references 18 and 19). Viral 3C-like protease (3CLpro) is responsible for processing of the majority of cleavage sites; thus, it is essential in the replication of coronaviruses and caliciviruses. The 3CLpro enzymes encoded by the genomes of those viruses share several common characteristics, such as a typical chymotrypsin-like fold, the presence of a Cys nucleophile in the catalytic triad or dyad, and a preference for a Glu or Gln residue at the P1 position (in the nomenclature of Schechter and Berger [20]) in the substrate. Therefore, 3CLpro may serve as a potential target for the development of broad-spectrum antiviral agents for coronaviruses and caliciviruses.

We have previously synthesized peptidyl inhibitors based on the conserved key features of 3CLpro of coronaviruses and caliciviruses or the related 3C protease (3Cpro) of picornaviruses and reported on their broad-spectrum antiviral activities against multiple viruses in enzyme- or cell-based assay systems (21–23). However, those compounds showed minimal antiviral activity against FCV in cell culture, suggesting that further evaluation of structure-activity relationships around these peptidyl scaffolds is required for the development of broad-spectrum therapeutic agents for FCoV and FCV. In this study, we evaluated the anti-FCoV and anti-FCV activities of newly synthesized compounds as well as those of compounds that were previously reported by us but were not tested against FCoV and FCV and identified compounds that are effective against both FCoV and FCV in cell-based assays. The efficacies of representative dipeptidyl and tripeptidyl compounds were evaluated in mice infected with murine hepatitis virus (MHV) A59, a hepatotropic murine coronavirus, as a model for FIP. Our findings show that tripeptidyl compounds in general exhibit increased dual inhibitory activity against FCV and FCoV in cell culture and the dipeptidyl and tripeptidyl compounds significantly reduced the viral titers and histopathological changes in the liver of mice infected with MHV compared to the viral titers and histopathology of the liver of the control group. In summary, our peptidyl compounds, especially the tripeptidyl compounds, may have the potential to be developed as antiviral therapeutics targeting both FCoV and FCV.

MATERIALS AND METHODS

Compounds. To identify potential broad-spectrum inhibitors against FCoV and FCV, the 3CLpro inhibitor libraries generated by our group were evaluated. The synthesis of dipeptidyl compounds GC373, GC376, GC543, GC546, GC551, and GC554 (22, 24, 25) and tripeptidyl compounds NPI52 (compound 2), NPI59 (compound 6), NPI64 (compound 7), and NPI71 (compound 8) (23) was described previously (22–25). Compounds NPI58, NPI65, and NPI66 were synthesized by modification of a previously reported method (23) and have not been previously reported. Compound confirmation and purity assessment were performed by nuclear magnetic resonance, mass spectrometry, and high-pressure liquid chromatography in the laboratory of D. H. Hua (Department of Chemistry, Kansas State University) or W. C. Groutas (Department of Chemistry, Wichita State University). The structures of the compounds are shown in Fig. 1A and B.

Cells and viruses. Crandell-Reese feline kidney (CRFK) cells were maintained in minimum essential medium (MEM) containing 2 to 5% fetal bovine serum and the antibiotics chlortetracycline (25 ffig/ml), penicillin (250 U/ml), and streptomycin (250 ffig/ml). FCoV WSU-79-1146, non-vs-FCV strains Urbana, 131, and F9, and vs-FCV strains 5, Ari, Deuce, and Jengo were propagated in CRFK cells. CRFK cells and WSU-79-1146 were obtained from ATCC (Manassas, VA). The FCVs were kind gifts from J. Parker at Cornell University. WSU-79-1146 is a cell culture-adapted group II FCoV strain which is reported to cause FIP in experimentally inoculated cats (26).

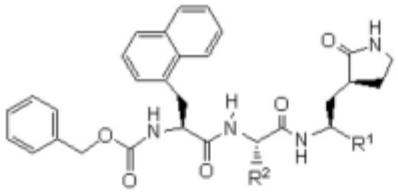
Antiviral effects of compounds in cell culture. Serial dilutions of each compound were added to confluent monolayers of CRFK cells in 24-well plates or cells were mock treated, and the cells were then immediately inoculated with virus at a multiplicity of infection (MOI) of 0.05 to 0.1. The cells were then further incubated at 37°C until an extensive cytopathic effect was observed in the mock-treated (untreated) well (up to 24 h). After freezing and thawing of the viruses in cell culture, virus titers were determined by the 50% tissue culture infective dose ($TCID_{50}$) method (27). Stock solutions of test compounds (10 mM) were prepared in dimethyl sulfoxide (DMSO), and the concentration of DMSO in the cell culture did not exceed 0.5%. The 50% effective concentrations (EC_{50}) were determined by nonlinear regression analyses of dose-response curves of virus titers against log inhibitor concentrations (variable slope) using GraphPad Prism software (GraphPad Software, San Diego, CA).

Nonspecific cytotoxic effect. CRFK cells in 96-well plates were incubated with each compound at various concentrations up to 150 ffiM for 24 h. Cell cytotoxicity was measured by use of a CytoTox 96 nonradioactive cytotoxicity assay kit (Promega, Madison, WI) following the manufacturer's instructions. The 50% cytotoxic concentration (CC_{50}) of each compound was determined using GraphPad Prism software.

Western blot analysis. CRFK cells were mock treated or treated with each compound and immediately infected with FCoV WSU-79-1146 or FCV Urbana at an MOI of 2. The cells were then further incubated at 37°C for 12 h. At 12 h postinfection, the cells were lysed with SDS-PAGE sample buffer containing 1% ffl-mercaptoethanol and the proteins were resolved on 10% NovexTris-bis gels (Invitrogen, Carlsbad, CA) and transferred to nitrocellulose membranes. Viral proteins were probed by using an antibody specific for FCV VP1 (28) or the FCoV nucleocapsid protein (Biocompare, Windham, NH) and then with peroxidase-conjugated goat anti-mouse IgG or rabbit anti-goat IgG. ffl-Actin was used as a loading control. Following incubation with a chemiluminescent substrate (Pierce Biotechnology, Rockford, IL), the chemiluminescent signals were detected using a Fotodyne transilluminator/digital camera system (FX; Fotodyne, Hartland, WI).

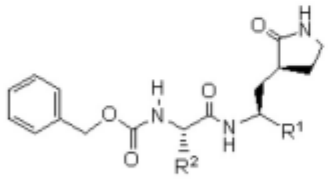
Multiple-sequence alignment and three-dimensional structural models for 3CLpro. Multiple-amino-acid-sequence alignment of the 3CLpro enzymes from FCV Urbana (GenBank accession number L40021.1), vs-FCV strains Jango (GenBank accession number DQ910793.1), Ari (GenBank accession number DQ910794.1), and Deuce (GenBank accession number DQ910789.1), FCoV strains WSU-79-1146 (GenBank accession number DQ010921.1), Black (GenBank accession number EU186072.1), and DF-2 (GenBank accession number JQ408981.1), and MHV A59 (GenBank accession number NC_001846.1) was performed using the ClustalW multiple-sequence-alignment program. FCoV strains WSU-79-1146, Black, and DF-2 are FIP-causing FCoVs. The three-dimensional structure of FCoV 3CLpro was built by use of the EasyModeller (version 4.0) program (29) and the 3CLpro structure of transmissible gastroenteritis virus (TGEV), a porcine coronavirus (Pro-

A



Compounds	R^1	R^2	FCoV (EC_{50}, μM)	FCV (EC_{50}, μM)	CC_{50} (μM)
NPI52	CHO	Isobutyl (Leu)	0.02±0.01	0.02±0.01	70.29±5.6
NPI58	CHO	Benzyl (Phe)	0.86±0.72	0.69±0.03	40.57±10
NPI59	(C=O)(C=O)NHCH$(CH_3)_2$	Isobutyl (Leu)	0.54±0.28	>5	32.34±1.9
NPI64	CH(OH) SO_3Na	Isobutyl (Leu)	0.04±0.03	0.08±0.01	61.91±0.2
NPI65	(C=O)(C=O)NHC$(CH_3)_3$	Isobutyl (Leu)	0.18±0.12	3.3±5.0	32.01±1.3
NPI66	CHO	Cyclohexylmethyl (Cha)	0.06±0.06	0.58±0.19	21.96±5.1
NPI71	CH(OH)P(O)$(OCH_2CH_3)_2$	Isobutyl (Leu)	0.06±0.001	4.10±1.15	>150

B



Compounds	R^1	R^2	FCoV (EC_{50}, μM)	FCV (EC_{50}, μM)	CC_{50} (μM)
GC373	CHO	Isobutyl (Leu)	0.02±0.01	>5	>150
GC376	CH(OH) SO_3Na	Isobutyl (Leu)	0.04±0.04	>5	>150
GC543	CHO	Cyclohexylmethyl (Cha)	0.10±0.03	5.35±3.91	>150
GC546	CHO	Benzyl (Phe)	0.43±0.31	2.09±1.59	>150
GC551	CH(OH) SO_3Na	Cyclohexylmethyl (Cha)	0.06±0.05	3.77±0.58	>150
GC554	CH(OH) SO_3Na	Benzyl (Phe)	0.12±0.05	6.0±2.082	>150

FIG 1 Chemical structures of tripeptidyl (A) and dipeptidyl (B) compounds and the mean and standard error of the means (SEM) of the EC_{50} of the compounds against FCoV or FCV. Each compound was added to CRFK cells, and the cells were immediately infected with FCoV WSU-79-1146 or FCV Urbana. Cells were further incubated in the presence of each compound for up to 24 h. Virus titers were determined using the $TCID_{50}$ method, and the EC_{50} were calculated. Compound cytotoxicity (CC_{50}) was measured after incubating the cells with each compound for 24 h.

tein Data Bank accession number 2AMP), as the template. The FCV 3CL-pro three-dimensional structure was built by use of the EasyModeller program and rhinovirus 3Cpro, poliovirus 3Cpro, human norovirus 3CL-pro, and hepatitis A virus 3Cpro (Protein Data Bank accession numbers 1CQQ, 1L1N, 2LNC, and 1QA7, respectively) (30) as the templates. The quality of the models was assessed using the Verify 3D program (31).

Animal experiments. The animal study was performed in accordance with a protocol approved by the Institutional Animal Care and Use Committee (IACUC) at Kansas State University. BALB/c mice were purchased from Charles River Labs (Wilmington, MA). Prior to the animal experiments, the EC_{50} of GC376 and NPI52 against MHV A59 were determined to be 0.2 to 1 ffiM in CCL9.1 mouse liver cells. To confirm that MHV A59 infection induces consistent and high levels of virus replication in the livers of the infected mice, we inoculated 4- to 5-week-old female BALB/c mice intraperitoneally with MHV A59 at 7.2! 10^4 or 5.2! 10^5 $TCID_{50}$/mouse. At 2 and 4 days postinfection (p.i.), the mice were sacrificed (4 to 6 mice/group), and the livers were collected and processed for virus titration by the $TCID_{50}$ method. For the *in vivo* efficacy study, 4- to 5-week-old female BALB/c mice were inoculated intraperitoneally with MHV A59 at 7.2! 10^4 or 5.2! 10^5 $TCID_{50}$/mouse. Mice were intraperitoneally given 50 ffil of drug vehicle (10% ethanol, 70% polyethylene glycol 400, 20% phosphate-buffered saline), GC376 (10, 50, or 100 mg/kg of body weight/day), or NPI52 (10 or 100 mg/kg/day) divided into two doses per day. Compound administration started 4 h prior to virus infection and con-

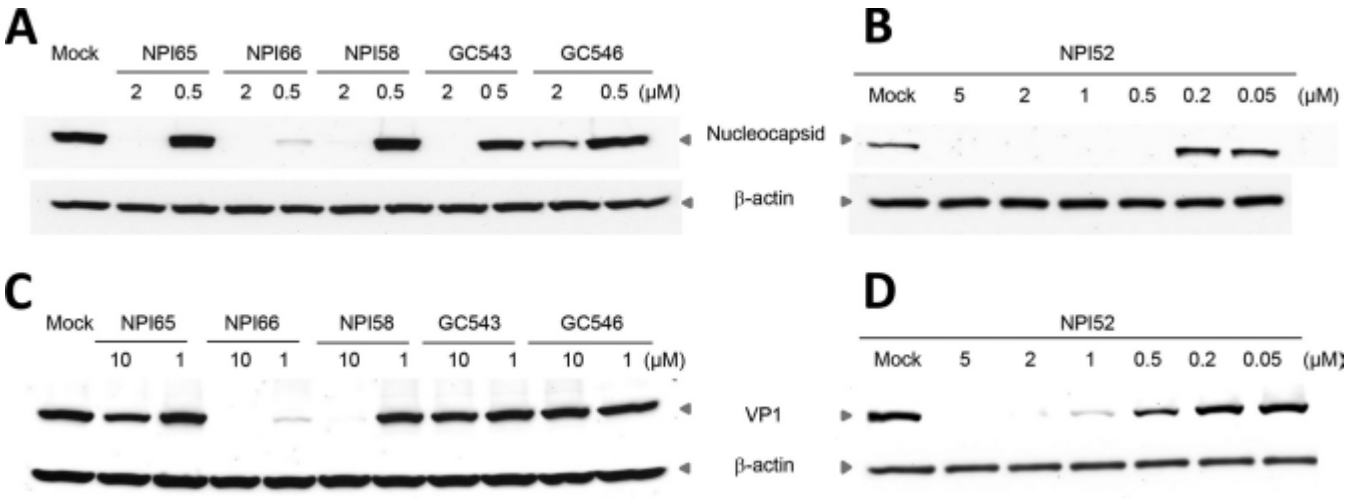


FIG 2 Western blot analysis of the effects of the compounds on expression of the FCoV nucleocapsid protein or FCV VP1 in CRFK cells. Cells were mock treated or treated with each compound and immediately infected with FCoV WSU-79-1146 or FCV Urbana. The cells were then further incubated for 12 h. Cell lysates were prepared and analyzed for expression of viral proteins on Western blots. ffl-Actin was used as a loading control.

tinued daily until the mice were euthanized. At 2 and 4 days p.i., the mice were sacrificed and the livers were collected and processed for virus titration. Virus titers were determined by the $TCID_{50}$ method, and the liver virus titers were compared by two-tailed Student's *t* test. Fold changes in the geometric mean liver virus titers in each group were calculated by dividing the virus titers in the control group by those in the treated group.

Liver histopathology. At 4 days p.i., the left lateral lobes were collected from NPI52-treated (10 and 100 mg/kg/day) mice, fixed with formalin, embedded in paraffin, sectioned, and stained with hematoxylin and eosin for histopathological examination by a board-certified pathologist. Five views were examined per mouse liver, and a score of from 0 to 5 was assigned to each lesion contained in the view on the basis of the severity of the histopathological changes. Each score in each sample was added to give a final total score, and then the mean of the total score per sample was calculated for each group. The mean number of lesions per sample was also calculated for each group. The mean total score per sample and the mean number of lesions per sample were compared among the different experimental groups using two-tailed Student's *t* test.

RESULTS

Antiviral effects of dipeptidyl and tripeptidyl compounds on the replication of FCoV and FCV. We evaluated the activities of dipeptidyl and tripeptidyl compounds with various R1 and R2 side chains against FCoV WSU-79-1146 and FCV Urbana in cell culture (Fig. 1A and B). For dipeptidyl compounds, replacing the R2 isobutyl (Leu side chain) with benzyl (Phe side chain) or cyclohexylmethyl (Cha side chain) on a representative dipeptidyl compound, GC373, increased the anti-FCV activity, while it decreased its potency toward FCoV. GC373 was previously shown to have potent anti-FCoV activity but minimal activity against FCV in cell culture (22). The tripeptidyl compound NPI52 has an additional residue of 1-napthylalanine compared to the structure of GC373 at the P3 position, and its activity against FCoV or FCV has not been previously tested (23). In this study, we found that NPI52 exhibited potent anti-FCoV and anti-FCV activity, with its EC_{50} being in the nanomolar range (Fig. 1A), which indicates that the presence of the additional residue at the P3 subsite dramatically increased its activity against FCV. When the R2 isobutyl was replaced with a benzyl or cyclohexylmethyl in NPI52, the benzyl substitution decreased the anti-FCoV activity more than the cyclohexylmethyl substitution, but the reduction in anti-FCV activity was similar between benzyl and cyclohexylmethyl substitutions. Replacement of the aldehyde warhead in NPI52 with ketoamides [(C" O)(C" O)NHCH$(CH_3)_2$ or (C" O)(C" O)NHC$(CH_3)_3$] greatly decreased the anti-FCV activity, but the activity of these compounds against FCoV was only moderately decreased. Similarly, replacement of aldehyde with #-hydroxy phosphonate [CH(OH)P(O)$(OCH_2CH_3)_2$] greatly decreased the anti-FCV activity but had only a minor effect on anti-FCoV activity. NPI64, GC376, GC551, and GC554 are bisulfite adducts of NPI52, GC373, GC543, and GC546, respectively, and they showed antiviral activities against FCoV and FCV comparable to those of their aldehyde counterparts in cell culture. The CC_{50} values of all compounds ranged from 21.96 ffiM to greater than 150 ffiM in CRFK cells (Fig. 1A and B). Western blot analysis confirmed the effects of our compounds on the expression of the FCoV nucleocapsid protein or FCV VP1 (Fig. 2).

Compound NPI52, which possesses potent antiviral activities against both FCoV WSU-79-1146 and FCV Urbana, was also tested for its activity against other non-vs-FCV and vs-FCV strains in cell culture to determine whether this compound is effective against various FCV strains. The EC_{50} in Table 1 show that NPI52

TABLE 1 EC_{50} of NPI52 against non-vs-FCV or vs-FCV strains

Virus and strain	EC_{50} (ffiM)
vs-FCV	
Jengo	0.03$ 0.01
5	0.35$ 0.27
Ari	0.10$ 0.09
Deuce	0.22$ 0.002
non-vs-FCV	
131	0.05$ 0.03
F9	0.05$ 0.05
Urbana	0.02$ 0.01

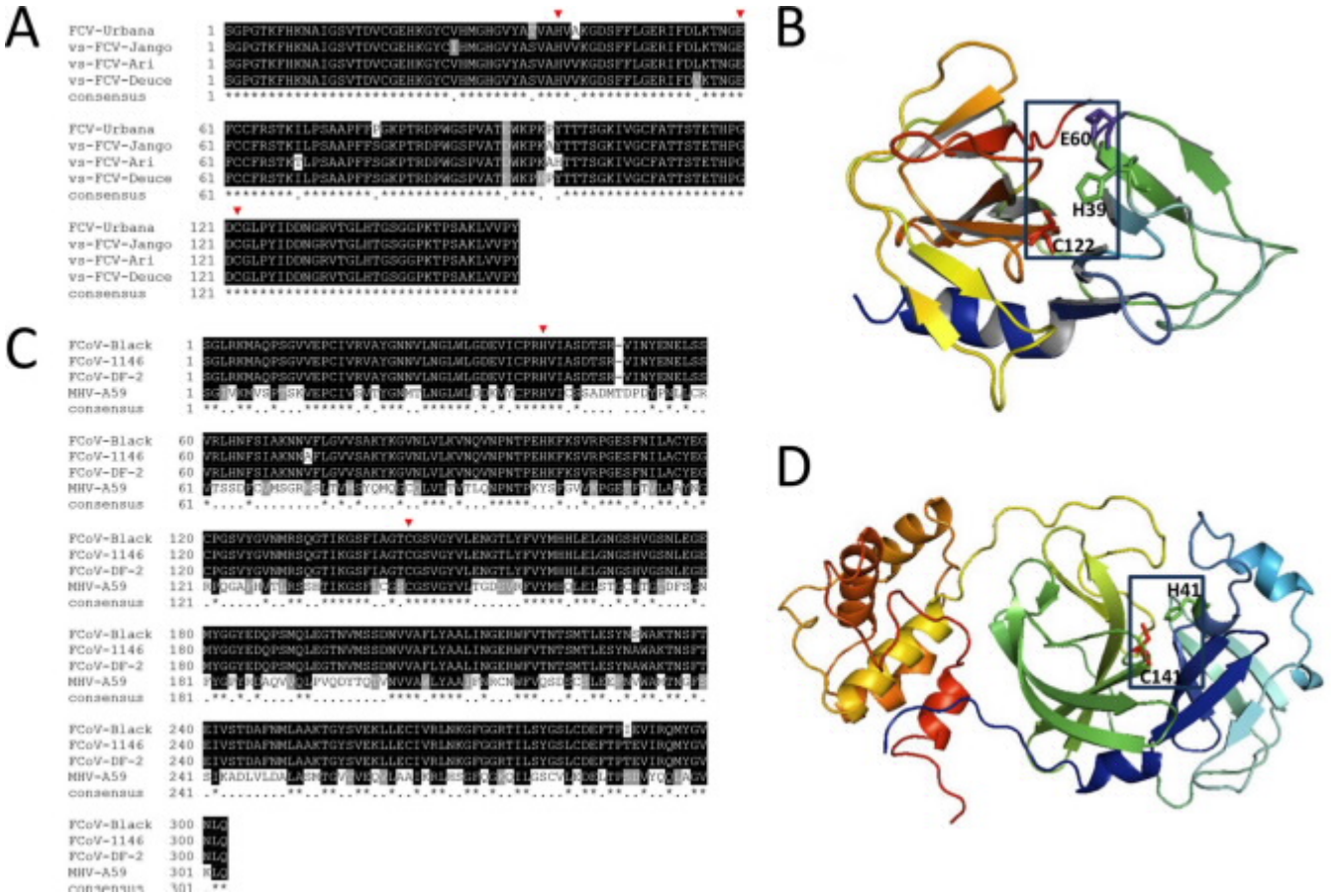


FIG 3 Multiple-sequence alignments of 3CLpro enzymes from FCV (A) and FCoV and MHV A59 (C) and ribbon presentations of three-dimensional structural models for FCV 3CLpro (B) and FCoV 3CLpro (D). (A and C) The catalytic residues E60, C122, and H39 of FCV 3CLpro (A) and H41 and C144 of FCoV 3CLpro and MHV A59 3CLpro are indicated by red arrowheads (C). (B and D) The structure model of FCoV 3CLpro was built by use of the EasyModeller (version 4.0) program (29) and the 3CLpro structure of TGEV (Protein Data Bank accession number 2AMP) as the template. The structural model of FCV 3CLpro was built by use of the EasyModeller program and the 3Cpro enzymes of rhinovirus, poliovirus, and hepatitis A virus and the 3CLpro of human norovirus (Protein Data Bank accession numbers 1CQQ, 1L1N, 1QA7, and 2LNC, respectively) (30) as the templates. The amino acids in the catalytic triad (E60, C122, and H39 for FCV 3CLpro) (B) and dyad (H41 and C144 for FCoV 3CLpro) (C) are shown in the blue boxes.

potently inhibited the replication of various non-vs-FCV and vs-FCV strains in cell culture.

Multiple-sequence alignment and three-dimensional structural models for 3CLpro. The amino acid sequences of the 3CLpro enzymes have high sequence homology of ~95% within strains of FCV or FCoV (Fig. 3A and C). However, there are substantial differences in the 3CLpro sequences (~19.72% homology) between FCV and FCoV strains. Although the sequence homology between FCV 3CLpro and FCoV 3CLpro is low, the catalytic residues are well conserved (Fig. 3A to D). MHV A59 3CLpro shares an amino acid sequence homology of 47.35% with FCoV 3CLpro, and the locations of the catalytic residues (red arrowheads in Fig. 3C) correspond well to those of FCoV strains. The residues in the catalytic dyad or triad are shown in the blue boxes in Fig. 3B and D.

***In vivo* efficacy of compounds in coronavirus-infected mice.** Intraperitoneal inoculation of MHV A59 at 7.2 × 10^4 or 5.2 × 10^5 $TCID_{50}$ per mouse led to high levels of virus replication in the liver, and the levels of virus replication were not significantly different between the two virus inocula, as determined by two-tailed Student's *t* test ($P > 0.05$) (data not shown). In the *in vivo* efficacy study, NPI52 and GC376 were tested in mice infected with MHV A59. In two separate experiments where mice were treated with GC376 or mock treated, the liver virus titers in mice treated with GC376 at 50 or 100 mg/kg were significantly lower than those in the no-treatment control mice at 4 days p.i. but not at 2 days p.i. ($P < 0.01$) (Fig. 4A and B). The fold reductions of the geometric mean virus titers in mice that received GC376 at 50 or 100 mg/kg at 4 days p.i. were 9.86 and 21.99, respectively, compared to the titers in the control mice (Fig. 4A and B, bar graphs). In contrast, GC376 at 10 mg/kg did not consistently lead to a significant reduction in virus titers at the two time points.

In two independent NPI52 treatment experiments, treatment with NPI52 at 100 mg/kg resulted in a significant reduction in liver virus titers at 4 days p.i. (fold reductions, 19.63 to 40.27) and at 2 days p.i. (fold reductions, 3.46 to 12.3) compared to the titers in the controls (Fig. 4C and D). However, NPI52 at 10 mg/kg failed to significantly reduce the virus titers compared to those in the controls at 2 days p.i. or 4 days p.i. (Fig. 4C and D), although a significant reduction in viral titer was observed at 4 days p.i. in one of the experiments (Fig. 4C and D). The mock-infected mice did not show any signs of illness during the duration of the experi-

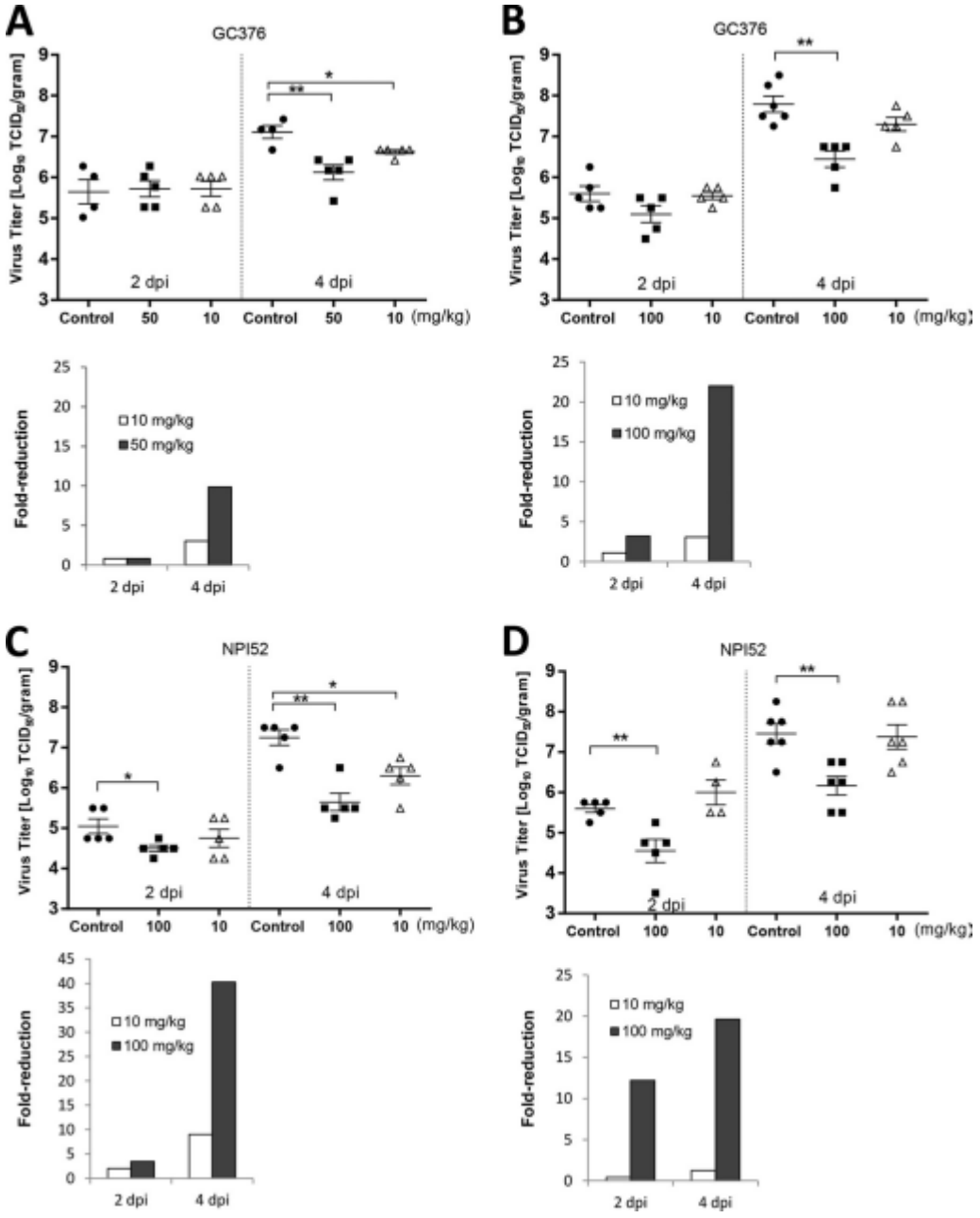
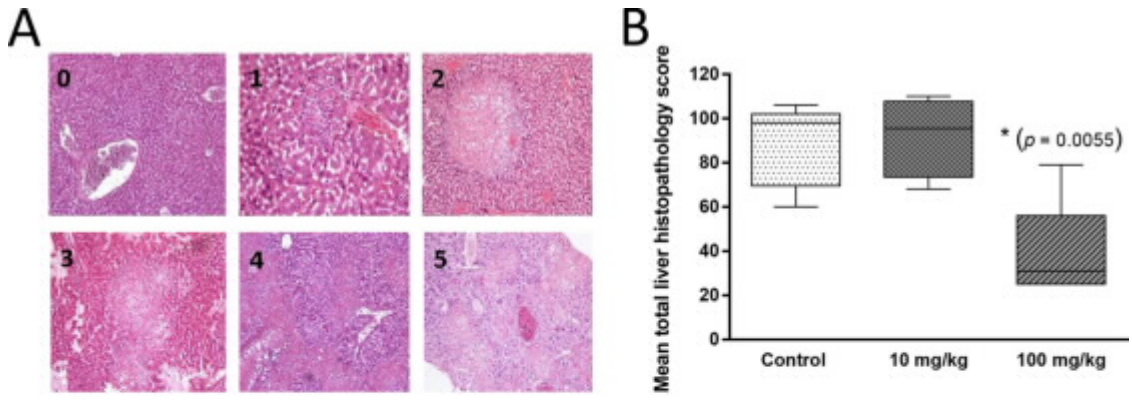


FIG 4 Effects of 3CLpro inhibitor treatment on MHV A59 titers. Four- to 5-week-old BALB/c mice were intraperitoneally inoculated with MHV A59 at 5.2! 10^5 (A) or 7.2! 10^4 (B to D) $TCID_{50}$/mouse and treated with drug vehicle, GC376 (10, 50, or 100 mg/kg/day), or NPI52 (10 or 100 mg/kg/day) divided into two doses per day starting at 4 h prior to virus infection. Scatter plots show the mean$ standard error of the mean virus titers in the livers of mice receiving mock treatment (drug vehicle) or treatment with GC376 (A and B) or NPI52 (C and D) at 2 or 4 days after virus infection (dpi, days postinfection). Virus titers are expressed as log_{10} $TCID_{50}$ per gram of liver tissue. Bar graphs show the fold reduction of the geometric mean virus titers in the treatment groups compared to the titers in the control group. Asterisks indicate significant differences between the control and the treated groups (*, P 0.05; **, P 0.01).

ments, and no gross pathological lesions were observed on necropsy.

Histopathology of liver. Panels 0 through 5 in Fig. 5A show microscopic lesions for increasing histopathology severity scores of from 0 through 5, respectively. On the basis of the lesion scoring, the group treated with NPI52 at 100 mg/kg had a significantly lower mean number of lesions and a significantly lower mean total histopathology scores per mouse liver than the controls (Fig. 5B and D). There was no statistically significant difference in the mean total histopathology scores and the mean number of lesions between the control group and the group treated with NPI52 at 10 mg/kg. However, the lesions in all drug-treated groups were scored 3 or lower, which is in contrast to the presence of lesions scored 4 or 5 in the no-treatment control group (Fig. 5C). Of note, the liver section from a mouse in the group treated with NPI52 at 10 mg/kg did not contain any histopathology lesion, and the data



C

	Frequency of lesions (%)		
Score	Control	10 mg/kg	100 mg/kg
1	29.1	35.6	30.8
2	23.2	35.6	57.9
3	32.4	28.8	11.2
4	10.3	0	0
5	4.9	0	0

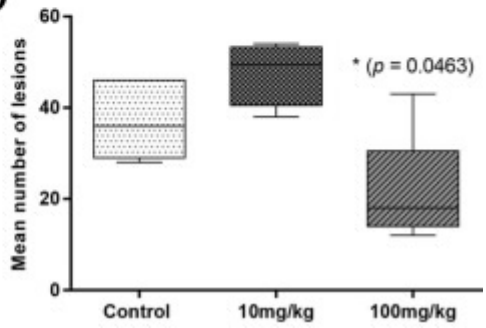


FIG 5 Histopathology changes in the livers of mice treated with NPI52. (A) Panels 0 through 5 show microscopic lesions for increasing histopathology severity scores of 0 through 5, respectively. Score 0, minimal changes; scores 1 and 2, multifocal areas of necrosis; and scores 3 to 5, coalescing areas of necrosis. (B) A box-and-whisker plot showing the mean total liver histopathology score for each group. (C) A table showing the frequency of histopathology scores in four liver samples per group (for the group treated with NPI52 at 10 mg/kg) or five liver samples per group (for the control group and the group treated with NPI52 at 100 mg/kg). (D) A box-and-whisker plot showing the mean number of lesions per mouse liver for each group. Asterisks indicate statistically significant differences between control mice and mice treated with NPI52 at 100 mg/kg (P 0.05). The whiskers represent the 5% and 95% confidence intervals, and the boxes represent the 25% and 75% confidence intervals. The lines in the middle of the boxes represent the medians for the data.

for that liver section were excluded from the statistical analysis for Fig. 5B to D. Examination of the liver samples from mock-infected mice revealed no significant microscopic lesions associated with compound toxicity.

DISCUSSION

Although infections with FCoV or FCV are generally asymptomatic or cause mild localized symptoms in cats, they can also cause systemic disease with high fatality rates among cats. These viruses are distinct in their genome organization, virus properties, and pathogenesis, but during replication they share a dependency on viral proteases for the production of functional structural or nonstructural virus proteins from a viral polyprotein(s). The amino acid sequence homology between FCV 3CLpro and FCoV 3CLpro is less than 20%; however, they have similar active-site configurations (Fig. 3A to D) (22, 30, 32). Based on the highly conserved key site of 3CLpro expressed by coronaviruses and caliciviruses, we have previously synthesized peptidyl compounds and identified compounds that exhibit broad-spectrum antiviral efficacy against viruses in the *Coronaviridae* and *Caliciviridae* families and also against viruses in the *Picornaviridae* family that encode closely related 3Cpro enzymes (22). The dipeptidyl compounds that were previously evaluated for broad-spectrum antiviral effects consist of a warhead, a Gln surrogate structure in a position that corresponds to the P1 position, Leu in the P2 position, and a cap structure. These compounds have EC_{50} against many members of the caliciviruses, picornaviruses, and coronaviruses, including FCoV, in the nanomolar or low micromolar range (22). These findings demonstrate that 3CLpro could serve as a target for the development of broad-spectrum antiviral agents for viruses whose genomes encode 3CLpro or 3Cpro. However, these compounds were only minimally effective against FCV in cell culture (EC_{50}, %30 ffiM) (22), and their low level of activity was speculated to be due to space constraints in the S2 pocket in the 3CLpro of FCV.

In the present study, we evaluated the newly synthesized and previously reported dipeptidyl and tripeptidyl compounds that were not previously tested against FCoV and FCV in cell culture. Our findings show that the presence of an additional residue in NPI52 remarkably enhances anti-FCV activity, while the potency against FCoV compared to that of dipeptidyl compounds (including GC373) is maintained, suggesting that tripeptidyl compounds may provide a more suitable platform for dual-spectrum antiviral drug design for FCoV and FCV. Our limited structure-activity relationship study revealed that replacing the Leu side chain at the P2 site or the warhead on dipeptidyl or tripeptidyl compounds changed the antiviral activity against FCoV and FCV to various degrees. The effects of different warheads on the tripeptidyl compound were more profound on the antiviral activity against FCV than that against FCoV, which may suggest that the interaction of the warhead and the nucleophile Cys in the active site of FCV

3CLpro may require a fit more stringent than that in the active site of FCoV 3CLpro. Further investigation, such as crystallographic studies with inhibitor-FCoV 3CLpro or inhibitor-FCV 3CLpro complexes, may illuminate the structural basis of our findings. Among our tested compounds, NPI64, GC376, GC551, and GC554 are bisulfite adducts of NPI52, GC373, GC543, and GC546, respectively, and in cell culture they showed antiviral activities against FCoV and FCV comparable to those of their aldehyde counterparts. Bisulfite adduct compound GC376 was previously reported to be dissociated into the corresponding aldehyde (GC373) and bisulfite ion when incubated with 3CLpro, with the resulting aldehyde subsequently forming a covalent adduct with the active-site Cys of 3CLpro in X-ray crystallographic studies (22). We also observed the facile transformation of GC376 and NPI64 to their respective aldehyde forms in the blood of rats and cats in our preliminary animal studies (data not shown). These observations suggest that the bisulfite adduct compounds may act as prodrugs with the active aldehyde metabolites in cell culture and animals.

We also determined the antiviral effects of NPI52 on the replication of various vs-FCV strains as well as non-vs-FCV strains in cell culture to determine the sensitivity of various strains of FCV to the compound. The results showed that the potency of NPI52 against four vs-FCV strains was generally lower than that against non-vs-FCV strains, but it still remained high, with EC_{50} being in the nanomolar range. The higher EC_{50} of NPI52 against vs-FCV may be attributed to faster multicycle growth kinetics of vs-FCV strains leading to yields of virus progeny higher than those for non-vs-FCV strains (33). These results indicate that our compounds may be of potential therapeutic value for the treatment of highly fatal vs-FCV infection and non-vs-FCV infection, which are important causes of respiratory diseases and oral ulceration in cats. The compounds have minimal or low cytotoxicity in CRFK cells; the CC_{50} values of the dipeptidyl compounds were greater than 150 ffiM, with the *in vitro* therapeutic indexes (TIs) being 349 to higher than 7,500. Tripeptidyl compounds also have good TIs, but they are lower than those of dipeptidyl compound: compounds with EC_{50} of 1 ffiM against FCoV or FCV had TIs that ranged from 31.8 to 3,514 (Fig. 1A). The *in vitro* TIs are expressed as the ratio of the CC_{50} to the EC_{50}, and these results indicate that our compounds have relatively high *in vitro* safety margins and can be suitable candidates for *in vivo* studies.

A number of classes of inhibitors of coronavirus 3CLpro have been identified in cell culture systems or in enzyme assays since the severe acute respiratory syndrome (SARS) coronavirus outbreaks in 2003 (34–41). However, few studies have reported on the efficacy of coronavirus 3CLpro inhibitors in experimental animals. Therefore, we evaluated a dipeptidyl compound (GC376) and a tripeptidyl compound (NPI52) in mice infected with a murine coronavirus, MHV. MHV causes systemic diseases, including hepatitis and a variety of immunological dysfunctions, in mice. Specifically, MHV A59 inoculation of mice by the peritoneal route causes severe liver disease and multiorgan infections (42,43). This animal model was used as a surrogate for FIP, since feline coronavirus naturally infects only members of the family Felidae. In our study, the antiviral effects of GC376 and NPI52 in reducing liver viral titers compared to those in the no-treatment control group were dose dependent, and a statistically significant reduction in the viral load in the liver was consistently observed at 4 days p.i. with higher doses of GC376 or NPI52 (Fig. 4A to D). It is also important to note that GC376 and NPI52 have much weaker activity against MHV A59 than FCoV in cell culture (EC_{50} are at least 10-fold-higher). Nonetheless, the compounds showed marked antiviral activity against MHV (providing a reduction in the virus load of up to 40-fold) without causing toxicity in mice.

Histopathology examination of liver samples from mice treated with NPI52 or mock treated demonstrated that NPI52 at 100 mg/kg significantly reduced the mean total scores and the mean number of lesions in the livers of mice treated with NPI52 compared to the findings for mice in the no-treatment control group. There was no statistically significant difference in the mean total histopathology scores or the mean number of lesions between the no-treatment control group and the group treated with NPI52 at 10 mg/kg. However, none of the mice in the groups treated with NPI52 had a lesion score of 4 or greater, indicating that NPI52 treatment at both doses inhibited the expansion of the lesions in the liver, since lesions develop as small foci and adjacent foci coalesce to form larger lesions. These *in vivo* results demonstrate that inhibition of coronavirus 3CLpro is a valid therapeutic approach to suppress coronavirus replication and virus-induced pathology.

In summary, we synthesized and tested derivatives of peptidyl compounds that target 3CLpro and identified compounds with dual antiviral activity against FCoV and FCV in cell culture. Their efficacy in a mouse model of coronavirus infection and wide safety margin in cell culture suggest that these compounds may be suitable for further investigation as broad-spectrum antiviral drugs targeting the 3CLpro enzymes of FCoV and FCV.

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Subject: RE: ACTIV Preclinical working group (Tuesday meeting)
Ma et al 2020 BioRxiv Boceprevir GC-376 and calpain inhibitors II XII inhibit SARS-CoV-2 viral replication by targeting the viral main protease.pdf

Thanks Prabha. Here is the recent submission to BioRxiv from Ma et al with the data on SARS-CoV-2 of the compound.

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<austinc@mail.nih.gov>; 'Melencio, Cheryl (FNIH) [T]' <cmelencio@fnih.org>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Desrosiers, Betsy' <elizabeth_desrosiers@merck.com>; 'Jansen, Kathrin' <kathrin.jansen@pfizer.com>; 'Kurilla, Michael (NIH/NCATS) [E]' <michael.kurilla@nih.gov>; 'Lowy, Douglas (NCI)' <dl60z@nih.gov>; 'Read, Sarah (NIH/NIAID) [E]' <readsa@niaid.nih.gov>; 'Tountas, Karen (FNIH) [T]' <ktountas@fnih.org>; 'Santos, Michael (FNIH) [T]' <msantos@fnih.org>; 'Adam, Stacey (FNIH) [T]' <sadam@fnih.org>; 'James, Stephanie (FNIH) [T]' <sjames@fnih.org>; 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>; 'Kim, Elizabeth' <elkim@deloitte.com>; 'Tolman, Brett' <btolman@deloitte.com>; 'Wachtel, Jonathan' <jwachtel@deloitte.com>; 'Prabhavathi Fernandes' <prabha.fernandes@outlook.com>; 'Diamond, Michael' <mdiamond@wustl.edu>; 'Rose Li' <rose.li@roseliassociates.com>; 'Dana Carluccio' <dana.carluccio@roseliassociates.com>; 'Lagos, Enrique (NIH/NCATS) [E]' <enrique.lagos@nih.gov>; 'Jonson, Samantha (NIH/NCATS) [E]' <samantha.jonson@nih.gov>; 'Burrus-Shaw, Cyndi (NIH/OD) [E]' <cyndi.burrus-shaw@nih.gov>; 'Rodriguez, Robin D' <rmdaigle@tulane.edu>; 'Dave Frankowski' <david.frankowski@roseliassociates.com>; 'Baric, Toni C' <antoinette_baric@med.unc.edu>; 'Lowy, Douglas (NIH/NCI) [E]' <lowyd@mail.nih.gov>; 'Florence, Clint (NIH/NIAID) [E]' <clint.florence@nih.gov>; 'Nancy Haigwood' <haigwoon@ohsu.edu>; 'Stratton, Benjamin' <bstratton@DELOITTE.com>
Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

[EXTERNAL]

Hi Joe,
When we prioritize re-purposed drugs..
Should we should include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.
Oral product.
Selectivity index is great..

Attached FYI in case you have not seen.

Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Friday, May 29, 2020 3:25 PM
To: jrappaport@tulane.edu; john.young.jy3@roche.com; david.j.payne@gsk.com; Hild, Sheri (NIH/OD) [E] <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph <rbaric@email.unc.edu>; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Tomas Cihlar <Tomas.Cihlar@gilead.com>; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) <margaret.l.pitt.civ@mail.mil>
Cc: Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Hughes, Eric <eric.hughes@novartis.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; Cutillo, Christine (NIH/NCATS) [E] <cutilloc@mail.nih.gov>; Simon, Dina (NIH/OD) [C] <dina.simon@nih.gov>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Austin, Christopher (NIH/NCATS) [E] <austinc@mail.nih.gov>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Desrosiers, Betsy <elizabeth_desrosiers@merck.com>; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Kurilla, Michael (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas (NCI) <dl60z@nih.gov>; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Tountas, Karen (FNIH) [T] <ktountas@fnih.org>; Santos, Michael (FNIH) [T] <msantos@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; James, Stephanie (FNIH) [T] <sjames@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kim, Elizabeth <elkim@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes <prabha.fernandes@outlook.com>; Diamond, Michael <mdiamond@wustl.edu>; Rose Li <rose.li@roseliassociates.com>; Dana Carluccio <dana.carluccio@roseliassociates.com>; Lagos, Enrique (NIH/NCATS) [E] <enrique.lagos@nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Burrus-Shaw, Cyndi (NIH/OD) [E] <cyndi.burrus-shaw@nih.gov>; Rodriguez, Robin D <rmdaigle@tulane.edu>; Dave Frankowski <david.frankowski@roseliassociates.com>; Baric, Toni C <antoinette_baric@med.unc.edu>; Lowy, Douglas (NIH/NCI) [E] <lowyd@mail.nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Nancy Haigwood <haigwoon@ohsu.edu>;

Stratton, Benjamin <bstratton@DELOITTE.com>
Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, April 14, 2020 6:43 PM
To: jrappaport@tulane.edu; john.young.jy3@roche.com; david.j.payne@gsk.com; Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; rbaric@email.unc.edu; prabha.fernandes@gmail.com; ottingerea@mail.nih.gov; ccolvis@mail.nih.gov; jh18v@nih.gov; Damon.Deming@fda.hhs.gov; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
Subject: ACTIV Preclinical working group (Tuesday meeting)
When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Meeting ID: 960 4240 3854
Password: 124630
One tap mobile
+13017158592,,96042403854#,,1#,124630# US (Germantown)
+13126266799,,96042403854#,,1#,124630# US (Chicago)

Dial by your location
- +1 301 715 8592 US (Germantown)
- +1 312 626 6799 US (Chicago)
- +1 646 876 9923 US (New York)
- +1 408 638 0968 US (San Jose)
- +1 669 900 6833 US (San Jose)
- +1 253 215 8782 US (Tacoma)
- +1 346 248 7799 US (Houston)

Meeting ID: 960 4240 3854
Password: 124630
Find your local number: https://fnih.zoom.us/u/aemFGSQrl

Boceprevir, GC-376, and calpain inhibitors II, XII inhibit SARS-CoV-2 viral replication by targeting the viral main protease

Chunlong Ma,[1] Michael D. Sacco,[2] Brett Hurst,[3,4] Julia A. Townsend,[5] Yanmei Hu,[1] Tommy Szeto,[1] Xiujun Zhang,[2] Bart Tarbet,[3,4] Michael T. Marty,[5] Yu Chen,[2,*] Jun Wang[1,*]

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Keywords: SARS-CoV-2, COVID-19, main protease, 3CL protease, calpain inhibitors, boceprevir, GC-376

A novel coronavirus SARS-CoV-2, also called novel coronavirus 2019 (nCoV-19), started to circulate among humans around December 2019, and it is now widespread as a global pandemic. The disease caused by SARS-CoV-2 virus is called COVID-19, which is highly contagious and has an overall mortality rate of 6.96% as of May 4, 2020. There is no vaccine or antiviral available for SARS-CoV-2. In this study, we report our discovery of inhibitors targeting the SARS-CoV-2 main protease (M^{pro}). Using the FRET-based enzymatic assay, several inhibitors including boceprevir, GC-376, and calpain inhibitors II, and XII were identified to have potent activity with single-digit to submicromolar IC_{50} values in the enzymatic assay. The mechanism of action of the hits was further characterized using enzyme kinetic studies, thermal shift binding assays, and native mass spectrometry. Significantly, four compounds (boceprevir, GC-376, calpain inhibitors II and XII) inhibit SARS-CoV-2 viral replication in cell culture with EC_{50} values ranging from 0.49 to 3.37 μM. Notably, boceprevir, calpain inhibitors II and XII represent novel chemotypes that are distinct from known M^{pro} inhibitors. A complex crystal structure of SARS-CoV-2 M^{pro} with GC-376, determined at 2.15 Å resolution with three monomers per asymmetric unit, revealed two unique binding configurations, shedding light on the molecular interactions and protein conformational flexibility underlying substrate and inhibitor binding by M^{pro}. Overall, the compounds identified herein provide promising starting points for the further development of SARS-CoV-2 therapeutics.

INTRODUCTION

An emerging respiratory disease COVID-19 started to circulate among human in December 2019. Since its first outbreak in China from an unknown origin, it quickly became a global pandemic. As of May 4, 2020, there are 239,740 deaths among 3,442,234 confirmed cases in 215 countries.[1] The etiological pathogen of COVID-19 is a new coronavirus, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), also called novel coronavirus (nCoV-2019). As the name indicates, SARS-CoV-2 is similar to SARS, the virus that causes severe respiratory symptoms in human and killed 774 people among 8098 infected worldwide in 2003.[2] SARS-CoV-2 shares ~82% of sequence identity as SARS and to a less extent for Middle East respiratory syndrome (MERS) (~50%).[3, 4] SARS-CoV-2 is an enveloped, positive-sense, single-stranded RNA virus that belongs to the β-lineage of the coronavirus.[5] The β-lineage also contains two other important human pathogens, the SARS coronavirus and MERS coronavirus. The mortality rate of SARS-CoV-2 is around 6.96% as of May 4, 2020, which is lower than that of SARS (~10%) and MERS (~34%).[2] However, current data indicate that SARS-CoV-2 is more contagious and has a larger R0 value than SARS and MERS,[6] resulting in higher overall death tolls than SARS and MERS. The SARS-CoV-2 virus is currently spreading at an alarming speed in Europe and the United States.

There is currently no antiviral or vaccine for SARS-CoV-2. The SARS-CoV-2 viral genome encodes a number of structural proteins (e.g. capsid spike glycoprotein), non-structural proteins (e.g. 3-chymotrypsin-like protease (3CL or main protease), papain-like protease, helicase, and RNA-dependent RNA polymerase), and accessary proteins. Compounds that target anyone of these viral proteins might be potential antiviral drug candidates.[7, 8] In this study, we focus on the viral 3CL protease, also called the main protease (M^{pro}), and aim to develop potent M^{pro}

inhibitors as SAR-CoV-2 antivirals. The M^{pro} plays an essential role in coronavirus replication by digesting the viral polyproteins at more than 11 sites, and it appears like a high profile target for antiviral drug discovery.[9-12] The M^{pro} has an unique substrate preference for glutamine at the P1 site (Leu-Gln↓(Ser,Ala,Gly)), a feature that is absent in closely related host proteases, suggesting it is feasible to achieve high selectivity by targeting viral M^{pro}. As such, we developed the Fluorescence Resonance Energy Transfer (FRET)-based enzymatic assay for the SARS-CoV-2 M^{pro} and applied it to screen a focused library of protease inhibitors. Here we report our findings of several novel hits targeting SARS-CoV-2 M^{pro} and their mechanism of action. The in vitro antiviral activity of the hits was also evaluated in cell culture using infectious SARS-CoV-2 virus. Overall, our study provides a list of drug candidates for SARS-CoV-2 with a confirmed mechanism of action, and the results might help speed up the drug discovery efforts in combating COVID-19. The compounds identified herein represent one of the most potent and selective SARS-CoV-2 M^{pro} inhibitors so far with both enzymatic inhibition and cellular antiviral activity.[9, 11, 12] The X-ray crystal structure of SARS-CoV-2 M^{pro} with GC-376 showed that the compound can adapt two configurations R and S, offering a molecular explanation of the high-binding affinity of the aldehyde-containing inhibitors. Significantly, the discovery of calpain II and XII inhibitors as potent SARS-CoV-2 antivirals suggest that it might be feasible to design dual inhibitors against the viral M^{pro} and the host calpains, both of which are important for viral replication.

RESULTS

Establishing the FRET-based assay for the SARS-CoV-2 main protease (M^{pro})

The M^{pro} gene from SARS-CoV-2 strain BetaCoV/Wuhan/WIV04/2019 was inserted into pET-29a(+) vector and expressed in BL21(DE3) *E. Coli.* with a His-tag in its C-terminus. The M^{pro} protein was purified with Ni-NTA column to high purity (Fig. 1A). To establish the FRET assay condition, we designed a FRET based substrate using the sequence between viral polypeptide NSP4-NSP5 junction from SARS-CoV-2: Dabcyl-KTSAVLQ/SGFRKME(Edans). We then tested the M^{pro} proteolytic activity in buffers with different pH. We found that M^{pro} displays highest activity in pH 6.5 buffer (Fig. 1B), which contains 20 mM HEPES, 120 mM NaCl, 0.4 mM EDTA, and 4 mM DTT and 20% glycerol. As such, all the following proteolytic assay was conducted using this pH 6.5 buffer. Next, we characterized the enzymatic activity of this SARS-CoV-2 M^{pro} by measuring the K_m and V_{max} values. When 100 nM M^{pro} was mixed with various concentration of FRET substrate (0 to 200 μM), the initial velocity was measured and plotted against substrate concentration. Curve fitting with Michaelis-Menton equation gave the best-fit values of K_m and V_{max} as 32.8 ± 3.5 μM and 29.4 ± 1.1 RFU/s, respectively (Fig. 1C).

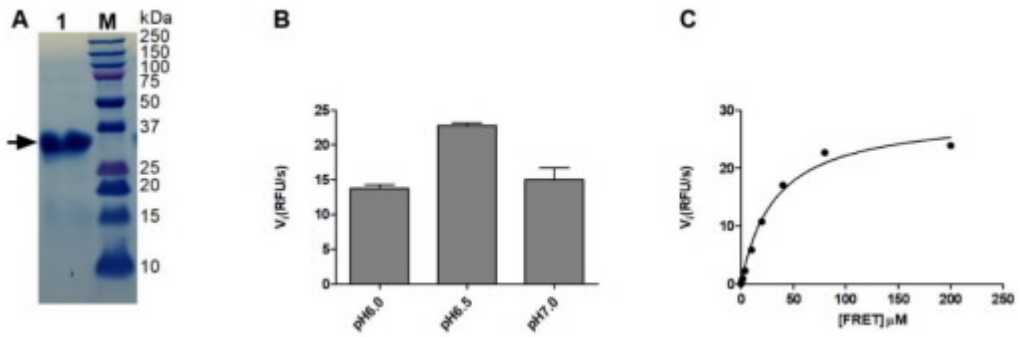


Figure 1: SARS-CoV-2 M^{pro} expression and characterization. (A) SDS-PAGE of His-tagged-Main protease (M^{pro}) (lane 1); Lane M, protein ladder; the calculated molecular weight of the His-tagged-M^{pro} is 34,992 Da. (B) Reaction buffer optimization: 250 nM His-tagged-M^{pro} was diluted into three reaction buffers with different pH values. (C) Michaelis-Menten plot of

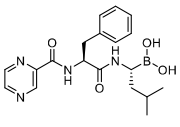
100 nM His-tagged- M^{pro} with the various concentrations of FRET substrate in pH 6.5 reaction buffer.

Primary screening of a focused protease library against the SARS-CoV-2 M^{pro}.

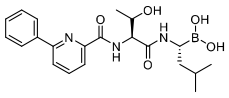
With the established FRET assay condition, we screened a collection of protease inhibitors from the Selleckchem bioactive compound library to identify potential SARS-CoV-2 M^{pro} inhibitors. The protease inhibitors are grouped based on their targets and mechanism of action and include proteasome inhibitors (**1**-**8**); HIV protease inhibitors (**9**-**14**); γ-secretase inhibitors (**15**-**22**); HCV NS3-4A protease inhibitors (**23**-**29**); DPP-4 inhibitors (**30**-**35**); miscellaneous serine protease inhibitors (**36**-**39**); cathepsin and calpain protease inhibitors (**40**-**43**); miscellaneous cysteine protease inhibitors (**44**-**48**); matrix metalloprotease inhibitors (**49**-**51**); and miscellaneous protease inhibitors (**52**-**55**). The inhibitors were pre-incubated with 100 nM of M^{pro} at 30 °C for 30 minutes in the presence of 4 mM 1,4-dithiothreitol (DTT) before the addition of 10 μM FRET substrate. The addition of DTT was to quench non-specific thiol reactive compounds and to ensure the M^{pro} is in the reducing condition. All compounds were tested at 20 μM, except compound **26**, which was tested at 2 μM due to its fluorescent background. Encouragingly, four inhibitors (**24**, **28**, **29** and **43**) showed more than 60% inhibition against M^{pro} at 20 μM. Among the hits, simeprevir (**24**), boceprevir (**28**), and narlaprevir (**29**) are HCV NS3-4A serine protease inhibitors, and compound MG-132 (**43**) inhibits both proteasome and calpain.

Table 1. List of protease inhibitors tested against SARS-CoV-2 M^{pro} in the primary FRET assay.

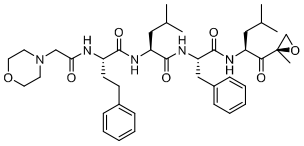
Proteosome inhibitors



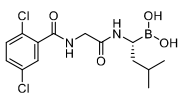
Bortezomib (PS-341) (**1**)



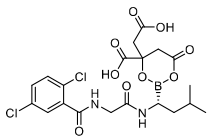
CEP-18770 (Delanzomib) (**2**)



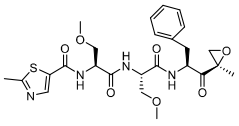
Carfilzomib (PR-171) (**3**)



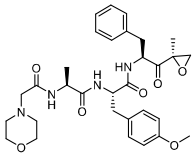
MLN2238 (**4**)



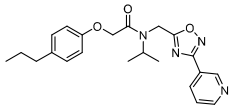
MLN9708 (**5**)



Oprozomib (ONX 0912) (**6**)

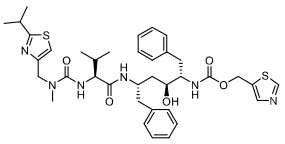


ONX-0914 (PR-957) (**7**)

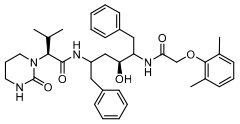


PI-1840 (**8**)

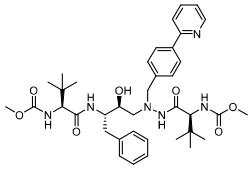
HIV protease (aspartic protease) inhibitors



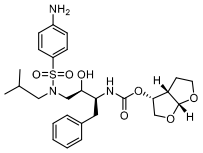
Ritonavir (**9**)



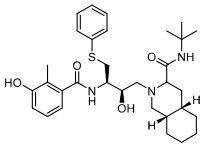
Lopinavir (**10**)



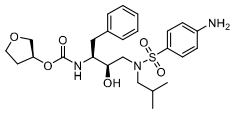
Atazanavir (**11**)



Darunavir (**12**)

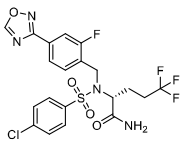


Nelfinavir (**13**)

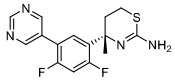


Amprenavir (**14**)

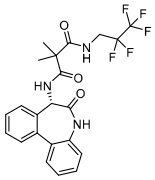
γ-secretase (aspartic protease) inhibitors



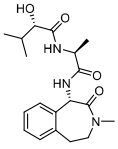
Avagacestat (**15**)



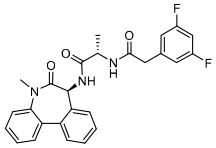
LY2811376 (**16**)



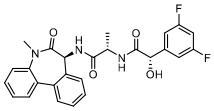
RO4929097 (**17**)



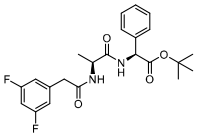
Semagacestat (LY450139) (**18**)



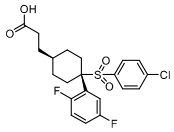
YO-01027 (**19**)



LY411575 (**20**)

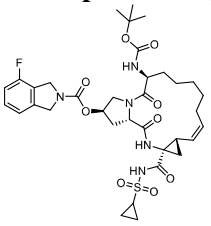


DAPT (GSI-IX) (**21**)

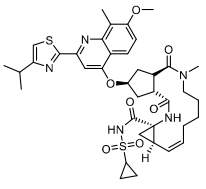


MK-0752 (**22**)

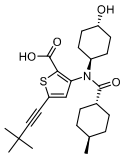
HCV protease (serine protease) inhibitors



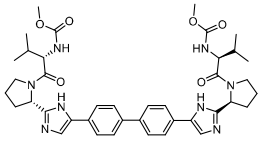
Danoprevir (**23**)



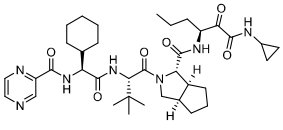
Simeprevir (**24**)



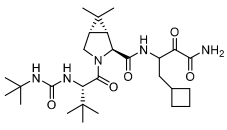
Lomibuvir (VX-222) (**25**)



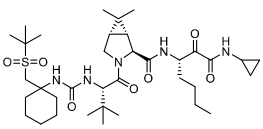
Daclatasvir (BMS-790052) (**26**)



Telaprevir (**27**)

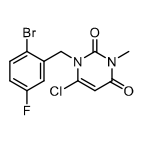


Boceprevir (**28**)

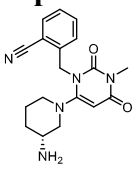


Narlaprevir (**29**)

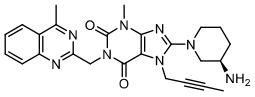
DPP-4 (serine protease) inhibitors



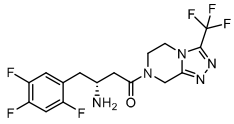
Trelagliptin (**30**)



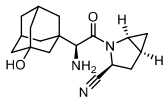
Alogliptin (**31**)



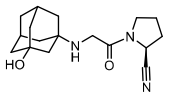
Linagliptin (**32**)



Sitagliptin (**33**)

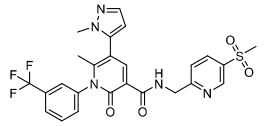


Saxagliptin (**34**)

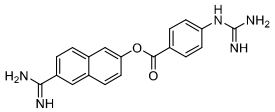


Vildagliptin (**35**)

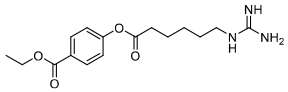
Miscellaneous serine protease inhibitors



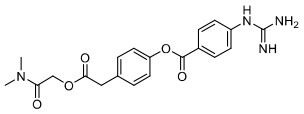
Alvelestat (**36**)



Nafamostat Mesylate (**37**)

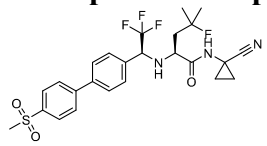


Gabexate (**38**)

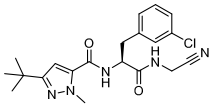


Camostat Mesilate (**39**)

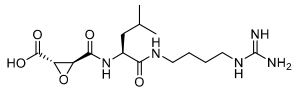
Cathepsin and calpain protease (cysteine protease) inhibitors



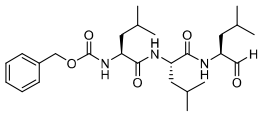
Odanacatib (MK-0822) (**40**)



Cathepsin Inhibitor **1** (**41**)

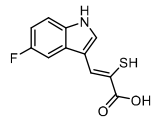


E-64 (**42**)

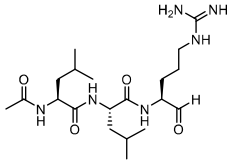


MG-132 (**43**)

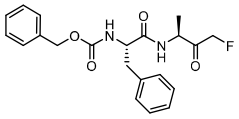
Miscellaneous cysteine protease inhibitors



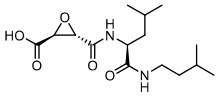
PD151746 (**44**)



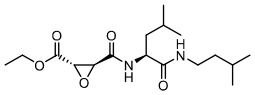
Leupeptin (**45**)



Z-FA-FMK (**46**)

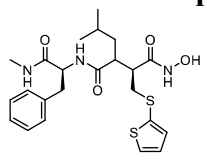


Loxistatin Acid (**47**)

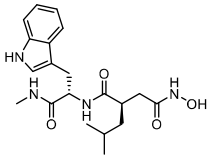


Aloxistatin (**48**)

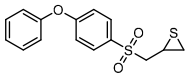
Matrix metallprotease inhibitors



Batimastat (BB-94) (**49**)

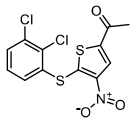


Ilomastat (**50**)

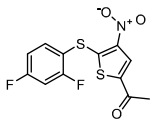


SB-3CT (**51**)

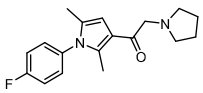
Miscellaneous protease inhibitors



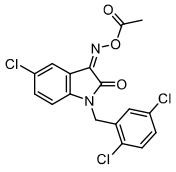
P5091 (P005091) (**52**)



P22077 (**53**)



IU1 S7134 (**54**)



LDN-57444 (**55**)

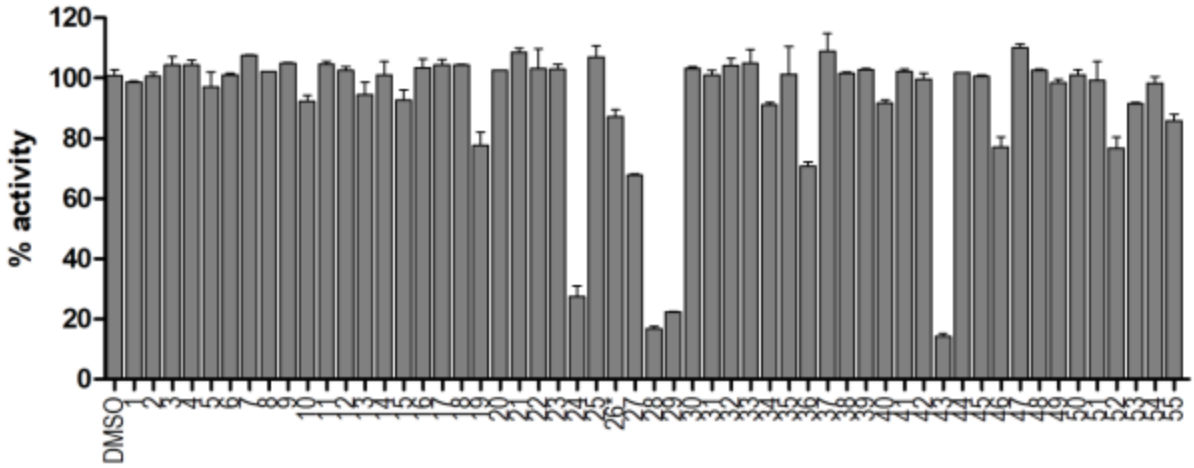


Figure 2: Screening of known protease inhibitors against SARS-CoV-2 M^{pro} using the FRET assay. 20 μM of compounds (**26** was tested at 2 μM) was pre-incubated with 100 nM of SARS-CoV-2 M^{pro} for 30 minutes at 30 °C, then 10 μM FRET substrate was added to reaction mixture to initiate the reaction. The reaction was monitored for 2 hours. The initial velocity was calculated by linear regression using the data points from the first 15 minutes of the reaction. The calculated initial velocity with each compound was normalized to DMSO control. The results are average ± standard deviation of two repeats.

Secondary screening of a focused library of calpain/cathepsin inhibitors and known viral 3CL^{pro} inhibitors

Given the encouraging results from the primary screening, we then further characterized the four hits (**24**, **28**, **29**, and **43**) in a consortium of assays including dose-response titration, thermal shift binding assay (TSA), and counter screening assays with two other viral cysteine proteases, the enterovirus A71 (EV-A71) 2A and 3C proteases, both of which are cysteine proteases (Table 2). The HCV NS3-4A protease inhibitors boceprevir (**28**) and narlaprevir (**29**) inhibited M^{pro} with IC_{50} values of 4.13 and 4.73 μM, respectively (Table 2), more potent than simeprevir (**24**) (IC_{50} =

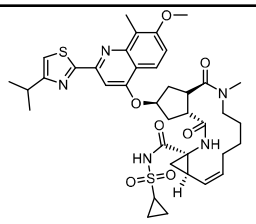
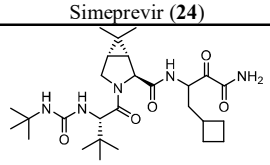
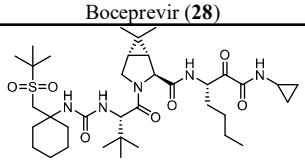
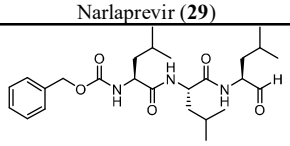
13.74 μM). Both compounds **28** and **29** also showed strong binding towards M^{pro} and shifted the melting temperature of the protein (ΔT_m) by 6.67 and 5.18 °C, respectively, at 40 μM. Despite their potent inhibition against the HCV NS3-4A serine protease and the SARS-CoV-2 cysteine M^{pro}, boceprevir (**28**) and narlaprevir (**29**) did not inhibit the EV-A71 2A and 3C proteases (IC_{50} > 20 μM), suggesting they are not non-specific cysteine protease inhibitors. The calpain inhibitor MG-132 (**43**) had an IC_{50} value of 3.90 μM against the M^{pro}, and was not active against the EV-A71 2A and 3C proteases (IC_{50} > 20 μM). The binding of MG-132 (**43**) to M^{pro} was also confirmed in the TSA assay with a ΔT_m of 4.02 °C.

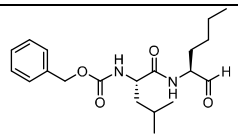
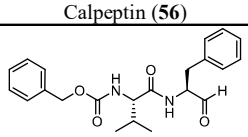
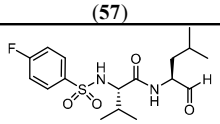
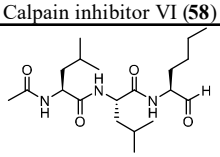
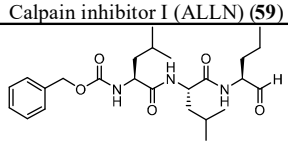
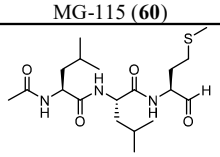
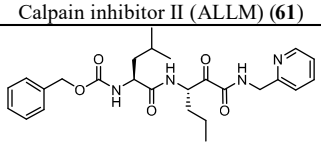
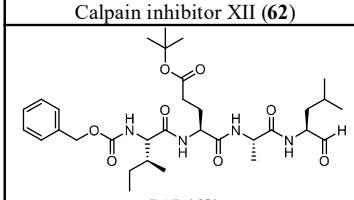
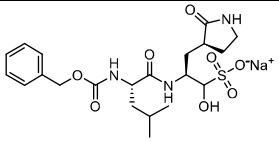
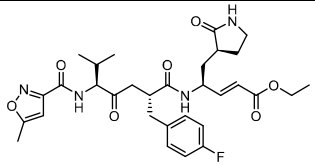
In light of the promising results of the calpain inhibitor MG-132 (**43**), we then pursued to testing other calpain and cathepsin inhibitors that are commercially available (**56-63**) (Table 2). These compounds were not included in the initial library because they have not been advanced to clinical studies. Among this series of analogs, calpain inhibitor II (**61**) and XII (**62**) are the most potent M^{pro} inhibitors with IC_{50} values of 0.97 and 0.45 μM, respectively. Binding of compounds **61** and **62** to M^{pro} shifted the melting curve of the protein by 6.65 and 7.86 °C, respectively. Encouragingly, both compounds **61** and **62** did not inhibit the EV-A71 2A and 3C proteases (IC_{50} > 20 μM). Calpain inhibitor I (**59**) and MG-115 (**60**) also showed potent inhibition against M^{pro} with IC_{50} values of 8.60 and 3.14 μM, respectively. Calpeptin (**56**) and PSI (**63**) had moderate activity against M^{pro} with IC_{50} values of 10.69 and 10.38 μM, respectively. In contrast, calpain inhibitors III (**57**) and VI (**58**) were not active (IC_{50} > 20 μM).

We also included two well-known viral 3CL protease inhibitors GC-376 (**64**) and rupintrivir (**65**) in the secondary screening. GC-376 (**64**) is an investigational veterinary drug that is being developed for feline infectious peritonitis (FIP).[13, 14] GC-376 (**64**) was designed to target the viral 3CL protease and had potent antiviral activity against multiple viruses including MERS, FIPV,

and norovirus.[13, 15] Rupintrivir (**65**) was developed as a rhinovirus antiviral by targeting the viral 3CL protease, but it was discontinued in clinical trials due to side effects.[16] In our study, we found that GC-376 (**64**) was the most potent M^{pro} inhibitor with an IC_{50} value of 0.03 μM. It shifted the melting curve of M^{pro} by 18.30 ºC upon binding. In contrast, rupintrivir (**65**) was not active against M^{pro} (IC_{50} > 20 μM). Previous report also showed that rupintrivir was not active against the SARS-CoV $3CL^{pro}$ (M^{pro}) (IC_{50} > 100 μM).[17] Both compounds **64** and **65** were not active against the EV-A71 2A protease, but showed potent inhibition against the EV-A71 3C protease, which is consistent with previously reported results.[15, 18, 19]

Table 2: Characterization of HCV and calpain proteases inhibitors against SARS-CoV-2 M^{pro} using a consortium of secondary assays[a]

ID / Results	SARS-CoV-2 M^{pro} IC_{50} (μM)	SARS-CoV-2 M^{pro} TSA Tm/ΔTm (°C)	EV-A71 2A IC_{50} (μM)	EV-A71 3C IC_{50} (μM)	Development stage
DMSO	--------	55.74 ± 0.00	------	-------	
 Simeprevir (**24**)	13.74 ± 3.45	N.T.[b]	N.T.	N.T.	FDA-approved HCV drug
 Boceprevir (**28**)	4.13 ± 0.61	62.41 ± 0.21/6.67	>20	>20	FDA-approved HCV drug
 Narlaprevir (**29**)	5.73 ± 0.67	60.92 ± 0.14/5.18	>20	>20	FDA-approved HCV drug
 MG-132 (ApexBio) (**43**)	3.90 ± 1.01	59.76 ± 0.45/4.02	>20	>20	Preclinical; tested in mice[20]

 Calpeptin (**56**)	10.69 ± 2.77	56.84 ± 0.00/1.1	>20	>20	Preclinical; tested in mice and felines[21, 22]
 Calpain inhibitor III (MDL28170) (**57**)	>20	55.36 ± 0.14/-0.38	N.T.	N.T.	Preclinical; not tested in animal model
 Calpain inhibitor VI (**58**)	>20	55.46 ± 0.14/-0.28	N.T.	>20	Preclinical; tested in rats[23]
 Calpain inhibitor I (ALLN) (**59**)	8.60 ± 1.46	N.T.	>20	>20	Preclinical; tested in mice[24]
 MG-115 (**60**)	3.14 ± 0.97	60.51 ± 0.28/4.77	>20	>20	Preclinical; not tested in animal model
 Calpain inhibitor II (ALLM) (**61**)	0.97 ± 0.27	62.93 ± 0.14/6.65	>20	>20	Preclinical; not tested in animal model
 Calpain inhibitor XII (**62**)	0.45 ± 0.06	63.60 ± 0.01/7.86	>20	>20	Preclinical; not tested in animal model
 PSI (**63**)	10.38 ± 2.90[c]	N.T.	1.22	13.74 ± 3.86	Preclinical; tested in rats[25]
 GC376 (more reliable) (**64**)	0.030 ± 0.008	74.04 ± 0.07/18.30	>20	0.136 ± 0.025	Preclinical; tested in felines[13, 14]
 Rupintrivir (**65**)	> 20	N.T.	>20	0.042 ± 0.014	Dropped out of clinical trial

a: Value = mean ± S.E. from 3 independent experiments;

b: N.T. = not tested;

c: The IC_{50} of PSI (**64**) on SARS CoV-2 M^{pro} was calculated by end point reading of 1 hour digestion, instead of the initial velocity.

When plotting the IC_{50} values (log scale) of the inhibitors against M^{pro} from the FRET enzymatic assay with the melting temperature shifts (ΔT_m) from thermal shift binding assay (Fig. 3A), a linear correlation was observed, and the r^2 of the linear regression fitting is 0.94. This suggests that there is a direct correlation between the enzymatic inhibition and protein binding: a more potent enzyme inhibitor also binds to the protein with higher affinity. The stabilization of the M^{pro} against thermal denaturation was also compound concentration dependent (Fig. 3B).

The binding of four most potent inhibitors boceprevir (**28**), calpain inhibitors II (**61**), XII (**62**), and GC-376 (**64**) to SARS-CoV-2 M^{pro} was further characterized by native mass spectrometry (MS) (Figs. 3C-F). Native MS analysis showed that the M^{pro} formed a dimer complex with a mass of 69,722 Da, indicating a cleaved N-terminal methionine (Fig. S1). A small amount of monomer and dimer with a single C-terminal truncation of the His-tag was also observed, but the intact dimer was the predominant signal (Fig. S1). Addition of all four ligands tested, boceprevir (**28**), calpain inhibitors II (**61**), XII (**62**), and GC-376 (**64**), showed binding of up to two ligands per dimer (Fig. 3C-F), suggesting a binding stoichiometry of one drug per monomer.

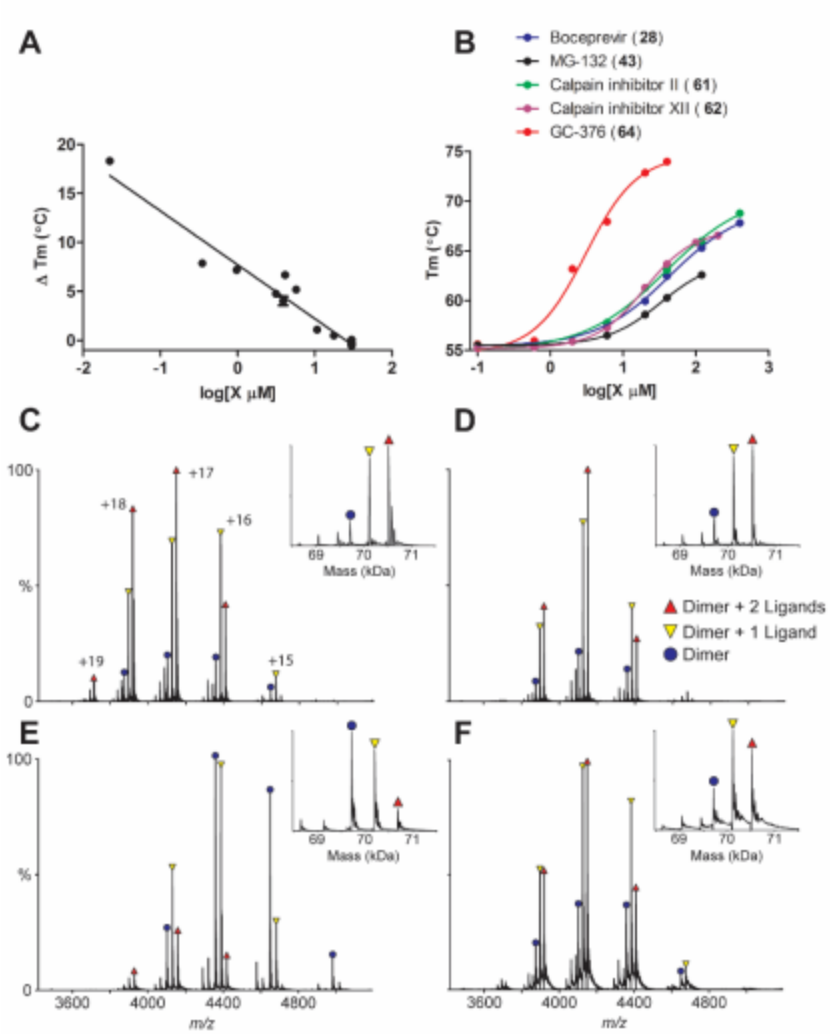


Figure 3: Binding of inhibitors to SARS-CoV-2 M^{pro} using thermal shift binding assay and native mass spectrometry. (A) Correlation of inhibition efficacy (IC_{50}) with ΔT_m from thermal shift binding assay. Data in Table 2 were used for the plot. The r^2 of fitting is 0.94. (B) Dose-dependent melting temperature (T_m) shift. Native MS reveals binding of SARS-CoV-2 M^{pro} to (C) GC-376 (**64**), (D) Calpain inhibitor II (**61**), (E) calpain inhibitor XII (**62**), and (F) Boceprevir (**28**). All ligand concentrations are 12.5 μM except E, which is 25 μM. Peak are annotated for dimer (*blue circle*), dimer with one bound ligand, (*yellow down triangle*), and dimer with two bound ligands (*red up triangle*). Other minor signals are truncated dimers, which bind ligands at

the same ratios. Charge states are annotated in C, and insets show the deconvolved zero-charge mass distribution.

Mechanism of action of hits

To elucidate the mechanism of action of hits against SARS-CoV-2 M^{pro}, we focus on five most potent compounds prioritized from the primary and secondary screenings including boceprevir (**28**), MG-132 (**43**), calpain inhibitor II (**61**), calpain inhibitor XII (**62**), and GC-376 (**64**). For this, we performed enzyme kinetic studies with different concentrations of inhibitors (Fig. 4). A biphasic enzymatic progression curve in the presence but not in the absence of inhibitor is typically a hallmark for a slow covalent binding inhibitor. In the Fig. 4, left column shows the progression curves up to 4 hours. Biphasic progression curves were observed for all 5 inhibitors at high drug concentrations. Significant substrate depletion was observed when the proteolytic reaction proceeded beyond 90 minutes, we therefore chose the first 90 minutes of the progression curves for curve fitting (Fig. 4 middle column). We fit the progression curves in the presence different concentrations of GC-376 (**64**) with the two-step Morrison equation (equation 3 in methods section). GC-376 (**64**) binds to SARS-CoV-2 M^{pro} with an equilibrium dissociation constant for the inhibitor (K_I) of 59.9 ± 21.7 nM in the first step. After initial binding, a slower covalent bond is formed between GC-376 (**64**) and M^{pro} with the second reaction rate constant (k_2) being 0.00245 ± 0.00047 s^{-1}, resulting an overall k_2/K_I value of 4.08 x 10^4 M^{-1} s^{-1} (Fig. 4A). However, when we tried to fit the proteolytic progression curves for boceprevir (**28**), MG-132 (**43**), calpain inhibitors II (**61**) and XII (**62**) using the same two-step reaction mechanism, we could not obtain accurate values for the second rate constant k_2. This is presumably due to significant substrate depletion before the equilibrium between EI and EI*, leading to very small values of k_2.

Accordingly, for these four inhibitors **28**, **43**, **61**, and **62**, only the dissociation constant K_I values from the first step were determined (Figs. 4B-4E). The inhibition constants (K_I) for boceprevir (**28**), MG-132 (**43**), calpain inhibitors II (**61**) and XII (**62**) are 1.18 ± 0.10 μM, 1.57 ± 0.13 μM, 0.40 ± 0.02 μM, and 0.13 ± 0.02 μM, respectively.

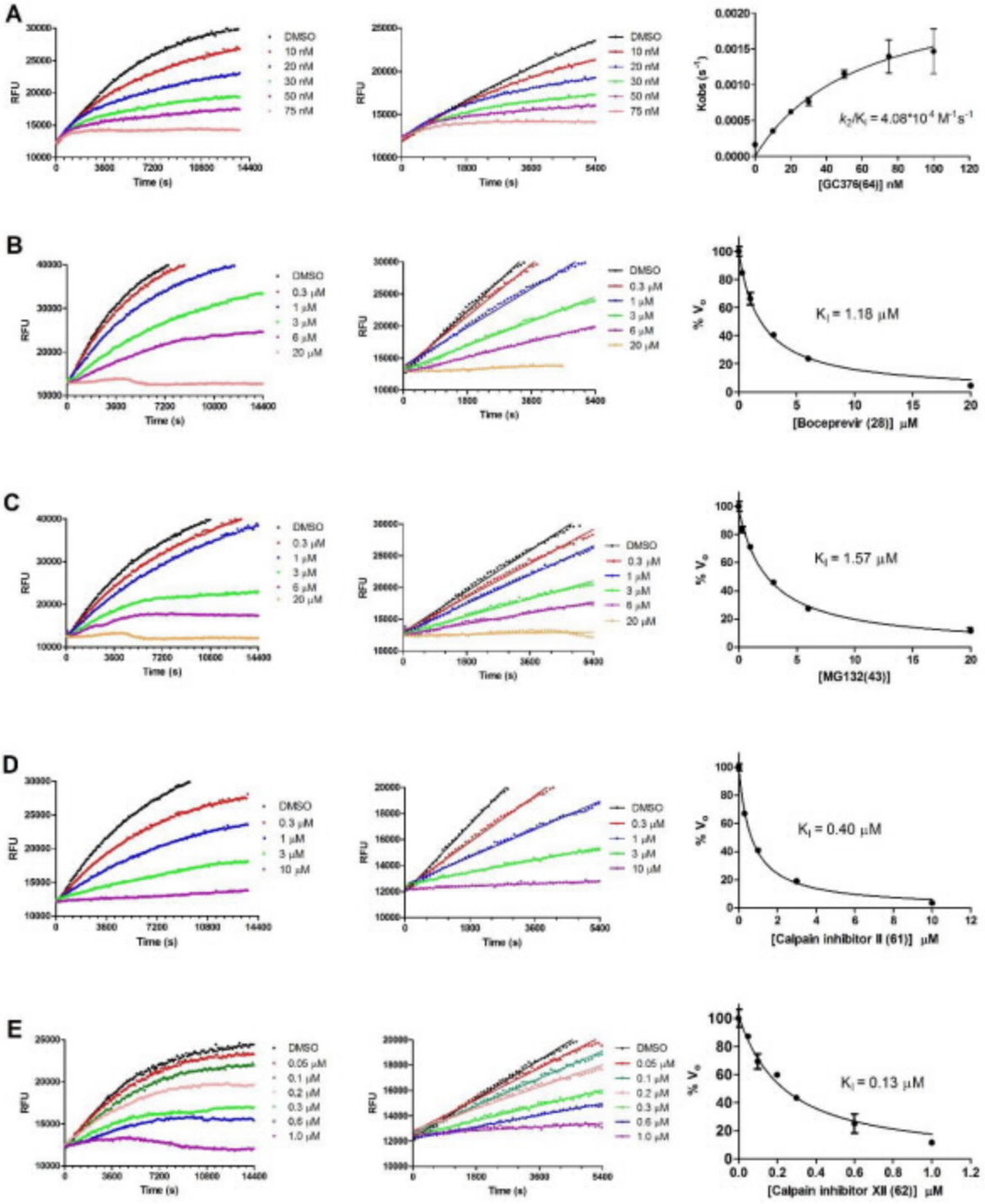


Figure 4: Proteolytic reaction progression curves of M^{pro} in the presence or the absence of compounds. In the kinetic studies, 5 nM M^{pro} was added to a solution containing various concentrations of protease inhibitors and 20 μM FRET substrate to initiate the reaction, the

reaction was then monitored for 4 hrs. Left column shows the reaction progression up to 4 hrs; middle column shows the progression curves for the first 90 minutes, which were used for curve fitting to generate the plot shown in the right column. Detailed methods were described in the Method section. (A) GC-376 (**64**); (B) Boceprevir (**28**); (C) MG-132 (**43**); (D) Calpian inhibitor II (**61**); (E) Calpain inhibitor XII (**62**).

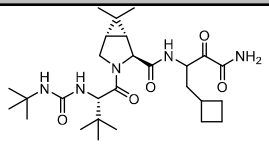
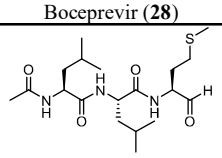
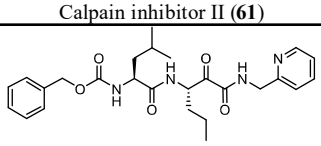
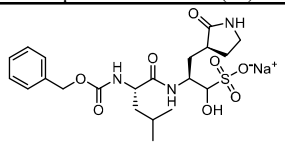
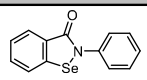
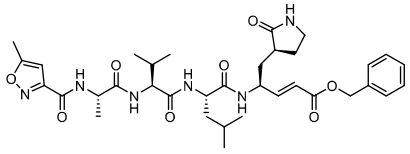
Cellular antiviral activity and cytotoxicity of hits

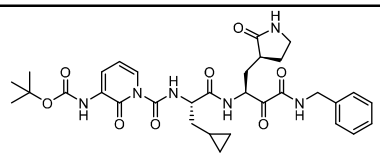
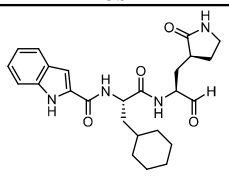
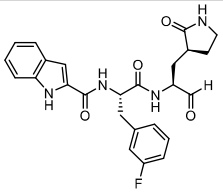
To test the hypothesis that inhibiting the enzymatic activity of M^{pro} will lead to the inhibition of SARS-CoV-2 viral replication, we performed cellular antiviral assays for the five promising hits **64**, **28**, **43**, **61**, and **62** against SARS-CoV-2. For this, we first tested the cellular cytotoxicity of these compounds in multiple cell lines (Table S1). GC-376 (**64**), boceprevir (**28**), and calpain inhibitor II (**61**) were well tolerated and had CC_{50} values of over 100 μM for all the cell lines tested. MG-132 (**43**) was cytotoxic to all the cells with CC_{50} values less than 1 μM except A549 cells. Calpain inhibitor XII (**62**) had acceptable cellular cytotoxicity with CC_{50} values above 50 μM for all the cell lines tested (Table S1).

Next, we chose four compounds boceprevir (**28**), calpain inhibitors II (**61**), XII (**62**), and GC-376 (**64**) for the antiviral assay with infectious SARS-CoV-2. MG-132 (**43**) was not included due to its cytotoxicity. Gratifyingly, all four compounds showed potent antiviral activity against SARS-CoV-2 in the primary viral cytopathic effect (CPE) assay with EC_{50} values ranging from 0.49 to 3.37 μM (Table 3). Their antiviral activity was further confirmed in the secondary viral yield reduction (VYR) assay. The most potent compound was calpain inhibitor XII (**62**), which showed EC_{50} of 0.49 μM in the primary CPE assay and EC_{90} of 0.45 μM in the secondary VYR assay. In comparison, remdesivir was reported to inhibit SARS-CoV-2 in the VYR assay with an

EC_{50} of 0.77 μM.[26] None of the compounds inhibited the unrelated influenza virus A/California/07/2009 (H1N1) virus (EC_{50} > 20 μM) (Table S1), suggesting the antiviral activity of the four compounds (boceprevir, calpain inhibitors II, XII, and GC-376) against SARS-CoV-2 is specific. In comparison with recently reported SARS-CoV-2 M^{pro} inhibitors (Table 3), the hits identified herein represent one of the most potent and selective drug candidates with broad chemical diversity.

Table 3: Antiviral activity of hits against SARS-CoV-2 and the comparison with recently reported M^{pro} inhibitors.

Compounds	SARS-CoV-2 M^{pro} inhibition (μM)	SARS-CoV-2 Antiviral activity (μM) Primary CPE assay[a]	SARS-CoV-2 Antiviral activity (μM) Secondary viral yield reduction assay[a]	Development Stage
SARS-Cov-2 M^{pro} inhibitors identified in this study				
 Boceprevir (**28**)	IC_{50} = 4.13 ± 0.61 K_I = 1.18	EC_{50} = 1.90 CC_{50} > 100 SI_{50} > 52.6	N.T.	FDA-approved HCV drug
 Calpain inhibitor II (**61**)	IC_{50} = 0.97 ± 0.27 K_I = 0.40	EC_{50} = 2.07 ± 0.76 CC_{50} > 100 SI_{50} > 48.3	EC_{90} = 2.40 ± 1.01	Preclinical; not tested in animal model
 Calpain inhibitor XII (**62**)	IC_{50} = 0.45 ± 0.06 K_I = 0.13	EC_{50} = 0.49 ± 0.18 CC_{50} > 100 SI_{50} > 204	EC_{90} = 0.45 ± 0.17	Preclinical; not tested in animal model
 GC-376 (**64**)	IC_{50} = 0.030 ± 0.008 k_2/K_I = 40, 800 $M^{-1}S^{-1}$	EC_{50} = 3.37 ± 1.68 CC_{50} > 100 SI_{50} > 29.7	EC_{90} = 2.13 ± 1.05	Preclinical; tested in felines[13, 14]
Recently reported SARS-Cov-2 M^{pro} inhibitors[b]				
 **Ebselen**[11]	IC_{50} = 0.67 ± 0.09	4.67 ± 0.80	N. A.	In clinical trials
 **N3**[11]	$k_{obs}/[I]$ = 11,300 ± 800 $M^{-1}S^{-1}$	16.77 ± 1.70	N. A.	Preclinical;[27] not tested in animal model

 **13b**[9]	IC_{50} = 0.67 ± 0.18	4 ~ 5	N. A.	Preclinical;[9] not tested in animal model
 **11a**[12]	IC_{50} = 0.053 ± 0.005	0.53 ± 0.01	N. A.	Preclinical;[12] favorable PK in rats and low toxicity in rats and dogs
 **11b**[12]	IC_{50} = 0.040 ± 0.002	0.72 ± 0.09	N. A.	Preclinical;[12] favorable PK in rats

[a]CPE EC_{50}, VYR EC_{90}, and cytotoxicity CC_{50} values are mean ± S.D. of 3 independent experiments. [b]Results were retrieved from recent publications.[9, 11, 12] N.T. = not tested. N. A. = not available

Complex crystal structure of SARS-CoV-2 M^{pro} with GC-376 (64)

The crystal structure of the SARS-CoV-2 M^{pro} in complex with GC-376 (**64**) was solved in the $p3_221$ space group at 2.15 Å resolution (Table S2). There are three monomers per asymmetric unit (ASU), with two constituting a biological dimer and the third forming a dimer with a crystallographic symmetry related neighboring protomer (Fig. S2). The presence of three monomers in our crystal structure allowed us to capture different binding configurations of GC-376 (**64**) (Fig. 5), a unique feature that was not observed in previous X-ray crystal structures [9, 11, 12]. The pairwise r.m.s.d among the monomer backbone C α atoms ranges from 0.435 Å to 0.564 Å. Previously, SARS-CoV M^{pro} and SARS-CoV-2 M^{pro} crystal structures have been solved most frequently as a monomer per ASU, and occasionally a dimer [9, 11, 12, 28, 29]. In its native state, M^{pro} requires dimerization to become catalytically active [30, 31], which is supported by our native MS

data (Fig. S1). In our crystal structures, all three protomers appear catalytically competent, with the third protomer activated by the N-finger from an adjacent asymmetric unit (Fig. S2B).

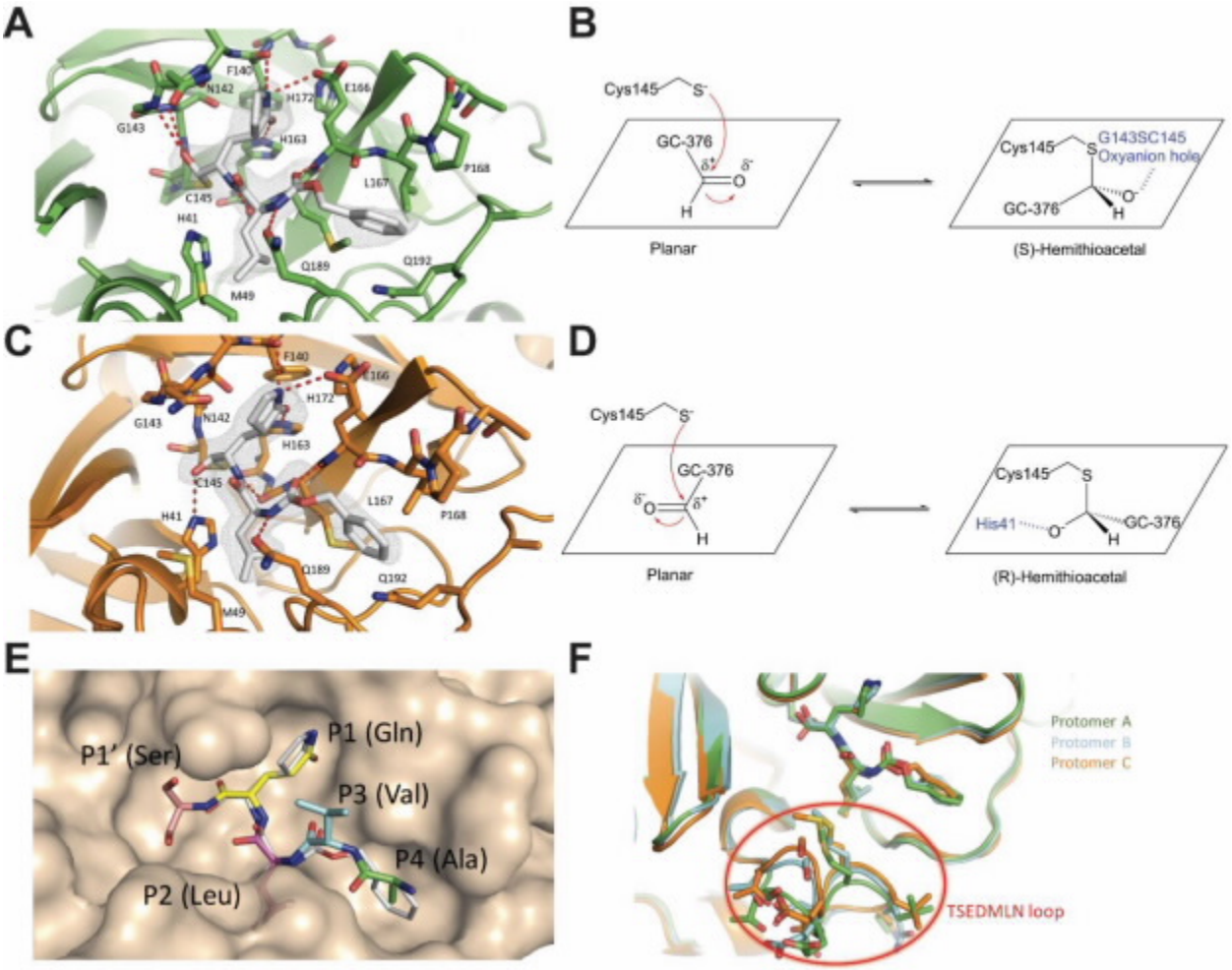


Figure 5: Molecular recognition of GC-376 (64) by SARS-CoV-2 M^{pro}. Complex of SARS-CoV-2 M^{pro} and GC-376 (**64**) with (A, B) protomer A and (C, D) protomer C. Unbiased F_o-F_c map, shown in grey, is contoured at 2 σ. Hydrogen bonds are shown as red dashed lines. (E) Surface representation of SARS-CoV-2 M^{pro} + GC-376 (**64**) (white) superimposed with the SARS-CoV M^{pro} natural, N-terminal substrate (PDB ID 2Q6G, with residues P1'-P4 in different colors). The SARS-CoV-2 M^{pro} cleaves between the P1' and P1 residues. (F) Superimposition of

the three protomers in the asymmetric subunit of SARS-CoV-2 M^{pro} with GC-376 (**64**). Significant conformational flexibility is observed, particularly in the TSEDMLN loop.

GC-376 (**64**) forms an extensive network of hydrogen bonds with the active site while also exhibiting excellent geometric complementarity (Fig. 5). These interactions are coupled with the thermodynamic payoff of covalent adduct formation between the aldehyde bisulfite warhead and Cys145, making GC-376 (**64**) one of the most potent SARS-CoV-2 M^{pro} inhibitors *in vitro* with an IC_{50} of 0.030 ± 0.008 μM (Table 3). Along with other known M^{pro} inhibitors **N3**, **13b**, **11a** and **11b** (Table 3), GC-376 (**64**) mimics the peptide substrate that is cleaved by this enzyme (Fig. 5E) [9, 27, 29, 32]. The glutamine surrogate γ-lactam ring is a cyclized derivative of the P1 glutamine side chain that normally occupies the S1 site; here it forms hydrogen bonds with the His163 and Glu166 side chains and the main chain of Phe140 (Figs. 5A & C). An amide bond connects the γ-lactam side chain to an isobutyl moiety that embeds itself in the hydrophobic S2 site formed by His41, Met49, and Met169. Normally, this S2 site in SARS-CoV-2 M^{pro} can accommodate a variety of hydrophobic substitutions such as isobutyl in GC-376 (**64**) and **N3**, cyclopropyl in **13b**, cyclohexyl in **11a**, and 3-fluorophenyl in **11b** (Table 3) [33, 34]. A carbamate bond in GC-376 (**64**), which forms hydrogen bonds with the main chain of Glu166 and the side chain of Gln189, connects the P2 isobutyl group to a phenylmethyl ester that interacts with the aliphatic S4 site. Compared with previous inhibitors, the phenylmethyl ester of GC-376 exhibits high complementarity with the S4 site, and the extensive non-polar interactions may contribute significantly to the potency of this compound (Fig. 5E).

Three copies of GC-376 (**64**) were found in the crystal structure, one in each protomer active site (Figs. 5A, 5C, S3). The configurations of G-C376 (**64**) were consistent in protomers A and B, where the thioacetal hydroxide is positioned in the "oxyanion hole" formed by the backbone amides of Gly143, Ser144, and Cys145 (Figs. 5A & S3), resulting in the (S)-configuration. It is noted that aldehydes **11a** and **11b** also bind in the active site of SARS-CoV-2 M^{pro} in the (S)-configuration (PDB: 6M0K and 6LZE) (Figs. S4A).[12] In protomer C, however, the same hydroxide group orients outwards from the oxyanion hole, forming hydrogen bonds with His41 (Fig. 5C), which gives the (R)-configuration. This (R)-configuration is consistent with the binding mode of α-ketoamide **13b** in the active site of SARS-CoV-2 M^{pro} (PDB: 6Y2F) (Fig. S4B).[9] These two unique configurations R and S might be a result of the Cys145 thiol nucleophilic attacking the aldehyde from two different faces (Figs. 5B & D). The fact that GC-376 (**64**) can adapt two different configurations R and S upon binding to the active site might explain its high binding affinity towards the target.

An additional difference between the configurations of GC-376 (**64**) in A, B and C is observed in the orientation of the phenylmethyl ester. In protomer C, the CH_2 of the phenylmethyl points towards the main chain of Leu167 in a 'cis' conformation (Fig. 5C), whereas in protomers A and B this same CH_2 points downwards in a 'trans' conformation (Figs. 5A & S3). Consequently, this influences the rotameric configuration of the Leu167 isobutyl moiety, where a rotational adjustment of 180° occurs at its "β" carbon. Furthermore, large rearrangements are observed in the flexible TSEDMLN loop consisting of residues 45-51 (TAEDMLN in SARS-CoV-2 M^{pro}) that form the S2 and S3' subsites (Fig. 5F), explaining the broad substrate scope in the P2 site (Table 3). The loop conformations in protomers B and C may be influenced by crystal packing interactions with protomers from adjacent asymmetric units and

resemble the conformations in previously determined structures [11, 12]. Meanwhile, the conformation of protomer A is less restrained and exhibits the most significant conformational divergence. The different loop conformations offer a glimpse of the protein plasticity that allows M^{pro} to accommodate peptides with differing amino acid composition, and underscores the importance of considering this flexibility when analyzing and modeling protein-ligand interactions for M^{pro}.

DISCUSSION

Coronaviruses have caused three epidemics/pandemics in the past twenty years including SARS, MERS, and COVID-19. With the ongoing pandemic of COVID-19, scientists and researchers around the globe are racing to find effective vaccines and antiviral drugs.[7] The viral polymerase inhibitor remdesivir holds the greatest promise and it is currently being evaluated in several clinical trials.[35, 36] The HIV drug combination lopinavir and ritonavir recently failed in a clinical trial for COVID-19 with no significant therapeutic efficacy was observed.[37] To address this unmet medical need, we initiated a drug repurposing screening to identify potent inhibitors against the SARS-CoV-2 M^{pro} from a collection of FDA-approved protease inhibitors. The M^{pro} has been shown to be a validated antiviral drug target for SARS and MERS.[38] As the SARS-CoV-2 M^{pro} shares a high sequence similarity with SARS and to a less extent with MERS, we reasoned that inhibiting the enzymatic activity of SARS-CoV-2 M^{pro} will similarly prevent viral replication.[9, 11]

Noticeable findings from our study include: 1) Boceprevir (**28**), an FDA-approved HCV drug, inhibits the enzymatic activity of M^{pro} with IC_{50} of 4.13 μM, and has an EC_{50} of 1.90 μM against the SARS-CoV-2 virus in the cellular viral cytopathic effect assay. The therapeutic

potential of boceprevir (**28**) should be further evaluated in relevant animal models and human clinic trials. Since boceprevir (**28**) is a FDA-approved drug, the dose, toxicity, formulation, and pharmacokinetic properties are already known, which will greatly speed up the design of follow up studies; 2) GC-376 (**64**), an investigational veterinary drug, showed promising antiviral activity against the SARS-CoV-2 virus (EC_{50} = 3.37 μM). It has the highest enzymatic inhibition against the M^{pro} with an IC_{50} value of 0.03 μM. This compound has promising in vivo efficacy in treating cats infected with FIP, and has favorable in vivo pharmacokinetic properties. Therefore, GC-376 (**64**) is ready to be tested in relevant animal models of SARS-CoV-2 when available. Importantly, the X-ray crystal structure of SARS-CoV-2 M^{pro} in complex with GC-376 (**64**) provides a molecular explanation of the high binding affinity of aldehyde-containing compounds as they can adapt two configurations R and S. The conformational flexibility at the TSEDMLN loop explains the broad substrate scope at the P2 position of M^{pro} inhibitors; 3) Three calpain/cathepsin inhibitors, MG-132 (**43**), calpain inhibitors II (**61**) and XII (**62**), are potent inhibitors of M^{pro} and inhibit SARS-CoV-2 with single-digit to submicromolar efficacy in the enzymatic assay. Calpain inhibitors II (**61**) and XII (**62**) also inhibit SARS-CoV-2 in the CPE assay with EC_{50} values of 2.07 and 0.49 μM, respectively. This result suggests that calpain/cathepsin inhibitors are rich sources of drug candidates for SARS-CoV-2. Indeed, previous studies have shown that calpain and cathepsin are required for the proteolytic processing of the coronavirus S protein, a step that is essential for the viral fusion and genome release during the early stage of viral replication.[39] Calpain and cathepsin inhibitors such as MDL28170 (calpain inhibitor III)[39], MG-132[40], calpain inhibitor VI[41] have been shown to inhibit SARS-CoV replication in cell culture. Other than the increased potency of targeting both M^{pro} and calpain/cathepsin, an additional benefit of such dual inhibitors might be their high genetic

barrier to drug resistance. A significant number of calpain/cathepsin inhibitors have been developed over the years for various diseases including cancer, neurodegeneration disease, kidney diseases, and ischemia/reperfusion injury.[42] Given our promising results of calpain inhibitors II (**61**) and XII (**62**) in inhibiting the SARS-CoV-2 M^{pro} and their potent antiviral activity in cell culture, it might be worthwhile to repurposing them as antivirals for SARS-CoV-2.

All potent SARS-CoV-2 M^{pro} inhibitors contain reactive warheads such as α-ketoamide (boceprevir (**28**), calpain inhibitor XII (**62**)) or aldehyde (MG-132 (**43**), calpain inhibitor II (**61**)) or aldehyde prodrug, the bisulfite (GC-376 (**64**)). This result suggests that reactive warheads might be essential for SARS-CoV-2 M^{pro} inhibition. The compounds identified in this study represent one of the most potent and selective hits reported so far, and are superior than recently reported SARS-CoV-2 M^{pro} inhibitors **ebselen**, **N3**, and **13b** (Table 3). Calpain inhibitor XII (**62**) had similar potency as the recently disclosed compounds **11a** and **11b** (Table 3).[12] Notably, calpain inhibitor II (**61**) and XII (**62**) have different chemical scaffolds as GC-376 (**64**), **N3**, **13b**, **11a**, and **11b**, therefore providing new opportunities for designing more potent and selective SARS-CoV-2 M^{pro} inhibitors.

Aside from the above positive results, we also showed that ritonavir (**9**) and lopinavir (**10**) failed to inhibit the SARS-CoV-2 M^{pro} (IC_{50} > 20 μM, Fig. 2), which might explain their lack efficacy in clinical trials for COVID-19.[37] Camostat (**39**) was recently proposed to inhibit SARS-CoV-2 entry through inhibiting the host TMPRSS2, a host serine protease that is important for viral S protein priming.[43] However, the antiviral activity of camostat has not been confirmed with infectious SARS-CoV-2 virus. In our study, we found camostat (**39**) has no inhibition against the SARS-CoV-2 M^{pro} (IC_{50} > 20 μM).

In summary, this study identified several potent SARS-CoV-2 M^{pro} inhibitors with potent enzymatic inhibition as well as cellular antiviral activity. Further development based on these hits might lead to clinically useful COVID-19 antivirals. They can be used either alone or in combination with polymerase inhibitors such as remdesivir as a means to achieve potential synergic antiviral effect as well as to suppress drug resistance.

MATERIALS AND METHODS

Details of materials and methods can be found in the supporting information.

DATA AVAILABILITY. The structure for SARS-CoV-2 Mpro has been deposited in the Protein Data Bank with accession number 6WTT.

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This research was partially supported by the National Institutes of Health (NIH) (Grant AI147325) and the Arizona Biomedical Research Centre Young Investigator grant (ADHS18-198859) to J. W. B. H. and B. T. thanks for the support from the Respiratory Diseases Branch, National Institute of Allergy and Infectious Diseases, NIH, USA (Contract N01-AI-30048). J. A. T. and M. T. M. were funded by the National Institute of General Medical Sciences and National Institutes of Health (Grant R35 GM128624 to M. T. M.). We thank Michael Kemp for assistance with crystallization and X-ray diffraction data collection. We also thank the staff members of the Advanced Photon Source of Argonne National Laboratory, particularly those at the Structural Biology Center (SBC), with X-ray diffraction data collection. SBC-CAT is operated by UChicago Argonne, LLC, for the U.S. Department of Energy, Office of Biological and Environmental Research under contract DE-AC02-06CH11357.

AUTHOR CONTRIBUTIONS

J. W. and C. M. conceived and designed the study; C. M. expressed the M^{pro} with the assistance of T. S.; C.M. performed the primary screening, secondary IC_{50} determination, thermal shift-binding assay, and enzymatic kinetic studies; M. S. carried out M^{pro} crystallization and structure determination with the assistance of X. Z, and analyzed the data with Y. C.; B. H. and B. T. performed the SARS-CoV-2 CPE and VYR assay; J .A. T. performed the native mass spectrometry experiments with the guidance from M. T. M.; Y. H. performed the plaque reduction assay with influenza A/California/07/2009 (H1N1) virus; J. W. and Y. C. secured funding and supervised the study; J. W., Y.C., and C. M. wrote the manuscript with the input from others.

ADDITIONAL INFORMATION

Supplementary information accompanies this paper at

Competing interests

J. W. and C. M. are inventors of a pending patent that claims the use of the identified compounds for COVID-19.

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Supporting information

Boceprevir, GC-376, and calpain inhibitors II, XII inhibit SARS-CoV-2 viral replication by targeting the viral main protease

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MATERIALS AND METHODS

Cell lines and viruses. Human rhabdomyosarcoma (RD); A549, MDCK, Caco-2, and Vero cells were maintained in Dulbecco's modified Eagle's medium (DMEM), BEAS2B and HCT-8 cells were maintained in RPMI 1640 medium. Both medium was supplemented with 10% fetal bovine serum (FBS) and 1% penicillin-streptomycin antibiotics. Cells were kept at 37°C in a 5% CO2 atmosphere. The USA_WA1/2020 strain of SARS-CoV-2 obtained from the World Reference Center for Emerging Viruses and Arboviruses (WRCEVA).

Protein expression and purification. SARS CoV-2 main protease (M^{pro} or 3CL) gene from strain BetaCoV/Wuhan/WIV04/2019 was ordered from GenScript (Piscataway, NJ) in the pET29a(+) vector with E. coli codon optimization. pET29a(+) plasmids with SARS CoV-2 main protease was transformed into competent E. coli BL21(DE3) cells, and a single colony was picked and used to inoculate 10 ml of LB supplemented with 50 g/ml kanamycin at 37°C and 250 rpm. The 10-ml inoculum was added to 1 liter of LB with 50 g/ml kanamycin and grown to an optical density at 600 nm of 0.8, then induced using 1.0 mM IPTG. Induced cultures were incubated at 37 °C for an additional 3 h and then harvested, resuspended in lysis buffer (25 mM Tris [pH 7.5], 750 mM NaCl, 2 mM dithiothreitol [DTT] with 0.5 mg/ml lysozyme, 0.5 mM phenylmethylsulfonyl fluoride [PMSF], 0.02 mg/ml DNase I), and lysed with alternating sonication and French press cycles. The cell debris were removed by centrifugation at 12,000 g for 45 min (20% amplitude, 1 s on/1 s off). The supernatant was incubated with Ni-NTA resin for over 2 h at 4°C on a rotator. The Ni-NTA resin was thoroughly washed with 30 mM imidazole in wash buffer (50 mM Tris [pH 7.0], 150 mM NaCl, 2 mM DTT); and eluted with 100 mM imidazole in 50 mM Tris [pH 7.0], 150 mM NaCl, 2 mM DTT. The imidazole was removed via dialysis or on a 10,000-molecular-weight-

cutoff centrifugal concentrator spin column. The purity of the protein was confirmed with SDS-PAGE. The protein concentration was determined via 260nM absorbance with ε 32890. EV-A71 2Apro and 3Cpro were expressed in the pET28b(+) vector as previously described (*1-3*).

Peptide synthesis. The SARS-CoV-2 M^{pro} FRET substrate Dabcyl-KTSAVLQ/SGFRKME(Edans) was synthesized by solid-phase synthesis through iterative cycles of coupling and deprotection using the previously optimized procedure.(*4*) Specifically, chemmatrix rink-amide resin was used. Typical coupling condition was 5 equiv of amino acid, 5 equiv of HATU, and 10 equiv of DIEA in DMF for 5 minutes at 80 ºC. For deprotection, 5% piperazine plus 0.1 M HOBt were used and the mixture was heated at 80ºC for 5 minutes. The peptide was cleaved from the resin using 95% TFA, 2.5% Tris, 2.5% H_2O and the crude peptide was precipitated from ether after removal of TFA. The final peptide was purified by preparative HPLC. The purify and identify of the peptide were confirmed by analytical HPLC (> 98% purity) and mass spectrometry. $[M+3]^{3+}$ calculated 694.15, detected 694.90; $[M+4]^{4+}$ calculated 520.86, detected 521.35;

Native Mass Spectrometry. Prior to analysis, the protein was buffer exchanged into 0.2 M ammonium acetate (pH 6.8) and diluted to 10 μM. DTT was dissolved in water and prepared at a 400 mM stock. Each ligand was dissolved in ethanol and diluted to 10X stock concentrations. The final mixture was prepared by adding 4 μL protein, 0.5 μL DTT stock, and 0.5 μL ligand stock for final concentration of 4 mM DTT and 8 μM protein. Final ligand concentrations were used as annotated. The mixtures were then incubated for 10 minutes at room temperature prior to analysis. Each sample was mixed and analyzed in triplicate.

Native mass spectrometry (MS) was performed using a Q-Exactive HF quadrupole-Orbitrap mass spectrometer with the Ultra-High Mass Range research modifications (Thermo Fisher

Scientific). Samples were ionized using nano-electrospray ionization in positive ion mode using 1.0 kV capillary voltage at a 150 °C capillary temperature. The samples were all analyzed with a 1,000–25,000 m/z range, the resolution set to 30,000, and a trapping gas pressure set to 3. Between 10 and 50 V of source fragmentation was applied to all samples to aid in desolvation. Data were deconvolved and analyzed with UniDec.(*5*)

Enzymatic assays. For reaction condition optimization, 200 μM SARS CoV-2 Main protease was used. pH6.0 buffer contains 20 mM MES pH6.0, 120 mM NaCl, 0.4 mM EDTA, 4 mM DTT and 20% glycerol; pH6.5 buffer contains 20 mM HEPES pH6.5, 120 mM NaCl, 0.4 mM EDTA, 4 mM DTT and 20% glycerol, pH7.0 buffer contains 20 mM HEPES pH7.0, 120 mM NaCl, 0.4 mM EDTA, 4 mM DTT and 20% glycerol. Upon addition of 20 μM FRET substrate, the reaction progress was monitored for 1 hr. The first 15 min of reaction was used to calculate initial velocity (V_i) via linear regression in prism 5. Main protease displays highest proteolytic activity in pH6.5 buffer. All the following enzymatic assays were carried in pH6.5 buffer.

For the measurements of K_m/V_{max}, screening the protease inhibitor library, as well as IC_{50} measurements, proteolytic reaction with 100 nM Main protease in 100 μl pH6.5 reaction buffer was carried out at 30 °C in a Cytation 5 imaging reader (Thermo Fisher Scientific) with filters for excitation at 360/40 nm and emission at 460/40 nm. Reactions were monitored every 90 s. For K_m/V_{max} measurements, a FRET substrate concentration ranging from 0 to 200 μM was applied. The initial velocity of the proteolytic activity was calculated by linear regression for the first 15 min of the kinetic progress curves. The initial velocity was plotted against the FRET concentration with the classic Michaelis-Menten equation in Prism 5 software. For the screening protease inhibitor library and IC_{50} measurements, 100 nM Main protease was incubated with protease inhibitor at 30°C for 30 min in reaction buffer, and then the reaction was initiated by adding 10

μM FRET substrate, the reaction was monitored for 1 h, and the initial velocity was calculated for the first 15 min by linear regression. The IC_{50} was calculated by plotting the initial velocity against various concentrations of protease inhibitors by use of a dose-response curve in Prism 5 software. Proteolytic reaction progress curve kinetics measurements with GC376, MG132, Boceprevir, Calpain inhibitor II, and Calpain inhibitor XII used for curve fitting, were carried out as follows: 5 nM Main protease protein was added to 20 μM FRET substrate with various concentrations of testing inhibitor in 200 μl of reaction buffer at 30 °C to initiate the proteolytic reaction. The reaction was monitored for 4 hrs. The progress curves were fit to a slow binding Morrison equation (equation 3) as described previously (*1, 6*):

$$E + I \leftrightarrows EI \leftrightarrows EI^* \quad (1)$$

$$K_I = k_{-1}/k_1 \quad (2)$$

$$P(t) = P_0 + V_s t - (Vs - V_0)(1 - e^{-kt})/k \quad (3)$$

$$k = k_2[I]/(K_I + [I]) \quad (4)$$

where P(t) is the fluorescence signal at time t, P_0 is the background signal at time zero, V_0, V_s, and and k represent, respectively, the initial velocity, the final steady-state velocity and the apparent first-order rate constant for the establishment of the equilibrium between EI and EI* (*6*). k_2/K_I is commonly used to evaluate the efficacy for covalent inhibitor. We observed substrate depletion when proteolytic reactions progress longer than 90 min, therefore only first 90 min of the progress curves were used in the curve fitting (Figure 6 middle column). In this study, we could not accurately determine the k_2 for the protease inhibitors: Calpain inhibitor II, MG132, Boceprevir, and Calpain inhibitor XII, due to the very slow k_2 in these case: significant substrate depletion before the establishment of the equilibrium between EI and EI*. In these

cases, K_I was determined with Morrison equation in Prism 5.

Differential scanning fluorimetry (DSF). The binding of protease inhibitors on Main protease protein was monitored by differential scanning fluorimetry (DSF) using a Thermal Fisher QuantStudio™ 5 Real-Time PCR System. TSA plates were prepared by mixing Main protease protein (final concentration of 3 μM) with inhibitors, and incubated at 30 °C for 30 min. 1× SYPRO orange (Thermal Fisher) were added and the fluorescence of the plates were taken under a temperature gradient ranging from 20 to 90 °C (incremental steps of 0.05 °C/s). The melting temperature (T_m) was calculated as the mid-log of the transition phase from the native to the denatured protein using a Boltzmann model (Protein Thermal Shift Software v1.3). Thermal shift which was represented as ΔT_m was calculated by subtracting reference melting temperature of proteins in DMSO from the T_m in the presence of compound.

Cytotoxicity measurement. A549, MDCK, HCT-8, Caco-2, Vero, and BEAS2B cells for cytotoxicity CPE assays were seeded and grown overnight at 37 °C in a 5% CO2 atmosphere to ~90% confluence on the next day. Cells were washed with PBS buffer and 200 μl DMEM with 2% FBS and 1% penicillin−streptomycin, and various concentration of protease inhibitors was added to each well. 48 hrs after addition the protease inhibitors, cells were stained with 66 μg/ mL neutral red for 2 h, and neutral red uptake was measured at an absorbance at 540 nm using a Multiskan FC microplate photometer (Thermo Fisher Scientific). The CC_{50} values were calculated from best-fit dose−response curves using GraphPad Prism 5 software.

SARS-CoV-2 CPE assay. Antiviral activities of test compounds were determined in nearly confluent cultures of Vero 76 cells. The assays were performed in 96-well Corning microplates. Cells were infected with approximately 60 cell culture infectious doses ($CCID_{50}$) of SARS-CoV-2 and 50% effective concentrations (EC_{50}) were calculated based on virus-induced cytopathic

effects (CPE) quantified by neutral red dye uptake after 5 days of incubation. Three microwells at each concentration of compound were infected. Two uninfected microwells served as toxicity controls. Cells were stained for viability for 2 h with neutral red (0.11% final concentration). Excess dye was rinsed from the cells with phosphate-buffered saline (PBS). The absorbed dye was eluted from the cells with 0.1 ml of 50% Sörensen's citrate buffer (pH 4.2)-50% ethanol. Plates were read for optical density determination at 540 nm. Readings were converted to the percentage of the results for the uninfected control using an Excel spreadsheet developed for this purpose. EC_{50} values were determined by plotting percent CPE versus $\log_{10}$ inhibitor concentration. Toxicity at each concentration was determined in uninfected wells in the same microplates by measuring dye uptake.

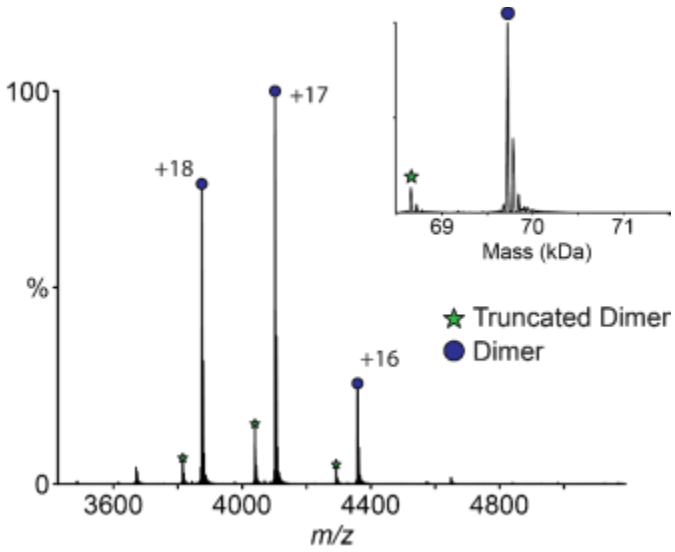
SARS-CoV-2 VYR assay. Virus yield reduction (VYR) assays were conducted by first replicating the viruses in the presence of test compound. Supernatant was harvested 3 days post-infection from each concentration of test compound and the virus yield was determined by endpoint dilution method. Briefly, supernatant virus was serially diluted in $\log_{10}$ increments then plated onto quadruplicate wells of 96-well plates seeded with Vero 76 cells. The presence or absence of CPE for determining a viral endpoint was evaluated by microscopic examination of cells 6 days after infection. From these data, 90% virus inhibitory concentrations (EC_{90}) were determined by regression analysis.

Influenza A virus A/California/07/2009 (H1N1) plaque reduction assay. The plaque assay was performed according to previously published procedures.(*7*)

M^{pro} crystallization and structure determination. 10 mg / mL of SARS-CoV-2 Mpro was incubated with 2 mM GC376 at 4˚ C O/N. The protein was diluted to 2.5 mg / mL the following

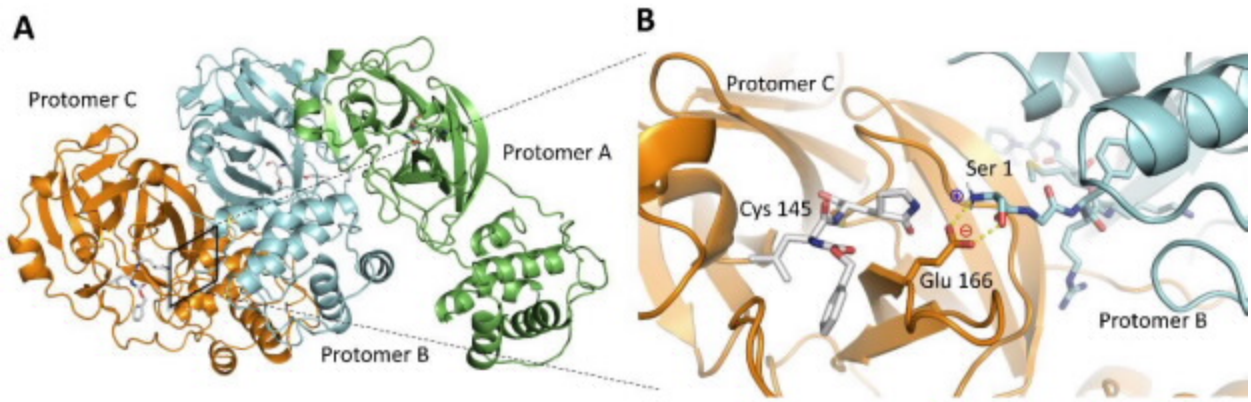
day in protein buffer (50 mM Tris pH 7.0, 150 mM NaCl, 4 mM DTT). Since GC3760 is water soluble, no precipitation was observed, and centrifugation was not necessary. Crystals were grown by mixing 2 uL of the protein solution with 1 ul of the precipitant solution (15 % PEG 2K, 10% 1,6-hexanediol, and 0.2 M NaCl) in a hanging-drop vapor-diffusion apparatus. Crystals were cryoprotected by transferring to a cryoprotectant solution (20% PEG 2K, 10% 1,6 -hexanediol, 20% glycerol) and flash-frozen in liquid nitrogen.

X-ray diffraction data for the SARS-CoV2-M^{pro} GC376 complex structure was collected on the SBC 19-ID beamline at the Advanced Photon Source (APS) in Argonne, IL, and processed with the HKL3000 software suite(*8*). The CCP4 versions of MOLREP were used for molecular replacement using a previously solved SARS-CoV-2 M^{pro} (PDB ID 5RGG) as a reference model(*9*). Rigid and restrained refinements were performed using REFMAC and model building with COOT(*10, 11*). Protein structure figures were made using PyMOL (Schrödinger, LLC).



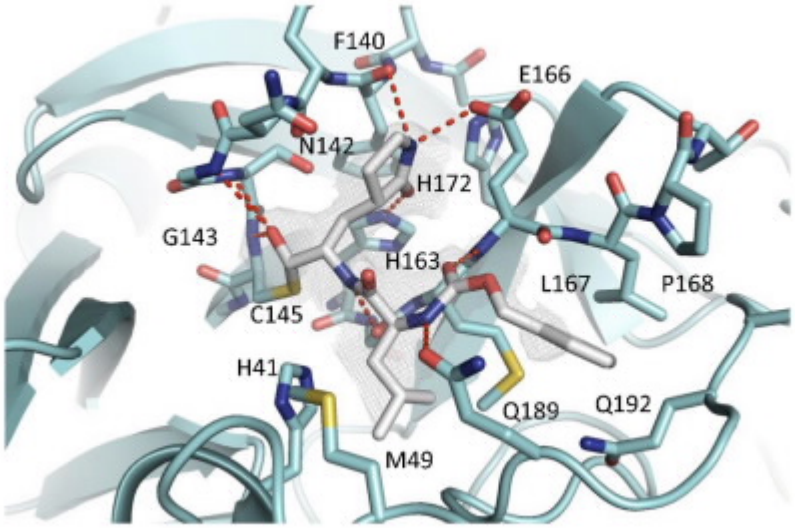
Supplementary Figure 1. Native mass spectrum of SARS-CoV-2 M^{pro}.

Native mass spectrum of SARS-CoV-2 M^{pro} with 4 mM DTT shows a dimer (*blue circle*) with a small amount of truncated dimer where one subunit has lost the C-terminal His tag (*green star*). The primary charge states are labeled, and the inset shows the deconvolved zero-charge mass distribution.

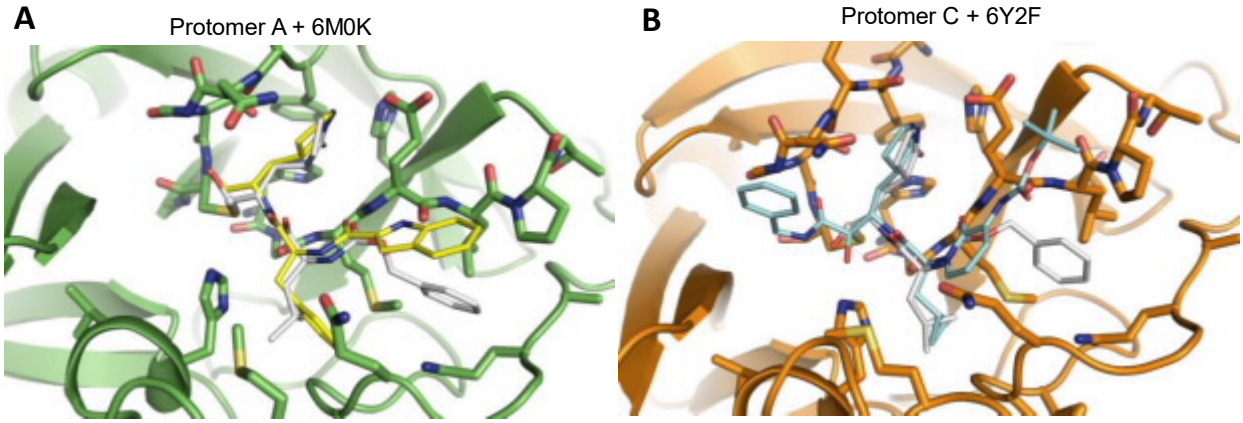


Supplementary Figure 2. Overall structure of SARS-CoV-2 M^{pro}.

(A) The three protomers in the asymmetric unit. Protomers B and C form a biological dimer. Protomer A dimerizes with a protomer from an adjacent asymmetric unit (not depicted). (B) The N-finger, or the N-terminal eight residues interact with Glu166 of the adjacent protomer, an important feature for catalytic activity.



Supplementary Figure 3. Complex structure of SARS-CoV-2 M^{pro} protomer B with GC-376 (64). Unbiased F_o-F_c map, shown in grey, is contoured at 2 σ. Hydrogen bonds are shown as red dashed lines.



Supplementary Figure 4. Overlay structures of current X-ray crystal structure with previously solved structures. (A) Overlay structures of protomer A with compound **13b** at the active site (PDB: 6M0K). (B) Overlay structures of protomer C with compound **N3** at the active site (PDB: 6Y2F). Unbiased F_o-F_c map, shown in grey, is contoured at 2 σ. Hydrogen bonds are shown as red dashed lines.

Supplementary Table 1: Cytotoxicity of SARS-CoV-2 M^{pro} inhibitors on various cell lines[a] and the counter screening against influenza virus.

	GC-376 (**64**)	Boceprevir (**28**)	MG-132 (**43**)	Calpain inhibitor II (**61**)	Calpain inhibitor XII (**62**)
MDCK	>100	>100	0.34 ± 0.02	>100	60.36 ± 2.28
Vero	>100	>100	0.45 ± 0.02	>100	>100
HCT-8	>100	>100	0.47 ± 0.02	>100	73.29 ± 11.80
A549	>100	>100	10.71 ± 3.50	>100	>100
Caco-2	>100	>100	<0.15	>100	82.02 ± 0.37
BEAS2B	>100	>100	0.14 ± 0.03	>100	78.91 ± 13.70
A/California/07/2009 (H1N1) antiviral activity[b] (μM)	> 20	> 20	N.T.	> 20	> 20

[a]Cytotoxicity was evaluated by measuring CC_{50} values (50% cytotoxic concentration) with CPE assay described in the method section. CC_{50} = mean ± S.E. of 3 independent experiments.

[b]Antiviral activity against influenza virus was tested in plaque assay.

Supplementary Table 2: Table of Crystallization Statistics

Data Collection	**PDB ID 6WTT**
Structure	SARS-CoV-2 M^{pro} + GC-376
Space Group	P 3_221
Cell Dimension	
a, b, c (Å)	101.83, 101.83, 160.02
α, β, γ (°)	90.00, 90.00, 120.00
Resolution (Å)	50.00 - 2.15
	(2.19 - 2.15)
R_{merge} (%)	0.107 (0.885)
<I>/σ<I>	5.9 (2.16)
Completeness (%)	100 (99.7)
Redundancy	9.12 (7.1)
Refinement	
Resolution (Å)	45.64 - 2.15
	(2.27 - 2.15)
No. reflections/free	52836 / 2711
R_{work}/R_{free}	0.227 /0.299
No. Heavy Atoms	7429
Protein	6968
Ligand/Ion	92
Water	369
B-Factors (Å^2)	
Protein	35.60
Ligand/Ion	33.07
Solvent	32.69
RMS Deviations	
Bond Lengths (Å)	0.015
Bond Angles (°)	1.84
Ramachandran Favored (%)	94.22
Ramachandran Allowed (%)	5.78
Ramachandran Outliers (%)	0.00
Rotameric Outliers (%)	2.08

* Numbers in parentheses represent the highest resolution shell.

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From: Prabha Fernandes[prabha.fernandes@gmail.com]
Sent: Fri 5/29/2020 3:42:01 PM (UTC-04:00)
Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Thx much Kara!

I just heard that it is being made and sold black market in China.

From: Kara Carter <Kara.Carter@evotec.com>
Sent: Friday, May 29, 2020 3:40 PM
To: Prabha Fernandes <prabha.fernandes@gmail.com>; 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; jrappaport@tulane.edu; john.young.jy3@roche.com; david.j.payne@gsk.com; 'Hild, Sheri (NIH/OD) [E]' <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jay_grobler@merck.com; ggatto@rti.org; 'Baric, Ralph' <rbaric@email.unc.edu>; 'Ottinger, Elizabeth (NIH/NCATS [E]' <elizabeth.ottinger@nih.gov>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Hewitt, Judith (NIH/NIAID) [E]' <jhewitt@niaid.nih.gov>; 'Deming, Damon (FDA/CDER)' <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; 'Parker, Ashley (NIH/OD) [E]' <ashley.parker@nih.gov>; ken.duncan@gatesfoundation.org; 'Adams, Peter (OS/ASPR/BARDA)' <Peter.Adams@hhs.gov>; 'Rao, Srinivas' <Srinivas.Rao@sanofi.com>; 'Qashu, Felicia (NIH/OD) [E]' <felicia.qashu@nih.gov>; 'Tomas Cihlar' <Tomas.Cihlar@gilead.com>; 'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)' <margaret.l.pitt.civ@mail.mil>
Cc: 'Gadbois, Ellen (NIH/OD) [E]' <gadboisel@od.nih.gov>; 'Hughes, Eric' <eric.hughes@novartis.com>; 'Gonzalez, Nina' <ningonzalez@deloitte.com>; 'Cutillo, Christine (NIH/NCATS) [E]' <cutilloc@mail.nih.gov>; 'Simon, Dina (NIH/OD) [C]' <dina.simon@nih.gov>; 'Wholley, David (FNIH) [T]' <dwholley@fnih.org>; 'Austin, Christopher (NIH/NCATS) [E]' <austinc@mail.nih.gov>; 'Melencio, Cheryl (FNIH) [T]' <cmelencio@fnih.org>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Desrosiers, Betsy' <elizabeth_desrosiers@merck.com>; 'Jansen, Kathrin' <kathrin.jansen@pfizer.com>; 'Kurilla, Michael (NIH/NCATS) [E]' <michael.kurilla@nih.gov>; 'Lowy, Douglas (NCI)' <dl60z@nih.gov>; 'Read, Sarah (NIH/NIAID) [E]' <readsa@niaid.nih.gov>; 'Tountas, Karen (FNIH) [T]' <ktountas@fnih.org>; 'Santos, Michael (FNIH) [T]' <msantos@fnih.org>; 'Adam, Stacey (FNIH) [T]' <sadam@fnih.org>; 'James, Stephanie (FNIH) [T]' <sjames@fnih.org>; 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>; 'Kim, Elizabeth' <elkim@deloitte.com>; 'Tolman, Brett' <btolman@deloitte.com>; 'Wachtel, Jonathan' <jwachtel@deloitte.com>; 'Prabhavathi Fernandes' <prabha.fernandes@outlook.com>; 'Diamond, Michael' <mdiamond@wustl.edu>; 'Rose Li' <rose.li@roseliassociates.com>; 'Dana Carluccio' <dana.carluccio@roseliassociates.com>; 'Lagos, Enrique (NIH/NCATS) [E]' <enrique.lagos@nih.gov>; 'Jonson, Samantha (NIH/NCATS) [E]' <samantha.jonson@nih.gov>; 'Burrus-Shaw, Cyndi (NIH/OD) [E]' <cyndi.burrus-shaw@nih.gov>; 'Rodriguez, Robin D' <rmdaigle@tulane.edu>; 'Dave Frankowski' <david.frankowski@roseliassociates.com>; 'Baric, Toni C' <antoinette_baric@med.unc.edu>; 'Lowy, Douglas (NIH/NCI) [E]' <lowyd@mail.nih.gov>; 'Florence, Clint (NIH/NIAID) [E]' <clint.florence@nih.gov>; 'Nancy Haigwood' <haigwoon@ohsu.edu>; 'Stratton, Benjamin' <bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Thanks Prabha. Here is the recent submission to BioRxiv from Ma et al with the data on SARS-CoV-2 of the compound.

Kara

Kara Carter, PhD
Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
kara.carter@evotec.com
www.evotec.com

From: Prabha Fernandes <prabha.fernandes@gmail.com>
Sent: Friday, May 29, 2020 3:31 PM
To: 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; jrappaport@tulane.edu; john.young.jy3@roche.com; david.j.payne@gsk.com; 'Hild, Sheri (NIH/OD) [E]' <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; Kara Carter <Kara.Carter@evotec.com>; jay_grobler@merck.com; ggatto@rti.org; 'Baric, Ralph' <rbaric@email.unc.edu>; 'Ottinger, Elizabeth (NIH/NCATS [E]' <elizabeth.ottinger@nih.gov>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Hewitt, Judith (NIH/NIAID) [E]' <jhewitt@niaid.nih.gov>; 'Deming, Damon (FDA/CDER)' <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; 'Parker, Ashley (NIH/OD) [E]' <ashley.parker@nih.gov>; ken.duncan@gatesfoundation.org; 'Adams, Peter (OS/ASPR/BARDA)' <Peter.Adams@hhs.gov>; 'Rao, Srinivas' <Srinivas.Rao@sanofi.com>; 'Qashu, Felicia (NIH/OD) [E]' <felicia.qashu@nih.gov>; 'Tomas Cihlar' <Tomas.Cihlar@gilead.com>; 'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)' <margaret.l.pitt.civ@mail.mil>
Cc: 'Gadbois, Ellen (NIH/OD) [E]' <gadboisel@od.nih.gov>; 'Hughes, Eric' <eric.hughes@novartis.com>; 'Gonzalez, Nina' <ningonzalez@deloitte.com>; 'Cutillo, Christine (NIH/NCATS) [E]' <cutilloc@mail.nih.gov>; 'Simon, Dina (NIH/OD) [C]' <dina.simon@nih.gov>; 'Wholley, David (FNIH) [T]' <dwholley@fnih.org>; 'Austin, Christopher (NIH/NCATS) [E]' <austinc@mail.nih.gov>; 'Melencio, Cheryl (FNIH) [T]' <cmelencio@fnih.org>; 'Colvis, Christine (NIH/NCATS) [E]' <christine.colvis@nih.gov>; 'Desrosiers, Betsy' <elizabeth_desrosiers@merck.com>; 'Jansen, Kathrin' <kathrin.jansen@pfizer.com>; 'Kurilla, Michael (NIH/NCATS) [E]' <michael.kurilla@nih.gov>; 'Lowy, Douglas (NCI)' <dl60z@nih.gov>; 'Read, Sarah (NIH/NIAID) [E]' <readsa@niaid.nih.gov>; 'Tountas, Karen (FNIH) [T]' <ktountas@fnih.org>; 'Santos, Michael (FNIH) [T]' <msantos@fnih.org>; 'Adam, Stacey (FNIH) [T]' <sadam@fnih.org>; 'James, Stephanie (FNIH) [T]' <sjames@fnih.org>; 'Alvarez, Rosa Maria' <rosalvarez@deloitte.com>; 'Kim, Elizabeth' <elkim@deloitte.com>; 'Tolman, Brett' <btolman@deloitte.com>; 'Wachtel, Jonathan' <jwachtel@deloitte.com>; 'Prabhavathi Fernandes' <prabha.fernandes@outlook.com>; 'Diamond, Michael' <mdiamond@wustl.edu>; 'Rose Li' <rose.li@roseliassociates.com>; 'Dana Carluccio' <dana.carluccio@roseliassociates.com>; 'Lagos, Enrique (NIH/NCATS) [E]' <enrique.lagos@nih.gov>; 'Jonson, Samantha (NIH/NCATS) [E]' <samantha.jonson@nih.gov>; 'Burrus-Shaw, Cyndi (NIH/OD) [E]' <cyndi.burrus-shaw@nih.gov>; 'Rodriguez, Robin D' <rmdaigle@tulane.edu>; 'Dave Frankowski' <david.frankowski@roseliassociates.com>; 'Baric, Toni C' <antoinette_baric@med.unc.edu>; 'Lowy, Douglas (NIH/NCI) [E]' <lowyd@mail.nih.gov>; 'Florence, Clint (NIH/NIAID) [E]' <clint.florence@nih.gov>; 'Nancy Haigwood' <haigwoon@ohsu.edu>; 'Stratton, Benjamin' <bstratton@DELOITTE.com>
Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

[EXTERNAL]

Hi Joe,
When we prioritize re-purposed drugs..
Should we should include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.
Oral product.
Selectivity index is great..

Attached FYI in case you have not seen.

Regards,
Prabha

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Friday, May 29, 2020 3:25 PM
To: jrappaport@tulane.edu; john.young.jy3@roche.com; david.j.payne@gsk.com; Hild, Sheri (NIH/OD) [E] <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph <rbaric@email.unc.edu>; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Tomas Cihlar <Tomas.Cihlar@gilead.com>; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) <margaret.l.pitt.civ@mail.mil>
Cc: Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Hughes, Eric <eric.hughes@novartis.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; Cutillo, Christine (NIH/NCATS) [E] <cutilloc@mail.nih.gov>; Simon, Dina (NIH/OD) [C] <dina.simon@nih.gov>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Austin, Christopher (NIH/NCATS) [E] <austinc@mail.nih.gov>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Desrosiers, Betsy <elizabeth_desrosiers@merck.com>; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Kurilla, Michael (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas (NCI) <dl60z@nih.gov>; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Tountas, Karen (FNIH) [T] <ktountas@fnih.org>; Santos, Michael (FNIH) [T] <msantos@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; James, Stephanie (FNIH) [T] <sjames@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kim, Elizabeth <elkim@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes <prabha.fernandes@outlook.com>; Diamond, Michael <mdiamond@wustl.edu>; Rose Li <rose.li@roseliassociates.com>; Dana Carluccio <dana.carluccio@roseliassociates.com>; Lagos, Enrique (NIH/NCATS) [E] <enrique.lagos@nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Burrus-Shaw, Cyndi (NIH/OD) [E] <cyndi.burrus-shaw@nih.gov>; Rodriguez, Robin D <rmdaigle@tulane.edu>; Dave Frankowski <david.frankowski@roseliassociates.com>; Baric, Toni C <antoinette_baric@med.unc.edu>; Lowy, Douglas (NIH/NCI) [E] <lowyd@mail.nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Nancy Haigwood <haigwoon@ohsu.edu>; Stratton, Benjamin <bstratton@DELOITTE.com>
Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, April 14, 2020 6:43 PM
To: jrappaport@tulane.edu; john.young.jy3@roche.com; david.j.payne@gsk.com; Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; rbaric@email.unc.edu; prabha.fernandes@gmail.com; ottingerea@mail.nih.gov; ccolvis@mail.nih.gov; jh18v@nih.gov; Damon.Deming@fda.hhs.gov; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Find your local number: https://fnih.zoom.us/u/aemFGSQrl

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Cc: jrappaport@tulane.edu[jrappaport@tulane.edu]; david.j.payne@gsk.com[david.j.payne@gsk.com]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; kara.carter@evotec.com[kara.carter@evotec.com]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Hughes, Eric[eric.hughes@novartis.com]; Gonzalez, Nina[ningonzalez@deloitte.com]; Cutillo, Christine (NIH/NCATS) [E][cutilloc@mail.nih.gov]; Simon, Dina (NIH/OD) [C][dina.simon@nih.gov]; Wholley, David (FNIH) [T][dwholley@fnih.org]; Austin, Christopher (NIH/NCATS) [E][austinc@mail.nih.gov]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Desrosiers, Betsy[elizabeth_desrosiers@merck.com]; Jansen, Kathrin[kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E][michael.kurilla@nih.gov]; Lowy, Douglas (NCI)[dl60z@nih.gov]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; James, Stephanie (FNIH) [T][sjames@fnih.org]; Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Kim, Elizabeth[elkim@deloitte.com]; Tolman, Brett[btolman@deloitte.com]; Wachtel, Jonathan[jwachtel@deloitte.com]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Diamond, Michael[mdiamond@wustl.edu]; Rose Li[rose.li@roseliassociates.com]; Dana Carluccio[dana.carluccio@roseliassociates.com]; Lagos, Enrique (NIH/NCATS) [E][enrique.lagos@nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Burrus-Shaw, Cyndi (NIH/OD) [E][cyndi.burrus-shaw@nih.gov]; Rodriguez, Robin D[rmdaigle@tulane.edu]; Dave Frankowski[david.frankowski@roseliassociates.com]; Baric, Toni C[antoinette_baric@med.unc.edu]; Lowy, Douglas (NIH/NCI) [E][lowyd@mail.nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Nancy Haigwood[haigwoon@ohsu.edu]; Stratton, Benjamin[bstratton@deloitte.com]
From: Young, John[john.young.jy3@roche.com]
Sent: Sat 5/30/2020 8:21:03 AM (UTC-04:00)
Subject: Re: ACTIV Preclinical working group (Tuesday meeting)

Thanks Joe. Minutes are clear and comprehensive. No further comments from my side.
Best regards
John

On Fri, May 29, 2020 at 9:41 PM Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org> wrote:

This time with the attachment.

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

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Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
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John A.T. Young, PhD
VP and Global Head Infectious Diseases
Immunology, Infectious Diseases and Ophthalmology (I2O) Discovery and Translational Area
Roche Pharma Research & Early Development

Roche Innovation Center Basel

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To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Adam, Stacey (FNIH) [T][sadam@fnih.org]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Wholley, David (FNIH) [T][dwholley@fnih.org]; James, Stephanie (FNIH) [T][sjames@fnih.org]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Mon 6/1/2020 9:33:46 AM (UTC-04:00)
Subject: FW: Follow-up from ACTIV TX-Clinical Working Group Meeting #8
building_the_critical_path_for_covid-19_therapeutics_final.pdf

Thank you Liz.

Dear All,

Thought you would be interested in this from Duke Margolis.

Joe

From: Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>
Sent: Monday, June 1, 2020 9:02 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Follow-up from ACTIV TX-Clinical Working Group Meeting #8

Hi Joe,
Saw this article this morning, in case, you want to share with the group.
Best,
Liz

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Saturday, May 30, 2020 4:28 PM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: FW: Follow-up from ACTIV TX-Clinical Working Group Meeting #8

Thought you all might be interested.

From: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Sent: Friday, May 29, 2020 9:44 PM
Subject: Follow-up from ACTIV TX-Clinical Working Group Meeting #8

Dear ACTIV TX-Clinical WG,

Thank you for another good discussion at our meeting yesterday. We'd like to thank our NHLBI colleagues who presented on their anticoagulation trial plans. I also appreciate all the feedback provided to the Agent Prioritization – mAb Sub team and on the RFI Survey Tool, which I will distribute to this group when live.

Please find attached the formal summary from the meeting. In addition, please find a couple of papers that Tim was kind enough to share with the group around anticoagulation treatment on the front lines of COVID-19.

The first is a reasonable primer for people who are not treating COVID patients with anticoagulation therapies. The authors are from the expert panel that presented to BARDA about 3.5 weeks ago that some of this group attended.
https://journals.lww.com/ccmjournal/Abstract/9000/Coagulopathy_of_Coronavirus_Disease_2019.95637.aspx

Also another paper that endeavors to estimate the failure of 'routine' VTE prophylaxis for COVID treatment.
https://journals.lww.com/ccmjournal/Abstract/9000/Routine_Venous_Thromboembolism_Prophylaxis_May_Be.95638.aspx

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: **(301) 435-8364** | Mobile: **(301) 318-8310**

Duke | Robert J. Margolis, MD Center *for* Health Policy

Mark McClellan
Scott Gottlieb
Jeff Allen
Luciana Borio
Pamela Tenaerts

MAY 20, 2020

BUILDING THE CRITICAL PATH FOR COVID-19 THERAPEUTICS

Duke | MARGOLIS CENTER for Health Policy

Building the Critical Path for COVID-19 Therapeutics

Mark McClellan, Scott Gottlieb, Jeff Allen, Luciana Borio, and Pamela Tenaerts

May 20, 2020

This Duke-Margolis resource on COVID-19 response policies is intended to inform and help guide policy makers addressing the evolving COVID-19 pandemic in the United States and around the globe, and will be updated as the pandemic and response capabilities change over time.

It contains recommendations for a U.S. Federal response as well as steps and resources for stakeholders across the health care ecosystem. We will add further resources to address a range of related, critical policy challenges.

We thank our many collaborators, co-authors, and reviewers who have contributed significant expertise and guidance on these rapidly evolving issues. Please reach out to us with additional suggestions for resources and effective policies at dukemargolis@duke.edu - we welcome your input.

Executive Summary

Hundreds of therapeutics are in preclinical or clinical development for treating COVID-19 patients. But as of May 2020, so far none have demonstrated effectiveness sufficient to warrant approval for general use, although one antiviral drug (remdesivir) has shown sufficient impact in ongoing clinical trials to support an authorization for emergency use. This is a reflection of the complexity, time, costs, and uncertainties associated with developing therapeutics – a process that not only encompasses preclinical evaluation and clinical trials to demonstrate safety and effectiveness, but also manufacturing at pandemic scale, and sufficient payment to enable appropriate and effective access. Recent major initiatives including the Administration's announcement of Operation Warp Speed, building on over $10 billion in Congressional support for research and development on vaccines and other COVID-19 therapeutics, reflect the unprecedented policy attention and financial support being directed to mitigate the health and economic impact of the pandemic.

Policy attention has understandably focused on the development of vaccines as the path to recovery. But even with these unprecedented actions, the widespread availability of effective vaccines remains many months away, if not longer. To reduce the impact of the pandemic in the

meantime, intensive effort is also needed to accelerate therapeutics development to help prevent infections, reduce their severity, and mitigate or prevent further outbreak waves.

Building on recent initiatives, we propose a comprehensive set of critical path steps to substantially shorten the time and increase the capacity for bringing safe and effective treatments to market at scale. Figure 1 on page 3 summarizes the overall approach, which does not relax the standards on safety and effectiveness of COVID-19 treatments. Rather, it lays out a hyper parallel path for promising therapeutics that replaces and augments the usual highly sequential development process. This critical path develops needed evidence in less time through more powerful and efficient clinical studies, while simultaneously preparing the manufacturing capacity needed to make the treatment available quickly to all patients who may benefit. It also recognizes that there are unprecedented opportunities to use electronic data systems, artificial intelligence, and other emerging analytic tools to learn more about COVID-19 treatments after they reach the market, enabling better clinical and policy choices to maximize their impact. Action on these reforms now would lead to much faster progress on clinical testing and achieving access to safe and effective therapies months before a vaccine is available.

Key steps on the critical path for new therapeutics include:

Create a clear pathway for promising therapeutics *(page 7)*

- Identify promising therapies early for additional support
- Track and share key nonproprietary information for better investment decisions and planning
- Create clear pathway all the way to widespread access, to help product developers plan effectively and execute quickly

Increase clinical trial effectiveness and capacity *(page 9)*

- Develop COVID-19 master protocols
- Encourage broad use and transparency of master protocols by publishing protocols and tools to facilitate their implementation
- Support broad COVID-19 trial networks, testing multiple treatments efficiently
- Share nonproprietary data using common data models, for use as control populations and to guide further clinical studies
- Implement expanded access programs with mechanisms for reliably collecting key data on patients and outcomes

Anticipate capacity for rapid access without shortages *(page 14)*

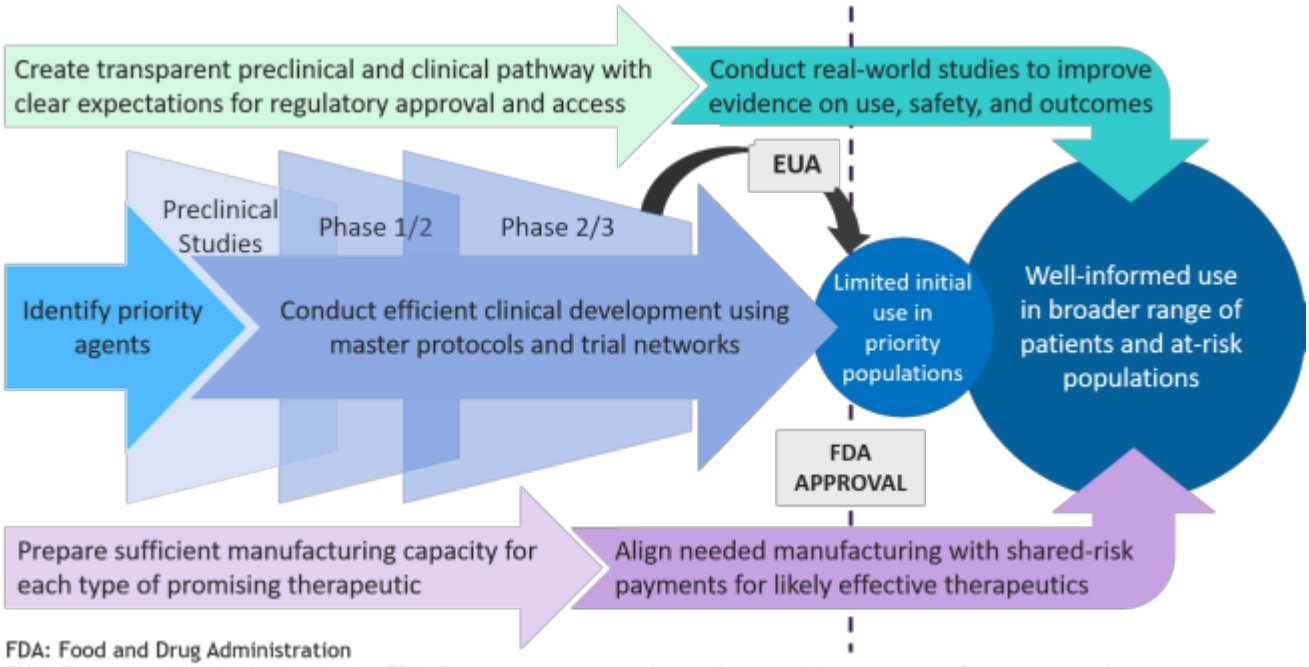
- Use product tracking to anticipate capacity needs to avoid delays in access
- Avoid potential shortages by redirecting capacity and developing new capacity, with shared risk financing if necessary
- Develop advance purchasing models that pre-commit sufficient volume for population access

Conduct effective real-world data collection and studies after emergency use authorizations and approvals *(page 18)*

- Plan for augmenting evidence at product approval or in emergency use authorization by building on existing common data models and electronic data networks
- Provide Federal funding to assure broad participation in key postmarket studies that meet benchmarks for speed and quality
- Link payment to implementing virtual postmarket registries and aligned studies

Most of these steps can be accomplished without further legislation, using some of the $10 billion appropriated by Congress through the CARES Act and other supplemental funding to support therapeutic development. In conjunction with the administrative steps and the private-sector actions we propose, further appropriations to accomplish these aims would enable more support for therapeutics development and could be linked to accomplishing some of the benchmarks we describe. A clear and comprehensive path from early development through effective widespread access to therapeutics is critical for reducing the enormous ongoing health and economic impact of the pandemic.

Figure 1: Parallel actions on the critical path for development and access to COVID-19 therapeutics



FDA: Food and Drug Administration
EUA: Emergency Use Authorization by FDA, for some pre-approval use of a promising treatment for unmet need

Introduction

The Federal government, researchers, industry, charitable foundations and the entire global community are mobilizing an intensive effort to develop treatments and vaccines for COVID-19. Much of this effort is appropriately directed toward developing vaccines capable of preventing infections of the novel SARS-CoV-2 virus.

While a focus on safe and effective vaccines is critical to our long-term ability to overcome the pandemic, other prophylactics and therapeutics are needed as quickly as possible to reduce the health impact of COVID-19 – and could be available much sooner than a vaccine. An effective prophylactic could potentially be used as a bridge to a vaccine for certain high-risk groups. Even after we develop and deploy successful vaccines, we will still need therapeutics that can help treat people for whom a vaccine may not be effective or those for whom it may not be an option.

To more efficiently advance these opportunities, we need to adopt a hyper parallel framework for discovery, development, manufacturing, and effective use – a process in which the usually highly sequential process for developing therapeutics is compressed, and activities are done in an overlapping fashion. Seamless trial designs can allow rapid transition from the early evaluation of a product's safety in small series to the large-scale evaluation of its efficacy in pivotal trials, while commercial scale manufacturing can be developed to avoid delays in broad availability as soon as safety and effectiveness is demonstrated. And as these treatments reach the market more quickly, we can use new analytic capabilities to assess large-scale real-world data to learn much more about how to use them effectively in particular patients and contexts – maximizing their real-world impact.

This new critical path for COVID-19 therapeutics will require us to engage in broader information sharing around early and later stage clinical development to maximize the chances of success and allow parallel planning where development and manufacturing challenges can be anticipated early. We need broader sharing of resources for pre-market assessment through standardized models and approaches, and more collaboration around clinical trial access through protocols that can be shared by multiple product developers. This requires collaboration around clinical trial access, manufacturing, and post market data collection to build in efficiencies that are needed to rapidly advance promising therapies.

Importantly, this critical path could be built for all four types of therapeutics that hold the potential to reduce the transmission and intensity of COVID-19 infections in the coming months:

- **Antivirals**: Drugs initially developed to treat other viral infections by interfering with viral replication are in clinical testing for COVID-19. Remdesivir was recently authorized for emergency use based on promising clinical trial results. Many more drugs, developed specifically for their ability to target this virus, are in preclinical testing. In addition, large-scale programs to screen a wide number of existing, pre-clinical compounds for potential activity against SARS-CoV2 are underway. Preliminary results from these studies have identified compounds that show promise, though more definitive trials are needed. While

the first generation of drugs that successfully target SARS-CoV-2 may have modest effect, the pattern for developing antivirals teaches us that the second and third generation drugs should offer greater benefits. In other conditions such as HIV and hepatitis C, early antiviral therapies had some impact on the course of infection, but also provided a foundation for the development of more effective next-generation therapies.

- **Immune modulators**: Most SARS-CoV2 infections do not have serious health consequences. However, severe complications in the minority of patients who are hospitalized – particularly elderly patients and those with comorbid conditions – have led to hundreds of thousands of deaths and to health care systems being pushed to or beyond crisis capacity worldwide. Studies have indicated that intense immune reactions, with "cytokine storm" and the release of other compounds involved in inflammatory response, may be important contributors to poor outcomes in these patients. Consequently, immune modulator drugs may be able to reduce the incidence of severe complications, critical illness and mortality in certain patients, as well as reduce the strain on health system capacity from COVID-19 in the months ahead. Because some COVID-19 patients also have serious complications from blood clotting, studies of anticoagulants and thrombolytic drugs are also getting underway.
- **Antibody-based treatments**: Serum from convalescent patients and hyperimmune globulins from the pooled antibodies of such patients have proven to be effective therapies and prophylactics in other viral conditions. Clinical studies using such antibody treatments in COVID-19 settings are underway. While supplies of such immune globulins will likely be limited, advances in monoclonal antibody technology permit large-scale synthesis of antibodies that could be effective against the virus. Through such an approach, the most potent antibodies that the body would normally produce to target the virus can be produced at large scale using biotechnology processes. These can be delivered as treatments in early infection, as well as used as post-exposure prophylaxis to prevent infection in those exposed to the virus. They may also be used as a prophylaxis in high risk populations. Some monoclonal antibodies can be engineered to have a prolonged half-life, perhaps requiring only monthly, bi-monthly, or even semi-annual infusions. Used in this way, the antibody drugs can serve as a bridge to a vaccine for certain patients. Promising monoclonal antibody compounds are expected to enter clinical testing soon, with results expected later in the summer.
- **Other drugs and biologics**: Hundreds of other compounds or approaches are in preclinical or clinical testing, ranging from cell-based therapies to treatments based on CRISPR technology. As evidence accumulates related to these diverse pathways of treating COVID-19, additional scientific and regulatory steps like those we propose for the other categories should be developed.

Supplemental Table 1 illustrates some of the promising treatments in the first three categories that are in advanced preclinical or clinical development.

Many efforts are underway to further advance the development of these treatments. **To accelerate this progress, we focus on four steps on the critical path of turning promising drug and biologic candidates into safe, effective, and widely available therapies:**

- **Create a clear pathway for promising therapeutic candidates**, including not only additional financial support from government programs designed to invest in promising therapeutics but also additional early support from regulators. Such supports cannot be provided to every product developer and must be prioritized. Prioritization starting with preclinical assessment should be based on publicly-available criteria that can be shared across industry and refined to enable more effective early assessment, including better informed funding decisions by foundations and private investors. Moreover, all priority products should have information made available – to the extent feasible – on each product's expected development milestones, including expectations about the start and duration of clinical testing and manufacturing needs. A shared understanding of key product development needs will avoid delays and shortages later.
- **Increase clinical trial effectiveness and capacity**, by using clear regulatory guidance on trial design to leverage master protocols that reduce the cost and increase the impact of expanding clinical trial sites, and to facilitate the development of networks capable of contributing to well-designed trials. The selection and enrollment of products into existing master protocols needs to be made highly efficient, so product developers don't undergo delays owing to the governance features of the master protocols. The master protocols should be designed and governed in a way to ensure that candidates are matched rapidly, trials enroll quickly and are conducted effectively, yielding meaningful results no matter where COVID-19 outbreaks are occurring.
- **Anticipate capacity for rapid access without shortages**, by planning ahead for each type of manufacturing capacity that may be needed, improving and reallocating existing capacity, and developing additional capacity that could be rapidly directed to particular treatments that show effectiveness. This may involve additional public investments in domestic manufacturing capacity, and contracts between manufacturers and public and private payers that commit to adequate supplies for covered populations rather than fee-for-service contracts.
- **Conduct effective real-world data collection and studies after emergency use authorizations and approvals**, by developing and then promoting the use of tools and resources to address key further questions about safety and effectiveness. A shared approach can answer many questions that cannot be fully addressed in pre-approval studies of reasonable duration and size, and can be done in collaboration with payers and real-world evidence networks.

These steps can be taken in conjunction with Federal actions and public-private collaborations that are already underway. The National Institutes of Health (NIH) and Foundation of the National Institutes of Health's (FNIH's) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Partnership, for example, has been established to prioritize candidates, help promising ones move forward, and expand streamlined trials including through NIH's trial networks. The Adaptive COVID-19 Treatment Trial (ACTT), supported by the National Institute of Allergy and Infectious Disease (NIAID) is already conducting randomized trials of prioritized agents at over 60 sites in the United States, Europe, and Asia. Other research and trial infrastructure efforts like I-SPY 2, an adaptive trial network for breast cancer therapies, have implemented their own

processes to prioritize studies of promising COVID-19 therapies. Robust coordination between these prioritization activities will help advance the most promising agents to clinical testing.

At the same time, the U.S. Food and Drug Administration (FDA) has established the Coronavirus Treatment Acceleration Project (CTAP) to support more the implementation of rapid and efficient development programs for sponsors entering human testing of COVID-19 treatments. A range of additional public and private collaborations and initiatives are also addressing various aspects of the broader critical path to COVID-19 therapeutics. Many of the organizations leading these efforts, like the Clinical Trials Transformation Initiative (CTTI), are working to apply concepts like quality by design to ensure that COVID-19 trials make use of the best and most efficient approaches to rapidly generating the evidence that FDA will need for approval.

The Administration's recently announced Operation Warp Speed seeks to bring Federally-supported efforts together in a national program to accelerate the development of therapeutics, as well as vaccines and better diagnostic technologies. In addition to supporting development of new therapeutics, Operation Warp Speed intends to focus on building adequate manufacturing and supply chain support and assuring widespread and timely distribution of affordable therapies.

Our report describes steps to build on this progress – steps that the Administration, Congress, and the private sector can take to make sure the nation can overcome the key challenges and rapidly advance the development of treatments and prophylactics that will help fulfill therapeutic needs and help patients until an effective vaccine is available. It addresses both treatments already available and being repurposed for potential use against COVID-19, as well as new treatments that are or will launch clinical studies in the coming months. The recommendations are relevant to all potential types of therapeutics, and we believe they should be considered and enacted in collaboration with world health authorities to ensure global coordination of critical development efforts. We believe these efforts to promote an efficient development path for therapeutics will complement the promising work of NIH, FDA, the World Health Organization (WHO), and others to advance a parallel development track for a vaccine.

Create a clear pathway for promising therapeutic candidates

Governmental agencies are taking unprecedented steps to support preclinical and clinical development of new products to treat COVID-19. NIAID, Biomedical Advanced Research and Development Authority (BARDA), the Department of Defense (DoD), and private entities are committing substantial funding and streamlined pathways to support product development. FDA is providing extra assistance to COVID-19 product developers through its expedited review and approval tools, like its Fast Track and Breakthrough designations, and its ability to grant Emergency Use Authorization (EUA). The agency has achieved rapid response times on study protocol reviews and other regulatory actions.

However, with hundreds of products at various stages of development, it is possible that promising new therapies – especially from smaller, less experienced developers – may not be

well connected to these resources. As such, they may benefit from additional assistance. The ACTIV public-private collaboration through NIH and FNIH aims to identify promising candidates that may face challenges in obtaining adequate funding for development, or in progressing to clinical testing and standing up timely, well-designed clinical trials. To speed development, ACTIV will also promote the use of shared protocols across clinical trial networks, starting with NIH's networks, to increase the capacity for clinical development of these prioritized products.

Improve tracking and support for rapid progress on promising treatments

To make informed decisions that accelerate product development and to anticipate challenges in subsequent stages of development, criteria for accelerated assistance and key information on priority candidates should be publicly available. Some of the product information shared with FDA, NIH, BARDA and other relevant government officials is proprietary, and so cannot be made publicly available to protect its confidential nature without permission by the product sponsor. In 2014, in response to the Ebola outbreaks, NIH and FDA convened clinical researchers to prioritize products for development in a common protocol. Legal guidance for this process enabled some commercial confidential information to be shared to help identify priorities. Along with similar steps, ACTIV should develop and encourage public awareness and input on the considerations and criteria that it takes into account in identifying promising treatments, and should provide non-identifiable summary information on ACTIV findings and actions to support development. Other funders have different approaches and perspectives that they will use to drive their investment decisions. But a better shared understanding of opportunities and challenges, how products are being assessed, and the kinds of approaches that are being considered in ACTIV's work can make allocation of capital to these efforts potentially more efficient and help product developers maximize their chances of success.

ACTIV or collaborating organizations should also facilitate reporting, where feasible, on milestones for products that receive public support through its initiatives. This may include non-proprietary information that helps product developers avoid delays in later phases of development, such as identification of manufacturing capacity so that shared decisions can be made around the proper allocation of limited domestic manufacturing resources. Such information can also help provide milestones of success to gauge progress on different potential therapies, and to inform private efforts to support therapeutics development. This would help private foundations, industry, venture capital, and other potential funders allocate resources to the most promising candidates and help less experienced companies with innovative products plan for development more effectively.

Alongside ACTIV-led efforts to track and report on candidates receiving enhanced resources and support from the public sector, companies and industry organizations could work with organizations like FasterCures and the CTTI to publicly collect and report a limited number of other critical nonproprietary features of promising products in development. **Key nonproprietary information that should be publicly available include:**

- For earlier-stage products: type of product, key milestones in preclinical development, expected initiation of Phase I testing
- For products in clinical testing: study design, start date, endpoints, use of a master protocol, expected size and power, expected readout dates, significant updates on enrollment and retention; planned manufacturing capacity
- For approved products: randomized and observational postmarket studies being supported by the manufacturer or other bodies, including information on key design features, (e.g., use of standard protocols for data collection and analysis, manufacturing capacity and plans for expansion)

Such key information is not consistently available today. Some of these key data points and other relevant information are already included in trial reporting to clinicaltrials.gov, in announcements of new Federal actions to support therapeutics, and in public releases by individual product developers. Further steps to make such information reliably available could improve our ability to assess whether a clinical development plan is likely to succeed, to plan ahead for adequate manufacturing capacity, and to anticipate and collect postmarket evidence needed to augment what is learned in premarket clinical trials. Such a reporting tool would also assist potential trial sites in assessing where they should focus their efforts, and would help with alignment on effective protocols and tools for integrating data and findings across studies.

Increase clinical trial effectiveness and capacity

Clinical development, especially the conduct of well-designed clinical trials that provide meaningful evidence on the effectiveness and safety of new treatments, can be time consuming and costly. In the setting of a public health emergency, every effort must be made to identify which of the many promising therapies are effective, so that resources to provide rapid access can be concentrated on therapies that truly impact patient health. Steps to reduce time and cost of development are consequently important but must be done in a way that does not compromise safety or significantly impede our ability to develop rigorous evidence about the scope of a product's effectiveness.

The number of trials underway for COVID-19 therapies is increasing rapidly, but many do not randomize patients using widely-accepted and thus comparable treatment protocols, are too small to provide definitive answers about a product's safety and effectiveness, or are planned using individual protocols that are hard to align with other studies underway. In addition, distancing and other measures are having a significant impact on the spread of the virus, meaning benefits from mitigation could inadvertently hinder clinical trial progress. There are concerns that a significant number of promising drugs and biologics currently in preclinical testing could progress to human testing at the same time as clinical trial sites have diminishing patients with active infections.

Sponsors and policymakers should prepare now for a surge in promising therapeutics that will need access to clinical trial sites to determine their safety and effectiveness, particularly using efficient Phase 2/3 study designs that may be in limited supply relative to the demand for

clinical studies. As we describe in more detail below, foundational steps are already underway to substantially enhance the availability of effective clinical trial capacity COVID-19 products.

FDA's Center for Drug Evaluation and Research has taken important steps to enable rapid progress. In particular, FDA's recent regulatory guidance on clinical studies for COVID-19 therapeutics includes clear and specific approaches for designing pivotal trials to provide substantial evidence on effectiveness and safety, with a set of clinical trial endpoints that can be observed in a limited period of time. For treatments used for severely ill patients, these include mortality, respiratory failure (e.g., use of noninvasive or invasive ventilation), need for intensive care, and time to discharge and recovery, all measured from time of randomization. For treatments used in less severe, ambulatory patients, endpoints include hospitalization and time to sustained recovery. For prophylactic treatments, outcomes include occurrence of a lab-confirmed COVID-19 diagnosis (with or without symptoms), and severity of infection (e.g., duration or need for hospitalization).

The guidance also outlines the range of patients that should be part of the trial design, including elderly individuals and individuals from communities with relatively high shares of low-income and minority patients, which have been disproportionately affected. It outlines how clinical investigators can implement pre-specified approaches to move quickly to expand evaluations that show promising results into pivotal trials, how to determine more quickly whether agents are ineffective, and how to adjust enrollment in a "multi-arm" trial to make those decisions as quickly as possible.

The guidance indicates that it should generally be possible to complete well-designed trials very quickly – within 28 days for treatments in more severe patients, and in no more than a few months for other less severe study populations. However, this pace is only likely to be achieved through well-powered studies, particularly those that use consistent, straightforward master protocols aligned with the FDA guidance and that are designed in advance to use multiple arms including a "standard of care" control arm that can evolve over time. As we describe below, most COVID-19 clinical trials do not have these features – but timely action can change that, enabling substantially more rapid progress in the clinical evaluation of a much larger number of potential therapeutics.

Implement master protocols

Potential bottlenecks in trial initiation and patient recruitment can be alleviated with further development and use of master protocols for COVID-19 studies. Master protocols are utilized in specific instances where a sponsor wishes to have one single protocol across multiple, parallel sub-studies that are being conducted at the same time. They can be designed to facilitate the study of multiple diseases, multiple candidates, or both, and typically have a set of core data elements, measures, and endpoints that are collected in each sub-study. They can evaluate, in parallel, different drugs compared to their respective controls or to a single common control. These trials can be updated to incorporate new scientific information, like novel biomarkers, as medical science advances. The infrastructure for these trials can last for many years. This reduces

administrative costs and time associated with standing up new trial sites for each drug candidate. It allows more efficient coordination around the rapid recruitment of patients with COVID-19 in the setting of a public health emergency, where clinical resources are likely to be strained and providers have limited time to devote to the implementation of clinical studies.

Leading institutions have announced major collaborations to develop and implement master protocols, including NIH's Adaptive COVID-19 Treatment Trial (ACTT), WHO's Solidarity Trial, the University of Oxford's RECOVERY and PRINCIPLE Trials, and an addition of COVID-specific arms to UCSF and Quantum Leap Health's ongoing I-SPY-2, among others. Supplemental Table 2 highlights several of these promising initiatives and their key characteristics.

Additional master protocols are likely needed for a range of study types in different clinical settings, including: hospitalized patients with serious COVID-19 complications (endpoints related to mortality, vent use, time in hospital, etc.), patients with significant COVID-19 complications being managed on an outpatient basis (endpoints related to hospitalization with complications), patients with milder disease in outpatient setting especially those with higher risk of progression (endpoints related to progression to serious complications or hospitalization), and individuals at high risk of contracting COVID-19 who would benefit from effective prophylaxis (endpoints related to infection or complications from COVID-19). Studies might also focus on particular subgroups of these populations.

In each situation, we should accelerate use of a specific master protocol that would be focused on enrolling patients in this particular care setting and disease stage. The goal should be to pursue coordination around recognized master protocols that can be widely adopted across many different institutions to support well-powered studies that can be completed rapidly.

As these and other master protocols begin trial initiation and are considered for additional study sites and treatment modalities, protocol developers should publish their work and identify ways to encourage alignment. The RECOVERY trial, for example, has published their master protocol publicly as a resource for other researchers and for sponsors of additional studies, as has REMAP-CAP-COVID. All such master protocols should be published to facilitate efforts to harmonize them where appropriate and encourage their wider adoption.

Tools linked to these leading protocols are needed to help potential sites and patients better understand how they can participate and the potential benefits of doing so, thereby increasing the opportunities for patient enrollment in well-powered, well-designed trials. Such templates and associated tools for using them would describe key data on patient characteristics, treatment conditions, and primary and secondary endpoints. Such resources could be useful to many sponsors in planning their studies, leading to more efficient design choices. They would help additional trial sites, such as individual hospitals around the country, accomplish the key features of well-designed clinical trials by leveraging the trial network resources: feasible patient consent; appropriate randomization; data and endpoint collection, generally using electronic methods; and the capacity to provide alternative treatments to participating patients.

These tools would aim to be helpful for particular sites, but potentially could be adopted by health care systems, payers, or consumer- and patient-facing organizations that can assist individual sites or participants in developing the critical capacities needed for trial participation. CTTI is developing a set of tools and resources to provide a roadmap to more rapid adoption of COVID-19 master protocols that could serve as a basis for setting goals and accelerating the use of master protocols more broadly. These should be used to identify promising additional participants from interested research networks created for other purposes, health care systems, payers, and other organizations. As we discuss below, clinical research organizations can also assist with the adoption and use of the protocols and support expansion of networks.

These tools should also be used by NIH and other funders to set clear guidance and expectations about study design and performance. There are reasons why particular trials may decide to use different endpoints or designs, but the urgency of developing meaningful clinical evidence on COVID-19 treatments means that funders should have clear reasons for supporting alternative approaches. All COVID-19 clinical trials should be well designed reflecting best practices on endpoints and statistical methods, and powered to support rapid enrollment and execution within a several-month time frame. Variants from the design suggested by these best practices may be appropriate but should be justified.

Support enhanced COVID-19 trial networks

Well-developed master protocols provide the foundation for developing larger COVID-19 clinical trial networks by enabling existing networks, clinical research organizations, and additional potential trial sites to enroll more patients in more places in well-designed trials. This will allow clinical trials to respond to likely shifting geographic distribution of patients with COVID-19 as the management of the pandemic advances. The existence of widely accessible master protocols will reduce the time needed to ramp up and complete trials, and can make clinical trials more accessible to sites that may not have the resources or infrastructure to participate in trials without the that provided by a formulated master protocol. Governance of the master protocols has to ensure that the evaluation and entry of drugs into the protocol is done efficiently, so that there are not long delays while decisions are made about which therapies to admit. Such a framework will make experimental drugs and clinical trials more accessible to more patients.

Similar trial networks have facilitated collaboration and reduced the cost and time of clinical trials in other disease areas, such as cancer, Alzheimer's disease, and antimicrobial-resistant pneumonia. **The COVID-19 networks should be fast, flexible, and well-organized enough that clinical development programs can quickly use them rather than having to invest time and development costs in a "one-off" clinical development program with FDA.** Using master protocols, these networks should be able to implement multi-arm trials that can compare multiple treatment alternatives or combinations, and to shift over time as evidence on particular treatments accumulates, with new arms added and others removed.

The goal of the COVID-19 trial networks is to have treatments that don't work fail as quickly as possible, and to enhance the pace of accumulating evidence necessary for approval for treatments that do work. Because the effectiveness of candidate products is unknown, this work should be guided by a statistical assessment of optimal treatment selection and removal, based on statistical designs that limit errors in missing products that do really work, and that use prespecified methods to incorporate preliminary evidence on the treatment. Greater use of such adaptive approaches can also give sponsors the flexibility to react to clinical evidence as it's being collected, and modify the design and enrollment in trials by including more patients with characteristics that predict they are more likely to derive a benefit from a particular treatment. It can also allow providers to exclude patients from clinical trials who possess characteristics that suggest that a patient is more likely to suffer a side effect from a particular experimental treatment.

By enriching the enrollment in the trial for patients with characteristics that are likely to predict clinical successful outcomes, these approaches have the potential to make the development process more efficient and patient benefit more likely. This approach also allows providers and sponsors to potentially learn much more about the characteristics that can inform safer prescribing. Those that demonstrate significant likelihood of effectiveness should be shifted to larger-scale evaluation, that is, a rapid or seamless shift from Phase 2 into Phase 3 evaluation within the same trial network. The greater the capacity of the trial networks for conducting such studies, the more treatments can be screened and then moved through late-stage development.

Using this approach, clinical research organizations or network sponsors could assist with recruiting additional providers, sites, and patients, expanding their reach into diverse populations and regions. Better network tools would also assure that the trial subjects' time and effort to participate in a study would be likely to lead to meaningful new evidence; that is less likely to be the case in a small, standalone, underpowered trial. CROs and existing research networks, such as PCORnet and cancer clinical trial networks such as I-SPY, can be key contributors to building this enhanced trial capability.

ACTIV is encouraging the development of such clinical trial networks using master protocols, starting with the adaptation of existing NIH trial networks to conduct effective COVID-19 studies. These activities can be augmented to extend to other potential trial sites and clinical research activities, with benchmark goals for clinical trial capacity to stay ahead of the need for promising trial sites. **Efforts to implement new trial networks at scale should be global – particularly as waves or outbreaks of COVID-19 ebb and flow geographically over time.** Trial networks since GUSTO have for decades shown that it is possible to get large-scale participation built around simple, straightforward templates based on master protocols that can be adopted in multiple centers; this should be easier with the digital technologies used to support the emerging COVID-19 master protocols. RECOVERY is providing strong early evidence that simple, effective protocols can drive widespread participation; over the course of 8 weeks it has already enrolled 10,000 eligible hospitalized patients in the UK.

To support these efforts, ACTIV and other research support programs should track and publicly report on progress made toward the goal of large-scale trial capacity, and on the pace of conducting clinical evaluations of COVID-19 treatments, ideally as part of tracking and reporting on the clinical trials themselves that are underway. Key measures include the capacity and throughput of the trial networks.

Implement effective expanded access programs

While rapid completion of clinical trials of promising treatments is a critical priority, it is likely that many patients who are not able to enroll in such trials will want access to the therapy before approval – particularly patients with serious COVID-19 complications. **FDA should support the timely implementation of a model expanded access program for COVID-19 patients in cases where manufacturers have additional treatment capacity available – which is likely if the sponsor is ramping up production as described below.** This model COVID-19 expanded access program should include guidance and tools for setting up a registry to track the characteristics and outcomes of patients who receive treatments under the expanded access program, and to support the critical postmarket evidence development steps also outlined below. Coupled with standard data protocols, the widespread availability of electronic data systems should facilitate registry implementation, at least for hospitalized patients.

Anticipate capacity for rapid access without shortages

Ensuring that new COVID-19 treatments can be available at scale with minimal delay following FDA's EUA or approval requires advance planning and investment. As evidence on effectiveness of a therapeutic accumulates rapidly, planning for manufacturing capacity with supporting supply chains is needed in advance to have adequate quantities of the therapeutic available, including for the possibility of further COVID-19 pandemic waves. For repurposed drugs, this supply must be sufficient to continue to meet the needs of patients who already depend on the treatment.

Assess future COVID-19 treatment capacity gaps

The diversity of potential therapies for COVID-19 requires a range of manufacturing platforms, including for small-molecule parenterals, monoclonal antibodies, and flexible single-use advanced biologics. Non-specific fill-and-finish capacity that can quickly be adapted to accommodate a wide range of therapies is also needed. This capacity can be costly and time-consuming to put in place, with only a limited supply available in the US and globally. Even products that are easier to manufacture, including small-molecule oral formulations, face supply constraints. They are often produced overseas and may be vulnerable to supply disruptions during the pandemic.

Major pharmaceutical companies with substantial capital and experience are already undertaking this type of advance planning for their COVID-19 therapies. For example, based on projections of potential high demand for remdesivir, Gilead has ramped up US manufacturing capacity and is entering into licensing agreements with additional manufacturers outside the US. However, smaller biotechnology companies may not have the capacity to make such advance

arrangements, and available manufacturing supply may fall short of needed capacity later this year, so that effective treatments without such advance arrangements in place may end up facing shortages.

To avoid such shortages for treatments that are shown to be effective, advance planning should be undertaken now to include an assessment of each major type of manufacturing capacity, in relation to the expected time to emergency use availability and approval for the promising treatments in development. An estimate of needed manufacturing capacity would reflect the treatments expected to reach late-stage clinical trials over time (e.g., in the next several months, fall, winter, and into 2021) along with an estimate of potential demand for such treatments accounting for the possibility of larger outbreaks later this year. The analysis should expect that the vast majority of products not yet in clinical development and most of those in early clinical development will fail, but (in the event that more succeed) that some excess capacity is needed because the value of having multiple effective treatments is high.

The assessment should match the different types of advanced manufacturing capacity with the promising therapies currently in development. For example, over 20 monoclonal antibodies to the SARS-CoV-2 virus are in development now; while many are unlikely to succeed, additional capacity that could be made available to manufacture those that do would help avoid shortages. There should be an assessment of the potential needs not only of COVID-19 patients with different risk and severity levels, but also use in prophylaxis. Some of the potential treatments to avoid the complications of severe immune responses are also monoclonal antibodies. Thus, monoclonal antibody manufacturing capacity planning should assure adequate supply for multiple manufacturers of all of these treatments. Similar analyses are needed of manufacturing capacity and flexibility for adequate production of other types of products.

The assessment should include each major step of the manufacturing process – from the acquisition or production of active pharmaceutical ingredients and biologic components, to purification, to the provision of glass for finished dosage forms – to identify and address potential barriers and bottlenecks that could affect availability. This assessment may identify practical opportunities to make existing manufacturing capacity nimbler and more flexible, as we describe below. Given that manufacturing capacity in other countries may be required for domestic production of COVID-19 therapeutics, the assessment should differentiate US-based capacity needs and gaps.

BARDA in collaboration with other government agencies involved in the COVID-19 response has already undertaken such assessments as part of its work to support product availability. To assure coordination with product developers (especially smaller companies with less resources), and to assess whether large companies that have already contracted for forward capacity are prepared to redirect it if their compound does not succeed, steps to increase manufacturing capacity and fill gaps should be reported publicly and updated regularly.

Develop plans for sufficient ramp-up of advanced manufacturing capacity

There are three sources of increased manufacturing capacity to address shortfalls identified in COVID-19 capacity assessments: using current capacity more efficiently, redirecting existing capacity to new treatments, and building additional capacity.

Working with FDA and other agencies, manufacturers should identify ways to optimize use of current manufacturing capacity, and prepare for flexibility in that capacity to support potential ramp-up in production of new therapies. For example, FDA has previously encouraged companies to adopt continuous manufacturing techniques instead of batch certification, both to increase productivity and enable more rapid shifts of production lines to avoid shortages. Companies with relevant capacity should also increase production to stockpile other drugs now so that more capacity is available when effective COVID-19 therapies are identified, and seek opportunities to increase production at other manufacturing facilities outside the US.

With support from BARDA, new manufacturing capacity should be added where critical to address potential shortages, using current best practices and supporting technologies. Building new advanced manufacturing capacity takes time, but it is not too late to undertake further activities now if assessments suggest key gaps. For example, recent advances in the technology used to manufacture therapeutic monoclonal antibodies have allowed new therapies to enter production in just 10-12 months, and with careful planning and investment this can be reduced further. Regulators can support efforts to bring these drugs into production: FDA should provide technical assistance during clinical development to precertify potential production facilities, before clinical trials are completed.

As limited advanced manufacturing capacity is repurposed toward producing therapies for COVID-19, stakeholders must ensure that such repurposing does not result in shortages of critical therapies for other conditions. Efforts to repurpose existing manufacturing capacity should include planning to avoid disruptions in access for patients who need products that may be repurposed for COVID-19 treatment. The recent increase in demand for hydroxychloroquine showed the importance of including existing products in planning. This may also be important for immune modulators that show promise in treating COVID-19 and yet are critical for patients with autoimmune conditions and other immune-related disorders.

To support these efforts, a public-private collaboration that includes FDA, biotechnology and manufacturer associations, and relevant companies could identify opportunities for manufacturers to shift existing capacity to produce the most promising therapies quickly, even if the production is for companies that are normally competitors. Such collaboration should be supported by financial incentives for companies that make their capacity available for production of effective therapies.

Provide financial support for expanded manufacturing and timely, adequate availability

New financial incentives and payment models will be needed to ensure sufficient investment in the manufacturing of COVID-19 therapies. Many manufacturers are planning ahead for manufacturing their own products in development. However, investing in large-scale manufacturing capacity before trial results are known entails significant financial risk, which may limit the amount of product available soon after trial completion. Even large manufacturers may have difficulty preparing to go at risk for the full scope of COVID-19 treatments likely needed, and advance financing of sufficient manufacturing capacity is likely to be particularly challenging for smaller product developers with less available capital.

The US government should expand investments now to secure adequate manufacturing capacity to meet potential COVID-19 patient needs. Given the cost involved in redirecting or developing new manufacturing capacity, additional public investments are needed to close gaps in any needed capacity. BARDA and other agencies are working to increase such capacity, both by working with specific product developers and by investing in advanced manufacturing technologies that can help scale that capacity. Such investments should include, for example, parenteral manufacturing capacity that could be quickly dedicated to augmenting manufacturing capacity for any particular parenteral drug that shows clinical effectiveness; and monoclonal antibody manufacturing capacity that could be quickly recruited for additional manufacturing of an antibody that shows clinical effectiveness.

Such payments for capacity development should be augmented by large-scale advance payment contracts for producing the therapies. Many manufacturers have already committed to producing COVID-19 therapies on a not-for-profit basis linked to cost of goods sold during the pandemic emergency. Because exact supply needs are hard to predict, advance payment contracts for a sufficient volume of production will enable all parties to share risk. Working out model versions of these contracts now will help avoid delays due to uncertainties about costs or needed manufacturing scale after products demonstrate effectiveness, and will also help avoid shortages.

Two types of large-scale, advance payment contracts should be explored. First, Federal funding administered through BARDA should support large-scale purchases of effective therapies, to reduce uncertainty for manufacturers and payers about the scale and cost of new COVID-19 therapeutics and to help ensure adequate supply. BARDA's authority and funding to supply the Strategic National Stockpile can be a basis for these contracts. Model contracts should be developed in collaboration with product developers and potential manufacturers. These Federal contracts could assure capacity for surge needs (e.g., large outbreaks), uninsured individuals, and to address potential shortages in public programs. With sufficient funding, they could also be used to provide access to therapies in publicly- and privately-insured populations.

Second, the Centers for Medicare & Medicaid Services (CMS) and private payers should explore the development of advance purchase contracts for adequate therapeutic supplies for their covered populations given the current public health emergency. Such contracts would be

implemented only for therapeutics that reach the market based on adequate evidence of safety and effectiveness, and could replace fee-for-service payment for individual drug purchases. These population-based payments would commit manufacturers to providing a minimum amount of a product expected to meet the needs for the covered population in the event of significant viral activity, for a population-based aggregate price. While that price may be significantly lower on a per-unit basis than might be achieved through traditional fee-for-service pricing, high per-unit prices and potentially high copays are not conducive to providing access to patients who need treatment to control the pandemic.

This approach is consistent with Congressional actions to limit copays for COVID-19 testing and treatments. Thus, this approach would reflect the special circumstances of pricing during the public health emergency, would help avoid shortages despite considerable uncertainty about the course of the pandemic, and would help assure that outbreaks can be rapidly treated. Because the marginal cost of production is low compared to the average price for most drug therapies, the approach should enable payers to commit to paying for a larger product supply than if only per-unit pricing was available, while allowing manufacturers to cover their costs for providing a larger supply.

A model contract for such emergency population-based purchasing could be developed by CMS for Medicare, alongside models for state adoption in Medicaid. Private payers would likely adopt similar models if available. Congress could encourage such contracts, for example in Medicare Advantage or Medicaid managed care plans, through authorizing partial matching funds or providing other guidance for providers and manufacturers who move away from fee-for-service contracts. These emergency supply contracts should also be exempt from usual pricing regulations such as Medicaid best price that are used in nonemergent circumstances. Even if such contracts cannot be executed in the short term as alternatives to fee-for-service pricing, their development would encourage needed collaborations and sharing of information among government, manufacturers, and payers to assure adequate access for COVID-19 treatments.

While challenging, the alternative to such advance manufacturing planning and purchase contracts is far less desirable. Shortages would be more likely to emerge especially in the event of further outbreaks or a surge in cases. This would be particularly challenging for specific insured or uninsured populations that do not secure advance contracts, requiring difficult government-directed determinations about priority access to therapies. The use of the Defense Procurement Act could address manufacturing shortages, but the time required to shift manufacturing lines for complex biologic products is likely to be longer than for protective equipment or ventilators, and would likely disrupt supplies of other needed drugs.

Conduct effective real-world data collection and studies after emergency use authorizations and approvals

The use of new COVID-19 therapeutics will be supported by meaningful evidence on safety and effectiveness resulting from randomized trials completed prior to product approval. However, pivotal trials for initial approval are likely to be based on evidence of safety and efficacy in specific

types of COVID-19 patients and treatment contexts, such as hospitalized patients with severe illness. Moreover, in the absence of robust treatment options, FDA will likely implement emergency use authorizations for treatments with promising clinical results before trials are complete. And there are also likely to be substantial gaps in the evidence available on products already on the market that are hypothesized to have activity against COVID-19, where significant "off-label" use may occur.

As a result, clinicians, patients, and the public will want additional evidence on new COVID-19 treatments following their initial approval or emergency availability, including evidence on:

- **effects in patient subgroups (e.g., elderly with complex conditions, different demographic subgroups)**
- **prophylaxis or earlier-stage treatment for drugs approved for patients with more severe COVID-19 cases**
- **effectiveness of treatment combinations**
- **comparative effectiveness and cost effectiveness of alternative COVID-19 treatment strategies as more become available over time**

Recent developments in real-world evidence systems and electronic data analytic capabilities provide new opportunities to address these critical evidence gaps. Analyses of "big data" from electronic medical records, insurance claims, patient-generated data, and other sources can support analyses of the evolving natural history of COVID-19 infections in different types of patients, and can help understand syndromes and risks such as late inflammatory syndromes in children and the consequences of alternative approaches to breathing assistance and ventilation. Such analyses can help improve clinical trial evidence, by guiding clinical trial design (e.g., informing statistical power calculations) and by making it easier for more sites of care to implement clinical trials using the tools like common data models and master protocols that we described previously. In addition, the improving infrastructure for conducting real-world studies can augment such clinical trial evidence.

Leverage existing RWE infrastructure to fill key evidence gaps

FDA, CMS, Federal research funders, private entities, and companies with expertise in large data analysis are supporting RWE studies to provide evidence on COVID-19 questions. These studies are leveraging a range of observational study networks using secondary electronic data generated through care delivery, common data models, and shared protocols for interventional studies analogous to those described for clinical trials above.

Existing distributed data networks such as FDA's Sentinel Initiative, the Patient Centered Outcomes Research Network (PCORnet), the Observational Health Data Sciences and Informatics (OHDSI) program, large health care systems (e.g., University of California Health System, US Veterans Health Administration), and EHR vendors (e.g., EPIC and Cerner), are also using their datasets to address priority questions involving therapeutics. These approaches can enable consistent, parallel analyses across multiple settings and data sources, and can be used to

conduct fast studies across a large number of patients and health care organizations. For example, the PCORI-funded HERO registry, which uses PCORnet, aims to understand the impact of COVID-19 in health care workers across hundreds of hospitals and other health care systems. In addition to evaluating clinical questions, Sentinel is also being used to answer questions about the drug supply chain (e.g., assessing products used in the inpatient and outpatient settings to anticipate potential drug shortages).

In addition, some organizations have made deidentified, HIPAA-compliant data available for research use. The COVID-19 Research Collaborative, for example, is a pro-bono initiative of data companies, data platform companies, and researchers that are collaborating to share and link claims, EHR, and mortality data and make them available to researchers. Supplemental Table 3 summarizes many of these activities and the evidence gaps they are aiming to fill.

Further steps are underway to leverage these efforts to accelerate the development of needed evidence. The Reagan-Udall Foundation and Friends of Cancer Research COVID-19 Evidence Accelerator, for example, is a public-private collaboration supported by the FDA that is bringing together a broad community of methodological experts, public health officials, diverse data sources and RWE evidence initiatives to take steps to cross-validate findings on priority questions identified by the FDA and stakeholders. By developing a common set of core data elements that can be analyzed using common protocols by a range of RWE groups, the Evidence Accelerator can facilitate more comparable and robust results. It also facilitates expert exchange and analysis to address key questions and methodologic issues. The data remains with its originator, and jointly developed analyses provides a research framework that can be applied to answer new questions over time. In a rapidly evolving clinical environment of COVID-19, confirmation of results and validation of methods across multiple sources of data can increase confidence in the findings, provide a stronger basis for clinical decisions and policymaking. In parallel, MITRE's COVID-19 Healthcare Coalition aims to integrate existing common data models by building a meta-data like model, mCOVID, to enable broader, more technically aligned analyses. EMR vendors and other groups are also supporting tools to make it easier for health care providers to contribute their electronic data to relevant studies.

To further accelerate needed evidence on therapeutics, broad multi-stakeholder collaborations like these should receive additional support to address key postmarket evidence questions – with the capabilities put in place ahead of product approvals so they are ready to use. Federal support should be linked to benchmarks for increasing the speed and capacity for conducting postmarket studies using the emerging distributed COVID RWE infrastructure. Funding should encourage the adoption of common data models, protocols for analyzing the data, and mechanisms to assess and improve these methods, to make available more generalizable RWE results from comparable analyses across a broad range of settings and participants. Studies that involve vulnerable and understudied populations should be prioritized.

This RWE infrastructure could be supported as part of the comprehensive response envisioned in CARES Act appropriations. While FDA-identified priorities should be addressed, the same infrastructure could be used for additional evidence questions. The recent reauthorization of

PCORI with $7 billion of additional funding could support accelerated evidence on comparative effectiveness questions involving alternative treatment approaches for COVID-19, as more treatments reach the market or the use of existing treatments might be varied (e.g., different timing or duration of treatment). The Agency for Healthcare Research and Quality (AHRQ) and NIH could also provide support. But practical steps need to be implemented rapidly, so that the infrastructure will be available to address key postmarket evidence questions ahead of further approvals and emergency use authorizations.

Link payment to a multi-stakeholder strategy for virtual COVID-19 registries and postmarket studies

The steps just described have the potential to create a readily-available infrastructure for better evidence to augment clinical trials on using COVID-19 treatments effectively. This includes a comprehensive approach to post-approval monitoring of safety, confirmation of benefits in real-world populations and vulnerable subgroups if patients, and long-term outcome assessment. **With the emerging opportunities for developing real-world evidence, payment contracts for COVID-19 treatments should also encourage manufacturers and health care providers to participate in the implementation of a COVID-19 evidence network.**

First, participation in this enhanced infrastructure to develop better evidence could be linked to EUAs and approvals, and to broader coverage in indications where evidence is suggestive but not conclusive. At a minimum, consideration of how such an evidence network could augment evidence available at the time of approval could become a regular component of purchasing contracts for COVID-19 therapeutics. Second, building on the current Medicare payment bonus for providers who participate in COVID-19 clinical trials, Medicare could provide financial incentives for providers who participate in the real-world evidence network.

Ideally, a collaboration involving sponsors, participating organizations, and payers would produce a virtual registry or registries to address key questions using RWE networks prior to product approval, to address postmarket safety questions for FDA as well as address additional types of questions relevant to patients, clinicians, and payers. Participation by providers would be voluntary, but would be supported by tools developed by the network participants to incorporate and standardizing data, and assuring its appropriate and secure use, with minimal cost and disruption for health care organizations. The tools and financial incentives would enable much broader participation by more providers in more settings of care.

The COVID-19 evidence collaboration could conduct faster and more comprehensive distributed analyses of key questions beyond those that are feasible to conduct using traditional FDA postmarket approaches or through activities involving single data sources. Insurers can conduct parallel studies using claims data, or potentially provide key data, like hospital admissions or the occurrence of other complications for studies in the outpatient setting, that are not captured in hospital-based datasets. Other data holders could conduct supplemental analyses using distinctive features of their own datasets.

This work would complement planning for advance purchases and timely distribution of therapeutics for the full duration of the COVID-19 threat, and would provide an infrastructure for addressing future questions involving the public health impact of other treatments.

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Table 1: Promising COVID-19 Therapeutics in Development

Therapy & Company	Key Clinical Trial Population(s)	Anticipated Trial Timeline	Therapeutic Manufacturing Capacity
Antiviral Therapeutics			
Remdesivir Gilead Sciences, Inc.	• Patients hospitalized with severe COVID-19 • Patients hospitalized with COVID-19	Severe disease results released April 2020 (ref) Moderate disease results expected May 2020 (ref)	• More than 140,000 treatment courses by the end of May 2020 • More than 500,000 treatment courses by October 2020 • More than 1 million treatment courses by December 2020 • Several million treatment courses in 2021, if required (ref)
Convalescent Plasma			
Convalescent plasma	• Patients hospitalized with COVID-19 • Patients hospitalized with severe COVID-19 • Patients hospitalized with severe COVID-19 on mechanical ventilation	Early expanded access safety metrics reported May 2020 (ref) Multiple phase 3 trials ongoing (ref)	
Hyperimmune Globulin			
Hyperimmune globulin (H-IG) Emergent BioSolutions Inc. -and- Grifols Shared Services North America, Inc.	• Patients hospitalized with severe COVID-19 pneumonia • Participants at risk of SARS-CoV-2 infection (prophylaxis)	Clinical study to begin as early as Q3 2020 (ref)	Emergent BioSolutions partnered with BARDA and NIAID. (ref) Emergent has initiated plasma collection efforts for both human and equine platforms with a goal of manufacturing clinical material within the next four to five months in anticipation of beginning a clinical study. (ref) Grifols partnered with BARDA and the Joint Program Executive Office for Chemical,

			Biological, Radiological and Nuclear Defense (JPEO-CBRND). (ref)
SAB-185 (polyclonal hyperimmune globulin) SAB Biotherapeutics, Inc.	• Clinical trial population(s) to be determined		Partnership with CSL Behring, BARDA, and JPEO-CBRND. SAB Biotherapeutics' novel immunotherapy platform provides a method to rapidly manufacture without the need for human plasma. (ref)
Interleukin-6 (IL-6) Receptor Antagonists & Inhibitors			
Sarilumab (Kevzara) Regeneron Pharmaceuticals Inc.	• Patients hospitalized with COVID-19 • Patients with severe community-acquired pneumonia resulting from SARS-CoV-2 infection	Preliminary phase 2 results released April 2020 (ref) Phase 3 results expected June 2020 (ref) Part of the REMAP-CAP adaptive platform trial (ref)	No specific information reported. (ref)
Siltuximab (Sylvant) EUSA Pharma	• Patients hospitalized with COVID-19 • Patients hospitalized with COVID-19 pneumonia	Compassionate use data reported April 2020 (ref)	No specific information reported. (ref)
Tocilizumab (Actemra) F. Hoffmann-La Roche Ltd & Genentech, Inc.	• Patients hospitalized with non-critical COVID-19 • Patients hospitalized with severe COVID-19 • Patients hospitalized with COVID-19 and cytokine release syndrome • Patients with severe community-acquired pneumonia resulting from SARS-CoV-2 infection	Roche trial results expected in May or June 2020 (ref) Part of the REMAP-CAP adaptive platform trial (ref)	Partnership with BARDA. (ref)

Janus Kinase (JAK) Inhibitors			
Baricitinib (Olumiant) Eli Lilly and Company	• Patients hospitalized with COVID-19 • Patients hospitalized with severe COVID-19		Partnership with the National Institute of Allergy and Infectious Diseases (NIAID). (ref) Lilly currently does not anticipate shortages for any of its medicines, including baricitinib, which remains widely available in countries where it is approved.
Ruxolitinib (Jakafi) Incyte Corporation	• Patients hospitalized with COVID-19 and cytokine release syndrome • Patients hospitalized with COVID-19-associated Acute Respiratory Distress Syndrome (ARDS)	Phase 3 trial ongoing (ref)	At present, there is ample commercial and clinical supply of ruxolitinib in the United States to meet the needs of U.S. patients receiving ruxolitinib in its approved indications and those participating in clinical trials. Incyte is increasing manufacturing efforts to respond to anticipated supply needs related to COVID-19 studies and working closely with distribution partners to monitor the supply of ruxolitinib. (ref)
Tofacitinib (Xeljanz) Pfizer Inc.	• Patients hospitalized with COVID-19 and interstitial pneumonia	Phase 2 trial ongoing (ref)	No specific information reported. (ref)
Interleukin-1 (IL-1) Receptor Antagonist			
Anakinra (Kineret) Shanghai CP Guojian Pharmaceutical	• Patients with severe community-acquired pneumonia resulting from SARS-CoV-2 infection	Part of the REMAP-CAP adaptive platform trial (ref)	
Novel Antibody Therapeutics			
S309 Vir Biotechnology, Inc.	• Patients with COVID-19 • Participants at risk of SARS-CoV-2 infection (prophylaxis)	Clinical trials “this summer” (ref)	Collaboration with Samsung for capacity to produce hundreds of thousands of doses by year end and tens of millions of doses next year. Investing in production capacity at risk ahead of product approval.
Multi-antibody cocktail Regeneron Pharmaceuticals Inc.	• Non-hospitalized patients • Hospitalized patients	Initial clinical testing at the beginning of summer (ref)	The company is working toward the goal of producing hundreds of thousands of

	• Participants at risk of SARS-CoV-2 infection (prophylaxis)		prophylactic doses per month by the end of summer. (ref) The company is working with the U.S. Health & Human Services' Biomedical Advanced Research and Defense Authority (BARDA) to increase capacity even further.
Antibody therapy Adaptive Biotechnologies Corporation	• Clinical trial population(s) to be determined		Partnership with Amgen. Amgen will leverage its antibody engineering and drug development capabilities to select, develop and manufacture antibodies. (ref)
VIR-7831 & VIR-7832 Vir Biotechnology, Inc.	• Clinical trial population(s) to be determined	Phase 2 clinical trial within the next three to five months (ref)	Partnership with GSK. (ref)

Table 2: Examples of COVID-19 Master Protocols and Trial Networks

Trial	Leadership	Anticipated Interventions*	Protocol/Study Detail Availability	Approach
Inpatient Settings				
RECOVERY Trial†	Sponsor: University of Oxford CI: Peter Horby, MD, PhD Study sites: 176 active sites	lopinavir-ritonavir low-dose corticosteroids (dexamethasone) hydroxychloroquine azithromycin	Published online at recoverytrial.net	Randomised, controlled, platform trial Pragmatic design with adaptive elements and use of real-world data
Solidarity Trial	World Health Organization in collaboration with regional sponsors	remdesivir lopinavir/ritonavir lopinavir/ritonavir with interferon beta-1a chloroquine or hydroxychloroquine	Canadian arm published online at clinicaltrials.gov/ct2/show/NCT04330690	Randomized, open-label, controlled clinical trial with adaptive elements
REMAP-CAP COVID†	International trial steering committee Regional sponsors/coordinating centers: Monash University (Australia and New Zealand) Utrecht Medical Center (Europe) Imperial College London/ICNARC (UK)	anti-viral therapies (lopinavir/ritonavir; hydroxychloroquine; remdesivir) corticosteroid therapy (multiple dosing strategies) innate immune modulation therapy (interferon beta; anakinra; tocilizumab;	Published online at remapcap.org/coronavirus	Randomized embedded multifactorial adaptive platform (REMAP) design Uses RAR and Bayesian inference Tests multiple interventions concurrently, nested within different domains Stratified by moderate and severe disease categories

	University of Toronto (Canada) Global Coalition for Adaptive Research/University of Pittsburgh (US) Study sites: >160 active sites (more being added) in 13 countries	sarilumab; multiple others) ACE2-RAAS modulation (ARBs, ACEi, others) ACE2-kinin-kallikrein modulation high dose vitamin C simvastatin anticoagulation and anti-platelet strategies immunoglobulin and convalescent plasma interventions		
Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)	Sponsor: National Institutes of Health	In development	In development	In development
Adaptive COVID-19 Treatment Trial I (ACTT I)	Sponsor: National Institute of Allergy and Infectious Diseases	remdesivir	Published online at clinicaltrials.gov/ct2/show/NCT04280705	
I-SPY COVID TRIAL (Response in an Adaptive Platform Trial to Reduce Mortality and Ventilator Requirements for	Sponsor: Quantum Leap Healthcare Collaborative PI: Carolyn Calfee, MD, UCSF; Kathleen Liu, MD, UCSF	(Tentative and under initial consideration for prioritization) Backbone/standard therapy: standard of	Published online at ispytrials.org/collaborate/covid-19-updates	Phase 2 interventional, multi-arm platform trial Flat randomization with adaptive components

Critically Ill Patients)†	Study sites: Approx 20 centers in the US with UCSF as lead site	care ventilatory management plus remdesivir (or alternative, will evolve as data emerges from this and other trials) Arm 1: remdesivir alone Arm 2: remdesivir w/ cenicriviroc [Allergan] Arm 3: remdesivir w/ icatibant [Takeda] Additional agents are undergoing review and prioritization (TBD)		
Outpatient Settings				
Healthcare Worker Exposure Response and Outcomes (HERO) – HCQ Trial†	Sponsor: Duke University / Adrian Hernandez, MD, MS PI: Susanna Naggie, MD Study sites: Approx 40 PCORnet sites in the US	hydroxychloroquine versus placebo as prophylaxis	Published online at https://heroesresearch.org/wp-content/uploads/2020/05/HERO-HCQ-Protocol-V2.0_5.1.20_clean.pdf	Double blind, placebo controlled study
Platform Randomized trial of INterventions against COVID-19	Sponsor: University of Oxford	hydroxychloroquine	Published online at phctrials.ox.ac.uk/principle-trial	Randomised, controlled platform trial in community care Prospective

in older peoPLE (PRINCIPLE) Trial†				Individual randomization Pragmatic elements
Efficacy of Novel Agents for Treatment of SARS-CoV-2 Infection Among High-Risk Outpatient Adults: An Adaptive Randomized Platform Trial	Sponsor: University of Washington / Bill and Melinda Gates Foundation	Control group: ascorbic acid rolic acid Interventional group: hydroxychloroquine sulfate azithromycin	Published online at https://clinicaltrials.gov/ct2/show/NCT04354428	Adaptive Randomized placebo-controlled Platform Trial Parallel design Double blind

* Table current as of 5/19/2020 – treatment arms in each protocol could be paused for futility, advanced or spun off given promising results, or newly included as additional treatments enter development

† Information provided by study teams

Table 3: Multi-Stakeholder Real-World Evidence Initiatives to Inform COVID-19 Therapeutics

Organization	Initiative Name	Description	Research Setting	Data Source	Data Models
Reagan-Udall Foundation for the FDA and Friends of Cancer Research	COVID-19 Evidence Accelerator	New, multi-stakeholder COVID-19-specific initiative that is developing a data shell with common data elements to answer the same research question across different data sources. Analyses to answer a research question are run in parallel, but qualitatively compared across researchers. New research questions can be rapidly added and aligned with different data partners. Data is housed by the collector. Additionally, weekly lab meetings are convened to share methods and advance COVID-19 RWE learnings. Current research questions include: • Among hospitalized patients with COVID-19, describe the following for hydroxychloroquine +/- azithromycin vs control: ○ Characterize COVID-19 patient populations ○ Characterize treatment (e.g., timing in COVID-19 illness trajectory; monotherapy vs co-prescription; dose) ○ Characterize safety signals, including by subpopulations (e.g., age, diabetes, COPD) ○ Describe comparative effectiveness on key outcomes ○ Identify potential predictors of treatment safety and effectiveness	Inpatient, Outpatient	Claims, EHR	Data shell with common data elements
COVID-19 Healthcare Coalition	mCOVID	New, multi-stakeholder COVID-19-specific initiative that is developing a minimum common data model with mapping to other data models, and creating standardized cohorts. Common research questions focusing on the inpatient setting are answered by researchers in parallel with the goal of pooling results in a meta-analysis. Data is housed by the	Inpatient, Outpatient	EHR	Mapping to OHDSI, I2B2, and exchange standards

		collector. Also developing data standardization tools such as a data dictionary and COVID-19 vocabulary. Current research questions include: • For patients with new COVID-19 infection, how does the addition of hydroxychloroquine (HCQ) affect the outcomes (1) severe disease (indicated by mechanical ventilation) and (2) inpatient death? • For patients with new COVID-19 infection, how does treatment with convalescent serum (CS) affect the outcomes (1) severe disease (indicated by mechanical ventilation) and (2) inpatient death?			such as FHIR
FDA Sentinel System	FDA Sentinel System's Coronavirus (COVID-19) Activities	Leveraging existing distributed data network and common data model to answer COVID-19-related questions regarding drug use, protocols for public health emergencies, and identification of new data sources and partners Current research questions include: • Near real-time monitoring of critical drugs for the care of patients with COVID-19 (also includes drug utilization in outpatient care) • Methods to monitor medical countermeasure safety and effectiveness (expanded to capture data on hospitalized patients diagnosed with COVID-19) • Horizon scan of EHR databases to identify EHR sources to strengthen the Sentinel System (expanded to identify data sources capable of monitoring the diagnosis and treatment of COVID-19 patients) • Natural history study to identify cohorts of patients diagnosed with COVID-19 in ambulatory and inpatient settings and to monitor their treatment patterns and disease progression (Planned) • Evaluating the impact of treatments used for COVID-19 using RWD (Planned)	Inpatient, Outpatient	Claims, EHR	Various data models possible, including Sentinel common data model, PCORnet, HCSRN, modified versions of standard models, and data source specific models as appropriate for the question

		• Validation of claims-based phenotypes for COVID-19 positive patients (Planned)			
Cerner	HealtheDataLab	Leveraging existing Cerner EHR records to develop database of de-identified COVID-19 patient data including COVID-19-related demographics to help track spread and surge, underlying illnesses and chronic conditions, treatments, lab results and clinical complications and outcomes that could help drive important medical decisions. Stored on Cerner HealtheDataLab™, powered by AWS. This initiative is in alignment with the Cerner Learning Health Network launched in 2019.	Inpatient, Outpatient	EHR	
CD2H and NCATS	National COVID Cohort Collaborative (N3C)	New, multi-stakeholder COVID-19 Initiative in partnership with distributed data networks. Goal of N3C is to develop a national, centralized, secure portal for hosting row level COVID-19 clinical data and deploying and evaluating methods and tools for clinicians, researchers, and health care to support COVID-19 analytics. N3C will apply a common data model to all data. Data resides with collector, but limited dataset will be stored in secure enclave. Four workstreams include: 1) Data Partnership & Governance, 2) Phenotype & Data Acquisition, 3) Data Ingestion & Harmonization, 4) Collaborative Analytics.	Inpatient, Outpatient	Claims, EHR	Mapping data models from various distributed data networks (PCORnet, TriNetX, OHDSI, ACT/i2b2) to OMOP
PCORI and Duke University	Preventing COVID-19 Infections: Healthcare Worker Exposure Response and Outcomes (HERO) Registry and HERO-	Leveraging existing PCORnet distributed data network for COVID-19 research to develop registry of health care workers on front lines who are at risk for developing COVID-19 infection. Participants can provide health information about relevant COVID-19 risk factors, medical encounters, and health status. As part of the HERO-HCQ trial, approximately 15,000 registry participants will be randomized to either one month of HCQ or placebo to determine whether HCQ is effective in decreasing the rate of COVID-19 infection. 40 medical centers in total have been selected to participate in the trial.	Health care workers exposed to inpatient and outpatient settings	Direct to participant	

	Hydroxy-chloroquine (HCQ) Trial				
University of California Health System	COVID-19 Data Collection in UC Health Data Warehouse	The UC Health system adapted ongoing data collection, aggregation, and mapping efforts in existing UC Health Data Warehouse to include data elements of COVID-related importance (e.g., test results, confirmed cases by geography, age and gender). UC Health Data Warehouse has data from six of the UC medical schools and systems (UC San Diego Health, UCR Health, UCI Health, UCLA Health, UCSF Health, and UC Davis Health). The current COVID-19 related repository has inpatient and ambulatory care data on more than 56,000 tested patients (of which more than 1,800 were positive for the virus).	Inpatient, Outpatient	EHR	OMOP
Aetion and HealthVerity	Real-Time Insights and Evidence Platform	Expanded existing partnership to offer new real-world evidence system designed for biopharma manufacturers and regulators to assess treatment approaches for COVID-19. The platform uses real-time data to offer insights about the usage, safety, and clinical effectiveness of proposed COVID-19 interventions. Also can provide insights on disease progression of COVID-19 across demographic subgroups and how COVID-19 is treated and managed over time in various settings. Additionally, Aetion is partnering with FDA through a research collaborative agreement to evaluate priority research questions including understanding the the natural history of the disease as well as treatment and diagnostic patterns using real-world data through its Evidence Platform®.	Inpatient, Outpatient	Claims, EHR	
US Department of Veteran Affairs		Leveraging existing data warehouse with common data model for observational studies to characterize COVID-19 patients, treatments, and outcomes.	Inpatient, Outpatient	EHR	OMOP

EPIC	EPIC Health Research Network	Leveraging existing EHR platform to conduct COVID-19 observational studies. Created online platform (Epic Health Research Network) to share findings. Report topics include comorbidities in COVID-19 patients, COVID-19 hospitalization statistics, racial disparities amongst COVID-19 patients.	Inpatient, Outpatient	EHR	
Public/Private Consortium	COVID-19 Research Database	New, COVID-19-specific initiative creating new data repository using existing collaborator-provided datasets. Data repository comprised of HIPAA-compliant, de-identified and limited longitudinal, patient-level data sets made available to public health and policy researchers. Datavant provides linking technology. Mirador responsible for statistical certification for linked data. Other collaborators include: Advarra, Aetion, AnalyticsIQ, Arcadia, BHE, BRG, Change Healthcare, Clarify, Datavant, Elsevier, Glooko, Health Care Cost Institute, Healthjump, Helix, Medidata, Munich RE, Mirador Analytics, Office Ally, OMNY, Parexel, Prognos Heath, Qiagen, Quertle, SAS, Snowflake, Sumitomo Dainippon Pharma, Symphony Health, Veradigm, Vizient.	Inpatient, Outpatient	Claims, EHR, Consumer Data	

To: Rusek, Benjamin[BRusek@nas.edu]
Cc: relman@stanford.edu[relman@stanford.edu]; Baric, Ralph S[rbaric@email.unc.edu]; saif.2@osu.edu[saif.2@osu.edu]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; harvey.fineberg@moore.org[harvey.fineberg@moore.org]; dgriffi6@jhmi.edu[dgriffi6@jhmi.edu]; jwleduc@UTMB.EDU[jwleduc@utmb.edu]; peshi@UTMB.EDU[peshi@utmb.edu]; Dzau, Victor J.[VDzau@nas.edu]; fsharples_3@hotmail.com[fsharples_3@hotmail.com]; Lowenthal, Micah[mlowenth@nas.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; andre@ecohealthalliance.org[andre@ecohealthalliance.org]; jennifer.ryan@moore.org[jennifer.ryan@moore.org]; Bowman, Katherine[KBowman@nas.edu]; Kanarek, Morgan[MKanarek@nas.edu]; Raymond JEANLOZ[jeanloz@berkeley.edu]; Hare, Hope[HHare@nas.edu]; davidrfranz@gmail.com[davidrfranz@gmail.com]
From: Peggy Hamburg[peggy@hbfam.net]
Sent: Mon 6/1/2020 10:40:14 AM (UTC-04:00)
Subject: Re: 3rd Virtual U.S. China dialogue meeting on COVID-19 Tuesday, June 9, 9-11PM ET

Thanks. Should be an interesting discussion

Sent from my iPhone

On Jun 1, 2020, at 10:03 AM, Rusek, Benjamin <BRusek@nas.edu> wrote:

Greetings,

Good news, just heard back from CAS. They agreed to hold the 3rd dialogue meeting on the proposed immunity topics on **Tuesday, June 9 from 9:00-11:00 PM ET** (9-11 AM the next morning, Beijing time). Please hold that time on your calendar.

CAS let us know that George Gao wants to add the following questions to the discussion:

- Could any US participant introduce the progress in the development of vaccine in the US, especially mRNA vaccine?
- How is the overall situation of serologic investigation in the US?
- What is the COVID-19 prevention and control strategy in the US for the second half of this year? When do you expect COVID-19 vaccine to be available in the US ?

We will send out a new agenda and Zoom link for the meeting later in the week.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Friday, May 22, 2020 3:55 PM
To: 'relman@stanford.edu' <relman@stanford.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'saif.2@osu.edu' <saif.2@osu.edu>; 'stanley-perlman@uiowa.edu' <stanley-perlman@uiowa.edu>; 'daszak@ecohealthalliance.org' <daszak@ecohealthalliance.org>; 'harvey.fineberg@moore.org' <harvey.fineberg@moore.org>; 'dgriffi6@jhmi.edu' <dgriffi6@jhmi.edu>; 'peggy@hbfam.net' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'peshi@UTMB.EDU' <peshi@UTMB.EDU>; Dzau, Victor J. <VDzau@nas.edu>
Cc: 'fsharples_3@hotmail.com' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'jennifer.ryan@moore.org' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>; Kanarek, Morgan <MKanarek@nas.edu>; 'Raymond JEANLOZ' <jeanloz@berkeley.edu>; Hare, Hope <HHare@nas.edu>; 'davidrfranz@gmail.com' <davidrfranz@gmail.com>
Subject: RE: 3rd Virtual U.S. China dialogue meeting on COVID-19

Importance: High

Greetings,

Good news: Last night CAS leadership agreed to hold the 3rd virtual dialogue (Zoom meeting) on the list of Immunity topics we proposed. However they would like to push the dates for the 3rd meeting back to the first or second week of June (so no Zoom meeting on Tuesday night next week). Some of our Chinese counterparts are involved in China's National People's Congress taking place next week.

We are targeting **one night on June 1-4 or on June 8-11** (at 9-11 PM ET for the Americans, the following morning for the Chinese group.)

Please send your availability to participate on those nights (or maybe simply send the nights you can't participate) to Hope Hare [HHare@nas.edu] so we can propose a date or dates to CAS that works best for the American group.

Thanks again for your availability and willingness to participate in this initiative and I hope you have a good long weekend.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Wednesday, May 20, 2020 11:44 PM
To: 'relman@stanford.edu' <relman@stanford.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'saif.2@osu.edu' <saif.2@osu.edu>; 'stanley-perlman@uiowa.edu' <stanley-perlman@uiowa.edu>; 'daszak@ecohealthalliance.org' <daszak@ecohealthalliance.org>; 'harvey.fineberg@moore.org' <harvey.fineberg@moore.org>; 'dgriffi6@jhmi.edu' <dgriffi6@jhmi.edu>; 'peggy@hbfam.net' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'peshi@UTMB.EDU' <peshi@UTMB.EDU>; Dzau, Victor J. <VDzau@nas.edu>
Cc: 'fsharples_3@hotmail.com' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'jennifer.ryan@moore.org' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>; Kanarek, Morgan <MKanarek@nas.edu>; 'Raymond JEANLOZ' <jeanloz@berkeley.edu>; Hare, Hope <HHare@nas.edu>; 'davidrfranz@gmail.com' <davidrfranz@gmail.com>
Subject: 3rd Virtual U.S. China dialogue meeting on COVID-19
Importance: High

Greetings,

As we discussed during our meeting on Monday we hope to hold a third virtual dialogue meeting with CAS and CCDC experts to discuss what is known about COVID-19 immunity, including the relationship between previous infection, antibody response, reinfection and convalescent plasma and preparing for a possible Fall 2020 resurgence of the virus.

We have proposed to CAS that this meeting take place on~~**Tuesday evening, May 26 from 9:00 -11:00 PM ET for the Americans**(and the morning of Wednesday, May 27 for the Chinese).~~ I have attached the list of questions on these topics we sent to CAS for your information. **Please let me know if you are interested and available to participate in the 3rd virtual dialogue meeting.**

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, May 18, 2020 10:18 AM
To: Hare, Hope <HHare@nas.edu>; 'relman@stanford.edu' <relman@stanford.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'saif.2@osu.edu' <saif.2@osu.edu>; 'stanley-perlman@uiowa.edu' <stanley-perlman@uiowa.edu>; 'daszak@ecohealthalliance.org' <daszak@ecohealthalliance.org>; 'harvey.fineberg@moore.org' <harvey.fineberg@moore.org>; 'dgriffi6@jhmi.edu' <dgriffi6@jhmi.edu>; 'peggy@hbfam.net' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'davidrfranz@gmail.com' <davidrfranz@gmail.com>; 'peshi@UTMB.EDU' <peshi@UTMB.EDU>; Dzau, Victor J. <VDzau@nas.edu>; 'fsharples_3@hotmail.com' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'jennifer.ryan@moore.org' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>; Kanarek, Morgan <MKanarek@nas.edu>; 'Raymond JEANLOZ' <jeanloz@berkeley.edu>
Subject: RE: Follow up Meeting to Discuss Results of the Virtual U.S. China dialogue meeting on COVID-19
Importance: High

Greetings,

Thought it would be helpful to send you a basic outline for the follow up call (**at 11:30 ET today**).

1) Intro
2) Comments on the Day 1 and Day 2 discussion
3) Ideas for topics (and additional American experts) for future virtual dialogue sessions
4) Discussion of George Gao's joint statement idea
5) CAS idea to post a blurb about the meetings on the CAS website
6) Other issues, concerns

I have attached the dialogue agenda (American version) for reference along with Jim's summaries of future collaboration ideas from the sessions.

I know a few people can't make it but I would be happy to follow up with you individually over the phone or email.

I look forward to talking to the group soon.
Zoom link: https://nasem.zoom.us/j/99353621870?pwd=cDM4WVE3YzFESDF4WGtKY0llVkFuZz09

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Hare, Hope <HHare@nas.edu>
Sent: Friday, May 15, 2020 4:26 PM
To: 'relman@stanford.edu' <relman@stanford.edu>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'saif.2@osu.edu' <saif.2@osu.edu>; 'stanley-perlman@uiowa.edu' <stanley-perlman@uiowa.edu>; 'daszak@ecohealthalliance.org' <daszak@ecohealthalliance.org>; 'harvey.fineberg@moore.org' <harvey.fineberg@moore.org>; 'dgriffi6@jhmi.edu' <dgriffi6@jhmi.edu>; 'peggy@hbfam.net' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'davidrfranz@gmail.com' <davidrfranz@gmail.com>; 'peshi@UTMB.EDU' <peshi@UTMB.EDU>; Dzau, Victor J. <VDzau@nas.edu>; 'fsharples_3@hotmail.com' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>;

'jennifer.ryan@moore.org' <jennifer.ryan@moore.org>; Bowman, Katherine <KBowman@nas.edu>; Kanarek, Morgan <MKanarek@nas.edu>; 'Raymond JEANLOZ' <jeanloz@berkeley.edu>
Cc: Rusek, Benjamin <BRusek@nas.edu>
Subject: RE: Follow up Meeting to Discuss Results of the Virtual U.S. China dialogue meeting on COVID-19

It is very difficult to find a time suitable for all—we apologize, but the one time that seemed to work is Monday, May 18th, at 11:30 AM. We understand that not all of you will be able to participate.
Here is the Zoom link for this meeting:
https://nasem.zoom.us/j/99353621870?pwd=cDM4WVE3YzFESDF4WGtKY0llVkFuZz09
We look forward to seeing you on Monday at 11:30 am.
Best wishes,
Hope

From: Hare, Hope
Sent: Thursday, May 14, 2020 3:16 PM
Subject: Follow up Meeting to Discuss Results of the Virtual U.S. China dialogue meeting on COVID-19

Ben has asked me to contact you to schedule a time for the follow up call. We need to do this early next week, as there was not a time that worked well for everyone this week. Please send me your availability for a one hour Zoom meeting between 9AM - 6PM ET, Monday - Wednesday next week.

Thank you and best wishes,

Hope Hare
Administrative Assistant
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW
Washington, DC 20001
Phone: 202-334-3435

<image001.png>

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt (louise.pitt@us.army.mil); Nancy Haigwood; Hild, Sheri (NIH/OD) [E]

Location: https://fnih.zoom.us/j/93028717745?pwd=cVFITjZwekRpSkN6SllsUThxZVRhUT09

Importance: Normal

Subject: ACTIV Preclinical working group (Friday meeting)

Start Time: Fri 4/24/2020 11:00:00 AM (UTC-04:00)

End Time: Fri 4/24/2020 12:00:00 PM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt (louise.pitt@us.army.mil); Nancy Haigwood; Hild, Sheri (NIH/OD) [E]

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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 6/4/2020 4:47:00 AM (UTC-04:00)
Subject: Agenda and Webex Invite-WHO Animal Models Group Call June 4
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Webex_Meeting.ics

Dear all,
Please find below the agenda for today's call. As before, please feel free to send us topics for discussion in the 'Open questions' section at the end of the call.

Best regards to all

César, Simon and Bill

WHO Ad hoc group Animal Models

Agenda June 4 2020

Pathogenesis

KSU (Jürgen Richt)

PHE (Miles Carroll)

Vaccines

VIDO Intervac (Darryl Falzarano)

Open questions

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 872 4056
Meeting password: sMV85mpdEd3

Thursday, June 4, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Start Time: 2020-06-04T15:00:00+02:00
End Time: 2020-06-04T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Start Time: 2020-06-04T15:00:00+02:00
End Time: 2020-06-04T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Cc: Adam, Stacey (FNIH) [T][sadam@fnih.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
From: Rappaport, Jay[jrappaport@tulane.edu]
Sent: Fri 6/5/2020 11:06:05 AM (UTC-04:00)
Subject: Re: URGENT: neutralizing antibody experience (especially combinations)

I would suggest David Montefiori at Duke of course. Mark Lewis at BIOQUAL who has done these studies in NHPs with cocktails.

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From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Friday, June 5, 2020 8:53:23 AM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: URGENT: neutralizing antibody experience (especially combinations)

Dear Preclinical Working Group,

The clinical master protocols group is setting up two protocols that will assess the efficacy of neutralizing monoclonal antibodies. The clinical group has generated a list of minimum standards that must be met for an agent to be admitted to the trial. This approach has focus on single antibody studies. However, there was a great deal of discussion at the Executive Committee about the use of mixtures or cocktails of antibodies that are likely to be needed to effectively contain the virus. The Executive committee and Dr Collins would like a list of people that are experts in neutralizing antibody preclinical testing that could help chose the appropriate preclinical information and assays to assess synergy in neutralization by multiple individual agents.

I am asking you if you are able to provide expert opinion for multiple neutralizing antibody preclinical testing. If you are not the right person, could you provide suggestions of who might be able to help in this effort. This is an urgent need, so I would appreciate a quick response, as we would like to get a meeting together early next week.

From what I understand we only need a few additional people, but I think they are really looking for people outside of NIH with an eye to practical drug development experience.

Thank you in advance for your help. Let me know if you have any questions.

Sincerely,
Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
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To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Adam, Stacey (FNIH) [T][sadam@fnih.org]
From: Nancy Haigwood[haigwoon@ohsu.edu]
Sent: Fri 6/5/2020 11:06:06 AM (UTC-04:00)
Subject: Re: URGENT: neutralizing antibody experience (especially combinations)

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Date: Friday, June 5, 2020 at 6:53 AM
To: "Adams, Peter (OS/ASPR/BARDA)" <Peter.Adams@hhs.gov>, "Alvarez, Rosa" <rosalvarez@deloitte.com>, "Anderson, Annaliesa" <Annaliesa.Anderson@pfizer.com>, "Baric, Ralph" <rbaric@email.unc.edu>, "Carter, Kara" <kara.carter@evotec.com>, "Charette, Marc (NIH/NHLBI) [E]" <marc.charette@nih.gov>, "Cihlar, Tomas" <tomas.cihlar@gilead.com>, "Colvis, Christine (NIH/NCATS) [E]" <christine.colvis@nih.gov>, "Deming, Damon (FDA/CDER)" <damon.deming@fda.hhs.gov>, "Diamond, Michael" <diamond@wusm.wustl.edu>, "Duncan, Ken" <ken.duncan@gatesfoundation.org>, "Fernandes, Prabhavathi" <prabha.fernandes@gmail.com>, "Fessel, Josh (NIH/NHLBI) [E]" <josh.fessel@nih.gov>, "Florence, Clint (NIH/NIAID) [E]" <clint.florence@nih.gov>, "Gadbois, Ellen (NIH/OD) [E]" <gadboisel@od.nih.gov>, "Gatto, Greg" <ggatto@rti.org>, "Grobler, Jay" <jay_grobler@merck.com>, Nancy Haigwood <haigwoon@ohsu.edu>, "Hewitt, Judith (NIH/NIAID) [E]" <jhewitt@niaid.nih.gov>, "Jonson, Samantha (NIH/NCATS) [E]" <samantha.jonson@nih.gov>, "Lutz, Cat" <Cat.Lutz@jax.org>, "Nestle, Frank" <Frank.Nestle@sanofi.com>, "Ottinger, Elizabeth (NIH/NCATS [E]" <elizabeth.ottinger@nih.gov>, "Parker, Ashley (NIH/OD) [E]" <ashley.parker@nih.gov>, "Payne, David" <david.j.payne@gsk.com>, "Pitt, Louise" <margaret.l.pitt.civ@mail.mil>, "Punturieri, Antonello (NIH/NHLBI) [E]" <punturieria@nhlbi.nih.gov>, "Qashu, Felicia (NIH/OD) [E]" <felicia.qashu@nih.gov>, "Rao, Srinivas" <Srinivas.Rao@sanofi.com>, "Rappaport, Jay" <jrappaport@tulane.edu>, "Stegmeier, Frank" <fstegmeier@ksqtx.com>, "Young, John" <john.young.jy3@roche.com>
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Cc: Adam, Stacey (FNIH) [T][sadam@fnih.org]
From: Grobler, Jay A[jay_grobler@merck.com]
Sent: Fri 6/5/2020 11:44:54 AM (UTC-04:00)
Subject: RE: URGENT: neutralizing antibody experience (especially combinations)

I highly recommend Kalpit Vora (Merck). He has tremendous depth of expertise and experience in this area.
-Jay

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EXTERNAL EMAIL – Use caution with any links or file attachments.
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Cc: Adam, Stacey (FNIH) [T][sadam@fnih.org]
From: Kara Carter[Kara.Carter@evotec.com]
Sent: Fri 6/5/2020 11:46:29 AM (UTC-04:00)
Subject: RE: URGENT: neutralizing antibody experience (especially combinations)

All three of these are excellent suggestions and folks with whom I have worked in the past to address exactly these types of questions either directly or indirectly.

Kara

evotec

Kara Carter, PhD
Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
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www.evotec.com

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Cc: david.j.payne@gsk.com[david.j.payne@gsk.com]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; kara.carter@evotec.com[kara.carter@evotec.com]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Simon, Dina (NIH/OD) [C][dina.simon@nih.gov]; Wholley, David (FNIH) [T][dwholley@fnih.org]; Austin, Christopher (NIH/NCATS) [E][austinc@mail.nih.gov]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Desrosiers, Betsy[elizabeth_desrosiers@merck.com]; Hughes, Eric[eric.hughes@novartis.com]; Jansen, Kathrin[kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E][michael.kurilla@nih.gov]; Lowy, Douglas (NCI)[dl60z@nih.gov]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; James, Stephanie (FNIH) [T][sjames@fnih.org]; Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Kim, Elizabeth[elkim@deloitte.com]; Tolman, Brett[btolman@deloitte.com]; Wachtel, Jonathan[jwachtel@deloitte.com]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Diamond, Michael[mdiamond@wustl.edu]; Rose Li[rose.li@roseliassociates.com]; Dana Carluccio[dana.carluccio@roseliassociates.com]; Lagos, Enrique (NIH/NCATS) [E][enrique.lagos@nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Gonzalez, Nina[ningonzalez@deloitte.com]; Burrus-Shaw, Cyndi (NIH/OD) [E][cyndi.burrus-shaw@nih.gov]; Rodriguez, Robin D[rmdaigle@tulane.edu]; Dave Frankowski[david.frankowski@roseliassociates.com]; Baric, Toni C[antoinette_baric@med.unc.edu]; Lowy, Douglas (NIH/NCI) [E][lowyd@mail.nih.gov]; Nancy Haigwood[haigwoon@ohsu.edu]; Stratton, Benjamin[bstratton@deloitte.com]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]
From: Young, John[john.young.jy3@roche.com]
Sent: Sat 6/6/2020 4:19:31 AM (UTC-04:00)
Subject: Re: ACTIV Preclinical working group (Tuesday meeting)

Hi Joe
Minutes look good. No major comments from my side.
We will need to identify owner(s) of the literature review action item at our next meeting.
Best regards
John

On Fri, Jun 5, 2020 at 8:28 PM Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org> wrote:

Dear Preclinical working group and attendees,

Please find the minutes from the meeting on Wednesday. Thank you for an interesting meeting and let me know if you have any questions or comments on the notes.

Thank you,

Joe

-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, April 14, 2020 6:43 PM
To: david.j.payne@gsk.com; ken.duncan@gatesfoundation.org; john.young.jy3@roche.com; Rao, Srinivas; Frank.Nestle@sanofi.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Menetski, Joseph

(FNIH) [T]; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; rbaric@email.unc.edu; prabha.fernandes@gmail.com; ottingerea@mail.nih.gov; ccolvis@mail.nih.gov; jh18v@nih.gov; Damon.Deming@fda.hhs.gov; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
Cc: Florence, Clint (NIH/NIAID) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Subject: ACTIV Preclinical working group (Tuesday meeting)
When: Wednesday, June 3, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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Immunology, Infectious Diseases and Ophthalmology (I2O) Discovery and Translational Area
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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Tue 6/9/2020 8:00:14 AM (UTC-04:00)
Subject: FW: NIH COVID-19 GWAS portal resource

FYI, for those of the genetic persuasion.

Joe

From: Johnson, Andrew (NIH/NHLBI) [E] <johnsonad2@nhlbi.nih.gov>
Sent: Monday, June 8, 2020 8:43 PM
To: List COVID19RESEARCH <COVID19RESEARCH@LIST.NIH.GOV>
Subject: NIH COVID-19 GWAS portal resource

This is to announce the availability of the first NIH-based COVID-19 GWAS statistics results portal: https://grasp.nhlbi.nih.gov/Covid19GWASResults.aspx

Results currently originate from the COVIDhg Consortium, and from analyses by the Johnson lab of UK Biobank COVID-19 cases and controls conducted on the NIH BioWulf cluster.

Top genetic markers from all sources have been annotated so far with: GTeX eQTLs (v.8), an eQTL literature database (>150 sources), GWAS catalog results from the NHLBI GRASP GWAS catalog (deep literature survey with P<0.05), the NHGRI-EBI GWAS, and the CADD annotation tool.

Future updates are expected nearly weekly with more studies, outcomes analyses, non-white cases and controls, and additional annotations.

If you have ,or know of further data to contribute, please contact us: ming-huei.chen@nih.gov, florian.thibord@nih.gov and johnsonad2@nih.gov

Please spread the word of this resource to any colleagues or forums where it could be used to advance COVID-19 related research.

Andrew D. Johnson, Ph.D. FAHA
Senior Investigator, NHLBI
Lab of Hemostasis & Platelet Biology
Head, Biomedical Informatics
NHLBI Population Sciences Branch
The Framingham Heart Study
@ADJOmics

To: William Dowling[william.dowling@cepi.net]
From: William Dowling[william.dowling@cepi.net]
Sent: Tue 6/9/2020 6:45:43 PM (UTC-04:00)
Subject: Agenda for WHO working group on viruses, reagents and immune assays

Hello all

We have two presentations for tomorrow's meeting.

1. Dr. Shinjini Bhatnagar – THSTI, India will present on serology standards being developed in India.
2. Dr. Jason S. McLellan from the University of Texas at Austin will present on "Structure-based Design of Prefusion-stabilized SARS-CoV-2 Spikes"

Best regards
Bill

William Dowling, PhD

Non-Clinical Vaccine Development Leader

CEPI New vaccines for a safer world

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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 6/10/2020 12:54:19 PM (UTC-04:00)
Subject: Agenda and Webex Invite-WHO Animal Models Group Call June 11
Mail Attachment.ics
Webex_Meeting.ics

Dear all,
Please find below the agenda and webex invite for this Thursday's group call.

We would also like to take the opportunity to remind you about our laboratory landscape survey. As a reminder the idea is to collect information of institutions that have capacity for doing COVID-19 animal models and would be willing to get in contact with vaccine developers to push preclinical development of vaccine candidates. We have made already some connections involving members of this group and would be very much willing to keep doing this.

Best regards to all

César, Simon and Bill.

Access to survey - https://enketo.lshtm.ac.uk/SVcm9oTW
Access to findings - https://www.who.int/publications/m/item/global-animal-laboratories-capacities-to-support-vaccine-and-therapeutic-evaluation

June 11-Agenda

Pathogenesis

1- Jürgen Richt (KSU)

2- Amy Hartman (PItt)

3- Lisa Gralinski (UNC)

4- Nadia Oreshkova (WUR)

Open questions

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 036 7656
Meeting password: Y2kDvbiDB67

Thursday, June 11, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Join by phone

Tap to call in from a mobile device (attendees only)

41445750282 SWITZERLAND Toll

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Join from a video system or application

Dial 1450367656@who.webex.com

You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 1450367656.who@lync.webex.com

Need help? Go to http://help.webex.com

Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 16th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=m9d318ba5fd9175c6525e32b9e7781358
Start Time: 2020-06-11T15:00:00+02:00
End Time: 2020-06-11T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

Meeting number (access code): 145 036 7656
Meeting password:Y2kDvbiDB67

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Start Time: 2020-06-11T15:00:00+02:00
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Need help? Go to http://help.webex.com

To: Alexandra Phelan (alp81@georgetown.edu)[alp81@georgetown.edu]; David A Relman (relman@stanford.edu)[relman@stanford.edu]; David Walt (dwalt@bwh.harvard.edu)[dwalt@bwh.harvard.edu]; Diane Griffin (dgriffi6@jhmi.edu)[dgriffi6@jhmi.edu]; Embrey, Ellen (eembrey@stratitia.com)[eembrey@stratitia.com]; Georges Benjamin (georges.benjamin@apha.org)[georges.benjamin@apha.org]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; John Hick (hick.john@gmail.com)[hick.john@gmail.com]; Jonna Mazet (jkmazet@ucdavis.edu)[jkmazet@ucdavis.edu]; Kent Kester (Kent.Kester@sanofi.com)[Kent.Kester@sanofi.com]; Kristian G. Andersen (kga1978@gmail.com)[kga1978@gmail.com]; Mark Smolinski (mark@endingpandemics.org)[mark@endingpandemics.org]; Mary Travis Bassett (mbassett@hsph.harvard.edu)[mbassett@hsph.harvard.edu]; Patricia King (patricia.king1@gmail.com)[patricia.king1@gmail.com]; Peggy Hamburg (peggy@hbfam.net)[peggy@hbfam.net]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; Phyllis D. Meadows (PDMeadows@kresge.org)[PDMeadows@kresge.org]; Richard Besser (rbesser@rwjf.org)[rbesser@rwjf.org]; Tara O'Toole (totoole@iqt.org)[totoole@iqt.org]; Trevor Bedford (trevor@bedford.io)[trevor@bedford.io]; Baric, Ralph S[rbaric@email.unc.edu]; Donald Berwick[donberwick@gmail.com]; alta.charo@wisc.edu[alta.charo@wisc.edu]; Jeff.Duchin@kingcounty.gov[Jeff.Duchin@kingcounty.gov]; Baruch Fischhoff[baruch@cmu.edu]; DHanfling@iqt.org[DHanfling@iqt.org]; bgroves@georgetown.edu[bgroves@georgetown.edu]
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From: Brown, Lisa[LBrown@nas.edu]
Sent: Thur 6/11/2020 11:23:58 AM (UTC-04:00)
Subject: July 1 Standing Committee and Genomics Roundtable Joint Meeting on COVID-19
2020-05-28-Draft Agenda Joint Meeting of the RT and SC- Host Genomics_revised.docx
Genomics Roundtable One Pager-June 2020.pdf
[External] AMP COVID-19 Virtual Town Hall

Dear Members of the Standing Committee ,

I'm writing to invite you to attend a joint virtual meeting of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats and the Roundtable on Genomics and Precision Health on Wednesday, July 1 from 1-3pm ET. An outlook invitation will follow shortly to secure the time on your calendar.

With this meeting, we aim to discuss the state of the science with regard to what is known about human genomics and susceptibility to and severity of COVID-19, what efforts are ongoing, and where some of the research needs are. We are also interested in understanding how data collection and sharing is occurring in new and innovation ways and what some of the gaps still are.

There are two audiences for this meeting—one being our Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, as we think about future areas that need attention through our rapid expert consultation reports and other ways of sharing information with our sponsors. The other audience is the members of the Roundtable on Genomics and Precision Health as they run, in parallel, a strategic planning process to define what areas they should prioritize in the next few years.

Please see the attached draft agenda for the meeting. We are hoping to have this meeting be under two hours, with short (10 min talks) and then plenty of time for discussion with the members.

Also, if you are interested, the Association for Molecular Pathology (AMP) is holding a virtual town hall today at 1:00 p.m. ET. AMP will present key preliminary findings from a recent COVID-19 survey of laboratories. This town hall will discuss various aspects of COVID-19 molecular diagnostic testing including:

- Current and anticipated testing capacity
- Testing turn-around times
- Supply chain issues
- Test performance and validation
- Processes for United States (US) public health reporting

Details are attached.

Please let me know if you have any questions.

Many thanks,
Lisa

Lisa Brown, MPH
Senior Program Officer
Board on Health Sciences Policy
Health and Medicine Division
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW, Washington, DC 20001
202-334-2487 (office)
lbrown@nas.edu

From: Brown, Lisa
Sent: Tuesday, June 2, 2020 2:43 PM
To: Alexandra Phelan (alp81@georgetown.edu) <alp81@georgetown.edu>; David A Relman (relman@stanford.edu) <relman@stanford.edu>; David Walt (dwalt@bwh.harvard.edu) <dwalt@bwh.harvard.edu>; Diane Griffin (dgriffi6@jhmi.edu) <dgriffi6@jhmi.edu>; Embrey, Ellen (eembrey@stratitia.com) <eembrey@stratitia.com>; Georges Benjamin (georges.benjamin@apha.org) <georges.benjamin@apha.org>; Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; John Hick (hick.john@gmail.com) <hick.john@gmail.com>; Jonna Mazet (jkmazet@ucdavis.edu) <jkmazet@ucdavis.edu>; Kent Kester (Kent.Kester@sanofi.com) <Kent.Kester@sanofi.com>; Kristian G. Andersen (kga1978@gmail.com) <kga1978@gmail.com>; Mark Smolinski (mark@endingpandemics.org) <mark@endingpandemics.org>; Mary Travis Bassett (mbassett@hsph.harvard.edu) <mbassett@hsph.harvard.edu>; Patricia King (patricia.king1@gmail.com) <patricia.king1@gmail.com>; Peggy Hamburg (peggy@hbfam.net) <peggy@hbfam.net>; Peter Daszak (daszak@ecohealthalliance.org) <daszak@ecohealthalliance.org>; Phyllis D. Meadows (PDMeadows@kresge.org) <PDMeadows@kresge.org>; Richard Besser (rbesser@rwjf.org) <rbesser@rwjf.org>; Tara O'Toole (totoole@iqt.org) <totoole@iqt.org>; Trevor Bedford (trevor@bedford.io) <trevor@bedford.io>; 'rbaric@email.unc.edu' <rbaric@email.unc.edu>; 'Donald Berwick' <donberwick@gmail.com>; 'alta.charo@wisc.edu' <alta.charo@wisc.edu>; 'Jeff.Duchin@kingcounty.gov' <Jeff.Duchin@kingcounty.gov>; 'Baruch Fischhoff' <baruch@cmu.edu>; 'DHanfling@iqt.org' <DHanfling@iqt.org>; 'bgroves@georgetown.edu' <bgroves@georgetown.edu>
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org) <harvey.fineberg@moore.org>; 'mnavish@iqt.org' <mnavish@iqt.org>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'Peisch, Samuel Francis' <speisch@hsph.harvard.edu>; 'jbaker@rwjf.org' <jbaker@rwjf.org>; 'antoinette_baric@med.unc.edu' <antoinette_baric@med.unc.edu>; 'Mary Radford' <maradford@ucdavis.edu>; Pope, Andrew <APope@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; Feit, Monica <MFeit@nas.edu>; Shore, Carolyn <CShore@nas.edu>; Wollek, Scott <SWollek@nas.edu>; Downey, Autumn <ADowney@nas.edu>; Fine, Emma <EFine@nas.edu>; Kahn, Benjamin <BKahn@nas.edu>
Subject: Note from Harvey - Update on the Activities of the Standing Committee on Emerging Infectious Diseases

Dear Members of the Standing Committee,

It has been just over a month since we convened our second standing committee meeting, and we wanted to update you on next steps. As you know, the standing committee is pivoting towards more intermediate to long-term topics, and staff and I have had ongoing discussions with the sponsors about the questions they would be most interested in, given the continually evolving situation. We will keep you informed of these discussions and topics as they progress, but we envision hosting some monthly mini-workshops and pursuing written products in the near future. Please stay tuned for additional details.

In addition to working with the sponsors to determine next steps, there are several different ad hoc activities connected to the standing committee currently underway.

- **Joint Meeting of the Standing Committee and the Roundtable on Genomics and Precision Health.** The

standing committee is invited to participate in a joint meeting with the Roundtable on Genomics and Precision Health to discuss host genomics research and data collection efforts related to COVID-19. This meeting date is tentatively scheduled for July 1. Additional details will be forthcoming.

- **Committee on Data Needs to Monitor the Evolution of SARS-CoV-2.** On May 7th, several members of the standing committee participated in a rapid telephonic consultation on potential mutations of the virus. As a result of these discussions, an ad hoc committee is currently being appointed lay out a framework to define and describe the data needs for a system to track and correlate viral genome sequences with clinical and epidemiological data. The committee will produce a short report with recommendations to address these issues, and the report will likely be released in mid-July.
- **Committee to Provide Guidance to K-12 Education on Responding to COVID-19.** The Division of Behavioral and Social Sciences and Education (DBASSE) appointed an ad hoc committee to provide states and districts with guidance about whether and how to reopen K-12 schools in the 2020-2021 school year safely. The committee will produce a short report with recommendations to address these issues, and the report will likely be released in mid-July. Phyllis Meadows, a member of the standing committee, is a member of this ad hoc committee.
- **Societal Experts Action Network (SEAN Network).** As we have previously discussed, DBASSE, in collaboration with NSF, has convened a network of experts in the social and behavioral sciences to facilitate rapid responses to actionable questions from decision-makers. This network is coordinated with the standing committee and is guided by an executive committee co-chaired by Bob Groves and Mary Bassett, both members of the standing committee. The SEAN Network is currently undertaking its first task to produce a short document to help state and local decision-makers better understand and evaluate various data sources as they make policy decisions related to COVID-19.

We continue at this time to explore other potential topics for further work, including a roadmap for diagnostic testing (this would incorporate considerations of purpose, technologies, target populations, frequency, validation and deployment by geographic area), vaccine immunization priorities and implementation, and longer-term prediction and management of emerging infections. Please let Andy, Lisa, or me know if you have any questions. We look forward to your feedback.

Warm regards,

Harvey

Harvey V. Fineberg, MD, PhD
President
Gordon and Betty Moore Foundation

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Palo Alto CA 94304

T: 650.213.3100

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Board on Health Sciences Policy

DRAFT

Host Genomics Research and Data Collection Efforts Related to COVID-19

Joint Meeting
of the
Roundtable on Genomics and Precision Health
and the
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

A VIRTUAL MEETING
July 1, 2020
1:00 PM – 2:45 PM ET
Zoom Link: Will be sent closer to the meeting date

Aims for the meeting:

- To understand the scientific challenges that the field of genomics is facing
  - What has been the effect of the pandemic on genomics research and data collection and sharing? What is the role of the genomics community during the pandemic? What research is underway? What research still needs to be done?
  - What gaps and challenges in the field is this crisis highlighting? What unique contributions of the field are not being leveraged effectively?
- To explore innovative approaches to overcoming those challenges
  - What new approaches are you using to solve a problem? Could these be applied to the field of genomics? Are there lessons from genomics that are being used in light of the pandemic? What are the opportunities for connecting efforts and data sets (e.g. across institutions, genotype and phenotype data)?
- To discuss opportunities for the Genomics Roundtable and for the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats to facilitate progress
  - Are there opportunities for the Roundtable and Standing Committee to act that align with strategic priorities?
  - Are the Roundtable and Standing Committee uniquely positioned to address specific challenges?

AGENDA:

1:00 p.m. ET Welcoming Remarks

GEOFFREY GINSBURG, *Roundtable Co-Chair*
Director, Duke Center for Applied Genomics & Precision Medicine
Professor, Medicine, Pathology, and Biomedical Engineering
Duke University Medical Center

MICHELLE PENNY, *Roundtable Co-Chair*
Vice President and Head of Genomics
Goldfinch Bio

HARVEY FINEBERG, *Standing Committee Chair*
President
Gordon and Betty Moore Foundation

1:15 p.m. **Understanding Host Genetics and Genomics Related to COVID-19 and Opportunities for Forming Data Sharing COVID-19 Communities**

MAXIMILIAN MUENKE (*confirmed*)
CEO
American College of Medical Genetics and Genomics (ACMG)

1:25 p.m. SHARON TERRY (*confirmed*)
Founder and CEO
Genetic Alliance

1:35 p.m. JOYCE TUNG (*confirmed*)
Vice President, Research
23andMe

1:45 p.m. GEOFFREY GINSBURG, *Roundtable Co-Chair (confirmed)*
Director, Duke Center for Applied Genomics & Precision Medicine
Professor, Medicine, Pathology, and Biomedical Engineering
Duke University Medical Center

1:55 p.m. **Discussion with Roundtable and Standing Committee Members**

2:30 p.m. **Next Steps**

Questions:

- What challenges or gaps were exposed today?
- Is there an area that should be incorporated into the Roundtable's strategic planning or the Standing Committee's work?

GEOFFREY GINSBURG, *Roundtable Co-Chair*
Director, Duke Center for Applied Genomics & Precision Medicine
Professor, Medicine, Pathology, and Biomedical Engineering
Duke University Medical Center

MICHELLE PENNY, *Roundtable Co-Chair*
Vice President and Head of Genomics
Goldfinch Bio

HARVEY FINEBERG, *Standing Committee Chair*
President
Gordon and Betty Moore Foundation

2:45 p.m. **Adjourn**

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The sequencing of the human genome is rapidly opening new doors to research and progress in biology, medicine, and health care. At the same time, these developments have produced a diversity of new issues to be addressed.

The National Academies of Sciences, Engineering, and Medicine has convened a Roundtable on Genomics and Precision Health (previously the Roundtable on Translating Genomic-Based Research for Health) that brings together leaders from academia, industry, government, foundations and associations, and representatives of patient and consumer interests who have a mutual concern and interest in addressing the issues surrounding the translation of genome-based research for use in maintaining and improving health. The mission of the Roundtable is to advance the field of genomics and improve the translation of research findings to health care, education, and policy. The Roundtable will discuss the translation process, identify challenges at various points in the process, and discuss approaches to address those challenges.

The field of genomics and its translation involves many disciplines, and takes place within different economic, social, and cultural contexts, necessitating a need for increased communication and understanding across these fields. As a convening mechanism for interested parties from diverse perspectives to meet and discuss complex issues of mutual concern in a neutral setting, the Roundtable: fosters dialogue across sectors and institutions; illuminates issues, but does not necessarily resolve them; and fosters collaboration among stakeholders.

To achieve its objectives, the Roundtable conducts structured discussions, workshops, and symposia. Workshop summaries will be published and collaborative efforts among members are encouraged (e.g., journal articles). Specific issues and agenda topics are determined by the Roundtable membership, and span a broad range of issues relevant to the translation process.

Issues may include the integration and coordination of genomic information into health care and public health including encompassing standards for genetic screening and testing, improving information technology for use in clinical decision making, ensuring access while protecting privacy, and using genomic information to reduce health disparities. The patient and family perspective on the use of genomic information for translation includes social and behavioral issues for target populations. There are evolving requirements for the health professional community, and the need to be able to understand and responsibly apply genomics to medicine and public health.

Of increasing importance is the need to identify the economic implications of using genome-based research for health. Such issues include incentives, cost-effectiveness, and sustainability.

Issues related to the developing science base are also important in the translation process. Such issues could include studies of gene-environment interactions, as well as the implications of genomics for complex disorders such as addiction, mental illness, and chronic diseases.

Roundtable sponsors include federal agencies, pharmaceutical companies, medical and scientific associations, foundations, and patient/public representatives. For more information about the Roundtable on Genomics and Precision Health, please visit our website at nationalacademies.org/GenomicsRT or contact Sarah Beachy at 202-334-2217, or by e-mail at sbeachy@nas.edu.

Roundtable on Genomics and Precision Health Membership

Geoffrey Ginsburg, M.D., Ph.D. (Co-Chair) Duke University
Michelle Penny, Ph.D. (Co-Chair) Goldfinch Bio

Naomi Aronson, Ph.D.
BlueCross/BlueShield Association

Aris Baras, M.D., M.B.A.
Regeneron Pharmaceuticals

Karina Bienfait, Ph.D.
Merck and Co., Inc.

Vence Bonham, Jr., J.D.
National Human Genome Research Institute

Robert B. Darnell, M.D. Ph.D.
The Rockefeller University / NY Genome Center

Stephanie Devaney, Ph.D.
All of Us Research Program, NIH

Katherine Donigan, Ph.D.
U.S. Food and Drug Administration

W. Gregory Feero, M.D., Ph.D.
Journal of the American Medical Association

Jessica M. Gill, Ph.D., R.N., FAAN
National Institute of Nursing Research

Marc Grodman, M.D.
Genosity

Richard Hodes, M.D.
National Institute on Aging

Praduman Jain, M.S.
Vibrent Health

Sally John, Ph.D.
Biogen

Sekar Kathiresan, M.D.
Massachusetts General Hospital

Muin Khoury, M.D., Ph.D.
Centers for Disease Control and Prevention

David Ledbetter, Ph.D.
Geisinger

Charles Lee, Ph.D., FACMG
The Jackson Laboratory for Genomic Medicine

Thomas Lehner, Ph.D., M.P.H.
National Institute of Mental Health

Debra Leonard, M.D., Ph.D.
College of American Pathologists

Patrick Loerch, Ph.D.
Johnson & Johnson

James Lu, M.D., Ph.D.
Helix

Sean McConnell, Ph.D.
American Medical Association

Mona Miller, M.P.P.
American Society of Human Genetics

Jennifer Moser, Ph.D.
U.S. Department of Veterans Affairs

Maximilian Muenke, M.D., FACMG
American College of Medical Genetics and Genomics

Anna Pettersson, Ph.D.
Pfizer Inc.

Victoria M. Pratt, Ph.D., FACMG
Association for Molecular Pathology

Nadeem Sarwar, Ph.D.
Eisai Inc.

Sheri Schully, Ph.D.
Formerly NIH Office of Disease Prevention, now All of Us

Joan A. Scott, M.S., C.G.C.
Health Resources and Services Administration

Nonniekaye Shelburne, C.R.N.P., M.S., A.O.C.N.
National Cancer Institute

Sam Shekar, M.D., M.P.H.
American College of Preventive Medicine

Nikoletta Sidiropoulos, M.D.
University of Vermont Health Network Medical Group

Katherine Johansen Taber, Ph.D.
Myriad Women's Health

Ryan Taft, Ph.D.
Illumina

Jacquelyn Taylor, Ph.D.
New York University

Sharon Terry, M.A.
Genetic Alliance

Joyce Tung, Ph.D.
23andMe, Inc.

Jameson Voss, M.D.
Air Force Medical Support Agency

Catherine A. Wicklund, M.S., C.G.C.
National Society of Genetic Counselors

Huntington F. Willard, Ph.D.
Genome Medical

Janet K. Williams, Ph.D., R.N., FAAN
American Academy of Nursing

Sarah Wordsworth, Ph.D.
University of Oxford

Alicia Zhou, Ph.D.
Color Genomics

Project Staff
Sarah H. Beachy, Ph.D., *Roundtable Director*
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To: Pratt, Victoria[vpratt@iu.edu]
From: Association for Molecular Pathology[ecampbell@amp.org]
Sent: Mon 6/8/2020 11:01:38 AM (UTC-04:00)
Subject: [External] AMP COVID-19 Virtual Town Hall

AMP COVID-19 Virtual Town Hall

Thursday, June 11, 2020, 1:00PM ET

Panelist
Frederick S. Nolte, PhD
Chair of AMP Infectious Disease Subdivision, Director of Clinical Laboratories, Medical University of South Carolina

Panelist
Karen L. Kaul, MD, PhD
Former AMP President, Chairman of Department of Pathology, NorthShore Research Institute

Panelist
Jordan Laser, MD
Chair of AMP Professional Relations Committee, Medical Director of Long Island Jewish Medical Center – Pathology and Laboratory Medicine

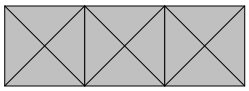
Moderator
Karen E. Weck, MD
AMP President
Professor of Pathology and Laboratory Medicine, Professor of Genetics and Director of Molecular Genetics and Pharmacogenomics, University of North Carolina Chapel Hill

The Association for Molecular Pathology (AMP) invites you to a virtual town hall on diagnostic testing for COVID-19. AMP will present key preliminary findings from a recent COVID-19 survey of laboratories. This survey assessed and we will discuss various aspects of COVID-19 molecular diagnostic testing including:

- Current and anticipated testing capacity
- Testing turn-around times
- Supply chain issues
- Test performance and validation
- Processes for United States (US) public health reporting

Initial data to be presented was gathered from over 100 US-based laboratories including academic medical centers, commercial reference laboratories, and community hospitals or health system laboratories. Additionally, the webinar will include timely policy recommendations based on the survey's findings, which aim to effectively leverage America's large and diverse laboratory network to best respond to the coronavirus pandemic. The survey data and recommendations presented will frame a subject matter expert panel discussion with an opportunity for town hall attendees to ask questions. We invite you to participate in the discussion to help inform, collaborate, and assist with AMP's ongoing clinical practice and advocacy initiatives during this pandemic and help improve future emerging pathogen responses.

Register



FOLLOW US

From: LBrown@nas.edu[LBrown@nas.edu]

Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; Harvey V. Fineberg (harvey.fineberg@moore.org)

Location: Zoom link TBA

Importance: Normal

Subject: FW: Joint Meeting of the Genomics Roundtable and the Standing Committee on Infectious Diseases

Start Time: Wed 7/1/2020 1:00:00 PM (UTC-04:00)

End Time: Wed 7/1/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; Harvey V. Fineberg (harvey.fineberg@moore.org)

-----Original Appointment-----
From: Choi, Kelly <KChoi@nas.edu>
Sent: Tuesday, June 2, 2020 9:57 AM
To: Choi, Kelly; 'Michelle Penny'; 'jennifer.ryan@moore.org'; 'harvey.fineberg@moore.org'; 'joyce@23andme.com'; 'Pamela G. Williams (Assistant to Drs. Ginsburg and Wray)'; 'geoffrey.ginsburg@duke.edu'; 'Sharon Terry'; 'Judith Woods'; 'mmuenke@acmg.net'; Addie, Siobhan; Hackmann, Meredith; Beachy, Sarah; Pope, Andrew; Brown, Lisa
Subject: Joint Meeting of the Genomics Roundtable and the Standing Committee on Infectious Diseases
When: Wednesday, July 1, 2020 1:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Zoom link TBA

From: Baric, Toni C[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6A7390851CF045E8BE4BB68C16F4F916-TONI C BARI]
Location: Microsoft Teams Meeting
Importance: Normal
Subject: FW: SARS-CoV-2 wt live virus neutralization assay
Start Time: Thur 6/11/2020 2:30:00 PM (UTC-04:00)
End Time: Thur 6/11/2020 3:15:00 PM (UTC-04:00)
Required Attendees: Baric, Ralph S; Jacqueline Kirchner; rbaric@email.unc.edu; Baric, Toni C
Optional Attendees: Monalisa Chatterji

-----Original Appointment-----
From: Karen Makar <Karen.Makar@gatesfoundation.org>
Sent: Tuesday, June 9, 2020 3:25 PM
To: Karen Makar; Jacqueline Kirchner; rbaric@email.unc.edu; Baric, Toni C
Cc: Monalisa Chatterji
Subject: Re: SARS-CoV-2 wt live virus neutralization assay
When: Thursday, June 11, 2020 11:30 AM-12:15 PM (UTC-08:00) Pacific Time (US & Canada).
Where: Microsoft Teams Meeting

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From: Baric, Ralph S[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb0d9cc80c184735a4e862c3bdd8a15d-Ralph S Bar]

Location: Microsoft Teams Meeting

Importance: Normal

Subject: Accepted: SARS-CoV-2 wt live virus neutralization assay

Start Time: Thur 6/11/2020 2:30:00 PM (UTC-04:00)

End Time: Thur 6/11/2020 3:15:00 PM (UTC-04:00)

Required Attendees: Karen Makar

From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical full working group

Start Time: Wed 4/22/2020 10:00:00 AM (UTC-04:00)

End Time: Wed 4/22/2020 11:00:00 AM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical full working group

Start Time: Wed 6/17/2020 10:00:00 AM (UTC-04:00)

End Time: Wed 6/17/2020 11:00:00 AM (UTC-04:00)

Required Attendees: john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Optional Attendees: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical full working group

Start Time: Wed 7/29/2020 10:00:00 AM (UTC-04:00)

End Time: Wed 7/29/2020 11:00:00 AM (UTC-04:00)

Required Attendees: Hild, Sheri (NIH/OD) [E]; david.j.payne@gsk.com; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; john.young.jy3@roche.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Frank.Nestle@sanofi.com; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Optional Attendees: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Changing time for preclinical WG

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Password: 124630
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From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]

Attendees: david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Importance: Normal

Subject: ACTIV Preclinical full working group

Start Time: Wed 6/24/2020 10:00:00 AM (UTC-04:00)

End Time: Wed 6/24/2020 11:00:00 AM (UTC-04:00)

Required Attendees: david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Anderson, Annaliesa; jrappaport@tulane.edu; kara.carter@evotec.com; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph S; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Fri 6/12/2020 9:49:37 AM (UTC-04:00)
Subject: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting
Assay WG Tracker _ Updated 6-4.xlsx

Dear Working group,

Our friends in the vaccines group have generated a list that will be interesting to think about.

From below, we should have Janet and Ashley talk to the group about including this list in our online resources?

"Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them."

Joe

From: Santos, Michael (FNIH) [T] <msantos@fnih.org>
Sent: Wednesday, June 10, 2020 9:45 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Hi Joe and Rosa,

I meant to follow up to you last night: FYI on the attached assay tracker from the USG assay WG co-chairs (Janet Lathey and Ashley Smith). If there's anything of interest here, Janet Lathey will be at next week's sub-group meeting on this topic.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, June 9, 2020 11:00 PM
To: Kathrin.Jansen@pfizer.com; paula_annunziato@merck.com; Jim.Tartaglia@sanofi.com; Donna.Boyce@pfizer.com; Gruber, Marion (FDA/CBER) <Marion.Gruber@fda.hhs.gov>; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Sahin@Uni-Mainz.de; lanzavecchia@irb.usi.ch; Arvin, Ann <Arvinam@Stanford.edu>; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>; Bett, Andrew J <andrew_bett@merck.com>; Gilbert PhD, Peter B <pgilbert@scharp.org>; Kathleen Neuzil <kneuzil@som.umaryland.edu>; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) <kayvon.modjarrad.civ@mail.mil>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; Greg Glenn <gglenn@novavax.com>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>; Kelly, Beth <beth.kelly@astrazeneca.com>
Cc: Tolman, Brett <btolman@deloitte.com>; Jessica.Zottoli@pfizer.com; Markay.Hopps@pfizer.com; denise_biehn@merck.com;

Jeneffer Haynes <jhaynes@Novavax.com>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Brian Rosen <brosen@Novavax.com>; Cheryl Keech <ckeech@Novavax.com>
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Wednesday, June 3, 2020 11:30 PM
Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Monday, June 1, 2020 1:04 PM
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
  - Develop specifics of what we are looking for from immunology research
  - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
  - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
  - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health

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Agency	Performer	Assay	Status	Description (including specific reagents & standards/controls)	Preclinical Use	Clincal Use	Reagent Needs	Target Timeline to Optimization	Target Timeline to Qualification	Target Timeline to Validation	High-Throughput?	Ability to assay serum immune response from vaccine developers' samples from Operation Warp Speed?
BARDA	Battelle	RT-qPCR	In progress	Quantify viral RNA in whole blood, nasal wash, BALF, swabs and tissues. Using N1 and N2 primers, and synthetic RNA control.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	May/June	Sept/Oct	Sept/Oct	No	N/A
		Plaque Assay	In progress	Quantify virus in challenge material.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	May/June	Sept/Oct	Sept/Oct	No	N/A
	Southern Research	RT-qPCR	In progress	Quantify viral RNA in whole blood, nasal wash, BALF, swabs and tissues. Using N1 and N2 primers, and synthetic RNA control.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	May/June	Sept/Oct	Sept/Oct	No	N/A
		Plaque Assay	In progress	Quantify virus in challenge material.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	May/June	Sept/Oct	Sept/Oct	No	N/A
		TCID50	In progress	VERO E6 cells Quantify infectious virus for assays and challenge material, UTM, Nasal Wash, PBS, lung tissue, serum and whole blood.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	May/June	Sept/Oct	Sept/Oct	No	N/A
		Microneutralization	In progress	Quantify neutralizing antibody in serum.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	May/June	Sept/Oct	Sept/Oct	No	Yes, species neutral assay.
	MRI Global	RT-qPCR	In progress	Quantify viral RNA in whole blood, nasal wash, BALF, swabs and tissues. Using N1 and N2 primers, and synthetic RNA control.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	May/June	Sept/Oct	Sept/Oct	No	N/A
		Plaque Assay	Not initiated.	Quantify virus in challenge material.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	May/June	Sept/Oct	Sept/Oct	No	N/A
		TCID50	In progress	VERO E6 cells Quantify infectious virus for assays and challenge material, UTM, Nasal Wash, PBS, lung tissue, serum and whole blood.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	May/June	Sept/Oct	Sept/Oct	No	N/A
		Microneutralization	Not initiated.	Quantify neutralizing antibody in serum.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	May/June	Sept/Oct	Sept/Oct	No	Yes, species neutral assay.
	Lovelace	RT-qPCR	Not initiated.	Quantify viral RNA in whole blood, nasal wash, BALF, swabs and tissues. Using N1 and N2 primers, and synthetic RNA control.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	June	Sept/Oct	Sept/Oct	No	N/A
		Plaque Assay	Not initiated.	Quantify virus in challenge material.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	June	Sept/Oct	Sept/Oct	No	N/A
		TCID50	Not initiated.	VERO E6 cells Quantify infectious virus for assays and challenge material, UTM, Nasal Wash, PBS, lung tissue, serum and whole blood.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	June	Sept/Oct	Sept/Oct	No	N/A
		Microneutralization	Not initiated.	Quantify neutralizing antibody in serum.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	Reference Standard and Positive control	June	Sept/Oct	Sept/Oct	No	Yes, species neutral assay.
NIAID - DMID	Battelle	TCID50	In progress	VERO E6 cells Quantify infectious virus for assays and challenge material, UTM, Nasal Wash, PBS, lung tissue, serum and whole blood.	ferret, hamster, and NHP	None, but assay is species-neutral.	Detection antibody to move away from CPE read out	Early June	Early August	Not currently planned	No	If needed. ~400 per week
		Microneutralization	In progress	VERO E6 cells Quantify neutralizing antibody in serum, WT Washington Strain	ferret, hamster, and NHP	Yes, Vaccine testing	Detection antibody to move away from CPE read out; positive control	Early June	Early August	Not currently planned	Medium	400 -800 per week (with resources could be ramped-up)
		ELISA	In progress	Quantify binding antibodies to Spike (Pre-fusion-Primer); secondary antibody cross-reactive between Human and NHP	NHP	Yes, Vaccine testing	Reference Standard and Positive control	Early June	Early August	Not currently planned	Medium	500-1000 per week (with resources could be ramped up
	Battelle / Moderna (BARDA)	PsV (lentivirus)	In progress	Luciferase Lentivirus with Spike (VRC) Stabilly ACE-2 tranfected cell line	NHP	Yes, Vaccine testing	Reference Standard and Positive control	June	August	?	No	270-540 per week (with resources could be ramped up)
	UTMB	WT Reporter Neutralization	In progress	Luciferase and Fluorescent reporter WT viruses	yes	Yes, Vaccine testing						
NIAID - VRC	Vaccine Immunology Program (VIP)	ELISA (S 2P, RBD, nucleoprotein)	Qualification and Validation ongoing	Quantifu ab response to immunogens	None	For the purposes of vaccine trial screening	Possibly large QC'd nucleoprtein stock	Opitmized	Qualified by May 29th 2020	Validated by July 20202	Yes	Yes
		ACE2 inhbition	Qualification ongoing	High throughput analyses of ability of trial recipient's sera to block binding of ACE2	None	For the purposes of vaccine trial screening	None.	Opitmized	Qualified by mid-June 2020	Validated by July 20202	Yes	Yes
		High throughput Pseudovirus neutralization	in development	Quantify antibody neutralizing activity of CoV pseudovirus	None	For the purposes of vaccine trial screening	None.	Jun-20	Qualified by mid-June 2020	Validated by July 20202	Yes	Yes
		MSD - 4-plex analysis	in development	Mulitplex RBD, S 2P, nucleprotein in 384 well format	None	For the purposes of vaccine trial screening	None.	Jun-20	Qualified by mid-June 2020	Validated by July 20202	Yes	Yes
		MSD - 10 plex analyses	in development	Circulating HCoV incl. SARS CoV-1 and CoV-2 proteins	None	Purpose of sero-surveys	None.	May-20	N/A	N/A	Yes	Correlates analyses?
		T cell analyses	Qualified	Ability to distinguish Th1 and Th2	None	For the purposes of vaccine trial screening	None.	May-20	May-20	Jul-20	Yes	Yes
USAMRIID	USAMRIID	Microneutralization	Completed	Quantify neutralizing antibody in serum.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	March	Jun	Jul/Aug	Low	Yes, species neutral assay.
	USAMRIID	PRNT	Completed	Quantify neutralizing antibody in serum.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	March	Jun	Jul/Aug	Low	Yes, species neutral assay.
	USAMRIID	ELISA IgG whole cell lysate	NHP Completed, Ferrret/hamster in	Quantify binding antibodies to SARS-Cov-2 whole cell lysate; secondary antibody cross-reactive between Human and NHP; transition to small animal models	NHP, ferret, hamster	Yes, Vaccine testing/Serological testing	None.	May	Jun	Jul/Aug	Medium	Yes
	USAMRIID	Plaque Assay	Completed	Quantify virus in challenge material.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	March	April	Jun	Low	N/A
	USAMRIID	RT-qPCR	NHP NP swabs completed, All other	Quantify viral RNA in NP swabs, OP swabs, rectal swabs, whole blood, and saliva. Using N2 primers, and synthetic RNA control.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	April	Jun	Jul/Aug	Medium	N/A
	USAMRIID	TCID50	Completed	VERO 76 cells Quantify infectious virus for assays and challenge material, UTM, Nasal Wash, PBS, and serum.	NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	March	April	Not currently planned	Low	N/A
	USAMRIID	Magpix full spike, S1, RBD, NP	NHP Completed, Ferrret/hamster in	Quantify binding antibodies to S1, full spike, RBD, and NP; secondary antibody cross-reactive between Human and NHP; transition to small animal models	NHP, ferret, hamster, mouse	Yes, Vaccine testing/Serological testing	None.	April	Jun	Jul/Aug	Medium	Yes
	USAMRIID	Pseuduovirion	In progress		NHP, ferret, hamster, mouse	None, but assay is species-neutral.	None.	June	Jul	August	Medium	Yes, species neutral assay.
	USAMRIID	Domain Programmable Arrays - Pha	In Progress	Epitope mapping for MAbs and antibodies in serum.	Species agnostic	Epitope mapping in human sera.	Phage Library - In progress	June	NA	NA	Medium	Yes, species neutral assay.
	USAMRIID	Sequencing Characterization (ample	Completed	Characterize viral variants	Population Genetics	Molecular Epidemiology	None.	Complete	NA	NA	Medium	Yes, supporting information
	USAMRIID	RNAseq Transcriptomics	Completed	Gene Expression, Host response to Rx and Infection	NHP, ferret, hamster, mouse	Human	None.	Complete	NA	NA	Medium	Yes, supporting information
FDA	CBER/Division of Viral Products	VSV replication-competent PsV mic	In progress	Luciferase and RT-qPCR readouts	Can monitor neutralizing antibodies	No, but assay is species neutral	Reference serum and positive controls	June/July				
NIAID - DAIDS. (HVTN Laboratory Center)	Tomaras Lab (Duke)	ELISA (S, RBD, NP)	Qualification and Validation ongoing	Quantify Ab response to immunogens	None	For the purposes of vaccine trial screening	None.	Opitmized	Qualified by June 15 2020	Validated by July 20202	Yes	Yes
	Tomaras Lab (Duke)	BAMA- multi-plex analysis (S, RBD, NP, IgG, IgA, IgG1, IgG2, IgG3, IgG4)	Qualification and Validation ongoing	Mulitplex RBD, S , NP, Ig subclasses, Circulating HCoV and SARS CoV-1	None	For the purposes of vaccine trial screening	None.	Jun-20	Qualified by June 15 2020	Validated by July 20202	Yes	Yes
	Tomaras Lab (Duke) and Farrari Lab (Duke)	ACE-2 blocking, peptide microarray, differential spike binding; Avidity: BioLayer Interferometry, Surface Plasmon Resonance, Avidity Index (Subclass); Ab Fc Function: ADCC, ADCP, ADNP, FcgRI, FcgRIIa, FcgRIIIa, Complement, Infected Cell	qualified			correlate analysis			N/A	N/A		yes
	Montefiori Lab (Duke) and standradized with VRC-VIP lab	High throughput Pseudovirus neutralization	in development	Quantify antibody neutralizing activity of CoV pseudovirus	None	For the purposes of vaccine trial screening	None.	Jun-20	Qualified by mid-June 2020	Validated by July 20202	Yes	Yes
	Ralph Baric Lab (UNC)	nanoluc neutralization assay:	standardized	recombinant live SARS-CoV-2 virus encoding nLuciferase.	mouse	For the purposes of vaccine trial screening	None.	Jun-20	Jul-20		Yes	20, 96 well plates/day or 60/week
	Mehul Suthar (Emory)	Focus reduction neutralziing assay and plaque reduction assay.	standarized	recombinant live SARS-CoV-2 virus		For the purposes of vaccine trial screening	None.		Sept-Oct		Yes	20 plates, 120 samples/week
	McElrath Lab (FH Seattle)	T cell analyses	Qualified	CoV-2-specific Th1/Th2 cell ICS assay: flow panel developed, assay now optimized for Th2 (including expression of IL-4, IL5, IL13 and CRTH2); cross-validated with 17-color assay for IL-2/IFNg and for Th2.	None	For the purposes of vaccine trial screening	None.	Jun-20	Qualified by June 15 2020	alidated by July 2020	Yes	Yes
DTRA	None											
CDC	Waiting to hear back.											
JPEO	Waiting to hear back.											
WRAIR	Waiting to hear back.											
NIAID - IRF	Waiting to hear back.											
NIAID - DAIT	Waiting to hear back.											
NMRC	Waiting to hear back.											

To: Young, John[john.young.jy3@roche.com]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Cc: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nancy Haigwood[haigwoon@ohsu.edu]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]
From: Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]
Sent: Fri 6/12/2020 10:55:07 AM (UTC-04:00)
Subject: RE: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Just to be clear, these are government/govt contract funded assay development efforts, non-proprietary assays, and not the universe of assay development efforts. I do think it's a very nice table and would be great to post! We could consider copying some categories, although these immunoassays are used differently than drug screening assays.

From: Young, John <john.young.jy3@roche.com>
Sent: Friday, June 12, 2020 10:32 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Cc: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nancy Haigwood <haigwoon@ohsu.edu>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>
Subject: Re: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Thanks Joe
Best regards
John

On Fri, 12 Jun 2020 at 3:50 PM, Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org> wrote:
Dear Working group,

Our friends in the vaccines group have generated a list that will be interesting to think about.

From below, we should have Janet and Ashley talk to the group about including this list in our online resources?

"Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them."

Joe

From: Santos, Michael (FNIH) [T] <msantos@fnih.org>
Sent: Wednesday, June 10, 2020 9:45 AM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: FW: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Hi Joe and Rosa,

I meant to follow up to you last night: FYI on the attached assay tracker from the USG assay WG co-chairs (Janet Lathey and Ashley Smith). If there's anything of interest here, Janet Lathey will be at next week's sub-group meeting on this topic.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, June 9, 2020 11:00 PM
To: Kathrin.Jansen@pfizer.com; paula_annunziato@merck.com; Jim.Tartaglia@sanofi.com; Donna.Boyce@pfizer.com; Gruber, Marion (FDA/CBER) <Marion.Gruber@fda.hhs.gov>; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Sahin@Uni-Mainz.de; lanzavecchia@irb.usi.ch; Arvin, Ann <Arvinam@Stanford.edu>; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>; Bett, Andrew J <andrew_bett@merck.com>; Gilbert PhD, Peter B <pgilbert@scharp.org>; Kathleen Neuzil <kneuzil@som.umaryland.edu>; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) <kayvon.modjarrad.civ@mail.mil>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; Greg Glenn <gglenn@novavax.com>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>; Kelly, Beth <beth.kelly@astrazeneca.com>
Cc: Tolman, Brett <btolman@deloitte.com>; Jessica.Zottoli@pfizer.com; Markay.Hopps@pfizer.com; denise_biehn@merck.com; Jeneffer Haynes <jhaynes@Novavax.com>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Brian Rosen <brosen@Novavax.com>; Cheryl Keech <ckeech@Novavax.com>
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, June 3, 2020 11:30 PM
Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Monday, June 1, 2020 1:04 PM
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
    - Develop specifics of what we are looking for from immunology research
    - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
    - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
    - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
301-402-6917 | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

From: DeStefano, Laura[LDestefano@nas.edu]
Location: zoom (see below)
Importance: Normal
Subject: Canceled: Advisory Group Call: NAM-APHA COVID-19 Webinar Series
Start Time: Fri 6/19/2020 2:00:00 PM (UTC-04:00)
End Time: Fri 6/19/2020 3:00:00 PM (UTC-04:00)
Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

We are canceling this meeting because the group is fairly caught up at the moment – we will keep in touch by email.

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Meeting: NAM-APHA COVID-19 Webinar Series
Time: May 8, 2020 02:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/526660780

Or iPhone one-tap :
US: +13126266799,,526660780# or +14702509358,,526660780#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 312 626 6799 or +1 470 250 9358 or +1 646 518 9805 or +1 646 558 8656 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 301 715 8592 or +1 602 753 0140 or +1 651 372 8299 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 526 660 780
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

Would you like to test your Zoom connection? Please click on the link below.
https://nasem.zoom.us/test

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Cc: Simon Funnell[Simon.Funnell@phe.gov.uk]; William Dowling[william.dowling@cepi.net]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 6/18/2020 4:19:23 AM (UTC-04:00)
Subject: Agenda and Webex Invite-WHO Animal Models Group Call June 18
Mail Attachment.ics
Webex_Meeting.ics

Dear all,

Please find below the agenda tor today's call which will be dedicated to show the progress of the group to vaccine developers. Below is also the webex invite.

See you all later,

César, Bill and Simon

Agenda draft (developers call) June 18

1-Welcome remarks (Pierre Gsell)

2- Presentation of the WHO-COM group objectives (César Muñoz Fontela)

3- Mouse models for COVID-19 (Stanley Perlman)

4- Hamster models (Jasper Chan)

5- Ferret models (Vasan vasan)

6- NHP (Dan Barouch)

7- Alternative models (Jürgen Richt)

8- Conclusions and future course (Bill Dowling and Simon Funnell)

9- Q/A

10- Laboratory landscape and final remarks (Pierre Gsell)

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 375 4953
Meeting password: NUka5Erie66

Thursday, June 18, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

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Tap to call in from a mobile device (attendees only)

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] WHO TC - Animal Models with Vaccine Developers
Location: https://who.webex.com/who/j.php?MTID=mafad2e251070c3c76e6e7236077832cb
Start Time: 2020-06-18T15:00:00+02:00
End Time: 2020-06-18T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

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Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Cc: Kingston, Tigga[Tigga.Kingston@ttu.edu]
From: Kading,Rebekah[Rebekah.Kading@colostate.edu]
Sent: Mon 6/22/2020 6:14:10 PM (UTC-04:00)
Subject: IUCN guidelines
IUCN infographic FINAL 062220.pdf

Dear colleagues,

Hot off the press! The IUCN Species Survival Commission Bat Specialist Group has released guidelines for researchers, to prevent the human-to-bat transmission of SARS-CoV-2. Our infographic is attached, and full guidelines available through either link below. Additional products are to follow shortly, tailored for other stakeholder groups. Please feel free to distribute as you see fit.

Best regards,
Rebekah

https://www.iucnbsg.org/publications.html
https://tinyurl.com/mapforbats

Rebekah C. Kading, PhD
Assistant Professor
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Colorado State University
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Rebekah.Kading@colostate.edu

Preventing human-to-bat transmission of SARS-CoV-2

Exposure Risks

Contact exposure
Bats coming into contact with contaminated hands or equipment

Aerosol exposure
Infectious droplets from handlers holding bats in close proximity

Environmental exposure
Sharing enclosed, poorly-ventilated spaces with bats, where virus may persist in the air or on surfaces

MAP your plan to prevent transmission to bats!

Mitigation Strategies

Minimize

Delay, prioritize, or avoid handling bats when possible, i.e. implement acoustic surveys

Assess

Postpone handling bats if there is a probability that you have been exposed to SARS-CoV-2 or if you have symptoms

Protect

Adopt practices that reduce exposure, i.e. face covering, gloves, disinfection procedures

IUCN SSC Bat Specialist Group

www.iucnbsg.org

Full recommendations @https://tinyurl.com/mapforbats

To: Tony Goldberg[tony.goldberg@wisc.edu]; jit8@cdc.gov[jit8@cdc.gov]; Kading,Rebekah[Rebekah.Kading@colostate.edu]; Joy O'Keefe[joyokeefe@gmail.com]; Diana Hews[Diana.Hews@indstate.edu]; Fagre,Anna[Anna.Fagre@colostate.edu]; Kevin Castle[castlekt@gmail.com]; Paul Cryan[cryanp@usgs.gov]; Bowen,Richard[Richard.Bowen@ColoState.EDU]; Schountz,Tony[Tony.Schountz@colostate.edu]; olival@ecohealthalliance.org[olival@ecohealthalliance.org]; epstein[epstein@ecohealthalliance.org]; Amman, Brian R. (CDC/DDID/NCEZID/DHCPP)[cxx1@cdc.gov]; raina.plowright@montana.edu[raina.plowright@montana.edu]; Karen Fox - DNR[karen.fox@state.co.us]; Stokes, Martha M CIV (USA)[martha.m.stokes.civ@mail.mil]; Robert Kityo[kityrob@gmail.com]; abelwade@gmail.com[abelwade@gmail.com]; Christine Kreuder Johnson[ckjohnson@UCDAVIS.EDU]; dreeder@bucknell.edu[dreeder@bucknell.edu]; Brian H Bird[bhbird@ucdavis.edu]; Piaggio, Antoinette J - APHIS[toni.j.piaggio@usda.gov]; Gilbert, Amy T - APHIS[amy.t.gilbert@usda.gov]; David Hayman[d.t.s.hayman@massey.ac.nz]; Grant, Evan H[ehgrant@usgs.gov]; Stoner,Kathryn[Kathryn.Stoner@colostate.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Bowen,Richard[Richard.Bowen@ColoState.EDU]; Bosco-Lauth,Angela[Angela.Bosco-Lauth@colostate.edu]; Robert Aruho[robert.aruho@ugandawildlife.org]; Patrick Atimnedi[atimpat36@gmail.com]; Luke Nyakarahuka[nyakarahuka@gmail.com]; Julian Kerbis[jkerbis@fieldmuseum.org]; Margaret Driciru[margaret.driciru@gmail.com]; Clif McKee[clifton.mckee@gmail.com]; spwa@hotmail.com[spwa@hotmail.com]; Charles Calisher[calisher@cybersafe.net]; kosoy[Michael.Kosoy@colostate.edu]; Franklin, Alan B - APHIS[alan.b.franklin@usda.gov]; Root, Jeff - APHIS[jeff.root@usda.gov]; Bevins, Sarah N - APHIS[sarah.n.bevins@usda.gov]; ksidamonidze@gmail.com[ksidamonidze@gmail.com]; lelincdc@gmail.com[lelincdc@gmail.com]; c_demetria@yahoo.com.ph[c_demetria@yahoo.com.ph]; wanda.markotter@up.ac.za[wanda.markotter@up.ac.za]; Julius Lutwama[jjlutwama03@yahoo.com]; VandeWoude,Susan[Sue.Vandewoude@ColoState.EDU]; Webb,Colleen[Colleen.Webb@ColoState.EDU]; nisreen.hmoud@rss.jo[nisreen.hmoud@rss.jo]; Schuh, Amy (CDC/DDID/NCEZID/DHCPP)[wuc2@cdc.gov]; Sealy, Tara K. (CDC/DDID/NCEZID/DHCPP)[tss3@cdc.gov]
Cc: Kingston, Tigga[Tigga.Kingston@ttu.edu]
From: Robert Aruho[robert.aruho@wildlife.go.ug]
Sent: Mon 6/22/2020 6:36:52 PM (UTC-04:00)
Subject: Re: IUCN guidelines

Dear Rebekah,
Thanks for sharing this.

Conserving for Generations

Dr. Robert Aruho, BVetMed, MSc.
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National Rhino Coordinator
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Please take note of the change in my official email. My current address is now: robert.aruho@wildlife.go.ug.

From: Tony Goldberg <tony.goldberg@wisc.edu>
Date: Tuesday, 23 June 2020 at 01:22
To: "jit8@cdc.gov" <jit8@cdc.gov>, "Kading,Rebekah" <Rebekah.Kading@colostate.edu>, Joy O'Keefe <joyokeefe@gmail.com>, Diana Hews <Diana.Hews@indstate.edu>, "Fagre,Anna" <Anna.Fagre@colostate.edu>, Kevin Castle <castlekt@gmail.com>, Paul Cryan <cryanp@usgs.gov>, "Bowen,Richard" <Richard.Bowen@ColoState.EDU>, "Schountz,Tony" <Tony.Schountz@colostate.edu>, "olival@ecohealthalliance.org" <olival@ecohealthalliance.org>, epstein <epstein@ecohealthalliance.org>, "Amman, Brian R. (CDC/DDID/NCEZID/DHCPP)" <cxx1@cdc.gov>, "raina.plowright@montana.edu" <raina.plowright@montana.edu>, Karen Fox - DNR <karen.fox@state.co.us>, "Stokes, Martha M CIV (USA)" <martha.m.stokes.civ@mail.mil>, Robert Kityo <kityrob@gmail.com>, "abelwade@gmail.com" <abelwade@gmail.com>, Christine Kreuder Johnson <ckjohnson@UCDAVIS.EDU>, "dreeder@bucknell.edu" <dreeder@bucknell.edu>, Brian H Bird <bhbird@ucdavis.edu>, "Piaggio, Antoinette J - APHIS" <toni.j.piaggio@usda.gov>, "Gilbert, Amy T - APHIS" <amy.t.gilbert@usda.gov>, David Hayman <d.t.s.hayman@massey.ac.nz>, "Grant, Evan H" <ehgrant@usgs.gov>, "Stoner,Kathryn" <Kathryn.Stoner@colostate.edu>, "Baric, Ralph S" <rbaric@email.unc.edu>, "Bowen,Richard"

<Richard.Bowen@ColoState.EDU>, "Bosco-Lauth,Angela" <Angela.Bosco-Lauth@colostate.edu>, "Dr.Robert Aruho" <robert.aruho@ugandawildlife.org>, Atimnedi Patrick <atimpat36@gmail.com>, Luke Nyakarahuka <nyakarahuka@gmail.com>, Julian Kerbis <jkerbis@fieldmuseum.org>, Margaret Driciru <margaret.driciru@gmail.com>, Clif McKee <clifton.mckee@gmail.com>, "spwa@hotmail.com" <spwa@hotmail.com>, Charles Calisher <calisher@cybersafe.net>, kosoy <Michael.Kosoy@colostate.edu>, "Franklin, Alan B - APHIS" <alan.b.franklin@usda.gov>, "Root, Jeff - APHIS" <jeff.root@usda.gov>, "Bevins, Sarah N - APHIS" <sarah.n.bevins@usda.gov>, "ksidamonidze@gmail.com" <ksidamonidze@gmail.com>, "lelincdc@gmail.com" <lelincdc@gmail.com>, "c_demetria@yahoo.com.ph" <c_demetria@yahoo.com.ph>, "wanda.markotter@up.ac.za" <wanda.markotter@up.ac.za>, Julius Lutwama <jjlutwama03@yahoo.com>, "VandeWoude,Susan" <Sue.Vandewoude@ColoState.EDU>, "Webb,Colleen" <Colleen.Webb@ColoState.EDU>, "nisreen.hmoud@rss.jo" <nisreen.hmoud@rss.jo>, "Schuh, Amy (CDC/DDID/NCEZID/DHCPP)" <wuc2@cdc.gov>, "Sealy, Tara K. (CDC/DDID/NCEZID/DHCPP)" <tss3@cdc.gov>
Cc: "Kingston, Tigga" <Tigga.Kingston@ttu.edu>
Subject: Re: IUCN guidelines

Wonderful! Thanks for sending this, Rebekah. It's very timely.

Tony

****

Tony L. Goldberg, PhD, DVM, MS
John D. MacArthur Chair
Professor of Epidemiology, Department of Pathobiological Sciences, School of Veterinary Medicine
and
Associate Director for Research, UW-Madison Global Health Institute

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Hanson Laboratories, room 137
1656 Linden Drive
Madison, Wisconsin 53706
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e-mail: tony.goldberg@wisc.edu
Website: http://www.vetmed.wisc.edu/goldberglab

From: jit8@cdc.gov <jit8@cdc.gov>
Sent: Monday, June 22, 2020 5:20 PM
To: Kading,Rebekah <Rebekah.Kading@colostate.edu>; Joy O'Keefe <joyokeefe@gmail.com>; Diana Hews <Diana.Hews@indstate.edu>; Fagre,Anna <Anna.Fagre@colostate.edu>; Kevin Castle <castlekt@gmail.com>; Paul Cryan <cryanp@usgs.gov>; Bowen,Richard <Richard.Bowen@ColoState.EDU>; Schountz,Tony <Tony.Schountz@colostate.edu>; olival@ecohealthalliance.org <olival@ecohealthalliance.org>; epstein <epstein@ecohealthalliance.org>; Amman, Brian R. (CDC/DDID/NCEZID/DHCPP) <cxx1@cdc.gov>; raina.plowright@montana.edu <raina.plowright@montana.edu>; Karen Fox - DNR <karen.fox@state.co.us>; Stokes, Martha M CIV (USA) <martha.m.stokes.civ@mail.mil>; Robert Kityo <kityrob@gmail.com>; abelwade@gmail.com <abelwade@gmail.com>; Tony Goldberg <tony.goldberg@wisc.edu>; Christine Kreuder Johnson <ckjohnson@UCDAVIS.EDU>; dreeder@bucknell.edu <dreeder@bucknell.edu>; Brian H Bird <bhbird@ucdavis.edu>; Piaggio, Antoinette J - APHIS <toni.j.piaggio@usda.gov>; Gilbert, Amy T - APHIS <amy.t.gilbert@usda.gov>; David Hayman <d.t.s.hayman@massey.ac.nz>; Grant, Evan H <ehgrant@usgs.gov>; Stoner,Kathryn <Kathryn.Stoner@colostate.edu>; Baric, Ralph S <rbaric@email.unc.edu>; Bowen,Richard <Richard.Bowen@ColoState.EDU>; Bosco-Lauth,Angela <Angela.Bosco-Lauth@colostate.edu>; Robert Aruho <robert.aruho@ugandawildlife.org>; Patrick Atimnedi <atimpat36@gmail.com>; Luke Nyakarahuka <nyakarahuka@gmail.com>; Julian Kerbis <jkerbis@fieldmuseum.org>; Margaret Driciru <margaret.driciru@gmail.com>; Clif McKee <clifton.mckee@gmail.com>; spwa@hotmail.com <spwa@hotmail.com>; Charles Calisher <calisher@cybersafe.net>; kosoy <Michael.Kosoy@colostate.edu>; Franklin, Alan B - APHIS <alan.b.franklin@usda.gov>;

Root, Jeff - APHIS <jeff.root@usda.gov>; Bevins, Sarah N - APHIS <sarah.n.bevins@usda.gov>; ksidamonidze@gmail.com <ksidamonidze@gmail.com>; lelincdc@gmail.com <lelincdc@gmail.com>; c_demetria@yahoo.com.ph <c_demetria@yahoo.com.ph>; wanda.markotter@up.ac.za <wanda.markotter@up.ac.za>; Julius Lutwama <jjlutwama03@yahoo.com>; VandeWoude,Susan <Sue.Vandewoude@ColoState.EDU>; Webb,Colleen <Colleen.Webb@ColoState.EDU>; nisreen.hmoud@rss.jo <nisreen.hmoud@rss.jo>; Schuh, Amy (CDC/DDID/NCEZID/DHCPP) <wuc2@cdc.gov>; Sealy, Tara K. (CDC/DDID/NCEZID/DHCPP) <tss3@cdc.gov>
Cc: Kingston, Tigga <Tigga.Kingston@ttu.edu>
Subject: RE: IUCN guidelines

Nice, well done Rebekah!
Cheers,
Jon

From: Kading,Rebekah <Rebekah.Kading@colostate.edu>
Sent: Monday, June 22, 2020 6:14 PM
To: Joy O'Keefe <joyokeefe@gmail.com>; Diana Hews <Diana.Hews@indstate.edu>; Fagre,Anna <Anna.Fagre@colostate.edu>; Kevin Castle <castlekt@gmail.com>; Paul Cryan <cryanp@usgs.gov>; Bowen,Richard <Richard.Bowen@ColoState.EDU>; Schountz,Tony <Tony.Schountz@colostate.edu>; olival@ecohealthalliance.org; epstein <epstein@ecohealthalliance.org>; Towner, Jonathan (Jon) (CDC/DDID/NCEZID/DHCPP) <jit8@cdc.gov>; Amman, Brian R. (CDC/DDID/NCEZID/DHCPP) <cxx1@cdc.gov>; raina.plowright@montana.edu; Karen Fox - DNR <karen.fox@state.co.us>; Stokes, Martha M CIV (USA) <martha.m.stokes.civ@mail.mil>; Robert Kityo <kityrob@gmail.com>; abelwade@gmail.com; Tony Goldberg <tony.goldberg@wisc.edu>; Christine Kreuder Johnson <ckjohnson@UCDAVIS.EDU>; dreeder@bucknell.edu; Brian H Bird <bhbird@ucdavis.edu>; Piaggio, Antoinette J - APHIS <toni.j.piaggio@usda.gov>; Gilbert, Amy T - APHIS <amy.t.gilbert@usda.gov>; David Hayman <d.t.s.hayman@massey.ac.nz>; Grant, Evan H <ehgrant@usgs.gov>; Stoner,Kathryn <Kathryn.Stoner@colostate.edu>; Baric, Ralph S <rbaric@email.unc.edu>; Bowen,Richard <Richard.Bowen@ColoState.EDU>; Bosco-Lauth,Angela <Angela.Bosco-Lauth@colostate.edu>; Robert Aruho <robert.aruho@ugandawildlife.org>; Patrick Atimnedi <atimpat36@gmail.com>; Luke Nyakarahuka <nyakarahuka@gmail.com>; Julian Kerbis <jkerbis@fieldmuseum.org>; Margaret Driciru <margaret.driciru@gmail.com>; Clif McKee <clifton.mckee@gmail.com>; spwa@hotmail.com; Charles Calisher <calisher@cybersafe.net>; kosoy <Michael.Kosoy@colostate.edu>; Franklin, Alan B - APHIS <alan.b.franklin@usda.gov>; Root, Jeff - APHIS <jeff.root@usda.gov>; Bevins, Sarah N - APHIS <sarah.n.bevins@usda.gov>; ksidamonidze@gmail.com; lelincdc@gmail.com; c_demetria@yahoo.com.ph; wanda.markotter@up.ac.za; Julius Lutwama <jjlutwama03@yahoo.com>; VandeWoude,Susan <Sue.Vandewoude@ColoState.EDU>; Webb,Colleen <Colleen.Webb@ColoState.EDU>; nisreen.hmoud@rss.jo; Schuh, Amy (CDC/DDID/NCEZID/DHCPP) <wuc2@cdc.gov>; Sealy, Tara K. (CDC/DDID/NCEZID/DHCPP) <tss3@cdc.gov>
Cc: Kingston, Tigga <Tigga.Kingston@ttu.edu>
Subject: IUCN guidelines

Dear colleagues,

Hot off the press! The IUCN Species Survival Commission Bat Specialist Group has released guidelines for researchers, to prevent the human-to-bat transmission of SARS-CoV-2. Our infographic is attached, and full guidelines available through either link below. Additional products are to follow shortly, tailored for other stakeholder groups. Please feel free to distribute as you see fit.

Best regards,
Rebekah

https://www.iucnbsg.org/publications.html
https://tinyurl.com/mapforbats

Rebekah C. Kading, PhD

Assistant Professor

Department of Microbiology Immunology and Pathology

Colorado State University

Office: 970-491-7833

Rebekah.Kading@colostate.edu

To: Kading,Rebekah[Rebekah.Kading@colostate.edu]
Cc: Joy O'Keefe[joyokeefe@gmail.com]; Diana Hews[Diana.Hews@indstate.edu]; Fagre,Anna[Anna.Fagre@colostate.edu]; Paul Cryan[cryanp@usgs.gov]; Bowen,Richard[Richard.Bowen@colostate.edu]; Schountz,Tony[Tony.Schountz@colostate.edu]; olival@ecohealthalliance.org[olival@ecohealthalliance.org]; epstein[epstein@ecohealthalliance.org]; Jonathan Towner[jit8@cdc.gov]; Brian Amman[cxx1@cdc.gov]; raina.plowright@montana.edu[raina.plowright@montana.edu]; Karen Fox - DNR[karen.fox@state.co.us]; Stokes, Martha M CIV (USA)[martha.m.stokes.civ@mail.mil]; Robert Kityo[kityrob@gmail.com]; abelwade@gmail.com[abelwade@gmail.com]; Tony Goldberg[tony.goldberg@wisc.edu]; Christine Kreuder Johnson[ckjohnson@ucdavis.edu]; dreeder@bucknell.edu[dreeder@bucknell.edu]; Brian H Bird[bhbird@ucdavis.edu]; Piaggio, Antoinette J - APHIS[toni.j.piaggio@usda.gov]; Gilbert, Amy T - APHIS[amy.t.gilbert@usda.gov]; David Hayman[d.t.s.hayman@massey.ac.nz]; Grant, Evan H[ehgrant@usgs.gov]; Stoner,Kathryn[Kathryn.Stoner@colostate.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Bosco-Lauth,Angela[Angela.Bosco-Lauth@colostate.edu]; Robert Aruho[robert.aruho@ugandawildlife.org]; Patrick Atimnedi[atimpat36@gmail.com]; Luke Nyakarahuka[nyakarahuka@gmail.com]; Julian Kerbis[jkerbis@fieldmuseum.org]; Margaret Driciru[margaret.driciru@gmail.com]; Clif McKee[clifton.mckee@gmail.com]; spwa@hotmail.com[spwa@hotmail.com]; Charles Calisher[calisher@cybersafe.net]; kosoy[Michael.Kosoy@colostate.edu]; Franklin, Alan B - APHIS[alan.b.franklin@usda.gov]; Root, Jeff - APHIS[jeff.root@usda.gov]; Bevins, Sarah N - APHIS[sarah.n.bevins@usda.gov]; ksidamonidze@gmail.com[ksidamonidze@gmail.com]; lelincdc@gmail.com[lelincdc@gmail.com]; c_demetria@yahoo.com.ph[c_demetria@yahoo.com.ph]; wanda.markotter@up.ac.za[wanda.markotter@up.ac.za]; Julius Lutwama[jjlutwama03@yahoo.com]; VandeWoude,Susan[Sue.Vandewoude@colostate.edu]; Webb,Colleen[Colleen.Webb@colostate.edu]; nisreen.hmoud@rss.jo[nisreen.hmoud@rss.jo]; Schuh, Amy (CDC/OID/NCEZID)[wuc2@cdc.gov]; Sealy, Tara K. (CDC/DDID/NCEZID/DHCPP)[tss3@cdc.gov]; Kingston, Tigga[Tigga.Kingston@ttu.edu]
From: Kevin Castle[castlekt@gmail.com]
Sent: Mon 6/22/2020 7:13:11 PM (UTC-04:00)
Subject: Re: IUCN guidelines

Great, thank you Rebekah!
Kevin

On Mon, Jun 22, 2020 at 4:14 PM Kading,Rebekah <Rebekah.Kading@colostate.edu> wrote:

> Dear colleagues,
>
> Hot off the press! The IUCN Species Survival Commission Bat Specialist Group has released guidelines for researchers, to prevent the human-to-bat transmission of SARS-CoV-2. Our infographic is attached, and full guidelines available through either link below. Additional products are to follow shortly, tailored for other stakeholder groups. Please feel free to distribute as you see fit.
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> Best regards,
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> https://www.iucnbsg.org/publications.html
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> **Rebekah C. Kading, PhD**
> Assistant Professor
> Department of Microbiology Immunology and Pathology
> Colorado State University
> Office: 970-491-7833
> *Rebekah.Kading@colostate.edu*

--
Kevin T. Castle, DVM, MS
Wildlife Veterinary Consulting, LLC
840 Sundance Dr.
Livermore, CO 80536

970-430-0205

To: Kading,Rebekah[Rebekah.Kading@colostate.edu]; Joy O'Keefe[joyokeefe@gmail.com]; Diana Hews[Diana.Hews@indstate.edu]; Fagre,Anna[Anna.Fagre@colostate.edu]; Kevin Castle[castlekt@gmail.com]; Paul Cryan[cryanp@usgs.gov]; Bowen,Richard[Richard.Bowen@ColoState.EDU]; Schountz,Tony[Tony.Schountz@colostate.edu]; olival@ecohealthalliance.org[olival@ecohealthalliance.org]; epstein[epstein@ecohealthalliance.org]; Towner, Jonathan (Jon) (CDC/DDID/NCEZID/DHCPP)[jit8@cdc.gov]; raina.plowright@montana.edu[raina.plowright@montana.edu]; Karen Fox - DNR[karen.fox@state.co.us]; Stokes, Martha M CIV (USA)[martha.m.stokes.civ@mail.mil]; Robert Kityo[kityrob@gmail.com]; abelwade@gmail.com[abelwade@gmail.com]; Tony Goldberg[tony.goldberg@wisc.edu]; Christine Kreuder Johnson[ckjohnson@UCDAVIS.EDU]; dreeder@bucknell.edu[dreeder@bucknell.edu]; Brian H Bird[bhbird@ucdavis.edu]; Piaggio, Antoinette J - APHIS[toni.j.piaggio@usda.gov]; Gilbert, Amy T - APHIS[amy.t.gilbert@usda.gov]; David Hayman[d.t.s.hayman@massey.ac.nz]; Grant, Evan H[ehgrant@usgs.gov]; Stoner,Kathryn[Kathryn.Stoner@colostate.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Bowen,Richard[Richard.Bowen@ColoState.EDU]; Bosco-Lauth,Angela[Angela.Bosco-Lauth@colostate.edu]; Robert Aruho[robert.aruho@ugandawildlife.org]; Patrick Atimnedi[atimpat36@gmail.com]; Luke Nyakarahuka[nyakarahuka@gmail.com]; Julian Kerbis[jkerbis@fieldmuseum.org]; Margaret Driciru[margaret.driciru@gmail.com]; Clif McKee[clifton.mckee@gmail.com]; spwa@hotmail.com[spwa@hotmail.com]; Charles Calisher[calisher@cybersafe.net]; kosoy[Michael.Kosoy@colostate.edu]; Franklin, Alan B - APHIS[alan.b.franklin@usda.gov]; Root, Jeff - APHIS[jeff.root@usda.gov]; Bevins, Sarah N - APHIS[sarah.n.bevins@usda.gov]; ksidamonidze@gmail.com[ksidamonidze@gmail.com]; lelincdc@gmail.com[lelincdc@gmail.com]; c_demetria@yahoo.com.ph[c_demetria@yahoo.com.ph]; wanda.markotter@up.ac.za[wanda.markotter@up.ac.za]; Julius Lutwama[jjlutwama03@yahoo.com]; VandeWoude,Susan[Sue.Vandewoude@ColoState.EDU]; Webb,Colleen[Colleen.Webb@ColoState.EDU]; nisreen.hmoud@rss.jo[nisreen.hmoud@rss.jo]; Schuh, Amy (CDC/DDID/NCEZID/DHCPP)[wuc2@cdc.gov]; Sealy, Tara K. (CDC/DDID/NCEZID/DHCPP)[tss3@cdc.gov]
Cc: Kingston, Tigga[Tigga.Kingston@ttu.edu]
From: Amman, Brian R. (CDC/DDID/NCEZID/DHCPP)[cxx1@cdc.gov]
Sent: Tue 6/23/2020 4:42:38 AM (UTC-04:00)
Subject: RE: IUCN guidelines

Thanks Rebekah!

From: Kading,Rebekah <Rebekah.Kading@colostate.edu>
Sent: Monday, June 22, 2020 6:14 PM
To: Joy O'Keefe <joyokeefe@gmail.com>; Diana Hews <Diana.Hews@indstate.edu>; Fagre,Anna <Anna.Fagre@colostate.edu>; Kevin Castle <castlekt@gmail.com>; Paul Cryan <cryanp@usgs.gov>; Bowen,Richard <Richard.Bowen@ColoState.EDU>; Schountz,Tony <Tony.Schountz@colostate.edu>; olival@ecohealthalliance.org; epstein <epstein@ecohealthalliance.org>; Towner, Jonathan (Jon) (CDC/DDID/NCEZID/DHCPP) <jit8@cdc.gov>; Amman, Brian R. (CDC/DDID/NCEZID/DHCPP) <cxx1@cdc.gov>; raina.plowright@montana.edu; Karen Fox - DNR <karen.fox@state.co.us>; Stokes, Martha M CIV (USA) <martha.m.stokes.civ@mail.mil>; Robert Kityo <kityrob@gmail.com>; abelwade@gmail.com; Tony Goldberg <tony.goldberg@wisc.edu>; Christine Kreuder Johnson <ckjohnson@UCDAVIS.EDU>; dreeder@bucknell.edu; Brian H Bird <bhbird@ucdavis.edu>; Piaggio, Antoinette J - APHIS <toni.j.piaggio@usda.gov>; Gilbert, Amy T - APHIS <amy.t.gilbert@usda.gov>; David Hayman <d.t.s.hayman@massey.ac.nz>; Grant, Evan H <ehgrant@usgs.gov>; Stoner,Kathryn <Kathryn.Stoner@colostate.edu>; Baric, Ralph S <rbaric@email.unc.edu>; Bowen,Richard <Richard.Bowen@ColoState.EDU>; Bosco-Lauth,Angela <Angela.Bosco-Lauth@colostate.edu>; Robert Aruho <robert.aruho@ugandawildlife.org>; Patrick Atimnedi <atimpat36@gmail.com>; Luke Nyakarahuka <nyakarahuka@gmail.com>; Julian Kerbis <jkerbis@fieldmuseum.org>; Margaret Driciru <margaret.driciru@gmail.com>; Clif McKee <clifton.mckee@gmail.com>; spwa@hotmail.com; Charles Calisher <calisher@cybersafe.net>; kosoy <Michael.Kosoy@colostate.edu>; Franklin, Alan B - APHIS <alan.b.franklin@usda.gov>; Root, Jeff - APHIS <jeff.root@usda.gov>; Bevins, Sarah N - APHIS <sarah.n.bevins@usda.gov>; ksidamonidze@gmail.com; lelincdc@gmail.com; c_demetria@yahoo.com.ph; wanda.markotter@up.ac.za; Julius Lutwama <jjlutwama03@yahoo.com>; VandeWoude,Susan <Sue.Vandewoude@ColoState.EDU>; Webb,Colleen <Colleen.Webb@ColoState.EDU>; nisreen.hmoud@rss.jo; Schuh, Amy (CDC/DDID/NCEZID/DHCPP) <wuc2@cdc.gov>; Sealy, Tara K. (CDC/DDID/NCEZID/DHCPP) <tss3@cdc.gov>
Cc: Kingston, Tigga <Tigga.Kingston@ttu.edu>
Subject: IUCN guidelines

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Best regards,
Rebekah

https://www.iucnbsg.org/publications.html
https://tinyurl.com/mapforbats

Rebekah C. Kading, PhD

Assistant Professor

Department of Microbiology Immunology and Pathology

Colorado State University

Office: 970-491-7833

Rebekah.Kading@colostate.edu

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Location: RESCHEDULED due to holiday - please reply if you can attend

Importance: Normal

Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Tue 6/30/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 6/30/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Meeting: NAM-APHA COVID-19 Webinar Series
Time: May 8, 2020 02:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/526660780

Or iPhone one-tap :
US: +13126266799,,526660780# or +14702509358,,526660780#
Or Telephone:
Dial(for higher quality, dial a number based on your current location) :
US: +1 312 626 6799 or +1 470 250 9358 or +1 646 518 9805 or +1 646 558 8656 or +1 669 219 2599 or +1 669 900 6833 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 301 715 8592 or +1 602 753 0140 or +1 651 372 8299 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 526 660 780
International numbers available: https://nasem.zoom.us/u/atQMQpnhh

Would you like to test your Zoom connection? Please click on the link below.
https://nasem.zoom.us/test

To: Kading,Rebekah[Rebekah.Kading@colostate.edu]
Cc: Joy O'Keefe[joyokeefe@gmail.com]; Diana Hews[diana.hews@indstate.edu]; Fagre,Anna[Anna.Fagre@colostate.edu]; Kevin Castle[castlekt@gmail.com]; Paul Cryan[cryanp@usgs.gov]; Bowen,Richard[Richard.Bowen@colostate.edu]; Schountz,Tony[Tony.Schountz@colostate.edu]; olival@ecohealthalliance.org[olival@ecohealthalliance.org]; epstein[epstein@ecohealthalliance.org]; Jonathan Towner[jit8@cdc.gov]; Brian Amman[cxx1@cdc.gov]; raina.plowright@montana.edu[raina.plowright@montana.edu]; Karen Fox - DNR[karen.fox@state.co.us]; Stokes, Martha M CIV (USA)[martha.m.stokes.civ@mail.mil]; abelwade@gmail.com[abelwade@gmail.com]; Tony Goldberg[tony.goldberg@wisc.edu]; Christine Kreuder Johnson[ckjohnson@ucdavis.edu]; dreeder@bucknell.edu[dreeder@bucknell.edu]; Brian H Bird[bhbird@ucdavis.edu]; Piaggio, Antoinette J - APHIS[toni.j.piaggio@usda.gov]; Gilbert, Amy T - APHIS[amy.t.gilbert@usda.gov]; David Hayman[d.t.s.hayman@massey.ac.nz]; Grant, Evan H[ehgrant@usgs.gov]; Stoner,Kathryn[Kathryn.Stoner@colostate.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Bosco-Lauth,Angela[Angela.Bosco-Lauth@colostate.edu]; Robert Aruho[robert.aruho@ugandawildlife.org]; Patrick Atimnedi[atimpat36@gmail.com]; Luke Nyakarahuka[nyakarahuka@gmail.com]; Julian Kerbis[jkerbis@fieldmuseum.org]; Margaret Driciru[margaret.driciru@gmail.com]; Clif McKee[clifton.mckee@gmail.com]; spwa@hotmail.com[spwa@hotmail.com]; Charles Calisher[calisher@cybersafe.net]; kosoy[Michael.Kosoy@colostate.edu]; Franklin, Alan B - APHIS[alan.b.franklin@usda.gov]; Root, Jeff - APHIS[jeff.root@usda.gov]; Bevins, Sarah N - APHIS[sarah.n.bevins@usda.gov]; ksidamonidze@gmail.com[ksidamonidze@gmail.com]; lelincdc@gmail.com[lelincdc@gmail.com]; c_demetria@yahoo.com.ph[c_demetria@yahoo.com.ph]; wanda.markotter@up.ac.za[wanda.markotter@up.ac.za]; Julius Lutwama[jjlutwama03@yahoo.com]; VandeWoude,Susan[Sue.Vandewoude@colostate.edu]; Webb,Colleen[Colleen.Webb@colostate.edu]; nisreen.hmoud@rss.jo[nisreen.hmoud@rss.jo]; Schuh, Amy (CDC/OID/NCEZID)[wuc2@cdc.gov]; Sealy, Tara K. (CDC/DDID/NCEZID/DHCPP)[tss3@cdc.gov]; Kingston, Tigga[Tigga.Kingston@ttu.edu]
From: Robert Kityo[kityrob@gmail.com]
Sent: Tue 6/23/2020 10:01:17 AM (UTC-04:00)
Subject: Re: IUCN guidelines

Thanks Rebekah for sharing this.

On Tue, 23 Jun 2020, 01:14 Kading,Rebekah <Rebekah.Kading@colostate.edu> wrote:

> Dear colleagues,
>
> Hot off the press! The IUCN Species Survival Commission Bat Specialist Group has released guidelines for researchers, to prevent the human-to-bat transmission of SARS-CoV-2. Our infographic is attached, and full guidelines available through either link below. Additional products are to follow shortly, tailored for other stakeholder groups. Please feel free to distribute as you see fit.
>
> Best regards,
> Rebekah
>
> https://www.iucnbsg.org/publications.html
> https://tinyurl.com/mapforbats
>
> **Rebekah C. Kading, PhD**
> Assistant Professor
> Department of Microbiology Immunology and Pathology
> Colorado State University
> Office: 970-491-7833
> *Rebekah.Kading@colostate.edu*

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; david.j.payne@gsk.com[david.j.payne@gsk.com]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; john.young.jy3@roche.com[john.young.jy3@roche.com]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Collins, Francis (NIH/OD) [E][collinsf@od.nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]
Cc: Wholley, David (FNIH) [T][dwholley@fnih.org]; Austin, Christopher (NIH/NCATS) [E][austinc@mail.nih.gov]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Desrosiers, Betsy[elizabeth_desrosiers@merck.com]; Hughes, Eric[eric.hughes@novartis.com]; Jansen, Kathrin[kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E][michael.kurilla@nih.gov]; Lowy, Douglas (NCI)[dl60z@nih.gov]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; James, Stephanie (FNIH) [T][sjames@fnih.org]; Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Kim, Elizabeth[elkim@deloitte.com]; Tolman, Brett[btolman@deloitte.com]; Wachtel, Jonathan[jwachtel@deloitte.com]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Diamond, Michael[mdiamond@wustl.edu]; Rose Li[rose.li@roseliassociates.com]; Dana Carluccio[dana.carluccio@roseliassociates.com]; Lagos, Enrique (NIH/NCATS) [E][enrique.lagos@nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Gonzalez, Nina[ningonzalez@deloitte.com]; Simon, Dina (NIH/OD) [C][dina.simon@nih.gov]; Burrus-Shaw, Cyndi (NIH/OD) [E][cyndi.burrus-shaw@nih.gov]; Rodriguez, Robin D[rmdaigle@tulane.edu]; Dave Frankowski[david.frankowski@roseliassociates.com]; Baric, Toni C[antoinette_baric@med.unc.edu]; Lowy, Douglas (NIH/NCI) [E][lowyd@mail.nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Nancy Haigwood[haigwoon@ohsu.edu]; Stratton, Benjamin[bstratton@DELOITTE.com]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]
From: Kara Carter[Kara.Carter@evotec.com]
Sent: Wed 6/24/2020 1:28:05 PM (UTC-04:00)
Subject: RE: ACTIV Preclinical full working group
COVID-19_06152020_F.pdf

Dear All,

I just discovered this amazingly comprehensive overview of COVID-19, vaccine development and drug development. It will likely take you a while to go through it as it did me!

Enjoy,
Kara

evotec

Kara Carter, PhD
Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
kara.carter@evotec.com
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-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Tuesday, April 14, 2020 6:43 PM
To: Menetski, Joseph (FNIH) [T]; david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; Kara Carter; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T];

Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Subject: ACTIV Preclinical full working group
When: Wednesday, June 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

[EXTERNAL]

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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+1 408 638 0968 US (San Jose)
+1 669 900 6833 US (San Jose)
+1 253 215 8782 US (Tacoma)
+1 346 248 7799 US (Houston)
Meeting ID: 960 4240 3854
Password: 124630
Find your local number: https://fnih.zoom.us/u/aemFGSQrl

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; david.j.payne@gsk.com[david.j.payne@gsk.com]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; john.young.jy3@roche.com[john.young.jy3@roche.com]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Collins, Francis (NIH/OD) [E][collinsf@od.nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]
Cc: Wholley, David (FNIH) [T][dwholley@fnih.org]; Austin, Christopher (NIH/NCATS) [E][austinc@mail.nih.gov]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Desrosiers, Betsy[elizabeth_desrosiers@merck.com]; Hughes, Eric[eric.hughes@novartis.com]; Jansen, Kathrin[kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E][michael.kurilla@nih.gov]; Lowy, Douglas (NCI)[dl60z@nih.gov]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; James, Stephanie (FNIH) [T][sjames@fnih.org]; Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Kim, Elizabeth[elkim@deloitte.com]; Tolman, Brett[btolman@deloitte.com]; Wachtel, Jonathan[jwachtel@deloitte.com]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Diamond, Michael[mdiamond@wustl.edu]; Rose Li[rose.li@roseliassociates.com]; Dana Carluccio[dana.carluccio@roseliassociates.com]; Lagos, Enrique (NIH/NCATS) [E][enrique.lagos@nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Gonzalez, Nina[ningonzalez@deloitte.com]; Simon, Dina (NIH/OD) [C][dina.simon@nih.gov]; Burrus-Shaw, Cyndi (NIH/OD) [E][cyndi.burrus-shaw@nih.gov]; Rodriguez, Robin D[rmdaigle@tulane.edu]; Dave Frankowski[david.frankowski@roseliassociates.com]; Baric, Toni C[antoinette_baric@med.unc.edu]; Lowy, Douglas (NIH/NCI) [E][lowyd@mail.nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Nancy Haigwood[haigwoon@ohsu.edu]; Stratton, Benjamin[bstratton@DELOITTE.com]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]
From: Kara Carter[Kara.Carter@evotec.com]
Sent: Wed 6/24/2020 1:30:01 PM (UTC-04:00)
Subject: RE: ACTIV Preclinical full working group
RACAP_COVID-19_MAP_INSIGHTS.pdf

And the guide to reading the map….

evotec

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Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
kara.carter@evotec.com
www.evotec.com

From: Kara Carter
Sent: Wednesday, June 24, 2020 1:27 PM
To: 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E] <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph <rbaric@email.unc.edu>; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Tomas Cihlar <Tomas.Cihlar@gilead.com>; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) <margaret.l.pitt.civ@mail.mil>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>
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Subject: RE: ACTIV Preclinical full working group

Dear All,

I just discovered this amazingly comprehensive overview of COVID-19, vaccine development and drug development. It will likely take you a while to go through it as it did me!

Enjoy,
Kara

evotec

Kara Carter, PhD
Executive Vice President Infectious Disease
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-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Tuesday, April 14, 2020 6:43 PM
To: Menetski, Joseph (FNIH) [T]; david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; Kara Carter; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
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When: Wednesday, June 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
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[EXTERNAL]

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

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One tap mobile
+13017158592,,96042403854#,,1#,124630# US (Germantown)
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Dial by your location
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+1 253 215 8782 US (Tacoma)
+1 346 248 7799 US (Houston)
Meeting ID: 960 4240 3854
Password: 124630
Find your local number: https://fnih.zoom.us/u/aemFGSQrl

MAY 12, 2020

RA CAPITAL'S COVID-19 MAP:
Insights into a Coordinated Response Strategy

PETER KOLCHINSKY, PHD
Managing Partner, RA Capital Management

For more information about RA Capital's COVID-19 coverage, please visit:
www.racap.com/covid-19

TABLE OF CONTENTS

INTRODUCTION

The world is now embarking on a massive initiative to fight COVID-19. Hundreds of companies, non-profits, academic institutions, and government agencies are playing a part in an effort that some have compared to the Manhattan Project. The US government calls its own portion of this effort Operation Warp Speed.

When executing on a large-scale, multi-pronged initiative, it is essential to have an overview of the totality of the ongoing work. If each individual vaccine or drug or test is a chess piece, then one needs to see the chessboard as a whole. Lists of all the programs fall short in conveying the interdependencies and opportunities for using different technologies together or in a particular sequence.

Our team has created a map that captures many of the major ongoing technology development efforts in the world to solve our COVID-19 crisis. The goals of the map are to not only lay out the competitive landscape of a given space, but to also reveal strategic insights that emerge when looking at the space in its totality. Historically, such technology landscape maps of cancer, auto-immune disorders, diabetes, and other diseases have guided our own investment of time and money into what we believed to be the most important projects. We hope that this map will be of use to BARDA, CEPI, and other grant-giving organizations as they consider the best uses of their resources, and we are making it available to the global community in the hopes that it allows leaders to formulate strategies to make the most of all the ongoing work.

As one example, today there is consi derable funding going to vaccines that focus the immune response on just the viral spike protein. While that is logical, it leaves us all undiversified in our vaccine development strategy. We would argue that at least some funding should go towards vaccines that rely on inactivated and attenuated virus.

On the treatment side, while remdesivir is authorized for emergency use to treat patients with serious COVID-19, it is in short supply, difficult to manufacture, and must be given intravenously (IV). But there are related drugs in testing whose probabilities of success are informed by remdesivir's. Some of these are oral and may be easier to manufacture. Remdesivir's success thus far should spark a shift in resources to make the most of those other programs.

Meanwhile, the map teaches us that we should be thinking ahead further: are there enough syringes and needles to meet an undoubtedly unprecedented demand for a COVID-19 vaccine? Who should receive the limited doses of COVID-19vaccine that may become available in late 2020 or early 2021? What drugs might work best in combination, or in what sequence? Will there be knock-on effects from COVID-19 that we need to prepare for, such as a surge in demand for flu vaccine; America normally only procures enough doses for half the population – should we put in a larger order now? How do we ensure that everyone can access COVID-19 treatments and vaccines? COVID-19 has accelerated all facets of drug and vaccine R&D and regulation. Only by looking at the big picture can we see the gaps in our vaccination and treatment strategies. Only by looking at the big picture can we more quickly anticipate where to shift resources when a project fails (there will be failures along the way). And only by looking at the big picture can we judge how to make the most of any success.

Below, you will find many of our key insights around vaccine, therapeutics, and diagnostic development that we have gleaned from looking at the big picture.

VACCINES

The vaccine programs that were first to reach clinical testing are considered difficult to manufacture at scale. Therefore, the vaccines that reach the market sooner than others might not be the ones that will necessarily be produced in sufficient amounts to meet the world's needs. Some of the vaccines that may be among the first scaled to billions of doses may not be able to be re-dosed every year if it turns out that we need to get seasonal booster shots. Some vaccines might be more readily combined with flu vaccines than others, which would be useful if we do someday need to give regular booster shots and want to avoid having to give people

two injections. So, the various vaccine programs may serve different purposes. The earliest ones to market might only benefit front-line workers; the first to scale to high levels of production will unlock the global economy; the ones that can be readily re-dosed and combined with flu vaccine may take a bit longer to develop but help keep SARS-CoV-2 permanently in-check.

mRNA

Vaccines that deliver mRNA encoding SARS-CoV-2 Spike antigen could be among the first to be approved, but most companies working with this technology can only manufacture them on the scale of a few kilograms. The most important two questions for those programs are how much mRNA will be required to generate an immune response and will the vaccines require more than one dose. If two doses are required (e.g. at least 50ug each, which Moderna suggests is likely), then those programs will initially serve to vaccinate tens of millions of people per month globally. But if some of these programs need only a single 5ug dose, then mRNA could quickly vaccinate hundreds of millions of people per month by the end of 2020 or by early 2021. We will know what doses are needed within a few months: trials for vaccines by CureVac, BioNTech, Moderna, and others should read out by fall 2020.

Adenoviral Vectors

Johnson & Johnson (J&J)is scaling up production of its adenoviral-vector-based COVID-19 vaccine and plans on initially delivering hundreds of millions of doses, with capacity to make 1 billion doses/year sometime in 2021. However, J&J is not yet in the clinic. Their trials will likely start this fall. But in late April, the University of Oxford ambitiously launched a controlled trial of a similar adenoviral vaccine in over 1000 people. This will tell us how good such a vaccine could be, point to an effective dose, and indicate whether it needs to be boosted with a second dose. The Oxford vaccine might scale up more slowly than J&J's but it will give us a sense of how well and how efficiently J&J's might work. In the event that it only needs to be given once and at a low dose, then we might speculate that J&J's manufacturing capacity will stretch to vaccinate many more people than originally planned. However, there is also a risk that a second dose of Oxford's adenoviral vaccine does not work as well because our immune systems generate antibodies against the viral vector in response to the first dose (a problem particular to vectorized vaccines). In that case, we could possibly boost with a different vaccine.

Exploring Combinations

Combining an adenoviral vaccine for the prime dose and other vaccines for the boost dose might even maximize vaccine production capacity due a vaccine phenomenon known as fractional dosing in which the booster dose can sometimes be much lower than the initial priming dose. So rather than using 1B adenoviral doses to vaccinate 500M people twice and 500M doses of a protein-based (or mRNA-based) vaccine to vaccinate 250M people twice for a total vaccination of 750M people, we might vaccinate 1B people with a combination of one dose of the adenoviral vaccine and a half-dose of the protein-based vaccine. The various large-scale vaccine groups should be collaborating on joint animal studies with a goal of exploring these "heterologous prime-boost" human studies. To our knowledge, such collaborations are not yet ongoing.

Protein Antigens and Combinations with Flu Vaccines

We will eventually have options that are more conventional than mRNA or viral-vector vaccines. Novavax, for example, will start trials in May 2020 of two doses of its nanoparticle vaccine. With enough investment, they might be able to scale up production considerably. Behind Novavax is Sanofi, which unlike all the other companies mentioned so far, is one of the world's few large vaccine manufacturers (Sanofi has support from GlaxoSmithKline, another large vaccine player, which has contributed a novel but proven adjuvant to Sanofi's effort). Sanofi sells conventional flu vaccines and is now working on a protein subunit version of the SARS-CoV-2 vaccine. That vaccine will be slow to market but is potentially the easiest to scale using tried and true methods. Depending on the adjuvant, it could also be combined with Sanofi's existing flu vaccine, allowing for streamlined global distribution over the long run. It makes sense for governments and payers to think now about how and

how much they would want to pay for a combination flu/SARS-CoV-2 vaccine versus just the individual parts. Making sure that people get the flu shot is going to be critical to minimizing false alarms from people getting the flu but scaring themselves and others into thinking it is COVID-19.

Vaccines and Antibody Tests

When we do have a vaccine, we need to anticipate that antibody tests of the future need to be able to tell the difference between antibodies from a vaccine and antibodies from an infection. We have both of these kinds of tests and need to make sure that the right ones are deployed and used at the right time in synchrony with vaccines to track the vaccines' real-world effectiveness. We will also need antibody tests that can accurately tell when a person has been reinfected; that is possible by looking for IgM antibodies, though those suffer from poor specificity (high false-positive rate). Better IgM tests are required if we hope to be able to detect rates of reinfection without having to use PCR to catch each reinfection (especially since reinfections might be milder or even asymptomatic in patients with some immunity after a vaccination or first infection).

Passing the Safety Hurdle

Hanging over the whole vaccine field are several questions about COVID-19 vaccine safety and efficacy. We all want to know if they will work in humans, and we know that several vaccines have been able to generate antibodies in animals that protect those animals from infection. We also know that these first few experiments have not observed a phenomenon called "enhanced disease" in which a vaccine helps the virus infect certain immune cells and leads to worse outcomes. However, before we can be sure these vaccines do not cause enhancement, it would be good to know that we can somehow induce enhancement in animals. Several laboratories are trying to do this (e.g. use an intentionally poorly prepared vaccine to cause enhancement). As soon as one does, that will allow everyone to compare their vaccines in this model. It will be essential that these preclinical studies are published as quickly as possible so that the field can learn from them.

Monitoring for Antigenic Drift (that would require updating vaccines)

Based on sequencing of SARS-CoV-2 from patients all over the world, we are seeing the emergence of mutations in the Spike protein, including the critical Receptor Binding Domain (RBD) that we consider the virus' greatest point of vulnerability to antibodies. It is feared that if the RBD changes too much, then our vaccines will stop working against these new strains. This phenomenon of antigen drift is one way the flu evolves slightly away from our vaccines each season, requiring us to update flu vaccines to keep them effective. Therefore, we need vaccine manufacturers to regularly test whether the antibodies their vaccines generate can neutralize these new RBD-mutated strains. If they detect waning efficacy, we need them to start working on updated versions of their vaccines. Reporting these findings to the public would go a long way towards reassuring the public that news of new strains with feared mutations in the RBD region does not mean that vaccines will not work.

Just in case: Preparing for Potential Challenge Studies

There is a complex relationship between social distancing and vaccine development. On the one hand, social distancing helps to flatten the curve until we get a vaccine. On the other hand, unless there is a certain rate of new infections in the tested population (i.e. the "attack rate", such as 2% of people getting infected each month), it is impossible to demonstrate that a vaccine actually works to prevent real-world infections. Therefore, it will be important for vaccine developers to be able to run studies wherever in the world there are high rates of infections.

Some have suggested testing vaccines on volunteers who are willing to then let themselves be exposed to the virus to see if the vaccine protected them (so-called "challenge studies"). However, we currently neither know the right dose of virus to simulate an infection in the real world nor do we have a supply of the virus that would be considered suitable for such a trial. It probably makes sense to solve those two problems quickly in case it turns out that most countries in the world have flattened their curves by this fall to such an extent that vaccine trials are undoable. Regardless

of their feasibility, the ethics of doing such challenge studies are unclear and also require study.

Making doses of remdesivir and any other proven antiviral therapeutics available to such volunteers in challenge studies would provide an added level of safety. After all, the point of a vaccine is primarily to prevent an infection. Volunteers could be vaccinated, exposed to virus, and then tested every day or two to catch an infection early. Anyone infected can be started right away on a therapeutic, lowering the risks to volunteers and making such a trial ethically more acceptable.

THERAPEUTICS

Drugs can help infected people recover more quickly, with fewer symptoms and reduced chance of death. Safe and effective therapies to treat COVID-19 and its symptoms can help bridge the way to widely available vaccines (likely in late 2021). Understanding what kinds of treatments might be on the horizon can help prioritize resources and anticipate future challenges, directing efforts to help plug gaps in our collective COVID-19 response. Once we know what types of drugs are showing signs of working, we can redouble our efforts to find the best among them and the best ways to use them. Such incremental improvements have turned good older types of drugs into much better newer ones, as we've seen with blood pressure medications and insulins. This same kind of iterative, incremental innovation can be accelerated to address COVID-19 if we look a few moves ahead.

Our COVID-19 arsenal can be split into two general buckets: drugs that attack SARS-CoV-2 itself, either by preventing it from getting inside our cells or disrupting replication once it is in there; or drugs that prevent or limit the damage the virus can inflict, by protecting vital organs or properly calibrating our immune responses – prodding an underactive immune response or dampening an overactive one that is doing more harm than good.

Antivirals – Repurposed and Novel

The first generation of drugs being tested for COVID-19 are those that are already on the market or were being developed to treat other viral infections, such as flu or hepatitis C. Gilead's polymerase inhibitor remdesivir, originally developed to fight Ebola, has already been proven to work to some extent and now has Emergency Use Authorization for the treatment of hospitalized COVID-19 patients. We will likely know by June or July whether any other repurposed drugs are effective against COVID-19. Especially promising are oral polymerase inhibitors; they work in the same way as remdesivir but are more convenient. Some of them may even be easier to manufacture. The challenge with these drugs is twofold: they may differ in their ability to get to the lungs and the potency with which they work on SARS-CoV-2.

Behind these repurposed drugs are those specially developed to target SARS-CoV-2, most prominently monoclonal antibodies. Antibodies are similar to antibiotics and antivirals in that resistance is possible. If the virus' Spike protein mutates in the region that an antibody binds to, then the antibody may lose its ability to bind to the virus. Regeneron is developing a cocktail of antibodies, much like we use a cocktail of antivirals to manage HIV and cure hepatitis C. In case a virus has one mutation that prevents one antibody from binding, then the other antibodies in the cocktail will still neutralize the virus. But there are a number of companies that are, at least initially, only testing one antibody in the clinic. They should consider collaborating to create multi-antibody cocktails, similarly to how HIV pioneers created combination pills to treat HIV.

One challenge with all novel drugs is that making them at scale might turn out to be harder than proving that they work. As we have seen with remdesivir, initial supply must be rationed. It is important that the discovery or approval of an effective drug does not prompt an uncontrolled easing of social distancing. Premature celebrations or overconfidence will lead to more infections than our drug supply can accommodate.

Further complicating the question of supply is whether drugs that each are partially effective would be best used together or individually. If we have 250,000 courses each of remdesivir and a similarly effective

antibody, should we treat 500,000 people with one of the drugs or should we treat 250,000 people with both? Remdesivir is only about 30% effective in terms of shortening the time to discharge from the hospital and it appears to reduce the chance of dying by about the same. An antibody might offer similar efficacy alone, but together maybe they would 95% effective. We need to answer these questions with clinical trials to make sure we get the most benefit from our early batches of proven drugs. For example, that means making sure that remdesivir is available at hospitals that are studying therapeutic antibodies and that antibodies are tested at hospitals that have access to remdesivir.

Some groups are working on generating polyclonal antibodies in animals. But they need a SARS-CoV-2 vaccine with which to vaccinate the animals so that they develop antibodies. Yet vaccine companies are focused on making vaccines, not helping other groups generate polyclonal antibodies for therapy. Still, it would be ideal if some of the companies that have had success making batches of their vaccines could collaborate with groups developing polyclonal antibodies in cows and horses to see if those might be a source of therapeutic antibodies before monoclonal antibodies come to market. Realistically, those would be only a few months apart at this point, so if this work does not start right away, then we may as well wait for monoclonal antibodies, which will be in clinical testing in 3Q20 and could plausibly come to market in 4Q20, about the same time as the first low-scale vaccines and about four to six months before we estimate some of the large-scale vaccines become available.

Taming inflammation and Efficient Development Strategies

There are many drugs that could potentially mitigate the severe symptoms of COVID-19 by preventing a patient's immune system from overreacting and causing more harm than good (these drugs are typically used to treat rheumatoid arthritis and other autoimmune disorders and therefore are all being repurposed). The trouble with the immune system is that we really do not understand it well enough to calculate the odds of any one of these drugs working. It therefore makes sense that we are taking a "throw everything at the wall" approach to treating this cytokine storm. However, especially as we get the rate of infection under some control, we need to think carefully about how we test these drugs in the context of fewer severely ill patients. Repeatedly searching for the particular circumstances where any one drug might work, as we have seen the world do with hydroxychloroquine, a generic drug that initially seemed promising before failing in multiple studies, is inefficient.

It is critical to learn from early trials and accept when a drug does not seem to work. We should carefully allocate the finite supply of patients (at facilities that can run high-quality trials) to other drugs that might have a better chance of working. This is less of a problem with antiviral drugs since those can always be tested in milder patients. But drugs meant to treat severe disease will face enrollment constraints. Like a hundred cars trying to get through an intersection without a system, no one makes progress. But if we are systematic, we can avoid a traffic jam and test the most promising candidates as quickly as possible.

How we prioritize which drugs get tested when patients are in short supply is a key question. If one IL-6 inhibitor fails, we might argue that it makes sense to run one more IL-6 inhibitor trial because of how plausible it is to believe that this mechanism should work to rein in cytokine storm. But if that second one fails, then all IL-6 inhibitors should be deprioritized in favor of other approaches. We can work our way through the various categories laid out on the map systematically, instead of judging each drug by its own trial.

PLANNING FOR ACCESS

We hope you agree that it is inspiring to see how humanity has mustered its technological know-how in response to this crisis. We have long seen this level of ingenuity and determination applied to hundreds of other diseases that represent urgent unmet needs – our team has made over 100 maps spanning hundreds of disease areas covering thousands of companies and technologies. We are certainly heartened to see what science can do to ease human suffering, if we continue to invest in biomedical progress.

Today, COVID-19 is an urgent unmet need for all of us that has revealed the major gaps in America's healthcare system, particularly early in the crisis when insurance plans started to deny coverage of testing and care that the CDC was recommending. In response to outcries and recognizing that patients disregarding guidelines due to out of pocket costs was a threat to public health, insurance plans and the government have patched up some of those holes. Tests are now generally well covered and the federal government has vowed to cover the costs of care of millions of uninsured Americans. We now need to likewise secure affordable access future vaccines, drugs, and tests for the long run, beyond the current crisis.

We should also remember that cancer, diabetes, and countless other diseases are a personal COVID-like crisis for all those who suffer from them and their families. The reforms we consider for COVID-19 are the reforms we should consider for every disease and for all of healthcare. With proper insurance, biomedical innovation can offer America great value and remain affordable to each of us when we become patients in need of care.

RACAPITAL

NAVIGATING A TECHATLAS MAP

MOST TECHATLAS MAPS ARE STRUCTURED IN A SIMILAR WAY:

Start at the center to learn some of the basics about the disease and how the map is structured. In this case, we teach that the major goals are prevention and treatment. Then follow the branches outwards, a bit like a "choose your own adventure" story, to learn about different approaches to achieving each goal. We teach in the nodes what might make one approach better than another to guide your choice.

Similar technologies are grouped together. That allows us to spot when data from one program changes the probabilities of success for related programs.

At the end of each branch, you get to the specific programs.
IN THESE ENDNODES, YOU'LL FIND:

SPONSOR: The name of the company or companies (sometimes universities) working on the technology (i.e. drug/vaccine/test).

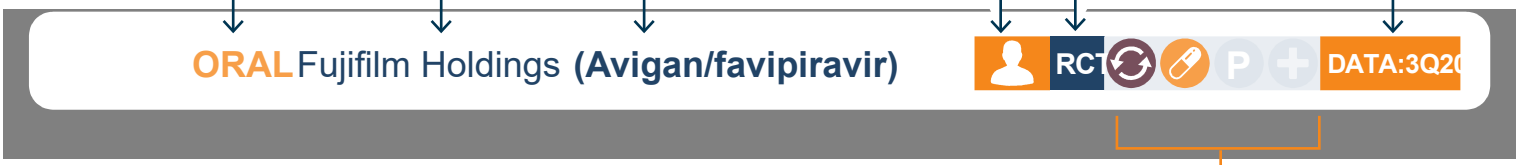
STAGE: Stage of development (in case of drugs, we use a mouse icon to indicate that it's still preclinical and a person icon to indicate that clinical studies have started).

TRIAL DESIGN:
If a clinical study has started, we indicate with "RCT" if the trial is randomized and controlled, which is important because uncontrolled trials are hard to interpret and learn from, so we're primarily focused on RCT data to know whether a drug really works.

ROUTE OF ADMINISTRATION:
Whether the drug is given orally, IV, or via some other way.

TECHNOLOGY NAME:
Some programs have special designations that their sponsors refer to.

DATA DATE:
When we expect to see data from a clinical study



FOR DRUGS:

REPURPOSED/NOVEL:
Some drugs were already available or in development to treat something else when COVID-19 struck and could be repurposed into testing for COVID-19 quickly. If the Repurposed icon is not illuminated, that means the drug is Novel, which means it likely will take longer to start clinical studies.

THERAPEUTIC vs PROPHYLAXIS:
We illuminate the corresponding icon to indicate whether a drug is being tested to treat infected patients or to prevent exposed people from becoming ill.

IN HOSPITAL OR POTENTIALLY OUT-PATIENT:
We illuminate an icon to teach whether a drug is likely to be limited to the hospital setting for various reasons or might be available at a pharmacy.

FOR VACCINES:

 # OF DOSES: Most vaccines will need to be given as a two-dose course (2D) but there is a chance that some might work with only one dose (1D).

GEOGRAPHY: Because some companies working on vaccines may prioritize their home regions (possibly because they are receiving grants from local agencies), we include a flag to indicate what region a company is based in. Where there are collaborations, we indicate the flags for each of the companies.

UPDATES:

With each update, we will highlight any changes since the previous update. This will include new programs being added, new Map structures being added, and updated Milestones.

THE MAP ALSO HAS MANY OTHER INFOGRAPHICS DESIGNED TO TEACH:

- how long it will take to develop vaccines and drugs,
- how quickly courses of various vaccines will become available,
- how COVID-19 progresses from the point of infection and when certain antibodies start showing up that diagnostic tests can detect,
- basic protective measures and how they work to flatten the curve,
- how the virus replicates and what that means for vaccine development.

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From: Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]
Sent: Wed 6/24/2020 3:35:19 PM (UTC-04:00)
Subject: Re: ACTIV Preclinical full working group

Wow!

Thanks!

From: Kara Carter <Kara.Carter@evotec.com>
Date: Wednesday, June 24, 2020 at 1:31 PM
To: "Menetski, Joseph (FNIH) [T]" <jmenetski@fnih.org>, "david.j.payne@gsk.com" <david.j.payne@gsk.com>, "Punturieri, Antonello (NIH/NHLBI) [E]" <punturieria@nhlbi.nih.gov>, "Fessel, Josh (NIH/NHLBI) [E]" <josh.fessel@nih.gov>, "Frank.Nestle@sanofi.com" <Frank.Nestle@sanofi.com>, "john.young.jy3@roche.com" <john.young.jy3@roche.com>, "Hild, Sheri (NIH/OD) [E]" <sheri.hild@nih.gov>, "fstegmeier@ksqtx.com" <fstegmeier@ksqtx.com>, "Annaliesa.Anderson@pfizer.com" <Annaliesa.Anderson@pfizer.com>, "jrappaport@tulane.edu" <jrappaport@tulane.edu>, "jay_grobler@merck.com" <jay_grobler@merck.com>, "ggatto@rti.org" <ggatto@rti.org>, "Baric, Ralph" <rbaric@email.unc.edu>, "prabha.fernandes@gmail.com" <prabha.fernandes@gmail.com>, "Ottinger, Elizabeth (NIH/NCATS [E]" <elizabeth.ottinger@nih.gov>, "Colvis, Christine (NIH/NCATS) [E]" <christine.colvis@nih.gov>, "Hewitt, Judith (NIH/NIAID) [E]" <jhewitt@niaid.nih.gov>, "Deming, Damon (FDA/CDER)" <damon.deming@fda.hhs.gov>, "diamond@wusm.wustl.edu" <diamond@wusm.wustl.edu>, "Cat.Lutz@jax.org" <Cat.Lutz@jax.org>, "Parker, Ashley (NIH/OD) [E]" <ashley.parker@nih.gov>, "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "ken.duncan@gatesfoundation.org" <ken.duncan@gatesfoundation.org>, "Adams, Peter (OS/ASPR/BARDA)" <Peter.Adams@hhs.gov>, "Rao, Srinivas" <Srinivas.Rao@sanofi.com>, "Qashu, Felicia (NIH/OD) [E]" <felicia.qashu@nih.gov>, Tomas Cihlar <Tomas.Cihlar@gilead.com>, "Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)" <margaret.l.pitt.civ@mail.mil>, "Charette, Marc (NIH/NHLBI) [E]" <marc.charette@nih.gov>
Cc: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Austin, Christopher (NIH/NCATS) [E]" <austinc@mail.nih.gov>, "Melencio, Cheryl (FNIH) [T]" <cmelencio@fnih.org>, "Desrosiers, Betsy" <elizabeth_desrosiers@merck.com>, "Hughes, Eric" <eric.hughes@novartis.com>, "Jansen, Kathrin" <kathrin.jansen@pfizer.com>, "Kurilla, Michael (NIH/NCATS) [E]" <michael.kurilla@nih.gov>, "Lowy, Douglas (NCI)" <dl60z@nih.gov>, "Read, Sarah (NIH/NIAID) [E]" <readsa@niaid.nih.gov>, "Tountas, Karen (FNIH) [T]" <ktountas@fnih.org>, "Santos, Michael (FNIH) [T]" <msantos@fnih.org>, "Adam, Stacey (FNIH) [T]" <sadam@fnih.org>, "James, Stephanie (FNIH) [T]" <sjames@fnih.org>, "Alvarez, Rosa Maria" <rosalvarez@deloitte.com>, "Kim, Elizabeth" <elkim@deloitte.com>, "Tolman, Brett"

<btolman@deloitte.com>, "Wachtel, Jonathan" <jwachtel@deloitte.com>, Prabhavathi Fernandes <prabha.fernandes@outlook.com>, "Diamond, Michael" <mdiamond@wustl.edu>, Rose Li <rose.li@roseliassociates.com>, Dana Carluccio <dana.carluccio@roseliassociates.com>, "Lagos, Enrique (NIH/NCATS) [E]" <enrique.lagos@nih.gov>, "Jonson, Samantha (NIH/NCATS) [E]" <samantha.jonson@nih.gov>, "Gonzalez, Nina" <ningonzalez@deloitte.com>, "Simon, Dina (NIH/OD) [C]" <dina.simon@nih.gov>, "Burrus-Shaw, Cyndi (NIH/OD) [E]" <cyndi.burrus-shaw@nih.gov>, "Rodriguez, Robin D" <rmdaigle@tulane.edu>, Dave Frankowski <david.frankowski@roseliassociates.com>, "Baric, Toni C" <antoinette_baric@med.unc.edu>, "Lowy, Douglas (NIH/NCI) [E]" <lowyd@mail.nih.gov>, "Florence, Clint (NIH/NIAID) [E]" <clint.florence@nih.gov>, Nancy Haigwood <haigwoon@ohsu.edu>, "Stratton, Benjamin" <bstratton@DELOITTE.com>, "Gadbois, Ellen (NIH/OD) [E]" <gadboisel@od.nih.gov>
Subject: RE: ACTIV Preclinical full working group

Dear All,

I just discovered this amazingly comprehensive overview of COVID-19, vaccine development and drug development. It will likely take you a while to go through it as it did me!

Enjoy,
Kara

evotec

Kara Carter, PhD
Executive Vice President Infectious Disease
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-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Tuesday, April 14, 2020 6:43 PM
To: Menetski, Joseph (FNIH) [T]; david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; Kara Carter; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Subject: ACTIV Preclinical full working group
When: Wednesday, June 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

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Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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+1 346 248 7799 US (Houston)
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Password: 124630
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To: Kara Carter[Kara.Carter@evotec.com]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; david.j.payne@gsk.com[david.j.payne@gsk.com]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; john.young.jy3@roche.com[john.young.jy3@roche.com]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Collins, Francis (NIH/OD) [E][collinsf@od.nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]
Cc: Wholley, David (FNIH) [T][dwholley@fnih.org]; Austin, Christopher (NIH/NCATS) [E][austinc@mail.nih.gov]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Desrosiers, Betsy[elizabeth_desrosiers@merck.com]; Hughes, Eric[eric.hughes@novartis.com]; Jansen, Kathrin[kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E][michael.kurilla@nih.gov]; Lowy, Douglas (NCI)[dl60z@nih.gov]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; James, Stephanie (FNIH) [T][sjames@fnih.org]; Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Kim, Elizabeth[elkim@deloitte.com]; Tolman, Brett[btolman@deloitte.com]; Wachtel, Jonathan[jwachtel@deloitte.com]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Diamond, Michael[mdiamond@wustl.edu]; Rose Li[rose.li@roseliassociates.com]; Dana Carluccio[dana.carluccio@roseliassociates.com]; Lagos, Enrique (NIH/NCATS) [E][enrique.lagos@nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Gonzalez, Nina[ningonzalez@deloitte.com]; Simon, Dina (NIH/OD) [C][dina.simon@nih.gov]; Burrus-Shaw, Cyndi (NIH/OD) [E][cyndi.burrus-shaw@nih.gov]; Rodriguez, Robin D[rmdaigle@tulane.edu]; Dave Frankowski[david.frankowski@roseliassociates.com]; Baric, Toni C[antoinette_baric@med.unc.edu]; Lowy, Douglas (NIH/NCI) [E][lowyd@mail.nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Nancy Haigwood[haigwoon@ohsu.edu]; Stratton, Benjamin[bstratton@DELOITTE.com]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]
From: Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]
Sent: Wed 6/24/2020 4:49:05 PM (UTC-04:00)
Subject: RE: ACTIV Preclinical full working group

Thank you Kara. I've put both documents in the Basecamp publications folder.

From: Kara Carter <Kara.Carter@evotec.com>
Sent: Wednesday, June 24, 2020 1:30 PM
To: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E] <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph <rbaric@email.unc.edu>; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Tomas Cihlar <Tomas.Cihlar@gilead.com>; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) <margaret.l.pitt.civ@mail.mil>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>
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Subject: RE: ACTIV Preclinical full working group

And the guide to reading the map….

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To: 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E] <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph <rbaric@email.unc.edu>; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Tomas Cihlar <Tomas.Cihlar@gilead.com>; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) <margaret.l.pitt.civ@mail.mil>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>
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Password: 124630
Find your local number: https://fnih.zoom.us/u/aemFGSQrl

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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 6/25/2020 12:23:34 AM (UTC-04:00)
Subject: Webex Invite-WHO-COM Call
Mail Attachment.ics
Webex_Meeting.ics

Dear all,

Please find below the agenda for today's call as well as the webex invite. See you all later.

Best

César, Simon and Bill.

Agenda WHO Animal Models Group Call, June 25th

1- Update on hACE2 mice: Taconic Farms

2- Nir Paran (IIBR)

3- Ricardo Carrion (TxBiomed)

4- Martin Beer (FLI)

5- Barry Rockx (Erasmus)

6- Hamster genomics resources (Bill Dowling)

7- Hamster genomic resources (David O'Connor)

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 908 3022
Meeting password: KmTxPWtT472

Thursday, June 25, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] WHO 18th TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=mc4e4de7fd9cabd737e92af3df4a34dfa
Start Time: 2020-06-25T15:00:00+02:00
End Time: 2020-06-25T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

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Start Time: 2020-06-25T15:00:00+02:00
End Time: 2020-06-25T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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To: Kara Carter[Kara.Carter@evotec.com]
Cc: Adam, Stacey (FNIH) [T][sadam@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Austin, Christopher (NIH/NCATS) [E][austinc@mail.nih.gov]; Baric, Ralph S[rbaric@email.unc.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Burrus-Shaw, Cyndi (NIH/OD) [E][cyndi.burrus-shaw@nih.gov]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Collins, Francis (NIH/OD) [E][collinsf@od.nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Dana Carluccio[dana.carluccio@roseliassociates.com]; Dave Frankowski[david.frankowski@roseliassociates.com]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Desrosiers, Betsy[elizabeth_desrosiers@merck.com]; Diamond, Michael[mdiamond@wustl.edu]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gonzalez, Nina[ningonzalez@deloitte.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; Hughes, Eric[eric.hughes@novartis.com]; James, Stephanie (FNIH) [T][sjames@fnih.org]; Jansen, Kathrin[kathrin.jansen@pfizer.com]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Kim, Elizabeth[elkim@deloitte.com]; Kurilla, Michael (NIH/NCATS) [E][michael.kurilla@nih.gov]; Lagos, Enrique (NIH/NCATS) [E][enrique.lagos@nih.gov]; Lowy, Douglas (NCI)[dl60z@nih.gov]; Lowy, Douglas (NIH/NCI) [E][lowyd@mail.nih.gov]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Nancy Haigwood[haigwoon@ohsu.edu]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Rodriguez, Robin D[rmdaigle@tulane.edu]; Rose Li[rose.li@roseliassociates.com]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Simon, Dina (NIH/OD) [C][dina.simon@nih.gov]; Stratton, Benjamin[bstratton@deloitte.com]; Tolman, Brett[btolman@deloitte.com]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Wachtel, Jonathan[jwachtel@deloitte.com]; Wholley, David (FNIH) [T][dwholley@fnih.org]; david.j.payne@gsk.com[david.j.payne@gsk.com]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; ggatto@rti.org[ggatto@rti.org]; jay_grobler@merck.com[jay_grobler@merck.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]
From: Young, John[john.young.jy3@roche.com]
Sent: Thur 6/25/2020 6:12:05 AM (UTC-04:00)
Subject: Re: ACTIV Preclinical full working group

Awesome. Thanks Kara!

On Wed, 24 Jun 2020 at 7:30 PM, Kara Carter <Kara.Carter@evotec.com> wrote:

And the guide to reading the map….

evotec

Kara Carter, PhD

Executive Vice President Infectious Disease

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From: Kara Carter
Sent: Wednesday, June 24, 2020 1:27 PM
To: 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Frank.Nestle@sanofi.com;

john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E] <sheri.hild@nih.gov>; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph <rbaric@email.unc.edu>; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Tomas Cihlar <Tomas.Cihlar@gilead.com>; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) <margaret.l.pitt.civ@mail.mil>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Austin, Christopher (NIH/NCATS) [E] <austinc@mail.nih.gov>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Desrosiers, Betsy <elizabeth_desrosiers@merck.com>; Hughes, Eric <eric.hughes@novartis.com>; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Kurilla, Michael (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas (NCI) <dl60z@nih.gov>; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Tountas, Karen (FNIH) [T] <ktountas@fnih.org>; Santos, Michael (FNIH) [T] <msantos@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; James, Stephanie (FNIH) [T] <sjames@fnih.org>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kim, Elizabeth <elkim@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes <prabha.fernandes@outlook.com>; Diamond, Michael <mdiamond@wustl.edu>; Rose Li <rose.li@roseliassociates.com>; Dana Carluccio <dana.carluccio@roseliassociates.com>; Lagos, Enrique (NIH/NCATS) [E] <enrique.lagos@nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Gonzalez, Nina <ningonzalez@deloitte.com>; Simon, Dina (NIH/OD) [C] <dina.simon@nih.gov>; Burrus-Shaw, Cyndi (NIH/OD) [E] <cyndi.burrus-shaw@nih.gov>; Rodriguez, Robin D <rmdaigle@tulane.edu>; Dave Frankowski <david.frankowski@roseliassociates.com>; Baric, Toni C <antoinette_baric@med.unc.edu>; Lowy, Douglas (NIH/NCI) [E] <lowyd@mail.nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Nancy Haigwood <haigwoon@ohsu.edu>; Stratton, Benjamin <bstratton@DELOITTE.com>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>
Subject: RE: ACTIV Preclinical full working group

Dear All,

I just discovered this amazingly comprehensive overview of COVID-19, vaccine development and drug development. It will likely take you a while to go through it as it did me!

Enjoy,

Kara

Kara Carter, PhD

Executive Vice President Infectious Disease

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-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Tuesday, April 14, 2020 6:43 PM
To: Menetski, Joseph (FNIH) [T]; david.j.payne@gsk.com; Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Frank.Nestle@sanofi.com; john.young.jy3@roche.com; Hild, Sheri (NIH/OD) [E]; fstegmeier@ksqtx.com; Annaliesa.Anderson@pfizer.com; jrappaport@tulane.edu; Kara Carter; jay_grobler@merck.com; ggatto@rti.org; Baric, Ralph; prabha.fernandes@gmail.com; Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); diamond@wusm.wustl.edu; Cat.Lutz@jax.org; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Subject: ACTIV Preclinical full working group
When: Wednesday, June 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

[EXTERNAL]

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Meeting ID: 960 4240 3854

Password: 124630

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+1 346 248 7799 US (Houston)

Meeting ID: 960 4240 3854

Password: 124630

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To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; david.j.payne@gsk.com[david.j.payne@gsk.com]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; john.young.jy3@roche.com[john.young.jy3@roche.com]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; kara.carter@evotec.com[kara.carter@evotec.com]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Diamond, Michael[mdiamond@wustl.edu]; Collins, Francis (NIH/OD) [E][collinsf@od.nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Nancy Haigwood[haigwoon@ohsu.edu]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; Chen, Helen Q.[qingchen@deloitte.com]
From: Alvarez, Rosa Maria[rosalvarez@deloitte.com]
Sent: Thur 6/25/2020 5:14:07 PM (UTC-04:00)
Subject: FW: ACTIV Therapeutics-Clinical Working Group Meeting
ACTIV Antivirals Candidates - Contacts Request.xlsx

Dear ACTIV Preclinical WG,

Please **see the email below** from the Tx- Clinical WG.

We need your help to identify contacts for antiviral candidate agents to solicit data survey submissions. Attached is a list of antiviral agents we've identified – It would be helpful if you could help us fill out the **names and emails of individuals who would be the best contacts for the agents.**

If possible, please provide any names/emails to Stacey Adam (sadam@fnih.org) and Helen Chen (qingchen@deloitte.com) by **noon ET tomorrow (6/26).**

Feel free to reach out if you have any questions.

Best,
Rosa

From: Chen, Helen Q.
Sent: Thursday, June 25, 2020 4:45 PM
To: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Draghia-Akli, Ruxandra <RDraghia@ITS.JNJ.com>; Garner, Carl <garner_carlos_o@lilly.com>; Stein, Peter (FDA/CDER) <Peter.Stein@fda.hhs.gov>; Bozzette, Sam (NIH/NCATS) [E] <sam.bozzette@nih.gov>; Butterton, Joan <joan_butterton@merck.com>; De Claro, R. Angelo (FDA/CDER) <romeo.declaro@fda.hhs.gov>; Eisner, Mark <eisner.mark@gene.com>; Gottesdiener, Keith <keith.gottesdiener@gmail.com>; Hughes, Eric <eric.hughes@novartis.com>; Judy Currier <jscurrier@mednet.ucla.edu>; Kim, Elizabeth <elkim@deloitte.com>; LaVange, Lisa <lisa.lavange@unc.edu>; Levy, Elliot <elliottl@amgen.com>; Mellors, John W <jwm1@pitt.edu>; Menon, Sandeep <Sandeep.M.Menon@pfizer.com>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Patel, Naimish <naimish.patel@sanofi.com>; Peppercorn, Amanda <amanda.f.peppercorn@gsk.com>; Poole, Mike <Mike.Poole@gatesfoundation.org>; Proschan, Michael (NIH/NIAID) [E] <proscham@niaid.nih.gov>; Read, Sarah (NIH/NIAID) [E] <readsa@niaid.nih.gov>; Santos, Michael (FNIH) [T] <msantos@fnih.org>; Shen, Yuan Li (FDA/CDER) <Yuan.Li.Shen@fda.hhs.gov>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Buchman, Tim (OS/ASPR/BARDA) (CTR) <Tim.Buchman@hhs.gov>; Collins, Sylva (FDA/CDER) <Sylva.Collins@fda.hhs.gov>; Amanda Peppercorn <amanda.peppercorn@gmail.com>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Koroshetz, Walter (NIH/NINDS) [E] <koroshetzw@ninds.nih.gov>; Timothy Burgess <timothy.burgess@usuhs.edu>; Reineck, Lora (NIH/NHLBI) [E] <lora.reineck@nih.gov>; Aggarwal, Neil (NIH/NHLBI) [E] <neil.aggarwal@nih.gov>; Rosenberg, Yves (NIH/NHLBI) [E] <rosenbey@nhlbi.nih.gov>; Goff, David (NIH/NHLBI) [E] <david.goff@nih.gov>; Brown, Jeremy (NIH/NINDS) [E] <jeremy.brown@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Jacqueline Kirchner <Jacqueline.Kirchner@gatesfoundation.org>; Beigel, John (NIH) [E] <jbeigel@niaid.nih.gov>
Cc: Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Desrosiers, Betsy <elizabeth_desrosiers@merck.com>; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Kurilla, Michael (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas (NCI)

<dl60z@nih.gov>; Young, John <john.young.jy3@roche.com>; Biggs, Mary <biggs.mary@gene.com>; Butcher, Tina <tina_butcher@merck.com>; Demarcus <demarcus@email.unc.edu>; Macone, Erin <erinm@amgen.com>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Salathin, Carla <carla.salathin@novartis.com>; Tountas, Karen (FNIH) [T] <ktountas@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; James, Stephanie (FNIH) [T] <sjames@fnih.org>; Wachtel, Jonathan <jwachtel@DELOITTE.com>; Tolman, Brett <btolman@deloitte.com>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; Dana Carluccio <dana.carluccio@roseliassociates.com>; Rose Li Central Account <FNIH@roseliassociates.com>; Anderson, Margaret <marganderson@deloitte.com>; Lucas Smalldon <Lucas.Smalldon@roseliassociates.com>; Stratton, Benjamin <bstratton@DELOITTE.com>; jennifer.j.palmer@pfizer.com; Mollica, Linda /US <Linda.Mollica@sanofi.com>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Patterson, Amy (NIH/NHLBI) [E] <amy.patterson@nih.gov>; Rubin, Daniel B. (FDA/CDER) <daniel.rubin@fda.hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Wung, Peter /US <Peter.Wung@sanofi.com>; Hoots, W. Keith (NIH/NHLBI) [E] <hootswk@nhlbi.nih.gov>; Groesch, Mary (NIH/NHLBI) [E] <mary.groesch@nih.gov>; Shipp, Allan (NIH/NHLBI) [E] <allan.shipp@nih.gov>; Kindzelski, Andrei (NIH/NHLBI) [E] <kindzelskial@nhlbi.nih.gov>
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical WG,

As mentioned during the meeting, our antivirals prioritization team is currently evaluating 11 candidates that have been submitted through the compound survey. In parallel, we would like to actively generate more survey submissions for our team to evaluate in early July.

To that end, **we need your help to identify contacts for additional candidate agents, from whom we will solicit survey submissions.** Please find attached a list of antiviral agents we've identified from public databases, as well as companies / academic institutes affiliated with those agents. Based on your network and industry knowledge, if you could help us fill out the **names and emails of individuals who would be the best contacts for the agents**, that would be much appreciated.

Please return the list to Stacey and me by noon ET tomorrow (6/26). This will allow sufficient time for the investigators to submit the compound survey in time for our next cycle of antiviral prioritization.

Feel free to reach out if you have any questions. Thank you very much!

Warm regards,
Helen

-----Original Appointment-----
From: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Draghia-Akli, Ruxandra; Garner, Carl; Stein, Peter (FDA/CDER); Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; jennifer.j.palmer@pfizer.com; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, June 25, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/94150866276?pwd=d2NCc1JQcmdPKzdQSkJ6RTVRYVVmQT09

Dear ACTIV TX-Clinical WG,

Please find attached the slides that we will use to update on the progress on the master protocols and antiviral prioritization in the last week.
We look forward to speaking with many of you tomorrow.

Kind regards,
Stacey

Join Zoom Meeting
https://fnih.zoom.us/j/94150866276?pwd=d2NCc1JQcmdPKzdQSkJ6RTVRYVVmQT09

Meeting ID: 941 5086 6276
Password: 169608
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Agent	Mechanism of Action	Requester Name	Requester Email	Requester Affiliation
4E2RCat	Eukaryotic translation initiation factor 4E (eIF4E)			UCSF
AIB-004	Viral RNA-dependent RNA polymerase			Ai-biopharma
Alferon LDO	Interferon alpha N3 agonist			AIM ImmunoTech
Aplidin	translation			PharmaMar, S.A.
ASC09	HIV protease inhibitor			Ascletis Pharma
ASC09 + ritonavir	protease			Johnson & Johnson
Atazanavir	HIV protease			Fiocruz/BMS
AT-H201	“chemical vaccine”			Atossa Therapeutics
Azithromycin	Ribosomal 50S subunit inhibitor			Multiple
Azvudine	reverse transcriptase inhibitor			Numerous trials with Chinese research sponsors
BCX4430	RNA directed RNA polymerase inhibitor			BioCryst Pharmaceuticals
Boceprevir, VICTRELIS	HCV protease inhibitor			Merck
Carrimycin	Protein 50S ribosomal subunit inhibitor			Shenyang Tonglian
Caspofungin acetate	1,3-Beta-glucan synthase inhibitor; Cell wall synthesis inhibitor			Merck
Chloramphenicol	Ribosomal 50S subunit inhibitor			Elan (Perrigo)
Clarithromycin	Protein 50S ribosomal subunit inhibitor			Abbott; Abbvie
Combination of ebastine, lopinavir, and interferon alpha	Inhibition of viral synthesis components			Multiple
CVL218	Poly(ADP-ribose) polymerase-1 (PARP-1)			Convalife
Dalbavancin	Cell wall synthesis inhibitor			Allergan, Pfizer
danoprevir	Serine protease inhibitor			Ascetis Pharma Inc
danoprevir + Ritonavir	Serine protease inhibitor			Roche
darunavir / cobicistat (Rezolsta) (Prezcobix)	HIV-1 protease inhibitor/ cytochrome P450 (CYP3A) inhibitor			Janssen-Cilag International N.V.
DAS181 (Fludase)	viral entry inhibitor			Ansun Biopharma
Ebselen,	SARS-CoV-2 protease inhibitor			Generic
ENU200	ORF1ab polyprotein inhibitor, SARS-CoV-2; surface glycoprotein (SARS-CoV-2) antagonist			Ennaid Therapeutics, Inc.
galidesivir	RNA directed RNA polymerage inhibitor			BioCryst Pharmaceuticals
Glecaprevir	HCV nonstructural protein 3 inhibitor HCV nonstructural protein 4A inhibitor			AbbVie
ISR-50				ISR Immune System Regulation
Kainos small molecule antivirals	Undisclosed			Kainos Medicine
Lamivudine (3TC)	Nucleoside reverse transcriptase inhibitor			Takeda/Pfizer/GSK
LB1148	Serine protease			Leading Biosceinces
Nelfinavir	protease inhibitor			Pfizer, GSK
NI007	Undisclosed SARS-CoV-2 antigen			Neurimmune; Ethris
Nitazoxanide	Pyruvate synthase inhibitor			Romark Laboratories
NKG2D-ACE2 CAR-NK	COV2 epitope			Chongqing Sidemu Biotechnology
Omacetaxine, SYNRIBO	Protein synthesis initiation inhibitor			Teva
Oritavancin	Cell wall synthesis inhibitor			The Medicines Company
Oseltamivir (Tamiflu)	neuraminidase inhibitor			Roche
PittCoVacc	SARS-CoV-2 spike protein (SARS-CoV-2 S)			University of Pittsburgh
posaconazole	Cell wall synthesis inhibitor; Sterol demethylase inhibitor			Ligand Pharmaceuticals
PS3061	SEC61 translocation subunit 1 (SEC61; SEC61A1)			UCSF
Remdesivir/GS-5734	Viral RNA-dependent RNA polymerase			Gilead Sciences
Ribavirin	Inosine monophosphate dehydrogenase inhibitor			Merck
SACT-COV19 (3 undisclosed repurposed drugs)	SARS-CoV-2 3CL-Protease; Viral RNA-dependent RNA polymerase; undisclosed			Aptorum / Covar
Simeprevir, Olysio	HCV nonstructural protein 3 inhibitor HCV nonstructural protein 4A inhibitor			Janssen Therapeutics
STI-4398	SARS-CoV-2 spike (SARS-Cov-2 S)			Sorrento Therapeutics
Telavancin (Vibative)	Cell wall synthesis inhibitor			Cumberland Pharmaceuticals
Tenofovir	Nucleotide reverse transcriptase inhibitor			Gilead Sciences
Tigecycline	Ribosomal 30S subunit			Pfizer
Truvada (emtricitabine and tenofovir)	both HIV-1 nucleoside analog reverse transcriptase inhibitors			Gilead
umifenovir (Arbidol)	neuraminidase			Multiple
Verdinexor	Exportin 1 (XPO1; CRM1)			UCSF
Vicromax, broad spectrum antiviral	broad spectrum antiviral			ViralClear Pharmaceuticals
Virazole (ribavirin for inhalation solution)	RNA-dependent RNA polymerase			Bausch Health
Xofluza (baloxavir marboxil)	polymerase acidic endonuclease inhibitor			Roche/The First Affiliated Hospital of Zhejiang University Medical School

From: DeStefano, Laura[LDestefano@nas.edu]

Location: RESCHEDULED due to holiday - please reply if you can attend

Importance: Normal

Subject: Canceled: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Start Time: Tue 6/30/2020 2:00:00 PM (UTC-04:00)

End Time: Tue 6/30/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; Baric, Ralph S; Baric, Toni C; 'Maria Jasen'; Chua, Peak Sen

Thanks to those of you who responded and held time on your calendars. We are canceling this instance and will follow up to seek feedback by email. Best wishes for an enjoyable holiday week.

To: Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; david.j.payne@gsk.com[david.j.payne@gsk.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; john.young.jy3@roche.com[john.young.jy3@roche.com]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; kara.carter@evotec.com[kara.carter@evotec.com]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Diamond, Michael[mdiamond@wustl.edu]; Collins, Francis (NIH/OD) [E][collinsf@od.nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Nancy Haigwood[haigwoon@ohsu.edu]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; Chen, Helen Q.[qingchen@deloitte.com]
From: Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]
Sent: Tue 6/30/2020 7:40:24 AM (UTC-04:00)
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting
STAT2 signaling as double-edged sword Syrian hamster model June 2020.pdf

All,

In case you have not seen the attached: Syrian Hamster as better model and, possibly even more relevant, type III IFN and not type I is the major player in restricting viral dissemination.

Tony

Antonello Punturieri, M.D., Ph.D.
Program Director, COPD and Environment Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
6705 Rockledge Drive, 403K MSC 7952
Bethesda, MD 20892
T 301-827-7844
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STAT2 signaling as double-edged sword restricting viral dissemination but driving severe pneumonia in SARS-CoV-2 infected hamsters

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Introductory paragraph

Since the emergence of SARS-CoV-2 causing COVID-19, the world is being shaken to its core with numerous hospitalizations and prospected hundreds of thousands of deaths. In search for key targets of effective therapeutics, robust animal models mimicking COVID-19 in humans are urgently needed. Here, we show that productive SARS-CoV-2 infection in the lungs of mice is limited and restricted by early type I interferon responses. In contrast, we show that Syrian hamsters are highly permissive to SARS-CoV-2. In wild-type hamsters, SARS-CoV-2 infection triggers bronchopneumonia and a strong inflammatory response in the lungs with neutrophil infiltration and edema. We further assess SARS-CoV-2-induced lung pathology in hamsters by micro-CT alike used in clinical practice. Finally, we identify an exuberant innate response as key player in immune pathogenesis, in which STAT2 signaling plays a double-edged role, driving severe lung injury on the one hand, yet restricting systemic virus dissemination on the other. Our results endorse hamsters as pre-clinical model to rationalize and assess the therapeutic benefit of new antivirals or immune modulators for the treatment of COVID-19 patients.

Keywords

SARS-CoV-2 (2019-nCoV), COVID-19, animal models, pneumonia, innate immunity, STAT2, IL28R, type I and III interferons, immune pathogenesis, micro-CT

Introduction and Results

SARS-CoV-2 (formerly 2019-nCoV) belongs to the family of Coronaviruses, which contains a large group of viruses that are constantly circulating in animals and humans. Illness in humans caused by coronaviruses is mostly mild and manifested by respiratory or digestive problems as leading symptoms[1]. However, some coronaviruses, such as SARS-CoV-1, MERS-CoV and the recent SARS-CoV-2, have been responsible for serious outbreaks of severe and lethal respiratory disease[2,3]. Unlike the previous outbreaks with SARS-CoV-1 and MERS-CoV, the current SARS-CoV-2 outbreak has undeniably evolved to the largest global health threat to humanity in this century.

The unprecedented scale and rapidity of the current pandemic urges the development of efficient vaccines, antiviral and anti-inflammatory drugs. A key step in expediting this process is to have animal models that recapitulate and allow to understand viral pathogenesis, and that can in particular be used to preclinically assess preventive and therapeutic countermeasures.

Acute respiratory disease caused by SARS-CoV-1 and MERS infections is characterized by a dysregulated inflammatory response in which a delayed type I interferon (IFN) response promotes the

accumulation of inflammatory monocyte-macrophages[4–6]. The severe lung disease in COVID-19 patients seems to result from a similar overshooting inflammatory response. However, because even non-human primates do not fully replicate COVID-19, little information and no appropriate animal models are currently available to address this hypothesis[7].

To address this knowledge gap, we compared the effect of SARS-CoV-2 infection in wild-type (WT) mice of different lineages (BALB/c and C57BL/6) and Syrian hamsters, as well as a panel of matched transgenic mouse and hamster strains with a knockout (KO) of key components of adaptive and innate immunity. We used an original patient isolate of SARS-CoV-2 (BetaCoV/Belgium/GHB-03021/2020) that was passaged on HuH7 and Vero-E6 cells (Fig. S1 and Fig. S2A). For full characterization and to exclude possible contaminants, we performed deep sequencing on the inoculum that was used to infect the animals (Fig. S2A). No adventitious agents could be detected (data not shown). However, two in-frame deletions in the N-terminal domain and the furin-cleavage site of Spike (S) glycoprotein (9aa and 5aa, respectively) had occurred between cell culture passage P4 and P6[8–10], likely as adaptation to growth in Vero-E6 cells *in vitro* (Fig. S2B).

To first examine whether adaptive immunity contributed to the susceptibility to SARS-CoV-2 infection, we inoculated WT (immune-competent) and SCID mice (lacking functional T and B cells) from the same BALB/c background intranasally with a high 2×10^5 $TCID_{50}$ viral dose (P4 virus) (Fig. 1A). On day 3 p.i., a viral RNA peak in the lungs was observed (Fig. 1B and Fig. S3) with no obvious differences in viral loads (Fig. 1B) nor lung pathology (Fig. 1D and Fig. S4A and S4B) between WT and SCID mice. These data indicate that mice that lack the human ACE2 receptor[11], can in principle be infected with SARS-CoV-2, although inefficiently and likely transiently, as also observed for SARS-CoV-1[4,12]. However, adaptive immunity did not markedly contribute to this low susceptibility.

Interferons are prototypic first-line innate immune mechanisms on viral infections. To evaluate interferons, we compared viral RNA levels and lung pathology in WT C57BL/6 mice, and C57BL/6 mice with a genetic ablation of their type I (*Ifnar1*$^{-/-}$) and III interferon (IFN) receptors (*Il28r*$^{-/-}$) (Fig. 1A). *Ifnar1*$^{-/-}$ mice showed a slightly, but significantly enhanced replication of SARS-CoV-2 in the lung on day 3 p.i. compared to both WT and *Il28r*$^{-/-}$ mice (Fig. 1C). Similar to BALB/c mice, overall viral loads were low. Likewise, *Ifnar1*$^{-/-}$ mice that were treated with human convalescent SARS-CoV-2 patient serum (HCS) prior to infection (Fig. 1E) had a one log_{10} reduction in viral loads, down to the residual input RNA levels observed in mice inoculated with inactivated SARS-CoV-2 (Fig. 1C). This provides further evidence for active, although inefficient virus replication.

WT and knockout mouse strains, all on C57BL/6 background, presented consistently with only a mild lung pathology. However, *Ifnar1*$^{-/-}$ mice showed increased levels of intra-alveolar hemorrhage,

sometimes accompanied by some peribronchiolar inflammation (Fig. 1D and Fig. S4A and S4B). Passive transfer of HCS did not result in an obvious improvement in histopathological scores (Fig. S4C), in line with other studies about partial protection from SARS-CoV-2 infection[13,14] and virus-induced inflammatory responses. Further evidence for true infection and hence viral replication is provided by transcriptomic analysis (Sharma, S. *et al.*, in press[15]) of infected lung tissues (Fig. 1F and Fig. S5), revealing (i) an upregulation of classically enriched ($p<0.001$) antiviral effector molecules[16] such as *cGAS*, *Mx1*, *IFIH1/MDA-5*, *IRF3*, *OAS1*, *OAS3* and *PKR/EIF2AK2* (Fig. S5, Cluster 1) and (ii) downregulation of upstream regulators *STAT1*, *STAT3* and *STING/TMEM173* (Suppl Fig. S5, Cluster 3) as shown previously[17]. Likewise, HCS treatment modulated, at least to some extent, the observed gene expression patterns (Fig. 1F and Fig. S5, Cluster 2) as shown by decreasing *Akt1* ($p=0.034$) or increasing *DDX58* (*RIG-I*, $p=0.028$) and *cGAS* (*MB21D1*, $p=0.094$) mRNA levels. In summary, our data are in line with restriction of SARS-CoV-2 infection by the interferon system in mice, and that the inflammatory response correlates with an increased virus replication. However, due to the limited virus replication, mice were considered as a poor model to study COVID-19 pathogenesis, or to assess the efficacy of vaccines and treatments.

In contrast, Syrian hamsters have been reported to be highly susceptible to SARS-CoV-1[18] and SARS-CoV-2[19] and might thus provide a small animal model to study SARS-CoV-induced pathogenicity and the involvement of the immune response in aggravating lung disease. We compared virus replication levels and lung pathology in WT hamsters and hamsters with ablated *Signal Transducer and Activator of Transcription 2* (*STAT2*$^{-/-}$ lacking type I and III IFN signaling)[20,21] and IL28R expression (*IL28R-a*$^{-/-}$ lacking IFN type III signaling) (Fig. 2A). In contrast to mice, intranasal inoculation of SARS-CoV-2 in WT hamsters resulted in high viral RNA loads (Fig. 2B and Fig. S6) and infectious titers (Fig. 2C) in the lungs. Also, a marked lung pathology [median cumulative score (MCS) 9 out of maximal score of 18; IQR=8.5-10.5 (P4 virus)] characterized by a multifocal necrotizing bronchiolitis, massive leukocyte infiltration and edema (Fig. 2D and Fig. S7A and S7B). This resembles histopathological findings in humans suffering from severe bronchopneumonia[22].

For many respiratory viruses, including SARS-CoV-1, type I and III interferon signaling has been described to play an important role in restricting infection[23]. No marked differences were observed in viral RNA levels in the lung of WT, *STAT2*$^{-/-}$ or *IL28R-a*$^{-/-}$ hamsters (Fig. 2B). However, *STAT2*$^{-/-}$ hamsters had higher titers of infectious virus in the lung (Fig. 2C), high titer viremia[24] (Fig. 2E) and high levels of viral RNA in the spleen, liver and upper and lower gastrointestinal tract[25] (Fig. 2F) in comparison with WT and *IL28R-a*$^{-/-}$ hamsters. Together, these data suggest STAT2 is critical for restricting SARS-CoV-2 systemic spread and suppressing viral replication outside of the lung compartment. Inversely, the observed lung pathology was much attenuated in *STAT2*$^{-/-}$ hamsters [MCS=3; IQR=1.5-3 (P4 virus)] with a limited infiltration of polymorphonuclear leukocytes

correlated with the detection of few apoptotic bodies in the bronchus walls (Fig. 2D and Fig. S7B). On the contrary, *IL28R-a*$^{-/-}$ hamsters showed clear signs of bronchopneumonia and peribronchiolar inflammation, yet of an intermediate score [MCS=7; IQR=6.5-7 (P4 virus)] (Fig. 2D and Fig. S7B). Matrix metalloprotease (MMP)-9 levels, which may serve as a sensitive marker for the infiltration and activation of neutrophils in inflamed tissues[26,27], were markedly elevated in the lungs of all infected hamsters (Fig. 2G). However, higher MMP-9 levels were found in *STAT2*$^{-/-}$ animals, thereby inversely correlating with the histological findings (Fig. 2D). In addition, biomarkers elevated in critically ill COVID-19 patients[2,28,29] such as the cytokines IL-6, IL-10 and IFN-γ were not found to be markedly elevated in the serum of infected hamsters (Fig. S8B). Nonetheless, infected *STAT2*$^{-/-}$ and *IL28R-a*$^{-/-}$ had clearly increased levels of IL-6 and IL-10 in their lungs (Fig. S8A). Such an inverse correlation between biomarkers and pathology in WT versus *STAT2*$^{-/-}$ hamsters is in line with findings in mouse models of SARS-CoV-1 infection in which pathology correlated with the induction and dysregulation of alternatively activated "wound-healing" monocytes/macrophages[4,6].

The lack of readily accessible serum markers or the absence of overt disease symptoms in hamsters prompted us to establish a non-invasive means to score for lung infection and SARS-CoV-2 induced lung disease by computed tomography (CT) as used in standard patient care to aid COVID-19 diagnosis with high sensitivity and monitor progression/recovery[28–31]. Similar as in humans[32], semi-quantitative lung pathology scores were obtained from high-resolution chest micro-CT scans of free-breathing animals[33]. Manifest consolidations were present in SARS-CoV-2 infected WT and *IL28R-a*$^{-/-}$ hamsters, but not in *STAT2*$^{-/-}$ hamsters (Fig. 3A-B and Fig. S9A). In the upper airways, no differences were observed between WT and STAT2$^{-/-}$ hamsters, whereas IL28R-a$^{-/-}$ hamsters presented with an obvious dilation of bronchi (Fig. 3A and 3C). Further quantitative analysis[34] revealed an increase of the non-aerated lung volume in SARS-CoV-2-infected WT and *IL28R-a*$^{-/-}$ hamsters, yet again not in *STAT2*$^{-/-}$ hamsters (Fig. 3D, Fig. S9B). Hence apart from lung consolidations and airway dilation as the main observed pathology, marked differences in other micro-CT-derived markers of specific lung pathology, such as hyperinflation, emphysema, or atelectasis[34,35] could not be observed, except in one animal that presented with hyperinflation (Fig. S9C and Fig. S10A-C). A matched comparison of the micro-CT-derived lung scores and viral loads in the lungs showed that, in line with our previous results, type I IFN responses downstream of STAT2 signaling drive lung pathology, yet has minor impact on viral replication in the lungs (Fig. 3E). Together, these data fully support micro-CT as a convenient adjunct to histological scoring (Fig. 2D and Fig. S9D) to visualize and quantify SARS-CoV-2-induced lung injury in the hamster model. Moreover, it may allow to monitor the impact of therapeutic measures non-invasively during disease progression.

Discussion

The development of efficient therapeutic interventions against SARS-CoV-2 asks for relevant small animal models that mimic the different clinical manifestations of COVID-19 and that provide fundamental mechanistic insight in the underlying pathology/pathogenesis. Transgenic mice expressing *hACE2,* the *bona fide* receptor of SARS-CoV-1 and SARS-CoV-2[36], have been suggested as COVID-19 model. We here demonstrate that also WT mice are susceptible to SARS-CoV-2 infection, yet resulting in very limited viral replication and inflammatory responses. Ablation of type I interferon signaling in *Ifnar*$^{-/-}$ mice results in the same small incremental 10-fold increase in viral replication as was reported for SARS-CoV-2 in *hACE2* transgenic mice[36,37]. Most likely, neither mouse model will fully recapitulate pathogenesis of COVID-19, nor allow the study of clinical SARS-CoV-2 isolates.

By contrast, SARS-CoV-2 infection and associated pathology in hamsters seems to resemble what has been reported for SARS-CoV-1 in the same model. An early peak of active virus replication was noted in the lungs with viremia and extra-pulmonary spread. This was accompanied by a strong acute inflammatory response[18] (as visualized by histopathology), the levels of which were correlated with those of MMP-9, a clinically relevant biomarker. Furthermore, micro-CT as established in this study may become a key instrument to non-invasively and quantitatively monitor SARS-CoV-2 lung disease. This will allow to conveniently monitor the effect of therapeutic strategies and test the preclinical efficacy of vaccine candidates.

By using unique knock-out hamster lines, we demonstrated that *STAT2* plays a critical role in mediating antiviral responses and restricting systemic dissemination of SARS-CoV-2. This is in line with the effect of *STAT1* in a mouse model of SARS-CoV-1 infection[38]. However and much in contrast to what is generally observed for viral infections in *Stat2*$^{-/-}$ mice[39] or *STAT2*$^{-/-}$ hamsters[21,40,41], the severe pathology induced by SARS-CoV-2 in WT hamsters is not observed in the absence of *STAT2.* Indeed, pneumonia as assessed by sensitive micro-CT was absent in *STAT2*$^{-/-}$ hamsters. Considering the negative regulation of IL-6 and other mediators of inflammation by STAT2[39,42], our hamster model may help to understand the immune pathogenesis of Acute Lung Injury (ALI) caused by highly-pathogenic coronaviruses[18,23,43] as well as other respiratory viruses[4].

The increase in replication of SARS-CoV-2 seen in *IL28R-a*$^{-/-}$ hamsters, on one hand, combined with a tempered inflammatory response and lung injury as compared to WT hamsters, on the other hand, is in line with the role of type III IFN plays during respiratory virus infections, including SARS-CoV-1[44]. This observation also suggests that in humans pegylated IFN-lambda[45,46] (or similar modulators of

innate immunity) may possibly be considered to protect medical staff and other frontline workers from SARS-CoV-2 infection or to dampen symptoms in critically ill patients[47].

In conclusion, hamsters may be a preferred above mice as infection model for the preclinical assessment of antiviral therapies, of convalescent serum transfer and of approaches that aim at tempering the COVID-19 immune pathogenesis in critically ill patients[48,49]. The latter may be achieved by repurposing anti-inflammatory drugs such as IL-6 receptor antagonists (e.g. Tocilizumab)[50], or small molecule Jak/STAT inhibitors (e.g. Ruxolitinib or Tofacitinib). Educated by our finding that STAT2 signaling plays a dual role in also limiting viral dissemination, targeting the virus-induced cytokine response and overshooting of macrophage activation may need to be complemented by (directly acting) antivirals[51].

Methods

Animals

Wild-type Syrian hamsters (*Mesocricetus auratus*) were purchased from Janvier Laboratories. All other mouse (C57BL/6, *Ifnar1*$^{-/-}$, *Il28r*$^{-/-}$, BALB/c and SCID) and hamster (*STAT2*$^{-/-}$ and *IL28R-a*$^{-/-}$) strains were bred in-house. Six- to eight-weeks-old female mice and wild-type hamsters were used throughout the study. Knock-out hamsters were used upon availability; seven- to twelve-week old female *STAT2*$^{-/-}$ hamsters; five- to seven-week-old *IL28R-a*$^{-/-}$ hamsters.

Ifnar1$^{-/-}$ mouse breeding couples were a generous gift of Dr. Claude Libert, IRC/VIB, University of Ghent, Belgium. *Il28r*$^{-/-}$ mice [C57B/6N-A<tm1Brd> Ifnlr1<tm1a(EUCOMM)Wtsi>/Wtsi, strain ID: EM:07988] were provided by the Wellcome Trust Sanger Institute Mouse Genetics Project (Sanger MGP)[52].

STAT2$^{-/-}$ and *IL28R-a*$^{-/-}$ hamsters were generated by CRISPR/Cas-mediated gene targeting. To ablate *STAT2* (Gene ID: 101830537) expression, a 1-nt frameshift mutation was introduced in exon 4 resulting in multiple premature stop codons[20]; to ablate *IL28R* (*IFNLR1;* Gene ID: 101833778) expression, a 22-nucleotides deletion was introduced in exon 2 resulting in multiple premature stop codons in the original open reading frame.

Animals were housed individually (hamsters) or per 5 (mice) in individually ventilated isolator cages (IsoCage N Biocontainment System, Tecniplast) with access to food and water *ad libitum*, and cage enrichment (cotton and cardboard play tunnels for mice, wood block for hamsters). Housing conditions and experimental procedures were approved by the ethical committee of KU Leuven (license P015-2020), following institutional guidelines approved by the Federation of European Laboratory Animal Science Associations (FELASA). Animals were euthanized by 100µl (mice) or 500µl (hamsters) of intraperitoneally administered Dolethal (200mg/ml sodium pentobarbital, Vétoquinol SA).

Prior to infection, the animals were anesthetized by intraperitoneal injection of a xylazine (16 mg/kg, XYL-M®, V.M.D.), ketamine (40 mg/kg, Nimatek, EuroVet) and atropine (0.2 mg/kg, Sterop) solution. Each animal was inoculated intranasally by gently adding 50µl droplets of virus stock containing 2×10^5 $TCID_{50}$ (P4 virus) or 2×10^6 $TCID_{50}$ (P6 virus) on both nostrils.

Cells, virus and sera

Vero-E6 (African green monkey kidney) and HuH7 (human hepatoma) cells were maintained in minimal essential medium (Gibco) supplemented with 10% fetal bovine serum (Integro), 1% bicarbonate (Gibco), and 1% L-glutamine (Gibco). All assays involving virus growth were performed using 2% fetal bovine serum instead of 10%.

SARS-CoV-2 strain BetaCov/Belgium/GHB-03021/2020 (EPI ISL 407976|2020-02-03) recovered from a nasopharyngeal swab taken from a RT-qPCR-confirmed asymptomatic patient returning from Wuhan, China beginning of February 2020[53] was directly sequenced on a MinION platform (Oxford Nanopore) as described previously[54]. Phylogenetic analysis confirmed a close relation with the prototypic Wuhan-Hu-1 2019-nCoV (GenBank accession number MN908947.3) strain. Infectious virus was isolated by serial passaging on HuH7 and Vero-E6 cells (see Figure S1). Virus used for animal experiments was from passages P4 and P6. Prior to inoculation of animals, virus stocks were confirmed to be free of mycoplasma (PlasmoTest, InvivoGen) and other adventitious agents by deep sequencing on a MiSeq platform (Illumina) following an established metagenomics pipeline[55,56]. The infectious content of virus stocks was determined by titration on Vero-E6 cells by the Spearman-Kärber method. All virus-related work was conducted in the high-containment BSL3+ facilities of the KU Leuven Rega Institute (3CAPS) under licenses AMV 30112018 SBB 219 2018 0892 and AMV 23102017 SBB 219 2017 0589 according to institutional guidelines.

Matched human convalescent serum (HCS) was donated from the same patient under informed consent.

RNA extraction and RT-qPCR

Animals were euthanized at different time-points post-infection, organs were removed and lungs were homogenized manually using a pestle and a 12-fold excess of cell culture medium (DMEM/2%FCS). RNA extraction was performed from homogenate of 4 mg of lung tissue with RNeasy Mini Kit (Qiagen), or 50µl of serum using the NucleoSpin kit (Macherey-Nagel), according to the manufacturer's instructions. Other organs were collected in RNALater (Qiagen) and homogenized in a bead mill (Precellys) prior to extraction. Of 100µl eluate, 4µl was used as template in RT-qPCR reactions. RT-qPCR was performed on a LightCycler96 platform (Roche) using the iTaq Universal Probes One-Step RT-qPCR kit (BioRad) with primers and probes (Table S1) specific for SARS-CoV-2, mouse β-actin and hamster β-actin (IDT). For each data point, qPCR reactions were carried out in duplicate. Standards of SARS-CoV-2 cDNA (IDT) and infectious virus were used to express the

amount of RNA as normalized viral genome equivalent (vge) copies per mg tissue, or as $TCID_{50}$ equivalents per mL serum, respectively. The mean of housekeeping gene β-actin was used for normalization. The relative fold change was calculated using the $2^{-\Delta\Delta Ct}$ method[57].

Quantification of SARS-CoV-2 infectious particles in lung tissues

After extensive transcardial perfusion with PBS, lungs were collected, extensively homogenized using manual disruption (Precellys24) in minimal essential medium (5% w/v) and centrifuged (12,000 rpm, 10min, 4°C) to pellet the cell debris. Infectious SARS-CoV-2 particles were quantified by means of endpoint titrations on confluent Vero-E6 cell cultures. Viral titers were calculated by the Spearman-Kärber method and expressed as the 50% tissue culture infectious dose ($TCID_{50}$) per 100mg tissue.

Differential gene expression and bioinformatics analysis

To study differential gene expression, RNA was extracted from lung tissues using Triazol, subjected to cDNA synthesis (High Capacity cDNA Reverse Transcription Kit, Thermo Fisher Scientific), and qPCR using a custom Taqman qRT-PCR array (Thermo Fisher Scientific) of 30 genes known to be activated in response to virus infection[15], as well as two housekeeping genes (Table S2). Data collected were analysed using the Quant Studio Design and Analysis (version 1.5.1) and Data Assist software (version 3.01, Thermo Fischer Scientific). Pathway, GO (Gene Ontology) and transcription factor target enrichment analysis was performed using GSEA (Gene Set Enrichment Analysis, Molecular Signatures Database (MSigDB), Broad Institute). Principal component analysis, correlation matrices, unsupervised hierarchical clustering (Eucledian distance) were performed using XLSTAT and visualized using MORPHEUS (https://software.broadinstitute.org/morpheus) as described previously[58].

Histology

For histological examination, the lungs were fixed overnight in 4% formaldehyde and embedded in paraffin. Tissue sections (4 µm) were stained with hematoxylin and eosin to visualize and score for lung damage.

Tissue and serum biomarker analysis

Cytokine levels in lung homogenates and serum of hamsters were determined by ELISA for IFN-γ (EHA0005), IL-6 (EHA0008) and IL-10 (EHA0006) following the manufacturer's instructions (Wuhan Fine Biotech Co., Ltd).

The levels of gelatinase B/metalloproteinase (MMP)-9 present in lung homogenates were analyzed using gelatin zymography[59], essentially as described previously[60]. For quantification of zymolytic bands internal control samples were spiked into each sample. Equivalent hamster enzyme

concentrations were calculated with the use of known amounts of recombinant human pro-MMP-9 and recombinant human pro-MMP-9ΔOGHem as standards[61].

Micro-computed tomography (CT) and image analysis

Hamsters were anaesthetized using isoflurane (Iso-Vet) (2-3% in oxygen) and installed in prone position into the X-cube micro-CT scanner (Molecubes) using a dedicated imaging bed. Respiration was monitored throughout. A scout view was acquired and the lung was selected for a non-gated, helical CT acquisition using the High-Resolution CT protocol, with the following parameters: 50kVp, 960 exposures, 32 ms/projection, 350 µA tube current, rotation time 120 s. Data were reconstructed using a regularized statistical (iterative) image reconstruction algorithm using non-negative least squares[62], using an isotropic 100 µm voxel size and scaled to Hounsfield Units (HUs) after calibration against a standard air/water phantom. The spatial resolution of the reconstruction was estimated at 200µm by minimizing the mean squared error between the 3D reconstruction of the densest rod in a micro-CT multiple density rod phantom (Smart Scientific) summed in the axial direction and a digital phantom consisting of a 2D disk of 17.5mm radius that was post-smoothed with Gaussian kernels using different full width half maxima (FWHM), after aligning the symmetry axis of the rod to the z-axis.

Visualization and quantification of reconstructed micro-CT data was performed with DataViewer and CTan software (Bruker micro-CT). As primary outcome parameter, a semi-quantitative scoring of micro-CT data was performed as previously described[33,34,63] with minor modifications towards optimization for COVID-19 lung disease in hamsters. In brief, visual observations were scored (from 0 – 2 depending on severity, both for parenchymal and airway disease) on 5 different, predefined transversal tomographic sections throughout the entire lung image for both lung and airway disease by two independent observers (L.S. and G.V.V.) and averaged. Scores for the 5 sections were summed up to obtain a score from 0 to 10 reflecting severity of lung and airway abnormalities compared to scans of healthy, WT control hamsters. As secondary measures, image-derived biomarkers (non-aerated lung volume, aerated lung volume, total lung volume, the respective densities within these volumes and large airways volume) were quantified as in[33,63] for a manually delineated VOI in the lung, avoiding the heart and main blood vessels. The threshold used to separate the airways and aerated (0-55) from non-aerated lung volume (56-255) was set manually on a 8-bit greyscale histogram and kept constant for all data sets.

Statistical analysis

GraphPad Prism (GraphPad Software, Inc.) was used for all statistical evaluations. The number of animals and independent experiments that were performed is indicated in the legends to figures. Statistical significance was determined using the non-parametric Mann Whitney U-test. Values were considered significantly different at P values of ≤ 0.05.

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Author Contributions

R.B., H.J.T. J.N. and K.D. designed experiments;

R.B., S.J.F.K, R.L., V.V., C.D.K., S.S., E.M., L.B., T.V.B., J.M. and W.C. carried out experiments;

R.B., H.J.T., L.S., S.J., J.V.W., E.M., B.W., C.C., G.V.V., Z.W. and K.D. analyzed data;

L.D., J.R.P., J.M., G.S., K.V.L., G.O. and P.M. provided advice on the interpretation of data;

R.B., H.J.T., and K.D wrote the original draft with input from co-authors;

R.B., H.J.T., L.S., J.V.W., C.C., G.V.V., J.N. and K.D. wrote the final draft;

R.L., Y.L., Z.W., and M.V.R. provided essential reagents;

H.E., D.S., and P.L. provided and facilitated access to essential infrastructure;

H.J.T., J.N. and K.D. supervised the study;

K.D., L.C., P.L. and J.N. acquired funding;

All authors approved the final manuscript.

Declaration of Interests

The authors declare no competing interests.

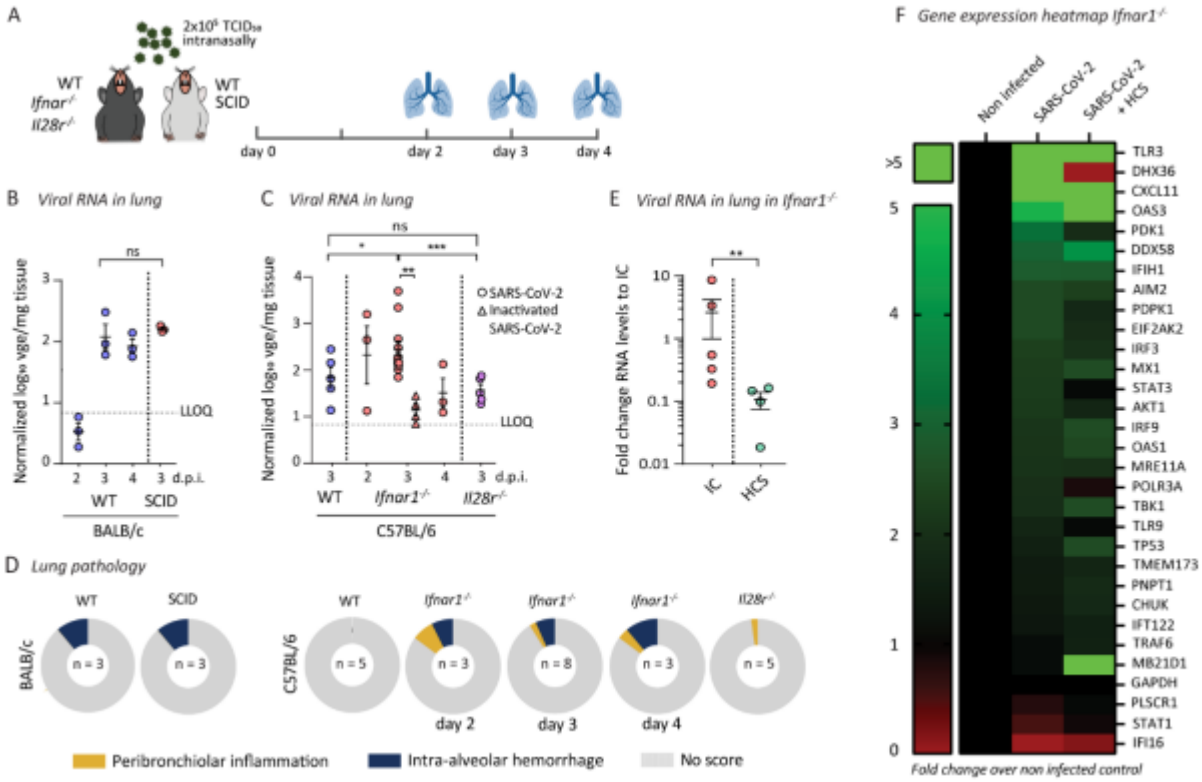

Figure 1. Type I interferon signaling restricts infection of the lungs of mice. (**A**) Schematic representation of SARS-CoV-2 inoculation schedule. Several wild-type (WT) and knock-out mouse strains were intranasally inoculated with 2×10^5 $TCID_{50}$ of passage 4 (P4) SARS-CoV-2. Convalescent serum treatment was given intraperitoneally (i.p.) 1 day prior to inoculation. On the indicated days post inoculation (d.p.i.), lungs were collected for determination of viral RNA levels and scored for lung damage. (**B-C**) Normalized viral RNA levels in the lungs of BALB/c WT and SCID mice and C57BL/6 WT, *Ifnar1*$^{-/-}$ and *Il28r*$^{-/-}$ mice. At the indicated time intervals p.i., viral RNA levels were determined by RT-qPCR, normalized against β-actin mRNA levels and transformed to estimate viral genome equivalents (vge) content per weight of the lungs (Figure S2). For heat-inactivation, SARS-CoV-2 was incubated for 30min at 56°C. Dotted line indicates lower limit of quantification (LLOQ). (**D**) Histopathological scoring of lungs for all different mouse strains. Mice were sacrificed on day 3 p.i. and lungs were stained with H&E and scored for signs of lung damage (inflammation and hemorrhage). Scores are calculated as percentage of the total maximal score. "No score" means not contributing to theoretical full cumulative score of 100%. Numbers (n) of animals analyzed per condition are given in the inner circle (**E**) Viral RNA levels in *Ifnar1*$^{-/-}$ mice after treatment with anti-SARS-CoV2 sera. Mice were either left untreated (IC, infection control) or treated with HCS (human convalescent serum) and sacrificed on day 3 p.i. Viral RNA levels were determined in the lungs, normalized against β-actin and fold-changes were calculated using the $2^{(-\Delta\Delta Cq)}$ method compared to mean of IC. The data shown are means ± SEM. (**F**) Heatmap showing gene expression profiles of 30 selected marker genes in the lungs of uninfected (n=3) and infected *Ifnar1*$^{-/-}$ mice that were either left untreated (n=5) or treated with HCS (n=4). The scale represents fold change compared to non-infected animals. Statistical significance between groups was calculated by the nonparametric Mann-Whitney U-test (ns $P > 0.05$, * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$).

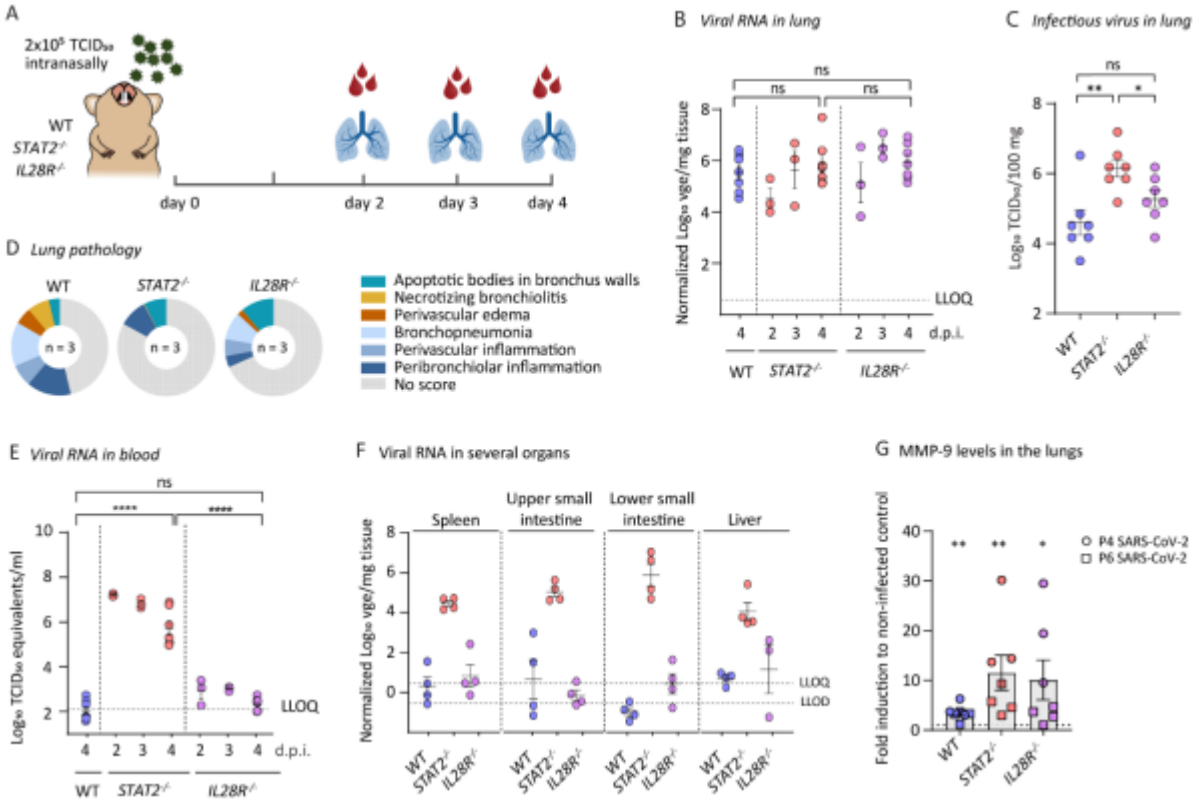

Figure 2. Exuberant innate response by *STAT2* drives SARS-CoV-2-induced lung pathology in hamsters. (A) Schematic representation of SARS-CoV-2 inoculation schedule. WT, *STAT2*$^{-/-}$ and *IL28R-a*$^{-/-}$ hamster strains were intranasally inoculated with 2×10^5 $TCID_{50}$ of passage 4 or 2×10^6 of passage 6 SARS-CoV-2. On the indicated days post inoculation (d.p.i.), organs and blood were collected to determine viral RNA levels, infectious virus load and score for lung damage. Viral loads in the indicated organs were quantified by RT-qPCR **(B, E and F)** or virus titration **(C)**. **(B,F)** Viral RNA levels in the indicated organs were normalized against β-actin mRNA levels and transformed to estimate viral genome equivalents (vge) content per weight of the lungs (Figure S5)**. (C)** Infectious virus loads in the lung are expressed as the number of infectious virus particles per 100 mg of lung tissue. **(E)** Viral RNA levels in the blood were calculated from a standard of infectious virus and expressed as $TCID_{50}$ equivalents per ml blood. Dotted lines indicate lower limit of quantification (LLOQ) or lower limit of detection (LLOD) **(D)** Histopathological scoring of lungs. Hamsters were sacrificed on day 4 p.i. with passage 4 SARS-CoV-2 and lungs were stained with H&E and scored for signs of lung damage (apoptotic bodies, necrotizing bronchiolitis, edema, pneumonia and inflammation). Scores are calculated as percentage of the total maximal score. **(G)** Levels of matrix metalloproteinase (MMP)-9 levels in lung homogenates of SARS-CoV-2 infected hamsters, relative to non-infected controls of the same strain. Values for infected animals (n=7 each) compiled from two independent experiments using either P4 (n=3, circles) and P6 (n=4, squares) SARS-CoV-2. Statistical significance was calculated between infected and non-infected animals within each group. The data shown are mean ± SEM. Statistical significance between groups was calculated by the nonparametric Mann-Whitney U-test (ns $P > 0.05$, * $P < 0.05$, ** $P < 0.01$, **** $P < 0.0001$).

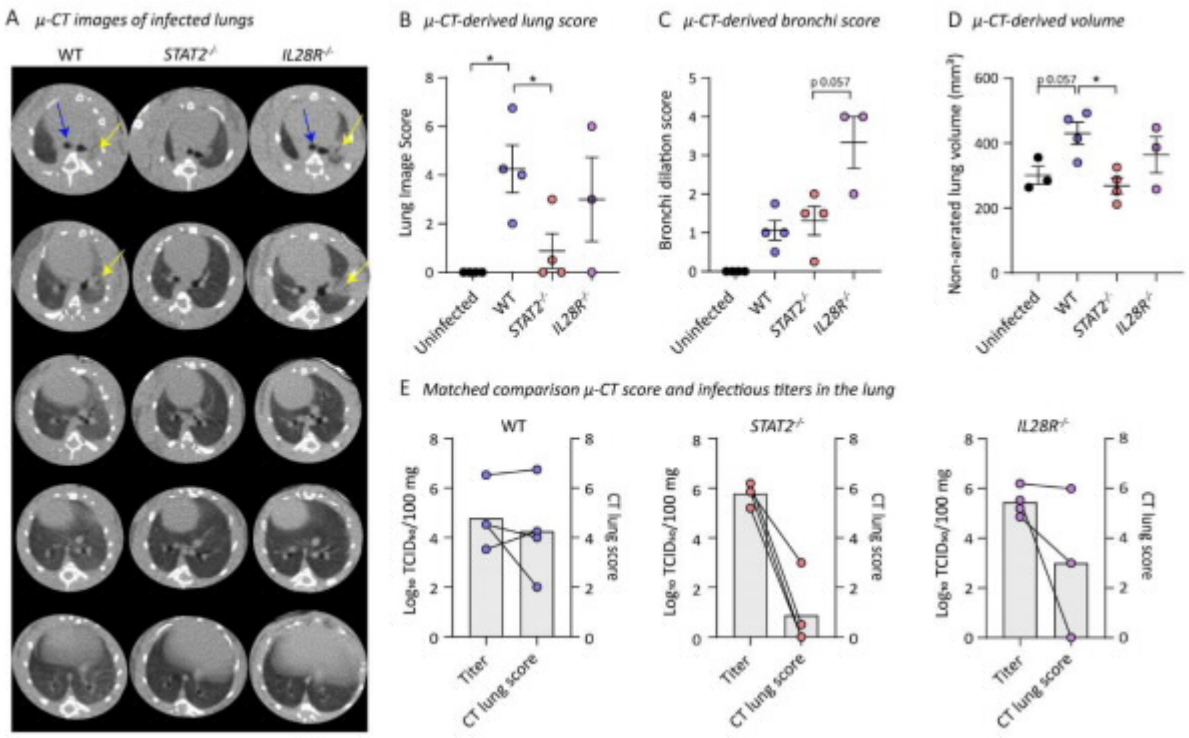

Figure 3. Micro-CT reveals severe lung injury in hamsters. (A) Representative transversal micro-CT images of infected (P6 SARS-CoV-2) WT, *STAT2*$^{-/-}$ and *IL28R-a*$^{-/-}$ hamster lungs at 4 d.p.i. (n=4 each). Arrows indicate examples of pulmonary infiltrates seen as consolidation of lung parenchyma (yellow) or dilatation of upper airways (blue). Five transverse cross sections at different positions in the lung were selected for each animal and scored to quantify lung consolidations **(B)** or dilatation of the bronchi **(C)**. **(D)** Quantification of the micro-CT-derived non-aerated lung volume biomarker, reflecting the volume consolidations in the lungs. **(E)** Matched comparison between micro-CT-derived lung scores **(B)** and infectious virus load in the lung (Fig. 2C). Lines indicate matched samples. The data shown are mean ± SEM. Statistical significance between groups was calculated by the nonparametric Mann Whitney U-test (ns $P > 0.05$, * $P < 0.05$).

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From: Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]
Sent: Wed 7/1/2020 11:39:02 AM (UTC-04:00)
Subject: Re: ACTIV Preclinical full working group
2020.06.20.137687v1.full.pdf

All –

U PITT's pre-print in YOUNG AGMs utilizes the Munich strain which I believe has the D614 mutant.

In their hands, they didn't report any dramatic increase in pathogenesis with the assays they implemented.

Might be of benefit in the EXE meeting tonight.

Just an FYI.

Clint

From: jmenetski@fnih.org
When: 10:00 AM - 11:00 AM July 1, 2020
Subject: ACTIV Preclinical full working group
Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Meeting ID: 960 4240 3854
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- +1 646 876 9923 US (New York)
- +1 408 638 0968 US (San Jose)
- +1 669 900 6833 US (San Jose)
- +1 253 215 8782 US (Tacoma)
- +1 346 248 7799 US (Houston)

Meeting ID: 960 4240 3854
Password: 124630
Find your local number: https://fnih.zoom.us/u/aemFGSQrl

Title: SARS-CoV-2 infection of African green monkeys results in mild respiratory disease discernible by PET/CT imaging and prolonged shedding of infectious virus from both respiratory and gastrointestinal tracts

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Abstract: Vaccines are urgently needed to combat the global coronavirus disease 2019 (COVID-19) pandemic, and testing of candidate vaccines in an appropriate non-human primate (NHP) model is a critical step in the process. Infection of African green monkeys (AGM) with a low passage human isolate of SARS-CoV-2 by aerosol or mucosal exposure resulted in mild clinical infection with a transient decrease in lung tidal volume. Imaging with human clinical-

grade ^{18}F-fluoro-2-deoxy-D-glucose positron emission tomography (^{18}F-FDG PET) co-registered with computed tomography (CT) revealed pulmonary lesions at 4 days post-infection (dpi) that resolved over time. Infectious virus was shed from both respiratory and gastrointestinal (GI) tracts in all animals in a biphasic manner, first between 2-7 dpi followed by a recrudescence at 14-21 dpi. Viral RNA (vRNA) was found throughout both respiratory and gastrointestinal systems at necropsy with higher levels of vRNA found within the GI tract tissues. All animals seroconverted simultaneously for IgM and IgG, which has also been documented in human COVID-19 cases. Young AGM represent an excellent species to study mild/subclinical COVID-19 disease and have shed light on unknown aspects of long-term virus shedding. They are ideally suited for preclinical evaluation of candidate vaccines and therapeutic interventions.

One Sentence Summary: Subclinical infection of African green monkeys infected with SARS-CoV-2 results in prolonged shedding of infectious virus from both respiratory and gastrointestinal tracts.

Main Text: The unprecedented and rapidly spreading coronavirus disease 2019 (COVID-19) pandemic caused by the emerging coronavirus SARS-CoV-2 calls for swift testing of vaccine candidates prior to initiation of human clinical trials. Safety must be prioritized over speed when considering a vaccine that will likely be administered to hundreds of millions of people. Non-human primates (NHPs) serve a unique and important purpose for pre-clinical testing of candidate human vaccines, given their close genetic relatedness with humans. As such, studies in NHPs are geared towards identifying the most appropriate species that recapitulates human disease. Comprehensive dissection of the longitudinal viral pathogenesis in NHP models is critical for successful evaluation of the efficacy of vaccines, antibody therapeutics, and small molecules in pre-clinical studies.

Several NHP models have been reported with SARS-CoV-2 using rhesus and/or cynomolgus macaques and African green monkeys (AGMs) (*1-4*). While used less frequently in biomedical research than rhesus or cynomolgus macaques, AGMs are an old-world NHP species and a natural host for simian immunodeficiency virus (SIV) (*5*). In addition to SIV, AGMs have been used as models for infectious diseases such as Rift Valley fever, pneumonic plague, human parainfluenza virus, SARS-CoV-1, and Nipah virus (*6-10*). To fully understand the pathogenesis

of human isolates of SARS-CoV-2 in AGM, it is critical to determine if there are differences between aerosol and mucosal exposure routes, to assess whether clinical-grade imaging of NHPs can be used to detect subclinical infections, and to understand the real-time dynamics of virus shedding.

Young adult male AGMs were infected with a low-passage clinical isolate of SARS-CoV-2 and comprehensive longitudinal disease parameters were compared after either small particle aerosol or multi-route mucosal/intratracheal infection. All AGMs developed mild disease regardless of the route of exposure or infectious dose. Pulmonary lesions were detectable by PET/CT in the acute phase and subsequently resolved. All AGMs exhibited prolonged shedding of infectious virus from oral, nasal, conjunctival, and rectal mucosal surfaces. Viral RNA (vRNA) remained detectable throughout both the respiratory and GI tissues at necropsy in the absence of replication-competent virus. These results show multiple routes are involved in viral shedding and that shedding occurs over a protracted period of time in subclinical animals, both of which will greatly impact SARS-CoV-2 transmission from COVID-19 patients.

Results: Infection of young AGMs with SARS-CoV-2 resulted in mild respiratory disease. Healthy male AGMs (~3.5 years of age) were infected with passage 3 (P3) of a human isolate of SARS-CoV-2 from Munich, Germany (Table S1)(*11*). Four animals were infected using a small particle aerosol (designated A1-A4) and two were infected by a multi-route mucosal exposure (designated M1, M2) involving administration of virus into the oral, nasal, and ocular mucosal surfaces and intratracheal instillation using a bronchoscope. Aerosol inhaled exposure doses ranged from 3.7–4.2 $\log_{10}$ pfu of virus due to the standard ~2 log loss of virus after nebulization. Multi-route mucosal exposures were 6.4 $\log_{10}$ pfu. After infection, animals were anesthetized for blood draws, mucosal swabs, plethysmography, and chest radiography at regular intervals post-infection.

Clinical disease was mild in all six animals (Fig. S1A). Respiratory function revealed a transient decrease in the volume of air inhaled, or tidal volume, at 7 dpi (Fig. S1B), while other parameters including frequency and expiratory time were within normal limits. In the two mucosally infected AGM and in one aerosol infected AGM, there were several short spikes of fever (maximum deviation 2.4-3.4 $^{\circ}$C) during the course of infection (Fig. S2). For these three animals, the average significant elevation in temperature was less than 1 $^{\circ}$C for either route of

infection, suggesting an overall low-grade fever. The other three aerosol-infected AGMs, A1-A3, developed mild hypothermia response around 5-7 dpi that persisted for most of the remainder of the study (Fig. S2). Complete blood counts (CBC) revealed a transient decrease in lymphocytes and platelets and an increase in neutrophils (Fig. S1); this is also seen in human COVID-19 patients (*12, 13*). Blood chemistry analysis demonstrated decreases in amylase and blood urea nitrogen (BUN) and no elevation in liver enzyme levels (Fig. S3).

SARS-CoV-2 infected AGMs shed infectious virus from respiratory and gastrointestinal tracts. Virus isolations and q-RT-PCR analysis were performed for oral, rectal, nasal, and conjunctival swab samples obtained over the course of the infection. SARS-CoV-2 isolations were confirmed using indirect immunofluorescence using an anti-spike antibody (Fig. 1A). Syncytia were present *in vitro* isolations, particularly at the later time points (e.g. 21 dpi). Replicating virus was detected in all nasal and oral swabs from all animals on 2 and 4 dpi (Fig. 1B). On 2 dpi, 5/6 rectal swabs and 2/6 ocular swabs were positive for infectious virus. All swabs were broadly negative from all animals at 11 dpi. However, there was a resurgence in the presence of replication competent virus on 14 and 21 dpi in samples from the respiratory and GI tracts (Fig. 1A and B). q-RT-PCR results confirmed the virus isolation results, with a peak in vRNA detection in oral, nasal and conjunctival swabs between 2-7 dpi and a second spike in rectal samples 21 dpi (Fig 1C-F). There was consistent detection of vRNA through 28 dpi although at the stage infectious virus was not isolated from either swabs or necropsy tissues.

Pulmonary infection in SARS-CoV-2 infected AGM was detected by PET/CT imaging. Molecular imaging using positron emission tomography (PET) with the radiotracer ^{18}F-FDG provides a sensitive measurement of metabolic activity within specific anatomical compart ments. When co-registered with computed tomography (CT), PET/CT can provide detailed anatomic structure overlaid with areas of high metabolic activity revealed by the tracer. FDG-based PET/CT has been used in NHPs for measurement of lung granulomas caused by infection with *Mycobacteria tuberculosis* (*14-19*). To determine whether lung infection with SARS-CoV-2 could be visualized using FDG-mediated PET/CT or CT alone, imaging was performed pre-infection, 4 dpi, and 11 dpi for most animals. To quantify overall disease burden in the lungs at the various time points, a disease-associated total lung FDG activity level was calculated to

measure the total lung inflammation. Analysis of the maximum SUVs in thoracic lymph nodes (LNs) was also conducted.

Both mucosally-infected animals and one of the aerosol animals (A4) had significant lung inflammation at 4 dpi based on FDG uptake; these lesions resolved by 11 dpi (Fig. 2A). The LNs in these three animals also showed the highest FDG uptake at 4 dpi, while all 6 AGM had substantial FDG uptake in the LNs at either 4 or 11 dpi (Fig. 2B). Overall, the extent of disease visualized within the lungs of infected AGMs was modest at all the time points examined (Figs. S4,S5). At 4 dpi, aerosol-infected animal A4 developed areas of disease with a pneumonia appearance in the anterior portions of the accessory lobe and left lower lobe as well as pleural ground glass opacities in the anterior portions of the right and left middle lobes (Fig. 2C). These lesions were resolving by 11 dpi. Peak uptake in the thoracic lymph nodes of this animal was seen at 4 dpi (Fig. 2B). AGM M1 was infected via mucosal exposure and had the most extensive lung disease of all AGMs based on PET imaging. Lesions consisted of diffuse ground glass opacities with corresponding high FDG uptake in the left lower and right upper lobes (Fig. 2D). These areas resolved by day 11, but a new focal area of disease was present that day (cyan arrow; Fig. 2D). Chest radiographs were taken on all longitudinal sampling days. Only animal M1 had detectable radiographic abnormalities with mild non-specific infiltrates present in the left lower lobe at 2 and 4 dpi that were resolving by 7 dpi (Fig S6).

Synchronous seroconversion in SARS-CoV-2-infected AGM. In order to evaluate the kinetics of seroconversion, serial plasma samples from each SARS-CoV-2 infected AGM were assayed for antibodies against the SARS-CoV-2 spike protein receptor binding domain (RBD) using an indirect ELISA (Fig. 3A). All animals generated both IgM and IgG antibodies against SARS-CoV-2. Notably, there was simultaneous seroconversion of both IgM and IgG. This contradicts the classic immunology paradigm of IgM proceeding IgG in response to antigen exposure, however this mirrors precisely what occurs in COVID-19 patients (*20-23*), further validating the utility of this AGM model. All animals seroconverted in the second week post exposure and those that were exposed via the mucosal route had higher overall titers than those that received the virus via the aerosol route. This could reflect the fact that mucosal infected animals received a higher challenge dose than aerosol infected animals. Neutralization of SARS-CoV-2 was measured in matched samples using a plaque-reduction neutralization-80% test ($PRNT_{80}$) (Fig. 3B). Neutralizing

antibodies were present in samples collected 7-11 dpi. There were no differences in kinetics or activity between the two exposure routes demonstrating that higher dose received during multi-route mucosal infection neither affected the onset nor strength of the humoral immune response.

Cytokinemia and immune activation over time revealed early response to viral infection. PBMC were isolated from whole blood and stained for flow cytometry using either a myeloid or lymphoid panel (Table S2; Figs. S7,S8). The proportions of proliferating (Ki-67+) CD4 and CD8 T cells increased transiently between 2-11 dpi in most animals (Fig. S9). Unlike in the aerosol infection, there were sustained increases in proliferating CD8 T cells in the mucosally-infected animals (Fig. S9D) which is similar to what occurs in human COVID-19 patients (*12, 13*). NK cell frequencies varied over the course of the experiment as did the mean fluorescence intensity (MFI) of CD16 on NK cells with no clear pattern emerging (Fig. S9E,F). This is relevant since COVID-19 patients with severe, but not moderate, disease demonstrated decreased CD16 MFI on NK cells (*12*). Most notably, an increased frequency of $CD20^{lo}$ B cells was noted in all animals in the second week of infection, accompanied by increased expression of Ki-67 in these cells, which is consisted with a plasmablast phenotype (Fig. S9H,I). In comparison, $CD20^{hi}$ B cells saw no increase in Ki-67. An NHP-specific multiplex cytokine and chemokine assay was used to measure the levels of 30 analytes in longitudinal plasma samples. The majority of cytokines, including IFN-α, IFN-γ, IL-6, and TNF- α, were undetectable in all animals at all time points tested. For the cytokines that were detectable, most AGMs had early transient peaks in expression of MCP-1, IL-1RA, IP-10, and ITAC at 2 dpi (Fig. S11), indicative of a general response to viral infection. Peak plasmablast frequency (Fig. S9H) and B lymphocyte chemoattractant (BLC) expression (Fig. S11E) coincided with the appearance of virus specific antibodies (Fig. 3).

SARS-CoV-2 vRNA was detected throughout respiratory and gastrointestinal tract at necropsy. Upon euthanasia of each animal at 28 dpi (35 dpi for A1 and A2), full necropsies were performed and tissues were tested by qRT-PCR for levels of vRNA (Fig. 4). vRNA was widespread throughout the upper and lower respiratory tracts including the soft palate and nasal turbinates. The overall levels of vRNA detected were comparable between the two exposure routes and doses, indicating that the 100-fold higher infectious dose that the mucosally infected animals received did not translate into higher levels of tissue vRNA at necropsy. More vRNA was detected

along the entire gastrointestinal (GI) tract compared to the lower and upper respiratory tracts, highlighting differential tropism of SARS-CoV-2. vRNA was detected in 5/6 olfactory bulbs but was largely absent from the cortex and cerebellum of most animals. The heart, liver, spleen, and kidney were largely devoid of vRNA. Virus isolation attempts on lung and gastrointestinal tissue obtained at necropsy were unsuccessful.

Residual histopathology detected at necropsy. Since the AGMs were euthanized at 28 or 35 dpi, tissue specimens for acute histopathology were not obtained. However, lung samples and lymph nodes from animals known to be positive by PET/CT were taken at necropsy and examined by a board-certified veterinary pathologist. Importantly, even 4-5 weeks after infection, several animals demonstrated multiple pulmonary foci of interstitial infiltration and expansion by either lymphocytic or mixed inflammatory infiltrates (Fig. 5). While not a specific diagnostic finding, this is a common pathological effect of many pneumotropic viruses and is also consistent with the convalescent stage of a respiratory infection. Interestingly, multiple syncytiated cells were observed in the germinal follicles of Peyer's patches from two animals (Fig 5B). Given the frequent propensity of coronaviruses, including SARS-CoV-1, to lead to fused cells *in vitro*, our observation that isolated virus from the AGMs form syncytia in Vero-E6 cells (Fig. 1A) and the observation of multinucleated syncytial cells in human cases of disease (*24, 25*), this finding is likely a viral cytopathic effect. Moreover, the Peyer's patches from 5 out of 6 AGMs contained some of the highest levels of vRNA (Fig. 4).

Discussion: AGMs were used as a non-human primate model for SARS-CoV-1 infection after the 2003 epidemic. Compared to rhesus macaques, AGMs supported enhanced SARS-CoV-1 virus replication and developed more severe lung pathology (*10, 26*). They are also an excellent species to model other respiratory diseases such as pneumonic plague and human parainfluenza virus (*7, 9*). In this study, COVID-19 disease in young AGMs was mild, reflecting what frequently occurs in young, healthy humans infected with SARS-CoV-2 (*27, 28*). Low-grade fever was observed and respiratory symptoms were limited to a transient decrease in tidal volume. Advanced imaging using a metabolic PET probe permitted visualization of pulmonary lesions undetectable by other modalities such as standard chest radiographs. PET/CT is used clinically in managing COVID-19 patients and is effective at visualizing lesions in asymptomatic patients (*29, 30*). It is notable that

the three AGM (A4, M1, M2) that had the most febrile responses also had the highest level of inflammation in the lungs and lymph nodes as detected by PET/CT. PET/CT imaging was also performed in crab-eating macaques infected intra-tracheally with SARS-CoV-2 (*31*). Disease in the macaques was mild/subclinical, and PET/CT scans showed areas of pneumonia and consolidation that were FDG avid. The importance of these studies lies in demonstrating that PET/CT imaging can be used to bridge human animal data, particularly with respect to determining reductions in disease burden following vaccination or therapeutic interventions.

A key finding here was that virus isolations followed by immunofluorescence confirmation demonstrated unequivocally that infectious virus was shed from the respiratory and GI early followed by a recrudescence around 14-21 dpi. The majority of *in vivo* SARS-CoV-2 studies use vRNA detection as a surrogate for infectious virus. The biphasic shedding pattern was unexpected and highlights the need to study longer term infection in animal models. vRNA was still detectable at substantial levels throughout the entire GI tract at 4-5 weeks after infection, and GI titers were 10-100-fold higher than what was found throughout the upper and lower respiratory tracts. This demonstrates the tropism of SARS-CoV-2 for intestinal tissues and the importance of GI replication in the viral pathogenesis. Transmission of SARS-CoV-1 through fecal matter contributed to super-spreader events during the 2003 outbreak (*32, 33*), and the mechanism underlying this remains largely unexplored. For SARS-CoV-2, vRNA and infectious virus has been detected in feces of COVID-19 patients with or without GI symptoms (*34-36*). The AGM model will allow an understanding of how SARS-CoV-2 is shed from the GI tract and potentially transmitted via feces.

In a recent study with cynomolgus macaques, SARS-CoV-2 infection was mild to subclinical even in aged animals, shedding of vRNA from mucosal surfaces was limited to early time points, and vRNA at necropsy was largely limited to respiratory tissues (*1*). A preprint study in rhesus macaques showed transient clinical disease marked by brief fever right after infection, transient weight loss, mild respiratory depression, and pulmonary infiltrates by chest radiograph (*2*). Upon necropsy, vRNA was found primarily in the lungs and upper respiratory tract and not in the GI tract. Another preprint study in rhesus macaques found similar limited disease with shedding of vRNA and infiltrates by chest radiograph (*3*).

The current consensus regardless of NHP species or viral isolates is that infection with SARS-CoV-2 leads to mild or subclinical infection, with shedding of virus from the respiratory

tract. Severe disease or lethality has been rarely seen after either mucosal or aerosol exposure. One distinguishing feature of the AGM model appears to be tropism of virus for tissues throughout the entire gastrointestinal tract, as we found here, including substantial shedding of infectious virus. A key finding from this study was the repeated isolation of infectious virus over time from mucosal swabs including the rectum. This is critically important for the fundamental understanding of both COVID-19 disease and person-to-person transmission.

The SARS-CoV-2-specific immune responses occurred in the second week of infection. The concurrent detection of both IgM and IgG against the receptor binding domain of the spike protein by ELISA coincided with the appearance of a neutralizing antibody response. Mucosally-infected animals had higher ELISA titers than aerosol exposed animals and increased levels of the B cell chemokine CXCL-13 in the plasma during the first week preceding the seroconversion. Plasmablasts peaked in all infected animals on 10 dpi. While a greater magnitude of B cell response seen in mucosal animals could have been secondary to higher inoculum dose, it could also reflect exposure route of which could have implications for optimal immunization. Virus specific T cell responses were not assessed directly. However, proliferation of both CD4 and CD8 T cells, as evidenced by Ki-67 staining, occurred in all animals in the first two weeks of infection. These data are analogous to what occurs in humans with moderate COVID-19 disease (*12, 13*).

The source of NHP used in pathogenesis and efficacy studies can play an important role in clinical outcome, and thus clear explanation of the source of animals and genetic background for future studies is important. The AGMs used in our study were from the Vervet Research Colony at Wake Forest University. The colony founders were 57 wild-caught animals from St. Kitts in the 1970's (*37, 38*). The animals used here were all male and all ~3.5 years of age (age range is 25-35 years in captivity), making them young and around the age of sexual maturity. Future studies should consider using older animals and/or those directly imported from St. Kitts. Particularly relevant to the COVID-19 pandemic is that AGM from the West Indies spontaneously develop hypertension without dietary intervention or inbreeding (*39*). Moreover, they naturally develop type II diabetes and atherosclerosis, making them an excellent species to study pathogenesis of SARS-CoV-2 under conditions representative of the comorbidities associated with severe COVID-19 in humans (*40, 41*). Increasing age, genetic variability, and spontaneous hypertension, diabetes, and cardiovascular disease may lead to more severe outcomes in AGMs when infected with SARS-CoV-2, and thus may more accurately reflect the variation seen in the human population.

In summary, we comprehensively evaluated the pathogenesis of SARS-CoV-2 in the AGM model. Our study suggests that AGMs are excellent models for many aspects of COVID-19 in humans: 1) young healthy AGMs may represent subclinical or mild human disease, 2) consistent shedding of infectious virus from respiratory and GI tracts in the absence of overt disease allows experimental understanding of the mechanisms underlying tissue tropism and transmission, and 3) PET/CT imaging modalities are effective at detecting SARS-CoV-2 infection. Critical vaccine trials could use the AGM model to measure virus shedding and/or lung lesions by PET/CT after post-vaccination challenge as measures of vaccine efficacy.

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Supplementary Materials:

Materials and Methods

Figures S1-S11

Tables S1-S2

References (*1-6*)

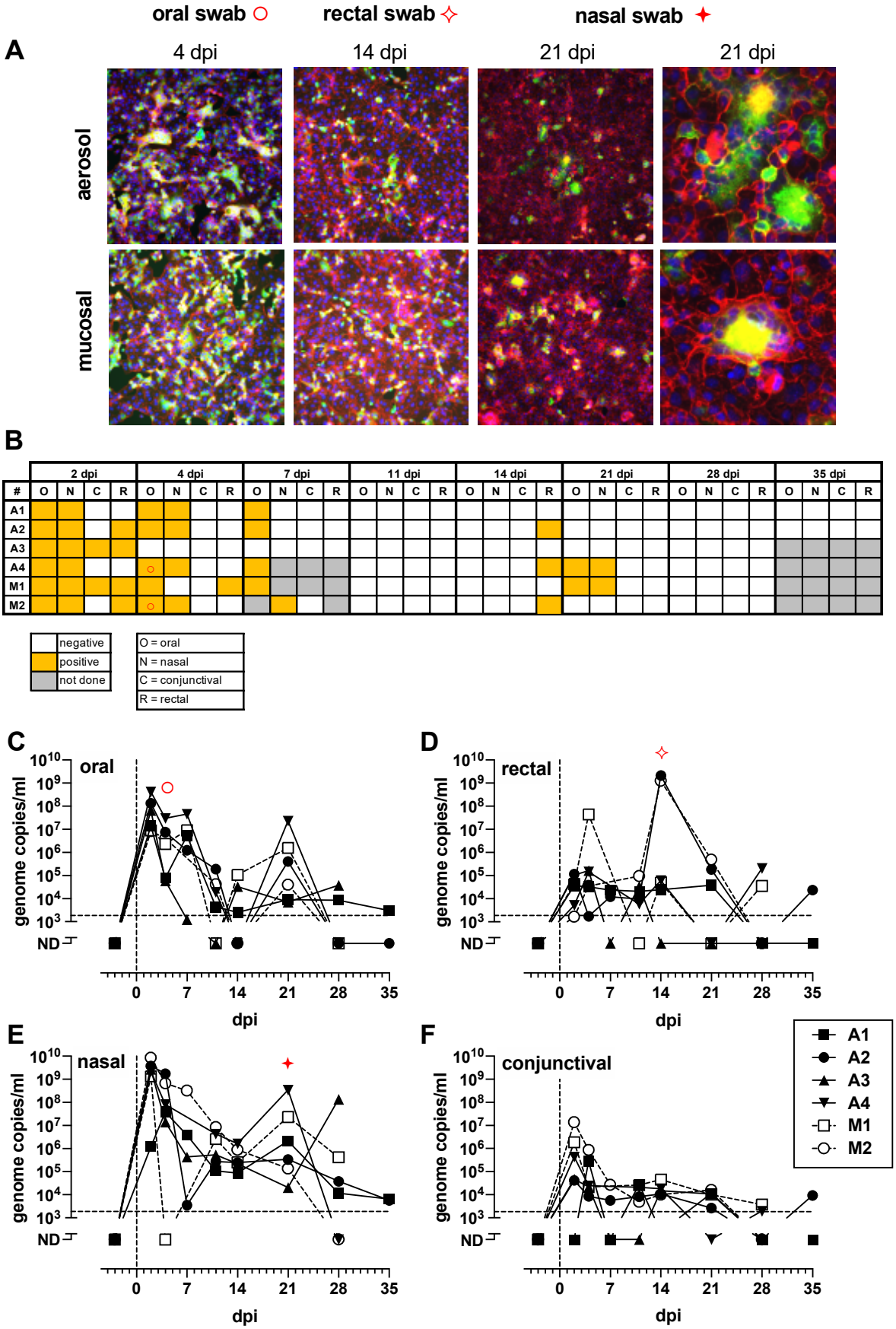

Fig. 1. Detection and isolation of SARS-CoV-2 in swabs. (A) Representative virus isolations confirmed by immunofluorescence using anti-SARS2 spike Ab (green) with phalloidin (red) as background and nuclei stained with DAPI (blue). (B) Isolation results from swabs. (B-D) vRNA in swabs measured by q-RT-PCR. AGM infected by aerosol (closed symbols/solid lines; n=4) or multi-route mucosal (open symbols/dashed lines; n=2). Red symbols highlight representative IFA images shown in (A).

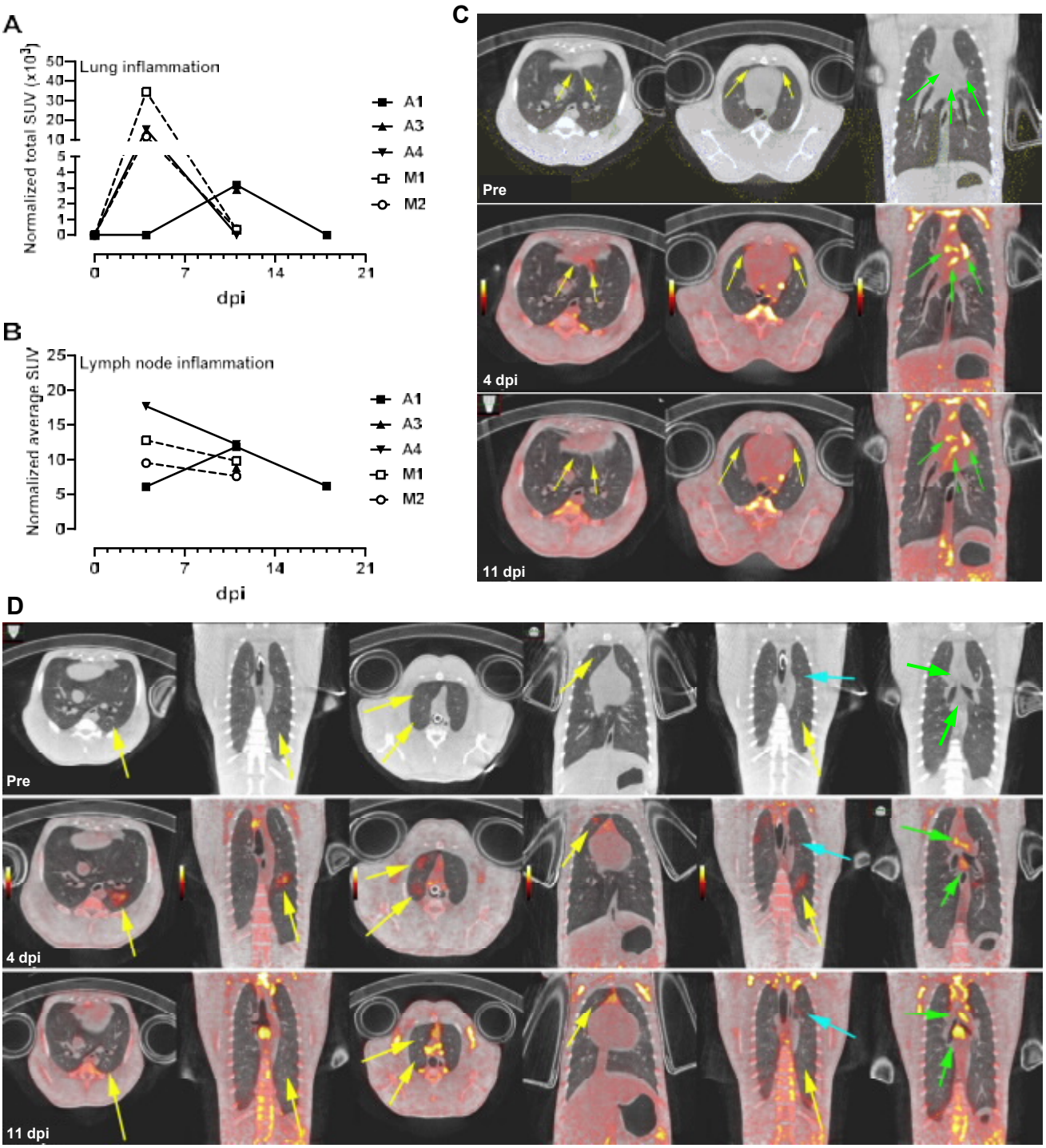

Fig. 2: PET/CT imaging of SARS-CoV-2-infected AGM. (A) and (B) Region-of-interest analysis on PET images of animals infected with SARS-CoV-2. (A) Measurement of total lung inflammation via FDG uptake over time. (B) Measurement of average lymph node inflammation over time. Aerosol (closed symbols/solid lines; n=3); multi-route mucosal (open symbols/dashed lines; n=2). Animal A2 is not included in (A) and (B) because only CT scans were performed. (C) For AGM A4 (aerosol), only CT scan was obtained pre-infection; PET/CT at was obtained at 4 dpi and 11 dpi. (D) For AGM M1 (multi-route mucosal), only CT scan was obtained pre-infection; PET/CT at was obtained at 4 dpi and 11 dpi. . Pulmonary infection (yellow arrows); thoracic lymph nodes (green arrows). Cyan arrow highlights new focal area of disease visible on 11 dpi. PET color scale is from 0 - 15 SUV.

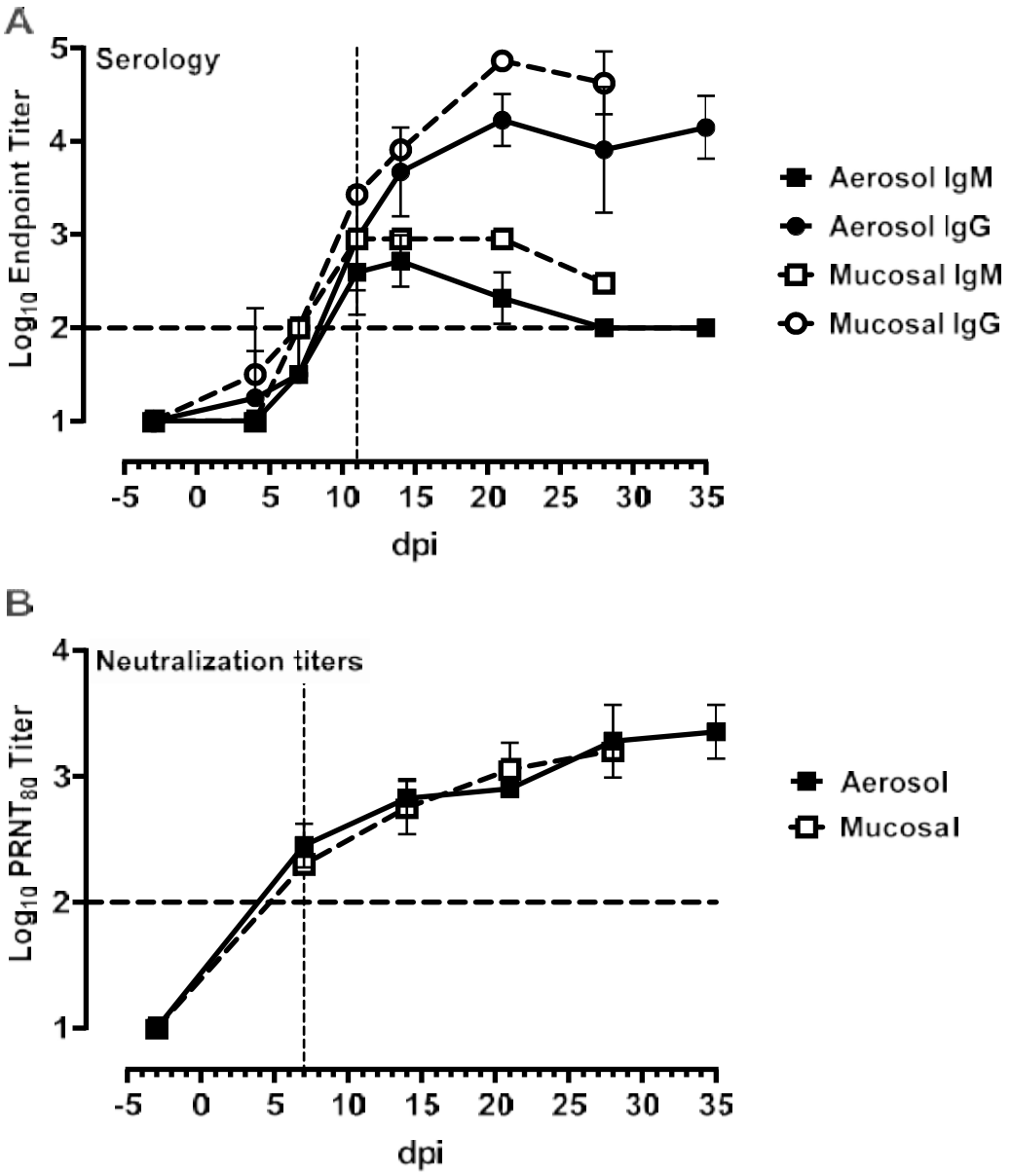

Fig. 3: Seroconversion and neutralization in SARS-CoV-2 infected AGMs. Serial plasma samples were assayed for virus specific antibodies or neutralization capacity. (A) virus-specific IgG and IgM were measured using a SARS-CoV-2 spike receptor binding domain-based ELISA. (B) neutralization titers were determined by a plaque-reduction neutralization 80% assay ($PRNT_{80}$). The horizontal dotted line represents the limit of detection of each assay.

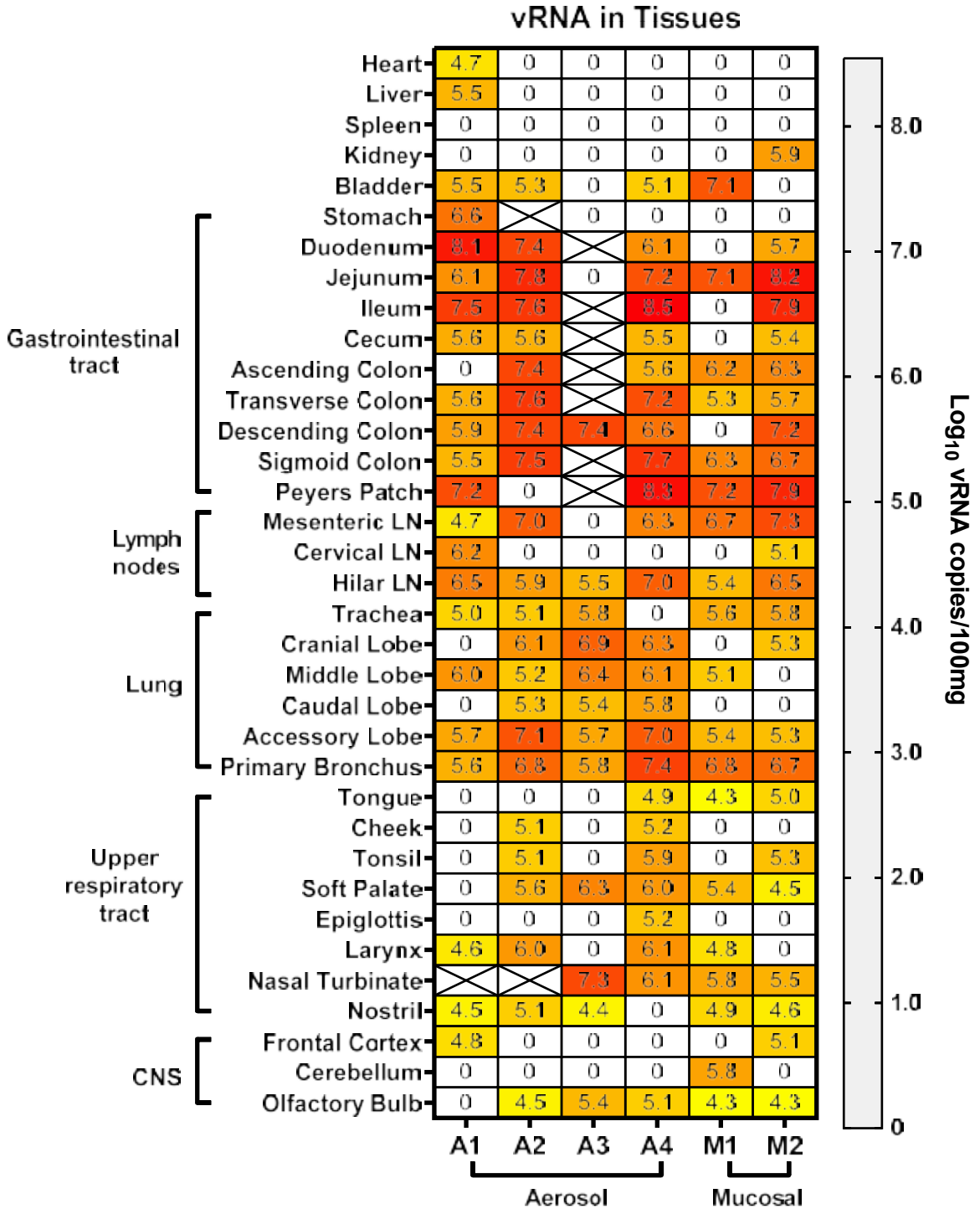

Fig. 4. Viral RNA within tissues of SARS-CoV-2 infected AGM. Animals underwent necropsy at 28 dpi (35 dpi for A1 and A2) and the indicated tissues were extracted and tested for viral RNA by q-RT-PCR. Heat map shows the log-transformed vRNA copies per 100 mg of tissue. X indicates the sample was not available or not tested.

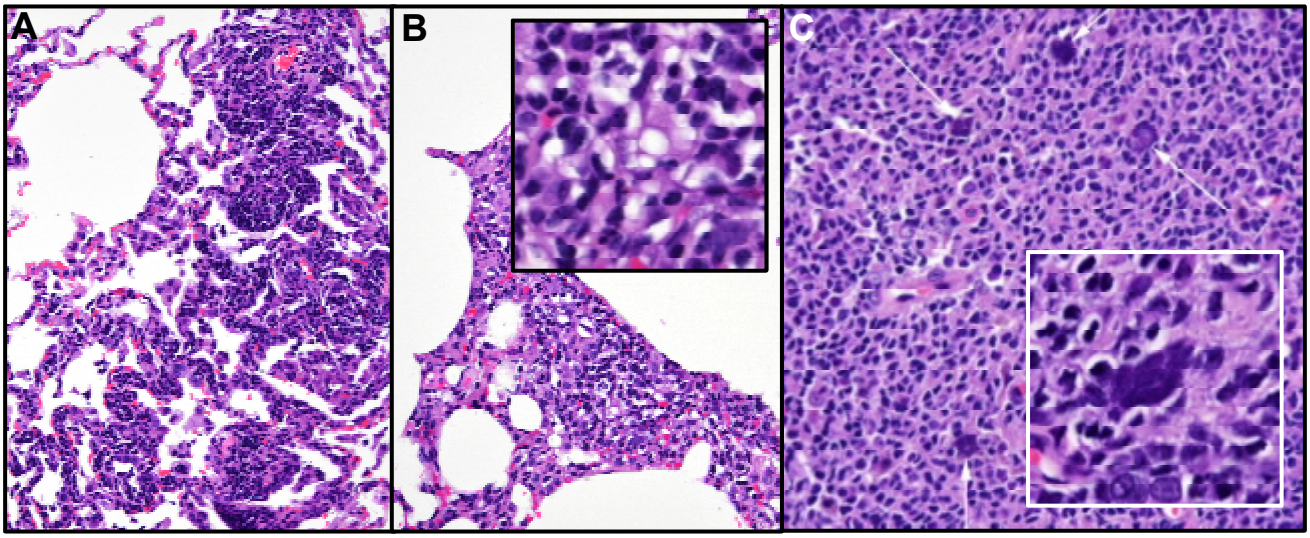

Fig. 5. Histopathology detected at necropsy. (A) and (B) Lung (20X) reveals pulmonary foci of mild infiltration and interstitial expansion by lymphocytic and mixed inflammatory cells. (C) Peyer's patch (20X) shows multiple, syncytialized cells (white arrows). Inset of Peyer's patch illustrates smudgy syncytia. Histopathology interpreted by a board-certified veterinary pathologist.

To: Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; david.j.payne@gsk.com[david.j.payne@gsk.com]; fstegmeier@ksqtx.com[fstegmeier@ksqtx.com]; jrappaport@tulane.edu[jrappaport@tulane.edu]; kara.carter@evotec.com[kara.carter@evotec.com]; jay_grobler@merck.com[jay_grobler@merck.com]; ggatto@rti.org[ggatto@rti.org]; Baric, Ralph S[rbaric@email.unc.edu]; prabha.fernandes@gmail.com[prabha.fernandes@gmail.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; diamond@wusm.wustl.edu[diamond@wusm.wustl.edu]; Cat.Lutz@jax.org[Cat.Lutz@jax.org]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Collins, Francis (NIH/OD) [E][collinsf@od.nih.gov]; ken.duncan@gatesfoundation.org[ken.duncan@gatesfoundation.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Tomas Cihlar[Tomas.Cihlar@gilead.com]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Frank.Nestle@sanofi.com[Frank.Nestle@sanofi.com]; Wholley, David (FNIH) [T][dwholley@fnih.org]; Austin, Christopher (NIH/NCATS) [E][austinc@mail.nih.gov]; Melencio, Cheryl (FNIH) [T][cmelencio@fnih.org]; Desrosiers, Betsy[elizabeth_desrosiers@merck.com]; Hughes, Eric[eric.hughes@novartis.com]; Jansen, Kathrin[kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E][michael.kurilla@nih.gov]; Lowy, Douglas (NCI)[dl60z@nih.gov]; Read, Sarah (NIH/NIAID) [E][readsa@niaid.nih.gov]; Tountas, Karen (FNIH) [T][ktountas@fnih.org]; Santos, Michael (FNIH) [T][msantos@fnih.org]; Adam, Stacey (FNIH) [T][sadam@fnih.org]; James, Stephanie (FNIH) [T][sjames@fnih.org]; Alvarez, Rosa Maria[rosalvarez@deloitte.com]; Kim, Elizabeth[elkim@deloitte.com]; Tolman, Brett[btolman@deloitte.com]; Wachtel, Jonathan[jwachtel@deloitte.com]; Prabhavathi Fernandes[prabha.fernandes@outlook.com]; Rose Li[rose.li@roseliassociates.com]; Dana Carluccio[dana.carluccio@roseliassociates.com]; Lagos, Enrique (NIH/NCATS) [E][enrique.lagos@nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Gonzalez, Nina[ningonzalez@deloitte.com]; Simon, Dina (NIH/OD) [C][dina.simon@nih.gov]; Burrus-Shaw, Cyndi (NIH/OD) [E][cyndi.burrus-shaw@nih.gov]; Rodriguez, Robin D[rmdaigle@tulane.edu]; Dave Frankowski[david.frankowski@roseliassociates.com]; Baric, Toni C[antoinette_baric@med.unc.edu]; Lowy, Douglas (NIH/NCI) [E][lowyd@mail.nih.gov]; Nancy Haigwood[haigwoon@ohsu.edu]; Stratton, Benjamin[bstratton@deloitte.com]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Anderson, James (NIH/OD) [E][james.anderson2@nih.gov]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Diamond, Michael[mdiamond@wustl.edu]
From: Young, John[john.young.jy3@roche.com]
Sent: Wed 7/1/2020 2:07:00 PM (UTC-04:00)
Subject: Re: ACTIV Preclinical full working group

Dear Clint
Thank you for this important update. The EC update went well. Francis asked a question about the D164G variant and was happy to hear that we have this on our radar.
Best regards
John

On Wed, Jul 1, 2020 at 5:41 PM Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov> wrote:

All –

U PITT's pre-print in YOUNG AGMs utilizes the Munich strain which I believe has the D614 mutant.

In their hands, they didn't report any dramatic increase in pathogenesis with the assays they implemented.

Might be of benefit in the EXE meeting tonight.

Just an FYI.

Clint

From: jmenetski@fnih.org
When: 10:00 AM - 11:00 AM July 1, 2020
Subject: ACTIV Preclinical full working group
Location: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Meeting ID: 960 4240 3854

Password: 124630

One tap mobile

+13017158592,,96042403854#,,1#,124630# US (Germantown)

+13126266799,,96042403854#,,1#,124630# US (Chicago)

Dial by your location

- +1 301 715 8592 US (Germantown)
- +1 312 626 6799 US (Chicago)
- +1 646 876 9923 US (New York)
- +1 408 638 0968 US (San Jose)
- +1 669 900 6833 US (San Jose)
- +1 253 215 8782 US (Tacoma)
- +1 346 248 7799 US (Houston)

Meeting ID: 960 4240 3854

Password: 124630

Find your local number: https://fnih.zoom.us/u/aemFGSQrl

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To: DeStefano, Laura[LDestefano@nas.edu]; Dzau, Victor J.[VDzau@nas.edu]; Georges Benjamin[georges.benjamin@apha.org]; Susan Polan[susan.polan@apha.org]; 'Nicole Lurie'[drnickilurie@gmail.com]; Carlos de Rio[cdelrio@emory.edu]; Ogilvie, Jenna[JOgilvie@nas.edu]; 'Sharon Inouye'[SharonInouye@hsl.harvard.edu]; 'Linda Degutis'[lcdegutis@gmail.com]; 'acasadevall@jhu.edu'[acasadevall@jhu.edu]; 'ushah@hcphes.org'[ushah@hcphes.org]; 'Lawrence Gostin'[gostin@georgetown.edu]; Figueroa, Angelica M[amfiguer@email.unc.edu]; Croitoru, Grace Nicole[gracenc@email.unc.edu]; Rimer, Barbara[brimer@unc.edu]; 'Shah, Umair MD (PHS)'[Umair.Shah@phs.hctx.net]; 'Arturo Casadevall'[acasade1@jhu.edu]; 'Jha, Ashish'[ajha@hsph.harvard.edu]; 'Gold, Jeffrey P'[jeffrey.gold@unmc.edu]; 'Perez, Elizabeth (PHS)'[Elizabeth.Perez@phs.hctx.net]; 'Castaneda, Tony (PHS)'[Tony.Castaneda@phs.hctx.net]; 'Heidi Larson'[Heidi.Larson@LSHTM.ac.uk]; 'Burke, Donald S'[donburke@pitt.edu]; 'Tom Inglesby'[tinglesby@jhu.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'Maria Jasen'[mjasen1@jhu.edu]; Chua, Peak Sen[PChua@nas.edu]
From: Andy Pavia[Andy.Pavia@hsc.utah.edu]
Sent: Wed 7/1/2020 6:29:58 PM (UTC-04:00)
Subject: Re: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Hi Laura,

I am working but I have a conflicting NIH call

Andy

From: "DeStefano, Laura" <LDestefano@nas.edu>
Date: Monday, June 29, 2020 at 11:23 AM
To: "Dzau, Victor J." <VDzau@nas.edu>, Georges Benjamin <georges.benjamin@apha.org>, Susan Polan <susan.polan@apha.org>, 'Nicole Lurie' <drnickilurie@gmail.com>, Carlos DelRio <cdelrio@emory.edu>, "Ogilvie, Jenna" <JOgilvie@nas.edu>, 'Sharon Inouye' <SharonInouye@hsl.harvard.edu>, 'Linda Degutis' <lcdegutis@gmail.com>, "'acasadevall@jhu.edu'" <acasadevall@jhu.edu>, "'ushah@hcphes.org'" <ushah@hcphes.org>, 'Lawrence Gostin' <gostin@georgetown.edu>, "'Figueroa, Angelica M'" <amfiguer@email.unc.edu>, "'Croitoru, Grace Nicole'" <gracenc@email.unc.edu>, "'brimer@unc.edu'" <brimer@unc.edu>, Andrew Pavia <Andy.Pavia@hsc.utah.edu>, "'Shah, Umair MD (PHS)'" <Umair.Shah@phs.hctx.net>, 'Arturo Casadevall' <acasade1@jhu.edu>, "'Jha, Ashish'" <ajha@hsph.harvard.edu>, "'Gold, Jeffrey P'" <jeffrey.gold@unmc.edu>, "'Perez, Elizabeth (PHS)'" <Elizabeth.Perez@phs.hctx.net>, "'Castaneda, Tony (PHS)'" <Tony.Castaneda@phs.hctx.net>, 'Heidi Larson' <Heidi.Larson@LSHTM.ac.uk>, "'Burke, Donald S'" <donburke@pitt.edu>, 'Tom Inglesby' <tinglesby@jhu.edu>, "'rbaric@email.unc.edu'" <rbaric@email.unc.edu>, "'antoinette_baric@med.unc.edu'" <antoinette_baric@med.unc.edu>, 'Maria Jasen' <mjasen1@jhu.edu>, "Chua, Peak Sen" <PChua@nas.edu>
Subject: Re: Advisory Group Call: NAM-APHA COVID-19 Webinar Series

Hi all, if you have not already, could you please reply to let me know whether or not you plan to attend this call tomorrow? It seems that many people will be out for the holiday week, so it may be that we should seek feedback by email instead.

Many thanks,

Laura

From: DeStefano, Laura
Sent: Monday, April 6, 2020 10:49 AM
To: DeStefano, Laura; Dzau, Victor J.; Georges Benjamin; Susan Polan; 'Nicole Lurie'; Carlos de Rio; Ogilvie, Jenna; 'Sharon Inouye'; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; 'Figueroa, Angelica M'; 'Croitoru, Grace Nicole'; 'brimer@unc.edu'; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; 'rbaric@email.unc.edu'; 'antoinette_baric@med.unc.edu'; 'Maria Jasen'; Chua, Peak Sen
Subject: Advisory Group Call: NAM-APHA COVID-19 Webinar Series
When: Tuesday, June 30, 2020 2:00 PM-3:00 PM.
Where: RESCHEDULED due to holiday - please reply if you can attend

To: Alexandra Phelan (alp81@georgetown.edu)[alp81@georgetown.edu]; David A Relman (relman@stanford.edu)[relman@stanford.edu]; David Walt (dwalt@bwh.harvard.edu)[dwalt@bwh.harvard.edu]; Diane Griffin (dgriffi6@jhmi.edu)[dgriffi6@jhmi.edu]; Embrey, Ellen (eembrey@stratitia.com)[eembrey@stratitia.com]; Georges Benjamin (georges.benjamin@apha.org)[georges.benjamin@apha.org]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; John Hick (hick.john@gmail.com)[hick.john@gmail.com]; Jonna Mazet (jkmazet@ucdavis.edu)[jkmazet@ucdavis.edu]; Kent Kester (Kent.Kester@sanofi.com)[Kent.Kester@sanofi.com]; Kristian G. Andersen (kga1978@gmail.com)[kga1978@gmail.com]; Mark Smolinski (mark@endingpandemics.org)[mark@endingpandemics.org]; Mary Travis Bassett (mbassett@hsph.harvard.edu)[mbassett@hsph.harvard.edu]; Patricia King (patricia.king1@gmail.com)[patricia.king1@gmail.com]; Peggy Hamburg (peggy@hbfam.net)[peggy@hbfam.net]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; Phyllis D. Meadows (PDMeadows@kresge.org)[PDMeadows@kresge.org]; Richard Besser (rbesser@rwjf.org)[rbesser@rwjf.org]; Tara O'Toole (totoole@iqt.org)[totoole@iqt.org]; Trevor Bedford (trevor@bedford.io)[trevor@bedford.io]; Baric, Ralph S[rbaric@email.unc.edu]; Donald Berwick[donberwick@gmail.com]; alta.charo@wisc.edu[alta.charo@wisc.edu]; Jeff.Duchin@kingcounty.gov[Jeff.Duchin@kingcounty.gov]; Baruch Fischhoff[baruch@cmu.edu]; DHanfling@iqt.org[DHanfling@iqt.org]; bgroves@georgetown.edu[bgroves@georgetown.edu]
Cc: Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; mnavish@iqt.org[mnavish@iqt.org]; andre@ecohealthalliance.org[andre@ecohealthalliance.org]; Peisch, Samuel Francis[speisch@hsph.harvard.edu]; jbaker@rwjf.org[jbaker@rwjf.org]; Baric, Toni C[antoinette_baric@med.unc.edu]; Mary Radford[maradford@ucdavis.edu]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@nas.edu]; Feit, Monica[MFeit@nas.edu]; Shore, Carolyn[CShore@nas.edu]; Wollek, Scott[SWollek@nas.edu]; Downey, Autumn[ADowney@nas.edu]; Fine, Emma[EFine@nas.edu]; Kahn, Benjamin[BKahn@nas.edu]; Beachy, Sarah[SBeachy@nas.edu]; Khandekar, Eeshan[EKhandekar@nas.edu]; Shore, Carolyn[CShore@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Thur 7/2/2020 5:30:58 PM (UTC-04:00)
Subject: July 9 Standing Committee and Drug Forum Joint Meeting on COVID-19 and the Clinical Trial Enterprise
Forum Jul 9 Virtual Meeting Agenda_FINAL.pdf

Dear Members of the Standing Committee ,

Thank you for joining us yesterday afternoon for the joint meeting with Roundtable on Genomics and Precision Health. The discussions were very engaging and informative. As an immediate next step, staff are preparing a meeting recap as a high level summary of the discussion to share with you. In the more intermediate term, we may consider a type of publication or other type of action to capture some of the ideas discussed. Please let us know if you have any additional feedback or thoughts related to this meeting.

On a similar note, **I'm writing to invite you to attend another joint virtual meeting of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats and the Forum on Drug Discovery, Development, and Translation on Thursday, July 9 from 1-4pm ET.**

An outlook invitation will follow shortly to secure the time on your calendar, and it would be great if you could complete this Survey Gizmo to indicate your attendance https://www.surveygizmo.com/s3/5615299/July-2020-Forum-Meeting-Forum-Members.

With this meeting, we aim to discuss the impact of COVID-19 on the clinical trial enterprise. There are two audiences for this meeting—one being our Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, as we think about future areas that need attention through our rapid expert consultation reports and other ways of sharing information with our sponsors. The other audience is the members of the Forum on Drug Discovery, Development, and Translation as they run, in parallel, a strategic planning process to define what areas they should prioritize in the next few years.

Please see the attached final agenda for the meeting.

Please let me know if you have any questions.

Many thanks,
Lisa

Lisa Brown, MPH
Senior Program Officer
Board on Health Sciences Policy
Health and Medicine Division

The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW, Washington, DC 20001
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The National Academies of SCIENCES ENGINEERING MEDICINE

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

FORUM MEETING

July 9, 2020, 1:00 p.m. – 4:00 p.m. (ET)/10:00 a.m. – 1:00 p.m. (PT)

Join from PC, Mac, Linux, iOS or Android:
https://nasem.zoom.us/j/91194229782?pwd=MGhNTTB2aGlteWVDditpOW9VdzBZdz09
Or by telephone: 1-877- 853-5257
Meeting ID: 911 9422 9782
Password: 826412
International numbers available: https://nasem.zoom.us/u/aeeOQqTAe

MEETING OBJECTIVES

- Provide input on the Forum-hosted workshop, *Envisioning a Transformed Clinical Trials Enterprise for 2030*;
- Receive a briefing on National Academies activities relevant to COVID-19 and drug R&D;
- Share lessons learned from the impact of COVID-19 on the clinical trials enterprise;
- Consider next step opportunities for a transformed clinical trials enterprise post-COVID-19.

Forum Virtual Meeting: July 9, 2020

1:00 p.m. – 4:00 p.m. (ET)/10:00 a.m. – 1:00 p.m. (PT)

12:45 p.m. **Forum membership dials into Zoom (via computer and phone)**

Join from PC, Mac, Linux, iOS or Android:
https://nasem.zoom.us/j/91194229782?pwd=MGhNTTB2aGlteWVDditpOW9VdzBZdz09
Or by telephone: 1-877- 853-5257
Meeting ID: 911 9422 9782
Password: 826412
For technical assistance, please contact Eeshan Khandekar (EKhandekar@nas.edu; (704) 616-8590).

Virtual Meeting Reminders:

- Please mute yourself if you are not presenting or asking a question (this will reduce background noise).
- Use the 'raise hand' feature to signal that you have a question. Unmute yourself once called upon.
- We welcome the use of video if you have a camera (it will be nice to see some friendly faces!)

1:00 P.M. SESSION III PART 1: LESSONS LEARNED FROM COVID-19

Session Objectives:

- Provide input on the workshop, *Envisioning a Transformed Clinical Trials Enterprise for 2030*;
- Receive a briefing on National Academies Standing Committee on *Emerging Infectious Diseases and 21st Century Health Threats*;
- Share lessons learned from the impact of COVID-19 on the clinical trials enterprise;
- Consider next step opportunities for a transformed clinical trials enterprise post-COVID-19.

1:00 p.m. **Overview of COVID-19-related activities at the National Academies**

Envisioning a Transformed Clinical Trials Enterprise: Establishing an Agenda for 2030 – A Virtual Workshop

STEVEN GALSON, *Workshop Co-chair*
Senior Vice President, Global Regulatory Affairs and Safety
Amgen, Inc.

ESTHER KROFAH, *Workshop Co-chair*
Executive Director
FasterCures, Milken Institute

Standing Committee on *Emerging Infectious Diseases and 21st Century Health Threats*

HARVEY FINEBERG, *Standing Committee Chair*
President
Gordon and Betty Moore Foundation

1:20 p.m. **Lessons learned from the impact of COVID-19 on the clinical trials enterprise** *(10 mins each)*

Industry Perspective
CARLOS GARNER
Vice President, Global Regulatory Affairs
Eli Lilly and Company

Technology Development Perspective
ROBERT CALIFF, *Forum Co-Chair*
Head of Clinical Policy and Strategy
Verily Life Sciences and Google Health

Research Perspective
DEBORAH HUNG
Associate Professor and Core Faculty Member
Harvard Medical School

Academic Institution Perspective
ANANTHA SHEKHAR
Senior Vice Chancellor for Health Science and Dean of the School of Medicine
University of Pittsburgh

Regulatory Perspective
JACQUELINE CORRIGAN-CURAY
Director, Office of Medical Policy
FDA/CDER

2:15 p.m. *Discussion with Forum Membership (30 mins)*

Discussion Questions

- What aspects of the clinical trials enterprise have changed in response to COVID-19?
- What gaps and challenges in the clinical trials enterprise is the pandemic highlighting?
- Are there specific lessons learned from the rapid transition towards virtualization of clinical trials as a result of COVID-19?
    - What practice changes made in response to COVID-19 are being especially embraced by sponsors and other stakeholders in the CTE?
    - Are there specific elements of clinical trials that are best suited for "virtualization" in the COVID-19 setting?
    - What digital health technologies have been used to support the change?

2:45 p.m. **Break** *(15 mins)*

3:00 P.M. SESSION III PART 2: APPLYING LESSONS LEARNED FROM COVID-19

Session Objectives:

- Discuss opportunities/lessons learned from the response to COVID-19 that could be applied over the next decade;
- Discuss topics for consideration for the workshop on *Envisioning a Transformed Clinical Trials Enterprise: Establishing an Agenda for 2030*;
- Discuss topics for consideration for the Standing Committee on *Emerging Infectious Diseases and 21st Century Health Threats*.

3:00 p.m. **Transforming the Clinical Trials Enterprise: Applying Lessons Learned from COVID-19**

Discussion questions: Workshop Topics

- What changes made in response to COVID-19 could support, or be modified to support, a clinical trials enterprise that is more efficient, effective, patient-centered, and integrated into health care delivery over the coming decade?
- Are there practices (e.g., patient access, regulatory, digitalization, or trial conduct practices) that may become established as the default way of conducting trials?
- What can the COVID-19 pandemic teach us about merging clinical research and practice that could be applied over the coming 10 years?

Discussion questions: Standing Committee Topics

- What topics might benefit from recommendations (tangible, focused, short-term actions for any stakeholder group) from the National Academies' consensus study on this topic?
- Are there opportunities for the Forum and the Standing Committee together to facilitate progress or address specific challenges?

3:50 P.M. WRAP-UP

3:50 p.m. **Next Steps and Closing Remarks**

ROBERT CALIFF, *Forum Co-Chair*
Head of Clinical Policy and Strategy
Verily Life Sciences and Google Health

GREGORY SIMON, *Forum Co-Chair*
Senior Investigator, Kaiser Permanente Washington Health Research Institute
Research Professor, University of Washington

4:00 p.m. **Adjourn Forum Meeting**

From: LBrown@nas.edu[LBrown@nas.edu]

Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; Harvey V. Fineberg (harvey.fineberg@moore.org); Mary Radford; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; Baric, Toni C

Location: https://nasem.zoom.us/j/91194229782?pwd=MGhNTTB2aGlteWVDditpOW9VdzBZdz09

Importance: Normal

Subject: FW: Meeting of the Forum on Drug Discovery, Development, and Translation - DAY 2

Start Time: Thur 7/9/2020 1:00:00 PM (UTC-04:00)

End Time: Thur 7/9/2020 4:00:00 PM (UTC-04:00)

Required Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; Harvey V. Fineberg (harvey.fineberg@moore.org); Mary Radford; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; Baric, Toni C

Forum Jul 9 Virtual Meeting Agenda_FINAL.pdf

Dear Colleagues,

We look forward to seeing many of you at the upcoming virtual meeting of the National Academies Forum on Drug Discovery, Development, and Translation. Please find attached a meeting agenda and the Zoom dial-in information below.

Forum Meeting
Thursday, July 9, 2020
1:00 pm – 4:00 pm ET/10:00 am – 1:00pm PT

Zoom
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/91194229782?pwd=MGhNTTB2aGlteWVDditpOW9VdzBZdz09
Or by telephone: 1-877- 853-5257
Meeting ID: 911 9422 9782
Password: 826412
International numbers available: https://nasem.zoom.us/u/aeeOQqTAe

Meeting Objectives

- Provide input on the Forum-hosted workshop, *Envisioning a Transformed Clinical Trials Enterprise for 2030*;
- Receive a briefing on the National Academies Standing Committee on *Emerging Infectious Diseases and 21st Century Health Threats*;
- Share lessons learned from the impact of COVID-19 on the clinical trials enterprise;
- Consider next step opportunities for a transformed clinical trials enterprise post-COVID-19.

Best,
Carolyn

_____
Carolyn Shore, PhD

Director, Forum on Drug Discovery, Development, and Translation
Senior Program Officer, Board on Health Sciences Policy
Health and Medicine Division | Find us at nationalacademies.org/DRUGFORUM
The National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW
Washington, DC 20001
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The National Academies of SCIENCES ENGINEERING MEDICINE

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

FORUM MEETING

July 9, 2020, 1:00 p.m. – 4:00 p.m. (ET)/10:00 a.m. – 1:00 p.m. (PT)

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Forum Virtual Meeting: July 9, 2020

1:00 p.m. – 4:00 p.m. (ET)/10:00 a.m. – 1:00 p.m. (PT)

12:45 p.m. **Forum membership dials into Zoom (via computer and phone)**

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- Use the 'raise hand' feature to signal that you have a question. Unmute yourself once called upon.
- We welcome the use of video if you have a camera (it will be nice to see some friendly faces!)

1:00 P.M. SESSION III PART 1: LESSONS LEARNED FROM COVID-19

Session Objectives:

- Provide input on the workshop, *Envisioning a Transformed Clinical Trials Enterprise for 2030*;
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1:00 p.m. **Overview of COVID-19-related activities at the National Academies**

Envisioning a Transformed Clinical Trials Enterprise: Establishing an Agenda for 2030 – A Virtual Workshop

STEVEN GALSON, *Workshop Co-chair*
Senior Vice President, Global Regulatory Affairs and Safety
Amgen, Inc.

ESTHER KROFAH, *Workshop Co-chair*
Executive Director
FasterCures, Milken Institute

Standing Committee on *Emerging Infectious Diseases and 21st Century Health Threats*

HARVEY FINEBERG, *Standing Committee Chair*
President
Gordon and Betty Moore Foundation

1:20 p.m. **Lessons learned from the impact of COVID-19 on the clinical trials enterprise** *(10 mins each)*

Industry Perspective
CARLOS GARNER
Vice President, Global Regulatory Affairs
Eli Lilly and Company

Technology Development Perspective
ROBERT CALIFF, *Forum Co-Chair*
Head of Clinical Policy and Strategy
Verily Life Sciences and Google Health

Research Perspective
DEBORAH HUNG
Associate Professor and Core Faculty Member
Harvard Medical School

Academic Institution Perspective
ANANTHA SHEKHAR
Senior Vice Chancellor for Health Science and Dean of the School of Medicine
University of Pittsburgh

Regulatory Perspective
JACQUELINE CORRIGAN-CURAY
Director, Office of Medical Policy
FDA/CDER

2:15 p.m. *Discussion with Forum Membership (30 mins)*

Discussion Questions

- What aspects of the clinical trials enterprise have changed in response to COVID-19?
- What gaps and challenges in the clinical trials enterprise is the pandemic highlighting?
- Are there specific lessons learned from the rapid transition towards virtualization of clinical trials as a result of COVID-19?
    - What practice changes made in response to COVID-19 are being especially embraced by sponsors and other stakeholders in the CTE?
    - Are there specific elements of clinical trials that are best suited for "virtualization" in the COVID-19 setting?
    - What digital health technologies have been used to support the change?

2:45 p.m. **Break** *(15 mins)*

3:00 P.M. SESSION III PART 2: APPLYING LESSONS LEARNED FROM COVID-19

Session Objectives:

- Discuss opportunities/lessons learned from the response to COVID-19 that could be applied over the next decade;
- Discuss topics for consideration for the workshop on *Envisioning a Transformed Clinical Trials Enterprise: Establishing an Agenda for 2030*;
- Discuss topics for consideration for the Standing Committee on *Emerging Infectious Diseases and 21st Century Health Threats*.

3:00 p.m. **Transforming the Clinical Trials Enterprise: Applying Lessons Learned from COVID-19**

Discussion questions: Workshop Topics

- What changes made in response to COVID-19 could support, or be modified to support, a clinical trials enterprise that is more efficient, effective, patient-centered, and integrated into health care delivery over the coming decade?
- Are there practices (e.g., patient access, regulatory, digitalization, or trial conduct practices) that may become established as the default way of conducting trials?
- What can the COVID-19 pandemic teach us about merging clinical research and practice that could be applied over the coming 10 years?

Discussion questions: Standing Committee Topics

- What topics might benefit from recommendations (tangible, focused, short-term actions for any stakeholder group) from the National Academies' consensus study on this topic?
- Are there opportunities for the Forum and the Standing Committee together to facilitate progress or address specific challenges?

3:50 P.M. WRAP-UP

3:50 p.m. **Next Steps and Closing Remarks**

ROBERT CALIFF, *Forum Co-Chair*
Head of Clinical Policy and Strategy
Verily Life Sciences and Google Health

GREGORY SIMON, *Forum Co-Chair*
Senior Investigator, Kaiser Permanente Washington Health Research Institute
Research Professor, University of Washington

4:00 p.m. **Adjourn Forum Meeting**

Organizer: Shore, Carolyn[CShore@nas.edu]

From: Shore, Carolyn[CShore@nas.edu]

Attendees: Alexandra Phelan (alp81@georgetown.edu); David A Relman (relman@stanford.edu); David Walt (dwalt@bwh.harvard.edu); Diane Griffin (dgriffi6@jhmi.edu); Embrey, Ellen (eembrey@stratitia.com); Georges Benjamin (georges.benjamin@apha.org); Harvey V. Fineberg (harvey.fineberg@moore.org); John Hick (hick.john@gmail.com); Jonna Mazet (jkmazet@ucdavis.edu); Kent Kester (Kent.Kester@sanofi.com); Kristian G. Andersen (kga1978@gmail.com); Mark Smolinski (mark@endingpandemics.org); Mary Travis Bassett (mbassett@hsph.harvard.edu); Patricia King (patricia.king1@gmail.com); Peggy Hamburg (peggy@hbfam.net); Peter Daszak (daszak@ecohealthalliance.org); Phyllis D. Meadows (PDMeadows@kresge.org); Richard Besser (rbesser@rwjf.org); Tara O'Toole (totoole@iqt.org); Trevor Bedford (trevor@bedford.io); Baric, Ralph S; Donald Berwick; alta.charo@wisc.edu; Jeff.Duchin@kingcounty.gov; Baruch Fischhoff; DHanfling@iqt.org; bgroves@georgetown.edu; Harvey V. Fineberg (harvey.fineberg@moore.org); Mary Radford; mnavish@iqt.org; andre@ecohealthalliance.org; Peisch, Samuel Francis; Baric, Toni C

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The National Academies of SCIENCES ENGINEERING MEDICINE

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

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Vice President, Global Regulatory Affairs
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Technology Development Perspective
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Verily Life Sciences and Google Health

Research Perspective
DEBORAH HUNG
Associate Professor and Core Faculty Member
Harvard Medical School

Academic Institution Perspective
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Senior Vice Chancellor for Health Science and Dean of the School of Medicine
University of Pittsburgh

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Head of Clinical Policy and Strategy
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GREGORY SIMON, *Forum Co-Chair*
Senior Investigator, Kaiser Permanente Washington Health Research Institute
Research Professor, University of Washington

4:00 p.m. **Adjourn Forum Meeting**

To: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
From: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Sent: Thur 7/2/2020 5:43:29 PM (UTC-04:00)
Subject: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)
mAb Scientific Summit expert input request_vShare.pptx

Dear Preclinical Working group,

ACTIV is working with OWS to setup a mAb summit. We were asked to solicited suggestions and recommendations from our working groups for those that would be appropriate to contribute to this event. Please see the note below and let me know if there is anyone that would fill the roles described.

Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

All,

I hope you're doing well. As you may know, OWS, NIH, and FNIH are hosting a mAb scientific summit mid to end of August. The objective of the summit is to facilitate discussion on mAb science and address how to optimize development and therapeutic use of mAbs going forward.

The summit will be facilitated in a panel format, with each panel focused on a white paper written and circulated in advance on a key topic in the space. We have attached a few slides capturing the key topics and the white paper format.

We are writing to you today to get your recommendations on experts that may be able to address each of the key topics, with a focus on 3 roles:

1. White paper author: Expert to write a paper providing an overview of the various positions on specific key topics in advance of the summit
2. Panelist: Additional experts to provide alternative perspectives on a panel during the summit to include industry partners
3. Moderator: Facilitator to develop questions for the panel and synthesize positions from white paper author and responses from panelists after the summit

We have included a slide in the attached file to be filled in with your recommendations on each of these roles for the key topics. We are looking for diversity in the panel. If you could please provide input by EOD on Monday July 7th, that would be great.

Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- 301-619-7516
Cell- 240-586-0856
Fax- 301-619-7230
email - nicole.r.kilgore.civ@mail.mil

mAb Scientific Summit

mAb scientific summit topics

Safety	**Antibody-dependent enhancement**	• Discuss lessons learned on ADE based enhanced respiratory disease from previous Tx • Review potential implications for COVID-19 nAbs • Review ADE screening and monitoring process for COVID-19 nAb development (for neutralizing and non-neutralizing antibodies that might contribute to ADE)
Efficacy	**Epitope binding & viral resistance**	• Discuss whether epitope binding sites or combinations of site predict therapeutic efficacy • Discuss range of epitopes being targeted by nAbs and likelihood of viral resistance based on epitope conservation and use of cocktail vs. single nAb
	Effector function	• Review mutations being explored to increase half-life or effector function (e.g. YTE, LS) and any initial efficacy/safety data from animal studies (AstraZeneca, Regeneron) • Discuss potential impact of mutations on Fc-mediated antibody effector functions and use of Fc region to specify and optimize immune response
	Lessons from other fields	• Discuss lessons learned from mAb development and efficacy results from flu (Genentech, Medimmune) and HIV • Discuss lessons learned and implications for Vaccine development
Assay dev't	**Assay standardization**	• Discuss in vitro and in vivo screening characteristics that predict efficacy and safety • Discuss process for screening for combinatorial nAb candidates and indicators of optimal mAb combinations

Preliminary

Proposed sections to be included in white papers

State of the field

Background on latest developments in field and overview of key issues

1 page

Position and supporting evidence

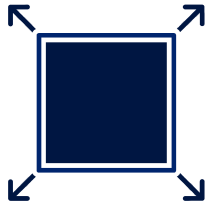
Position on key issues (to discuss further during panelist discussion at summit)

1-2 pages

Immediate lessons for nAb development

Recommended actions for COVID-19 nAb development

1-2 pages



Long term implications

Lessons for future nAb development

1 page

For Your Input: Expert recommendations for key roles

To be filled out and returned to OWS research team or NIH/FNIH team

		White paper author	Panelists	Moderator for panel
Safety	**Antibody-dependent enhancement**	• TBD	• TBD	• TBD
Efficacy	**Epitope binding & viral resistance**	• TBD	• TBD	• TBD
	Effector function & half-life	• TBD	• TBD	• TBD
	Lessons from other diseases	• TBD	• TBD	• TBD
Assay dev't	**Assay standardization**	• TBD	• TBD	• TBD


DEPARTMENT OF HEALTH & HUMAN SERVICES
USA


OPERATION
WARP SPEED


DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA

Thank you!

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]
Sent: Thur 7/2/2020 5:52:21 PM (UTC-04:00)
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Suggest:

Jonathan Abraham
e- mail: jonathan_abraham@hms.harvard.edu

Massachusetts Consortium
on Pathogen Readiness,
Boston, MA, USA.

FOR:

Lessons from other fields or Effector function or Antibody-dependent enhancement

Tony

-----Original Message-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Thursday, July 2, 2020 5:43 PM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>

Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

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Thank you,
Joe

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CLASSIFICATION: UNCLASSIFIED

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Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- 301-619-7516
Cell- 240-586-0856
Fax- 301-619-7230
email - nicole.r.kilgore.civ@mail.mil

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]
Sent: Thur 7/2/2020 8:39:11 PM (UTC-04:00)
Subject: Re: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Michel Nussenzeig Michel Nussenzweig <nussen@mail.rockefeller.edu>

Thomas J. Hope <thope@northwestern.edu>

On 7/2/20, 5:45 PM, "Menetski, Joseph (FNIH) [T]" <jmenetski@fnih.org> wrote:

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email - nicole.r.kilgore.civ@mail.mil

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]
Cc: Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]
From: Young, John[john.young.jy3@roche.com]
Sent: Fri 7/3/2020 2:35:41 PM (UTC-04:00)
Subject: Re: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

David Ho (Columbia University) (Panelist)

On Thu, Jul 2, 2020 at 11:45 PM Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org> wrote:

> Dear Preclinical Working group,
>
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>
> Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)
>
> CLASSIFICATION: UNCLASSIFIED
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Fax- 301-619-7230
email - nicole.r.kilgore.civ@mail.mil

CLASSIFICATION: UNCLASSIFIED

--

John A.T. Young, PhD
VP and Global Head Infectious Diseases
Roche Pharma Research & Early Development
Roche Innovation Center Basel
F.Hoffmann-La Roche Ltd
Grenzacherstrasse 124
4070 Basel, Switzerland
Mobile + 41 79 418 22 67
Mail to: john.young.jy3@roche.com

PA: Gianni Micheloni
Phone +41 61 68 75840
Mobile +41 79 136 49 01
Mail to: gianni.micheloni@roche.com

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Rappaport, Jay[jrappaport@tulane.edu]
Sent: Sat 7/4/2020 4:33:54 PM (UTC-04:00)
Subject: Re: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Dear Joe and All,
I would recommend the following :
1. Galit Alter, (Harvard. MGH)
2. David C. Montefiori; Duke
3. Michel Nussenzweig: Rockefeller University
4. Roshan Kumar or Jennifer Watkins-Yoon; HiFiBio Therapeutics; Cambridge, Mass./Paris, France

Best ,
Jay

Jay Rappaport, Ph.D.
Director and Chief Academic Officer
Tulane National Primate Research Center
Division of Comparative Pathology

Professor, Department of Microbiology and Immunology
Tulane University School of Medicine
Tulane University

18703 Three Rivers Road
Covington, LA
70433-8915
Tel 985-871-6201
Fax 985-871-6569
On 7/2/20, 4:45 PM, "Menetski, Joseph (FNIH) [T]" <jmenetski@fnih.org> wrote:

External Sender. Be aware of links, attachments and requests.

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email - nicole.r.kilgore.civ@mail.mil

CLASSIFICATION: UNCLASSIFIED

To: 'relman@stanford.edu'[relman@stanford.edu]; Baric, Ralph S[rbaric@email.unc.edu]; 'saif.2@osu.edu'[saif.2@osu.edu]; 'stanley-perlman@uiowa.edu'[stanley-perlman@uiowa.edu]; 'daszak@ecohealthalliance.org'[daszak@ecohealthalliance.org]; 'harvey.fineberg@moore.org'[harvey.fineberg@moore.org]; 'peshi@UTMB.EDU'[peshi@UTMB.EDU]; Dzau, Victor J.[VDzau@nas.edu]; 'peggy@hbfam.net'[peggy@hbfam.net]; 'jwleduc@UTMB.EDU'[jwleduc@UTMB.EDU]; 'davidrfranz@gmail.com'[davidrfranz@gmail.com]; jwleduc@UTMB.EDU[jwleduc@UTMB.EDU]
Cc: 'fsharples_3@hotmail.com'[fsharples_3@hotmail.com]; Lowenthal, Micah[mlowenth@nas.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'andre@ecohealthalliance.org'[andre@ecohealthalliance.org]; 'jennifer.ryan@moore.org'[jennifer.ryan@moore.org]; Bowman, Katherine[KBowman@nas.edu]; Kanarek, Morgan[MKanarek@nas.edu]; 'Raymond JEANLOZ'[jeanloz@berkeley.edu]; Hare, Hope[HHare@nas.edu]; 'Nancy Connell'[NancyConnell@jhu.edu]; 'dgriffi6@jhmi.edu'[dgriffi6@jhmi.edu]; Sharples, Fran[FSharples@nas.edu]
From: Rusek, Benjamin[BRusek@nas.edu]
Sent: Sat 7/4/2020 7:27:59 PM (UTC-04:00)
Subject: U.S. China Gene Editing Technologies to Detect and Respond to Viral Pathogens - workshop - July 14 and July 16

Greetings,

I wanted to let you all know that as a follow on to our bio dialogue discussions NASEM is holding a small invitation only virtual workshop on ***Opportunities and Best Practices for Using Gene Editing Technologies to Detect and Respond to Viral Pathogens***. The virtual workshop will take place over Zoom on the evenings on **Tuesday, July 14 and Thursday, July 16 for U.S. participants (6-8 PM U.S. PT / 9-11 PM U.S. ET on both evenings)** and the mornings of Wednesday July 15 and Friday July 17 for Chinese participants (9-11 AM Beijing time)**.**

The workshop will explore the use of genome editing technologies, such as those based on CRISPR-Cas systems, to understand and combat viral pathogens. Issues to be discussed include the use of genome editing as a research tool to better understand the basic biology of viral infection and interactions with the immune system; the development of rapid CRISPR-based diagnostic systems to detect viral pathogens; and the potential to use genome editing as an innovative anti-viral strategy as well as best practices for biosafety and biosecurity. Diane Griffin and George Gao will co-chair and Nancy Connell is organizing with help from Katie Bowman, Fran Sharples and Hui Sun from CAS. We expect that the workshop will include approximately 6 or 7 invited speakers with about 30 total participants split between the U.S. and China. The preliminary agenda is below. The first day will focus on the development of CRISPR-based diagnostic systems to detect viral pathogens such as SARS-CoV2. The second day will focus on the potential to use genome editing as an innovative anti-viral strategy, as well as best practices for biosafety and biosecurity.

We hope that you can participate in some or all of the workshop. If you plan to participate please RSVP, and we will send the Zoom link to you before the call.

Happy to answer any questions that you have. Hope you have a great July 4th.

PS as we discussed at the end of the 3rd bio dialogue Zoom meeting last month we plan to hold another bio dialogue meeting in August. I will be back in touch to start planning that meeting after the gene editing workshop.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Virtual Workshop on Opportunities and Best Practices for Using Gene Editing Technologies to Detect and Respond to Viral Pathogens
Agenda

Day 1: **Evening of July 14 in US (Tuesday) and** M**orning of July 15 in Beijing (Wednesday)**

- Welcome
  - US welcome and focus of the 2 sessions and how they extend the topics of the 3 bio dialogue meetings held in May/June *[5min]* – **Diane Griffin**, NASEM
  - China welcome *[5 min]* – **George Gao**, China CDC

- Opening Presentation: Introduction to how CRISPR-based technologies can be applied to diagnosis and treatment of disease *[10 min]*
  Nancy Connell, Johns Hopkins University

- Detecting Viral Pathogens *[75 min] – 3 presentations x 15 min each followed by panel discussion*
  Session moderator: **David Walt**, Harvard University
  - **Feng Zhang** [invited], Massachusetts Institute of Technology*: Development of CRISPR/Cas-based systems to detect viral pathogens)*
  - **Chunbo Lou** [invited]**,** Shenzhen Institutes of Advanced Technology, Chinese Academy of Sciences: *Paired Design of dCas9 as a Systematic Platform for the Detection of Featured Nucleic Acid Sequences in Pathogenic Strains*
  - **Charles Chiu** [invited]*,* University of California San Francisco: *Detection of SARS-CoV-2 using CRISPR/Cas-based systems)*
  - Moderated Discussion *[30 min]*

- Looking ahead to session 2 – **Nancy Connell**, Johns Hopkins University *[5 min]*
- Adjourn until second session

Day 2: **Evening of July 16 in US (Thursday) and Morning of July 17 in Beijing (Friday)**

- Welcome – **Nancy Connell**, Johns Hopkins University [*5min]*

- Responding to viral pathogens [60 min] - *3 presentations x 15 min each followed by panel discussion.*
  Session moderator: **Nancy Connell**, Johns Hopkins University
  - **Deyin Guo** [invited], School of Medicine (Shenzhen), Sun Yat-sen University: *CRISPR-Cas Targeting of Host Genes as an Antiviral Strategy*
  - **Xin Zhao** [invited]**,** Institute of Microbiology, Chinese Academy of Sciences: *Receptor hunting of Enterovirus B by CRISPR screening*
  - **Stanley Qi** [invited, recommended colleague]*,* Stanford University: *Development of CRISPR as an Antiviral Strategy to Combat SARS-CoV-2 and Influenza")*
  - Moderated Discussion *[30 min]*

- Capturing the opportunities through responsible development *[30 min]*
  - **Weiwen Zhang** [invited], Tianjin University: The importance of promoting responsible development around technologies such as gene editing, including following good biosafety/biosecurity practices) [15 min]
  - Discussion among all participants *[20 min]*

- Thanks to all speakers and participants and adjourn virtual workshop

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

To: Rusek, Benjamin[BRusek@nas.edu]
Cc: relman@stanford.edu[relman@stanford.edu]; Baric, Ralph S[rbaric@email.unc.edu]; saif.2@osu.edu[saif.2@osu.edu]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; harvey.fineberg@moore.org[harvey.fineberg@moore.org]; peshi@UTMB.EDU[peshi@utmb.edu]; Dzau, Victor J.[VDzau@nas.edu]; jwleduc@UTMB.EDU[jwleduc@utmb.edu]; davidrfranz@gmail.com[davidrfranz@gmail.com]; fsharples_3@hotmail.com[fsharples_3@hotmail.com]; Lowenthal, Micah[mlowenth@nas.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; andre@ecohealthalliance.org[andre@ecohealthalliance.org]; jennifer.ryan@moore.org[jennifer.ryan@moore.org]; Bowman, Katherine[KBowman@nas.edu]; Kanarek, Morgan[MKanarek@nas.edu]; Raymond JEANLOZ[jeanloz@berkeley.edu]; Hare, Hope[HHare@nas.edu]; Nancy Connell[NancyConnell@jhu.edu]; dgriffi6@jhmi.edu[dgriffi6@jhmi.edu]; Sharples, Fran[FSharples@nas.edu]
From: Peggy Hamburg[peggy@hbfam.net]
Sent: Sat 7/4/2020 9:56:41 PM (UTC-04:00)
Subject: Re: U.S. China Gene Editing Technologies to Detect and Respond to Viral Pathogens - workshop - July 14 and July 16

Sounds interesting. Thanks for letting me know. I would like to participate. Can invitation be extended to anyone else or would that be inappropriate? I was thinking of Alta Charro who has worked on several academy reports on gene editing etc Thank you.
Peggy

Sent from my iPhone

On Jul 4, 2020, at 7:28 PM, Rusek, Benjamin <BRusek@nas.edu> wrote:

Greetings,

I wanted to let you all know that as a follow on to our bio dialogue discussions NASEM is holding a small invitation only virtual workshop on ***Opportunities and Best Practices for Using Gene Editing Technologies to Detect and Respond to Viral Pathogens***. The virtual workshop will take place over Zoom on the evenings on **Tuesday, July 14 and Thursday, July 16 for U.S. participants (6-8 PM U.S. PT / 9-11 PM U.S. ET on both evenings)** and the mornings of Wednesday July 15 and Friday July 17 for Chinese participants (9-11 AM Beijing time)**.**

The workshop will explore the use of genome editing technologies, such as those based on CRISPR-Cas systems, to understand and combat viral pathogens. Issues to be discussed include the use of genome editing as a research tool to better understand the basic biology of viral infection and interactions with the immune system; the development of rapid CRISPR-based diagnostic systems to detect viral pathogens; and the potential to use genome editing as an innovative anti-viral strategy as well as best practices for biosafety and biosecurity. Diane Griffin and George Gao will co-chair and Nancy Connell is organizing with help from Katie Bowman, Fran Sharples and Hui Sun from CAS. We expect that the workshop will include approximately 6 or 7 invited speakers with about 30 total participants split between the U.S. and China. The preliminary agenda is below. The first day will focus on the development of CRISPR-based diagnostic systems to detect viral pathogens such as SARS-CoV2. The second day will focus on the potential to use genome editing as an innovative anti-viral strategy, as well as best practices for biosafety and biosecurity.

We hope that you can participate in some or all of the workshop. If you plan to participate please RSVP, and we will send the Zoom link to you before the call.

Happy to answer any questions that you have. Hope you have a great July 4th.

PS as we discussed at the end of the 3rd bio dialogue Zoom meeting last month we plan to hold another bio dialogue meeting in August. I will be back in touch to start planning that meeting after the gene editing workshop.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Virtual Workshop on Opportunities and Best Practices for Using Gene Editing Technologies to Detect and Respond to Viral Pathogens
Agenda

Day 1: **Evening of July 14 in US (Tuesday) and** M**orning of July 15 in Beijing (Wednesday)**

- Welcome
  - US welcome and focus of the 2 sessions and how they extend the topics of the 3 bio dialogue meetings held in May/June *[5min]* – **Diane Griffin**, NASEM
  - China welcome *[5 min]* – **George Gao**, China CDC

- Opening Presentation: Introduction to how CRISPR-based technologies can be applied to diagnosis and treatment of disease *[10 min]*
  Nancy Connell, Johns Hopkins University

- Detecting Viral Pathogens *[75 min] – 3 presentations x 15 min each followed by panel discussion*
  Session moderator: **David Walt**, Harvard University
  - **Feng Zhang** [invited], Massachusetts Institute of Technology*: Development of CRISPR/Cas-based systems to detect viral pathogens)*
  - **Chunbo Lou** [invited]**,** Shenzhen Institutes of Advanced Technology, Chinese Academy of Sciences: *Paired Design of dCas9 as a Systematic Platform for the Detection of Featured Nucleic Acid Sequences in Pathogenic Strains*
  - **Charles Chiu** [invited]*,* University of California San Francisco: *Detection of SARS-CoV-2 using CRISPR/Cas-based systems)*
  - Moderated Discussion *[30 min]*

- Looking ahead to session 2 – **Nancy Connell**, Johns Hopkins University *[5 min]*
- Adjourn until second session

Day 2: **Evening of July 16 in US (Thursday) and Morning of July 17 in Beijing (Friday)**

- Welcome – **Nancy Connell**, Johns Hopkins University [*5min]*

- Responding to viral pathogens [60 min] - *3 presentations x 15 min each followed by panel discussion.*
  Session moderator: **Nancy Connell**, Johns Hopkins University
  - **Deyin Guo** [invited], School of Medicine (Shenzhen), Sun Yat-sen University: *CRISPR-Cas Targeting of Host Genes as an Antiviral Strategy*
  - **Xin Zhao** [invited]**,** Institute of Microbiology, Chinese Academy of Sciences: *Receptor hunting of Enterovirus B by CRISPR screening*
  - **Stanley Qi** [invited, recommended colleague]*,* Stanford University: *Development of CRISPR as an Antiviral Strategy to Combat SARS-CoV-2 and Influenza")*
  - Moderated Discussion *[30 min]*

- Capturing the opportunities through responsible development *[30 min]*
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Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Kara Carter[Kara.Carter@evotec.com]
Sent: Sun 7/5/2020 12:05:49 PM (UTC-04:00)
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Hi Joe,

I suggest the following folks, but don't have a sense for the role they should play with regard to white paper author, panelist or moderator.

Harry Kleanthous - previously Head of Discovery Research North America for Sanofi Pasteur, currently at BMGF. Expertise in ADE and broadly neutralizing influenza antibodies.
Alina Baum - Regeneron. Head of their Ebola antibody program. Focus on clinical efficacy and antibody combinations.
Jim Crowe - Vanderbilt. Identification of neutralizing antibodies from convalescent patient serum to emerging viral pathogens.
Erica Sapphire - Scripps. Identification and characterization of neutralizing antibodies.
Jonathan Abraham - Harvard. Antibodies to emerging viruses. Focus on deciphering roles of effector function for both neutralizing and non-neutralizing antibodies.
Mike Diamond - You know him well, but assessment of potential and combination of neutralizing antibodies to emerging viral pathogens.
Dean Petit - Just Biotherapeutics - an Evotec company. Antibody optimization and manufacturability. This is a critical aspect that I think is missing for the key roles captured in slide 3.
Rebecca Sendak - Global Head of Biologics for Sanofi. Antibody optimization and manufacturability. Same comment as above.

Best,
Kara

Kara Carter, PhD
Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
kara.carter@evotec.com
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-----Original Message-----

From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Thursday, July 2, 2020 5:43 PM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Kara Carter <Kara.Carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

[EXTERNAL]

Dear Preclinical Working group,

ACTIV is working with OWS to setup a mAb summit. We were asked to solicited suggestions and recommendations from our working groups for those that would be appropriate to contribute to this event. Please see the note below and let me know if there is anyone that would fill the roles described.

Thank you,
Joe

Subject: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

All,

I hope you're doing well. As you may know, OWS, NIH, and FNIH are hosting a mAb scientific summit mid to end of August. The objective of the summit is to facilitate discussion on mAb science and address how to optimize development and therapeutic use of mAbs going forward.

The summit will be facilitated in a panel format, with each panel focused on a white paper written and circulated in advance on a key topic in the space. We have attached a few slides capturing the key topics and the white paper format.

We are writing to you today to get your recommendations on experts that may be able to address each of the key topics, with a focus on 3 roles:

1. White paper author: Expert to write a paper providing an overview of the various positions on specific key topics in advance of the summit
2. Panelist: Additional experts to provide alternative perspectives on a panel during the summit to include industry partners
3. Moderator: Facilitator to develop questions for the panel and synthesize positions from white paper

author and responses from panelists after the summit

We have included a slide in the attached file to be filled in with your recommendations on each of these roles for the key topics. We are looking for diversity in the panel. If you could please provide input by EOD on Monday July 7th, that would be great.

Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- 301-619-7516
Cell- 240-586-0856
Fax- 301-619-7230
email - nicole.r.kilgore.civ@mail.mil

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Kara Carter[Kara.Carter@evotec.com]
Sent: Sun 7/5/2020 12:09:25 PM (UTC-04:00)
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Joe,

One more: Jason McLellan - UT Austin. Identification of therapeutic antibodies to viruses.

Kara

Kara Carter, PhD
Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
kara.carter@evotec.com
www.evotec.com

-----Original Message-----
From: Kara Carter
Sent: Sunday, July 5, 2020 12:06 PM
To: 'Menetski, Joseph (FNIH) [T]' <jmenetski@fnih.org>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
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Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- 301-619-7516
Cell- 240-586-0856
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email - nicole.r.kilgore.civ@mail.mil

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Cc: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[tomas.cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]
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Subject: Re: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

I would also recommend Dennis Burton (Scripps), Bart Haynes (Duke), Julie Overbaugh (Fred Hutch, Seattle),

On Sun, Jul 5, 2020 at 6:05 PM Kara Carter <Kara.Carter@evotec.com> wrote:

Hi Joe,

I suggest the following folks, but don't have a sense for the role they should play with regard to white paper author, panelist or moderator.

Harry Kleanthous - previously Head of Discovery Research North America for Sanofi Pasteur, currently at BMGF. Expertise in ADE and broadly neutralizing influenza antibodies.
Alina Baum - Regeneron. Head of their Ebola antibody program. Focus on clinical efficacy and antibody combinations.
Jim Crowe - Vanderbilt. Identification of neutralizing antibodies from convalescent patient serum to emerging viral pathogens.
Erica Sapphire - Scripps. Identification and characterization of neutralizing antibodies.
Jonathan Abraham - Harvard. Antibodies to emerging viruses. Focus on deciphering roles of effector function for both neutralizing and non-neutralizing antibodies.
Mike Diamond - You know him well, but assessment of potential and combination of neutralizing antibodies to emerging viral pathogens.
Dean Petit - Just Biotherapeutics - an Evotec company. Antibody optimization and manufacturability. This is a critical aspect that I think is missing for the key roles captured in slide 3.
Rebecca Sendak - Global Head of Biologics for Sanofi. Antibody optimization and manufacturability. Same comment as above.

Best,
Kara

Kara Carter, PhD
Executive Vice President Infectious Disease
+1-617-763-6855 (Mobile)
kara.carter@evotec.com
www.evotec.com

-----Original Message-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Thursday, July 2, 2020 5:43 PM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson,

Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Kara Carter <Kara.Carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport, Jay <jrappaport@tulane.edu>; Stegmeier, Frank <fstegmeier@ksqtx.com>; Young, John <john.young.jy3@roche.com>
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: FW: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

[EXTERNAL]

Dear Preclinical Working group,

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Thank you,
Joe

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CLASSIFICATION: UNCLASSIFIED

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Thank you,
Nicole

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
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Cell- 240-586-0856
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Mail to: john.young.jy3@roche.com

PA: Gianni Micheloni
Phone +41 61 68 75840
Mobile +41 79 136 49 01
Mail to: gianni.micheloni@roche.com

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Cihlar, Tomas[Tomas.Cihlar@gilead.com]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Nancy Haigwood[haigwoon@ohsu.edu]
Sent: Sun 7/5/2020 4:18:16 PM (UTC-04:00)
Subject: Re: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Joe,
I believe I previously suggested to this group, or a subgroup:
James Crowe, Vanderbilt any of these roles, highly knowledgeable about antibodies from humans that are directed to all diseases
Erica Ollmann-Saphire (Erica Ollmann Saphire <erica@lji.org>), structural biologists who now has a new affiliation at La Jolla Institute for Immunology and leads a large antibody-based therapy consortium, would be great for the white paper, also an outstanding speaker
John Mascola at the VRC or Mark Connors at NIAID intramural, both human mAb experts.

Best wishes,
Nancy

On 7/2/20, 2:44 PM, "Menetski, Joseph (FNIH) [T]" <jmenetski@fnih.org> wrote:

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To: 'Menetski, Joseph (FNIH) [T]'[jmenetski@fnih.org]; 'Adams, Peter (OS/ASPR/BARDA)'[Peter.Adams@hhs.gov]; 'Alvarez, Rosa'[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; 'Carter, Kara'[kara.carter@evotec.com]; 'Charette, Marc (NIH/NHLBI) [E]'[marc.charette@nih.gov]; 'Cihlar, Tomas'[tomas.cihlar@gilead.com]; 'Colvis, Christine (NIH/NCATS) [E]'[christine.colvis@nih.gov]; 'Deming, Damon (FDA/CDER)'[damon.deming@fda.hhs.gov]; 'Diamond, Michael'[diamond@wusm.wustl.edu]; 'Duncan, Ken'[ken.duncan@gatesfoundation.org]; 'Fessel, Josh (NIH/NHLBI) [E]'[josh.fessel@nih.gov]; 'Florence, Clint (NIH/NIAID) [E]'[clint.florence@nih.gov]; 'Gadbois, Ellen (NIH/OD) [E]'[gadboisel@od.nih.gov]; 'Gatto, Greg'[ggatto@rti.org]; 'Grobler, Jay'[jay_grobler@merck.com]; 'Nancy Haigwood'[haigwoon@ohsu.edu]; 'Hewitt, Judith (NIH/NIAID) [E]'[jhewitt@niaid.nih.gov]; 'Jonson, Samantha (NIH/NCATS) [E]'[samantha.jonson@nih.gov]; 'Lutz, Cat'[Cat.Lutz@jax.org]; 'Nestle, Frank'[Frank.Nestle@sanofi.com]; 'Ottinger, Elizabeth (NIH/NCATS [E]'[elizabeth.ottinger@nih.gov]; 'Parker, Ashley (NIH/OD) [E]'[ashley.parker@nih.gov]; 'Payne, David'[david.j.payne@gsk.com]; 'Pitt, Louise'[margaret.l.pitt.civ@mail.mil]; 'Punturieri, Antonello (NIH/NHLBI) [E]'[punturieria@nhlbi.nih.gov]; 'Qashu, Felicia (NIH/OD) [E]'[felicia.qashu@nih.gov]; 'Rao, Srinivas'[Srinivas.Rao@sanofi.com]; 'Rappaport, Jay'[jrappaport@tulane.edu]; 'Stegmeier, Frank'[fstegmeier@ksqtx.com]; 'Young, John'[john.young.jy3@roche.com]
From: Prabha Fernandes[prabha.fernandes@gmail.com]
Sent: Sun 7/5/2020 4:33:55 PM (UTC-04:00)
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Hi Joe,
You have many names, but here are a couple from Infectious diseases expertise..
S. A. Plotkin, (Stanley.plotkin@vaxconsult.com). (Measles vaccine - immune response characterization)
Pamela Bjorkman, Caltech, bjorkman@caltech.edu. (Zika immune response)
Bali Pulendran, Institute for Immunity, Stanford. bpulend@stanford.edu (host factors, that impact immunity).

Regards,
Prabha
-----Original Message-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Thursday, July 02, 2020 5:43 PM
To: Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa <Annaliesa.Anderson@pfizer.com>; Baric, Ralph <rbaric@email.unc.edu>; Carter, Kara <kara.carter@evotec.com>; Charette, Marc (NIH/NHLBI) [E] <marc.charette@nih.gov>; Cihlar, Tomas <tomas.cihlar@gilead.com>; Colvis, Christine (NIH/NCATS) [E] <christine.colvis@nih.gov>; Deming, Damon (FDA/CDER) <damon.deming@fda.hhs.gov>; Diamond, Michael <diamond@wusm.wustl.edu>; Duncan, Ken <ken.duncan@gatesfoundation.org>; Fernandes, Prabhavathi <prabha.fernandes@gmail.com>; Fessel, Josh (NIH/NHLBI) [E] <josh.fessel@nih.gov>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Gadbois, Ellen (NIH/OD) [E] <gadboisel@od.nih.gov>; Gatto, Greg <ggatto@rti.org>; Grobler, Jay <jay_grobler@merck.com>; Nancy Haigwood <haigwoon@ohsu.edu>; Hewitt, Judith (NIH/NIAID) [E] <jhewitt@niaid.nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Lutz, Cat <Cat.Lutz@jax.org>; Nestle, Frank <Frank.Nestle@sanofi.com>; Ottinger, Elizabeth (NIH/NCATS [E] <elizabeth.ottinger@nih.gov>; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Payne, David <david.j.payne@gsk.com>; Pitt, Louise <margaret.l.pitt.civ@mail.mil>; Punturieri, Antonello (NIH/NHLBI) [E] <punturieria@nhlbi.nih.gov>; Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Rao, Srinivas <Srinivas.Rao@sanofi.com>; Rappaport,

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CLASSIFICATION: UNCLASSIFIED

To: Menetski, Joseph (FNIH) [T][jmenetski@fnih.org]; Adams, Peter (OS/ASPR/BARDA)[Peter.Adams@hhs.gov]; Alvarez, Rosa[rosalvarez@deloitte.com]; Anderson, Annaliesa[Annaliesa.Anderson@pfizer.com]; Baric, Ralph S[rbaric@email.unc.edu]; Carter, Kara[kara.carter@evotec.com]; Charette, Marc (NIH/NHLBI) [E][marc.charette@nih.gov]; Colvis, Christine (NIH/NCATS) [E][christine.colvis@nih.gov]; Deming, Damon (FDA/CDER)[damon.deming@fda.hhs.gov]; Diamond, Michael[diamond@wusm.wustl.edu]; Duncan, Ken[ken.duncan@gatesfoundation.org]; Fernandes, Prabhavathi[prabha.fernandes@gmail.com]; Fessel, Josh (NIH/NHLBI) [E][josh.fessel@nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Gadbois, Ellen (NIH/OD) [E][gadboisel@od.nih.gov]; Gatto, Greg[ggatto@rti.org]; Grobler, Jay[jay_grobler@merck.com]; Nancy Haigwood[haigwoon@ohsu.edu]; Hewitt, Judith (NIH/NIAID) [E][jhewitt@niaid.nih.gov]; Jonson, Samantha (NIH/NCATS) [E][samantha.jonson@nih.gov]; Lutz, Cat[Cat.Lutz@jax.org]; Nestle, Frank[Frank.Nestle@sanofi.com]; Ottinger, Elizabeth (NIH/NCATS [E][elizabeth.ottinger@nih.gov]; Parker, Ashley (NIH/OD) [E][ashley.parker@nih.gov]; Payne, David[david.j.payne@gsk.com]; Pitt, Louise[margaret.l.pitt.civ@mail.mil]; Punturieri, Antonello (NIH/NHLBI) [E][punturieria@nhlbi.nih.gov]; Qashu, Felicia (NIH/OD) [E][felicia.qashu@nih.gov]; Rao, Srinivas[Srinivas.Rao@sanofi.com]; Rappaport, Jay[jrappaport@tulane.edu]; Stegmeier, Frank[fstegmeier@ksqtx.com]; Young, John[john.young.jy3@roche.com]
From: Tomas Cihlar[Tomas.Cihlar@gilead.com]
Sent: Mon 7/6/2020 2:43:19 AM (UTC-04:00)
Subject: RE: OWS mAb Scientific Summit - SMEs recommendations (UNCLASSIFIED)

Dear Joe,
In addition to names already suggested, colleagues from NIH VRC should be considered namely John Mascola and Rick Koup; as well as perhaps more representatives from biotech - Kara suggested several, I would add Larry Zeitlin (MappBio CSO) and Ester Falconer (AbCellera Head of R&D).
Best regards, Tomas

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CLASSIFICATION: UNCLASSIFIED

Cc: William Dowling[william.dowling@cepi.net]; Mark Page[Mark.Page@nibsc.org]
From: GSELL, Pierre[gsellp@who.int]
Sent: Wed 7/8/2020 5:04:56 AM (UTC-04:00)
Subject: [COVID-19 Assays call] Today's agenda

Dear All,

Please see below the agenda of today's call.

1. Adrian McDermott, NIAID – Multiplex Assays
2. Mary Matheson, PHE – ELISA optimization

Thanks all for your continuous participation.
Kind regards

Pierre-Stéphane Gsell
Technical Officer
R&D Blueprint | Health Emergencies Programme | 1156
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From: Alvarez, Rosa Maria[rosalvarez@deloitte.com]
Sent: Wed 7/8/2020 9:13:47 AM (UTC-04:00)
Subject: RE: ACTIV Preclinical full working group

Hi all,

Please see below for today's agenda. Looking forward to our discussion at 10am.

Agenda Topic	Duration	Facilitator
Debrief from Leadership Meeting	5 mins	John Young
Discuss approach for preclinical development of combination therapies	15 mins	Christine Colvis
Debrief on NHP prioritization strategy updates	10 mins	Jim Anderson, Joe Menetski
Discuss potential plan for genotypic monitoring	10 mins	Tomas Cihlar, Marco Salemi
Sub Group Updates	15 mins	Sub Group Leads
Align on action items and next steps	5 mins	Joe Menetski Rosa Alvarez

Best regards,
Joe and Rosa

-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Sent: Tuesday, April 14, 2020 6:44 PM
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Subject: ACTIV Preclinical full working group
When: Wednesday, July 8, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://fnih.zoom.us/j/96042403854?pwd=NEdrbGRvUjBPMVZLUjhCY2RqR0Q2QT09

Meeting ID: 960 4240 3854
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Password: 124630
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v.E.1

To: Carter Mecher[cmecher@charter.net]; Dr. Eva Lee[eva.evalee.lee64@gmail.com]
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From: Mark Keim, MD MBA[mark@disasterdoc.org]
Sent: Wed 7/8/2020 11:28:32 AM (UTC-04:00)
Subject: Mischaracterization of COVID19 transmission as droplet-based

Colleagues,

Sharing this pertinent correspondence with the group. Feel free to forward.

-Mark-

From: Mark Keim, MD MBA
Sent: Wednesday, July 8, 2020 11:00 AM
To:
Cc:
Subject: RE: Question?

Hi Bill,

I'd be happy to address the issue from the perspective of an environmental and occupational health scientist (as compared to a communicable disease scientist).

I apologize for speaking up briefly at the end of your last webinar but I felt that some of the statements being made regarding the "unknown" effectiveness of cloth facemasks and how their protection is indistinguishable from that of N95 respirators were somewhat misleading and based more upon media reports than scientific data. I along with others, also feel that US business is being hamstrung by this approach because it ignores PPE as an opportunity to partially reopen at least some of the more densely populated commercial environments (e.g. offices, sales, airlines, hotels).

As I mentioned during the webinar, the fundamental mistake is that SARS-COV2 transmission has been miscategorized as a droplet-based instead of an airborne agent. This is a BIG deal because the way we prevent infections is different for the two. Droplet precautions require facemasks (that shield your mouth and nose but don't filter air). They don't stop most respiratory viruses, like measles, chickenpox, smallpox, etc. Droplet precautions also invoke the 6 foot rule for distancing. In comparison, N95 masks are designed to filter air for breathing at a 95% efficiency and stop all major respiratory viruses. People (even some excellent but

poorly informed epidemiologists) attribute this to some illogical assumption that masks don't work. That's absurd considering the tight OSAH regs that have been in place for millions of workers wearing N95's over decades. They are called N95's because they are 95% effective in filtering the air for particulates of a certain size of greater. In addition to pore size, N95's filter and hold COVID19 particulates through electrostatic qualities imparted by the polypropylene polymers (PPP) integrated within the respirator.

For many of us involved in environmental health issues or may have had to deal with this issue of masks before during anthrax, this information regarding airborne transmission is hardly surprising. We base our decisions on a 30 year old model called "transmission-based precautions" that are the foundation of infection control for all healthcare settings in the world. This includes not only a study of the infectious disease itself (like most infectious disease specialists do) but also involves an environmental component in the analysis involving he physics of transmission, not merely the biology, so to speak. Our colleagues at USAMRIID also understand these issues very well - some of them remain classified.

While others in public health may have not fully appreciated this interaction between agent, environment and host, it is the foundation of environmental health. So, to date, our understanding of the environmental transmission of chemicals, smoke, radiation, particulates AND viruses is actually very good. For example, the recent observation published in the March 2020 Journal of American Medical Association (JAMA) regarding the airborne travel of COVID19 23-27 feet surprised everyone this year. But it was actually a review of prior work done by MIT and published in the Journal of Fluid Mechanics in 2014!

So then came these early worrisome indicators that COVID19 was transmissible as an asymptomatic carrier. This told me that EVERYONE should wear an N95 until proven otherwise. This is the fundamental rule of "respiratory protection logic" as administered by occupational health experts.
We always assume a higher level of personal protection until a lower level of protection is proven adequate. For example, in hazmat, we start out in level A ("moonsuits") until we measure ambient oxygen levels and identify the agent. The we move down to level B, level C, etc. (PS. I bought my N100 on Feb 5)

Feb 19, 2020 Lancet - Asymptomatic cases in a family cluster with SARS-CoV-2 infection

And right away came the US Surgeon General's first fateful tweet that some have deemed as "public health malpractice".

Feb 29, 2020 U.S. Surgeon General @Surgeon General - Feb 29
"Seriously people- STOP BUYING MASKS!
They are NOT effective in preventing general public from catching #Coronavirus, but if healthcare providers can't get them to care for sick patients, it puts them and our communities at risk! http://bit.ly/37Ay6Cm"

Then came early indications that COVID, was indeed, airborne.

March 4, 2020 Ong et al. JAMA – Swabs taken from the air exhaust outlets tested positive, suggesting that small virus-laden droplets may be displaced by airflows and deposited on equipment such as vents.

March 19 WHO recommends N95 (FFP2) masks for healthcare and community settings

March 26 Potential Implications for Reducing Transmission of COVID-19
JAMA articles reminds us of the 2014 MIT study that found micro-droplets travel 23-27 feet

This month, a group of 239 scientists representing 32 countries is reportedly preparing to ask the World Health Organization (WHO) to revise its recommendations for the novel coronavirus due to evidence it says supports the claim the disease is airborne. https://thehill.com/policy/healthcare/505936-hundreds-of-scientists-write-letter-to-who-arguing-coronavirus-is-airborne

I offer this as background for my current thinking and what I would be willing to share with the group. In addition, I also have the perspective that the actual sources of transmission among this younger demographic remain unclear. While it's easy to attribute it to "partying" without social distancing, we could also be seeing a failure of our social distancing and mask policies in the workplace that is confounded other activities among that age group. As a doctor, I wear an N95 mask to protect myself from someone that I know has COVID or measles or chicken pox – anywhere in the room, not merely 6 feet. Why would I not want my young employee to do so, when the cost/benefit ratio is so low and the public health consequences are so high to society?

Sorry for the opus. Hope this helps you to add context to the event from my own personal perspective.

Mark

Mark Keim, MD, MBA
CEO, DisasterDoc, LLC
www.disasterdoc.org

Cc: William Dowling[william.dowling@cepi.net]; Mark Page[Mark.Page@nibsc.org]
From: GSELL, Pierre[gsellp@who.int]
Sent: Wed 7/15/2020 6:55:21 AM (UTC-04:00)
Subject: RE: [COVID-19 Assays call] Today's agenda

Dear All,

Please see below the agenda of today's call.

1. Eric van Gieson , DARPA, host signatures
2. Supaporn Phumiamorn , IBP Thailand , Serology methods
3. Data collection on virus propagation
4. D614 and G614 Spike Assays
5. Open discussion

Thanks all for your continuous participation.
Kind regards

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To: sandra cordo[scordo@qb.fcen.uba.ar]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; Vasan Vasan[Vasan.Vasan@csiro.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; Alyson Kelvin[AKelvin@dal.ca]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; 秦川[qinchuan@pumc.edu.cn]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; Roger Le[roger.le-grand@cea.fr]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Martin Beer[Martin.Beer@fli.de]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Pierre Gsell[gsellp@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; KNEZEVIC, Ivana[knezevici@who.int]; moorthyv@who.int[moorthyv@who.int]; preziosim@who.int[preziosim@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; amy.c.shurtleff@cepi.net[amy.c.shurtleff@cepi.net]; swaminathans@who.int[swaminathans@who.int]; Chi Van Dang[cdang@lcr.org]; woodd@who.int[woodd@who.int]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; Nir Paran[nirp@iibr.gov.il]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; ldenisy@yahoo.com[ldenisy@yahoo.com]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; sekim@krict.re.kr[sekim@krict.re.kr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Quim Segales[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; tverakit@gmail.com[tverakit@gmail.com]; rkiatchula@gmail.com[rkiatchula@gmail.com]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; B. 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Rockx[b.rockx@erasmusmc.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; Neil Berry[Neil.Berry@nibsc.org]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Simon Funnell[Simon.Funnell@phe.gov.uk]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; Mark Page[Mark.Page@nibsc.org]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Randy Albrecht[randy.albrecht@mssm.edu]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Dan Barouch[dbarouch@bidmc.harvard.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; Cartner, Samuel Corbin[scartner@uab.edu]; fcassels@path.org[fcassels@path.org]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; que.dang@nih.gov[que.dang@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Erik Dohm[edohm@uab.edu]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Duprex, Paul[pduprex@pitt.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; clint.florence@nih.gov[clint.florence@nih.gov]; Flynn, Joanne L[joanne@pitt.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; Matthew Frieman[MFrieman@som.umaryland.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; golinger@mriglobal.org[golinger@mriglobal.org]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; Griffiths, Anthony[ahgriff@bu.edu]; Geraldine Hamilton[geraldine.hamilton@emulatebio.com]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Amelia Karlsson[amelia.karlsson@duke.edu]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; fkoide@southernresearch.org[fkoide@southernresearch.org]; Krammer, Florian[florian.krammer@mssm.edu];

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From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 7/16/2020 6:02:50 AM (UTC-04:00)
Subject: WHO Animal Models Call July 16 2020-Agenda and Webex Invite
Mail Attachment.ics
Webex_Meeting.ics

Dear all,

Please find below the agenda and webex invite for our group call this week.

Best regards

César, Bill and Simon.

Agenda July 16 2020

Pathogenesis

1- Sara Johnston (USAMRIID)

2- Lisa Gralinski (UNC)

3- Nicolas Meunier (INRA-Biotechnologies)

Vaccines

1- Kiat Ruxrungtham - Chulalongkorn University

Open questions

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 528 4668
Meeting password: ePxbxWky224

Thursday, July 16, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Tap to join from a mobile device (attendees only)

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Need help? Go to http://help.webex.com

Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] WHO 20th TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=me102d00515127a146f173067cb6346a8
Start Time: 2020-07-16T15:00:00+02:00
End Time: 2020-07-16T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

When it's time, join the Webex meeting here.

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From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; georges.benjamin@apha.org; susan.polan@apha.org; drnickilurie@gmail.com; cdelrio@emory.edu; Ogilvie, Jenna; SharonInouye@hsl.harvard.edu; lcdegutis@gmail.com; acasadevall@jhu.edu; ushah@hcphes.org; gostin@georgetown.edu; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; Andy.Pavia@hsc.utah.edu; Umair.Shah@phs.hctx.net; acasade1@jhu.edu; ajha@hsph.harvard.edu; jeffrey.gold@unmc.edu; Elizabeth.Perez@phs.hctx.net; Tony.Castaneda@phs.hctx.net; Heidi.Larson@LSHTM.ac.uk; donburke@pitt.edu; tinglesby@jhu.edu; Baric, Ralph S; Baric, Toni C; mjasen1@jhu.edu

Location: zoom (see below)

Importance: Normal

Subject: NAM-APHA webinar series advisory group meetings

Start Time: Fri 7/31/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 7/31/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; georges.benjamin@apha.org; susan.polan@apha.org; drnickilurie@gmail.com; cdelrio@emory.edu; Ogilvie, Jenna; SharonInouye@hsl.harvard.edu; lcdegutis@gmail.com; acasadevall@jhu.edu; ushah@hcphes.org; gostin@georgetown.edu; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; Andy.Pavia@hsc.utah.edu; Umair.Shah@phs.hctx.net; acasade1@jhu.edu; ajha@hsph.harvard.edu; jeffrey.gold@unmc.edu; Elizabeth.Perez@phs.hctx.net; Tony.Castaneda@phs.hctx.net; Heidi.Larson@LSHTM.ac.uk; donburke@pitt.edu; tinglesby@jhu.edu; Baric, Ralph S; Baric, Toni C; mjasen1@jhu.edu

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Meeting: NAM-APHA COVID-19 Webinar Series
Time:
Every week on Fri, until Sep 25, 2020, 10 occurrence(s)
Jul 31, 2020 02:00 PM
Aug 7, 2020 02:00 PM
Aug 14, 2020 02:00 PM
Aug 21, 2020 02:00 PM
Aug 28, 2020 02:00 PM
Sep 4, 2020 02:00 PM
Sep 11, 2020 02:00 PM
Sep 18, 2020 02:00 PM
Sep 25, 2020 02:00 PM
Please download and import the following iCalendar (.ics) files to your calendar system.
Weekly: https://nasem.zoom.us/meeting/uJYrce-oqTMqFSiiy_lbDfo_TtNsKl4ZGg/ics?icsToken=98tyKuyqqD0sGtOdsFz9a7QqE8Hib8_Mk1d9o6pEoxPnJyZcXTfiGPFpPuZFN9-B

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Meeting ID: 526 660 780
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Organizer: DeStefano, Laura[LDestefano@nas.edu]

From: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; georges.benjamin@apha.org; susan.polan@apha.org; drnickilurie@gmail.com; cdelrio@emory.edu; Ogilvie, Jenna; SharonInouye@hsl.harvard.edu; lcdegutis@gmail.com; acasadevall@jhu.edu; ushah@hcphes.org; gostin@georgetown.edu; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; Andy.Pavia@hsc.utah.edu; Umair.Shah@phs.hctx.net; acasade1@jhu.edu; ajha@hsph.harvard.edu; jeffrey.gold@unmc.edu; Elizabeth.Perez@phs.hctx.net; Tony.Castaneda@phs.hctx.net; Heidi.Larson@LSHTM.ac.uk; donburke@pitt.edu; tinglesby@jhu.edu; Baric, Ralph S; Baric, Toni C; mjasen1@jhu.edu

Location: zoom (see below)

Importance: Normal

Subject: Canceled: NAM-APHA webinar series advisory group meetings

Start Time: Fri 7/31/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 7/31/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; georges.benjamin@apha.org; susan.polan@apha.org; drnickilurie@gmail.com; cdelrio@emory.edu; Ogilvie, Jenna; SharonInouye@hsl.harvard.edu; lcdegutis@gmail.com; acasadevall@jhu.edu; ushah@hcphes.org; gostin@georgetown.edu; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; Andy.Pavia@hsc.utah.edu; Umair.Shah@phs.hctx.net; acasade1@jhu.edu; ajha@hsph.harvard.edu; jeffrey.gold@unmc.edu; Elizabeth.Perez@phs.hctx.net; Tony.Castaneda@phs.hctx.net; Heidi.Larson@LSHTM.ac.uk; donburke@pitt.edu; tinglesby@jhu.edu; Baric, Ralph S; Baric, Toni C; mjasen1@jhu.edu

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Dial(for higher quality, dial a number based on your current location) :
US: +1 470 250 9358 or +1 646 518 9805 or +1 646 558 8656 or +1 651 372 8299 or +1 301 715 8592 or +1 312 626 6799 or +1 720 928 9299 or +1 971 247 1195 or +1 213 338 8477 or +1 253 215 8782 or +1 602 753 0140 or +1 669 219 2599 or +1 669 900 6833 or 877 853 5257 (Toll Free) or 888 475 4499 (Toll Free)
Meeting ID: 526 660 780

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Organizer: DeStefano, Laura[LDestefano@nas.edu]

Attendees: Dzau, Victor J.; georges.benjamin@apha.org; Ogilvie, Jenna; Rimer, Barbara; SharonInouye@hsl.harvard.edu; susan.polan@apha.org; drnickilurie@gmail.com; cdelrio@emory.edu; lcdegutis@gmail.com; acasadevall@jhu.edu; ushah@hcphes.org; gostin@georgetown.edu; Figueroa, Angelica M; Croitoru, Grace Nicole; Andy.Pavia@hsc.utah.edu; Umair.Shah@phs.hctx.net; acasade1@jhu.edu; ajha@hsph.harvard.edu; jeffrey.gold@unmc.edu; Elizabeth.Perez@phs.hctx.net; Tony.Castaneda@phs.hctx.net; Heidi.Larson@LSHTM.ac.uk; donburke@pitt.edu; tinglesby@jhu.edu; Baric, Ralph S; Baric, Toni C; mjasen1@jhu.edu

Start Time: Fri 7/31/2020 2:00:00 PM (UTC-04:00)

End Time: Fri 7/31/2020 3:00:00 PM (UTC-04:00)

Required Attendees: Dzau, Victor J.; georges.benjamin@apha.org; Ogilvie, Jenna; Rimer, Barbara; SharonInouye@hsl.harvard.edu; susan.polan@apha.org; drnickilurie@gmail.com; cdelrio@emory.edu; lcdegutis@gmail.com; acasadevall@jhu.edu; ushah@hcphes.org; gostin@georgetown.edu; Figueroa, Angelica M; Croitoru, Grace Nicole; Andy.Pavia@hsc.utah.edu; Umair.Shah@phs.hctx.net; acasade1@jhu.edu; ajha@hsph.harvard.edu; jeffrey.gold@unmc.edu; Elizabeth.Perez@phs.hctx.net; Tony.Castaneda@phs.hctx.net; Heidi.Larson@LSHTM.ac.uk; donburke@pitt.edu; tinglesby@jhu.edu; Baric, Ralph S; Baric, Toni C; mjasen1@jhu.edu

We look forward to chatting with you all at 2 pm today! Please see the agenda below.

AGENDA

- Debrief from 7/29 webinar (Preparing for Surges)
- Update on 8/12 webinar (Reopening K-12)
- Planning the remainder of the series
  - Flu
  - Building a stronger health system

Hi there,

Laura DeStefano is inviting you to a scheduled Zoom meeting.

Topic: Advisory Group Meeting: NAM-APHA COVID-19 Webinar Series
Time:
Every week on Fri, until Sep 25, 2020, 10 occurrence(s)
Jul 31, 2020 02:00 PM
Aug 7, 2020 02:00 PM
Aug 14, 2020 02:00 PM
Aug 21, 2020 02:00 PM
Aug 28, 2020 02:00 PM
Sep 4, 2020 02:00 PM
Sep 11, 2020 02:00 PM
Sep 18, 2020 02:00 PM
Sep 25, 2020 02:00 PM
Please download and import the following iCalendar (.ics) files to your calendar system.
Weekly: https://nasem.zoom.us/meeting/uJYrce-oqTMqFSiiy_lbDfo_TtNsKl4ZGg/ics?icsToken=98tyKuyqqD0sGtOdsFz9a7QqE8Hib8_Mk1d9o6pEoxPnJyZcXTfiGPFpPuZFN9-B

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Meeting ID: 526 660 780
International numbers available: https://nasem.zoom.us/u/ajbU8GFhe

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Organizer: DeStefano, Laura[LDestefano@nas.edu]
Importance: Normal
Subject: Canceled: NAM-APHA webinar series advisory group meetings
Start Time: Fri 8/14/2020 2:00:00 PM (UTC-04:00)
End Time: Fri 8/14/2020 3:00:00 PM (UTC-04:00)
Required Attendees: Dzau, Victor J.; georges.benjamin@apha.org; susan.polan@apha.org; drnickilurie@gmail.com; cdelrio@emory.edu; Ogilvie, Jenna; SharonInouye@hsl.harvard.edu; lcdegutis@gmail.com; acasadevall@jhu.edu; ushah@hcphes.org; gostin@georgetown.edu; Figueroa, Angelica M; Croitoru, Grace Nicole; Rimer, Barbara; Andy.Pavia@hsc.utah.edu; Umair.Shah@phs.hctx.net; acasade1@jhu.edu; ajha@hsph.harvard.edu; jeffrey.gold@unmc.edu; Elizabeth.Perez@phs.hctx.net; Tony.Castaneda@phs.hctx.net; Heidi.Larson@LSHTM.ac.uk; donburke@pitt.edu; tinglesby@jhu.edu; Baric, Ralph S; Baric, Toni C; mjasen1@jhu.edu

Hi all – apologies for my misuse of Zoom which resulted in this meeting appearing on your calendar EVERY Friday. The meeting is currently scheduled for every other week, on the following dates:

August 14, August 28, September 11, September 25

Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/526660780

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Meeting ID: 526 660 780
International numbers available: https://nasem.zoom.us/u/ajbU8GFhe

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Organizer: Pierre GSELL[gsellp@who.int]

From: Pierre GSELL[gsellp@who.int]

Attendees: sandra cordo; Pearl.Bamford@health.gov.au; kanta.subbarao@influenzacentre.org; Vasan Vasan; Jin.Zhu@health.gov.au; kristine.macartney@health.nsw.gov.au; Kai Dallmeier; Johan Neyts; Alyson Kelvin; Darryl Falzarano; Volker.gerdts@usask.ca; Hodgson, Paul; dustin.johnson@canada.ca; Jason Kindrachuk; darwyn.kobasa@canada.ca; Gary Kobinger; Li, Sean (HC/SC); dean.smith@canada.ca; 秦川; shanchao@wh.iov.cn; kandeil_a@hotmail.com; Marco.Cavaleri@ema.europa.eu; mariette.ducatez@envt.fr; christiane.gerke@pasteur.fr; Roger Le; LESELLIER Sandrine; Pauline Maisonnasse; romain.volmer@envt.fr; Martin Beer; CarlosAlberto.Guzman@helmholtz-hzi.de; Kerscher, Bernhard; kupke@staff.uni-marburg.de; Mettenleiter, Thomas C.; Cesar Munoz-Fontela; Estefania Bni; Barbara.Schnierle@pei.de; sutter@micro.vetmed.uni-muenchen.de; Carolyn Clark; William Dowling; HENAO RESTREPO, Ana Maria; KNEZEVIC, Ivana; moorthyv@who.int; preziosim@who.int; RIVEROS BALTA, Alina Ximena; amy.c.shurtleff@cepi.net; swaminathans@who.int; Chi Van Dang; woodd@who.int; jfwchan; hlchen@hku.hk; anna@thsti.res.in; Nir Paran; tomeri@iibr.gov.il; nnagata@niid.go.jp; tksuzuki@nih.go.jp; s.a.arakelov@spbniivs.ru; i.v.krasilnikov@spbniivs.ru; ldenisy@yahoo.com; y.m.vasiliev@spbniivs.ru; danielle.anderson@duke-nus.edu.sg; sekim@krict.re.kr; seungtaek.kim@ip-korea.org; mksong@ivi.int; Luis Enjuanes; Mariano Esteban Rodriguez; JUAN FRANCISCO GARCIA ARRIAZA; Quim Segales; Vergara, Julia; Ali.Mirazimi@folkhalsomyndigheten.se; Paul.Lambert@unige.ch; tverakit@gmail.com; rkiatchula@gmail.com; suchinda.m@chula.ac.th; jorgen.de.jonge@rivm.nl; nora.gerhards@wur.nl; B. Haagmans; Kortekaas, Jeroen; langermans@bprc.nl; Nadia Oreshkova; B. Rockx; Koert Stittelaar; wim.vanderpoel@wur.nl; Neil Berry; Miles Carroll; Simon Funnell; fgrey@exseed.ed.ac.uk; Yper Hall; REIRELAND@mail.dstl.gov.uk; MSLEVER@dstl.gov.uk; Giada.Mattiuzzo@nibsc.org; philip.minor2@gmail.com; muhammad.munir@lancaster.ac.uk; MNELSON@mail.dstl.gov.uk; Mark Page; JLPRIOR@dstl.gov.uk; Ann Rawkins; Nicola.Rose@nibsc.org; Javier Salguero; Sally Sharpe; J.P.Stewart@liverpool.ac.uk; Julia Tree; Randy Albrecht; Martha.Alexander-Miller@wakehealth.edu; Baric, Ralph S; Dan Barouch; sinabavari@comcast.net; terry.k.besch.ctr@mail.mil; Angela Bosco-Lauth; trbrasel@utmb.edu; abukreye@utmb.edu; Ricardo Carrion, Jr.; Cartner, Samuel Corbin; fcassels@path.org; MONALISA.CHATTERJI@gatesfoundation.org; Crozier, Ian (NIH) [C]; que.dang@nih.gov; De wit, Emmie (NIH/NIAID) [E]; Erik Dohm; Ruben.Donis@hhs.gov; Duprex, Paul; mmeitzen@utmb.edu; Karl.Erlandson@hhs.gov; Feldmann, Heinrich (NIH/NIAID) [E]; clint.florence@nih.gov; Flynn, Joanne L; thomasf@primate.wisc.edu; Matthew Frieman; Adolfo Garcia-Sastre; golinger@mriglobal.org; Hana.Golding@fda.hhs.gov; barney.graham@nih.gov; Gralinski, Lisa E; Griffiths, Anthony; Geraldine Hamilton; kevinharrod@uabmc.edu; Hensley, Lisa (NIH/NIAID) [E]; sheri.hild@nih.gov; christian.c.hofer.mil@mail.mil; Michael.holbrook@nih.gov; Lakshmi.Jayashankar@hhs.gov; Amelia Karlsson; Jacqueline.Kirchner@gatesfoundation.org; Harry.Kleanthous@gatesfoundation.org; fkoide@southernresearch.org; Krammer, Florian; philip.krause@fda.hhs.gov; mary.lane@nih.gov; Lee-Parritz, David; robin.levis@fda.hhs.gov; Dr. Mark Lewis; grace.m.lidl.mil@mail.mil; Little, James (OS/ASPR/BARDA); MacGill, Tracy; Karen.Makar@gatesfoundation.org; paul-mccray@uiowa.edu; cjmiller@ucdavis.edu; woodd@who.int, jfwchan <jfwchan@hku.hk> , hlchen@hku.hk, anna@thsti.res.in, nnagata@niid.go.jp, tksuzuki@nih.go.jp, ldenisy@yahoo.com, y.m.vasiliev@spbniivs.ru, s.a.arakelov@spbniivs.ru, i.v.krasilnikov@spbniivs.ru, danielle.anderson@duke-nus.edu.sg, sekim@krict.re.kr, seungtaek.kim@ip-korea.org, mksong@ivi.int, Mariano Esteban Rodriguez <mesteban@cnb.csic.es>, JUAN FRANCISCO GARCIA ARRIAZA <jfgarcia@cnb.csic.es>, Luis Enjuanes <l.enjuanes@cnb.csic.es>, Quim Segales <joaquim.segales@irta.cat>, Vergara Julia; Kayvon Modjarrad; Munster, Vincent (NIH/NIAID) [E]; aysegul.nalca.civ@mail.mil; DAVID H O'CONNOR; gustavo.palacios@gmail.com; Stanley Perlman; pickettte@niaid.nih.gov; margaret.l.pitt.civ@mail.mil; troyrandall@uabmc.edu; Angela Rasmussen; dsreed@cvr.pitt.edu; drevelli@lovelacebiomedical.org; Juergen Richt; Chad Roy; Carol.Sabourin@hhs.gov; Padmini Salgame; erica@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Michael Schotsaert; sivkog@battelle.org; Spergel, Jonathan; erik.stemmy@nih.gov; nax3@cdc.gov; John.Treanor@hhs.gov; john.c.trefry.civ@mail.mil; sktseng@utmb.edu; luk_vandenberghe@meei.harvard.edu; David.Vaughn@gatesfoundation.org; Wang, Tony; renee.wegrzyn@darpa.mil; White, Alexander G; jay.w.hooper.civ@mail.mil

Location: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70

Importance: Normal

Subject: FW: Webex meeting invitation: [COVID-19] 21th WHO TC - Animal Models

Start Time: Thur 7/23/2020 9:00:00 AM (UTC-04:00)

End Time: Thur 7/23/2020 10:30:00 AM (UTC-04:00)

Required Attendees: sandra cordo; Pearl.Bamford@health.gov.au; kanta.subbarao@influenzacentre.org; Vasan Vasan; Jin.Zhu@health.gov.au; kristine.macartney@health.nsw.gov.au; Kai Dallmeier; Johan Neyts; Alyson Kelvin; Darryl Falzarano; Volker.gerdts@usask.ca; Hodgson, Paul; dustin.johnson@canada.ca; Jason Kindrachuk; darwyn.kobasa@canada.ca; Gary Kobinger; Li, Sean (HC/SC); dean.smith@canada.ca; 秦川; shanchao@wh.iov.cn; kandeil_a@hotmail.com; Marco.Cavaleri@ema.europa.eu; mariette.ducatez@envt.fr; christiane.gerke@pasteur.fr; Roger Le; LESELLIER Sandrine; Pauline Maisonnasse; romain.volmer@envt.fr;

Martin Beer; CarlosAlberto.Guzman@helmholtz-hzi.de; Kerscher, Bernhard; kupke@staff.uni-marburg.de; Mettenleiter, Thomas C.; Cesar Munoz-Fontela; Estefania Bni; Barbara.Schnierle@pei.de; sutter@micro.vetmed.uni-muenchen.de; Carolyn Clark; William Dowling; HENAO RESTREPO, Ana Maria; KNEZEVIC, Ivana; moorthyv@who.int; preziosim@who.int; RIVEROS BALTA, Alina Ximena; amy.c.shurtleff@cepi.net; swaminathans@who.int; Chi Van Dang; woodd@who.int; jfwchan; hlchen@hku.hk; anna@thsti.res.in; Nir Paran; tomeri@iibr.gov.il; nnagata@niid.go.jp; tksuzuki@nih.go.jp; s.a.arakelov@spbniivs.ru; i.v.krasilnikov@spbniivs.ru; ldenisy@yahoo.com; y.m.vasiliev@spbniivs.ru; danielle.anderson@duke-nus.edu.sg; sekim@krict.re.kr; seungtaek.kim@ip-korea.org; mksong@ivi.int; Luis Enjuanes; Mariano Esteban Rodriguez; JUAN FRANCISCO GARCIA ARRIAZA; Quim Segales; Vergara, Julia; Ali.Mirazimi@folkhalsomyndigheten.se; Paul.Lambert@unige.ch; tverakit@gmail.com; rkiatchula@gmail.com; suchinda.m@chula.ac.th; jorgen.de.jonge@rivm.nl; nora.gerhards@wur.nl; B. Haagmans; Kortekaas, Jeroen; langermans@bprc.nl; Nadia Oreshkova; B. Rockx; Koert Stittelaar; wim.vanderpoel@wur.nl; Neil Berry; Miles Carroll; Simon Funnell; fgrey@exseed.ed.ac.uk; Yper Hall; REIRELAND@mail.dstl.gov.uk; MSLEVER@dstl.gov.uk; Giada.Mattiuzzo@nibsc.org; philip.minor2@gmail.com; muhammad.munir@lancaster.ac.uk; MNELSON@mail.dstl.gov.uk; Mark Page; JLPRIOR@dstl.gov.uk; Ann Rawkins; Nicola.Rose@nibsc.org; Javier Salguero; Sally Sharpe; J.P.Stewart@liverpool.ac.uk; Julia Tree; Randy Albrecht; Martha.Alexander-Miller@wakehealth.edu; Baric, Ralph S; Dan Barouch; sinabavari@comcast.net; terry.k.besch.ctr@mail.mil; Angela Bosco-Lauth; trbrasel@utmb.edu; abukreye@utmb.edu; Ricardo Carrion, Jr.; Cartner, Samuel Corbin; fcassels@path.org; MONALISA.CHATTERJI@gatesfoundation.org; Crozier, Ian (NIH) [C]; que.dang@nih.gov; De wit, Emmie (NIH/NIAID) [E]; Erik Dohm; Ruben.Donis@hhs.gov; Duprex, Paul; mmeitzen@utmb.edu; Karl.Erlandson@hhs.gov; Feldmann, Heinrich (NIH/NIAID) [E]; clint.florence@nih.gov; Flynn, Joanne L; thomasf@primate.wisc.edu; Matthew Frieman; Adolfo Garcia-Sastre; golinger@mriglobal.org; Hana.Golding@fda.hhs.gov; barney.graham@nih.gov; Gralinski, Lisa E; Griffiths, Anthony; Geraldine Hamilton; kevinharrod@uabmc.edu; Hensley, Lisa (NIH/NIAID) [E]; sheri.hild@nih.gov; christian.c.hofer.mil@mail.mil; Michael.holbrook@nih.gov; Lakshmi.Jayashankar@hhs.gov; Amelia Karlsson; Jacqueline.Kirchner@gatesfoundation.org; Harry.Kleanthous@gatesfoundation.org; fkoide@southernresearch.org; Krammer, Florian; philip.krause@fda.hhs.gov; mary.lane@nih.gov; Lee-Parritz, David; robin.levis@fda.hhs.gov; Dr. Mark Lewis; grace.m.lidl.mil@mail.mil; Little, James (OS/ASPR/BARDA); MacGill, Tracy; Karen.Makar@gatesfoundation.org; paul-mccray@uiowa.edu; cjmiller@ucdavis.edu; woodd@who.int, jfwchan <jfwchan@hku.hk> , hlchen@hku.hk, anna@thsti.res.in, nnagata@niid.go.jp, tksuzuki@nih.go.jp, ldenisy@yahoo.com, y.m.vasiliev@spbniivs.ru, s.a.arakelov@spbniivs.ru, i.v.krasilnikov@spbniivs.ru, danielle.anderson@duke-nus.edu.sg, sekim@krict.re.kr, seungtaek.kim@ip-korea.org, mksong@ivi.int, Mariano Esteban Rodriguez <mesteban@cnb.csic.es>, JUAN FRANCISCO GARCIA ARRIAZA <jfgarcia@cnb.csic.es>, Luis Enjuanes <l.enjuanes@cnb.csic.es>, Quim Segales <joaquim.segales@irta.cat>, Vergara Julia; Kayvon Modjarrad; Munster, Vincent (NIH/NIAID) [E]; aysegul.nalca.civ@mail.mil; DAVID H O'CONNOR; gustavo.palacios@gmail.com; Stanley Perlman; pickettte@niaid.nih.gov; margaret.l.pitt.civ@mail.mil; troyrandall@uabmc.edu; Angela Rasmussen; dsreed@cvr.pitt.edu; drevelli@lovelacebiomedical.org; Juergen Richt; Chad Roy; Carol.Sabourin@hhs.gov; Padmini Salgame; erica@lji.org; Schmaljohn, Connie (NIH/NIAID) [E]; Michael Schotsaert; sivkog@battelle.org; Spergel, Jonathan; erik.stemmy@nih.gov; nax3@cdc.gov; John.Treanor@hhs.gov; john.c.trefry.civ@mail.mil; sktseng@utmb.edu; luk_vandenberghe@meei.harvard.edu; David.Vaughn@gatesfoundation.org; Wang, Tony; renee.wegrzyn@darpa.mil; White, Alexander G; jay.w.hooper.civ@mail.mil

Webex_Meeting.ics

Dear WHO telecon participants,
Please find attached the agenda for this week's Thursday WHO infection models working group.
We look forward to your participation in another interesting up-date from multiple groups.
Regards,
Simon, Cesar and Bill.

Agenda
21st telecon of the WHO's COVID-19 infection models working group

23rd JULY 2020 at 15:00 CET

Pathogenesis

1. Jurgen Richt (KSU).
2. Quim Segales (IRTA-CRcSA)
3. Dan Barouch (HMFP/DVR)

Vaccines and therapeutics

4. Barney Graham (NIH/VRC)

Open questions

5. Working stock survey
6. Open questions

-----Original Appointment-----
From: Pierre GSELL <gsellp@who.int>
Sent: 19 July 2020 21:12
To: Pierre GSELL; Simon Funnell
Subject: Webex meeting invitation: [COVID-19] 21th WHO TC - Animal Models
When: 23 July 2020 15:00-16:30 Europe/Paris.
Where: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 140 7103

Meeting password: QgrNJmqU793

Thursday, July 23, 2020

3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Tap to join from a mobile device (attendees only)

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You can also dial 173.243.2.68 and enter your meeting number.

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 21th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70
Start Time: 2020-07-23T15:00:00+02:00
End Time: 2020-07-23T16:30:00+02:00
Attendees: Simon.Funnell@phe.gov.uk : Simon.Funnell@phe.gov.uk

When it's time, join the Webex meeting here.

Meeting number (access code): 145 140 7103
Meeting password:QgrNJmqU793

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To: 'Sharon Inouye'[SharonInouye@hsl.harvard.edu]; 'Linda Degutis'[lcdegutis@gmail.com]; 'acasadevall@jhu.edu'[acasadevall@jhu.edu]; 'ushah@hcphes.org'[ushah@hcphes.org]; 'Lawrence Gostin'[gostin@georgetown.edu]; Figueroa, Angelica M[amfiguer@email.unc.edu]; Croitoru, Grace Nicole[gracenc@email.unc.edu]; Rimer, Barbara[brimer@unc.edu]; 'Andy Pavia'[Andy.Pavia@hsc.utah.edu]; 'Shah, Umair MD (PHS)'[Umair.Shah@phs.hctx.net]; 'Arturo Casadevall'[acasade1@jhu.edu]; 'Jha, Ashish'[ajha@hsph.harvard.edu]; 'Gold, Jeffrey P'[jeffrey.gold@unmc.edu]; 'Perez, Elizabeth (PHS)'[Elizabeth.Perez@phs.hctx.net]; 'Castaneda, Tony (PHS)'[Tony.Castaneda@phs.hctx.net]; 'Heidi Larson'[Heidi.Larson@LSHTM.ac.uk]; 'Burke, Donald S'[donburke@pitt.edu]; 'Tom Inglesby'[tinglesby@jhu.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'Maria Jasen'[mjasen1@jhu.edu]; 'mvnovotny@unmc.edu'[mvnovotny@unmc.edu]
Cc: Dzau, Victor J.[VDzau@nas.edu]; Georges Benjamin[georges.benjamin@apha.org]; Nicole Lurie[drnickilurie@gmail.com]; Del Rio, Carlos[cdelrio@emory.edu]; Susan Polan[susan.polan@apha.org]; DeStefano, Laura[LDestefano@nas.edu]
From: Ogilvie, Jenna[JOgilvie@nas.edu]
Sent: Tue 7/21/2020 12:33:59 PM (UTC-04:00)
Subject: COVID-19 Conversations: K-12 School Reopening Webinar - Draft Agenda

Good afternoon, COVID-19 Conversations Advisory Group –

I hope this message finds you all healthy and safe.

The National Academies of Sciences, Engineering, and Medicine released a consensus study report on *Reopening K-12 Schools During the COVID-19 Pandemic* on Wednesday, July 15. You can find the report here: https://www.nap.edu/catalog/25858/reopening-k-12-schools-during-the-covid-19-pandemic-prioritizing

Due to the release of this report and the continuing conversation and controversy about schools reopening across the country, we felt that a webinar on K-12 reopening is both timely and necessary, but would like your input on the topics to cover and speakers to represent those topics. We have assembled a draft agenda, below, with some options for speakers underneath each topic area. We would greatly appreciate your feedback both on the topic areas and on the speakers for each (if you could please let us know your choice for speaker under each category, that would be very helpful – suggestions for speakers not listed are also welcome!)

Please note: We currently list 5 panelists and 5 topic areas, which is too much for one webinar, so we'd also appreciate your input onto which topics we could save for another webinar or topics that could wrap into another speaker's presentation.

We are hoping to hold this webinar on Wednesday, August 5 so **would appreciate your feedback on this draft agenda by Thursday, July 23 at 2pm ET.**

Also, a reminder that our next webinar is scheduled for Wednesday, July 29 at 5pm and will focus on Managing Ongoing Surges: Lessons from the Front Lines. We have invited Sanjay Gupta to moderate and are waiting to hear back if he will be able to participate. Jonathan Lewin, Executive Vice President for Health Affairs at Emory University; Greg Adams, Chairman and CEO of Kaiser Permanente; and Howard Zucker, Commissioner of Health for New York State have all agreed to participate. We have invitations out to female, red state public health department officials and are waiting to hear back to finalize the panel lineup. We anticipate opening registration for this webinar later this week and will let you all know when it is live.

Please don't hesitate to reach out to me, Laura, or Susan with any questions or concerns.

With best wishes,
Jenna

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Returning to K-12 Education: Using Science to Keep Children, Teachers, and Staff Safe
Tentatively scheduled for Wednesday, August 5 at 5pm ET

Moderator (5 min intro)

- Josh Sharfstein, Vice Dean, Bloomberg School of Public Health, Johns Hopkins (white, male) https://hub.jhu.edu/2020/06/03/sharfstein-morphew-urge-public-schools-to-reopen/
- Rochelle Walensky, Chief, Division of Infectious Diseases, Mass General (white, woman) https://www.massgeneral.org/doctors/17245/rochelle-walensky
    - Note: We'll want the moderator to comment on the emerging evidence about spread in children older than 10 (https://www.nytimes.com/2020/07/18/health/coronavirus-children-schools.html)
~~~~~

Overview of recommendations from NASEM report (10 min)

- Dimitri Christakis, Director, Center for Child Health, Behavior, and Development, Seattle Children's Hospital (white, male) https://www.seattlechildrens.org/directory/dimitri-a-christakis/
    - Note: hopefully Dr. Christakis could also speak to what we know about transmission in children as included in the report, published before the large-scale study on children older than 10
- Enriqueta Bond, QE Philanthropic Advisors, NASEM report committee chair (white, woman) https://www.healtheffects.org/about/board/enriqueta-bond

Lessons from Europe (10 min)

- Peter Andersen, Infectious Disease Epidemiology and Vaccines, Statens Serum Institut Copenhagen, Demark (white, male) https://www.tbvi.eu/team/prof-peter-andersen-dvm-dmsc/
- Dorte Lange, Vice President, Danish Union of Teachers (white, woman) https://www.telegraph.co.uk/education-and-careers/2020/06/27/denmark-won-lockdown-battle-got-children-back-school/
- Steffen Handal, President of Education Union, Norway (white, male) https://www.ei-ie.org/en/detail_eb/4621/steffen-handal

The role of the school nurse during in-person reopening (10 min)

- Linda Mendonca, President Elect, National Association of School Nurses (white, woman) https://schoolnursenet.nasn.org/nasn/blogs/nasn-profile/2019/05/10/national-association-of-school-nurses-elects-linda
- Robin Cogan, National Certified School Nurse (white, woman) https://relentlessschoolnurse.com/about/

Role of antigen testing in opening schools and keeping them open (10 min)

- Kathryn Edwards, Professor of Pediatrics, Scientific Director, Vanderbilt Vaccine Research Program (white, woman) https://www.vumc.org/viiii/person/kathryn-m-edwards-md
- Any additional excellent expert suggestions here would be welcome

Planning for Spring 2021 (10 min)

- Lily Eskelsen Garcia, President, National Education Association (Hispanic, woman) http://www.nea.org/home/NEA-President-Profile.html
- Nancy Hill, Professor of Education, Harvard University (Black, woman) https://www.gse.harvard.edu/faculty/nancy-hill
- Sara H. Goza, President, American Academy of Pediatrics (white, woman) https://www.npr.org/sections/coronavirus-live-updates/2020/07/08/888853601/school-reopenings-should-keep-public-health-in-mind-pediatric-group-says
- Randi Weingarten, President, American Federation of Teachers (white, woman) https://www.aft.org/about/leadership/randi-weingarten

Q&A (~30 min)

Jenna Ogilvie
Deputy Director of Communications
National Academy of Medicine
202-334-1348
nam.edu | @theNAMedicine

Cc: William Dowling[william.dowling@cepi.net]; Mark Page[Mark.Page@nibsc.org]
From: GSELL, Pierre[gsellp@who.int]
Sent: Tue 7/21/2020 4:03:41 PM (UTC-04:00)
Subject: [COVID-19 WHO Assays call] Tomorrow's agenda

Dear All,

Please see below the agenda of the next WHO COVID-19 Assays call.
The TC is planned **Wednesday 22 July at 2.30pm-3.30pm CET time.**
TC Link - https://who.webex.com/who/j.php?MTID=m796d67bac63ce4d3c2b8d5773763fe89

1. Katie Doors – «Longitudinal evaluation and decline of antibody responses in SARS-CoV-2 infection»
2. Florian Krammer – «SARS-CoV-2 infection induces antibody responses that are stable for at least three months»
3. Youchou Wang – "The impact of mutations in SARS-CoV-2 on viral infectivity and antigenicity"

Thanks all for your continuous participation.
Kind regards

Pierre-Stéphane Gsell
Technical Officer
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Desk: +41.22.791.50.74 | Mob: +41.79.213.25.30 | gsellp@who.int

From: Simon.Funnell@phe.gov.uk[Simon.Funnell@phe.gov.uk]

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Location: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70

Importance: Normal

Subject: FW: Webex meeting invitation: [COVID-19] 21th WHO TC - Animal Models

Start Time: Thur 7/23/2020 9:00:00 AM (UTC-04:00)

End Time: Thur 7/23/2020 10:30:00 AM (UTC-04:00)

Required Attendees: sandra cordo; Pearl.Bamford@health.gov.au; kanta.subbarao@influenzacentre.org; Vasan Vasan; Jin.Zhu@health.gov.au; kristine.macartney@health.nsw.gov.au; Kai Dallmeier; Johan Neyts; Alyson Kelvin; Darryl Falzarano; Volker.gerdts@usask.ca; Hodgson, Paul; dustin.johnson@canada.ca; Jason Kindrachuk; darwyn.kobasa@canada.ca; Gary Kobinger; Li, Sean (HC/SC); dean.smith@canada.ca; 秦川; shanchao@wh.iov.cn; kandeil_a@hotmail.com; Marco.Cavaleri@ema.europa.eu; mariette.ducatez@envt.fr; christiane.gerke@pasteur.fr; Roger Le; LESELLIER Sandrine; Pauline Maisonnasse; romain.volmer@envt.fr; Martin Beer; CarlosAlberto.Guzman@helmholtz-hzi.de; Kerscher, Bernhard; kupke@staff.uni-marburg.de; Mettenleiter, Thomas C.; Cesar Munoz-Fontela; Estefania Bni; Barbara.Schnierle@pei.de;

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Webex_Meeting.ics

Dear WHO telecon participants,
Please find attached the agenda for this week's Thursday WHO infection models working group.
We look forward to your participation in another interesting up-date from multiple groups.
Regards,
Simon, Cesar and Bill.

Agenda
21st telecon of the WHO's COVID-19 infection models working group

23rd JULY 2020 at 15:00 CET

Pathogenesis

1. Jurgen Richt (KSU).
2. Quim Segales (IRTA-CRcSA)
3. Dan Barouch (HMFP/DVR)

Vaccines and therapeutics

4. Barney Graham (NIH/VRC)

Open questions

5. Working stock survey
6. Open questions

-----Original Appointment-----
From: Pierre GSELL <gsellp@who.int>
Sent: 19 July 2020 21:12
To: Pierre GSELL; Simon Funnell
Subject: Webex meeting invitation: [COVID-19] 21th WHO TC - Animal Models
When: 23 July 2020 15:00-16:30 Europe/Paris.
Where: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 140 7103

Meeting password: QgrNJmqU793

Thursday, July 23, 2020

3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

Tap to join from a mobile device (attendees only)

+41445750282,,1451407103## SWITZERLAND Toll

+1-415-655-0003,,1451407103## US Toll

Join by phone

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Global call-in numbers

Join from a video system or application

Dial 1451407103@who.webex.com

You can also dial 173.243.2.68 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 1451407103.who@lync.webex.com

Need help? Go to http://help.webex.com

Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 21th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70
Start Time: 2020-07-23T15:00:00+02:00
End Time: 2020-07-23T16:30:00+02:00
Attendees: Simon.Funnell@phe.gov.uk : Simon.Funnell@phe.gov.uk

When it's time, join the Webex meeting here.

Meeting number (access code): 145 140 7103
Meeting password:QgrNJmqU793

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From: GSELL, Pierre[gsellp@who.int]
Sent: Wed 7/22/2020 11:26:06 AM (UTC-04:00)
Subject: FW: Webex meeting invitation: [COVID-19] 21th WHO TC - Animal Models
EXT FW_ Webex meeting invitation_ _COVID-19_ 21th WHO TC - Animal Models.ics

Dear WHO telecon participants,

Please find attached the agenda for this week's Thursday WHO infection models working group.
We look forward to your participation in another interesting up-date from multiple groups.
Regards,
Simon, Cesar and Bill.

Agenda
21st telecon of the WHO's COVID-19 infection models working group

23rd JULY 2020 at 15:00 CET

Pathogenesis

1. Jurgen Richt (KSU).
2. Quim Segales (IRTA-CRcSA)
3. Dan Barouch (HMFP/DVR)

Vaccines and therapeutics

1. Barney Graham (NIH/VRC)

Open questions

1. Working stock survey
2. Open questions

Organizer: Pierre GSELL : gsellp@who.int

Subject: [EXT] FW: Webex meeting invitation: [COVID-19] 21th WHO TC - Animal Models

Location: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70

Start Time: 2020-07-23T15:00:00+02:00

End Time: 2020-07-23T16:30:00+02:00

Attendees: scordo : scordo@qb.fcen.uba.ar, BAMFORD, Pearl : Pearl.Bamford@health.gov.au, kanta.subbarao : kanta.subbarao@influenzacentre.org, Vasan, Vasan (H&B, Geelong ACDP) : Vasan.Vasan@csiro.au, ZHU, Jin, Jin.Zhu@health.gov.au, Kristine Macartney : kristine.macartney@health.nsw.gov.au, kai.dallmeier : kai.dallmeier@kuleuven.be, johan.neyts : johan.neyts@kuleuven.be, AKelvin : AKelvin@dal.ca, Falzarano, Darryl, darryl.falzarano@usask.ca, Volker.gerdts@usask.ca : Volker.gerdts@usask.ca, Hodgson, Paul : paul.hodgson@usask.ca, dustin.johnson : dustin.johnson@canada.ca, Jason Kindrachuk : Jason.Kindrachuk@umanitoba.ca, darwyn.kobasa@canada.ca : darwyn.kobasa@canada.ca, Gary Kobinger : Gary.Kobinger@crchudequebec.ulaval.ca, sean.li : sean.li@canada.ca, dean.smith : dean.smith@canada.ca, qinchuan, qinchuan@pumc.edu.cn, shanchao : shanchao@wh.iov.cn, kandeil_a : kandeil_a@hotmail.com, Cavaleri Marco, Marco.Cavaleri@ema.europa.eu, mariette.ducatez@envt.fr : mariette.ducatez@envt.fr, Christiane Gerke, christiane.gerke@pasteur.fr, Roger Le Grand : roger.le-grand@cea.fr, LESELLIER Sandrine, sandrine.lesellier@anses.fr, Pauline Maisonnasse : pauline.maisonnasse@cea.fr, Romain Volmer : romain.volmer@envt.fr, Martin.Beer : Martin.Beer@fli.de, CarlosAlberto.Guzman : CarlosAlberto.Guzman@helmholtz-hzi.de, Bernhard Kerscher (PEI-DE) : bernhard.kerscher@pei.de, kupke : kupke@staff.uni-marburg.de, ThomasC.Mettenleiter : ThomasC.Mettenleiter@fli.de, Cesar Munoz-Fontela : munoz-fontela@bnitm.de, estefania.rodriguez : estefania.rodriguez@bnitm.de, Barbara.Schnierle : Barbara.Schnierle@pei.de, sutter : sutter@micro.vetmed.uni-muenchen.de, Carolyn Clark : carolyn.clark@cepi.net, William Dowling : william.dowling@cepi.net, HENAO RESTREPO, Ana Maria : henaorestrepoa@who.int, KNEZEVIC, Ivana : knezevici@who.int, SATHIYAMOORTHY, Vaseeharan : moorthyv@who.int, PREZIOSI, Marie-pierre : preziosim@who.int, RIVEROS BALTA, Alina Ximena : lauriex@who.int, Amy C. 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lgralins@email.unc.edu

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Dear WHO telecon participants,
Please find attached the agenda for this week's Thursday WHO infection models working group.
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Regards,
Simon, Cesar and Bill.

Agenda
21st telecon of the WHO's COVID-19 infection models working group

23rd JULY 2020 at 15:00 CET

Pathogenesis

1. Jurgen Richt (KSU).
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3. Dan Barouch (HMFP/DVR)

Vaccines and therapeutics

4. Barney Graham (NIH/VRC)

Open questions

5. Working stock survey
6. Open questions

-----Original Appointment-----
From: Pierre GSELL <gsellp@who.int>
Sent: 19 July 2020 21:12
To: Pierre GSELL; Simon Funnell
Subject: Webex meeting invitation: [COVID-19] 21th WHO TC - Animal Models
When: 23 July 2020 15:00-16:30 Europe/Paris.
Where: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 140 7103

Meeting password: QgrNJmqU793

Thursday, July 23, 2020

3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 21th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=ma1cb4696b399f202d7a1aa0818e62b70
Start Time: 2020-07-23T15:00:00+02:00
End Time: 2020-07-23T16:30:00+02:00
Attendees: Simon.Funnell@phe.gov.uk : Simon.Funnell@phe.gov.uk

When it's time, join the Webex meeting here.

Meeting number (access code): 145 140 7103
Meeting password:QgrNJmqU793

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To: Ogilvie, Jenna[JOgilvie@nas.edu]; 'Linda Degutis'[lcdegutis@gmail.com]; 'acasadevall@jhu.edu'[acasadevall@jhu.edu]; 'ushah@hcphes.org'[ushah@hcphes.org]; 'Lawrence Gostin'[gostin@georgetown.edu]; Figueroa, Angelica M[amfiguer@email.unc.edu]; Croitoru, Grace Nicole[gracenc@email.unc.edu]; Rimer, Barbara[brimer@unc.edu]; 'Andy Pavia'[Andy.Pavia@hsc.utah.edu]; 'Shah, Umair MD (PHS)'[Umair.Shah@phs.hctx.net]; 'Arturo Casadevall'[acasade1@jhu.edu]; 'Jha, Ashish'[ajha@hsph.harvard.edu]; 'Gold, Jeffrey P'[jeffrey.gold@unmc.edu]; 'Perez, Elizabeth (PHS)'[Elizabeth.Perez@phs.hctx.net]; 'Castaneda, Tony (PHS)'[Tony.Castaneda@phs.hctx.net]; 'Heidi Larson'[Heidi.Larson@LSHTM.ac.uk]; 'Burke, Donald S'[donburke@pitt.edu]; 'Tom Inglesby'[tinglesby@jhu.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'Maria Jasen'[mjasen1@jhu.edu]; 'mvnovotny@unmc.edu'[mvnovotny@unmc.edu]
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From: Sharon Inouye[SharonInouye@hsl.harvard.edu]
Sent: Thur 7/23/2020 4:40:58 PM (UTC-04:00)
Subject: RE: COVID-19 Conversations: K-12 School Reopening Webinar - Draft Agenda

Dear Jenna, Nikki, Carlos, Laura, and the Advisory Group—please see my comments and votes (as requested by Jenna) highlighted below. All the speakers are well qualified choices, so it was hard to vote but I tried.

Gestalt: Wonderful session! Very relevant and important. Looking forward to zooming with everyone soon. Stay safe, stay well. Sharon

Sending by voice to text, so please forgive typos and odd words.

From: Ogilvie, Jenna [mailto:JOgilvie@nas.edu]
Sent: Tuesday, July 21, 2020 12:34 PM
To: Sharon Inouye; 'Linda Degutis'; 'acasadevall@jhu.edu'; 'ushah@hcphes.org'; 'Lawrence Gostin'; 'Figueroa, Angelica M'; 'Croitoru, Grace Nicole'; 'brimer@unc.edu'; 'Andy Pavia'; 'Shah, Umair MD (PHS)'; 'Arturo Casadevall'; 'Jha, Ashish'; 'Gold, Jeffrey P'; 'Perez, Elizabeth (PHS)'; 'Castaneda, Tony (PHS)'; 'Heidi Larson'; 'Burke, Donald S'; 'Tom Inglesby'; 'rbaric@email.unc.edu'; 'antoinette_baric@med.unc.edu'; 'Maria Jasen'; 'mvnovotny@unmc.edu'
Cc: Dzau, Victor J.; Georges Benjamin; Nicole Lurie; Del Rio, Carlos; Susan Polan; DeStefano, Laura
Subject: COVID-19 Conversations: K-12 School Reopening Webinar - Draft Agenda

Good afternoon, COVID-19 Conversations Advisory Group –

I hope this message finds you all healthy and safe.

The National Academies of Sciences, Engineering, and Medicine released a consensus study report on *Reopening K-12 Schools During the COVID-19 Pandemic* on Wednesday, July 15. You can find the report here: https://www.nap.edu/catalog/25858/reopening-k-12-schools-during-the-covid-19-pandemic-prioritizing

Due to the release of this report and the continuing conversation and controversy about schools reopening across the country, we felt that a webinar on K-12 reopening is both timely and necessary, but would like your input on the topics to cover and speakers to represent those topics. We have assembled a draft agenda, below, with some options for speakers underneath each topic area. We would greatly appreciate your feedback both on the topic areas and on the speakers for each (if you could please let us know your choice for speaker under each category, that would be very helpful – suggestions for speakers not listed are also welcome!)

Please note: We currently list 5 panelists and 5 topic areas, which is too much for one webinar, so we'd also appreciate your input onto which topics we could save for another webinar or topics that could wrap into another speaker's presentation.

We are hoping to hold this webinar on Wednesday, August 5 so **would appreciate your feedback on this draft agenda by Thursday, July 23 at 2pm ET.**

Also, a reminder that our next webinar is scheduled for Wednesday, July 29 at 5pm and will focus on Managing Ongoing Surges: Lessons from the Front Lines. We have invited Sanjay Gupta to moderate and are waiting to hear back if he will be able to participate. Jonathan Lewin, Executive Vice President for Health Affairs at Emory University; Greg Adams, Chairman and CEO of Kaiser Permanente; and Howard Zucker, Commissioner of Health for New York State have all agreed to participate. We have invitations out to female, red state public health department officials and are waiting to hear back to finalize the panel lineup. We anticipate opening registration for this webinar later this week and will let you all know when it is live.

Please don't hesitate to reach out to me, Laura, or Susan with any questions or concerns.

With best wishes,
Jenna

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Returning to K-12 Education: Using Science to Keep Children, Teachers, and Staff Safe
Tentatively scheduled for Wednesday, August 5 at 5pm ET

Moderator (5 min intro) Comment: I was wondering if the moderator might also be able to summarize major report recommendations in the intro, this would then help with consolidating. If not, then another suggestion below….

- Josh Sharfstein, Vice Dean, Bloomberg School of Public Health, Johns Hopkins (white, male) https://hub.jhu.edu/2020/06/03/sharfstein-morphew-urge-public-schools-to-reopen/
- [My vote] Rochelle Walensky, Chief, Division of Infectious Diseases, Mass General (white, woman) https://www.massgeneral.org/doctors/17245/rochelle-walensky
  - Note: We'll want the moderator to comment on the emerging evidence about spread in children older than 10 (https://www.nytimes.com/2020/07/18/health/coronavirus-children-schools.html)

Overview of recommendations from NASEM report (10 min)

- [My vote] Dimitri Christakis, Director, Center for Child Health, Behavior, and Development, Seattle Children's Hospital (white, male) https://www.seattlechildrens.org/directory/dimitri-a-christakis/
  - Note: hopefully Dr. Christakis could also speak to what we know about transmission in children as included in the report, published before the large-scale study on children older than 10
- Enriqueta Bond, QE Philanthropic Advisors, NASEM report committee chair (white, woman) https://www.healtheffects.org/about/board/enriqueta-bond

Lessons from Europe (10 min)

- Peter Andersen, Infectious Disease Epidemiology and Vaccines, Statens Serum Institut Copenhagen, Demark (white, male) https://www.tbvi.eu/team/prof-peter-andersen-dvm-dmsc/
- [My vote] Dorte Lange, Vice President, Danish Union of Teachers (white, woman) https://www.telegraph.co.uk/education-and-careers/2020/06/27/denmark-won-lockdown-battle-got-children-back-school/
- Steffen Handal, President of Education Union, Norway (white, male) https://www.ei-ie.org/en/detail_eb/4621/steffen-handal

The role of the school nurse during in-person reopening (10 min) [Another idea for consolidation is combining this one with the one below on antigen testing—since the nurse would be doing it most likely—talk about practicalities of implementing, what to do if kids are sick, role in contact tracing, etc.]

- [My vote] Linda Mendonca, President Elect, National Association of School Nurses (white, woman) https://schoolnursenet.nasn.org/nasn/blogs/nasn-profile/2019/05/10/national-association-of-school-nurses-elects-linda
- Robin Cogan, National Certified School Nurse (white, woman) https://relentlessschoolnurse.com/about/

Role of antigen testing in opening schools and keeping them open (10 min) [see above—possibly consolidate, since we have already had several prior conversations on scientific aspects of testing]

- Kathryn Edwards, Professor of Pediatrics, Scientific Director, Vanderbilt Vaccine Research Program (white, woman) https://www.vumc.org/viiii/person/kathryn-m-edwards-md
- Any additional excellent expert suggestions here would be welcome

Planning for Spring 2021 (10 min)

- [My vote] Lily Eskelsen Garcia, President, National Education Association (Hispanic, woman) http://www.nea.org/home/NEA-President-Profile.html [has written some thoughtful pieces about how to reopen schools safely
- Nancy Hill, Professor of Education, Harvard University (Black, woman) https://www.gse.harvard.edu/faculty/nancy-hill
- [close second] Sara H. Goza, President, American Academy of Pediatrics (white, woman) https://www.npr.org/sections/coronavirus-live-updates/2020/07/08/888853601/school-reopenings-should-keep-
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public-health-in-mind-pediatric-group-says

- Randi Weingarten, President, American Federation of Teachers (white, woman) https://www.aft.org/about/leadership/randi-weingarten

Q&A (~30 min)

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To: GSELL, Pierre[gsellp@who.int]
Cc: William Dowling[william.dowling@cepi.net]; Mark Page[Mark.Page@nibsc.org]
From: GSELL, Pierre[gsellp@who.int]
Sent: Wed 7/29/2020 7:00:24 AM (UTC-04:00)
Subject: [COVID-19 WHO Assays call] Today's agenda

Dear All,

Please see below the agenda of the next WHO COVID-19 Assays call.
The TC is planned **Wednesday 29 July at 2.30pm-3.30pm CET time.**
TC Link - https://who.webex.com/who/j.php?MTID=md7e36a12ba6ddf74e117a7c86cf71001

1. Julie McElrath – «Cellular Immune Analyses for COVID-19 Infection and Clinical Trials»
2. Phlip Norris – «Leveraging blood donor networks to study SARS CoV 2 immunity»

Thanks all for your continuous participation.
Kind regards

Pierre-Stéphane Gsell
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