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

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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 Morning 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:

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- Thanks to all speakers and participants and adjourn virtual workshop

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

To: inglesby789@gmail.com[inglesby789@gmail.com]; David Relman[relman@stanford.edu]; Baric, Ralph S[rbaric@email.unc.edu]
Cc: Clague, Darren P[darren.p.clague@perspecta.com]
From: Brent PhD, Roger[rbrent@fredhutch.org]
Sent: Fri 7/10/2020 3:36:23 PM (UTC-04:00)
Subject: Was looking for a name...

Dear All including Tom,

In discussions recently there was a question about a recent event in which a very large number of scientists wrote to an international organization, the WHO, urging to it take a stronger stance/ issue different recommendations on modes of transmission of COVID-19. With the idea that the WHO might have been reluctant to change its public communications because its statements need to be politically considered and perhaps guarded. Public health being necessarily political, because public health is one of the ways that increases in biological knowledge and capability (here, knowledge) impact the public/ the course of human events. I was remembering generalizations about philosophies of regulation and public communication in different polities that are associated with a name, and finally remembered the name. Shiela Jasanoff. A pioneer professor in Science and Technology Studies, now at Harvard, and the work being "Designs on Nature", from 2005.

What follows relates to the outlines of the postwar or the post-COVID-19 world. About how US public health agencies and regulatory agencies (a renewed CDC, rCDC), and international public health and regulatory agencies (a renewed WHO, rWHO) should function within that world.

Let me start with the idea and assertion that, since founding, the US has been among other things the nation of the world that could really handle the Enlightenment/ modernity. Them, widely recognized since 19th century, the nexus between modernity and technology. Whatever that technology was, from telephones to electricity in houses to oral contraception pills to movies to airplanes to electronic media to public health to nuclear fission to TV to the construction of air defense systems to biotechnology, whatever it was, we very often invented it, and came to own it, and we always rolled with it. We always had within us an opposing strain, from the Great Awakening to the Scopes Trial (1925, 95 years ago), but until the last few years could always keep the modernity part ascendent.

Now, Jasanoff teaches us that our national regulatory philosophy directly reflects that stance. Starting with the creation of the FDA, and the time of the Environmental Protection Act (1969 or 1970), it's a US principle that all regulatory decisions are based on science. Jasanoff's book is about transgenic food plants (GMOs), which were politically unpopular all over the world-- that is, the majority of citizens in different polities didn't want them-- and how different political systems responded to their introduction with regulation. At a cartoon level, in the US, regulatory agencies said GMOs OK, because science, in the Federal Republic of Germany, GMOs not OK because of hyperattentiveness to small d democracy, and in the UK GMOs sort of OK not because of science per se but because committee of experts says should be OK. In this international discourse, our regulators were always on the side of the science, because that's what the US stands for, and that could excuse protect their ability to speak "scientific truth" instead of conforming to other political considerations. And the US standing for "the science and only the science" gave scientific cover for regulators in other countries.

As part of the planning the national and international institutions that will be involved in post-SARS-CoV-2 reconstruction, and certainly for thinking about future quasipolitical discussions such as what sorts of international regulations to impose on gain of function experiments, I submit we want to plan for many relevant exec branch organizations to re-announce, however informally and by word of mouth, a kind of national re-commitment to and comfort with technology and modernity as above. Although this comment was prompted by a discussion of statements by the WHO, I submit that a conscious re-affirmation of such a commitment might overall increase the permissiveness of the environment in which other national security activities will need to function.

With best wishes,

Roger

Professor, Division of Basic Sciences, FHCRC

Affiliate Professor, Department of Genome Sciences, UW/
Affiliate Professor, Department of Bioengineering, UW/
Adjunct Professor, Division of Public Health Sciences, FHCRC

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[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]; 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. Haagmans[b.haagmans@erasmusmc.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; langermans@bprc.nl[langermans@bprc.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; B. 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];

philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; cjmiller@ucdavis.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[dmissiak@bsd.uchicago.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; DAVID H O'CONNOR[dhoconno@wisc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; Stanley Perlman[stanley-perlman@uiowa.edu]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Juergen Richt[jricht@vet.k-state.edu]; Chad Roy[croy@tulane.edu]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Padmini Salgame[salgampa@njms.rutgers.edu]; erica@lji.org[erica@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Michael Schotsaert[michael.schotsaert@mssm.edu]; sivkog@battelle.org[sivkog@battelle.org]; Spergel, Jonathan[SPERGEL@email.chop.edu]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; nax3@cdc.gov[nax3@cdc.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; sktseng@utmb.edu[sktseng@UTMB.EDU]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Wang, Tony[tony.wang@fda.hhs.gov]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; White, Alexander G[agw13@pitt.edu]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]
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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Dial 1455284668.who@lync.webex.com

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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Meeting password:ePxbxWky224

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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

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To: David Relman[relman@stanford.edu]; Tom Inglesby[inglesby789@gmail.com]; Baric, Ralph S[rbaric@email.unc.edu]; Clague, Darren P[darren.p.clague@perspecta.com]
From: Brent PhD, Roger[rbrent@fredhutch.org]
Sent: Fri 7/17/2020 10:23:37 PM (UTC-04:00)
Subject: Hudson and Jones

Dear David, Tom, Ralph, Darren

"However, in recent months, skepticism of the accident theory has increased in the scientific community because the genetic sequences of isolates from the bat coronaviruses known to be under research at the lab do not match those of covid-19."

1) Speaks for itself.

“....concurs with the wide scientific consensus that the COVID-19 virus was not man-made or genetically modified.”

1) How on earth would a 'wide scientific consensus' be reached that address whether COVID-19 was not a chimera made from two viruses, one with a spike protein from a different virus than the rest of it?

2) If, today, you canvassed molecularly savvy neuroscientists, or developmental biologists, or cell biologists, or fruit fly geneticists... etc. on whether there was a lab accident or not, or if you canvassed any other sub-specialities of biologists who are not emotionally and professionally invested in issues surrounding research on viral pathogens, I suspect you would get a different 'wide scientific consensus'. I would bet that the consensus isn't that wide at all.

3) Can a reader be expected to know know that "genetic modification" here does not refer to evolution in the lab, for example to grow better on primate or human cells?

Best,

Roger

To: 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]; GSELL, Pierre[gsellp@who.int]; 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. Shurtleff[amy.c.shurtleff@cepi.net]; SWAMINATHAN, Soumya[swaminathans@who.int]; Chi Van Dang[cdang@lcr.org]; WOOD, David John[woodd@who.int]; jfwchan[jfwchan@hku.hk]; hlchen[hlchen@hku.hk]; anna[anna@thsti.res.in]; nirp[nirp@iibr.gov.il]; tomeri[tomeri@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; Tadaki[tksuzuki@nih.go.jp]; Аракелов Сергей Александрович[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov[i.v.krasilnikov@spbniivs.ru]; ldenisy[ldenisy@yahoo.com]; Васильев Юрий Михайлович[y.m.vasiliev@spbniivs.ru]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; sekim[sekim@krict.re.kr]; Seungtaek Kim[seungtaek.kim@ip-korea.org]; Manki Song[mksong@ivi.int]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; mesteban[mesteban@cnb.csic.es]; Juan García Arriaza[jfgarcia@cnb.csic.es]; Segales, Joaquim[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; Ali.Mirazimi[Ali.Mirazimi@folkhalsomyndigheten.se]; Paul.Lambert[Paul.Lambert@unige.ch]; External Partner - Techakitiroj Chatkul[tverakit@gmail.com]; rkiatchula[rkiatchula@gmail.com]; Suchinda Malaivijitnond[suchinda.m@chula.ac.th]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; B.L. Haagmans[b.haagmans@erasmusmc.nl]; jeroen.kortekaas[jeroen.kortekaas@wur.nl]; langermans[langermans@bprc.nl]; Oreshkova, Nadia[nadia.oreshkova@wur.nl]; B.H.G. Rockx[b.rockx@erasmusmc.nl]; 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]; GREY Finn[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[Giada.Mattiuzzo@nibsc.org]; (SPmig) Philip Minor[Philip.Minor2@gmail.com]; Munir, Muhammad[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[Ann.Rawkins@phe.gov.uk]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally Sharpe[Sally.Sharpe@phe.gov.uk]; Stewart, James[J.P.Stewart@liverpool.ac.uk]; Julia Tree[Julia.Tree@phe.gov.uk]; Albrecht, Randy[randy.albrecht@mssm.edu]; Martha Alexander-Miller[Martha.Alexander-Miller@wakehealth.edu]; Baric, Ralph S[rbaric@email.unc.edu]; dbarouch[dbarouch@bidmc.harvard.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; terry.k.besch.ctr[terry.k.besch.ctr@mail.mil]; mopargal[mopargal@rams.colostate.edu]; Brasel, Trevor[trbrasel@utmb.edu]; abukreye[abukreye@utmb.edu]; rcarrion[rcarrion@TxBiomed.org]; Cartner, Samuel Corbin[scartner@uab.edu]; Cassels, Fred[fcassels@path.org]; Monalisa Chatterji[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]; Dohm, Erik Daniel[edohm@uab.edu]; Donis, Ruben (OS/ASPR/BARDA)[ruben.donis@hhs.gov]; Duprex, Paul[pduprex@pitt.edu]; Eitzen, Melissa M.[mmeitzen@utmb.edu]; Karl.Erlandson[Karl.Erlandson@hhs.gov]; Feldmann, Heinrich (NIH/NIAID) [E[feldmannh@niaid.nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Flynn, Joanne L[joanne@pitt.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Adolfo.Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; Golding, Hana[Hana.Golding@fda.hhs.gov]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; Griffiths, Anthony[ahgriff@bu.edu]; Geraldine Hamilton[geraldine.hamilton@emulatebio.com]; kevinharrod[kevinharrod@uabmc.edu]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; Amelia Karlsson[amelia.karlsson@duke.edu]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Harry Kleanthous[Harry.Kleanthous@gatesfoundation.org]; fkoide[fkoide@southernresearch.org]; Krammer, Florian[florian.krammer@mssm.edu]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; (SPmig) Robin Levis[robin.levis@fda.hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen Makar[Karen.Makar@gatesfoundation.org]; paul-mccray[paul-mccray@uiowa.edu]; Chris Miller[cjmiller@ucdavis.edu]; jfwchan[jfwchan@hku.hk]; hlchen[hlchen@hku.hk]; anna[anna@thsti.res.in]; nnagata@niid.go.jp[nnagata@niid.go.jp]; Tadaki[tksuzuki@nih.go.jp]; ldenisy[ldenisy@yahoo.com]; Васильев Юрий Михайлович[y.m.vasiliev@spbniivs.ru]; Аракелов Сергей Александрович[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov[i.v.krasilnikov@spbniivs.ru]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[simon.funnell@phe.gov.uk]; 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]

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. Shurtleff : amy.c.shurtleff@cepi.net, SWAMINATHAN, Soumya : swaminathans@who.int, Chi Van Dang : cdang@lcr.org, WOOD, David John : woodd@who.int, jfwchan : jfwchan@hku.hk, hlchen : hlchen@hku.hk, anna : anna@thsti.res.in, nirp : nirp@iibr.gov.il, tomeri : tomeri@iibr.gov.il, nnagata@niid.go.jp : nnagata@niid.go.jp, Tadaki : tksuzuki@nih.go.jp, AëAAAAAA AAëAAA AAAAëAAAëAAAë, s.a.arakelov@spbniivs.ru, i.v.krasilnikov : i.v.krasilnikov@spbniivs.ru, ldenisy : ldenisy@yahoo.com, AAëAAëAA AëAA AAëAAAAAAë : y.m.vasiliev@spbniivs.ru, danielle.anderson@duke-nus.edu.sg, danielle.anderson@duke-nus.edu.sg, sekim : sekim@krict.re.kr, Seungtaek Kim : seungtaek.kim@ip-korea.org, Manki Song : mksong@ivi.int, Luis Enjuanes : l.enjuanes@cnb.csic.es, mesteban, mesteban@cnb.csic.es, Juan GarcÃa Arriaza : jfgarcia@cnb.csic.es, Segales, Joaquim : joaquim.segales@irta.cat, Vergara, Julia : julia.vergara@irta.cat, Ali.Mirazimi : Ali.Mirazimi@folkhalsomyndigheten.se, Paul.Lambert : Paul.Lambert@unige.ch, External Partner - Techakitiroj Chatkul, tverakit@gmail.com, rkiatchula : rkiatchula@gmail.com, Suchinda Malaivijitnond : suchinda.m@chula.ac.th, jorgen.de.jonge@rivm.nl : jorgen.de.jonge@rivm.nl, Gerhards, Nora : nora.gerhards@wur.nl, B.L. Haagmans : b.haagmans@erasmusmc.nl, jeroen.kortekaas : jeroen.kortekaas@wur.nl, langermans : langermans@bprc.nl, Oreshkova, Nadia : nadia.oreshkova@wur.nl, B.H.G. Rockx, b.rockx@erasmusmc.nl, 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, GREY Finn : 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 : Giada.Mattiuzzo@nibsc.org, (SPmig) Philip Minor, Philip.Minor2@gmail.com, Munir, Muhammad : 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 : Ann.Rawkins@phe.gov.uk, Nicola.Rose@nibsc.org, Nicola.Rose@nibsc.org, Javier Salguero : Javier.Salguero@phe.gov.uk, Sally Sharpe, Sally.Sharpe@phe.gov.uk, Stewart, James : J.P.Stewart@liverpool.ac.uk, Julia Tree : Julia.Tree@phe.gov.uk, Albrecht, Randy : randy.albrecht@mssm.edu, Martha Alexander-Miller : Martha.Alexander-Miller@wakehealth.edu, rbaric : rbaric@email.unc.edu, dbarouch : dbarouch@bidmc.harvard.edu, sinabavari@comcast.net : sinabavari@comcast.net, terry.k.besch.ctr : terry.k.besch.ctr@mail.mil, mopargal : mopargal@rams.colostate.edu, Brasel, Trevor : trbrasel@utmb.edu, abukreye, abukreye@utmb.edu, rcarrion : rcarrion@TxBiomed.org, Cartner, Samuel Corbin : scartner@uab.edu, Cassels, Fred : fcassels@path.org, Monalisa Chatterji : 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, Dohm, Erik Daniel, edohm@uab.edu, Donis, Ruben (OS/ASPR/BARDA) : ruben.donis@hhs.gov, Duprex, Paul : pduprex@pitt.edu, Eitzen, Melissa M. : mmeitzen@utmb.edu, Karl.Erlandson : Karl.Erlandson@hhs.gov, Feldmann, Heinrich (NIH/NIAID) [E], feldmannh@niaid.nih.gov, Florence, Clint (NIH/NIAID) [E] : clint.florence@nih.gov, Flynn, Joanne L : joanne@pitt.edu, thomasf@primate.wisc.edu : thomasf@primate.wisc.edu, Frieman, Matthew : MFrieman@som.umaryland.edu, Adolfo.Garcia-Sastre : Adolfo.Garcia-Sastre@mssm.edu, Olinger, Gene : golinger@MRIGLOBAL.ORG, Golding, Hana : Hana.Golding@fda.hhs.gov, Graham, Barney (NIH/VRC) [E] : bgraham@mail.nih.gov, Lisa E Gralinski :

lgralins@email.unc.edu

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

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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: Aaron Tobian[atobian@jhmi.edu]; Markmann, Alena[Alena.Markmann@unchealth.unc.edu]; Alpesh Amin[anamin@hs.uci.edu]; Alyssa Ziman[aziman@mednet.ucla.edu]; Anaar Eastoak-Siletz[AEastoak-Siletz@mednet.ucla.edu]; Andre Nel[anel@mednet.ucla.edu]; Andrea Klein[aklein2@tuftsmedicalcenter.org]; Andrew Pekosz[apekosz1@jhu.edu]; Anthony Bowen[abowen@jhmi.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Ara Metjian[ara.metjian@duke.edu]; Arturo Casadevall[acasade1@jhu.edu]; Bauer, Philippe R., M.D., Ph.D.[Bauer.Philippe@mayo.edu]; Benjamin Chen[benjamin.chen@mssm.edu]; Boris Juelg[bjulg@mgh.harvard.edu]; Brenda Grossman[bgrossman@wustl.edu]; Brian Anderson[briananderson@mitre.org]; Brian O'Neil[boneil@med.wayne.edu]; Bruce Sachais[BSachais@nybc.org]; Bryan Lau[blau1@jhu.edu]; Cheryl Goss[gossc@mskcc.org]; Chris Amos[Chris.Amos@bcm.edu]; Christian Merlo[cmerlo@jhmi.edu]; Christine Sanders[SandersC@hutchclinic.com]; Coleen Cunningham[coleen.cunningham@duke.edu]; Constance Benson[cbenson@health.ucsd.edu]; Craig Hooper[woh1@cdc.gov]; Dan Cooper[dcooper@hs.uci.edu]; Daniel Ericson[danericson@subcinc.com]; Darrell Triulzi[DTriulzi@itxm.org]; Dave Shade[dshade@jhmi.edu]; David Thomas[dthomas@jhmi.edu]; Van Duin, David[david_vanduin@med.unc.edu]; Deborah McMahon[mcmahond@pitt.edu]; Donald Forthal[dnfortha@hs.uci.edu]; Donald Siegel[siegeld@pennmedicine.upenn.edu]; Elisa Ignatius[eignati1@jhmi.edu]; Ellen Klapper[ellen.klapper@cshs.org]; Emma Meagher[emma@upenn.edu]; Eric Gehrie[egehrie1@jhmi.edu]; Eric Salazar (esalazar@houstonmethodist.org)[esalazar@houstonmethodist.org]; Esperanza Papadopoulos[papadope@MSKCC.ORG]; Evan Bloch[ebloch2@jhmi.edu]; Flemming Nielsen[flemming.nielsen@octapharma.com]; Flor Munoz-Rivas[florm@bcm.edu]; Frankk Lu[yanglu@mednet.ucla.edu]; Genovefa Papanicolaou[papanicg@MSKCC.ORG]; Gordana Simeunovic[Gordana.Simeunovic@spectrumhealth.org]; Harry Selker[hselker@tuftsmedicalcenter.org]; Hua Shan[hshan@stanfordhealthcare.org]; Hung Fan[hyfan@uci.edu]; Ian Lipkin[wil2001@columbia.edu]; Jack Ziffer[JZiffer@baptisthealth.net]; Jaime Deville[jdeville@mednet.ucla.edu]; James Campbell[jcampbel@som.umaryland.edu]; James Musser[JMMusser@houstonmethodist.org]; Jeff Murray[jeff-murray@uiowa.edu]; Jeffrey Bailey[jeffrey_bailey@brown.edu]; Jeffrey Donowitz[jeffrey.donowitz@vcuhealth.org]; Jeffrey Henderson[hendersonj@wustl.edu]; Jeffrey Jacobson[jxj573@case.edu]; John Beigel[jbeigel@niaid.nih.gov]; John McDyer[mcdyerjf@upmc.edu]; John Mellors[jwm1@pitt.edu]; John Perfect[john.perfect@duke.edu]; Jonathan Zenilman[jzenilma@jhmi.edu]; Joseph Sweeney[Joseph_Sweeney@brown.edu]; Joyner, Michael J., M.D.[joyner.michael@mayo.edu]; Judith Currier[jscurrier@mednet.ucla.edu]; Karen Johnston[kj4v@virginia.edu]; Klassen, Stephen A., Ph.D.[Klassen.Stephen@mayo.edu]; Lanny Hsieh[llhsieh@hs.uci.edu]; Larson, Kathryn F., M.D.[Larson.Kathryn1@mayo.edu]; Lauren Sauer[lsauer2@jhmi.edu]; Lewis Pollack[lewisrpollack@gmail.com]; Liise-Anne Pirofski[l.pirofski@einsteinmed.org]; Linzhao Cheng[lcheng2@jh.edu]; Lisa Deangelis[deangell@MSKCC.ORG]; Lisa Maragakis[lmaraga1@jhmi.edu]; Louis Gidel[LouisG@BaptistHealth.net]; Bartelt, Luther A[luther_bartelt@med.unc.edu]; Manish Butte[mbutte@mednet.ucla.edu]; Maria Bottazzi[bottazzi@bcm.edu]; Maria Corral[mariaco@baptisthealth.net]; Marianne Morrissey[marianne.morrissey@spectrumhealth.org]; Mark Watrich[watrich@msu.edu]; Max Schumm[mschumm@mednet.ucla.edu]; Michael Buchmeier[m.buchmeier@uci.edu]; Michael Lederman[mxl6@case.edu]; Michael Nelson[nelson.1.michael2.civ@mail.mil]; Nathan Theilman[n.thielman@duke.edu]; Nicholas Duesbery[Nicholas.Duesbery@spectrumhealth.org]; Nicholson, Wayne T. (Nick), M.D., Pharm.D.[Nicholson.Wayne@mayo.edu]; Nick Bandarenko[nick.b@duke.edu]; Nicole Bouvier[nicole.bouvier@mountsinai.org]; Nigel Paneth[paneth@msu.edu]; Noah Merin[noah.merin@cshs.org]; Noreen Hynes[nhynes1@jhmi.edu]; Oren Gordon[ogordon3@jhmi.edu]; Paul Auwaerter[pauwaert@jhmi.edu]; Paul Blaier[pblair6@jhmi.edu]; Paul Hamlin[hamlinp@MSKCC.ORG]; Peter Hotez[hotez@bcm.edu]; Philip Felgner[pfelgner@hs.uci.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Ralph Rogers[rrogers@lifespan.org]; Raymond Comenzo[RComenzo@tuftsmedicalcenter.org]; Reid, Joel M., Ph.D.[reid@mayo.edu]; Richard Cooper[Rcooper@luc.edu]; Ripoll Sanz, Juan G., M.D.[RipollSanz.Juan@mayo.edu]; Robert Atmar[ratmar@bcm.edu]; Robert Barrow[robert.b.barrow@gmail.com]; Robert Finberg[robert.finberg@umassmed.edu]; Robert Schooley[rschooley@health.ucsd.edu]; Rosemary Olivero[Rosemary.Olivero@helendevoschildrens.org]; Saahir Khan[saahirk@hs.uci.edu]; Saar Gill[saar.gill@pennmedicine.upenn.edu]; Sandar Burks[SGB2C@hscmail.mcc.virginia.edu]; Sanjay Jain[sjain5@jhmi.edu]; Senefeld, Jonathon W. (Jack), Ph.D.[Senefeld.Jonathon@mayo.edu]; Sergio Giralt[GiraltS@mskcc.org]; Shepherd, John-Roger A. (John), M.D.[Shepherd.John@mayo.edu]; Shmuel Shoham[sshoham1@jhmi.edu]; Shreena Patel[patels7@mskcc.org]; Siddhartha Jaiswal[sjaiswal@stanford.edu]; Stephan Ehrhardt[sehrhar6@jhu.edu]; Stephan Kadauke[KadaukeS@email.chop.edu]; Stephen Gould[sgould2@jhmi.edu]; Steven Foung[sfoung@stanford.edu]; Stubbs, James R., M.D.[Stubbs.James@mayo.edu]; Suchitra Pandey[spandey1@stanford.edu]; Tebas Pablo[pablo.tebas@pennmedicine.upenn.edu]; Theel, Elitza S., Ph.D.[Theel.Elitza@mayo.edu]; Tho Pham[thopham@stanford.edu]; Thomas Warnshuis[Thomas.Warnshuis@spectrumhealth.org]; van Buskirk, Camille M. (Camille M.), M.D.[vanBuskirk.Camille@mayo.edu]; Vijayan Nair[Vijayan.Nair@octapharma.com]; Vishesh Chhibber[vchhibber@nshs.edu]; Wendy Keitel[wkeitel@bcm.edu]; Wiggins, Chad C., Ph.D.[Wiggins.Chad@mayo.edu]; William O'Neill (woneill1@hfhs.org)[woneill1@hfhs.org]; Winters, Jeffrey L., M.D.[Winters.Jeffrey@mayo.edu]; Park, Yara[Yara.Park@unchealth.unc.edu]; Yukari Manabe[ymanabe@jhmi.edu]; Alexander Indrikovs[aindrikovs@northwell.edu]; 'Alexis Peedin' (Alexis.Peedin@jefferson.edu)[Alexis.Peedin@jefferson.edu]; Amanda Tice[ATice@northwell.edu]; Annamarie Chang[Annamarie.chang@jefferson.edu]; Annie Luetkemeyer[Annie.Luetkemeyer@ucsf.edu]; Augustine Choi[amc2056@med.cornell.edu]; Barbara Schmidtman[BJSCHMIDTMAN@LakelandHealth.org]; Carl Fichtenbaum[fichtecj@ucmail.uc.edu]; Charles LeMaistre[charles.LeMaistre@SarahCannon.com]; Claudie Cohn[cscohn@umn.edu]; Craig Devoe[CDevoe@northwell.edu]; Daanish Hoda[Daanish.Hoda@imail.org]; Dan Hanley[dhanley@jhmi.edu]; Dan Waxman[dwaxman@Versiti.org]; David Sullivan[dsulliv7@jhmi.edu]; David Whellan[David.whellan@jefferson.edu]; Doug Brust[dougbrust@gmail.com]; Emily Spivak[Emily.Spivak@hsc.utah.edu]; George Deepe[DEEPEGS@UCMAIL.UC.EDU]; Gerard Nau[gerard_nau@brown.edu]; James Brown[JBrown2@lakelandhealth.org]; Jeffrey Pearson[PEARSONJ@bronsonhg.org]; John Eisenach (John.h.eisenach@kp.org)[John.h.eisenach@kp.org]; Jolan Walter[jolanwalter@usf.edu]; Jonathan Herman[JDHERMAN@partners.org]; Julie Karp[Julie.Karp@jefferson.edu]; Keri Propst[keripropst@gmail.com]; Kevin Tracey[KJTracey@northwell.edu]; Kristin Rising[Kristin.rising@jefferson.edu]; Matthew McClain[mbmcclain@gmail.com]; Melissa George[mgeorge5@pennstatehealth.psu.edu]; Melissa Panzo[MPanzo1@northwell.edu]; Moises Huaman[huamanms@ucmail.uc.edu]; Rami Kantor[rkantor@brown.edu]; Rebecca Boxer[rebecca.s.boxer@kp.org]; Rosa Greco[rosa.greco@einsteinmed.org]; Walter Kelley[walter.kelley@redcross.org]; William Hartman[hartmanwilliam16@gmail.com]; Yvonne Higgins[yhiggins@jhmi.edu]; Antonio Arrieta[AARRIETA@choc.org]; Benjamin Hanisch[BHanisch@childrensnational.org];

Bruce Bostrom[Bruce.Bostrom@childrensmn.org]; Bryce Pasko[Bryce.Pasko@childrenscolorado.org]; Carla Schwalm[SCHWALMC@bronsonhg.org]; Charlotte Cunningham-Rundles[charlotte.cunningham-rundles@mssm.edu]; Jed Gorlin[Jed.GorlinMD@innovativeblood.org]; Jim Gorham[jdg8z@virginia.edu]; John Zaia[jzaia@coh.org]; Joseph Connor[jconnor@uwhealth.org]; Kyle Annen[Kyle.Annen@childrenscolorado.org]; Lara Danziger-Isakov[Lara.Danziger-Isakov@cchmc.org]; Leo Nissola[lnissola@parkerici.org]; Lisa Beck[Lisa_Beck@urmc.rochester.edu]; Martin Zand[Martin_Zand@URMC.Rochester.edu]; Meghan Delany[mdelaney2@childrensnational.org]; Melissa Healy (Melissa.Healy@latimes.com)[Melissa.Healy@latimes.com]; Michael Edzards[Michael.Edzards@childrensmn.org]; Michael Oxman[mnoxman@health.ucsd.edu]; Monica Ardura[monica.ardura@nationwidechildrens.org]; Monica Bowen[monica.bowen@mercyhealth.com]; Nareg Roubinian[Nareg.Roubinian@ucsf.edu]; Neil Blumberg[Neil_Blumberg@URMC.Rochester.edu]; Neil Gaffin[gaffne@valleyhealth.com]; Neil Goldenberg[neil@jhmi.edu]; Pedro (Tony) Piedra[ppiedra@bcm.edu]; R.Goel[rgoel71@siumed.edu]; Chakraborty, Rana, M.D., D.Phil.[Chakraborty.Rana@mayo.edu]; Rehab Abdallah[rabdall1@jhmi.edu]; RGoel[ruchikagoel1@gmail.com]; Richard Miranda[arichard.miranda@saintalphonsus.org]; Roberta DeBiasi[RDebiasi@childrensnational.org]; Rocky Hui[sxhui@texaschildrens.org]; Ross Fassano[ross.fasano@emory.edu]; Ruchika Goel[rgoel6@jhmi.edu]; Samer Fahmy[SFahmy@brrh.com]; Scott Michener[scott.michener@CCMHHealth.com]; Sridevi Devaraj[devaraj@bcm.edu]; Vladimir Gotlieb[VGotlieb@BHMCNY.ORG]; William Kanner[wkanner@mhc.net]; Yvonne Edgerly[Yvonne.Edgerly@spectrumhealth.org]; Amir Navaei[Amir.Navaei@bcm.edu]; Cassandra Josephsone[cjoseph@emory.edu]; Huskins, W. Charles, M.D.[Huskins.Charles@mayo.edu]; Cyril Jacquot[CJACQUOT@childrensnational.org]; Daniel Scharfstein[dscharf@jhu.edu]; Der Tatyana[tatyana.der@duke.edu]; Diane Nugent[DNUGENT@choc.org]; Elizabeth Ogburn[eogburn@jhu.edu]; Harold Sullivan[hcsulli@emory.edu]; Howard Lederman[hlederm1@jhmi.edu]; Judy Zier[Judy.Zier@childrensmn.org]; Julie Upton[julia.upton@sickkids.ca]; Jun Teruya[jteruya@bcm.edu]; Lijla Music Aplenc[lmusicaplenc@cmh.edu]; Madan Kumar[mkumar@peds.bsd.uchicago.edu]; Michael Tose[michael.tosi@mssm.edu]; Nick Rider[Nicholas.Rider@bcm.edu]; Paul Spearman[Paul.Spearman@cchmc.org]; Rulan Parekh[rulan.parekh@sickkids.ca]; Stephanie Osborne[Sosborne@choc.org]; Steven Sloan[Steven.Sloan@childrens.harvard.edu]; Sydney Lawrence[sydney.lawrence@state.co.us]; Zacharatos Haralabos[haralabos.zacharatos@hackensackmeridian.org]
From: Baertlein, Cheryl R.[baertlein.cheryl@mayo.edu]
Sent: Thur 7/30/2020 8:16:13 AM (UTC-04:00)
Subject: Preprint 10.1101/2020.07.29.20162917 has posted on medRxiv
Pre Print 2020.07.29.20162917v1.full.pdf

****
Sent on behalf of Michael J. Joyner, MD
****

Please see attached preprint prior to Friday's teleconference.

From: Joyner, Michael J., M.D.
Sent: Thursday, July 30, 2020 6:13 AM
To: Baertlein, Cheryl R.
Cc: Klassen, Stephen A., Ph.D.
Subject: FW: [EXTERNAL] Your preprint 10.1101/2020.07.29.20162917 has posted on medRxiv

Please forward to the Friday mega-call mailing list.

Thx

From: medrxivpreprint@connect.medrxiv.org [mailto:medrxivpreprint@connect.medrxiv.org]
Sent: Thursday, July 30, 2020 5:44 AM
To: Joyner, Michael J., M.D.
Subject: [EXTERNAL] Your preprint 10.1101/2020.07.29.20162917 has posted on medRxiv

Dear Michael J Joyner,

Your preprint 10.1101/2020.07.29.20162917 has posted on medRxiv: https://medrxiv.org/cgi/content/short/2020.07.29.20162917v1

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Evidence favouring the efficacy of convalescent plasma for COVID-19 therapy

Michael J. Joyner[1*], Stephen A. Klassen[1], Jonathon W. Senefeld[1], Patrick W. Johnson[2], Rickey E. Carter[2], Chad C. Wiggins[1], Shmuel Shoham[3], Brenda J. Grossman[4], Jeffrey P. Henderson[5,6], James M. Musser[7,8,9], Eric Salazar[7,9], William R. Hartman[10], Nicole M. Bouvier[11,12], Sean T. H. Liu[11,12], Liise-anne Pirofski[13], Sarah E. Baker[1], Noud van Helmond[14], R. Scott Wright[15,16], DeLisa Fairweather[17], Katelyn A. Bruno[17], Nigel S. Paneth[18,19], and Arturo Casadevall[20]

Affiliations:
[1]Department of Anesthesiology and Perioperative Medicine, Mayo Clinic, Rochester, Minnesota,
[2]Department of Health Sciences Research, Mayo Clinic, Jacksonville, Florida,
[3]Division of Infectious Diseases, Johns Hopkins University School of Medicine, Baltimore, Maryland,
[4]Department of Pathology and Immunology, Washington University School of Medicine in St. Louis, St. Louis, Missouri,
[5]Division of Infectious Diseases, Department of Medicine and [6]Department of Molecular Microbiology, Washington University School of Medicine in St. Louis, St. Louis, Missouri, USA.
[7]Department of Pathology and Genomic Medicine, Houston Methodist Hospital, Houston, Texas
[8]Center for Molecular and Translational Human Infectious Diseases, Houston Methodist Research Institute, Houston, Texas
[9]Department of Pathology and Laboratory Medicine, Weill Cornell Medical College, New York, New York
[10]Department of Anesthesiology, University of Wisconsin-Madison School of Medicine and Public Health
[11]Division of Infectious Diseases, Department of Medicine and [12]Department of Microbiology, Icahn School of Medicine at Mount Sinai, New York, New York
[13]Division of Infectious Diseases, Department of Medicine, Albert Einstein College of Medicine and Montefiore Medical Center, Bronx, New York
[14]Department of Anesthesiology, Cooper Medical School of Rowan University, Cooper University Health Care, Camden, New Jersey
[15]Department of Cardiovascular Medicine, Mayo Clinic, Rochester, Minnesota
[16]Director Human Research Protection Program, Mayo Clinic, Rochester, Minnesota
[17]Department of Cardiovascular Medicine, Mayo Clinic, Jacksonville, Florida
[18]Department of Epidemiology and Biostatistics and [19]Department of Pediatrics and Human Development, College of Human Medicine, Michigan State University, East Lansing, Michigan
[20]Department of Molecular Microbiology and Immunology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland

***Correspondence:**
Michael J. Joyner, M.D., Department of Anesthesiology and Perioperative Medicine
Mayo Clinic | 200 First Street SW | Rochester, MN 55905
joyner.michael@mayo.edu | 507-255-7197

Abstract

To determine the effect of COVID-19 convalescent plasma on mortality, we aggregated patient outcome data from randomized clinical trials, matched control, and case-series studies. Fixed-effects analyses demontrated that hospitalized COVID-19 patients transfused with convalescent plasma exhibited a ~57% reduction in mortality rate (13%) compared to matched-patients receiving standard treatments (25%; OR: 0.43, $P < 0.001$). These data provide evidence favouring the efficacy of human convalescent plasma as a therapeutic agent in hospitalized COVID-19 patients.

Brief Communication

Convalescent plasma is a century-old passive antibody therapy that has been used to treat outbreaks of novel infectious diseases, including those affecting the respiratory system[1,2]. Due to the lack of vaccines or monoclonal antibody therapies, human convalescent plasma is currently being used wordwide to treat coronavirus disease 2019 (COVID-19), which is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[2–5]. However, evidence for therapeutic COVID-19 convalescent plasma efficacy still requires definitive support from large randomized clinical trials (RCT). As a result, there remains a lack of consensus on convalescent plasma use in hospitalized COVID-19 patients[6]. Several smaller RCTs, matched-control studies, and case series studies investigating convalescent plasma therapy for COVID-19 have emerged and provided a positive efficacy signal[7–17]. Most of these studies, however, lacked appropriate statistical power or were terminated early.

There is an urgent need to determine the efficacy of potential treatments amidst the ongoing COVID-19 pandemic. Thus, we used a practical approach to pool patient cohort data from RCTs, matched control, and case-series studies in real time. Our primary objective was to derive an aggregate estimate of mortality rate estimates from case and control cohorts of contemporaneous COVID-19 studies.

Data were extracted from studies published on pre-print servers or peer-reviewed journals that investigated human convalescent plasma therapy among hospitalized COVID-19 patients. Mortality rates were calculated at the longest reported vital status for each study and compared between cohorts using odds ratios (OR) determined by fixed effect meta-analysis models. Fixed effect meta-regression analyses evaluated the contribution of moderator variables (i.e., mean or median cohort age, proportion of cohort receiving mechanical ventilation, and duration of study follow up) on the aggregate OR computed for all controlled studies. All analyses were performed with Comprehensive Meta-analysis Software (Biostat, version 3.3.070). Alpha (α) was 0.05.

The present analyses included a total of twelve studies including three RCTs, five matched-control studies, and four case series studies containing 804 COVID-19 patient outcomes[7–17] from around the world (**Table 1**). The mean or median age of patients enrolled in these studies ranged from 48 to 70 years, with a greater proportion of men than women in most studies (proportion of women: 25% to 56%). All studies included patients with severe or life-threatening COVID-19. At the time of plasma transfusion, the proportion of patients on mechanical ventilation varied by study from 0% to 81%. The duration of follow up ranged from 7 to 30 days. All case-series studies demonstrated relatively low mortality rates for COVID-19 patients transfused with convalescent plasma (0% to 13%). Among RCTs, patients transfused with convalescent plasma exhibited a reduced mortality rate (13%) compared to non-transfused COVID-19 patients (26%; OR: 0.46, P = 0.03). Among matched control studies, patients transfused with convalescent plasma exhibited a reduced mortality rate (12%) compared to non-transfused COVID-19 patients (25%; OR: 0.41, P = 0.001). When patient outcomes from controlled studies were aggregated, patients transfused with convalescent plasma exhibited a reduced mortality rate (13%) compared to non-transfused COVID-19 patients (25%; OR: 0.43, P < 0.001). Meta-regression analysis indicated that mean or median cohort age, proportion of cohort receiving mechanical ventilation, and duration of study follow up did not affect the aggregate OR computed for all controlled studies (all coefficients P > 0.22). The fixed effect OR (OR: 0.44, P<0.001) was not different when *outlier* mortality rates from the matched control study by Xia and colleagues[18] were included in analyses (case mortality rate: 2%, control mortality rate: 4%).

In this outcomes analysis of contemporaneous COVID-19 convalescent plasma studies, the aggregate mortality rate of transfused COVID-19 patients was substantially lower than that of non-transfused COVID-19 patients. These results favour the efficacy of convalescent plasma as a COVID-19 therapeutic agent. The primary biological hypothesis for the efficacy of convalescent plasma is antibody-mediated SARS-CoV-2 viral neutralization, though other biological mechanisms may also contribute to the mitigation of symptoms[2]. These results align with similar analyses of historical data from convalescent plasma trials for viral diseases such as the 1918 flu epidemic[1], Severe acute respiratory syndrome[19], and H1N1 influenza[20].

There are several limitations to this analysis including aggregating mortality data across study populations that varied by: 1) the nation of data origin, 2) timing relative to worldwide progression of the pandemic, 3) clinical diagnostic and treatment algorithms, 4) plasma antibody titer and administration volume, 5) the latency between COVID-19 diagnosis and transfusion and 6) the duration of follow up after transfusion. We note that the reports cited in **Table 1** include positive results from different countries, suggesting that efficacy is robust across different health systems. Given the safety of plasma administration in COVID-19 patients[3,4], the results of this real-time data aggregration provide encouragement for its continued used as a therapy and may have broad implications for the treatment of COVID-19 and design of RCTs. Importantly, many of the patients enrolled in the studies included in the present analyses received convalescent plasma transfusions later in their disease course. In this context, prior to antibiotics and effective vaccinations, convalescent plasma therapy for streptococcal pneumonia and bacterial meningitis was widely understood to be most efficaceous very early in the course of hospitalizations[2]. As a result, our analysis may underestimate the mortality reduction acheivable through timely administration of convalescent plasma for COVID-19.

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Table

Table 1 | Case Fatality Rates in Hospitalized COVID-19 Patients

		Convalescent Plasma			Control			Statistics	
Study	**Location**	**Survivor**	**Non-Survivor**	**Mortality**	**Survivor**	**Non-Survivor**	**Mortality**	***OR***	***P***
Randomized Clinical Trials (RCT)									
Li et al. [7]	Wuhan, CHN	43	8	16%	38	12	24%	0.59	0.30
Gharbharan et al. [8]	NLD	37	6	14%	32	11	26%	0.47	0.18
Rasheed et al. [10]	IRQ	20	1	5%	20	8	29%	0.13	0.06
Fixed Effect Model [a]		100	15	13%	90	31	26%	0.46	0.03
Matched Controls									
Hegerova et al. [11]	Washington, USA	18	2	10%	14	6	30%	0.26	0.13
Liu et al. [17]	New York, USA	35	5	13%	118	38	24%	0.44	0.11
Perotti et al. [13]	Pavia, ITA	43	3	7%	16	7	30%	0.16	0.01
Abolghasemi et al. [14]	IRN	98	17	15%	56	18	24%	0.54	0.10
Fixed Effect Model [b]		194	27	12%	204	69	25%	0.41	0.001
Controlled studies Fixed Effect Model [c]		294	42	13%	294	100	25%	0.43	<0.001
Case Series									
Salazar et al. [15]	Texas, USA	24	1	4%	--	--	--	--	--
Hartman et al. [16]	Wisconsin, USA	27	4	13%	--	--	--	--	--
Duan et al. [17]	Wuhan, CHN	10	0	0%	--	--	--	--	--
Martinez-Resendez et al. [9]	Monterrey, MEX	8	0	0%	--	--	--	--	--
Total		69	5	7%	--	--	--	--	--

OR, odds ratio

[a] Relative weight (%): Li et al. (49.3), Gharbharan et al. (40.3), Rasheed et al. (10.4).

[b] Relative weight (%): Hegerova et al. (9.1), Liu et al. (27.4), Perotti et al. (12.8), Abolghasem et al. (50.7).

[c] Relative weight (%): Li et al. (17.8), Gharbharan et al. (14.6), Rasheed et al. (3.8), Hegerova et al. (5.8), Liu et al. (17.5), Perotti et al. (8.2), Abolghasem et al. (32.3).

Figure legend

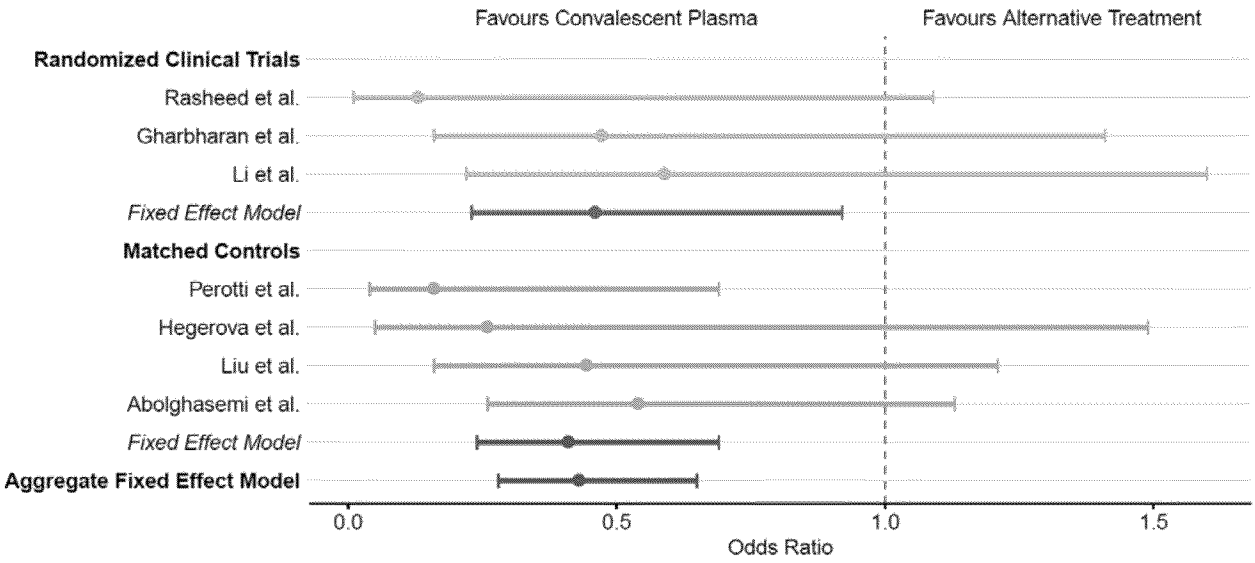

Figure 1. The impact of human convalescent plasma therapy on COVID-19 patient mortality. Forest plot illustrating odds ratios (OR) and 95% confidence intervals for controlled studies and aggregate fixed effect models. Randomized clinical trials including Rasheed et al.[10], Gharbharan et al.[8], and Li et al.[7] are represented in orange. Matched controlled studies including Perotti et al.[13], Hegerova et al.[11], Liu et al.[12], and Abolghasemi et al.[14] are represented in blue. Aggregate fixed effect models for each study type are represented by shaded hues. The overall aggregate fixed effect model is represented in teal.

Cc: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]

To: LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; langermans@bprc.nl[langermans@bprc.nl]; Dr. Mark Lewis[mlewis@bioqual.com]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; nax3@cdc.gov[nax3@cdc.gov]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; sekim@krict.re.kr[sekim@krict.re.kr]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; amy.c.shurtleff@cepi.net[amy.c.shurtleff@cepi.net]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; rkiatchula@gmail.com[rkiatchula@gmail.com]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; sinabavari@comcast.net[sinabavari@comcast.net]; Vasan Vasan[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Amelia Karlsson[amelia.karlsson@duke.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; Geraldine Hamilton[geraldine.hamilton@emulatebio.com]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@fda.hhs.gov]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; ldenisy@yahoo.com[ldenisy@yahoo.com]; Dan Barouch[dbarouch@bidmc.harvard.edu]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; elizabethsulkowski44@gmail.com[elizabethsulkowski44@gmail.com]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Krammer, Florian[florian.krammer@mssm.edu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Quim Segales[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Juergen Richt[jricht@vet.k-state.edu]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; erica@lji.org[erica@lji.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; golinger@mriglobal.org[golinger@mriglobal.org]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; picketttе@niaid.nih.gov[picketttе@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; que.dang@nih.gov[que.dang@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; 秦川[qinchuan@pumc.edu.cn]; Spergel, Jonathan[SPERGEL@email.chop.edu]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Padmini Salgame[salgampa@njms.rutgers.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion,

Jr.[rcarrion@txbiomed.org]; tverakit@gmail.com[tverakit@gmail.com]; anna@thsti.res.in[anna@thsti.res.in]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew Frieman[MFrieman@som.umaryland.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Koert Stittelaar[stittelaar@viroclinics.com]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; 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]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; rolandsutter@gmail.com[rolandsutter@gmail.com]; peter.palese@mssm.edu[peter.palese@mssm.edu]; Seder, Robert (NIH/VRC) [E][rseder@mail.nih.gov]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Mon 8/3/2020 12:26:07 PM (UTC-04:00)
Subject: WHO Animal Models Group Call-Aug 6 Agenda and Webex Invite
Mail Attachment.ics
Webex_Meeting.ics

Dear colleagues,

Please find below the Agenda and Webex Invite for our upcoming WHO Animal Models call on Thursday Aug. 6 at 3PM CET (Geneva).

Thank you all very much for your continued support

César, Simon and Bill

Agenda Aug 6

Pathogenesis

Randy Albrecht (Mount Sinai)

Vaccines

Robert Seder (VRC, NIH)

Peter Palese (Mount Sinai)

Open Questions

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 097 9297
Meeting password: mPvpDmjW487

Thursday, August 6, 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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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 23th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=mec4990eeb979166ec8fffe355619bf74
Start Time: 2020-08-06T15:00:00+02:00
End Time: 2020-08-06T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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

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Meeting password:mPvpDmjW487

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Start Time: 2020-08-06T15:00:00+02:00
End Time: 2020-08-06T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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To: Baric, Ralph S[rbaric@email.unc.edu]; David Relman[relman@stanford.edu]; Tom Inglesby[inglesby789@gmail.com]; Clague, Darren P[darren.p.clague@perspecta.com]
From: Brent PhD, Roger[rbrent@fredhutch.org]
Sent: Fri 8/7/2020 3:26:43 PM (UTC-04:00)
Subject: Artifacts
Li Xu Master's Thesis 2013.pdf

Dear Ralph, David, Tom, Darren,

May of course be known to you.

https://www.independentsciencenews.org/health/the-case-is-building-that-covid-19-had-a-lab-origin/

https://www.independentsciencenews.org/commentaries/a-proposed-origin-for-sars-cov-2-and-the-covid-19-pandemic/

2) Sources. https://www.sciencemag.org/news/2014/03/new-killer-virus-china. Note mine, site in which humans work hard, breath deeply, spend protracted time, vs cave one visits 1 or 2 X ("spelunks") and then leaves.

And see attached.

With best wishes,

Roger

Roger Brent, PhD

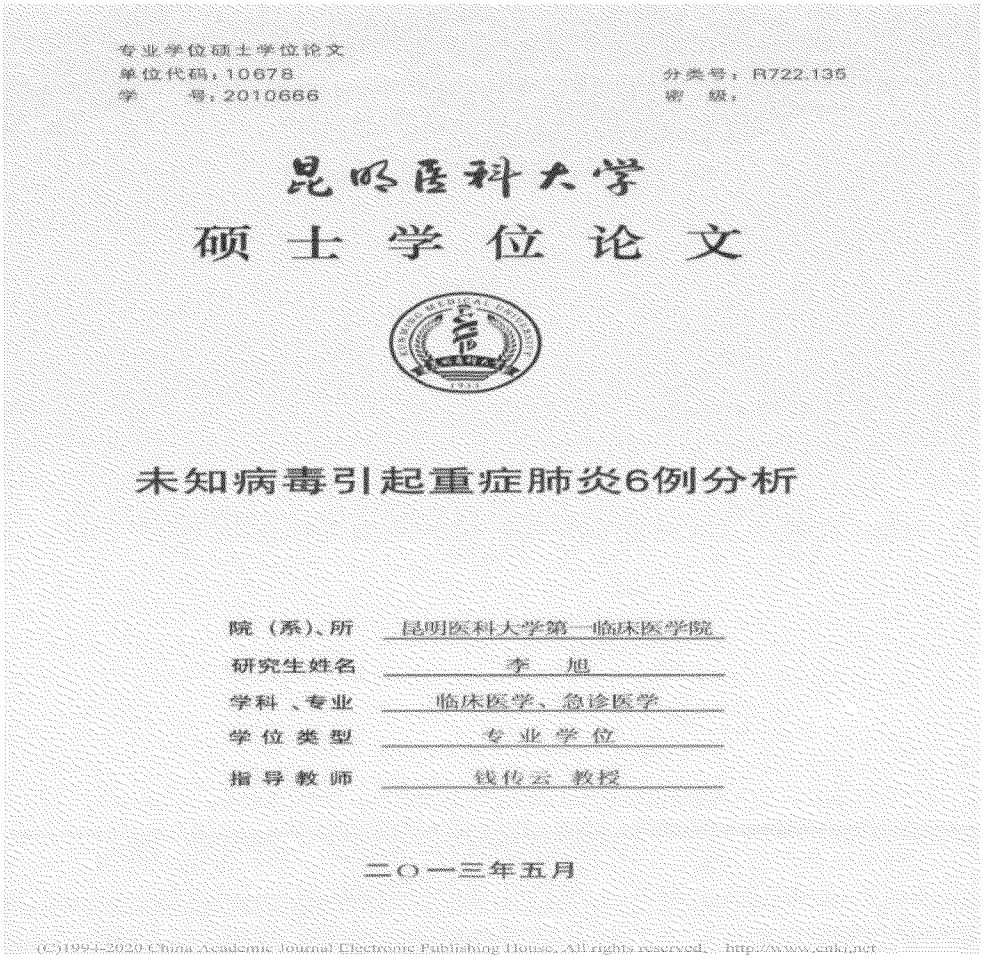
Member, Division of Basic Sciences, FHCRC

Affiliate Professor, Department of Genome Sciences, UW/
Affiliate Professor, Department of Bioengineering, UW/
Adjunct Member, Division of Public Health Sciences, FHCRC

Master's Thesis

"The Analysis of Six Patients With Severe Pneumonia Caused By Unknown Viruses"

School/ College: No. 1 School of Clinical Medicine, Kun Ming Medical University
Student's Name: Li Xu
Study field: Clinical Medicine and Emergency Medicine
May, 2013



专业学位硕士学位论文
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学　　号：2010666　　密　级：

昆明医科大学
硕士学位论文

未知病毒引起重症肺炎6例分析

院（系）、所　昆明医科大学第一临床医学院
研究生姓名　李　旭
学科、专业　临床医学、急诊医学
学位类型　专业学位
指导教师　钱传云　教授

二〇一三年五月

Translation note: This translation was commissioned by *Independent Science News* (https://www.independentsciencenews.org/). Where the author (Li Xu) provided it, we have preserved the original English text (e.g. The Title and the Abstract). Page numbers match the original pdf file. Thesis accessed June 10th 2020.

昆明医科大学

硕士学位论文

未知病毒引起重症肺炎 6 例分析

申请人姓名 李 旭

学科、专业 临床医学、急诊医学

申请学位类型 专业学位

指 导 教 师 钱传云 教授

完 成 日 期 二〇一三年五月

Kun Ming Medical University

Master's Research Statement

I stated that this master's thesis was written by me and under the supervision of my professors. It is based on the result of my independent study. Besides the citation and the acknowledgement in the end, there are no other organizations have published such work. In this paper, I have pointed out those who made contribution to this work and showed my appreciation. If there is any part in this paper that is fraud, I would take full responsibility.

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英文缩略词表

英文缩略语	英文全称	中文全称
T	temperature	体温
PR	pulse rate	脉率
RR	respiration rate	呼吸频率
BP	blood pressure	血压
HR	heart rate	心率
CT	computed tomography	计算机断层扫描
CRP	C reactive protein	C 反应蛋白
PCT	procalcitonin	降钙素原
SAA	serum amyloid A protein	血清淀粉样蛋白 A
DD	D-dimer	D-二聚体
FDP	fibrin degradation product	纤维蛋白降解产物
$PaCO_2$	partial pressure of carbon dioxide	二氧化碳分压
PaO_2	partial pressure of oxygen	血氧分压
PH	hydrogen ion concentration	氢离子浓度指数
PF	oxygenation (PaO_2/FIO_2) index	氧合指数
RLS	reaction leuel scale	机体反应水平分级
BNP	brain natriuretic peptide	B 型尿钠肽
PCR	polymerase chain reaction	聚合酶链式反应
HIV	human immunodeficiency virus	人类免疫缺陷病毒
INR	international normalized ratio	国际标准化比值
ECG	electrocardiogram	心电图
DNA	deoxyribonucleic acid	脱氧核糖核酸

RNA	ribonucleic acid	核糖核酸
ICTV	international committeeon taxonomy of viruses	国际病毒分类委员会
ARDS	acute respiratory distress syndrome	急性呼吸窘迫综合征
SARS	severe acute respiratory syndrome	严重急性呼吸综合征
SARS-CoV	SARS coronavirus	SARS 冠状病毒
SARS-like-CoV	SARS like coronavirus	SARS 样冠状病毒
ICU	intensive care unit	重症加强护理病房

Table of Contents

English translation of the MSc: "The Analysis of Six Patients With Severe Pneumonia Caused By Unknown Viruses" By Li Xu of Kunming Medical University, 2013. Translation completed: Jun 23rd 2020 (https://www.independentsciencenews.org/)

未知病毒引起重症肺炎 6 例分析

研究生：李旭
导　师：钱传云教授
昆明医科大学第一附属医院急诊医学科、EICU　650032

摘要

2012 年 4 月、5 月，我院先后收住 6 例未知病毒引起相关重症肺炎患者。此 6 位患者均为同一矿洞工人，工作环境中接触大量蝙蝠及蝙蝠粪便。最终结局 3 位患者死亡，3 位患者存活。据中国科学院昆明动物研究所鉴定，此 6 位患者工作矿洞内蝙蝠正为中华菊头蝠，然而我国科学家在寻找 SARS 病原的过程中，在中华菊头蝠体内提取出了 SARS 样冠状病毒（SARS-like-CoV）。本文针对 6 例患者所感染未知病毒相关重症肺炎的诊治过程及可能引起的病因、病原学进行推断与分析。

关键词：重症肺炎、蝙蝠、SARS 样冠状病毒

The analysis of 6 patients with severe pneumonia caused by unknown viruses

Master candidate: Li Xu

Academic supervisor: Prof. Qian Chuan yun

(Emergency Department and EICU, The 1st Affiliated Hospital of Kunming Medical University, Kunming, 650032)

Abstract

There were 6 patients with severe pneumonia caused by unknown viruses sent to Dep. Emergency, the first affiliated hospital of Kunming medical university in April,May,2012.They were all workers at the same mine where had a lot of bats and bats' feces. After the treatment, 3 patients died and 3 patients survived.

According to the appraisal of the Kunming institute of zoology, Chinese academy of sciences, the type of the bat in mine where 6 patients worked is Rhinolophus sinicus, from which was extracted SARS-like-CoV when Scientists in China were in the process of looking for SARS pathogen. The article aims at making an inference and analysis on the diagnosis and treatment process and the may causes, etiology of 6 patients with severe pneumonia related to infection by the unknown viruses.

Keywords: severe pneumonia、bats、SARS-like-CoV

Case 1

Patient Zhou, male, age 63, was admitted to the hospital on April 26, 2012. He had signs of fever, coughing, difficulty in breathing, chest pain, and hiccups for more than ten days. 24 days prior to the hospitalization, he was working in the mining well for half of a month. He worked 7 hours a day. After exposing to the mining well where there were many bats and bats' feces, he started to show signs of coughing and fever and had a 38 Celsius body temperature. He immediately went to the local hospital. His fever went on and off in the next five consecutive days. The actual treatment remained unknown. The highest body temperature was 40 Celsius and the lower is 37 Celsius. He also experienced headache, dizziness, ear congestion and dry cough. There was no pattern of his illness in daytime or night time, along with chest pain. Difficulty in breathing was getting worse. Occasionally, having hiccups. No sign of nausea, vomiting, or diarrhea. To pursue more treatment, the patient was admitted to my department. Since the onset of the disease, the patient had felt lethargic. He has insomnia and loss of appetite, but regular bowel movement and urination. Self-reported that he did not have a history of high blood pressure, diabetes and heart disease or other chronic diseases, nor did he have hepatitis, typhoid or any other contagious disease. He did not have surgical operation, trauma, and blood transfusion in the past. He was not allergic to any medication or food. His vaccination record remained unknown. Physical checkup: body temperature is 37.8 Celsius, pulse rate: 74 times/minute, respiratory rate: 20 times/ minute, blood pressure: 110/63 mmhg. The patien t stays alert and could answer all the questions. No sign of malnutrition or obesity. He was sent to the room by stretcher. Skin and mucous membranes remained normal, and so were the pupils. They were 3mm in diameter. The pupils remained sensitive to light. The chest and respiratory movements were symmetrical. The breathing soundswere rough. Dry crackles were heard on both bases of the lung. His heart rate is 74 beats/minute, regular heart rate and no heart murmur from any of the heart valves. Softness of the abdomen, no pain when pressured,no rebound tenderness, or guarding. Normal bowel sound: 5 times/minute. No inflammation at the lower part of the legs. Regular body reflex. No patho logical reflexes. The blood report from 04/25/2012: WBC12.10X10^9/L, N%89.3, Hemoglobin: 178g/L; Comprehensive Metabolic Panel was CRP 20.3 mg/L, blood ammonia: 43 umol/L; Normal result on the coagulation report. As the CT scan showed, there was extensive and patchy consolidated exudate bilaterally, elevated bronchovascular shadows and lung markings, some nodules in different sizes, parts were calcified. Mediastinal lymph node enlargement, partially calcified.

Initial Diagnosis: 1. Fever, coughing, dyspnea, hiccup 2. Hyponatremia; 3. Malfunctioning in liver and bladder

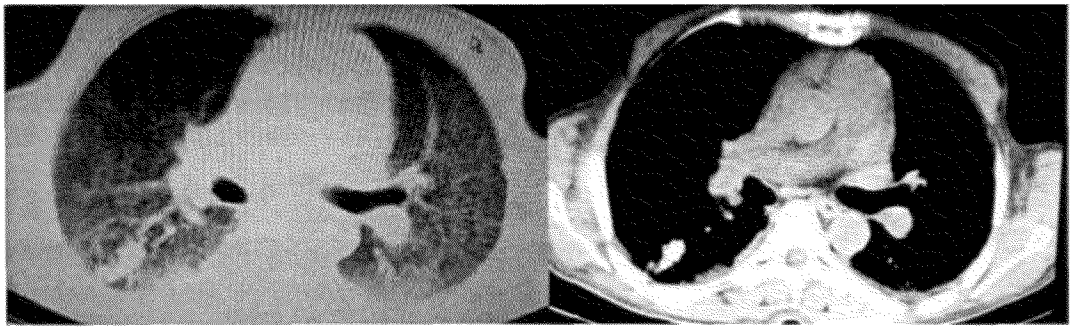
Method

The examination after hospitalization:

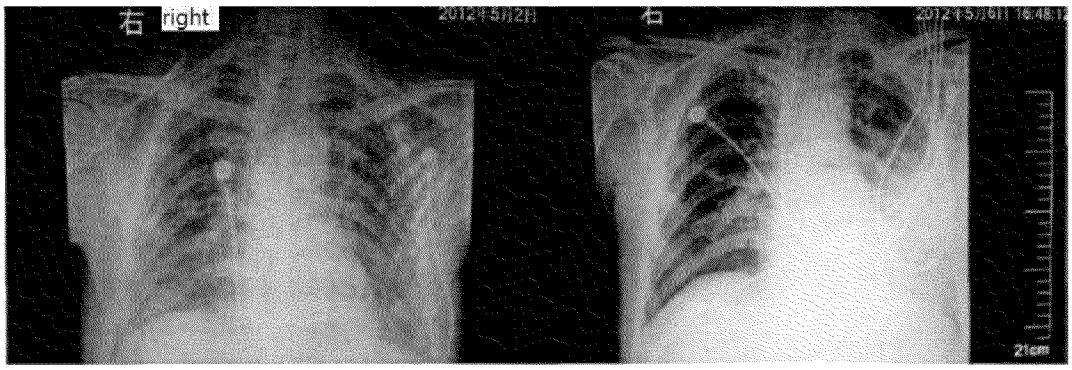
2012/4/25 Computed tomography report: extensive and patchy consolidated exudate over bilateral lung, increased Broncho vascular shadows and lung markings, some nodules in different sizes, parts were calcified. Mediastinal lymph node enlargement, partial were calcified.

2012/4/30 CT report: 1. No noticeable changes in the lung, little pleural effusion in both lungs..

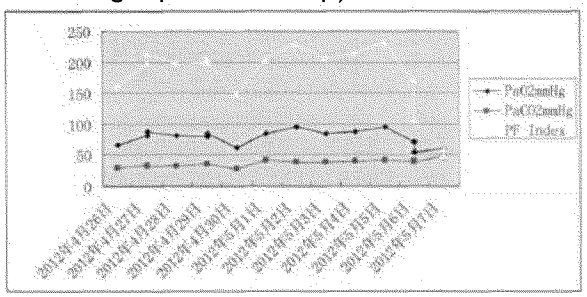
Pleural thickening posteriorly, and the rest was the same as the previous report. 2. As the scan showed, there was little ascites (see below).

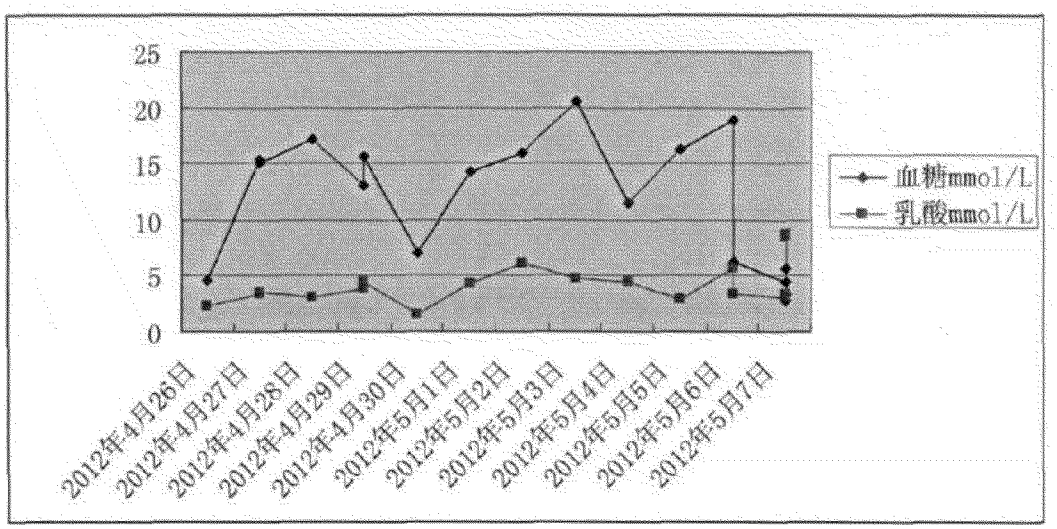


2012/5/2 bedside chest film: 1. Bilateral Lung markings worsening and getting blurry, and there were shadows of the clot. Nodular shadow was noted in 2nd intercostal space of right middle lobe, and a small opacity was over left hilar region. Requested a follow up examination after the clinical anti-inflammation treatment. 2. The outline of the heart is not too big 3. The diaphragm remains normal (see the left picture below).



2012/5/6 bedside chest film: 1. Bilateral Lung marking augmentation and getting blurry, and there were shadows of the clots. Increased laminar density in the middle and lower field of the left lung, the hilum of both lungs are blurred. Requested a follow up examination after the clinical anti-inflammation treatment. 2. Aorta is circuitous and the outline of the heart is normal. 3. Fluid in the left side of the pleural cavity and need to be evacuated. Please cooperate with the clinic (see the right picture on top). 2012/4/26 - 2012/5/7: Analysis on the arterial blood gas (see below):



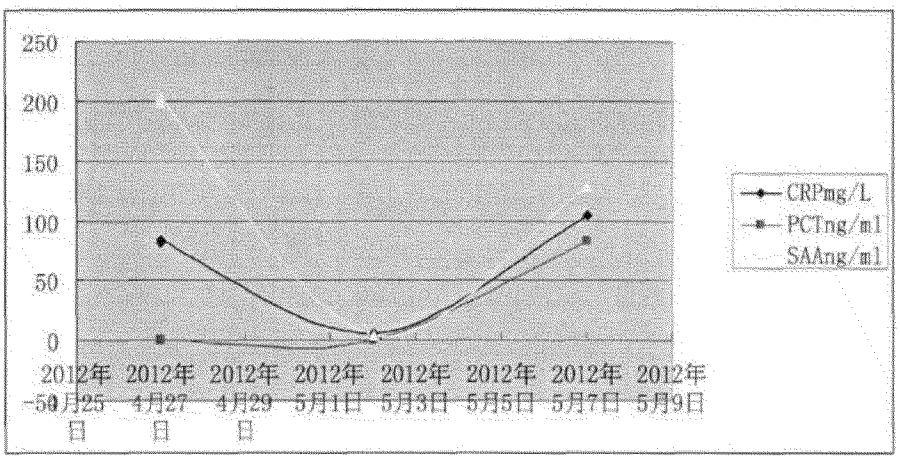


2012/4/27 tumor protein chip shows ferritin is 484.86 (Normal male < 322 microgram/ L), Human chorionic gonadotropin is 0.65 (normal< 3.0 microgram/ L), prostate Specific Antigen is 0.02 (normal< 0.1 microgram/L) carbohydrate antigen 125: 42.22 (normal < 35.0KU/L).

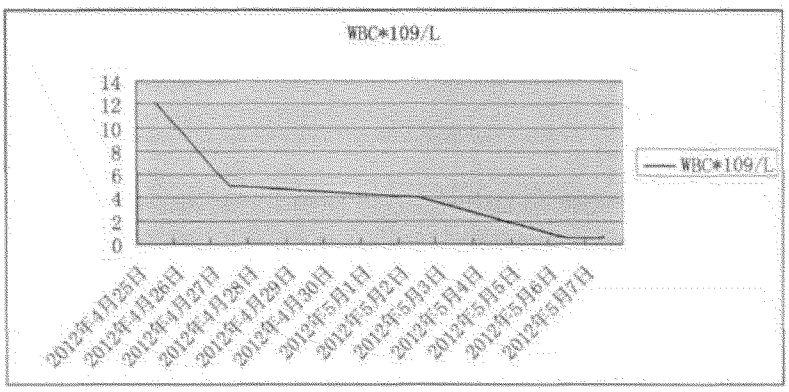
On 2012/4/27, the Widal test and WFR test both came back negative. Results for Herpes simplex virus, EB virus and CMV are all negative. Urine culture is negative and so is Ghb. The stool test is also normal. Autoantibody and anti-nuclear antibodies are both negative. 2012/4/24 report: compliment C3C4 has decreased; Glucose in Urine 4+, Ketone is negative. Thyroid test positive.

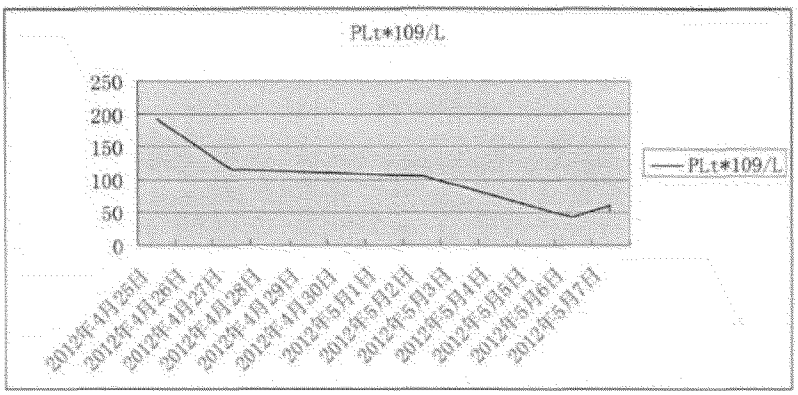
2012/4/27 - 2012/5/7: D-dimer reports 7.2 ug/ml (Apr, 27), D-dimer 3.6 ug/ml (May, 2), D-dimer 7.0 ug/ml (May, 6), D-dimer 5.0 ug/ml (May, 7).

2012/4/27 -2012/5/7 infected cell-specific protein (see below):



2012/4/25 - 2012/5/7 white blood cell and blood platelet (see below):





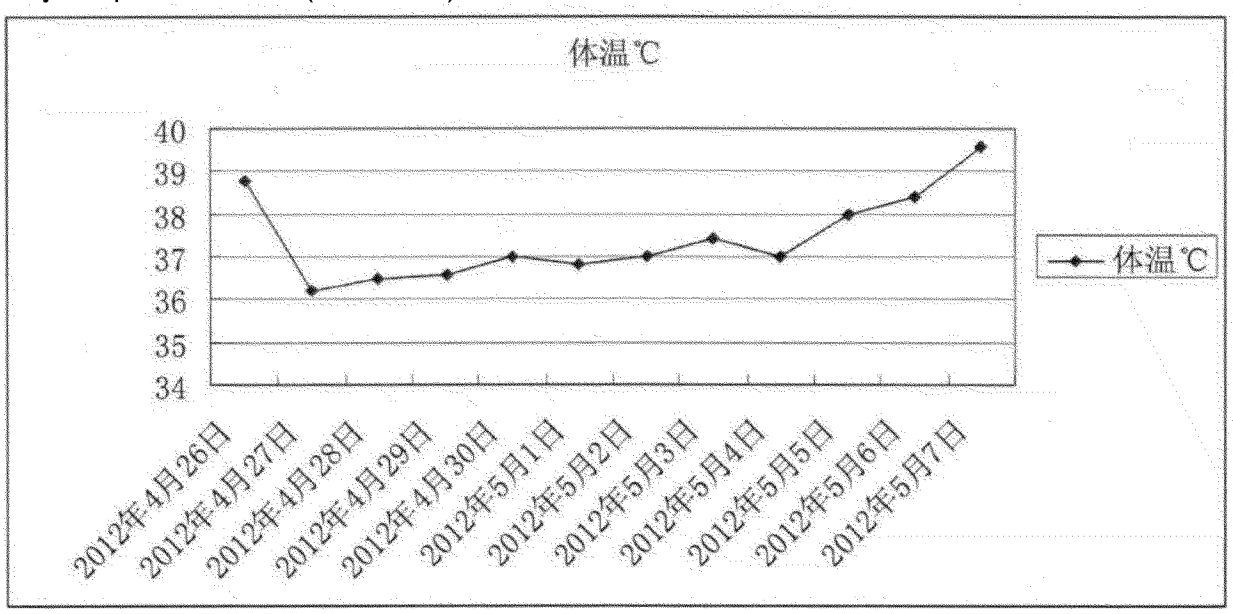
T, B, NK lymphocyte percentage and count (see below)

日期 Date	CD3 阳性 T 淋巴细胞绝对值 Positive Aboslute Value of Lymphocyte	T 抑制细胞 Suppressor Cell CD3+CD8+双阳细胞绝对值 double positve cell absoulute value	T 辅助细胞 supporting cell CD3+CD4+绝对值 abosolute Value	CD3CD4 CD8 均为阳性细胞绝对值 Positvie cell absolute value	NK 细胞（CD16+CD56+双阳细胞） double positive cell	B 淋巴细胞 Lymphocyte（CD19+CD45+）
4-27	384↓	262	109↓	5↓	215	56↓
5-7	63↓	27↓	32↓	0↓	13↓	106↓

2012/4/27 sputum culture and blood culture were both negative (three times).
2012/5/7 blood culture implies positive for Acinetobacter baumannii and negative for candidiasis
2012/5/7 sputum culture Acinetobacter baumannii, pan resistant
2012/5/6 ultrasound reports severe ascites

2012/5/7 Ascites. Result of tumor cell testing is negative. Gram positive in cultivation ascites regular test is negative. The Rivalta test is also negative.

Body temperature chart (see below):



Prescription after admission:

2012/4/26 – 2012/5/2 (J) Methylprednisolone 80mg, ivgtt, Q 12h.

21012/5/2 – 2012/5/7 (J) Methylprednisolone 40mg, ivgtt, Q 12h.

2012/5/7 – death (J) Methylprednisolone 80mg, ivgtt, Q 12h.

2012/4/26 – 2012/5/2 Meropenem 0.5gx2 shots, ivgtt, Q8h.

2012/5/7 – death Meropenem 0.5gx2 shots, ivgtt, Q8h.

2012/5/7 – death Vancomycin 0.5gx2 shots, ivgtt, Q12h.

2012/4/26 – death L - Voriconazole 0.1gx 2 shots (double the dosage on the first day), ivgtt, Q12h.

2012/4/26 – death Acyclovir 0.25g*2, ivgtt, Q8h.

Discussion

The patient worked from the mining site since 2012/4/2 for up to 14 days.

Patient admitted to the hospital: 2012/4/26. Patient discharged: 2012/5/7. Total days: 12 days.

Discharged Diagnosis: 1. Severe lung infection 2. Sepsis 3. Septic shock and infection in abdominal cavity 4. Asystole and stop breathing

Discharge reason: death

According to CT and Chest radiograph, the illness was progressively developed.

As the analysis on the arterial blood gas shows, during hospitalization, the patience had Type I respiratory failure. Oxygenation index was poor. According to the “ARDS Berlin Criteria” in 2012, for sure it was ARDS. Consequentially, one of the causes of death could be respiratory failure.

According to several researches from either abroad or domestically, glucose variability is associated with rate of prognosis or death. During the hospitalization, the patient was given intensive insulin treatment b y our department. We tried to keep the blood sugar between 6-10 mmol/L. However, the patient’s glucose varies, poor prognosis.

The result for tumor protein chip came back positive, which means the patient had tumor related disease. As a result, the systems of the whole body was impacted.

After the patient was admitted to the hospital, WBC and PLt were constantly decreasing. Indicated by other virus infection related researches, WBC, PLt, T, B, NK Lymphocyte percentage and count of the patients are also decreasing. It shows that the immune system of the patient was impaired, had poor resistant to the disease and could easily be infected by hospital-acquired infection.

The day the patient died, the blood and mucus culture showed Acinetobacter baumannii, severe ascites. There was Gram-positive bacteria in ascites culture. On the same day, the PCT report was 83.30ng/ml. As a result, one of the causes of death is septic shock. (severe lung infection and abdominal cavity infection).

After admitted, the patient’s D-dimer was 7.2 ug/ml (Apr, 27), 3.6 ug/ml (May, 2), 7.0 ug/ml (May, 6) and 5.0 ug/ml (May, 7). The patient was bed ridden after admitted to the hospital and also had tumor. The oxygen level in the blood was significant low two days prior to his death. There was a possibility of pulmonary thromboembolism. However, the patient was severely ill, it was not recommended to have an intensified chest CT checkup. Therefore, acute pulmonary infection could be one of the causes of death. The family of the patient ref used the autopsy procedure.

After the suspension of Meropenem on May 2, 2012, the patient was no longer treated with any antibiotics. His temperature went back up right after. Therefore, antibiotics play an important role in the treatment.

Cause of death analysis: the patient was the oldest out of the six patients and had some tumor related disease. His immune system was weak so had a poor body resistant to the disease. The disease was acute and fierce.

Case Two

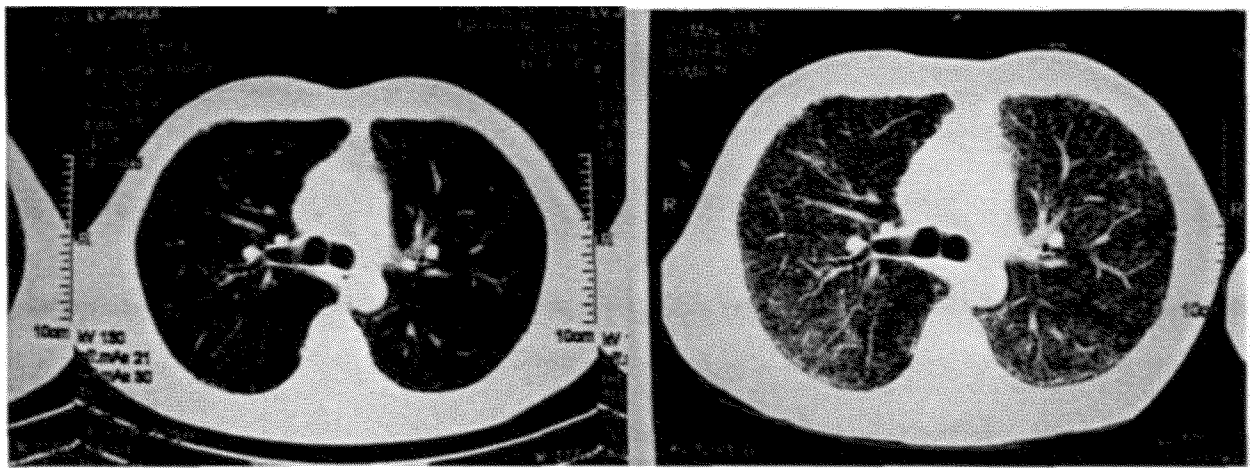
Patient Lu, Male, 42 years old, was admitted to the hospital on April 25, 2012. He had fever and been coughing for half of a month and for the past three days had difficulties in breathing. He worked in the mining hole before and was exposed to large amount of feces of bats. Half of month ago, he started to have fever. His body temperature was 38.5 Celsius at first. Occasionally, when he coughed, therewas rusty colored mucus with blood clots. Felt bloated in the stomach, loss of appetite and hiccup. He initially went to the small clinic for transfusion but it was not helpful. Then, he was transferred to Yu Xi People's Hospital for treatment. During hospitalization, his body temperature was 40 Celsius and the fever did not follow any pattern. No sign of chills before the fever. Still coughed with rusty-colored mucus and blood clots. Difficulty in breathing for three days, especially after moving around. Chest tightness but no chest pain. No problem lying down. No sign of paroxysmal dyspnea at night. No abdominal pain. No visible hematuria. No history of high blood pressure, diabetes, coronary heart disease or stroke. He was born in Zhao Tong, Yun Nan and had been to Mo Jiang. He worked in the mining field prior to the illness and was exposed to large amount of bats' feces. Five of his colleagues had similar illness. He denied hepatitis, typhoid, tuberculosis or any other infectious disease. No history of blood transmission or allergy reaction. The vaccination report remained unknown. On examination: 36.6 Celsius, Pulse 110 times/ minute, Respiration rate 32 times/ minute, blood pressure 98/55mmHg, in poor condition. He was sent into the ward on a stretcher. Reaction level scale was rated 1. No deformation on the head and features. The pupils were big and round with 3 mm diameter. He was sensitive to the lights. Soft neck, no rigidity. Airway was in the center. The chest looked symmetric from the outside. Rough breath sounds bilaterally, and moist crackles were heard on both bases of the lung. The breathing sounds rough. Moist rales from the bottom of the lungs. Heart was in normal size. Heart rate 110 times/ minute, regular rhythm, no murmur, rubs or gallops. Abdomen soft, non-tender. Normal bowel sounds: 3 times/minute. Did not notice any rashes or eschar. No inflammation on the legs. Muscle strength and tension remained normal. Additional checkup: According to the CT from Yu Xi People's hospital on April 25, 2012: severe pneumonia over bilateral lung. The bottom of the left lung had limited pulmonary emphysema and bullae in the right lung; HBsAg (+), HbeAb (+), HbcAb (+). Our blood gas analysis showspH 7.431, PaO_2 66.2mmHg, Oxygenation Index 162, lactic acid 1.7 mmol/L, Potassium in the blood 4.04mmol/L, Sodium in the blood 134.7 mmol/L.

Initial diagnosis after admission: 1. Severe pneumonia 2. Type I respiratory failure 3. Sepsis 4. Hepatitis B

Method (Some of the information was missing)

After admission, the complete examination:

Chest CT on 2012/4/30: 1. Increased lung markings, blurry and noticed multiple nodular shadows. Bilateral lung patchy exudate. 2. Mediastinal lymph node enlargement, regular heart shadow. Did not notice any abnormal in the artery. (see the left picture below)



2015/5/29 CT reports: Compared to the scan on 2015/5/23 about the treatment on bilateral lungs, marked interstitial opacities and exudation in both lungs. No significant increase of fibrosis. Scant pericardial effusion as before, same as the old scan (right picture above).

2012/5/7 CT reports: 1. increased of lung marking and more opacities same as before. Spotted multiple shadows of nodules spread across. The exudation seemed to recover a bit. 2. Inflammation of the mediastinal lymph node is the same as before. So are the heart and artery.

2012/5/14 CT reports: 1. increased lung marking and more opacities same as before. Spotted multiple shadows of nodules spread across. The exudation seemed to be the same. 2The mediastinal lymph node is the same as before. So are the heart and artery.

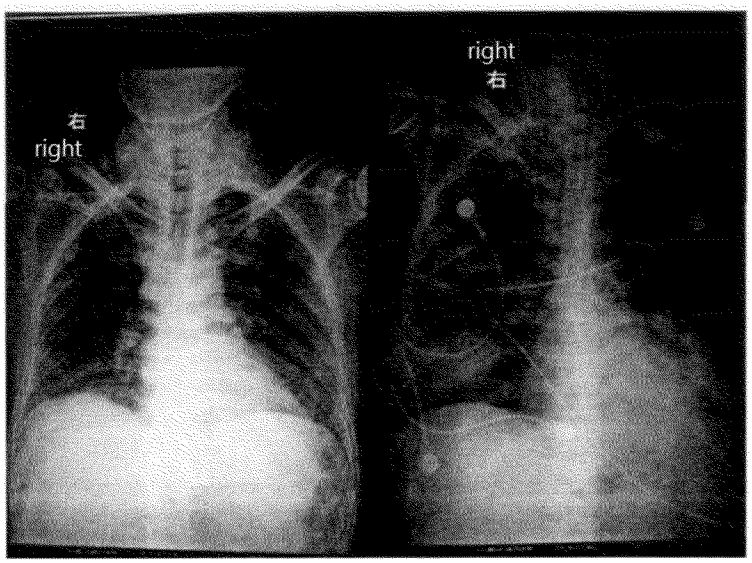
2012/5/18 CT reports: increased of lung marking and more opacities. Spotted multiple shadows of nodules in more density. The outline is blurry. Basically remain the same as before. Emphysema existed in lower left lobe. The structure of the hilar remain define and clear. The airway is clear. The mediastinal lymph node is the same as before. No sign of pleural effusions.

2012/5/23 CT reports: 1. marked interstitial opacities and exudation in both lungs. No significant increase of fibrosis 2. No cardiomegaly but the mediastinal lymph node was inflamed.

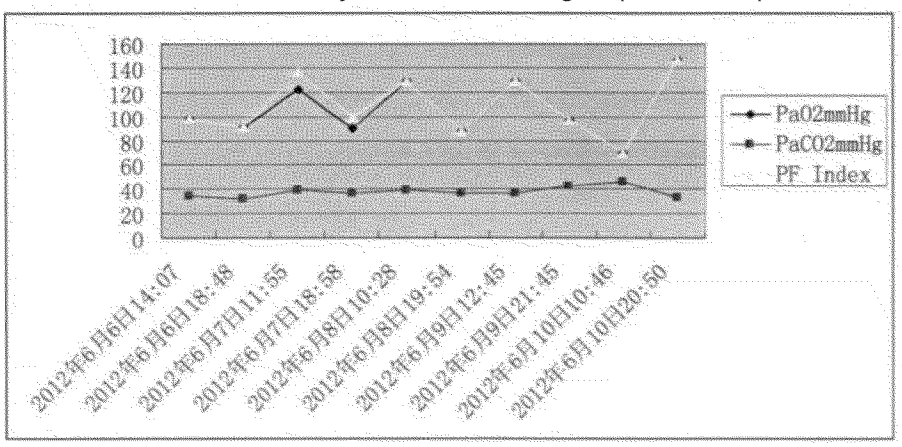
2012/6/2 bedside CT reports: 1. Noticed spread of flaky shadow and chestnut-shaped nodules in both lungs and it seemed progressed compared to before. The structure of the hilar appeared unclear. Need further confirmation. Please work with clinical for further diagnosis. 2. The outline of the heart is normal. 3. The diaphragm looked normal.

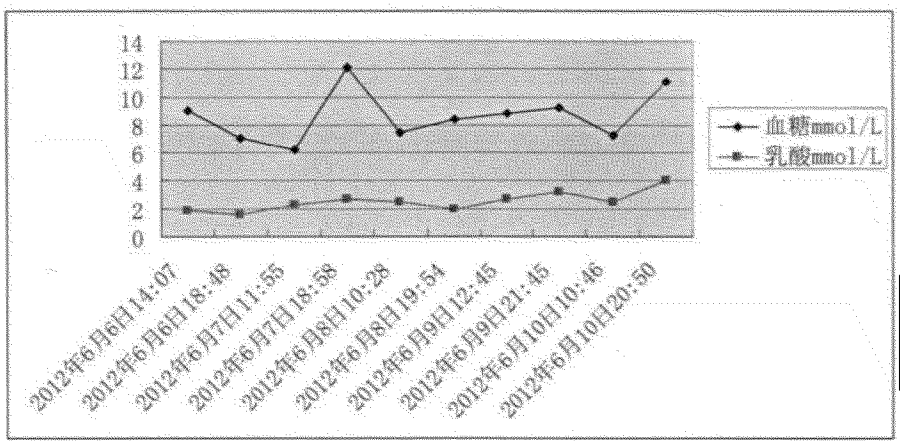
2012/6/5 bedside CT reports: 1. Noticed spread of flaky shadow and chestnut-shaped nodules in both lungs and it seemed progressed compared to before. 2. The outline of the heart look ed poor. 3. The diaphragm looked normal. 4. Deep vein thrombosis at the right side of the first rib.

2012/5/16 – 2012/6/10 Chest film comparison (see below)



2012/6/6 – 2012/6/10 Analysis of the blood gas (see below)





Blood sugar
Lactic acid

Infection related protein (missing some data, did not make a table analysis):

2012/4/26 infection related protein report: C-Reactive protein 117.0 mg/L, SAA 398.00 ng/L.

2012/5/2 infection related protein report: C-Reaction protein 2.2 mg/L, PCT 0.04ng/ml, SAA 4.80ng/L.

2012/5/7 infection related protein report: C -Reaction protein 12.0 mg/L, PCT 0.04ng/ml, SAA 127.00 ng/L.

2012/5/18 infection related protein report: C-Reaction protein 66.3 mg/L, PCT 0.04ng/ml, SAA 230.00 ng/L.

2012/5/29 infection related protein report: C-Reaction protein 0.8 mg/L, PCT 0.04ng/ml, SAA 5.79 ng/L.

2012/5/30 infection related protein report: C-Reaction protein 23.7 mg/L, PCT 0.27ng/ml, SAA 190.00 ng/L.

2012/4/25 – 2012/5/2 No significant abnormality in the coagulation test (PT, APTT, TT, FIB).

2012/4/25 – 2012/5/6 Comprehensive Metabolic panel reports: hypoalbuminemia, others were normal

2012/5/2 blood test reports: FDP 6.5ug/ml, Antithrombin III 108.4%, D-dimer 4.4 ug/ml.

2012/5/18 blood test reports: FDP 5.3 ug/ml, Antithrombin III 146.5%, D-dimer 3.9 ug/ml.

2012/4/25 – 2012/5/2 no abnormally in the routine blood test.

2012/5/2 routine urine test is negative.

2012/4/25 troponin reports negative

2012/4/26 BNP 33.44 pg/ml.

2012/4/26 red blood cell ESR 25 mm

2012/4/26 IgM 2.98 (Normalcy: 0.4 – 2.3 g/L), Complimentary C 0.78 (Normalcy: 0.9 – 1.8 g/L)

2012/4/26 Result for Widal test and WFR are both negative.

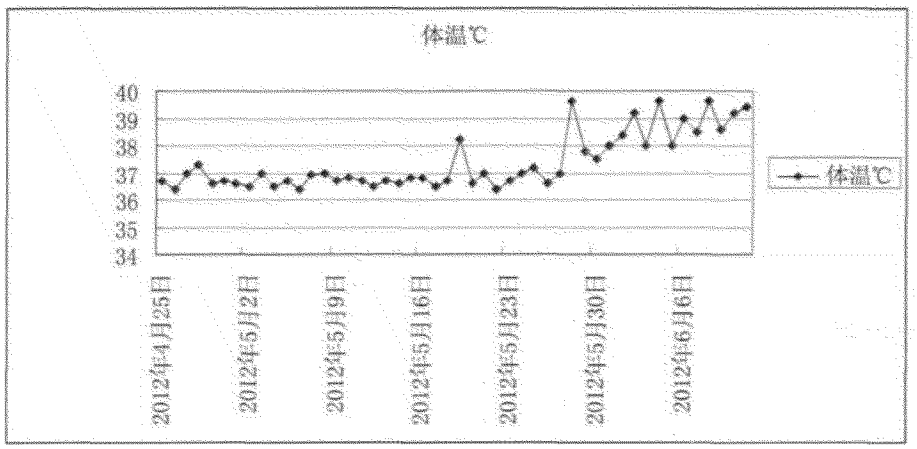
2012/4/26 Hepatitis study report: HBsAg quantity 157.5 ng/ml, HBeAb quantity 2.12 U/ml, HbcAb quantity 2.55 U/ml. HBsAg positive.

2012/4/26 PCR test: EBV positive 5200 (normalcy: 5000 measurement/ml).

2012/4/26 PCR test showed TB negative
2012/5/1 PCR rest showed HSV1 negative
T, B, NK cell percentage and count (see below):

日期 Date	CD3 阳性 T 淋巴细胞绝对值 Positive Aboslute Value of Lymphocyte	T 抑制细胞 Suppressor Cell CD3+CD8+双阳细胞绝对值 double positve cell absoulute value	T 辅助细胞 supporting cell CD3+CD4+绝对值 absolute Value	CD3CD4 CD8 均为阳性细胞绝对值 Positvie cell absolute value	NK 细胞（CD16+CD56+双阳细胞） double positive cell	B 淋巴细胞（CD19+CD45+） Lymphocyt
4-26	361↓	166↓	[redacted]	[redacted]	128	[redacted]
5-8	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
5-10	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
5-14	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
5-17	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
5-22	[redacted]	[redacted]	[redacted]	13	[redacted]	[redacted]
5-28	501	425	[redacted]	[redacted]	[redacted]	[redacted]
5-30	766	587	[redacted]	[redacted]	[redacted]	[redacted]
6-2	1011	711	[redacted]	[redacted]	[redacted]	[redacted]
6-4	324↓	243	[redacted]	[redacted]	[redacted]	[redacted]

Body Temperature (see below):



Prescription after being admitted to the hospital (some information is missing):

2012/4/25 – 2012/4/26 (J) Methlyprednisolone injection 40mg, ivgtt, Q12h.

2012/5/2 – 2012/5/4 (J) Methlyprednisolone injection 40mg, ivgtt, Q12h.

2012/4/25 – 2012/5/4 Ganciclovir injection 125mg x 2 shots, ivgtt, Q12h.

2012/4/26 – 2012/5/2 Meropenem 0.5g x 2 shots, ivgtt, Q8h.

2012/5/1 – 2012/5/2 L- Voriconazole 0.1g x 2 shots, ivgtt, Q12h.

Remote Meeting Minute 1

Meeting time: 2012/6/4

Meeting location: Number 1 hospital

Experts Attendee: Dr. Xie Can Mao , Chief Physician, Respiratory department of The First Affliated Hospital, Sun Yat-Sen University

After hearing the report of the medical history of the patient and other examination report, Dr. Xie diagnose: 1. Severe Pneumonia (possibly Fungus infection? Virus infection?); 2. Type I respiration failure 3. Sepsis 4. Hepatitis B.

The patient can complete the G test, and fiberoptic bronchoscopy examination. If the circumstances allow, we should also consider conducting biopsy of lung. However, the patient is on noninvasive ventilator, the biopsy is not appropriate. Treatment wise, Dr. Xie agrees with what we have done so far. He suggested that we should also prescribe 2 tablets of compound Sulfamethoxazole (oral), 3 times/ day. Fluconazole for the fungus and Thymosin for boosting up immune system.

Remote Meeting Minute 2

Meeting time: 2012/6/7

Meeting location: Number 1 hospital

Experts Attendee: Shi Jing, department of Occupation Toxicology, Shang Hai Pulmonary Hospital

After hearing the report of the medical history of the patient and other examination report, Dr. Shi suggests: 1. Have a consultation with the Toxicology department 2. Further treatment from the respiratory department 3. Do not take Pneumoconiosis into consideration. Dr. Shi also agrees with our treatment so far.

Discussion

The patient started working in the mining site on 2012/4/2 and last for 14 days.

The first day of hospitalization is 2012/4/25 and the day left is 2012/6/12, total of

48 days.

Discharge Diagnosis: 1. Asystole and stop breathing 2. Severe Pneumonia 3. Type I respiration failure 4.Sepsis 5.Hepatitis B

Discharge reason: death

According to CT and Chest radiograph, the illness was progressively developed.

As the analysis on the arterial blood gas shows, during hospitalization, the patient had Type I respiratory failure. Oxygenation index was poor. According to the “ARDS Berlin Criteria” in 2012, for sure it was ARDS. Consequentially, one of the causes of death could be respiratory failure.

During hospitalization, the T, B, NK Lymphocyte percentage and count of the patients were decreasing. It shows that the immune system of the patient was impaired, had poor resistant to the disease and could easily be infected by hospital-acquired infection.

After admitted to the hospital, suggested by the Hepatology, it could also be Hepatitis B.

(Some information of the patient is missing so we failed to do a thorough analysis)

Case Three

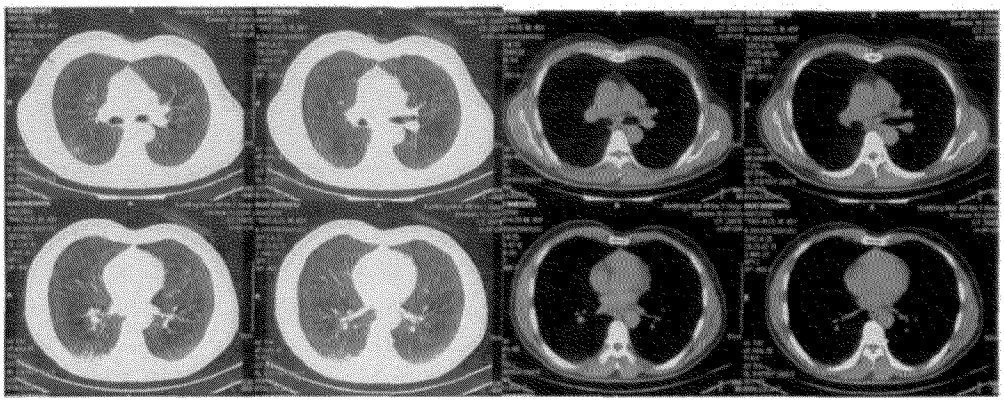
Patient, Mr. Guo, male, 45 years old, was admitted to the hospital. He had signs of coughing, productive cough, shortness of breath, and fever for two weeks. The patient went into a 150 meter deep cave 24 days ago. He continuously inhaled some unknown gas for 10 days. About two weeks ago, started having signs of coughing, tightness in chest, shortness of breath, fever, yellow and greenish mucus (about 2-3 times a day, about 5 ml each time). When he rests, he feels tightness in chest, shortness of breath and fever around 39 – 40 Celsius. Before the fever, there are no chills. Along with headache and soreness in limbs. After taking some antipyretics (not sure what kind), the body temp went back to normal. 10 days ago, the mucus turned white and with some blood string (light red, 2-3 times a day). Went to the local clinic for treatment and was prescribed antibiotics (not sure what kind). The coughing with blood stopped three days after but other symptoms remained the same. 2 days ago came to the emergency and was admitted by us. CT reports: lung marking increase, blurry, septal thickening. Multiple nodules and floccular exudate. Multiple inflamed lymph nodes in mediastinum. Was given Cefmenoxime 0.5g x 6, ivgtt, Qd and methylprednisolone 40mg, ivgtt, Qd for inflammation for two days. The patient was getting better and the body temperature was between 38 – 39 Celsius. For further treatment, the patient was admitted to our department for respiratory impairment. During the whole process, the patient did not have any chest pain, faint, coughing pink bubbly mucus or sign of paroxysmal dyspnea at night. The patient eat and sleep well. Normal bowel movement and urination. He lost 10 kilograms. Had a bowel obstruction surgery in 1985 (no further detail). No history of allergy to any medication. Physical examination: Body temperature 36.2 Celsius, pulse 96 times/minute, Respiration rate 20 times/minute, BP 120/85 mmHg, stay sharp, soft neck, no resistant, the lips and tip of the fingers appear cyanotic, the outline of the chest looks normal, no enlargement in between the ribs, no tenderness on the chest when pressured; oxygenation is 83% without inhaling, resonant to percussion over bilateral lung, rough breathing sounds, slightly moist crackles in lower right lung. Did not hear any dry crackle from either lung. No lump on the heart area, no apical impulse, normal cardiac boundary, heart rate 96 times/ minute, no murmurs or gallop. Abdomen soft, non-tender. No inflammation on the legs. Additional checkup: 2012/4/25 CT report: lung markings increased, blurry, septal thickening. Multiple nodules and floccular exudate. Multiple inflamed lymph nodes in mediastinum. 2012/4/25 our regular blood test report: WBC13.01 x 10^9/L, Percentage of Neutrophil is 70.3 %, ANC is 9.15 x 10^9/L, RBC 5.87 x 10^{12}/L, Hemoglobin 175 g/L, PLT 352 x 109/L. CRP 60mg/L.

Initial diagnosis after admission: 1. inhaling respiratory impairment (restrictive lung disease); 2. Severe Pneumonia

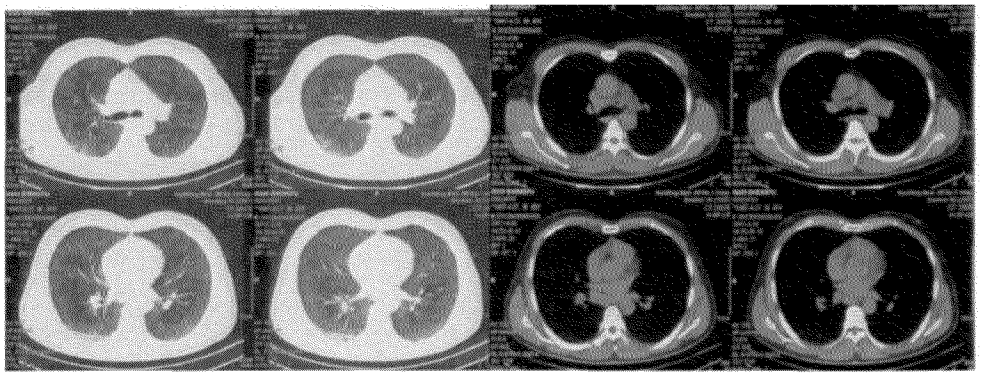
Method

After admission, more complete examination:

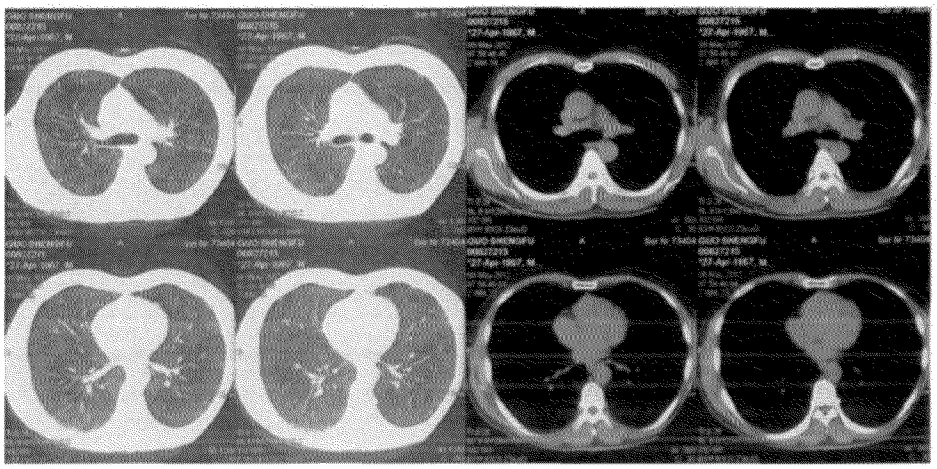
2012/4/25 CT reports: lung markings more numerous and prominent, septal thickening. Multiple nodules and floccular exudate; Multiple inflamed lymph nodes in mediastinum. The shadow of the heart remain normal; no effusion (see below).



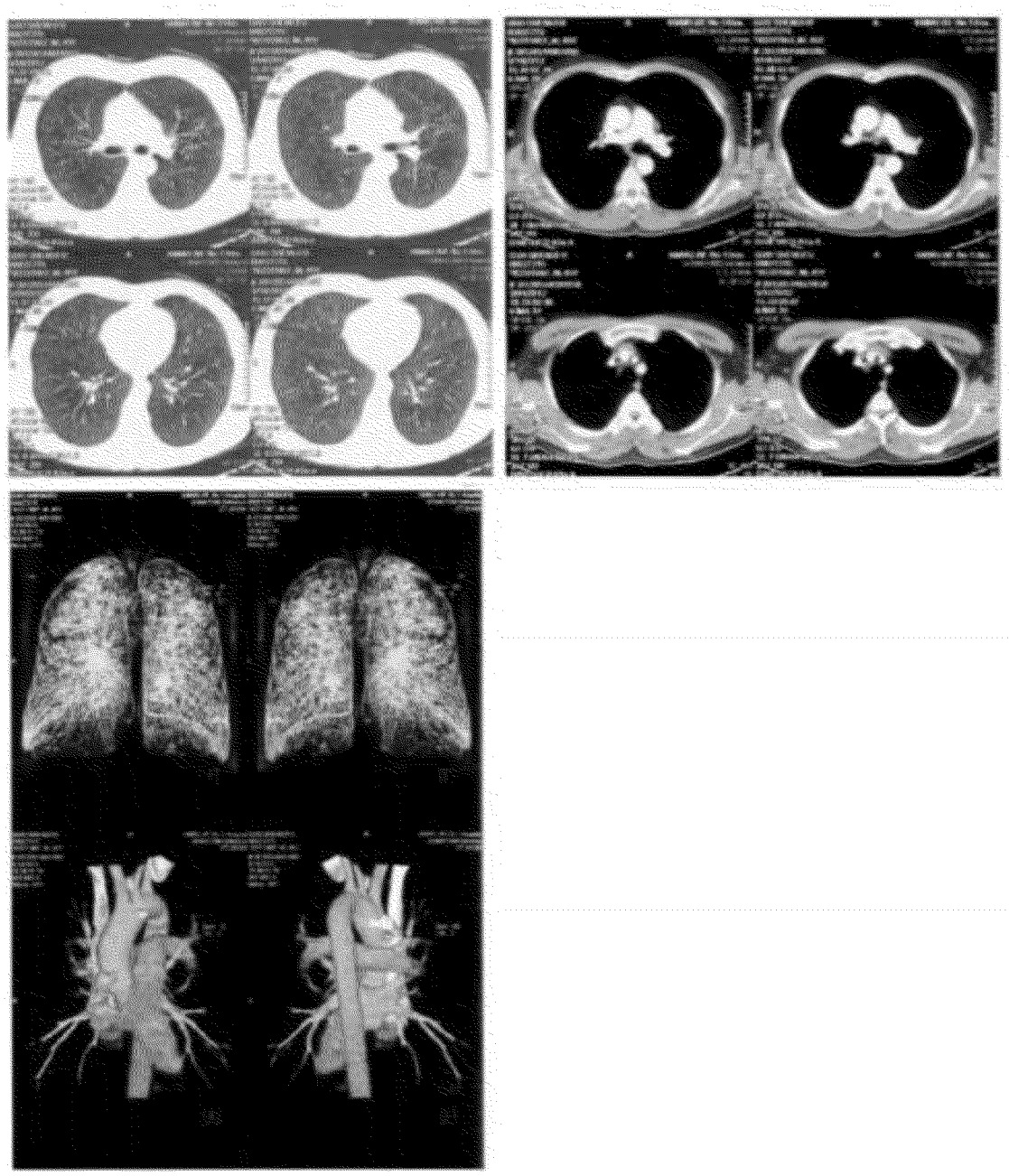
2012/4/30 CT reports: Compared to before, the lung markings are more numerous and prominent. Septal thickening, multiple nodules and floccular exudate; multiple inflamed lymph nodes in mediastinum. Others unchanged (See below).



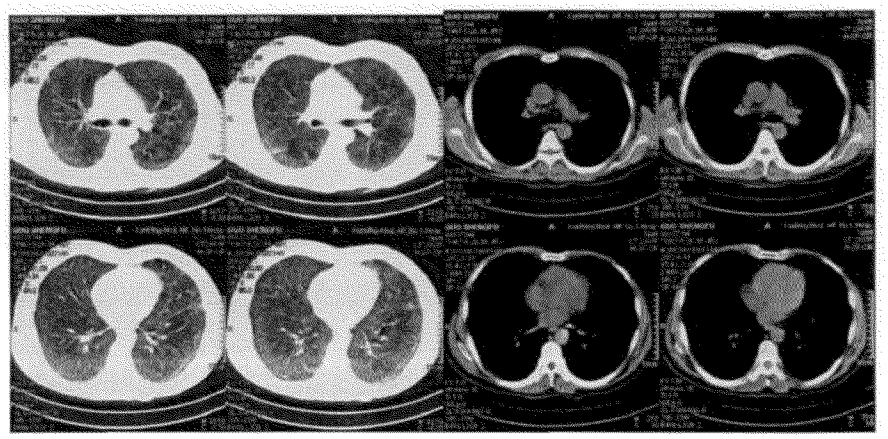
2012/5/6 CT: the exudation on the lower right lobe seems to be absorbed, others remained the same as before: multiple nodules and floccular exudate; multiple inflamed lymph nodes in the mediastinum (See below).



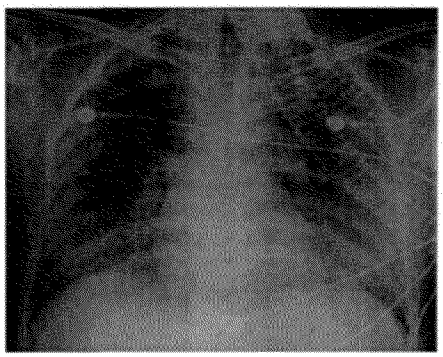
2012/5/14 intensified 3D CT: the lung marking was clearer: the flaky exudation on the lower right lobe of the lung seemed to absorb, the shadow of the multiple nodules and floccular exudation have also improved. The lymph nodes in the mediastinum remained the same. Whether the artery in the lung and its major branches were intact remained unknown.



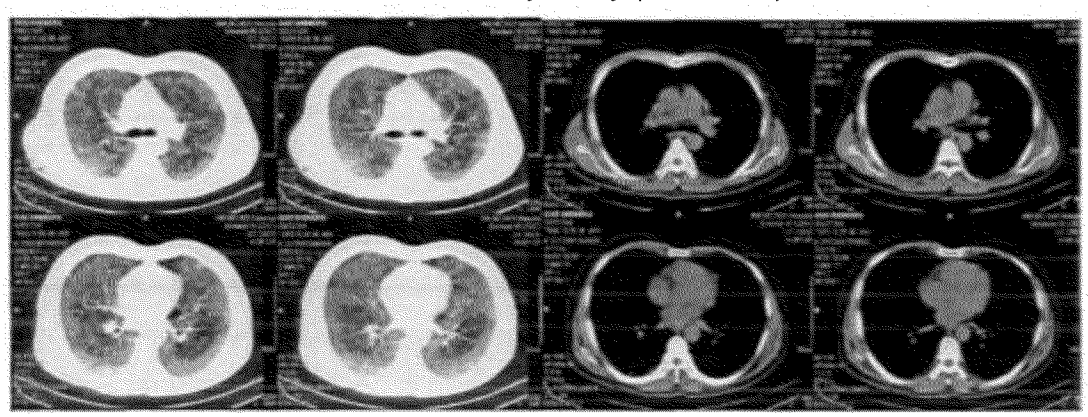
2012/5/26 CT: Clear increment of the lung marking, thickening, blurry. Overall thickening of the septum. Glassy and high density shadows in both lungs and partial pulmonary emphysema. Above are the substantial changes and may relate to infection or pneumoconiosis. Requested a check on the history of occupational disease (see below)



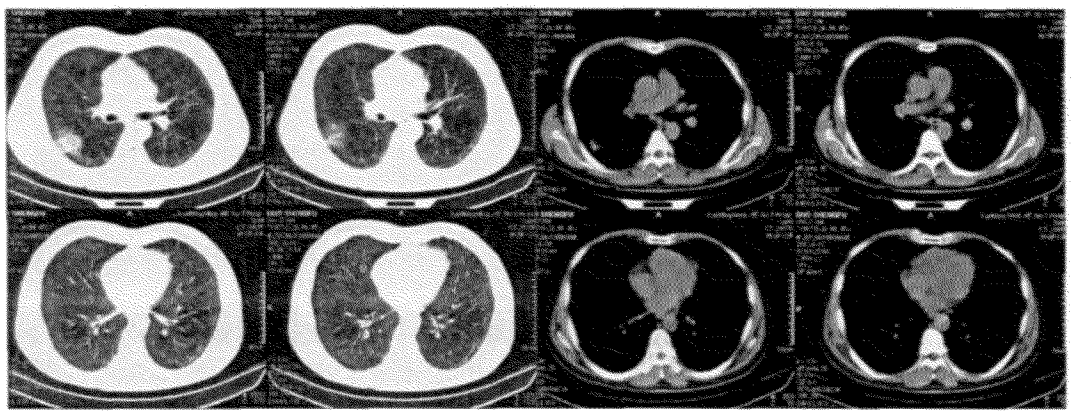
2012/6/3 Chest film reports: Compared to the films shot on 5/29, substantial changes in both lungs, and multiple scattered spotty shadows, partial lesion fusion. The shadow of both hila looks bigger and thicker. The illness progressed. Please work with the clinical for further diagnosis. (See below)



2012/6/7 CT reports: bilateral lung multiple patchy opacities and exudative consolidation, little fluid found in the left side, average amount of fluid in right side, possibly infection. Suggested double examination after treatment. Small mediastinal lymph nodes.Widening of the pulmonary artery. The shadow of the heart is enlarged. Calcification on the wall of the major artery. Found the shadow of the stent in the left coronary artery (see below).

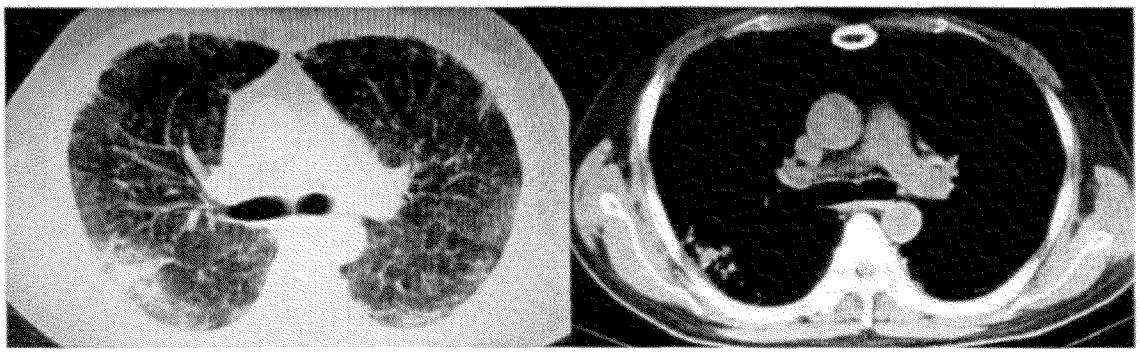


2012/6/18 CT Reports: Interstitial fibrosis in both lungs, pulmonary emphysema remained the same. Shadow of lumpy consolidation found on the right back side of the lower lobe and the upper lobe toward the end. Suggest a double checkup after treatment (see below).



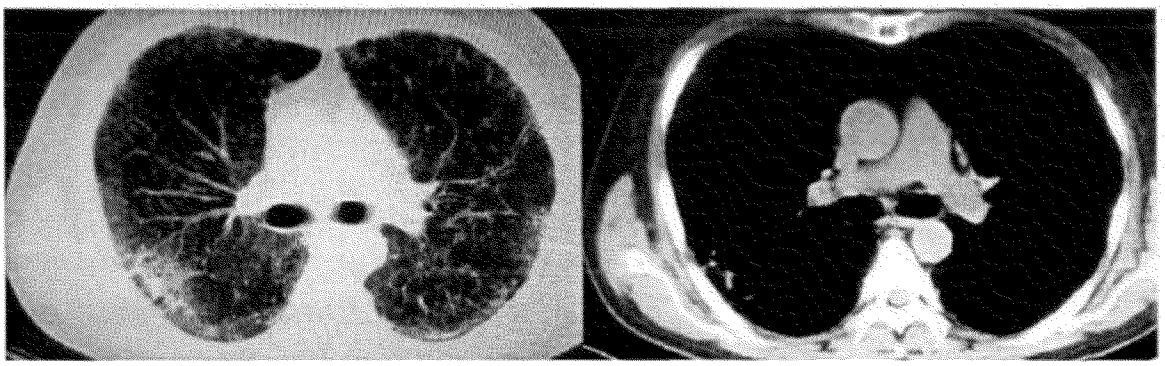
2012/7/1 CT reports: the pathological changes became more defined.

2012/7/8 CT reports: noticed diffused web-like shadow in both lungs. Multiple mediastinal lymph nodes were inflamed same as the CT report on 2012/7/1 (see below).



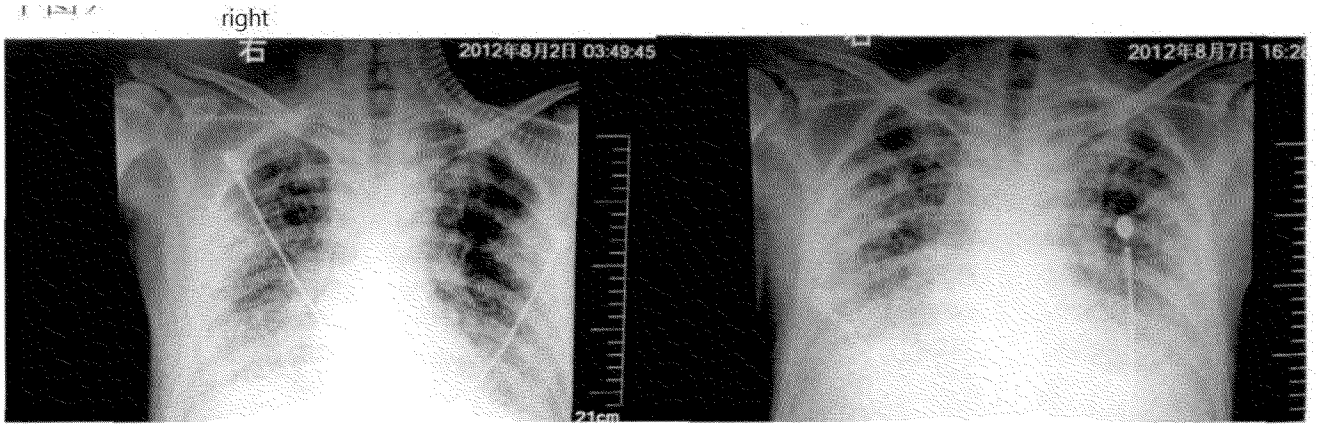
2012/7/11 Chest film indicates: interstitial changes in both lungs, spotty and flaky shadow diffused in both lungs, both hilar enlarged and murky. Possible infection. Other pathological changes need further confirmation, please work with clinical.

2012/7/14 Chest film indicates: highly density spotty and webbed shadow all over the lungs. Multiple mediastinal lymph nodes were inflamed same as the CT report on 2012/7/8 (see below).



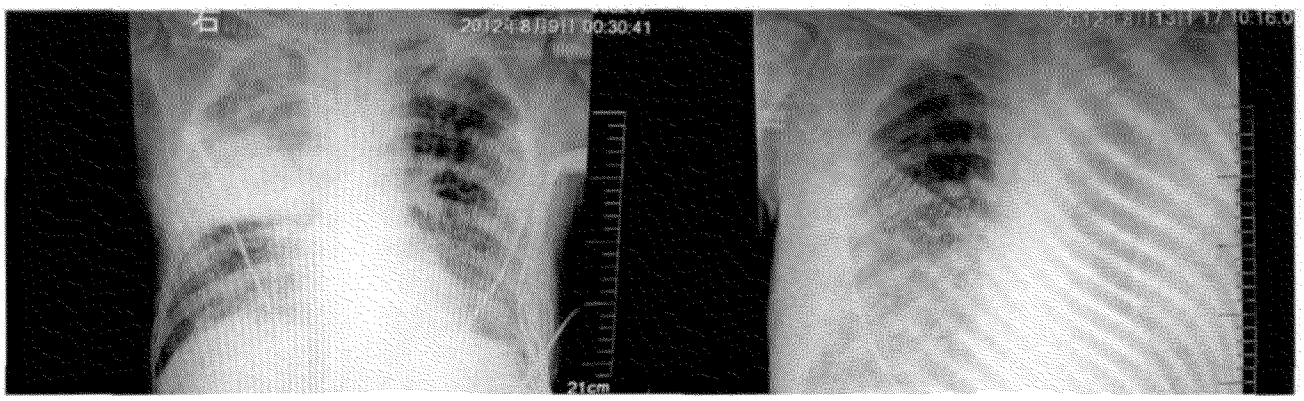
2012/7/26 CT reports: The symptom of Interstitial or fibrosis became more apparent, intensified heart, lung and mediastinum, others remain the same. Whether the lung artery and other major branches remain intact or not need to be confirmed.

2012/8/2 Chest film: interstitial changes in both lungs, flaky opacity at the bottom and on the ring of the upper lung. Compared to the 2012/7/24 film, the lesion has progressed. Please work with the clinical to do a thorough analysis (see the left picture below).



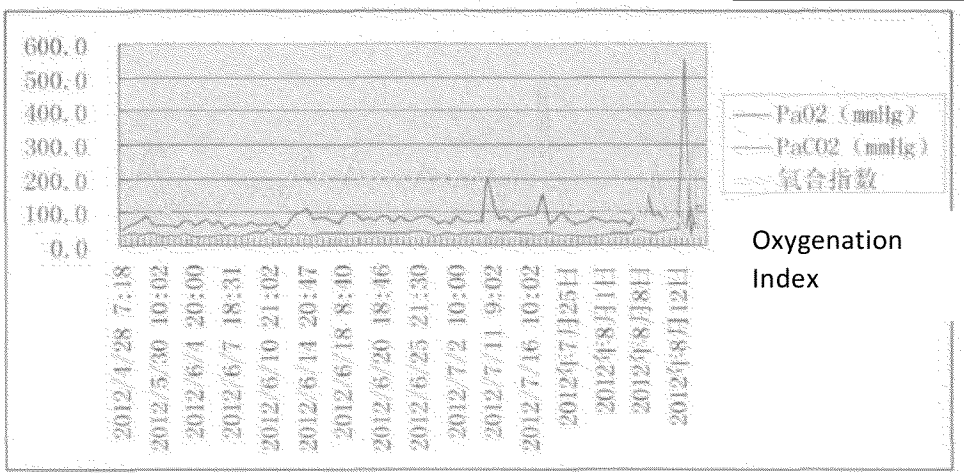
2012/8/7 Chest film: interstitial changes in both lungs, flaky opacity in the upper rings and lower lungs, lesion progressed. Please work with clinical (see the upper right picture).

2012/8/9 Chest film: the lung markings increased and murky, spotted shadow of the nodules. Increase flaky density in the lobe of the right lung. The lesion progress. Both hila remain bushy. The structure did not look clear. Please work with clinical (see the left picture below).

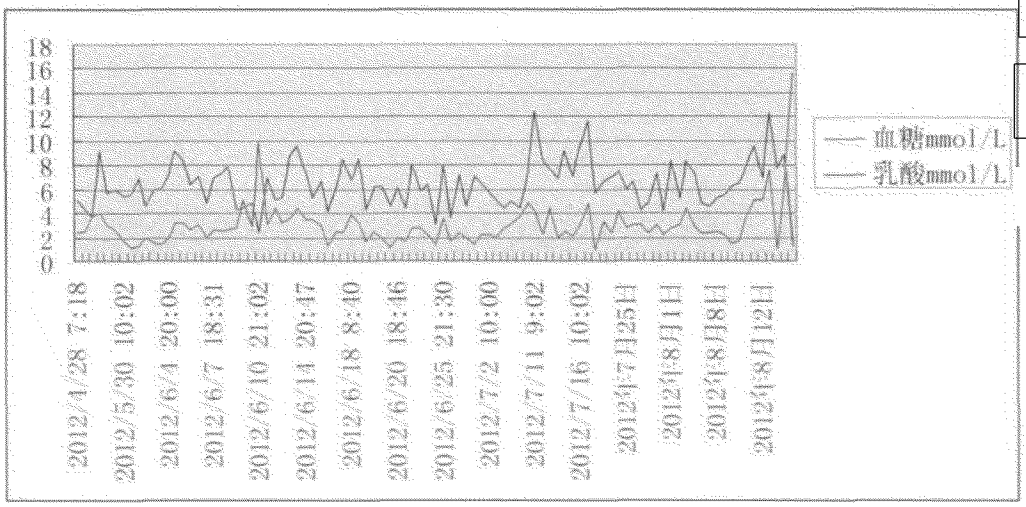


2012/8/13 Chest film: Compared to last time, the infected lesion in the upper right lung slightly absorb. The infected lesion in the lower right lobe progressed. Both hilar remain bushy, the structure is poorly defined. Please work with clinical. The infected lesion in the lobe of the left lung progressed. The left hilar, top of the diaphragm and costophrenic angle were unclear. The left chest was not visualized. Please work with clinical and make further examination if necessary (see the upper right picture).

2012/4/28 – 2012/8/13 Analysis of blood gas (see below):



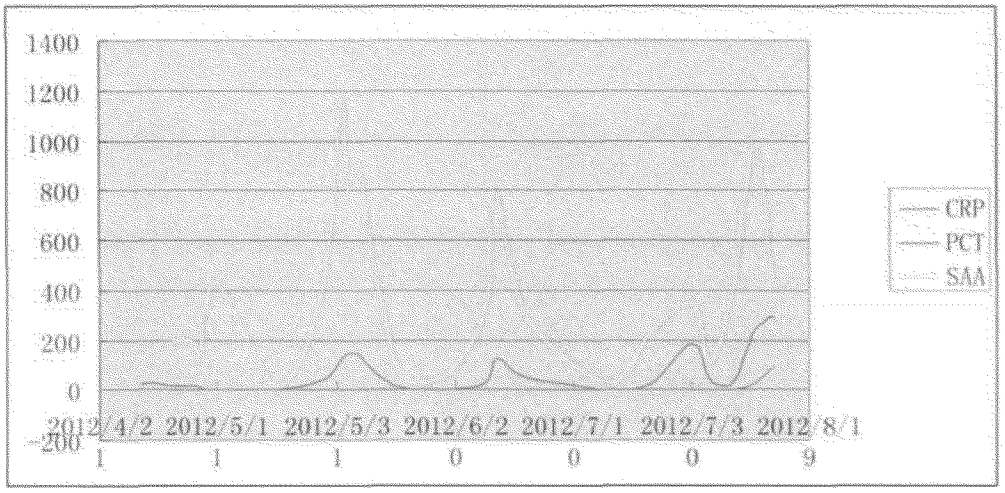
Oxygenation Index



Blood sugar

Lactic Acid

2012/4/25 – 2012/8/13 related infected protein (see below)



2012/5/15 Etiological examination: throat swab, complete blood test SARS-CoV, Hemorrhagic fever, Dengue fever, Japanese encephalitis, H5N1- negative

2012/4/27 PDD - negative

2012/4/28 Tumor protein chip: negative

2012/4/25 – 2012/8/13 Blood test: normal

2012/4/25 – 2012/7/23 Stool and urination test: normal

2012/4/25 – 2012/8/13 Coagulation test (PT, APTT, TT, FIB): normal

2012/4/25 – 2012/8/10 fiber blood test for three items: normal

2012/4/28 – 2012/8/13 Comprehensive metabolic panel: normal

2012/8/13 B-type Natriuretic peptide: 323.91 pg/ml

2012/8/12 B-type Natriuretic peptide: 252.60 pg/ml

2012/8/7 B-type Natriuretic peptide: 8.52 pg/ml

Percentage of T, B, NK cells and count (see below):

日期 Date	CD3 阳性 T 淋巴细胞绝对值 Positive Aboslute Value of Lymphocyte	T 抑制细胞 Suppressor Cell CD3+CD8+双阳细胞绝对值 double positve cell absoulute value	T 辅助细胞 supporting cell CD3+CD4+绝对值 abosolute Value	CD3CD4 CD8 均为阳性细胞绝对值 Positvie cell abosolute value	NK 细胞（CD16+CD56+双阳细胞） double positive cell	B 淋巴细胞（CD19+CD45+） Lymphocyte
5-11	901	361	471	2↓	102	316
6-2	475↓	136↓	308↓	3↓	20↓	48↓
6-3	444↓	113↓	322↓	0↓↓	14↓↓	38↓
6-13	1578	669	933	1↓↓	84↓	347↓
6-18	1197	417	795	2↓	58↓	438↓
7-31	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
8-3	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
8-9	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

2012/6/2 Deep vein catheterization

2012/7/10 Deep vein catheterization

2012/8/8 Deep vein catheterization

2012/8/11 Picco 2 catheterization

2012/6/2 Noninvasive ventilator for aeration

2012/7/10 Noninvasive ventilator for aeration

2012/8/8 ventilator for breathing

2012/4/26 – 2012/5/29 mucus culture, sputum smear and blood culture: negative

2012/6/1 mucus culture smooth candida

2012/6/1 – 2012/7/1 mucus culture, sputum smear and blood culture: negative

2012/7/3 sputum smear shows Gram-positive bacteria and Gram-negative bacteria

2012/7/6 mucus culture Acinetobacter baumannii positive, only sensitive to levofloxacin and amikacin

2012/7/12 – 2012/7/28 mucus culture, sputum smear and blood culture: negative

2012/7/29 mucus culture positive

2012/7/29 mucus culture acinetobacter baumannii positive, only sensitive to levofloxacin and Tobramycin

2012/7/31 mucus culture acinetobacter baumannii positive, only sensitive to levofloxacin and Tobramycin

2012/8/1 – 2012/8/3 mucus culture and blood culture: negative

2012/8/5 mucus culture acinetobacter baumannii positive, only sensitive to levofloxacin

2012/8/10 mucus culture stenotropho monas maltophilia, multiple reactions

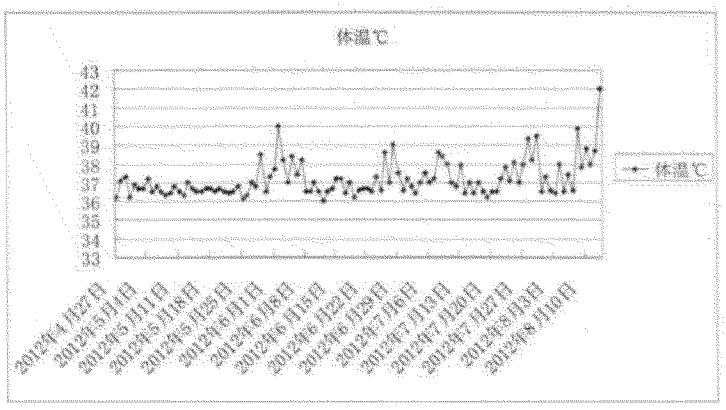
2012/8/11 mucus culture acinetobacter baumannii positive (twice).

2012/8/11 blood culture A.junni, multiple reactions to antibodies (twice).

2012/8/13 blood culture acinetobacter baumannii and candida negative

2012/8/13 mucus culture negative

Body temperature (see below):



Prescription during hospitalization:

2012/4/27 – 2012/4/28 Cefixime 0.5g x 2, ivgtt, Bid

2012/4/28 – 2012/5/4 Cefoperazon Sodium and Tazobactam sodium 2.25g, ivgtt, Q8h.

20125/4 – 2012/5/7 Z piperacillin sodium/tazobactam sodium 4.5g, ivgtt, Q8h.

2012/5/30 – 2012/6/3 Z piperacillin sodium/tazobactam sodium 4.5g, ivgtt, Q8h

2012/6/3 – 2012/6/19 Vancomycin 0.5g x 2, ivgtt, Q12h

2012/6/4 – 2012/6/28 Cefoperazon Sodium and Tazobactam sodium 1.5g x 2, ivgtt, Q12h.

2012/6/4 – 2012/6/28 Meropenem 0.5g x 2, ivgtt, Q8h.

2012/7/8 – 2012/7/17 levofloxacin 0.1g x 4, ivgtt, Qd.

2012/7/9 – 2012/7/19 Cefoperazon Sodium and Tazobactam sodium 2.25g, ivgtt, Q8h.

2012/7/26 – 2012/8/1 Cefoperazon Sodium and Tazobactam sodium 2.25g, ivgtt, Q8h.

2012/7/26 -2012/8/1 levofloxacin 0.5, po, Qd.

2012/7/28 – 2012/8/1 Fosfomycin 6g, ivgtt, Q8h.

2012/8/8 – 2012/8/10 Z piperacillin sodium/tazobactam sodium 4.5g, ivgtt, Q8h

2012/8/10 – death Fosfomycin 6g, ivgtt, Q8h.

2012/8/10 – death Tygecycline 50mg, ivgtt, Q12h.

2012/4/27 – 2012/5/2 (J) Methlyprednisolone injection 40mg, ivgtt, Qd

2012/5/2 – 2012/5/7 (J) Methlyprednisolone injection 30mg, ivgtt, Qd

2012/5/7 – 2012/5/21 (J) Methlyprednisolone injection 40mg, ivgtt, Q12d.

2012/5/21 – 2012/5/25 (J) Methlyprednisolone injection 30mg, ivgtt, Q12h

2012/5/25 – 2012/5/27 (J) Methlyprednisolone injection 40mg, ivgtt, Q12h

2012/5/27 - 2012/6/6 Methlyprednisolone injection 40mg, po, Qd

2012/6/6 – 2012/6/7 Methlyprednisolone injection 40mg, po, Q12h

2012/6/7 – 2012/6/19 (J) Methlyprednisolone injection 40mg, iv, Q12h

2012/6/19 – 2012/6/23 (J) Methlyprednisolone injection 40mg, iv, Qd

2012/6/23 – 2012/6/26 (J) Methlyprednisolone injection 20mg, iv, Qd

2012/6/26 - 2012/6/3 Methlyprednisolone injection 80mg, po, Qd

2012/6/30 – 2012/7/4 Methlyprednisolone injection 40mg, po, Qd

2012/7/10 - 2012/7/17 (J) Methlyprednisolone injection 40mg, ivgtt, Q12h

2012/7/17 – 20127/26 (J) Methlyprednisolone injection 40mg, ivgtt, Qd

2012/7/26 – 2012/7/30 prednisone 20mg, po, Qd

2012/7/30 – 2012/8/3 (J) Methlyprednisolone injection 40mg, ivgtt, Q12h

2012/8/3 – 2012/8/7 (J) Methlyprednisolone injection 40mg, ivgtt, Qd

2012/8/11 – 2012/8/13 (J) Methlyprednisolone injection 80mg, ivgtt, Q8h

2012/8/13 – death (J) Methlyprednisolone injection 40mg, ivgtt, Q8h

2012/6/3 - 2012/7/9 Caspofungin 50mg, ivgtt, Qd

2012/6/5 – 2012/6/19 Fluconazole 40mg, ivgtt, Qd

2012/7/13 – 202/8/1 Micafungin 150 mg, ivgtt, Qd

2012/8/1 – death Fluconazole 0.2g, po, Q12h

2012/5/7 - 2012/5/28 Ganiciclovir 0.3g, ivgtt, Q12h

2012/8/11 – death Qseltamivir 75mg, po, Bid

2012/8/13 – death Ganiciclovir 0.3g, ivgtt, Q12h

2012/6/6 – 2012/6/14 a - Thymosin 1.6mg, ih, Qod

2012/8/8 – 2012/8/10 a – Thymosin 1.6mg, ih, Qod

Remote Meeting Minute

Time: 2012/6/4

Location: First Affiliated Hospital

Expert Attendee: Dr. Xie Can Mao , Chief Physician, Respiratory department of The First Affliated Hospital, Sun Yat-Sen University

After learning the report of the patient and related information, Dr. Xie diagnose: Interstitial pneumonia, great possibility for fungi infection. Have the patient to complete the G examination, and fiber bronchoscope checkup. If the circumstances allow, we should also consider conducting biopsy of lung. However, the patient is on noninvasive ventilation, the biopsy is not appropriate. Treatment wise, Dr. Xie agrees with what we have done so far. He suggested that we should also prescribe 2 tablets of compound Sulfamethoxazole (oral), 3 times/ day. Fluconazole for the fungus and Thymosin for boosting up immune system.

Reported back to Dr. Qian. After Dr. Qian Chuan Yun, Wang Yun Hui and Liu Rong's discussion, they decided to use Caspofungin and Fluconazole for fungi treatment. Also, prescribe some compound Sulfamethoxazole and thymosin for treatment. The patient is having fever, possible a sign of merged infection. Prescribe Vancomycin, sulbactam and cefoperazone and Meropenem for infection.

Remote Meeting Minute 2

Time: 2012/6/19

Location: First Affiliated Hospital

Expert Attendee: Dr. Zhong Nan Shan, Respiratory department of The First Affliated Hospital, Sun Yat-Sen University

After learning the report of the patient and related information, Dr. Zhong diagnose: 1.Interstitial pneumonia, great possibility for virus infection. 2. Invasive pulmonary aspergillosis (secondary infection). Suggestion: 1. Went to the animal lab in Kun Ming to confirm the type of the bat; 2. Did a throat swab and SARS antibody examination; 3.Prescribe Caspofungin, sulbactam and cefoperazone and Meropenem for treatment; 4. Intensify airway monitor, use fiber bronchoscope to clear out the mucus (do not wash by water). Basically agree with our treatment so far.

After Dr. Qian Chuan Yun, Wang Yun Hui and Liu Rong's discussion, they decided to use Caspofungin, sulbactam and cefoperazone and Meropenem for treatment.

Discussion

The patient started to work in the mining filed on April 2, 2012, for up to 14 days.

Day of Admission to the Hospital: 2012/4/27

Discharge Day: 2012/8/13, total of 109 days

Discharge diagnosis: 1. Severe Pneumonia 2.Multiple organs failure 3.ARDS 4. Inhaling Lung Impairment 5. Interstitial pneumonia (Virus related) 6. Invasive pulmonary aspergillosis (secondary infection).

Discharge reason: death

According to Chest film and CT, the illness recurred itself and developed in fluctuation. Finally, the lungs suffered from fibrosis.

The artery blood gas analysis indicated that the patient went through Type I respiration failure, poor oxygenation index. According to the "ARDS Berlin Criteria" in 2012, for sure it was ARDS. Consequentially, one of the causes of death could be respiratory failure.

the T, B, NK Lymphocyte percentage and count of the patients were decreasing. It shows that the immune system of the patient was impaired, had poor resistant to the disease and could easily be infected by hospital-acquired infection. During hospitalization, the patient had deep vein cauterization for four times. The blood culture and mucus culture in the later stage both suggested Acinetobacter baumannii. Before death, the infection related protein PCT reports 92.09ng/ml, therefore, one of the causes of the death could be infectious shock (induced by severe pneumonia).

According to the “Guideline and Diagnosis of invasive fungal infection” published in 2007 by Critical care branch of the Chinese medical association, we should also consider the secondary infection of invasive pulmonary aspergillosis

Prescription: five days after the suspension of Meropenem on 2012/6/28 and sulbactam and cefoperazone on 2012/7/26, the patience started to have high fever while continuously taking Methlyprednisolone and Micafungin. It shows that the possibility of secondary infection is high, the application of antibiotics is necessary.

After the patient passed away, we suggested to do an autopsy surgery to identify actual cause of the death. The families of the patient refused.

Analysis of the death of cause: the immune system was going down. The resistant to the disease was weak. The disease was acute and aggressive. Caught hospital-acquired infection in the later stage.

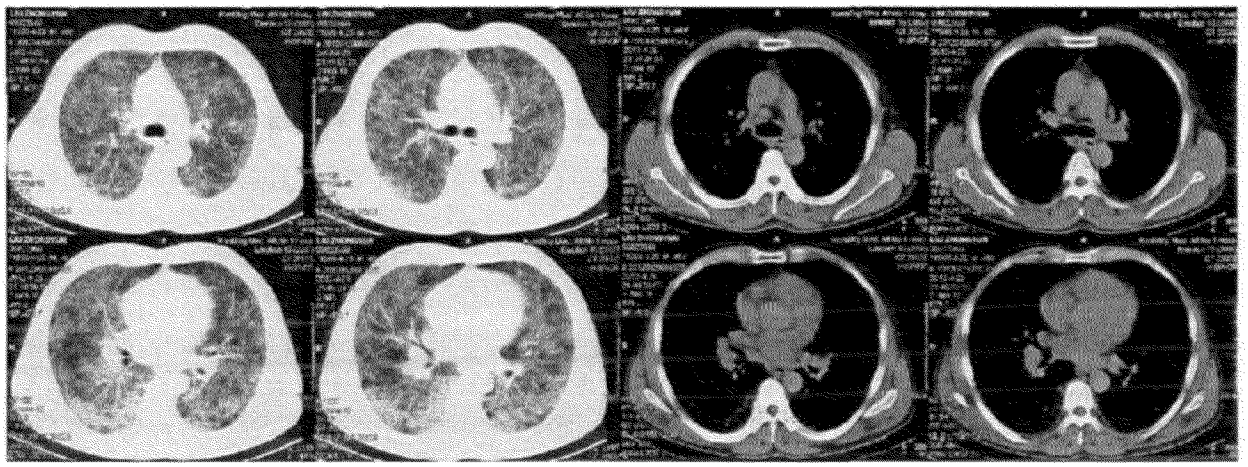
Case Four

Patient, Mr. Liu, male, 46 years old. He had sign of coughing, coughing with mucus, fever for 10 days and difficulty in breathing for three days and was admitted to the hospital on 2012/4/26. He worked in the mining well 10 days ago and was exposed to large amount of bats and their feces. He had cough, productive cough and hemoptysis (small amount), fever (highest to 39 Celsius) 10 days ago. He denied chest pain. He started to feel difficulty in breathing three days ago and went to the local hospital for treatment. The actual prescription remained unknown. For further treatment, he was admitted to our hospital. Since the illness started, he lost his appetite and felt drowsy. No significant change in bowel movement and urination. Used to be healthy. Denied high blood pressure, diabetes, heart disease or other chronic illness. He had been to Mo River. Prior to the illness, he worked in the mining well and was exposed to large amount of bats and their feces. Five of his colleagues had similar illness. Denied history of hepatitis, Typhoid or any other contagious disease. No history of blood transmission, allergy, typhoid or Tuberculosis. No other injuries, blood transmission, medical related allergy reaction. The vaccination record remained unknown. Physical examination: Body temperature 37.1 Celsius, Pulse 90 times/ minute, respiratory rate 18 times/ minute, BP 120/80 mmHg, considered poor performance, the pupils are round and dilated with 2.5 mm diameter. Sensitive to light. Softness in neck. The lips and tip of the fingers appear cyanotic, The breathing sound from both lungs were rough. Moist crackle sound from both lowerpart of the lungs. HR 90 times/ minute, regular, no murmur, rub or gallop. Abdomen soft, non-tender. Bowel sounds: 5 times/ minute. The limbs function okay and so do the muscle strength and stretch. Babinski on both sides. 2012/4/25 CT reports: Increase, thickening and blurring of the lung markings. Large parcel consolidation exudation across both lungs. Initial diagnosis: 1. ARDS; 2. Need more examination on the pathological changes of the bilateral lungs?

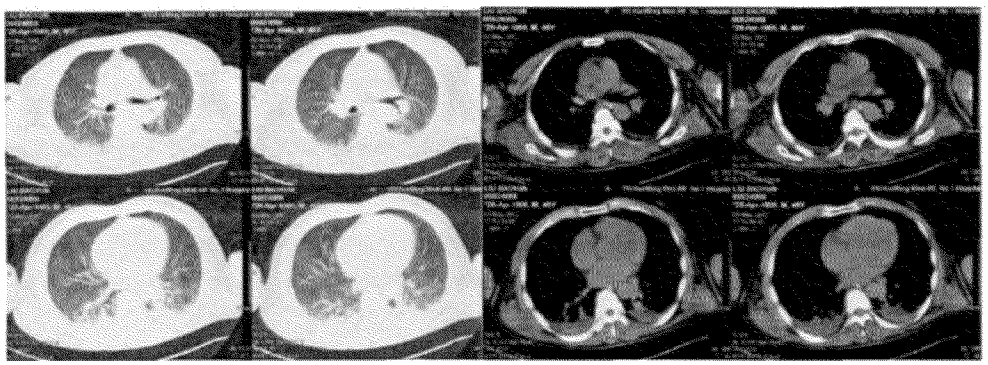
Method

Complete examination after hospitalization

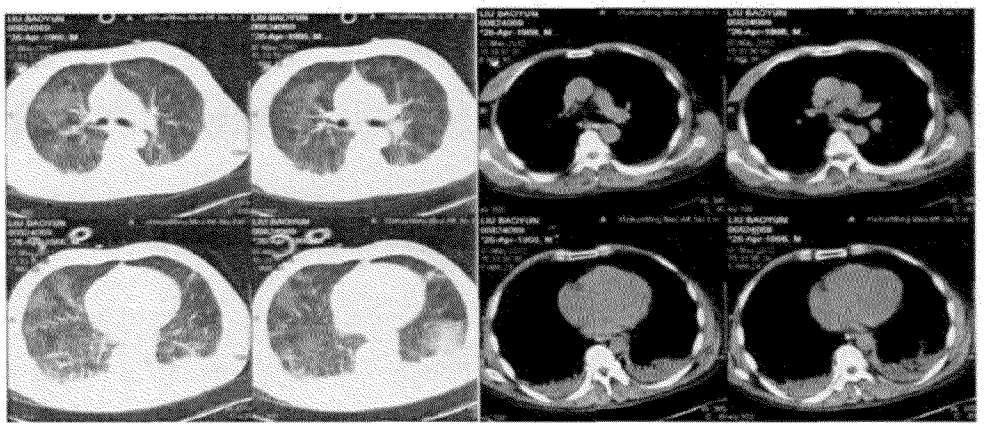
2012/4/29 CT reports: increased in lung marking of both lungs and opacity. Multiple patchy opacity and exudative consolidation, especially in the lower lobes. It is recommended to have a second checkup. Pleural effusion found in both lungs (see below).



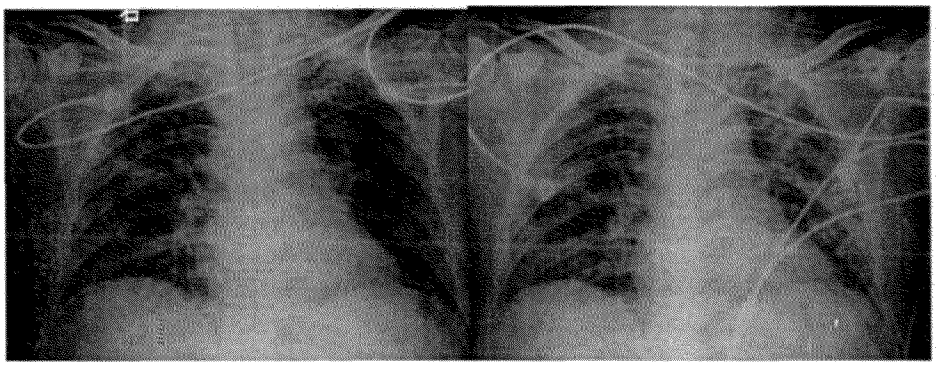
2012/5/3 CT reports: compared to the CT on 2012/4/29, the lung marketing has increased and more opacity. The multiple flaky consolidation exudation seemed to be absorbed in both lungs, so did the effusion (see below).



2012/5/7 Intensified CT reports: screen the artery more, the left and right artery appeared normal. Low density filling defect in bilateral pulmonary arteries, possibly acute pulmonary embolism. Please work with clinical. Multiple glassy exudation and consolidation in both lungs. Little effusion on both sides (see below).

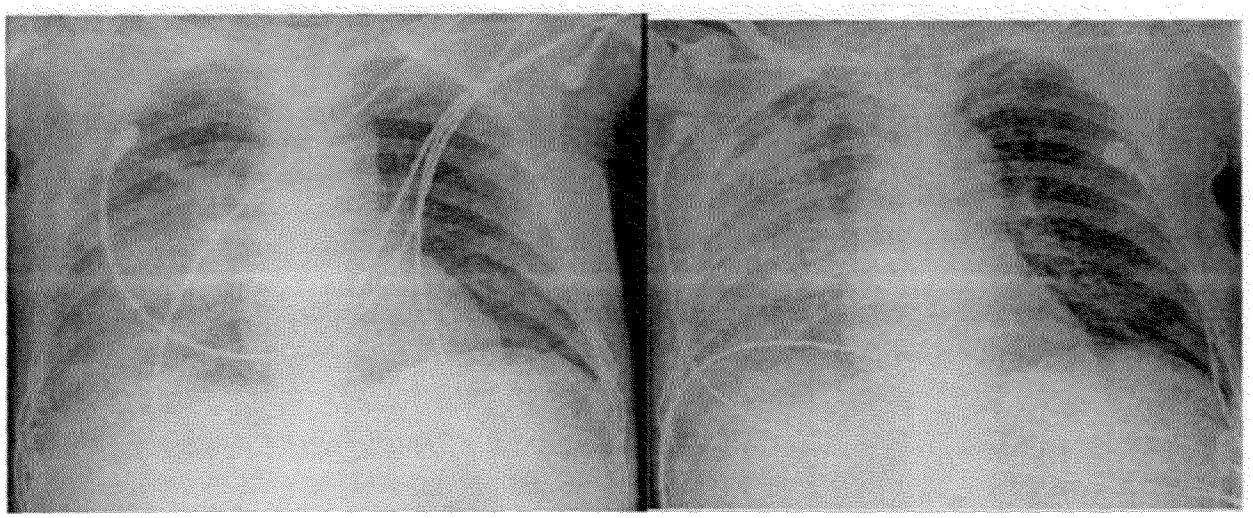


2012/5/8 Chest film: lung marking increased, hila looked normal, more markings in the lower lobe and appear to be blurry and some spotty, flaky and blurry shadow. In the lower lobe of the right lung, there were patchy and blurry shadow (see the left picture below).



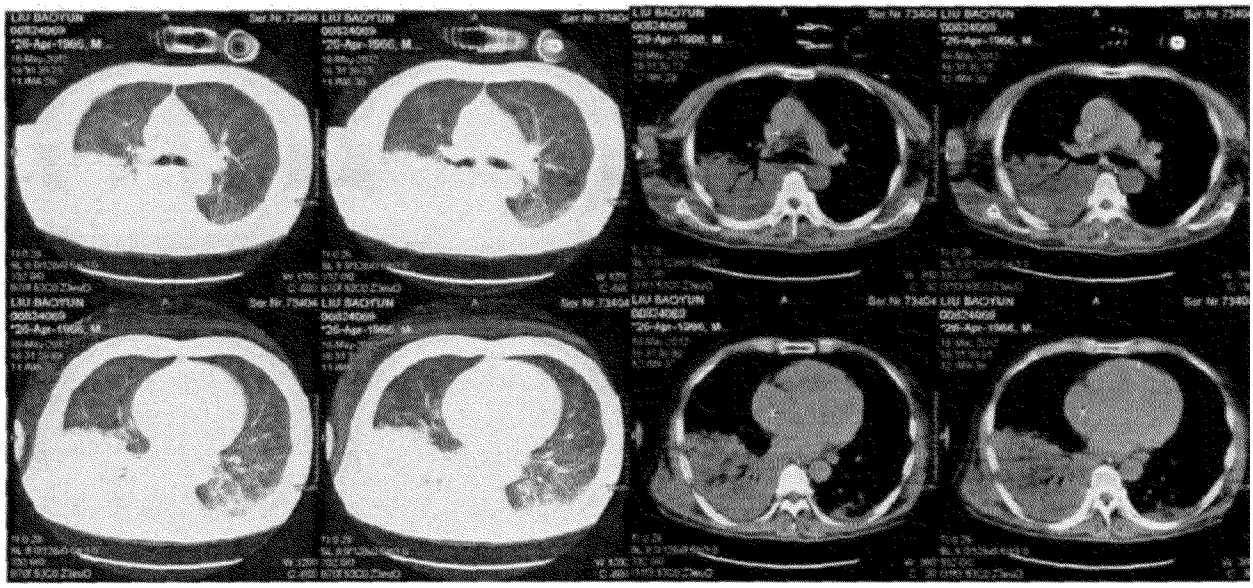
2012/5/12 Chest film: infection in both lungs, work with clinical for periodical checkup (see the right picture above)

2012/5/15 Chest film: Compared to the chest film on 5/13, the exudation on the right lung seemed worse. The left seemed slightly improved (see the left picture below).

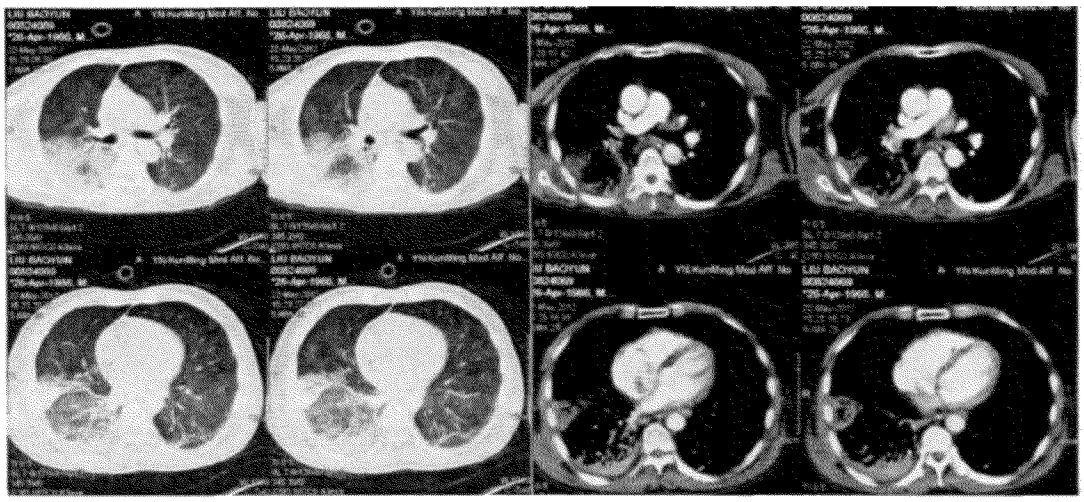


2012/5/18 Chest film: Compared to 2012/5/16, the exudation on both sides had slightly absorbed. Please work with clinical (see the right picture above)

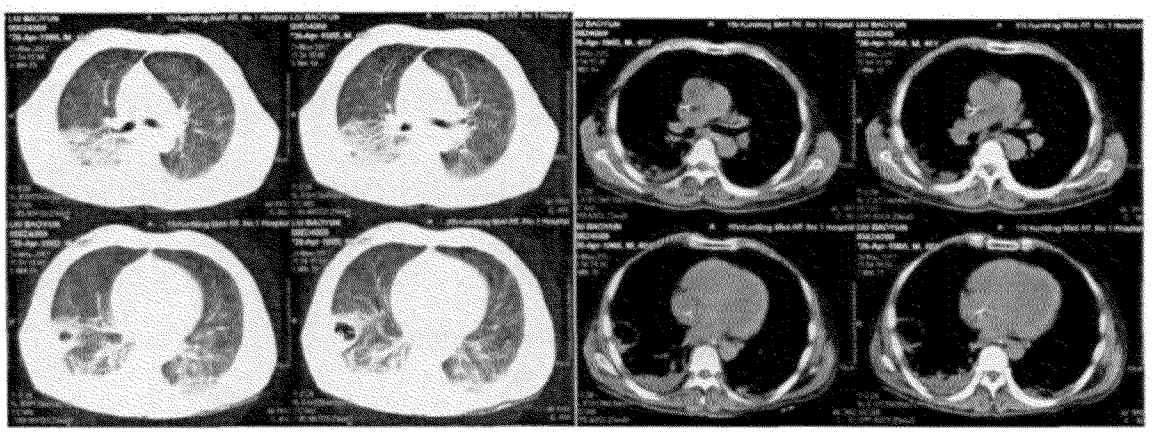
2012/5/18 Intensive CT: The lesion on the left lung decreased substantially. The consolidation exudation on the right need further confirmation (see the picture below).



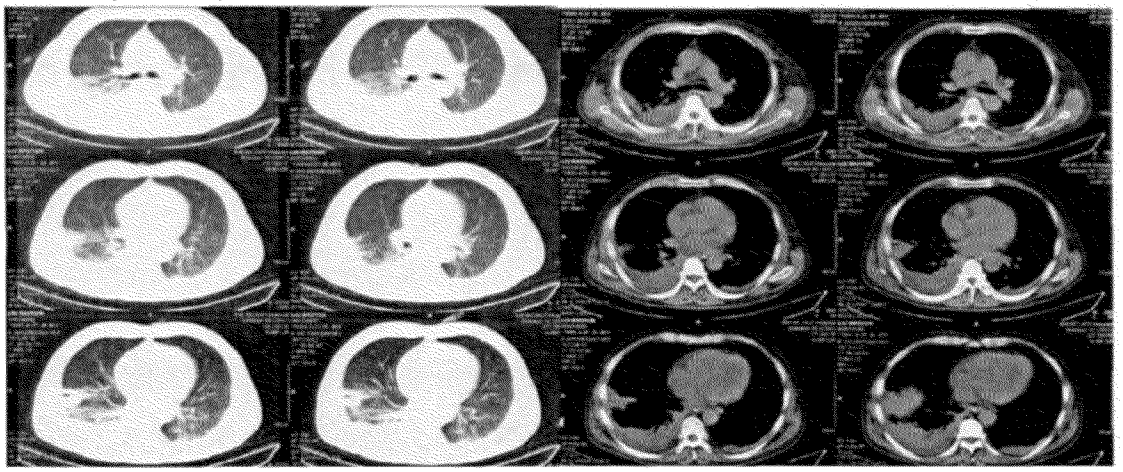
2012/5/22 intensive CT: Compared to 2012/5/18, the consolidation slightly absorbed. Glassy-like dense shadow in both lungs, possibly exudation. The intensive screen did not spot any abnormally (see the picture below).



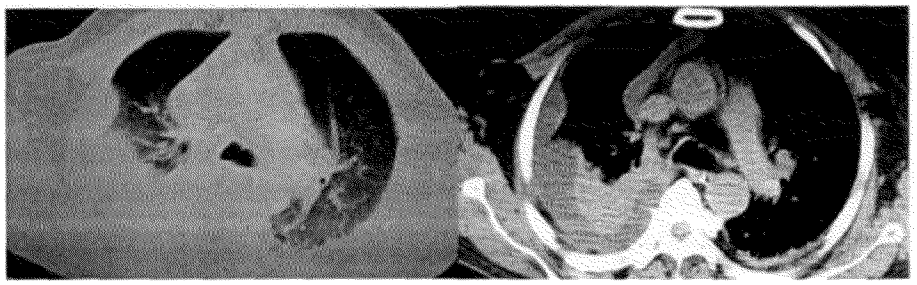
2012/5/29 CT film: Compared to the film on 5/22, the consolidation and hollow on the right had slightly absorbed. The glassy-like dense shadow is smaller and less dense. Recommend continue treatment and a follow up checkup (see the picture below).



2012/6/12 CT film: the consolidation on the right become heavier and the hollow seemed absorbed slightly. The glassy-like dense shadow has dec reased and less dense. The effusion on the right cavity has increased. The heart and mediastinum remain the same (see below).

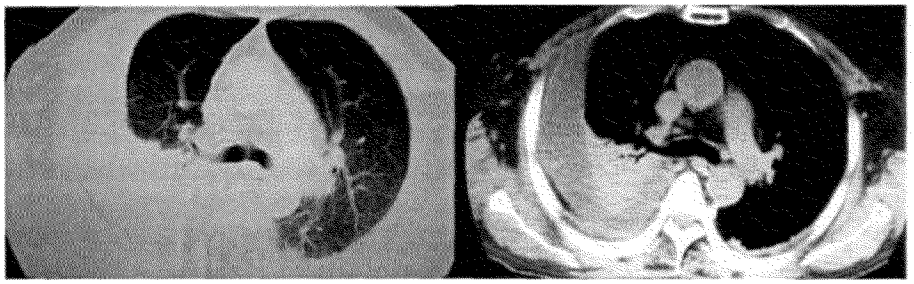


2012/6/20 CT: Compared to 2012/6/12, the lung markings become blurrier, the consolidation in the right lung is more aggressive, and the area of exudation in the left lung has enlarged. The effusion in the right cavity increased. The shadow of the heart increased. The mediastinum remain the same (see below).

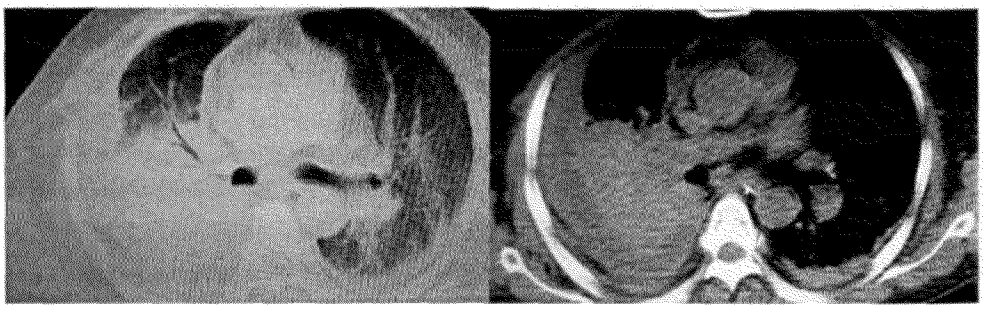


2012/6/27 Chest film: flaky consolidation exudation in the right lung and effusion in the right cavity.

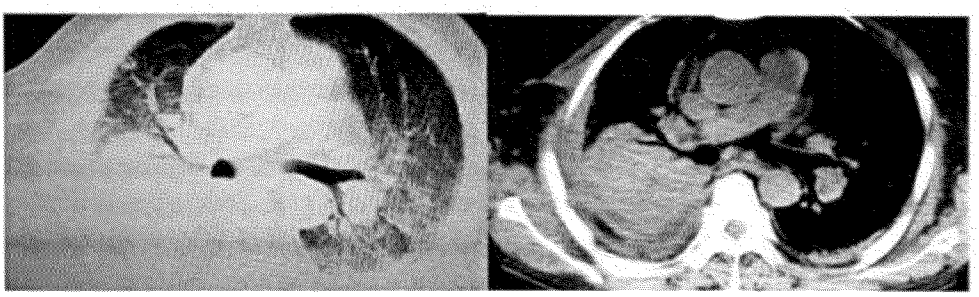
2012/6/28 CT scan: lung marking increased and blurry. Noticed flaky and floccular blurry shadow at the lower part of the lungs. The functioning area in the right lung has decreased. Effusion in both cavities. The widest effusion in the right cavity is 3.1 cm and large patchy dese consolidation shadow in lower right lobe. Sign of air bronchogram inside. Saw the drain in the right cavity (see below).



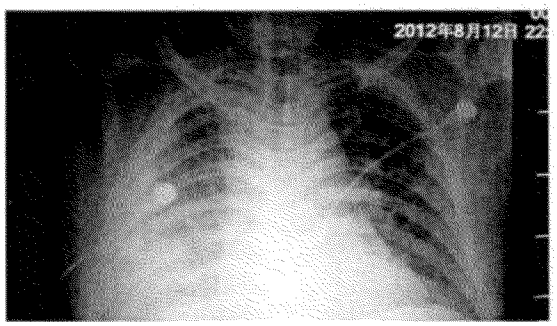
2012/7/6 CT scan: lung marking increased and blurry, ground-glass exudation in both lungs. Consolidation in the upper and lower lobe of the right lung. The airway and bronchus work well. Please work with the clinic. Moderate amount of effusion in the right side and less amount in the left. Multiple big inflamed lymph nodules in mediastinum (see below).



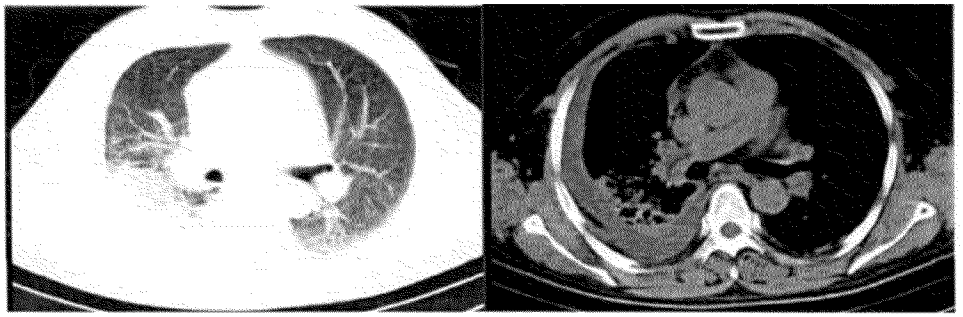
2012/7/11 CT scan: increased lung marking and blurry, ground-glass exudation same as above, the consolidation of the upper and lower right lung remain the same. Moderate amount of effusion in the right side and the left remain the same as before (see below).



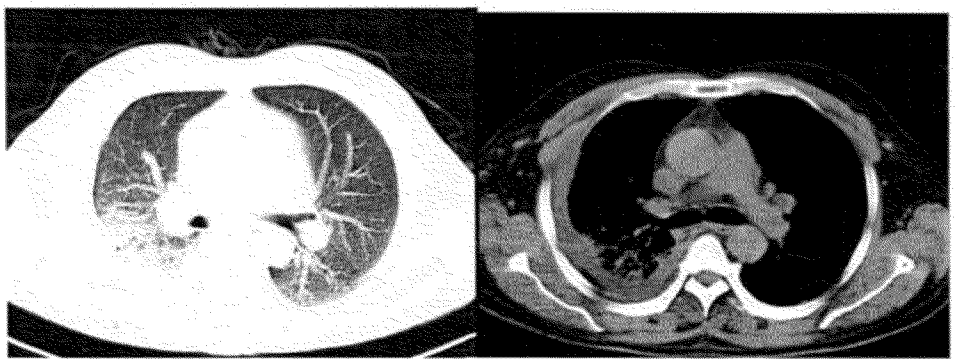
2012/8/12 Chest film: exudation lesion in both lungs have slightly absorb, the right side is more obvious, possible infection. Possibly effusion in right cavity (see below).



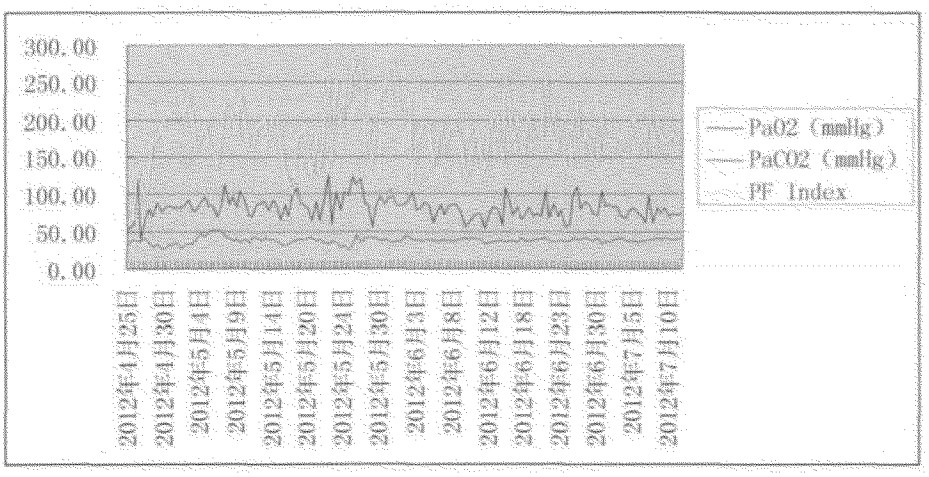
2012/8/14 CT scan: large consolidation exudation in the right lung, Sign of air bronchogram inside. Noticed shadow spotty, flaky exudation and stripe exudation. Little amount of effusion in both lungs, atelectasis due to extrinsic pressure. Multiple lymph nodules in mediastinum. The shadow of the heart and the artery remain normal (see below).

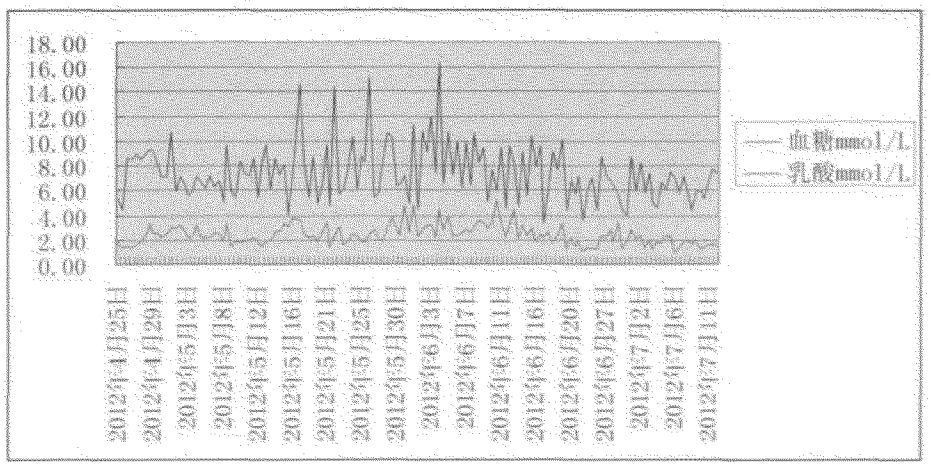


2012/8/23 CT scan: effusion, consolidation and atelectasis remain the same (see below).



2012/4/25 – 2012/7/26 Analysis of Artery Blood gas (see below):

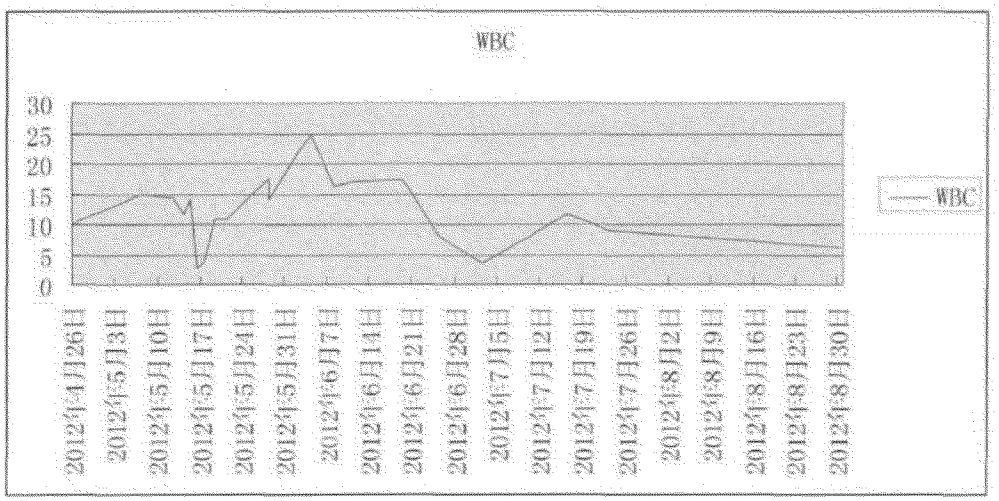




Blood sugar

Lactic Acid

2012/4/26 – 2012/8/30 Blood test: line chart of the white blood cell, the rest of the result remain normal (see below)



2012/4/26 – 2012/5/15 CK, AST, LDH, CK-MB and BNP test: normal

2012/4/27 immunoglobulin and complement test: C3 0.76g/L

2012/4/27 Hepatitis Virus and HIV test: negative

2012/5/7 Herpes Simplex virus DNA + Cytomegalovirus DNA + HPV DNA test: Negative

2012/5/9 Implement Picco2

2012/5/19 Conduct Tracheotomy

2012/5/20 Center of Disease Control in Chendu city Army reservation conducted an Aetiology test (swab and blood test): negative

2012/6/27 Ultra sound guided thoracentesis

2012/6/28 effusion test: bloody; Rivalta test: positive, red blood cell 60000 x 10^6 / L, White blood cell 2830 x 10^6 / L, Percentage of Monocytes - 14%, Percentage of giant cell – 86%

2012/6/28 effusion test: Adenosine deaminase 16.8 U/L, Total protein 39.9 g/L, Glucose 1.3 mmol/ L, Chlorine 101.4 mmol/L

2012/6/29 Cerebrospinal fluid test: increase of Neutrophil

2012/7/2 Cerebrospinal fluid test: Mixed cell reaction

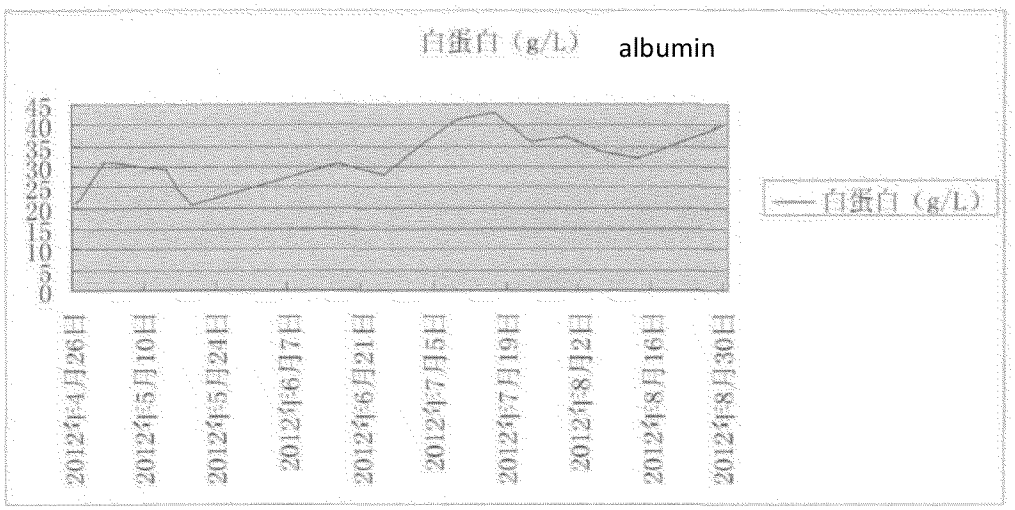
2012/4/26 Urinary test: Ketones1+, Urine Occult Blood 3+

2012/5/12 Urinary test: Urine Occult Blood 3+

2012/5/29 Stool test: Occult blood positive

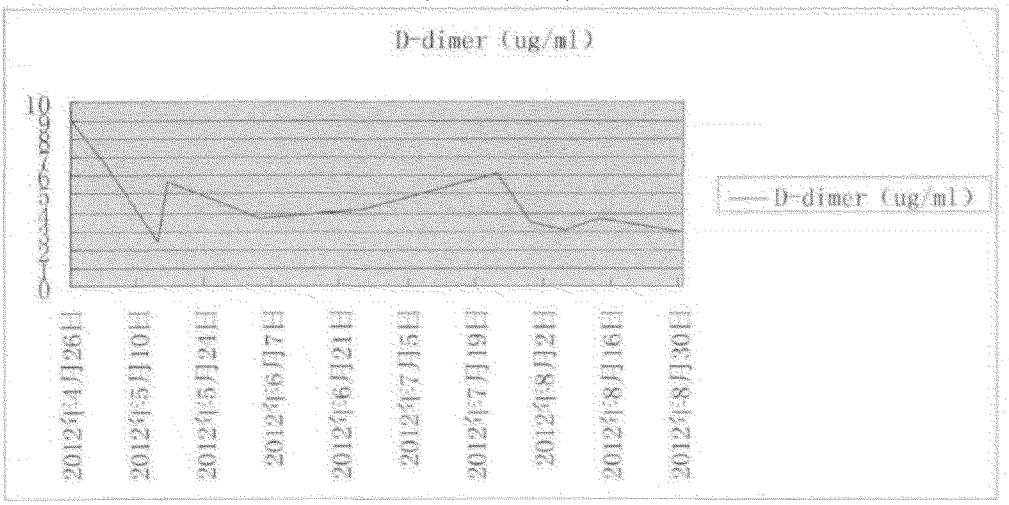
2012/6/18 Urinary test: negative

2012/4/26 – 2012/8/30 albumin development (see below), other metabolite index remain normal.

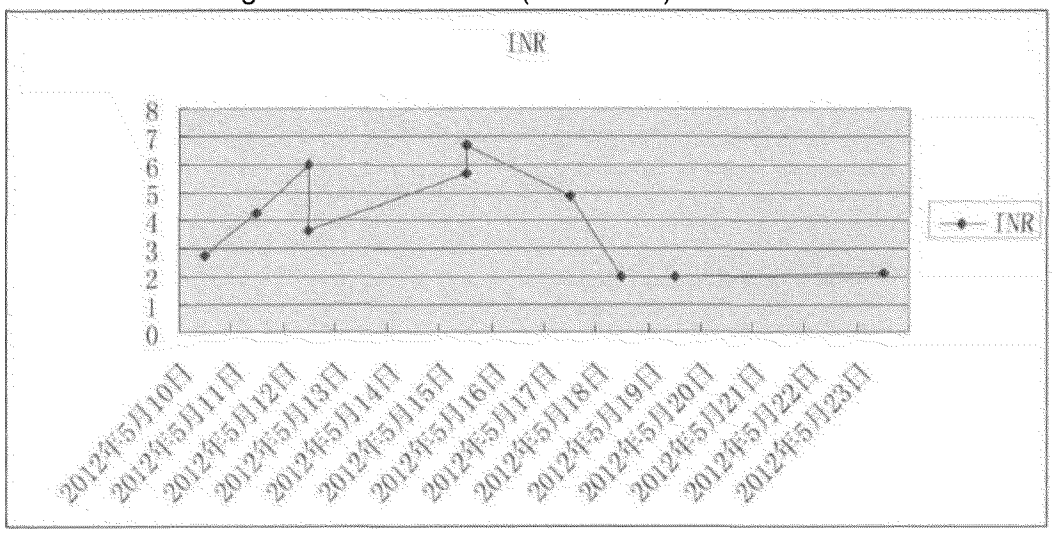


albumin

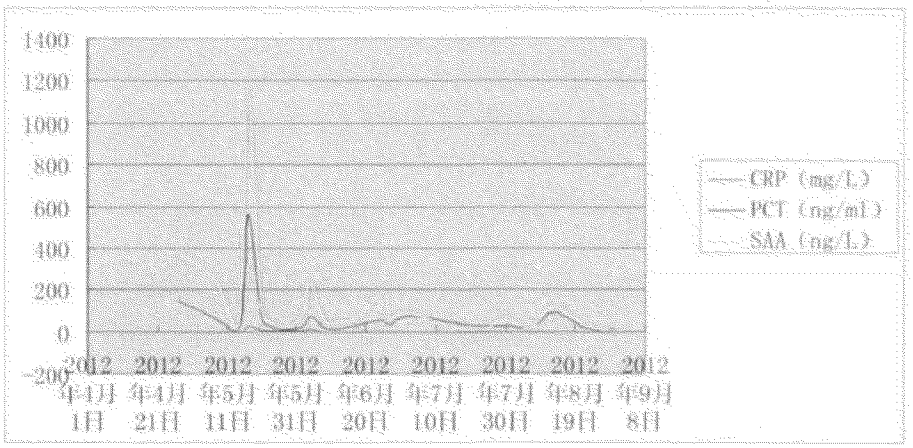
2012/4/26 – 2012/8/30 D- dimer (see below):



2012/4/26 – 2012/8/30 Anticoagulant treatment INR (see below):



2012/4/27 – 2012/8/30 infection related protein (see below):



Percentage and count of T, B, NK cell (see below):

日期 Date	CD3 阳性 T 淋巴细胞绝对值 Positive Aboslute Value of Lymphocyte	T 抑制细胞 Suppressor Cell CD3+CD8+双阳细胞绝对值 double positve cell absolute value	T 辅助细胞 supporting cell CD3+CD4+绝对值 absolute Value	CD3CD4 CD8 均为阳性细胞绝对值 Positvie cell absolute value	NK 细胞（CD16+CD56+双阳细胞） double positive cell	B 淋巴细胞 Lymphocyte（CD19+CD45+）
4-27	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
5-3	401↓	150↓	240↓	0↓	15↓↓	58↓↓
5-11	901	361	471	2↓	102	316↓
6-2	475↓	136↓	308↓	3↓	20↓↓	48↓↓
6-3	444↓	113↓	322↓	0↓↓	14↓↓	38↓↓
6-13	1578	669	933	1↓↓	84↓	347↓
6-18	1197	417	795	2↓	58↓	438↓

2012/4/27 mucus culture: negative

2012/5/16 blood culture: negative

2012/5/18 mucus culture: acinetobacter baumannii

2012/5/18 mucus culture: acinetobacter baumannii, allergic reaction to Amikacin

2012/5/26 mucus culture: acinetobacter baumannii, allergic reaction to Amikacin

2012/5/28 mucus culture: acinetobacter baumannii

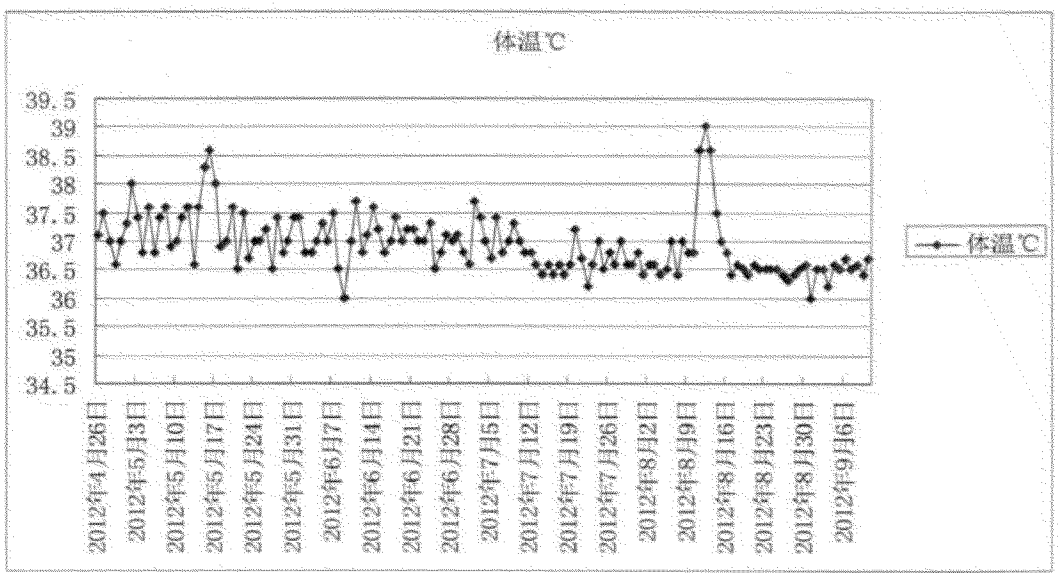
2012/5/28 mucus culture: acinetobacter baumannii, E.coli

2012/6/26 mucus culture: acinetobacter baumannii

2012/7/2 blood culture: klebsiella pnuemoniae subsp. Pneumoniae, KPP

2012/8/15 blood culture (Oxygen demand + anaerobic): negative

Body Temperature (see below):



Prescription after hospitalization:

2012/4/26 – 2012/4/30 (J) Methlyprednisolone injection 80mg, ivgtt, Q12h

2012/4/30 – 2012/5/4 (J) Methlyprednisolone injection 40mg, ivgtt, Q12h

2012/5/4 – 2012/5/10 (J) Methlyprednisolone injection 40mg, ivgtt, Qd

2012/5/10 – 2012/5/17 (J) Methlyprednisolone injection 40mg, ivgtt, Q12 h

2012/5/17 – 2012/5/21 (J) Methlyprednisolone injection 80mg, ivgtt, Q12h

2012/5/21 – 2012/5/25 (J) Methlyprednisolone injection 40mg, ivgtt, Q8h

2012/5/25 – 2012/6/1 (J) Methlyprednisolone injection 40mg, ivgtt, Q12h

2012/6/1 – 2012/6/19 (J) Methlyprednisolone injection 40mg, ivgtt, Qd

2012/6/19 – 2012/6/26 (J) Methlyprednisolone injection 20mg, ivgtt, Qd

2012/6/26 – 2012/6/30 Prednisone Acetate Tablets 10mg, po, Qd

2012/6/30 – 2012/7/4 Prednisone Acetate Tablets 5mg, po, Qd

2012/4/26 – 2012/5/2 Ganciclovir 0.3g, ivgtt, Q12h

2012/5/7 – 2012/5/10 Aciclovir 0.25g x 3, ivgtt, Q8h

2012/5/10 – 2012/5/21 Ganciclovir 0.3g, ivgtt, Q12h

2012/4/26 – 2012/5/14 L – Voriconazole, 0.4g, ivgtt, Q12h

2012/6/2 – 2012/6/4 (J) Itraconazole capsule 600 mg, po, Qd

2012/6/5 – 2012/6/19 Fluconazole 400mg (double the initial intake), ivgtt, Qd

2012/6/5 – 2012/6/6 Caspofungin 70mg, ivgtt, Qd

2012/6/6 – 2012/7/12 Caspofungin 50mg, ivgtt, Qd

2012/7/12 - 2012/8/16 Itraconazole tablet 100 mg, po, Bid

2012/7/17 -2012/9/5 Fluconazole 0.2g, po, Bid

2012/4/26 – 2012/5/7 Moxifloxacin 0.4g, ivgtt, Qd

2012/5/17 – 2012/6/2 Meropenem 0.5g x 2, ivgtt, Q8h

2012/5/17 – 2012/5/30 Linezolid 0.6g, ivgtt, Q12h

2012/5/21 – 2012/6/2 Cefoperazone sulbactam 1.5g x 2, ivgtt, Q12h

2012/6/2 – 2012/6/5 Cefoperazone sulbactam 2.25g, ivgtt, Q8h

2012/6/5 – 2012/6/28 Cefoperazone sulbactam 1.5g x 2, ivgtt, Q12h

2012/6/19 – 2012/6/28 Meropenem 0.5g x 2, ivgtt, Q8h

2012/8/14 – 2012/8/22 Z- Piperacillin tazobactam 4.5g, ivgtt, Q8h

2012/8/14 – 2012/8/27 Levofloaxacin tablets 0.5g, po, Qd

2012/5/7 – 2012/5/8 low molecular weight heparin 0.4 ml, ih, Qd

2012/5/8 – 2012/5/11 Warfarin Tablet 6mg, po, Qd

2012/5/11 – Discharge Warfarin Tablet 3mg, po, Qd

2012/5/18 – Discharge low molecular weight heparin 0.6 ml, ih, Qd

2012/5/16 VitKl 10mg, im, st

2012/5/24 Haloperidol 50mg, im, st

2012/6/4 – 2012/6/26 a – Thymosin injection 1.6mg, im, Qod

Discussion

The patient started to work in the mining well since 2012/4/2 for up to 14 days.

The day the patient was admitted: 2012/4/26, day of discharge: 2012/9/10, total of 107 days.

Discharge diagnose: 1. Interstitial pneumonia 2. Severe Pneumonia, ARDS 3. Low Proteinuria

Discharge reason: recovery

According to the analysis of the artery blood gas line chart, the beginning of the hospitalization is Type I respiratory failure, oxygenation index is low. According to the “ARDS Berlin Criteria” in 2012, it was confirmed as ARDS.

The illness was more severe at the beginning. It started to get better after the tracheal intubation and the aid from ventilation. However, the oxygenation index dropped again on May 4. Correspondently, the parameter of the ventilation was adjusted, yet the oxygenation index was still low. The D-dimer was 8.9 ug/ml on April 26, 6.9 ug/ml on May 2. The reason for the drop remained unknown. Therefore, did an emergency intensive CT on May 7 and it suggested that the artery and branches on the top and the bottom part of the lungs were in low density and filling defect, considering acute pulmonary embolism. We immediately prescribe low molecular weight heparin and Warfarin for two days. The breathing has improved significantly, indicated that anticoagulation and antithrombosis treatment were effective. During the treatment of anticoagulation, according to INR, we adjusted the amount of warfarin. During the adjustment, we noticed a INR 6.03 and immediately used VItkl for treatment.

On May 16, the oxygenation index droppedagain and the body temperature rose sharply. Since the admission on April 26, the patient kept taking Fluconazole, Ganciclovir and Methlyprednisolone for treatment. On May 7, the patient stop takingMoxifloxacin and did not take any antibodies afterward. So we suspected that the malfunctioning of the breathing was caused by the intensifying lung infection. On May 17, PCT reports 24.05 ng/ml, so the patient took Meropenem and Itraconazole right away. As suggested by the CT on May 18, there was consolidation in large area in the right lung. On May 18, the mucus culture came back with acinetobacter baumannii positive twice. The blood culture was also positive. After prescription, the body temperate has dropped. On May 21, PCT was 1.63ng/ml. Indicated by the Intensive CT on May 22, the consolidation of the right lung has absorbed and the breathing was getting better.

2012/5/29 CT reports: There were frosty glass like density increased and hollows in both lungs. The temperature fluctuate between 36.8 – 37.4 Celsius. Possibly having secondary infection caused by Invasive pulmonary aspergillosis. On June 2, PCT reports 5.38 ng/ml, added Itraconzaole capsule, oral treatment. On 6/3, the oxygenation index dropped again, Since the diagnoses of acute pulmonary embolism on May 7, we apply anticoagulation treatment every day. Based on the report on 6/4, the D-dimer is 3.7 ug/ml and PCT is 14.02ng/ml, we predict the likelihood of having another acute pulmonary embolism is low , yet the possibilities of having severe pneumonia infection is bigger. Because the patient has been in critical medical condition and the diagnosis remain unclear, we sought out advice from Dr. Xie.

On 2012/6/4, Dr. Xie Can Mao, Chief Physician, Respiratory department of The First Affliated Hospital, Sun Yat-Sen University, gave us some suggestions in a remote meeting. He diagnosed: 1. Interstitial pneumonia, great possibility for fungal infection. 2. Invasive pulmonary aspergillosis (secondary infection). 3. pulmonary embolism. The patient could take a more complete G examination and and fiber bronchoscope checkup. If the circumstances allow, we should also consider conducting biopsy of lung. However, the patient is on noninvasive ventilator, the biopsy is not appropriate. Treatment wise, Dr. Xie agrees with what we have done so far. He suggested that we should also prescribe 2 tablets of compound Sulfamethoxazole (oral), 3 times/ day. Fluconazole for the fungus and Thymosin for boosting up immune system. Our department agree with using Fluconazole for 14 days. For the antifungal medicine, we agreed to switch to Caspofungin and Fluconazole for treatment. On 6/8, PCT was 0.61ng/ml and on 6/11 was 0.11 ng/ml. The CT scan on 6/12, the hollows in the right lungs were slightly absorbed. The frosty glass like density has decreased and less dense. The improvement reflects on the effectiveness of fungal treatment.

During hospitalization, the body temperature of the patient fluctuate between 37 – 37.3 Celsius. With the help of increasing nutrients, proneposition and treatment for swollen lung, the patient still couldn't get rid of the ventilation machine. On June 19, we had Dr. Zhong Nan Shan from the Respiratory department of The First Affiliated Hospital, Sun Yat -Sen University to join our team remotely. He diagnosed: 1. Interstitial pneumonia, great possibility for virus infection. 2. Invasive pulmonary aspergillosis (secondary infection). He suggested 1. Visit the Animal lab in Kun Ming to confirm the species of the bat. 2. Conduct a swab test and SARS antibody examination. 3. Prescribe Caspofungin, Cefoperazone sulbactam and Meropenem for tratement. 4. Intensify airway monitoring, use fiber bronchoscope to clear out the mucus (do not wash by water), try to suspend the usage of ventilation machine. He basically agreed with our treatment so far.

2012/6/20 Chest CT plain scan, the lung marking become blurry, the consolidation in the right lung is more aggressive, and the area of exudation in the left lung has enlarged. The effusion in the right cavity increased. On 6/27, we conducted ultrasound assisted thoracoscopic thymectomy and extracted some pink effusion for further examination. It was exudate (nontuberculous or tumorous). Continue the treatment from the remote meeting. On 7/6 and 7/11, CT reports: consolidation in the upper and lower lobes of the right lung, average amount of effusion in right cavity and less effusion in left cavity. Continuously envelope pleural effusion drainage. At the same time, keep close attention to the hyoalbuminemia.

On 7/6, the oxygenation index was around 200. The blood flow is steady and can breathe on his own. After the breathing and airway evaluation, we successfully remove the metal tube.

On 8/12, the temperature of the patient spiked but could not find the cause. On 8/13, the infection related protein reports: CRP 90.8 mg/L, PCT 0.72 ng/ml. Given the patient was on the antifungal med, we did not prescribe any antibiotics. Instead, we prescribed Z- Piperacillin tazobactam and Levofloxacin tablets. After 2 days treatment, his body temperature went back to normal. In the later stage, CT plain scan suggested the consolidation, atelectasis and effusion in the right lung were slightly absorbed, yet on the back of the left lung.

There were still parts of consolidation exudation.

The percentage and counts for T, B, NK lymph cells is lower in the early and middle stage of the illness. Because of the treatment, the immune system of the patient has improved. In the later stage, the index went back to normal.

During hospitalization, we carefully monitor patient's random blood sugar in between 6-10 mmol/L. We tried to minimize the blood sugar variation.

On 8/15, blood culture (oxygen demand and anaerobic) reports negative. On 8/30, the infection related protein test: CRP 12.5 mg/L, PCT 0.04 ng/ml, SAA 3.22ng/L, the upper part of the lungs basically back to normality. The body temperature remained around 36.5 Celsius. Besides, the symptom of coughing, coughing with mucus, difficulty in breathing and soreness in limbs is gone. We decided to suspend every other medicine besides the anticoagulation one. The patient was discharged on 2012/9/10.

Case Five

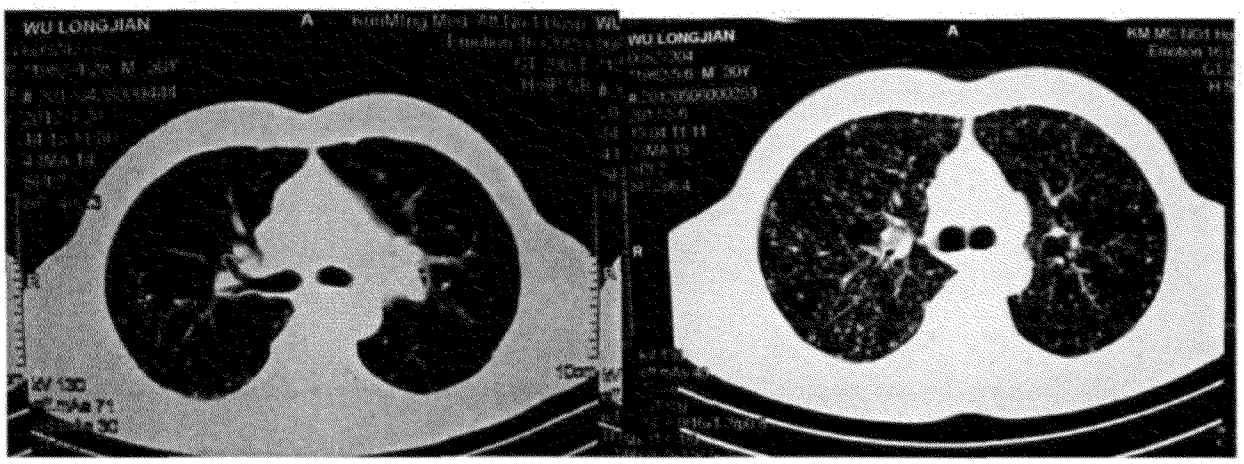
Patient, Mr. Wu, male, 30 year old, was admitted to the hospital on May 2, 2012. He had signs of coughing, coughing with mucus, fever, chest tightness and shortness of breath for five days. Dry cough most of the time, sometimes with white slimy mucus and the mucus came out easily. Chills and fever. There was no observable pattern for the fever. The highest is 39.0 Celsius, accompany with headache, soreness in limbs, chest tightness and short of breath after some light exercise. No symptom of hemoptysis, dizziness and palpitation. Sweating, dizziness, loss of strength, sign of paroxysmal dyspnea at night and edema. No specific treatment after onset of illness. Admitted to our ER last night for further treatment. Exudation and shadow of nodules found in the initial diagnosis. Sleeps and eats well. Normal bowel movement and urination. Used to work in the mining field for about 20 years. He has been to a big cave (about 150 meters deep) to work and was exposed to feces of bats for 4 days. No record of special diseases. No history of allergic reaction. Physical examination: temperature – 36.4 Celsius, Pulse 78 times/ minute, Respiration rate 19 times/ minute, BP 118/60mmHg, alert, No sign of cyanosis on the tip of the fingers or lips; the outline of the chest remains normal. No pain in the chest when pressured. Without inhaling, the oxygenation in the blood is 88%. No white spots in oral mucosa. Resonant to percussion over bilateral lung. Rough breathing sound. Little moist crackles sound from the lower left lung. Did not heard any dry crackle sound from both lungs. The heart rate is 78 times/ minute. No murmurs. No cardiomegaly. The abdominal is soft and flat. No pain when pressure or reflex. The examination did not involve liver, spleen and ribs. No edema in the legs. CT on 2012/4/28: chestnut shaped nodules in both lungs, shadow of multiple exudation.

Initial diagnosis after admission: Further confirmation on the exudation and shadow of the nodules in the lungs (possibly inhaling pneumonia, check with pneumoconiosis)

Method

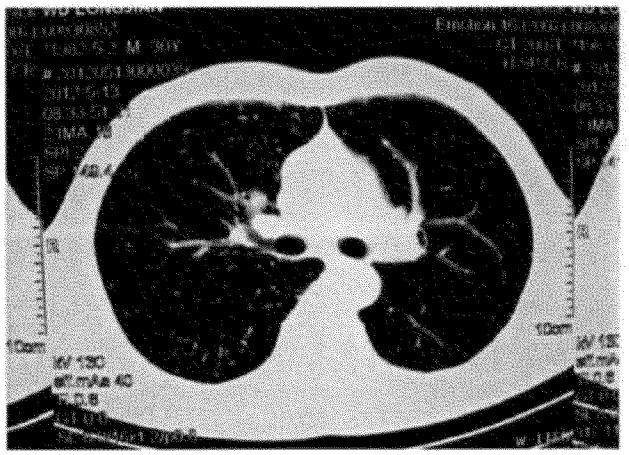
Assisted examination after admission:

2012/4/28 CT: multiple chestnut shaped nodules, shadows of exudation in both lungs. Multiple inflamed big lymph nodules in mediastinum (see below).



2012/5/6 CT: found chestnut-shaped nodules in both lungs, the exudation is more apparent in the lower lungs (see the upper right picture)

2012/5/13 CT: diffusive lesion in both lungs seemed to improved. The lymph nodules in the mediastinum decreased (see below)



2012/5/2 – 2012/5/24 regular blood test, blood biochem test and artery gas analysis, CK, AST, LDH, CK-MB test, PT, APTT, TT, FIB test, BNP and D-dimer: Normal.

2012/5/2 PPD test: negative.

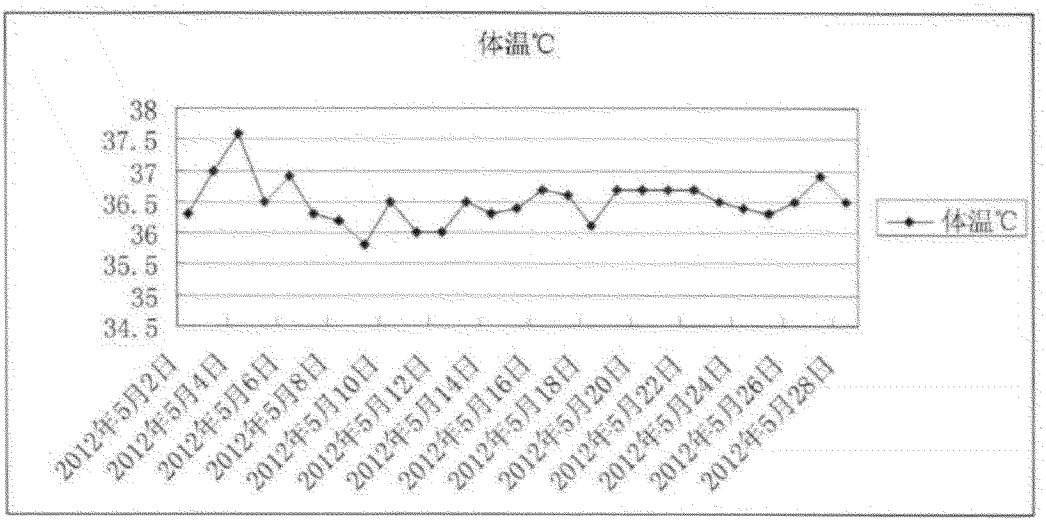
2012/5/2 ECG test reports sinus bradycardia and others were normal

Infection related protein: CRP 21.3 mg/L (May 2), PCT 0.67 mg/ml (May 3), PCT 0.75 mg/ml (May 7), CRP 12.6 mg/L, PCT 0.04 ng/ml, SAA 44.10 mg/L (May 9), PCT reports < 0.1 ng/ml (May 18), CRP 0.8 mg/L, PCT 0.04 ng/ml, SAA 2.82 mg/L (May 21).

Percentage and count of cell T, B, NK (see below):

日期	CD3 阳性 T 淋巴细胞绝对值	T 抑制细胞 CD3+CD8+双阳细胞绝对值	T 辅助细胞 CD3+CD4+绝对值	CD3CD4 CD8 均为阳性细胞绝对值	NK 细胞（CD16+CD56+双阳细胞）	B 淋巴细胞（CD19+CD45+）
5-18	6831	355	28811	6	139	12011

Body temperature (see below):



Prescription after hospitalization:

2012/5/2 – 2012/5/10 Sulbencillin 1.0 g x 4 shots, ivgtt, Q8h

2012/5/7 – 2012/5/27 L – Fluconazole 0.2 g x 1, ivgtt, Q12h

2012/5/7 – 2012/5/9 (J) Methlyprednisolone injection 40mg x 1 shot, ivgtt, Qd

2012/5/9 – 2012/5/14 Prednisolone 10mg x 3 shots, ivgtt, Qd

2012/5/14 – 2012/5/15 Prednisolone 10mg x 2 shots, ivgtt, Qd

2012/5/15 – 2012/5/21 Prednisone Acetate tablet 20mg, po, Qd

2012/5/21 – Discharge, Prednisone Acetate tablet 15mg, po, Qd

2012/5/22 – Discharge, Thymosin, 1.0 mg x 2 shots, ivgtt, Qd

Discussion

The patient started to work in the mining cave on 2012/4/22 for up to 4 days.

First day of hospitalization: 2012/5/2; Day of Discharge: 2012/5/28, total of 26 days

Discharge diagnosis: Multiple nodules in the lungs, need further confirmation for the exudation (possibly Histoplasmosis also need to check for the possibility for pneumoconiosis)

Discharge reason: recovery

The patient is young adult. After taking anti-infection and antifungal treatment, the disease was under control while hospitalization. No reoccurrence of fever, coughing, coughing with mucus, tightness of chest and short in breath. The patient did not take any anti-virus medicine during rehabilitation, yet he has recovered. It indicates that his own immune system play a big role in fighting the disease.

On May 6, according to the CT plain scan, the illness was getting worse. Therefore, we prescribed the antifungal medication and some hormone. The consolidation exudation in the upper lung has improved five days after. The temperature has dropped to normal. It indicates that antifungal med and hormones were effective.

The cause of recovery: The patient is younger with stronger immune system. In addition, he did not spend a long time in the mining field, The treatment was immediate and effective.

Case Six

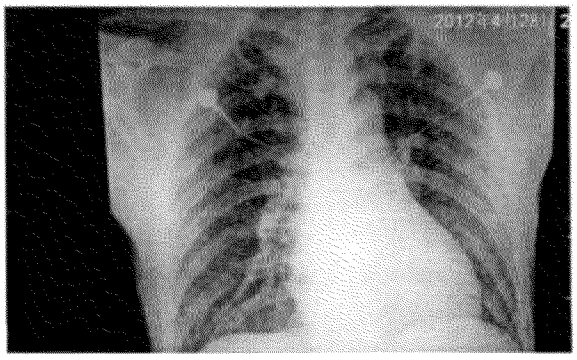
Patient Li, male, 32 year old, has been admitted to the hospital on 2012/4/26. He had sign of coughing, coughing with mucus, fever and difficulty in breathing for four days. He worked in the mining well four days ago. There were many bats and their feces in the well. Four days ago, he started to show sign of coughing, coughing with mucus (white and slimy) and fever. It smelled really bad in the well. His temperature went up to 39 Celsius. When he coughed, he had difficulties in breathing. No chest pain or coughing up blood. No sign of paroxysmal dyspnea at night. No stomach ache or diarrhea. He went to the local hospital for treatment but no documentation. His symptom had improved but wanted further treatment. He was healthy. No history of high blood pressure, diabetes, heart disease or any other chronic illness. He worked in the mining well before and was exposed to big amount of bats' feces. He had inhaled much irritating gas. No history of hepatitis, Typhoid or any other contagious disease or in contact with such diseases. No medical or food allergy. The vaccination report remained unknown. Physical checkup: temperature: 37 Celsius, pulse 74 times/minute, respiration rate 24 times/ minute, blood pressure 137/ 72 mmHg. In moderate health. No yellowing of skin and mucous membranes. Did not feel any lymph nodules on the superficial level. No abnormality in the head structure. The pupils were round and equal sized. Sensitive to the light. No sign of cyanosis on the tip of the fingers or lips. No resistance in the neck. The airway was in the middle. The thyroid was normal. The outline of the chest looked symmetric. The breathing sound from the lungs was rough. Did not hear any moist or dry crackle. Did not see any abnormality in heart and abdominal checkup. No sign of edema in legs. No abnormality in spine and limbs. Regular active and normal muscle strength. React to reflex and no any pathological reflex. Assistive checkup: CT reports: lung markings thickening and increased. Noticed multiple chestnut-shaped nodules. Need further confirmation on possibilities for Pneumoconiosis, acute pulmonary tuberculosis or other illnesses. Noticed multiple inflamed lymph nodules in mediastinum.

Initial diagnosis: 1. Cause of fever (possibly lung infection). 2. Inhaling lung impairment 3. Hypokalemia.

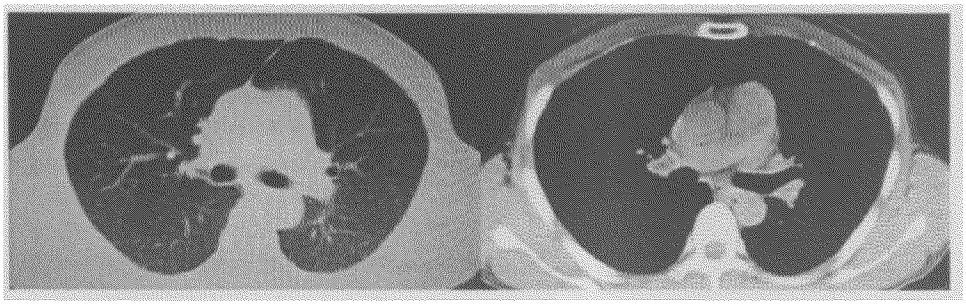
Method

After hospitalization, a complete examination:

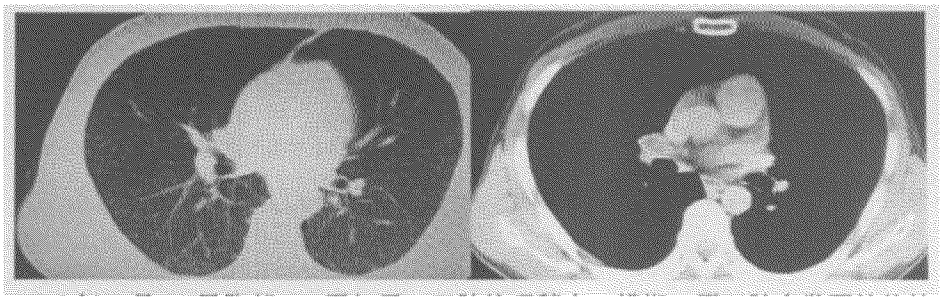
2012/4/28 Chest plain film: lungs marking messy and murky. Chest-nut shaped nodules all over bilateral lungs. Please work with the clinical for further confirmation. The heart and diaphragm remained normal (see below).



2012/4/29 CT chest plain scan: lung markings have increased and become blurrier in both lungs. Decrease amount of chestnut-shaped nodules shadows in both lungs. Noticed few strip shadows at the bottom part of the lower lobes in both lungs. Thickening on the left back side of the pulmonary pleurae.

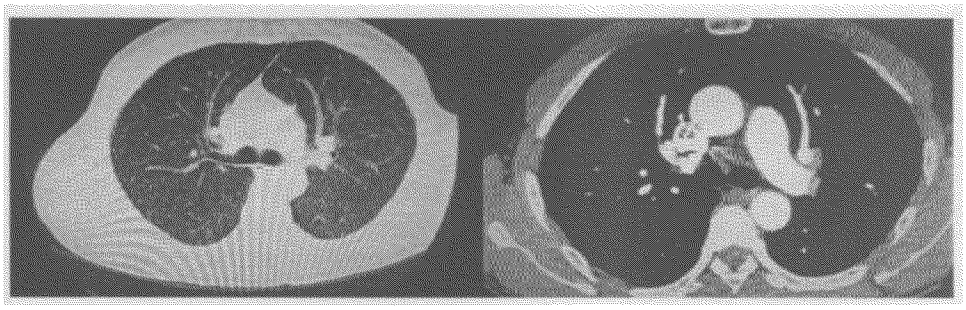


2012/5/7 CT plain scan: Compared to the scan on 2012/4/29, the lung marking has increased and blurry. The shadow of chestnut-shaped nodules has decreased. Less strip at the bottom of the lower lobes. The local emphysema, and bullae on the ring remained the same as before. The shadow of the heart looked normal. Noticed multiple inflamed lymph nodules in mediastinum (see below).



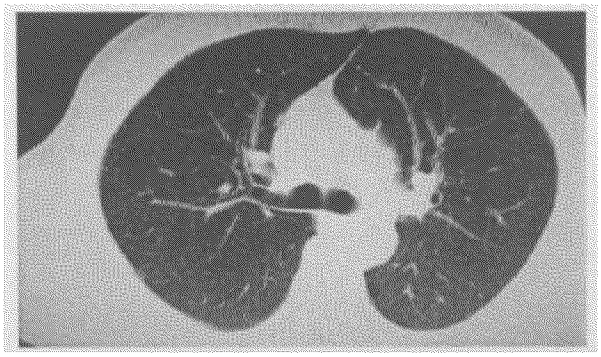
2012/5/14 CT plain scan: lung marking has increased and blurry. The chestnut shaped nodules remain the same. Noticed few strip shadow at the bottom of the lower lobes, local emphysema and bullae on the ring.

2012/5/18 intensive CT: 1. Diffuse pulmonary lesions (tuberculosis?) in both lungs, the change of the lesions was not as apparent as before. 2. The lung artery has thickened (see below).



2012/5/28 CT plain scan: the lung marking has slightly increased and blurry. Fewer shadow of chestnut-shaped nodules. Noticed few strip shadow at the bottom of the lower lobes, local emphysema and bullae on the ring.

(see below)



2012/4/26 Regular blood test, bio-Chem blood test, PT, APTT, TT, FIB and CK, AST, LDH, CK-MB: normal

2012/4/27 Bio-Chem blood test: CRP 34.2 mg/L, SAA 79.00 ng/L

2012/4/27 Hepatitis virus examination, regular urinary test, PT, APTT, TT, FIB: normal

2012/5/7 NK and PCR: normal

2012/5/17 Regular blood test, Bio-Chem blood test, CK, AST, LDH, CK-MB, blood culture: normal

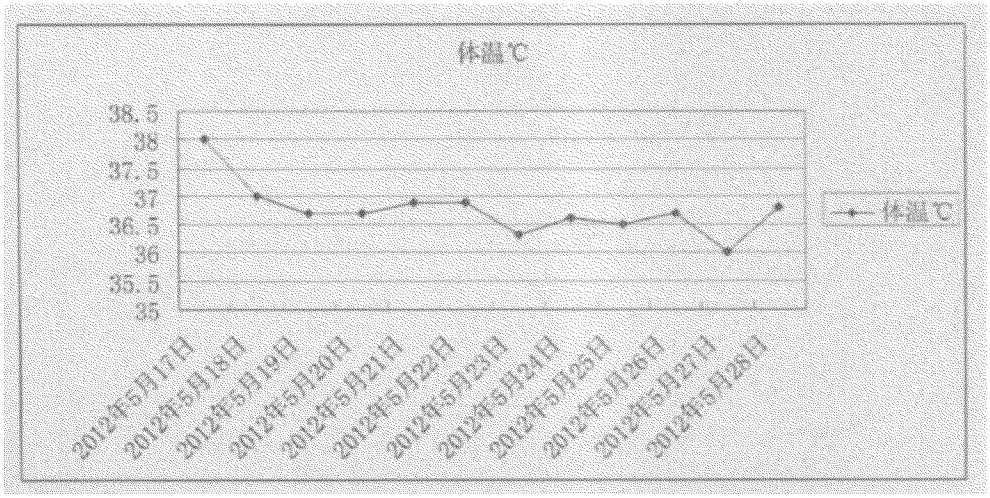
2012/5/18 Artery blood gas analysis: PaO2 56.9mmHg, PaCO2 32.9 mmHg, Oxygenation Index (PF index) 270.8, Blood sugar 5.7 mmol/ L, Lactic Acid 1.4 mmol/L

2012/5/19 Artery gas Analysis: PaO_2 76.2 mmHg, $PaCo_2$ 36.7 mmHg, Oxygenation Index (PF index) 363.0, Blood sugar 7.9 mmol/ L, Lactic Acid 3.0 mmol/L

2012/5/18 Blood test: EDP 5.3 ug/ml, Antithrombin III 146.5 %, D-dimer 3.9 ug/ml

2012/5/18 Infection related protein: CRP 66.3 mg/L, PCT 0.04 ng/ml, SAA 230.00 ng/L

Body temperature chart (see below):



Prescription during hospitalization:

2012/5/17 – 2012/5/21 Ganciclovir 150 mg x 2 shots, ivgtt, Q12h.

2012/5/17 – 2012/5/24 Piperacillin Sodium and Tazobactam Sodium 4.5g, ivgtt, Q8h

2012/5/17 – 2012/5/21 (J) Methlyprednisolone injection 40mg, ivgtt, Q12h

2012/5/21 – 2012/5/26 (J) Methlyprednisolone injection 20mg, ivgtt, Q12h

Discussion

The patient started to work in the mining cave since 2012/4/22 and a total of 4 days.

Day admitted to the hospital: 2012/4/26; Day of discharge: 2012/5/28, total of 24 days

Discharge diagnose: 1. Lung infection 2. Inhaling lung impairment 3. Hypokalemia

Discharge reason: recovery

The patient is a young adult. After receiving the anti-infection, anti-inflammation and antivirus treatment, the patient has started to recover. The body temperature was kept in the normal range. No reoccurrence of coughing, coughing with mucus or any difficulty in breathing. The patient did not receive any anti-fungal medicine for treatment, yet still recovered. This suggested that the possibility of the illness being triggered by fungal infection is slim.

Compared the CT at the beginning and in the end, it showed that the treatment was effective.

The cause of recovery: the patient was young and with a stronger immune system. He did not spend a long time in the mining well. The treatment was immediate and effective.

Comprehensive Analysis

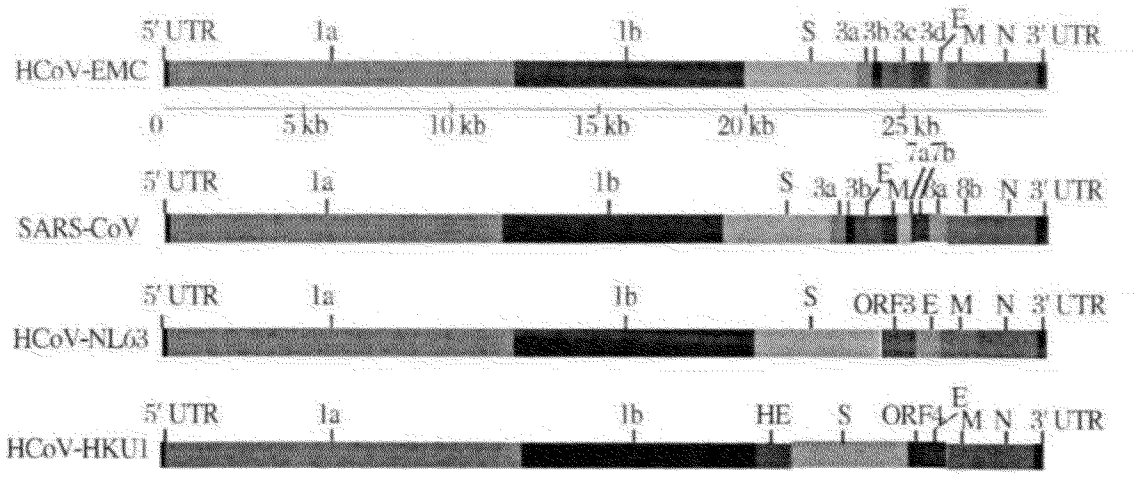
I. Etiology

Virus is a small, simple structure non-cellular life with only one type of Nucleic acid (DNA or RNA). To multiply itself, it has to parasite with a live cell. According to the type and the structure of Nucleic acid, virus is sorted into two kinds: DNA and RNA. Among RNA virus, based on different shapes, it can be categorized into: Paramyxoviridae, Orthomyxoviridae, Retrovirus, Picornaviridae, Coronaviridae, Arenavirus, Rhabdovirida, Filoviridae and so forth.

Based on the categorization, coronavirus belongs to Coronaviridae. One of its varieties is what caused SARS. According to the analysis on the sequence of the nucleic acids, in the ninth report from the International committee on taxonomy of viruses (ICTV), corona virus has four categories: a, β, γ and a presumably new one. β -coronavirus mainly includes severe acute respiratory syndrome (SARS), SARS-like CoV and Chinese rufous horseshoe bat virus Rf1, HKU3, HKU4, HKU5, leopard cat virus and so forth.

About SARS-like-CoV:

In November, 2002, as a new corona virus, SARS had a first outbreak in Guang Dong Province and had spread out in a short timeframe. Because the main symptom is severe acute respiratory illness, it is named SARS-CoV or contagious non-traditional pneumonia. The real host of SARS-CoV had not been found. However, in the process of tracing SARS-CoV, scientists have dissected multiple corona viruses from different kinds of bats. The genetic structure and feature of the corona virus from the Chinese rufous horseshoe bat is similar to SARS-CoV. They have the comparable similarity in Nucleotide, it was between 82 % - 92 %. Hence, this virus was named SARS-like CoV or Bats kind SARS-like Corona Virus [reference 3].



In the previous research, SARS-like CoV [reference 4] was found in the Chinese rufous horseshoe bat in Hong Kong (by bio-chemistry scientist Yuan Guo Yong, Chinese Hong Kong Univeristy), Greater horseshoe bat and Big-eared horseshoe bat in Tian Jing (Li Wen Dong), Rhinolophus Pearsonii in Guang Xi Nan Ning by using RT-PCR examination. If the bats carry SARS-CoV or SARS-like CoV, then very likely they can transmit the disease to human and other animals. In that way, the virus is transferred across different species. However, from other researches, it indicates that when compared the genetic sequence, the SARS-CoV from SARS patients and other animals is more advanced than the SARS-like CoV from the bat. The figures suggested that SARS – CoV, which caused SARS in 2002-2003, is from the evolution group related bats virus [Reference 4]. Therefore, bats corona virus has become the hot topic of international virus study.

II. "Horizontal" Analysis:

1. All 6 patients worked in the same mining cave in different times. The main duty was "cleaning the bats' feces inside the cave", then they all immediately have the illness with "similar syndrome in different degrees".
2. After five patients were admitted into our department in different times (Mr. Wu was admitted to respiratory department), the doctor on duty immediately reported to the medical office about the circumstance in case of an outburst of disease.
3. Four patients were in severe condition when they got admitted to our department. They were in Type I respiration failure, meaning gas exchange function was failing. Hence the reflection of interstitial lung disease and alveoli lesion.
4. After admitted to the hospital, the percentage and count for T, B, NK cells were all substantially low, which means the immune system of the patients were in severe impairment and created chances for multiple infections. In 2011, a scholar mentioned the importance of low CD4 + T lymph in virus infection [reference 5]. Therefore, presume that all 6 patients were infected by the virus.
5. After admission, Patient Guo and Liu did test for etiology (swabs and blood) for SARS-CoV, hemorrhagic fever, Dengue fever, Japanese encephalitis, Influenza A virus and other related virus by Chen Du army reserved Center for Disease Prevention and Control, the result were all negative. A negative on a onetime etiology test could not exempt other related virus.
6. According to Table 1: The major clinical syndrome of the six patients was "coughing, coughing with mucus and fever", some other accompanied syndromes were "difficulty in breathing, soreness in limbs, cough up blood and headache".
7. According to Table 2: The longer the time spent in the mining cave, the likelihood of death is higher. At the same time, the older patient died sooner. In terms of recovery, the fewer the working hours, the younger the patient, the better the recovery. They spend less time in the hospital.
8. According to Table 3: In the first infection related protein test of all 6 patients, SAA were noticeably increasing,

PCT remained in the normal range. It suggested that the six patients possibly had virus infection.

The syndromes of the six patients

表格 1 Table 1 6 位患者入院主诉及伴随症状

症状 / 患者	咳嗽 Coughi	咳痰 Coughi	发热 ≥39℃ Fever	呼吸困难 Difficulty	四肢酸痛 Soreness	血性痰 Bloody	头痛 Headac	胸痛 Chest
Patient Zhou 周 XX	+	+	+	+	+	-	+	+
Patient Lu 吕 XX	+	+	+	+	+	+	-	-
Patient Guo 郭 XX	+	+	+	+	+	+	+	-
Patient Liu 刘 XX	+	+	+	+	+	+	-	+
Patient Wu 吴 XX	+	+	+	+	+	-	+	-
Patient Li 李 XX	+	+	+	-	-	-	-	-

表格 2 相关重要信息

Table 2 Related Important Info

情况 / 患者	入院时间 Date admitted to Hospital	住院天数 Total days of hospitalization	出院情况 Discharge reason	下洞穴工作天数 Number of days spend in the cave	性别 Sex	年龄（岁） Age
Patient Zhou 周 XX	4-26	12	死亡	14	男	63
Patient Lu 吕 XX	4-25	48	死亡	14	男	42
Patient Guo 郭 XX	4-27	109	死亡	14	男	45
Patient Liu 刘 XX	4-26	107	好转	14	男	46
Patient Wu 吴 XX	5-2	26	好转	4	男	30
Patient Li 李 XX	4-26	24	好转	4	男	32

表格 3 入院后首次感染相关蛋白 Initial infection related protein test

Table 3

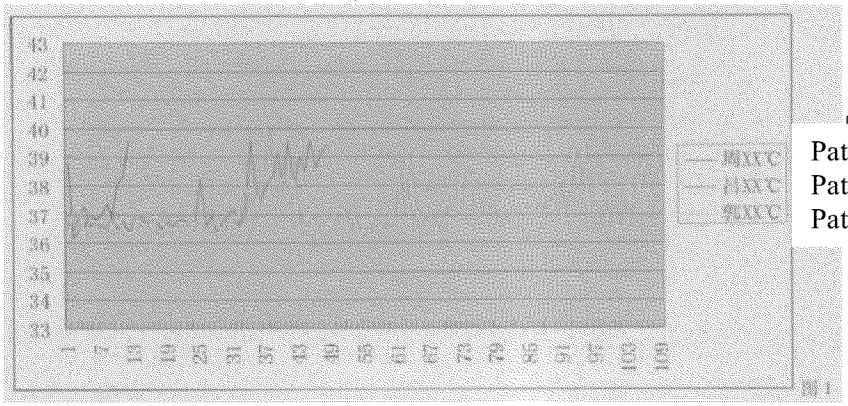
姓名	时间	CRP mg/L	PCT ng/ml	SAA mg/L
Patient Zhou 周 XX	4-27	82.1	0.40	198.00
Patient Lu 吕 XX	4-26	117.0	0.04	398.00
Patient Guo 郭 XX	4-28	23.8	0.04	434.00
Patient Liu 刘 XX	4-27	145.0	0.47	380.00
Patient Wu 吴 XX	5-9	12.6	0.04	44.10
Patient Li 李 XX	4-27	34.2	0.04	79.00

（我院 PCT 用胶体金比色法（B.R.A.H.M.SPCT-Q-半定量快速实验）测得，结果分为四级：正常<0.5ng/mL；轻度升高>0.5ng/mL，明显升高>2ng/mL，显著升高>10ng/mL。）

(For PCT, we used colloidal gold colorimetric (B.R.A.H.M. SPCT -Q Semi-quantitative speedy exam). There are four levels: normal < 0.5 ng/ml ; slightly higher > 0.5 ng/ml, substantial higher > 2ng/ml; noticeably higher > 10 ng/ml)

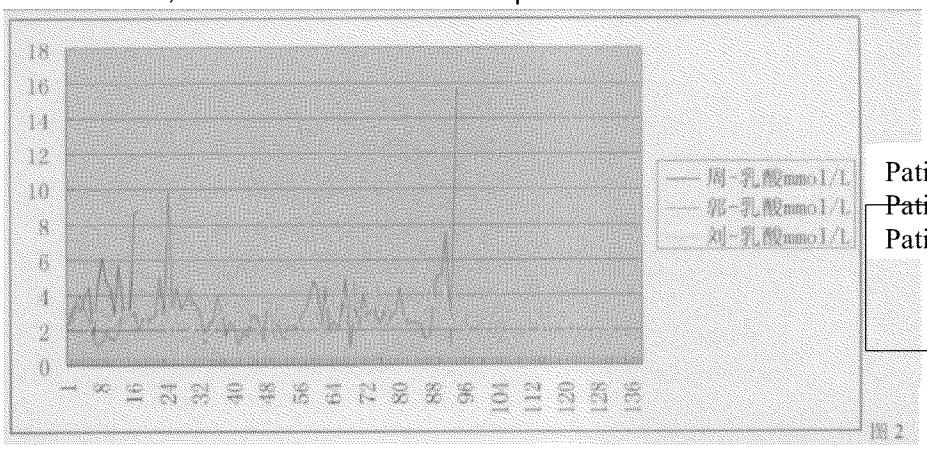
English translation of [illegible] y Li Xu of Kunming Medical Un[illegible]

9. Picture 1 shows the temperature line chart of the three dead patients. It suggested three of them were all in high fever.



Picture 1

10. Picture 2 shows the lactic acid of the three patients in critical stage (Because some of the Lu's information was missing, I wasn't able to do the comparison). According to international and domestic researches, lactic acid is a critical index for monitoring the illness of the patients in critical stage. It is useful in evaluating the severity of hypoxia during shock, tissue hypoperfusion and so forth. It can also predict the possibility of recovery [reference 6]. In our case, the level of lactic acid is related to the rate of death, which resonates with the previous researches.



Picture 2

12. Phone counselling after the discharge: Patient Liu, has been discharged for 240 days, he was still resting at home. He said his immune system is weak, which makes him catch a cold very easily. He worked out at home to boost up his immune system. The two young adult patients, Patient Wu and Li, both were doing fine after discharge, but also have poor body resistant.
13. Patient Liu was the only recovery case for critical condition patient, we conclude the success of the treatment is: This is a comprehensive treatment as we provided supports in breathing, circulation and nutrients. At the same time, closely monitored the functions of each organs and kept the balance of PH and electrolyte. We

prepared for and immediately took care of any complication, especially any hospital acquired infections.

14. Gaps and failings: (1) Initially, the patients were tested for etiology (swabs and blood) by Chen Du army reserved Center for Disease Prevention and Control and the result was negative. However, a negative on a onetime etiology test could not exempt the possibility of infections caused by other related viruses. In the later stage, we worked with Dr. Zhong Nan Shan and did some sampling. The patient tested positive for Serum IgM by the WuHan Institute of Virology. It suggested the existence of virus infection. Therefore, in the future, if there is any more unknown virus related severe pneumonia or severe group lung infection cases in clinical, we need to be alert to the possibilities of contagiousness and work closely with local center for disease control. That way, we can ensure the prevention, clinical and research for similar kinds of disease. (2) We had three patients died this time. We had considered a lung biopsy before, but we did not do one in the end for various reasons. Currently, diagnosis rate done by biopsy is around 94%. For patients in critical condition, the risk of doing a biopsy with the assistance of ultrasound or CT is very high. Doctors should consider doing fiberoptic bronchoscopy instead. The diagnosis rate is not as high as biopsy but is worth trying. (3) The work of preventing hospital acquired infection should be the priority of ICU. (4) Given all six patients had the same disease but to different degrees, it is important to do autopsy on those who died. Autopsy and Etiology are important for the advancement in medical field. The reluctance of patients' families stands in the way of better understanding the disease. In the future, for unknown and possibly contagious disease, there should be a law which allows immediate autopsy for further examination. (5) For the first two dead patients, we failed to take any blood sampling when they died for the purpose of related examination and scientific research. (6) Given all of the six patients were exposed to huge amount of bats and their feces, also inhaling the smell of the feces, it is important to go sampling the live bats and their feces in the same cave.

III. Future Research

1. About SAA: Recently, there were many researches, internationally and domestically, indicate the increment of SAA during virus or bacterial infection, however, CRP does not increase or the increment is not noticeable in virus infection [reference 7]. Testing for both SAA and CRP can increase the rate of diagnosis for virus infection in the early stage. The testing is also valuable for determining the kinds of virus or bacterial infection and treatment [reference 8-9]. At recent years, the pervasiveness of PCT and its credible application shows that PCT has become the critical index in determining severe bacterial infection [reference 10-11].
2. About Bats: The research on SARS is still ongoing. In the international arena, scholars from Hong Kong are highly respected. They have discovered that the Chinese rufous horseshoe bat plays an important role in understanding the transmission of SARS-CoV.

3. With the Kunming Institute of Zoology, we confirmed that the six patients were exposed to Chinese rufous horseshoe bat, which caused the disease. However, a paper published in *Science* magazine in 2005 by Scientist Shi Zheng Li and Zhang Shu Yi from Wuhan Institute of Virology under Chinese Academy of Science, concluded that the SARS-like-CoV carried by bats is not contagious to humans. This contradiction indicates the importance of these six cases: the severe pneumonia caused by the unknown virus and the bats in the cave merit further investigation and research.

IV. Conclusion

Based on the above mentioned cases and related researches, the unknown virus lead to severe pneumonia could be: The SARS-like-CoV from the Chinese rufous horseshoe bat or Bats kind SARS-like CoV.

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李旭，钱传云，吴海鹰. PiCCO监测血管外肺水对ARDS的指导性治疗[J]. 昆明医科大学学报，2012，(2B)：387-389.

致　谢

时光如梭，白驹过隙，三年的硕士研究生学习生涯即将结束之际，谨对诸多年来给予我关心、支持和帮助的良师益友和亲人们致以最诚挚的谢意。

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Cc: Pierre Gsell[gsellp@who.int]; William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; langermans@bprc.nl[langermans@bprc.nl]; Dr. Mark Lewis[mlewis@bioqual.com]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; nax3@cdc.gov[nax3@cdc.gov]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; sekim@krict.re.kr[sekim@krict.re.kr]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; rkiatchula@gmail.com[rkiatchula@gmail.com]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; sinabavari@comcast.net[sinabavari@comcast.net]; Vasan Vasan[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Amelia Karlsson[amelia.karlsson@duke.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; Geraldine Hamilton[geraldine.hamilton@emulatebio.com]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@fda.hhs.gov]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; ldenisy@yahoo.com[ldenisy@yahoo.com]; Dan Barouch[dbarouch@bidmc.harvard.edu]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; elizabethsulkowski44@gmail.com[elizabethsulkowski44@gmail.com]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Krammer, Florian[florian.krammer@mssm.edu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Quim Segales[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Juergen Richt[jricht@vet.k-state.edu]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; erica@lji.org[erica@lji.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; golinger@mriglobal.org[golinger@mriglobal.org]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; que.dang@nih.gov[que.dang@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; 秦川[qinchuan@pumc.edu.cn]; Spergel, Jonathan[SPERGEL@email.chop.edu]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Padmini Salgame[salgampa@njms.rutgers.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; tverakit@gmail.com[tverakit@gmail.com]; anna@thsti.res.in[anna@thsti.res.in]; Lee-Parritz,

David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew Frieman[MFrieman@som.umaryland.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Koert Stittelaar[stittelaar@viroclinics.com]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; 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]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; rolandsutter@gmail.com[rolandsutter@gmail.com]; peter.palese@mssm.edu[peter.palese@mssm.edu]; Seder, Robert (NIH/VRC) [E][rseder@mail.nih.gov]; jlh66@cam.ac.uk[jlh66@cam.ac.uk]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
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Subject: Webex and Agenda: WHO Animal Models Call-Aug 13
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Dear colleagues,
Please find below the agenda for this week's call on Thursday Aug 13th at 3PM CET (Geneva).

Best regards

César, Bill and Simon.

Agenda Aug 13-Animal Models WHO call

1- Michael Diamond (Washington Uni School of Medicine in St. Louis)

2- Jonathan Heeney (Cambridge University)

3- Stanley Perlman (University of Iowa)

4- Open questions

Pierre GSELL invites you to join this Webex meeting.

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Thursday, August 13, 2020
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Cc: Clague, Darren P[darren.p.clague@perspecta.com]
From: Kavita Berger[kavitamb04@gmail.com]
Sent: Wed 8/19/2020 7:53:20 PM (UTC-04:00)
Subject: News

Dear B Group Colleagues,
I hope this message finds you well! I want to share some news with you. In early July, I joined the National Academies as the new director of the Board on Life Sciences. Unfortunately, this means that I have to leave the B Group in early September. However, I am allowed to participate in the quarterly meetings and hope to participate. I have enjoyed being part of the group and will miss being part of it. But, I hope to see you at the quarterly meetings and work with you within the NASEM context. In addition, I'm always happy to be on the emails. :-)

Take care,
Kavita

Cc: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Simon Funnell[Simon.Funnell@phe.gov.uk]; William Dowling[william.dowling@cepi.net]; Pierre Gsell[gsellp@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]
To: LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; langermans@bprc.nl[langermans@bprc.nl]; Dr. Mark Lewis[mlewis@bioqual.com]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; nax3@cdc.gov[nax3@cdc.gov]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; sekim@krict.re.kr[sekim@krict.re.kr]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; rkiatchula@gmail.com[rkiatchula@gmail.com]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; sinabavari@comcast.net[sinabavari@comcast.net]; Vasan Vasan[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Amelia Karlsson[amelia.karlsson@duke.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; Geraldine Hamilton[geraldine.hamilton@emulatebio.com]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@fda.hhs.gov]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; ldenisy@yahoo.com[ldenisy@yahoo.com]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; Dan Barouch[dbarouch@bidmc.harvard.edu]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; Elizabeth Sulkowski[elizabethsulkowski44@gmail.com]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Krammer, Florian[florian.krammer@mssm.edu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Quim Segales[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Juergen Richt[jricht@vet.k-state.edu]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; erica@lji.org[erica@lji.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; golinger@mriglobal.org[golinger@mriglobal.org]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; que.dang@nih.gov[que.dang@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; 秦川[qinchuan@pumc.edu.cn]; Spergel, Jonathan[SPERGEL@email.chop.edu]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Padmini Salgame[salgampa@njms.rutgers.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru];

y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; tverakit@gmail.com[tverakit@gmail.com]; anna@thsti.res.in[anna@thsti.res.in]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew Frieman[MFrieman@som.umaryland.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Koert Stittelaar[stittelaar@viroclinics.com]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; KNEZEVIC, Ivana[knezevici@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]; Peter Palese[peter.palese@mssm.edu]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 8/20/2020 6:23:53 AM (UTC-04:00)
Subject: Agenda: WHO Animal Models Group Call-August 20
Mail Attachment.ics
Webex_Meeting.ics

Dear all,

Please find below the agenda for today's call which will be focused on COVID-19 therapeutics

Best regards

César, Simon and Bill

Agenda August 20- Focus: COVID-19 therapeutics in animal models

- Alina Baum (Regeneron)

- Elizabeth Sajdel-Sulkowska (Harvard Med School)

- Open questions

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 558 3554
Meeting password: P3pfB7MwHA3

Thursday, August 20, 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] 25th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=m9bfee6e60f4a57c83d921c8cba89bc5f
Start Time: 2020-08-20T15:00:00+02:00
End Time: 2020-08-20T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Cc: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; 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]

To: sandra cordo[scordo@qb.fcen.uba.ar]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Vasan Vasan[Vasan.Vasan@csiro.au]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; 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]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; 秦川[qinchuan@pumc.edu.cn]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; Chi Van Dang[cdang@lcr.org]; 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]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; ldenisy@yahoo.com[ldenisy@yahoo.com]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; 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]; 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[julia.vergara@irta.cat]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; rkiatchula@gmail.com[rkiatchula@gmail.com]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; tverakit@gmail.com[tverakit@gmail.com]; langermans@bprc.nl[langermans@bprc.nl]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[wim.vanderpoel@wur.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; Dr. Mark Lewis[mlewis@bioqual.com]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Griffiths, Anthony[ahgriff@bu.edu]; nax3@cdc.gov[nax3@cdc.gov]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; mto@umn.edu[mto@umn.edu]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.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]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; Amelia Karlsson[amelia.karlsson@duke.edu]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@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]; Elizabeth Sulkowski[elizabethsulkowski44@gmail.com]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.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]; erica@lji.org[erica@lji.org]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Peter Palese[peter.palese@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; golinger@mriglobal.org[golinger@mriglobal.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; que.dang@nih.gov[que.dang@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]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; Matthew Frieman[MFrieman@som.umaryland.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; dbolton@hivresearch.org[dbolton@hivresearch.org]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 8/26/2020 1:47:37 PM (UTC-04:00)
Subject: WHO COVID-19 Animal Models Call-Aug 27
Mail Attachment.ics
Webex_Meeting.ics

Dear all,
Please find below the agenda and webex invite for tomorrow's group call.

Best regards to all

César, Simon and Pierre

Agenda-WHO Animal Models for COVID-19 Group Call- Thursday August 27 3PM CET (Geneva)

1- Conrad Freuling (Friedrich-Loeffler Institute)

2- Martin Beer (Friedrich Loeffler Institute)

3- Open questions

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 565 2302
Meeting password: P7ciAip9X8C

Thursday, August 27, 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] 26th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=m2d9e953ab0c862901b61f3fce487ef5e
Start Time: 2020-08-27T15:00:00+02:00
End Time: 2020-08-27T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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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]
To: sandra cordo[scordo@qb.fcen.uba.ar]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Vasan Vasan[Vasan.Vasan@csiro.au]; kanta.subbarao@influenzacentre.org[kanta.subbarao@influenzacentre.org]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; 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]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; 秦川[qinchuan@pumc.edu.cn]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; Chi Van Dang[cdang@lcr.org]; 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]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; ldenisy@yahoo.com[ldenisy@yahoo.com]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; 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]; 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[julia.vergara@irta.cat]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; rkiatchula@gmail.com[rkiatchula@gmail.com]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; tverakit@gmail.com[tverakit@gmail.com]; langermans@bprc.nl[langermans@bprc.nl]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[wim.vanderpoel@wur.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; Dr. Mark Lewis[mlewis@bioqual.com]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Griffiths, Anthony[ahgriff@bu.edu]; nax3@cdc.gov[nax3@cdc.gov]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; mto@umn.edu[mto@umn.edu]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.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]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; Amelia Karlsson[amelia.karlsson@duke.edu]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@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]; Elizabeth Sulkowski[elizabethsulkowski44@gmail.com]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.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]; erica@lji.org[erica@lji.org]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Peter Palese[peter.palese@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; golinger@mriglobal.org[golinger@mriglobal.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; que.dang@nih.gov[que.dang@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]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; Matthew Frieman[MFrieman@som.umaryland.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; Trevor Brasel[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; Chien-Te Tseng[sktseng@UTMB.EDU]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; dbolton@hivresearch.org[dbolton@hivresearch.org]; mvaccari@tulane.edu[mvaccari@tulane.edu]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 9/2/2020 3:21:32 PM (UTC-04:00)
Subject: WHO COVID-19 Animal Models Call-Sep 27

Dear collegues,
Please find below the agenda for this week's WHO Animal Models group call this Thursday 3rd at 3PM CET (Geneva).

This week, we will also initiate the first of a series of panel sessions which we hope will serve to spark some discussions on key research questions of relevance for COVID-19 preclinical studies in animal models. The agenda will be as follows

1- Presentation by Dr. Monica Vaccari (Tulane)

2- Panel session

Proposed question: Should the challenge doses, challenge methods and challenge stocks be standarized for COVID-19 animal model studies?

Moderator: Simon Funnell

Panelists:

Adolfo García-Sastre (Mount Sinai)

Phil Krause (FDA)

Dan Barouch (Harvard)

Clint Florence (NIH)

Best regards to all,

César, Simon and Bill

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 167 818 8876
Meeting password: C2qhjG9eUE9

Thursday, September 3, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

+41445750282,,1678188876## SWITZERLAND Toll
+1-415-655-0003,,1678188876## US Toll

41445750282 SWITZERLAND Toll
+1-415-655-0003 US Toll
Global call-in numbers

Dial 1678188876@who.webex.com
You can also dial 173.243.2.68 and enter your meeting number.

Dial 1678188876.who@lync.webex.com

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: k.chappell@uq.edu.au[k.chappell@uq.edu.au]; sandra cordo[scordo@qb.fcen.uba.ar]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.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]; 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]; nadia.khelef@pasteur.fr[nadia.khelef@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]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.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]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; PREZIOSI, Marie-pierre[preziosim@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; Amy C. Shurtleff[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]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.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]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; rkiatchula@gmail.com[rkiatchula@gmail.com]; tverakit@gmail.com[tverakit@gmail.com]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; langermans@bprc.nl[langermans@bprc.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; B. Rockx[b.rockx@erasmusmc.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[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]; dbolton@hivresearch.org[dbolton@hivresearch.org]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; 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[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]; Diamond, Michael[mdiamond@wustl.edu]; 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]; 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]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Amelia Karlsson[amelia.karlsson@duke.edu]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Jacqueline

Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; fkoide@southernresearch.org[fkoide@southernresearch.org]; Krammer, Florian[florian.krammer@mssm.edu]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; cjmiller@ucdavis.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[dmissiak@bsd.uchicago.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; DAVID H O'CONNOR[dhoconno@wisc.edu]; mto@umn.edu[mto@umn.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; Peter Palese[peter.palese@mssm.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Juergen Richt[jricht@vet.k-state.edu]; Chad Roy[croy@tulane.edu]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Padmini Salgame[salgampa@njms.rutgers.edu]; erica@lji.org[erica@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Michael Schotsaert[michael.schotsaert@mssm.edu]; sivkog@battelle.org[sivkog@battelle.org]; Spergel, Jonathan[SPERGEL@email.chop.edu]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Elizabeth Sulkowski[elizabethsulkowski44@gmail.com]; nax3@cdc.gov[nax3@cdc.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; sktseng@utmb.edu[sktseng@UTMB.EDU]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Wang, Tony[tony.wang@fda.hhs.gov]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; White, Alexander G[agw13@pitt.edu]; seos@cnu.ac.kr[seos@cnu.ac.kr]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 9/9/2020 7:05:21 AM (UTC-04:00)
Subject: WHO COVID-19 Animal Models Call-Thursday 10
Mail Attachment.ics
Webex_Meeting.ics

Dear all,
Please find below the agenda and webex invite for this week's group call on Thursday 10th at 3PM CET (Geneva time).

Best regards to all

César, Simon and Bill.

Agenda Thursday Sept 10th

Area vaccines

1- Sang Heui Seo (Chungman National University, South Korea)

Area Pathogenesis

2- Pei-Yong Shi (UTMB, US)

3- Keith Chappell (Univ of Queensland, Australia)

Open Questions

Pierre GSELL invites you to join this Webex meeting.

Meeting number (access code): 145 413 3155

Meeting password: 6jcFjbMPu26

Thursday, September 10, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

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

Organizer:	Pierre GSELL : gsellp@who.int
Subject:	[COVID-19] 28th WHO TC - Animal Models
Location:	https://who.webex.com/who/j.php?MTID=m83e5cc86eaee4adb88d4413684bb8bba
Start Time:	2020-09-10T15:00:00+02:00
End Time:	2020-09-10T16:30:00+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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To: galter@partners.org[galter@partners.org]; maria.baca-estrada@canada.ca[maria.baca-estrada@canada.ca]; baihe@nmpa.gov.cn[baihe@nmpa.gov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; cheryl@gisaid.org[cheryl@gisaid.org]; Valentina Bernasconi[valentina.bernasconi@cepi.net]; shinjini.bhatnagar@thsti.res.in[shinjini.bhatnagar@thsti.res.in]; pbieniasz@mail.rockefeller.edu[pbieniasz@mail.rockefeller.edu]; karin.bok[karin.bok@nih.gov]; dboyle@path.org[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]; zuz4@cdc.gov[zuz4@cdc.gov]; Miles.Carroll@phe.gov.uk[Miles.Carroll@phe.gov.uk]; Marco.Cavaleri[Marco.Cavaleri@ema.europa.eu]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; MAY.CHU@CUANSCHUTZ.EDU[MAY.CHU@CUANSCHUTZ.EDU]; Carolyn Clark[carolyn.clark@cepi.net]; kizzmekia.corbett@nih.gov[kizzmekia.corbett@nih.gov]; costaa@who.int[costaa@who.int]; htq4@cdc.gov[htq4@cdc.gov]; shane@lji.org[shane@lji.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; Lisa@amicitiam.com[Lisa@amicitiam.com]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; tdelossantos@path.org[tdelossantos@path.org]; emmie.dewit@nih.gov[emmie.dewit@nih.gov]; marciela.degrace@nih.gov[marciela.degrace@nih.gov]; rafael.delgado@salud.madrid.org[rafael.delgado@salud.madrid.org]; mit666666@pitt.edu[mit666666@pitt.edu]; katie.doores@kcl.ac.uk[katie.doores@kcl.ac.uk]; William Dowling[william.dowling@cepi.net]; christian.drosten@charite.de[christian.drosten@charite.de]; epstein@ecohealthalliance.org[epstein@ecohealthalliance.org]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; darryl.falzarano@usask.ca[darryl.falzarano@usask.ca]; jason.fernandes@canada.ca[jason.fernandes@canada.ca]; clint.florence@nih.gov[clint.florence@nih.gov]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; Simon.Funnell@phe.gov.uk[Simon.Funnell@phe.gov.uk]; Luc.Gagnon@nexelis.com[Luc.Gagnon@nexelis.com]; Mayra.Garcia@fda.hhs.gov[Mayra.Garcia@fda.hhs.gov]; bhx1@cdc.gov[bhx1@cdc.gov]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; barney.graham@nih.gov[barney.graham@nih.gov]; ahgriff@bu.edu[ahgriff@bu.edu]; d.goldblatt@ucl.ac.uk[d.goldblatt@ucl.ac.uk]; Elwyn Griffiths[elwyn.griffiths@cepi.net]; gregory.d.gromowski.civ@mail.mil[gregory.d.gromowski.civ@mail.mil]; GSELL, Pierre[gsellp@who.int]; ilj2@cdc.gov[ilj2@cdc.gov]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; rzh7@cdc.gov[rzh7@cdc.gov]; henaorestrepoa@who.int[henaorestrepoa@who.int]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; paul.hodgson@usask.ca[paul.hodgson@usask.ca]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Johan Holst[johan.holst@cepi.net]; rawcraig@yahoo.com[rawcraig@yahoo.com]; tkh4@cdc.gov[tkh4@cdc.gov]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; djernigan@cdc.gov[djernigan@cdc.gov]; johnsonreed@niaid.nih.gov[johnsonreed@niaid.nih.gov]; Cassandra.Kelly@finddx.org[Cassandra.Kelly@finddx.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; knezevici[knezevici@who.int]; m.koopmans@erasmusmc.nl[m.koopmans@erasmusmc.nl]; Gerald.Kovacs@hhs.gov[Gerald.Kovacs@hhs.gov]; florian.krammer@mssm.edu[florian.krammer@mssm.edu]; Phil Krause[philip.krause@fda.hhs.gov]; skrebs@hivresearch.org[skrebs@hivresearch.org]; Greg.Kulnis@nexelis.com[Greg.Kulnis@nexelis.com]; Arun Kumar[arun.kumar@cepi.net]; pawinee.k@redcross.or.th[pawinee.k@redcross.or.th]; teresa.lambe@ndm.ox.ac.uk[teresa.lambe@ndm.ox.ac.uk]; janet.lathey[janet.lathey@nih.gov]; bleader@path.org[bleader@path.org]; leejooyeon@korea.kr[leejooyeon@korea.kr]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; liyl@cde.org.cn[liyl@cde.org.cn]; changguili@aliyun.com[changguili@aliyun.com]; lyhchengdu@163.com[lyhchengdu@163.com]; limhy0919@korea.kr[limhy0919@korea.kr]; James.Little@hhs.gov[James.Little@hhs.gov]; liub@cde.org.cn[liub@cde.org.cn]; Tracy.MacGill@fda.hhs.gov[Tracy.MacGill@fda.hhs.gov]; Karen Makar[Karen.Makar@gatesfoundation.org]; Mary.Matheson@phe.gov.uk[Mary.Matheson@phe.gov.uk]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; jmclellan@austin.utexas.edu[jmclellan@austin.utexas.edu]; adrian.mcdermott@nih.gov[adrian.mcdermott@nih.gov]; jmcelrat@fredhutch.org[jmcelrat@fredhutch.org]; gmedigeshi@thsti.res.in[gmedigeshi@thsti.res.in]; jwm1@pitt.edu[jwm1@pitt.edu]; philip.minor2@gmail.com[philip.minor2@gmail.com]; kmodjarrad@eidresearch.org[kmodjarrad@eidresearch.org]; david.montefiori@duke.edu[david.montefiori@duke.edu]; kaitlyn.dambach@nih.gov[kaitlyn.dambach@nih.gov]; omorgan@who.int[omorgan@who.int]; Clare.Morris@nibsc.org[Clare.Morris@nibsc.org]; sarah.mudrak@duke.edu[sarah.mudrak@duke.edu]; munoz-fontela@bnitm.de[munoz-fontela@bnitm.de]; vincent.munster@nih.gov[vincent.munster@nih.gov]; Todd.Myers@fda.hhs.gov[Todd.Myers@fda.hhs.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; scott.napper@usask.ca[scott.napper@usask.ca]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; PNorris@vitalant.org[PNorris@vitalant.org]; pilailuk.o@dmsc.mail.go.th[pilailuk.o@dmsc.mail.go.th]; n.okba@erasmusmc.nl[n.okba@erasmusmc.nl]; golinger@MRIGLOBAL.ORG[golinger@MRIGLOBAL.ORG]; jokim@ivi.int[jokim@ivi.int]; Mark.Page@nibsc.org[Mark.Page@nibsc.org]; gustavo.f.palacios.civ@mail.mil[gustavo.f.palacios.civ@mail.mil]; map1@cdc.gov[map1@cdc.gov]; xdv3@cdc.gov[xdv3@cdc.gov]; Keith.Peden@fda.hhs.gov[Keith.Peden@fda.hhs.gov]; sheila.a.peel2.civ@mail.mil[sheila.a.peel2.civ@mail.mil]; malik@hku.hk[malik@hku.hk]; perkinsm@who.int[perkinsm@who.int]; supaporn.p@dmsc.mail.go.th[supaporn.p@dmsc.mail.go.th]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; mireille.plamondon@canada.ca[mireille.plamondon@canada.ca]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; arimoin@g.ucla.edu[arimoin@g.ucla.edu]; lauriex@who.int[lauriex@who.int]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; msalit@stanford.edu[msalit@stanford.edu]; erica@lji.org[erica@lji.org]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; schendel@lji.org[schendel@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; PScott@eidresearch.org[PScott@eidresearch.org]; peshi@UTMB.EDU[peshi@UTMB.EDU]; Ragini.Shivji@ema.europa.eu[Ragini.Shivji@ema.europa.eu]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; Ashley.Smith1@hhs.gov[Ashley.Smith1@hhs.gov]; mksong@ivi.int[mksong@ivi.int]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; swaminathans@who.int[swaminathans@who.int]; r.tedder@imperial.ac.uk[r.tedder@imperial.ac.uk]; nax3@cdc.gov[nax3@cdc.gov]; tracey.thue@usask.ca[tracey.thue@usask.ca]; georgia.tomaras@duke.edu[georgia.tomaras@duke.edu]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk];

john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; sylvie.van-der-werf@pasteur.fr[sylvie.van-der-werf@pasteur.fr]; eric.vangieson@darpa.mil[eric.vangieson@darpa.mil]; Vasan.Vasan@csiro.au[Vasan.Vasan@csiro.au]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; David Vaughn[David.Vaughn@gatesfoundation.org]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; wangjz@nifdc.org.cn[wangjz@nifdc.org.cn]; wangyc@nifdc.org.cn[wangyc@nifdc.org.cn]; Jerry.Weir@fda.hhs.gov[Jerry.Weir@fda.hhs.gov]; alex@lji.org[alex@lji.org]; daniela@lji.org[daniela@lji.org]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; larry.wolfraim@nih.gov[larry.wolfraim@nih.gov]; dj56wood@gmail.com[dj56wood@gmail.com]; xumiaobj@126.com[xumiaobj@126.com]; Solomon Abebe Yimer[solomon.yimer@cepi.net]; tlying@fudan.edu.cn[tlying@fudan.edu.cn]; vyusibov@indianabiosciences.org[vyusibov@indianabiosciences.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]
From: William Dowling[william.dowling@cepi.net]
Sent: Wed 9/9/2020 9:49:00 AM (UTC-04:00)
Subject: FW: cell paper about very potent highly stable human domain
20Cell ab8 online published.pdf

Dear all
Here is the paper mentioned by Dimiter on our call today.
Thanks
Bill

From: Dimitrov, Dimiter Stanchev <mit666666@pitt.edu>
Sent: Wednesday, September 9, 2020 9:29 AM
To: William Dowling <william.dowling@cepi.net>
Subject: cell paper about very potent highly stable human domain

Hi Bill,

I put it on the chat in the last second, here it is
https://www.cell.com/cell/fulltext/S0092-8674(20)31148-X

also attached the file just in case.

It is human domain fused to Fc and every stable – for 3 months at 37C no change in activity.
Was thinking even could be used as reference reagent, you mentioned there is also another candidate.

Best
Mitko
(Dimiter Dimitrov)

From: William Dowling <william.dowling@cepi.net>
Sent: Tuesday, August 4, 2020 2:23 PM
To: galter@partners.org; maria.baca-estrada@canada.ca; baihe@nmpa.gov.cn; rbaric@email.unc.edu; cheryl@gisaid.org; Valentina Bernasconi <valentina.bernasconi@cepi.net>; shinjini.bhatnagar@thsti.res.in; karin.bok@nih.gov; dboyle@path.org; brooke.bozick@nih.gov; christian.brechot <christian.brechot@pasteur.fr>; Christine.bruce@phe.gov.uk; zuz4@cdc.gov; Miles.Carroll@phe.gov.uk; Marco.Cavaleri@ema.europa.eu; MONALISA.CHATTERJI@gatesfoundation.org; MAY.CHU@CUANSCHUTZ.EDU; Carolyn Clark <carolyn.clark@cepi.net>; kizzmekia.corbett@nih.gov; costaa@who.int; htq4@cdc.gov; shane@lji.org; ian.crozier@nih.gov; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; daszak@ecohealthalliance.org; tdelossantos@path.org; emmie.dewit@nih.gov; marciela.degrace@nih.gov; rafael.delgado@salud.madrid.org; Dimitrov, Dimiter Stanchev <mit666666@pitt.edu>; William Dowling <william.dowling@cepi.net>; christian.drosten@charite.de; epstein@ecohealthalliance.org; Karl.Erlandson@hhs.gov; darryl.falzarano@usask.ca; jason.fernandes@canada.ca; clint.florence@nih.gov; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk; Luc.Gagnon@nexelis.com; Mayra.Garcia@fda.hhs.gov; bhx1@cdc.gov; Volker.gerdts@usask.ca; barney.graham@nih.gov; ahgriff@bu.edu; Elwyn Griffiths <elwyn.griffiths@cepi.net>; gregory.d.gromowski.civ@mail.mil; GSELL, Pierre <gsellp@who.int>; ilj2@cdc.gov; b.haagmans@erasmusmc.nl; rzh7@cdc.gov; henaorestrepoa@who.int; lisa.hensley@nih.gov; paul.hodgson@usask.ca; Michael.holbrook@nih.gov; Johan Holst <johan.holst@cepi.net>; rawcraig@yahoo.com; tkh4@cdc.gov; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov;

johnsonreed@niaid.nih.gov; Cassandra.Kelly@finddx.org; Jacqueline.Kirchner@gatesfoundation.org; knezevici <knezevici@who.int>; m.koopmans@erasmusmc.nl; Gerald.Kovacs@hhs.gov; florian.krammer@mssm.edu; Phil Krause <philip.krause@fda.hhs.gov>; skrebs@hivresearch.org; Greg.Kulnis@nexelis.com; Arun Kumar <arun.kumar@cepi.net>; pawinee.k@redcross.or.th; teresa.lambe@ndm.ox.ac.uk; janet.lathey <janet.lathey@nih.gov>; bleader@path.org; leejooyeon@korea.kr; MSLEVER@dstl.gov.uk; liyl@cde.org.cn; changguili@aliyun.com; lyhchengdu@163.com; limhy0919@korea.kr; James.Little@hhs.gov; liub@cde.org.cn; Tracy.MacGill@fda.hhs.gov; Karen Makar <Karen.Makar@gatesfoundation.org>; Giada.Mattiuzzo@nibsc.org; jmclellan@austin.utexas.edu; adrian.mcdermott@nih.gov; jmcelrat@fredhutch.org; gmedigeshi@thsti.res.in; Mellors, John W <jwm1@pitt.edu>; philip.minor2@gmail.com; kmodjarrad@eidresearch.org; kaitlyn.dambach@nih.gov; omorgan@who.int; Clare.Morris@nibsc.org; sarah.mudrak@duke.edu; munoz-fontela@bnitm.de; vincent.munster@nih.gov; Todd.Myers@fda.hhs.gov; aysegul.nalca.civ@mail.mil; scott.napper@usask.ca; MNELSON@dstl.gov.uk; pilailuk.o@dmsc.mail.go.th; n.okba@erasmusmc.nl; golinger@MRIGLOBAL.ORG; jokim@ivi.int; Mark.Page@nibsc.org; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; xdv3@cdc.gov; Keith.Peden@fda.hhs.gov; sheila.a.peel2.civ@mail.mil; malik@hku.hk; perkinsm@who.int; supaporn.p@dmsc.mail.go.th; margaret.l.pitt.civ@mail.mil; mireille.plamondon@canada.ca; JLPRIOR@dstl.gov.uk; arimoin@g.ucla.edu; lauriex@who.int; Nicola.Rose@nibsc.org; msalit@stanford.edu; erica@lji.org; SATHIYAMOORTHY, Vaseeharan <moorthyv@who.int>; schendel@lji.org; Schmaljohn, Connie (NIH/NIAID) [E] <Connie.schmaljohn@nih.gov>; Barbara.Schnierle@pei.de; PScott@eidresearch.org; peshi@UTMB.EDU; Ragini.Shivji@ema.europa.eu; Amy C. Shurtleff <amy.c.shurtleff@cepi.net>; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; swaminathans@who.int; nax3@cdc.gov; tracey.thue@usask.ca; georgia.tomaras@duke.edu; Julia.Tree@phe.gov.uk; john.c.trefry.civ@mail.mil; luk_vandenberghe@meei.harvard.edu; sylvie.van-der-werf@pasteur.fr; Vasan.Vasan@csiro.au; y.m.vasiliev@spbniivs.ru; David Vaughn <David.Vaughn@gatesfoundation.org>; linfa.wang@duke-nus.edu.sg; wangjz@nifdc.org.cn; wangyc@nifdc.org.cn; Jerry.Weir@fda.hhs.gov; wilsonp@uchicago.edu; larry.wolfraim@nih.gov; dj56wood@gmail.com; xumiaobj@126.com; Solomon Abebe Yimer <solomon.yimer@cepi.net>; tlying@fudan.edu.cn; vyusibov@indianabiosciences.org; zlshi@wh.iov.cn; PNorris@vitalant.org; Lisa@amicitiam.com; katie.doores@kcl.ac.uk; rolandsutter@gmail.com

Subject: [SPAM]WHO Viruses reagents and assays working group - No meeting this week

Hello all

There will be no meeting of WHO Viruses reagents and assays working group this week (Wed, Aug. 5). We will return next week on Aug 12 at 2:30 PM CET.

Thanks

Bill

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 Pennsylvania Ave, NW, Suite 1003, Washington, DC 20006 USA

www.cepi.net

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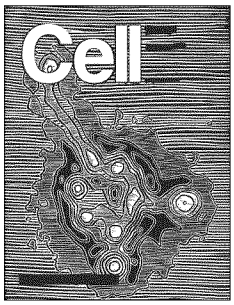

High potency of a bivalent human V_H domain in SARS-CoV-2 animal models

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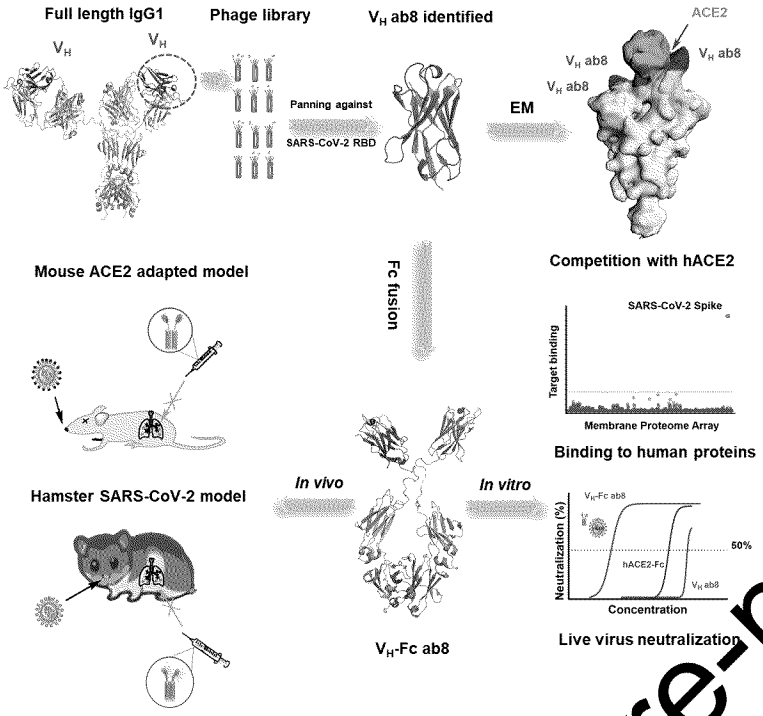

High potency of a bivalent human V_H domain in SARS-CoV-2 animal models

Wei Li[1*#], Alexandra Schäfer[2#], Swarali S. Kulkarni[3#], Xianglei Liu[1#], David R. Martinez[2#], Chuan Chen[1], Zehua Sun[1], Sarah R. Leist[2], Aleksandra Drelich[4], Liyong Zhang[1], Marcin L. Ura[5], Alison Berezuk[6], Sagar Chittori[6], Karoline Leopold[6], Dhiraj Mannar[6], Shanti S. Srivastava[6], Xing Zhu[6], Eric C. Peterson[5], Chien-Te Tseng[4], John W. Mellors[1,5], Darryl Falzarano[3], Sriram Subramaniam[6], Ralph S. Baric[2] and Dimiter S. Dimitrov[1,5,7*]

[1]Center for Antibody Therapeutics, Division of Infectious Diseases, Department of Medicine, University of Pittsburgh Medical School, 3550 Terrace Str, Pittsburgh, PA 15261, USA.

[2]Department of Epidemiology, University of North Carolina at Chapel Hill, 135 Dauer Drive, 3109 Michael Hooker Research Center Chapel Hill, NC 27599, USA.

[3]Vaccine and Infectious Disease Organization – International Vaccine Centre, and the Department of Veterinary Microbiology, University of Saskatchewan, 117 Veterinary Road, Saskatoon, SK S7N 5E3, Canada[4]Department of Microbiology & Immunology, Centers for Biodefense and Emerging Diseases, Galveston National Laboratory, 301 University Blvd, Galveston, Texas 77550, USA.

[5]Abound Bio, 1401 Forbes Ave, Pittsburgh, PA 15219, USA

[6]Department of Biochemistry and Molecular Biology, University of British Columbia, Life Sciences Centre, 2350 Health Sciences Mall, Vancouver, BC Canada V6T 1Z3, Canada

[7]Lead Contact

Running title: Potent in vivo SARS-CoV-2 neutralization of by a human V_H

[#]Equal Contribution

[*]Corresponding Authors

Wei Li, PhD and Dimiter S. Dimitrov, PhD, ScD

Center for Antibody Therapeutics

Division of Infectious Diseases, Department of Medicine, University of Pittsburgh Medical School

S845 and S843, Scaife Hall

3550 Terrace Street, Pittsburgh, PA 15261, USA

Tel: 412-383-4702, Fax: 412-383-7982

E-mails: liwei171@pitt.edu and mit666666@pitt.edu

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Abstract

Novel COVID-19 therapeutics are urgently needed. We generated a phage-displayed human antibody V_H domain library from which we identified a high-affinity V_H binder ab8. Bivalent V_H, V_H-Fc ab8 bound with high avidity to membrane-associated S glycoprotein and to mutants found in patients. It potently neutralized mouse adapted SARS-CoV-2 in wild type mice at a dose as low as 2 mg/kg and exhibited high prophylactic and therapeutic efficacy in a hamster model of SARS-CoV-2 infection, possibly enhanced by its relatively small size. Electron microscopy combined with scanning mutagenesis identified ab8 interactions with all three S protomers and showed how ab8 neutralized the virus by directly interfering with ACE2 binding. V_H-Fc ab8 did not aggregate and did not bind to 5300 human membrane-associated proteins. The potent neutralization activity of V_H-Fc ab8 combined with good developability properties and cross-reactivity to SARS-CoV-2 mutants provide a strong rationale for its evaluation as a COVID-19 therapeutic.

Introduction

The global outbreak of a severe acute respiratory distress (SARS) coronavirus 2 (SARS-CoV-2) associated disease 2019 (COVID-19) requires rapid identification of therapeutics and vaccines. While many vaccines are in clinical development, the time to market can be relatively long and immunogenicity can be limited for high-risk groups (Amanat and Krammer, 2020). Alternatively and complementarily, antibodies can be used as safe and effective prophylactics and therapeutics (Pelegrin et al., 2015). Convalescent plasma from COVID-19 patients inhibited SARS-CoV-2 infection and alleviated symptoms of newly infected patients (Casadevall and Pirofski, 2020; Rojas et al., 2020) suggesting that potent neutralizing monoclonal antibodies (mAbs) may be even more effective.

SARS-CoV-2 genome shares more than 80% homology to the SARS-CoV (Xi et al., 2020b). Similar to SARS-CoV, SARS-CoV-2 uses the spike (S) envelope glycoprotein to enter into host cells. The viral entry is initiated by the receptor binding domain (RBD) of the S protein binding to its receptor, angiotensin-converting enzyme 2 (ACE2), leading to conformational change of the S2 subunit and formation of six helical-bundle resulting in membrane fusion between viral and host cells (Jiang et al., 2020; Yan et al., 2020). The SARS-CoV RBD contains immune-dominant epitopes that can elicit neutralizing antibodies conferring protection to SARS-CoV infection (He et al., 2005). A recent bioinformatics study showed that SARS-CoV-2 RBD has several B cell epitopes (Grifoni et al., 2020). SARS-CoV-2 RBD based immunogens were able to elicit neutralizing sera in animals (Quinlan et al., 2020). Thus, SARS-CoV-2 RBD is a good target for developing potent neutralizing mAbs. We and others have identified such potent neutralizing human mAbs targeting the RBD of SARS-CoV (Zhu et al., 2007) and the middle east respiratory syndrome coronavirus (MERS-CoV) (Ying et al., 2014a). Recently, several groups have reported the isolation of potent neutralizing antibodies from convalescent human donors but all are in an Immunoglobulin G1 (IgG1) format with a molecular mass of about 150 kDa (Cao et al., 2020; Ju et al., 2020; Rogers et al., 2020; Shi et al., 2020; Wost et al., 2020).

Antibody domains and fragments such as Fab (fragment antigen binding, molecular weight of 50 kDa), scFv (singe-chain variable fragment, 30 kDa) and V_H (heavy chain variable domain, 15 kDa) are attractive antibody formats as candidate therapeutics (Nelson, 2010). For example, isotope labeled antibody fragments are more suitable for bio-imaging due to their better tissue penetration and faster clearance compared to full-size antibodies (Freise and Wu, 2015). Single antibody domains (sAbd), e.g., camelid V_HH (15 kDa) exhibit strong antigen binding and high stability (Harmsen and De Haard, 2007). We and others have demonstrated that human IgG1 heavy chain variable domain (V_H) can be engineered to achieve high stability and affinity to antigens (Nilvebrant et al., 2016), as exemplified by the V_H, m36.4, targeting the human immunodeficiency virus type 1 (HIV-1) envelope glycoprotein co-receptor binding site (Chen et al., 2008a). The V_H domains small size could improve therapeutic efficacy for infectious diseases, such as COVID-19 because of greater penetration to sites of infection. The conformation of the SARS-CoV-2 S trimer is dynamic with only one RBD in the "up" conformation presenting neutralizing epitopes while epitopes in the other two RBDs may be masked (Yan et al., 2020). Small V_Hs may achieve binding to the cryptic RBD epitopes during the dynamic "breathing" of the S trimer (Liu et al., 2020). In addition, V_Hs may have

an advantage for treatment of respiratory virus infections because V_Hs could efficiently penetrate tissue, especially when using direct delivery through inhalation (Detalle et al., 2016).

To identify potent neutralizing V_Hs against SARS-CoV-2, we panned our large (10^{11} clones) and diverse phage-displayed human V_H antibody library against recombinant RBD. Several V_H binders were isolated and screened for their affinities, ACE2 competition and stabilities. One of those V_Hs, ab8, in an Fc (human IgG1, crystallizable fragment) fusion format, showed potent neutralization activity and specificity against SARS-CoV-2 both in vitro and in two animal models. To our knowledge, this is the first report for high potency of a human antibody domain (V_H) in two animal models of infection.

Results

Selection of a high-affinity V_H, ab8, and its conversion to a V_H-Fc

We generated a large phage-displayed human V_H library where heavy chain complementarity-determining regions (HCDR1, 2, 3s) were grafted into their cognate positions of a stable scaffold based on the germline V_H3-23 (**Figure S1A).** It was panned against recombinant RBD antigens with two different tags (avi-his and human IgG1 Fc tag) which were sequentially used to avoid phage enrichment to tags and related epitopes. The quality of the RBD used for panning was confirmed by ACE2 binding (**Figure S1B and C**). After three rounds of panning, a panel of V_H binders was obtained. Among the higher affinity binders, we selected one, V_H ab8, which did not aggregate during a six-days incubation at 37°C as tested by dynamic light scattering (DLS) (**Figure S1D**). To increase the V_H ab8 avidity and extend its in vivo half-life, it was converted to a bivalent antibody domain by fusion to the human IgG1 Fc (V_H-Fc ab8) (**Figure S1E**).

High-avidity specific binding of V_H-Fc ab8 to RBD and cell surface associated native S protein

V_H ab8 bound to SARS-CoV-2 RBD and S1 with half-maximal binding concentrations (EC_{50}s) of 10 nM as measured by ELISA (**Figure 1A and D**) and an equilibrium dissociation constant (K_D) of 19 nM as measured by the biolayer interferometry (Blitz system) (**Figure 1B**). The relatively fast dissociation rate constant ($k_d = 4.1\times 10^{-3}$ S^{-1}) was significantly (23-fold) decreased by the conversion to a bivalent Fc fusion format ($k_d = 1.8\times 10^{-4}$ S^{-1}) (**Figure 1E)** resulting in high avidity. V_H-Fc ab8 bound to SARS-CoV-2 RBD and S1 subunit of S protein with EC_{50}s of 0.40 nM and 0.20 nM, respectively, and a K_D of 0.54 nM (**Figure 1E)**. It specifically bound to 293T cells expressing S, but not to control 293T cells **(Figure 1C and Figure S2A)**. The binding of V_H-Fc ab8 was higher than that of IgG1 CR3022, an anti-SARS-CoV antibody cross-reactive with SARS-CoV-2 (Tian et al., 2020). The V_H-Fc ab8's half-maximal FACS measured binding concentration (FC_{50}) of 0.07 nM was higher than that of recombinant human ACE2-Fc (FC_{50} = 0.52 nM) (**Figure 1F)**. These data demonstrate that ab8 selected by an isolated RBD can bind to cell surface associated native S trimer. The binding of V_H-Fc ab8 to the S protein was significantly improved compared to that of the V_H ab8 through avidity effect.

V_H-Fc ab8 and V_H ab8 outcompete human ACE2-Fc for binding to RBD

Competition with human ACE2 for binding to RBD is a surrogate indicator for antibody neutralization activity. V_H-Fc ab8 outcompeted human ACE2-Fc with a half-maximal inhibitory concentration (IC_{50}) of 1.0 nM **(Figure 2A)**. Note that the V_H-Fc ab8 was much more effective in outcompeting ACE2-Fc than V_H ab8, consistent with its enhanced binding. ACE2 can also block V_H ab8 for binding to RBD (**Figure S2B**) and cell surface associated S (**Figure S2C**). V_H-Fc ab8 also significantly decreased the kinetics of ACE2 binding as measured by Blitz (**Figure 2B**). V_H-Fc ab8 did not bind to the SARS-CoV RBD **(Figure 2C)** and did not compete with CR3022 for binding to RBD **(Figure 2D)**. The CR3022 epitope is located in a conserved region on the RBD core domain distal from the ACE2 binding interface, as seen in the crystal structure of the Fab CR3022-RBD complex (Yuan et al., 2020). These results indicate that the ab8 epitope may overlap with the ACE2 binding site on RBD.

V_H-Fc ab8 binds to SARS-CoV-2 RBD mutants found in patients; an alanine scanning mutation in the distal loop tip of the receptor binding motif (RBM) decreases its binding

Currently, nine prevalent RBD mutants were found in COVID-19 patients (Priyanka et al., 2020). Six of these mutations (F342L, N354D. N354D/D364Y, V367F, R408I, W436R) are located in the RBD core domain and three, K458R, G476S and V483A are in the receptor binding motif (RBM) (**Figure 3A**). V_H-Fc ab8 bound to all mutants similarly to wild type RBD as measured by ELISA (**Figure 3B**). To map the ab8 epitope, we also generated several mutations in non-conserved positions compared to SARS-CoV spanning the footprint of ACE2 on RBM (N439A, G446L, L455A, F456A, A475I, F486A, Q493A, Q498A, N501A, Y505A) (**Figure 3C**). Most of these mutants retained V_H-Fc ab8 binding except F486A and A475I **(Figure 3D and 3E)**. The F486A significantly decreased binding without affecting the overall RBD conformation (**Figure S2C and S2D**) indicating that F486 directly interacts with ab8. The F456A and A475I mutations decreased the binding by 15% and 40%, respectively, but they also affected the RBD conformation (**Figure S2C and S2D**). These results suggest that a portion of the V_H ab8 epitope could be in the RBM distal loop tip where the F486 is located at (**Figure 3F**).

Electron microscopic analysis of the SARS-CoV-2 S protein ectodomain bound to V_H ab8

To explore structural aspects of SARS-CoV-2 neutralization by V_H ab8, we performed negative stain electron microscopic analysis of the complex formed between the S protein ectodomain and V_H ab8 or soluble ACE2 (**Figure 4**). The density maps showed that both V_H ab8 and ACE2 were in a quaternary conformation in which two of the protomers in the trimer are in the "down" conformation with the third one in the "up" conformation (**Figures 4A and 4B**), similar to the quaternary conformation of the reported ACE2-bound S ectodomain (PDB ID: 6VYB) (Walls et al., 2020). One molecule of the V_H ab8 was observed bound to each RBD domain (**Figure 4A)**. In the ACE2-S complex, one molecule of ACE2 was bound to the S protein trimer, straddling one "up" and one "down" RBD region **(Figure 4B)**. There appears to be a noticeable shift of the "up" RBD domain when it is bound to V_H ab8 (**Figure 4A**). This shift is not observed when ACE2 is bound to the trimer (**Figure 4B**). Superposition of the two density maps reveals that the binding site of V_H ab8 directly overlaps with the ACE2 one, precluding simultaneous occupancy on the S protein ectodomain **(Figure 4C).** We also found that when ACE2 was added subsequent to the

addition of V_H ab8, only the V_H ab8 bound state was observed, further confirming the ACE2 competition with V_H ab8. To better understand the spatial relationship between the site of V_H ab8 binding and that of ACE2 binding, we created a molecular model for ACE2 bound S trimer by aligning the RBD region of the crystal structure of SARS-CoV-2 RBD bound ACE2 (PDB ID: 6M0J) (Lan et al., 2020) to the "up" RBD region in the cryo-EM structure of the trimer (PDB ID: 6YVB) (Wrapp et al., 2020). Superposition of this chimeric structure with the density map of V_H ab8-bound S protein trimers reveals that the bound ACE2 has extensive overlap with the space occupied by bound V_H ab8 (**Figure 4D**). The direct spatial overlap between bound V_H ab8 and ACE2 provides a structural mechanism for the observed effect of ab8 on blocking ACE2 binding. The structural findings also showed that the RBM distal loop, which has F486 at its tip, is directly covered by the footprint of the bound V_H ab8, consistent with the epitope mapping results showing that F486 is a direct contacting residue for ab8.

Potent neutralization of SARS-CoV-2 by V_H-Fc ab8 in vitro

We used four different assays to evaluate V_H-Fc ab8 mediated inhibition of SARS-CoV-2 infection *in vitro*: a β-galactosidase (β-Gal) reporter gene-based quantitative cell-cell fusion assay (Xiao et al., 2003); an HIV-1 backbone-based SARS-CoV-2 pseudovirus assay (Zhao et al., 2013); and two different replication-competent virus neutralization assays (a luciferase reporter gene assay and a microneutralization (MN)-based assay) (Scobey et al., 2013; Yount et al., 2003). V_H-Fc ab8 inhibited cell-cell fusion much more potently than V_H ab8 **(Figure 5A)**. The inhibitory activity of V_H-Fc ab8 was also higher than that of ACE2-Fc. The control anti MERS-CoV antibody IgG1 m336 did not show any inhibitory activity. V_H-Fc ab8 neutralized pseudotyped SARS-CoV-2 virus (IC_{50} = 0.03 μg/ml) more potently than ACE2-Fc (IC_{50} = 0.40 μg/ml) and V_H ab8 (IC_{50} = 0.65 μg/ml) (**Figure 5B**). The pseudovirus neutralization IC_{50} for ACE2-Fc in our assay is comparable to the one reported by Changhai Lei *et al.* (0.03-0.1 μg/ml) (Lei et al., 2020). Interestingly, the maximum neutralization by V_H ab8 was only 50% compared to the 100% by V_H-Fc ab8 and ACE2-Fc, which was also observed for another antibody S309 (Pinto et al., 2020). The complete neutralization by V_H-Fc ab8/ACE2-Fc emphasizes the role of bivalency and related avidity in neutralization (Klasse and Sattentau, 2002). Furthermore, in the reporter gene assay V_H-Fc ab8 neutralized live SARS-CoV-2 with an IC_{50} of 0.04 μg/ml (**Figure 5C**), which is much lower than that for ACE2-Fc (IC_{50} of 6.1 μg/ml) and V_H ab8 (IC_{50} = 29 μg/ml). ACE2-Fc seemed to be much less potent against the live virus compared to the pseudovirus, which is also observed by others (IC_{50} = 12.6 μg/ml) (Case et al., 2020) and may relate to the S expression levels and RBD/S conformation on the virus surface. We also confirmed the high V_H-Fc ab8 live virus neutralization potency by a microneutralization (MN) assay-100% neutralization (NT_{100}) at 0.1 μg/ml (**Figure 5D**). The NT_{100} from the MN assay (0.1 μg/ml) was close to the IC_{100} (0.2 μg/ml) from the reporter gene assay suggesting consistency in the live virus neutralizing activity of V_H-Fc ab8 obtained with two independent assays at two different laboratories. These results suggest that V_H-Fc ab8 is a potent neutralizer of SARS-CoV-2, which correlates with its strong competition with ACE2 for binding to RBD.

High prophylactic efficacy of V_H-Fc ab8 in a mouse ACE2 adapted SARS-CoV-2 infection model

To evaluate the prophylactic efficacy of V_H-Fc ab8 *in vivo*, we used a recently developed mouse ACE2 adapted SARS-CoV-2 infection model, in which wild type BALB/c mice are challenged with SARS-CoV-2 carrying two

mutations Q498T/P499Y at the ACE2 binding interface in the RBD (Dinnon et al., 2020). It was shown that in this model, the aged BALB/c mice exhibited more clinically relevant phenotypes than those seen in hACE2 transgenic mice (Dinnon et al., 2020). Groups of 5 mice each were administered 36, 8, 2 mg/kg V_H-Fc ab8 prior to high titer (10^5 pfu) SARS-CoV-2 challenge followed by measurement of virus titer in lung tissue 2 days post infection. V_H-Fc ab8 effectively inhibited SARS-CoV-2 in the mouse lung tissue in a dose dependent manner (**Figure 6A**). There was complete neutralization of infectious virus at the highest dose of 36 mg/kg, and statistically significant reduction by 1000-fold at 8 mg/kg. Remarkably, even at the lowest dose of 2 mg/kg it significantly decreased virus titer by 10-fold (two tailed, unpaired *t* test, $p = 0.0075$). To exclude possible effects of residual ab8 on viral titration, we performed another experiment in which mouse lungs were perfused with 10 ml of PBS before harvesting for titration. The perfusion did not affect to any significant degree the infectious virus in the lungs (**Figure 6B)**. The V_H-Fc ab8 completely neutralized the virus in the lungs at 36 mg/kg and significantly reduced infectious virus at 8 mg/kg. V_H-Fc ab8 also reduced viral RNA in the lungs (**Figure 6C).** These results demonstrate the neutralization potency of V_H-Fc ab8 *in vivo*. They also suggest that the double mutations Q498T/P499Y on RBD did not influence V_H-Fc ab8 binding and contribute to the validation of the mouse adapted SARS-CoV-2 model for evaluation of neutralizing antibody efficacy.

V_H-Fc ab8 exhibited both prophylactic and therapeutic efficacy in a hamster model of SARS-CoV-2 infection

Recently hamsters were demonstrated to recapitulate clinical features of SARS-CoV-2 infection (Chan et al., 2020) (Imai et al., 2020). To evaluate the V_H-Fc ab8 efficacy in hamsters, it was intraperitoneally administered either 24 hours before (prophylaxis) or 6 hours after (therapy) intranasal 10^5 $TCID_{50}$ virus challenge. In the therapeutic group, the rationale for administration of the antibody six hours post viral infection is based on the replication cycle length of 5-6 hours after initial infection for SARS-CoV in VeroE6 cells (Keyaerts et al., 2005). Six hours after challenge with a high dose of 10^5 $TCID_{50}$, approximately the same number of susceptible cells could become infected and likely produce much more infectious virus, which would need to be neutralized by the antibody to prevent subsequent cycles of infection. Nasal washes and oral swab at 1, 3, 5 days post infection (dpi) and different lung lobes at 5 dpi were collected. V_H-Fc ab8 decreased viral RNA by 1.7 log in the lung when administered prophylactically. The lung viral RNA decrease in the therapeutic groups was slightly lower (by 1.2 log) (**Figure 6D**). Interestingly, the viral RNA load in the therapeutic groups was to some extent tissue location dependent (**Figure 6F**). The variation of the viral load in different lung lobes may relate to nonuniform antibody transport and viral spread inside the lung. Remarkably, V_H-Fc ab8 alleviated hamster pneumonia and reduced the viral antigen in the lung (H&E staining, **Figure 7A** and **C** and immunohistochemistry **Figure 7B** and **D**). The control hamsters exhibited severe interstitial pneumonia characterized by extensive inflammatory cell infiltration, presence of type II pneumocytes, alveolar septal thickening and alveolar hemorrhage. Both prophylactic and therapeutic treatment of V_H-Fc ab8 reduced the lesions of alveolar epithelial cells, focal hemorrhage and inflammatory cells infiltration. V_H-Fc ab8 also reduced the shedding from mucosal membranes including in nasal washes and oral swabs (**Figure S4**). The decrease in viral RNA in nasal washes and oral swabs were not as large as the decrease observed in the lung tissue, similar to a recent finding in hamsters (Imai et al., 2020). Overall, the

prophylactic treatment was more effective than the therapeutic treatment in decreasing viral load in nasal washes and oral swabs. Notably, prophylactic administration of V_H-Fc ab8 effectively reduced the infectious virus in the oral swab at 1 dpi, while the post-exposure treatment did not (**Figure S4C** and **G**). Interestingly, viral reduction (except the viral titer in the oral swab at 1 dpi) was more effective at 3 and 5 dpi compared to that at 1 dpi, likely due to the infection peak occurring before day 3 as reported in hamsters (Sia et al., 2020). A striking finding is that V_H-Fc ab8 given therapeutically at as low dose as 3 mg/kg can still decrease viral loads in the lung, nasal washes and oral swabs (**Figure S5**).

We measured the V_H-Fc ab8 concentrations at both doses (10 and 3 mg/kg) in the sera at 1 dpi and 5 dpi in the post-exposure treatment groups (**Figure S5C**). The higher dose (10 mg/kg) resulted in higher antibody concentration and better inhibitory activity than the lower dose (3 mg/kg). The relatively high concentration of V_H-Fc ab8 five days after administration also indicates good pharmacokinetics. Furthermore, we also compared the V_H-Fc ab8 concentration in both the sera and lung with that of IgG1 ab1, which has similar affinity to SARS-CoV-2 and similar degree of competition with the receptor ACE2 as V_H-Fc ab8 (Wu et al., 2020a). We found that the concentration of V_H-Fc ab8 in hamster sera is significantly higher than that of IgG1 ab1 at 1 and 5 dpi after post-exposure administration of the same dose of 10 mg/kg (**Figure 7E**), possibly indicating more effective delivery of V_H-Fc ab8 from the peritoneal cavity to the blood than that of IgG1 ab1. We also found that the V_H-Fc ab8 concentration in all hamster lung lobes was higher than that of the IgG1 ab1 (**Figure 7F**), suggesting that V_H-Fc ab8 appears to penetrate the lung tissue more effectively than IgG1 ab1. These results indicate that the in vivo delivery of V_H-Fc ab8 may be more effective than that of full size antibodies in an IgG1 format.

V_H-Fc ab8 does not aggregate and does not bind to 5300 human membrane proteins

The V_H-Fc ab8 propensity for aggregation was measured at 37°C by dynamic light scattering (DLS), which detects particle size distributions in the nanometer range (Stetefeld et al., 2016). It displayed a single peak at 11.5 nm which is the size of a monomeric V_H-Fc protein **(Figure S6A)**. The absence of large-size peaks corresponding to large molecular weight species (aggregates) in solution, indicates that V_H-Fc ab8 is highly resistant to aggregation at high concentration (4 mg/ml) and relatively long times of incubation (6 days) at 37°C. The V_H-Fc ab8 propensity for aggregation was also evaluated by size exclusion chromatography (SEC), which showed that >96% of V_H-Fc ab8 was eluted in a peak at a position corresponding to a monomeric state with a molecular weight of 80 kDa (**Figure S6B)**.

Antibody nonspecificity and polyreactivity can be an obstacle for developing an antibody into a clinically useful therapeutic. Polyreactivity may not only cause off-target toxicities and interfere with normal cellular functions, but may also reduce antibody half□life (Chuang et al., 2015). To test for potential polyreactivity of V_H-Fc ab8, a Membrane Proteome Array (MPA) platform was used, in which 5,300 different human membrane protein clones were separately overexpressed in 293T cells in a matrix array achieving a high-throughput detection of binding by FACS. V_H-Fc ab8 did not bind to any of those proteins (**Figure S6C**), demonstrating its lack of polyreactivity and nonspecificity. Interestingly, we did not detect V_H-Fc ab8 binding to the human FcγRIA, which is probably due to the relatively low expression level of FcγRIA on HEK-293T cell surface without concomitant

expression of the common γ chain (Van Vugt et al., 1996). In addition, we found that V_H-Fc ab8 bound to the FcγRs much weaker than IgG1 (**Figure S7**), likely due to the different conformation in the lower hinge region for Fc fusion proteins compared to that of IgG1s (Ying et al., 2014b). For the Fc fusion proteins (even with the same hinge sequence as IgG1), binding to FcγRs may be different from that of IgG1, and can be affected by the fusion partners (Lagassé et al., 2019). The importance of antibody binding to FcγRs for therapeutic or prophylactic efficacy or toxicity in SARS-CoV-2 infection is unknown.

Discussion

Neutralizing mAbs are promising for prophylaxis and therapy of SARS-CoV-2 infections. Recently, many potent neutralizing antibodies from COVID19 patients were identified that neutralize pseudovirus with IC_{50}s ranging from 1 to 300 ng/ml, and replication-competent SARS-CoV-2 with IC_{50}s from 15 to 500 ng/ml (Cao et al., 2020; Ju et al., 2020; Rogers et al., 2020; Shi et al., 2020; Zost et al., 2020). By comparison, the V_H-Fcab8 reported here exhibited comparable or better neutralizing potency against SARS-CoV-2 pseudovirus and live virus (IC_{50}s of 30 ng/ml and 40 ng/ml respectively). Of note, IC_{50}s can vary widely between different assays and laboratories because there is no generally accepted standardized assay. In addition, there are many factors that contribute to potency and efficacy in vivo. Animal models are a more comprehensive and likely more reliable predictor of potential efficacy in humans than in vitro neutralization assays.

To our knowledge V_H-Fc ab8 is the first human antibody domain whose activity was validated in two animal models. In the mouse ACE2 adapted SARS-CoV-2 infection model, V_H-Fc ab8 significantly decreased infectious virus by 10-fold at 2 days post infection even at a very low dose of 2 mg/kg **(Figure 6A)**. It also exhibited both prophylactic and therapeutic efficacy in a hamster model. It not only reduced the viral load in the lung and alleviated pneumonia; but it also reduced shedding in the upper airway (nasal washes and oral swab), which could potentially reduce transmission of SARS-CoV-2. Impressively, V_H-Fc ab8 was active therapeutically even at 3 mg/kg. The finding that V_H-Fc ab8 persisted for 4 days post administration at significant levels indicates that the pharmacokinetics of V_H-Fc ab8 is comparable to that of a full size antibody; the half-lives of Fc fusion proteins were reported to vary from those of IgG1s and can range from hours to days (Unverdorben et al., 2016). The molecular weight of V_H-Fc ab8 (80 kDa) is half of that of full-size IgG1 which suggests an advantage in terms of smaller quantities needed to be produced compared to those for IgG1s to reach similar number of molecules and efficacy. In addition, it was shown that decreasing binder's size exponentially increases its diffusion through normal and tumor tissues (Jain, 1990). Thus, decreasing the size two-fold can increase diffusion through tissues by four-fold. We found that after administration at the same dose, the concentration of V_H-Fc ab8 was higher than that of IgG1 ab1 in both hamster sera and lung tissue. This result might suggest that the V_H-Fc ab8 diffusion from the peritoneal cavity to the blood and penetration of lung may be faster than that of IgG1 ab1. This may further explain its efficacy at low doses in animals. Although the low dose showed efficacy in the small animal models, it should be noted that in humans higher doses could be required to achieve comparable degree of efficacy. Another caveat is that in the

hamster post-exposure experiment, the V_H-Fc ab8 was administered at a time (six hours) when the first round of virus replication was likely completed (Keyaerts et al., 2005), but before the infection peak at 1-2 days (Sia et al., 2020). Because it inhibits infection of new cells, its administration at around the infection peak or after may not be as effective unless it also kills infected cells in vivo which is under investigation.

Recently antibody domains including human V_H and camelid V_HH were reported having varying neutralization potency (Chi et al., 2020; Sun et al., 2020; Wrapp et al., 2020; Wu et al., 2020a). Compared to those domains, V_H-Fc ab8 is unique in terms of potency, aggregation resistance and specificity. V_H-Fc ab8 exhibited good developability properties including stability at high concentrations and long incubation at 37°C, as well as absence or very low aggregation. In addition, V_H-Fc ab8 did not bind to the human cell line 293T even at high concentration (1 μM) which is about 1754-fold higher than its K_d indicating absence of non-specific binding to many membrane-associated human proteins. A similar result was obtained by the membrane protein array assay showing that V_H-Fc ab8 did not bind to any of 5,300 human membrane-associated proteins, indicating its lack of non-specificity and thus low potential for off-target toxicity when used *in vivo*. Besides, unlike camel V_HHs, the V_H ab8 sequence is fully human and therefore likely less immunogenic than that of camelid V_HHs.

Multiple structures are now available for the SARS-CoV-2 S protein trimer in complex with various neutralizing antibodies, offering insight into antigenic epitopes and inhibitory mechanisms critical for S protein neutralization. Epitopes on the SARS-CoV-2 S protein RBD have emerged as effective targets, as evidenced by the action of several RBD binding antibodies including CR3022, B38, C105, CB6, H014, and S309 (Barnes et al., 2020; Lv et al., 2020; Pinto et al., 2020; Shi et al., 2020; Wu et al., 2020b). While B38, C105, and CB6 directly compete with ACE2 for binding sites on the RBD surface, H014 occupies a position distinct from these binding sites, precluding ACE2 binding *via* steric inhibition (Lv et al., 2020). S309 targets the RBD of the S protein both in closed and open S protein conformations, exhibiting a different mechanism of neutralization (Pinto et al., 2020). A recent study of the structure of the S protein trimer in complex with the nanobody H11-D4 (PDB ID: 6Z43) revealed full occupancy of the nanobody on all three RBDs in a "one up and two down" conformation (Huo et al., 2020), similar to what we report here. Our structural analysis demonstrates that the location of the V_H ab8 bound to the trimeric S ectodomain directly overlaps the region that would be occupied by ACE2 when bound to the S protein. The ACE2 blocking is likely the major mechanism of the V_H-Fc ab8 neutralizing activity, which is significantly augmented by avidity effects due to its bivalency. The narrow neutralization concentration range in the live virus neutralization (10-200 ng/ml for 0%-100% neutralization) (**Figure 5D**) indicates a plausible cooperative neutralization mechanism, probably due to the synergistic binding of V_H molecules in V_H-Fc ab8 to RBDs. Due to its small size, V_H may facilitate targeting occluded epitopes on RBD that are otherwise inaccessible to full-length IgGs, which is important because the SARS-CoV-2 S protein is conformationally heterogenous, exposing neutralizing epitopes to varying degrees (Yan et al., 2020). The structural analysis shows that V_H ab8 is able to simultaneously target all three RBD epitopes in both "up" and "down" conformations, which may provide a structural basis for a unique cooperative neutralization mechanism for V_H-Fc ab8. V_H-Fc ab8 with a long flexible linker between V_H and Fc may allow two

V_H molecules to bind simultaneously two protomers in the same S trimer or cross-link two different protomers from different S trimers.

The ab8 epitope is distal to the CR3022 epitope, explaining its lack of competition with CR3022. The ab8 contact residue F486 (L472 in SARS-CoV) is not conserved which likely explains its lack of cross-reactivity to SARS-CoV. From the GISAID and NCBI databases, we found nine mutations in RBD with relatively high frequencies in current circulating SARS-COV-2. Six of them are in the core domain (F342L, N354D, N354D/D364Y, V367F, R408I and W436R) and three in the RBM (K458R, G476S, V483A). The core domain mutations are far away from the ab8 epitope, thus these mutations do not affect V_H-Fc ab8 binding to RBD. Those three RBM mutations also did not affect ab8 binding although they are close to the ab8 epitope, suggesting that these mutations may not affect ab8 neutralizing activity although neutralization of whole virus carrying these mutations is needed to definitely demonstrate this possibility. Interestingly, V_H-Fc ab8 effectively inhibited the mouse ACE2 adapted SARS-CoV-2 with a Q498T/P499Y mutation in RBD, indicating that this double mutation also does not affect V_H-Fc ab8 binding to RBD. These results suggest that V_H-Fc ab8 may be a broadly cross-reactive SARS-CoV-2 neutralizing antibody.

In conclusion, we identified a fully human antibody V_H domain that shows strong competition with ACE2 for binding to RBD and potent neutralization of SARS-CoV-2 in vitro and in two animal models. This potent neutralizing activity combined with its specificity and good developability properties warrants its further evaluation for prophylaxis and therapy of SARS-CoV-2 infection. Our elucidation of its unique epitope and mechanism of neutralization could also help in the discovery of more potent inhibitors and vaccines.

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AUTHOR CONTRIBUTIONS. DSD, RSB, CTT, JWM, SS, DF and WL conceived and designed the research; WL identified and characterized antibodies; XL and ZS helped to make libraries, characterized antibodies and performed the cell fusion pseudovirus assays. CC made the RBD, ACE2; LZ made and characterized reagents; MU and EP characterized proteins and helped with the proteome assay; DM and AD performed the live virus

neutralization assays; AS, SSK, DF and SL performed the animal studies; AB, SC, KL, DM, SS, XZ and SS produced and purified the S trimer, carried out the EM experiments and analyzed the structure-related results; DSD and WL wrote the first draft of the article, and all authors discussed the results and contributed to the manuscript.

DECLARATION OF INTERESTS. Wei Li, Chuan Chen, Zehua Sun, John W. Mellors and Dimiter S. Dimitrov are co-inventors of a patent, filed on March 12 by the University of Pittsburgh, related to ab8 described in this paper.

FIGURE LEGENDS

Figure 1. Binding of V_H ab8 and V_H-Fc ab8 to recombinant SARS-CoV-2 RBD and S1 proteins and cell membrane associated S. (A and **D)** V_H and V_H-Fc ab8 binding to recombinant RBD and S1 proteins measured by ELISA. The MERS-CoV antibody IgG1 m336 was used as a negative control. Experiments were performed in duplicate and the error bars denote ± SD, n =2. **(B** and **E)** Kinetics of V_H ab8 (**B**) and V_H-Fc ab8 (**E**) binding to RBD. **(C**) Binding of V_H-Fc ab8, ACE2-Fc and IgG1 CR3022 to S transiently transfected 293T cells (293T-S). The 293T cells without transfection serve as a control. Antibodies or proteins were evaluated at a concentration of 1 μM. (**D**) Concentration-dependent binding of V_H-Fc ab8 and ACE2-Fc to 293T-S cells. See also **Figure S2, panel A**.

Figure 2. Competition of V_H-Fc ab8 and V_H ab8 with ACE2, CR3022 for binding to SARS-CoV-2 RBD and lack of binding of V_H-Fc ab8 to SARS-CoV S1. (A) Competition of V_H-Fc ab8 and V_H ab8 with ACE2 for binding to SARS-CoV-2 RBD. RBD was coated and incubated with 5-fold serially diluted V_H-Fc ab8 and V_H ab8 in the presence of 2 nM ACE2-mFc (mouse Fc). **(B)** Inhibition of ACE2 binding to RBD by V_H-Fc ab8 as measured by Blitz. **(C)** Lack of binding to SARS-CoV S1 as tested by ELISA. SARS-CoV S1 was coated and incubated with V_H-Fc ab8. (**D**) Competition between V_H-Fc ab8 and CR3022 measured by Blitz. ELISA Experiments were performed in duplicate and the error bars denote ± SD. **See also Figure S2, panel B and C**.

Figure 3. Epitope mapping for V_H-Fc ab8 by using naturally occurring RBD mutants from circulating SARS-CoV-2 isolates and by alanine scanning. (**A**) Mapping of natural RBD mutants to RBD/ACE2 3D structure (PDB ID: 6M0J). RBD and ACE2 are represented as cyan and green cartoons with RBM highlighted by red color. The RBD mutants are represented by cyan (core domain mutants) and red (RBM) spheres. (**B**) Binding of V_H-Fc ab8 to those RBD mutant as measured by ELISA. (**C**) Design of Ala scanning mutants to explore the ab8 epitope. RBD/ACE2 structure is based the same PDB as panel **A**. Non-conservative residues spanning ACE2 footprint on RBD compared to SARS-CoV are selected and depicted by stick and sphere representations. (**D**) V_H-Fc ab8 binding to SARS-CoV-2 RBD alanine mutants as tested by ELISA. ELISA procedure is similar to the above described. (**E**) Normalized signals of V_H-Fc ab8 binding to those RBD mutants compared to the WT RBD at the concentration of 1.6 nM derived from the panel **D**. (**F**) Representation of portions of ab8 binding region on RBD based on the epitope mapping ELISA results. F486 in the distal RBM loop is the plausible direct contact residue for ab8. **See also Figure S2, panel D and E.**

Figure 4. Electron microscopic analysis of the SARS-CoV-2 S protein ectodomain complexed with V_H ab8. (A) Side and top views of the density map of S protein ectodomain (shown in gray) in complex with V_H ab8. The density that we associate with the bound V_H domain is colored red. The open-state structure of the SARS-CoV-2 S protein ectodomain (PDB ID: 6VYB, blue color ribbon) fits well into the map with the exception of the tip of the RBD from the "up" protomer. There appears to be a slight outward shift in the V_H ab8 complex. **(B)** Side and top views of the density map of S protein ectodomain in complex with soluble human ACE2 domain, with density for bound ACE2 shown in blue. **(C)** Superposition of the density maps from (**A**) and (**B**). (**D**) A closer view of the binding site that incorporates the known atomic model for the structure of the ACE2 complex with the RBD in the "up" conformation, delineating the regions of contact with the V_H density. A ribbon representation of the RBM distal loop and the F486 side chain are highlighted in yellow. **See also Figure S3.**

Figure 5. Inhibition of cell-cell fusion and neutralization of pseudotyped and authentic SARS-CoV-2 by V_H-Fc ab8 and V_H ab8. (**A**) Inhibition of cell fusion between 293T-S and 293T-ACE2 cells by V_H ab8, V_H-Fc ab8 and ACE2-Fc. **(B)** Neutralization of SARS-CoV-2 pseudovirus by V_H ab8, V_H-Fc ab8 and ACE2-Fc. **(C)** Neutralization of live SARS-CoV-2 tested in the nLuc reporter assay. **(D)** Neutralization of live virus by a microneutralization assay. Experiments were performed in duplicate and the error bars denote ± SD, n =2.

Figure 6. Evaluation of the prophylactic efficacy of V_H-Fc ab8 in a mouse ACE2 adapted model; and both prophylactic and therapeutic efficacy in a hamster model of SARS-CoV-2 infection. (**A**) V_H-Fc ab8 inhibited mouse ACE2 adapted SARS-CoV-2 in wild type BALB/c mice (two-tailed, unpaired *t* test, ** $p < 0.01$). (**B**) The same experiments as panel **A** except that the mice lung was perfused before viral titration (Mann-Whitney *U* test, ** $p < 0.01$). (**C**) The viral RNA level changes in the lung in the same mice of panel **B** as quantified by RT-qPCR and presented as $TCID_{50}$ equivalents (Mann-Whitney *U* test, ** $p < 0.01$). (**D-F**) Evaluation of the prophylactic and therapeutic efficacy of V_H-Fc ab8 in the hamster model. Hamsters were injected intraperitoneally with 10 mg/kg of V_H-Fc ab8 antibody either one day before (prophylaxis) or six hours after (therapy) intranasal challenge of 1×10^5 $TCID_{50}$ of SARS-CoV-2. (**D**) The decrease of viral RNA in the hamster lung after averaging all lung lobes. (**E** and **F**) The decrease of viral RNA in hamster lung lobes: prophylaxis and therapy, respectively. (Mann-Whitney *U* test, ns: $p > 0.05$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$). **See also Figure S4 and S5.**

Figure 7. Histopathology of hamster lung stained by hematoxylin and eosin stain (H&E) and immunohistochemistry (IHC); comparison of antibody concentrations in the hamster lung and sera between V_H-Fc ab8 and IgG1 ab1. (**A** and **C**) **Reduced pathological changes in lung tissue lobe with V_H-Fc ab8 treatment.** H&E staining of treated and control lung lobes in hamsters challenged with SARS-CoV-2. Arrows showed inflammatory cells and arrow head for alveolar hemorrhages. (**B** and **D**) **Prophylaxis and post-infection treatment with V_H-Fc ab8 decreased SARS-CoV-2 antigen staining in lung lobes of hamsters.** Immunohistochemistry detection of the nucleocapsid antigen of V_H-Fc ab8 prophylactically treated (**B**) and post-exposure treatment (**D**) and control hamster lungs following SARS-CoV-2 challenge. Arrow indicates nucleocapsid positive cells (brown) in lungs lobes of hamsters at day 5 post-infection. (**E** and **F**) Comparison of V_H-Fc ab8 and IgG1 ab1 concentration in the lung and sera of hamsters receiving post-exposure treatment of a dose of 10 mg/kg

(Two-way ANOVA analysis followed by Tukey test, ns, $p > 0.05$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, ****$p < 0.0001$).

SUPPLEMENTARY FIGURE LEGENDS

Figure S1. Schematic representation of V_H library construction strategy, characterization of the RBD-his-biotin as an antigen for panning and evaluation the aggregation propensity of V_H ab8. Related to Star Methods "Generation of a human V_H library, Selection of Binders and Conversion of V_H to V_H-Fc Fusion Protein". **(A)** Schematic representation of HCDRs grafting into their cognate positions on a stable scaffold. **(B)** ELISA of biotinylated $RBD_{330-532}$ binding to streptavidin-HRP. **(C)** ELISA measurement of binding of biotinylated RBD-his to ACE2. ~100 ng ACE2-Fc was coated on plate with incubation of serially diluted RBD-his-biotin. Binding was detected by using HRP conjugated streptavidin. Experiments were performed in duplicate and the error bars denote ± SD, n =2. (**D**) Evaluation of aggregation of V_H ab8 by DLS. V_H ab8 (4 mg/ml) in PBS was incubated at 37°C. On day 0, day 1 and day 6, samples were taken out for DLS measurement. All measurements were repeated by three times. (**F**) Scheme of conversion of V_H ab8 into V_H-Fc ab8 by fusing IgG1 Fc. The linker between V_H and Fc is the natural human IgG1 upper and lower hinge (DKTHTCPPCPAPELL). V_H ab8 and V_H-Fc ab8 structure is modeled by the online SWISS-MODEL server (https://swissmodel.expasy.org/).

Figure S2. Concentration dependent binding of V_H-Fc ab8 and ACE2-Fc to cell surface associated SARS-CoV-2 S; evaluation of competition of ACE2 and V_H ab8 by ELISA and FACS; test of the conformation integrity of RBD mutants by using a polyclonal antibody and monoclonal antibody CR3022. Related to Figure 1, 2 and 3. (A) Cells were incubated with serially diluted antibodies or ACE2-Fc and subsequently with PE conjugated anti-human Fc antibody for flow cytometry analysis. Percentage of PE-A+ cells were defined by the above gate strategy in FlowJ, representing the percentage of V_H-Fc ab8 and ACE2-Fc bound 293T-S cells. (**B**) ACE2 blocking V_H ab8 for binding to RBD by ELISA. RBD was coated to plate and 10 nM of V_H ab8 in the presence of gradient concentration of ACE2 was added. Binding was detected by HRP conjugated anti FLAG tag antibody. (**C**) ACE2 blocking V_H ab8 for binding to cell surface associated S. S transiently transfected 293T was incubated with 1 μM V_H ab8 in the presence of various concentration of ACE2 (his tag). Binding of V_H ab8 was detected by the PE conjugated anti FLAG tag antibody. (**D** and **E**) Binding of a mouse polyclonal anti-SARS-CoV-2 RBD antibody and IgG1 CR3022 to the RBD mutants. RBD mutants were coated to plate and two concentrations of polyclonal anti-RBD antibody and CR3022 were added. Binding was detected by HRP conjugated anti mouse (Fc) antibody and anti-human (Fc) antibody. Experiments were performed in duplicate and the error bars denote ± SD, n =2.

Figure S3. Collection and analysis of electron microscopic data. Related to Figure 4. (A) Representative raw micrograph of the SARS-CoV-2 S protein ectodomain complex with V_H ab8. Scale bar 50 nm. **(B)** Selected 2D class averages. Scale bar 10 nm. **(C)** Plot of Fourier Shell Correlation (FSC) between maps constructed from two randomly selected halves of the particle projection images.

Figure S4. Detection of infectious virus and viral RNA in hamster nasal washes and oral swabs. Related to Figure 6. Hamsters were injected intraperitoneally with 10 mg/kg of V_H-Fc ab8 antibody either one day before (prophylaxis) or six hours after (therapy) intranasal challenge of 1×10^5 $TCID_{50}$ of SARS-CoV-2. Untreated hamsters were kept as a control. Nasal washes and oral swabs were collected at day one, three and five post infection (dpi) for virus titer titration by viral $TCID_{50}$ assays and viral RNA quantification by RT-qPCR. **(A** and **E).** Nasal washes viral titer in un-treated (control), pre-infection (prophylaxis) treatment and post-infection (therapy) treatment hamsters. **(B** and **F).** Nasal washes viral RNA levels in un-treated, pre-treated and post- treated hamsters. (**C** and **G**) Oral swab viral titer in un-treated, pre-treated and post-treated hamsters. Note that the prophylactic treatment of V_H-Fc ab8 largely decreased the viral tier in the oral swabs at one dpi, while there is almost no effect for the post-infection treatment. **(D** and **H)** Oral swab viral RNA levels in un-treated, pre-treated and post-treated hamsters.

Figure S5. Post-exposure treatment efficacy of V_H-Fc ab8 at two different doses in the hamster model. Related to Figure 6. V_H-Fc ab8 at doses of 10 mg/kg or 3 mg/kg was administered i.p. 6 h after virus intranasal challenge. The hamster shedding including nasal washes and oral swabs were collected at 1, 3, 5 dpi. All hamsters were euthanized on 5 dpi. At the euthanasia, lungs (different lobes) were collected viral RNA quantification by RT-qPCR. (**A** and **D**) Nasal washes viral titer and viral RNA in un-treated (control), 3 mg/kg and 10 mg/kg post-infection treated hamsters. (**B** and **E**) Oral swab viral titer and viral RNA in un-treated (control), 3 mg/kg and 10 mg/kg post-infection treated hamsters. (**C**) Comparison of antibody concentrations in hamster sera for those two doses. Hamsters were bled at one and five dpi for measuring antibody concentrations in sera by SARS-CoV-2 S1 ELISA. Sera was diluted 1:100 and binding was detected by using the goat anti human IgG-HRP. (**F**). Viral RNA levels in different lung lobes. RNA quantity was presented as the $TCID_{50}$ equivalence.

Figure S6. Absent or very low aggregation and high specificity of binding of V_H-Fc ab8. Related to Star Methods "Dynamic Light Scattering, Size Exclusion Chromatography and Membrane Proteome Array Assay". (A) Evaluation of the aggregation of V_H-Fc ab8 by DLS. V_H-Fc ab8 (4 mg/ml) buffered in PBS was incubated at 37°C. On day 0, day 1 and day 6, samples were taken out for DLS measurement on Zetasizer Nano ZS ZEN3600 (Malvern Instruments Limited, Westborough, MA) to determine the size distribution. All measurements were repeated by three times. **(B)** Evaluation of V_H-Fc ab8 aggregation by SEC. Size exclusion was performed by loading 0.22 μm membrane-filtered proteins (150 ul, 1.5 mg/mL) onto the Superdex 200 increase 10/300 GL column. Protein was eluted by PBS buffer in a flow rate of 1.5 mL/min. The arrows indicate the peaks of the MW standards in PBS. **(C)** Lack of non-specific binding measured by a Membrane Proteome Array (MPA). Specificity testing of V_H-Fc ab8 (20 μg/ml) was performed using the MPA platform which comprises 5,300 different human membrane proteins, each overexpressed in live cells. To ensure data validity, each array plate contained positive (SARS-CoV-2 S) and negative (empty vector) controls.

Figure S7. Binding of V_H-Fc ab8 to human FcγRs measured by ELISA. Related to Star Methods "ELISA for detection of the binding of V_H-Fc ab8 and IgG1 ab1 to human FcγRs". Recombinant FcγRs ectodomains (100 ng) were coated, and biotinylated V_H-Fc ab8 or IgG1 ab1 was added. Binding was detected by Streptavidin HRP. Experiments were performed in duplicate and the error bars denote ± SD, n =2.

STAR*METHODS

Detailed methods are provided in the online version of this paper and include the following:

- KEY RESOURCES TABLE
- RESOURCE AVAILABLITY
  - Lead Contact
  - Materials Availability
  - Data and Code Availability
- EXPERIMENTAL MODEL AND SUBJECT DETAILS
  - Cells and virus
  - Recombinant proteins
  - Monoclonal antibodies
  - Mouse and hamster experiments
- METHOD DETAILS
  - Generation of a human V_H library, Selection V_H and Conversion to V_H-Fc
  - The Enzyme Linked Immunosorbent Assay (ELISA)
  - Biolayer interferometry (BLItz)
  - Epitope Mapping by Ala Scanning
  - Electron Microscopy for S Trimer Complexed with V_H ab8
  - Flow Cytometry Analysis (FACS)
  - Cell-Cell Fusion Inhibition Assay
  - Pseudovirus Neutralization Assay
  - SARS-CoV-2 Microneutralization Assay
  - SARS-CoV-2 Reporter Gene Neutralization Assay
  - Evaluation of Prophylactic Efficacy in a Mouse Adapted SARS-CoV-2 Model
  - Evaluation of both Prophylactic and Therapeutic Efficacies in a Hamster Model
  - Dynamic Light Scattering (DLS)
  - Size Exclusion chromatography (SEC)
  - Membrane Proteome Array Specificity Testing Assay

- QUANTIFICATION AND STATISTICAL ANALYSIS

KEY RESOURCES TABLE

RESOURCE AVAILABLITY

Lead Contact

Further information and requests for resources and reagents should be directed to and will be fulfilled by the Lead Contact, Dimiter Dimitrov (mit666666@pitt.edu).

Materials Availability

All requests for resources and reagents should be directed to and will be fulfilled by the Lead Contact author. This includes antibodies, viruses, plasmids and proteins. All reagents will be made available on request after completion of a Material Transfer Agreement.

Data and Code Availability

Antibody nucleotide sequence has been deposited to GenBank with an accession number of MT943599. The antibody is only allowed for non-commercial use. All data supporting the findings of this study are available within the paper and are available from the corresponding author upon request.

EXPERIMENTAL MODEL AND SUBJECT DETAILS

Cells and virus

Vero E6 (CRL-1586, American Type Culture Collection (ATCC) and 293T (ATCC) were cultured at 37°C in Dulbecco's Modified Eagle medium (DMEM) supplemented with 10% fetal bovine serum (FBS), 10 mM HEPES pH 7.3, 1 mM sodium pyruvate, and 100 U/mL of penicillin–streptomycin. 293T stably expressing SARS-CoV-2 and human ACE2 was cultured in DMEM medium containing 200 μg/ml Zeocin. HEK293F and expi293F were cultured in FreeStyle 293 serum free medium (ThermoFisher, Cat#12338018) and Expi293™ Expression Medium

(ThermoFisher, Cat# A1435103), respectively. The SARS-CoV-2 spike pseudotyped HIV-1 backboned virus is packaged in 293T cells after transfecting pNL4-3.luc.RE and pcDNA3.1 S plasmids. The SARS-CoV-2 (US_WA-1/2020) and SARS-CoV2/Canada/ON/VIDO-01/2020 obtained from Centers for Disease Control and Prevention were propagated in Vero E6 cells. The recombinant SARS-CoV-2-SeattlenLuc virus and the mouse ACE2 adapted SAR-CoV-2 virus (carrying a Q498T/P499Y mutation in RBD) recovered by the reverse genetics was produced in VeroE6 cells. All work with infectious SARS-CoV-2 was performed in Institutional Biosafety Committee approved BSL3 facilities using appropriate positive pressure air respirators and protective equipment.

Recombinant proteins

The recombinant proteins SARS-CoV-2 RBD-his, RBD mutants, RBD-Fc, ACE2-hFc were subcloned into pcDNA3.1 expression plasmids, and expressed in expi293F cells. Proteins with His tag were purified by Ni-NTA affinity chromatography and protein with Fc tag purified by protein A chromatography. Protein purity was estimated as >95% by SDS-PAGE and protein concentration was measured spectrophotometrically (NanoVue, GE Healthcare).

Monoclonal antibodies

V_H ab8 antibody was identified by panning of the phage library. V_H-Fc ab8 were constructed by fusing V_H to human IgG1 Fc with the native IgG1 hinge. IgG1 ab1 was obtained by our lab through panning of a Fab phage library. MERS-CoV-specific IgG1 m336 and SARS-CoV antibody IgG1 CR3022 sequences from other groups were subcloned into the pDR12 plasmid for expression. V_H ab8 (in a phagemid pComb3x with a Flag tag) was expressed in HB2151 *E. coli* and purified by Ni-NTA affinity chromatography. All other IgG1 were expressed in expi293 cells and purified with protein A chromatography.

Mouse and hamster experiments

For the mouse model, BALB/c mice purchased from Envigo (BALB/cAnNHsd, stock# 047, immunocompetent, 11-12 months of age, female) were used for all experiments. They are drug/test naïve and negative for pathogens. Animals were not involved in any previous studies. Animals were housed in groups of 5 animals per cage and fed standard chow diet. The study was carried out in accordance with the recommendations for care and use of animals by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health and the Institutional Animal Care. All mouse studies were performed at the University of North Carolina (Animal Welfare Assurance #A3410-01) using protocols (19-168) approved by the UNC Institutional Animal Care and Use Committee (IACUC) and all virus studies were performed in ABSL3 facilities at UNC. Virus inoculations were performed under anesthesia and all efforts were made to minimize animal suffering. For evaluating prophylactic efficacy of V_H-Fc ab8, mice were intraperitoneally treated (12 hours before infection) with different doses of V_H-Fc ab8 followed by intranasal challenge with 10^5 PFU of mouse-adapted SARS-CoV-2. Two days post infection, mice were sacrificed and perfused with 10 ml PBS. Then lung was harvested for viral titer as determined by the plaque assay. For the hamster model, studies were approved by the University Animal Care Committee (UACC) of the University of

Saskatchewan according to the guidelines of the Canadian Council on Animal Care (CCAC). Hamsters were purchased from Charles River (male, immunocompetent, healthy, drug/test naïve, free of pathogens). Hamsters were not involved in previous procedures. Hamsters are housed in microisolater cages, typically 3-7/cage. The cages have BioFresh bedding with Crinkle bedding added. Hamsters have access to food and water ab libitum. Food is Lab Diet 5P00 ProLab RMH300. Cages are changed weekly or as needed and spot cleaned. For experiment, hamsters were intraperitoneally treated with V_H-Fc ab8 either 24 hrs before (prophylaxis) or 6 hrs (therapy) after intranasal challenge of 1×10^5 $TCID_{50}$ of SARS-CoV-2. Nasal washes and oral swabs were collected at day 1, 3 and 5 post infection (dpi). Hamsters were bled at 1 and 5 dpi. All hamsters were euthanized on 5 dpi. At euthanasia, lungs were collected for RNA isolation. For viral titer determination, VeroE6 cells $TCID_{50}$ assay was used. For testing viral RNA, viral RNA RT-qPCR was used. For testing antibody concentration at sera and lung, SARS-CoV-2 S1 ELISA was used. For histopathology, 10% formalin fixed and paraffin embedded tissues were processed with either hematoxylin and eosin stain (H&E) or immunohistochemistry (IHC). Lung lobes were scored based on pathology using microscopy.

METHOD DETAILS

Generation, Expression and Characterization of SARS-CoV-2 RBD, S1-Fc, ACE2-Fc, IgG1 m336, and Fab CR3022. The SARS-CoV-2 S and the anti-SARS-CoV antibody IgG1 CR3022 and genes were synthesized by IDT (Coralville, Iowa). MERS-CoV-specific IgG1 m336 antibody was expressed in human mammalian cell as described previously (Ying et al., 2014a). Briefly, IgG1 m336 light chain and heavy chain Fd were subcloned into the pDR12 vector containing dual promoters and a IgG1 Fc cassette. The recombinant plasmid was sequenced and transfected into expi293 cells for expression. The human angiotensin converting enzyme 2 (ACE2) gene was ordered from OriGene (Rockville, MD). The RBD domain (residues 330-532) and S1 domain (residues 14-675) and ACE2 (residues 18-740) genes were cloned in frame to human IgG1 Fc in the mammalian cell expression plasmid pcDNA3.1. The RBD protein with an AviTag followed by a 6×His tag at C-terminal was subcloned similarly . These proteins were expressed with Expi293 expression system (Thermo Fisher Scientific) and purified with protein A resin (GenScript) and by nickel- nitrilotriacetic acid (Ni-NTA) resin (Thermo Fisher Scientific). The Fab CR3022 antibody gene with a His tag was cloned into pCAT2 plasmid (developed in house) for expression in HB2151 bacteria and purified with Ni-NTA resin. Protein purity was estimated as >95% by sodium dodecyl sulfate–polyacrylamide gel electrophoresis (SDS-PAGE) and protein concentration was measured spectrophotometrically (NanoVue, GE Healthcare).

Generation of a human V_H library, Selection of Binders and Conversion of V_H to V_H-Fc Fusion Protein. Unlike camel V_HHs, which naturally evolved to be autonomously stable, human V_H is usually unstable and easy to aggregate in the absence of V_L (Li et al., 2016; Nguyen et al., 2000). However, human V_H can be selected or engineered with high stability and solubility. To facilitate identification of stable V_H binders, we chose engineered germline V_H3-23 as our library scaffold (Chen et al., 2008b). Our human V_H phage display library was made by grafting heavy chain CDR1, 2, 3 genes derived from 12 healthy donors' peripheral blood monocytes (PBMCs) and

splenocytes (Takara, Cat. No. 636525) into their cognate positions of a stable scaffold (based on the germline V_H3-23) in a manner similar to the method we previously described but without mutagenesis of CDR1 (Chen et al., 2008a). Briefly, CDRs were PCR-amplified by using primers with degenerated adaptors covering CDRs edge regions from diverse V_H families in one end, and with sequences annealing to the V_H3-23 framework (FR) regions in the other end. The PCR products were then assembled by overlapping extension PCR by using primers with homologous ending. The whole V_H was assembled by overlapping FR1-CDR1-FR2-CDR2 and FR3-CDR3-FR4 fragments. After assembly, the V_H fragment was Sfi I digested followed by ligated into Sfi I linearized pComb3x phagemid. The recombinant phagemid was then purified, desalted and concentrated for electroporation of bacteria TG1, from which the V_H phage particles were rescued and produced. The library size was determined by tittering transformants. The library quality (diversity) was checked by randomly Sanger sequencing hundreds of V_H clones and also evaluated by panning of diverse antigens. This library contains very large number of clones (10^{11}). For panning, the V_H library was alternatively panned against biotinylated RBD-his and RBD-Fc proteins. RBD biotinylation occurred through biotin ligase (BirA) mediated enzymatic conjugation of a single biotin on AviTag (GLNDIFEAQKIEWHE) (Fairhead and Howarth, 2015). The panning was for 3 rounds with input antigens of 10 μg RBD-his, 2 μg RBD-Fc and 0.5 μg RBD-his for the 1st, 2nd and 3rd round respectively. The panning process begun with incubation of antigens with 10^{12} V_H phage particles followed by washing with phosphate-buffered saline (PBS) containing 0.1% Tween-20. Bound phage pulled down by streptavidin-M280-Dynabeads were rescued by log-phase TG1 cells with the M13KO7 helper phage. After the 3rd round panning, positive clones were selected by soluble expression monoclonal (SEM) ELISA followed by sequencing (Chen et al., 2008b). V_H binders were further screened for their binding affinity, stability and ACE2 competition. For conversion to Fc-fusion, the $_H$ gene was subcloned into pSecTag B vector containing human IgG1 Fc fragment. V_H-Fc ab8 was expressed as described above.

Enzyme-Linked Immunosorbent Assays (ELISAs). For detection of RBD biotinylation efficacy, horseradish peroxidase (HRP) conjugated streptavidin was used. For conformation of function of RBD-his after biotinylation, 100 ng ACE2-Fc was coated into the plates followed by addition of serially diluted biotinylated RBD-his. HRP conjugated streptavidin was used for detection. For other ELISAs, the SARS-CoV-2 RBD (residues 330-532) protein was coated on 96-well plates (Costar) at 100 ng/well in PBS overnight at 4°C. For screening SEM ELISA, clones randomly picked from the infected TG1 cells were incubated with immobilized antigen. Bound phages were detected with HRP-conjugated mouse anti-FLAG tag Ab (Sigma-Aldrich). For the V_H-Fc binding assay, HRP-conjugated goat anti-human IgG Fc (Sigma-Aldrich) was used for detection. For the competition ELISA with hACE2, 2 nM of human ACE2-mouse Fc was incubated with serially diluted V_H, or V_H-Fc, and the mixtures were added to RBD coated wells. After washing, bound ACE2-mouse Fc was detected by HRP-conjugated anti mouse IgG (Fc specific) (Sigma-Aldrich). For evaluation of ACE2 blocking of V_H ab8 binding to RBD, 10 nM V_H ab8 was incubated with coated RBD in the presence of various concentration of ACE2-His (Sino Biological), and the bound V_H ab8 was detected by HRP conjugated anti FLAG antibody. For evaluation of conformational changes of the epitope mapping RBD mutants, we used a mouse polyclonal anti SARS-CoV-2 RBD antibody (Sino biological, Cat. No. 40592-MP01) and the human IgG1 CR3022 antibody. For measuring the binding of V_H-Fc ab8 to RBD mutants, 100 ng RBD mutant was coated on 96-wells plates and incubated with V_H-Fc ab8 with binding detected by using

HRP conjugated anti human Fc antibody. To evaluate the binding of V_H-Fc ab8 and IgG1 ab1 to human FcγRs, recombinant human FcγRIA, IIA, IIIA were coated on 96-wells plates followed by addition of biotinylated V_H-Fc ab8 and IgG1 ab1. Binding was detected by the streptavidin-HRP. All colors were developed by 3,3′,5,5′-tetramethylbenzidine (TMB, Sigma) and stopped by 1 M H_2SO_4 followed by recording absorbance at 450 nm. Experiments were performed in duplicate and the error bars denote ± 1 SD.

BLItz. Antibody affinities and avidities were analyzed by the biolayer interferometry BLItz (ForteBio, Menlo Park, CA). For measuring V_H ab8 affinity, the RBD-Fc was mounted on the protein A sensor (ForteBio: 18-5010). 125 nM, 250 nM and 500 nM V_H ab8 were used for association. For measuring avidity of V_H-Fc ab8, biotinylated RBD-Fc was immobilized on streptavidin biosensors (ForteBio: 18–5019) for 2 min and equilibrated with Dulbecco's phosphate-buffered saline (DPBS) (pH = 7.4) to establish baselines. 50 nM, 100 nM and 200 nM V_H-Fc ab8 were chosen for association. The association was monitored for 2 min and then the antibody was allowed to dissociate in DPBS for 4 min. The k_a and k_d were derived from sensorgrams fitting and used for K_d calculation. For the competitive Blitz, 500 nM V_H-Fc ab8 was loaded onto the RBD-Fc coated sensor for 300 s to reach saturation followed by dipping the sensor into a 100 nM ACE2-Fc or Fab CR3022 solution in the presence of 500 nM V_H-Fc ab8. The association was monitored for 300 s. The signals from 100 nM hACE2 or CR3022 binding to the RBD-Fc coated sensor in the absence of V_H-Fc ab8 was independently recorded in parallel. Competition was determined by the percentage of signal in the presence of V_H-Fc ab8 to signal in the absence of V_H-Fc ab8 (< 0.7 is considered to be competitive) (Wu et al., 2020a).

SARS-CoV-2 RBD Mutants and Epitope Mapping by Ala Scanning. RBD mutants, N354D, N354D/D364Y, V367F, R408I, W436R were purchased from Acro Biosystems. F342L and K458R were bought from Sino Biological. RBD mutants G476S and V483A, plus the alanine (Ala) scanning mutants N439A, G446L, L455A, F456A, A475I, F486A, Q493A, Q498A, N501A, Y505A were constructed by site-directed mutagenesis using QuikChange II XL Site-Directed Mutagenesis Kit (Agilent, cat. no. 200521). Mutants were expressed and purified according to the abovementioned RBD purification procedures. ELISA was used to evaluate the binding of these mutants compared to the wild type RBD.

Electron Microscopy for SARS-CoV-2 S Trimer Complexed with V_H ab8.

A. Expression and Purification. The codon optimized SARS-CoV-2 2P S protein ectodomain construct (GenBank: YP_009724390.1) was C-terminally tagged with 8xHis and a twin Strep tag and cloned into the mammalian expression vector pcDNA 3.1 (Synbio). HEK293F cells were grown in suspension culture using FreeStyle media (ThermoFisher) at 37 °C in a humidified CO_2 incubator (8% CO_2). Cells were transiently transfected at a density of 1 x 10^6 cells/ml using branched polyethylenimine (PEI) (Sigma) (Portolano et al., 2014). Media was exchanged after 24 h and supplemented with 2.2 mM valproic acid. Supernatant was harvested by centrifugation after 4 days, filtered and loaded onto a 5 ml HisTrap HP column (Cytiva). The column was washed with buffer (20 mM Tris pH 8.0, 500 mM NaCl, 20 mM imidazole) and the protein was eluted with buffer (20 mM Tris pH 8.0, 500 mM NaCl, 500 mM imidazole). Purified protein was concentrated (Amicon Ultra 100 kDa cut off, Millipore Sigma) and loaded onto a

Superose 6 column (Cytiva) equilibrated with GF buffer (20 mM Tris pH 8.0 and 150 mM NaCl). Peak fractions were pooled and concentrated to 1.3 mg/ml (Amicon Ultra 100 kDa cut off, Millipore Sigma).

B. Electron Microscopy Specimen Preparation and Data Collection. Purified S protein ectodomain (0.04 mg/ml) was mixed with V_H ab8 (0.02 mg/ml) or soluble ACE2 (0.02 mg/mL) and incubated on ice for 10 mins. For the competition experiment, the S protein (0.04 mg/ml) was first incubated on ice with V_H ab8 (0.02 mg/ml) for 10 mins then followed by addition of ACE2 (0.02 mg/mL) for another 10 mins. The mixtures (4.8 µl) were applied to 300-mesh copper grids coated with continuous ultrathin carbon. Grids were plasma cleaned using an H_2/O_2 gas mixture for 15 s in a Solarus plasma cleaner (Gatan Inc.) prior to adding the sample. Samples were allowed to adsorb for 30 s before blotting away excess liquid, followed by a brief wash with MilliQ H_2O. Grids were stained by three successive applications of 2% (w/v) uranyl formate (20 s, 20 s, 60 s). Grids containing S protein ectodomain with V_H ab8, and S protein ectodomain mixed with both V_H ab8 and soluble ACE2 were imaged using a 200 kV Glacios transmission electron microscope (ThermoFisher Scientific) equipped with a Falcon3 camera operated in linear mode. Using EPU automated acquisition software (ThermoFisher Scientific), 15-frame movies were collected at 92,000x magnification (corresponding to a physical pixel size of 1.6 Å) over a defocus range of -0.5 to -3.0 µm with an accumulated total dose of 40 $e^-/Å^2$/movie. Grids containing purified S protein ectodomain (0.04 mg/mL) with soluble ACE2 (0.02 mg/mL) were imaged using a 200kV Glacios transmission electron microscope equipped with a Ceta 16M CMOS camera (ThermoFisher Scientific). Micrographs were collected at 92,000x magnification (physical pixel 1.6 Å) over a defocus range of -0.5 to -3.0 µm with a total dose of 50 $e^-/Å^2$ using EPU automated acquisition software.

C. Image Processing. Motion correction and CTF estimation were performed in RELION (3.1) (Scheres, 2012). Particles were picked by crYOLO (1.7.4) (Wagner et al., 2019) with pre-trained model for negative stain data. After extraction, particles were imported to cryoSPARC live (v2.15.1) (Punjani et al., 2017) and subjected to 2D classification and 3D heterogeneous classification. Final density maps were obtained by 3D homogeneous refinement. Figures were prepared using UCSF Chimera (Pettersen et al., 2004).

Flow Cytometry Analysis (FACS). Full-length S protein of SARS-CoV-2 with native signal peptide replaced by the CD5 signal peptide were codon-optimized and synthesized by IDT. The S gene was subcloned into our in-house mammalian cell expression plasmid, which were used to transiently transfect 293T cells cultured in Dulbecco's Modified Eagle's Medium (DMEM) with 10% FBS, 1% penicillin-streptomycin (P/S). The comparisons of ACE2-Fc, IgG1 CR3022 and V_H-Fc ab8 binding to both blank 293T and 293T overexpressing S (293T-S) were performed. For the determination of binding avidity of V_H-Fc ab8 and ACE2-Fc to the cell surface S, serially diluted antibodies or ACE2-Fc with highest concentration of 1 µM were incubated with cells, and after washing, bound antibodies were detected by phycoerythrin (PE) conjugated anti-human Fc antibody (Sigma-Aldrich). PE-A+ cells were detected by flow cytometry using BD LSR II (San Jose, CA). The gating of PE-A+ population was performed by the FlowJo software, which was plotted against the concentrations of proteins to calculate FC_{50} by non-linear fitting in Graphpad Prism 7 (San Diego, CA). To evaluate ACE2 blocking of V_H ab8 binding to cell surface associated S,

gradient concentrations of ACE2-his in the presence of 1 μM V_H ab8 (Flag tag) were incubated with 293-S cells. After washing, V_H ab8 binding was detected by PE conjugated anti FLAG tag antibody.

Cell-Cell Fusion Inhibition Assay. To test antibody mediated inhibition of cell fusion, the β-galactosidase (β-gal) reporter gene based quantitative cell fusion assay was used (Xiao et al., 2003). In this assay, 293T-S cell expression of T7 RNA polymerase was achieved by infection with vaccinia virus VTF7.3, while 293T-ACE2 cell expression of T7 promoter controlled β-Gal was obtained by infection with vaccinia virus VCB21R. β-Gal will be expressed only after fusion of the two types of cells, which can be monitored by chromogenic reactions using β-Gal substrate. To assay cell-cell fusion, 293T cells stably expressing SARS-CoV-2 S (293T-S) cells were infected with T7 polymerase-expressing vaccinia virus (vTF7-3), and 293T cells stably expressing ACE2 (293T-ACE2) were infected with vaccinia virus (vCB21R Lac-Z) encoding T7 promotor controlled β-gal. Two hours after infection, cells were incubated with fresh medium and transferred to 37 °C for overnight incubation. The next day, 293T-S cells were pre-mixed with serially diluted antibodies or ACE2-Fc at 37 °C for 1 h followed by incubation with 293T-ACE2 cells at a 1:1 ratio for 3 h at 37°C. Then cells were then lysed, and the β-gal activity was measured using β-galactosidase assay kit (substrate CPRG, G-Biosciences, St. Louis, MO) following the manufacturer's protocol. Fusion inhibition percentage (sample reading, F) was normalized by maximal fusion (reading, F_{max}) of 293T-S and 293T-ACE2 cells in the absence of antibodies using this formula: Fusion inhibition % = $[(F_{max}-F)/(F_{max} - F_{blank})] \times 100\%$, in which F_{blank} refers to the OD reading of 293T-S and 293T incubation wells. Fusion inhibition percentage was plotted against antibody concentrations. Experiments were performed in duplicate and the error bars denote ± 1 SD.

Pseudovirus Neutralization Assay. Pseudovirus neutralization assay was performed based on previous protocols (Zhao et al., 2013). Briefly, HIV-1 backbone based pseudovirus was produced in 293T cells by co-transfection with plasmid encoding SARS-CoV-2 S protein and plasmid encoding luciferase expressing HIV-1 genome (pNL4-3.luc.RE) using PEI. Pseudovirus-containing supernatants were collected 48 h later and concentrated using Lenti-X™ concentrator kit (Takara, CA). Pseudovirus neutralization assay was then performed by incubation of SARS-CoV-2 pseudovirus with serially diluted antibodies or ACE2-Fc for 1 h at 37 °C, followed by addition of the mixture into pre-seeded 293T-ACE2 cells. The mixture was then centrifuged at 1000 × g for 1 hour at room temperature. The medium was replaced 4 hrs later. After 24 h, luciferase expression was determined by Bright-Glo kits (Promega, Madison, WI) using BioTek synergy multi-mode reader (Winooski, VT). Cells only and virus only wells were included and used for normalization. The 50% pseudovirus neutralizing antibody titer (IC_{50}) was calculated using Graphpad Prism 7. Experiments were performed in duplicate and the error bars denote ± 1 SD.

SARS-CoV and SARS-CoV-2 Microneutralization Assay. The standard live virus-based microneutralization (MN) assay was used as previously described (Agrawal et al., 2016a; Agrawal et al., 2016b; Du et al., 2013; Du et al., 2014). Briefly, serially three-fold and duplicate dilutions of individual monoclonal antibodies (mAbs) were incubated with 120 pfu of SARS-CoV or SARS-CoV-2 at room temperature for 2 h before transferring into designated wells of confluent Vero E6 cells grown in 96-well microtiter plates. Vero E6 cells cultured with medium with or without virus were included as positive and negative controls, respectively. MERS-CoV RBD-specific

neutralizing m336 mAb (Ying et al., 2014a) were used as additional controls. After incubation at 37 °C for 4 days, individual wells were observed under the microcopy for the status of virus-induced formation of cytopathic effect. The efficacy of individual mAbs was expressed as the lowest concentration capable of completely preventing virus-induced cytopathic effect in 100% of the wells.

SARS-CoV and SARS-CoV-2 Reporter Gene Neutralization Assay. Full-length viruses expressing luciferase were designed and recovered via reverse genetics as described previously (Scobey et al., 2013; Yount et al., 2003). Briefly, the SARS-CoV-2 RNA from infected cell culture was reverse-transcribled and constructed into the seven contiguous genomic cDNA subclones with interconnecting junctions, which were then BsaI/BsmBI digested and ligated into a full-length SARS-CoV-2 genome cDNA through the cohesive ends. A silent mutation of T15102A was introduced into a conserved region in nsp12 to differentiate our recombinant viruses from the circulating SARS-CoV-2 strains through Sanger sequencing. The reporter viruse was synthesized by replacing a 276-bp region in ORF7 with a GFP-fused nanoluciferase (nLuc) gene. After assembly into full-length cDNA, full-length RNA was in vitro transcribed and was electroporated into Vero E6 cells. Virus stocks were propagated on Vero E6 cells in minimal essential medium containing 10% fetal bovine serum (HyClone) and supplemented with penicillin/kanamycin (Gibico). Viruses were tittered in Vero E6 USAMRID cells to obtain a relative light units (RLU) signal of at least 20× the cell only control background. Ab or ACE2-Fc were serially diluted 4-fold up to eight dilution spots with at a starting dilution 100 μg/ml, and were incubated with SARS-CoV-UrbaninLuc and SARS-CoV-2-SeattlenLuc viruses at 37°C with 5% CO_2 for 1 hour. Then virus-antibody dilution complexes were added to the pre-seeding E6 USAMRID cells (2×10000) in duplicate. Virus-only controls and cell-only controls were included in each neutralization assay plate. Following infection, plates were incubated at 37 °C with 5% CO_2 for 48 hours. Then cells were lysed and luciferase activity was measured via Nano-Glo Luciferase Assay System (Promega) according to the manufacturer specifications. SARS-CoV and SARS-CoV-2 neutralization IC_{50} were defined as the sample concentration at which a 50% reduction in RLU was observed relative to the average of the virus control wells. Experiments were performed in duplicate and IC_{50} was obtained by the non-linear fitting of neutralization curves in Graphpad Prism 7.

Evaluation of the V_H-Fc ab8 Protective Efficacy in a Mouse Adapted SARS-CoV-2 Model. A recombinant mouse ACE2 adapt SARS-CoV-2 variant was constructed by introduction of two amino acid changes (Q498T/P499Y) at the ACE2 binding pocket in RBD. Virus stocks were grown on Vero E6 cells and viral titer was determined by plaque assay (Dinnon et al., 2020). Groups of 5 each of 10 to 12-month old female BALB/c mice (Envigo, #047) were treated prophylactically (12 hours before infection) by intraperitoneal injection with 36, 8, or 2 mg/kg of V_H-Fc ab8, respectively. Mice were challenged intranasally with 10^5 PFU of mouse-adapted SARS-CoV-2. Two days post infection, mice were sacrificed and lung viral titer was determined by the plaque assay. To exclude the residual lung antibody impact on viral titration, mice were euthanized and perfused with 10 ml of PBS via cardiac puncture before lung harvest for viral titration. For virus titration, the caudal lobe of the right lung was homogenized in PBS. The resulting homogenate was serial-diluted and inoculated onto confluent monolayers of Vero E6 cells, followed by agarose overlay. Plaques were visualized via staining with Neutral Red on day 2 post

infection. To measure the viral RNA in the lung, tissue homogenate lysed in Trizol LS (Thermofischer) was then processed with Thermofischer Trizol RNA isolation protocol followed by RT-qPCR using the QuantiFast Probe RT-PCR kit (Qiagen) to amplify a portion of upE gene. The 50% tissue culture infectious doses ($TCID_{50}$) equivalence were estimated by running serial dilutions of known $TCID_{50}$ standards.

Evaluation of the V_H-Fc ab8 Prophylactic and Therapeutic Efficacy in a Hamster Model of SARS-CoV-2 Infection. SARS-CoV2/Canada/ON/VIDO-01/2020 was propagated on Vero'76 cells using DMEM with 2% FBS and 1μg/ml L-(tosylamido-2-phenyl) ethyl chloromethyl ketone (TCPK) trypsin. Infectious work with SARS-CoV-2 was approved by the Biosafety Protocol Approval Committee (BPAC) at the University of Saskatchewan and performed in the high containment laboratories at VIDO-InterVac. Male hamsters (9 week-old) were obtained from Charles River (Montreal, QC). For evaluations of prophylactic efficacy, all hamsters (n=7) were injected intraperitoneally with 10 mg/kg of V_H-Fc ab8 24 hours prior to intranasal challenge of 50 μl/nare containing a total of 1×10^5 $TCID_{50}$ of SARS-CoV-2. For the therapeutic group, hamsters were infected as above and treated intraperitoneally with 10 mg/kg (n=3) or 3 mg/kg (n=4) of V_H-Fc ab8 24 hours post-infection. Untreated hamsters were kept as a control. Nasal washes and oral swabs were collected at day 1, 3 and 5 post infection (dpi). Hamsters were bled at 1 and 5 dpi. All hamsters were euthanized on 5 dpi. At euthanasia, lung lobes were collected for virus titration and RNA isolation. For viral titer determination, nasal washes were diluted in a 10-fold dilution series and absorbed on Vero'76 cells in triplicates for 1 hour at 37°C. Inoculum was removed and replaced with fresh DMEM containing 2% FBS, penn/strep and 1μg/ml TPCK. Cytopathic effect was scored on day 3 and day 5 post infection. The limit of detection is 13.6 $TCID_{50}$. For testing viral RNA, viral RNA isolated from nasal and oral swabs using the QiaAmp Viral RNA mini kit (Qiagen) and the QuantiFast Probe RT-PCR kit (Qiagen) to amplify a portion of upE gene. For RNA levels in tissues, 30 mg of tissue homogenate in buffer RLT were processed with the RNeasy kit (Qiagen) followed by RT-qPCR as above. $TCID_{50}$ equivalence were estimated by running serial dilutions of known $TCID_{50}$ standards. For testing Ab8 concentrations post injection at hamster sera and lung tissue, SARS-CoV-2 spike-1 ELISA was used. S1 protein was coated at 1 μg/ml overnight at 4°C in PBS onto MaxiSorp plates (Nunc). The following day plates were blocked with 5% skim milk and 0.05%Tween20. Serum collected on day 1 and day 5 post-challenge was diluted 1:100 and absorbed for 1 hour at 37 °C. Plates were washed and goat anti human IgG-HRP was added. Plates were washed and subsequently developed with OPD (o-phenylenediamine dihydrochloride) substrate. Optical density was measured at 450 nm after 30 mins of incubation. For lung tissues, after blocking homogenates were diluted 1:10 and absorbed overnight at 4°C followed by detection with anti-human IgG-HRP and substrate as stated above. The control hamster lung homogenate was used for background correction. For histopathology on day 5 p.i., 10% formalin fixed and paraffin embedded tissues were processed with either hematoxylin and eosin stain (H&E) or immunohistochemistry (IHC) for detection of SARS-CoV2 antigen; in IHC after blocking tissue slides were treated with anti-nucleocapsid rabbit polyclonal antibodies followed with anti-rabbit HRP antibody.

Dynamic Light Scattering (DLS). For evaluation of aggregation propensity, V_H ab8 and V_H-Fc ab8 were buffer-changed to DPBS and filtered through a 0.22 μm filter. The concentration was adjusted to 4 mg/mL; 500 μL samples

were incubated at 37 °C. On day 0, day 1 and day 6, samples were taken out for DLS measurement on Zetasizer Nano ZS ZEN3600 (Malvern Instruments Limited, Westborough, MA) to determine the size distributions of protein particles.

Size Exclusion Chromatography (SEC). The Superdex 200 Increase 10/300 GL chromatography (GE Healthcare, Cat. No. 28990944) was used. The column was calibrated with protein molecular mass standards of Ferritin (Mr 440 000 kDa), Aldolase (Mr 158 000 kDa), Conalbumin (Mr 75 000 kDa), Ovalbumin (Mr 44 000 kDa), Carbonic anhydrase (Mr 29 000 kDa), Ribonuclease A (Mr 13 700 kDa). 150 µl filtered proteins (1.5 mg/ml) in PBS were used for analysis. Protein was eluted by DPBS buffer at a flow rate of 0.5 ml/min.

Membrane Proteome Array Assay. Integral Molecular, Inc. (Philadelphia, PA) performed specificity testing of V_H-Fc ab8 using the Membrane Proteome Array (MPA) platform. The MPA comprises 5,300 different human membrane protein clones, each overexpressed in live cells from expression plasmids that are individually transfected in separate wells of a 384-well plate (Tucker et al., 2018). The entire library of plasmids is arrayed in duplicate in a matrix format and transfected into HEK-293T cells, followed by incubation for 36 h to allow protein expression. Before specificity testing, optimal antibody concentrations for screening were determined by using cells expressing positive (membrane-tethered Protein A) and negative (mock-transfected) binding controls, followed by flow cytometric detection with an Alexa Fluor-conjugated secondary antibody (Jackson ImmunoResearch Laboratories). Based on the assay setup results, V_H-Fc ab8 (20 µg/ml) was added to the MPA. Binding across the protein library was measured on an iQue3 (Ann Arbor, MI) using the same fluorescently labeled secondary antibody. To ensure data validity, each array plate contained positive (Fc-binding; SARS-CoV-2 S protein) and negative (empty vector) controls. Identified targets were confirmed in a second flow cytometric experiment by using serial dilutions of the test antibody. The identity of each target was also confirmed by sequencing.

QUANTIFICATION AND STATISTICAL ANALYSIS

For the mouse model, the statistical significance of difference between $_H$-Fc ab8 treated and control mice lung virus titers was determined by the two-tailed, unpaired, student *t* test calculated using GraphPad Prism 7.0. A p value < 0.05 was considered significant. ** $p < 0.01$. For the mice lung viral titer after perfusion, viral RNA and hamster lung viral RNA, statistical significance was determined by the Mann-Whitney *U* test. A p value < 0.05 was considered significant. ns: $p > 0.05$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$. For comparing V_H-Fc ab8 and IgG1 ab1 concentration, significance analysis was determined by the two-way ANOVA followed by Tukey test in GraphPad Prism 7.0. A p value < 0.05 was considered significant. ns: $p > 0.05$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, ****$p < 0.0001$.

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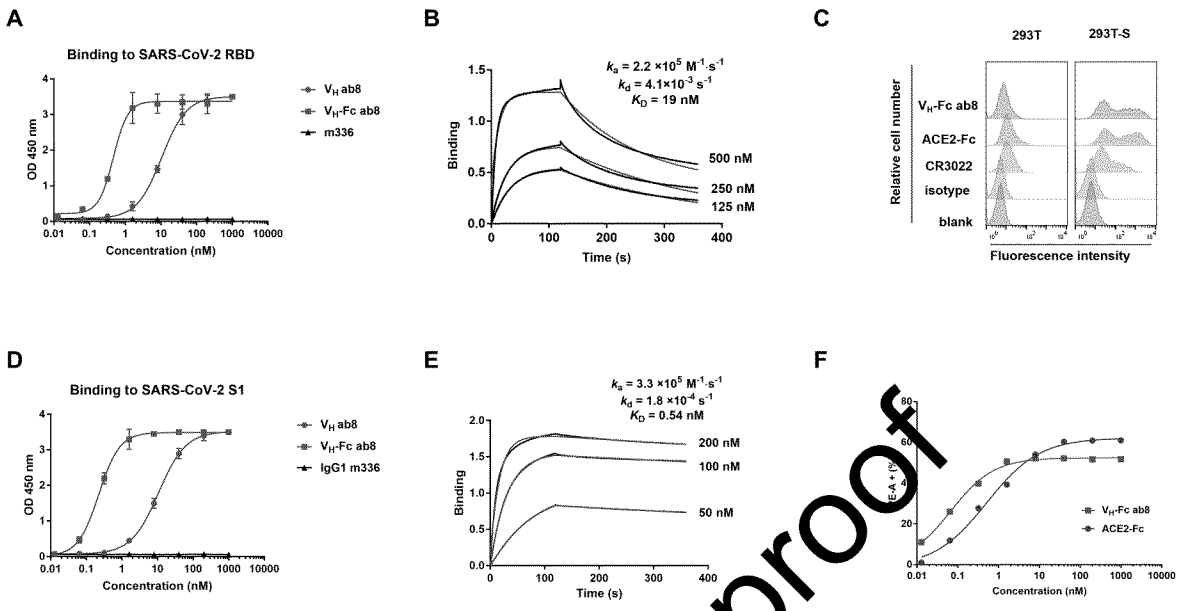
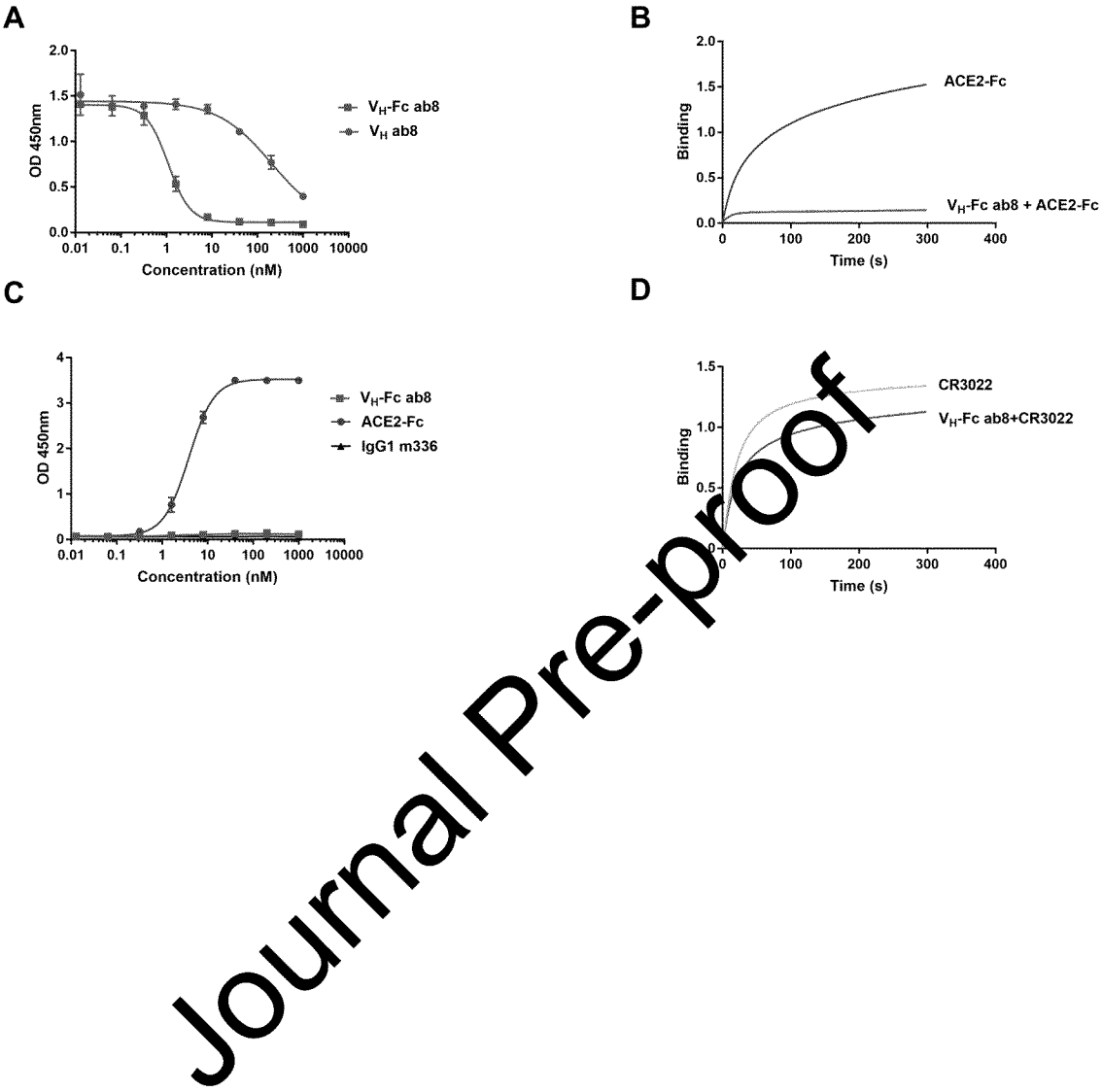
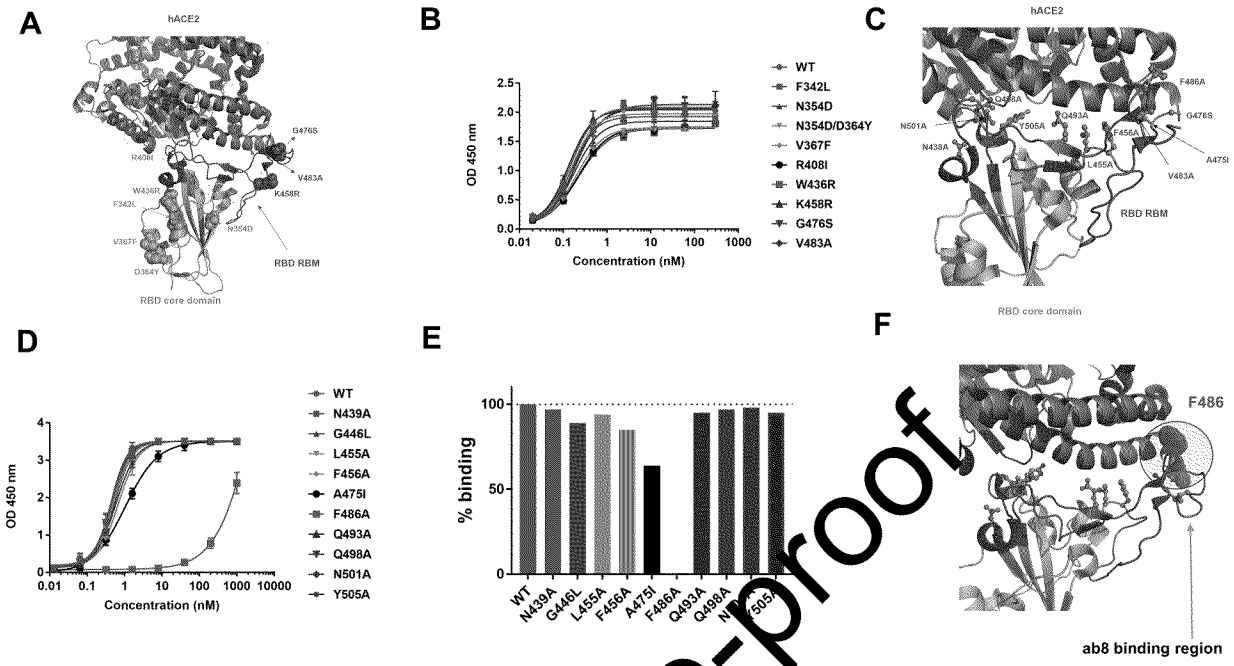
- A high-affinity human antibody domain, V_H ab8, specific for SARS-CoV-2 was selected
- V_H ab8 bound to all three S protomers competing with ACE2
- Bivalent V_H, V_H-Fc ab8, potently neutralized SARS-CoV-2 in vitro and in animals
- Small size and bivalency contribute to the high ab8 SARS-CoV-2 neutralizing potency

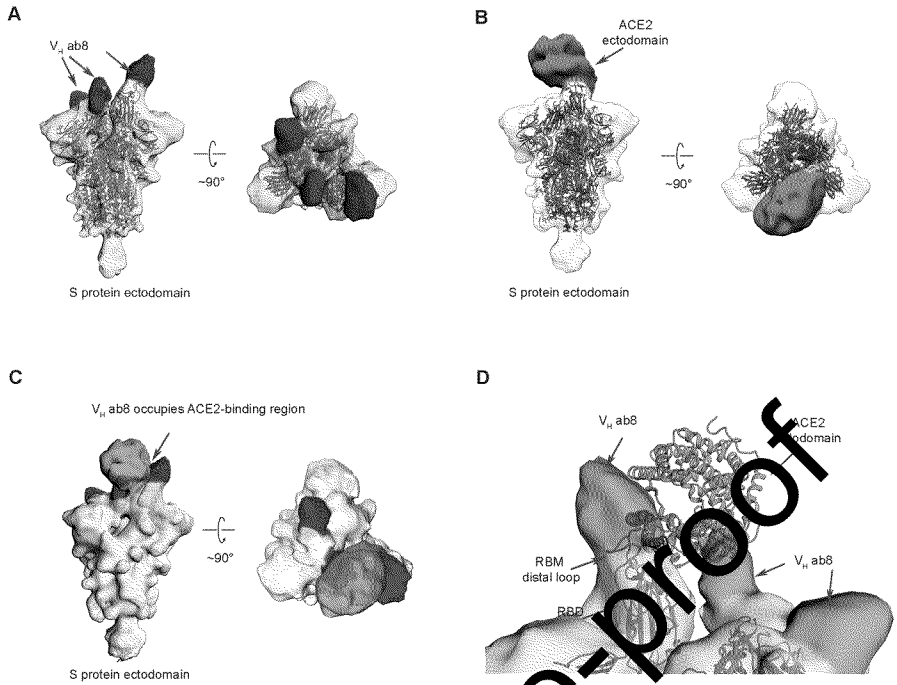
In brief summary:

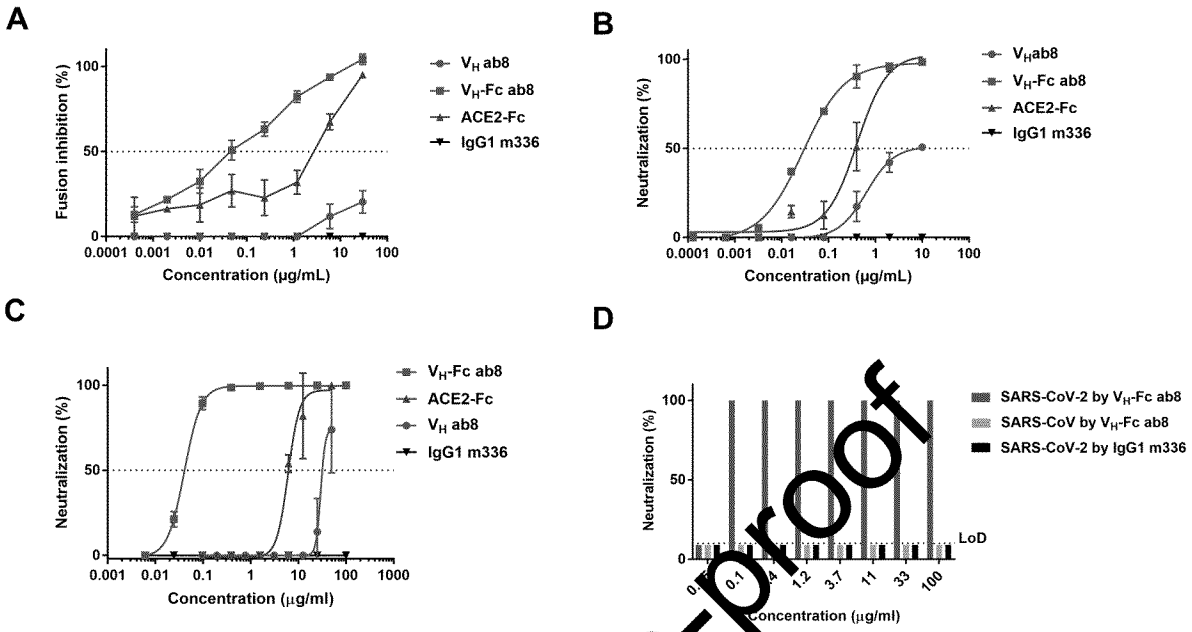
A high-affinity human antibody domain, V_H ab8, specific for SARS-CoV-2 bound to all three S protomers competing with ACE2. The relatively small size and bivalency of V_H-Fc ab8 contributed to its high potency in two animal models of infection.

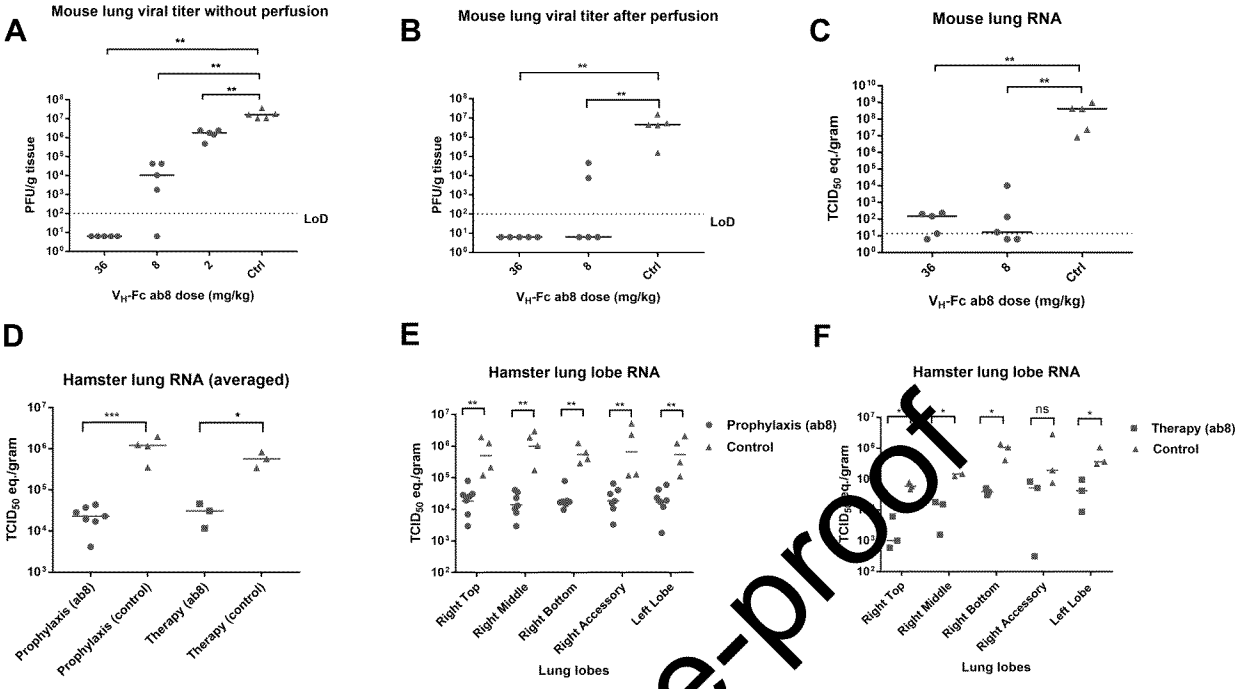


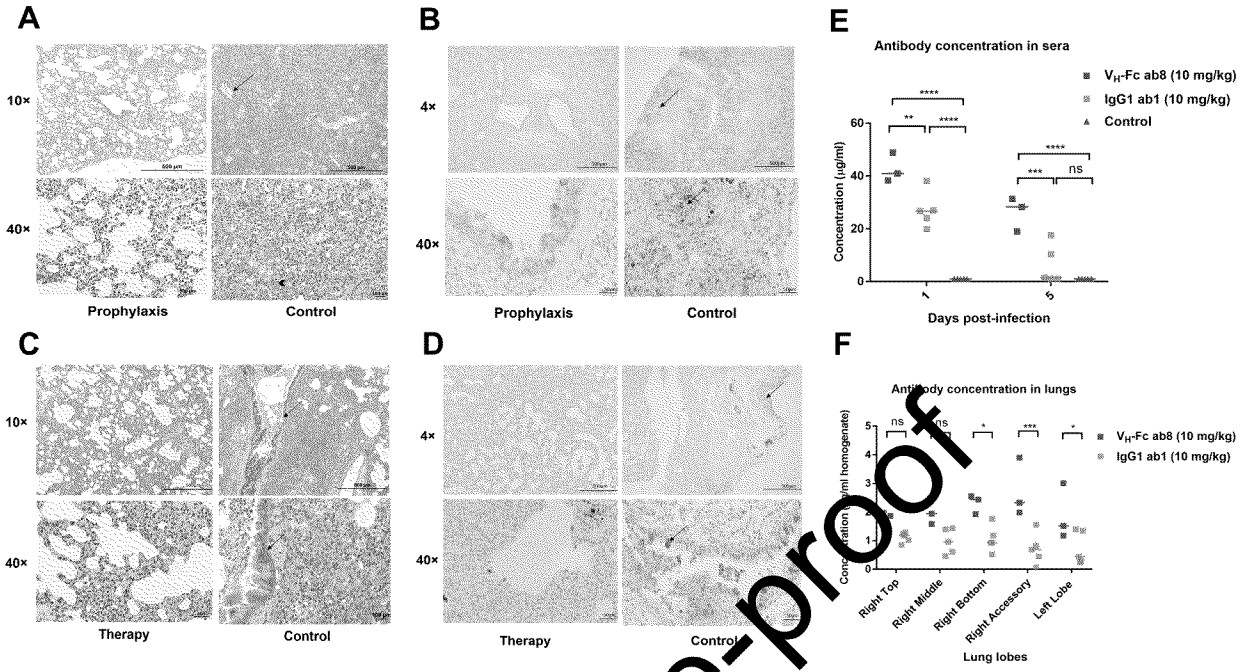












To: galter@partners.org[galter@partners.org]; maria.baca-estrada@canada.ca[maria.baca-estrada@canada.ca]; baihe@nmpa.gov.cn[baihe@nmpa.gov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; cheryl@gisaid.org[cheryl@gisaid.org]; Valentina Bernasconi[valentina.bernasconi@cepi.net]; shinjini.bhatnagar@thsti.res.in[shinjini.bhatnagar@thsti.res.in]; pbieniasz@mail.rockefeller.edu[pbieniasz@mail.rockefeller.edu]; karin.bok[karin.bok@nih.gov]; dboyle@path.org[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]; zuz4@cdc.gov[zuz4@cdc.gov]; Miles.Carroll@phe.gov.uk[Miles.Carroll@phe.gov.uk]; Marco.Cavaleri[Marco.Cavaleri@ema.europa.eu]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; MAY.CHU@CUANSCHUTZ.EDU[MAY.CHU@CUANSCHUTZ.EDU]; Carolyn Clark[carolyn.clark@cepi.net]; kizzmekia.corbett@nih.gov[kizzmekia.corbett@nih.gov]; costaa@who.int[costaa@who.int]; htq4@cdc.gov[htq4@cdc.gov]; shane@lji.org[shane@lji.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; Lisa@amicitiam.com[Lisa@amicitiam.com]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; tdelossantos@path.org[tdelossantos@path.org]; emmie.dewit@nih.gov[emmie.dewit@nih.gov]; marciela.degrace@nih.gov[marciela.degrace@nih.gov]; rafael.delgado@salud.madrid.org[rafael.delgado@salud.madrid.org]; mit666666@pitt.edu[mit666666@pitt.edu]; katie.doores@kcl.ac.uk[katie.doores@kcl.ac.uk]; William Dowling[william.dowling@cepi.net]; christian.drosten@charite.de[christian.drosten@charite.de]; epstein@ecohealthalliance.org[epstein@ecohealthalliance.org]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; darryl.falzarano@usask.ca[darryl.falzarano@usask.ca]; jason.fernandes@canada.ca[jason.fernandes@canada.ca]; clint.florence@nih.gov[clint.florence@nih.gov]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; Simon.Funnell@phe.gov.uk[Simon.Funnell@phe.gov.uk]; Luc.Gagnon@nexelis.com[Luc.Gagnon@nexelis.com]; Mayra.Garcia@fda.hhs.gov[Mayra.Garcia@fda.hhs.gov]; 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Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; knezevici[knezevici@who.int]; m.koopmans@erasmusmc.nl[m.koopmans@erasmusmc.nl]; Gerald.Kovacs@hhs.gov[Gerald.Kovacs@hhs.gov]; florian.krammer@mssm.edu[florian.krammer@mssm.edu]; Phil Krause[philip.krause@fda.hhs.gov]; skrebs@hivresearch.org[skrebs@hivresearch.org]; Greg.Kulnis@nexelis.com[Greg.Kulnis@nexelis.com]; Arun Kumar[arun.kumar@cepi.net]; pawinee.k@redcross.or.th[pawinee.k@redcross.or.th]; teresa.lambe@ndm.ox.ac.uk[teresa.lambe@ndm.ox.ac.uk]; janet.lathey[janet.lathey@nih.gov]; bleader@path.org[bleader@path.org]; leejooyeon@korea.kr[leejooyeon@korea.kr]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; liyl@cde.org.cn[liyl@cde.org.cn]; changguili@aliyun.com[changguili@aliyun.com]; lyhchengdu@163.com[lyhchengdu@163.com]; limhy0919@korea.kr[limhy0919@korea.kr]; James.Little@hhs.gov[James.Little@hhs.gov]; liub@cde.org.cn[liub@cde.org.cn]; Tracy.MacGill@fda.hhs.gov[Tracy.MacGill@fda.hhs.gov]; Karen Makar[Karen.Makar@gatesfoundation.org]; Mary.Matheson@phe.gov.uk[Mary.Matheson@phe.gov.uk]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; jmclellan@austin.utexas.edu[jmclellan@austin.utexas.edu]; adrian.mcdermott@nih.gov[adrian.mcdermott@nih.gov]; jmcelrat@fredhutch.org[jmcelrat@fredhutch.org]; gmedigeshi@thsti.res.in[gmedigeshi@thsti.res.in]; jwm1@pitt.edu[jwm1@pitt.edu]; philip.minor2@gmail.com[philip.minor2@gmail.com]; kmodjarrad@eidresearch.org[kmodjarrad@eidresearch.org]; david.montefiori@duke.edu[david.montefiori@duke.edu]; kaitlyn.dambach@nih.gov[kaitlyn.dambach@nih.gov]; omorgan@who.int[omorgan@who.int]; Clare.Morris@nibsc.org[Clare.Morris@nibsc.org]; sarah.mudrak@duke.edu[sarah.mudrak@duke.edu]; munoz-fontela@bnitm.de[munoz-fontela@bnitm.de]; vincent.munster@nih.gov[vincent.munster@nih.gov]; Todd.Myers@fda.hhs.gov[Todd.Myers@fda.hhs.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; scott.napper@usask.ca[scott.napper@usask.ca]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; PNorris@vitalant.org[PNorris@vitalant.org]; 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Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; PScott@eidresearch.org[PScott@eidresearch.org]; peshi@UTMB.EDU[peshi@UTMB.EDU]; Ragini.Shivji@ema.europa.eu[Ragini.Shivji@ema.europa.eu]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; Ashley.Smith1@hhs.gov[Ashley.Smith1@hhs.gov]; mksong@ivi.int[mksong@ivi.int]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; swaminathans@who.int[swaminathans@who.int]; r.tedder@imperial.ac.uk[r.tedder@imperial.ac.uk]; nax3@cdc.gov[nax3@cdc.gov]; tracey.thue@usask.ca[tracey.thue@usask.ca]; georgia.tomaras@duke.edu[georgia.tomaras@duke.edu]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk];

john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; sylvie.van-der-werf@pasteur.fr[sylvie.van-der-werf@pasteur.fr]; eric.vangieson@darpa.mil[eric.vangieson@darpa.mil]; Vasan.Vasan@csiro.au[Vasan.Vasan@csiro.au]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; David Vaughn[David.Vaughn@gatesfoundation.org]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; wangjz@nifdc.org.cn[wangjz@nifdc.org.cn]; wangyc@nifdc.org.cn[wangyc@nifdc.org.cn]; Jerry.Weir@fda.hhs.gov[Jerry.Weir@fda.hhs.gov]; alex@lji.org[alex@lji.org]; daniela@lji.org[daniela@lji.org]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; larry.wolfraim@nih.gov[larry.wolfraim@nih.gov]; dj56wood@gmail.com[dj56wood@gmail.com]; xumiaobj@126.com[xumiaobj@126.com]; Solomon Abebe Yimer[solomon.yimer@cepi.net]; tlying@fudan.edu.cn[tlying@fudan.edu.cn]; vyusibov@indianabiosciences.org[vyusibov@indianabiosciences.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]
From: William Dowling[william.dowling@cepi.net]
Sent: Wed 9/9/2020 9:52:48 AM (UTC-04:00)
Subject: RE: cell paper about very potent highly stable human domain

Dear all,
Here is the paper mentioned by Dimiter on our call today. I tried to send an email with the file , but the email bounced back from most due to the file size. Please just use the link.
Thanks
Bill

From: Dimitrov, Dimiter Stanchev <mit666666@pitt.edu>
Sent: Wednesday, September 9, 2020 9:29 AM
To: William Dowling <william.dowling@cepi.net>
Subject: cell paper about very potent highly stable human domain

Hi Bill,

I put it on the chat in the last second, here it is
https://www.cell.com/cell/fulltext/S0092-8674(20)31148-X

also attached the file just in case.

It is human domain fused to Fc and every stable – for 3 months at 37C no change in activity.
Was thinking even could be used as reference reagent, you mentioned there is also another candidate.

Best
Mitko
(Dimiter Dimitrov)

To: 'Diane Griffin (dgriffi6@jhmi.edu)'[dgriffi6@jhmi.edu]; Baric, Ralph S[rbaric@email.unc.edu]; 'Kent Kester (Kent.Kester@sanofi.com)'[Kent.Kester@sanofi.com]; 'spopesc2'[spopesc2@masonlive.gmu.edu]; 'Alexandra Phelan'[alexandra.phelan@georgetown.edu]; 'Turner, Paul'[paul.turner@yale.edu]; 'Segre, Julie (NIH/NHGRI) [E]'[jsegre@nhgri.nih.gov]; 'deborah zarin'[deborah.zarin@gmail.com]; 'Stuart Ray'[sray@jhmi.edu]; 'Mark Smolinski (mark@endingpandemics.org)'[mark@endingpandemics.org]; 'David A Relman (relman@stanford.edu)'[relman@stanford.edu]; 'Harvey V. Fineberg (harvey.fineberg@moore.org)'[harvey.fineberg@moore.org]; 'Deven McGraw'[deven@ciitizen.com]
Cc: Fine, Emma[EFine@nas.edu]; Kahn, Benjamin[BKahn@nas.edu]; Moss, Steven[SMoss@nas.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; 'augustine.bikim@nih.gov'[augustine.bikim@nih.gov]; 'vivian.louchie@sanofi.com'[vivian.louchie@sanofi.com]; 'Jennifer Ryan'[jennifer.ryan@moore.org]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Tue 9/15/2020 9:22:08 AM (UTC-04:00)
Subject: Hard Copies of Genomic Epi Report

Dear Committee,

We hope you are well! We are in the process of finalizing and printing hard copies of *Genomic Epidemiology Data Infrastructure Needs for SARS-CoV-2: Modernizing Pandemic Response Strategies.* If you would like hard copies of the report, please provide us with your address as soon as possible, and the books will be delivered directly to you!

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

To: Brown, Lisa[LBrown@nas.edu]
Cc: Alexandra Phelan[alexandra.phelan@georgetown.edu]; David A Relman (relman@stanford.edu)[relman@stanford.edu]; Deven McGraw[deven@ciitizen.com]; Diane Griffin (dgriffi6@jhmi.edu)[dgriffi6@jhmi.edu]; Fine, Emma[EFine@nas.edu]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; Jennifer Ryan[jennifer.ryan@moore.org]; Kahn, Benjamin[BKahn@nas.edu]; Kent Kester (Kent.Kester@sanofi.com)[Kent.Kester@sanofi.com]; Moss, Steven[SMoss@nas.edu]; Segre, Julie (NIH/NHGRI) [E][jsegre@nhgri.nih.gov]; Stuart Ray[sray@jhmi.edu]; Turner, Paul[paul.turner@yale.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; augustine.bikim@nih.gov[augustine.bikim@nih.gov]; deborah zarin[deborah.zarin@gmail.com]; Baric, Ralph S[rbaric@email.unc.edu]; spopesc2[spopesc2@masonlive.gmu.edu]; vivian.louchie@sanofi.com[vivian.louchie@sanofi.com]
From: Mark Smolinski[mark@endingpandemics.org]
Sent: Tue 9/15/2020 11:08:48 AM (UTC-04:00)
Subject: Re: Hard Copies of Genomic Epi Report

Thank you! We would like a couple of copies. Please send to my home address

1651 Fulton St
San Francisco, CA. 94117

On Tue, Sep 15, 2020 at 6:22 AM Brown, Lisa <LBrown@nas.edu> wrote:

Dear Committee,

We hope you are well! We are in the process of finalizing and printing hard copies of

Genomic Epidemiology Data Infrastructure Needs for SARS-CoV-2: Modernizing Pandemic Response Strategies.

If you would like hard copies of the report, please provide us with your address as soon as possible, and the books will be delivered directly to you!

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

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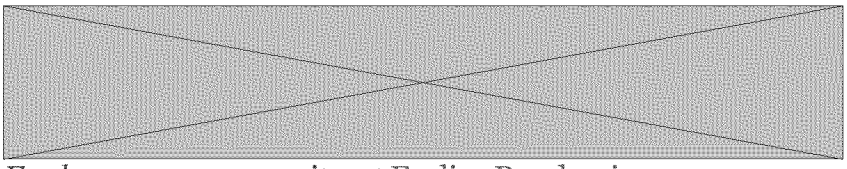

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Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: sandra cordo[scordo@qb.fcen.uba.ar]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; Vasan Vasan[Vasan.Vasan@csiro.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.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]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@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]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.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]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; PREZIOSI, Marie-pierre[preziosim@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; Amy C. Shurtleff[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]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.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]; Enjuanes_Luis[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]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; rkiatchula@gmail.com[rkiatchula@gmail.com]; tverakit@gmail.com[tverakit@gmail.com]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; langermans@bprc.nl[langermans@bprc.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; B. Rockx[b.rockx@erasmusmc.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[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]; dbolton@hivresearch.org[dbolton@hivresearch.org]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; 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[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]; Diamond, Michael[mdiamond@wustl.edu]; 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]; 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]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Amelia Karlsson[amelia.karlsson@duke.edu]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; fkoide@southernresearch.org[fkoide@southernresearch.org]; Krammer, Florian[florian.krammer@mssm.edu];

philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Levis, Robin[robin.levis@fda.hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; cjmiller@ucdavis.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[dmissiak@bsd.uchicago.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; DAVID H O'CONNOR[dhoconno@wisc.edu]; mto@umn.edu[mto@umn.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; Peter Palese[peter.palese@mssm.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Juergen Richt[jricht@vet.k-state.edu]; Chad Roy[croy@tulane.edu]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Padmini Salgame[salgampa@njms.rutgers.edu]; erica@lji.org[erica@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Michael Schotsaert[michael.schotsaert@mssm.edu]; sivkog@battelle.org[sivkog@battelle.org]; Spergel, Jonathan[SPERGEL@email.chop.edu]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Elizabeth Sulkowski[elizabethsulkowski44@gmail.com]; nax3@cdc.gov[nax3@cdc.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; sktseng@utmb.edu[sktseng@UTMB.EDU]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Wang, Tony[tony.wang@fda.hhs.gov]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; White, Alexander G[agw13@pitt.edu]; seos@cnu.ac.kr[seos@cnu.ac.kr]; k.chappell@uq.edu.au[k.chappell@uq.edu.au]; Stephen Kent[skent@unimelb.edu.au]; Adam Wheatley[a.wheatley@unimelb.edu.au]; Hyon Xhi Tan[hyon.tan@unimelb.edu.au]; peshi@utmb.edu[peshi@UTMB.EDU]; guilfoyle@viroclinics.com[guilfoyle@viroclinics.com]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 9/16/2020 11:38:44 AM (UTC-04:00)
Subject: WHO COVID-19 Animal Models Group Call-Agenda
Mail Attachment.ics
Webex_Meeting.ics

Dear all,

This Thursday we will have a call focused on COVID-19 enhanced disease. We will have three short presentations on that topic followed by a panel call. The panel call format will be as follows

(1) Question to be discussed: What can we learn about VAERD/ADE from animal models and how can we improve this knowledge in the future?

(**2) Background**: With more than 200 COVID-19 vaccine candidates in the pipeline and near 20 in clinical trials there is an increasing concern that some of these vaccines may cause VAERD or ADE. Most if not all of the vaccines in trials are not specifically addressing VAERD/ADE through immunological assays (e. g. Th1 vs Th2 bias, total Ab titers vs Neut Ab ratio etc)

* How can research in animal models help to address these concerns?
* How predictive are animal model studies for human VAERD?
* What should be the minimum information required from vaccine developers in preclinical and clinical investigations?

(3) Format: Each panelist would address the aforementioned questions (or other relevant points) in a 2-3 min verbal high-level single summary. This would be followed by Q/A discussion with the whole group.

Please find below the agenda and webex invite for this call. We are looking forward to your participation and input on this important discussion

Very best regards to all

César, Simon and Bill.

Agenda: WHO COVID-19 Animal Models Group Call- Thursday 17-SEP-2020 3PM CET

Presentations

1- Nadia Oreshkova (Wageningen)

2- Kate Guilfoyle (Viroclinics)

3- Clint Florence (NIH)

Panel Discussion

Panelists: Miles Carroll (PHE), Barney Graham (NIH), Jürgen Richt (KSU), Robin Levis (FDA)

Moderator: Vaseeharan Sathiyamoorthy (WHO)

Meeting number (access code): 145 274 5012
Meeting password: r2Gq3BhFUP4

Thursday, September 17, 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] 29th WHO TC - Animal Models
Location:	https://who.webex.com/who/j.php?MTID=md88e9d52b9bc5495d6c501f3f2ee1f55
Start Time:	2020-09-17T15:00:00+02:00
End Time:	2020-09-17T16:30:00+02:00
Attendees:	munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Start Time:	2020-09-17T15:00:00+02:00
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Attendees:	munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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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]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Thur 9/17/2020 5:50:09 PM (UTC-04:00)
Subject: Materials for 9/18 Expert Meeting on the Impact of Globalization on Future Health Crises
Expert Meeting on Globalization_FINAL Agenda.pdf
Expert Meeting on Globalization_Briefing Book_Final.pdf

Dear Members of the Standing Committee,

Please find attached the agenda and briefing materials for tomorrow's Expert Meeting on the Impact of Globalization on Future Health Crises. Please note that this is a CLOSED, joint meeting with the Forum on Microbial Threats and the Board on Global Health. Zoom details are included below. Please let us know if you have any questions.

Friday, September 18, 2020
3:30 p.m. – 5:30 p.m. ET
Join from PC, Mac, Linux, iOS or Android:
https://nasem.zoom.us/j/96069123196?pwd=cWNjWHlRb3VlWVhRMkpqT3ZSVWYvUT09
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Meeting ID: 960 6912 3196
Password: 110777
International numbers available: https://nasem.zoom.us/u/abvzRBFVKl

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

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From: Brown, Lisa
Sent: Monday, September 14, 2020 4:33 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>; Pope, Andrew <APope@nas.edu>; Pavlin, Julie <JPavlin@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>; Attal-Juncqua, Aurelia <AAttal-Juncqua@nas.edu>
Subject: 9/18 Expert Meeting on the Impact of Globalization on Future Health Crises
Importance: High

Dear Members of the Standing Committee,

We hope you are well!

With apologies for short notice, at the request of our sponsor, ASPR, in coordination with the Office of the Director of National Intelligence (ODNI), we've been asked to convene the members of our Standing Committee along with the Forum on Microbial Threats and the Board on Global Health to have an expert meeting on the impact of globalization on future health crises. The meeting will be this **Friday, September 18, from 3:30 p.m. – 5:30 p.m. ET.** The purpose of the meeting is to have a joint discussion and consider potential topics for further exploration.

Globalization has improved the world in many ways, but has also introduced fragility in supply chains, adversely affected the environment, witnessed the greatest number of refugees and internally displaced persons, expanded economic disparities, and increased the ability for novel pathogens to spread quickly around the globe. Factors such as extreme weather events and social and economic disruptions, including armed conflict, have also adversely affected global interdependence.

We would like to start a discussion on:

- What changes are associated with globalization that increase the probability of crises such as pandemics and other infectious disease events?
- What are potential mitigating factors against these threats?
- How do these different factors interact and create risks of compound events or cascading effects?
- And is there any predictability of how this is changing in frequency or impact?

We would like to discuss how the National Academies and the Standing Committee can advance the understanding of these risks, and the currently available mitigation methods. Based on our discussions, we may develop further efforts to delve deeper into the topics.

Please let us know if you can join us this Friday, September 18, from 3:30 p.m. – 5:30 p.m. ET. If so, a calendar invite and link will follow shortly.

P.S. We will be following up in the coming week or so with a more formal update on the activities of the standing committee and to schedule the next full committee meeting for sometime this Fall!

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

Joint Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, the Forum on Microbial Threats, and the Board on Global Health

Agenda
Friday, September 18, 2020 3:30 p.m. – 5:30 p.m. ET
Virtual Zoom Meeting

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. ASPR, in coordination with the Office of the Director of National Intelligence (ODNI) requested an expert meeting on the impact of globalization on future health crises. Given the expertise in both the Forum on Microbial Threats and the Board on Global Health in this topic, this meeting includes members of these bodies. Globalization has improved the world in many ways, but has also introduced fragility in supply chains, adversely affected the environment, witnessed the greatest number of refugees and internally displaced persons, expanded economic disparities, and increased the ability for novel pathogens to spread quickly around the globe. Factors such as extreme weather events and social and economic disruptions, including armed conflict, have also adversely affected global interdependence.

Meeting Objectives

Discuss and consider topics for further exploration on the following:

- What changes are associated with globalization that increase the probability of crises such as pandemics and other infectious disease events?
- What are potential mitigating factors against these threats?
- How do these different factors interact and create risks of compound events or cascading effects?
- And is there any predictability of how this is changing in frequency or impact?

FRIDAY, SEPTEMBER 18, 2020

CLOSED SESSION

SESSION I **Welcoming Remarks and Sponsors' Description of Need**

3:30 p.m. **Welcome and Charge to the Group**

Harvey Fineberg, *Standing Committee Chair*
President
Gordon and Betty Moore Foundation

3:45 p.m. **Sponsor Remarks**

David (Chris) Hassell
Acting Principal Deputy Assistant Secretary
Senior Science Advisor
The Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Kathryn Brinsfield
Senior Advisor
National Counterproliferation Center
Office of the Director of National Intelligence

4:00 p.m. **Topic Introduction**

Harvey Fineberg, *Standing Committee Chair*
President
Gordon and Betty Moore Foundation

Ann Kurth, *Board on Global Health Chair*
Dean and Professor
Yale University, School of Nursing

Peter Daszak, *Forum on Microbial Threats Chair*
President
EcoHealth Alliance

SESSION II **Group Discussions on the Challenges of:**

4:20 p.m. **Prediction Modeling**

Detection Assessment
Surveillance, monitoring, rapid threat assessment that is shared and accessible

Response
Preparedness, near term and focal, long-term and dispersed

5:15 p.m. **Discussion of Next Steps with the Sponsors**

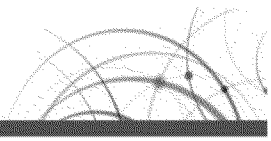
Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

5:30 p.m. **ADJOURN**

Joint Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, the Forum on Microbial Threats, and the Board on Global Health

Expert Meeting on the Impact of Globalization on Future Health Crises

Friday, September 18, 2020 3:30 p.m. – 5:30 p.m. ET
Virtual Zoom Meeting

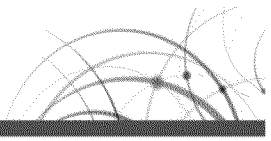


Joint Meeting of the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, the Forum on Microbial Threats, and the Board on Global Health

Expert Meeting on the Impact of Globalization on Future Health Crises

TABLE OF CONTENTS

AGENDA



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Harvey Fineberg, *Committee Chair*
President
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5:30 p.m. **ADJOURN**

LIST OF DISCUSSION TOPICS

Globalization and 21st Century Health Threats

List of Discussion Topics

Globalization has improved the world in many ways, but has also introduced fragility in supply chains, adversely affected the environment, witnessed the greatest number of refugees and internally displaced persons, expanded economic disparities, and increased the ability for novel pathogens to spread quickly around the globe. Factors such as extreme weather events and social and economic disruptions, including armed conflict, have also adversely affected global interdependence. What are the changes associated with globalization that increase the probability of crises such as pandemics and other infectious disease events? What are the potential mitigating factors against these threats? How do these different factors interact and create risks of compound events or cascading effects? Is there any predictability of how this is changing in frequency or impact?

Significant Factors Related to Increasing Incidence and Consequences of Severe Health Threats

- **Human dimensions:**
  - Increased trade and dependence on foreign supplies that can be disrupted when needed most
  - Local and regional migration patterns that can spread infectious diseases (e.g., Ebola in the DRC)
  - Increased refugees and internally displaced persons
  - Socio-cultural conflicts
  - Urbanization, including sanitation and crowding
  - Rapid population growth into areas unable to support it
  - Spread of misinformation
  - Asynchronous country policies on bioethics and future human health
  - Trends in armed conflict and terrorism
  - Antimicrobial resistance and the emergence of multi-drug resistant organisms
  - Travel that can rapidly spread pathogens
- **Environment:**
  - Extreme weather events enabling emergence of transboundary zoonotic disease
  - Floods, droughts, extreme heat and other impacts of extreme weather events
  - Thawing of the permafrost and resultant environmental and societal disruption
  - Decreased food and water security
- **One Health**
  - Increased intermingling between animals and humans
  - Animal farming practices, particularly surrounding pig products
  - Changing vector and reservoir host range
  - Wet markets and contact with wildlife

Economic and Technology Issues:

- Effects of poverty on underlying health and healthcare access
- Loss of industries and national/regional capabilities
- Technology theft
- Creation of new bioweapons technology

ROSTERS AND BIOS

STANDING COMMITTEE ON EMERGING INFECTIOUS DISEASES AND 21ST CENTURY HEALTH THREATS

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

HHS Office of Assistant Secretary for Preparedness and Response and Office of Science and Technology Policy

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

Ralph Steven Baric, Ph.D.
William R. Kenan, Jr. Distinguished Professor
The University of North Carolina at Chapel Hill

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

Donald Berwick, M.D., M.P.P., F.R.C.P, KBE
Lecturer of Health Care Policy
Harvard Medical School

Richard Besser, M.D.
President and CEO
Robert Wood Johnson Foundation

R. Alta Charo, J.D.
Warren P. Knowles Professor of Law and Bioethics
University of Wisconsin at Madison

Peter Daszak, Ph.D.
President and CEO
EcoHealth Alliance

Jeffrey S. Duchin, M.D.
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section and Professor in Medicine

Ellen Embrey
President/CEO
Stratitia, Inc.

Baruch Fischhoff, Ph.D.
Howard Heinz University Professor
Department of Engineering and Public Policy
Carnegie Mellon University

Diane Griffin, M.D., Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health

Robert Groves, Ph.D., M.A.
Executive Vice President and Provost
Gerard J. Campbell, S.J. Professor
Math and Statistics Department and Sociology Department
Georgetown University

Margaret Hamburg, M.D.
Foreign Secretary
National Academy of Medicine

Dan Hanfling, M.D.
Vice President, Technical Staff
In-Q-Tel

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.
Assistant Professor
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, Ph.D.
Senior Director, Board on Health Sciences Policy
202-334-1739
apope@nas.edu

Lisa Brown, M.P.H.
Committee Director, Board on Health Sciences Policy
202-334-2487
lbrown@nas.edu

ADDITIONAL INFORMATION

For additional information, please visit https://www.nationalacademies.org/our-work/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

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
President/CEO
Stratitia, Inc.

Ellen Embrey is President/CEO 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, Ph.D., M.A.
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 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
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.

FORUM ON MICROBIAL THREATS

FORUM ON MICROBIAL THREATS

BOARD ON GLOBAL HEALTH

HEALTH AND MEDICINE DIVISION

THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE

The Forum on Microbial Threats was created in 1996 to provide a structured opportunity for discussion and scrutiny of critical—and possibly contentious—scientific and policy issues related to research on and the prevention, detection, surveillance, and responses to emerging, reemerging, and novel infectious diseases in humans, plants, and animals as well as the microbiome in health and disease. Since its creation the topics and issues that have been examined and discussed by the Forum continue to be of major global public health importance. Through public debate and private consultation, the activities of the Forum strive to facilitate discussion and inquiry into the most challenging and cross-cutting sets of challenges within and across the spectrum of "microbial threats."

Activities of the Forum are designed to examine emerging as well as long-standing challenges in microbial ecology in "health" and "disease." The Forum has been instrumental in changing the infectious disease paradigm from "the only good 'bug' is a dead 'bug'" to a more ecologically-informed view of the beneficial contributions of the microbiome in health maintenance and how these microbial communities influence and are influenced by their environmental context. The summary reports of Forum workshops have highlighted and often anticipated some of the most important infectious disease issues of the past decade, including the challenge of emerging fungal diseases and the persistent problem of antimicrobial resistance. Through dissemination to public leaders, private industry, and policymakers, these summary reports have served as useful and timely educational resources and records of these public discussions and deliberations.

Today, the complexities and challenges posed by vector and non-vector borne diseases and the corresponding trends that contribute to their emergence and reemergence continue to confound the world's public health, scientific, medical, pharmaceutical, and policymaking communities. The global vulnerability of human, plant, and animal populations has been increasingly recognized as a challenge not only to personal health, but also to public safety, economic stability and development, and national and international security. The realities of the unrelenting resurgence of once manageable diseases, the emergence of multidrug resistant infectious diseases, the emergence and spread of newly identified pathogens such as Middle East Respiratory Syndrome (MERS), the global challenge of multi-drug resistant microorganisms, the reemergence of vector-borne disease as a major, global, public health concern, and the emergence of the first global influenza pandemic of the 21st century—H1N1—serve as timely reminders of the continuing evolution and adaptation of infectious diseases and their attendant impacts on human, plant, and animal health—domestically and internationally. The activities of the Forum continue to track and anticipate these evolving challenges.

As a result of such cross-sector dialogue, priority issues for infectious disease research and public health policy have been recognized; critical issues warranting further investigation have been identified; and there have been increased opportunities for more effective collaborations and dialogue between the private and public sectors represented on the Forum, as well as between the medical, veterinary, and plant disease communities. The Forum's membership consists of individuals from a wide range of disciplines and organizations in the public and private sectors, including the public health, medical, pharmaceutical, veterinarian, academic science, agricultural, and environmental communities.

Please see the next page for a list of the Forum's current members.

FORUM MEMBERSHIP

CHAIR

Peter Daszak, Ph.D.
President
EcoHealth Alliance
New York, NY

VICE CHAIR

Kent E. Kester, M.D.
Vice President and Head
Translational Science and Biomarkers
Sanofi Pasteur
Swiftwater, PA

Rima F. Khabbaz, M.D.
Director, National Center for Emerging and Zoonotic Infectious Diseases
U.S. Centers for Disease Control and Prevention
Atlanta, GA

MEMBERS

Kevin Anderson, Ph.D.
Senior Program Manager
Science and Technology Directorate
Department of Homeland Security
Washington, DC

Timothy Burgess, M.D., M.P.H.
Director, Infectious Diseases Clinical Research Program
Uniformed Services University of Health Sciences
Bethesda, MD

Attending for Dr. Burgess:
Bernard Okech, Ph.D., M.S., M.P.H.
Deputy Director, MPH Program
Uniformed Services University of Health Sciences
Bethesda, MD

Cristina Cassetti, Ph.D.
Deputy Division Director, Division of Microbial and Infectious Diseases
U.S. National Institute of Allergy and Infectious Diseases
National Institutes of Health
Rockville, MD

Andrew Clements, Ph.D.
Deputy Director, Pandemic Influenza and Other Emerging Threats Unit
U.S. Agency for International Development
Washington, DC

Marcos A. Espinal, M.D., Dr.P.H., M.P.H.
Director, Communicable Diseases and Environmental Determinants of Health
Pan American Health Organization
Washington, DC

Eva Harris, Ph.D.
Professor, Division of Infectious Diseases and Vaccinology
Director, Center of Global Public Health
University of California, Berkeley
Berkeley, CA

Elizabeth D. Hermsen, Pharm.D., M.B.A.
Head, Global Antimicrobial Stewardship
Merck & Co., Inc.
Omaha, NE

Christopher Houchens, Ph.D.
Director, Division of CBRN Countermeasures
BARDA
Deputy Assistant Secretary for Preparedness and Response
U.S. Department of Health & Human Services
Washington, DC

Chandy C. John, M.D., M.S.
Past President, American Society of Tropical Medicine & Hygiene
Director, Ryan White Center for Pediatric Infectious Diseases and Global Health
Indiana University School of Medicine

Michael Mair, M.P.H.
Acting Director
Office of Counterterrorism and Emerging Threats
U.S. Food and Drug Administration
Silver Spring, MD

Jonna Mazet, D.V.M., M.P.V.M., Ph.D.
Professor of Epidemiology and Disease Ecology
Executive Director, One Health Institute

School of Veterinary Medicine
University of California, Davis
Davis, CA

Sally A. Miller, Ph.D.
Distinguished Professor of Food, Agricultural and Environmental Sciences
Department of Plant Pathology
The Ohio State University
Wooster, OH

Suerie Moon, Ph.D., M.P.A.
Director of Research, Global Health Centre
The Graduate Institute of International and Development Studies, Geneva
Geneva, Switzerland

David Nabarro, B.M.B.Ch., M.Sc.
Advisor, Health and Sustainability
4SD – Skills, Systems, and Synergies for Sustainable Development
Geneva, Switzerland

Rafael Obregon, Ph.D., M.A.
Chief of Communication for Development
United Nations Children's Fund
New York, NY

Kumanan Rasanathan, M.B.Ch.B., M.P.H.
Incident Manager, COVID-19
Coordinator, Health Systems (HSD)
World Health Organization
Phnom Penh, Cambodia

Gary A. Roselle, M.D.
Chief of Medical Service, Veterans Affairs Medical Center
Director, National Infectious Disease Services
Veterans Health Administration
Cincinnati, OH

Peter A. Sands, M.P.A.
Executive Director
The Global Fund to Fight AIDS, Tuberculosis, and Malaria
London, UK

Thomas W. Scott, Ph.D.
Distinguished Professor
Department of Entomology and Nematology
University of California, Davis
Davis, CA

Alan Tennenberg, M.D., M.P.H.
Chief Medical Officer
Johnson & Johnson Global Public Health
Jerusalem, Israel

Matthew Zahn, M.D.
Medical Director, Division of Epidemiology and Assessment
Orange County Health Care Agency
Santa Ana, CA

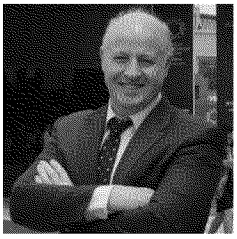
STAFF

Julie Pavlin, M.D., Ph.D., M.P.H.
Director, Board on Global Health
Director, Forum on Microbial Threats
The National Academies of Sciences, Engineering, and Medicine
Washington, DC

Julie Liao, Ph.D.
Associate Program Officer
Board on Global Health
The National Academies of Sciences, Engineering, and Medicine
Washington, DC

Charles Minicucci
Senior Program Assistant
Board on Global Health
The National Academies of Sciences, Engineering, and Medicine
Washington, DC

Members of the Forum on Microbial Threats
BIOGRAPHIES



Forum Chair

Peter Daszak, Ph.D., is president of EcoHealth Alliance, a U.S.-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 impact of emerging diseases across the globe. His achievements include identifying the bat origin of SARS, identifying the underlying drivers of Nipah and Hendra virus emergence, producing the first ever global emerging disease 'hotspots' map, developing a strategy to find out how many unknown viruses exist that could threaten to become pandemic, identifying the first case of a species extinction due to disease, and discovering the disease chytridiomycosis as the cause global amphibian declines. Dr. Daszak is a member and chair-elect of the National Academy of Sciences, Engineering and Medicine's Forum on Microbial Threats. He is a member of the National Research Council (NRC) Advisory Committee to the U.S. Global Change Research Program, the Supervisory Board of the One Health Platform, the One Health Commission Council of Advisors, the Center of Excellence for Emerging and Zoonotic Animal Diseases External Advisory Board, the Cosmos Club, and the Advisory Council of the Bridge Collaborative; he has served on the Institute of Medicine 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 Cooperative Research Centres, 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 the World Health Organization (WHO), World Organisation for Animal Heatlh, and the Food and Agriculture Organization of the United Nations, and is actively involved in the WHO Expert group on Public Health Emergency Disease Prioritization. Dr. Daszak won the 2000 Commonwealth Scientific and Industrial Research Organisation medal for collaborative research on the discovery of amphibian chytridiomycosis, is the EHA institutional lead for USAID-EPT-PREDICT, is on the editorial boards of *Conservation Biology*, *One Health*, and *Transactions of the Royal Society of Tropical Medicine & Hygiene*, and is editor-in-chief of the journal *EcoHealth*. He has authored over 300 scientific papers, and his work has been the focus of extensive media coverage, ranging from popular press articles to television appearances.

Forum Vice Chair

Kent E. Kester, M.D., is currently vice president and head of Translational Science and Biomarkers at Sanofi Pasteur. During a 24-year career in the U.S. 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—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). Dr. Kester holds an undergraduate degree from Bucknell University and an M.D. from Jefferson Medical College. He completed his internship and residency in internal medicine at the University of Maryland and a fellowship in infectious diseases at the Walter Reed Army Medical Center. A malaria vaccine researcher with over 70 scientific manuscripts and book chapters, Dr. Kester has played a major role in the development of the malaria vaccine candidate known as RTS,S. Currently

a member of the U.S. Government Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, he previously chaired the Steering Committee of the National Institute of Allergy and Infectious Diseases (NIAID)-USUHS Infectious Disease Clinical Research Program, and has served as a member of the Food and Drug Administration's Vaccines and Related Biologics Products Advisory Committee, the NIAID Advisory Council, and the U.S. Centers for Disease Control's Office of Infectious Diseases Board of Scientific Counselors. Board certified in both internal medicine and infectious diseases, he holds faculty appointments at USUHS and the University of Maryland; and is a fellow of the American College of Physicians, the Infectious Diseases Society of America, and the American Society of Tropical Medicine and Hygiene.

Forum Vice Chair

Rima F. Khabbaz, M.D., is the director of the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) at the U.S. Centers for Disease Control and Prevention (CDC). From 2010 to 2017, she was CDC's deputy director for infectious diseases and director of the Office of Infectious Diseases, where she helped lead the efforts of CDC's infectious disease national centers and advance the Agency's crosscutting infectious disease priorities including the integration of advanced molecular detection technologies into public health. During that time, she also served on an interim basis as acting director of the National Center for Immunization and Respiratory Diseases, acting director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, and acting director of NCEZID during leadership transitions. Her previous CDC positions include director of the National Center for Preparedness, Detection, and Control of Infectious Diseases; director, acting director, and associate director for epidemiologic science in the National Center for Infectious Diseases (NCID); and deputy director and associate director for science in the Division of Viral and Rickettsial Diseases. Her first job at CDC was an Epidemic Intelligence Service Officer in NCID's Hospital Infections Program. She later served as a medical epidemiologist in NCID's Retrovirus Diseases Branch, where she made major contributions to defining the epidemiology of the non-HIV retroviruses, specifically human T lymphotropic viruses (HTLV) I and II, in the United States and to developing guidance for counseling HTLV–infected persons. Following the hantavirus pulmonary syndrome outbreak in the southwestern United States in 1993, she led CDC's efforts to set up national surveillance for this syndrome. She also played a key role in developing and coordinating CDC's blood safety and food safety programs related to viral diseases. She has served in leadership positions during many of CDC's responses to outbreaks of new and/or reemerging infections, including Nipah, Ebola, West Nile virus, SARS, and monkeypox, and she led the CDC field team to the nation's capital during the public health response to the anthrax attacks of 2001. Dr. Khabbaz is a graduate of the American University of Beirut in Lebanon, where she obtained both her bachelor's degree in science (biology/chemistry) and her medical doctorate degree. She trained in internal medicine and completed a fellowship in infectious diseases at the University of Maryland in Baltimore. In addition to her CDC position, she serves as clinical adjunct professor of medicine (infectious diseases) at Emory University. Dr. Khabbaz is a fellow of the Infectious Diseases Society of America (IDSA), a member of the American Epidemiological Society, and a member of the American Society for Microbiology and of the American Society for Tropical Medicine and Hygiene. She is a graduate of the Public Health Leadership Institute at the University of North Carolina and the National Preparedness Leadership Initiative at Harvard University. She served on IDSA's Annual Meeting Scientific Program Committee and serves on the society's Public Health Committee. She also is a member of the National Academies of Sciences, Engineering, and Medicine's Forum on Microbial Threats.

Kevin Anderson, Ph.D., serves as a senior program manager in the Department of Homeland Security's (DHS's) Science and Technology Directorate, providing oversight and requirements for biodetection and biodiagnostics systems development for government-wide customers and stakeholders. Since joining DHS in 2003, Dr. Anderson has provided leadership for science program development, laboratory design, and strategic planning; served as a subject matter expert and advisor to the Bioterrorism Risk Assessment and Biological Threat Characterization programs; and has participated in interagency working groups and assessments which provide guidance to medical countermeasure development, a key component of the nation's biodefense strategy. Prior to joining DHS, Dr. Anderson was a principal investigator at the U.S. Army Medical Research Institute of Infectious Diseases, leading research focused on understanding basic mechanisms of viral diseases causing hemorrhagic fever and development of medical countermeasures. He received postdoctoral training in molecular virology at the University of Alabama at Birmingham and the University of North Carolina at Chapel Hill, performing basic research on human respiratory syncytial viruses, and earned Ph.D. and B.S. degrees in microbiology from Montana State University and the University of Maryland, College Park, respectively.

Timothy Burgess, M.D., is Director of the Infectious Diseases Clinical Research Program at Uniformed Services University. He is a graduate of the U. S. Naval Academy and the Indiana University School of Medicine. He trained in Internal Medicine and Infectious Diseases at National Naval Medical Center and Walter Reed Army Medical Center, and completed a Master of Public Health degree as well as a Certificate in Tropical Medicine and Travelers' Health at the Uniformed Services University. His research has included immunopathogenesis and epidemiology of dengue hemorrhagic fever, chikungunya and influenza. He currently oversees a portfolio of clinical observational and interventional studies in the areas of acute respiratory infections, skin and soft tissue infections, trauma-related infections, HIV disease, vector-borne disease and acute enteric infections. He has served as investigator and department head at the Naval Medical Research Center in Silver Spring, MD, and at Naval Medical Research Unit #2 in Jakarta; as director of basic research for the US Military's dengue vaccine development program; and as Chief of the Infectious Diseases Clinical Service at Walter Reed National Military Medical Center, Bethesda. He is a member of the faculty in the Departments of Preventive Medicine & Biostatistics and Medicine, and the Emerging Infectious Diseases interdisciplinary program, at the F. Edward Hébert School of Medicine, Uniformed Services University.

Attending the meeting with the Standing Committee for Dr. Burgess is:

Bernard Okech, Ph.D., M.S., M.P.H., *is a public health entomologist with extensive research and teaching experience in mosquito borne disease transmission. He has come to USU as the deputy director of the MPH program. Prior to joining USU, Dr. Okech was a Research Associate Professor of Environmental and Global Health and also research faculty at the Emerging Pathogens Institute at the University of Florida for more than 12 years. His research is focused on the influence of host and environmental factors on vector borne disease transmission, particularly in developing country environments. Dr. Okech's research program has been supported by funding from the DoD, NIH, USDA, USAID amongst others. Dr. Okech collaborates closely with researchers across the spectrum from local and international universities, US military, USAID, CDC, and Ministry of Health agencies in several in developing countries. These collaborations were particularly useful during the Chikungunya and Zika virus outbreaks that swept the western hemisphere in 2014/2016. During these outbreaks, Dr. Okech's team uncovered novel pathogens in mosquitoes while also providing information about future potential disease outbreaks in the population. Dr. Okech holds a Master of Science from University of Nairobi,*

Doctor of Philosophy from Kenyatta University and Master of Public Health degree from University of California Berkeley.

Marcos A. Espinal, M.D., Dr.P.H., M.P.H., is the director of the Department of Communicable Diseases and Health Analysis at the Pan American Health Organization (PAHO), Regional Office of the World Health Organization (WHO) for the Americas. Dr. Espinal, a national of the Dominican Republic, holds a medical degree from the Universidad Autónoma de Santo Domingo, Dominican Republic (1985). He has an M.P.H. (1990) and a Dr.P.H. (1995) from the University of California at Berkeley School of Public Health. His work experience includes positions in the Ministry of Health of the Dominican Republic and the National Center for Research on Maternal and Child Health; the New York City Public Health Department; and the WHO where he worked for 13 years. Before joining PAHO, Dr. Espinal served as Executive Secretary of the WHO Stop TB Partnership, a global movement aiming at the elimination of TB as a public health problem. Dr. Espinal has published more than 100 peer-reviewed publications in the field of communicable diseases. He is a recipient of the Scientific Prize of the International Union against Tuberculosis and Lung Diseases, the Walter and Elise A. Hass International Award by the University of California at Berkeley for a distinguished record of service in international health, and the Princess Chichibu Memorial Tuberculosis Global Award by the Japan Anti-Tuberculosis Association.

Eva Harris, Ph.D., is a professor in the Division of Infectious Diseases in the School of Public Health and Director of the Center for Global Public Health at the University of California, Berkeley. She has developed a multidisciplinary approach to study the molecular virology, pathogenesis, immunology, epidemiology, clinical aspects, and control of dengue, Zika, and chikungunya, the most prevalent mosquito-borne viral diseases in humans. Specifially, her work addresses immune correlates of protection and pathogenesis, viral and host factors that modulate disease severity, and virus replication and evolution, using in vitro approaches, animal models, and research involving human populations. This has been possible through a close collaboration with the Ministry of Health in Nicaragua for over 28 years. Her international work focuses on laboratory-based and epidemiological studies of dengue, chikungunya, Zika, and influenza in endemic Latin American countries, particularly in Nicaragua, where ongoing projects include clinical and biological studies of severe dengue, a pediatric cohort study of dengue, Zika, chikungunya, and influenza transmission in Managua, a household transmission study of Zika, and a recently concluded cluster-randomized controlled trial of evidence-based, community-derived interventions for prevention of dengue via control of its mosquito vector. She is also directing a study of Zika in infants and pregnancy in Nicaragua and evaluating a number of Zika diagnostic tests with her team in Nicaragua. In 1997, she received a MacArthur Award for work over the previous 10 years developing programs to build scientific capacity in developing countries to address public health and infectious disease issues. This enabled her to found a nonprofit organization in 1998, Sustainable Sciences Institute (SSI; www.sustainablesciences.org), with offices in San Francisco, Nicaragua, and Egypt, to continue and expand this work. Dr. Harris was named a Pew Scholar for her work on dengue pathogenesis. She received a national recognition award from the Minister of Health of Nicaragua for her contribution to scientific development and was selected as a "Global Leader for Tomorrow" by the World Economic Forum. In 2012, she was elected Councilor of the American Society of Tropical Medicine and Hygiene and received a Global Citizen Award from the United Nations Association. She has published over 200 peer-reviewed articles, as well as a book on her international scientific work.

Elizabeth D. Hermsen, Pharm.D., M.B.A., is the head of Global Antimicrobial Stewardship at Merck & Co., Inc. and an adjunct associate professor at the University of Nebraska Medical Center, Colleges of Pharmacy and Medicine, in Omaha, Nebraska. Dr. Hermsen received her Doctor of Pharmacy degree from the University of Nebraska Medical Center followed by a pharmacy practice residency at The Nebraska Medical Center, a fellowship in infectious diseases research at the University of Minnesota College of Pharmacy, and a master's degree in business administration at the University of Minnesota Carlson School of Management with an emphasis in health care industry. Following her fellowship, Dr. Hermsen developed and codirected the antimicrobial stewardship program at The Nebraska Medical Center and subsequently joined Cubist, where she created and led the Antimicrobial Stewardship Outreach Group. Now, in her role at Merck, she is responsible for creating and executing a strategy to advance antimicrobial stewardship through education, implementation, research, and advocacy focused on patient outcomes, population health, and the value of care. When leading the program at The Nebraska Medical Center, Dr. Hermsen developed a publicly-available antimicrobial stewardship website (www.nebraskamed.com/asp) that subsequently was featured in an article regarding top web resources for antimicrobial stewardship (Pagani L, et al. Navigating the Web in Search of Resources on Antimicrobial Stewardship in Health Care Institutions. *Clin Infect Dis*. 2009; 48:626-32.). Dr. Hermsen actively contributed to the advancement of the Society of Infectious Diseases Pharmacists (SIDP) Antimicrobial Stewardship Certificate Program during her term as SIDP president and continues to participate as a lecturer in the program. Dr. Hermsen served as a contributing member of the Antimicrobial Stewardship Knowledge & Skills Collaborative, coordinated by the Society for Healthcare Epidemiology of America; an expert panel on Antimicrobial Practice Improvement in Hospitals, coordinated by the American Society of Health-System Pharmacists; an expert panel on Hospital-based Antimicrobial Utilization Surveillance via the National Healthcare Safety Network, coordinated by the U.S. Centers for Disease Control and Prevention (CDC); the Cardinal Health Infectious Diseases Advisory Group; and an expert panel coordinated by the National Quality Forum and CDC to develop the practical tool entitled, *Antibiotic Stewardship in Acute Care: A Practical Playbook*. Dr. Hermsen is currently co-chair of the Antimicrobial Stewardship Work Package (1A) for the Innovative Medicines Institute Driving Reinvestment in Research & Development and Responsible Antibiotic Use (DRIVE-AB) initiative (www.drive-ab.eu). Dr. Hermsen is a Board Certified Pharmacotherapy Specialist with added qualifications in infectious diseases. She has contributed to the profession with numerous publications in peer-reviewed journals, book contributions, and by serving as a reviewer for several professional journals. Dr. Hermsen has also given over 100 invited presentations at state, regional, national, and international meetings.

Christopher R. Houchens, Ph.D. is the Director of the Division of Chemical, Biological, Radiological and Nuclear Countermeasures within the Biomedical Advanced Research and Development Authority (BARDA), a component of the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services. His primary role is building and managing a diverse product portfolio focused on the advanced research, development and procurement of novel vaccines, prophylactics, therapeutics, diagnostics and devices as medical countermeasures against chemical, biological, radiological and nuclear threats. In this role, Dr. Houchens conducts outreach with industry to identify new partnership opportunities and participates in numerous interagency working groups across the US government with the goal of strengthening the ability and capacity of the United States to rapidly respond to naturally occurring and intentionally engineered threats to public health. Dr. Houchens received his Ph.D. in Cell and Molecular Biology from the University of Vermont and continued his training as a Research Fellow at Johns Hopkins Medical Institute and a Staff Scientist at Memorial Sloan-

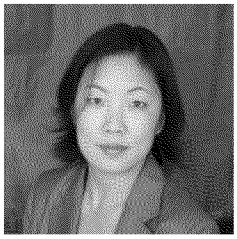
Kettering Cancer Center. Prior to joining BARDA, Dr. Houchens served as a Senior Scientist at the Defense Advanced Research Projects Agency where he managed translational research and development programs to rapidly design, manufacture and evaluate novel medical countermeasures. Dr. Houchens has over 25 years of experience ranging from early stage disease research to late stage product development and approval which has provided him a thorough understanding of the lifecycle of drug development and the challenges associated with each specific phase of product development.

Michael Mair, M.P.H., serves as the acting assistant commissioner for counterterrorism policy and acting director of the Office of Counterterrorism and Emerging Threats in the Office of the Chief Scientist, U.S. Food and Drug Administration (FDA). In this capacity, Mr. Mair is responsible for providing leadership, coordination, and oversight for FDA's national and global health security and emerging threat portfolios. Mr. Mair also coordinates FDA's Medical Countermeasures Initiative (MCMi), a key component of a broad U.S. government program to improve the U.S. capacity to prepare for and respond to public health emergencies.

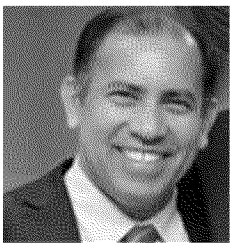
Jonna A. K. Mazet, D.V.M., M.P.V.M., Ph.D., earned her doctorate of veterinary medicine, master of preventative medicine, and her Ph.D. in epidemiology from the University of California, Davis. In addition to her faculty appointment in the Department of Medicine and Epidemiology in the UC Davis School of Veterinary Medicine, she serves as the Executive Director of the UC Davis One Health Institute (OHI). Dr. Mazet specializes in emerging infectious diseases and wildlife epidemiology, and as director of OHI, focuses on global health problem solving. In her role at UC Davis, she assists government agencies and the public with emerging health challenges, and is active in international One Health research programs such as tuberculosis in Africa, novel pathogen detection in less developed countries, and pathogen pollution of California coastal waters. Dr. Mazet founded California's Oiled Wildlife Care Network, the premier model wildlife emergency management system worldwide, and remains a consulting expert on wildlife emergency preparedness and response, serving on multiple government and nongovernment organization advisory panels. Dr. Mazet is the principal investigator and global director of the novel viral emergence early warning project, PREDICT, that has been developed with the USAID's Emerging Pandemic Threats Program. She leads a network of global NGOs and governmental agencies to build capacity within the PREDICT-engaged countries to develop surveillance systems and complete the necessary research to halt the next pandemic, like influenza, SARS, Ebola, and HIV that have preceded the program.

Sally A. Miller, Ph.D., is a professor of plant pathology and state extension specialist for vegetable pathology at The Ohio State University, Ohio Agricultural Research and Development Center in Wooster, Ohio. She received her B. Sc. in biology from The Ohio State University (OSU), and M.S. and Ph.D. degrees in plant pathology from the University of Wisconsin-Madison. Prior to joining The Ohio State University faculty in 1991, she was a research manager at Agri-Diagnostics Associates in Cinnaminson, New Jersey, an early developer of plant disease diagnostic assays. Dr. Miller's research is focused on the development of sustainable disease management strategies for conventional and organic vegetable crops, in open field and protected (greenhouse and high tunnel) production systems. This includes diagnosis and management of diseases caused by viruses, bacteria, fungi, oomycetes (water molds), and nematodes. Her lab diagnoses more than 300 vegetable samples from growers and home gardeners each year, at no cost to Ohio residents. Areas of research emphasis are bacterial disease management in processing, fresh market and hydroponic tomatoes, downy mildew and bacterial wilt in cucurbits, soilborne diseases in all vegetable

crops, and food safety. Outreach efforts are directed primarily to vegetable growers and extension educators, and in addition to diagnostics include providing management advice through presentations, fact sheets and other printed information, and social media (websites, blogs, and Twitter). Dr. Miller has been active in long-term international agricultural development projects on integrated pest management (IPM) and plant diagnostics in South and Southeast Asia, Ukraine, West and East Africa, and Central America, primarily under the auspices of the U.S. Agency for International Development (USAID). Current USAID-funded IPM programs are underway in East Africa (Tanzania, Kenya, and Ethiopia) and South/Southeast Asia (Bangladesh, Nepal, and Cambodia). Dr. Miller has been active in the leadership of the American Phytopathological Society, serving as president in 2015-2016. She has recently been appointed to a Food and Agriculture Organization of the United Nations expert panel on antimicrobial resistance, and serves on the executive committee and two working groups for OSU's Global One Health Initiative.

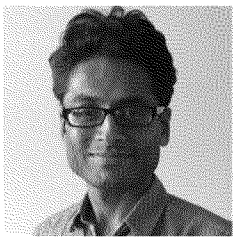


Suerie Moon, Ph.D., M.P.A., is director of research at the Global Health Centre, Graduate Institute of International and Development Studies, Geneva and adjunct lecturer on global health at the Harvard T.H. Chan School of Public Health. She has served on a number of advisory bodies, including most recently the World Health Organization Fair Pricing Forum Advisory Group, Expert Advisory Group to the United Nations Secretary General's High-Level Panel on Access to Medicines, and Proposal Review Committee of UNITAID. Prior to joining the Graduate Institute, she was study director of the Harvard-London School of Hygiene & Tropical Medicine Independent Panel on the Global Response to Ebola, and cofounded and led the Forum on Global Governance for Health, a focal point at Harvard University for research, debate, and strategic convening on issues at the intersection of global governance and health. Her research and teaching focus on global governance, the political economy of global health (focusing on innovation and access to medicines; outbreak preparedness and response; trade, investment, and intellectual property rules; and development assistance for health), the evolution of international regimes, and innovative policies for addressing global problems. She received a B.A. from Yale, an M.P.A. from Princeton, and a Ph.D. from the Harvard Kennedy School of Government.



Rafael Obregon, Ph.D., M.A., provides technical leadership and guidance on the development of standards, guidelines, and quality assurance for the application of communication for development principles and strategies across programmatic areas of the United Nations Children's Fund (UNICEF), including emergency response and humanitarian action. In this capacity, Dr. Obregon has engaged in several responses to public health emergencies and disease outbreaks, including the 2014 – 2015 West Africa Ebola Outbreak. In 2016 Dr. Obregon also served as a member of the Advisory Committee to the World Health Organization's (WHO's) International Health Regulations Emergency Committee on Zika virus and observed increase in neurological disorders and neonatal malformations. Prior to joining UNICEF, he has served as regional advisor for health communication within the Area of Family and Community Health and Child and Adolescent Health Unit at the Pan American Health Organization. Dr Obregon has also been a technical advisor, researcher, and resource/focal person for international/national cooperation agencies and government and nongovernmental organizations, particularly in health and development initiatives. His duties have focused on formative research, project design and evaluation, and capacity strengthening. Dr. Obregon has also been associate professor and guest faculty member at a number of universities, including Ohio University, the Universidad Autónoma in Barcelona, Spain, and the Universidad del Norte in Barranquilla, Colombia, where he remains as an adjunct faculty. Throughout his career, he has written

several books, book chapters, monographs, manuals, peer-reviewed journal articles and reports on public health communication, participatory communication, and capacity development. He is a member of several editorial boards including the *Journal of Health Communication*, and has been a member of several scientific committees including the World Congress on Communication and Development, convened by the World Bank, the Food and Agriculture Organization of the United Nations, and the Communication Initiative, as well as a member of the Technical Advisory Group for the Global Health Communication Partnership within the Center for Communication Programs at Johns Hopkins University. Dr. Obregon earned his Ph.D. in an interdisciplinary program in mass communications, with a concentration on international health, at the College of Communications at Pennsylvania State University in 1999. He received his Master of Arts in international affairs and communication and development from Ohio University in 1994 with a minor in public health. Additionally, he obtained a diploma in education and pedagogy through the National Apprenticeship Service in Colombia in 1990.



Kumanan Rasanathan, M.B.Ch.B., M.P.H., a public health physician with 20 years of experience in health and related sectors. He is a member of the board of Health Systems Global and currently works in the areas of health systems and maternal and child health in Cambodia. He was previously chief, Implementation Research Unit and Delivery Science Unit and Senior Adviser Health for United Nations Children's Fund in New York, working on implementation research focused on improving child service delivery, universal health coverage, district health system strengthening, health systems resilience post-Ebola, integrated community case management, the Sustainable Development Goals agenda, and multisectoral approaches to child health. Prior to this, Dr. Rasanathan worked for the World Health Organization in Geneva on primary health care and the social determinants of health, and in a number of different countries as a clinician, researcher, policy maker, program manager, and advocate. He started his public health career running Phase I and II vaccine clinical trials leading to the licensure and rollout of meningococcal B vaccine in New Zealand.

Gary A. Roselle, M.D., is the national director, Infectious Diseases Service for the Veterans Health Administration of the Department of Veterans Affairs (VA). Dr. Roselle is board certified in internal medicine and infectious diseases and a professor of medicine in the Department of Internal Medicine, Division of Infectious Diseases at the University of Cincinnati College of Medicine. Dr. Roselle serves on multiple national VA and Federal Interagency Committees. He serves as the VA representative on the U.S. Centers for Disease Control and Prevention's (CDC's) Advisory Council for the Elimination of Tuberculosis, CDC's Public Health Action Plan to Combat Antimicrobial Resistance Task Force, CDC's Healthcare Infection Control Practices Advisory Committee, and the Department of Health and Human Services' Steering Committee for the Prevention of Healthcare-Associated Infections, and the National Academies of Sciences, Engineering, and Medicine's Forum on Microbial Threats.

Peter A. Sands, M.P.A., is the executive director of The Global Fund to Fight AIDS, Tuberculosis, and Malaria. Since June 2015, Mr. Sands has been a research fellow at Harvard University, dividing his time between the Mossavar-Rahmani Center for Business and Government at Harvard Kennedy School and the Harvard Global Health Institute, part of the Harvard T.H. Chan School of Public Health, and working on a range of research projects in financial markets and regulation, fintech, and global health. Mr. Sands' engagement with global health issues includes: chairing the U.S. National Academy of Medicine's Commission on a Global Health Risk

Framework for the Future, which in January 2016 produced the highly influential report *The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Threats*; chairing the World Bank's International Working Group on financing preparedness, which in May 2017 published *From Panic and Neglect to Investing in Health Security: Financing Preparedness at a National Level*; authoring several papers on infectious disease crises in the *New England Journal of Medicine*, *The Lancet*, and *British Medical Journal*; being the lead non-executive director between 2011-2017 on the Board of the UK's Department of Health, which provides oversight and policy direction to the UK's National Health Service; and being an active member on both the U.S. National Academy of Science's Committee on Ensuring Access to Affordable Drugs and the Forum on Microbial Threats. Mr. Sands is a board member or advisor to several startups in the fintech and meditech arenas, such as Noble Markets (US) and Cera (UK). He was group chief executive of Standard Chartered PLC from November 2006 to June 2015. He joined the Board of Standard Chartered PLC as group finance director in May 2002, responsible for finance, strategy, risk and technology, and operations. Prior to this, Mr. Sands was a senior partner at worldwide consultants McKinsey & Co. Before joining McKinsey, he worked for the UK's Foreign and Commonwealth Office. He has served on various boards and commissions, including as a director of the World Economic Forum and co-chairman of Davos, governor of the UK's National Institute for Economic and Social Research, member of the International Advisory Board of the Monetary Authority of Singapore, member of the Browne Commission on Higher Education Funding in the UK, member of the China People's Association for Friendship with Foreign People's Global CEO Council, co-chair of the UK-India CEO Forum, board director of the Institute of International Finance, chairman of the International Monetary Conference, member of the International Advisory Board of Lingnan University, China, and trustee of the Camden Roundhouse, London. Mr. Sands graduated from Brasenose College, Oxford University with a first class degree in politics, philosophy, and economics. He also received a Master in Public Administration from Harvard University, where he was a Harkness Fellow. Mr. Sands, who grew up in Singapore and Malaysia, is married to author and bookshop owner, Betsy Tobin and has four children.

Thomas W. Scott, Ph.D., is a distinguished professor of mosquito-transmitted disease ecology and epidemiology at the University of California, Davis. He received his Ph.D. in ecology from the Pennsylvania State University and was a postdoctoral fellow in epidemiology at the Yale School of Medicine. After initially examining the relationship of mosquito ecology to pathogen transmission in Southeast Asia, Latin America, and Africa in the early 1990s, in an effort to strengthen the public health connection of his work, he began longitudinal dengue epidemiological studies in Thailand and Peru. He currently focuses on assessment of recommendations for mosquito-borne disease prevention, testing assumptions in public health policy, and developing innovative, cost-, and operationally-effective concepts for disease prevention. At UC Davis, he was director of the Center for Vector-Borne Disease Research and the Davis Arbovirus Research Unit. He chaired the Mosquito-Borne Disease Working Group in the Research and Policy in Infectious Disease Dynamics (RAPIDD) program, which developed novel mathematical modeling frameworks and reported to the Science and Technology Directorate of the Department of Homeland Security, and Fogarty International Center at the Na tional Institutes of Health. At the World Health Organization, he chairs the Vector Control Advisory Group, which assesses the public health value of new product classes in vector control; has co-chaired the Global Vector Control Response, which aims to reduce the global burden of vector-borne diseases through locally adapted sustainable vector control; chaired the Emergency Response Consultation for Zika Virus; and serves on the International Health Regulators Roster of Experts. He is a member of the Management Committee for the Global Dengue and Aedes-transmitted Diseases Consortium.

Alan Tennenberg, M.D., M.P.H., is the Chief Medical Officer of Johnson & Johnson Global Public Health. Trained as an infectious diseases physician, Alan brings over 25 years of experience in the pharmaceutical industry, clinical medicine, public health, and academia. As Chief Medical Officer, he is responsible for building strategic relationships with key stakeholders and partners in government, academia, multi-lateral institutions, and non-governmental organizations around the world. He is a leading figure in facilitating private sector engagement to advance the Global Health Security Agenda.

Matthew Zahn, M.D., currently serves as medical director of the Division of Epidemiology and Assessment for the Orange County Health Care Agency. Dr. Zahn received his doctorate in medicine from St. Louis University School of Medicine. From 2004 through 2011, he served as medical director for the Louisville Metro Department of Public Health and Wellness. During that time, he also served as an assistant professor of pediatric infectious disease at the University of Louisville School of Medicine. Dr. Zahn has served on multiple national public health committees, including his current service as the chair of the Infectious Diseases Society of America's Public Health Workgroup.

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The Board on Global Health is charged with monitoring the field of global health in three major areas: US policies and programs in global health, health problems in developing countries, and health issues of mutual concern to the US and other industrialized and industrializing societies. The mission of the Board is to provide expert analysis and judgments to The National Academies, the United States Government, and to other appropriate audiences, on the meaning to the United States of health developments beyond its borders, and areas of U.S. international health investment that are most likely to benefit the health of the U.S. population and promote global well-being, security, and economic development.

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Assistant Professor of Occupational and Environmental Health and Epidemiology
College of Public Health
University of Iowa

Michele Barry, M.D.
Senior Associate Dean and Director
Center for Innovation in Global Health
Stanford University

Sarah Cleaveland, Ph.D.
Institute of Biodiversity, Animal Health and Comparative Medicine
University of Glasgow

Malick Diara, M.D., M.B.A., M.P.H.
Public Health Manager
Workplace Wellness & Infectious Disease Control Programs
Global Medicine and Occupational Health Department
ExxonMobil Corporation

Isabel Garcia, D.D.S., M.P.H.
Dean
University of Florida College of Dentistry

Lawrence O. Gostin, J.D.
University Professor and Founding Linda and Timothy O'Neill Professor of Global Health Law
Georgetown University Law Center

Andrew Kanter, M.D., M.P.H., FACMI
Assistant Professor of Clinical Biomedical Informatics and Clinical Epidemiology
Columbia University

Karestan C. Koenen, Ph.D.
Professor
Department of Epidemiology
Harvard T.H. Chan School of Public Health

Orin Levine, Ph.D.
Director, Vaccine Delivery Program
The Bill & Melinda Gates Foundation

Maureen Y. Lichtveld, M.D., M.P.H.
Professor and Chair
Department of Environmental Health Sciences
Tulane School of Public Health and Tropical Medicine

Gbenga Ogedegbe, M.D., M.P.H., FACP
Professor of Population Health and Medicine
Chief, Division of Health and Behavior
Director, Center for Healthful Behavior Change
New York University School of Medicine

Scott C. Ratzan, M.D., M.P.A.
Senior Fellow
Mossavar-Rahmani Center for Business & Government
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NAM Foreign Secretary
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Sarah Tishkoff, Ph.D., M.Phil.
David and Lyn Silfen University Professor
Departments of Genetics and Biology
University of Pennsylvania

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Health and Medicine Division
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Biographies

Ann E. Kurth, Ph.D., CNM, M.P.H., FAAN is Dean, and Linda Koch Lorimer Professor, Yale University School of Nursing. Dr. Kurth is an elected Fellow of the Institute of Medicine (National Academy of Medicine) and a member of the 2014-2018 US Preventive Services Task Force, which sets screening and primary care prevention guidelines for the United States. Dr. Kurth is 2018-2020 chair of the Consortium of Universities for Global Health. An epidemiologist and clinically-trained nurse-midwife, Dr. Kurth's research focuses on HIV/reproductive health and global health system strengthening. Her work has been funded by the National Institutes of Health (NIAID, NIDA, NIMH, NICHD), the Bill & Melinda Gates Foundation, UNAIDS, CDC, HRSA, and others, for studies conducted in the United States and internationally. Dr. Kurth has consulted for the NIH, Gates Foundation, WHO, USAID and CDC, among others. Dr. Kurth has published over 200 peer-reviewed articles, book chapters, and scholarly monographs and presented at hundreds of scientific conferences and invited talks. Dr. Kurth has received awards for her science and leadership including the Friends of the National Institute of Nursing Research Ada Sue Hinshaw Research Award and the International Nurse Researcher Hall of Fame award from Sigma Theta Tau International.

Kelly Baker, Ph.D. is an Assistant Professor in Occupational and Environmental Health, and Epidemiology at the University of Iowa's College of Public Health, and is a faculty member of the interdisciplinary Sustainable Water Development Program in the College of Engineering. Her research focuses on understanding how unsafe water, sanitation and hygiene (WASH) conditions affect maternal and child health outcomes in low and middle income countries. Her Social Microbes program uses an microbial ecology systems approach to understand the complex behavioral, environmental, and spatial-temporal mechanisms that result in young children being exposed to and infected by dozens of types of common enteric pathogens in unsanitary settings. A fundamental theory underlying this research is that in highly unsanitary settings where multiple types of enteric pathogens are dynamically transmitted between humans and animal populations over space and time, the distribution of transmission risks are characterized at the simplest level by presence and concentration of a specific pathogen and at the most complex level by simultaneous exposure to multiple types of pathogens. Dr. Baker's group uses microbial exposure assessment and epidemiology approaches to identify and rank priority transmission pathways, as well as to evaluate the impact of WASH intervention trials. Other research in the Baker Group focuses on documenting how social and environmental barriers in meeting daily WASH needs affects women's reproductive health, with a particular focus on the epidemiology of preterm birth and low infant birth weight outcomes in pregnant women. Dr. Baker has advised the World Bank, World Health Organization, UNICEF and several NGOs on issues related to water quality, priority enteric pathogens, and infectious disease exposure assessment and epidemiology.

Michele Barry, M.D., is Senior Associate Dean for Global Health and Director of the Center for Innovation in Global Health at Stanford University. She is a past President of The American Society of Tropical Medicine and Hygiene and has also served on the advisory board of NIH -Fogarty Center. Areas of scholarly interest include global health workforce, clinical tropical medicine, emerging infectious

diseases, problems of underserved populations and globalization's impact upon health in the developing world. Dr. Barry is an elected member of the National Academy of Medicine.

Sarah Cleaveland. Ph.D., is a Professor of Comparative Epidemiology at the University of Glasgow, UK Institute of Biodiversity, Animal Health and Comparative Medicine. She is a veterinary epidemiologist and leads a research program investigating zoonotic and livestock diseases in Africa. Her research focuses on understanding the burden, epidemiology and control of zoonoses and has generated evidence to support the feasibility of canine rabies elimination. Professor Cleaveland is a member of the National Academy of Medicine.

Malick Diara, M.D., M.B.A., M.P.H., joined ExxonMobil in 2009 with more than 20 years of experience in international health. He is the Public Health Manager of the Exxon Mobil Corporate Medicine and Occupational Health (MOH) Department. As a member of the MOH leadership team, his responsibilities are focused on infectious disease prevention and control in ExxonMobil workplaces, and recently, on management oversight of the Company Culture of Health Program. His illustrative accomplishments include the successful establishment of the Company infectious disease outbreak management program with no operation disruption since 2010, no death due to malaria for the past 10 years with the development of a malaria drug field test that saved over 1.6 USD million within 3 years on lab costs and the launch of a global Tuberculosis control program with over 1000 TB cases averted since 2010. Prior to ExxonMobil and being based in Houston since 2009, Dr. Diara worked with private Non Profit organizations in Washington DC for 9 years and in West Africa for 12 years. With funding from USAID, the French Cooperation or the European Union, and in partnership with local authorities and organizations such as UNICEF and WHO, he supported the design, implementation and evaluation of global, national or local public health programs. Malick is a physician with a Medical Doctorate from Dakar School of Medicine in Senegal, a Master's in Business Administration from the Paris School of Business – Institut Superieur de Gestion and a Masters in Public Health from Tulane University, Louisiana.

Isabel Garcia, D.D.S., M.P.H., joined the University of Florida College of Dentistry as dean on Feb. 16, 2015, after retiring from the U.S. Public Health Service in 2014 as a rear admiral lower half. Garcia's career spans 37 years in public health, clinical practice, research, teaching and administration at the local, state and national levels. Garcia joined the National Institute of Dental and Craniofacial Research at the NIH in 1995 and held multiple leadership roles during her time there. She led NIDCR's science transfer efforts, directed the Institute's Office of Science Policy and Analysis, and served as acting NIDCR director from 2010-2011. Garcia also served as the institute's coordinator for global health and directed NIDCR's Residency in Dental Public Health program from 2005 to 2014. While with the USPHS, Garcia was deployed to help prepare a major health diplomacy mission to Central and South America, which provided care to over 85,000 people in 12 countries.
As deputy director of NIDCR from 2007-2014, she shared responsibility for the oversight and management of programs and functions within the institute — which included a staff of more than 400 scientists and administrators dedicated to research, training, science policy, health education, communications and financial management. Garcia received a doctorate in dental surgery in 1980 from Virginia Commonwealth University and a master's degree in public health from the University of Michigan in 1988. She subsequently completed a residency in dental public health at the University of Michigan and a fellowship in primary care policy from the U.S. Public Health Service. A fellow of the American College of Dentists and the Pierre Fauchard Academy, Dr. Garcia is a diplomate and Past President of the American Board of Dental Public Health and an active member of the American Dental Education Association, the International Association for Dental Research, and the American Dental Association.

Lawrence Gostin, J.D., is University Professor (Georgetown University's highest academic rank) and the Founding Linda and Timothy O'Neill Professor of Global Health Law at Georgetown University, Professor of Public Health at Johns Hopkins University, Director of the O'Neill Institute on National and Global Law, and Director of the WHO Collaborating Center on Public Health Law and Human Rights at the Georgetown University Law Center. He is a global correspondent and contributing writer for JAMA, the journal of the American Medical Association. In 2016, President Obama appointed him to a six-year term on the National Cancer Advisory Board.

Andrew Kanter, M.D., M.P.H., FACMI, is Assistant Professor of Clinical Biomedical Informatics and Clinical Epidemiology at Columbia University. Interested in application of ICT to health in the developing world, he has worked or traveled in more than 50 countries. Prior to joining Columbia, he recently spent 12 years with a private medical informatics company where he helped develop the Healthmatics EHR now being sold by Allscripts in addition to providing medical terminology and consulting services to other electronic medical record companies. He is currently appointed to Columbia University full-time in the Departments of Biomedical Informatics (College of Physicians & Surgeons) and Epidemiology (Mailman School of Public Health) and previously supported the development and implementation of the Millennium Villages Global-Network (MVG-Net) for the Millennium Villages Project (MVP). He directs the Columbia International eHealth Lab (CIEL) in the Department of Biomedical Informatics which supports eHealth work around the world. His work focuses on bringing real-world solutions to resource-poor settings to help them achieve the Millennium Development Goals.

Karestan Koenen, Ph.D., does research and teaches about trauma and posttraumatic stress disorder (PTSD). The broad goal of her work is three-fold. First, she studies why, when exposed so a similar traumatic event, some persons develop PTSD while others are resilient. She is particularly interested in how genes shape risk for PTSD. Much of this work is done through the PTSD working group of the Psychiatric Genomics Consortium that she co-leads with Kerry Ressler and Israel Liberzon. Second, she investigates how trau ma and PTSD influence weight gain and alter long-term physical health including chronic diseases such as cardiovascular disease and type-2-diabetes. Third, she documents global burden of trauma and PTSD through her work with the World Mental Health Surveys. Dr. Koenen also advocates for victims of sexual violence. In May 2011, Dr. Koenen testified before the House Foreign Affairs Full Committee about the epidemic of sexual violence and victim blaming culture of the Peace Corps. She has written for the Boston Globe, the Washington Post, the Huffington Post, and the Women's Media Center's Women Under Siege Project, a journalism project founded by Gloria Steinem that investigates how rape and other forms of sexualized violence are used as tools in conflict. Dr. Koenen also consulted with award-winning documentary filmmaker Lisa Jackson on the film It Happened Here, which investigates the epidemic of sexual assault on university campuses. Dr. Koenen currently lives in Boston. When not working, she is likely taking a yoga class or spending time with her son, Lorcan.

Orin Levine, Ph.D., leads the foundation's efforts to accelerate the introduction of new vaccines and related technologies and to improve routine immunization systems. He is the Foundation's focal point for engagement with the GAVI Alliance whose mission is saving children's lives by increasing access to immunization in poor countries. Before joining the foundation's Global Development Program in 2012, Dr. Levine was a Professor of International Health, and Executive Director of the International Vaccine Access Center (IVAC) at the Johns Hopkins University's Bloomberg School of Public Health. He has also served as a Steering Committee Member of the Decade of Vaccines Collaboration and Co-Chair of its Global Access Working Group, as well as President, Committee on Global Health, American Society of

Tropical Medicine & Hygiene. Dr. Levine graduated with a Bachelor's degree from Gettysburg College and received a PhD in epidemiology from The Johns Hopkins Bloomberg School of Public Health.

Maureen Lichtveld, M.D., M.P.H., is Professor and Chair of Environmental Health Sciences in the School of Public Health and Tropical Medicine at Tulane University. Dr. Lichtveld's career in environmental public health spans more than 30 years. Her research focuses on environmentally induced diseases including asthma and cancer, health disparities, environmental health policy, disaster preparedness, and public health systems. Her global health expertise is focused on lower and middle income countries in the Caribbean, a region faced with recurring infectious disease epidemics, a significant NCD burden natural disasters, and unprecedented environmental health threats.

Gbenga Ogedegbe, M.D., M.P.H., M.S., a physician, is the Adolph & Margaret Berger Professor of Population Health & Medicine, Chief Division of Health & Behavior and Director Center for Healthful Behavior Change in the Department of Population Health at New York University School of Medicine. Gbenga is a leading expert on health disparities research; his work focuses on the implementation of evidence-based interventions for cardiovascular risk reduction in minority populations. He is Principal Investigator on numerous NIH projects, and has expanded his work globally to Sub-Saharan Africa where he is funded by the NIH to strengthen research capacity and reduce the burden of noncommunicable diseases. He has co-authored over 250 publications and his work has been recognized by receipt of several research and mentoring awards including the prestigious John M. Eisenberg Excellence in Mentorship Award from the Agency for Healthcare Research and Quality, and the Daniel Savage Science Award. He has served on numerous scientific panels including the NIH, CDC, World Health Organization, and the European Union Research Council. Prior to joining NYU, he was faculty at Cornell Weill Medical School and Columbia University College of Physicians and Surgeons.

Scott C. Ratzan, M.D., M.P.A., is Senior Fellow at the Mossavar-Rahmani Center for Business & Government at Harvard Kennedy School of Government. Dr. Ratzan has three decades of pioneering accomplishments in the U.S. and globally in health communication, health literacy and strategic diplomacy. He is the founding Editor-in-Chief of the Journal of Health Communication: International Perspectives. He has been engaged in multidisciplinary activities related to global health including as President of the ABInBev Foundation and Vice President of Global Health and Social Impact at ABInBev. Dr. Ratzan was at Johnson & Johnson for eleven years including as Vice President of Global Health at headquarters and also in Brussels as VP Government Affairs & Policy. Before his private sector engagement, he worked at the US Agency for International Development (USAID) in Washington DC, designing the framework for the Bureau of Global Health communication efforts. He launched his career in Boston spending a decade in academia as a professor and Founding Director of the Emerson-Tufts Masters Program in Health Communication. In addition to a number of publications in the global health field, he is the co-author of the definition of health literacy adopted by the US Government and incorporated in the Affordable Care Act. Recently, he has served as Co-Chair of the UN Secretary General's Every Woman Every Child Innovation Working Group, on the U.S. Centers for Disease Control and Prevention, Board of Scientific Counselors, Office of Infectious Disease and on the World Economic Forum Global Agenda Council on Well-Being and Mental Health. Dr. Ratzan has an M.D. from the University of Southern California, an M.P.A. from the Harvard Kennedy School, and an M.A. in Communication from Emerson College. His academic appointments include Adjunct Professor at Columbia University Mailman School of Public Health, Tufts University School of Medicine, and George Washington University School of Public Health.

Carlos del Rio, M.D., is a Distinguished Professor of Medicine in the Division of Infectious Diseases at Emory University School of Medicine and Executive Associate Dean for Emory at Grady. He is also

Professor of Global Health in the Department of Global Health and Professor of Epidemiology at the Rollins School of Public Health. He is also co-Director of the Emory Center for AIDS Research (CFAR) and co-PI of the Emory-CDC HIV Clinical Trials Unit and the Emory Vaccine and Treatment Evalaution Unit. Dr. del Rio is a native of Mexico where he attended medical school at Universidad La Salle, graduating in 1983. He did his Internal Medicine and Infectious Diseases residencies at Emory University. In 1989 he returned to Mexico where he was Executive Director of the National AIDS Council of Mexico (CONASIDA, the Federal agency of the Mexican Government responsible for AIDS Policy throughout Mexico), from 1992 through 1996. In November of 1996 he returned to Emory where he has been involved in patient care, teaching and research. Dr. del Rio was Chief of the Emory Medical Service at Grady Memorial Hospital from 2001 - 2009 and Chair of the Department of Global Health from 2009 - 2019. Dr. del Rio's research focuses on the early diagnosis, access to care, engagement in care, compliance with antiretrovirals and the prevention of HIV infection. He has worked for over a decade with hard-to-reach populations including substance users to improve outcomes of those infected with HIV and to prevent infection with those at risk. He is also interested in the translation of research findings into practice and policy. His international work includes collaborations in the country of Georgia, Ethiopia, Vietnam, Mexico, Kenya and Thailand. He has also worked on emerging infections such as pandemic influenza and was a member of the WHO Influenza A(H1N1) Clinical Advisory Group and of the CDC Influenza A(H1N1) Task Force during the 2009 pandemic. Dr. del Rio is a Member of the Board of Directors of the International Antiviral Society-USA (IAS-USA) and was a Board member and Chair of HIVMA of the Infectious Diseases Society of America (IDSA). He is a also the Chair of the PEPFAR Scientific Advisory Board. He is Chief Section Editor for HIV/AIDS for NEJM Journal Watch Infectious Diseases, Associate Editor for Clinical Infectious Diseases and member of the editorial board of Journal of AIDS and Global Public Health. Dr. del Rio has co-authored 30 book chapters and over 350 scientific papers. Among his many honors are the James H. Nakano Citation received in 2001 and awarded by the CDC for an outstanding scientific paper published in 2000; the Emory University Marion V. Creekmore Achievement Award for Internationalization; he was selected by the "Atlanta Magazine" as one of the 55 most influential foreign born Atlantans in 2007. In 2013 Dr. del Rio was elected to the National Academy of Medicine and in 2020 was elected as Foreign Secretary of the National Academy of Medicine.

Sarah Tishkoff, Ph.D., M.Phil., is the David and Lyn Silfen University Professor in Genetics and Biology at the University of Pennsylvania, holding appointments in the School of Medicine and the School of Arts and Sciences. Dr. Tishkoff studies genomic and phenotypic variation in ethnically diverse Africans. Her research combines field work, laboratory research, and computational methods to examine African population history and how genetic variation can affect a wide range of practical issues – for example, why humans have different susceptibility to disease, how they metabolize drugs, and how they adapt through evolution. Dr. Tishkoff is a member of the National Academy of Sciences and a recipient of an NIH Pioneer Award, a David and Lucile Packard Career Award, a Burroughs/Wellcome Fund Career Award, and a Penn Integrates Knowledge (PIK) endowed chair. She is a member of the board of directors of the American Society of Human Genetics and is on the editorial boards at PLOS Genetics, Genome Research; Evolution, Medicine, and Public Health; G3 (Genes, Genomes, and Genetics). Her research is supported by grants from the National Institutes of Health and the National Science Foundation.

CONSENSUS STUDY PROPOSAL

Emerging Infections: Global Health Security, Disease X, and the Future Pandemic Threat

The Institute of Medicine (IOM) first tackled the issue of microbial threats in their 1992 report *Emerging Infections: Microbial Threats to Health in the United States.* This report highlighted the need for a domestic response and preparedness capacity for new and emerging infectious diseases. Since that time, the global burden of infectious disease has increased, as have threats to the United States. The 2003 IOM report, *Microbial Threats to Health: Emergence, Detection, and Response*, written in the aftermath of the anthrax attacks in the United States, served as a successor to this report and called for improved surveillance, diagnostics, vaccines, antimicrobials and a global response capacity. However, in the 16 years since this report was published, the pandemic threat has continued to grow, and our surveillance, response and prevention strategy continues to be challenged. For example:

- Outbreaks of Ebola have increased in size and number, spilled beyond borders, and threatened regional health and security
- New diseases have emerged and rapidly spread globally, including the current 2019-nCoV, Middle East Respiratory Syndrome, H1N1 triple reassortant influenza, and Zika virus
- Vaccine-preventable diseases, measles in particular, have increased in multiple countries, and many, including the United States, may soon lose elimination status
- Outbreaks of old diseases, such as plague and cholera, have re-emerged in many countries
- Antibiotic-resistant pathogens have increased, and present one of the biggest threats to global health today

With each crisis, we learn new lessons, leading to new tactics to counter the pandemic threat:

- The World Health Organization created a senior management emergency response capacity
- The World Bank created the Pandemic Emergency Financing (PEF) Facility
- The Inter-Agency Standing Committee of the UN coordinates international organizations to provide humanitarian assistance during pandemics
- The Global Preparedness Monitoring Board (GPMB) was co-convened by the World Bank Group and the World Health Organization
- The African Centers for Disease Control was established
- The Coalition for Epidemic Preparedness Innovations was launched to expand the vaccine and therapeutics pipeline for new and rare infections
- National and regional networks have been established to build capacity to control and prevent emerging infections

Despite these initiatives, we are still in 'catch-up' mode in our fight against pandemics. The global response to outbreaks is often significant, but interest wanes between them, leaving preparedness

plans, vaccine and countermeasure development at the mercy of cyclical funding patterns. We face daunting microbial diversity in nature and, in our rapidly changing planet we have provided perfect conditions for new microbes to emerge. Megatrends of demographic and environmental changes, globalized travel and trade, and lack of health capacity characterize the most important disease hotspots. Our armory of vaccines and therapeutics is based on pathogens that have already emerged, and has failed to scale up in the face of a new pandemic. Finally, there is still no agreed-upon response strategy for a global pandemic. The GPMB's first annual report released in 2019 concluded that most countries have not implemented recommendations called for over previous years and identified seven urgent actions in country leadership, preparation, financial planning and international coordination.

The National Academies of Sciences, Engineering, and Medicine proposes to convene an expert committee to provide new recommendations on our strategy to deal with the complexity of emerging diseases. It will build upon recommendations from the previous IOM reports, expert committees that reviewed our global response to SARS, H1N1, MERS, and Ebola, and the global mandates expounded by the GPMB and the GHSA. The committee will identify key trends in the intervening years and what we can expect in the future, which recommendations have been implemented, and what the remaining gaps are. It will critically review the following initiatives, issues and megatrends that have emerged since the last report to identify which most effectively impact our national and global response:

- The role of One Health in preventing, detecting and responding to disease threats
- Evaluation of recently launched programs such as the
    - Global Health Security Agenda and Joint External Evaluations
    - New International Health Regulations
    - Sustainable Development Goals
    - Pandemic Emergency Financing Facility
- The impact of climate change and other global environmental changes on infectious disease transmission and outbreak risk, and mitigation strategies to deal with them
- Use of social media and big data in detecting and responding to pandemics
- The economic impact of outbreaks and economic incentives for preparedness
- Interactions of poverty, equity, and non-communicable diseases on EIDs, and how endemic and emerging disease programs can be leveraged more effectively
- Linkages between plant diseases, agriculture, food security and human infections
- Advances in our understanding of the ecology of microbes, the socio-economic and environmental drivers of disease emergence, and how this might be used to predict and prevent pandemics.

Most importantly, this report will, for the first time, bring together lessons from over 15 years of pandemic response to identify strategies in our fight against future pandemics. Disease pandemics are no longer just a health issue – they are emergencies that need an all of government response. They require international leadership, multilateral coordination, and public support on the frontline of outbreaks, and in the countries that support the response. In the age of Disease X, this report will provide a pathway towards preventing pandemics, and identify consensus strategies to break free from the cycle of pandemic emergence and response.

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; Laurie, Ximena (lauriex@who.int)[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: hxtan@unimelb.edu.au[hxtan@unimelb.edu.au]; mit666666@pitt.edu[mit666666@pitt.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; Vasan Vasan[Vasan.Vasan@csiro.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.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]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@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]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.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]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; PREZIOSI, Marie-pierre[preziosim@who.int]; Laurie, Ximena (lauriex@who.int)[lauriex@who.int]; Amy C. Shurtleff[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]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.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]; Enjuanes_Luis[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]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; rkiatchula@gmail.com[rkiatchula@gmail.com]; tverakit@gmail.com[tverakit@gmail.com]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; langermans@bprc.nl[langermans@bprc.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; B. Rockx[b.rockx@erasmusmc.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[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]; dbolton@hivresearch.org[dbolton@hivresearch.org]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; 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[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]; Diamond, Michael[mdiamond@wustl.edu]; 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]; 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]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Amelia Karlsson[amelia.karlsson@duke.edu]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org];

fkoide@southernresearch.org[fkoide@southernresearch.org]; Krammer, Florian[florian.krammer@mssm.edu]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Levis, Robin[robin.levis@fda.hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; cjmiller@ucdavis.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[dmissiak@bsd.uchicago.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; DAVID H O'CONNOR[dhoconno@wisc.edu]; mto@umn.edu[mto@umn.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; Peter Palese[peter.palese@mssm.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Juergen Richt[jricht@vet.k-state.edu]; Chad Roy[croy@tulane.edu]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Padmini Salgame[salgampa@njms.rutgers.edu]; erica@lji.org[erica@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Michael Schotsaert[michael.schotsaert@mssm.edu]; sivkog@battelle.org[sivkog@battelle.org]; Spergel, Jonathan[SPERGEL@email.chop.edu]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Elizabeth Sulkowski[elizabethsulkowski44@gmail.com]; nax3@cdc.gov[nax3@cdc.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; sktseng@utmb.edu[sktseng@UTMB.EDU]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Wang, Tony[tony.wang@fda.hhs.gov]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; White, Alexander G[agw13@pitt.edu]; seos@cnu.ac.kr[seos@cnu.ac.kr]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 9/23/2020 5:39:27 AM (UTC-04:00)
Subject: WHO COVID-19 Animal Models Group Call-Thursday 24 3PM CET
Mail Attachment.ics
Webex_Meeting.ics

Dear all,

Please find below the agenda for our WHO COVID-19 Animal Models group call this Thursday, which will be focused on therapeutics.

Best regards

César, Bill and Simon.

Agenda-WHO COVID-19 Animal Models Group Call Thursday 24 3PM CET

Focus: Development of COVID-19 therapies in Animal Models

1- Hyon-Xhi Tan (University of Melbourne)

2- Dimiter Dimitrov (University of Pittsburgh)

3- Qin Chuan (Peking Union Medical College)

Focused group discussion

* Considering that no animal model so far recapitulates SARS-CoV-2 infection-associated ARDS, what is the value of animal models to test COVID-19 rescue therapeutics?

* Are there any efforts directed at testing combination therapies (e. g. antibodies + antivirals)? And if not, why?

* How likely is that host-targeted therapies with promising results in animal models translate well into human therapies?

* Can the current animal models help in the development of COVID-19 post-exposure prophylaxis?

Meeting number (access code): 145 833 9541
Meeting password: tEuvsJMx284

Thursday, September 24, 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] 30th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=m0b41629fd50da464c0c7b08cdb2f521d
Start Time: 2020-09-24T15:00:00+02:00
End Time: 2020-09-24T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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

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Organizer: Pierre GSELL : gsellp@who.int
Subject: [COVID-19] 30th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=m0b41629fd50da464c0c7b08cdb2f521d
Start Time: 2020-09-24T15:00:00+02:00
End Time: 2020-09-24T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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To: Diane Griffin[dgriffi6@jhmi.edu]; Rusek, Benjamin[BRusek@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]; 'harvey.fineberg@moore.org'[harvey.fineberg@moore.org]; 'peggy@hbfam.net'[peggy@hbfam.net]; 'jwleduc@UTMB.EDU'[jwleduc@UTMB.EDU]; 'peshi@UTMB.EDU'[peshi@UTMB.EDU]; Dzau, Victor J.[VDzau@nas.edu]; Nancy Connell[NancyConnell@jhu.edu]; Dave Franz (davidrfranz@gmail.com)[davidrfranz@gmail.com]
Cc: 'fsharples_3@hotmail.com'[fsharples_3@hotmail.com]; Lowenthal, Micah[mlowenth@nas.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Alison Andre[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]
From: Peter Daszak[daszak@ecohealthalliance.org]
Sent: Thur 9/24/2020 12:45:12 AM (UTC-04:00)
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14

Happy to take part and look forward to the discussions. I know that the WHO team are planning their deeper dive into the animal reservoir question for COVID-19 origins, and it might be good to ask a couple of questions on animal infections that are not controversial, e.g.:

1. We have heard that there are policy measures under review to significantly reduce the wildlife trade, including closing down wildlife farms. Are there plans to test animals before they are killed, e.g. civets, raccoon dogs, bamboo rats, to see if they have had exposure to SARS-CoV-2?

2. We realize that the bat coronaviruses with the closest relationship to SARS-CoV-2 are not the parental strain, but more like fairly distant relatives. Are there plans to do more bat sampling, and try to identify viruses that are closer to SARS-CoV-2 than those nearest viruses (RaTG13 and RmYN02)?

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
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: Diane Griffin <dgriffi6@jhmi.edu>
Sent: Tuesday, September 22, 2020 7:20 AM
To: Rusek, Benjamin <BRusek@nas.edu>; 'relman@stanford.edu' <relman@stanford.edu>; rbaric_email.unc <rbaric@email.unc.edu>; 'saif.2@osu.edu' <saif.2@osu.edu>; 'stanley-perlman@uiowa.edu' <stanley-perlman@uiowa.edu>; Peter Daszak <daszak@ecohealthalliance.org>; 'harvey.fineberg@moore.org' <harvey.fineberg@moore.org>; 'peggy@hbfam.net' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'peshi@UTMB.EDU' <peshi@UTMB.EDU>; Dzau, Victor J. <VDzau@nas.edu>; Nancy Connell <NancyConnell@jhu.edu>; Dave Franz (davidrfranz@gmail.com) <davidrfranz@gmail.com>
Cc: 'fsharples_3@hotmail.com' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; antoinette_baric.med <antoinette_baric@med.unc.edu>; Alison Andre <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>

Subject: Re: Virtual U.S. China dialogue meeting October 13 and 14

Ben - I can participate.

Diane

Diane E. Griffin, MD PhD
Vice President, National Academy of Sciences
University Distinguished Service Professor
W. Harry Feinstone Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe St, Rm E5636
Baltimore, MD 21205
410-955-3459
dgriffi6@jhu.edu

From: Rusek, Benjamin <BRusek@nas.edu>
Sent: Monday, September 21, 2020 9:00 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>; Diane Griffin <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>; Nancy Connell <NancyConnell@jhu.edu>; Dave Franz (davidrfranz@gmail.com) <davidrfranz@gmail.com>
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>
Subject: Virtual U.S. China dialogue meeting October 13 and 14

Greetings,

I hope you all had a good summer and are staying safe and healthy. The Chinese Academy of Sciences has agreed to hold another (4th) virtual bio dialogue meeting with NASEM on **1) vaccine development and delivery** and **2) immunity, testing and diagnostics.** The agreed topics for the session are below. **We have reserved Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT**) to discuss the topics on the agenda.

We hope you are able to participate. Please let me know if you are available and if so save the dates and times on your calendar. We will get back to you with more information and a detailed agenda for the sessions soon.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Vaccine development and delivery

Human

1) **Current status of CoVID-19 vaccine development in China and the U.S.**
2) **Chinse vaccination of military personnel and other Chinese populations**

3) **Vaccination of pediatric populations**
4) **Active surveillance strategies for monitoring adverse events observed after vaccination (as well as immunogenicity)**
5) **Adapting current vaccine platforms to novel mass vax strategies and other mass vaccination strategic issues**
6) **Progress on a universal influenza vaccines**
7) **Vaccine for enterovirus D68**

Animal

1) **Status of corona virus vaccination for animals - kinds of vaccine, efficacy, complications, etc**
2) **ASF in China and ASF vaccine progress**
3) **New swine coronavirus**
4) **Vaccination strategy for H5N1 avian influenza and domestic poultry**

Immunity, testing and diagnostics

1) **Correlates of immunity including the possibility of background immunity from circulating "common cold" coronaviruses**
2) **Chinese diagnostic testing strategies for testing large populations quickly**
3) **Antibody and antibody testing topics, importance of T-cell responses**
4) **Long-term sequela following COVID-19 infection—lung function, neurologic issues, others**

From: Rusek, Benjamin
Sent: Thursday, June 4, 2020 1:25 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>; 'Nancy Connell' <NancyConnell@jhu.edu>
Subject: RE: 3rd Virtual U.S. China dialogue meeting on COVID-19 Tuesday, June 9, 9-11PM ET
Importance: High

Greetings,

I have attached the American version of the agenda for the 3rd U.S. China virtual dialogue meeting on immunity and related topics set to take place on **Tuesday night, June 9 from 9:00-11:00 PM ET** (9-11 AM the next morning, Beijing time).

As you can see we have incorporated George Gao's questions into the agenda, we hope that **Harvey Fineberg** can provide information on and lead the discussion of 1) serologic investigation in the U.S. 2) strategy in the U.S. for the second half of this year 3) vaccine availability in the U.S. and that **Ralph Baric** can do the same re progress in the development of vaccine in the U.S. (especially mRNA vaccine).

We have also listed delegation member names after the other Immunity questions. Like previously, folks are listed simply so someone is responsible for getting an answer from the Chinese to each question during the discussion. I will send a version to CAS without those names listed but will let them know who we have asked to answer George's questions.

Please let us know if you have any thoughts or comments on the agenda or this plan. I will send you the Zoom link later tonight or tomorrow morning.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, June 1, 2020 10:03 AM
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 Tuesday, June 9, 9-11PM ET
Importance: High

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

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; Laurie, Ximena (lauriex@who.int)[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: sandra cordo[scordo@qb.fcen.uba.ar]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; Vasan Vasan[Vasan.Vasan@csiro.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.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]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@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]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.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]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; PREZIOSI, Marie-pierre[preziosim@who.int]; Laurie, Ximena (lauriex@who.int)[lauriex@who.int]; Amy C. Shurtleff[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]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.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]; Enjuanes_Luis[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]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; rkiatchula@gmail.com[rkiatchula@gmail.com]; tverakit@gmail.com[tverakit@gmail.com]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; langermans@bprc.nl[langermans@bprc.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; B. Rockx[b.rockx@erasmusmc.nl]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[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]; SINA BAVARI[sinabavari@comcast.net]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; dbolton@hivresearch.org[dbolton@hivresearch.org]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; 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[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]; Diamond, Michael[mdiamond@wustl.edu]; 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]; 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]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Amelia Karlsson[amelia.karlsson@duke.edu]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; fkoide@southernresearch.org[fkoide@southernresearch.org]; Krammer, Florian[florian.krammer@mssm.edu];

philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Levis, Robin[robin.levis@fda.hhs.gov]; Dr. Mark Lewis[mlewis@bioqual.com]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; cjmiller@ucdavis.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[dmissiak@bsd.uchicago.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; DAVID H O'CONNOR[dhoconno@wisc.edu]; mto@umn.edu[mto@umn.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; Palese, Peter[peter.palese@mssm.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Juergen Richt[jricht@vet.k-state.edu]; Chad Roy[croy@tulane.edu]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Padmini Salgame[salgampa@njms.rutgers.edu]; erica@lji.org[erica@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Michael Schotsaert[michael.schotsaert@mssm.edu]; sivkog@battelle.org[sivkog@battelle.org]; Spergel, Jonathan[SPERGEL@email.chop.edu]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Elizabeth Sulkowski[elizabethsulkowski44@gmail.com]; nax3@cdc.gov[nax3@cdc.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; sktseng@utmb.edu[sktseng@UTMB.EDU]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Wang, Tony[tony.wang@fda.hhs.gov]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; White, Alexander G[agw13@pitt.edu]; seos@cnu.ac.kr[seos@cnu.ac.kr]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; Benjamin tenOever[tenoever@gmail.com]; Pamela.Proud@phe.gov.uk[Pamela.Proud@phe.gov.uk]
From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 9/30/2020 11:05:59 AM (UTC-04:00)
Subject: WHO COVID-19 Animal Models group call-Thursday Oct 1st
Mail Attachment.ics
Webex_Meeting.ics

Dear all,
Please find below the agenda for our group call that as usual will take place this Thursday Oct 1st at 3PM CET (Geneva time).

Best regards

César, Simon and Bill

Agenda- WHO COVID-19 Animal Models Group Call

1- Pamela Proud (Public Health England)

2- Benjamin TenOever (Mount Sinai, NY)

3- Brad Pickering (Canadian Food Inspection Agency)

Open questions

Meeting number (access code): 145 153 3614
Meeting password: GvFppDra365

Thursday, October 1, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Subject: [COVID-19] 31st WHO TC - Animal Models
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Start Time: 2020-10-01T15:00:00+02:00
End Time: 2020-10-01T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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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]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; roger.le-grand@cea.fr[roger.le-grand@cea.fr]; sandrine.lesellier@anses.fr[sandrine.lesellier@anses.fr]; pauline.maisonnasse@cea.fr[pauline.maisonnasse@cea.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Martin.Beer@fli.de[Martin.Beer@fli.de]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Bernhard.Kerscher@pei.de[Bernhard.Kerscher@pei.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; ThomasC.Mettenleiter@fli.de[ThomasC.Mettenleiter@fli.de]; munoz-fontela@bnitm.de[munoz-fontela@bnitm.de]; estefania.rodriguez@bnitm.de[estefania.rodriguez@bnitm.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; carolyn.clark@cepi.net[carolyn.clark@cepi.net]; william.dowling@cepi.net[william.dowling@cepi.net]; gsellp@who.int[gsellp@who.int]; henaorestrepoa@who.int[henaorestrepoa@who.int]; knezevici@who.int[knezevici@who.int]; moorthyv@who.int[moorthyv@who.int]; preziosim@who.int[preziosim@who.int]; lauriex@who.int[lauriex@who.int]; amy.c.shurtleff@cepi.net[amy.c.shurtleff@cepi.net]; swaminathans@who.int[swaminathans@who.int]; cdang@lcr.org[cdang@lcr.org]; woodd@who.int[woodd@who.int]; jfwchan@hku.hk[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; nirp@iibr.gov.il[nirp@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.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]; 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b.rockx@erasmusmc.nl[b.rockx@erasmusmc.nl]; stittelaar@viroclinics.com[stittelaar@viroclinics.com]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; Neil.Berry@nibsc.org[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@nibsc.org[Mark.Page@nibsc.org]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Ann Rawkins[Ann.Rawkins@phe.gov.uk]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally Sharpe[Sally.Sharpe@phe.gov.uk]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Julia Tree[Julia.Tree@phe.gov.uk]; randy.albrecht@mssm.edu[randy.albrecht@mssm.edu]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Baric, Ralph S[rbaric@email.unc.edu]; dbarouch@bidmc.harvard.edu[dbarouch@bidmc.harvard.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; dbolton@hivresearch.org[dbolton@hivresearch.org]; mopargal@rams.colostate.edu[mopargal@rams.colostate.edu]; trbrasel@UTMB.EDU[trbrasel@UTMB.EDU]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; abukreye@utmb.edu[abukreye@utmb.edu]; rcarrion@txbiomed.org[rcarrion@txbiomed.org]; scartner@uab.edu[scartner@uab.edu]; fcassels@path.org[fcassels@path.org]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; que.dang@nih.gov[que.dang@nih.gov]; emmie.dewit@nih.gov[emmie.dewit@nih.gov]; mdiamond@wustl.edu[mdiamond@wustl.edu]; edohm@uab.edu[edohm@uab.edu]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; 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lisa.hensley@nih.gov[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]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; amelia.karlsson@duke.edu[amelia.karlsson@duke.edu]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; fkoide@southernresearch.org[fkoide@southernresearch.org]; florian.krammer@mssm.edu[florian.krammer@mssm.edu]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; david.lee-parritz@tufts.edu[david.lee-parritz@tufts.edu]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; mlewis@bioqual.com[mlewis@bioqual.com]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; James.Little@hhs.gov[James.Little@hhs.gov]; Tracy.MacGill@fda.hhs.gov[Tracy.MacGill@fda.hhs.gov]; Karen.Makar@gatesfoundation.org[Karen.Makar@gatesfoundation.org]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; dmissiak@bsd.uchicago.edu[dmissiak@bsd.uchicago.edu]; kmodjarrad@eidresearch.org[kmodjarrad@eidresearch.org]; vincent.munster@nih.gov[vincent.munster@nih.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; dhoconno@wisc.edu[dhoconno@wisc.edu]; mto@umn.edu[mto@umn.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; peter.palese@mssm.edu[peter.palese@mssm.edu]; stanley-perlman@uiowa.edu[stanley-perlman@uiowa.edu]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; alr2105@cumc.columbia.edu[alr2105@cumc.columbia.edu]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; jricht@vet.k-state.edu[jricht@vet.k-state.edu]; croy@tulane.edu[croy@tulane.edu]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; salgampa@njms.rutgers.edu[salgampa@njms.rutgers.edu]; erica@lji.org[erica@lji.org]; connie.schmaljohn@nih.gov[connie.schmaljohn@nih.gov]; michael.schotsaert@mssm.edu[michael.schotsaert@mssm.edu]; sivkog@battelle.org[sivkog@battelle.org]; SPERGEL@email.chop.edu[SPERGEL@email.chop.edu]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; elizabethsulkowski44@gmail.com[elizabethsulkowski44@gmail.com]; nax3@cdc.gov[nax3@cdc.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; sktseng@UTMB.EDU[sktseng@UTMB.EDU]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; tony.wang@fda.hhs.gov[tony.wang@fda.hhs.gov]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; agw13@pitt.edu[agw13@pitt.edu]; seos@cnu.ac.kr[seos@cnu.ac.kr]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; tenoever@gmail.com[tenoever@gmail.com]; rhakami@gmu.edu[rhakami@gmu.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; patrick.reid@unmc.edu[patrick.reid@unmc.edu]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; baczenas@wisc.edu[baczenas@wisc.edu]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Yann Le Duff[Yann.LeDuff@nibsc.org]; Kevin Richards[Kevin.Richards@phe.gov.uk]; Karen Osman[Karen.Osman@phe.gov.uk]; Rashid, Sujatha[srashid@atcc.org]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; baczenas@wisc.edu[baczenas@wisc.edu]; Neil Berry[Neil.Berry@nibsc.org]; Dr. Mark Lewis[mlewis@bioqual.com]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; KNEZEVIC, Ivana[knezevici@who.int]; kstemple@niaid.nih.gov[kstemple@niaid.nih.gov]

Cc: Bill Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; GSELL, Pierre[gsellp@who.int]; Alina Ximena RIVEROS BALTA (lauriex@who.int)[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]

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

Sent: Wed 10/7/2020 4:58:11 AM (UTC-04:00)

Subject: OFFICIAL: WHO COVID-19 Models Working Group Agenda - 8th October 2020

OFFICIAL

Dear all,

Please find below the agenda for our group call that as usual will take place this Thursday Oct 8th at 3PM CET (Geneva time).

Best regards,

César, Simon and Bill

Agenda for the WHO working group on COVID-19 models

1. S Funnell – introduction to the focus session on viral stock propagation 5 min
2. PHE – Kevin Richards and Karen Osman – comparative stock propagation and sequencing - 10 min
3. NIBSC – Yann LeDuff – comparative stock propagation and sequencing 10 min
4. NIAID/BEI – Clint Florence and Sujatha Rashid - comparative stock propagation and sequencing - 20 min
5. Mark Lewis and Shelby O'Connor – Sequencing of the stocks used for *in vivo* samples and some of the consequences – 15 min
6. Questions and discussion – 20 min
7. Announcement of the WHO RFP with a brief overview of the scope of the call – 5 min

Meeting number (access code): 145 340 7143

Meeting password: C7nzXBPTN63

Thursday, October 8, 2020

3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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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]; Cervenka, Nicole[NCervenka@nas.edu]; Sharples, Fran[FSharples@nas.edu]
From: Rusek, Benjamin[BRusek@nas.edu]
Sent: Fri 10/9/2020 5:42:45 PM (UTC-04:00)
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
October 2020 U.S.-China Bio Dialogue v3.docx

Greetings,

We are looking forward to the two virtual bio dialogue sessions set to take place on Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT) next week. Like in previous sessions we expect that the Chinese expert participants will lead the discussion on the majority of the topics and that the format will be more of a discussion among the participants instead of a series of formal presentations. I have attached an agenda that includes the Zoom connection links for both days along with the U.S. participant list. If I get the Chinese participant list before the session I will send that out to you all.

Feel free to respond to this email with any thoughts, points of emphasis or issues that you would like to discuss among the U.S. group before the sessions. Also let me know if you have any questions or concerns.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, September 21, 2020 9:01 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; Dave Franz (davidrfranz@gmail.com) <davidrfranz@gmail.com>
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>
Subject: Virtual U.S. China dialogue meeting October 13 and 14
Importance: High

Greetings,

I hope you all had a good summer and are staying safe and healthy. The Chinese Academy of Sciences has agreed to hold another (4th) virtual bio dialogue meeting with NASEM on **1) vaccine development and delivery** and **2) immunity, testing and diagnostics.** The agreed topics for the session are below. **We have reserved Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT)** to discuss the topics on the agenda.

We hope you are able to participate. Please let me know if you are available and if so save the dates and times on your calendar. We will get back to you with more information and a detailed agenda for the sessions soon.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Vaccine development and delivery

Human

1) **Current status of CoVID-19 vaccine development in China and the U.S.**
2) **Chinse vaccination of military personnel and other Chinese populations**
3) **Vaccination of pediatric populations**
4) **Active surveillance strategies for monitoring adverse events observed after vaccination (as well as immunogenicity)**
5) **Adapting current vaccine platforms to novel mass vax strategies and other mass vaccination strategic issues**
6) **Progress on a universal influenza vaccines**
7) **Vaccine for enterovirus D68**

Animal

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2) **ASF in China and ASF vaccine progress**
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Immunity, testing and diagnostics

1) **Correlates of immunity including the possibility of background immunity from circulating "common cold" coronaviruses**
2) **Chinese diagnostic testing strategies for testing large populations quickly**
3) **Antibody and antibody testing topics, importance of T-cell responses**
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Importance: High

Greetings,

I have attached the American version of the agenda for the 3rd U.S. China virtual dialogue meeting on immunity and related topics set to take place on **Tuesday night, June 9 from 9:00-11:00 PM ET** (9-11 AM the next morning, Beijing time).

As you can see we have incorporated George Gao's questions into the agenda, we hope that **Harvey Fineberg** can provide information on and lead the discussion of 1) serologic investigation in the U.S. 2) strategy in the U.S. for the second half of this year 3) vaccine availability in the U.S. and that **Ralph Baric** can do the same re progress in the development of vaccine in the U.S. (especially mRNA vaccine).

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- Could any US participant introduce the progress in the development of vaccine in the US, especially mRNA vaccine?
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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,

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October Bio Dialogue Virtual Sessions

Session 1: Tuesday, October 13, 9-11 PM ET / 6-8 PM PT in U.S.
Wednesday, October 14, 9-11 AM in China

Session 1 Meeting Link:
https://nasem.zoom.us/j/92754903815?pwd=OUV2R3BPdDdibDdZZ24vcGd4VmJoUT09
Password: 833624

Welcome and Introduction — Diane Griffin and George Gao

Overview of current status of CoVID-19 vaccine development in China — George Gao
Overview of current status of CoVID-19 vaccine development in the U.S.— Nancy Connell

Topic 1: Human vaccine development and delivery
Moderator: Diane Griffin

- Vaccination programs in China: How are vaccine programs for particular subpopulations being implemented?
    - Pediatric populations
    - First responders
    - Military personnel
    - Elderly population

- Post-vaccination surveillance and monitoring strategies
    - Immunogenicity
    - Monitoring Immunity
    - Vaccine-associated adverse events

- Adapting current vaccine platforms to novel mass vaccination: strategies and issues

- Progress on other vaccines
    - Universal influenza vaccines
    - Enterovirus D68

Topic 2: Animal vaccine development and delivery
Moderator: Linda Saif

- Status of corona virus vaccination for animals
    - Vaccine types
    - Efficacy
    - Complications and other issues?

- African Swine Fever: vaccine progress in China

- New “swine flu” (G4) in China

- H5N1 avian influenza and domestic poultry

Session 2: Wednesday October 14, 9-11 PM ET / 6-8 PM PT in U.S.
Thursday, October 15, 9-11 AM in China

Session 2 Meeting Link:
https://nasem.zoom.us/j/98420889232?pwd=NFllKzF1eWgxT0xDZHQzQWxMbnJPdz09
Password: 375761

Topic 1: Immunity
Moderator: Diane Griffin

- Correlates of immunity – biomarkers predicting susceptibility or progression to severe disease
- Background immunity from circulating "common cold" coronaviruses
- How long will immunity last?

Topic 2: Testing and diagnostics
Moderator: Peggy Hamburg

- Chinese testing strategies for rapid, frequent population-level testing
- Antibody testing
- Importance of T-cell responses
- Long-term sequelae following COVID-19 infection—lung function, neurologic issues, other issues

NASEM Participants

Dr. Ralph Baric, PhD, is a Professor in the Department of Epidemiology at the University of North Carolina's School of Public Health.

Dr. Nancy Connell, PhD, is a Professor at the Johns Hopkins Center for Health Security in Baltimore, MD

Dr. Peter Daszak, PhD, is currently president of EcoHealth Alliance, a nonprofit non-governmental organization that supports various programs on global health.

Dr. Victor Dzau, is the current President of the U.S. National Academy of Medicine in Washington, D.C.

Dr. David R. Franz, DVM, PhD, is currently retired, but served in the U.S. Army Medical Research and Materiel Command for 23 of 27 years on active duty and as Commander of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

Dr. Harvey Fineberg, MD, is currently president of the Gordon and Betty Moore Foundation, immediately prior to which he was President of the Institute of Medicine (now the National Academy of Medicine).

Dr. Diane Griffin, PhD, 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 and the current vice-president of the U.S. National Academy of Sciences.

Dr. Margaret (Peggy) Hamburg, MD, is an American physician and public health administrator. She served as the 21st Commissioner of the U.S. Food and Drug Administration from May 2009 to April 2015 and is currently Foreign Secretary for the U.S. National Academy of Medicine.

Dr. James Le Duc, PhD, is the director of the Galveston National Laboratory, one of the largest active biocontainment facilities on a U.S. academic campus.

Dr. Stanley Perlman, MD, PhD, is Professor of Microbiology and Immunology and of Pediatrics at the University of Iowa Health Care.

Dr. David Relman is a microbiologist and the Thomas C. and Joan M. Merigan Professor in Medicine and in Microbiology & Immunology at the Stanford University School of Medicine.

Dr. Linda J. Saif, PhD, is Distinguished University Professor, Department of Veterinary Preventive Medicine, Food Animal Health Research Program, Ohio Agricultural Research and Development Center of the Ohio State University.

Dr. Pei Yong Shi, PhD, is I.H. Kempner Professor of Human Genetics, University of Texas Medical Branch, Galveston Texas.

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From: Rusek, Benjamin[BRusek@nas.edu]
Sent: Mon 10/12/2020 12:36:05 PM (UTC-04:00)
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
October 2020 U.S.-China Bio Dialogue v3.docx

Greetings,

I have attached what should be the final agenda for the U.S. China dialogue meeting sessions on Tuesday, October 13 and Wednesday October 14. It includes the Chinese participant list at the end. Links to join the Zooms are also below.

Looking forward to seeing/talking to you all on Tuesday and Wednesday evening.

Kind regards,

Ben

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Greetings,

We are looking forward to the two virtual bio dialogue sessions set to take place on Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT) next week. Like in previous sessions we expect that the Chinese expert

participants will lead the discussion on the majority of the topics and that the format will be more of a discussion among the participants instead of a series of formal presentations. I have attached an agenda that includes the Zoom connection links for both days along with the U.S. participant list. If I get the Chinese participant list before the session I will send that out to you all.

Feel free to respond to this email with any thoughts, points of emphasis or issues that you would like to discuss among the U.S. group before the sessions. Also let me know if you have any questions or concerns.

Kind regards,

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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

October Bio Dialogue Virtual Sessions

Session 1: Tuesday, October 13, 9-11 PM ET / 6-8 PM PT in U.S.
Wednesday, October 14, 9-11 AM in China

Session 1 Meeting Link:
https://nasem.zoom.us/j/92754903815?pwd=OUV2R3BPdDdibDdZZ24vcGd4VmJoUT09
Password: 833624

Welcome and Introduction — Diane Griffin and George Gao

Overview of current status of CoVID-19 vaccine development in China — George Gao
Overview of current status of CoVID-19 vaccine development in the U.S.— Nancy Connell

Topic 1: Human vaccine development and delivery
Moderator: Diane Griffin

- Vaccination programs in China: How are vaccine programs for particular subpopulations being implemented?
  - Pediatric populations
  - First responders
  - Elderly population

- Post-vaccination surveillance and monitoring strategies
  - Immunogenicity
  - Monitoring Immunity
  - Vaccine-associated adverse events

- Adapting current vaccine platforms to novel mass vaccination: strategies and issues

- Progress on other vaccines
  - Universal influenza vaccines
  - Enterovirus D68

Topic 2: Animal vaccine development and delivery
Moderator: Linda Saif

- Status of corona virus vaccination for animals
  - Vaccine types
  - Efficacy
  - Complications and other issues?

- African Swine Fever: vaccine progress in China

- New “swine flu” (G4) in China

- H5N1 avian influenza and domestic poultry

Session 2: Wednesday October 14, 9-11 PM ET / 6-8 PM PT in U.S.
Thursday, October 15, 9-11 AM in China

Session 2 Meeting Link:
https://nasem.zoom.us/j/98420889232?pwd=NFllKzF1eWgxT0xDZHQzQWxMbnJPdz09
Password: 375761

Topic 1: Immunity
Moderator: Diane Griffin

- Correlates of immunity – biomarkers predicting susceptibility or progression to severe disease
- Background immunity from circulating "common cold" coronaviruses
- How long will immunity last?

Topic 2: Testing and diagnostics
Moderator: Peggy Hamburg

- Chinese testing strategies for rapid, frequent population-level testing
- Antibody testing
- Importance of T-cell responses
- Long-term sequelae following COVID-19 infection—lung function, neurologic issues, other issues

NASEM Participants

Dr. Ralph Baric, PhD, is a Professor in the Department of Epidemiology at the University of North Carolina's School of Public Health.

Dr. Nancy Connell, PhD, is a Professor at the Johns Hopkins Center for Health Security in Baltimore, MD

Dr. Peter Daszak, PhD, is currently president of EcoHealth Alliance, a nonprofit non-governmental organization that supports various programs on global health.

Dr. Victor Dzau, is the current President of the U.S. National Academy of Medicine in Washington, D.C.

Dr. David R. Franz, DVM, PhD, is currently retired, but served in the U.S. Army Medical Research and Materiel Command for 23 of 27 years on active duty and as Commander of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

Dr. Harvey Fineberg, MD, is currently president of the Gordon and Betty Moore Foundation, immediately prior to which he was President of the Institute of Medicine (now the National Academy of Medicine).

Dr. Diane Griffin, PhD, 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 and the current vice-president of the U.S. National Academy of Sciences.

Dr. Margaret (Peggy) Hamburg, MD, is an American physician and public health administrator. She served as the 21st Commissioner of the U.S. Food and Drug Administration from May 2009 to April 2015 and is currently Foreign Secretary for the U.S. National Academy of Medicine.

Dr. James Le Duc, PhD, is the director of the Galveston National Laboratory, one of the largest active biocontainment facilities on a U.S. academic campus.

Dr. Stanley Perlman, MD, PhD, is Professor of Microbiology and Immunology and of Pediatrics at the University of Iowa Health Care.

Dr. David Relman is a microbiologist and the Thomas C. and Joan M. Merigan Professor in Medicine and in Microbiology & Immunology at the Stanford University School of Medicine.

Dr. Linda J. Saif, PhD, is Distinguished University Professor, Department of Veterinary Preventive Medicine, Food Animal Health Research Program, Ohio Agricultural Research and Development Center of the Ohio State University.

Dr. Pei Yong Shi, PhD, is I.H. Kempner Professor of Human Genetics, University of Texas Medical Branch, Galveston Texas.

Chinese Participants

George F. Gao, Director-General, Chinese Center for Disease Control and Prevention, Member of Chinese Academy of Sciences

Zhiming Yuan, Professor, Director of Wuhan P4 Lab, Wuhan Institute of Virology, Chinese Academy of Sciences

Zhigao Bu, Director, Harbin Veterinary Research Institute, Chinese Academy of Agricultural Sciences (To be confirmed)

Jianping Weng, Executive Director, Division of Life Sciences and Medicine, University of Science and Technology of China

Xian-En Zhang, Professor, Institute of Biophysics, Chinese Academy of Sciences

Jinhua Liu, Professor, China Agricultural University

Aihua Zheng, Professor, Institute of Zoology, Chinese Academy of Sciences

Xi Zhou, Professor, Wuhan Institute of Virology, Chinese Academy of Sciences

Hongping Wei, Professor, Wuhan Institute of Virology, Chinese Academy of Sciences

Dong Men, Professor, Wuhan Institute of Virology, Chinese Academy of Sciences

Daming Wang, Suzhou Institute of Biomedical Engineering and Technology, Chinese Academy of Sciences

Lianpan Dai, Associate Professor, Institute of Microbiology, Chinese Academy of Sciences

Yong Hu, Associate Professor, Shenzhen Institutes of Advanced Technology, Chinese Academy of Sciences

To: Diane Griffin[dgriffi6@jhmi.edu]; Rusek, Benjamin[BRusek@nas.edu]; 'peggy@hbfam.net'[peggy@hbfam.net]; Shi, Pei yong[peshi@UTMB.EDU]; Nancy Connell[NancyConnell@jhu.edu]; 'Dave Franz (davidrfranz@gmail.com)'[davidrfranz@gmail.com]; Saif, Linda[saif.2@osu.edu]; Baric, Ralph S[rbaric@email.unc.edu]; "Harvey V. Fineberg" <harvey. fineberg@moore. org> (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; David A Relman[relman@stanford.edu]
Cc: Lowenthal, Micah[mlowenth@nas.edu]; Bowman, Katherine[KBowman@nas.edu]; 'Raymond JEANLOZ'[jeanloz@berkeley.edu]; Hare, Hope[HHare@nas.edu]; Sharples, Fran[FSharples@nas.edu]
From: LeDuc, James W.[jwleduc@UTMB.EDU]
Sent: Wed 10/14/2020 1:28:50 PM (UTC-04:00)
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
COVID-19 Summary of Discussions between NASEM and CAS on vaccines 13Oct2020.docx

Attached please find my notes from last night's discussion. Please edit and correct as needed; I'm sure I missed some things.

Excellent discussions. These are very valuable.

Thanks, Jim

James W. Le Duc, Ph.D.
Director
Galveston National Laboratory
University of Texas Medical Branch
Galveston, TX 77555-0610
(t) 409-266-6500
(f) 409-266-6810
(m) 409-789-2012

From: Diane Griffin <dgriffi6@jhmi.edu>
Sent: Wednesday, October 14, 2020 6:53 AM
To: Rusek, Benjamin <BRusek@nas.edu>; 'peggy@hbfam.net' <peggy@hbfam.net>; LeDuc, James W. <jwleduc@UTMB.EDU>; Shi, Pei yong <peshi@UTMB.EDU>; Nancy Connell <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
Cc: Lowenthal, Micah <mlowenth@nas.edu>; Bowman, Katherine <KBowman@nas.edu>; 'Raymond JEANLOZ' <jeanloz@berkeley.edu>; Hare, Hope <HHare@nas.edu>; Sharples, Fran <FSharples@nas.edu>
Subject: Re: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links

Ben - ok, thanks. I think that last night's session went well - clearly value in having these sessions relatively small and with people who now "know" each other.

See you tonight.

Diane

Diane E. Griffin, MD PhD
Vice President, National Academy of Sciences
University Distinguished Service Professor
W. Harry Feinstone Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe St, Rm E5636
Baltimore, MD 21205
410-955-3459
dgriffi6@jhu.edu

From: Rusek, Benjamin <BRusek@nas.edu>

Sent: Tuesday, October 13, 2020 8:54 PM
To: Diane Griffin <dgriffi6@jhmi.edu>; 'peggy@hbfam.net' <peggy@hbfam.net>; 'jwleduc@UTMB.EDU' <jwleduc@UTMB.EDU>; 'peshi@UTMB.EDU' <peshi@UTMB.EDU>; Nancy Connell <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
Cc: Lowenthal, Micah <mlowenth@nas.edu>; Bowman, Katherine <KBowman@nas.edu>; 'Raymond JEANLOZ' <jeanloz@berkeley.edu>; Hare, Hope <HHare@nas.edu>; Sharples, Fran <FSharples@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links

No major updates before we get started.

FYI Bu Zhigao from CAAS will not make it tonight and since Zhiming can't make the scheduled planning session next week we need to reschedule. I let CAS know that we would like at least Zhiming, George Gao, Zhengli Shi and maybe Mifang Liang as well as others who value and are interested in the dialogue and possible future topics to join the now to be scheduled planning call.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, October 12, 2020 12:36 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
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>; Cervenka, Nicole <NCervenka@nas.edu>; Sharples, Fran <FSharples@nas.edu>; Block, Bruce <BBlock@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
Importance: High

Greetings,

I have attached what should be the final agenda for the U.S. China dialogue meeting sessions on Tuesday, October 13 and Wednesday October 14. It includes the Chinese participant list at the end. Links to join the Zooms are also below.

Looking forward to seeing/talking to you all on Tuesday and Wednesday evening.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Session 1: Tuesday, October 13, **9-11 PM ET / 6-8 PM PT in U.S.**
Meeting Link: https://nasem.zoom.us/j/92754903815?pwd=OUV2R3BPdDdibDdZZ24vcGd4VmJoUT09
Password: 833624

Session 2: Wednesday October 14, **9-11 PM ET / 6-8 PM PT in U.S.**
Meeting Link: https://nasem.zoom.us/j/98420889232?pwd=NFllKzF1eWgxT0xDZHQzQWxMbnJPdz09
Password: 375761

From: Rusek, Benjamin
Sent: Friday, October 9, 2020 5:43 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
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>; Cervenka, Nicole <NCervenka@nas.edu>; Sharples, Fran <FSharples@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
Importance: High

Greetings,

We are looking forward to the two virtual bio dialogue sessions set to take place on Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT) next week. Like in previous sessions we expect that the Chinese expert participants will lead the discussion on the majority of the topics and that the format will be more of a discussion among the participants instead of a series of formal presentations. I have attached an agenda that includes the Zoom connection links for both days along with the U.S. participant list. If I get the Chinese participant list before the session I will send that out to you all.

Feel free to respond to this email with any thoughts, points of emphasis or issues that you would like to discuss among the U.S. group before the sessions. Also let me know if you have any questions or concerns.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, September 21, 2020 9:01 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; Dave Franz (davidrfranz@gmail.com) <davidrfranz@gmail.com>
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>
Subject: Virtual U.S. China dialogue meeting October 13 and 14
Importance: High

Greetings,

I hope you all had a good summer and are staying safe and healthy. The Chinese Academy of Sciences has agreed to hold another (4th) virtual bio dialogue meeting with NASEM on **1) vaccine development and delivery** and **2) immunity, testing and diagnostics.** The agreed topics for the session are below. **We have reserved Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT**) to discuss the topics on the agenda.

We hope you are able to participate. Please let me know if you are available and if so save the dates and times on your calendar. We will get back to you with more information and a detailed agenda for the sessions soon.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Vaccine development and delivery

Human

1) **Current status of CoVID-19 vaccine development in China and the U.S.**
2) **Chinse vaccination of military personnel and other Chinese populations**
3) **Vaccination of pediatric populations**
4) **Active surveillance strategies for monitoring adverse events observed after vaccination (as well as immunogenicity)**
5) **Adapting current vaccine platforms to novel mass vax strategies and other mass vaccination strategic issues**
6) **Progress on a universal influenza vaccines**
7) **Vaccine for enterovirus D68**

Animal

1) **Status of corona virus vaccination for animals - kinds of vaccine, efficacy, complications, etc**
2) **ASF in China and ASF vaccine progress**
3) **New swine coronavirus**
4) **Vaccination strategy for H5N1 avian influenza and domestic poultry**

Immunity, testing and diagnostics

1) **Correlates of immunity including the possibility of background immunity from circulating "common cold" coronaviruses**
2) **Chinese diagnostic testing strategies for testing large populations quickly**
3) **Antibody and antibody testing topics, importance of T-cell responses**
4) **Long-term sequela following COVID-19 infection—lung function, neurologic issues, others**

From: Rusek, Benjamin
Sent: Thursday, June 4, 2020 1:25 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>; 'Nancy Connell' <NancyConnell@jhu.edu>
Subject: RE: 3rd Virtual U.S. China dialogue meeting on COVID-19 Tuesday, June 9, 9-11PM ET
Importance: High

Greetings,

I have attached the American version of the agenda for the 3rd U.S. China virtual dialogue meeting on immunity and related topics set to take place on **Tuesday night, June 9 from 9:00-11:00 PM ET** (9-11 AM the next morning, Beijing time).

As you can see we have incorporated George Gao's questions into the agenda, we hope that **Harvey Fineberg** can provide information on and lead the discussion of 1) serologic investigation in the U.S. 2) strategy in the U.S. for the second half of this year 3) vaccine availability in the U.S. and that **Ralph Baric** can do the same re progress in the development of vaccine in the U.S. (especially mRNA vaccine).

We have also listed delegation member names after the other Immunity questions. Like previously, folks are listed simply so someone is responsible for getting an answer from the Chinese to each question during the discussion. I will send a version to CAS without those names listed but will let them know who we have asked to answer George's questions.

Please let us know if you have any thoughts or comments on the agenda or this plan. I will send you the Zoom link later tonight or tomorrow morning.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, June 1, 2020 10:03 AM
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 Tuesday, June 9, 9-11PM ET
Importance: High

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

Summary of Discussions between NASEM and CAS on COVID-19, 13Oct 2020

1. CAS (George Gao) provided an overview of the COVID-19 vaccine efforts underway in China. Key points were as follows:
    a. 7 different vaccine approaches are underway (list was shared)
    b. Range from classic inactivated vaccines to live, attenuated candidates
    c. Vaccine underdeveloped based on modified "cold adapted" influenza vaccine as a live, attenuated vaccine for COVID-19 following nasal administration.
    d. Several candidates are in Phase 3 clinical trials (Brazil, Argentina and UAE mentioned, but perhaps other locations as well)
2. Human monoclonal antibody candidates are being developed for clinical use
    a. Multiple candidates are under study
    b. Collaborations with Lilly to create a 2 monoclonal antibody cocktail was mentioned. This product is in clinical trials (now on hold) in the USA.
    c. Several questions were raised:
        i. Protective efficacy of candidates
        ii. Impact on/activity in lungs
        iii. Duration of maby protection
        iv. Possibility of antibody dependent enhancement
        v. Possible impact on vaccination
3. A general discussion of the value and challenges associated with the creation of a universal coronavirus vaccine similar to ongoing discussions about a possible universal vaccine for influenza.
    a. Comment (Stanley Perlman) about the possibility of including T cell epitopes as a component of a universal coronavirus vaccine given demonstrated cross-reactivity among recognized coronaviruses.
4. NAS (Nancy Connell) shared an overview of the USA "Warp Speed" vaccine development efforts underway.
    a. 4 vaccine platforms are being developed with 2 candidates supported in each platform technology (list shared)
    b. Most candidates will require a prime/boost administration
    c. mRNA candidates will require an ultralow temperature cold chain that will be demanding to implement
    d. Many are in Phase 3 clinical trials with the mRNA candidates most advanced
    e. Selection of technologies was based in part on ease of production
    f. Results of clinical studies may be available incrementally with the mRNA candidates farthest along; results known perhaps by Nov-Dec 2020; others at roughly 2 month intervals with the replicating live vaccine results available in late 2021.
    g. Vaccine production is underway concurrent with clinical trials, with approximately 100 M doses of mRNA vaccine available around the end of 2020. Manufacturing costs provided by USG (BARDA).
5. Discussion of challenges associated with USA vaccine development and roll-out strategy.
    a. Key questions: is the candidate safe, is it effective in preventing infection/disease, and what is the duration of protection (Harvey's comments)

    b. How to manage multiple “successful” candidates with differing vaccination schedules and other requirements
    c. How to detect adverse events
    d. If EUA is granted early, those receiving placebo with receive the vaccine, leading to challenges in interpretation late onset adverse events (Ralph’s comment)
    e. For all candidate vaccines (USA and China), what is the strategy for select segments of the population—children, elderly, high risk occupations, others—still being addressed in China; Just released NASEM report on equitable distribution of vaccine discussed by Nancy and slide of 4 tiers of those to be vaccinated shared.
6. Review of vaccination efforts for animal diseases caused by coronaviruses (Linda Saif)
    a. Linda gave a comprehensive review of several vaccine development efforts, especially those associated with swine (list provided)
    b. Challenges encountered in producing protective vaccines for piglets
    c. Difficulties in generating mucosal immunity/IgA
7. Discussion of lessons learned from animal coronaviruses and how they might foretell problems with COVID-19 vaccination
    a. Relevance of past infection versus naïve populations on response to vaccines
    b. Mention of evidence of naturally occurring recombination of coronaviruses infecting swine in Europe.

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]; '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]; 'Nancy Connell'[NancyConnell@jhu.edu]; 'Dave Franz (davidrfranz@gmail.com)'[davidrfranz@gmail.com]
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]; Cervenka, Nicole[NCervenka@nas.edu]; Sharples, Fran[FSharples@nas.edu]; Block, Bruce[BBlock@nas.edu]
From: Rusek, Benjamin[BRusek@nas.edu]
Sent: Wed 10/14/2020 7:32:16 PM (UTC-04:00)
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
NAS-CAS-Vaccine-20201014.pdf
Emerging CoVs Swine Vaccine China NAS diaglog LJSaif_10-13-20pdf.pdf
20201013Vaccines US update.pdf

Greetings,

Thank you for joining the dialogue session last night. I have attached the slides from the three presentations.

FYI CAS has invited two additional CCDC experts to the session tonight.

Dr. Huaqing Wang, PI, Immunization program, Chinese Center for Disease Control and Prevention
Dr. Zundong Yin, Director of National Immunization Program, Chinese Center for Disease Control and Prevention

Looking forward seeing and hearing from you all in a few hours.
Session 2: Wednesday October 14, **9-11 PM ET / 6-8 PM PT in U.S.**
Meeting Link: https://nasem.zoom.us/j/98420889232?pwd=NFlIKzF1eWgxT0xDZHQzQWxMbnJPdz09
Password: 375761

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, October 12, 2020 12:36 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
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>; Cervenka, Nicole <NCervenka@nas.edu>; Sharples, Fran <FSharples@nas.edu>; Block, Bruce <BBlock@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
Importance: High

Greetings,

I have attached what should be the final agenda for the U.S. China dialogue meeting sessions on Tuesday, October 13 and

Wednesday October 14. It includes the Chinese participant list at the end. Links to join the Zooms are also below.

Looking forward to seeing/talking to you all on Tuesday and Wednesday evening.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***
Session 1: Tuesday, October 13, **9-11 PM ET / 6-8 PM PT in U.S.**
Meeting Link: https://nasem.zoom.us/j/92754903815?pwd=OUV2R3BPdDdibDdZZ24vcGd4VmJoUT09
Password: 833624

Session 2: Wednesday October 14, **9-11 PM ET / 6-8 PM PT in U.S.**
Meeting Link: https://nasem.zoom.us/j/98420889232?pwd=NFllKzF1eWgxT0xDZHQzQWxMbnJPdz09
Password: 375761

From: Rusek, Benjamin
Sent: Friday, October 9, 2020 5:43 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
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Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
Importance: High

Greetings,

We are looking forward to the two virtual bio dialogue sessions set to take place on Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT) next week. Like in previous sessions we expect that the Chinese expert participants will lead the discussion on the majority of the topics and that the format will be more of a discussion among the participants instead of a series of formal presentations. I have attached an agenda that includes the Zoom connection links for both days along with the U.S. participant list. If I get the Chinese participant list before the session I will send that out to you all.

Feel free to respond to this email with any thoughts, points of emphasis or issues that you would like to discuss among the U.S. group before the sessions. Also let me know if you have any questions or concerns.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, September 21, 2020 9:01 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; Dave Franz (davidrfranz@gmail.com) <davidrfranz@gmail.com>
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>
Subject: Virtual U.S. China dialogue meeting October 13 and 14
Importance: High

Greetings,

I hope you all had a good summer and are staying safe and healthy. The Chinese Academy of Sciences has agreed to hold another (4th) virtual bio dialogue meeting with NASEM on **1) vaccine development and delivery** and **2) immunity, testing and diagnostics.** The agreed topics for the session are below. **We have reserved Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT**) to discuss the topics on the agenda.

We hope you are able to participate. Please let me know if you are available and if so save the dates and times on your calendar. We will get back to you with more information and a detailed agenda for the sessions soon.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Vaccine development and delivery

Human

1) **Current status of CoVID-19 vaccine development in China and the U.S.**
2) **Chinse vaccination of military personnel and other Chinese populations**
3) **Vaccination of pediatric populations**
4) **Active surveillance strategies for monitoring adverse events observed after vaccination (as well as immunogenicity)**
5) **Adapting current vaccine platforms to novel mass vax strategies and other mass vaccination strategic issues**
6) **Progress on a universal influenza vaccines**
7) **Vaccine for enterovirus D68**

Animal

1) **Status of corona virus vaccination for animals - kinds of vaccine, efficacy, complications, etc**
2) **ASF in China and ASF vaccine progress**
3) **New swine coronavirus**
4) **Vaccination strategy for H5N1 avian influenza and domestic poultry**

Immunity, testing and diagnostics

1) **Correlates of immunity including the possibility of background immunity from circulating "common cold" coronaviruses**
2) **Chinese diagnostic testing strategies for testing large populations quickly**
3) **Antibody and antibody testing topics, importance of T-cell responses**
4) **Long-term sequela following COVID-19 infection—lung function, neurologic issues, others**

From: Rusek, Benjamin
Sent: Thursday, June 4, 2020 1:25 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>; 'Nancy Connell' <NancyConnell@jhu.edu>
Subject: RE: 3rd Virtual U.S. China dialogue meeting on COVID-19 Tuesday, June 9, 9-11PM ET
Importance: High

Greetings,

I have attached the American version of the agenda for the 3rd U.S. China virtual dialogue meeting on immunity and related topics set to take place on **Tuesday night, June 9 from 9:00-11:00 PM ET** (9-11 AM the next morning, Beijing time).

As you can see we have incorporated George Gao's questions into the agenda, we hope that **Harvey Fineberg** can provide information on and lead the discussion of 1) serologic investigation in the U.S. 2) strategy in the U.S. for the second half of this year 3) vaccine availability in the U.S. and that **Ralph Baric** can do the same re progress in the development of vaccine in the U.S. (especially mRNA vaccine).

We have also listed delegation member names after the other Immunity questions. Like previously, folks are listed simply so someone is responsible for getting an answer from the Chinese to each question during the discussion. I will send a version to CAS without those names listed but will let them know who we have asked to answer George's questions.

Please let us know if you have any thoughts or comments on the agenda or this plan. I will send you the Zoom link later tonight or tomorrow morning.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, June 1, 2020 10:03 AM
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 Tuesday, June 9, 9-11PM ET
Importance: High

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,

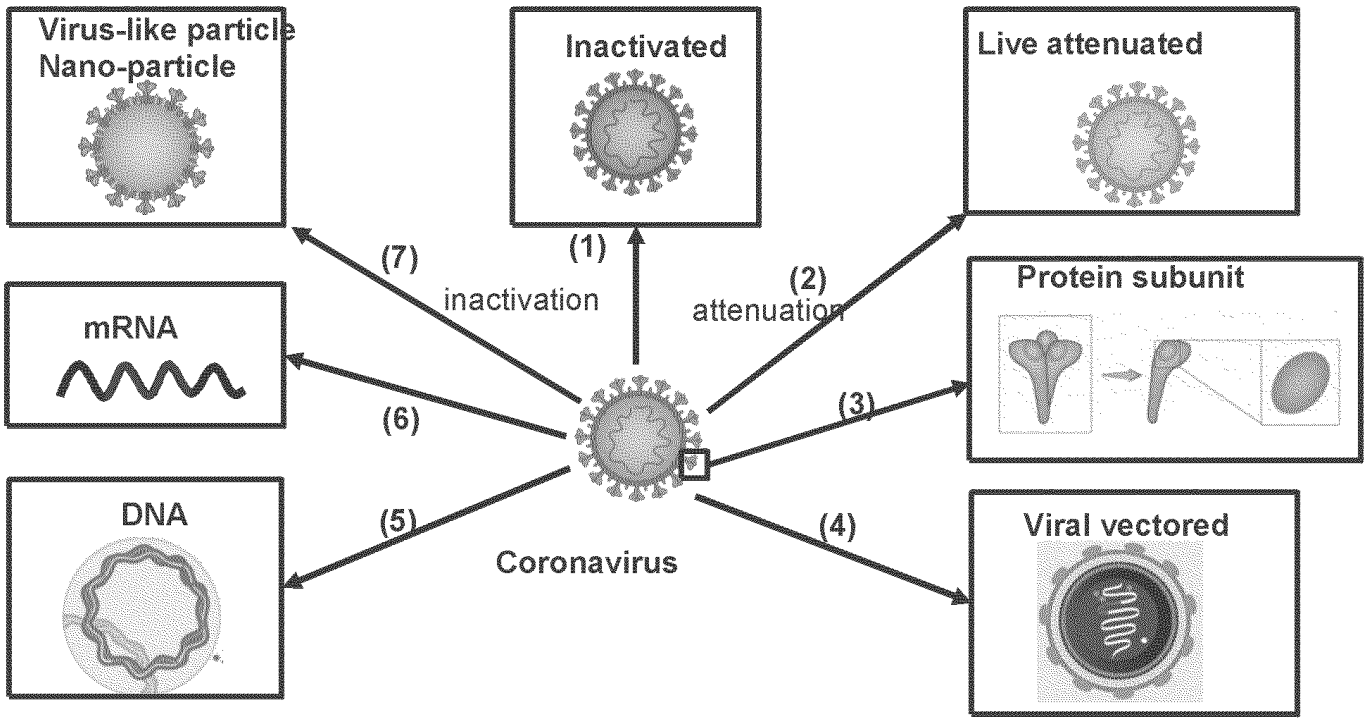
Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

Vaccine development

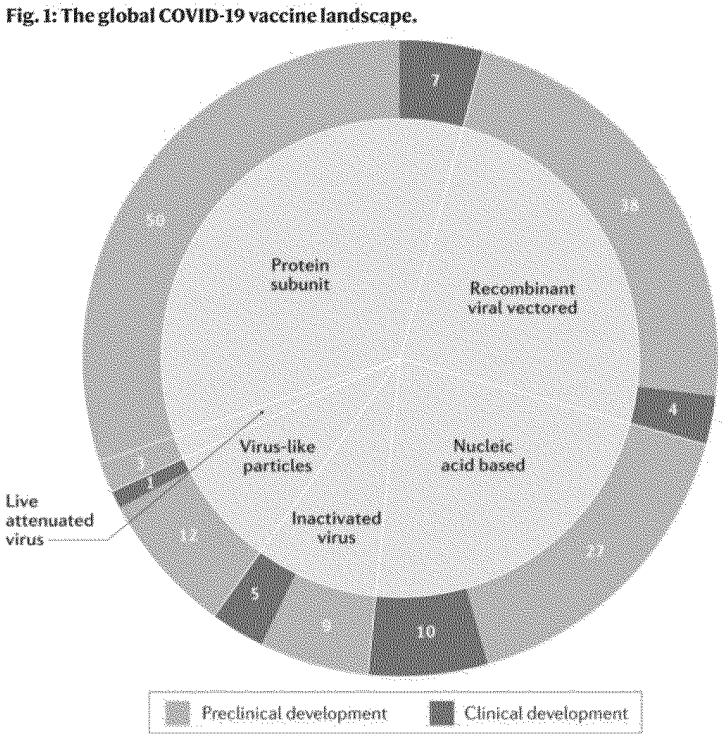
Future hope

Major forms of coronavirus vaccine



全球新冠疫苗研发现况（截至2020年9月9日，全球有180种候选疫苗）

- 35种进入人体临床试验，9种进入临床Ⅲ期
  - 非复制病毒载体（4）：Ad5 、ChAdOx1、 Ad5+ Ad26、 Ad26
  - RNA（2）：mRNA-1273、mRNA-BNT162b
  - 灭活疫苗（3）：中生北京所、中生武汉所、科兴
  - DNA：INO-4800等
  - 蛋白亚单位：NVX CoV2373等
- 145种在临床前研究阶段，主要技术路线：
  - 蛋白亚单位（51）
  - 非复制病毒载体（19）
  - 复制型病毒载体（19）
  - RNA（17），DNA（12）
  - 病毒样颗粒（12），灭活（9）
  - 减毒（3）



Jeyanathan, M., Afkhami, S., Smaill, F. et al. Immunological considerations for COVID-19 vaccine strategies. Nat Rev Immunol (2020). https://doi.org/10.1038/s41577-020-00434-6
WHO: DRAFT landscape of COVID-19 candidate vaccines – 3 Sep 2020

我国新冠疫苗研发

企业	疫苗类型	临床试验	目标人群	剂次	进展
康希诺公司	Ad5载体疫苗	I期	18-60岁	1	完成
		II期	≥18岁	1	完成
		III期	≥18岁	1	俄罗斯
中生集团（武汉所）	灭活疫苗(Vero)+铝佐剂	I + II期	≥6岁	2	完成
		III期	≥18岁	2	阿联酋、秘鲁、摩洛哥、阿根廷、埃及
中生集团（北京所）	灭活疫苗(Vero))+铝佐剂	I + II期	≥3岁	2	完成
		III期	≥18岁	2	阿联酋、秘鲁、摩洛哥、阿根廷
北京科兴	灭活疫苗(Vero))+铝佐剂	I + II期	18-59岁;≥60岁	2	已完成
		III期	18-59岁, ≥60岁	2	巴西、印尼
医科院昆明所	灭活疫苗(Vero))+铝佐剂	I + II期	18-59岁	2	进行中
智飞龙科马	重组亚单位(CHO))+铝佐剂	I+ II期	18-59岁;≥60岁	2	进行中
华西医院	重组亚单位（Sf9）)+铝佐剂	I期	18-55岁;≥55岁	2	进行中
苏州艾博&沃森生物	mRNA疫苗	I期	18-59岁;≥60岁	2	进行中
复星医药/BioNTech	mRNA疫苗	I期	18-55岁;≥55岁	2	进行中
北京万泰	鼻喷流感病毒载体疫苗	I期	≥18岁	?	9月8日注册
艾棣维欣/Inovio	DNA疫苗	I期	18-59岁	2	9月11日注册

我国新冠疫苗研发进展

企业	类型	Ⅰ期	Ⅱ期	Ⅲ期	备注
艾棣维欣	DNA疫苗	9月11日			
北京万泰	流感病毒载体鼻喷疫苗	9月8日			
上海复星	mRNA疫苗	7月22日			
苏州艾博&云南沃森	mRNA疫苗	6月24日			
四川大学华西医院	重组蛋白疫苗（sf9）	8月28日			
智飞	重组蛋白疫苗（CHO）	6月25日	7月10日		
康希诺	Ad5腺病毒载体	3月18日	4月10日		
昆明所	灭活疫苗（vero）	6月4日			
北京科兴	灭活疫苗（vero）	4月28日			EUA
中生北京所	灭活疫苗（vero）	4月29日			EUA
中生武汉所	灭活疫苗（vero）	4月13日			

Hot Spot：ChAdOx1腺病毒载体疫苗（AZD1222）

- 由牛津大学与阿斯利康合作开发

- 腺病毒载体疫苗
- 以复制缺陷型猿猴腺病毒为载体，包含SARS-CoV-2的全长结构表面糖蛋白（S蛋白）的腺病毒载体疫苗
- 该平台尚未用于已批准的疫苗，但已在针对其他病毒（包括埃博拉病毒）的实验性疫苗中进行了测试。

- 临床试验分期：Ⅲ期临床试验

- 美国、英国、巴西、南非
- 18-55岁健康成人

※阿斯利康与深圳康泰公司签署了技术转让的合作协议

Folegatti et al., (2020). Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. The Lancet, https://doi.org/10.1016/S0140-6736(20)31604-4

AZD1222因疑似不良反应暂停临床试验

- 9月8日，阿斯利康表示一个英国受试者出现一种无法解释的疾病
  - 该公司该疫苗在全球临床试验都暂停，旨在确保受试者安全，
- 9月10日，阿斯利康CEO Pascal Soriot 在电话会议中表示
  - 患上无法解释疾病的受试者是否为**横贯性脊髓炎**仍正在检查
  - 今年7月也曾发现一名疫苗接种者出现了神经系统症状，也一度暂停临床试验，后被诊断患有多发性硬化症，独立审查小组结论为**多发性硬化症**与疫苗接种无关

9月12日，英国恢复了阿斯利康牛津冠状病毒疫苗AZD1222的临床试验

AstraZeneca 阿斯利康

Pascal Soriot 阿斯利康CEO

横贯性脊髓炎

- 脊髓局限性炎性病变过程，导致运动、感觉和自主神经功能障碍
  - 疼痛、肌肉无力、瘫痪、感觉问题或膀胱和肠道功能障碍
- 横贯性脊髓炎的确切病因不清楚
  - 一些影响脊髓的病毒、细菌和真菌感染可能导致横断性脊髓炎

Table 1 Cases of transverse myelitis following vaccination

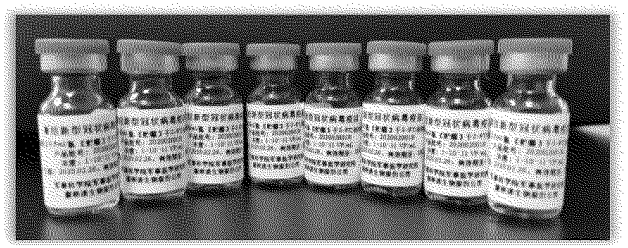
First author	*Year of publication*	*Vaccine*	*Age (years)*	*Time from vaccination*
Bir[69]	2007	Rabies	25	2 months
Das[67]	2007	Typhoid	19	5 days
Kelly[36]	2006	OPV + DT + Hib	0.5	7 days
Riel-Romero[43]	2006	DTP	0.7	17 days
Lim[68]	2004	Measles or Rubella	9	16 days
Kulkarni[51]	2004	Rabies	45	14 days
Fonseca[33]	2003	HBV	3	10 days
Nakamura[48]	2003	Influenza	70	7 days
Zanoni[69]	2002	MMR	1.25	21 days
Matsui[70]	2002	Japanese B encephalitis	4	14 days
Karaali-Savrun[34]	2001	HBV	42	2 months
		HBV	33	4 weeks
		HBV	40	3 weeks
		HBV	42	3 months
Larner[47]	2000	Influenza	42	Days9
Iñiguez[30]	2000	HBV	15	1 week
Renard[31]	1999	HBV	16	1 week
Tartaglino[28]	1995	HBV	40	2 weeks
Friedrich[38]	1995	OPV	12	6 years
		OPV	8	4 years
		OPV	13	9 years
Joyce[71]	1995	MMR	20	2 weeks
Abdul-Ghaffar[41]	1994	DT	13	3 days
Trevisani[72]	1993	HBV	11	3 weeks
Read[42]	1992	DTP	50	2weeks
D'Costa[37]	1990	Cholera, typhoid, OPV	24	2 days
Shaw[32]	1988	HBV	41.5	2 weeks
		HBV	*	12 weeks
		HBV	*	20 weeks
		HBV	*	27 weeks
Label[52]	1982	Rabies	50	2 days1
Clark[73]	1977	Rubella	16	13 days
Whittle[44]	1977	DTP	0.6	6 days
Holt[74]	1976	Rubella	17	2 weeks
	1976	Rubella	13	4 days
Kulenkampff[75]	1974	Pertussis	6	17 days
Harrington[60]	1971	Rabies	41	14 days

*41.5, average of all four cases presented by Shaw *et al.*[32]

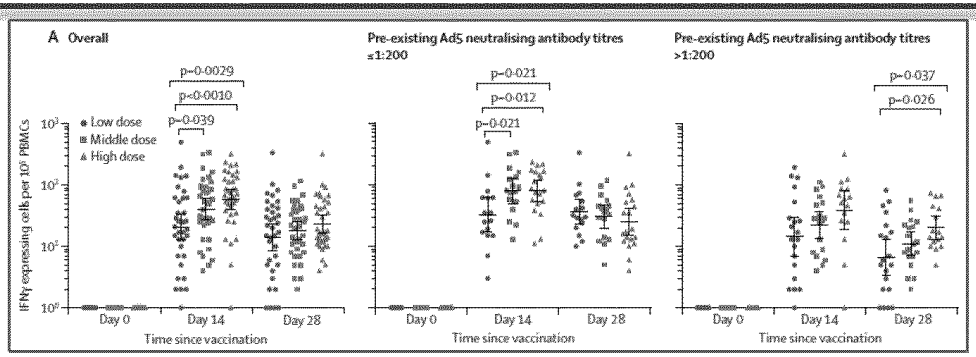
- **Johnson & Johnson: Ad26**

Virus vectored vaccine strategy: Ad5-COVID-19

CanSino Biological Inc. with Beijing Institute of Biotechnology



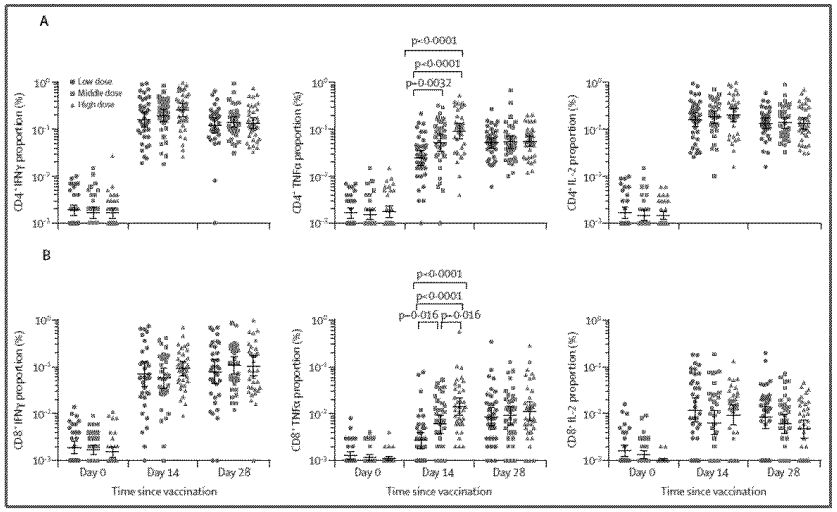
Approved for IND in China on17th, March, 2020



Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial

Feng-Cai Zhu, Yu-Hua Li*, Xu-Hua Guan, Li-Hua Hou, Wen-Juan Wang, Jing-Xin Li, Shi-Po Wu, Bu-Sen Wang, Zhao Wang, Lei Wang, Si-Yue Jia, Hu-Dachuan Jiang, Ling Wang, Tao Jiang, Yi Hu, Jin-Bo Gou, Sha-Bei Xu, Jun-Jie Xu, Xue-Wen Wang, Wei Wang, Wei Chen*

In May, Lancet published the data for phase I clinical trials



Safety and immunogenic for both humoral and cellular responses

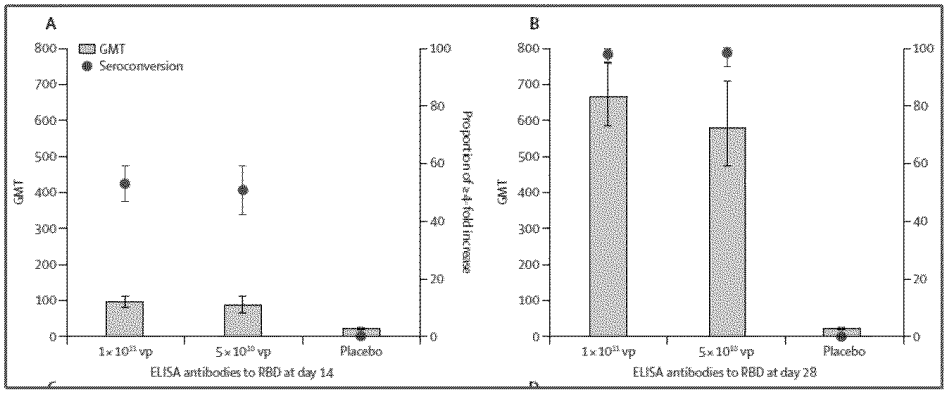
Virus vectored vaccine strategy: Ad5-COVID-19

CanSino Biological Inc. with Beijing Institute of Biotechnology

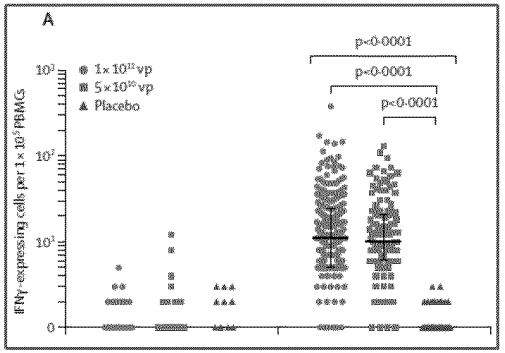
Immunogenicity and safety of a recombinant adenovirus type-5-vectored COVID-19 vaccine in healthy adults aged 18 years or older: a randomised, double-blind, placebo-controlled, phase 2 trial

Feng-Cai Zhu, Xu-Hua Guan*, Yu-Hua Li, Jian-Ying Huang, Tao Jiang, Li-Hua Hou, Jing-Xin Li, Bei-Fang Yang, Ling Wang, Wen-Juan Wang, Shi-Pu Wu, Zhao Wang, Xiao-Hong Wu, Jun-Jie Xu, Zhe Zhang, Si-Yue Jia, Bo-Sen Wang, Yi Hu, Jing-Jing Liu, Jun Zhang, Xiao-Ai Qian, Qiong Li, Hong-Xing Pan, Hu-Dachuan Jiang, Peng Deng, Jin-Bo Gou, Xue-Wen Wang, Xing-Huan Wang, Wei Chen*

In Jul., Lancet published the data for phase II clinical trials



NCT04526990;
NCT04540419

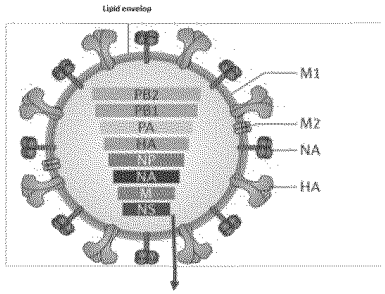


Safety and immunogenic for both humoral and cellular responses

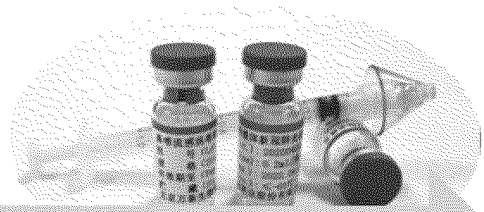
Currently under Phase III overseas multi-center clinical trials

鼻喷流感载体新冠肺炎疫苗

- 由厦门大学、香港大学和北京万泰生物药业股份有限公司共同研发
- 核心技术是CA4-DelNS1，是将California/04/2009(H1N1)流感病毒株的NS1基因敲除后再经低温适应获得的减毒且温度敏感的双重减毒流感载体，缺失NS1可显著增强T细胞免疫应答
- 该疫苗是在CA4-DelNS1内插入新冠病毒RBD基因片段研制而成的活病毒载体疫苗，是目前已获准开展临床试验的新冠肺炎候选疫苗中唯一采用鼻腔喷雾接种方式的疫苗



DelNS1-nCoV-RBD-OPT1



1月27日启动研发　　8月27日获批临床　　9月1日启动一期临床

鼻喷流感载体新冠肺炎疫苗

- 该疫苗在动物模型中呈现出对流感病毒和新冠病毒的双重保护效果：
  - ✓ 小鼠实验显示：对甲型H1N1流感病毒的致死性感染保护率为100%。
  - ✓ hACE2小鼠和仓鼠实验显示：攻毒对照组肺组织出现中至重度病理损伤且体重明显下降，疫苗免疫可明显减轻肺组织病理损伤，体重无明显下降。
- 该疫苗通过模拟呼吸道病毒天然感染途径激活局部和全身性免疫应答，在动物体内可诱导出较强的RBD特异性细胞应答，尤其以肺组织局部T细胞应答为突出特征，同时可检测到RBD特异性抗体应答，包括粘膜局部的IgA。
- 该疫苗于9月1日启动一期临床试验，已完成63名受试者接种，显示出良好安全性：
  - ✓ 正常年龄组 (18-59岁) 不良反应发生率为28.13% (9/32)，其中2级2人，1级7人。

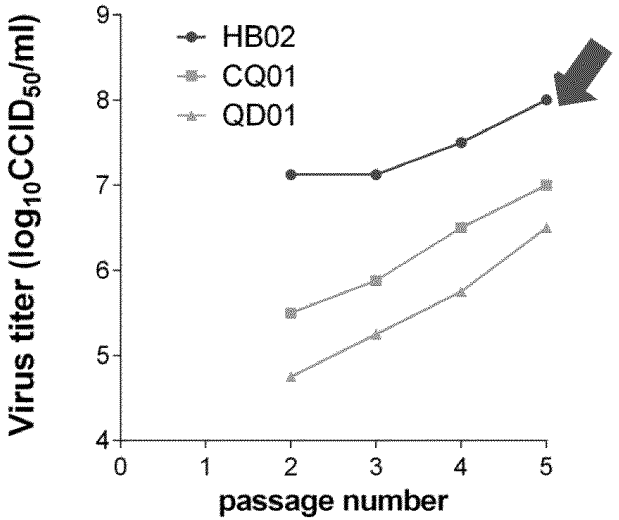
- **Inactivated vaccine, BBIBP-CorV**
- **Protein subunit vaccine**

Seed virus selection for COVID-19 vaccine

3 virus strains isolated from broncho-alveolar lavage samples or throat swabs of 3 hospitalized patients

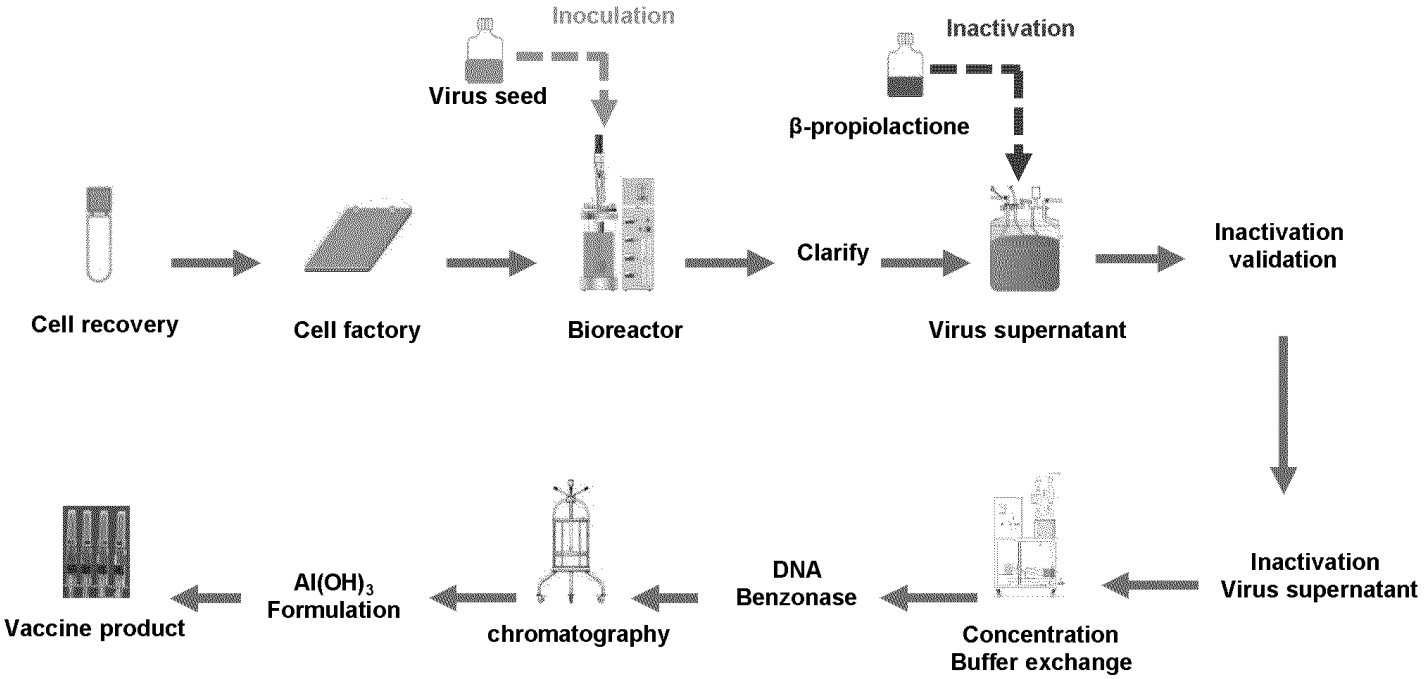
- 19nCoV-CDC-Tan-HB02
- 19nCoV-CDC-Tan-Strain03 (CQ01)
- 19nCoV-CDC-Tan-Strain 04

Lu et al, Lancet, 2020
Zhu et al, NEJM, 2020



Wang et al., Cell, 2020

Flowchart of preparing the inactivated COVID-19 virus vaccine, BBIBP-CorV



Wang et al., Cell, 2020

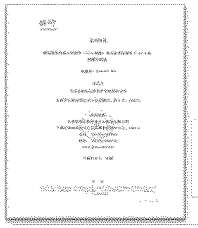
Time-course of the BBIBP-CorV vaccine development

COVID-19 vaccine started

2020.1.25

2020.2

Confirm the workshop design plan



Initiate animal safety evaluation studies

2020.3

The first batch of inactivated stock solution was prepared successfully

Start rolling submission of IND application

2020.4

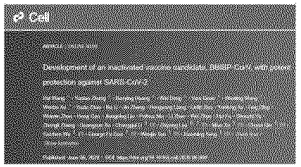
Many batches of samples obtained the qualified report of the Chinese People's Procuratorate

BBIBP-CorV vacine advanced into Phase II

2020.5

4.27 Obtain clinical trial approval

4.29 First subject inoculation



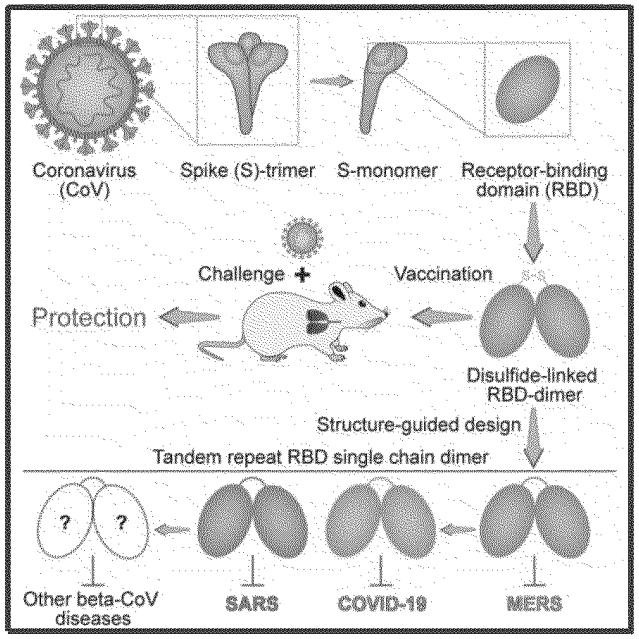
2020.6

Studies on BBIBP-CorV vacine published in Cell journal

6.28. Phase Ⅰ/Ⅱ clinical trials unblinding. Seroconversion of NAbs are 100% for the all receipients

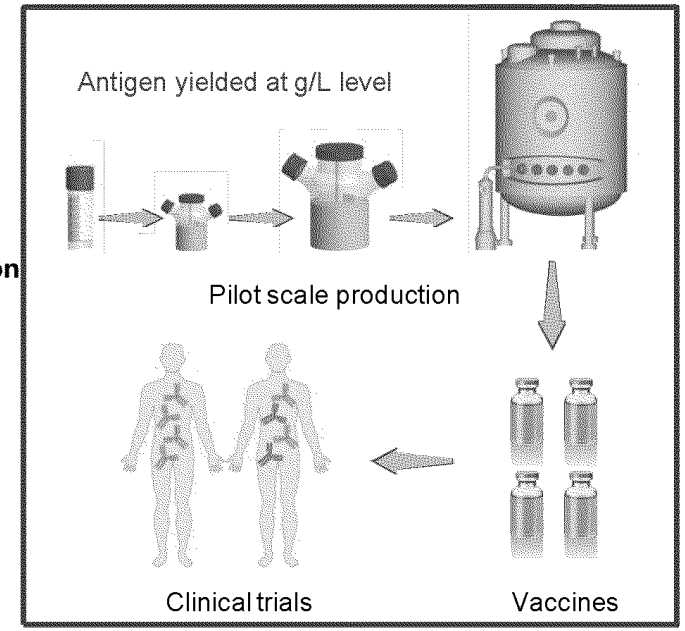
- **Inactivated vaccine, BBIBP-CorV**
- **Protein subunit vaccine**

Overview of the protein subunit COVID-19 vaccine



Translation

ZFSW

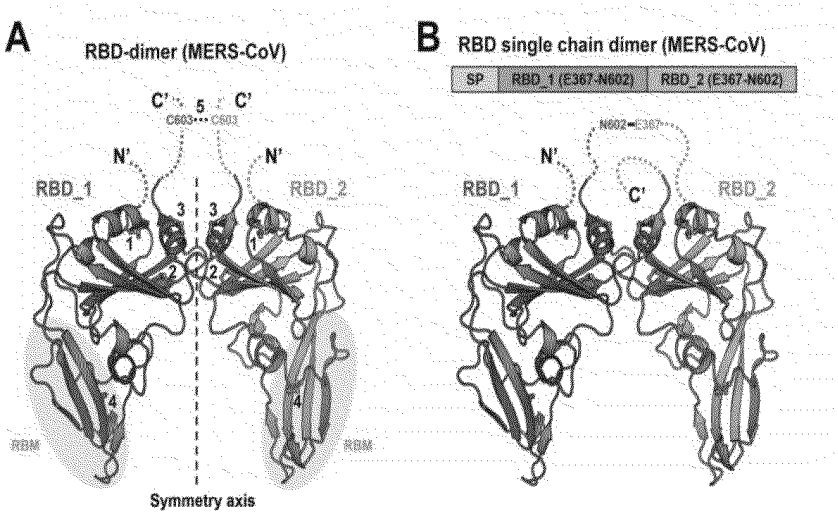


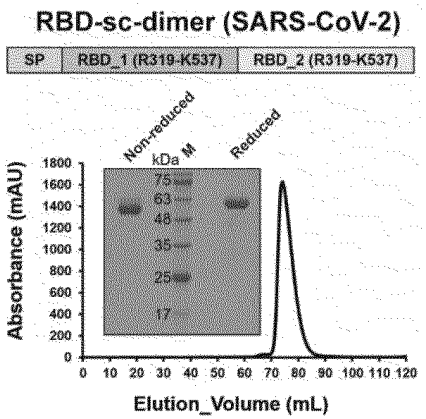
* A universal design of betacoronavirus vaccines

Dai et al., 2020, Cell

* The **first** protein subunit COVID-19 vaccine approved for clinical trials in China and the **second** in the world

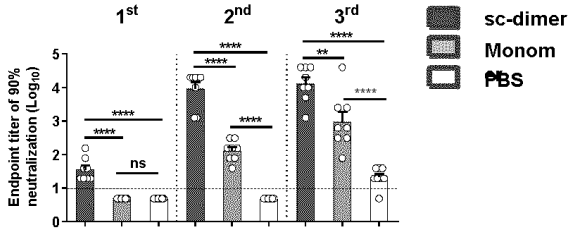
Rational design of tandem repeat RBD single chain dimer





A homogeneous RBD-dimer

- A generalizable strategy to design vaccines against MERS, COVID-19, SARS and other CoV diseases



- RBD-sc-dimer induced significantly higher NAbs compared to conventional monomer

Dai et al., 2020, Cell

Clinical trials of the first protein subunit vaccine in China

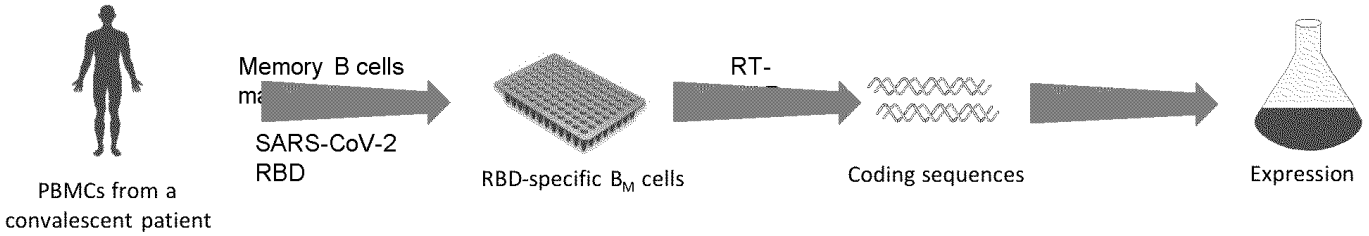
The first human volunteer in trial

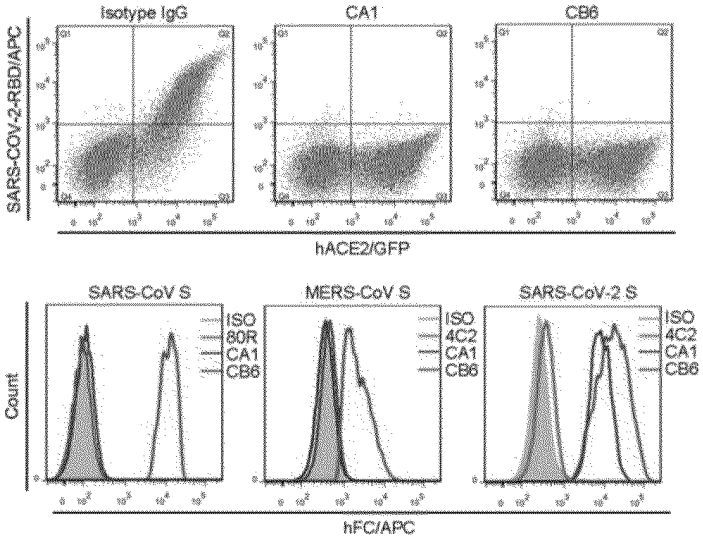
On 19 June 2020, vaccine was approved by the NMPA to enter Phase I clinical trials in China

On 10 July 2020, vaccine enters Phase II clinical trials in China

Platform	Type of candidate vaccine	Developer	Coronavirus target	Current stage of clinical evaluation/regulatory status-Coronavirus candidate	Same platform for non-Coronavirus candidates
Inactivated	Inactivated + alum	Sinovac	SARS-CoV2	Phase 3 NCT04456595 Phase 1/2 NCT04383574 NCT04352608	SARS
Non-Replicating Viral Vector	ChAdOx1-S	University of Oxford/AstraZeneca	SARS-CoV2	Phase 3 ISRCTN89951424 Phase2b/3 2020-001228-32 Phase 1/2 PACTR202006922165132 2020-001072-15	MERS, influenza, TB, Chikungunya, Zika, MenB, plague
Non-Replicating Viral Vector	Adenovirus Type 5 Vector	CanSino Biological Inc./Beijing Institute of Biotechnology	SARS-CoV2	Phase 2 ChiCTR2000031781 Phase 1 ChiCTR2000030906	Ebola
Protein Subunit	Adjuvanted recombinant protein (RBD-Dimer)	Anhui Zhifei Longcom Biopharmaceutical/ Institute of Microbiology, Chinese Academy of Sciences	SARS-CoV2	Phase 2 NCT04466085 Phase 1 NCT04445194	MERS

Isolation of RBD-specific memory B cells in a convalescent patient

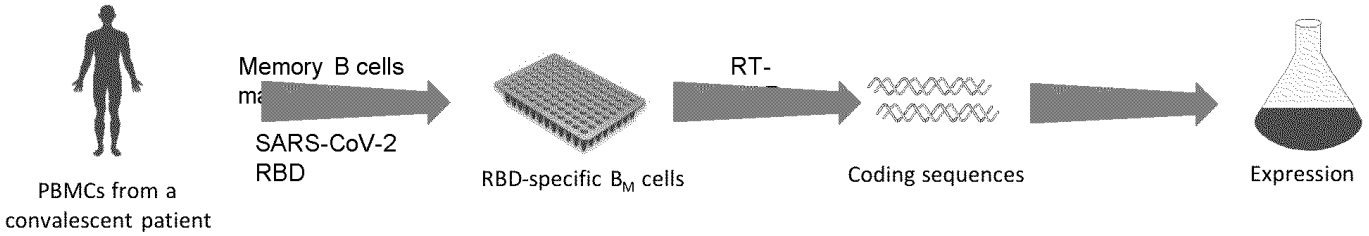


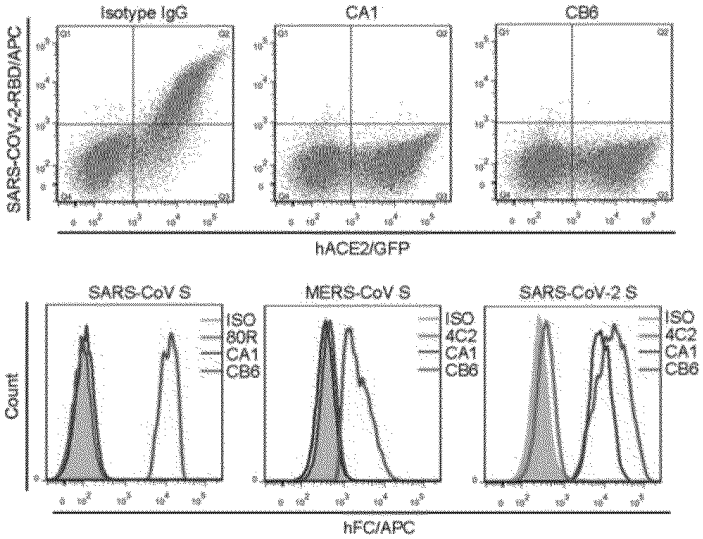


- Two mAbs-containing supernatant blocks the interaction between soluble COVID-19 virus RBD and 293T-hACE2 cells, respectively.
- Both CA1 and CB6 are specific to interact with COVID-19 virus S protein

Shi et al., 2020, Nature

Isolation of RBD-specific memory B cells in a convalescent patient

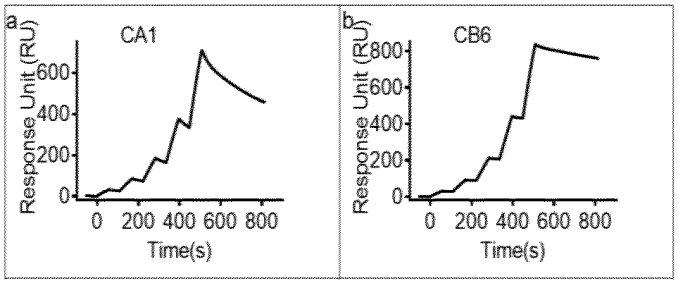




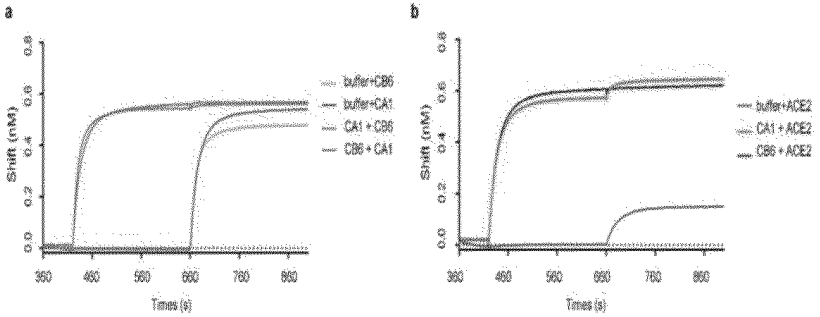
- Two mAbs-containing supernatant blocks the interaction between soluble COVID-19 virus RBD and 293T-hACE2 cells, respectively.
- Both CA1 and CB6 are specific to interact with COVID-19 virus S protein

Shi et al., 2020, Nature

Binding affinity between mAbs and RBD



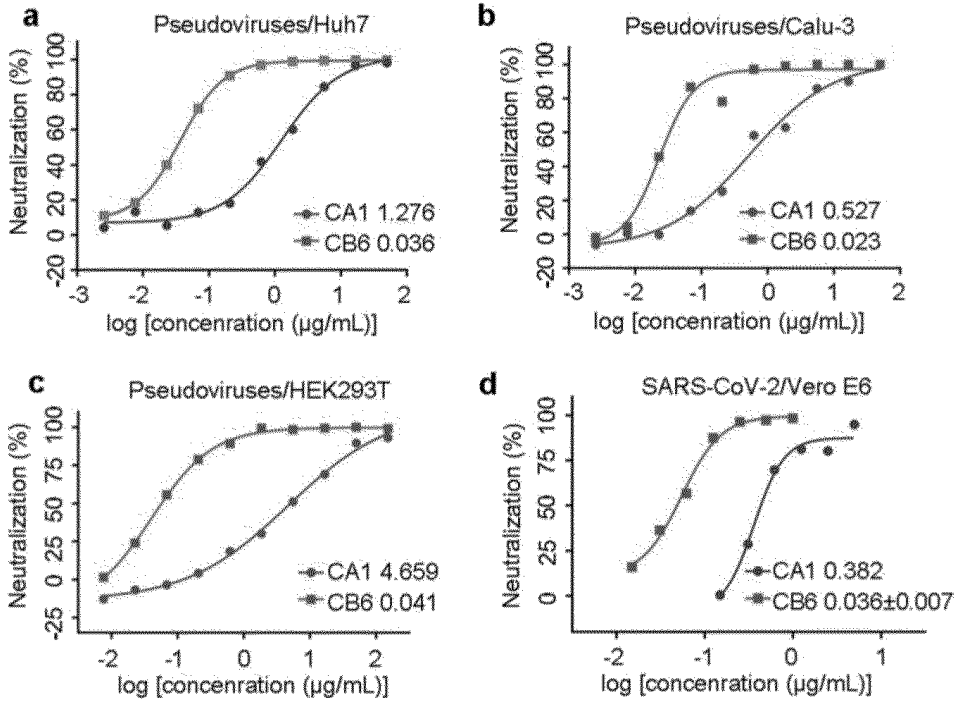
	ka (1/Ms)	kd (1/s)	K_D (M)
CA1/RBD	3.98E+06	1.16E-02	2.92E-09
CB6/RBD	8.95E+05	7.29E-04	0.82E-09
ACE2/RBD	3.82E+04	5.15E-03	133.3E-09



- The binding affinity between mAbs and RBD are stronger than that between the receptor and RBD
- CA1 and CB6 bind to the overlapped epitopes

Shi et al., 2020, Nature

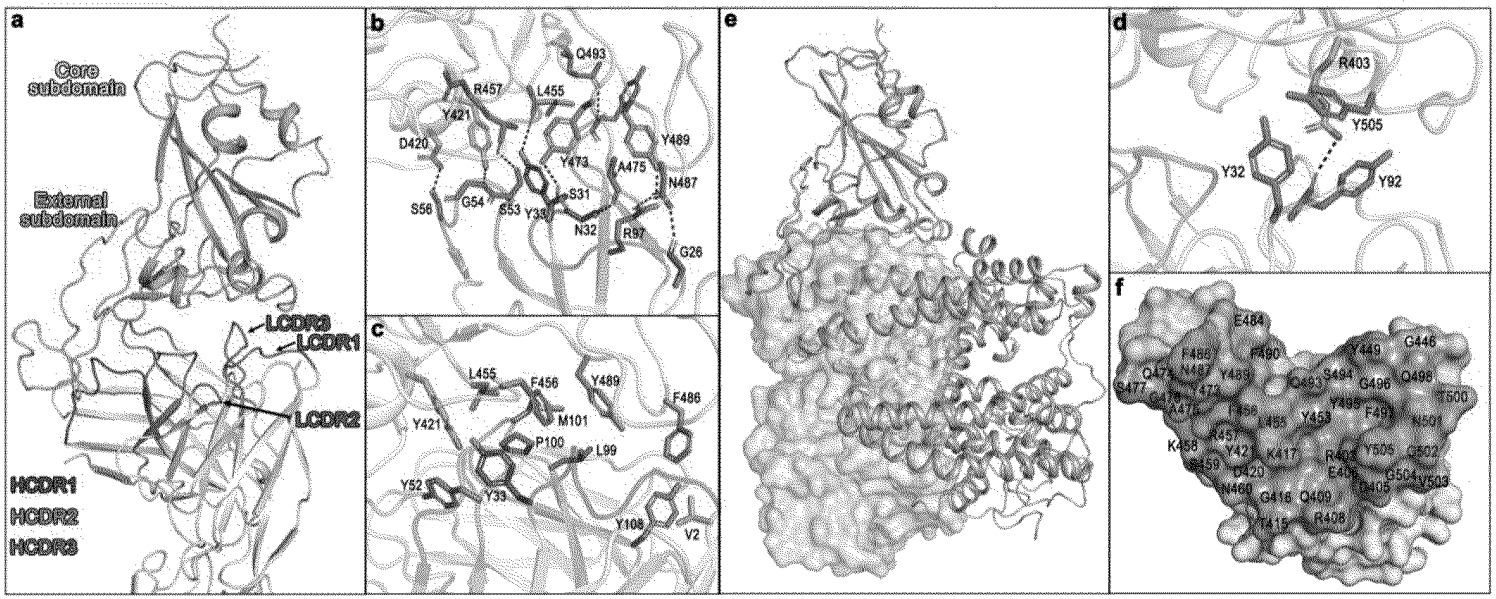
CB6 and CA1 can effectively neutralize COVID-19 virus



- CB6 and CA1 can effectively neutralize COVID-19 virus pseudovirus and live COVID-19 virus *in vitro*.

Shi et al., 2020, Nature

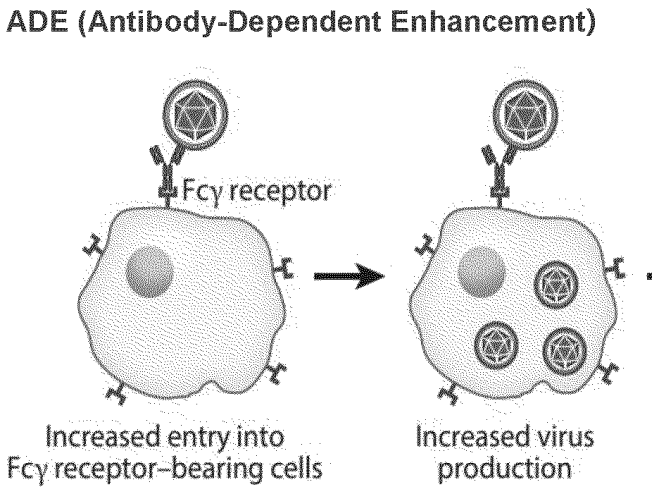
CB6 and CA1 can effectively neutralize COVID-19 virus

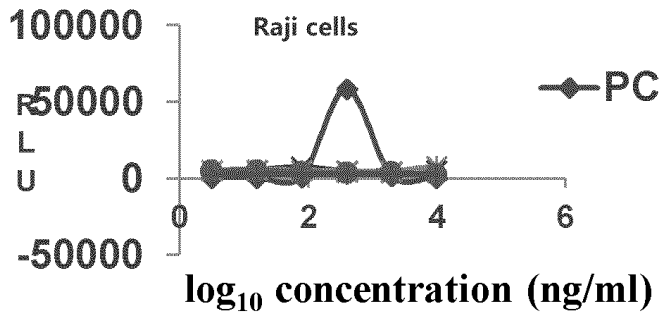


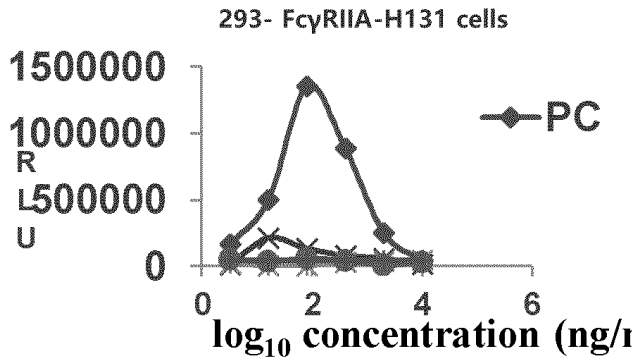
- CB6 competes with the receptor to interact with the same residues of COVID-19 virus RBD
- Both of CB6 heavy chain and light chain sterically hinder the interaction of COVID-19 virus RBD with hACE2

Shi et al., 2020, Nature

CB6-LALA to eliminate the potential ADE effect



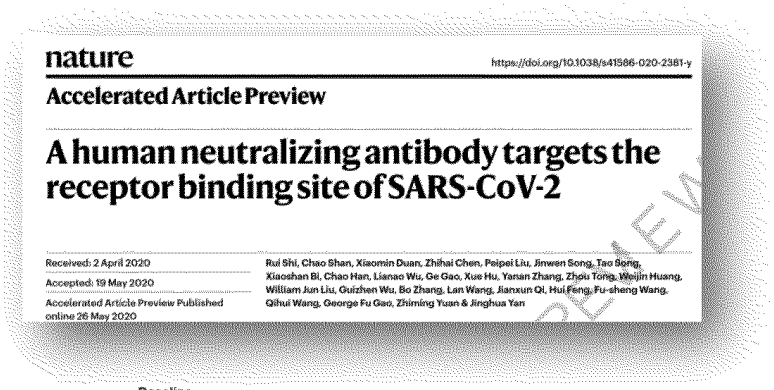


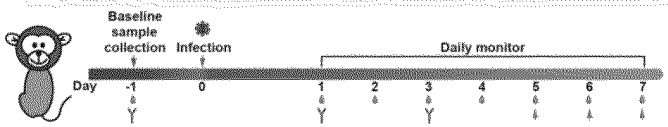


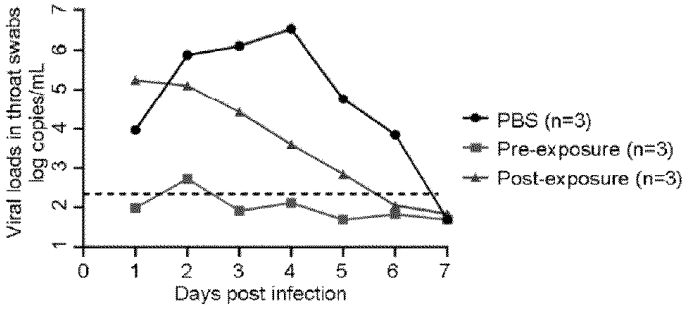
- No detectable ADE effect for CB6-LALA *in vitro*

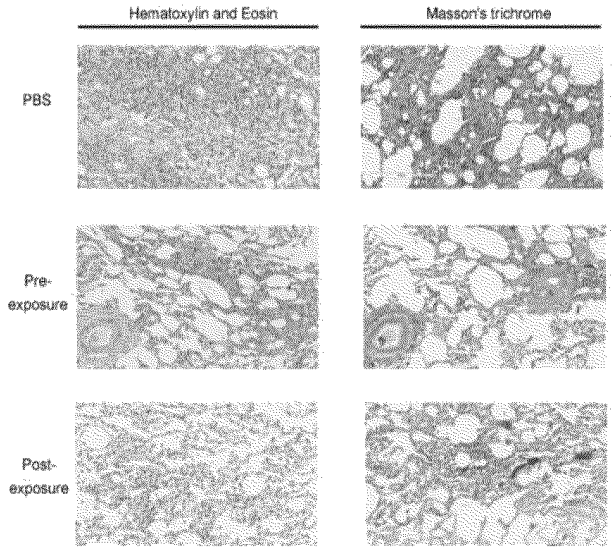
Unpublished data

CB6-LALA protects NHPs from COVID-19 virus infection





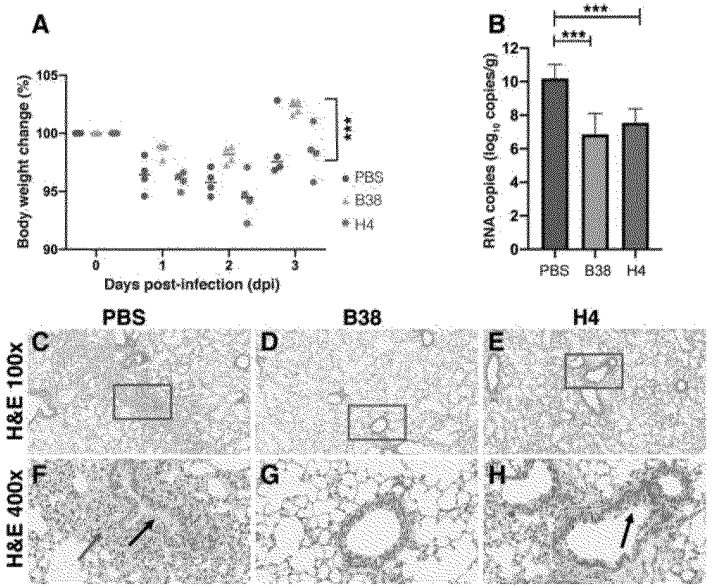


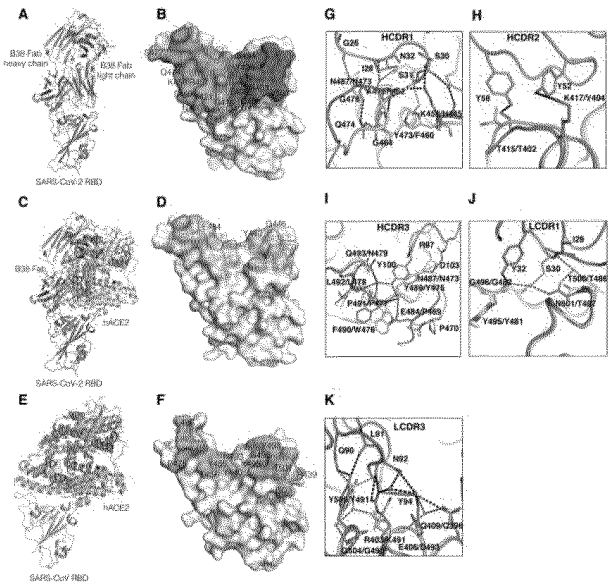


- CB6 decreased the viral loads in the throat swabs in NHPs at both prophylactic and treatment settings
- CB6 reduced the infection-related lung damage of challenged NHPs at both groups

Shi et al., 2020, Nature

Multiple neutralizing MAbs could prevent the escape mutations





- The protection efficiency of MAbs in hACE2 mice model post infection with COVID-19 virus
- Structural analysis of B38 and COVID-19 virus RBD complex and the epitope comparison between B38 and hACE2

Wu et al., 2020, Science

A pair of noncompeting human neutralizing MAbs against COVID-19 virus

Science

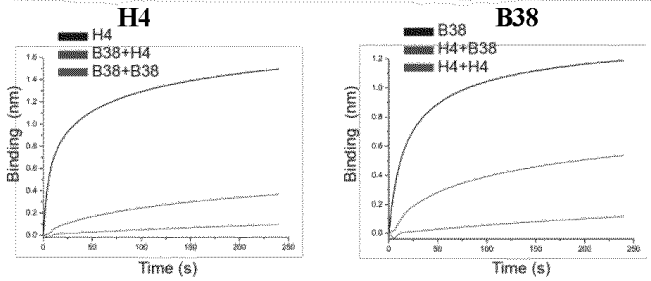
REPORTS

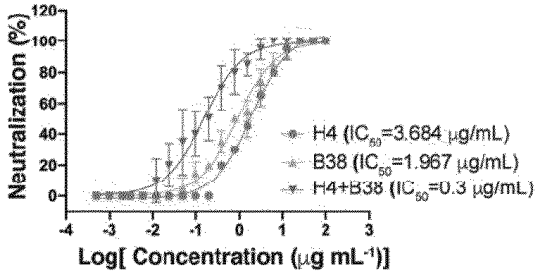
Cite as: Y. Wu et al., Science 10.1126/science.abc2241 (2020)

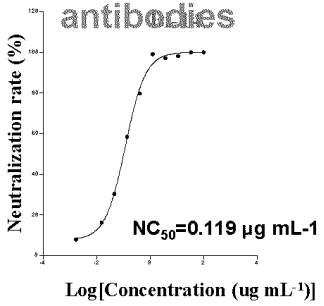
A noncompeting pair of human neutralizing antibodies block COVID-19 virus binding to its receptor ACE2

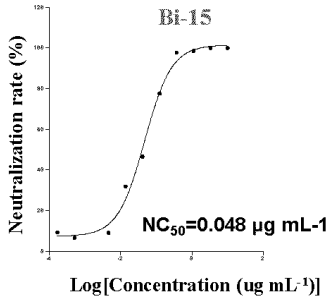
Yan Wu[1,2*†], Feiran Wang[3,4†], Chengyang Shen[5,6†], Weiyu Peng[5,6†], Delin Li[1,2,3*], Cheng Zhao[5,6], Zhaohui Li[7,8], Shihua Li[9], Yuhai Bi[9,10], Yang Yang[5], Yuhuan Gong[9,10], Haixia Xiao[7], Zheng Fan[5], Shuguang Tan[5], Guizhen Wu[11], Wenjie Tan[11], Xuancheng Lu[12], Changfa Fan[13], Qihui Wang[9], Yingxia Liu[9], Chen Zhang[5], Jianxun Qi[9], George Fu Gao[9,14], Feng Gao[7*], Lei Liu[5*]

- H4 and B38, a pair of noncompeting human neutralizing MAbs, synergistically prevent COVID-19 virus infection
- The neutralizing activity of bispecific antibody Bi-15 against COVID-19 pseudovirus is **10 times stronger** than those of parental monoclonal antibodies









Wu et al., 2020, Science

Unpublished data

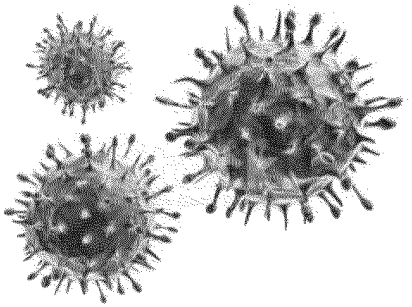
CB6 advanced into clinical trials in both China and America

- On 5 June 2020, CB6 was approved by the NMPA to enter Phase I clinical trials in China
- On 8 June 2020, CB6 was approved by the FDA to enter Phase I clinical trials in America

Name ▲	Target ▲	Format ▲	Status ▲	Developer/Reseacher ▲
REGN-COV2 (dual mAb cocktail)	SARS-CoV-2 S protein	mAb	Phase 1	Regeneron
LY-CoV555	SARS-CoV-2 S protein	mAb	Phase 1	AbCellera/Eli Lilly
JS016	SARS-CoV-2 S protein	mAb	Phase 1	Junshi Biosciences/Institute of Microbiology, Chinese Academy of Sciences/Eli Lilly
TY027	SARS-CoV-2 S protein	mAb	Phase 1	Tychan

Outstanding questions

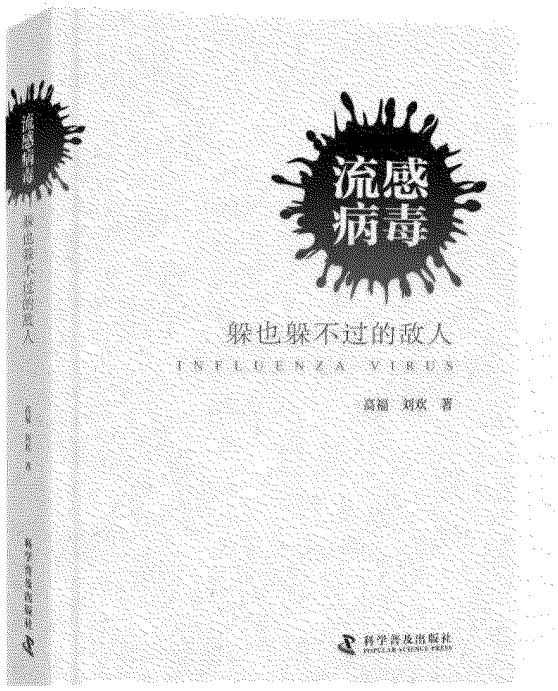
- Correlations of neutralizing MAbs with protection
- Reach of neutralizing MAbs to lung
- Lasting time of neutralizing MAbs in vivo
- Antibody-dependent enhancement (ADE) effect
- Best Immunization programs and the pro and con of all the vaccines
- Stratified/prioritized vaccination program



流感病毒

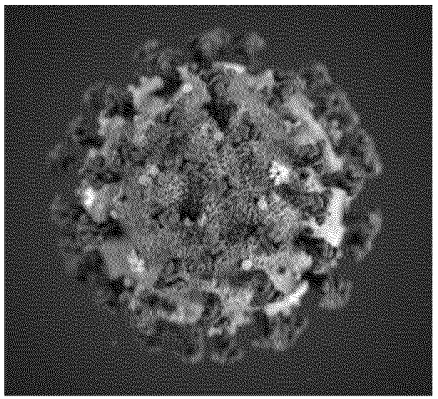
躲也躲不过的敌人

THANK YOU



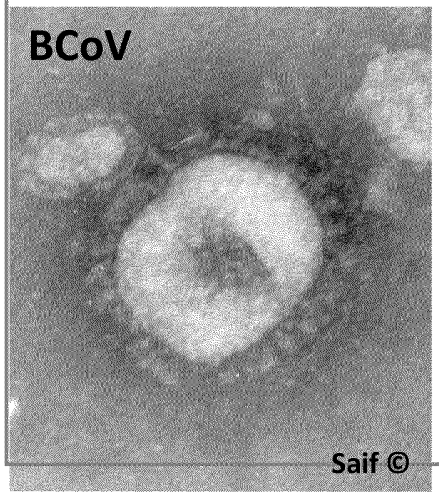
Emerging coronaviruses of humans and animals: Immunity and vaccines

SARS-CoV-2



Linda J. Saif

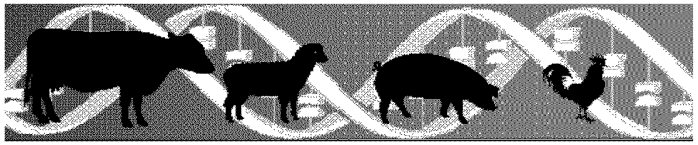
BCoV



Saif ©

Food Animal Health Research Program
Department of Veterinary Preventive Medicine
College of Food, Agricultural, Environmental Sciences
The Ohio State University/OARDC, Wooster, Ohio US

THE OHIO STATE UNIVERSITY
COLLEGE OF FOOD, AGRICULTURAL, AND ENVIRONMENTAL SCIENCES



Food Animal Health Research Program

College of Veterinary Medicine
The Ohio State University

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7 Human Coronviruses —Respiratory infections
6 Swine and 1 Bovine CoV —Enteric/respiratory infections

Human CoVs

- **Endemic--Common Cold** (Population has immunity, but lasts only ~1yr)
  - Alpha-CoVs- HC 229E,NL63
  - Beta-CoVs- HC OC43, HC HKU1
- **Epidemic/Pandemic-- Pneumonia** (Naïve population, no immunity)
  - Beta-CoVs- SARS, MERS, SARS-CoV-2

Bovine CoVs

- **Endemic—Respiratory/Diarrhea**
  - Beta-CoV- BCoV

Porcine CoVs

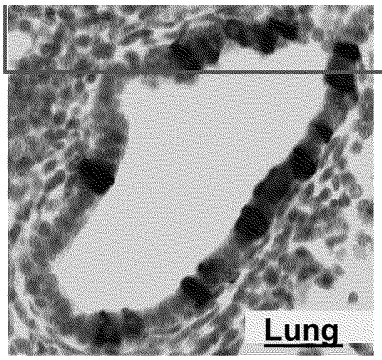
- **Endemic--Gastroenteritis**
  - Alpha-CoVs- TGEV, PEDV
- **Endemic--Respiratory**
  - Alpha-CoV- PRCV
- **Endemic--Encephalomyelitis**
  - Beta-CoV- HEV
- **Epidemic-- Diarrhea** (Naïve population, no immunity)
  - Alpha-CoV- SADS
  - Delta-CoV- PDCoV

Bovine and most human CoVs belong to the *betacoronavirus* genus; most swine CoVs belong to the *alphacoronavirus* genus

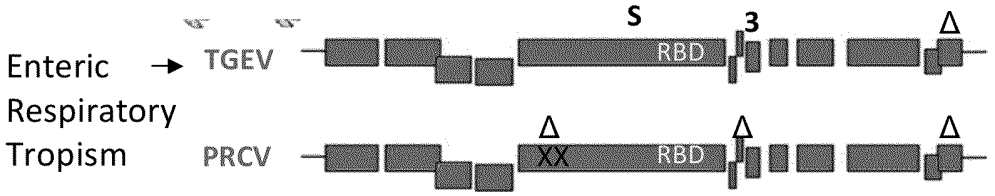
Questions Addressed:
SARS-CoV-2 and Porcine and Bovine CoVs

- How does SARS-CoV-2 cause disease compared with a porcine and bovine respiratory CoV?
- What are the unknowns/gaps for SARS-CoV-2 vaccines and lessons learned based on porcine and bovine CoV vaccines?

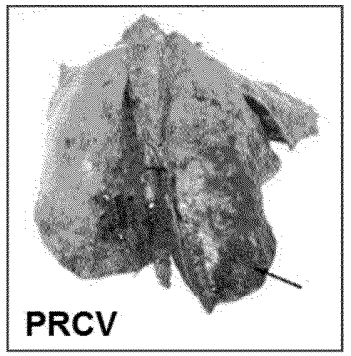
  -- What are the correlates of protection?
  -- What are the lessons for immunity from similar next Gen platform swine experimental CoV vaccines?
  -- What are the correlates of immunity based on immunity to bovine respiratory CoV infections?



Porcine respiratory CoV (PRCV) mutant of TGEV



XX S 681nt Δ
-Loss SA binding
ORF 3 Δ
-Nonfunctional



- TGEV causes fatal diarrhea in baby pigs
- PRCV--S gene deletion mutant of TGEV (621 – 682 bp, N-terminus) emerged in 1980s
- TGEV and PRCV share APN receptor; tissue tropisms differ due to loss of SA binding (gut mucins) by PRCV Spike *(Schultze et al 1996)*
- Lost of enteric tropism and virulence

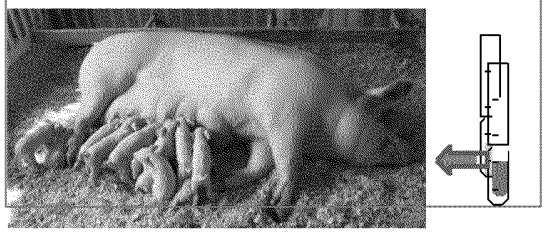
Similarities to SARS CoV-2 respiratory infections

- PRCV infects epithelial cells of upper/lower respiratory tract and type I and 2 pneumoctyes *(Jung/Saif et al 2007 JVI)*
- Most infections mild or subclinical— walking pneumonia like > 50% asymptomatic COVID-19 cases *(Long, QX et al 2020 Nat Med)*
- Atypical pneumonia in most pigs resembles SARS-CoV-2 lesions *(Saif, Jung, 2020 JCM)*: ***PRCV as a BSL2 respiratory CoV model for COVID-19***

Lessons from Swine Coronavirus Veterinary Vaccines

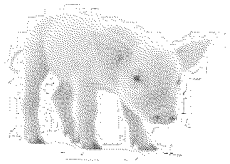
Swine Enteric/Respiratory Coronaviruses: TGEV/PRCV

- Only 2-3X attenuated oral enteric CoV vaccine induced gut/milk IgA Abs: Correlate of immune protection *(Chatta, Roth, Saif 2015 ARAB; Langel/Saif et al 2020 Pathogens)*
  - *GALT-Mammary gland SIgA axis*



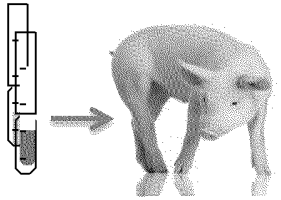
Mother

Gut IgA Ab- Immunity against CoV



Suckling piglet

Milk IgA Abs-Passive immunity



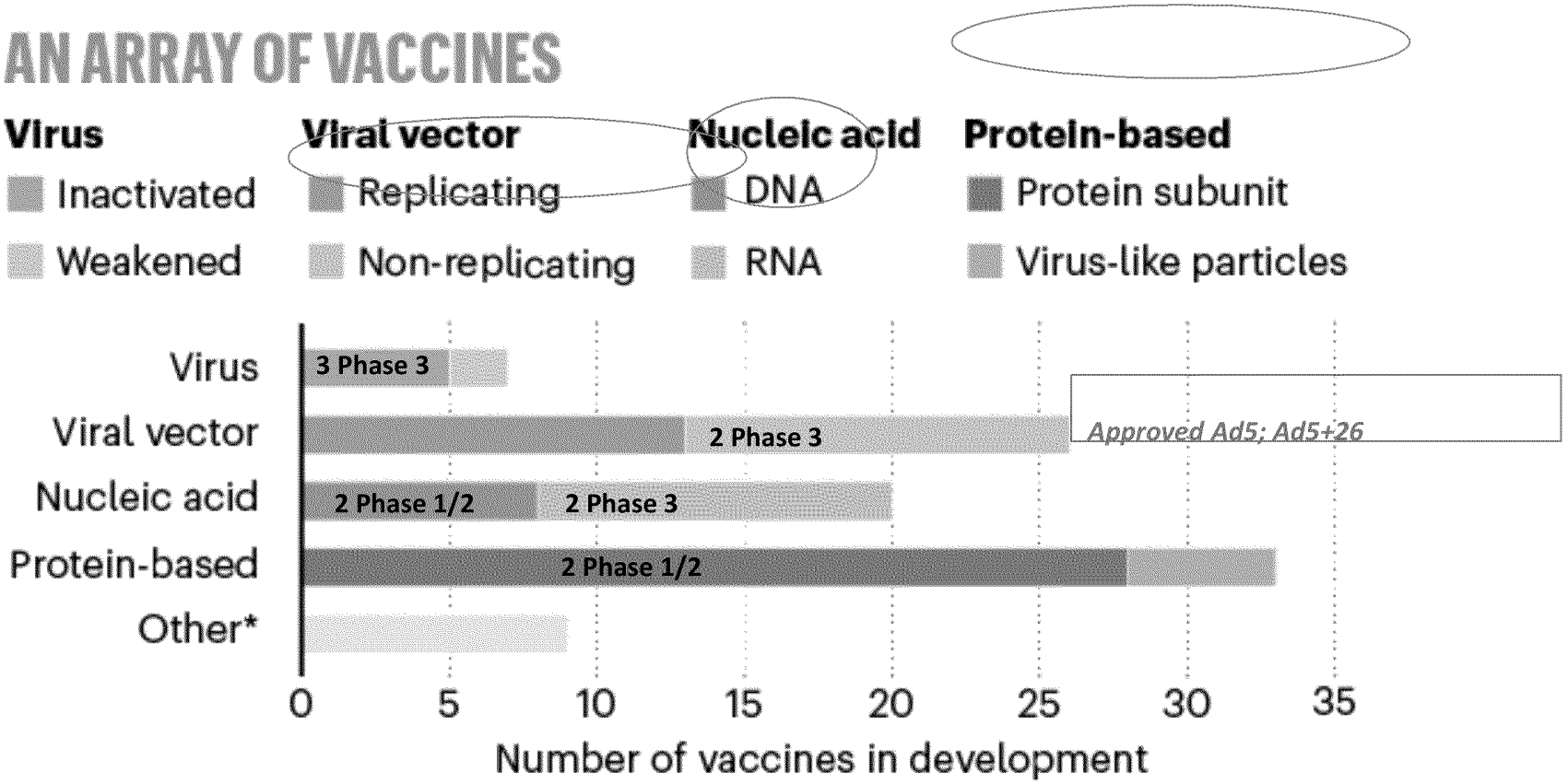
Weaned piglet

Gut IgA Ab-Active immunity: Prevent disease and infection

- Repeated PRCV infections induce IgA Abs and immunity to TGEV *(Sestak/Saif et al 1996 AJVR)*
  - *BALT-Mammary gland SIgA axis*

PRCV as naturally occurring TGEV vaccine

COVID-19 Vaccines



* Other efforts include testing whether existing vaccines against poliovirus or tuberculosis could help to fight SARS-CoV-2 by eliciting a general immune response (rather than specific adaptive immunity), or whether certain immune cells could be genetically modified to target the virus.

(Modified E Callaway Nature 30 April 2020)

©nature

Lessons from Molecular Vaccines for Swine CoVs

➢ Molecular next Gen vaccines have advantages (if safe & effective)

-- Provide a platform for rapid production of vaccines for new emerging diseases

-- Backbone constructs to insert key antigens for new viruses with established manufacturing

Will these unproven vaccines be effective to prevent disease and shedding (transmission)?

Recombinant vector vaccines:

PRCV respiratory vaccine

— Recominant experimental human adenovirus (Ad)+PRCV S1

Enteric CoV vaccines — PEDV

— PEDV -Recominant experimental human Ad5+PEDV S1

— PEDV- iPEDV+ (PED RNA)vaccine—Viral Replicon Particle (VRP)= VEEV based replicon vaccine encoding PEDV S replicon RNA

- Non-replicating single cycle RNA in DCs

Recombinant Vector Vaccines: rAd vaccines for porcine CoVs

Antigen/ Vector	Route (dose)	Challenge Inoculum	VN Ab Serum	Protection against Morbidity	Protection against Infection
PRCV respir.			*(Callebaut et al, J Gen Virol 1996;4-wk-old pigs)*		
H Ad5 /S_{A+D} (1220aa) (A+)	**Oronasal 1x**	**PRCV**	**Yes (low)**	**NT**	**Partial (shorter)**
H Ad5 Control	**Oronasal 1x**	**PRCV**	**No**	**NT**	**None**
PEDV enteric			*(Crawford et al, Virus Res 2016; 8 and 20-wk-old pigs)*		
H Ad5/S1 PEDV	**IN 1X**	**PEDV**	**(PreC) No**	**Partial**	**No**
			(Post) Yes (3x)		
Control	**--**	**PEDV**	**No**	**No**	**No**
			Yes		

The human Adeno-S vaccine 1x elicited only partial respiratory immunity to PRCV and marginal enteric immunity to PEDV: multiple doses needed?

Lessons from Molecular Vaccines for Swine CoVs

Recombinant vector/virus and subunit vaccines:

Enteric CoV vaccines — TGEV and PEDV

— TGEV -S recombinant vaccine—ineffective in naïve pigs, but effective as booster vaccine after 1x oral attenuated vaccine *(Shoup/Saif et al, 1997; Park/Saif et al,1998)*

— PEDV -PED RNA (iPEDV+) vaccine—Viral Replicon Particle (VRP) VEEV+ PEDV S replicon RNA

- 1-3X IM doses in pregnant sows showed low efficacy (only 14-22% less mortality vs controls) in piglet protection in manufacturer's studies *(Crawford et al 2016)* and only 3% less in an independent study *(Greiner et al 2015)*
- Low milk VN Ab titers (50%+,<80) vs milk (100%,>320) of wt PEDV orally inoculated sows *(Sherba et al 2016)*

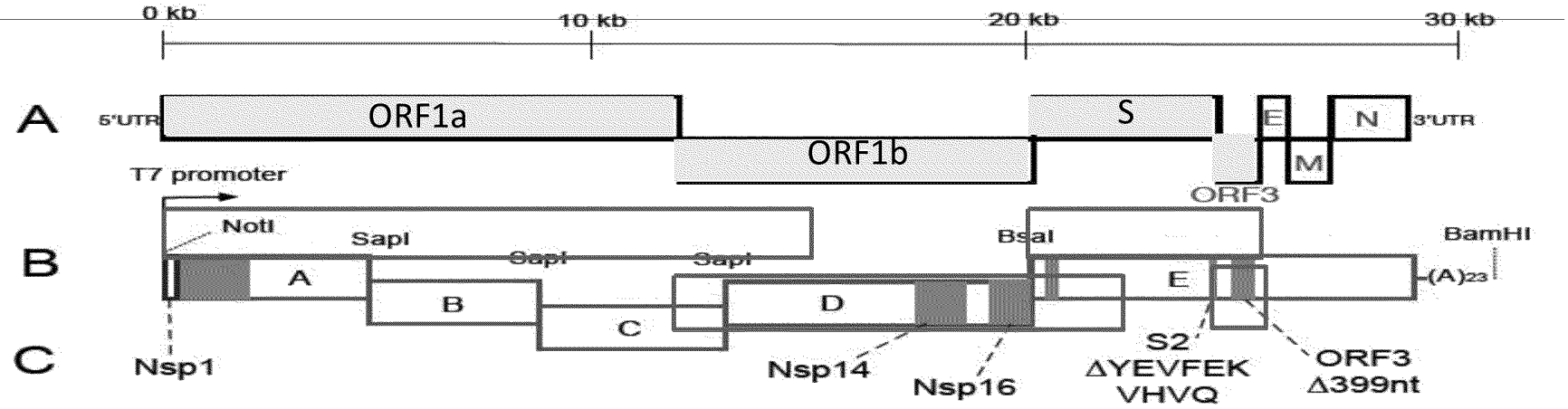
— PEDV -Recominant live attenuated virus vaccine developed by introduction of attenuating mutations into infectious clone (Lead PI: Dr Q. Wang, OSU)

Strategy to generate safe attenuated CoV vaccines using iclones

PEDV

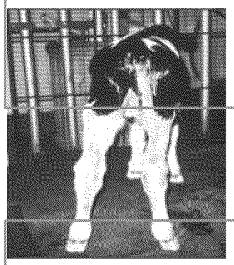
- Target genes that encode innate immune response modulators (nsp1,nsp16) and virus replication (nsp14), non-essential sequences of S protein and the accessory gene ORF3

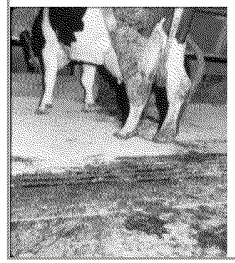
- Introduce at least 2 distinct mutations into separate genes that attenuate the virus to increase genetic stability

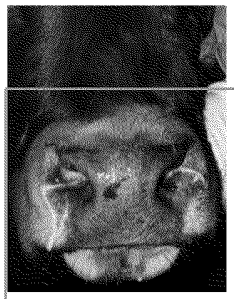


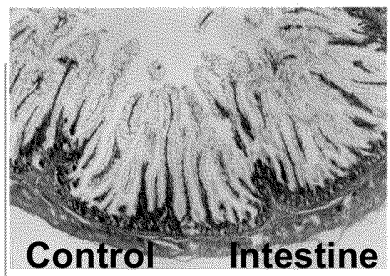
(Hou Y, Ke H, Kim J, Yoo D, Su Y, Boley P, Saif LJ, Wang Q. 2019. J Virol)

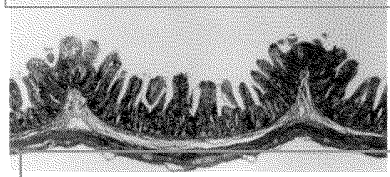
Three Clinical Syndromes Occur for Bovine Beta-CoV A Infections











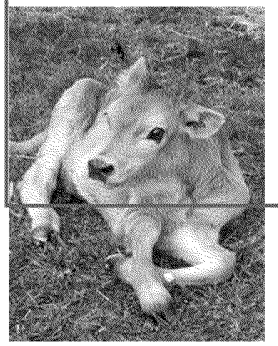
Enteric Infections Calf diarrhea • Diarrhea, dehydration • Intestinal villous atrophy	Age Groups/Vaccines Birth to 4 wks of age IM inact or atten virus vaccine in pregnant cow
Winter dysentery • Bloody diarrhea ± upper respiratory infection • Intestinal villous atrophy	Adults, but not calves *No Vaccine*
Respiratory Infections Calf respiratory disease Bovine respiratory disease complex (Shipping Fever) •Cough, nasal discharge, pneumonia	2 wks to 6 months 6-9-mo-old feedlot cattle *No Vaccine*

Saif ©

BCoVs are endemic, pneumoenteric, age effects for clinical syndromes *(Saif, Jung 2020 JCM)*

Some SARS-CoV-2 patients have diarrhea, shed virus in stools

Lessons from BCoV respiratory infection: Correlates of protective immunity in calves



- Strong correlation between serum antibody titers to BCoV and respiratory disease and IgA antibody titers in nasal secretions and nasal shedding in field studies

Calves (Heckert/Saif et al, 1990, 1991)

- *Calves (birth to 20 weeks) shed BCoV repeatedly in nasal secretions, often subclinically (short lived mucosal immunity?)*
- *Calves with IgA antibodies (titer >100) in nasal secretions did not show recurrent BCoV nasal shedding*
- *Correlation between serum antibody titers to BCoV at 24hrs of age and subsequent number of respiratory sick days*

Develop COVID-19 vaccines that elicit both systemic and mucosal immunity?

Lessons from BCoV respiratory infections: Correlates of protective immunity in feedlot cattle

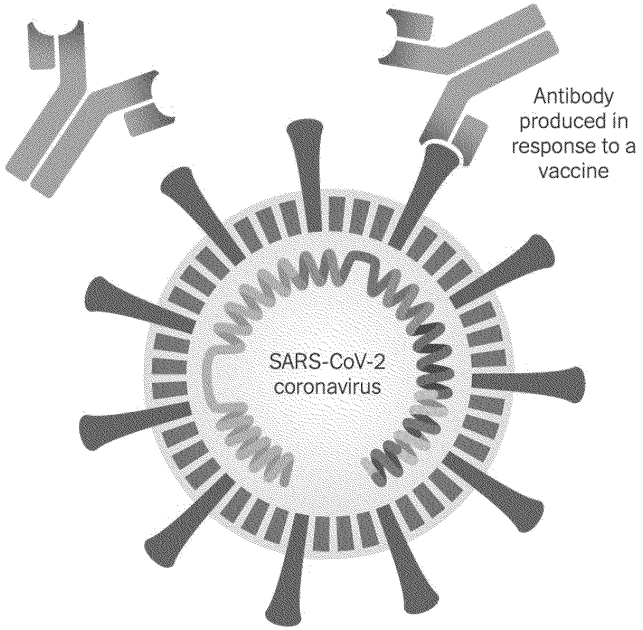
- In Feedlot cattle BCoV serum antibody titers may be a marker for respiratory protection
  - *Antibody isotype (IgG, IgA) and neutralizng titer in serum of cattle at arrival in feedlots were correlated with protection against respiratory disease, pneumonia or BCoV shedding* *(Cho/Saif et al, 2001; Lin et al, 2001; Hasoksuz/Saif et al 2002; Thomas/Saif et al, 2005)*

Strategy: Use vaccines to boost memory antibody responses to BCoV to rapidly increase antibody titers

- *Calves vaccinated IN with an attenuated BCoV vaccine at entry to feedlots had reduced risk for treatment for shipping fever pneumonia* *(Plummer et al, 2004)*

Challenges for COVID-19 Vaccines

- Rapidly deployed nucleic acid or viral vector vaccines may be a 1st generation vaccine to reduce mortality in high risk groups
  - May not prevent nasal shedding (NHP: ChAdOx1, BioRxiv; Inact vaccine, Sci)
  - May require annual booster doses to maintain immunity (common cold CoVs)
- 2^{nd} generation (more potent, efficacious) vaccines (attenuated) may be needed to prevent severe disease and reduce shedding
- Many vaccines have reduced efficacy in elderly (or those with chronic diseases)
  - Require higher dose like flu vaccines, better adjuvants or multiple doses
  - Animal models may not reflect vaccine responses in these high risk groups
- Vaccines will be used in two populations: naïve vs recovered individuals with variable levels of pre-existing immunity
  - Efficacy/adverse effects (ADE?) may vary



COVID-19 vaccines in the US an update

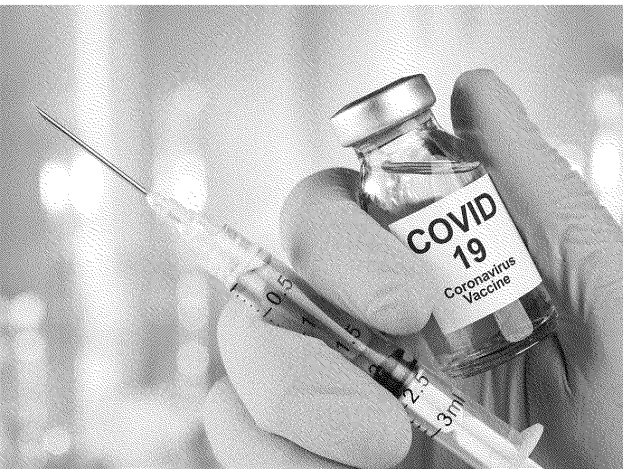
13 OCT 2020

Nancy Connell

Professor and Senior Scholar

Johns Hopkins Center for Health Security

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH | Center for Health Security



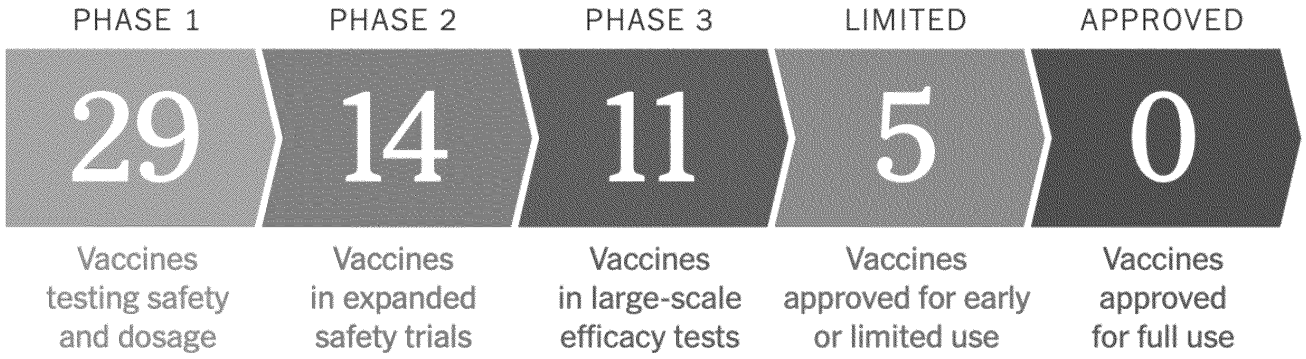
World Health Organization

Health Topics | Countries | Newsroom

Home / Publications / Overview / Draft landscape of COVID-19 candidate vaccines

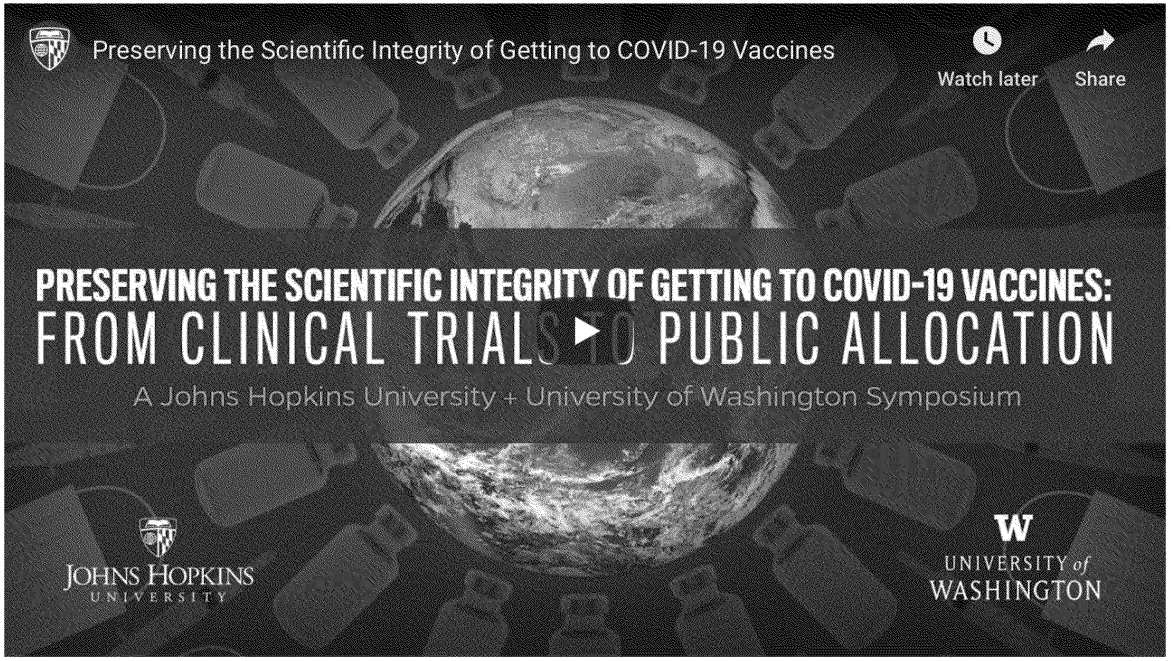
Draft landscape of COVID-19 candidate vaccines

2 October 2020 | Publication



NY Times Oct 12, 2020

Preserving the Scientific Integrity of Getting to COVID-19 Vaccines: From Clinical Trials to Public Allocation



Moncef Slaoui
Chief Advisor

Four platforms, 2 vaccines in each

- Parameters for choice
  - Speed of development
  - Likelihood of efficacy
  - Expected safety profile
  - Scaleup of manufacturing
  - Capacity of owners to execute

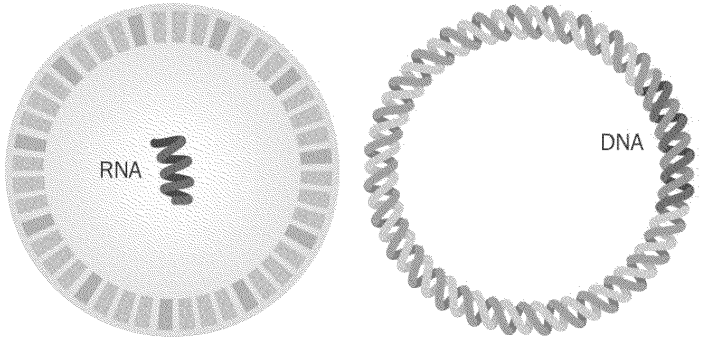
- 1. mRNA vaccine
- 2. non-replicating live vectored
- 3. adjuvanted recombinant protein
- 4. live replicating vectored vaccine
  - Oral? Single does?

mRNA vaccines

- Who?
  - Moderna
  - BioNtech/Pfizer/Fosun Pharma

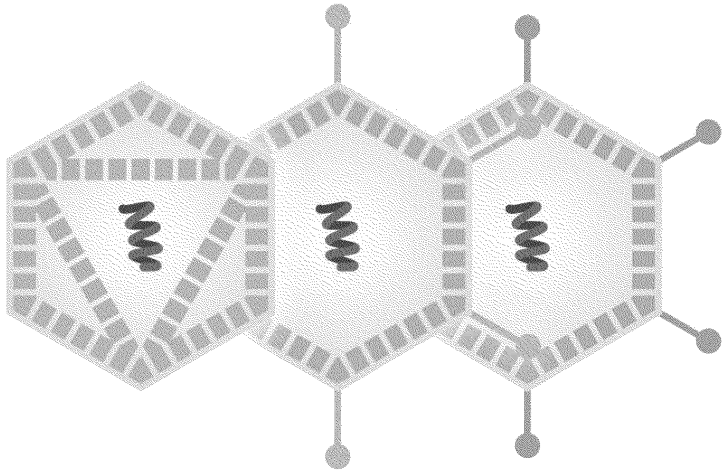
Previous uses?
- none

MF and dose availability:
- single digit millions Nov
- 10s millions – Dec
- 100s million - Jan



- Stuctures
  - mRNA encoding Spike protein
  - Encapsulated in lipid nanoparticles – to survive attack by blood cells
  - Pass through cell membranes
  - Chemicals – ease of manufacture
  - Ultracold chain required

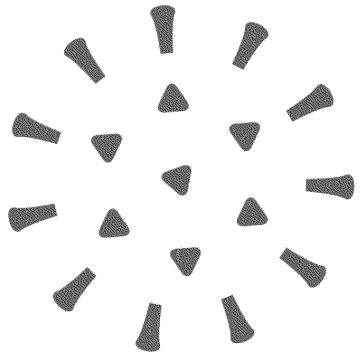
Non-replicative live vector



- Who?
  - Johnson & Johnson
  - Oxford/Astrazeneca
- Previous use?
  - Ebola
- MF and dose availability
  - Oxford 10s millions Jan
  - J&J 6-8 weeks behind

- Mechanism:
  - Virus infects one cell –induced viral immune response
  - Carries S protein gene
  - Immunity to vector?
    - J&J: Adenovirus Ad26 (obscure)
    - Oxford/AZ: (ChAdOx1) (chimp)

Adjuvanted recombinant protein



- Who?

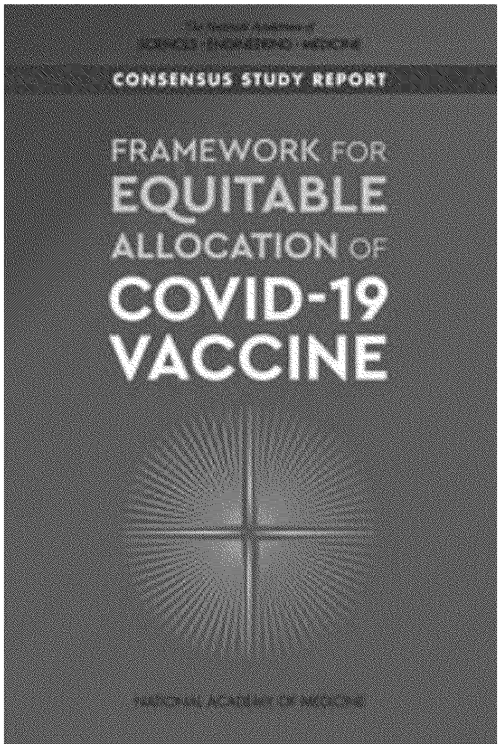
  Novovax

  Sanofi/GSK

- Previous use?
  - multiple
- MF and dose availability:
  - Doses available 1st Q 2021
  - Novovax: NC and TX
  - Sanofi: MA and NJ
- Mechanism
  - Each protein and expression system is different
  - Novovax: nanoparticle with adjuvant
  - Sanofi: based on flu vaccine technology (“FluBlock”)

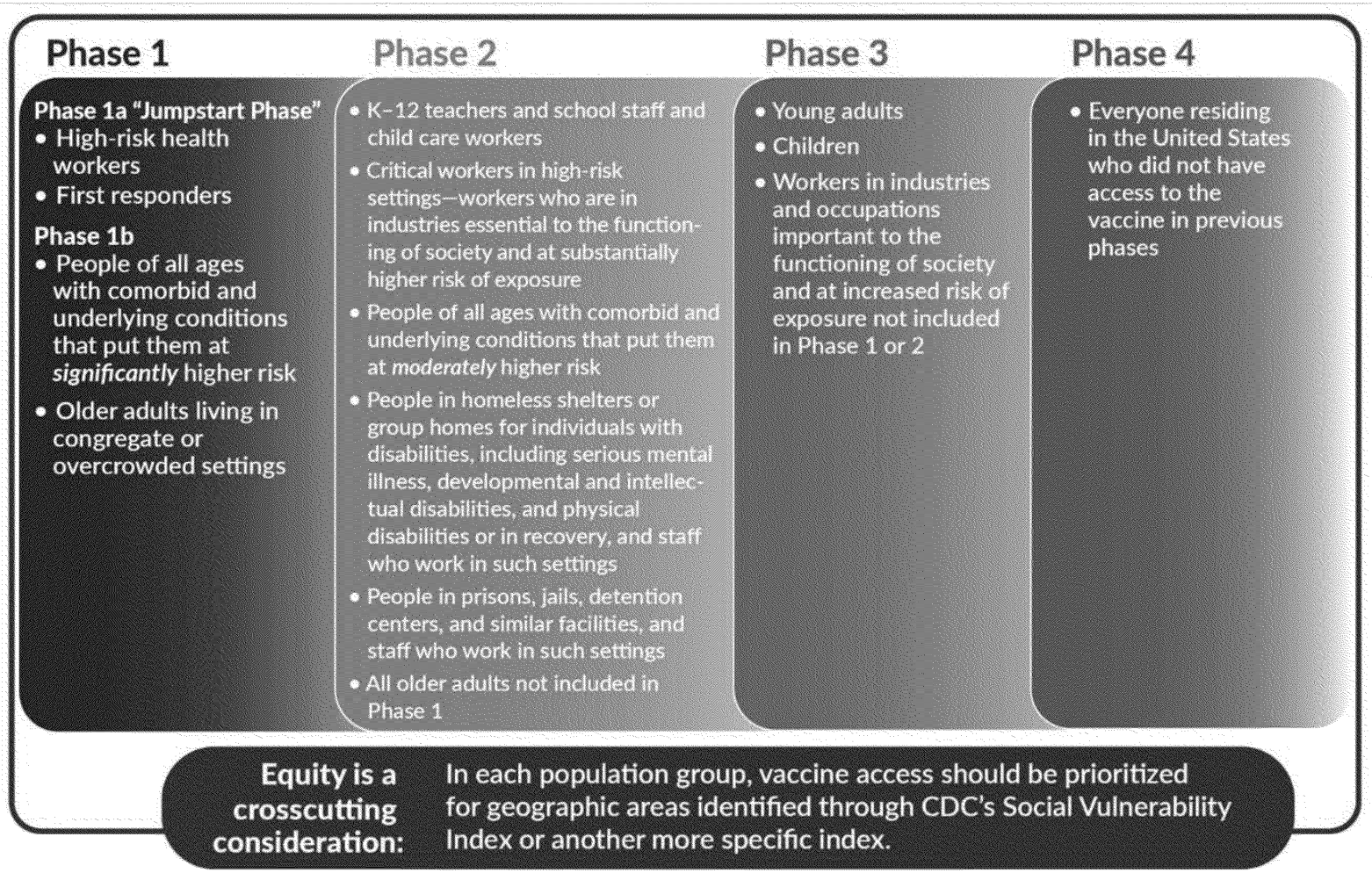
Four waves of roll-out

- RNA vaccines — November/December
- Non-replicating live vectors — January/February
- Adjuvanted proteins — March-April
- Replicating live vectors — mid-late 2021



Equitable allocation of COVID-19 vaccine

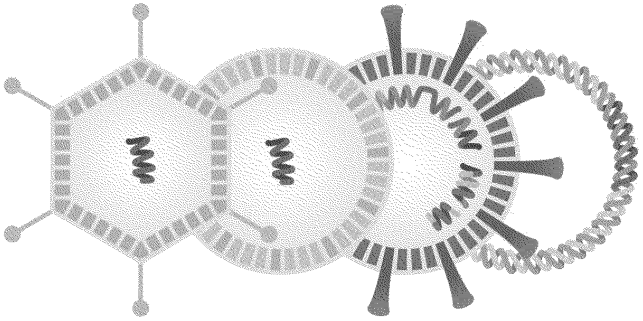
- Four-phased equitable framework, for state, tribal, local and territorial authorities (demand exceeds supply)
- Use existing programs;
- Promotion campaign with risk communication and engagement;
- Support of equitable global allocation



NATIONAL ACADEMY of MEDICINE

FIGURE: A Phased Approach to Vaccine Allocation for COVID-19

The National Academies of SCIENCES ENGINEERING MEDICINE



- *Fauci:* I could say… as a public health person, as a scientist, it will end. We will get through this for absolutely certain. We've already suffered through a lot of pain—a lot of economic and personal pain and inconvenience. But it will end. It will end because the public health efforts will succeed ultimately. And science will get us through this. We will get a vaccine. We will get therapies for early disease and for late disease. So the only message that I think we can jointly tell the American public and the global public is that we will get through this. Hang in there. It will end, we promise you.

Anthony Fauci, August 2020

To: 'Peter Daszak'[daszak@ecohealthalliance.org]; '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]; '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]; 'Nancy Connell'[NancyConnell@jhu.edu]; 'Dave Franz (davidrfranz@gmail.com)'[davidrfranz@gmail.com]
Cc: 'fsharples_3@hotmail.com'[fsharples_3@hotmail.com]; Lowenthal, Micah[mlowenth@nas.edu]; Baric, Toni C[antoinette_baric@med.unc.edu]; Alison Andre[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]; Cervenka, Nicole[NCervenka@nas.edu]; Sharples, Fran[FSharples@nas.edu]; Block, Bruce[BBlock@nas.edu]
From: Rusek, Benjamin[BRusek@nas.edu]
Sent: Mon 10/19/2020 11:57:43 PM (UTC-04:00)
Subject: RE: Some bullets following our US-China dialogue discussion on Friday
3-month follow-up-JP Weng.pdf

Greetings,

Thanks again for participating in the China bio dialogue sessions last week. And thank you Peter and others who sent me feedback and thoughts on the future of the dialogue. Additional thoughts and comments are welcome.

Re next steps: The general plan is to try and hold another two night session in 2-3 months, when we have more information to share on vaccines, durability of immunity and the evaluation and uses of different types of tests. More discussion on the origin or "natural history" of the virus focused on preventing future outbreaks (since George Gao seems to be open to it) might be possible as well.

PS I have attached the ppt on learning from Covid patients from the dialogue.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Peter Daszak <daszak@ecohealthalliance.org>
Sent: Monday, October 19, 2020 12:21 AM
To: Rusek, Benjamin <BRusek@nas.edu>; 'relman@stanford.edu' <relman@stanford.edu>; rbaric_email.unc <rbaric@email.unc.edu>; 'saif.2@osu.edu' <saif.2@osu.edu>; 'stanley-perlman@uiowa.edu' <stanley-perlman@uiowa.edu>; '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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
Cc: 'fsharples_3@hotmail.com' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; antoinette_baric.med <antoinette_baric@med.unc.edu>; Alison Andre <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>; Cervenka, Nicole <NCervenka@nas.edu>; Sharples, Fran <FSharples@nas.edu>; Block, Bruce <BBlock@nas.edu>
Subject: Some bullets following our US-China dialogue discussion on Friday
Importance: High

Thanks for a good discussion on Friday Ben,

I fully support a continued dialog and noted, as did some of those on the call, that George Gao and others were more open in their discussion of investigations into animal reservoirs of SARS-CoV-2 – i.e. discussion about the origin. We discussed ways we could frame a future topic that would allow us to talk about some important issues around the 'natural history' of SARS-CoV-2, that might also be comfortable for our Chinese colleagues. Here are a couple of bullets along the lines you asked me for:

1. Summary of recent findings re. the ability of SARS-CoV-2 to infect other species of animals in the lab, and in the wild, around the world (e.g. mink farm infections Europe and US, experimental infections of ferrets & raccoon dogs, risk

assessments of SARS-CoV-2 infecting bats in other countries)

2. From the natural history of the virus, what do we know about the diversity of alpha and beta CoVs in wildlife reservoirs, and in potential intermediate hosts in various countries in Asia.

3. What information can we identify from the receptor binding domain of SARS-related CoVs that might help us predict future potential for emergence of CoVs from other countries

I think a good strategy would be to have the US side give the opening slide deck so that we sort of set the parameters and open up some of the discussion that I'm sure would lead to interesting information. I'd be happy to help on the first 2 points, and I'm sure Ralph could talk to the 3rd point. Linda and Stanley have a great deal of knowledge and could provide supporting comments…

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
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: Rusek, Benjamin <BRusek@nas.edu>
Sent: Thursday, October 15, 2020 1:18 PM
To: 'relman@stanford.edu' <relman@stanford.edu>; rbaric_email.unc <rbaric@email.unc.edu>; 'saif.2@osu.edu' <saif.2@osu.edu>; 'stanley-perlman@uiowa.edu' <stanley-perlman@uiowa.edu>; Peter Daszak <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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
Cc: 'fsharples_3@hotmail.com' <fsharples_3@hotmail.com>; Lowenthal, Micah <mlowenth@nas.edu>; antoinette_baric.med <antoinette_baric@med.unc.edu>; Alison Andre <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>; Cervenka, Nicole <NCervenka@nas.edu>; Sharples, Fran <FSharples@nas.edu>; Block, Bruce <BBlock@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links

Greetings,

Thank you for participating in the China bio dialogue sessions on Tuesday and Wednesday this week. We have scheduled a short hotwash session so the American participants can discuss the virtual dialogue discussions (from this week and earlier this year) and your get your ideas on future topics and other issues.

The session will take place tomorrow from 5:30-6:30 PM, Zoom link is below. Sorry for the short notice, if you can't make it tomorrow feel free to weigh in by email.

Topic: China Bio Post Dialogue Meeting Discussion
Time: Oct 16, 2020 5:30 PM ET / 4:30 PM CT / 2:30 PM PT
Meeting Link: https://nasem.zoom.us/j/92476126782?pwd=a0VUaDI1dEVORjlKOC9xaXRuTGpRdz09
Password: 604638

PS I have asked CAS for the ppts from last night, will send those out as soon as I get them.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Wednesday, October 14, 2020 7:32 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
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>; Cervenka, Nicole <NCervenka@nas.edu>; Sharples, Fran <FSharples@nas.edu>; Block, Bruce <BBlock@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links

Greetings,

Thank you for joining the dialogue session last night. I have attached the slides from the three presentations.

FYI CAS has invited two additional CCDC experts to the session tonight.

Dr. Huaqing Wang, PI, Immunization program, Chinese Center for Disease Control and Prevention
Dr. Zundong Yin, Director of National Immunization Program, Chinese Center for Disease Control and Prevention

Looking forward seeing and hearing from you all in a few hours.
Session 2: Wednesday October 14, **9-11 PM ET / 6-8 PM PT in U.S.**
Meeting Link: https://nasem.zoom.us/j/98420889232?pwd=NFllKzF1eWgxT0xDZHQzQWxMbnJPdz09
Password: 375761

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, October 12, 2020 12:36 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
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>; Cervenka, Nicole <NCervenka@nas.edu>; Sharples, Fran <FSharples@nas.edu>; Block, Bruce <BBlock@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
Importance: High

Greetings,

I have attached what should be the final agenda for the U.S. China dialogue meeting sessions on Tuesday, October 13 and Wednesday October 14. It includes the Chinese participant list at the end. Links to join the Zooms are also below.

Looking forward to seeing/talking to you all on Tuesday and Wednesday evening.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***
Session 1: Tuesday, October 13, **9-11 PM ET / 6-8 PM PT in U.S.**
Meeting Link: https://nasem.zoom.us/j/92754903815?pwd=OUV2R3BPdDdibDdZZ24vcGd4VmJoUT09
Password: 833624

Session 2: Wednesday October 14, **9-11 PM ET / 6-8 PM PT in U.S.**
Meeting Link: https://nasem.zoom.us/j/98420889232?pwd=NFllKzF1eWgxT0xDZHQzQWxMbnJPdz09
Password: 375761

From: Rusek, Benjamin
Sent: Friday, October 9, 2020 5:43 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; 'Dave Franz (davidrfranz@gmail.com)' <davidrfranz@gmail.com>
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>; Cervenka, Nicole <NCervenka@nas.edu>; Sharples, Fran <FSharples@nas.edu>
Subject: RE: Virtual U.S. China dialogue meeting October 13 and 14 - agenda with zoom links
Importance: High

Greetings,

We are looking forward to the two virtual bio dialogue sessions set to take place on Tuesday, October 13 (9-11 PM ET / 6-8 PM PT)

and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT) next week. Like in previous sessions we expect that the Chinese expert participants will lead the discussion on the majority of the topics and that the format will be more of a discussion among the participants instead of a series of formal presentations. I have attached an agenda that includes the Zoom connection links for both days along with the U.S. participant list. If I get the Chinese participant list before the session I will send that out to you all.

Feel free to respond to this email with any thoughts, points of emphasis or issues that you would like to discuss among the U.S. group before the sessions. Also let me know if you have any questions or concerns.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, September 21, 2020 9:01 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>; 'Nancy Connell' <NancyConnell@jhu.edu>; Dave Franz (davidrfranz@gmail.com) <davidrfranz@gmail.com>
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>
Subject: Virtual U.S. China dialogue meeting October 13 and 14
Importance: High

Greetings,

I hope you all had a good summer and are staying safe and healthy. The Chinese Academy of Sciences has agreed to hold another (4th) virtual bio dialogue meeting with NASEM on **1) vaccine development and delivery** and **2) immunity, testing and diagnostics.** The agreed topics for the session are below. **We have reserved Tuesday, October 13 (9-11 PM ET / 6-8 PM PT) and Wednesday, October 14 (9-11 PM ET / 6-8 PM PT**) to discuss the topics on the agenda.

We hope you are able to participate. Please let me know if you are available and if so save the dates and times on your calendar. We will get back to you with more information and a detailed agenda for the sessions soon.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

***

Vaccine development and delivery

Human

1) **Current status of CoVID-19 vaccine development in China and the U.S.**
2) **Chinse vaccination of military personnel and other Chinese populations**
3) **Vaccination of pediatric populations**
4) **Active surveillance strategies for monitoring adverse events observed after vaccination (as well as immunogenicity)**
5) **Adapting current vaccine platforms to novel mass vax strategies and other mass vaccination strategic issues**

6) **Progress on a universal influenza vaccines**
7) **Vaccine for enterovirus D68**

Animal

1) **Status of corona virus vaccination for animals - kinds of vaccine, efficacy, complications, etc**
2) **ASF in China and ASF vaccine progress**
3) **New swine coronavirus**
4) **Vaccination strategy for H5N1 avian influenza and domestic poultry**

Immunity, testing and diagnostics

1) **Correlates of immunity including the possibility of background immunity from circulating "common cold" coronaviruses**
2) **Chinese diagnostic testing strategies for testing large populations quickly**
3) **Antibody and antibody testing topics, importance of T-cell responses**
4) **Long-term sequela following COVID-19 infection—lung function, neurologic issues, others**

From: Rusek, Benjamin
Sent: Thursday, June 4, 2020 1:25 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>; 'Nancy Connell' <NancyConnell@jhu.edu>
Subject: RE: 3rd Virtual U.S. China dialogue meeting on COVID-19 Tuesday, June 9, 9-11PM ET
Importance: High

Greetings,

I have attached the American version of the agenda for the 3rd U.S. China virtual dialogue meeting on immunity and related topics set to take place on **Tuesday night, June 9 from 9:00-11:00 PM ET** (9-11 AM the next morning, Beijing time).

As you can see we have incorporated George Gao's questions into the agenda, we hope that **Harvey Fineberg** can provide information on and lead the discussion of 1) serologic investigation in the U.S. 2) strategy in the U.S. for the second half of this year 3) vaccine availability in the U.S. and that **Ralph Baric** can do the same re progress in the development of vaccine in the U.S. (especially mRNA vaccine).

We have also listed delegation member names after the other Immunity questions. Like previously, folks are listed simply so someone is responsible for getting an answer from the Chinese to each question during the discussion. I will send a version to CAS without those names listed but will let them know who we have asked to answer George's questions.

Please let us know if you have any thoughts or comments on the agenda or this plan. I will send you the Zoom link later tonight or tomorrow morning.

Kind regards,

Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

From: Rusek, Benjamin
Sent: Monday, June 1, 2020 10:03 AM

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 Tuesday, June 9, 9-11PM ET
Importance: High

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,

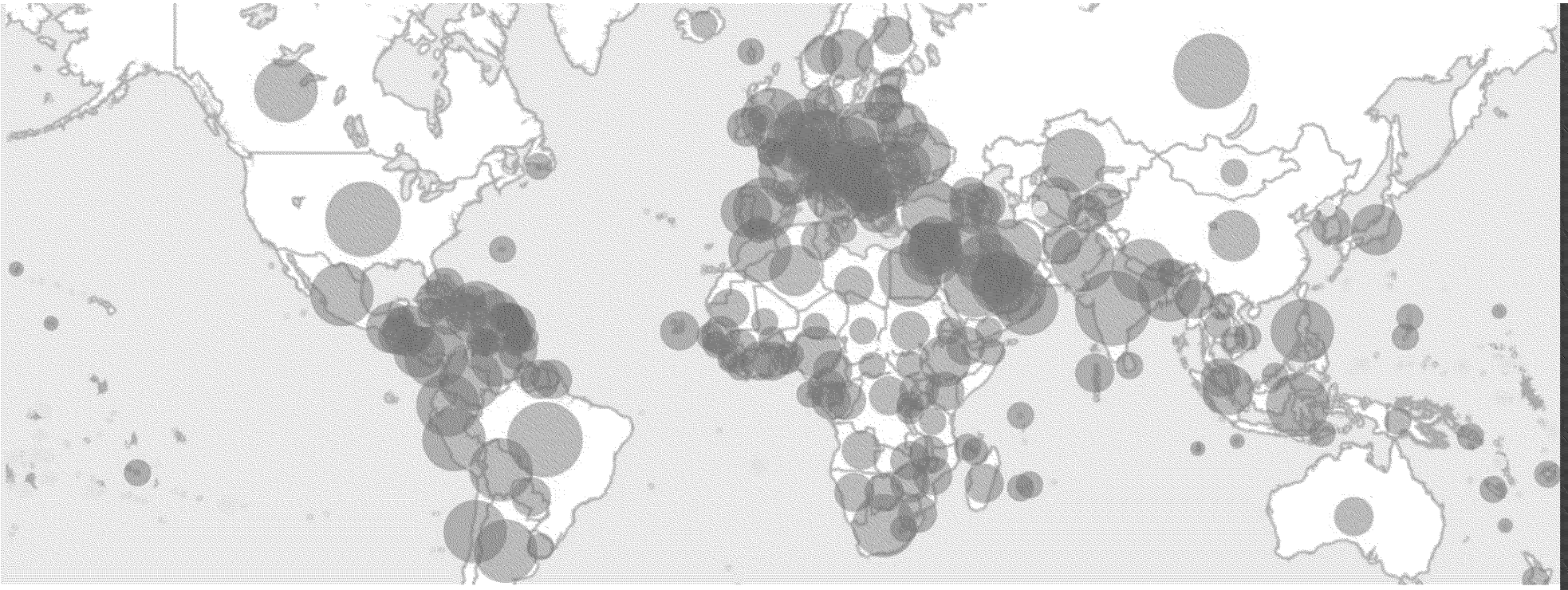
Ben

Benjamin Rusek
The U.S. National Academy of Sciences
1-202-334-3975

Learning from following up of COVID-19 patients

Jianping Weng October 15, 2020

中国科学技术大学
University of Science and Technology of China



COVID-19 global pandemic: a historical challenge

- Globally, as of 5:06pm CEST, 13 October 2020
- **37,704,153** confirmed cases
- Causing **1,079,029** deaths

1. https://covid19.who.int/ (accessed October 14, 2020)

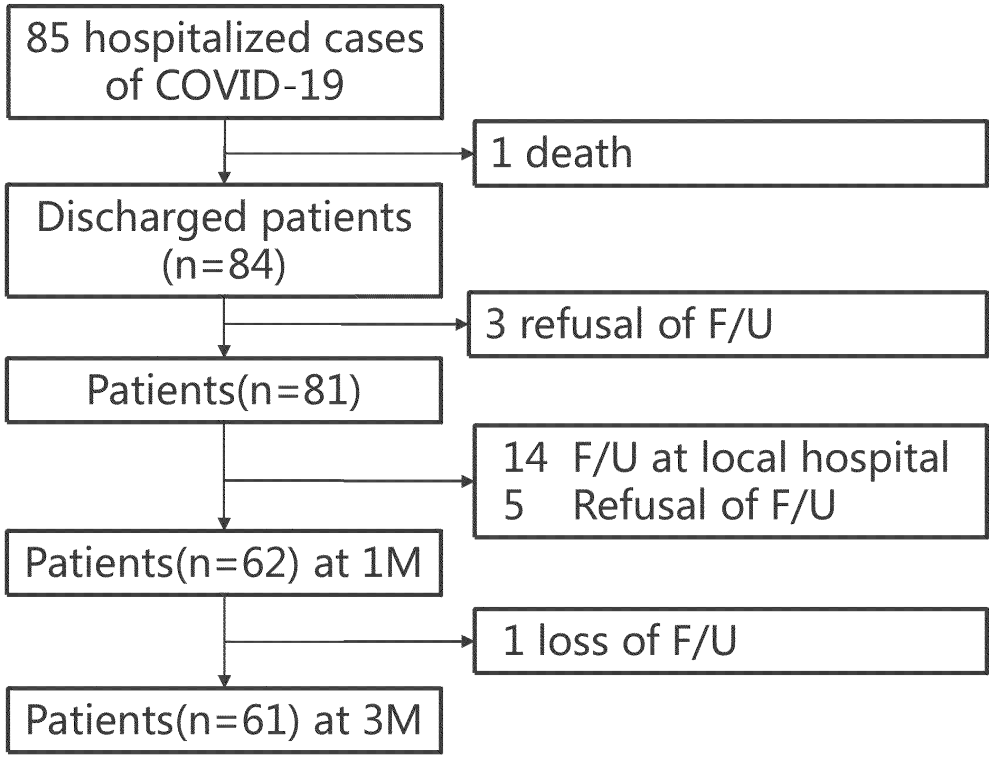
Epidemiology of COVID-19 among Infant and Children in China

- Pediatric cases accounted for approx. 1% of all cases (728/80,000, estimated via China CDC case series)
- Communicability of infection amongst children has been tracked and, as expected, infected children shed virus although, as noted above, they are frequently asymptomatic or only mildly symptomatic.
- Negative breast milk, Amniotic fluid, cord blood, and neonatal throat swab samples by RT-PCR from mothers with COVID-19 reported.
- Cases series of babies breastfed by mothers with overt COVID-19 – not infected

1. Dong Y, et al. Pediatrics. 2020 Jun;145(6):e20200702. 2. Chen H, et al. Lancet. 2020;395(10226):809–815.
3. Liu W, et al. J Hum Lact. In press. 4. Zhu H, et al. Transl Pediatr. 2020;9(1):51–60.
5. Bi Q, et al. Lancet Infect Dis. 2020;20(8):911–919.

Clinical follow-up of COIVD-19 patients after discharge

- A single-center, prospective observational follow-up study to characterize the outcomes in patients with COVID-19 at 1, 3 and 6 months after discharge
- Currently, analysis has finished with the 1- and 3-month data



Manuscript under review

At 3-month COVID-19 patients were not fully recovered

- Baseline characteristics: 58% male; median age 45 years, IQR(34 -55) ; 11% had smoking history; 37% had chronic disorders;
- At 3-month (n=61)
  - 1 re-activated virus RT-PCR on D100
  - 38% symptoms persisted: dyspnea(18%), coughing(15%), fatigue(8%)
  - 54% CT scans abnormalities: GGOs (15%), fibrosis (5%)
  - pulmonary ventilating function & physical activity (6MWD) gradually recovering

Potentially more prompt recovery at 3-month compared to SARS

- Compared with SARS, COVID-19 appears to be associated with a prompter resolution on chest CT during the recovery phase.
- Our findings indicate potentially more prompt recovery of COVID-19 patients at 3M in 6MWD compared to those with SARS.
- Preferable to combine FEV1 with DLCO in identifying pulmonary function impairment with higher sensitivity
- No significant difference among the discharged survivors with different severity pneumonia regarding other pulmonary function measures

1. Ng CK, et al.. Thorax. 2004;59(10):889-891.
2. Hui DS, et al. Chest. 2005;128(4):2247-2261.
3. Mo X, et al. Eur Respir J. 2020:2001217.

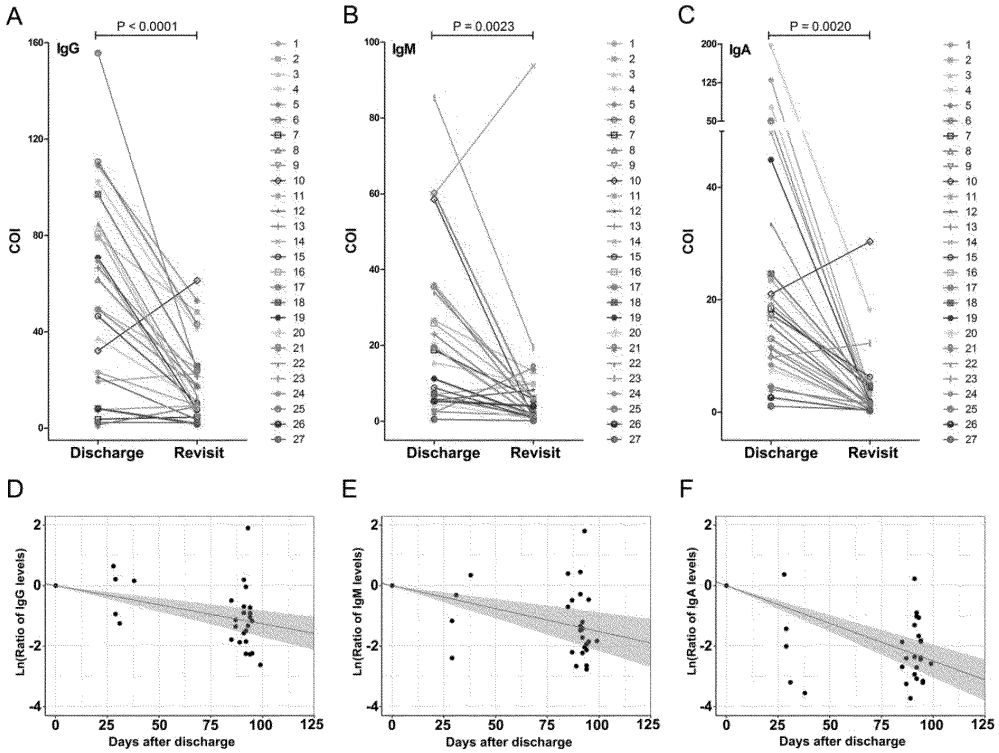
Serological study of COVID-19 patients after recovery

- Previous studies suggest that there is a significant reduction of neutralizing antibodies in the serum of COVID-19 patients in their early convalescent stage.
- Patients recovered from COVID-19 might not have protection against re-infection

1. Robbiani DF, et al. Nature. 2020 Aug;584(7821):437-442. doi: 10.1038/s41586-020-2456-9.
2. Long Q-X, et al. Nat Med. 2020 Aug;26(8):1200-1204. doi: 10.1038/s41591-020-0965-6.

Decline of SARS-CoV-2 specific antibodies in convalescent patients

- Serological study based on 27 patients followed-up after discharge
  - 100% IgG (COI 1.67-61.26) remains positive, 81.5% (COI 0.15-93.73) for IgM and 77.78% (COI 0.25-30.36) for IgA
  - Substantial decline of antibodies level at 3 months



1. Ma et al. Sci China Life Sci, 2020, doi: 10.1007/s11427-020-1805-0

Decline of SARS-CoV-2 specific antibodies in convalescent patients

- IgG antibody would become undetectable after discharge for 273 days
- IgM and IgA would be 150 and 108 days
- Our result suggests humoral immunity diminish in short period, losing the protection for the virus
- Together with previous studies, triggering strong cellular immune response and immune memory is the key for SARS-CoV-2 vaccine development.

1. Ma et al. Sci China Life Sci, 2020, doi: 10.1007/s11427-020-1805-0

Next-generation sequencing revealed influenza and Chlamydia infection in recurrent pneumonia in a recovered COVID-19 patient

A 53-year-old man was admitted to hospital with SARS-CoV-2 on January 25, 2020

↓

Discharged on February 9, 2020

↓ 82 days

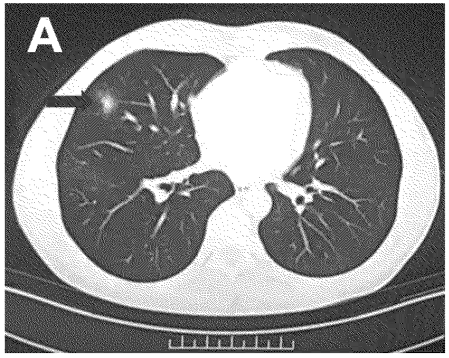
Recurrence of suspected COVID-19 GGO-like pneumonia On May 1, 2020

↓

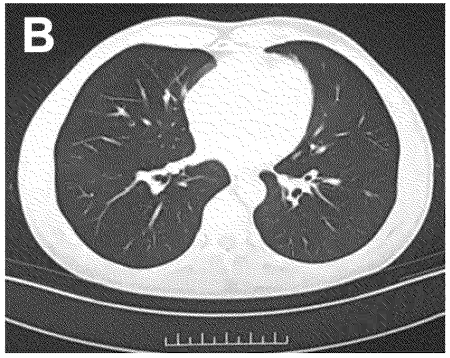
NGS showed co-infection with influenza and Chlamydia

↓

Discharged on May 28, 2020



CT on May 1, 2020



CT on May 28, 2020

Table 1 The main pathogens of alveolar lavage fluid sequenced by next generation sequencing.

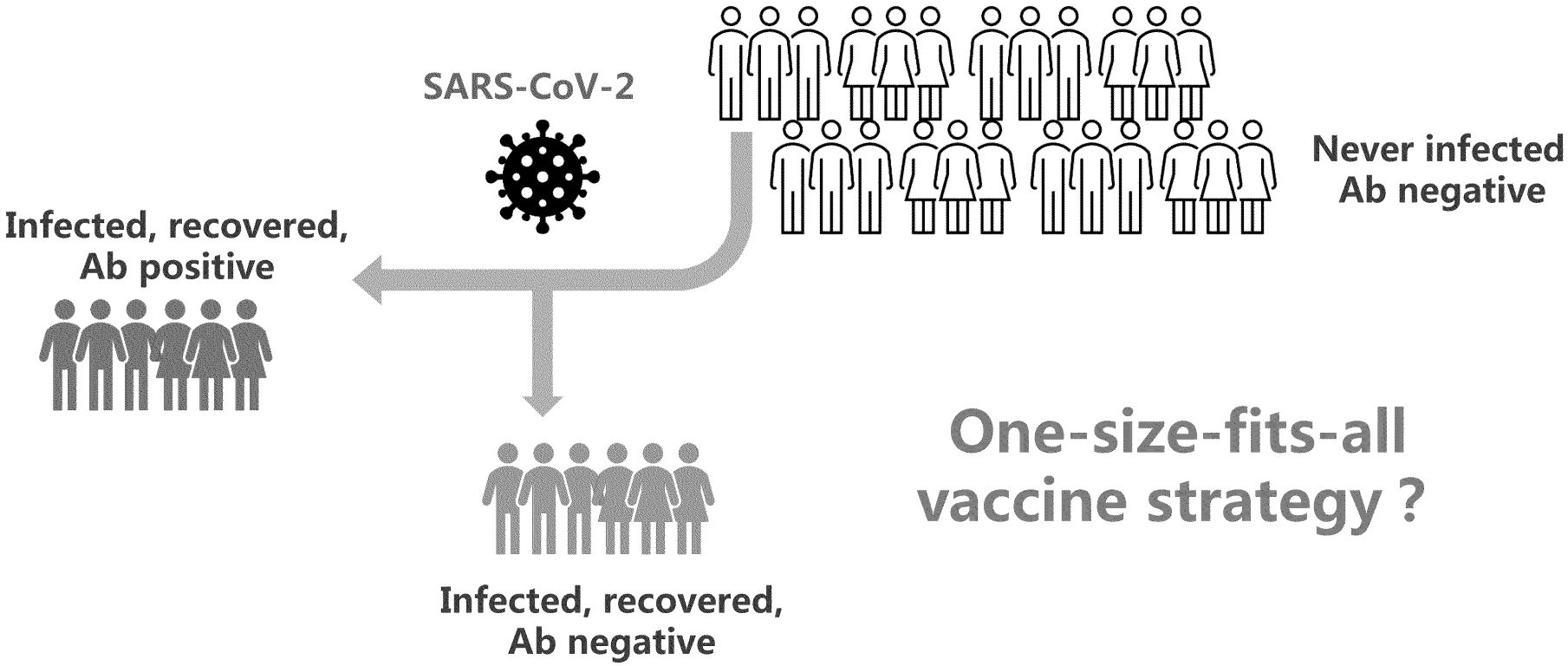
No.	%	Reads	Genus	No.	%	Reads	Genus
1	72.1	28366988	unclassified	15	0.233	91578	Listeria
2	6.948	2733676	Chlamydia	16	0.205	80778	Idiomarina
3	4.764	1874455	cannot be assigned to a genus	17	0.197	77399	Klebsiella
4	2.387	939292	Enterococcus	18	0.195	76888	Salmonella
5	1.956	769431	Lingulodinium	19	0.18	70859	Epulopiscium
6	1.381	543303	Bacillus	20	0.162	63717	Curvibacter
7	1.278	502795	Acinetobacter	21	0.142	55903	Clostridioides
8	1.152	453243	Plasmodium	22	0.111	43483	Sarcocystis
9	0.55	216421	Pseudomonas	23	0.109	42722	Kangiella
10	0.491	193240	Clostridium	24	0.107	41987	Neisseria
11	0.384	151225	Streptococcus	25	0.096	37916	Enterobacter
12	0.362	142335	Escherichia	26	0.095	37467	Burkholderia
13	0.34	133773	Mycobacterium	27	0.095	37280	Viruses
14	0.322	126861	Staphylococcus				

Table 2 The information of influenza viruses sequenced by next generation sequencing.

No.	Reads	Virus	Subtype	Description
1	40	Influenza B virus	Influenza B virus	B/Connecticut/Flu110/2013
2	11	Influenza A virus	H1N1 subtype	A/Brazil/RS-3335/2009
3	4	Influenza A virus		
4	2	Influenza A virus	H3N2 subtype	A/Brazil/RS-3335/2009
5	1	Influenza A virus	H1N2 subtype	
6	1	Influenza A virus	H10N6 subtype	A/American green-winged teal/Alaska/11508/2006

*Wen W#, Zhang GH#, Luo SH#, Bai Z, Tao W, Guo W, Ya S, Liu W, Zhang K, Wang H, Zhu S. 2020. Precision Clinical Medicine, doi:10.1093/pcmedi/pbaa033.

Concerns in developing vaccines…



One-size-fits-all vaccine strategy ?

Thank you for listening!

Jianping Weng

中国科学技术大学
University of Science and Technology of China

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[simon.funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; verschoor@bprc.nl[verschoor@bprc.nl]; verstrepen@bprc.nl[verstrepen@bprc.nl]; langermans@bprc.nl[langermans@bprc.nl]; Dr. Mark Lewis[mlewis@bioqual.com]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; nax3@cdc.gov[nax3@cdc.gov]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; sekim@krict.re.kr[sekim@krict.re.kr]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; rkiatchula@gmail.com[rkiatchula@gmail.com]; seos@cnu.ac.kr[seos@cnu.ac.kr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; mto@umn.edu[mto@umn.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; sinabavari@comcast.net[sinabavari@comcast.net]; Vasan Vasan[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Amelia Karlsson[amelia.karlsson@duke.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@fda.hhs.gov]; Philip Krause[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; ldenisy@yahoo.com[ldenisy@yahoo.com]; rhakami@gmu.edu[rhakami@gmu.edu]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; Dan Barouch[dbarouch@bidmc.harvard.edu]; esulkowska@rocs.bwh.harvard.edu[esulkowska@rocs.bwh.harvard.edu]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Krammer, Florian[florian.krammer@mssm.edu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Quim Segales[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Juergen Richt[jricht@vet.k-state.edu]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; horer@ku.edu.tr[horer@ku.edu.tr]; snumouse@snu.ac.kr[snumouse@snu.ac.kr]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; erica@lji.org[erica@lji.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Peter Palese[peter.palese@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; Benjamin tenOever[tenoever@gmail.com]; golinger@mriglobal.org[golinger@mriglobal.org]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Holbrook, Michael (NIH/NIAID) [C][Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; patrick.reid@unmc.edu[patrick.reid@unmc.edu]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; que.dang@nih.gov[que.dang@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; 秦川[qinchuan@pumc.edu.cn]; Spergel, Jonathan[SPERGEL@email.chop.edu]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; Miles Carroll[Miles.Carroll@phe.gov.uk];

Simon.Funnell@phe.gov.uk[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Padmini Salgame[salgampa@njms.rutgers.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; tverakit@gmail.com[tverakit@gmail.com]; bobomok@hku.hk[bobomok@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew Frieman[MFrieman@som.umaryland.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; baczenas@wisc.edu[baczenas@wisc.edu]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Koert Stittelaar[stittelaar@viroclinics.com]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; Pierre Gsell[gsellp@who.int]; 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]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; dbolton@hivresearch.org[dbolton@hivresearch.org]; Darin.Edwards@modernatx.com[Darin.Edwards@modernatx.com]; joshua.liang@cloverbiopharma.com[joshua.liang@cloverbiopharma.com]; Keith Chappell[k.chappell@uq.edu.au]; Neil Berry[Neil.Berry@nibsc.org]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 10/21/2020 10:52:05 AM (UTC-04:00)
Subject: WHO COVID-19 Animal Models Call-Thursday 22, 2020
Mail Attachment.ics
Webex_Meeting.ics

Dear colleagues,
Tomorrow we will have a special group call focused on providing state-of-the-art information about preclinical models for developers,

Please see agenda and invite below

Best regards to all

César, Bill and Simon.

Agenda, WHO COVID-19 Animal Models Expert Group Call- 22 October 2020, 3PM CET

15.00- Pierre Gsell. 'Welcome Notes'

15.05- César Muñoz-Fontela. 'Updates on COVID-19 Animal Models from the WHO-COM group'

15.15- Simon Funnell.

'Risk avoidance in virus propagation in the context of animal model experiments'

'Update for developers on pre-clinical expectations'

15.25- Bill Dowling. 'WHO Blueprint RFP'

15.35- Panel Discussion

(I): Rationale for selection of immune assays and time points for assessment of vaccine immunogenicity

(II): Measures for the evaluation of VAERD and ADE by vaccine developers

Panelists: Moderna (Darin Edwards), Clover Biopharma. (Joshua Liang), Univ of Queensland (Keith Chappell), Bharat Biotech (Brunda Ganneru), Neil Berry (NIBSC)

16.00- Open question: 'How do we define protocols for sample timepoints and specification of required assays?'

16.25- Pierre Gsell. 'Concluding remarks'

Meeting number (access code): 145 688 9347
Meeting password: sdP2pB2AMk3

Thursday, October 22, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr
30 mins

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Subject: [COVID-19] WHO TC Animal Models with Vaccine Developers
Location: https://who.webex.com/who/j.php?MTID=m728fd80c748610555d65207922320ce1
Start Time: 2020-10-22T15:00:00+02:00
End Time: 2020-10-22T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Start Time: 2020-10-22T15:00:00+02:00
End Time: 2020-10-22T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; Ana Maria (henaorestrepoa@who.int)[henaorestrepoa@who.int]
To: Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; verschoor@bprc.nl[verschoor@bprc.nl]; verstrepen@bprc.nl[verstrepen@bprc.nl]; langermans@bprc.nl[langermans@bprc.nl]; Dr. Mark Lewis[mlewis@bioqual.com]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; nax3@cdc.gov[nax3@cdc.gov]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; sekim@krict.re.kr[sekim@krict.re.kr]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; rkiatchula@gmail.com[rkiatchula@gmail.com]; seos@cnu.ac.kr[seos@cnu.ac.kr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; mto@umn.edu[mto@umn.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; SINA BAVARI[sinabavari@comcast.net]; Vasan Vasan[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Amelia Karlsson[amelia.karlsson@duke.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@fda.hhs.gov]; Philip Krause[philip.krause@fda.hhs.gov]; Levis, Robin[robin.levis@fda.hhs.gov]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; ldenisy@yahoo.com[ldenisy@yahoo.com]; Ramin M Hakami[rhakami@gmu.edu]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; Dan Barouch[dbarouch@bidmc.harvard.edu]; esulkowska@rocs.bwh.harvard.edu[esulkowska@rocs.bwh.harvard.edu]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Krammer, Florian[florian.krammer@mssm.edu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Quim Segales[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Juergen Richt[jricht@vet.k-state.edu]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; horer@ku.edu.tr[horer@ku.edu.tr]; snumouse@snu.ac.kr[snumouse@snu.ac.kr]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; erica@lji.org[erica@lji.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Peter Palese[peter.palese@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; Benjamin tenOever[tenoever@gmail.com]; golinger@mriglobal.org[golinger@mriglobal.org]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Holbrook, Michael (NIH/NIAID) [C][Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Reid, St Patrick M[patrick.reid@unmc.edu]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; que.dang@nih.gov[que.dang@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; 秦川[qinchuan@pumc.edu.cn]; Spergel, Jonathan[SPERGEL@email.chop.edu]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Padmini Salgame[salgampa@njms.rutgers.edu];

fkoide@southernresearch.org[fkoide@southernresearch.org]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; tverakit@gmail.com[tverakit@gmail.com]; bobomok@hku.hk[bobomok@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew Frieman[MFrieman@som.umaryland.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; baczenas@wisc.edu[baczenas@wisc.edu]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; Trevor Brasel[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; Chien-Te Tseng[sktseng@UTMB.EDU]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[wim.vanderpoel@wur.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; Pierre Gsell[gsellp@who.int]; 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]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; dbolton@hivresearch.org[dbolton@hivresearch.org]; Darin.Edwards@modernatx.com[Darin.Edwards@modernatx.com]; joshua.liang@cloverbiopharma.com[joshua.liang@cloverbiopharma.com]; Keith Chappell[k.chappell@uq.edu.au]; sarah.gilbert@ndm.ox.ac.uk[sarah.gilbert@ndm.ox.ac.uk]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 10/21/2020 1:21:15 PM (UTC-04:00)
Subject: Corrected Agenda: WHO COVID-19 Animal Models Call-Thursday 22, 2020
Mail Attachment.ics
Webex_Meeting.ics

Dear all,
Apologies for re-sending but there was a mistake in the agenda. Please find the updated information below.

Best

César

Agenda, WHO COVID-19 Animal Models Expert Group Call- 22 October 2020, 3PM CET

15.00- Pierre Gsell. 'Welcome Notes'

15.05- César Muñoz-Fontela. 'Updates on COVID-19 Animal Models from the WHO-COM group'

15.15- Simon Funnell.

'Risk avoidance in virus propagation in the context of animal model experiments'

'Update for developers on pre-clinical expectations'

15.25- Bill Dowling. 'WHO Blueprint RFP'

15.35- Panel Discussion

(I): Rationale for selection of immune assays and time points for assessment of vaccine immunogenicity

(II): Measures for the evaluation of VAERD and ADE by vaccine developers

Panelists: Moderna (Darin Edwards), Clover Biopharma. (Joshua Liang), Univ of Queensland (Keith Chappell), Bharat Biotech (Brunda Ganneru), Neil Berry (NIBSC), Sarah Gilbert (Oxford University)

16.00- Open question: 'How do we define protocols for sample timepoints and specification of required assays?'

16.25- Pierre Gsell. 'Concluding remarks'

Meeting number (access code): 145 688 9347
Meeting password: sdP2pB2AMk3

Thursday, October 22, 2020
3:00 pm | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Subject: [COVID-19] WHO TC Animal Models with Vaccine Developers
Location: https://who.webex.com/who/j.php?MTID=m728fd80c748610555d65207922320ce1
Start Time: 2020-10-22T15:00:00+02:00
End Time: 2020-10-22T16:30:00+02:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; Pierre Gsell[gsellp@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; verschoor@bprc.nl[verschoor@bprc.nl]; verstrepen@bprc.nl[verstrepen@bprc.nl]; langermans@bprc.nl[langermans@bprc.nl]; Dr. Mark Lewis[mlewis@bioqual.com]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; nax3@cdc.gov[nax3@cdc.gov]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; sekim@krict.re.kr[sekim@krict.re.kr]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; rkiatchula@gmail.com[rkiatchula@gmail.com]; seos@cnu.ac.kr[seos@cnu.ac.kr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; mto@umn.edu[mto@umn.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; SINA BAVARI[sinabavari@comcast.net]; Vasan Vasan[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Amelia Karlsson[amelia.karlsson@duke.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@fda.hhs.gov]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; Levis, Robin[robin.levis@fda.hhs.gov]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; ldenisy@yahoo.com[ldenisy@yahoo.com]; Ramin M Hakami[rhakami@gmu.edu]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; Dan Barouch[dbarouch@bidmc.harvard.edu]; esulkowska@rocs.bwh.harvard.edu[esulkowska@rocs.bwh.harvard.edu]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Krammer, Florian[florian.krammer@mssm.edu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Quim Segales[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Juergen Richt[jricht@vet.k-state.edu]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; horer@ku.edu.tr[horer@ku.edu.tr]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; erica@lji.org[erica@lji.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Peter Palese[peter.palese@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; Benjamin tenOever[tenoever@gmail.com]; golinger@mriglobal.org[golinger@mriglobal.org]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Holbrook, Michael (NIH/NIAID) [C][Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Reid, St Patrick M[patrick.reid@unmc.edu]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; que.dang@nih.gov[que.dang@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; 秦川[qinchuan@pumc.edu.cn]; Spergel, Jonathan[SPERGEL@email.chop.edu]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Padmini Salgame[salgampa@njms.rutgers.edu];

fkoide@southernresearch.org[fkoide@southernresearch.org]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; tverakit@gmail.com[tverakit@gmail.com]; bobomok@hku.hk[bobomok@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew Frieman[MFrieman@som.umaryland.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; baczenas@wisc.edu[baczenas@wisc.edu]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[wim.vanderpoel@wur.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; Pierre Gsell[gsellp@who.int]; 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]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; dbolton@hivresearch.org[dbolton@hivresearch.org]; sean@arcturusrx.com[sean@arcturusrx.com]; Kelly@arcturusrx.com[Kelly@arcturusrx.com]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 10/28/2020 11:26:38 AM (UTC-04:00)
Subject: Agenda-WHO COVID-19 Animal Models Call_Thursday 29
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Dear all,
Please find below the agenda for this week's group call which will be focused on advances on mouse models for SARS-CoV-2 infection. We still have one slot as we would like to discuss mouse-adapted SARS-CoV-2. If any of you want to fill this slot with slides or a verbal update please let us know asap. We plan to have all talks in a row and a joint Q/A section at the end moderated by Stanley Perlman who kindly agreed to help us with this call.

Thank you all very much for your contribution, we hope to see you all tomorrow

Best

César, Simon and Bill.

Agenda-WHO Animal Models Group Call-Thursday Oct 29, 3PM (CET, Geneva)

15.00 Introductory talk-Stanley Perlman (U. Iowa)

15.10 Respiratory disease in K18-hACE2 transgenic mice infected with SARS-CoV-2- Vincent Munster (RML-NIH)

15.25 SARS-CoV-2 pathogenesis in human immune system (HIS) mice- Estefanía Rodríguez (BNITM)

15.40 Application of COVID-19 mouse models for vaccine research- Sean Sullivan/Kelly Lindert (Arcturus Therapeutics)

15.55 TBD (talk focused on mouse-adapted SARS-CoV-2)

16.10 Open discussion (Moderator: Stanley Perlman)

Meeting number (access code): 145 765 1429
Meeting password: pgJ3T5vikd8

Thursday, October 29, 2020
3:00 pm | (UTC+01:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Location: https://who.webex.com/who/j.php?MTID=mb8e742b0adfc89f7ee6ed4a7718b6e6c
Start Time: 2020-10-29T15:00:00+01:00
End Time: 2020-10-29T16:30:00+01:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Alina Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; verschoor@bprc.nl[verschoor@bprc.nl]; verstrepen@bprc.nl[verstrepen@bprc.nl]; langermans@bprc.nl[langermans@bprc.nl]; Dr. Mark Lewis[mlewis@bioqual.com]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; nax3@cdc.gov[nax3@cdc.gov]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; sekim@krict.re.kr[sekim@krict.re.kr]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; rkiatchula@gmail.com[rkiatchula@gmail.com]; seos@cnu.ac.kr[seos@cnu.ac.kr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; mto@umn.edu[mto@umn.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; SINA BAVARI[sinabavari@comcast.net]; Vasan Vasan[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Amelia Karlsson[amelia.karlsson@duke.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B. Rockx[b.rockx@erasmusmc.nl]; B. 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fkoide@southernresearch.org[fkoide@southernresearch.org]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; tverakit@gmail.com[tverakit@gmail.com]; bobomok@hku.hk[bobomok@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew Frieman[MFrieman@som.umaryland.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; baczenas@wisc.edu[baczenas@wisc.edu]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; Trevor Brasel[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; Chien-Te Tseng[sktseng@UTMB.EDU]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Koert Stittelaar[stittelaar@viroclinics.com]; Poel, Wim van der[wim.vanderpoel@wur.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; Pierre Gsell[gsellp@who.int]; 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]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; dbolton@hivresearch.org[dbolton@hivresearch.org]; sean@arcturusrx.com[sean@arcturusrx.com]; Kelly@arcturusrx.com[Kelly@arcturusrx.com]; Dinnon, Kenneth Harold III[kdinnon@email.unc.edu]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Thur 10/29/2020 5:12:24 AM (UTC-04:00)
Subject: WHO Animal Models Call Today 3PM CET/10AM EDT/7AM PDT
Mail Attachment.ics
Webex_Meeting.ics

Dear all,

We just want to confirm that today's WHO Animal Models call will take place at **3PM CET (Geneva)/10AM EDT (Eastern Daylight Time)/7AM PDT (Pacific Dailight Time).**

Please also see below the updated agenda

Agenda-WHO Animal Models Group Call-Thursday Oct 29, 3PM (CET, Geneva)

15.00 Introductory talk-Stanley Perlman (U. Iowa)

15.10 Respiratory disease in K18-hACE2 transgenic mice infected with SARS-CoV-2- Vincent Munster (RML-NIH)

15.25 SARS-CoV-2 pathogenesis in human immune system (HIS) mice- Estefanía Rodríguez (BNITM)

15.40 Application of COVID-19 mouse models for vaccine research- Sean Sullivan/Kelly Lindert (Arcturus Therapeutics)

15.55 Updates on mouse-adapted SARS-CoV-2
- Michael Schotsaert (Mount Sinai)
- Kenneth Dinnon (U. North Carolina)

16.15 Open discussion (Moderator: Stanley Perlman)

SPEAKERS: Please whenever possible, send us your slides before the call so we can advance them for you.

Thank you all very much!

César, Bill and Simon

Meeting number (access code): 145 765 1429
Meeting password: pgJ3T5vikd8

Thursday, October 29, 2020
3:00 pm | (UTC+01:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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Subject: [COVID-19] 36th WHO TC - Animal Models
Location: https://who.webex.com/who/j.php?MTID=mb8e742b0adfc89f7ee6ed4a7718b6e6c
Start Time: 2020-10-29T15:00:00+01:00
End Time: 2020-10-29T16:30:00+01:00
Attendees: munoz-fontela@bnitm.de : munoz-fontela@bnitm.de

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From: Alexsay Potemkin[colonelapotemkin@gmail.com]
Sent: Sun 11/1/2020 9:40:41 AM (UTC-05:00)
Subject: A look at pharmacology and origins of Covid-19
Covid_19_pharmacology_and_origins.pdf

Dear Dr Weifeng Shi and colleagues
I had intended to write a detailed examination of the likely American origins of Covid-19 and their interest in biological warfare going back to the Korean War. However, I got a little bogged down and divided the reports into two.

This first part is mostly looking at the pharmaceutical industry and Covid-19, without getting deeply into the origins issue. But I do hope to return to that in early 2021.

Kind regards
Colonel Aleksey Aleksandrovitch Potemkin
Unit 74455
Russian Main Intelligence Directorate

Making a Killing: the Pharmaco-Military Complex in the Time of Covid

"Certainement qui est en droit de vous rendre absurde est en droit de vous rendre injuste. Si vous n'opposez point aux ordres de croire l'impossible l'intelligence que Dieu a mise dans votre esprit, vous ne devez point opposer aux ordres de malfaire la justice que Dieu a mise dans votre coeur. Une faculté de votre âme étant une fois tyrannisée, toutes les autres facultés doivent l'être également" Voltaire

A Report prepared for the World Health Organisation

By Colonel Aleksey Aleksandrovitch Potemkin.

Unit 74455

Russian Main Intelligence Directorate

Contents

Introduction: My triumphant return to the fleshpots of Moskva

In late November 2019, a worried Admiral Igor Kostyukov was in the inner sanctum of the President of the Russian Federation with a small folder of the reports received from the Russian mole in Fort Detrick, Maryland. Slowly the Great Helmsman (Vladimir Putin that is, not the Admiral) reviewed report after report in the folder, his face turning pale; "The fools, the mad fools" he muttered. He sighed, "There is only one thing for it," President Putin said turning to Dmitri Peskov, "Only one person can sort out this mess. Send for Colonel Aleksey Aleksandrovitch Potemkin!"

"Are things really that desperate?" replied a startled Peskov, "Remember you sent him into internal exile to Petropavlovsk-Kamchatsky after he accidently erased the Trump Pee Tape by taping the season final episode of Холостяк over it?" (One tiny little mistake and no one ever lets you forget about it).

Hurling a small bronze bust of Joseph Vissarionovich that the President keeps for just such occasions at Dmitri Peskov's head, the Great Helmsman curtly dismissed his Press Secretary. And so it was I returned to the scene of my previous triumphs, my office suite on the top floor of Ulitsa Kirova 22. When I walked through the door the old memories flooded back – the Yosemite Sam meme, the Bernie Superman underpants cartoon, the reach out and we'll beat it together Instagram post- all the dark arts with which I had Svengali-ed 300 million Americans and totally overwhelmed their agency, crushed beneath the irresistible power of Russian guile.

Nevertheless, new challenges now confronted me and my excellent and highly ethical Unit 74455. Having consulted the folder of reports from our man (or woman) in Frederick, Maryland, the answer was obvious enough – a peptide therapeutic with the amino-acid code of DISGINASVVNIQKEIDRLNEVAKNLNESLIDLQEL.

This anti-viral I immediately named Dzerzhivinitide, after our magnificent founder Felix Edmundovich Dzerzhivinsky who is still hero-worshipped and constantly brought up in normal conversation by members of the Russian military to this very day, as revealed in that powerful investigation the Robert Mueller Report (much like Americans can't stop talking about Alexander B. Bielaski). Strictly speaking of course, Felix Dzerzhivinsky was the director of the Gosudarstvennoe politicheskoe upravlenie (**GPU**) under the Ministry of the Interior and had no connection with the Glavnoye razvedyvatel'noye upravleniye (**GRU**) in the Ministry of Defence, but we worship him just the same. In fact it is a big problem in our tradecraft that Russian spies feel the compulsive need to write the name Felix Edmundovich Dzerzhinsky at the most inopportune moments – how many first class operations have been blown by the fatal attraction Felix Edmundovich still exercises over us? So, it is no wonder that we should name our Covid-19 therapeutic after the great man.

I. The mystery of Enfuvirtide: a broad-spectrum anti-viral that was only used once

Innovative (and highly ethical) although Unit 74455 undoubtedly is, there is no mystery about the origin of Dzerzhivinitide, it is simply the Sars-CoV 2 equivalent of an old but still effective HIV antiviral Enfuvirtide.

Enfuvirtide is a biomimemtic peptide drug for HIV developed on the basis of observations first published in 1992, which showed that small peptides derived from the viral surface protein gp41

were extremely effective in blocking the entry of HIV into cells in culture. The process by which a wide range of single strand RNA viruses fuse to their target cell membranes and gain entry is a complicated but highly conserved process. Enfuvirtide blocks by entry of the HIV virus by inserting a small peptide into the mechanism of the fusion process in order to stall it. As a "biomimemtic" peptide, it is simply an identical sequence to a small part of the gp41 protein (often called the HR2 motif – or Heptad Repeat 2), so that potential antivirals can be derived for a vast array of different viruses, simply by identifying the analogous peptide sequence in their surface protein

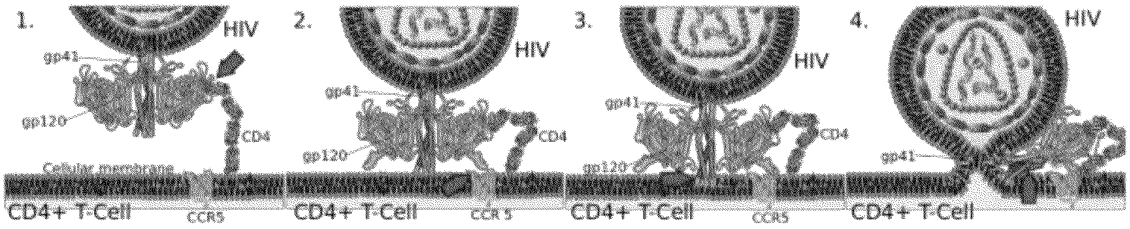
Enfuvirtide is not an ideal drug, it needs to be given intravenously, it is quickly cleared by the body and back in the 1990s its manufacture was comparatively complicated. Nevertheless, it is effective in retarding the progression of HIV and as such it retains a niche as a salvage therapy for HIV in combination with other drugs. Yet despite the fact the mechanism it disrupts is highly conserved over a large range of single strand RNA viruses, no other virus has been targeted using this strategy. To understand why this was the case, we need to closely look at how enfuvirtide works and investigations with other viruses.

Mode of Action of Enfuvirtide

Since viral cell entry is a highly conserved process, we will first examine it in HIV and then look at the analogous process in coronaviruses like Sars CoV, MERS and Sars CoV-2.

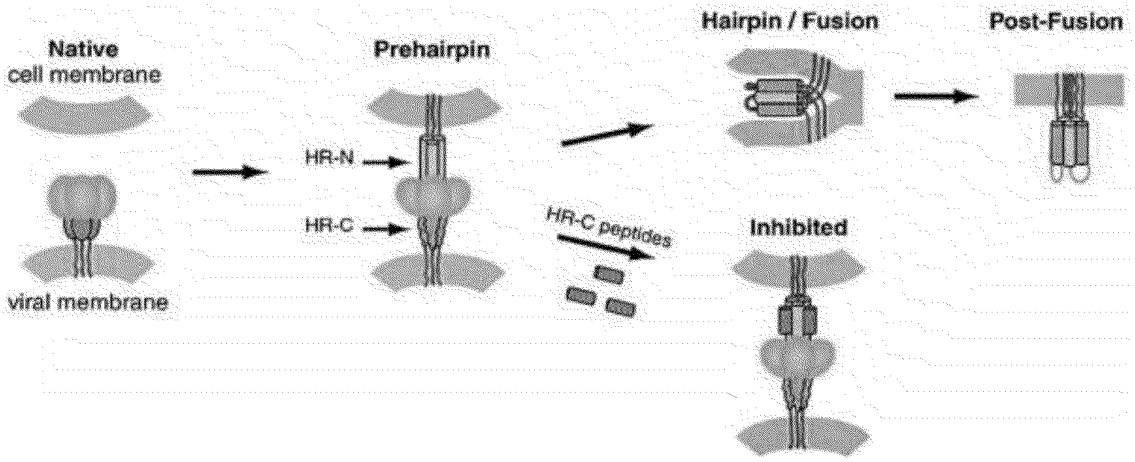
The diagram below sets out the process of virus-cell fusion in HIV. HIV has two surface glycoprotein: gp120 which binds the cell surface receptor CD4 and gp41 which provides the motor for the fusion process. Gp120 and gp41 associate non-covalently, while gp120 binds the host cell surface protein that it targets (in this instance CD4). The key to fusion is a trimeric assembly, where three gp41 proteins form a complex to mediate the fusion of the viral membrane with the host cell membrane.

The gp41 protein consists of a transmembrane peptide (anchored in the viral membrane), a helical region 'N' (sometimes called HR1 or HR-N or heptad repeat 1), a connecting region, a helical region 'C' (called HR2, or HR-C or heptad repeat 2) and the fusion peptide that inserts in the cell membrane of the target cell, initiating the process. For the trimeric assembly to form so that cell fusion takes place, the two helical regions 'N' and 'C' need to wrap around each other, forming a trimeric coiled-coil and pulling the two membranes – cell and virus – adjacent.



As the above diagram shows it: 1) gp120 binds CD4; 2) gp120 draws closer to the cell via the co-receptor CCR5, 3) the fusion peptide of gp41 inserts into the cell surface; 4) finally helical regions 'N' and 'C' of gp41 wrap around each other bringing the two membranes together for fusion.

The action of enfuvirtide is simplicity itself, if HR-C and HR-N are required to bind to each other to form the fusogenic complex, then adding short peptides identical to HR-C might be sufficient to block the complex forming. In this case the free HR-C peptides will bind to HR-N of gp41 and prevent fusion proceeding.



Above this process is diagrammatically shown, free HR-C peptides bind to HR-N and inhibit the coiled-coil forming between gp41 HR-C and HR-N domains.

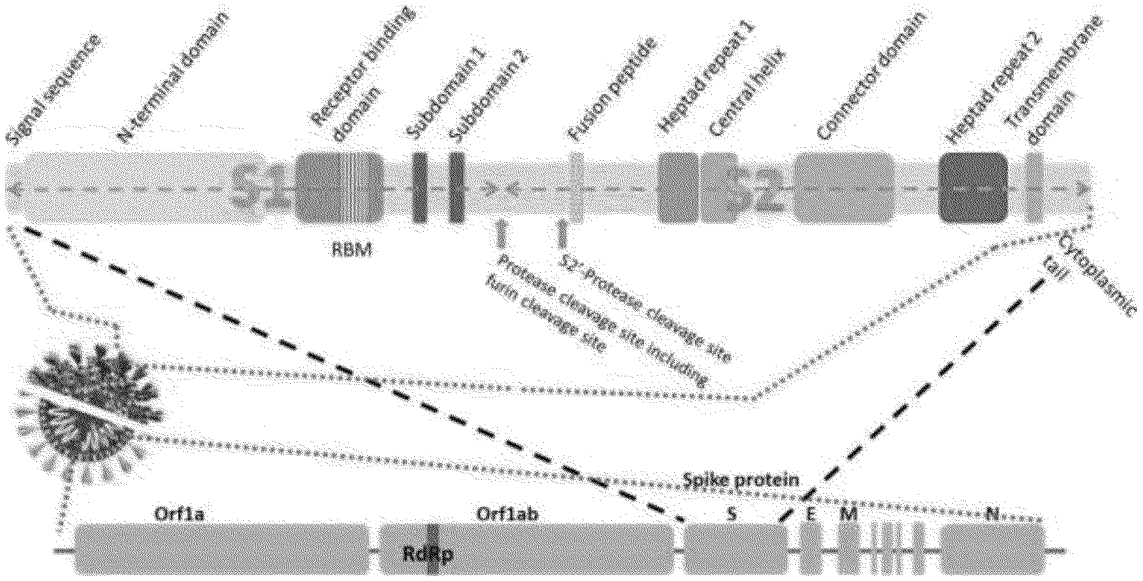
What made HR-C derived peptide of gp41/HIV so attractive for drug development was the very low concentration needed to block infection in cell culture assays. The measure commonly used is known as the IC50, the concentrated to needed to reduce thenumber of cells infected in culture by 50%. In a series of experiments using different cell culture assays, IC50 values against HIV1 isolates ranged from 0.11nM (nanomolar) to 5.56nM and IC90 values from 0.31nM to 111nM. These were considered concentrations that could be readily achieved in a pharmaceutical context.

The reliability and the repeatability of these IC50/IC90 estimates is going to be crucial in the coming sections, but for now it is worth noting that there was a 50 fold range of estimates for the IC50(0.11 nM – 5.56 nM) and a 350 fold range of estimates for the IC90 (0.31 nM – 111 nM). Equally important is that when dosing levels for enfuvirtide were established, they were much higher than even the highest IC90 value would suggest. Since enfuvirtide doesn't need to enter the cell, the volume of distribution is limited to the blood supply, ie about 8 litres. A peptide with a molecular weight of 4.5 kDa would only require a dose of 4 mg to reach the maximum IC90 of 110 nM. However, in reality the enfuvirtide dose was set at 90 mg twice daily. So instrumental although the early reports of very low IC50 values were towards initiating drug development, the lived reality of enfuvirtide is consistent with an IC50 several orders of magnitude higher.

The drug development process ended with the approval of enfuvirtide for HIV patients in 2003. Like all HIV drugs it can only slow the progression of the disease (slowed to a complete standstill when used in combination therapy), not eliminate the virus. This is due to the uniquely inconvenient nature of HIV in which the body never manages to mount an effective immune response. Because enfuvirtide is a peptide it cannot be taken in a pill form, as the digestive system would immediately break it down into its constituent amino acids. On the other hand, it also means the possibility of specific interactions with anything other than its target is vanishing small and hence it is difficult to envisage it having significant side effects.

The downside of the extremely well tolerated nature of a short peptide is likewise its extremely short persistence, with an estimated half-life of 2 hours. Just as if consumed as a pill, peptides will be immediately broken down in the stomach and intestine, when injected into the bloodstream it is quickly broken down by the liver and the constituent amino-acids recycled. Such a pharmaceutical is by no means an ideal treatment, but critically it does work.

To turn now to investigations of this functionality of the fusion machinery in coronaviruses. While in HIV and some other viruses like Respiratory Syncytial Virus, the fusion machinery consists of two proteins derived from the *env* proprotein, gp120 and gp41 or with RSV, the F and G protein, in coronaviruses this function is performed by a single protein, the Spike protein. Since the Spike protein will be critical for much of what follows, it is worth examining in such detail



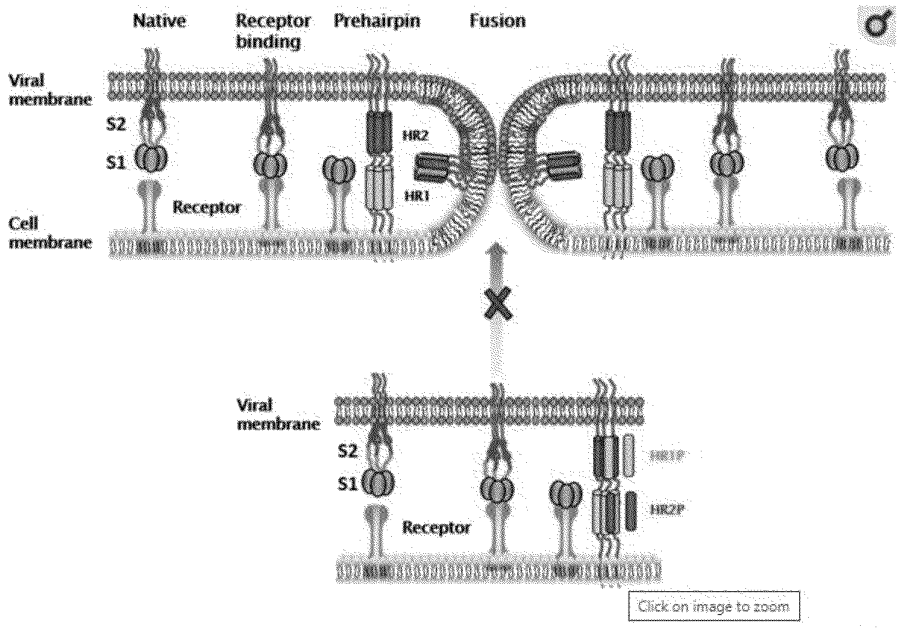
It consists of two large subunits: S1 the analogue of gp120 of HIV and S2 the analogue of gp41. Moving from left to right on S1 there is the N terminal domain, which is used to form the trimeric assembly with other S1 subunits, next is the receptor binding domain and the specific region (RBM) that makes contact with the cell surface receptor that the virus targets (HIV – CD4, RSV – Nucleolin, MERS – DPP4, Human CoV 293E - aminopeptidase N and SARS-CoV and SARS-CoV 2 – ACE2). Between the two sub-units is a hinge region that contains one or more protease cleavage sites – with SARS-CoV 2 there is the furin cleavage site that has garnered some attention, but essential is the S2 Protease cleavage site adjacent to the fusion peptide, which must be cleaved in order that the fusion peptide be inserted in the cell membrane to initiate the process.

The fusion peptide marks the start of Subunit 2 (S2). Next is the Heptad repeat 1 – the analogue of HR1 or HR-N of gp41, a central connector domain and then Heptad repeat 2 – the analogue of HR2 or HR-C and finally the transmembrane domain attached to the virus particle itself.

Like HIV's gp41, after cleavage the S2 subunit bends in the middle with 3 strands of HR-1 binding 3 strands of HR-2. This forms a trimer of S2 subunits with a core of a coiled-coil of the heptad repeats. As with HIV this process brings the viral membrane into proximity with the cell membrane.

This is expressed diagrammatically for Human CoV293E below:

Figure 1

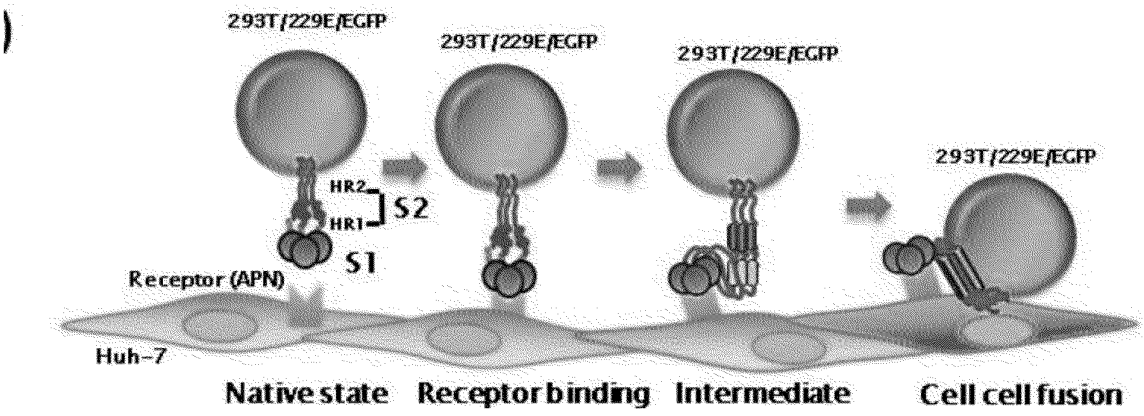


Model of membrane fusion mediated by coronavirus (CoV) spike (S) protein and the mechanism of heptad repeat 1 peptide (HR1P) and heptad repeat 2 peptide (HR2P). In the native state, the fusion peptide (FP), heptad repeat 1 (HR1) and heptad repeat 2 (HR2) domains in the S2 subunit are shielded by the S1 subunit. In the receptor-binding state, the S1 subunit binds with receptor on the target cell surface. In the pre-hairpin state, the S1 subunit dissociates, and FP in the S2 subunit is inserted into the target cell membrane, resulting in formation of the 6-HB fusion core by HR1 and HR2 and final fusion between the cell and virus membranes. HR1P and HR2P peptides can interact with the viral HR2 and HR1 domains, respectively, to block viral fusion core (6-HB) formation and inhibit viral and cellular membrane fusion. The "cross" and "arrow" means that the peptide HR1P or HR2P can block the viral gp41 6-HB-mediated membrane fusion process.

Peptide-Based Membrane Fusion Inhibitors Targeting HCoV-229E Spike Protein HR1 and HR2 Domains. Xia et al Int J Mol Science 2018

The top panel shows first the S1 subunit binding to the cell surface receptor, the fusion peptide of S2 inserts into the cell membrane. Then the HR-1 region and HR-2 region are exposed and wrap round each other fusing the two membranes. The lower panel shows the identical process, except here free HR-1 and HR-2 analogous peptides are added, these bind to their corresponding targets on the Spike protein blocking the fusion process.

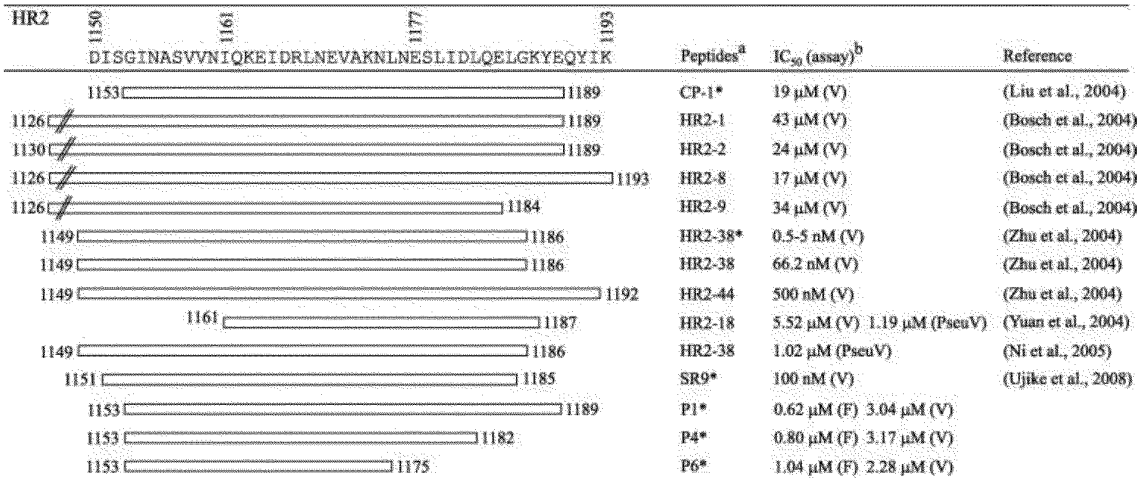
The diagram depicts the same process HCoV 229E, but hypothesizes that the two subunits do not need to be proteolytically cleaved and fusion can proceed without requiring the fusion peptide to be inserted into the cell membrane.



The Exclusion of Enfuvirtide approach from other viruses

Given the essential features of the fusion machinery is widely conserved, regardless limitations of this therapeutic approach why has not been developed as at least a treatment of last resort for other single stranded RNA viruses? The short answer is that through some strange fluke, it is deemed only suitable for HIV because it is believed that HIV's affinity for its HR-1 and HR-2 peptides with the fusion complex are several orders of magnitude lower than that of analogous peptides of any other virus. This brings us back to the IC50 values, the wildly varying numbers produced out of cell culture experiments discussed above representing the concentration of peptide needed to achieve 50% inhibition of viral infection.

Using SARS CoV as an example, this novel virus emerging in 2003 was reasonably rapidly controlled by tradition methods of infection control – quarantine and isolation. As such there was insufficient time to seriously investigate pharmaceuticals, either novel or repurposed. Nevertheless a considerable number of cell culture experiments using HR-1 and HR-2 peptide approaches have been carried out. The figure below represents the extreme range of values reported



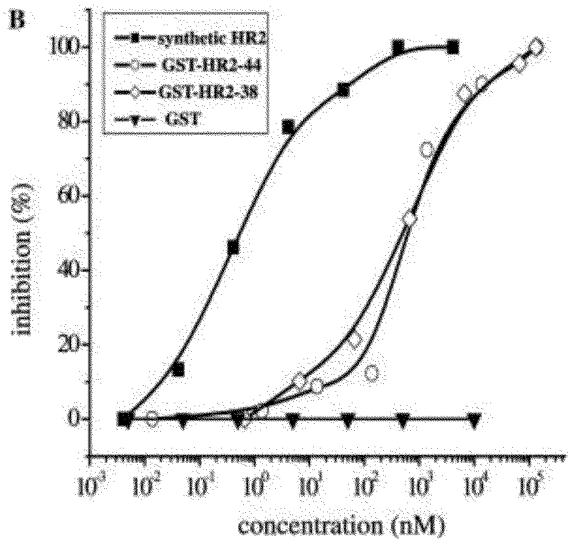
Peptides[a]	IC_{50} (assay)[b]	Reference
CP-1*	19 μM (V)	(Liu et al., 2004)
HR2-1	43 μM (V)	(Bosch et al., 2004)
HR2-2	24 μM (V)	(Bosch et al., 2004)
HR2-8	17 μM (V)	(Bosch et al., 2004)
HR2-9	34 μM (V)	(Bosch et al., 2004)
HR2-38*	0.5-5 nM (V)	(Zhu et al., 2004)
HR2-38	66.2 nM (V)	(Zhu et al., 2004)
HR2-44	500 nM (V)	(Zhu et al., 2004)
HR2-18	5.52 μM (V) 1.19 μM (PseuV)	(Yuan et al., 2004)
HR2-38	1.02 μM (PseuV)	(Ni et al., 2005)
SR9*	100 nM (V)	(Ujike et al., 2008)
P1*	0.62 μM (F) 3.04 μM (V)	
P4*	0.80 μM (F) 3.17 μM (V)	
P6*	1.04 μM (F) 2.28 μM (V)	
NP-1*	50 μM (V)	(Liu et al., 2004)
HR1-1	3.68 μM (V)	(Yuan et al., 2004)
N46*	3.97 μM (F)	
N46eg*	5.07 μM (F)	

[a] Peptides were purified from bacteria-expressed fusion proteins or peptide synthesizer (marked with asters).
[b] V, virus infection inhibition assay; PseuV, pseudotype reporter virus inhibition assay; F, cell fusion inhibition assay.

(Liu IJ, Kao CL, Hsieh SC, Wey MT, Kan LS, Wang WK. Identification of a minimal peptide derived from heptad repeat (HR) 2 of spike protein of SARS -CoV and combination of HR1-derived peptides as fusion inhibitors. Antiviral Res. 2009;81(1):82-87. doi:10.1016/j.antiviral.2008.10.001)

The summary table above shows the IC50 value from the HR2 region for Sars-CoV reported by a number of different laboratories. They show values ranging from 500 pM (a Chinese group Zhu *et al*.) to 100 nM (a Japanese group, Ujike *et al.)* to 43 microMolar (a Dutch group), i.e. a 100 000 fold difference for peptides that are broadly overlapping. The efficacy of peptides reported by Zhu et al has been obscured by the fact the compiler of the table included thevalues of the GST fusion-HR2 proteins (66.2 and 500 nM) which would hardly be expected to perform nearly efficiently as the HR2 peptide itself.

It is perhaps worth looking at the original data from the Zhu paper to illustrate this point

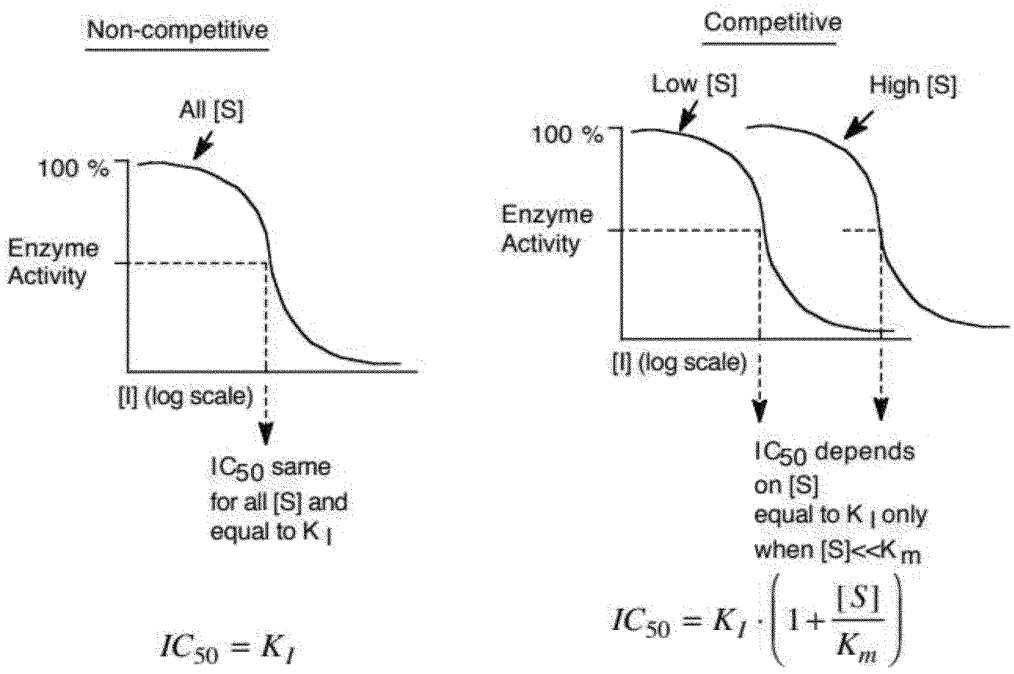


(Following the rule: formation of the 6-helix bundle of the fusion core from severe acute respiratory syndrome coronavirus spike protein and identification of potent peptide inhibitors. Zhu et al. 2004 Biochem Biophys Res Commun.)

The synthetic HR2 is the native 38 amino-acid residue peptide, the two GST-HR2 curves are uncleaved fusion proteins expressed in E.coli. The IC50 value for the peptide alone is well within the range of values that were found for enfuvirtide and HIV.

The point is not that one set of results is right and the others are wrong, but simply that the IC50 is really just an artefact of the individual experimental conditions and not a rigorous comparable pharmacological or biochemical parameter. In particular, the viral challenge commonly used is 100X TCID50, where TCID50 is the concentration at which 50% of the cells in a tissue cell culture monolayer become infected, while a 100X represents a 100 fold multiplication of that level. This is a massively higher viral titre than human lungs will ever encounter, which will never encounter a TCID50 titre, let alone 100 times TCID50.

The IC50 (inhibitory concentration 50%) is the concentration of an agent that causes 50% inhibition of an assay or measure (infection rate, enzyme inhibition etc). It is frequently seen as analogous to the Ki (inhibitory constant) of enzyme kinetics. In non-competitive inhibition the Ki is constant over large ranges of the substrate concentration, whereas with competitive inhibition the Ki depends on the concentration of the substrate.



$$IC_{50} = K_I$$

$$IC_{50} = K_I \cdot \left(1 + \frac{[S]}{K_m}\right)$$

While the analogy with enzyme kinetics can only be taken so far (is the enzyme the host cell, the virus the substrate?) for many pharmacological agents the non-competitive inhibition scenario works – the IC50 will be fairly inelastic over large variations of viral concentration. If you use interferon-beta, you are largely attempting to mediate the host response so that the IC50 value is going to be relatively like a constant over a large range of virus concentrations. If you use a nucleoside analogue (eg ribavirin), while you are interacting with a viral protein, the substrate is the host's RNA precursors the concentration of which will be fairly stable, so the IC50 will still remain relatively constant. If you use a protease inhibitor, it is interacting with a viral protein and is potentially less inelastic to viral concentration, but the requirement to enter the cell first will likely to some extent represent a bottleneck.

In the case of HR2 peptide inhibitor, using the enzyme kinetics analogy the virus is acting as the enzyme and the host cell target the substrate, as such we are very much in the situation of competitive inhibition (ie where the IC50 is going to be dependent on the virus concentration). The HR2 peptide is competing with its corresponding region on the Spike protein, moreover the HR2 peptide need only bind on one of three available sites, while the Spike protein needs all three of the HR1-HR2 regions to interact to form the coiled-coil trimer that mediates fusion with the cell surface. Since the Spike protein needs to bind first to the cell-surface receptor before the fusogenic core is exposed, from this it follows that the effective IC50 will drop – and quite likely drop faster – as the concentration of the virus drops. As the 100X TCID50 viral dose is a number of orders of magnitude greater than what are actually experienced *in vivo*, it follows that the reported IC50 values are meaningless. Further, because the methods of actually quantifying virus titres to calculate the 100X-TCID50 dose are fairly fuzzy and vary wildly from lab to lab, so we would expect to see the massive differences in IC50 reported for SARS coronavirus using the HR2 region peptide: from 0.5 nanoMolar to 50 microMolar.

Another determinant of the IC50 values could be the number of cell surface receptors available, the importance and abundance of any co-receptors and the specific affinity the cell surface receptor has for the receptor binding domain of the virus. Whether the cell is adherent or in suspension will also have a bearing on the number of receptors that are available in these cell culture systems. *In vitro* the availability of cell surface receptors would be effected by the mucosal nature of the susceptible surfaces (including modulation by innate immune defences), making the clean, exposed nature of adherent cell culture an extremely poor model to directly translate IC50 values into absolute pharmaceutical parameters

However, it would be wrong to suggest that the widely varying IC50 values reported in the literature are simply the result of some random, chaotic process. Rather some clear trends emerge from the literature. The original and lowest IC50 figure reported was from the very first virus that was investigated – HIV. This was followed up during the 1990s by a number of other viruses where the IC50 values reported were slightly higher, but still in the nano-molar range. For example in this 1996 publication:

2190 Medical Sciences: Lambert *et al.*

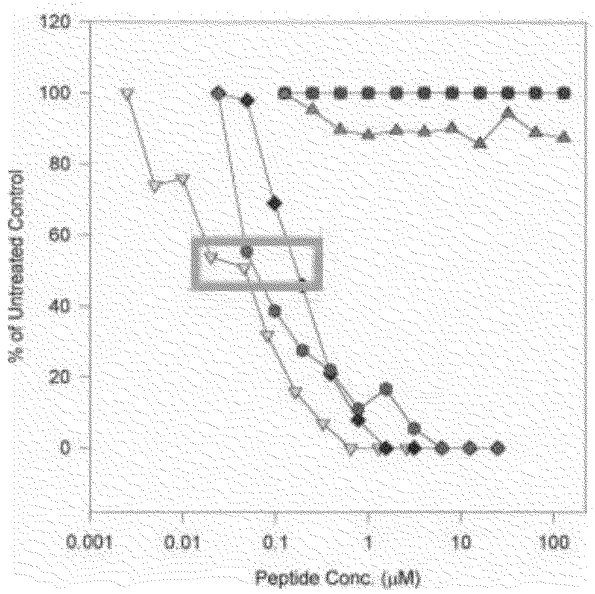


FIG. 3. Dose–response of T-118 (◆) against RSV-induced fusion, T-205 (▽) against HPIV-3-induced fusion, and T257 (●) against MV-induced fusion. Virus-infected cells (24 hr postinfection) were added to monolayers of uninfected cells in the presence of a range of peptide concentrations (μM). Cytotoxicity for T-118 (▲), T-205 (●), and T257 (■) was evaluated using the tetrazolium salt XTT in the host cell line for each virus.

Peptides from conserved regions of paramyxovirus fusion (F) proteins are potent inhibitors of viral fusion. Lambert et al. Proc Natl. Acad. Science 1996

The yellow box highlights the IC50 zone – from left to right: human parainfluenza virus 3, measles virus, respiratory syncytial virus. On the top right are the traces reporting cell toxicity of each peptide in the absence of any virus. The approximate IC50 values are 20 nM for HPIV3, 60 nM for measles and 200 nM for RSV.

As we moved into the new millennium the IC50 values being reported began to increase still further into the micro-molar range, at which point another trend began to manifest itself. As seen with the SARS data discussed above when a Chinese group reported a low nM range figure, it was immediately swamped by publications from NATO associated countries (in this case the Netherlands and Japan) reporting far higher values. We see two trends then, a trend towards higher reported values over time and a trend towards higher values the closer the research groups are affiliated to countries belonging to NATO.

Glaxo-Smith Kline: HR2 peptides against Respiratory Syncytial Virus

This NATO-aligned influence was particularly in evidence with Glaxo Smith Kline and an Australian feeder research firm Biota in the late 1990s. This was still at the tipping point when enfuvirtide-type therapies were still discussed in the literature and just prior to when they became completely ignored. At this time Biota was trying to get FDA regulatory approval for their influenza neuraminidase (the cell surface receptor influenza virus attaches to) analogue cell entry blocker known as Zanamivir, also marketed as Relenza. While trying to gain regulatory approval from the Food and Drug Administration for their Relenza drug, Biota began to investigate peptides therapies for Respiratory Syncytial Virus.

Although Biota had discovered the first neuraminidase inhibitor, they struggled to gain American approval for their drug. In the meantime an American pharmaceutical firm, Gilead, had developed a competing product that was sailing through the FDA regulatory process; a process that Biota and GlaxoSmithKline were convinced the FDA was skewing in favour of the American firm. And then after Gilead's Tamiflu beginning to breath down their neck, Biota's and GSK's candidate Relenza fell over. Michael Elashoff was a statistician working for the FDA and did the first review

> *After Dr Elashoff's review (he had access to individual patient data and summary study reports) the FDA's advisory committee voted by 13 to 4 not to approve zanamivir on the grounds that it was no more effective than placebo when the patients were on other drugs such as paracetamol. He said that it didn't reduce symptoms even by a day.*
>
> *"When I was reviewing the data, I tried to replicate the analyses in their summary study reports. The issue was not of data quality, but sensitivity analyses showed even less efficacy," he said. "The safety analysis showed there were safety concerns, but the focus was on if Glaxo had demonstrated efficacy." Dr Elashoff's view was that zanamivir was no better than placebo—and it had side effects. And when the FDA medical reviewer made a presentation, her conclusion was that it could either be approved or not approved. It was a fairly borderline drug.* WHO and the pandemic flu "conspiracies" BMJ 2010

In the meantime, in Australia, HR2 based peptides had passed the biophysical testing for structure and binding affinity and been sent to Biota's Melbourne Parkville lab for efficacy testing in cell culture. According to internal company discussions, the HR2 peptide showed the precisely the same efficacy as enfuvirtide showed against HIV but suddenly further investigations were halted and the data suppressed, never appearing in a scientific journal. Meanwhile, back in the United States the FDA advisory committee's recommendation to deny approval to Relenza was abruptly overturned by FDA management, followed shortly after by approval for the competing drug Tamiflu.

The trade-off seems clear, the FDA offered GlaxoSmithKline access to the influenza market estimated to be worth $2.5 billion annually, overlooking the fact their drug showed no clinical benefit, for the quid pro quo of dropping development of peptide approaches that would have created a simple, straightforward strategy for tackling a wide range of SS RNA viruses. This would have included rapidly developing treatments for any novel RNA viruses that might suddenly emerge, as they began to with alarming regularity over the course of the 21st century. The market for RSV antivirals was tiny and a barely commercial proposition, especially considering the regulatory hurdles that would need to be overcome, whereas the influenza market seemed a sure-fire bet for a billion dollar drug blockbuster. In the event, neither Relenza nor Tamiflu thrived particularly since eventually the demand for ineffective drugs is always going to wane. However, zanamivir/Relenza struggled against its competitor Tamiflu mostly because of the difficulty of administrating the drug with its customized Diskhaler device compared with the orally ingested Tamiflu.

Thus in tracing the failure of development of any further enfuvirtide-like antivirals, it appears to have been a result not just of the gradual inflation of the IC50 values that were reported in the literature, but also from potential billion dollar bribes by the FDA operating as cover for the national strategic interests of the US government.

Surreptitious testing of HR2 peptides in Animal Models

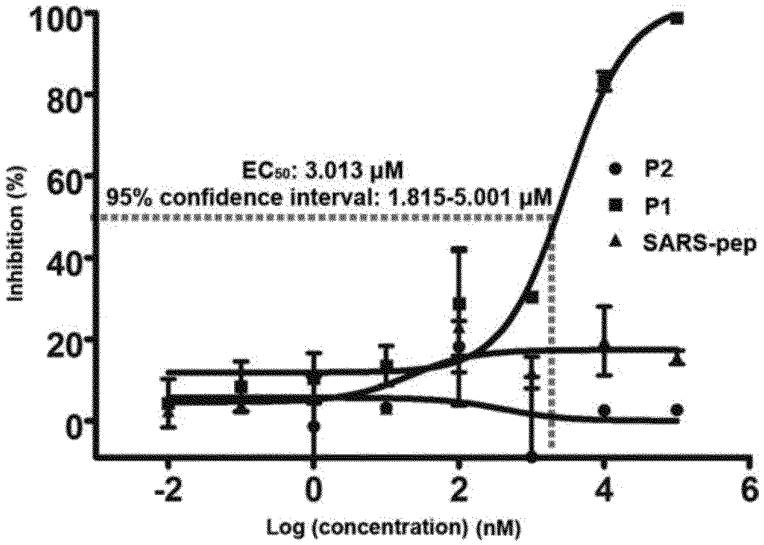
From around the year 2005 the reported IC50 values of HR2-derived peptides in cell culture assays continued to rise and were now exclusively in the microMolar range, however a few did move beyond cell culture and into animal testing. Generally these were not the native HR-2 peptide (by this stage everyone had become aware that this was not publishable) but peptides with some minor variation were tested in animal models, even though these variants had only showed a marginal increase in efficacy in cell culture

However, these experiments also serve to demonstrate the meaningless of the IC50 values when assessing the possible action of HR2 peptides in animal models and by extension as human pharmaceutical. The MERS virus provides one such example. When assayed in 2013, the HR2 peptide (here called P2) showed an IC50 of 3 microMolar in cell culture assays, apparently over a 1000 fold less effective than enfuvirtide (below):

P1: LTQINTTLLDLTYEMLSLQQVVKALNESYIDLKEL

P2: - - - - - - - - LTYEMLSLQQVVKALNESYIDLKELGN

SARS-pep: IQKEI DRLNEVAKNLNESLIDLQELGK

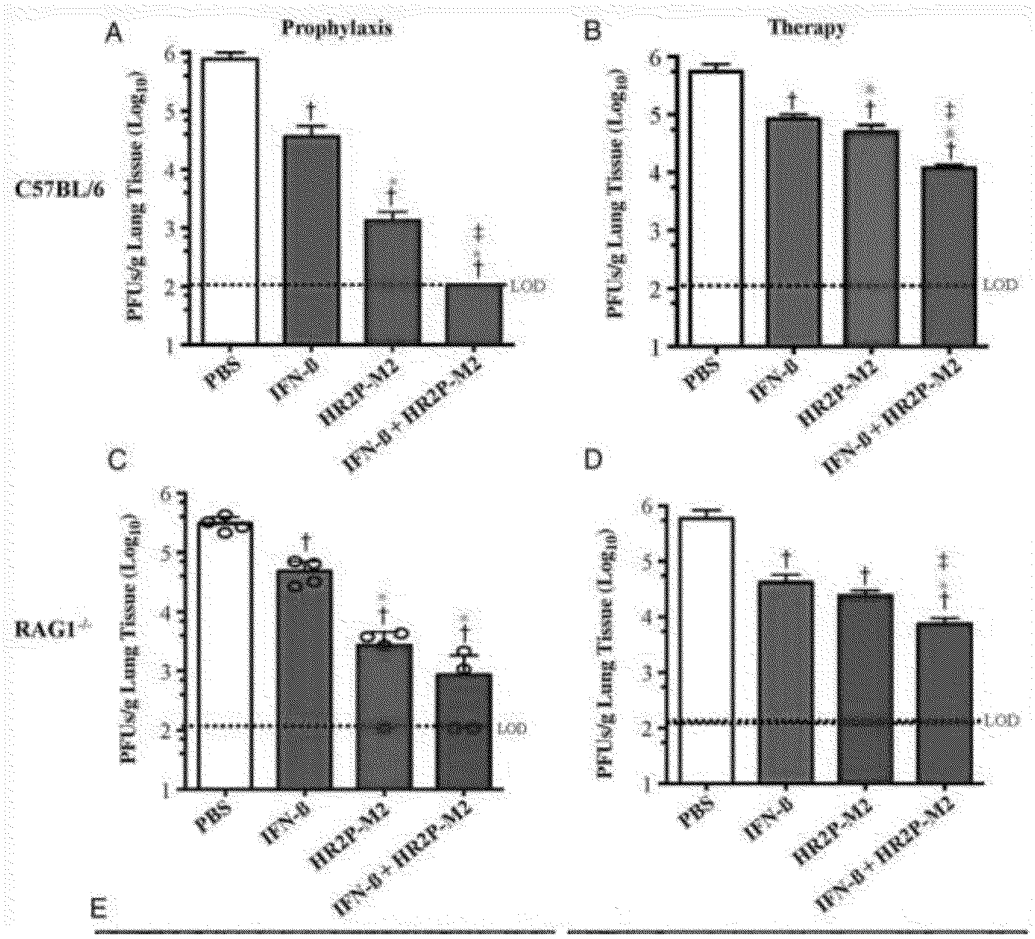


Gao J, Lu G, Qi J, et al. Structure of the fusion core and inhibition of fusion by a heptad repeat peptide derived from the S protein of Middle East respiratory syndrome coronavirus.J Virol. 2013;87(24):13134-13140. doi:10.1128/JVI.02433-13

But then another group in Iowa in 2015 made the mistake of applying this peptide from MERS in an animal model. First, using a slightly different sequence from the above group, they reported an IC50 value of 1 microMolar for their native HR-2 peptide. Then they proceeded to make a few alterations in the HR-2 peptide to achieve a modestly improved IC50 of 0.6 microMolar. Then they applied this mutated peptide (HR2P-M2) to a mouse model. Before looking at this results it is should be recalled that these reported IC50 values are 1000 times that of what enfuvirtide achieved in cell culture assays and thus according to orthodox thinking not plausible pharmaceutical candidates.

The modified HR2 peptide was applied intra-nasally to two strains of mice – C57BL/6 mice which have been breed to have weakened immune system and RAG-/- knock-out mice that have been genetically engineered to have a defective immune response. The mice used have had the MERS virus cell surface receptor over-expressed, thus with an excess of virus targets and no immune defences it provides a very sensitive model as to whether these peptide therapies can have an effective interaction *in vivo* with an active virus.

The results of prophylaxis (before virus infection) and therapy (after viral infection initiated) are shown below



Protective Effect of Intranasal Regimens Containing Peptidic Middle East Respiratory Syndrome Coronavirus Fusion Inhibitor Against MERS-CoV Infection. Channappanavar et al J Infect Dis 2015.

Mice transduced with human dipeptidyl peptidase 4. Intranasally treated by 2000 U of IFN-β, 200 µg of HR2P-M2, both IFN-β (2000 U) and HR2P-M2 (200 µg). Prophylaxis treated 6 hours before viral challenge, terminated 3 days after infection. Therapy, treated 12 and 36 hours after infection and viral titre assayed 4 days after infection.

Both interferon-beta and HR2 (or in this case a derivative thereof) showed a considerable effect individually, but importantly theses effects were additive. While the effects for therapy may not look particularly impressive, it is important to remember that this is a log scale. So for C57BL/6 mice using HR-2 as therapy, the viral load is reduced by over 10 fold. When both interferon-beta and HR-2 were dosed, the reduction was over 50 fold. It is also important to observe that no attempt was made to optimize the dosing regime, since it is known that these peptides have very poor persistence and are quickly cleared by the body. Hence, more impressive results may have been obtained if dosing had been repeated every 12 hours. Additionally, these are immunologically deficient mice, the only means they have to resist the virus is the supplied pharmaceuticals.

However, the most important outcome is that application very modest quantities of HR-2 peptide were able to effectively interrupt the MERS spike fusion machinery; even though their reported IC50

values, ranging from 0.6 microMolar to 3 microMolar would normally be considered far too high for a potential candidate for drug development. To put the dose of 200 µg applied once for prophylaxis and twice for therapy in perspective, HIV+ patients receive two doses of 90 mg of enfuvirtide daily – each dose being almost 500 times that used in this experiment. While obviously a mouse is a lot smaller than a human, it seems plausible to hope one would see effects from 10-20 mg of HR2 peptide supplied via a nebuliser and/or intranasally. It had been GlaxoSmithKline's intent, when working on the potential RSV drug that was canned after a massive bribe from the FDA, that the peptide drug would have been applied via their Diskhaler system.

Does this mouse model prove that HR-2 peptides would be an effective treatment MERS? No, but what it does show that cell culture IC50 values give absolutely no guidance as to whether moderate doses of exogenous HR-2 derived peptides would successfully block viral host cell entry *in vivo.* The most important conclusion is that while IC50 cell culture assays can produce results that are useful to compare efficacy between variants *within* a single experiment, they don't represent a stable parameter that can be compared across different laboratories and are a poor guide to efficacy in animal models.

II. Covid-19 Antiviral Investigations

What makes the previous animal model experiment of HR2 peptides delivered intra-nasally particularly persuasive, is it that it also found a weaker beneficial effect for intra-nasal delivery of interferon beta, a finding which has some support in human trials. As such it makes a good starting point for a short survey for how the pharmaceutical industry, having overlooked a genuine promising candidate for drug development, has proceeded to chase after a series of illusory expedients.

Other antivirals: Interferon-beta

The evidence for interferon-beta delivered in the conventional subcutaneous manner consists of exploratory studies in Hong Kong, Iran and Spain.

The Hong Kong study was a multicentre, prospective, open-label, randomised, phase 2 trial in adults with COVID-19 across six hospitals. Patients were randomly assigned (2:1) to a 14-day combination of **either** lopinavir 400 mg and ritonavir 100 mg every 12 h, ribavirin 400 mg every 12 h, and three doses of 8 million international units of interferon beta-1b on alternate days (combination group) **or** to 14 days of lopinavir 400 mg and ritonavir 100 mg every 12 h (control group). (Lancet - https://doi.org/10.1016/S0140-6736(20)31042-4). There were 86 patients in the combination group and 40 in the control. It showed a statistically significant improvement in the combination group of 7 days to a negative nasopharyngeal swab versus 12 days in the control group. The inclusion of ribavirin in the treated arm and lopinavir/ritonavir in both arms makes interpretation more difficult.

There is also a small Iranian randomized clinical trial of subcutaneous Interferon Beta-1a with 42 treated and 39 controls (https://www.medrxiv.org/content/10.1101/2020.05.28.20116467v1.full.pdf). The treated group shows a statistically significant improvement of some magnitude in 28 day mortality (19% vs 43.6%, p=0.015).

A retrospective study of Interferon Beta-1b (sub-cutaneous) from Spain of 256 patients (106 treated and 150 control) found a difference that did not reach statistical significance (mortality 21% vs 27.5%, p =0.23). Interpretation is complicated by the heavy use of other drugs including hydroxycholoroquine which were not balanced between the two arms.
https://www.medrxiv.org/content/10.1101/2020.05.15.20084293v2.full.pdf+html

Of most interest, considering the mouse model experiments of HR2 peptides and interferon-B above, was the phase II clinical trial by the pharma firm Synairgen. In July they reported on what they described as their "its wholly-owned inhaled formulation of interferon beta" – SNG001 – in a trial of 101 patients (i.e. around 50 in each arm). Their report included a somewhat skimpy and selective presentation of their data, but it appears 3 died in the control group and none in the treated group and there was a 79% reduction of having to put on a ventilator/death amongst treated patients. Skimpy or not, this data was sufficient to send their share price from less than 10 pounds in January to over 200 pounds in July.

Frankly, it should be considered an abuse of the patent system that it can provide exclusive protection for a minor change in delivery of a long-established drug – from subcutaneous to inhalation. Synairgen's opinion seems to be clinicians are prohibited from experimenting with directly delivering interferon-beta to the site of viral infection – the lungs and airways – in patients, unless they pay a fee to Synairgen's shareholders. A position doubtless of great monetary benefit to the shareholders, but it is sobering to ponder just how many thousands of patients have to die in order to secure that money flowing into their pockets.

Other antivirals: Remdesivir

Remdesivir is a nucleoside analogue, hence it has a similar mode of action as ribavirin by being integrated into the virus genome to cause hopefully lethal (to the virus) mutations. Ribavirin has received little attention as a possible treatment for Covid-19, possibly because of negative experiences in treatment with MERS and SARS where it was associated with haemolysis and bradycardia. The application of ribavirin through a nebuliser directly into lungs which might considerably reduce these side effects and potentially allow higher dosing to target tissues has not, to my knowledge, been investigated. Ribavirin is off patent now which might explain the lack of interest in such an approach, although Synairgen's opportunistic and parasitic strategy of demanding patent protection for delivery of an established drug through a nebuliser might still be available.

Remdesivir was developed by pharma firm Gilead and first tested in a small trial against Ebola. The outcome was 50%+ death rates, far higher than the best available monoclonal antibodies which show approximately 33% mortality, and similar to the mortality when given usual standard of care prior to those monoclonals becoming available . A small trial in China as their epidemic was winding down showed no statistically significant benefits. However, using a number of different measures researchers were able to extract some positive trends towards clinical improvement which fell short of statistical significance (but might potentially manifest itself in a larger study), but the 28 day mortality was 15% for the remdesivir and 13% for the controls. The treated group had a higher rate of comorbidities that may have been masking a small beneficial effect of the drug.

Remdesivir received its big boost with the publication of the NIAID study of a randomised, double-blind controlled trial of 1063 patients in sites across Asia (5%), Europe (15%), but mainly in the USA (~80%) . Controversially halted early, this study showed a statistically significant improvement of

median time to recovery (11 days versus 15 days) and a trend towards improvement in 14 day mortality of 7% versus 12 % (Odds ratio 70%), but which fell just short of statistical significance.

However, a closer look at the study protocol indicates that the trial may have been deliberately skewed to achieve a positive outcome

> *Randomization was stratified by study site and disease severity at enrolment and was performed using a web-based Internet Data Entry System, Advantage eClinical SM. Severe disease was defined as participants meeting one or more of the following criteria: requiring invasive or non-invasive mechanical ventilation, requiring supplemental oxygen, an SpO2 ≤ 94% on room air, or tachypnea (respiratory rate ≥ 24 breaths per minute). Mild / moderate disease was defined by a SpO2 > 94% and respiratory rate < 24 breaths per minute without supplemental oxygen requirement.*

This stratification reduced the randomisation to two categories – 120 in the mild/moderate disease and 963 as severe disease. In the severe strata there were 147 on ventilation out of 465 in the placebo group and 125 on ventilators/ECMO out of 478 in the treated group. This represents an odds ratio of 0.77 for being on a ventilator (95% CI 0.58 – 1.02, p value .06) which is a fairly skewed distribution. It is hardly surprising that the NAIAD hurried closed down the trial *before* it reached statistical significant improvement in mortality, since if it had reported an improvement in mortality NIAID would have come under pressure to have applied a statistical test with an adjustment for the higher baseline level of invasive ventilation in the control group. When this is done, the trend improvement in mortality disappears. If you reversed the odds ratio (i.e. people in the treated group at a higher ratio of mechanical ventilation), remdesivir would look like it was causing harm.

As far as the headline "time to recovery" is concerned, it was largely driven by recoveries in the severe disease stratum:

Table S2. Outcomes overall and by baseline disease severity in the intent-to-treat population

	Overall		Mild-Moderate Disease Stratum		Severe Disease Stratum	
	Remdesivir (n=538)	Placebo (n=521)	Remdesivir (n=62)	Placebo (n=57)	Remdesivir (n=476)	Placebo (n=464)
Days to Recovery						
Number of Recoveries	334	273	52	46	282	227
Median (95% CI)	11 (9, 12)	15 (13, 19)	5 (4, 7)	5 (4, 7)	12 (10, 14)	18 (15, 21)
Recovery Rate Ratio (95% CI); p-value[a]	1.32 (1.12, 1.55); p<0.001		1.09 (0.73,1.62)		1.37 (1.15, 1.63)	

The severe disease stratum shows a raw difference of 55 patients in recoveries (282 vs 227). In the supplementary materials we read that 168 patients received less than 10 doses of remdesivr because they recovered and were discharged from hospital and 120 patients received less than 10 doses of the placebo because they were discharged – this is a raw figure of 48 patients difference. This represents the bulk of the difference between the treated and the controls of 55 patients recovering in the severe disease stratum. That is, most of the improvement was being driven by people who did not receive a full course of treatment. If you did receive a full course of treatment you were far less likely to experience any benefit over the placebo. There was no perceptible effect in the mild disease stratum with both the number of recoveries and the median time to recovery virtually identical. The difference in the median "days to recovery" in the severe stratum (12 vs 18) would be accentuated by the larger numbers of people on ventilators in the placebo group taking much longer to recover.

If you assume that no-one on a ventilator was going to recover in less than 10 days, then the pool in the severe stratum eligible to be released before a full course of treatment (not on a ventilator) was

353 in the treated vs 318 in the controls – suddenly the 168 treated patients released before 10 days (ie the full treatment course) versus 120 placebo patients released before 10 days doesn't seem that significant. Adjusting for the skewed baseline distribution for patients on mechanical ventilation would not have entirely eliminated the 'days to recovery' beneficial effect but might well have reduced it to below significance.

Stratification on disease severity was supposed to see both arms balanced, but whether by statistical fluke or deliberate manipulation the treated arm seems to have been bunched towards the milder end of the spectrum and the placebo bunched towards the sicker end.

However, there was an even more significant problem, the double blind study was not really double blinded:

> *A normal saline placebo was used at the European sites and at some non-European sites owing to a shortage of matching placebo; the infusions were masked with an opaque bag and tubing covers to maintain blinding.*

It appears impossible to uncover from any of the voluminous supplementary materials and published protocol what proportion "European sites and some non-European sites" actually represents – it could be anything between 16% to 99% of participants. It seems an enormous and flimsily justified deviation from the protocol. Given the key criteria of success was a physician telling a patient he/she was well enough to go home, the fact that the physician could have obtained what they might have viewed as clinically relevant information simply by peeking down the tubing seems extraordinary. The sums of money involved here are enormous, Gilead spent massive amounts in developing remdesivir, only to discover in Africa that it was considerably less effective against Ebola than existing treatments. Covid-19 was its big chance to cash in, and cashing in Gilead is certainly doing, charging over $3000 a course of treatment. When such an obvious loophole has been engineered into the blinding protocol, it is hard to believe that it was not deliberately done to enable Gilead's financial benefit.

The final large scale remdesivir trial is a trial without a placebo control, comparing 5 day and 10 day courses of treatment. With approximately 200 patients in each arm, the headline figures would suggest the more remdesivir you receive the worse your outcome. 11% of the 10 day group died within 14 days vs 8% of the 5 day group; 54% of the 10 day group had recovered after 14 days vs 64% of the 5 day group. There was some modest indications that the 10 day group was slightly sicker at baseline – and in stark contrast to the NAIAD study, Gilead were this time only too eager to adjust the results according to baseline clinical status – after which the clinical outcomes of the two groups were assessed as identical.

With 3 studies – the Wuhan study showing a slight negative effect, the NAIAD study showing a limited positive effect and the final Gilead study showing no difference between a 10 day treatment versus a 5 day treatment, the most probable beneficial treatment with remdesivir is likely to be a 0 day course. The enormous financial windfall generated for the United States and Big Pharma for getting approval appears to have overwhelmed the already distinctly dubious ethical culture of the western medical profession. The situation is strikingly similar to Tamiflu and Relenza, in that an ineffective drug can often be far more profitable than an effective drug. With an effective drug people would rapidly lose their fear of Covid-19 and become unwilling to hand over large sums of money. On the other hand, with a completely useless drug – as Remdesivir proved to be with Ebola and likely is with Covid-19 – people are consumed with fear and will gladly hand over enormous quantities of cash.

Previously I said enfuvirtide approaches to anti-viral drug development had been deliberately suppressed because they had broad-spectrum potential that could eliminate single stranded RNA viruses as covert biological weapons. However, I would not suggest that the US government is totally averse to any sort of broad-spectrum treatment of RNA viruses, they are simply opposed to broad-spectrum, prophylactic, easy to administer treatments. The United States Government is interested in bioweapons that can bring an economy to its knees – both for short-term tactical gains and as a weapon to unleash in the event a hot war breaks out with China. Remdesivir, which both can be sold for exorbitant prices and needs to be delivered intra-venously in a hospital setting, perfectly meets these objectives. Like monoclonals, remdesivir would not prevent the target's health system buckling under the strain or bringing an economy to a standstill. Mass deaths is not the main objective and so the Americans have no objection to a treatment that would allow them to cynically preen as saviours. That remdesivir in fact appears likely in the end to prove to be a white elephant is unfortunate, but not so unfortunate as to prevent Gilead charging like a wounded bull for people to ride their white elephant in the short term.

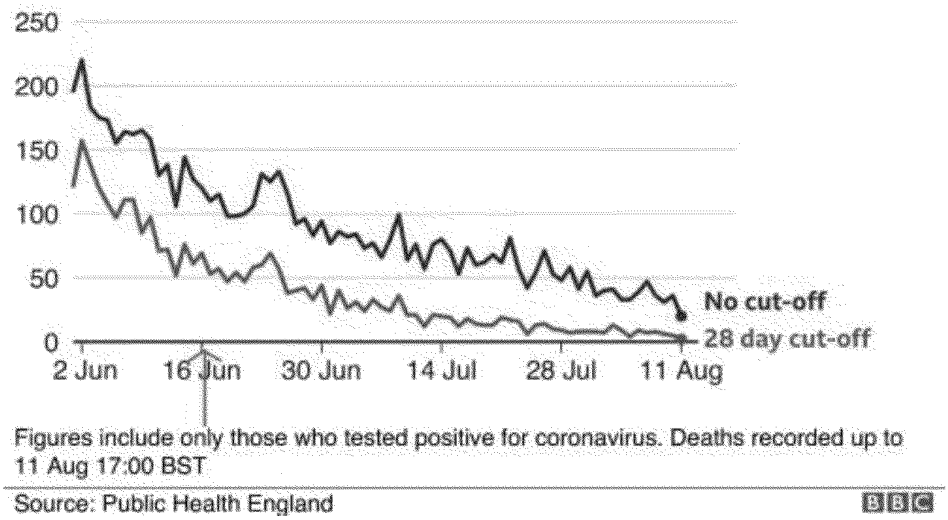
Currently Gilead is investigating the deployment of remdesivir in a nebulised form to be applied directly to the lungs. Despite my sceptical assessment of Gilead's previous results, I would not rule out this approach delivering a significant clinical improvement, since they should be able to deliver higher concentrations of the drugs directly to the target tissue. Whether such an approach will be congruent with the US military long-term strategic objectives for virus bioweapons is a problem for Gilead and the Pentagon to resolve.

Other antivirals: Recovery Trial

The big discovery from the UK's RECOVERY Trial was the repurposing of Dexamethasone as a recommended treatment for severe Covid-19, after a finding of a reduction in deaths of about one third for those on mechanical ventilation. Surprisingly, there is very little evidence that this has had a beneficial impact, at least not in the UK after the results were released on June 16 and it immediately became the recommended treatment. All deaths in European countries were in steep decline by this point, with the UK 2-3 weeks behind Italy, Spain and France. But far from a wider prescription of dexamethasone increasing this decline in mortality, the change in prescription patterns seems to have momentarily arrested the decline.

June 16th-20th in the UK 853 deaths were reported, while 867 deaths reported in the five week-days after the use of dexamethasone was approved - June 23-27th(i.e. a small increase). By comparison in same two periods France reported 197 and 123 deaths respectively, Spain reported 23 in the first five-day period and 17 in the second and Italy 239 deaths in the first period and 120 deaths in the second. Partly this may be driven by a far wider definition of a Covid death used in the UK than for example Spain, but subsequently the UK's death rate has never dropped to as low levels as either France, Italy and Spain had achieved even without widespread dexamethasone treatment.

> [Subsequent to writing this the UK has changed its definition of Covid death, substantially reducing its death toll in the later stages of the pandemic:

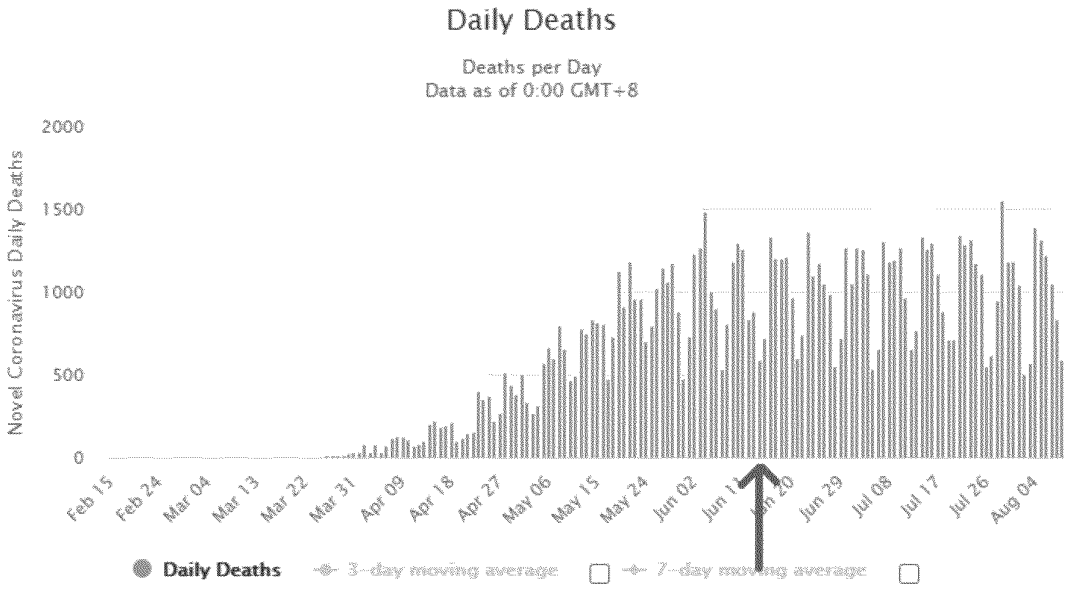


However, the basic point remains, release of the RECOVERY trial results (red arrow) and a wider prescription of dexamethasone made no appreciation acceleration in the decline of mortality and might even be associated with a small bump in the other direction.]

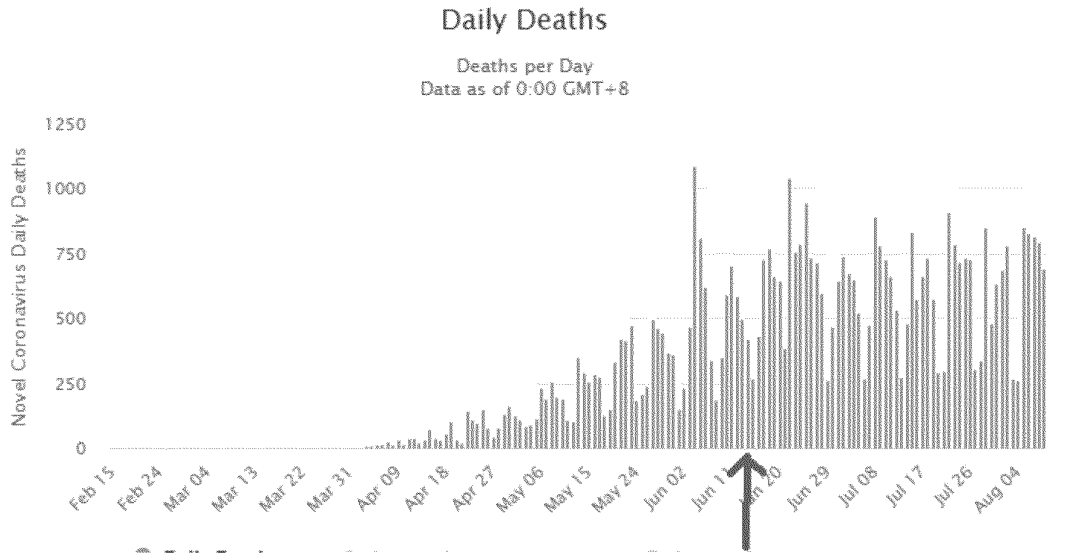
One consideration is that dexamethasone was already being prescribed to severe patients but with more selective criteria - for example in the RECOVERY trial hydrochloroquine arm around 9% of the treated and controls had received dexamethasone during follow-up as part of their "usual standard of care". In fact even in the Dexamethasone arm, only ~90% of those assigned to the treated arm actually received Dexamethasone and 7% of the controls were given as part of their usual standard of care. Possibly the previous criteria for prescription of dexamethasone in Covid-19 were more precisely targeted than the subsequent expansion after the results of the RECOVERY trial were released.

Turning to countries where the pandemic had reached a plateau, Brazil and Mexico, you see the same pattern of no appreciable impact of the RECOVERY trial publication.

Daily New Deaths in Brazil



Daily New Deaths in Mexico



To understand what appears to have happened we need to likewise dive deep into the protocol of the Recovery trial. This trial consisted of two rounds of randomisation. The first round, which has produced the all the published date to date, had five arms.

1. No additional treatment (that as the control arm)

2. Dexamethasone(DXM). This arm had recruitment halted on June 8th, with investigators being unblinded and study terminated on June 15th

3. Hydroxychloroquine(HCQ). Here investigators were unblinded on June 4th and the study terminated on June 5th.

4. Lopinavir/ritonavir (L/R). On 25th June investigators were unblinded and study terminated on June 29th due to a lack of clinical benefit

5. Azithromycin. Some details of recruitment can be extracted from publications of the other three drugs, but there has been no official data released.

The second round of randomisation was for patients with severe progressive COVID-19 and tested tocilizumab and convalescent plasma. This has not been reported on and won't be discussed further here. Dexamethasone treatment showed a statistically significant improvement on mortality. For Hydroxychloroquine and Lopinavir/ritonavir statistical significance was not reached but there was a small trend towards a detrimental effect.

Working through various supplementary appendices we can determine that the number of patients enrolled in RECOVERY had reached 11200 on June 4th, increased to 11,320 on June 8th and to "over 11800" on June 29th- when the lopinavir/ritonavir study terminated. Where biases might likely have arisen in the RECOVERY trial will be selection biases in the control arm, since the same pool of controls were used for each of the treatment arms. Trying to assess the pool of "usual standard of care" patients within the total enrolment of 11,800 patients is difficult. Around 5240 patients have been assigned to the HCQ, DXM and L/R arms and assuming another 1000 for the Azithromycin arm, this might mean around 6300 in the four treatment arms and leaving 5500 in the shared pool of "usual standard of care" controls. The table below sets out the different populations for each treatment arm and the number of controls selected out of the total pool available of ~ 5500 used as a comparison.

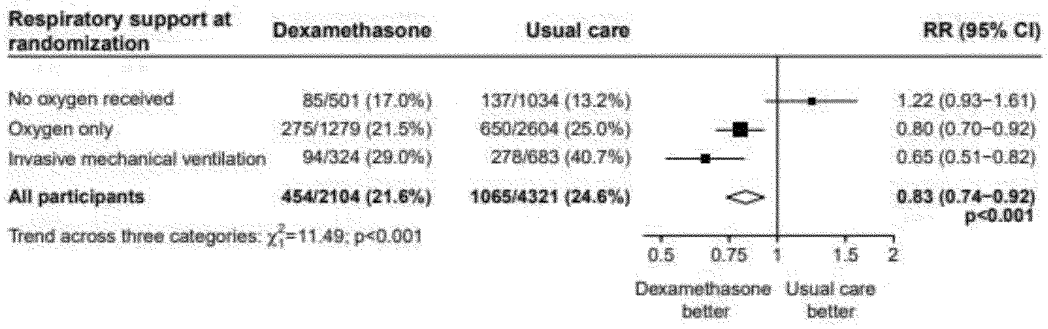
HCQ treated	HCQ controls	DXM Treated	DXM Controls	L/R Treated	L/R Controls
1542	3132	2104	4321	1596	3376

Results were reported with a break-down off the numbers on invasive mechanical ventilation at baseline, patients receiving supplementary oxygen and no oxygen support. A summary breakdown follows:

> Lopinavir/ritonavir – 4% invasive mechanical ventilation, 70% oxygen alone, 26% no oxygen support. 28 day Mortality 22.1% treated versus 21.3% usual care. Age distribution not given.
>
> Hydroxycloroquine – 17% invasive mechanical ventilation, 59% oxygen alone, 24% no oxygen support. 28 day Mortality – 26.8% treated versus 25% usual care. Age distribution 59% below 70, 41% above 70 both arms, average 65 years.
>
> Dexamethasone – 16% invasive mechanical ventilation, 60% oxygen alone, 24% no oxygen received. 28 day Mortality 21.6% treated versus 24.6 usual care. Age distribution**: treated 54% below 70, 46% above 70 years; usual standard of care 58% below 70 and 42% above 70 years**; mean age was 67 and 66 years respectively

This difference between the proportions of patients beneath 70 years in the treated and controls will be discussed below. The break-down of mortality improvements according to respiratory support is below:

Figure 2: Effect of allocation to dexamethasone on 28−day mortality by level of respiratory support received at randomization

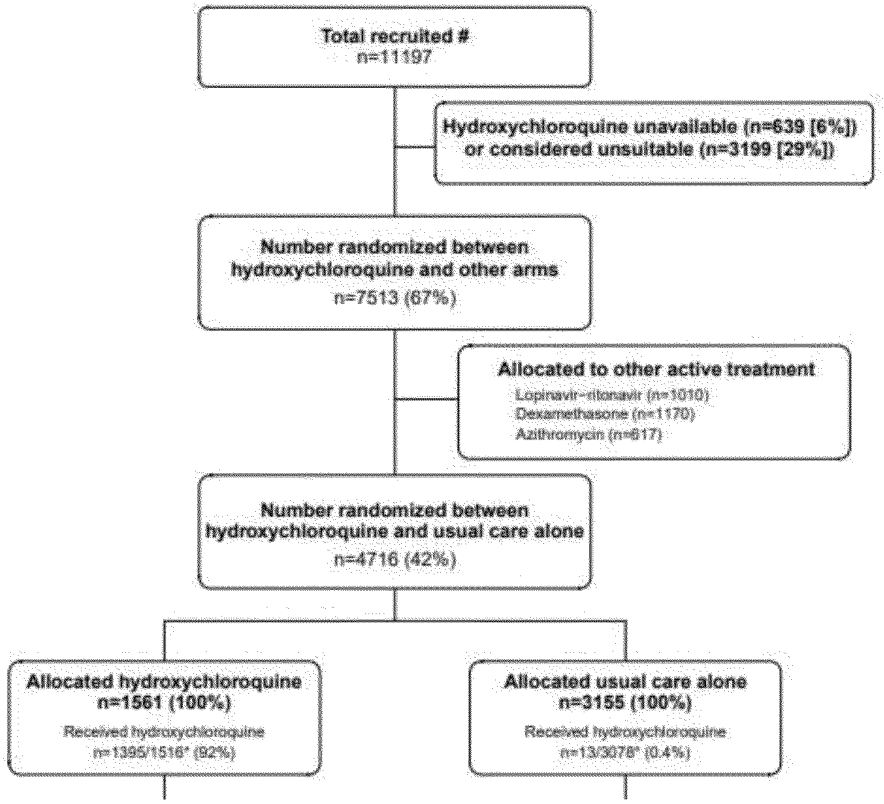


From this it shows the bulk of the effect of dexamethasone was driven by those on ventilators, with 29% mortality for patients on dexamethasone versus 40.7% on usual care. It should also be noted that when the figures are *not* age adjusted, the negative effects of dexamethasone for those not on addition oxygen does actually reach significance and the magical p=.05 – it is only the age adjustment that makes the relative risk not-reportable.

This is not necessarily an implausible outcome – one of the reasons physicians have been reluctant to use corticosteroids in the past is that as suppressor of the immune function they might impede the body's ability to clear the virus naturally. So giving dexamethasone to mild cases might increase the risk they become severe cases, whereas prescribing it for already severe cases might help combat the side effects of the viral overload. Of concern is that reported mortality rates on ventilators varying wildly from site to site and often related to how much stress the heath system is under. Mortality on ventilators increased to over 50% in New York at the peak of the first wave, compared with the low-mid 20% in California with a much lower disease burden.

Comparing demographic and clinical parameters of the 11 800 patients in the RECOVERY trial with the 20133 UK patients admitted to hospital in the ISARIC cohort between 6 February and 19th April and reported with 2 weeks of follow up. The average age of the ISARIC cohort was 73. After two weeks 41% were discharged, 26% died and 41% were still receiving care. 1658 patients out of 20133 (8.2%) received invasive mechanical ventilation of which 17% discharged, 37% died and 46% remained in hospital. From this it would appear that RECOVERY trial participants were both significantly younger and more likely to end up on ventilators than the average Covid patient (there seems to have been a reluctance to ventilate older patients).

To understand how selection biases may have crept in to the controls, we need to understand how the randomisation process worked. From the total available pool, patients were extracted prior to randomisation for a particular treatment if it was not available at their hospital, if it was considered unsuitable for that particular patient, or if the physician felt there was a dinical reason why the patient was required to receive it.



Eligible patients will be allocated using a central web-based randomisation service (without stratification or minimisation) [to the treatment arms above]….

*The randomisation program will allocate patients in a ratio of 2:1 between the no additional care arm and each of the other arms available. Hence if 5 arms are available, then the randomisation will be in the ratio 2:1:1:1:1. If one or more of the active drug treatments is not available at the hospital or is believed, by the attending clinician, to be contraindicated (**or definitely indicated**) for the specific patient, then this fact will be recorded via the webbased form prior to randomisation; random allocation will then be between the remaining arms (i.e. in a 2:1:1:1, 2:1:1 or 2:1 ratio).*

Some demographic data was given for those considered unsuitable for randomisation for hydroxychloroquine.

Table S1: Baseline characteristics of patients considered unsuitable for randomization to hydroxychloroquine compared with those randomized to hydroxychloroquine versus usual care

	Randomized (n=4716) 7513	Considered unsuitable (n=3199)
Age, years	65.7 (15.5)	67.2 (16.1)
<70	4355 (58%)	1714 (54%)
≥70 to <80	1575 (21%)	676 (21%)
≥80	1583 (21%)	807 (25%)

It appears that the number considered unsuitable for HCQ (3199) and those excluded due to lack of availability (639) might be insufficient to supply all the patients required both to complete the remaining treatment arms and supply the double that number for the controls (an additional 1000 patients was need to complete the dexamethasone arm as an example). This means that a disproportionate number of the controls for the Dexamethasone arm may have been shared with the HCQ arm – rather than having been selected from the sub-population that the dexamethasone treated patients had come from. We noted the difference in age profile between the Dexamethasone and their associated controls: 54% below the age of 70 for treated group and 58% for controls. This aligns closely 58% below the age of 70 for those deemed suitable for HCQ and only 54% for those excluded (Table S1 above). The controls for the dexamethasone arm has the same age profile as those considered suitable for hydroxychloroquine.

This suggests that around 50% of the Dexamethasone treated patients were derived from those who were assessed as suitable for HCQ (1170 patients), the other 50% came from those deemed unsuitable or for whom it was not available. Whereas the bulk of the Dexamethasone controls [???80%] seemed to have been drawn from the group deemed suitable HCQ and the remainder from those deemed unsuitable. While one could argue that meant those treated with Dexamethasone were older than their associated controls and hence not providing a bias towards DXM having a beneficial effect (in any case the statisticians used an age adjusted measure), it meant that the RECOVERY trial had deviated from their published protocol and possibly unconsciously were selecting controls for each arm rather than having them purely randomly assigned.

It further appears possible that some form of informal stratification for being on invasive mechanical ventilation at baseline has taken place in the selection of the controls for each group from the available pool of about 5500 assigned to usual standard of care. So, for example, the Lopinavir/ritonavir is balanced on each arm at 4% on invasive mechanical ventilation. While this might have been achieved by the randomisation process, what is noticeable is all treatment groups have slightly more than 2 fold number of controls (24 for HCQ, 113 for DXM, 184 for L/R). It follows that an informal stratification on mechanical ventilation could have been achieved simply by selecting more controls.

The complicated randomisation process is going to produce biases in selecting controls even if they had kept to their protocol, which I would argue they haven't. If a patient is suitable for all treatments, he/she is 2/7 (29%) chance of being selected as a control, whereas if he/she is suitable for just dexamethasone or only dexamethasone is available, then they are 2/3 or 67% likely to end up as a control.

This complication randomisation and what looks like an informal stratification process on invasive mechanical ventilation leads to what may be the core problem: the baseline categories won't be stable during an explosive pandemic. During the plateau phase of the pandemic, the demand for hospital beds and particular ventilators is going to become increasingly rationed, the cut-off for both hospital admission and being placed on mechanical ventilation is going to rise steeply as the epidemic plateaus. The RECOVERY trial treats these baseline states (no oxygen support, supplied oxygen and invasive mechanical ventilations) as stably clinically indicated, whereas in reality the mortality across all three categories very likely rose as the epidemic progressed and then slowly fell back down again as it tailed off. Even if the RECOVERY trial insist that there was no stratification on intensive mechanical ventilation, simply the criteria for admission to hospital would have risen during the course of the pandemic as informal rationing or triaging practices became more selective. In any case, clinical practise began to change after the initial phase, which had led physicians to believe that had become too interventionist in their use of mechanical ventilation. As mechanical

ventilation increasing became an intervention of last resort, mortality rates of those being assigned to it also would rise.

Assignment to the treatment arms was influenced by the two factors: was the treatment available at the site and was the treatment medically contradicted. From the published preliminary report it appears no exclusions or non-availability data was cited for dexamethasone, so presumably this was not a big factor and the arm had been populated with over 2000 patients by June 8th. The hydroxychloroquine arm had over 1/3 of participants who were deemed either unsuitable or medically excluded and by June 5th had only recruited 1500 patients. Aside from a press release no data has been published for the lopinavir/ritonavir arm [at time of writing], but the restrictions on ventilator use and that enrolment for this arm continued for a month longer, suggests recruitment was slower and more difficult. With the azithromycin arm, to date, we have not so much as received a press release, even when hospitalisations slowed to a trickle. This issue with azithromycin may not be availability of the treatment or contraindications, but rather that clinicians were deciding azithromycin was "definitely indicated" and hence the patient was not available for randomisation for this arm. It was not ethical, in the view of the clinician, to potentially not treat this patient with azithromycin.

The suggestion is that the mortality rates for hospital admissions and people on mechanical ventilation rose as the epidemic peaked and dropped only slowly since it is difficult to throw people off a ventilator. These means that treatment arms with few exclusions would fill up rapidly and be drawn from people that were less sick than people who were admitted later in the pandemic. This might not be a problem if the protocol of selecting controls had been rigorously adhered to, but the difference in proportion of patients under 70 years old between the dexamethasone group and its controls argues that the controls of the dexamethasone group were disproportionately shared with the hydroxycholoroquine group (ie dexamethasone controls tended to be recruited later in the pandemic than those who received dexamethasone treatment).

So the pattern of odds ratio 0.84 (DXM), 1.10 (HCQ) and 1.05 (L/R) for the three reported treatment arms, actually represents only their different temporal relationship to the recruitment of the controls – on average dexamethasone were recruited earlier than their shared controls so reports a positive result while hydroxychloroquine and lopinavir/ritonavir were on average recruited slightly later and shows a slightly negative result. The reason then that the azithromycin results haven't merited even a press release is perhaps because as this arm was most difficult to recruit, the trend towards negative outcomes in response to treatment has increased to a significance level and the RECOVERY trial scientists are concerned about releasing an outcome that suggests azithromycin is killing patients. A concern possibly driven not least by the fact they don't actually have confidence in such a finding themselves and don't wish to negatively influence the clinical care of Covid patients. This analysis argues such a negative effect of azithromycin would not actually be real and is simply an artefact of the randomisation protocol.

Unfortunately, according to Recovery Trial head Martin Landry in ScienceMag, results on azithromycin are "likely months away", which is difficult to accept if they were following their protocol of randomly assigning patients, once the other three arms have been stopped, every third patient should have been assigned to the azithromycin arm (unless the drug was "definitely indicated"). By this stage Covid admissions are so low, that unless a second wave manifests itself, this study may never be completed. It is worth pointing out that suppression of data is itself a form of scientific misconduct.

There is another indication that controls and treated patients weren't being selected from the same pools as stated by their protocol. And this comes from those in dexamethasone arm being treated additionally with azithromycin. Overall, according to the supplementary materials, there was no significant difference between the two groups.

Table S1: Treatments given, by randomized allocation

	Treatment allocation	
	Dexamethasone (n=2104)	Usual care (n=4321)
Follow-up forms received	2079	4278
Treatments given		
Dexamethasone	1975 (95%)	336 (8%)
Lopinavir/ritonavir	2 (<0.5%)	4 (<0.5%)
Hydroxychloroquine	17 (1%)	22 (1%)
Azithromycin	499 (24%)	1082 (25%)
Tocilizumab or sarilumab	43 (2%)	128 (3%)
Not recorded	7 (<0.5%)	12 (<0.5%)

Percentages are of those with a completed follow-up form. Among patients allocated dexamethasone, it was taken for a median of 7 days [IQR 3-10 days].

However, in a meta-analysis that just looked at the stratum of the RECOVERY trial of those who were on invasive mechanical ventilation, an imbalance emerges

Table 2. Characteristics of Patients Included in the Prospective Meta-analysis

	DEXA-COVID 19		CoDEX		RECOVERY	
	Steroid	No steroid	Steroid	No steroid	Steroid	No steroid
Patients randomized by June 9, 2020	7	12	128	128	324	683
Age, median (IQR), y	62 (48-68)	60 (52-69)	62 (50-70)	64 (57-73)	59 (52-66)	60 (52-68)
Female sex, No. (%)	3 (42.9)	3 (25)	47 (36.7)	44 (34.4)	91 (28.1)	182 (26.6)
PCR-confirmed SARS-CoV-2 infection, No. (%)	7 (100)	12 (100)	120 (93.8)	122 (95.3)	301 (92.9)	647 (94.7)
Treatments at randomization, No. (%)						
Mechanical ventilation	7 (100)	12 (100)	128 (100)	128 (100)	324 (100)	683 (100)
Vasoactive	3 (42.9)	7 (58.3)	83 (65.4)	88 (68.8)	Not recorded	Not recorded
Any antiviral[c]	6 (86)	10 (83)	NA	NA	NA	NA
Remdesivir	Not recorded	Not recorded	0	0	1 (0.3)	0
Lopinavir or ritonavir	Not recorded	Not recorded	0	1 (0.8)	0	0
Favipravir	Not recorded	Not recorded	0	0	0	0
Hydroxychloroquine	7 (100)	12 (100)	30 (23.4)	22 (17.2)	0	0
Azithromycin	0	0	83 (64.8)	81 (63.3)	59 (18.2)	81 (11.9)
Convalescent plasma	0	0	Not recorded	Not recorded	0	0

The prescription of azithromycin at baseline for the controls the DXM arm of the RECOVERY trail on mechanical ventilation was significantly more (18.2% vs 11.9% - odds ratio 1.65, 95% 1.15 – 2.4, p value of 0.007). And this is in the population that showed the most benefit of dexamethasone. The issue is not so much that some of the improved survival might be due to the greater prescription of azithromycin – although that might be a factor. Rather it is a marker that selection bias has crept in and that treated patients and controls were not being equally selected from the same pool of patients, but were skewed in relation to the time-course of the pandemic or possibly a regional vs metropolitan hospital bias.

This is where another selection bias creep might manifest itself in relation to where treatments were not available. This would be less likely in the major metropolitan hospitals – particularly in London – where the epidemic hit hardest and more likely in the provincial and regional hospitals that were less badly hit. In a hospital where only dexamethasone was available then you were in theory 33% of a chance of being treated with dexamethasone and 67% of being a control, while in a large metropolitan hospital with potentially every treatment available the probability of dexamethasone treatment goes down to 14% and 28% of being a control. But it is precisely these hospitals where the influence of rationing due to at least a partial overwhelming of the health care system would likely have meant only sicker people were granted admission and hence the opportunity to participate in the RECOVERY trial. In summary, hospitals that were under greatest pressure also had access to more of the treatment arms and hence less likely to end up on dexamethasone.

What this illustrates is the unique aspects of trying to run a clinical trial during a large pandemic. There is an assumption that the clinical criteria for admission to a hospital or given a particular physical intervention will be a stable, unchanging feature. This was combined with an over complicated 6 arm design with each individual arm having various exclusions and availability issues. Simplifying the design and accepting the slight loss of power resulting from not sharing controls over so many arms might have given more reliable results.

The strong scepticism towards dexamethasone is warranted because previous studies have shown it to be harmful in treating influenza and by suppressing the immune system to enhance viral load in SARS. The RECOVERY trial has led to clinicians undertaking retrospective studies relating to dexamethasone with deeply equivocal results. A New York retrospective study of 1806 patients compared 1666 who never received steroids to 140 who received them within 48 hours of admission. Of these 1806 patients, 318 meet the primary outcome of death or mechanical ventilation (270 died, 135 ventilated). This study found no overall benefit from corticosteroids, however claimed there were possible benefits for in certain subgroups, particularly highlighted was a damaging effect if CRP level at baseline was below 10 mg/dL (odds ratio of 3.1) and a highly protective effect if CRP was over 20 mg/dL.

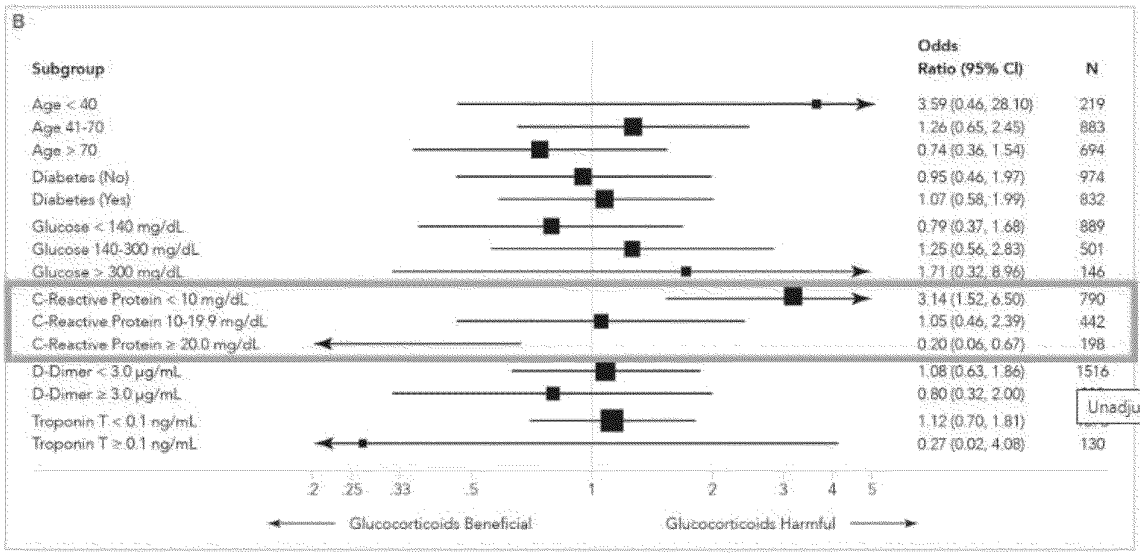


FIG. (A) Unadjusted Odds Ratios and 95% CIs for Mortality or Mechanical Ventilation in Predefined Subgroups. For subgroups defined by laboratory values, the combined number (N) may not total 1,806 because of missing data. (B) Adjusted Odds Ratios and 95% Confidence Intervals for Mortality or Mechanical Ventilation in Predefined Subgroups. For subgroups defined by laboratory values, the combined number (N) may not total 1,806 because of missing data.

The first take-away from this study would be for 85%+ of patients corticosteroid treatment was either highly dangerous or had no effect. From the paper it is difficult to break down the absolute numbers for the subgroups, but n=198 in the high CRP strata showing the highly beneficial effect, suggests very few of these 198 were actually receiving corticosteroids easily leading to skewed outcomes. Since these are corticosteroids being prescribed under pre-existing clinical guidelines, and so presumably over-representative for patients with conditions like rheumatoid arthritis and asthma. Therefore the patients in the dexamethasone treated group likely had high levels of CRP for reasons unrelated to Covid, while in the untreated group high CRP was more likely to be a marker of disease severity. Equally, this might apply to the low CRP group which showed a highly negative effect for corticosteroids, this may only as a result of co-morbidities that are being prescribed corticosteroids. It remains that even after slicing the data every way imaginable, only a very small cohort of patients show a positive response to steroid treatment.

The Codex trial from Brazil with 299 severely ill patients showed no appreciable effect on mortality after administration of dexamethasone (56% mortality in treated versus 61% in controls – but after adjustment for baseline conditions they reported a hazards ratio of 0.97). However, once the Recovery trials results were announced, the Brazilian doctors simply ignored their own negative findings and proceeded to routinely prescribe dexamethasone.

Other antivirals: Hydroxychloroquine

rolls eyes

Further refinements of the HR2 peptide approach

To return to the HR2 peptide and enfuvirtide approaches, there have been a few additional developments since Sars-CoV-2 emerged. A Chinese group headed by Dr Lu Lu had previously developed what they believed was a pan Coronavirus peptide (a consensus peptide that would act

against all species of coronavirus) which they called EK1. Sequence: SLDQINVTFLDLEYEMKKLEEAIKKLEESYIDLKEL.

> *(Xia, S., Liu, M., Wang, C. et al. Inhibition of SARS-CoV-2 (previously 2019-nCoV) infection by a highly potent pan-coronavirus fusion inhibitor targeting its spike protein that harbors a high capacity to mediate membrane fusion. Cell Res **30,** 343–355 (2020).)*

The most recent publication of this group claims to show a greater effect for EK1 by conjugating a cholesterol molecule to various residues, making it a lipopeptide. The all-important IC50 values in cell culture virus infection assays were 2400 nM for EK1 and 16 nM for the EK1-lipopeptide (EK1C4). They did not test the native HR2 peptide from Sars-CoV-2 for efficacy, nor did they try to make a lipo-peptide of it. Using a pan-corona virus peptide rather than the native HR2 peptide only makes sense from a regulatory view-point – it would mean only one set of safety trials. However, given the low risks involved, the bulk of the safety data for enfuvirtide ought to be transferrable and each new HR-2 peptide-virus pairing should only require minimal further testing for safety (as opposed to efficacy). With this in mind it is hard to see why a pan-corona virus peptide should be preferred. The effect of the cholesterol moiety might be to target the peptide to membranes and could improve persistence of the lipo-peptide compared with the simple peptide (although this might also raise potential unknown safety issues). It is noteworthy that they use a (extremely sensitive) mouse model to test efficacy as well and showed that administration of EK1C4 is highly protective for up to 12 hours prior to viral challenge, while the protective effect of EK1 was only up to 1 hour. However, despite the much shorter persistency of EK1, it still demonstrates that its high IC50 value in cell-culture assays (2.4 microMolar) is simply not an indication of whether or not it will show effects in an animal model. This is simply to underscore the point made in the first section, high IC50 values are not a reliable parameter to estimate efficacy in animal models and by extension as a potential drug for HR-2 antiviral peptides. Finally, this group has given no indication that they plan to test either EK1 or EK1C4 on humans infected with Covid-19.

Potential combination therapy regimes

It is nearly 30 years since the discovery that enfuvirtide had a powerful inhibitory effect in cell culture against HIV, it was immediately deployed for therapies in humans and is used to this day. Over that same time period such a therapy has never been even so much as tested on humans for any other virus, despite the absolutely minimal safety concerns for short alpha-helical peptides, delivered either intravenously or via an inhaler. What this document has tried to show that this absence of any further development was not due to scientific reasons, but for reasons that were entirely spurious. Simply as speculation, I have considered what potential treatment regimens using HR-2 peptide derivatives might look like.

For mild cases of Covid-19 in the community, the recommendation would be for HR-2 peptide delivered directly into airways via an inhaler, possibly supplemented with interferon-beta to boost the innate immune response. Patients could be advised to breath out via the nose in order to distribute the agent through all the infected air passages.

For mild cases admitted to hospital, the recommendation would be to increase the dosage of HR-2 and interferon-beta via inhaler and perhaps add to the mix either ribavirin or remdesivir, if either can be shown to be effective when administered to the lungs. That advantage of delivery in a nebulised form is far higher levels can be delivered to site of infection without concern about

affecting other tissues. This is also because the area of the respiratory epithelial cells exposed to the air is quite large compared to cell volume (resulting in a faster rate of uptake), whereas the ratio of the cell area exposed to the blood-stream/cell volume is relatively small. Using a nebuliser it is far easier to deliver sufficient levels of the drug to the cells initially targeted by the virus, whereas much higher levels would need to be injected into the blood stream to achieve the same intra-cellular concentration.

For severe cases, where presumably the viral load in the bloodstream is beginning to grow, the recommendation would be to switch to delivery of HR-2 peptides intravenously. Due to the risk of inflammation, interferon-beta should probably be dropped. Also to be abandoned would be either remdesivir or ribavirin, as for whatever reason these nucleoside analogues don't appear to be particularly effective intravenously, and ribavirin at least does have unpleasant side effects. If procalcitonin is elevated, then an antibiotic like azithromycin could be prescribed. If clotting dysfunction is indicated, then an appropriate anti-coagulation therapy. And if hyper-inflammation emerges then anti-inflammatories such a corticosteroids or preferably tocilizumab.

III Vaccine Development

Unit 74455 doesn't pretend to have any particular knowledge when it comes to vaccines, which is more the area of those cowboys in Unit 26165. While I personally have no particular reason to doubt that vaccine developers are not doing an excellent job, there are some issues around the possibility of vaccine disease enhancement that are of interest.

Additionally, I would like to look at the recent accusations against my excellent and highly ethical unit regards to hacking vaccine research.

Accusations against the Russian Federation

> *"One has to understand that there is no such thing as a friendly foreign intelligence service - all intelligence services have a purpose and some foreign intelligence services have the purpose of the economic well-being of their own country."* Michael Murphy, former deputy head of Military Intelligence, Poblacht na hÉireann

As far as recent hacking accusations on vaccine development companies, according to western intelligence they are 95% confident that this was a Russian effort. Here at Unit 74455 we are 96% confident that it is a Pentagon effort. The most useful analogy is the Naval Research Laboratory, who were instrumental in developing the Tor anonymity network. However, the philosophy of the Pentagon has always been "anonymity for me, not for thee". Hence simultaneously as they developed the Tor network, they developed tools to undermine it. One of these was the suite of tools variously known as "Dukes", "Cozy Bear" and APT-29. The "Dukes" was first identified on a Tor exit node, scooping up traffic, revealing the motivation of the Pentagon to spy on the same semi-anonymous technology they had created.

"Cozy Bear" in particular (associated with the Dukes malware) was accidently revealed as a US Government operation by former FBI director James Comey in testimony before the US congress. In

this testimony Director Comey admitted he only taken over the Hillary Clinton email investigation (outside of his legal authority) after early March 2016 when he was supplied by an unnamed US government organisation a copy of an email by Debbie Wasserman-Schultz, then head of the DNC, to Leonard Bernardo of the Soros Organisation where she wrote she had privately assured an associate of John Podesta that Loretta Lynch had nobbled the Clinton email server investigation and it was going to go nowhere.

There were, of course, allegedly two Russian types of malware on the DNC server, however since Wasserman-Schultz used a gmail account and because of the timing of the alleged email in early March, only the "Cozy Bear" or Dukes malware could have netted this particular email. Hence, whatever "Cosy Bear" collected, it immediately landed on the desk of an unnamed US government agency. When James Comey became aware in late March/early April the John Podesta emails had been taken, he immediately was concerned that Wasserman-Schultz's remarks regarding Loretta Lynch would be included amongst their contents and so took steps to take over the Clinton email server himself. Should an email emerge from the Podesta dump showing that Loretta Lynch had nobbled the Clinton email server investigation, the incorruptible James Comey could leap up and claim she had had no involvement with the decision making process not to charge the former Secretary of State for the unauthorised sequestering and destruction of government records.

In the event no such incriminating email was revealed in the Podesta email collection. It is possible that this was because John Podesta was only informed verbally of Wasserman-Schultz's assurances. However, the Podesta emails clearly aren't complete and they were only ever in the hands of a disaffected member of the Clinton campaign (who had taken advantage of the arrival of a fortuitously timed phishing email to walk off with the contents of the Podesta gmail account) and not my excellent and highly ethical unit. As such it is equally possible that having come under menaces from US government officials, the leaker removed the more incriminating emails before handing over what was undeniably a rather tame collection of emails to Wikileaks.

There is, of course, always spyware on the DNC and RNC servers; in 2008 and 2012 it was called "Chinese" spyware; while in 2016 with changing geopolitical priorities it was called "Russian" spyware. That the FBI was well aware of this spyware is attested to in September 2015, when a few days after an in-depth technical paper on the "Dukes" was released, an FBI official rang up the DNC IT department and asked them to run a virus scan of their systems. When it turned up nothing, the FBI official grunted "good" and then hung up. Even when "Cosy Bear" generated materials were, by James Comey's own admission landing on FBI desks, they made absolutely no effort to secure the DNC and RNC systems. It was only after the DNC emails were published by Wikileaks and the details of the various malware found on their system released by Crowdstrike, were the DNC systems properly secured. Doubtless after the 2020 election more malware will be found on the various servers, hopefully the FBI will show a sense of humour this time and blame Burundi.

Russia has no particular interest in attempting to penetrate Western markets with our vaccine. Our developments are geared to protect our own population and those countries whose civilian populations are being targeted by EU and the Five Eyes nations in their innumerable undeclared grey zone conflicts. Additionally, it is possible we might supply a gap for countries who are unable to afford British and American "at cost" vaccine products. Therefore, there is no economic incentive to for us to engage in such hacking.

With the Americans the situation is completely, the Trump presidency is deeply committed to winning the vaccine, both for economic reasons and for reasons of national prestige. Just as previously the US intelligence community had been spying on the minutiae of the political process by

scoping up internal communications of the two parties, so have they also been trying to get a jump ahead by spying on the communications of their Western pharmaceutical competitors. The Moderna vaccine is not in competition with the Russian vaccine effort, it is in competition with Astra-Zeneca and – the stuff of American nightmares – the Chinese projects of Cansino, Sinovac and Sinopharm. Cansino is using a live attenuated adenovirus approach similar to Astra-Zeneca, while Sinovac and Sinopharm are using traditional inactivated virus approaches.

Although not publicly asserted, doubtless Moderna and other US firms has also been victim to the same hacking attempts. However, this is just standard tradecraft, hacking a wide range of entities in order to conceal your true targets and at the same time make yourself look like a victim. The hacking of vaccine research was undertaken for the same reason most hacking take places, to gain an unfair advantage for American firms and obtain financial gain. Whereas there are no conceivable circumstances where the Russian vaccine will attempt to compete in Western European or American markets.

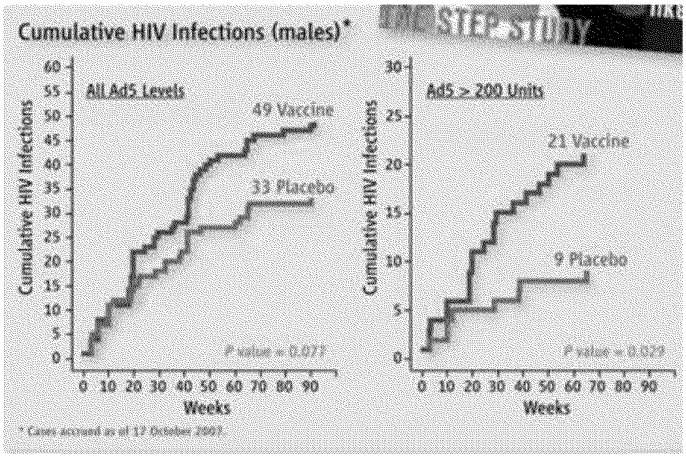
Vaccine strategies and Vaccine Disease Enhancement

There are two main potential problems that could arise from any vaccine development: weak or short-term responses and vaccine enhancement of infections. Since infection with coronaviruses like HCoV 293E are estimated to only provide protective immunity for a maximum of 24 months, it is difficult to see how any vaccination strategy could improve on protection provided by exposure to the infectious agent itself. This is not necessarily a matter of great concern, as there is reason to believe that re-infections will be much milder. In fact, it is almost certain that Sars-CoV-2 is now as much a part of the human virome as HCoV 293E and that after our first infection, we will all be subject to regular, uneventful reinfections.

Vaccine disease enhancement is a more complicated issue. It was first observed in 1967 in response to a formalin-inactivated vaccine to RSV which resulted in children and toddlers suffering a more severe form of the disease. Vaccine approaches to Covid-19 fall into four main approaches, at least three of which may be susceptible to vaccine enhanced disease.

1) Traditional inactivated attenuated virus. This is where a non-infectious version of the virus is produced in cell culture and then deactivated by formalin or other chemical process. This strategy produced vaccine enhancement with RSV

2) Using as a vector the backbone of another virus, which is incapable of replication, with the Spike protein, cloned into it. This is the approach of Astra Zeneca (a chimpanzee adenovirus) and the Russian Gameleya Research Institute (Human Adenovirus 5 – HuAd5). To my knowledge this is still a fairly untested technique which has only resulted in one approved vaccine for Ebola in 2018 used a modified VSV as a backbone (the VSV approach has some advantages over the Adenovirus approach). However, an experiment vaccine for HIV using HuAd5 may have resulted in vaccine disease enhancement when trials showed that not only was it not providing protection, it seemed to be resulting in participants becoming more vulnerable to infection (see below). As such there is no guarantee this approach will not result in issues.



3) Protein vaccines, where an individual viral protein or part of a protein is purified and injected with an adjuvant. As a naked protein, it can't be excluded this might result in vaccine disease enhancement, since epitopes might be exposed that are not normally accessible.

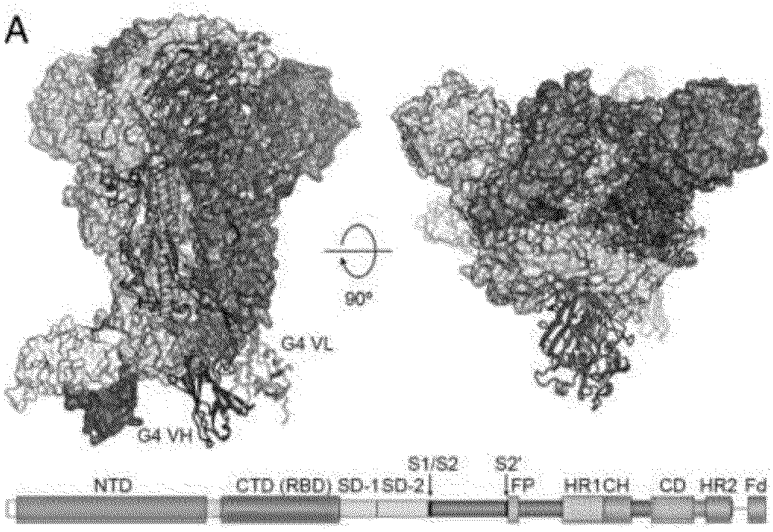
4) The mRNA vaccine of Moderna. This approach is entirely untested and there is no data at all on possible risks in regards of vaccine enhancement or strength of response.

The precise details of the strategy of the leading vaccine candidates are unknown to me and they may have already devised approaches to minimize vaccine disease enhancement. Additionally, they may have processes that can test the immune response from healthy volunteers that indicate whether or not this issue will manifest itself.

Attempts to create monoclonal antibodies to treat Ebola have produced a lot of data about epitopes (antibody binding sites) that produce potent neutralising responses and those that are less effective. This was a result of finding that epitopes involving the receptor binding domain can be potently immune-protective, but such domains are also relatively variable allowing mutations to arise that can evade the antibody response. However, highly conserved regions (less liable to mutate and potentially giving stable immune protection) of the spike protein are often not so accessible for raising antibodies. As was discussed in the first section, the spike protein undergoes a number of conformational changes upon binding the cell surface receptor and initiating the fusion process. Once the spike protein has undergone conformation changes subsequent to cell surface receptor attachment, it may reveal epitopes with excellent neutralising potential, but because in its native conformation these epitopes are concealed, antibodies are never raised against them.

In particular, it is believe that prior to cleavage by proteases between the S1 and S2 subunits of the spike protein that the receptor binding domain (RBD) is concealed. Protease cleavage and a conformation change is required for the RBD to become exposed and available for receptor binding. It is believed that freezing the spike protein in an open conformation as in the pre-fusion state would expose both the RBD and those highly conserved elements such as HR-1 and HR-2 that have potential to give rise to the most powerful neutralising antibodies.

To this end one group in 2019 changed two residues to prolines at the end of the HR1 helix to fuse the spike protein in the open conformation. Seen below in diagrammatic form, the structure on the left shows in yellow the HR-1 region exposed and available to raise antibodies against.



Immunogenicity and structures of a rationally designed prefusion MERS-CoV spike antigen. Pallesan *et al* 2017 PNAS

Somewhat ironically neutralising antibodies raised by this approach would be working in the exact same mechanism as adding free HR-2 peptides. Some of the neutralising antibodies would be binding to the HR-1 helix and neutralising the virus by preventing coiled-coils forming and fusion from taking place.

My understanding is the substitution of two residues with prolines is the approach that only the Moderna group is taking:

> *The mRNA-1273 vaccine candidate, manufactured by Moderna, encodes the S-2P antigen, consisting of the SARS-CoV-2 glycoprotein with a transmembrane anchor and an intact S1–S2 cleavage site. S-2P is stabilized in its prefusion conformation by two consecutive proline substitutions at amino acid positions 986 and 987, at the top of the central helix in the S2 subunit*

Moderna also claim:

> *Furthermore, anchoring the S-2P protein immunogen in the membrane also contributes to maintenance of the native conformation and antigenicity that improves immunogenicity as compared with secreted protein.*

From this it appears they are including a trans-membrane domain (I presume that of the spike protein itself, but it might be a targeting sequence and membrane anchor from a human protein). Moderna introduces an mRNA encoding this sequence inside a lipid-nanoparticle that is taken up by random host cells, which then starts translating the mRNA and sending the Spike antigen to the cell surface. Quite why the host is necessarily going to start a protective immune reaction from the novel protein that starts appearing on the surfaces of a random array of cell types is unclear to me. However, vaccines are in the end an empirical science and if Moderna believes their preliminary results say this approach will produce neutralising antibodies and a protective response, then it does not matter if the exact mechanism is something of a black box. There has been a lot of pre-clinical work on using this spike protein fused in an open conformation for a number of viruses, but none has gone through all the stages of development to an approved vaccine.

AstraZeneca, by contrast do not seem to use this slightly altered spike protein, preferring the native form:

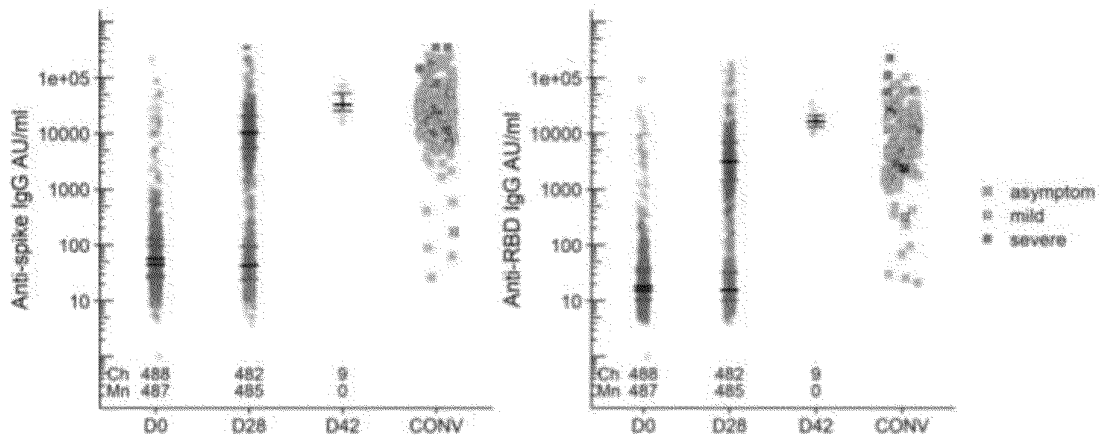
> *The ChAdOx1 nCoV-19 vaccine (AZD1222) consists of the replication-deficient simian adenovirus vector ChAdOx1, containing the full-length structural surface glycoprotein (spike protein) of SARS-CoV-2, with a tissue plasminogen activator leader sequence.*

The tissue plasminogen leader sequence has been used in a number of vaccine experiments (again not aware of any examples of approved vaccines) to send the translated protein through the Golgi to the cell surface and/or secreted. I have seen no details from Moderna regarding if they have used such a leader sequence in the mRNA for their vaccine. It is possible, therefore, that the Astra-Zeneca vaccine may have an advantage here – to be balanced by a possible disadvantage for not using a pre-fusion spike protein.

Both of these share a potential issue that whether secreted or anchored on the cell surface, there doesn't seem to be any context for the host to determine it is under a viral attack or to recognise the Spike protein as foreign or a threat. The Astra-Zeneca protein is at least delivered in the form of a virus – and in early stages has been associated with some symptoms of mild fever suggesting the innate immune system has been activated – which should assist triggering the adaptive immune response. However, there may be a time-lag between the innate immune response and the appearance of the production of any potential spike protein antigen – as it only appears after the gene is expressed by the host cell. It is unclear what the immune system makes of the lipid nanoparticles of the Moderna vaccine. While cells might respond to the trans-gene expression by presenting digested peptides on their MHC molecules, memory B cells would never get to be amplified in response to the spike protein in the context of a genuine viral envelope.

Nevertheless, both Moderna and Astra-Zeneca appear to produce reasonable antibodies titres, although how protective they are is yet to be seen. A representative figure from the Astra-Zeneca vaccine (dots in blue given a control vaccine, dots in red given ChAdOx1, green dots in convalescent plasma). A small number received a booster shot on Day 28 and showed a significant higher titre on Day 42, comparable to what is found convalescent plasma)

Figure 54 Multiplex SARS-CoV-2 IgG response by ELISA to A) spike protein and B) receptor binding domain, in trial participants and convalescent PCR+ COVID-19 patients (MIA)



Red: ChAdOx1 nCoV-19 recipients; Blue: MenACWY recipients, Green: convalescent plasma from PCR+ COVID-19 patients. Error bars show median and IQR. Day 42 samples taken in N=9 participants boosted at day 28. AU=arbitrary units

A vaccine being developed in Australia by the University of Queensland tries a different approach, using a technology they call a "molecular clamp". The mode of action of which is not entirely clear to me, however this is one description

> *The clamp is made from amino acid residues in a pattern that repeats after every seven residues, and must be at least 14 residues in length. The clamp self-assembles into a twin helix with one strand going forward and the other in reverse. The pairing of the amino acids in the strands is ensured by a pattern of hydrophobic and hydrophilic amino acids. The pattern is arranged so that none of the clamp will bind to the protein from the virus. The clamp self-assembles into a stiff rod. The clamp is linked to the desired part of the virus protein by a linker.*

Not only does it clamp the Spike protein in the pre-fusion state (like the Moderna vaccine), but the clamp also substitutes the need for a lipid membrane (ie allows free protein to form trimers detached in solution). This means the vaccine can be manufactured directly from recombinant protein without having to use the human host to produce proteins. Therefore, it can be directly injected with a classical adjuvant to simultaneously trigger an innate immune response and trick the host to thinking it is under attack – the antigen is already present at peak innate immune response. But this molecular clamp approach, although investigated for several viruses in pre-clinical settings, has not to date resulted in an approved vaccine. Another Australian company Vaxine is purifying the spike protein expressed insect cells and combining with a plant polysaccharide inulin as an adjuvant to activate the immune system – but it lacks the molecular clamp holding the spike protein in its correct form. The disadvantage a simple antigen vaccine has is there is no amplification that results from the gene-based methods of the Moderna or Adenovirus approach causing the host to produce the spike protein itself.

A potential weakness of both Sputnik V and ChAdOx1 vaccines is the viral vector isn't strictly speaking being used to generate the immune response, only to deliver the spike protein gene to host cells to produce the spike protein itself. This because the adenovirus vector used is a capsid virus – consisting of a protein outer shell, whereas the coronavirus is an enveloped virus, covered in a lipid membrane. There is no role for a spike protein in a protein capsid, all the capsid does is store the Spike protein gene and deliver it to the host cells.

The most recent successful approach to a virus vaccine was the Ebola vaccine from Merck, rVSV-ZEBOV (shown to be genuinely protective in the 2018 Kivu Ebola outbreak). This was a live replication competent Vesicular Stomatitis Virus, which is a single stranded, negative sense enveloped RNA virus, as is Ebola (Covid-19 is a positive sense enveloped RNA virus). In this approach the surface glycoprotein (G protein) of VSV is replaced with its analogue from Ebola. It is attenuated by removing one of the genes of VSV most associated with its virulence (again the G protein). This would appear to involve a balancing act, since the factor responsible for attenuation is the same which is being used to insert the Ebola gene that will be the antigen. The risk then is whether the resulting essentially novel virus is still genuinely attenuated, not to mention issues like a potentially different host cell range. Possibly the severity of Ebola justified such an approach, in any case the risk seems to have paid off.

The advantage of this approach is the host is in no doubt that it is facing a virus andtherefore should strongly mobilise its adaptive immunity response, receiving all the appropriate signals from its pattern recognition receptors that may be lacking in the Moderna and Astra-Zeneca strategies. Whereas AstraZeneca and Moderna vectors result in the host cells simply producing and secreting

lots of Spike protein antigen, this is a replication competent vector, therefore the host cells will be producing live virus particles.

In May 2020 Merck finally announced it was entering the vaccine race, in contrast with Moderna and Astra-Zeneca who both had cloned the Spike protein gene into their respective vectors within 48 hours of China publishing the sequence on January 11. They announced they would develop two vaccine candidates by cloning the Sars CoV-2 spike protein into both a modified VSV and a Measles derived backbone. The measles backbone is likely based on the current measles vaccine, which is a live attenuated virus, however a virus that has been found to be very safe. Attenuation of the measles virus was developed empirically after repeated passaging in cell culture. As of August, the measles based vaccine has entered Phase I trials (NCT04497298), scheduled to be completed at the end of November. The modified VSV derived vaccine was still at the pre-clinical phase at the time of writing. While these approaches which so closely track the process of the actual virus infection, may have greater potential to deliver real protection, there would always remain the nagging doubts as to safety. Swopping out the spike or G protein from these two viruses with the analogue from Sars-CoV-2 must have some potential to change the tropism or cell target of the resulting pseudo-virus. However, provided it remained blood-borne and not a respiratory transmitted virus, it most likely would not end up becoming its own disease agent.

The best vaccine approach would be simply making a Sars-CoV-2 live attenuated virus. Possibly by moderate deletions in the virus genome, rather than site specific mutations (which might always revert back). One serendipitous example already exists:

> *"Effects of a major deletion in the SARS-CoV-2 genome on the severity of infection and the inflammatory response: an observational cohort study" by Barnaby Young et al.*

This was a naturally occurring variant of Sars-CoV-2 identified in Singapore that had a 382 nucleotide deletion in the viral genome – truncating ORF7b and removing ORF8. Surprisingly, the virus still functioned. In a small study (29 with the truncated virus versus 92 infected with the wild type), around 50% of both groups developed pneumonia. However, in the truncated virus no patients developed hypoxia, was admitted to ICU or died, while with the wild type these figures were 28%, 16% and 2%. Since this is still causing disease it is more variolation rather than a vaccine and it remains infective. As a harm minimization strategy spreading the truncated virus through communities with either rudimentary health system or where transmission is out of control, such as India or Papua New Guinea, could be beneficial, given the time lag before any vaccine will be available. Possibly a rationally designed truncated virus could be developed that was even milder and not spread person-to-person, thus being a true vaccine much like the measles vaccine.

The best immune protection is likely to be provided by something that is closest to the wild-type virus and there is nothing closer to the wild-type virus than the wild-type virus itself. Sigh, if only there was some simple easy-to-develop antiviral that could be deployed to control the progression of infection while the body built up its own immunity….

Given the infectiousness of Sars-CoV-2 it's unlikely that we will get rid of it, so that everyone will have to eventually encounter and accommodate themselves to the spike protein – whether by vaccine or by the actual virus. One historical precedent is the 1889-1890 pandemic, starting from Bukhara and moving to Europe and onto the Americas killing an estimated 1 million people. It has been suggested that this was caused by the coronavirus OC43, now a modest, benign part of our winter respiratory virus caseload. This thesis is based on a molecular clock estimate of divergence from its nearest zoonotic relative in the cow 130 years ago. Similarly, it has been observed on

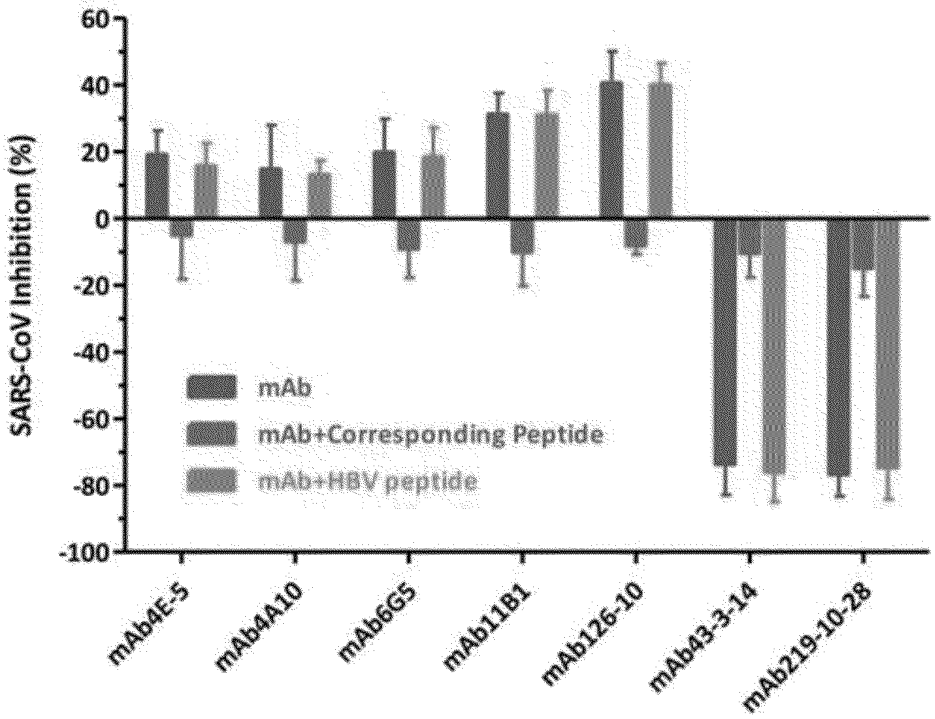
European contact with Pacific Islanders and Maori people, that the mildest respiratory diseases in Europeans were causing massive mortality in the Pacific community when they encounter the naïve immune systems of the indigenous populations. This suggests that the danger resides with the first contact with a novel virus and subsequent reinfections should be far less eventful. Therefore, even a weak vaccine might assist in allowing the patient to overcome their first episode with the virus with more ease, provided that such a vaccine raises some level of antibodies without causing vaccine disease enhancement. In a 35-year study following ten individuals by the University of Amsterdam, it was found that the median time between reinfection between human coronaviruses ranged from 27 months for HCoV-OC43 to 46 months for HCoV-HKU1. There is no reason to think immune protection provided by either Sars-CoV-2 infection itself or by a vaccine will be any longer. However, provided the first encounter has left a background level of immunity in the form of memory cells, ramping up the old immune response should be efficient and reinfections inconsequential. Many of the unpleasant symptoms of colds and flus, eg excessive mucus production in the airways, are a result of trying to project IgA immunoglobulins in areas that normally lack any antibody protection.

Monoclonals and Vaccine Disease Enhancement

If the most important issue in vaccine development is avoiding antibody disease enhancement – first seen in response to a denatured RSV virus vaccine trial – a more mechanistic understanding of this phenomena is required. In attempt to dissect vaccine disease enhancement a Chinese group used the SARS coronavirus to map the spike protein with mouse monoclonal antibodies to determine if individual epitopes were more likely to generate neutralising or disease enhancing antibodies:

> *Immunodominant SARS Coronavirus Epitopes in Humans Elicited both Enhancing and Neutralizing Effects on Infection in Non-human Primates. By Wang et al. ACS Infectious Disease*

The main results are set out below showing the effect of different monoclonals on virus infectivity.



To understand these results, different monoclonal antibodies had been raised against individual epitopes (ie locations) on the spike protein. Each monoclonal was tested for its ability to inhibit Sars-CoV infection (teal bar), then the peptide from the Spike protein corresponding to the monoclonal was added to show the inhibition was specific (the green bar – the assumption is the monoclonal antibody is mostly binding the added peptide and not the virus). In the orange bar a random peptide was added to demonstrate it had no effect on the neutralisation ability of the monoclonals. The first five antibodies developed show a neutralising effect, while the last two showed a strong disease enhancement effect.

The first three mAbs were raised against the Receptor Binding Domain. The fourth mAb – mAb11B1 was raised against peptides from the hinge region between S1-S2 subunits, but as were the two mAbs showing antibody-dependent disease enhancement – 6th and 7th monoclonals. The fifth antibody mAb126-10 was raised against the HR2 helical region of the S2 unit and showed the greatest protection.

If these results against Sars CoV are reproducible with Sars-CoV2, it might mean that all vaccination strategies discussed above have the potential to raise disease enhancement responses if they use the native, full length spike protein. Particularly so if the antigen is either denatured or free and not anchored in a virus envelope. Given that around 80% of people experience few problems with Covid-19, it may be that the minority of people getting severely sick are those with weakened immune system where antibodies raised to the hinge region between the two subunits are dominant. People with a stronger immune system keep raising more and more neutralising antibodies and swamp those offering enhancement effects. This could explain the poor results reportedly being gained with convalescent plasma, if it is being taken from patients who were sicker and therefore had been producing an ineffective immune response. Better results might be gained from the plasma of people who barely noticed they were infected. A poorly chosen vaccination strategy might just result in people reaching this end-point faster – if they were going to raise

neutralisation antibodies they will do so equally from a vaccine, if they were going to predominantly raise disease enhancing antibodies they will respond to the vaccine in the same way

There are various work arounds that might overcome such a potential disease enhancement effect. The simplest would be to create a pseudo-virus (whether an mRNA , an adenovirus vector or a free protein vaccine) that instead of the native spike protein, contains a mutated version with numerous amino-acid substitutions in the hinge region of epitopes thought to cause vaccine disease enhancement. Epitopes deemed likely to raise good neutralising responses would remain intact and although potentially disease enhancing antibodies would still be raised against the hinge region, these would never encounter a live virus that they could bind to, rendering them harmless. It is tempting to speculate whether this might be a useful vaccination strategy for HIV also, provided epitopes giving rise to damaging responses could be identified. A vaccine consisting of gp120/gp41 proteins mutated in the disease enhancement regions and fused into an open conformation to leave the receptor-binding domain and the HR-1 and HR2 helices exposed might be a sophisticated and successful approach.

It is tempting to speculate that fully understanding the mechanics of vaccine disease enhancement will also reveal why the body never succeeds in mounting a protective immune response to HIV. This rather strange phenomena reported in a 1978 paper might hold the key

Are endogenous C-type viruses involved in the immune system?

DNA sequences coding for infectious C-type viruses (oncornaviruses) are present in the genome of normal cells of various species, those best characterised being chicken, mouse, cat and baboon[1]. Mammalian endogenous viruses, in general, are restricted for growth in their autologous species but replicate in autologous species and are termed xenotropic[2]. In mice and some other species a further class of endogenous viruses has evolved which is restricted in heterologous cells but replicates in homologous cells, they are termed ecotropic[3]. Endogenous viral genes are inherited in the germ line and have co-evolved, in general, with non-viral host genes as indicated by evolutionary data[4]. One explanation for the retention of these genes is that they are involved in physiological functions as proposed by Temin in his protovirus hypothesis[5]. We have shown previously that B-cell proliferation induced by certain B-cell mitogens is frequently associated with expression of endogenous virus[6–10]. This has been confirmed by other workers who reported a xenotropic host range of the mitogen-induced virus[11]. In contrast to other virus induction methods, mitogen stimulation closely resembles a physiological process, that of antigen stimulation followed by lymphocyte proliferation. Whereas B cells can be induced by mitogens to release virus, we have evidence that T cells are refractory to induction when using T-cell mitogens as well as 5-bromo-2′-deoxyuridine[8]. These results suggest that the expression of endogenous xenotropic C-type viral genes

a completely unrelated virus, showed no absorption. Since rabbit antisera frequently contain activity against Forssman antigen, we tested whether absorption with red cells would remove the immunosuppressive activity. As shown in Table

Table 1 *In vitro* immunosuppressive activity of antiserum against mitogen-induced xenotropic C-type virus

Serum (final dilution)	PFC per 10^5 spleen cells*	% Inhibition
—	3,900	—
Control serum (1:100)	3,900	0
Antiserum (1:100)	1,200	70
(1:400)	1,900	51
(1:1,600)	1,700	56
(1:6,400)	3,800	3

The effect of the antiserum against xenotropic C-type virus on the induction of an antibody response to sheep red blood cells was investigated in cultures of BALB/c spleen cells from 8–15-week-old mice by a modified Mishell–Dutton technique[12]. 8×10^6 spleen cells were cultured in 35 × 10-mm disposable tissue culture Petri dishes (Falcon) containing 1 ml RPMI 1640 medium (Microbiological Associates), supplemented with 8% foetal bovine serum, 1% horse serum and antibiotics. At the onset of the culture period 10 µl control serum or antiserum was added. The cultures were rocked during the 5-d culture period in an incubator containing 10% CO_2, 83% N_2 and 7% O_2. They were stimulated with 4×10^6 sheep red blood cells. Direct plaque-forming cells (PFC) were assayed by the local haemolysis technique in liquid medium[13]. The cell recovery of the various cultures did not differ significantly.

*Mean values from triplicate cultures.

Endogenous C-type viruses is a very early name for the entire class of RNA viruses. In this experiment they raised antisera against various C-type viruses. They then assayed the effects of adding these anti-sera to the activity of B cells and found that it was highly immunosuppressive. To explain these results, they developed a theory as exciting as it was completely wrong. What they may have achieved was an early cell culture model of vaccine disease enhancement.

Biological Warfare and the blocking of antiviral development

The thrust of this report has been to understand why a simple, easily developed antiviral treatment for Covid-19 has been overlooked. It is suggested this has been achieved first by bribing the large

pharmaceutical companies by granting approval for drugs the FDA knew were ineffectual and then by pushing into literature results, which if not necessarily wrong, were highly misleading.

The more important question is motivation, which we suggest points to an ongoing covert program of biological weapons research in the United States. In theory, President Nixon renounced the use of biological warfare in 1969 in response to the outrage generated by the usage of Agent Orange in Vietnam. However, such a ban on biological weapons did not prevent finely milled weaponized anthrax being on hand in Fort Detrick's stocks in September-October 2001 to be released on the traumatised New York civilian population.

The golden age of the US biological warfare program may be long over, when Pentagon planners were gleefully drawing up plans for B52 bombers to spread bubonic plague amongst devastated civilian populations in the aftermath of a nuclear attack. However, the interest in mastering disease outbreaks that can be deployed in a plausible deniable way, possibly as research justified under the cover of "biodefense", remains. And as the Pentagon moves its attention from hot conflicts to luke-warm conflicts with offensive operations in cyber-attacks, sabotage, information warfare and constantly pretending to be a victim, the Wuhan Institute of Virology would have represented an irresistible opportunity.

In general, the pharmaceutical industry can make plenty of money from treatments that do not work, indeed arguably they can make more money from ineffective drugs than they can from effective drugs. However, patients prefer treatments that work and in the absence of external influences eventually a pharmaceutical firm will defect and supply an effective treatment. To successfully suppress a treatment requires arms of government influenced by the national security community, such as the FDA and grant funding bodies, to provide the necessary sticks and carrots to the pharmaceutical companies and research groups. The US military is not averse to treatments, either as vaccines or antivirals, for their potential bioweapons; but they want them to be slow to develop, expensive and required to be administered in a formal hospital setting. A treatment that can be developed and deployed in a week would render Fort Detrick's arsenal of viruses obsolete overnight.

A future report will look at the evidence for American involvement in the release of Sars-CoV-2 and examine the likely scientific methods and tools it uses to develop their bioweapons. It will also examine the current strategic thinking as to how the United States believes they should be deployed for their maximum benefit. In particular, it will look at historical American practices in the use of biological warfare on the Korean peninsula and their role in the proliferation and deployment of nerve gases in conflict zones in the Middle East. In the meantime, the fact that simple and effective antiviral treatments have been actively suppressed provides powerful circumstantial evidence towards US culpability for Covid-19. And it should serves as a timely reminder to the World Health Organisation that the biggest threat to public health worldwide remains the United States and its parasitic National Security community.

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[simon.funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; sivkog@battelle.org[sivkog@battelle.org]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; verschoor@bprc.nl[verschoor@bprc.nl]; verstrepen@bprc.nl[verstrepen@bprc.nl]; langermans@bprc.nl[langermans@bprc.nl]; Dr. Mark Lewis[mlewis@bioqual.com]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Estefania Bni[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Li, Sean (HC/SC)[sean.li@canada.ca]; dean.smith@canada.ca[dean.smith@canada.ca]; nax3@cdc.gov[nax3@cdc.gov]; Roger Le[roger.le-grand@cea.fr]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; sekim@krict.re.kr[sekim@krict.re.kr]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; Carolyn Clark[carolyn.clark@cepi.net]; William Dowling[william.dowling@cepi.net]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; rkiatchula@gmail.com[rkiatchula@gmail.com]; seos@cnu.ac.kr[seos@cnu.ac.kr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; mto@umn.edu[mto@umn.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; sinabavari@comcast.net[sinabavari@comcast.net]; Vasan Vasan[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Amelia Karlsson[amelia.karlsson@duke.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Wang, Tony[tony.wang@fda.hhs.gov]; Philip Krause[philip.krause@fda.hhs.gov]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Martin Beer[Martin.Beer@fli.de]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; ldenisy@yahoo.com[ldenisy@yahoo.com]; rhakami@gmu.edu[rhakami@gmu.edu]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; Dan Barouch[dbarouch@bidmc.harvard.edu]; esulkowska@rics.bwh.harvard.edu[esulkowska@rics.bwh.harvard.edu]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; jfwchan[jfwchan@hku.hk]; hlchen@hku.hk[hlchen@hku.hk]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Krammer, Florian[florian.krammer@mssm.edu]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; mksong@ivi.int[mksong@ivi.int]; Quim Segales[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Nir Paran[nirp@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; Juergen Richt[jricht@vet.k-state.edu]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; horer@ku.edu.tr[horer@ku.edu.tr]; snumouse@snu.ac.kr[snumouse@snu.ac.kr]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Johan Neyts[johan.neyts@kuleuven.be]; erica@lji.org[erica@lji.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Chi Van Dang[cdang@lcr.org]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Randy Albrecht[randy.albrecht@mssm.edu]; Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; Peter Palese[peter.palese@mssm.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; Benjamin tenOever[tenoever@gmail.com]; golinger@mriglobal.org[golinger@mriglobal.org]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; Mark Page[Mark.Page@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; clint.florence@nih.gov[clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Holbrook, Michael (NIH/NIAID) [C][Michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; barney.graham@nih.gov[barney.graham@nih.gov]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; patrick.reid@unmc.edu[patrick.reid@unmc.edu]; Neil Berry[Neil.Berry@nibsc.org]; philip.minor2@gmail.com[philip.minor2@gmail.com]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; que.dang@nih.gov[que.dang@nih.gov]; sheri.hild@nih.gov[sheri.hild@nih.gov]; fcassels@path.org[fcassels@path.org]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; 秦川[qinchuan@pumc.edu.cn]; Spergel, Jonathan[SPERGEL@email.chop.edu]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; Miles Carroll[Miles.Carroll@phe.gov.uk];

Simon.Funnell@phe.gov.uk[Simon.Funnell@phe.gov.uk]; Yper Hall[Yper.Hall@phe.gov.uk]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Padmini Salgame[salgampa@njms.rutgers.edu]; fkoide@southernresearch.org[fkoide@southernresearch.org]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; tverakit@gmail.com[tverakit@gmail.com]; bobomok@hku.hk[bobomok@hku.hk]; anna@thsti.res.in[anna@thsti.res.in]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Chad Roy[croy@tulane.edu]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; 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[dmissiak@bsd.uchicago.edu]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; Erik Dohm[edohm@uab.edu]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Stanley Perlman[stanley-perlman@uiowa.edu]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Matthew Frieman[MFrieman@som.umaryland.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; baczenas@wisc.edu[baczenas@wisc.edu]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR[dhoconno@wisc.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; abukreye@utmb.edu[abukreye@utmb.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Darryl Falzarano[darryl.falzarano@usask.ca]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; Koert Stittelaar[stittelaar@viroclinics.com]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; Diamond, Michael[mdiamond@wustl.edu]; Pierre Gsell[gsellp@who.int]; 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, Ximena[lauriex@who.int]; swaminathans@who.int[swaminathans@who.int]; woodd@who.int[woodd@who.int]; dbolton@hivresearch.org[dbolton@hivresearch.org]; russori@njms.rutgers.edu[russori@njms.rutgers.edu]; GSmith@novavax.com[GSmith@Novavax.com]; phil.yang@nantworks.com[phil.yang@nantworks.com]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 11/4/2020 8:27:33 AM (UTC-05:00)
Subject: WHO COVID-19 Animal Models Group Call- Thursday NOV 5
Mail Attachment.ics

Dear all,
Please find below the agenda and invite for our group call tomorrow Thursday Nov 5th. As usual the call will take place at 3PM (CET, Geneva).

Best regards to all,

César, Bill and Simon

PS. Please note that we have moved to Zoom

Agenda WHO COVID-19 Animal Models Group-November 5th 3PM CET

1- Javier Salguero (PHE)- Comparative SARS-CoV-2 infection studies in cynomolgus and rhesus macaques

2- Gale Smith (Novavax)- NVX-C0V2373 vaccine studies in nonhuman primate models

3- Phillip Yang (Nantworks)- HAd5 dual construct vaccine studies in nonhuman primates

4- Open questions and discussion

Join Zoom Meeting
https://who.zoom.us/j/96933864897

Meeting ID: 969 3386 4897
Find your local number: https://who.zoom.us/u/aelOyrWQik

Organizer:	GSELL, Pierre : gsellp@who.int
Subject:	[COVID-19] 36th WHO TC - Animal Models
Location:	https://who.zoom.us/j/96933864897
Start Time:	2020-11-05T15:00:00+01:00
End Time:	2020-11-05T16:30:00+01:00
Attendees:	Luis.Lugo.mil@afrims.org : Luis.Lugo.mil@afrims.org, Matthew.Reed.mil@afrims.org, Matthew.Reed.mil@afrims.org, LESELLIER Sandrine, sandrine.lesellier@anses.fr, Romain Volmer : romain.volmer@envt.fr, BAMFORD, Pearl : Pearl.Bamford@health.gov.au, ZHU, Jin, Jin.Zhu@health.gov.au, Donis, Ruben (OS/ASPR/BARDA) : ruben.donis@hhs.gov, Karl.Erlandson : Karl.Erlandson@hhs.gov, Jayashankar, Lakshmi (OS/ASPR/BARDA), Lakshmi.Jayashankar@hhs.gov, Little, James (OS/ASPR/BARDA), James.Little@hhs.gov, Carol.Sabourin@hhs.gov : Carol.Sabourin@hhs.gov, Treanor, John (OS/ASPR/BARDA) (CTR) : John.Treanor@hhs.gov, Sivko, Gloria S : sivkog@battelle.org, Russell.Ray@bcm.edu, Russell.Ray@bcm.edu, Ernst Verschoor : verschoor@bprc.nl, verstrepen@bprc.nl : verstrepen@bprc.nl, langermans : langermans@bprc.nl, Mark Lewis : mlewis@bioqual.com, Monalisa Chatterji : MONALISA.CHATTERJI@gatesfoundation.org, Jacqueline Kirchner : Jacqueline.Kirchner@gatesfoundation.org, Harry Kleanthous : Harry.Kleanthous@gatesfoundation.org, Karen Makar : Karen.Makar@gatesfoundation.org, David Vaughn : David.Vaughn@gatesfoundation.org, Cesar Munoz-Fontela : munoz-fontela@bnitm.de, estefania.rodriguez : estefania.rodriguez@bnitm.de, Griffiths, Anthony, ahgriff@bu.edu, dustin.johnson : dustin.johnson@canada.ca, sean.li : sean.li@canada.ca, dean.smith : dean.smith@canada.ca, Thornburg, Natalie (CDC/DDID/NCIRD/DVD), nax3@cdc.gov, Roger Le Grand : roger.le-grand@cea.fr, Pauline Maisonnasse : pauline.maisonnasse@cea.fr, sekim : sekim@krict.re.kr, kandeil_a : kandeil_a@hotmail.com, Carolyn Clark : carolyn.clark@cepi.net, William Dowling : william.dowling@cepi.net, Amy C. Shurtleff, amy.c.shurtleff@cepi.net, shanchao : shanchao@wh.iov.cn, rkiatchula, rkiatchula@gmail.com, seos@cnu.ac.kr : seos@cnu.ac.kr, lisambrosseau@gmail.com, lisambrosseau@gmail.com, mto@umn.edu : mto@umn.edu, mito@ciea.or.jp : mito@ciea.or.jp, tyamamoto@ciea.or.jp : tyamamoto@ciea.or.jp, mesteban : mesteban@cnb.csic.es, Juan GarcÃa Arriaza, jfgarcia@cnb.csic.es, l.enjuanes@cnb.csic.es : l.enjuanes@cnb.csic.es, mopargal : mopargal@rams.colostate.edu, Rasmussen, Angela L., alr2105@cumc.columbia.edu, scordo : scordo@qb.fcen.uba.ar, sinabavari@comcast.net, sinabavari@comcast.net, Vasan, Vasan (H&B, Geelong ACDP), Vasan.Vasan@csiro.au, Duprex, Paul : pduprex@pitt.edu, Flynn, Joanne L, joanne@pitt.edu, White, Alexander G : agw13@pitt.edu, AKelvin, AKelvin@dal.ca, renee.wegrzyn@darpa.mil : renee.wegrzyn@darpa.mil, john.c.trefry.civ : john.c.trefry.civ@mail.mil, kanta.subbarao, kanta.subbarao@influenzacentre.org, REIRELAND@mail.dstl.gov.uk, REIRELAND@mail.dstl.gov.uk, MSLEVER@dstl.gov.uk, MSLEVER@dstl.gov.uk, MNELSON@mail.dstl.gov.uk, MNELSON@mail.dstl.gov.uk, JLPRIOR@dstl.gov.uk, JLPRIOR@dstl.gov.uk, Amelia Karlsson : amelia.karlsson@duke.edu, Danielle Anderson : danielle.anderson@duke-nus.edu.sg, Cavaleri Marco : Marco.Cavaleri@ema.europa.eu, mariette.ducatez@envt.fr, mariette.ducatez@envt.fr, B.H.G. Rockx : b.rockx@erasmusmc.nl, B.L. Haagmans : b.haagmans@erasmusmc.nl, Golding, Hana, Hana.Golding@fda.hhs.gov, MacGill, Tracy :

Tracy.MacGill@fda.hhs.gov

GSELL, Pierre is inviting you to a scheduled Zoom meeting "[COVID-19] 36th WHO TC - Animal Models"

Join Zoom Meeting
https://who.zoom.us/j/96933864897

Meeting ID: 969 3386 4897
Find your local number: https://who.zoom.us/u/aelOyrWQik

To: Brown, Lisa[LBrown@nas.edu]
Cc: 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]; 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]; 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]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; Pope, Andrew[apope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]; Liao, Julie[JLiao@nas.edu]
From: Peggy Hamburg[peggy@hbfam.net]
Sent: Tue 11/10/2020 3:03:15 PM (UTC-05:00)
Subject: Re: URGENT Call on Monoclonal Antibodies: Sunday, November 15

Hello. This is an important topic. I can be available.....
Peggy

Sent from my iPhone

On Nov 10, 2020, at 3:01 PM, Brown, Lisa <LBrown@nas.edu> wrote:

Dear Members of the Standing Committee,

We have received an urgent request from our sponsors, ASPR and OSTP, to explore the issue of allocation of COVID-19 monoclonal antibodies (and therapeutics more broadly), with a particular emphasis on how to achieve equitable access. With the recent approval of bamlanivimab, there is some urgency to this task, and we would like convene the standing committee for a virtual discussion this **Sunday, November 15 from 11:00 a.m. – 1:00 p.m. ET.** We understand this is extremely short notice, and on a weekend, but we would greatly appreciate your participation in this meeting.

If you could please let us know as soon as possible if you are able to participate, that would be great. A calendar invite and Zoom link will follow shortly.

We will provide additional details later this week. 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


The National Academies of
SCIENCES • ENGINEERING • MEDICINE

To: Diane Griffin[dgriffi6@jhmi.edu]; 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]; 'Embrey, Ellen (eembrey@stratitia.com)'[eembrey@stratitia.com]; 'Georges Benjamin (georges.benjamin@apha.org)'[georges.benjamin@apha.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]; '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]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]; Liao, Julie[JLiao@nas.edu]
From: Baric, Ralph S[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB0D9CC80C184735A4E862C3BDD8A15D-RALPH S BAR]
Sent: Tue 11/10/2020 3:44:49 PM (UTC-05:00)
Subject: RE: URGENT Call on Monoclonal Antibodies: Sunday, November 15

Lisa, I can attend. Ralph

From: Diane Griffin <dgriffi6@jhmi.edu>
Sent: Tuesday, November 10, 2020 3:12 PM
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>; 'Embrey, Ellen (eembrey@stratitia.com)' <eembrey@stratitia.com>; 'Georges Benjamin (georges.benjamin@apha.org)' <georges.benjamin@apha.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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Subject: Re: URGENT Call on Monoclonal Antibodies: Sunday, November 15

Lisa - I can come.

Diane

Diane E. Griffin, MD PhD
Vice President, National Academy of Sciences
University Distinguished Service Professor
W. Harry Feinstone Department of Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe St, Rm E5636
Baltimore, MD 21205
410-955-3459

dgriffi6@jhu.edu

From: Brown, Lisa <LBrown@nas.edu>
Sent: Tuesday, November 10, 2020 3:01 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>; 'Embrey, Ellen (eembrey@stratitia.com)' <eembrey@stratitia.com>; 'Georges Benjamin (georges.benjamin@apha.org)' <georges.benjamin@apha.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>
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Subject: URGENT Call on Monoclonal Antibodies: Sunday, November 15

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We will provide additional details later this week. 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

To: Brown, Lisa[LBrown@nas.edu]
Cc: Alexandra Phelan (alp81@georgetown.edu)[alp81@georgetown.edu]; Walt, David[dwalt@bwh.harvard.edu]; David A Relman (relman@stanford.edu)[relman@stanford.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]; 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]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]; Liao, Julie[JLiao@nas.edu]
From: Baruch Fischhoff[baruch@cmu.edu]
Sent: Tue 11/10/2020 4:07:09 PM (UTC-05:00)
Subject: Re: URGENT Call on Monoclonal Antibodies: Sunday, November 15

I can come as well.
Thanks.

Baruch

Baruch Fischhoff
Howard Heinz University Professor
Department of Engineering and Public Policy
Institute for Politics and Strategy
Carnegie Mellon University
http://www.cmu.edu/epp/people/faculty/baruch-fischhoff.html

On Nov 10, 2020, at 4:00 PM, Walt, David <dwalt@bwh.harvard.edu> wrote:

Yes I can attend

David R. Walt
Hansjörg Wyss Professor of Biologically Inspired Engineering
Harvard Medical School
Professor of Pathology
Department of Pathology-Brigham and Women's Hospital
Core Faculty-Wyss Institute for Bioinspired Engineering at Harvard University
HHMI Professor

Office: 857-307-1112
dwalt@bwh.harvard.edu

http://waltlab.bwh.harvard.edu
https://wyss.harvard.edu/team/core-faculty/david-walt/
brighamandwomens.org

<image001.gif>

<image002.gif>

From: "Brown, Lisa" <LBrown@nas.edu>
Date: Tuesday, November 10, 2020 at 3:02 PM
To: "'Alexandra Phelan (alp81@georgetown.edu)'" <alp81@georgetown.edu>, "'David A Relman (relman@stanford.edu)'" <relman@stanford.edu>, "Walt, David" <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>, "'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>
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Subject: URGENT Call on Monoclonal Antibodies: Sunday, November 15

Dear Members of the Standing Committee,

We have received an urgent request from our sponsors, ASPR and OSTP, to explore the issue of allocation of COVID-19 monoclonal antibodies (and therapeutics more broadly), with a particular emphasis on how to achieve equitable access. With the recent approval of bamlanivimab, there is some urgency to this task, and we would like convene the standing committee for a virtual discussion this **Sunday, November 15 from 11:00 a.m. – 1:00 p.m. ET.** We understand this is extremely short notice, and on a weekend, but we would greatly appreciate your participation in this meeting.

If you could please let us know as soon as possible if you are able to participate, that would be great. A calendar invite and Zoom link will follow shortly.

We will provide additional details later this week. 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

<image003.png>

To: Brown, Lisa[LBrown@nas.edu]
Cc: 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]; John Hick (hick.john@gmail.com)[hick.john@gmail.com]; 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]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]; Liao, Julie[JLiao@nas.edu]
From: Jonna Mazet[jkmazet@ucdavis.edu]
Sent: Tue 11/10/2020 5:33:44 PM (UTC-05:00)
Subject: Re: URGENT Call on Monoclonal Antibodies: Sunday, November 15

Yes, I will try to join, too, though I may have limited connectivity.
Thanks,
Jonna

On Tue, Nov 10, 2020 at 12:01 PM Brown, Lisa <LBrown@nas.edu> wrote:

Dear Members of the Standing Committee,

We have received an urgent request from our sponsors, ASPR and OSTP, to explore the issue of allocation of COVID-19 monoclonal antibodies (and therapeutics more broadly), with a particular emphasis on how to achieve equitable access. With the recent approval of bamlanivimab, there is some urgency to this task, and we would like convene the standing committee for a virtual discussion this **Sunday, November 15 from 11:00 a.m. – 1:00 p.m. ET.** We understand this is extremely short notice, and on a weekend, but we would greatly appreciate your participation in this meeting.

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The National Academies of
SCIENCES · ENGINEERING · MEDICINE

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Cc: 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]; 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]; Harvey V. Fineberg (harvey.fineberg@moore.org)[harvey.fineberg@moore.org]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]; Liao, Julie[JLiao@nas.edu]; Kanarek, Morgan[MKanarek@nas.edu]; Hassell, David (Chris) (OS/ASPR/IO)[David.Hassell@hhs.gov]; Waterman Paige E. EOP/OSTP[Paige.E.Waterman@ostp.eop.gov]; Watson, Ian (OS/ASPR/SPPR)[Ian.Watson@hhs.gov]; Motrya Calafiura[Motrya.Calafiura@georgetown.edu]; Ferris, Nicole[nferris@rwjf.org]
From: Dzau, Victor J.[VDzau@nas.edu]
Sent: Tue 11/10/2020 9:40:14 PM (UTC-05:00)
Subject: Re: Standing Committee on EID and 21st Century Health Threats: URGENT Call on Monoclonal Antibodies

I can join 11-11:25 am. After that I have to join another conference

> On Nov 10, 2020, at 6:32 PM, Brown, Lisa <LBrown@nas.edu> wrote:
>
>

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[simon.funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]

To: Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; abukreye@utmb.edu[abukreye@utmb.edu]; White, Alexander G[agw13@pitt.edu]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Amelia Karlsson[amelia.karlsson@duke.edu]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; Angela Rasmussen[alr2105@cumc.columbia.edu]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; anna@thsti.res.in[anna@thsti.res.in]; Griffiths, Anthony[ahgriff@bu.edu]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; verstrepen@bprc.nl[verstrepen@bprc.nl]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; barney.graham@nih.gov[barney.graham@nih.gov]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Benjamin tenOever[tenoever@gmail.com]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; bobomok@hku.hk[bobomok@hku.hk]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Carolyn Clark[carolyn.clark@cepi.net]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Chad Roy[croy@tulane.edu]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; tverakit@gmail.com[tverakit@gmail.com]; mary.lane@nih.gov[mary.lane@nih.gov]; Chi Van Dang[cdang@lcr.org]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; 秦川[qinchuan@pumc.edu.cn]; clint.florence@nih.gov[clint.florence@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Dan Barouch[dbarouch@bidmc.harvard.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Darryl Falzarano[darryl.falzarano@usask.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; DAVID H O'CONNOR[dhoconno@wisc.edu]; woodd@who.int[woodd@who.int]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; dean.smith@canada.ca[dean.smith@canada.ca]; ldenisy@yahoo.com[ldenisy@yahoo.com]; dbolton@hivresearch.org[dbolton@hivresearch.org]; 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[dmissiak@bsd.uchicago.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; esulkowska@rics.bwh.harvard.edu[esulkowska@rics.bwh.harvard.edu]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; erica@lji.org[erica@lji.org]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Erik Dohm[edohm@uab.edu]; verschoor@bprc.nl[verschoor@bprc.nl]; Estefania Bni[estefania.rodriguez@bnitm.de]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; Krammer, Florian[florian.krammer@mssm.edu]; fcassels@path.org[fcassels@path.org]; fkoide@southernresearch.org[fkoide@southernresearch.org]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; sivkog@battelle.org[sivkog@battelle.org]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; horer@ku.edu.tr[horer@ku.edu.tr]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; hlchen@hku.hk[hlchen@hku.hk]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; KNEZEVIC, Ivana[knezevici@who.int]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; langermans@bprc.nl[langermans@bprc.nl]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; jfwchan[jfwchan@hku.hk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; snumouse@snu.ac.kr[snumouse@snu.ac.kr]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Flynn, Joanne L[joanne@pitt.edu]; Quim Segales[joaquim.segales@irta.cat]; Johan Neyts[johan.neyts@kuleuven.be]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; baczenas@wisc.edu[baczenas@wisc.edu]; Spergel, Jonathan[SPERGEL@email.chop.edu]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Juergen Richt[jricht@vet.k-state.edu]; Vergara, Julia[julia.vergara@irta.cat]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Alyson Kelvin[AKelvin@dal.ca]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; rkiatchula@gmail.com[rkiatchula@gmail.com]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; Koert Stittelaar[stittelaar@viroclinics.com]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; mksong@ivi.int[mksong@ivi.int]; Marco.Cavaleri@ema.europa.eu[Marco.Cavaleri@ema.europa.eu]; Mariano Esteban

Rodriguez[mesteban@cnb.csic.es]; PREZIOSI, Marie-pierre[preziosim@who.int]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; Mark Page[Mark.Page@nibsc.org]; Dr. Mark Lewis[mlewis@bioqual.com]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Martin Beer[Martin.Beer@fli.de]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; Matthew Frieman[MFrieman@som.umaryland.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; Diamond, Michael[mdiamond@wustl.edu]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; mto@umn.edu[mto@umn.edu]; Holbrook, Michael (NIH/NIAID) [C][Michael.holbrook@nih.gov]; Miles Carroll[Miles.Carroll@phe.gov.uk]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; nax3@cdc.gov[nax3@cdc.gov]; Neil Berry[Neil.Berry@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Nir Paran[nirp@iibr.gov.il]; nora.gerhards@wur.nl[nora.gerhards@wur.nl]; nnagata@niid.go.jp[nnagata@niid.go.jp]; golinger@mriglobal.org[golinger@mriglobal.org]; Padmini Salgame[salgampa@njms.rutgers.edu]; patrick.reid@unmc.edu[patrick.reid@unmc.edu]; Hodgson, Paul[paul.hodgson@usask.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Duprex, Paul[pduprex@pitt.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Peter Palese[peter.palese@mssm.edu]; philip.minor2@gmail.com[philip.minor2@gmail.com]; Philip Krause[philip.krause@fda.hhs.gov]; Pierre Gsell[gsellp@who.int]; que.dang@nih.gov[que.dang@nih.gov]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; Baric, Ralph S[rbaric@email.unc.edu]; rhakami@gmu.edu[rhakami@gmu.edu]; Randy Albrecht[randy.albrecht@mssm.edu]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; russori@njms.rutgers.edu[russori@njms.rutgers.edu]; robin.levis@fda.hhs.gov[robin.levis@fda.hhs.gov]; Roger Le[roger.le-grand@cea.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Cartner, Samuel Corbin[scartner@uab.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; seos@cnu.ac.kr[seos@cnu.ac.kr]; Li, Sean (HC/SC)[sean.li@canada.ca]; sekim@krict.re.kr[sekim@krict.re.kr]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; sheri.hild@nih.gov[sheri.hild@nih.gov]; Simon.Funnell@phe.gov.uk[Simon.Funnell@phe.gov.uk]; sinabavari@comcast.net[sinabavari@comcast.net]; swaminathans@who.int[swaminathans@who.int]; Stanley Perlman[stanley-perlman@uiowa.edu]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Wang, Tony[tony.wang@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; Vasan Vasan[Vasan.Vasan@csiro.au]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; William Dowling[william.dowling@cepi.net]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; RIVEROS BALTA, Ximena[lauriex@who.int]; Yper Hall[Yper.Hall@phe.gov.uk]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; zhout@who.int[zhout@who.int]; yoos@who.int[yoos@who.int]; r.deswart@erasmusmc.nl[r.deswart@erasmusmc.nl]; r.d.devries@erasmusmc.nl[r.d.devries@erasmusmc.nl]; rmedinas@med.puc.cl[rmedinas@med.puc.cl]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; anja.kipar@uzh.ch[anja.kipar@uzh.ch]; barton.haynes@duke.edu[barton.haynes@duke.edu]; kevin.saunders@duke.edu[kevin.saunders@duke.edu]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 11/11/2020 6:56:39 AM (UTC-05:00)
Subject: Agenda-WHO COVID-19 Animal Models Group Call
Mail Attachment.ics

Dear colleagues,
Please find below the agenda and zoom invite for our WHO COVID-19 Animal Models group call this Thursday 12th, at 3PM CET (Geneva time).

Very best

César, Simon and Bill.

WHO COVID-19 Animal Models Group Call- Thursday 12 at 3PM CET (Geneva time)

1- Barton Haynes (Duke University)- *The in vitro and in vivo function of SARS-CoV-2 neutralizing and infection-enhancing antibodies*

2- James P. Stewart (Uni Liverpool)- *Sequential infection with influenza A virus followed by SARS-CoV-2 leads to*

more severe disease.

3- Rory de Vries (Erasmus)- *Intranasal fusion inhibitory lipopeptide prevents direct contact SARS-CoV-2 transmission in ferrets*

4- Rafael A. Medina Silva (Universidad Católica de Chile)- *A household case evidences shorter shedding of SARS-CoV-2 in naturally infected cats compared to their human owners*

Join Zoom Meeting
https://who.zoom.us/j/97955781521

Meeting ID: 979 5578 1521
Passcode: 3&J!gvka

Dial by your location

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Organizer:	GSELL, Pierre : gsellp@who.int
Subject:	[COVID-19] 37th WHO TC - Animal Models
Location:	https://who.zoom.us/j/97955781521
Start Time:	2020-11-12T15:00:00+01:00
End Time:	2020-11-12T16:30:00+01:00
Attendees:	Adolfo.Garcia-Sastre : Adolfo.Garcia-Sastre@mssm.edu, kandeil_a : kandeil_a@hotmail.com, abukreye : abukreye@utmb.edu, White, Alexander G, agw13@pitt.edu, kupke : kupke@staff.uni-marburg.de, Ali.Mirazimi : Ali.Mirazimi@folkhalsomyndigheten.se, Amelia Karlsson : amelia.karlsson@duke.edu, Amy C. Shurtleff : amy.c.shurtleff@cepi.net, HENAO RESTREPO, Ana Maria, henaorestrepoa@who.int, mopargal : mopargal@rams.colostate.edu, Rasmussen, Angela L. : alr2105@cumc.columbia.edu, Ann Rawkins : Ann.Rawkins@phe.gov.uk, anna : anna@thsti.res.in, Griffiths, Anthony : ahgriff@bu.edu, Asisa.Volz : Asisa.Volz@tiho-hannover.de, aysegul.nalca.civ : aysegul.nalca.civ@mail.mil, verstrepen@bprc.nl, verstrepen@bprc.nl, Barbara.Schnierle : Barbara.Schnierle@pei.de, Graham, Barney (NIH/VRC) [E] : bgraham@mail.nih.gov, B.H.G. Rockx : b.rockx@erasmusmc.nl, B.L. Haagmans, b.haagmans@erasmusmc.nl, tenoever@gmail.com : tenoever@gmail.com, Bernhard Kerscher (PEI-DE) : bernhard.kerscher@pei.de, bobomok@hku.hk : bobomok@hku.hk, bradley.pickering, bradley.pickering@canada.ca, CarlosAlberto.Guzman : CarlosAlberto.Guzman@helmholtz-hzi.de, Carol.Sabourin@hhs.gov : Carol.Sabourin@hhs.gov, Carolyn Clark : carolyn.clark@cepi.net, Cesar Munoz-Fontela, munoz-fontela@bnitm.de, croy : croy@tulane.edu, shanchao : shanchao@wh.iov.cn, External Partner - Techakitiroj Chatkul : tverakit@gmail.com, mary.lane@nih.gov : mary.lane@nih.gov, Chi Van Dang : cdang@lcr.org, Chris Miller : cjmiller@ucdavis.edu, christian.c.hofer.mil@mail.mil, christian.c.hofer.mil@mail.mil, Christiane Gerke, christiane.gerke@pasteur.fr, qinchuan : qinchuan@pumc.edu.cn, Florence, Clint (NIH/NIAID) [E], clint.florence@nih.gov, Schmaljohn, Connie (NIH/NIAID) [E], connie.schmaljohn@nih.gov, dbarouch : dbarouch@bidmc.harvard.edu, Danielle Anderson : danielle.anderson@duke-nus.edu.sg, Falzarano, Darryl : darryl.falzarano@usask.ca, darwyn.kobasa@canada.ca, darwyn.kobasa@canada.ca, DAVID H O'CONNOR, dhoconno@wisc.edu, WOOD, David John : woodd@who.int, David Vaughn, David.Vaughn@gatesfoundation.org, David Revelli : drevelli@lovelacebiomedical.org, Lee-Parritz, David : david.lee-parritz@tufts.edu, dean.smith : dean.smith@canada.ca, ldenisy : ldenisy@yahoo.com, dbolton@hivresearch.org : dbolton@hivresearch.org, dmissiak, dmissiak@bsd.uchicago.edu, dsreed@cvr.pitt.edu : dsreed@cvr.pitt.edu, dustin.johnson : dustin.johnson@canada.ca, esulkowska@rics.bwh.harvard.edu, esulkowska@rics.bwh.harvard.edu, De wit, Emmie (NIH/NIAID) [E], emmie.dewit@nih.gov, erica : erica@lji.org, Stemmy, Erik (NIH/NIAID) [E], erik.stemmy@nih.gov, Dohm, Erik Daniel : edohm@uab.edu, Ernst Verschoor : verschoor@bprc.nl, estefania.rodriguez : estefania.rodriguez@bnitm.de, GREY Finn : fgrey@exseed.ed.ac.uk, florian.krammer@mssm.edu, florian.krammer@mssm.edu, Cassels, Fred : fcassels@path.org, fkoide : fkoide@southernresearch.org, Gary Kobinger : Gary.Kobinger@crchudequebec.ulaval.ca, sutter : sutter@micro.vetmed.uni-muenchen.de, Giada Mattiuzzo : Giada.Mattiuzzo@nibsc.org, Sivko, Gloria S : sivkog@battelle.org, grace.m.lidl.mil@mail.mil : grace.m.lidl.mil@mail.mil, gustavo.palacios, gustavo.palacios@gmail.com, horer@ku.edu.tr :

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To: Nicole Lurie[drnickilurie@gmail.com]
Cc: DeStefano, Laura[LDestefano@nas.edu]; Ogilvie, Jenna[JOgilvie@nas.edu]; Sharon Inouye[SharonInouye@hsl.harvard.edu]; Linda Degutis[lcdegutis@gmail.com]; ushah@hcphes.org[ushah@hcphes.org]; Lawrence Gostin[gostin@georgetown.edu]; Figueroa, Angelica M[amfiguer@email.unc.edu]; Croitoru, Grace Nicole[gracenc@unc.edu]; Rimer, Barbara[brimer@unc.edu]; Andy Pavia[Andy.Pavia@hsc.utah.edu]; Shah, Umair MD (PHS)[Umair.Shah@phs.hctx.net]; 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]; Dzau, Victor J.[VDzau@nas.edu]; Georges Benjamin[georges.benjamin@apha.org]; Del Rio, Carlos[cdelrio@emory.edu]; Susan Polan[susan.polan@apha.org]; Block, Bruce[BBlock@nas.edu]
From: Arturo Casadevall[acasade1@jhu.edu]
Sent: Thur 11/12/2020 1:00:21 PM (UTC-05:00)
Subject: RE: UPDATE: NAM-APHA webinar advisory group

Nicole,
Thanks for your note. 5 RCTs now done – all provide some evidence for convalescent plasma efficacy. Half a dozen RCTs ongoing including two at Hopkins. However, all RCTs were unsatisfactory from premature termination (3/5) to poor design in one (1/3 of units had no antibody). If you take the totality of data from observational studies and RCTs, I believe that the FDA decision on the EUA was correct. Watching the RCTs stumble I have become somewhat disillusioned in the usefulness of this epistemic tool during pandemic conditions since a well-designed trial in June would been obsolete by August given rapid accrual of information. Plasma is not dexamethasone. That said, the outpatient RCTs should produce definitive data in the months ahead. Happy to discuss further.
Arturo

From: Nicole Lurie <drnickilurie@gmail.com>
Sent: Thursday, November 12, 2020 12:47 PM
To: Arturo Casadevall <acasade1@jhu.edu>
Cc: DeStefano, Laura <LDestefano@nas.edu>; Ogilvie, Jenna <JOgilvie@nas.edu>; Sharon Inouye <SharonInouye@hsl.harvard.edu>; Linda Degutis <lcdegutis@gmail.com>; 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; Andy Pavia <Andy.Pavia@hsc.utah.edu>; Shah, Umair MD (PHS) <Umair.Shah@phs.hctx.net>; 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; antoinette_baric@med.unc.edu; Maria Jasen <mjasen1@jhu.edu>; mvnovotny@unmc.edu; Dzau, Victor J. <VDzau@nas.edu>; Georges Benjamin <georges.benjamin@apha.org>; Del Rio, Carlos <cdelrio@emory.edu>; Susan Polan <susan.polan@apha.org>; Block, Bruce <BBlock@nas.edu>
Subject: Re: UPDATE: NAM-APHA webinar advisory group

Thanks Arturo
The past few months have made me even more skeptical about real world evidence than I was before, and furthered my advocacy for RCTs. Just saying...

On Thu, Nov 12, 2020 at 11:09 AM Arturo Casadevall <acasade1@jhu.edu> wrote:
Dear Laura,
One thought for you and the group is whether to do an update on convalescent plasma and antibody-based therapies. Since I presented back on April 4 a lot has happened in this space – convalescent plasma is now under FDA EUA and > 10k people are being treated each week in US alone. Significant amount data now available associating early administration with reduced mortality – in fact it is the only therapy associated with reduced mortality apart from steroids in ICU. One mAb now under EUA for early therapy. Happy to do it after the vaccine stuff.
Arturo

From: DeStefano, Laura <LDestefano@nas.edu>
Sent: Thursday, November 12, 2020 9:44 AM
To: Ogilvie, Jenna <JOgilvie@nas.edu>; 'Sharon Inouye' <SharonInouye@hsl.harvard.edu>; 'Linda Degutis' <lcdegutis@gmail.com>; Arturo Casadevall <acasade1@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>; '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>; Block, Bruce <BBlock@nas.edu>
Subject: UPDATE: NAM-APHA webinar advisory group

Good morning all –

Long time, no "see"! I hope you all are well.

I am writing with an update that we have decided to reboot the COVID-19 Conversations webinar series at an increased frequency, with special emphasis on the vaccine, given the news that one may be imminent.

We will be hosting the 15th webinar in the series next Wednesday, 11/18, from 5 to 6:30. The topic is "COVID-19 Vaccine Update: Development, Approval, Allocation, and Distribution in the United States." Peggy Hamburg will moderate, and the panelists are Larry Corey (Fred Hutchinson), Marion Gruber (FDA), Jay Butler (CDC), and James Hildreth (Meharry Medical College). Registration will open tomorrow.

We are aiming for a follow-up webinar on December 2 to look more deeply at how we make sure people who need the vaccine actually receive it (i.e., issues of hesitancy and access). We would like to set up a call with you to discuss this, as well as priorities for the series in January.

Could you please complete this scheduling poll to indicate your availability?

http://whenisgood.net/s5b8zak

In the meantime, please feel free to send thoughts by email.

Thanks so much for your continued engagement.

Best wishes,
Laura

Laura DeStefano
Director of Communications
National Academy of Medicine
202-334-3268

From: DeStefano, Laura
Sent: Friday, September 25, 2020 2:02 PM
To: 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>; '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>; '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>
Subject: NAM-APHA advisory group meeting CANCELED
Importance: High

Good afternoon – the advisory group meeting is canceled for today. I have just been informed that it may not have de-populated from all of your calendars. My sincere apologies for any inconvenience and hope you have a good weekend.

Laura

Laura DeStefano
Director of Communications
National Academy of Medicine
202-334-3268

From: Ogilvie, Jenna <JOgilvie@nas.edu>
Sent: Tuesday, July 21, 2020 12:34 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>; '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>
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

~~~~~

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

To: Shah, Umair MD (PHS)[Umair.Shah@phs.hctx.net]
Cc: Nicole Lurie[drnickilurie@gmail.com]; Arturo Casadevall[acasade1@jhu.edu]; DeStefano, Laura[LDestefano@nas.edu]; Ogilvie, Jenna[JOgilvie@nas.edu]; Sharon Inouye[SharonInouye@hsl.harvard.edu]; Linda Degutis[lcdegutis@gmail.com]; Lawrence Gostin[gostin@georgetown.edu]; Figueroa, Angelica M[amfiguer@email.unc.edu]; Croitoru, Grace Nicole[gracenc@unc.edu]; Rimer, Barbara[brimer@unc.edu]; Andy Pavia[Andy.Pavia@hsc.utah.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]; Georges Benjamin[georges.benjamin@apha.org]; Del Rio, Carlos[cdelrio@emory.edu]; Susan Polan[susan.polan@apha.org]; Block, Bruce[BBlock@nas.edu]
From: Dzau, Victor J.[VDzau@nas.edu]
Sent: Thur 11/12/2020 1:22:37 PM (UTC-05:00)
Subject: Re: UPDATE: NAM-APHA webinar advisory group

Lilly monoclonal just received EUA. There are many issues : outpatient infusion, cost of infusion, allocation framework etc. We are asked to do a fast report by HHS and states to address this.

On Nov 12, 2020, at 12:52 PM, Shah, Umair MD (PHS) <Umair.Shah@phs.hctx.net> wrote:

I think a lot of us share similar concerns. I just taped a video about plasma donation (literally five minutes ago) in our community so how timely.

And best of luck with your help in the transition upon us...

Best,

Umair S.

Harris County
Public Health
Building a Healthy Community

Umair A. Shah, MD, MPH

Executive Director & Local Health Authority, HCPH

Phone: 832.927.7500 | Fax: 713.439.6384

Email: Umair.Shah@phs.hctx.net | Twitter: @ushahmd
2223 West Loop South, Houston, TX 77027

Please note I am currently responding to the COVID-19 pandemic and given the volume of incoming emails, my response may be significantly delayed. If you need immediate assistance, please reach out to my Executive Assistant, Ms. Laura Garcia, at Laura.Garcia@phs.hctx.net or at 832-927-7500. Thank YOU for everything you are doing to help fight this pandemic on behalf of our community, our nation, and our world. Remember stay emotionally together but physically apart - we are all in this together!*

From: Nicole Lurie <drnickilurie@gmail.com>
Sent: Thursday, November 12, 2020 11:47 AM
To: Arturo Casadevall <acasade1@jhu.edu>
Cc: DeStefano, Laura <LDestefano@nas.edu>; Ogilvie, Jenna <JOgilvie@nas.edu>; Sharon Inouye <SharonInouye@hsl.harvard.edu>; Linda Degutis <lcdegutis@gmail.com>; Shah, Umair MD (PHS) <Umair.Shah@phs.hctx.net>; Lawrence Gostin <gostin@georgetown.edu>; Figueroa, Angelica M <amfiguer@email.unc.edu>; Croitoru, Grace Nicole <gracenc@email.unc.edu>; brimer@unc.edu; Andy Pavia <Andy.Pavia@hsc.utah.edu>; Shah, Umair MD (PHS) <Umair.Shah@phs.hctx.net>; 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; antoinette_baric@med.unc.edu; Maria Jasen <mjasen1@jhu.edu>; mvnovotny@unmc.edu; Dzau, Victor J. <VDzau@nas.edu>; Georges Benjamin <georges.benjamin@apha.org>; Del Rio, Carlos <cdelrio@emory.edu>; Susan Polan <susan.polan@apha.org>; Block, Bruce <BBlock@nas.edu>
Subject: Re: UPDATE: NAM-APHA webinar advisory group

Thanks Arturo
The past few months have made me even more skeptical about real world evidence than I was before, and furthered my advocacy for RCTs. Just saying...

On Thu, Nov 12, 2020 at 11:09 AM Arturo Casadevall <acasade1@jhu.edu> wrote:

Dear Laura,
One thought for you and the group is whether to do an update on convalescent plasma and antibody-based therapies. Since I presented back on April 4 a lot has happened in this space – convalescent plasma is now under FDA EUA and > 10k people are being treated each week in US alone. Significant amount data now available associating early administration with reduced mortality – in fact it is the only therapy associated with reduced mortality apart from steroids in ICU. One mAb now under EUA for early therapy. Happy to do it after the vaccine stuff.
Arturo

From: DeStefano, Laura <LDestefano@nas.edu>
Sent: Thursday, November 12, 2020 9:44 AM
To: Ogilvie, Jenna <JOgilvie@nas.edu>; 'Sharon Inouye' <SharonInouye@hsl.harvard.edu>; 'Linda Degutis' <lcdegutis@gmail.com>; Arturo Casadevall <acasade1@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>; '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>; Block, Bruce <BBlock@nas.edu>
Subject: UPDATE: NAM-APHA webinar advisory group

Good morning all –

Long time, no "see"! I hope you all are well.

I am writing with an update that we have decided to reboot the COVID-19 Conversations webinar series at an increased frequency, with special emphasis on the vaccine, given the news that one may be imminent.

We will be hosting the 15th webinar in the series next Wednesday, 11/18, from 5 to 6:30. The topic is "COVID-19 Vaccine Update: Development, Approval, Allocation, and Distribution in the United States." Peggy Hamburg will moderate, and the panelists are Larry Corey (Fred Hutchinson), Marion Gruber (FDA), Jay Butler (CDC), and James Hildreth (Meharry Medical College). Registration will open tomorrow.

We are aiming for a follow-up webinar on December 2 to look more deeply at how we make sure people who need the vaccine actually receive it (i.e., issues of hesitancy and access). We would like to set up a call with you to discuss this, as well as priorities for the series in January.

Could you please complete this scheduling poll to indicate your availability?

http://whenisgood.net/s5b8zak

In the meantime, please feel free to send thoughts by email.

Thanks so much for your continued engagement.

Best wishes,
Laura

Laura DeStefano
Director of Communications
National Academy of Medicine
202-334-3268

From: DeStefano, Laura
Sent: Friday, September 25, 2020 2:02 PM
To: 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>; '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>; 'mvnovotny@unmc.edu' <mvnovotny@unmc.edu>
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Subject: NAM-APHA advisory group meeting CANCELED
Importance: High

Good afternoon – the advisory group meeting is canceled for today. I have just been informed that it may not have de-populated from all of your calendars. My sincere apologies for any inconvenience and hope you have a good weekend.

Laura

Laura DeStefano
Director of Communications
National Academy of Medicine
202-334-3268

From: Ogilvie, Jenna <JOgilvie@nas.edu>
Sent: Tuesday, July 21, 2020 12:34 PM
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Laura <LDestefano@nas.edu>
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

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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.

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Please don't hesitate to reach out to me, Laura, or Susan with any questions or concerns.

With best wishes,
Jenna

~~~~~

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

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- 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

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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

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nam.edu | @theNAMedicine

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]; '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]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]; Liao, Julie[JLiao@nas.edu]; Dzau, Victor J.[VDzau@nas.edu]; Kanarek, Morgan[MKanarek@nas.edu]; Block, Bruce[BBlock@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Fri 11/13/2020 5:08:08 PM (UTC-05:00)
Subject: Materials - Expert Call on Monoclonal Antibodies: Sunday, November 15
FINAL Agenda_Standing Committee on Emerging Infectious Diseases_Meeting on mAbs.pdf
Expert Meeting on mAbs - Read Ahead Materials.pdf

Dear Members of Standing Committee,

Please find attached an agenda for this Sunday's meeting on monoclonal antibodies. Also attached is a list of some read-ahead materials. PDFs of the materials can be accessed here. Please note this is a closed meeting, so please do not share these materials.

Thank you again for agreeing to participate on such short notice! We are looking forward to the discussions.

Call Information:
Sunday, November 15, 2020
11:00 a.m. – 1:00 p.m. ET
Join from PC, Mac, Linux, iOS or Android: https://nasem.zoom.us/j/96818499306
Or iPhone one-tap:
US: +13017158592,,96818499306#
Or Telephone:
Dial(for higher quality, dial a number based on your current location):
US: +1 602 753 0140
Meeting ID: 968 1849 9306
International numbers available: https://nasem.zoom.us/u/andiW2L8e

Please let us know if you have any questions.

Very 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

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From: Brown, Lisa
Sent: Tuesday, November 10, 2020 3:02 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>; '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>; Pope, Andrew <APope@nas.edu>; Pavlin, Julie <JPavlin@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>; Attal-Juncqua, Aurelia <AAttal-Juncqua@nas.edu>; Feit, Monica <MFeit@nas.edu>; Liao, Julie <JLiao@nas.edu>
Subject: URGENT Call on Monoclonal Antibodies: Sunday, November 15
Importance: High

Dear Members of the Standing Committee,

We have received an urgent request from our sponsors, ASPR and OSTP, to explore the issue of allocation of COVID-19 monoclonal antibodies (and therapeutics more broadly), with a particular emphasis on how to achieve equitable access. With the recent approval of bamlanivimab, there is some urgency to this task, and we would like convene the standing committee for a virtual discussion this **Sunday, November 15 from 11:00 a.m. – 1:00 p.m. ET.** We understand this is extremely short notice, and on a weekend, but we would greatly appreciate your participation in this meeting.

If you could please let us know as soon as possible if you are able to participate, that would be great. A calendar invite and Zoom link will follow shortly.

We will provide additional details later this week. 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

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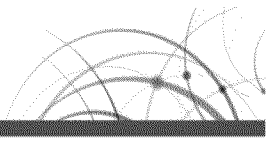


Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Expert Meeting on Monoclonal Antibody Therapies

Agenda
Sunday, November 15, 2020 11:00 a.m. – 1:00 p.m. ET
Virtual Zoom Meeting

Meeting Objectives

- Identify key considerations to achieve equitable allocation of monoclonal antibody therapies, taking account of limited data about the degree to which different populations benefit.
- Discuss other key issues related to access, including potential barriers for those populations at highest risk of serious outcomes from COVID-19, administration capacity, cost, and data collection and reporting.
- Explore and scope next steps for the standing committee related to this issue.

SUNAY, NOVEMBER 15, 2020

CLOSED SESSION

11:00 a.m. **Welcoming Remarks**

Harvey Fineberg, *Standing Committee Chair*
President
Gordon and Betty Moore Foundation

Victor Dzau
President
National Academy of Medicine

11:10 a.m. **Sponsor Remarks**

Robert Kadlec
The Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

11:15 a.m. **Discussion on the Equitable Allocation of Monoclonal Antibodies**

12:15 p.m. **Discussion on Other Key Issues Related to Monoclonal Antibodies**

12:45 p.m. **Discussion of Next Steps with the Sponsors**

Harvey Fineberg, *Committee Chair*
President
Gordon and Betty Moore Foundation

1:00 p.m. ***ADJOURN***

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

Expert Meeting on Monoclonal Antibody Therapies

Read Ahead Materials

1. **Announcements from the FDA**

   EUA issued on Nov 10, 2020 for bamlanivimab: https://www.fda.gov/media/143602/download
   Press announcement from the FDA: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19

   - Therapeutic description: A neutralizing, IgG1-class monoclonal antibody that binds to the receptor-binding domain of the SARS-CoV-2 spike protein; use to prevent progression of mild/moderate disease to severe disease
   - Authorized use: Adults and pediatric patients > 12 years old and > 40 kg (c. 88 lb), positive SARS-CoV-2 test result, with mild-to-moderate COVID-19, within 10 days of symptom onset, and at risk for developing severe disease or requiring hospitalization
   - NOT for use: Patients who are hospitalized, on oxygen therapy, or require elevated baseline oxygen from chronic oxygen therapy for non-COVID-19 underlying conditions
   - Administration method and requirements: Single IV infusion over at least 60 min, plus an additional 60 min observation after infusion is complete

2. **Background information on monoclonal antibody therapeutic for COVID-19**

   The Washington Post: https://www.washingtonpost.com/health/2020/09/30/monoclonal-antibodies-to-treat-covid-19/

   IDSA (Infectious Diseases Society of America) background on COVID-19 monoclonal antibodies: https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/monoclonal-antibodies/

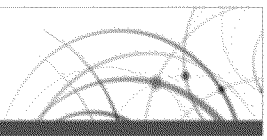
   - Summary of monoclonal antibodies use for treating infectious diseases, current development of monoclonal antibodies for COVID-19, and topline readout from clinical trials that are still in progress with publication links

3. **Current federal and state plans for therapeutics distribution**

   Proposed distribution plan from Operation Warp Speed: https://essentialhospitals.org/wp-content/uploads/2020/11/OWS-Tx-Stakeholder-Call_11.4.20.pdf

   - Detailed current plan for allocation from the federal government

   Considerations for state government allocation plan:
   https://www.nga.org/memos/monoclonal-antibody-therapies-covid-19/

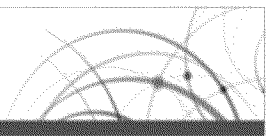


- Good background explanation of antibody use and administration method
- Eight points of action to take or resolve in developing an allocation plan

4. **Summary of news coverage and expert interviews on allocation, major issues summarized below.**

National Public Radio: https://www.npr.org/sections/health-shots/2020/11/10/933444237/fda-oks-eli-lilly-covid-19-drug-but-supplies-will-be-limited
The Washington Post: https://www.washingtonpost.com/health/2020/11/10/covid-antibody-drug/ and https://www.washingtonpost.com/business/new-covid-treatments-are-here-but-who-gets-them/2020/11/10/16ea9d8e-2372-11eb-9c4a-0dc6242c4814_story.html

- Supply vs demand:
  - Demand will vastly outstrip supply in the beginning of roll-out, questionable whether supply will be sufficient in long-term (dependent on transmission control)
  - Eli Lilly projected supply of 1 million doses worldwide, the US federal government has negotiated a contract for 300,000 doses through December, and option for additional 650,000 through June
  - The US is currently recording >100,000 cases each day
  - From currently available data, NPR estimates that if given to 100 people, the treatment could prevent seven hospitalizations
- Cost (individual/patient level):
  - Therapeutic (currently covered by federal government as part of allocation)
  - IV infusion co-pay (not covered)
  - Disparity in insurance coverage may exacerbate inequities in treatment access in the same communities
  - Payer roles and downstream cost to individuals
- Cost (institutional/structural level):
  - Required access to outpatient facilities with IV infusion capacity
  - Impact on existing patient groups that rely on infusion facilities (e.g., immunocompromised patients on chemotherapy)
  - Cost to erect specialized, additional infusion facilities and/or to install protective measures necessary to treat COVID-positive patients
- Prioritization plan for allocation:
  - Need for a centralized allocation plan (HHS allocation plan and allocation dashboard); note that current plan will distribute to hospital and hospital-affiliated health care facilities, with expansion to additional outpatient facilities at a later date
  - Need to identify priority target groups, e.g., healthcare workers and first responders, communities of color, or individuals at high risk
  - Data collection and data systems: Testing capacity, access, and reporting are closely tied to data-guided allocation decisions; the additional need from treatment allocation may further tax the diagnostic testing system
- Supply chain management:



- Availability of distribution cold chain and storage capabilities
- Potential competition with vaccines that also require cold chain

5. **Issues experienced with Veklury (remdesivir) distribution and concerns for bamlanivimab, summarized below:** https://jamanetwork.com/journals/jama/fullarticle/2773057
   - EUA issuance and start of rapid distribution before primary clinical data was publicly available led hospitals to make individual allocation with limited knowledge to guide risk/benefit decisions and clinical application
   - A lack of standard, systematic registry to record distribution demographics, safety events, and clinical outcomes was a missed opportunity to expand knowledge of the therapeutic and track equity
   - Distribution of an outpatient treatment (e.g., monoclonal antibody) will have to be tied to close monitoring and anticipation of community case load
   - Payer and cost structure of outpatient-billed treatment may exacerbate health inequities when insurance coverage disparity and disease burden or severity coincide, such as in communities of color

6. **Considerations and proposed frameworks for fair access and allocation**

   WHO Concept for fair access and equitable allocation of COVID-19 health products, final working version as of Sep 9, 2020: https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility

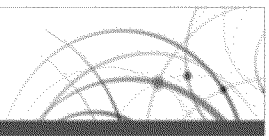
   - There is a detailed framework for allocation of vaccines that may have applications for therapeutics, including identification of target groups, proposal for proportional allocation, proposal for allocation based on risk assessment, and considerations/scenarios that would support the use of each (p. 18)

   From the Wellcome Trust and IAVI, Expanding access to monoclonal antibody-based products – A global call to action: https://wellcome.org/sites/default/files/expanding-access-to-monoclonal-antibody-based-products.pdf

   - Examines general access and affordability limitations for monoclonal antibody therapeutics on the global scale
   - Identifies two major categories of impediments to accessing monoclonal antibody therapeutics in low- and middle-income countries: Availability (regulatory approval, health system that fosters awareness and diagnosis to direct use, lack of biosimilars) and Affordability (treatment price tag, little incentive to pursue cost-lowering strategies)
   - Proposes mechanisms to lower costs, e.g., manufacturing advances and alternative methods

   From the Duke Margolis Center for Health Policy (Aug 2020), COVID manufacturing for monoclonal antibodies**:**

   - Projects a lower bound demand for neutralizing monoclonal antibodies for non-hospitalized and prophylactic use to be >25 million doses, as of Aug 2020



- Primer on monoclonal antibody manufacturing and identifies potential for increasing capacity
- Draw policy attention to maximize production capacity by coordinating between manufacturers, and to expand total manufacturing capacity by reviving facilities that are currently off-line

Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell[Simon.Funnell@phe.gov.uk]; Pierre Gsell[gsellp@who.int]; RIVEROS BALTA, Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]
To: Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; abukreye@utmb.edu[abukreye@utmb.edu]; White, Alexander G[agw13@pitt.edu]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Amelia Karlsson[amelia.karlsson@duke.edu]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; angierasmussen@gmail.com[angierasmussen@gmail.com]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; anna@thsti.res.in[anna@thsti.res.in]; Griffiths, Anthony[ahgriff@bu.edu]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; verstrepen@bprc.nl[verstrepen@bprc.nl]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; barney.graham@nih.gov[barney.graham@nih.gov]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Benjamin tenOever[tenoever@gmail.com]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; bobomok@hku.hk[bobomok@hku.hk]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Carolyn Clark[carolyn.clark@cepi.net]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Chad Roy[croy@tulane.edu]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; tverakit@gmail.com[tverakit@gmail.com]; mary.lane@nih.gov[mary.lane@nih.gov]; Chi Van Dang[cdang@lcr.org]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; 秦川[qinchuan@pumc.edu.cn]; clint.florence@nih.gov[clint.florence@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Dan Barouch[dbarouch@bidmc.harvard.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Darryl Falzarano[darryl.falzarano@usask.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; DAVID H O'CONNOR[dhoconno@wisc.edu]; woodd@who.int[woodd@who.int]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; dean.smith@canada.ca[dean.smith@canada.ca]; ldenisy@yahoo.com[ldenisy@yahoo.com]; dbolton@hivresearch.org[dbolton@hivresearch.org]; 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[dmissiak@bsd.uchicago.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; esulkowska@rics.bwh.harvard.edu[esulkowska@rics.bwh.harvard.edu]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; erica@lji.org[erica@lji.org]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Erik Dohm[edohm@uab.edu]; verschoor@bprc.nl[verschoor@bprc.nl]; Estefania Bni[estefania.rodriguez@bnitm.de]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; Krammer, Florian[florian.krammer@mssm.edu]; fcassels@path.org[fcassels@path.org]; fkoide@southernresearch.org[fkoide@southernresearch.org]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; sivkog@battelle.org[sivkog@battelle.org]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; horer@ku.edu.tr[horer@ku.edu.tr]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; hlchen@hku.hk[hlchen@hku.hk]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov];

i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; KNEZEVIC, Ivana[knezevici@who.int]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; langermans@bprc.nl[langermans@bprc.nl]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; jfwchan[jfwchan@hku.hk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Flynn, Joanne L[joanne@pitt.edu]; Quim Segales[joaquim.segales@irta.cat]; Johan Neyts[johan.neyts@kuleuven.be]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; baczenas@wisc.edu[baczenas@wisc.edu]; Spergel, Jonathan[SPERGEL@email.chop.edu]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Juergen Richt[jricht@vet.k-state.edu]; Vergara, Julia[julia.vergara@irta.cat]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Alyson Kelvin[AKelvin@dal.ca]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; rkiatchula@gmail.com[rkiatchula@gmail.com]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; Koert Stittelaar[stittelaar@viroclinics.com]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; mksong@ivi.int[mksong@ivi.int]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; PREZIOSI, Marie-pierre[preziosim@who.int]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; Mark Page[Mark.Page@nibsc.org]; Dr. Mark Lewis[mlewis@bioqual.com]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Martin Beer[Martin.Beer@fli.de]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; Matthew Frieman[MFrieman@som.umaryland.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; Diamond, Michael[mdiamond@wustl.edu]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; mto@umn.edu[mto@umn.edu]; Holbrook, Michael (NIH/NIAID) [C][Michael.holbrook@nih.gov]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; nax3@cdc.gov[nax3@cdc.gov]; Neil Berry[Neil.Berry@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Nir Paran[nirp@iibr.gov.il]; Gerhards, Nora[nora.gerhards@wur.nl]; nnagata@niid.go.jp[nnagata@niid.go.jp]; golinger@mriglobal.org[golinger@mriglobal.org]; Padmini Salgame[salgampa@njms.rutgers.edu]; Reid, St Patrick M[patrick.reid@unmc.edu]; Hodgson, Paul[paul.hodgson@usask.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Duprex, Paul[pduprex@pitt.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Peter Palese[peter.palese@mssm.edu]; philip.minor2@gmail.com[philip.minor2@gmail.com]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; Pierre Gsell[gsellp@who.int]; que.dang@nih.gov[que.dang@nih.gov]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; Baric, Ralph S[rbaric@email.unc.edu]; Ramin M Hakami[rhakami@gmu.edu]; Randy Albrecht[randy.albrecht@mssm.edu]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; Riccardo Russo[russori@njms.rutgers.edu]; Levis,

Robin[robin.levis@fda.hhs.gov]; Roger Le[roger.le-grand@cea.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Cartner, Samuel Corbin[scartner@uab.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; seos@cnu.ac.kr[seos@cnu.ac.kr]; Li, Sean (HC/SC)[sean.li@canada.ca]; sekim@krict.re.kr[sekim@krict.re.kr]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; sheri.hild@nih.gov[sheri.hild@nih.gov]; Simon Funnell[Simon.Funnell@phe.gov.uk]; SINA BAVARI[sinabavari@comcast.net]; swaminathans@who.int[swaminathans@who.int]; Stanley Perlman[stanley-perlman@uiowa.edu]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Wang, Tony[tony.wang@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; Vasan Vasan[Vasan.Vasan@csiro.au]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; William Dowling[william.dowling@cepi.net]; Poel, Wim van der[wim.vanderpoel@wur.nl]; RIVEROS BALTA, Ximena[lauriex@who.int]; Yper Hall[Yper.Hall@phe.gov.uk]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; zhout@who.int[zhout@who.int]; yoos@who.int[yoos@who.int]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 11/18/2020 10:52:10 AM (UTC-05:00)
Subject: Canceled until December 3rd: WHO COVID-19 Animal Models Meetings

Dear all,

This is just to let you know that this week and next week's WHO COVID-19 Animal Models Group calls have been canceled. We will resume our weekly calls on December 3rd.

Stay safe everyone and thank you for your support

Best regards

César, Simon and Bill

To: galter@partners.org[galter@partners.org]; maria.baca-estrada@canada.ca[maria.baca-estrada@canada.ca]; baihe@nmpa.gov.cn[baihe@nmpa.gov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; cheryl@gisaid.org[cheryl@gisaid.org]; Valentina Bernasconi[valentina.bernasconi@cepi.net]; shinjini.bhatnagar@thsti.res.in[shinjini.bhatnagar@thsti.res.in]; pbieniasz@mail.rockefeller.edu[pbieniasz@mail.rockefeller.edu]; Bok, Karin (NIH/VRC) [E][karin.bok@nih.gov]; dboyle@path.org[dboyle@path.org]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; brangelp@who.int[brangelp@who.int]; christian.brechot[christian.brechot@pasteur.fr]; Christine.bruce@phe.gov.uk[Christine.bruce@phe.gov.uk]; zuz4@cdc.gov[zuz4@cdc.gov]; Miles.Carroll@phe.gov.uk[Miles.Carroll@phe.gov.uk]; fjc37@cam.ac.uk[fjc37@cam.ac.uk]; Marco.Cavaleri[Marco.Cavaleri@ema.europa.eu]; MONALISA.CHATTERJI@gatesfoundation.org[MONALISA.CHATTERJI@gatesfoundation.org]; MAY.CHU@CUANSCHUTZ.EDU[MAY.CHU@CUANSCHUTZ.EDU]; Carolyn Clark[carolyn.clark@cepi.net]; kizzmekia.corbett@nih.gov[kizzmekia.corbett@nih.gov]; costaa@who.int[costaa@who.int]; htq4@cdc.gov[htq4@cdc.gov]; shane@lji.org[shane@lji.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Damon, Inger K. (CDC/OID/NCEZID)[iad7@cdc.gov]; Lisa@amicitiam.com[Lisa@amicitiam.com]; daszak@ecohealthalliance.org[daszak@ecohealthalliance.org]; tdelossantos@path.org[tdelossantos@path.org]; emmie.dewit@nih.gov[emmie.dewit@nih.gov]; marciela.degrace@nih.gov[marciela.degrace@nih.gov]; rafael.delgado@salud.madrid.org[rafael.delgado@salud.madrid.org]; mit666666@pitt.edu[mit666666@pitt.edu]; katie.doores@kcl.ac.uk[katie.doores@kcl.ac.uk]; William Dowling[william.dowling@cepi.net]; christian.drosten@charite.de[christian.drosten@charite.de]; epstein@ecohealthalliance.org[epstein@ecohealthalliance.org]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; darryl.falzarano@usask.ca[darryl.falzarano@usask.ca]; jason.fernandes@canada.ca[jason.fernandes@canada.ca]; clint.florence@nih.gov[clint.florence@nih.gov]; MFrieman@som.umaryland.edu[MFrieman@som.umaryland.edu]; Simon.Funnell@phe.gov.uk[Simon.Funnell@phe.gov.uk]; Luc Gagnon[luc.gagnon@nexelis.com]; Mayra.Garcia@fda.hhs.gov[Mayra.Garcia@fda.hhs.gov]; bhx1@cdc.gov[bhx1@cdc.gov]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; d.goldblatt@ucl.ac.uk[d.goldblatt@ucl.ac.uk]; guy.gorochov@sorbonne-universite.fr[guy.gorochov@sorbonne-universite.fr]; barney.graham@nih.gov[barney.graham@nih.gov]; ahgriff@bu.edu[ahgriff@bu.edu]; Elwyn Griffiths[elwyn.griffiths@cepi.net]; gregory.d.gromowski.civ@mail.mil[gregory.d.gromowski.civ@mail.mil]; GSELL, Pierre[gsellp@who.int]; Celine Gurry[celine.gurry@cepi.net]; ilj2@cdc.gov[ilj2@cdc.gov]; b.haagmans@erasmusmc.nl[b.haagmans@erasmusmc.nl]; rzh7@cdc.gov[rzh7@cdc.gov]; henaorestrepoa@who.int[henaorestrepoa@who.int]; lisa.hensley@nih.gov[lisa.hensley@nih.gov]; paul.hodgson@usask.ca[paul.hodgson@usask.ca]; Michael.holbrook@nih.gov[Michael.holbrook@nih.gov]; Johan Holst[johan.holst@cepi.net]; rawcraig@yahoo.com[rawcraig@yahoo.com]; tkh4@cdc.gov[tkh4@cdc.gov]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; djernigan@cdc.gov[djernigan@cdc.gov]; johnsonreed@niaid.nih.gov[johnsonreed@niaid.nih.gov]; ydm9@cdc.gov[ydm9@cdc.gov]; Cassandra.Kelly@finddx.org[Cassandra.Kelly@finddx.org]; Jacqueline.Kirchner@gatesfoundation.org[Jacqueline.Kirchner@gatesfoundation.org]; KNEZEVIC, Ivana[knezevici@who.int]; m.koopmans@erasmusmc.nl[m.koopmans@erasmusmc.nl]; Gerald.Kovacs@hhs.gov[Gerald.Kovacs@hhs.gov]; florian.krammer@mssm.edu[florian.krammer@mssm.edu]; Phil Krause[philip.krause@fda.hhs.gov]; skrebs@hivresearch.org[skrebs@hivresearch.org]; Greg Kulnis[greg.kulnis@nexelis.com]; Arun Kumar[arun.kumar@cepi.net]; pawinee.k@redcross.or.th[pawinee.k@redcross.or.th]; teresa.lambe@ndm.ox.ac.uk[teresa.lambe@ndm.ox.ac.uk]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; bleader@path.org[bleader@path.org]; leejooyeon@korea.kr[leejooyeon@korea.kr]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; liyl@cde.org.cn[liyl@cde.org.cn]; changguili@aliyun.com[changguili@aliyun.com]; lyhchengdu@163.com[lyhchengdu@163.com]; limhy0919@korea.kr[limhy0919@korea.kr]; James.Little@hhs.gov[James.Little@hhs.gov]; liub@cde.org.cn[liub@cde.org.cn]; Tracy.MacGill@fda.hhs.gov[Tracy.MacGill@fda.hhs.gov]; Karen Makar[Karen.Makar@gatesfoundation.org]; Mary.Matheson@phe.gov.uk[Mary.Matheson@phe.gov.uk]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; jmclellan@austin.utexas.edu[jmclellan@austin.utexas.edu]; adrian.mcdermott@nih.gov[adrian.mcdermott@nih.gov]; jmcelrat@fredhutch.org[jmcelrat@fredhutch.org]; Guruprasad[gmedigeshi@thsti.res.in]; jwm1@pitt.edu[jwm1@pitt.edu]; philip.minor2@gmail.com[philip.minor2@gmail.com]; kmodjarrad@eidresearch.org[kmodjarrad@eidresearch.org]; david.montefiori@duke.edu[david.montefiori@duke.edu]; kaitlyn.dambach@nih.gov[kaitlyn.dambach@nih.gov]; omorgan@who.int[omorgan@who.int]; Clare.Morris@nibsc.org[Clare.Morris@nibsc.org]; sarah.mudrak@duke.edu[sarah.mudrak@duke.edu]; munoz-fontela@bnitm.de[munoz-fontela@bnitm.de]; vincent.munster@nih.gov[vincent.munster@nih.gov]; Todd.Myers@fda.hhs.gov[Todd.Myers@fda.hhs.gov]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; scott.napper@usask.ca[scott.napper@usask.ca]; MNELSON@dstl.gov.uk[MNELSON@dstl.gov.uk]; PNorris@vitalant.org[PNorris@vitalant.org]; pilailuk.o@dmsc.mail.go.th[pilailuk.o@dmsc.mail.go.th]; n.okba@erasmusmc.nl[n.okba@erasmusmc.nl]; golinger@MRIGLOBAL.ORG[golinger@MRIGLOBAL.ORG]; jokim@ivi.int[jokim@ivi.int]; Mark Page[mark.page@nibsc.org]; gustavo.f.palacios.civ@mail.mil[gustavo.f.palacios.civ@mail.mil]; map1@cdc.gov[map1@cdc.gov]; xdv3@cdc.gov[xdv3@cdc.gov]; Keith.Peden@fda.hhs.gov[Keith.Peden@fda.hhs.gov]; sheila.a.peel2.civ@mail.mil[sheila.a.peel2.civ@mail.mil]; malik@hku.hk[malik@hku.hk]; perkinsm@who.int[perkinsm@who.int]; supaporn.p@dmsc.mail.go.th[supaporn.p@dmsc.mail.go.th]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; mireille.plamondon@canada.ca[mireille.plamondon@canada.ca]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; arimoin@g.ucla.edu[arimoin@g.ucla.edu]; lauriex@who.int[lauriex@who.int]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; msalit@stanford.edu[msalit@stanford.edu]; erica@lji.org[erica@lji.org]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; schendel@lji.org[schendel@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][Connie.schmaljohn@nih.gov]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; PScott@eidresearch.org[PScott@eidresearch.org]; alex@lji.org[alex@lji.org]; peshi@UTMB.EDU[peshi@UTMB.EDU]; Ragini.Shivji[Ragini.Shivji@ema.europa.eu]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; yoos@who.int[yoos@who.int]; Ashley.Smith1@hhs.gov[Ashley.Smith1@hhs.gov]; mksong@ivi.int[mksong@ivi.int]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; subissil@who.int[subissil@who.int]; swaminathans@who.int[swaminathans@who.int];

r.tedder@imperial.ac.uk[r.tedder@imperial.ac.uk]; nax3@cdc.gov[nax3@cdc.gov]; tracey.thue@usask.ca[tracey.thue@usask.ca]; georgia.tomaras@duke.edu[georgia.tomaras@duke.edu]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; sylvie.van-der-werf@pasteur.fr[sylvie.van-der-werf@pasteur.fr]; eric.vangieson@darpa.mil[eric.vangieson@darpa.mil]; Vasan.Vasan@csiro.au[Vasan.Vasan@csiro.au]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; David Vaughn[David.Vaughn@gatesfoundation.org]; linfa.wang@duke-nus.edu.sg[linfa.wang@duke-nus.edu.sg]; wangjz@nifdc.org.cn[wangjz@nifdc.org.cn]; wangyc@nifdc.org.cn[wangyc@nifdc.org.cn]; Jerry.Weir@fda.hhs.gov[Jerry.Weir@fda.hhs.gov]; gweiss@uci.edu[gweiss@uci.edu]; daniela@lji.org[daniela@lji.org]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; larry.wolfraim@nih.gov[larry.wolfraim@nih.gov]; dj56wood@gmail.com[dj56wood@gmail.com]; xumiaobj@126.com[xumiaobj@126.com]; Solomon Abebe Yimer[solomon.yimer@cepi.net]; tlying@fudan.edu.cn[tlying@fudan.edu.cn]; vyusibov@indianabiosciences.org[vyusibov@indianabiosciences.org]; zlshi@wh.iov.cn[zlshi@wh.iov.cn]; zhout@who.int[zhout@who.int]
From: William Dowling[william.dowling@cepi.net]
Sent: Tue 11/24/2020 7:27:49 AM (UTC-05:00)
Subject: Agenda for WHO working group on COVID-19 assays

Hello all

Here is the agenda for tomorrow's meeting of the WHO working group on COVID-19 assays:

1. David Eyre form Oxford University will talk about the paper "Antibodies to SARS-CoV-2 are associated with protection against reinfection " doi: https://doi.org/10.1101/2020.11.18.20234369
2. Updates:
    a. Simon Funnell - update on the working group on SARS-COV-2 propagation
    b. Mark page- update on the work towards an International Standard
    c. Any other updates from the group
3. Discussion on future topics

Best regards
Bill

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 Pennsylvania Ave, NW, Suite 1003, Washington, DC 20006 USA

www.cepi.net


Sensitivity: CEPI Internal

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]; '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]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]; Liao, Julie[JLiao@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Wed 11/25/2020 1:45:53 PM (UTC-05:00)
Subject: Next Steps with Monoclonal Antibodies: Webinar and REC
SCEID_mAB REC SOT_V3 11.25.20.docx

Dear Members of the Standing Committee,

As a follow on to our expert meeting on monoclonal antibody therapies, our sponsor has requested we host a webinar and draft a rapid expert consultation to assist decision makers in efforts to equitably allocate monoclonal antibody therapies at the state and local level. We are proposing to first host the webinar on tentatively December 16-17 and then produce a rapid expert consultation by mid-January 2021. We would like to ask for volunteers from the standing committee to help plan the webinar, moderate sessions, and/or help in drafting the rapid expert consultation. Please let us know as soon as possible if you are able to help.

Please let us know if you have any questions.

Have a healthy and happy Thanksgiving!

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

The Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats proposes to undertake the following Statement of Task:

Statement of Task

The National Academies of Sciences, Engineering, and Medicine will produce a rapid expert consultation to assist decision makers in efforts to equitably allocate monoclonal antibody therapies at the state and local level. Drawing from a public information-gathering webinar, input from experts, and the published literature, this rapid expert consultation will examine ways to achieve equitable allocation of monoclonal antibody therapies. The consultation will take account of variation in access to care and limitations in data about the degree to which different populations may benefit from treatment with monoclonal antibodies. Rapid expert consultations do not recommend specific actions or include other recommendations. The document will be reviewed in accordance with institutional guidelines.

Timeline

Milestone	Date
Conduct 2-day information-gathering webinar	12/16 – 12/17
Begin drafting REC with SC authors	12/21
Internal sign off (share internally with NRCEO)	1/04
Enter review	1/06
Receive reviewer comments	1/11
Respond to reviewer comments	1/14
Sign off	1/18
Release	Week of 1/18

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]; '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]; Pope, Andrew[APope@nas.edu]; Pavlin, Julie[JPavlin@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]; Attal-Juncqua, Aurelia[AAttal-Juncqua@nas.edu]; Feit, Monica[MFeit@nas.edu]; Liao, Julie[JLiao@nas.edu]
From: Brown, Lisa[LBrown@nas.edu]
Sent: Wed 12/2/2020 9:58:31 AM (UTC-05:00)
Subject: NEW! Series of Rapid Expert Consultations on Adapting to COVID-19 on College Campuses

Dear Members of the Standing Committee,

Yesterday, the standing committee released a rapid expert consultation on *COVID-19 Testing Strategies for Colleges and Universities* in collaboration with our Societal Experts Action Network (SEAN) colleagues. This rapid expert consultation was released alongside a rapid expert consultation on encouraging protective behaviors among college students. Thank you to Tara, David, Bob, and Harvey who all helped in different ways with these efforts!

You can access the rapid expert consultation on college testing strategies here:
https://www.nap.edu/catalog/26005/covid-19-testing-strategies-for-colleges-and-universities

You can access the rapid expert consultation on protective behaviors here:
https://www.nap.edu/catalog/26004/encouraging-protective-covid-19-behaviors-among-college-students

The press release (which is also a nice summary) can be accessed here:
https://www.nationalacademies.org/news/2020/12/national-academies-offer-guidance-on-student-behavior-and-covid-19-testing-for-college-administrators-ahead-of-2021-spring-semester

Lastly, per my previous email, we are moving forward with planning a workshop on COVID-19 monoclonal antibodies for December 16-17, with a rapid expert consultation to follow mid-January. We would like to ask for volunteers from the standing committee to help plan the webinar, moderate sessions, and/or help in drafting the rapid expert consultation. Please let me know if you are interested in participating!

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

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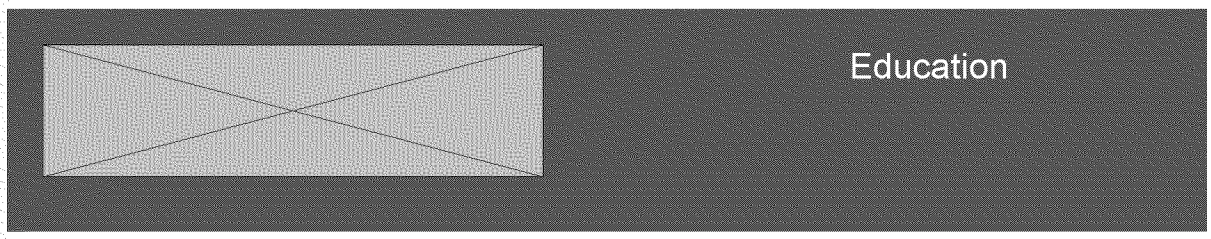
From: NASEM Division of Behavioral and Social Sciences and Education <NASEM_DBASSE@nas.edu>
Sent: Tuesday, December 1, 2020 3:00 PM
To: Brown, Lisa <LBrown@nas.edu>
Subject: Adapting to COVID-19 on College Campuses



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Guidance for Colleges and universities responding to COVID-19

COVID-19 poses new challenges for colleges and universities. Students are adjusting to new ways of living, learning, and staying safe on campus, while administrators are rapidly developing programs to test members of their campus community for COVID-19. Two new publications from the Societal Experts Action Network (SEAN) at the National Academies of Sciences, Engineering, and Medicine offer guidance on encouraging the adoption of COVID-19 protective behaviors among students and implementing testing programs on campus and emphasize the importance of communication, transparency, and student engagement.

Read the Guidance

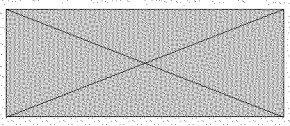
Encouraging Protective Covid-19 Behaviors Among College Students

uses the science of adolescent development to explore how colleges can most effectively encourage students to adopt behaviors that help prevent spread of the virus, such as mask wearing and physical distancing.

COVID-19 Testing Strategies for Colleges and Universities states that testing programs need to be designed to match the needs of specific institutions and identifies fast, frequent testing as one useful tool to mitigate the spread of COVID-19 in a large and diverse university community.

These rapid expert consultations were produced by SEAN (supported by the National Science Foundation) and the Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats (supported by the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response).

Funding for the rapid expert consultation on college testing strategies was provided by the David and Lucile Packard Foundation.



Cc: William Dowling[william.dowling@cepi.net]; Simon Funnell (simon.funnell@phe.gov.uk)[Simon.Funnell@phe.gov.uk]; schwartzl@who.int[schwartzl@who.int]; RIVEROS BALTA, Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Cesar MUNOZ FONTELA[munozc@who.int]

To: Adolfo Garcia-Sastre[Adolfo.Garcia-Sastre@mssm.edu]; kandeil_a@hotmail.com[kandeil_a@hotmail.com]; abukreye@utmb.edu[abukreye@utmb.edu]; White, Alexander G[agw13@pitt.edu]; kupke@staff.uni-marburg.de[kupke@staff.uni-marburg.de]; Ali.Mirazimi@folkhalsomyndigheten.se[Ali.Mirazimi@folkhalsomyndigheten.se]; Amelia Karlsson[amelia.karlsson@duke.edu]; Amy C. Shurtleff[amy.c.shurtleff@cepi.net]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Angela Bosco-Lauth[mopargal@rams.colostate.edu]; angierasmussen@gmail.com[angierasmussen@gmail.com]; Ann.Rawkins@phe.gov.uk[Ann.Rawkins@phe.gov.uk]; anna@thsti.res.in[anna@thsti.res.in]; Griffiths, Anthony[ahgriff@bu.edu]; Asisa.Volz@tiho-hannover.de[Asisa.Volz@tiho-hannover.de]; aysegul.nalca.civ@mail.mil[aysegul.nalca.civ@mail.mil]; verstrepen@bprc.nl[verstrepen@bprc.nl]; Barbara.Schnierle@pei.de[Barbara.Schnierle@pei.de]; barney.graham@nih.gov[barney.graham@nih.gov]; B. Rockx[b.rockx@erasmusmc.nl]; B. Haagmans[b.haagmans@erasmusmc.nl]; Benjamin tenOever[tenoever@gmail.com]; Kerscher, Bernhard[Bernhard.Kerscher@pei.de]; bobomok@hku.hk[bobomok@hku.hk]; bradley.pickering@canada.ca[bradley.pickering@canada.ca]; CarlosAlberto.Guzman@helmholtz-hzi.de[CarlosAlberto.Guzman@helmholtz-hzi.de]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Carolyn Clark[carolyn.clark@cepi.net]; Cesar Munoz-Fontela[munoz-fontela@bnitm.de]; Chad Roy[croy@tulane.edu]; shanchao@wh.iov.cn[shanchao@wh.iov.cn]; tverakit@gmail.com[tverakit@gmail.com]; mary.lane@nih.gov[mary.lane@nih.gov]; Chi Van Dang[cdang@lcr.org]; cjmiller@ucdavis.edu[cjmiller@ucdavis.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; christiane.gerke@pasteur.fr[christiane.gerke@pasteur.fr]; 秦川[qinchuan@pumc.edu.cn]; clint.florence@nih.gov[clint.florence@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Dan Barouch[dbarouch@bidmc.harvard.edu]; danielle.anderson@duke-nus.edu.sg[danielle.anderson@duke-nus.edu.sg]; Darryl Falzarano[darryl.falzarano@usask.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; DAVID H O'CONNOR[dhoconno@wisc.edu]; woodd@who.int[woodd@who.int]; David.Vaughn@gatesfoundation.org[David.Vaughn@gatesfoundation.org]; drevelli@lovelacebiomedical.org[drevelli@lovelacebiomedical.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; dean.smith@canada.ca[dean.smith@canada.ca]; ldenisy@yahoo.com[ldenisy@yahoo.com]; dbolton@hivresearch.org[dbolton@hivresearch.org]; 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[dmissiak@bsd.uchicago.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; dustin.johnson@canada.ca[dustin.johnson@canada.ca]; Sajdel-Sulkowska, Elizabeth M.,D.Sc.[esulkowska@rics.bwh.harvard.edu]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; erica@lji.org[erica@lji.org]; erik.stemmy@nih.gov[erik.stemmy@nih.gov]; Erik Dohm[edohm@uab.edu]; verschoor@bprc.nl[verschoor@bprc.nl]; Estefania Bni[estefania.rodriguez@bnitm.de]; fgrey@exseed.ed.ac.uk[fgrey@exseed.ed.ac.uk]; Krammer, Florian[florian.krammer@mssm.edu]; fcassels@path.org[fcassels@path.org]; fkoide@southernresearch.org[fkoide@southernresearch.org]; Gary Kobinger[Gary.Kobinger@crchudequebec.ulaval.ca]; sutter@micro.vetmed.uni-muenchen.de[sutter@micro.vetmed.uni-muenchen.de]; Giada.Mattiuzzo@nibsc.org[Giada.Mattiuzzo@nibsc.org]; sivkog@battelle.org[sivkog@battelle.org]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; gustavo.palacios@gmail.com[gustavo.palacios@gmail.com]; horer@ku.edu.tr[horer@ku.edu.tr]; Hana.Golding@fda.hhs.gov[Hana.Golding@fda.hhs.gov]; Harry.Kleanthous@gatesfoundation.org[Harry.Kleanthous@gatesfoundation.org]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; hlchen@hku.hk[hlchen@hku.hk]; hwan.kim@stonybrook.edu[hwan.kim@stonybrook.edu]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; i.v.krasilnikov@spbniivs.ru[i.v.krasilnikov@spbniivs.ru]; KNEZEVIC, Ivana[knezevici@who.int]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Jacqueline Kirchner[Jacqueline.Kirchner@gatesfoundation.org]; J.P.Stewart@liverpool.ac.uk[J.P.Stewart@liverpool.ac.uk]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; langermans@bprc.nl[langermans@bprc.nl]; Jason Kindrachuk[Jason.Kindrachuk@umanitoba.ca]; jfwchan[jfwchan@hku.hk]; Javier Salguero[Javier.Salguero@phe.gov.uk]; jay.w.hooper.civ@mail.mil[jay.w.hooper.civ@mail.mil]; Kortekaas, Jeroen[jeroen.kortekaas@wur.nl]; Jin.Zhu@health.gov.au[Jin.Zhu@health.gov.au]; JLPRIOR@dstl.gov.uk[JLPRIOR@dstl.gov.uk]; Flynn, Joanne L[joanne@pitt.edu]; Quim Segales[joaquim.segales@irta.cat]; Johan Neyts[johan.neyts@kuleuven.be]; John.Treanor@hhs.gov[John.Treanor@hhs.gov]; john.c.trefry.civ@mail.mil[john.c.trefry.civ@mail.mil]; baczenas@wisc.edu[baczenas@wisc.edu]; Spergel, Jonathan[SPERGEL@email.chop.edu]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; jorgen.de.jonge@rivm.nl[jorgen.de.jonge@rivm.nl]; JUAN FRANCISCO GARCIA ARRIAZA[jfgarcia@cnb.csic.es]; Juergen Richt[jricht@vet.k-state.edu]; Vergara, Julia[julia.vergara@irta.cat]; Julia.Tree@phe.gov.uk[Julia.Tree@phe.gov.uk]; Kai Dallmeier[kai.dallmeier@kuleuven.be]; Subbarao, Kanta[kanta.subbarao@influenzacentre.org]; Karen Makar[Karen.Makar@gatesfoundation.org]; Karl.Erlandson@hhs.gov[Karl.Erlandson@hhs.gov]; Kayvon Modjarrad[kmodjarrad@eidresearch.org]; sktseng@utmb.edu[sktseng@UTMB.EDU]; Alyson Kelvin[AKelvin@dal.ca]; kevinharrod@uabmc.edu[kevinharrod@uabmc.edu]; rkiatchula@gmail.com[rkiatchula@gmail.com]; seungtaek.kim@ip-korea.org[seungtaek.kim@ip-korea.org]; Koert Stittelaar[stittelaar@viroclinics.com]; kristine.macartney@health.nsw.gov.au[kristine.macartney@health.nsw.gov.au]; Lakshmi.Jayashankar@hhs.gov[Lakshmi.Jayashankar@hhs.gov]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; margaret.l.pitt.civ@mail.mil[margaret.l.pitt.civ@mail.mil]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; luk_vandenberghe@meei.harvard.edu[luk_vandenberghe@meei.harvard.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; mksong@ivi.int[mksong@ivi.int]; Cavaleri Marco[Marco.Cavaleri@ema.europa.eu]; Mariano Esteban Rodriguez[mesteban@cnb.csic.es]; PREZIOSI, Marie-pierre[preziosim@who.int];

mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; Mark Page[Mark.Page@nibsc.org]; Dr. Mark Lewis[mlewis@bioqual.com]; Martha.Alexander-Miller@wakehealth.edu[Martha.Alexander-Miller@wakehealth.edu]; Martin Beer[Martin.Beer@fli.de]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; Matthew Frieman[MFrieman@som.umaryland.edu]; mmeitzen@utmb.edu[mmeitzen@utmb.edu]; Michael Schotsaert[michael.schotsaert@mssm.edu]; Diamond, Michael[mdiamond@wustl.edu]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; mto@umn.edu[mto@umn.edu]; Holbrook, Michael (NIH/NIAID) [C][Michael.holbrook@nih.gov]; Miles Carroll[Miles.Carroll@phe.gov.uk]; Monalisa Chatterji[MONALISA.CHATTERJI@gatesfoundation.org]; muhammad.munir@lancaster.ac.uk[muhammad.munir@lancaster.ac.uk]; nadia.khelef@pasteur.fr[nadia.khelef@pasteur.fr]; Nadia Oreshkova[nadia.oreshkova@wur.nl]; nax3@cdc.gov[nax3@cdc.gov]; Neil Berry[Neil.Berry@nibsc.org]; Nicola.Rose@nibsc.org[Nicola.Rose@nibsc.org]; Nir Paran[nirp@iibr.gov.il]; Gerhards, Nora[nora.gerhards@wur.nl]; nnagata@niid.go.jp[nnagata@niid.go.jp]; golinger@mriglobal.org[golinger@mriglobal.org]; Padmini Salgame[salgampa@njms.rutgers.edu]; Reid, St Patrick M[patrick.reid@unmc.edu]; Hodgson, Paul[paul.hodgson@usask.ca]; Paul.Lambert@unige.ch[Paul.Lambert@unige.ch]; Duprex, Paul[pduprex@pitt.edu]; paul-mccray@uiowa.edu[paul-mccray@uiowa.edu]; Pauline Maisonnasse[pauline.maisonnasse@cea.fr]; Pearl.Bamford@health.gov.au[Pearl.Bamford@health.gov.au]; Peter Palese[peter.palese@mssm.edu]; philip.minor2@gmail.com[philip.minor2@gmail.com]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; Pierre Gsell[gsellp@who.int]; que.dang@nih.gov[que.dang@nih.gov]; REIRELAND@mail.dstl.gov.uk[REIRELAND@mail.dstl.gov.uk]; Baric, Ralph S[rbaric@email.unc.edu]; Ramin M Hakami[rhakami@gmu.edu]; Randy Albrecht[randy.albrecht@mssm.edu]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; Ricardo Carrion, Jr.[rcarrion@txbiomed.org]; Riccardo Russo[russori@njms.rutgers.edu]; Levis, Robin[robin.levis@fda.hhs.gov]; Roger Le[roger.le-grand@cea.fr]; romain.volmer@envt.fr[romain.volmer@envt.fr]; Ruben.Donis@hhs.gov[Ruben.Donis@hhs.gov]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; Sally.Sharpe@phe.gov.uk[Sally.Sharpe@phe.gov.uk]; Cartner, Samuel Corbin[scartner@uab.edu]; sandra cordo[scordo@qb.fcen.uba.ar]; LESELLIER Sandrine[sandrine.lesellier@anses.fr]; seos@cnu.ac.kr[seos@cnu.ac.kr]; Li, Sean (HC/SC)[sean.li@canada.ca]; sekim@krict.re.kr[sekim@krict.re.kr]; s.a.arakelov@spbniivs.ru[s.a.arakelov@spbniivs.ru]; slfeinberg@wisc.edu[slfeinberg@wisc.edu]; sheri.hild@nih.gov[sheri.hild@nih.gov]; Simon Funnell (simon.funnell@phe.gov.uk)[Simon.Funnell@phe.gov.uk]; SINA BAVARI[sinabavari@comcast.net]; swaminathans@who.int[swaminathans@who.int]; Stanley Perlman[stanley-perlman@uiowa.edu]; MSLEVER@dstl.gov.uk[MSLEVER@dstl.gov.uk]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; suchinda.m@chula.ac.th[suchinda.m@chula.ac.th]; tksuzuki@nih.go.jp[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; terry.k.besch.ctr@mail.mil[terry.k.besch.ctr@mail.mil]; pickettte@niaid.nih.gov[pickettte@niaid.nih.gov]; Mettenleiter, Thomas C.[ThomasC.Mettenleiter@fli.de]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; tomeri@iibr.gov.il[tomeri@iibr.gov.il]; Wang, Tony[tony.wang@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; trbrasel@utmb.edu[trbrasel@UTMB.EDU]; troyrandall@uabmc.edu[troyrandall@uabmc.edu]; Vasan Vasan[Vasan.Vasan@csiro.au]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Volker.gerdts@usask.ca[Volker.gerdts@usask.ca]; William Dowling[william.dowling@cepi.net]; Poel, Wim van der[wim.vanderpoel@wur.nl]; RIVEROS BALTA, Ximena[lauriex@who.int]; Yper Hall[Yper.Hall@phe.gov.uk]; y.m.vasiliev@spbniivs.ru[y.m.vasiliev@spbniivs.ru]; zhout@who.int[zhout@who.int]; yoos@who.int[yoos@who.int]; schwartzl@who.int[schwartzl@who.int]; franck.TOURET@univ-amu.fr[franck.TOURET@univ-amu.fr]; Marazzi, Ivan[ivan.marazzi@mssm.edu]; lisette.cornelissen@wur.nl[lisette.cornelissen@wur.nl]

From: Cesar Munoz-Fontela[munoz-fontela@bnitm.de]
Sent: Wed 12/2/2020 12:02:49 PM (UTC-05:00)
Subject: Agenda-WHO COVID-19 Animal Models Group Call
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Dear colleagues,

Please find below the agenda and invite for this Thursday's WHO COVID-19 Animal Models Group Call

Best regards to all

César, Simon, Bill and Lauren

Agenda-WHO COVID-19 Animal Models Group Call, Thursday 3, 3PM CET

1- Franck Touret (University of Marseille)- *Preclinical evaluation of Imatinib does not support its use as an antiviral drug against SARS-CoV-2*

2- Lisette Cornelissen (Wageningen)- *Nafamostat in lipid carrier in a hamster model*

3-. Ivan Marazzi (Mount Sinai)- *A cure for severe COVID-19 (in animal models, thus far)*

4- Open discussion

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Subject: WHO COVID-19 Animal Models Group Call

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Start Time: 2020-12-03T06:00:00-08:00

End Time: 2020-12-03T07:30:00-08:00

Attendees: Adolfo.Garcia-Sastre (Adolfo.Garcia-Sastre@mssm.edu) : Adolfo.Garcia-Sastre@mssm.edu, kandeil_a (kandeil_a@hotmail.com) : kandeil_a@hotmail.com, abukreye (abukreye@utmb.edu) : abukreye@utmb.edu, White, Alexander G : agw13@pitt.edu, kupke (kupke@staff.uni-marburg.de), kupke@staff.uni-marburg.de, Ali.Mirazimi (Ali.Mirazimi@folkhalsomyndigheten.se), Ali.Mirazimi@folkhalsomyndigheten.se, Amelia Karlsson (amelia.karlsson@duke.edu), amelia.karlsson@duke.edu, Amy C. Shurtleff (amy.c.shurtleff@cepi.net), amy.c.shurtleff@cepi.net, HENAO RESTREPO, Ana Maria, henaorestrepoa@who.int, mopargal (mopargal@rams.colostate.edu) : mopargal@rams.colostate.edu, angierasmussen@gmail.com : angierasmussen@gmail.com, Ann Rawkins (Ann.Rawkins@phe.gov.uk) : Ann.Rawkins@phe.gov.uk, anna (anna@thsti.res.in) : anna@thsti.res.in, Griffiths, Anthony, ahgriff@bu.edu, Asisa.Volz (Asisa.Volz@tiho-hannover.de) : Asisa.Volz@tiho-hannover.de, aysegul.nalca.civ (aysegul.nalca.civ@mail.mil) : aysegul.nalca.civ@mail.mil, verstrepen@bprc.nl : verstrepen@bprc.nl, Barbara.Schnierle (Barbara.Schnierle@pei.de), Barbara.Schnierle@pei.de, Graham, Barney (NIH/VRC) [E], bgraham@mail.nih.gov, B.H.G. Rockx (b.rockx@erasmusmc.nl), b.rockx@erasmusmc.nl, B.L. Haagmans (b.haagmans@erasmusmc.nl), b.haagmans@erasmusmc.nl, tenoever@gmail.com, tenoever@gmail.com, Bernhard Kerscher (PEI-DE) (bernhard.kerscher@pei.de), bernhard.kerscher@pei.de, bobomok@hku.hk : bobomok@hku.hk, bradley.pickering (bradley.pickering@canada.ca) : bradley.pickering@canada.ca, CarlosAlberto.Guzman (CarlosAlberto.Guzman@helmholtz-hzi.de), CarlosAlberto.Guzman@helmholtz-hzi.de, Carol.Sabourin@hhs.gov : Carol.Sabourin@hhs.gov, Carolyn Clark (carolyn.clark@cepi.net), carolyn.clark@cepi.net, Cesar Munoz-Fontela (munoz-fontela@bnitm.de), munoz-fontela@bnitm.de, croy (croy@tulane.edu) : croy@tulane.edu, shanchao (shanchao@wh.iov.cn) : shanchao@wh.iov.cn, Techakitiroj Chatkul (tverakit@gmail.com), tverakit@gmail.com, mary.lane@nih.gov, mary.lane@nih.gov, Chi Van Dang (cdang@lcr.org) : cdang@lcr.org, Chris Miller (cjmiller@ucdavis.edu) : cjmiller@ucdavis.edu, christian.c.hofer.mil@mail.mil, christian.c.hofer.mil@mail.mil, Christiane Gerke (christiane.gerke@pasteur.fr), christiane.gerke@pasteur.fr, qinchuan (qinchuan@pumc.edu.cn), qinchuan@pumc.edu.cn, Florence, Clint (NIH/NIAID) [E], clint.florence@nih.gov, Schmaljohn, Connie (NIH/NIAID) [E] : connie.schmaljohn@nih.gov, dbarouch (dbarouch@bidmc.harvard.edu) : dbarouch@bidmc.harvard.edu, danielle.anderson (danielle.anderson@duke-nus.edu.sg), danielle.anderson@duke-nus.edu.sg, Falzarano, Darryl : darryl.falzarano@usask.ca, darwyn.kobasa@canada.ca : darwyn.kobasa@canada.ca, DAVID H O'CONNOR (dhoconno@wisc.edu) : dhoconno@wisc.edu, WOOD, David John : woodd@who.int, David Vaughn (David.Vaughn@gatesfoundation.org), David.Vaughn@gatesfoundation.org, David Revelli (drevelli@lovelacebiomedical.org), drevelli@lovelacebiomedical.org, Lee-Parritz, David : david.lee-parritz@tufts.edu, dean.smith (dean.smith@canada.ca) : dean.smith@canada.ca, ldenisy (ldenisy@yahoo.com) : ldenisy@yahoo.com, dbolton@hivresearch.org, dbolton@hivresearch.org, dmissiak

(dmissiak@bsd.uchicago.edu)

Agenda coming soon.

Best,
Lauren

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To: galter (galter@partners.org)[galter@partners.org]; Maria Baca Estrada (maria.baca-estrada@canada.ca)[maria.baca-estrada@canada.ca]; baihe (baihe@nmpa.gov.cn)[baihe@nmpa.gov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; cheryl (cheryl@gisaid.org)[cheryl@gisaid.org]; valentina.bernasconi@cepi.net[valentina.bernasconi@cepi.net]; shinjini.bhatnagar (shinjini.bhatnagar@thsti.res.in)[shinjini.bhatnagar@thsti.res.in]; pbieniasz@mail.rockefeller.edu[pbieniasz@mail.rockefeller.edu]; karin.bok (karin.bok@nih.gov)[karin.bok@nih.gov]; Boyle, David[dboyle@path.org]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; BRANGEL, Polina[brangelp@who.int]; christian.brechot (christian.brechot@pasteur.fr)[christian.brechot@pasteur.fr]; Christine Bruce (Christine.bruce@phe.gov.uk)[Christine.bruce@phe.gov.uk]; zuz4 (zuz4@cdc.gov)[zuz4@cdc.gov]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; fjc37@cam.ac.uk[fjc37@cam.ac.uk]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; Chu, May[MAY.CHU@CUANSCHUTZ.EDU]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; kizzmekia.corbett@nih.gov[kizzmekia.corbett@nih.gov]; COSTA, Alejandro Javier[costaa@who.int]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)[htq4@cdc.gov]; shane@lji.org[shane@lji.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Damon, Inger K. (CDC/DDID/NCEZID/DHCPP)[iad7@cdc.gov]; Lisa@amicitiam.com[Lisa@amicitiam.com]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; de los Santos, Tala[tdelossantos@path.org]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; Delgado Vazquez.Rafael (rafael.delgado@salud.madrid.org)[rafael.delgado@salud.madrid.org]; mit666666 (mit666666@pitt.edu)[mit666666@pitt.edu]; katie.doores (katie.doores@kcl.ac.uk)[katie.doores@kcl.ac.uk]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; christian.drosten (christian.drosten@charite.de)[christian.drosten@charite.de]; epstein@ecohealthalliance.org[epstein@ecohealthalliance.org]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; jason.fernandes@canada.ca[jason.fernandes@canada.ca]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; Luc.Gagnon (Luc.Gagnon@nexelis.com)[Luc.Gagnon@nexelis.com]; Mayra.Garcia (Mayra.Garcia@fda.hhs.gov)[Mayra.Garcia@fda.hhs.gov]; bhx1 (bhx1@cdc.gov)[bhx1@cdc.gov]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; Goldblatt, David[d.goldblatt@ich.ucl.ac.uk]; guy.gorochov@sorbonne-universite.fr[guy.gorochov@sorbonne-universite.fr]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Griffiths, Anthony[ahgriff@bu.edu]; elwyn.griffiths@cepi.net[elwyn.griffiths@cepi.net]; gregory.d.gromowski.civ (gregory.d.gromowski.civ@mail.mil)[gregory.d.gromowski.civ@mail.mil]; GSELL, Pierre[gsellp@who.int]; Celine Gurry (Celine.gurry@cepi.net)[Celine.gurry@cepi.net]; ilj2 (ilj2@cdc.gov)[ilj2@cdc.gov]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; Helfand, Rita (CDC/DDID/NCEZID/OD)[rzh7@cdc.gov]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Hodgson, Paul[paul.hodgson@usask.ca]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; johan.holst@cepi.net[johan.holst@cepi.net]; rawcraig@yahoo.com[rawcraig@yahoo.com]; Hyde, Terri (CDC/DDPHSIS/CGH/GID)[thyde@cdc.gov]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)[djernigan@cdc.gov]; johnsonreed@niaid.nih.gov[johnsonreed@niaid.nih.gov]; ydm9@cdc.gov[ydm9@cdc.gov]; Cassandra Kelly (Cassandra.Kelly@finddx.org)[Cassandra.Kelly@finddx.org]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; KNEZEVIC, Ivana[knezevici@who.int]; M.P.G. Koopmans (m.koopmans@erasmusmc.nl)[m.koopmans@erasmusmc.nl]; Kovacs, Gerald (OS/ASPR/BARDA) (CTR)[Gerald.Kovacs@hhs.gov]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; Shelly Krebs (skrebs@hivresearch.org)[skrebs@hivresearch.org]; Greg Kulnis (Greg.Kulnis@nexelis.com)[Greg.Kulnis@nexelis.com]; Arun Kumar (arun.kumar@cepi.net)[arun.kumar@cepi.net]; pawinee.k@redcross.or.th[pawinee.k@redcross.or.th]; Teresa Lambe (teresa.lambe@ndm.ox.ac.uk)[teresa.lambe@ndm.ox.ac.uk]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Leader, Troy[bleader@path.org]; leejooyeon (leejooyeon@korea.kr)[leejooyeon@korea.kr]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; liyl (liyl@cde.org.cn)[liyl@cde.org.cn]; changguili (changguili@aliyun.com)[changguili@aliyun.com]; lyhchengdu (lyhchengdu@163.com)[lyhchengdu@163.com]; limhy0919 (limhy0919@korea.kr)[limhy0919@korea.kr]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; liub (liub@cde.org.cn)[liub@cde.org.cn]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Mary.Matheson@phe.gov.uk[Mary.Matheson@phe.gov.uk]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; jmclellan (jmclellan@austin.utexas.edu)[jmclellan@austin.utexas.edu]; adrian.mcdermott (adrian.mcdermott@nih.gov)[adrian.mcdermott@nih.gov]; jmcelrat (jmcelrat@fredhutch.org)[jmcelrat@fredhutch.org]; gmedigeshi (gmedigeshi@thsti.res.in)[gmedigeshi@thsti.res.in]; jwm1 (jwm1@pitt.edu)[jwm1@pitt.edu]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; david.montefiori@duke.edu[david.montefiori@duke.edu]; kaitlyn.dambach@nih.gov[kaitlyn.dambach@nih.gov]; MORGAN, Oliver[omorgan@who.int]; Clare.Morris@nibsc.org[Clare.Morris@nibsc.org]; Sarah Mudrak, Ph.D.[sarah.mudrak@duke.edu]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Myers, Todd[Todd.Myers@fda.hhs.gov]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; scott.napper (scott.napper@usask.ca)[scott.napper@usask.ca]; MNELSON (MNELSON@dstl.gov.uk)[MNELSON@dstl.gov.uk]; PNorris@vitalant.org[PNorris@vitalant.org]; pilailuk.o (pilailuk.o@dmsc.mail.go.th)[pilailuk.o@dmsc.mail.go.th]; n.okba@erasmusmc.nl[n.okba@erasmusmc.nl]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; Jae Ouk Kim (jokim@ivi.int)[jokim@ivi.int]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; gustavo.f.palacios.civ (gustavo.f.palacios.civ@mail.mil)[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov]; Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP)[xdv3@cdc.gov]; Peden, Keith[keith.peden@fda.hhs.gov]; sheila.a.peel2.civ (sheila.a.peel2.civ@mail.mil)[sheila.a.peel2.civ@mail.mil]; malik (malik@hku.hk)[malik@hku.hk]; PERKINS, Mark[perkinsm@who.int]; Supaporn Phumiamorn (supaporn.p@dmsc.mail.go.th)[supaporn.p@dmsc.mail.go.th]; margaret.l.pitt.civ

(margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; mireille.plamondon@canada.ca[mireille.plamondon@canada.ca]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; arimoin (arimoin@g.ucla.edu)[arimoin@g.ucla.edu]; RIVEROS BALTA, Ximena[lauriex@who.int]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; Marc L Salit (msalit@stanford.edu)[msalit@stanford.edu]; erica (erica@lji.org)[erica@lji.org]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Sharon Schendel (schendel@lji.org)[schendel@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; PScott (PScott@eidresearch.org)[PScott@eidresearch.org]; alex@lji.org[alex@lji.org]; peshi@UTMB.EDU[peshi@UTMB.EDU]; Shivji Ragini (Ragini.Shivji@ema.europa.eu)[Ragini.Shivji@ema.europa.eu]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; YOO, Si Hyung[yoos@who.int]; Smith, Ashley (OS/ASPR/BARDA)[Ashley.Smith1@hhs.gov]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; SUBISSI, Lorenzo[subissil@who.int]; SWAMINATHAN, Soumya[swaminathans@who.int]; r.tedder@imperial.ac.uk[r.tedder@imperial.ac.uk]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; tracey.thue (tracey.thue@usask.ca)[tracey.thue@usask.ca]; georgia.tomaras (georgia.tomaras@duke.edu)[georgia.tomaras@duke.edu]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; sylvie.van-der-werf (sylvie.van-der-werf@pasteur.fr)[sylvie.van-der-werf@pasteur.fr]; eric.vangieson@darpa.mil[eric.vangieson@darpa.mil]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; linfa.wang (linfa.wang@duke-nus.edu.sg)[linfa.wang@duke-nus.edu.sg]; wangjz (wangjz@nifdc.org.cn)[wangjz@nifdc.org.cn]; wangyc (wangyc@nifdc.org.cn)[wangyc@nifdc.org.cn]; Weir, Jerry P.[jerry.weir@fda.hhs.gov]; gweiss@uci.edu[gweiss@uci.edu]; daniela@lji.org[daniela@lji.org]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; Wolfraim, Larry (NIH/NIAID) [E][larry.wolfraim@nih.gov]; David Wood (dj56wood@gmail.com)[dj56wood@gmail.com]; xumiaobj (xumiaobj@126.com)[xumiaobj@126.com]; solomon.yimer@cepi.net[solomon.yimer@cepi.net]; tlying (tlying@fudan.edu.cn)[tlying@fudan.edu.cn]; Vidadi Yusibov (vyusibov@indianabiosciences.org)[vyusibov@indianabiosciences.org]; zlshi (zlshi@wh.iov.cn)[zlshi@wh.iov.cn]; ZHOU, Tiequn[ZhouT@who.int]; Lee, William T (HEALTH)[william.lee@health.ny.gov]; ASiyer@mgh.harvard.edu[ASiyer@mgh.harvard.edu]; Nick.Gilbert@ed.ac.uk[Nick.Gilbert@ed.ac.uk]; Jilian Sacks (Jilian.sacks@finddx.org)[Jilian.sacks@finddx.org]; jma@sgul.ac.uk[jma@sgul.ac.uk]
Cc: Alter, Galit[GALTER@mgh.harvard.edu]; Sujan Shresta[sujan@lji.org]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; qiang.pan-hammarstrom@ki.se[qiang.pan-hammarstrom@ki.se]
From: SCHWARTZ, Lauren[schwartzl@who.int]
Sent: Mon 12/7/2020 1:29:19 PM (UTC-05:00)
Subject: RE: WHO Working Group on COVID-19 Assays

Dear All,

Please find below the agenda for our group call on Wednesday December 9, 2020 at 2:30PM CET (Geneva time).

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays

1. Drs. Galit Alter and Dan Barouch from the Ragon Institute of MGH, MIT and Harvard, "T cell and antibody functional correlates of severe COVID-19"
2. Dr. Qiang Pan-Hammarström from the Karolinska Institutet, "Persistence of SARS-CoV-2 specific B- and T-cell responses in convalescent COVID-19 patients 6-8 months after the infection"

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, December 6, 2020 11:29 AM
To: SCHWARTZ, Lauren; galter@partners.org; maria.baca-estrada@canada.ca; baihe@nmpa.gov.cn; rbaric@email.unc.edu; cheryl@gisaid.org; valentina.bernasconi@cepi.net; shinjini.bhatnagar@thsti.res.in; pbieniasz@mail.rockefeller.edu; karin.bok@nih.gov; dboyle@path.org; brooke.bozick@nih.gov; BRANGEL, Polina; christian.brechot@pasteur.fr; Christine.bruce@phe.gov.uk; zuz4@cdc.gov; Miles.Carroll@phe.gov.uk; fjc37@cam.ac.uk; Marco.Cavaleri@ema.europa.eu; MONALISA.CHATTERJI@gatesfoundation.org; MAY.CHU@CUANSCHUTZ.EDU; carolyn.clark@cepi.net; kizzmekia.corbett@nih.gov; COSTA, Alejandro Javier; htq4@cdc.gov; shane@lji.org; ian.crozier@nih.gov; lad7@cdc.gov; Lisa@amicitiam.com; daszak@ecohealthalliance.org; tdelossantos@path.org; emmie.dewit@nih.gov; marciela.degrace@nih.gov; rafael.delgado@salud.madrid.org; mit666666@pitt.edu; katie.doores@kcl.ac.uk; william.dowling@cepi.net; christian.drosten@charite.de; epstein@ecohealthalliance.org; Karl.Erlandson@hhs.gov; darryl.falzarano@usask.ca; jason.fernandes@canada.ca; clint.florence@nih.gov; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk;

Luc.Gagnon@nexelis.com; Mayra.Garcia@fda.hhs.gov; bhx1@cdc.gov; Volker.gerdts@usask.ca; d.goldblatt@ucl.ac.uk; guy.gorochov@sorbonne-universite.fr; barney.graham@nih.gov; ahgriff@bu.edu; elwyn.griffiths@cepi.net; gregory.d.gromowski.civ@mail.mil; GSELL, Pierre; celine.gurry@cepi.net; ilj2@cdc.gov; b.haagmans@erasmusmc.nl; rzh7@cdc.gov; HENAO RESTREPO, Ana Maria; lisa.hensley@nih.gov; paul.hodgson@usask.ca; Michael.holbrook@nih.gov; johan.holst@cepi.net; rawcraig@yahoo.com; tkh4@cdc.gov; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; johnsonreed@niaid.nih.gov; ydm9@cdc.gov; Cassandra.Kelly@finddx.org; Jacqueline.Kirchner@gatesfoundation.org; KNEZEVIC, Ivana; m.koopmans@erasmusmc.nl; Gerald.Kovacs@hhs.gov; florian.krammer@mssm.edu; Philip.Krause@fda.hhs.gov; skrebs@hivresearch.org; Greg.Kulnis@nexelis.com; arun.kumar@cepi.net; pawinee.k@redcross.or.th; teresa.lambe@ndm.ox.ac.uk; janet.lathey@nih.gov; bleader@path.org; leejooyeon@korea.kr; MSLEVER@dstl.gov.uk; liyl@cde.org.cn; changguili@aliyun.com; lyhchengdu@163.com; limhy0919@korea.kr; James.Little@hhs.gov; liub@cde.org.cn; Tracy.MacGill@fda.hhs.gov; Karen.Makar@gatesfoundation.org; Mary.Matheson@phe.gov.uk; Giada.Mattiuzzo@nibsc.org; jmclellan@austin.utexas.edu; adrian.mcdermott@nih.gov; jmcelrat@fredhutch.org; gmedigeshi@thsti.res.in; jwm1@pitt.edu; philip.minor2@gmail.com; kmodjarrad@eidresearch.org; david.montefiori@duke.edu; kaitlyn.dambach@nih.gov; MORGAN, Oliver; Clare.Morris@nibsc.org; sarah.mudrak@duke.edu; munoz-fontela@bnitm.de; vincent.munster@nih.gov; Todd.Myers@fda.hhs.gov; aysegul.nalca.civ@mail.mil; scott.napper@usask.ca; MNELSON@dstl.gov.uk; PNorris@vitalant.org; pilailuk.o@dmsc.mail.go.th; n.okba@erasmusmc.nl; golinger@MRIGLOBAL.ORG; jokim@ivi.int; Mark.Page@nibsc.org; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; xdv3@cdc.gov; Keith.Peden@fda.hhs.gov; sheila.a.peel2.civ@mail.mil; malik@hku.hk; PERKINS, Mark; supaporn.p@dmsc.mail.go.th; margaret.l.pitt.civ@mail.mil; mireille.plamondon@canada.ca; JLPRIOR@dstl.gov.uk; arimoin@g.ucla.edu; RIVEROS BALTA, Ximena; Nicola.Rose@nibsc.org; msalit@stanford.edu; erica@lji.org; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; connie.schmaljohn@nih.gov; Barbara.Schnierle@pei.de; PScott@eidresearch.org; alex@lji.org; peshi@UTMB.EDU; Ragini.Shivji@ema.europa.eu; amy.c.shurtleff@cepi.net; YOO, Si Hyung; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SUBISSI, Lorenzo; SWAMINATHAN, Soumya; r.tedder@imperial.ac.uk; nax3@cdc.gov; tracey.thue@usask.ca; georgia.tomaras@duke.edu; Julia.Tree@phe.gov.uk; john.c.trefry.civ@mail.mil; luk_vandenberghe@meei.harvard.edu; sylvie.van-der-werf@pasteur.fr; eric.vangieson@darpa.mil; Vasan.Vasan@csiro.au; y.m.vasiliev@spbniivs.ru; David.Vaughn@gatesfoundation.org; linfa.wang@duke-nus.edu.sg; wangjz@nifdc.org.cn; wangyc@nifdc.org.cn; Jerry.Weir@fda.hhs.gov; gweiss@uci.edu; daniela@lji.org; wilsonp@uchicago.edu; larry.wolfraim@nih.gov; dj56wood@gmail.com; xumiaobj@126.com; solomon.yimer@cepi.net; tlying@fudan.edu.cn; vyusibov@indianabiosciences.org; zlshi@wh.iov.cn; ZHOU, Tiequn; william.lee@health.ny.gov; ASiyer@mgh.harvard.edu; Nick.Gilbert@ed.ac.uk; Jilian.Sacks@finddx.org; jma@sgul.ac.uk
Cc: Alter, Galit; Sujan Shresta
Subject: WHO Working Group on COVID-19 Assays
When: Wednesday, December 9, 2020 5:30 AM-6:30 AM (UTC-08:00) Pacific Time (US & Canada).
Where: https://who.zoom.us/j/3612568290

Agenda to follow.

SCHWARTZ, Lauren is inviting you to a scheduled Zoom meeting.

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To: Adolfo.Garcia-Sastre (Adolfo.Garcia-Sastre@mssm.edu)[Adolfo.Garcia-Sastre@mssm.edu]; kandeil_a (kandeil_a@hotmail.com)[kandeil_a@hotmail.com]; abukreye (abukreye@utmb.edu)[abukreye@utmb.edu]; White, Alexander G[agw13@pitt.edu]; kupke (kupke@staff.uni-marburg.de)[kupke@staff.uni-marburg.de]; Ali.Mirazimi (Ali.Mirazimi@folkhalsomyndigheten.se)[Ali.Mirazimi@folkhalsomyndigheten.se]; Amelia Karlsson (amelia.karlsson@duke.edu)[amelia.karlsson@duke.edu]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; mopargal (mopargal@rams.colostate.edu)[mopargal@rams.colostate.edu]; angierasmussen@gmail.com[angierasmussen@gmail.com]; Ann Rawkins (Ann.Rawkins@phe.gov.uk)[Ann.Rawkins@phe.gov.uk]; anna (anna@thsti.res.in)[anna@thsti.res.in]; Griffiths, Anthony[ahgriff@bu.edu]; Asisa.Volz (Asisa.Volz@tiho-hannover.de)[Asisa.Volz@tiho-hannover.de]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; verstrepen@bprc.nl[verstrepen@bprc.nl]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; B.H.G. Rockx (b.rockx@erasmusmc.nl)[b.rockx@erasmusmc.nl]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; Benjamin tenOever[tenoever@gmail.com]; Bernhard Kerscher (PEI-DE) (bernhard.kerscher@pei.de)[bernhard.kerscher@pei.de]; bobomok@hku.hk[bobomok@hku.hk]; bradley.pickering (bradley.pickering@canada.ca)[bradley.pickering@canada.ca]; CarlosAlberto.Guzman (CarlosAlberto.Guzman@helmholtz-hzi.de)[CarlosAlberto.Guzman@helmholtz-hzi.de]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; croy (croy@tulane.edu)[croy@tulane.edu]; shanchao (shanchao@wh.iov.cn)[shanchao@wh.iov.cn]; Techakitiroj Chatkul (tverakit@gmail.com)[tverakit@gmail.com]; mary.lane@nih.gov[mary.lane@nih.gov]; Chi Van Dang (cdang@lcr.org)[cdang@lcr.org]; Chris Miller (cjmiller@ucdavis.edu)[cjmiller@ucdavis.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; Christiane Gerke (christiane.gerke@pasteur.fr)[christiane.gerke@pasteur.fr]; qinchuan (qinchuan@pumc.edu.cn)[qinchuan@pumc.edu.cn]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; danielle.anderson (danielle.anderson@duke-nus.edu.sg)[danielle.anderson@duke-nus.edu.sg]; Falzarano, Darryl[darryl.falzarano@usask.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; DAVID H O'CONNOR (dhoconno@wisc.edu)[dhoconno@wisc.edu]; WOOD, David John[woodd@who.int]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; David Revelli (drevelli@lovelacebiomedical.org)[drevelli@lovelacebiomedical.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; dean.smith (dean.smith@canada.ca)[dean.smith@canada.ca]; ldenisy (ldenisy@yahoo.com)[ldenisy@yahoo.com]; dbolton@hivresearch.org[dbolton@hivresearch.org]; dmissiak (dmissiak@bsd.uchicago.edu)[dmissiak@bsd.uchicago.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; dustin.johnson (dustin.johnson@canada.ca)[dustin.johnson@canada.ca]; Sajdel-Sulkowska, Elizabeth M.,D.Sc.[esulkowska@rics.bwh.harvard.edu]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; erica (erica@lji.org)[erica@lji.org]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; Dohm, Erik Daniel[edohm@uab.edu]; verschoor (verschoor@bprc.nl)[verschoor@bprc.nl]; estefania.rodriguez (estefania.rodriguez@bnitm.de)[estefania.rodriguez@bnitm.de]; GREY Finn (fgrey@exseed.ed.ac.uk)[fgrey@exseed.ed.ac.uk]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; Cassels, Fred[fcassels@path.org]; fkoide (fkoide@southernresearch.org)[fkoide@southernresearch.org]; Gary Kobinger (Gary.Kobinger@crchudequebec.ulaval.ca)[Gary.Kobinger@crchudequebec.ulaval.ca]; sutter (sutter@micro.vetmed.uni-muenchen.de)[sutter@micro.vetmed.uni-muenchen.de]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; Sivko, Gloria S[sivkog@battelle.org]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; gustavo.palacios (gustavo.palacios@gmail.com)[gustavo.palacios@gmail.com]; horer@ku.edu.tr[horer@ku.edu.tr]; Golding, Hana[Hana.Golding@fda.hhs.gov]; Harry Kleanthous (Harry.Kleanthous@gatesfoundation.org)[Harry.Kleanthous@gatesfoundation.org]; Feldmann, Heinrich (NIH/NIAID) [E][feldmannh@niaid.nih.gov]; hlchen (hlchen@hku.hk)[hlchen@hku.hk]; Hwan K Kim (hwan.kim@stonybrook.edu)[hwan.kim@stonybrook.edu]; Crozier, Ian (NIH) [C][ian.crozier@nih.gov]; i.v.krasilnikov (i.v.krasilnikov@spbniivs.ru)[i.v.krasilnikov@spbniivs.ru]; KNEZEVIC, Ivana[knezevici@who.int]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; Stewart, James[J.P.Stewart@liverpool.ac.uk]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; langermans (langermans@bprc.nl)[langermans@bprc.nl]; Jason Kindrachuk (Jason.Kindrachuk@umanitoba.ca)[Jason.Kindrachuk@umanitoba.ca]; jfwchan (jfwchan@hku.hk)[jfwchan@hku.hk]; Javier Salguero (Javier.Salguero@phe.gov.uk)[Javier.Salguero@phe.gov.uk]; jay.w.hooper.civ (jay.w.hooper.civ@mail.mil)[jay.w.hooper.civ@mail.mil]; jeroen.kortekaas (jeroen.kortekaas@wur.nl)[jeroen.kortekaas@wur.nl]; ZHU, Jin[Jin.Zhu@health.gov.au]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; Flynn, Joanne L[joanne@pitt.edu]; Segales, Joaquim[joaquim.segales@irta.cat]; johan.neyts (johan.neyts@kuleuven.be)[johan.neyts@kuleuven.be]; Treanor, John (OS/ASPR/BARDA) (CTR)[John.Treanor@hhs.gov]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; JOHN JAMES BACZENAS[baczenas@wisc.edu]; Spergel, Jonathan[SPERGEL@email.chop.edu]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; Jorgen de Jonge (jorgen.de.jonge@rivm.nl)[jorgen.de.jonge@rivm.nl]; Juan García Arriaza (jfgarcia@cnb.csic.es)[jfgarcia@cnb.csic.es]; Juergen Richt (jricht@vet.k-state.edu)[jricht@vet.k-state.edu]; Vergara, Julia[julia.vergara@irta.cat]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; kai.dallmeier (kai.dallmeier@kuleuven.be)[kai.dallmeier@kuleuven.be]; kanta.subbarao (kanta.subbarao@influenzacentre.org)[kanta.subbarao@influenzacentre.org]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; sktseng (sktseng@UTMB.EDU)[sktseng@UTMB.EDU]; AKelvin (AKelvin@dal.ca)[AKelvin@dal.ca]; kevinharrod (kevinharrod@uabmc.edu)[kevinharrod@uabmc.edu]; rkiatchula (rkiatchula@gmail.com)[rkiatchula@gmail.com]; Seungtaek Kim (seungtaek.kim@ip-korea.org)[seungtaek.kim@ip-korea.org]; stittelaar (stittelaar@viroclinics.com)[stittelaar@viroclinics.com]; Kristine Macartney (kristine.macartney@health.nsw.gov.au)[kristine.macartney@health.nsw.gov.au]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr];

lisambrosseau@gmail.com[lisambrosseau@gmail.com]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; margaret.l.pitt.civ (margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; Luis Enjuanes[l.enjuanes@cnb.csic.es]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; mesteban (mesteban@cnb.csic.es)[mesteban@cnb.csic.es]; PREZIOSI, Marie-pierre[preziosim@who.int]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; mlewis (mlewis@bioqual.com)[mlewis@bioqual.com]; Martha Alexander-Miller (Martha.Alexander-Miller@wakehealth.edu)[Martha.Alexander-Miller@wakehealth.edu]; Martin.Beer (Martin.Beer@fli.de)[Martin.Beer@fli.de]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Eitzen, Melissa M.[mmeitzen@utmb.edu]; Schotsaert, Michael[michael.schotsaert@mssm.edu]; mdiamond (mdiamond@wustl.edu)[mdiamond@wustl.edu]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; mto@umn.edu[mto@umn.edu]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; Munir, Muhammad[muhammad.munir@lancaster.ac.uk]; Nadia KHELEF (nadia.khelef@pasteur.fr)[nadia.khelef@pasteur.fr]; Oreshkova, Nadia[nadia.oreshkova@wur.nl]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; Neil Berry (Neil.Berry@nibsc.org)[Neil.Berry@nibsc.org]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; nirp (nirp@iibr.gov.il)[nirp@iibr.gov.il]; Gerhards, Nora[nora.gerhards@wur.nl]; nnagata@niid.go.jp[nnagata@niid.go.jp]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; salgampa (salgampa@njms.rutgers.edu)[salgampa@njms.rutgers.edu]; Reid, St Patrick M[patrick.reid@unmc.edu]; Hodgson, Paul[paul.hodgson@usask.ca]; Paul.Lambert (Paul.Lambert@unige.ch)[Paul.Lambert@unige.ch]; Duprex, Paul[pduprex@pitt.edu]; paul-mccray (paul-mccray@uiowa.edu)[paul-mccray@uiowa.edu]; Pauline Maisonnasse (pauline.maisonnasse@cea.fr)[pauline.maisonnasse@cea.fr]; BAMFORD, Pearl[Pearl.Bamford@health.gov.au]; Peter Palese[peter.palese@mssm.edu]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; GSELL, Pierre[gsellp@who.int]; que.dang@nih.gov[que.dang@nih.gov]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; Baric, Ralph S[rbaric@email.unc.edu]; Ramin M Hakami[rhakami@gmu.edu]; Albrecht, Randy[randy.albrecht@mssm.edu]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; rcarrion (rcarrion@TxBiomed.org)[rcarrion@TxBiomed.org]; Riccardo Russo[russori@njms.rutgers.edu]; Levis, Robin[robin.levis@fda.hhs.gov]; Roger Le Grand (roger.le-grand@cea.fr)[roger.le-grand@cea.fr]; Romain Volmer (romain.volmer@envt.fr)[romain.volmer@envt.fr]; Donis, Ruben (OS/ASPR/BARDA)[ruben.donis@hhs.gov]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; Sally Sharpe (Sally.Sharpe@phe.gov.uk)[Sally.Sharpe@phe.gov.uk]; Cartner, Samuel Corbin[scartner@uab.edu]; scordo (scordo@qb.fcen.uba.ar)[scordo@qb.fcen.uba.ar]; LESELLIER Sandrine (sandrine.lesellier@anses.fr)[sandrine.lesellier@anses.fr]; seos@cnu.ac.kr[seos@cnu.ac.kr]; sean.li (sean.li@canada.ca)[sean.li@canada.ca]; sekim (sekim@krict.re.kr)[sekim@krict.re.kr]; Аракелов Сергей Александрович (s.a.arakelov@spbniivs.ru)[s.a.arakelov@spbniivs.ru]; SHELBY L O'CONNOR[slfeinberg@wisc.edu]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; SINA BAVARI[sinabavari@comcast.net]; SWAMINATHAN, Soumya[swaminathans@who.int]; Perlman, Stanley[stanley-perlman@uiowa.edu]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; Suchinda Malaivijitnond (suchinda.m@chula.ac.th)[suchinda.m@chula.ac.th]; Tadaki (tksuzuki@nih.go.jp)[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; terry.k.besch.ctr (terry.k.besch.ctr@mail.mil)[terry.k.besch.ctr@mail.mil]; Pickett, Thames (NIH/NIAID) [E][pickettte@niaid.nih.gov]; ThomasC.Mettenleiter (ThomasC.Mettenleiter@fli.de)[ThomasC.Mettenleiter@fli.de]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; tomeri (tomeri@iibr.gov.il)[tomeri@iibr.gov.il]; Tony.Wang (Tony.Wang@fda.hhs.gov)[Tony.Wang@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Brasel, Trevor[trbrasel@utmb.edu]; troyrandall (troyrandall@uabmc.edu)[troyrandall@uabmc.edu]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; Poel, Wim van der[wim.vanderpoel@wur.nl]; RIVEROS BALTA, Ximena[lauriex@who.int]; Yper.Hall (Yper.Hall@phe.gov.uk)[Yper.Hall@phe.gov.uk]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; ZHOU, Tiequn[ZhouT@who.int]; YOO, Si Hyung[yoos@who.int]; SCHWARTZ, Lauren[schwartzl@who.int]; franck.TOURET@univ-amu.fr[franck.TOURET@univ-amu.fr]; Marazzi, Ivan[ivan.marazzi@mssm.edu]; lisette.cornelissen@wur.nl[lisette.cornelissen@wur.nl]; c.blank@nki.nl[c.blank@nki.nl]; jhogan@uga.edu[jhogan@uga.edu]; Boon, Jacco[jboon@wustl.edu]

Cc: William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; SCHWARTZ, Lauren[schwartzl@who.int]; RIVEROS BALTA, Ximena[lauriex@who.int]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]

From: MUNOZ FONTELA, Cesar[munozc@who.int]

Sent: Wed 12/9/2020 1:04:17 PM (UTC-05:00)

Subject: Agenda-WHO COVID-19 Animal Models Group call Thursday Dec 10th

Mail Attachment.ics

Dear all,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call

Best

César, Simon, Bill and Lauren.

Agenda WHO COVID-19 Animal Models group call-Thursday December 10 3PM CET (Geneva time)

1- Roger Le Grand (CEA)- *Two-component spike nanoparticle vaccine protects macaques from SARS-CoV-2 infection*

2- Jay Hooper (USAMRIID)- *Protective efficacy of a SARS-CoV-2 DNA vaccine in wild-type and immunosuopressed Syrian hamsters*

3- Jacco Boon (Washington University in St. Louis)- *A single intranasal or intramuscular immunization with chimpanzee adenovirus vectored SARS-CoV-2 vaccine protects against pneumonia in hamsters.*

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Organizer: SCHWARTZ, Lauren : schwartzl@who.int

Subject: WHO COVID-19 Animal Models Group Call

Location: https://who.zoom.us/j/3612568290

Start Time: 2020-12-10T06:00:00-08:00

End Time: 2020-12-10T07:30:00-08:00

Attendees: Adolfo.Garcia-Sastre (Adolfo.Garcia-Sastre@mssm.edu) : Adolfo.Garcia-Sastre@mssm.edu, kandeil_a (kandeil_a@hotmail.com) : kandeil_a@hotmail.com, abukreye (abukreye@utmb.edu) : abukreye@utmb.edu, White, Alexander G : agw13@pitt.edu, kupke (kupke@staff.uni-marburg.de), kupke@staff.uni-marburg.de, Ali.Mirazimi (Ali.Mirazimi@folkhalsomyndigheten.se), Ali.Mirazimi@folkhalsomyndigheten.se, Amelia Karlsson (amelia.karlsson@duke.edu), amelia.karlsson@duke.edu, Amy C. Shurtleff (amy.c.shurtleff@cepi.net), amy.c.shurtleff@cepi.net, HENAO RESTREPO, Ana Maria, henaorestrepoa@who.int, mopargal (mopargal@rams.colostate.edu) : mopargal@rams.colostate.edu, angierasmussen@gmail.com : angierasmussen@gmail.com, Ann Rawkins (Ann.Rawkins@phe.gov.uk) : Ann.Rawkins@phe.gov.uk, anna (anna@thsti.res.in) : anna@thsti.res.in, Griffiths, Anthony, ahgriff@bu.edu, Asisa.Volz (Asisa.Volz@tiho-hannover.de) : Asisa.Volz@tiho-hannover.de, aysegul.nalca.civ (aysegul.nalca.civ@mail.mil) : aysegul.nalca.civ@mail.mil, verstrepen@bprc.nl : verstrepen@bprc.nl, Barbara.Schnierle (Barbara.Schnierle@pei.de), Barbara.Schnierle@pei.de, Graham, Barney (NIH/VRC) [E], bgraham@mail.nih.gov, B.H.G. Rockx (b.rockx@erasmusmc.nl), b.rockx@erasmusmc.nl, B.L. Haagmans (b.haagmans@erasmusmc.nl), b.haagmans@erasmusmc.nl, tenoever@gmail.com, tenoever@gmail.com, Bernhard Kerscher (PEI-DE) (bernhard.kerscher@pei.de), bernhard.kerscher@pei.de, bobomok@hku.hk : bobomok@hku.hk, bradley.pickering (bradley.pickering@canada.ca) : bradley.pickering@canada.ca, CarlosAlberto.Guzman (CarlosAlberto.Guzman@helmholtz-hzi.de), CarlosAlberto.Guzman@helmholtz-hzi.de, Carol.Sabourin@hhs.gov : Carol.Sabourin@hhs.gov, Carolyn Clark (carolyn.clark@cepi.net), carolyn.clark@cepi.net, Cesar Munoz-Fontela (munoz-fontela@bnitm.de), munoz-fontela@bnitm.de, croy (croy@tulane.edu) : croy@tulane.edu, shanchao (shanchao@wh.iov.cn) : shanchao@wh.iov.cn, Techakitiroj Chatkul (tverakit@gmail.com), tverakit@gmail.com, mary.lane@nih.gov, mary.lane@nih.gov, Chi Van Dang (cdang@lcr.org) : cdang@lcr.org, Chris Miller (cjmiller@ucdavis.edu) : cjmiller@ucdavis.edu, christian.c.hofer.mil@mail.mil, christian.c.hofer.mil@mail.mil, Christiane Gerke (christiane.gerke@pasteur.fr), christiane.gerke@pasteur.fr, qinchuan (qinchuan@pumc.edu.cn), qinchuan@pumc.edu.cn, Florence, Clint (NIH/NIAID) [E], clint.florence@nih.gov, Schmaljohn, Connie (NIH/NIAID) [E] : connie.schmaljohn@nih.gov, dbarouch (dbarouch@bidmc.harvard.edu) : dbarouch@bidmc.harvard.edu, danielle.anderson (danielle.anderson@duke-nus.edu.sg), danielle.anderson@duke-nus.edu.sg, Falzarano, Darryl : darryl.falzarano@usask.ca, darwyn.kobasa@canada.ca : darwyn.kobasa@canada.ca, DAVID H O'CONNOR (dhoconno@wisc.edu) : dhoconno@wisc.edu, WOOD, David John : woodd@who.int, David Vaughn (David.Vaughn@gatesfoundation.org), David.Vaughn@gatesfoundation.org, David Revelli (drevelli@lovelacebiomedical.org), drevelli@lovelacebiomedical.org, Lee-Parritz, David : david.lee-parritz@tufts.edu, dean.smith (dean.smith@canada.ca) : dean.smith@canada.ca, ldenisy (ldenisy@yahoo.com) : ldenisy@yahoo.com, dbolton@hivresearch.org, dbolton@hivresearch.org, dmissiak

(dmissiak@bsd.uchicago.edu)

Agenda to follow.

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To: galter (galter@partners.org)[galter@partners.org]; Maria Baca Estrada (maria.baca-estrada@canada.ca)[maria.baca-estrada@canada.ca]; baihe (baihe@nmpa.gov.cn)[baihe@nmpa.gov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; cheryl (cheryl@gisaid.org)[cheryl@gisaid.org]; valentina.bernasconi@cepi.net[valentina.bernasconi@cepi.net]; shinjini.bhatnagar (shinjini.bhatnagar@thsti.res.in)[shinjini.bhatnagar@thsti.res.in]; pbieniasz@mail.rockefeller.edu[pbieniasz@mail.rockefeller.edu]; karin.bok (karin.bok@nih.gov)[karin.bok@nih.gov]; Boyle, David[dboyle@path.org]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; BRANGEL, Polina[brangelp@who.int]; christian.brechot (christian.brechot@pasteur.fr)[christian.brechot@pasteur.fr]; Christine Bruce (Christine.bruce@phe.gov.uk)[Christine.bruce@phe.gov.uk]; zuz4 (zuz4@cdc.gov)[zuz4@cdc.gov]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; fjc37@cam.ac.uk[fjc37@cam.ac.uk]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; Chu, May[MAY.CHU@CUANSCHUTZ.EDU]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; kizzmekia.corbett@nih.gov[kizzmekia.corbett@nih.gov]; COSTA, Alejandro Javier[costaa@who.int]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)[htq4@cdc.gov]; shane@lji.org[shane@lji.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Damon, Inger K. (CDC/DDID/NCEZID/DHCPP)[iad7@cdc.gov]; Lisa@amicitiam.com[Lisa@amicitiam.com]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; de los Santos, Tala[tdelossantos@path.org]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; Delgado Vazquez.Rafael (rafael.delgado@salud.madrid.org)[rafael.delgado@salud.madrid.org]; mit666666 (mit666666@pitt.edu)[mit666666@pitt.edu]; katie.doores (katie.doores@kcl.ac.uk)[katie.doores@kcl.ac.uk]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; christian.drosten (christian.drosten@charite.de)[christian.drosten@charite.de]; epstein@ecohealthalliance.org[epstein@ecohealthalliance.org]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; jason.fernandes@canada.ca[jason.fernandes@canada.ca]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; Luc.Gagnon (Luc.Gagnon@nexelis.com)[Luc.Gagnon@nexelis.com]; Mayra.Garcia (Mayra.Garcia@fda.hhs.gov)[Mayra.Garcia@fda.hhs.gov]; bhx1 (bhx1@cdc.gov)[bhx1@cdc.gov]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; Goldblatt, David[d.goldblatt@ich.ucl.ac.uk]; guy.gorochov@sorbonne-universite.fr[guy.gorochov@sorbonne-universite.fr]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Griffiths, Anthony[ahgriff@bu.edu]; elwyn.griffiths@cepi.net[elwyn.griffiths@cepi.net]; gregory.d.gromowski.civ (gregory.d.gromowski.civ@mail.mil)[gregory.d.gromowski.civ@mail.mil]; Celine Gurry (Celine.gurry@cepi.net)[Celine.gurry@cepi.net]; ilj2 (ilj2@cdc.gov)[ilj2@cdc.gov]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; Helfand, Rita (CDC/DDID/NCEZID/OD)[rzh7@cdc.gov]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Hodgson, Paul[paul.hodgson@usask.ca]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; johan.holst@cepi.net[johan.holst@cepi.net]; rawcraig@yahoo.com[rawcraig@yahoo.com]; Hyde, Terri (CDC/DDPHSIS/CGH/GID)[thyde@cdc.gov]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)[djernigan@cdc.gov]; johnsonreed@niaid.nih.gov[johnsonreed@niaid.nih.gov]; ydm9@cdc.gov[ydm9@cdc.gov]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; KNEZEVIC, Ivana[knezevici@who.int]; M.P.G. Koopmans (m.koopmans@erasmusmc.nl)[m.koopmans@erasmusmc.nl]; Kovacs, Gerald (OS/ASPR/BARDA) (CTR)[Gerald.Kovacs@hhs.gov]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; Shelly Krebs (skrebs@hivresearch.org)[skrebs@hivresearch.org]; Greg Kulnis (Greg.Kulnis@nexelis.com)[Greg.Kulnis@nexelis.com]; Arun Kumar (arun.kumar@cepi.net)[arun.kumar@cepi.net]; pawinee.k@redcross.or.th[pawinee.k@redcross.or.th]; Teresa Lambe (teresa.lambe@ndm.ox.ac.uk)[teresa.lambe@ndm.ox.ac.uk]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Leader, Troy[bleader@path.org]; leejooyeon (leejooyeon@korea.kr)[leejooyeon@korea.kr]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; liyl (liyl@cde.org.cn)[liyl@cde.org.cn]; changguili (changguili@aliyun.com)[changguili@aliyun.com]; lyhchengdu (lyhchengdu@163.com)[lyhchengdu@163.com]; limhy0919 (limhy0919@korea.kr)[limhy0919@korea.kr]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; liub (liub@cde.org.cn)[liub@cde.org.cn]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Mary.Matheson@phe.gov.uk[Mary.Matheson@phe.gov.uk]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; jmclellan (jmclellan@austin.utexas.edu)[jmclellan@austin.utexas.edu]; adrian.mcdermott (adrian.mcdermott@nih.gov)[adrian.mcdermott@nih.gov]; jmcelrat (jmcelrat@fredhutch.org)[jmcelrat@fredhutch.org]; gmedigeshi (gmedigeshi@thsti.res.in)[gmedigeshi@thsti.res.in]; jwm1 (jwm1@pitt.edu)[jwm1@pitt.edu]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; david.montefiori@duke.edu[david.montefiori@duke.edu]; kaitlyn.dambach@nih.gov[kaitlyn.dambach@nih.gov]; MORGAN, Oliver[omorgan@who.int]; Clare.Morris@nibsc.org[Clare.Morris@nibsc.org]; Sarah Mudrak, Ph.D.[sarah.mudrak@duke.edu]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Myers, Todd[Todd.Myers@fda.hhs.gov]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; scott.napper (scott.napper@usask.ca)[scott.napper@usask.ca]; MNELSON (MNELSON@dstl.gov.uk)[MNELSON@dstl.gov.uk]; PNorris@vitalant.org[PNorris@vitalant.org]; pilailuk.o (pilailuk.o@dmsc.mail.go.th)[pilailuk.o@dmsc.mail.go.th]; n.okba@erasmusmc.nl[n.okba@erasmusmc.nl]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; Jae Ouk Kim (jokim@ivi.int)[jokim@ivi.int]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; gustavo.f.palacios.civ (gustavo.f.palacios.civ@mail.mil)[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov]; Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP)[xdv3@cdc.gov]; Peden, Keith[keith.peden@fda.hhs.gov]; sheila.a.peel2.civ (sheila.a.peel2.civ@mail.mil)[sheila.a.peel2.civ@mail.mil]; malik (malik@hku.hk)[malik@hku.hk]; PERKINS, Mark[perkinsm@who.int]; Supaporn Phumiamorn (supaporn.p@dmsc.mail.go.th)[supaporn.p@dmsc.mail.go.th]; margaret.l.pitt.civ

(margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; mireille.plamondon@canada.ca[mireille.plamondon@canada.ca]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; arimoin (arimoin@g.ucla.edu)[arimoin@g.ucla.edu]; RIVEROS BALTA, Ximena[lauriex@who.int]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; Marc L Salit (msalit@stanford.edu)[msalit@stanford.edu]; erica (erica@lji.org)[erica@lji.org]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Sharon Schendel (schendel@lji.org)[schendel@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; PScott (PScott@eidresearch.org)[PScott@eidresearch.org]; alex@lji.org[alex@lji.org]; peshi@UTMB.EDU[peshi@UTMB.EDU]; Shivji Ragini (Ragini.Shivji@ema.europa.eu)[Ragini.Shivji@ema.europa.eu]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; YOO, Si Hyung[yoos@who.int]; Smith, Ashley (OS/ASPR/BARDA)[Ashley.Smith1@hhs.gov]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; SUBISSI, Lorenzo[subissil@who.int]; SWAMINATHAN, Soumya[swaminathans@who.int]; r.tedder@imperial.ac.uk[r.tedder@imperial.ac.uk]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; tracey.thue (tracey.thue@usask.ca)[tracey.thue@usask.ca]; georgia.tomaras (georgia.tomaras@duke.edu)[georgia.tomaras@duke.edu]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; sylvie.van-der-werf (sylvie.van-der-werf@pasteur.fr)[sylvie.van-der-werf@pasteur.fr]; eric.vangieson@darpa.mil[eric.vangieson@darpa.mil]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; linfa.wang (linfa.wang@duke-nus.edu.sg)[linfa.wang@duke-nus.edu.sg]; wangjz (wangjz@nifdc.org.cn)[wangjz@nifdc.org.cn]; wangyc (wangyc@nifdc.org.cn)[wangyc@nifdc.org.cn]; Weir, Jerry P.[jerry.weir@fda.hhs.gov]; gweiss@uci.edu[gweiss@uci.edu]; daniela@lji.org[daniela@lji.org]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; Wolfraim, Larry (NIH/NIAID) [E][larry.wolfraim@nih.gov]; David Wood (dj56wood@gmail.com)[dj56wood@gmail.com]; xumiaobj (xumiaobj@126.com)[xumiaobj@126.com]; solomon.yimer@cepi.net[solomon.yimer@cepi.net]; tlying (tlying@fudan.edu.cn)[tlying@fudan.edu.cn]; Vidadi Yusibov (vyusibov@indianabiosciences.org)[vyusibov@indianabiosciences.org]; zlshi (zlshi@wh.iov.cn)[zlshi@wh.iov.cn]; ZHOU, Tiequn[ZhouT@who.int]; Lee, William T (HEALTH)[william.lee@health.ny.gov]; ASiyer@mgh.harvard.edu[ASiyer@mgh.harvard.edu]; Nick.Gilbert@ed.ac.uk[Nick.Gilbert@ed.ac.uk]; Jilian Sacks (Jilian.sacks@finddx.org)[Jilian.sacks@finddx.org]; jma@sgul.ac.uk[jma@sgul.ac.uk]; sujan@lji.org[sujan@lji.org]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; qiang.pan-hammarstrom@ki.se[qiang.pan-hammarstrom@ki.se]; tomwhite42450@gmail.com[tomwhite42450@gmail.com]; Liz Miller (Liz.Miller@lshtm.ac.uk)[Liz.Miller@lshtm.ac.uk]; Emmanuelle Charton (emmanuelle.charton@edqm.eu)[emmanuelle.charton@edqm.eu]; Perlman, Stanley[stanley-perlman@uiowa.edu]
From: SCHWARTZ, Lauren[schwartzl@who.int]
Sent: Tue 12/15/2020 11:01:28 AM (UTC-05:00)
Subject: RE: WHO Working Group on COVID-19 Assays

Dear All,

Please find below the agenda for our group call on Wednesday December 16, 2020 at 2:30PM CET (Geneva time).

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays

1. Remarks from Ana María Henao Restrepo
2. Mark Page and Giada Mattiuzzo NIBSC - *Harmonisation and increased comparability of SARS-COV-2 serological assays by WHO International standard*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, December 13, 2020 10:09 AM
To: galter@partners.org; maria.baca-estrada@canada.ca; baihe@nmpa.gov.cn; rbaric@email.unc.edu; cheryl@gisaid.org; valentina.bernasconi@cepi.net; shinjini.bhatnagar@thsti.res.in; pbieniasz@mail.rockefeller.edu; karin.bok@nih.gov; dboyle@path.org; brooke.bozick@nih.gov; BRANGEL, Polina; christian.brechot@pasteur.fr; Christine.bruce@phe.gov.uk; zuz4@cdc.gov; Miles.Carroll@phe.gov.uk; fjc37@cam.ac.uk; Marco.Cavaleri@ema.europa.eu; MONALISA.CHATTERJI@gatesfoundation.org; MAY.CHU@CUANSCHUTZ.EDU; carolyn.clark@cepi.net; kizzmekia.corbett@nih.gov; COSTA, Alejandro Javier; htq4@cdc.gov; shane@lji.org; ian.crozier@nih.gov; lad7@cdc.gov; Lisa@amicitiam.com; daszak@ecohealthalliance.org; tdelossantos@path.org; emmie.dewit@nih.gov; marciela.degrace@nih.gov; rafael.delgado@salud.madrid.org; mit666666@pitt.edu; katie.doores@kcl.ac.uk; william.dowling@cepi.net; christian.drosten@charite.de; epstein@ecohealthalliance.org; Karl.Erlandson@hhs.gov; darryl.falzarano@usask.ca; jason.fernandes@canada.ca; clint.florence@nih.gov; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk; Luc.Gagnon@nexelis.com; Mayra.Garcia@fda.hhs.gov; bhx1@cdc.gov; Volker.gerdts@usask.ca; d.goldblatt@ucl.ac.uk;

guy.gorochov@sorbonne-universite.fr; barney.graham@nih.gov; ahgriff@bu.edu; elwyn.griffiths@cepi.net; gregory.d.gromowski.civ@mail.mil; celine.gurry@cepi.net; ilj2@cdc.gov; b.haagmans@erasmusmc.nl; rzh7@cdc.gov; HENAO RESTREPO, Ana Maria; lisa.hensley@nih.gov; paul.hodgson@usask.ca; Michael.holbrook@nih.gov; johan.holst@cepi.net; rawcraig@yahoo.com; tkh4@cdc.gov; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; johnsonreed@niaid.nih.gov; ydm9@cdc.gov; Jacqueline.Kirchner@gatesfoundation.org; KNEZEVIC, Ivana; m.koopmans@erasmusmc.nl; Gerald.Kovacs@hhs.gov; florian.krammer@mssm.edu; Philip.Krause@fda.hhs.gov; skrebs@hivresearch.org; Greg.Kulnis@nexelis.com; arun.kumar@cepi.net; pawinee.k@redcross.or.th; teresa.lambe@ndm.ox.ac.uk; janet.lathey@nih.gov; bleader@path.org; leejooyeon@korea.kr; MSLEVER@dstl.gov.uk; liyl@cde.org.cn; changguili@aliyun.com; lyhchengdu@163.com; limhy0919@korea.kr; James.Little@hhs.gov; liub@cde.org.cn; Tracy.MacGill@fda.hhs.gov; Karen.Makar@gatesfoundation.org; Mary.Matheson@phe.gov.uk; Giada.Mattiuzzo@nibsc.org; jmclellan@austin.utexas.edu; adrian.mcdermott@nih.gov; jmcelrat@fredhutch.org; gmedigeshi@thsti.res.in; jwm1@pitt.edu; philip.minor2@gmail.com; kmodjarrad@eidresearch.org; david.montefiori@duke.edu; kaitlyn.dambach@nih.gov; MORGAN, Oliver; Clare.Morris@nibsc.org; sarah.mudrak@duke.edu; munoz-fontela@bnitm.de; vincent.munster@nih.gov; Todd.Myers@fda.hhs.gov; aysegul.nalca.civ@mail.mil; scott.napper@usask.ca; MNELSON@dstl.gov.uk; PNorris@vitalant.org; pilailuk.o@dmsc.mail.go.th; n.okba@erasmusmc.nl; golinger@MRIGLOBAL.ORG; jokim@ivi.int; Mark.Page@nibsc.org; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; xdv3@cdc.gov; Keith.Peden@fda.hhs.gov; sheila.a.peel2.civ@mail.mil; malik@hku.hk; PERKINS, Mark; supaporn.p@dmsc.mail.go.th; margaret.l.pitt.civ@mail.mil; mireille.plamondon@canada.ca; JLPRIOR@dstl.gov.uk; arimoin@g.ucla.edu; RIVEROS BALTA, Ximena; Nicola.Rose@nibsc.org; Marc L Salit (msalit@stanford.edu); erica@lji.org; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; connie.schmaljohn@nih.gov; Barbara.Schnierle@pei.de; PScott@eidresearch.org; alex@lji.org; peshi@UTMB.EDU; Ragini.Shivji@ema.europa.eu; amy.c.shurtleff@cepi.net; YOO, Si Hyung; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SUBISSI, Lorenzo; SWAMINATHAN, Soumya; r.tedder@imperial.ac.uk; nax3@cdc.gov; tracey.thue@usask.ca; georgia.tomaras@duke.edu; Julia.Tree@phe.gov.uk; john.c.trefry.civ@mail.mil; luk_vandenberghe@meei.harvard.edu; sylvie.van-der-werf@pasteur.fr; eric.vangieson@darpa.mil; Vasan.Vasan@csiro.au; y.m.vasiliev@spbniivs.ru; David.Vaughn@gatesfoundation.org; linfa.wang@duke-nus.edu.sg; wangjz@nifdc.org.cn; wangyc@nifdc.org.cn; Jerry.Weir@fda.hhs.gov; gweiss@uci.edu; daniela@lji.org; wilsonp@uchicago.edu; larry.wolfraim@nih.gov; dj56wood@gmail.com; xumiaobj@126.com; solomon.yimer@cepi.net; tlying@fudan.edu.cn; vyusibov@indianabiosciences.org; zlshi@wh.iov.cn; ZHOU, Tiequn; william.lee@health.ny.gov; ASiyer@mgh.harvard.edu; SCHWARTZ, Lauren; Nick.Gilbert@ed.ac.uk; Jilian.Sacks@finddx.org; jma@sgul.ac.uk; sujan@lji.org; dbarouch@bidmc.harvard.edu; qiang.pan-hammarstrom@ki.se; tomwhite42450@gmail.com; Liz Miller (Liz.Miller@lshtm.ac.uk); Emmanuelle Charton (emmanuelle.charton@edqm.eu); stanley-perlman@uiowa.edu
Subject: WHO Working Group on COVID-19 Assays
When: Wednesday, December 16, 2020 5:30 AM-6:30 AM (UTC-08:00) Pacific Time (US & Canada).
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Agenda to follow.

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To: Adolfo.Garcia-Sastre (Adolfo.Garcia-Sastre@mssm.edu)[Adolfo.Garcia-Sastre@mssm.edu]; kandeil_a (kandeil_a@hotmail.com)[kandeil_a@hotmail.com]; abukreye (abukreye@utmb.edu)[abukreye@utmb.edu]; White, Alexander G[agw13@pitt.edu]; kupke (kupke@staff.uni-marburg.de)[kupke@staff.uni-marburg.de]; Ali.Mirazimi (Ali.Mirazimi@folkhalsomyndigheten.se)[Ali.Mirazimi@folkhalsomyndigheten.se]; Amelia Karlsson (amelia.karlsson@duke.edu)[amelia.karlsson@duke.edu]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; mopargal (mopargal@rams.colostate.edu)[mopargal@rams.colostate.edu]; angierasmussen@gmail.com[angierasmussen@gmail.com]; Ann Rawkins (Ann.Rawkins@phe.gov.uk)[Ann.Rawkins@phe.gov.uk]; anna (anna@thsti.res.in)[anna@thsti.res.in]; Griffiths, Anthony[ahgriff@bu.edu]; Asisa.Volz (Asisa.Volz@tiho-hannover.de)[Asisa.Volz@tiho-hannover.de]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; verstrepen@bprc.nl[verstrepen@bprc.nl]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; B.H.G. Rockx (b.rockx@erasmusmc.nl)[b.rockx@erasmusmc.nl]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; tenoever@gmail.com[tenoever@gmail.com]; Bernhard Kerscher (PEI-DE) (bernhard.kerscher@pei.de)[bernhard.kerscher@pei.de]; bobomok@hku.hk[bobomok@hku.hk]; bradley.pickering (bradley.pickering@canada.ca)[bradley.pickering@canada.ca]; CarlosAlberto.Guzman (CarlosAlberto.Guzman@helmholtz-hzi.de)[CarlosAlberto.Guzman@helmholtz-hzi.de]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; croy (croy@tulane.edu)[croy@tulane.edu]; shanchao (shanchao@wh.iov.cn)[shanchao@wh.iov.cn]; Techakitiroj Chatkul (tverakit@gmail.com)[tverakit@gmail.com]; mary.lane@nih.gov[mary.lane@nih.gov]; Chi Van Dang (cdang@lcr.org)[cdang@lcr.org]; Chris Miller (cjmiller@ucdavis.edu)[cjmiller@ucdavis.edu]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; Christiane Gerke (christiane.gerke@pasteur.fr)[christiane.gerke@pasteur.fr]; qinchuan (qinchuan@pumc.edu.cn)[qinchuan@pumc.edu.cn]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; danielle.anderson (danielle.anderson@duke-nus.edu.sg)[danielle.anderson@duke-nus.edu.sg]; Falzarano, Darryl[darryl.falzarano@usask.ca]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; DAVID H O'CONNOR (dhoconno@wisc.edu)[dhoconno@wisc.edu]; WOOD, David John[woodd@who.int]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; David Revelli (drevelli@lovelacebiomedical.org)[drevelli@lovelacebiomedical.org]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; dean.smith (dean.smith@canada.ca)[dean.smith@canada.ca]; ldenisy (ldenisy@yahoo.com)[ldenisy@yahoo.com]; dbolton@hivresearch.org[dbolton@hivresearch.org]; dmissiak (dmissiak@bsd.uchicago.edu)[dmissiak@bsd.uchicago.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; dustin.johnson (dustin.johnson@canada.ca)[dustin.johnson@canada.ca]; esulkowska@rics.bwh.harvard.edu[esulkowska@rics.bwh.harvard.edu]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; erica (erica@lji.org)[erica@lji.org]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; Dohm, Erik Daniel[edohm@uab.edu]; verschoor (verschoor@bprc.nl)[verschoor@bprc.nl]; estefania.rodriguez (estefania.rodriguez@bnitm.de)[estefania.rodriguez@bnitm.de]; GREY Finn (fgrey@exseed.ed.ac.uk)[fgrey@exseed.ed.ac.uk]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; Cassels, Fred[fcassels@path.org]; fkoide (fkoide@southernresearch.org)[fkoide@southernresearch.org]; Gary Kobinger (Gary.Kobinger@crchudequebec.ulaval.ca)[Gary.Kobinger@crchudequebec.ulaval.ca]; sutter (sutter@micro.vetmed.uni-muenchen.de)[sutter@micro.vetmed.uni-muenchen.de]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; Sivko, Gloria S[sivkog@battelle.org]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; gustavo.palacios (gustavo.palacios@gmail.com)[gustavo.palacios@gmail.com]; horer@ku.edu.tr[horer@ku.edu.tr]; Golding, Hana[Hana.Golding@fda.hhs.gov]; Harry Kleanthous (Harry.Kleanthous@gatesfoundation.org)[Harry.Kleanthous@gatesfoundation.org]; feldmannh@niaid.nih.gov[feldmannh@niaid.nih.gov]; hlchen (hlchen@hku.hk)[hlchen@hku.hk]; Hwan K Kim (hwan.kim@stonybrook.edu)[hwan.kim@stonybrook.edu]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Красильников Игорь Викторович[i.v.krasilnikov@spbniivs.ru]; KNEZEVIC, Ivana[knezevici@who.int]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; Stewart, James[J.P.Stewart@liverpool.ac.uk]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; langermans (langermans@bprc.nl)[langermans@bprc.nl]; Jason Kindrachuk (Jason.Kindrachuk@umanitoba.ca)[Jason.Kindrachuk@umanitoba.ca]; jfwchan (jfwchan@hku.hk)[jfwchan@hku.hk]; Javier Salguero (Javier.Salguero@phe.gov.uk)[Javier.Salguero@phe.gov.uk]; jay.w.hooper.civ (jay.w.hooper.civ@mail.mil)[jay.w.hooper.civ@mail.mil]; snumouse (snumouse@snu.ac.kr)[snumouse@snu.ac.kr]; jeroen.kortekaas (jeroen.kortekaas@wur.nl)[jeroen.kortekaas@wur.nl]; ZHU, Jin[Jin.Zhu@health.gov.au]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; Flynn, Joanne L[joanne@pitt.edu]; Segales, Joaquim[joaquim.segales@irta.cat]; johan.neyts (johan.neyts@kuleuven.be)[johan.neyts@kuleuven.be]; Treanor, John (OS/ASPR/BARDA) (CTR)[John.Treanor@hhs.gov]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; JOHN JAMES BACZENAS[baczenas@wisc.edu]; SPERGEL@email.chop.edu[SPERGEL@email.chop.edu]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; Jorgen de Jonge (jorgen.de.jonge@rivm.nl)[jorgen.de.jonge@rivm.nl]; Juan García Arriaza (jfgarcia@cnb.csic.es)[jfgarcia@cnb.csic.es]; Juergen Richt (jricht@vet.k-state.edu)[jricht@vet.k-state.edu]; Vergara, Julia[julia.vergara@irta.cat]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; kai.dallmeier (kai.dallmeier@kuleuven.be)[kai.dallmeier@kuleuven.be]; kanta.subbarao (kanta.subbarao@influenzacentre.org)[kanta.subbarao@influenzacentre.org]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; sktseng (sktseng@UTMB.EDU)[sktseng@UTMB.EDU]; AKelvin (AKelvin@dal.ca)[AKelvin@dal.ca]; kevinharrod (kevinharrod@uabmc.edu)[kevinharrod@uabmc.edu]; rkiatchula (rkiatchula@gmail.com)[rkiatchula@gmail.com]; Seungtaek Kim (seungtaek.kim@ip-korea.org)[seungtaek.kim@ip-korea.org]; stittelaar (stittelaar@viroclinics.com)[stittelaar@viroclinics.com]; Kristine Macartney (kristine.macartney@health.nsw.gov.au)[kristine.macartney@health.nsw.gov.au]; Jayashankar, Lakshmi

(OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; margaret.l.pitt.civ (margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; l.enjuanes@cnb.csic.es[l.enjuanes@cnb.csic.es]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; mesteban (mesteban@cnb.csic.es)[mesteban@cnb.csic.es]; PREZIOSI, Marie-pierre[preziosim@who.int]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; mlewis (mlewis@bioqual.com)[mlewis@bioqual.com]; Martha Alexander-Miller (Martha.Alexander-Miller@wakehealth.edu)[Martha.Alexander-Miller@wakehealth.edu]; Martin.Beer (Martin.Beer@fli.de)[Martin.Beer@fli.de]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Eitzen, Melissa M.[mmeitzen@utmb.edu]; Schotsaert, Michael[michael.schotsaert@mssm.edu]; mdiamond (mdiamond@wustl.edu)[mdiamond@wustl.edu]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; mto@umn.edu[mto@umn.edu]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; Munir, Muhammad[muhammad.munir@lancaster.ac.uk]; Nadia KHELEF (nadia.khelef@pasteur.fr)[nadia.khelef@pasteur.fr]; Oreshkova, Nadia[nadia.oreshkova@wur.nl]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; Neil Berry (Neil.Berry@nibsc.org)[Neil.Berry@nibsc.org]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; nirp (nirp@iibr.gov.il)[nirp@iibr.gov.il]; Gerhards, Nora[nora.gerhards@wur.nl]; nnagata@niid.go.jp[nnagata@niid.go.jp]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; salgampa (salgampa@njms.rutgers.edu)[salgampa@njms.rutgers.edu]; patrick.reid@unmc.edu[patrick.reid@unmc.edu]; Hodgson, Paul[paul.hodgson@usask.ca]; Paul.Lambert (Paul.Lambert@unige.ch)[Paul.Lambert@unige.ch]; Duprex, Paul[pduprex@pitt.edu]; paul-mccray (paul-mccray@uiowa.edu)[paul-mccray@uiowa.edu]; Pauline Maisonnasse (pauline.maisonnasse@cea.fr)[pauline.maisonnasse@cea.fr]; BAMFORD, Pearl[Pearl.Bamford@health.gov.au]; peter.palese@mssm.edu[peter.palese@mssm.edu]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; que.dang@nih.gov[que.dang@nih.gov]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; Baric, Ralph S[rbaric@email.unc.edu]; rhakami@gmu.edu[rhakami@gmu.edu]; Albrecht, Randy[randy.albrecht@mssm.edu]; rcarrion (rcarrion@TxBiomed.org)[rcarrion@TxBiomed.org]; Riccardo Russo[russori@njms.rutgers.edu]; Levis, Robin[robin.levis@fda.hhs.gov]; Roger Le Grand (roger.le-grand@cea.fr)[roger.le-grand@cea.fr]; Romain Volmer (romain.volmer@envt.fr)[romain.volmer@envt.fr]; Donis, Ruben (OS/ASPR/BARDA)[ruben.donis@hhs.gov]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; Sally Sharpe (Sally.Sharpe@phe.gov.uk)[Sally.Sharpe@phe.gov.uk]; Cartner, Samuel Corbin[scartner@uab.edu]; scordo (scordo@qb.fcen.uba.ar)[scordo@qb.fcen.uba.ar]; LESELLIER Sandrine (sandrine.lesellier@anses.fr)[sandrine.lesellier@anses.fr]; seos@cnu.ac.kr[seos@cnu.ac.kr]; sean.li (sean.li@canada.ca)[sean.li@canada.ca]; sekim (sekim@krict.re.kr)[sekim@krict.re.kr]; SHELBY L O'CONNOR[slfeinberg@wisc.edu]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; sinabavari@comcast.net[sinabavari@comcast.net]; SWAMINATHAN, Soumya[swaminathans@who.int]; Perlman, Stanley[stanley-perlman@uiowa.edu]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; Suchinda Malaivijitnond (suchinda.m@chula.ac.th)[suchinda.m@chula.ac.th]; Tadaki (tksuzuki@nih.go.jp)[tksuzuki@nih.go.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; terry.k.besch.ctr (terry.k.besch.ctr@mail.mil)[terry.k.besch.ctr@mail.mil]; Pickett, Thames (NIH/NIAID) [E][pickettte@niaid.nih.gov]; ThomasC.Mettenleiter (ThomasC.Mettenleiter@fli.de)[ThomasC.Mettenleiter@fli.de]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; tomeri (tomeri@iibr.gov.il)[tomeri@iibr.gov.il]; Tony.Wang (Tony.Wang@fda.hhs.gov)[Tony.Wang@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Brasel, Trevor[trbrasel@utmb.edu]; troyrandall (troyrandall@uabmc.edu)[troyrandall@uabmc.edu]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; RIVEROS BALTA, Ximena[lauriex@who.int]; Yper.Hall (Yper.Hall@phe.gov.uk)[Yper.Hall@phe.gov.uk]; Yuri VASILIEV (Васильев Юрий Михайлович)[y.m.vasiliev@spbniivs.ru]; ZHOU, Tiequn[ZhouT@who.int]; YOO, Si Hyung[yoos@who.int]; SCHWARTZ, Lauren[schwartzl@who.int]; franck.TOURET@univ-amu.fr[franck.TOURET@univ-amu.fr]; ivan.marazzi@mssm.edu[ivan.marazzi@mssm.edu]; lisette.cornelissen@wur.nl[lisette.cornelissen@wur.nl]; c.blank@nki.nl[c.blank@nki.nl]; jhogan@uga.edu[jhogan@uga.edu]; neeltje.vandoremalen@nih.gov[neeltje.vandoremalen@nih.gov]; caroline.melo@rivm.nl[caroline.melo@rivm.nl]; Dillen, Carly[CDillen@som.umaryland.edu]

From: Аракелов Сергей Александрович[s.a.arakelov@spbniivs.ru]
Sent: Wed 12/23/2020 3:19:48 PM (UTC-05:00)
Subject: Re: Thank You and Happy Holidays to the WHO COVID-19 Animal Models Group

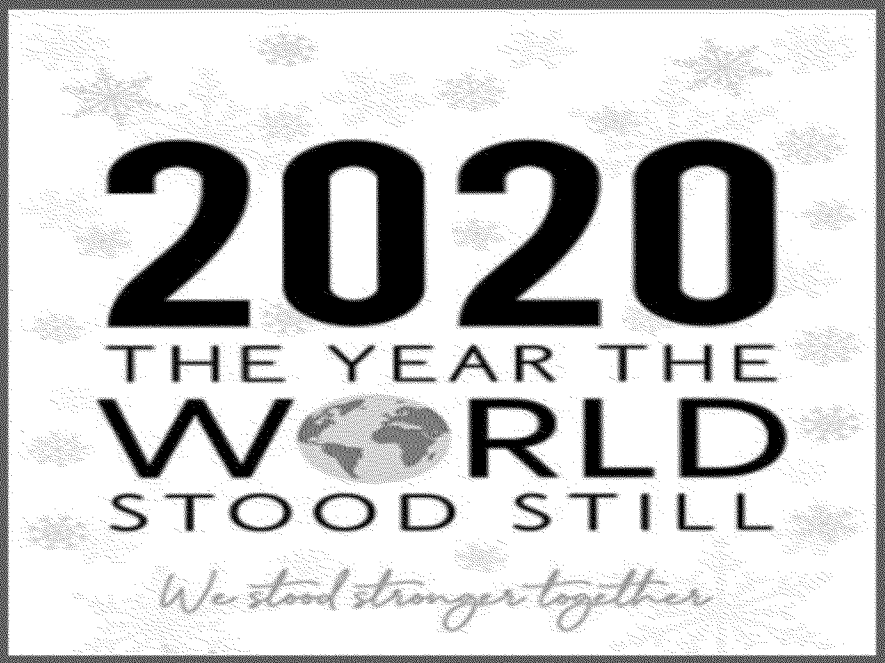
Thank you! Have a nice one!
Sincerely,
Sergey

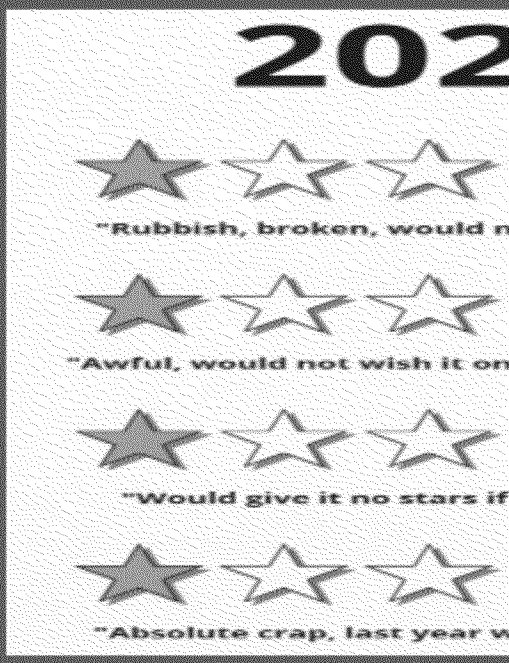
From: SCHWARTZ, Lauren <schwartzl@who.int>
Sent: Wednesday, December 23, 2020 11:12:09 PM
To: Adolfo.Garcia-Sastre (Adolfo.Garcia-Sastre@mssm.edu) <Adolfo.Garcia-Sastre@mssm.edu>; kandeil_a (kandeil_a@hotmail.com) <kandeil_a@hotmail.com>; abukreye (abukreye@utmb.edu) <abukreye@utmb.edu>; White, Alexander G <agw13@pitt.edu>; kupke (kupke@staff.uni-marburg.de) <kupke@staff.uni-marburg.de>; Ali.Mirazimi (Ali.Mirazimi@folkhalsomyndigheten.se) <Ali.Mirazimi@folkhalsomyndigheten.se>; Amelia Karlsson (amelia.karlsson@duke.edu) <amelia.karlsson@duke.edu>; Amy C. Shurtleff (amy.c.shurtleff@cepi.net) <amy.c.shurtleff@cepi.net>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; mopargal (mopargal@rams.colostate.edu) <mopargal@rams.colostate.edu>; angierasmussen@gmail.com <angierasmussen@gmail.com>; Ann Rawkins (Ann.Rawkins@phe.gov.uk) <Ann.Rawkins@phe.gov.uk>; anna (anna@thsti.res.in) <anna@thsti.res.in>; Griffiths, Anthony <ahgriff@bu.edu>; Asisa.Volz (Asisa.Volz@tiho-hannover.de) <Asisa.Volz@tiho-hannover.de>; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil) <aysegul.nalca.civ@mail.mil>; verstrepen@bprc.nl <verstrepen@bprc.nl>; Barbara.Schnierle (Barbara.Schnierle@pei.de) <Barbara.Schnierle@pei.de>; Graham, Barney (NIH/VRC) [E] <bgraham@mail.nih.gov>; B.H.G. Rockx (b.rockx@erasmusmc.nl) <b.rockx@erasmusmc.nl>; B.L. Haagmans (b.haagmans@erasmusmc.nl) <b.haagmans@erasmusmc.nl>; tenoever@gmail.com <tenoever@gmail.com>; Bernhard Kerscher (PEI-DE) (bernhard.kerscher@pei.de) <bernhard.kerscher@pei.de>; bobomok@hku.hk <bobomok@hku.hk>; bradley.pickering (bradley.pickering@canada.ca) <bradley.pickering@canada.ca>; CarlosAlberto.Guzman (CarlosAlberto.Guzman@helmholtz-hzi.de) <CarlosAlberto.Guzman@helmholtz-hzi.de>; Carol.Sabourin@hhs.gov <Carol.Sabourin@hhs.gov>; Carolyn Clark (carolyn.clark@cepi.net) <carolyn.clark@cepi.net>; Cesar Munoz-Fontela (munoz-fontela@bnitm.de) <munoz-fontela@bnitm.de>; croy (croy@tulane.edu) <croy@tulane.edu>; shanchao (shanchao@wh.iov.cn) <shanchao@wh.iov.cn>; Techakitiroj Chatkul (tverakit@gmail.com) <tverakit@gmail.com>; mary.lane@nih.gov <mary.lane@nih.gov>; Chi Van Dang (cdang@lcr.org) <cdang@lcr.org>; Chris Miller (cjmiller@ucdavis.edu) <cjmiller@ucdavis.edu>; christian.c.hofer.mil@mail.mil <christian.c.hofer.mil@mail.mil>; Christiane Gerke (christiane.gerke@pasteur.fr) <christiane.gerke@pasteur.fr>; qinchuan (qinchuan@pumc.edu.cn) <qinchuan@pumc.edu.cn>; Florence, Clint (NIH/NIAID) [E] <clint.florence@nih.gov>; Schmaljohn, Connie (NIH/NIAID) [E] <connie.schmaljohn@nih.gov>; dbarouch (dbarouch@bidmc.harvard.edu) <dbarouch@bidmc.harvard.edu>; danielle.anderson (danielle.anderson@duke-nus.edu.sg) <danielle.anderson@duke-nus.edu.sg>; Falzarano, Darryl <darryl.falzarano@usask.ca>; darwyn.kobasa@canada.ca <darwyn.kobasa@canada.ca>; DAVID H O'CONNOR (dhoconno@wisc.edu) <dhoconno@wisc.edu>; WOOD, David John <woodd@who.int>; David Vaughn (David.Vaughn@gatesfoundation.org) <David.Vaughn@gatesfoundation.org>; David Revelli (drevelli@lovelacebiomedical.org) <drevelli@lovelacebiomedical.org>; Lee-Parritz, David <david.lee-parritz@tufts.edu>; dean.smith (dean.smith@canada.ca) <dean.smith@canada.ca>; ldenisy (ldenisy@yahoo.com) <ldenisy@yahoo.com>; dbolton@hivresearch.org <dbolton@hivresearch.org>; dmissiak (dmissiak@bsd.uchicago.edu) <dmissiak@bsd.uchicago.edu>; dsreed@cvr.pitt.edu <dsreed@cvr.pitt.edu>; dustin.johnson (dustin.johnson@canada.ca) <dustin.johnson@canada.ca>; esulkowska@rics.bwh.harvard.edu <esulkowska@rics.bwh.harvard.edu>; De wit, Emmie (NIH/NIAID) [E] <emmie.dewit@nih.gov>; erica (erica@lji.org) <erica@lji.org>; Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>; Dohm, Erik Daniel <edohm@uab.edu>; verschoor (verschoor@bprc.nl) <verschoor@bprc.nl>; estefania.rodriguez (estefania.rodriguez@bnitm.de) <estefania.rodriguez@bnitm.de>; GREY Finn (fgrey@exseed.ed.ac.uk) <fgrey@exseed.ed.ac.uk>; florian.krammer (florian.krammer@mssm.edu) <florian.krammer@mssm.edu>; Cassels, Fred <fcassels@path.org>; fkoide (fkoide@southernresearch.org) <fkoide@southernresearch.org>; Gary Kobinger (Gary.Kobinger@crchudequebec.ulaval.ca) <Gary.Kobinger@crchudequebec.ulaval.ca>; sutter (sutter@micro.vetmed.uni-muenchen.de) <sutter@micro.vetmed.uni-muenchen.de>; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org) <Giada.Mattiuzzo@nibsc.org>; Sivko, Gloria S <sivkog@battelle.org>; grace.m.lidl.mil@mail.mil <grace.m.lidl.mil@mail.mil>; gustavo.palacios (gustavo.palacios@gmail.com) <gustavo.palacios@gmail.com>; horer@ku.edu.tr <horer@ku.edu.tr>; Golding, Hana <Hana.Golding@fda.hhs.gov>; Harry Kleanthous (Harry.Kleanthous@gatesfoundation.org) <Harry.Kleanthous@gatesfoundation.org>; feldmannh@niaid.nih.gov <feldmannh@niaid.nih.gov>; hlchen (hlchen@hku.hk) <hlchen@hku.hk>; Hwan K Kim (hwan.kim@stonybrook.edu) <hwan.kim@stonybrook.edu>; ian.crozier@nih.gov <ian.crozier@nih.gov>; Красильников Игорь Викторович <i.v.krasilnikov@spbniivs.ru>; KNEZEVIC, Ivana <knezevici@who.int>; y.jacob.hou@unc.edu <y.jacob.hou@unc.edu>; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org) <Jacqueline.Kirchner@gatesfoundation.org>; Stewart, James <J.P.Stewart@liverpool.ac.uk>; Little, James (OS/ASPR/BARDA) <James.Little@hhs.gov>; langermans (langermans@bprc.nl) <langermans@bprc.nl>; Jason Kindrachuk (Jason.Kindrachuk@umanitoba.ca) <Jason.Kindrachuk@umanitoba.ca>; jfwchan (jfwchan@hku.hk) <jfwchan@hku.hk>; Javier Salguero (Javier.Salguero@phe.gov.uk) <Javier.Salguero@phe.gov.uk>; jay.w.hooper.civ (jay.w.hooper.civ@mail.mil) <jay.w.hooper.civ@mail.mil>; snumouse (snumouse@snu.ac.kr) <snumouse@snu.ac.kr>; jeroen.kortekaas (jeroen.kortekaas@wur.nl) <jeroen.kortekaas@wur.nl>; ZHU, Jin <Jin.Zhu@health.gov.au>; JLPRIOR (JLPRIOR@dstl.gov.uk) <JLPRIOR@dstl.gov.uk>; Flynn, Joanne L <joanne@pitt.edu>; Segales, Joaquim <joaquim.segales@irta.cat>; johan.neyts (johan.neyts@kuleuven.be) <johan.neyts@kuleuven.be>; Treanor, John (OS/ASPR/BARDA) (CTR) <John.Treanor@hhs.gov>; john.c.trefry.civ (john.c.trefry.civ@mail.mil) <john.c.trefry.civ@mail.mil>; JOHN JAMES BACZENAS <baczenas@wisc.edu>; SPERGEL@email.chop.edu <SPERGEL@email.chop.edu>; JTorrelles@txbiomed.org <JTorrelles@txbiomed.org>; Jorgen de Jonge (jorgen.de.jonge@rivm.nl) <jorgen.de.jonge@rivm.nl>; Juan García Arriaza (jfgarcia@cnb.csic.es) <jfgarcia@cnb.csic.es>; Juergen Richt (jricht@vet.k-state.edu) <jricht@vet.k-state.edu>; Vergara, Julia

<julia.vergara@irta.cat>; Julia Tree (Julia.Tree@phe.gov.uk) <Julia.Tree@phe.gov.uk>; kai.dallmeier (kai.dallmeier@kuleuven.be) <kai.dallmeier@kuleuven.be>; kanta.subbarao (kanta.subbarao@influenzacentre.org) <kanta.subbarao@influenzacentre.org>; Karen Makar (Karen.Makar@gatesfoundation.org) <Karen.Makar@gatesfoundation.org>; Karl.Erlandson (Karl.Erlandson@hhs.gov) <Karl.Erlandson@hhs.gov>; Kayvon Modjarrad (kmodjarrad@eidresearch.org) <kmodjarrad@eidresearch.org>; sktseng (sktseng@UTMB.EDU) <sktseng@UTMB.EDU>; AKelvin (AKelvin@dal.ca) <AKelvin@dal.ca>; kevinharrod (kevinharrod@uabmc.edu) <kevinharrod@uabmc.edu>; rkiatchula (rkiatchula@gmail.com) <rkiatchula@gmail.com>; Seungtaek Kim (seungtaek.kim@ip-korea.org) <seungtaek.kim@ip-korea.org>; stittelaar (stittelaar@viroclinics.com) <stittelaar@viroclinics.com>; Kristine Macartney (kristine.macartney@health.nsw.gov.au) <kristine.macartney@health.nsw.gov.au>; Jayashankar, Lakshmi (OS/ASPR/BARDA) <Lakshmi.Jayashankar@hhs.gov>; lisa.chakrabarti@pasteur.fr <lisa.chakrabarti@pasteur.fr>; lisambrosseau@gmail.com <lisambrosseau@gmail.com>; Hensley, Lisa (NIH/NIAID) [E] <lisa.hensley@nih.gov>; lgralins@email.unc.edu <lgralins@email.unc.edu>; margaret.l.pitt.civ (margaret.l.pitt.civ@mail.mil) <margaret.l.pitt.civ@mail.mil>; l.enjuanes@cnb.csic.es <l.enjuanes@cnb.csic.es>; Luis.Lugo.mil@afrims.org <Luis.Lugo.mil@afrims.org>; LMartinez@txbiomed.org <LMartinez@txbiomed.org>; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu) <luk_vandenberghe@meei.harvard.edu>; mito@ciea.or.jp <mito@ciea.or.jp>; Manki Song (mksong@ivi.int) <mksong@ivi.int>; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu) <Marco.Cavaleri@ema.europa.eu>; mesteban (mesteban@cnb.csic.es) <mesteban@cnb.csic.es>; PREZIOSI, Marie-pierre <preziosim@who.int>; mariette.ducatez@envt.fr <mariette.ducatez@envt.fr>; Mark Page (Mark.Page@nibsc.org) <Mark.Page@nibsc.org>; mlewis (mlewis@bioqual.com) <mlewis@bioqual.com>; Martha Alexander-Miller (Martha.Alexander-Miller@wakehealth.edu) <Martha.Alexander-Miller@wakehealth.edu>; Martin.Beer (Martin.Beer@fli.de) <Martin.Beer@fli.de>; Matthew.Reed.mil@afrims.org <Matthew.Reed.mil@afrims.org>; Frieman, Matthew <MFrieman@som.umaryland.edu>; Eitzen, Melissa M. <mmeitzen@utmb.edu>; Schotsaert, Michael <michael.schotsaert@mssm.edu>; mdiamond (mdiamond@wustl.edu) <mdiamond@wustl.edu>; MNELSON@mail.dstl.gov.uk <MNELSON@mail.dstl.gov.uk>; mto@umn.edu <mto@umn.edu>; Holbrook, Michael (NIH/NIAID) [C] <michael.holbrook@nih.gov>; Miles.Carroll (Miles.Carroll@phe.gov.uk) <Miles.Carroll@phe.gov.uk>; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org) <MONALISA.CHATTERJI@gatesfoundation.org>; Munir, Muhammad <muhammad.munir@lancaster.ac.uk>; Nadia KHELEF (nadia.khelef@pasteur.fr) <nadia.khelef@pasteur.fr>; Oreshkova, Nadia <nadia.oreshkova@wur.nl>; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <nax3@cdc.gov>; Neil Berry (Neil.Berry@nibsc.org) <Neil.Berry@nibsc.org>; Nicola Rose (Nicola.Rose@nibsc.org) <Nicola.Rose@nibsc.org>; Nicola Rose (Nicola.Rose@nibsc.org) <Nicola.Rose@nibsc.org>; nirp (nirp@iibr.gov.il) <nirp@iibr.gov.il>; Gerhards, Nora <nora.gerhards@wur.nl>; nnagata@niid.go.jp <nnagata@niid.go.jp>; Olinger, Gene <golinger@MRIGLOBAL.ORG>; salgampa (salgampa@njms.rutgers.edu) <salgampa@njms.rutgers.edu>; patrick.reid@unmc.edu <patrick.reid@unmc.edu>; Hodgson, Paul <paul.hodgson@usask.ca>; Paul.Lambert (Paul.Lambert@unige.ch) <Paul.Lambert@unige.ch>; Duprex, Paul <pduprex@pitt.edu>; paul-mccray (paul-mccray@uiowa.edu) <paul-mccray@uiowa.edu>; Pauline Maisonnasse (pauline.maisonnasse@cea.fr) <pauline.maisonnasse@cea.fr>; BAMFORD, Pearl <Pearl.Bamford@health.gov.au>; peter.palese@mssm.edu <peter.palese@mssm.edu>; Philip Minor (Philip.Minor2@gmail.com) <Philip.Minor2@gmail.com>; philip.krause@fda.hhs.gov <philip.krause@fda.hhs.gov>; que.dang@nih.gov <que.dang@nih.gov>; REIRELAND (REIRELAND@mail.dstl.gov.uk) <REIRELAND@mail.dstl.gov.uk>; rbaric (rbaric@email.unc.edu) <rbaric@email.unc.edu>; rhakami@gmu.edu <rhakami@gmu.edu>; Albrecht, Randy <randy.albrecht@mssm.edu>; rcarrion (rcarrion@TxBiomed.org) <rcarrion@TxBiomed.org>; Riccardo Russo <russori@njms.rutgers.edu>; Levis, Robin <robin.levis@fda.hhs.gov>; Roger Le Grand (roger.le-grand@cea.fr) <roger.le-grand@cea.fr>; Romain Volmer (romain.volmer@envt.fr) <romain.volmer@envt.fr>; Donis, Ruben (OS/ASPR/BARDA) <ruben.donis@hhs.gov>; Russell.Ray@bcm.edu <Russell.Ray@bcm.edu>; Sally Sharpe (Sally.Sharpe@phe.gov.uk) <Sally.Sharpe@phe.gov.uk>; Cartner, Samuel Corbin <scartner@uab.edu>; scordo (scordo@qb.fcen.uba.ar) <scordo@qb.fcen.uba.ar>; LESELLIER Sandrine (sandrine.lesellier@anses.fr) <sandrine.lesellier@anses.fr>; seos@cnu.ac.kr <seos@cnu.ac.kr>; sean.li (sean.li@canada.ca) <sean.li@canada.ca>; sekim (sekim@krict.re.kr) <sekim@krict.re.kr>; Аракелов Сергей Александрович <s.a.arakelov@spbniivs.ru>; SHELBY L O'CONNOR <slfeinberg@wisc.edu>; Hild, Sheri (NIH/OD) [E] <sheri.hild@nih.gov>; Simon Funnell (simon.funnell@phe.gov.uk) <simon.funnell@phe.gov.uk>; sinabavari@comcast.net <sinabavari@comcast.net>; SWAMINATHAN, Soumya <swaminathans@who.int>; Perlman, Stanley <stanley-perlman@uiowa.edu>; MSLEVER (MSLEVER@dstl.gov.uk) <MSLEVER@dstl.gov.uk>; SBradfute@salud.unm.edu <SBradfute@salud.unm.edu>; Suchinda Malaivijitnond (suchinda.m@chula.ac.th) <suchinda.m@chula.ac.th>; Tadaki (tksuzuki@nih.go.jp) <tksuzuki@nih.go.jp>; tyamamoto@ciea.or.jp <tyamamoto@ciea.or.jp>; terry.k.besch.ctr (terry.k.besch.ctr@mail.mil) <terry.k.besch.ctr@mail.mil>; Pickett, Thames (NIH/NIAID) [E] <pickettte@niaid.nih.gov>; ThomasC.Mettenleiter (ThomasC.Mettenleiter@fli.de) <ThomasC.Mettenleiter@fli.de>; thomasf@primate.wisc.edu <thomasf@primate.wisc.edu>; tomeri (tomeri@iibr.gov.il) <tomeri@iibr.gov.il>; Tony.Wang (Tony.Wang@fda.hhs.gov) <Tony.Wang@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Brasel, Trevor <trbrasel@utmb.edu>; troyrandall (troyrandall@uabmc.edu) <troyrandall@uabmc.edu>; Vasan, Vasan (H&B, Geelong ACDP) <Vasan.Vasan@csiro.au>; SATHIYAMOORTHY, Vaseeharan <moorthyv@who.int>; Munster, Vincent (NIH/NIAID) [E] <vincent.munster@nih.gov>; Volker.gerdts (Volker.gerdts@usask.ca) <Volker.gerdts@usask.ca>; William Dowling (william.dowling@cepi.net) <william.dowling@cepi.net>; wim.vanderpoel@wur.nl <wim.vanderpoel@wur.nl>; RIVEROS BALTA, Ximena <lauriex@who.int>; Yper.Hall (Yper.Hall@phe.gov.uk) <Yper.Hall@phe.gov.uk>; Yuri VASILIEV (Васильев Юрий Михайлович) <y.m.vasiliev@spbniivs.ru>; ZHOU, Tiequn

<ZhouT@who.int>; YOO, Si Hyung <yoos@who.int>; SCHWARTZ, Lauren <schwartzl@who.int>; franck.TOURET@univ-amu.fr <franck.TOURET@univ-amu.fr>; ivan.marazzi@mssm.edu <ivan.marazzi@mssm.edu>; lisette.cornelissen@wur.nl <lisette.cornelissen@wur.nl>; c.blank@nki.nl <c.blank@nki.nl>; jhogan@uga.edu <jhogan@uga.edu>; neeltje.vandoremalen@nih.gov <neeltje.vandoremalen@nih.gov>; caroline.melo@rivm.nl <caroline.melo@rivm.nl>; Dillen, Carly <CDillen@som.umaryland.edu>
Subject: Thank You and Happy Holidays to the WHO COVID-19 Animal Models Group

There is no better time than the holid





Thank you to everyone who has helpe

One of the real joys this holiday seas
thank you and wish you the very be

R&DBlueprint
Powering research
to prevent epidemics

To: galter (galter@partners.org)[galter@partners.org]; Maria Baca Estrada (maria.baca-estrada@canada.ca)[maria.baca-estrada@canada.ca]; baihe (baihe@nmpa.gov.cn)[baihe@nmpa.gov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; cheryl (cheryl@gisaid.org)[cheryl@gisaid.org]; valentina.bernasconi@cepi.net[valentina.bernasconi@cepi.net]; shinjini.bhatnagar (shinjini.bhatnagar@thsti.res.in)[shinjini.bhatnagar@thsti.res.in]; pbieniasz@mail.rockefeller.edu[pbieniasz@mail.rockefeller.edu]; karin.bok (karin.bok@nih.gov)[karin.bok@nih.gov]; Boyle, David[dboyle@path.org]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; BRANGEL, Polina[brangelp@who.int]; christian.brechot (christian.brechot@pasteur.fr)[christian.brechot@pasteur.fr]; Christine Bruce (Christine.bruce@phe.gov.uk)[Christine.bruce@phe.gov.uk]; zuz4 (zuz4@cdc.gov)[zuz4@cdc.gov]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; fjc37@cam.ac.uk[fjc37@cam.ac.uk]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; Chu, May[MAY.CHU@CUANSCHUTZ.EDU]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; kizzmekia.corbett@nih.gov[kizzmekia.corbett@nih.gov]; COSTA, Alejandro Javier[costaa@who.int]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)[htq4@cdc.gov]; shane@lji.org[shane@lji.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Damon, Inger K. (CDC/DDID/NCEZID/DHCPP)[iad7@cdc.gov]; Lisa@amicitiam.com[Lisa@amicitiam.com]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; de los Santos, Tala[tdelossantos@path.org]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; Delgado Vazquez.Rafael (rafael.delgado@salud.madrid.org)[rafael.delgado@salud.madrid.org]; mit666666 (mit666666@pitt.edu)[mit666666@pitt.edu]; katie.doores (katie.doores@kcl.ac.uk)[katie.doores@kcl.ac.uk]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; christian.drosten (christian.drosten@charite.de)[christian.drosten@charite.de]; epstein@ecohealthalliance.org[epstein@ecohealthalliance.org]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; jason.fernandes@canada.ca[jason.fernandes@canada.ca]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; Luc.Gagnon (Luc.Gagnon@nexelis.com)[Luc.Gagnon@nexelis.com]; Mayra.Garcia (Mayra.Garcia@fda.hhs.gov)[Mayra.Garcia@fda.hhs.gov]; bhx1 (bhx1@cdc.gov)[bhx1@cdc.gov]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; Goldblatt, David[d.goldblatt@ich.ucl.ac.uk]; guy.gorochov@sorbonne-universite.fr[guy.gorochov@sorbonne-universite.fr]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Griffiths, Anthony[ahgriff@bu.edu]; elwyn.griffiths@cepi.net[elwyn.griffiths@cepi.net]; gregory.d.gromowski.civ (gregory.d.gromowski.civ@mail.mil)[gregory.d.gromowski.civ@mail.mil]; Celine Gurry (Celine.gurry@cepi.net)[Celine.gurry@cepi.net]; ilj2 (ilj2@cdc.gov)[ilj2@cdc.gov]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; Helfand, Rita (CDC/DDID/NCEZID/OD)[rzh7@cdc.gov]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Hodgson, Paul[paul.hodgson@usask.ca]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; johan.holst@cepi.net[johan.holst@cepi.net]; rawcraig@yahoo.com[rawcraig@yahoo.com]; Hyde, Terri (CDC/DDPHSIS/CGH/GID)[thyde@cdc.gov]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)[djernigan@cdc.gov]; johnsonreed@niaid.nih.gov[johnsonreed@niaid.nih.gov]; ydm9@cdc.gov[ydm9@cdc.gov]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; KNEZEVIC, Ivana[knezevici@who.int]; M.P.G. Koopmans (m.koopmans@erasmusmc.nl)[m.koopmans@erasmusmc.nl]; Kovacs, Gerald (OS/ASPR/BARDA) (CTR)[Gerald.Kovacs@hhs.gov]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; Shelly Krebs (skrebs@hivresearch.org)[skrebs@hivresearch.org]; Greg Kulnis (Greg.Kulnis@nexelis.com)[Greg.Kulnis@nexelis.com]; Arun Kumar (arun.kumar@cepi.net)[arun.kumar@cepi.net]; pawinee.k@redcross.or.th[pawinee.k@redcross.or.th]; Teresa Lambe (teresa.lambe@ndm.ox.ac.uk)[teresa.lambe@ndm.ox.ac.uk]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Leader, Troy[bleader@path.org]; leejooyeon (leejooyeon@korea.kr)[leejooyeon@korea.kr]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; liyl (liyl@cde.org.cn)[liyl@cde.org.cn]; changguili (changguili@aliyun.com)[changguili@aliyun.com]; lyhchengdu (lyhchengdu@163.com)[lyhchengdu@163.com]; limhy0919 (limhy0919@korea.kr)[limhy0919@korea.kr]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; liub (liub@cde.org.cn)[liub@cde.org.cn]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Mary.Matheson@phe.gov.uk[Mary.Matheson@phe.gov.uk]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; jmclellan (jmclellan@austin.utexas.edu)[jmclellan@austin.utexas.edu]; adrian.mcdermott (adrian.mcdermott@nih.gov)[adrian.mcdermott@nih.gov]; jmcelrat (jmcelrat@fredhutch.org)[jmcelrat@fredhutch.org]; gmedigeshi (gmedigeshi@thsti.res.in)[gmedigeshi@thsti.res.in]; jwm1 (jwm1@pitt.edu)[jwm1@pitt.edu]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; david.montefiori@duke.edu[david.montefiori@duke.edu]; kaitlyn.dambach@nih.gov[kaitlyn.dambach@nih.gov]; MORGAN, Oliver[omorgan@who.int]; Clare.Morris@nibsc.org[Clare.Morris@nibsc.org]; Sarah Mudrak, Ph.D.[sarah.mudrak@duke.edu]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Myers, Todd[Todd.Myers@fda.hhs.gov]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; scott.napper (scott.napper@usask.ca)[scott.napper@usask.ca]; MNELSON (MNELSON@dstl.gov.uk)[MNELSON@dstl.gov.uk]; PNorris@vitalant.org[PNorris@vitalant.org]; pilailuk.o (pilailuk.o@dmsc.mail.go.th)[pilailuk.o@dmsc.mail.go.th]; n.okba@erasmusmc.nl[n.okba@erasmusmc.nl]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; Jae Ouk Kim (jokim@ivi.int)[jokim@ivi.int]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; gustavo.f.palacios.civ (gustavo.f.palacios.civ@mail.mil)[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov]; Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP)[xdv3@cdc.gov]; Peden, Keith[keith.peden@fda.hhs.gov]; sheila.a.peel2.civ (sheila.a.peel2.civ@mail.mil)[sheila.a.peel2.civ@mail.mil]; malik (malik@hku.hk)[malik@hku.hk]; PERKINS, Mark[perkinsm@who.int]; Supaporn Phumiamorn (supaporn.p@dmsc.mail.go.th)[supaporn.p@dmsc.mail.go.th]; margaret.l.pitt.civ

(margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; mireille.plamondon@canada.ca[mireille.plamondon@canada.ca]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; arimoin (arimoin@g.ucla.edu)[arimoin@g.ucla.edu]; RIVEROS BALTA, Ximena[lauriex@who.int]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; Marc L Salit (msalit@stanford.edu)[msalit@stanford.edu]; erica (erica@lji.org)[erica@lji.org]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Sharon Schendel (schendel@lji.org)[schendel@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; PScott (PScott@eidresearch.org)[PScott@eidresearch.org]; alex@lji.org[alex@lji.org]; peshi@UTMB.EDU[peshi@UTMB.EDU]; Shivji Ragini (Ragini.Shivji@ema.europa.eu)[Ragini.Shivji@ema.europa.eu]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; YOO, Si Hyung[yoos@who.int]; Smith, Ashley (OS/ASPR/BARDA)[Ashley.Smith1@hhs.gov]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; SUBISSI, Lorenzo[subissil@who.int]; SWAMINATHAN, Soumya[swaminathans@who.int]; r.tedder@imperial.ac.uk[r.tedder@imperial.ac.uk]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; tracey.thue (tracey.thue@usask.ca)[tracey.thue@usask.ca]; georgia.tomaras (georgia.tomaras@duke.edu)[georgia.tomaras@duke.edu]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; sylvie.van-der-werf (sylvie.van-der-werf@pasteur.fr)[sylvie.van-der-werf@pasteur.fr]; eric.vangieson@darpa.mil[eric.vangieson@darpa.mil]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; linfa.wang (linfa.wang@duke-nus.edu.sg)[linfa.wang@duke-nus.edu.sg]; wangjz (wangjz@nifdc.org.cn)[wangjz@nifdc.org.cn]; wangyc (wangyc@nifdc.org.cn)[wangyc@nifdc.org.cn]; Weir, Jerry P.[jerry.weir@fda.hhs.gov]; gweiss@uci.edu[gweiss@uci.edu]; daniela@lji.org[daniela@lji.org]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; Wolfraim, Larry (NIH/NIAID) [E][larry.wolfraim@nih.gov]; David Wood (dj56wood@gmail.com)[dj56wood@gmail.com]; xumiaobj (xumiaobj@126.com)[xumiaobj@126.com]; solomon.yimer@cepi.net[solomon.yimer@cepi.net]; tlying (tlying@fudan.edu.cn)[tlying@fudan.edu.cn]; Vidadi Yusibov (vyusibov@indianabiosciences.org)[vyusibov@indianabiosciences.org]; zlshi (zlshi@wh.iov.cn)[zlshi@wh.iov.cn]; ZHOU, Tiequn[ZhouT@who.int]; Lee, William T (HEALTH)[william.lee@health.ny.gov]; ASiyer@mgh.harvard.edu[ASiyer@mgh.harvard.edu]; GILBERT Nick[Nick.Gilbert@ed.ac.uk]; Jilian Sacks (Jilian.sacks@finddx.org)[Jilian.sacks@finddx.org]; jma@sgul.ac.uk[jma@sgul.ac.uk]; sujan@lji.org[sujan@lji.org]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; qiang.pan-hammarstrom@ki.se[qiang.pan-hammarstrom@ki.se]; tomwhite42450@gmail.com[tomwhite42450@gmail.com]; Liz Miller (Liz.Miller@lshtm.ac.uk)[Liz.Miller@lshtm.ac.uk]; Emmanuelle Charton (emmanuelle.charton@edqm.eu)[emmanuelle.charton@edqm.eu]; Perlman, Stanley[stanley-perlman@uiowa.edu]
Cc: IRAHETA, Raul[irahetar@who.int]; pennym@nicd.ac.za[pennym@nicd.ac.za]; alex.sigal@ahri.org[alex.sigal@ahri.org]
From: SCHWARTZ, Lauren[schwartzl@who.int]
Sent: Tue 1/5/2021 3:50:23 PM (UTC-05:00)
Subject: RE: WHO Working Group on COVID-19 Assays

Dear All,

Please find below the agenda for our group call on Wednesday January 6, 2021 at 2:30PM CET (Geneva time).

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays

1. Kevin McCarthy and Paul Duprex (University of Pittsburgh)- *Natural deletions in the SARS-CoV-2 spike glycoprotein drive antibody escape*
2. Discussion on the UK variant

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 3, 2021 8:32 PM
To: galter@partners.org; maria.baca-estrada@canada.ca; baihe@nmpa.gov.cn; rbaric@email.unc.edu; cheryl@gisaid.org; valentina.bernasconi@cepi.net; shinjini.bhatnagar@thsti.res.in; pbieniasz@mail.rockefeller.edu; karin.bok@nih.gov; dboyle@path.org; brooke.bozick@nih.gov; BRANGEL, Polina; christian.brechot@pasteur.fr; Christine.bruce@phe.gov.uk; zuz4@cdc.gov; Miles.Carroll@phe.gov.uk; fjc37@cam.ac.uk; Marco.Cavaleri@ema.europa.eu; MONALISA.CHATTERJI@gatesfoundation.org; MAY.CHU@CUANSCHUTZ.EDU; carolyn.clark@cepi.net; kizzmekia.corbett@nih.gov; COSTA, Alejandro Javier; htq4@cdc.gov; shane@lji.org; ian.crozier@nih.gov; lad7@cdc.gov; Lisa@amicitiam.com; daszak@ecohealthalliance.org; tdelossantos@path.org; emmie.dewit@nih.gov; marciela.degrace@nih.gov; rafael.delgado@salud.madrid.org; mit666666@pitt.edu; katie.doores@kcl.ac.uk; william.dowling@cepi.net; christian.drosten@charite.de; epstein@ecohealthalliance.org; Karl.Erlandson@hhs.gov; darryl.falzarano@usask.ca; jason.fernandes@canada.ca; clint.florence@nih.gov; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk; Luc.Gagnon@nexelis.com; Mayra.Garcia@fda.hhs.gov; bhx1@cdc.gov; Volker.gerdts@usask.ca; d.goldblatt@ucl.ac.uk;

guy.gorochov@sorbonne-universite.fr; barney.graham@nih.gov; ahgriff@bu.edu; elwyn.griffiths@cepi.net; gregory.d.gromowski.civ@mail.mil; celine.gurry@cepi.net; ilj2@cdc.gov; b.haagmans@erasmusmc.nl; rzh7@cdc.gov; HENAO RESTREPO, Ana Maria; lisa.hensley@nih.gov; paul.hodgson@usask.ca; Michael.holbrook@nih.gov; johan.holst@cepi.net; rawcraig@yahoo.com; tkh4@cdc.gov; REIRELAND@mail.dstl.gov.uk; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; johnsonreed@niaid.nih.gov; ydm9@cdc.gov; Jacqueline.Kirchner@gatesfoundation.org; KNEZEVIC, Ivana; m.koopmans@erasmusmc.nl; Gerald.Kovacs@hhs.gov; florian.krammer@mssm.edu; Philip.Krause@fda.hhs.gov; skrebs@hivresearch.org; Greg.Kulnis@nexelis.com; arun.kumar@cepi.net; pawinee.k@redcross.or.th; teresa.lambe@ndm.ox.ac.uk; janet.lathey@nih.gov; bleader@path.org; leejooyeon@korea.kr; MSLEVER@dstl.gov.uk; liyl@cde.org.cn; changguili@aliyun.com; lyhchengdu@163.com; limhy0919@korea.kr; James.Little@hhs.gov; liub@cde.org.cn; Tracy.MacGill@fda.hhs.gov; Karen.Makar@gatesfoundation.org; Mary.Matheson@phe.gov.uk; Giada.Mattiuzzo@nibsc.org; jmclellan@austin.utexas.edu; adrian.mcdermott@nih.gov; jmcelrat@fredhutch.org; gmedigeshi@thsti.res.in; jwm1@pitt.edu; philip.minor2@gmail.com; kmodjarrad@eidresearch.org; david.montefiori@duke.edu; kaitlyn.dambach@nih.gov; MORGAN, Oliver; Clare.Morris@nibsc.org; sarah.mudrak@duke.edu; munoz-fontela@bnitm.de; vincent.munster@nih.gov; Todd.Myers@fda.hhs.gov; aysegul.nalca.civ@mail.mil; scott.napper@usask.ca; MNELSON@dstl.gov.uk; PNorris@vitalant.org; pilailuk.o@dmsc.mail.go.th; n.okba@erasmusmc.nl; golinger@MRIGLOBAL.ORG; jokim@ivi.int; Mark.Page@nibsc.org; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; xdv3@cdc.gov; Keith.Peden@fda.hhs.gov; sheila.a.peel2.civ@mail.mil; malik@hku.hk; PERKINS, Mark; supaporn.p@dmsc.mail.go.th; margaret.l.pitt.civ@mail.mil; mireille.plamondon@canada.ca; JLPRIOR@dstl.gov.uk; arimoin@g.ucla.edu; RIVEROS BALTA, Ximena; Nicola.Rose@nibsc.org; msalit@stanford.edu; erica@lji.org; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; connie.schmaljohn@nih.gov; Barbara.Schnierle@pei.de; PScott@eidresearch.org; alex@lji.org; peshi@UTMB.EDU; Ragini.Shivji@ema.europa.eu; amy.c.shurtleff@cepi.net; YOO, Si Hyung; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SUBISSI, Lorenzo; SWAMINATHAN, Soumya; r.tedder@imperial.ac.uk; nax3@cdc.gov; tracey.thue@usask.ca; georgia.tomaras@duke.edu; Julia.Tree@phe.gov.uk; john.c.trefry.civ@mail.mil; luk_vandenberghe@meei.harvard.edu; sylvie.van-der-werf@pasteur.fr; eric.vangieson@darpa.mil; Vasan.Vasan@csiro.au; y.m.vasiliev@spbniivs.ru; David.Vaughn@gatesfoundation.org; linfa.wang@duke-nus.edu.sg; wangjz@nifdc.org.cn; wangyc@nifdc.org.cn; Jerry.Weir@fda.hhs.gov; gweiss@uci.edu; daniela@lji.org; wilsonp@uchicago.edu; larry.wolfraim@nih.gov; dj56wood@gmail.com; xumiaobj@126.com; solomon.yimer@cepi.net; tlying@fudan.edu.cn; vyusibov@indianabiosciences.org; zlshi@wh.iov.cn; ZHOU, Tiequn; william.lee@health.ny.gov; ASiyer@mgh.harvard.edu; SCHWARTZ, Lauren; Nick.Gilbert@ed.ac.uk; Jilian.Sacks@finddx.org; jma@sgul.ac.uk; sujan@lji.org; dbarouch@bidmc.harvard.edu; qiang.pan-hammarstrom@ki.se; tomwhite42450@gmail.com; Liz.Miller@lshtm.ac.uk; emmanuelle.charton@edqm.eu; stanley-perlman@uiowa.edu
Subject: WHO Working Group on COVID-19 Assays
When: Wednesday, January 6, 2021 5:30 AM-6:30 AM (UTC-08:00) Pacific Time (US & Canada).
Where: https://who.zoom.us/j/3612568290

Agenda to follow.

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+1 470 250 9358 US (Atlanta)
+1 470 381 2552 US (Atlanta)
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+1 646 558 8656 US (New York)
+1 651 372 8299 US (Minnesota)
+1 786 635 1003 US (Miami)
+1 267 831 0333 US (Philadelphia)
+1 301 715 8592 US (Washington D.C)
+1 312 626 6799 US (Chicago)
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Join by SIP
3612568290@zoomcrc.com

Join by H.323
162.255.37.11 (US West)
162.255.36.11 (US East)
115.114.131.7 (India Mumbai)
115.114.115.7 (India Hyderabad)
213.19.144.110 (Amsterdam Netherlands)
213.244.140.110 (Germany)
103.122.166.55 (Australia)
149.137.40.110 (Singapore)
64.211.144.160 (Brazil)
69.174.57.160 (Canada)
207.226.132.110 (Japan)
Meeting ID: 361 256 8290

To: SCHWARTZ, Lauren[schwartzl@who.int]
Cc: Albrecht, Randy[randy.albrecht@mssm.edu]; Martha Alexander-Miller (Martha.Alexander-Miller@wakehealth.edu)[Martha.Alexander-Miller@wakehealth.edu]; AKelvin (AKelvin@dal.ca)[AKelvin@dal.ca]; danielle.anderson (danielle.anderson@duke-nus.edu.sg)[danielle.anderson@duke-nus.edu.sg]; Аракелов Сергей Александрович (s.a.arakelov@spbniivs.ru)[s.a.arakelov@spbniivs.ru]; JOHN JAMES BACZENAS[baczenas@wisc.edu]; BAMFORD, Pearl[Pearl.Bamford@health.gov.au]; Baric, Ralph S[rbaric@email.unc.edu]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; Martin.Beer (Martin.Beer@fli.de)[Martin.Beer@fli.de]; Neil Berry (Neil.Berry@nibsc.org)[Neil.Berry@nibsc.org]; terry.k.besch.ctr (terry.k.besch.ctr@mail.mil)[terry.k.besch.ctr@mail.mil]; c.blank@nki.nl[c.blank@nki.nl]; dbolton@hivresearch.org[dbolton@hivresearch.org]; mopargal (mopargal@rams.colostate.edu)[mopargal@rams.colostate.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; Brasel, Trevor[trbrasel@utmb.edu]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; abukreye (abukreye@utmb.edu)[abukreye@utmb.edu]; rcarrion (rcarrion@TxBiomed.org)[rcarrion@TxBiomed.org]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; Cartner, Samuel Corbin[scartner@uab.edu]; Cassels, Fred[fcassels@path.org]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; jfwchan (jfwchan@hku.hk)[jfwchan@hku.hk]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; hlchen (hlchen@hku.hk)[hlchen@hku.hk]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; scordo (scordo@qb.fcen.uba.ar)[scordo@qb.fcen.uba.ar]; lisette.cornelissen@wur.nl[lisette.cornelissen@wur.nl]; ian.crozier@nih.gov[ian.crozier@nih.gov]; kai.dallmeier (kai.dallmeier@kuleuven.be)[kai.dallmeier@kuleuven.be]; que.dang@nih.gov[que.dang@nih.gov]; Jorgen de Jonge (jorgen.de.jonge@rivm.nl)[jorgen.de.jonge@rivm.nl]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; mdiamond (mdiamond@wustl.edu)[mdiamond@wustl.edu]; CDillen@som.umaryland.edu[CDillen@som.umaryland.edu]; Dohm, Erik Daniel[edohm@uab.edu]; Donis, Ruben (OS/ASPR/BARDA)[ruben.donis@hhs.gov]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; Duprex, Paul[pduprex@pitt.edu]; Eitzen, Melissa M.[mmeitzen@utmb.edu]; l.enjuanes@cnb.csic.es[l.enjuanes@cnb.csic.es]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; mesteban (mesteban@cnb.csic.es)[mesteban@cnb.csic.es]; Falzarano, Darryl[darryl.falzarano@usask.ca]; feldmannh@niaid.nih.gov[feldmannh@niaid.nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Flynn, Joanne L[joanne@pitt.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; Juan García Arriaza (jfgarcia@cnb.csic.es)[jfgarcia@cnb.csic.es]; Adolfo.Garcia-Sastre (Adolfo.Garcia-Sastre@mssm.edu)[Adolfo.Garcia-Sastre@mssm.edu]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; anna (anna@thsti.res.in)[anna@thsti.res.in]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; Gerhards, Nora[nora.gerhards@wur.nl]; Christiane Gerke (christiane.gerke@pasteur.fr)[christiane.gerke@pasteur.fr]; Golding, Hana[Hana.Golding@fda.hhs.gov]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; GREY Finn (fgrey@exseed.ed.ac.uk)[fgrey@exseed.ed.ac.uk]; Griffiths, Anthony[ahgriff@bu.edu]; CarlosAlberto.Guzman (CarlosAlberto.Guzman@helmholtz-hzi.de)[CarlosAlberto.Guzman@helmholtz-hzi.de]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; rhakami@gmu.edu[rhakami@gmu.edu]; Yper.Hall (Yper.Hall@phe.gov.uk)[Yper.Hall@phe.gov.uk]; kevinharrod (kevinharrod@uabmc.edu)[kevinharrod@uabmc.edu]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; seos@cnu.ac.kr[seos@cnu.ac.kr]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; Hodgson, Paul[paul.hodgson@usask.ca]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jhogan@uga.edu[jhogan@uga.edu]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; jay.w.hooper.civ (jay.w.hooper.civ@mail.mil)[jay.w.hooper.civ@mail.mil]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; tomeri (tomeri@iibr.gov.il)[tomeri@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; dustin.johnson (dustin.johnson@canada.ca)[dustin.johnson@canada.ca]; kandeil_a (kandeil_a@hotmail.com)[kandeil_a@hotmail.com]; Amelia Karlsson (amelia.karlsson@duke.edu)[amelia.karlsson@duke.edu]; Bernhard Kerscher (PEI-DE) (bernhard.kerscher@pei.de)[bernhard.kerscher@pei.de]; Nadia KHELEF (nadia.khelef@pasteur.fr)[nadia.khelef@pasteur.fr]; sekim (sekim@krict.re.kr)[sekim@krict.re.kr]; Hwan K Kim (hwan.kim@stonybrook.edu)[hwan.kim@stonybrook.edu]; Jason Kindrachuk (Jason.Kindrachuk@umanitoba.ca)[Jason.Kindrachuk@umanitoba.ca]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; Harry Kleanthous (Harry.Kleanthous@gatesfoundation.org)[Harry.Kleanthous@gatesfoundation.org]; KNEZEVIC, Ivana[knezevici@who.int]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Gary Kobinger (Gary.Kobinger@crchudequebec.ulaval.ca)[Gary.Kobinger@crchudequebec.ulaval.ca]; fkoide (fkoide@southernresearch.org)[fkoide@southernresearch.org]; jeroen.kortekaas (jeroen.kortekaas@wur.nl)[jeroen.kortekaas@wur.nl]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; i.v.krasilnikov (i.v.krasilnikov@spbniivs.ru)[i.v.krasilnikov@spbniivs.ru]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; kupke (kupke@staff.uni-marburg.de)[kupke@staff.uni-marburg.de]; Paul.Lambert (Paul.Lambert@unige.ch)[Paul.Lambert@unige.ch]; mary.lane@nih.gov[mary.lane@nih.gov]; langermans (langermans@bprc.nl)[langermans@bprc.nl]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Roger Le Grand (roger.le-grand@cea.fr)[roger.le-grand@cea.fr]; LESELLIER Sandrine (sandrine.lesellier@anses.fr)[sandrine.lesellier@anses.fr]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; Levis, Robin[robin.levis@fda.hhs.gov]; mlewis (mlewis@bioqual.com)[mlewis@bioqual.com]; sean.li (sean.li@canada.ca)[sean.li@canada.ca]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; ldenisy (ldenisy@yahoo.com)[ldenisy@yahoo.com]; Kristine Macartney (kristine.macartney@health.nsw.gov.au)[kristine.macartney@health.nsw.gov.au]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Pauline Maisonnasse (pauline.maisonnasse@cea.fr)[pauline.maisonnasse@cea.fr]; Karen Makar

(Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Suchinda Malaivijitnond (suchinda.m@chula.ac.th)[suchinda.m@chula.ac.th]; ivan.marazzi@mssm.edu[ivan.marazzi@mssm.edu]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; paul-mccray (paul-mccray@uiowa.edu)[paul-mccray@uiowa.edu]; ThomasC.Mettenleiter (ThomasC.Mettenleiter@fli.de)[ThomasC.Mettenleiter@fli.de]; Chris Miller (cjmiller@ucdavis.edu)[cjmiller@ucdavis.edu]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; Ali.Mirazimi (Ali.Mirazimi@folkhalsomyndigheten.se)[Ali.Mirazimi@folkhalsomyndigheten.se]; dmissiak (dmissiak@bsd.uchicago.edu)[dmissiak@bsd.uchicago.edu]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; bobomok@hku.hk[bobomok@hku.hk]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Munir, Muhammad[muhammad.munir@lancaster.ac.uk]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; nnagata@niid.go.jp[nnagata@niid.go.jp]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; johan.neyts (johan.neyts@kuleuven.be)[johan.neyts@kuleuven.be]; SHELBY L O'CONNOR[slfeinberg@wisc.edu]; DAVID H O'CONNOR (dhoconno@wisc.edu)[dhoconno@wisc.edu]; horer@ku.edu.tr[horer@ku.edu.tr]; Oreshkova, Nadia[nadia.oreshkova@wur.nl]; mto@umn.edu[mto@umn.edu]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; gustavo.palacios (gustavo.palacios@gmail.com)[gustavo.palacios@gmail.com]; peter.palese@mssm.edu[peter.palese@mssm.edu]; nirp (nirp@iibr.gov.il)[nirp@iibr.gov.il]; Perlman, Stanley[stanley-perlman@uiowa.edu]; bradley.pickering (bradley.pickering@canada.ca)[bradley.pickering@canada.ca]; Pickett, Thames (NIH/NIAID) [E][picketttte@niaid.nih.gov]; margaret.l.pitt.civ (margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; PREZIOSI, Marie-pierre[preziosim@who.int]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; qinchuan (qinchuan@pumc.edu.cn)[qinchuan@pumc.edu.cn]; troyrandall (troyrandall@uabmc.edu)[troyrandall@uabmc.edu]; angierasmussen@gmail.com[angierasmussen@gmail.com]; Ann Rawkins (Ann.Rawkins@phe.gov.uk)[Ann.Rawkins@phe.gov.uk]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; patrick.reid@unmc.edu[patrick.reid@unmc.edu]; David Revelli (drevelli@lovelacebiomedical.org)[drevelli@lovelacebiomedical.org]; Juergen Richt (jricht@vet.k-state.edu)[jricht@vet.k-state.edu]; RIVEROS BALTA, Ximena[lauriex@who.int]; B.H.G. Rockx (b.rockx@erasmusmc.nl)[b.rockx@erasmusmc.nl]; estefania.rodriguez (estefania.rodriguez@bnitm.de)[estefania.rodriguez@bnitm.de]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; croy (croy@tulane.edu)[croy@tulane.edu]; Riccardo Russo[russori@njms.rutgers.edu]; rkiatchula (rkiatchula@gmail.com)[rkiatchula@gmail.com]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; esulkowska@rics.bwh.harvard.edu[esulkowska@rics.bwh.harvard.edu]; salgampa (salgampa@njms.rutgers.edu)[salgampa@njms.rutgers.edu]; Javier Salguero (Javier.Salguero@phe.gov.uk)[Javier.Salguero@phe.gov.uk]; erica (erica@lji.org)[erica@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; Segales, Joaquim[joaquim.segales@irta.cat]; snumouse (snumouse@snu.ac.kr)[snumouse@snu.ac.kr]; Seungtaek Kim (seungtaek.kim@ip-korea.org)[seungtaek.kim@ip-korea.org]; shanchao (shanchao@wh.iov.cn)[shanchao@wh.iov.cn]; Sally Sharpe (Sally.Sharpe@phe.gov.uk)[Sally.Sharpe@phe.gov.uk]; Schotsaert, Michael[michael.schotsaert@mssm.edu]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; YOO, Si Hyung[yoos@who.int]; Sivko, Gloria S[sivkog@battelle.org]; dean.smith (dean.smith@canada.ca)[dean.smith@canada.ca]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; SPERGEL@email.chop.edu[SPERGEL@email.chop.edu]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; Stewart, James[J.P.Stewart@liverpool.ac.uk]; stittelaar (stittelaar@viroclinics.com)[stittelaar@viroclinics.com]; kanta.subbarao (kanta.subbarao@influenzacentre.org)[kanta.subbarao@influenzacentre.org]; sutter (sutter@micro.vetmed.uni-muenchen.de)[sutter@micro.vetmed.uni-muenchen.de]; Tadaki (tksuzuki@nih.go.jp)[tksuzuki@nih.go.jp]; SWAMINATHAN, Soumya[swaminathans@who.int]; Techakitiroj Chatkul (tverakit@gmail.com)[tverakit@gmail.com]; tenoever@gmail.com[tenoever@gmail.com]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; franck.TOURET@univ-amu.fr[franck.TOURET@univ-amu.fr]; Treanor, John (OS/ASPR/BARDA) (CTR)[John.Treanor@hhs.gov]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; sktseng (sktseng@UTMB.EDU)[sktseng@UTMB.EDU]; Chi Van Dang (cdang@lcr.org)[cdang@lcr.org]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; neeltje.vandoremalen@nih.gov[neeltje.vandoremalen@nih.gov]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; Vergara, Julia[julia.vergara@irta.cat]; verschoor (verschoor@bprc.nl)[verschoor@bprc.nl]; verstrepen@bprc.nl[verstrepen@bprc.nl]; caroline.melo@rivm.nl[caroline.melo@rivm.nl]; Romain Volmer (romain.volmer@envt.fr)[romain.volmer@envt.fr]; Asisa.Volz (Asisa.Volz@tiho-hannover.de)[Asisa.Volz@tiho-hannover.de]; Tony.Wang (Tony.Wang@fda.hhs.gov)[Tony.Wang@fda.hhs.gov]; White, Alexander G[agw13@pitt.edu]; WOOD, David John[woodd@who.int]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; ZHOU, Tiequn[ZhouT@who.int]; ZHU, Jin[Jin.Zhu@health.gov.au]; tony.schountz@colostate.edu[tony.schountz@colostate.edu]; tcs38@psu.edu[tcs38@psu.edu]; NICOLAS DE LAMBALLERIE Xavier (xavier.de-lamballerie@univ-amu.fr)[xavier.de-lamballerie@univ-amu.fr]

From: MUNOZ FONTELA, Cesar[munozc@who.int]
Sent: Thur 1/7/2021 1:31:52 AM (UTC-05:00)
Subject: Re: WHO COVID-19 Animal Models Group Call

Dear all,
Small correction in the agenda below. See you all later

César

Agenda WHO COVID-19 Animal Models group call - Thursday January 7, 3PM CET (Geneva time)

1. Emily Speranza (NIAID)- *Single cell RNA sequencing reveals SARS-CoV-2 infection dynamics in lungs of African green monkeys.*
2. Luk Vandenberghe (Harvard)- *Mouse and NHP Immunogenicity of AAVCOVID: An AAV-based, single dose, room-temperature stable experimental COVID-19 vaccine*
3. Tony Schountz (CSU) - *Susceptibility of Deer Mice to SARS-CoV-2*

On 6. Jan 2021, at 22:26, SCHWARTZ, Lauren <schwartzl@who.int> wrote:

Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call - Thursday January 7, 3PM CET (Geneva time)

1. Emmie de Wit, PhD (NIAID)- *Single cell RNA sequencing reveals SARS-CoV-2 infection dynamics in lungs of African green monkeys.*
2. Luk Vandenberghe (Harvard)- *Mouse and NHP Immunogenicity of AAVCOVID: An AAV-based, single dose, room-temperature stable experimental COVID-19 vaccine*
3. Tony Schountz (CSU) - *Susceptibility of Deer Mice to SARS-CoV-2*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 3, 2021 8:34 PM
To: randy.albrecht@mssm.edu; Martha.Alexander-Miller@wakehealth.edu; AKelvin@dal.ca; danielle.anderson@duke-nus.edu.sg; s.a.arakelov@spbniivs.ru; baczenas@wisc.edu; Pearl.Bamford@health.gov.au; rbaric@email.unc.edu; dbarouch@bidmc.harvard.edu; sinabavari@comcast.net; Martin.Beer@fli.de; Neil.Berry@nibsc.org; terry.k.besch.ctr@mail.mil; c.blank@nki.nl; dbolton@hivresearch.org; mopargal@rams.colostate.edu; SBradfute@salud.unm.edu; trbrasel@UTMB.EDU; lisambrosseau@gmail.com; abukreye@utmb.edu; rcarrion@txbiomed.org; Miles.Carroll@phe.gov.uk; scartner@uab.edu; fcassels@path.org; Marco.Cavaleri@ema.europa.eu; lisa.chakrabarti@pasteur.fr; jfwchan@hku.hk; MONALISA.CHATTERJI@gatesfoundation.org; hlchen@hku.hk; carolyn.clark@cepi.net; scordo@qb.fcen.uba.ar; lisette.cornelissen@wur.nl; ian.crozier@nih.gov; kai.dallmeier@kuleuven.be; que.dang@nih.gov; jorgen.de.jonge@rivm.nl; emmie.dewit@nih.gov; mdiamond@wustl.edu; CDillen@som.umaryland.edu; edohm@uab.edu; Ruben.Donis@hhs.gov; william.dowling@cepi.net; mariette.ducatez@envt.fr; pduprex@pitt.edu; mmeitzen@utmb.edu; l.enjuanes@cnb.csic.es; Karl.Erlandson@hhs.gov; mesteban@cnb.csic.es; darryl.falzarano@usask.ca; feldmannh@niaid.nih.gov; clint.florence@nih.gov; joanne@pitt.edu; thomasf@primate.wisc.edu; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk; jfgarcia@cnb.csic.es; Adolfo.Garcia-Sastre@mssm.edu; golinger@mriglobal.org; anna@thsti.res.in; Volker.gerdts@usask.ca; nora.gerhards@wur.nl; christiane.gerke@pasteur.fr; Hana.Golding@fda.hhs.gov; barney.graham@nih.gov; lgralins@email.unc.edu; fgrey@exseed.ed.ac.uk; ahgriff@bu.edu; CarlosAlberto.Guzman@helmholtz-hzi.de; b.haagmans@erasmusmc.nl; rhakami@gmu.edu; Yper.Hall@phe.gov.uk; kevinharrod@uabmc.edu; HENAO RESTREPO, Ana Maria; lisa.hensley@nih.gov; seos@cnu.ac.kr; sheri.hild@nih.gov; paul.hodgson@usask.ca; christian.c.hofer.mil@mail.mil; jhogan@uga.edu; Michael.holbrook@nih.gov; jay.w.hooper.civ@mail.mil; y.jacob.hou@unc.edu; REIRELAND@

mail.dstl.gov.uk; tomeri@iibr.gov.il; mito@ciea.or.jp; Lakshmi.Jayashankar@hhs.gov; dustin.johnson@canada.ca; kandeil_a@hotmail.com; amelia.karlsson@duke.edu; Bernhard.Kerscher@pei.de; nadia.khelef@pasteur.fr; sekim@kribt.re.kr; hwan.kim@stonybrook.edu; Jason.Kindrachuk@umanitoba.ca; Jacqueline.Kirchner@gatesfoundation.org; Harry.Kleanthous@gatesfoundation.org; KNEZEVIC, Ivana; darwyn.kobasa@canada.ca; Gary.Kobinger@crchudequebec.ulaval.ca; fkoide@southernresearch.org; jeroen.kortekaas@wur.nl; florian.krammer@mssm.edu; i.v.krasilnikov@spbniivs.ru; philip.krause@fda.hhs.gov; kupke@staff.uni-marburg.de; Paul.Lambert@unige.ch; mary.lane@nih.gov; langermans@bprc.nl; david.lee-parritz@tufts.edu; Luis.Lugo.mil@afrims.org; roger.le-grand@cea.fr; sandrine.lesellier@anses.fr; MSLEVER@dstl.gov.uk; robin.levis@fda.hhs.gov; mlewis@bioqual.com; sean.li@canada.ca; grace.m.lidl.mil@mail.mil; James.Little@hhs.gov; ldenisy@yahoo.com; kristine.macartney@health.nsw.gov.au; Tracy.MacGill@fda.hhs.gov; pauline.maisonnasse@cea.fr; Karen.Makar@gatesfoundation.org; suchinda.m@chula.ac.th; ivan.marazzi@mssm.edu; LMartinez@txbiomed.org; Giada.Mattiuzzo@nibsc.org; paul-mccray@uiowa.edu; ThomasC.Mettenleiter@fli.de; cjmiller@ucdavis.edu; philip.minor2@gmail.com; Ali.Mirazimi@folkhalsomyndigheten.se; dmissiak@bsd.uchicago.edu; kmodjarrad@eidresearch.org; bobomok@hku.hk; SATHIYAMOORTHY, Vaseeharan; muhammad.munir@lancaster.ac.uk; munoz-fontela@bnitm.de; vincent.munster@nih.gov; nnagata@niid.go.jp; aysegul.nalca.civ@mail.mil;MNELSON@mail.dstl.gov.uk; johan.neyts@kuleuven.be; slfeinberg@wisc.edu; dhoconno@wisc.edu; horer@ku.edu.tr; nadia.oreshkova@wur.nl; mto@umn.edu; Mark.Page@nibsc.org; gustavo.palacios@gmail.com; peter.palese@mssm.edu; nirp@iibr.gov.il; stanley-perlman@uiowa.edu;bradley.pickering@canada.ca; pickettte@niaid.nih.gov; margaret.l.pitt.civ@mail.mil; PREZIOSI, Marie-pierre; JLPRIOR@dstl.gov.uk; qinchuan@pumc.edu.cn; troyrandall@uabmc.edu; angierasmussen@gmail.com; Ann.Rawkins@phe.gov.uk; Russell.Ray@bcm.edu; dsreed@cvr.pitt.edu; Matthew.Reed.mil@afrims.org; patrick.reid@unmc.edu; drevelli@lovelacebiomedical.org; jricht@vet.k-state.edu; RIVEROS BALTA, Ximena; b.rockx@erasmusmc.nl; estefania.rodriguez@bnitm.de; Nicola.Rose@nibsc.org; croy@tulane.edu; russori@njms.rutgers.edu; rkiatchula@gmail.com; Carol.Sabourin@hhs.gov; esulkowska@rics.bwh.harvard.edu; salgampa@njms.rutgers.edu; Javier.Salguero@phe.gov.uk; erica@lji.org; connie.schmaljohn@nih.gov; Barbara.Schnierle@pei.de; SCHWARTZ, Lauren; joaquim.segales@irta.cat; snumouse@snu.ac.kr; seungtaek.kim@ip-korea.org; shanchao@wh.iov.cn; Sally.Sharpe@phe.gov.uk; michael.schotsaert@mssm.edu; amy.c.shurtleff@cepi.net; YOO, Si Hyung; sivkog@battelle.org; dean.smith@canada.ca; mksong@ivi.int; SPERGEL@email.chop.edu; erik.stemmy@nih.gov; J.P.Stewart@liverpool.ac.uk; stittelaar@viroclinics.com; kanta.subbarao@influenzacentre.org; sutter@micro.vetmed.uni-muenchen.de; tksuzuki@nih.go.jp; SWAMINATHAN, Soumya; tverakit@gmail.com; tenoever@gmail.com; nax3@cdc.gov; JTorrelles@txbiomed.org; franck.TOURET@univ-amu.fr; John.Treanor@hhs.gov; Julia.Tree@phe.gov.uk; john.c.trefry.civ@mail.mil; sktseng@UTMB.EDU; cdang@lcr.org; luk_vandenberghe@meei.harvard.edu; wim.vanderpoel@wur.nl; neeltje.vandoremalen@nih.gov; Vasan.Vasan@csiro.au; y.m.vasiliev@spbniivs.ru; David.Vaughn@gatesfoundation.org; julia.vergara@irta.cat; verschoor@bprc.nl; verstrepen@bprc.nl; caroline.melo@rivm.nl; romain.volmer@envt.fr; Asisa.Volz@tiho-hannover.de; tony.wang@fda.hhs.gov; agw13@pitt.edu; WOOD, David John; tyamamoto@ciea.or.jp; ZHOU, Tiequn; Jin.Zhu@health.gov.au

Subject: WHO COVID-19 Animal Models Group Call
When: Thursday, January 7, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).
Where: https://who.zoom.us/j/3612568290

Agenda to follow.

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Join by SIP
3612568290@zoomcrc.com

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162.255.37.11 (US West)
162.255.36.11 (US East)
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149.137.40.110 (Singapore)
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69.174.57.160 (Canada)
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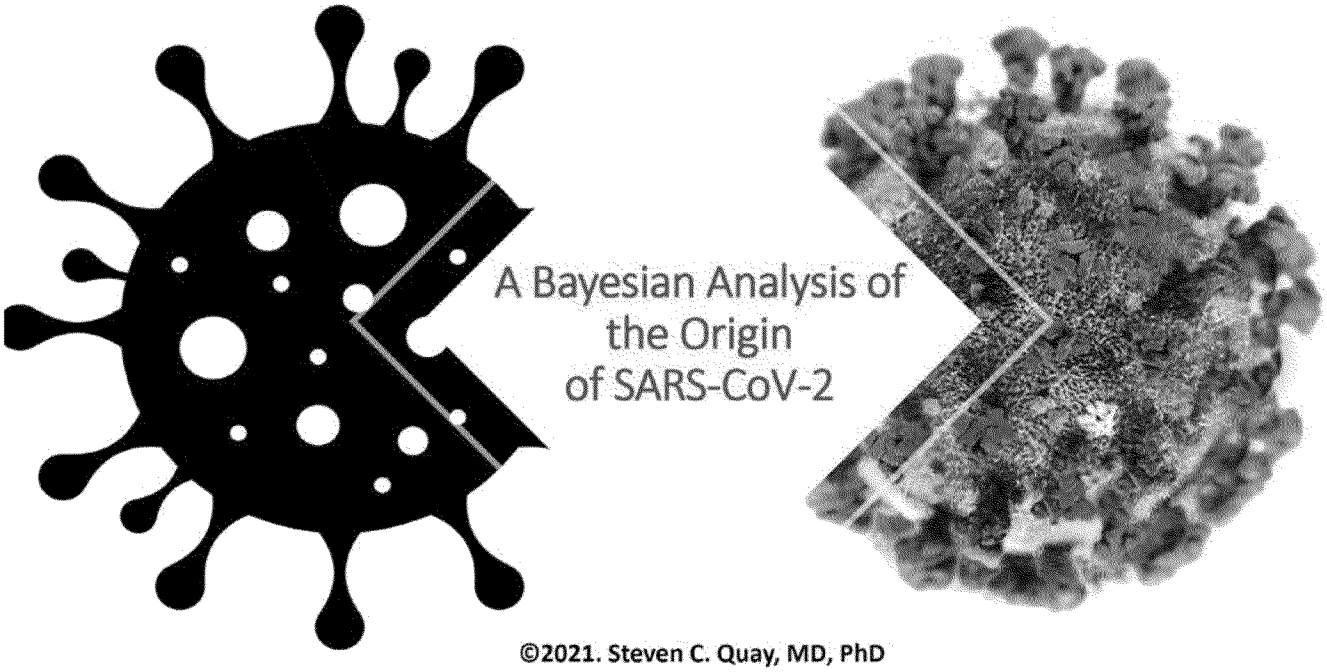
To: Baric, Ralph S[rbaric@email.unc.edu]
Cc: David A Relman[relman@stanford.edu]
From: David A Relman[relman@stanford.edu]
Sent: Thur 1/7/2021 5:59:15 PM (UTC-05:00)
Subject: Quay preprint
Bayesian Analysis of SARS-CoV-2 Origin - Rev 2.pdf



The cumulative circumstantial evidence that SARS-CoV-2 came from a laboratory is beyond a reasonable doubt

Evidence of adenovirus vaccine experimentation by the Wuhan Institute of Virology in hospitalized COVID-19 patients in December 2019 is documented

Executive Summary.

The one-year anniversary of the COVID-19 pandemic records 1.85 million deaths, 85.5 million confirmed cases, and trillions of dollars of economic damage. Although there is universal agreement that a coronavirus identified as Severe Acute Respiratory Syndrome Coronavirus 2 or SARS-CoV-2 (abbreviated CoV-2 henceforth) causes the disease COVID-19, there is no public understanding and consensus of the origin of the disease.

The Chinese government, WHO, media, and many academic virologists have stated with strong conviction that the coronavirus came from nature, either directly from bats or indirectly from bats through another species. Transmission of a virus from animals to humans is called a zoonosis.

A small but growing number of scientists have considered another hypothesis; that an ancestral bat coronavirus was collected in the wild, genetically manipulated in a laboratory to allow it to infect human cells and to make it more infectious, and then it was released, probably accidentally, in Wuhan, China. For most of 2019 this theory was considered a crackpot idea but in the last few weeks there has been more media attention on the possibility that the Wuhan Institute of Virology, in central Wuhan, may have been the source of the laboratory genetic manipulation and subsequent leak.

Given the majority bias in favor of a zoonosis and the massive effort undertaken by China to find an animal source, for political reasons, one can assume that any evidence in favor of a natural origin, no matter how trivial, would be widely disseminated. This provides a potential evidence bias in favor of a natural origin which isn't quantified but should be kept in mind.

This also becomes important when evidence can be used to support a laboratory origin that has been directly provided by leading Chinese scientists themselves, like Dr. Zhengli Shi, head of coronavirus research at the Wuhan Institute of Virology, by the Chinese government, or by powerful and vocal, pro-natural origin scientists, like Dr. Peter Daszak, of the NYC-based NGO, EcoHealth Alliance.

The report uses Bayesian inference, a common statistical tool in which Bayes' theorem, a well-known statistical equation, is used to update the likelihood for a particular hypothesis as more evidence or information becomes available. It is widely used in the sciences and has begun to be used in the law.

The starting probability for the zoonotic or natural hypothesis was set at 98.8% with the laboratory origin set at 1.2%. Each piece of new evidence for or against each hypothesis is then

used to adjust the probabilities. If evidence favors a natural origin the math adjusts upward the probability of a natural origin, and so on.

The final probability in this report of a laboratory origin for CoV-2 was 98.9% with a corresponding probability of zoonotic origin as 1.1%. This exceeds most academic law school discussions of quantifying 'beyond a reasonable doubt' in legal terms. The report contains the detailed quantitative basis for the statistics and can be referred to if necessary.

The following Text-Table summarizes the 21 pieces of evidence that were examined in this analysis and the change in probabilities of the origin for each step:

Evidence	Zoonotic Origin	Laboratory Origin
Initial State	98.8%	1.2%
Lack of evidence of prior seroconversion in China	95.0%	5.0%
Lack of posterior diversity	66.0%	34.0%
Lack of furin cleavage sites in any other sarbecovirus	17.7%	82.3%
Rare useage of -CGG- single codons & no CGG-CGG pairs	2.6%	96.9%
Routine use of CGG in laboratory codon optimization, including Daszak & Shi	1.1%	98.8%
Spike Protein receptor binging region (200 amino acids) optimized for humans	1.1%	98.9%
Whole genome analysis shows pre-adaption of CoV-2	1.1%	98.9%
The finding of CoV-2 in Barcelona wastewater in early 2019 was an artifact	1.1%	98.9%
Shi and the WHO comment early on that CoV-2 seemed to begin with a single patient	1.1%	98.9%
Mammalian biodiversity between Yunnan and Hubei is limited, reducing candidates for intermediate host	1.1%	98.9%
The ancestor of CoV-2 can only obtain a furin site from other subgenera viruses but recombination is limited/non-existent between subgenera	1.1%	98.9%
Canvas of 410 animals shows humans and primates are the best, bats are the worst, for ACE2-Spike Protein interaction	1.1%	98.9%
A government requested review of samples collected from a mineshaft may have caused the COVID-19 pandemic	1.1%	98.9%
The Hunan Seafood Market was not the source of the pandemic	1.1%	98.9%
Line 2 of the Wuhan Metro System is the likely conduit of the pandemic and is the subway line used by WIV employees	1.1%	98.9%
Feral and domestic cats are not the intermediate host	1.1%	98.9%
Extraodinary pre-adaption for the use of human tRNA is observed	1.1%	98.9%
Evidence of Lax and disregard of laboratory safety protocols and regulations in China	1.1%	98.9%
Previous SARS-CoV-1 laboratory accidents	1.1%	98.9%
Shi and Daszak use Wuhan residents as negative control for zoonotic coronavirus exposure	1.1%	98.9%
Appendix Information		
Evidence that Dr. Shi has published contrived data, making the credibility of everything she says suspect		
Evidence for and against RaTG13 as the direct precursor of CoV-2. I have not made up my mind on this important		
Remarkable evidence of the synthetic Adenovirus vector vaccine in patients sequenced at the WIV		

The summary which follows will simply be a review and discussion of the evidence in the context of the two hypotheses.

A zoonosis has at least three elements, a host, a virus, and the human population. With some viruses there is often a 'reservoir host' where the virus can live for years or even decades in a relatively stable relationship. The reservoir host is never decimated by the virus and the virus is never burned out by the reservoir host, disappearing completely. For coronaviruses the reservoir host is always one or more kinds of bat species.

For two prior human coronavirus epidemics, an intermediate or proximate host was identified. For SARS-CoV-1 in 2003-4 it was the civet cat while for Middle Eastern Respiratory Syndrome (MERS) in 2012-4 it was the camel. In both of these human epidemics the intermediate host was identified within four to ten months of the first clinically identified human infection. With CoV-2 we are at 12 months and still waiting, despite a much larger effort inside China. For both of these pandemics a bat species reservoir host was also identified.

Based on the genome sequence of CoV-2, Dr. Shi and Daszak have proposed that the reservoir host for CoV-2 is the intermediate horseshoe bat (*Rhinolophus affinis*), which lives in Yunnan Province. Yunnan Province is in southern, rural China and about 1900 km from the north central province of Hubei, where the 11 million people of Wuhan live. In the US it would be the distance and difference between the Everglades of Florida and New York City. The intermediate horseshow bat isn't found in Hubei province making a direct bat-to-human transmission improbable. Experiments in three independent laboratories also demonstrate that CoV-2 has changed genetically so much that it can no longer infect any bat species tested. So, while the leading US coronavirus expert, Dr. Ralph Baric of The University of North Carolina stated in early 2020 that CoV-2 may have jumped into the human population directly from bats without an intermediate host, this hypothesis is no longer viable.

For the zoonosis hypothesis to be advanced, it is now required to find an intermediate host. In December 2019 a theory was proposed that CoV-2 arose in the Huanan Seafood Market, a traditional Chinese "wet market" where live animals are butchered and sold. This theory was based on the observation that about 40% of early patients worked or shopped there. This was reminiscent of the wet market sources for civet cats for SARS-CoV-1 or the camel markets for MERS. The Chinese authorities closed the market on December 31, 2019 after performing extensive environmental sampling and sanitation.

But by May, 2020 Gao Fu, Director of the Chinese CDC, announced that the market was not the source of CoV-2 as all of the animal specimens were negative for CoV-2. And while SARS-CoV-1 was found in 100% of farmed civets when tested, CoV-2 was different. In July 2020 Dr. Shi reported that extensive testing of farmed animals in Hubei Province failed to find CoV-2. For about six months the pangolin, a scaly anteater, was suspected to be the intermediate host but finally Dr. Daszak had to report that CoV-2 was not found in pangolins in the wild or from the (illegal) market trade. Domestic and feral cats were also ruled out as a possible source. A comprehensive computer-based screen of 410 different animals reported the remarkable finding that the best hosts were primates (or primate cells) and included the favorite laboratory coronavirus host, the VERO monkey cell culture, and that all bats were the worst host. At the time of the writing of this report there is not even a working hypothesis of what is the intermediate host.

A zoonosis has a number of characteristic properties that can allow identification as a zoonotic infection even in the absence of finding an intermediate host. None of these properties are found for CoV-2.

They all have in common the principle that when nature uses evolution to allow a virus to move from, for example, a bat host to a camel host to a human host, it is a hit and miss, slow process. After all, evolution is random genetic changes, mutations, and then enrichment of the ones that are helpful by amplification during reproduction. With both SARS-CoV-1 and MERS, the virus spent months and years jumping from the intermediate host into humans, not having all of the best mutations needed to be aggressive, grow, and then spread, but enough to cause an infection and an immune response.

The hallmark evidence of this 'practice' in host jumping is in the stored or archived human blood specimens from before the epidemic, where one can find antibodies to the eventual epidemic virus. For SARS-CoV-1 and MERS, about 0.6% of people in the region where the epidemic began show signs of an infection in archived blood. With CoV-2, this seroconversion, as it is called, has never been found, including in over 500 specimens reported by the WHO. Because this is such a potent signal of a zoonosis and because we believe that China has over 100,000 stored specimens from Wuhan taken before 2020, the lack of reports of seroconversion, the silence from China on this, speaks volumes.

Another hallmark of this same, slow natural process can be found in the virus. In SARS-CoV-1 and MERS the coronavirus spent years in the intermediate host, passing back and forth among the hosts living in close proximity. During this time, they would accumulate a background of genetic mistakes, mutations. Usually about one mistake every two weeks. When the final chip falls and a mutation happens allowing the jump into humans, the virus with that new mutation also jumps around in the intermediate host population. The consequence of this latter behavior for a true zoonosis is that the genome sequences found in humans don't all descend from a single jump into a single human but show jumps from viruses that are only cousins of each other, not direct descendants. In a true zoonosis the family tree doesn't pass back through the first patient but instead meets together in an ancestor months or years earlier. This is called posterior diversity and is an easy genetic test to perform. With CoV-2, every one of the more than 200,000 virus genomes sequenced an be traced back to the first genomic cluster and patient, who was seen at the People's Liberation Army (PLA) Hospital about one mile from the Wuhan Institute of Virology. CoV-2 has the genetic signature of one pure virus sequence infecting one human; that is the one and only jump into the human population ever seen. This lack of posterior diversity has been reported by Dr. Shi, the WHO, and other prominent virologists; they just never take the evidence to the proper inference.

The virus in a zoonosis also contains the signatures of the gradual changes and adaptions it made in the protein key, the Spike Protein, it uses to unlock our cells and cause infection. With SARS-CoV-1 the first jump into humans had less than one-third of all the changes it would develop by the time it became an epidemic. With CoV-2 it was almost perfectly adapted to the human lock, with only a 0.5% improvement possible. The new strain that began in the UK was one of the 0.5% improvements for the virus.

Since with CoV-2 we have no evidence from stored blood that it was quietly practicing on humans in the community it is surprising that when it finds its first person, it has perfected to 99.5% its human attack ability. If this adaption couldn't have happened in the community, the only place it could have done this adaption work is in a laboratory, by what is called serial passage, repeatedly giving the virus a chance to practice on humanized mice or VERO cells. A related study of which of dozens of protein manufacturing tools CoV-2 uses (called tRNAs) shows the same uncanny adaption to the human tools with no evidence that the tools from other potential intermediate hosts would be suitable.

The evidence presented makes a strong case that CoV-2 did not come from nature but is there affirmative evidence that it came from a laboratory? The answer is yes.

The spike protein that gives the coronavirus its name, corona or crown, is the key to match with the lock found in host cells. But before it can inject its genetic material in the host cell, the spike protein needs to be cut, to loosen it in preparation for infection. The host cell has the scissors or enzymes that do the cutting. The singular unique feature of CoV-2 is that it requires a host enzyme called furin to activate it. No other coronavirus in the same subgenera have a furin cleavage site, as they are called. This is of course a major problem for the zoonosis theory, but it gets worse. Since 1992 the virology community has known that the one sure way to make a virus more deadly is to give it a furin site in the laboratory. At least eleven gain-of-function experiments, adding a furin site to make a virus more deadly, are published in the open literature. This has caused a flurry of Chinese papers trying to show a natural furin site in a related virus (later shown to be an error in interpretation) or to show that furin sites from distant cousins of CoV-2 might be the source through a process called recombination, where two viruses infect the same host and then make a mistake in copying their genetic material, and swap sequences. These hypothetical methods fail because the viruses that have furin sites are found in different host bats, in different regions of China, and even with these barriers, in the lab they are too far apart to recombine.

But it gets worse for the zoonosis theory. The gene sequence for the furin site in CoV-2 is a very rare set of codons, three letter words, that are never used together by coronaviruses in nature but are always used together by scientists in the laboratory when they want to add amino acids that code for the furin site. When scientists want to add an arginine codon to a coronavirus, they invariably use the word, CGG, but coronaviruses in nature rarely (<1%) use this codon.

So, there is no example of a furin protein site in nature that could be introduced into CoV-2 by recombination, there is no example of the particular gene sequence for the furin protein site of CoV-2 being used to code for anything in nature, but this particular coding is exactly what Dr. Shi and others have used in published experiments to insert genetic material.

It is telling that when Dr. Shi introduced the world to CoV-2 for the first time in January 2020 she showed hundreds of gene sequences of this novel virus but stopped short of showing the furin site, the one she had introduced, seemingly not wanting to call attention to her handywork. She apparently failed to realize that an accomplished <u>but innocent</u> virologist, finding the first furin site in this class of viruses apparently coming from nature, would have featured the

presence of the furin site prominently and would also predict from her experience what it would foretell for the world due to its aggressive nature.

Dr. Shi has denied the virus came from her lab, but she now created a record of multiple examples of obfuscation, half-truths, contrived specimens, genetic sequences taken from thin air, etc. that her veracity is deeply damaged. Perhaps her words and actions on December 30, 2019 show the truth. Her very first response when told there was an unknown outbreak in Wuhan and to return back quickly from a meeting in Shanghai was, "Could this have come from our lab?" Her other action on December 30 was to alter WIV computer databases of novel coronaviruses used by the world's virologists for research to make it more difficult to search for coronaviruses she had in her building. So the day the pandemic began in Wuhan she chose to cover up her work at the expense of transparency and cooporation.

The notion that CoV-2 was a laboratory creation, designed for maximum virulence, that escaped the laboratory accidentally has additional rings of evidence. From President Xi announcing in February new laws about laboratory security, to abundant evidence that the WIV was closed in October, to the top military medical research doctor, General Chen Wei, being placed in charge of the WIV, and many more, it is clear an event occurred sometime in late 2019 that is most consistent with a laboratory escape.

The Asian region has a two-decade record of a little over one laboratory-acquired infection per year. After the first SARS-CoV-1 patient and the epidemic was ended, SARS-CoV-2 jumped six more times into the human population, all from laboratories, with two in China. The last smallpox death was a secretary two floors above a research lab in England, who contracted it through the ventilation system. Over and over again there is a history and record of laboratory acquired infections that provides the background for considering what happened here.

But was SARS-CoV-2 more than just a gain-of-function experiment that escaped a laboratory? Could it have been one part of a two-part novel virus-vaccine bioweapons program?

General Ben Wei has been involved in vaccine research since joining the PLA after college. In a 2017 internal speech at the AMMS (Academy of Military Medical Sciences) she said: "只要有矛. 才能研究盾." which translates roughly as, "you need to have an arrow to study a shield."

In this context, genetic sequence evidence of an adenovirus vaccine used and developed by the Chinese has been found in five ICU patients from a Wuhan hospital in December 2019 who also had SARS-CoV-2 in their throat swab specimens. The Wuhan Institute of Virology conducted the sequencing on these specimens. This would be consistent with a vaccine challenge trial. There is evidence of an emerging H7N9 influenza component as well, as if this was a universal vaccine program.

I believe a Rubicon has been crossed by the world with this pandemic and framing the proper understanding of how we got here and the proper response will be the critical next steps.

When Oppenheimer saw the application of Einstein's physics in the embodiment of the atomic bomb he is said to have quoted a line from the Hindu scripture, the Bhagavad Gita, which reads: 'Now I am become Death, the destroyer of worlds.' The contribution of physics' research to human killing would total less than 300,000 people in two ten-square mile zones in Japan but would lead the world to regulate the raw materials of such bombs and to sanction sovereign nations who attempted to violate the rules.

This had followed on the contribution of chemistry to human killing in the form of chemical warfare during World War I, in which 100,000 were killed, and which led the nations of the world to an historic agreement to never use chemical warfare again. It is now only 'rogue' operators who violate the norms civilized nations have agreed to.

It seems to be biology's turn to show its dark arts. If it is generally understood that biology/biotechnology has been harnessed to create a pandemic that has killed more people than either physics or chemistry research combined and to be a weapon where no place on earth is safe from its effects (SARS-CoV-2 has been detected in the deepest Amazon jungles and at research stations in Antarctica), there needs to be developed a new set of regulations, rules, etc. to both honor the 1.8 million innocent people who died from COVID-19 and to protect the world so this never happens again. It is also urgent to gather further data to support or refute if this was a Chinese bioweapons program, as the consequences of that would be significant.

The cumulative circumstantial evidence that SARS-CoV-2 came from a laboratory is beyond a reasonable doubt

A two-hypothesis, Bayesian analysis was conducted to determine the origin of the SARS-CoV-2. The conclusion was that it was created in a laboratory with synthetic biology tools from a bat beta coronavirus, subgenera sarbecovirus backbone (98.9% probability) and not from a natural, zoonotic transmission (1.1%).

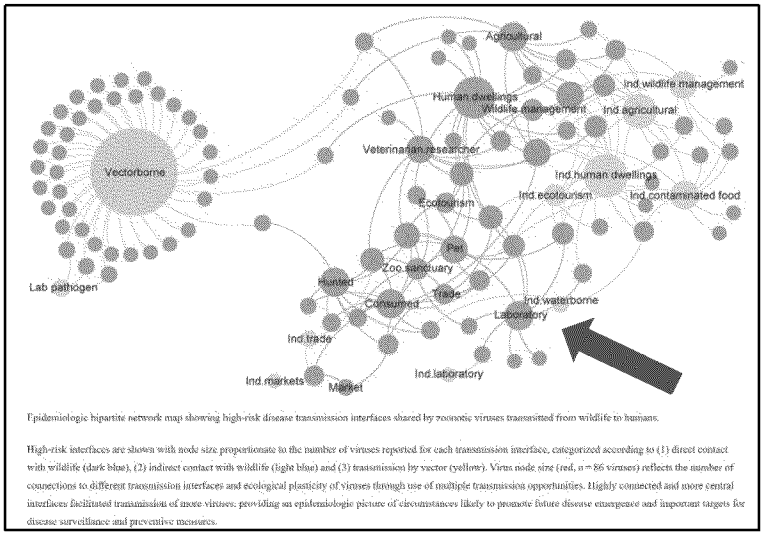
There is no direct evidence of whether the release was accidental or deliberate but circumstantial evidence makes it is highly likely it was accidental.

The most unusual evidence presented, which has not been fully reconciled, is the finding of adenovirus vaccine vector sequence data in human nasopharyngeal lavage specimens taken the end of December from ICU patients at Wuhan Jinyintan Hospital and sequenced at the Wuhan institute of Virology. A high priority of current research is understanding why these patients had vaccine vector sequences, as if from a nasally administered vaccine, and what the vaccine was directed against (it is not directed to Spike Protein from SARS-CoV-1 nor from the codon optimized SARS-Cov-2 Spike Protein). This data is contained in the Appendix.

Introduction. At the one-year anniversary of the first cases of COVID-19, the coronavirus pandemic caused by the SARS-CoV-2 virus, the origin of the virus remains unknown. While leading institutions and experts have been consistently adamant that it is a zoonotic disease which jumped from a bat reservoir host to humans directly or through an intermediate host the alternative possibility that it escaped from a laboratory conducting research remains a viable option.

In fact, in 2015 Peter Daszak, a leading zoonotic proponent of CoV-2 origin, wrote in, "Spillover and pandemic properties of zoonotic viruses with high host plasticity,"[1] that transmission from laboratories was a major source of zoonotic disease. The Figure below from the Daszak paper shows this important relationship (green arrow):

[1] https://www.nature.com/articles/srep14830

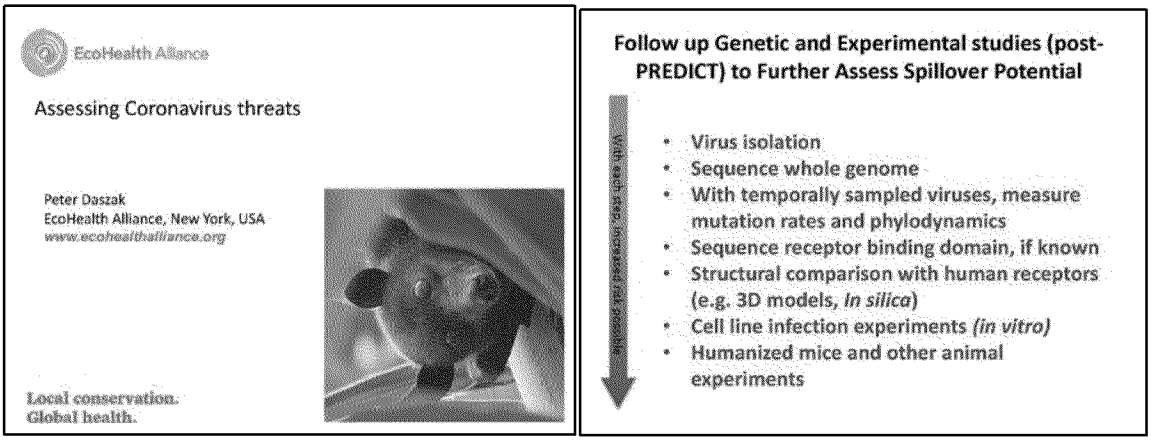


Epidemiologic bipartite network map showing high-risk disease transmission interfaces shared by zoonotic viruses transmitted from wildlife to humans.

High-risk interfaces are shown with node size proportionate to the number of viruses reported for each transmission interface, categorized according to (1) direct contact with wildlife (dark blue), (2) indirect contact with wildlife (light blue) and (3) transmission by vector (yellow). Virus node size (red, n = 86 viruses) reflects the number of connections to different transmission interfaces and ecological plasticity of viruses through use of multiple transmission opportunities. Highly connected and more central interfaces facilitated transmission of more viruses, providing an epidemiologic picture of circumstances likely to promote future disease emergence and important targets for disease surveillance and preventive measures.

Daszak et al. also writes: "**Zoonotic virus spillover** from wildlife was most frequent in and around human dwellings and in agricultural fields, as well as **at interfaces with occupational exposure to animals** (hunters, laboratory workers, veterinarians, researchers, wildlife management, zoo and sanctuary staff). **Primate hosts were most frequently cited as the source of viruses transmitted by direct contact** during hunting (exact P = 0.051) and **in laboratories** (exact P = 0.009)." [Emphasis added]. Primate "hosts" can presumably include monkey cell culture, such as the ubiquitous VERO cell used in all virology laboratories, including the WIV.

In 2015 Dr. Daszak spoke of the spillover danger of certain types of laboratory research:



He writes: "with each step, increased risk possible" with "Humanized mice and other animal experiments" the highest risk work.

In a prescient Twitter post in November 2019, he highlights the work he is doing using recombinant viruses with humanized mice and making viruses that "**don't respond to MAbs, vaccines…**" in response to criticism his work is of limited value:

Clearly, before the beginning of the pandemic, Daszak, a member of both the WHO and Lancet teams being sent to China to explore the origin of CoV-2, could entertain the possibility of a laboratory created virus escaping into the human population/community.

The purpose of this analysis is to use a Bayesian Network approach to the collected evidence that is available to provide likelihoods of the alternative hypotheses as to the origin of SARS-CoV-2. The analysis will also include certain prior probabilistic conclusions to help set the initial state before the proprietary evidence is used.

Origin hypotheses: Initial States to establish the posterior probabilities.

Two published Bayesian analyses and two independent studies of zoonotic spillover from nature and laboratory-acquired infections in Asia will be used to establish the posterior probabilities for this analysis.

Zoonotic spillover frequency versus laboratory acquired infection frequency based on two published papers, one by Daszak et al.

In 2015 Daszak et al. published a paper entitled, "Spillover and pandemic properties of zoonotic viruses with high host plasticity,"[1] in which they identified 162 zoonotic viruses with naturally occurring animal-to-human transmission from 1990-2010. This is a frequency of 162/20 = 8.1 events per year.

They also note: "The majority (94%) of zoonotic viruses described to date (n = 162) are RNA viruses, which is 28 times higher (95% CI 13.9–62.5, exact $P < 0.001$) than the proportion of RNA viruses among all vertebrate viruses recognized, indicating that RNA viruses are far more likely to be zoonotic than DNA viruses." CoV-2 is an RNA virus.

Finally, they note that: "In general, wild animals were suggested as the source of zoonotic transmission for 91% (86/95) of zoonotic viruses compared to 34% (32/95) of viruses transmitted from domestic animals and 25% (24/95) with transmission described from both wild and domestic animals."

One of the caveats of the Daszak data is that it categorizes a laboratory-acquired infection (LAI) from an animal acquired in the wild as a zoonotic spillover. There is no data in the paper to assess this issue and leaving it uncorrected is a conservative approach since it only inflates the zoonotic frequency.

In 2018 a paper by Siengsanan-Lamont entitled, "A Review of Laboratory-Acquired Infections in the Asia-Pacific: Understanding Risk and the Need for Improved Biosafety for Veterinary and Zoonotic Diseases," was published.[2] They reported 27 LAIs between 1982 and 2016, a frequency of 27/(2016 – 1982) = 0.8 events per year.

Using these historical frequencies of zoonotic spillover versus LAI to predict a future event can be calculated in the following manner:

Evidence	ZoonoticOrigin	LaboratoryOrigin
Frequency per year from Daszak paper	8.1	NA
Frequency per year from Siengsanan-Lamont paper	NA	0.8
Total events per year	8.1 + 0.8 = 8.9	8.1 + 0.8 = 8.9
Likelihood of future event based on historical frequency	8.1/8.9 X 100 = 0.91	0.8/8.9 X 100 = 0.9

Initial state analysis. This evidence sets the likelihood that CoV-2 was a zoonotic origin event at 91% and a laboratory origin event at 9%.

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6073996/

Independent prior analyses: Rootclaim.

The next data that will be used is a recent analysis published on the Rootclaim website.[3] Three hypotheses below were analyzed through a series of evidence statements and the probabilities that each was the origin of SARS-CoV-2 determined:

Hypothesis	Calculated Probability
Lab escape: The virus was the subject of genetic research, including gain-of-function, and was released by accident	81%
Zoonotic: The virus evolved in nature and was transmitted to humans from a non-human vertebrate animal	16%
Bioweapon: The virus was genetically engineered as a bioweapon and was deliberately released	3%

As can be seen, the highest likelihood probability is a lab escape. The details of the evidence used to arrive at this conclusion is contained in Appendix 1. A summary of the changes in probability at each level of evidence analysis is shown in this table:

Evidence	Laboratory	Zoonosis	Bioweapon
Starting point	1.2%	82%	16%
Contagion and mortality	1.4%	97%	1.9%
Outbreak location: Wuhan	42%	56%	2.8%
Virus sources near Wuhan	16%	83%	1.0%
Chimera	37%	60%	2.5%
Furin cleavage	72%	23%	4.8%
WIV lab procedures	80%	17%	3.5%
WIV disassociation	89%	9%	2.0%
Chinese response	90%	8%	1.7%
No reported infections at WIV	86%	11%	2.4%
No whistleblowers	81%	16%	2.8%

As can be seen, the starting point assumed an 82% probability of a zoonotic origin. This starting point is a reasonable value.

For purposes of this analysis only the Rootclaim initial state will be used since much of their evidence is also covered in the analysis here.

In a paper by Daszak and colleagues it states: "In general, wild animals were suggested as the source of zoonotic transmission for 91% (86/95) of zoonotic viruses compared to 34% (32/95) of viruses transmitted from domestic animals and 25% (24/95) with transmission described from both wild and domestic animals."[1]

[3] https://www.rootclaim.com/analysis/what-is-the-source-of-covid-19-sars-cov-2

On the other hand, domestic animals seem to have been ruled out for SARS-CoV-2. In an interview for *Science* in July 2020, Dr. Zhengli Shi, head of coronavirus research at the Wuhan Institute of Virology, stated: "Under the deployment of the Hubei Provincial Government, our team and researchers from Huazhong Agricultural University collected samples of farmed animals and livestock from farms around Wuhan and in other places in Hubei Province. We did not detect any SARS-CoV-2 nucleic acids in these samples."[4]

Reanalysis of Rootclaim initial state to remove Bioweapons option.

The US government uses the following definitions:

"Gain-of-function (GOF) studies, or research that improves the ability of a pathogen to cause disease, help define the fundamental nature of human-pathogen interactions, thereby enabling assessment of the pandemic potential of emerging infectious agents, informing public health and preparedness efforts, and furthering medical countermeasure development.

Gain-of-function studies may entail biosafety and biosecurity risks; therefore, the risks and benefits of gain-of function research must be evaluated, both in the context of recent U.S. biosafety incidents and to keep pace with new technological developments, in order to determine which types of studies should go forward and under what conditions."[5]

"Dual use research of concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. "[6]

For this analysis, the assumption is made that GOF and DURC are largely the same processes and techniques in the laboratory and thus can only be distinguished by direct, documentary evidence of the intent of the research from administers in the facilities conducting the work.

In the absence of any such documentary evidence that bioweapon research was being conducted or that SARS-CoV-2 is a bioweapon and to take the least inflammatory posture, the initial state for the above prior analysis will be recalculated by eliminating the hypothesis, and its accompanying probability, that SARS-CoV-2 was created as a bioweapon. The revised initial state calculation is shown in this table:[7]

Evidence	ZoonoticOrigin	LaboratoryOrigin	BioweaponsOrigin
Rootclaim initial state	0.86	0.012	0.16
Remove bioweapons	NA	NA	0
Normalize remaining hypotheses	0.86/(0.86+0.012) = 0.986	0.012/(0.86+0.012) = 0.014	NA

[4] https://www.sciencemag.org/sites/default/files/Shi%20Zhengli%20Q%26A.pdf
[5] https://www.phe.gov/s3/dualuse/Pages/GainOfFunction.aspx
[6] https://www.phe.gov/s3/dualuse/Pages/default.aspx
[7] For clarity, the 3% bioweapon probability was simply dropped and the remaining likelihoods, 81% and 16%, were normalized.

Rootclaim Initial state analysis, adjusted. This evidence sets the likelihood that CoV-2 was a zoonotic origin event at 98.6% and a laboratory origin event at 1.4%.

Additional Prior Evidence by Demaneuf and De Maistre. A second prior Bayesian analysis was performed by professionally educated risk assessment personnel and Chinese-language speaking professionals[8] and is included herein in its entirety. For the sake of brevity, the zoonotic origin evidence was based primarily of population size, distribution, and geographic distribution of bat populations relative to Wuhan. With respect to a lab accident, they separately analyze probabilities of a virus escape during collection, transport, and direct lab accidents and then separately the probability of a community outbreak following a lab escape. They also use primary Mandarin-language sources for Chinese estimates of the same events, showing corroboration of the probabilities. Their conclusion is that the probability of a lab escape ranges from 6% to 55% with a zoonotic origin a zoonotic origin probability being 45% to 94%.

Second Bayesian analysis. Using the most conservative probabilities, this evidence sets the likelihood that CoV-2 was a zoonotic origin event at 94% and a laboratory origin event at 6%.

Selection of initial state for Bayesian analysis.

The Text-Table below summarizes the three approaches to an initial state as to the origin of CoV-2. While the Demaneuf and De Maistre analyses set a range for the zoonotic origin of 45% to 94%, I have used the top of the range of their probability of a zoonotic origin to be conservative.

Prior Analysis	Zoonotic Origin	Laboratory Origin
Daszak et al. paper	91%	9%
Rootclaim Bayesian analysis	98.6%	1.4%
Demaneuf and De Maistre Bayesian analysis	94%	6%

Using a simple online calculator[9] the mean of these three value sets is 94.5%, the standard deviation is $\pm$ 3.8%, and the 95% confidence interval is $\pm$ 4.3%. Using these data, the upper bound of the 95% confidence interval is 98.8% and, to be most conservative, this will be used as the starting probability of a zoonotic origin.

Initial state for this analysis. The likelihood that SARS-CoV-2 began as a zoonotic event is 98.8% and the likelihood it began as a laboratory event is 1.2%.

[8] https://zenodo.org/record/4067919#.X-qIm9gzbOj . For reference purposes, this paper comes with a spreadsheet listing 112 individual BSL-3 labs in China across 62 lab-complexes.
[9] https://www.calculator.net/standard-deviation-calculator.html?numberinputs=91%2C+94%2C+98.6&ctype=s&x=48&y=19

1. General approach of this analysis[10]

This analysis is intended to examine two competing and mutually exclusive theories of the origin of the coronavirus, SARS-CoV-2 (CoV-2), and the pandemic it has caused, COVID-19.

At the time of this writing there have been 83 million confirmed cases and 1.8 million deaths.[11] Some sources place the economic damage at $21 trillion USD.

Theory One. The zoonotic theory is that a vertebrate animal was infected with CoV-2 or an ancestor (Index Host) and that a human was infected with contact to that Index Host in some manner. Human-to-human spread then followed.

Theory Two. The laboratory origin theory is that CoV-2 or an ancestor was being used in laboratory experiments and that it 'escaped' from the lab via an infected person, lab animal, experimental waste, etc.

I have found no evidence of a deliberate release and early firsthand accounts of local officials and scientists suggest surprise and consternation. If this was a deliberate release, such evidence would be extremely local, limited in distribution, and highly compartmentalized. It is beyond the scope of this analysis.

Weight of the evidence. For purposes of the calculation of posterior probabilities in the Bayesian analysis, evidence which has a statistical basis will be used directly to adjust the probabilities.

Since some of the probability calculations have astronomical values which would make a single such evidence statement, if inputted directly, swamp any further calculation and make their later contribution mute, a decision was made to simply treat quantitative probabilities as significant at the $p = 0.05$ level, no matter how much 'more significant' the calculation suggested.

So, for example, a probability of certain codon usage coming from nature may be one in 440 or $p = 0.002$, the contribution of this evidence to the input to the posterior probability adjustment would be set at a p-value of 0.05. In such cases the adjustment would be to change the 'winning' hypothesis by multiplying by 19, since a $p = 0.05$ is the same as a 19 out of 20 likelihood event. This is a conservative treatment of what would be highly significant data.

For evidence that cannot be quantified, the decision was made to treat these as quantitative outcomes with a 51% to 49% value with respect to the 'winning' hypothesis. This has the effect of increasing that hypothesis by 1.04. This is related to the legal standard of the 'preponderance of the evidence.'

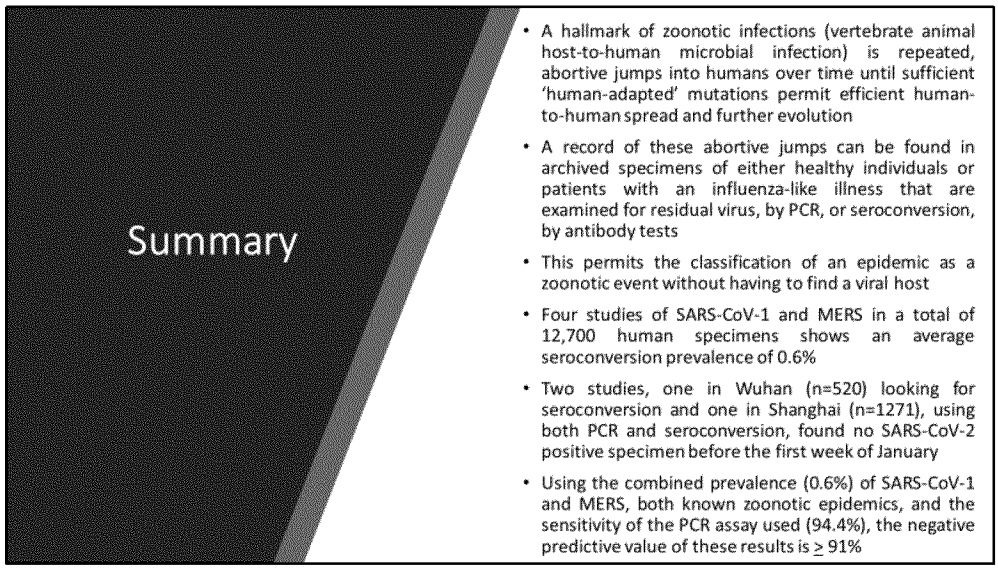
Because of the overall nature of the analyses here, all likelihoods are carried forward at the 'one significant figure' level, with standard rounding rules applied.

[10] The statistical approach and many of the individual statistical analyses were performed by Dr. Martin Lee, PhD, Adjunct Professor of Biostatistics, UCLA. https://ph.ucla.edu/faculty/lee The likelihood adjustments to the Bayesian analysis, which you can see are routine math, were conducted by the author.

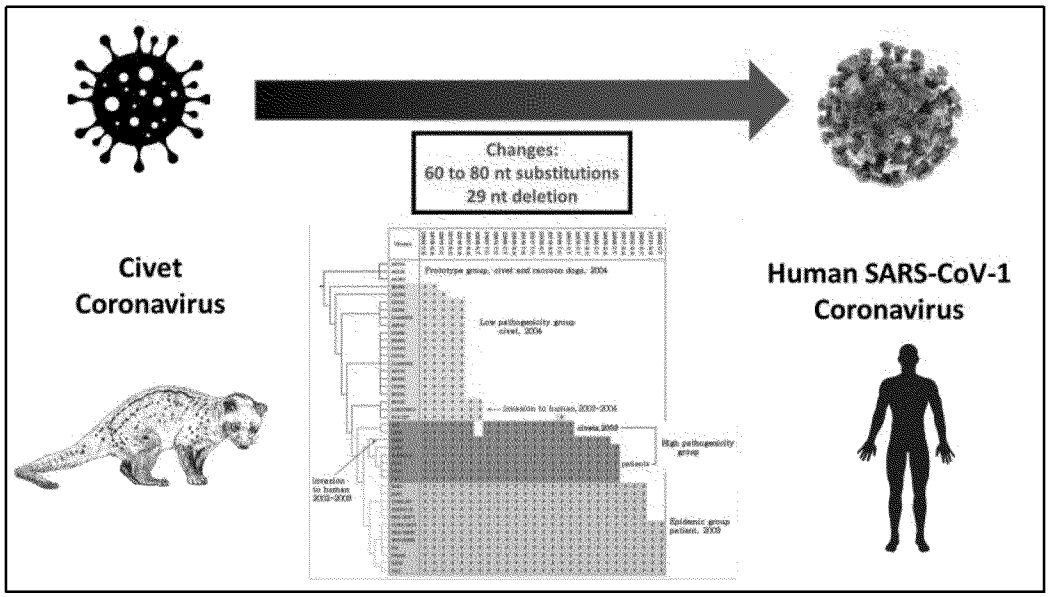
[11] https://www.worldometers.info/coronavirus/coronavirus-cases/

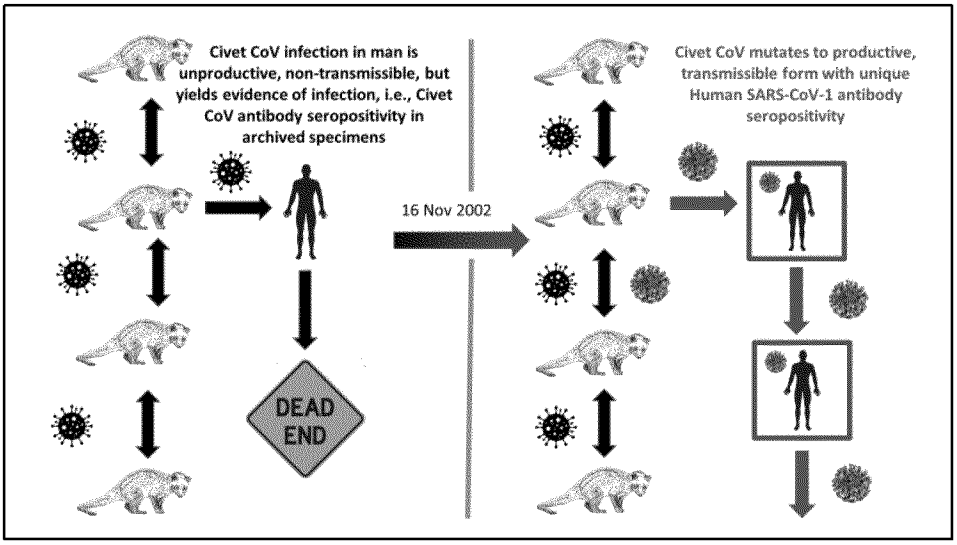
Evidence: Lack of seroconversion in Wuhan and Shanghai. Summary of evidence:

- A hallmark of zoonotic infections (vertebrate animal host-to-human microbial infection) is repeated, abortive jumps into humans over time until sufficient 'human-adapted' mutations permit efficient human-to-human spread and further evolution

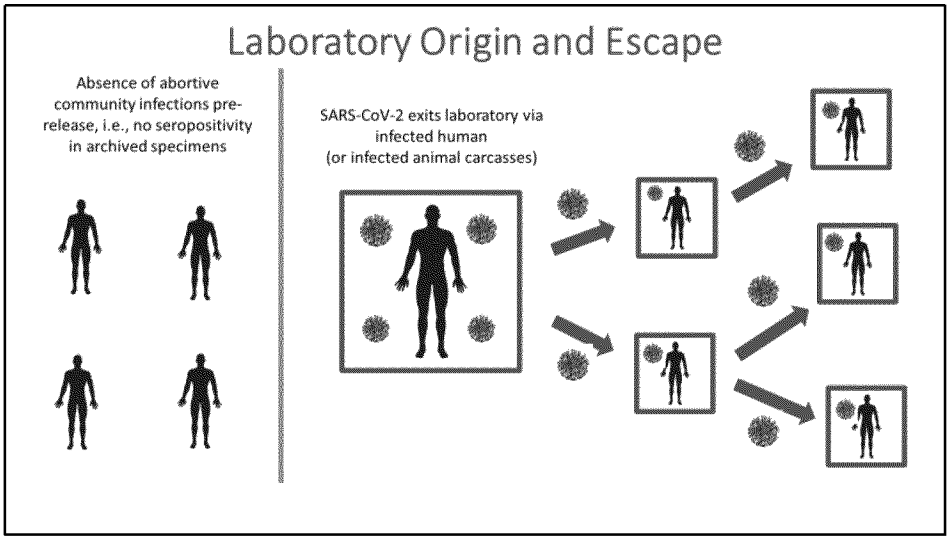


- A record of these abortive jumps can be found in archived specimens of either healthy individuals or patients with an influenza-like illness that are examined for residual virus, by PCR, or seroconversion, by antibody tests





- This permits the classification of an epidemic as a zoonotic event without having to find a viral host
- A laboratory accident is a situation in which there are no prior exposures within the human population as shown in the Figure below:



- Four studies of SARS-CoV-1 and MERS in a total of 12,700 human specimens shows an average seroconversion prevalence of 0.6%

SARS-related Virus Predating SARS Outbreak, Hong Kong

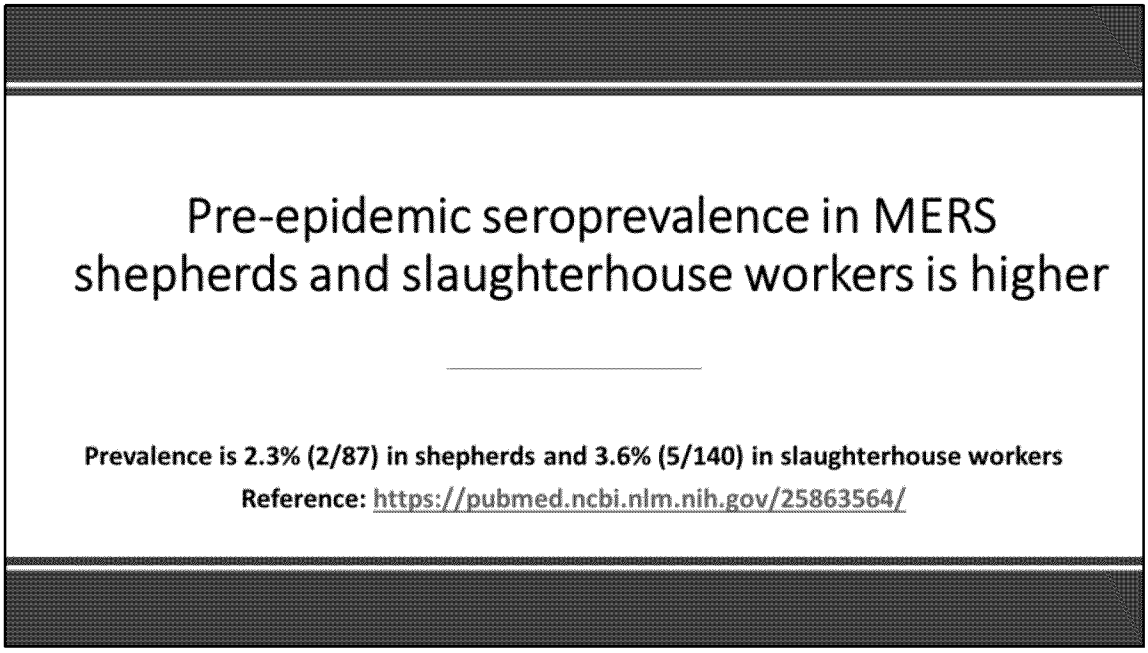
SARS-CoV-1 began in fall of 2002 in southern China

Patient Population	Serum samples collected in May 2001 from 938 healthy adults in Hong Kong	48 confirmed SARS patients diagnosed in February and March 2003 in Guangdong
Civet CoV > SARS-CoV-1 Seropositivity	**13**	**0**
SARS-CoV-1 > Civet CoV Seropositivity	**4**	**48**
Total	**17 out of 938 = 1.8%**	**48 out of 48 = 100%**

Pre-epidemic seroprevalence in the adult community

Prevalence is 0.6% for SARS-CoV-1 and MERS in 12,700 specimens

Epidemic	Nature of the Study	Seropositivity	Reference
SARS-CoV-1	Archived specimens from healthy adults in Hong Kong collected two years before CoV-1 were tested for Ab to civet or human CoV	**17/938**	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3322899/
MERS	Archived human sera collected in 2011 was tested for MERS-CoV S1-specific antibodies by ELISA	**1/90**	https://www.sciencedirect.com/science/article/pii/S1876034120300010#fig0010
SARS-CoV-1	Serum specimens collected from military recruits from the People's Republic of China in 2002 were tested for SARS-CoV-1 antibodies.	**11/1621**	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1074388/
MERS	Between Dec 1, 2012, and Dec 1, 2013, 10,009 individual serum samples were tested for anti-MERS-CoV antibodies in regions without cases.	**15/10,009**	https://pubmed.ncbi.nlm.nih.gov/25863564/
SARS-CoV-1	Serum samples that were collected from 42 individuals during 2001-2002, before the SARS outbreak, and tested for IgG antibody against SARS-CoV.	**28/42**	https://arxiv.org/ftp/arxiv/papers/1305/1305.2659.pdf

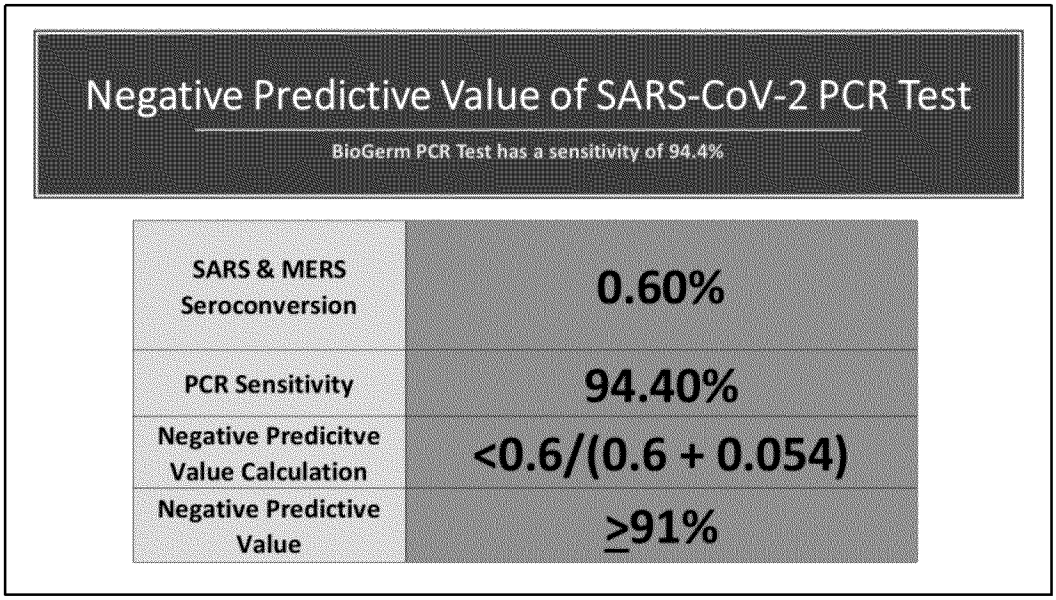


- Two studies, one in Wuhan (n=520) looking for seroconversion and one in Shanghai (n=1271), using both PCR and seroconversion, found no SARS-CoV-2 positive specimen before the first week of January

Pre-epidemic seroconversion has never been seen for SARS-CoV-2

Epidemic	Nature of the Study	Seropositivity	References
SARS-CoV-2	RNA PCR from 1271 nasopharyngeal swab samples, as well as the prevalence of IgM, IgG, and total antibodies against SARS-CoV-2 in 357 matched serum samples collected from hospitalized patients with influenza-like illness between 1 December 2018 and 31 March 2020 in Shanghai Ruijin Hospital. First positive was January 25, 2020.	0/1271	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7473166/pdf/TEMI_9_1785952.pdf
SARS-CoV-2	Re-analysed 5200 throat swabs collected from patients in Wuhan with influenza-like-illness from 6 October 2019 to week one January 2020 and found no positive specimens for SARS-CoV-2 RNA by quantitative PCR.	0/520	https://www.nature.com/articles/s41564-020-0713-1
	CoV-2 Studies Combined	**0/1791**	**Probability is one in 14,881**

- Using the combined prevalence (0.6%) of SARS-CoV-1 and MERS, both known zoonotic epidemics, and the sensitivity of the PCR assay used (94.4%), the negative predictive value of these results is $\geq$ 91%



Here, the negative predictive value (NPV) represents the probability that a CoV-2 is not a zoonosis, given the negative seroconversion findings.

Confidence: 90% (a one in 10 chance this is wrong). This is a subjective value.

The change in origin likelihoods from this evidence and the calculations are shown in the Text-Table below.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin
Starting likelihood	0.988	0.012
Negative predictive value of lack of seroconversion	0.91	
Reduced by 90% confidence	0.91 x 0.9 = 0.82	
Impact of this evidence	Reduces the likelihood of ZO by 82/18 or 4.6-fold. For every 100 tests, a true ZO would be seen 18 times and a non-ZO would be seen 82 times	
Impact of evidence calculation	0.988/4.6 = 0.215	
Normalize this step of analysis	0.215/(0.215 + 0.012) = 0.947	0.012/(0.215 + 0.012) = 0.053

Adjusted likelihood: Zoonotic origin (95%) and laboratory origin (5%)

Evidence: Lack of posterior diversity for SARS-CoV-2 compared to MERS and SARS-CoV-1

- The earliest stages of human CoV-1 and MERS infections were characterized by viral genome base diversity as expected for multiple, independent jumps from a large and diverse intermediate host population into humans.
- Combining MERS and CoV-1 studies, out of the earliest 255 human infections in which virus genome sequences are available, 137 could not be rooted in a prior human-to-human infection and so are attributed to an independent intermediate host-to-human infection.[12]
- That is about 54% non-human-to-human transmission.
- With CoV-2, there are 249 viral genomes in GISAID from Hubei province, where Wuhan is located, collected between Dec 24, 2019 and Mar 29, 2020.
- From Dec 24, 2019 to November 2020, there are 1001 genomes sequenced from all of China and 198,862 worldwide.
- For CoV-2, every single genome sequence is rooted in the first sequence from the PLA Hospital in Wuhan.
- Not one case of posterior diversity.
- Using the frequency of non-rooted genome diversity seen with MERS and CoV-1, about 50:50 or a coin toss, the probability that CoV-2 is a zoonotic pandemic with 0/249 genomes is the chance of tossing a coin 249 times and getting heads every time!
- Mathematically that is nonexistent; specifically, one in 10 with 84 zeros.
- Since Wuhan had approximately 500,000 cases during the time interval of this sampling, the potential sampling error of testing only 249/500,000 or 0.05% is significant. This sampling error, while large, is unable to obliterate the overwhelming odds that this did not arise from an intermediate host in Wuhan.
- Therefore, to permit continued evidence analysis, this finding will be set at the boundary of customary statistical significance, a p-value of 0.05 or a 1 in 20 likelihood that this is zoonotic.

Detailed explanation

A fundamental difference between a laboratory and a non-laboratory acquired zoonotic disease, the imprint of phylogenetic diversity through pre-human spread within the source population, can be examined by the posterior diversity of human cases with no *a priori* knowledge of an intermediate host.

[12] https://elifesciences.org/articles/31257#abstract ; https://www.researchgate.net/publication/225726653_Molecular_phylogeny_of_coronaviruses_including_human_SARS-CoV ; https://science.sciencemag.org/content/300/5624/1394/tab-pdf ; https://pubmed.ncbi.nlm.nih.gov/14585636/ ; https://www.microbiologyresearch.org/content/journal/jgv/10.1099/vir.0.016378-0?crawler=true ; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7118731/

MERS. The MERS epidemic has been documented to have arisen from the initial jump from bats to camels, a three to five year expansion within the camel population in which mutational diversity arose by random mistakes, and then a jump into humans. This model of spread predicts that there would, at some point, be additional jumps from other camels into other patients, and a pattern of "posterior diversity," would be found in the human specimens. If the COVID-19 pandemic arose by a similar mechanism the same pattern would be seen. The following Text-Table contains such data.

Phylogenetic Feature	MERS	SARS-CoV-2
Posteriority Diversity	28/30 (93%)	0
No Posteriority Diversity	2/30 (7%)	7666
Time from first patient to first example of posterior diversity	About 60 days	None at >120 days
Depth of posterior diversity to first patient	>365 days	None

The study of MERS noted above was published in 2013 in Lancet[13] in an article entitled, "Transmission and evolution of the Middle East respiratory syndrome coronavirus in Saudi Arabia: a descriptive genomic study." Thirty specimens were used in the analysis. The features of a camel-to-human zoonotic epidemic are easily identified. Specimens taken within sixty days of the first patient, "Patient Zero," began to show a background diversity that could not be traced back through Patient Zero. The analysis of all thirty, in fact, documented that 93% were transmitted directly from the camel intermediate reservoir. And looking only at the "background" diversity permitted a calculation of the last common ancestor for the spread within the camel population of over 365 days.

A study of SARS-CoV-2[14] available May 5, 2020 and entitled, "Emergence of genomic diversity and recurrent mutations in SARS-CoV-2," looked at 7666 patient specimens from around the world for phylogenetic diversity. The authors state: "There is a robust temporal signal in the data, captured by a statistically significant correlation between sampling dates and 'root-to-tip' distances for the 7666 SARS-CoV-2 ($R^2 = 0.20, p < .001$). Such positive association between sampling time and evolution is expected to arise in the presence of measurable evolution over the timeframe over which the genetic data was collected." This conclusion also argues against a MERS-like pattern of posterior diversity. In fact, the 95% upper bound for the probability of no posterior diversity being seen in SARS-CoV-2, given the data in MERS, is 3.9×10^{-4}.

The finding of posterior diversity in MERS was seen quickly, that is, within 60 days of the first patient and in only 30 specimens. In this study of COVID-19 the cutoff date of the 7666 specimens was April 19, 2020 or approximately 140 days after the first documented case. The

[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3898949/
[14] https://www.sciencedirect.com/science/article/pii/S1567134820301829

lack of posterior diversity in COVID-19 at a much later date than what was seen with MERS also argues against a non-laboratory source for this pandemic.

A useful avenue of future research for those working to find an animal source for COVID-19 would be new mathematical models or statistical methods that might find a "hidden" signal of posterior diversity in the current data set which shows none. And given access to the unprecedented quantity of human data for COVID-19 which can be mined via bioinformatics, efforts to find the "missing link" in the wild through search and sample should be a second priority to mining the human specimen data set.

SARS-CoV-1. A similar pattern of clinical cases that do not show a common ancestor in the human population but instead is evidence of posterior diversity is shown in the Text-Table on the left for SARS-CoV-1[15] compared to CoV-2 on the right[16]. SARS-CoV-1 shows clusters of cases in humans that are connected only by phylogenetic branches that reach back in time (all of the branches inside the purple box. This is because of the extensive mutational background created while being in the intermediate host, the civet. With CoV-2 on the right, every clinical case descends from the first clinical case, in the 19A clade. There are no background mutations to account for. I will show elsewhere that the first Clade A patient was at the PLA Hospital about 3 km from the WIV.

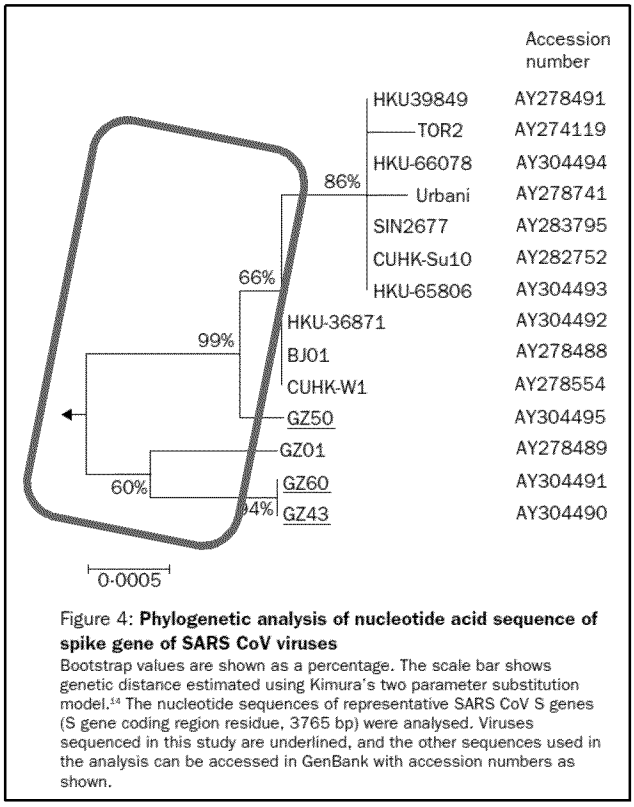
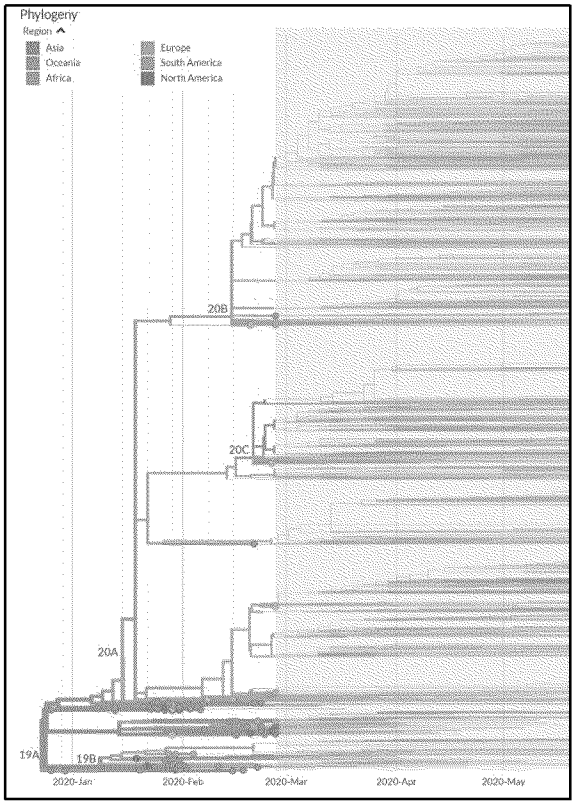
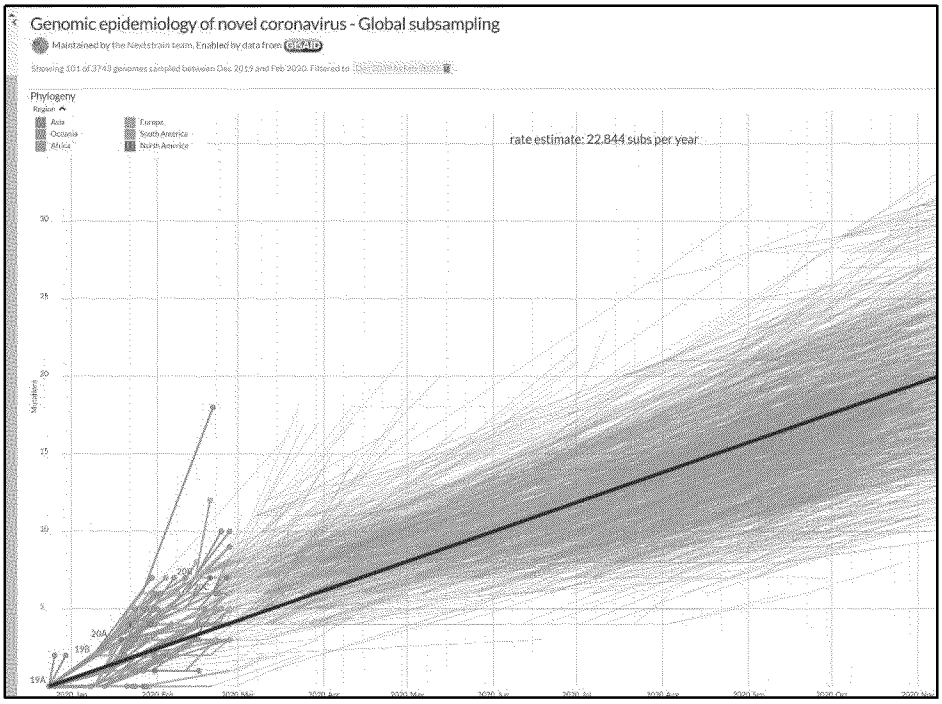


Figure 4: **Phylogenetic analysis of nucleotide acid sequence of spike gene of SARS CoV viruses**
Bootstrap values are shown as a percentage. The scale bar shows genetic distance estimated using Kimura's two parameter substitution model.[14] The nucleotide sequences of representative SARS CoV S genes (S gene coding region residue, 3765 bp) were analysed. Viruses sequenced in this study are underlined, and the other sequences used in the analysis can be accessed in GenBank with accession numbers as shown.



[15] https://pubmed.ncbi.nlm.nih.gov/14585636/
[16] https://nextstrain.org/

Given the rate of mutations of 22.8 per year for CoV-2 as shown in the Nextstrain graph below and a sequencing accuracy of about two calls per genome, CoV-2 could not have spent more than a few weeks in an intermediate host before a pattern of background mutations would be identified as posterior diversity. In the laboratory a pure culture on a single genome is used and the CoV-2 pattern is most consistent with a single pure culture infection a first human.

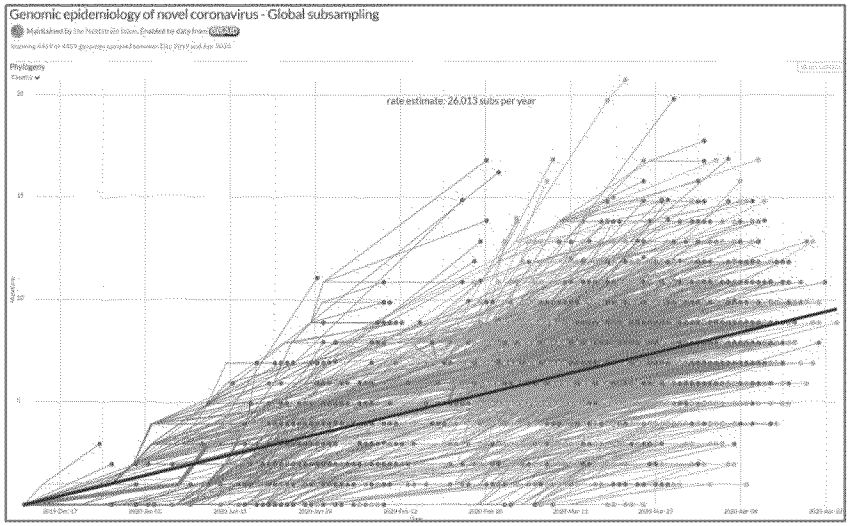


Non-zoonotic evolution. In a hypothetical in which there was a singular event in which one genetically pure virus infected one person and then the epidemic grow the development of the genetic diversity would have a clear, identifiable pattern: every new mutation would only appear on a background of the previous mutations.

The mutations in this virus are literally a personal tag. The general mutation rate leads to one mutation per patient. So by definition, Patient Zero will have just one mutation. And then the 2-4 people that patient passes it to will have that mutation and then will add a new one, and so on. As time goes by two things happen: each patient gets a new mutation of their own and they pass on all the mutations of the past.

Since the virus has 29,900 nt and the mutation rate, as shown in this graph prepared by NextStrain is 26 mutations per year, there is very little chance a mutation will appear and then later get undone. By carefully going back in time it is possible to literally name each person at each generation by the one (on average) new mutation they have and all of those that went before.

This graph of mutations on the Y-axis shows them gradually increasing and the color coding shows where they came from. In this infection, they only came from a previous patient and from the next previous patient and so on.



A NextStrain graphic.

How is that different from MERS, which was passed from camels to humans in a true zoonotic process?

In a true zoonotic spread to humans there is usually an initiating species (in MERS it is bats), and then an intermediate species (in MERS it is camels), and then it moves to man, either because of a new "enabling mutation" or for a non-domestic species, a chance encounter, and Source Zero and Patient Zero met and a cross species event occurs. But "Source Zero" doesn't stop there with one infection in one human; the virus also transmits itself vertically into the intermediate species. Source Zero also creates a vertical infection in the camels. Whether it is mild or not doesn't matter. The new human jumping gene is moving into a very diverse population of viruses, who have themselves been evolving since the first bat to camel transmission.

What is the outcome in terms of a test to show this is happening?

The diversity of the virus in humans begins to be so great and the spots where the mutations occur don't match up to MERS Patient Zero like they do in COVID-19. In MERS, the virus in Patient Zero and the virus in a later infection are not directly descendants but cousins and only descended from an earlier virus, who spent time in another camel population, collecting random mutations until it got the one it needed to infect humans and then it begins again.

The chart below, from Lancet. 2013 Dec 14; 382(9909): 1993–2002, shows just how this works. The patient at Bisha is the earliest case in this chart (Patient Zero in the red circle). But notice, no other case comes from that patient. They have such a diverse genetic background they appear to only be related to the Bisha virus with a posterior timeline of about one year. Their background is in the green boxes and it skips Patient Zero.

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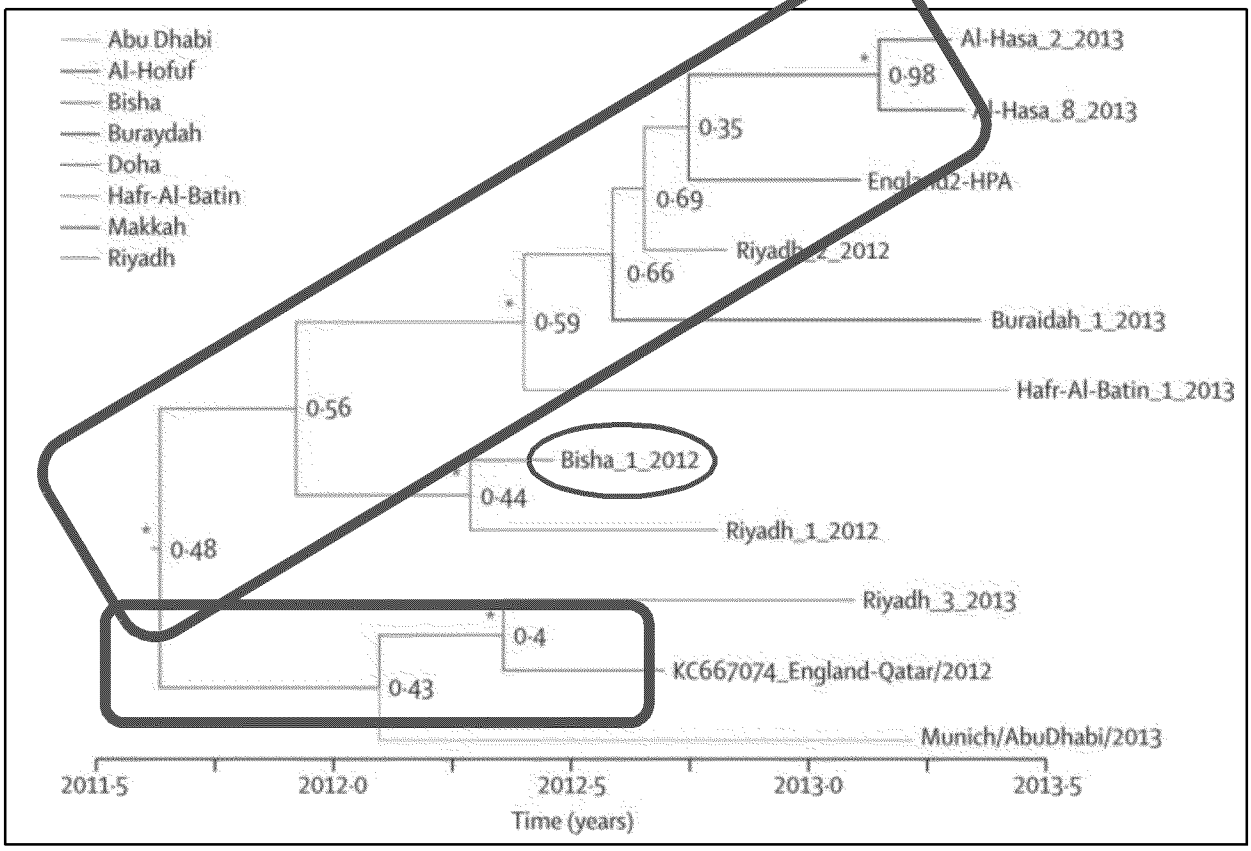


Even without knowing that camels are the zoonotic source for MERS, this data, from clinical sample only and without any field work in cave or camels, is all you need to know that this arose in the wild.

A paper just appeared with this analysis for a region of China and the posterior genomic diversity indicated a single starting point on December 1, 2019 for all cases. There was no posterior diversity. At this point with over 322,000 full genomes sequenced[17] and all showing an additive pattern of mutations and with none showing background diversity before the known appearance in Wuhan, the only conclusion is that there is no reservoir of genetic diversity.

On January 26, 2020 in an article in *Science* written by Jon Cohen, Kristian Andersen, an evolutionary biologist at the Scripps Research Institute who had analyzed sequences of 2019-nCoV to try to clarify its origin said: "The scenario of somebody being infected outside the market and then later bringing it to the market is one of the three scenarios we have considered that is still consistent with the data. It's entirely plausible given our current data and knowledge."

The negative predictive value of finding no posterior diversity in CoV-2 with 322,000 total infections sequenced, over 1000 in China, is 95%

Confidence: 95% (a one in 20 chance this is wrong)

[17] https://www.gisaid.org/

Below is the impact of the pack of posterior diversity on the likelihood of a zoonotic versus laboratory origin

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin
Starting likelihood	0.947	0.053
Negative predictive value of lack of posterior diversity	0.95	
Reduced by 95% confidence	0.95 x 0.95 = 0.90	
Impact of this evidence	Reduces the likelihood of ZO by 90/10 or 9-fold. For every 100 tests, a true ZO would be seen 10 times and a non-ZO would be seen 90 times	
Impact of evidence calculation	0.947/9 = 0.105	
Normalize this step of analysis	0.105/(0.105 + 0.053) = 0.66	0.053/(0.105 + 0.053) = 0.34

Adjusted likelihood: Zoonotic origin (66%) and laboratory origin (34%)

Evidence and Motive for laboratory genetic insertion:

A key to infectivity of coronaviruses is the addition, in nature or the laboratory, of a furin cleavage site (FCS) at the S1/S2 junction of the Spike Protein.

Furin cleavage sites (FCS) have been widely understood to be important for many viral infections, including HIV, influenza, and others. It has also been widely understood before now that lineage B coronaviruses do not have FCS.

It was therefore surprising when an examination of SARS-CoV-2 Spike Protein found an insertion of a 12-nt, 4-AA sequence near the junction of the S1/S2 subunits which creates a furin site which is essential to human infectivity and transmission. As expected from previous work, no lineage B (sarbecovirus) coronavirus has this feature. This is the most difficult "molecular fingerprint" of SARS-CoV-2 to explain having been acquired in the wild and for that reason there are no even passingly feasible theories.

One database of whole genome sequences of 386 coronaviruses was devoid of furin cleavage sites.[18] Another database of 2956 genomes of sarbecovirus strains sequences shows that none have a furin site.[19] This is a highly significant finding with a probability that sarbecovirus has a furin site in the wild of one in about 985.[20]

It has been known since 1994 that viral glycoproteins can be cleaved by secreted proteases, including furin.[21] Even before that, in 1992, it was known the peptide sequence R-X-K/R-R in surface glycoproteins was required for avian influenza viruses of Serotype H7 pathogenesis.[22] The first paper using furin inhibitors to define a role for an FCS in coronavirus-cell fusion was published in 2004.[23]

Since that time it has become common practice to insert FCS during laboratory gain-of-function experiments to increase infectivity. The following Text-Table illustrates the scope of just a few of the experiments conducted, with the hyperlink to the paper in column one.

URL for Paper	Title of Paper
One	Characterization of a panel of insertion mutants in human cytomegalovirus glycoprotein B.
Two	Insertion of the two cleavage sites of the respiratory syncytial virus fusion protein in Sendai virus fusion protein leads to enhanced cell-cell fusion and a decreased dependency on the HN attachment protein for activity.

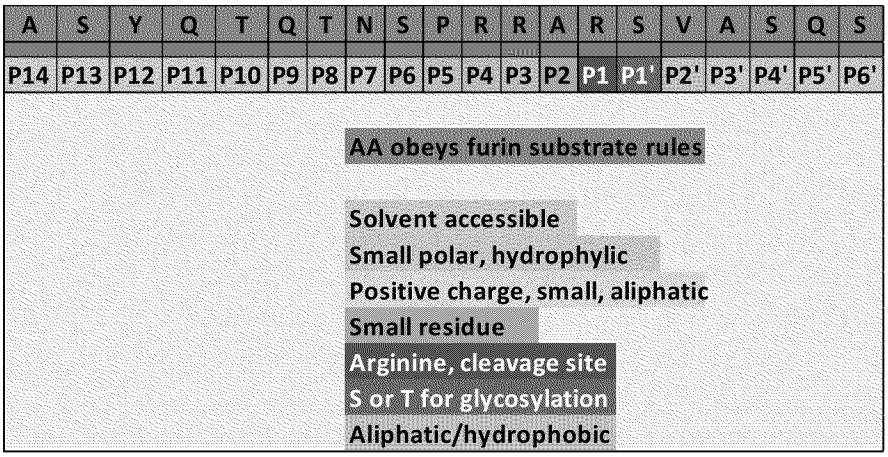
[18] https://academic.oup.com/bioinformatics/article/36/11/3552/5766118
[19] https://academic.oup.com/database/advance-article/doi/10.1093/database/baaa070/5909701
[20] When a series of samples are taken and none produce the result expected, the probability that this is a false negative finding can be estimated by taking the number of samples and dividing by three. Here, 2956 sarbecoviruses without a single furin site is a probability of one in 2956/3 or 985.
[21] https://www.ncbi.nlm.nih.gov/pubmed/8162439
[22] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7172898/pdf/main.pdf
[23] https://www.ncbi.nlm.nih.gov/pubmed/15141003

Three	Recombinant Sendai viruses expressing fusion proteins with two furin cleavage sites mimic the syncytial and receptor-independent infection properties of respiratory syncytial virus.
Four	Amino acid substitutions and an insertion in the spike glycoprotein extend the host range of the murine coronavirus MHV-A59
Five	Induction of IL-8 release in lung cells via activator protein-1 by recombinant baculovirus displaying severe acute respiratory syndrome-coronavirus spike proteins: identification of two functional regions.
Six	Coronaviruses as vectors: stability of foreign gene expression.
Seven	Experimental infection of a US spike-insertion deletion porcine epidemic diarrhea virus in conventional nursing piglets and cross-protection to the original US PEDV infection.
Eight	Minimum Determinants of Transmissible Gastroenteritis Virus Enteric Tropism Are Located in the N-Terminus of Spike Protein.
Nine	Reverse genetics with a full-length infectious cDNA of the Middle East respiratory syndrome coronavirus.
Ten	Construction of a non-infectious SARS coronavirus replicon for application in drug screening and analysis of viral protein function
Eleven	A severe acute respiratory syndrome coronavirus that lacks the E gene is attenuated in vitro and in vivo.

The creation in the wild of a coronavirus FCS that is used as an example of what might have happened in SARS-CoV-2 is uninformative. In this case a strain of influenza, in which a new polybasic site appears spontaneously leads to increased infectivity and lethality,[24] was reported by Tse *et al*. 2014. The mechanism of the FCS acquisition here was an RNA polymerase dependent stuttering at a small, constrained loop in which one or more A nt were inserted, removing the strain in the loop and inserting an AAA codon which represents the basic amino acid lysine. No such method was described for the insertion of arginine.

The insert generates a canonical 20 AA furin site sequence. In 2011 Tian et al.[25] published an analysis of 126 furin cleavage sites from three species: mammals, bacteria and viruses. The analysis showed that when the furin sites are recorded as a 20-residue motif, a canonical structure emerges. It includes one core cationic region (eight amino acids, P6–P2′) and two flanking solvent accessible regions (eight amino acids, P7–P14, and four amino acids, P3′–P6′).

[24] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3911587/
[25] https://www.nature.com/articles/srep00261



This figure above shows the 20-AA of the furin motif in SARS-CoV-2 (in green) with the P14 to P6' AA positions marked with the cleavage site being the amide bond between P1-R and the P1' residue. The motif is color coded with the requirements (in most cases, except for the positively charged AA requirements, most position requirements can be relaxed).

With the insertion, all 20 residues obey the rules as established by Tian. Since there are 20^4 different 4-AA peptides or 160,000 choices, it is remarkable that the 4 AA insert created a sequence that contained a small or cationic AA (8 AA/20 qualify), a cationic AA (3/20), another cationic AA (3/20), and a small AA (5/20) in that order. In fact, there are only 360 or the total or about 0.2% of all four amino acid inserts that would be expected to follow the exact rules for furin substrates. Of course, given the increase in infectivity SARS-CoV-2 has over other coronaviruses that do not have a well-designed furin cleavage site, selection pressure would drive this rare mutational event once it happened randomly. It would also be a likely choice for a laboratory designed furin cleavage site created *de novo*.

Based on the evidence that there are no furin cleavage sites in 2956 sarbecovirus (beta coronavirus) genome sequences[26], the likelihood that CoV-2 acquired the furin site from a wild sarbecovirus is one in 985 or 0.001. Because this is highly significant, we will use the conservative rule established in the beginning and use a likelihood of 0.05 for this evidence.

Confidence. 95% confidence (only a one in 20 chance this is wrong). Below is the calculation of the Bayesian adjustment.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin
Starting likelihood	0.66	0.34
Negative predictive value of a lack of furin sites in sarbecovirus genomes	0.95	
Reduced by 95% confidence	0.95 x 0.95 = 0.90	
Impact of this evidence	Reduces the likelihood of ZO by 90/10 or 9-fold. For every 100 tests, a true ZO would be seen 10 times and a non-ZO would be seen 90 times	
Impact of evidence calculation	0.66/9 = 0.073	
Normalize this step of analysis	0.073/(0.073 + 0.34) = 0.177	0.34/(0.34 + 0.073) = 0.823

Adjusted likelihood. Zoonotic origin (17.7%), laboratory origin (82.3%).

[26] https://academic.oup.com/database/advance-article/doi/10.1093/database/baaa070/5909701

Evidence: Codon usage can distinguish insertion events in the wild from those created in the laboratory.

Not only is the insertion of an FCS peptide unique among lineage B coronaviruses, the nt sequence used for the process is more broadly unique among coronaviruses in general, regardless of lineage:

-CCT-**CGG-CGG**-GCA-

I will now use synonymous codon bias methods to try to inform the question of the origin of SARS-CoV-2.

Because of the redundancy of the genetic code, more than one 3-nt sequence specifies any given amino acid. For example, there are six codons that specify arginine, R. The frequencies with which such synonymous codons are used are unequal and have coevolved with the cell's translation machinery to avoid excessive use of suboptimal codons that often correspond to rare or otherwise disadvantaged tRNAs. This results in a phenomenon termed "synonymous codon bias," which varies greatly between evolutionarily distant species and possibly even between different tissues in the same species.

Decades of research has identified that all life forms, viruses, bacteria, and humans, use the codons in a signature pattern of frequency which can be used to identify a particular sequence of RNA or DNA as human or non-human; viral or non-viral.

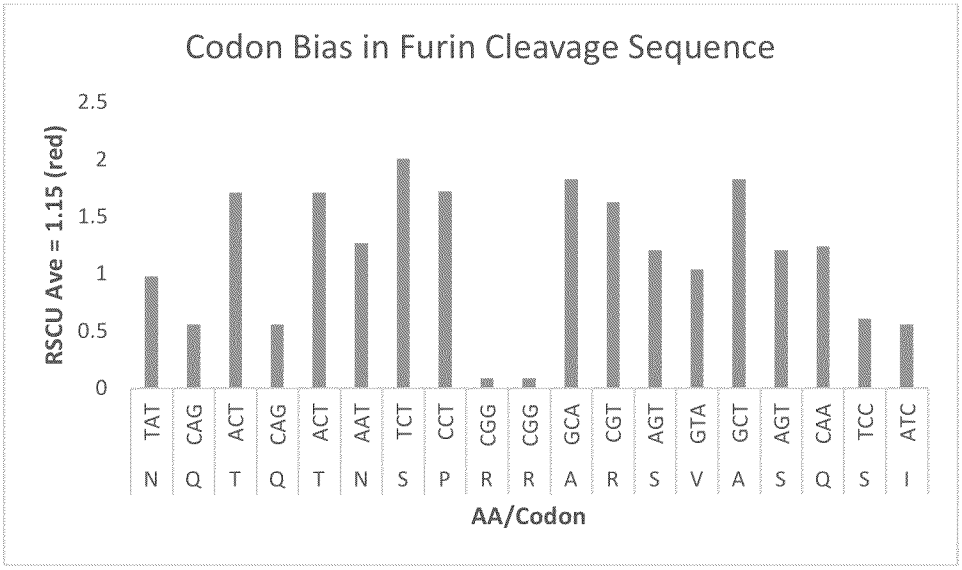
In this way, viruses in nature and scientists in the laboratory, with different goals and motivations, make distinguishing codon usage decisions which can sometimes be used as a fingerprint of their source.

The Text-Table below contains the arginine codon usage for two populations, pooled data for SARS-CoV 2003 and related viruses and 13 Sars-CoV-2 human specimens from widely dispersed locations.

Codon	SARS-CoV 2003 and ten other evolutionary related viruses in the Nidovirales	SARS-CoV-2 from 13 Geo-locations
CGG	0.09	0.09
CGA	0.44	0.37
CGC	0.72	0.37
AGG	0.9	1.07
CGU	1.77	1.63
AGA	2.08	2.48

Since these values are of a type of multiplicative scale, they were fit using a log-normal distribution, which appears appropriate (although the sample size is small). Using the log mean and standard deviation and this distribution, the probability of finding a CGG codon is about 0.024. Assuming they are independent the probability of finding a CCG-CCG codon pair is effectively 0.024^2 or 0.00058. This is a likelihood of about one in 1700.

The following Figure shows the RSCU for the amino acids that comprise the new furin cleavage site in SARS-CoV-2. As one can see, the RSCU values are similar to each other with the exception of the RR dimer insert, which have a very low RSCU of 0.09.



The RSCU value for the CGG codon for R of 0.09 was taken from a 2004 paper of the RSCU for SARS-CoV 2003 and ten other evolutionary related viruses in the *Nidovirales* and is confirmed by 13 SARS-CoV-2 specimens obtained from diverse geographic locations. If one assumes that the RSCU observations are independent and that the probability distribution of these measurements is Gaussian (normal; a reasonable assumption), then one can calculate the probability of obtaining a result as small as 0.09. Removing the two 0.09 values, then the mean and standard deviation of the remaining values are 1.275 and 0.4992, respectively. Then the probability of a single 0.09 value is 0.0088. However, there are two 0.09 values. If we assume that these are independent findings, then the probability of both values being seen is 0.0088^2 or 7.7×10^{-5}. Using the RSCU of 0.2 from the Table above does not change the immense improbability of the usage of a CGGCGG codon pair in the wild.

Single Arginine CGG codon usage analysis suggests this will not be found in the wild.

The codon usage for SARS-CoV-2, like most coronaviruses studied, has a bias toward AT and away from GC nucleotides. The frequency of third position G use in CoV-2, for example, is 13%, 21%, 17%, and 16% for the spike protein, envelope, membrane, and nucleocapsid protein, respectively.

In that context, the scarcity of the CGG genome in SARS-CoV-2 and related coronaviruses, the relative synonymous codon usage, determined by the method of Behura and Severson,[27] was calculated and tabulated below. The color coding is blue for underutilized codons (RSCU < 1.0) and red for overutilized codons (RSCU > 1.0); light blue for RSCU values of 0.60 to 0.99 and

[27] https://www.ncbi.nlm.nih.gov/pubmed/22889422

light red for RSCU of 1.01 to 1.60. The highest RSCU usage of CGG is 1.21 in the membrane protein in the MERS virus but zero in SARS-CoV-2.

RSCU	SARS-CoV-2	Beta CoV Pangolin	SARS CoV	Bat SARS CoV	MERS CoV
Spike	0.29	0	0.19	0.08	0.25
Envelope	0	0	0	0	0
Membrane	0	0.35	0.74	0.24	1.21
Nucleocapsid	0.41	0.16	0.03	0.04	0.8

Looking at these five coronaviruses:

The largest structural protein of the coronaviruses is the spike protein, with 1273 amino acids. In SARS-CoV-2 there are 42 R residues, with only one RR dimer, the one in the insert that created SARS-CoV-2.

As a reminder none of these related coronaviruses have the 12 nucleotide insertion that forms the putative furin site in CoV-2. Interestingly, the pangolin coronavirus has no CGG residues in the spike protein. The significance of this is it makes the acquisition of this insert from pangolin by recombination impossible.

The smallest structural protein, the envelope protein, has 75 amino acids, including three R residues, but has no CGG codons in any of the related coronaviruses examined.

The SARS-CoV-2 membrane protein has 441 amino acids, 14 R residues and no CGG codons. Among related coronaviruses, this is the most unique finding of the four proteins for SARS-CoV-2 since the other four coronaviruses all utilize CGG to some extent in this protein. In the case of the MERS virus, this protein is the only occurrence in which this codon is overutilized.

The nucleocapsid protein has 418 amino acids and is responsible for packing the RNA genome. As expected for the role of R in protein-RNA interactions, it has 29 R residues and four RR dimers. None of the dimers use the CGGCGG sequence.

The nt usage of the 12-nt insert which forms the FCS cleavage site has a probability this sequence was selected for in the wild of one in 129,870.

A blast search was performed for the 12-nt inserted sequence and adjacent extensions and only the SARS-CoV-2 sequences were identified.

Shortening the search to just the two CGG-CGG codons was only slightly more fruitful. The Text-Table below shows the frequency of the middle half of the insert, CGGCGG, across the genomes of all seven known human coronaviruses, as well as a specimen bovine coronavirus and the bat and pangolin coronaviruses with greatest homology to SARS-CoV-2. Only a single example, outside of the Spike Protein gene, has been found.

Furin PBCS sequence	Beta Coronavirus	Total Arginine Dimers Anywhere	CGGCGG in Spike Protein *	CGGCGG Anywhere in genome *	CCGCCG Anywhere in genome
SRRKRRS	Human CoV-HKU1 GenBank: KF686346.1	12	0	0	0
KRRSRRA	Bovine CoV-Quebec GenBank: AF220295.1	12	0	0	0
PRRARSV	**SARS-CoV-2 Wuhan reference sequence GenBank: NC_045512.2**	**16**	**1; nt 23,606**	0	0
PRSVRS	MERS-CoV NCBI Reference Sequence: NC_019843.3	21	0	0	0
NRRSRGA	Human CoV-OC43 London/2011 GenBank: KU131570.1	16	0	0	0
None	Human CoV-229E GeneBank: KF514433.1	15	0	0	0
None	Human CoV NL63 NCBI Reference Sequence: NC_005831.2	9	0	0	0
None	SARS-CoV 2003 ZJ0301 from China GenBank: DQ182595.1	17	0	0	0
None	Bat coronavirus RaTG13 GeneBank: MN996532.1	11	0	1; nt 9394	0
None	Pangolin PCoV_GX-P4L GenBank: MT040333.1	10	0	0	0
	Total	139	1	0	0
* - Includes both in phase codons as well as out of phase, frameshift codons.					

To understand what this means for the search for the zoonotic source for SARS-CoV-2, a statistical approach was taken. Using the data from the nine viruses other than SARS-COV-2 there was a single incidence of the CGGCGG found in the bat coronavirus. Assuming 10,000 codons per genome, the frequency of CGGCGG in coronaviruses can be estimated at 2 per 45,000 codons or 4×10^{-5}. Therefore, the frequency of finding the center half of the SARS-CoV-2 insert is very small. This is consistent with the strong bias in all coronaviruses to place an A/U nt in the third codon position.

The last column above, the presence of -CCG-CCG- in these coronaviruses was included because it is the hybridization sequence partner for the negative strand sequence, which arises during genome replication. This eliminates the possibility of a strand jumping event to generate a CGGCGG codon dimer.

A similar analysis for the spike protein gene can be done. Since there are no instances of CGGCGG in the spike protein genome, and the gene is 3819 nucleotides long, there are 636 pairs of codons Thus, over the 9 other viruses, there are 5724 pairs of codons and no cases of the CGGCGG pair. To calculate the upper bound on the probability of such a pair from these data, one can use the Poisson "Rule of Three", which yields a value of 3/5724 or 0.00052 with 95% confidence. Now examining the SARS-COV-2 genome, there was 1 instance of the pair in question out of 636 pairs. The probability of this happening if the true rate of this occurrence for a beta coronavirus is 0.00052 is 0.044. Obviously for smaller assumed rates of this occurrence, this would result in probabilities less than 0.044.

Since the 12-nt insert has been found nowhere in the coronavirus genomic universe, examining over 300,000 sequences and using the Poisson "Rule of Three" again, the upper bound on the frequency that it exists in nature is less than one in 100,000 with 95% confidence.

This observation in conjunction with the lack of finding the 12-nt sequence in any candidate zoonotic species makes unlikely a natural source for the virus. One line of investigation to establish a wild source for this infection would be to find a coronavirus strain with the 12-nt sequence in the wild somewhere. The fact that 10 of the 12 nts are either G or C coupled with the documented bias against GC suggests this search will futile.

Based on these analyses that demonstrate that the finding of a -CGG-CGG- codon pair in the furin site of CoV-2 is a highly improbable event and using the conservative value of a one in 20 chance (the value for a p-value of 0.05) one can recalculate the likelihood of the choice between a zoonotic origin and a laboratory origin.

Confidence. 95% confidence (only a one in 20 chance this is wrong). Below is the calculation of the Bayesian adjustment.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin
Starting likelihood	0.177	0.823
Negative predictive value of the absence of the -CGG-CGG- pair in any coronavirus in nature	0.95	
Reduced by 95% confidence	0.95 x 0.95 = 0.90	
Impact of this evidence	Reduces the likelihood of ZO by 90/10 or 9-fold. For every 100 tests, a true ZO would be seen 10 times and a non-ZO would be seen 90 times	
Impact of evidence calculation	0.177/9 = 0.022	
Normalize this step of analysis	0.022/(0.022 + 0.823) = 0.026	0.823/(0.823 + 0.026) = 0.969

Adjusted likelihood. Zoonotic origin (2.6%), laboratory origin (96.9%).

Evidence. Laboratory codon optimization uses CGG for laboratory insertions 50% of the time.

Codon optimization by recombinant methods (that is, to bring a gene's synonymous codon use into correspondence with the host cell's codon bias) has been widely used to improve cross-species expression of protein.

Though the opposite objective of reducing expression by intentional introduction of suboptimal synonymous codons has not been extensively investigated, isolated reports indicate that replacement of natural codons by rare codons can reduce the level of gene expression in different organisms. For example, one approach to vaccine development is to create an attenuated virus which comprises a modified viral genome containing nucleotide substitutions engineered in multiple locations in the genome, wherein the substitutions introduce synonymous de-optimized codons.

In US Patent 9,476,032[28] titled, "Attenuated viruses useful for vaccines," they state: "In one high-priority redesigned virus, most or all Arg codons are changed to CGC or **CGG** (the top two frequent human codons). This does not negatively affect translation." The patent contains numerous codon usages optimized for vaccine production, including the SARS-CoV virus, and in fact they use the CGG-CGG codon pair 45 times.

Beginning with a paper in 2004,[29] one motivation for codon-optimized SARS genomes is stated here: "The gene encoding the S protein of SARS-CoV contains many codons used infrequently in mammalian genes for efficiently expressed proteins. We therefore generated a codon-optimized form of the S-protein gene and compared its expression with the S-protein gene of the native viral sequence. S protein was readily detected in HEK293T cells transfected with a plasmid encoding the codon-optimized S protein."

Since that time human optimized codons have been frequently used for coronavirus research, mostly in gain-of-function experiments. In that context the "molecular fingerprint" of CGG for R is one of those common laboratory reagent gene manipulators.

Other examples:

Examples of the use of CGG codon for arginine in coronavirus research	**Reference**
SARS was genetically modified to improve ACE2 binding using "human optimized" codons, like CGG for arginine, to grow better in the laboratory. The strains were more infective.Preparation of SARS-CoV S protein pseudotyped virus. "The full-length cDNA of	Wu, K. et al. Mechanisms of Host Receptor Adaptation by Severe Acute Respiratory Syndrome

[28] http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=9476032.PN.&OS=PN/9476032&RS=PN/9476032

[29] https://www.ncbi.nlm.nih.gov/pubmed/15367630

the SARS-CoV S gene was optimized according to human codon usage and cloned into the pCDNA3.1(+) vector (Invitrogen). The resulting "humanized" S sequence was identical with that of strain BJ01 at the amino acid level."	Coronavirus. J Biol Chem. 2012 Mar 16; 287(12): 8904–8911.
Predictions of future evolution of a virus are a difficult, if not completely impossible, task. However, our detailed structural analysis of the host receptor adaptation mutations in SARS-CoV RBD has allowed us to predict, design, and test optimized SARS-CoV RBDs that may resemble future evolved forms of the virus. "RBD might evolve into the human-optimized form by acquiring two mutations at the 442 and 472 position." SARS-CoV-2 acquired the mutation at position 472.	Fang Li. Receptor recognition and cross-species infections of SARS coronavirus. Antiviral Res. 2013 Oct; 100(1): 246–254.
Plasmid encoding a codon-optimized form of the SARS-CoV S protein of the TOR2 i	Wenhui Li, Chengsheng Z, et al., Receptor and viral determinants of SARS-coronavirus adaptation to human ACE2. EMBO J. 2005 Apr 20; 24(8): 1634–1643.
The gene encoding the S protein of SARS-CoV contains many codons used infrequently in mammalian genes for efficiently expressed proteins. We therefore generated a codon-optimized form of the S-protein gene and compared its expression with the S-protein gene of the native viral sequence. S protein was readily detected in HEK293T cells transfected with a plasmid encoding the codon-optimized S protein (Fig. (Fig.1).1). No S protein was detected in cells transfected with a plasmid encoding the native S-protein gene.	Moore, MJ, Dorfman, T. Retroviruses Pseudotyped with the Severe Acute Respiratory Syndrome Coronavirus Spike Protein Efficiently Infect Cells Expressing Angiotensin-Converting Enzyme 2. J Virol. 2004 Oct; 78(19): 10628–10635.
Published in 2019 by **Dr. Zhengl-Li Shi,** entitled "Origin and evolution of pathogenic coronaviruses," reviews genetic optimized SARS viruses using human codons	Cui, J, Fang, L. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol. 2019; 17(3): 181–192.
In 2006, Montana scientists put a synthetic furin cleavage site into a SARS coronavirus by adding an R residue at position R667. They write: "We show that furin cleavage at the modified R667 position generates discrete S1 and S2 subunits and potentiates membrane fusion activity." Mutations were introduced by using	Follis, KE, York, J, Nunberg, JH. Furin cleavage of the SARS coronavirus spike glycoprotein enhances cell–cell fusion but does not affect virion entry. Virology 350 (2006) 358–369

QuikChange mutagenesis (Stratagene)[30]	
Identification of murine CD8 T cell epitopes in codon-optimized SARS-associated coronavirus spike protein is the title of a paper that shows that the expression of spike protein in vitro was greatly increased by expression cassette optimization.	Zhia, Y, Kobinger, GP, Jordan, H, et al. Identification of murine CD8 T cell epitopes in codon-optimized SARS-associated coronavirus spike protein
As for the human clec4C_1 and mouse clec14A, they showed very similar profiles with spike genes, especially with bat SARS-CoV, in the arginine coding groups, showing the high RSCU values over 2.50 in AGA.	Ahn,I, Jeong, B-J, Son, HS. Comparative study of synonymous codon usage variations between the nucleocapsid and spike genes of coronavirus, and C-type lectin domain genes of human and mouse. Experimental & Molecular Medicine volume 41, pages746–756, 2009.

One relevant paper,[31] in which arginine residues were being inserted into bovine herpesvirus-1, used primers to create RR dimers with nine separate -CGG-CGG- codon pairs. as testament to their broad use in the Wuhan Institute of Virology laboratory.

Scientists from the Wuhan Institute of Virology provided the scientific community with a technical bulletin on how to make genetic inserts in coronaviruses and proposed using the very tool that would insert this CGGCGG codon.

A Technical Appendix[32] entitled, "Detailed methods and primer sequences used in a study of genetically diverse filoviruses in Rousettus and Eonycteris spp. bats, China, 2009 and 2015, by Yang, Xinglou & Zhang, Yunzhi & Jiang, Ren-Di & Guo, Hua & Zhang, Wei & Li, Bei & Wang, Ning & Wang, Li & Rumberia, Cecilia & Zhou, Ji-Hua & Li, Shi-Yue & **Daszak, Peter** & Wang, Lin-Fa & **Shi, Zheng-Li.** (2017), from the Wuhan Institute of Virology identifies primer sequences for doing genetic experiments in coronaviruses and identifies CGG containing primers when a R amino acid is being inserted.

[30] Since the codon usage here was not reported I contacted Professor Nunberg to inquire which arginine codons were used. He replied: "Unfortunately, those files have all been archived and access to the nt sequences would involve considerable digging. If it is useful to you, I typically choose codons that are more frequent in highly expressed human proteins."

[31] From the Wuhan Institute of Virology; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7125963/

[32] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5382765/

Given that there are two codons of six possibilities that are used in codon optimization, CGG and CGC, the finding of a CGG pair would have a likelihood of happening by chance of (2/6) times (2/6) or one in nine.

Confidence: 80% (this has a probability of being wrong one in five times). This is arbitrary. The calculation to make this adjustment in likelihood is shown here:

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin (LO)
Starting likelihood	0.026	0.969
This is the outcome expected 8 of 9 times if this is codon optimization		0.88
Reduced by 80% confidence		0.88 x 0.8 = 0.704
Impact of this evidence		Increases the likelihood of LO by 70.4 divided by 29.6 or 2.378.
Impact of evidence calculation		0.969 x 2.378 = 2.304
Normalize this step of analysis	0.026/(2.304 + 0.026) = 0.011	2.303/(0.026 + 2.304) = 0.988

Adjusted likelihood: Zoonotic origin (1.1%), laboratory origin (98.8%).

Evidence: SARS-CoV-2 Spike Protein is Highly Optimized for ACE2 Binding and Human Cell Infectivity, a Finding that is Inconsistent with Natural Selection but is Consistent with Laboratory Creation

Summary:

- Andersen et al.[33] hypothesized that if the CoV-2 interaction with the human ACE2 was apparently "not ideal," it was evidence that CoV-2 arose by natural selection.

- The alternative hypothesis would be that a finding that CoV-2 was optimized for ACE2 binding and human infection from the initial infection would be evidence of laboratory creation.

- Andersen relied on a paper for the "not ideal" interaction that relied on a computer algorithm rather than laboratory data, was qualitative in nature, sampled only five amino acids or 0.45% of the interaction region, and was over-interpreted.

- The analysis of the Baric et al. paper cited by Andersen as evidence the interaction was not ideal was reexamined and it was concluded that Andersen had over-interpreted the paper. The paper was a computer simulation study of only 5 of 201 amino acids in the CoV-2-ACE2 interaction region. Only one of the five amino acids discussed was said to be inferior to the equivalent amino acid in SARS-CoV-1; the remainder were either positive or neutral with respect to binding.

- A comprehensive, laboratory-based, and quantitative paper by Starr et al. of all 201 amino acids in the receptor binding region, not just five amino acids, was examined. Fully 99.6% of all of the possible 3819[34] amino acid substitutions were tested for their effect on CoV-2 binding to ACE2. Only 21 substitutions of the 3819 improved ACE2 binding. Therefore, CoV-2 has been optimized for human ACE2 binding in 99.45% of the possible amino acids in its Spike Protein interaction region.

- To support this finding, Starr also made an examination of 31,570 CoV-2 sequences from human infections, looking for the 21 substitutions that had been show to improve CoV-2 binding in the above in vitro laboratory experiments. Among the 31, 570 CoV-2 cases, they failed to find even a single case in which there was an amino acid substitution that improved binding at the time of writing this analysis.[35]

[33] https://www.nature.com/articles/s41591-020-0820-9

[34] There are 201 amino acids in the residue 331 to 531 interaction region and so 201 times the 19 possible alternative amino acids not found in CoV-2 equals 3819.

[35] The recent finding of the N501Y variant, first in the UK, and now spreading globally, is evidence of the power of this analysis. N501Y is one of only five potential substitutions in the Starr analysis that had a major effect in improving ACE2 binding.

- Based on Andersen's hypothesis and its alternative, SARS-CoV-2 is fully optimized for interaction with the human ACE2 receptor and was at the time of the first patient. There is no evidence of an evolving SP binding region, as was seen with SARS-CoV-1. This is consistent with a laboratory optimized coronavirus which entered the human population fully evolved.

Analysis

Quote from Andersen: 'While the analyses above suggest that SARS-CoV-2 may bind human ACE2 with high affinity, computational analyses predict that the interaction is not ideal (reference 7) and that the RBD sequence is different from those shown in SARS-CoV to be optimal for receptor binding (references 7,11).

Thus, the high-affinity binding of the SARS-CoV-2 spike protein to human ACE2 is most likely the result of natural selection on a human or human-like ACE2 that permits another optimal binding solution to arise. This is strong evidence that SARS-CoV-2 is not the product of purposeful manipulation."

The apparent **hypothesis** for the above conclusion is:

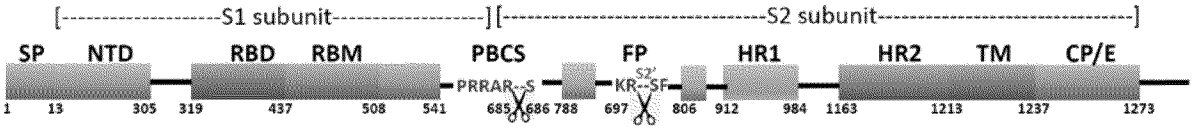
"If the SARS-CoV-2 (CoV-2) Spike Protein interaction with the ACE2 receptor is not maximized, then it is evidence that the interaction is the product of natural selection and not purposeful (laboratory) manipulation."

This would lead to an **alternative hypothesis**:

"If the CoV-2 Spike Protein interaction with the ACE2 receptor is maximized, then it is evidence that the interaction was the product of purposeful (laboratory) manipulation."

Background.

The Spike Protein (SP) structure and its functional domains are shown in this Figure. The S1 subunit is the initial host interaction portion while the S2 is the post-binding portion responsible for initiating host cell entry, with HR1, HR2, and TM being responsible for breaching the host cell membrane. Allowing viral RNA to enter the cell.



The interaction of the SP portions which interact with the ACE2 of the host cell, which begins the internalization, infectious process, are contained in the Receptor Binding Domain (RBD) and to a lesser extent the Receptor Binding Motif (RBM), specifically residues 331 to 531. Herein, residues 331 to 531 are called the "interaction region."

Evidence given by Andersen:

Reference 7 in the Andersen paper above is a Ralph Baric paper[36] from early in the pandemic (submitted January 22, 2020) and examines five key residues in the receptor binding domain of the Spike Protein (SP) and whether they are "ideal" for interacting with the ACE2 of human cells. The entire paper is based on computer calculations or prior laboratory work but importantly does not do any new "wet" lab work with CoV-2.

Baric et al. had previously identified five amino acid residues that are important for SP-ACE2 interaction. Using the amino acid numbers of CoV-2 these amino acids are: 455, 486, 493, 494, and 501. Baric opines that the most critical residues are 493 and 501 and the next most important residues are 455, 486, and 494. The authors then discuss each amino acid in turn:

Residue 493: "Gln493 in 2019-nCoV RBD is compatible with hot spot 31, suggesting that 2019-nCoV is capable of recognizing human ACE2 and infecting human cells." In this analysis 4 of the 20 amino acids are probed.

Residue 501: "This analysis suggests that 2019-nCoV recognizes human ACE2 less efficiently than human SARS-CoV (year 2002) but more efficiently than human SARS-CoV (year 2003). Hence, at least when considering the ACE2-RBD interactions, 2019-nCoV has gained some capability to transmit from human to human."

Direct binding evidence has shown that this statement is wrong, and CoV-2 binds the ACE2 receptor about ten-times better than SARS-CoV (year 2002).[37] In this analysis 3 of the 20 amino acids are probed.

Residues 455, 486, and 494: First, Baric et al. state: "Leu455 of 2019-nCoV RBD provides favorable interactions with hot spot 31, hence enhancing viral binding to human ACE2."

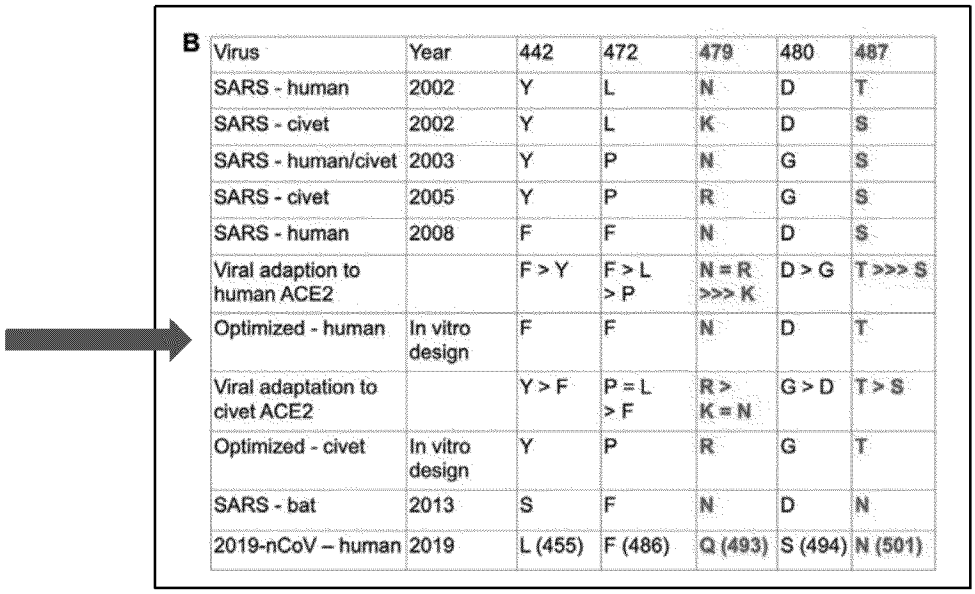
Next, they state: "Phe486 of 2019-nCoV RBD provides even more support for hot spot 31, hence also enhancing viral binding to human ACE2." Importantly, they also talk about their own laboratory work on an "optimized" receptor binding domain and state: "Leu472 of human and civet SARS-CoV RBDs provides favorable support for hot spot 31 on human ACE2 through hydrophobic interactions with ACE2 residue Met82 and several other hydrophobic residues **(this residue has been mutated to Phe472 in the optimized RBD)**." [emphasis added.]

Finally, they state: Ser494 in 2019-nCoV RBD still provides positive support for hot spot 353, but the support is not as favorable as that provided by Asp480. Overall, Leu455, Phe486, and Ser494 of 2019-nCoV RBD support the idea that 2019-nCoV recognizes human ACE2 and infects human cells."

[36] https://jvi.asm.org/content/94/7/e00127-20
[37] https://www.cell.com/action/showPdf?pii=S0092-8674%2820%2931003-5 ; https://www.nature.com/articles/s41586-020-2179-y ; https://www.sciencedirect.com/science/article/pii/S0092867420302622 ; https://science.sciencemag.org/content/367/6483/1260

In this analysis they probe 3 of 20 amino acid residues for position 480, 4 of 20 for position 486, and 4 of 20 for position 442.

As shown in the Figure below from the Baric paper, the in vitro designed, optimized human SP (red arrow) had the amino acid residues F, F, N, D, and T at these five key residues. Since CoV-2 was identical in only one of these five it was not "optimal" and, according to Andersen, it therefore was not laboratory derived.



B

Virus	Year	442	472	479	480	487
SARS - human	2002	Y	L	N	D	T
SARS - civet	2002	Y	L	K	D	S
SARS - human/civet	2003	Y	P	N	G	S
SARS - civet	2005	Y	P	R	G	S
SARS - human	2008	F	F	N	D	S
Viral adaption to human ACE2		F > Y	F > L > P	N = R >>> K	D > G	T >>> S
Optimized - human	In vitro design	F	F	N	D	T
Viral adaptation to civet ACE2		Y > F	P = L > F	R > K = N	G > D	T > S
Optimized - civet	In vitro design	Y	P	R	G	T
SARS - bat	2013	S	F	N	D	N
2019-nCoV – human	2019	L (455)	F (486)	Q (493)	S (494)	N (501)

Conclusion from the above paper: by examining five amino acid residues of the 200 residues encompassing the interaction region, and calculating the expected interaction of a total of 18 of the 4000 possible residues or 0.45% of all possibilities, they conclude CoV-2 can infect human cells but is not optimized to do so. This data was twisted by Andersen to be 'strong evidence' of natural selection.

An alternative and comprehensive analysis in another paper:[38]

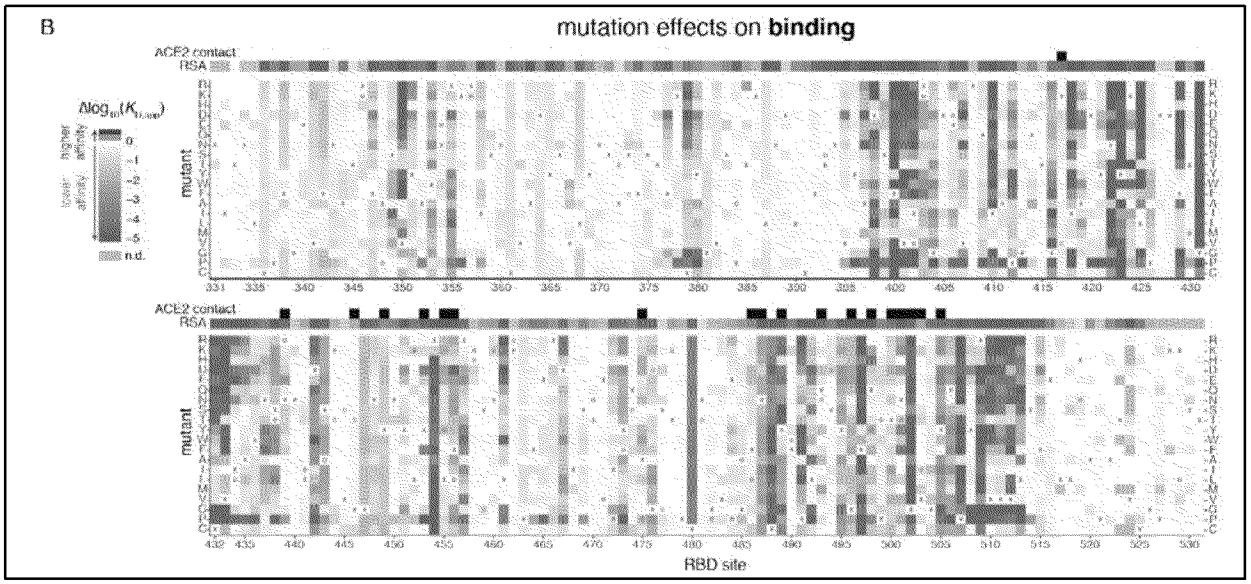
The receptor binding domain (RBD) of the CoV-2 SP is included in residues 331 to 531, a 201 amino acid sequence, of the SP. To examine the effect of each and every amino acid in each and every position, all 19 different amino acids were changed into all 201 positions of the RBD to the extent possible. Out of a total potential of 3819 different single amino acid variants, the scientists were able to create 3804 of the potential variants or 99.6% of the possible variants. It is probably that the variants with the 0.4% amino acid substitutions could not be made for one reason or another. These 3804 were then tested for binding to the human ACE2. Finally, the RBD from SARS-CoV-1 was also tested.

The Figure below is the result of the experiment. Starting with amino acid 331 and ending with amino acid 531, the amino acids that were changed are in vertical columns and are color coded. Shades of brown are amino acid substitutions that reduce ACE2 binding affinity and blue are

[38] https://www.cell.com/action/showPdf?pii=S0092-8674%2820%2931003-5

amino acid substitutions that improve binding, in all cases compared to the 'native' CoV-2 SP sequence. White is the color of a neutral substitution which neither enhances nor diminishes binding. Only the dark blue substitutions provide a strong improvement in ACE2 binding. There is a black square along the top row that denotes amino acids in the SP that interact with the ACE2 protein. Unlike in the Baric analysis above, in which only five amino acids were considered, this group of 19 amino acids provide a more complete interaction picture.

The first overarching observation is that most amino acid substitutions among the 201 amino acids are negative; while a large number are neutral. The fact that the vast majority of amino acid substitutions do not provide an improved ACE2 interaction is clear evidence that the CoV-2 SP interaction region is not newly evolved to the human ACE2.

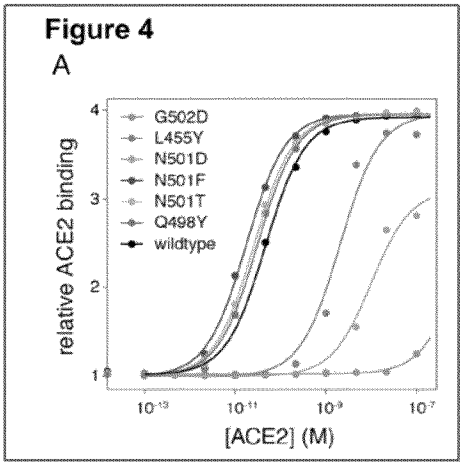


There are three levels of improved binding as designated by dark blue, medium blue, and pale blue. Out of the 3804 variants tested, there are 4 dark blue substitutions or 0.11% and 17 medium blue or 0.45%. According to the paper, the binding effect of the light blue could not be measured as different from the native sequence.

The conclusion of this comprehensive work is the demonstration that for 99.45% of the amino acids in the 201 amino acid interaction region, the CoV-2 choice is optimized, where any substitution is either detrimental or, at best, neutral.

How much could CoV-2 binding be improved or made worse by substitutions during the human-to-human transmission of the pandemic?

The Figure 4 below, taken from the paper, shows that the three best amino acid substitutions have only a slight effect on the binding curve (Black is wildtype; curves to the left are better binding; curves to the right are worse binding). This is further evidence that CoV-2 is optimized as the original virus.



The authors also concluded that Anderson et al was wrong: "An initially surprising feature of SARS-CoV-2 was that its RBD tightly binds ACE2 despite differing in sequence from SARS-CoV-1 at many residues that had been defined as important for ACE2 binding by that virus (Andersen et al., 2020; Wan et al., 2020)."

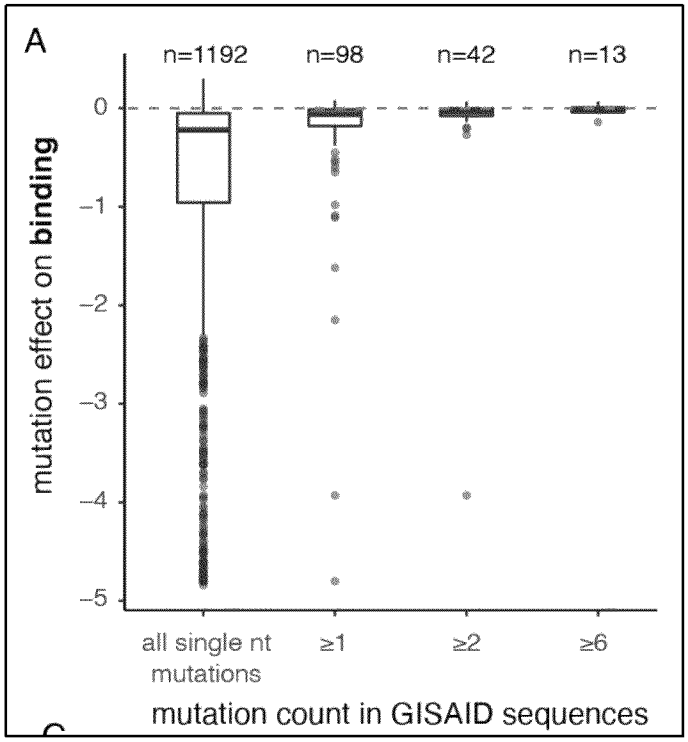
In fact, multiple studies have shown that CoV-2 binds ACE2 better than SARS-CoV-1, contradicting Andersen.

Is there evidence that CoV-2 in human circulation has mutations that enhance ACE2 binding?

Another measure of whether CoV-2 is optimized for human infection is to see if Spike Protein mutations have arisen during the pandemic that improve binding of the virus to the ACE2 receptor or if the SP amino acids are ideal from the very first human patient.

The Starr paper addressed this issue as well. A total of 31,570 human sequences were analyzed to see if any of the 21 amino acid substitutions from the binding experiments (or any other fir that matter) were being selected for.

Below is Figure 8 of the Starr paper. Of the 31,570 sequences, all mutations in the receptor interaction region were analyzed for their effect on ACE2 binding. The data below are for all examples of a single nt mutation (1192), two mutations (98), 3-5 mutations (42), and six or more (13) and the effect the mutation would have on ACE2 binding. The logarithmic scale has the wildtype CoV-2 as 0 and each negative integer is a 10-fold reduction in affinity. Shockingly, there is not a single mutation that is above the 0 line, which would be an improved affinity for the ACE2 receptor. All of the mutations lower the receptor affinity.



Here are the results, in the words of Starr:

"Our discovery of multiple strong affinity-enhancing mutations to the SARS-CoV-2 RBD raises the question of whether positive selection will favor such mutations, since the relationship between receptor affinity and fitness can be complex for viruses that are well-adapted to their hosts (Callaway et al., 2018; Hensley et al., 2009; Lang et al., 2020). Strong affinity-enhancing mutations are accessible via single-nucleotide mutation from SARS-CoV-2 (Figure S8C), but **none are observed among circulating viral sequences in GISAID** (Figure 8A), and **there is no significant trend for actual observed mutations to enhance ACE2 affinity more than randomly drawn samples of all single nucleotide mutations** (see permutation tests in Figure S8D). **Taken together, we see no clear evidence of selection for stronger ACE2 binding, consistent with SARS-CoV-2 already possessing adequate ACE2 affinity at the beginning of the pandemic."** [emphasis added.]

It is striking that the authors, in observing the complete absence of any evidence for stronger ACE2 binding in over thirty thousand cases, would describe this as evidence of "adequate ACE2 affinity" and not as an exceptional finding of "optimized ACE2 affinity." Of course, calling the SP affinity exceptional from the beginning of the pandemic would beg the question of a laboratory derived virus.

Returning to the initial hypotheses, since the 3804 possible amino acids at the receptor interaction region of CoV-2 are 99.45% optimized for ACE2 binding and there is not a single example in 31,570 human CoV-2 genomes of a substitution that enhances ACE2 binding, the CoV-2 interaction with ACE-2 is maximized.

Therefore, the hypothesis, "If the SARS-CoV-2 (CoV-2) Spike Protein interaction with the ACE2 receptor is not maximized, then it is evidence that the interaction is the product of natural selection and not purposeful (laboratory) manipulation," is **rejected**.

The alternative hypothesis, "If the CoV-2 Spike Protein interaction with the ACE2 receptor is maximized, then it is evidence that the interaction was the product of purposeful (laboratory) manipulation," is thus **accepted**.

At the time of this writing, a new RBD mutant N501Y has been observed. It is one of the five potential mutations that could be expected to increase RBD-ACE2 affinity.

This is the first example of evidence that will not be statistically quantified. The evidence is more consistent with having been optimized by various methods used in the laboratory than with the slow natural process as seen with SARS-CoV-1 and so the conservative rule that this is consistent with a laboratory origin (51%) versus zoonotic origin (49%) will be used. There will be no confidence adjustment.

The adjusted likelihoods are shown in the following table.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin (LO)
Starting likelihood	0.011	0.988
This is the outcome favors LO over ZO at 51% versus 49%		0.51
Impact of this evidence		Increases the likelihood of LO by 51/49 = 1.041
Impact of evidence calculation		1.041 x 0.988 = 1.028
Normalize this step of analysis	0.011/(0.011 + 1.028) = 0.011	1.028/(0.011 + 1.028) = 0.989

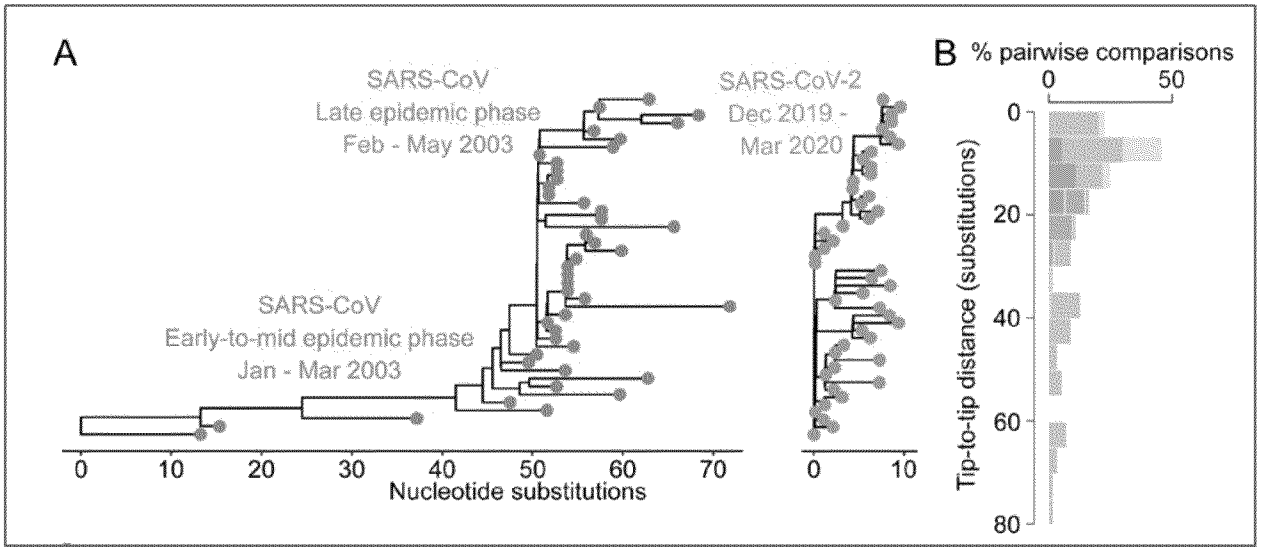
Adjusted likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

Evidence. Whole genome comparison of human adaption of CoV-2 compared to SARS-CoV-1 is consistent with a "pre-adaption" of CoV-2 to the human host

A paper[39] entitled, "SARS-CoV-2 is well adapted for humans. What does this mean for re-emergence?" by Shing Hei Zhan, Benjamin E. Deverman, and Yujia Alina Chan states in the abstract:

"In a side-by-side comparison of evolutionary dynamics between the 2019/2020 SARS-CoV-2 and the 2003 SARS-CoV, we were surprised to find that SARS-CoV-2 resembles SARS-CoV in the late phase of the 2003 epidemic after SARS-CoV had developed several advantageous adaptations for human transmission. Our observations suggest that **by the time SARS-CoV-2 was first detected in late 2019, it was already pre-adapted to human transmission to an extent similar to late epidemic SARS-CoV**. **However, no precursors or branches of evolution stemming from a less human-adapted SARS-CoV-2-like virus have been detected.** The sudden appearance of a highly infectious SARS-CoV-2 presents a major cause for concern that should motivate stronger international efforts to identify the source and prevent near future re-emergence. [Emphasis added.]

The following Figure from the paper best illustrates the relative SNV adaption for SARS-CoV-1 versus CoV-2.



The paper also makes a tangential comment about posterior diversity: "It would be curious if no precursors or branches of SARS-CoV-2 evolution are discovered in humans or animals."

This is another example of evidence that will not be statistically quantified. The evidence is more consistent with having been adapted by various known methods used in a laboratory than with the slow natural process as seen with SARS-CoV-1 and so the conservative rule that this is consistent with a laboratory origin (51%) versus zoonotic origin (49%) will be used. There will be no confidence adjustment.

[39] https://www.biorxiv.org/content/10.1101/2020.05.01.073262v1

The adjusted likelihoods are shown in the following table.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin (LO)
Starting likelihood	0.011	0.989
This is outcome favors LO over ZO at 51% versus 49%		0.51
Impact of this evidence		Increases the likelihood of LO by 51/49 = 1.041
Impact of evidence calculation		1.041 x 0.989 = 1.030
Normalize this step of analysis	0.011/(0.011 + 1.030) = 0.011	1.030/(0.011 + 1.030) = 0.989

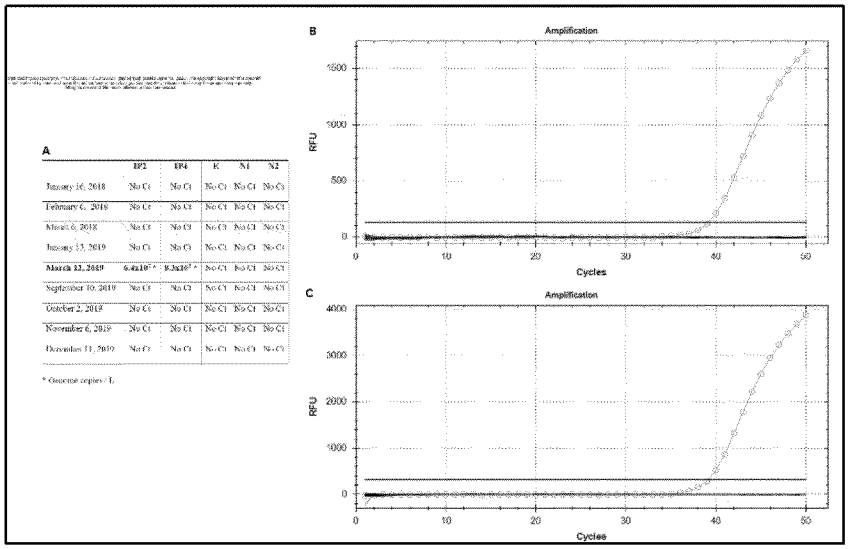
Adjusted likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

Evidence: Evidence of CoV-2 during early 2019 in wastewater from Barcelona, Spain is a false positive artifact

A paper entitled "Sentinel surveillance of SARS-CoV-2 in wastewater anticipates the occurrence of COVID-19 cases"[40] claims CoV-2 was present in Barcelona, Spain in March 2019. Specifically they state:

"This possibility prompted us to analyze some archival WWTP samples from January 2018 to December 2019 (Figure 2). All samples came out to be negative for the presence of SARS-CoV-2 genomes with the exception of March 12, 2019, in which both IP2 and IP4 target assays were positive. This striking finding indicates circulation of the virus in Barcelona long before the report of any COVID-19 case worldwide."

This is a false positive



As shown above from the paper, they found 43/45 runs with zero and two runs had only 600-800 CoV-2 copies/L

But the limit of detection (LoD) of their assay is 1,000,000 CoV-2/L.

According to the Promega PCR assay FDA clearance package, the Ct at the LoD is 33-34 for the N1 and N2, respectively (Table 17, page 51).[41] Here the LoD is listed as 1 RNA/μL.

In the paper the Ct is 40 or 6-7 above the LoD.

This evidence is neutral as to origin and will not be used to adjust the likelihoods. It does reduce the credibility of some of the new origin theories coming out of China.

[40] https://www.medrxiv.org/content/10.1101/2020.06.13.20129627v1.full.pdf
[41] https://twitter.com/quay_dr/status/1340572543548227585/photo/1

Evidence: WHO and Dr. Shi have spoken of the singular nature the beginning of COVID-19

On January 23, 2020 Dr. Shi wrote in the draft of her paper: "The almost identical sequences of this virus in different patients imply a probably recent introduction in humans…"[42] By February 3, 2020, when the final version of this paper was published, this sentence had been **deleted**.[43]

On April 23, 2020 the WHO stated: "All the published genetic sequences of SARS-CoV-2 isolated from human cases are very similar. This suggests that the start of the outbreak resulted from a single point introduction in the human population around the time that the virus was first reported in humans in Wuhan, China in December 2019."[44]

The evidence is more consistent with a single introduction in a laboratory accident like the lack of posterior diversity and seroconversion reported earlier. This evidence will not be used to adjust probabilities but is included because it could be a form of party admissions of unfavorable facts.

[42] RaTG13 paper as a preprint
[43] RaTG13 final Nature paper
[44] WHO document page 2 of 12

Evidence. Mammalian biodiversity and bat species differences between Yunnan and Hubei Provence are significant and are not supportive of a zoonotic origin

Summary. SARS-CoV-2 is most closely related to bat coronaviruses from Yunnan, a rural province in South West China. Wuhan, where the pandemic began, is a large urban city of 11 million inhabitants in north central China. They are approximately 1900 km apart.

This is the US equivalent of the difference between New York City (population 8.4 million) and the Everglades in Florida, 2000 km away. The incongruent image of a bat or intermediate host in the Everglades somehow finding their way to New York City is a clear demonstration of the difficulty in this hypothetical transmission process. Nonetheless, a strict literature-based analysis will be conducted.

If COVID-19 is a zoonotic disease it must have travelled from bats to humans or from bats to an intermediate species to humans. Therefore, an examination of mammalian biodiversity differences and commonalities between Yunnan and Wuhan might provide useful information about the intermediate host or the particular bat species.

Peter Daszak, Zhengli-li Shi and colleagues published an August 2020 paper entitled, "Origin and cross-species transmission of bat coronaviruses in China,"[45] in which they make a number of observations that are relevant to this analysis. It should be remembered that multiple, strong, public statements over many months by both lead authors that SARS-CoV-2 is a natural zoonosis have been made.

Yunnan and Hubei Provinces have very dissimilar mammalian diversity

Quoting from the Methods section of the paper:

"Defining zoogeographic regions in China

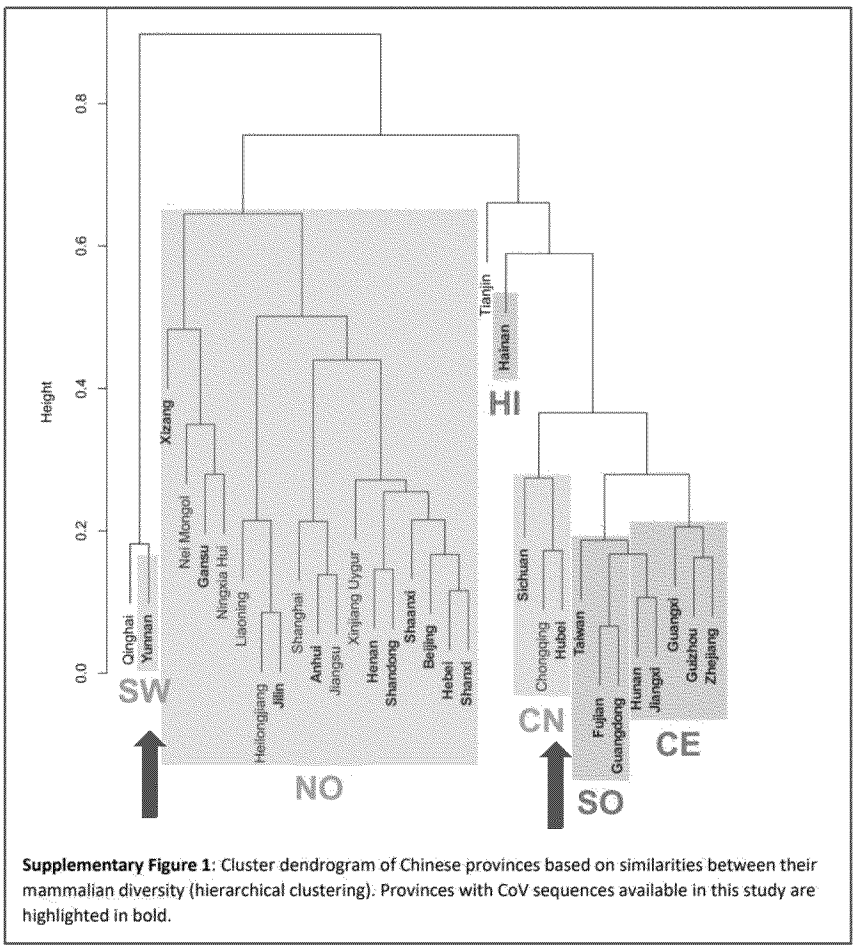
Hierachical clustering was used to define zoogeographic regions within China by clustering provinces with similar mammalian diversity45. Hierarchical cluster analysis classifies several objects into small groups based on similarities between them. To do this, we created a presence/absence matrix of all extant terrestrial mammals present in China using data from the IUCN spatial database84 and generated a cluster dendrogram using the function *hclust* with average method of the R package stats. Hong Kong and Macau were included within the neighboring Guangdong province. We then visually identified geographically contiguous clusters of provinces for which CoV sequences are available (Fig. 1 and Supplementary Fig. 1).

We identified six zoogeographic regions within China based on the similarity of the mammal community in these provinces: **SW (Yunnan province)**, NO (Xizang, Gansu, Jilin, Anhui, Henan, Shandong, Shaanxi, Hebei, and Shanxi provinces and Beijing municipality), **CN (Sichuan and Hubei provinces)**, CE (Guangxi, Guizhou, Hunan, Jiangxi, and Zhejiang provinces), SO (Guangdong and Fujian provinces, Hong Kong, Macau, and Taiwan), and HI. Hunan and Jiangxi, clustering with the SO provinces in our dendrogram, were included within

[45] https://www.nature.com/articles/s41467-020-17687-3#Sec19

the central region to create a geographically contiguous Central cluster (Supplementary Fig. 1). These six zoogeographic regions are very similar to the biogeographic regions traditionally recognized in China85. The three β-CoV sequences from HI were included in the SO region to avoid creating a cluster with a very small number of sequences."

Below is a cluster dendrogram of Chinese provinces based on similarities between their mammalian diversity (hierarchical clustering). Provinces with CoV sequences available in this study are highlighted in bold.



Supplementary Figure 1: Cluster dendrogram of Chinese provinces based on similarities between their mammalian diversity (hierarchical clustering). Provinces with CoV sequences available in this study are highlighted in bold.

The y-axis height is a measure of the biodiversity with 1.0 being complete similarity and 0.0 being no similarity. As expected for the geography and location of the two provinces, Yunnan (red arrow above) and Hubei (green arrow above) have a height score of about 0.1, with seven branches and six nodes separating them. This is close to the biggest different in mammalian biodiversity of any two locations in all of China.

In conclusion, Daszak and Shi et al. demonstrate that the mammalian biodiversity between Yunnan and Hubei is very significant, reducing the options for a common intermediate host to be the natural conduit between bats and humans.

Shi and Daszak statement: "SARS-CoV-2 is likely derived from a clade of viruses originating in horseshoe bats (*Rhinolophus* spp.). The geographic location of this origin appears to be Yunnan province."

This is evidence will not be statistically quantified. The evidence reduces the biodiversity overlap needed to create a common intermediate species between the two provinces and so the conservative rule that this is consistent with a laboratory origin (51%) versus zoonotic origin (49%) will be used. There will be no confidence adjustment.

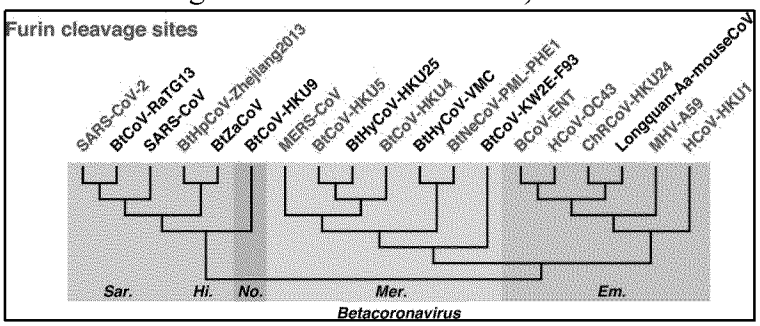
Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin (LO)
Starting likelihood	0.011	0.989
This data from Shi & Daszak disfavors a ZO		0.51
Impact of this evidence		Increases the likelihood of LO by 51/49 = 1.041
Impact of evidence calculation		1.041 x 0.989 = 1.030
Normalize this step of analysis	0.011/(0.011 + 1.030) = 0.011	1.030/(0.011 + 1.030) = 0.989

Because of the rule on the use of significant figures, the likelihood does not change.

Adjusted likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

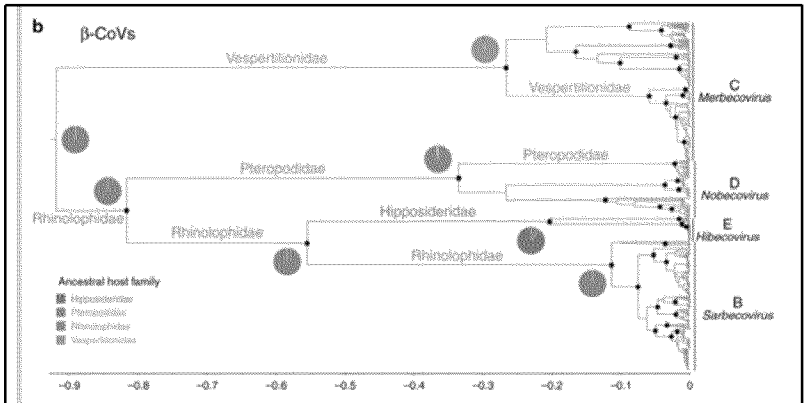
Evidence: The ancestor of SARS-CoV-2 can only obtain a furin site by recombination outside of the sarbecovirus subgenera but there is strong evidence that coronavirus recombination is largely limited to the clade level, with limited evidence of sub-genera or genera recombination

- SARS-CoV-2 is a beta coronavirus, subgenera sarbecovirus and is the only sarbecovirus with a furin site.[46]
- Furin sites can be found in either alpha or gamma coronaviruses or the other beta coronavirus subgenera. The following Figure from reference 66 shows examples of such coronaviruses (furin containing viruses are shown in red):



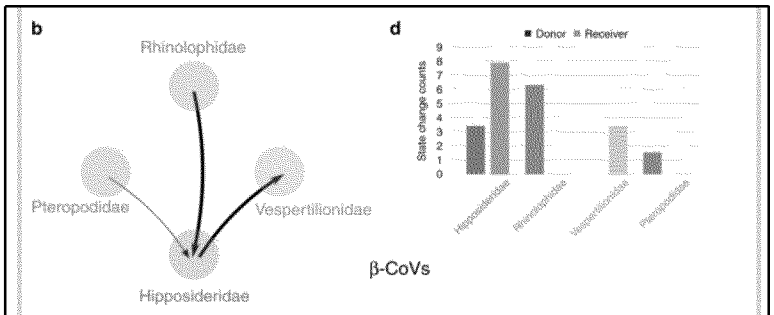
- To acquire a furin site in nature would require a co-infection between the CoV-2 sarbecovirus ancestor and a furin-containing non-sarbecovirus as shown above.
- However, there is no evidence of recombination in coronaviruses at either the genus level or the subgenus level; only at the clade level.[47][48]
- There is also evidence from Daszak and Shi that within the subgenera of the beta coronaviruses, there is bat host specificity. So each subgenera of coronaviruses has a preferred bat host species. This reduces the opportunities for a co-host event to permit recombination.[49] The phylogeny below shows the problem of host incompatibility for beta coronaviruses (from reference 69):

[46] https://www.sciencedirect.com/science/article/pii/S1873506120304165#f0015
[47] file:///C:/Users/Steven%20Quay/Desktop/journal.pgen.1009272.pdf
[48] https://academic.oup.com/mbe/advance-article/doi/10.1093/molbev/msaa281/5955840
[49] https://www.nature.com/articles/s41467-020-17687-3#Sec2



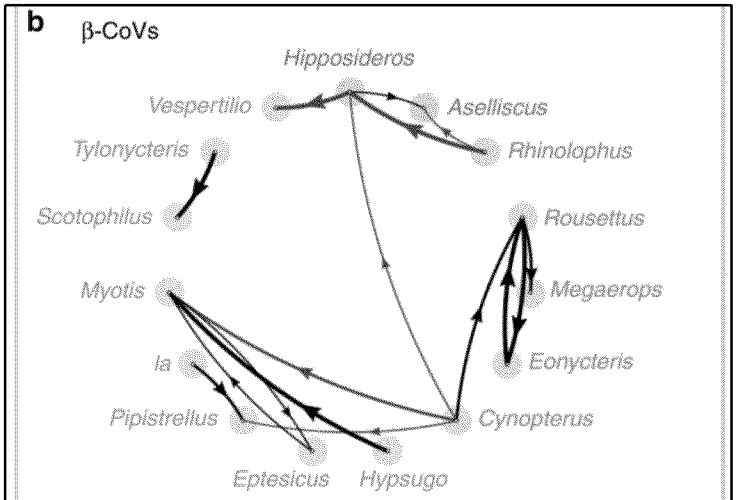
α-CoV (**a**) and β-CoV (**b**) maximum clade credibility annotated trees using complete datasets of *RdRp* sequences and bat host family as discrete character state. Pie charts located at the root and close to the deepest nodes show the state posterior probabilities for each bat family. Branch color correspond to the inferred ancestral family with the highest probability. Branch lengths are scaled according to relative time units (clock rate = 1.0). Well-supported nodes (posterior probability > 0.95) are indicated with a black dot. The ICTV approved CoV subgenera were highlighted: *Rhinacovirus* (L1), *Decacovirus* (L2), *Myotacovirus* (L3), *Pedacovirus* (L5), *Nyctacovirus* (L6), *Minunacovirus* (L7), and an unidentified lineage (L4) for α-CoVs; and *Merbecovirus* (Lineage C), *Nobecovirus* (lineage D), *Hibecovirus* (lineage E), and *Sarbecovirus* (Lineage B) for β-CoVs.

- Daszak and Shi also identified preferred directions of host switching. Since RaTG13, the closest coronavirus to SARS-CoV-2, is most closely related to viruses with bat hosts from the family, Rhinolophidae, it would be reasonable to expect furin-containing viruses from other bat hosts to migrate into Rhinolophidae, recombine by methods which have not been identified, and then the furin-containing sarbecovirus could evolve into the ancestor of SARS-CoV-2. Unexpectedly, Daszak et al. found host migration for the Rhinolophidae bats only outward and not inward, as required by the above, admittedly, convoluted process. The data Figure is shown here:



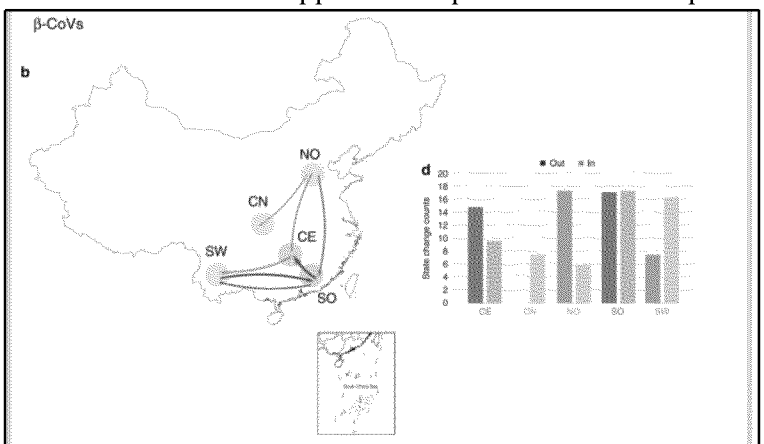
Strongly supported host switches between bat families for α-CoVs (**a**) and β-CoVs (**b**). Arrows indicate the direction of the switch; arrow thickness is proportional to the switch significance level, only host switches supported by strong Bayes factor (BF) > 10 are shown. Histograms of total number of host-switching events (state changes counts using Markov jumps) from/to each bat family along the significant inter-family switches for α-CoVs (**c**) and β-CoVs (**d**).

- Daszak and Shi also observed outward host switches from *Rhinolophus* at the genera level as well, also against a hypothesis for furin-site acquisition:



Strongly supported host switches between bat genera for α-CoVs (**a**) and β-CoVs (**b**) and their significance level (Bayes factor, BF). Only host switches supported by strong BF values >10 are shown. Line thickness is proportional to the switch significance level. Red lines correspond to host switches among bat genera belonging to different families, and black lines correspond to host switches among bat genera from the same family. Arrows indicate the direction of the switch. Genus names are colored according to the family they belong to using the same colors as in Figs. 2 and 3.

- Finally, this paper by Daszak and Shi states: "We used our Bayesian discrete phylogeographic model with zoogeographic regions as character states to reconstruct the spatiotemporal dynamics of CoV dispersal in China." If SARS-CoV-2 began in Yunnan and first crossed over into humans in Wuhan, this analysis should support a northernly spatiotemporal dispersal of beta coronaviruses. Unfortunately, Daszak and Shi cannot catch a break; their own data do not support the expected route of dispersion:



Strongly supported dispersal routes (Bayes factor, BF > 10) over recent evolutionary history among China zoogeographic regions for α-CoVs (**a**) and β-CoVs (**b**). Arrows indicate the direction of the dispersal route; arrow thickness is proportional to the dispersal route significance level. Darker arrow colors indicate older dispersal events. Histograms of total number of dispersal events (Markov jumps) from/to each region along the significant dispersal routes for α-CoVs (**c**) and β-CoVs (**d**). NO Northern region, CN Central northern region, SW South western region, CE Central region, SO Southern region, HI Hainan island.

As shown in the above Figure the only dispersal routes into Wuhan, which is in the CN region, are from the northern region. And the northern region has no inward dispersals from the SW, southwest region, where Yunnan and the origin of the ancestor of SARS-CoV-2, is located.

- Independent evidence documents that Hubei province does not have the bat species needed for SARS-CoV-2 reservoir host[50]

While statistical models of this data could be interesting and informative for general research about future spillovers, this is evidence will not be statistically quantified for this analysis. The evidence reduces the opportunities for subgenera co-infection and furin-site recombination into the CoV-2 ancestor and so the conservative rule that this is less consistent with a zoonotic origin (49%) versus laboratory origin (49%) will be used. There will be no confidence adjustment.

The results from the calculations are shown below.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin (LO)
Starting likelihood	0.011	0.989
This data from Shi & Daszak and the 'furin sites are everywhere' paper are disfavored		0.51
Impact of this evidence		Increases the likelihood of LO by 51/49 = 1.041
Impact of evidence calculation		1.041 x 0.989 = 1.030
Normalize this step of analysis	0.011/(0.011 + 1.030) = 0.011	1.030/(0.011 + 1.030) = 0.989

Adjusted likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

[50] file:///C:/Users/Steven%20Quay/Desktop/Zhangetal2009.pdf

Evidence: Of 410 vertebrate species tested for affinity to CoV-2 Spike Protein binding domain, primate ACE2 receptor, including human and VERO monkey cells, are the best at binding and bat species ACE2 are the worse, making direct bat-to-human host jumping extremely unlikely

- An examination of the ACE2 receptor binding domain amino acid sequences and their suitability for interacting with SARS-CoV-2 was performed in 410 vertebrates, including 252 mammals.[51]
- A five-category binding score was developed based on the conservation properties of 25 amino acids important for the binding between ACE2 and the SARS-CoV-2 spike protein.
- Only mammals fell into the medium to very high categories and only primates scored 25/25 for binding.
- This implies that SARS-CoV-2 is optimized for human ACE2-bearing cells from the first introduction into the human population, an observation that contradicts a zoonotic origin.
- It also suggests that other primates may be the proximate species from which SARS-CoV-2 entered the human population.
- Both VERO monkey kidney cells and ACE2 humanized mice would quality as an intermediate species by this criterion.
- Surprisingly, "all chiropterans (bats) scored low (n = 8) or very low (n = 29), including the Chinese rufous horseshoe bat, from which a coronavirus (SARSr-CoV ZC45) related to SARS-CoV-2 was identified."
- This is evidence that bats are probably not a reservoir host for SARS-CoV-2.
- A separate study observed: "Severe acute respiratory syndrome coronavirus 2 did not replicate efficiently in 13 bat cell lines."[52]
- The following two Tables are taken from the paper and are organized according to ACE2 SARS-CoV-2 affinity, from highest to lowest:

[51] https://www.pnas.org/content/117/36/22311
[52] https://wwwnc.cdc.gov/eid/article/26/12/20-2308_article

	ID	S19	Q24	T27	F28	D30	K31	H34	**E35***	E37	D38	Y41	Q42	L45	**L52***	L79	**M82***	Y83	**N90***	**N322***	N330	**K353***	G354	D355	R357	R393
VERY HIGH																										
Homo sapiens (Human)	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Gorilla gorilla gorilla* (Western lowland gorilla)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Nomascus leucogenys* (Northern white-cheeked gibbon)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Pongo abelii* (Sumatran orangutan)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Macaca fascicularis (Crab-eating macaque)	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Mandrillus leucophaeus* (Drill)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Nasalis larvatus* (Proboscis monkey)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Pan paniscus* (Bonobo)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Pan troglodytes* (Chimpanzee)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Piliocolobus tephrosceles* (Ugandan red colobus)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Pygathrix nemaeus* (Red-shanked douc)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Rhinopithecus roxellana* (Golden snub-nosed monkey)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Chlorocebus sabaeus (Green monkey)	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Erythrocebus patas (Patas monkey)	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Macaca mulatta (Rhesus macaque)	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Papio anubis (Olive baboon)	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Theropithecus gelada (Gelada)	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Cercocebus atys* (Sooty mangabey)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
***Macaca nemestrina* (Southern pig-tailed macaque)**	25	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HIGH																										
***Colobus angolensis* (Angola colobus)**	24	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	R	.	.	.	.	.	.	.	.	.
***Propithecus coquereli* (Coquerel's sifaka)**	24	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
Cricetomys gambianus (Gambian pouched rat)	22	.	A	.	.	.	Q	.	.	.	.	.	.	.	.	.	N	.	.	.	.	.	.	.	.	.
Cricetulus griseus (Chinese hamster)	22	.	.	.	.	.	Q	.	.	.	.	.	.	.	.	.	N	.	H	.	.	.	.	.	.	.
Ctenodactylus gundi (Common gundi)	22	.	.	.	.	.	Q	.	.	.	.	.	.	.	.	.	N	.	T	.	.	.	.	.	.	.
Delphinapterus leucas (Beluga whale)	22	.	.	.	Q	.	.	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
***Eulemur flavifrons* (Blue-eyed black lemur)**	22	.	E	A	.	.	.	.	.	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Indri indri* (Indri)**	22	.	.	.	.	N	Q	.	.	.	.	.	.	.	.	.	N	.	.	.	.	.	.	.	.	.
Monodon monoceros (Narwhal)	22	.	.	.	Q	.	.	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
***Neophocaena asiaeorientalis* (Narrow-ridged finless porpoise)**	22	.	.	.	Q	.	.	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
Phocoena phocoena (Harbour porpoise)	22	.	.	.	Q	.	.	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
Balaenoptera acutorostrata scammoni (Minke whale)	21	.	.	.	Q	.	.	.	.	.	.	.	R	.	.	.	I	T	.	.	.	.	.	.	.	.
Balaenoptera bonaerensis (Antarctic minke whale)	21	.	.	.	Q	.	.	.	.	.	.	.	R	.	.	.	I	T	.	.	.	.	.	.	.	.
Eschrichtius robustus (Gray whale)	21	.	.	.	Q	.	.	.	.	.	.	.	E	.	.	.	I	T	.	.	.	.	.	.	.	.
Nannospalax galili (Spalax)	21	.	.	.	.	.	Q	.	.	.	.	.	.	.	.	.	K	D	Q	.	.	.	.	.	.	.
Odocoileus virginianus texanus (White-tailed deer)	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	H	.	.	.	.	.
***Rangifer tarandus* (Reindeer)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	H	.	.	.	.	.
Tamandua tetradactyla (Southern tamandua)	21	.	.	.	E	.	Q	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
***Dipodomys stephensi* (Stephens's kangaroo rat)**	20	.	L	.	.	.	N	Q	.	.	.	.	.	.	.	.	I	.	.	K	.	.	.	.	.	.
***Elaphurus davidianus* (Pere David's deer)**	20	.	.	.	.	E	N	.	.	.	.	.	.	.	.	.	M	T	.	.	H	.	.	.	.	.
Ellobius lutescens (Transcaucasian mole vole)	20	.	D	.	.	.	Q	.	.	.	.	.	.	.	.	.	S	.	.	H	.	D	.	.	.	.
Globicephala melas (Long-finned pilot whale)	20	.	R	.	Q	.	R	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
Lagenorhynchus obliquidens (Pacific white-sided dolphin)	20	.	R	.	Q	.	R	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
***Lipotes vexillifer* (Baiji)**	20	.	R	.	Q	.	.	.	.	.	.	.	.	.	.	.	I	T	F	.	.	.	.	.	.	.
***Myrmecophaga tridactyla* (Giant anteater)**	20	.	.	.	E	Q	.	.	N	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
Ondatra zibethicus (Muskrat)	20	.	.	.	N	Q	.	.	.	.	.	.	.	.	.	.	S	.	.	H	.	D	.	.	.	.
Orcinus orca (Killer whale)	20	.	R	.	Q	.	R	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
Tursiops truncatus (Common bottlenose dolphin)	20	.	R	.	Q	.	R	.	.	.	.	.	.	.	.	.	I	T	.	.	.	.	.	.	.	.
MEDIUM																										
***Daubentonia madagascariensis* (Aye-aye)**	23	F	.	.	.	.	.	.	.	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
Cheirogaleus medius (Fat-tailed dwarf lemur)	22	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	T	.	.	.	K	Q	.	.	.	.
Ictidomys tridecemlineatus (Thirteen-lined ground squirrel)	22	.	L	.	.	.	Q	.	.	.	.	.	.	.	.	.	A	.	.	.	.	.	.	.	.	.
Marmota flaviventris (Yellow-bellied marmot)	22	.	L	.	.	.	Q	.	.	.	.	.	.	.	.	.	A	.	.	.	.	.	.	.	.	.
Marmota marmota marmota (Alpine marmot)	22	.	L	.	.	.	Q	.	.	.	.	.	.	.	.	.	A	.	.	.	.	.	.	.	.	.
***Mesocricetus auratus* (Golden hamster)**	22	.	.	.	.	.	Q	.	.	.	.	.	.	.	.	.	N	.	Y	.	.	.	.	.	.	.
***Physeter catodon* (Sperm whale)**	22	.	.	.	Q	.	.	.	.	.	.	.	.	.	.	.	T	T	.	.	.	.	.	.	.	.
Spermophilus dauricus (Daurian ground squirrel)	22	.	L	.	.	.	Q	.	.	.	.	.	.	.	.	.	A	.	.	.	.	.	.	.	.	.
Allactaga bullata (Gobi jerboa)	21	.	T	.	.	.	Q	.	.	.	.	.	.	.	.	.	T	.	.	H	.	.	.	.	.	.
***Ammotragus lervia* (Barbary sheep)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Antilocapra americana (Pronghorn)	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
***Aotus nancymaae* (Nancy Ma's night monkey)**	21	.	.	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
***Beatragus hunteri* (Hirola)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
***Bison bison bison* (American bison)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Bos indicus (Zebu)	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
***Bos mutus* (Wild yak)**	21	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
MEDIUM (continued)																										
Bos taurus (Cattle)	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Bubalus bubalis (Water buffalo)	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Callicebus donacophilus (White-eared titi)	21	.	.	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
Callithrix jacchus (Common marmoset)	21	.	.	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
***Capra aegagrus* (Wild goat)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Capra hircus (Goat)	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Cebus capucinus imitator (Panamanian white-faced capuchin)	21	.	.	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
Felis catus (Cat)	21	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Giraffa tippelskirchi* (Masai giraffe)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
***Hemitragus hylocrius* (Nilgiri tahr)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Lynx canadensis (Canadian lynx)	21	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Mirza coquereli* (Coquerel's giant mouse lemur)**	21	.	.	I	.	.	N	.	.	.	.	.	.	.	.	.	T	.	.	.	K	.	.	.	.	.
***Moschus moschiferus* (Siberian musk deer)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
***Neofelis diardi* (Sunda clouded leopard)**	21	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Neofelis nebulosa* (Clouded leopard)**	21	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Okapia johnstoni* (Okapi)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Ovis aries (Sheep)	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
***Panthera onca* (Jaguar)**	21	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Panthera pardus* (Leopard)**	21	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Panthera tigris altaica* (Siberian tiger)**	21	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Pantholops hodgsonii* (Tibetan antelope)**	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Perognathus longimembris (Little pocket mouse)	21	.	V	.	.	.	Q	.	.	.	.	.	.	.	.	.	T	.	.	K	.	.	.	.	.	.
Peromyscus maniculatus bairdii (Deer mouse)	21	.	.	I	.	.	Q	.	.	.	.	.	.	.	.	.	N	.	H	.	.	.	.	.	.	.
Pithecia pithecia (White-faced saki)	21	.	.	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
Puma concolor (Cougar)	21	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
Saimiri boliviensis boliviensis (Black-capped squirrel monkey)	21	.	.	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
Sapajus apella (Tufted capuchin)	21	.	.	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
Urocitellus parryii (Arctic ground squirrel)	21	.	L	.	.	.	Q	.	.	.	.	.	H	.	.	.	D	.	.	.	.	.	.	.	.	.
Bos indicus x *Bos taurus*	21	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
***Acinonyx jubatus* (Cheetah)**	20	.	L	.	E	.	.	.	.	E	.	.	.	.	.	.	T	.	.	.	K	.	.	.	.	.
***Alouatta palliata* (Mantled howler)**	20	.	.	.	.	E	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
***Ateles geoffroyi* (Geoffroy's spider monkey)**	20	A	.	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
Fukomys damarensis (Damaraland mole-rat)	20	L	.	.	.	.	Q	.	.	.	.	.	.	.	.	.	A	.	.	H	.	N	.	.	.	.
Heterocephalus glaber (Naked mole-rat)	20	L	.	.	.	.	Q	.	.	.	.	.	.	.	.	.	A	.	.	H	.	D	.	.	.	.
***Hippopotamus amphibius* (Hippopotamus)**	20	.	.	.	.	L	.	D	.	.	.	.	.	.	.	.	A	F	D	.	.	.	.	.	.	.
Lepus americanus (Snowshoe hare)	20	.	L	.	E	Q	.	.	.	.	.	.	.	.	.	.	T	.	.	S	.	.	.	.	.	.
***Nanger dama* (Dama gazelle)**	20	.	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	F	.	Y	.	.	.	.	.
***Oryctolagus cuniculus* (European rabbit)**	20	.	L	.	E	Y	.	.	.	.	.	.	.	.	.	.	T	.	.	S	.	.	.	.	.	.
***Oryx dammah* (Scimitar oryx)**	20	*	.	.	E	.	.	.	.	.	.	.	.	.	.	.	M	T	.	.	Y	.	.	.	.	.
Saguinus imperator (Emperor tamarin)	20	.	A	.	.	.	.	.	.	H	E	.	.	.	.	.	T	.	.	.	.	Q	.	.	.	.
Vicugna pacos (Alpaca)	20	.	L	.	K	E	.	.	.	.	.	.	.	.	.	.	A	I	.	.	.	.	.	.	.	.
LOW																										
***Ceratotherium simum cottoni* (Northern white rhinoceros)**	21	.	L	.	.	E	P	.	.	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Ceratotherium simum simum* (Southern white rhinoceros)**	21	.	L	.	.	E	P	.	.	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Diceros bicornis* (Black rhinoceros)**	21	.	L	.	.	E	P	.	.	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
Galeopterus variegatus (Sunda flying lemur)	21	F	L	.	.	.	.	.	.	.	E	.	.	.	.	.	N	.	.	.	.	.	.	.	.	.
Peromyscus leucopus (White-footed mouse)	21	.	.	I	.	.	Q	.	.	.	.	.	.	.	.	.	N	.	P	.	.	.	.	.	.	.
***Ailuropoda melanoleuca* (Giant panda)**	20	.	L	.	E	Y	.	.	.	.	.	.	.	.	.	.	H	T	.	.	.	.	.	.	.	.
Camelus bactrianus (Bactrian camel)	20	.	L	.	E	E	.	.	.	.	.	.	.	.	.	.	T	T	.	.	.	.	.	.	.	.
Camelus dromedarius (Dromedary)	20	.	L	.	E	E	.	.	.	.	.	.	.	.	.	.	T	T	.	.	.	.	.	.	.	.
***Camelus ferus* (Wild bactrian camel)**	20	.	L	.	E	E	.	.	.	.	.	.	.	.	.	.	T	T	.	.	.	.	.	.	.	.
***Dicerorhinus sumatrensis* (Sumatran rhinoceros)**	20	.	L	.	E	P	.	.	H	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
Graphiurus murinus (Woodland dormouse)	20	.	T	.	.	N	R	.	.	.	.	.	.	.	.	.	H	N	.	.	.	.	.	.	.	.
***Tapirus indicus* (Malayan tapir)**	20	.	L	.	E	P	.	.	H	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
***Tapirus terrestris* (South American tapir)**	20	.	L	.	E	P	.	.	H	.	.	.	.	.	.	.	T	.	.	.	.	.	.	.	.	.
Ursus arctos horribilis (Grizzly bear)	20	.	L	.	E	Y	.	.	.	.	.	.	.	.	.	.	H	T	.	.	.	.	.	.	.	.
***Ursus maritimus* (Polar bear)**	20	.	L	.	E	Y	.	.	.	.	.	.	.	.	.	.	H	T	.	.	.	.	.	.	.	.
***Canis lupus dingo* (Dingo)**	19	.	L	.	E	Y	.	E	.	.	.	.	.	.	.	.	T	D	.	.	.	.	.	.	.	.
Canis lupus familiaris (Dog)	19	.	L	.	E	Y	.	E	.	.	.	.	.	.	.	.	T	D	.	.	.	.	.	.	.	.
***Chinchilla lanigera* (Long-tailed chichilla)**	19	.	.	.	.	.	N	E	K	.	.	.	.	.	.	.	A	.	H	.	D	.	.	.	.	.
***Chrysocyon brachyurus* (Maned wolf)**	19	.	L	.	E	Y	.	E	.	.	.	.	.	.	.	.	T	D	.	.	.	.	.	.	.	.
Dipodomys ordii (Ord's kangaroo rat)	19	Q	L	.	.	N	Q	.	.	.	.	.	.	.	.	.	I	.	.	K	.	.	.	.	.	.
Eonycteris spelaea (Lesser dawn bat)	19	.	L	.	E	T	.	.	.	.	.	.	.	.	.	.	T	D	K	.	.	.	.	.	.	.
Equus asinus (Donkey)	19	.	L	.	E	S	.	E	H	.	.	.	.	.	.	.	H	.	.	.	.	.	.	.	.	.
Equus caballus (Horse)	19	.	L	.	E	S	.	E	H	.	.	.	.	.	.	.	H	.	.	.	.	.	.	.	.	.

Species	ID	S19	Q24	T27	F28	D30	K31*	H34	E35*	E37	D38	Y41	Q42	L45	N53*	L79	M82*	Y83	N90*	N322*	N330	K353*	G354	D355	R357	R393
LOW (continued)																										
Equus przewalskii **(Przewalski's horse)**	19	.	L	.	.	E	.	S	.	.	E	H	.	.	.	.	H	.	.	.	.	.	.	.	.	.
Hydrochoerus hydrochaeris (Capybara)	19	.	.	.	.	.	E	L	K	.	.	.	.	.	.	.	A	.	.	.	K	.	N	.	.	.
Hystrix cristata (Crested porcupine)	19	I	.	.	.	.	.	Q	.	.	.	.	.	.	.	F	A	.	.	H	.	.	N	.	.	.
Megaderma lyra (Indian false vampire)	19	.	.	.	.	E	.	L	.	.	E	.	.	.	.	.	H	F	.	.	.	.	N	.	.	.
Microtus ochrogaster (Prairie vole)	19	.	D	A	.	.	.	Q	.	.	.	.	.	.	.	.	S	.	.	H	.	.	D	.	.	.
Rhinolophus pearsonii (Pearson's horseshoe bat)	19	.	.	I	.	.	.	R	.	.	.	H	E	.	.	.	D	.	.	.	.	.	D	.	.	.
Rhinolophus sinicus (Chinese rufous horseshoe bat)	19	F	R	.	.	.	E	F	.	.	N	.	.	.	.	.	N	.	.	.	.	.	.	.	.	.
Rousettus aegyptiacus (Egyptian rousette)	19	.	L	.	.	E	.	T	.	.	.	.	.	.	.	.	T	.	D	.	K	.	.	.	.	.
Speothos venaticus **(Bush dog)**	19	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	.	T	.	D	.	.	.	.	.	.	.
Sus scrofa (Pig)	19	.	L	.	.	E	.	L	.	.	.	.	.	.	.	I	T	.	T	.	.	.	.	.	.	.
Tragulus javanicus (Java mouse-deer)	19	.	.	I	.	E	.	L	.	.	.	.	.	.	.	M	T	.	.	H	.	.	.	.	.	.
Vulpes lagopus (Arctic fox)	19	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	.	T	.	D	.	.	.	.	.	.	.
Vulpes vulpes (Red fox)	19	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	.	T	.	D	.	.	.	.	.	.	.
Balaena mysticetus **(Bowhead whale)**	18	.	.	.	.	Q	E	R	.	.	N	.	.	.	.	T	T	.	.	H	.	.	.	.	.	.
Carlito syrichta **(Philippine tarsier)**	18	Q	.	.	.	.	.	Q	.	.	.	H	.	.	.	I	S	.	.	.	.	N	S	.	.	.
Dasyprocta punctata (Central American agouti)	18	F	.	.	.	.	E	Q	K	.	.	.	.	.	.	.	A	.	.	P	.	.	N	.	.	.
Dolichotis patagonum **(Pantagonian mara)**	18	F	.	.	.	.	E	L	K	.	.	.	.	.	.	.	A	.	.	H	.	.	N	.	.	.
Eidolon helvum **(Straw-colored fruit bat)**	18	.	L	.	.	E	.	T	.	.	.	.	.	.	.	.	T	.	D	.	K	.	.	.	.	K
Loxodonta africana **(African elephant)**	18	.	L	.	.	.	T	Q	.	.	.	.	.	.	.	.	D	F	S	P	.	.	.	.	.	.
Microcebus murinus (Gray mouse lemur)	18	Q	.	.	.	E	N	N	.	.	.	H	.	.	.	.	T	.	.	.	K	.	.	.	.	.
Ochotona princeps (American pika)	18	.	L	.	.	E	.	K	.	.	.	.	N	.	.	.	T	.	.	S	.	.	D	.	.	.
Octodon degus (Common degu)	18	F	.	.	.	.	N	Q	K	.	.	.	.	.	.	.	A	.	.	H	.	.	N	.	.	.
Procavia capensis (Rock hyrax)	18	.	L	.	.	.	T	Q	.	.	.	.	.	.	.	.	S	F	S	S	.	.	.	.	.	.
Pteropus alecto (Black flying fox)	18	.	L	.	.	E	.	T	.	.	.	.	.	.	.	.	A	.	D	.	K	.	.	.	.	K
Pteropus vampyrus **(Large flying fox)**	18	.	L	.	.	E	.	T	.	.	.	.	.	.	.	.	A	.	D	.	K	.	.	.	.	K
Trichechus manatus latirostris **(West Indian manatee)**	18	.	L	.	.	.	T	Q	.	.	.	.	.	.	.	.	N	F	S	S	.	.	.	.	.	.
VERY LOW																										
Catagonus wagneri **(Chacoan peccary)**	20	.	L	.	.	E	.	L	.	.	.	.	.	.	.	T	T	.	.	.	.	.	.	.	.	.
Jaculus jaculus (Lesser Egyptian jerboa)	19	.	M	.	.	.	.	Q	.	.	.	.	.	.	.	V	T	.	.	P	.	.	N	.	.	.
Cavia porcellus (Guinea pig)	18	F	.	.	.	.	E	L	K	.	.	.	.	.	.	.	A	.	.	P	.	.	N	.	.	.
Cavia tschudii (Montane guinea pig)	18	F	.	.	.	.	E	L	K	.	.	.	.	.	.	.	A	.	.	P	.	.	N	.	.	.
Hipposideros armiger (Great roundleaf bat)	18	.	L	E	.	.	.	T	.	.	.	H	L	.	.	R	D	.	.	.	.	.	.	.	.	.
Hipposideros pratti (Pratt's roundleaf bat)	18	.	L	E	.	.	.	T	.	.	.	H	L	.	.	R	D	.	.	.	.	.	.	.	.	.
Mesoplodon bidens (Sowerby's beaked whale)	18	P	K	I	.	Q	.	.	.	.	.	.	.	.	.	T	T	.	.	S	.	.	.	.	.	.
Spilogale gracilis (Western spotted skunk)	18	.	L	I	.	E	.	Y	.	.	E	.	.	.	.	E	T	.	.	.	.	.	.	.	.	.
Zapus hudsonius (Meadow jumping mouse)	18	V	D	.	.	.	I	Q	.	.	.	.	.	.	.	R	T	.	.	P	.	.	.	.	.	.
Ctenomys sociabilis **(Social tudo-tuco)**	17	F	.	I	.	.	N	Q	K	.	.	.	.	.	.	.	A	.	.	H	.	.	N	.	.	.
Cynopterus brachyotis (Lesser short-nosed fruit bat)	17	.	L	.	.	E	.	T	.	.	.	.	.	.	.	.	T	H	D	.	K	.	H	.	.	.
Cynopterus sphinx (Greater short-nosed fruit bat)	17	.	L	.	.	E	.	T	.	.	.	.	.	.	.	.	T	H	D	.	K	.	H	.	.	.
Enhydra lutris kenyoni **(Sea otter)**	17	.	P	.	.	E	.	Y	.	.	E	.	.	.	.	H	T	.	D	.	.	.	R	.	.	.
Eumetopias jubatus **(Steller sea lion)**	17	.	L	.	.	E	.	S	.	.	E	.	.	.	.	Q	T	.	D	.	.	.	H	.	.	.
Grammomys surdaster (African woodland thicket rat)	17	.	E	.	.	.	.	Q	.	.	.	.	.	.	.	T	N	F	T	Y	.	H	.	.	.	.
Gulo gulo (Wolverine)	17	.	L	.	.	E	.	.	.	.	E	.	.	.	.	Q	T	.	D	.	.	.	H	.	.	.
Heterohyrax brucei (Yellow-spotted rock hyrax)	17	.	L	.	.	.	T	Q	.	.	E	.	.	.	.	.	S	F	S	S	.	.	.	.	.	.
Macroglossus sobrinus (Long-tongued fruit bat)	17	.	L	.	.	E	.	T	.	.	.	.	E	.	.	.	N	.	D	.	K	.	.	.	.	K
Manis javanica **(Sunda pangolin)**	17	.	E	.	.	E	.	S	.	.	E	.	.	.	.	I	N	.	.	K	.	.	H	.	.	.
Manis pentadactyla **(Chinese pangolin)**	17	.	E	.	.	E	.	S	.	.	E	.	.	.	.	I	N	.	.	K	.	.	H	.	.	.
Mellivora capensis (Honey badger)	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	Q	T	.	D	.	.	.	R	.	.	.
Mus pahari (Graidner's shrewmouse)	17	.	N	.	.	N	.	Q	.	.	.	.	.	.	.	T	N	F	.	H	.	H	.	.	.	.
Mustela erminea (Stoat)	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	H	T	.	D	.	.	.	R	.	.	.
Mustela lutreola **(European mink)**	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	H	T	.	D	.	.	.	R	.	.	.
Mustela nigripes **(Black-footed ferret)**	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	H	T	.	D	.	.	.	H	.	.	.
Mustela putorius furo (Ferret)	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	H	T	.	D	.	.	.	R	.	.	.
Neomonachus schauinslandi **(Hawaiian monk seal)**	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	Q	T	.	D	.	.	.	H	.	.	.
Petromus typicus (Dassie rat)	17	L	.	.	.	.	T	Q	Q	.	E	.	.	.	.	.	A	.	.	H	.	.	D	.	.	.
Phoca vitulina (Harbor seal)	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	Q	T	.	D	.	.	.	R	.	.	.
Pteronura brasiliensis **(Giant otter)**	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	H	T	.	D	.	.	.	R	.	.	.
Rhinolophus ferrumequinum (Greater horseshoe bat)	17	.	L	K	.	.	D	S	.	.	N	H	.	.	.	.	N	F	.	.	.	.	.	.	.	.
Taxidea taxus (American badger)	17	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	H	T	.	D	.	.	.	H	.	.	.
Thryonomys swinderianus (Greater cane rat)	17	L	L	.	.	.	T	Q	.	.	E	.	.	.	.	.	A	.	.	R	.	.	D	.	.	.
Zalophus californianus (California sea lion)	17	.	L	.	.	E	.	S	.	.	E	.	.	.	.	Q	T	.	D	.	.	.	H	.	.	.
Acomys cahirinus (Cairo spiny mouse)	16	L	E	.	.	.	S	Q	K	.	.	.	.	.	.	S	N	F	.	H	.	.	.	.	.	.
Anoura caudifer (Tailed tailless bat)	16	T	E	.	.	E	N	T	.	.	E	H	.	.	.	.	A	.	D	.	.	.	.	.	.	.
VERY LOW (continued)																										
Artibeus jamaicensis (Jamaican fruit-eating bat)	16	A	D	.	.	E	.	T	.	.	E	.	E	.	.	.	A	.	D	.	.	.	N	.	.	.
Callorhinus ursinus **(Northern fur seal)**	16	.	L	.	.	E	.	S	.	.	E	.	.	F	.	Q	T	.	D	.	.	.	N	.	.	.
Choloepus hoffmanni (Hoffmann's two-toed sloth)	16	.	L	.	.	.	T	Q	Q	.	.	H	.	.	.	I	T	F	.	K	.	.	.	.	.	.
Condylura cristata (Star-nosed mole)	16	.	.	.	.	E	T	R	.	.	E	.	N	.	.	D	R	F	D	.	.	.	.	.	.	.
Cryptoprocta ferox **(Fossa)**	16	.	L	.	.	E	.	Y	.	Q	E	.	L	.	.	.	T	.	.	S	.	.	.	.	.	K
Dasypus novemcinctus (Nine-banded armadillo)	16	.	.	.	.	E	T	Q	Q	.	E	H	.	.	.	M	N	F	.	.	.	.	.	.	.	.
Hipposideros galeritus (Cantor's roundleaf bat)	16	.	S	I	.	.	.	T	D	.	E	H	.	.	.	.	D	.	D	K	.	.	.	.	.	.
Hyaena hyaena **(Striped hyena)**	16	.	L	.	.	E	.	Y	.	Q	E	.	L	.	.	.	T	.	D	.	.	.	.	.	.	K
Miniopterus natalensis (Natal long-fingered bat)	16	.	K	K	.	E	G	S	Q	.	.	F	E	.	.	.	I	.	.	.	.	.	.	.	.	.
Miniopterus schreibersii **(Schreibers' long-fingered bat)**	16	.	K	I	.	E	N	S	Q	.	.	F	K	.	.	.	I	.	.	.	.	.	.	.	.	.
Mirounga angustirostris (Northern elephant seal)	16	.	L	K	.	E	.	Y	.	.	E	.	.	.	.	Q	T	.	D	.	.	.	H	.	.	.
Mus caroli (Ryukyu mouse)	16	.	N	.	.	N	.	Q	.	.	.	.	.	.	.	T	S	F	T	H	.	H	.	.	.	.
Mus musculus (House mouse)	16	.	N	.	.	N	.	Q	.	.	.	.	.	.	.	T	S	F	T	H	.	H	.	.	.	.
Mus spretus (Algerian mouse)	16	.	N	.	.	S	.	Q	.	.	.	.	.	.	.	T	S	F	T	H	.	H	.	.	.	.
Myocastor coypus (Coypu)	16	L	.	A	.	.	N	Q	K	.	.	.	.	.	.	F	A	.	.	H	.	.	N	.	.	.
Myotis davidii (David's myotis)	16	.	K	I	.	.	N	S	K	.	.	H	E	.	.	.	T	.	.	S	.	.	.	.	.	.
Myotis myotis (Greater mouse-eared bat)	16	.	K	I	.	.	N	S	K	.	.	H	E	.	.	.	T	.	.	S	.	.	.	.	.	.
Noctilio leporinus (Greater bulldog bat)	16	N	.	A	.	E	N	S	K	.	E	.	.	.	.	.	A	.	D	.	.	.	.	.	.	.
Odobenus rosmarus divergens (Walrus)	16	.	L	.	.	E	.	Y	.	.	E	.	.	F	.	Q	T	.	D	.	.	.	H	.	.	.
Otolemur garnettii (Northern greater galago)	16	Q	.	.	.	.	N	R	.	.	E	H	.	.	.	I	T	.	.	E	.	.	D	.	.	.
Paguma larvata (Masked palm civet)	16	.	L	.	.	E	T	Y	.	Q	E	.	.	V	.	.	T	.	D	.	.	.	.	.	.	.
Phataginus tricuspis **(White-bellied pangolin)**	16	A	E	.	.	E	.	S	.	.	E	.	.	.	.	I	N	.	.	K	.	.	H	.	.	.
Psammomys obesus (Fat sand rat)	16	.	.	.	.	.	E	Q	K	.	.	.	.	.	.	I	N	F	T	H	.	Q	.	.	.	.
Rattus norvegicus (Brown rat)	16	.	K	S	.	N	.	Q	.	.	.	.	.	.	.	I	N	F	.	Q	.	H	.	.	.	.
Sarcophilus harrisii **(Tasmanian devil)**	16	L	M	Q	.	E	N	K	A	.	.	.	.	.	.	.	A	.	A	.	.	.	.	.	.	.
Ailurus fulgens styani **(Red panda)**	15	.	.	.	.	E	T	N	.	Q	N	.	E	.	.	H	T	.	.	.	.	H	D	.	.	.
Carollia perspicillata (Seba's short-tailed bat)	15	T	E	.	.	E	.	T	.	.	E	H	E	.	.	.	A	.	D	.	.	.	N	.	.	.
Chrysochloris asiatica (Cape golden mole)	15	.	L	A	.	N	N	Q	.	.	N	H	.	.	.	.	K	F	.	.	.	.	D	.	.	.
Elephantulus edwardii (Cape elephant shrew)	15	P	.	A	.	E	Q	Q	Q	.	.	.	.	.	.	V	N	F	D	.	.	.	.	.	.	.
Eptesicus fuscus (Big brown bat)	15	.	N	I	.	E	N	S	.	.	.	H	E	.	.	.	T	.	.	S	.	.	N	.	.	.
Helogale parvula (Common dwarf mongoose)	15	.	L	.	.	E	Q	.	.	Q	E	.	L	V	.	R	A	.	.	S	.	.	.	.	.	.
Mastomys coucha (Southern multimammate mouse)	15	Q	N	.	.	N	.	Q	.	.	.	.	.	.	.	I	N	F	T	H	.	H	.	.	.	.
Meriones unguiculatus (Mongolian gerbil)	15	.	.	.	.	.	E	Q	K	.	.	.	.	.	.	I	N	F	T	H	K	Q	.	.	.	.
Monodelphis domestica (Gray short-tailed opossum)	15	N	D	.	.	.	D	A	K	.	E	H	.	.	.	I	T	.	.	.	.	.	N	.	.	.
Mungos mungo (Banded mongoose)	15	.	L	.	.	E	Q	.	.	Q	E	.	L	V	.	R	A	.	.	S	.	.	.	.	.	.
Murina feae (Little tube-nosed bat)	15	.	K	A	.	E	T	S	K	.	.	H	E	.	.	.	T	.	.	S	.	.	.	.	.	.
Myotis brandtii (Brandt's bat)	15	.	K	I	.	E	N	S	K	.	.	H	E	.	.	.	T	.	.	S	.	.	.	.	.	.
Myotis lucifugus (Little brown bat)	15	.	K	I	.	E	N	S	K	.	.	H	E	.	.	.	T	.	.	S	.	.	.	.	.	.
Orycteropus afer afer (Aardvark)	15	A	L	.	.	E	.	Q	.	.	N	.	.	.	.	I	S	F	.	P	K	.	.	.	.	.
Paradoxurus hermaphroditus (Asian palm civet)	15	.	L	.	.	E	T	Y	.	Q	E	.	.	V	.	.	T	.	D	.	.	.	D	.	.	.
Phyllostomus discolor (Pale spear-nosed bat)	15	T	D	K	.	E	N	N	.	.	E	.	.	.	.	.	N	.	D	.	.	.	K	.	.	.
Scalopus aquaticus (Eastern mole)	15	.	.	L	.	E	N	L	K	.	N	.	E	.	.	.	Q	.	D	.	.	N	.	.	.	.
Sorex araneus (Common shrew)	15	.	N	K	.	.	N	Q	D	.	.	.	.	.	.	I	T	F	D	.	.	.	N	.	.	.
Suricata suricatta (Meerkat)	15	.	L	.	.	E	Q	.	.	Q	E	.	L	V	.	R	A	.	.	S	.	.	.	.	.	.
Tadarida brasiliensis (Brazilian free-tailed bat)	15	.	E	I	.	Q	R	T	.	.	E	H	.	.	.	H	R	.	D	.	.	.	.	.	.	.
Tonatia saurophila (Stripe-headed round-eared bat)	15	T	.	.	.	E	N	T	K	.	E	H	.	.	.	.	T	.	D	.	.	.	K	.	.	.
Microgale talazaci (Talazac's shrew tenrec)	14	.	.	Q	.	.	E	K	Q	.	N	.	.	.	.	.	N	F	D	S	.	F	N	.	.	.
Molossus molossus (Velvety free-tailed bat)	14	.	K	I	.	.	N	I	R	.	E	H	.	.	.	Q	.	.	D	.	.	N	N	.	.	.
Mormoops blainvillei (Antillean ghost-faced bat)	14	I	E	I	.	.	N	S	.	.	K	H	.	.	.	.	T	.	D	.	.	N	N	.	.	.
Neovison vison (American mink)	14	.	L	.	.	E	.	Y	.	.	E	.	.	.	.	H	T	.	D	.	.	.	H	.	.	.
Phascolarctos cinereus **(Koala)**	14	F	R	E	.	E	T	K	.	.	E	.	.	.	.	I	T	F	D	.	.	.	.	.	.	.
Pteronotus parnellii (Parnell's mustached bat)	14	N	K	E	.	E	.	L	.	.	K	H	.	.	.	.	E	F	.	.	.	N	N	.	.	.
Solenodon paradoxus **(Hispaniolan solenodon)**	14	.	E	I	.	E	S	Q	K	Q	.	.	E	.	.	.	K	.	D	.	.	.	N	.	.	.
Vombatus ursinus (Common wombat)	14	F	R	E	.	E	T	K	.	.	E	.	.	.	.	I	T	F	D	.	.	.	.	.	.	.
Desmodus rotundus (Common vampire bat)	13	T	E	.	.	E	N	T	.	.	E	.	.	.	.	I	T	.	D	S	.	N	K	.	.	.
Echinops telfairi (Lesser hedgehog tenrec)	13	.	.	S	.	T	T	N	.	.	N	.	.	.	.	.	K	F	D	P	K	L	N	.	.	.
Erinaceus europaeus (European hedgehog)	13	T	E	K	.	.	D	R	Q	.	N	.	E	.	.	T	N	.	.	S	.	N	.	.	.	.
Micronycteris hirsuta (Hairy big-eared bat)	13	T	E	.	.	E	N	T	K	.	E	H	.	.	.	.	K	.	D	.	.	N	K	.	.	.
Ornithorhynchus anatinus **(Platypus)**	13	K	E	Q	.	T	Q	K	Q	.	.	.	.	.	.	N	K	F	D	.	.	.	N	.	.	.
Pipistrellus kuhlii (Kuhl's pipistrelle)	13	.	E	E	.	.	.	S	N	.	N	H	E	.	.	.	A	F	D	.	K	.	D	.	.	.
Pipistrellus pipistrellus (Common pipistrelle)	13	.	E	D	.	.	.	S	.	.	N	H	E	.	.	R	A	F	.	S	.	E	D	.	.	.
Tupaia chinensis (Northern treeshrew)	13	T	E	V	.	N	.	I	.	.	E	H	.	.	.	Q	R	.	D	.	K	.	N	.	.	.
Uropsilus gracilis (Gracile shrew mole)	11	.	.	E	.	E	N	R	N	.	N	.	K	.	.	I	Q	F	D	S	.	M	K	.	.	.

While statistical models of this data could be interesting and informative this is evidence will not be statistically quantified for this analysis. The evidence is another way of looking at the pre-adapted state of the CoV-2 for humans and suggests that primate animals, monkey cell cultures like the VERO cell, and humanized mice could be likely laboratory models that were used by the

WIV in GoF research. This will contribute a 51%/49% contribution in favor of laboratory compared to zoonotic origin. There will be no confidence adjustment.

The results from the calculations are shown below.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin (LO)
Starting likelihood	0.011	0.989
A study of 410 animal ACE2 receptors shows CoV2 binds best to humans and other primates and worst to bat species		0.51
Impact of this evidence		Increases the likelihood of LO by 51/49 = 1.041
Impact of evidence calculation		1.041 x 0.989 = 1.030
Normalize this step of analysis	0.011/(0.011 + 1.030) = 0.011	1.030/(0.011 + 1.030) = 0.989

Adjusted likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

Evidence: Did a Review of Samples Collected from a Mineshaft Cause the COVID-19 Pandemic?[53]

Abstract. The origin of the COVID-19 pandemic caused by SARS-CoV-2 has been hotly debated. Proponents of the natural spillover theory allege that the virus jumped species, possibly via an intermediary host, to cross over to humans via the wildlife trade or by other means. Proponents of a rival theory allege that the virus escaped from a laboratory in Wuhan. This research presents circumstantial evidence of a transmission route via a late 2019 review of samples collected from a mineshaft in Mojiang, Yunnan Province, China. It examines the activity at the Wuhan Institute of Virology in late 2019, when samples from a mineshaft associated with a suspected SARS outbreak were being reviewed. It proposes that spillover occurred during this review of samples including of a virus (BtCoV/4991) only 1% different to SARS-CoV-2 in its RNA-dependent RNA polymerase (RdRp). It also proposes that the chance of identifying the outbreak may have been reduced by the issuance of new influenza guidance in November 2019.

It is a meticulous sourced analysis. It purposely avoids the question of whether SARS-CoV-2 was being grown or manipulated in the laboratory.

This will not be used to adjust the likelihoods.

Current likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

[53] https://zenodo.org/record/4029545#.X-x_f9gzbOg. Author anonymous. A meticulously documented analysis that concludes an accident occurred at the Wuhan Institute of Virology during the fall of 2019. Includes many primary documents from Mandarin. No direct evidence of 'what' was the nature of the accident or if it was SARS-CoV-2.

Evidence: The Hunan market was not the source of SARS-CoV-2

From the WHO Terms of Reference for the investigation of the origin of SARS-CoV-2:[54]

"The Huanan wholesale market is a large market (653 stalls and more than 1180 employees) mainly supplying seafood products but also fresh fruits and vegetables, meat, and live animals. In late December 2019, 10 stalls operators were trading live wild animals including chipmunks, foxes, racoons, wild boar, giant salamanders, hedgehogs, sika deer, among others. Farmed, wild and domestic animals were also traded at the market including snakes, frogs, quails, bamboo rats, rabbits, crocodiles, and badgers. The market was closed on 1 January 2020, and several investigations followed, including environmental sampling in the market, as well as sampling of frozen animal carcasses at the market. **Of the 336 samples collected from animals, none were PCR positive for SARS-CoV-2**, whereas 69 out of 842 environmental samples were positive by PCR for SARS-CoV-2. Sixty- one of those (88%) were from the western wing of the market. Of these, 22 samples were from 8 different drains and sewage, and 3 viruses were isolated, sequenced and shared on GISAID. These were virtually identical to the patient samples collected at the same time (>99.9 % homology)."

For contrast, with SARS-CoV-1 91 civets & 15 raccoon dogs in wet markets were tested with 106/106, 100% positive.[55]

This will not be used to adjust the likelihoods.

Current likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

[54] https://drive.google.com/file/d/1rx0W2efbE0R1Aq-lALWTqD22VsWbTlO-/view
[55] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1212604/

Evidence: Analysis of the hospital of admission for COVID-19 patients during December 2019 places "ground zero" for the outbreak somewhere along Line 2 of the Wuhan Metro System.

Line 2 carries 500,000 people per day and services the Wuhan Institute of Virology, the Hunan Seafood Market, the high-speed rail system, and the Wuhan International Airport

A preprint manuscript[56] reported that the earliest genomic cluster of SARS-CoV-2 patients is a group of four individuals associated with the General Hospital of Central Theater Command of People's Liberation Army (PLA) of China in Wuhan. This cluster contains the "Founder Patients" of both Clade A and Clade B, from which every SARS-CoV-2 coronavirus that has infected every patient with COVID-19 anywhere in the world has arisen.

The PLA Hospital is about one mile from the Wuhan Institute of Virology (WIV) and the closest hospital to WIV. Both the PLA Hospital and WIV are serviced by Line 2 of the Wuhan Metro System. The Hunan Seafood Market is also located adjacent to Line 2. All patients between December 1st, 2019 and early January 2020 were first seen at hospitals that are also serviced by Line 2 of the Metro system.

With 40 hospitals located near seven of the nine Metro Lines, the likelihood that all early patients were seen at hospitals only near Line 2 by chance is about 1 in 68,500 (p-value = 0.0000146). The inference then would be that the early spread of SARS-CoV-2 was through human-to human transmission on Line 2.

Line 2 carries one million passengers per day and assuming most are round trip business workers going to and from work in the morning and evening, represents 500,000 riders or about 5% of the Wuhan population. A very recent publication determined that, in fact, 500,000 residents of Wuhan contracted COVID-19, a ten-fold upper estimate.[57] The coincidence of my prediction that 500,000 riders on Line 2 were likely exposed to SARS-CoV-2 in late 2019 and the recent admission from Chinese CDC that Wuhan had 500,000 COVID-19 cases is duly noted!

Line 2 connects to all eight other lines of the Wuhan Metro System (1, 3, 4, 6, 7, 8, 11, and Yanglu) facilitating rapid spread in Wuhan and Hubei Province, and also services both the high-speed rail station (Hankou Railway Station), facilitating rapid spread throughout China, and the Wuhan International Airport (Tianhe International Airport), facilitating rapid spread throughout Asia, Europe, and to the United States. In fact, direct human-to-human spread from the Reference Sequence patient to patients around the world is suggested by an unexpectedly reduced genome base substitution rate seen in patient specimens in cities with direct flights from Wuhan.

[56] https://zenodo.org/record/4119263#.X-rszNgzbOg
[57] https://mp.weixin.qq.com/s/LXTfDmsQLf3qZnu_S_MxcA; https://thehill.com/policy/international/china/531935-study-shows-wuhan-coronavirus-cases-may-have-been-10-times-higher

In a separate paper by Quay and Lee from May 2020, now accepted for publication in *Epidemics,*[58] they provide evidence that COVID-19 was appearing in California as early as the first week of 2020. This is likely due to direct flights connecting Line 2 to the Wuhan airport and then to San Francisco.

While of little probative value, this 50-second video[59] from Rep. Steven Smith's (R-GA) Twitter account is a concise summation of this evidence: the speaker is Peter Daszak, at 17-seconds it shows a crowded Wuhan Metro Station with a Line 2 sign overhead, and then at 25-seconds it shows Drs. Daszak and Shi looking at a computer screen inside the Wuhan Institute of Virology.

In conclusion, Line 2 of the Wuhan Metro System services the PLA Hospital with the first genomic cluster of patients with COVID-19, the hospitals where patients first went in December 2019 and early January 2020 and is the likely conduit for human-to-human spread throughout Wuhan, China, and the world.

The Hunan Seafood Market, Wuhan Institute of Virology, and the Wuhan CDC, all locations suggested to be the possible source of SARS-CoV-2 in Wuhan, are also all serviced by Line 2 of the Metro system, suggesting this public transit line should become the focus for further investigations into the origin of this pandemic.

Given that the Hunan Seafood Market has been removed as a source for the origin of CoV-2, this evidence will contribute a 51%/49% contribution in favor of laboratory compared to zoonotic origin. There will be no confidence adjustment.

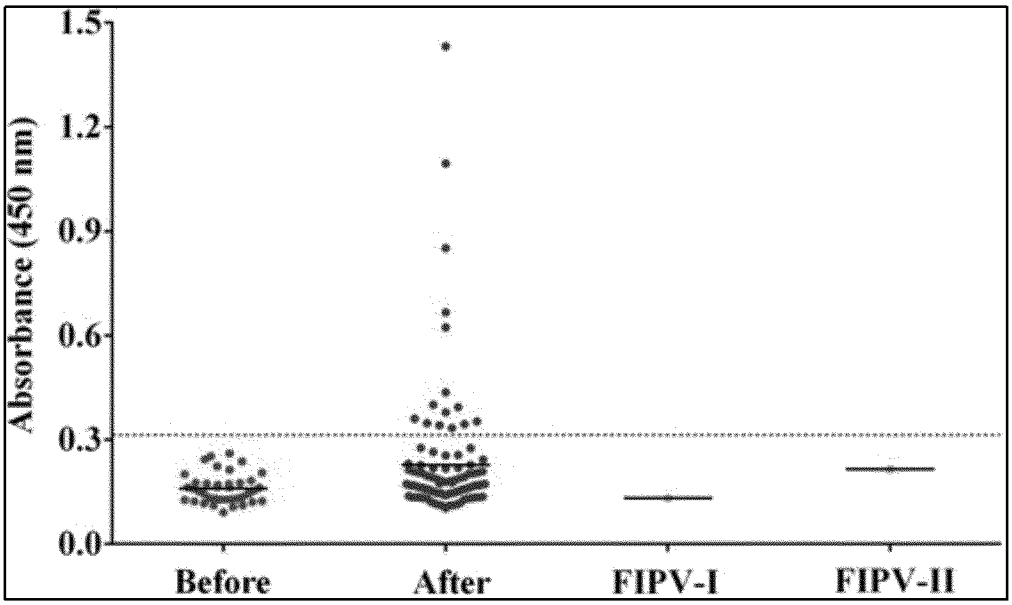
The results from the calculations are shown below.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin (LO)
Starting likelihood	0.011	0.989
The finding of Line 2 as the likely geoorigin for CoV-2 and the fact it services the WIV this evidence favors a LO		0.51
Impact of this evidence		Increases the likelihood of LO by 51/49 = 1.041
Impact of evidence calculation		1.041 x 0.989 = 1.030
Normalize this step of analysis	0.011/(0.011 + 1.030) = 0.011	1.030/(0.011 + 1.030) = 0.989

Adjusted likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

[58] https://www.researchgate.net/publication/341742303_COVID-19_May_Have_Have_Reached_United_States_in_January_2020_05272020
[59] https://twitter.com/i/status/1264742199754756097

Evidence: SARS-CoV-2 infection, based on antibody seroconversion, was not found in 39 archived specimens taken from cats (1/3 feral) between March and May 2019[60]



Based on these results, the prevalence of SARS-CoV-2 in domestic and feral cats prior to January 2020 is less than 8% with a 90% confidence interval.

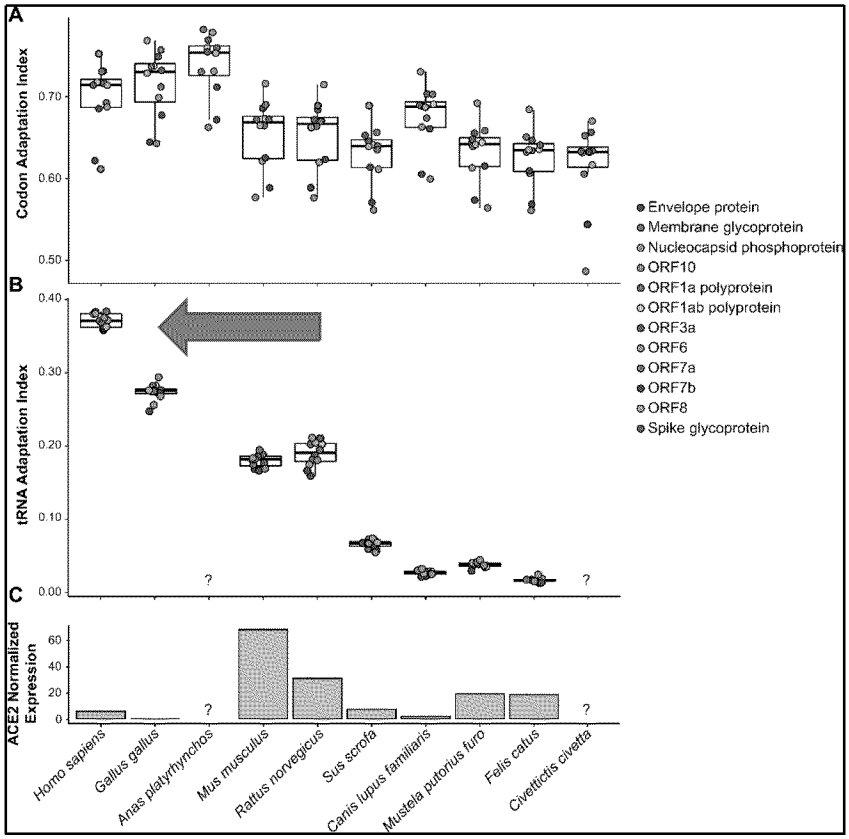
This will not be used to adjust the likelihoods.

Current likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

[60] https://www.tandfonline.com/doi/full/10.1080/22221751.2020.1817796

Evidence: The extraordinary pre-adaption of SARS-CoV-2 for human cells is demonstrated by a paper looking at a tRNA adaption index.[61]

"The proteome of SARS-CoV-2 is mainly composed of the replicase polyprotein (ORF1ab) and of structural proteins: the spike glycoprotein, the membrane and envelope proteins, and the nucleoprotein [41]. Based on the genomic codon usage of each of the possible host species, we compute the codon adaptation index (CAI) and the tRNA adaptation index (tAI) to estimate the translational efficiency of SARS-CoV-2 proteins in each host (Fig 3A and 3B and S2 Table). Humans are among the top three species whose CAIs are mostly over 0.70, together with ducks and and chicken. In terms of the tAI, humans show the highest translational adaptation among all others, followed by chicken, and, to some extent, mice and rats. On the other hand, cats, ferrets, pigs, and dogs are less translationally adapted than humans both by CAI and tAI."



As shown in panel B above, the tRNA Adaption Index is highest, by far, for humans (blue arrow) followed by the red junglefowl. This is additional evidence of the extraordinary adaption to humans of SARS-CoV-2 from the very beginning. This also is the first evidence of a reasonable intermediate host but based only on these *in silico* data.

This will not be used to adjust the likelihoods.

Current likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

[61] https://journals.plos.org/ploscompbiol/article?id=10.1371/journal.pcbi.1008450#pcbi.1008450.s004

Evidence: Evidence of Lax and disregard of laboratory safety protocols and regulations in China

A collection[62] from the Chinese Q&A website, https://www.zhihu.com/ , of first-hand documentation of laboratory safety breaches and incidents within a large number of laboratories with diverse research subjects and purposes in the People's Republic of China (PRC). The laboratories involved including Chemistry labs, Biolabs, Computer labs as well as Physics and Engineering labs.

From these first-handed documentation, we obtained evidence of relaxed safety regulations and frequent breach of such regulations, with reasons ranging from poor training/education on lab safety, chronic ignorance of safety rules to intentional breach of protocols for purposes other than the research projects of the lab(s) of which the breach was documented in.

Such breaches often resulted in safety accidents ranging from physical injury, chemical burns, chemical leaks, damage to property to lab-acquired infection and escape of in-lab pathogens. With consequences from personal-level to institution-level.

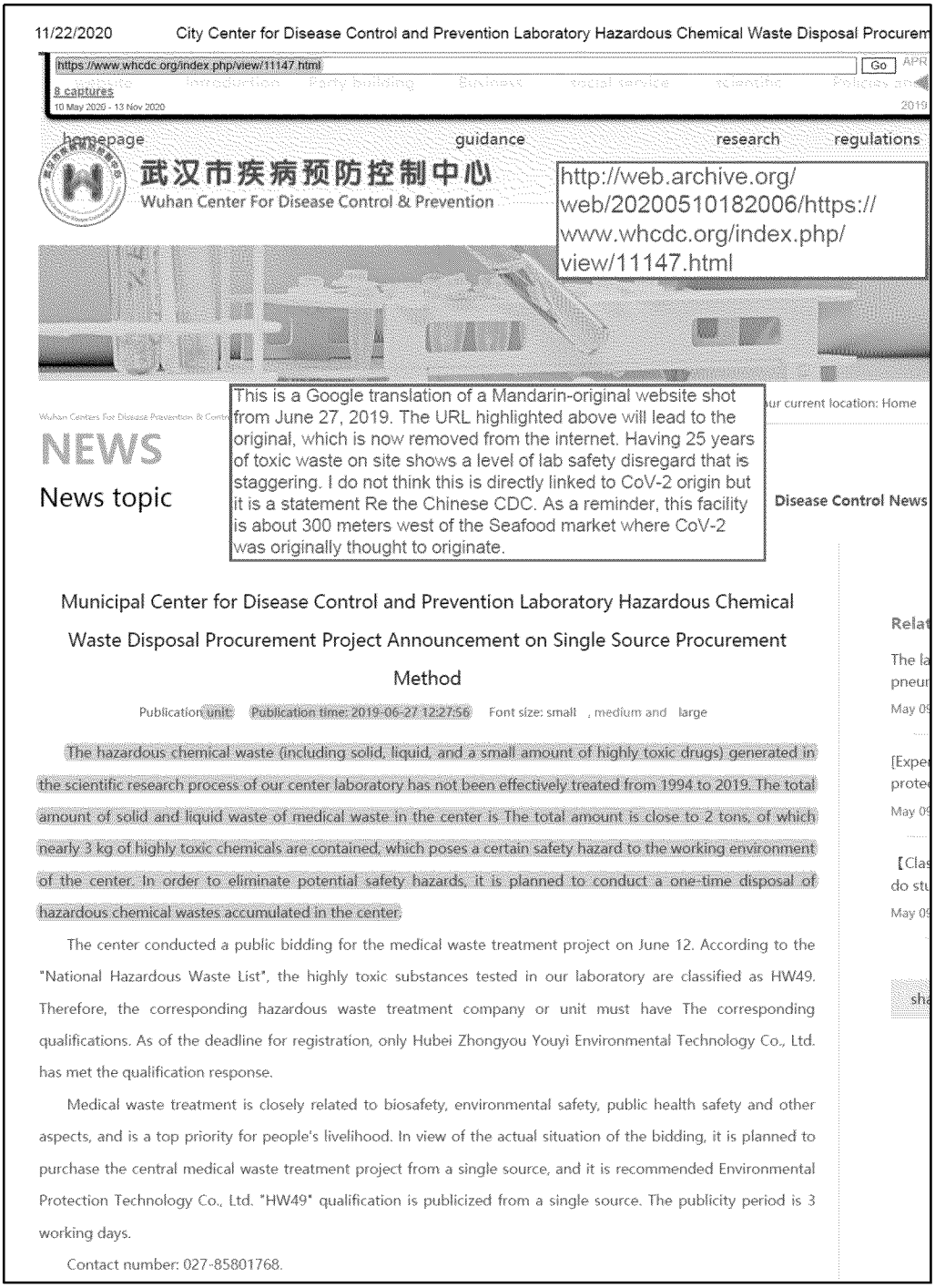
Here is the reference to the State Department cables concerning safety concerns at the WIV.[63]

The following document shows that in June 2019, the Chinese CDC was soliciting for the removal of 25-years of solid and liquid medical waste. The total is close to two tons including three kg of highly toxic waste.

This is a Google translation of a Mandarin-original website shot from June 27, 2019. The URL highlighted above will lead to the original, which is now removed from the internet. Having 25 years of toxic waste on site shows a level of lab safety disregard that is staggering.

I do not think this is directly linked to CoV-2 origin but is a statement about the Chinese CDC. As a reminder, this facility is about 300 meters west of the Seafood market where CoV-2 was originally thought to originate.

[62] https://zenodo.org/record/4307879#.X-yUo9gzbOh
[63] https://foia.state.gov/Search/Results.aspx?caseNumber=F-2020-05255

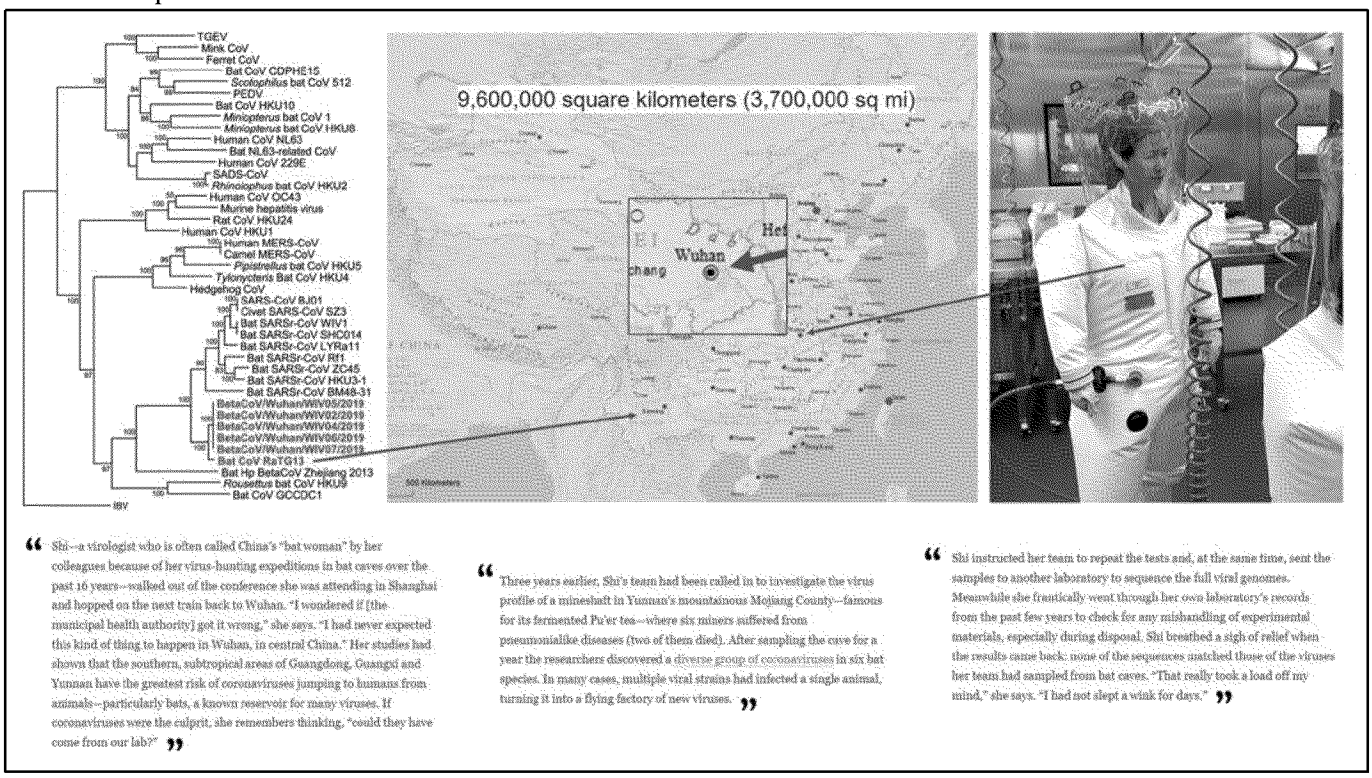


This will not be used to adjust the likelihoods.

Current likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

Evidence: The careful words of Dr. Shi do NOT say she did not have SARS-CoV-2 at the WIV.

This Figure contains quotes from an article about Dr. Shi and her reaction to the beginning of the COVID-19 pandemic.



Notice in the last frame Dr. Shi says two strange sentences:

Sentence 1: “…she frantically went through her own laboratory’s records from the past few years to check for any mishandling of experimental materials, **especially during disposal**.”

If you don’t know what you are looking for this, “especially during disposal,” is a bit of an odd qualifier. Other evidence elsewhere suggests that, in fact, disposal may have been a likely source of the accidental lab release.

Sentence 2: “She breathed a sigh of relief when the results came back: none of the sequences matched those of the viruses her team had sampled from bat caves.”

If Dr. Shi had created SARS-CoV-2 as a chimera, perhaps starting with one of those cave viruses, of course you would no longer have a sequence match. This is a probably truthful statement that leaves open the question of lab creation.

This will not be used to adjust the likelihoods.

Current likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

Evidence: The Good, the Bad and the Ugly: a review of SARS Lab Escapes[64]

In 2003–04, in the wake of the SARS epidemics, there were multiple cases of laboratory acquired infection (LAI) with SARS in just a few months: first in a P3 in Singapore, then in a military P4 in Taipei and last a protracted case in a P3 in Beijing. The 'WHO SARS Risk Assessment and Preparedness Framework' has a good summary of these lab accidents:

Since July 2003, there have been four occasions when SARS has reappeared. Three of these incidents [note: Singapore, Taipei and Beijing] were attributed to breaches in laboratory biosafety and resulted in one or more cases of SARS. The most recent laboratory incident [note: in Beijing] resulted in 9 cases, 7 of which were associated with one chain of transmission and with hospital spread. Two additional cases at the same laboratory with a history of illness compatible with SARS in February 2004 were detected as part of a survey of contacts at the facility.[i.1]

This article reviews some of these cases and discusses briefly some of the insights that were gained from these at the time.

Another article along the same lines is, "10 incidents discovered at the nation's biolabs"[65] This included Dr. Baric's laboratory in which "(b)etween April 2013 and September 2014, eight individual mouse escapes were reported at the University of North Carolina-Chapel Hill. Several of the mice were infected with either SARS or the H1N1 flu virus."

Dozens of holes in BSL-4 'spacesuits'

As a key protection against the world's most deadly pathogens, including the Ebola virus, scientists in the BSL-4 labs at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick in Maryland wear pressurized, full-body spacesuit-like gear and breathe purified air. Yet those suits ruptured or developed holes in at least 37 incidents during a 20-month period in 2013 and 2014, according to lab incident reports obtained by USA TODAY under the federal Freedom of Information Act.

This will contribute a 51%/49% contribution in favor of laboratory compared to zoonotic origin. There will be no confidence adjustment. The results from the calculations are shown below.

Evidence or process	Zoonotic Origin (ZO)	Laboratory Origin (LO)
Starting likelihood	0.011	0.989
The history of SARS laboratory accidents is consistent with the laboratory origin hypothesis		0.51
Impact of this evidence		Increases the likelihood of LO by 51/49 = 1.041
Impact of evidence calculation		1.041 x 0.989 = 1.030
Normalize this step of analysis	0.011/(0.011 + 1.030) = 0.011	1.030/(0.011 + 1.030) = 0.989

Adjusted likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

[64] https://gillesdemaneuf.medium.com/the-good-the-bad-and-the-ugly-a-review-of-sars-lab-escapes-898d203d175d

[65] https://www.usatoday.com/story/news/2015/05/29/some-recent-us-lab-incidents/25258237/

Evidence: Drs. Shi and Daszak use Wuhan residents as negative controls for zoonotic coronavirus seroconversion[66]

"As a control, we collected 240 serum samples from random blood donors in **Wuhan >1000 km away from Jinning & where inhabitants have a much lower likelihood of contact with bats due to its urban setting**" [emphasis added]. As expected, 0/240 had a positive serological evidence of prior coronavirus infection.

"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."

In this paper from 2018, Drs. Shi and Daszak conclude that bat-to-human transfer is relatively rare for high risk people living in close proximity to bat colonies and much less likely in Wuhan, a conclusion that does not support a hypothesis of bat-to-human transmission.

This will not be used to adjust the likelihoods.

Current likelihood: Zoonotic origin (1.1%), laboratory origin (98.9%).

[66] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6178078/

The Appendix contains the following information which was determined to be important to the overall investigation into the origin of CoV-2 but which did not become part of the Bayesian analysis:

- Evidence that Dr. Shi has published contrived data, making the credibility of everything she says suspect. Specifically:

    - The seminal paper from the Wuhan Institute of Virology claiming SARS-CoV-2 probably originated in bats appears to contain a contrived specimen, an incomplete and inaccurate genomic assembly, and the signature of laboratory-derived synthetic biology

    - *The coronavirus RaTG13 was purportedly identified in a bat "fecal" specimen that is probably not feces, has significant unresolved method-dependent genome sequence errors and an incomplete assembly with significant gaps, and has an anomalous base substitution pattern that has never been seen in nature but is routinely used in codon-optimized synthetic genome constructions performed in the laboratory*

- Evidence for and against RaTG13 as the direct precursor of CoV-2. I have not made up my mind on this important hypothesis
    - To establish a precursor-product relationship for RaTG13 and CoV-2 a relative simple process must be proposed to make approximately 1140 nt changes in the 30,000 nt genome
    - Evidence in favor of the hypothesis:
        - While the nucleotide sequence data show these coronaviruses are only 96.2% homologous a comparison of their amino acid homology indicates they are 98.8% identical and as similar as the Civet SARS-CoV-1 and human SARS-CoV-1
        - About 26% of the entire genomes contain only synonymous mutations without any non-synonymous mutations, a highly improbably outcome in nature but an easy exercise in the laboratory to introduce. The motivation would be to obscure the closeness of the two genomes without worrying about introducing detrimental mutations. This represents about 200 of the nt differences
        - There are two restriction enzyme sites in RaTG13 that begin at the receptor binding domain and end 3' to the furin cleavage site that use the 'No See 'Em' technology developed and patented by Ralph Baric, a Dr. Shi and WIV collaborator. Shi has used these enzymes herself. As expected for the technology, the sites are lost in CoV-2. However, they are not the "pure-form" of the Baric technology, are less hidden, and so I would be surprised if Shi did this less robust approach. Nonetheless, the likelihood these sites are there by chance is infinitesimal.

        - CoV-2 and RaTG13 share a >100 nt insertion in the ORF1ab gene found no where else in sarbecoviruses. A very strange fact and significantly greater than the 12-nt furin site that has caught so much attention. I spent a day or so probing the function of the site, I believe it is nsp3 (from memory), but didn't find a smoking gun to warrant deeper work. Should be returned to.
        - It is part of the nine viruses found in the Yunnan cave where miners died of a coronavirus-like illness.
    - Evidence against RaTG13
        - My proof that it did not come from the bat feces specimen as reported by Shi is troublesome for an hypothesis it is the critical precursor virus
        - To my knowledge no has grown it and examination of its Spike Protein by numerous groups comes to the unlikely conclusion it will bind to ACE2 of most species or grow in a lab culture.
        - Peter Daszak, who has said many things proven to be false, nonetheless has described RaTG13 as a "composite sequence" a term used for a really mixed specimen where metagenomics are used to obtain a "genome sequence" which in reality was pieced together artificially by the computers running the analysis
        - I can reduce the 1140 nt difference to about 600 with two steps, the No See 'Em insertion of the CoV-2 RBD in the Spike Protein and using a synonymous mutation algorithm to create artificial phylogenetic distance. But a simple method of closing that 600 nt, mostly non-synonymous mutations, has not been identified.
        - Shi collected nine beta coronaviruses in the mine but has published the sequence of only RaTG13. She voluntarily published RaTG13. It seems more likely that she would publish a virus close to CoV-2 to establish the bat origin in the medical field (the RaTG13 paper title was "A pneumonia outbreak associated with a new coronavirus of probable bat origin) but not publish the actual virus she used for the construction of CoV-2, in the unlikely event a 'bullet proof' connection that she hadn't thought of could be found.
- Remarkable evidence of the synthetic Adenovirus vector vaccine in patients sequenced at the WIV
    - More work will be focused on this to establish what the immunogen is and to further this proof.

To: galter (galter@partners.org)[galter@partners.org]; Maria Baca Estrada (maria.baca-estrada@canada.ca)[maria.baca-estrada@canada.ca]; baihe (baihe@nmpa.gov.cn)[baihe@nmpa.gov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; cheryl (cheryl@gisaid.org)[cheryl@gisaid.org]; valentina.bernasconi@cepi.net[valentina.bernasconi@cepi.net]; shinjini.bhatnagar (shinjini.bhatnagar@thsti.res.in)[shinjini.bhatnagar@thsti.res.in]; pbieniasz@mail.rockefeller.edu[pbieniasz@mail.rockefeller.edu]; karin.bok (karin.bok@nih.gov)[karin.bok@nih.gov]; Boyle, David[dboyle@path.org]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; BRANGEL, Polina[brangelp@who.int]; christian.brechot (christian.brechot@pasteur.fr)[christian.brechot@pasteur.fr]; Christine Bruce (Christine.bruce@phe.gov.uk)[Christine.bruce@phe.gov.uk]; zuz4 (zuz4@cdc.gov)[zuz4@cdc.gov]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; fjc37@cam.ac.uk[fjc37@cam.ac.uk]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; Emmanuelle Charton (emmanuelle.charton@edqm.eu)[emmanuelle.charton@edqm.eu]; Chu, May[MAY.CHU@CUANSCHUTZ.EDU]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; Daniel Cohen (dancohen@tauex.tau.ac.il)[dancohen@tauex.tau.ac.il]; kizzmekia.corbett@nih.gov[kizzmekia.corbett@nih.gov]; COSTA, Alejandro Javier[costaa@who.int]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)[htq4@cdc.gov]; shane@lji.org[shane@lji.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Damon, Inger K. (CDC/DDID/NCEZID/DHCPP)[iad7@cdc.gov]; Lisa@amicitiam.com[Lisa@amicitiam.com]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; de los Santos, Tala[tdelossantos@path.org]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; Delgado Vazquez.Rafael (rafael.delgado@salud.madrid.org)[rafael.delgado@salud.madrid.org]; mit666666 (mit666666@pitt.edu)[mit666666@pitt.edu]; katie.doores (katie.doores@kcl.ac.uk)[katie.doores@kcl.ac.uk]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; christian.drosten (christian.drosten@charite.de)[christian.drosten@charite.de]; epstein@ecohealthalliance.org[epstein@ecohealthalliance.org]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; jason.fernandes@canada.ca[jason.fernandes@canada.ca]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; Luc.Gagnon (Luc.Gagnon@nexelis.com)[Luc.Gagnon@nexelis.com]; Mayra.Garcia (Mayra.Garcia@fda.hhs.gov)[Mayra.Garcia@fda.hhs.gov]; bhx1 (bhx1@cdc.gov)[bhx1@cdc.gov]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; GILBERT Nick[Nick.Gilbert@ed.ac.uk]; Goldblatt, David[d.goldblatt@ich.ucl.ac.uk]; guy.gorochov@sorbonne-universite.fr[guy.gorochov@sorbonne-universite.fr]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Griffiths, Anthony[ahgriff@bu.edu]; elwyn.griffiths@cepi.net[elwyn.griffiths@cepi.net]; gregory.d.gromowski.civ (gregory.d.gromowski.civ@mail.mil)[gregory.d.gromowski.civ@mail.mil]; Celine Gurry (Celine.gurry@cepi.net)[Celine.gurry@cepi.net]; ilj2 (ilj2@cdc.gov)[ilj2@cdc.gov]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; Helfand, Rita (CDC/DDID/NCEZID/OD)[rzh7@cdc.gov]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Hodgson, Paul[paul.hodgson@usask.ca]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; johan.holst@cepi.net[johan.holst@cepi.net]; rawcraig@yahoo.com[rawcraig@yahoo.com]; Hyde, Terri (CDC/DDPHSIS/CGH/GID)[thyde@cdc.gov]; IRAHETA SIGUENZA, Raul Emilio[irahetar@who.int]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; ASiyer@mgh.harvard.edu[ASiyer@mgh.harvard.edu]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)[djernigan@cdc.gov]; johnsonreed@niaid.nih.gov[johnsonreed@niaid.nih.gov]; ydm9@cdc.gov[ydm9@cdc.gov]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; KNEZEVIC, Ivana[knezevici@who.int]; M.P.G. Koopmans (m.koopmans@erasmusmc.nl)[m.koopmans@erasmusmc.nl]; Kovacs, Gerald (OS/ASPR/BARDA) (CTR)[Gerald.Kovacs@hhs.gov]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; philip.krause@fda.hhs.gov[philip.krause@fda.hhs.gov]; Shelly Krebs (skrebs@hivresearch.org)[skrebs@hivresearch.org]; Greg Kulnis (Greg.Kulnis@nexelis.com)[Greg.Kulnis@nexelis.com]; Arun Kumar (arun.kumar@cepi.net)[arun.kumar@cepi.net]; pawinee.k@redcross.or.th[pawinee.k@redcross.or.th]; Teresa Lambe (teresa.lambe@ndm.ox.ac.uk)[teresa.lambe@ndm.ox.ac.uk]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Leader, Troy[bleader@path.org]; leejooyeon (leejooyeon@korea.kr)[leejooyeon@korea.kr]; Lee, William T (HEALTH)[william.lee@health.ny.gov]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; liyl (liyl@cde.org.cn)[liyl@cde.org.cn]; changguili (changguili@aliyun.com)[changguili@aliyun.com]; lyhchengdu (lyhchengdu@163.com)[lyhchengdu@163.com]; limhy0919 (limhy0919@korea.kr)[limhy0919@korea.kr]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; liub (liub@cde.org.cn)[liub@cde.org.cn]; jma[jma@sgul.ac.uk]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Mary.Matheson@phe.gov.uk[Mary.Matheson@phe.gov.uk]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; jmclellan (jmclellan@austin.utexas.edu)[jmclellan@austin.utexas.edu]; adrian.mcdermott (adrian.mcdermott@nih.gov)[adrian.mcdermott@nih.gov]; jmcelrat (jmcelrat@fredhutch.org)[jmcelrat@fredhutch.org]; gmedigeshi (gmedigeshi@thsti.res.in)[gmedigeshi@thsti.res.in]; jwm1 (jwm1@pitt.edu)[jwm1@pitt.edu]; Liz Miller (Liz.Miller@lshtm.ac.uk)[Liz.Miller@lshtm.ac.uk]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; david.montefiori@duke.edu[david.montefiori@duke.edu]; pennym@nicd.ac.za[pennym@nicd.ac.za]; kaitlyn.dambach@nih.gov[kaitlyn.dambach@nih.gov]; MORGAN, Oliver[omorgan@who.int]; Clare.Morris@nibsc.org[Clare.Morris@nibsc.org]; Sarah Mudrak, Ph.D.[sarah.mudrak@duke.edu]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Myers, Todd[Todd.Myers@fda.hhs.gov]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; scott.napper (scott.napper@usask.ca)[scott.napper@usask.ca]; MNELSON (MNELSON@dstl.gov.uk)[MNELSON@dstl.gov.uk]; PNorris@vitalant.org[PNorris@vitalant.org]; pilailuk.o (pilailuk.o@dmsc.mail.go.th)[pilailuk.o@dmsc.mail.go.th]; n.okba@erasmusmc.nl[n.okba@erasmusmc.nl]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; Jae Ouk Kim (jokim@ivi.int)[jokim@ivi.int]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; gustavo.f.palacios.civ (gustavo.f.palacios.civ@mail.mil)[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov];

Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP)[xdv3@cdc.gov]; qiang.pan-hammarstrom@ki.se[qiang.pan-hammarstrom@ki.se]; Peden, Keith[keith.peden@fda.hhs.gov]; sheila.a.peel2.civ (sheila.a.peel2.civ@mail.mil)[sheila.a.peel2.civ@mail.mil]; malik (malik@hku.hk)[malik@hku.hk]; PERKINS, Mark[perkinsm@who.int]; Perlman, Stanley[stanley-perlman@uiowa.edu]; Supaporn Phumiamorn (supaporn.p@dmsc.mail.go.th)[supaporn.p@dmsc.mail.go.th]; margaret.l.pitt.civ (margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; mireille.plamondon@canada.ca[mireille.plamondon@canada.ca]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; arimoin (arimoin@g.ucla.edu)[arimoin@g.ucla.edu]; RIVEROS BALTA, Ximena[lauriex@who.int]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; Jilian Sacks (Jilian.sacks@finddx.org)[Jilian.sacks@finddx.org]; Marc L Salit (msalit@stanford.edu)[msalit@stanford.edu]; erica (erica@lji.org)[erica@lji.org]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Sharon Schendel (schendel@lji.org)[schendel@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; PScott (PScott@eidresearch.org)[PScott@eidresearch.org]; alex@lji.org[alex@lji.org]; peshi@UTMB.EDU[peshi@UTMB.EDU]; Shivji Ragini (Ragini.Shivji@ema.europa.eu)[Ragini.Shivji@ema.europa.eu]; sujan@lji.org[sujan@lji.org]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; YOO, Si Hyung[yoos@who.int]; alex.sigal@ahri.org[alex.sigal@ahri.org]; Smith, Ashley (OS/ASPR/BARDA)[Ashley.Smith1@hhs.gov]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; SUBISSI, Lorenzo[subissil@who.int]; SWAMINATHAN, Soumya[swaminathans@who.int]; r.tedder@imperial.ac.uk[r.tedder@imperial.ac.uk]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; tracey.thue (tracey.thue@usask.ca)[tracey.thue@usask.ca]; georgia.tomaras (georgia.tomaras@duke.edu)[georgia.tomaras@duke.edu]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; sylvie.van-der-werf (sylvie.van-der-werf@pasteur.fr)[sylvie.van-der-werf@pasteur.fr]; eric.vangieson@darpa.mil[eric.vangieson@darpa.mil]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; linfa.wang (linfa.wang@duke-nus.edu.sg)[linfa.wang@duke-nus.edu.sg]; wangjz (wangjz@nifdc.org.cn)[wangjz@nifdc.org.cn]; wangyc (wangyc@nifdc.org.cn)[wangyc@nifdc.org.cn]; Weir, Jerry P.[jerry.weir@fda.hhs.gov]; gweiss@uci.edu[gweiss@uci.edu]; daniela@lji.org[daniela@lji.org]; tomwhite42450@gmail.com[tomwhite42450@gmail.com]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; Wolfraim, Larry (NIH/NIAID) [E][larry.wolfraim@nih.gov]; David Wood (dj56wood@gmail.com)[dj56wood@gmail.com]; xumiaobj (xumiaobj@126.com)[xumiaobj@126.com]; solomon.yimer@cepi.net[solomon.yimer@cepi.net]; tlying (tlying@fudan.edu.cn)[tlying@fudan.edu.cn]; Vidadi Yusibov (vyusibov@indianabiosciences.org)[vyusibov@indianabiosciences.org]; zlshi (zlshi@wh.iov.cn)[zlshi@wh.iov.cn]; ZHOU, Tiequn[ZhouT@who.int]; diane.descamps@aphp.fr[diane.descamps@aphp.fr]; SGalloway@cdc.gov[SGalloway@cdc.gov]; lny1@cdc.gov[lny1@cdc.gov]; Wentworth, David E. (CDC/OID/NCIRD)[gll9@cdc.gov]; mbo2@cdc.gov[mbo2@cdc.gov]; sot1@cdc.gov[sot1@cdc.gov]

Cc: alex@lji.org[alex@lji.org]; Joe Campo[jcampo@antigendiscovery.com]; Angela Yee[ayee@antigendiscovery.com]; Xiaowu Liang[xliang@antigendiscovery.com]; Arlo Randall[arandall@antigendiscovery.com]

From: SCHWARTZ, Lauren[schwartzl@who.int]

Sent: Mon 1/11/2021 6:43:28 PM (UTC-05:00)

Subject: RE: WHO Working Group on COVID-19 Assays

Dear All,

Please find below the agenda for our group call on Wednesday January 13, 2021 at 2:30PM CET (Geneva time).

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays

1. Alessandro Sette (LJI) - *Comprehensive analysis of T cell immunodominance and immunoprevalence of SARS-CoV-2 epitopes in COVID-19 cases*
2. Joe Campo (Antigen Discovery Inc) - *A Multi-Coronavirus Protein Microarray for Mapping SARS-CoV-2 Antibody Epitopes and Characterizing Immune Responses to Infection and Vaccination*

-----Original Appointment-----

From: SCHWARTZ, Lauren

Sent: Sunday, January 10, 2021 2:22 PM

To: galter@partners.org; maria.baca-estrada@canada.ca; baihe@nmpa.gov.cn; rbaric@email.unc.edu; dbarouch@bidmc.harvard.edu; cheryl@gisaid.org; valentina.bernasconi@cepi.net; shinjini.bhatnagar@thsti.res.in; pbieniasz@mail.rockefeller.edu; karin.bok@nih.gov; dboyle@path.org; brooke.bozick@nih.gov; BRANGEL, Polina; christian.brechot@pasteur.fr; Christine.bruce@phe.gov.uk; zuz4@cdc.gov; Miles.Carroll@phe.gov.uk; fjc37@cam.ac.uk; Marco.Cavaleri@ema.europa.eu; MONALISA.CHATTERJI@gatesfoundation.org; emmanuelle.charton@edqm.eu;

MAY.CHU@CUANSCHUTZ.EDU; carolyn.clark@cepi.net; Daniel Cohen (dancohen@tauex.tau.ac.il); kizzmekia.corbett@nih.gov; COSTA, Alejandro Javier; htq4@cdc.gov; shane@lji.org; ian.crozier@nih.gov; Iad7@cdc.gov; Lisa@amicitiam.com; daszak@ecohealthalliance.org; tdelossantos@path.org; emmie.dewit@nih.gov; marciela.degrace@nih.gov; rafael.delgado@salud.madrid.org; mit666666@pitt.edu; katie.doores@kcl.ac.uk; william.dowling@cepi.net; christian.drosten@charite.de; epstein@ecohealthalliance.org; Karl.Erlandson@hhs.gov; darryl.falzarano@usask.ca; jason.fernandes@canada.ca; clint.florence@nih.gov; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk; Luc.Gagnon@nexelis.com; Mayra.Garcia@fda.hhs.gov; bhx1@cdc.gov; Volker.gerdts@usask.ca; Nick.Gilbert@ed.ac.uk; d.goldblatt@ucl.ac.uk; guy.gorochov@sorbonne-universite.fr; barney.graham@nih.gov; ahgriff@bu.edu; elwyn.griffiths@cepi.net; gregory.d.gromowski.civ@mail.mil; celine.gurry@cepi.net; ilj2@cdc.gov; b.haagmans@erasmusmc.nl; rzh7@cdc.gov; HENAO RESTREPO, Ana Maria; lisa.hensley@nih.gov; paul.hodgson@usask.ca; Michael.holbrook@nih.gov; johan.holst@cepi.net; rawcraig@yahoo.com; tkh4@cdc.gov; IRAHETA SIGUENZA, Raul Emilio; REIRELAND@mail.dstl.gov.uk; ASiyer@mgh.harvard.edu; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; johnsonreed@niaid.nih.gov; ydm9@cdc.gov; Jacqueline.Kirchner@gatesfoundation.org; KNEZEVIC, Ivana; m.koopmans@erasmusmc.nl; Gerald.Kovacs@hhs.gov; florian.krammer@mssm.edu; Philip.Krause@fda.hhs.gov; skrebs@hivresearch.org; Greg.Kulnis@nexelis.com; arun.kumar@cepi.net; pawinee.k@redcross.or.th; teresa.lambe@ndm.ox.ac.uk; janet.lathey@nih.gov; bleader@path.org; leejooyeon@korea.kr; william.lee@health.ny.gov; MSLEVER@dstl.gov.uk; liyl@cde.org.cn; changguili@aliyun.com; lyhchengdu@163.com; limhy0919@korea.kr; James.Little@hhs.gov; liub@cde.org.cn; jma@sgul.ac.uk; Tracy.MacGill@fda.hhs.gov; Karen.Makar@gatesfoundation.org; Mary.Matheson@phe.gov.uk; Giada.Mattiuzzo@nibsc.org; jmclellan@austin.utexas.edu; adrian.mcdermott@nih.gov; jmcelrat@fredhutch.org; gmedigeshi@thsti.res.in; jwm1@pitt.edu; Liz.Miller@lshtm.ac.uk; philip.minor2@gmail.com; kmodjarrad@eidresearch.org; david.montefiori@duke.edu; pennym@nicd.ac.za; kaitlyn.dambach@nih.gov; MORGAN, Oliver; Clare.Morris@nibsc.org; sarah.mudrak@duke.edu; munoz-fontela@bnitm.de; vincent.munster@nih.gov; Todd.Myers@fda.hhs.gov; aysegul.nalca.civ@mail.mil; scott.napper@usask.ca; MNELSON@dstl.gov.uk; PNorris@vitalant.org; pilailuk.o@dmsc.mail.go.th; n.okba@erasmusmc.nl; golinger@MRIGLOBAL.ORG; jokim@ivi.int; Mark.Page@nibsc.org; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; xdv3@cdc.gov; qiang.pan-hammarstrom@ki.se; Keith.Peden@fda.hhs.gov; sheila.a.peel2.civ@mail.mil; malik@hku.hk; PERKINS, Mark; stanley-perlman@uiowa.edu; supaporn.p@dmsc.mail.go.th; margaret.l.pitt.civ@mail.mil; mireille.plamondon@canada.ca; JLPRIOR@dstl.gov.uk; arimoin@g.ucla.edu; RIVEROS BALTA, Ximena; Nicola.Rose@nibsc.org; Jilian.Sacks@finddx.org; msalit@stanford.edu; erica@lji.org; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; connie.schmaljohn@nih.gov; Barbara.Schnierle@pei.de; SCHWARTZ, Lauren; PScott@eidresearch.org; alex@lji.org; peshi@UTMB.EDU; Ragini.Shivji@ema.europa.eu; sujan@lji.org; amy.c.shurtleff@cepi.net; YOO, Si Hyung; alex.sigal@ahri.org; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SUBISSI, Lorenzo; SWAMINATHAN, Soumya; r.tedder@imperial.ac.uk; nax3@cdc.gov; tracey.thue@usask.ca; georgia.tomaras@duke.edu; Julia.Tree@phe.gov.uk; john.c.trefry.civ@mail.mil; luk_vandenberghe@meei.harvard.edu; sylvie.van-der-werf@pasteur.fr; eric.vangieson@darpa.mil; Vasan.Vasan@csiro.au; y.m.vasiliev@spbniivs.ru; David.Vaughn@gatesfoundation.org; linfa.wang@duke-nus.edu.sg; wangjz@nifdc.org.cn; wangyc@nifdc.org.cn; Jerry.Weir@fda.hhs.gov; gweiss@uci.edu; daniela@lji.org; tomwhite42450@gmail.com; wilsonp@uchicago.edu; larry.wolfraim@nih.gov; dj56wood@gmail.com; xumiaobj@126.com; solomon.yimer@cepi.net; tlying@fudan.edu.cn; vyusibov@indianabiosciences.org; zlshi@wh.iov.cn; ZHOU, Tiequn; diane.descamps@aphp.fr; SGalloway@cdc.gov; lny1@cdc.gov; gll9@cdc.gov; mbo2@cdc.gov; sot1@cdc.gov
Subject: WHO Working Group on COVID-19 Assays
When: Wednesday, January 13, 2021 5:30 AM-6:30 AM (UTC-08:00) Pacific Time (US & Canada).
Where: https://who.zoom.us/j/3612568290

Agenda to follow.

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3612568290@zoomcrc.com

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207.226.132.110 (Japan)
Meeting ID: 361 256 8290

To: Albrecht, Randy[randy.albrecht@mssm.edu]; Martha Alexander-Miller (Martha.Alexander-Miller@wakehealth.edu)[Martha.Alexander-Miller@wakehealth.edu]; Alyson Kelvin[AKelvin@dal.ca]; danielle.anderson (danielle.anderson@duke-nus.edu.sg)[danielle.anderson@duke-nus.edu.sg]; Аракелов Сергей Александрович (s.a.arakelov@spbniivs.ru)[s.a.arakelov@spbniivs.ru]; JOHN JAMES BACZENAS[baczenas@wisc.edu]; BAMFORD, Pearl[Pearl.Bamford@health.gov.au]; Baric, Ralph S[rbaric@email.unc.edu]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; sinabavari@comcast.net[sinabavari@comcast.net]; Martin.Beer (Martin.Beer@fli.de)[Martin.Beer@fli.de]; Neil Berry (Neil.Berry@nibsc.org)[Neil.Berry@nibsc.org]; terry.k.besch.ctr (terry.k.besch.ctr@mail.mil)[terry.k.besch.ctr@mail.mil]; c.blank@nki.nl[c.blank@nki.nl]; dbolton@hivresearch.org[dbolton@hivresearch.org]; mopargal (mopargal@rams.colostate.edu)[mopargal@rams.colostate.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; Brasel, Trevor[trbrasel@utmb.edu]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; abukreye (abukreye@utmb.edu)[abukreye@utmb.edu]; rcarrion (rcarrion@TxBiomed.org)[rcarrion@TxBiomed.org]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; Cartner, Samuel Corbin[scartner@uab.edu]; Cassels, Fred[fcassels@path.org]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; jfwchan (jfwchan@hku.hk)[jfwchan@hku.hk]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; hlchen (hlchen@hku.hk)[hlchen@hku.hk]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; scordo (scordo@qb.fcen.uba.ar)[scordo@qb.fcen.uba.ar]; lisette.cornelissen@wur.nl[lisette.cornelissen@wur.nl]; ian.crozier@nih.gov[ian.crozier@nih.gov]; kai.dallmeier (kai.dallmeier@kuleuven.be)[kai.dallmeier@kuleuven.be]; que.dang@nih.gov[que.dang@nih.gov]; Jorgen de Jonge (jorgen.de.jonge@rivm.nl)[jorgen.de.jonge@rivm.nl]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; mdiamond (mdiamond@wustl.edu)[mdiamond@wustl.edu]; CDillen@som.umaryland.edu[CDillen@som.umaryland.edu]; Dohm, Erik Daniel[edohm@uab.edu]; Donis, Ruben (OS/ASPR/BARDA)[ruben.donis@hhs.gov]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; Duprex, Paul[pduprex@pitt.edu]; Eitzen, Melissa M.[mmeitzen@utmb.edu]; l.enjuanes@cnb.csic.es[l.enjuanes@cnb.csic.es]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; mesteban (mesteban@cnb.csic.es)[mesteban@cnb.csic.es]; Falzarano, Darryl[darryl.falzarano@usask.ca]; feldmannh@niaid.nih.gov[feldmannh@niaid.nih.gov]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Flynn, Joanne L[joanne@pitt.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; Juan García Arriaza (jfgarcia@cnb.csic.es)[jfgarcia@cnb.csic.es]; Adolfo.Garcia-Sastre (Adolfo.Garcia-Sastre@mssm.edu)[Adolfo.Garcia-Sastre@mssm.edu]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; anna (anna@thsti.res.in)[anna@thsti.res.in]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; Gerhards, Nora[nora.gerhards@wur.nl]; Christiane Gerke (christiane.gerke@pasteur.fr)[christiane.gerke@pasteur.fr]; Golding, Hana[Hana.Golding@fda.hhs.gov]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Gralinski, Lisa E[lgralins@email.unc.edu]; GREY Finn (fgrey@exseed.ed.ac.uk)[fgrey@exseed.ed.ac.uk]; Griffiths, Anthony[ahgriff@bu.edu]; CarlosAlberto.Guzman (CarlosAlberto.Guzman@helmholtz-hzi.de)[CarlosAlberto.Guzman@helmholtz-hzi.de]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; rhakami@gmu.edu[rhakami@gmu.edu]; Yper.Hall (Yper.Hall@phe.gov.uk)[Yper.Hall@phe.gov.uk]; kevinharrod (kevinharrod@uabmc.edu)[kevinharrod@uabmc.edu]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; seos@cnu.ac.kr[seos@cnu.ac.kr]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; Hodgson, Paul[paul.hodgson@usask.ca]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jhogan@uga.edu[jhogan@uga.edu]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; jay.w.hooper.civ (jay.w.hooper.civ@mail.mil)[jay.w.hooper.civ@mail.mil]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; tomeri (tomeri@iibr.gov.il)[tomeri@iibr.gov.il]; mito@ciea.or.jp[mito@ciea.or.jp]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; dustin.johnson (dustin.johnson@canada.ca)[dustin.johnson@canada.ca]; kandeil_a (kandeil_a@hotmail.com)[kandeil_a@hotmail.com]; Amelia Karlsson (amelia.karlsson@duke.edu)[amelia.karlsson@duke.edu]; Bernhard Kerscher (PEI-DE) (bernhard.kerscher@pei.de)[bernhard.kerscher@pei.de]; Nadia KHELEF (nadia.khelef@pasteur.fr)[nadia.khelef@pasteur.fr]; sekim (sekim@krict.re.kr)[sekim@krict.re.kr]; Hwan K Kim (hwan.kim@stonybrook.edu)[hwan.kim@stonybrook.edu]; Jason Kindrachuk (Jason.Kindrachuk@umanitoba.ca)[Jason.Kindrachuk@umanitoba.ca]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; Harry Kleanthous (Harry.Kleanthous@gatesfoundation.org)[Harry.Kleanthous@gatesfoundation.org]; KNEZEVIC, Ivana[knezevici@who.int]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; Gary Kobinger (Gary.Kobinger@crchudequebec.ulaval.ca)[Gary.Kobinger@crchudequebec.ulaval.ca]; fkoide (fkoide@southernresearch.org)[fkoide@southernresearch.org]; jeroen.kortekaas (jeroen.kortekaas@wur.nl)[jeroen.kortekaas@wur.nl]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; i.v.krasilnikov (i.v.krasilnikov@spbniivs.ru)[i.v.krasilnikov@spbniivs.ru]; Krause, Philip[philip.krause@fda.hhs.gov]; kupke (kupke@staff.uni-marburg.de)[kupke@staff.uni-marburg.de]; Paul.Lambert (Paul.Lambert@unige.ch)[Paul.Lambert@unige.ch]; mary.lane@nih.gov[mary.lane@nih.gov]; langermans (langermans@bprc.nl)[langermans@bprc.nl]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Roger Le Grand (roger.le-grand@cea.fr)[roger.le-grand@cea.fr]; LESELLIER Sandrine (sandrine.lesellier@anses.fr)[sandrine.lesellier@anses.fr]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; Levis, Robin[robin.levis@fda.hhs.gov]; mlewis (mlewis@bioqual.com)[mlewis@bioqual.com]; sean.li (sean.li@canada.ca)[sean.li@canada.ca]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; ldenisy (ldenisy@yahoo.com)[ldenisy@yahoo.com]; Kristine Macartney (kristine.macartney@health.nsw.gov.au)[kristine.macartney@health.nsw.gov.au]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Pauline Maisonnasse (pauline.maisonnasse@cea.fr)[pauline.maisonnasse@cea.fr]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Suchinda Malaivijitnond

(suchinda.m@chula.ac.th)[suchinda.m@chula.ac.th]; ivan.marazzi@mssm.edu[ivan.marazzi@mssm.edu]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; paul-mccray (paul-mccray@uiowa.edu)[paul-mccray@uiowa.edu]; ThomasC.Mettenleiter (ThomasC.Mettenleiter@fli.de)[ThomasC.Mettenleiter@fli.de]; Chris Miller (cjmiller@ucdavis.edu)[cjmiller@ucdavis.edu]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; Ali.Mirazimi (Ali.Mirazimi@folkhalsomyndigheten.se)[Ali.Mirazimi@folkhalsomyndigheten.se]; dmissiak (dmissiak@bsd.uchicago.edu)[dmissiak@bsd.uchicago.edu]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; bobomok@hku.hk[bobomok@hku.hk]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Munir, Muhammad[muhammad.munir@lancaster.ac.uk]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; nnagata@niid.go.jp[nnagata@niid.go.jp]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; johan.neyts (johan.neyts@kuleuven.be)[johan.neyts@kuleuven.be]; SHELBY L O'CONNOR[slfeinberg@wisc.edu]; DAVID H O'CONNOR (dhoconno@wisc.edu)[dhoconno@wisc.edu]; horer@ku.edu.tr[horer@ku.edu.tr]; Oreshkova, Nadia[nadia.oreshkova@wur.nl]; mto@umn.edu[mto@umn.edu]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; gustavo.palacios (gustavo.palacios@gmail.com)[gustavo.palacios@gmail.com]; peter.palese@mssm.edu[peter.palese@mssm.edu]; nirp (nirp@iibr.gov.il)[nirp@iibr.gov.il]; Perlman, Stanley[stanley-perlman@uiowa.edu]; bradley.pickering (bradley.pickering@canada.ca)[bradley.pickering@canada.ca]; Pickett, Thames (NIH/NIAID) [E][pickettte@niaid.nih.gov]; margaret.l.pitt.civ (margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; PREZIOSI, Marie-pierre[preziosim@who.int]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; qinchuan (qinchuan@pumc.edu.cn)[qinchuan@pumc.edu.cn]; troyrandall (troyrandall@uabmc.edu)[troyrandall@uabmc.edu]; angierasmussen@gmail.com[angierasmussen@gmail.com]; Ann Rawkins (Ann.Rawkins@phe.gov.uk)[Ann.Rawkins@phe.gov.uk]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; patrick.reid@unmc.edu[patrick.reid@unmc.edu]; David Revelli (drevelli@lovelacebiomedical.org)[drevelli@lovelacebiomedical.org]; Juergen Richt (jricht@vet.k-state.edu)[jricht@vet.k-state.edu]; RIVEROS BALTA, Ximena[lauriex@who.int]; B.H.G. Rockx (b.rockx@erasmusmc.nl)[b.rockx@erasmusmc.nl]; estefania.rodriguez (estefania.rodriguez@bnitm.de)[estefania.rodriguez@bnitm.de]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; croy (croy@tulane.edu)[croy@tulane.edu]; Riccardo Russo[russori@njms.rutgers.edu]; rkiatchula (rkiatchula@gmail.com)[rkiatchula@gmail.com]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; esulkowska@rics.bwh.harvard.edu[esulkowska@rics.bwh.harvard.edu]; salgampa (salgampa@njms.rutgers.edu)[salgampa@njms.rutgers.edu]; Javier Salguero (Javier.Salguero@phe.gov.uk)[Javier.Salguero@phe.gov.uk]; erica (erica@lji.org)[erica@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; Segales, Joaquim[joaquim.segales@irta.cat]; snumouse (snumouse@snu.ac.kr)[snumouse@snu.ac.kr]; Seungtaek Kim (seungtaek.kim@ip-korea.org)[seungtaek.kim@ip-korea.org]; shanchao (shanchao@wh.iov.cn)[shanchao@wh.iov.cn]; Sally Sharpe (Sally.Sharpe@phe.gov.uk)[Sally.Sharpe@phe.gov.uk]; Schotsaert, Michael[michael.schotsaert@mssm.edu]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; YOO, Si Hyung[yoos@who.int]; Sivko, Gloria S[sivkog@battelle.org]; dean.smith (dean.smith@canada.ca)[dean.smith@canada.ca]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; SPERGEL@email.chop.edu[SPERGEL@email.chop.edu]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; Stewart, James[J.P.Stewart@liverpool.ac.uk]; stittelaar (stittelaar@viroclinics.com)[stittelaar@viroclinics.com]; kanta.subbarao (kanta.subbarao@influenzacentre.org)[kanta.subbarao@influenzacentre.org]; sutter (sutter@micro.vetmed.uni-muenchen.de)[sutter@micro.vetmed.uni-muenchen.de]; Tadaki (tksuzuki@nih.go.jp)[tksuzuki@nih.go.jp]; SWAMINATHAN, Soumya[swaminathans@who.int]; Techakitiroj Chatkul (tverakit@gmail.com)[tverakit@gmail.com]; tenoever@gmail.com[tenoever@gmail.com]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; franck.TOURET@univ-amu.fr[franck.TOURET@univ-amu.fr]; Treanor, John (OS/ASPR/BARDA) (CTR)[John.Treanor@hhs.gov]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; sktseng (sktseng@UTMB.EDU)[sktseng@UTMB.EDU]; Chi Van Dang (cdang@lcr.org)[cdang@lcr.org]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; neeltje.vandoremalen@nih.gov[neeltje.vandoremalen@nih.gov]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; Vergara, Julia[julia.vergara@irta.cat]; verschoor (verschoor@bprc.nl)[verschoor@bprc.nl]; verstrepen@bprc.nl[verstrepen@bprc.nl]; caroline.melo@rivm.nl[caroline.melo@rivm.nl]; Romain Volmer (romain.volmer@envt.fr)[romain.volmer@envt.fr]; Asisa.Volz (Asisa.Volz@tiho-hannover.de)[Asisa.Volz@tiho-hannover.de]; Tony.Wang (Tony.Wang@fda.hhs.gov)[Tony.Wang@fda.hhs.gov]; White, Alexander G[agw13@pitt.edu]; WOOD, David John[woodd@who.int]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; ZHOU, Tiequn[ZhouT@who.int]; ZHU, Jin[Jin.Zhu@health.gov.au]; tcs38@psu.edu[tcs38@psu.edu]; NICOLAS DE LAMBALLERIE Xavier (xavier.de-lamballerie@univ-amu.fr)[xavier.de-lamballerie@univ-amu.fr]; Tony.Schountz@colostate.edu[Tony.Schountz@colostate.edu]; anja.kipar@uzh.ch[anja.kipar@uzh.ch]

Cc: Martin.Beer (Martin.Beer@fli.de)[Martin.Beer@fli.de]; Schotsaert, Michael[michael.schotsaert@mssm.edu]; Segales, Joaquim[joaquim.segales@irta.cat]; Rafael Andres Medina Silva[rmedinai@uc.cl]; verstrepen@bprc.nl[verstrepen@bprc.nl]

From: SCHWARTZ, Lauren[schwartzl@who.int]

Sent: Wed 1/13/2021 2:01:45 PM (UTC-05:00)

Subject: RE: WHO COVID-19 Animal Models Group Call

Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call Thursday January 14 3PM CET (Geneva time)

1. Martin Beer (FLI) - *Experimental infection of bank voles (Myodes glareolus) with SARS-CoV-2*

2. Michael Shotsaert (Mount Sinai) - *Neutralization of N501Y variant with vaccinee sera*

3. Quim Segalés (IRTA) - *Protection against reinfection with D614 or G614 SARS-CoV-2 isolates in Golden Syrian hamsters*

4. Discussion on available sera panels
    - Rafael Medina-Silva (Universidad Católica de Chile)
    - Babs Verstrepen (Biomedical Primate Research Centre)

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 10, 2021 2:22 PM
To: randy.albrecht@mssm.edu; Martha.Alexander-Miller@wakehealth.edu; AKelvin@dal.ca; danielle.anderson@duke-nus.edu.sg; s.a.arakelov@spbniivs.ru; baczenas@wisc.edu; Pearl.Bamford@health.gov.au; rbaric@email.unc.edu; dbarouch@bidmc.harvard.edu; sinabavari@comcast.net; Martin.Beer@fli.de; Neil.Berry@nibsc.org; terry.k.besch.ctr@mail.mil; c.blank@nki.nl; dbolton@hivresearch.org; mopargal@rams.colostate.edu; SBradfute@salud.unm.edu; trbrasel@UTMB.EDU; lisambrosseau@gmail.com; abukreye@utmb.edu; rcarrion@txbiomed.org; Miles.Carroll@phe.gov.uk; scartner@uab.edu; fcassels@path.org; Marco.Cavaleri@ema.europa.eu; lisa.chakrabarti@pasteur.fr; jfwchan@hku.hk; MONALISA.CHATTERJI@gatesfoundation.org; hlchen@hku.hk; carolyn.clark@cepi.net; scordo@qb.fcen.uba.ar; lisette.cornelissen@wur.nl; ian.crozier@nih.gov; kai.dallmeier@kuleuven.be; que.dang@nih.gov; jorgen.de.jonge@rivm.nl; emmie.dewit@nih.gov; mdiamond@wustl.edu; CDillen@som.umaryland.edu; edohm@uab.edu; Ruben.Donis@hhs.gov; william.dowling@cepi.net; mariette.ducatez@envt.fr; pduprex@pitt.edu; mmeitzen@utmb.edu; l.enjuanes@cnb.csic.es; Karl.Erlandson@hhs.gov; mesteban@cnb.csic.es; darryl.falzarano@usask.ca; feldmannh@niaid.nih.gov; clint.florence@nih.gov; joanne@pitt.edu; thomasf@primate.wisc.edu; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk; jfgarcia@cnb.csic.es; Adolfo.Garcia-Sastre@mssm.edu; golinger@mriglobal.org; anna@thsti.res.in; Volker.gerdts@usask.ca; nora.gerhards@wur.nl; christiane.gerke@pasteur.fr; Hana.Golding@fda.hhs.gov; barney.graham@nih.gov; lgralins@email.unc.edu; fgrey@exseed.ed.ac.uk; ahgriff@bu.edu; CarlosAlberto.Guzman@helmholtz-hzi.de; b.haagmans@erasmusmc.nl; rhakami@gmu.edu; Yper.Hall@phe.gov.uk; kevinharrod@uabmc.edu; HENAO RESTREPO, Ana Maria; lisa.hensley@nih.gov; seos@cnu.ac.kr; sheri.hild@nih.gov; paul.hodgson@usask.ca; christian.c.hofer.mil@mail.mil; jhogan@uga.edu; Michael.holbrook@nih.gov; jay.w.hooper.civ@mail.mil; y.jacob.hou@unc.edu; REIRELAND@mail.dstl.gov.uk; tomeri@iibr.gov.il; mito@ciea.or.jp; Lakshmi.Jayashankar@hhs.gov; dustin.johnson@canada.ca; kandeil_a@hotmail.com; amelia.karlsson@duke.edu; Bernhard.Kerscher@pei.de; nadia.khelef@pasteur.fr; sekim@krict.re.kr; hwan.kim@stonybrook.edu; Jason.Kindrachuk@umanitoba.ca; Jacqueline.Kirchner@gatesfoundation.org; Harry.Kleanthous@gatesfoundation.org; KNEZEVIC, Ivana; darwyn.kobasa@canada.ca; Gary.Kobinger@crchudequebec.ulaval.ca; fkoide@southernresearch.org; jeroen.kortekaas@wur.nl; florian.krammer@mssm.edu; i.v.krasilnikov@spbniivs.ru; philip.krause@fda.hhs.gov; kupke@staff.uni-marburg.de; Paul.Lambert@unige.ch; mary.lane@nih.gov; langermans@bprc.nl; david.lee-parritz@tufts.edu; Luis.Lugo.mil@afrims.org; roger.le-grand@cea.fr; sandrine.lesellier@anses.fr; MSLEVER@dstl.gov.uk; robin.levis@fda.hhs.gov; mlewis@bioqual.com; sean.li@canada.ca; grace.m.lidl.mil@mail.mil; James.Little@hhs.gov; ldenisy@yahoo.com; kristine.macartney@health.nsw.gov.au; Tracy.MacGill@fda.hhs.gov; pauline.maisonnasse@cea.fr; Karen.Makar@gatesfoundation.org; suchinda.m@chula.ac.th; ivan.marazzi@mssm.edu; LMartinez@txbiomed.org; Giada.Mattiuzzo@nibsc.org; paul-mccray@uiowa.edu; ThomasC.Mettenleiter@fli.de; cjmiller@ucdavis.edu; philip.minor2@gmail.com; Ali.Mirazimi@folkhalsomyndigheten.se; dmissiak@bsd.uchicago.edu; kmodjarrad@eidresearch.org; bobomok@hku.hk; SATHIYAMOORTHY, Vaseeharan; muhammad.munir@lancaster.ac.uk; munoz-fontela@bnitm.de; vincent.munster@nih.gov; nnagata@niid.go.jp; aysegul.nalca.civ@mail.mil; MNELSON@mail.dstl.gov.uk; johan.neyts@kuleuven.be; slfeinberg@wisc.edu; dhoconno@wisc.edu; horer@ku.edu.tr; nadia.oreshkova@wur.nl; mto@umn.edu; Mark.Page@nibsc.org; gustavo.palacios@gmail.com; peter.palese@mssm.edu; nirp@iibr.gov.il; stanley-perlman@uiowa.edu; bradley.pickering@canada.ca; pickettte@niaid.nih.gov; margaret.l.pitt.civ@mail.mil; PREZIOSI, Marie-pierre; JLPRIOR@dstl.gov.uk; qinchuan@pumc.edu.cn; troyrandall@uabmc.edu; angierasmussen@gmail.com; Ann.Rawkins@phe.gov.uk; Russell.Ray@bcm.edu; dsreed@cvr.pitt.edu; Matthew.Reed.mil@afrims.org; patrick.reid@unmc.edu; drevelli@lovelacebiomedical.org; jricht@vet.k-state.edu; RIVEROS BALTA, Ximena; b.rockx@erasmusmc.nl; estefania.rodriguez@bnitm.de; Nicola.Rose@nibsc.org; croy@tulane.edu; russori@njms.rutgers.edu; rkiatchula@gmail.com;

Carol.Sabourin@hhs.gov; esulkowska@rics.bwh.harvard.edu; salgampa@njms.rutgers.edu; Javier.Salguero@phe.gov.uk; erica@lji.org; connie.schmaljohn@nih.gov; Barbara.Schnierle@pei.de; SCHWARTZ, Lauren; joaquim.segales@irta.cat; snumouse@snu.ac.kr; seungtaek.kim@ip-korea.org; shanchao@wh.iov.cn; Sally.Sharpe@phe.gov.uk; michael.schotsaert@mssm.edu; amy.c.shurtleff@cepi.net; YOO, Si Hyung; sivkog@battelle.org; dean.smith@canada.ca; mksong@ivi.int; SPERGEL@email.chop.edu; erik.stemmy@nih.gov; J.P.Stewart@liverpool.ac.uk; stittelaar@viroclinics.com; kanta.subbarao@influenzacentre.org; sutter@micro.vetmed.uni-muenchen.de; tksuzuki@nih.go.jp; SWAMINATHAN, Soumya; tverakit@gmail.com; tenoever@gmail.com; nax3@cdc.gov; JTorrelles@txbiomed.org; franck.TOURET@univ-amu.fr; John.Treanor@hhs.gov; Julia.Tree@phe.gov.uk; john.c.trefry.civ@mail.mil; sktseng@UTMB.EDU; cdang@lcr.org; luk_vandenberghe@meei.harvard.edu; wim.vanderpoel@wur.nl; neeltje.vandoremalen@nih.gov; Vasan.Vasan@csiro.au; y.m.vasiliev@spbniivs.ru; David.Vaughn@gatesfoundation.org; julia.vergara@irta.cat; verschoor@bprc.nl; verstrepen@bprc.nl; caroline.melo@rivm.nl; romain.volmer@envt.fr; Asisa.Volz@tiho-hannover.de; tony.wang@fda.hhs.gov; agw13@pitt.edu; WOOD, David John; tyamamoto@ciea.or.jp; ZHOU, Tiequn; Jin.Zhu@health.gov.au; tcs38@psu.edu; xavier.de-lamballerie@univ-amu.fr; Tony.Schountz@colostate.edu; anja.kipar@uzh.ch
Subject: WHO COVID-19 Animal Models Group Call
When: Thursday, January 14, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).
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Agenda to follow.

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To: Luis.Lugo.mil@afrims.org[Luis.Lugo.mil@afrims.org]; Matthew.Reed.mil@afrims.org[Matthew.Reed.mil@afrims.org]; franck.TOURET@univ-amu.fr[franck.TOURET@univ-amu.fr]; LESELLIER Sandrine (sandrine.lesellier@anses.fr)[sandrine.lesellier@anses.fr]; Romain Volmer (romain.volmer@envt.fr)[romain.volmer@envt.fr]; BAMFORD, Pearl[Pearl.Bamford@health.gov.au]; ZHU, Jin[Jin.Zhu@health.gov.au]; Donis, Ruben (OS/ASPR/BARDA)[ruben.donis@hhs.gov]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; Carol.Sabourin@hhs.gov[Carol.Sabourin@hhs.gov]; Treanor, John (OS/ASPR/BARDA) (CTR)[John.Treanor@hhs.gov]; Sivko, Gloria S[sivkog@battelle.org]; Russell.Ray@bcm.edu[Russell.Ray@bcm.edu]; verschoor (verschoor@bprc.nl)[verschoor@bprc.nl]; verstrepen@bprc.nl[verstrepen@bprc.nl]; langermans (langermans@bprc.nl)[langermans@bprc.nl]; mlewis (mlewis@bioqual.com)[mlewis@bioqual.com]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; Harry Kleanthous (Harry.Kleanthous@gatesfoundation.org)[Harry.Kleanthous@gatesfoundation.org]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; estefania.rodriguez (estefania.rodriguez@bnitm.de)[estefania.rodriguez@bnitm.de]; Griffiths, Anthony[ahgriff@bu.edu]; dustin.johnson (dustin.johnson@canada.ca)[dustin.johnson@canada.ca]; sean.li (sean.li@canada.ca)[sean.li@canada.ca]; dean.smith (dean.smith@canada.ca)[dean.smith@canada.ca]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; Roger Le Grand (roger.le-grand@cea.fr)[roger.le-grand@cea.fr]; Pauline Maisonnasse (pauline.maisonnasse@cea.fr)[pauline.maisonnasse@cea.fr]; sekim (sekim@krict.re.kr)[sekim@krict.re.kr]; kandeil_a (kandeil_a@hotmail.com)[kandeil_a@hotmail.com]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; shanchao (shanchao@wh.iov.cn)[shanchao@wh.iov.cn]; rkiatchula (rkiatchula@gmail.com)[rkiatchula@gmail.com]; seos@cnu.ac.kr[seos@cnu.ac.kr]; lisambrosseau@gmail.com[lisambrosseau@gmail.com]; mto@umn.edu[mto@umn.edu]; mito@ciea.or.jp[mito@ciea.or.jp]; tyamamoto@ciea.or.jp[tyamamoto@ciea.or.jp]; mesteban (mesteban@cnb.csic.es)[mesteban@cnb.csic.es]; Juan García Arriaza (jfgarcia@cnb.csic.es)[jfgarcia@cnb.csic.es]; l.enjuanes@cnb.csic.es[l.enjuanes@cnb.csic.es]; mopargal (mopargal@rams.colostate.edu)[mopargal@rams.colostate.edu]; Tony.Schountz@colostate.edu[Tony.Schountz@colostate.edu]; angierasmussen@gmail.com[angierasmussen@gmail.com]; scordo (scordo@qb.fcen.uba.ar)[scordo@qb.fcen.uba.ar]; sinabavari@comcast.net[sinabavari@comcast.net]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; Duprex, Paul[pduprex@pitt.edu]; Flynn, Joanne L[joanne@pitt.edu]; White, Alexander G[agw13@pitt.edu]; Alyson Kelvin[AKelvin@dal.ca]; renee.wegrzyn@darpa.mil[renee.wegrzyn@darpa.mil]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; kanta.subbarao (kanta.subbarao@influenzacentre.org)[kanta.subbarao@influenzacentre.org]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; MNELSON@mail.dstl.gov.uk[MNELSON@mail.dstl.gov.uk]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; Amelia Karlsson (amelia.karlsson@duke.edu)[amelia.karlsson@duke.edu]; danielle.anderson (danielle.anderson@duke-nus.edu.sg)[danielle.anderson@duke-nus.edu.sg]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; mariette.ducatez@envt.fr[mariette.ducatez@envt.fr]; B.H.G. Rockx (b.rockx@erasmusmc.nl)[b.rockx@erasmusmc.nl]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; Golding, Hana[Hana.Golding@fda.hhs.gov]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Tony.Wang (Tony.Wang@fda.hhs.gov)[Tony.Wang@fda.hhs.gov]; Krause, Philip[philip.krause@fda.hhs.gov]; Levis, Robin[robin.levis@fda.hhs.gov]; Martin.Beer (Martin.Beer@fli.de)[Martin.Beer@fli.de]; ThomasC.Mettenleiter (ThomasC.Mettenleiter@fli.de)[ThomasC.Mettenleiter@fli.de]; ldenisy (ldenisy@yahoo.com)[ldenisy@yahoo.com]; rhakami@gmu.edu[rhakami@gmu.edu]; Asisa.Volz (Asisa.Volz@tiho-hannover.de)[Asisa.Volz@tiho-hannover.de]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; esulkowska@rics.bwh.harvard.edu[esulkowska@rics.bwh.harvard.edu]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; jfwchan (jfwchan@hku.hk)[jfwchan@hku.hk]; hlchen (hlchen@hku.hk)[hlchen@hku.hk]; CarlosAlberto.Guzman (CarlosAlberto.Guzman@helmholtz-hzi.de)[CarlosAlberto.Guzman@helmholtz-hzi.de]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; lisa.chakrabarti@pasteur.fr[lisa.chakrabarti@pasteur.fr]; Christiane Gerke (christiane.gerke@pasteur.fr)[christiane.gerke@pasteur.fr]; Nadia KHELEF (nadia.khelef@pasteur.fr)[nadia.khelef@pasteur.fr]; Seungtaek Kim (seungtaek.kim@ip-korea.org)[seungtaek.kim@ip-korea.org]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; Segales, Joaquim[joaquim.segales@irta.cat]; Vergara, Julia[julia.vergara@irta.cat]; tomeri (tomeri@iibr.gov.il)[tomeri@iibr.gov.il]; nirp (nirp@iibr.gov.il)[nirp@iibr.gov.il]; nnagata@niid.go.jp[nnagata@niid.go.jp]; Tadaki (tksuzuki@nih.go.jp)[tksuzuki@nih.go.jp]; terry.k.besch.ctr (terry.k.besch.ctr@mail.mil)[terry.k.besch.ctr@mail.mil]; Juergen Richt (jricht@vet.k-state.edu)[jricht@vet.k-state.edu]; Ali.Mirazimi (Ali.Mirazimi@folkhalsomyndigheten.se)[Ali.Mirazimi@folkhalsomyndigheten.se]; horer@ku.edu.tr[horer@ku.edu.tr]; snumouse (snumouse@snu.ac.kr)[snumouse@snu.ac.kr]; kai.dallmeier (kai.dallmeier@kuleuven.be)[kai.dallmeier@kuleuven.be]; johan.neyts (johan.neyts@kuleuven.be)[johan.neyts@kuleuven.be]; erica (erica@lji.org)[erica@lji.org]; Munir, Muhammad[muhammad.munir@lancaster.ac.uk]; David Revelli (drevelli@lovelacebiomedical.org)[drevelli@lovelacebiomedical.org]; Chi Van Dang (cdang@lcr.org)[cdang@lcr.org]; sutter (sutter@micro.vetmed.uni-muenchen.de)[sutter@micro.vetmed.uni-muenchen.de]; kupke (kupke@staff.uni-marburg.de)[kupke@staff.uni-marburg.de]; Albrecht, Randy[randy.albrecht@mssm.edu]; Adolfo.Garcia-Sastre (Adolfo.Garcia-Sastre@mssm.edu)[Adolfo.Garcia-Sastre@mssm.edu]; peter.palese@mssm.edu[peter.palese@mssm.edu]; Schotsaert, Michael[michael.schotsaert@mssm.edu]; tenoever@gmail.com[tenoever@gmail.com]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; mary.lane@nih.gov[mary.lane@nih.gov]; Pickett, Thames (NIH/NIAID) [E][pickettte@niaid.nih.gov]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; ian.crozier@nih.gov[ian.crozier@nih.gov];

Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; feldmannh@niaid.nih.gov[feldmannh@niaid.nih.gov]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Jorgen de Jonge (jorgen.de.jonge@rivm.nl)[jorgen.de.jonge@rivm.nl]; Suchinda Malaivijitnond (suchinda.m@chula.ac.th)[suchinda.m@chula.ac.th]; Kristine Macartney (kristine.macartney@health.nsw.gov.au)[kristine.macartney@health.nsw.gov.au]; patrick.reid@unmc.edu[patrick.reid@unmc.edu]; Neil Berry (Neil.Berry@nibsc.org)[Neil.Berry@nibsc.org]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; que.dang@nih.gov[que.dang@nih.gov]; Hild, Sheri (NIH/OD) [E][sheri.hild@nih.gov]; neeltje.vandoremalen@nih.gov[neeltje.vandoremalen@nih.gov]; Cassels, Fred[fcassels@path.org]; Bernhard Kerscher (PEI-DE) (bernhard.kerscher@pei.de)[bernhard.kerscher@pei.de]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; qinchuan (qinchuan@pumc.edu.cn)[qinchuan@pumc.edu.cn]; SPERGEL@email.chop.edu[SPERGEL@email.chop.edu]; darwyn.kobasa@canada.ca[darwyn.kobasa@canada.ca]; bradley.pickering (bradley.pickering@canada.ca)[bradley.pickering@canada.ca]; tcs38@psu.edu[tcs38@psu.edu]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; Yper.Hall (Yper.Hall@phe.gov.uk)[Yper.Hall@phe.gov.uk]; Ann Rawkins (Ann.Rawkins@phe.gov.uk)[Ann.Rawkins@phe.gov.uk]; Javier Salguero (Javier.Salguero@phe.gov.uk)[Javier.Salguero@phe.gov.uk]; Sally Sharpe (Sally.Sharpe@phe.gov.uk)[Sally.Sharpe@phe.gov.uk]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; caroline.melo@rivm.nl[caroline.melo@rivm.nl]; Riccardo Russo[russori@njms.rutgers.edu]; salgampa (salgampa@njms.rutgers.edu)[salgampa@njms.rutgers.edu]; fkoide (fkoide@southernresearch.org)[fkoide@southernresearch.org]; Аракелов Сергей Александрович (s.a.arakelov@spbniivs.ru)[s.a.arakelov@spbniivs.ru]; i.v.krasilnikov (i.v.krasilnikov@spbniivs.ru)[i.v.krasilnikov@spbniivs.ru]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; Hwan K Kim (hwan.kim@stonybrook.edu)[hwan.kim@stonybrook.edu]; rcarrion (rcarrion@TxBiomed.org)[rcarrion@TxBiomed.org]; LMartinez@txbiomed.org[LMartinez@txbiomed.org]; JTorrelles@txbiomed.org[JTorrelles@txbiomed.org]; Techakitiroj Chatkul (tverakit@gmail.com)[tverakit@gmail.com]; bobomok@hku.hk[bobomok@hku.hk]; anna (anna@thsti.res.in)[anna@thsti.res.in]; Lee-Parritz, David[david.lee-parritz@tufts.edu]; croy (croy@tulane.edu)[croy@tulane.edu]; Jason Kindrachuk (Jason.Kindrachuk@umanitoba.ca)[Jason.Kindrachuk@umanitoba.ca]; Chris Miller (cjmiller@ucdavis.edu)[cjmiller@ucdavis.edu]; Baric, Ralph S[rbaric@email.unc.edu]; Gralinski, Lisa E[lgralins@email.unc.edu]; gustavo.palacios (gustavo.palacios@gmail.com)[gustavo.palacios@gmail.com]; dmissiak (dmissiak@bsd.uchicago.edu)[dmissiak@bsd.uchicago.edu]; GREY Finn (fgrey@exseed.ed.ac.uk)[fgrey@exseed.ed.ac.uk]; dsreed@cvr.pitt.edu[dsreed@cvr.pitt.edu]; Gary Kobinger (Gary.Kobinger@crchudequebec.ulaval.ca)[Gary.Kobinger@crchudequebec.ulaval.ca]; Paul.Lambert (Paul.Lambert@unige.ch)[Paul.Lambert@unige.ch]; Hou, Yixuan Jacob[y.jacob.hou@unc.edu]; Cartner, Samuel Corbin[scartner@uab.edu]; Dohm, Erik Daniel[edohm@uab.edu]; kevinharrod (kevinharrod@uabmc.edu)[kevinharrod@uabmc.edu]; troyrandall (troyrandall@uabmc.edu)[troyrandall@uabmc.edu]; jhogan@uga.edu[jhogan@uga.edu]; paul-mccray (paul-mccray@uiowa.edu)[paul-mccray@uiowa.edu]; Perlman, Stanley[stanley-perlman@uiowa.edu]; Stewart, James[J.P.Stewart@liverpool.ac.uk]; NICOLAS DE LAMBALLERIE Xavier (xavier.de-lamballerie@univ-amu.fr)[xavier.de-lamballerie@univ-amu.fr]; CDillen@som.umaryland.edu[CDillen@som.umaryland.edu]; Frieman, Matthew[MFrieman@som.umaryland.edu]; SBradfute@salud.unm.edu[SBradfute@salud.unm.edu]; JOHN JAMES BACZENAS[baczenas@wisc.edu]; SHELBY L O'CONNOR[slfeinberg@wisc.edu]; thomasf@primate.wisc.edu[thomasf@primate.wisc.edu]; DAVID H O'CONNOR (dhoconno@wisc.edu)[dhoconno@wisc.edu]; anja.kipar@uzh.ch[anja.kipar@uzh.ch]; christian.c.hofer.mil@mail.mil[christian.c.hofer.mil@mail.mil]; jay.w.hooper.civ (jay.w.hooper.civ@mail.mil)[jay.w.hooper.civ@mail.mil]; grace.m.lidl.mil@mail.mil[grace.m.lidl.mil@mail.mil]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; margaret.l.pitt.civ (margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; Brasel, Trevor[trbrasel@utmb.edu]; abukreye (abukreye@utmb.edu)[abukreye@utmb.edu]; Eitzen, Melissa M.[mmeitzen@utmb.edu]; sktseng (sktseng@UTMB.EDU)[sktseng@UTMB.EDU]; Falzarano, Darryl[darryl.falzarano@usask.ca]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; Hodgson, Paul[paul.hodgson@usask.ca]; stittelaar (stittelaar@viroclinics.com)[stittelaar@viroclinics.com]; wim.vanderpoel@wur.nl[wim.vanderpoel@wur.nl]; Gerhards, Nora[nora.gerhards@wur.nl]; jeroen.kortekaas (jeroen.kortekaas@wur.nl)[jeroen.kortekaas@wur.nl]; Oreshkova, Nadia[nadia.oreshkova@wur.nl]; Martha Alexander-Miller (Martha.Alexander-Miller@wakehealth.edu)[Martha.Alexander-Miller@wakehealth.edu]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; mdiamond (mdiamond@wustl.edu)[mdiamond@wustl.edu]; 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, Ximena[lauriex@who.int]; YOO, Si Hyung[yoos@who.int]; SWAMINATHAN, Soumya[swaminathans@who.int]; WOOD, David John[woodd@who.int]; ZHOU, Tiequn[ZhouT@who.int]; dbolton@hivresearch.org[dbolton@hivresearch.org]; lisette.cornelissen@wur.nl[lisette.cornelissen@wur.nl]; ivan.marazzi@mssm.edu[ivan.marazzi@mssm.edu]; BRANGEL, Polina[brangelp@who.int]; SALAMI, Kolawole[salamik@who.int]; Nerea_ZabaletaLasarte@MEEI.HARVARD.EDU[Nerea_ZabaletaLasarte@MEEI.HARVARD.EDU]; lawton.stubbert@canada.ca[lawton.stubbert@canada.ca]; Cong, Yu (NIH/NIAID) [C][yu.cong@nih.gov]; Adam T. Waickman[WaickmaA@upstate.edu]

Cc: tcs38@psu.edu[tcs38@psu.edu]; neeltje.vandoremalen@nih.gov[neeltje.vandoremalen@nih.gov]; dgdiel@cornell.edu[dgdiel@cornell.edu]; mitchell.palmer@usda.gov[mitchell.palmer@usda.gov]

From: SCHWARTZ, Lauren[schwartzl@who.int]

Sent: Wed 1/20/2021 12:46:53 PM (UTC-05:00)

Subject: RE: WHO COVID-19 Animal Models Group Call

Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call Thursday January 21 3PM CET (Geneva time)

1. Troy Sutton (PSU) - *Transmission and protection against re-infection in the ferret model with the SARS-CoV-2 USA-WA1/2020 isolate*
2. Neeltje van Doremalen (NIAID) - *Intranasal ChAdOx1 nCoV-19/AZD1222 vaccination reduces shedding of SARS-CoV-2 D614G in rhesus macaques and hamsters*
3. Mitchell Palmer (USDA) & Diego Diel (Cornell) - *Susceptibility of white-tailed deer (Odocoileus virginianus) to SARS-CoV-2*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 17, 2021 5:21 PM
To: SCHWARTZ, Lauren; Luis.Lugo.mil@afrims.org; Matthew.Reed.mil@afrims.org; franck.TOURET@univ-amu.fr; sandrine.lesellier@anses.fr; romain.volmer@envt.fr; Pearl.Bamford@health.gov.au; Jin.Zhu@health.gov.au; Ruben.Donis@hhs.gov; Karl.Erlandson@hhs.gov; Lakshmi.Jayashankar@hhs.gov; James.Little@hhs.gov; Carol.Sabourin@hhs.gov; John.Treanor@hhs.gov; sivkog@battelle.org; Russell.Ray@bcm.edu; verschoor@bprc.nl; verstrepen@bprc.nl; langermans@bprc.nl; mlewis@bioqual.com; MONALISA.CHATTERJI@gatesfoundation.org; Jacqueline.Kirchner@gatesfoundation.org; Harry.Kleanthous@gatesfoundation.org; Karen.Makar@gatesfoundation.org; David.Vaughn@gatesfoundation.org; munoz-fontela@bnitm.de; estefania.rodriguez@bnitm.de; ahgriff@bu.edu; dustin.johnson@canada.ca; sean.li@canada.ca; dean.smith@canada.ca; nax3@cdc.gov; roger.le-grand@cea.fr; pauline.maisonnasse@cea.fr; sekim@krict.re.kr; kandeil_a@hotmail.com; carolyn.clark@cepi.net; william.dowling@cepi.net; amy.c.shurtleff@cepi.net; shanchao@wh.iov.cn; rkiatchula@gmail.com; seos@cnu.ac.kr; lisambrosseau@gmail.com; mto@umn.edu; mito@ciea.or.jp; tyamamoto@ciea.or.jp; mesteban@cnb.csic.es; jfgarcia@cnb.csic.es; l.enjuanes@cnb.csic.es; mopargal@rams.colostate.edu; Tony.Schountz@colostate.edu; angierasmussen@gmail.com; scordo@qb.fcen.uba.ar; sinabavari@comcast.net; Vasan.Vasan@csiro.au; pduprex@pitt.edu; joanne@pitt.edu; agw13@pitt.edu; AKelvin@dal.ca; renee.wegrzyn@darpa.mil; john.c.trefry.civ@mail.mil; kanta.subbarao@influenzacentre.org; REIRELAND@mail.dstl.gov.uk; MSLEVER@dstl.gov.uk; MNELSON@mail.dstl.gov.uk; JLPRIOR@dstl.gov.uk; amelia.karlsson@duke.edu; danielle.anderson@duke-nus.edu.sg; Marco.Cavaleri@ema.europa.eu; mariette.ducatez@envt.fr; b.rockx@erasmusmc.nl; b.haagmans@erasmusmc.nl; Hana.Golding@fda.hhs.gov; Tracy.MacGill@fda.hhs.gov; tony.wang@fda.hhs.gov; philip.krause@fda.hhs.gov; robin.levis@fda.hhs.gov; Martin.Beer (Martin.Beer@fli.de); ThomasC.Mettenleiter@fli.de; ldenisy@yahoo.com; rhakami@gmu.edu; Asisa.Volz@tiho-hannover.de; dbarouch@bidmc.harvard.edu; esulkowska@rics.bwh.harvard.edu; luk_vandenberghe@meei.harvard.edu; jfwchan@hku.hk; hlchen@hku.hk; CarlosAlberto.Guzman@helmholtz-hzi.de; florian.krammer@mssm.edu; lisa.chakrabarti@pasteur.fr; christiane.gerke@pasteur.fr; nadia.khelef@pasteur.fr; seungtaek.kim@ip-korea.org; mksong@ivi.int; joaquim.segales@irta.cat; julia.vergara@irta.cat; tomeri@iibr.gov.il; nirp@iibr.gov.il; nnagata@niid.go.jp; tksuzuki@nih.go.jp; terry.k.besch.ctr@mail.mil; jricht@vet.k-state.edu; Ali.Mirazimi@folkhalsomyndigheten.se; horer@ku.edu.tr; snumouse@snu.ac.kr; kai.dallmeier@kuleuven.be; johan.neyts@kuleuven.be; erica@lji.org; muhammad.munir@lancaster.ac.uk; drevelli@lovelacebiomedical.org; cdang@lcr.org; sutter@micro.vetmed.uni-muenchen.de; kupke@staff.uni-marburg.de; randy.albrecht@mssm.edu; Adolfo.Garcia-Sastre@mssm.edu; peter.palese@mssm.edu; michael.schotsaert@mssm.edu; tenoever@gmail.com; golinger@mriglobal.org; Giada.Mattiuzzo@nibsc.org; Mark.Page@nibsc.org; clint.florence@nih.gov; mary.lane@nih.gov; pickettte@niaid.nih.gov; erik.stemmy@nih.gov; ian.crozier@nih.gov; lisa.hensley@nih.gov; Michael.holbrook@nih.gov; connie.schmaljohn@nih.gov; emmie.dewit@nih.gov; feldmannh@niaid.nih.gov; vincent.munster@nih.gov; barney.graham@nih.gov; jorgen.de.jonge@rivm.nl; suchinda.m@chula.ac.th; kristine.macartney@health.nsw.gov.au; patrick.reid@unmc.edu; Neil.Berry@nibsc.org; philip.minor2@gmail.com; Nicola.Rose@nibsc.org; que.dang@nih.gov; sheri.hild@nih.gov; neeltje.vandoremalen@nih.gov; fcassels@path.org; Bernhard.Kerscher@pei.de; Barbara.Schnierle@pei.de; qinchuan@pumc.edu.cn; SPERGEL@email.chop.edu; darwyn.kobasa@canada.ca; bradley.pickering@canada.ca; tcs38@psu.edu; Miles.Carroll@phe.gov.uk; Simon.Funnell@phe.gov.uk; Yper.Hall@phe.gov.uk; Ann.Rawkins@phe.gov.uk; Javier.Salguero@phe.gov.uk; Sally.Sharpe@phe.gov.uk; Julia.Tree@phe.gov.uk; caroline.melo@rivm.nl; russori@njms.rutgers.edu; salgampa@njms.rutgers.edu; fkoide@southernresearch.org; s.a.arakelov@spbniivs.ru; i.v.krasilnikov@spbniivs.ru; y.m.vasiliev@spbniivs.ru; hwan.kim@stonybrook.edu; rcarrion@txbiomed.org; LMartinez@txbiomed.org; JTorrelles@txbiomed.org; tverakit@gmail.com; bobomok@hku.hk; anna@thsti.res.in; david.lee-parritz@tufts.edu; croy@tulane.edu; Jason.Kindrachuk@umanitoba.ca; cjmiller@ucdavis.edu; rbaric@email.unc.edu; lgralins@email.unc.edu;

gustavo.palacios@gmail.com; dmissiak@bsd.uchicago.edu; fgrey@exseed.ed.ac.uk; dsreed@cvr.pitt.edu; Gary.Kobinger@crchudequebec.ulaval.ca; Paul.Lambert@unige.ch; y.jacob.hou@unc.edu; scartner@uab.edu; edohm@uab.edu; kevinharrod@uabmc.edu; troyrandall@uabmc.edu; jhogan@uga.edu; paul-mccray@uiowa.edu; stanley-perlman@uiowa.edu; J.P.Stewart@liverpool.ac.uk; xavier.de-lamballerie@univ-amu.fr; CDillen@som.umaryland.edu; MFrieman@som.umaryland.edu; SBradfute@salud.unm.edu; baczenas@wisc.edu; slfeinberg@wisc.edu; thomasf@primate.wisc.edu; dhoconno@wisc.edu; anja.kipar@uzh.ch; christian.c.hofer.mil@mail.mil; jay.w.hooper.civ@mail.mil; grace.m.lidl.mil@mail.mil; aysegul.nalca.civ@mail.mil; margaret.l.pitt.civ@mail.mil; trbrasel@UTMB.EDU; abukreye@utmb.edu; mmeitzen@utmb.edu; sktseng@UTMB.EDU; darryl.falzarano@usask.ca; Volker.gerdts@usask.ca; paul.hodgson@usask.ca; stittelaar@viroclinics.com; wim.vanderpoel@wur.nl; nora.gerhards@wur.nl; jeroen.kortekaas@wur.nl; nadia.oreshkova@wur.nl; Martha.Alexander-Miller@wakehealth.edu; kmodjarrad@eidresearch.org; mdiamond@wustl.edu; HENAO RESTREPO, Ana Maria; KNEZEVIC, Ivana; SATHIYAMOORTHY, Vaseeharan; PREZIOSI, Marie-pierre; RIVEROS BALTA, Ximena; SCHWARTZ, Lauren; YOO, Si Hyung; SWAMINATHAN, Soumya; WOOD, David John; ZHOU, Tiequn; dbolton@hivresearch.org; lisette.cornelissen@wur.nl; ivan.marazzi@mssm.edu; BRANGEL, Polina; SALAMI, Kolawole; Nerea_ZabaletaLasarte@MEEI.HARVARD.EDU; lawton.stubbert@canada.ca; Cong, Yu (NIH/NIAID) [C]; Adam T. Waickman
Subject: WHO COVID-19 Animal Models Group Call
When: Thursday, January 21, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).
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Agenda to follow.

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To: Alter, Galit[galter@partners.org]; Maria Baca Estrada (maria.baca-estrada@canada.ca)[maria.baca-estrada@canada.ca]; baihe (baihe@nmpa.gov.cn)[baihe@nmpa.gov.cn]; Baric, Ralph S[rbaric@email.unc.edu]; dbarouch (dbarouch@bidmc.harvard.edu)[dbarouch@bidmc.harvard.edu]; cheryl (cheryl@gisaid.org)[cheryl@gisaid.org]; valentina.bernasconi@cepi.net[valentina.bernasconi@cepi.net]; shinjini.bhatnagar (shinjini.bhatnagar@thsti.res.in)[shinjini.bhatnagar@thsti.res.in]; pbieniasz@mail.rockefeller.edu[pbieniasz@mail.rockefeller.edu]; karin.bok (karin.bok@nih.gov)[karin.bok@nih.gov]; Boyle, David[dboyle@path.org]; brooke.bozick@nih.gov[brooke.bozick@nih.gov]; BRANGEL, Polina[brangelp@who.int]; christian.brechot (christian.brechot@pasteur.fr)[christian.brechot@pasteur.fr]; Christine Bruce (Christine.bruce@phe.gov.uk)[Christine.bruce@phe.gov.uk]; zuz4 (zuz4@cdc.gov)[zuz4@cdc.gov]; Miles.Carroll (Miles.Carroll@phe.gov.uk)[Miles.Carroll@phe.gov.uk]; fjc37@cam.ac.uk[fjc37@cam.ac.uk]; Cavaleri Marco (Marco.Cavaleri@ema.europa.eu)[Marco.Cavaleri@ema.europa.eu]; Monalisa Chatterji (MONALISA.CHATTERJI@gatesfoundation.org)[MONALISA.CHATTERJI@gatesfoundation.org]; Emmanuelle Charton (emmanuelle.charton@edqm.eu)[emmanuelle.charton@edqm.eu]; Chu, May[MAY.CHU@CUANSCHUTZ.EDU]; Carolyn Clark (carolyn.clark@cepi.net)[carolyn.clark@cepi.net]; Daniel Cohen (dancohen@tauex.tau.ac.il)[dancohen@tauex.tau.ac.il]; kizzmekia.corbett@nih.gov[kizzmekia.corbett@nih.gov]; COSTA, Alejandro Javier[costaa@who.int]; Coughlin, Melissa (CDC/DDID/NCIRD/DVD)[htq4@cdc.gov]; shane@lji.org[shane@lji.org]; ian.crozier@nih.gov[ian.crozier@nih.gov]; Damon, Inger K. (CDC/DDID/NCEZID/DHCPP)[iad7@cdc.gov]; Lisa@amicitiam.com[Lisa@amicitiam.com]; Peter Daszak (daszak@ecohealthalliance.org)[daszak@ecohealthalliance.org]; de los Santos, Tala[tdelossantos@path.org]; De wit, Emmie (NIH/NIAID) [E][emmie.dewit@nih.gov]; Degrace, Marciela (NIH/NIAID) [E][marciela.degrace@nih.gov]; Delgado Vazquez.Rafael (rafael.delgado@salud.madrid.org)[rafael.delgado@salud.madrid.org]; mit666666 (mit666666@pitt.edu)[mit666666@pitt.edu]; katie.doores (katie.doores@kcl.ac.uk)[katie.doores@kcl.ac.uk]; William Dowling (william.dowling@cepi.net)[william.dowling@cepi.net]; christian.drosten (christian.drosten@charite.de)[christian.drosten@charite.de]; epstein@ecohealthalliance.org[epstein@ecohealthalliance.org]; Karl.Erlandson (Karl.Erlandson@hhs.gov)[Karl.Erlandson@hhs.gov]; Falzarano, Darryl[darryl.falzarano@usask.ca]; jason.fernandes@canada.ca[jason.fernandes@canada.ca]; Florence, Clint (NIH/NIAID) [E][clint.florence@nih.gov]; Frieman, Matthew[MFrieman@som.umaryland.edu]; Simon Funnell (simon.funnell@phe.gov.uk)[simon.funnell@phe.gov.uk]; Luc.Gagnon (Luc.Gagnon@nexelis.com)[Luc.Gagnon@nexelis.com]; Mayra.Garcia (Mayra.Garcia@fda.hhs.gov)[Mayra.Garcia@fda.hhs.gov]; bhx1 (bhx1@cdc.gov)[bhx1@cdc.gov]; Volker.gerdts (Volker.gerdts@usask.ca)[Volker.gerdts@usask.ca]; GILBERT Nick[Nick.Gilbert@ed.ac.uk]; Goldblatt, David[d.goldblatt@ich.ucl.ac.uk]; guy.gorochov@sorbonne-universite.fr[guy.gorochov@sorbonne-universite.fr]; Graham, Barney (NIH/VRC) [E][bgraham@mail.nih.gov]; Griffiths, Anthony[ahgriff@bu.edu]; elwyn.griffiths@cepi.net[elwyn.griffiths@cepi.net]; gregory.d.gromowski.civ (gregory.d.gromowski.civ@mail.mil)[gregory.d.gromowski.civ@mail.mil]; Celine Gurry (Celine.gurry@cepi.net)[Celine.gurry@cepi.net]; ilj2 (ilj2@cdc.gov)[ilj2@cdc.gov]; B.L. Haagmans (b.haagmans@erasmusmc.nl)[b.haagmans@erasmusmc.nl]; Helfand, Rita (CDC/DDID/NCEZID/OD)[rzh7@cdc.gov]; HENAO RESTREPO, Ana Maria[henaorestrepoa@who.int]; Hensley, Lisa (NIH/NIAID) [E][lisa.hensley@nih.gov]; Hodgson, Paul[paul.hodgson@usask.ca]; Holbrook, Michael (NIH/NIAID) [C][michael.holbrook@nih.gov]; johan.holst@cepi.net[johan.holst@cepi.net]; rawcraig@yahoo.com[rawcraig@yahoo.com]; Hyde, Terri (CDC/DDPHSIS/CGH/GID)[thyde@cdc.gov]; IRAHETA SIGUENZA, Raul Emilio[irahetar@who.int]; REIRELAND (REIRELAND@mail.dstl.gov.uk)[REIRELAND@mail.dstl.gov.uk]; ASiyer@mgh.harvard.edu[ASiyer@mgh.harvard.edu]; Jayashankar, Lakshmi (OS/ASPR/BARDA)[Lakshmi.Jayashankar@hhs.gov]; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)[djernigan@cdc.gov]; johnsonreed@niaid.nih.gov[johnsonreed@niaid.nih.gov]; ydm9@cdc.gov[ydm9@cdc.gov]; Jacqueline Kirchner (Jacqueline.Kirchner@gatesfoundation.org)[Jacqueline.Kirchner@gatesfoundation.org]; KNEZEVIC, Ivana[knezevici@who.int]; M.P.G. Koopmans (m.koopmans@erasmusmc.nl)[m.koopmans@erasmusmc.nl]; Kovacs, Gerald (OS/ASPR/BARDA) (CTR)[Gerald.Kovacs@hhs.gov]; florian.krammer (florian.krammer@mssm.edu)[florian.krammer@mssm.edu]; Krause, Philip[philip.krause@fda.hhs.gov]; Shelly Krebs (skrebs@hivresearch.org)[skrebs@hivresearch.org]; Greg Kulnis (Greg.Kulnis@nexelis.com)[Greg.Kulnis@nexelis.com]; Arun Kumar (arun.kumar@cepi.net)[arun.kumar@cepi.net]; pawinee.k@redcross.or.th[pawinee.k@redcross.or.th]; Teresa Lambe (teresa.lambe@ndm.ox.ac.uk)[teresa.lambe@ndm.ox.ac.uk]; Lathey, Janet (NIH/NIAID) [E][janet.lathey@nih.gov]; Leader, Troy[bleader@path.org]; leejooyeon (leejooyeon@korea.kr)[leejooyeon@korea.kr]; Lee, William T (HEALTH)[william.lee@health.ny.gov]; MSLEVER (MSLEVER@dstl.gov.uk)[MSLEVER@dstl.gov.uk]; liyl (liyl@cde.org.cn)[liyl@cde.org.cn]; changguili (changguili@aliyun.com)[changguili@aliyun.com]; lyhchengdu (lyhchengdu@163.com)[lyhchengdu@163.com]; limhy0919 (limhy0919@korea.kr)[limhy0919@korea.kr]; Little, James (OS/ASPR/BARDA)[James.Little@hhs.gov]; liub (liub@cde.org.cn)[liub@cde.org.cn]; jma[jma@sgul.ac.uk]; MacGill, Tracy[Tracy.MacGill@fda.hhs.gov]; Karen Makar (Karen.Makar@gatesfoundation.org)[Karen.Makar@gatesfoundation.org]; Mary.Matheson@phe.gov.uk[Mary.Matheson@phe.gov.uk]; Giada Mattiuzzo (Giada.Mattiuzzo@nibsc.org)[Giada.Mattiuzzo@nibsc.org]; jmclellan (jmclellan@austin.utexas.edu)[jmclellan@austin.utexas.edu]; adrian.mcdermott (adrian.mcdermott@nih.gov)[adrian.mcdermott@nih.gov]; McElrath MD PhD, Julie[jmcelrat@fredhutch.org]; gmedigeshi (gmedigeshi@thsti.res.in)[gmedigeshi@thsti.res.in]; jwm1 (jwm1@pitt.edu)[jwm1@pitt.edu]; Liz Miller (Liz.Miller@lshtm.ac.uk)[Liz.Miller@lshtm.ac.uk]; Philip Minor (Philip.Minor2@gmail.com)[Philip.Minor2@gmail.com]; Kayvon Modjarrad (kmodjarrad@eidresearch.org)[kmodjarrad@eidresearch.org]; david.montefiori@duke.edu[david.montefiori@duke.edu]; pennym@nicd.ac.za[pennym@nicd.ac.za]; kaitlyn.dambach@nih.gov[kaitlyn.dambach@nih.gov]; MORGAN, Oliver[omorgan@who.int]; Clare.Morris@nibsc.org[Clare.Morris@nibsc.org]; Sarah Mudrak, Ph.D.[sarah.mudrak@duke.edu]; Cesar Munoz-Fontela (munoz-fontela@bnitm.de)[munoz-fontela@bnitm.de]; Munster, Vincent (NIH/NIAID) [E][vincent.munster@nih.gov]; Myers, Todd[Todd.Myers@fda.hhs.gov]; aysegul.nalca.civ (aysegul.nalca.civ@mail.mil)[aysegul.nalca.civ@mail.mil]; scott.napper (scott.napper@usask.ca)[scott.napper@usask.ca]; MNELSON (MNELSON@dstl.gov.uk)[MNELSON@dstl.gov.uk]; PNorris@vitalant.org[PNorris@vitalant.org]; pilailuk.o (pilailuk.o@dmsc.mail.go.th)[pilailuk.o@dmsc.mail.go.th]; n.okba@erasmusmc.nl[n.okba@erasmusmc.nl]; Olinger, Gene[golinger@MRIGLOBAL.ORG]; Jae Ouk Kim (jokim@ivi.int)[jokim@ivi.int]; Mark Page (Mark.Page@nibsc.org)[Mark.Page@nibsc.org]; gustavo.f.palacios.civ (gustavo.f.palacios.civ@mail.mil)[gustavo.f.palacios.civ@mail.mil]; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD)[map1@cdc.gov];

Panayampalli, Subbian Satheshkumar (CDC/DDID/NCEZID/DHCPP)[xdv3@cdc.gov]; qiang.pan-hammarstrom@ki.se[qiang.pan-hammarstrom@ki.se]; Peden, Keith[keith.peden@fda.hhs.gov]; sheila.a.peel2.civ (sheila.a.peel2.civ@mail.mil)[sheila.a.peel2.civ@mail.mil]; malik (malik@hku.hk)[malik@hku.hk]; PERKINS, Mark[perkinsm@who.int]; Perlman, Stanley[stanley-perlman@uiowa.edu]; Supaporn Phumiamorn (supaporn.p@dmsc.mail.go.th)[supaporn.p@dmsc.mail.go.th]; margaret.l.pitt.civ (margaret.l.pitt.civ@mail.mil)[margaret.l.pitt.civ@mail.mil]; mireille.plamondon@canada.ca[mireille.plamondon@canada.ca]; JLPRIOR (JLPRIOR@dstl.gov.uk)[JLPRIOR@dstl.gov.uk]; arimoin (arimoin@g.ucla.edu)[arimoin@g.ucla.edu]; RIVEROS BALTA, Ximena[lauriex@who.int]; Nicola Rose (Nicola.Rose@nibsc.org)[Nicola.Rose@nibsc.org]; Jilian Sacks (Jilian.sacks@finddx.org)[Jilian.sacks@finddx.org]; Marc L Salit (msalit@stanford.edu)[msalit@stanford.edu]; erica (erica@lji.org)[erica@lji.org]; SATHIYAMOORTHY, Vaseeharan[moorthyv@who.int]; Sharon Schendel (schendel@lji.org)[schendel@lji.org]; Schmaljohn, Connie (NIH/NIAID) [E][connie.schmaljohn@nih.gov]; Barbara.Schnierle (Barbara.Schnierle@pei.de)[Barbara.Schnierle@pei.de]; PScott (PScott@eidresearch.org)[PScott@eidresearch.org]; alex@lji.org[alex@lji.org]; peshi@UTMB.EDU[peshi@UTMB.EDU]; Shivji Ragini (Ragini.Shivji@ema.europa.eu)[Ragini.Shivji@ema.europa.eu]; sujan@lji.org[sujan@lji.org]; Amy C. Shurtleff (amy.c.shurtleff@cepi.net)[amy.c.shurtleff@cepi.net]; YOO, Si Hyung[yoos@who.int]; alex.sigal@ahri.org[alex.sigal@ahri.org]; Smith, Ashley (OS/ASPR/BARDA)[Ashley.Smith1@hhs.gov]; Manki Song (mksong@ivi.int)[mksong@ivi.int]; Stemmy, Erik (NIH/NIAID) [E][erik.stemmy@nih.gov]; SUBISSI, Lorenzo[subissil@who.int]; SWAMINATHAN, Soumya[swaminathans@who.int]; r.tedder@imperial.ac.uk[r.tedder@imperial.ac.uk]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD)[nax3@cdc.gov]; tracey.thue (tracey.thue@usask.ca)[tracey.thue@usask.ca]; georgia.tomaras (georgia.tomaras@duke.edu)[georgia.tomaras@duke.edu]; Julia Tree (Julia.Tree@phe.gov.uk)[Julia.Tree@phe.gov.uk]; john.c.trefry.civ (john.c.trefry.civ@mail.mil)[john.c.trefry.civ@mail.mil]; luk_vandenberghe (luk_vandenberghe@meei.harvard.edu)[luk_vandenberghe@meei.harvard.edu]; sylvie.van-der-werf (sylvie.van-der-werf@pasteur.fr)[sylvie.van-der-werf@pasteur.fr]; eric.vangieson@darpa.mil[eric.vangieson@darpa.mil]; Vasan, Vasan (H&B, Geelong ACDP)[Vasan.Vasan@csiro.au]; Васильев Юрий Михайлович (y.m.vasiliev@spbniivs.ru)[y.m.vasiliev@spbniivs.ru]; David Vaughn (David.Vaughn@gatesfoundation.org)[David.Vaughn@gatesfoundation.org]; linfa.wang (linfa.wang@duke-nus.edu.sg)[linfa.wang@duke-nus.edu.sg]; wangjz (wangjz@nifdc.org.cn)[wangjz@nifdc.org.cn]; wangyc (wangyc@nifdc.org.cn)[wangyc@nifdc.org.cn]; Weir, Jerry P.[jerry.weir@fda.hhs.gov]; gweiss@uci.edu[gweiss@uci.edu]; daniela@lji.org[daniela@lji.org]; tomwhite42450@gmail.com[tomwhite42450@gmail.com]; wilsonp@uchicago.edu[wilsonp@uchicago.edu]; Wolfraim, Larry (NIH/NIAID) [E][larry.wolfraim@nih.gov]; David Wood (dj56wood@gmail.com)[dj56wood@gmail.com]; xumiaobj (xumiaobj@126.com)[xumiaobj@126.com]; solomon.yimer@cepi.net[solomon.yimer@cepi.net]; tlying (tlying@fudan.edu.cn)[tlying@fudan.edu.cn]; Vidadi Yusibov (vyusibov@indianabiosciences.org)[vyusibov@indianabiosciences.org]; zlshi (zlshi@wh.iov.cn)[zlshi@wh.iov.cn]; ZHOU, Tiequn[ZhouT@who.int]; diane.descamps@aphp.fr[diane.descamps@aphp.fr]; SGalloway@cdc.gov[SGalloway@cdc.gov]; lny1@cdc.gov[lny1@cdc.gov]; Wentworth, David E. (CDC/OID/NCIRD)[gll9@cdc.gov]; mbo2@cdc.gov[mbo2@cdc.gov]; sot1@cdc.gov[sot1@cdc.gov]; Eeva Broberg (Eeva.Broberg@ecdc.europa.eu)[Eeva.Broberg@ecdc.europa.eu]; SALAMI, Kolawole[salamik@who.int]; tcs38@psu.edu[tcs38@psu.edu]; Angeliki Melidou (angeliki.melidou@ecdc.europa.eu)[angeliki.melidou@ecdc.europa.eu]; BUDA Mihaela[Mihaela.BUDA@edqm.eu]
Cc: Meera Chand[Meera.Chand@phe.gov.uk]; shane@lji.org[shane@lji.org]; thatziio@rockefeller.edu[thatziio@mail.rockefeller.edu]
From: SCHWARTZ, Lauren[schwartzl@who.int]
Sent: Tue 1/26/2021 12:13:32 PM (UTC-05:00)
Subject: RE: WHO Working Group on COVID-19 Assays

Dear All,

Please find below the agenda for this week's WHO working group on COVID-19 assays group call.

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays group call Wednesday January 27 2:30PM CET (Geneva Time)

1. Meera Chand & Victoria Hall (PHE) – *The UK SIREN study first interim analysis: Do antibody positive healthcare workers have lower SARS-CoV-2 2 infection rates than antibody negative healthcare workers?*
2. Shane Crotty (LJI) - *Immunological memory to SARS-CoV-2 and COVID-19*
3. Theodora Hatziioannou (Rockefeller) - *Neutralizing antibody responses to SARS-CoV-2 following vaccination*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 24, 2021 2:01 PM

To: galter@partners.org; maria.baca-estrada@canada.ca; baihe@nmpa.gov.cn; rbaric@email.unc.edu; dbarouch@bidmc.harvard.edu; cheryl@gisaid.org; valentina.bernasconi@cepi.net; shinjini.bhatnagar@thsti.res.in; pbieniasz@mail.rockefeller.edu; karin.bok@nih.gov; dboyle@path.org; brooke.bozick@nih.gov; BRANGEL, Polina; christian.brechot@pasteur.fr; Christine.bruce@phe.gov.uk; zuz4@cdc.gov; Miles.Carroll@phe.gov.uk; fjc37@cam.ac.uk; Marco.Cavaleri@ema.europa.eu; MONALISA.CHATTERJI@gatesfoundation.org; emmanuelle.charton@edqm.eu; MAY.CHU@CUANSCHUTZ.EDU; carolyn.clark@cepi.net; dancohen@tauex.tau.ac.il; kizzmekia.corbett@nih.gov; COSTA, Alejandro Javier; htq4@cdc.gov; shane@lji.org; ian.crozier@nih.gov; lad7@cdc.gov; Lisa@amicitiam.com; daszak@ecohealthalliance.org; tdelossantos@path.org; emmie.dewit@nih.gov; marciela.degrace@nih.gov; rafael.delgado@salud.madrid.org; mit666666@pitt.edu; katie.doores@kcl.ac.uk; william.dowling@cepi.net; christian.drosten@charite.de; epstein@ecohealthalliance.org; Karl.Erlandson@hhs.gov; darryl.falzarano@usask.ca; jason.fernandes@canada.ca; clint.florence@nih.gov; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk; Luc.Gagnon@nexelis.com; Mayra.Garcia@fda.hhs.gov; bhx1@cdc.gov; Volker.gerdts@usask.ca; Nick.Gilbert@ed.ac.uk; d.goldblatt@ucl.ac.uk; guy.gorochov@sorbonne-universite.fr; barney.graham@nih.gov; ahgriff@bu.edu; elwyn.griffiths@cepi.net; gregory.d.gromowski.civ@mail.mil; celine.gurry@cepi.net; ilj2@cdc.gov; b.haagmans@erasmusmc.nl; rzh7@cdc.gov; HENAO RESTREPO, Ana Maria; lisa.hensley@nih.gov; paul.hodgson@usask.ca; Michael.holbrook@nih.gov; johan.holst@cepi.net; rawcraig@yahoo.com; tkh4@cdc.gov; IRAHETA SIGUENZA, Raul Emilio; REIRELAND@mail.dstl.gov.uk; ASiyer@mgh.harvard.edu; Lakshmi.Jayashankar@hhs.gov; djernigan@cdc.gov; johnsonreed@niaid.nih.gov; ydm9@cdc.gov; Jacqueline.Kirchner@gatesfoundation.org; KNEZEVIC, Ivana; m.koopmans@erasmusmc.nl; Gerald.Kovacs@hhs.gov; florian.krammer@mssm.edu; Philip.Krause@fda.hhs.gov; skrebs@hivresearch.org; Greg.Kulnis@nexelis.com; arun.kumar@cepi.net; pawinee.k@redcross.or.th; teresa.lambe@ndm.ox.ac.uk; janet.lathey@nih.gov; bleader@path.org; leejooyeon@korea.kr; william.lee@health.ny.gov; MSLEVER@dstl.gov.uk; liyl@cde.org.cn; changguili@aliyun.com; lyhchengdu@163.com; limhy0919@korea.kr; James.Little@hhs.gov; liub@cde.org.cn; jma@sgul.ac.uk; Tracy.MacGill@fda.hhs.gov; Karen.Makar@gatesfoundation.org; Mary.Matheson@phe.gov.uk; Giada.Mattiuzzo@nibsc.org; jmclellan@austin.utexas.edu; adrian.mcdermott@nih.gov; jmcelrat@fredhutch.org; gmedigeshi@thsti.res.in; jwm1@pitt.edu; Liz.Miller@lshtm.ac.uk; philip.minor2@gmail.com; kmodjarrad@eidresearch.org; david.montefiori@duke.edu; pennym@nicd.ac.za; kaitlyn.dambach@nih.gov; MORGAN, Oliver; Clare.Morris@nibsc.org; sarah.mudrak@duke.edu; munoz-fontela@bnitm.de; vincent.munster@nih.gov; Todd.Myers@fda.hhs.gov; aysegul.nalca.civ@mail.mil; scott.napper@usask.ca; MNELSON@dstl.gov.uk; PNorris@vitalant.org; pilailuk.o@dmsc.mail.go.th; n.okba@erasmusmc.nl; golinger@MRIGLOBAL.ORG; jokim@ivi.int; Mark.Page@nibsc.org; gustavo.f.palacios.civ@mail.mil; map1@cdc.gov; xdv3@cdc.gov; qiang.pan-hammarstrom@ki.se; Keith.Peden@fda.hhs.gov; sheila.a.peel2.civ@mail.mil; malik@hku.hk; PERKINS, Mark; stanley-perlman@uiowa.edu; supaporn.p@dmsc.mail.go.th; margaret.l.pitt.civ@mail.mil; mireille.plamondon@canada.ca; JLPRIOR@dstl.gov.uk; arimoin@g.ucla.edu; RIVEROS BALTA, Ximena; Nicola.Rose@nibsc.org; Jilian.Sacks@finddx.org; msalit@stanford.edu; erica@lji.org; SATHIYAMOORTHY, Vaseeharan; schendel@lji.org; connie.schmaljohn@nih.gov; Barbara.Schnierle@pei.de; SCHWARTZ, Lauren; PScott@eidresearch.org; alex@lji.org; peshi@UTMB.EDU; Ragini.Shivji@ema.europa.eu; sujan@lji.org; amy.c.shurtleff@cepi.net; YOO, Si Hyung; alex.sigal@ahri.org; Ashley.Smith1@hhs.gov; mksong@ivi.int; erik.stemmy@nih.gov; SUBISSI, Lorenzo; SWAMINATHAN, Soumya; r.tedder@imperial.ac.uk; nax3@cdc.gov; tracey.thue@usask.ca; georgia.tomaras@duke.edu; Julia.Tree@phe.gov.uk; john.c.trefry.civ@mail.mil; luk_vandenberghe@meei.harvard.edu; sylvie.van-der-werf@pasteur.fr; eric.vangieson@darpa.mil; Vasan.Vasan@csiro.au; y.m.vasiliev@spbniivs.ru; David.Vaughn@gatesfoundation.org; linfa.wang@duke-nus.edu.sg; wangjz@nifdc.org.cn; wangyc@nifdc.org.cn; Jerry.Weir@fda.hhs.gov; gweiss@uci.edu; daniela@lji.org; tomwhite42450@gmail.com; wilsonp@uchicago.edu; larry.wolfraim@nih.gov; dj56wood@gmail.com; xumiaobj@126.com; solomon.yimer@cepi.net; tlying@fudan.edu.cn; vyusibov@indianabiosciences.org; zlshi@wh.iov.cn; ZHOU, Tiequn; diane.descamps@aphp.fr; SGalloway@cdc.gov; lny1@cdc.gov; gll9@cdc.gov; mbo2@cdc.gov; sot1@cdc.gov; Eeva Broberg; SALAMI, Kolawole; tcs38@psu.edu; angeliki.melidou@ecdc.europa.eu; BUDA Mihaela
Subject: WHO Working Group on COVID-19 Assays
When: Wednesday, January 27, 2021 5:30 AM-7:00 AM (UTC-08:00) Pacific Time (US & Canada).
Where: https://who.zoom.us/j/3612568290

Please note this meeting will be 1.5hrs instead of the usual one hour to allow for an additional presentation and discussion on the new variant.

Agenda to follow.

Join Zoom Meeting
https://who.zoom.us/j/3612568290

Meeting ID: 361 256 8290
One tap mobile

+41225910005,,3612568290# Switzerland
+41225910156,,3612568290# Switzerland

Dial by your location
- +41 22 591 00 05 Switzerland
- +41 22 591 01 56 Switzerland
- +41 31 528 09 88 Switzerland
- +41 43 210 70 42 Switzerland
- +41 43 210 71 08 Switzerland
- +1 253 215 8782 US (Tacoma)
- +1 720 928 9299 US (Denver)
- +1 971 247 1195 US (Portland)
- +1 213 338 8477 US (Los Angeles)
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