
From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/30/2020 3:08:46 PM
To: Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM
Attachments: 06_2019-nCoV Outbreak_FDA SITREP_30 January 2019.docx

Indeed – can you take a quick look at attached and let me know what u think?

Trying to clarify the HCT/Ps one – but maybe made it worse - Thx

From: Rouse, David <David.Rouse@fda.hhs.gov>
Sent: Thursday, January 30, 2020 2:45 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

That is awfully specific! 🤔

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Thursday, January 30, 2020 2:44 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Hi Michael,
Here is today's SITREP.
Thanks,
David

CBER Activities for 01/30/2020

- FDA in monitoring whether there is need for additional recommendations for the assessment of donors of HCTPs in case of exposure to nCoV. FDA has received inquiries from multiple tissue establishments including NYU Langone Health, Eye Bank Association of America, and Eye Donor America.
- FDA had a discussion with (b)(4) regarding the strategy and concerns surrounding use of convalescent plasma for clinical trials in response to the nCoV outbreak in China.
- FDA is preparing its BSL-3 labs to make reference material for the nCoV assay and other purposes.
- FDA is working with HHS and the USG Sample Sharing WG to pursue obtaining a viral sample from the Wuhan Institute of Virology through a connection with one of our investigators.
- FDA is working with CDC to prepare a message to blood establishments about donor information in regards to nCoV.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 30, 2020 1:53 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara

<Barbara.Styrt@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kim, Christine <Christine.Kim@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>

Cc: FDA Emergency Operations <emergency.operations@fda.hhs.gov>

Subject: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Hi. Attached is the draft 30 Jan SITREP on the FDA response to the 2019-nCoV outbreak.

Please **provide any updates you to me by 3:00 PM.**

Please highlight any info that should not be shared outside of FDA in red.

Many thx for your continued assistance with this. -m

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On 31 December 2019, Chinese authorities informed the World Health Organization (WHO) of a cluster of cases of pneumonia of unknown cause detected in Wuhan City, Hubei Province of China. Chinese authorities subsequently identified the novel coronavirus (2019-nCoV) as the etiologic agent. This update provides a daily snapshot of [[HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-2019-ncov"](https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-2019-ncov)] to respond to the 2019-nCoV outbreak. Non-public / CCI information is highlighted in red.

Situation Update

- As of 30 Jan at 11 AM ETS, 8,236 cases of 2019-nCoV have been [[HYPERLINK "https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html" \l "bda7594740fd40299423467b48e9ecf6"](https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6)] with 171 deaths.
 - On 30 Jan, CDC [[HYPERLINK "https://www.cdc.gov/media/releases/2020/p0130-coronavirus-spread.html"](https://www.cdc.gov/media/releases/2020/p0130-coronavirus-spread.html)] that the 2019-nCoV has spread between two people in the United States, representing the first instance of person-to-person spread in the US. ([[HYPERLINK "https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html"](https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html)])
 - On 30 Jan, the White House [[HYPERLINK "https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/"](https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/)] the formation of the President's Coronavirus Task Force, which is charged with leading the United States Government response to the novel 2019 coronavirus.
 - On 30 Jan, the WHO declared the 2019-nCoV outbreak a public health emergency of international concern.
 - On 30 Jan, it was [[HYPERLINK "https://www.ft.com/content/75adafb6-4306-11ea-abea-0c7a29cd66fe"](https://www.ft.com/content/75adafb6-4306-11ea-abea-0c7a29cd66fe)] that Russia has ordered the closure of its land border with China to prevent the spread of 2019-nCoV.
- On 29 Jan, the U.S. Department of State [[HYPERLINK "https://travel.state.gov/content/travel/en/traveladvisories/traveladvisories/china-travel-advisory.html"](https://travel.state.gov/content/travel/en/traveladvisories/traveladvisories/china-travel-advisory.html)] the departure of family members and all non-emergency U.S. government employees at the U.S. Embassy in Beijing, China and the Consulates General in Chengdu, Guangzhou, Shanghai, and Shenyang.

Interagency / NGO Coordination and Collaboration

- **USG Interagency:**
 - FDA participated in the daily 2019-nCoV briefing for the HHS Secretary.
 - FDA participated in the daily nCoV PCC held by NSC.
 - FDA participated in the HHS Supply Chain Task Force Meeting.
 - FDA participated in the nCoV Stakeholder Industry Call hosted by BARDA.

Interagency Requests for Information (RFIs)

- Nothing to report.

Devices

- Additional IVD Developers have requested and received EUA review template [; 6 IVD developers have requested the EUA review template to date]
- CDC 2019-nCoV diagnostic test: Interactive review with CDC continues – .

Drugs

- FDA approved the second EIND for remdesivir for a 68 year old male with a history of COPD who was PCR positive for 2019-nCoV; also with RLL pneumonia. Patient is (b)(6)

(b)(6)

Biologics

- Convalescent plasma: FDA had a discussion with (b)(4) regarding the strategy and concerns surrounding use of convalescent plasma for clinical trials in response to the nCoV outbreak in China.
- Regulatory Science: FDA is preparing its BSL-3 labs to make reference material for the 2019-nCoV assay and other purposes.
- Regulatory Science: FDA is working with HHS and the USG Sample Sharing WG to pursue obtaining a viral sample from the Wuhan Institute of Virology through a connection with one of our investigators.
- Blood Safety: FDA is working with CDC to prepare a message to blood establishments about donor information in regard to 2019-nCoV.
- Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): FDA has received inquiries from multiple tissue establishments regarding the assessment of donors of HCT/Ps in case of exposure to 2019-nCoV, including NYU Langone Health, Eye Bank Association of America, and Eye Donor America, and is [developing recommendations...?].

Communications

-

Fraudulent Product Claims

-

Medical Product Supply Chain

- To date, no manufacturers have reported an impact or drug shortages due to the 2019-nCoV outbreak in China.

Legislative Activities

- RADM Hinton, FDA Chief Scientist represented FDA at a member level briefing for the full House E&C committee.
- Bipartisan HELP Committee staff have requested a novel coronavirus briefing for next week with representatives from CDC, NIH, ASPR, and FDA. FDA Briefer TBD.

Budget

-

Workforce / Travel Policy

- Workforce Protection: FDA is working to develop a consistent policy across FDA centers and offices regarding employee travel.

External Situation Reports

- USG [information is for internal government use only]**
 - CDC: [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/CDC%20SITREP/CDC%20Novel%20Coronavirus%20\(nCoV\)%20SITREP%200003%2001-29-2020.pdf"](http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/CDC%20SITREP/CDC%20Novel%20Coronavirus%20(nCoV)%20SITREP%200003%2001-29-2020.pdf)] 3 (29 Jan 2020)
- WHO:**

- WHO 2019-nCoV [HYPERLINK "<http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/WHO%20SITREP/WHO%20Situation%20Report%2010%20nCoV.pdf>" \t "_blank"] (29 January 2020)

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From: Rouse, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=185BAE767862490D88EDA44DB74A75B3-ROUSED]
Sent: 1/30/2020 3:19:26 PM
To: Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

I know he was trying to cut back on the deserts a bit, but I think he overdid it!

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:18 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Is that a selfie Michael? I know all this CoV was keeping you running around but you really lost weight. 😊

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:17 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Awesome thx. Yes a PHEIC



From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:16 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Overall, looks good. How about my little tweak for the HCT/Ps section? BTW, sounds like we may have a WHO PHEIC.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:09 PM

To: Rouse, David <David.Rouse@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

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To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kim, Christine <Christine.Kim@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>

Cc: FDA Emergency Operations <emergency.operations@fda.hhs.gov>

Subject: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

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From: Rouse, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=185BAE767862490D88EDA44DB74A75B3-ROUSED]
Sent: 12/27/2019 2:56:30 PM
To: Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Devore, Nicolette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cd9d011e02c45d6b1005d46342cad69-Devore]
Subject: RE: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Okay, I'll send this along to Jeff and copy you guys.

Thanks,
D2

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Friday, December 27, 2019 2:50 PM
To: Rouse, David <David.Rouse@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>
Subject: RE: FMT June 2020 Workshop (and more!) - ACTION NEEDED

All fine. Maybe Jeff first and let him ask his bosses 😊

From: Rouse, David <David.Rouse@fda.hhs.gov>
Date: December 27, 2019 at 2:39:18 PM EST
To: Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Possibly Marion and Phil, but certainly not necessary.

From: Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>
Sent: Friday, December 27, 2019 2:06 PM
To: Rouse, David <David.Rouse@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Yeah, I was thinking to send to Jeff since he is out MCM contact. Who else were you thinking of sending it to?

From: Rouse, David <David.Rouse@fda.hhs.gov>
Sent: Friday, December 27, 2019 1:00 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>
Subject: FW: FMT June 2020 Workshop (and more!) - ACTION NEEDED
Importance: High

I assume we would forward to Jeff and possibly others in OVRP to see if there is any interest in sending someone from OVRP to participate?

D2

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, December 27, 2019 12:32 PM
To: Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David

<David.Rouse@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>

Subject: FW: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Importance: High

I'm sorry this message slipped through the cracks. OCET in the past has supported the National Academies of Science Forum on Microbial Threats"... CDER was involved in the last session "Exploring the Frontiers of Innovation to Tackle Microbial Threats," and historically, CVM has more involved from a "One Health" perspective.

The next proposed workshop is vaccine focused, so I thought CBER may want to offer an SME to participate. NAS is looking at dates for the meeting in the survey below. If you are interested and have the time to look it over, you might let us know of your interest and respond to the survey (also letting us know of your response). The deadline is today, but I doubt that is hard and fixed.... I assume we can send messaging on this well into January.

Thanks! Liz

From: Amponsah, Edith <EAmponsah@nas.edu>

Sent: Wednesday, December 18, 2019 5:05 PM

To: atennenb@ITS.JNJ.com; Chandy C. Johnson <chjohn@iu.edu>; David Nabarro <david@4sd.info>; Elizabeth Hermsen <elizabeth.hermsen@merck.com>; Eva Harris <eharris@berkeley.edu>; Gary A. Roselle <gary.roselle@va.gov>; Jay P. Siegel <(b)(6)@gmail.com>; Cassetti, Cristina G (NIH) <ccassetti@niaid.nih.gov>; Andrew Clements <aclements@usaid.gov>; Jonna Mazet <jkmazet@ucdavis.edu>; Kent Kester <Kent.Kester@sanofi.com>; Kevin Anderson <kevin.anderson@dhs.gov>; Kumanan Rasanathan <rasanathank@who.int>; Marcos A. Espinal <espinalm@paho.org>; Matthew Zahn <mzahn@ochca.com>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Peter Sands <peter.sands@theglobalfund.org> <peter.sands@theglobalfund.org>; Peter Daszak <daszak@ecohealthalliance.org>; Rafael Obregon <robregon@unicef.org>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Khabbaz, Rima F (CDC) <rfk1@cdc.gov>; Sally A. Miller <miller.769@osu.edu>; Suerie Moon <suerie.moon@graduateinstitute.ch>; Thomas W. Scott <twscott@ucdavis.edu>; Timothy Burgess <timothy.burgess@usuhs.edu>

Cc: Rita Mueller <rmuelle5@its.jnj.com>; Karen Goraleski <kgoraleski@astmh.org>; 'magali@4sd.info' <magali@4sd.info>; 'Kathleen.Lee@va.gov' <Kathleen.Lee@va.gov>; 'Mary Radford' <maradford@ucdavis.edu>; 'vivian.louchie@sanofipasteur.com' <vivian.louchie@sanofipasteur.com>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'lolmedo@unicef.org' <lolmedo@unicef.org>; Blatner, Gretta L (OS) <Gretta.Blatner@hhs.gov>; Grant, Celeste (CDC) <vj1@cdc.gov>; Grosshans, Denise <DGrossha@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; Goodtree, Hannah <HGoodtree@nas.edu>

Subject: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Importance: High

Dear Forum Members,

A special thank you to all of you for your contributions and support of the Forum. The recent workshop on "Exploring the Frontiers of Innovation to Tackle Microbial Threats" this past month was a success and we appreciate all of your support in accomplishing that. We have incorporated your feedback during the closed session meeting and have begun planning for our next workshop "The Critical Public Health Value of Vaccines in the Age of Pandemics." As many of you know, it was brought to our attention that GAVI will be hosting their replenishment pledging conference the same dates we had originally slated for our workshop (June 3-4, 2020). As such, we have decided to reschedule our next workshop. Please visit the link below to select your preferred dates from the proposed list. Please complete this by **COB December 27, 2019** so that we can go ahead and reserve the space while it is still available.

Survey: <https://www.surveymzmo.com/s3/5378175/June-2020-Vaccine-Workshop-Planning-Survey-Version-2>

I also wanted to share with you all this exciting TEDx Omaha talk Forum member Elizabeth Hermsen gave on November 9th. The theme of the event was "Reframe" and her talk focused on reframing the way we think about antibiotics. See Elizabeth in action here: <https://www.youtube.com/watch?v=7VuoCVbXDm8>.

Please let me know if you have any questions.

Thank you and Happy Holidays to you all,
Edith

Edith Amponsah

Research Associate

Forum on Microbial Threats

Health and Medicine Division

The National Academies of Sciences, Engineering, and Medicine

500 Fifth Street, NW

Phone: 202-334-3222

www.nationalacademies.org/HMD

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From: Sadove, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C627000D4F34B9DB362FF2B6AF4B-SADOVEE]
Sent: 12/28/2019 10:36:06 AM
To: Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Devore, Nicolette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cd9d011e02c45d6b1005d46342cad69-Devore]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]
CC: Roberts, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f99ba866ca234f6d826007b9f1429e8e-RobertsJ]
Subject: RE: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Great. Thanks!

From: Rouse, David <David.Rouse@fda.hhs.gov>
Date: December 28, 2019 at 9:29:18 AM EST
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>, Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Cc: Roberts, Jeff <Jeff.Roberts@fda.hhs.gov>
Subject: RE: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Hi Liz,

I reached out to Jeff Roberts in OVR. They will likely send a representative, but would like to review the agenda and conference dates when available.

Thanks,
Dave

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, December 27, 2019 12:32 PM
To: Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>
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From: Amponsah, Edith <EAmponsah@nas.edu>

Sent: Wednesday, December 18, 2019 5:05 PM

To: atennenb@ITS.JNJ.com; Chandy C. Johnson <chjohn@iu.edu>; David Nabarro <david@4sd.info>; Elizabeth Hermsen <elizabeth.hermsen@merck.com>; Eva Harris <eharris@berkeley.edu>; Gary A. Roselle <gary.roselle@va.gov>; Jay P. Siegel <(b)(6)@gmail.com>; Cassetti, Cristina G (NIH) <ccassetti@niaid.nih.gov>; Andrew Clements <aclements@usaid.gov>; Jonna Mazet <jkmazet@ucdavis.edu>; Kent Kester <Kent.Kester@sanofi.com>; Kevin Anderson <kevin.anderson@dhs.gov>; Kumanan Rasanathan <rasanathan@who.int>; Marcos A. Espinal <espinalm@paho.org>; Matthew Zahn <mzahn@ochca.com>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Peter Sands <peter.sands@theglobalfund.org> <peter.sands@theglobalfund.org>; Peter Daszak <daszak@ecohealthalliance.org>; Rafael Obregon <robregon@unicef.org>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Khabbaz, Rima F (CDC) <rfk1@cdc.gov>; Sally A. Miller <miller.769@osu.edu>; Suerie Moon <suerie.moon@graduateinstitute.ch>; Thomas W. Scott <twscott@ucdavis.edu>; Timothy Burgess <timothy.burgess@usuhs.edu>

Cc: Rita Mueller <rmuelle5@its.jnj.com>; Karen Goraleski <kgoraleski@astmh.org>; 'magali@4sd.info' <magali@4sd.info>; 'Kathleen.Lee@va.gov' <Kathleen.Lee@va.gov>; 'Mary Radford' <maradford@ucdavis.edu>; 'vivian.louchie@sanofipasteur.com' <vivian.louchie@sanofipasteur.com>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'lolmedo@unicef.org' <lolmedo@unicef.org>; Blatner, Gretta L (OS) <Gretta.Blatner@hhs.gov>; Grant, Celeste (CDC) <vjk1@cdc.gov>; Grosshans, Denise <DGrossha@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; Goodtree, Hannah <HGoodtree@nas.edu>

Subject: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Importance: High

Dear Forum Members,

A special thank you to all of you for your contributions and support of the Forum. The recent workshop on “Exploring the Frontiers of Innovation to Tackle Microbial Threats” this past month was a success and we appreciate all of your support in accomplishing that. We have incorporated your feedback during the closed session meeting and have begun planning for our next workshop “The Critical Public Health Value of Vaccines in the Age of Pandemics.” As many of you know, it was brought to our attention that GAVI will be hosting their replenishment pledging conference the same dates we had originally slated for our workshop (June 3-4, 2020). As such, we have decided to reschedule our next workshop. Please visit the link below to select your preferred dates from the proposed list. Please complete this by **COB December 27, 2019** so that we can go ahead and reserve the space while it is still available.

Survey: <https://www.surveymzmo.com/s3/5378175/June-2020-Vaccine-Workshop-Planning-Survey-Version-2>

I also wanted to share with you all this exciting TEDx Omaha talk Forum member Elizabeth Hermsen gave on November 9th. The theme of the event was “Reframe” and her talk focused on reframing the way we think about antibiotics. See Elizabeth in action here: <https://www.youtube.com/watch?v=7VuoCVbXDm8>.

Please let me know if you have any questions.

Thank you and Happy Holidays to you all,
Edith

Edith Amponsah

Research Associate

Forum on Microbial Threats

Health and Medicine Division

The National Academies of Sciences, Engineering, and Medicine

500 Fifth Street, NW

Phone: 202-334-3222

www.nationalacademies.org/HMD

From: Rouse, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=185BAE767862490D88EDA44DB74A75B3-ROUSED]
Sent: 12/28/2019 9:27:10 AM
To: Roberts, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f99ba866ca234f6d826007b9f1429e8e-RobertsJ]
CC: Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Devore, Nicolette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cd9d011e02c45d6b1005d46342cad69-Devore]
Subject: RE: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Hi Jeff,

I'll let Liz know that OVRP will likely send someone after you have had a chance to review the agenda and workshop dates.

Thanks,
Dave

From: Roberts, Jeff <Jeff.Roberts@fda.hhs.gov>
Sent: Saturday, December 28, 2019 9:22 AM
To: Rouse, David <David.Rouse@fda.hhs.gov>
Cc: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>
Subject: RE: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Hi Dave

It's likely that OVRP will send someone. But would like to take a look at the agenda. When they have selected a date and have at least a draft agenda, can you let me know?

Thanks,
Jeff

From: Rouse, David <David.Rouse@fda.hhs.gov>
Sent: Friday, December 27, 2019 3:03 PM
To: Roberts, Jeff <Jeff.Roberts@fda.hhs.gov>
Cc: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>
Subject: FW: FMT June 2020 Workshop (and more!) - ACTION NEEDED
Importance: High

Hi Jeff,

Please see the email below from Liz Sadove and let us know if someone from OVRP would like to support the NAS workshop focused on vaccines. If interested, there is a survey for potential dates.

Thanks,
Dave

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, December 27, 2019 12:32 PM
To: Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>

Subject: FW: FMT June 2020 Workshop (and more!) - ACTION NEEDED

Importance: High

I'm sorry this message slipped through the cracks. OCET in the past has supported the National Academies of Science Forum on Microbial Threats" ... CDER was involved in the last session "Exploring the Frontiers of Innovation to Tackle Microbial Threats," and historically, CVM has more involved from a "One Health" perspective.

The next proposed workshop is vaccine focused, so I thought CBER may want to offer an SME to participate. NAS is looking at dates for the meeting in the survey below. If you are interested and have the time to look it over, you might let us know of your interest and respond to the survey (also letting us know of your response). The deadline is today, but I doubt that is hard and fixed.... I assume we can send messaging on this well into January.

Thanks! Liz

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Cc: Rita Mueller <rmuelle5@its.jnj.com>; Karen Goraleski <kgoraleski@astmh.org>; 'magali@4sd.info' <magali@4sd.info>; 'Kathleen.Lee@va.gov' <Kathleen.Lee@va.gov>; 'Mary Radford' <maradford@ucdavis.edu>; 'vivian.louchie@sanofipasteur.com' <vivian.louchie@sanofipasteur.com>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; 'andre@ecohealthalliance.org' <andre@ecohealthalliance.org>; 'lolmedo@unicef.org' <lolmedo@unicef.org>; Blatner, Gretta L (OS) <Gretta.Blatner@hhs.gov>; Grant, Celeste (CDC) <vj1@cdc.gov>; Grosshans, Denise <DGrossha@nas.edu>; Pavlin, Julie <JPavlin@nas.edu>; Goodtree, Hannah <HGoodtree@nas.edu>

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Please let me know if you have any questions.

Thank you and Happy Holidays to you all,
Edith

Edith Amponsah

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The National Academies of
SCIENCES • ENGINEERING • MEDICINE

From: Cho, David S (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D47AF9D991AF4C1FBF7CB4C1D287F83E-CHOD]
Sent: 1/30/2020 3:15:57 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM
Attachments: 06_2019-nCoV Outbreak_FDA SITREP_30 January 2019.docx

Overall, looks good. How about my little tweak for the HCT/Ps section? BTW, sounds like we may have a WHO PHEIC.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:09 PM
To: Rouse, David <David.Rouse@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Indeed – can you take a quick look at attached and let me know what u think?

Trying to clarify the HCT/Ps one – but maybe made it worse - Thx

From: Rouse, David <David.Rouse@fda.hhs.gov>
Sent: Thursday, January 30, 2020 2:45 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

That is awfully specific! 😬

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Thursday, January 30, 2020 2:44 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Hi Michael,
Here is today's SITREP.
Thanks,
David

CBER Activities for 01/30/2020

- FDA is monitoring whether there is need for additional recommendations for the assessment of donors of HCTPs in case of exposure to nCoV. FDA has received inquiries from multiple tissue establishments including NYU Langone Health, Eye Bank Association of America, and Eye Donor America.
- FDA had a discussion with (b)(4) regarding the strategy and concerns surrounding use of convalescent plasma for clinical trials in response to the nCoV outbreak in China.
- FDA is preparing its BSL-3 labs to make reference material for the nCoV assay and other purposes.
- FDA is working with HHS and the USG Sample Sharing WG to pursue obtaining a viral sample from the Wuhan Institute of Virology through a connection with one of our investigators.
- FDA is working with CDC to prepare a message to blood establishments about donor information in regards to nCoV.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>

Sent: Thursday, January 30, 2020 1:53 PM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kim, Christine <Christine.Kim@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>

Cc: FDA Emergency Operations <emergency.operations@fda.hhs.gov>

Subject: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Hi. Attached is the draft 30 Jan SITREP on the FDA response to the 2019-nCoV outbreak.

Please **provide any updates you to me by 3:00 PM.**

Please highlight any info that should not be shared outside of FDA in red.

Many thx for your continued assistance with this. -m

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On 31 December 2019, Chinese authorities informed the World Health Organization (WHO) of a cluster of cases of pneumonia of unknown cause detected in Wuhan City, Hubei Province of China. Chinese authorities subsequently identified the novel coronavirus (2019-nCoV) as the etiologic agent. This update provides a daily snapshot of [[HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-2019-ncov"](https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-2019-ncov)] to respond to the 2019-nCoV outbreak. Non-public / CCI information is highlighted in red.

Situation Update

- As of 30 Jan at 11 AM ETS, 8,236 cases of 2019-nCoV have been [[HYPERLINK "https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html" \l "bda7594740fd40299423467b48e9ecf6"](https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6)] with 171 deaths.
 - On 30 Jan, CDC [[HYPERLINK "https://www.cdc.gov/media/releases/2020/p0130-coronavirus-spread.html"](https://www.cdc.gov/media/releases/2020/p0130-coronavirus-spread.html)] that the 2019-nCoV has spread between two people in the United States, representing the first instance of person-to-person spread in the US. ([[HYPERLINK "https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html"](https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html)])
 - On 30 Jan, the White House [[HYPERLINK "https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/"](https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/)] the formation of the President's Coronavirus Task Force, which is charged with leading the United States Government response to the novel 2019 coronavirus.
 - On 30 Jan, the WHO declared the 2019-nCoV outbreak a public health emergency of international concern.
 - On 30 Jan, it was [[HYPERLINK "https://www.ft.com/content/75adafb6-4306-11ea-abea-0c7a29cd66fe"](https://www.ft.com/content/75adafb6-4306-11ea-abea-0c7a29cd66fe)] that Russia has ordered the closure of its land border with China to prevent the spread of 2019-nCoV.
- On 29 Jan, the U.S. Department of State [[HYPERLINK "https://travel.state.gov/content/travel/en/traveladvisories/traveladvisories/china-travel-advisory.html"](https://travel.state.gov/content/travel/en/traveladvisories/traveladvisories/china-travel-advisory.html)] the departure of family members and all non-emergency U.S. government employees at the U.S. Embassy in Beijing, China and the Consulates General in Chengdu, Guangzhou, Shanghai, and Shenyang.

Interagency / NGO Coordination and Collaboration

- **USG Interagency:**
 - FDA participated in the daily 2019-nCoV briefing for the HHS Secretary.
 - FDA participated in the daily nCoV PCC held by NSC.
 - FDA participated in the HHS Supply Chain Task Force Meeting.
 - FDA participated in the nCoV Stakeholder Industry Call hosted by BARDA.

Interagency Requests for Information (RFIs)

- Nothing to report.

Devices

- Additional IVD Developers have requested and received EUA review template [; 6 IVD developers have requested the EUA review template to date]
- CDC 2019-nCoV diagnostic test: Interactive review with CDC continues – .

Drugs

- FDA approved the second EIND for remdesivir for a 68 year old male with a history of COPD who was PCR positive for 2019-nCoV; also with RLL pneumonia. Patient is (b)(6)

Biologics

- Convalescent plasma: FDA had a discussion with (b)(4) regarding the strategy and concerns surrounding use of convalescent plasma for clinical trials in response to the nCoV outbreak in China.
- Regulatory Science: FDA is preparing its BSL-3 labs to make reference material for the 2019-nCoV assay and other purposes.
- Regulatory Science: FDA is working with HHS and the USG Sample Sharing WG to pursue obtaining a viral sample from the Wuhan Institute of Virology through a connection with one of our investigators.
- Blood Safety: FDA is working with CDC to prepare a message to blood establishments about donor information in regard to 2019-nCoV.
- Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): FDA has received inquiries from multiple tissue establishments regarding the assessment of donors of HCT/Ps in case of exposure to 2019-nCoV, including NYU Langone Health, Eye Bank Association of America, and Eye Donor America. No change in donor recommendations are suggested at this time.

Communications

-

Fraudulent Product Claims

-

Medical Product Supply Chain

- To date, no manufacturers have reported an impact or drug shortages due to the 2019-nCoV outbreak in China.

Legislative Activities

- RADM Hinton, FDA Chief Scientist represented FDA at a member level briefing for the full House E&C committee.
- Bipartisan HELP Committee staff have requested a novel coronavirus briefing for next week with representatives from CDC, NIH, ASPR, and FDA. FDA Briefer TBD.

Budget

-

Workforce / Travel Policy

- Workforce Protection: FDA is working to develop a consistent policy across FDA centers and offices regarding employee travel.

External Situation Reports

- **USG [information is for internal government use only]**
 - CDC: [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/CDC%20SITREP/CDC%20Novel%20Coronavirus%20\(nCoV\)%20SITREP%200003%2001-29-2020.pdf"](http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/CDC%20SITREP/CDC%20Novel%20Coronavirus%20(nCoV)%20SITREP%200003%2001-29-2020.pdf)] 3 (29 Jan 2020)
- **WHO:**

- WHO 2019-nCoV [HYPERLINK "<http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/WHO%20SITREP/WHO%20Situation%20Report%2010%20nCoV.pdf>" \t "_blank"] (29 January 2020)

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Sent: 1/30/2020 3:32:14 PM
To: Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

So now can we officially panic. 😬

From: Rouse, David <David.Rouse@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:17 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Looks good to me. PHEIC confirmed by CNN according to my phone.

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:16 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

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To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styr, Barbara <Barbara.Styr@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Finner, April <April.Finner@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kim, Christine <Christine.Kim@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>

Cc: FDA Emergency Operations <emergency.operations@fda.hhs.gov>

Subject: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Hi. Attached is the draft 30 Jan SITREP on the FDA response to the 2019-nCoV outbreak.

Please **provide any updates you to me by 3:00 PM.**

Please highlight any info that should not be shared outside of FDA in red.

Many thx for your continued assistance with this. -m

From: Cho, David S (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D47AF9D991AF4C1FBF7CB4C1D287F83E-CHOD]
Sent: 1/30/2020 3:20:44 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Easy way to lose weight....cut back on the Coronas! ☺☺☺ That one deserves three smiley faces.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:19 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Yeah – I've been trying to lose a few.

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:18 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Is that a selfie Michael? I know all this CoV was keeping you running around but you really lost weight. ☺

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:17 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Awesome thx. Yes a PHEIC



From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:16 PM

To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Overall, looks good. How about my little tweak for the HCT/Ps section? BTW, sounds like we may have a WHO PHEIC.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 30, 2020 3:09 PM
To: Rouse, David <David.Rouse@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Indeed – can you take a quick look at attached and let me know what u think?

Trying to clarify the HCT/Ps one – but maybe made it worse - Thx

From: Rouse, David <David.Rouse@fda.hhs.gov>
Sent: Thursday, January 30, 2020 2:45 PM
To: Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

That is awfully specific! 😊

From: Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Sent: Thursday, January 30, 2020 2:44 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Request for Input for 30 Jan Update on FDA 2019-nCoV SITREP - input needed by 3:00 PM

Hi Michael,
Here is today's SITREP.
Thanks,
David

CBER Activities for 01/30/2020

- FDA in monitoring whether there is need for additional recommendations for the assessment of donors of HCTPs in case of exposure to nCoV. FDA has received inquiries from multiple tissue establishments including NYU Langone Health, Eye Bank Association of America, and Eye Donor America.
- FDA had a discussion with (b)(4) regarding the strategy and concerns surrounding use of convalescent plasma for clinical trials in response to the nCoV outbreak in China.
- FDA is preparing its BSL-3 labs to make reference material for the nCoV assay and other purposes.
- FDA is working with HHS and the USG Sample Sharing WG to pursue obtaining a viral sample from the Wuhan Institute of Virology through a connection with one of our investigators.
- FDA is working with CDC to prepare a message to blood establishments about donor information in regards to nCoV.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 30, 2020 1:53 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Simms, Joshua

<Joshua.Simms@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kim, Christine <Christine.Kim@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>

Cc: FDA Emergency Operations <emergency.operations@fda.hhs.gov>

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Sent: 5/6/2020 11:04:14 AM
Subject: situational awareness...COVID-19 animal models

(b)(4) (b)(5)

Sent: 1/30/2020 2:25:18 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]
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Sent: Thursday, January 30, 2020 1:53 PM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kim, Christine <Christine.Kim@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>

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Many thx for your continued assistance with this. -m

Sent: 1/4/2021 10:37:19 AM
Subject: FW: China COVID-19 Vaccine Development December 2020 Update

China COVID-19 Vaccine Development Update as of December 30th, 2020

This update on COVID-19 vaccine developments in China summarizes information from sources including news/media releases, pharmaceutical company websites, WHO/Chinese/NIH Clinical Trial Registries and peer-reviewed publications. As of 30 December 2020, 11 COVID-19 candidate vaccines are in human clinical trials and 5 of them are in phase III clinical trials.

Table 1: China COVID-19 Candidate Vaccines under Clinical Evaluation as of 30 December 2020 (items updated this month shown in red)

Type of candidate vaccine

Developer

Other partners

Registration No.

Outcome/Status

Inactivated: CoronaVac

Sinovac

Butantan (Brazil)

Indonesia

NCT04456595 NCT04508075

NCT04582344 NCT04617483

NCT04651790

Phase I/II study report ;

Phase III study protocol;

Phase III ongoing in Brazil, Bangladesh, Turkey, Indonesia, Chile

Inactivated: BBIBP-CorV

CNBG Beijing; Sinopharm

Tiantan Bio Product Inc; China CDC; Henan CDC; NHC; Chinese Academy of Medical Science

ChiCTR2000034780 ChiCTR2000039000 NCT04612972

ChiCTR2000034780 NCT04560881

Interim result;

BBIBP-CorV Phase I/II result;

Phase III ongoing in Peru, Morocco, Argentina, UAE, Jordan, Bahrain and Egypt

Inactivated

CNBG Wuhan; Sinopharm

Wuhan Institute of Virology; Henan CDC

Inactivated

IMBCAMS*

West China Second Hospital

Yun Nan CDC

NCT04412538

NCT04470609

NCT04659239

Phase III ongoing in Brazil, Malaysia

(Phase III started)

Inactivated+

Beijing Minhai Bio technology Co., Ltd.

Shenzhen Kangtai Bio

Jiangsu CDC

ChiCTR2000038804

ChiCTR2000039462

Phase I/II ongoing

Adenovirus Type 5 Vector

Ad5-nCoV

Cansino;

Institute of Biotechnology; Military Medical Science; PLA

Beijing Institute of Biotechnology

ChiCTR2000030906 ChiCTR2000031781

NCT04398147

NCT04341389

NCT04540419

Phase I result;

Phase II result;

Phase III ongoing in Argentina, Chile, Mexico, Pakistan, Russia

(Participating countries changed)

Intranasal flu-based-RBD

HK University, Xiamen University

BJ WanTai Inc.

JiangSu CDC

ChiCTR2000037782

ChiCTR2000039715

Phase I/II ongoing

Protein subunit

Anhui Zhifei Longkema
Institute of Microbiology; Chinese
Academy of Sciences
NCT04445194
NCT04550351
NCT04466085
ChiCTR2000040153
Phase III ongoing in Hu'nan, China+
(Phase III started)
Protein subunit
West China Hospital
Jiangsu CDC
ChiCTR2000037518;
ChiCTR2000039994;
Phase II ongoing
(Phase II started)
mRNA

Walvax, Suzhou Abogen Pharm; Academy of Military Medicine; PLA
Shulan Hospital (Hangzhou); Yongfu County CDC (Guangxi)
ChiCTR2000034112;
ChiCTR2000039212
Phase I ongoing
RNA/BNT162b1
BionTech/Fosun Pharma/Pfizer
Jiangsu CDC
ChiCTR2000034825
NCT04649021

Phase II ongoing in Jiangsu, China
(Phase II started)

* IMBCAMS: Institute of Medical Biology Chinese Academy of Medical Sciences

+ International locations yet to be identified

Figure 1: Planned/ongoing Chinese COVID-19 Candidate Vaccine Phase III trial locations as of 30 Dec 2020

Vaccine Use (Domestic):

On Dec 08, at a Chengdu municipal government press conference, the Chengdu NHC COVID Response Group said they will start to plan for vaccination in Chengdu. The priority populations will be the frontline medical/epidemic response and border control personnel.

On Dec 19, the State Council Information Office held a press conference to introduce priority populations and plans for vaccination of these groups. According to Zeng Yixin, Vice-Minister of NHC, China will start nationwide vaccination among high risk populations through the emergency use program initiated in June. The priority populations include cold chain workers; point of entry staff; workers in the shipping, aviation, public transportation sectors and agricultural markets; medical and disease control personnel; and those going abroad for work or study. In order to process the vaccination work smoothly, the State Council issued a requirement to the relevant provincial departments and units to effectively control and inspect the quality of vaccines to ensure safe and smooth cold chain transportation and timely and accurate distribution. It is required that all provinces must carefully design their vaccination plans, reasonably set up vaccination locations, and organize vaccination work in a stable and orderly manner. Particular attention should be paid to medical observation following vaccination and timely management and reporting of any adverse reactions. Provinces should educate people to raise awareness of the obligation and responsibility of vaccination and should vaccinate all eligible high-risk groups on time and with informed consent. "This is only the first step for us, more people especially hundreds of millions of the elderly people and those with underlying disease will get vaccinated after the vaccine products are conditionally or officially approved, and the production capacity is improved. Our goal is trying to establish herd immunity actively through vaccination to control the COVID-19 epidemic as soon as possible." Zeng said.

As of Dec 21, according to China NHC statistics, more than 1 million doses of China vaccine products have been used under China's emergency use strategy. Another 50 million doses are expected to be given to the priority populations before the Chinese New Year. [Link](#)

On Dec 30, CNBG Beijing announced that the results of the interim analysis of their inactivated vaccine phase III clinical trial showed that the vaccine safety is good, all vaccine group participants produced high-titer antibodies, the neutralizing antibody positive conversion rate is 99.52%, and the protective efficacy is 79.34% which has reached the WHO and other related standards. CNBG Beijing has formally submitted a conditional marketing application to the National Medical Product Administration. [Link 1](#)
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On Dec 31, China's State Council announced that the National Medical Product Administration approved the CNBG Sinopharm vaccine for general use (had already been given EUA). The National Health Commission also announced that China has already administered more than 4.5 million doses of COVID-19 vaccine nationwide. [Link](#)

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On Dec 11, Egypt MoH approved for EUA of CNBG's COVID vaccine product. The next day, the first 50k doses arrived in Cairo, donated by UAE.

On Dec 09, the UAE MoH announced the official registration of CNBG's COVID-19 vaccine product, citing interim data showing that it could provide 86% efficacy, 99% neutralizing antibody seroconversion, and 100% prevention of moderate and severe COVID-19 disease among 42,299 vaccinated volunteers. On Dec 13, the Bahrain MoH followed suit. [Note, see above December 30 CNBG announcement.]

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Sent: 1/4/2021 8:03:00 AM
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West China Hospital
Jiangsu CDC
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ChiCTR2000039994;
Phase II ongoing
(Phase II started)
mRNA

Walvax, Suzhou Abogen Pharm; Academy of Military Medicine; PLA
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From: Stanley Plotkin [stanley.plotkin@vaxconsult.com]
Sent: 5/15/2020 11:40:16 AM
To: Cassetti, Cristina G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5a44e839c5642abb30e10feb69800b4-HHS-CCasset]; 'Kathleen Neuzil' [kneuzil@som.umaryland.edu]; 'Durbin, Anna (NIH)' [adurbin@jhsph.edu]; Graham, Barney S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=973d6f4da1a94dad93621a6b52be9059-HHS-bgraham]; Mascola, John R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63aa50129c1f4d39bc0a31b3851a34c5-HHS-jmascol]; 'Baric, Ralph' [rbaric@email.unc.edu]; 'Denison, Mark (NIH)' [mark.denison@vanderbilt.edu]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Embry, Alan C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b7c944cd334abe9c6ee0ff4cb53320-HHS-embrya-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Roberts, Chris C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e83b8d7a3a59481baca190f63a04316f-HHS-paul.ro]; Erbelding, Emily J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c981f04015d64d27b1afdd9c06111071-HHS-emily.e]
CC: McCormick, Christina B (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e851ea50744ca7b402fbf7ba0e32da-HHS-christi]
Subject: RE: CoV strain selection for possible/eventual CHIM studies

Dear Cristina:

This is terrific. Your initiative is entirely right, but it must move fast if it is to be useful. I am available on May 18 or 19.

Regards,
Stanley

From: Cassetti, Cristina (NIH/NIAID) [E] <ccassetti@niaid.nih.gov>
Sent: Friday, May 15, 2020 11:35 AM
To: 'Stanley Plotkin (stanley.plotkin@vaxconsult.com)' (stanley.plotkin@vaxconsult.com) <stanley.plotkin@vaxconsult.com>; Kathleen Neuzil <kneuzil@som.umaryland.edu>; Durbin, Anna (NIH) <adurbin@jhsph.edu>; Graham, Barney (NIH/VRC) [E] <bgraham@mail.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Baric, Ralph <rbaric@email.unc.edu>; Denison, Mark (NIH) <mark.denison@vanderbilt.edu>; Gruber, Marion (FDA/CBER) <Marion.Gruber@fda.hhs.gov>; Embry, Alan (NIH/NIAID) [E] <embrya@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Roberts, Chris (NIH/NIAID) [E] <paul.roberts@nih.gov>; Erbelding, Emily (NIH/NIAID) [E] <emily.erbelding@nih.gov>
Cc: McCormick, Christina (NIH/NIAID) [E] <christina.mccormick@nih.gov>
Subject: CoV strain selection for possible/eventual CHIM studies

Dear colleagues,

For the last several weeks, many of us have been involved in discussions on the value and potential risks of a SARS-CoV 2 CHIM model to learn about correlates of protection and support the development of vaccines and therapeutics.

As more data becomes available on the pathogenesis of this new infection, the evolution of the epidemic and the availability of new therapies to treat patients, the risk/benefit calculations for conducting such studies are going to change.

NIAID has not committed to initiate SARS-CoV-2 CHIM studies yet, but we see value in selecting some virus challenge strains that we could manufacture as cGMP lots soon in preparation for eventual CHIM studies. Strains might include live attenuated strains, seasonal CoV strains and possibly a wt SARS CoV-2 strain from a mild case.

We would like to set up a call with this group of experts to discuss considerations for strain selection and prioritization. Please let our colleague Christina McCormick know if you can be available for a 2 hours call on:

Monday May 18 at 5-7 pm
Tuesday May 19, 4,30-6,30 pm
Wednesday May 20, 5-7 pm

Thank you,

Cristina

Cristina Cassetti, Ph.D.
Deputy Director
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases, NIH
5601 Fishers Lane, Room 7G51
Rockville, MD 20852
Tel: (240) 292-4149
ccassetti@niaid.nih.gov

Sent: 1/4/2021 10:22:24 AM
Subject: FW: China COVID-19 Vaccine Development December 2020 Update

China COVID-19 Vaccine Development Update as of December 30th, 2020

This update on COVID-19 vaccine developments in China summarizes information from sources including news/media releases, pharmaceutical company websites, WHO/Chinese/NIH Clinical Trial Registries and peer-reviewed publications. As of 30 December 2020, 11 COVID-19 candidate vaccines are in human clinical trials and 5 of them are in phase III clinical trials.

Table 1: China COVID-19 Candidate Vaccines under Clinical Evaluation as of 30 December 2020 (items updated this month shown in red)

Type of candidate vaccine

Developer

Other partners

Registration No.

Outcome/Status

Inactivated: CoronaVac

Sinovac

Butantan (Brazil)

Indonesia

NCT04456595 NCT04508075

NCT04582344 NCT04617483

NCT04651790

Phase I/II study report ;

Phase III study protocol;

Phase III ongoing in Brazil, Bangladesh, Turkey, Indonesia, Chile

Inactivated: BBIBP-CorV

CNBG Beijing; Sinopharm

Tiantan Bio Product Inc; China CDC; Henan CDC; NHC; Chinese Academy of Medical Science

ChiCTR2000034780 ChiCTR2000039000 NCT04612972

ChiCTR2000034780 NCT04560881

Interim result;

BBIBP-CorV Phase I/II result;

Phase III ongoing in Peru, Morocco, Argentina, UAE, Jordan, Bahrain and Egypt

Inactivated

CNBG Wuhan; Sinopharm

Wuhan Institute of Virology; Henan CDC

Inactivated

IMBCAMS*

West China Second Hospital

Yun Nan CDC

NCT04412538

NCT04470609

NCT04659239

Phase III ongoing in Brazil, Malaysia

(Phase III started)

Inactivated+

Beijing Minhai Bio technology Co., Ltd.

Shenzhen Kangtai Bio

Jiangsu CDC

ChiCTR2000038804

ChiCTR2000039462

Phase I/II ongoing

Adenovirus Type 5 Vector

Ad5-nCoV

Cansino;

Institute of Biotechnology; Military Medical Science; PLA

Beijing Institute of Biotechnology

ChiCTR2000030906 ChiCTR2000031781

NCT04398147

NCT04341389

NCT04540419

Phase I result;

Phase II result;

Phase III ongoing in Argentina, Chile, Mexico, Pakistan, Russia

(Participating countries changed)

Intranasal flu-based-RBD

HK University, Xiamen University

BJ WanTai Inc.

JiangSu CDC

ChiCTR2000037782

ChiCTR2000039715

Phase I/II ongoing

Protein subunit

Anhui Zhifei Longkema
Institute of Microbiology; Chinese
Academy of Sciences
NCT04445194
NCT04550351
NCT04466085
ChiCTR2000040153
Phase III ongoing in Hu'nan, China+
(Phase III started)
Protein subunit
West China Hospital
Jiangsu CDC
ChiCTR2000037518;
ChiCTR2000039994;
Phase II ongoing
(Phase II started)
mRNA

Walvax, Suzhou Abogen Pharm; Academy of Military Medicine; PLA
Shulan Hospital (Hangzhou); Yongfu County CDC (Guangxi)
ChiCTR2000034112;
ChiCTR2000039212
Phase I ongoing
RNA/BNT162b1
BionTech/Fosun Pharma/Pfizer
Jiangsu CDC
ChiCTR2000034825
NCT04649021

Phase II ongoing in Jiangsu, China
(Phase II started)

* IMBCAMS: Institute of Medical Biology Chinese Academy of Medical Sciences

+ International locations yet to be identified

Figure 1: Planned/ongoing Chinese COVID-19 Candidate Vaccine Phase III trial locations as of 30 Dec 2020

Vaccine Use (Domestic):

On Dec 08, at a Chengdu municipal government press conference, the Chengdu NHC COVID Response Group said they will start to plan for vaccination in Chengdu. The priority populations will be the frontline medical/epidemic response and border control personnel.

On Dec 19, the State Council Information Office held a press conference to introduce priority populations and plans for vaccination of these groups. According to Zeng Yixin, Vice-Minister of NHC, China will start nationwide vaccination among high risk populations through the emergency use program initiated in June. The priority populations include cold chain workers; point of entry staff; workers in the shipping, aviation, public transportation sectors and agricultural markets; medical and disease control personnel; and those going abroad for work or study. In order to process the vaccination work smoothly, the State Council issued a requirement to the relevant provincial departments and units to effectively control and inspect the quality of vaccines to ensure safe and smooth cold chain transportation and timely and accurate distribution. It is required that all provinces must carefully design their vaccination plans, reasonably set up vaccination locations, and organize vaccination work in a stable and orderly manner. Particular attention should be paid to medical observation following vaccination and timely management and reporting of any adverse reactions. Provinces should educate people to raise awareness of the obligation and responsibility of vaccination and should vaccinate all eligible high-risk groups on time and with informed consent. "This is only the first step for us, more people especially hundreds of millions of the elderly people and those with underlying disease will get vaccinated after the vaccine products are conditionally or officially approved, and the production capacity is improved. Our goal is trying to establish herd immunity actively through vaccination to control the COVID-19 epidemic as soon as possible." Zeng said.

As of Dec 21, according to China NHC statistics, more than 1 million doses of China vaccine products have been used under China's emergency use strategy. Another 50 million doses are expected to be given to the priority populations before the Chinese New Year. [Link](#)

On Dec 30, CNBG Beijing announced that the results of the interim analysis of their inactivated vaccine phase III clinical trial showed that the vaccine safety is good, all vaccine group participants produced high-titer antibodies, the neutralizing antibody positive conversion rate is 99.52%, and the protective efficacy is 79.34% which has reached the WHO and other related standards. CNBG Beijing has formally submitted a conditional marketing application to the National Medical Product Administration. [Link 1](#)
[Link 2](#)

On Dec 31, China's State Council announced that the National Medical Product Administration approved the CNBG Sinopharm vaccine for general use (had already been given EUA). The National Health Commission also announced that China has already administered more than 4.5 million doses of COVID-19 vaccine nationwide. [Link](#)

Vaccine Use (International):

On Dec 11, Egypt MoH approved for EUA of CNBG's COVID vaccine product. The next day, the first 50k doses arrived in Cairo, donated by UAE.

On Dec 09, the UAE MoH announced the official registration of CNBG's COVID-19 vaccine product, citing interim data showing that it could provide 86% efficacy, 99% neutralizing antibody seroconversion, and 100% prevention of moderate and severe COVID-19 disease among 42,299 vaccinated volunteers. On Dec 13, the Bahrain MoH followed suit. [Note, see above December 30 CNBG announcement.]

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Sent: 1/5/2021 11:11:07 AM
Subject: FW: China COVID-19 Vaccine Development December Update

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From: Lang, Jean /FR [Jean.Lang@sanofi.com]
Sent: 1/15/2020 7:07:44 AM
To: Stig Tollefsen [stig.tollefsen@cepi.net]; Barrett, Alan [abarrett@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu]; Allouèche, Ali [Ali.allouèche@takeda.com]; christian.brechot@pasteur.fr; cbrechot@usf.edu; happic@run.edu.ng; Connie [connie.s.schmaljohn.civ@mail.mil]; Daniel Brasseur [(b)(6)]@gmail.com; mimi darko [(b)(6)]@yahoo.co.uk; dongxp238@sina.com; hrees@wrhi.ac.za; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; James Robinson [(b)(6)]@outlook.com; JVHOOF1@its.jnj.com; John Edmunds [John.Edmunds@LSHTM.ac.uk]; Josie Golding [j.golding@wellcome.ac.uk]; kneuzil@som.umaryland.edu; Jansen, Kathrin [kathrin.jansen@pfizer.com]; kenji.shibuya@kcl.ac.uk; Michel De Wilde [(b)(6)]@aol.com; Levine, Myron [Mlevine@som.umaryland.edu]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; Penny Heaton [penny.heaton@gatesmri.org]; Peter Smith [Peter.Smith@lshtm.ac.uk]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Ralf Clemens [(b)(6)]@outlook.com; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Tom Kariuki [t.kariuki@aasciences.ac.ke]; SATHIYAMOORTHY, Vaseeharan [moorthyv@who.int]; yves.levy@inserm.fr
CC: smrivas@utmb.edu; oumunna@ihvnigeria.org; Ryanto.Ryanto@takeda.com; graca@health.usf.edu; maisha.j.lewis-ceaser.ctr@mail.mil; [(b)(6)]@yahoo.com; [(b)(6)]@yahoo.co.uk; Susie Cornell [scornell@wrhi.ac.za]; Malik, Sabahat Z (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ac937f0a474e10a6b69c537a0fa348-HHS-fmw1-cd]; Bayrat, Camille (Marcy) /FR [Camille.Bayrat@sanofi.com]; Van Tulden, Karin [JRD BE] [kvtulden@its.jnj.com]; DEgorugwu@som.umaryland.edu; markay.hopps@pfizer.com; Zottoli, Jessica [Jessica.Zottoli@pfizer.com]; shinoyamaz@m.u-tokyo.ac.jp; Small, Dottie [Dsmall@som.umaryland.edu]; Mary Burke [Mary.burke@gatesmri.org]; admin@vaxconsult.com; Anita Chami [a.chami@aasciences.ac.ke]; bruniquel@who.int; benassiv@who.int; Richard Hatchett [richard.hatchett@cepi.net]; Raimonda Viburiene [raimonda.viburiene@cepi.net]; Frederik Kristensen [frederik.kristensen@cepi.net]; Melanie Saville [melanie.saville@cepi.net]; Joseph Simmonds-Issler [jsi@cepi.net]; Jakob Cramer [jakob.cramer@cepi.net]; Paul Kristiansen [paul.kristiansen@cepi.net]; Nick Jackson [nick.jackson@cepi.net]
Subject: RE: SAC meeting minutes 20200110

Sorry, I could not join the meeting..nor open the file.

As a Vaccine developer I wanted to share FYI our prior “historical” timelines for developing (under a company priority) Phase I clinical Lots for another Coronavirus (SARS) under a US NIH Grant.

A the SARS epidemic was over at the time of starting Phase I clinical testing, the prepared lots were not used by the US NIH as the benefits/risks shifted in the wrong direction.

So this was a wake-up call in terms of Coronavirus low “Basic Reproduction Number” usually controlled by patient isolation/containment measures .

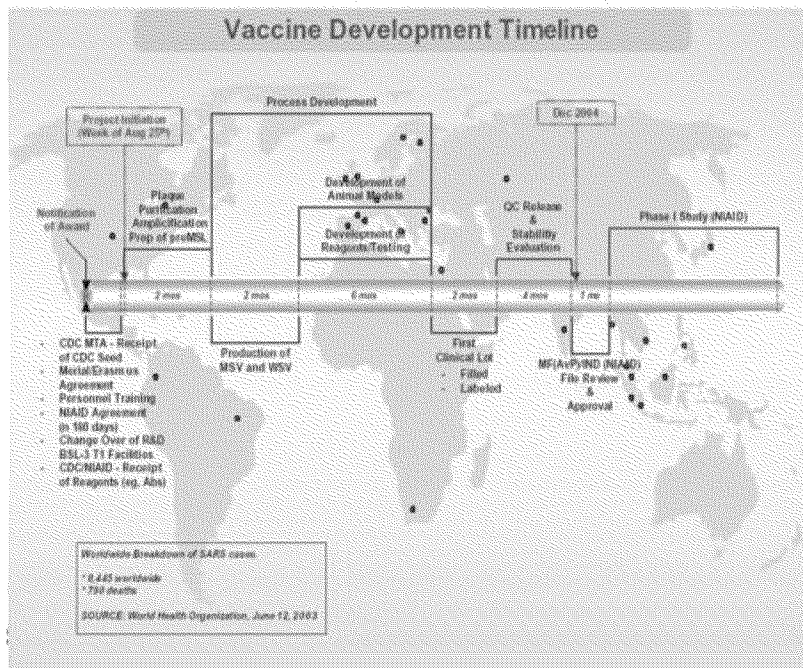
Having said that these are 15 years old benchmarks, the coronavirus at hand might exhibit super-spreading ability and, last but not least, CEPI was not existing at the time and has changed some way to handle such threats.

Best

Jean

PS : Michel de Wilde was in charge at the time at SP R&D so he could mitigate by his own perspective this SARS Vaccine case study that has been share in many public forums eg WHO, CEPI etc.

The SARS Research to Phase I 2003 – 2004 sp Experience



De : Stig Tollefsen <stig.tollefsen@cepi.net>

Envoyé : mercredi 15 janvier 2020 08:20

À : Barrett, Alan <abarrett@utmb.edu>; Alash'le Abimiku <aabimiku@ihv.umaryland.edu>; Allouche, Ali <Ali.allouche@takeda.com>; christian.brecht@pasteur.fr; cbrecht@usf.edu; happic@run.edu.ng; Connie <connie.s.schmaljohn.civ@mail.mil>; Daniel Brasseur: (b)(6)@gmail.com; mimi darko (b)(6)@yahoo.co.uk; dongxp238@sina.com; hrees@wrhi.ac.za; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; James Robinson (b)(6)@outlook.com; Lang, Jean /FR <Jean.Lang@sanofi.com>; JVHOOF1@its.jnj.com; John Edmunds <John.Edmunds@LSHTM.ac.uk>; Josie Golding <j.golding@wellcome.ac.uk>; kneuzil@som.umaryland.edu; Jansen, Kathrin <kathrin.jansen@pfizer.com>; kenji.shibuya@kcl.ac.uk; Michel De Wilde (b)(6)@aol.com; Levine, Myron <mlevine@som.umaryland.edu>; Bryant, Paula (NIH/NIAID) [E] <paula.bryant@nih.gov>; Penny Heaton <penny.heaton@gatesmri.org>; Peter Smith <Peter.Smith@lshtm.ac.uk>; Phil Krause <philip.krause@fda.hhs.gov>; Ralf Clemens (b)(6)@outlook.com; Stanley Plotkin <stanley.plotkin@vaxconsult.com>; Tom Kariuki <t.kariuki@aasciences.ac.ke>; SATHIYAMOORTHY, Vaseeharan <moorthyv@who.int>; yves.levy@inserm.fr

Cc : smrivas@utmb.edu; oumunna@ihvnigeria.org; Ryanto.Ryanto@takeda.com; graca@health.usf.edu; maisha.j.lewis-ceaser.ctr@mail.mil; (b)(6)@yahoo.com; (b)(6)@yahoo.co.uk; Susie Cornell <scornell@wrhi.ac.za>; fmw1@cdc.gov; Bayrat, Camille (Marcy) /FR <Camille.Bayrat@sanofi.com>; Van Tulden, Karin [JRDBE] <kvtulden@its.jnj.com>; DEgorugwu@som.umaryland.edu; markay.hopps@pfizer.com; Zottoli, Jessica <Jessica.Zottoli@pfizer.com>; shinoyamaz@m.u-tokyo.ac.jp; Small, Dottie <Dsmall@som.umaryland.edu>; Mary Burke <Mary.burke@gatesmri.org>; admin@vaxconsult.com; Anita Chami <a.chami@aasciences.ac.ke>; bruniquelv@who.int; benassiv@who.int; Richard Hatchett <richard.hatchett@cepi.net>; Raimonda Viburiene <raimonda.viburiene@cepi.net>; Frederik Kristensen <frederik.kristensen@cepi.net>; Melanie Saville <melanie.saville@cepi.net>; Joseph Simmonds-Issler <jsi@cepi.net>; Jakob Cramer <jakob.cramer@cepi.net>; Paul Kristiansen <paul.kristiansen@cepi.net>; Nick Jackson <nick.jackson@cepi.net>

Objet : [EXTERNAL] SAC meeting minutes 20200110

EXTERNAL : Real sender is stig.tollefsen@cepi.net

Dear SAC member,

The meeting minutes from the ad hoc SAC meeting January 10 have been prepared and posted on the SAC SharePoint site: [https://\(b\)\(6\)](https://(b)(6))

We are happy to have your edits and/or comments by COB Friday January 17.

Best wishes
Stig

STIG TOLLEFSEN
Head of Strategic Science

CEPI New vaccines
for a safer world

(+47) 901 50 770
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From: Michel De Wilde [(b)(6)]@aol.com
Sent: 1/15/2020 4:41:04 AM
To: Stig Tollefsen [stig.tollefsen@cepi.net]
CC: Barrett, Alan [abarrett@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu]; Allouèche, Ali [Ali.allouèche@takeda.com]; christian.brechot@pasteur.fr; cbrechot@usf.edu; happic@run.edu.ng; Connie [connie.s.schmaljohn.civ@mail.mil]; Daniel Brasseur [(b)(6)]@gmail.com; mimi darko [(b)(6)]@yahoo.co.uk; dongxp238@sina.com; hrees@wrhi.ac.za; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; James Robinson [(b)(6)]@outlook.com; Jean Lang [Jean.Lang@sanofipasteur.com]; JVHOOF1@its.jnj.com; John Edmunds [John.Edmunds@lshtm.ac.uk]; Josie Golding [j.golding@wellcome.ac.uk]; kneuzil@som.umaryland.edu; Jansen, Kathrin [kathrin.jansen@pfizer.com]; kenji.shibuya@kcl.ac.uk; Levine, Myron [Mlevine@som.umaryland.edu]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; Penny Heaton [penny.heaton@gatesmri.org]; Peter Smith [Peter.Smith@lshtm.ac.uk]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Ralf Clemens [(b)(6)]@outlook.com; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Tom Kariuki [t.kariuki@aasciences.ac.ke]; SATHIYAMOORTHY, Vaseeharan [moorthyv@who.int]; yves.levy@inserm.fr; smrivas@utmb.edu; oumunna@ihvnigeria.org; Ryanto.Ryanto@takeda.com; graca@health.usf.edu; maisha.j.lewis-ceaser.ctr@mail.mil [(b)(6)]@yahoo.com; [(b)(6)]@yahoo.co.uk; Susie Cornell [SCornell@wrhi.ac.za]; Malik, Sabahat Z (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ac937f0a474e10a6b69c537a0fa348-HHS-fmw1-cd]; Camille.Bayrat@sanofi.com; Van Tulden, Karin [JRD BE] [kvtulden@its.jnj.com]; DEgorugwu@som.umaryland.edu; markay.hopps@pfizer.com; Zottoli, Jessica [Jessica.Zottoli@pfizer.com]; shinoyamaz@m.u-tokyo.ac.jp; Small, Dottie [Dsmall@som.umaryland.edu]; Mary Burke [Mary.burke@gatesmri.org]; admin@vaxconsult.com; Anita Chami [a.chami@aasciences.ac.ke]; bruniquel@who.int; benassiv@who.int; Richard Hatchett [richard.hatchett@cepi.net]; Raimonda Viburiene [raimonda.viburiene@cepi.net]; Frederik Kristensen [frederik.kristensen@cepi.net]; Melanie Saville [melanie.saville@cepi.net]; Joseph Simmonds-Issler [jsi@cepi.net]; Jakob Cramer [jakob.cramer@cepi.net]; Paul Kristiansen [paul.kristiansen@cepi.net]; Nick Jackson [nick.jackson@cepi.net]
Subject: Re: SAC meeting minutes 20200110

Thank you Stig. With the sequence published, I recommend a GO from a diseaseX perspective, as discussed. I also recommend to link with R Baric (UNC) and possibly others who are attempting to retro-engineer the virus from the sequence.

This is a unique moment to show our ability for rapid response, even if the epi was to die out.

Michel

Sent from my iPhone, forgive the typos.

[(b)(6)]

On Jan 15, 2020, at 09:20, Stig Tollefsen <stig.tollefsen@cepi.net> wrote:

Dear SAC member,

The meeting minutes from the ad hoc SAC meeting January 10 have been prepared and posted on the SAC SharePoint site: [https://\[redacted\]](https://[redacted]) [(b)(6)]

We are happy to have your edits and/or comments by COB Friday January 17.

Best wishes
Stig

STIG TOLLEFSEN

Head of Strategic Science

<image007.png>

(+47) 901 50 770

stig.tollefsen@cepi.net

Visiting address: Marcus Thranes gate 2, 0473 Oslo, Norway

Postal address: P.O. BOX 123, Torshov, 0412 Oslo, Norway

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<image008.png> <image009.png>

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From: Stig Tollefsen [stig.tollefsen@cepi.net]
Sent: 1/15/2020 2:20:03 AM
To: Barrett, Alan [abarrett@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu]; Allouèche, Ali [Ali.allouèche@takeda.com]; christian.brechot@pasteur.fr; cbrechot@usf.edu; happic@run.edu.ng; Connie [connie.s.schmaljohn.civ@mail.mil]; Daniel Brasseur [(b)(6)]@gmail.com; mimi darko [(b)(6)]@yahoo.co.uk; dongxp238@sina.com; hrees@wrhi.ac.za; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; James Robinson [(b)(6)]@outlook.com; Jean Lang [Jean.Lang@sanofipasteur.com]; JVH00F1@its.jnj.com; John Edmunds [John.Edmunds@LSHTM.ac.uk]; Josie Golding [j.golding@wellcome.ac.uk]; kneuzil@som.umaryland.edu; Jansen, Kathrin [kathrin.jansen@pfizer.com]; kenji.shibuya@kcl.ac.uk; Michel De Wilde [(b)(6)]@aol.com; Levine, Myron [Mlevine@som.umaryland.edu]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; Penny Heaton [penny.heaton@gatesmri.org]; Peter Smith [Peter.Smith@lshtm.ac.uk]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Ralf Clemens [(b)(6)]@outlook.com; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Tom Kariuki [t.kariuki@aasciences.ac.ke]; SATHIYAMOORTHY, Vaseeharan [moorthyv@who.int]; yves.levy@inserm.fr
CC: smrivas@utmb.edu; oumunna@ihvnigeria.org; Ryanto.Ryanto@takeda.com; graca@health.usf.edu; maisha.j.lewis-ceaser.ctr@mail.mil; [(b)(6)]@yahoo.com; [(b)(6)]@yahoo.co.uk; Susie Cornell [scornell@wrhi.ac.za]; Malik, Sabahat Z (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ac937f0a474e10a6b69c537a0fa348-HHS-fmw1-cd]; Camille.Bayrat@sanofi.com; Van Tulden, Karin [JRDBE] [kvtulden@its.jnj.com]; DEgorugwu@som.umaryland.edu; markay.hopps@pfizer.com; Zottoli, Jessica [Jessica.Zottoli@pfizer.com]; shinoyamaz@m.u-tokyo.ac.jp; Small, Dottie [Dsmall@som.umaryland.edu]; Mary Burke [Mary.burke@gatesmri.org]; admin@vaxconsult.com; Anita Chami [a.chami@aasciences.ac.ke]; bruniquel@who.int; benassiv@who.int; Richard Hatchett [richard.hatchett@cepi.net]; Raimonda Viburiene [raimonda.viburiene@cepi.net]; Frederik Kristensen [frederik.kristensen@cepi.net]; Melanie Saville [melanie.saville@cepi.net]; Joseph Simmonds-Issler [jsi@cepi.net]; Jakob Cramer [jakob.cramer@cepi.net]; Paul Kristiansen [paul.kristiansen@cepi.net]; Nick Jackson [nick.jackson@cepi.net]
Subject: SAC meeting minutes 20200110

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We are happy to have your edits and/or comments by COB Friday January 17.

Best wishes

Stig

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Head of Strategic Science

CEPI New vaccines
for a safer world

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From: Helen Rees [HRees@wrhi.ac.za]
Sent: 1/16/2020 1:52:33 AM
To: Lang, Jean /FR [Jean.Lang@sanofi.com]; Stig Tollefsen [stig.tollefsen@cepi.net]; Barrett, Alan [abarrett@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu]; Allouche, Ali [Ali.allouche@takeda.com]; christian.brechot@pasteur.fr; cbrechot@usf.edu; happic@run.edu.ng; Connie [connie.s.schmaljohn.civ@mail.mil]; Daniel Brasseur [redacted (b)(6)@gmail.com]; mimi darko [redacted (b)(6)@yahoo.co.uk]; dongxp238@sina.com; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; James Robinson [redacted (b)(6)@outlook.com]; JVHOOF1@its.jnj.com; John Edmunds [John.Edmunds@LSHTM.ac.uk]; Josie Golding [j.golding@wellcome.ac.uk]; kneuzil@som.umaryland.edu; Jansen, Kathrin [kathrin.jansen@pfizer.com]; kenji.shibuya@kcl.ac.uk; Michel De Wilde [redacted (b)(6)@aol.com]; Levine, Myron [Mlevine@som.umaryland.edu]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; Penny Heaton [penny.heaton@gatesmri.org]; Peter Smith [Peter.Smith@lshtm.ac.uk]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Ralf Clemens [redacted (b)(6)@outlook.com]; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Tom Kariuki [t.kariuki@aasciences.ac.ke]; SATHIYAMOORTHY, Vaseeharan [moorthyv@who.int]; yves.levy@inserm.fr
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Subject: Re: SAC meeting minutes 20200110

Thanks Jean

Very interesting. We are trying to set up another SAC call in the next day or two so there will be more time for discussion.

Best
Helen

From: "Lang, Jean /FR" <Jean.Lang@sanofi.com>

Date: Wednesday, 15 January 2020 at 14:09

To: Stig Tollefsen <stig.tollefsen@cepi.net>, "Barrett, Alan" <abarrett@utmb.edu>, Alash'le Abimiku <aabimiku@ihv.umaryland.edu>, "Allouche, Ali" <Ali.allouche@takeda.com>, "christian.brechot@pasteur.fr" <christian.brechot@pasteur.fr>, "cbrechot@usf.edu" <cbrechot@usf.edu>, "happic@run.edu.ng" <happic@run.edu.ng>, Connie <connie.s.schmaljohn.civ@mail.mil>, Daniel Brasseur [redacted (b)(6)@gmail.com], mimi darko [redacted (b)(6)@yahoo.co.uk], "dongxp238@sina.com" <dongxp238@sina.com>, Helen Rees <HRees@wrhi.ac.za>, "Damon, Inger K. (CDC/OID/NCEZID)" <iad7@cdc.gov>, James Robinson [redacted (b)(6)@outlook.com], "JVHOOF1@its.jnj.com" <JVHOOF1@its.jnj.com>, John Edmunds <John.Edmunds@LSHTM.ac.uk>, Josie Golding <j.golding@wellcome.ac.uk>, "kneuzil@som.umaryland.edu" <kneuzil@som.umaryland.edu>, "Jansen, Kathrin" <kathrin.jansen@pfizer.com>, "kenji.shibuya@kcl.ac.uk" <kenji.shibuya@kcl.ac.uk>, Michel De Wilde [redacted (b)(6)@aol.com], "Levine, Myron" <Mlevine@som.umaryland.edu>, "Bryant, Paula (NIH/NIAID) [E]" <paula.bryant@nih.gov>, Penny Heaton <penny.heaton@gatesmri.org>, "peter.smith@lshtm.ac.uk"

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Camille (Marcy) /FR" <Camille.Bayrat@sanofi.com>, "Van Tulden, Karin [JRDBE]" <kvtulden@its.jnj.com>,
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Paul Kristiansen <paul.kristiansen@cepi.net>, Nick Jackson <nick.jackson@cepi.net>

Subject: RE: SAC meeting minutes 20200110

Sorry, I could not join the meeting..nor open the file.

As a Vaccine developer I wanted to share FYI our prior "historical" timelines for developing
(under a company priority) Phase I clinical Lots for another Coronavirus (SARS) under a US NIH
Grant.

A the SARS epidemic was over at the time of starting Phase I clinical testing, the prepared lots
were not used by the US NIH as the benefits/risks shifted in the wrong direction.

So this was a wake-up call in terms of Coronavirus low "Basic Reproduction Number" usually
controlled by patient isolation/containment measures .

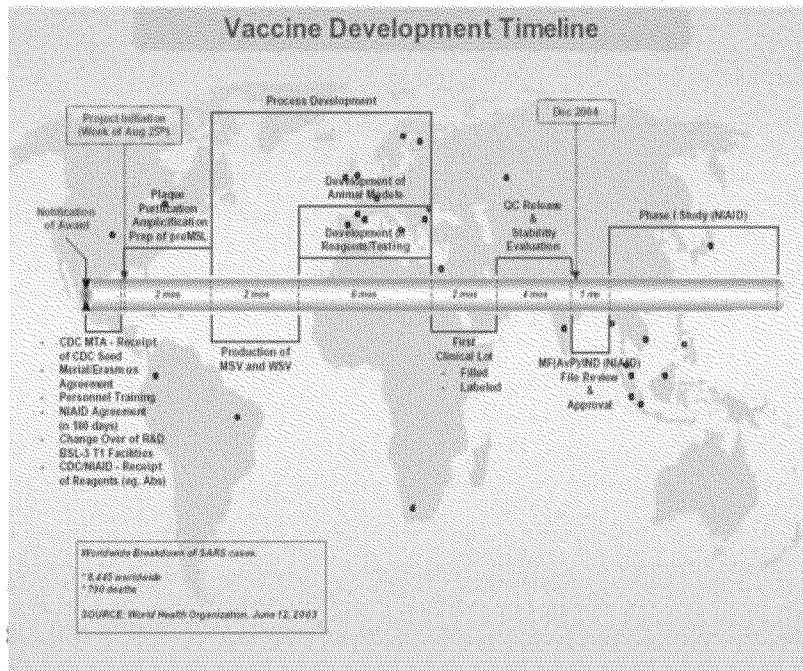
Having said that these are 15 years old benchmarks, the coronavirus at hand might exhibit
super-spreading ability and, last but not least, CEPI was not existing at the time and has
changed some way to handle such threats.

Best

Jean

PS : Michel de Wilde was in charge at the time at SP R&D so he could mitigate by his own
perspective this SARS Vaccine case study that has been share in many public forums eg WHO,
CEPI etc.

The SARS Research to Phase I 2003 – 2004 sp Experience



De : Stig Tollefsen <stig.tollefsen@cepi.net>

Envoyé : mercredi 15 janvier 2020 08:20

À : Barrett, Alan <abarrett@utmb.edu>; Alash'le Abimiku <aabimiku@ihv.umaryland.edu>; Allouche, Ali <Ali.allouche@takeda.com>; christian.brechot@pasteur.fr; cbrechot@usf.edu; happic@run.edu.ng; Connie <connie.s.schmaljohn.civ@mail.mil>; Daniel Brasseur <(b)(6)@gmail.com>; mimi darko <(b)(6)@yahoo.co.uk>; dongxp238@sina.com; hrees@wrhi.ac.za; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; James Robinson <(b)(6)@outlook.com>; Lang, Jean /FR <Jean.Lang@sanofi.com>; JVHOOF1@its.jnj.com; John Edmunds <John.Edmunds@LSHTM.ac.uk>; Josie Golding <j.golding@wellcome.ac.uk>; kneuzil@som.umaryland.edu; Jansen, Kathrin <kathrin.jansen@pfizer.com>; kenji.shibuya@kcl.ac.uk; Michel De Wilde <(b)(6)@aol.com>; Levine, Myron <Mlevine@som.umaryland.edu>; Bryant, Paula (NIH/NIAID) [E] <paula.bryant@nih.gov>; Penny Heaton <penny.heaton@gatesmri.org>; Peter Smith <Peter.Smith@lshtm.ac.uk>; Phil Krause <philip.krause@fda.hhs.gov>; Ralf Clemens <(b)(6)@outlook.com>; Stanley Plotkin <stanley.plotkin@vaxconsult.com>; Tom Kariuki <t.kariuki@aasciences.ac.ke>; SATHIYAMOORTHY, Vaseeharan <moorthyv@who.int>; yves.levy@inserm.fr

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Objet : [EXTERNAL] SAC meeting minutes 20200110

EXTERNAL : Real sender is stig.tollefsen@cepi.net

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Best wishes

Stig

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Head of Strategic Science

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for a safer world

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From: (b)(6)
Sent: 3/23/2020 8:00:58 PM
To: Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Regine.Lehnert@bfarm.de; julia.tree@phe.gov.uk; Ken.Duncan@gatesfoundation.org; eh63a@nih.gov; sina.bavari.civ@mail.mil; marco.cavaleri@ema.europa.eu
Subject: Role of Chloroquine (WHO consultation)

Ladies and Gentlemen

I am a doctor in the UK, desperately reviewing all available data and outcomes with regards to Covid-19. I assure you of my credentials and probity. I have read the WHO document on Chloroquine to which all of you have contributed. I am disappointed by the lack of urgency, drive and imagination in investigating Chloroquine.

Your approach to and current planned studies for Pre Exposure Prophylaxis (PrEP) and Post Exposure Prophylaxis (PoEP) in the utility of Chloroquine or its derivatives are wide off the mark. There is only one planned study (RCT), the dose selection is questionable, and it does not clearly differentiate between PrEP and PoEP, the study period is 3 months! By then potentially hundreds of thousands of patients and scores of medical personnel would have died - There is a faster and better approach of delivering the drug to a much wider at risk population and scientifically studying it at the same time, please give it serious thought and consideration. This is the time to think big and deliver. Pharmaceuticals stand ready to provide the drug free of cost to the US government and indeed worldwide. Its distribution to pharmacies can be expedited in real time.

PROPOSAL:

PrEP for Covid-19 (online - state or countrywide application)

Study Design:

Large scale, pragmatic, open label, observational study, on-line recruitment, registry design, single intervention.

Study population:

Frontline medical staff, high exposure risk (carers, nursing home residents), immunosuppressed, patients with co-morbidities at risk of significant infection.

Study Flow:

Online risk stratification. Differentiate between PrEP and PoEP and follow two separate pathways. One for no known exposure, the other for exposed participants but without symptoms.

Each arm to assess (online) suitability with regards to co-morbidity, drug interactions and disclaimer on side effects. If suitable, proceed to consent and printing of a pharmacy prescription. The PrEP arm to get Hydroxychloroquine 400mg once weekly, the PrOP arm to receive 5 days of 400mg/day, followed by weekly 400mg/week. Study period 4 months.

Outcome measures:

Self reported weekly outcome measures of either proven Covid-19 infectivity or symptoms suggestive of Covid-19, after at least two weeks of completed treatment. Real-time data capture and analyses.

I trust this is of interest to you all. The world is waiting for affirmative action!

Regards

(b)(6)

From: Helen Rees [HRees@wrhi.ac.za]
Sent: 12/13/2020 12:42:42 PM
To: Mimi Darko [(b)(6)]@yahoo.co.uk; Melanie Saville [melanie.saville@cepi.net]
CC: Barrett, Alan [abarrett@utmb.edu]; smrivas [smrivas@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu];
oumunna [oumunna@ihvnigeria.org]; ali.allouche@hillemanlabs.org; christian.brechot
[christian.brechot@pasteur.fr]; cbrechot [cbrechot@usf.edu]; graca [graca@health.usf.edu]; happic
[happic@run.edu.ng]; Schmaljohn, Connie S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8ba6458b80904995986f4a7257137cc5-HHS-connie.]; Daniel Brasseur
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[dongxp238@sina.com]; Susie Cornell [SCornell@wrhi.ac.za]; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd];
Malik, Sabahat Z (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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[markay.hopps@pfizer.com]; Zottoli, Jessica [Jessica.Zottoli@pfizer.com]; Shibuya, Kenji [kenji.shibuya@kcl.ac.uk];
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Richard Wilder [richard.wilder@cepi.net]; Joseph Simmonds-Issler [jsi@cepi.net]; Samia Saad [samia.saad@cepi.net]
Subject: Re: Update on University of Queensland COVID-19 vaccine

Dear Melanie

Thanks. This is very helpful and of course disappointing.

Perhaps we should reflect on whether we could have identified this as a potential problem earlier on. Are there lessons to be learnt for other vaccines in development from this experience?

Best
Helen

Subject: Re: Update on University of Queensland COVID-19 vaccine

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From: Mimi Darko [(b)(6)]@yahoo.co.uk]
Sent: 12/12/2020 3:13:28 PM
To: Melanie Saville [melanie.saville@cepi.net]
CC: Barrett, Alan [abarrett@utmb.edu]; smrivas [smrivas@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu];
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Richard Wilder [richard.wilder@cepi.net]; Joseph Simmonds-Issler [jsi@cepi.net]; Samia Saad [samia.saad@cepi.net]
Subject: Re: Update on University of Queensland COVID-19 vaccine

Dear Melanie

Thank you for this important update. Although disappointing not reaching the hopeful goal, considering initial safety and efficacy results, I believe that this decision is overall best considering the potential ambiguities and public health concerns that could arise.

I also say thank you to all who have been involved in the project and in reaching this final decision, which couldn't have been an easy one 🙏

Be blessed,

Delese Mimi Darko (B.Pharm, MBA, FGCPHarm)
Chief Executive Officer
Food and Drugs Authority
P.O. Box CT 2783
Cantonments
Accra - Ghana
[(b)(6)]

On 10 Dec 2020, at 10:19 PM, Melanie Saville <melanie.saville@cepi.net> wrote:

Dear SAC members,

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Regards,
Melanie

MELANIE SAVILLE

Director, Vaccine Research & Development

<image001.png>

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melanie.saville@cepi.net

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Sensitivity: CEPI Internal

From: SWAMINATHAN, Soumya [swaminathans@who.int]
Sent: 12/11/2020 6:12:36 AM
To: LYDON, Patrick [lydonp@who.int]
CC: sylvie.van-der-werf (sylvie.van-der-werf@pasteur.fr) [sylvie.van-der-werf@pasteur.fr]; isabella.eckerle@hcuge.ch; karesh@ecohealthalliance.org; falhosani@adphc.gov.ae; gmleung (gmleung@hku.hk) [gmleung@hku.hk]; (b)(6)@gmail.com; marshallj@smh.ca; Murthy, Srinivas [CWBC] [Srinivas.Murthy@cw.bc.ca]; John Conly [john.conly@albertahealthservices.ca] [john.conly@albertahealthservices.ca]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Jacobs, Michael [michael.jacobs@ucl.ac.uk]; (b)(6)@gmail.com; Ross Upshur [ross.upshur@utoronto.ca]; emily.chan@cuhk.edu.hk; PERKINS, Mark [perkinsm@who.int]; BEN EMBAREK, Peter Karim [benembarekp@who.int]; MORGAN, Oliver [omorgan@who.int]; Dr VAN KERKHOVE, Maria [vankerkhovem@who.int]; DIAZ, Janet Victoria [diazj@who.int]; ALLEGGRANZI, Benedetta [alleggranzib@who.int]; HENAO RESTREPO, Ana Maria [henaorestrepa@who.int]; PREZIOSI, Marie-pierre [preziosim@who.int]; RIVEROS BALTA, Ximena [lauriex@who.int]; SATHIYAMOORTHY, Vaseeharan [moorthyv@who.int]; REIS, Andreas Alois [reisa@who.int]; LITTLER, Katherine [littlerk@who.int]; BAYUGO, Yolanda [bayugo@who.int]; GOBAT, Nina [gobatn@who.int]; BORGES, Andrea [borgesa@who.int]; MAFUNGA, Neddy [mafungan@who.int]
Subject: Re: minder [Submitting Scientific Achievement 2020 by 14 December]

Dear chairs of our WGs

We would really appreciate getting this 1 min video from each of you with your key takeaway on the greatest scientific advance for this year, in your area. You could also send a short para if you are unable to do the video.

The DG will highlight the work of the research community during his year end speech.

Many thanks

Regards

Soumya

Sent from my iPad

On 11 Dec 2020, at 15:38, LYDON, Patrick <lydonp@who.int> wrote:

Dear Research leads and Working Group chairs,

This is a gentle reminder that we are looking forward to your submissions on **14 December**.

For those working groups that have co-chairs, the suggestion is to either have one chair send the 1 minute video. The alternative is for co-chairs to have a Zoom call and record their session with the 1 minute achievement.

We look forward to your inputs on **Monday**.

All the very best,

Patrick

From: LYDON, Patrick

Sent: 06 December 2020 10:48

Subject: WHO Scientific Achievement 2020 – What is yours for your thematic area? [Inputs by 14 December]

Importance: High

Dear _____,

On behalf of Soumya, we are reaching out to you with a time-sensitive request.

On **December 21** our Director General (Dr Tedros) will host an end-of-year WHO Press Conference which will include a strong focus on science and research for Covid-19.

In preparation for this, we are inviting each chair of the 9 working groups of the Global Research Roadmap to submit their top achievement or scientific advance for their thematic area. **This top achievement or scientific advance needs to be the one that had the greatest impact in the control of the pandemic during 2020.**

In addition, we would like to **also receive from you, a list of all publications (peer reviewed or not) produced** this year that are critical for advancing the science for your thematic area (especially if these were generated with WHO contributions).

Achievements submitted by 14 December will be compiled for Tedros and Soumya to highlight during this end-of-year press conference. Our suggestion for the submission is to **produce a 1 minutes video using your smartphone** (or other device) describing your top scientific achievement for the year. Depending on the submission, you may be invited to formally present achievements during the 21 December press-conference.

Thank you for your attention and follow-up to this request by **14 December**.

All the very best,
Patrick

Patrick Lydon

Research & Development Blueprint Unit – *World Health Emergencies (WHE/HEO)*

World Health Organization | 20 Avenue Appia | CH-1211 Geneva 27 Switzerland | Office: M1156

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Promote health, keep the world safe, and serve the vulnerable

From: Melanie Saville [melanie.saville@cepi.net]
Sent: 12/10/2020 5:19:52 PM
To: Barrett, Alan [abarrett@utmb.edu]; smrivas [smrivas@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu];
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Regards,
Melanie

MELANIE SAVILLE

Director, Vaccine Research & Development



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Sensitivity: CEPI Internal

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Sent: 12/13/2020 12:59:20 PM
To: HRees@wrhi.ac.za; mimi darko (b)(6)@yahoo.co.uk]
CC: Barrett, Alan [abarrett@utmb.edu]; smrivas [smrivas@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu]; oumunna [oumunna@ihvnigeria.org]; ali.allouche@hillemanlabs.org; christian.brechot [christian.brechot@pasteur.fr]; cbrechot [cbrechot@usf.edu]; graca [graca@health.usf.edu]; happic [happic@run.edu.ng]; Schmaljohn, Connie S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ba6458b80904995986f4a7257137cc5-HHS-connie.]; Daniel Brasseur (b)(6)@gmail.com; (b)(6)@yahoo.com; (b)(6)@yahoo.co.uk; dongxp238 [dongxp238@sina.com]; SCornell@wrhi.ac.za; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; Malik, Sabahat Z (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ac937f0a474e10a6b69c537a0fa348-HHS-fmw1-cd]; James Robinson (b)(6)@outlook.com; Jean Lang [Jean.Lang@sanofipasteur.com]; Camille.Bayrat [Camille.Bayrat@sanofi.com]; Van Hoof, Johan [JRDBE] [JVHOOF1@its.jnj.com]; Van Tulden, Karin [JRDBE] [kvtulden@its.jnj.com]; John Edmunds [John.Edmunds@LSHTM.ac.uk]; Josie Golding [j.golding@wellcome.ac.uk]; E.Mroz-Dawes@wellcome.org; kneuzil [kneuzil@som.umaryland.edu]; Bethanne.Smith@som.umaryland.edu; KBozylinski-Bulos@som.umaryland.edu; Jansen, Kathrin [kathrin.jansen@pfizer.com]; Hopps, Markay [markay.hopps@pfizer.com]; Zottoli, Jessica [Jessica.Zottoli@pfizer.com]; Shibuya, Kenji [kenji.shibuya@kcl.ac.uk]; shinoyamaz [shinoyamaz@m.u-tokyo.ac.jp]; Michel De Wilde (b)(6)@aol.com; Levine, Myron [Mlevine@som.umaryland.edu]; Small, Dottie [Dsmall@som.umaryland.edu]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; Penny Heaton [penny.heaton@gatesmri.org]; Mary Burke [Mary.burke@gatesmri.org]; Peter.Smith@lshtm.ac.uk; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Ralf Clemens (b)(6)@outlook.com; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; admin@vaxconsult.com; Tom Kariuki [t.kariuki@aasciences.ac.ke]; Anita Chami [a.chami@aasciences.ac.ke]; SATHIYAMOORTHY, Vaseeharan [moorthyv@who.int]; bruniquel [bruniquel@who.int]; benassiv [benassiv@who.int]; yves.levy [yves.levy@inserm.fr]; Rachel Grant [rachel.grant@cepi.net]; Frederik Kristensen [frederik.kristensen@cepi.net]; Richard Wilder [richard.wilder@cepi.net]; Joseph Simmonds-Issler [jsi@cepi.net]; Samia Saad [samia.saad@cepi.net]
Subject: RE: Update on University of Queensland COVID-19 vaccine

Indeed Helen, the potential risk of anti clamp antibodies had been identified as a theoretical risk however the extent of the observation in humans came as somewhat a surprise. This risk had been taken into account in the stagegate process. I do agree with you that in such circumstances a thorough lessons learnt is advisable and will be carried out.

Kind regards

Melanie

Sensitivity: CEPI Internal

From: Helen Rees <HRees@wrhi.ac.za>
Sent: 13 December 2020 17:43
To: mimi darko (b)(6)@yahoo.co.uk; Melanie Saville <melanie.saville@cepi.net>
Cc: Barrett, Alan <abarrett@utmb.edu>; smrivas <smrivas@utmb.edu>; Alash'le Abimiku <aabimiku@ihv.umaryland.edu>; oumunna <oumunna@ihvnigeria.org>; ali.allouche@hillemanlabs.org; christian.brechot <christian.brechot@pasteur.fr>; cbrechot <cbrechot@usf.edu>; graca <graca@health.usf.edu>; happic <happic@run.edu.ng>; Schmaljohn, Connie (NIH/NIAID) [E] <Connie.schmaljohn@nih.gov>; Daniel Brasseur (b)(6)@gmail.com; (b)(6)@yahoo.com; (b)(6)@yahoo.co.uk; dongxp238 <dongxp238@sina.com>; SCornell@wrhi.ac.za; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; fmw1 <fmw1@cdc.gov>; James Robinson (b)(6)@outlook.com; Jean Lang <Jean.Lang@sanofipasteur.com>; Camille.Bayrat <Camille.Bayrat@sanofi.com>; Van Hoof, Johan [JRDBE] <JVHOOF1@its.jnj.com>; Van Tulden, Karin [JRDBE] <kvtulden@its.jnj.com>; John Edmunds <John.Edmunds@LSHTM.ac.uk>; Josie Golding <j.golding@wellcome.ac.uk>; E.Mroz-Dawes@wellcome.org; kneuzil <kneuzil@som.umaryland.edu>;

Bethanne.Smith@som.umaryland.edu; KBozylinski-Bulos@som.umaryland.edu; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Hopps, Markay <markay.hopps@pfizer.com>; Zottoli, Jessica <Jessica.Zottoli@pfizer.com>; Shibuya, Kenji <kenji.shibuya@kcl.ac.uk>; shinoyamaz <shinoyamaz@m.u-tokyo.ac.jp>; Michel De Wilde (b)(6)@aol.com>; Levine, Myron <Mlevine@som.umaryland.edu>; Small, Dottie <Dsmall@som.umaryland.edu>; Bryant, Paula (NIH/NIAD) [E] <paula.bryant@nih.gov>; Penny Heaton <penny.heaton@gatesmri.org>; Mary Burke <Mary.burke@gatesmri.org>; Peter.Smith@lshtm.ac.uk; Phil Krause <philip.krause@fda.hhs.gov>; Ralf Clemens (b)(6)@outlook.com>; Stanley Plotkin <stanley.plotkin@vaxconsult.com>; admin@vaxconsult.com; Tom Kariuki <t.kariuki@aasciences.ac.ke>; Anita Chami <a.chami@aasciences.ac.ke>; SATHIYAMOORTHY, Vaseeharan <moorthyv@who.int>; bruniquelv <bruniquelv@who.int>; benassiv <benassiv@who.int>; yves.levy <yves.levy@inserm.fr>; Rachel Grant <rachel.grant@cepi.net>; Frederik Kristensen <frederik.kristensen@cepi.net>; Richard Wilder <richard.wilder@cepi.net>; Joseph Simmonds-Issler <jsi@cepi.net>; Samia Saad <samia.saad@cepi.net>

Subject: Re: Update on University of Queensland COVID-19 vaccine

CAUTION: This message was sent by an address external to CEPI. Please do not click on links or open attachments unless you recognize the source of this email and know the content is safe. Contact support@intility.no or it@cepi.net if uncertain.

Dear Melanie

Thanks. This is very helpful and of course disappointing.

Perhaps we should reflect on whether we could have identified this as a potential problem earlier on. Are there lessons to be learnt for other vaccines in development from this experience?

Best
Helen

Subject: Re: Update on University of Queensland COVID-19 vaccine

The University of Queensland (UQ) and CSL today announced that they will not progress UQ's COVID-19 vaccine candidate to Phase 2/3 clinical trials. CEPI supports this decision, and will not continue to fund further development of the vaccine beyond completion of the Phase 1 clinical trial.

The Phase 1 trial has shown that the vaccine candidate elicits a robust response towards the virus and has a strong safety profile. However, the Phase 1 data also showed the generation of antibodies directed towards fragments of a HIV protein (gp41), a component used to stabilize the vaccine. These antibodies led to false-positive HIV results in a subset of rapid HIV diagnostic tests (containing full length gp41). There is no possibility the vaccine causes infection, and routine follow up tests confirmed there is no HIV virus present. However, some of the tests generating false-positive results are widely used in developing countries and in many locations positive results on such tests will result in the initiation of HIV treatment.

We have concluded that this attribute means the vaccine candidate does not meet CEPI's global deployment and distribution requirements and does not meet the criteria for further CEPI funding. This decision was taken after consultation with, and reflects the recommendations of, the CEPI Board Executive and Investment Committee; the COVAX Research, Development, and Manufacturing Committee; and the COVAX Technical Review Group. It was also discussed during the closed session of CEPI's Board meeting, 4 December.

While this is disappointing, identifying issues such as this - which could impact the practical use of the vaccine - is a critical part of the vaccine development process, and illustrates why it is so important that robust and thorough clinical trials such as this one take place.

Historically most vaccines in development do not progress through to licensure, so CEPI has invested in a broad portfolio of COVID-19 vaccine candidates to maximize our chances of success. The remaining vaccine candidates supported by

CEPI are unaffected by this issue, and through our portfolio approach we aim to develop at least three safe and effective vaccines which can be distributed and deployed to the world through COVAX.

I would like to recognise the hard work and commitment of the CEPI team working on the project, and our partners at UQ and CSL in enabling the progress of the vaccine candidate to this point. Before the emergence of COVID-19, CEPI entered into a framework agreement with UQ in January 2019 to develop the rapid response 'Molecular Clamp' platform for potential use against 'Disease X'. The concepts underlying UQ's 'Molecular Clamp' vaccine technology show great promise, so CEPI is committed to continuing to work with UQ to resolve this issue so that the platform can be used to develop vaccines against other diseases in the future. We have a stage gate review on 15 December where we will discuss how to do this.

From: Peter Smith [Peter.Smith@lshtm.ac.uk]
Sent: 12/26/2020 1:14:30 PM
To: Stanley Plotkin [stanley.plotkin@vaxconsult.com]; 'Melanie Saville' [melanie.saville@cepi.net]; 'Barrett, Alan' [abarrett@utmb.edu]; 'smrivas' [smrivas@utmb.edu]; 'Alash'le Abimiku' [aabimiku@ihv.umaryland.edu]; 'oumunna' [oumunna@ihvnigeria.org]; ali.allouche@hillemanlabs.org; 'christian.brechot' [christian.brechot@pasteur.fr]; 'cbrechot' [cbrechot@usf.edu]; 'graca' [graca@health.usf.edu]; 'happic' [happic@run.edu.ng]; Schmaljohn, Connie S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ba6458b80904995986f4a7257137cc5-HHS-connie.]; 'Daniel Brasseur' [(b)(6)]@gmail.com; 'mimi darko' [(b)(6)]@yahoo.co.uk; [(b)(6)]@yahoo.com; [(b)(6)]@yahoo.co.uk; 'dongxp238' [dongxp238@sina.com]; HRees@wrhi.ac.za; SCornell@wrhi.ac.za; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; Malik, Sabahat Z (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ac937f0a474e10a6b69c537a0fa348-HHS-fmw1-cd]; 'James Robinson' [(b)(6)]@outlook.com; 'Jean Lang' [Jean.Lang@sanofipasteur.com]; 'Camille.Bayrat' [Camille.Bayrat@sanofi.com]; 'Van Hoof, Johan [JRDBE]' [JVHOOF1@its.jnj.com]; 'Van Tulden, Karin [JRDBE]' [kvltulden@its.jnj.com]; John Edmunds [John.Edmunds@LSHTM.ac.uk]; 'Josie Golding' [j.golding@wellcome.ac.uk]; E.Mroz-Dawes@wellcome.org; 'kneuzil' [kneuzil@som.umaryland.edu]; Bethanne.Smith@som.umaryland.edu; KBozylinski-Bulos@som.umaryland.edu; 'Jansen, Kathrin' [kathrin.jansen@pfizer.com]; 'Hopps, Markay' [markay.hopps@pfizer.com]; 'Zottoli, Jessica' [Jessica.Zottoli@pfizer.com]; 'Shibuya, Kenji' [kenji.shibuya@kcl.ac.uk]; 'shinoyamaz' [shinoyamaz@m.u-tokyo.ac.jp]; 'Michel De Wilde' [(b)(6)]@aol.com; 'Levine, Myron' [Mlevine@som.umaryland.edu]; 'Small, Dottie' [Dsmall@som.umaryland.edu]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; 'Penny Heaton' [penny.heaton@gatesmri.org]; 'Mary Burke' [Mary.burke@gatesmri.org]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; 'Ralf Clemens' [(b)(6)]@outlook.com; admin@vaxconsult.com; 'Tom Kariuki' [t.kariuki@aasciences.ac.ke]; 'Anita Chami' [a.chami@aasciences.ac.ke]; 'SATHIYAMOORTHY, Vaseeharan' [moorthyv@who.int]; 'bruniquel' [bruniquel@who.int]; 'benassiv' [benassiv@who.int]; 'yves.levy' [yves.levy@inserm.fr]
Subject: RE: SARS CoV2 new variants

Dear Melanie,

Many thanks for this update. The projections from John's group are particularly alarming. I agree that the response by CEPI that you outline seems to cover many of the bases. I suspect this is already planned, but animal challenge studies with both the UK and SA variants, using vaccines in the near pipeline, would seem to be a high priority, as well as rehearsing what the shortest timelines are for reformulating vaccines, with advice from regulators about what they will require to enable rapid approval of reformulated vaccines.

I hope you are managing to have a few hours off!

Very best wishes

Peter

Prof Peter Smith, MRC International Statistics and Epidemiology Group,

London School of Hygiene & Tropical Medicine, Keppel St, London WC1E 7HT. Tel: +44 20 7927 2246. Skype: [(b)(6)]

Free download of 3rd Edition of "Field Trials of Health Interventions: a Toolbox" <https://bit.ly/2J1XXcl> or free access online at <https://bit.ly/2FLACd3>

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>

Sent: 24 December 2020 16:06

To: 'Melanie Saville' <melanie.saville@cepi.net>; 'Barrett, Alan' <abarrett@utmb.edu>; 'smrivas' <smrivas@utmb.edu>;

'Alash'le Abimiku' <aabimiku@ihv.umaryland.edu>; 'oumunna' <oumunna@ihvnigeria.org>; ali.allouche@hillemanlabs.org; 'christian.brechot' <christian.brechot@pasteur.fr>; 'cbrechot' <cbrechot@usf.edu>; 'graca' <graca@health.usf.edu>; 'happic' <happic@run.edu.ng>; 'Schmaljohn, Connie (NIH/NIAID) [E]' <Connie.schmaljohn@nih.gov>; 'Daniel Brasseur' (b)(6)@gmail.com>; 'mimi darko' (b)(6)@yahoo.co.uk>; (b)(6)@yahoo.com>; (b)(6)@yahoo.co.uk>; 'dongxp238' <dongxp238@sina.com>; HRees@wrhi.ac.za; SCornell@wrhi.ac.za; 'Damon, Inger K. (CDC/OID/NCEZID)' <iad7@cdc.gov>; 'fmw1' <fmw1@cdc.gov>; 'James Robinson' (b)(6)@outlook.com>; 'Jean Lang' <Jean.Lang@sanofipasteur.com>; 'Camille.Bayrat' <Camille.Bayrat@sanofi.com>; 'Van Hoof, Johan [JRDBE]' <JVHOOF1@its.jnj.com>; 'Van Tulden, Karin [JRDBE]' <kvtulden@its.jnj.com>; John Edmunds <John.Edmunds@LSHTM.ac.uk>; 'Josie Golding' <j.golding@wellcome.ac.uk>; E.Mroz-Dawes@wellcome.org; 'kneuzil' <kneuzil@som.umaryland.edu>; Bethanne.Smith@som.umaryland.edu; KBozylinski-Bulos@som.umaryland.edu; 'Jansen, Kathrin' <kathrin.jansen@pfizer.com>; 'Hopps, Markay' <markay.hopps@pfizer.com>; 'Zottoli, Jessica' <Jessica.Zottoli@pfizer.com>; 'Shibuya, Kenji' <kenji.shibuya@kcl.ac.uk>; 'shinoyamaz' <shinoyamaz@m.u-tokyo.ac.jp>; 'Michel De Wilde' (b)(6)@aol.com>; 'Levine, Myron' <Mlevine@som.umaryland.edu>; 'Small, Dottie' <Dsmall@som.umaryland.edu>; 'Bryant, Paula (NIH/NIAID) [E]' <paula.bryant@nih.gov>; 'Penny Heaton' <penny.heaton@gatesmri.org>; 'Mary Burke' <Mary.burke@gatesmri.org>; Peter Smith <Peter.Smith@lshtm.ac.uk>; 'Phil Krause' <philip.krause@fda.hhs.gov>; 'Ralf Clemens' (b)(6)@outlook.com>; admin@vaxconsult.com; 'Tom Kariuki' <t.kariuki@aasciences.ac.ke>; 'Anita Chami' <a.chami@aasciences.ac.ke>; 'SATHIYAMOORTHY, Vaseeharan' <moorthyv@who.int>; 'bruniquelv' <bruniquelv@who.int>; 'benassiv' <benassiv@who.int>; 'yves.levy' <yves.levy@inserm.fr>

Subject: RE: SARS CoV2 new variants

*** This message originated outside LSHTM ***

Dear Melanie:

I thank you for an impressive and relevant response of CEPI to this worrying development. I would only add that the threat of escape from antibodies to the RBD reemphasizes the need to characterize T cell responses. Also, we don't know the value or the danger of including nucleoprotein in the vaccine, which is dependent on the T cell responses induced. I suspect (purely a guess) that vaccine-induced neutralizing antibodies will still give protection, but a higher titer may be necessary. Once again, to grind an ax, human challenge studies comparing old and new isolates could give critical information.

Kind Regards,

Stanley

From: Melanie Saville <melanie.saville@cepi.net>

Sent: Thursday, December 24, 2020 6:14 AM

To: Barrett, Alan <abarrett@utmb.edu>; smrivas <smrivas@utmb.edu>; Alash'le Abimiku <aabimiku@ihv.umaryland.edu>; oumunna <oumunna@ihvnigeria.org>; ali.allouche@hillemanlabs.org; christian.brechot <christian.brechot@pasteur.fr>; cbrechot <cbrechot@usf.edu>; graca <graca@health.usf.edu>; happic <happic@run.edu.ng>; Schmaljohn, Connie (NIH/NIAID) [E] <Connie.schmaljohn@nih.gov>; Daniel Brasseur (b)(6)@gmail.com>; mimi darko (b)(6)@yahoo.co.uk>; (b)(6)@yahoo.com>; (b)(6)@yahoo.co.uk>; dongxp238 <dongxp238@sina.com>; HRees@wrhi.ac.za; SCornell@wrhi.ac.za; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; fmw1 <fmw1@cdc.gov>; James Robinson (b)(6)@outlook.com>; Jean Lang <Jean.Lang@sanofipasteur.com>; Camille.Bayrat <Camille.Bayrat@sanofi.com>; Van Hoof, Johan [JRDBE] <JVHOOF1@its.jnj.com>; Van Tulden, Karin [JRDBE] <kvtulden@its.jnj.com>; John Edmunds <John.Edmunds@LSHTM.ac.uk>; Josie Golding <j.golding@wellcome.ac.uk>; E.Mroz-Dawes@wellcome.org; kneuzil <kneuzil@som.umaryland.edu>; Bethanne.Smith@som.umaryland.edu; KBozylinski-Bulos@som.umaryland.edu; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Hopps, Markay <markay.hopps@pfizer.com>; Zottoli, Jessica

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Subject: SARS CoV2 new variants

Dear All

As you know there has been significant activity around 2 new variants of SARS CoV2, one isolated in the UK and a second in RSA. Both are showing evidence of increased transmissibility and work has been done to initially assess any impact on diagnostics, treatments and vaccine effectiveness.

I would like to share with you our initial thinking on actions that CEPI should take as part of the investigation. Please see below a summary of proposed actions from a meeting with our Executive and Investment committee yesterday. Specifically, through the Agility project we are working with GISAID, PHE and NIBSC on the biological relevance of these new strains and although the evidence does not suggest that the current vaccines will not be effective against these strains it does lead us to believe we should consider this eventuality carefully in the new year to which we welcome your input.

Helen has been intimately involved in the RSA strain evaluation and John for the UK and welcome their comments.

I take the opportunity to wish you a very happy holiday period.

Kind regards

Melanie

UK

<https://cmmid.github.io/topics/covid19/uk-novel-variant.html>

https://www.gov.uk/government/news/covid-19-sars-cov-2-information-about-the-new-virus-variant?utm_source=b9311705-d7b8-4353-a9de-b3f6b9362465&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

<https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom>

South Africa: <https://www.krisp.org.za/publications.php?pubid=315>

WHO: <https://www.who.int/csr/don/21-december-2020-sars-cov2-variant-united-kingdom/en/>

EIC summary

1. EIC perspective on high-level overall priorities in response to emerging SARS CoV2 variants:

- Increased surveillance, and WHO guidance on how such surveillance should be standardized
- Faster and wider roll out of vaccines
- Definition of longer-term approach to vaccine development and portfolio composition
- Defining areas where CEPI can contribute meaningfully to public discourse. These could include
 - Taking advantage of and/or adapting clinical trials in areas where the new strains are circulating to understand their impact if any on vaccine efficacy
 - Managing expectations about vaccines, e.g. how long it will take to impact pandemic, and how long making new vaccines might take
 - Working with regulators and developers to map out processes for updating Spike and RBD components of successful vaccines and to identify how steps in development and manufacturing processes might be shortened if and when this becomes necessary

- Emphasizing the ongoing need for NPIs even as people get vaccinated
- Underscoring that the emergence of these mutations, the first that appear to have a significant impact on transmission, amplifies the importance of global equitable access to vaccines to achieve epidemic control as quickly as possible
- Defining areas where CEPI investments could contribute to the global assessment of and response to the new viruses, including:
 - Enabling sciences as the pre-clinical 'on ramp' with a focus towards standardization of protocols, seed stocks, and reagents
 - Sequencing isolates in vaccine efficacy trials, through and beyond trials CEPI is funding - especially in UK and SA
- Supporting WHO
 - Guidance on surveillance/epidemiology
 - Data sharing

2. GlopID R call

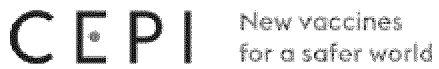
Subsequent to our call, CEPI participated in a GloPID-R call, where WHO Blueprint team indicated they have activated their workgroups and will host a meeting in early January on the new strain.

3. Proposed next steps from CEPI

- Immediate
 - CEPI has already invested MUSD1.4 through the Agility project looking at biological relevance of variants with a partnership with GISAID, PHE and NIBSC. Work will be on developing well characterized virus stocks, development of neutralizing antibody assays and testing convalescent and vaccinated sera. The UK strain has been prioritized in the project and we have offered to fund work on the RSA strain if appropriate. We will work actively to ensure this moves forward expeditiously and there are no funding issues. We will also determine whether to conduct hamster challenge studies. The ultimate goal is to make available to the broader scientific community high quality, standardized material for animal model and other needed studies.
 - *Timing: ongoing*
 - We will engage with partners CEPI is funding on appropriate strategies for sequence/data capture, cross neutralization tests both post dose 1 and 2 from trials, and how to manage and aggregate data from breakthrough cases. In addition, we will contact partners such as Operation Warp Speed, Chinese manufacturers, and consider what a global approach might look like to ensure consistency and rapid action.
 - *Timing: to be in place by early January*
 - Communications: we have developed a reactive statement on the new strain, vaccine development, and messaging on key issues, as below. After we have determined further actions CEPI might take, we could consider a proactive statement.
 - *Partner engagement*
 - We will engage with WHO on the upcoming workshop and offer to provide support as needed
 - We will engage with our animal models network, so if work is needed, it is ready to go
 - We will follow up with Chinese manufacturers
 - We will determine which enabling science activities CEPI leads on, and which it should partner with others, e.g. WHO, to ensure appropriate systems/standards are in place.
 - *Timing – to determine by time of WHO workshop*
- Mid term
 - Review issues relating to mutations and vaccines, including:
 - Is there a need to focus beyond spike protein vaccines? If so, when, and what is the priority?
 - What vaccine platforms should we focus on for strain changes with new variants e.g. mRNA, inactivated, recombinant proteins etc ?
 - Thinking through pros/cons of single dose/deferred dose vaccine approaches
 - *Timing: propose to work on this through January, with the RDMIC*

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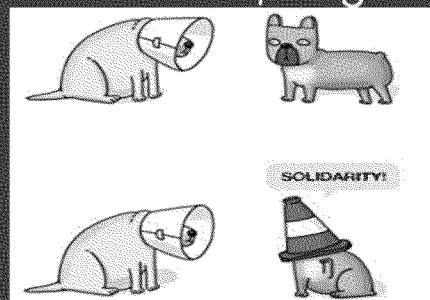
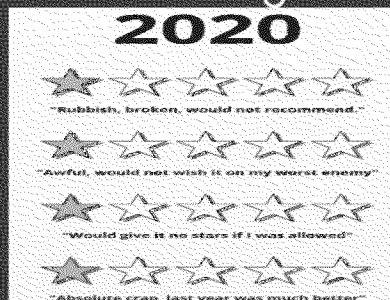
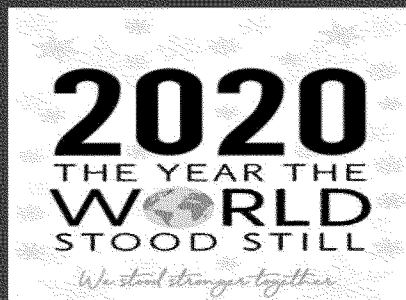
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Thank You and Happy Holidays to the WHO Working Group on COVID-19 Assays

Subject:

There is no better time than the holidays to reminisce on the past year.



Thank you to everyone who has helped support the COVID research !



One of the real joys this holiday season is the opportunity to say thank you and wish you the very best in 2021. Stay safe!



The R&D Blueprint team

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CC: (b)(6)@aol.com
Subject: RE: SARS CoV2 new variants

Dear Melanie, dear all,

I think the actions listed are appropriate for the short term. For the mid-term, RNA appears the best platform to ensure rapid adaptation to a new S variant but is limited in terms of global supply. Next would be adeno and let's hope J&J pans out. For the longer term I would recommend investment in vaccine that do not solely rely on S. Which other protein to target requires some thinking and discussion. Platforms that induce CD8s should be privileged. Probably a specific call for proposals is in order to see what comes up. These are my 5 cents

Wishing everyone restful and happy Holliday.

Michel

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Subject: SARS CoV2 new variants

Dear All

As you know there has been significant activity around 2 new variants of SARS CoV2, one isolated in the UK and a second in RSA. Both are showing evidence of increased transmissibility and work has been done to initially assess any impact on diagnostics, treatments and vaccine effectiveness.

I would like to share with you our initial thinking on actions that CEPI should take as part of the investigation. Please see below a summary of proposed actions from a meeting with our Executive and Investment committee yesterday. Specifically, through the Agility project we are working with GISAID, PHE and NIBSC on the biological relevance of these new strains and although the evidence does not suggest that the current vaccines will not be effective against these strains it does lead us to believe we should consider this eventuality carefully in the new year to which we welcome your input.

Helen has been intimately involved in the RSA strain evaluation and John for the UK and welcome their comments.

I take the opportunity to wish you a very happy holiday period.

Kind regards

Melanie

UK

<https://cmmid.github.io/topics/covid19/uk-novel-variant.html>

https://www.gov.uk/government/news/covid-19-sars-cov-2-information-about-the-new-virus-variant?utm_source=b9311705-d7b8-4353-a9de-b3f6b9362465&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

<https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom>

South Africa: <https://www.krisp.org/publications.php?pubid=315>

WHO: <https://www.who.int/csr/don/21-december-2020-sars-cov2-variant-united-kingdom/en/>

EIC summary

1. EIC perspective on high-level overall priorities in response to emerging SARS CoV2 variants:

- Increased surveillance, and WHO guidance on how such surveillance should be standardized
- Faster and wider roll out of vaccines
- Definition of longer-term approach to vaccine development and portfolio composition
- Defining areas where CEPI can contribute meaningfully to public discourse. These could include
 - Taking advantage of and/or adapting clinical trials in areas where the new strains are circulating to understand their impact if any on vaccine efficacy
 - Managing expectations about vaccines, e.g. how long it will take to impact pandemic, and how long making new vaccines might take

- Working with regulators and developers to map out processes for updating Spike and RBD components of successful vaccines and to identify how steps in development and manufacturing processes might be shortened if and when this becomes necessary
- Emphasizing the ongoing need for NPIs even as people get vaccinated
- Underscoring that the emergence of these mutations, the first that appear to have a significant impact on transmission, amplifies the importance of global equitable access to vaccines to achieve epidemic control as quickly as possible
- Defining areas where CEPI investments could contribute to the global assessment of and response to the new viruses, including:
 - Enabling sciences as the pre-clinical 'on ramp' with a focus towards standardization of protocols, seed stocks, and reagents
 - Sequencing isolates in vaccine efficacy trials, through and beyond trials CEPI is funding - especially in UK and SA
- Supporting WHO
 - Guidance on surveillance/epidemiology
 - Data sharing

2. GloPID R call

Subsequent to our call, CEPI participated in a GloPID-R call, where WHO Blueprint team indicated they have activated their workgroups and will host a meeting in early January on the new strain.

3. Proposed next steps from CEPI

- Immediate
 - CEPI has already invested MUS\$1.4 through the Agility project looking at biological relevance of variants with a partnership with GISAID, PHE and NIBSC. Work will be on developing well characterized virus stocks, development of neutralizing antibody assays and testing convalescent and vaccinated sera. The UK strain has been prioritized in the project and we have offered to fund work on the RSA strain if appropriate. We will work actively to ensure this moves forward expeditiously and there are no funding issues. We will also determine whether to conduct hamster challenge studies. The ultimate goal is to make available to the broader scientific community high quality, standardized material for animal model and other needed studies.
 - *Timing: ongoing*
 - We will engage with partners CEPI is funding on appropriate strategies for sequence/data capture, cross neutralization tests both post dose 1 and 2 from trials, and how to manage and aggregate data from breakthrough cases. In addition, we will contact partners such as Operation Warp Speed, Chinese manufacturers, and consider what a global approach might look like to ensure consistency and rapid action.
 - *Timing: to be in place by early January*
 - Communications: we have developed a reactive statement on the new strain, vaccine development, and messaging on key issues, as below. After we have determined further actions CEPI might take, we could consider a proactive statement.
 - *Partner engagement*
 - We will engage with WHO on the upcoming workshop and offer to provide support as needed
 - We will engage with our animal models network, so if work is needed, it is ready to go
 - We will follow up with Chinese manufacturers
 - We will determine which enabling science activities CEPI leads on, and which it should partner with others, e.g. WHO, to ensure appropriate systems/standards are in place.
 - *Timing – to determine by time of WHO workshop*
- Mid term
 - Review issues relating to mutations and vaccines, including:
 - Is there a need to focus beyond spike protein vaccines? If so, when, and what is the priority?
 - What vaccine platforms should we focus on for strain changes with new variants e.g. mRNA, inactivated, recombinant proteins etc ?
 - Thinking through pros/cons of single dose/deferred dose vaccine approaches
 - *Timing: propose to work on this through January, with the RDMIC*

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Subject: Re: Thank You and Happy Holidays to the WHO COVID-19 Animal Models Group

Thank you! Have a nice one!
Sincerely,
Sergey

Скачайте [Outlook для Android](#)

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>; [(b)(6)]

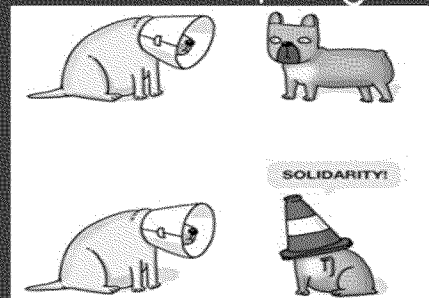
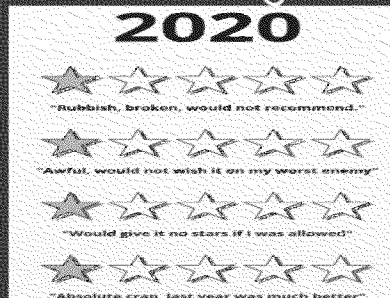
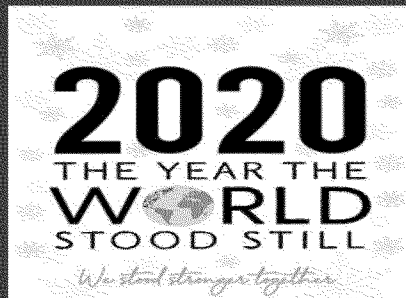
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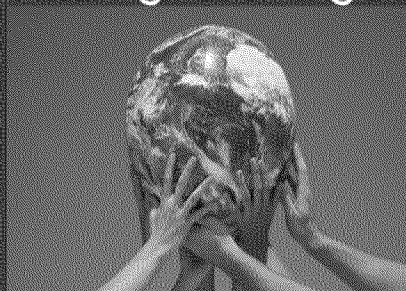
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Subject: Thank You and Happy Holidays to the WHO COVID-19 Animal Models Group

There is no better time than the holidays to reminisce on the past year.



Thank you to everyone who has helped support the COVID research !



One of the real joys this holiday season is the opportunity to say thank you and wish you the very best in 2021. Stay safe!



The R&D Blueprint team

From: Bryant, Paula (NIH/NIAID) [E] [paula.bryant@nih.gov]
Sent: 10/26/2020 1:59:50 PM
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Subject: RE: Request for SAC input regarding call for "wave 2" vaccines

Hi Stig,
I could participate in the peer review....

Thanks,
Paula

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Subject: Request for SAC input regarding call for "wave 2" vaccines

Dear SAC members,

I write to you on behalf of the CEPI secretariat to seek your advice and guidance.

As you are well aware of and some of you have contributed substantially to the peer review processes for support of vaccine development against the COVID-19 pandemic, our last round of call for “wave 1” candidate vaccines closed on September 28.

In collaboration with the Bill and Melinda Gates Foundation, CEPI has been discussing the potential of supporting vaccine candidates relevant for a “wave 2” of vaccines. Through our previous calls, we have received proposals from some applicants that could fill gaps in the current portfolio of vaccines in “wave 1” based on differentiating scientific or technical features, even though these “wave 2” candidates may be somewhat behind the “wave 1” candidates in terms of pre-clinical and clinical development timelines.

With this in mind, we would like to open a call for vaccine technology platforms in order to support the development of these “wave 2” COVID-19 candidates. The call will be a sort of hybrid between our technology platform call CfP2R and the COVID-19 calls. We are specifically asking for vaccines technologies that also could be used in case of Disease X. The total budget for this call is 45 m USD and we aim to support 4-5 developers. Applications that have applied for and already been found eligible for previous COVID-19 calls, but rejected on peer review level, can be considered for this “wave 2” portfolio as long as they have relevant scientific/technological features.

Please find attached the draft call text for the “wave 2” call. Could you please have a look at the call text and write back to me with your comments and suggestions by **COB Wednesday October 28**.

The call will be run as previous calls from CEPI with eligibility review and the peer review process with external expert reviewers. In addition, could you please indicate if you would be available and willing to perform peer review for eligible applications?

In advance, thank you for your contribution.

Best wishes
Stig

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Sensitivity: CEPI Internal

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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.bernasoni@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@amiciti.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.gerds@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; (b)(6)@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; jmcclrat@fredhutch.org; gmedigeshi@thsti.res.in; jwm1@pitt.edu; (b)(6)@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@dmcs.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@dmcs.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_vandenbergh@mei.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.wolfram@nih.gov; (b)(6)@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; (b)(6)@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).

Where: <https://who.zoom.us/j/3612568290>

Agenda to follow.

Join Zoom Meeting

<https://who.zoom.us/j/3612568290> (b)(6)

Meeting ID: (b)(6)

One tap mobile

+41225910005, (b)(6) Switzerland
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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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+1 602 753 0140 US (Phoenix)
+1 669 219 2599 US (San Jose)
+1 669 900 9128 US (San Jose)
+1 470 250 9358 US (Atlanta)
+1 470 381 2552 US (Atlanta)
+1 646 518 9805 US (New York)
+1 646 558 8656 US (New York)
+1 651 372 8299 US (Minnesota)
+1 786 635 1003 US (Miami)
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+1 301 715 8592 US (Washington D.C.)
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Join by SIP

(b)(6)@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: (b)(6)

Join by Skype for Business

<https://who.zoom.us/skype/> (b)(6)

From: LYDON, Patrick [lydonp@who.int]
Sent: 12/15/2020 5:29:42 AM
To: Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]
CC: RIVEROS BALTA, Ximena [lauriex@who.int]; HENAO RESTREPO, Ana Maria [henaorestrepoa@who.int]
Subject: RE: [EXT] RE: minder [Submitting Scientific Achievement 2020 by 14 December]

This is great. Many thanks Phil.
Much appreciated.
Patrick
(on behalf of the Blueprint team)

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: 15 December 2020 05:05
To: LYDON, Patrick <lydonp@who.int>
Cc: RIVEROS BALTA, Ximena <lauriex@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>
Subject: [EXT] RE: minder [Submitting Scientific Achievement 2020 by 14 December]

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N Engl J Med. 2020 Dec 2. doi: 10.1056/NEJMp2033538. Online ahead of print.

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Nature. 2020 Oct;586(7830):509-515. doi: 10.1038/s41586-020-2787-6. Epub 2020 Sep 23.

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Lancet. 2020 Sep 12;396(10253):741-743. doi: 10.1016/S0140-6736(20)31821-3. Epub 2020 Aug 27.

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Clin Infect Dis. 2020 Aug 28;ciaa1290. doi: 10.1093/cid/ciaa1290. Online ahead of print.

From: LYDON, Patrick <lydonp@who.int>

Sent: Friday, December 11, 2020 5:08 AM

To: sylvie.van-der-werf (sylvie.van-der-werf@pasteur.fr) <sylvie.van-der-werf@pasteur.fr>; isabella.eckerle@hcuge.ch; karesh@ecohealthalliance.org; falhosani@adphc.gov.ae; gmleung (gmleung@hku.hk) <gmleung@hku.hk>;

(b)(6)@gmail.com; marshallj@smh.ca; Murthy, Srinivas [CWBC] <Srinivas.Murthy@cw.bc.ca>; John Conly (john.conly@albertahealthservices.ca) <john.conly@albertahealthservices.ca>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Jacobs, Michael <michael.jacobs@ucl.ac.uk> (b)(6)@gmail.com; Ross Upshur <ross.upshur@utoronto.ca>; emily.chan@cuhk.edu.hk; PERKINS, Mark <perkinsm@who.int>; BEN EMBAREK, Peter Karim <benembarekp@who.int>; MORGAN, Oliver <omorgan@who.int>; Dr VAN KERKHOVE, Maria <vankerkhovem@who.int>; DIAZ, Janet Victoria <diazj@who.int>; ALLEGIANZI, Benedetta <allegianzib@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepa@who.int>; PREZIOSI, Marie-pierre <preziosim@who.int>; RIVEROS BALTA, Ximena <lauriex@who.int>; SATHIYAMOORTHY, Vaseeharan <moorthyv@who.int>; REIS, Andreas Alois <reisa@who.int>; LITTLER, Katherine <littlerk@who.int>; BAYUGO, Yolanda <bayugo@who.int>; GOBAT, Nina <gobatin@who.int>

Cc: SWAMINATHAN, Soumya <swaminathans@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepa@who.int>; BORGES, Andrea <borgesa@who.int>; MAFUNGA, Neddy <mafungan@who.int>

Subject: RE:minder [Submitting Scientific Achievement 2020 by 14 December]

Importance: High

Dear Research leads and Working Group chairs,

This is a gentle reminder that we are looking forward to your submissions on **14 December**.

For those working groups that have co-chairs, the suggestion is to either have one chair send the 1 minute video. The alternative is for co-chairs to have a Zoom call and record their session with the 1 minute achievement.

We look forward to your inputs on **Monday**.

All the very best,

Patrick

From: LYDON, Patrick

Sent: 06 December 2020 10:48

Subject: WHO Scientific Achievement 2020 – What is yours for your thematic area? [Inputs by 14 December]

Importance: High

Dear _____,

On behalf of Soumya, we are reaching out to you with a time-sensitive request.

On **December 21** our Director General (Dr Tedros) will host an end-of-year WHO Press Conference which will include a strong focus on science and research for Covid-19.

In preparation for this, we are inviting each chair of the 9 working groups of the Global Research Roadmap to submit their top achievement or scientific advance for their thematic area. **This top achievement or scientific advance needs to be the one that had the greatest impact in the control of the pandemic during 2020.**

In addition, we would like to **also receive from you, a list of all publications (peer reviewed or not) produced** this year that are critical for advancing the science for your thematic area (especially if these were generated with WHO contributions).

Achievements submitted by 14 December will be compiled for Tedros and Soumya to highlight during this end-of-year press conference. Our suggestion for the submission is to **produce a 1 minutes video using your smartphone** (or other device) describing your top scientific achievement for the year. Depending on the submission, you may be invited to formally present achievements during the 21 December press-conference.

Thank you for your attention and follow-up to this request by **14 December**.

All the very best,
Patrick

Patrick Lydon

Research & Development Blueprint Unit – *World Health Emergencies (WHE/HEO)*

World Health Organization | 20 Avenue Appia | CH-1211 Geneva 27 Switzerland | Office: M1156

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Promote health, keep the world safe, and serve the vulnerable

From: HENAO RESTREPO, Ana Maria [henaorestrepa@who.int]
Sent: 12/15/2020 5:17:44 AM
To: Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; LYDON, Patrick [lydonp@who.int]
CC: RIVEROS BALTA, Ximena [lauriex@who.int]
Subject: Re: [EXT] RE: minder [Submitting Scientific Achievement 2020 by 14 December]

Spectacular !!“many thanks!!”

Ana Maria

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Tuesday, December 15, 2020 5:04 AM
To: LYDON, Patrick <lydonp@who.int>
Cc: RIVEROS BALTA, Ximena <lauriex@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepa@who.int>
Subject: [EXT] RE: minder [Submitting Scientific Achievement 2020 by 14 December]

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(b)(6)@gmail.com; marshallj@smh.ca; Murthy, Srinivas [CWBC] <Srinivas.Murthy@cw.bc.ca>; John Conly (john.conly@albertahealthservices.ca) <john.conly@albertahealthservices.ca>; Krause, Philip

<Philip.Krause@fda.hhs.gov>; Jacobs, Michael <michael.jacobs@ucl.ac.uk>; (b)(6)@gmail.com; Ross Upshur <ross.upshur@utoronto.ca>; emily.chan@cuhk.edu.hk; PERKINS, Mark <perkinsm@who.int>; BEN EMBAREK, Peter Karim <benembarekp@who.int>; MORGAN, Oliver <omorgan@who.int>; Dr VAN KERKHOVE, Maria <vankerkhovem@who.int>; DIAZ, Janet Victoria <diazj@who.int>; ALLEGRAZI, Benedetta <allegrazib@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepa@who.int>; PREZIOSI, Marie-pierre <preziosim@who.int>; RIVEROS BALTA, Ximena <lauriex@who.int>; SATHIYAMOORTHY, Vaseeharan <moorthyv@who.int>; REIS, Andreas Alois <reisa@who.int>; LITTLER, Katherine <littlerk@who.int>; BAYUGO, Yolanda <bayugo@who.int>; GOBAT, Nina <gobatin@who.int>

Cc: SWAMINATHAN, Soumya <swaminathans@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepa@who.int>; BORGES, Andrea <borgesa@who.int>; MAFUNGA, Neddy <mafungan@who.int>

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Promote health, keep the world safe, and serve the vulnerable

From: SCHWARTZ, Lauren [schwartzl@who.int]
Sent: 12/16/2020 8:20:30 PM
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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 December 17 3PM CET (Geneva time)

1. Remarks from Ana María Henao Restrepo
2. Roland Zahn (J&J) - *Immunogenicity of 1- and 2- dose vaccine regimens with Ad26.COV2.S in NHP*
3. Julia Port (NIH)- *SARS-CoV-2 disease severity and transmission efficiency in the Syrian hamster is increased for airborne but not fomite exposure*
4. Lisa Gralinski (UNC)

-----Original Appointment-----

From: SCHWARTZ, Lauren

Sent: Sunday, December 13, 2020 10:16 AM

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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, December 17, 2020 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

Where: [https://who.zoom.us/j/\(b\)\(6\)](https://who.zoom.us/j/(b)(6))

Agenda to follow.

Join Zoom Meeting

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+1 786 635 1003 US (Miami)
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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)

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Join by Skype for Business

<https://who.zoom.us/skype/> (b)(6)

From: Krause, Philip [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=00C6330FEA0042FDB5571C3FDEF792ED-KRAUSE]
Sent: 12/14/2020 11:04:43 PM
To: LYDON, Patrick [lydonp@who.int]
CC: RIVEROS BALTA, Alina Ximena [lauriex@who.int]; HENAO RESTREPO, Ana Maria [henaorestrepa@who.int]
Subject: RE: minder [Submitting Scientific Achievement 2020 by 14 December]
Attachments: who video vaccines.mp4

Hi Patrick, Attached is the video for the vaccines subgroup. Warm regards, Phil

The vaccines group published the 21 linked documents on the WHO R&D blueprint website:
<https://www.who.int/teams/blueprint/covid-19>

Here are recent peer reviewed publications from the vaccines group:

Placebo-Controlled Trials of Covid-19 Vaccines - Why We Still Need Them.

WHO Ad Hoc Expert Group on the Next Steps for Covid-19 Vaccine Evaluation, Krause PR, Fleming TR, Longini IM, Peto R, Beral V, Bhargava B, Cravioto A, Cramer J, Ellenberg SS, Figueroa JP, Halloran E, Henao-Restrepo AM, Ryan MJ, Levine MM, Nason M, Nohynek HM, Plotkin S, Rees H, Singh JA, Swaminathan S.

N Engl J Med. 2020 Dec 2. doi: 10.1056/NEJMp2033538. Online ahead of print.

Maintaining confidentiality of emerging results in COVID-19 vaccine trials is essential.

Krause PR, Fleming TR, Ellenberg SS, Henao-Restrepo AM; WHO Ad Hoc Clinical Trial Expert Group.

Lancet. 2020 Nov 21;396(10263):1611-1613. doi: 10.1016/S0140-6736(20)32259-5. Epub 2020 Oct 27.

Animal models for COVID-19.

Muñoz-Fontela C, Dowling WE, Funnell SGP, Gsell PS, Riveros-Balta AX, Albrecht RA, Andersen H, Baric RS, Carroll MW, Cavaleri M, Qin C, Crozier I, Dallmeier K, de Waal L, de Wit E, Delang L, Dohm E, Duprex WP, Falzarano D, Finch CL, Frieman MB, Graham BS, Gralinski LE, Guilfoyle K, Haagmans BL, Hamilton GA, Hartman AL, Herfst S, Kaptein SJF, Klimstra WB, Knezevic I, Krause PR, Kuhn JH, Le Grand R, Lewis MG, Liu WC, Maisonnasse P, McElroy AK, Munster V, Oreshkova N, Rasmussen AL, Rocha-Pereira J, Rockx B, Rodríguez E, Rogers TF, Salguero FJ, Schotsaert M, Stittelaar KJ, Thibaut HJ, Tseng CT, Vergara-Alert J, Beer M, Brasel T, Chan JFW, García-Sastre A, Neyts J, Perlman S, Reed DS, Richt JA, Roy CJ, Segalés J, Vasan SS, Henao-Restrepo AM, Barouch DH.

Nature. 2020 Oct;586(7830):509-515. doi: 10.1038/s41586-020-2787-6. Epub 2020 Sep 23.

COVID-19 vaccine trials should seek worthwhile efficacy.

Krause P, Fleming TR, Longini I, Henao-Restrepo AM, Peto R; World Health Organization Solidarity Vaccines Trial Expert Group.

Lancet. 2020 Sep 12;396(10253):741-743. doi: 10.1016/S0140-6736(20)31821-3. Epub 2020 Aug 27.

Viewpoint of a WHO Advisory Group Tasked to Consider Establishing a Closely-Monitored Challenge Model of COVID-19 in Healthy Volunteers.

Levine MM, Abdullah S, Arabi YM, Darko DM, Durbin AP, Estrada V, Jamrozik E, Kremsner PG, Lagos R, Pitisuttithum P, Plotkin SA, Sauerwein R, Shi SL, Sommerfelt H, Subbarao K, Treanor JJ, Vratil S, King D, Balasingam S, Weller C, Aguilar AO, Cassetti MC, Krause PR, Restrepo AMH.

Clin Infect Dis. 2020 Aug 28;ciaa1290. doi: 10.1093/cid/ciaa1290. Online ahead of print.

From: LYDON, Patrick <lydonp@who.int>

Sent: Friday, December 11, 2020 5:08 AM

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Cc: SWAMINATHAN, Soumya <swaminathans@who.int>; HENAO RESTREPO, Ana Maria <henaorestrepa@who.int>; BORGES, Andrea <borgesa@who.int>; MAFUNGA, Neddy <mafungan@who.int>
Subject: RE:minder [Submitting Scientific Achievement 2020 by 14 December]
Importance: High

Dear Research leads and Working Group chairs,

This is a gentle reminder that we are looking forward to your submissions on **14 December**.

For those working groups that have co-chairs, the suggestion is to either have one chair send the 1 minute video. The alternative is for co-chairs to have a Zoom call and record their session with the 1 minute achievement.

We look forward to your inputs on **Monday**.

All the very best,
Patrick

From: LYDON, Patrick
Sent: 06 December 2020 10:48
Subject: WHO Scientific Achievement 2020 – What is yours for your thematic area? [Inputs by 14 December]
Importance: High

Dear _____,

On behalf of Soumya, we are reaching out to you with a time-sensitive request.

On **December 21** our Director General (Dr Tedros) will host an end-of-year WHO Press Conference which will include a strong focus on science and research for Covid-19.

In preparation for this, we are inviting each chair of the 9 working groups of the Global Research Roadmap to submit their top achievement or scientific advance for their thematic area. **This top achievement or scientific advance needs to be the one that had the greatest impact in the control of the pandemic during 2020.**

In addition, we would like to **also receive from you, a list of all publications (peer reviewed or not) produced** this year that are critical for advancing the science for your thematic area (especially if these were generated with WHO contributions).

Achievements submitted by 14 December will be compiled for Tedros and Soumya to highlight during this end-of-year press conference. Our suggestion for the submission is to **produce a 1 minutes video using your smartphone** (or other device) describing your top scientific achievement for the year. Depending on the submission, you may be invited to formally present achievements during the 21 December press-conference.

Thank you for your attention and follow-up to this request by **14 December**.

All the very best,
Patrick

Patrick Lydon

Research & Development Blueprint Unit – *World Health Emergencies (WHE/HEO)*

World Health Organization | 20 Avenue Appia | CH-1211 Geneva 27 Switzerland | Office: M1156

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Promote health, keep the world safe, and serve the vulnerable

Document produced natively.

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Subject: [EXTERNAL] RE: WHO COVID-19 Animal Models Group Call
Attachments: Confidentiality Undertaking_animal_models_covid19.docx

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Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

As a reminder, all participants are required to provide a signed confidentiality agreement. **If we identify participants on the call without a signed CDA they will be removed. The CDA is attached - please sign and return to me in advance of the call if you're not on the regular distribution list and/or haven't signed this document in the past.** We appreciate your understanding of this important agreement that allows shared data to be discussed and treated with the respect that unpublished data demands.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call Thursday February 25 3PM CET (Geneva time)

1. Ivette Nunez (FDA) - *B1.1.7 Variant Infection of Aged Syrian Hamsters*
2. Tim Sheahan (UNC) - *Evaluating monoclonal antibodies in mouse adapted models of SARS-CoV-2 pathogenesis*
3. Vincent Munster (NIAID) - *Preliminary evaluation of AZD1222 efficacy against B1.1.7 and B1.3.5.1 in the hamster model*

-----Original Appointment-----

From: SCHWARTZ, Lauren

Sent: Sunday, February 21, 2021 2:42 PM

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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, February 25, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

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2. WHO is willing to provide the Information to the Undersigned, or arrange for the provision of the Information to the Undersigned, whether during or in relation to a meeting or a telephone conference, or through an internet-based collaborative workspace, or for a contractual arrangement, or otherwise (hereinafter referred to as “the Activities”), for the purpose of the *Working Group on COVID-19 animal models* (hereinafter referred to as “the Purpose”), provided that the Undersigned undertakes to treat the Information as confidential and proprietary, to use the Information only for the aforesaid Purpose and to disclose it only to persons who have a need to know for the Purpose and are bound by like obligations of confidentiality and non-use as are contained in this Undertaking.
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Sent: Tuesday, February 9, 2021 5:03 PM

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Cc: Griffiths, Anthony; Dr. Hanne Andersen; Thomas Friedrich; S. Herfst; Sinha, Tanima (OS/ASPR/BARDA); Lohman, Kent

Subject: Canceled: WHO COVID-19 Animal Models Group Call

When: Thursday, February 11, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

Where: <https://who.zoom.us/j/9181212121> (b)(6)

Importance: High

Hi All,

We are going to cancel the call this week due to a conflict with a global consultation scheduled for Thursday (see note below). We can circulate details to the group when they become available.

WHO will host a global consultation on **Thursday, 11 February 2021** to urgently discuss

COVID-19 Vaccines- methodological approaches to assess variants effect on vaccine efficacy. The webinar will be scheduled between **13:00 – 18:00 Central European Time (CET)**.

Best,
Lauren

Lauren Schwartz, PhD
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**World Health
Organization**

**WHO ad hoc consultation
COVID Vaccines
Methodological approaches to assess
variants effect on vaccine effects**

11 February 2021

13:00 – 18:30 Central European Time CET

DRAFT Agenda

Version 9 February 2021



R&DBlueprint

Powering research
to prevent epidemics

Introduction

We all need to implement the known proven public health control measures that can to reduce circulation of the virus. As we identify emerging variants for COVID 19 with public health relevance, we will have to consider options to adapt vaccines, so they remain effective.

Since the start of the COVID-19 pandemic, WHO has received several reports of public health events possibly due to variants of SARS-CoV-2. WHO has an existing mechanism for tracking and evaluating variants of the virus that causes COVID-19.

WHO is now expanding that mechanism to provide guidance to developers/manufacturers and countries on changes that may be needed for vaccines and how reformulated vaccines may be evaluated. WHO routinely assesses if variants of SARS-CoV-2 result in changes in transmissibility, clinical presentation and severity, or if they impact on countermeasures, including diagnostics, therapeutics and vaccines.

It's critical that countries continue to report emerging variants to WHO, to assure there is a globally coordinated mechanism to monitor their impact and advise countries and vaccine developers accordingly.

To serve these objectives there is a need to continue designing and conducting new trials and studies and advance the systems for close monitoring of the vaccines impact on overall epidemiology and virus transmission and disease severity, severe disease and death so vaccines to maximum effect.

This consultation is being organized bearing in mind the emerging evidence and the WHO Members States requests for the prompt establishment of a global framework for vaccines evaluation.

Objectives of the ad-hoc consultation

- To outline current WHO efforts to set up a mechanism to provide guidance to developers/manufacturers and countries, and to coordinate changes that may be needed for vaccines.
- To discuss the most robust methodological approaches to assess – during vaccine roll-out- if a circulating new COVID variant – considered of public health relevance- has an impact on vaccine effect.
- To deliberate on the research approaches that could be considered when assessing vaccines that have been adjusted to address vaccine efficacy issues with new variants.

DRAFT AGENDA

Chairperson – Philip Krause

Time	Topic	Speakers
13:00 – 13:05	Welcoming remarks	WHO
13:05 – 13:10	Objectives of the meeting	Philip Krause
PLENARY SESSION - SETTING THE SCENE		
13:10 - 13:20	Outline of WHO integrated risk evaluation framework and the decision-making process for changes to vaccine composition	Sylvie Briand
13:20-13:30	New COVID-19 variants and research priorities	TBD
GENERATING RANDOMIZED EVIDENCE DURING COVID VACCINES ROLL -OUT		
13:30 -13:45	Evaluating Experimental COVID-19 Vaccines: Randomized Clinical Endpoint Trials	Thomas Fleming
13:45 - 14:00	Randomize trial on alternating vaccine doses study in the United Kingdom	Mathew Snape TBC
14:00 -14:15	Randomising millions in routine breast screening clinics – the AgeX trial	Valerie Beral
14:15 – 14:30	Randomising hundreds of thousands during vaccine deployment	Richard Peto
14:30 – 15:15	What are the benefits and challenges of generating randomized evidence during vaccine deployment? Panel Members (TBC): Jerome Singh, Elizabeth Halloran, Peter Figueroa, Flavia Sobral, Cheryl Cohen, Samba Sow, Susan Ellenberg	Plenary discussion
CONDUCTING OBSERVATIONAL STUDIES DURING VACCINE DEPLOYMENT		
15:15 – 15:30	Stepped introduction of each vaccine in South Africa	Salim S. Abdool Karim TBC
15:30 – 15:45	Using seasonal influenza vaccine effectiveness surveillance platforms to evaluate COVID vaccines efficacy	Alba Maria Roperio
15:45 – 16:00	Cohort studies during deployment to assess vaccine effects: the experience in Israel	Ran Balicer TBC
16:00 – 16:15	Possible estimation of variant-specific vaccine effectiveness from observational studies	Ira Longini
16:15 – 16:45	In which context can observational studies contribute to evaluate vaccine effect against variants and, what are the considerations for interpreting the results?	Plenary discussion

COVID Vaccines
Methodological approaches to assess variants effect
on efficacy and effectiveness



R&D Blueprint
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 to prevent epidemics

	Panel Members (TBC): Peter Smith, Rakesh Agarwal, Tom Fleming, Richard Peto, Martha von Horoch, , Danuta Skowronski, Manoj Murhekar	
RESEARCH TO SUPPORT EVALUATION OF EFFICACY AND EFFECTIVENESS OF NEW VACCINES AGAINST VARIANTS		
16:45 – 17:00	Clinical development aspects regarding vaccines modifications	Jakob Crammer
17:0 – 17:15	Animal studies to assess modified vaccines' efficacy against variants: immunization response and challenge data	César Muñoz- Fontela
17:15 – 17:30	Studies on clinical immunogenicity and immunobridging studies	Marion Gruber
17:30 – 17:45	Using the influenza experience to assess vaccine effectiveness	Kanta Subarao
17:45 – 18:15	What are the research requirements to support vaccine evaluation after a strain change, if needed ? Panel Members (TBC): Mike Levine, Arnaud Didierlaurent, May Ling Choong, Alicia Fry, Sheena Sullivan, Jorge Kalil, Moji Adeyeye	Plenary discussion
18:15 – 18:30	Conclusions and next steps	Chairperson
18:30	End of meeting	

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Subject: RE: WHO COVID-19 Animal Models Group Call

Dear Colleagues,

For this week's WHO COVID-19 animal models call on Thursday February 4 (3PM CET), we have organized a panel call focused on transmission studies in animal models with the following panelists:

- Quim Segales (IRTA)
- Nora Gerhards (Wageningen)
- Chad Roy (Tulane)
- Rory de Vries (Erasmus)
- Jürgen Richt (KSU)

The panelists will focus their presentations around the following questions and specific points:

What is the current knowledge about SARS-CoV-2 transmission and the main gaps?

- 1) How do we advance the knowledge on transmission using the multi-model framework developed by the WHO expert group?
- 2) How can we compare transmission of wt and VOC SARS-CoV-2?
- 3) Is there a benefit for interspecies transmission studies? Are these feasible?
- 4) What is the best way to study the correlation between transmission and virulence in animal models?
- 5) How well do transmission studies in animal models translate into humans?
- 6) Should we be comparing the viability of aerosols of different VOC or are transmission differences associated to infectious dose?

We thank the panelists in advance for their contribution and we are looking forward to a fruitful group discussion.

Best,
Lauren – César, Simon, and Bill

-----Original Appointment-----

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Sent: Sunday, January 31, 2021 9:19 AM

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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, February 4, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

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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 28 3PM CET (Geneva time)

1. Juan García Arriaza / Mariano Esteban (CNB) - *COVID-19 vaccine candidates based on modified vaccinia virus Ankara expressing the SARS-CoV-2 spike protein induce robust T- and B-cell immune responses and full efficacy in mice*
2. Bernard Moss (NIAID) - *One or Two Injections of MVA-Vectored Vaccine Shields hACE2 Transgenic Mice From SARS-CoV-2 Upper and Lower Respiratory Tract Infection*
3. Kris White (Icahn School of Medicine) - *Plitidepsin has potent preclinical efficacy against SARS-CoV-2 by targeting the host protein eEF1A*

-----Original Appointment-----

From: SCHWARTZ, Lauren

Sent: Sunday, January 24, 2021 2:04 PM

To: Luis.Lugo.mil@afirms.org; Matthew.Reed.mil@afirms.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.maisonasse@cea.fr; sekim@krikt.re.kr; (b)(6)@hotmail.com; carolyn.clark@cepi.net; william.dowling@cepi.net; amy.c.shurtleff@cepi.net; shanchao@wh.iov.cn; (b)(6)@gmail.com; seos@cnu.ac.kr; (b)(6)@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; (b)(6)@gmail.com; scordo@qb.fcen.uba.ar; (b)(6)@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@fli.de; ThomasC.Mettenleiter@fli.de; (b)(6)@yahoo.com; rhakami@gmu.edu; Asisa.Volz@tiho-hannover.de; dbarouch@bidmc.harvard.edu; esulkowska@rics.bwh.harvard.edu; luk_vandenbergh@mei.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;

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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, January 28, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

Where: [https://who.zoom.us/\(b\)\(6\)](https://who.zoom.us/(b)(6))

Agenda to follow.

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69.174.57.160 (Canada)
207.226.132.110 (Japan)

Meeting ID: (b)(6)

From: Melanie Saville [melanie.saville@cepi.net]
Sent: 1/17/2021 10:44:02 AM
To: HRees@wrhi.ac.za; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Barrett, Alan [abarrett@utmb.edu]; smrivas [smrivas@utmb.edu]; Alash'le Abimiku [aabimiku@ihv.umaryland.edu]; oumunna [oumunna@ihvnigeria.org]; ali.allouche@hillemanlabs.org; christian.brechot [christian.brechot@pasteur.fr]; cbrechot [cbrechot@usf.edu]; graca [graca@health.usf.edu]; happic [happic@run.edu.ng]; Schmaljohn, Connie S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ba6458b80904995986f4a7257137cc5-HHS-connie.]; Daniel Brasseur [(b)(6)]@gmail.com; mimi darko [(b)(6)]@yahoo.co.uk; [(b)(6)]@yahoo.com; [(b)(6)]@yahoo.co.uk; dongxp238 [dongxp238@sina.com]; SCornell@wrhi.ac.za; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; Malik, Sabahat Z (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ac937f0a474e10a6b69c537a0fa348-HHS-fmw1-cd]; James Robinson [(b)(6)]@outlook.com; Jean Lang [Jean.Lang@sanofipasteur.com]; Camille.Bayrat [Camille.Bayrat@sanofi.com]; Van Hoof, Johan [JRDBE] [JVHOOF1@its.jnj.com]; Van Tulden, Karin [JRDBE] [kvtulden@its.jnj.com]; John Edmunds [John.Edmunds@LSHTM.ac.uk]; Josie Golding [j.golding@wellcome.ac.uk]; E.Mroz-Dawes@wellcome.org; kneuzil [kneuzil@som.umaryland.edu]; Bethanne.Smith@som.umaryland.edu; KBozylinski-Bulos@som.umaryland.edu; Jansen, Kathrin [kathrin.jansen@pfizer.com]; Hopps, Markay [markay.hopps@pfizer.com]; Zottoli, Jessica [Jessica.Zottoli@pfizer.com]; Shibuya, Kenji [kenji.shibuya@kcl.ac.uk]; shinoyamaz [shinoyamaz@m.u-tokyo.ac.jp]; Michel De Wilde [(b)(6)]@aol.com; Levine, Myron [Mlevine@som.umaryland.edu]; Small, Dottie [Dsmall@som.umaryland.edu]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; Penny Heaton [penny.heaton@gatesmri.org]; Mary Burke [Mary.burke@gatesmri.org]; Peter.Smith@lshtm.ac.uk; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Ralf Clemens [(b)(6)]@outlook.com; admin@vaxconsult.com; Tom Kariuki [t.kariuki@aasciences.ac.ke]; Anita Chami [a.chami@aasciences.ac.ke]; SATHIYAMOORTHY, Vaseeharan [moorthyv@who.int]; bruniquelv [bruniquelv@who.int]; benassiv [benassiv@who.int]; yves.levy [yves.levy@inserm.fr]
CC: Richard Hatchett [richard.hatchett@cepi.net]
Subject: RE: SARS CoV2 new variants

Dear Helen,

Many thanks for your very important comments and questions to address. We will be seeking your input into these questions at the SAC meeting of 26th January.

Information will be forwarded to you shortly.

Kind regards

Melanie

Sensitivity: CEPI Internal

From: Helen Rees <HRees@wrhi.ac.za>

Sent: 16 January 2021 14:35

To: Stanley Plotkin <stanley.plotkin@vaxconsult.com>; Melanie Saville <melanie.saville@cepi.net>; Barrett, Alan <abarrett@utmb.edu>; smrivas <smrivas@utmb.edu>; Alash'le Abimiku <aabimiku@ihv.umaryland.edu>; oumunna <oumunna@ihvnigeria.org>; ali.allouche@hillemanlabs.org; christian.brechot <christian.brechot@pasteur.fr>; cbrechot <cbrechot@usf.edu>; graca <graca@health.usf.edu>; happic <happic@run.edu.ng>; Schmaljohn, Connie (NIH/NIAID) [E] <Connie.schmaljohn@nih.gov>; Daniel Brasseur [(b)(6)]@gmail.com; mimi darko [(b)(6)]@yahoo.co.uk; [(b)(6)]@yahoo.com; [(b)(6)]@yahoo.co.uk; dongxp238 <dongxp238@sina.com>; SCornell@wrhi.ac.za; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; fmw1 <fmw1@cdc.gov>; James Robinson [(b)(6)]@outlook.com; Jean Lang <Jean.Lang@sanofipasteur.com>; Camille.Bayrat <Camille.Bayrat@sanofi.com>; Van Hoof, Johan [JRDBE] <JVHOOF1@its.jnj.com>; Van Tulden, Karin [JRDBE] <kvtulden@its.jnj.com>; John Edmunds <John.Edmunds@LSHTM.ac.uk>; Josie Golding

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Subject: Re: SARS CoV2 new variants

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Dear Colleagues

I didn't pick up on this earlier email below as I was out of internet contact at that time. On this topic and on the question of vaccine efficacy against the new variants, WHO held two R&D Blueprint discussions this week on variants and on COVID vaccines. Obviously the emergence of several variants that might render current vaccines less effective was a major concern. There will be data emerging soon on this question for the two variants of concern but from the SA NICD, it appears that convalescent plasma from recovered patients from the first wave without the new variant appears to have reduced neutralising activity against the variant.

In yesterday's vaccine R&D Blueprint discussion, Mike Levine gave a very good talk on next generation vaccines, and Richard mentioned in his talk that CEPI is considering the characteristics of next generation vaccines. I am highlighting the following from Melanie below and I would add to the list below route of administration e.g. intranasal:

"Review issues relating to mutations and vaccines, including:

- Is there a need to focus beyond spike protein vaccines? If so, when, and what is the priority?
- What vaccine platforms should we focus on for strain changes with new variants e.g. mRNA, inactivated, recombinant proteins etc ?
- Thinking through pros/cons of single dose/deferred dose vaccine approaches."

I will discuss with Melanie and Richard whether a SAC discussion about the next generation of vaccines would be helpful at this stage, recognising that everyone is very busy.

Wishing you all happiness and health in this difficult 2021.

Best
Helen

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>

Date: Thursday, 24 December 2020 at 18:07

To: 'Melanie Saville' <melanie.saville@cepi.net>, "'Barrett, Alan'" <abarrett@utmb.edu>, 'smrivas' <smrivas@utmb.edu>, 'Alash'le Abimiku' <aabimiku@ihv.umaryland.edu>, 'oumunna' <oumunna@ihvnigeria.org>, "ali.alloueche@hillemanlabs.org" <ali.alloueche@hillemanlabs.org>, "'christian.brechot'" <christian.brechot@pasteur.fr>, 'cbrechot' <cbrechot@usf.edu>, 'graca' <graca@health.usf.edu>, 'happic' <happic@run.edu.ng>, "'Schmaljohn, Connie (NIH/NIAID) [E]'" <Connie.schmaljohn@nih.gov>, 'Daniel Brasseur' <(b)(6)@gmail.com>, 'mimi darko'

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Subject: RE: SARS CoV2 new variants

Dear Melanie:

I thank you for an impressive and relevant response of CEPI to this worrying development. I would only add that the threat of escape from antibodies to the RBD reemphasizes the need to characterize T cell responses. Also, we don't know the value or the danger of including nucleoprotein in the vaccine, which is dependent on the T cell responses induced. I suspect (purely a guess) that vaccine-induced neutralizing antibodies will still give protection, but a higher titer may be necessary. Once again, to grind an ax, human challenge studies comparing old and new isolates could give critical information.

Kind Regards,

Stanley

From: Melanie Saville <melanie.saville@cepi.net>

Sent: Thursday, December 24, 2020 6:14 AM

To: Barrett, Alan <abarrett@utmb.edu>; smrivas <smrivas@utmb.edu>; Alash'le Abimiku <aabimiku@ihv.umaryland.edu>; oumunna <oumunna@ihvnigeria.org>; ali.allouche@hillemanlabs.org; christian.brechot <christian.brechot@pasteur.fr>; cbrechot <cbrechot@usf.edu>; graca <graca@health.usf.edu>; happic <happic@run.edu.ng>; Schmaljohn, Connie (NIH/NIAID) [E] <Connie.schmaljohn@nih.gov>; Daniel Brasseur (b)(6)@gmail.com>; mimi darko (b)(6)@yahoo.co.uk>; (b)(6)@yahoo.com>; (b)(6)@yahoo.co.uk>; dongxp238 <dongxp238@sina.com>; HRees@wrhi.ac.za; SCornell@wrhi.ac.za; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; fmw1 <fmw1@cdc.gov>; James Robinson (b)(6)@outlook.com>; Jean Lang <Jean.Lang@sanofipasteur.com>; Camille.Bayrat <Camille.Bayrat@sanofi.com>; Van Hoof, Johan [JRDBE] <JVHOOF1@its.jnj.com>; Van Tulden, Karin [JRDBE] <kvtulden@its.jnj.com>; John Edmunds <John.Edmunds@LSHTM.ac.uk>; Josie Golding <j.golding@wellcome.ac.uk>; E.Mroz-Dawes@wellcome.org; kneuzil <kneuzil@som.umaryland.edu>; Bethanne.Smith@som.umaryland.edu; KBozylinski-Bulos@som.umaryland.edu; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Hopps, Markay <markay.hopps@pfizer.com>; Zottoli, Jessica

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Subject: SARS CoV2 new variants

Dear All

As you know there has been significant activity around 2 new variants of SARS CoV2, one isolated in the UK and a second in RSA. Both are showing evidence of increased transmissibility and work has been done to initially assess any impact on diagnostics, treatments and vaccine effectiveness.

I would like to share with you our initial thinking on actions that CEPI should take as part of the investigation. Please see below a summary of proposed actions from a meeting with our Executive and Investment committee yesterday. Specifically, through the Agility project we are working with GISAID, PHE and NIBSC on the biological relevance of these new strains and although the evidence does not suggest that the current vaccines will not be effective against these strains it does lead us to believe we should consider this eventuality carefully in the new year to which we welcome your input.

Helen has been intimately involved in the RSA strain evaluation and John for the UK and welcome their comments.

I take the opportunity to wish you a very happy holiday period.

Kind regards

Melanie

UK

<https://cmmid.github.io/topics/covid19/uk-novel-variant.html>

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<https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom>

South Africa: <https://www.krisp.org.za/publications.php?pubid=315>

WHO: <https://www.who.int/csr/don/21-december-2020-sars-cov2-variant-united-kingdom/en/>

EIC summary

1. EIC perspective on high-level overall priorities in response to emerging SARS CoV2 variants:

- Increased surveillance, and WHO guidance on how such surveillance should be standardized
- Faster and wider roll out of vaccines
- Definition of longer-term approach to vaccine development and portfolio composition
- Defining areas where CEPI can contribute meaningfully to public discourse. These could include
 - Taking advantage of and/or adapting clinical trials in areas where the new strains are circulating to understand their impact if any on vaccine efficacy
 - Managing expectations about vaccines, e.g. how long it will take to impact pandemic, and how long making new vaccines might take
 - Working with regulators and developers to map out processes for updating Spike and RBD components of successful vaccines and to identify how steps in development and manufacturing processes might be shortened if and when this becomes necessary

- Emphasizing the ongoing need for NPIs even as people get vaccinated
- Underscoring that the emergence of these mutations, the first that appear to have a significant impact on transmission, amplifies the importance of global equitable access to vaccines to achieve epidemic control as quickly as possible
- Defining areas where CEPI investments could contribute to the global assessment of and response to the new viruses, including:
 - Enabling sciences as the pre-clinical 'on ramp' with a focus towards standardization of protocols, seed stocks, and reagents
 - Sequencing isolates in vaccine efficacy trials, through and beyond trials CEPI is funding - especially in UK and SA
- Supporting WHO
 - Guidance on surveillance/epidemiology
 - Data sharing

2. GlopID R call

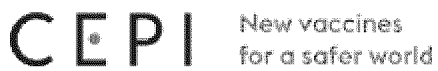
Subsequent to our call, CEPI participated in a GloPID-R call, where WHO Blueprint team indicated they have activated their workgroups and will host a meeting in early January on the new strain.

3. Proposed next steps from CEPI

- Immediate
 - CEPI has already invested MUSD1.4 through the Agility project looking at biological relevance of variants with a partnership with GISAID, PHE and NIBSC. Work will be on developing well characterized virus stocks, development of neutralizing antibody assays and testing convalescent and vaccinated sera. The UK strain has been prioritized in the project and we have offered to fund work on the RSA strain if appropriate. We will work actively to ensure this moves forward expeditiously and there are no funding issues. We will also determine whether to conduct hamster challenge studies. The ultimate goal is to make available to the broader scientific community high quality, standardized material for animal model and other needed studies.
 - *Timing: ongoing*
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 - *Partner engagement*
 - We will engage with WHO on the upcoming workshop and offer to provide support as needed
 - We will engage with our animal models network, so if work is needed, it is ready to go
 - We will follow up with Chinese manufacturers
 - We will determine which enabling science activities CEPI leads on, and which it should partner with others, e.g. WHO, to ensure appropriate systems/standards are in place.
 - *Timing – to determine by time of WHO workshop*
- Mid term
 - Review issues relating to mutations and vaccines, including:
 - Is there a need to focus beyond spike protein vaccines? If so, when, and what is the priority?
 - What vaccine platforms should we focus on for strain changes with new variants e.g. mRNA, inactivated, recombinant proteins etc ?
 - Thinking through pros/cons of single dose/deferred dose vaccine approaches
 - *Timing: propose to work on this through January, with the RDMIC*

MELANIE SAVILLE

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Sensitivity: CEPI Internal

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Sent: 1/16/2021 9:35:13 AM
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Subject: Re: SARS CoV2 new variants

Dear Colleagues

I didn't pick up on this earlier email below as I was out of internet contact at that time. On this topic and on the question of vaccine efficacy against the new variants, WHO held two R&D Blueprint discussions this week on variants and on COVID vaccines. Obviously the emergence of several variants that might render current vaccines less effective was a major concern. There will be data emerging soon on this question for the two variants of concern but from the SA NICD, it appears that convalescent plasma from recovered patients from the first wave without the new variant appears to have reduced neutralising activity against the variant.

In yesterday's vaccine R&D Blueprint discussion, Mike Levine gave a very good talk on next generation vaccines, and Richard mentioned in his talk that CEPI is considering the characteristics of next generation vaccines. I am highlighting the following from Melanie below and I would add to the list below route of administration e.g. intranasal:

"Review issues relating to mutations and vaccines, including:

- Is there a need to focus beyond spike protein vaccines? If so, when, and what is the priority?
- What vaccine platforms should we focus on for strain changes with new variants e.g. mRNA, inactivated, recombinant proteins etc ?
- Thinking through pros/cons of single dose/deferred dose vaccine approaches."

I will discuss with Melanie and Richard whether a SAC discussion about the next generation of vaccines would be helpful at this stage, recognising that everyone is very busy.

Wishing you all happiness and health in this difficult 2021.

Best
Helen

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>

Date: Thursday, 24 December 2020 at 18:07

To: 'Melanie Saville' <melanie.saville@cepi.net>, "'Barrett, Alan'" <abarrett@utmb.edu>, 'smrivas' <smrivas@utmb.edu>, 'Alash'le Abimiku' <aabimiku@ihv.umaryland.edu>, 'oumunna' <oumunna@ihvnigeria.org>, "ali.alloueché@hillemanlabs.org" <ali.alloueché@hillemanlabs.org>, "'christian.brechot'" <christian.brechot@pasteur.fr>, 'cbrechot' <cbrechot@usf.edu>, 'graca' <graca@health.usf.edu>, 'happic' <happic@run.edu.ng>, "'Schmaljohn, Connie (NIH/NIAID) [E]'" <Connie.schmaljohn@nih.gov>, 'Daniel Brasseur' <(b)(6)@gmail.com>, 'mimi darko' <(b)(6)@yahoo.co.uk>, <(b)(6)@yahoo.com> <(b)(6)@yahoo.com>, <(b)(6)@yahoo.co.uk>, 'dongxp238' <dongxp238@sina.com>, Helen Rees <HRees@wrhi.ac.za>, Cornell <SCornell@wrhi.ac.za>, "'Damon, Inger K. (CDC/OID/NCEZID)'" <iad7@cdc.gov>, 'fmw1' <fmw1@cdc.gov>, 'James Robinson' <(b)(6)@outlook.com>, 'Jean Lang' <Jean.Lang@sanofipasteur.com>, "'Camille.Bayrat'" <Camille.Bayrat@sanofi.com>, "'Van Hoof, Johan [JRDBE]'" <JVHOOF1@its.jnj.com>, "'Van Tulden, Karin [JRDBE]'" <kvtulden@its.jnj.com>, John Edmunds <John.Edmunds@LSHTM.ac.uk>, 'Josie Golding' <j.golding@wellcome.ac.uk>, 'E.Mroz-Dawes@wellcome.org' <E.Mroz-Dawes@wellcome.org>, 'kneuzil' <kneuzil@som.umaryland.edu>, 'Bethanne.Smith@som.umaryland.edu' <Bethanne.Smith@som.umaryland.edu>, 'KBozylinski-Bulos@som.umaryland.edu' <KBozylinski-Bulos@som.umaryland.edu>, "'Jansen, Kathrin'" <kathrin.jansen@pfizer.com>, "'Hopps, Markay'" <markay.hopps@pfizer.com>, "'Zottoli, Jessica'" <Jessica.Zottoli@pfizer.com>, "'Shibuya, Kenji'" <kenji.shibuya@kcl.ac.uk>, 'shinoyamaz' <shinoyamaz@m.u-tokyo.ac.jp>, 'Michel De Wilde' <(b)(6)@aol.com>, "'Levine, Myron'" <Mlevine@som.umaryland.edu>, "'Small, Dottie'" <Dsmall@som.umaryland.edu>, "'Bryant, Paula (NIH/NIAID) [E]'" <paula.bryant@nih.gov>, 'Penny Heaton' <penny.heaton@gatesmri.org>, 'Mary Burke' <Mary.burke@gatesmri.org>, 'peter.smith@lshtm.ac.uk' <Peter.Smith@lshtm.ac.uk>, 'Phil Krause' <philip.krause@fda.hhs.gov>, 'Ralf Clemens' <(b)(6)@outlook.com>, 'admin@vaxconsult.com' <admin@vaxconsult.com>, 'Tom Kariuki' <t.kariuki@aasciences.ac.ke>, 'Anita Chami' <a.chami@aasciences.ac.ke>, Vaseeharan SATHIYAMOORTHY <moorthyv@who.int>, 'bruniquel' <bruniquel@who.int>, 'benassiv' <benassiv@who.int>, "'yves.levy'" <yves.levy@inserm.fr>

Subject: RE: SARS CoV2 new variants

Dear Melanie:

I thank you for an impressive and relevant response of CEPI to this worrying development. I would only add that the threat of escape from antibodies to the RBD reemphasizes the need to characterize T cell responses. Also, we don't know the value or the danger of including nucleoprotein in the vaccine, which is dependent on the T cell responses induced. I suspect (purely a guess) that vaccine-induced neutralizing antibodies will still give protection, but a higher titer may be necessary. Once again, to grind an ax, human challenge studies comparing old and new isolates could give critical information.

Kind Regards,

Stanley

From: Melanie Saville <melanie.saville@cepi.net>

Sent: Thursday, December 24, 2020 6:14 AM

To: Barrett, Alan <abarrett@utmb.edu>; smrivas <smrivas@utmb.edu>; Alash'le Abimiku <aabimiku@ihv.umaryland.edu>; oumunna <oumunna@ihvnigeria.org>; ali.allouche@hillemanlabs.org; christian.brechot <christian.brechot@pasteur.fr>; cbrechot <cbrechot@usf.edu>; graca <graca@health.usf.edu>; happic <happic@run.edu.ng>; Schmaljohn, Connie (NIH/NIAID) [E] <Connie.schmaljohn@nih.gov>; Daniel Brasseur <(b)(6)@gmail.com>; mimi darko <(b)(6)@yahoo.co.uk>; <(b)(6)@yahoo.com>; <(b)(6)@yahoo.co.uk>; dongxp238 <dongxp238@sina.com>; HRees@wrhi.ac.za; SCornell@wrhi.ac.za; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; fmw1 <fmw1@cdc.gov>; James Robinson <(b)(6)@outlook.com>; Jean Lang <Jean.Lang@sanofipasteur.com>; Camille.Bayrat <Camille.Bayrat@sanofi.com>; Van Hoof, Johan [JRDBE] <JVHOOF1@its.jnj.com>; Van Tulden, Karin [JRDBE] <kv tulden@its.jnj.com>; John Edmunds <John.Edmunds@LSHTM.ac.uk>; Josie Golding <j.golding@wellcome.ac.uk>; E.Mroz-Dawes@wellcome.org; kneuzil <kneuzil@som.umaryland.edu>; Bethanne.Smith@som.umaryland.edu; KBozylinski-Bulos@som.umaryland.edu; Jansen, Kathrin <kathrin.jansen@pfizer.com>; Hopps, Markay <markay.hopps@pfizer.com>; Zottoli, Jessica <Jessica.Zottoli@pfizer.com>; Shibuya, Kenji <kenji.shibuya@kcl.ac.uk>; shinoyamaz <shinoyamaz@m.u-tokyo.ac.jp>; Michel De Wilde <(b)(6)@aol.com>; Levine, Myron <Mlevine@som.umaryland.edu>; Small, Dottie <Dsmall@som.umaryland.edu>; Bryant, Paula (NIH/NIAID) [E] <paula.bryant@nih.gov>; Penny Heaton <penny.heaton@gatesmri.org>; Mary Burke <Mary.burke@gatesmri.org>; Peter.Smith@lshtm.ac.uk; Phil Krause <philip.krause@fda.hhs.gov>; Ralf Clemens <(b)(6)@outlook.com>; Stanley Plotkin <stanley.plotkin@vaxconsult.com>; admin@vaxconsult.com; Tom Kariuki <t.kariuki@aasciences.ac.ke>; Anita Chami <a.chami@aasciences.ac.ke>; SATHIYAMOORTHY, Vaseeharan <moorthyv@who.int>; bruniquelv <bruniquelv@who.int>; benassiv <benassiv@who.int>; yves.levy <yves.levy@inserm.fr>

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Subject: Call for nominations for experts to the Independent allocation of vaccines group (IAVG)

Dear SAC,

Happy New Year!

CEPI wants to inform its collaboration partners of the following important COVAX call for nominations for experts to the Independent allocation of vaccines group (IAVG).

Background: COVAX is the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, and it is co-led by Gavi, the CEPI and WHO. One of the principal objectives of COVAX is to promote the fair and equitable allocation of COVID-19 vaccines that are procured or distributed through the COVAX Facility (the "vaccines") to countries and economies participating in such Facility ("COVAX participants"). The IAVG is expected to play a pivotal role in the allocation of vaccines under COVAX and to ensure the independence of, and provide transparency into, the vaccine allocation decision-making under COVAX.

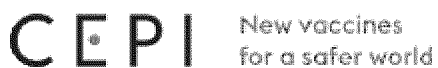
Please take a moment to explore and feel free to leverage and share within your network as appropriate. Please note that the deadline is **January 8th**.

<https://www.who.int/news-room/articles-detail/covax-independent-allocation-of-vaccines-group>

Kind regards
Melanie

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Subject: [EXTERNAL] RE: WHO COVID-19 Animal Models Group Call

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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 March 11 3PM CET (Geneva time)

1. Alexander Bukreyev (UTMB) - *mRNA-1273 efficacy in a severe COVID-19 model: Attenuated activation of pulmonary immune cells after the challenge*
2. James Stewart (Liverpool) - *Naturally-acquired immunity in Syrian Golden Hamsters provides protection from re-exposure to emerging heterosubtypic SARS-CoV-2 variants B.1.1.7 and B.1.351*
3. Sonja Best (NIAID) - *Harnessing genetic diversity to model COVID-19 in mice*

-----Original Appointment-----

From: SCHWARTZ, Lauren

Sent: Sunday, March 7, 2021 8:54 AM

To: SCHWARTZ, Lauren; Luis.Lugo.mil@afirms.org; Matthew.Reed.mil@afirms.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; Andrew.Phipps@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.rodriquez@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.maisonasse@cea.fr; sekim@krikt.re.kr; (b)(6)@hotmail.com; carolyn.clark@cepi.net; william.dowling@cepi.net; amy.c.shurtleff@cepi.net; shanchao@wh.iov.cn; (b)(6)@gmail.com; seos@cnu.ac.kr; (b)(6)@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; (b)(6)@gmail.com; scordo@qb.fcen.uba.ar; (b)(6)@comcast.net; dgdiel@cornell.edu; Vasan.Vasan@csiro.au; pduprex@pitt.edu; joanne@pitt.edu; agw13@pitt.edu; AKelvin@dal.ca; 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; Lowen, Anice; mariette.ducatez@envt.fr; S. Herfst; 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@fli.de; ThomasC.Mettenleiter@fli.de; (b)(6)@yahoo.com; rhakami@gmu.edu; Asisa.Volz@tiho-

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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, March 11, 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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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)

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Subject: Re: Update on Undiagnosed Pneumonia - China - 13 JAN

Thanks!

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Date: January 13, 2020 at 1:11:56 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: Update on Undiagnosed Pneumonia - China - 13 JAN

Hi – wanted to provide u w/updates of what happened over the weekend – m

Overview:

- As of 12 JAN, WHO reports that there are 41 confirmed cases and one death:
 - 41 cases with novel coronavirus infection have been preliminarily diagnosed in Wuhan City.
 - Of the 41 cases reported, seven are severely ill.
 - The 1 death reported was in a patient with other underlying health conditions.
 - Six patients have been discharged from hospital.
 - Symptom onset of the 41 confirmed nCoV cases ranges from 8 December 2019 to 2 January 2020.
 - No additional cases have been detected since 3 January 2020.
 - According to the preliminary epidemiological investigation, most cases worked at or were handlers and frequent visitors to the Huanan Seafood Wholesale Market.
 - The Chinese government reports that there is no clear evidence that the virus passes easily from person to person.
 - A total of 763 close contacts including healthcare workers, have been identified and followed up and no additional cases of infection with the novel coronavirus have been identified
- On 13 JAN, WHO reported confirmation of the novel coronavirus in a person in Thailand who was a traveler from Wuhan, China, and was identified by Thai officials on 8 January, and hospitalized that day. The person is recovering from the illness according to Thai officials.
- The Shanghai Public Health Clinical Center & School of Public Health, in collaboration with the Central Hospital of Wuhan, Huazhong University of Science and Technology, the Wuhan Center for Disease Control and Prevention, the National Institute for Communicable Disease Control and Prevention, Chinese Center for Disease Control, and the University of Sydney, Sydney, Australia released a coronavirus genome from a case of a respiratory disease from the Wuhan outbreak. The sequence has also been deposited on GenBank (accession MN908947).
- CIDRAP reported that Vineet Menachery, PhD, with the University of Texas Medical Branch (UTMB) said on Twitter that nCoV appears to be a group 2B coronavirus, which puts it in the same family as the SARS (severe acute respiratory syndrome) virus and that Andrew Rambaut, PhD, administrator of Virological.org and professor of molecular

evolution at the University of Edinburgh, said on Twitter that nCoV is 89% similar to SARS-related bat coronavirus in the Sarbecovirus group of betacoronaviruses.

WHO Activities:

- WHO released [Technical guidance for novel coronavirus](#)

Sent: 7/2/2020 9:36:30 AM

Subject: RE: Question: (b)(4) (b)(5)

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June 29, 2020

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Sent: 7/1/2020 10:19:33 PM

Subject: Information for FRMM Members on Recent Report of Novel H1N1 Reassortant in Swine in China with Pandemic Potential

LETTER Emergence of Eurasian Avian-Like Swine Influenza A (H1N1) Virus from an Adult Case in Fujian Province, China Jian-Feng Xie 1,2 • Yan-Hua Zhang 1 • Lin Zhao 1 • Wen-Qiong Xiu 1 • Hong-Bin Chen 1 • Qi Lin 1 • Yu-Wei Weng 1,2 • Kui-Cheng Zheng 1,2 Published online: 24 May 2018 Wuhan Institute of Virology, CAS and Springer Nature Singapore Pte Ltd. 2018 Dear Editor, As we known, pigs play a vital role as genetic mixing vessels for human and avian influenza viruses as their tracheal epitheliums possess both sialic acid a-2,6-Gal and a-2,3-Gal receptors (Ma et al. 2008), and swine influenza viruses occasionally infect humans (Shinde et al. 2009). The Eurasian avian-like swine influenza A (H1N1) virus (EAS-H1N1) spread into China around 2007, when the first isolate (A/swine/Fujian/204/2007) from pigs in Fujian was reported via swine influenza surveillance program (Liu et al. 2009). Much later, three cases of EAS-H1N1 infection in human were reported in China and they were all children under the age of three (Yang et al. 2012; Wang et al. 2013; Zhu et al. 2016), whereas the forth case was an adult, who was confirmed in October, 2016, in Fujian province. The patient was a 46-year-old man with fever of 39 C and started coughing on October 19, 2016. In the day after onset, he was treated in a prefectural hospital on account of hemoptysis and dyspnea, and then he was transferred to the intensive care unit (ICU) of Fuzhou Pulmonary Hospital because of severe pneumonia on October 21. A throat-swab specimen of patient was collected and transferred to Fujian CDC rapidly with cryogenic storage container for confirming influenza virus. Clinical examination revealed white blood cell (WBC) count of 5.4 9 10 9 /L, blood platelet count of 27 9 10 9 /L, and creatinine 300 1mol/L. At last, the patient died on October 28 due to multi-organ failure. A retrospective investigation was conducted to identify the potential infection source and any other possible cases. The patient lived with his wife, son, brother and sister in an argillous house, with pigs, chickens, and ducks being bred around it. The patient had not the history of feeding poultry or swine and visiting live poultry market before he got sick. A total of 9 close contacts (6 family members and 3 healthcare workers) of the patient did not develop any influenza-like symptoms during the longest incubation period. On October 23, we collected 12 specimens (including 3 poultry drinking water samples, 3 poultry cage surface wipes, 1 chicken feces sample, 3 duck feces samples and 2 pig feces samples) from the surrounding environment where the patient lived, but no influenza viruses were identified at that time. A throat-swab specimen of the patient was collected and the virus was isolated using 9-to-10-days-old specific pathogen-free (SPF) embryonated chicken eggs in the Biosafety Level 3 Laboratory, terming influenza A/Fujiancangshan/SWL624/2016 (FJ/624/16) virus. To study the genomic characterization of FJ/624/16 virus, we sequenced the complete genomes of the viral isolate in November, 2016. Sequences were assembled using the SeqMan of the Lasergene Package (DNASTar Corporation, USA). Nucleotide alignments and phylogenetic tree were constructed using the MEGA version 6.0 software (the Biodesign Institute, USA) by the Neighbor-Joining method with 1000 bootstrap replicates as implemented. Phylogenetic analysis of genome showed that the isolate was a novel triple-reassortant H1N1 virus with genes containing from Eurasian avian-like swine (HA, NA), A (H1N1) pdm09 (PB2, PB1, PA, NP, M) and classical swine (NS) lineages (Tables 1, 2 and Fig. 1). Complete sequences of FJ/624/16 virus were 94.3%-98.2% and 91.2%-95.4% identical in all 8 gene segments with A/Hunan/42443/2015 virus and A/swine/Guangdong/1/2010 virus respectively. Jian-Feng Xie, Yan-Hua Zhang and Lin Zhao have contributed equally to this work. & Kui-Cheng Zheng kingdadi9909@126.com 1 Fujian Provincial Center for Disease Control and Prevention, Fujian Provincial Key Laboratory of Zoonoses Research, Fuzhou 350001, China 2 School of Public Health, Fujian Medical University, Fuzhou 350001, China 123 virologica Sinica (2018) 33:282-286 www.virosin.org <https://doi.org/10.1007/s12250-018-0034-1> www.springer.com/12250(0123456789(..-volV) (0123456789(..-volV) Nevertheless, the M gene segment of FJ/624/16 virus showed the highest homology (98.4%) with A/california/ 07/2009 virus than other viruses and shared the closely related with A (H1N1) pdm09 viruses via blast (the sequences of viruses from the Global Initiative on Sharing Avian Influenza Data, GISAID; Accession No. EPI_ISL_239998, EPI_ISL_206573, EPI_ISL_75321, EPI_ISL_227813, EPI_ISL_85649, EPI_ISL_138290 and EPI_ISL_33887). We compared the newly sequenced genomes with 3 available genomes of human influenza virus strains in public databases to determine if they had attained key molecular features associated with increased virulence in mammals, mammalian transmissibility, and antiviral resistance (Table 3). In this study, FJ/624/16 possessed E190D and D225E (H3 numbering) in HA protein, suggesting the preference to a-2,6-linked sialosides and increase in the binding force of H1N1 virus in human upper respiratory tract (Matrosovich et al. 2000; Zhu et al. 2016). FJ/624/16 was found to contain an amino acid motif PSIQSR * GL at its HA cleavage sites, a characteristic of low pathogenic influenza virus (Korteweg and Gu 2008). The amino acid substitutions (H274Y, N294S, et al.) associated with neuraminidase inhibitory drugs were not observed in the NA protein of FJ/624/16, indicating sensitivity to neuraminidase inhibitors, but an S31N substitution in M2 protein suggested resistant to adamantanes. In addition, our data showed that several amino acid residues of FJ/624/16 might increase viral virulence or adaptation in mammals, such as 89V and 591R in the PB2, 336M, 356R and 409N in the PA, 215A in the M1, and 42S in the NS1 (Nguyen et al. 2012; Gao et al. 2013; Yamada et al. 2010; Wang et al. 2016; Fan et al. 2009; Jiao et al. 2008). So far, a total of 4 human cases of Eurasian avian-like swine influenza A (H1N1) virus infection had been reported in China. All three cases reported previously were children under 3 years old, but the first adult case-patient was confirmed in China in this study, signifying the EASH1N1 virus infection was not confined to children. The 8 gene segments of human infection with EAS-H1N1 virus reported in China during 2011-2012 originated from Eurasian avian influenza virus, however, the two EAS-H1N1 viruses reported in China lately differed from those: HA and NA gene clustered with Eurasian avian influenza virus, and other 6 genes shared the closely related with A (H1N1) pdm09 virus or classical swine influenza virus by phylogenetic analysis, implying that the genes of A (H1N1) pdm09 virus might have been recombined in swine since 2009. According to previous reports and this study, human Table 1 Homology analysis of sequences of all genes identified in the A/Fujian-cangshan/ SWL624/2016 virus. Isolates

A/Fujian-cangshan/SWL624/2016 (identities %) PB2 PB1 PA HA NP NA M NS A/California/07/2009 97.8 97.9 97.3 55.7 97.8 88.4 98.4 91.0 A/Hunan/42443/2015 96.3 98.2 96.0 97.8 96.9 97.9 94.3 97.4 A/swine/Guangdong/1/2010 93.4 93.2 92.5 91.2 93.1 92.1 94.1 95.4 A/Jiangsu/1/2011 81.1 81.6 81.2 97.3 78.9 98.0 94.8 79.0 A/Hebei-Yuhua/SWL1250/2012 80.8 82.0 80.9 96.8 79.3 97.7 94.3 78.2 A/swine/Fujian/204/2007 81.3 81.8 81.9 95.5 79.4 96.0 94.4 78.6 PB, polymerase basic protein; PA, polymerase acidic protein; HA, hemagglutinin; NP, nucleocapsid protein; NA, neuraminidase; M, matrix; NS, nonstructural. Table 2 Genetic origin of A/Fujian-cangshan/SWL624/2016 virus isolated from human in Fujian, China. Isolates Lineage assigned to gene segment PB2 PB1 PA HA NP NA M NS A/Fujian-cangshan/SWL624/2016 a PDM PDM PDM EAS PDM EAS PDM CS A/Hunan/42443/2015 a PDM PDM PDM EAS PDM EAS EAS CS A/swine/Guangdong/1/2010 PDM PDM PDM EAS PDM EAS EAS CS A/Jiangsu/1/2011 a EAS EAS EAS EAS EAS EAS EAS EAS A/Hebei-Yuhua/SWL1250/2012 a EAS EAS EAS EAS EAS EAS EAS A/swine/Fujian/204/2007 EAS EAS EAS EAS EAS EAS EAS PDM, genes closest homology to A(H1N1)pdm09 viruses; EAS, genes with closest homology to Eurasian avian-like swine influenza viruses; CS, genes with closest homology to classical swine influenza viruses. a Human infection with Eurasian avian-like swine influenza virus. J.-F. Xie et al.: Eurasian Avian-Like Swine Influenza A (H1N1) Virus 283 123 Fig. 1 Phylogenetic analysis of all eight genes on A/Fujian-cangshan/SWL624/2016 virus. Red, light blue, green, and blue are marked at the A/Fujian-cangshan/SWL624/2016, A/Hunan/42443/2015, A/Hebei-Yuhua/SWL1250/2012 and A/Jiangsu/1/2011, respectively. The reliability of the trees was assessed via bootstrap analysis with 1000 replications. The horizontal distances are proportional to the genetic distance. Scale bars indicate nucleotide substitutions per site. 284 Virologica Sinica 123 infections with EAS-H1N1 virus might have been underestimated in China. To analyze the virulence, transmissibility and drugresistance of the EAS-H1N1 virus from the adult patient, we performed an in-depth analysis of genetic characteristics of the FJ/624/16 virus. The virus might preferentially bind to influenza virus-binding receptor of human upper respiratory tract due to the amino acid mutations E190D and D225E within HA protein, hinting the potential risk of human-to-human transmission. In addition, several amino acid residues of FJ/624/16 virus might increase viral virulence or adaptation in mammals, so the severity of disease caused by EAS-H1N1 should be valued in future studies. In our study, we found that the virus was resistant to adamantanes and sensitive to neuraminidase inhibitors, suggesting that early administration of oseltamivir or peramivir may help to reduce the severity of the disease. In summary, human infection with the EAS-H1N1 virus could lead to severe clinical syndrome, even death. However, increasing evidences show that the EAS-H1N1 virus becomes more adaptative to mammal infection, and was equipped with viral molecular basis of cross-species transmission (Yang et al. 2012; Wang et al. 2013; Zhu et al. 2016; Qiet al. 2012). Thus, it is a great significance to strengthen the surveillance for EAS-H1N1 virus among swine and humans, and virologic analyses to assess genetic changes of EAS-H1N1 virus also highlighted the great value to determine the viral transmissibility among humans and pandemic potential. Acknowledgements We thank Fuzhou Center for Disease Control and Prevention and Fuzhou Pulmonary Hospital for providing the sample. We acknowledge the contributions of authors and laboratories for sharing the influenza virus sequences in GISAID's EpiFlu Database. This study was supported by the fund of Natural Science Foundation of Fujian Province (2015J01294), the Youth Backbone Talents Cultivation Program of Health System in Fujian Province (2015-ZQNZD-10) and the National Science and Technology Major Project (2017ZX10103008). Compliance with Ethical Standards Conflict of interest The authors declare that they have no conflict of interest. Animal and Human Rights Statement The study was approved by the ethics committees of Fujian Provincial Center for Disease Control and Prevention. All participants provided written informed consent. Written consents were obtained from all participants involved in the study. 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Gene Function Mutation FJ/624/16 HN/42443/15 HB/1250/12 JS/1/11 FJ/204/07 GD/1/10 CA/07/09 HA Altered receptor specificity E190D D D D D D V D D225E E E E E G E D NA Antiviral resistance (Oseltamivir) H274Y H H H H H H H N294S N N N N N N N PB2 Enhanced polymerase activity L89 V V V V V V V V V V V Virus replication in mammals Q591R Q R Q Q Q R R E627 K E E E E E E D701 N D D N N N D D PA Increased polymerase activity in mice L336 M M M L L L L M Species-associated signature positions K356R R R K K K K R S409 N N N N N N N M1 Increased virulence in mice T215A A A A A A A M2 Antiviral resistance (Amantadine) S31 N N N N N N N N N N N S1 Increased virulence in mice P42S S S S S S S FJ/624/16, A/Fujian-cangshan/SWL624/2016; HN/42443/15, A/Hunan/42443/2015; HB/1250/12, A/Hebei-Yuhua/SWL1250/2012; JS/1/11, A/Jiangsu/1/2011; FJ/204/07, A/swine/Fujian/204/2007; GD/1/10, A/swine/Guangdong/1/2010; CA/07/09, A/California/07/2009. J.-F. 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infection with Eurasian avian-like influenza A (H1N1) virus, China. *Emerg Infect Dis* 19:1709–1711 Wang D, Yang L, Zhu W, Zhang Y, Zou S, Bo H, Gao R, Dong J, Huang W, Guo J, Li Z, Zhao X, Li X, Xin L, Zhou J, Chen T, Dong L, Wei H, Li X, Liu L, Tang J, Lan Y, Yang J, Shu Y (2016) Two outbreak sources of influenza A (H7N9) viruses have been established in China. *J Virol* 90:5561–5573 Yamada S, Hatta M, Staker BL, Watanabe S, Imai M, Shinya K, Sakai-Tagawa Y, Ito M, Ozawa M, Watanabe T, Sakabe S, Li C, Kim JH, Myler PJ, Phan I, Raymond A, Smith E, Stacy R, Nidom CA, Lank SM, Wiseman RW, Bimber BN, O'Connor DH, Neumann G, Stewart LJ, Kawaoka Y (2010) Biological and structural characterization of a host-adapting amino acid in influenza virus. *PLoS Pathog* 6:e1001034 Yang HL, Qiao CL, Tang X, Chen Y, Xin XG, Chen HL (2012) Human infection from avian-like influenza A (H1N1) viruses in pigs, China. *Emerg Infect Dis* 18:1144–1146 Zhu W, Zhang H, Xiang X, Zhong L, Yang L, Guo J, Xie Y, Li F, Deng Z, Feng H, Huang Y, Hu S, Xu X, Zou X, Li X, Bai T, Chen Y, Li Z, Li J, Shu Y (2016) Reassortant Eurasian avian-like influenza A(H1N1) virus from a severely ill child, Hunan province, China. *Emerg Infect Dis* 22:1930–1936 286 *Virologica Sinica* 123

Sent: 3/8/2021 3:44:21 PM
To: Tierney, Julia (Julia.Tierney@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Julia.Tierney]
CC: lorrie.mcneill@fda.hhs.gov; Maloney, Diane (Diane.Maloney@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=MaloneyD]
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Dear Julie,

I am pretty upset that CDC asked us to review this guidance for vaccinated individuals with a deadline of this morning, and then just went ahead with this without seeing our comments. I think that we had some useful suggestions. (We won't mention the wasted time we spent.) Can someone flag this for CDC possibly? We have been castigated for doing similar things to CDC in the past.

Best Regards,
Peter

From: Costa, Kevin <kevincosta@alumni.brown.edu>

Sent: Monday, March 8, 2021 3:37 PM

To: Michael S. Dukakis <m.dukakis@neu.edu>; Amesh Adalja <aadalja1@jhu.edu>; Alex Gorsky <agorsky@its.jnj.com>; Paula Annunziato <paula.annunziato@merck.com>; Johan Van Hoof <(b)(6)@gmail.com>; Xavier Becerra <xavier.becerra@doj.ca.gov>; Rochelle Walensky <RWALENSKY@mgh.harvard.edu>; Rachana Pradhan <rpradhan@kff.org>; Marcella Nunez-Smith <marcella.nunez-smith@yale.edu>; Sarah Mbaeyi <smbaeyi@cdc.gov>; Oliver, Sara E (CDC) <yxo4@cdc.gov>; Dooling, Kathleen L (CDC) <vic9@cdc.gov>; Dariush Mozaffarian <orsolya.szabo@tufts.edu>; Junxiu Liu <junxiu.liu@tufts.edu>; Frederick Cudhea <Frederick.Cudhea@tufts.edu>; Renata Micha <renata.micha@tufts.edu>; Meghan O'Hearn <Meghan.O_Hearn@tufts.edu>; Yves Smith <yves@nakedcapitalism.com>; Jesse Goodman <jlg251@georgetown.edu>; Gregory Poland <poland.gregory@mayo.edu>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Arnold S. Monto <asmonto@umich.edu>; Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>; Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>; Vert, Christina <Christina.Vert@fda.hhs.gov>; Devine, Jeannette <Jeannette.Devine@fda.hhs.gov>; Hill, Monique <Monique.Hill@fda.hhs.gov>; Cody Meissner <cmeissner@tuftsmedicalcenter.org>; Hayley Gans <hagans@stanford.edu>; Kurilla, Michael G (NIH) <michael.kurilla@nih.gov>; Steven Pergam <spergam@fhcrc.org>; Oveta Fuller <fullerao@umich.edu>; Eric Rubin <erubin@hsph.harvard.edu>; James Hildreth <officeofthepresident@mmc.edu>; Jay Portnoy <jportnoy@cmh.edu>; Jennette Lee <JYLee@uams.edu>; Mark Sawyer <mhsawyer@health.ucsd.edu>; Ofer Levy <ofer.levy@childrens.harvard.edu>; Patrick Moore <psm9@pitt.edu>; Stanley Perlman <stanley-perlman@uiowa.edu>; Macneil, Adam (CDC) <aho3@cdc.gov>; Rachel Levine <rll12@psu.edu>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Brian Castrucci <castrucci@beaumont.org>; Eric Lander <eric.s.lander@ostp.eop.gov>; Rana Hogarth <rhogarth@illinois.edu>; David Schildmeier <DSchildmeier@mnarn.org>; Mary Lou Hennebry <(b)(6)@hotmail.com>; Ezekiel Emanuel <zemanuel@upenn.edu>; Philip Landrigan <landrignp@bc.edu>; Messonnier, Nancy E (CDC) <nar5@cdc.gov>; Robert R. Redfield <olx1@cdc.gov>; Schuchat, Anne (CDC) <acs1@cdc.gov>; Brooks, John T (CDC) <zud4@cdc.gov>; Armstrong, Gregory L (CDC) <gca3@cdc.gov>; Yong-Zhen Zhang <zhangyongzhen@shphc.org.cn>; George Gao <gaof@im.ac.cn>; Lawrence Gostin <gostin@law.georgetown.edu>; Yanzhong Huang <yanzhong.huang@shu.edu>; Ian Lipkin <wil2001@columbia.edu>; Edward Holmes <edward.holmes@sydney.edu.au>; Peter Daszak <daszak@ecohealthalliance.org>; Wang Linfa <linfa.wang@duke-nus.edu.sg>; Dake Kang <dkang@ap.org>; James Palmer <james.palmer@foreignpolicy.com>; Wang Guangfa <(b)(6)@hotmail.com>; Gauden Galea <GaleaG@who.int>; Andrew Rambaut <a.rambaut@ed.ac.uk>; Maria Van Kerkhove <m.vankerkhove@imperial.ac.uk>; Ngozi Ezike <Ngozi.Ezike@illinois.gov>; Courtney Phillips <Courtney.Phillips@la.gov>; Jill Hunsaker Ryan <Jill.Ryan@state.co.us>; John Barry <(b)(6)@aol.com>; Andrew Stanley Pekosz <apekosz1@jhu.edu>; Aaron David Miller <Aaron.Miller@ceip.org>; John Komlos <John.Komlos@gmx.de>; Libby Watson <(b)(6)@gmail.com>; Peter Hotez <hotez@bcm.edu>; Orsega, Susan (OS) <Susan.Orsega@hhs.gov>; Jason Schwartz <jason.l.schwartz@yale.edu>; Amy Zheng <amzheng@ucsd.edu>; Atul

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Subject: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

MARCH 8, 2021 | CLIP OF WHITE HOUSE COVID-19 RESPONSE TEAM BRIEFING
CDC Issues New Guidelines for Fully Vaccinated Individuals
CDC Director Rochelle Walensky announces new guidelines for people who have been fully vaccinated. Individuals must have had their final shot two weeks prior and can meet in another household without wearing a mask with people who have not yet being vaccinated--unless there is a high-risk individual in that household. Fully vaccinated individuals should continue to wear masks in public settings, avoid large crowds, maintain physical distance and wash their hands. Travel guidelines remain unchanged for everyone, Dr. Walensky says.

<https://www.c-span.org/video/?c4950597/cdc-issues-guidelines-fully-vaccinated-individuals#> **(3 minute video)**



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On Mon, Mar 8, 2021 at 11:20 AM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

The White House COVID-19 response team holds a briefing on the administration's efforts to combat the pandemic.

<https://www.c-span.org/video/?509660-1/white-house-covid-19-response-team-briefing&live>

Best regards,

Kevin Costa

From: Costa, Kevin [kevincosta@alumni.brown.edu]
Sent: 3/10/2021 6:46:13 PM
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Subject: [EXTERNAL] Fwd: BREAKING: CMS Releases New Visitation Guidance for Nursing Homes

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From: **National Consumer Voice for Quality Long-Term Care** <info@theconsumervoice.org>

Date: Wed, Mar 10, 2021 at 5:54 PM

Subject: BREAKING: CMS Releases New Visitation Guidance for Nursing Homes

To: Kevin Costa <kevincosta@alumni.brown.edu>

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CMS Releases New Guidance Around Visitation for Nursing Homes

Today, the Centers for Medicare & Medicaid Services (CMS) released new guidance around visitation for nursing homes. It is effective immediately.

After a year of significant restrictions imposed because of COVID-19, the new guidance allows indoor and outdoor visits for all residents, except in limited circumstances. Infection prevention protocols are still in place and must be followed by all visitors. Visitation is allowed regardless of vaccination status.

Limitations on visitation may occur: for unvaccinated residents if the COVID-19 county positivity rate is greater than 10% and less than 70% of residents in the facility are fully vaccinated; for residents with COVID-19, regardless of vaccination status, until they have met criteria to discontinue precautions; or for residents in quarantine, regardless of vaccination status, until they have met criteria to be released from quarantine.

Compassionate care visits should be allowed at all times, regardless of vaccination status, an outbreak in the facility, or the county's positivity rate.

While CMS and CDC recommend that the core principles of infection prevention be followed at all times, including physical distancing, if a resident is fully vaccinated, they can choose to have close contact (including touch) with their visitor while wearing a well-fitting mask and performing hand hygiene.

The guidance can be found on the CMS website - [QSO-20-39-NH REVISED](#). Also, see the [fact sheet](#) on the guidance from CMS.

The Consumer Voice will be sharing more information in the coming days. Sign up for our [Action Network](#) or follow us on social media ([Facebook](#) and [Twitter](#)) for updates.

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National Consumer Voice for Quality Long-Term Care

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Subject: [EXTERNAL] The 2021 Medicare for All Bill

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The 2021 Medicare for All Bill

We're joined by Stephanie Kang from Rep. Pramila Jayapal's office to discuss the upcoming Medicare for All Act, which will be reintroduced on Tuesday, March 17th.

<https://www.facebook.com/HealthcareNow/videos/425303672105749/>

Best regards,

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Subject: [EXTERNAL] President Biden visited the Washington, DC veterans medical center with VA Secretary Denis McDonough. He observed COVID-19 vaccine doses being prepared and administered to veterans.

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President Biden visited the Washington, DC veterans medical center with VA Secretary Denis McDonough. He observed COVID-19 vaccine doses being prepared and administered to veterans.

<https://www.c-span.org/video/?509663-1/president-biden-visits-va-medical-center-vaccination-site>

Best regards,

Kevin Costa



Virus-free. www.avast.com

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Subject: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Appalling that ventilation and aerosols never make it into CDC briefings as bullet points.

* * *

Every communication from this account is off the record, unless explicitly put on the record.

On Monday, March 8, 2021, 03:37:19 PM EST, Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

MARCH 8, 2021 | CLIP OF WHITE HOUSE COVID-19 RESPONSE TEAM BRIEFING
CDC Issues New Guidelines for Fully Vaccinated Individuals
CDC Director Rochelle Walensky announces new guidelines for people who have been fully vaccinated. Individuals must have had their final shot two weeks prior and can meet in another household without wearing a mask with people who have not yet being vaccinated--unless there is a high-risk individual in that household. Fully vaccinated individuals should continue to wear masks in public settings, avoid large crowds, maintain physical distance and wash their hands. Travel guidelines remain unchanged for everyone, Dr. Walensky says.

<https://www.c-span.org/video/?c4950597/cdc-issues-guidelines-fully-vaccinated-individuals#> **(3 minute video)**



Virus-free. www.avast.com

On Mon, Mar 8, 2021 at 11:20 AM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

The White House COVID-19 response team holds a briefing on the administration's efforts to combat the pandemic.

<https://www.c-span.org/video/?509660-1/white-house-covid-19-response-team-briefing&live>

Best regards,

Kevin Costa

From: Costa, Kevin [kevincosta@alumni.brown.edu]
Sent: 3/10/2021 2:22:25 AM
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Subject: [EXTERNAL] Public Health Leaders Testify on COVID-19 Response

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Public Health Leaders, Ashish Jha, Umair Shah, Jerry Abraham, Mary Ann Fuchs Testify on COVID-19 Response

Public health leaders testified before the Senate Health, Education, Labor and Pensions Committee about the U.S. COVID-19 response one year after the pandemic began.

<https://www.c-span.org/video/?509636-1/public-health-leaders-testify-covid-19-response>

Best regards,

Kevin Costa

From: Maloney, Diane [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E59205500E944C9EACC4524EA18ED5BB-MALONEYD]
Sent: 3/8/2021 3:46:04 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Thanks, Peter. I wondered about this as well and thought addressing your comments would have resulted in a clearer document.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 8, 2021 3:45 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Dear Julie,

I am pretty upset that CDC asked us to review this guidance for vaccinated individuals with a deadline of this morning, and then just went ahead with this without seeing our comments. I think that we had some useful suggestions. (We won't mention the wasted time we spent.) Can someone flag this for CDC possibly? We have been castigated for doing similar things to CDC in the past.

Best Regards,
Peter

From: Costa, Kevin <kevincosta@alumni.brown.edu>
Sent: Monday, March 8, 2021 3:37 PM
To: Michael S. Dukakis <m.dukakis@neu.edu>; Amesh Adalja <aadalja1@jhu.edu>; Alex Gorsky <agorsky@its.jnj.com>; Paula Annunziato <paula.annunziato@merck.com>; Johan Van Hoof <(b)(6)@gmail.com>; Xavier Becerra <xavier.becerra@doj.ca.gov>; Rochelle Walensky <RWALENSKY@mgh.harvard.edu>; Rachana Pradhan <rpradhan@kff.org>; Marcella Nunez-Smith <marcella.nunez-smith@yale.edu>; Sarah Mbaeyi <smbaeyi@cdc.gov>; Oliver, Sara E (CDC) <yxo4@cdc.gov>; Dooling, Kathleen L (CDC) <vic9@cdc.gov>; Dariush Mozaffarian <orsolya.szabo@tufts.edu>; Junxiu Liu <junxiu.liu@tufts.edu>; Frederick Cudhea <Frederick.Cudhea@tufts.edu>; Renata Micha <renata.micha@tufts.edu>; Meghan O'Hearn <Meghan.O Hearn@tufts.edu>; Yves Smith <yves@nakedcapitalism.com>; Jesse Goodman <jlg251@georgetown.edu>; Gregory Poland <poland.gregory@mayo.edu>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Arnold S. Monto <asmonto@umich.edu>; Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>; Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>; Vert, Christina <Christina.Vert@fda.hhs.gov>; Devine, Jeannette <Jeannette.Devine@fda.hhs.gov>; Hill, Monique <Monique.Hill@fda.hhs.gov>; Cody Meissner <cmeissner@tuftsmedicalcenter.org>; Hayley Gans <hagans@stanford.edu>; Kurilla, Michael G (NIH) <michael.kurilla@nih.gov>; Steven Pergam <spergam@fhcrc.org>; Oveta Fuller <fullerao@umich.edu>; Eric Rubin <erubin@hsph.harvard.edu>; James Hildreth <officeofthepresident@mmc.edu>; Jay Portnoy <jportnoy@cmh.edu>; Jennette Lee <JYLee@uams.edu>; Mark Sawyer <mhsawyer@health.ucsd.edu>; Ofer Levy <ofer.levy@childrens.harvard.edu>; Patrick Moore <psm9@pitt.edu>; Stanley Perlman <stanley-perlman@uiowa.edu>; Macneil, Adam (CDC) <aho3@cdc.gov>; Rachel Levine <rll12@psu.edu>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Brian Castrucci <castrucci@beaumont.org>; Eric Lander <eric.s.lander@ostp.eop.gov>; Rana Hogarth <rhogarth@illinois.edu>; David Schildmeier <DSchildmeier@mnarn.org>; Mary Lou Hennebry <(b)(6)@hotmail.com>; Ezekiel Emanuel <zemanuel@upenn.edu>; Philip Landrigan <landrigp@bc.edu>; Messonnier, Nancy E (CDC) <nar5@cdc.gov>; Robert R. Redfield <olx1@cdc.gov>; Schuchat, Anne (CDC) <acs1@cdc.gov>; Brooks, John T (CDC) <zud4@cdc.gov>; Armstrong, Gregory L (CDC) <gca3@cdc.gov>; Yong-Zhen

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Subject: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

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MARCH 8, 2021 | CLIP OF WHITE HOUSE COVID-19 RESPONSE TEAM BRIEFING
CDC Issues New Guidelines for Fully Vaccinated Individuals
CDC Director Rochelle Walensky announces new guidelines for people who have been fully vaccinated. Individuals must have had their final shot two weeks prior and can meet in another household without wearing a mask with people who have not yet being vaccinated--unless there is a high-risk individual in that household. Fully vaccinated individuals should continue to wear masks in public settings, avoid large crowds, maintain physical distance and

wash their hands. Travel guidelines remain unchanged for everyone, Dr. Walensky says.

<https://www.c-span.org/video/?c4950597/cdc-issues-guidelines-fully-vaccinated-individuals#> **(3 minute video)**



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On Mon, Mar 8, 2021 at 11:20 AM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

The White House COVID-19 response team holds a briefing on the administration's efforts to combat the pandemic.

<https://www.c-span.org/video/?509660-1/white-house-covid-19-response-team-briefing&live>

Best regards,

Kevin Costa

From: Costa, Kevin [kevincosta@alumni.brown.edu]
Sent: 3/10/2021 5:19:55 PM
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Subject: [EXTERNAL] MARCH 10, 2021 - White House COVID-19 Response Team Briefing

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MARCH 10, 2021

White House COVID-19 Response Team Briefing

The White House gave an update on the federal response to the coronavirus pandemic. COVID-19 adviser Andy Slavitt announced President Biden is ordering an additional 100 million doses of the Johnson & Johnson vaccine that would be used later in the year. Infectious disease expert Dr. Anthony Fauci said pregnant women can choose to get the vaccine, later adding the antibodies will likely transfer to the fetus during the pregnancy.

<https://www.c-span.org/video/?509764-1/white-house-covid-19-response-team-briefing>

Best regards,

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Subject: [EXTERNAL] Dr. Amesh Adalja on the U.S. COVID-19 Pandemic Response

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Dr. Amesh Adalja on the U.S. COVID-19 Pandemic Response

Dr. Amesh Adalja, of Johns Hopkins University's Center for Health Security, discussed the latest developments in efforts to combat COVID-19, including vaccinations and the impacts of variants.

<https://www.c-span.org/video/?509562-3/washington-journal-dr-amesh-adalja-discusses-us-covid-19-pandemic-response>

Best regards,

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Subject: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

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MARCH 8, 2021 | CLIP OF WHITE HOUSE COVID-19 RESPONSE TEAM BRIEFING
CDC Issues New Guidelines for Fully Vaccinated Individuals
CDC Director Rochelle Walensky announces new guidelines for people who have been fully vaccinated. Individuals must have had their final shot two weeks prior and can meet in another household without wearing a mask with people who have not yet being vaccinated--unless there is a high-risk individual in that household. Fully vaccinated individuals should continue to wear masks in public settings, avoid large crowds, maintain physical distance and wash their hands. Travel guidelines remain unchanged for everyone, Dr. Walensky says.

<https://www.c-span.org/video/?c4950597/cdc-issues-guidelines-fully-vaccinated-individuals#> **(3 minute video)**



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On Mon, Mar 8, 2021 at 11:20 AM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

The White House COVID-19 response team holds a briefing on the administration's efforts to combat the pandemic.

<https://www.c-span.org/video/?509660-1/white-house-covid-19-response-team-briefing&live>

Best regards,

Kevin Costa

From: Costa, Kevin [kevincosta@alumni.brown.edu]
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Subject: [EXTERNAL] Dr. Fauci & CDC Director Walensky Address Congressional City Conference

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Dr. Fauci & CDC Director Walensky Address Congressional City Conference

National Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci and CDC Director Dr. Rochelle Walensky are among the featured speakers on the first day of the 2021 Congressional City Conference

<https://www.c-span.org/video/?509640-1/transportation-secretary-buttigieg-dr-fauci-amp-cdc-director-walensky-address-congressional-city>

Best regards,

Kevin Costa



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CC: Mike Bowen [mike@prestigeam.com]

Subject: [EXTERNAL] President Biden Hosts Event with Johnson & Johnson CEO Alex Gorsky, and Merck CEO Ken Frazier

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President Biden Hosts Event with Johnson & Johnson CEO Alex Gorsky, and Merck CEO Ken Frazier

President Biden Hosts Event with Johnson & Johnson CEO Alex Gorsky and Merck CEO Ken Frazier, where he announces the purchase of another 100 million vaccine doses to fully vaccinate every American. "A vaccinated America is the only way to beat the pandemic," he says.

<https://www.c-span.org/video/?509757-1/president-biden-announces-plan-purchase-additional-100-million-single-shot-covid-19-vaccines>

Best regards,

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Subject: [EXTERNAL] White House COVID-19 Response Team Briefing - MARCH 8, 2021

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The White House COVID-19 response team holds a briefing on the administration's efforts to combat the pandemic.

<https://www.c-span.org/video/?509660-1/white-house-covid-19-response-team-briefing&live>

Best regards,

Kevin Costa

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Subject: [EXTERNAL] Confirmation Hearing for Surgeon General and Assistant Health Secretary Nominees

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Confirmation Hearing for Surgeon General and Assistant Health Secretary Nominees

Surgeon General Nominee Dr. Vivek Murthy and Assistant Secretary for Health Nominee Dr. Rachel Levine spoke about their prior professional experience and how it prepared them to manage the coronavirus pandemic during their confirmation hearing before the Senate Health, Education, Labor and Pensions Committee. Both nominees said managing the pandemic would be a priority if confirmed. They also spoke about addressing other public health issues such as the opioid crisis, mental health and depression, and underage drug use. During the hearing, Sen. Rand Paul (R-KY) questioned Dr. Levine, who if confirmed would be the highest-ranking transgender public official in the U.S., about her thoughts on children undergoing medical treatment to change their gender, calling the treatment “genital mutilation.” Later, Chair Patty Murray (D-WA) warned members to be respectful of the witnesses during questioning.

<https://www.c-span.org/video/?509143-1/confirmation-hearing-surgeon-general-assistant-health-secretary-nominees>

Best regards,

Kevin Costa

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Subject: [EXTERNAL] HHS Secretary Nominee Xavier Becerra Testifies Before Senate Finance Committee

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HHS Secretary Nominee Xavier Becerra Testifies Before Senate Finance Committee

Health and Human Services Secretary Nominee Xavier Becerra testified at a confirmation hearing before the Senate Finance Committee.

<https://www.c-span.org/video/?509117-1/hhs-secretary-nominee-xavier-becerra-testifies-senate-finance-committee>

Best regards,

Kevin Costa

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Subject: [EXTERNAL] Why You Can't Find An N95 Mask Despite Plenty For Sale

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Why You Can't Find An N95 Mask Despite Plenty For Sale

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Best regards,

Kevin Costa

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Subject: [EXTERNAL] Health and Human Services Secretary Nominee Xavier Becerra Testifies at Confirmation Hearing

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Health and Human Services Secretary Nominee Xavier Becerra Testifies at Confirmation Hearing

The Senate Health Committee held a confirmation hearing to consider the nomination of Xavier Becerra to serve as the next Health and Human Services secretary. Lawmakers questioned the nominee on a range of issues including COVID-19 vaccine distribution, guidelines for reopening schools, rural health care access, prescription drug costs and mental health services. Mr. Becerra currently serves as the attorney general for California.

<https://www.c-span.org/video/?509069-1/health-human-services-secretary-nominee-xavier-becerra-testifies-confirmation-hearing#>

Best regards,

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Subject: [EXTERNAL] Biden Administration to distribute 25 million masks to community health centers and food banks .

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White House COVID-19 Response Team Briefing The White House COVID-19 response team provides an update on the federal response to the pandemic. Coordinator Jeff Zients says they will distribute 25 million masks to community health centers and food banks in March at a cost of \$86 million.

<https://www.c-span.org/video/?509299-1/biden-administration-distribute-25-million-masks-health-centers-food-banks>

Best regards,

Kevin Costa

From: Costa, Kevin [kevincosta@alumni.brown.edu]
Sent: 2/24/2021 9:32:37 PM
To: Nurses' Campaign To Win Medicare For All [info@medicare4all.org]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Xavier Becerra [xavier.becerra@doj.ca.gov]; Brian Castrucci [castrucci@beaumont.org]; Eric Lander [eric.s.lander@ostp.eop.gov]; Rana Hogarth [rhogarth@illinois.edu]; Marcella Nunez-Smith [marcella.nunez-smith@yale.edu]; Rochelle Walensky [RWALENSKY@mgm.harvard.edu]; David Schildmeier [DSchildmeier@mnarn.org]; Mary Lou Hennebry [(b)(6)]@hotmail.com; Ezekiel Emanuel [zemanuel@upenn.edu]; Philip Landrigan [landrigp@bc.edu]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Robert R. 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Subject: [EXTERNAL] Fwd: [Before Feb 28] Get in your application

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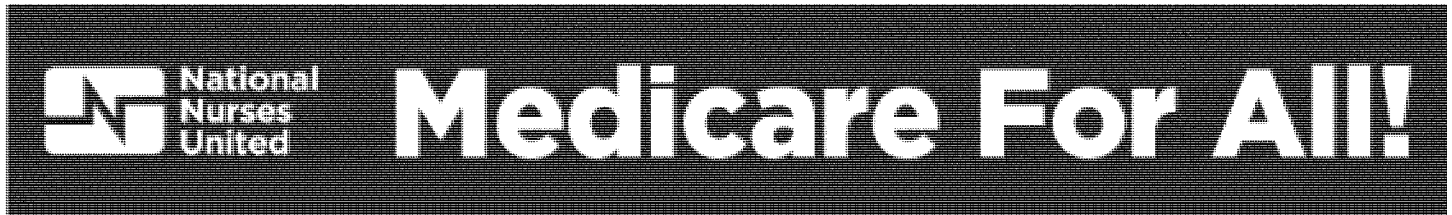
----- Forwarded message -----

From: **Max Cotterill** <info@medicare4all.org>

Date: Wed, Feb 24, 2021 at 7:43 PM

Subject: [Before Feb 28] Get in your application

To: Kevin Costa <kevincosta@alumni.brown.edu>



The deadline is coming up, Kevin.

Applications for our exciting Medicare for All Leadership School — a free two-month program to help develop your organizing skills — are due **THIS Sunday, February 28.**

We want to make sure our most dedicated supporters like you, Kevin, are able to get your applications in, and here's why: The more people we have with a clear local action plan fighting for Medicare for All in their communities, the more quickly and effectively we'll win — and this training program will do just that.

Our program, starting March 31, will teach you the skills you need to take your skills to the next level, grow and develop your confidence as an organizer for the long haul, and teach you how to lead the fight for Medicare for All in your community.

We want you to apply, Kevin. Please fill out the *Medicare for All Leadership School* interest form and complete the full written or video application before the deadline THIS Sunday, February 28.

APPLY NOW »

If you have any friends or family you think should apply as well, please share the application with them! We will be accepting 20 - 30 people for the first session of the Leadership School and plan to offer additional sessions later in the year.

There's a reason why we set up this opportunity now. We have a new window of opportunity with Democrats in control of the House, Senate, and Presidency. In order to take advantage of this moment, we need to scale up our on-the-ground organizing to push our leaders to pass Medicare for All.

This training is for everyone – those new to organizing or seasoned organizers! We'll help you become an even more effective agent of change for Medicare for All in your community.

The more people we have with a clear local plan of action fighting for Medicare for All in their communities – the more quickly and effectively we'll win.

The school will require a time commitment of roughly 5 hours per week for two months, and you must be able to participate through the duration of the course.

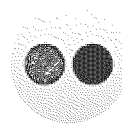
Please submit your application before THIS Sunday, February 28, and reply to this email if you have any questions.

Excited to get started.

Max Cotterill

Organizer

Nurses' Campaign for Medicare for All



Email us: info@medicare4all.org

This email was sent to kevincosta@alumni.brown.edu.



Virus-free. www.avast.com

From: Costa, Kevin [kevincosta@alumni.brown.edu]
Sent: 2/25/2021 4:38:30 PM
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Subject: [EXTERNAL] President Biden Hosts Ceremony for 50 Millionth COVID-19 Vaccine

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President Biden Hosts Ceremony for 50 Millionth COVID-19 Vaccine

President Biden and Vice President Harris participate in an event commemorating the 50 millionth COVID-19 vaccine shot. The president also urges Americans to not let their guard down as new variants could cause another surge in cases in the spring.

<https://www.c-span.org/video/?509332-1/president-biden-delivers-remarks-administering-50-millionth-covid-19-vaccine>

Best regards,

Kevin Costa

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Subject: Biden moving to withdraw Trump-approved Medicaid work rules

Biden moving to withdraw Trump-approved Medicaid work rules

Democrats long complained the rules were illegal and aimed at shrinking health coverage for poor adults.

<https://www.politico.com/news/2021/02/11/biden-withdraws-trump-medicaid-rules-468759?fbclid=IwAR3D4Eq7kpp4AjFczt3kvjQPHOqe7p9jmYVA9cqSIXMOXtWWAmrYou1Ro>

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Subject: New Allegations of Cover-Up by Cuomo Over Nursing Home Virus Toll

New Allegations of Cover-Up by Cuomo Over Nursing Home Virus Toll

In a private conversation, the governor's top aide admitted that data was withheld on nursing homes, where more than 10,000 New Yorkers have died during the pandemic.

<https://www.nytimes.com/2021/02/12/nyregion/new-york-nursing-homes-cuomo.html>

Best regards,

Kevin Costa



Virus-free. www.avast.com

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Subject: Fwd: Join the Twitter Storm Today and Sign the Petition to Open Nursing Home Doors

----- Forwarded message -----

From: **National Consumer Voice for Quality Long-Term Care** <info@theconsumervoice.org>

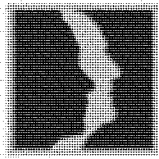
Date: Fri, Feb 12, 2021 at 9:32 AM

Subject: Join the Twitter Storm Today and Sign the Petition to Open Nursing Home Doors

To: Kevin Costa <kevincosta@alumni.brown.edu>

[View this message on our website.](#)

National Consumer Voice for Quality Long-Term Care



ACTION ALERT

The louder our voice, the stronger our advocacy.

SHARE:  

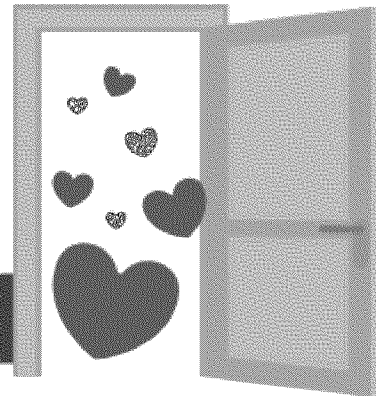
Open Nursing Home Doors!

Join Us for a Twitter Storm TODAY
and
Sign Our Petition

HAVE A HEART

It's been almost a year since
nursing homes closed.

#OpenNursingHomeDoors



It's been almost one year since nursing homes shut their doors. Take part in a Valentine's Day Twitter Storm TODAY urging CMS and members of Congress to **#HaveAHeart** and **#OpenNursingHomeDoors** so nursing home residents can be reunited with their loved ones.

How to Participate:

1. Tweet today tagging CMS ([@CMSgov](#) and [@CMSgovPress](#)) and your federal legislators to ask them to **#HaveAHeart** and **#OpenNursingHomeDoors**
 - Find out who your members of Congress are.
 - Find your members' Twitter handles.
2. If you have a friend or loved one who lives in a nursing home or you are a nursing home resident: Personalize your tweet with your story ([see examples](#)) and include a photo of your friend/loved one or yourself.
3. If you don't have anyone in a nursing home, share your thoughts about what residents are experiencing ([see examples](#)). Download and attach our [#OpenNursingHomeDoors graphic](#).

4. Tag us [@ConsumerVoices](#)

By using a common hashtag and tagging CMS and your representatives, our voices will be amplified!

Don't have a Twitter account?

1. You can [sign up](#) - it's easy and free!
2. On Facebook, tag us [@theconsumervoice](#) and use the same hashtags. Plus, add [this frame](#) to your Facebook profile picture for the month.

Forward this message to your friends and family! Encourage them to join our Valentine's Day Twitter Storm!

For more information about reuniting nursing home residents with their loved ones and details about today's Twitter Storm, visit our website.

We Must Reunite Nursing Home Residents with Their Loved Ones Now - Sign the Petition

On March 13, 2021, it will be one year since state and federal officials banned visits in nursing homes. Initially put in place to protect residents from COVID-19, the visitation ban has resulted in tens of thousands of residents suffering and dying from isolation, loneliness, and poor care. It is time to stop the suffering and open the doors.

Sign the petition to call on federal and state officials to immediately:

- Allow every resident to designate an Essential Support Person (ESP). ESPs must be allowed unrestricted access to the resident who has designated them in order to provide physical and emotional support, as well as assistance in meeting the resident's needs. ESPs should be treated as employees of the facility for infection control purposes, including routine COVID-19 testing and the wearing of PPE.
- Allow general indoor and outdoor visitation for all residents in accordance with the CMS Core Principles of COVID-19 Infection Prevention consistent with CDC guidance. Visitation must occur in addition to resident designation of an ESP. Length and number of visits must be in accordance with a resident's needs and preferences but be at least one hour weekly. Visitation must occur regardless of the level of COVID-19 positivity in the surrounding community or in the facility.

Safe visitation and support for residents are possible through proper infection control procedures. Importantly, residents will be reunited with their loved ones after a year of being isolated alone without proper care.

Sign the Petition Now

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National Consumer Voice for Quality Long-Term Care

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Subject: How Trump Affected Americans' Health

February 11, 2021



By **Giovanni Russonello**



President Donald Trump tossing masks into a crowd at a rally in Sanford, Fla., in October. Jonathan Ernst/Reuters

Former President Donald Trump stands accused of inciting a riot that left at least five people dead and more than 100 police officers injured.

But according to a new report from The Lancet, a respected medical journal, that's just the tip of the iceberg when it comes to the harm that Trump did to public health during his time in office.

Released today, the [49-page report](#) ticks off the health effects of Trump's policies on everything from the environment to taxes to Covid-19. And the results aren't pretty.

Soon after Trump took office in 2017, The Lancet established the Commission on Public Policy and Health in the Trump Era to study the health impact of his decisions in the White House. Over the past four years, the commission analyzed his policies as they took shape while seeking to place them in a broader historical context.

They found that Trump's mismanagement of the coronavirus pandemic caused tens of thousands of deaths that might have been avoided if the country's response had been more effectively coordinated.

"I think the huge number of deaths from Covid, compared to the other G7 wealthy nations, was striking," said Steffie Woolhandler, a co-chairman of the committee and a distinguished professor at Hunter College in New York.

But even before the pandemic, the report found, Trump's attempts to dismantle the Affordable Care Act had increased the number of uninsured Americans by two million to three million people.

His trillion-dollar tax cuts primarily benefited high-income Americans, while stripping the federal government of resources that it had used to pay for social-welfare programs.

“Even prior to the pandemic,” said Woolhandler, a physician, “the United States’ policies had so thoroughly failed to provide the conditions to protect health that 461,000 people who died in 2018 would have survived if our death rate were the same as other healthy nations.”

Yet she noted that many of the United States’ public health problems predated not only the pandemic, but also the Trump administration. In many cases, the authors wrote, the health decline under Trump was only a continuation of a broader trend — one that seems to have begun in the early 1980s.

“In 1980, life expectancy in the United States was the same as in all our developed nation counterparts — Germany, France, Japan,” said Kevin Grumbach, a member of the commission and a professor at the University of California, San Francisco. “Every year since 1980, the U.S. started falling farther and farther behind these other nations. So now we are three or four years behind the average life expectancy of these other nations.”

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Grumbach, who is also a physician, said that over the same period, the cost of health care had risen far more quickly in the United States than in other nations — a trend that Trump contributed to. The report found that his administration increased the privatization of government health programs like Medicare, most likely leading to a rise in costs for consumers.

The report also concluded that by loosening scores of regulations, Trump caused environmental harm that led to the deaths of over 22,000 people in 2019 alone. That was significantly more than had died for similar reasons in 2016.

“That was very surprising, because it’s one area the United States has been improving on in recent decades,” Woolhandler said. “And Trump very quickly managed to reverse the progress.”

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Subject: President Biden Gives Remarks at National Institutes of Health

President Biden Gives Remarks at National Institutes of Health

In remarks at the National Institutes of Health (NIH), President Biden criticizes President Trump, saying he did not do his job and that there was no federal plan for vaccines. He pledges to ramp up vaccinations, but says it will take time.

<https://www.c-span.org/video/?508926-1/president-biden-urges-country-mask-deadliest-month-pandemic>

Best regards,

Kevin Costa



Virus-free. www.avast.com

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Subject: Fwd: BREAKING NEWS: Senate acquits Trump of inciting deadly Capitol attack

----- Forwarded message -----

From: **POLITICO** <alert@email.politico.com>

Date: Sat, Feb 13, 2021 at 3:53 PM

Subject: BREAKING NEWS: Senate acquits Trump of inciting deadly Capitol attack

To: <KevinCosta@alumni.brown.edu>

The Senate voted to acquit former President Donald Trump on the House's charge of inciting the Jan. 6 insurrection at the Capitol.

The 57-43 vote marks the first time since 1868 that a majority of the Senate voted to convict a president on an impeachment charge. But it still fell short of the two-thirds majority needed to secure a conviction. The seven Republicans who broke ranks are by far the most to support the conviction of a president from their own party.

The vote marks the second time in 13 months that Trump was acquitted by the Senate on impeachment charges brought by the House. The verdict followed a brief but emotional trial at which House prosecutors displayed hours of footage of violence wrought by a pro-Trump mob.

Trump's attorneys maintained that it was unconstitutional to try a former president for impeachment and said the House managers did not meet the standard for an incitement charge.

Read [more](#).

POLITICO

This email was sent to KevinCosta@alumni.brown.edu by: POLITICO, LLC 1000 Wilson Blvd. Arlington, VA, 22209, USA

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Subject: Public policy and health in the Trump era

Public policy and health in the Trump era

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Best regards,

Kevin Costa



Virus-free. www.avast.com

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Subject: Four potential COVID-19 therapeutics enter Phase 2/3 testing in NIH ACTIV-2 trial

Four potential COVID-19 therapeutics enter Phase 2/3 testing in NIH ACTIV-2 trial

<https://www.nih.gov/news-events/news-releases/four-potential-covid-19-therapeutics-enter-phase-2-3-testing-nih-activ-2-trial?fbclid=IwAR1uFrVyosoopiya-KGBkoxcf1kEibL8KPj2Jzi4ojAXjytSkAQQ8Nbifho>

Best regards,

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Subject: President Biden Visits NIH Viral Pathogenesis Laboratory

Flag: Follow up

President Biden Visits NIH Viral Pathogenesis Laboratory

President Biden visited the Viral Pathogenesis Laboratory at the National Institutes of Health (NIH) in Bethesda, Maryland. He spoke with Viral Pathogenesis Lab Chief Dr. Barney Graham and COVID-19 Vaccine Program Scientific Lead Kizzmekia Corbett. They discussed development of the vaccine and challenges posed by the coronavirus variants. NIH Director Dr. Francis Collins and National Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci joined the president on the tour.

<https://www.c-span.org/video/?508940-1/president-biden-visits-nih-viral-pathogenesis-laboratory>

Best regards,

Kevin Costa



Virus-free. www.avast.com

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Subject:

FEBRUARY 10, 2021 - White House COVID-19 Response Team Briefing

FEBRUARY 10, 2021 - White House COVID-19 Response Team Briefing
<https://www.c-span.org/video/?508882-1/white-house-covid-19-response-team-briefing>

Best regards,

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Subject: Operational Strategy for K-12 Schools through Phased Mitigation - Updated Feb. 12, 2021

Operational Strategy for K-12 Schools through Phased Mitigation - Updated Feb. 12, 2021

<https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html>

Best regards,

Kevin Costa

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Sent: 2/3/2021 1:31:57 AM
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Subject: CHINA'S COVID SECRETS

CHINA'S COVID SECRETS

The untold story of the beginning of the coronavirus pandemic and how China responded. Chinese scientists and doctors, international disease experts and health officials reveal missed opportunities to suppress the outbreak and lessons for the world.

<https://www.pbs.org/wgbh/frontline/film/chinas-covid-secrets/>

Best regards,

Kevin Costa

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 3/8/2021 4:26:00 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
CC: Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Dear Julie,

Sorry – I meant to add the quotation marks to “guidance” when describing their recommendations. 😊

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, March 8, 2021 4:24 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Thanks. I had assumed that it was “guidance” so that’s a helpful clarification.

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Monday, March 8, 2021 4:10 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Hi Julie –

We were asked to send comments back by 10:00am, and I sent to OMA at 9:44am.

Lorrie

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 8, 2021 4:03 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Dear Julie,

Thanks so much!

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, March 8, 2021 4:02 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Peter – I will make sure that this gets flagged.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, March 8, 2021 3:45 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

Dear Julie,

I am pretty upset that CDC asked us to review this guidance for vaccinated individuals with a deadline of this morning, and then just went ahead with this without seeing our comments. I think that we had some useful suggestions. (We won't mention the wasted time we spent.) Can someone flag this for CDC possibly? We have been castigated for doing similar things to CDC in the past.

Best Regards,
Peter

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Sent: Monday, March 8, 2021 3:37 PM
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Subject: [EXTERNAL] Re: White House COVID-19 Response Team Briefing - MARCH 8, 2021

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

MARCH 8, 2021 | CLIP OF WHITE HOUSE COVID-19 RESPONSE TEAM BRIEFING
CDC Issues New Guidelines for Fully Vaccinated Individuals
CDC Director Rochelle Walensky announces new guidelines for people who have been fully vaccinated. Individuals must have had their final shot two weeks prior and can meet in another household without wearing a mask with people who have not yet being vaccinated--unless there is a high-risk individual in that household. Fully vaccinated individuals should continue to wear masks in public settings, avoid large crowds, maintain physical distance and wash their hands. Travel guidelines remain unchanged for everyone, Dr. Walensky says.

<https://www.c-span.org/video/?c4950597/cdc-issues-guidelines-fully-vaccinated-individuals#> **(3 minute video)**



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On Mon, Mar 8, 2021 at 11:20 AM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

The White House COVID-19 response team holds a briefing on the administration's efforts to combat the pandemic.

<https://www.c-span.org/video/?509660-1/white-house-covid-19-response-team-briefing&live>

Best regards,

Kevin Costa

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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,

Agenda for WHO working group on COVID-19 assays group call Wednesday February 3 2:30PM CET (Geneva Time)

1. Kurt Wibmer (NICD) - *SARS-CoV-2 501Y.V2 escapes neutralization by South African COVID-19 donor plasma*
2. Aodhán Breathnach (St. George's NHS) - *A laboratory-based study of COVID-19 Immunity and Reinfections in South-West London*

-----Original Appointment-----

From: SCHWARTZ, Lauren

Sent: Sunday, January 31, 2021 9:16 AM

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@amiciti.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.gerds@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; (b)(6)@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; jmcclrat@fredhutch.org; gmedigeshi@thsti.res.in; jwm1@pitt.edu; Liz.Miller@lshst.ac.uk; (b)(6)@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@dmcs.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@dmcs.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_vandenbergh@mei.harvard.edu; sylvie.van-der-werf@pasteur.fr; eric.vangieson@darpa.mil; Vasan.Vasan@csiro.au; y.m.vasiliev@spbnii.ru; David.Vaughn@gatesfoundation.org;

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Subject: WHO Working Group on COVID-19 Assays

When: Wednesday, February 3, 2021 5:30 AM-6:30 AM (UTC-08:00) Pacific Time (US & Canada).

Where: [https://who.zoom.us/j/\(b\)\(6\)](https://who.zoom.us/j/(b)(6))

Agenda to follow.

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Subject: [EXTERNAL] RE: WHO Working Group on COVID-19 Assays

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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 March 10 2:30PM CET (Geneva Time)

1. Alex Sette (LJI) - *Negligible impact of SARS-CoV-2 variants on CD4+ and CD8+ T cell reactivity in COVID-19 exposed donors and vaccinees*
2. Viviana Simon (MSSM) - *Analysis of immune responses to SARS-CoV-2 mRNA vaccination on a serological and monoclonal level*

-----Original Appointment-----

From: SCHWARTZ, Lauren

Sent: Sunday, March 7, 2021 8:51 AM

To: SCHWARTZ, Lauren; alex.sigal@ahri.org; (b)(6)@yahoo.com; Karl.Erlandson@hhs.gov; Lakshmi.Jayashankar@hhs.gov; Gerald.Kovacs@hhs.gov; James.Little@hhs.gov; Ashley.Smith1@hhs.gov; munoz-fontela@bnitm.de; ahgriff@bu.edu; fjc37@cam.ac.uk; SGalloway@cdc.gov; lny1@cdc.gov; gll9@cdc.gov; mbo2@cdc.gov; sot1@cdc.gov; angeliki.melidou@ecdc.europa.eu; liyl@cde.org.cn; liub@cde.org.cn; zuz4@cdc.gov; htq4@cdc.gov; lad7@cdc.gov; bnx1@cdc.gov; ilj2@cdc.gov; rzh7@cdc.gov; tkh4@cdc.gov; djernigan@cdc.gov; map1@cdc.gov; xdv3@cdc.gov; nax3@cdc.gov; valentina.bernasconi@cepi.net; carolyn.clark@cepi.net; william.dowling@cepi.net; elwyn.griffiths@cepi.net; celine.gurry@cepi.net; johan.holst@cepi.net; arun.kumar@cepi.net; amy.c.shurtleff@cepi.net; solomon.yimer@cepi.net; christian.drosten@charite.de; MAY.CHU@CUANSCHUTZ.EDU; Vasan.Vasan@csiro.au; eric.vangieson@darpa.mil; REIRELAND@mail.dstl.gov.uk; MSLEVER@dstl.gov.uk; MNELSON@dstl.gov.uk; JLPRIOR@dstl.gov.uk; john.c.trefry.civ@mail.mil; georgia.tomaras@duke.edu; david.montefiori@duke.edu; sarah.mudrak@duke.edu; linfa.wang@duke-nus.edu.sg; Eeva Broberg; epstein@ecohealthalliance.org; daszak@ecohealthalliance.org; emmanuelle.charton@edqm.eu; BUDA Mihaela; Marco.Cavaleri@ema.europa.eu; Ragini.Shivji@ema.europa.eu; b.haagmans@erasmusmc.nl; m.koopmans@erasmusmc.nl; n.okba@erasmusmc.nl; Mayra.Garcia@fda.hhs.gov; Philip.Krause@fda.hhs.gov; Tracy.MacGill@fda.hhs.gov; Todd.Myers@fda.hhs.gov; Keith.Peden@fda.hhs.gov; Jerry.Weir@fda.hhs.gov; Jilian.Sacks@finddx.org; jmcclrat@fredhutch.org; tlying@fudan.edu.cn; MONALISA.CHATTERJI@gatesfoundation.org; Jacqueline.Kirchner@gatesfoundation.org; Karen.Makar@gatesfoundation.org; David.Vaughn@gatesfoundation.org; cheryl@gisaid.org; christian.brechot@pasteur.fr; dbarouch@bidmc.harvard.edu; luk_vandenbergh@mei.harvard.edu; ASiyer@mgh.harvard.edu; maria.baca-estrada@canada.ca; jason.fernandes@canada.ca; mireille.plamondon@canada.ca; malik@hku.hk; r.tedder@imperial.ac.uk; vyusibov@indianabiosciences.org; guy.gorochov@sorbonne-universite.fr; sylvie.van-der-werf@pasteur.fr; supaporn.p@dmcs.mail.go.th; jokim@ivi.int; mksong@ivi.int; qiang.pan-hammarstrom@ki.se; katie.doores@kcl.ac.uk; leejooyeon@korea.kr; limhy0919@korea.kr; shane@lji.org; erica@lji.org; schendel@lji.org; alex@lji.org; sujan@lji.org; daniela@lji.org; Liz.Miller@lshtm.ac.uk; florian.krammer@mssm.edu; golinger@MRIGLOBAL.ORG; Luc.Gagnon@nexelis.com; Greg.Kulnis@nexelis.com; brooke.bozick@nih.gov; marciela.degrace@nih.gov; clint.florence@nih.gov; janet.lathey@nih.gov; erik.stemmy@nih.gov; larry.wolfraim@nih.gov; ian.crozier@nih.gov; lisa.hensley@nih.gov; Michael.holbrook@nih.gov; johnsonreed@niaid.nih.gov; connie.schmaljohn@nih.gov; emmie.dewit@nih.gov; vincent.munster@nih.gov;

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Subject: WHO Working Group on COVID-19 Assays

When: Wednesday, March 10, 2021 5:30 AM-6:30 AM (UTC-08:00) Pacific Time (US & Canada).

Where: [https://who.zoom.us/\(b\)\(6\)](https://who.zoom.us/(b)(6))

Agenda to follow.

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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)

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From: Himebaugh, Laurie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E7DC44DA46346B6B6DB7947C0AD7159-LAURIE.HIME]
Sent: 2/25/2021 2:43:09 PM
To: Anatol, Rachael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cfcb4d0fc9bc4f28902a8f0001d9cc32-Strong]; Bryan, Wilson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4d0683bebdb4047ab504f2204e810a2-BryanW]; Byrnes, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fc51f414b514aefa42ba4db40ae8116-ByrnesA]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Chumakov, Konstantin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38b94ccd62474755ae952ea31fa71e6e-Chumakov]; Epstein, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=312f0be7b0bc46dc8cb14a857aaa3aab-epsteins]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Robinson, Latasha A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a07ad5b9a3741908a70b145fd6f16c1-Latasha.Rob]; Kumar, Sanjai [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8d86daaa8104c3f9bac0241ee408260-KumarS]; Schmitt, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b7941ca742d4cc094a2a1edc35cbce0-Schmitt]; Shahabuddin, Muhammad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284daf53421d455fae52a3ed30540074-shahabuddin]; Shaw-Dore, Vanessa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0aa5c7f0e50642f1975116efa24829ad-Vanessa.Sha]; Weir, Jerry P. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d220ee1a49746899d88fd8077e08486-Weirj]; Ye, Zhiping [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd853bb14fa24b0c896a31594e772c06-yez]
CC: Brockner Ryan, Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a0b6b35a3aa43249a825bfbfdaeb408-brockner]; Burk, Suzann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83015d2cd30a4c62a4e661ac9324f4ee-BurkS]; Finan, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42860369666f4dfefbde8ad02109c9109-Daniel.Fina]; Kotler, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13024875752041d9b6883ad277902181-Sarah.Kotle]; Shane, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=608703ed77794ea0b8e9823e1a8e7299-Michael.Sha]; Ward, Ricci [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f140603a55a242f496273c68946f91ac-WardR]; OP Policy Review Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=880566a7249e4495973f6957997d7031-OP Policy R]; Litigation Hold [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae774ddb5d84977aac503990e4b3710-Litigation]; Weinfield, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acf3dd242e6043e1b5782486772d1051-Douglas.Wei]
Subject: LITIGATION HOLD: US Right to Know v. FDA et al.
Attachments: ECF No. 1 - Complaint.pdf; ECF No. 1.1 Exhibit A.pdf

Sent on behalf of Mike Shane, OCC attorney.

Re: **Requirement/obligation to Preserve (i.e., not destroy) Documents and Electronic Communication/data**

All:

You are receiving this e-mail because you may have documents and electronic data that must be preserved for litigation purposes. FDA has been sued in the United States District Court for the Northern District of California by US Right to Know ("USRTK" or "Plaintiff"). The Plaintiff alleges, among other things, that FDA has failed to provide agency records under the Freedom of Information Act. Full copies of the Plaintiff's Complaint and underlying FOIA request (No. 2020-5341) are attached.

The FOIA request seeks documents from seventeen FDA officials from January 1, 2017 to the present. The request has three parts: Part I seeks communications that pertain to several particular institutions set forth in the request (eg., East China Normal University, Wuhan Institute of Virology, etc.); Part II seeks communications that contain specific combinations of words (eg., "Global Health Security Agenda" and "China"); Part III seeks documents to or from the named employees and a list of people from outside FDA.

While this litigation is pending, the agency is under an obligation to retain documents and communications, including e-mails and other electronically stored information, that are potentially relevant to the case. Preservation must occur even if the information that is sought may ultimately be withheld as privileged or determined to be unreasonably burdensome to produce.

This is a new lawsuit, which relates to FOIA request 2020-5341. During any lawsuit, the opposing party may use the discovery process to obtain agency records about the allegations related to the case. The law requires FDA to preserve such information in whatever form it is generated and maintained. **Therefore, the agency requires your assistance to preserve documents and other evidence, including electronic data, in connection with USRTK's FOIA request and subsequent lawsuit. Furthermore, if counsel for USRTK or anyone associated with USRTK contacts you about this FOIA request or this lawsuit please advise them that you are unable to discuss substantive issues with them because we are involved in active litigation.**

Because the FOIA request at issue in this case seeks documents from a specific group of custodians, we are not requesting that this notice be distributed to additional personnel in your office at this time. However, if your responsive documents are maintained or stored by other individuals (such as administrative assistants), please notify us and we will determine whether the litigation hold notice should be forwarded to those people as well.

As an FDA employee, you are required to preserve all documents and data related to the subject of this lawsuit, including information stored in hard copy, on computer systems, on removable or portable electronic storage media, and on your personal computer, if used to create agency records. All electronically stored data, including e-mails and other electronic communication, word processing documents, spreadsheets, databases, calendars, telephone voice-mails, and other kinds of media, must be retained until resolution of this matter. In addition, you must retain non-electronic documents and evidence in whatever form, including personal or desk files, calendars, notes, correspondence, and other things relevant to the case. Any routine data destruction policies related to these records must be discontinued until further notice from me.

You do not need to collect and produce the documents/electronic data at this time; rather, we are only seeking to preserve and prevent the destruction of existing documents. Failure to preserve and retain information may result in sanctions against the agency. Consequently, if you are unsure whether certain information should be preserved, err on the side of caution and preserve the information until you have discussed the issue with the contact below. If production of some or all of the material is required at a later date, you will receive further instructions from an attorney assigned to this matter. If you have any questions about your obligations to preserve information, please contact Mike Shane at (301) 796-8593. If you have any questions about how to preserve electronically stored information, please contact Hilary Wanke.

Finally, please be advised that using FDA's eDiscovery resources, we plan to initiate a process whereby responsive records will be collected remotely from your FDA computer. If this type of remote collection is initiated, no further action will be required at this time beyond ensuring that records are preserved.

Please click the "yes" voting button above to confirm that you have received this notice, understand your obligations, and agree to comply with the instructions.*

***Clicking on the voting button is a MANDATORY step that provides evidence for DOJ to prove that you were advised of this litigation hold and understand your obligations as well as your agreement to comply with those obligations.**

Laurie B. Himebaugh

Laurie B. Himebaugh

Paralegal

OC/OCC

(Cell)

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Attorneys for Plaintiff US RIGHT TO KNOW

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

US RIGHT TO KNOW, a California Non-
Profit Corporation,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION

and

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

Defendants.

Case No. 3:21-cv-00884

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

Freedom of Information Act

INTRODUCTION

1. This action, through which Plaintiff US Right to Know (“USRTK” or “Plaintiff”) seeks access to government records held by Defendants United States Department of Health and Human Services and United States Food and Drug Administration (individually, “FDA”) (collectively “Defendants”) is premised upon, and consequent to, violations of the federal Freedom of Information Act (“FOIA”), 5 U.S.C. section 552 *et seq.*, and FDA FOIA regulations promulgated thereunder, 21 C.F.R. Part 20 – “PUBLIC INFORMATION.” This action challenges the unlawful failure of the Defendants to abide by the statutory requirements of the FOIA and the FDA’s implementing regulations.

2. Defendants are unlawfully withholding from public disclosure information sought by USRTK, information to which USRTK is entitled and for which no valid disclosure exemption applies or has been properly asserted. In particular, Defendants have violated, and remain in violation of, the statutory mandates imposed by the FOIA by: (Count I) failing to provide a timely final determination on USRTK’s FOIA Request; (Count II) unlawfully withholding records from public disclosure for which no valid disclosure exemption applies or has been properly asserted, or to provide the reasonably segregable portions of those records; (Count III) failing to grant USRTK’s request for a fee waiver under the FOIA; and (Count IV) failing to provide an “estimated date of completion.”

3. The records requested by USRTK are likely to contribute significantly to the understanding of the operations or the activities of the government. USRTK is a 501(c)(3) nonprofit organization and, by its nature, has no commercial interest in the requested records.

4. USRTK seeks declaratory relief establishing that Defendants have violated the FOIA and that such actions entitle USRTK to relief thereunder. USRTK also seeks injunctive relief directing Defendants to conduct a reasonably adequate search for records and to promptly provide responsive material, to reasonably segregate portions of non-exempt records, and to provide proper justifications for any disclosure exemptions that are applied. Finally, USRTK requests that the Court award it its reasonable attorneys’ fees and costs incurred in bringing this action.

JURISDICTION AND VENUE

5. This Court has jurisdiction pursuant to 5 U.S.C. section 552(a)(4)(B). That provision of

1 the FOIA grants jurisdiction to “the district court of the United States in the district in which the
2 complainant resides, or has his principal place of business[.]” USRTK both resides and maintains its
3 principal place of business in the Northern District of California.

4 6. The Court also has federal question jurisdiction pursuant to 28 U.S.C. section 1331
5 because this action arises under the FOIA and the Declaratory Judgment Act, 28 U.S.C. section 2201 et
6 seq.

7 INTRADISTRICT ASSIGNMENT

8 7. Pursuant to Local Rule 3-2(c), this case is properly brought in the San Francisco Division
9 of the Northern District of California because a substantial part of the events and omissions which give
10 rise to the claims alleged herein occurred in the County of San Francisco.

11 8. Under the FOIA, 5 U.S.C. section 552(a)(4)(B), jurisdiction vests in the district court
12 where “the complainant resides” or “has its principal place of business.”

13 9. Plaintiff resides in the County of San Francisco.

14 10. Plaintiff has its principal place of business in the County of San Francisco.

15 11. As such, under the L.R. 3-2(c), (d), intradistrict assignment to the San Francisco division
16 is proper.

17 PARTIES

18 12. Plaintiff USRTK is a 501(c)(3) nonprofit corporation organized under the laws of the
19 State of California. USRTK is a public interest, investigative research group focused on promoting
20 transparency for public health. USRTK works nationally and globally to expose corporate wrongdoing
21 and government failures that threaten the integrity of food systems, the environment, and human health.

22 13. Defendant United States Department of Health and Human Services is an agency of the
23 United States executive branch and is administered by the Secretary of Health and Human Services.

24 14. Defendant United States Food and Drug Administration is a federal agency that is part of
25 the Department of Health and Human Services. FDA is responsible for protecting and promoting public
26 health.

27 15. Defendants both qualify as an “agency” under the FOIA, the records sought are “records”
28

under the FOIA, and because Defendants are in possession and control of the records sought by USRTK, Defendants are subject to the FOIA pursuant to 5 U.S.C. section 552(f).

LEGAL FRAMEWORK

16. The FOIA requires U.S. government agencies to “promptly” make public records available to any person if that person makes a request which (1) reasonably describes the records sought and (2) complies with any applicable agency rules for making such a request. 5 U.S.C. § 552(a)(3)(A).

17. The FOIA requires an agency to issue a final determination on any such information request within twenty business days from the date of its receipt. 5 U.S.C. § 552(a)(6)(A)(i). In issuing a final determination, an agency is required to inform the requester of three things: (1) the agency’s determination of whether or not it must comply with the request; (2) the reasons for its decision; and (3) notice of the right of the requester to appeal to the head of the agency. 5 U.S.C. § 552(a)(6)(A)(i).

18. The FOIA allows an agency to extend the twenty-day determination deadline, however, by ten working days when “unusual circumstances” exist and when the agency so notifies a requester in writing. 5 U.S.C. § 552(a)(6)(B)(i)-(iii); 21 C.F.R. § 20.41(b)(3). A notice informing a requester of the invocation of the “unusual circumstances” provision must specify the applicable “unusual circumstances.” *Id.*

19. Permissible “unusual circumstances” are limited to: (1) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request; (2) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or (3) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein. 5 U.S.C. § 552(a)(6)(B)(iii); 21 C.F.R. § 20.41(b)(3)(ii).

20. An agency is entitled to one ten-business day extension. 5 U.S.C. § 552(a)(6)(B)(i). The written notice provided to the requester must specify the specific unusual circumstances justifying the extension and the date on which a final determination is expected to be dispatched. *Id.*; 21 C.F.R. §

1 20.41(b)(3)(i)(A).

2 21. In some circumstances, the FOIA allows an agency to invoke an extension beyond ten
3 days. To invoke a longer extension, the FOIA requires an agency to provide written notification to the
4 requester that (1) offers the requester an opportunity to limit the scope of the request so that it may be
5 processed within that time limit, or (2) offers the requester an opportunity to arrange with the agency an
6 “alternative time frame” for processing the request. 5 U.S.C. § 552(a)(6)(B)(ii); 21 C.F.R.
7 § 20.41(b)(3)(i)(B).

8 22. As part of invoking an “alternative time frame” extension, the agency must also make
9 available to the requester its FOIA Public Liaison, who is tasked to resolve any dispute between the
10 requester and the agency. 5 U.S.C. § 552(a)(6)(B)(ii).

11 23. FOIA Public Liaisons “shall serve as supervisory officials” and “shall be responsible for
12 assisting in reducing delays, increasing transparency and understanding of the status of requests, and
13 assisting in the resolution of disputes.” 5 U.S.C. § 552(l).

14 24. Even when an “unusual circumstances” extension is made, the agency must still notify
15 the requester of its expected date on which a final determination will be dispatched. 5 U.S.C. §
16 552(a)(6)(B)(i); 21 C.F.R. § 20.41(b)(3)(i)(A).

17 25. “Exceptional circumstances” for failure to comply with applicable time limits “does not
18 include a delay that results from predictable agency workload of requests under this section, unless the
19 agency demonstrates reasonable progress in reducing its backlog of pending requests.” 5 U.S.C. §
20 552(a)(6)(C)(ii).

21 26. If an agency fails to provide a final determination on a FOIA request within the statutory
22 timeframe, the requester is deemed to have exhausted its administrative remedies and may immediately
23 file suit against the agency. 5 U.S.C. § 552(a)(6)(C)(i).

24 27. The FOIA also requires agencies to provide “an estimated date on which the agency will
25 complete action on the request.” 5 U.S.C. § 552(a)(7)(B)(ii); *see also* 5 U.S.C. § 552(a)(6)(B)(i).

26 28. Agencies shall make reasonable efforts to maintain their records so they are reproducible
27 for FOIA purposes, and “shall make reasonable search efforts” for responsive records. 5 U.S.C. §
28

552(a)(3)(B), (C). The term “search” “means to review, manually or by automated means, agency records for the purpose of locating those records which are responsive to a request.” 5 U.S.C. § 552(a)(3)(D).

29. In furnishing records responsive to a request under the FOIA, an agency may, for a limited set of categories of information, exclude or withhold such information from disclosure. 5 U.S.C. § 552(b). However, even where proper justification exists for withholding such information, the agency must provide the remaining portions of records that are reasonably segregable from the properly withheld portions thereof. *Id.*

30. Except in certain circumstances, when an agency produces a record in response to a FOIA request but withholds a portion thereof, the agency must indicate the volume of information withheld and the exemption under which such information has been withheld. *Id.*; 5 U.S.C. § 552(a)(6)(F).

31. An agency that withholds public records from a requestor under the FOIA bears the burden of sustaining the legality of its action. 5 U.S.C. § 552(a)(4)(B).

32. Requesters under the FOIA may ask that an agency waive fees associated with any request for records “if disclosure of the information is in the public interest because it is likely to contribute significantly to the public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester. 5 U.S.C. § 552(a)(4)(E)(iii).

33. An agency may only charge certain fees depending on the category of requester. For non-commercial requesters such as USRTK, fees “shall be limited to reasonable standard charges for document search and duplication.” 5 U.S.C. § 552(a)(4)(E)(ii)(III).

34. Agencies are prohibited from assessing search fees if the agency fails to comply the FOIA’s twenty-day determination deadline or any lawful extension under the statute’s “unusual circumstances” provisions. 5 U.S.C. § 552(a)(4)(A)(viii).

STATEMENT OF OPERATIVE FACTS

35. USRTK submitted a FOIA Request (the “Request”) to FDA on July 21, 2020. The Request sought a waiver of all fees associated with processing the Request. A copy of the Request is

1 attached hereto as Exhibit A.

2 36. The Request seeks agency records involving communications involving a specific set of
3 FDA employees and containing specific keywords, including but not limited to “Wuhan Institute of
4 Virology.”

5 37. USRTK has no commercial interest or value in records responsive to the Request.

6 38. The records requested by USRTK are likely to contribute significantly to the public
7 understanding of the operations and activities of the government, especially as they pertain to the origins
8 of the SARS-CoV-2 virus and the COVID-19 pandemic in the United States.

9 39. USRTK has a demonstrated track record of obtaining and disseminating information
10 obtained under the FOIA and state public records laws concerning public health. Since 2015, USRTK
11 has obtained, posted online, and reported on thousands of industry and government documents gathered
12 via public records requests. USRTK’s work has contributed to three New York Times investigations,
13 eleven academic papers, ten articles in the BMJ, one of the world’s top medical journals, and global
14 media coverage documenting how food and chemical corporations impact public health and the
15 environment. USRTK’s staff has expertise in investigative journalism and advanced research, especially
16 as it concerns impacts on human health.

17 40. USRTK shares its findings with media outlets, public health and medical journals, and
18 through its own library of information, available online at: <<http://www.usrtk.org>>. Many of USRTK’s
19 documents are available through the USRTK Agrichemical Collection of the UCSF Chemical Industry
20 Documents Archive, available online at:
21 <<https://www.industrydocuments.ucsf.edu/chemical/collections/usrtk-agrichemical-collection/>>, and the
22 USRTK Food Industry Collection of the UCSF Food Industry Documents Archive, available online at:
23 <<https://www.industrydocuments.ucsf.edu/food/collections/usrtk-food-industry-collection/>>.

24 41. The Request was received and acknowledged by FDA via email on July 22, 2020, and
25 assigned tracking number “2020-5341.”

26 42. On August 20, 2020, FDA’s “Office of International Programs,” a division within FDA,
27 informed USRTK by email that it had completed processing of the Request and did not locate any
28

1 responsive records.

2 43. On September 10, 2020, USRTK wrote by email to Sarah Kotler, the Director of the
3 “Division of Freedom of Information” at FDA, asking for a status update concerning the Request. Ms.
4 Kotler directed that communication to the FDA’s “Center for Biologics Evaluation and Research
5 (CBER).”

6 44. On September 11, 2020, Cathy Wilusz, the Consumer Safety Officer at the Center for
7 Biologics Evaluation and Research, responded by email to USRTK’s September 10 correspondence. In
8 that email, Ms. Wilusz informed USRTK that its request was “in the process of being triaged to be
9 placed in the proper FOIA queue for processing.” Ms. Wilusz asked USRTK to contact Beth Brockner
10 Ryan for future status update regarding the request.

11 45. On September 16, 2020, Ms. Brockner Ryan wrote by email to USRTK, informing
12 Plaintiff that its Request had been placed onto the Center for Biologic Evaluation and Research’s
13 “Complex FOIA track,” and estimating that it will be “at least 18-24 months before it is up in the queue
14 for processing.” Furthermore, that estimate was “just for the time to reach the front of the queue for
15 processing and does not include time for processing the records/disclosure review.”

16 46. Having received no further response or official “determination” on the Request, on
17 October 7, 2020, USRTK served a formal correspondence by email to Ms. Brockner Ryan. That
18 correspondence requested that the FDA issue a lawful “determination” on the Request within the
19 twenty-day timeframe required by the FOIA. It also requested that FDA provide an estimated
20 completion date for the Request.

21 47. To date, no further communication has been received by USRTK from FDA about the
22 Request.

23 48. To date, no estimated date of completion has been provided to USRTK by FDA.

24 49. To date, FDA has not provided USRTK with a timely and lawful “determination” that
25 informs USRTK of (1) FDA’s determination of whether or not to comply with the Request; (2) the
26 reasons for its decision; and (3) notice of the right of USRTK to appeal to the head of the agency. 5
27 U.S.C. § 552(a)(6)(A)(i).

50. At no time has the FDA lawfully invoked the FOIA’s “unusual circumstances” exception to the FOIA’s twenty-day determination deadline.

51. FDA has not shown due diligence in responding to the request. 5 U.S.C. § 552(a)(6)(C)(i).

52. To date, FDA has failed to issue a decision on USRTK’s request for a waiver of fees associated with the processing of the Request.

53. To date, FDA has not produced a single record responsive to the Request.

54. USRTK has constructively exhausted all administrative remedies required by the FOIA. 5 U.S.C. § 552(a)(6)(A), (a)(6)(C).

55. USRTK has been forced to retain the services of counsel and to expend funds litigating Defendants’ unlawful actions and omissions under the FOIA.

CAUSES OF ACTION

COUNT I

VIOLATIONS OF THE FREEDOM OF INFORMATION ACT AND FDA REGULATIONS:

FAILURE TO PROVIDE TIMELY FINAL DETERMINATION

56. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

57. USRTK has a statutory right to have Defendants process its FOIA request in a manner that complies with the FOIA. USRTK’s rights in this regard were violated by FDA’s failure to provide a timely and legally adequate final determination.

58. To date, USRTK has not received any written communication from FDA about whether the agency will comply with the FOIA Request, the agency’s reasons for making that decision, and any right of USRTK to administratively appeal that decision. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. § 20.41(b).

59. Based on the nature of USRTK’s organizational activities, USRTK will continue to employ FOIA’s provisions to request information from Defendants in the foreseeable future. These

1 activities will be adversely affected if Defendants are allowed to continue violating FOIA's response
2 deadlines.

3 60. Unless enjoined and made subject to a declaration of USRTK's legal rights by this Court,
4 Defendants will continue to violate the rights of USRTK to receive public records under the FOIA.

5 61. Defendants' failure to make a final determination on USRTK's FOIA Request within the
6 statutory timeframe has prejudiced USRTK's ability to timely obtain public records.

7 **COUNT II**

8 **VIOLATION OF THE FREEDOM OF INFORMATION ACT:**

9 **UNLAWFUL WITHHOLDING OF NON-EXEMPT PUBLIC RECORDS**
10

11 62. The allegations made in all preceding paragraphs are realleged and incorporated by
12 reference herein.

13 63. USRTK has a statutory right to have Defendants process its FOIA request in a manner
14 that complies with FOIA.

15 64. USRTK's rights in this regard were violated when FDA failed to promptly provide
16 public, non-exempt records to USRTK, 5 U.S.C. §§ 552(a)(3)(A) & (b), to provide a reasonable estimate
17 of the volume of withheld records, 5 U.S.C. § 552(a)(6)(F), and to reasonably segregate all non-exempt
18 portions of otherwise exempt material, 5 U.S.C. § 552(b).

19 65. Defendants are unlawfully withholding public disclosure of information sought by
20 USRTK, information to which it is entitled and for which no valid disclosure exemption applies.

21 66. USRTK has constructively exhausted its administrative remedies with respect to this
22 claim.

23 67. USRTK is entitled to injunctive relief to compel production of all non-exempt,
24 responsive records.

25 68. Based on the nature of USRTK's organizational activities, USRTK will undoubtedly
26 continue to employ FOIA's provisions to request information from Defendants in the foreseeable future.

27 69. USRTK's organizational activities will be adversely affected if Defendants are allowed to
28 continue violating FOIA's response deadlines as it has in this case.

70. Unless enjoined and made subject to a declaration of USRTK's legal rights by this Court, Defendants will continue to violate the rights of USRTK to receive public records under the FOIA.

COUNT III

VIOLATION OF THE FREEDOM OF INFORMATION ACT:

FAILURE TO TIMELY APPROVE USRTK'S FEE WAIVER REQUEST

71. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

72. USRTK has a statutory right to have Defendants process its FOIA request in a manner that complies with FOIA.

73. USRTK's rights in this regard were violated by Defendants' unlawful delay in informing USRTK of its decision concerning USRTK's request for a fee waiver.

74. Based on the nature of USRTK's organizational activities, USRTK will continue to employ FOIA's provisions to request information from Defendants in the foreseeable future. These activities will be adversely affected if Defendants are allowed to continue violating the FOIA's requirements and deadlines for fee waiver requests.

75. USRTK's request for a waiver of all fees associated with the FOIA Request is appropriate and satisfies all elements required for approval of a fee waiver.

76. Unless enjoined and made subject to a declaration of USRTK's legal rights by this Court, Defendants will continue to violate the rights of USRTK to receive public records under the FOIA.

77. Defendants' failure to make a timely determination on USRTK's fee waiver request has prejudiced USRTK's ability to timely obtain public records.

COUNT IV

VIOLATION OF THE FREEDOM OF INFORMATION ACT:

FAILURE TO PROVIDE ESTIMATED DATE OF COMPLETION

78. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

1 79. USRTK has a statutory right to have Defendants process its FOIA request in a manner
2 that complies with FOIA.

3 80. USRTK's rights in this regard were violated by Defendants' unlawful failure to provide
4 an estimated date of completion, as required by the FOIA, 5 U.S.C. section 552(a)(7)(B)(ii).

5 81. USRTK formally requested that Defendants provide an estimated date of completion
6 following FDA's acknowledgment of the FOIA Request.

7 82. At no time have Defendants provided an estimated date of completion.

8 83. Based on the nature of USRTK's organizational activities, USRTK will continue to
9 employ FOIA's provisions to request information from Defendants in the foreseeable future. These
10 activities will be adversely affected if Defendants are allowed to continue violating the FOIA's
11 requirements for providing USRTK with an estimated date of completion on its FOIA requests.

12 84. Unless enjoined and made subject to a declaration of USRTK's legal rights by this Court,
13 Defendants will continue to violate the rights of USRTK to receive public records under the FOIA.

14 85. Defendants' failure to make a timely determination on USRTK's fee waiver request has
15 prejudiced USRTK's ability to timely obtain public records.

16 **REQUEST FOR RELIEF**

17 Wherefore, USRTK prays that this Court:

18 1. Order Defendants to promptly provide USRTK all of the information sought in this
19 action and to immediately disclose the requested documents in unredacted format unless an exemption is
20 properly claimed and properly applies.

21 2. Declare Defendants' failure to provide USRTK with a final determination as unlawful
22 under the FOIA.

23 3. Declare Defendants' failure to promptly provide USRTK with all non-exempt records as
24 unlawful under the FOIA.

25 4. Declare Defendants' failure to timely approve USRTK's request for a waiver of all fees
26 associated with the FOIA Request unlawful, and order Defendants to approve USRTK's fee waiver
27 request.

5. Award USRTK its reasonable attorneys' fees and costs pursuant to 5 U.S.C. section 552(a)(4)(E) or 28 U.S.C. section 2412.

6. Grant such other and further relief to USRTK as the Court may deem just and proper.

DATED: February 4, 2021.

DATED: February 4, 2021. SHUTE, MIHALY & WEINBERGER LLP

By: /s/
LAURA D. BEATON

Attorneys for Plaintiff US RIGHT TO KNOW

1335505.1

Exhibit A to Complaint

*U.S. Right to Know v. United States Food and Drug Administration &
United States Department of Health and Human Services*

Case No. 3:21-cv-00884
N.D. Cal. (February 4, 2021)



July 21, 2020

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

RE: Freedom of Information Act request

Dear FOIA Officer:

This request under the Freedom of Information Act, 5 U.S.C. § 552, *et seq*, to the U. S. Food & Drug Administration ("FDA") consists of three parts regarding the following employees:

1. Vanessa Shaw-Dore, Director, Office of Global Policy and Strategy, China Office
2. Latasha Robinson, Deputy Director, Office of Global Policy and Strategy, China Office
3. Peter Marks, Director, Center for Biologics Evaluation and Research (CBER)
4. Carolyn Wilson, Associate Director of Research, CBER
5. David S. Cho, Senior Scientist for Emerging & Pandemic Threat Preparedness, CBER
6. Sanjai Kumar, Laboratory of Emerging Pathogens, Office Of Blood Research And Review, CBER
7. Marion F. Gruber, Director, Office of Vaccines Research and Review, CBER
8. Phillip R. Krause, Deputy Director, Office of Vaccines Research and Review, CBER
9. Konstantin Chumakov, Associate Director for Research, Office of Vaccines Research and Review, CBER
10. Jerry P. Weir, Division of Viral Products, Office of Vaccines Research and Review, CBER
11. Zhiping Ye, Laboratory of Pediatric & Respiratory Viral Diseases, Office of Vaccines Research and Review, CBER
12. Michael Schmitt, Laboratory of Respiratory & Special Pathogens, Office of Vaccines Research and Review, CBER
13. Muhammad Shahabuddin, Laboratory of Biochemistry, Virology and Immunology, Office of Compliance and Biologics Quality, CBER
14. Bryan Wilson, Director, Office of Tissues and Advanced Therapies, CBER
15. Rachael Anatol, Deputy Director, Office of Tissues and Advanced Therapies, CBER
16. Suzanne L. Epstein, Associate Director for Research, Office of Tissues and Advanced Therapies, CBER
17. Andrew Byrnes, Gene Transfer and Immunogenicity Branch, Office of Tissues and Advanced Therapies, CBER

For this FOIA request we are seeking copies of records created, received and/or in the possession of FDA, including cross-references. Specifically, we are seeking records that reflect communications – whether in writing or verbal communications that were later reduced to writing (including any emails

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FDA-CBER-2020-5341-0007528

and their attachments, non-email correspondence, or other forms of communication) – to, from, or in the possession of the above-named individuals -- containing any of the following keywords or domains:

Part I of this request pertains to communications containing any of the following keywords or domains:

- East China Normal University
- Wuhan Institute of Virology OR WIV OR @wh.iov.cn
- Wuhan Center for Disease Control and Prevention
- Wuhan University State Key Laboratory of Virology OR SKLV OR @whu.edu.cn
- Wuhan University Institute of Medical Virology
- EcoHealth Alliance OR EcoHealth OR @ecohealthalliance.org
- Christophe Mérieux Laboratory located in Beijing

Part II of this request pertains to communications containing any of the following combinations of keywords:

- “Global Health Security Agenda” AND “China” OR “GHSA” AND “China”
- “Coalition for emerging preparedness innovations” AND “China” OR “CEPI” AND “China” OR “@cepi.net” AND “China”
- “PREDICT 2” AND “China” OR “USAID” AND “China”
- “China” AND “biothreat”
- “China” AND “bioincident”
- “China” AND “Dual Use Research” OR “China” AND “DURC” OR “China” AND “GOF”
- “China” AND “US Army Medical Research Institute of Infectious Diseases” OR “China” AND “USAMRIID”

For Part III, please search for all email correspondence to or from above listed employees– including attachments, CC and BCC – and the following person(s):

- Dennis Carroll OR dcarroll@usaid.gov
- Sina Bavari OR sina.bavari.civ@mail.mil
- Shi Zheng-Li OR Shi Zhengli OR zlishi@wh.iov.cn
- Fang Li OR lifang@umn.edu
- Yuan Zhiming OR yzm@wh.iov.cn
- Anthony Fauci OR afauci@niaid.nih.gov
- Peter Daszak OR daszak@ecohealthalliance.org
- William Karesh OR Billy Karesh OR karesh@ecohealthalliance.org
- Jonathan Epstein OR epstein@ecohealthalliance.org
- Jonna Mazet OR jkmazet@ucdavis.edu
- George Gao OR gaof@im.ac.cn
- Linfa Wang OR linfa.wang@duke-nus.edu.sg
- Christian Bréchet OR cbrechet@usf.edu
- Ralph Baric OR rbaric@email.unc.edu
- Ian Lipkin OR wil2001@columbia.edu
- James Le Duc OR jwleduc@utmb.edu
- Thomas Ingelsby OR tinglesby@jhu.edu

We respectfully request that in conducting its searches implicating e-mail correspondence the FDA ensures that the scope encompasses emails to or from the FDA personnel named above, including e-mails on which they or anyone else was carbon copied ("CC") or blind carbon copied ("BCC").

FDA may limit the timeframe to January 1, 2017, or the earliest date after which such records exist, and up until the date upon which FDA begins conducting searches for responsive records.

The scope of the searches should not be limited to FDA-originated records and should be construed to include records that are currently in the possession of a U.S. Government contractor for purposes of records management. The scope of the search should encompass all individual hard drives, shared drives, e-mail accounts and/or communication devices (including personal e-mail accounts and communication devices) that would be reasonably likely to maintain responsive records.

We request that you disclose the listed documents and materials as they become available to you, without waiting until all the documents have been assembled.

If documents are denied in whole or in part, please specify which exemption(s) is (are) claimed for each passage or whole document denied. Give the number of pages in each document and the total number of pages pertaining to this request and the dates of documents withheld. We request that excised material be "blackened out" rather than "whited out" or cut out and that the remaining non-exempt portions of documents be released as provided under the Freedom of Information Act. Please send a memo (with a copy or copies to me) to the appropriate unit(s) in your office to assure that no records related to this request are destroyed.

Please advise of any destruction of records and include the date of and authority for such destruction. As we expect to appeal any denials, please specify the office and address to which an appeal should be directed.

U.S. Right to Know is requesting a waiver of or, at a minimum, a reduction in fees related to this request. We are a 501(c)(3) nonprofit research organization based in Oakland, California. As a public interest organization, we have no commercial interest in the records that are the subject of this FOIA request and would derive no financial benefit from their disclosure. Our research has been featured many times in newspapers such as the *New York Times* and *The Guardian*, as well as in medical and public health journals such as the *BMJ*. As with our prior work, we intend to disseminate newsworthy information to the general public by way of academic or media articles, or fact sheets, relying upon any records released in response to this FOIA request. These records, which are not publicly available at present, may shed light on the activities of the FDA and its employees in relation to biosafety research networks operating both within the U.S. and abroad, and specifically linked to China. Such disclosure is in the public interest because it is likely to contribute to the public's understanding of the extent to which U.S. taxpayer dollars and resources might be facilitating dual use research of concern on dangerous pathogens in China. Further, documentation of such influence is important, and is in the public interest because it concerns how taxpayer resources are allocated, whether or not they are being wasted or squandered, and whether the public interest is being served.

We ask, if fees are assessed, that they not exceed \$25 without first contacting our office for authorization.

Please send the documents electronically in PDF format to Sainath Suryanarayanan at sainath@usrtk.org.

Please call, rather than write Gary Ruskin, if there are any questions or if you need additional information. He can be reached at (415) 944-7350.

Thank you for your help in filling this FOIA request.

Sincerely,

A handwritten signature in cursive script, appearing to read "Sainath".

Sainath Suryanarayanan, PhD
Staff Scientist

A handwritten signature in cursive script, appearing to read "Gary Ruskin".

Gary Ruskin
Executive Director

From: (b)(6)@hotmail.com]
Sent: 2/2/2021 9:00:42 AM
To: Bryan, Wilson [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4d0683bebdb4047ab504f2204e810a2-BryanW]
Subject: Re: Bayesian_wuhan virus

It's not my suspicious. Every step of your life is controlled with a QR code (as a personal identity) in China under their network surveillance and watch. But yet, it has been more than a year after the pandemic, they still don't know who the patient "zero" is. In 2003, it took few months to know SARS-COV -1 passed through civets before reaching human (actually I doubt this as well. Because in 2003 they killed all civets in Guang Dong Province as they said people got the virus by handling and eating the civets. One year later in 2005, you can see civets were sold in markets again for food. It's too much terrible the eating habit over there. If civets were really the intermediate host, why people were not re-infected?

It also took few months to know MERS-COV virus intermediate host, camel. But Now, all great viral scientists, WHO and infectious disease experts all over the world don't have any clue about where the virus came from and how it passed through and reaching human? These are not rocky sciences. Even in current era, people know rocky sciences better. Something is wrong and covered.

(b)(6)

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From: Bryan, Wilson <Wilson.Bryan@fda.hhs.gov>
Sent: Sunday, January 31, 2021 11:16:14 AM
To: (b)(6)@hotmail.com>
Subject: RE: Bayesian_wuhan virus

Very sad.

I hope your suspicions are wrong about that lab origin; we'll see.

Wilson

From: (b)(6)@hotmail.com>
Sent: Saturday, January 30, 2021 7:07 PM
To: Bryan, Wilson <Wilson.Bryan@fda.hhs.gov>
Subject: Bayesian_wuhan virus

Dear Wilson

Bayesian analysis concluded: 99.8% probability of lab origin (from lab) ; 0.2% zoonotic origin (from Nature).

When I learned that the patient "zero" was a graduate student and a researcher in Wuhan institute of virology, I searched the institute website to view her name in the listing of staff. Her name was there but her photograph was removed from the view board. She was censored. Not sure she died or left from the institute. Hope she lives safe...

The most easy way for them was to use the censorship and the punishment to deal with "rumours" they scare of because they had "Gun". Can't imagine that FaceBook and Twitter do censorship similar to that Gov. Do they think that they are God? God is never stand with them.

This is to remember there are more than 2192304 (millions) people died due to the infection. Hope they RIP and God are always with them.

Best regards,

(b)(6)

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From: Bryan, Wilson [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4D0683BEBDB4047AB504F2204E810A2-BRYANW]
Sent: 2/8/2021 10:07:56 PM
To: (b)(6)@hotmail.com
Subject: RE: Bayesian_wuhan virus

Dear (b)(6)

Sorry to hear of the overwork and its consequences for your health. I hope the rest is sufficient to get you back on track.

(b)(6)

Best,
Wilson

From: (b)(6)@hotmail.com>
Sent: Monday, February 8, 2021 9:56 PM
To: Bryan, Wilson <Wilson.Bryan@fda.hhs.gov>
Subject: Re: Bayesian_wuhan virus

Dear Wilson,

My company really gave us too many work so that I got

(b)(6)

(b)(6)

My workload increased by 47% last year. Now i got

(b)(6)

(b)(6)

I am so happy that I don't need to stare the computers for saving my eyes.

Have you got vaccinated?

Best regards,

(b)(6)

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From: Bryan, Wilson <Wilson.Bryan@fda.hhs.gov>
Sent: Sunday, January 31, 2021 11:16:14 AM
To: (b)(6)@hotmail.com>
Subject: RE: Bayesian_wuhan virus

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The most easy way for them was to use the censorship and the punishment to deal with “rumours” they scare of because they had “Gun”. Can’t imagine that FaceBook and Twitter do censorship similar to that Gov. Do they think that they are God? God is never stand with them.

This is to remember there are more than 2192304 (millions) people died due to the infection. Hope they RIP and God are always with them.

Best regards,

(b)(6)

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From: Folkers, Greg (NIH/NIAID) [E] [gfolkers@niaid.nih.gov]
Sent: 12/19/2017 4:18:01 PM
Subject: FAO: H7N9 situation update, 19 December 2017

H7N9 situation update

19 December 2017, 15:00 hours; Rome

The next update will be issued on 24 January 2018

Disclaimer

Information provided herein is current as of the date of issue. Information added or changed since the last H7N9 situation update appears in **red**. Human cases are depicted in the geographic location of their report. For some cases, exposure may have occurred in one geographic location but reported in another. For cases with unknown onset date, reporting date was used instead. FAO compiles information drawn from multiple national (Ministries of Agriculture or Livestock, Ministries of Health, Provincial Government websites; Centers for Disease Prevention and Control [CDC]) and international sources (World Health Organization [WHO], World Organisation for Animal Health [OIE]) as well as peer-reviewed scientific articles. FAO makes every effort to ensure, but does not guarantee, accuracy, completeness or authenticity of the information. The designation employed and the presentation of material on the map do not imply the expression of any opinion whatsoever on the part of FAO concerning the legal or constitutional status of any country, territory or sea area, or concerning the delimitation of frontiers.

Overview

Hazard: Influenza A(H7N9) virus with pandemic potential.

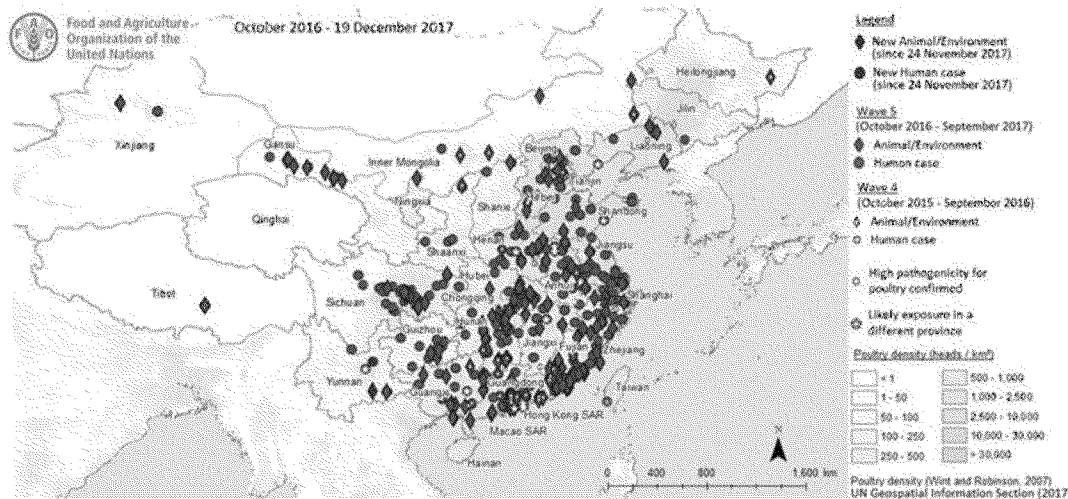
Country: China; imported cases in Malaysia (1) and Canada (2).

Number of human cases: **1,623** confirmed; **620** deaths (since February 2013).

New findings in birds / environment since last update (24 November 2017): **3**

New human cases since last update (24 November 2017): **1**

Map 1. Human cases and positive findings in birds or the environment



Click to enlarge - Note: Human cases are depicted in the geographic location where they were reported; for some cases, exposure may have occurred in a different geographic location. Precise location of 63 human cases in Anhui (2), Beijing (2), Guangdong (1), Guangxi (1), Hebei (3), Hunan (1), Hubei (2), Jiangsu (2), Jiangxi (6), Sichuan (2), Zhejiang (3) and unknown (38) Provinces are currently not known, these cases are therefore not shown on the map.

Provinces/municipalities affected: Beijing, Chongqing, Shanghai and Tianjin Municipalities; Anhui, Fujian, Gansu, Guangdong, Guizhou, Hebei, Heilongjiang, Henan, Hubei, Hunan, Jiangsu, Jiangxi, Jilin, Liaoning, Qinghai, Shaanxi, Shanxi, Shandong, Sichuan, Taiwan, Yunnan and Zhejiang Provinces; Hong Kong SAR, Macao SAR; Guangxi, Inner Mongolia, Ningxia Hui, Tibet and Xinjiang Uyghur Autonomous Regions (China); Sabah (Malaysia); British Columbia (Canada).

Highly pathogenic virus findings: Since 10 January 2017, highly pathogenic avian influenza (HPAI) type H7N9 virus was detected in a total of 54 poultry or environmental samples (42 chickens, 2 duck and 10 environmental samples); H7N9 virus isolates from 25 human cases were found to be HPAI virus.

Table. Number of locations testing positive for H7N9 HPAI virus (n=38) in birds and/or the environment, by province and sampling site as of 19 December 2017.

Province	LBM*	Farm	Backyard	Airport	Total
Anhui	0	1	0	0	1
Fujian	1	0	0	0	1
Guangdong	22	0	0	0	22
Guangxi	0	1	0	0	1
Hebei	0	1	0	0	1
Heilongjiang	0	1	0	0	1
Henan	0	1	0	0	1
Hunan	3	1	1	0	5
Inner Mongolia	0	2	0	0	2
Shaanxi	0	1	0	0	1
Tianjin	0	1	0	0	1
Unknown	0	0	0	1	1
TOTAL	26	10	1	1	38

*LBM: live bird market

Situation update

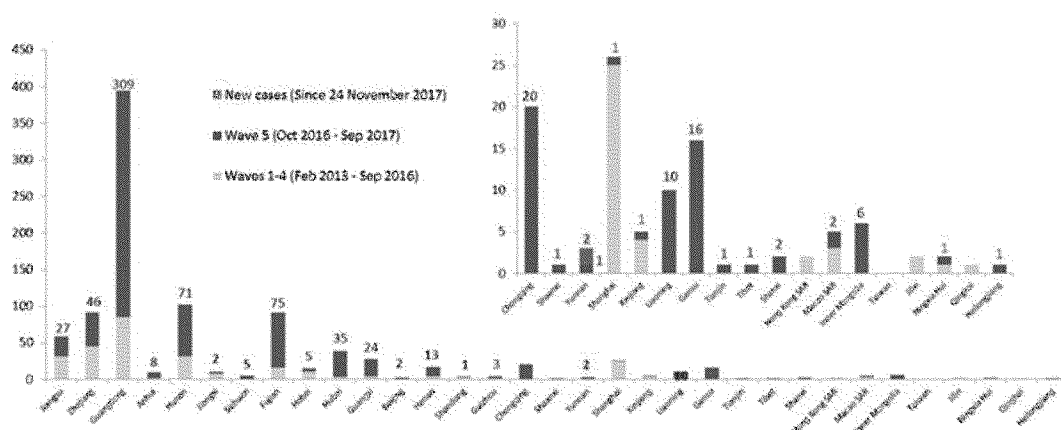
Animals

- 13 December, MoA published the results of the national animal H7N9 surveillance and post-vaccination monitoring for the month of November. Overall post-vaccination monitoring* result from 28 provinces was of 88.01%**, while vaccination in some provinces were not completed at the time of sampling; and two chicken samples tested positive for H7N9 in Yunnan Province out of the 41,506 virology samples collected from 23 provinces [reference]. *: antibody titre ≥ 24 as required by the MoA regulation. **: ratio of poultry samples which achieved required immunity level.

- 2 December, **Yunnan Province**: sick and dead chickens were reported in relation to the confirmed H7N9 human case in Kunming City on 30 November 2017. No information is available whether the deaths of poultry was due to H7N9 infection [reference].
- 2 December, **Anhui Province**: Hefei City announced a new plan to gradually withdraw live poultry trading from the city centre [reference].
- 1 December, **Guangdong Province**: Huizhou City restricts live poultry trade in Zhongkai Hi-tech Industry Development District and promotes centralized slaughtering, cold chain distribution and fresh meat marketing from 20 December 2017[reference].
- In November, Japan's animal border control again detected a H7N9 virus strain in duck meat from China; No information is available about pathogenicity of the virus [reference].
- 30 November, **Guangdong Province**: Zhongshan City closes all LBMs in the whole city from 1st to 3rd and from 15th to 17th (i.e. twice a month for three days each) from November 2017 to April 2018, and strengthen emptying cages, cleaning and disinfection. Random on site investigation on 11 live poultry markets will also be conducted [reference].
- 28 November, MoA published the results of the national animal H7N9 surveillance for the month of October. A total of 19,936 virology samples have been collected from 27 provinces, no sample tested positive for H7N9 [reference].

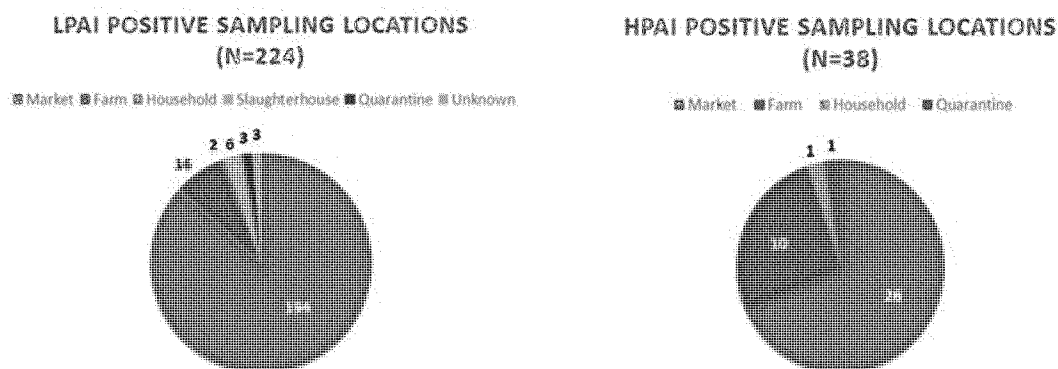
Animal/environmental findings: Since 4 April 2013 around 2500 virological samples from the environment, chickens, pigeons, ducks and a tree sparrow tested positive; positives mainly from live bird markets, vendors and some commercial or breeding farms.

Figure 1. Number of positive virological samples from birds or the environment, by province and origin as of 19 December 2017. Data include both high and low pathogenic H7N9 viruses.



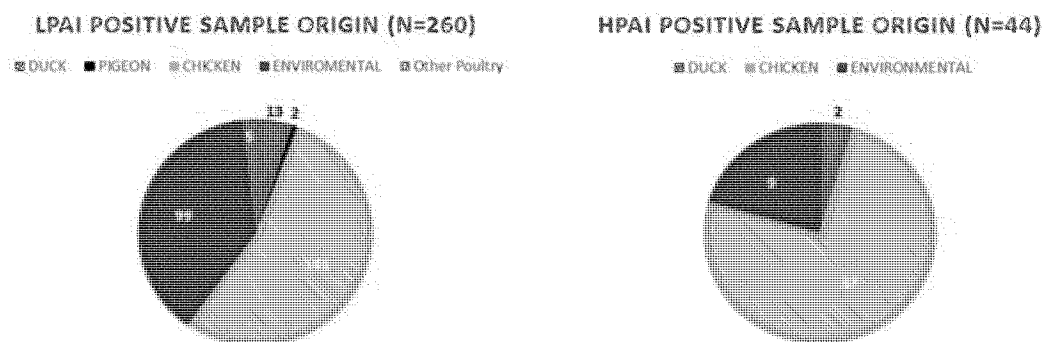
[Click to enlarge](#)

Figure 2. Distributions of low* and highly pathogenic H7N9 virologically positive samples ($n^{LPAI}=224$; $n^{HPAI}=38$) collected from birds or the environment, by sampling location, between October 2016 and 19 December 2017 (wave 5). Samples from the same location and time are grouped.



[Click to enlarge](#) - *may contain unconfirmed HPAI at the time of publishing

Figure 3. Distributions of low* and highly pathogenic H7N9 virologically positive samples ($n^{LPAI}=260$; $n^{HPAI}=44$) collected from birds or the environment, by sample origin between October 2016 and 19 December 2017 (wave 5). Samples from the same origin, location and time are grouped.

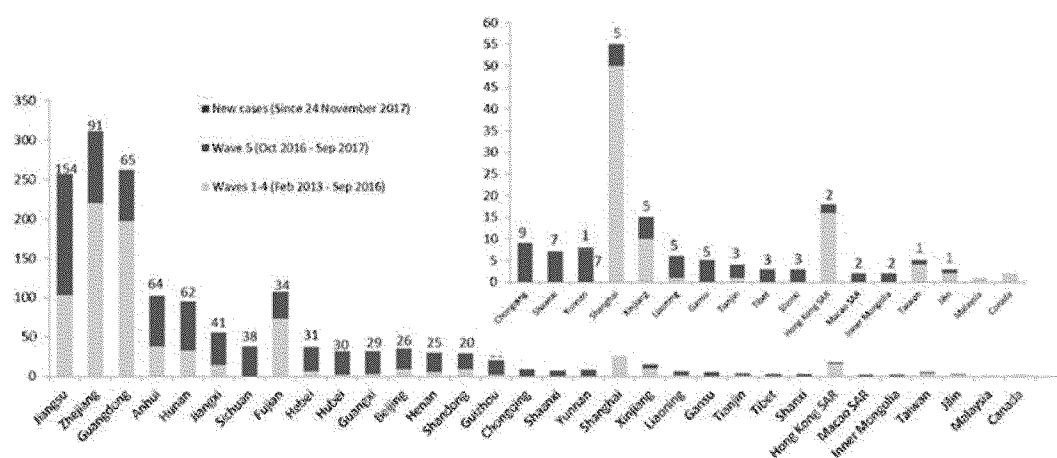


Click to enlarge - *may contain unconfirmed HPAI at the time of publishing

Humans

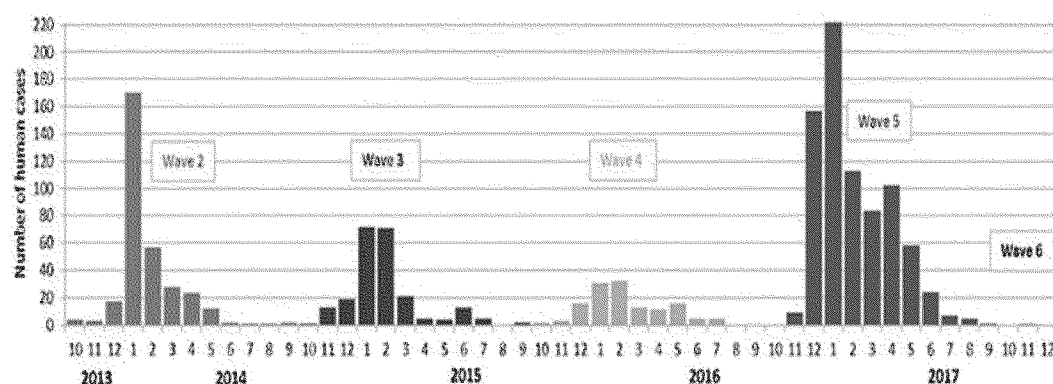
- Since the last update (24 November 2017), one new human cases has been reported in Yunnan.
- For detailed information on human cases, please refer to WHO's [Disease Outbreak News](#)

Figure 4. Number of officially reported human cases since February 2013 as of 19 December 2017. Data include both high and low pathogenic H7N9 viruses



Click to enlarge

Figure 5. Incidence of officially reported human cases by month, based on onset date as of 19 December 2017. Both high and low pathogenic H7N9 viruses are included.



Click to enlarge - Note: For cases with unknown onset dates from wave 1 ($n=7$), wave 2 ($n=2$), wave 3 ($n=146$), wave 4 ($n=27$) and wave 5 ($n=55$), reporting dates were used instead.

Publications

- Jean Artois, *et al.* **Changing Geographic Patterns and Risk Factors for Avian Influenza A(H7N9) Infections in Humans, China.** *Emerging Infectious Disease*. 2018 Jan. doi: 10.3201/eid2401.171393 [reference]. *An investigation on the effect of anthropogenic, poultry, and wetland variables on all epidemic waves showed that poultry predictor variables became much more important in the last two epidemic waves than they were previously, supporting the assumption of much wider H7N9 transmission in the chicken reservoir. Future range expansion of H7N9 to northern China may increase the risk of H7N9 epidemic peaks coinciding in time and space with those of seasonal influenza, leading to a higher risk of reassortments than before, although the risk is still low so far.*
- Wei Cheng, *et al.* **Comparison of the three waves of avian influenza A(H7N9) virus circulation since live poultry markets were permanently closed in the main urban areas in Zhejiang Province July, 2014 –June, 2017.** *Influenza and Other Respiratory Viruses*. 2017 Dec 15. doi: 10.1111/irv.12532. [reference]. *A study showed that epidemiological characteristics of human cases infected with avian influenza A(H7N9) virus had generally remained unchanged since the massive closure of LPMs in the main urban area of Zhejiang province. The sudden increase of the number of H7N9 cases in the fifth wave were mainly attributed to the excessive cases reported from areas where LPMs were not permanently closed.*

FAO actions:

- FAO published a risk assessment entitled, “Chinese-Origin H7N9 Highly Pathogenic Avian Influenza: Spread in poultry and human exposure” [reference]
- FAO guidance and risk assessments are available on a dedicated website [link]
- Liaise with China and partners, monitor situation, monitor virus evolution, conduct market chain analysis, risk assessment, surveillance guidance and communication.

FAO’s support to countries

- FAO continues supporting at-risk countries with surveillance and preparedness for H7N9 incursion
- FAO is providing surveillance and sampling guidance for South and Southeast Asia
- Funding to date: US\$ 8.1 million mobilized (US\$ 6.7 million USAID, US\$ 1.9 million TCPs)

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Subject: Re: Merck to make more Ebola vaccine, WHO declines to declare global emergency

Yes, ProMed had sent that out today, as well. 12 months to get there, but more good news along with the DRC MOH fractional dosing news. NLM

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Subject: Merck to make more Ebola vaccine, WHO declines to declare global emergency

<https://www.devex.com/news/merck-to-make-more-ebola-vaccine-who-declines-to-declare-global-emergency-95114>

“Merck has determined with the U.S. Government, WHO and others that additional vaccine supply would benefit overall public health preparedness — both, to support the current DRC outbreak and preparedness against any new Ebola ... outbreak(s) that might occur,” Pamela Eisele, product, pipeline, and supply media relations at Merck, told Devex in an email, just days after the first case of Ebola was reported in Uganda. Eisele said the decision was made “recently.”...Mike Ryan, head of WHO’s health emergencies program, said in a press conference on Friday that there are “a quarter of a million doses” of Ebola experimental vaccines ready to ship, and a further 100,000 doses by the end of the year. While adjustments on vaccine dose usage has been made to double its reach, WHO welcomes Merck’s decision to produce more from its plant in West Point, Pennsylvania. ..“We do not give out specific numbers at any given point in time, because it fluctuates. The stockpile, as with any vaccine stockpile, is inherently dynamic — numbers change due to shipments, expiry, and replenishment,” Eisele said. But she said that in addition to the currently available supply, Merck would produce an estimated 450,000 additional doses of investigational V920 that should be available “in about 12 +/- months.”

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CC: Marco.Cavaleri@ema.europa.eu; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Browne, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43044a5f1d3c4548b627436ddd2d7fcd-Sarah.Brown]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Muyembe Jean-Jacques [(b)(6)@gmail.com]; Mulangu Sabue [(b)(6)@yahoo.fr]; [(b)(6)@yahoo.fr]; Richard KOJAN [richard.kojan@alima.ngo]; Augustin AUGIER [aug@alima.ngo]; Rebecca GRAIS [rebecca.grais@epicentre.msf.org]; Armand Sprecher [Armand.Sprecher@brussels.msf.org]; MVitek@samaritan.org; sina.bavari.civ@mail.mil; Jacobs, Michael [michael.jacobs@ucl.ac.uk]; yazdan.yazdanpanah@aphp.fr; xavier.anglaret@u-bordeaux.fr; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Timo.Wolf@kgu.de; PREZIOSI, Marie-pierre [preziosim@who.int]; HENAO RESTREPO, Ana Maria [henaorestrepa@who.int]; GSELL, Pierre [gsellp@who.int]; COSTA, Alejandro Javier [costaa@who.int]; DIAZ, Janet Victoria [diazj@who.int]; FALL, Ibrahima Soce [socef@who.int]
Subject: Re: PEP use of investigational therapeutics agents for high risk contacts

Bonsoir Xavier, je participerai (m'organise); on en dit un mot ces jours-ci ? J'étais ces deux jours avec M Jacobs et T Wolff
Amicalement, Denis
Envoyé de mon iPhone

Le 29 oct. 2019 à 18:53, BENASSI, Virginia <benassiv@who.int> a écrit :

Dear Colleagues,

We hope this email finds you all well.

In light of recent discussions on the potential **PEP use of investigational therapeutics agents (and vaccines) for high risk contacts**, we would like to reconvene a group of independent experts and invite you for a 60 minute teleconference **Friday, 8 November at 4:00 pm Geneva time**, to start developing an updated statement on such use (based on available emerging evidence).

We would be grateful if you could confirm your availability the soonest. In the meantime, please do not hesitate to email us, should you have any questions.

A warm thank-you in advance to you all for your time and invaluable expertise,
Virginia *on behalf of* the WHO Secretariat

Virginia Benassi
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<image002.png>

<Conf_undertaking_Ebola_protocol PEP.PDF>

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From: BENASSI, Virginia [benassiv@who.int]
Sent: 10/29/2019 1:09:59 PM
To: Marco.Cavaleri@ema.europa.eu; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Browne, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43044a5f1d3c4548b627436ddd2d7fcd-Sarah.Brown]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Muyembe Jean-Jacques [(b)(6)]@gmail.com; Mulangu Sabue [(b)(6)]@yahoo.fr [(b)(6)]@yahoo.fr; Richard KOJAN [richard.kojan@alima.ngo]; Augustin AUGIER [aug@alima.ngo]; Rebecca GRAIS [rebecca.grais@epicentre.msf.org]; Rebecca GRAIS [rebecca.grais@epicentre.msf.org]; Armand Sprecher [Armand.Sprecher@brus sels.msf.org]; MVitek@samaritan.org; sina.bavari.civ@mail.mil; Jacobs, Michael [michael.jacobs@ucl.ac.uk]; MALVY Jean-Marie Deni [denis.malvy@chu-bordeaux.fr]; yazdan.yazdanpanah@aphp.fr; xavier.anglaret@u-bordeaux.fr; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Timo.Wolf@kgu.de
CC: PREZIOSI, Marie-pierre [preziosim@who.int]; HENAO RESTREPO, Ana Maria [henaorestrepa@who.int]; GSELL, Pierre [gsellp@who.int]; COSTA, Alejandro Javier [costaa@who.int]; DIAZ, Janet Victoria [diazj@who.int]; FALL, Ibrahima Soce [socef@who.int]
Subject: PEP use of investigational therapeutics agents for high risk contacts
Attachments: Conf_undertaking_Ebola protocol PEP.PDF

Importance: High

Dear Colleagues,

We hope this email finds you all well.

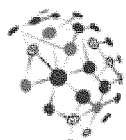
In light of recent discussions on the potential **PEP use of investigational therapeutics agents (and vaccines) for high risk contacts**, we would like to reconvene a group of independent experts and invite you for a 60 minute teleconference **Friday, 8 November at 4:00 pm Geneva time**, to start developing an updated statement on such use (based on available emerging evidence).

We would be grateful if you could confirm your availability the soonest. In the meantime, please do not hesitate to email us, should you have any questions.

A warm thank-you in advance to you all for your time and invaluable expertise,
Virginia *on behalf of* the WHO Secretariat

Virginia Benassi

Technical Officer, Flagship Projects
Initiative for Vaccine Research, WHO/IVB
World Health Organization
Avenue Appia 20
CH-1211 Geneva 27, Switzerland
+41 22 79 14274



R&D Blueprint

Powering research
to prevent epidemics



WORLD HEALTH ORGANIZATION
CONFIDENTIALITY UNDERTAKING

1. The World Health Organization (WHO), through its Department of Information, Evidence and Research, has access to certain Information relating to experimental Ebola vaccine and therapeutics for post-exposure-prophylaxis use, which it considers to be proprietary to itself or to parties collaborating with it (*hereinafter referred to as "the Information"*).
2. WHO is willing to provide the Information to the Undersigned, or arrange for the provision of the Information to the Undersigned, whether during or in relation to a meeting or a telephone conference, or through an internet-based collaborative workspace, or for a contractual arrangement, or otherwise (*hereinafter referred to as "the Activities"*), for the purpose of providing advice on the use of Ebola vaccine and therapeutics for post-exposure prophylaxis use (*hereinafter referred to as "the Purpose"*), provided that the Undersigned undertakes to treat the Information as confidential and proprietary, to use the Information only for the aforesaid Purpose and to disclose it only to persons who have a need to know for the Purpose and are bound by like obligations of confidentiality and non-use as are contained in this Undertaking.
3. The Undersigned undertakes to regard the Information as confidential and proprietary to WHO or parties collaborating with WHO, and agrees to take all reasonable measures to ensure that the Information is not used, disclosed or copied, in whole or in part, other than as provided in paragraph 2, except that the Undersigned shall not be bound by any such obligations of confidentiality and restrictions on use, if and to the extent he/she is clearly able to demonstrate that the Information:
 - a) was known to him/her prior to any disclosure by or for WHO to the Undersigned; or
 - b) was in the public domain at the time of disclosure by or for WHO to the Undersigned; or
 - c) becomes part of the public domain through no fault of the Undersigned; or
 - d) becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality.
4. If requested to do so, the Undersigned agrees to return to WHO any and all copies of the Information.
5. The obligations of the Undersigned shall not cease on termination of the Activities.
6. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

Name: _____

Signature: _____

Date: _____

From: Richard KOJAN [richard.kojan@alima.ngo]
Sent: 9/16/2018 6:57:17 AM
To: BENASSI, Virginia [benassiv@who.int]
CC: Cox, Edward M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=162e42f507494baca7b6b8299a7b6bbb-COXE]; Augustin AUGIER [aug@alima.ngo]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; michael.jacobs@ucl.ac.uk; Rebecca GRAIS [rebecca.grais@epicentre.msf.org]; sina.bavari.civ@mail.mil; timo.wolf@kgu.de; mvitek@samaritan.org; Cavaleri Marco [Marco.Cavaleri@ema.europa.eu]; Armand Sprecher [Armand.Sprecher@brussels.msf.org]; Browne, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43044a5f1d3c4548b627436ddd2d7fcd-Sarah.Brown]; PREZIOSI, Marie-pierre [preziosim@who.int]; RIVEROS BALTA, Alina Ximena [lauriex@who.int]; DIAZ, Janet Victoria [diazj@who.int]; DIXIT, Devika [dixitd@who.int]; GSELL, Pierre [gsellp@who.int]
Subject: Re: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group

Hi all

When the team on the field will chose and decide therapeutic for PEP, example for zmap or remdesivir. The consequence for the patient will be hospitalisation on the CTE or in the office, individual room, for several days versus Mab 114, for only one day; favipiravir, the patient will take it home.
Well to think about randomisation, and consent about the patient. Or the field will think and decide on this point.

Richard Kojan

Le 14 sept. 2018 16:01, "BENASSI, Virginia" <benassiv@who.int> a écrit :

Dear All,

Hope you are doing very well.

Following Ed's message below, a kind reminder to those of you would like to do so, to please send Ed and myself **any comments you may have on the proposed draft (attached) by Monday 17 Sept (ideally midday GVA time) at the very latest**. If we don't hear from you by then, we assume you are in agreement with the content and we will proceed with finalization and clearance.

Many thanks in advance for your continuous support. Wishing you all a lovely weekend.

Kind regards,

Virginia

From: Cox, Edward M [mailto:Edward.Cox@fda.hhs.gov]
Sent: 12 September 2018 01:35
To: BENASSI, Virginia; aug@alima.ngo; Gruber, Marion; michael.jacobs@ucl.ac.uk; Rebecca GRAIS; Mulangu Sabue; sina.bavari.civ@mail.mil; timo.wolf@kgu.de; mvitek@samaritan.org; Cavaleri Marco; richard.kojan@alima.ngo; Armand Sprecher; Browne, Sarah; Cox, Edward M
Cc: PREZIOSI, Marie-pierre; RIVEROS BALTA, Alina Ximena; DIAZ, Janet Victoria; DIXIT, Devika; GSELL, Pierre
Subject: RE: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group

Hello All,

Attached I've tried to summarize some key points from our discussions regarding PEP for potential Ebola virus exposures. I used material from the paper by Mike Jacobs and colleagues and have tried to cite the material so as to recognize the source of the work.

Please feel free to edit, correct, improve, etc.

Thank you for the discussion earlier today. It was very helpful!

-Ed

From: BENASSI, Virginia <benassiv@who.int>
Sent: Tuesday, September 11, 2018 9:33 AM
To: Cox, Edward M <Edward.Cox@fda.hhs.gov>; aug@alima.ngo; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; michael.jacobs@ucl.ac.uk; Rebecca GRAIS <rebecca.grais@epicentre.msf.org>; Mulangu Sabue <[\(b\)\(6\)@yahoo.fr](mailto:(b)(6)@yahoo.fr)>; sina.bavari.civ@mail.mil; timo.wolf@kgu.de; mvitek@samaritan.org; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>; richard.kojan@alima.ngo; Armand Sprecher <Armand.Sprecher@brussels.msf.org>; Browne, Sarah <Sarah.Browne@fda.hhs.gov>
Cc: PREZIOSI, Marie-pierre <preziosim@who.int>; RIVEROS BALTA, Alina Ximena <lauriex@who.int>; DIAZ, Janet Victoria <diazj@who.int>; DIXIT, Devika <dixitd@who.int>; GSELL, Pierre <gsellp@who.int>
Subject: RE: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group

Dear All,

Please find here attached a Summary of inclusion/exclusion criteria, dose and route of administration for the investigational agents that could inform our discussion in a few minutes,

Many thanks,

Virginia

From: BENASSI, Virginia
Sent: 11 September 2018 09:40
To: 'Cox, Edward M'; 'aug@alima.ngo'; 'Marion.Gruber@fda.hhs.gov'; 'michael.jacobs@ucl.ac.uk'; 'Rebecca GRAIS'; 'Mulangu Sabue'; sina.bavari.civ@mail.mil; 'timo.wolf@kgu.de'; 'mvitek@samaritan.org'; 'Cavaleri Marco'; richard.kojan@alima.ngo; Armand Sprecher; Browne, Sarah
Cc: PREZIOSI, Marie-pierre; RIVEROS BALTA, Alina Ximena; DIAZ, Janet Victoria; DIXIT, Devika; GSELL, Pierre
Subject: RE: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group

Dear Colleagues,

Hoping this finds you all well.

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Below the dial in details:

+41.58.262.0722 / Participant code: (b)(6)

Looking forward to continuing our discussion today.

Best wishes,

Virginia

-----Original Appointment-----

From: BENASSI, Virginia

Sent: 05 September 2018 16:40

To: BENASSI, Virginia; Cox, Edward M; aug@alima.ngo; Marion.Gruber@fda.hhs.gov; michael.jacobs@ucl.ac.uk; Rebecca GRAIS; Mulangu Sabue; sina.bavari.civ@mail.mil; timo.wolf@kgu.de; mvitek@samaritan.org; Cavaleri Marco; PREZIOSI, Marie-pierre; RIVEROS BALTA, Alina Ximena; GSELL, Pierre; DIXIT, Devika; richard.kojan@alima.ngo; Armand Sprecher; DIAZ, Janet Victoria

Cc: Browne, Sarah

Subject: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group

When: 11 September 2018 15:30-16:30 (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna.

Where: Teleconference

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As anticipated, we are inviting you for a second teleconference **Tuesday 11 September 2018, at 15:30 Geneva time.**

Dial in details will be provided in the coming days by my colleagues. Hopefully this time the line will work better on our side. Apologies again for delay once again.

A warm thank-you in advance to you all,

Virginia *on behalf of the* WHO Secretariat

Virginia Benassi, LLM, MA

Technical Officer, Flagship Projects

Initiative for Vaccine Research, WHO/IVB

World Health Organization
Avenue Appia 20
CH-1211 Geneva 27, Switzerland
+41 22 79 14274

<< OLE Object: Picture (Device Independent Bitmap) >>

From: BENASSI, Virginia [benassiv@who.int]
Sent: 9/11/2018 9:32:52 AM
To: Cox, Edward M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=162e42f507494baca7b6b8299a7bbbbb-COXE]; aug@alima.ngo; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; michael.jacobs@ucl.ac.uk; Rebecca GRAIS [rebecca.grais@epicentre.msf.org]; Mulangu Sabue (b)(6)@yahoo.fr]; sina.bavari.civ@mail.mil; timo.wolf@kgu.de; mvitek@samaritan.org; Cavaleri Marco [Marco.Cavaleri@ema.europa.eu]; richard.kojan@alima.ngo; Armand Sprecher [Armand.Sprecher@brussels.msf.org]; Browne, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43044a5f1d3c4548b627436ddd2d7fcd-Sarah.Brown]
CC: PREZIOSI, Marie-pierre [preziosim@who.int]; RIVEROS BALTA, Alina Ximena [lauriex@who.int]; DIAZ, Janet Victoria [diazj@who.int]; DIXIT, Devika [dixitd@who.int]; GSELL, Pierre [gsellp@who.int]
Subject: RE: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group 1
Attachments: Summary table_CRITERIA for PEP use of Investigational Agents_10Sept2018.....docx

Flag: Follow up

Dear All,

Please find here attached a Summary of inclusion/exclusion criteria, dose and route of administration for the investigational agents that could inform our discussion in a few minutes,

Many thanks,
Virginia

From: BENASSI, Virginia
Sent: 11 September 2018 09:40
To: 'Cox, Edward M'; 'aug@alima.ngo'; 'Marion.Gruber@fda.hhs.gov'; 'michael.jacobs@ucl.ac.uk'; 'Rebecca GRAIS'; 'Mulangu Sabue'; sina.bavari.civ@mail.mil; 'timo.wolf@kgu.de'; 'mvitek@samaritan.org'; 'Cavaleri Marco'; richard.kojan@alima.ngo; Armand Sprecher; Browne, Sarah
Cc: PREZIOSI, Marie-pierre; RIVEROS BALTA, Alina Ximena; DIAZ, Janet Victoria; DIXIT, Devika; GSELL, Pierre
Subject: RE: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group

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Below the dial in details:

+41.58.262.0722 / Participant code: (b)(6)

Looking forward to continuing our discussion today.

Best wishes,
Virginia

-----Original Appointment-----

From: BENASSI, Virginia
Sent: 05 September 2018 16:40
To: BENASSI, Virginia; Cox, Edward M; aug@alima.ngo; Marion.Gruber@fda.hhs.gov; michael.jacobs@ucl.ac.uk; Rebecca

GRAIS; Mulangu Sabue; sina.bavari.civ@mail.mil; timo.wolf@kgu.de; mvitek@samaritan.org; Cavaleri Marco; PREZIOSI, Marie-pierre; RIVEROS BALTA, Alina Ximena; GSELL, Pierre; DIXIT, Devika; richard.kojan@alima.ngo; Armand Sprecher; DIAZ, Janet Victoria
Cc: Browne, Sarah
Subject: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group
When: 11 September 2018 15:30-16:30 (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna.
Where: Teleconference

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Virginia *on behalf of the* WHO Secretariat

Virginia Benassi, LLM, MA
Technical Officer, Flagship Projects
Initiative for Vaccine Research, WHO/IVB
World Health Organization
Avenue Appia 20
CH-1211 Geneva 27, Switzerland
+41 22 79 14274

<< OLE Object: Picture (Device Independent Bitmap) >>

Investigational vaccine and/or investigational therapeutic agents for post-exposure prophylaxis (PEP) in individuals who have been exposed to Ebola virus

Summary of inclusion/exclusion criteria, dose and route of administration

Product	Target population Inclusion criteria PEP use	Exclusion criteria PEP use	Administration PEP use	Administration Therapeutic use	Storage conditions
rVSVΔG-ZEBOV-GP (V920) Vaccine	<i>Individuals with a high-risk exposure to Ebola virus (PEP protocol)</i> • Aged 2 years or older. • Must have a high-risk exposure to Ebola virus within the preceding 24 hours, which includes any of the following: ▪ Percutaneous (e.g., needle stick) or mucous membrane exposure to blood or body fluids of a person with Ebola while the person was symptomatic. ▪ Exposure to the blood or body fluids (including but not limited to feces, saliva, sweat, urine, vomit, and semen) of a person with Ebola while the person was symptomatic without appropriate personal protective equipment (PPE; as defined at [HYPERLINK "http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html"]). ▪ Processing blood or body fluids of a person with Ebola while the person was symptomatic without appropriate PPE or standard biosafety precautions. ▪ Direct contact with a dead body without appropriate PPE in a country with widespread Ebola virus transmission (as defined at [HYPERLINK "http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html"]). ▪ Having lived in the immediate household and provided direct care to a person with Ebola while the person was symptomatic. Option for Enrollment of Pregnant or Breastfeeding Women • Pregnancy: Pregnant women are typically excluded from receipt of a novel live viral vaccine. This is the	• Positive urine or serum pregnancy test. ▪ Exception: see below - Option for Enrollment of Pregnant or Breastfeeding Women. • Females currently breastfeeding ▪ Exception: see below - Option for Enrollment of Pregnant or Breastfeeding Women • Known immunodeficiency condition that, in the judgment of the PI, would significantly alter the potential risk of harm versus potential benefit in the emergency PEP situation	IM injection A nominal dose of $\geq 2 \times 10^7$ pfu Subjects will be advised to avoid any immunosuppressive drugs such as corticosteroids in the 14-day period following administration of the study agent.	Not applicable	-60°C to -80°C for long-term storage

Product	<i>Target population</i> Inclusion criteria PEP use	Exclusion criteria PEP use	Administration PEP use	Administration Therapeutic use	Storage conditions
	case in this study because the effects of the V920 on the developing human fetus are unknown. However, the protocol does permit an exception in cases where an EBOV exposure is felt to be very high risk of harm and the patient is fully informed and willing to accept the unknown risk of harm to herself or the fetus from V920 PEP. The special informed consent addendum must be utilized for this scenario. • Breastfeeding: Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with the V920, breastfeeding should be discontinued before vaccine administration and should not be resumed until medically indicated.	• Known anaphylactic reaction to the components of the V920 (e.g., VSV, albumin, Tris buffer). • Any condition that, in the opinion of the PI, would contraindicate participation in this protocol.			

Product	Target population Inclusion criteria PEP use	Exclusion criteria PEP use	Administration PEP use	Administration Therapeutic use	Storage conditions
ZMapp	<i>Individuals with high-risk exposure to Zaire ebolavirus (same protocol for PEP and TTT)</i> - Males or females of any age with high risk exposure to <i>Ebolavirus</i> within the last 10 days. High risk exposure may include the following: - Direct contact with bodily fluids from a confirmed <i>Ebolavirus</i> case - Needle stick injury with a potentially <i>Ebolavirus</i> contaminated needle - Prolonged exposure to an <i>Ebolavirus</i> infected person without personal protective equipment (PPE) - Willingness to provide informed consent personally, or by a legally authorized representative (LAR) [per applicable local laws and regulations, in instances where the patient is unable to do so]. - All females of childbearing potential must be willing to use highly effective [e.g. absolute abstinence from potentially reproductive sexual activity, hormonal, surgical or multiple barrier/combined] methods of contraception, from time of enrollment through at least 90 days after receiving ZMapp. All sexually active men must be willing to use condoms for at least 90 days after ZMapp treatment.	Any medical condition that, in the opinion of the site investigator, would place the patient at an unreasonably increased risk through participation in this treatment protocol.	Same as TTT.	IV infusions Three infusions of 50 mg/kg with three days intervals. First infusion will take at least 5 hours and 30 minutes for an individual of 70 Kg. Second and third infusion will last at least 4 hours and 45 minutes. They can take longer depending on the reaction linked to the infusions.	-20°C ± 5 °C until time to thaw drug in preparation for infusion. If there is no - 20 ± 5 °C storage freezer available at a clinical site, the investigational product may be stored at 2-8°C for no longer than three (3) months.

Product	Target population Inclusion criteria PEP use	Exclusion criteria PEP use	Administration PEP use	Administration Therapeutic use	Storage conditions
Remdesivir	<i>Individuals with exposure to Ebola virus (PEP protocol)</i>		IV infusion (30 minutes) 100 mg once-daily (q24h) for 5 days. Upon completion of a 5-day course of treatment, the investigator (in consultation with Gilead) will determine if additional treatment should be administered. The recommended initial dosing duration is no more than 5 days but duration may vary depending on the condition of the patient.	150 mg followed by 9 days of the 100 mg once-daily maintenance dose for patients with acute EVD 30 min infusion for lyophilized formulation and 60 to 120 minutes for solution formulation	Solution formulation should be stored frozen between -25°C and -10°C. After thawing sealed vials can be stored up to 12 hours at room temperature. After diluting the formulation can be stored up to 4 hours at room temperature or 24 hours 2-8°C.
MAb114	<i>Not specifically defined for PEP (same protocol for PEP and TTT)</i>	Any medical condition that, in the opinion of the Treating Physician, would place the patient at an unreasonably increased risk through	Same as TTT.	IV infusion single dose of about 50 mg/kg.	long-term storage temperature at 2-8°C.

Product	<i>Target population</i> Inclusion criteria PEP use	Exclusion criteria PEP use	Administration PEP use	Administration Therapeutic use	Storage conditions
		participation in this treatment protocol			
REGN3470- 3471-3479	<i>Not specifically defined for PEP (same protocol for PEP and TTT)</i>	Must not have received other antibodies (monoclonal or polyclonal) that bind to the same target (Ebola GP) within the last 30 days as these antibodies may reduce the efficacy of REGN3470-3471-3479 by preventing the binding of REGN3470-3471-3479 to Ebola GP.	Same as TTT.	Single dose of 150 mg/kg (total dose, at 1:1:1 ratio for each antibody) Investigators should not administer other antibodies (monoclonal or polyclonal) that may target Ebola GPs within 30 days of infusion of REGN3470-3471-3479 due to the potential of the other	Between 2-8°C

Product	<i>Target population</i> Inclusion criteria PEP use	Exclusion criteria PEP use	Administration PEP use	Administration Therapeutic use	Storage conditions
				antibodies to block the binding of REGN3470-3471-3479 to Ebola virus and thereby reduce the efficacy of REGN3470-3471-3479 • Patients should not receive another anti-ebola investigational product within 30 days of infusion of REGN3470-3471-3479 • Investigators should be aware that the presence of REGN3470-3471-3479 in the blood may interfere with the	

Product	<i>Target population</i> Inclusion criteria PEP use	Exclusion criteria PEP use	Administration PEP use	Administration Therapeutic use	Storage conditions
				activity of Ebola vaccines	

From: BENASSI, Virginia [benassiv@who.int]
Sent: 9/11/2018 3:40:29 AM
To: Cox, Edward M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=162e42f507494baca7b6b8299a7bbbbb-COXE]; aug@alima.ngo; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; michael.jacobs@ucl.ac.uk; Rebecca GRAIS [rebecca.grais@epicentre.msf.org]; Mulangu Sabue (b)(6)@yahoo.fr]; sina.bavari.civ@mail.mil; timo.wolf@kgu.de; mvitek@samaritan.org; Cavaleri Marco [Marco.Cavaleri@ema.europa.eu]; richard.kojan@alima.ngo; Armand Sprecher [Armand.Sprecher@brussels.msf.org]; Browne, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43044a5f1d3c4548b627436ddd2d7fcd-Sarah.Brown]
CC: PREZIOSI, Marie-pierre [preziosim@who.int]; RIVEROS BALTA, Alina Ximena [lauriex@who.int]; DIAZ, Janet Victoria [diazj@who.int]; DIXIT, Devika [dixitd@who.int]; GSELL, Pierre [gsellp@who.int]
Subject: RE: Follow up - EVD Therapeutics and Vaccines for compassionate PEP use Working Group
Attachments: DRAF_TC_WHOConsultation_PEP_InvestigationalThXorVaccine_5_Sept2018_ts.docx

Flag: Follow up

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+41.58.262.0722 / Participant code: (b)(6)

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Virginia

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Thank you very much for your time on the call today and for the excellent discussion. A warm thank-you to our chair, Dr Ed Cox.

As anticipated, we are inviting you for a second teleconference **Tuesday 11 September 2018, at 15:30 Geneva time.**

Dial in details will be provided in the coming days by my colleagues. Hopefully this time the line will work better on our side. Apologies again for delay once again.

A warm thank-you in advance to you all,
Virginia *on behalf of the* WHO Secretariat

Virginia Benassi, LLM, MA

Technical Officer, Flagship Projects

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<< OLE Object: Picture (Device Independent Bitmap) >>

Notes for the record:

**WHO Consultation on Post-Exposure Prophylaxis Utilizing Investigational
Therapeutics or Investigational Vaccine**

An independent group of experts was convened by the WHO for the purpose of discussing the use of investigational vaccine and or investigational therapies post-exposure for persons who have been exposed to Ebola virus, 5 September 2018.

Participating Experts:

Dr. Edward Cox (Chair), Mr. Augustin Augier*, Dr. Sina Bavari, Dr Marco Cavaleri, Dr Rebecca Graïs, Dr Marion Gruber, Dr Michael Jacobs, Dr Richard Kojan, , Dr Sabue Mulangu*, Dr Armand Sprecher, Dr Megan Vitek, Dr Timo Wolf* (*unable to attend)

A range of factors to consider in the discussion included the following:

- Potential investigational agents used for post exposure prophylaxis
 - Vaccine -- Merck 920 vaccine
 - Therapeutics – ZMapp, Remdesivir, Regeneron’s 3470-3471-3479, mAb114, (and possibly favipiravir in certain select circumstances)
- Anticipated number of events for which post-exposure prophylaxis (PEP) would be considered / utilized
 - Individual patient use with data collection vs. protocol randomizing to one of the investigational agents
- Available drug supply for each of the different agents that might be used for PEP
- Risk Criteria for an exposure event – when to consider the use of PEP – level of risk and how to define
- Potential for Vaccine / Therapeutic interaction(s) that might lead to potentially reduced protection from Ebola virus disease (EVD) that may be afforded by use of these investigational agents

Vaccine

- The potential use of the Merck 920 vaccine as PEP was discussed.
- It was noted that there is some data from NHP studies that vaccine administered soon after Ebola inoculation did provide protective immunity.
- There was mention of cases where persons received vaccine after an exposure event, however there was uncertainty around the exposure and whether the exposure was such that it would have led to Ebola infection making it very difficult to assess whether vaccine provided benefit or if infection would not have occurred anyways.
- Ideally healthcare workers would already have been vaccinated (as part of a healthcare worker vaccination program) given their potential risk of exposure.
- Vaccine immunity should be present 2-3 weeks after receiving vaccination and is expected to last at least for several months after vaccination.

- There may also be innate immunity stimulation after vaccination that occurs early after vaccination.
- Some PEP vaccination protocols used a dose of 1×10^8 units rather than the 2×10^7 dose used in routine vaccination.
- Vaccination as PEP could be considered at up to 24, 48, or even 72 hours after the exposure event as it is possible that later vaccination (i.e., vaccination at 48 to 72 hours after the exposure event could possibly provide some degree of partial protection or disease modification).
- There is uncertainty and a lack of data to address the question of whether co-administration of an investigational therapeutic and vaccine would interfere with the potential protective capacity of the agent(s) to prevent EVD. It is quite possible that a monoclonal antibody(ies) against Ebola could, to some degree, interfere with the development of vaccine induced immunity (or potentially vice versa). Remdesivir should not interfere with the VSV-based vaccine. Vaccine administration that precedes the use of an anti-Ebola monoclonal antibody by several weeks is unlikely to be associated with vaccine / drug interference.
- It is possible that vaccinated individuals may develop a febrile response after vaccination and this could create some uncertainty as to the etiology of their fever (e.g., vaccine associated fever vs. fever secondary to EVD). PCR testing should be able to help with assessing the etiology for the fever. Some type of isolation of the person with a fever post exposure event and post vaccination may be implemented when a fever occurs while sorting out the possible etiology for the fever.
- Even if a vaccine is highly effective in a very high percentage of patients, there may be some persons who after a high-risk exposure in whom there may be reasons to consider PEP.

Therapeutics

- For high-risk exposures the consultant group thought that it was reasonable to consider post exposure prophylaxis with ZMapp, Remdesivir, Regeneron 3470, 3471, 3479 or mAb114.
- There was uncertainty as to projections about how many events (e.g., high risk exposures) that could lead to PEP would occur, but some thought that it would be a limited number of cases.
- There was mention of if there were only a few anticipated uses of PEP that use in individual patients is probably a reasonable way to proceed at this point in time. Should it be anticipated that there would be more than the a very limited amount of use of PEP, there was a suggestion that a randomized controlled trial be implemented that could compare different agents as PEP. Collection of data in any circumstance when PEP was utilized was suggested.
- Possible risk exposures with differing levels of risk were mentioned, such as:
 - A deep needle stick with a bloody hollow bore needle from a patient with Ebola virus disease
 - Persons involved in a burial ritual
 - Household contacts of person diagnosed with EVD
 - Many people attending a burial ceremony
- There was mention of different levels of risk depending on the type of exposure and how this may impact consideration for PEP.
 - The topic of level of risk and how it impacts PEP will be discussed at a next teleconference.

From: Richard Hatchett [richard.hatchett@cepi.net]
Sent: 9/20/2018 8:21:42 AM
To: Nora Indrehus [nora.indrehus@cepi.net]; Melanie Saville [melanie.saville@cepi.net]; Hinta Meijerink [hinta.meijerink@cepi.net]; Carolyn Clark [carolyn.clark@cepi.net]; Raul Gomez Roman [raul.gomezroman@cepi.net]; Frederik Kristensen [frederik.kristensen@cepi.net]; Gerard Cunningham [(b)(6)]@outlook.com; Dimitrios Gouglas [dimitrios.gouglas@cepi.net]; Nicole Lurie [nicole.lurie@cepi.net]; Dawn OConnell [dawn.oconnell@cepi.net]; Shannon Quinlan [shannon.quinlan@cepi.net]; Barrett, Alan [abarrett@utmb.edu]; Alash'le Abimiku [a.abimiku@ihv.umaryland.edu]; Allouche, Ali [Ali.allouche@takeda.com]; Charlie Weller [C.Weller@wellcome.ac.uk]; christian.brechot@pasteur.fr; happic@run.edu.ng; connie.s.schmaljohn.civ@mail.mil; Daniel Brasseur [(b)(6)]@gmail.com; mimi darko [(b)(6)]@yahoo.co.uk; gaof@im.ac.cn; hrees@wrhi.ac.za; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; James Robinson [(b)(6)]@outlook.com; Jean Lang [Jean.Lang@sanofipasteur.com]; JVHOF1@its.jnj.com; John Edmunds [John.Edmunds@LSHTM.ac.uk]; Josie Golding [j.golding@wellcome.ac.uk]; kneuzil@som.umaryland.edu; kathrin.jansen@pfizer.com; shibuyak@m.u-tokyo.ac.jp; Michel De Wilde [(b)(6)]@aol.com; Levine, Myron [Mlevine@som.umaryland.edu]; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; Penny Heaton [penny.heaton@gatesmri.org]; Peter Smith [Peter.Smith@lshtm.ac.uk]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Ralf Clemens [(b)(6)]@outlook.com; admin@vaxconsult.com [stanley.plotkin@vaxconsult.com]; Tom Kariuki [t.kariuki@aaesciences.ac.ke]; moorthyv@who.int; yves.levy@inserm.fr; Joseph Simmonds-Issler [jsi@cepi.net]; Gunnstein Norheim [gunnstein.norheim@cepi.net]; Jean.Lang@sanofi.com; michel De Wilde [(b)(6)]@outlook.com
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Subject: RE: Notes from SAC meeting last week
Attachments: Feedback and comments from SAC members 12 Sep 2018.docx; WHO Priority Pathogen Pipeline.pptx; SAC 18-3 DC TC Summary of proceedings 12092018.docx; SAC Interests.pdf; Slides for SAC roundtable discussions 20.09.18 (2).pdf

Dear all,

In case helpful, we wanted to share a consolidated summary of the input that we have received from individual SAC members, some of whom won't be able to participate on tomorrow's call, as well as a summary slide of the pipelines, as we understand them, for the WHO Priority Pathogens. We focused principally on Chikungunya in the presentations on last week's call, but the Secretariat would welcome your thoughts or guidance about investments in other priority pathogens. We did not cover Rift, Zika, CCHF, or other pathogens exhaustively but recognize that a case can be made for these as well.

In order to maintain trust and integrity in the advisory process of CEPI's SAC, it is important that you declare any interests in regard to the investment areas being explored to the CEPI Secretariat ahead of the meeting. Please find attached the most recent overview of DOI as received at the last SAC meeting. Please check and update this with regards to the issues being discussed at today's SAC.

Please send any questions or comments to Nora Indrehus at CEPI, and we look forward to the TC later today.

Best Regards,
Richard

From: Nora Indrehus

Sent: 18 September 2018 15:15

To: Richard Hatchett <richard.hatchett@cepi.net>; Melanie Saville <melanie.saville@cepi.net>; Hinta Meijerink <hintameijerink@cepi.net>; Carolyn Clark <carolyn.clark@cepi.net>; Raul Gomez Roman <raul.gomezroman@cepi.net>; Frederik Kristensen <frederik.kristensen@cepi.net>; Gerard Cunningham <(b)(6)@outlook.com>; Dimitrios Gouglas <dimitrios.gouglas@cepi.net>; Nicole Lurie <nicole.lurie@cepi.net>; Dawn OConnell <dawn.oconnell@cepi.net>; Shannon Quinlan <shannon.quinlan@cepi.net>; Barrett, Alan <abarrett@utmb.edu>; Alash'le Abimiku <aabimiku@ihv.umaryland.edu>; Allouche, Ali <Ali.allouche@takeda.com>; Charlie Weller <C.Weller@wellcome.ac.uk>; christian.brechot@pasteur.fr; happic@run.edu.ng; connie.s.schmaljohn.civ@mail.mil; Daniel Brasseur <(b)(6)@gmail.com>; mimi darko <(b)(6)@yahoo.co.uk>; gaof@im.ac.cn; hrees@wrhi.ac.za; Damon, Inger K. (CDC/OID/NCEZID) <iad7@cdc.gov>; James Robinson <(b)(6)@outlook.com>; Jean Lang <Jean.Lang@sanofipasteur.com>; JVHOOF1@its.jnj.com; John Edmunds <John.Edmunds@LSHTM.ac.uk>; Josie Golding <j.golding@wellcome.ac.uk>; kneuzil@som.umaryland.edu; kathrin.jansen@pfizer.com; shibuyak@m.u-tokyo.ac.jp; Michel De Wilde <(b)(6)@aol.com>; Levine, Myron <Mlevine@som.umaryland.edu>; Bryant, Paula (NIH/NIAID) [E] <paula.bryant@nih.gov>; Penny Heaton <penny.heaton@gatesmri.org>; Peter Smith <Peter.Smith@lshtm.ac.uk>; Phil Krause <philip.krause@fda.hhs.gov>; Ralf Clemens <(b)(6)@outlook.com>; admin@vaxconsult.com <stanley.plotkin@vaxconsult.com>; Tom Kariuki <t.kariuki@aasciences.ac.ke>; moorthyv@who.int; yves.levy@inserm.fr; Joseph Simmonds-Issler <jsi@cepi.net>; Gunnstein Norheim <gunnstein.norheim@cepi.net>; Jean.Lang@sanofi.com; michel De Wilde <(b)(6)@outlook.com>
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Subject: Notes from SAC meeting last week

Dear SAC members,

Please find attached draft notes from the SAC meeting on September 12th 2018, and do not hesitate to send us your revisions to this (to Raul Gomez Roman raul.gomezroman@cepi.net).

In order to maintain trust and integrity in the advisory process of CEPIs SAC, it is important that you declare any interests in regard to the investment areas being explored to the CEPI secretariat ahead of the meeting (e.g. will you or affiliated colleagues benefit by investments in this area). We further trust that your insights are put forward in a manner not affected by these should there be any COI.

Attached you will also find slides for the TC and dial-in info below.

Please communicate any questions or comments to me, and we look forward to the TC on Thursday.

Best regards,

Nora Indrehus

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US +13152940334	(b)(6) (Intility)	English (United Kingdom)
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Feedback and comments from SAC members

Received per 19 Sept 2018

SAC member	Feedback
Jean Lang, Sanofi	-Outbreak Response Remarkable document and analysis. No further comments at my end -Epidemiology. This is a key area whether to have sentinel sites to detect threshold outbreaks / emerging pathogens or as a prelude to an efficacy trial (will it be IIb or III) for an established pathogen like Lassa (see slide 12 of the OR deck). So I will expand the question beyond Lassa which is an obvious need. Two recommendations in terms of future positioning 1) Map out the Ecosystem of the involved Structures and Public Sector Initiatives/ PPPs to avoid duplication (eg GLOPID-R, EDCTP, H2020 etc.) by regions eg LatAm, SEA, Africa, and ensure catalytic investment of CEPI 2) Ensure synergies with the CEPI Dx/ FIND Initiative
Penny Heaton, BMGF	1. Regarding the recommendation for Chikungunya, I find this intriguing. A chikungunya vaccine could be a quick win for CEPI given the advanced stage of development of some candidates. My only hesitation with funding a new CfP is that I believe there is a market – and CEPI’s mission is to focus on those vaccines with a market failure. I think a reasonable compromise would be a CfP for funding development through Phase 2 with the provision for a commitment from the manufacturer to provide vaccine at a very affordable price (e.g., COGS+5%) in the event of outbreaks in LICs. A CfP for phase 3 development should only be done with major co-funding (e.g., 75% from other funders) including significant funding (in-kind and other) from the commercial manufacturer. It also seems a Chikungunya vaccine program could be a candidate for innovative financing mechanisms. 2. Regarding gene-encoded antibodies - I don’t think it matters whether they fit the definition of a classic vaccine or not. The question is whether they could be a good tool against outbreaks with epidemic/pandemic potential. Despite the hurdles mentioned, I think this is an important tool to have in our epidemic tool box, particularly for pathogens with a short incubation period. Ideally there would be a dual approach – 1) pre-identification of antibodies against pathogens at high risk of causing outbreaks (i.e., WHO’s list of priority pathogens that have a short incubation period and for which protection is antibody-mediated) and development/testing of gene-encoded antibodies for those pathogens; and 2) Evaluation of timing/how long it would take to identify protective antibodies against diseases caused by as-of-yet unknown pathogens and subsequently develop “vaccine” to deliver gene(s) coding for those antibodies. Such an exercise may pre-identify gaps and drive innovation to fill those gaps. I’m unsure of DARPA, but it appears other investors are not focused on outbreak pathogens per se (with the exception of flu); therefore, this is a gap. While I think this is very important, I recognize this would likely not provide the quick CEPI win that a Chikungunya vaccine would. 3. Regarding adjuvants – Adjuvants potentially have an important role in dose sparing and duration of immunity (although with an outbreak, how important is duration?). However, a vaccine product is the combination of the antigen and adjuvant, i.e., one cannot get regulatory approval of an adjuvant alone. Therefore, I think adjuvant access should have been considered with CfP1. In fact, adjuvant access will be difficult until they can be made synthetically and fully characterized like a small molecule. And that is an investment more appropriate for DARPA and/or NIH. I would not recommend CEPI investments in current adjuvants beyond those being evaluated in CfP1 projects. It would be good for CEPI to influence organizations whose focus is upstream to consider investments to accelerate development of synthetic adjuvants.

	4. With regard to novel approaches to vaccine development and rapid response - First, I am not entirely clear on what approaches would be suggested and/or what constitutes a novel approach. Several novel technologies (i.e., platforms not previously utilized for currently licensed vaccines) are included in CfP1 and CfP2. If this is referencing “hyper-novel” approaches, I think that is something best left to organizations that fund upstream work (e.g., DARPA); such investments are unlikely to lead to tangible deliverables by 2022. 5. Regarding epidemic vaccines for pregnant women - this is an important consideration given the relative immunosuppression and vulnerability of pregnant women in outbreaks. Ideally it would have been considered in CfP1 development programs. That said, it’s not too late. One approach would be to develop criteria for studying the current CfP 1 vaccines in a subgroup of pregnant women – e.g., vaccines on platforms already utilized for pregnant women (i.e., recombinant/subunit proteins, toxoids, inactivated viruses/bacteria), vaccines that appear safe and immunogenic in phase 1 studies (i.e., successfully pass that stage gate), vaccines against pathogens for which there is evidence of severe disease in pregnant women (i.e., Lassa), etc... This approach would at least be a start while the issue is considered on a larger scale. 6. Regarding epi studies for Lassa, I fully support these – the need is great and the data will increase the probability of executional success of phase 2 and phase 3 studies.
Stanley Plotkin	May I say that I heartily endorse Ralf’s views. A success with Chikungunya would put CEPI on the map and all the tools are available. With regard to Zika, I think an analysis of the field including the issues surrounding interactions with dengue, could clarify matters and determine whether or not to go in that direction.
Ralf Clemens	- It is my understanding that CEPI’s goal of having at least 2 different vaccines – ideally from the WHO blueprint list – licensed for EUL use by end 2022. The current portfolio of Lassa and MERS candidates is rich, less so the Nipah pipeline. Given the typical attrition rates in industry and given the fact the some of the consortia have limited experience in bringing a vaccine candidate to the finish line one of the key CEPI’s objectives is at risk. The only way to enrich our portfolio is in my opinion to screen again the Nipah field and identify candidates with a different profile than VLPs to hedge a technology risk. I understand that most of them are early stages but these candidates could benefit from RA/ Clin Dev experience of more advanced candidates and hence could make up some time. - My recommendation would be to focus on Chikungunya, and here on the 3 or 4 most advanced candidates. Vaccine attritions at end of phase 2 is less than 30%, so we have good chances to have a winner. I would invest in their phase 3 trials – and here I do NOT talk about a pre-licensure efficacy trial but generation of safety data (typical exposure 3,000 subjects), lot-to-lot consistency, individuals with underlying diseases, etc. And these trials are contrary to what is often portrait not that expensive if one does the studies outside of US and Europe. I guess that costs per subject can be in the vicinity of 6-8.000 US\$ per subject. I would NOT invest in projects which are not at end of phase 1 because they will most likely not make it to licensure by end 2022. The second area of focus would be for me RA – whilst 2 companies I know of have received already RA advice, we should try to get a clear position from regulators in general. Chik is on the priority list and hence might be available for a voucher. The last vaccine voucher was sold by Paxvax to Gilead for a value of more than 200 Mio US\$. If we fund a vaccine which makes it to licensure, gets a voucher and the voucher is capitalized, CEPI should get a return of its investment. Zika: there is indeed less enthusiasm for a Zika vaccine in the field, including with donors. Like Chick, it will most likely not be possible nor required to show clinical efficacy pre-licensure. We could identify 2-3 lead candidates and support them thru phase 3. Again, this is less expensive than one might think. The benefit would also be that one of the lead candidates is a DNA vaccine from Inovio where we could at the same time learn a lot about the platform.

	• Whilst the presentations about adjuvants and gene encoded antibodies were scientifically very interesting an investment in any of these at this point does not help to achieve the objectives. We should not lose track of what is going on in these areas but not actively invest now. Midterm we might want to consider more downstream invest in the gene encoded antibodies but not before the delivery and packing issues have been solved. With respect to adjuvants my recommendation would be to NOT actively engage in R&D but try to get access from companies like GSK or IDRI to some of their compounds for selective public health use. This will not be trivial however for reasons such as safety monitoring and IP.
Jim Robinson	a. On outbreak, the outline and thinking is clear. It is important to align stakeholders in advance of an outbreak to move more quickly when things break, but of course it is difficult when we do not know the disease or the country (although we can make assumptions). The key points for me are (1) reserve funding available, (2) regulatory pathways, (3) pipeline surveillance in parallel with disease surveillance. I am not sure we can have “one plan”, but perhaps we could have a plan per disease area in our portfolio and we can start with L, M, N; as they are the most relevant for CEPI. Perhaps from those, we could create a generic plan and decision tree for disease X and CfP2 targets. b. On Epi – It is certainly not in my area of specialty, but I think this is well done from an overall planning and stakeholder engagement. The latter is key (to Jean’s point) as engagement now with key stakeholders will improve acceptance of results later. 3. On our discussion Thursday – from Richard’s opening slides at the SAC, there have been changes in priorities since CEPI’s original strategy was set. In particular, Finishing Ebola and changes in funding for Zika. The lesson we often re-learn is that we must continue to advance development even when the issue is not in outbreak mode in order to be ready for the outbreak. So I would want to understand how we may continue a point of focus on these programs within CEPI (not running the programs, but understanding status of programs and what gaps we might help fill), and fund development as needed, while looking at other new opportunities presented in the deck.
Connie Schmaljohn, USAMRIID	Just a few comments: Outbreak response: I agree that CEPI could play a role for reasons listed, such as building relationships and especially collecting samples to be used for vaccine development. However, this will not eliminate the problem of getting those samples out of the impacted country, to where they could be used for vaccine efforts. <u>Outbreak response can be a very large and costly endeavor, and I am not sure that CEPI should try to take on as much as is listed there.</u> It might be possible to collaborate with other outbreak response groups as on slide 4, but many are Government organizations (e.g., Public Health Canada, CDC, USAMRIID, etc), which would probably present some contracting challenges. We could consider setting up or supplementing prepositioned laboratory capabilities to accomplish goals on slide 5. Personally, I think that CEPI's role should not be in all of those areas, but should focus on the first 2 (collecting acute and convalescent samples and gene sequencing/sharing). Epidemiology is entirely different and is the subject of the next discussion. One thought is that we could consider reviewing the Global Virus Network (GVN) centers of excellence to see if there are any laboratories that would be useful for CEPI's purposes. Or CEPI could identify different laboratories that have some capabilities and would be on standby for an outbreak to do the CEPI work. I think that slides 6-10 are very well thought through and right on target. Starting at Slide 11, I am not so sure that developing diagnostic tests is as important. Yes, it is important to have diagnostic tests, but if you have a virus isolate or even a gene sequence, vaccine development and animal modeling can begin. But if supporting FIND to develop the assays is what is being

	considered, that might be a worthwhile investment. As reiterated below, I am in favor of funding animal model development to provide accurate assessment of vaccines. I think that for vaccine development, the epidemiological studies are a separate issue, not part of outbreak response and should be conducted prior to an outbreak. Also, while community mobilization is needed, is that really CEPI's role? It seems that CEPI is drifting kind of far from the original goal of vaccines for emerging epidemics. I am not sure what is being asked for in slide 16, so will withhold comment. Epidemiology: I think it is very important to support LASV epidemiological studies. I am not sure how easy it is going to be to work across countries, as usually there are a lot of political hurdles. Nevertheless, to get a truer picture of the disease in each country would be very useful for planning. With regard to the workshop in Ghana, I am very interested, but already have a commitment in Paris the following week, so not sure it would work out logistically. Areas suggested for exploration. Prioritizing near term research. I am not sure additional cFP1 projects are needed right now. It appeared from the presentations that nothing really new came from the RFI. <u>There are 2 additional areas that I feel need attention 1. animal modeling using consistent and defined reagents and procedures. (Maybe this is really 2 separate investments) 2. defining acceptable correlates of immunity to compare vaccines</u> Antibody therapy is definitely a hot topic right now (and has been in the past). It can't replace a vaccine though. So, I am in favor of funding some of these efforts, but they should be tested in animal models of one of the priority pathogens, not surrogates. I feel the same way about adjuvants. Important, but need reality checks. I am not sure that I agree with supporting innovation in vaccine manufacturing capabilities per se, but do favor it if it is a promising technology that would speed up vaccine production for items already in the CEPI portfolio.
Inger Damon	Outbreak response – considerations are all encompassing of what is needed in understanding an outbreak, and coordinating a response efforts – and worthwhile for the SAC to consider which are a good use of CEPI resources vs. leveraging others' resources Lassa epidemiology – is the driver for this to understand at risk populations, and how to apply vaccinations to prevent endemic disease or to prevent outbreaks? if so, some disease related outcomes would be important to include in the studies -
Michel De Wilde	On outbreak response: This is a very comprehensive, well-articulated proposal. While addressing need swell beyond vaccines, it my view that CEPI should play a key role in this. A key issue is to ensure minimum duplication and establish the leadership roles in each aspects. The RACI matrix will be key in this regard and I look forward to see it. Another element is resources. I think that CEPI's resources are already spread quite thin. As much as I would hate to see CEPI evolving into a large slow moving organization, I do believe that this initiative requires dedicated resources. On Lassa epi studies:

	Clearly necessary undertaking. Same question on duplication of effort and leadership. I am unclear on the site selection process. Will it be done internally within CEPI? Before or after the workshop?
Johan von Hoof	Finishing the job on Ebola: “identify research gaps that facilitates vaccine licensure”. - The workshop organized by CEPI in Washington last year has stimulated the dialogue between all stakeholders, especially vaccine developers and the agencies. It certainly has helped progress for the vaccines in development. - I have concerns around the process through which ‘research gaps’ referred to above will be identified; investments made. I would encourage CEPI to ensure vaccine developers are included in this discussion, and can contribute to the final decisions taken. It will be important also to ensure this does not interfere with the ongoing dialogue with the agencies regarding the path to licensure based on the animal rule. It should in my view focus on how to best address questions such as persistence of protection, optimized vaccination schedule, path towards cross filo virus protection. (ie discussion about a multivalent vs. monovalent vaccines). Might it be a good idea to organize a workshop, similar to the one of last year, around this theme ?. Zika: - As Richard highlighted, funding of a Zika Vaccine has declined. The dynamics of the epidemic has made its market less to non-attractive for commercial development. If CEPI aims to show results by 2021, contributing to creation of a Zika stockpile vaccine by that time is in my view within reach. The protection data obtained in NHP models, combined with successful positive transfer tests would make this feasible. <u>New investment areas -</u> - All of the investment opportunities presented look very exciting. This creates the challenge of prioritization, having to balance several factors such as ‘degree of medical need’, ‘time to success’, ‘probability of success’, investment till next milestone, investment till ‘use’, balancing risks ‘short/mid/and long term’. I recognize a lot of similarities with the portfolio prioritization we have to make in pharm Industry. - I would suggest CEPI to ensure keeping the right balance between short/mid/long term; high/medium and low risk. There are some pretty good project Management tools that allow to keep track of this through a score card system which also takes into account the forward looking financial commitments. - As to the specifics : I would like to echo Stanley’s advice : if possible, focus on existing adjuvants which have a substantial ‘human’ safety data base. The narcolepsy observed in Finland with the 2009 Swine Flu vaccine (AS03 adjuvanted) has made regulators even more cautious, especially for new adjuvants not having been in human previously. <u>Vaccines and pregnancy</u> - I have highly appreciated the presentation ‘Prevent’ aiming to include prgnance women in vaccine R&D and employment unless there is scientific and ethical justification. An approach we fully embrace. - Several factors which could enhance the success on reaching this target which could be considered by CEPI :

	○ Importance of use of a platform approach, – once data are generated for one vaccine (genotox/embryo tox/reproductive tox) results can be extrapolated for other vaccine candidates leveraging the platform data ○ Importance of platform selection keeping this target in mind (if available avoid non replicating approaches) ○ Encouraging/funding doing embryo tox/reproductive tox studies early onwards ○ Foster the creation of an external expert panel which would validate/assess the scientific risk assessments made by the vaccine developers. <u>Sustainable Manufacturing:</u> - I fully appreciate the fact that this working group is ‘starting up’. - A few thoughts (which I will also flag to Patrick) : ○ It is important to define scope, and eventually propose a stage-wise approach : i.e. focus first on establishments of stockpiles for (limited) emergency use; address later on high volume needs (millions) ○ Definition of volumes (ranges) will be needed in either case . ○ Is it worth considering two alternative options : ▪ Cepi to Invest in bricks and mortar (carrying all the Capex – that needs also accountancy wise handling amortization afterwards) ▪ Cepi establishing a network of ‘preferred trusted partners’ where it pays for allocated capacity. (sharing facilities with governments ? ; academia; industry, contract manufacturing. ○ How much is all of this driven by/dependent on selection of platforms, intrinsic yields etc.... ○ Importance of building flexibility in mft capacity/capabilities
Daniel Brasseur	New investment areas Concerning the current projects currently under discussion/negotiations with applicants/awardees, a main issue (on top of having a promising candidate vaccine) remains to create the opportunity (more than a capacity) to conduct clinical trials. This means not only to find places, investigators, technical and logistical support but also have a design agreed by authorities (regulatory & ethical) and a IMP (investigational medical product) acceptable for entering in human studies (stability & safety). Developing a ‘vaccine construct’ is as such always possible...but starting human investigations is the real hurdle. Chik (slide 7) is a current and nice example of a fluctuating epidemics having pushed to rethink the possibility to move to human challenge studies. Indeed, CEPI will not only refrain from financing phase III trials for reasons of costs, but also for reasons of feasibility. Looking for alternatives (challenges, animal) will probably be a obliged option for ‘access’ to disease. Looking at <i>Considerations for new investments</i>, one would argue that CEPI should invest in prevention of life-threatening diseases (relative high case-fatality rate even if absolute figures remain low). The reason lies in the impossibility for CEPI as an organisation to show that a vaccine preventing rare events (microcephalia after Zika infection during pregnancy for instance) requires huge safety cohorts to demonstrate that the immunisation is safer (not inducing side-effects) than the very rare disease complications (see also timelines 2022). Considering the Novel platform approaches (e.g. <i>gene-encoded monoclonal antibodies (mAbs)</i>), one should be aware of the regulatory challenges facing such development.

Although not intended for chronic use (single or few administrations), such medicines can be highly immunogenic (causing auto-immune reactions) or allergenic (causing shocks) and require exhaustive purification/stability assurance. Further, on the regulatory side, the platform has (see slide 21- Pervin Anlesaria) only generated limited clinical data, only AAV containing gene-encoded mAb has been evaluated to date in phase I clinical trial and antibody levels were undetectable, the optimal formulation and route of administration remains to be established). On the regulatory side, the status of the 'medicinal product' requires clarification (gene therapy ? biological product?)

Sustainable manufacturing is a major point illustrated by the current difficulties to maintain the oral polio vaccine stocks (see WHO) causing on top regulatory questions (who should take care of/pay for prolonging validity of products reaching end of shelf life?). CEPI could surely play a role here in facilitating knowledge (following stability of limited pilot lots and demonstrate their efficacy/safety and labelling).

Where should CEPI prioritize investment in near term (2019 and 2020), and why?(slide 12)

Old technologies have shown their limitations in terms of production yields and timing (see current world shortage of the global vaccine production) recognizing that the vaccines offered are as a whole safe and efficacious. However, this strategy does not fit with urgent emergency situations. New platforms exploring new technical concepts should be supported on the mid-term. Only alternative production methods based on new concepts (DNA, RNA...) and pleioform vaccine candidates will be able to do the job.

Which if any proposed investment areas should CEPI not consider investing in at all either now or in the future, and why?

CEPI should not invest frequent diseases but causing only rarely (even severe) complications (see flu, Zika, Chik, congenital CMV...) because the investment is above CEPI's capacities for a benefit/risk impossible to assess without huge safety cohorts (see above). Further, the acceptance in the population of such vaccines (even when life-saving) remains poor (see measles in developed countries).

Are there specific attributes or conditions that CEPI should seek in weighing potential future investments?

(see above for attributes). Conditions transmitted by airways (see SARS) should probably be looked very closely since these are the pathogens with the highest likelihood of high and quick spreading.

Are there any other investment areas that CEPI should consider engaging in now or in the future, which have not been captured by the proposed alternatives to the SAC, and why?

The heterogeneity of the target populations to protect remains a point of concern since a variable likely to influence the safety and/or efficacy of a recognized vaccine (age, nutritional status, ethnic group, underlying disease...): the so-called groups at risk. Remember that over 55% of Ebola fatalities were children and that nearly all pregnant women aborted, thus population to prioritize....(see slides Ruth Karron).

To note: the welcome concept of 'Presumption of exclusion' applies even more to children representing more than 60% of the population in the regions at high of epidemic outbreak.

This is a fact that CEPI should not disregard in their preparedness scenario and avoid that the once again, development of medicinal products are mostly directed towards privileged populations (adults)

Should CEPI support development of a Chikungunya vaccine?

The short is no since many candidates are currently running and the public health interest (not economical) remains a point of discussion. All challenges of the vaccine development due to the disease pattern are well described (Unpredictable nature of outbreaks: challenges with efficacy trials, lack of knowledge of the disease burden, low public sector funding as not considered a serious disease, uncertainty of revenue generating capacity...) (slide 2).

However (see S. Plotkin) the economic impact of prevalent chronic sequelae (arthritis of variable degree of severity) in high endemic regions might justify an immunization programme. But this aspect might also be outside the scope of CEPI's.

The only argument to support a 'close-to-registration' vaccine would be the rewarding image for CEPI of a success story.

Should we support the development of Adjuvants? (see slide 22+, S. Blayer & W. Leitner))

(The background reason (increasing immunogenicity of subunit proteins) for such support is clear). One should remember that many existing vaccines would not work if devoid of adjuvants, even simply alum!

What about existing/registered adjuvants?

Their use should be preferred since their knowledge is supported by wide if not huge data-bases (Alum, ASO3,4-MF59...) even if these adjuvants are sometimes suspected of side-effects. However, the magnitude of the risk linked to their use is far lower than the burden of any pandemic disease (even when quoting ASO³ adjuvanting a flu pandemic vaccine).

What about investing in novel adjuvants?

Their use should be discouraged in *novel* vaccines (lacking large safety data-bases) if these are intended for *mass* vaccination campaigns. In such situation side-effects will unavoidably occur and it will be impossible to ascribe such complication whether to the antigen, the adjuvant, a potential carrier, even a mitigated form of the natural disease...).

Their use could be considered if necessary to develop vaccines intended to limit a disease propagation whilst vaccinating at risk populations only (ring vaccination, for instance or poultry workers...)

Whereas it makes sense to develop platforms (multiple antigens produced on a single concept) it does make far less sense to develop an adjuvant toolbox (one adjuvant enhancing the immune response of various antigens) since their mode of action is oversimplified when quoted as Th1, Th2, CD... inducers). Their specificity is often very narrow, a property that is required for efficacy when targeting viral diseases (see inulin and flu) but also for safety to avoid auto-immune reactions.

New adjuvants are needed, not as a toolbox but as surgical instruments.

CEPI's role during outbreaks (when no vaccine [yet] available)

The most important task is two-fold (see slides Nicole Lurie)

1. Update list of priority knowledge/data gaps, and identify any acute vaccine development needs that could be addressed during the outbreak
2. Support projects and rapid action likely to fill these gaps

The practical aspects to meet such goals are well taken in the presentation. However, ahead of triggering appropriate actions (far before the design of study protocols), time could be saved on top by having identified and listed partners one could call upon.

Having a database with names of experts, their qualifications, capacities of analyzing-storing, availabilities and personnel, response-time, costs for several services, auditing

and approval by official bodies...could better picture opportunities and decision-making.

Collecting and updating such information (register?) could be taken over by CEPI as part of their preparedness strategy (and would also meet a WHO request) (see slide 12).

Sustainable manufacturing

The points presented are well taken (P. Florent) such as (slide 6):

Manufacturing

Quality, regulatory interactions and submission, process qualification and validation for production and testing, process transferability

Infrastructure

Local logistic and utilities, regulatory environment: NRA capabilities, Government support: import/export, permitting, ...

The issues to note are not really difficulties to interact with, or capabilities of regulators but rather in general the poor reliability of data generated during development. Not every investigations should be conducted under under GXP conditions, but CEPI should convince (require from?) investigators to validate the credibility of the data generated (even simple procedures can help greatly). The illustrative example is 'transferability' from one product to another, from one producer to another. Changes in every step/location in a process should be avoided as much as possible. They often create concern since not having been validated, what can be understood for cost-saving reasons. Changing, adapting, transferring, modifying are often made to improve one or another aspect of the production. Here the better can be the enemy of the good. Thorough reflection should be made before making such decisions since 'regulatory' implications could be underestimated.

Funding epidemio?

On top of the points mentioned (H. Meijerink, slide 20), epidemio study are needed to define the target population particularly for priority vaccination (age, conditions of naivety), the impact of natural infection in vaccinees (different responses between initial sero-negative versus sero-positives), the cut-off level of immune protection.

Future investments

Should CEPI invest in more vaccine candidates for CfP1, in the near term or in the long term?

The short answer is yes.

The choice of new candidates should be based on their potential for easy and quick, thus large contamination in humans causing severe disease (propensity to mutations)

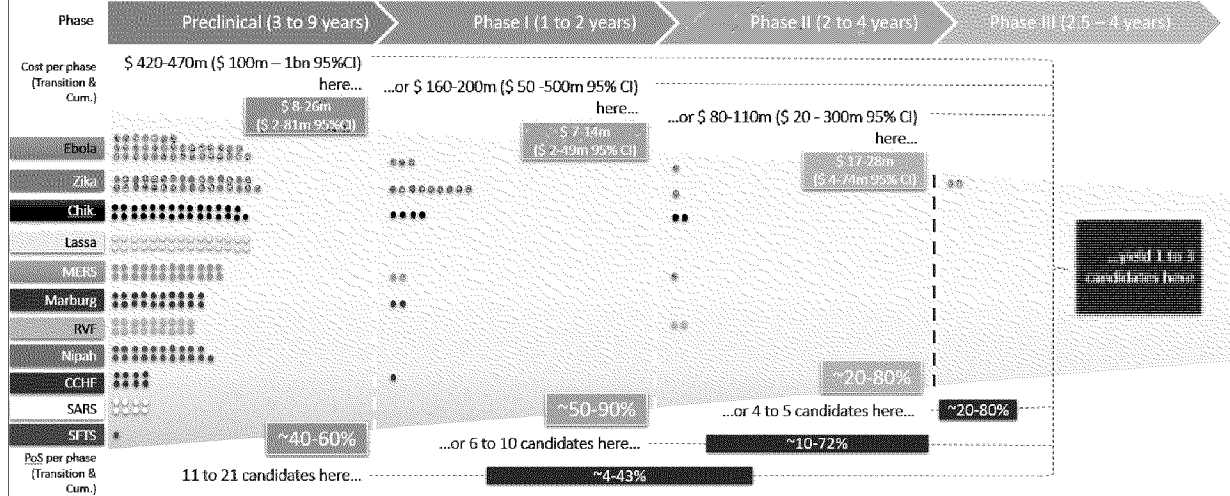
Collaboration with WHO and regulatory bodies

A closer collaboration should be envisaged with WHO, to define nuances within

- the Product Target Profiles
- the Platform Target Profiles, the latter with an aim at opening a discussion with regulatory bodies.

Indeed, the platform concept is recognized in the field of animal vaccines but far less accepted (since lacking an agreed definition) in the field of human medicinal products. CEPI could take an initiative (Workshop?) in order to share ideas and experience gained by experts regulating animal vaccines.

WHO Blueprint EID vaccine R&D pipeline and cost estimates



Sources: (1) Gargallo D et al. Estimating the cost of vaccine development against epidemic infectious diseases. The Lancet Global Health. 2018. (in press); (2) CEPI B1, Lassa-MERS-Nipah-Chikungunya; (3) CEPI c/P1

CEPI

CEPI
Coalition for Epidemic Preparedness Innovations
CEPI Scientific Advisory Committee (SAC) Teleconference
September 12, 2018
Washington DC, U.S. and teleconference

SUMMARY FROM SAC PROCEEDINGS (CEPI/SAC TC 18.3)

The following Scientific Advisory Committee members participated:

Committee members		Invited and CEPI
Present • Helen Rees (Chairperson) • James Robinson (co-chair) • Alash'le Abimiku • Connie Schmaljohn • Inger Damon • John Edmunds • Michel De Wilde • Myron Levine • Peter Smith • Phil Krause • Stanley Plotkin Apologies: • Christian Bréchet • Christian Happi • Daniel Brasseur • Delese Mimi Darko • Paula Bryant • George Fu Gao • Kathleen Neuzil • Kenji Shibuya • Penny Heaton • Thomas Kariuki • Yves Lévy	Non voting members • Ali Allouche, Takeda • Jean Lang, Sanofi • Johan van Hoof, J&J • Kathrin Jansen, Pfizer • Vasee Sathiyamoorthy, WHO	Invited: • Amy Jenkins, DARPA • Charlie Weller, WT • David Vaugh, BMGF • Jeremy Blum, BMGF • Matt Hepburn, DARPA • Mike Osterholm, CIDRAP • Peter Dull, BMGF • Wolfgang Leitner, NIAID • Ruth Faden, PREVENT • Ruth Karron, PREVENT CEPI Secretariat: • Richard Hatchett • Gunnstein Norheim • Melanie Saville • Hinta Meijerink • Nicole Lurie • Dawn O'Connell • Nora Indrehus • Shannon Quinnon • Raul Gomez • Joe Simmonds

Notes to readers

- Pre-read documents for the meeting were shared ahead of the meeting. Slides are found [

(b)(6)

- This meeting was originally planned in Atlanta, but due to hurricane warnings it was moved to Washington DC and for most attendees conducted as a telecon.

- The main agenda item for the meeting was to discuss exploration of new investment areas.
- Meeting rapporteur: Raul Gomez, CEPI Secretariat

1. Exploration of new investment areas

Introduction (Richard Hatchett)

CEPIs CEO gave an overview of the current funding portfolio and the context for this meeting.

One of CEPIs strategic goals is sustainability.

Currently: Total amount funded through CfP1 and CfP2 currently stands at around 430 million USD. The “Enabling Science” elements under Vaccine Science are funded for the next 5 years.

What has changed since CEPI’s first strategy in 2016?

Assumptions in 2016	Developments
CEPI to take a gap filling role in Ebola.	CEPI has been part of a working group to identify gaps leading to licensure. New outbreaks.
Zika is well funded and likely to have good potential in the market. No need for CEPI involvement.	Funding has declined.
Chikungunya likely has a potential market.	Chikungunya vaccines now eligible for FDA Priority Review Voucher
CEPI should not focus on Phase III studies.	WHO Priority Pathogens list has shifted slightly.

The main objective of this SAC meeting is to explore new investment areas. The reason is that the funding opportunities are widening, with potentially 90 million euro from the EC to become available for new projects in emerging infectious diseases (30 mEUR in 2019 and 60 mEUR in 2020). This is a good time to identify areas of investment 5 yrs down the road. Considerations for new investments, new areas to be discussed, and questions for the SAC roundtable discussion were presented (slides 9, 10 & 11, respectively).

The Chair asked if CEPI had enough resources to co-fund any EC-funded projects and the answer was affirmative. The WHO representative asked if there were requirements for funds to be spent in Europe and the answer was no. The only requirements to access the incoming EC funding are that the projects be new and that they be co-funded at 70:30 (EC:CEPI) ratio.

Priority Pathogens Vaccine Portfolio

The Director of Vaccine Development Melanie Saville gave an overview of the current Priority Pathogens Vaccine Portfolio.

Currently, contracts have been signed with 6 partners for 8 vaccines in total: 4 for Lassa, 3 for MERS and 1 for Nipah. Negotiations are underway and CEPI anticipates to have more partners for CfP1 and CfP2 implementation.

The Lassa portfolio (slide 15) consists of 6 candidates (5 viral vectors and one DNA approach), with the first first in human (FIH) trials will take place in 1QY2019. The MERS CoV portfolio (slide 16) consists of 4 candidates (3 viral vectors and one DNA approach), with three FIH trials already ongoing. The Nipah portfolio (slide 17) consists of 4 candidates (3 viral vector and one adjuvanted protein approach), with the first FIH trials scheduled for 1QY2019.

Additional vaccines against priority pathogens are likely to be funded through the CfP2, increasing also the portfolio of technologies with over 30 vaccine candidates of which 20 against WHO R&D Blueprint pathogens.

Roundtable discussion:

What is the priority approach in bringing vaccines forward, and what data will be used to select the best candidates to move to the clinic? Experience from BARDA and other programs suggests it that due to attrition it is best to have three to six programs funded to end up with a single licensed product. CEPI does not plan to down-select candidates right after Phase I; instead, if several products make it past pre-defined stage-gates, then they would be down-selected in a portfolio review.

A question was raised as to why CEPI's Nipah approach is so focused on Bangladesh, and why not include sites in India given the recent outbreak. Response from Secretariat was that we are exploring including sites in India as well with the developers and has a flexible approach.

Results from Request for Information (Rfi) on Lassa, MERS, Nipah and Chikungunya vaccines

Gerard Cunningham (consultant to CEPI) presented results from the Rfi. The purpose of the exercise was to identify any vaccine candidates for Lassa, MERS or Nipah that could increase the likelihood for achieving CEPI's Strategic objective 1 by 2022. The main conclusion from the Rfi was that there are no additional, compelling opportunities for funding that are not already being funded/considered by CEPI in the current portfolio for Lassa, MERS and Nipah.

Roundtable discussion:

For Nipah, the over representation of vectored-approaches is a concern. Should CEPI not actively seek other platforms/approaches? What about RNA or pre-stabilized fusion proteins? University of Queensland is proposing a molecular clamp approach to stabilize glycoproteins for MERS, RSF and flu, but they also have some preliminary work on Nipah and perhaps could be approached.

Chikungunya

Should CEPI support development of a Chikungunya vaccine? Chikungunya originally ranked 4th in priority in the SAC's 2016 list, and high disease burden was considered (slide 53). A CEPI Chikungunya workshop was co-organized with DBT & PATH in February 2018, which highlighted many of the gaps and areas of opportunity. A draft report of the meeting was provided in the pre-read materials for this SAC.

A request for information (Rfi) to map interested developers was conducted in July 2018 and the results were presented (slides 54-64). The main conclusion is that the pipeline is well matured, with several candidates are advanced in development and ready/moving into phase 3, supplemented by multiple pre-clinical stage candidates and ready to move into phase I. Implications for CEPI: CEPI could provide co-funding, either of Phase III with EC co-funding, or fund phase I-ready programs.

Stanley Plotkin gave an overview on the epidemiology and human impact of Chikungunya on the global population, with 217 thousand cases worldwide. The correlates of protection (slide 72) were highlighted, with IgG3 antibodies shown to be the main neutralizing and protective antibodies (as demonstrated by passive transfer challenge studies), while T cell responses may be detrimental and

responsible for disease symptoms. Again, the vaccine pipeline is good; and in Stanley's view, there are three leading candidates (slide 74).

Roundtable discussion:

Comments/Questions to the SAC were: there are several Chikungunya vaccine candidates that could be put into Phase III rapidly, with a high probability of success. This is a disease that causes sequelae and a vaccine funded by CEPI could have important impact and provide a rather short-term success (low hanging fruit). Chikungunya is not on the current WHO priority list category of urgent action, but that doesn't mean it shouldn't be funded. The notion "Phase III trial" was, due to unpredictable and short nature of Chikungunya outbreaks, interpreted as a safety, immunogenicity and immunobridging trial.

There was no unison view in regard to CEPI investing in Chikungunya vaccines. On the positive side, the feasibility of the vaccine development (pipeline, mechanism of protection, disease burden) as well as the possibility of CEPI taking part in a achievement by 2022, whereas others expressed concern that Phase III studies could be extremely challenging because Chikungunya outbreaks are very explosive and unpredictable, and suggested going for the FDA Animal Rule rather than a Phase III. The CEPI Delhi workshop was again referenced. A way to predict outbreaks would be by surveys of the vector. From the regulators perspective, it would be important to pay attention to the Animal Rule, conduct passive transfer studies and see if this streamlines licensure/post-licensure.

Other questions and answers were raised: Why is Chikungunya now listed as a lower priority for research in the WHO priority pathogen list as compared to the 2016 list? A closer look into the methodology should be taken. What would make Chikungunya different from Zika, i.e. why invest in a Chikungunya and not in a Zika vaccine? What is the added value of CEPI funding this, i.e. what would happen if CEPI did not fund it? Is there a commercial market for Chikungunya vaccines? The elements will be further discussed in the forthcoming SAC Roundtable session.

WHO R&D Roadmap priorities as investment areas

An overview was given by Vasee Moorthy from WHO & Mike Osterholm from CIDRAP, who had worked closely developing the WHO R&D roadmaps for Lassa, MERS and Nipah. The WHO makes efforts not to change its priority diseases too frequently. There is a generic methodology applied to each priority disease for [[HYPERLINK "http://www.who.int/blueprint/priority-diseases/en/"](http://www.who.int/blueprint/priority-diseases/en/)], for example, Baseline Situation Analysis (background papers describing each pathogen & disease) are drafted, while pathogen-specific taskforces are created. New developments with relevance to CEPI were highlighted (slide 103): Nigeria, the DRC and India have approached WHO for assistance through the R&D Blueprint during outbreaks; and Ebola vaccines have been/are being administered under the R&D Blueprint.

Strategic goals and research priorities were presented for the three CEPI priority diseases (slides 79-95), with Lessons Learned (slide 95) highlighted during the presentation. In the Roundtable discussion, the need for a One Health Approach was expressed.

Gene-encoded antibodies

Matt Hepburn & Amy Jenkins were invited to present an overview of DARPA's work on gene-encoded antibodies (slides 104-120). DARPA has niche role in being able to take on early-stage, high-risk vaccine projects, de-risk the technology, and transfer them to other partners (i.e. potentially CEPI). The Pandemic Prevention Platform (P3, slide 110) was highlighted. All studies rely on first taking convalescent patient sera, getting the sequence of (protective) antibodies, and then administer the corresponding genes (in DNA or mRNA format) to express antibodies in vivo in a relatively short time

(within days). Approaches from Duke University (anti-flu and anti-Chikungunya abs in mRNA expression cassette), MedImmune (mRNA, DNA & AAV platforms), Vanderbilt University (mRNA in cationic emulsion), and Abcellera (abs from several species encoded in DNA) were mentioned. Studies on Chik (Moderna) have entered Phase I. Potential collaborations with CEPI were highlighted at the end (slide 120).

Pervin Anklesaria and other from BMGF gave an overview of how the Foundation is also supporting this area of investment. The goal is not to replace a vaccine, but to provide an alternative intervention. The main target pathogen has been HIV and features of a potential TPP for that pathogen were outlined (slide 122). The BMGF portfolio (slide 123) consists of 7 products at very early stages, with 2 entering clinical trials. The gaps for this platform were briefly described (slide 124).

Roundtable discussion:

Are monoclonal antibodies part of CEPIs mission/mandate? CEPI does not fund therapeutics as part of its remit. Nonetheless, “vaccine-like” products or technologies can be pursued to buy time in case of an outbreak/epidemic.

What to do when etiologic agent of an outbreak is not known? There are groups working on how to isolate new, unknown viruses.

Strength of the approach: high and rapid antibody concentrations are achieved in vivo in animals.

To be followed up in the SAC Roundtable session.

Adjuvants

CEPI is exploring two scenarios with the SAC: (1) accessing licensed adjuvants for non-profit use in Emerging Infectious Diseases, and/or (2) funding development of unlicensed adjuvant systems.

To inform the discussion, Wolfgang Leitner, NIAID, was invited to give an overview of their Adjuvant Programs. A long term objective of this program is to build an “Adjuvant Toolbox” allowing for antigens and adjuvants to be matched, as described by the [[HYPERLINK](https://www.niaid.nih.gov/sites/default/files/NIAID-StrategicPlanVaccineAdjuvants.pdf)

"<https://www.niaid.nih.gov/sites/default/files/NIAID-StrategicPlanVaccineAdjuvants.pdf>] for Research on Vaccine Adjuvants. Recent developments in the field were outlined (slide 134) with Inulin (Advax) being the most advanced product in NIAID's adjuvant portfolio (slide 137).

Roundtable discussion:

How do you see CEPI investing in adjuvants? CEPI has a number of recombinant vaccines that would require adjuvants and we would give preference to licensed/commercial adjuvants, but with openness to pursue new adjuvants that may promote dose-sparing (reduce the number of doses to achieve protective immunity in an outbreak) or antigen sparing. CEPI should consider approaching well tested adjuvants (e.g. GSK for its adjuvant portfolio, in particular AS01B). From the WHO perspective, pursuing adjuvants that have not been licensed would not be recommended.

Sustainable Manufacturing

Patrick Florent, consultant to CEPI/GSK presented sustainable manufacturing as an area of investment addressing CEPI's Sustainability Strategic Objective (slides 167-173). A small working group including representatives from the DCMN, GAVI, UNICEF and large pharmaceutical manufacturers is being formed to advise on solutions for long-term sustainability issues. The group

will give recommendations to the CEPI Board in December. Questions to the SAC were posed (slide 173).

Roundtable discussion:

There are many considerations and questions that need to be weighed before making a conclusion or recommendation. Is there a financial envelope or limit attached to these investments? What are the time considerations, 3 years from now? Do we want to achieve continuous production of vaccines, or just stockpiles and replenishing stockpiles for sporadic outbreaks? What are the expected demand and the shelf life for specific products to be considered for sustainable manufacturing?

2. Pregnant Women and vaccines against emerging epidemic threats (PREVENT)

Ruth Karron gave an overview of the PREVENT program and the challenges associated with maternal immunization (slides 174-185). The aim would be to shift the presumption to inclusion of pregnant women in clinical trials. PREVENT has 22 recommendations, out of which five are very relevant to CEPI. Of these, three were highlighted: Recommendation 7, suitability for use in pregnancy should be considered; Recommendation 9, conduct non-clinical studies early, i.e. reproductive toxicology studies; and Recommendation 12, to assume pregnancies will occur.

Roundtable discussion:

There are theoretical possibilities of risks for a live attenuated vaccine to be used in pregnancy, but these concerns should be weighed against the risks of *not* vaccinating a pregnant woman (distinguish between the R&D scenario and the real life/vaccine delivery setting). An example would be the Ebola case. The need to include social/behavioural specialists when considering this area of investment was mentioned. The bottom line for PREVENT is to change the default position. One challenge would be to involve regulators to understand their role; for example, what was the evidence and process by the DRC ministry of health/regulatory authorities that formed the decision that pregnant women not be vaccinated against Ebola.

3. Closing and next steps

Topics not covered due to time limitations were: Update on Cfp2 (Melanie Saville), Update on Epidemiology studies for Lassa update (Hinta Meijerink) and Rapid Outbreak Response (Nicole Lurie).

A follow-up session for the SAC is planned for 20 September, 2018, with the purpose of a concluding advice from SAC to the Secretariat to guide its process to suggest new investment areas to the CEPI Board in October 2018.

SAC disclosed interests

1 None disclosed

Helen Rees	Wits. Repr. Health and HIV Institute
Kathrin Jansen	Pfizer
Kenji Shibuya	The University of Tokyo
Mimi Darko	Ghana FDA
Myron Levine	University of Maryland
Paula Bryant	NIAID
Philip Krause	FDA
Thomas Kariuki	

2 No declaration made

Ali Allouche	Takeda
Daniel Brasseur	Independent
George Fu Gao	China CDC
Kathleen Neuzil	University of Maryland School of Medicine
Yves Lévy	INSERM

3 Interests declared

Alan Barrett

University of Texas Medical Branch

Conflict Description

I have no involvement in any work by my university academics as subcontractors on CEPI projects but there may be a perceived conflict of interest. I serve on a number of WHO working groups that work on the pathogens being researched by CEPI.

Potential subcontractors to CEPI applicants from university colleagues.

Alash'le Abimiku

Institute of Human Virology, Nigeria

Conflict Description

Africa-CDC

I serve on Africa-CDC strategic advisory committee and i know that Africa-CDC has listed CEPI as one of its key partners

Christian Brechot

Global Virus Network

Conflict Description

Global Virus Network, Institut Pasteur

Formerly employed at Institut Pasteur

Christian Happi

ACEGID, Redeemer's University

Conflict Description

NIH-H3Africa

Research support, including grants, collaborations, sponsorships, other funding

NIH-H3 Africa Programme

I have no conflicts to declare.

Connie Schmaljohn, Ph.D.

USAMRIID

Conflict Description

USAMRIID, (Inovio)

Inovio has a LASV application to CEPI with due diligence and USAMRIID is a partner in that work.

Inovio and USAMRIID have a joint patent on the LASV DNA vaccine delivered by electroporation

I should be recused from reviewing proposals that were submitted by investigators at USAMRIID.

Inger Damon

CDC

Conflict Description

CDC, DHCPP

I work at the CDC. Our work deals in DHCPP with emerging dangerous pathogens. My knowledge is based on what is or is not available to combat these diseases in response efforts. This is an interest which aligns with CEPI's interests, but is an interest of my organization. I do not believe it is a conflict, but it is a disclosure which should be apparent from my Curriculum Vitae.

James Robinson

James Robinson Biologics Consulting

Conflict Description

Ology Bio

I serve on the Board of Directors of Ology Bio, a Contract Mfg Organization who may partner with Cfp applicants.

The board seat at Ology Bio is pending confirmation in February. The firm may be a contractor of choice for Cfp1 applicants. As an independent consultant, I may be approached by companies involved in CEPI development, but in the event this happens, I would disclose any engagements to CEPI and abstain from any influence on those company proposals.

Johan Van Hoof

Janssen

Conflict Description

Janssen, JnJ, Jenner Institute UK, BARDA, IMI, GSK, Sanofi, Gilead

Janssen, pharmaceutical division of JnJ, collaborates with the Jenner Institute UK

Receiving funds from BARDA, and fund and non-monetary support IMI

Use of proprietary platforms of Janssen as part of the collaboration with Jenner institute

Stock, bonds, stock options, other securities: GSK, Sanofi, Gilead, JnJ

I am full time employee of Janssen, involved in vaccine development. We work with the Jenner institute and are part of the consortium currently in discussion with CEPI on call for proposal one.

John Edmunds

London School of Hygiene & Tropical Medicine

Conflict Description

GSK

My partner works for GSK as an epidemiologist. I presume that they may have an interest in CEPI. She does not work in the vaccines division of GSK. I have no other conflict of interest.

Jean Lang

Sanofi Pasteur

Conflict Description

Sanofi Pasteur

Responsible for R&D Public Partnerships with Public Philanthropic Non-Profit Organizations

Stock holder of Sanofi

Michel De Wilde

Independent

Conflict Description

IDRI

Curevac

Sanofi

GSK

Board member of IDRI and SAB member of Curevac.

Stocks in Sanofi and GSK

Travel costs to attend IDRI's BoD and Curevac's SAB have been reimbursed

As Board or SAB member of organizations that have or might apply for CEPI funding, I might get exposed to discussions of these proposals within these organizations. In practice this has not been the case. I have and will be participating in CfP-2 reviews. I have not and will not participate in the discussions related to the applications from organization I am involved with as Board member or otherwise.

Penny Heaton

Gates MRI

Conflict Description

Bill and Melinda Gates Foundation, Gates MRI

Former employee of BMGF, Gates MRI is wholly supported by the Bill and Melinda Gates Foundation.

Travel through December 2017 was supported by the Bill and Melinda Gates Foundation.

I was an employee of the Bill and Melinda Gates Foundation from January, 2013 to December 2017. Currently, I am the CEO of the Gates MRI, which is wholly funded by the Bill and Melinda Gates Foundation. BMGF is also a funder of CEPI. I don't think this represents a conflict of interest and does not affect my scientific objectivity but felt it important to be transparent about this.

Peter Smith

London School of Hygiene & Tropical Medicine

Conflict Description

London School of Hygiene & Tropical Medicine

Sanofi-Pasteur

Serum Institute of India

Vaccitech

Oxford

Travel paid to attend IDMC/DSMB meetings detailed below:

Member of Independent Data Monitoring Committee, for Sanofi-Pasteur clinical trials of dengue vaccines.

Member of Data Safety and Monitoring Board for clinical trials of Serum Institute of India polyvalent conjugate vaccine (NmCV-5) against serogroups A, C, Y, W & X of N. meningitides.

Member of Independent Data Safety Monitoring Committee and Trial Steering Committee (DMEC/TSC) for a T-cell based universal influenza vaccine trial (INVICTUS), sponsored by Vaccitech, Oxford."

Ralf Clemens

Bill and Melinda Gates Foundation

Conflict Description

Bill and Melinda Gates Foundation

Curevac

Valneva

IVI

GHIT

AREF

Supervisory Board Member, chair SAC Curevac. SB member Valneva. Chair SAC IVI.

Stock, bonds, stock options, other securities: Valneva

Travel paid by: Curevac, Valneva: Board meetings; IVI SAC meetings

I received fees as independant board member (non-employee) from Curevac and Valneva. As stated above, I am Supervisory Board Member of Curevac and Valneva and also chair Curevac scientific advisory committee. Furthermore I am chair if IVI SAC. Of no conflict - I am also member of GHIT selection committee and Board of AREF (African Research Excellence Fund).

Stanley Plotkin

University of Pennsylvania

Conflict Description

University of Pennsylvania

GSK

Merck

Pfizer

Sanofi

Inovio

Hookipa

CureVac

Dynavax, Serum

Inst India

Consulting: GSK, Merck, Pfizer, Sanofi, Inovio, Hookipa, CureVac, Dynavax, Serum, Inst India.

Stock, bonds, stock options, other securities: DynaVax

Travel paid by: GSK, Merck, Sanofi, DynaVax

I give advice to most vaccine manufacturers but maintain my independence.

CEPI

SAC roundtable discussion

Helen Rees, SAC chair

Areas suggested for exploration

1	Further investments in CfP1 targets, to maximize the chance of advancing two to three vaccines for two to three diseases through phase IIb/III, by end of 2021
2	Chikungunya clinical vaccine development and other WHO priority pathogens
3	Novel platform approaches (e.g. gene-encoded monoclonal antibodies (mAbs))
4	Sustainable manufacturing
5	Investing in enabling technologies (e.g., adjuvants)
6	Addressing WHO R&D Blueprint Roadmap gaps (epidemiology, clinical characteristics, pathogen, immunological response, etc.)
7	Other suggestions from SAC

Questions for the SAC roundtable discussion

- Which areas should CEPI prioritize investing in in **near term** (2019 and 2020), and why?
- Which of the other proposed areas should CEPI support, resources permitting?
 - For these items, what additional evidence-gathering or other preparatory work should CEPI implement prior to any further consideration for funding, and why?
- Which if any proposed investment areas should CEPI **not** consider investing in at all either now or in the future, and why?
- Are there specific attributes or conditions that CEPI should seek in weighing potential future investments?
- Are there any **other investment areas** that CEPI should consider engaging in now or in the future, which have not been captured by the proposed alternatives to the SAC, and why?

Strategic fit and timing for investment areas

YES	Near term (2019, 2020)	Longer term (2021 -)
SO1		
SO2		

NO		
----	--	--

- Adding to current CfP1 and CfP2 portfolios
- Addressing WHO R&D Roadmap gaps
- Chikungunya clinical vaccine development
- Gene-encoded antibodies for immunoprophylaxis
- Adjuvants
- Sustainable manufacturing capabilities
- Other ideas – SO1/2

Factors to consider

- What should CEPI fund?
- Increasing the likelihood of achieving SO1 and -2
- Feasibility – maturity of technology area
- Public health impact of a vaccine

1. Further investments in CfP1 targets

- Should CEPI invest in more vaccine candidates for CfP1, in the near term or in the long term?
- Any specific attributes or conditions that CEPI should seek in potential future investments?
 - I.e. what would justify investment in new candidates?

2. Chikungunya clinical vaccine development

Background

Chikungunya was voted number 4 in the Oct 2016 CEPI SAC meetings ranking of pathogens to invest in vaccine development for among WHO's 2016 list of priority pathogens

What should CEPI fund?

- GMP manufacturing
- Clinical trials
 - Safety and immunogenicity?
 - Efficacy if feasible?
- Animal studies?
 - Correlates of protection?
 - Immunobridging?

Feasibility – likelihood of increasing SO1 if funding this area?

Public health impact: Chikungunya vaccines versus investment in other WHO priority pathogens?

3. Gene-encoded monoclonal antibodies

Questions

- Gene-encoded antibodies are vaccine-like in some of their potential prophylactic benefits but do not produce enduring humoral or cellular immunity. Do they fall within the remit of CEPI's mission?"
- In which scenarios would gene-encoded mAbs be useful, and what characteristics do they need to have to be useful? What characteristics might limit their utility?
- Any avenues for synergy with organizations already investing in gene-encoded mAbs (NIH, DARPA, Gates Foundation), without duplication?

What should CEPI fund?

Feasibility

Public health impact

4. Sustainable manufacturing

Questions to SAC

- How can CEPI best facilitate the long-term sustainability of technically successful programs?
- When do we need to have sustainable manufacturing solutions in place?
- How can these best be integrated into existing programs and at what stages?
- Should CEPI directly support innovation in vaccine manufacturing technology (i.e., continuous manufacturing, etc.)?
- With your knowledge, are there any promising technologies that you would recommend for further assessment by the WG?
- Is there anything we are missing, or should pay more attention to?

5. Investing in enabling technologies (e.g. adjuvants)

Question

Which adjuvants are likely to be most appropriate for emerging pathogens vaccines?

What should CEPI fund?

Two proposed investment scenarios:

1. Assessing licensed adjuvants for non-profit use in the setting of emerging infectious diseases
2. Funding development of unlicensed adjuvant systems.

Impact on achieving strategic objectives – SO1 (CfP1 vaccines) or SO2 (response)

Feasibility?

Public health impact?

CEPI

6. Addressing WHO Blueprint gaps

Background

The WHO roadmaps have defined priorities for research – Lassa, MERS, Nipah, Ebola/Marburg, CCHF.

What should CEPI fund?

Multiple priorities – which of these are key to vaccine development? For L/M/N, several are being addressed in ongoing CfP1 portfolio and Enabling Science work.

Impact on achieving strategic objectives – SO1 (CfP1 vaccines) or SO2 (response)

Feasibility?

Public health impact?

From: FDA_NEWS@OC.FDA.GOV [FDA_NEWS@OC.FDA.GOV]
Sent: 6/1/2018 12:13:22 AM
To: FDA-Wide [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ffe86b3c2f71463c9100bfdcc3d7b4f-FDA-Wide]
Subject: FDA Notices

FDA Announcements

New England Journal of Medicine.

Article by Dr. Throckmorton, Dr. Gottlieb, Dr. Woodcock. The FDA and the Next Wave of Drug Abuse — Proactive Pharmacovigilance. GPL.

Register now for UCSF-Stanford CERSI online mini-courses in Pharmacogenomics and Mobile Health

2018 UCSF-Stanford CERSI mini-courses are now open for registration. The mini-courses are taught by faculty and staff from Stanford University. The mini-courses are fee-based and there is a 50% discount for government and academic employees. Please click the link above for additional information and registration details. For questions, contact education@ucsfstanfordcersi.org

“How Nutrition Can Impact Gut Microbiome Composition, Intestinal Permeability and Antigen Trafficking Leading to Chronic Inflammatory Diseases” by Dr. Alessio Fasano, Harvard Medical School on 6/6 at WO31-Great Room, 1:30-2:30pm

The FDA Microbiome Working Group (MWG) is pleased to host guest speaker Alessio Fasano, M.D., Mucosal Immunology and Biology Research Center, Massachusetts General Hospital for Children – Harvard Medical School, Boston, MA – U.S.A./ European Biomedical Research Institute Salerno (EBRIS) Salerno - Italy. He will address the topic above. Remote Viewing available. Click link in title for more info. For questions, please contact Shari.Solomon@FDA.hhs.gov.

Johns Hopkins University CERSI Lecture: “Non-Invasive Quantification of Drug-Target Engagement at the Tumor: Lessons from Small Molecules and Biologics” on 6/5 from 3-4 pm, FDA WO Bldg. 2, Rm. 2047E
Sridhar Nimmagadda, PhD of Johns Hopkins University School of Medicine will discuss drug-target engagement in cancer therapy and how non-invasive imaging technologies, such as positron emission tomography (PET) can be used to quantify this engagement and improve therapeutic success. Questions? Contact Amal.Manseur@fda.hhs.gov.

Registration and Abstract Submission for 2nd NIH-FDA Joint Agency Microbiome Meeting on Fri. 6/15 at CFSAN, 9a-5p

Sponsored by the NIH-FDA Intramural Microbiome Working Group. The yearly meeting presents the ongoing microbiome research at NIH and FDA, ensures NIH/FDA communities are aware of and current in their knowledge of intramural microbiome research and provides regulatory scientists related to microbiome a platform to discuss data gaps and key questions for where future research needs to be focused. Click link above for website. Adobe available with preregistration.

Looking for scientific events? FDA Toxicology Working Group (TWG) SharePoint (SP) site is available!

On the Scientific Info Sharing page, you can identify events by checking their schedules. Hovering the cursor over the event title, an event preview appears on your right-side window. The site offers a centralized scientific info hub for scientists within the Agency to post, browse, search, and create/manage scientific activities. Please share the site with colleagues. User guide manual and video are available. Questions? Contact Tracy.Chen@fda.hhs.gov.

Watch OIP's New Video: Living and Working Abroad for FDA

You may have seen FDA's Office of International Programs "Gamechangers" video which described the benefits of working internationally. OIP has now completed a longer video that further illustrates the character of the cities and landscapes where FDA staff work in Europe, China, India and Latin America. Interviews with FDA staff describe the exciting challenges, opportunities and experiences working in FDA's ever-growing overseas workforce! Contact: Carl.Sciacchitano@fda.hhs.gov

The FDA Distinguished Lecture Series presents "The Pathogenesis of Research Misconduct" by Dr. Ferric C. Fang, Univ. of Washington, 6/28 at WO31-The Great Room, 1-2:30pm

Hosted by OCS/ORSI and The Committee for Advancement of FDA Science (CAFDAS) this lecture by Dr. Fang, as Deputy Editor-IDS Journal Clinical Infectious Diseases, will examine research misconduct, focusing on retracted publications in the scientific literature and the underlying factors contributing to the recent increase in misconduct, along with potential measures for reform. In-person attendance encouraged. Remote Access available. Questions? Contact Shari.Solomon@FDA.hhs.gov

5th Annual Drug Discovery and Development Symposium for Pulmonary Hypertension

PVRI and FDA 5th Annual Drug Discovery and Development Symposium for Pulmonary Hypertension, July 9-10, 2018, Hyatt Regency Bethesda, Bethesda, MD 20814.

June 5 2018, Regulating a Changing Marketplace, hosted by the Office of Medical Products and Tobacco (OMPT)

OMPT is excited to host the next Cross Center Seminar Series, featuring short presentations from senior Center staff discussing their Center's approach to regulating a changing marketplace. It will be followed by a panel discussion and questions from the audience. Please join us on June 5th from 3:00-4:00 P.M. on the White Oak Campus, CSU (Building 2), Room 2040W or via Adobe Connect <https://collaboration.fda.gov/ccss18/>.

Federal Employee Viewpoint Survey (FEVS) Flash #3 - Influencing Change

Have you ever wondered if your FEVS feedback truly leads to change? Yes, it does! Click the link above and read FEVS Flash #3 to learn more. Don't forget to check your inbox and complete the 2018 Federal Employee Viewpoint Survey - Now open through June 18th!

OEIO/DWCI, Supervisory Consumer Safety Officer, (DIB) GS-0696-14, Selection Announcement

Acting Program Director, Armando Zamora and I are pleased to announce the selection of Gordon Chu as the Investigations Branch Director for the ORA Office of Enforcement and Import Operations (OEIO), Division of West Coast Imports, effective June 10, 2018. Gordon Chu joined FDA in May 2002 as a Consumer Safety Officer in the Los Angeles District (LOS-DO) Import Operations Branch. In April 2010, he became Supervisory CSO in the LOS-DO Import Branch and served as the District Import Program M ...

Fun at Kings Dominion

On Saturday, August 4th, please join your FDA employees, contractors, friends and family for a day of fun at Kings Dominion! The cost of this event is \$48.00 per person and includes park admission, parking and a catered meal from 1:30pm - 3:00pm (Full Service) in the Pavilion. Children under three years of age are admitted for free. Please visit www.kingsdominion.com/save or copy and paste it into your browser. Login https://cf-kd.secure.accesso.com/embed/login.php?emerchant_id=400 with user ...

Embase-Drug Safety/Pharmapendium - Introduction, Jun 14, 1:30-2:30

Learn how to use Embase for tracking and identifying adverse events, and Pharmapendium for pharmacovigilance reporting. Brought to you the FDA Library.

Embase: Adverse Events Monitoring – PV Wizard – Pharmapendium, Jun 28, 1:30-3 EDT

Learn how to use the Pharmacovigilance (PV) Wizard form and the Pharmapendium database to retrieve relevant literature to monitor adverse events, and to identify relationships between drugs, diseases and devices and their associated events. Brought to you by the FDA Library.

June 6 and 7 (only three hours per day) - Create Custom Stencils and Templates in Visio 2013 Intermediate Class

Join OIMT via WebEx on June 6 and 7 for our \$150 Visio 2013 Intermediate class. We'll show you how to create custom stencils, add/remove shapes in a stencil, and delete a stencil. Later we'll teach you how to create, save, use, and edit a template. Stencils and Templates are in addition to other lessons on Master Shapes, Comments/Markup Tools/Ink Tools, Legends, and Pivot Diagrams. Follow the link above for the full class description and registration instructions.

Don't Let Excel's PivotTables and PivotCharts Scare You. They Are Great for Analyzing Data. Take a Class at White Oak on June 14 to Learn All About Them.

OIMT is offering our Excel 2016 Intermediate (Level 2) class at White Oak. In this \$150 class on June 14, you'll learn about PivotTables, Slicers, and PivotCharts. Specifically, you'll Create a PivotTable, Filter Data by Using Slicers, and Analyze Data with PivotCharts. Find out what other topics are in this class, and how to register, by clicking the link above.

Did You Know That ALL Files Shared Electronically Need to be 508 Compliant? Our Virtual Class on June 26 & 27 Will Explain How in Just Three Hours a Day...

Have you ever created a document or presentation and sent it around electronically? What about a flyer? Did you know those documents have to be 508 compliant? OIMT's class on Taking the Mystique Out of 508 will give an overview of the standards of Section 508. We'll explain how to make documents, spreadsheets, and presentations compliant. Class will be held June 26 & 27 via WebEx (just three hours/day) and is just \$150. Click the link above for registration instructions and more information.

Did You Know That Files Shared Electronically (Even if Just by Email) Need to be 508 Compliant? Our Class at White Oak on July 12 Will Explain...

Have you ever created a document or spreadsheet and sent it around electronically? What about a presentation or a flyer? Did you know those documents have to be 508 compliant? OIMT's class on Taking the Mystique Out of 508 will give an overview of the standards of Section 508. We will explain how to make documents, spreadsheets, and presentations compliant. Class will be held July 12 at White Oak and is just \$150. Follow the link above for registration instructions and more information.

Do you want to restrict records or validate data with a macro in Access 2016? Do you know how to automate data entry with a macro? Join OIMT's Access 2016 Advanced (Level 3) class on July 18 and 19 at White Oak. Meet OIMT at White Oak on July 18 and 19 for our two-day, \$300 Access 2016 Advanced class. In this class we'll explore Using Macros to Improve Interface Design. Topics include: Create a Macro, Restrict Records Using a Condition, Validate Data Using a Macro, Automate Data Entry Using a Macro, and Convert a Macro to VBA. Selected non-macro topics include advanced form design, data validation, and switchboards. Click the link above for the complete class description and registration instructions.

Outlook 2016 Intermediate Virtual Class - July 18 & 19 - Just Three Hours a Day. Learn How to Insert Advanced Characters & Objects. Set Importance, Sensitivity, and Delivery Options.

OIMT's \$150 Outlook 2016 Intermediate (Level 2) class via WebEx is July 18 & 19. Learn how to insert equations, symbols, WordArt & more. Understand the difference between importance and sensitivity levels. See how to direct replies to someone else. Save sent messages to another folder. Delay delivery of a message. These topics are in addition to others on email organization and calendar management. Click the link above for the complete course description and registration instructions.

Work With Design Templates in PowerPoint - Class is July 24 and 25 (Three Hours per Day)

OIMT's \$150 PowerPoint 2016 Intermediate class will teach you about Design Templates. We'll teach you how to Create & Manage Sections, Modify Slide Masters & Slide Layouts, Add Headers & Footers, and Modify the Notes Master & the Handout Master. Design Templates topics are in addition to others on Working with Media

and Animations, and Customizing a Slide Show. Class will be held via WebEx July 24 and 25. See the link above for the complete class description and registration instructions.

We can't keep others from sending you email, but we can show you how to organize and find it in our Outlook 2016 Intermediate Class at White Oak on July 26.

In OIMT's Outlook 2016 Intermediate class we'll devote an entire lesson to Advanced Message Management. See how to sort and filter messages. Learn how to organize and search messages. Learn about managing junk mail. Set up rules. Use the Instant Search feature. These topics are in addition to others on calendar, task, and contact management. Class is just \$150 and will be held at White Oak on July 26. Click the link above for the complete class description and registration instructions.

Work with Network Diagrams & Calendar View in Project 2013. Take a Class at White Oak on June 12 to Learn More.

OIMT's \$150 Project 2013 Intermediate class at White Oak on June 12 has modules on Network Diagrams and Calendar View. Working with Network Diagrams: Viewing a Network Diagram, Changing the Network Diagram Layout, Formatting Boxes, & Modifying Box Styles. Working with Calendar View: Viewing the Calendar, Viewing the Task List, Modifying Text Styles, Modifying Bar Styles, Formatting Gridlines, & Changing Calendar View. Click the link above for registration instructions and more class topics.

Watch OIP's New Video: Living and Working Abroad for FDA

You may have seen FDA's Office of International Programs "Gamechangers" video which described the benefits of working internationally. OIP has now completed a longer video that further illustrates the character of the cities and landscapes where FDA staff work in Europe, China, India and Latin America. Interviews with FDA staff describe the exciting challenges, opportunities and experiences working in FDA's ever-growing overseas workforce! Contact: Carl.Sciacchitano@fda.hhs.gov

ORA/OMPTO/OPQO Division 4 - DIB Selection

Alonza Cruse and I are pleased to announce the selection of CAPT Katherine Jacobitz as the Investigations Branch Director for the ORA Office of Pharmaceutical Quality Operations Division IV, effective immediately.

JOIN US Wednesday, June 6 for the OIP International Forum: "Considering an Overseas Assignment? What You Need to Know!"

If you're looking for a life experience with unique challenges, consider working abroad to help our agency meet its global public health mission. Join Carl Sciacchitano and Tina Harrison from the Office of International Programs and Patrick Bowen former International Program and Policy Analyst (Foods), in the FDA/OIP China Office, as they discuss hot topics and things to consider about working abroad for the FDA!

Guest Speaker Gus Palacios, PhD-USAMRIID on "Viral Population Genetics on Translational Sciences: Supporting Therapeutic Development from the Field" in WO22-Rm 1421 on 6/14 at 1-2:30p

FDA Genomics Working Group (GWG) is pleased to host Dr. Palacios - Director, Center for Genome Sciences, USAMRIID. Dr. Palacios will describe how his lab is using Next Generation Sequencing (NGS) approaches to support the mechanism of action of an antiviral drug and provide an update on how his lab employs NGS technology to track and characterize Ebola virus outbreaks. Remote Access available. Questions? Please contact Shari.Solomon@fda.hhs.gov.

Friday Prayer Services at the White Oak Campus

Friday (Jumu'ah) congregational prayer for employees at the White Oak campus will be held on Friday 6/1/2018 VENUE: Room 2045 Building 2 (CSU Building)(***NOTE VENUE***) TIME: Start at 1:15
***NOTE: Please check CSU activity board for last minute venue changes

Syneos Health (formerly inVentiv, LLC.) will be on site June 21, 2018 from 9-12 at WO, Bldg. 22, Room 4440 to provide hands on training. ***PLEASE BRING YOUR LAPTOPS**

Syneos Health, LLC. is a monthly survey designed to provide descriptive information on the patterns and treatment of diseases encountered in office-based physician practices in the U.S. The survey consists of data collected from over 3,200 office-based physicians representing 30 specialties across the United States that report on all patient activity during one typical workday per month. These data may include profiles and trends of diagnoses, patients, drug products mentioned during the office ...

Employee News

College Funding Coach - Free Seminar - June 26, 1 p.m.

For many families, the high cost of higher education is a daunting proposition. The College Funding Coach® is here to help families figure out HOW to pay for it! Employees can join in person or via Webex. Email Avery Wilson for more info. (See attached flyer)

White Oak Evening Toastmasters 2nd and 4th Tuesdays, 5:00 pm

Do you want to improve your public speaking skills? Come to Toastmasters. Our next meeting is Tuesday May 29th 5:00 pm in Building 51 room 1219. If you are interested, just show up. Visitors are welcome. If you would like more information, e-mail or call Hussein Ezzeldin Hussein.ezzeldin@fda.hhs.gov 240-402-8629.

FOH/EAP Webinar – Pursuing Your Dreams

Please join us for this EAP webinar on “Pursuing Your Dreams” on Wednesday, 06/13/2018, from 1:00PM-2:00PM ET. The website is www.FOH4you.com; then CLICK on “enter site” and click on “webinars”.

Everyone has personal and professional aspirations. Our dreams don’t have to take a backseat to daily life. This webinar will help you discover what energizes you, how to set effective goals and realistic expectations, and the importance of rewarding yourself. Register for this webinar on the websit ...

BIG-Parklawn Chapter - Care Packages for the Homeless

The Parklawn Chapter of Blacks in Government (BIG) requests your assistance to assist in preparing items for the homeless community. (See flyer for details)

FOH/EAP Seminar – Resilience and Stress – Everyday Challenges

Please join this Seminar on June 12, 2018, in Building 2, Room 2047W from 12:30PM-1:30PM. Resilience is a key factor when facing the stressors of everyday life. This seminar covers the social and emotional components of resilience, along with how the stress response affects us. With this understanding, options emerge for cultivating and restoring resilience. Please click on the link below to register. This program is brought to you by OHR, Human Capital Solutions, Work Life Programs Branch.

Yoga for Strength

Strength and flexibility are among the most important factors when it comes to feeling comfortable and confident in your body. It’s time to become the best version of you by practicing Yoga. Join us for a Lunch Break Yoga practice to stretch, balance, Restore and Revitalize during mid-day!

(b)(6)

Celebration

Please join us for a Meow-nificent Retirement Celebration
from the FDA after

(b)(6)

(b)(6)

(b)(6)

Leave Donation Requests

Appeal for Leave Donations for (b)(6)

An appeal for leave donations under the Voluntary Leave Transfer Program is being issued on behalf of (b)(6)

(b)(6)

(b)(6) Under the Voluntary Leave Transfer Program a Federal employee is allowed to donate unused annual leave to another employee who needs it due to a personal medic ...

Commuter News

New vanpool from Westfield, NJ to White Oak campus

We are looking for riders/drivers for a new vanpool starting from Westfield Train Station, New Jersey (NJ) to White Oak Campus. The van will be departing on Sunday (3:30 pm) from the Westfield Train Station and leaving FDA on Thursday/Friday at 3:30pm. This is a direct ride, non-stop. Transhare benefits will cover all costs. If you are interested, please contact (b)(6)

(b)(6)

Westminster to White Oak Campus Vanpool

Looking for additional drivers/riders starting from Fenby Park and Ride, at the intersection of MD Routes 97 & 32 in Westminster, traveling non-stop to the White Oak campus. The group will meet at 5:45 am. Working hours for this van are 7:00 am to 3:30 pm. If you have an interest in participating in the vanpool, please contact

(b)(6)

No out of pocket costs.

Bethesda (Montgomery Mall Park and Ride) to WO vanpool

We are looking for one rider/driver for our vanpool starting from the Montgomery Mall Park and Ride in Bethesda, MD. The van will leave at 7:20 am. Working hours are 7:50 am to 4:20 pm. If you have an interest in participating in the vanpool, please contact

(b)(6)

Existing Germantown (Milestone) to White Oak vanpool has 1 spaces for new members

Existing Germantown (Milestone) to White Oak vanpool has 1 spaces for new members. Work hours are from 7:15 am to 3:45 pm. We leave the Milestone Park and Ride (from behind Aldi store) at 6:30 am and leave White Oak at 4:00 pm. If you have questions or want to schedule a free trial, please contact

(b)(6)

(b)(6)

A new vanpool forming from North Potomac, MD to the White Oak Campus

The new vanpool will depart near Aberdeen Park, North Potomac, MD (Potomac Chase), at 8:00 AM, and leave FDA at 5:25 PM (Work hours 8:45 AM 5:15 PM). If you are interested in this vanpool and hours, please contact

(b)(6)

Employees willing to take a turn driving are preferred.

South Riding, VA vanpool looking for additional rider:

Existing vanpool has 1 vacancy. Departure point is East Gate Park and Ride South Riding, VA off Tall Cedars Parkway, leaving at 6:00 AM arriving to FDA by 7 AM, leaving at 3:30 PM from White Oak. Working hours are 7:00 AM to 3:30 PM. Direct ride, no stops. No Out-of-Pocket Costs and we have Wi-Fi. If interested please contact

(b)(6)

Vanpool Vacancy from Herndon, Virginia to White Oak

Seeking a new member to join a Herndon vanpool. The van leaves from Herndon-Monroe Park & Ride near Dulles Toll Road at 6:15 AM and arrives at White Oak campus by 7:00 AM. Proposed work hours are 7:00 AM – 3:30 PM. Please contact

(b)(6)

for more information.

New Vanpool starting in the Bowie area

The starting point is at the Fairwood Safeway/Gold's gym (corner of Rt. 450 and Fairwood parkway) and leaving at 8 AM and leaving the FDA at 4:30 pm (working hours TBD 7:30 to 4 PM, 8:30 AM to 4:30 PM or 9 AM to 5 PM). As proposed this is a direct ride, non-stop (35-50 minutes each way, depending on the traffic), from the Bowie Crossing Park and Ride to the FDA White Oak Campus. The maximum monthly subsidy is now \$255.00. Based on the recently attained estimates for a 2016 van there would be no ...

Riders needed for the Waldorf, MD. Vanpool to White Oak

Existing Waldorf Vanpool needs riders for the commute from the Park & Ride at U.S. 301 and Smallwood Drive, Waldorf, MD 20602 to FDA White Oak. Van leaves at 5:45 AM and arrives to FDA White Oak by 7 00 AM. The reverse trip is at 3:30 PM and arrives in Waldorf around 4:45 PM. Alternate work hours are being explored, therefore, if interested, contact (b)(6)

New vanpool is forming from Clarksburg Cabin Branch area, Clarksburg, MD to White Oak campus

We will start from Broadway Ave at 7:00 AM (close to Cabin Branch community swimming pool). We will leave WO at 4:20 PM. The working hours will be 7:45 to 4:15 PM. Van starting location and times are tentative at this point as it is a new vanpool. Van belongs to the capital vanpool company which allows you to switch between the 5 other capital vanpools already running from the nearby vicinity (Clarksburg town center, Harris Teeter and Bennigan's), if needed. If interested, please contact (b)(6)

The vanpool is starting from Kings view Park & Ride, Germantown

The starting point is the Kings view Park & Ride, Germantown (The crossing of Clopper Rd and Germantown Rd, Germantown, MD 20874). We meet at 6:40 am and leaving the FDA at approximately 3:45 pm (working hours 7:30 am to 3:30 pm). This is a direct ride, non-stop (40-50 minutes each way, depending on the traffic), from Germantown to the FDA White Oak Campus Building 75. There is no out of pocket expense with enough ridership on the van. If you are in the Germantown area and prefer a vanpool, ple ...

Leesburg/Ashburn, VA to White Oak Vanpool is operating and seeks additional riders

Vanpool from Target 45130 Columbia Pl in Sterling, VA to White Oak seeks additional riders. All charges covered by GoCard, no out of pocket expense. Take a free test ride before signing up. Office hours are 7:00am-3:30pm. Please contact vanpool coordinator at (b)(6)

Existing Fairfax County/Centreville/Chantilly, VA (Stringfellow Park and Ride) to White Oak Campus Vanpool

Existing vanpool has space for one more rider/driver from the Park and Ride at 4920 Stringfellow Road, Centreville, VA, near the intersection of Stringfellow Rd. & Fair Lakes Pkwy., with plenty of parking spaces. Working hours 7am-3:30pm. Departure to WOC is 6:15 am, leaving FDA at 3:30 pm, respectively. A direct, non-stop ride in a Toyota Sienna. If you are interested in joining the vanpool as a rider and driver, please contact (b)(6) No out o ...

The vanpool starting in Kingsview Park & Ride, Germantown is recruiting riders

The starting point is the Kingsview Park & Ride, Germantown (The crossing of Clopper Rd and Germantown Rd, Germantown, MD 20874). We meet at 7:10 am and leaving the FDA at approximately 4:20 pm (working hours 7:50 am to 4:20 pm). This is a direct ride, non-stop (35-50 minutes each way, depending on the traffic), from the Kingsview Park & Ride, Germantown to the FDA White Oak Campus (Building 75). There is no out of pocket expenses with enough ridership on the van. If you are in the Germantown ar ...

North Potomac, MD (Dufief Mill) to White Oak Vanpool

Two seats available at the vanpool starting from Dufief Mill at 8:00 AM to White Oak campus and leaving FDA at 5:00 PM (working hours are 8:35 AM – 5:00 PM). This is a direct ride, non-stop. If you are interested, please contact (b)(6)

Electric/Plug-In Vehicle Commuter Group

Do you commute to White Oak in an electric or plug-in vehicle, or are thinking about buying one soon? Join the White Oak Electric Vehicle Commuter Group to find out more about charging at White Oak! ***Click on "Request Access"

Glenwood, Glenelg, West Friendship, Woodbine to White Oak, MD Vanpool has Vacancies:

Glenwood Vanpool #2 is looking for additional riders to join our vanpool which operates on a work schedule of 7:00am to 3:30 pm. Pickup location is at 6:15 AM at Gethsemane Baptist Church, 14135 Burntwoods Road, Glenwood, conveniently located off of RT 32. We have an easy-to-drive comfortable mini-van. If you are interested or need additional information, contact (b)(6)

Seats available in greater Towson area vanpool

Seats are available in greater Towson area vanpool. We are looking for drivers (preferred)/riders. Office hours are 7am-3:30pm. No out of pocket cost. We meet at Kenilworth Shopping Mall (near 25th exit off I-695). For test rides and additional information, please contact vanpool coordinator at (b)(6)

Kingstowne, VA to White Oak Vanpool is Looking for Additional Riders Who Are Willing and Eligible to Drive on a Rotating Basis

The vanpool from Kingstowne to White Oak has openings. Departure daily at 6:20 am from 6400 block of Lake Village Drive (intersection of Lake Village Drive and Grange Lane), Kingstowne, VA 22315. Work hours are 7:00 AM-3:30 PM. To test-ride or join, please contact (b)(6)

A new Vanpool is forming as the third van from Walmart at North Ridge Road, Ellicott City, MD to White Oak campus

The new vanpool will start from Walmart at 7:15 am (the other vans starts at 7:00 am and 7:15 am), and leaving FDA at 4:15 pm. Working hours are 7:45 am to 4:15 pm. This is a direct ride, non-stop. If you are interest in participating in the vanpool, please contact (b)(6) There is no out-of-pocket money.

Bethesda (Ashburton Elementary School) to WO vanpool forming

We are looking for riders/drivers for our vanpool starting from North Bethesda United Methodist Church (10100 Old Georgetown Rd, Bethesda, 20814), which is close to Ashburton Elementary School in North Bethesda, MD. The group will leave at 8:30 am. Working hours are 9:00 am to 5:30 pm. If you have an interest in participating in the vanpool, please contact (b)(6) We already have 4 people and we are looking one more person to start the vanpool. There is no out-of-pocket cost. ...

Vanpool from Crabbs Branch Plaza, Rockville to White Oak is looking for riders.

Our van departs from the Crabs Branch Plaza, Rockville, MD 20855 at 8:05 AM sharp, and returns from White Oak campus (in front of Building #75) at 5:00 PM. . The van can accommodate 11 passengers. This is a non-stop direct ride. No out-of-pocket costs. Transhare benefits will cover all costs. If you are interested or want to have a free trial ride, please contact (b)(6) for more information.

Three seats to fill for New Vanpool starting from Alexandria VA Landmark Mall/BJ's

The starting point is the BJ's Shopping Center, south west of South Van Dom Street and Duke Street. From S. Van Dom Street to I-495/95 either East toward National Harbor/MGM or West toward Tyson Corner all the way to New Hampshire Ave, and to FDA White Oak. We will depart from BJ's at 6:30 AM and leave FDA at 4:30 pm (working hours TBD 7:30/8:00 am to 4:00/4:30pm). As proposed this is a direct ride, non-stop (50-75 minutes each way, depending on the traffic). The maximum monthly subsidy is now ...

Recruiting new riders in Travilah area

This vanpool group meets at the Nancy H. Dacek North Potomac Community Recreation Center, 13850 Travilah Rd, Rockville, MD 20850. We depart for White Oak at 8:00 AM, and return from the parking garage near Building 51 at 5:30 PM. Come to the vanpool to enjoy the smooth ride via ICC (route 200). If interested, please contact (b)(6) for more information.

Annapolis area vanpool looking for more riders/drivers

Vanpool meets at the Davidsonville exit Park & Ride off I-50 and Rt. 424 going to White Oak Campus, Silver Spring, MD. The group leaves at 6:45 am and returns at approximately 4:45 pm for a 7:30 to 4:00 work schedule. If you have an interest in joining the vanpool, please contact (b)(6)

(b)(6) There is no out of pocket cost.

Mount Airy/Damascus/ Clarksburg/Monrovia area vanpool seeking new riders

There are openings in a well-established vanpool on a stress-free commute route with beautiful sceneries. Wi-Fi access included. Departure daily at 7:00 am from the Damascus shopping center (we are willing to change the time slightly if necessary). WO campus work hours are 8:00 AM-4:30 PM. No out-of-pocket expenses. If you are interested or want to have a free ride, please contact (b)(6)

New Eastern Baltimore County/City Vanpool Forming

Looking for riders/drivers for a new vanpool starting from the Dundalk Home Depot parking lot (6315 Eastern Ave). to the White Oak Campus. Depart in a Dodge Caravan at 5:45 AM with work hours of 6:30 AM to 3:00 PM. Transhare benefits will cover all costs. If you are interested, please contact (b)(6)

(b)(6)

Germantown (Kingsview, park & ride) Vanpool Forming

Looking for riders/drivers for our van starting from Germantown (Kingsview park & ride). The group will meet at 9:10 am. Working hours are 10:00 am to 6:00 pm. If you have an interest in participating in the vanpool, please contact (b)(6) It's a direct non-stop ride. There is no out-of-pocket cost.

Germantown Existing Vanpool Looking for a Few Additional Members!!

Clean, comfortable, spacious, and easy to drive 15-passenger van departs the Milestone Park & Ride (behind Target/Aldi) at 6:30 am to the White Oak Campus (Bldgs 1, 75, and 66). Work hours: 7 am 3:30 pm). We depart the Campus at 3:30 pm. Non-stop and no out of pocket expense when using your Transhare benefits. Please contact (b)(6) for more info and/or free test ride. Hurry!! Only a few remaining seats available.

Germantown vanpool is recruiting

Work hours are from 9am to 5:30 pm. We gather at Kingsview Park & Ride in Germantown. Van leaves Germantown on 8:10 in the morning and WO on 5:30 in the afternoon. Van parks right in front of Building 75. Contact (b)(6) if you are interested.

Existing vanpool from Bethesda (Montgomery mall) to White Oak has opening for rider/driver

We are able to add one more rider to our vanpool. We start at the Park & Ride in Montgomery mall at 7:30 am and we leave WO at 4:30 pm. If interested, please contact (b)(6)

Existing vanpool starting from Rio/Crown Farm area

Existing vanpool starting from Rio/Crown Farm area at 7:45 AM to White Oak campus and leaving FDA at 4:45 PM (work hours are 8:15 AM – 4:45 PM). This is a direct, non-stop ride to the FDA. We encourage free test rides on Mondays, Wednesday, and Fridays. If you are interested, please contact (b)(6)

(b)(6)

New vanpool is forming from Clarksburg, (Harris Teeter in Clarksburg Village), MD to White Oak campus

Looking for a stress-free and economical way to get to White Oaks? The Clarksburg vanpool is welcoming new members. We will start at 7:00/7:15 AM and leave WO at 4:15/4:30 PM. The working hours will be 7:45 (or 8:00am) to 4:15pm (or 4:30 pm). This is a direct ride, non-stop. Van starting and end times are flexible as this point as it is a new vanpool. We can decide considering the views of all riders. There is no out-of-pocket money. If interested, please contact (b)(6)

New vanpool from Gaithersburg/Rockville/N. Potomac to White Oak campus

We are actively looking for riders/drivers for a new vanpool forming from Muddy Branch Shopping Center, Gaithersburg, MD to White Oak Campus. Campus work hours will likely be 8:15AM – 4:45PM, but negotiable. The vanpool will utilize the ICC which is the fastest route (~40 mins). Please contact (b)(6) (b)(6) for more details.

Urbana vanpool has vacancies for Drivers

This vanpool group meets at the ExxonMobil/Urbana Park and Ride lot (8816 Fingerboard Rd, Frederick, MD 21704). We depart at 7:00 AM sharp. Work hours are 8:30 5pm. We are averaging 50-60 minutes commuting time. If you are interested, and have a good driving record or have any questions, please contact (b)(6) (b)(6) Take a free trial ride!

Owings Mills Metro Center to White Oak has 1 seat available!

We meet at the covered parking garage on Painters Mill Road in Owings Mills, MD. Work hours at White Oak are 7 am – 3:30 pm. We drive a Toyota Sienna Minivan and have a seat available for someone who is willing to drive at least 1 per week. If interested, please contact (b)(6) (b)(6)

Warrenton Road Fredericksburg VA Commuter Lot / Route 17 Commuter Lot, 627 Warrenton Rd to White Oak Campus Vanpool

Riders needed to form a new vanpool from the commuter lot at 627 Warrenton Road, Fredericksburg VA. Working hours TBD. Proposed departure from the commuter lot time is 5:30/5:45/6:00 a.m. This will be a direct, non-stop ride. If you are interested in joining the vanpool, please contact (b)(6) (b)(6) Transhare benefits will cover all costs including gas and tolls.

New Vanpool from McLean VA to White Oak campus

We are looking for riders/drivers for a new vanpool starting from McLean VA (Total Wine shopping center on Chain Bridge) to White Oak campus. The van will depart 7:15 am from McLean and leaves WO at 4:15 pm. Working hours are from 7:45 am to 4:15 pm. If you are interested in joining us, please contact (b)(6) (b)(6)

Sterling, Leesburg, Ashburn, and Chantilly, VA, vanpool is now running

One seat is available at this time at no out of pocket cost. The starting point is Target next to Wegman's (45131 Columbia Place), Ashburn/Sterling at 6:00am and leaving the FDA at 3:15pm (working hours 6:45am to 3:15pm). This is a direct ride, non-stop (40-50 minutes each way), from Sterling to the FDA. If you are interested, please contact (b)(6)

Dumfries, VA to White Oak Campus

Several riders needed to form a new vanpool from the Dumfries, VA Park and Ride located at 17361 Dumfries Road, Dumfries, VA, (located off Exit 152 and east of I-95 and just prior to Route 1 across McDonald's) with plenty of parking spaces. Working hours are 7:00am -3:30pm Monday-Thursday and 6:30am-3:00pm on Fridays. We will be departing the Dumfries Park and Ride Lot at 6:00am Monday-Thursday and 5:30am on Fridays. We will depart the White Oak Campus at 3:30 pm Monday-Thursday and 3:00pm on Fr ...

Vanpool from Middletown, NY to White Oak Campus is seeking new riders/drivers

Looking for Riders / Drivers for the Vanpool from Middletown New York, via Suffern New York, with a possible stop in New Jersey along GSP/NJtpk to White Oak. The van leaves Suffern at 5:00 AM (Monday) and White Oak at 3:00 PM (Tuesday or Wednesday) for once a week roundtrip. If you are interested, please contact (b)(6) (b)(6)

Dumfries, VA to White Oak Campus

Summer time is here and the weather is AMAZING and who wouldn't want to get in to work and leave early to enjoy it? Well you can: Existing vanpool needs riders for the commute from Dumfries commuters lot: 17361 Dumfries Road, Dumfries VA across from McDonalds. The working hours are: 6:30am – 3:00pm Monday – Thursday and 6:00 – 2:30 on Fridays. We will be departing the Dumfries Commuters lot at 5:30am Monday – Thursday and 5:00am on Friday. Leaving White Oak Campus 3:00pm Mon-Thursday and arrivin ...

A new Vanpool is forming from Centennial Overlook, Old Annapolis Rd, Ellicott City, MD to White Oak campus

The new vanpool will start from Centennial Overlook at 8:10 am and leaving FDA at 5:15 pm. Working hours are 8:40 am to 5:10 pm. This is a direct ride, non-stop. If you are interested in participating in the vanpool, please contact (b)(6) There will be no out of pocket expenses.

New Vanpool in Clarksburg/MD

Looking for drivers/riders in the Clarksburg area near the outlets. Working hours will be 7 a.m. to 3:30 p.m. If you are interested, please contact (b)(6)

New vanpool covering Rockville, MD is forming now

The starting point is the Guitar Center (or Target) in Rockville at 8 am and leaving the FDA (southwest parking garage) at 5pm (working hours 8:30 am to 5 pm). If you are interested, please contact (b)(6)

A New Columbia to White Oak Vanpool is Looking for Riders

We are starting a new vanpool aiming to improve the quality of life for all Columbia vanpool riders. Van will depart Broken Land Park & Ride at 7:15 AM and leave White Oak Campus at 4:15 PM, thus adding another option to the existing 6:30 and 7:00 AM vanpools from the same location. There are no drawbacks: you are guaranteed a ride home in case of an emergency, you will save money, make new friends and feel good about your choices. If you would like to join, please contact (b)(6)

New Vanpool starting in Burke/Springfield/Annandale/Fairfax!

The starting point is on Wakefield Park Rd. (8100 Braddock Rd, Annandale, VA 22003). We will depart at 6:15 am and leave the FDA at 3:30 pm (working hours 7:00 am to 3:30pm, may be flexible up to 30mins later if requested by members). If you are interested, please contact (b)(6)

New Lutherville-Timonium, MD to FDA (Fishers Lane), Rockville Vanpool Forming

New vanpool covers Timonium, Towson City SE, and York Road, is forming now. The starting point is Meadowood Regional Park (10650 Falls Rd) at 6:10 am and leaving the FDA at 3:30pm (working hours 7:00am to 3:30 pm). This is a direct ride, non-stop (typically 50 min – 1 h 5 min, depending on the traffic), from Timonium to FDA Fishers Ln, Rockville, MD. If you are interested, please contact (b)(6)

New Oxon Hill to White Oak Vanpool Forming (Only 1 more needed)

Looking for riders/drivers for a new vanpool starting from Oxon Hill (at Tanger Outlet National Harbor Shopping-mall and Rt. 414), Maryland going to White Oak Campus, Silver Spring, MD. The group will meet at 6:00am departing from Oxon Hill Rd at 6:15am. Working hours for the vanpool will be 7:00am -3:30pm. If you have an interest in participating in the vanpool, please contact (b)(6) There is no out-of-pocket cost.

New vanpool from Northern New Jersey to White Oak campus

We are looking for riders/drivers for a new vanpool starting from Northern New Jersey area to White Oak Campus (with potential pickups/drop-offs in NJ and PA). The van will be departing on Sunday (3:30 pm) from

Northern New Jersey area and leaving FDA on Tuesday (Week 1) and Wednesday (Week 2) at 3:30pm.

Transhare benefits will cover all costs. If you are interested, please contact (b)(6)

(b)(6)

New vanpool is forming from Clarksburg, MD to White Oak Campus

We will start from Clarksburg (Right across Harris Teeter in Clarksburg Village) at 8:00 am and leave WO at 5:30 pm. The working hours will be 9:00 am to 5:30 pm. This is a direct ride, non-stop (around 45 minutes each way). If interested, please contact (b)(6)

Germantown - White Oak Vanpool: Availability of spaces for New Members

Our Office hours are from 9:00 am to 5:30 pm. We depart at 7:55 am in the morning from the Milestone Park & Ride (behind Aldi/Staples/Target) and at 5:30 pm in the evening from the White Oak campus. If interested in joining or wish to take a test ride, please contact (b)(6)

(b)(6)

Germantown (Kingsview, Park & Ride) Vanpool Forming

Looking for riders/drivers for our van starting from Germantown (Kingsview Park & Ride). The group will meet at 9:10 am. Working hours are 9:45 am to 6:05 pm. If you have an interest in participating in the vanpool, please contact (b)(6) It's a direct non-stop ride. There is no out-of-pocket cost.

Germantown Vanpool is Looking for New Members

The starting point is the Kingsview Park and Ride (Germantown) at 6:00 am and leaving the FDA at 3:05pm (working hours 6:30 am to 3:00 pm). This is a direct ride, non-stop (30-35 minutes each way, depending on the traffic), from the Kingsview Park and Ride to the FDA (Building 75 surface parking lot). If you are interested, please contact (b)(6)

(b)(6)

This existing, friendly vanpool from Columbia to White Oak has an opening

Departure daily at 7 a.m. from the Broken Land Parkway Park & Ride East Lot, Columbia, MD. WO campus work hours are 7:30 AM-4:00 PM. Currently there are no out of pocket costs. You are welcome to try out a ride with no obligation to join. If interested, please contact (b)(6)

Existing Falls Church vanpool that serves riders from Annandale, Tysons, and Merrifield

Existing Falls Church vanpool that serves riders from Annandale, Tysons, and Merrifield has room for one additional safe driver for our Nissan Pathfinder, our work hours are 6:30 am 3 pm. We meet in Falls Church (Pioneer Ln & Shreve Road near 495) at 6 am and depart WO 3 pm. There are no out of pocket costs. Partial schedules due to working from home are ok. Please contact: (b)(6)

(b)(6)

Existing Clinton Vanpool looking for additional riders

The Clinton vanpool is currently seeking additional riders, our work hours are 7:00am – 3:30pm. Clinton vanpool leaves from Stuart Lane/Woodyard Road Park & Ride. The van leaves Clinton promptly at 6:10am to arrive to White Oak for 7:00am work day. We depart WO at 3:20pm promptly. Clinton Coordinator is (b)(6)

(b)(6)

Existing Germantown 8:00 am vanpool seeks additional riders/drivers:

The starting point is the Kingsview Park & Ride, Germantown (southwest corner of Clopper Rd/Kingsview Village Ave). The van leaves the Park & Ride at 8:00 am and leaves the FDA (Bldg 51) at 5:15 pm for working hours 8:45 am to 5:15 pm. This is a non-stop direct ride with No out-of-pocket costs. Almost every 15 minutes from 5:30 am to 8:40 am there is a van leaving for the FDA campus from there, providing with great flexibility to all riders. If interested, contact (b)(6)

Existing Bel Air, MD to White Oak Vanpool has space for a new member to join immediately

Save money on gas, tolls and preserve your energy and join the Bel Air Vanpool now! We are looking for riders to join our vanpool leaving from the Bel Air area, Abingdon Park & Ride, Route 24 and Edgewood Rd, to the White Oak campus. The vanpool departs the Abingdon P&R at 6:20am and leaves FDA at 4:00pm. Work hours are 7:30 - 4:00 PM. Enjoy the benefits of vanpooling. Please contact (b)(6)

(b)(6)

for more information.

This existing vanpool from Ellicott City to White Oak has few openings

This existing vanpool from Ellicott City to White Oak departs daily at 7 AM from Long Gate Park & Ride, Ellicott City, MD. WO campus working hours are 7:30 AM-4:00 PM. There is no out-of-pocket money. If interested, please contact (b)(6)

Existing Severn to White Oak Vanpool with two openings

We have two seats available in our established Severn Vanpool. Our ride and hours make the commute easy! We leave from Telegraph Rd and Rt 32 at 6:10am. WO campus hours are 6:45a to 3:30p. If you are interested or want to take a test ride, please contact (b)(6)

Vanpool from Herndon, VA to White Oak still has seats available for a new member

Our van departs from the Herndon-Monroe park and ride. We leave the "park and ride" at 6:15 am and return from FDA at 3:30 pm. We have a Toyota/Sienna van that can accommodate 6-7 passengers. If you are interested, please contact (b)(6) for more information.

Riders needed for a Woodbridge Vanpool

Existing Woodbridge Vanpool needs riders for the commute from Telegraph Rd. commuter parking lot, Woodbridge, VA to FDA White Oak. Van leaves at 7:00 AM and arrives FDA White Oak at 8 00 AM. The reverse trip is at 4:30 PM and arrives in Woodbridge at 6:00 PM. If interested, contact (b)(6)

(b)(6)

Fulton (Maple Lawn Blvd) to White Oak Vanpool

We have one open seat in the Fulton/Scaggsville vanpool second van. The van departs from Maple Lawn Blvd/Market St in Fulton at 8:00 am. The campus hours are 8:00 – 5:00. If you are interested, please contact (b)(6)

You are welcome to try vanpooling for a few days without obligation to join.

Gaithersburg to White Oak Vanpool Is Looking for Riders

Our 12-seat van leaves at 8:05 am at the end of Industrial Drive off Gaither Road in Gaithersburg, and return from White Oak north surface vanpool lot (in front of Bldg. 21/22) at 5:15 pm. To arrange a free trial ride or have any question, please contact (b)(6)

Columbia to White Oak Vanpool looking for New Riders!!

Looking for a stress-free and economical way to get to work? The Columbia vanpool is looking for new members. Van departs Broken Land Park & Ride at 6:30 AM. Work hours are 7 - 3:30. All vanpool members are guaranteed a ride home in case of an emergency. Leave your personal vehicle at the park & ride. Save miles and gas money! Please contact (b)(6) for more information.

Opening in Clarksburg 7 AM Vanpool

Opening in Clarksburg Town Center/Harris Teeter vanpool. Vanpool leaves Clarksburg Town Center (close to community swimming pool) at 6.53 AM, stops at Harris Teeter and leaves at 7 AM. Vanpool leaves WO at 4:15 PM. The working hours are 7:45 to 4:15 PM. Van belongs to the capital vanpool company which allows you to switch between the 4 other capital vanpools already running from the nearby vicinity (Harris Teeter, Premium Factory Outlets and Bennigan's). Other vanpool's coordinator concurrence ...

Germantown Existing Vanpool Looking for a Few Additional Members!!

Clean, comfortable, spacious, and easy to drive 15-passenger van departs the Milestone Park & Ride (behind Target/Aldi) at 6:30 am to the White Oak Campus (Bldgs 1, 75, and 66). Work hours: 7 am – 3:30 pm). We depart the Campus at 3:30 pm. Non-stop and no “out of pocket” expense when using your Transhare benefits. Please contact (b)(6) for more info and/or free test ride. Hurry!! Only a few remaining seats available.

Vacancy/Detail Announcements

ACED Vacancy Announcement

The Advisory Committee for Employees with Disabilities (ACED) is currently seeking two ORA Representatives. One to represent the Pacific and one to represent the Southwest Areas. The term of an ACED Member is 2 years, with the option to renew. The person selected, will be required to attend the monthly meetings, join and actively participate on one of the ACED subcommittees and share important information with employees and managers in his/her respective Center/Office.

CDER/OND/IO/RAT – Unclassified Duties Detail Announcement (Appropriate for GS 12/13)

This position is located in the Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Office of New Drugs (OND), Immediate Office (IO), Regulatory Affairs Team (RAT).

OND/IO/RAT -CDER-wide Detail Opportunity: Unclassified Duties (Appropriate for a GS14)

This position is located in the Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Office of New Drugs (OND), Immediate Office (IO). Please see attachment.

CTP Vacancy Announcement: Regulatory Health Project Manager, GS-0601-11/12, (MP)

This position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Tobacco Products (CTP), Office of Science (OS), located in Silver Spring, MD. The Office of Science (OS) will be permanently relocated to Beltsville, Maryland; tentatively scheduled for the end of Summer/Fall 2018.

CTP Vacancy Announcement: Regulatory Health Project Manager, GS-0601-13, (MP)

This position is located in the Department of Health and Human Services, Center for Tobacco Products, Office of Science, located in Silver Spring, Maryland. The Office of Science (OS) will permanently relocate to Beltsville, Maryland; tentatively scheduled for the end of summer/fall 2018.

CDER/OEP/DEO DETAIL-TEMPORARY PROMOTION OPPORTUNITY – PROJECT MANAGER – GS-0301-12/13

CDER OEP is looking for candidates to join the Drug and Policy Teams in the Division of Executive Operations. You will coordinate CDER-wide initiatives with other parts of the Agency, oversee Center activities related to drug review programs/office operations, manage the Center Director’s correspondence and CDER related oversight activities. You will have an opportunity to develop messaging for CDER, utilize your project management skills, and practice diplomacy with broad project teams.

DETAIL OPPORTUNITY: OGD/IO/CS: Project Manager GS-0301-14

Position: Project Manager Series & Grade: GS-0301-14 Organization: Center for Drug Evaluation and Research Office of Generic Drugs Immediate Office Communications Staff Detail Length: 120 days PHS Commissioned Corps candidates may apply Supervisory Concurrence is required prior to applying. Temporary Promotion will be offered. Location: White Oak, Bldg 75 10903 New Hampshire Ave. Silver Spring, MD 20993 Area of Consideration: CDER-Wide Bargaining Unit Status ...

CFSAN-18-5-CORE-PS - Temporary Promotion - Supervisory Interdisciplinary Scientist, GS-0401, 0403, 0415, 1320-14

This position is located in the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Coordinated Outbreak Response and Evaluation Network (CORE), Response Staff located in College Park, Maryland.

CBER Detail NTE 120 Days - Regulatory Counsel, GS-301-14

This position is located in the Immediate Office, Office of Blood Research and Review, Center for Biologics Evaluation and Research. This is a non-bargaining unit position. See attached.

CTP Vacancy Announcement: Regulatory Health Project Manager, GS-0601-7/9, (MP)

This position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Tobacco Products (CTP), Office of Science (OS), located in Silver Spring, Maryland. The Office of Science (OS) will be permanently relocated to Beltsville, Maryland; tentatively scheduled for end of Summer/Fall 2018.

CBER Vacancy: Associate Director for Management (Executive Officer), ES-0341-00

The Center for Biologics Evaluation and Research (CBER) is seeking qualified candidates for a critical Senior Executive Service (SES) position in the Office of Management (OM). To apply for the Associate Director for Management (Executive Officer), ES-0341-00 position, please refer to the official job opportunity announcement on USA Jobs. This announcement closes on June 18, 2018.

CDRH/OCD FDA-Wide Detail Opportunity: Deputy Ombudsman

This position is located in the Policy Team within the Office of the Center Director (OCD), Center for Devices and Radiological Health (CDRH) in Silver Spring, MD. The incumbent serves as Deputy Ombudsman, providing advice and assistance to the Ombudsman in making recommendations to the Center Director, program directors, scientific and professional personnel, industry officials, FDA representatives and others. Please see attached for additional details.

ORA/Office of Criminal Investigations (OCI), Vacancy Announcement: Director, Office of Criminal Investigations- Multiple locations

This is a SES position; the candidate will have to be reviewed by the agency Ethics staff for conformance with public filer income reporting requirements. 1811 Series Announcement # FDA-ORA-SES-18-10205501

CDER-wide Temporary Promotion Opportunity: Clinical Analyst, GS-0601-14

The incumbent serves as a Clinical Analyst for the Therapeutic Biologics and Biosimilars Staff in the Center for Drug Evaluation and Research (CDER), Office of New Drugs (OND), Immediate Office, Therapeutic Biologics and Biosimilars Staff. See attachment for more information on this opportunity and for instructions on how to apply.

CDER/OND/IO - Temporary Promotion Detail - Regulatory Health Project Manager- GS-0601-13

This position is located in the Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Office of New Drugs (OND), Immediate Office (IO). See Attached.

CDER/OND/IO/Transition Team - CDER-wide Detail Opportunity Science Policy Analyst, GS-0601-14

This position is located in the Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Office of New Drugs (OND), Immediate Office (IO). Please see attachment.

FDA/CDER Office of Communications Detail Opportunity Not to Exceed 60 Days: Pharmacist GS-0660-13

This announcement is for a detail as a Pharmacist in the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information (DDI).

CTP Vacancy Announcement: Training Specialist, GS-1712-11/12, (MP)

This position is located in the U.S. Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Office of Management, Silver Spring, Maryland.

ORA/Office of the Associate Commissioner for Regulatory Affairs (OACRA), Vacancy Announcement: Deputy Associate Commissioner for Regulatory Affairs— Silver Spring, MD

This is a SES position; the candidate will have to be reviewed by the agency Ethics staff for conformance with public filer income reporting requirements. 1811 Series Announcement # FDA-ORA-SES-18-10205501

ORA/Office of Criminal Investigations (OCI), Vacancy Announcement: Director, Office of Criminal Investigations— Multiple locations

This is a SES position; the candidate will have to be reviewed by the agency Ethics staff for conformance with public filer income reporting requirements. 0301 Series Announcement # FDA-ORA-SES-18-10205519

CBER Detail Opportunity: CBER/OCBQ/DCM - Consumer Safety Officer

CBER's Office of Compliance and Biologics Quality (OCBQ), Division of Case Management, Biological Drug & Device Compliance Branch is offering a non-reimbursable detail opportunity for qualified candidates to serve on details NTE 90 days.

CTP Detail Opportunity: Lead Mathematical Statistician GS-1529-14, (Reimbursable Detail)

The Center for Tobacco Products is offering a detail opportunity for a Lead Mathematical Statistician GS-1529-14 within the Office of Science. The incumbent acts as a team leader and statistician expert. The detail is available immediately for a period not-to-exceed 120 days. PHS Commissioned Corps Officers may apply. A temporary promotion will be considered.

DETAIL OPPORTUNITY - OO/OIMT/OTD/DMSS - IT Specialist (SYSANALYSIS/APPSW) GS-2210-13

The Office of Operations (OO)/Office of Information Management and Technology (OIMT), is seeking an IT Specialist to serve under the Change Control, Configuration and Release Management (CCRM) Program in Delivery Management and Support Staff (DMSS). Please see attachment for more details.

FDA/ORA/OMPTO/Office of Bioresearch Monitoring Operations (OBIMO) Vacancy Announcement: Consumer Safety Officer (Program Expert) GS-0696-13 Location Negotiable (MP)

This position is in the Office of Bioresearch Monitoring Operations (OBIMO). Serves as an expert of inspection techniques for Food and Drug Consumer Safety Officers in the Field and Headquarters in the ORA. Duty station will be determined upon selection. Open to Current FDA Employees Only.

OFVM Detail Opportunity, Staff Assistant-GS-301-11/12

The Office of Foods and Veterinary Medicine is offering a 120-day Detail Opportunity for a Staff Assistant, GS-301-11/12. This detail is reimbursable and a temporary promotion may be offered to eligible applicants.

CDER/OPSA Detail Opportunity Operations Research Analyst GS-12

This position is located within the Performance Analysis & Data Services Staff (PADSS), Office of Program and Strategic Analysis (OPSA), Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER).

Vacancy announcement: CSO (State Liaison) - GS-0696-12/13

A vacancy announcement for a CSO (State Liaison), GS-0696-12/13 has been posted on USAJOBS. The announcement is open, Friday, June 1, 2018 and closes on June 15, 2018. Please follow the link for more details.

Voluntary Reassignment Opportunity - CDER/OMP/OMPI/DCTQ - Supervisory Medical Officer (Deputy Division Director), GP-602-15

The Center for Drug Evaluation and Research, Office of Medical Policy, Office of Medical Policy Initiatives, Division of Clinical Trial Quality is offering a voluntary reassignment opportunity for a Supervisory Medical Officer (Deputy Division Director), GP-602-15. The reassignment opportunity is open to all current CDER employees. This is a non-bargaining unit position.

OFVM Detail Opportunity Program Analyst, GS-343-13

Office of Foods and Veterinary Medicine(OFVM) is offering a 120-day Detail Opportunity - Program Analyst, GS-343-13. This individual will assist with the integration and application of strategic management practices across the FVM enterprise, including the integration of performance management, strategic planning, implementation planning, and budget formulation and execution:

Vacancy Announcement: Intl Relations Specialist (India Office), GS-0131-14

This is an overseas assignment. Positions may be filled as Temporary promotions/Reassignments. Overseas assignments filled as temporary promotions are not to exceed two years, may be extended for two year, up to a maximum of five years based on the needs of the agency.

CBER Detail NTE 120 Days - Supervisory Physician, GP-602-15

This position is located in the Immediate Office, Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER). This is a non-bargaining unit position. See attached.

CBER VACANCY ANNOUNCEMENT – LEAD PHYSICIAN, GP-0602-15

This position is located in the Center for Biologics Evaluation and Research (CBER), Office of Tissues and Advanced Therapies (OTAT), Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT), Clinical Hematology Branch, located in Silver Spring, MD.

CBER DETAIL ANNOUNCEMENT-SCIENTIFIC INFORMATION SPECIALIST, GS-12, NTE 120 DAYS

This position is located in the Center for Biologics Evaluation and Research (CBER), Office of the Center Director (OD), under the Associate Director for Research (ADR). As a Scientific Information Specialist, the incumbent will assist in managing multiple computer-based systems used for monitoring and tracking regulatory science and research activities, such as research programs, publications, and budget tracking.

CDER/OND/IO- CDER-wide Detail Opportunity Unclassified Duties, (Appropriate forGS-0301-14)

This position is located in the Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Office of New Drugs (OND), Immediate Office (IO). Please see attachment.

CBER DETAIL OPPORTUNITY: CBER/OBRR/IO MANAGEMENT OFFICER, GS-0301-13

The Center for Biologics Evaluation and Research (CBER), Office of Blood Research and Review (OBRR) has a detail opportunity for a Management Officer, GS-0301-13, in their Immediate Office Administrative Staff. To apply for this detail opportunity, please review the attached memo from the Acting Director, OBRR. This announcement closes on June 11, 2018.

OPQ Vacancy Announcement: Supervisory Interdisciplinary Scientist GS-15

This position is located in the Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Quality (OPQ); Office of New Drug Products (ONDP); Office of Process and Facilities (OPF) in Silver Spring, MD.

OPQ Vacancy Announcement: Supervisory Interdisciplinary Scientist GS-15

This position is located in the Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Quality (OPQ); Office of New Drug Products (ONDP); Office of Process and Facilities (OPF) in Silver Spring, MD.

Supervisory Regulatory Health Project Manager, GS-601-14 - Detail Announcement (Temporary promotion opportunity available). The position is located in CDER/OMP/OMPI/Division of Clinical Trial Quality. Medical Policy/Office of Medical Policy Initiatives/Division of Clinical Trial Quality. Supervisory Regulatory Health Project Manager, GS-601-14 (temporary promotion available). Click link for additional information.

DETAIL OPPORTUNITY: OGD/OGDP/DPD Project Specialist, GS-0301-09

Position: Project Specialist, GS-0301-09 Organization: Center for Drug Evaluation and Research Office of Generic Drugs Office of Generic Drug Policy Division of Policy Development Detail Length: 120 Days Temporary Promotion may be offered. Supervisory Concurrence is required prior to applying. Location: White Oak, Bldg 75 10903 New Hampshire Ave. Silver Spring, MD 20993 Area of Consideration: FDA-WIDE Bargaining Unit Status: This is a Bargaining Unit Positi ...

OMPT Unclassified Duties Detail - Talent Systems Analyst (equiv to GS-343-12/13)

Please see attached for more information

OGROP/ORO/OFFICE OF REGULATORY SCIENCE (ORS), VACANCY ANNOUNCEMENT; SUPERVISORY INTERDISCIPLINARY SCIENTIST (DEPUTY DIRECTOR) GS-401/403/1320-15, LOCATION-JEFFERSON, AR/ROCKVILLE, MD (MP)

The incumbent serves as Deputy Director and alter ego to the ORS Office Director on planning and implementation of administrative policy and business process improvements in accomplishing the Office's substantive objectives, in an atmosphere of continuously changing conditions and needs

CTP Detail Opportunity: Unclassified Duties (equivalent to Science Advisor, GS-14), (Reimbursable Detail)

The Center for Tobacco Products, Office of Science, Division of Regulatory Science Informatics (DRSI) organization is offering a Detail opportunity for Unclassified Duties. Applicants at the GS-14 level are encouraged to apply. The Detail is available immediately for a period of 120 days.

ORA/Office of Partnerships & Operational Policy (OPOP)/Office of Partnerships (OP)/Division of Integration Vacancy Announcement: SCSO, GS-696-14, Location Negotiable, (MP)

Please see link for more information.

ORA/OPOP/Office of Partnerships (OP) Detail Announcement: Management Analyst, GS-343-9-13, Rockville, MD (Non-reimbursable)

Please see attachment for more information.

CTP Vacancy Announcement: Paralegal Specialist, GS-0950-11/12, (MP)

This position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Tobacco Products (CTP), Office of Compliance and Enforcement (OCE) in Silver Spring, MD.

CTP Vacancy Announcement: Paralegal Specialist, GS-0950-11/12, (DE)

This position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Center for Tobacco Products (CTP), Office of Compliance and Enforcement (OCE) in Silver Spring, MD.

OC-IO Temporary Promotion Detail : Program Support Specialist, GS-0301-9 (Reimbursable Detail)

The Office of the Commissioner (OC), Immediate Office (IO), is offering a Temporary Promotion Detail opportunity for a Program Support Specialist, GS-0301-9. The position is available immediately for a period of 90 days. Please see attachment for additional information on the position.

Vancancy Announcement- ORA 1515 11/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

Vancancy Announcement- ORA- 1515-11/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

Vancancy Announcement- ORA 1515 11/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

Vacancy Announcement- ORA-1515-11/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

Vacancy Announcement- ORA-1515-11/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

Vacancy Announcement- ORA-1515-11/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

Vancancy Announcement- ORA-1515-11/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

Vacancy Announcement- ORA-1515-12/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former

government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

Vacancy Announcement-ORA-1515-11/12

Job Opportunity- Operation Research Analyst(ORA) 11/12 Announcement number -FDA-CDER-DE-18-10215693WH All Sources- Open to the public <https://www.usajobs.gov/GetJob/ViewDetails/500311600>
Announcement number - FDA-CDER-MP-18-10215688WH Merit Promotion- Open to Current or former government status employees or those eligible under special hiring authorities
<https://www.usajobs.gov/GetJob/ViewDetails/501045400>

CDER/OM/DUFMBF/GB detail/temp promotion NTE 120 days for a Management Analyst GS-0343-09/11/12

The CDER/OM Division of User Fee Management and Budget Formulation (DUFMBF), Generic Branch is currently advertising a Detail/Temporary Promotion NTE 120 days for a Management Analyst GS-0343-9/11/12. This Detail/Temporary Promotion Announcement will close June 1, 2018. Please see the following announcement attached.

From: FDA_NEWS@OC.FDA.GOV [FDA_NEWS@OC.FDA.GOV]
Sent: 4/2/2018 12:13:10 AM
To: FDA-Wide [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ffe86b3c2f71463c9100bfdcc3d7b4f-FDA-Wide]
Subject: FDA Notices

FDA Announcements

FDA Scientific Professional Development Calendar

The calendar serves as a resource to the FDA scientific community with a comprehensive listing of relevant Agency-wide scientific training and continuing education events.

FDA/ORA/OHAFO Vacancy Announcement: Supervisory Consumer Safety Officer (FOOD) GS-0696-14, location negotiable after selection, US

This vacancy is open to current permanent employees of the Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations (OHAFO) only. Current FDA/ORA/OHAFO employees serving under a Schedule A appointment are eligible for consideration. Title 42 employees not eligible for reinstatement will not be considered.

FDA/OGROP/ORA/OHAFO/Division East Vacancy Announcement: Consumer Safety Officer (CSO) GS-0696-07

The position serves as a trainee who accompanies senior Consumer Safety Officers in the conduct of more complex inspections and investigations. Positions are located in the Food and Drug Administration (FDA), Office of Global Regulatory Operations and Policy (OGROP), Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations (HAF), Division East. Duty station will be determined upon selection.

Catalyze Your Research with these April Tech Transfer Workshops

MTAs, RCAs, and CRADAs: What can they do for you? Don't miss this Wed., April 11th workshop from 1:30 p.m. to 3:00 p.m., Bldg. 1, Room 4101-4105. Presented by Tech Transfer's Bill Ronnenberg and on April 18th, Charlene Maddox gives FDA inventors a toolkit for identifying potential discoveries and using resources from FDA's Technology Transfer Program.

Introduction to Clinical Pharmacology and Pharmacokinetics

Sponsored by the Office of Scientific Professional Development (OSPD), the Office of the Chief Scientist (OCS), and the Center for Drug Evaluation and Research, Office of Clinical Pharmacology will take place on April 20, 2018 from 8:30am-4:00pm at FDA White Oak. Please select the following link for registration instructions and additional information:

<http://inside.fda.gov:9003/EmployeeResources/Training/FDAScientificProfessionalDevelopmentResources/ucm397383.htm> POC: marcy.wexler@fda.hhs.gov

FDA/OGROP/ORA/OHAFO/Division East Vacancy Announcement: Consumer Safety Officer (CSO) GS-0696-09

The positions are located in the Food and Drug Administration (FDA), Office of Global Regulatory Operations and Policy (OGROP), Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations (HAF), Division East. Duty station will be determined upon selection.

Developing and Applying The Next Generation Of Microbiome Bioinformatics, 4/23 at FDA WO2-Rm 2046, 2:30-5pm

The FDA Genomics Working Group (GWG) & the FDA Microbiome Working Group (MWG) are pleased to host guest speakers Greg Caporaso, PhD and Evan Bolyen, Northern Arizona University. Remote viewing available. Click title for more info. and Adobe link. Questions? Please contact Shari.Solomon@fda.hhs.gov.

Create Measures and KPIs for Large Sets of Data in Excel. Take Our May 23 Excel 2016 PowerPivot Class at White Oak to Learn More.

A measure is a formula that is created specifically for use in a PivotTable (or PivotChart) that uses PowerPivot data. A Key Performance Indicator (KPI) is designed to help evaluate the current value, status, and trend of a metric. OIMT's Excel 2016 PowerPivot class will teach you how to create measures and KPIs. This \$150 class will be held at White Oak on May 23. For registration instructions (including prerequisite information) and the complete class description, click the link above.

Federal Employees Prescription Drug Take Back Day

FDA will host another Drug Enforcement Administration (DEA) Drug Take-Back Day event for employees on the White Oak Campus. FDA employees in the field can check the National Prescription Drug Take-Back Day website to get additional locations throughout the U.S. This initiative aims to provide a safe, convenient, and responsible means of disposing of prescription drugs, while also educating the public about the potential for abuse of medications. Please bring all expired, unused and unwanted ov ...

Create and Work with Master Shapes and Shape Reports in Visio 2013. Class is May 22 at White Oak.

Don't see the exact shape you need? Create a new one (master shape). OIMT's Visio 2013 Intermediate class will teach you how. We'll also edit master shape properties, add master shapes to a stencil, modify master shape icons, and Use My Shapes & Quick Shapes. After Master Shapes, we'll get into Shape Reports, which are used to catalog what shapes and how many of each are included in a drawing. This \$150 class is May 22 at White Oak. Click above for registration instructions and more info.

Work with Network Diagrams & Calendar View in Project 2013. Take a Class via WebEx on April 18 and 19 to Learn More.

OIMT's \$150 Project 2013 Intermediate class via WebEx April 18 & 19 has modules on Network Diagrams and Calendar View. Working with Network Diagrams: Viewing a Network Diagram, Changing the Network Diagram Layout, Formatting Boxes, & Modifying Box Styles. Working with Calendar View: Viewing the Calendar, Viewing the Task List, Modifying Text Styles, Modifying Bar Styles, Formatting Gridlines, & Changing Calendar View. Click the link above for registration instructions and more class topics.

FDA/OGROP/ORAO/OHAFO/Division West Vacancy Announcement: Consumer Safety Officer (CSO) GS-0696-09

The positions are located in the Food and Drug Administration (FDA), Office of Global Regulatory Operations and Policy (OGROP), Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations (HAF), Division West. Duty station will be determined upon selection.

FDA/OGROP/ORAO/OHAFO/Division West Vacancy Announcement: Consumer Safety Officer (CSO) GS-0696-07

The position serves as a trainee who accompanies senior Consumer Safety Officers in the conduct of more complex inspections and investigations. Positions are located in the Food and Drug Administration (FDA), Office of Global Regulatory Operations and Policy (OGROP), Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations (HAF), Division West. Duty station will be determined upon selection.

Embase-Finding the Right Information for Medical Device Clinical Evaluation and Post-Market Surveillance, Thu, Apr 12, 1:30-2:30 pm EDT

Learn how Embase can be used to assist medical device manufacturers in preparing clinical evaluation reports. Sponsored by the FDA Library.

Reducing the Burden of Chronic Disease.

Remarks. Commissioner Gottlieb at the National Food Policy Conference. GPL.

State Liaison Selection - Seattle District/OHAFO Division 6

Joann Givens and I are pleased to announce the selection of Dawn Barkans and Ian Thomson as state liaisons in Seattle District/OHAFO Division 6 West. We wish to thank all the applicants that applied for the position. Our decision was difficult due to the robust panel of applicants and the quality of the skills, abilities and experiences of the applicants. Dawn Barkans will be responsible for the Human Food contract in Oregon and the Animal Food contracts in Washington and Montana. Dawn bega ...

FDA/OGROP/ORR/OHAFO East/DFHFAFO Vacancy Announcement Supervisory Consumer Safety Officer (Division Director) GS-0696-15

This position serves as Supervisory Consumer Safety Officer (Division Director) in the Food and Drug Administration (FDA), Office of Global Regulatory Operations and Policy (OGROP), Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations (OHAFO) - East, in Rockville, MD.

April 25 OIP International Forum: Regulatory Challenges of Globalization

DIAL-IN April 25 to the Office of Information Programs International Forum where FDA/OIP foreign Office Directors will discuss collaborations and approaches to global engagement. They will talk about the increasingly complex supply chains, combined with increased global production and manufacturing capability, that require FDA to use innovative approaches to resource utilization. Visit the International Forum page for dial-in information.

April 5, 2018 – MCMi Lecture: Orthogonal Diagnostics: Results with Confidence

Join MCMi for a lecture on USAMRIID's development, testing, and evaluation of sustainable immunodiagnostics in the orthogonal system and deployment to austere environments in West Africa as part of the Ebola response. Randal J. Schoepp, Ph.D., Chief of the Immunodiagnostics and Biologics Department at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), will present on April 5, 2018, 1:00 - 2:00 p.m. in White Oak bldg. 32, room 1243 and remote (must register in advance).

Watch OIP's New Video: Living and Working Abroad for FDA

You may have seen FDA's Office of International Programs "Gamechangers" video which described the benefits of working internationally. OIP has now completed a longer video that further illustrates the character of the cities and landscapes where FDA staff work in Europe, China, India and Latin America. Interviews with FDA staff describe the exciting challenges, opportunities and experiences working in FDA's ever-growing overseas workforce! Contact: Carl.Sciacchitano@fda.hhs.gov.

Human Genome Variation in Disease Susceptibility and Health Disparities in Minority Populations- CE Opportunity!

Committee for the Advancement of Clinical and Scientific Education (CACSE): April 18, 2018, 1:30-2:30 PM, WO Bldg 2, Room 2031. This lecture will explore how big data science generated from sequencing the genome also profoundly challenges the validity of prevailing constructs of human populations, which partition humanity into bounded ethnic and/or racial groups.

Find Out the Best Practices for Making Files Accessible to Users with Disabilities. Our Class at White Oak on April 18 Will Explain...

Take OIMT's \$150 Taking the Mystique Out of 508 Class on April 18. We will talk about best practices and provide instructions for making your files accessible according to the standards of Section 508 of the Rehabilitation Act. Registration instructions and a complete course description can be found by clicking the link above.

Romania. Hungary. Greece. Czech Republic.

Four more in the MRA.

FY19 Office of Chief Scientist's Intramural Grant Programs

Office of the Chief Scientist is proud to announce the 1-page quad charts are being accepted for the following FY19 OCS Intramural Grant programs-Chief Scientist's Challenge Grants, Nanotechnology(CORES)Grants, MCMi Challenge Grants, Office of Minority Health(OMH) Intramural Research Program and Office of Women's Health (OWH) Intramural Scientific Research Funding. Pre-submission with the quad is required for all programs. Pre-submissions are accepted from 04/02/2018 to 05/14/2018 via the link.

New York Medical College 50% Tuition Discount

New York Medical College School of Health Sciences and Practice is currently offering 50% tuition discount for its online Master of Public Health (MPH) programs to all HHS employees and U.S Public Health Service Commissioned Corps officers. Courses available are Masters of Public Health with concentration in Environmental Health Science, Health Policy and Management, Epidemiology, Behavioral Science and Health Promotions. Certificates in Global Health, Emergency Preparedness, Industrial Hygiene ...

Employee News

Wanted: Children's Books

The FDA Library is now accepting book donations for the book giveaway on April 26 during Bring Your Child Back to Work Day. We are accepting donations of new or gently used children's and young adult books, appropriate for ages 1-17. If you are located at White Oak, please bring books to the Library information desk in WO Building 2, 3rd floor, between 9:00 am-4:00pm. You can also mail them to us at: FDA Library, White Oak Building 2, Room 3303, 10903 New Hampshire Avenue, Silver Spring MD 2 ...

Yoga Session - Great Room (1503 B) on Friday, April 13th 12:30-1:30pm

April is Stress Awareness Month and the White Oak Fitness Center will be hosting a campus wide Yoga class on Friday, April 13th, 12:30-1:30pm in the Great Room (1503 B) of Building 31. All are welcome to attend. Some Yoga mats will be available, but please bring your own mat (or towel) if you have one. Register in advance by emailing whiteoakfitnesscenter@fda.hhs.gov with the subject line "Yoga for Stress Relief". This program is sponsored by Work Life Programs Branch - Dwayne Parris, Direct ...

White Oak Evening Toastmasters 2nd and 4th Tuesdays, 5:00 pm

Do you want to improve your public speaking skills? Come to Toastmasters. Our next meeting is Tuesday April 10th 5:00 pm in Building 51 room 1219. If you are interested, just show up. Visitors are welcome. If you would like more information, e-mail or call Hussein Ezzeldin Hussein.ezzeldin@fda.hhs.gov 240-402-8629.

OHR/Retirement & Benefits-Financial Planning Seminars

Please join the OHR/ESSD/Retirement and Benefits Branch, on April 27, 2018. We will be at White Oak, Bldg. 31, and RM 1503 A, from 09:30 a.m. to 2:30 p.m. Come out and learn about the following topics: Advantages of Home Ownership, The Real Estate Market in the DMV, and steps to set your Financial Priorities and Estate Planning. See the attached flier.

Parklawn Sailing Association Open Boat Event

The Parklawn Sailing Association (PSA) is hosting an Open Boat Event on Sunday, 4/22 (RAIN DATE 4/29), 11am-4pm at the West River Yacht Harbour in Galesville, MD. PSA, one of the finest sailing clubs on the Bay, is recruiting new members. Join us to meet members, tour our three 30-34 foot sailboats, and go for a sail! You can crew or skipper during our Club sails for as little as \$35 per person per day. RSVP to info@parklawnsailingassociation.org. PSA is the best sailing value on the Bay!

FOH/EAP Seminar – Relationships (New)

Please join us for the EAP Seminar on Tuesday, April 3, 2018, from 12:30PM-1:30PM, in Building 2, Room 2033, on the topic of "Relationships", which is a "new" presentation. This seminar reviews the qualities of both a healthy and unhealthy relationship and discusses the importance of both communication and boundaries in forging a healthy relationship. Please click on the url below to register. This program is brought to you by OHR| Human Capital Solutions, Work Life Programs Branch.

White Oak Evening Toastmasters 2nd and 4th Tuesdays, 5:00 pm

Do you want to improve your public speaking skills? Come to Toastmasters. Our next meeting is Tuesday April 10th 5:00 pm in Building 51 room 1219. If you are interested, just show up. Visitors are welcome. If you would like more information, e-mail or call Hussein Ezzeldin Hussein.ezzeldin@fda.hhs.gov 240-402-8629.

Commuter News

Warrenton Road Fredericksburg VA Commuter Lot / Route 17 Commuter Lot, 627 Warrenton Rd to White Oak Campus Vanpool

Riders needed to form a new vanpool from the commuter lot at 627 Warrenton Road, Fredericksburg VA. Working hours TBD. Proposed departure from the commuter lot time is 5:30/5:45/6:00 a.m. This will be a direct, non-stop ride. If you are interested in joining the vanpool, please contact: (b)(6)
(b)(6) Transshare benefits will cover all costs including gas and tolls.

Germantown Existing Vanpool Looking for a Few Additional Members!!

Clean, comfortable, spacious, and easy to drive 15-passenger van departs the Milestone Park & Ride (behind Target/Aldi) at 6:30 am to the White Oak Campus (Bldgs 1, 75, and 66). Work hours: 7 am 3:30 pm). We depart the Campus at 3:30 pm. Non-stop and no out of pocket expense when using your Transshare benefits. Please contact (b)(6) for more info and/or free test ride. Hurry!! Only a few remaining seats available.

Sterling, Leesburg, Ashburn, and Chantilly, VA, vanpool is now running

One seat is available at this time at no out of pocket cost. The starting point is Target next to Wegman's (45131 Columbia Place), Ashburn/Sterling at 6:00am and leaving the FDA at 3:15pm (working hours 6:45am to 3:15pm). This is a direct ride, non-stop (40-50 minutes each way), from Sterling to the FDA. If you are interested, please contact (b)(6)

New Eastern Baltimore County/City Vanpool Forming

Looking for riders/drivers for a new vanpool starting from the Dundalk Home Depot parking lot (6315 Eastern Ave). to the White Oak Campus. Depart in a Dodge Caravan at 5:45 AM with work hours of 6:30 AM to 3:00 PM. Transshare benefits will cover all costs. If you are interested, please contact (b)(6)
(b)(6)

Bike to Work Day, Friday May 18, 2018 Registration now available

On Friday, May 18, 2018 Commuter Connections and the Washington Area Bicyclist Association invite you to celebrate bicycling as a clean, fun, and healthy way to get to work. Be one of the first 20,000 to register and attend this FREE EVENT, then bike to your choice of more than 100 pit stops in D.C., MD, and VA and receive a free T-shirt, refreshments, and be entered into a raffle for a new bicycle.

Riders needed for a Woodbridge Vanpool

Existing Woodbridge Vanpool needs riders for the commute from Telegraph Rd. commuter parking lot, Woodbridge, VA to FDA White Oak. Van leaves at 7:00 AM and arrives FDA White Oak at 8:00 AM. The reverse trip is at 4:30 PM and arrives in Woodbridge at 6:00 PM. If interested, contact (b)(6)
(b)(6)

Germantown vanpool is recruiting

Work hours are from 9am to 5:30 pm. We gather at Kingsview Park & Ride in Germantown. Van leaves Germantown on 8:10 in the morning and WO on 5:30 in the afternoon. Van parks right in front of Building 75. Contact (b)(6) if you are interested.

Glenwood, Glenelg, West Friendship, Woodbine to White Oak, MD Vanpool has Vacancies:

Glenwood Vanpool #2 is looking for additional riders to join our vanpool which operates on a work schedule of 7:00am to 3:30 pm. Pickup location is at 6:15 AM at Gethsemane Baptist Church, 14135 Burntwoods Road, Glenwood, conveniently located off of RT 32. We have an easy-to-drive comfortable mini-van. If you are interested or need additional information, contact (b)(6)

Three seats to fill for New Vanpool starting from Alexandria VA Landmark Mall/BJ's

The starting point is the BJ's Shopping Center, south west of South Van Dorn Street and Duke Street. From S. Van Dorn Street to I-495/95 either East toward National Harbor/MGM or West toward Tyson Corner all the way to New Hampshire Ave, and to FDA White Oak. We will depart from BJ's at 6:30 AM and leave FDA at 4:30 pm (working hours TBD 7:30/8:00 am to 4:00/4:30pm). As proposed this is a direct ride, non-stop (50-75 minutes each way, depending on the traffic). The maximum monthly subsidy is now ...

Kingstowne, VA to White Oak Vanpool is Looking for Additional Riders Who Are Willing and Eligible to Drive on a Rotating Basis

The vanpool from Kingstowne to White Oak has openings. Departure daily at 6:20 am from 6400 block of Lake Village Drive (intersection of Lake Village Drive and Grange Lane), Kingstowne, VA 22315. Work hours are 7:00 AM-3:30 PM. To test-ride or join, please contact (b)(6)

(b)(6)

Bethesda (Montgomery Mall Park and Ride) to WO vanpool

We are looking for one rider/driver for our vanpool starting from the Montgomery Mall Park and Ride in Bethesda, MD. The van will leave at 7:20 am. Working hours are 7:50 am to 4:20 pm. If you have an interest in participating in the vanpool, please contact (b)(6)

Sykesville/W. Friendship Vanpool has openings for Drivers/Riders

No out-of-pocket costs! We have WI-FI! Van leaves Sykesville Park & Ride off MD32 at 6:10 AM and stops at Park & Ride near I-70 exit 80 around 6:20 AM. Campus work hours are 7:00 - 3:30. Please contact (b)(6)

(b)(6)

for more information. Take a free trial ride.

Mount Airy/Damascus/ Clarksburg/Monrovia area vanpool seeking new riders

There are openings in a well-established vanpool on a stress-free commute route with beautiful sceneries. Wi-Fi access included. Departure daily at 7:00 am from the Damascus shopping center (we are willing to change the time slightly if necessary). WO campus work hours are 8:00 AM-4:30 PM. No out-of-pocket expenses. If you are interested or want to have a free ride, please contact (b)(6)

Urbana vanpool has vacancies for Drivers

This vanpool group meets at the ExxonMobil/Urbana Park and Ride lot (8816 Fingerboard Rd, Frederick, MD 21704). We depart at 7:00 AM sharp. Work hours are 8:30 – 5pm. We are averaging 50-60 minutes commuting time. If you are interested, and have a good driving record or have any questions, please contact (b)(6)

(b)(6)

Take a free trial ride!

Vanpool Vacancy from Herndon, Virginia to White Oak

Seeking a new member to join a Herndon vanpool. The van leaves from Herndon-Monroe Park & Ride near Dulles Toll Road at 6:15 AM and arrives at White Oak campus by 7:00 AM. Proposed work hours are 7:00 AM – 3:30 PM. Please contact (b)(6) for more information.

Existing vanpool covering McLean, VA looking for additional members

Looking for drivers/riders in the McLean, VA area. The starting point will be at Giant in McLean Shopping Center, 1454 Chain Bridge Road, McLean, VA 22101. We will depart at 7:30 am and leave FDA at 4:30 pm (working hours 8:00am to 4:30pm). This is a direct ride, non-stop (about 30-50 minutes each way, depending on the traffic). The van can accommodate 7 passengers. There are no out-of-pocket costs. If you are interested or need further information, please contact (b)(6)

New vanpool is forming from Clarksburg Cabin Branch area, Clarksburg, MD to White Oak campus

We will start from Broadway Ave at 7:00 AM (close to Cabin Branch community swimming pool). We will leave WO at 4:20 PM. The working hours will be 7:45 to 4:15 PM. Van starting location and times are tentative at this point as it is a new vanpool. Van belongs to the capital vanpool company which allows you to switch between the 5 other capital vanpools already running from the nearby vicinity (Clarksburg town center, Harris Teeter and Bennigan's), if needed. If interested, please contact (b)(6)

New Vanpool starting in the Bowie area

The starting point is at the Fairwood Safeway/Gold's gym (corner of Rt. 450 and Fairwood parkway) and leaving at 8 AM and leaving the FDA at 4:30 pm (working hours TBD 7:30 to 4 PM, 8:30 AM to 4:30 PM or 9 AM to 5 PM). As proposed this is a direct ride, non-stop (35-50 minutes each way, depending on the traffic), from the Bowie Crossing Park and Ride to the FDA White Oak Campus. The maximum monthly subsidy is now \$255.00. Based on the recently attained estimates for a 2016 van there would be no ...

A new Vanpool is forming as the third van from Walmart at North Ridge Road, Ellicott City, MD to White Oak campus

The new vanpool will start from Walmart at 7:15 am (the other vans start at 7:00 am and 7:15 am), and leaving FDA at 4:15 pm. Working hours are 7:45 am to 4:15 pm. This is a direct ride, non-stop. If you are interested in participating in the vanpool, please contact (b)(6) There is no out-of-pocket money.

New vanpool from Northern New Jersey to White Oak campus

We are looking for riders/drivers for a new vanpool starting from Northern New Jersey area to White Oak Campus (with potential pickups/drop-offs in NJ and PA). The van will be departing on Sunday (3:30 pm) from Northern New Jersey area and leaving FDA on Tuesday (Week 1) and Wednesday (Week 2) at 3:30pm. Transhare benefits will cover all costs. If you are interested, please contact (b)(6)

(b)(6)

Olney Vanpool (Georgia Avenue Bus Parking Lot) Space Available

A vanpool which meets at the Georgia Ave., bus parking lot at 7:30 a.m. is looking for a driver/rider. This vanpool is suitable for those working in White Oak campus from 8:00 a.m. to 4:30 p.m. We have a very easy-to-drive mini-van and take the 200 IC route for a fast commute to and from work. If you are interested or need further information, please contact (b)(6)

Riders needed for the Waldorf, MD. Vanpool to White Oak

Existing Waldorf Vanpool needs riders for the commute from the Park & Ride at U.S. 301 and Smallwood Drive, Waldorf, MD 20602 to FDA White Oak. Van leaves at 5:45 AM and arrives to FDA White Oak by 7 00 AM. The reverse trip is at 3:30 PM and arrives in Waldorf around 4:45 PM. Alternate work hours are being explored, therefore, if interested, contact (b)(6)

New vanpool from Westfield, NJ to White Oak campus

We are looking for riders/drivers for a new vanpool starting from Westfield Train Station, New Jersey (NJ) to White Oak Campus. The van will be departing on Sunday (3:30 pm) from the Westfield Train Station and leaving FDA on Thursday/Friday at 3:30pm. This is a direct ride, non-stop. Transhare benefits will cover all costs. If you are interested, please contact (b)(6)

(b)(6)

New Vanpool Forming - River Road/Potomac Village to White Oak

Looking to start a new vanpool from Potomac Village/River Road to White Oak. We need 2 more people to get started!!! The van will start at 7AM from River Road and leave the FDA at 4PM. Working hours will be

7:30AM-4:00PM. If you are interested, please contact (b)(6)
(b)(6)

A new Vanpool is forming from Montjoy Place, Ellicott city, MD (near The Elms At Montjoy Apts and Orchard crossing townhomes) to White Oak

The new vanpool will start from Montjoy Place, Ellicott city, MD at 7:00 am (or 7:15 am) and leaving FDA at 4:00 pm (or 4:15 pm). Working hours are 7:30 am (or 7:45 am) to 4:00 pm (or 4:15 pm). This is a direct ride, non-stop. If you are interest in participating in the vanpool, please contact (b)(6)

(b)(6) There is no out-of-pocket money.

A new Vanpool is forming from Centennial Overlook, Old Annapolis Rd, Ellicott City, MD to White Oak campus

The new vanpool will start from Centennial Overlook at 8:10 am and leaving FDA at 5:15 pm. Working hours are 8:40 am to 5:10 pm. This is a direct ride, non-stop. If you are interested in participating in the vanpool, please contact (b)(6) There will be no out of pocket expenses.

Existing vanpool from Bethesda (Montgomery mall) to White Oak has opening for driver

We are looking to add one more driver to our vanpool. We start at the Park & Ride in Montgomery mall at 7:30 am and we leave WO at 4:30 pm. If interested, please contact (b)(6)

(b)(6)

Bethesda (Ashburton Elementary School) to WO vanpool forming

We are looking for riders/drivers for our vanpool starting from North Bethesda United Methodist Church (10100 Old Georgetown Rd, Bethesda, 20814), which is close to Ashburton Elementary School in North Bethesda, MD. The group will leave at 8:30 am. Working hours are 9:00 am to 5:30 pm. If you have an interest in participating in the vanpool, please contact (b)(6) We already have 4 people and we are looking one more person to start the vanpool. There is no out-of-pocket cost. ...

Fulton (Maple Lawn Blvd) to White Oak Vanpool

We have one open seat in the Fulton/Scaggsville vanpool second van. The van departs from Maple Lawn Blvd/Market St in Fulton at 8:00 am. The campus hours are 8:00 – 5:00. If you are interested, please contact

(b)(6) You are welcome to try vanpooling for a few days without obligation to join.

Vanpool from Crabbs Branch Plaza, Rockville to White Oak is looking for riders.

Our van departs from the Crabs Branch Plaza, Rockville, MD 20855 at 8:05 AM sharp, and returns from White Oak campus (in front of Building #75) at 5:00 PM. . The van can accommodate 11 passengers. This is a non-stop direct ride. No out-of-pocket costs. Transhare benefits will cover all costs. If you are interested or want to have a free trial ride, please contact (b)(6) for more information.

South Riding, VA vanpool looking for additional rider:

Existing vanpool has 1 vacancy. Departure point is East Gate Park and Ride South Riding, VA off Tall Cedars Parkway, leaving at 6:00 AM arriving to FDA by 7 AM, leaving at 3:30 PM from White Oak. Working hours are 7:00 AM to 3:30 PM. Direct ride, no stops. No Out-of-Pocket Costs and we have Wi-Fi. If interested please contact (b)(6)

Electric/Plug-In Vehicle Commuter Group

Do you commute to White Oak in an electric or plug-in vehicle, or are thinking about buying one soon? Join the White Oak Electric Vehicle Commuter Group to find out more about charging at White Oak! ***Click on "Request Access"

Existing Gaithersburg (Kentlands / Lakelands) to White Oak Vanpool Has Space for a New Member
Kentlands / Lakelands Vanpool in Gaithersburg, MD has space for a new member to join immediately. Work hours are from 8:00 am to 4:30 pm. The van leaves from the Kentlands Post Office parking lot at 7:20 am. This vanpool is an SUV that seats 7. If interested, please contact (b)(6)

Seats available in greater Towson area vanpool

Seats are available in greater Towson area vanpool. We are looking for drivers (preferred)/riders. Office hours are 7am-3:30pm. No out of pocket cost. We meet at Kenilworth Shopping Mall (near 25th exit off I-695). For test rides and additional information, please contact vanpool coordinator at (b)(6)

New vanpool is forming from Clarksburg, MD to White Oak Campus

We will start from Clarksburg (Right across Harris Teeter in Clarksburg Village) at 8:00 am and leave WO at 5:30 pm. The working hours will be 9:00 am to 5:30 pm. This is a direct ride, non-stop (around 45 minutes each way). If interested, please contact (b)(6)

Existing Severn to White Oak Vanpool with two openings

We have two seats available in our established Severn Vanpool. Our ride and hours make the commute easy! We leave from Telegraph Rd and Rt 32 at 6:10am. WO campus hours are 6:45a to 3:30p. If you are interested or want to take a test ride, please contact (b)(6)

Existing Clinton Vanpool looking for additional riders

The Clinton vanpool is currently seeking additional riders, our work hours are 7:00am – 3:30pm. Clinton vanpool leaves from Stuart Lane/Woodyard Road Park & Ride. The van leaves Clinton promptly at 6:10am to arrive to White Oak for 7:00am work day. We depart WO at 3:20pm promptly. Clinton Coordinator is (b)(6)

This existing vanpool from Ellicott City to White Oak has few openings

This existing vanpool from Ellicott City to White Oak departs daily at 7 AM from Long Gate Park & Ride, Ellicott City, MD. WO campus working hours are 7:30 AM-4:00 PM. There is no out-of-pocket money. If interested, please contact (b)(6)

Existing Bel Air, MD to White Oak Vanpool has space for a new member to join immediately

Save money on gas, tolls and preserve your energy and join the Bel Air Vanpool now! We are looking for riders to join our vanpool leaving from the Bel Air area, Abingdon Park & Ride, Route 24 and Edgewood Rd, to the White Oak campus. The vanpool departs the Abingdon P&R at 6:20am and leaves FDA at 4:00pm. Work hours are 7:30 - 4:00 PM. Enjoy the benefits of vanpooling. Please contact (b)(6) for more information.

Existing Germantown 8:00 am vanpool seeks additional riders/drivers:

The starting point is the Kingsview Park & Ride, Germantown (southwest corner of Clopper Rd/Kingsview Village Ave). The van leaves the Park & Ride at 8:00 am and leaves the FDA (Bldg 51) at 5:15 pm for working hours 8:45 am to 5:15 pm. This is a non-stop direct ride with No out-of-pocket costs. Almost every 15 minutes from 5:30 am to 8:40 am there is a van leaving for the FDA campus from there, providing with great flexibility to all riders. If interested, contact (b)(6)

Germantown (Kingsview, Park & Ride) Vanpool Forming

Looking for riders/drivers for our van starting from Germantown (Kingsview Park & Ride). The group will meet at 9:10 am. Working hours are 9:45 am to 6:05 pm. If you have an interest in participating in the vanpool, please contact (b)(6) It's a direct non-stop ride. There is no out-of-pocket cost.

Columbia to White Oak Vanpool looking for New Riders!!

Looking for a stress-free and economical way to get to work? The Columbia vanpool is looking for new members. Van departs Broken Land Park & Ride at 6:30 AM. Work hours are 7 - 3:30. All vanpool members are guaranteed a ride home in case of an emergency. Leave your personal vehicle at the park & ride. Save miles and gas money! Please contact (b)(6) for more information.

New vanpool covering Rockville, MD is forming now

The starting point is the Guitar Center (or Target) in Rockville at 8 am and leaving the FDA (southwest parking garage) at 5pm (working hours 8:30 am to 5 pm). If you are interested, please contact (b)(6)

Existing Germantown (Milestone) to White Oak vanpool has 1 spaces for new members

Existing Germantown (Milestone) to White Oak vanpool has 1 spaces for new members. Work hours are from 7:15 am to 3:45 pm. We leave the Milestone Park and Ride (from behind Aldi store) at 6:30 am and leave White Oak at 4:00 pm. If you have questions or want to schedule a free trial, please contact (b)(6)

New Vanpool in Clarksburg/MD

Looking for drivers/riders in the Clarksburg area near the outlets. Working hours will be 7 a.m. to 3:30 p.m. If you are interested, please contact (b)(6)

New Vanpool Forming – Ellicott City, MD to White Oak

Looking for riders/drivers for a new vanpool starting from Long Gate Park and Ride (Meadowbrook Lane) to White Oak Campus. Van will be departing at 6:20am and leaving FDA at 3:30pm (working hours are 7:00am – 3:30pm). This is a direct ride, non-stop. Transhare benefits will cover all costs. If you are interested, please contact (b)(6)

New Oxon Hill to White Oak Vanpool Forming (Only 1 more needed)

Looking for riders/drivers for a new vanpool starting from Oxon Hill (at Tanger Outlet National Harbor Shopping-mall and Rt. 414), Maryland going to White Oak Campus, Silver Spring, MD. The group will meet at 6:00am departing from Oxon Hill Rd at 6:15am. Working hours for the vanpool will be 7:00am -3:30pm. If you have an interest in participating in the vanpool, please contact (b)(6) There is no out-of-pocket cost.

New Vanpool starting in Burke/Springfield/Annandale/Fairfax!

The starting point is on Wakefield Park Rd. (8100 Braddock Rd, Annandale, VA 22003). We will depart at 6:15 am and leave the FDA at 3:30 pm (working hours 7:00 am to 3:30pm, may be flexible up to 30mins later if requested by members). If you are interested, please contact (b)(6)

A New Columbia to White Oak Vanpool is Looking for Riders

We are starting a new vanpool aiming to improve the quality of life for all Columbia vanpool riders. Van will depart Broken Land Park & Ride at 7:15 AM and leave White Oak Campus at 4:15 PM, thus adding another option to the existing 6:30 and 7:00 AM vanpools from the same location. There are no drawbacks: you are guaranteed a ride home in case of an emergency, you will save money, make new friends and feel good about your choices. If you would like to join, please contact (b)(6)

Gaithersburg to White Oak Vanpool Is Looking for Riders

Our 12-seat van leaves at 8:05 am at the end of Industrial Drive off Gaither Road in Gaithersburg, and return from White Oak north surface vanpool lot (in front of Bldg. 21/22) at 5:15 pm. To arrange a free trial ride or have any question, please contact (b)(6)

Germantown Vanpool is Looking for New Members

The starting point is the Kingsview Park and Ride (Germantown) at 6.00 am and leaving the FDA at 3:05pm (working hours 6.30 am to 3:00 pm). This is a direct ride, non-stop (30-35 minutes each way, depending on the traffic), from the Kingsview Park and Ride to the FDA (Building 75 surface parking lot). If you are interested, please contact (b)(6)

(b)(6)

Gaithersburg, MD (Giant food store @ Muddy Branch Rd) to White Oak Vanpool

New vanpool starting from Giant food store @842 Muddy Branch Rd at 8:00 AM to White Oak campus and leaving FDA at 5:00 PM (working hours are 8:30 AM – 5:00 PM). We will need 2 more rider/driver to join us. If you are interested, please contact (b)(6)

Leesburg/Ashburn, VA to White Oak Vanpool is operating and seeks additional riders

Vanpool from Target 45130 Columbia Pl in Sterling, VA to White Oak seeks additional riders. All charges covered by GoCard, no out of pocket expense. Take a free test ride before signing up. Office hours are 7:00am-3:30pm. Please contact vanpool coordinator at (b)(6)

Welcome to the easiest ride from Bowie MD to FDA

Bowie Vanpool Existing vanpool has 1 vacancy. Departure point is Bowie Crossing Park & Ride which is located at the intersection of 197 and Northview. It sits next door to the Regal Theater and we are a 2 minute drive off of Route 50. We meet at 5:45 am and Depart at 5:50 am arriving at FDA by 6:30 AM, leaving at 3:00 PM from White Oak. Working hours are 6:30 AM to 3:00 PM. Direct ride, no stops. No Out-of-Pocket Costs. If interested please contact (b)(6)

The vanpool starting in Kingsview Park & Ride, Germantown is recruiting riders

The starting point is the Kingsview Park & Ride, Germantown (The crossing of Clopper Rd and Germantown Rd, Germantown, MD 20874). We meet at 7:10 am and leaving the FDA at approximately 4:20 pm (working hours 7:50 am to 4:20 pm). This is a direct ride, non-stop (35-50 minutes each way, depending on the traffic), from the Kingsview Park & Ride, Germantown to the FDA White Oak Campus (Building 75). There is no out of pocket expenses with enough ridership on the van. If you are in the Germantown area ...

Need 1 more driver to a current vanpool covering the Fairfax, VA area

The starting point is the Fairfax, VA 22031 area. The vanpool departs at 7:00 am and leaves the FDA at 4:15 pm (working hours 7:45 am to 4:15 pm). This is a direct ride, non-stop (around 45 minutes each way, depending on the traffic), from the Fairfax area to the FDA White Oak Campus. No out-of-pocket costs. Transhare benefits will cover all costs. If you are interested or need further information please email: (b)(6)

Existing Fairfax County/Centreville/Chantilly, VA (Stringfellow Park and Ride) to White Oak Campus Vanpool

Existing vanpool has space for one more rider/driver from the Park and Ride at 4920 Stringfellow Road, Centreville, VA, near the intersection of Stringfellow Rd. & Fair Lakes Pkwy., with plenty of parking spaces. Working hours 7am-3:30pm. Departure to WOC is 6:15 am, leaving FDA at 3:30 pm, respectively. A direct, non-stop ride in a Toyota Sienna. If you are interested in joining the vanpool as a rider and driver, please contact (b)(6) No out o ...

E-ZPass Maryland on Campus, Tuesday, 3 April

Get there faster with E-ZPass and the Intercounty Connector (ICC)/MD200. Since there are no toll booths, having an E-ZPass is the most convenient way to use the ICC. Video Tolling is an alternative to E-ZPass, but is not recommended for frequent travelers. E-ZPass Maryland team members will be on campus, set-up next to the elevators across from the WO32 Cafeteria from 11 a.m. – 1:30 p.m. to answer questions and sell E-ZPass “On the Go” transponders. If you have any questions, please feel free ...

Vanpool from Herndon, VA to White Oak still has seats available for a new member

Our van departs from the Herndon-Monroe park and ride. We leave the “park and ride” at 6:15 am and return from FDA at 3:30 pm. We have a Toyota/Sienna van that can accommodate 6-7 passengers. If you are interested, please contact (b)(6) for more information.

Vacancy/Detail Announcements

FDA/ORA/OMPTO/OBPO SCSO (BIOLOGICAL PRODUCTS INSPECTION STAFF/STAFF DIRECTOR)

GS-0696-14 Vacancy Announcement

Please see announcement for details.

OGROP/ORA/OMPTO/OPQO/DPQOIV Vacancy Announcement: SCSO (DIB), GS-0696-14, multiple locations.

Supervisory Consumer Safety Officer Director of Investigations GS-0696-14, Division of Pharmaceutical Quality Operations IV. Vacancy has been posted on USAJOBS (FDA-ORA-18-MP- 10167755). Open on 04/02/2018 and closes on 04/13/2018. If searching for this vacancy directly from USAJOBS, enter the announcement number in the “Keyword” box and refine the search by selecting the “Federal Employees” radio button to view this announcement.

OGROP/ORA/OMPTO/OBIMO Vacancy Announcement: CSO, GS-0696-11, multiple locations

Consumer Safety Officer GS-0696-11, Office of Bioresearch Monitoring Operations (OBIMO) Vacancy has been posted on USAJOBS (FDA-ORA-18-DE-10170675). Open on 03/29/2018 and closes on 04/04/2018. If searching for this vacancy directly from USAJOBS, enter the announcement number in the “Keyword” box.

OGROP/ORA/OMPTO/OBIMO Vacancy Announcement: CSO, GS-0696-07/09, multiple locations

Consumer Safety Officer GS-0696-07/09, Office of Bioresearch Monitoring Operations (OBIMO) Vacancy has been posted on USAJOBS (FDA-ORA-18-DE-10168410). Open on 03/29/2018 and closes on 04/04/2018. If searching for this vacancy directly from USAJOBS, enter the announcement number in the “Keyword” box.

CDER/OPQ/SRS - Notice of Reassignment

A decision has been made to fill one position of Chemist Engineer, GS-0893-13, in the Office of Pharmaceutical Quality, Science Research Staff, Silver Spring MD 20903 via reassignment. This notice is being issued in accordance with Article 35 of the FDA/NTEU Collective Bargaining Agreement.

Vacancy Announcement: FDA-CDER-MP-18-10142148

Supervisory Computer Scientist GS-1550-15 **Vacancy Announcement** CDER/OTS/OCS - (MP)
Supervisory Computer Scientist

Vacancy Announcement: FDA-CDER-DE-18-10142147

Supervisory Computer Scientist GS-1550-15 **Vacancy Announcement** CDER/OTS/OCS - (DE)
Supervisory Computer Scientist

CTP Vacancy Announcement: Lead Chemist GS-1320-14, (MP)

This position is located in the Department of Health and Human Services, Center for Tobacco Products, Office of Science, located in Silver Spring, Maryland. The Office of Science (OS) will permanently relocate to Beltsville, Maryland; tentatively scheduled for spring 2018.

CDER-wide Temporary Promotion Opportunity for a Project Specialist, GS-0301- 09/11: Program Management and Analysis Staff (PMAS) in the Office of New Drugs (OND), Immediate Office (IO)

Please see the attachment for more information on this great opportunity and for information on how to apply.

OHR/ESSD Detail Opportunity Program Analyst (Information Systems) GS 11/12

Candidates should send the following to Matthew Swanson, Matthew.Swanson@fda.hhs.gov, by Friday, April 13th at 5:00pm ET. 1. Resume 2. Letter of interest / cover letter 3. References (2-3 are fine)

CBER VACANCY ANNOUNCEMENT – CONSUMER SAFETY OFFICER, GS-696-13

This position is located in the Center for Biologics Evaluation and Research (CBER), Office of Compliance Biologics and Quality (OCBQ), Division of Case Management (DCM), Advertising & Promotional Labeling Branch (APLB), located in Silver Spring, MD.

CTP Detail Opportunity: Health Communications Specialist GS-1001-13, (Reimbursable Detail)

The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is offering a Detail opportunity for a Health Communications Specialist GS-1001-13. Current FDA employees at the GS-12 and GS-13 levels are encouraged to apply. The Detail is available immediately for a period of 90 days. PHS Commissioned Corps Officers may apply. A temporary promotion may be considered.

OGROP/ORO/OMPTO/OBIMO Vacancy Announcement: CSO, GS-0696-11/12, multiple locations

Consumer Safety Officer GS-0696-11/12, Office of Bioresearch Monitoring Operations (OBIMO) Vacancy has been posted on USAJOBS (FDA-ORA-18-MP-10165988). Open on 04/02/2018 and closes on 04/13/2018. If searching for this vacancy directly from USAJOBS, enter the announcement number in the “Keyword” box and refine the search by selecting the “Federal Employees” radio button to view this announcement.

Temporary Promotion/Detail - Supervisory Workforce Resource Specialist

CBER is offering a detail/temporary promotion opportunity NTE 120 days.

CBER Detail NTE 90 Days - Physician (Team Lead) - GP-0602-15

This position is located in the Oncology Branch, Division of Clinical Evaluation and Pharmacology/Toxicology, Office of Tissues and Advanced Therapies, CBER. This is a non-bargaining unit position. See attached.

CFSAN-18-1-OCORE-PS - Temporary Promotion - Supervisory Interdisciplinary Scientist, GS-0401, 0403, 0415, 1320-14

This position is located in the Food and Drug Administration, Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition, Office of Coordinated Outbreak Response and Evaluation Network (OCORE), Prevention Staff located in College Park, Maryland.

FDA/ORA/OMPTO/OMDRHO CONSUMER SAFETY OFFICER GS-0696-7/9 DE Vacancy Announcement

Please see announcement for details.

CBER Vacancy: Director, Office of Blood Research and Review (OBRR)

The Center for Biologics Evaluation and Research (CBER) is seeking qualified candidates to serve as the Director, Office of Blood Research and Review (OBRR). The Director, OBRR is responsible for the planning, development, and administration of the Office's broad national programs and operational activities, providing leadership and technical direction in the execution of programs and the day-to-day management of OBRR activities. Please follow the link for more information and to apply.

Pathways Vacancy Announcement for GS-0499, 0699, 1399

The FDA Pathways Team has prepared a scientific vacancy announcement that will open, Monday, April 2, 2018. Appointment is based on continued need/funds for the position and the student's continued compliance in the Pathways Internship Program. This is a developmental program while interns complete their education. After successful completion of the Program, interns may be non-competitively converted to a term (not-to-exceed one to four years) or permanent appointment in the competitive service.

CDER/OPQ/OPPQ/EPMS - Notice of Reassignment

A decision has been made to fill one position of Technical Writer-Editor, GS-1083-13, in the Office of Pharmaceutical Quality, Office of Policy for Pharmaceutical Quality, Editorial and Project Management Staff, Silver Spring MD 20903 via reassignment. This notice is being issued in accordance with Article 35 of the FDA/NTEU Collective Bargaining Agreement.

CDER/OPQ/OPPQ/DIPAP - Notice of Reassignment

A decision has been made to fill one position of Chemical Engineer, GS-0893-14, in the Office of Pharmaceutical Quality, Office of Policy for Pharmaceutical Quality, Division of Internal Policies and Program, Silver Spring MD 20903 via reassignment. This notice is being issued in accordance with Article 35 of the FDA/NTEU Collective Bargaining Agreement.

ORA/Office of Human and Animal Foods East Division 2 (OHAFO E2) Vacancy Announcement: DIB, GS-0696-14, Baltimore, MD, Philadelphia District Office, or New Jersey District Office

This position is located in the Department of Health and Human Services (HHS), Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Human and Animal Foods East II Division (OHAFOE2). Please see link for more information.

ORA/OMPTO Vacancy Announcement - OBIMO/OPQO/OBPO/OMDRHO Supervisory Consumer Safety Officer GS-0696-14

This position is in the Office of Regulatory Affairs (ORA)/ Office of Medical Products and Tobacco Operations (OMPTO) / Office of Bioresearch Monitoring Operations (OBIMO) / Office of Pharmaceutical Quality Operations (OPQO) / Office of Biological Products Operations (OBPO) and Office of Medical Devices and Radiological Health (OMDRHO). For more details on how to apply, please see attachment.

Voluntary Reassignment Notice, CDER/OND/ODEII/DPARP, Supervisory Physician GP-0602-15 (Supervisory Associate Director for Rheumatology)

The Center for Drug Evaluation and Research, Office of New Drugs, Office of Drug Evaluation II, Division of Pulmonary, Allergy, and Rheumatology Products is offering a voluntary reassignment opportunity for a Supervisory Physician, GP-0602-15 (Supervisory Associate Director for Rheumatology). The reassignment opportunity is open to all current FDA employees. No promotions will be offered through this notice. This is a non-bargaining unit position.

CBER Detail NTE 120 Days - Biologist, GS-401-13 (Reimbursable)

This position is located in the Product Review Branch, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review. This is a bargaining unit position. Please see attached.

CTP Detail Opportunity: Supervisory Consumer Safety Officer GS-0696-15 or Supervisory Regulatory Counsel GS-301-15, (Reimbursable Detail)

The Center for Tobacco Products is offering a detail opportunity for a position as Supervisory Consumer Safety Officer GS-0696-15 or Supervisory Regulatory Counsel GS-301-15. The Detail is available immediately for a period up to 90 days.

Consumer Safety Officer, GS-696-14-Merit Promotion Vacancy

This position is located in the Center for Biologics Evaluation and Research (CBER), Office of Products and Tobacco (OMPT), Office of Vaccines Research and Review (OVRR), Division of Bacterial Parasitic & Allergenic Products in Silver Spring, Maryland.

CDRH, Office of the Center Director Chief of Staff (GS-301-15) Vacancy Announcement (Merit Promotion)

The incumbent serves as a Chief of Staff, advising, assisting, and presenting the CDRH Director in areas of management for CDRH. As delegated by the CDRH Director, exercises staff control and supervision for administrative subordinates. The incumbent has responsibility for ensuring coordination in the development and

implementation of programs, processes, and strategic initiatives to support important Office, Center, and Agency priorities.

Voluntary Reassignment Opportunity - CDER/OMP/OMPI/IO – Medical Officer, GP-602-14

The Center for Drug Evaluation and Research, Office of Medical Policy, Office of Medical Policy Initiatives, Division of Clinical Trial Quality is offering a voluntary reassignment opportunity for a Medical Officer, (GP-602-14). The reassignment opportunity is open to all current FDA employees. No promotions will be offered through this notice. This is a non-bargaining unit position.

CDER/OTS/OCS - Detail Temporary Promotion Announcement Opportunity, Lead Medical Officer, GP-0602-15 (NTE-120 Days)

This position is in the Office of Computational Science, Office of Translational Sciences, Center for Drug Evaluation and Research (CDER). The incumbent serves as a Lead Medical Officer, a scientist and an expert in the quantitative assessment of clinical data collected through the lifecycle of drug or biological products during the regulatory review process.

CTP Detail Opportunity: Regulatory Counsel, GS-301-11/12, or Consumer Safety Officer, GS-696-11/12, (Reimbursable Detail)

The Center for Tobacco Products, Office of Compliance and Enforcement (OCE) is offering a reimbursable, temporary promotion detail opportunity for a period not to exceed 120 days. U.S. Public Health Service Commissioned Corps Officers are encouraged to apply.

Vacancy Announcement – Support Services Specialist - GS-0342-12 FPL 13

Please see attachment

CBER Detail/Temporary Promotion Opportunity Not to Exceed 120 Days- Administrative Specialist (Program Manager), GS-0301-11/12

This position serves as a Program Manager, in the Immediate Office of the Director, Office of Compliance and Biologics Quality (OCBQ/IOD), Center for Biologics Evaluation and Research (CBER), located in Silver Spring, MD. Please see the link below for more details.

CTP Vacancy Announcement: Management Specialist, GS-0301-13, (MP)

This position is located in the Department of Health and Human Service (DHHS), Food and Drug Administration (FDA), Center for Tobacco Products (CTP), Office of Science (OS), Silver Spring, Maryland. The Office of Science (OS) will be permanently relocated to Beltsville, Maryland; tentatively scheduled for spring 2018. This position is open to FDA-wide employees only.

CBER Detail NTE 120 Days - Interdisciplinary Engineer, 801/855/585 - GS-13

This position is located in the Product Review Branch (PRB), Division of Emerging and Transfusion Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR). This is a Bargaining Unit position. See attached.

From: Biochemistry [Biochemistry@suggette.com]
Sent: 11/10/2018 1:06:08 PM
To: Ye, Zhiping [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd853bb14fa24b0c896a31594e772c06-yez]
Subject: 第4届[生物化学与分子生物学]

邀请函：第四届【生物化学与分子生物学】国际研讨会

时间：2018年12月1-3日

地点：三亚·亚太国际会议中心

议题：生物化学与分子生物学相关领域

简版日程

2018年12月1日：报名注册

2018年12月2日：特邀嘉宾报告

2018年12月3日：口头报告

诚邀各位专家和代表的参加，如需正式邀请函或有参会意向，请回复邮件联系组委会。

特邀演讲嘉宾（更新中）

Invited Speech 1: Battle between virus and host immunity: the role of type I interferon signaling in HCV and HBV persistent infections

Speaker: Prof. Limin Chen, Chinese Academy of Medical Sciences, China

Invited Speech 2: The Structure-Function Relationship and Inhibition of Peptidoglycan O-Acetyltransferases, Potential New Antivirulence Targets in Both Gram-Positive and Gram-Negative Bacteria

Speaker: Prof. Anthony J. Clarke, University of Guelph, Canada

Invited Speech 3: Development of C-based single domain antibodies as therapeutic candidates against infectious diseases

Speaker: Prof. Rui Gong, Wuhan Institute of Virology, Chinese Academy of Sciences, China

Invited Speech 4: Reverse transcript recombinaase polymerase amplification assay for rapid detection of tick-borne encephalitis virus infection

Speaker: Prof. Xiaoping Kang, Beijing Institute of Microbiology and Epidemiology, China

Invited Speech 5: Ultrasound-switchable fluorescence Imaging

Speaker: Prof. Baohong Yuan, University of Texas at Arlington (UTA), USA

Invited Speech 6: Morphologic, morphometric and molecular characterization of Anisakids obtained from edible fish in Bushehr region, Iran

Speaker: Prof. Seyed Mahmoud Sadjjadi, Shiraz University of Medical Sciences, Iran

Invited Speech 7: Dirofilariasis in Iran

Speaker: Prof. Sharif Maraghi, Ahvaz Jundishapur University of Medical Sciences, Iran

Invited Speech 8: Assessment on Free Fatty Acid of Crude Palm Oil using Near-Infrared Spectroscopy

Speaker: Prof. Herlina Abdul Rahim, Universiti Teknologi Malaysia, Malaysia