(U) Summary of Conclusions for
Policy Coordinating Committee on Countering Biological Threats

Topic: (U//FOUO) United States Novel Corona Virus (nCoV) Response
Wednesday, January 22, 2020
1:30 - 3:00 p.m.
WHSR

(U) PARTICIPANTS:

Chair
Anthony Ruggiero

NSC Staff
Phil Ferro
Lauren Fabina
Gary Seffel
Hillary Carter
Katelyn Christ
Michael Sinclair
Patrick Lowry
Ivan Kanapathy

OSTP
Kelvin Droegemeier
Ian Watson
Paige Waterman

DPC
James Baehr
Maria Bonner
Kamran Daran

OMB
Christine Farquharson

USAID
Richared Greene

FAA
Alex Naar

GSA
Paul Detitta

State
Gregory Martin
Eric Carlson
Rich Waters
Nausher Ali
Virgil Carstens
Larry Padget

HHS
Robert Redfield
Rick Bright
Robert Johnson
Erika Elvander
Chris Hassell
Marty Cetron (SVTC)

DHS
Chris Magrino
William Ferrara
Debbie Seguin

DOD
Nathan Pawlick
CDR Amber Biles
MAJ Katherine Kinder
Vanessa Eddy
John Trigilio

DOT
Brett Feddersen
Amie Kalsbeek

Sent: 7/2/2020 9:36:30 AM
Subject: RE: Question: Cross Assay Validation (Vx)

DRAFT – PRE-DECISIONAL & DELIBERATIVE
FOR OFFICIAL USE ONLY - DO NOT DISTRIBUTE
June 29, 2020
Vaccine Development Team, Operation Warp Speed
SARS-CoV-2 Vaccine Neutralizing Antibody Assay Sub Working Group
HHS Confidential Information – For Official Use Only – Not to be Disseminated

Agenda
Introductions - All

Brief overview (Montefiori)
Vaccines and timelines for phase 3 trials
The assays and who is doing them
Timelines for readiness
Backup plans
Technology transfer plans

General discussion - All
What should be our goals?
How to facilitate licensure?
Should we be prepared to advance one of the assays for potency testing?
Technical and regulatory advice for assay optimization, qualification and validation
Capacity building and technology transfer
Other?
OWS Vaccine NAb Assay Sub Working Group
Name
Expertise
David Montefiori
Pseudovirus assays, immune monitoring
Ralph Baric
Live virus assays, immune monitoring
Marcella Sarzotti-Kelsoe
Quality assurance, data master file
Chris Cirimotich
Assay expertise, reagents
Thomas Denny
Assay qualification and validation
Tomas Rudge
Tech transfer
Janet Lathey
Project officer, Battelle assay development
Chris Badorrek
Gregory Rutkowski
John Hural
Assay development and regulatory compliance
Assay development and regulatory compliance
HVTN Laboratory Operations
Rick Koup
Co-chair, OWS Lab Group
Ruben Donis
Co-chair, OWS Lab Group

SARS-CoV-2 Vx Candidates and Deployment Timeline
Phase I-II
August 2020
Phase III
100K subject-pregnancy study being considered
October 2020
Scale up
Non-US manufacturing and U.S. Emergent Mfr.
40M doses by Q12021
Phase I

460 subjects
Q4 2020
Phase II-III
6K subjects
TBD
Scape up
100-600M doses
Phase I
Phase II-III
Scale up
NHP studies
July 2020
Phase I-II-III
TBD
Scale up
100-150K doses/run
Phase I/II
May 2020
Phase III
Late July 2020-Follow-up pediatric study
At least 300M doses total first doses in
September 2020
Phase I
105 subjects
Q1 2020
Phase II
600 subjects
June 2020
Phase III
30K subjects
July 2020
Scale up
10-23M doses in 2020
Plus Lonza Mfr.
Phase I
May 2020
Phase II
July 2020
Phase III
September 2020
First batch–10-100M doses
November 2020

Clinical trial timelines (I of II)
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Phase 2 start
Phase 3 start
Phase 3 doses
P3 Interim readout
10M doses
P2 Interim readout
P2 Interim readout
EUA
mRNA - 1273
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Phase 3 (UK) start
Phase 3 (US) start
EUA
Phase 3 doses from UK
Interim readout
10M dose
60M Doses
100M doses
Efficacy readout

Pedi-atric Study start
AZD1222 (ChAdOx1 nCoV-19)
Notes view:

Clinical trial timelines (II of II)
Ad26-NCOV030
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Phase 1 CTM
Phase 1
Phase 2 CTM
rS + adjuvant
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Phase 1-2a start
Interim readout
Phase 3 start
EUA
Phase 3 doses from NE
Notes view:

Sampling Plan for Phase 3 Trial (Peter Gilbert)
Primary Analysis / Stage 1 (at 153 COV-DIS endpoints)
Random subcohort x 2 time points (Day 1, 57) = 760*2 = 1520
COV-INF cases = 68 vaccine grp*1.4 x 2 time points + 20 placebo x 2 time points= 230
Assume at most 68*1.4 of 153*1.4 infections in the vaccine group (assume estimated VE against infection >= 20%)
Do not need to measure markers in all placebo cases, because most values are ‘structural zeros’
Total samples primary analysis / Stage 1 = 1750
Budget for up to 40% of infections not qualifying for COV-DIS primary endpoint
Final Analysis / Stage 2 (Through to Month 25)
Random subcohort x 4 additional time points (Day 29, Month 7, 13, 25) = 760*4 = 3040
Takes out the Month 4/Day 119 time point
Additional COV-INF cases = 3*68 vaccine grp*1.4 x 4.5 time points on average before diagnosis + 20 placebo x 4.5 time points on average before diagnosis = 1375
Assume Stage 2 adds 3 times as many infections as Stage 1, and again assume estimated VE against infection >= 20%
Total sample size final analysis / Stage 2 = 4405
Grand total samples: 1750 + 4405 = 6155

OWS - Overview of neutralization assays for phase 3 trials of COVID-19 vaccines

Pseudo-virus Live virus			
Assay	Developer	Capacity (per wk)	Assay status
Pseudovirus Lentiviral system 293T/ACE2 cells firefly-Luc	NIH (Duke-Montefiori Lab)	500	Qualification - Aug 15 Validation - Sep 15
	NIH (VIP - McDermott Lab)	500	Qualification - Aug 15 Validation - Sept 15
	NIH (Battelle)	1,000	Qualification - Aug 15 Validation - Sep 15
Micro-neutralization IMC virus Vero-6 cells nano-Luc	UNC (Baric Lab)	800	Qualification - Aug 15
	UNC (Heissen Lab)	800	Validation - Sep 15
Micro-neutralization WT virus Vero-6 in situ ELISA	Battelle	1,000	Qualification - Jul 20 Validation - Sep 1

SARS-CoV-2 Neutralizing Assay Concordance Survey (NIAID/DAIDS Virology Quality Assessment Program SNACS Project)
Tom Denny, Mike Busch, Marcella Sarzotti-Kelsoe, David Montefiori

An initial survey of assay concordance across a large number of labs and assay types. Assess specificity, accuracy and precision of labs. Baseline data for further concordance testing and design of a proficiency testing program for key labs involved in clinical trials.
Samples:
COVID-19 convalescent sera
High, medium and low titers
Built-in replicates
Negative controls
Assays:
Live virus assay = 34 labs
Pseudovirus assay= 46 labs
Binding and ACE2-inhibition= 10 labs
Schedule:
Send-out: July 15, 2020
Data close-out: August 7, 2020
Statistical analysis: August 8-14, 2020
Report: August 15, 2020
Lab PI
Assay Type
Institution
Greg Sempowski
Live Virus
Duke University - RBL
Ralph Baric / David Martinez
Live Virus
University of North Carolina at Chapel Hill
Michael Diamond
Live Virus
Washington University
Anthony Griffiths
Live Virus
Boston University, NEIDL-NBL
Colleen Beth Jonsson
Live Virus
University of Tennessee - RBL
Aarthi Narayanan
Live Virus
George Mason University - RBL
Dominique Missiakas
Live Virus
University of Chicago - RBL
Jeffrey Adamovicz
Live Virus
University of Missouri - RBL
Mehul Suthar
Live Virus
Emory University Vaccine Center
Sue VandeWoude, Christie Mayo
Live Virus
Colorado State University - RBL
Marila Gennaro
Live Virus
Rutgers University – RBL
William Severson, Donghoon Chung
Live Virus
University of Louisville - RBL
Jame LeDuc
Live Virus
University of Texas Medical Branch – NBL
Mark Dension
Live Virus
Vanderbilt University Medical Center
Adolfo Garcia-Sastre
Live Virus
Icahn School of Medicine at Mount Sinai
Pei-Yong Shi
Live Virus
University of Texas Medical Branch
Yoshihiro Kawaoka
Live Virus
University of Wisconsin-Madison
Matthew Frieman
Live Virus
University of Maryland
Dan Ewing
Live Virus
Navy Medical Research Center
Jay Hooper

Live Virus
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
John Dye
Live Virus
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
Landon Westfall, Fusatake Koide
Live Virus
Southern Reasearch Institude
Bassam Hallis
Live Virus
Public Health England, UK
Christopher Cirimotich and Jennifer Garver
Live Virus
Battelle Memorial Institute
Bassam Hallis
Pseudo Virus
Public Health England, UK
Christopher Cirimotich and Jennifer Garver
Pseudo Virus
Battelle Memorial Institute
David Montefiori
Pseudo Virus
Duke University
Nicole Doria-Rose, John Masocla
Pseudo Virus
Vaccine Research Center
Adrian McDermott, Britta Flach
Pseudo Virus
Vaccine Immunology Program at Vaccine Research Center (VIP-VRC)
Mike Seaman
Pseudo Virus
Beth Israel Deaconess Medical Center
Simon Cocklin
Pseudo Virus
Drexel University College of Medicine
Theodora Hatziioannou, Paul Bieniasz
Pseudo Virus
Rockefeller University
John Moore, Tom Ketas
Pseudo Virus
Cornell University
Beatrice Hahn, Ronnie Russell
Pseudo Virus
University of Pennsylvania
Paul Bates
Pseudo Virus
University of Pennsylvania
Erica Ollman Saphire / Kate Hastie
Pseudo Virus
La Jolla Institute for Immunology
Linqi Zhang
Pseudo Virus
Tsinghua University, China
Penny Moore and Lynn Morris
Pseudo Virus
National Institute of Infections Diseases, S. Africa
Youchun Wang
Pseudo Virus
National Institute for Food and Drug Control, China
Miao Xu
Pseudo Virus
National Institute for Food and Drug Control, China
Michael Farzan
Pseudo Virus
Scripps Research
Barney Graham
Pseudo Virus
Vaccine Research Center
Rogier Sanders, Marit van Gils
Pseudo Virus
Amsterdam - Academic Medical Center (AMC)
Leonidas Stamatatos
Pseudo Virus
Fred Hutchinson Cancer Research Center
Ian Lipkin
Pseudo Virus
Columbia
James Binley

Pseudo Virus
San Diego Biomedical Research Institute
Dan Barouch
Pseudo Virus
Beth Israel Deaconess Medical Center
Xuping Xie, Pei-Yong Shi
Pseudo Virus
University of Texas Medical Branch
Warner Greene
Pseudo Virus
Gladstone Institute of Virology and immunology
John Mellors
Pseudo Virus
University of Pittsburg School of Medicine
Jesse Bloom
Pseudo Virus
Fred Hutchinson Cancer Research Center
Graham Simmons
Pseudo Virus
Vitalant Research Instite
John Mills, Elizabeth Theel
Pseudo Virus
Mayo Clinic
Luc Gagnon
Pseudo Virus
Nexelis
Shelly Krebs, Gregory Gromowski
Pseudo Virus
Walter Reed Army Institute of Research (WRAIR)
Stephen J. Russell, Rianna Vandergaast
Pseudo Virus
Imanis Life Sciences
Kai Wu
Pseudo Virus
Moderna
Mike Holbrook
Pseudo Virus
NIH
Linfa (Lin-Fa) WANG
Pseudo Virus / Live Virus (TBD)
Duke University
Rafael Delgado
Pseudo Virus
University Hospital, Spain
Emanuele Montomoli
Pseudo Virus / Live Virus & ELISA (TBD)
VisMederi, Italy
Ivo Ploemen
Pseudo Virus / Live Virus & ELISA (TBD)
Viroclinics, The Netherlands
Giada Mattiuzzo
Pseudo Virus / Live Virus & ELISA (TBD)
NIBSC, UK
Guruprasad Medigeshi
Pseudo Virus / Live Virus & ELISA (TBD)
Translational Health Science and Technology Institute, India
Wendy Barclay
Pseudo Virus / Live Virus (TBD)
Imperial College London
Le Sun
Pseudo Virus / Live Virus (TBD)
China
Jay Rappaport
Pseudo Virus / Live Virus (TBD)
Tulane University
Florian Krammer
Pseudo Virus / Live Virus (TBD)
Icahn School of Medicine at Mount Sinai
Tom Rogers
Pseudo Virus / Live Virus (TBD)
Scripps Research
Vincent Munster
Pseudo Virus / Live Virus (TBD)
Rocky Mountain Labs

Other Assays
Georgia Tomaras
Binding Ab Assay

Duke University
Guiod Ferrari
ADCC
Duke University
Nicole Doria-Rose, John Masocla
Binding Ab Assay
Vaccine Research Center
Adrian McDermott, Britta Flach
ACE2 inhibition assay
Vaccine Immunology Program at Vaccine Research Center (VIP-VRC)
Melicia Gainey, Christopher Cirimotich and Jennifer Garver
ELISA Spike
Battelle Memorial Institute
John Dye
ELISA Spike
USAMRIID
Luc Gagnon
ELISA Spike & RDB
Nexelis
Landon Westfall, Fusatake Koide
ELISA Spike
Southern Reasearch Institude
Shelly Krebs, Greg Gromowski
Single ELISA & Multiplex Luminex
Walter Reed Army Institute of Research (WRAIR)
Dan Ewing
ELISA
Navy Medical Research Center

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R&DBlueprint

Powering research
to prevent epidemics

Notes from Teleconference of the R&D Blueprint GCM
January 10, 2020
Friday 14:00-15:00 GVA time

Pneumonia of unknown etiology in Wuhan China

agenda items

1. WHO Overview of emerging data on disease epidemiology
    - 59 cases of pneumonia listed as unknown etiology, 7 listed as severe. Now know Chinese have identified as a novel coronavirus, which we understand they have confirmed by PCR testing and whole genome sequencing.
    - Limited clinical picture. Symptom onset from 12-29 December. All known cases are linked to live fish market in Wuhan that also sells other animals. No reported health care worker infection. No reported human-to-human transmission, which is surprising given suspected cause of novel corona virus.
    - Market was closed on December 1
    - 153 known close contacts being monitored. This is lower than would be expected given cause and expected respiratory transmission
    - WHO has requested more information on epidemiological situation but also ongoing investigations
    - No known international spread, but many countries in the region have activated protocols to monitor pneumonia patients of unknown etiology who have recently been to china. Difficult to confirm without
    - Currently potential zoonotic spill over event but very concerned about potential international spread.
    - WHO developing guidance for member states
    - Understand there have been investigations from the market where samples have been tested from animals, but do not know methodology or details.
    - Know there may be other investigations ongoing in China

Questions:
David ____ (BMGF) Who are you communicating with in China? Heard Hu Jing Jiao (Sp?) from Chinese Academy of Engineering is leading. Also would like to offer use of BMGF grantee open data sharing platform

- WHO Communicating with WHO Country office who is in touch with the national focal point and working through formal channels. This has been raised as high as the DG within WHO, who is currently on the phone with China. Many requests for information. Priority questions:
    - Any information on human to human transmission
    - Sequence information and PCR primers. Understand the coronavirus has been sequenced and there are PCR primers developed. These need to be shared asap.

How many cases have there been in the last two weeks since the close of the Market Dec. 1?

- Last report WHO received from China was from Dec 5 and that had the last case's symptom onset as Dec 29, so do not know if there have been any confirmed cases with symptom onset after market was closed.
- Jeremy: Summarizing on animal side, do not have a confirmed vector or confirmation that the corona virus has been found or sequenced from animals

Jeremy Ferrar (Wellcome Trust) Encourage all GCM members who may have additional information through formal or informal channels to please share that with Ana Maria Henao Restrepo and WHO.

Hilary Marston, NIAID: Who in China is doing the sequencing? Appreciate WHO's emphesis on sequence sharing. What our researchers are emphasizing is the critical need for sequence data. Ready to develop and work on animal models and other research, but need sequences to start.

- WHO: We understand it is China CDC, although we know there is also a very competent BSL3/4 lab in Wuhan.

2. Overview of research priorities and a collaborative process to offer support -if requested- to the national authorities in China and elsewhere.

Ana Maria Henao Restrepo: Have received many offers and suggestions and bilateral discussions are ongoing about research priorities. We just had a call with members of the SAG and now have GCM. Discussed 4 points

- Diagnostics: outlined importance of reliable and standardized process for diagnostics. Also need for understanding of epidemiology. Need protocols and standardization of data collection. Suggestion of a generic protocol for diagnostics development and data collection. Vasee Moorthy from R&D Blueprint team and Marion Koopmans and Cathy Roth from SAG were going to work on this.
- Therapeutics: WHO working on review of all current therapeutics available for coronavirus, including those in china and make this available
  - Also a review of which therapeutics could be advanced rapidly
  - With R&D Blueprint did a generic protocol for coronavirus/MERS therapeutics and want to see how this might be applied or adapted
- Vaccines Similarly, want to look at candidate vaccines. There was an invitation from CEPI, which has some of the candidates, but want to have a full list of vaccine candidates including those available in China.
- Data Sharing and Sample Sharing: Two points discussed. One was proposal of a standardized approach to data collection. Second was that WHO should promote data sharing, sequence sharing, but wanted to have a secondary conversation with some of you to discuss how to do this in a way that is satisfactory to all parties.

Peter Horby: Question: Ana Maria, other aspects of clinical features like clinical epi, natural epi, pathogenesis…I know this is not typically captured by Blueprint, but is this being captured elsewhere in WHO,

- Yes, being led by Janet Diaz. Key is developing optimized supportive care protocol and this work has begun.
- Peter: In terms of data standardization, we have had some conversations informally with contacts in China and shared some standardized data collection tools. Also shared some protocols for establishing risk (protocols on sero-epi etc. for HCWs), which we understand are being used to some extent. Miracle study protocol has also been shared.

Jeremy: We tried very hard to get someone from China on the call, but it was not authorized. We encourage others with contacts in China to please share any additional information you may have

Marie Paul Kieny: How much sequence data has been shared by the Chinese?

- So far the sequence has not been shared by the Chinese, but this is a top WHO priority being handled directly by WHO DG

Richard Hatchett CEPI: CEPI will have a call of CEPI SAG immediately after this call. We

invited WHO to call. CEPI taking an alert, forward leaning posture. Doing outreach to CEPI vaccine manufacturers working on coronavirus to start some exploratory conversations on what might be possible if it is needed/asked for.

- CEPI stands ready if WHO and colleagues require to support enabling work for development of vaccines and potentially also diagnostics including development of reference materials.
- CEPI understands WHO set up a site for standardized, open information flow during Zika and encourage a similar approach for this.

Ana Maria: Yes understand there are a number of vaccine candidates and also understand there are some candidates in China. What we are doing now is asking for partners to share what information they have and we will analyse and make it available.

Rita Helfand: Once you have sequencing, CDC stands ready to help with all elements of diagnostics development similar to what we do with flu.

- Ana Maria: Thank you, we are doing work on generic protocol for diagnostics development and would welcome CDC's input into this work

GloPID-R: China not a GloPID member but some of the neighbouring countries are. We are holding a call soon and will share any information that becomes available.

Institute Pasteur: Have reached out to colleagues in Shanghai, China, have not heard response, but will communicate anything we learn.

Jeremy: If all the key groups who have mentioned that they plan to have calls to share information in your networks, can plan to share summaries of those calls to share information with Ana Maria and WHO.

- Although information flow may not be as good as would like out of China, recognize that if there is spread to other countries, we may have additional opportunities for sharing information through our networks of partners.

- Mechanisms for coordination/collaboration in terms of international research

Ana Maria: Propose regular (potentially weekly) calls to keep partners updated.

- Two, pleas share any information you hear thorugh your networks with WHO
- Three: plan to share summary of SAG call that just competed
- Four: Please consider any ways you may be able to support WHO and also China. Purpose of GCM calls is to think of ways we can better work together an so welcome suggestions and offers of resources.

3. Next steps including considerations of potential spread scenarios vis a vis research priorities

Ana Maria: Best approach for China is to engage with them and not seem as if we are trying to tell them what they should do. We plan to share summaries of this GCM call as well as the SAG call. Also plan to reach out to GCM members individually to discuss ways they may be able to assist or contribute.

Jeremy Ferrar: plan to set up additional GCM calls going forward in January, will follow up with schedule. Think this is a very effective mechanism for sharing information, whether GCM members or their colleagues are able to join, we would welcome that.

- We wish there was more information being shared, but we believe that maximum pressure is being applied to encourage sharing of information. Encourage partners

P4 Lab is Open and Transparent, Officials Emphasize

3. (SBU) The Wuhan P4 lab, referring to labs with the highest level of safety precautions, became fully operational and began working with live viruses early this year. Institute officials said they believed it is the only operational P4 lab in Asia aside from a U.S. Centers for Disease Control (CDC)-supported facility in Pune, India (Ref C). China plans to stand up a second P4 lab in Harbin. Institute officials said Japan's biosafety labs are "old" and lack cutting-edge equipment, so they consider Japan's labs to be "P3 Plus" (Note: the Japanese government says it has one P4-level lab in the Tokyo suburbs, though its activities are limited, and Japan is building a new P4 lab in Nagasaki, see Ref D. Taiwan operates at least HYPERLINK "https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5404250/"one P4 lab. South Korea was close to HYPERLINK "http://www.koreaherald.com/view.php?ud=20170316000902"opening a P4 lab as of last year, see Ref E. End Note.) Wuhan's lab is located about 20 miles from the city center in Zhengdian district, and the institute plans to gradually consolidate its other training, classroom and lab facilities at that location.

4. (U) Officials described the lab as a "regional node" in the global biosafety system and said it would play an emergency response role in an epidemic or pandemic. The lab's English brochure highlighted a national security role, saying that it "is an effective measure to improve China's availability in safeguarding national bio-safety if [a] possible biological warfare or terrorist attack happens."

5. (SBU) Institute officials said there would be "limited availability" for international and domestic scientists who had gone through the necessary approval process to do research at the lab. They stressed that the lab aimed to be a "worldwide, open platform" for virology. They said they welcomed U.S. Centers for Disease Control (CDC) experts, noting that the Chinese Academy of Sciences was not strong on human disease expertise, having only focused on it in the last 15 years, after the SARS outbreak. A Wuhan-based French consulate official who works on science and technology cooperation with China also emphasized that the lab, which was initiated in 2004 as a France-China joint project, was meant to be "open and transparent" to the global scientific community. "The intent was to set up a lab to international standards, and open to international research," he said. French experts have provided guidance and biosafety training to the lab, which will continue, the French official said. Institute officials said that France provided the lab's design and much of its technology, but that it is entirely China-funded and has been completely China-run since a "handover" ceremony in 2016.

6. (U) In addition to French assistance, experts from the NIH-supported P4 lab at the University of Texas Medical Branch in Galveston have trained Wuhan lab technicians in lab management and maintenance, institute officials said. The Wuhan institute plans to invite scientists from the Galveston lab to do research in Wuhan's lab. One Wuhan Institute of Virology researcher trained for two years at the Galveston lab, and the institute also sent one scientist to U.S. CDC headquarters in Atlanta for six months' work on influenza.

NIH-Supported Research Revises SARS Origin Story

7. (U) NIH was a major funder, along with the Natural Science Foundation of China (NSFC), of SARS research by the Wuhan Institute of Virology's Shi Zhengli and Cui Jie. The researchers spent five

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 4/20/2018 12:35:23 PM
To: Valdez, Mary Lou [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80d9c6b02db946618f69aa301d484a7c-MaryLou.Val]; Blair, Joan W. (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cc3d088be164491a76b9ce048d71a02-BLAIR]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: MCB Cables for HHS U.S 19Apr18

Lou – Hi and thx for sending. Do you happen to have 'Ref A' referred to in the cable on China Virus Institute? We (in collaboration w/other partners) offer a course every year in achieving data quality and integrity in BSL 4 labs e (this year's course runs next week). Might provide an additional opportunity bilateral cooperation…maybe worth discussing…?

From: Valdez, Mary Lou
Sent: Friday, April 20, 2018 8:10 AM
To: Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: MCB Cables for HHS U.S 19Apr18

Thought both of these cables would be of general interest to you. Thanks, Lou

Lou Valdez
Associate Commissioner for International Programs
Office of International Programs
U.S. Food and Drug Administration
Office: 301 794 8400
Direct: (b) (6)
Mobile:

From: OS Secretarys Operations Center [mailto:hhs.soc@hhs.gov]
Sent: Thursday, April 19, 2018 11:59 PM
To: MCB Cables for HHS U.S <MCBCablesforHHSU.S@ees.hhs.gov>
Cc: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Subject: MCB Cables for HHS U.S 19Apr18

China Virus Institute Welcomes More U.S. Cooperation on Global Health Security

(SBU) Summary with Comment: China's Wuhan Institute of Virology, a global leader in virus research, is a key partner for the United States in protecting global health security. Its role as operator of the just-launched Biosafety Level 4 (or "P4") lab -- the first such lab in China -- opens up even more opportunities for expert exchange, especially in light of the lab's shortage of trained staff (Ref A). Given the legacy of