

From: Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>
Sent: Friday, January 22, 2021 2:37 PM EST
To: FOIA <foia@americanoversight.org>
CC: Russ, Wilson <Wilson.Russ@fda.hhs.gov>
Subject: FDA 2020-2623
Attachment(s): "2020-2623 Records - Redact - Final.pdf"

EXTERNAL SENDER

Requester: foia@americanoversight.org

Dear Requester,

The records you are seeking are attached.

Certain information has been redacted from the records under Exemption 4 (trade secret/confidential commercial information), Exemption 5 (deliberative process) and Exemption 6 of the FOIA (personal privacy information). You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Katherine Uhl at 301-796-8975. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road-OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Sincerely,

Sarah B. Kotler, J.D.
Director, Division of Freedom of Information
US FDA
301-796-8976



From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 6/24/2020 12:44:40 PM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]
CC: Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]
Subject: RE: Inquiry

Hi Peter –

Hope you are well too.

Thanks for your note

I'm copying my colleague Mary Beth Clarke, Director of the Office of Executive Programs, to help us identify the best POC in CDER.

Thank you,

Anand

Anand Shah, MD

Deputy Commissioner for Medical and Scientific Affairs

U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Wednesday, June 24, 2020 12:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Inquiry

Anand,

Good day to you. Trust all is well.

I'm looking for help to find a contact within CDER in the drug review group. (b) (4)

(b) (4) I have some questions to understand FDA's requests.

Do you have a contact there I could reach out to?

Thanks and take care,

Peter

Peter E. Shearstone

Vice President

Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.

168 Third Avenue | Waltham, Massachusetts 02451

Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642

Internal extension 110-1333

peter.shearstone@thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/15/2020 9:13:07 AM
To: Wilkins, Donna M. [donna.wilkins@thermofisher.com]
Subject: Read: RE: Ext Call - Thermo Fisher / FDA (Follow up)

Your message

To: Shah, Anand
Subject: RE: Ext Call - Thermo Fisher / FDA (Follow up)
Sent: 5/15/2020 8:55:41 AM

was read on 5/15/2020 9:13:07 AM

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/14/2020 5:01:41 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; O'Neill, Kimberly [Kimberly.Oneill@thermofisher.com]
Subject: RE: Ext Call - Thermo Fisher / FDA (Follow up)

Great, Mark. Also looping in Jeff so we can compare notes and next steps
Anand

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Thursday, May 14, 2020 4:42 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>; O'Neill, Kimberly <Kimberly.Oneill@thermofisher.com>
Subject: Re: Ext Call - Thermo Fisher / FDA (Follow up)

Hi Anand,

I put my assistant in copy here to connect with Jenna.

Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Thursday, May 14, 2020 at 4:38 PM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: "Zembower, Jenna" <Jenna.Zembower@fda.hhs.gov>
Subject: Ext Call - Thermo Fisher / FDA (Follow up)

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Mark -

Good conversation today.

Can I briefly touch base with you and your team so that we talk through the various follow up items – perhaps 15 min tomorrow?

Jenna can help us schedule

Thanks,

Anand

Anand Shah, MD

Deputy Commissioner for Medical and Scientific Affairs

U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Sent: Thursday, May 14, 2020 9:49 AM

To: Hahn, Stephen ^{(b) (6)} <[\[REDACTED\]@fda.hhs.gov](mailto:[REDACTED]@fda.hhs.gov)>

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

Dear Steve,

Yes, fine to share email. The attachment was more related to vaccine proposal note diagnostic testing.

For clarity here are the 5 items I regard as follow up.

(b) (4)



Regards

Mark

From: Steve Hahn ^{(b) (6)} @fda.hhs.gov>

Date: Thursday, May 14, 2020 at 8:31 AM

To: Mark Stevenson <mark.stevenson@thermofisher.com>

Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark,

We are setting up a call with Dr. Birx and Jeff Shuren. Is it ok if I share this email and the attachments with Dr. Birx prior to the call?

Thanks

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 10, 2020 at 8:17:11 AM EDT

To: Hahn, Stephen ^{(b) (6)} @fda.hhs.gov>

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

Steve

Janice and my assistant are connected and to arrange a call. Plenty of topics to cover around public health.

Our submissions to amendment to our FDA EUA to expand our qPCR platforms and protocols was approved which will greatly expand platforms already installed able to run the COVID19 assay, including in a 384 well throughput. ^{(b) (4)}

^{(b) (4)}

^{(b) (4)}

We proposed to BARDA (i) short-term solution to enable sterile manufacturing production capacity in Q4 2020 for vaccines to support the COVID-19 pandemic at this critical time ^{(b) (4)}

^{(b) (4)}

Best Mark

From: Steve Hahn ^{(b) (6)} @fda.hhs.gov>

Date: Saturday, May 9, 2020 at 10:14 AM

To: Mark Stevenson <mark.stevenson@thermofisher.com>

Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah,

Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send toSOC@thermofisher.com.

Mark,

thank you very much for your message. Great work on all counts. We very much appreciate the work with Thermo Fisher. It would be great to arrange a call in the upcoming week. I'll ask Janice to arrange.

I am in self-quarantine but doing well.

Best

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 9, 2020 at 9:53:38 AM EDT

To: Hahn, Stephen (b) (6) <toSOC@fda.hhs.gov>

Subject: COVID diagnostics

Dear Steve,

I had read you will self-quarantine for 14 days after exposure to White House spokesperson Katie Miller, who tested positive for Covid-19 on Friday, so it prompted me to send a note. I hope you remain negative but I know you will have plenty of access to FDA EUA tests!

Quick update from Thermo Fisher. (b) (4)

We have also followed up on the work done with Mayo Clinic on ELISA lab based serology testing and signed an agreement with Mayo/WuXi for that test for total antibodies (IgM/IgG). We will make a submission for that serology test will be coming to the FDA in the next few weeks.

We have also engaged with the NIH on their RADx to continue to innovative around diagnostic testing for COVID.

Let me know if we can be helpful during this unprecedented times. I'm sure at some point we can also spend time to share observations and lessons learnt in a post COVID world for how industry and FDA work together.

Best Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T +1 (781) 622-1344
Mobile (+WhatsApp) :+1 760 576 9897

mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill

T (781) 419-3222

kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/15/2020 5:43:03 PM
To: Madeline Grant [grantm5@uw.edu]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]
Subject: RE: response from FDA

Hi Madeline -

Nice to chat today. Thanks for the additional background.

Our team is in touch with Tina Lockwood of SCAN on the various questions.

Anand

From: Madeline Grant <grantm5@uw.edu>
Sent: Friday, May 15, 2020 12:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: response from FDA

From: Katims, Casey (GOV) <casey.katims@gov.wa.gov>
Sent: Friday, May 15, 2020 7:39 AM
To: Madeline Grant <grantm5@uw.edu>
Cc: Nick Bath@help.senate.gov; Fristedt, Andi (HELP Committee) <Andi.Fristedt@help.senate.gov>; Peterson, Kristin I (DOH) <Kristin.Peterson@DOH.WA.GOV>
Subject: response from FDA

Madeline:

Below is the response I just received from FDA to our inquiry about SCAN. (b) (4)

(b) (4)

Can you let us know if this meets UW's needs or if further clarification and encouragement is needed from us?

Happy to keep pushing! Let us know how we can help.

Casey

(b)(6)

From: White, Erica <Erica.White@fda.hhs.gov>
Sent: Friday, May 15, 2020 10:29 AM

To: Katims, Casey (GOV) <casey.katims@gov.wa.gov>

Cc: Wilson, Morgan (GOV) <Morgan.Wilson@gov.wa.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>

Subject: FW: urgent question on state EUAs

Good morning Casey,

Thank you for your email below regarding the SCAN state-issued EUA. HHS referred your email to us, FDA Intergovernmental Affairs, for a response. FDA's recommendations for COVID-19 testing on the use of at-home testing, including at-home specimen collection have not changed. The FDA's guidance has provided a [Policy for Coronavirus Disease-2019 Tests](#), which does not apply to home collection of specimens to be sent for testing at a laboratory certified under CLIA for high-complexity testing. The recent guidance updates did not change the policy regarding state oversight. Home collection raises additional concerns about safety and accuracy that require FDA review, as we have discussed in our FAQs and other communications about home collection.

Research studies conducted under supervision of an Institutional Review Board (IRB) are handled separately, and in such case, an IRB may determine that home collection may occur with appropriate mitigations under such a supervised study.

We had previously understood that SCAN was being conducted as a surveillance study. As appropriately determined by the applicable IRB, such an option for home collection may be available to the project sponsors.

I also wanted to let you know that FDA reached out to UWA and is continuing to work with them on their options.

If you have additional questions please feel free to contact me.

Thank you,

Erica M. White, J.D.

Intergovernmental Affairs (IGA)
Office of the Commissioner/OPLIA
U.S. Food and Drug Administration
Office: (301)796-8309

Erica.White@fda.hhs.gov



From: Katims, Casey (GOV) <casey.katims@gov.wa.gov>

Sent: Wednesday, May 13, 2020 3:56 PM

To: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>

Cc: Wilson, Morgan (GOV) <Morgan.Wilson@gov.wa.gov>

Subject: urgent question on state EUAs

Darcie:

As I mentioned by phone, the Greater Seattle Coronavirus Assessment Network (SCAN) has been operating under a state-issued EUA for its community surveillance partnership with Seattle-King County Public Health since early March, (b) (4) They have been using at-home collection kits for this study.

Pursuant to FDA's changes requiring an approved EUA for home testing, they have been forced to pause their work.

Can you confirm whether it was FDA's intent to halt home testing under state-issued EUAs (b) (4)

(b) (4) **Is it also FDA's intent to halt the state's authority to issue EUAs?**

Thanks for any help. Our folks are confused and would appreciate any clarity. They are also eager to get the SCAN efforts back up and running.

Casey

(b) (6)

From: Jay Shendure <jshendure@uw.edu>

Sent: Tuesday, May 12, 2020 10:49:33 PM

To: Lindquist, Scott W (DOH) <scott.lindquist@doh.wa.gov>; Estes, Honora L (DOH) <honora.estes@doh.wa.gov>; kristin.peterson@doh.wa.gov <kristin.peterson@doh.wa.gov>

Cc: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Christina M Lockwood <tinalock@uw.edu>; Apa, James <James.Apa@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Mark Rieder <mrieder@uw.edu>

Subject: important SCAN updates

[EXTERNAL Email Notice!] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Dear Honora, Scott and Kristin --

I am writing on behalf of the SCAN team to let you know about some important developments that occurred earlier today. As you know, the Northwest Genomics Center SARS-CoV-2 RT-PCR test for SCAN has been operating under a WA-issued EUA for our community surveillance partnership with PHSKC since early March,

(b) (4)

We were notified this morning that consequent to changes in the FDA's EUA guidance around home testing that were made last Friday (5/8), returning SARS-CoV-2 results to patients using at-home collection kits is no longer allowed (b) (4)

(b) (4)

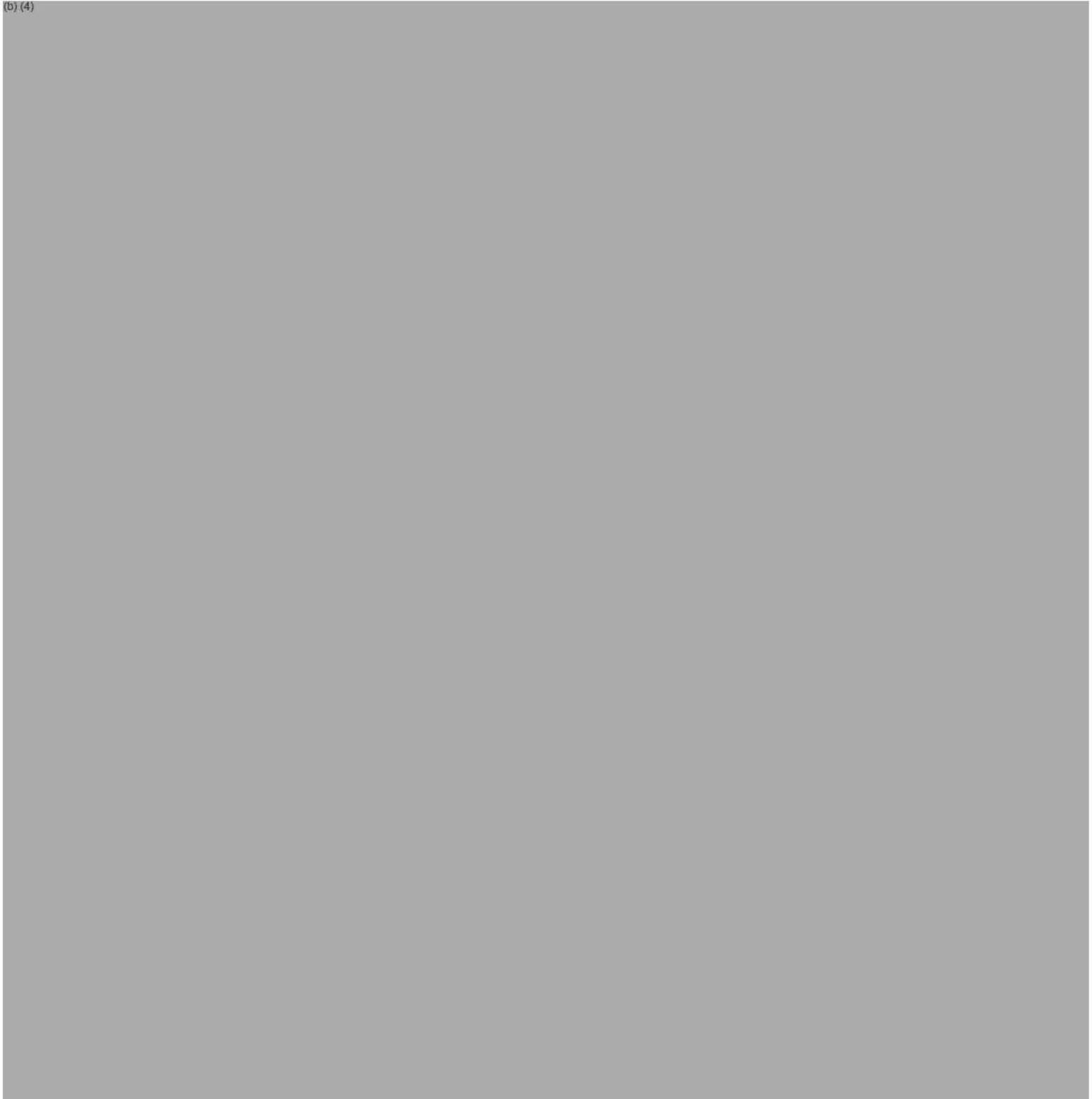
We would welcome the opportunity to discuss these developments with you in the next day or two if we can arrange it. I have cc'd Jeff Duchin and several of his colleagues at PHSKC, as well as Tina Lockwood (our lab director) and Mark Rieder (SCAN's program director).

Best regards,

Jay Shendure

SCAN Statement

(b) (4)



Jay Shendure, MD, PhD
Investigator, Howard Hughes Medical Institute
Director, Allen Discovery Center for Lineage Tracing
Director, Brotman Baty Institute for Precision Medicine
Professor, Genome Sciences, University of Washington
shendure@uw.edu | 206.685.8543



From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/14/2020 1:11:09 PM
To: Madeline Grant [grantm5@uw.edu]
Subject: Accepted: Call with FDA Deputy Commissioner Anand Shah and UW Medicine
Location: (b)(6)
Start: 5/15/2020 12:30:00 PM
End: 5/15/2020 1:00:00 PM
Show Time As: Busy

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/14/2020 10:11:00 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
CC: Stein, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d30a87acb0184261961264ba984b0a51-Peter.Stein]
Subject: RE: Follow up

Dear Gianrico –

I am including Dr. Peter Stein, Director of the Office of New Drugs, who also leads our Coronavirus Treatment Acceleration Program.

Here's an update from Dr. Stein and team:

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



Thanks,
Anand

PRE-DECISIONAL, CONFIDENTIAL

From: Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>
Sent: Wednesday, May 13, 2020 7:57 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Follow up

Here they are and thank you.

(b) (4)



(b) (4)



(b) (4)



Thank you.

From: Shah, Anand [mailto:Anand.Shah@fda.hhs.gov]
Sent: Tuesday, May 12, 2020 4:22 PM
To: Farrugia, Gianrico, M.D.
Subject: [EXTERNAL] Follow up

Dear Gianrico –

Nice to chat with you on today's call with Dr. Hahn.

(b) (4)



Thanks,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/27/2020 2:52:40 PM
To: Rusckowski, Stephen H [Stephen.H.Rusckowski@questdiagnostics.com]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: RE: Unobserved COVID 19 Self Collection Kit EUA for Quest Diagnostics

Dear Steve –

Thanks for checking in. I've cc'd our Device center leadership team and we will reach out shortly.

Best,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Rusckowski, Stephen H <Stephen.H.Rusckowski@questdiagnostics.com>
Sent: Monday, April 27, 2020 10:06 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Unobserved COVID 19 Self Collection Kit EUA for Quest Diagnostics

Anand:

I am writing to ask for your help.

We have been working with the FDA on an EUA for an observed self collection kit for COVID19. We were hopeful that we would hear soon since the FDA team says they have everything they need from us.

This kit approval is very important to simplify our testing and increasing our capacity.

We would appreciate any help to move the process along.

Thank you very much.

Steve Rusckowski
Quest Diagnostics
Chairman, President and CEO

Get [Outlook for iOS](#)

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/4/2020 5:11:31 PM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: RE: Thank You

Thanks for your kind note, Peter
Anand

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Monday, May 4, 2020 5:08 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Thank You

Dear Jeff and Anand,
Just a quick note to share a sincere thank you for the Insight Antibody test column today on FDA.gov.
Very much appreciate all that you and your staff members are doing to keep our country safe.
Warm regards,
Peter

Peter E. Shearstone
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642
Internal extension 110-1333
peter.shearstone@thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/8/2020 10:20:59 AM
To: Eppler, Machele M. [machele.eppler@thermofisher.com]; Sipes, Grail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccee8d18ee1f4a36885078f780c2f2f8-SIPESG]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Thermo Fisher Covid-19 (b) (4)

Also meant to include Julie Tierney, Chief of Staff, Center for Biologics Evaluation and Research (CBER)
Thank you
Anand

From: Shah, Anand
Sent: Friday, May 8, 2020 10:20 AM
To: Eppler, Machele M. <machele.eppler@thermofisher.com>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Subject: RE: Thermo Fisher Covid-19 (b) (4)

Hi Machele -

Thanks for your note. I'm looping in my colleague Grail Sipes, Deputy Center Director for Regulatory Policy at our Center for Drug Evaluation and Research (CDER), for guidance.
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Eppler, Machele M. <machele.eppler@thermofisher.com>
Sent: Thursday, May 7, 2020 11:52 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Thermo Fisher Covid-19 (b) (4)

Dear Mr. Anand Shah,

My name is Machele Eppler and I am the VP of Quality, North America Drug Product Division, Pharma Services Group at Thermo Fisher Scientific.

(b) (4)



Best regards,
Machelle Eppler
VP of Quality, North America Drug Product Division
Thermo Fisher Scientific.

Machelle Eppler
Vice President Quality & Global Regulatory
Drug Product Division – North America
(919) 268-1262
Machelle.eppler@thermofisher.com



From: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Sent: 4/6/2020 9:01:47 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Casper, Marc N. [marc.casper@thermofisher.com]
CC: Werner, Mechelle [mechelle.werner@thermofisher.com]
Subject: Ext Call - Marc Casper (Thermo Fisher) / Anand Shah (FDA)
Location: (b)(6)
Start: 4/6/2020 12:00:00 PM
End: 4/6/2020 12:30:00 PM
Show Time As: Busy

Required Attendees: Casper, Marc N.

Marc's direct line: (b)(6)

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

210-795-0506 US Toll

877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

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

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/6/2020 8:59:01 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
CC: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]
Subject: RE: Note from FDA

Thanks, Marc. Jenna will send a cal invite with this number at 12pm today.
Anand

From: Casper, Marc N. <marc.casper@thermofisher.com>
Sent: Monday, April 6, 2020 8:57 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: RE: Note from FDA

Anand,
Before 9:30AM at (b)(6) or noon to 1:30 at same number.
Thanks,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, April 6, 2020 8:55 AM
To: Casper, Marc N. <marc.casper@thermofisher.com>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: RE: Note from FDA

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Marc -
TF platform expansion for COVID serology testing
Anand

From: Casper, Marc N. <marc.casper@thermofisher.com>
Sent: Monday, April 6, 2020 8:54 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: RE: Note from FDA

Dear Anand,
What is the topic so that I can be prepared to be helpful?

Thanks,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, April 6, 2020 8:44 AM
To: Casper, Marc N. <marc.casper@thermofisher.com>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: Note from FDA

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Dear Marc –
What is the best mobile # to reach you this morning?
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/6/2020 9:57:26 AM
To: farrugia.gianrico@mayo.edu
CC: Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: Follow up from HHS

Dear Dr. Farrugia –

It was great to connect with you and your team on today's call with the Secretary. We look forward to working with you.

(b) (4)

I've also included my colleagues including Dr. Rick Bright from BARDA and Dr. Tammy Beckham from HHS.

Thank you

Best,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Sent: 4/6/2020 9:01:49 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Ext Call - Marc Casper (Thermo Fisher) / Anand Shah (FDA)
Location: AS to call (b)(6)
Start: 4/6/2020 12:00:00 PM
End: 4/6/2020 12:30:00 PM
Show Time As: Tentative

Required Attendees: Casper, Marc N.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/7/2020 5:25:52 PM
To: Sachs, Alan B. [Alan.Sachs@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
CC: Casper, Marc N. [marc.casper@thermofisher.com]; Shearstone, Peter E. [peter.shearstone@thermofisher.com]
Subject: Ext Call - Thermo Fisher Follow Up

Hi Alan,
Good to connect and thanks for this follow up
Jenna is going to help us schedule a call with me, Dr. Tim Stenzel, and Dr. Jeet Guram.
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Sachs, Alan B. <Alan.Sachs@thermofisher.com>
Sent: Monday, April 6, 2020 12:28 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Casper, Marc N. <marc.casper@thermofisher.com>
Subject: Alan Sachs Thermo Fisher Scientific contact information

Anand,

Thank you very much for reaching out to Thermo Fisher Scientific today. My contact information is listed below.

(b) (4)



Alan

Alan Sachs, M.D., Ph.D.
Chief Scientific Officer

Thermo Fisher Scientific
5781 Van Allen Way | Carlsbad, CA 92008
Tel: +1 510 410 6921
Mobile: alan.sachs@thermofisher.com | www.thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/6/2020 1:31:49 PM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]; Casper, Marc N. [marc.casper@thermofisher.com]; alan.sachs@thermofisher.com
CC: Zembowier, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]
Subject: Ext Call - Mayo / Thermo Fisher / FDA

Hi Gianrico –

I've copied Marc Casper and Alan Sachs from Thermo Fisher.

Can this group find 20 min later today for a brief intro to Mayo and TF (b) (4) I'd like to help connect dots.

Please feel free to include your SMEs.

Jenna can help us schedule

Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/8/2020 2:40:46 PM
To: Sachs, Alan B. [Alan.Sachs@thermofisher.com]; Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]
CC: Casper, Marc N. [marc.casper@thermofisher.com]; peter.shearstone@thermofisher.com
Subject: RE: Alan Sachs Thermo Fisher Scientific contact information

Hi Tammy –

Per our discussion earlier this morning, I am connecting you and Admiral Giroir with the leadership of Thermo Fisher.

FDA had a follow up call with TF today, and we thought it would be great if they could connect with you as well.

Best,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Sachs, Alan B. <Alan.Sachs@thermofisher.com>
Sent: Monday, April 6, 2020 12:28 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Casper, Marc N. <marc.casper@thermofisher.com>
Subject: Alan Sachs Thermo Fisher Scientific contact information

Anand,

Thank you very much for reaching out to Thermo Fisher Scientific today. My contact information is listed below.

(b) (4)



Alan

Alan Sachs, M.D., Ph.D.
Chief Scientific Officer

Thermo Fisher Scientific
5781 Van Allen Way | Carlsbad, CA 92008
Tel: +1 510 410 6921
Mobile: alan.sachs@thermofisher.com | www.thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/8/2020 12:31:23 PM
To: Pettiti, Gianluca [Gianluca.Pettiti@thermofisher.com]; Sachs, Alan B. [Alan.Sachs@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; peter.shearstone@thermofisher.com; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
CC: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Wilkins, Donna M. [donna.wilkins@thermofisher.com]
Subject: Ext Call - Thermo Fisher Follow Up
Location: (b)(6)
Start: 4/8/2020 2:30:00 PM
End: 4/8/2020 2:45:00 PM
Show Time As: Tentative

Required Attendees: Pettiti, Gianluca; Sachs, Alan B.; Stenzel, Timothy; peter.shearstone@thermofisher.com; Guram, Jeet

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

210-795-0506 US Toll

877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/7/2020 5:05:54 PM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]
CC: Sachs, Alan B. [Alan.Sachs@thermofisher.com]
Subject: RE: Serology Opportunities

Hi Peter –

I am going to copy you on my reply to Alan's note momentarily
Anand

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Tuesday, April 7, 2020 3:47 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Sachs, Alan B. <Alan.Sachs@thermofisher.com>
Subject: Serology Opportunities

Dear Dr. Shah,

Hope you and yours are well.

Reaching out to check on your availability for a call with our Chief Scientific Officer Alan Sachs and I to discuss feedback and questions from yesterday's call concerning serology COVID testing.

Dr. Sachs and I can be available as your schedule allows.

Warm regards,
Peter

Peter E. Shearstone

Vice President

Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.

168 Third Avenue | Waltham, Massachusetts 02451

Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642

Internal extension 110-1333

peter.shearstone@thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 1/30/2020 9:00:20 AM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
Subject: RE: FDA visit 1/30

Hi Nilay –

Thanks for your note and good to hear from you

Unfortunately today doesn't work for me, but do let me know next time you're here

Thanks,

Anand

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Wednesday, January 29, 2020 12:09 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FDA visit 1/30

Dear Anand –

Congratulations on your new role at the FDA! I suspect you wouldn't remember me, but we met last year as part of a Mayo Clinic visit to CMMI (with Kavita Patel). As I saw that you recently transitioned to the FDA, I wanted to reach out to you. I co-lead (with Joe Ross from Yale) a FDA-funded Center for Excellence in Regulatory Science and Innovation (CERSI) and we have had great opportunities to partner with the agency on a variety of important problems. As part of the CERSI, Joe and I visit the FDA almost every month and will be at the agency tomorrow. I wanted to see if you would have a few minutes to meet with us tomorrow. I am sure you are very busy with the recent move, but thought I would reach out in case you had some time to meet. If not, it would be great to connect with you during one of our future visits.

Thanks in advance for considering this.

Nilay

Nilay Shah, PhD

Chair, Division of Health Care Policy and Research

Robert E. and Patricia E. Kern Endowed Director for Research, Kern Center for the Science of Health Care Delivery

Associate Professor of Health Services Research

Mayo Clinic

Rochester, MN

Ph: 507-266-5130

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/12/2020 8:45:37 PM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Accepted: APHL/Commissioner Hahn
Location: (b)(6)
Start: 4/14/2020 10:30:00 AM
End: 4/14/2020 11:00:00 AM
Recurrence: (none)

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/17/2020 10:48:29 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE:

Hi Mark -
Thank you very much.
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 10:36 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

Dear Anand

Per your phone call, Thermo Fisher

(b) (4)



Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 10:24 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Subject: <no subject>

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/17/2020 4:23:21 PM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Patel, Chaitali [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815d91f3d5e143b387acd82539f7e149-Chaitali.Pa]
Subject: RE:

Thank you –
Anand

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Tuesday, March 17, 2020 3:03 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Stevenson, Mark <mark.stevenson@thermofisher.com>
Cc: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>
Subject: RE:

Dr Shah – short update

(b) (4)

Thank you.
Peter

Peter E. Shearstone
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642
Internal extension 110-1333
peter.shearstone@thermofisher.com

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 1:56 PM
To: Stevenson, Mark <mark.stevenson@thermofisher.com>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>
Subject: RE:

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Mark -
Do you have additional details on the highlighted?
Anand

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 11:28 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

(b) (4)

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 11:17 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: Peter Shearstone <peter.shearstone@thermofisher.com>
Subject: RE:

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark -
To clarify, (b) (4)
Anand

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 10:36 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

Dear Anand

Per your phone call, Thermo Fisher

(b) (4)

Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 10:24 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Subject: <no subject>

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/18/2020 11:56:29 AM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Fenton, Tim [tim.fenton@thermofisher.com]
Subject: RE: Daily Production and Shipping Data - Thermo Fisher Scientific

Thank you, Peter

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Wednesday, March 18, 2020 11:54 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Fenton, Tim <tim.fenton@thermofisher.com>
Subject: Daily Production and Shipping Data - Thermo Fisher Scientific

Dear Dr. Shah, Dr. Stenzel,

Good morning.

Please see attached our daily report for Thermo Fisher COVID-19 kit production and shipments.
Please revert with questions.

Best,
Peter

Peter E. Shearstone
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642
Internal extension 110-1333
peter.shearstone@thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/17/2020 11:30:39 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
Subject: RE:

Thanks for this additional data.

+Tim Stenzel and flagging below for him

PRE-DECISIONAL, CONFIDENTIAL

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 11:28 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

(b) (4)



From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 11:17 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: Peter Shearstone <peter.shearstone@thermofisher.com>
Subject: RE:

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark –
To clarify, (b) (4)
Anand

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 10:36 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

Dear Anand

Per your phone call, Thermo Fisher

(b) (4)



Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 10:24 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Subject: <no subject>

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000045

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/26/2020 4:59:20 PM
To: McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]
CC: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; 'nietersSu.Piper@mayo.edu' [nietersSu.Piper@mayo.edu]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]
Subject: RE: Assistance with serologic test kit clearance/delivery

Hi Judy -
Thank you!
Anand

From: McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Sent: Thursday, March 26, 2020 4:49 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; 'nietersSu.Piper@mayo.edu' <nietersSu.Piper@mayo.edu>; Cave, Carol <Carol.Cave@fda.hhs.gov>
Subject: FW: Assistance with serologic test kit clearance/delivery

Hi Anand---I heard back from Dan Solis, Director, Division of West Coast Imports who stated this shipment has been cleared and the entry has been released.
I left a voice message for Piper letting her know the entry has been released, thanks!
Judy

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Thursday, March 26, 2020 2:29 PM
To: McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: FW: Assistance with serologic test kit clearance/delivery

Hi Judy -
Is ORA able to reach out to Mayo here?
Anand

From: Nieters Su, Piper L. <NietersSu.Piper@mayo.edu>
Sent: Thursday, March 26, 2020 2:16 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Assistance with serologic test kit clearance/delivery

Good afternoon,

I am writing with the hope that you may be able to point me in the right direction. As you may know, Mayo Clinic has been working to quickly develop serologic test for use in fighting the COVID-19 pandemic. We are making good progress and awaiting a shipment of tests kits from (b) (4) that we hope to receive tomorrow. We are tracking the shipment

closely and know that it has been received at (b) (4) The shipment is released from USDA and Customs but FDA status is still pending. The customs agent is optimistic that it will clear FDA but we have experienced delays and want to assure that this shipment of serology kits can make it to the lab for assessment and/or validation tomorrow. I am attaching the relevant shipping forms and documents that may be helpful but is there someone at FDA who might be able to assist us with clearance for the final leg of this journey?

Thanks so much- your team has helped with many issues over the past few weeks and it is much appreciated as we try to enhance our testing capabilities.

Best, Piper

Piper Nieters Su
Chair, Division of External Relations
Mayo Clinic
200 First Street SW
Rochester, MN 55905
507.266.4812 (office) 703.340.6926 (cell)

Mayo Clinic is again the No. 1 hospital in U.S. News & World Report's "Best Hospitals" rankings and top ranked in twelve specialties.

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 9/11/2020 10:39:42 AM
To: Thomas Sparkman [tsparkman@acla.com]; Weems, Peter [PWeems@medicalimaging.org]; Mark Leahey [mleahey@medicaldevices.org]; Trunzo, Janet [JTrunzo@advamed.org]; Plato, Carole [CPlato@advamed.org]; Sheri Devinney [sdevinney@medicaldevices.org]; Zimmerman, Barbara C. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ad72be1b154a9b9700564ccbb765b5-BXZ]
CC: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Olson, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95aa7d534c3f49fe8622f8a895b218ea-EOlson]
Subject: RE: Preparation for MDUFA V Negotiations
Attachments: October 27: Virtual Public Meeting – Reauthorization of MDUFA for 2023-2027

Tom,

Thank you for sending this. I am adding Barb Zimmerman to this thread, as she has agreed to be FDA's point person for the data request and will be reaching out directly to discuss timing and any follow-up questions that we may have.

Separately, I hope you all saw that FDA published the Federal Register Notice announcing the public meeting to be held on October 27th. I am attaching the email that was sent to stakeholders with the relevant details. We very much look forward to your organizations' participation in the meeting.

Best regards,
Lauren

Lauren K. Roth
Associate Commissioner for Policy
U.S. Food and Drug Administration

From: Thomas Sparkman <tsparkman@acla.com>
Sent: Friday, September 11, 2020 10:19 AM
To: Weems, Peter <PWeems@medicalimaging.org>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Mark Leahey <mleahey@medicaldevices.org>; Trunzo, Janet <JTrunzo@advamed.org>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>
Cc: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: RE: Preparation for MDUFA V Negotiations

Picking back up on this e-mail chain and Peter's August question.

I'm attaching ACLA's additions to the data requests from AdvaMed, MIDA, and MDMA shared earlier this year.

Best,
--Tom

Tom Sparkman | Senior Vice President, Government Affairs and Policy | ACLA | tsparkman@acla.com | 202-637-9466 (o)

From: Weems, Peter <PWeems@medicalimaging.org>
Sent: Wednesday, August 19, 2020 9:19 AM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Mark Leahey <mleahey@medicaldevices.org>; Trunzo, Janet <JTrunzo@advamed.org>; Thomas Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri

Devinney <sdevinney@medicaldevices.org>

Cc: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>

Subject: RE: Preparation for MDUFA V Negotiations

Hi Lauren,

I just wanted to check in on the status of the data request we put in earlier this year. Do you have any updates on when you will be able to share more information?

Thanks,

Peter

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>

Sent: Thursday, July 23, 2020 10:16 AM

To: Mark Leahey <mleahey@medicaldevices.org>; Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>

Cc: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>

Subject: RE: Preparation for MDUFA V Negotiations

All,

Thank you again for your quick replies yesterday. We will plan to move forward with the public meeting on **Tuesday, October 27th**.

Best regards,
Lauren

From: Roth, Lauren

Sent: Wednesday, July 22, 2020 10:09 AM

To: Mark Leahey <mleahey@medicaldevices.org>

Cc: Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>

Subject: RE: Preparation for MDUFA V Negotiations

All,

Thanks to Mark and Janet for the quick reply yesterday. Based on those replies, there did not appear to be one day that worked well, so I'm suggesting two new dates below. Can you please let me know if either **October 27 or October 28** will not work for you?

Many thanks,
Lauren

Lauren K. Roth
Associate Commissioner for Policy
U.S. Food and Drug Administration

From: Mark Leahey <mleahey@medicaldevices.org>

Sent: Tuesday, July 21, 2020 2:19 PM

To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>

Cc: Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: Re: Preparation for MDUFA V Negotiations

Lauren,
Good to hear from you and thanks for all your efforts.

(b) (4)

Can make all other dates work.
All the best,
Mark

On Tue, Jul 21, 2020 at 10:41 AM Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

Janet, Mark, Peter, and Tom,

I hope this finds you safe and well. When we last spoke, we agreed it made sense to postpone the MDUFA V public meeting, given the around-the-clock focus on COVID-19 response. CDRH continues to work at a breakneck pace on the response effort, but given that we're rounding into the second half of 2020, Dr. Shuren agrees that we should also restart MDUFA V negotiation planning. To that end, we're looking to reschedule the public meeting for date in October. Like the GDUFA and PDUFA public meetings that are occurring this week, the MDUFA meeting would be entirely virtual, and I anticipate that it would last from 9 a.m. – approximately 2 p.m.

We hope that you'll be able to join us and participate in the meeting. To aid our planning process, can you please advise if any of the following dates would not work for your schedules? They are:

- **Friday, October 2**
- **Thursday, October 15**
- **Wednesday, October 21**
- **Friday, October 23**

Please don't hesitate to reach out to me with any questions.

Many thanks,
Lauren

Lauren K. Roth, J.D.
Associate Commissioner for Policy

Office of Policy
U.S. Food and Drug Administration
(240) 402-1671
lauren.roth@fda.hhs.gov



U.S. FOOD & DRUG
ADMINISTRATION

--

Mark B. Leahey
President & CEO
MDMA
1333 H St
Suite 400 West
Washington, DC 20005
www.medicaldevices.org

From: U.S. Food and Drug Administration [fda@info.fda.gov]
Sent: 9/4/2020 10:21:10 AM
To: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaeef84cef160-DJS]
Subject: October 27: Virtual Public Meeting – Reauthorization of MDUFA for 2023-2027

If your email program has trouble displaying this email, [view it as a web page](#).

October 27: Virtual Public Meeting – Reauthorization of MDUFA for 2023-2027

The U.S. Food and Drug Administration (FDA) is announcing that the public meeting “Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027” will now be held on Tuesday, October 27, 2020 by webcast only beginning at 9:00 a.m. Eastern Time. If you have already registered, no action on your part is necessary.

The purpose of this public meeting is to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years 2023 through 2027. Interested participants may continue to register and, if applicable, specify that they would like to present during the meeting.

[Learn More and Register](#)

Important Deadlines

- September 28, 2020: Request to make oral presentations during the public comment session or a specific session.
- October 23, 2020: Register to view the meeting.
- November 27, 2020: Submit comments to the docket FDA-2020-N-0907.

Questions?

If you have questions about this public workshop, contact CDRH-OPEQ-StrategicInitiatives@fda.hhs.gov.



U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

[Privacy Policy](#) | www.fda.gov

[Manage Preferences or Unsubscribe from this List](#) | [Unsubscribe from all Email Lists](#)

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 9/25/2020 11:31:35 AM
To: Trunzo, Janet [JTrunzo@advamed.org]; Mark Leahey [mleahey@medicaldevices.org]; Weems, Peter [PWeems@medicalimaging.org]; Tom Sparkman [tsparkman@acla.com]
CC: Malone, Misti [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3b751d45f1e4749af19f1b5250ba753-Misti.Malon]; Zimmerman, Barbara C. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ad72be1b154a9b9700564ccbb765b5-BXZ]
Subject: MDUFA 5 Public Meeting and Negotiation Planning

Janet, Mark, Peter, and Tom,

I hope this finds you all well. The team gave me an update on your call yesterday about the MDUFA data call; we appreciated the dialogue so we can get started with pulling the requested information.

They mentioned that you had asked about logistics for the public meeting as well. To confirm what they explained, you do not need to register to participate as speakers, since we are already planning to include an industry panel on the agenda. However, we ask that you complete the general registration for the meeting at least; this way, you will automatically receive updates with the agenda and other logistics. (Tom and Peter -- We have your registration confirmation, so you are all set.) After registration for speakers closes next week, we will reach out to discuss potential agenda times for the industry panel. We request that you provide your presentation slides, if any, by October 20, 2020.

As we begin to prepare for the negotiations, I would like to connect with you about scheduling and logistics in the next few weeks. My initial thinking is that, because the public docket for the meeting is scheduled to close on November 27th, I would like to plan for one initial kickoff negotiation meeting in early December. Then, starting in January, we could begin a more robust series of negotiations. The team will reach out to you about scheduling that touch-base discussion under separate cover.

I look forward to getting started!

Best regards,
Lauren

Lauren K. Roth
Associate Commissioner for Policy
Office of Commissioner
Office of Policy
U.S. Food and Drug Administration
Tel: (240) 402-1671
lauren.roth@fda.hhs.gov



From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 7/22/2020 11:05:37 AM
To: Thomas Sparkman [tsparkman@acla.com]
Subject: RE: Preparation for MDUFA V Negotiations

Great. Thank you again.

From: Thomas Sparkman <tsparkman@acla.com>
Sent: Wednesday, July 22, 2020 10:15 AM
To: Weems, Peter <PWeems@medicalimaging.org>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Mark Leahey <mleahey@medicaldevices.org>
Cc: Trunzo, Janet <JTrunzo@advamed.org>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: RE: Preparation for MDUFA V Negotiations

10/27 and 10/28 are open for me at this time.

Tom Sparkman | Senior Vice President, Government Affairs and Policy | ACLA | tsparkman@acla.com | 202-637-9466 (o)

From: Weems, Peter <PWeems@medicalimaging.org>
Sent: Wednesday, July 22, 2020 10:14 AM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Mark Leahey <mleahey@medicaldevices.org>
Cc: Trunzo, Janet <JTrunzo@advamed.org>; Thomas Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: RE: Preparation for MDUFA V Negotiations

Hi Lauren,

Either 10/27 or 10/28 would work for me.

Thanks,

Peter

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Wednesday, July 22, 2020 10:09 AM
To: Mark Leahey <mleahey@medicaldevices.org>
Cc: Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: RE: Preparation for MDUFA V Negotiations

All,

Thanks to Mark and Janet for the quick reply yesterday. Based on those replies, there did not appear to be one day that worked well, so I'm suggesting two new dates below. Can you please let me know if either **October 27** or **October 28** will not work for you?

Many thanks,
Lauren

Lauren K. Roth
Associate Commissioner for Policy
U.S. Food and Drug Administration

From: Mark Leahey <mleahey@medicaldevices.org>
Sent: Tuesday, July 21, 2020 2:19 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: Re: Preparation for MDUFA V Negotiations

Lauren,
Good to hear from you and thanks for all your efforts.

(b) (4)

Can make all other dates work.
All the best,
Mark

On Tue, Jul 21, 2020 at 10:41 AM Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

Janet, Mark, Peter, and Tom,

I hope this finds you safe and well. When we last spoke, we agreed it made sense to postpone the MDUFA V public meeting, given the around-the-clock focus on COVID-19 response. CDRH continues to work at a breakneck pace on the response effort, but given that we're rounding into the second half of 2020, Dr. Shuren agrees that we should also restart MDUFA V negotiation planning. To that end, we're looking to reschedule the public meeting for date in October. Like the GDUFA and PDUFA public meetings that are occurring this week, the MDUFA meeting would be entirely virtual, and I anticipate that it would last from 9 a.m. – approximately 2 p.m.

We hope that you'll be able to join us and participate in the meeting. To aid our planning process, can you please advise if any of the following dates would not work for your schedules? They are:

- **Friday, October 2**
- **Thursday, October 15**
- **Wednesday, October 21**
- **Friday, October 23**

Please don't hesitate to reach out to me with any questions.

Many thanks,
Lauren

Lauren K. Roth, J.D.
Associate Commissioner for Policy

Office of Policy

U.S. Food and Drug Administration

(240) 402-1671

lauren.roth@fda.hhs.gov



--

Mark B. Leahey

President & CEO

MDMA

1333 H St

Suite 400 West

Washington, DC 20005

www.medicaldevices.org

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 3/25/2020 8:30:54 AM
To: Trunzo, Janet [JTrunzo@AdvaMed.org]; Leahey, Mark B. [mleahey@medicaldevices.org]
CC: Weems, Peter [PWeems@medicalimaging.org]; Tom Sparkman [tsparkman@acla.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Sheri Devinney [sdevinney@medicaldevices.org]
Subject: RE: MDUFA V Data request

Thank you all. Looks like May 5th is the best for all. Please hold that date, and I will confirm once it is settled.

Best regards,
Lauren

From: Trunzo, Janet <JTrunzo@AdvaMed.org>
Sent: Tuesday, March 24, 2020 3:59 PM
To: Leahey, Mark B. <mleahey@medicaldevices.org>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Sheri Devinney <sdevinney@medicaldevices.org>
Subject: RE: MDUFA V Data request

Prefer May 5 but could make the 4th as a second option.

From: Mark Leahey <mleahey@medicaldevices.org>
Sent: Tuesday, March 24, 2020 3:54 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Trunzo, Janet <JTrunzo@AdvaMed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Sheri Devinney <sdevinney@medicaldevices.org>
Subject: Re: MDUFA V Data request

Will make MAY 4th adn 5th work.
Conflict on the 8th.
thx

On Tue, Mar 24, 2020 at 2:59 PM Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

Janet, Mark, Peter, and Tom,

Thank you again for the call on Friday about the public meeting. We've looked at calendars and teleconference capabilities here, and the best potential new dates for FDA are:

- Monday, May 4th
- Tuesday, May 5th, or
- Friday, May 8th.

If you have a preference for any of these dates, please let me know and we'll do our best to find a date that works for everyone. If possible, I would appreciate your reply by tomorrow, so that we can provide a timely update on our website.

Best regards,

Lauren

From: Roth, Lauren

Sent: Friday, March 20, 2020 5:33 PM

To: Trunzo, Janet <JTrunzo@AdvaMed.org>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>

Cc: Leahey, Mark B. <mleahey@medicaldevices.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>

Subject: RE: MDUFA V Data request

Janet,

Thanks very much, and have a safe weekend.

From: Trunzo, Janet <JTrunzo@AdvaMed.org>

Sent: Friday, March 20, 2020 4:39 PM

To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>

Cc: Leahey, Mark B. <mleahey@medicaldevices.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>

Subject: MDUFA V Data request

Dear Lauren

Attached is the MDUFA V Data request from AdvaMed, MDMA and MITA. ACLA will provide its request later. Once all date requests are submitted, I recommend that we have a brief conference call to clarify the requests.

Thank you for the conference call today.

Best regards

Janet

--

Mark B. Leahey
President & CEO
MDMA
1333 H St
Suite 400 West
Washington, DC 20005
www.medicaldevices.org

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 3/20/2020 1:11:05 PM
To: Trunzo, Janet [JTrunzo@AdvaMed.org]; Mark Leahey [mleahey@medicaldevices.org]; tsparkman@acla.com; jkhani@acla.com; pweems@medicalimaging.org
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
Subject: Touch base re: preparation for MDUFA

All,

I look forward to joining this afternoon's call to discuss next steps in planning for the MDUFA public meeting. For those of you whom I haven't met yet, I am CDRH veteran and now in FDA's Office of Policy, and I will be FDA's lead negotiator for MDUFA V.

We appreciate you making time to touch base this afternoon, given all of the work that is happening for the COVID-19 response. I know our discussion today will be focused on the public meeting, so I wanted to separately note that we also welcome receiving the industry's data call as soon as possible. We know there are essential, non-COVID related programmatic priorities that must continue to move forward during this time, including preparations for M5 to facilitate negotiations later this year. To the extent that members of our team who are not directly engaged in the COVID response can begin gathering responsive information, that is helpful advance work that we can accomplish.

Should you have any questions related to M5 as we move forward, please don't hesitate to reach out to me.

Best regards,
Lauren

Lauren K. Roth
Associate Commissioner for Policy

Office of Policy
U.S. Food and Drug Administration
(240) 402-1671
lauren.roth@fda.hhs.gov



From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 5/13/2020 11:19:30 AM
To: farrugia.gianrico@mayo.edu; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: Introduction

Hello Dr. Farrugia,

To follow up on the conversation with the Commissioner yesterday, I wanted to introduce you to Dr. Woodcock, who is leading the response on therapeutics, and Dr. Marks, who is leading the vaccine response. Both of them would be happy to chat with you about the work going on at Mayo and their new roles in the COVID response. Please let me know if you need anything else.

Thank you Dr. Marks and Dr. Woodcock in advance for your help here.

Thanks,
Keagan

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 1:59:47 PM
To: Fenton, Tim [tim.fenton@thermofisher.com]
CC: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: VP call follow up

Thanks Tim, been in back to back meetings and haven't caught up with Dr. Hahn yet on the call. I will get back to you shortly.

Thanks,
KL

Sent from my iPhone

On Mar 3, 2020, at 1:11 PM, Fenton, Tim <tim.fenton@thermofisher.com> wrote:

Hi Keagan – Quick follow up on the call w/ VP Pence, Dr. Hahn, Sec. Azar, etc.

Can Peter Shearstone, our VP Global Regulatory, have a quick call w/ Dr. Hahn to make sure we're good to go forward based on the Vice President's comments?

And I can arrange details for Marc's trip to DC tomorrow with you.

Thank you,
Tim

Tim Fenton

Vice President, Global Government Relations

Thermo Fisher Scientific

+1 (202) 257-4277

[@ThermoFisherDC on Twitter](#)

[GR on Yammer internal only](#)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 4:16:28 PM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: RE: VP call follow up

Hi Marc – have asked multiple folks for details, when I receive I will shoot them your way.

KL

From: Casper, Marc N. <marc.casper@thermofisher.com>
Sent: Tuesday, March 3, 2020 3:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: VP call follow up

Keagan,
Do you have any of the logistics details for the meeting tomorrow?
Thanks,
Marc

Sent from my iPhone

On Mar 3, 2020, at 3:49 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hey Tim,

Can you have Peter touch base with Jeff Shuren, I have added him here, on next steps. The Commissioner has not made it back to the office, so if you can explain to Jeff about what was discussed we can figure out the best way to move forward.

Appreciate your help.

Thanks,
Keagan

From: Fenton, Tim <tim.fenton@thermofisher.com>
Sent: Tuesday, March 3, 2020 1:10 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Casper, Marc N. <marc.casper@thermofisher.com>
Subject: VP call follow up

Hi Keagan – Quick follow up on the call w/ VP Pence, Dr. Hahn, Sec. Azar, etc.

Can Peter Shearstone, our VP Global Regulatory, have a quick call w/ Dr. Hahn to make sure we're good to go forward based on the Vice President's comments?

And I can arrange details for Marc's trip to DC tomorrow with you.

Thank you,
Tim

Tim Fenton

Vice President, Global Government Relations

Thermo Fisher Scientific

+1 (202) 257-4277

@ThermoFisherDC on Twitter

GR on Yammer internal only

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 5:41:03 PM
To: Fenton, Tim [tim.fenton@thermofisher.com]
Subject: RE: VP call follow up

Appreciate the follow up.

From: Fenton, Tim <tim.fenton@thermofisher.com>
Sent: Tuesday, March 3, 2020 5:38 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: VP call follow up

Thanks they talked. Appreciate it

Tim Fenton
+1 (202) 257-4277

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 3:49:46 PM
To: Fenton, Tim <tim.fenton@thermofisher.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Casper, Marc N. <marc.casper@thermofisher.com>
Subject: RE: VP call follow up

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hey Tim,

Can you have Peter touch base with Jeff Shuren, I have added him here, on next steps. The Commissioner has not made it back to the office, so if you can explain to Jeff about what was discussed we can figure out the best way to move forward.

Appreciate your help.

Thanks,
Keagan

From: Fenton, Tim <tim.fenton@thermofisher.com>
Sent: Tuesday, March 3, 2020 1:10 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Casper, Marc N. <marc.casper@thermofisher.com>
Subject: VP call follow up

Hi Keagan – Quick follow up on the call w/ VP Pence, Dr. Hahn, Sec. Azar, etc.

Can Peter Shearstone, our VP Global Regulatory, have a quick call w/ Dr. Hahn to make sure we're good to go forward based on the Vice President's comments?

And I can arrange details for Marc's trip to DC tomorrow with you.

Thank you,

Tim

Tim Fenton

Vice President, Global Government Relations

Thermo Fisher Scientific

+1 (202) 257-4277

@ThermoFisherDC on Twitter

GR on Yammer internal only

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/9/2020 5:50:20 PM
To: Fenton, Tim [tim.fenton@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: O'Brien, Ron [ron.obrien@thermofisher.com]; Shearstone, Peter E. [peter.shearstone@thermofisher.com]
Subject: RE: EUA announcement collaboration on press release?

Hi Tim,

Thank you for reaching out. I will check with our media team, but we do not normally do joint communication with a company we would be authorizing, nor would we include a quote from the Commissioner. As you know, the Commissioner has been speaking almost daily with the press after the task force meetings, so once you all go public, it would likely come up in one of those briefings and he would likely reference your authorization.

Let me know if you have questions.

Thanks,
Keagan

From: Fenton, Tim <tim.fenton@thermofisher.com>
Sent: Monday, March 9, 2020 1:02 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: O'Brien, Ron <ron.obrien@thermofisher.com>; Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Fenton, Tim <tim.fenton@thermofisher.com>
Subject: EUA announcement collaboration on press release?

Keagan, Tim – Thinking ahead and optimistically, Thermo Fisher Scientific is interested in collaborating with FDA on a press release, should we receive approval for the COVID19 EUA. This could take one of several forms: a quotation from Dr. Hahn in our release; a joint release between us; or plenty of other options.

Is FDA interested in working collaboratively on a media release, which would only be used when/if we receive EUA? If so, we'd like to get ahead of the process.

Who's the best person to work thru? From Thermo Fisher, I'm including Ron O'Brien, our head of Public Relations, here. (b)(6) is his cell.

Thanks for considering.

Tim

Tim Fenton

Vice President, Global Government Relations
Thermo Fisher Scientific
+1 (202) 257-4277
@ThermoFisherDC on Twitter
GR on Yammer internal only

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)]
Sent: 4/3/2020 4:12:52 PM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: RE: Do you have time for a call today?

What is best number for you, can call you now?

-----Original Message-----

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Sent: Friday, April 3, 2020 12:59 PM
To: Hahn, Stephen (b) (6) <[REDACTED]@fda.hhs.gov>
Subject: RE: Do you have time for a call today?

Yes, of course. I can jump off a call early at 145 or also have 3-330 open or after 4 pm.

-----Original Message-----

From: Hahn, Stephen (b) (6) <[REDACTED]@fda.hhs.gov>
Sent: Friday, April 3, 2020 12:47 PM
To: Becker, Scott | APHL <Scott.Becker@aphl.org>
Subject: Do you have time for a call today?

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.

Sent from my iPhone

This email has been scanned for spam and viruses by Proofpoint Essentials. Visit the following link to report this email as spam:
https://us1.proofpointessentials.com/index01.php?mod_id=&mod_option=gitem&mail_id=85932414-wkfN9zw0GU0U&r_address=ott.becker%40aphl.org&report=

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/14/2020 10:47:22 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Contact info

Hi Scott – this is my email address. Feel free to pass things along my way.

Thanks,
Keagan

(b)(6) (cell)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/13/2020 7:58:05 AM
To: Julie Khani [jkhani@acla.com]
Subject: Re: Serology

Thanks Julie if we can help your members with these pieces let us know. Appreciate your help.

Sent from my iPhone

> On Apr 13, 2020, at 7:44 AM, Julie Khani <jkhani@acla.com> wrote:
>
> Hi Keagan. Sorry for the delay. I have at least one member working on it. I imagine this will be discussed on the call today with the Commissioner along with collaboration with manufacturers on platforms, some of the challenges with supply shortages, lack of reagent availability, etc. In the meantime, if I have more information before then, I will pass it on.
>
> Thanks.
>
> Julie
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Monday, April 13, 2020 7:35 AM
> To: Julie Khani <jkhani@acla.com>
> Subject: Serology
>
> Hey Julie- checking back if you found any of your labs looking at serology tests. It would be great if they could look into making those tests as they will be imperative to getting folks back to work.
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/9/2020 6:01:02 PM
To: Julie Khani [jkhani@acla.com]
Subject: RE: Serology LDT

Thanks for checking Julie.

From: Julie Khani <jkhani@acla.com>
Sent: Thursday, April 9, 2020 5:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Serology LDT

Hi Keagan. Unlike the molecular testing for COVID-19, I don't think there are/will be many LDTs in the serology space. As I understand it, you'll have labs working with manufacturers on platforms.

Will double check and let you know.

Thanks for reaching out.

Julie

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, April 9, 2020 5:05 PM
To: Julie Khani <jkhani@acla.com>
Subject: Serology LDT

Hi Julie –

Hope you are well.

The Commissioner asked me to check in with you to see if you know how many of your members have done LDT serology tests? Is it possible to get a list, capabilities and where the locations of those labs that have them?

Thanks,
Keagan

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 4/13/2020 7:58:01 AM
To: Julie Khani [jkhani@acla.com]
Subject: Re: Serology

Thanks Julie if we can help your members with these pieces let us know. Appreciate your help.

Sent from my iPhone

> On Apr 13, 2020, at 7:44 AM, Julie Khani <jkhani@acla.com> wrote:
>
> Hi Keagan. Sorry for the delay. I have at least one member working on it. I imagine this will be discussed on the call today with the Commissioner along with collaboration with manufacturers on platforms, some of the challenges with supply shortages, lack of reagent availability, etc. In the meantime, if I have more information before then, I will pass it on.
>
> Thanks.
>
> Julie
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Monday, April 13, 2020 7:35 AM
> To: Julie Khani <jkhani@acla.com>
> Subject: Serology
>
> Hey Julie- checking back if you found any of your labs looking at serology tests. It would be great if they could look into making those tests as they will be imperative to getting folks back to work.
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONER]
Sent: 4/9/2020 12:41:06 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]; morice.william@mayo.edu; sherrie.perkins@aruplab.com; stephen.h.rusckowski@questdiagnostics.com; schecha@labcorp.com; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: EXTERNAL Telecon: Lab CEOs and FDA Commissioner Hahn
Location: (b) (6)
Start: 4/14/2020 11:30:00 AM
End: 4/14/2020 12:00:00 PM
Show Time As: Tentative

Required Attendees: morice.william@mayo.edu; sherrie.perkins@aruplab.com; stephen.h.rusckowski@questdiagnostics.com; schecha@labcorp.com; Shuren, Jeff; Stenzel, Timothy; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anand Shah (Anand.Shah@fda.hhs.gov); Colin Rom (Colin.Rom@fda.hhs.gov)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 4/10/2020 6:10:54 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; morice.william@mayo.edu; sherrie.perkins@aruplab.com; stephen.h.rusckowski@questdiagnostics.com; schecha@labcorp.com; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: EXTERNAL Telecon: Lab CEOs and FDA Commissioner Hahn
Location: (b) (6)
Start: 4/14/2020 11:30:00 AM
End: 4/14/2020 12:00:00 PM
Show Time As: Tentative

Required Attendees: morice.william@mayo.edu; sherrie.perkins@aruplab.com; stephen.h.rusckowski@questdiagnostics.com; schecha@labcorp.com; Shuren, Jeff; Stenzel, Timothy; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anand Shah (Anand.Shah@fda.hhs.gov); Colin Rom (Colin.Rom@fda.hhs.gov)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/26/2020 8:08:52 PM
To: Julie Khani [jkhani@acla.com]
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Ok, let me see if we can get the FDA/CDC team to partner here on that.

Yes, she passed along thanks.

Sent from my iPhone

On Feb 26, 2020, at 7:16 PM, Julie Khani <jkhani@acla.com> wrote:

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

From: Julie Khani <jkhani@acla.com>
Sent: Wednesday, February 26, 2020 2:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available [here](#).

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update and answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ 202-841-8196 (m)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/3/2020 1:59:39 PM
To: Fenton, Tim [tim.fenton@thermofisher.com]
CC: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: VP call follow up

Thanks Tim, been in back to back meetings and haven't caught up with Dr. Hahn yet on the call. I will get back to you shortly.

Thanks,
KL

Sent from my iPhone

On Mar 3, 2020, at 1:11 PM, Fenton, Tim <tim.fenton@thermofisher.com> wrote:

Hi Keagan – Quick follow up on the call w/ VP Pence, Dr. Hahn, Sec. Azar, etc.

Can Peter Shearstone, our VP Global Regulatory, have a quick call w/ Dr. Hahn to make sure we're good to go forward based on the Vice President's comments?

And I can arrange details for Marc's trip to DC tomorrow with you.

Thank you,
Tim

Tim Fenton

Vice President, Global Government Relations

Thermo Fisher Scientific

+1 (202) 257-4277

@ThermoFisherDC on Twitter

GR on Yammer internal only

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/14/2020 4:00:26 PM
To: Bartkus, Joanne (MDH) [joanne.bartkus@state.mn.us]; Becker, Scott | APHL [Scott.Becker@aphl.org]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) -Stephen.Hah]
Subject: RE: Serology Result

Thanks for flagging, Scott and Joanne. I am working with Jeff to identify the right person for you to filter these examples to in the future. We greatly appreciate the information.

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Sent: Tuesday, April 14, 2020 3:19 PM
To: Becker, Scott | APHL <Scott.Becker@aphl.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6)@fda.hhs.gov
Subject: RE: Serology Result

I believe that this company does the collection and sends the specimen out to another laboratory for testing, so it's not clear what test is being used. It is concerning to me that individuals are being told to discontinue social distancing based solely on the results of this test. I am wondering if FDA can provide additional wording to their guidance regarding the interpretation of individual test results in the context of public health guidance and state executive orders.

Joanne

Joanne Bartkus, PhD
Director | Public Health Laboratory

Minnesota Department of Health
Office: 651-201-5256 | Mobile: 651-303-6229



From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Sent: Tuesday, April 14, 2020 2:08 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6)@fda.hhs.gov; Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Subject: FW: Serology Result

Hi all,

As discussed, here a recent example of the kind of problem that members described on our call. I did not see this firm on the section IV.D list so an example of what's going on. Joanne Bartkus (MN) copied here, sent this our way. Keagan, shall I just forward these to you directly in the future?

Thanks, Scott

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>

Sent: Tuesday, April 14, 2020 2:53 PM

To: Becker, Scott | APHL <Scott.Becker@aphl.org>; Crumpler, Megan <mcrumpler@ochca.com>; Ishida, Maria <maria.ishida@agriculture.ny.gov>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>; Steece, Richard <richard.steece@tn.gov>; Toney, Denise <denise.toney@dgs.virginia.gov>; Tran, Tony <Anthony.tran@dc.gov>; Wade, Mark <mark.wade@sanantonio.gov>; Ware, Daphne <daphne.ware@msdh.ms.gov>; Whitmar, Bill <Bill.Whitmar@health.mo.gov>; Shult, Peter <peter.shult@slh.wisc.edu>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Taylor, Jill <jill.taylor@health.ny.gov>; Ball, Chris <BallC1@dhw.idaho.gov>; Southern, Tim <tim.southern@state.sd.us>; Kimsey, Paul <paul.kimsey@cdph.ca.gov>; Kyriacopoulos, Peter | APHL <Peter.Kyriacopoulos@aphl.org>; Mangal, Chris | APHL <Chris.Mangal@aphl.org>; Wroblewski, Kelly | APHL <kelly.wroblewski@aphl.org>; Blank, Eric | APHL <eric.blank@aphl.org>; Hahn, Stephen ^{(b) (6)} <@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>

Subject: Serology Result

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.

Hi All,

Please see the attached serology report . Note that the result indicates that a positive result indicates that the individual should stop social distancing even though the report has a disclaimer that the test may cross-react with other coronaviruses. This is, as Jen has stated repeatedly, dangerous.

Here is the wording from their website

The ARCpoint Labs COVID-19 Antibody Test was designed for this purpose. With this simple finger stick test, you will learn whether you have been exposed to the virus and if your immune system has produced antibodies and already fought off the infection, making it safe for you to return to work/school.

Joanne Bartkus, PhD

Director | Public Health Laboratory

Minnesota Department of Health

Office: 651-201-5256 | Mobile: 651-303-6229

**m1 DEPARTMENT
OF HEALTH**

[Redacted]

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

From: Becker, Scott | APHL <Scott.Becker@aphl.org>

Sent: Saturday, April 11, 2020 5:42 PM

To: Becker, Scott | APHL; Bartkus, Joanne (MDH); Crumpler, Megan; Ishida, Maria; Kubin, Grace; Steece, Richard; Toney, Denise; Tran, Tony; Wade, Mark; Ware, Daphne; Whitmar, Bill; Shult, Peter; Rakeman, Jennifer; Taylor, Jill; Ball, Chris;

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000083

Southern, Tim; Kimsey, Paul; Kyriacopoulos, Peter | APHL; Mangal, Chris | APHL; Wroblewski, Kelly | APHL; Blank, Eric | APHL; Hahn, Stephen; Sheehy, Janice

Subject: APHL/Commissioner Hahn

When: Tuesday, April 14, 2020 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: (b) (6)

This message may be from an external email source.

Do not select links or open attachments unless verified. Report all suspicious emails to Minnesota IT Services Security Operations Center.

Please hold for discussion between APHL BOD and select members and Dr. Stephen Hahn, Commissioner of FDA.

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/26/2020 8:08:56 PM
To: Julie Khani [jkhani@acla.com]
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Ok, let me see if we can get the FDA/CDC team to partner here on that.

Yes, she passed along thanks.

Sent from my iPhone

On Feb 26, 2020, at 7:16 PM, Julie Khani <jkhani@acla.com> wrote:

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

From: Julie Khani <jkhani@acla.com>
Sent: Wednesday, February 26, 2020 2:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available [here](#).

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update and answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ 202-841-8196 (m)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 4/14/2020 3:15:12 PM
To: Becker, Scott | APhL [Scott.Becker@aphl.org]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) -Stephen.Hah]; Bartkus, Joanne [joanne.bartkus@state.mn.us]
Subject: Re: Serology Result

Thanks Scott. Feel free to send my way and I can filter appropriately.

Sent from my iPhone

On Apr 14, 2020, at 3:13 PM, Becker, Scott | APhL <Scott.Becker@aphl.org> wrote:

Hi all,

As discussed, here a recent example of the kind of problem that members described on our call. I did not see this firm on the section IV.D list so an example of what's going on. Joanne Bartkus (MN) copied here, sent this our way. Keagan, shall I just forward these to you directly in the future?

Thanks, Scott

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Sent: Tuesday, April 14, 2020 2:53 PM
To: Becker, Scott | APhL <Scott.Becker@aphl.org>; Crumpler, Megan <mcrumpler@ochca.com>; Ishida, Maria <maria.ishida@agriculture.ny.gov>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>; Steece, Richard <richard.steece@tn.gov>; Toney, Denise <denise.toney@dgs.virginia.gov>; Tran, Tony <Anthony.tran@dc.gov>; Wade, Mark <mark.wade@sanantonio.gov>; Ware, Daphne <daphne.ware@msdh.ms.gov>; Whitmar, Bill <Bill.Whitmar@health.mo.gov>; Shult, Peter <peter.shult@slh.wisc.edu>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Taylor, Jill <jill.taylor@health.ny.gov>; Ball, Chris <BallC1@dhw.idaho.gov>; Southern, Tim <tim.southern@state.sd.us>; Kimsey, Paul <paul.kimsey@cdph.ca.gov>; Kyriacopoulos, Peter | APhL <Peter.Kyriacopoulos@aphl.org>; Mangal, Chris | APhL <Chris.Mangal@aphl.org>; Wroblewski, Kelly | APhL <kelly.wroblewski@aphl.org>; Blank, Eric | APhL <eric.blank@aphl.org>; Hahn, Stephen (b) (6)@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: Serology Result

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.

Hi All,

Please see the attached serology report . Note that the result indicates that a positive result indicates that the individual should stop social distancing even though the report has a disclaimer that the test may cross-react with other coronaviruses. This is, as Jen has stated repeatedly, dangerous.

Here is the wording from their website

The ARCPoint Labs COVID-19 Antibody Test was designed for this purpose. With this simple finger stick test, you will learn whether you have been exposed to the virus and if your immune system has produced antibodies and already fought off the infection, making it safe for you to return to work/school.

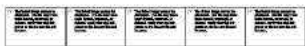
Joanne Bartkus, PhD

Director | Public Health Laboratory

Minnesota Department of Health

Office: 651-201-5256 | Mobile: 651-303-6229

<image001.gif>



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

From: Becker, Scott | APHL <Scott.Becker@aphl.org>

Sent: Saturday, April 11, 2020 5:42 PM

To: Becker, Scott | APHL; Bartkus, Joanne (MDH); Crumpler, Megan; Ishida, Maria; Kubin, Grace; Steece, Richard; Toney, Denise; Tran, Tony; Wade, Mark; Ware, Daphne; Whitmar, Bill; Shult, Peter; Rakeman, Jennifer; Taylor, Jill; Ball, Chris; Southern, Tim; Kimsey, Paul; Kyriacopoulos, Peter | APHL; Mangal, Chris | APHL; Wroblewski, Kelly | APHL; Blank, Eric | APHL; Hahn, Stephen; Sheehy, Janice

Subject: APHL/Commissioner Hahn

When: Tuesday, April 14, 2020 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: (b) (6)

This message may be from an external email source.

Do not select links or open attachments unless verified. Report all suspicious emails to Minnesota IT Services Security Operations Center.

Please hold for discussion between APHL BOD and select members and Dr. Stephen Hahn, Commissioner of FDA.

<sero.jpg>

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(b) (6)] -Stephen.Hah]
Sent: 9/13/2020 8:53:47 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Testing Updates

Mark,
This is great news. Thanks for the update. We'll discuss internally.
Steve

From: Mark Stevenson <mark.stevenson@thermofisher.com>
Date: Friday, September 11, 2020 at 6:23 PM
To: Stephen Hahn (b) (6) @fda.hhs.gov>
Subject: Testing Updates

Dear Steve,

I appreciated the 9/9 NEJM article on FDA CDRH lessons learned by Shuren and Stenzel, highlighting the need, in future pandemics, to work with a smaller number of rt-PCR test manufacturers who have the scale and instrument census to get the testing done – as well as a few POC assays. Their conclusion that this is a better use of their resources than the current approach to have authorized in excess of 200 separate tests.

Couple of updates on what Thermo Fisher are working on expansion

(b) (4)



Open to discuss how Thermo Fisher can best support.

Best and nice weekend

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T +1 (781) 622-1344
Mobile (+WhatsApp) :+1 760 576 9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222

kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 7/27/2020 11:11:10 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: (b) (4)

Dr. Farrugia,

Thank you for your message and thank you for Mayo Clinic's leadership. (b) (4) In the meantime, I will circle back with the Center.

Best
Steve

From: Gianrico Farrugia <farrugia.gianrico@mayo.edu>
Date: Monday, July 27, 2020 at 9:59 AM
To: Stephen Hahn (b) (6) .@fda.hhs.gov>
Subject: (b) (4)

Commissioner Hahn,

(b) (4)



Thank you and thank you for all you and the FDA team are doing to lead during this pandemic, Gianrico

Gianrico Farrugia, M.D.
President and CEO Mayo Clinic
Professor of Medicine and Physiology and Biomedical Engineering
Mayo Clinic
200 Ist Street SW, Rochester, MN 55905
Phone: 507-266-4861
Phone: 507-284-4695
E-mail: Farrugia.gianrico@mayo.edu

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 6/12/2020 9:55:42 AM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: Re: Mayo EAP data

Mike and Scott,
Thank you so much for all of your teams' hard work.
It is much appreciated by FDA and the American people.
Steve

From: "Joyner, Michael J., M.D." <joyner.michael@mayo.edu>
Date: Friday, June 12, 2020 at 8:18 AM
To: Peter Marks <Peter.Marks@fda.hhs.gov>, Stephen Hahn (b) (6) @fda.hhs.gov>
Cc: "Wright, R. Scott, M.D." <wright.scott@mayo.edu>
Subject: RE: Mayo EAP data

Peter, thx

Commissioner - a lot of efforts, ideas, energy and so forth between FDA and Mayo have converged and generated amplification loops. Agree the data is very promising. (b) (4)

Mike

From: Marks, Peter [mailto:Peter.Marks@fda.hhs.gov]
Sent: Friday, June 12, 2020 6:34 AM
To: Hahn, Stephen
Cc: Wright, R. Scott, M.D.; Joyner, Michael J., M.D.
Subject: [EXTERNAL] Mayo EAP data

Dear Commissioner,

Just to let you know, we are incredibly grateful to the Mayo team for (b) (4)
(b) (4) The very preliminary read on these data looks promising (and is completely consistent with what is emerging from other studies) and we look forward to presenting the data to you after we have additional patients and a formal analysis completed.

Wanted to take a moment to provide a real shout out of thanks to the entire Mayo team, which has been working tirelessly and doing an incredible job.

Best Regards,
Peter

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/19/2020 10:03:45 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
CC: Bruno, Katelyn A., Ph.D. [Bruno.Katelyn@mayo.edu]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]; Bolton, Jeffrey W. [Bolton.Jeffrey@mayo.edu]
Subject: RE: (b)(4)

Thanks, Mike

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: April 19, 2020 at 8:41:08 AM EDT
To: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Hahn, Stephen (b)(6)@fda.hhs.gov
Cc: Bruno, Katelyn A., Ph.D. <Bruno.Katelyn@mayo.edu>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>, Bolton, Jeffrey W. <Bolton.Jeffrey@mayo.edu>
Subject: RE: (b)(4)

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/17/2020 12:43:49 PM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

Thanks, Mike. So great to hear from you. Thank you, Peter, Scott and Nicole for all of your hard work on this effort for the American people.

Mike, it would be great to catch up at some point.

Best
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: April 17, 2020 at 11:33:09 AM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Cc: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/17/2020 12:51:59 PM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: thanks

Thanks, Marc. Please let me know how I can personally assist.

Best
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 16, 2020 at 9:51:04 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: thanks

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/17/2020 1:17:25 PM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: Re: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

Thank you very much Dr. Wright. The partnership with you have been exemplary.
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: April 17, 2020 at 1:16:28 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>, Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/1/2020 8:49:14 AM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: Re: Updated Plasma COVID-19 Numbers

Thanks, Mike. I'm having trouble seeing the information about (b) (4) on this email chain.
Terrific work you all are doing - thank you.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:42:54 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: FW: Updated Plasma COVID-19 Numbers

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/1/2020 10:18:46 AM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: RE: Updated Plasma COVID-19 Numbers

Thanks, Mike. Peter has been working with the Private Sector on this same issue so perhaps we should synch up.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:58:39 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: RE: Updated Plasma COVID-19 Numbers

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/1/2020 10:20:58 AM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
CC: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Scott. Thank you for the terrific work and will definitely be in touch.
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: May 1, 2020 at 9:19:02 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/1/2020 10:21:14 AM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

My cell is (b)(6)
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: May 1, 2020 at 9:19:02 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(b) (6)] -Stephen.Hah]
Sent: 5/29/2020 11:27:41 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: Recap of Morning Call

Thanks, Gianrico. If I can help (b) (4), please let me know. Your team is terrific as are you.
Steve

From: Gianrico Farrugia <farrugia.gianrico@mayo.edu>
Date: Friday, May 29, 2020 at 11:26 AM
To: Stephen Hahn (b) (6) @fda.hhs.gov>
Subject: RE: Recap of Morning Call

Thanks, mine is (b) (6)

(b) (4)

Gianrico

From: Hahn, Stephen [mailto:(b) (6) @fda.hhs.gov]
Sent: Friday, May 29, 2020 10:19 AM
To: Farrugia, Gianrico, M.D.
Subject: [EXTERNAL] Re: Recap of Morning Call

Will do. Was the number you used last night your cell?
For reference, mine is (b) (6)
Steve

From: Gianrico Farrugia <farrugia.gianrico@mayo.edu>
Date: Friday, May 29, 2020 at 8:03 AM
To: Stephen Hahn (b) (6) @fda.hhs.gov>
Subject: RE: Recap of Morning Call

Call me anytime if something comes up that does not seem right – Gianrico

From: Hahn, Stephen [mailto:(b) (6) @fda.hhs.gov]
Sent: Friday, May 29, 2020 7:01 AM
To: Farrugia, Gianrico, M.D.
Subject: [EXTERNAL] Re: Recap of Morning Call

Thx much. Have a great day

Sent from my iPhone

On May 28, 2020, at 6:37 PM, Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu> wrote:

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 5:32 PM
To: Farrugia, Gianrico, M.D.
Subject: FW: Recap of Morning Call

FYI, share..... as needed.

Mike

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 3:18 PM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Witten, Celia (CBER) (Celia.Witten@fda.hhs.gov)
Cc: Wright, R. Scott, M.D.; Carter, Rickey E., Ph.D.; Arturo Casadevall (acasade1@jhu.edu)
Subject: Recap of Morning Call

Dear Peter, Nicole and Celia - here is an outline of where we will head based on our call this morning.

(b) (4)



Also, if we can agree on this framework with just minor modifications, and loop BARDA in we can just start and get moving. Patton's maxim on a good plan executed now may apply to the tasks ahead.....

"A good plan, violently executed now, is better than a perfect plan next week."

We have already started working on this framework and things are starting to line up.

Mike

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/11/2020 11:40:08 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Accepted: COVID Diagnostics: Steve Hahn (FDA) and Mark Stevenson (Thermo Fisher Scientific)
Location: WebEx enclosed

Start: 5/13/2020 8:30:00 AM
End: 5/13/2020 9:00:00 AM

Recurrence: (none)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/14/2020 12:22:46 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID diagnostics

Thanks, Mark.

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 14, 2020 at 9:49:10 AM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

Dear Steve,

Yes, fine to share email. The attachment was more related to vaccine proposal note diagnostic testing.

For clarity here are the 5 items I regard as follow up.

(b) (4)



Regards

Mark

From: Steve Hahn (b) (6) @fda.hhs.gov>
Date: Thursday, May 14, 2020 at 8:31 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah,

HHS-FDA-20-0571-B-000104

Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark,

We are setting up a call with Dr. Birx and Jeff Shuren. Is it ok if I share this email and the attachments with Dr. Birx prior to the call?

Thanks

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 10, 2020 at 8:17:11 AM EDT

To: Hahn, Stephen (b)(6) @fda.hhs.gov>

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

Steve

Janice and my assistant are connected and to arrange a call. Plenty of topics to cover around public health.

Our submissions to amendment to our FDA EUA to expand our qPCR platforms and protocols was approved which will greatly expand platforms already installed able to run the COVID19 assay, including in a 384 well throughput. (b)(4)

(b)(4)

We proposed to BARDA (i) short-term solution to enable sterile manufacturing production capacity in Q4 2020 for vaccines to support the COVID-19 pandemic at this critical time (b)(4)

Best Mark

From: Steve Hahn (b)(6) @fda.hhs.gov>

Date: Saturday, May 9, 2020 at 10:14 AM

To: Mark Stevenson <mark.stevenson@thermofisher.com>

Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark,
thank you very much for your message. Great work on all counts. We very much appreciate the work with Thermo Fisher. It would be great to arrange a call in the upcoming week. I'll ask Janice to arrange.

I am in self-quarantine but doing well.

Best

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 9, 2020 at 9:53:38 AM EDT

To: Hahn, Stephen (b)(6) @fda.hhs.gov>

Subject: COVID diagnostics

Dear Steve,

I had read you will self-quarantine for 14 days after exposure to White House spokesperson Katie Miller, who tested positive for Covid-19 on Friday, so it prompted me to send a note. I hope you remain negative but I know you will have plenty of access to FDA EUA tests!

Quick update from Thermo Fisher. (b) (4)

We have also followed up on the work done with Mayo Clinic on ELISA lab based serology testing and signed an agreement with Mayo/WuXi for that test for total antibodies (IgM/IgG). We will make a submission for that serology test will be coming to the FDA in the next few weeks.

We have also engaged with the NIH on their RADx to continue to innovative around diagnostic testing for COVID.

Let me know if we can be helpful during this unprecedented times. I'm sure at some point we can also spend time to share observations and lessons learnt in a post COVID world for how industry and FDA work together.

Best Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T +1 (781) 622-1344
Mobile (+WhatsApp) :+1 760 576 9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/29/2020 12:52:02 PM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: We have a plan

Excellent and thanks

From: Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>
Date: May 29, 2020 at 12:15:34 PM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: FW: We have a plan

(b) (4)

Thanks, Gianrico

From: Halamka, John D., M.D., M.S.
Sent: Friday, May 29, 2020 10:42 AM
To: Farrugia, Gianrico, M.D.; Joyner, Michael J., M.D.; Campbell, Janet; Andrea Noel; Peter Marks (Peter.Marks@fda.hhs.gov); Abernethy, Amy; Anderson, Brian S. (briananderson@mitre.org)
Subject: We have a plan

Folks:

(b) (4)

John

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6)] -STEPHEN.HAH]
Sent: 4/17/2020 1:17:16 PM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: Re: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

Thank you very much Dr. Wright. The partnership with you have been exemplary.
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: April 17, 2020 at 1:16:28 PM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>, Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

Thank you for the note Director Hahn.

(b) (4)



R Scott Wright, MD
Senior Chair and Medical Director, Mayo Clinic IRB
Director, Mayo Clinic Human Research Protection Program
Professor of Medicine, Department of Cardiology
Wright.scott@mayo.edu
Office: 1-507-284-8087 (Administrative)
Office: 1-507-284-0783 (Patient related)
Fax: 1-507-266-0103

From: "Hahn, Stephen" (b)(6) @fda.hhs.gov>
Date: Friday, April 17, 2020 at 11:44 AM
To: Michael Joyner <Joyner.Michael@mayo.edu>, Peter Marks <Peter.Marks@fda.hhs.gov>, "R. Scott Wright" <wright.scott@mayo.edu>, Nicole Verdun <Nicole.Verdun@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

Thanks, Mike. So great to hear from you. Thank you, Peter, Scott and Nicole for all of your hard work on this effort for the American people.

Mike, it would be great to catch up at some point.

Best
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: April 17, 2020 at 11:33:09 AM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Cc: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

Thx, Dr. Hahn..... your folks are crushing it. Happy to answer any questions and give you any of the many examples of the superior performance of the CBER group. (b) (4)

(b) (4)

Mike

(b) (4)

From: Marks, Peter [mailto:Peter.Marks@fda.hhs.gov]
Sent: Friday, April 17, 2020 10:21 AM
To: Wright, R. Scott, M.D.; Joyner, Michael J., M.D.; Verdun, Nicole
Cc: Hahn, Stephen
Subject: [EXTERNAL] RE: RE: 9am 4-17 stats

Dear Scott,

Thank you once again to the Mayo for taking this on and for all of Mike and your efforts – you were actually the ones who made this a reality. Copying our Commissioner for his awareness.

Best Regards,
Peter

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>

Sent: Friday, April 17, 2020 11:06 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Joyner, Michael J., M.D. <joyner.michael@mayo.edu>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>

Subject: Re: [EXTERNAL] RE: 9am 4-17 stats

Peter and Nicole

My congratulations to you and the FDA for conceiving and organizing a study/EAP that is meeting the needs of the USA! It is clear to me that the numbers reflect that we are meeting a real public health and clinical need! I am grateful as a citizen of the USA and a physician for your leadership on this. The nation is grateful as well based upon the number of calls we are getting from physicians and others. Please feel free to forward this note of compliment to your Director if appropriate.

R Scott Wright, MD

Senior Chair and Medical Director, Mayo Clinic IRB

Director, Mayo Clinic Human Research Protection Program

Professor of Medicine, Department of Cardiology

Wright.scott@mayo.edu

Office: 1-507-284-8087 (Administrative)

Office: 1-507-284-0783 (Patient related)

Fax: 1-507-266-0103

From: Peter Marks <Peter.Marks@fda.hhs.gov>

Date: Friday, April 17, 2020 at 10:00 AM

To: Michael Joyner <Joyner.Michael@mayo.edu>, Nicole Verdun <Nicole.Verdun@fda.hhs.gov>, "R. Scott Wright" <wright.scott@mayo.edu>

Subject: [EXTERNAL] RE: 9am 4-17 stats

Dear Mike,

Amazing! Thank you.

Best Regards,

Peter

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>

Sent: Friday, April 17, 2020 10:28 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>; Wright, R. Scott, M.D. <wright.scott@mayo.edu>

Subject: 9am 4-17 stats

FYI many things coming together - keep going. Song for the day.....

<https://youtu.be/HUvngfDy-Bo>

(b) (4)



Sent from my iPhone

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/17/2020 12:43:40 PM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

Thanks, Mike. So great to hear from you. Thank you, Peter, Scott and Nicole for all of your hard work on this effort for the American people.

Mike, it would be great to catch up at some point.

Best
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: April 17, 2020 at 11:33:09 AM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

Thx, Dr. Hahn..... your folks are crushing it. Happy to answer any questions and give you any of the many examples of the superior performance of the CBER group. (b) (4)

(b) (4)

Mike

(b) (4)



From: Marks, Peter [mailto:Peter.Marks@fda.hhs.gov]
Sent: Friday, April 17, 2020 10:21 AM
To: Wright, R. Scott, M.D.; Joyner, Michael J., M.D.; Verdun, Nicole
Cc: Hahn, Stephen
Subject: [EXTERNAL] RE: RE: 9am 4-17 stats

Dear Scott,

Thank you once again to the Mayo for taking this on and for all of Mike and your efforts – you were actually the ones who made this a reality. Copying our Commissioner for his awareness.

Best Regards,
Peter

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Sent: Friday, April 17, 2020 11:06 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Joyner, Michael J., M.D. <joyner.michael@mayo.edu>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: 9am 4-17 stats

Peter and Nicole

My congratulations to you and the FDA for conceiving and organizing a study/EAP that is meeting the needs of the USA! It is clear to me that the numbers reflect that we are meeting a real public health and clinical need! I am grateful as a citizen of the USA and a physician for your leadership on this. The nation is grateful as well based upon the number of calls we are getting from physicians and others. Please feel free to forward this note of compliment to your Director if appropriate.

R Scott Wright, MD
Senior Chair and Medical Director, Mayo Clinic IRB
Director, Mayo Clinic Human Research Protection Program
Professor of Medicine, Department of Cardiology
Wright.scott@mayo.edu
Office: 1-507-284-8087 (Administrative)
Office: 1-507-284-0783 (Patient related)
Fax: 1-507-266-0103

From: Peter Marks <Peter.Marks@fda.hhs.gov>
Date: Friday, April 17, 2020 at 10:00 AM
To: Michael Joyner <Joyner.Michael@mayo.edu>, Nicole Verdun <Nicole.Verdun@fda.hhs.gov>, "R. Scott Wright" <wright.scott@mayo.edu>
Subject: [EXTERNAL] RE: 9am 4-17 stats

Dear Mike,

Amazing! Thank you.

Best Regards,
Peter

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>

Sent: Friday, April 17, 2020 10:28 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>; Wright, R. Scott, M.D. <wright.scott@mayo.edu>

Subject: 9am 4-17 stats

FYI many things coming together - keep going. Song for the day.....

<https://youtu.be/HUvngfDy-Bo>

(b) (4)



Sent from my iPhone

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/17/2020 12:51:51 PM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: thanks

Thanks, Marc. Please let me know how I can personally assist.
Best
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 16, 2020 at 9:51:04 PM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: thanks

Dear Doctor Hahn,
Thanks for your rapid follow through. We had a productive discussion with Peter Marks and Rick Bright. (b) (4)

(b) (4)

Best regards,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/19/2020 10:03:36 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
CC: Bruno, Katelyn A., Ph.D. [Bruno.Katelyn@mayo.edu]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]; Bolton, Jeffrey W. [Bolton.Jeffrey@mayo.edu]
Subject: RE: (b) (4)

Thanks, Mike

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: April 19, 2020 at 8:41:08 AM EDT
To: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Hahn, Stephen (b) (6) <[REDACTED]@fda.hhs.gov>
Cc: Bruno, Katelyn A., Ph.D. <Bruno.Katelyn@mayo.edu>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>, Bolton, Jeffrey W. <Bolton.Jeffrey@mayo.edu>
Subject: RE: (b) (4)

Dear Mike,

Thanks so much for this update.

Best Regards,
Peter

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Sent: Saturday, April 18, 2020 10:16 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>; Hahn, Stephen (b) (6) <[REDACTED]@fda.hhs.gov>
Cc: Bruno, Katelyn A., Ph.D. <Bruno.Katelyn@mayo.edu>; Wright, R. Scott, M.D. <wright.scott@mayo.edu>; Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>; Bolton, Jeffrey W. <Bolton.Jeffrey@mayo.edu>
Subject: (b) (4)

Peter, Nicole & Commissioner Hahn, (b) (4)

Mike

From: Bruno, Katelyn A., Ph.D.
Sent: Saturday, April 18, 2020 8:59 PM
To: Joyner, Michael J., M.D.; Wright, R. Scott, M.D.
Subject: Sorry for all emails... we may want to update 60 minutes before tomorrow!

(b) (4)

Katelyn Bruno, PhD
Instructor of Medicine

Department of Cardiovascular Medicine

Office: 904-953-6740

Pager: (78)3-8804

Secretary: 904-953-2439

Fax: 904-953-7117

Email: Bruno.Katelyn@mayo.edu

Mayo Clinic

4500 San Pablo Road

Jacksonville, FL 32224

mayoclinic.org

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(b) (6) -Stephen.Hah]
Sent: 5/29/2020 10:34:31 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: Recap of Morning Call

Thanks. My understanding is that (b) (4) Peter
will address this with Michael
Really appreciate your help with this.
Steve

From: Gianrico Farrugia <farrugia.gianrico@mayo.edu>
Date: Thursday, May 28, 2020 at 6:39 PM
To: Stephen Hahn (b) (6) @fda.hhs.gov>
Subject: FW: Recap of Morning Call

(b) (4)

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 5:32 PM
To: Farrugia, Gianrico, M.D.
Subject: FW: Recap of Morning Call

FYI, share..... as needed.

Mike

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 3:18 PM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Witten, Celia (CBER) (Celia.Witten@fda.hhs.gov)
Cc: Wright, R. Scott, M.D.; Carter, Rickey E., Ph.D.; Arturo Casadevall (acasade1@jhu.edu)
Subject: Recap of Morning Call

Dear Peter, Nicole and Celia - here is an outline of where we will head based on our call this morning.

(b) (4)

Also, if we can agree on this framework with just minor modifications, and loop BARDA in we can just start and get moving. Patton's maxim on a good plan executed now may apply to the tasks ahead.....

"A good plan, violently executed now, is better than a perfect plan next week."

We have already started working on this framework and things are starting to line up.

Mike

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/1/2020 10:18:37 AM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: RE: Updated Plasma COVID-19 Numbers

Thanks, Mike. Peter has been working with the Private Sector on this same issue so perhaps we should synch up.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:58:39 AM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: RE: Updated Plasma COVID-19 Numbers

Steve.... From another email chain. To some higher ups in (b) (4) who had questions about Plasma. (b) (4)

(b) (4)
Mike

(b) (4)
Mike

From: Hahn, Stephen [mailto:(b) (6) @fda.hhs.gov]
Sent: Friday, May 01, 2020 7:49 AM
To: Joyner, Michael J., M.D.
Cc: Marks, Peter; Verdun, Nicole; Wright, R. Scott, M.D.
Subject: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Thanks, Mike. I'm having trouble seeing the information about (b) (4) on this email chain.
Terrific work you all are doing - thank you.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:42:54 AM EDT

To: Hahn, Stephen (b)(6) @fda.hhs.gov>

Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>

Subject: FW: Updated Plasma COVID-19 Numbers

Commish.... FYI. See also the note about (b) (4)

Mike

From: Joyner, Michael J., M.D.

Sent: Friday, May 01, 2020 7:40 AM

To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Farrugia, Gianrico, M.D.; Bolton, Jeffrey W.

Cc: Wright, R. Scott, M.D.; Arturo Casadevall (acasade1@jhu.edu); Lee, Pete (petelee@microsoft.com); Halamka, John D., M.D., M.S.; Claire Pomeroy (cpomeroy@laskerfoundation.org); 'Chaim Lebovits'

Subject: FW: Updated Plasma COVID-19 Numbers

(b) (4)

Peter (Lee), John H, and Claire..... (b) (4)

MJJ

From: Spiegel, Matthew R. (Matt)

Sent: Friday, May 01, 2020 7:25 AM

To: Bruno, Katelyn A., Ph.D.; Muenkel, Lisa K.; Wiggins, Chad C., Ph.D.

Cc: Joyner, Michael J., M.D.; Wright, R. Scott, M.D.; Tree, Kristine M.

Subject: Updated Plasma COVID-19 Numbers

Hi all,

Attached are the numbers for the website (excel file) as well as the table for the M/W/F meeting (Word document).

Chad, also find the (b) (4) dataset attached for the plots.

Let me know if you need anything else.

Thanks,

Matt

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/1/2020 10:20:49 AM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
CC: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Scott, Thank you for the terrific work and will definitely be in touch.
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: May 1, 2020 at 9:19:02 AM EDT
To: Hahn, Stephen (b) (6) [REDACTED]@fda.hhs.gov>
Cc: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Dr. Hahn

It was great to meet you this week and thanks for taking the time to travel to Rochester. You and your team at FDA are doing great work!

The EAP for Convalescent Plasma is on target to enroll (b) (4) [REDACTED]
(b) (4) [REDACTED]

We will work with Dr. Marks and Dr. Verdun to create a process that we can transfer data to the agency ASAP so your team can analyze what we have collected for safety and possibly efficacy.

You and I have both spent many years enrolling patients into studies and trials. The enrollment of the EAP has exceeded total enrollment goals and expectations about pace of enrollment. My congratulations and gratitude to the FDA for fostering the EAP which has clearly met a public health need. Everyone working on it believes it is a great honor and commitment to the nation to be associated with its conduct.

We want to make sure we get data to the agency as soon as your team wants it to allow the regulatory review process to provide critical oversight and guidance.

Never hesitate to reach out if I can be of assistance.

Sincerely,

Scott Wright

On May 1, 2020, at 7:49 AM, Hahn, Stephen (b) (6) [REDACTED]@fda.hhs.gov> wrote:

Thanks, Mike. I'm having trouble seeing the information about (b) (4) on this email chain.
Terrific work you all are doing - thank you.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:42:54 AM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: FW: Updated Plasma COVID-19 Numbers

Commish.... FYI. See also the note about (b) (4)

Mike

From: Joyner, Michael J., M.D.
Sent: Friday, May 01, 2020 7:40 AM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Farrugia, Gianrico, M.D.; Bolton, Jeffrey W.
Cc: Wright, R. Scott, M.D.; Arturo Casadevall (acasade1@jhu.edu); Lee, Pete (petelee@microsoft.com); Halamka, John D., M.D., M.S.; Claire Pomeroy (cpomeroy@laskerfoundation.org); 'Chaim Lebovits'
Subject: FW: Updated Plasma COVID-19 Numbers

FYI..... this just gets wilder every day. Safety data is encouraging. Fulfillment gap is dropping thx in large part to Chaim et al.

Peter (Lee), John H, and Claire..... (b) (4)

MJJ

From: Spiegel, Matthew R. (Matt)
Sent: Friday, May 01, 2020 7:25 AM
To: Bruno, Katelyn A., Ph.D.; Muenkel, Lisa K.; Wiggins, Chad C., Ph.D.
Cc: Joyner, Michael J., M.D.; Wright, R. Scott, M.D.; Tree, Kristine M.
Subject: Updated Plasma COVID-19 Numbers

Hi all,

Attached are the numbers for the website (excel file) as well as the table for the M/W/F meeting (Word document).

Chad, also find the (b) (4) dataset attached for the plots.

Let me know if you need anything else.

Thanks,

Matt

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/1/2020 10:21:05 AM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

My cell is (b)(6)
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: May 1, 2020 at 9:19:02 AM EDT
To: Hahn, Stephen (b) (6) [REDACTED]@fda.hhs.gov>
Cc: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Dr. Hahn

It was great to meet you this week and thanks for taking the time to travel to Rochester. You and your team at FDA are doing great work!

The EAP for Convalescent Plasma is on target to enroll (b) (4)
(b) (4)

We will work with Dr. Marks and Dr. Verdun to create a process that we can transfer data to the agency ASAP so your team can analyze what we have collected for safety and possibly efficacy.

You and I have both spent many years enrolling patients into studies and trials. The enrollment of the EAP has exceeded total enrollment goals and expectations about pace of enrollment. My congratulations and gratitude to the FDA for fostering the EAP which has clearly met a public health need. Everyone working on it believes it is a great honor and commitment to the nation to be associated with its conduct.

We want to make sure we get data to the agency as soon as your team wants it to allow the regulatory review process to provide critical oversight and guidance.

Never hesitate to reach out if I can be of assistance.

Sincerely,

Scott Wright

On May 1, 2020, at 7:49 AM, Hahn, Stephen (b)(6) [REDACTED]@fda.hhs.gov> wrote:

Thanks, Mike. I'm having trouble seeing the information about (b) (4) on this email chain.
Terrific work you all are doing - thank you.

Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:42:54 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: FW: Updated Plasma COVID-19 Numbers

Commish.... FYI. See also the note about (b)(4)

Mike

From: Joyner, Michael J., M.D.
Sent: Friday, May 01, 2020 7:40 AM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Farrugia, Gianrico, M.D.; Bolton, Jeffrey W.
Cc: Wright, R. Scott, M.D.; Arturo Casadevall (acasade1@jhu.edu); Lee, Pete (petelee@microsoft.com); Halamka, John D., M.D., M.S.; Claire Pomeroy (cpomeroy@laskerfoundation.org); 'Chaim Lebovits'
Subject: FW: Updated Plasma COVID-19 Numbers

FYI..... this just gets wilder every day. Safety data is encouraging. Fulfillment gap is dropping thx in large part to Chaim et al.

Peter (Lee), John H, and Claire..... (b)(4)

MJJ

From: Spiegel, Matthew R. (Matt)
Sent: Friday, May 01, 2020 7:25 AM
To: Bruno, Katelyn A., Ph.D.; Muenkel, Lisa K.; Wiggins, Chad C., Ph.D.
Cc: Joyner, Michael J., M.D.; Wright, R. Scott, M.D.; Tree, Kristine M.
Subject: Updated Plasma COVID-19 Numbers

Hi all,

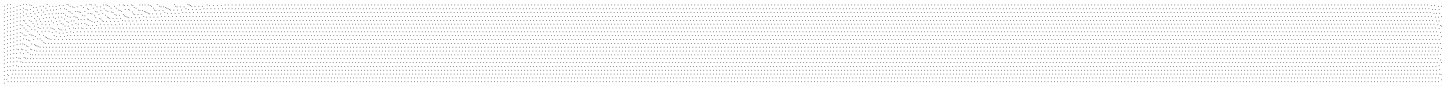
Attached are the numbers for the website (excel file) as well as the table for the M/W/F meeting (Word document).

Chad, also find the (b)(4) dataset attached for the plots.

Let me know if you need anything else.

Thanks,

Matt



From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/14/2020 8:31:55 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID diagnostics

Mark,

We are setting up a call with Dr. Birx and Jeff Shuren. Is it ok if I share this email and the attachments with Dr. Birx prior to the call?

Thanks

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 10, 2020 at 8:17:11 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/14/2020 12:22:54 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID diagnostics

Thanks, Mark.

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 14, 2020 at 9:49:10 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/29/2020 12:52:11 PM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: We have a plan

Excellent and thanks

From: Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>
Date: May 29, 2020 at 12:15:34 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: FW: We have a plan

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/9/2020 10:13:09 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID diagnostics

Mark,
thank you very much for your message. Great work on all counts. We very much appreciate the work with Thermo Fisher. It would be great to arrange a call in the upcoming week. I'll ask Janice to arrange.

I am in self-quarantine but doing well.
Best
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 9, 2020 at 9:53:38 AM EDT
To: Hahn, Stephen (b) (6)@fda.hhs.gov>
Subject: COVID diagnostics

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/29/2020 8:01:18 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: Recap of Morning Call

Thx much. Have a great day

Sent from my iPhone

On May 28, 2020, at 6:37 PM, Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu> wrote:

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 5:32 PM
To: Farrugia, Gianrico, M.D.
Subject: FW: Recap of Morning Call

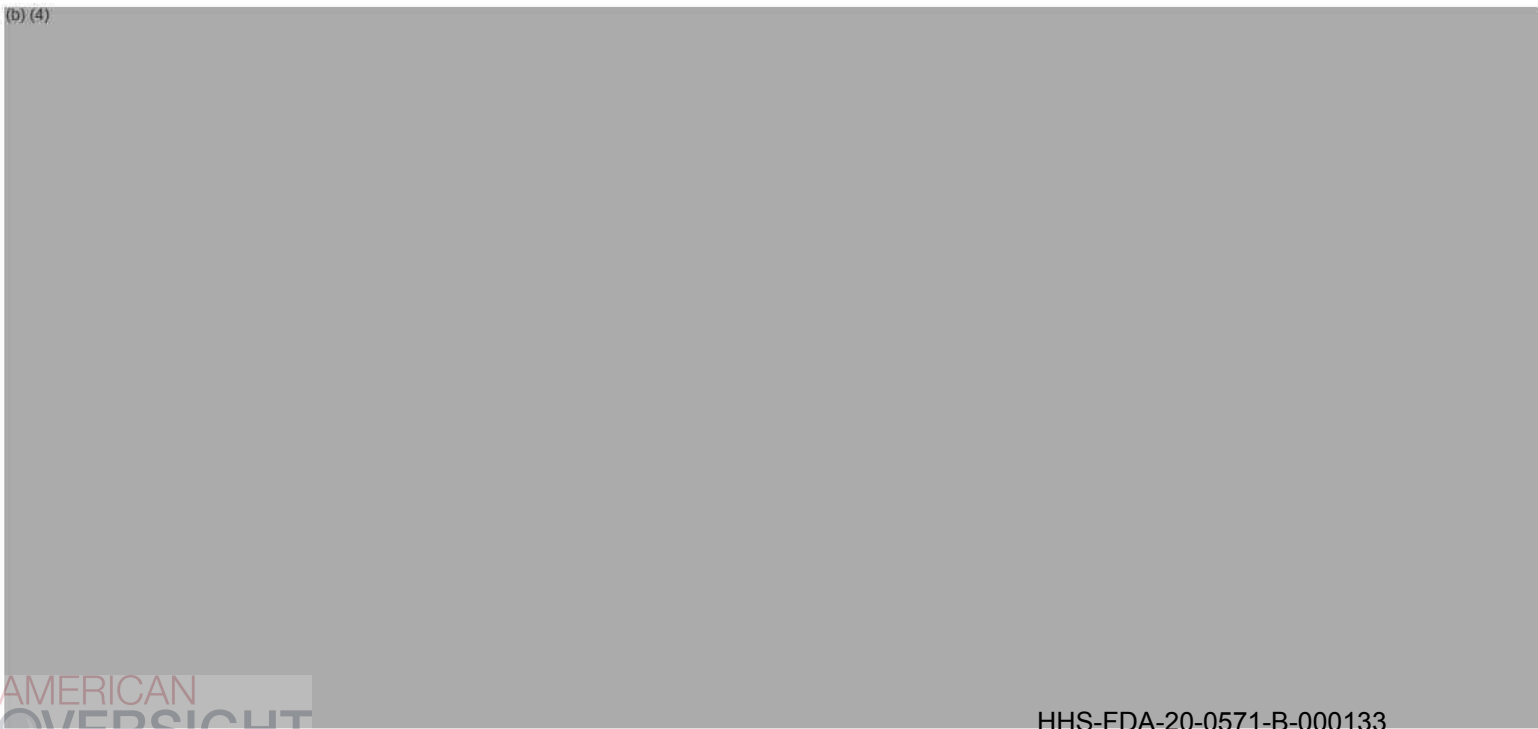
FYI, share..... as needed.

Mike

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 3:18 PM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Witten, Celia (CBER) (Celia.Witten@fda.hhs.gov)
Cc: Wright, R. Scott, M.D.; Carter, Rickey E., Ph.D.; Arturo Casadevall (acasade1@jhu.edu)
Subject: Recap of Morning Call

Dear Peter, Nicole and Celia - here is an outline of where we will head based on our call this morning.

(b) (4)



Also, if we can agree on this framework with just minor modifications, and loop BARDA in we can just start and get moving. Patton's maxim on a good plan executed now may apply to the tasks ahead.....

"A good plan, violently executed now, is better than a perfect plan next week."

We have already started working on this framework and things are starting to line up.

Mike

From: (b) (6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 3/14/2020 1:44:46 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Install based

Mark,
thanks much. I believe our teams have already started working on this. If you have any questions or have concerns about progress, please reach out to me by phone or email.
thanks again.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 14, 2020 at 11:54:53 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Install based

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 3/14/2020 1:40:21 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Install based

Mark,
This is excellent. Thank you.
I'm working with our team to address the last two points. I'll be back in touch.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 14, 2020 at 11:54:53 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Install based

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 3/22/2020 3:19:32 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

Thanks, Mark. Our team has the information and will be reviewing. I have copied Jeff Shuren.
Best
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 22, 2020 at 10:48:28 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Re: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/14/2020 4:00:26 PM
To: Bartkus, Joanne (MDH) [joanne.bartkus@state.mn.us]; Becker, Scott | APHL [Scott.Becker@aphl.org]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) -Stephen.Hah]
Subject: RE: Serology Result

Thanks for flagging, Scott and Joanne. I am working with Jeff to identify the right person for you to filter these examples to in the future. We greatly appreciate the information.

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Sent: Tuesday, April 14, 2020 3:19 PM
To: Becker, Scott | APHL <Scott.Becker@aphl.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6) @fda.hhs.gov
Subject: RE: Serology Result

I believe that this company does the collection and sends the specimen out to another laboratory for testing, so it's not clear what test is being used. It is concerning to me that individuals are being told to discontinue social distancing based solely on the results of this test. I am wondering if FDA can provide additional wording to their guidance regarding the interpretation of individual test results in the context of public health guidance and state executive orders.

Joanne

Joanne Bartkus, PhD
Director | Public Health Laboratory

Minnesota Department of Health
Office: 651-201-5256 | Mobile: 651-303-6229



From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Sent: Tuesday, April 14, 2020 2:08 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6) @fda.hhs.gov; Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Subject: FW: Serology Result

Hi all,

As discussed, here a recent example of the kind of problem that members described on our call. I did not see this firm on the section IV.D list so an example of what's going on. Joanne Bartkus (MN) copied here, sent this our way. Keagan, shall I just forward these to you directly in the future?

Thanks, Scott

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>

Sent: Tuesday, April 14, 2020 2:53 PM

To: Becker, Scott | APHL <Scott.Becker@aphl.org>; Crumpler, Megan <mcrumpler@ochca.com>; Ishida, Maria <maria.ishida@agriculture.ny.gov>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>; Steece, Richard <richard.steece@tn.gov>; Toney, Denise <denise.toney@dgs.virginia.gov>; Tran, Tony <Anthony.tran@dc.gov>; Wade, Mark <mark.wade@sanantonio.gov>; Ware, Daphne <daphne.ware@msdh.ms.gov>; Whitmar, Bill <Bill.Whitmar@health.mo.gov>; Shult, Peter <peter.shult@slh.wisc.edu>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Taylor, Jill <jill.taylor@health.ny.gov>; Ball, Chris <BallC1@dhw.idaho.gov>; Southern, Tim <tim.southern@state.sd.us>; Kimsey, Paul <paul.kimsey@cdph.ca.gov>; Kyriacopoulos, Peter | APHL <Peter.Kyriacopoulos@aphl.org>; Mangal, Chris | APHL <Chris.Mangal@aphl.org>; Wroblewski, Kelly | APHL <kelly.wroblewski@aphl.org>; Blank, Eric | APHL <eric.blank@aphl.org>; Hahn, Stepher (b) (6) <[fda.hhs.gov](mailto:(b)(6)@fda.hhs.gov)>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>

Subject: Serology Result

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.

Hi All,

Please see the attached serology report . Note that the result indicates that a positive result indicates that the individual should stop social distancing even though the report has a disclaimer that the test may cross-react with other coronaviruses. This is, as Jen has stated repeatedly, dangerous.

Here is the wording from their website

The ARCpoint Labs COVID-19 Antibody Test was designed for this purpose. With this simple finger stick test, you will learn whether you have been exposed to the virus and if your immune system has produced antibodies and already fought off the infection, making it safe for you to return to work/school.

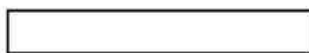
Joanne Bartkus, PhD

Director | Public Health Laboratory

Minnesota Department of Health

Office: 651-201-5256 | Mobile: 651-303-6229

**m1 DEPARTMENT
OF HEALTH**



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

From: Becker, Scott | APHL <Scott.Becker@aphl.org>

Sent: Saturday, April 11, 2020 5:42 PM

To: Becker, Scott | APHL; Bartkus, Joanne (MDH); Crumpler, Megan; Ishida, Maria; Kubin, Grace; Steece, Richard; Toney, Denise; Tran, Tony; Wade, Mark; Ware, Daphne; Whitmar, Bill; Shult, Peter; Rakeman, Jennifer; Taylor, Jill; Ball, Chris;

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000139

Southern, Tim; Kimsey, Paul; Kyriacopoulos, Peter | APHL; Mangal, Chris | APHL; Wroblewski, Kelly | APHL; Blank, Eric | APHL; Hahn, Stephen; Sheehy, Janice

Subject: APHL/Commissioner Hahn

When: Tuesday, April 14, 2020 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: (b) (6)

This message may be from an external email source.

Do not select links or open attachments unless verified. Report all suspicious emails to Minnesota IT Services Security Operations Center.

Please hold for discussion between APHL BOD and select members and Dr. Stephen Hahn, Commissioner of FDA.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/5/2020 9:37:42 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Re: Can we chat today if possible re serology

Ok to call around 10:30 am EST?

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Date: April 4, 2020 at 5:04:58 PM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: Can we chat today if possible re serology

(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/9/2020 9:30:38 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Coronavirus (COVID-19) Update: Serological Tests

Definitely Scott.
I am copying Janice.
Steve

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Date: April 8, 2020 at 9:23:22 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: RE: Coronavirus (COVID-19) Update: Serological Tests

Perfect, thanks for your leadership on this issue and your call just now. I haven't forgotten your offer to meet with our leadership, but this week has gotten away from us. Who should I work with on your staff I can work with for next week?

Thanks again, Scott

From: Hahn, Stephen (b)(6) @fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:02 AM
To: Becker, Scott | APHL <Scott.Becker@aphl.org>
Subject: Fwd: Coronavirus (COVID-19) Update: Serological Tests

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.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: April 8, 2020 at 9:00:00 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Coronavirus (COVID-19) Update: Serological Tests

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests>

For Immediate Release:

April 07, 2020

Statement From:

Statement Author

Leadership Role

Commissioner of Food and Drugs - Food and Drug Administration

Stephen M. Hahn M.D.

Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection, like COVID-19. In other words, the test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself. In the early days of an infection when the body's immune response is still building, antibodies may not be detected. This limits the test's effectiveness for diagnosing COVID-19 and why it should not be used as the sole basis to diagnose COVID-19.

Serological tests can play a critical role in the fight against COVID-19 by helping healthcare professionals to identify individuals who have overcome an infection in the past and have developed an immune response. In the future, this may potentially be used to help determine, together with other clinical data, that such individuals are no longer susceptible to infection and can return to work. In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19. This is why Vice President Mike Pence called on the laboratory community to develop serological tests for COVID-19.

In March, the FDA issued a policy to allow developers of certain serological tests to begin to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable. This includes allowing developers to market their tests without prior FDA review if certain conditions outlined in the guidance document are met. The FDA issued this policy to allow early patient access to certain serological tests with the understanding that the FDA has not reviewed and authorized them.

The FDA can also authorize tests for COVID-19 under an Emergency Use Authorization (EUA). To date, FDA has authorized one EUA for a serological test that is intended for use by clinical laboratories.

Since the FDA issued the policy, over 70 test developers have notified the agency that they have serological tests available for use. However, some firms are falsely claiming that their serological tests are FDA approved or authorized, or falsely claiming that they can diagnose COVID-19. The FDA will take appropriate action against firms making false claims or marketing tests that are not accurate and reliable.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

This email has been scanned for spam and viruses by Proofpoint Essentials. Click [here](#) to report this email as spam.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6)] -STEPHEN.HAH]
Sent: 4/13/2020 11:42:12 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Call follow up

Marc,

I am looping in Peter Marks who is part of the team looking at our efforts here. Peter, Marc and his company have been terrific partners. Do you think their offer would fit into our plans moving forward?
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 8, 2020 at 9:47:27 AM EDT
To: Hahn, Stephen (b)(6) <[REDACTED]@fda.hhs.gov>
Subject: RE: Call follow up

Dear Dr. Hahn,

Thanks for the follow up. Anand Shah has been super helpful in linking us up to the right people on serological testing and I did participate in your call with Advamed DX earlier in the week.

(b) (4)



We don't need a deep discussion with you on the topic but rather to explain it and get your reaction on whether it seems relevant.

Let me know if you have time to speak later in the week.

Thanks,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Hahn, Stephen (b)(6) @fda.hhs.gov>
Sent: Tuesday, April 7, 2020 8:54 AM
To: Casper, Marc N. <marc.casper@thermofisher.com>
Subject: Re: Call follow up

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Marc,
Just following up. I believe our teams are connecting.
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 2, 2020 at 8:07:45 PM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: Call follow up

Dear Dr. Hahn,
Thanks for the call this evening.

(b) (4)



Sincerely yours,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6)] -STEPHEN.HAH]
Sent: 3/14/2020 1:40:12 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Install based

Mark,
This is excellent. Thank you.
I'm working with our team to address the last two points. I'll be back in touch.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 14, 2020 at 11:54:53 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: Install based

Dear Steve,

(b) (4)



Let me know how else we can be helpful

Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

We will keep you up to date as this situation changes.

Kent

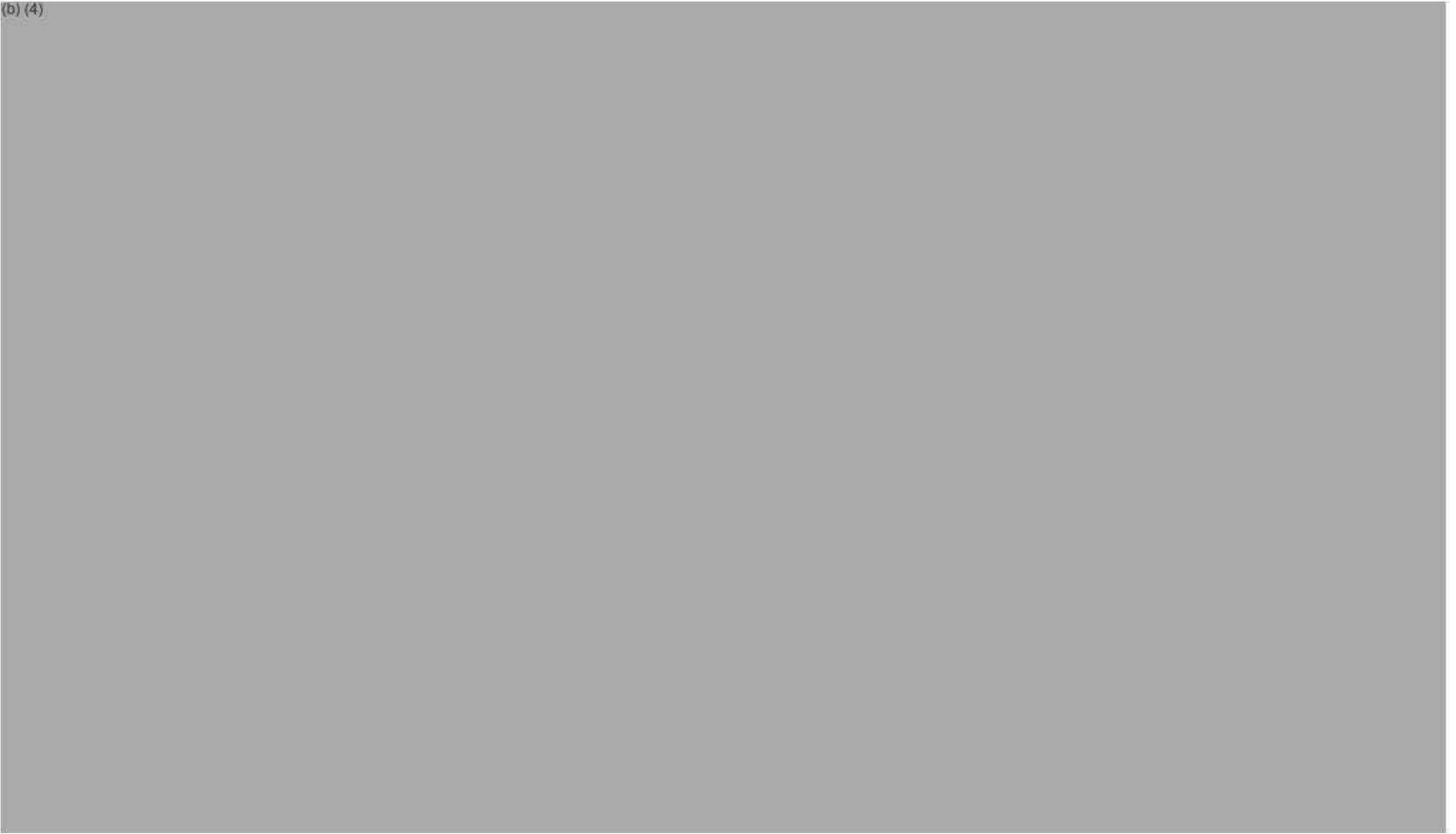
From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6)] -STEPHEN.HAH]
Sent: 3/14/2020 1:44:36 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Install based

Mark,
thanks much. I believe our teams have already started working on this. If you have any questions or have concerns about progress, please reach out to me by phone or email.
thanks again.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 14, 2020 at 11:54:53 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: Install based

Dear Steve,

(b) (4)



Let me know how else we can be helpful

Mark

Mark Stevenson

Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

We will keep you up to date as this situation changes.

Kent

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 3/22/2020 3:19:23 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

Thanks, Mark. Our team has the information and will be reviewing. I have copied Jeff Shuren.
Best
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 22, 2020 at 10:48:28 AM EDT
To: Hahn, Stephen (b) (6) <(b) (6)@fda.hhs.gov>
Subject: Re: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

Dear Steve,

(b) (4)

A large rectangular area of the email is redacted with a solid grey background. The redaction covers the main body of the email, leaving only the header and footer visible.

Let me know if you have questions.

Mark Stevenson

(b) (6)

From: "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>
Date: Saturday, March 21, 2020 at 9:20 PM
To: Peter Shearstone <peter.shearstone@thermofisher.com>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>, (b) (6) " (b) (6) >
Cc: Tim Fenton <tim.fenton@thermofisher.com>, Mark Stevenson <mark.stevenson@thermofisher.com>, "Chen, Mark" <Mark.Chen@fda.hhs.gov>
Subject: RE: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Peter,

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/5/2020 9:37:51 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Re: Can we chat today if possible re serology

Ok to call around 10:30 am EST?

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Date: April 4, 2020 at 5:04:58 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Can we chat today if possible re serology

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/8/2020 9:02:17 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Fwd: Coronavirus (COVID-19) Update: Serological Tests

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: April 8, 2020 at 9:00:00 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Coronavirus (COVID-19) Update: Serological Tests

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/9/2020 9:30:47 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Coronavirus (COVID-19) Update: Serological Tests

Definitely Scott.
I am copying Janice.
Steve

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Date: April 8, 2020 at 9:23:22 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: RE: Coronavirus (COVID-19) Update: Serological Tests

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/7/2020 8:54:38 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: Call follow up

Marc,
Just following up. I believe our teams are connecting.
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 2, 2020 at 8:07:45 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Call follow up

From: (b) (6)@fda.hhs.gov (b) (6)@fda.hhs.gov]
Sent: 4/13/2020 11:42:21 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Call follow up

Marc,

I am looping in Peter Marks who is part of the team looking at our efforts here. Peter, Marc and his company have been terrific partners. Do you think their offer would fit into our plans moving forward?

Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 8, 2020 at 9:47:27 AM EDT
To: Hahn, Stephen (b) (6)@fda.hhs.gov>
Subject: RE: Call follow up

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 8/6/2020 1:23:40 PM
To: Kaufman, Harvey W [Harvey.W.Kaufman@questdiagnostics.com]
CC: Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]
Subject: Re: check in

Fascinating. I would love to see it whenever you are ready to share. And this would be a great topic for an EA meeting in the future too, if you are keen.

From: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Sent: Thursday, August 6, 2020 1:21 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Valo, Gina <Gina.Valo@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: check in

We are preparing short communication – publication – that looks at loss of detectable SARS-CoV-2 IgG seropositivity among patients retested. Interestingly, patients who are 55 years and older have higher rates of persistence of seropositivity than younger patients.

Harvey W. Kaufman, MD, MBA, FCAP, Senior Medical Director, Medical Informatics
Quest Diagnostics | Action from Insight | 15 Pleasant Street, Needham, MA 02492 USA
| phone 201.213.8452 | Harvey.W.Kaufman@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/
For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Thursday, August 6, 2020 1:01 PM
To: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Cc: Valo, Gina <Gina.Valo@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: check in

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.

Hi Harvey,

Saw your note at the end of the call. Look forward to hearing more!

Take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 8/6/2020 12:08:03 PM
To: Kaufman, Harvey W [Harvey.W.Kaufman@questdiagnostics.com]
CC: Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]
Subject: Re: Today's Dx EA

Thank you so much. You were definitely busy!

From: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Sent: Thursday, August 6, 2020 11:48 AM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Valo, Gina <Gina.Valo@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: Today's Dx EA

Feel free to share:

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2768946> Link to open access of research letter from this week showing number of newly identified patients with six common cancer types fell 46% in first seven weeks of pandemic (March 1, 2020 onward). Getting enormous media coverage (US, Mexico, and elsewhere).

Other recent hot publication is non-COVID-19 related: cervical cancer screening:
<https://academic.oup.com/ajcp/advance-article/doi/10.1093/ajcp/aqaa074/5865067> Also open access. Guidelines are misdirected and will likely cause harm and deaths.

Harvey W. Kaufman, MD, MBA, FCAP, Senior Medical Director, Medical Informatics
Quest Diagnostics | Action from Insight | 15 Pleasant Street, Needham, MA 02492 USA
| phone 201.213.8452 | Harvey.W.Kaufman@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/

For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Thursday, August 6, 2020 11:07 AM
To: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Cc: Valo, Gina <Gina.Valo@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: Today's Dx EA

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.

During today's Diagnostics Evidence Accelerator meeting at Noon ET, Sara Brenner from CDRH is going to present on the recent HHS lab reporting guidance and the implementation guide. You always have thoughtful observations and suggestions, so I wanted to make sure to flag this as a great meeting where your voice and observations will be (as always!) appreciated.

Cheers-

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)
Email: amy.abernethy@fda.hhs.gov

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/10/2020 3:53:05 PM
To: Edward Abrahams [eabrahams@personalizedmedicinecoalition.org]
CC: jay.g.wohlgemuth@questdiagnostics.com
Subject: Re: JW email

Thank you so much, Ed!

Hi Jay - Sending you a separate email.

Take care,

Amy

From: Edward Abrahams <eabrahams@personalizedmedicinecoalition.org>
Sent: Wednesday, June 10, 2020 3:40 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: jay.g.wohlgemuth@questdiagnostics.com <jay.g.wohlgemuth@questdiagnostics.com>
Subject: Re: JW email

Amy:

I am 101 percent sure that Jay would love to hear from you.

His address is: Jay.G.Wohlgemuth@questdiagnostics.com.

Best wishes,

Ed

Edward Abrahams, Ph.D.
President
eabrahams@personalizedmedicinecoalition.org
Direct: 202-787-5907 | Cell: 202-580-5141

Personalized Medicine Coalition
1710 Rhode Island Ave. NW | Suite 700 | Washington, DC 20036
www.PersonalizedMedicineCoalition.org



From: Amy Abernethy <Amy.Abernethy@fda.hhs.gov>
Date: Wednesday, June 10, 2020 at 3:26 PM
To: Edward Abrahams <eabrahams@personalizedmedicinecoalition.org>
Subject: JW email

Hi Ed,

I hope that you are safe and well. Quick question... Do you have Jay Wohlgemuth's email address? Feel free to check with him first before sending it to me.

Thanks and take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/12/2020 9:57:35 AM
To: Wohlgemuth, Jay G [Jay.G.Wohlgemuth@questdiagnostics.com]
CC: Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Waters, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bc2639c6ebd4ecc96e8c0fc6e7bb96f-Michael.Wat]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]; Brenner, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5916ba05b26e4fd0a602fc0049eb382b-Sara.Brenne]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Quick convo

Hi Jay,

Thank you so much. We got caught up in a bunch of meetings yesterday, but are definitely looking forward to talking to you. Since you are on the West Coast, are you able to talk after 2pm today PT (ie after 5p ET)? I am not sure who all from FDA will be able to join, but I can definitely update you and then help to connect the dots to other folks at FDA as appropriate.

Thanks and take care,

Amy

From: Wohlgemuth, Jay G <Jay.G.Wohlgemuth@questdiagnostics.com>
Sent: Thursday, June 11, 2020 9:51 AM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Waters, Michael <Michael.Waters@fda.hhs.gov>; Canos, Daniel <Daniel.Canos@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>
Subject: RE: Quick convo

Amy,

Sorry for the delay. Yes it would be good to talk. I am free today from 10-11 (pac) 12-1230 (pac) and could be free many times tomorrow (Friday).

Let me know if something works for you to catch up

Jay

Jay Wohlgemuth, M.D.
Chief Medical Officer and Senior VP R&D, Medical and Population Health
Quest Diagnostics
33608 Ortega Highway, San Juan Capistrano, CA 92675
mobile +1.949.491.2698
jay.g.wohlgemuth@questdiagnostics.com

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000163

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Sent: Wednesday, June 10, 2020 1:05 PM

To: Wohlgemuth, Jay G <Jay.G.Wohlgemuth@questdiagnostics.com>

Cc: Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Waters, Michael <Michael.Waters@fda.hhs.gov>; Canos, Daniel <Daniel.Canos@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>

Subject: Quick convo

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.

Hi Jay,

I hope that you are safe and well.

Would you be willing to have a quick chat with us about COVID-19 lab data and the work that is happening through the Evidence Accelerator? I can call you in the late afternoon if you want to talk quickly today. There is also a meeting tomorrow at Noon that you might find interesting and that I wanted to tell you about too. Regardless, it would be great to talk even after the meeting tomorrow if/when you are available.

Take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/11/2020 11:13:41 PM
To: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]
Subject: Re: Apologies

Hi Bill,

No worries at all - I totally get it, especially given the complexities of life at the moment.

We are enthusiastic about the work that you are doing and I am looking forward to hearing more. It is really important.

Talk soon!

Take care,

Amy

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Sent: Thursday, June 11, 2020 10:23 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: Apologies

Amy
Just want to be sure you've received my apologies for missing the Evidence Accelerator meeting today. I was looking forward to the discussion, and the chance to contribute. I should have confirmed it was in my calendar in Outlook. My missing the meeting is only a reflection of my poor calendar management. This is an important effort and I'm grateful that Mayo DLMP has been given the opportunity to participate.

Sincerely
Bill Mo

Sent from my iPhone which may account for some typographical errors

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/16/2020 7:47:20 PM
To: Wohlgemuth, Jay G [Jay.G.Wohlgemuth@questdiagnostics.com]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]; Waters, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bc2639c6ebd4ecc96e8c0fc6e7bb96f-Michael.Wat]; Brenner, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5916ba05b26e4fd0a602fc0049eb382b-Sara.Brenne]
CC: Martin, Lauren A [Lauren.A.Martin@questdiagnostics.com]; Sabol, Christine E [Christine.E.Sabol@questdiagnostics.com]; Kaufman, Harvey W [Harvey.W.Kaufman@questdiagnostics.com]; Walsh, Tom P [Tom.P.Walsh@questdiagnostics.com]; Wagner, Tom R [Tom.R.Wagner@questdiagnostics.com]
Subject: Re: FDA-Quest Diagnostics Chat

Thank you very much, Jay. This is exceptionally helpful.

Christine, Harvey, Tom - it is great to meet you. We will work with you to schedule a time to talk via a different email trail.

Please stay safe and well,

Amy

From: Wohlgemuth, Jay G <Jay.G.Wohlgemuth@questdiagnostics.com>
Sent: Tuesday, June 16, 2020 7:26 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Canos, Daniel <Daniel.Canos@fda.hhs.gov>; Waters, Michael <Michael.Waters@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>
Cc: Martin, Lauren A <Lauren.A.Martin@questdiagnostics.com>; Sabol, Christine E <Christine.E.Sabol@questdiagnostics.com>; Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>; Walsh, Tom P <Tom.P.Walsh@questdiagnostics.com>; Wagner, Tom R <Tom.R.Wagner@questdiagnostics.com>
Subject: RE: FDA-Quest Diagnostics Chat

Amy and FDA team,

Thanks for the call yesterday, I'd like to introduce 2 Quest team members who can have a discussion with you on the opportunity to work more closely on public health reporting and data sharing in the COVID and broader ecosystem. I understand the opportunity to be to improve and bring up a level the informatics programs and data sharing which enables our public health infrastructure. There is a lot to that but there are 3 people at Quest who I think should have the discussion with FDA on the needs and opportunities

Christine Sabol, our Regulatory leader for our laboratories, Dr. Harvey Kaufman, our medical informatics leader who works with CDC and others on data sharing initiatives and Tom Walsh who is a leader on our technology team and is working with Christine on public health reporting needs and capabilities at Quest.

Christine can take the lead in scheduling a follow up call with the FDA team.

Christine and team, Amy is Principal Deputy Commissioner and Acting Chief Information Officer for the FDA.

She and her team have a collaborative effort going to upgrade data sharing and public health reporting.

Best,

Jay

Jay Wohlgemuth, M.D.

Chief Medical Officer and Senior VP R&D, Medical and Population Health

Quest Diagnostics

33608 Ortega Highway, San Juan Capistrano, CA 92675

mobile +1.949.491.2698

jay.g.wohlgemuth@questdiagnostics.com

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

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Sent: Friday, June 12, 2020 9:21 AM

To: Abernethy, Amy; Tunis, Sean; Roe, Laura; Franklin, Joseph; Nguyen, Mimi; Wohlgemuth, Jay G; Canos, Daniel; Waters, Michael; Brenner, Sara

Cc: Martin, Lauren A

Subject: FDA-Quest Diagnostics Chat

When: Monday, June 15, 2020 6:00 PM-6:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: WebEx

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.

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [click here](#) to view host information.

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

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/18/2020 10:52:50 AM
To: Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Ross, Joseph [joseph.ross@yale.edu]
CC: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Davies, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]
Subject: Re: Yale / Mayo presentation for dx-EA mtg on 6/18
Attachments: ross Hugo projects RUF 20-06-17aa.ppt

Hi Joe - Thank you so much for being willing to join us today. It will be great to have your presentation.

I took the liberty of editing the deck a bit to focus the discussion. Please see attached and see what you think. I tried to focus on what Hugo could do (without logos) and then the fact that a study will be done. I will weave this together in my presentation as to how I think that this will help for the future of diagnostics.

Thank you!

Amy

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Sent: Thursday, June 18, 2020 8:47 AM
To: Ross, Joseph <joseph.ross@yale.edu>
Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>; Davies, Kathleen <Kathleen.Davies@fda.hhs.gov>
Subject: RE: Yale / Mayo presentation for dx-EA mtg on 6/18

Joe

Thanks again for helping out with this. I think you might be able to remove or skip over slides 13-18. They are interesting projects, but risk losing virtual audience by going too quickly over a lot of info. I think it will go over better to spend more time on the Dhruva study so people understand what the Hugo platform can do, and then jump to slide 19 with the COVID-19 study you are planning. This takes us directly into the focus of the dx-EA program. One of our goals is to understand the various types of RWD that can be collected by various groups/platforms, and yours is pretty unique.

I am copying Amy who may have additional suggestions. Much appreciated!

Sean

From: Ross, Joseph <joseph.ross@yale.edu>
Sent: Wednesday, June 17, 2020 5:41 PM
To: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Amar Bhat <abhat@reaganudall.org>

Subject: RE: Yale / Mayo presentation for dx-EA mtg on 6/18

Sean, I just spoke with Nilay and we agreed that I would be the one to present.

Amar, here are the slides I will use.

Will I control the presentation or will you?

Best, Joe

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Sent: Wednesday, June 17, 2020 4:11 PM

To: Ross, Joseph <joseph.ross@yale.edu>

Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Amar Bhat <abhat@reaganudall.org>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Subject: RE: Yale / Mayo presentation for dx-EA mtg on 6/18

Joe

We would be happy to have either of you present tomorrow. I think it would be great to hear more about Hugo has been used, as described in the Dhruva paper, and also in the context of NEST projects. It would be ideal if you could craft the content with an eye towards the goals for the COVID dx-EA program, as we are most interested in insights about strategies to rapidly learn about the real world performance of COVID-19 dx tests and serology. I think a slide on the OHHHE study would also be worthwhile. We would have about 7-8 minutes for this talk.

Please let us know whether it will be you or Nilay presenting. You can send your slides to Amar Bhat any time tomorrow morning (the earlier the better).

I would be happy to have a look at your slides whenever you have something, Please email or call if you have any more questions. Thnx.

Sean

From: Ross, Joseph <joseph.ross@yale.edu>

Sent: Wednesday, June 17, 2020 1:56 PM

To: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>

Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

If Nilay is available, that's great. If not, I can present and talk about how we have used Hugo for past and current CERSI and NEST projects.

He and I have co-led all these projects, so it doesn't matter which of us presents.

And we can add a slide with the OHHHE study proposal, explaining what my colleagues are hoping to pursue with FDA. Joe

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Sent: Wednesday, June 17, 2020 10:29 AM

To: Ross, Joseph <joseph.ross@yale.edu>

Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>

Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

I was thinking of the Dhuva paper you sent, on which Nilay was the senior author.

So perhaps that is the same as the Hugo platform.

The group is trying to figure out how to pull together RWD in ways that will help us learn about real world performance of COVID-19 dx tests, and it seems that this model might be of interest.

From: Ross, Joseph <joseph.ross@yale.edu>
Sent: Wednesday, June 17, 2020 10:16 AM
To: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Sean, do you mean a discussion of the Hugo platform we've used for research?

Or of the proposal we submitted to OMHHE?

2 of my colleagues at Yale led the OMHHE submission, and I would be happy to see if there were able to present.

Joe

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 9:49 AM
To: Ross, Joseph <joseph.ross@yale.edu>
Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Thanks Joe – good to talk with you, and good to get these blurbs.

Nilay – might you be available tomorrow at noon ET to do a brief summary of your patient-centered data sharing platform for the COVID-19 diagnostics accelerator weekly meeting? Probably about 5-7 min, or a bit more.

Will send more details if the timing works. thnx

Sean

From: Ross, Joseph <joseph.ross@yale.edu>
Sent: Tuesday, June 16, 2020 5:39 PM
To: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Subject: FW: Yale side of the Yale-Mayo CERSI diagnostic test work

Sean,

Good to speak today.

Here are the blurbs I had originally sent Amy about the projects being led by my colleagues in the School of Public Health.

Also, I've attached the proposal our team submitted to OMHHE as part of the CERSI program. This builds on some work we recently published (attached), which I think you'd find interesting.

Nilay (cc'd here) and I would be happy to find a time to follow-up – (b)(6)

(b)(6)

Nilay can definitely speak to the potential of using OptumLabs EHR data for RWE of diagnostic tests – even though, as we discussed, it's a bit of a long shot!

Joe

From: Ross, Joseph <joseph.ross@yale.edu>

Sent: Wednesday, June 10, 2020 5:31 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>

Cc: Ko, Albert <albert.ko@yale.edu>; Grubaugh, Nathan <nathan.grubaugh@yale.edu>; Wyllie, Anne <anne.wyllie@yale.edu>; Krumholz, Harlan <harlan.krumholz@yale.edu>; Shah, Nilay <shah.nilay@mayo.edu>

Subject: Yale side of the Yale-Mayo CERSI diagnostic test work

Amy, Joe and Laura,

Thanks for making the time to connect on Monday about the RUF Diagnostics Evidence Accelerator Workgroup and to learn more about what Yale folks are pursuing in this space that might be relevant to FDA.

I'm cc'ing the principal investigators I've connected to, who will be able to answer specific questions or would welcome the opportunity to present their work in greater detail to the RUF workgroup (they have been joining some of the meetings).

(b) (4)



Thanks again for your time on Monday. Happy to join a call to discuss further,
Joe

Joseph S. Ross, MD, MHS (@jsross119)

Professor of Medicine and Public Health

Center for Outcomes Research and Evaluation (CORE)

Director, Yale-Mayo Clinic Center of Excellence in Regulatory Science and Innovation (CERSI)

Co-Director, Yale Open Data Access (YODA) Project

Co-Director, Yale Collaboration for Research Integrity and Transparency (CRIT)

Co-Director, National Clinician Scholars Program (NCSP) at Yale

Aggregating Real-World Data Sources using a Patient-Centered Data Sharing Platform

Reagan Udall Foundation

Diagnostics Evidence Accelerator Workgroup

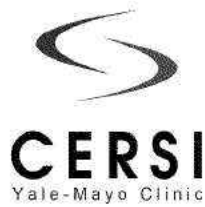
June 18, 2020

Joseph S. Ross, MD, MHS

Section of General Internal Medicine, School of Medicine
Center for Outcomes Research and Evaluation, Yale-New Haven Hospital



Yale SCHOOL OF MEDICINE



The Yale-Mayo Clinic Center of Excellence in Regulatory Science and Innovation (CERSI) is a joint effort between Yale University, Mayo Clinic, and the FDA to conduct research to address key gaps in knowledge and develop tools to support regulatory decision-making and the overall mission of FDA.



The National Evaluation System for health Technologies (NEST) is a voluntary network of health organizations, including Yale-New Haven Hospital, aiming to efficiently develop RWE using RWD to inform medical device evaluation and support regulatory decision-making throughout the total product life cycle.

ARTICLE OPEN



Aggregating multiple real-world data sources using a patient-centered health-data-sharing platform

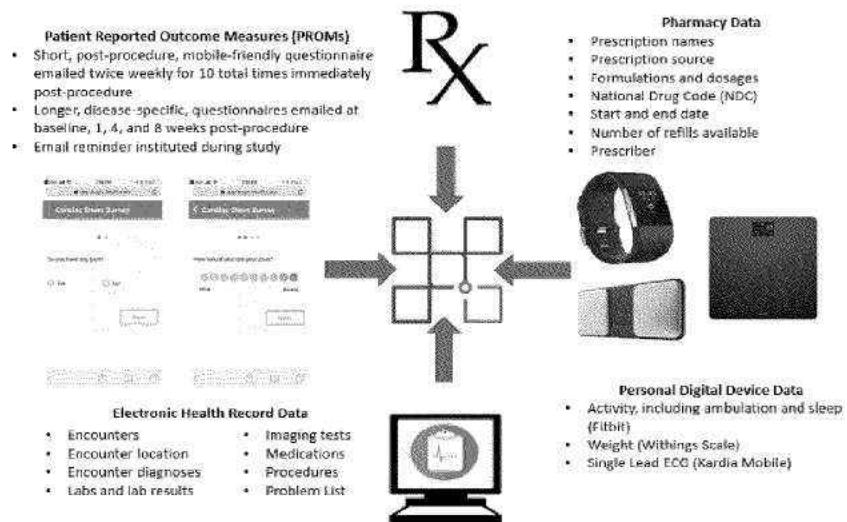
Sanket S. Dhruva¹, Joseph S. Ross^{2,3,4,5}, Joseph G. Akar^{4,5}, Brittany Caldwell⁶, Karla Childers⁷, Wing Chow⁷, Laura Ciaccio⁸, Paul Coplan⁹, Jun Dong⁶, Hayley J. Dykhoff¹⁰, Stephen Johnston⁷, Todd Kellogg⁹, Cynthia Long⁶, Peter A. Noseworthy^{10,11}, Kurt Roberts¹², Anindita Saha⁶, Andrew Yoo⁷ and Nilay D. Shah^{6,11}

Real-world data sources, including electronic health records (EHRs) and personal digital device data, are increasingly available, but are often siloed and cannot be easily integrated for clinical, research, or regulatory purposes. We conducted a prospective cohort study of 60 patients undergoing bariatric surgery or catheter-based atrial fibrillation ablation at two U.S. tertiary care hospitals, testing the feasibility of using a patient-centered health-data-sharing platform to obtain and aggregate health data from multiple sources. We successfully obtained EHR data for all patients at both hospitals, as well as from ten additional health systems, which were successfully aggregated with pharmacy data obtained for patients using CVS or Walgreens pharmacies; personal digital device data from activity monitors, digital weight scales, and single-lead ECGs, and patient-reported outcome measure data obtained through surveys to assess post-procedure recovery and disease-specific symptoms. A patient-centered health-data-sharing platform successfully aggregated data from multiple sources.

npj Digital Medicine (2020)3:60; <https://doi.org/10.1038/s41746-020-0265-z>

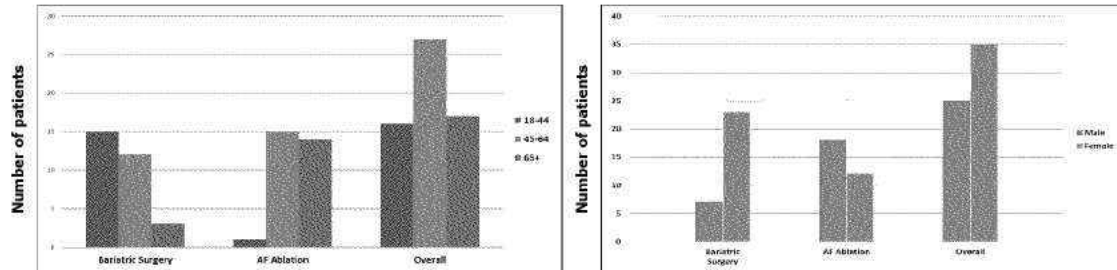


Source: Dhruva et. al., npj Digital Medicine 2020;3:60.



Participation and Enrollment

- 60 patients enrolled; 15 patients per procedure, per site
- 59 patients underwent procedures and completed 8-week follow-up
- Median enrollment time: 70 min (IQR, 58 -100)



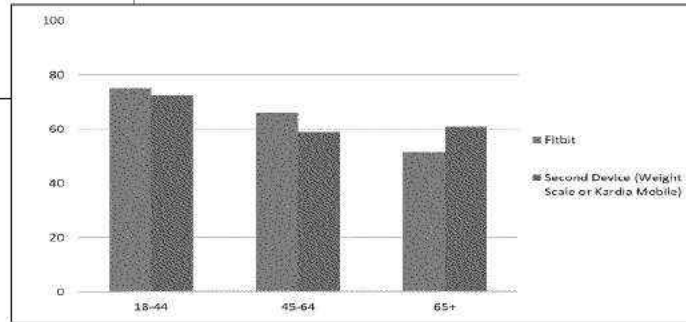
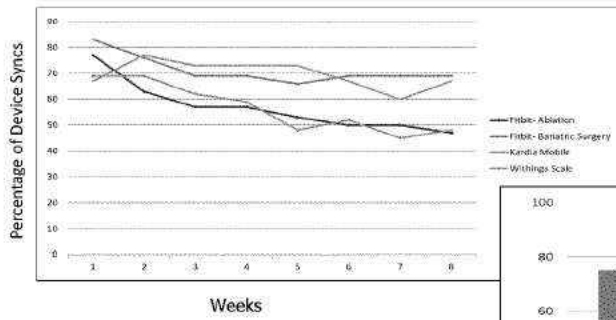
Source: Dhruva et. al., npj Digital Medicine 2020;3:60.

Aggregating EHR and Pharmacy Data

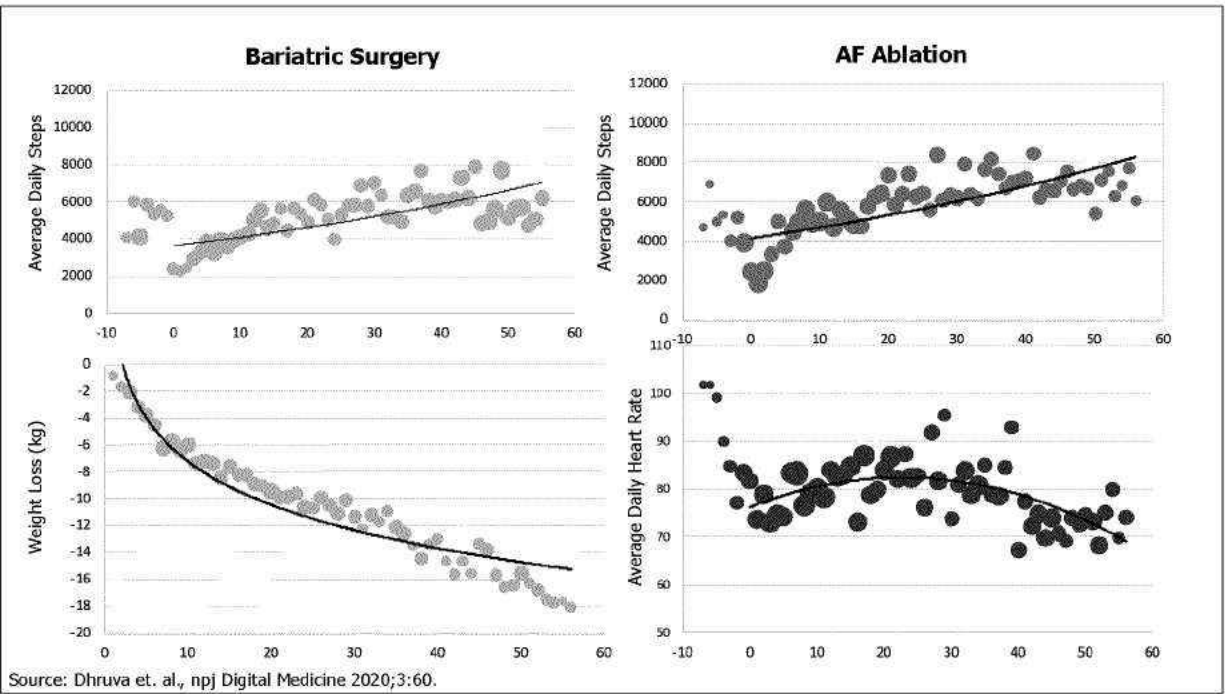
- **Yale and Mayo Clinic health records received for 100% of patients**
- **33 of 60 (55%) patients also with primary care based at Yale or Mayo**
 - **10 patients linked an additional 13 portals from other health systems**
- **24 of 60 (40%) patients connected CVS or Walgreens pharmacy accounts (Walmart now available too)**
 - **Medication names, dosages, start and end dates, refills and prescriber**
- **All data were passively aggregated after initial enrollment, allowing for near real-time streaming data**

Source: Dhruva et. al., npj Digital Medicine 2020;3:60.

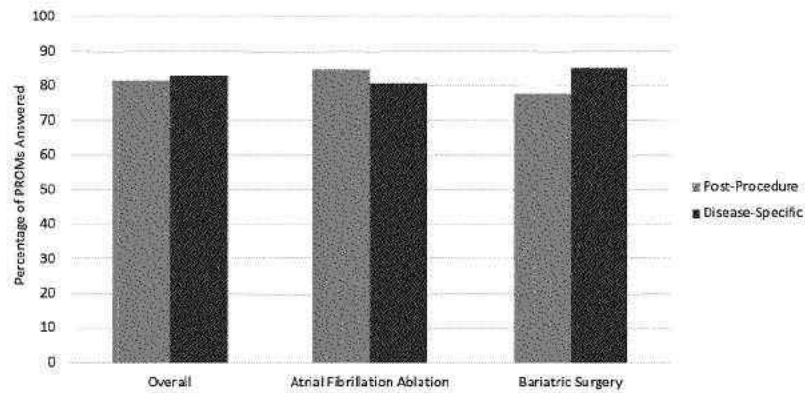
Personal Digital Device Syncs



Source: Dhruva et. al., npj Digital Medicine 2020;3:60.



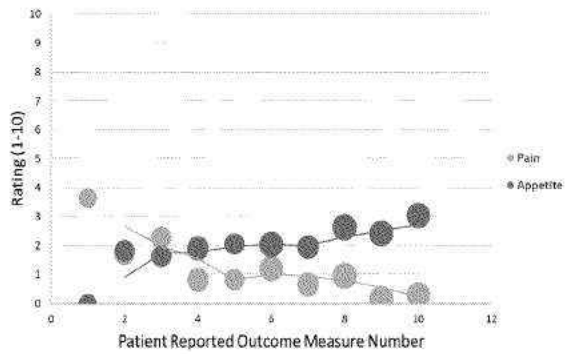
PROMs Completed



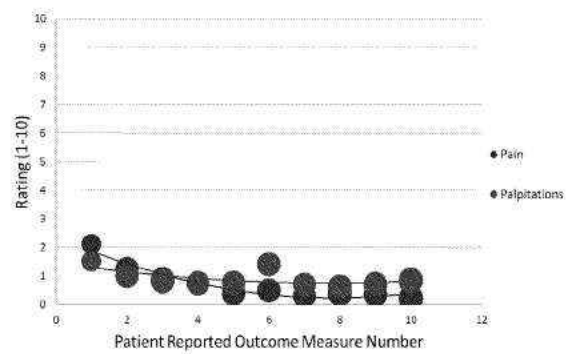
Of all PROMs answered, only 4 were not at least 90% complete

Source: Dhruva et. al., npj Digital Medicine 2020;3:60.

Post-Bariatric Surgery



Post-AF Ablation



Source: Dhruva et. al., npj Digital Medicine 2020;3:60.

**Real-World Data to Characterize COVID19
Disease Progression and Symptom Burden
in Diverse Populations**

Project Aim: Develop representative, real-world data source characterizing experience of patients diagnosed with COVID19 to better understand disease progression and symptom burden in minority and other vulnerable populations.



Proposed Study Design

- **Prospectively enroll 600 patients who are undergoing testing for SARS-CoV-2**
 - CVS Health testing sites in New Haven, CT and Atlanta, GA
- **All patients enrolled in Hugo for PROM surveys over a 180-day follow-up period (clinical course, physical and mental health symptom burden), as well as to connect EHR, pharmacy, and personal digital devices**

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/21/2020 7:46:53 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]
CC: Ross, Joseph [joseph.ross@yale.edu]; Davies, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Yale side of the Yale-Mayo CERSI diagnostic test work

Hi Nilay,

Terrific! We are looking forward to talking. Mimi is cc'ed here and can help us get a call on the calendar.

Thank you and talk soon,

Amy

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Friday, June 19, 2020 2:02 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>; Davies, Kathleen <Kathleen.Davies@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Hi Amy –

My apologies for the delayed response. Joe and I are very excited about the potential of Hugo after our initial project and how it can be an additional (and potentially, unique) data source.

It would be great to find a time to talk about the diagnostics work. Are there days/times that work best on your end? I can do my best to move things around to work around your schedule.

(b) (4)

Thanks
Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Thursday, June 18, 2020 12:10 PM
To: Tunis, Sean; Shah, Nilay D., Ph.D.; Roe, Laura; Franklin, Joseph
Cc: Ross, Joseph; Davies, Kathleen; Valo, Gina
Subject: [EXTERNAL] Re: Yale side of the Yale-Mayo CERSI diagnostic test work

Hi Nilay,

Indeed - Joe's presentation today was excellent and was exactly what I think was needed.

In terms of your point about having one person from Mayo being the point person, this would be great especially as it relates to the Diagnostics work. I have some additional ideas here that I would like to talk to you about as well. Perhaps a quick call?

Thanks,

Amy

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Sent: Thursday, June 18, 2020 1:03 PM
To: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>; Davies, Kathleen <Kathleen.Davies@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Nilay

Thanks for offering to coordinate on the Mayo side. Joe did a great job presenting today. We will definitely be in touch to explore ways we can work together. No worries about Bill last week – we realize that everyone is maxed out. Best,

Sean

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Thursday, June 18, 2020 12:35 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Amy and Sean –

Apologies for Bill not being able to join last week – he is incredibly busy as you might imagine with a variety of testing related projects and got the time wrong on his schedule. To make our participation easier, I am happy to be the point person for Mayo and can coordinate internally. As the diagnostic accelerator goes live, please let me know how I can be helpful.

Thanks
Nilay

From: Abernethy, Amy [<mailto:Amy.Abernethy@fda.hhs.gov>]
Sent: Thursday, June 11, 2020 6:51 AM
To: Roe, Laura; Shah, Nilay D., Ph.D.; Franklin, Joseph
Cc: Ross, Joseph; Tunis, Sean
Subject: [EXTERNAL] Re: Yale side of the Yale-Mayo CERSI diagnostic test work

Thank you, Nilay. This is incredibly helpful information.

@Sean - Can you share with CDRH?

Thanks,

A

From: Roe, Laura <Laura.Roe@fda.hhs.gov>
Sent: Thursday, June 11, 2020 7:04 AM
To: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Thank you, this is very interesting. Adding in Sean.

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Date: June 10, 2020 at 11:56:16 PM EDT
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Roe, Laura <Laura.Roe@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

I also wanted to follow-up on the information related to the type of specific tests. Below is a breakdown to date – I suspect Bill will share this tomorrow, if not FYI:

(b) (4)



From: Abernethy, Amy [<mailto:Amy.Abernethy@fda.hhs.gov>]
Sent: Wednesday, June 10, 2020 7:57 PM
To: Ross, Joseph; Franklin, Joseph; Roe, Laura
Cc: Ko, Albert; Grubaugh, Nathan; Wyllie, Anne; Krumholz, Harlan; Shah, Nilay D., Ph.D.; Tunis, Sean
Subject: [EXTERNAL] Re: Yale side of the Yale-Mayo CERSI diagnostic test work

Hi Joe,

Thank you so much for taking the time to write this out and introduce us to the different projects. Very interesting!

I am cc'ing Sean Tunis here; he helps to advance the Diagnostics Evidence Accelerator work and can tell you more.

There is also a new NCI announcement you should know about:

<https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-20-039.html>

RFA-CA-20-039: Emergency Awards: Research Projects in SARS-CoV-2 Serological Sciences (U01 Clinical Trial Optional)

July 22, 2020. All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

grants.nih.gov

Take care,

Amy

From: Ross, Joseph <joseph.ross@yale.edu>

Sent: Wednesday, June 10, 2020 5:31 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>

Cc: Ko, Albert <albert.ko@yale.edu>; Grubaugh, Nathan <nathan.grubaugh@yale.edu>; Wyllie, Anne <anne.wyllie@yale.edu>; Krumholz, Harlan <harlan.krumholz@yale.edu>; Shah, Nilay <shah.nilay@mayo.edu>

Subject: Yale side of the Yale-Mayo CERSI diagnostic test work

Amy, Joe and Laura,

Thanks for making the time to connect on Monday about the RUF Diagnostics Evidence Accelerator Workgroup and to learn more about what Yale folks are pursuing in this space that might be relevant to FDA.

I'm cc'ing the principal investigators I've connected to, who will be able to answer specific questions or would welcome the opportunity to present their work in greater detail to the RUF workgroup (they have been joining some of the meetings).

(b) (4)

Thanks again for your time on Monday. Happy to join a call to discuss further,
Joe

Joseph S. Ross, MD, MHS ([@jsross119](#))

Professor of Medicine and Public Health

Center for Outcomes Research and Evaluation ([CORE](#))

Director, Yale-Mayo Clinic Center of Excellence in Regulatory Science and Innovation ([CERSI](#))

Co-Director, Yale Open Data Access ([YODA](#)) Project

Co-Director, Yale Collaboration for Research Integrity and Transparency ([CRIT](#))

Co-Director, National Clinician Scholars Program ([NCSP](#)) at Yale

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 7/7/2020 1:01:12 PM
To: Wohlgemuth, Jay G [Jay.G.Wohlgemuth@questdiagnostics.com]
Subject: Accepted: Quest/FDA Call RE: Critical Next Steps
Location: (b) (6)
Start: 7/7/2020 5:00:00 PM
End: 7/7/2020 5:30:00 PM
Recurrence: (none)

From: Amy.Abernethy@fda.hhs.gov [Amy.Abernethy@fda.hhs.gov]
Sent: 7/21/2020 5:02:17 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
Subject: Re: quick primer?

Bingo - this is exactly the type of info that is needed. I imagine 5-7 slides that also include the details of how we calculate sensitivity and specificity and why it matters. Can we chat maybe this evening at 6 ET or tomorrow?

On Jul 21, 2020, at 4:55 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

Hi Amy –

This sounds like a great idea – and would be very helpful to discuss. The diagnostics area is moving very rapidly. We had created something very high level for the newer tests (attached). This does not fully address everything you had outlined below, but may be a starting point.

Count us in – either myself or one of my colleagues will be able to present on Thursday. I will let you know who it will be tomorrow AM.

Thanks for thinking of us.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 3:45 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] quick primer?

Hi Nilay,

I am sitting here thinking through the Therapeutics Lab Meeting on Thursday at 3pm. This is the big one - the original lab meeting that is always 150+ people. A former FDA Commissioner is leading us off. The topic is the implications of diagnostic testing performance on RWD/RWE analyses. I am wondering if you or someone from Mayo would be available to give a 5-10 min primer on diagnostics as a part of this meeting (different COVID tests, sensitivity, specificity, why these aren't each 100%). I can help you prepare and ensure it is fun. It would be great to showcase Mayo.

Thanks for thinking about it!

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

<Non routine COVID test options 07112020_table.docx>

From: Amy.Abernethy@fda.hhs.gov [Amy.Abernethy@fda.hhs.gov]
Sent: 7/21/2020 5:31:07 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
Subject: Re: quick primer?

Great! I will call you then

On Jul 21, 2020, at 5:26 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

I can chat at 6pmET tonight. Is there a best number to call you at? Alternatively, I will be on my cell (b)(6) and you can call me when you are available.

Thanks
Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 4:02 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] Re: quick primer?

Bingo - this is exactly the type of info that is needed. I imagine 5-7 slides that also include the details of how we calculate sensitivity and specificity and why it matters. Can we chat maybe this evening at 6 ET or tomorrow?

On Jul 21, 2020, at 4:55 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

Hi Amy –

This sounds like a great idea – and would be very helpful to discuss. The diagnostics area is moving very rapidly. We had created something very high level for the newer tests (attached). This does not fully address everything you had outlined below, but may be a starting point.

Count us in – either myself or one of my colleagues will be able to present on Thursday. I will let you know who it will be tomorrow AM.

Thanks for thinking of us.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 3:45 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] quick primer?

Hi Nilay,

I am sitting here thinking through the Therapeutics Lab Meeting on Thursday at 3pm. This is the big one - the original lab meeting that is always 150+ people. A former FDA Commissioner is leading us off. The topic is the implications of diagnostic testing performance on RWD/RWE analyses. I am wondering if you or someone from Mayo would be available to give a 5-10 min primer on diagnostics as a part of this meeting (different COVID tests, sensitivity, specificity, why these aren't each 100%). I can help you prepare and ensure it is fun. It would be great to showcase Mayo.

Thanks for thinking about it!

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)
Email: amy.abernethy@fda.hhs.gov

<Non routine COVID test options 07112020_table.docx>

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 6/4/2020 3:24:38 PM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; 'Shah, Nilay D., Ph.D.' [Shah.Nilay@mayo.edu]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
CC: Ross, Joseph [joseph.ross@yale.edu]
Subject: Discussion with Nilay (Mayo)
Attachments: Re: follow-up to the Accelerator call
Location: virtual
Start: 6/8/2020 10:00:00 AM
End: 6/8/2020 10:30:00 AM
Show Time As: Busy

Required Attendees: Abernethy, Amy; 'Shah, Nilay D., Ph.D.'; Franklin, Joseph; Roe, Laura; Nguyen, Mimi



Re: follow-up to
the Accelerator call

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

If you are a host, [click here](#) to view host information.

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

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 6/23/2020 11:23:59 AM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Davies, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; 'Shah, Nilay D., Ph.D.' [Shah.Nilay@mayo.edu]; 'Ross, Joseph' [joseph.ross@yale.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]

Subject: Yale-Mayo CERSI Dx Discussion
Attachments: Re: Yale side of the Yale-Mayo CERSI diagnostic test work
Location: virtual

Start: 6/26/2020 11:30:00 AM
End: 6/26/2020 12:00:00 PM
Show Time As: Busy

Required Attendees: Franklin, Joseph; Tunis, Sean; Roe, Laura; Davies, Kathleen; Valo, Gina; Shah, Nilay D., Ph.D.; Ross, Joseph; Nguyen, Mimi



Re: Yale side of
the Yale-Mayo C...

Please contact [@Nguyen, Mimi](#) to update this meeting.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

[Join meeting](#)

Join by phone

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

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [click here](#) to view host information.

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

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 7/17/2020 4:17:56 PM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; 'Brian S Anderson' [briananderson@mitre.org]; 'Sullivan, Mary Jo' [mjsullivan@mitre.org]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; 'carter.rickey@mayo.edu' [carter.rickey@mayo.edu]; 'Aarthi.G.Shenoy@MedStar.net' [Aarthi.G.Shenoy@MedStar.net]
CC: Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Shoaibi, Azadeh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4aa05659992541c5913af3802c2e8dba-AZS]; Wong, Hui-Lee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6eb0e876aa84bd3afe52eb7d0691a5c-HLW]; Francis X Campion [fcampion@mitre.org]; Andrea Noel [anoel@epic.com]; Stephen Dove [sdove@epic.com]; Eric Lindgren [elindgre@epic.com]; Ryan Luginbuhl [rluginbuhl@mitre.org]; Waheed,Rehan [Rehan.Waheed@cerner.com]; Kunze, Katie L., Ph.D., M.A. [Kunze.Katie@mayo.edu]; Janet Campbell [Janet@epic.com]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]
Subject: RWE Convalescent Plasma Discussion with MITRE
Attachments: Re: Pulling together the team for RWD Convalescent Plasma Research
Location: webex
Start: 7/23/2020 11:00:00 AM
End: 7/23/2020 11:30:00 AM
Show Time As: Busy

Required Attendees: Abernethy, Amy; Roe, Laura; 'Brian S Anderson'; 'Sullivan, Mary Jo'; Nguyen, Mimi; 'carter.rickey@mayo.edu'; 'Aarthi.G.Shenoy@MedStar.net'



Re: Pulling
together the tea...

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting
here.**

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Tap to join from a mobile device (attendees only)

+1-210-795-0506,,1998348282## US Toll

+1-877-465-7975,,1998348282## US Toll Free

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

If you are a host, [click here](#) to view host information.

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

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/16/2020 5:18:27 PM
To: Dr. Brian S Anderson [briananderson@mitre.org]
CC: Mary Jo Sullivan [mjsullivan@mitre.org]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Pulling together the team for RWD Convalescent Plasma Research

Hi - I think that it would be best to have a call with my team and Steve Anderson first, then we can do the deep dive review and get back to Peter. Adding Mimi to help organize from our side. (Mimi - please check with Laura re the list of attendees from the FDA side. We should do this Tues or Wed if possible.)

Thanks,

A

From: Dr. Brian S Anderson <briananderson@mitre.org>
Sent: Wednesday, July 15, 2020 6:35 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Mary Jo Sullivan <mjsullivan@mitre.org>
Subject: Pulling together the team for RWD Convalescent Plasma Research

Hi Amy –

Good chatting just now. Who may I ask MJ to work with on the FDA's end to pull together Peter, Steven and anyone else you'd like us to include in meeting with our team to dive into the initial findings, and the RWD methods and approach? MJ is going to coordinate on our end as well to find a time that works best for everyone.

Thanks,
brian

Brian S. Anderson, MD
Chief Digital Health Physician
The MITRE Corporation
Mobile: 781-640-9391

COVID-19 Healthcare Coalition

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/23/2020 12:37:46 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
CC: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]
Subject: Re: Quick question

These are excellent! Thank you!

@Laura - can you send them to RUF?

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Thursday, July 23, 2020 12:24 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: RE: Quick question

Hi Amy –

Attached are the updated slides that incorporate your comments. Please let us know if there are any additional suggestions or changes.

Thanks again – we are looking forward to the discussion later today.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Thursday, July 23, 2020 8:46 AM
To: Shah, Nilay D., Ph.D.
Cc: Morice, William G. II, M.D., Ph.D.; Roe, Laura
Subject: [EXTERNAL] Re: Quick question

Thank you! Please send to me first.

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Thursday, July 23, 2020 9:45 AM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: RE: Quick question

Hi Amy –

Thanks for this great feedback – we will incorporate the changes and send an updated set of slides late morning. Should we send it to Amar and copy you/Laura or would you prefer we send it to you first? We will remove slide 8 and make sure to keep it at 7 minutes.

Thanks again
Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Thursday, July 23, 2020 6:45 AM
To: Shah, Nilay D., Ph.D.

Cc: Morice, William G. II, M.D., Ph.D.; Roe, Laura

Subject: [EXTERNAL] Re: Quick question

Hi Nilay, Hi Bill,

First of all, thank you! This is great and thank you for working on it. A couple of quick suggestions...

1. Can you start off with a slide on test performance characteristics, how they are calculated (i.e., sensitivity and specificity), and what that means in terms of false negative and false positive rates? I just want to make sure that the audience understands this and has it in their head.
 2. Can you add information with example sensitivities and specificities of the various kinds of tests (ranges/approximations are fine)? You don't need to do it for all of the types of tests, but I just want the audience to see how variable it can be.
 3. For the slides currently numbered 2, 5 and 6:
 - a. The dark text on the colorful background probably won't show up well. Can you change the text to white - or modify the background? (I really like the colors; shifting to white text might be easier.)
 - b. The slides are wordy and we don't have much time. If you want to keep the words, that is fine. Just hit the highlights.
 - c. The key message should be that the tests have different purposes and different performance characteristics; you need to know the test in order to make sense of the rest of the information about the patient.
 4. For the slide currently numbered as Slide 7 - it is great. I think that you can briefly just signal that newer tests are coming. The key message should be that accuracy of diagnostic information available should be improving with time, so we need to keep this shifting landscape of sensitivity and specificity in our heads as we think about analyses with real-world datasets that incorporate diagnostic tests.
 5. For the slide currently numbered as Slide 8, it is great but we are going to get into this later in the hour. Is it OK to cut this slide?
 6. Because it is going to be a packed hour, we need to do this quickly - so 7 min total. That being said, it is so important and critical to the whole discussion - it frames everything. I am very appreciative of your doing this - and also very excited to see how it all comes together.
- Let me know if you want me to call and explain any of my comments.

Thank you!

Amy

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>

Sent: Wednesday, July 22, 2020 11:40 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>

Subject: RE: Quick question

Hi Amy –

I have attached a draft presentation for tomorrow. Would appreciate your thoughts on this.

Thanks

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]

Sent: Wednesday, July 22, 2020 3:27 PM

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000203

To: Shah, Nilay D., Ph.D.

Subject: [EXTERNAL] Re: Quick question

Awesome - I am preparing the agenda now!

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>

Sent: Wednesday, July 22, 2020 4:25 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Subject: RE: Quick question

It will be both me and Bill Morice – we will make sure to do it efficiently.

Will send you the slides this evening.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]

Sent: Wednesday, July 22, 2020 3:25 PM

To: Shah, Nilay D., Ph.D.

Subject: [EXTERNAL] Quick question

Hi - I am trying to prepare the agenda for the email to send out re Lab Meeting. Will you be presenting or will it be someone else from Mayo?

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/23/2020 12:43:23 PM
To: Kaufman, Harvey W [Harvey.W.Kaufman@questdiagnostics.com]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]
Subject: Re: Therapeutics EA

Thank you, Harvey! This is terrific!

If you are on the line, I will plan to call on you for one of these questions, as long as we stay on schedule (sometimes hard!)

From: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Sent: Thursday, July 23, 2020 12:40 PM
To: Roe, Laura <Laura.Roe@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: RE: Therapeutics EA

Got it.

Harvey W. Kaufman, MD, MBA, FCAP, Senior Medical Director, Medical Informatics
Quest Diagnostics | Action from Insight | 15 Pleasant Street, Needham, MA 02492 USA
| phone 201.213.8452 | Harvey.W.Kaufman@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/

For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Roe, Laura <Laura.Roe@fda.hhs.gov>
Sent: Thursday, July 23, 2020 12:19 PM
To: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: RE: Therapeutics EA

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.

Hi Harvey,

Great to hear from you, the official agenda (pasted below) is set. However, Amy would like to be able to engage you in the conversation and have you as an active discussant into this critical topic. She will likely put some specific questions to you, if you are able to be in the meeting. The details for joining are included below, the meeting is at 12 noon PST / 3p EST.

If I can help with anything, please let feel free to text/call me directly at (b)(6)

Thanks,
Laura

All,

You read about it in the news - tests, tests, tests! There are many questions regarding COVID-19 diagnostic tests. Some of the issues have implications for real-world data research and clinical trials as well. Come to the Thursday Therapeutics Evidence Accelerator at 3pm ET to explore:

The implications of COVID-19 diagnostic testing accuracy (inaccuracy?) in COVID-19 research and how to manage it

Our discussion-stimulators include:

- COVID-19 Diagnostics, a quick primer; Bill Morice & Nilay Shah, Mayo Clinic
- Linking the Test, to the Results, to the Clinical Dataset; Ed Michael, Lionbird
- Observational research methods to address in RWE studies; Sebastian Schneeweiss, Harvard Medical School
- Implications for clinical trial patient selection; Rob Califf, Alphabet/Verily
- Thinking about this with an FDA lens; Bob Ball, FDA/CDER

Join us! Information on how to join is below.

Regards,
Amar

Amar Bhat, PhD
Reagan-Udall Foundation for the FDA
M: 202-415-0385

From: abhat@reaganudall.org

When: 3:00 PM - 4:00 PM July 23, 2020

Subject: COVID-19 Evidence Accelerator Collaborative Meeting

Location:

<https://reaganudallfoundationforthefda.my.webex.com/reaganudallfoundationforthefda.my/j.php?MTID=m1872a2db3a22fc817d0bac0949709218>

All,

Thank you very much for your continued interest in the weekly Lab meetings of the COVID-19 Evidence Accelerator, an initiative of the Reagan-Udall Foundation for the FDA and Friends of Cancer Research. We have heard from a large number of you confirming your interest in the activities of the Accelerator and your organization's willingness to be listed as a participant in future communications. If you haven't already responded, please feel free to send me a note.

We are keeping with the same time of 3:00 pm ET on Thursday, April 30. This will be a recurring meeting time. We will be developing the agenda over the course of the week, but anticipate 2-3 presentations this Thursday. If you have suggestions for presenters, please forward them to Carla (crodriguezwatson@reaganudall.org) and/or Jeff (jallen@focr.org).

Please be sure to RSVP and refer any interested colleagues to us. We will forward the invite as long as space allows.

Meeting link:

<https://reaganudallfoundationforthefda.my.webex.com/reaganudallfoundationforthefda.my/j.php?MTID=m1872a2db3a22fc817d0bac0949709218>

Meeting number: (b)(6)

Password: Accelerator2020 (b)(6) from phones and video systems)

If you are experiencing issues dialing in through the +1-510-338-9438 number, additional call in numbers are listed below:

+1-617-315-0704; +1-312-535-8110; +1-469-210-7159; +1-720-650-7664; +1-904-900-2303; +1-213-306-3065; +1-646-992-2010; +1-206-207-1700; +1-202-860-2110; +1-602-666-0783

From: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Sent: Thursday, July 23, 2020 12:01 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: RE: Therapeutics EA

YES!!!

Harvey W. Kaufman, MD, MBA, FCAP, Senior Medical Director, Medical Informatics
Quest Diagnostics | Action from Insight | 15 Pleasant Street, Needham, MA 02492 USA
| phone 201.213.8452 | Harvey.W.Kaufman@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/
For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Tuesday, July 21, 2020 6:32 PM
To: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Cc: Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: Re: Therapeutics EA

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.

Hi Harvey - Checking in one more time. I am just finalizing the plans for Thursday. Let me know if you want to talk for 5 min and I will update you as to the plans. It will be a fun meeting!
Thanks!
Amt

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Tuesday, July 21, 2020 1:17 PM
To: harvey.w.kaufman@questdiagnostics.com <harvey.w.kaufman@questdiagnostics.com>
Cc: Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: Re: Therapeutics EA

Hi Harvey - I wanted to check in with you about this. It is turning into a really interesting and exciting meeting. A former FDA Commissioner is going to open the meeting and frame the topic, and there will be 2-3 other presentations to complement your comments. Please let me know if you want to chat about the plan.

Take care,

Amy

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Monday, July 20, 2020 8:09 PM
To: harvey.w.kaufman@questdiagnostics.com <harvey.w.kaufman@questdiagnostics.com>

Cc: Roe, Laura <Laura.Roe@fda.hhs.gov>

Subject: Therapeutics EA

Hi Harvey,

Your talk was so great during the Diagnostics Evidence Accelerator meeting last Thursday, we have another request!

Would you be willing to speak during the Therapeutics Evidence Accelerator Lab Meeting between 3-4pm on Thursday of this week. Similar topic... It would be good to talk about why the performance of COVID-19 diagnostic tests matters to real-world analyses writ large and how to think about the issue. I will help you shape the talk.

The Therapeutics Evidence Accelerator Lab Meeting was the original EA Lab Meeting and has a bit of a larger audience. It is usually a very interesting meeting and a lot of fun. It would be great to have you.

Thank you for considering it!

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile (b)(6)
Email: amy.abernethy@fda.hhs.gov

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/23/2020 12:44:22 PM
To: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]
Subject: Re: (b)(6)

BTW, actually, I do think it should be a focus of this group. We are looking at something similar for therapeutics - why not for diagnostics.

Adding Laura to help me put it on the list...

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Thursday, July 23, 2020 12:39 PM
To: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Subject: Re: (b)(6)

I loved it!

And I think that you are spot on. I am thinking about how we deal with this issue. It forces me to think about how we might build the data connections to pull it off. Would be worth talking about it more.

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Sent: Thursday, July 23, 2020 12:37 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: (b)(6)

(b)(6) Just wanted to get the point about supply chain in. (b)(6)
(b)(6)

William G. Morice, M.D., Ph.D.
Chair, Department of Laboratory Medicine and Pathology
Professor of Laboratory Medicine and Pathology
Mayo Clinic, Rochester, MN 55905

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 7/21/2020 5:31:11 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
Subject: Re: quick primer?

Great! I will call you then

On Jul 21, 2020, at 5:26 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

I can chat at 6pmET tonight. Is there a best number to call you at? Alternatively, I will be on my cell (b)(6) and you can call me when you are available.

Thanks
Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 4:02 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] Re: quick primer?

Bingo - this is exactly the type of info that is needed. I imagine 5-7 slides that also include the details of how we calculate sensitivity and specificity and why it matters. Can we chat maybe this evening at 6 ET or tomorrow?

On Jul 21, 2020, at 4:55 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

Hi Amy –

This sounds like a great idea – and would be very helpful to discuss. The diagnostics area is moving very rapidly. We had created something very high level for the newer tests (attached). This does not fully address everything you had outlined below, but may be a starting point.

Count us in – either myself or one of my colleagues will be able to present on Thursday. I will let you know who it will be tomorrow AM.

Thanks for thinking of us.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 3:45 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] quick primer?

Hi Nilay,

I am sitting here thinking through the Therapeutics Lab Meeting on Thursday at 3pm. This is the big one - the original lab meeting that is always 150+ people. A former FDA Commissioner is leading us off. The topic is the implications of diagnostic testing performance on RWD/RWE analyses. I am wondering if you or someone from Mayo would be available to give a 5-10 min primer on diagnostics as a part of this meeting (different COVID tests, sensitivity, specificity, why these aren't each 100%). I can help you prepare and ensure it is fun. It would be great to showcase Mayo.

Thanks for thinking about it!

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)
Email: amy.abernethy@fda.hhs.gov

<Non routine COVID test options 07112020_table.docx>

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/23/2020 1:20:08 PM
To: Ross, Joseph [joseph.ross@yale.edu]; Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Davies, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Schulz, Wade [wade.schulz@yale.edu]
CC: Lueck, Heather D. [Lueck.Heather@mayo.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Yale-Mayo COVID-19 Dx Discussion

Terrific. Thank you, Joe. We are looking forward to the conversation tomorrow.

From: Ross, Joseph <joseph.ross@yale.edu>
Sent: Thursday, July 23, 2020 12:15 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>; Davies, Kathleen <Kathleen.Davies@fda.hhs.gov>; Schulz, Wade <wade.schulz@yale.edu>
Cc: Lueck, Heather D. <Lueck.Heather@mayo.edu>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>
Subject: RE: Yale-Mayo COVID-19 Dx Discussion

Amy and Sean,

I'm looking forward to our call tomorrow to discuss the Project 1 idea.

I have forwarded the meeting invite to Wade Schulz, a close colleague of mine at Yale in Lab Medicine, who can better address the feasibility of the project using real-world data. In addition, I am attaching a short grant proposal that he just received funding for, that aligns well with your goals to better understand the accuracy of diagnostic and serology tests.

Best, Joe

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

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Tuesday, July 14, 2020 11:10 AM
To: Abernethy, Amy; Shah, Nilay D., Ph.D.; Ross, Joseph; Tunis, Sean; Roe, Laura; Franklin, Joseph; Valo, Gina; Davies, Kathleen
Cc: Lueck, Heather D.; Nguyen, Mimi
Subject: Yale-Mayo COVID-19 Dx Discussion
When: Friday, July 24, 2020 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: webex

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Tap to join from a mobile device (attendees only)

+1-210-795-0506,,1992993976## US Toll

+1-877-465-7975,,1992993976## US Toll Free

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [click here](#) to view host information.

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

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/11/2020 11:17:24 PM
To: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; 'abhat@reaganudall.org' [abhat@reaganudall.org]
CC: Jenkinson, William G. (Garrett), Ph.D., M.S. [Jenkinson.William@mayo.edu]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]
Subject: Re: Diagnostic Evidence Accelerator today.

Hi Bill,

Thank you for your note. We are really interested in what you have to say and will appreciate the opportunity to pull you in for future conversations.

Looking forward,

Amy

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Sent: Thursday, June 11, 2020 1:51 PM
To: 'abhat@reaganudall.org' <abhat@reaganudall.org>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Jenkinson, William G. (Garrett), Ph.D., M.S. <Jenkinson.William@mayo.edu>
Subject: Diagnostic Evidence Accelerator today.

Amar and Amy

My apologies for missing the meeting today. I was prepared to go, but the meeting wasn't on my Outlook calendar and I neglected to account for the time difference between EST and CST. If I would have done so, I would have realized I had a conflict.

I hope that Dr. Jenkinson from Mayo was able to join as he has been leading our COVID data innovation group. If there is something you need in follow up from me or Mayo please let me know.

Again, my sincere apologies
Bill

William G. Morice, M.D., Ph.D.
Chair, Department of Laboratory Medicine and Pathology
Professor of Laboratory Medicine and Pathology
Mayo Clinic, Rochester, MN 55905

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/10/2020 7:23:27 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
CC: Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]
Subject: Re: Mayo participation in the Diagnostic Evidence Accelerator work group

Hi - Terrific! Thanks for the follow up, Nilay and Sean. Have a great night.

Amy

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Wednesday, June 10, 2020 6:13 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: Mayo participation in the Diagnostic Evidence Accelerator work group

Hi Amy (and Sean) –

Bill did confirm that he is planning on presenting at the Accelerator work group tomorrow. Garrett Jenkinson will co-present with him.

Thanks
Nilay

From: Shah, Nilay D., Ph.D.
Sent: Wednesday, June 10, 2020 3:39 PM
To: 'Abernethy, Amy'
Cc: Tunis, Sean
Subject: RE: Mayo participation in the Diagnostic Evidence Accelerator work group

I believe Bill or one of our colleagues from lab medicine are planning presenting based on the agenda that was sent out. I will double check and confirm shortly.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Wednesday, June 10, 2020 3:26 PM
To: Shah, Nilay D., Ph.D.
Cc: Tunis, Sean
Subject: [EXTERNAL] Fw: Mayo participation in the Diagnostic Evidence Accelerator work group

Hi Nilay,

Please see the email below. We didn't hear back from Bill. Do you have advice as to the best steps?

Thanks,

Amy

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Sent: Monday, June 8, 2020 9:16 PM

To: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Beck, Scott A. <beck.scott@mayo.edu>; Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>; Jenkinson, William G. (Garrett), Ph.D., M.S. <Jenkinson.William@mayo.edu>; Rinaldo, Piero, M.D., Ph.D. <Rinaldo@mayo.edu>; Bennett, Shannon A., M.S. <Bennett.Shannon@mayo.edu>; Hanson, Curtis A., M.D. <cahanson@mayo.edu>; Carla Rodriguez <crodriguezwatson@reaganudall.org>; Susan Winckler <swinckler@reaganudall.org>; Amar Bhat <abhat@reaganudall.org>; Roe, Laura <Laura.Roe@fda.hhs.gov>

Subject: RE: Mayo participation in the Diagnostic Evidence Accelerator work group

Bill and Mayo colleagues

Thanks for your help so far with the COVID-19 dx-EA effort. It is helpful for us to learn about the rich data resources available that may help to answer questions about COVID-19 diagnostics.

For this Thursday's meeting, we were wondering if someone from the Mayo team would be willing to help get a discussion going by making a few minutes of opening comments. The question we would like you to address is: "What will be necessary to make it possible to generate useful evidence about COVID-19 diagnostic test performance using RWD?"

I am not quite sure the phrasing of the question is ideal, but you can feel free to tweak the question if that helps you offer more useful comments. The overall intent of this discussion is to get people like you who really know RWD to provide insights about what it will take to make it helpful in answering questions about test performance/accuracy/etc.

Happy to discuss by phone.

Thanks!

Sean

Sean Tunis MD, MSc
Senior Advisor, FDA/OC/OCPP
sean.tunis@fda.hhs.gov
(410) 963-8876

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>

Sent: Sunday, May 31, 2020 11:18 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Cc: Beck, Scott A. <beck.scott@mayo.edu>; Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>; Jenkinson, William G. (Garrett), Ph.D., M.S. <Jenkinson.William@mayo.edu>; Rinaldo, Piero, M.D., Ph.D. <Rinaldo@mayo.edu>; Bennett, Shannon A., M.S. <Bennett.Shannon@mayo.edu>; Hanson, Curtis A., M.D. <cahanson@mayo.edu>

Subject: Mayo participation in the Diagnostic Evidence Accelerator work group

Hi Amy and Sean

Thanks again for the invitation to the Diagnostic Evidence Accelerator Work Group. I was able to participate in the meeting last week and I think this will be an important effort and I really want Mayo Clinic laboratory medicine to participate. There are 4 individuals who are better suited than I to represent Mayo Lab Medicine, these are Dr. Piero Rinaldo (creator of the CLIR program), Dr. Garret Jenkinson, Shannon Bennett, and Dr. Curt Hanson. They are cc'ed.

Would it be possible for this group to be included and get an invite from the group at the Reagan Udall Foundation?

Thanks!

Bill Mo

William G. Morice II, M.D., Ph.D.

Chair and Professor, Department of Laboratory Medicine and Pathology, Mayo Clinic

President, Mayo Clinic Laboratories

Rochester, Minnesota, USA

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 5/19/2020 9:13:05 AM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Anderson, Brian S. [briananderson@mitre.org]; 'Halamka, John' [halamka.john@mayo.edu]
CC: Mary Jo Sullivan [mjsullivan@mitre.org]; 'Keane, Jean M.' [jkeane@mayo.edu]; Heather E Hawley [hhawley@mitre.org]
Subject: MITRE-Mayo Discussion
Attachments: Re: Recap and Next Steps: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases
Location: virtual
Start: 5/29/2020 8:00:00 AM
End: 5/29/2020 9:00:00 AM
Show Time As: Busy

Required Attendees: Abernethy, Amy; Franklin, Joseph; Roe, Laura; Robb, Melissa; Nguyen, Mimi; Anderson, Brian S.; 'Halamka, John'

Please contact @Nguyen, Mimi to update/change this invite.



Re: Recap and
Next Steps: Con...

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [go here](#) to view host information.

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

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 5/19/2020 10:54:23 AM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]; Leon, Patrick J. (Pat) [Leon.Patrick@mayo.edu]; Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; Beck, Scott A. [beck.scott@mayo.edu]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Halamka, John D., M.D., M.S. [Halamka.John@mayo.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: FDA-Mayo Clinic COVID 19 Discussion
Attachments: Re: intro - Mayo Clinic Labs, FDA
Location: virtual
Start: 5/26/2020 4:00:00 PM
End: 5/26/2020 4:30:00 PM
Show Time As: Busy

Required Attendees: Franklin, Joseph; Tunis, Sean; Canos, Daniel; Leon, Patrick J. (Pat); Morice, William G. II, M.D., Ph.D.; Beck, Scott A.; Roe, Laura; Halamka, John D., M.D., M.S.; Nguyen, Mimi

Update: We had to shift this meeting to 4pm due to an urgent call at 4:30pm ET.



Re: intro - Mayo
Clinic Labs, FDA

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000220

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [go here](#) to view host information.

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

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/13/2020 11:51:21 AM
To: Carolyn Magill [carolyn.magill@aetion.com]; Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]
CC: Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Elizabeth DeMatteis [liz.dematteis@aetion.com]; Leon, Patrick J. (Pat) [Leon.Patrick@mayo.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Jeremy Rassen [jeremy.rassen@aetion.com]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]
Subject: Re: intro - Mayo Clinic Labs, FDA

Thank you, Carolyn

Hi Bill,

It would be great to talk to you about about what Mayo Clinic's approach. We are very interested in learning more.

Adding Mimi here who can help with scheduling; Sean should be on the call, with Joe and Daniel as optional.

Please take care,

Amy

From: Carolyn Magill <carolyn.magill@aetion.com>
Sent: Wednesday, May 13, 2020 11:06 AM
To: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Elizabeth DeMatteis <liz.dematteis@aetion.com>; Leon, Patrick J. (Pat) <Leon.Patrick@mayo.edu>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Jeremy Rassen <jeremy.rassen@aetion.com>
Subject: intro - Mayo Clinic Labs, FDA

Dear Bill and Amy (Dr. Morice, Dr. Abernethy),

It's my pleasure to introduce you and your teams.

As we've talked about, Mayo Clinic Labs is supporting national testing related to covid-19, both molecular and serologic.

(b) (4)

We'll continue to explore with them how their data can inform our understanding of ordering patterns, linkages to outcomes, reinfection rates, etc. In the meantime, thought it would be helpful for you to connect directly.

Enjoy connecting,
Carolyn

Carolyn Magill
Chief Executive Officer
+1 646 279 3735
Aetion | aetion.com

Visit the [Evidence Hub](#), where we share our thinking—and invite yours—about one of the most powerful levers we have to fix health care: data.

This message and any included attachments are confidential. If you are not the intended recipient, please reply to the sender that you received the message in error and delete it without further distribution.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/18/2020 3:10:28 PM
To: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; Carolyn Magill [carolyn.magill@aetion.com]
CC: Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Elizabeth DeMatteis [liz.dematteis@aetion.com]; Leon, Patrick J. (Pat) [Leon.Patrick@mayo.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Jeremy Rassen [jeremy.rassen@aetion.com]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]; Beck, Scott A. [beck.scott@mayo.edu]; Halamka, John D., M.D., M.S. [Halamka.John@mayo.edu]
Subject: Re: intro - Mayo Clinic Labs, FDA

Hi - I am just checking if we have been able to get this scheduled. We are looking forward to the next steps, especially as we start to consider questions about RWD/RWE and diagnostics. It will be great to include John as well.

Thanks and please take care,

Amy

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Sent: Wednesday, May 13, 2020 3:02 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Carolyn Magill <carolyn.magill@aetion.com>
Cc: Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Elizabeth DeMatteis <liz.dematteis@aetion.com>; Leon, Patrick J. (Pat) <Leon.Patrick@mayo.edu>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Jeremy Rassen <jeremy.rassen@aetion.com>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Canos, Daniel <Daniel.Canos@fda.hhs.gov>; Beck, Scott A. <beck.scott@mayo.edu>; Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>
Subject: RE: intro - Mayo Clinic Labs, FDA

Carolyn

Thank you for making the connection. Dr. Abernethy, nice to "e-meet" you. I will work with Pat and my administrative assistant JoAnn to get a meeting arranged. I think it would be good to have my colleague Scott Beck included. We may also want to ask Dr. John Halamka to join, as he is leading Mayo Clinic's efforts in data and platform analytics, but that will depend on his availability. Both are cc'ed.

Look forward to connect. Also to clarify, (b) (4)

[REDACTED]

[REDACTED]

Look forward to our discussion.

Bill Morice

William G. Morice II, M.D., Ph.D.
Professor and Chair, Department of Laboratory Medicine & Pathology
Mayo Clinic

President, Mayo Clinic Laboratories
Rochester, MN

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Wednesday, May 13, 2020 10:51 AM
To: Carolyn Magill; Morice, William G. II, M.D., Ph.D.
Cc: Franklin, Joseph; Elizabeth DeMatteis; Leon, Patrick J. (Pat); Nguyen, Mimi; Jeremy Rassen; Tunis, Sean; Nguyen, Mimi; Canos, Daniel
Subject: [EXTERNAL] Re: intro - Mayo Clinic Labs, FDA

Thank you, Carolyn

Hi Bill,

It would be great to talk to you about about what Mayo Clinic's approach. We are very interested in learning more.

Adding Mimi here who can help with scheduling; Sean should be on the call, with Joe and Daniel as optional.

Please take care,

Amy

From: Carolyn Magill <carolyn.magill@aetion.com>
Sent: Wednesday, May 13, 2020 11:06 AM
To: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Elizabeth DeMatteis <liz.dematteis@aetion.com>; Leon, Patrick J. (Pat) <Leon.Patrick@mayo.edu>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Jeremy Rassen <jeremy.rassen@aetion.com>
Subject: intro - Mayo Clinic Labs, FDA

Dear Bill and Amy (Dr. Morice, Dr. Abernethy),

It's my pleasure to introduce you and your teams.

As we've talked about, Mayo Clinic Labs is supporting national testing related to covid-19, both molecular and serologic.

(b) (4)



We'll continue to explore with them how their data can inform our understanding of ordering patterns, linkages to outcomes, reinfection rates, etc. In the meantime, thought it would be helpful for you to connect directly.

Enjoy connecting,
Carolyn

Carolyn Magill
Chief Executive Officer
+1 646 279 3735
Aetion | aetion.com

Visit the [Evidence Hub](#), where we share our thinking—and invite yours—about one of the most powerful levers we have to fix health care: data.

This message and any included attachments are confidential. If you are not the intended recipient, please reply to the sender that you received the message in error and delete it without further distribution.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/17/2020 8:07:06 PM
To: Dr. Brian S Anderson [briananderson@mitre.org]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; halamka.john@mayo.edu
Subject: Re: Recap and Next Steps: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases

Hi Brian,

Thank you so much. This is great and very much in line with our interests with respect to understanding the impact of convalescent plasma. I have definitely been tracking along with what is happening.

1. Do you have a copy of the data model used for the REDCAP database mentioned in the paper? I am mainly interested in the CDEs.
2. Is there a current plan for a natural history benchmark?

Perhaps we can catch up by phone; Mimi is cc'ed to help get it scheduled. It would be great to include John when he is available; I cc'ed him here to keep things moving (Hi John!).

Thanks,

Amy

From: Dr. Brian S Anderson <briananderson@mitre.org>
Sent: Sunday, May 17, 2020 8:26 AM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: Re: Recap and Next Steps: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases

Hi Amy,

I wanted to also follow-up on our conversation and your request for more information on what we were doing to support the Convalescent Plasma research in particular. After we spoke, my team and I met with Steven Anderson (CBER) last week. On our call with Steven I shared that our team would be working closely with the Mayo Clinic Research team, running the National Expanded Access Treatment Protocol. We've also been working closely with the lead researchers from the National COVID-19 Convalescent Plasma Project.

Working with researchers from both organizations, MITRE is bringing together various stakeholders across EHR vendors (e.g. (b) (4) etc.) and Data Analytics companies (e.g. (b) (4) etc.) to partner with the enrolling health system sites in a federated analytics approach to create cohort comparator groups based on the RWD within the health systems.

These critical cohort comparators will look to provide better clarity in terms of any efficacy benefit for convalescent plasma. (b) (4)

I'm sure you've already seen the pre-publication release from the Mayo Clinic on the Safety Indicators. Re-attaching to this email in case you haven't seen it yet. (b) (4)

Let me know if you'd like to follow-up more on Convalescent Plasma. John Halamka and I are working very closely together with the leadership on the Convalescent Plasma Projects.

Hope you are doing well!

brian

From: "Williams, Erin D." <erinw@mitre.org>

Date: Tuesday, May 12, 2020 at 11:59 AM

To: "Abernethy, Amy" <amy.abernethy@fda.hhs.gov>

Cc: "Robb, Melissa" <Melissa.Robb@fda.hhs.gov>, "Nguyen, Mimi" <Mimi.Nguyen@fda.hhs.gov>, "Anderson, Brian S." <briananderson@mitre.org>, "Schnitzer, Jay J" <jschnitzer@mitre.org>, "Laura.Roe@fda.hhs.gov" <Laura.Roe@fda.hhs.gov>, "Hawley, Heather E." <hhawley@mitre.org>

Subject: Recap and Next Steps: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases

Dear Amy,

Thank you for carving out time for our conversation this morning. As promised, we will link arms to launch timely an elegant approach to what is required on behalf of the nation: *(Please correct/amend liberally)*

(b) (4)

We value your input to ensure our aligned understanding. Heather and I will follow up with OAGS to close the loop on a rapid launch. As promised, we will also send you a copy of the (b) (4), and Brian will follow up with an update on convalescent plasma.

We look forward to what comes next.

Best Regards,
Erin

Erin D. Williams, JD

Executive Director, Biomedical Innovation
Health and Human Services Portfolio Director
The Health Federally Funded Research and Development Center
Operated by The MITRE Corporation
O: 703-983-5107; M: 703-462-0369
erinw@mitre.org

Administrative Assistant:

Nawina Matshona
O: 703-983-7121; Fax: 703-983-2852
nmatshona@mitre.org

MITRE

The MITRE Corporation is a not-for-profit organization that operates federally funded research and development centers on behalf of the United States government.

From: briananderson@mitre.org

When: 9:30 AM - 10:00 AM May 12, 2020

Subject: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases

Location: <https://mitre.zoomgov.com/j/1607184557?pwd=eVV1SSt6bG42bUJ3d3VNVmIJVkJN2dz09>

From: "Anderson, Brian S." <briananderson@mitre.org>

Date: Monday, May 11, 2020 at 4:20 PM

To: "Abernethy, Amy" <amy.abernethy@fda.hhs.gov>, "Sullivan, Mary Jo" <mjsullivan@mitre.org>, Heather Hawley <hhawley@mitre.org>

Cc: "Schnitzer, Jay J" <jschnitzer@mitre.org>, "Williams, Erin D." <erinw@mitre.org>, "Roe, Laura" <Laura.Roe@fda.hhs.gov>, "Nguyen, Mimi" <Mimi.Nguyen@fda.hhs.gov>, "Robb, Melissa" <Melissa.Robb@fda.hhs.gov>

Subject: Re: [EXT] Re: Time for a quick chat?

Hi Amy,
Wonderful!

We can make 9:30am ET work. I'm adding @Sullivan, Mary Jo who can help pull together the critical calendars on our end, including Erin, Jay and @Hawley, Heather E..

Thanks again Amy and look forward to chatting!

brian

From: "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>

Date: Monday, May 11, 2020 at 1:18 PM

To: "Anderson, Brian S." <briananderson@mitre.org>

Cc: "Schnitzer, Jay J" <jschnitzer@mitre.org>, "Williams, Erin D." <erinw@mitre.org>, "Roe, Laura" <Laura.Roe@fda.hhs.gov>, "Nguyen, Mimi" <Mimi.Nguyen@fda.hhs.gov>, "Robb, Melissa"

<Melissa.Robb@fda.hhs.gov>

Subject: [EXT] Re: Time for a quick chat?

Hi Brian,

Terrific! I look forward to talking. Would tomorrow morning around 9:30am work for you? @Mimi is cc'ed here and can help us get organized asap.

Thanks!

Amy

From: Anderson, Brian S. <briananderson@mitre.org>

Sent: Monday, May 11, 2020 11:36 AM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Schnitzer, Jay J <jschnitzer@mitre.org>; Williams, Erin D. <erinw@mitre.org>

Subject: Time for a quick chat?

Hi Amy –

I heard from some of our colleagues inside MITRE that there were some exciting conversations around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases.

Do you have 15 minutes today (or tomorrow) for a quick chat about some possible next steps?

Would love to make sure we're on the same page as your vision for this.

Best,

Brian

Brian S. Anderson, MD

Chief Digital Health Physician

The MITRE Corporation

Mobile: 781-640-9391

COVID-19 Healthcare Coalition

Mary Jo Sullivan is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

(b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

One tap mobile

(b)(6) US (San Jose)

(b)(6) US (New York)

Dial by your location

(b)(6) US (San Jose)

(b)(6) US (New York)

Meeting ID: (b)(6)

Find your local number: (b)(6)

Join by SIP

(b)(6)

Join by H.323

(b)(6)

(US West)

(b)(6)

(US East)

Meeting ID: (b)(6)

Password: (b)(6)

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/17/2020 7:03:05 AM
To: Jay Shendure [shendure@uw.edu]
CC: Carla Rodriguez [crodriguezwatson@reaganudall.org]; Cowgill, Karen [n-kcowgill@kingcounty.gov]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; esigal@focr.org; jallen@focr.org; Susan Winckler [swinckler@reaganudall.org]; Dewan, Puneet [n-pdewan@kingcounty.gov]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: SCAN

Jay and Karen,

Thank you very much for taking the time to talk to the group about your work at SCAN. It was really helpful. The Reagan Udall / Friends of Cancer Research team will be following up, as the Evidence Accelerator work is expanded in the diagnostics space.

Kind regards,
Amy

From: Jay Shendure <shendure@uw.edu>
Sent: Friday, May 15, 2020 8:17 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Carla Rodriguez <crodriguezwatson@reaganudall.org>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; esigal@focr.org <esigal@focr.org>; jallen@focr.org <jallen@focr.org>; Susan Winckler <swinckler@reaganudall.org>; Dewan, Puneet <n-pdewan@kingcounty.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>
Subject: Re: SCAN

Dear Amy & all,

On behalf of myself and Karen, it was very nice to speak with you earlier this afternoon. I am attaching here some of the documents that came up on the call, e.g. our questionnaires, as well as technical and situation reports from the analysis of the resulting data. Happy to answer any questions about them.

We look forward to seeing the questions that the Diagnostics Accelerator is prioritizing when they are available.

Best regards,

Jay (& Karen)

Jay Shendure, MD, PhD
Investigator, Howard Hughes Medical Institute
Director, Allen Discovery Center for Lineage Tracing
Director, Brotman Baty Institute for Precision Medicine
Professor, Genome Sciences, University of Washington

On Tue, May 12, 2020 at 6:23 PM Abernethy, Amy <Amy.Abernethy@fda.hhs.gov> wrote:

Hi Jay,

Thank you very much for your willingness to talk to us about your work with SCAN.

Mimi, cc'ed here, can help us with scheduling. (Please include Sean, Joe, Laura R from FDA)

We look forward to talking.

Take care,

Amy

From: Carla Rodriguez <crodriguezwatson@reaganudall.org>

Sent: Tuesday, May 12, 2020 5:28 PM

To: Jay Shendure <shendure@uw.edu>

Cc: Cowgill, Karen <n-kcowgill@kingcounty.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; esigal@focr.org <esigal@focr.org>; jallen@focr.org <jallen@focr.org>; Susan Winckler <swinckler@reaganudall.org>; Dewan, Puneet <n-pdewan@kingcounty.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>

Subject: RE: SCAN

Dear Dr. Shendure,

Thanks so much for reaching out! I believe Mimi Nguyen from FDA will reach out to coordinate a call.

Excited to talk with you.

Best,

Carla

From: Jay Shendure <shendure@uw.edu>

Sent: Tuesday, May 12, 2020 5:23 PM

To: Carla Rodriguez <crodriguezwatson@reaganudall.org>

Cc: Cowgill, Karen <n-kcowgill@kingcounty.gov>; Sean <Sean.Tunis@fda.hhs.gov>; amy.abernethy@fda.hhs.gov; Melissa <Melissa.Robb@fda.hhs.gov>; Laura <Laura.Roe@fda.hhs.gov>; esigal@focr.org; jallen@focr.org; Susan Winckler <swinckler@reaganudall.org>; Dewan, Puneet <n-pdewan@kingcounty.gov>

Subject: Re: SCAN

Hi Carla & all,

Nice to meet you by email. I am the co-lead of SCAN (Seattle Coronavirus Assessment Network).

Karen Cowgill (cc'd) asked that I pick up this thread as I may be in a better position to discuss SCAN.

I would be very happy to talk to Dr. Abernethy this week about SCAN and how it might inform your efforts.

Best regards,

Jay Shendure

Investigator, Howard Hughes Medical Institute
Director, Allen Discovery Center for Lineage Tracing
Director, Brotman Baty Institute for Precision Medicine
Professor, Genome Sciences, University of Washington
shendure@uw.edu | 206.685.8543

From: Carla Rodriguez <crodriguezwatson@reaganudall.org>
Sent: Monday, May 11, 2020 6:50 AM
To: Dewan, Puneet <n-pdewan@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>
Cc: Tunis, Sean <Sean.Tunis@fda.hhs.gov>; amy.abernethy@fda.hhs.gov; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; esigal@focr.org; jallen@focr.org; Susan Winckler <swinckler@reaganudall.org>
Subject: RE: SCAN

[EXTERNAL Email Notice!] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Resending because Karen wasn't on original message....

Dear Karen and Puneet,

We appreciate that you might not be able to discuss results from SCAN at this point and will keep checking back!

Would it be possible to schedule a 30 min call with Dr. Abernethy this week to discuss how SCAN might inform work we are doing to launch a Diagnostics Accelerator?

I've copied her team, who will take the coordination from here.

Thanks again for all you're doing.

Best,
Carla

From: Carla Rodriguez <crodriguezwatson@reaganudall.org>
Sent: Sunday, May 10, 2020 9:28 AM
To: Cowgill, Karen <n-kcowgill@kingcounty.gov>
Subject: Re: Introduction

Dear Karen,

Thanks for checking. We will be starting a Diagnostics Accelerator (~ week of 5/21) in Parallel to the Therapeutics Accelerator. Is there info in that space that might be shared? Our focus will be in describing the environments & populations where different diagnostics/serology have been deployed, as well as describing accuracy of the different tests in real- world (compared to PCR, for example).

As with the existing Evidence Accelerator, we are not trying to supplant ongoing studies, but understand what's been collected and see if there is room for alignment so that we can run parallel analyses with other datasets and be able to identify trends.

This info is not being widely circulated- so please limit circulation.

Thanks!
Carla

Get [Outlook for iOS](#)

From: Cowgill, Karen <n-kcowgill@kingcounty.gov>
Sent: Saturday, May 9, 2020 8:56:51 PM
To: Carla Rodriguez <crodriguezwatson@reaganudall.org>
Subject: RE: Introduction

Hi Carla,

I brought this offer to the rest of the SCAN team and the consensus is that this looks interesting but that it's a little premature for SCAN to present at this point as the system is still getting established ... please keep us in mind in the months ahead and reach out again if this might still be of interest to the group.

Thanks,
Karen

From: Cowgill, Karen
Sent: Friday, May 8, 2020 1:23 PM
To: Carla Rodriguez <crodriguezwatson@reaganudall.org>; Baer, Atar <Atar.Baer@kingcounty.gov>; Dewan, Puneet <n-pdewan@kingcounty.gov>
Subject: RE: Introduction

Thanks, Carla, and thanks, Atar, for the introduction!

Carla, my apologies for the slow reply, and thank you for the opportunity for SCAN to consider presenting as part of the COVID-19 Evidence Accelerator initiative. This looks interesting -- a quick call to discuss how we might contribute to this effort might be a good next step. I will check in with SCAN colleagues and follow up with you.

Best regards,
Karen

Karen Cowgill, PhD, MSc (*she/her*)
COVID-19 Response Epidemiologist
Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Affiliate Assistant Professor in Global Health, University of Washington
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (206) 263-3087; Fax: (206) 296-4803
E-mail: n-kcowgill@kingcounty.gov

From: Carla Rodriguez <crodriguezwatson@reaganudall.org>
Sent: Monday, May 4, 2020 12:10 PM
To: Baer, Atar <Atar.Baer@kingcounty.gov>; Dewan, Puneet <n-pdewan@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>
Subject: RE: Introduction

[EXTERNAL Email Notice!] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Dear Atar, Karen and Puneet,

Thanks very much for this introduction. Being both a UW and PHSKC alum, I am so proud of the work coming out of Seattle!

I am writing in the hopes that you all might be willing to share the SCAN experience on surveillance and/or natural history of COVID-19 at one of our Accelerator Lab meetings. If it's OK, I'd like to connect you with Dr. Amy Abernethy, Deputy Commissioner of the FDA, to discuss further.

The Foundation, in collaboration with the Friends of Cancer Research, is working closely with the FDA on the COVID-19 Evidence Accelerator. Essentially, the Accelerator operates through two distinct workstreams:

1) Accelerator Parallel Analyses: Developing key research questions that multiple organizations and teams can address simultaneously.

Initial activities of this work stream include (1) rapidly revising a list of core data elements; (2) identifying those critical to answering the primary question; and (3) establishing uniform collection parameters. It will be necessary to work collaboratively to determine how data elements are being extracted and how they are being defined in order to operationalize a platform that can not only answer questions now, but also inform how research activities could be conducted in the future.

Repeating analyses in parallel by collaborators using different analytical techniques and data sources will help strengthen findings and learnings. Furthermore, this effort will help validate the role of real-world data as a tool for rapidly learning about patient characteristics, treatment patterns and outcomes associated with management strategies for COVID-19.

The first question we are organizing around is around COVID-19 treatments. For more detail, please see our [website](#). We sent an initial survey of critical questions and core data elements around, to which approximately 25 organizations responded with their data availability and feedback. Working with 8 organizations so far, we have since refined the definitions of these data elements, including inclusion, exclusion, exposure and outcome definitions. **These meetings occur every Wednesday**. Time varies but is generally from 4-5 pm ET.

2) Accelerator Lab Meetings: Share findings from interested data partners on critical questions.

Results are generated and analyzed in many different ways and using different methods and data sources. Lab meetings will provide a venue for scientists across the country to discuss data generated from quick turnaround queries and share results with peers and experts from FDA, major data organizations, academic research institutions, professional societies, and health systems to help accelerate, and potentially even confirm, findings from different data sources and leverage existing expertise. **These meetings occur every Thursday** from 3-4 pm ET. Summaries of past presentations are posted on our website (mentioned above).

There have been some nice reviews of this work in the press, which you can see [here](#).

Please let me know if you think you might be able to present at an upcoming Lab Meetings; or if you'd be able to have a quick call to discuss other ways to participate.

Best,
Carla

Carla Rodriguez-Watson, PhD, MPH

Scientific Director of IMEDS

Direct: 202-849-2069 | Main: 202-849-2075

1900 L Street, N.W., Suite 835, Washington, DC 20036

www.reaganudall.org / www.focr.org/covid19

From: Baer, Atar <Atar.Baer@kingcounty.gov>

Sent: Monday, May 4, 2020 10:16 AM

To: Carla Rodriguez <crodriguezwatson@reaganudall.org>; Dewan, Puneet <n-pdewan@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>

Subject: Introduction

Hi Karen and Puneet -- a former colleague, Carla Rodriguez, is working for the Reagan-Udall Foundation for the Food and Drug Administration to organize info coming out of the many studies related to COVID.

Carla, I am connecting you with Karen, who is our SCAN liaison -- please follow up with Karen with specific questions you have about SCAN.

Puneet is with Global Good, and has been leading all aspects related to coordination of COVID testing -- please follow up with Puneet with specific questions you have related to testing.

Thanks in advance for your willingness to share your expertise with Carla.

Atar

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/31/2020 5:43:06 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: follow-up to the Accelerator call

Hi Nilay,

Thank you so much for your message. Apologize for being slow in following up - I am still catching up on email after a long week.

I spoke with John Halamka and team about both diagnostics and convalescent plasma related work. It would be great to follow up with you about the VIRUS registry and other activities going on in your CERSI if you are available. Perhaps a call the week of Jun 8? Adding Mimi here to help us get it set up. It would be great to include Joe and/or Laura as well.

Take care,

Amy

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Wednesday, May 27, 2020 7:43 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: follow-up to the Accelerator call

Hi Amy –

Hope you are well. I wanted to follow-up on a couple ideas that were discussed on the Accelerator call:

1. We have discussed a variety of datasets as part of the Accelerator...not sure if the VIRUS registry was discussed? I have talked to my colleagues who are leading it and it might be a good dataset for natural history of patients during their hospitalization as well as for evaluating various treatments that were discussed: <https://www.sccm.org/Research/Research/Discovery-Research-Network/VIRUS-COVID-19-Registry>. Happy to invite the investigators to present about the data on one of the calls if that would be helpful.
2. There are a variety of strategies that are in the works related to identifying a control group for the convalescent plasma study. Was the goal today to discuss potential options for the control group? I wonder if having the study team present their approaches and getting feedback might be helpful?
3. It sounds like you have also connected with our medical lab leadership – I have invited them to the diagnostic accelerator meeting tomorrow.

(b) (4)

Please let me/our CERSI know if we can be helpful in any way as the agency looks at various aspects of diagnostics and therapeutic agents.

Thanks

Nilay

Nilay Shah, PhD

Chair, Division of Health Care Policy and Research

Robert E. and Patricia E. Kern Endowed Director for Research, Kern Center for the Science of Health Care Delivery

Associate Professor of Health Services Research

Mayo Clinic

Rochester, MN

Ph: 507-266-5130

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/29/2020 11:33:28 AM
To: Halamka, John D., M.D., M.S. [Halamka.John@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: Re: I think we have a plan

Thanks, Peter. Since our emails crossed in the ether, can you check my edits below. And then I think we are good to go.

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Friday, May 29, 2020 11:32 AM
To: Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Re: I think we have a plan

Thanks so much, John. This is in line with the direction from my understanding. I am also working on a summary of the current situation to send to Peter so that we all have the same information.

A couple of minor amendments in the proposed message below:

Folks:

I've talked to all the stakeholders about the June 15 deadlines requested by the FDA

1. The Expanded Access Program (EAP) has a Red Cap database of (b) (4) COVID patients which is used to prepare safety data and will be analyzed in the coming days for outcomes/efficacy measures. Amy Abernethy confirmed that Stephen Hahn and Peter Mark's focus for June 15 is this Red Cap database. Peter Marks has provided the EAP team with the analytics desired by the FDA and all is aligned for a June 15th delivery.

2. Next week we'll begin the process of collecting line-level patient data directly from Epic and Cerner sites to contribute to this effort.

This Epic/Cerner federated approach will be extremely valuable but does not need to part of the June 15 analysis. Amy Abernethy is also directly involved in this effort.

3. Epic and Cerner will also continue to work together in consultation with MSU and Mayo researchers to further analyze available consolidated data.

John

From: Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>
Sent: Friday, May 29, 2020 11:27 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: I think we have a plan

Before I send this email to Epic/Cerner, Mitre, Expanded Access Program, Mayo leadership and the two of you, are there any edits you'd like?

Thanks so much

Folks:

I've talked to all the stakeholders about the June 15 deadlines requested by the FDA

1. The Expanded Access Program (EAP) has a Red Cap database of (b) (4) COVID patients which is used to prepare safety data and will be analyzed in the coming days for outcomes/efficacy measures. Amy Abernathy confirmed that Stephen Hahn's focus for June 15 is this Red Cap database. Peter Marks has provided the EAP team with the analytics desired by the FDA and all is aligned for a June 15th delivery

2. Next week we'll begin the process of collecting line-level patient data directly from Epic and Cerner sites to contribute to this effort.

This Epic/Cerner federated approach will be extremely valuable but does not need to part of the June 15 analysis. Amy Abernathy is also directly involved in this effort.

3. Epic and Cerner will also continue to work together in consultation with MSU and Mayo researchers to further analyze available consolidated data.

John

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 1/19/2020 2:58:30 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
CC: Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Invitation to present the Plenary at the Mayo Clinic AI Symposium

Hi Nilay,

Thank you so much for the invitation. I am honored.

I am cc'ing Allison and team here to see what might be possible. We are trying to schedule a trip to Minnesota/Wisconsin & Mayo for several reasons so it is possible that we could align schedules, though there is already another meeting to which I have committed on 5/13 so it might still be tough. But let's see what we can do.

Thanks and take care,

Amy

From: "Shah, Nilay D., Ph.D." <Shah.Nilay@mayo.edu>
Date: Friday, January 17, 2020 at 3:54 PM
To: "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>
Subject: Invitation to present the Plenary at the Mayo Clinic AI Symposium

Dear Amy –

It was great to see you at the UCSF-Stanford meeting in San Francisco last weekend. I was reaching out to invite you to present at the Mayo Clinic AI Symposium which is being held on May 12-13. The goal of this meeting is focused on use of AI algorithms at the front lines of healthcare delivery and describe experiences of implementation in the EHR and impact of these algorithms on patient outcomes. I suspect that this will likely not work with your schedule, but I thought I would try.

If this does not work, we would love to have you visit Mayo Clinic as part of the CERSI to identify opportunities to further partner with the FDA. We can work around your schedule to find a time that might work in the future.

Thanks in advance for considering this.

Nilay

Nilay Shah, PhD
Chair, Division of Health Care Policy and Research
Robert E. and Patricia E. Kern Endowed Director for Research, Kern Center for the Science of Health Care Delivery
Associate Professor of Health Services Research
Mayo Clinic
Rochester, MN
Ph: 507-266-5130



From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 6/24/2020 12:44:40 PM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]
CC: Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]
Subject: RE: Inquiry

Hi Peter –

Hope you are well too.

Thanks for your note

I'm copying my colleague Mary Beth Clarke, Director of the Office of Executive Programs, to help us identify the best POC in CDER.

Thank you,

Anand

Anand Shah, MD

Deputy Commissioner for Medical and Scientific Affairs

U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Wednesday, June 24, 2020 12:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Inquiry

Anand,

Good day to you. Trust all is well.

I'm looking for help to find a contact within CDER in the drug review group. (b) (4)

(b) (4) I have some questions to understand FDA's requests.

Do you have a contact there I could reach out to?

Thanks and take care,

Peter

Peter E. Shearstone

Vice President

Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.

168 Third Avenue | Waltham, Massachusetts 02451

Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642

Internal extension 110-1333

peter.shearstone@thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/15/2020 9:13:07 AM
To: Wilkins, Donna M. [donna.wilkins@thermofisher.com]
Subject: Read: RE: Ext Call - Thermo Fisher / FDA (Follow up)

Your message

To: Shah, Anand
Subject: RE: Ext Call - Thermo Fisher / FDA (Follow up)
Sent: 5/15/2020 8:55:41 AM

was read on 5/15/2020 9:13:07 AM

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/14/2020 5:01:41 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; O'Neill, Kimberly [Kimberly.Oneill@thermofisher.com]
Subject: RE: Ext Call - Thermo Fisher / FDA (Follow up)

Great, Mark. Also looping in Jeff so we can compare notes and next steps
Anand

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Thursday, May 14, 2020 4:42 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>; O'Neill, Kimberly <Kimberly.Oneill@thermofisher.com>
Subject: Re: Ext Call - Thermo Fisher / FDA (Follow up)

Hi Anand,

I put my assistant in copy here to connect with Jenna.

Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Thursday, May 14, 2020 at 4:38 PM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: "Zembower, Jenna" <Jenna.Zembower@fda.hhs.gov>
Subject: Ext Call - Thermo Fisher / FDA (Follow up)

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Mark -

Good conversation today.

Can I briefly touch base with you and your team so that we talk through the various follow up items – perhaps 15 min tomorrow?

Jenna can help us schedule

Thanks,

Anand

Anand Shah, MD

Deputy Commissioner for Medical and Scientific Affairs

U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Sent: Thursday, May 14, 2020 9:49 AM

To: Hahn, Stephen ^{(b) (6)} <[\[REDACTED\]@fda.hhs.gov](mailto:[REDACTED]@fda.hhs.gov)>

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

Dear Steve,

Yes, fine to share email. The attachment was more related to vaccine proposal note diagnostic testing.

For clarity here are the 5 items I regard as follow up.

(b) (4)



Regards

Mark

From: Steve Hahn ^{(b) (6)} @fda.hhs.gov>

Date: Thursday, May 14, 2020 at 8:31 AM

To: Mark Stevenson <mark.stevenson@thermofisher.com>

Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark,

We are setting up a call with Dr. Birx and Jeff Shuren. Is it ok if I share this email and the attachments with Dr. Birx prior to the call?

Thanks

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 10, 2020 at 8:17:11 AM EDT

To: Hahn, Stephen ^{(b) (6)} @fda.hhs.gov>

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

Steve

Janice and my assistant are connected and to arrange a call. Plenty of topics to cover around public health.

Our submissions to amendment to our FDA EUA to expand our qPCR platforms and protocols was approved which will greatly expand platforms already installed able to run the COVID19 assay, including in a 384 well throughput. ^{(b) (4)}

^{(b) (4)}

We proposed to BARDA (i) short-term solution to enable sterile manufacturing production capacity in Q4 2020 for vaccines to support the COVID-19 pandemic at this critical time ^{(b) (4)}

Best Mark

From: Steve Hahn ^{(b) (6)} @fda.hhs.gov>

Date: Saturday, May 9, 2020 at 10:14 AM

To: Mark Stevenson <mark.stevenson@thermofisher.com>

Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah,

Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send toSOC@thermofisher.com.

Mark,

thank you very much for your message. Great work on all counts. We very much appreciate the work with Thermo Fisher. It would be great to arrange a call in the upcoming week. I'll ask Janice to arrange.

I am in self-quarantine but doing well.

Best

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 9, 2020 at 9:53:38 AM EDT

To: Hahn, Stephen (b) (6) <Stephen.Hahn@fda.hhs.gov>

Subject: COVID diagnostics

Dear Steve,

I had read you will self-quarantine for 14 days after exposure to White House spokesperson Katie Miller, who tested positive for Covid-19 on Friday, so it prompted me to send a note. I hope you remain negative but I know you will have plenty of access to FDA EUA tests!

Quick update from Thermo Fisher. (b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

We have also followed up on the work done with Mayo Clinic on ELISA lab based serology testing and signed an agreement with Mayo/WuXi for that test for total antibodies (IgM/IgG). We will make a submission for that serology test will be coming to the FDA in the next few weeks.

We have also engaged with the NIH on their RADx to continue to innovative around diagnostic testing for COVID.

Let me know if we can be helpful during this unprecedented times. I'm sure at some point we can also spend time to share observations and lessons learnt in a post COVID world for how industry and FDA work together.

Best Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T +1 (781) 622-1344
Mobile (+WhatsApp) :+1 760 576 9897

mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill

T (781) 419-3222

kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/15/2020 5:43:03 PM
To: Madeline Grant [grantm5@uw.edu]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]
Subject: RE: response from FDA

Hi Madeline -

Nice to chat today. Thanks for the additional background.

Our team is in touch with Tina Lockwood of SCAN on the various questions.

Anand

From: Madeline Grant <grantm5@uw.edu>
Sent: Friday, May 15, 2020 12:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: response from FDA

From: Katims, Casey (GOV) <casey.katims@gov.wa.gov>
Sent: Friday, May 15, 2020 7:39 AM
To: Madeline Grant <grantm5@uw.edu>
Cc: Nick Bath@help.senate.gov; Fristedt, Andi (HELP Committee) <Andi.Fristedt@help.senate.gov>; Peterson, Kristin I (DOH) <Kristin.Peterson@DOH.WA.GOV>
Subject: response from FDA

Madeline:

Below is the response I just received from FDA to our inquiry about SCAN. (b) (4)

(b) (4)

Can you let us know if this meets UW's needs or if further clarification and encouragement is needed from us?

Happy to keep pushing! Let us know how we can help.

Casey

(b)(6)

From: White, Erica <Erica.White@fda.hhs.gov>
Sent: Friday, May 15, 2020 10:29 AM

To: Katims, Casey (GOV) <casey.katims@gov.wa.gov>

Cc: Wilson, Morgan (GOV) <Morgan.Wilson@gov.wa.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>

Subject: FW: urgent question on state EUAs

Good morning Casey,

Thank you for your email below regarding the SCAN state-issued EUA. HHS referred your email to us, FDA Intergovernmental Affairs, for a response. FDA's recommendations for COVID-19 testing on the use of at-home testing, including at-home specimen collection have not changed. The FDA's guidance has provided a [Policy for Coronavirus Disease-2019 Tests](#), which does not apply to home collection of specimens to be sent for testing at a laboratory certified under CLIA for high-complexity testing. The recent guidance updates did not change the policy regarding state oversight. Home collection raises additional concerns about safety and accuracy that require FDA review, as we have discussed in our FAQs and other communications about home collection.

Research studies conducted under supervision of an Institutional Review Board (IRB) are handled separately, and in such case, an IRB may determine that home collection may occur with appropriate mitigations under such a supervised study.

We had previously understood that SCAN was being conducted as a surveillance study. As appropriately determined by the applicable IRB, such an option for home collection may be available to the project sponsors.

I also wanted to let you know that FDA reached out to UWA and is continuing to work with them on their options.

If you have additional questions please feel free to contact me.

Thank you,

Erica M. White, J.D.

Intergovernmental Affairs (IGA)
Office of the Commissioner/OPLIA
U.S. Food and Drug Administration
Office: (301)796-8309
Erica.White@fda.hhs.gov



From: Katims, Casey (GOV) <casey.katims@gov.wa.gov>

Sent: Wednesday, May 13, 2020 3:56 PM

To: Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>

Cc: Wilson, Morgan (GOV) <Morgan.Wilson@gov.wa.gov>

Subject: urgent question on state EUAs

Darcie:

As I mentioned by phone, the Greater Seattle Coronavirus Assessment Network (SCAN) has been operating under a state-issued EUA for its community surveillance partnership with Seattle-King County Public Health since early March, (b) (4) They have been using at-home collection kits for this study.

Pursuant to FDA's changes requiring an approved EUA for home testing, they have been forced to pause their work.

Can you confirm whether it was FDA's intent to halt home testing under state-issued EUAs (b) (4)

(b) (4) **Is it also FDA's intent to halt the state's authority to issue EUAs?**

Thanks for any help. Our folks are confused and would appreciate any clarity. They are also eager to get the SCAN efforts back up and running.

Casey

(b) (6)

From: Jay Shendure <shendure@uw.edu>

Sent: Tuesday, May 12, 2020 10:49:33 PM

To: Lindquist, Scott W (DOH) <scott.lindquist@doh.wa.gov>; Estes, Honora L (DOH) <honora.estes@doh.wa.gov>; kristin.peterson@doh.wa.gov <kristin.peterson@doh.wa.gov>

Cc: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Christina M Lockwood <tinalock@uw.edu>; Apa, James <James.Apa@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Mark Rieder <mrieder@uw.edu>

Subject: important SCAN updates

[EXTERNAL Email Notice!] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Dear Honora, Scott and Kristin --

I am writing on behalf of the SCAN team to let you know about some important developments that occurred earlier today. As you know, the Northwest Genomics Center SARS-CoV-2 RT-PCR test for SCAN has been operating under a WA-issued EUA for our community surveillance partnership with PHSKC since early March,

(b) (4)

We were notified this morning that consequent to changes in the FDA's EUA guidance around home testing that were made last Friday (5/8), returning SARS-CoV-2 results to patients using at-home collection kits is no longer allowed (b) (4)

(b) (4)

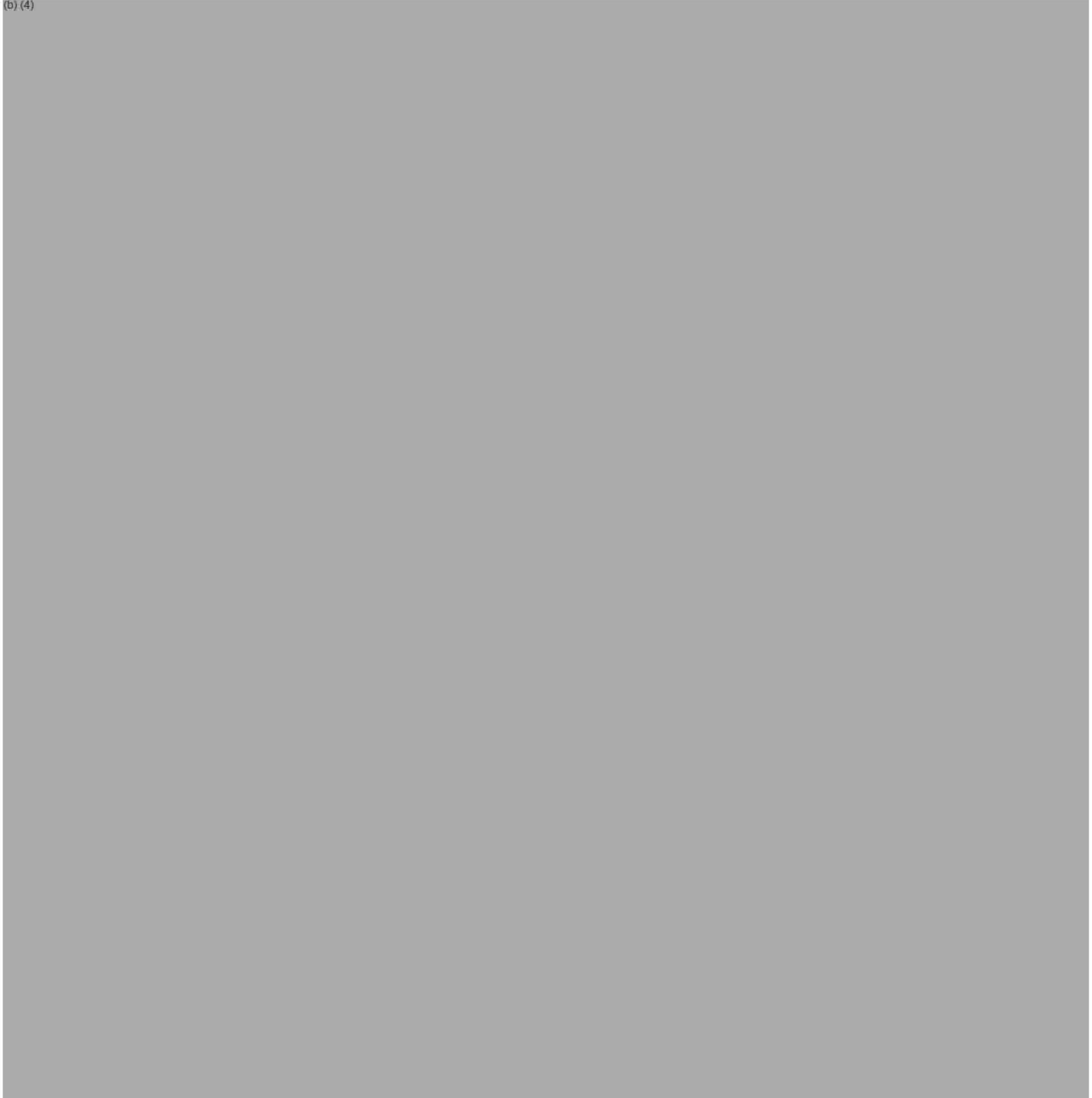
We would welcome the opportunity to discuss these developments with you in the next day or two if we can arrange it. I have cc'd Jeff Duchin and several of his colleagues at PHSKC, as well as Tina Lockwood (our lab director) and Mark Rieder (SCAN's program director).

Best regards,

Jay Shendure

SCAN Statement

(b) (4)



Jay Shendure, MD, PhD
Investigator, Howard Hughes Medical Institute
Director, Allen Discovery Center for Lineage Tracing
Director, Brotman Baty Institute for Precision Medicine
Professor, Genome Sciences, University of Washington
shendure@uw.edu | 206.685.8543



From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/14/2020 1:11:09 PM
To: Madeline Grant [grantm5@uw.edu]
Subject: Accepted: Call with FDA Deputy Commissioner Anand Shah and UW Medicine
Location: (b)(6)
Start: 5/15/2020 12:30:00 PM
End: 5/15/2020 1:00:00 PM
Show Time As: Busy

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/14/2020 10:11:00 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
CC: Stein, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d30a87acb0184261961264ba984b0a51-Peter.Stein]
Subject: RE: Follow up

Dear Gianrico –

I am including Dr. Peter Stein, Director of the Office of New Drugs, who also leads our Coronavirus Treatment Acceleration Program.

Here's an update from Dr. Stein and team:

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



Thanks,
Anand

PRE-DECISIONAL, CONFIDENTIAL

From: Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>
Sent: Wednesday, May 13, 2020 7:57 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Follow up

Here they are and thank you.

(b) (4)



(b) (4)



(b) (4)

Thank you.

From: Shah, Anand [mailto:Anand.Shah@fda.hhs.gov]
Sent: Tuesday, May 12, 2020 4:22 PM
To: Farrugia, Gianrico, M.D.
Subject: [EXTERNAL] Follow up

Dear Gianrico –

Nice to chat with you on today's call with Dr. Hahn.

(b) (4)



Thanks,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/27/2020 2:52:40 PM
To: Rusckowski, Stephen H [Stephen.H.Rusckowski@questdiagnostics.com]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: RE: Unobserved COVID 19 Self Collection Kit EUA for Quest Diagnostics

Dear Steve –

Thanks for checking in. I've cc'd our Device center leadership team and we will reach out shortly.

Best,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Rusckowski, Stephen H <Stephen.H.Rusckowski@questdiagnostics.com>
Sent: Monday, April 27, 2020 10:06 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Unobserved COVID 19 Self Collection Kit EUA for Quest Diagnostics

Anand:

I am writing to ask for your help.

We have been working with the FDA on an EUA for an observed self collection kit for COVID19. We were hopeful that we would hear soon since the FDA team says they have everything they need from us.

This kit approval is very important to simplify our testing and increasing our capacity.

We would appreciate any help to move the process along.

Thank you very much.

Steve Rusckowski
Quest Diagnostics
Chairman, President and CEO

Get [Outlook for iOS](#)

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/4/2020 5:11:31 PM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: RE: Thank You

Thanks for your kind note, Peter
Anand

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Monday, May 4, 2020 5:08 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Thank You

Dear Jeff and Anand,
Just a quick note to share a sincere thank you for the Insight Antibody test column today on FDA.gov.
Very much appreciate all that you and your staff members are doing to keep our country safe.
Warm regards,
Peter

Peter E. Shearstone
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642
Internal extension 110-1333
peter.shearstone@thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 5/8/2020 10:20:59 AM
To: Eppler, Machele M. [machele.eppler@thermofisher.com]; Sipes, Grail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccee8d18ee1f4a36885078f780c2f2f8-SIPESG]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Thermo Fisher Covid-19 (b) (4)

Also meant to include Julie Tierney, Chief of Staff, Center for Biologics Evaluation and Research (CBER)
Thank you
Anand

From: Shah, Anand
Sent: Friday, May 8, 2020 10:20 AM
To: Eppler, Machele M. <machele.eppler@thermofisher.com>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Subject: RE: Thermo Fisher Covid-19 (b) (4)

Hi Machele -

Thanks for your note. I'm looping in my colleague Grail Sipes, Deputy Center Director for Regulatory Policy at our Center for Drug Evaluation and Research (CDER), for guidance.
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Eppler, Machele M. <machele.eppler@thermofisher.com>
Sent: Thursday, May 7, 2020 11:52 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Thermo Fisher Covid-19 (b) (4)

Dear Mr. Anand Shah,

My name is Machele Eppler and I am the VP of Quality, North America Drug Product Division, Pharma Services Group at Thermo Fisher Scientific.

(b) (4)



Best regards,
Machelle Eppler
VP of Quality, North America Drug Product Division
Thermo Fisher Scientific.

Machelle Eppler
Vice President Quality & Global Regulatory
Drug Product Division – North America
(919) 268-1262
Machelle.eppler@thermofisher.com



From: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Sent: 4/6/2020 9:01:47 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Casper, Marc N. [marc.casper@thermofisher.com]
CC: Werner, Mechelle [mechelle.werner@thermofisher.com]
Subject: Ext Call - Marc Casper (Thermo Fisher) / Anand Shah (FDA)
Location: (b)(6)
Start: 4/6/2020 12:00:00 PM
End: 4/6/2020 12:30:00 PM
Show Time As: Busy

Required Attendees: Casper, Marc N.

Marc's direct line: (b)(6)

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

210-795-0506 US Toll

877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

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

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/6/2020 8:59:01 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
CC: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]
Subject: RE: Note from FDA

Thanks, Marc. Jenna will send a cal invite with this number at 12pm today.
Anand

From: Casper, Marc N. <marc.casper@thermofisher.com>
Sent: Monday, April 6, 2020 8:57 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: RE: Note from FDA

Anand,
Before 9:30AM at (b)(6) or noon to 1:30 at same number.
Thanks,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, April 6, 2020 8:55 AM
To: Casper, Marc N. <marc.casper@thermofisher.com>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: RE: Note from FDA

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Marc -
TF platform expansion for COVID serology testing
Anand

From: Casper, Marc N. <marc.casper@thermofisher.com>
Sent: Monday, April 6, 2020 8:54 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: RE: Note from FDA

Dear Anand,
What is the topic so that I can be prepared to be helpful?

Thanks,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, April 6, 2020 8:44 AM
To: Casper, Marc N. <marc.casper@thermofisher.com>
Cc: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Subject: Note from FDA

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Dear Marc –
What is the best mobile # to reach you this morning?
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/6/2020 9:57:26 AM
To: farrugia.gianrico@mayo.edu
CC: Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: Follow up from HHS

Dear Dr. Farrugia –

It was great to connect with you and your team on today's call with the Secretary. We look forward to working with you.

(b) (4)

I've also included my colleagues including Dr. Rick Bright from BARDA and Dr. Tammy Beckham from HHS.

Thank you

Best,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Sent: 4/6/2020 9:01:49 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Ext Call - Marc Casper (Thermo Fisher) / Anand Shah (FDA)
Location: AS to call (b)(6)
Start: 4/6/2020 12:00:00 PM
End: 4/6/2020 12:30:00 PM
Show Time As: Tentative

Required Attendees: Casper, Marc N.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/7/2020 5:25:52 PM
To: Sachs, Alan B. [Alan.Sachs@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
CC: Casper, Marc N. [marc.casper@thermofisher.com]; Shearstone, Peter E. [peter.shearstone@thermofisher.com]
Subject: Ext Call - Thermo Fisher Follow Up

Hi Alan,
Good to connect and thanks for this follow up
Jenna is going to help us schedule a call with me, Dr. Tim Stenzel, and Dr. Jeet Guram.
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Sachs, Alan B. <Alan.Sachs@thermofisher.com>
Sent: Monday, April 6, 2020 12:28 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Casper, Marc N. <marc.casper@thermofisher.com>
Subject: Alan Sachs Thermo Fisher Scientific contact information

Anand,

Thank you very much for reaching out to Thermo Fisher Scientific today. My contact information is listed below.

(b) (4)



Alan

Alan Sachs, M.D., Ph.D.
Chief Scientific Officer

Thermo Fisher Scientific
5781 Van Allen Way | Carlsbad, CA 92008
Tel: +1 510 410 6921
Mobile: alan.sachs@thermofisher.com | www.thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/6/2020 1:31:49 PM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]; Casper, Marc N. [marc.casper@thermofisher.com]; alan.sachs@thermofisher.com
CC: Zembowier, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]
Subject: Ext Call - Mayo / Thermo Fisher / FDA

Hi Gianrico –

I've copied Marc Casper and Alan Sachs from Thermo Fisher.

Can this group find 20 min later today for a brief intro to Mayo and TF (b) (4) I'd like to help connect dots.

Please feel free to include your SMEs.

Jenna can help us schedule

Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/8/2020 2:40:46 PM
To: Sachs, Alan B. [Alan.Sachs@thermofisher.com]; Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]
CC: Casper, Marc N. [marc.casper@thermofisher.com]; peter.shearstone@thermofisher.com
Subject: RE: Alan Sachs Thermo Fisher Scientific contact information

Hi Tammy –

Per our discussion earlier this morning, I am connecting you and Admiral Giroir with the leadership of Thermo Fisher.

FDA had a follow up call with TF today, and we thought it would be great if they could connect with you as well.

Best,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Sachs, Alan B. <Alan.Sachs@thermofisher.com>
Sent: Monday, April 6, 2020 12:28 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Casper, Marc N. <marc.casper@thermofisher.com>
Subject: Alan Sachs Thermo Fisher Scientific contact information

Anand,

Thank you very much for reaching out to Thermo Fisher Scientific today. My contact information is listed below.

(b) (4)



Alan

Alan Sachs, M.D., Ph.D.
Chief Scientific Officer

Thermo Fisher Scientific
5781 Van Allen Way | Carlsbad, CA 92008
Tel: +1 510 410 6921
Mobile: alan.sachs@thermofisher.com | www.thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/8/2020 12:31:23 PM
To: Pettiti, Gianluca [Gianluca.Pettiti@thermofisher.com]; Sachs, Alan B. [Alan.Sachs@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; peter.shearstone@thermofisher.com; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
CC: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Wilkins, Donna M. [donna.wilkins@thermofisher.com]
Subject: Ext Call - Thermo Fisher Follow Up
Location: (b)(6)
Start: 4/8/2020 2:30:00 PM
End: 4/8/2020 2:45:00 PM
Show Time As: Tentative

Required Attendees: Pettiti, Gianluca; Sachs, Alan B.; Stenzel, Timothy; peter.shearstone@thermofisher.com; Guram, Jeet

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

210-795-0506 US Toll

877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/7/2020 5:05:54 PM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]
CC: Sachs, Alan B. [Alan.Sachs@thermofisher.com]
Subject: RE: Serology Opportunities

Hi Peter –

I am going to copy you on my reply to Alan's note momentarily
Anand

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Tuesday, April 7, 2020 3:47 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Sachs, Alan B. <Alan.Sachs@thermofisher.com>
Subject: Serology Opportunities

Dear Dr. Shah,

Hope you and yours are well.

Reaching out to check on your availability for a call with our Chief Scientific Officer Alan Sachs and I to discuss feedback and questions from yesterday's call concerning serology COVID testing.

Dr. Sachs and I can be available as your schedule allows.

Warm regards,
Peter

Peter E. Shearstone

Vice President

Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.

168 Third Avenue | Waltham, Massachusetts 02451

Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642

Internal extension 110-1333

peter.shearstone@thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 1/30/2020 9:00:20 AM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
Subject: RE: FDA visit 1/30

Hi Nilay –

Thanks for your note and good to hear from you

Unfortunately today doesn't work for me, but do let me know next time you're here

Thanks,

Anand

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Wednesday, January 29, 2020 12:09 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FDA visit 1/30

Dear Anand –

Congratulations on your new role at the FDA! I suspect you wouldn't remember me, but we met last year as part of a Mayo Clinic visit to CMMI (with Kavita Patel). As I saw that you recently transitioned to the FDA, I wanted to reach out to you. I co-lead (with Joe Ross from Yale) a FDA-funded Center for Excellence in Regulatory Science and Innovation (CERSI) and we have had great opportunities to partner with the agency on a variety of important problems. As part of the CERSI, Joe and I visit the FDA almost every month and will be at the agency tomorrow. I wanted to see if you would have a few minutes to meet with us tomorrow. I am sure you are very busy with the recent move, but thought I would reach out in case you had some time to meet. If not, it would be great to connect with you during one of our future visits.

Thanks in advance for considering this.

Nilay

Nilay Shah, PhD

Chair, Division of Health Care Policy and Research

Robert E. and Patricia E. Kern Endowed Director for Research, Kern Center for the Science of Health Care Delivery

Associate Professor of Health Services Research

Mayo Clinic

Rochester, MN

Ph: 507-266-5130

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 4/12/2020 8:45:37 PM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Accepted: APHL/Commissioner Hahn
Location: (b)(6)
Start: 4/14/2020 10:30:00 AM
End: 4/14/2020 11:00:00 AM
Recurrence: (none)

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/17/2020 10:48:29 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE:

Hi Mark -
Thank you very much.
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 10:36 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

Dear Anand

Per your phone call, Thermo Fisher

(b) (4)



Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 10:24 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Subject: <no subject>

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/17/2020 4:23:21 PM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Patel, Chaitali [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815d91f3d5e143b387acd82539f7e149-Chaitali.Pa]
Subject: RE:

Thank you –
Anand

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Tuesday, March 17, 2020 3:03 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Stevenson, Mark <mark.stevenson@thermofisher.com>
Cc: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>
Subject: RE:

Dr Shah – short update

(b) (4)

Thank you.
Peter

Peter E. Shearstone
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642
Internal extension 110-1333
peter.shearstone@thermofisher.com

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 1:56 PM
To: Stevenson, Mark <mark.stevenson@thermofisher.com>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>
Subject: RE:

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Mark -
Do you have additional details on the highlighted?
Anand

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 11:28 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

(b) (4)

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 11:17 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: Peter Shearstone <peter.shearstone@thermofisher.com>
Subject: RE:

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark -
To clarify, (b) (4)
Anand

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 10:36 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

Dear Anand

Per your phone call, Thermo Fisher

(b) (4)

Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 10:24 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Subject: <no subject>

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/18/2020 11:56:29 AM
To: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Fenton, Tim [tim.fenton@thermofisher.com]
Subject: RE: Daily Production and Shipping Data - Thermo Fisher Scientific

Thank you, Peter

From: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Sent: Wednesday, March 18, 2020 11:54 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Fenton, Tim <tim.fenton@thermofisher.com>
Subject: Daily Production and Shipping Data - Thermo Fisher Scientific

Dear Dr. Shah, Dr. Stenzel,

Good morning.

Please see attached our daily report for Thermo Fisher COVID-19 kit production and shipments.
Please revert with questions.

Best,
Peter

Peter E. Shearstone
Vice President
Global Quality Assurance & Regulatory Affairs

Thermo Fisher Scientific Inc.
168 Third Avenue | Waltham, Massachusetts 02451
Office: +1 (781) 622-1333 | Mobile: +1 (781) 530-7642
Internal extension 110-1333
peter.shearstone@thermofisher.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/17/2020 11:30:39 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
Subject: RE:

Thanks for this additional data.

+Tim Stenzel and flagging below for him

PRE-DECISIONAL, CONFIDENTIAL

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 11:28 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

(b) (4)

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 11:17 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: Peter Shearstone <peter.shearstone@thermofisher.com>
Subject: RE:

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark –
To clarify, (b) (4)
Anand

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Sent: Tuesday, March 17, 2020 10:36 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>
Subject: Re:

Dear Anand

Per your phone call, Thermo Fisher

(b) (4)

Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 10:24 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Subject: <no subject>

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000287

PRE-DECISIONAL, CONFIDENTIAL

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/26/2020 4:59:20 PM
To: McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]
CC: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; 'nietersSu.Piper@mayo.edu' [nietersSu.Piper@mayo.edu]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]
Subject: RE: Assistance with serologic test kit clearance/delivery

Hi Judy -
Thank you!
Anand

From: McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Sent: Thursday, March 26, 2020 4:49 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; 'nietersSu.Piper@mayo.edu' <nietersSu.Piper@mayo.edu>; Cave, Carol <Carol.Cave@fda.hhs.gov>
Subject: FW: Assistance with serologic test kit clearance/delivery

Hi Anand---I heard back from Dan Solis, Director, Division of West Coast Imports who stated this shipment has been cleared and the entry has been released.
I left a voice message for Piper letting her know the entry has been released, thanks!
Judy

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Thursday, March 26, 2020 2:29 PM
To: McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: FW: Assistance with serologic test kit clearance/delivery

Hi Judy -
Is ORA able to reach out to Mayo here?
Anand

From: Nieters Su, Piper L. <NietersSu.Piper@mayo.edu>
Sent: Thursday, March 26, 2020 2:16 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Assistance with serologic test kit clearance/delivery

Good afternoon,

I am writing with the hope that you may be able to point me in the right direction. As you may know, Mayo Clinic has been working to quickly develop serologic test for use in fighting the COVID-19 pandemic. We are making good progress and awaiting a shipment of tests kits from (b) (4) that we hope to receive tomorrow. We are tracking the shipment

closely and know that it has been received at (b) (4) The shipment is released from USDA and Customs but FDA status is still pending. The customs agent is optimistic that it will clear FDA but we have experienced delays and want to assure that this shipment of serology kits can make it to the lab for assessment and/or validation tomorrow. I am attaching the relevant shipping forms and documents that may be helpful but is there someone at FDA who might be able to assist us with clearance for the final leg of this journey?

Thanks so much- your team has helped with many issues over the past few weeks and it is much appreciated as we try to enhance our testing capabilities.

Best, Piper

Piper Nieters Su
Chair, Division of External Relations
Mayo Clinic
200 First Street SW
Rochester, MN 55905
507.266.4812 (office) 703.340.6926 (cell)

Mayo Clinic is again the No. 1 hospital in U.S. News & World Report's "Best Hospitals" rankings and top ranked in twelve specialties.

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 9/11/2020 10:39:42 AM
To: Thomas Sparkman [tsparkman@acla.com]; Weems, Peter [PWeems@medicalimaging.org]; Mark Leahey [mleahey@medicaldevices.org]; Trunzo, Janet [JTrunzo@advamed.org]; Plato, Carole [CPlato@advamed.org]; Sheri Devinney [sdevinney@medicaldevices.org]; Zimmerman, Barbara C. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ad72be1b154a9b9700564ccbb765b5-BXZ]
CC: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Olson, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95aa7d534c3f49fe8622f8a895b218ea-EOlson]
Subject: RE: Preparation for MDUFA V Negotiations
Attachments: October 27: Virtual Public Meeting – Reauthorization of MDUFA for 2023-2027

Tom,

Thank you for sending this. I am adding Barb Zimmerman to this thread, as she has agreed to be FDA's point person for the data request and will be reaching out directly to discuss timing and any follow-up questions that we may have.

Separately, I hope you all saw that FDA published the Federal Register Notice announcing the public meeting to be held on October 27th. I am attaching the email that was sent to stakeholders with the relevant details. We very much look forward to your organizations' participation in the meeting.

Best regards,
Lauren

Lauren K. Roth
Associate Commissioner for Policy
U.S. Food and Drug Administration

From: Thomas Sparkman <tsparkman@acla.com>
Sent: Friday, September 11, 2020 10:19 AM
To: Weems, Peter <PWeems@medicalimaging.org>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Mark Leahey <mleahey@medicaldevices.org>; Trunzo, Janet <JTrunzo@advamed.org>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>
Cc: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: RE: Preparation for MDUFA V Negotiations

Picking back up on this e-mail chain and Peter's August question.

I'm attaching ACLA's additions to the data requests from AdvaMed, MIDA, and MDMA shared earlier this year.

Best,
--Tom

Tom Sparkman | Senior Vice President, Government Affairs and Policy | ACLA | tsparkman@acla.com | 202-637-9466 (o)

From: Weems, Peter <PWeems@medicalimaging.org>
Sent: Wednesday, August 19, 2020 9:19 AM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Mark Leahey <mleahey@medicaldevices.org>; Trunzo, Janet <JTrunzo@advamed.org>; Thomas Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri

Devinney <sdevinney@medicaldevices.org>

Cc: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>

Subject: RE: Preparation for MDUFA V Negotiations

Hi Lauren,

I just wanted to check in on the status of the data request we put in earlier this year. Do you have any updates on when you will be able to share more information?

Thanks,

Peter

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>

Sent: Thursday, July 23, 2020 10:16 AM

To: Mark Leahey <mleahey@medicaldevices.org>; Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>

Cc: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>

Subject: RE: Preparation for MDUFA V Negotiations

All,

Thank you again for your quick replies yesterday. We will plan to move forward with the public meeting on **Tuesday, October 27th**.

Best regards,
Lauren

From: Roth, Lauren

Sent: Wednesday, July 22, 2020 10:09 AM

To: Mark Leahey <mleahey@medicaldevices.org>

Cc: Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>

Subject: RE: Preparation for MDUFA V Negotiations

All,

Thanks to Mark and Janet for the quick reply yesterday. Based on those replies, there did not appear to be one day that worked well, so I'm suggesting two new dates below. Can you please let me know if either **October 27 or October 28** will not work for you?

Many thanks,
Lauren

Lauren K. Roth
Associate Commissioner for Policy
U.S. Food and Drug Administration

From: Mark Leahey <mleahey@medicaldevices.org>

Sent: Tuesday, July 21, 2020 2:19 PM

To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>

Cc: Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: Re: Preparation for MDUFA V Negotiations

Lauren,
Good to hear from you and thanks for all your efforts.

(b) (4)

Can make all other dates work.
All the best,
Mark

On Tue, Jul 21, 2020 at 10:41 AM Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

Janet, Mark, Peter, and Tom,

I hope this finds you safe and well. When we last spoke, we agreed it made sense to postpone the MDUFA V public meeting, given the around-the-clock focus on COVID-19 response. CDRH continues to work at a breakneck pace on the response effort, but given that we're rounding into the second half of 2020, Dr. Shuren agrees that we should also restart MDUFA V negotiation planning. To that end, we're looking to reschedule the public meeting for date in October. Like the GDUFA and PDUFA public meetings that are occurring this week, the MDUFA meeting would be entirely virtual, and I anticipate that it would last from 9 a.m. – approximately 2 p.m.

We hope that you'll be able to join us and participate in the meeting. To aid our planning process, can you please advise if any of the following dates would not work for your schedules? They are:

- **Friday, October 2**
- **Thursday, October 15**
- **Wednesday, October 21**
- **Friday, October 23**

Please don't hesitate to reach out to me with any questions.

Many thanks,
Lauren

Lauren K. Roth, J.D.
Associate Commissioner for Policy

Office of Policy
U.S. Food and Drug Administration
(240) 402-1671
lauren.roth@fda.hhs.gov



--

Mark B. Leahey
President & CEO
MDMA
1333 H St
Suite 400 West
Washington, DC 20005
www.medicaldevices.org

From: U.S. Food and Drug Administration [fda@info.fda.gov]
Sent: 9/4/2020 10:21:10 AM
To: St. Pierre, Don J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93259f8093b043f6aca0eaeef84cef160-DJS]
Subject: October 27: Virtual Public Meeting – Reauthorization of MDUFA for 2023-2027

If your email program has trouble displaying this email, [view it as a web page](#).

October 27: Virtual Public Meeting – Reauthorization of MDUFA for 2023-2027

The U.S. Food and Drug Administration (FDA) is announcing that the public meeting “Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027” will now be held on Tuesday, October 27, 2020 by webcast only beginning at 9:00 a.m. Eastern Time. If you have already registered, no action on your part is necessary.

The purpose of this public meeting is to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years 2023 through 2027. Interested participants may continue to register and, if applicable, specify that they would like to present during the meeting.

[Learn More and Register](#)

Important Deadlines

- September 28, 2020: Request to make oral presentations during the public comment session or a specific session.
- October 23, 2020: Register to view the meeting.
- November 27, 2020: Submit comments to the docket FDA-2020-N-0907.

Questions?

If you have questions about this public workshop, contact CDRH-OPEQ-StrategicInitiatives@fda.hhs.gov.



U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

[Privacy Policy](#) | www.fda.gov

[Manage Preferences or Unsubscribe from this List](#) | [Unsubscribe from all Email Lists](#)

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 9/25/2020 11:31:35 AM
To: Trunzo, Janet [JTrunzo@advamed.org]; Mark Leahey [mleahey@medicaldevices.org]; Weems, Peter [PWeems@medicalimaging.org]; Tom Sparkman [tsparkman@acla.com]
CC: Malone, Misti [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3b751d45f1e4749af19f1b5250ba753-Misti.Malon]; Zimmerman, Barbara C. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ad72be1b154a9b9700564ccbb765b5-BXZ]
Subject: MDUFA 5 Public Meeting and Negotiation Planning

Janet, Mark, Peter, and Tom,

I hope this finds you all well. The team gave me an update on your call yesterday about the MDUFA data call; we appreciated the dialogue so we can get started with pulling the requested information.

They mentioned that you had asked about logistics for the public meeting as well. To confirm what they explained, you do not need to register to participate as speakers, since we are already planning to include an industry panel on the agenda. However, we ask that you complete the general registration for the meeting at least; this way, you will automatically receive updates with the agenda and other logistics. (Tom and Peter -- We have your registration confirmation, so you are all set.) After registration for speakers closes next week, we will reach out to discuss potential agenda times for the industry panel. We request that you provide your presentation slides, if any, by October 20, 2020.

As we begin to prepare for the negotiations, I would like to connect with you about scheduling and logistics in the next few weeks. My initial thinking is that, because the public docket for the meeting is scheduled to close on November 27th, I would like to plan for one initial kickoff negotiation meeting in early December. Then, starting in January, we could begin a more robust series of negotiations. The team will reach out to you about scheduling that touch-base discussion under separate cover.

I look forward to getting started!

Best regards,
Lauren

Lauren K. Roth
Associate Commissioner for Policy
Office of Commissioner
Office of Policy
U.S. Food and Drug Administration
Tel: (240) 402-1671
lauren.roth@fda.hhs.gov



From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 7/22/2020 11:05:37 AM
To: Thomas Sparkman [tsparkman@acla.com]
Subject: RE: Preparation for MDUFA V Negotiations

Great. Thank you again.

From: Thomas Sparkman <tsparkman@acla.com>
Sent: Wednesday, July 22, 2020 10:15 AM
To: Weems, Peter <PWeems@medicalimaging.org>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Mark Leahey <mleahey@medicaldevices.org>
Cc: Trunzo, Janet <JTrunzo@advamed.org>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: RE: Preparation for MDUFA V Negotiations

10/27 and 10/28 are open for me at this time.

Tom Sparkman | Senior Vice President, Government Affairs and Policy | ACLA | tsparkman@acla.com | 202-637-9466 (o)

From: Weems, Peter <PWeems@medicalimaging.org>
Sent: Wednesday, July 22, 2020 10:14 AM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Mark Leahey <mleahey@medicaldevices.org>
Cc: Trunzo, Janet <JTrunzo@advamed.org>; Thomas Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: RE: Preparation for MDUFA V Negotiations

Hi Lauren,

Either 10/27 or 10/28 would work for me.

Thanks,

Peter

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Wednesday, July 22, 2020 10:09 AM
To: Mark Leahey <mleahey@medicaldevices.org>
Cc: Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: RE: Preparation for MDUFA V Negotiations

All,

Thanks to Mark and Janet for the quick reply yesterday. Based on those replies, there did not appear to be one day that worked well, so I'm suggesting two new dates below. Can you please let me know if either **October 27** or **October 28** will not work for you?

Many thanks,
Lauren

Lauren K. Roth
Associate Commissioner for Policy
U.S. Food and Drug Administration

From: Mark Leahey <mleahey@medicaldevices.org>
Sent: Tuesday, July 21, 2020 2:19 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Trunzo, Janet <JTrunzo@advamed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Plato, Carole <CPlato@advamed.org>; Sheri Devinney <sdevinney@medicaldevices.org>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Olson, Ellen <Ellen.Olson@fda.hhs.gov>
Subject: Re: Preparation for MDUFA V Negotiations

Lauren,
Good to hear from you and thanks for all your efforts.

(b) (4)

Can make all other dates work.
All the best,
Mark

On Tue, Jul 21, 2020 at 10:41 AM Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

Janet, Mark, Peter, and Tom,

I hope this finds you safe and well. When we last spoke, we agreed it made sense to postpone the MDUFA V public meeting, given the around-the-clock focus on COVID-19 response. CDRH continues to work at a breakneck pace on the response effort, but given that we're rounding into the second half of 2020, Dr. Shuren agrees that we should also restart MDUFA V negotiation planning. To that end, we're looking to reschedule the public meeting for date in October. Like the GDUFA and PDUFA public meetings that are occurring this week, the MDUFA meeting would be entirely virtual, and I anticipate that it would last from 9 a.m. – approximately 2 p.m.

We hope that you'll be able to join us and participate in the meeting. To aid our planning process, can you please advise if any of the following dates would not work for your schedules? They are:

- **Friday, October 2**
- **Thursday, October 15**
- **Wednesday, October 21**
- **Friday, October 23**

Please don't hesitate to reach out to me with any questions.

Many thanks,
Lauren

Lauren K. Roth, J.D.
Associate Commissioner for Policy

Office of Policy

U.S. Food and Drug Administration

(240) 402-1671

lauren.roth@fda.hhs.gov



--

Mark B. Leahey

President & CEO

MDMA

1333 H St

Suite 400 West

Washington, DC 20005

www.medicaldevices.org

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 3/25/2020 8:30:54 AM
To: Trunzo, Janet [JTrunzo@AdvaMed.org]; Leahey, Mark B. [mleahey@medicaldevices.org]
CC: Weems, Peter [PWeems@medicalimaging.org]; Tom Sparkman [tsparkman@acla.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Sheri Devinney [sdevinney@medicaldevices.org]
Subject: RE: MDUFA V Data request

Thank you all. Looks like May 5th is the best for all. Please hold that date, and I will confirm once it is settled.

Best regards,
Lauren

From: Trunzo, Janet <JTrunzo@AdvaMed.org>
Sent: Tuesday, March 24, 2020 3:59 PM
To: Leahey, Mark B. <mleahey@medicaldevices.org>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Sheri Devinney <sdevinney@medicaldevices.org>
Subject: RE: MDUFA V Data request

Prefer May 5 but could make the 4th as a second option.

From: Mark Leahey <mleahey@medicaldevices.org>
Sent: Tuesday, March 24, 2020 3:54 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Trunzo, Janet <JTrunzo@AdvaMed.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Sheri Devinney <sdevinney@medicaldevices.org>
Subject: Re: MDUFA V Data request

Will make MAY 4th adn 5th work.
Conflict on the 8th.
thx

On Tue, Mar 24, 2020 at 2:59 PM Roth, Lauren <Lauren.Roth@fda.hhs.gov> wrote:

Janet, Mark, Peter, and Tom,

Thank you again for the call on Friday about the public meeting. We've looked at calendars and teleconference capabilities here, and the best potential new dates for FDA are:

- Monday, May 4th
- Tuesday, May 5th, or
- Friday, May 8th.

If you have a preference for any of these dates, please let me know and we'll do our best to find a date that works for everyone. If possible, I would appreciate your reply by tomorrow, so that we can provide a timely update on our website.

Best regards,

Lauren

From: Roth, Lauren

Sent: Friday, March 20, 2020 5:33 PM

To: Trunzo, Janet <JTrunzo@AdvaMed.org>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>

Cc: Leahey, Mark B. <mleahey@medicaldevices.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>

Subject: RE: MDUFA V Data request

Janet,

Thanks very much, and have a safe weekend.

From: Trunzo, Janet <JTrunzo@AdvaMed.org>

Sent: Friday, March 20, 2020 4:39 PM

To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>

Cc: Leahey, Mark B. <mleahey@medicaldevices.org>; Weems, Peter <PWeems@medicalimaging.org>; Tom Sparkman <tsparkman@acla.com>

Subject: MDUFA V Data request

Dear Lauren

Attached is the MDUFA V Data request from AdvaMed, MDMA and MITA. ACLA will provide its request later. Once all date requests are submitted, I recommend that we have a brief conference call to clarify the requests.

Thank you for the conference call today.

Best regards

Janet

--

Mark B. Leahey
President & CEO
MDMA
1333 H St
Suite 400 West
Washington, DC 20005
www.medicaldevices.org

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 3/20/2020 1:11:05 PM
To: Trunzo, Janet [JTrunzo@AdvaMed.org]; Mark Leahey [mleahey@medicaldevices.org]; tsparkman@acla.com; jkhani@acla.com; pweems@medicalimaging.org
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]
Subject: Touch base re: preparation for MDUFA

All,

I look forward to joining this afternoon's call to discuss next steps in planning for the MDUFA public meeting. For those of you whom I haven't met yet, I am CDRH veteran and now in FDA's Office of Policy, and I will be FDA's lead negotiator for MDUFA V.

We appreciate you making time to touch base this afternoon, given all of the work that is happening for the COVID-19 response. I know our discussion today will be focused on the public meeting, so I wanted to separately note that we also welcome receiving the industry's data call as soon as possible. We know there are essential, non-COVID related programmatic priorities that must continue to move forward during this time, including preparations for M5 to facilitate negotiations later this year. To the extent that members of our team who are not directly engaged in the COVID response can begin gathering responsive information, that is helpful advance work that we can accomplish.

Should you have any questions related to M5 as we move forward, please don't hesitate to reach out to me.

Best regards,
Lauren

Lauren K. Roth
Associate Commissioner for Policy

Office of Policy
U.S. Food and Drug Administration
(240) 402-1671
lauren.roth@fda.hhs.gov



From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 5/13/2020 11:19:30 AM
To: farrugia.gianrico@mayo.edu; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: Introduction

Hello Dr. Farrugia,

To follow up on the conversation with the Commissioner yesterday, I wanted to introduce you to Dr. Woodcock, who is leading the response on therapeutics, and Dr. Marks, who is leading the vaccine response. Both of them would be happy to chat with you about the work going on at Mayo and their new roles in the COVID response. Please let me know if you need anything else.

Thank you Dr. Marks and Dr. Woodcock in advance for your help here.

Thanks,
Keagan

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 1:59:47 PM
To: Fenton, Tim [tim.fenton@thermofisher.com]
CC: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: VP call follow up

Thanks Tim, been in back to back meetings and haven't caught up with Dr. Hahn yet on the call. I will get back to you shortly.

Thanks,
KL

Sent from my iPhone

On Mar 3, 2020, at 1:11 PM, Fenton, Tim <tim.fenton@thermofisher.com> wrote:

Hi Keagan – Quick follow up on the call w/ VP Pence, Dr. Hahn, Sec. Azar, etc.

Can Peter Shearstone, our VP Global Regulatory, have a quick call w/ Dr. Hahn to make sure we're good to go forward based on the Vice President's comments?

And I can arrange details for Marc's trip to DC tomorrow with you.

Thank you,
Tim

Tim Fenton

Vice President, Global Government Relations

Thermo Fisher Scientific

+1 (202) 257-4277

@ThermoFisherDC on Twitter

GR on Yammer internal only

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 4:16:28 PM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: RE: VP call follow up

Hi Marc – have asked multiple folks for details, when I receive I will shoot them your way.

KL

From: Casper, Marc N. <marc.casper@thermofisher.com>
Sent: Tuesday, March 3, 2020 3:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: VP call follow up

Keegan,
Do you have any of the logistics details for the meeting tomorrow?
Thanks,
Marc

Sent from my iPhone

On Mar 3, 2020, at 3:49 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hey Tim,

Can you have Peter touch base with Jeff Shuren, I have added him here, on next steps. The Commissioner has not made it back to the office, so if you can explain to Jeff about what was discussed we can figure out the best way to move forward.

Appreciate your help.

Thanks,
Keagan

From: Fenton, Tim <tim.fenton@thermofisher.com>
Sent: Tuesday, March 3, 2020 1:10 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Casper, Marc N. <marc.casper@thermofisher.com>
Subject: VP call follow up

Hi Keagan – Quick follow up on the call w/ VP Pence, Dr. Hahn, Sec. Azar, etc.

Can Peter Shearstone, our VP Global Regulatory, have a quick call w/ Dr. Hahn to make sure we're good to go forward based on the Vice President's comments?

And I can arrange details for Marc's trip to DC tomorrow with you.

Thank you,
Tim

Tim Fenton

Vice President, Global Government Relations

Thermo Fisher Scientific

+1 (202) 257-4277

@ThermoFisherDC on Twitter

GR on Yammer internal only

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/3/2020 5:41:03 PM
To: Fenton, Tim [tim.fenton@thermofisher.com]
Subject: RE: VP call follow up

Appreciate the follow up.

From: Fenton, Tim <tim.fenton@thermofisher.com>
Sent: Tuesday, March 3, 2020 5:38 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: VP call follow up

Thanks they talked. Appreciate it

Tim Fenton
+1 (202) 257-4277

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 3:49:46 PM
To: Fenton, Tim <tim.fenton@thermofisher.com>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Casper, Marc N. <marc.casper@thermofisher.com>
Subject: RE: VP call follow up

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hey Tim,

Can you have Peter touch base with Jeff Shuren, I have added him here, on next steps. The Commissioner has not made it back to the office, so if you can explain to Jeff about what was discussed we can figure out the best way to move forward.

Appreciate your help.

Thanks,
Keagan

From: Fenton, Tim <tim.fenton@thermofisher.com>
Sent: Tuesday, March 3, 2020 1:10 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Casper, Marc N. <marc.casper@thermofisher.com>
Subject: VP call follow up

Hi Keagan – Quick follow up on the call w/ VP Pence, Dr. Hahn, Sec. Azar, etc.

Can Peter Shearstone, our VP Global Regulatory, have a quick call w/ Dr. Hahn to make sure we're good to go forward based on the Vice President's comments?

And I can arrange details for Marc's trip to DC tomorrow with you.

Thank you,

Tim

Tim Fenton

Vice President, Global Government Relations

Thermo Fisher Scientific

+1 (202) 257-4277

@ThermoFisherDC on Twitter

GR on Yammer internal only

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/9/2020 5:50:20 PM
To: Fenton, Tim [tim.fenton@thermofisher.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: O'Brien, Ron [ron.obrien@thermofisher.com]; Shearstone, Peter E. [peter.shearstone@thermofisher.com]
Subject: RE: EUA announcement collaboration on press release?

Hi Tim,

Thank you for reaching out. I will check with our media team, but we do not normally do joint communication with a company we would be authorizing, nor would we include a quote from the Commissioner. As you know, the Commissioner has been speaking almost daily with the press after the task force meetings, so once you all go public, it would likely come up in one of those briefings and he would likely reference your authorization.

Let me know if you have questions.

Thanks,
Keagan

From: Fenton, Tim <tim.fenton@thermofisher.com>
Sent: Monday, March 9, 2020 1:02 PM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: O'Brien, Ron <ron.obrien@thermofisher.com>; Shearstone, Peter E. <peter.shearstone@thermofisher.com>; Fenton, Tim <tim.fenton@thermofisher.com>
Subject: EUA announcement collaboration on press release?

Keagan, Tim – Thinking ahead and optimistically, Thermo Fisher Scientific is interested in collaborating with FDA on a press release, should we receive approval for the COVID19 EUA. This could take one of several forms: a quotation from Dr. Hahn in our release; a joint release between us; or plenty of other options.

Is FDA interested in working collaboratively on a media release, which would only be used when/if we receive EUA? If so, we'd like to get ahead of the process.

Who's the best person to work thru? From Thermo Fisher, I'm including Ron O'Brien, our head of Public Relations, here. (b)(6) is his cell.

Thanks for considering.

Tim

Tim Fenton
Vice President, Global Government Relations
Thermo Fisher Scientific
+1 (202) 257-4277
@ThermoFisherDC on Twitter
GR on Yammer internal only

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] [REDACTED] [STEPHEN.HAH]
Sent: 4/3/2020 4:12:52 PM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: RE: Do you have time for a call today?

What is best number for you, can call you now?

-----Original Message-----

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Sent: Friday, April 3, 2020 12:59 PM
To: Hahn, Stephen (b) (6) [REDACTED]@fda.hhs.gov>
Subject: RE: Do you have time for a call today?

Yes, of course. I can jump off a call early at 145 or also have 3-330 open or after 4 pm.

-----Original Message-----

From: Hahn, Stephen (b) (6) [REDACTED]@fda.hhs.gov>
Sent: Friday, April 3, 2020 12:47 PM
To: Becker, Scott | APHL <Scott.Becker@aphl.org>
Subject: Do you have time for a call today?

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.

Sent from my iPhone

This email has been scanned for spam and viruses by Proofpoint Essentials. Visit the following link to report this email as spam:

https://us1.proofpointessentials.com/index01.php?mod_id=&mod_option=gitem&mail_id=85932414-wkfN9zw0GU0U&r_address=ott.becker%40aphl.org&report=

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/14/2020 10:47:22 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Contact info

Hi Scott – this is my email address. Feel free to pass things along my way.

Thanks,
Keagan

(b)(6) (cell)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/13/2020 7:58:05 AM
To: Julie Khani [jkhani@acla.com]
Subject: Re: Serology

Thanks Julie if we can help your members with these pieces let us know. Appreciate your help.

Sent from my iPhone

> On Apr 13, 2020, at 7:44 AM, Julie Khani <jkhani@acla.com> wrote:
>
> Hi Keagan. Sorry for the delay. I have at least one member working on it. I imagine this will be discussed on the call today with the Commissioner along with collaboration with manufacturers on platforms, some of the challenges with supply shortages, lack of reagent availability, etc. In the meantime, if I have more information before then, I will pass it on.
>
> Thanks.
>
> Julie
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Monday, April 13, 2020 7:35 AM
> To: Julie Khani <jkhani@acla.com>
> Subject: Serology
>
> Hey Julie- checking back if you found any of your labs looking at serology tests. It would be great if they could look into making those tests as they will be imperative to getting folks back to work.
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/9/2020 6:01:02 PM
To: Julie Khani [jkhani@acla.com]
Subject: RE: Serology LDT

Thanks for checking Julie.

From: Julie Khani <jkhani@acla.com>
Sent: Thursday, April 9, 2020 5:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Serology LDT

Hi Keagan. Unlike the molecular testing for COVID-19, I don't think there are/will be many LDTs in the serology space. As I understand it, you'll have labs working with manufacturers on platforms.

Will double check and let you know.

Thanks for reaching out.

Julie

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, April 9, 2020 5:05 PM
To: Julie Khani <jkhani@acla.com>
Subject: Serology LDT

Hi Julie –

Hope you are well.

The Commissioner asked me to check in with you to see if you know how many of your members have done LDT serology tests? Is it possible to get a list, capabilities and where the locations of those labs that have them?

Thanks,
Keagan

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 4/13/2020 7:58:01 AM
To: Julie Khani [jkhani@acla.com]
Subject: Re: Serology

Thanks Julie if we can help your members with these pieces let us know. Appreciate your help.

Sent from my iPhone

> On Apr 13, 2020, at 7:44 AM, Julie Khani <jkhani@acla.com> wrote:
>
> Hi Keagan. Sorry for the delay. I have at least one member working on it. I imagine this will be discussed on the call today with the Commissioner along with collaboration with manufacturers on platforms, some of the challenges with supply shortages, lack of reagent availability, etc. In the meantime, if I have more information before then, I will pass it on.
>
> Thanks.
>
> Julie
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Monday, April 13, 2020 7:35 AM
> To: Julie Khani <jkhani@acla.com>
> Subject: Serology
>
> Hey Julie- checking back if you found any of your labs looking at serology tests. It would be great if they could look into making those tests as they will be imperative to getting folks back to work.
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONER]
Sent: 4/9/2020 12:41:06 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]; morice.william@mayo.edu; sherrie.perkins@aruplab.com; stephen.h.rusckowski@questdiagnostics.com; schecha@labcorp.com; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: EXTERNAL Telecon: Lab CEOs and FDA Commissioner Hahn
Location: (b) (6)
Start: 4/14/2020 11:30:00 AM
End: 4/14/2020 12:00:00 PM
Show Time As: Tentative

Required Attendees: morice.william@mayo.edu; sherrie.perkins@aruplab.com; stephen.h.rusckowski@questdiagnostics.com; schecha@labcorp.com; Shuren, Jeff; Stenzel, Timothy; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anand Shah (Anand.Shah@fda.hhs.gov); Colin Rom (Colin.Rom@fda.hhs.gov)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 4/10/2020 6:10:54 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; morice.william@mayo.edu; sherrie.perkins@aruplab.com; stephen.h.rusckowski@questdiagnostics.com; schecha@labcorp.com; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: EXTERNAL Telecon: Lab CEOs and FDA Commissioner Hahn
Location: (b) (6)
Start: 4/14/2020 11:30:00 AM
End: 4/14/2020 12:00:00 PM
Show Time As: Tentative

Required Attendees: morice.william@mayo.edu; sherrie.perkins@aruplab.com; stephen.h.rusckowski@questdiagnostics.com; schecha@labcorp.com; Shuren, Jeff; Stenzel, Timothy; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anand Shah (Anand.Shah@fda.hhs.gov); Colin Rom (Colin.Rom@fda.hhs.gov)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 2/26/2020 8:08:52 PM
To: Julie Khani [jkhani@acla.com]
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Ok, let me see if we can get the FDA/CDC team to partner here on that.

Yes, she passed along thanks.

Sent from my iPhone

On Feb 26, 2020, at 7:16 PM, Julie Khani <jkhani@acla.com> wrote:

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

From: Julie Khani <jkhani@acla.com>
Sent: Wednesday, February 26, 2020 2:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available [here](#).

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update and answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ 202-841-8196 (m)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 3/3/2020 1:59:39 PM
To: Fenton, Tim [tim.fenton@thermofisher.com]
CC: Shearstone, Peter E. [peter.shearstone@thermofisher.com]; Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: VP call follow up

Thanks Tim, been in back to back meetings and haven't caught up with Dr. Hahn yet on the call. I will get back to you shortly.

Thanks,
KL

Sent from my iPhone

On Mar 3, 2020, at 1:11 PM, Fenton, Tim <tim.fenton@thermofisher.com> wrote:

Hi Keagan – Quick follow up on the call w/ VP Pence, Dr. Hahn, Sec. Azar, etc.

Can Peter Shearstone, our VP Global Regulatory, have a quick call w/ Dr. Hahn to make sure we're good to go forward based on the Vice President's comments?

And I can arrange details for Marc's trip to DC tomorrow with you.

Thank you,
Tim

Tim Fenton

Vice President, Global Government Relations

Thermo Fisher Scientific

+1 (202) 257-4277

@ThermoFisherDC on Twitter

GR on Yammer internal only

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/14/2020 4:00:26 PM
To: Bartkus, Joanne (MDH) [joanne.bartkus@state.mn.us]; Becker, Scott | APHL [Scott.Becker@aphl.org]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) -Stephen.Hah]
Subject: RE: Serology Result

Thanks for flagging, Scott and Joanne. I am working with Jeff to identify the right person for you to filter these examples to in the future. We greatly appreciate the information.

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Sent: Tuesday, April 14, 2020 3:19 PM
To: Becker, Scott | APHL <Scott.Becker@aphl.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6)@fda.hhs.gov
Subject: RE: Serology Result

I believe that this company does the collection and sends the specimen out to another laboratory for testing, so it's not clear what test is being used. It is concerning to me that individuals are being told to discontinue social distancing based solely on the results of this test. I am wondering if FDA can provide additional wording to their guidance regarding the interpretation of individual test results in the context of public health guidance and state executive orders.

Joanne

Joanne Bartkus, PhD
Director | Public Health Laboratory

Minnesota Department of Health
Office: 651-201-5256 | Mobile: 651-303-6229



From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Sent: Tuesday, April 14, 2020 2:08 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6)@fda.hhs.gov; Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Subject: FW: Serology Result

Hi all,

As discussed, here a recent example of the kind of problem that members described on our call. I did not see this firm on the section IV.D list so an example of what's going on. Joanne Bartkus (MN) copied here, sent this our way. Keagan, shall I just forward these to you directly in the future?

Thanks, Scott

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>

Sent: Tuesday, April 14, 2020 2:53 PM

To: Becker, Scott | APhL <Scott.Becker@aphl.org>; Crumpler, Megan <mcrumpler@ochca.com>; Ishida, Maria <maria.ishida@agriculture.ny.gov>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>; Steece, Richard <richard.steece@tn.gov>; Toney, Denise <denise.toney@dgs.virginia.gov>; Tran, Tony <Anthony.tran@dc.gov>; Wade, Mark <mark.wade@sanantonio.gov>; Ware, Daphne <daphne.ware@msdh.ms.gov>; Whitmar, Bill <Bill.Whitmar@health.mo.gov>; Shult, Peter <peter.shult@slh.wisc.edu>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Taylor, Jill <jill.taylor@health.ny.gov>; Ball, Chris <BallC1@dhw.idaho.gov>; Southern, Tim <tim.southern@state.sd.us>; Kimsey, Paul <paul.kimsey@cdph.ca.gov>; Kyriacopoulos, Peter | APhL <Peter.Kyriacopoulos@aphl.org>; Mangal, Chris | APhL <Chris.Mangal@aphl.org>; Wroblewski, Kelly | APhL <kelly.wroblewski@aphl.org>; Blank, Eric | APhL <eric.blank@aphl.org>; Hahn, Stephen ^{(b) (6)} <@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>

Subject: Serology Result

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.

Hi All,

Please see the attached serology report . Note that the result indicates that a positive result indicates that the individual should stop social distancing even though the report has a disclaimer that the test may cross-react with other coronaviruses. This is, as Jen has stated repeatedly, dangerous.

Here is the wording from their website

The ARCpoint Labs COVID-19 Antibody Test was designed for this purpose. With this simple finger stick test, you will learn whether you have been exposed to the virus and if your immune system has produced antibodies and already fought off the infection, making it safe for you to return to work/school.

Joanne Bartkus, PhD

Director | Public Health Laboratory

Minnesota Department of Health

Office: 651-201-5256 | Mobile: 651-303-6229

**m1 DEPARTMENT
OF HEALTH**

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

From: Becker, Scott | APhL <Scott.Becker@aphl.org>

Sent: Saturday, April 11, 2020 5:42 PM

To: Becker, Scott | APhL; Bartkus, Joanne (MDH); Crumpler, Megan; Ishida, Maria; Kubin, Grace; Steece, Richard; Toney, Denise; Tran, Tony; Wade, Mark; Ware, Daphne; Whitmar, Bill; Shult, Peter; Rakeman, Jennifer; Taylor, Jill; Ball, Chris;

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000325

Southern, Tim; Kimsey, Paul; Kyriacopoulos, Peter | APHL; Mangal, Chris | APHL; Wroblewski, Kelly | APHL; Blank, Eric | APHL; Hahn, Stephen; Sheehy, Janice

Subject: APHL/Commissioner Hahn

When: Tuesday, April 14, 2020 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: (b) (6)

This message may be from an external email source.

Do not select links or open attachments unless verified. Report all suspicious emails to Minnesota IT Services Security Operations Center.

Please hold for discussion between APHL BOD and select members and Dr. Stephen Hahn, Commissioner of FDA.

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/26/2020 8:08:56 PM
To: Julie Khani [jkhani@acla.com]
Subject: Re: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Ok, let me see if we can get the FDA/CDC team to partner here on that.

Yes, she passed along thanks.

Sent from my iPhone

On Feb 26, 2020, at 7:16 PM, Julie Khani <jkhani@acla.com> wrote:

It's a hotel ballroom. I could look into videoconferencing?

Also, just FYI, I reached out to Danielle Steele on this as well, re both FDA and CDC participation.

Sent from my iPhone

On Feb 26, 2020, at 5:41 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Not sure we could get anyone to do it in person. Could the FDA person participate by phone?

From: Julie Khani <jkhani@acla.com>
Sent: Wednesday, February 26, 2020 2:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: ACLA Annual Meeting, Role of Commercial Labs in Coronavirus Testing

Hi Keagan. As you may be aware, next week Commissioner Hahn has graciously agreed to speak at the ACLA annual meeting. The meeting is on March 4th at the Grand Hyatt in DC and he is scheduled to speak from 9:00-9:15. Elizabeth Hillebrenner is also speaking on a panel at 11:00am to discuss diagnostics generally. Meeting agenda available [here](#).

I am reaching out because in addition to Commissioner Hahn's remarks, I think the ACLA meeting would provide an excellent opportunity for the FDA to address the diagnostics community about the Coronavirus. I've extended the same invitation to the CDC. There will be approximately 200 people in attendance at the meeting, including CEOs and senior leadership from companies such as LabCorp, Quest, Mayo Clinic Laboratories, Hologic, and Siemens. ACLA and several member companies have a weekly call with the CDC, and the FDA has participated on some of the calls. We have shared information with the CDC about lab capacity and other information, in the event that public health labs are unable to handle testing needs, and surge capacity is necessary.

While these calls have been helpful, numerous questions remain about the availability of the CDC assay to commercial labs, the FDA EUA process, and other issues. I'd be happy to modify the agenda to allow time for a representative from the FDA, CDC, or both, to provide an update and answer questions.

I know the situation is changing quickly, and I can only imagine how busy it is at the FDA. But, as a lot of the key players in the diagnostics community will be together at our meeting next week, I wanted to extend the opportunity.

My office and mobile numbers are below if you have questions or if you would like to discuss.

Thanks.

Julie

Julie Khani \ President \ ACLA \ jkhani@acla.com \ 202-637-9466 (o) \ 202-841-8196 (m)

From: Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]
Sent: 4/14/2020 3:15:12 PM
To: Becker, Scott | APhL [Scott.Becker@aphl.org]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) -Stephen.Hah]; Bartkus, Joanne [joanne.bartkus@state.mn.us]
Subject: Re: Serology Result

Thanks Scott. Feel free to send my way and I can filter appropriately.

Sent from my iPhone

On Apr 14, 2020, at 3:13 PM, Becker, Scott | APhL <Scott.Becker@aphl.org> wrote:

Hi all,

As discussed, here a recent example of the kind of problem that members described on our call. I did not see this firm on the section IV.D list so an example of what's going on. Joanne Bartkus (MN) copied here, sent this our way. Keagan, shall I just forward these to you directly in the future?

Thanks, Scott

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Sent: Tuesday, April 14, 2020 2:53 PM
To: Becker, Scott | APhL <Scott.Becker@aphl.org>; Crumpler, Megan <mcrumpler@ochca.com>; Ishida, Maria <maria.ishida@agriculture.ny.gov>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>; Steece, Richard <richard.steece@tn.gov>; Toney, Denise <denise.toney@dgs.virginia.gov>; Tran, Tony <Anthony.tran@dc.gov>; Wade, Mark <mark.wade@sanantonio.gov>; Ware, Daphne <daphne.ware@msdh.ms.gov>; Whitmar, Bill <Bill.Whitmar@health.mo.gov>; Shult, Peter <peter.shult@slh.wisc.edu>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Taylor, Jill <jill.taylor@health.ny.gov>; Ball, Chris <BallC1@dhw.idaho.gov>; Southern, Tim <tim.southern@state.sd.us>; Kimsey, Paul <paul.kimsey@cdph.ca.gov>; Kyriacopoulos, Peter | APhL <Peter.Kyriacopoulos@aphl.org>; Mangal, Chris | APhL <Chris.Mangal@aphl.org>; Wroblewski, Kelly | APhL <kelly.wroblewski@aphl.org>; Blank, Eric | APhL <eric.blank@aphl.org>; Hahn, Stephen (b) (6)@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: Serology Result

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.

Hi All,

Please see the attached serology report . Note that the result indicates that a positive result indicates that the individual should stop social distancing even though the report has a disclaimer that the test may cross-react with other coronaviruses. This is, as Jen has stated repeatedly, dangerous.

Here is the wording from their website

The ARCPoint Labs COVID-19 Antibody Test was designed for this purpose. With this simple finger stick test, you will learn whether you have been exposed to the virus and if your immune system has produced antibodies and already fought off the infection, making it safe for you to return to work/school.

Joanne Bartkus, PhD

Director | Public Health Laboratory

Minnesota Department of Health

Office: 651-201-5256 | Mobile: 651-303-6229

<image001.gif>



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

From: Becker, Scott | APHL <Scott.Becker@aphl.org>

Sent: Saturday, April 11, 2020 5:42 PM

To: Becker, Scott | APHL; Bartkus, Joanne (MDH); Crumpler, Megan; Ishida, Maria; Kubin, Grace; Steece, Richard; Toney, Denise; Tran, Tony; Wade, Mark; Ware, Daphne; Whitmar, Bill; Shult, Peter; Rakeman, Jennifer; Taylor, Jill; Ball, Chris; Southern, Tim; Kimsey, Paul; Kyriacopoulos, Peter | APHL; Mangal, Chris | APHL; Wroblewski, Kelly | APHL; Blank, Eric | APHL; Hahn, Stephen; Sheehy, Janice

Subject: APHL/Commissioner Hahn

When: Tuesday, April 14, 2020 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: (b) (6)

This message may be from an external email source.

Do not select links or open attachments unless verified. Report all suspicious emails to Minnesota IT Services Security Operations Center.

Please hold for discussion between APHL BOD and select members and Dr. Stephen Hahn, Commissioner of FDA.

<sero.jpg>

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(b) (6)] -Stephen.Hah]
Sent: 9/13/2020 8:53:47 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Testing Updates

Mark,
This is great news. Thanks for the update. We'll discuss internally.
Steve

From: Mark Stevenson <mark.stevenson@thermofisher.com>
Date: Friday, September 11, 2020 at 6:23 PM
To: Stephen Hahn (b) (6) @fda.hhs.gov>
Subject: Testing Updates

Dear Steve,

I appreciated the 9/9 NEJM article on FDA CDRH lessons learned by Shuren and Stenzel, highlighting the need, in future pandemics, to work with a smaller number of rt-PCR test manufacturers who have the scale and instrument census to get the testing done – as well as a few POC assays. Their conclusion that this is a better use of their resources than the current approach to have authorized in excess of 200 separate tests.

Couple of updates on what Thermo Fisher are working on expansion

(b) (4)



Open to discuss how Thermo Fisher can best support.

Best and nice weekend

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T +1 (781) 622-1344
Mobile (+WhatsApp) :+1 760 576 9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222

kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 7/27/2020 11:11:10 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: (b) (4)

Dr. Farrugia,

Thank you for your message and thank you for Mayo Clinic's leadership. (b) (4) In the meantime, I will circle back with the Center.

Best
Steve

From: Gianrico Farrugia <farrugia.gianrico@mayo.edu>
Date: Monday, July 27, 2020 at 9:59 AM
To: Stephen Hahn (b) (6) .@fda.hhs.gov>
Subject: (b) (4)

Commissioner Hahn,

(b) (4)



Thank you and thank you for all you and the FDA team are doing to lead during this pandemic, Gianrico

Gianrico Farrugia, M.D.
President and CEO Mayo Clinic
Professor of Medicine and Physiology and Biomedical Engineering
Mayo Clinic
200 Ist Street SW, Rochester, MN 55905
Phone: 507-266-4861
Phone: 507-284-4695
E-mail: Farrugia.gianrico@mayo.edu

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 6/12/2020 9:55:42 AM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: Re: Mayo EAP data

Mike and Scott,
Thank you so much for all of your teams' hard work.
It is much appreciated by FDA and the American people.
Steve

From: "Joyner, Michael J., M.D." <joyner.michael@mayo.edu>
Date: Friday, June 12, 2020 at 8:18 AM
To: Peter Marks <Peter.Marks@fda.hhs.gov>, Stephen Hahn (b) (6) @fda.hhs.gov>
Cc: "Wright, R. Scott, M.D." <wright.scott@mayo.edu>
Subject: RE: Mayo EAP data

Peter, thx

Commissioner - a lot of efforts, ideas, energy and so forth between FDA and Mayo have converged and generated amplification loops. Agree the data is very promising. (b) (4)

Mike

From: Marks, Peter [mailto:Peter.Marks@fda.hhs.gov]
Sent: Friday, June 12, 2020 6:34 AM
To: Hahn, Stephen
Cc: Wright, R. Scott, M.D.; Joyner, Michael J., M.D.
Subject: [EXTERNAL] Mayo EAP data

Dear Commissioner,

Just to let you know, we are incredibly grateful to the Mayo team for (b) (4)
(b) (4) The very preliminary read on these data looks promising (and is completely consistent with what is emerging from other studies) and we look forward to presenting the data to you after we have additional patients and a formal analysis completed.

Wanted to take a moment to provide a real shout out of thanks to the entire Mayo team, which has been working tirelessly and doing an incredible job.

Best Regards,
Peter

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/19/2020 10:03:45 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
CC: Bruno, Katelyn A., Ph.D. [Bruno.Katelyn@mayo.edu]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]; Bolton, Jeffrey W. [Bolton.Jeffrey@mayo.edu]
Subject: RE: (b)(4)

Thanks, Mike

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: April 19, 2020 at 8:41:08 AM EDT
To: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Hahn, Stephen (b)(6)@fda.hhs.gov
Cc: Bruno, Katelyn A., Ph.D. <Bruno.Katelyn@mayo.edu>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>, Bolton, Jeffrey W. <Bolton.Jeffrey@mayo.edu>
Subject: RE: (b)(4)

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/17/2020 12:43:49 PM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

Thanks, Mike. So great to hear from you. Thank you, Peter, Scott and Nicole for all of your hard work on this effort for the American people.

Mike, it would be great to catch up at some point.

Best
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: April 17, 2020 at 11:33:09 AM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Cc: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/17/2020 12:51:59 PM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: thanks

Thanks, Marc. Please let me know how I can personally assist.

Best
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 16, 2020 at 9:51:04 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: thanks

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/17/2020 1:17:25 PM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: Re: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

Thank you very much Dr. Wright. The partnership with you have been exemplary.
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: April 17, 2020 at 1:16:28 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>, Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/1/2020 8:49:14 AM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: Re: Updated Plasma COVID-19 Numbers

Thanks, Mike. I'm having trouble seeing the information about (b) (4) on this email chain.
Terrific work you all are doing - thank you.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:42:54 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: FW: Updated Plasma COVID-19 Numbers

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/1/2020 10:18:46 AM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: RE: Updated Plasma COVID-19 Numbers

Thanks, Mike. Peter has been working with the Private Sector on this same issue so perhaps we should synch up.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:58:39 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: RE: Updated Plasma COVID-19 Numbers

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/1/2020 10:20:58 AM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
CC: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Scott. Thank you for the terrific work and will definitely be in touch.
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: May 1, 2020 at 9:19:02 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/1/2020 10:21:14 AM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

My cell is (b)(6)
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: May 1, 2020 at 9:19:02 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(b) (6)] -Stephen.Hah]
Sent: 5/29/2020 11:27:41 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: Recap of Morning Call

Thanks, Gianrico. If I can help (b) (4), please let me know. Your team is terrific as are you.
Steve

From: Gianrico Farrugia <farrugia.gianrico@mayo.edu>
Date: Friday, May 29, 2020 at 11:26 AM
To: Stephen Hahn (b) (6) @fda.hhs.gov>
Subject: RE: Recap of Morning Call

Thanks, mine is (b) (6)

(b) (4)

Gianrico

From: Hahn, Stephen [mailto:(b) (6) @fda.hhs.gov]
Sent: Friday, May 29, 2020 10:19 AM
To: Farrugia, Gianrico, M.D.
Subject: [EXTERNAL] Re: Recap of Morning Call

Will do. Was the number you used last night your cell?
For reference, mine is (b) (6)
Steve

From: Gianrico Farrugia <farrugia.gianrico@mayo.edu>
Date: Friday, May 29, 2020 at 8:03 AM
To: Stephen Hahn (b) (6) @fda.hhs.gov>
Subject: RE: Recap of Morning Call

Call me anytime if something comes up that does not seem right – Gianrico

From: Hahn, Stephen [mailto:(b) (6) @fda.hhs.gov]
Sent: Friday, May 29, 2020 7:01 AM
To: Farrugia, Gianrico, M.D.
Subject: [EXTERNAL] Re: Recap of Morning Call

Thx much. Have a great day

Sent from my iPhone

On May 28, 2020, at 6:37 PM, Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu> wrote:

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 5:32 PM
To: Farrugia, Gianrico, M.D.
Subject: FW: Recap of Morning Call

FYI, share..... as needed.

Mike

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 3:18 PM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Witten, Celia (CBER) (Celia.Witten@fda.hhs.gov)
Cc: Wright, R. Scott, M.D.; Carter, Rickey E., Ph.D.; Arturo Casadevall (acasade1@jhu.edu)
Subject: Recap of Morning Call

Dear Peter, Nicole and Celia - here is an outline of where we will head based on our call this morning.

(b) (4)



Also, if we can agree on this framework with just minor modifications, and loop BARDA in we can just start and get moving. Patton's maxim on a good plan executed now may apply to the tasks ahead.....

"A good plan, violently executed now, is better than a perfect plan next week."

We have already started working on this framework and things are starting to line up.

Mike

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/11/2020 11:40:08 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Accepted: COVID Diagnostics: Steve Hahn (FDA) and Mark Stevenson (Thermo Fisher Scientific)
Location: WebEx enclosed

Start: 5/13/2020 8:30:00 AM
End: 5/13/2020 9:00:00 AM

Recurrence: (none)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/14/2020 12:22:46 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID diagnostics

Thanks, Mark.

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 14, 2020 at 9:49:10 AM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

Dear Steve,

Yes, fine to share email. The attachment was more related to vaccine proposal note diagnostic testing.

For clarity here are the 5 items I regard as follow up.

(b) (4)



Regards

Mark

From: Steve Hahn (b) (6) @fda.hhs.gov>
Date: Thursday, May 14, 2020 at 8:31 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah,

HHS-FDA-20-0571-B-000346

Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark,

We are setting up a call with Dr. Birx and Jeff Shuren. Is it ok if I share this email and the attachments with Dr. Birx prior to the call?

Thanks

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 10, 2020 at 8:17:11 AM EDT

To: Hahn, Stephen (b)(6) @fda.hhs.gov>

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

Steve

Janice and my assistant are connected and to arrange a call. Plenty of topics to cover around public health.

Our submissions to amendment to our FDA EUA to expand our qPCR platforms and protocols was approved which will greatly expand platforms already installed able to run the COVID19 assay, including in a 384 well throughput. (b) (4)

(b) (4)

We proposed to BARDA (i) short-term solution to enable sterile manufacturing production capacity in Q4 2020 for vaccines to support the COVID-19 pandemic at this critical time (b) (4)

Best Mark

From: Steve Hahn (b)(6) @fda.hhs.gov>

Date: Saturday, May 9, 2020 at 10:14 AM

To: Mark Stevenson <mark.stevenson@thermofisher.com>

Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark,
thank you very much for your message. Great work on all counts. We very much appreciate the work with Thermo Fisher. It would be great to arrange a call in the upcoming week. I'll ask Janice to arrange.

I am in self-quarantine but doing well.

Best

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 9, 2020 at 9:53:38 AM EDT

To: Hahn, Stephen (b)(6) @fda.hhs.gov>

Subject: COVID diagnostics

Dear Steve,

I had read you will self-quarantine for 14 days after exposure to White House spokesperson Katie Miller, who tested positive for Covid-19 on Friday, so it prompted me to send a note. I hope you remain negative but I know you will have plenty of access to FDA EUA tests!

Quick update from Thermo Fisher. (b) (4)

We have also followed up on the work done with Mayo Clinic on ELISA lab based serology testing and signed an agreement with Mayo/WuXi for that test for total antibodies (IgM/IgG). We will make a submission for that serology test will be coming to the FDA in the next few weeks.

We have also engaged with the NIH on their RADx to continue to innovative around diagnostic testing for COVID.

Let me know if we can be helpful during this unprecedented times. I'm sure at some point we can also spend time to share observations and lessons learnt in a post COVID world for how industry and FDA work together.

Best Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T +1 (781) 622-1344
Mobile (+WhatsApp) :+1 760 576 9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/29/2020 12:52:02 PM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: We have a plan

Excellent and thanks

From: Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>
Date: May 29, 2020 at 12:15:34 PM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: FW: We have a plan

(b) (4)

Thanks, Gianrico

From: Halamka, John D., M.D., M.S.
Sent: Friday, May 29, 2020 10:42 AM
To: Farrugia, Gianrico, M.D.; Joyner, Michael J., M.D.; Campbell, Janet; Andrea Noel; Peter Marks (Peter.Marks@fda.hhs.gov); Abernethy, Amy; Anderson, Brian S. (briananderson@mitre.org)
Subject: We have a plan

Folks:

(b) (4)

John

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6)] -STEPHEN.HAH]
Sent: 4/17/2020 1:17:16 PM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: Re: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

Thank you very much Dr. Wright. The partnership with you have been exemplary.
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: April 17, 2020 at 1:16:28 PM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>, Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

Thank you for the note Director Hahn.

(b) (4)



R Scott Wright, MD
Senior Chair and Medical Director, Mayo Clinic IRB
Director, Mayo Clinic Human Research Protection Program
Professor of Medicine, Department of Cardiology
Wright.scott@mayo.edu
Office: 1-507-284-8087 (Administrative)
Office: 1-507-284-0783 (Patient related)
Fax: 1-507-266-0103

From: "Hahn, Stephen" (b)(6) @fda.hhs.gov>
Date: Friday, April 17, 2020 at 11:44 AM
To: Michael Joyner <Joyner.Michael@mayo.edu>, Peter Marks <Peter.Marks@fda.hhs.gov>, "R. Scott Wright" <wright.scott@mayo.edu>, Nicole Verdun <Nicole.Verdun@fda.hhs.gov>
Subject: [EXTERNAL] RE: RE: RE: 9am 4-17 stats

Thanks, Mike. So great to hear from you. Thank you, Peter, Scott and Nicole for all of your hard work on this effort for the American people.

Mike, it would be great to catch up at some point.

Best
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: April 17, 2020 at 11:33:09 AM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Cc: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

Thx, Dr. Hahn..... your folks are crushing it. Happy to answer any questions and give you any of the many examples of the superior performance of the CBER group. (b) (4)

(b) (4)

Mike

(b) (4)

From: Marks, Peter [mailto:Peter.Marks@fda.hhs.gov]
Sent: Friday, April 17, 2020 10:21 AM
To: Wright, R. Scott, M.D.; Joyner, Michael J., M.D.; Verdun, Nicole
Cc: Hahn, Stephen
Subject: [EXTERNAL] RE: RE: 9am 4-17 stats

Dear Scott,

Thank you once again to the Mayo for taking this on and for all of Mike and your efforts – you were actually the ones who made this a reality. Copying our Commissioner for his awareness.

Best Regards,
Peter

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>

Sent: Friday, April 17, 2020 11:06 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Joyner, Michael J., M.D. <joyner.michael@mayo.edu>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>

Subject: Re: [EXTERNAL] RE: 9am 4-17 stats

Peter and Nicole

My congratulations to you and the FDA for conceiving and organizing a study/EAP that is meeting the needs of the USA! It is clear to me that the numbers reflect that we are meeting a real public health and clinical need! I am grateful as a citizen of the USA and a physician for your leadership on this. The nation is grateful as well based upon the number of calls we are getting from physicians and others. Please feel free to forward this note of compliment to your Director if appropriate.

R Scott Wright, MD

Senior Chair and Medical Director, Mayo Clinic IRB

Director, Mayo Clinic Human Research Protection Program

Professor of Medicine, Department of Cardiology

Wright.scott@mayo.edu

Office: 1-507-284-8087 (Administrative)

Office: 1-507-284-0783 (Patient related)

Fax: 1-507-266-0103

From: Peter Marks <Peter.Marks@fda.hhs.gov>

Date: Friday, April 17, 2020 at 10:00 AM

To: Michael Joyner <Joyner.Michael@mayo.edu>, Nicole Verdun <Nicole.Verdun@fda.hhs.gov>, "R. Scott Wright" <wright.scott@mayo.edu>

Subject: [EXTERNAL] RE: 9am 4-17 stats

Dear Mike,

Amazing! Thank you.

Best Regards,

Peter

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>

Sent: Friday, April 17, 2020 10:28 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>; Wright, R. Scott, M.D. <wright.scott@mayo.edu>

Subject: 9am 4-17 stats

FYI many things coming together - keep going. Song for the day.....

<https://youtu.be/HUvngfDy-Bo>

(b) (4)



Sent from my iPhone

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/17/2020 12:43:40 PM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

Thanks, Mike. So great to hear from you. Thank you, Peter, Scott and Nicole for all of your hard work on this effort for the American people.

Mike, it would be great to catch up at some point.
Best
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: April 17, 2020 at 11:33:09 AM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: RE: 9am 4-17 stats

Thx, Dr. Hahn..... your folks are crushing it. Happy to answer any questions and give you any of the many examples of the superior performance of the CBER group. (b) (4)

(b) (4)

Mike

(b) (4)



From: Marks, Peter [mailto:Peter.Marks@fda.hhs.gov]
Sent: Friday, April 17, 2020 10:21 AM
To: Wright, R. Scott, M.D.; Joyner, Michael J., M.D.; Verdun, Nicole
Cc: Hahn, Stephen
Subject: [EXTERNAL] RE: RE: 9am 4-17 stats

Dear Scott,

Thank you once again to the Mayo for taking this on and for all of Mike and your efforts – you were actually the ones who made this a reality. Copying our Commissioner for his awareness.

Best Regards,
Peter

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Sent: Friday, April 17, 2020 11:06 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Joyner, Michael J., M.D. <joyner.michael@mayo.edu>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: 9am 4-17 stats

Peter and Nicole

My congratulations to you and the FDA for conceiving and organizing a study/EAP that is meeting the needs of the USA! It is clear to me that the numbers reflect that we are meeting a real public health and clinical need! I am grateful as a citizen of the USA and a physician for your leadership on this. The nation is grateful as well based upon the number of calls we are getting from physicians and others. Please feel free to forward this note of compliment to your Director if appropriate.

R Scott Wright, MD
Senior Chair and Medical Director, Mayo Clinic IRB
Director, Mayo Clinic Human Research Protection Program
Professor of Medicine, Department of Cardiology
Wright.scott@mayo.edu
Office: 1-507-284-8087 (Administrative)
Office: 1-507-284-0783 (Patient related)
Fax: 1-507-266-0103

From: Peter Marks <Peter.Marks@fda.hhs.gov>
Date: Friday, April 17, 2020 at 10:00 AM
To: Michael Joyner <Joyner.Michael@mayo.edu>, Nicole Verdun <Nicole.Verdun@fda.hhs.gov>, "R. Scott Wright" <wright.scott@mayo.edu>
Subject: [EXTERNAL] RE: 9am 4-17 stats

Dear Mike,

Amazing! Thank you.

Best Regards,
Peter

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>

Sent: Friday, April 17, 2020 10:28 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>; Wright, R. Scott, M.D. <wright.scott@mayo.edu>

Subject: 9am 4-17 stats

FYI many things coming together - keep going. Song for the day.....

<https://youtu.be/HUvngfDy-Bo>

(b) (4)



Sent from my iPhone

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/17/2020 12:51:51 PM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: thanks

Thanks, Marc. Please let me know how I can personally assist.
Best
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 16, 2020 at 9:51:04 PM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: thanks

Dear Doctor Hahn,
Thanks for your rapid follow through. We had a productive discussion with Peter Marks and Rick Bright. (b) (4)

(b) (4)

Best regards,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/19/2020 10:03:36 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
CC: Bruno, Katelyn A., Ph.D. [Bruno.Katelyn@mayo.edu]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]; Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]; Bolton, Jeffrey W. [Bolton.Jeffrey@mayo.edu]
Subject: RE: (b) (4)

Thanks, Mike

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: April 19, 2020 at 8:41:08 AM EDT
To: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Hahn, Stephen (b) (6) <(b) (6)@fda.hhs.gov>
Cc: Bruno, Katelyn A., Ph.D. <Bruno.Katelyn@mayo.edu>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>, Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>, Bolton, Jeffrey W. <Bolton.Jeffrey@mayo.edu>
Subject: RE: (b) (4)

Dear Mike,

Thanks so much for this update.

Best Regards,
Peter

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Sent: Saturday, April 18, 2020 10:16 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>; Hahn, Stephen (b) (6) <(b) (6)@fda.hhs.gov>
Cc: Bruno, Katelyn A., Ph.D. <Bruno.Katelyn@mayo.edu>; Wright, R. Scott, M.D. <wright.scott@mayo.edu>; Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>; Bolton, Jeffrey W. <Bolton.Jeffrey@mayo.edu>
Subject: (b) (4)

Peter, Nicole & Commissioner Hahn, (b) (4)

Mike

From: Bruno, Katelyn A., Ph.D.
Sent: Saturday, April 18, 2020 8:59 PM
To: Joyner, Michael J., M.D.; Wright, R. Scott, M.D.
Subject: Sorry for all emails... we may want to update 60 minutes before tomorrow!

(b) (4)

Katelyn Bruno, PhD
Instructor of Medicine

Department of Cardiovascular Medicine

Office: 904-953-6740

Pager: (78)3-8804

Secretary: 904-953-2439

Fax: 904-953-7117

Email: Bruno.Katelyn@mayo.edu

Mayo Clinic

4500 San Pablo Road

Jacksonville, FL 32224

mayoclinic.org

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(b) (6)] -Stephen.Hah]
Sent: 5/29/2020 10:34:31 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: Recap of Morning Call

Thanks. My understanding is that (b) (4) Peter
will address this with Michael
Really appreciate your help with this.
Steve

From: Gianrico Farrugia <farrugia.gianrico@mayo.edu>
Date: Thursday, May 28, 2020 at 6:39 PM
To: Stephen Hahn (b) (6) @fda.hhs.gov>
Subject: FW: Recap of Morning Call

(b) (4)

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 5:32 PM
To: Farrugia, Gianrico, M.D.
Subject: FW: Recap of Morning Call

FYI, share..... as needed.

Mike

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 3:18 PM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Witten, Celia (CBER) (Celia.Witten@fda.hhs.gov)
Cc: Wright, R. Scott, M.D.; Carter, Rickey E., Ph.D.; Arturo Casadevall (acasade1@jhu.edu)
Subject: Recap of Morning Call

Dear Peter, Nicole and Celia - here is an outline of where we will head based on our call this morning.

(b) (4)

Also, if we can agree on this framework with just minor modifications, and loop BARDA in we can just start and get moving. Patton's maxim on a good plan executed now may apply to the tasks ahead.....

"A good plan, violently executed now, is better than a perfect plan next week."

We have already started working on this framework and things are starting to line up.

Mike

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/1/2020 10:18:37 AM
To: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]; Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: RE: Updated Plasma COVID-19 Numbers

Thanks, Mike. Peter has been working with the Private Sector on this same issue so perhaps we should synch up.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:58:39 AM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: RE: Updated Plasma COVID-19 Numbers

Steve.... From another email chain. To some higher ups in (b) (4) who had questions about Plasma. (b) (4)

Mike

From: Hahn, Stephen [mailto:(b) (6) @fda.hhs.gov]
Sent: Friday, May 01, 2020 7:49 AM
To: Joyner, Michael J., M.D.
Cc: Marks, Peter; Verdun, Nicole; Wright, R. Scott, M.D.
Subject: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Thanks, Mike. I'm having trouble seeing the information about (b) (4) on this email chain.
Terrific work you all are doing - thank you.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:42:54 AM EDT

To: Hahn, Stephen (b)(6) @fda.hhs.gov>

Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>

Subject: FW: Updated Plasma COVID-19 Numbers

Commish.... FYI. See also the note about (b) (4)

Mike

From: Joyner, Michael J., M.D.

Sent: Friday, May 01, 2020 7:40 AM

To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Farrugia, Gianrico, M.D.; Bolton, Jeffrey W.

Cc: Wright, R. Scott, M.D.; Arturo Casadevall (acasade1@jhu.edu); Lee, Pete (petelee@microsoft.com); Halamka, John D., M.D., M.S.; Claire Pomeroy (cpomeroy@laskerfoundation.org); 'Chaim Lebovits'

Subject: FW: Updated Plasma COVID-19 Numbers

(b) (4)

Peter (Lee), John H, and Claire..... (b) (4)

MJJ

From: Spiegel, Matthew R. (Matt)

Sent: Friday, May 01, 2020 7:25 AM

To: Bruno, Katelyn A., Ph.D.; Muenkel, Lisa K.; Wiggins, Chad C., Ph.D.

Cc: Joyner, Michael J., M.D.; Wright, R. Scott, M.D.; Tree, Kristine M.

Subject: Updated Plasma COVID-19 Numbers

Hi all,

Attached are the numbers for the website (excel file) as well as the table for the M/W/F meeting (Word document).

Chad, also find the (b) (4) dataset attached for the plots.

Let me know if you need anything else.

Thanks,

Matt

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/1/2020 10:20:49 AM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
CC: Joyner, Michael J., M.D. [joyner.michael@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Verdun, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3aa59faf502446fa6c7a9b2bbe5a946-VERDUNN]
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Scott, Thank you for the terrific work and will definitely be in touch.
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: May 1, 2020 at 9:19:02 AM EDT
To: Hahn, Stephen (b) (6) [REDACTED]@fda.hhs.gov>
Cc: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Dr. Hahn

It was great to meet you this week and thanks for taking the time to travel to Rochester. You and your team at FDA are doing great work!

The EAP for Convalescent Plasma is on target to enroll (b) (4) [REDACTED]
(b) (4) [REDACTED]

We will work with Dr. Marks and Dr. Verdun to create a process that we can transfer data to the agency ASAP so your team can analyze what we have collected for safety and possibly efficacy.

You and I have both spent many years enrolling patients into studies and trials. The enrollment of the EAP has exceeded total enrollment goals and expectations about pace of enrollment. My congratulations and gratitude to the FDA for fostering the EAP which has clearly met a public health need. Everyone working on it believes it is a great honor and commitment to the nation to be associated with its conduct.

We want to make sure we get data to the agency as soon as your team wants it to allow the regulatory review process to provide critical oversight and guidance.

Never hesitate to reach out if I can be of assistance.

Sincerely,

Scott Wright

On May 1, 2020, at 7:49 AM, Hahn, Stephen (b) (6) [REDACTED]@fda.hhs.gov> wrote:

Thanks, Mike. I'm having trouble seeing the information about (b) (4) on this email chain.
Terrific work you all are doing - thank you.
Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:42:54 AM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: FW: Updated Plasma COVID-19 Numbers

Commish.... FYI. See also the note about (b) (4)

Mike

From: Joyner, Michael J., M.D.
Sent: Friday, May 01, 2020 7:40 AM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Farrugia, Gianrico, M.D.; Bolton, Jeffrey W.
Cc: Wright, R. Scott, M.D.; Arturo Casadevall (acasade1@jhu.edu); Lee, Pete (petelee@microsoft.com); Halamka, John D., M.D., M.S.; Claire Pomeroy (cpomeroy@laskerfoundation.org); 'Chaim Lebovits'
Subject: FW: Updated Plasma COVID-19 Numbers

FYI..... this just gets wilder every day. Safety data is encouraging. Fulfillment gap is dropping thx in large part to Chaim et al.

Peter (Lee), John H, and Claire..... (b) (4)

MJJ

From: Spiegel, Matthew R. (Matt)
Sent: Friday, May 01, 2020 7:25 AM
To: Bruno, Katelyn A., Ph.D.; Muenkel, Lisa K.; Wiggins, Chad C., Ph.D.
Cc: Joyner, Michael J., M.D.; Wright, R. Scott, M.D.; Tree, Kristine M.
Subject: Updated Plasma COVID-19 Numbers

Hi all,

Attached are the numbers for the website (excel file) as well as the table for the M/W/F meeting (Word document).

Chad, also find the (b) (4) dataset attached for the plots.

Let me know if you need anything else.

Thanks,

Matt

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 5/1/2020 10:21:05 AM
To: Wright, R. Scott, M.D. [wright.scott@mayo.edu]
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

My cell is (b)(6)
Steve

From: Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Date: May 1, 2020 at 9:19:02 AM EDT
To: Hahn, Stephen (b) (6) <[REDACTED]@fda.hhs.gov>
Cc: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Updated Plasma COVID-19 Numbers

Dr. Hahn

It was great to meet you this week and thanks for taking the time to travel to Rochester. You and your team at FDA are doing great work!

The EAP for Convalescent Plasma is on target to enroll (b) (4)
(b) (4)

We will work with Dr. Marks and Dr. Verdun to create a process that we can transfer data to the agency ASAP so your team can analyze what we have collected for safety and possibly efficacy.

You and I have both spent many years enrolling patients into studies and trials. The enrollment of the EAP has exceeded total enrollment goals and expectations about pace of enrollment. My congratulations and gratitude to the FDA for fostering the EAP which has clearly met a public health need. Everyone working on it believes it is a great honor and commitment to the nation to be associated with its conduct.

We want to make sure we get data to the agency as soon as your team wants it to allow the regulatory review process to provide critical oversight and guidance.

Never hesitate to reach out if I can be of assistance.

Sincerely,

Scott Wright

On May 1, 2020, at 7:49 AM, Hahn, Stephen (b)(6) <[REDACTED]@fda.hhs.gov> wrote:

Thanks, Mike. I'm having trouble seeing the information about (b) (4) on this email chain.
Terrific work you all are doing - thank you.

Steve

From: Joyner, Michael J., M.D. <joyner.michael@mayo.edu>
Date: May 1, 2020 at 8:42:54 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>, Verdun, Nicole <Nicole.Verdun@fda.hhs.gov>, Wright, R. Scott, M.D. <wright.scott@mayo.edu>
Subject: FW: Updated Plasma COVID-19 Numbers

Commish.... FYI. See also the note about (b)(4)

Mike

From: Joyner, Michael J., M.D.
Sent: Friday, May 01, 2020 7:40 AM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Farrugia, Gianrico, M.D.; Bolton, Jeffrey W.
Cc: Wright, R. Scott, M.D.; Arturo Casadevall (acasade1@jhu.edu); Lee, Pete (petelee@microsoft.com); Halamka, John D., M.D., M.S.; Claire Pomeroy (cpomeroy@laskerfoundation.org); 'Chaim Lebovits'
Subject: FW: Updated Plasma COVID-19 Numbers

FYI..... this just gets wilder every day. Safety data is encouraging. Fulfillment gap is dropping thx in large part to Chaim et al.

Peter (Lee), John H, and Claire..... (b)(4)

MJJ

From: Spiegel, Matthew R. (Matt)
Sent: Friday, May 01, 2020 7:25 AM
To: Bruno, Katelyn A., Ph.D.; Muenkel, Lisa K.; Wiggins, Chad C., Ph.D.
Cc: Joyner, Michael J., M.D.; Wright, R. Scott, M.D.; Tree, Kristine M.
Subject: Updated Plasma COVID-19 Numbers

Hi all,

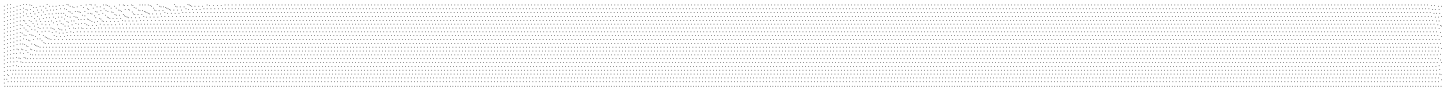
Attached are the numbers for the website (excel file) as well as the table for the M/W/F meeting (Word document).

Chad, also find the (b)(4) dataset attached for the plots.

Let me know if you need anything else.

Thanks,

Matt



From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/14/2020 8:31:55 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID diagnostics

Mark,

We are setting up a call with Dr. Birx and Jeff Shuren. Is it ok if I share this email and the attachments with Dr. Birx prior to the call?

Thanks

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 10, 2020 at 8:17:11 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/14/2020 12:22:54 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID diagnostics

Thanks, Mark.

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 14, 2020 at 9:49:10 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/29/2020 12:52:11 PM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: We have a plan

Excellent and thanks

From: Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu>
Date: May 29, 2020 at 12:15:34 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: FW: We have a plan

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/9/2020 10:13:09 AM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID diagnostics

Mark,
thank you very much for your message. Great work on all counts. We very much appreciate the work with Thermo Fisher. It would be great to arrange a call in the upcoming week. I'll ask Janice to arrange.

I am in self-quarantine but doing well.
Best
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 9, 2020 at 9:53:38 AM EDT
To: Hahn, Stephen (b) (6)@fda.hhs.gov>
Subject: COVID diagnostics

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 5/29/2020 8:01:18 AM
To: Farrugia, Gianrico, M.D. [farrugia.gianrico@mayo.edu]
Subject: Re: Recap of Morning Call

Thx much. Have a great day

Sent from my iPhone

On May 28, 2020, at 6:37 PM, Farrugia, Gianrico, M.D. <farrugia.gianrico@mayo.edu> wrote:

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 5:32 PM
To: Farrugia, Gianrico, M.D.
Subject: FW: Recap of Morning Call

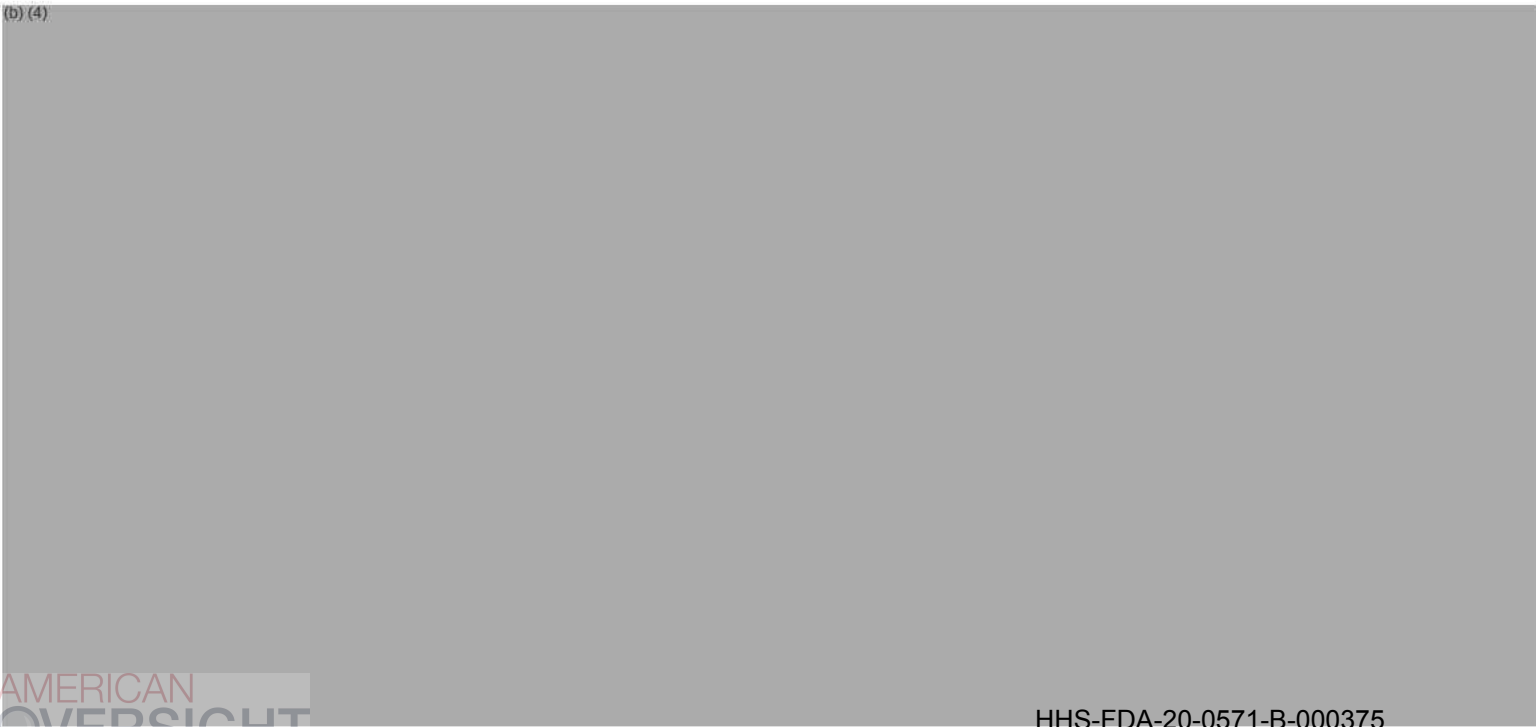
FYI, share..... as needed.

Mike

From: Joyner, Michael J., M.D.
Sent: Thursday, May 28, 2020 3:18 PM
To: Peter Marks (Peter.Marks@fda.hhs.gov); Verdun, Nicole (Nicole.Verdun@fda.hhs.gov); Witten, Celia (CBER) (Celia.Witten@fda.hhs.gov)
Cc: Wright, R. Scott, M.D.; Carter, Rickey E., Ph.D.; Arturo Casadevall (acasade1@jhu.edu)
Subject: Recap of Morning Call

Dear Peter, Nicole and Celia - here is an outline of where we will head based on our call this morning.

(b) (4)



Also, if we can agree on this framework with just minor modifications, and loop BARDA in we can just start and get moving. Patton's maxim on a good plan executed now may apply to the tasks ahead.....

"A good plan, violently executed now, is better than a perfect plan next week."

We have already started working on this framework and things are starting to line up.

Mike

From: (b) (6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 3/14/2020 1:44:46 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Install based

Mark,
thanks much. I believe our teams have already started working on this. If you have any questions or have concerns about progress, please reach out to me by phone or email.
thanks again.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 14, 2020 at 11:54:53 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Install based

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 3/14/2020 1:40:21 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Install based

Mark,

This is excellent. Thank you.

I'm working with our team to address the last two points. I'll be back in touch.

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 14, 2020 at 11:54:53 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Install based

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 3/22/2020 3:19:32 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

Thanks, Mark. Our team has the information and will be reviewing. I have copied Jeff Shuren.
Best
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 22, 2020 at 10:48:28 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Re: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/14/2020 4:00:26 PM
To: Bartkus, Joanne (MDH) [joanne.bartkus@state.mn.us]; Becker, Scott | APHL [Scott.Becker@aphl.org]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) -Stephen.Hah]
Subject: RE: Serology Result

Thanks for flagging, Scott and Joanne. I am working with Jeff to identify the right person for you to filter these examples to in the future. We greatly appreciate the information.

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Sent: Tuesday, April 14, 2020 3:19 PM
To: Becker, Scott | APHL <Scott.Becker@aphl.org>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6) @fda.hhs.gov
Subject: RE: Serology Result

I believe that this company does the collection and sends the specimen out to another laboratory for testing, so it's not clear what test is being used. It is concerning to me that individuals are being told to discontinue social distancing based solely on the results of this test. I am wondering if FDA can provide additional wording to their guidance regarding the interpretation of individual test results in the context of public health guidance and state executive orders.

Joanne

Joanne Bartkus, PhD
Director | Public Health Laboratory

Minnesota Department of Health
Office: 651-201-5256 | Mobile: 651-303-6229



From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Sent: Tuesday, April 14, 2020 2:08 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen (b) (6) @fda.hhs.gov; Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>
Subject: FW: Serology Result

Hi all,

As discussed, here a recent example of the kind of problem that members described on our call. I did not see this firm on the section IV.D list so an example of what's going on. Joanne Bartkus (MN) copied here, sent this our way. Keagan, shall I just forward these to you directly in the future?

Thanks, Scott

From: Bartkus, Joanne (MDH) <joanne.bartkus@state.mn.us>

Sent: Tuesday, April 14, 2020 2:53 PM

To: Becker, Scott | APHL <Scott.Becker@aphl.org>; Crumpler, Megan <mcrumpler@ochca.com>; Ishida, Maria <maria.ishida@agriculture.ny.gov>; Kubin, Grace <Grace.Kubin@dshs.texas.gov>; Steece, Richard <richard.steece@tn.gov>; Toney, Denise <denise.toney@dgs.virginia.gov>; Tran, Tony <Anthony.tran@dc.gov>; Wade, Mark <mark.wade@sanantonio.gov>; Ware, Daphne <daphne.ware@msdh.ms.gov>; Whitmar, Bill <Bill.Whitmar@health.mo.gov>; Shult, Peter <peter.shult@slh.wisc.edu>; Rakeman, Jennifer <jrakeman@health.nyc.gov>; Taylor, Jill <jill.taylor@health.ny.gov>; Ball, Chris <BallC1@dhw.idaho.gov>; Southern, Tim <tim.southern@state.sd.us>; Kimsey, Paul <paul.kimsey@cdph.ca.gov>; Kyriacopoulos, Peter | APHL <Peter.Kyriacopoulos@aphl.org>; Mangal, Chris | APHL <Chris.Mangal@aphl.org>; Wroblewski, Kelly | APHL <kelly.wroblewski@aphl.org>; Blank, Eric | APHL <eric.blank@aphl.org>; Hahn, Stephen (b) (6) <[fda.hhs.gov](mailto:(b)(6)@fda.hhs.gov)>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>

Subject: Serology Result

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.

Hi All,

Please see the attached serology report . Note that the result indicates that a positive result indicates that the individual should stop social distancing even though the report has a disclaimer that the test may cross-react with other coronaviruses. This is, as Jen has stated repeatedly, dangerous.

Here is the wording from their website

The ARCpoint Labs COVID-19 Antibody Test was designed for this purpose. With this simple finger stick test, you will learn whether you have been exposed to the virus and if your immune system has produced antibodies and already fought off the infection, making it safe for you to return to work/school.

Joanne Bartkus, PhD

Director | Public Health Laboratory

Minnesota Department of Health

Office: 651-201-5256 | Mobile: 651-303-6229

**m1 DEPARTMENT
OF HEALTH**

[Redacted]

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

From: Becker, Scott | APHL <Scott.Becker@aphl.org>

Sent: Saturday, April 11, 2020 5:42 PM

To: Becker, Scott | APHL; Bartkus, Joanne (MDH); Crumpler, Megan; Ishida, Maria; Kubin, Grace; Steece, Richard; Toney, Denise; Tran, Tony; Wade, Mark; Ware, Daphne; Whitmar, Bill; Shult, Peter; Rakeman, Jennifer; Taylor, Jill; Ball, Chris;

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000381

Southern, Tim; Kimsey, Paul; Kyriacopoulos, Peter | APHL; Mangal, Chris | APHL; Wroblewski, Kelly | APHL; Blank, Eric | APHL; Hahn, Stephen; Sheehy, Janice

Subject: APHL/Commissioner Hahn

When: Tuesday, April 14, 2020 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: (b) (6)

This message may be from an external email source.

Do not select links or open attachments unless verified. Report all suspicious emails to Minnesota IT Services Security Operations Center.

Please hold for discussion between APHL BOD and select members and Dr. Stephen Hahn, Commissioner of FDA.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/5/2020 9:37:42 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Re: Can we chat today if possible re serology

Ok to call around 10:30 am EST?

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Date: April 4, 2020 at 5:04:58 PM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: Can we chat today if possible re serology

(b) (6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 4/9/2020 9:30:38 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Coronavirus (COVID-19) Update: Serological Tests

Definitely Scott.
I am copying Janice.
Steve

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Date: April 8, 2020 at 9:23:22 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: RE: Coronavirus (COVID-19) Update: Serological Tests

Perfect, thanks for your leadership on this issue and your call just now. I haven't forgotten your offer to meet with our leadership, but this week has gotten away from us. Who should I work with on your staff I can work with for next week?

Thanks again, Scott

From: Hahn, Stephen (b)(6) @fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:02 AM
To: Becker, Scott | APHL <Scott.Becker@aphl.org>
Subject: Fwd: Coronavirus (COVID-19) Update: Serological Tests

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.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: April 8, 2020 at 9:00:00 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Coronavirus (COVID-19) Update: Serological Tests

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests>

For Immediate Release:

April 07, 2020

Statement From:

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000384

Statement Author

Leadership Role

Commissioner of Food and Drugs - Food and Drug Administration

Stephen M. Hahn M.D.

Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection, like COVID-19. In other words, the test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself. In the early days of an infection when the body's immune response is still building, antibodies may not be detected. This limits the test's effectiveness for diagnosing COVID-19 and why it should not be used as the sole basis to diagnose COVID-19.

Serological tests can play a critical role in the fight against COVID-19 by helping healthcare professionals to identify individuals who have overcome an infection in the past and have developed an immune response. In the future, this may potentially be used to help determine, together with other clinical data, that such individuals are no longer susceptible to infection and can return to work. In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19. This is why Vice President Mike Pence called on the laboratory community to develop serological tests for COVID-19.

In March, the FDA issued a policy to allow developers of certain serological tests to begin to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable. This includes allowing developers to market their tests without prior FDA review if certain conditions outlined in the guidance document are met. The FDA issued this policy to allow early patient access to certain serological tests with the understanding that the FDA has not reviewed and authorized them.

The FDA can also authorize tests for COVID-19 under an Emergency Use Authorization (EUA). To date, FDA has authorized one EUA for a serological test that is intended for use by clinical laboratories.

Since the FDA issued the policy, over 70 test developers have notified the agency that they have serological tests available for use. However, some firms are falsely claiming that their serological tests are FDA approved or authorized, or falsely claiming that they can diagnose COVID-19. The FDA will take appropriate action against firms making false claims or marketing tests that are not accurate and reliable.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

This email has been scanned for spam and viruses by Proofpoint Essentials. Click [here](#) to report this email as spam.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6)] -STEPHEN.HAH]
Sent: 4/13/2020 11:42:12 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Call follow up

Marc,

I am looping in Peter Marks who is part of the team looking at our efforts here. Peter, Marc and his company have been terrific partners. Do you think their offer would fit into our plans moving forward?
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 8, 2020 at 9:47:27 AM EDT
To: Hahn, Stephen (b)(6) <[REDACTED]@fda.hhs.gov>
Subject: RE: Call follow up

Dear Dr. Hahn,

Thanks for the follow up. Anand Shah has been super helpful in linking us up to the right people on serological testing and I did participate in your call with Advamed DX earlier in the week.

(b) (4)



We don't need a deep discussion with you on the topic but rather to explain it and get your reaction on whether it seems relevant.

Let me know if you have time to speak later in the week.

Thanks,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Hahn, Stephen (b)(6) @fda.hhs.gov>
Sent: Tuesday, April 7, 2020 8:54 AM
To: Casper, Marc N. <marc.casper@thermofisher.com>
Subject: Re: Call follow up

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Marc,
Just following up. I believe our teams are connecting.
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 2, 2020 at 8:07:45 PM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: Call follow up

Dear Dr. Hahn,
Thanks for the call this evening.

(b) (4)



Sincerely yours,
Marc

Marc N. Casper
Chairman, President and CEO

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
Tel: +1 (781) 622-1105 | Fax: +1 (781) 768-6603
marc.casper@thermofisher.com | www.thermofisher.com

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6)] -STEPHEN.HAH]
Sent: 3/14/2020 1:40:12 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Install based

Mark,
This is excellent. Thank you.
I'm working with our team to address the last two points. I'll be back in touch.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 14, 2020 at 11:54:53 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: Install based

Dear Steve,

(b) (4)



Let me know how else we can be helpful

Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

We will keep you up to date as this situation changes.

Kent

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6)] -STEPHEN.HAH]
Sent: 3/14/2020 1:44:36 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
Subject: Re: Install based

Mark,
thanks much. I believe our teams have already started working on this. If you have any questions or have concerns about progress, please reach out to me by phone or email.
thanks again.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 14, 2020 at 11:54:53 AM EDT
To: Hahn, Stephen (b)(6) @fda.hhs.gov>
Subject: Install based

Dear Steve,

(b) (4)



Let me know how else we can be helpful

Mark

Mark Stevenson

Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
168 Third Avenue | Waltham, MA 02451
T (781) 622-1344 C: (760) 576-9897
mark.stevenson@thermofisher.com | www.thermofisher.com

Assistant: Kimberly O'Neill
T (781) 419-3222
kimberly.oneill@thermofisher.com

The world leader in serving science

WORLDWIDE CONFIDENTIALITY NOTE: Dissemination, distribution or copying of this e-mail or the information herein by anyone other than the intended recipient, or an employee or agent of a system responsible for delivering the message to the intended recipient, is prohibited. If you are not the intended recipient, please inform the sender and delete all copies.

We will keep you up to date as this situation changes.

Kent

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6)] -STEPHEN.HAH]
Sent: 3/22/2020 3:19:23 PM
To: Stevenson, Mark [mark.stevenson@thermofisher.com]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

Thanks, Mark. Our team has the information and will be reviewing. I have copied Jeff Shuren.
Best
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: March 22, 2020 at 10:48:28 AM EDT
To: Hahn, Stephen (b) (6) <(b) (6)@fda.hhs.gov>
Subject: Re: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

Dear Steve,

(b) (4)

A large rectangular area of the email is redacted with a solid grey background. The redaction covers the main body of the message.

Let me know if you have questions.

Mark Stevenson

(b) (6)

A small rectangular area of the signature is redacted with a solid grey background.

From: "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>
Date: Saturday, March 21, 2020 at 9:20 PM
To: Peter Shearstone <peter.shearstone@thermofisher.com>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>, (b) (6) " (b) (6) <(b) (6)>
Cc: Tim Fenton <tim.fenton@thermofisher.com>, Mark Stevenson <mark.stevenson@thermofisher.com>, "Chen, Mark" <Mark.Chen@fda.hhs.gov>
Subject: RE: COVID-19 Production and Distribution Report - Thermo Fisher - 3/21/2020

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Hi Peter,

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/5/2020 9:37:51 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Re: Can we chat today if possible re serology

Ok to call around 10:30 am EST?

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Date: April 4, 2020 at 5:04:58 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Can we chat today if possible re serology

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/8/2020 9:02:17 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
Subject: Fwd: Coronavirus (COVID-19) Update: Serological Tests

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: April 8, 2020 at 9:00:00 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Coronavirus (COVID-19) Update: Serological Tests

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/9/2020 9:30:47 AM
To: Becker, Scott | APHL [Scott.Becker@aphl.org]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Coronavirus (COVID-19) Update: Serological Tests

Definitely Scott.
I am copying Janice.
Steve

From: Becker, Scott | APHL <Scott.Becker@aphl.org>
Date: April 8, 2020 at 9:23:22 AM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: RE: Coronavirus (COVID-19) Update: Serological Tests

From: (b)(6)@fda.hhs.gov (b)(6)@fda.hhs.gov]
Sent: 4/7/2020 8:54:38 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
Subject: Re: Call follow up

Marc,
Just following up. I believe our teams are connecting.
Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 2, 2020 at 8:07:45 PM EDT
To: Hahn, Stephen (b)(6)@fda.hhs.gov>
Subject: Call follow up

From: (b) (6)@fda.hhs.gov (b) (6)@fda.hhs.gov]
Sent: 4/13/2020 11:42:21 AM
To: Casper, Marc N. [marc.casper@thermofisher.com]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Call follow up

Marc,

I am looping in Peter Marks who is part of the team looking at our efforts here. Peter, Marc and his company have been terrific partners. Do you think their offer would fit into our plans moving forward?

Steve

From: Casper, Marc N. <marc.casper@thermofisher.com>
Date: April 8, 2020 at 9:47:27 AM EDT
To: Hahn, Stephen (b) (6)@fda.hhs.gov>
Subject: RE: Call follow up

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 8/6/2020 1:23:40 PM
To: Kaufman, Harvey W [Harvey.W.Kaufman@questdiagnostics.com]
CC: Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]
Subject: Re: check in

Fascinating. I would love to see it whenever you are ready to share. And this would be a great topic for an EA meeting in the future too, if you are keen.

From: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Sent: Thursday, August 6, 2020 1:21 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Valo, Gina <Gina.Valo@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: check in

We are preparing short communication – publication – that looks at loss of detectable SARS-CoV-2 IgG seropositivity among patients retested. Interestingly, patients who are 55 years and older have higher rates of persistence of seropositivity than younger patients.

Harvey W. Kaufman, MD, MBA, FCAP, Senior Medical Director, Medical Informatics
Quest Diagnostics | Action from Insight | 15 Pleasant Street, Needham, MA 02492 USA
| phone 201.213.8452 | Harvey.W.Kaufman@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/
For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Thursday, August 6, 2020 1:01 PM
To: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Cc: Valo, Gina <Gina.Valo@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: check in

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.

Hi Harvey,

Saw your note at the end of the call. Look forward to hearing more!

Take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 8/6/2020 12:08:03 PM
To: Kaufman, Harvey W [Harvey.W.Kaufman@questdiagnostics.com]
CC: Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]
Subject: Re: Today's Dx EA

Thank you so much. You were definitely busy!

From: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Sent: Thursday, August 6, 2020 11:48 AM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Valo, Gina <Gina.Valo@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: Today's Dx EA

Feel free to share:

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2768946> Link to open access of research letter from this week showing number of newly identified patients with six common cancer types fell 46% in first seven weeks of pandemic (March 1, 2020 onward). Getting enormous media coverage (US, Mexico, and elsewhere).

Other recent hot publication is non-COVID-19 related: cervical cancer screening: <https://academic.oup.com/ajcp/advance-article/doi/10.1093/ajcp/aqaa074/5865067> Also open access. Guidelines are misdirected and will likely cause harm and deaths.

Harvey W. Kaufman, MD, MBA, FCAP, Senior Medical Director, Medical Informatics
Quest Diagnostics | Action from Insight | 15 Pleasant Street, Needham, MA 02492 USA
| phone 201.213.8452 | Harvey.W.Kaufman@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/

For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Thursday, August 6, 2020 11:07 AM
To: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Cc: Valo, Gina <Gina.Valo@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: Today's Dx EA

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.

During today's Diagnostics Evidence Accelerator meeting at Noon ET, Sara Brenner from CDRH is going to present on the recent HHS lab reporting guidance and the implementation guide. You always have thoughtful observations and suggestions, so I wanted to make sure to flag this as a great meeting where your voice and observations will be (as always!) appreciated.

Cheers-

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)
Email: amy.abernethy@fda.hhs.gov

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/10/2020 3:53:05 PM
To: Edward Abrahams [eabrahams@personalizedmedicinecoalition.org]
CC: jay.g.wohlgemuth@questdiagnostics.com
Subject: Re: JW email

Thank you so much, Ed!

Hi Jay - Sending you a separate email.

Take care,

Amy

From: Edward Abrahams <eabrahams@personalizedmedicinecoalition.org>
Sent: Wednesday, June 10, 2020 3:40 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: jay.g.wohlgemuth@questdiagnostics.com <jay.g.wohlgemuth@questdiagnostics.com>
Subject: Re: JW email

Amy:

I am 101 percent sure that Jay would love to hear from you.

His address is: Jay.G.Wohlgemuth@questdiagnostics.com.

Best wishes,

Ed

Edward Abrahams, Ph.D.
President
eabrahams@personalizedmedicinecoalition.org
Direct: 202-787-5907 | Cell: 202-580-5141

Personalized Medicine Coalition
1710 Rhode Island Ave. NW | Suite 700 | Washington, DC 20036
www.PersonalizedMedicineCoalition.org



From: Amy Abernethy <Amy.Abernethy@fda.hhs.gov>
Date: Wednesday, June 10, 2020 at 3:26 PM
To: Edward Abrahams <eabrahams@personalizedmedicinecoalition.org>
Subject: JW email

Hi Ed,

I hope that you are safe and well. Quick question... Do you have Jay Wohlgemuth's email address? Feel free to check with him first before sending it to me.

Thanks and take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/12/2020 9:57:35 AM
To: Wohlgemuth, Jay G [Jay.G.Wohlgemuth@questdiagnostics.com]
CC: Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Waters, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bc2639c6ebd4ecc96e8c0fc6e7bb96f-Michael.Wat]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]; Brenner, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5916ba05b26e4fd0a602fc0049eb382b-Sara.Brenne]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Quick convo

Hi Jay,

Thank you so much. We got caught up in a bunch of meetings yesterday, but are definitely looking forward to talking to you. Since you are on the West Coast, are you able to talk after 2pm today PT (ie after 5p ET)? I am not sure who all from FDA will be able to join, but I can definitely update you and then help to connect the dots to other folks at FDA as appropriate.

Thanks and take care,

Amy

From: Wohlgemuth, Jay G <Jay.G.Wohlgemuth@questdiagnostics.com>
Sent: Thursday, June 11, 2020 9:51 AM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Waters, Michael <Michael.Waters@fda.hhs.gov>; Canos, Daniel <Daniel.Canos@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>
Subject: RE: Quick convo

Amy,

Sorry for the delay. Yes it would be good to talk. I am free today from 10-11 (pac) 12-1230 (pac) and could be free many times tomorrow (Friday).

Let me know if something works for you to catch up

Jay

Jay Wohlgemuth, M.D.
Chief Medical Officer and Senior VP R&D, Medical and Population Health
Quest Diagnostics
33608 Ortega Highway, San Juan Capistrano, CA 92675
mobile +1.949.491.2698
jay.g.wohlgemuth@questdiagnostics.com

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000405

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Sent: Wednesday, June 10, 2020 1:05 PM

To: Wohlgemuth, Jay G <Jay.G.Wohlgemuth@questdiagnostics.com>

Cc: Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Waters, Michael <Michael.Waters@fda.hhs.gov>; Canos, Daniel <Daniel.Canos@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>

Subject: Quick convo

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.

Hi Jay,

I hope that you are safe and well.

Would you be willing to have a quick chat with us about COVID-19 lab data and the work that is happening through the Evidence Accelerator? I can call you in the late afternoon if you want to talk quickly today. There is also a meeting tomorrow at Noon that you might find interesting and that I wanted to tell you about too. Regardless, it would be great to talk even after the meeting tomorrow if/when you are available.

Take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/11/2020 11:13:41 PM
To: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]
Subject: Re: Apologies

Hi Bill,

No worries at all - I totally get it, especially given the complexities of life at the moment.

We are enthusiastic about the work that you are doing and I am looking forward to hearing more. It is really important.

Talk soon!

Take care,

Amy

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Sent: Thursday, June 11, 2020 10:23 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: Apologies

Amy
Just want to be sure you've received my apologies for missing the Evidence Accelerator meeting today. I was looking forward to the discussion, and the chance to contribute. I should have confirmed it was in my calendar in Outlook. My missing the meeting is only a reflection of my poor calendar management. This is an important effort and I'm grateful that Mayo DLMP has been given the opportunity to participate.

Sincerely
Bill Mo

Sent from my iPhone which may account for some typographical errors

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/16/2020 7:47:20 PM
To: Wohlgemuth, Jay G [Jay.G.Wohlgemuth@questdiagnostics.com]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]; Waters, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bc2639c6ebd4ecc96e8c0fc6e7bb96f-Michael.Wat]; Brenner, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5916ba05b26e4fd0a602fc0049eb382b-Sara.Brenne]
CC: Martin, Lauren A [Lauren.A.Martin@questdiagnostics.com]; Sabol, Christine E [Christine.E.Sabol@questdiagnostics.com]; Kaufman, Harvey W [Harvey.W.Kaufman@questdiagnostics.com]; Walsh, Tom P [Tom.P.Walsh@questdiagnostics.com]; Wagner, Tom R [Tom.R.Wagner@questdiagnostics.com]
Subject: Re: FDA-Quest Diagnostics Chat

Thank you very much, Jay. This is exceptionally helpful.

Christine, Harvey, Tom - it is great to meet you. We will work with you to schedule a time to talk via a different email trail.

Please stay safe and well,

Amy

From: Wohlgemuth, Jay G <Jay.G.Wohlgemuth@questdiagnostics.com>
Sent: Tuesday, June 16, 2020 7:26 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Canos, Daniel <Daniel.Canos@fda.hhs.gov>; Waters, Michael <Michael.Waters@fda.hhs.gov>; Brenner, Sara <Sara.Brenner@fda.hhs.gov>
Cc: Martin, Lauren A <Lauren.A.Martin@questdiagnostics.com>; Sabol, Christine E <Christine.E.Sabol@questdiagnostics.com>; Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>; Walsh, Tom P <Tom.P.Walsh@questdiagnostics.com>; Wagner, Tom R <Tom.R.Wagner@questdiagnostics.com>
Subject: RE: FDA-Quest Diagnostics Chat

Amy and FDA team,

Thanks for the call yesterday, I'd like to introduce 2 Quest team members who can have a discussion with you on the opportunity to work more closely on public health reporting and data sharing in the COVID and broader ecosystem. I understand the opportunity to be to improve and bring up a level the informatics programs and data sharing which enables our public health infrastructure. There is a lot to that but there are 3 people at Quest who I think should have the discussion with FDA on the needs and opportunities

Christine Sabol, our Regulatory leader for our laboratories, Dr. Harvey Kaufman, our medical informatics leader who works with CDC and others on data sharing initiatives and Tom Walsh who is a leader on our technology team and is working with Christine on public health reporting needs and capabilities at Quest.

Christine can take the lead in scheduling a follow up call with the FDA team.

Christine and team, Amy is Principal Deputy Commissioner and Acting Chief Information Officer for the FDA.

She and her team have a collaborative effort going to upgrade data sharing and public health reporting.

Best,

Jay

Jay Wohlgemuth, M.D.

Chief Medical Officer and Senior VP R&D, Medical and Population Health

Quest Diagnostics

33608 Ortega Highway, San Juan Capistrano, CA 92675

mobile +1.949.491.2698

jay.g.wohlgemuth@questdiagnostics.com

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

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Sent: Friday, June 12, 2020 9:21 AM

To: Abernethy, Amy; Tunis, Sean; Roe, Laura; Franklin, Joseph; Nguyen, Mimi; Wohlgemuth, Jay G; Canos, Daniel; Waters, Michael; Brenner, Sara

Cc: Martin, Lauren A

Subject: FDA-Quest Diagnostics Chat

When: Monday, June 15, 2020 6:00 PM-6:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: WebEx

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.

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [click here](#) to view host information.

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

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/18/2020 10:52:50 AM
To: Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Ross, Joseph [joseph.ross@yale.edu]
CC: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Davies, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]
Subject: Re: Yale / Mayo presentation for dx-EA mtg on 6/18
Attachments: ross Hugo projects RUF 20-06-17aa.ppt

Hi Joe - Thank you so much for being willing to join us today. It will be great to have your presentation.

I took the liberty of editing the deck a bit to focus the discussion. Please see attached and see what you think. I tried to focus on what Hugo could do (without logos) and then the fact that a study will be done. I will weave this together in my presentation as to how I think that this will help for the future of diagnostics.

Thank you!

Amy

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Sent: Thursday, June 18, 2020 8:47 AM
To: Ross, Joseph <joseph.ross@yale.edu>
Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>; Davies, Kathleen <Kathleen.Davies@fda.hhs.gov>
Subject: RE: Yale / Mayo presentation for dx-EA mtg on 6/18

Joe

Thanks again for helping out with this. I think you might be able to remove or skip over slides 13-18. They are interesting projects, but risk losing virtual audience by going too quickly over a lot of info. I think it will go over better to spend more time on the Dhruva study so people understand what the Hugo platform can do, and then jump to slide 19 with the COVID-19 study you are planning. This takes us directly into the focus of the dx-EA program. One of our goals is to understand the various types of RWD that can be collected by various groups/platforms, and yours is pretty unique.

I am copying Amy who may have additional suggestions. Much appreciated!

Sean

From: Ross, Joseph <joseph.ross@yale.edu>
Sent: Wednesday, June 17, 2020 5:41 PM
To: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Amar Bhat <abhat@reaganudall.org>

Subject: RE: Yale / Mayo presentation for dx-EA mtg on 6/18

Sean, I just spoke with Nilay and we agreed that I would be the one to present.

Amar, here are the slides I will use.

Will I control the presentation or will you?

Best, Joe

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Sent: Wednesday, June 17, 2020 4:11 PM

To: Ross, Joseph <joseph.ross@yale.edu>

Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Amar Bhat <abhat@reaganudall.org>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Subject: RE: Yale / Mayo presentation for dx-EA mtg on 6/18

Joe

We would be happy to have either of you present tomorrow. I think it would be great to hear more about Hugo has been used, as described in the Dhruva paper, and also in the context of NEST projects. It would be ideal if you could craft the content with an eye towards the goals for the COVID dx-EA program, as we are most interested in insights about strategies to rapidly learn about the real world performance of COVID-19 dx tests and serology. I think a slide on the OHHHE study would also be worthwhile. We would have about 7-8 minutes for this talk.

Please let us know whether it will be you or Nilay presenting. You can send your slides to Amar Bhat any time tomorrow morning (the earlier the better).

I would be happy to have a look at your slides whenever you have something, Please email or call if you have any more questions. Thnx.

Sean

From: Ross, Joseph <joseph.ross@yale.edu>

Sent: Wednesday, June 17, 2020 1:56 PM

To: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>

Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

If Nilay is available, that's great. If not, I can present and talk about how we have used Hugo for past and current CERSI and NEST projects.

He and I have co-led all these projects, so it doesn't matter which of us presents.

And we can add a slide with the OHHHE study proposal, explaining what my colleagues are hoping to pursue with FDA. Joe

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Sent: Wednesday, June 17, 2020 10:29 AM

To: Ross, Joseph <joseph.ross@yale.edu>

Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>

Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

I was thinking of the Dhuva paper you sent, on which Nilay was the senior author.

So perhaps that is the same as the Hugo platform.

The group is trying to figure out how to pull together RWD in ways that will help us learn about real world performance of COVID-19 dx tests, and it seems that this model might be of interest.

From: Ross, Joseph <joseph.ross@yale.edu>
Sent: Wednesday, June 17, 2020 10:16 AM
To: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Sean, do you mean a discussion of the Hugo platform we've used for research?

Or of the proposal we submitted to OMHHE?

2 of my colleagues at Yale led the OMHHE submission, and I would be happy to see if there were able to present.

Joe

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 9:49 AM
To: Ross, Joseph <joseph.ross@yale.edu>
Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Thanks Joe – good to talk with you, and good to get these blurbs.

Nilay – might you be available tomorrow at noon ET to do a brief summary of your patient-centered data sharing platform for the COVID-19 diagnostics accelerator weekly meeting? Probably about 5-7 min, or a bit more.

Will send more details if the timing works. thnx

Sean

From: Ross, Joseph <joseph.ross@yale.edu>
Sent: Tuesday, June 16, 2020 5:39 PM
To: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Cc: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Subject: FW: Yale side of the Yale-Mayo CERSI diagnostic test work

Sean,

Good to speak today.

Here are the blurbs I had originally sent Amy about the projects being led by my colleagues in the School of Public Health.

Also, I've attached the proposal our team submitted to OMHHE as part of the CERSI program. This builds on some work we recently published (attached), which I think you'd find interesting.

Nilay (cc'd here) and I would be happy to find a time to follow-up – (b)(6)

(b)(6)

Nilay can definitely speak to the potential of using OptumLabs EHR data for RWE of diagnostic tests – even though, as we discussed, it's a bit of a long shot!

Joe

From: Ross, Joseph <joseph.ross@yale.edu>

Sent: Wednesday, June 10, 2020 5:31 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>

Cc: Ko, Albert <albert.ko@yale.edu>; Grubaugh, Nathan <nathan.grubaugh@yale.edu>; Wyllie, Anne <anne.wyllie@yale.edu>; Krumholz, Harlan <harlan.krumholz@yale.edu>; Shah, Nilay <shah.nilay@mayo.edu>

Subject: Yale side of the Yale-Mayo CERSI diagnostic test work

Amy, Joe and Laura,

Thanks for making the time to connect on Monday about the RUF Diagnostics Evidence Accelerator Workgroup and to learn more about what Yale folks are pursuing in this space that might be relevant to FDA.

I'm cc'ing the principal investigators I've connected to, who will be able to answer specific questions or would welcome the opportunity to present their work in greater detail to the RUF workgroup (they have been joining some of the meetings).

(b) (4)



Thanks again for your time on Monday. Happy to join a call to discuss further,
Joe

Joseph S. Ross, MD, MHS (@jsross119)

Professor of Medicine and Public Health

Center for Outcomes Research and Evaluation (CORE)

Director, Yale-Mayo Clinic Center of Excellence in Regulatory Science and Innovation (CERSI)

Co-Director, Yale Open Data Access (YODA) Project

Co-Director, Yale Collaboration for Research Integrity and Transparency (CRIT)

Co-Director, National Clinician Scholars Program (NCSP) at Yale

Aggregating Real-World Data Sources using a Patient-Centered Data Sharing Platform

Reagan Udall Foundation

Diagnostics Evidence Accelerator Workgroup

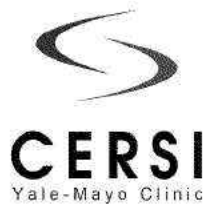
June 18, 2020

Joseph S. Ross, MD, MHS

Section of General Internal Medicine, School of Medicine
Center for Outcomes Research and Evaluation, Yale-New Haven Hospital



Yale SCHOOL OF MEDICINE



The Yale-Mayo Clinic Center of Excellence in Regulatory Science and Innovation (CERSI) is a joint effort between Yale University, Mayo Clinic, and the FDA to conduct research to address key gaps in knowledge and develop tools to support regulatory decision-making and the overall mission of FDA.



The National Evaluation System for health Technologies (NEST) is a voluntary network of health organizations, including Yale-New Haven Hospital, aiming to efficiently develop RWE using RWD to inform medical device evaluation and support regulatory decision-making throughout the total product life cycle.

ARTICLE OPEN



Aggregating multiple real-world data sources using a patient-centered health-data-sharing platform

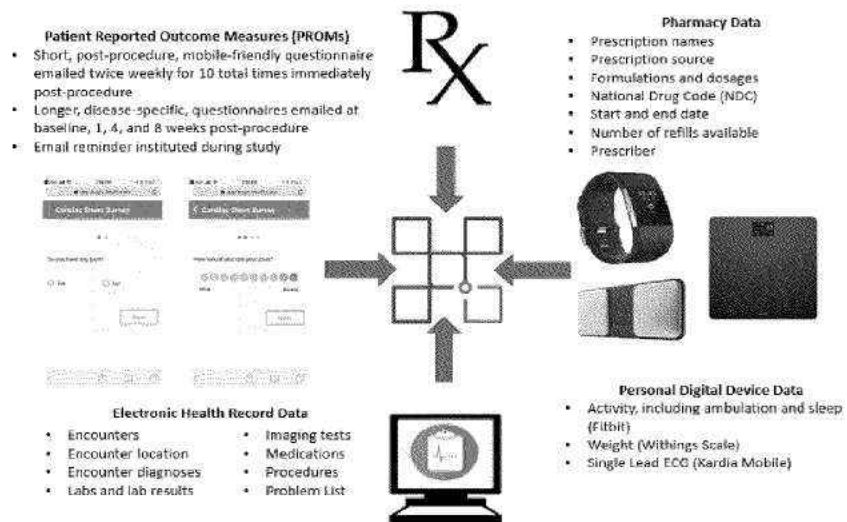
Sanket S. Dhruva¹, Joseph S. Ross^{2,3,4,5}, Joseph G. Akar^{4,5}, Brittany Caldwell⁶, Karla Childers⁷, Wing Chow⁷, Laura Ciacchio⁸, Paul Coplan⁹, Jun Dong⁶, Hayley J. Dykhoff¹⁰, Stephen Johnston⁷, Todd Kellogg⁹, Cynthia Long⁶, Peter A. Noseworthy^{10,11}, Kurt Roberts¹², Anindita Saha⁶, Andrew Yoo⁷ and Nilay D. Shah^{6,11}

Real-world data sources, including electronic health records (EHRs) and personal digital device data, are increasingly available, but are often siloed and cannot be easily integrated for clinical, research, or regulatory purposes. We conducted a prospective cohort study of 60 patients undergoing bariatric surgery or catheter-based atrial fibrillation ablation at two U.S. tertiary care hospitals, testing the feasibility of using a patient-centered health-data-sharing platform to obtain and aggregate health data from multiple sources. We successfully obtained EHR data for all patients at both hospitals, as well as from ten additional health systems, which were successfully aggregated with pharmacy data obtained for patients using CVS or Walgreens pharmacies; personal digital device data from activity monitors, digital weight scales, and single-lead ECGs, and patient-reported outcome measure data obtained through surveys to assess post-procedure recovery and disease-specific symptoms. A patient-centered health-data-sharing platform successfully aggregated data from multiple sources.

npj Digital Medicine (2020)3:60; <https://doi.org/10.1038/s41746-020-0265-z>

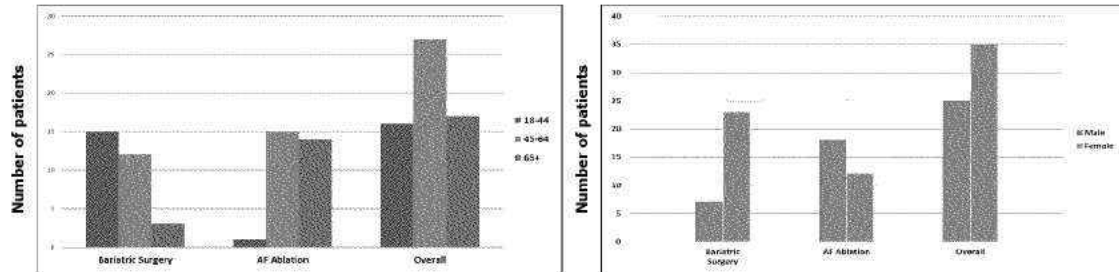


Source: Dhruva et. al., npj Digital Medicine 2020;3:60.



Participation and Enrollment

- 60 patients enrolled; 15 patients per procedure, per site
- 59 patients underwent procedures and completed 8-week follow-up
- Median enrollment time: 70 min (IQR, 58 -100)



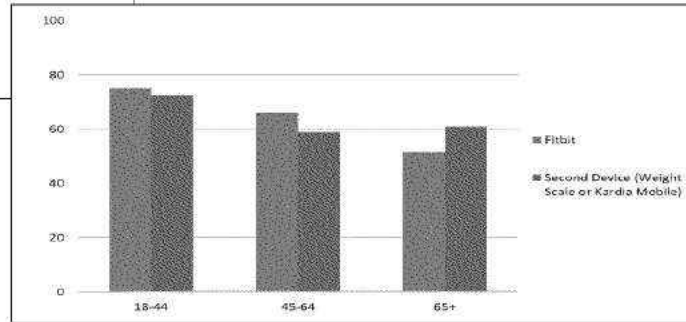
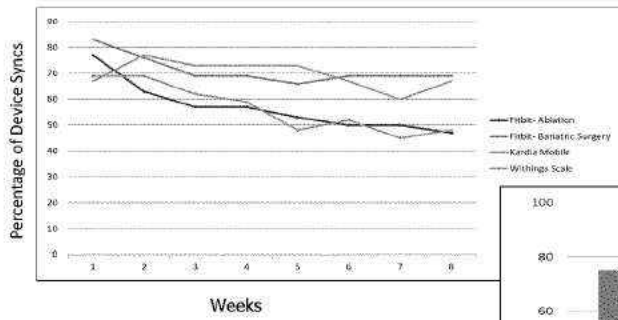
Source: Dhruva et. al., npj Digital Medicine 2020;3:60.

Aggregating EHR and Pharmacy Data

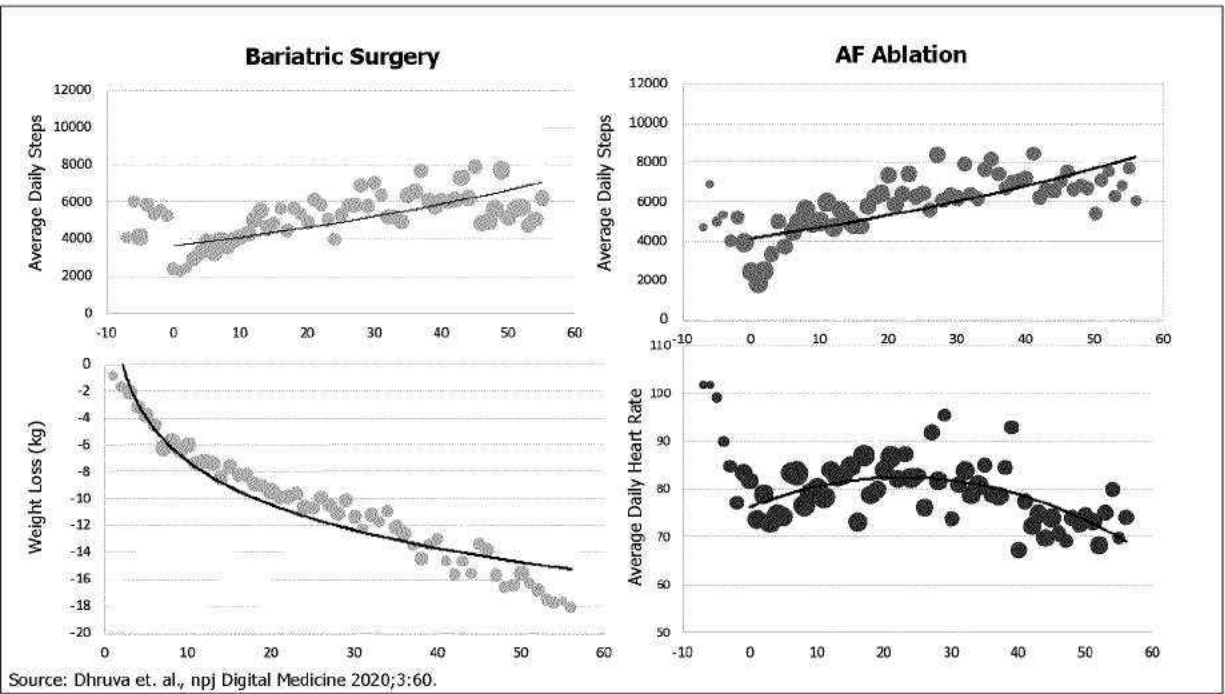
- **Yale and Mayo Clinic health records received for 100% of patients**
- **33 of 60 (55%) patients also with primary care based at Yale or Mayo**
 - **10 patients linked an additional 13 portals from other health systems**
- **24 of 60 (40%) patients connected CVS or Walgreens pharmacy accounts (Walmart now available too)**
 - **Medication names, dosages, start and end dates, refills and prescriber**
- **All data were passively aggregated after initial enrollment, allowing for near real-time streaming data**

Source: Dhruva et. al., npj Digital Medicine 2020;3:60.

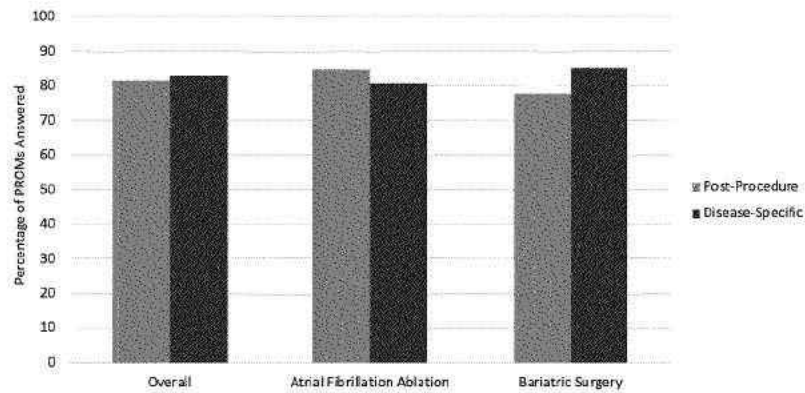
Personal Digital Device Syncs



Source: Dhruva et. al, npj Digital Medicine 2020;3:60.



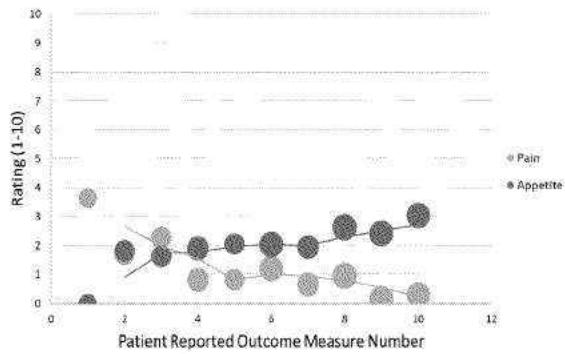
PROMs Completed



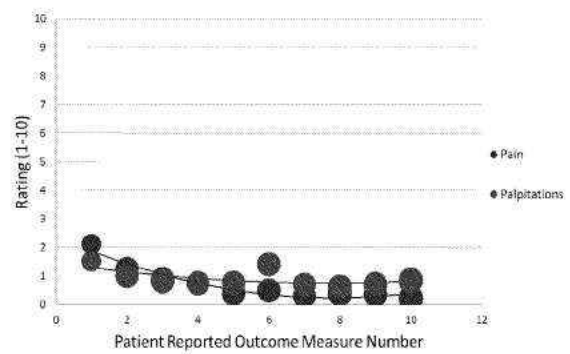
Of all PROMs answered, only 4 were not at least 90% complete

Source: Dhruva et. al., npj Digital Medicine 2020;3:60.

Post-Bariatric Surgery



Post-AF Ablation



Source: Dhruva et. al., npj Digital Medicine 2020;3:60.

**Real-World Data to Characterize COVID19
Disease Progression and Symptom Burden
in Diverse Populations**

Project Aim: Develop representative, real-world data source characterizing experience of patients diagnosed with COVID19 to better understand disease progression and symptom burden in minority and other vulnerable populations.



Proposed Study Design

- **Prospectively enroll 600 patients who are undergoing testing for SARS-CoV-2**
 - CVS Health testing sites in New Haven, CT and Atlanta, GA
- **All patients enrolled in Hugo for PROM surveys over a 180-day follow-up period (clinical course, physical and mental health symptom burden), as well as to connect EHR, pharmacy, and personal digital devices**

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/21/2020 7:46:53 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]
CC: Ross, Joseph [joseph.ross@yale.edu]; Davies, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Yale side of the Yale-Mayo CERSI diagnostic test work

Hi Nilay,

Terrific! We are looking forward to talking. Mimi is cc'ed here and can help us get a call on the calendar.

Thank you and talk soon,

Amy

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Friday, June 19, 2020 2:02 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>; Davies, Kathleen <Kathleen.Davies@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Hi Amy –

My apologies for the delayed response. Joe and I are very excited about the potential of Hugo after our initial project and how it can be an additional (and potentially, unique) data source.

It would be great to find a time to talk about the diagnostics work. Are there days/times that work best on your end? I can do my best to move things around to work around your schedule.

(b) (4)

Thanks
Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Thursday, June 18, 2020 12:10 PM
To: Tunis, Sean; Shah, Nilay D., Ph.D.; Roe, Laura; Franklin, Joseph
Cc: Ross, Joseph; Davies, Kathleen; Valo, Gina
Subject: [EXTERNAL] Re: Yale side of the Yale-Mayo CERSI diagnostic test work

Hi Nilay,

Indeed - Joe's presentation today was excellent and was exactly what I think was needed.

In terms of your point about having one person from Mayo being the point person, this would be great especially as it relates to the Diagnostics work. I have some additional ideas here that I would like to talk to you about as well. Perhaps a quick call?

Thanks,

Amy

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Sent: Thursday, June 18, 2020 1:03 PM
To: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>; Davies, Kathleen <Kathleen.Davies@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Nilay

Thanks for offering to coordinate on the Mayo side. Joe did a great job presenting today. We will definitely be in touch to explore ways we can work together. No worries about Bill last week – we realize that everyone is maxed out. Best,

Sean

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Thursday, June 18, 2020 12:35 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Amy and Sean –

Apologies for Bill not being able to join last week – he is incredibly busy as you might imagine with a variety of testing related projects and got the time wrong on his schedule. To make our participation easier, I am happy to be the point person for Mayo and can coordinate internally. As the diagnostic accelerator goes live, please let me know how I can be helpful.

Thanks
Nilay

From: Abernethy, Amy [<mailto:Amy.Abernethy@fda.hhs.gov>]
Sent: Thursday, June 11, 2020 6:51 AM
To: Roe, Laura; Shah, Nilay D., Ph.D.; Franklin, Joseph
Cc: Ross, Joseph; Tunis, Sean
Subject: [EXTERNAL] Re: Yale side of the Yale-Mayo CERSI diagnostic test work

Thank you, Nilay. This is incredibly helpful information.

@Sean - Can you share with CDRH?

Thanks,

A

From: Roe, Laura <Laura.Roe@fda.hhs.gov>
Sent: Thursday, June 11, 2020 7:04 AM
To: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

Thank you, this is very interesting. Adding in Sean.

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Date: June 10, 2020 at 11:56:16 PM EDT
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Roe, Laura <Laura.Roe@fda.hhs.gov>
Cc: Ross, Joseph <joseph.ross@yale.edu>
Subject: RE: Yale side of the Yale-Mayo CERSI diagnostic test work

I also wanted to follow-up on the information related to the type of specific tests. Below is a breakdown to date – I suspect Bill will share this tomorrow, if not FYI:

(b) (4)



From: Abernethy, Amy [<mailto:Amy.Abernethy@fda.hhs.gov>]
Sent: Wednesday, June 10, 2020 7:57 PM
To: Ross, Joseph; Franklin, Joseph; Roe, Laura
Cc: Ko, Albert; Grubaugh, Nathan; Wyllie, Anne; Krumholz, Harlan; Shah, Nilay D., Ph.D.; Tunis, Sean
Subject: [EXTERNAL] Re: Yale side of the Yale-Mayo CERSI diagnostic test work

Hi Joe,

Thank you so much for taking the time to write this out and introduce us to the different projects. Very interesting!

I am cc'ing Sean Tunis here; he helps to advance the Diagnostics Evidence Accelerator work and can tell you more.

There is also a new NCI announcement you should know about:

<https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-20-039.html>

RFA-CA-20-039: Emergency Awards: Research Projects in SARS-CoV-2 Serological Sciences (U01 Clinical Trial Optional)

July 22, 2020. All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

grants.nih.gov

Take care,

Amy

From: Ross, Joseph <joseph.ross@yale.edu>

Sent: Wednesday, June 10, 2020 5:31 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>

Cc: Ko, Albert <albert.ko@yale.edu>; Grubaugh, Nathan <nathan.grubaugh@yale.edu>; Wyllie, Anne <anne.wyllie@yale.edu>; Krumholz, Harlan <harlan.krumholz@yale.edu>; Shah, Nilay <shah.nilay@mayo.edu>

Subject: Yale side of the Yale-Mayo CERSI diagnostic test work

Amy, Joe and Laura,

Thanks for making the time to connect on Monday about the RUF Diagnostics Evidence Accelerator Workgroup and to learn more about what Yale folks are pursuing in this space that might be relevant to FDA.

I'm cc'ing the principal investigators I've connected to, who will be able to answer specific questions or would welcome the opportunity to present their work in greater detail to the RUF workgroup (they have been joining some of the meetings).

(b) (4)

Thanks again for your time on Monday. Happy to join a call to discuss further,
Joe

Joseph S. Ross, MD, MHS ([@jsross119](#))

Professor of Medicine and Public Health

Center for Outcomes Research and Evaluation ([CORE](#))

Director, Yale-Mayo Clinic Center of Excellence in Regulatory Science and Innovation ([CERSI](#))

Co-Director, Yale Open Data Access ([YODA](#)) Project

Co-Director, Yale Collaboration for Research Integrity and Transparency ([CRIT](#))

Co-Director, National Clinician Scholars Program ([NCSP](#)) at Yale

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 7/7/2020 1:01:12 PM
To: Wohlgemuth, Jay G [Jay.G.Wohlgemuth@questdiagnostics.com]
Subject: Accepted: Quest/FDA Call RE: Critical Next Steps
Location: (b) (6)
Start: 7/7/2020 5:00:00 PM
End: 7/7/2020 5:30:00 PM
Recurrence: (none)

From: Amy.Abernethy@fda.hhs.gov [Amy.Abernethy@fda.hhs.gov]
Sent: 7/21/2020 5:02:17 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
Subject: Re: quick primer?

Bingo - this is exactly the type of info that is needed. I imagine 5-7 slides that also include the details of how we calculate sensitivity and specificity and why it matters. Can we chat maybe this evening at 6 ET or tomorrow?

On Jul 21, 2020, at 4:55 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

Hi Amy –

This sounds like a great idea – and would be very helpful to discuss. The diagnostics area is moving very rapidly. We had created something very high level for the newer tests (attached). This does not fully address everything you had outlined below, but may be a starting point.

Count us in – either myself or one of my colleagues will be able to present on Thursday. I will let you know who it will be tomorrow AM.

Thanks for thinking of us.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 3:45 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] quick primer?

Hi Nilay,

I am sitting here thinking through the Therapeutics Lab Meeting on Thursday at 3pm. This is the big one - the original lab meeting that is always 150+ people. A former FDA Commissioner is leading us off. The topic is the implications of diagnostic testing performance on RWD/RWE analyses. I am wondering if you or someone from Mayo would be available to give a 5-10 min primer on diagnostics as a part of this meeting (different COVID tests, sensitivity, specificity, why these aren't each 100%). I can help you prepare and ensure it is fun. It would be great to showcase Mayo.

Thanks for thinking about it!

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

<Non routine COVID test options 07112020_table.docx>

From: Amy.Abernethy@fda.hhs.gov [Amy.Abernethy@fda.hhs.gov]
Sent: 7/21/2020 5:31:07 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
Subject: Re: quick primer?

Great! I will call you then

On Jul 21, 2020, at 5:26 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

I can chat at 6pmET tonight. Is there a best number to call you at? Alternatively, I will be on my cell (b)(6) and you can call me when you are available.

Thanks
Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 4:02 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] Re: quick primer?

Bingo - this is exactly the type of info that is needed. I imagine 5-7 slides that also include the details of how we calculate sensitivity and specificity and why it matters. Can we chat maybe this evening at 6 ET or tomorrow?

On Jul 21, 2020, at 4:55 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

Hi Amy –

This sounds like a great idea – and would be very helpful to discuss. The diagnostics area is moving very rapidly. We had created something very high level for the newer tests (attached). This does not fully address everything you had outlined below, but may be a starting point.

Count us in – either myself or one of my colleagues will be able to present on Thursday. I will let you know who it will be tomorrow AM.

Thanks for thinking of us.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 3:45 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] quick primer?

Hi Nilay,

I am sitting here thinking through the Therapeutics Lab Meeting on Thursday at 3pm. This is the big one - the original lab meeting that is always 150+ people. A former FDA Commissioner is leading us off. The topic is the implications of diagnostic testing performance on RWD/RWE analyses. I am wondering if you or someone from Mayo would be available to give a 5-10 min primer on diagnostics as a part of this meeting (different COVID tests, sensitivity, specificity, why these aren't each 100%). I can help you prepare and ensure it is fun. It would be great to showcase Mayo.

Thanks for thinking about it!

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)
Email: amy.abernethy@fda.hhs.gov

<Non routine COVID test options 07112020_table.docx>

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 6/4/2020 3:24:38 PM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; 'Shah, Nilay D., Ph.D.' [Shah.Nilay@mayo.edu]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
CC: Ross, Joseph [joseph.ross@yale.edu]
Subject: Discussion with Nilay (Mayo)
Attachments: Re: follow-up to the Accelerator call
Location: virtual
Start: 6/8/2020 10:00:00 AM
End: 6/8/2020 10:30:00 AM
Show Time As: Busy

Required Attendees: Abernethy, Amy; 'Shah, Nilay D., Ph.D.'; Franklin, Joseph; Roe, Laura; Nguyen, Mimi



Re: follow-up to
the Accelerator call

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

If you are a host, [click here](#) to view host information.

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

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 6/23/2020 11:23:59 AM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Davies, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; 'Shah, Nilay D., Ph.D.' [Shah.Nilay@mayo.edu]; 'Ross, Joseph' [joseph.ross@yale.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]

Subject: Yale-Mayo CERSI Dx Discussion
Attachments: Re: Yale side of the Yale-Mayo CERSI diagnostic test work
Location: virtual

Start: 6/26/2020 11:30:00 AM
End: 6/26/2020 12:00:00 PM
Show Time As: Busy

Required Attendees: Franklin, Joseph; Tunis, Sean; Roe, Laura; Davies, Kathleen; Valo, Gina; Shah, Nilay D., Ph.D.; Ross, Joseph; Nguyen, Mimi



Re: Yale side of
the Yale-Mayo C...

Please contact [@Nguyen, Mimi](#) to update this meeting.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

[Join meeting](#)

Join by phone

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

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [click here](#) to view host information.

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

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 7/17/2020 4:17:56 PM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; 'Brian S Anderson' [briananderson@mitre.org]; 'Sullivan, Mary Jo' [mjsullivan@mitre.org]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; 'carter.rickey@mayo.edu' [carter.rickey@mayo.edu]; 'Aarthi.G.Shenoy@MedStar.net' [Aarthi.G.Shenoy@MedStar.net]
CC: Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Shoaibi, Azadeh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4aa05659992541c5913af3802c2e8dba-AZS]; Wong, Hui-Lee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6eb0e876aa84bd3afe52eb7d0691a5c-HLW]; Francis X Campion [fcampion@mitre.org]; Andrea Noel [anoel@epic.com]; Stephen Dove [sdove@epic.com]; Eric Lindgren [elindgre@epic.com]; Ryan Luginbuhl [rluginbuhl@mitre.org]; Waheed,Rehan [Rehan.Waheed@cerner.com]; Kunze, Katie L., Ph.D., M.A. [Kunze.Katie@mayo.edu]; Janet Campbell [Janet@epic.com]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]
Subject: RWE Convalescent Plasma Discussion with MITRE
Attachments: Re: Pulling together the team for RWD Convalescent Plasma Research
Location: webex
Start: 7/23/2020 11:00:00 AM
End: 7/23/2020 11:30:00 AM
Show Time As: Busy

Required Attendees: Abernethy, Amy; Roe, Laura; 'Brian S Anderson'; 'Sullivan, Mary Jo'; Nguyen, Mimi; 'carter.rickey@mayo.edu'; 'Aarthi.G.Shenoy@MedStar.net'



Re: Pulling
together the tea...

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting
here.**

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Tap to join from a mobile device (attendees only)

+1-210-795-0506,,1998348282## US Toll

+1-877-465-7975,,1998348282## US Toll Free

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

If you are a host, [click here](#) to view host information.

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

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/16/2020 5:18:27 PM
To: Dr. Brian S Anderson [briananderson@mitre.org]
CC: Mary Jo Sullivan [mjsullivan@mitre.org]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Pulling together the team for RWD Convalescent Plasma Research

Hi - I think that it would be best to have a call with my team and Steve Anderson first, then we can do the deep dive review and get back to Peter. Adding Mimi to help organize from our side. (Mimi - please check with Laura re the list of attendees from the FDA side. We should do this Tues or Wed if possible.)

Thanks,

A

From: Dr. Brian S Anderson <briananderson@mitre.org>
Sent: Wednesday, July 15, 2020 6:35 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Mary Jo Sullivan <mjsullivan@mitre.org>
Subject: Pulling together the team for RWD Convalescent Plasma Research

Hi Amy –

Good chatting just now. Who may I ask MJ to work with on the FDA's end to pull together Peter, Steven and anyone else you'd like us to include in meeting with our team to dive into the initial findings, and the RWD methods and approach? MJ is going to coordinate on our end as well to find a time that works best for everyone.

Thanks,
brian

Brian S. Anderson, MD
Chief Digital Health Physician
The MITRE Corporation
Mobile: 781-640-9391

COVID-19 Healthcare Coalition

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/23/2020 12:37:46 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
CC: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]
Subject: Re: Quick question

These are excellent! Thank you!

@Laura - can you send them to RUF?

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Thursday, July 23, 2020 12:24 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: RE: Quick question

Hi Amy –

Attached are the updated slides that incorporate your comments. Please let us know if there are any additional suggestions or changes.

Thanks again – we are looking forward to the discussion later today.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Thursday, July 23, 2020 8:46 AM
To: Shah, Nilay D., Ph.D.
Cc: Morice, William G. II, M.D., Ph.D.; Roe, Laura
Subject: [EXTERNAL] Re: Quick question

Thank you! Please send to me first.

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Thursday, July 23, 2020 9:45 AM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: RE: Quick question

Hi Amy –

Thanks for this great feedback – we will incorporate the changes and send an updated set of slides late morning. Should we send it to Amar and copy you/Laura or would you prefer we send it to you first? We will remove slide 8 and make sure to keep it at 7 minutes.

Thanks again
Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Thursday, July 23, 2020 6:45 AM
To: Shah, Nilay D., Ph.D.

Cc: Morice, William G. II, M.D., Ph.D.; Roe, Laura

Subject: [EXTERNAL] Re: Quick question

Hi Nilay, Hi Bill,

First of all, thank you! This is great and thank you for working on it. A couple of quick suggestions...

1. Can you start off with a slide on test performance characteristics, how they are calculated (i.e., sensitivity and specificity), and what that means in terms of false negative and false positive rates? I just want to make sure that the audience understands this and has it in their head.
 2. Can you add information with example sensitivities and specificities of the various kinds of tests (ranges/approximations are fine)? You don't need to do it for all of the types of tests, but I just want the audience to see how variable it can be.
 3. For the slides currently numbered 2, 5 and 6:
 - a. The dark text on the colorful background probably won't show up well. Can you change the text to white - or modify the background? (I really like the colors; shifting to white text might be easier.)
 - b. The slides are wordy and we don't have much time. If you want to keep the words, that is fine. Just hit the highlights.
 - c. The key message should be that the tests have different purposes and different performance characteristics; you need to know the test in order to make sense of the rest of the information about the patient.
 4. For the slide currently numbered as Slide 7 - it is great. I think that you can briefly just signal that newer tests are coming. The key message should be that accuracy of diagnostic information available should be improving with time, so we need to keep this shifting landscape of sensitivity and specificity in our heads as we think about analyses with real-world datasets that incorporate diagnostic tests.
 5. For the slide currently numbered as Slide 8, it is great but we are going to get into this later in the hour. Is it OK to cut this slide?
 6. Because it is going to be a packed hour, we need to do this quickly - so 7 min total. That being said, it is so important and critical to the whole discussion - it frames everything. I am very appreciative of your doing this - and also very excited to see how it all comes together.
- Let me know if you want me to call and explain any of my comments.

Thank you!

Amy

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>

Sent: Wednesday, July 22, 2020 11:40 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>

Subject: RE: Quick question

Hi Amy –

I have attached a draft presentation for tomorrow. Would appreciate your thoughts on this.

Thanks

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]

Sent: Wednesday, July 22, 2020 3:27 PM

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000445

To: Shah, Nilay D., Ph.D.

Subject: [EXTERNAL] Re: Quick question

Awesome - I am preparing the agenda now!

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>

Sent: Wednesday, July 22, 2020 4:25 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Subject: RE: Quick question

It will be both me and Bill Morice – we will make sure to do it efficiently.

Will send you the slides this evening.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]

Sent: Wednesday, July 22, 2020 3:25 PM

To: Shah, Nilay D., Ph.D.

Subject: [EXTERNAL] Quick question

Hi - I am trying to prepare the agenda for the email to send out re Lab Meeting. Will you be presenting or will it be someone else from Mayo?

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)

Email: amy.abernethy@fda.hhs.gov

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/23/2020 12:43:23 PM
To: Kaufman, Harvey W [Harvey.W.Kaufman@questdiagnostics.com]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]
Subject: Re: Therapeutics EA

Thank you, Harvey! This is terrific!

If you are on the line, I will plan to call on you for one of these questions, as long as we stay on schedule (sometimes hard!)

From: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Sent: Thursday, July 23, 2020 12:40 PM
To: Roe, Laura <Laura.Roe@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: RE: Therapeutics EA

Got it.

Harvey W. Kaufman, MD, MBA, FCAP, Senior Medical Director, Medical Informatics
Quest Diagnostics | Action from Insight | 15 Pleasant Street, Needham, MA 02492 USA
| phone 201.213.8452 | Harvey.W.Kaufman@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/

For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Roe, Laura <Laura.Roe@fda.hhs.gov>
Sent: Thursday, July 23, 2020 12:19 PM
To: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: RE: Therapeutics EA

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.

Hi Harvey,

Great to hear from you, the official agenda (pasted below) is set. However, Amy would like to be able to engage you in the conversation and have you as an active discussant into this critical topic. She will likely put some specific questions to you, if you are able to be in the meeting. The details for joining are included below, the meeting is at 12 noon PST / 3p EST.

If I can help with anything, please let feel free to text/call me directly at (b)(6)

Thanks,
Laura

All,

You read about it in the news - tests, tests, tests! There are many questions regarding COVID-19 diagnostic tests. Some of the issues have implications for real-world data research and clinical trials as well. Come to the Thursday Therapeutics Evidence Accelerator at 3pm ET to explore:

The implications of COVID-19 diagnostic testing accuracy (inaccuracy?) in COVID-19 research and how to manage it

Our discussion-stimulators include:

- COVID-19 Diagnostics, a quick primer; Bill Morice & Nilay Shah, Mayo Clinic
- Linking the Test, to the Results, to the Clinical Dataset; Ed Michael, Lionbird
- Observational research methods to address in RWE studies; Sebastian Schneeweiss, Harvard Medical School
- Implications for clinical trial patient selection; Rob Califf, Alphabet/Verily
- Thinking about this with an FDA lens; Bob Ball, FDA/CDER

Join us! Information on how to join is below.

Regards,
Amar

Amar Bhat, PhD
Reagan-Udall Foundation for the FDA
M: 202-415-0385

From: abhat@reaganudall.org

When: 3:00 PM - 4:00 PM July 23, 2020

Subject: COVID-19 Evidence Accelerator Collaborative Meeting

Location:

<https://reaganudallfoundationfortheFDA.my.webex.com/reaganudallfoundationfortheFDA.my/j.php?MTID=m1872a2db3a22fc817d0bac0949709218>

All,

Thank you very much for your continued interest in the weekly Lab meetings of the COVID-19 Evidence Accelerator, an initiative of the Reagan-Udall Foundation for the FDA and Friends of Cancer Research. We have heard from a large number of you confirming your interest in the activities of the Accelerator and your organization's willingness to be listed as a participant in future communications. If you haven't already responded, please feel free to send me a note.

We are keeping with the same time of 3:00 pm ET on Thursday, April 30. This will be a recurring meeting time. We will be developing the agenda over the course of the week, but anticipate 2-3 presentations this Thursday. If you have suggestions for presenters, please forward them to Carla (crodriguezwatson@reaganudall.org) and/or Jeff (jallen@focr.org).

Please be sure to RSVP and refer any interested colleagues to us. We will forward the invite as long as space allows.

Meeting link:

<https://reaganudallfoundationfortheFDA.my.webex.com/reaganudallfoundationfortheFDA.my/j.php?MTID=m1872a2db3a22fc817d0bac0949709218>

Meeting number: (b)(6)

Password: Accelerator2020 (b)(6) from phones and video systems)

If you are experiencing issues dialing in through the +1-510-338-9438 number, additional call in numbers are listed below:

+1-617-315-0704; +1-312-535-8110; +1-469-210-7159; +1-720-650-7664; +1-904-900-2303; +1-213-306-3065; +1-646-992-2010; +1-206-207-1700; +1-202-860-2110; +1-602-666-0783

From: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Sent: Thursday, July 23, 2020 12:01 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: RE: Therapeutics EA

YES!!!

Harvey W. Kaufman, MD, MBA, FCAP, Senior Medical Director, Medical Informatics
Quest Diagnostics | Action from Insight | 15 Pleasant Street, Needham, MA 02492 USA
| phone 201.213.8452 | Harvey.W.Kaufman@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/
For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Tuesday, July 21, 2020 6:32 PM
To: Kaufman, Harvey W <Harvey.W.Kaufman@questdiagnostics.com>
Cc: Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: Re: Therapeutics EA

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.

Hi Harvey - Checking in one more time. I am just finalizing the plans for Thursday. Let me know if you want to talk for 5 min and I will update you as to the plans. It will be a fun meeting!
Thanks!
Amt

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Tuesday, July 21, 2020 1:17 PM
To: harvey.w.kaufman@questdiagnostics.com <harvey.w.kaufman@questdiagnostics.com>
Cc: Roe, Laura <Laura.Roe@fda.hhs.gov>
Subject: Re: Therapeutics EA

Hi Harvey - I wanted to check in with you about this. It is turning into a really interesting and exciting meeting. A former FDA Commissioner is going to open the meeting and frame the topic, and there will be 2-3 other presentations to complement your comments. Please let me know if you want to chat about the plan.

Take care,

Amy

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Monday, July 20, 2020 8:09 PM
To: harvey.w.kaufman@questdiagnostics.com <harvey.w.kaufman@questdiagnostics.com>

Cc: Roe, Laura <Laura.Roe@fda.hhs.gov>

Subject: Therapeutics EA

Hi Harvey,

Your talk was so great during the Diagnostics Evidence Accelerator meeting last Thursday, we have another request!

Would you be willing to speak during the Therapeutics Evidence Accelerator Lab Meeting between 3-4pm on Thursday of this week. Similar topic... It would be good to talk about why the performance of COVID-19 diagnostic tests matters to real-world analyses writ large and how to think about the issue. I will help you shape the talk.

The Therapeutics Evidence Accelerator Lab Meeting was the original EA Lab Meeting and has a bit of a larger audience. It is usually a very interesting meeting and a lot of fun. It would be great to have you.

Thank you for considering it!

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)
Email: amy.abernethy@fda.hhs.gov

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/23/2020 12:44:22 PM
To: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]
Subject: Re: (b)(6)

BTW, actually, I do think it should be a focus of this group. We are looking at something similar for therapeutics - why not for diagnostics.

Adding Laura to help me put it on the list...

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Thursday, July 23, 2020 12:39 PM
To: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Subject: Re: (b)(6)

I loved it!

And I think that you are spot on. I am thinking about how we deal with this issue. It forces me to think about how we might build the data connections to pull it off. Would be worth talking about it more.

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Sent: Thursday, July 23, 2020 12:37 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: (b)(6)

(b)(6) Just wanted to get the point about supply chain in. (b)(6)
(b)(6)

William G. Morice, M.D., Ph.D.
Chair, Department of Laboratory Medicine and Pathology
Professor of Laboratory Medicine and Pathology
Mayo Clinic, Rochester, MN 55905

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 7/21/2020 5:31:11 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
Subject: Re: quick primer?

Great! I will call you then

On Jul 21, 2020, at 5:26 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

I can chat at 6pmET tonight. Is there a best number to call you at? Alternatively, I will be on my cell (b)(6) and you can call me when you are available.

Thanks
Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 4:02 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] Re: quick primer?

Bingo - this is exactly the type of info that is needed. I imagine 5-7 slides that also include the details of how we calculate sensitivity and specificity and why it matters. Can we chat maybe this evening at 6 ET or tomorrow?

On Jul 21, 2020, at 4:55 PM, Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu> wrote:

Hi Amy –

This sounds like a great idea – and would be very helpful to discuss. The diagnostics area is moving very rapidly. We had created something very high level for the newer tests (attached). This does not fully address everything you had outlined below, but may be a starting point.

Count us in – either myself or one of my colleagues will be able to present on Thursday. I will let you know who it will be tomorrow AM.

Thanks for thinking of us.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Tuesday, July 21, 2020 3:45 PM
To: Shah, Nilay D., Ph.D.
Subject: [EXTERNAL] quick primer?

Hi Nilay,

I am sitting here thinking through the Therapeutics Lab Meeting on Thursday at 3pm. This is the big one - the original lab meeting that is always 150+ people. A former FDA Commissioner is leading us off. The topic is the implications of diagnostic testing performance on RWD/RWE analyses. I am wondering if you or someone from Mayo would be available to give a 5-10 min primer on diagnostics as a part of this meeting (different COVID tests, sensitivity, specificity, why these aren't each 100%). I can help you prepare and ensure it is fun. It would be great to showcase Mayo.

Thanks for thinking about it!

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: (b)(6)
Email: amy.abernethy@fda.hhs.gov

<Non routine COVID test options 07112020_table.docx>

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 7/23/2020 1:20:08 PM
To: Ross, Joseph [joseph.ross@yale.edu]; Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Davies, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Schulz, Wade [wade.schulz@yale.edu]
CC: Lueck, Heather D. [Lueck.Heather@mayo.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Yale-Mayo COVID-19 Dx Discussion

Terrific. Thank you, Joe. We are looking forward to the conversation tomorrow.

From: Ross, Joseph <joseph.ross@yale.edu>
Sent: Thursday, July 23, 2020 12:15 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>; Davies, Kathleen <Kathleen.Davies@fda.hhs.gov>; Schulz, Wade <wade.schulz@yale.edu>
Cc: Lueck, Heather D. <Lueck.Heather@mayo.edu>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>
Subject: RE: Yale-Mayo COVID-19 Dx Discussion

Amy and Sean,

I'm looking forward to our call tomorrow to discuss the Project 1 idea.

I have forwarded the meeting invite to Wade Schulz, a close colleague of mine at Yale in Lab Medicine, who can better address the feasibility of the project using real-world data. In addition, I am attaching a short grant proposal that he just received funding for, that aligns well with your goals to better understand the accuracy of diagnostic and serology tests.

Best, Joe

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

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Tuesday, July 14, 2020 11:10 AM
To: Abernethy, Amy; Shah, Nilay D., Ph.D.; Ross, Joseph; Tunis, Sean; Roe, Laura; Franklin, Joseph; Valo, Gina; Davies, Kathleen
Cc: Lueck, Heather D.; Nguyen, Mimi
Subject: Yale-Mayo COVID-19 Dx Discussion
When: Friday, July 24, 2020 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: webex

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Tap to join from a mobile device (attendees only)

+1-210-795-0506,,1992993976## US Toll

+1-877-465-7975,,1992993976## US Toll Free

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [click here](#) to view host information.

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

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/11/2020 11:17:24 PM
To: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; 'abhat@reaganudall.org' [abhat@reaganudall.org]
CC: Jenkinson, William G. (Garrett), Ph.D., M.S. [Jenkinson.William@mayo.edu]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]
Subject: Re: Diagnostic Evidence Accelerator today.

Hi Bill,

Thank you for your note. We are really interested in what you have to say and will appreciate the opportunity to pull you in for future conversations.

Looking forward,

Amy

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Sent: Thursday, June 11, 2020 1:51 PM
To: 'abhat@reaganudall.org' <abhat@reaganudall.org>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Jenkinson, William G. (Garrett), Ph.D., M.S. <Jenkinson.William@mayo.edu>
Subject: Diagnostic Evidence Accelerator today.

Amar and Amy

My apologies for missing the meeting today. I was prepared to go, but the meeting wasn't on my Outlook calendar and I neglected to account for the time difference between EST and CST. If I would have done so, I would have realized I had a conflict.

I hope that Dr. Jenkinson from Mayo was able to join as he has been leading our COVID data innovation group. If there is something you need in follow up from me or Mayo please let me know.

Again, my sincere apologies
Bill

William G. Morice, M.D., Ph.D.
Chair, Department of Laboratory Medicine and Pathology
Professor of Laboratory Medicine and Pathology
Mayo Clinic, Rochester, MN 55905

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 6/10/2020 7:23:27 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
CC: Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]
Subject: Re: Mayo participation in the Diagnostic Evidence Accelerator work group

Hi - Terrific! Thanks for the follow up, Nilay and Sean. Have a great night.

Amy

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Wednesday, June 10, 2020 6:13 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Tunis, Sean <Sean.Tunis@fda.hhs.gov>
Subject: RE: Mayo participation in the Diagnostic Evidence Accelerator work group

Hi Amy (and Sean) –

Bill did confirm that he is planning on presenting at the Accelerator work group tomorrow. Garrett Jenkinson will co-present with him.

Thanks
Nilay

From: Shah, Nilay D., Ph.D.
Sent: Wednesday, June 10, 2020 3:39 PM
To: 'Abernethy, Amy'
Cc: Tunis, Sean
Subject: RE: Mayo participation in the Diagnostic Evidence Accelerator work group

I believe Bill or one of our colleagues from lab medicine are planning presenting based on the agenda that was sent out. I will double check and confirm shortly.

Nilay

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Wednesday, June 10, 2020 3:26 PM
To: Shah, Nilay D., Ph.D.
Cc: Tunis, Sean
Subject: [EXTERNAL] Fw: Mayo participation in the Diagnostic Evidence Accelerator work group

Hi Nilay,

Please see the email below. We didn't hear back from Bill. Do you have advice as to the best steps?

Thanks,

Amy

From: Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Sent: Monday, June 8, 2020 9:16 PM

To: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Beck, Scott A. <beck.scott@mayo.edu>; Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>; Jenkinson, William G. (Garrett), Ph.D., M.S. <Jenkinson.William@mayo.edu>; Rinaldo, Piero, M.D., Ph.D. <Rinaldo@mayo.edu>; Bennett, Shannon A., M.S. <Bennett.Shannon@mayo.edu>; Hanson, Curtis A., M.D. <cahanson@mayo.edu>; Carla Rodriguez <crodriguezwatson@reaganudall.org>; Susan Winckler <swinckler@reaganudall.org>; Amar Bhat <abhat@reaganudall.org>; Roe, Laura <Laura.Roe@fda.hhs.gov>

Subject: RE: Mayo participation in the Diagnostic Evidence Accelerator work group

Bill and Mayo colleagues

Thanks for your help so far with the COVID-19 dx-EA effort. It is helpful for us to learn about the rich data resources available that may help to answer questions about COVID-19 diagnostics.

For this Thursday's meeting, we were wondering if someone from the Mayo team would be willing to help get a discussion going by making a few minutes of opening comments. The question we would like you to address is: "What will be necessary to make it possible to generate useful evidence about COVID-19 diagnostic test performance using RWD?"

I am not quite sure the phrasing of the question is ideal, but you can feel free to tweak the question if that helps you offer more useful comments. The overall intent of this discussion is to get people like you who really know RWD to provide insights about what it will take to make it helpful in answering questions about test performance/accuracy/etc.

Happy to discuss by phone.

Thanks!

Sean

Sean Tunis MD, MSc
Senior Advisor, FDA/OC/OCPP
sean.tunis@fda.hhs.gov
(410) 963-8876

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>

Sent: Sunday, May 31, 2020 11:18 PM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>

Cc: Beck, Scott A. <beck.scott@mayo.edu>; Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>; Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>; Jenkinson, William G. (Garrett), Ph.D., M.S. <Jenkinson.William@mayo.edu>; Rinaldo, Piero, M.D., Ph.D. <Rinaldo@mayo.edu>; Bennett, Shannon A., M.S. <Bennett.Shannon@mayo.edu>; Hanson, Curtis A., M.D. <cahanson@mayo.edu>

Subject: Mayo participation in the Diagnostic Evidence Accelerator work group

Hi Amy and Sean

Thanks again for the invitation to the Diagnostic Evidence Accelerator Work Group. I was able to participate in the meeting last week and I think this will be an important effort and I really want Mayo Clinic laboratory medicine to participate. There are 4 individuals who are better suited than I to represent Mayo Lab Medicine, these are Dr. Piero Rinaldo (creator of the CLIR program), Dr. Garret Jenkinson, Shannon Bennett, and Dr. Curt Hanson. They are cc'ed.

Would it be possible for this group to be included and get an invite from the group at the Reagan Udall Foundation?

Thanks!

Bill Mo

William G. Morice II, M.D., Ph.D.

Chair and Professor, Department of Laboratory Medicine and Pathology, Mayo Clinic

President, Mayo Clinic Laboratories

Rochester, Minnesota, USA

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 5/19/2020 9:13:05 AM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Anderson, Brian S. [briananderson@mitre.org]; 'Halamka, John' [halamka.john@mayo.edu]
CC: Mary Jo Sullivan [mjsullivan@mitre.org]; 'Keane, Jean M.' [jkeane@mayo.edu]; Heather E Hawley [hhawley@mitre.org]
Subject: MITRE-Mayo Discussion
Attachments: Re: Recap and Next Steps: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases
Location: virtual
Start: 5/29/2020 8:00:00 AM
End: 5/29/2020 9:00:00 AM
Show Time As: Busy

Required Attendees: Abernethy, Amy; Franklin, Joseph; Roe, Laura; Robb, Melissa; Nguyen, Mimi; Anderson, Brian S.; 'Halamka, John'

Please contact @Nguyen, Mimi to update/change this invite.



Re: Recap and
Next Steps: Con...

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [go here](#) to view host information.

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

From: Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Sent: 5/19/2020 10:54:23 AM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]; Leon, Patrick J. (Pat) [Leon.Patrick@mayo.edu]; Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; Beck, Scott A. [beck.scott@mayo.edu]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Halamka, John D., M.D., M.S. [Halamka.John@mayo.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: FDA-Mayo Clinic COVID 19 Discussion
Attachments: Re: intro - Mayo Clinic Labs, FDA
Location: virtual
Start: 5/26/2020 4:00:00 PM
End: 5/26/2020 4:30:00 PM
Show Time As: Busy

Required Attendees: Franklin, Joseph; Tunis, Sean; Canos, Daniel; Leon, Patrick J. (Pat); Morice, William G. II, M.D., Ph.D.; Beck, Scott A.; Roe, Laura; Halamka, John D., M.D., M.S.; Nguyen, Mimi

Update: We had to shift this meeting to 4pm due to an urgent call at 4:30pm ET.



Re: intro - Mayo
Clinic Labs, FDA

Please contact @Nguyen, Mimi to update this invite.

-- Do not delete or change any of the following text. --

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

Meeting number (access code): (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone

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

AMERICAN
OVERSIGHT

HHS-FDA-20-0571-B-000462

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [go here](#) to view host information.

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

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/13/2020 11:51:21 AM
To: Carolyn Magill [carolyn.magill@aetion.com]; Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]
CC: Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Elizabeth DeMatteis [liz.dematteis@aetion.com]; Leon, Patrick J. (Pat) [Leon.Patrick@mayo.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Jeremy Rassen [jeremy.rassen@aetion.com]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]
Subject: Re: intro - Mayo Clinic Labs, FDA

Thank you, Carolyn

Hi Bill,

It would be great to talk to you about about what Mayo Clinic's approach. We are very interested in learning more.

Adding Mimi here who can help with scheduling; Sean should be on the call, with Joe and Daniel as optional.

Please take care,

Amy

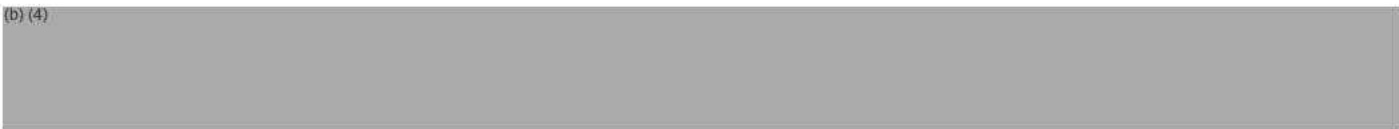
From: Carolyn Magill <carolyn.magill@aetion.com>
Sent: Wednesday, May 13, 2020 11:06 AM
To: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Elizabeth DeMatteis <liz.dematteis@aetion.com>; Leon, Patrick J. (Pat) <Leon.Patrick@mayo.edu>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Jeremy Rassen <jeremy.rassen@aetion.com>
Subject: intro - Mayo Clinic Labs, FDA

Dear Bill and Amy (Dr. Morice, Dr. Abernethy),

It's my pleasure to introduce you and your teams.

As we've talked about, Mayo Clinic Labs is supporting national testing related to covid-19, both molecular and serologic.

(b) (4)

A large rectangular area of the document is redacted, indicated by a grey box and the text "(b) (4)" in the top left corner.

We'll continue to explore with them how their data can inform our understanding of ordering patterns, linkages to outcomes, reinfection rates, etc. In the meantime, thought it would be helpful for you to connect directly.

Enjoy connecting,
Carolyn

Carolyn Magill
Chief Executive Officer
+1 646 279 3735
Aetion | aetion.com

Visit the [Evidence Hub](#), where we share our thinking—and invite yours—about one of the most powerful levers we have to fix health care: data.

This message and any included attachments are confidential. If you are not the intended recipient, please reply to the sender that you received the message in error and delete it without further distribution.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/18/2020 3:10:28 PM
To: Morice, William G. II, M.D., Ph.D. [morice.william@mayo.edu]; Carolyn Magill [carolyn.magill@aetion.com]
CC: Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Elizabeth DeMatteis [liz.dematteis@aetion.com]; Leon, Patrick J. (Pat) [Leon.Patrick@mayo.edu]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Jeremy Rassen [jeremy.rassen@aetion.com]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Canos, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1270299954af4f7bbfe8701d50aba1cd-Daniel.Cano]; Beck, Scott A. [beck.scott@mayo.edu]; Halamka, John D., M.D., M.S. [Halamka.John@mayo.edu]
Subject: Re: intro - Mayo Clinic Labs, FDA

Hi - I am just checking if we have been able to get this scheduled. We are looking forward to the next steps, especially as we start to consider questions about RWD/RWE and diagnostics. It will be great to include John as well.

Thanks and please take care,

Amy

From: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>
Sent: Wednesday, May 13, 2020 3:02 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Carolyn Magill <carolyn.magill@aetion.com>
Cc: Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Elizabeth DeMatteis <liz.dematteis@aetion.com>; Leon, Patrick J. (Pat) <Leon.Patrick@mayo.edu>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Jeremy Rassen <jeremy.rassen@aetion.com>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Canos, Daniel <Daniel.Canos@fda.hhs.gov>; Beck, Scott A. <beck.scott@mayo.edu>; Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>
Subject: RE: intro - Mayo Clinic Labs, FDA

Carolyn

Thank you for making the connection. Dr. Abernethy, nice to "e-meet" you. I will work with Pat and my administrative assistant JoAnn to get a meeting arranged. I think it would be good to have my colleague Scott Beck included. We may also want to ask Dr. John Halamka to join, as he is leading Mayo Clinic's efforts in data and platform analytics, but that will depend on his availability. Both are cc'ed.

Look forward to connect. Also to clarify, (b) (4)

[REDACTED]

[REDACTED]

Look forward to our discussion.

Bill Morice

William G. Morice II, M.D., Ph.D.
Professor and Chair, Department of Laboratory Medicine & Pathology
Mayo Clinic

President, Mayo Clinic Laboratories
Rochester, MN

From: Abernethy, Amy [mailto:Amy.Abernethy@fda.hhs.gov]
Sent: Wednesday, May 13, 2020 10:51 AM
To: Carolyn Magill; Morice, William G. II, M.D., Ph.D.
Cc: Franklin, Joseph; Elizabeth DeMatteis; Leon, Patrick J. (Pat); Nguyen, Mimi; Jeremy Rassen; Tunis, Sean; Nguyen, Mimi; Canos, Daniel
Subject: [EXTERNAL] Re: intro - Mayo Clinic Labs, FDA

Thank you, Carolyn

Hi Bill,

It would be great to talk to you about about what Mayo Clinic's approach. We are very interested in learning more.

Adding Mimi here who can help with scheduling; Sean should be on the call, with Joe and Daniel as optional.

Please take care,

Amy

From: Carolyn Magill <carolyn.magill@aetion.com>
Sent: Wednesday, May 13, 2020 11:06 AM
To: Morice, William G. II, M.D., Ph.D. <morice.william@mayo.edu>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Elizabeth DeMatteis <liz.dematteis@aetion.com>; Leon, Patrick J. (Pat) <Leon.Patrick@mayo.edu>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Jeremy Rassen <jeremy.rassen@aetion.com>
Subject: intro - Mayo Clinic Labs, FDA

Dear Bill and Amy (Dr. Morice, Dr. Abernethy),

It's my pleasure to introduce you and your teams.

As we've talked about, Mayo Clinic Labs is supporting national testing related to covid-19, both molecular and serologic.

(b) (4)

We'll continue to explore with them how their data can inform our understanding of ordering patterns, linkages to outcomes, reinfection rates, etc. In the meantime, thought it would be helpful for you to connect directly.

Enjoy connecting,
Carolyn

Carolyn Magill
Chief Executive Officer
+1 646 279 3735
Aetion | aetion.com

Visit the [Evidence Hub](#), where we share our thinking—and invite yours—about one of the most powerful levers we have to fix health care: data.

This message and any included attachments are confidential. If you are not the intended recipient, please reply to the sender that you received the message in error and delete it without further distribution.

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/17/2020 8:07:06 PM
To: Dr. Brian S Anderson [briananderson@mitre.org]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; halamka.john@mayo.edu
Subject: Re: Recap and Next Steps: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases

Hi Brian,

Thank you so much. This is great and very much in line with our interests with respect to understanding the impact of convalescent plasma. I have definitely been tracking along with what is happening.

1. Do you have a copy of the data model used for the REDCAP database mentioned in the paper? I am mainly interested in the CDEs.
2. Is there a current plan for a natural history benchmark?

Perhaps we can catch up by phone; Mimi is cc'ed to help get it scheduled. It would be great to include John when he is available; I cc'ed him here to keep things moving (Hi John!).

Thanks,

Amy

From: Dr. Brian S Anderson <briananderson@mitre.org>
Sent: Sunday, May 17, 2020 8:26 AM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: Re: Recap and Next Steps: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases

Hi Amy,

I wanted to also follow-up on our conversation and your request for more information on what we were doing to support the Convalescent Plasma research in particular. After we spoke, my team and I met with Steven Anderson (CBER) last week. On our call with Steven I shared that our team would be working closely with the Mayo Clinic Research team, running the National Expanded Access Treatment Protocol. We've also been working closely with the lead researchers from the National COVID-19 Convalescent Plasma Project.

Working with researchers from both organizations, MITRE is bringing together various stakeholders across EHR vendors (e.g. (b) (4) etc.) and Data Analytics companies (e.g. (b) (4) etc.) to partner with the enrolling health system sites in a federated analytics approach to create cohort comparator groups based on the RWD within the health systems.

These critical cohort comparators will look to provide better clarity in terms of any efficacy benefit for convalescent plasma. (b) (4)

I'm sure you've already seen the pre-publication release from the Mayo Clinic on the Safety Indicators. Re-attaching to this email in case you haven't seen it yet. (b) (4)

Let me know if you'd like to follow-up more on Convalescent Plasma. John Halamka and I are working very closely together with the leadership on the Convalescent Plasma Projects.

Hope you are doing well!

brian

From: "Williams, Erin D." <erinw@mitre.org>

Date: Tuesday, May 12, 2020 at 11:59 AM

To: "Abernethy, Amy" <amy.abernethy@fda.hhs.gov>

Cc: "Robb, Melissa" <Melissa.Robb@fda.hhs.gov>, "Nguyen, Mimi" <Mimi.Nguyen@fda.hhs.gov>, "Anderson, Brian S." <briananderson@mitre.org>, "Schnitzer, Jay J" <jschnitzer@mitre.org>, "Laura.Roe@fda.hhs.gov" <Laura.Roe@fda.hhs.gov>, "Hawley, Heather E." <hhawley@mitre.org>

Subject: Recap and Next Steps: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases

Dear Amy,

Thank you for carving out time for our conversation this morning. As promised, we will link arms to launch timely an elegant approach to what is required on behalf of the nation: *(Please correct/amend liberally)*

(b) (4)

We value your input to ensure our aligned understanding. Heather and I will follow up with OAGS to close the loop on a rapid launch. As promised, we will also send you a copy of the (b) (4), and Brian will follow up with an update on convalescent plasma.

We look forward to what comes next.

Best Regards,
Erin

Erin D. Williams, JD

Executive Director, Biomedical Innovation
Health and Human Services Portfolio Director
The Health Federally Funded Research and Development Center
Operated by The MITRE Corporation
O: 703-983-5107; M: 703-462-0369
erinw@mitre.org

Administrative Assistant:

Nawina Matshona
O: 703-983-7121; Fax: 703-983-2852
nmatshona@mitre.org

MITRE

The MITRE Corporation is a not-for-profit organization that operates federally funded research and development centers on behalf of the United States government.

From: briananderson@mitre.org

When: 9:30 AM - 10:00 AM May 12, 2020

Subject: Conversation w/ MITRE//FDA around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases

Location: <https://mitre.zoomgov.com/j/1607184557?pwd=eVV1SSt6bG42bUJ3d3VNVmIJVkJN2dz09>

From: "Anderson, Brian S." <briananderson@mitre.org>

Date: Monday, May 11, 2020 at 4:20 PM

To: "Abernethy, Amy" <amy.abernethy@fda.hhs.gov>, "Sullivan, Mary Jo" <mjsullivan@mitre.org>, Heather Hawley <hhawley@mitre.org>

Cc: "Schnitzer, Jay J" <jschnitzer@mitre.org>, "Williams, Erin D." <erinw@mitre.org>, "Roe, Laura" <Laura.Roe@fda.hhs.gov>, "Nguyen, Mimi" <Mimi.Nguyen@fda.hhs.gov>, "Robb, Melissa" <Melissa.Robb@fda.hhs.gov>

Subject: Re: [EXT] Re: Time for a quick chat?

Hi Amy,
Wonderful!

We can make 9:30am ET work. I'm adding @Sullivan, Mary Jo who can help pull together the critical calendars on our end, including Erin, Jay and @Hawley, Heather E..

Thanks again Amy and look forward to chatting!

brian

From: "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>

Date: Monday, May 11, 2020 at 1:18 PM

To: "Anderson, Brian S." <briananderson@mitre.org>

Cc: "Schnitzer, Jay J" <jschnitzer@mitre.org>, "Williams, Erin D." <erinw@mitre.org>, "Roe, Laura" <Laura.Roe@fda.hhs.gov>, "Nguyen, Mimi" <Mimi.Nguyen@fda.hhs.gov>, "Robb, Melissa"

<Melissa.Robb@fda.hhs.gov>

Subject: [EXT] Re: Time for a quick chat?

Hi Brian,

Terrific! I look forward to talking. Would tomorrow morning around 9:30am work for you? @Mimi is cc'ed here and can help us get organized asap.

Thanks!

Amy

From: Anderson, Brian S. <briananderson@mitre.org>

Sent: Monday, May 11, 2020 11:36 AM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Schnitzer, Jay J <jschnitzer@mitre.org>; Williams, Erin D. <erinw@mitre.org>

Subject: Time for a quick chat?

Hi Amy –

I heard from some of our colleagues inside MITRE that there were some exciting conversations around leveraging RWD and a widely adopted open data model for COVID-19 data sets and specific use-cases.

Do you have 15 minutes today (or tomorrow) for a quick chat about some possible next steps?

Would love to make sure we're on the same page as your vision for this.

Best,

Brian

Brian S. Anderson, MD

Chief Digital Health Physician

The MITRE Corporation

Mobile: 781-640-9391

COVID-19 Healthcare Coalition

Mary Jo Sullivan is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

(b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

One tap mobile

(b)(6) US (San Jose)

(b)(6) US (New York)

Dial by your location

(b)(6) US (San Jose)

(b)(6) US (New York)

Meeting ID: (b)(6)

Find your local number: (b)(6)

Join by SIP

(b)(6)

Join by H.323

(b)(6)

(US West)

(b)(6)

(US East)

Meeting ID: (b)(6)

Password: (b)(6)

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/17/2020 7:03:05 AM
To: Jay Shendure [shendure@uw.edu]
CC: Carla Rodriguez [crodriguezwatson@reaganudall.org]; Cowgill, Karen [n-kcowgill@kingcounty.gov]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; esigal@focr.org; jallen@focr.org; Susan Winckler [swinckler@reaganudall.org]; Dewan, Puneet [n-pdewan@kingcounty.gov]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: SCAN

Jay and Karen,

Thank you very much for taking the time to talk to the group about your work at SCAN. It was really helpful. The Reagan Udall / Friends of Cancer Research team will be following up, as the Evidence Accelerator work is expanded in the diagnostics space.

Kind regards,
Amy

From: Jay Shendure <shendure@uw.edu>
Sent: Friday, May 15, 2020 8:17 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Carla Rodriguez <crodriguezwatson@reaganudall.org>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; esigal@focr.org <esigal@focr.org>; jallen@focr.org <jallen@focr.org>; Susan Winckler <swinckler@reaganudall.org>; Dewan, Puneet <n-pdewan@kingcounty.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>
Subject: Re: SCAN

Dear Amy & all,

On behalf of myself and Karen, it was very nice to speak with you earlier this afternoon. I am attaching here some of the documents that came up on the call, e.g. our questionnaires, as well as technical and situation reports from the analysis of the resulting data. Happy to answer any questions about them.

We look forward to seeing the questions that the Diagnostics Accelerator is prioritizing when they are available.

Best regards,

Jay (& Karen)

Jay Shendure, MD, PhD
Investigator, Howard Hughes Medical Institute
Director, Allen Discovery Center for Lineage Tracing
Director, Brotman Baty Institute for Precision Medicine
Professor, Genome Sciences, University of Washington

On Tue, May 12, 2020 at 6:23 PM Abernethy, Amy <Amy.Abernethy@fda.hhs.gov> wrote:

Hi Jay,

Thank you very much for your willingness to talk to us about your work with SCAN.

Mimi, cc'ed here, can help us with scheduling. (Please include Sean, Joe, Laura R from FDA)

We look forward to talking.

Take care,

Amy

From: Carla Rodriguez <crodriguezwatson@reaganudall.org>

Sent: Tuesday, May 12, 2020 5:28 PM

To: Jay Shendure <shendure@uw.edu>

Cc: Cowgill, Karen <n-kcowgill@kingcounty.gov>; Tunis, Sean <Sean.Tunis@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; esigal@focr.org <esigal@focr.org>; jallen@focr.org <jallen@focr.org>; Susan Winckler <swinckler@reaganudall.org>; Dewan, Puneet <n-pdewan@kingcounty.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>

Subject: RE: SCAN

Dear Dr. Shendure,

Thanks so much for reaching out! I believe Mimi Nguyen from FDA will reach out to coordinate a call.

Excited to talk with you.

Best,

Carla

From: Jay Shendure <shendure@uw.edu>

Sent: Tuesday, May 12, 2020 5:23 PM

To: Carla Rodriguez <crodriguezwatson@reaganudall.org>

Cc: Cowgill, Karen <n-kcowgill@kingcounty.gov>; Sean <Sean.Tunis@fda.hhs.gov>; amy.abernethy@fda.hhs.gov; Melissa <Melissa.Robb@fda.hhs.gov>; Laura <Laura.Roe@fda.hhs.gov>; esigal@focr.org; jallen@focr.org; Susan Winckler <swinckler@reaganudall.org>; Dewan, Puneet <n-pdewan@kingcounty.gov>

Subject: Re: SCAN

Hi Carla & all,

Nice to meet you by email. I am the co-lead of SCAN (Seattle Coronavirus Assessment Network).

Karen Cowgill (cc'd) asked that I pick up this thread as I may be in a better position to discuss SCAN.

I would be very happy to talk to Dr. Abernethy this week about SCAN and how it might inform your efforts.

Best regards,

Jay Shendure

Investigator, Howard Hughes Medical Institute
Director, Allen Discovery Center for Lineage Tracing
Director, Brotman Baty Institute for Precision Medicine
Professor, Genome Sciences, University of Washington
shendure@uw.edu | 206.685.8543

From: Carla Rodriguez <crodriguezwatson@reaganudall.org>
Sent: Monday, May 11, 2020 6:50 AM
To: Dewan, Puneet <n-pdewan@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>
Cc: Tunis, Sean <Sean.Tunis@fda.hhs.gov>; amy.abernethy@fda.hhs.gov; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; esigal@focr.org; jallen@focr.org; Susan Winckler <swinckler@reaganudall.org>
Subject: RE: SCAN

[EXTERNAL Email Notice!] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Resending because Karen wasn't on original message....

Dear Karen and Puneet,

We appreciate that you might not be able to discuss results from SCAN at this point and will keep checking back!

Would it be possible to schedule a 30 min call with Dr. Abernethy this week to discuss how SCAN might inform work we are doing to launch a Diagnostics Accelerator?

I've copied her team, who will take the coordination from here.

Thanks again for all you're doing.

Best,
Carla

From: Carla Rodriguez <crodriguezwatson@reaganudall.org>
Sent: Sunday, May 10, 2020 9:28 AM
To: Cowgill, Karen <n-kcowgill@kingcounty.gov>
Subject: Re: Introduction

Dear Karen,

Thanks for checking. We will be starting a Diagnostics Accelerator (~ week of 5/21) in Parallel to the Therapeutics Accelerator. Is there info in that space that might be shared? Our focus will be in describing the environments & populations where different diagnostics/serology have been deployed, as well as describing accuracy of the different tests in real- world (compared to PCR, for example).

As with the existing Evidence Accelerator, we are not trying to supplant ongoing studies, but understand what's been collected and see if there is room for alignment so that we can run parallel analyses with other datasets and be able to identify trends.

This info is not being widely circulated- so please limit circulation.

Thanks!
Carla

Get [Outlook for iOS](#)

From: Cowgill, Karen <n-kcowgill@kingcounty.gov>
Sent: Saturday, May 9, 2020 8:56:51 PM
To: Carla Rodriguez <crodriguezwatson@reaganudall.org>
Subject: RE: Introduction

Hi Carla,

I brought this offer to the rest of the SCAN team and the consensus is that this looks interesting but that it's a little premature for SCAN to present at this point as the system is still getting established ... please keep us in mind in the months ahead and reach out again if this might still be of interest to the group.

Thanks,
Karen

From: Cowgill, Karen
Sent: Friday, May 8, 2020 1:23 PM
To: Carla Rodriguez <crodriguezwatson@reaganudall.org>; Baer, Atar <Atar.Baer@kingcounty.gov>; Dewan, Puneet <n-pdewan@kingcounty.gov>
Subject: RE: Introduction

Thanks, Carla, and thanks, Atar, for the introduction!

Carla, my apologies for the slow reply, and thank you for the opportunity for SCAN to consider presenting as part of the COVID-19 Evidence Accelerator initiative. This looks interesting -- a quick call to discuss how we might contribute to this effort might be a good next step. I will check in with SCAN colleagues and follow up with you.

Best regards,
Karen

Karen Cowgill, PhD, MSc (*she/her*)
COVID-19 Response Epidemiologist
Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Affiliate Assistant Professor in Global Health, University of Washington
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (206) 263-3087; Fax: (206) 296-4803
E-mail: n-kcowgill@kingcounty.gov

From: Carla Rodriguez <crodriguezwatson@reaganudall.org>
Sent: Monday, May 4, 2020 12:10 PM
To: Baer, Atar <Atar.Baer@kingcounty.gov>; Dewan, Puneet <n-pdewan@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>
Subject: RE: Introduction

[EXTERNAL Email Notice!] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Dear Atar, Karen and Puneet,

Thanks very much for this introduction. Being both a UW and PHSKC alum, I am so proud of the work coming out of Seattle!

I am writing in the hopes that you all might be willing to share the SCAN experience on surveillance and/or natural history of COVID-19 at one of our Accelerator Lab meetings. If it's OK, I'd like to connect you with Dr. Amy Abernethy, Deputy Commissioner of the FDA, to discuss further.

The Foundation, in collaboration with the Friends of Cancer Research, is working closely with the FDA on the COVID-19 Evidence Accelerator. Essentially, the Accelerator operates through two distinct workstreams:

1) Accelerator Parallel Analyses: Developing key research questions that multiple organizations and teams can address simultaneously.

Initial activities of this work stream include (1) rapidly revising a list of core data elements; (2) identifying those critical to answering the primary question; and (3) establishing uniform collection parameters. It will be necessary to work collaboratively to determine how data elements are being extracted and how they are being defined in order to operationalize a platform that can not only answer questions now, but also inform how research activities could be conducted in the future.

Repeating analyses in parallel by collaborators using different analytical techniques and data sources will help strengthen findings and learnings. Furthermore, this effort will help validate the role of real-world data as a tool for rapidly learning about patient characteristics, treatment patterns and outcomes associated with management strategies for COVID-19.

The first question we are organizing around is around COVID-19 treatments. For more detail, please see our [website](#). We sent an initial survey of critical questions and core data elements around, to which approximately 25 organizations responded with their data availability and feedback. Working with 8 organizations so far, we have since refined the definitions of these data elements, including inclusion, exclusion, exposure and outcome definitions. **These meetings occur every Wednesday.** Time varies but is generally from 4-5 pm ET.

2) Accelerator Lab Meetings: Share findings from interested data partners on critical questions.

Results are generated and analyzed in many different ways and using different methods and data sources. Lab meetings will provide a venue for scientists across the country to discuss data generated from quick turnaround queries and share results with peers and experts from FDA, major data organizations, academic research institutions, professional societies, and health systems to help accelerate, and potentially even confirm, findings from different data sources and leverage existing expertise. **These meetings occur every Thursday** from 3-4 pm ET. Summaries of past presentations are posted on our website (mentioned above).

There have been some nice reviews of this work in the press, which you can see [here](#).

Please let me know if you think you might be able to present at an upcoming Lab Meetings; or if you'd be able to have a quick call to discuss other ways to participate.

Best,
Carla

Carla Rodriguez-Watson, PhD, MPH

Scientific Director of IMEDS

Direct: 202-849-2069 | Main: 202-849-2075

1900 L Street, N.W., Suite 835, Washington, DC 20036

www.reaganudall.org / www.focr.org/covid19

From: Baer, Atar <Atar.Baer@kingcounty.gov>

Sent: Monday, May 4, 2020 10:16 AM

To: Carla Rodriguez <crodriguezwatson@reaganudall.org>; Dewan, Puneet <n-pdewan@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>

Subject: Introduction

Hi Karen and Puneet -- a former colleague, Carla Rodriguez, is working for the Reagan-Udall Foundation for the Food and Drug Administration to organize info coming out of the many studies related to COVID.

Carla, I am connecting you with Karen, who is our SCAN liaison -- please follow up with Karen with specific questions you have about SCAN.

Puneet is with Global Good, and has been leading all aspects related to coordination of COVID testing -- please follow up with Puneet with specific questions you have related to testing.

Thanks in advance for your willingness to share your expertise with Carla.

Atar

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/31/2020 5:43:06 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: follow-up to the Accelerator call

Hi Nilay,

Thank you so much for your message. Apologize for being slow in following up - I am still catching up on email after a long week.

I spoke with John Halamka and team about both diagnostics and convalescent plasma related work. It would be great to follow up with you about the VIRUS registry and other activities going on in your CERSI if you are available. Perhaps a call the week of Jun 8? Adding Mimi here to help us get it set up. It would be great to include Joe and/or Laura as well.

Take care,

Amy

From: Shah, Nilay D., Ph.D. <Shah.Nilay@mayo.edu>
Sent: Wednesday, May 27, 2020 7:43 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: follow-up to the Accelerator call

Hi Amy –

Hope you are well. I wanted to follow-up on a couple ideas that were discussed on the Accelerator call:

1. We have discussed a variety of datasets as part of the Accelerator...not sure if the VIRUS registry was discussed? I have talked to my colleagues who are leading it and it might be a good dataset for natural history of patients during their hospitalization as well as for evaluating various treatments that were discussed: <https://www.sccm.org/Research/Research/Discovery-Research-Network/VIRUS-COVID-19-Registry>. Happy to invite the investigators to present about the data on one of the calls if that would be helpful.
2. There are a variety of strategies that are in the works related to identifying a control group for the convalescent plasma study. Was the goal today to discuss potential options for the control group? I wonder if having the study team present their approaches and getting feedback might be helpful?
3. It sounds like you have also connected with our medical lab leadership – I have invited them to the diagnostic accelerator meeting tomorrow.

(b) (4)

Please let me/our CERSI know if we can be helpful in any way as the agency looks at various aspects of diagnostics and therapeutic agents.

Thanks

Nilay

Nilay Shah, PhD

Chair, Division of Health Care Policy and Research

Robert E. and Patricia E. Kern Endowed Director for Research, Kern Center for the Science of Health Care Delivery

Associate Professor of Health Services Research

Mayo Clinic

Rochester, MN

Ph: 507-266-5130

From: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Sent: 5/29/2020 11:33:28 AM
To: Halamka, John D., M.D., M.S. [Halamka.John@mayo.edu]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: Re: I think we have a plan

Thanks, Peter. Since our emails crossed in the ether, can you check my edits below. And then I think we are good to go.

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Sent: Friday, May 29, 2020 11:32 AM
To: Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Re: I think we have a plan

Thanks so much, John. This is in line with the direction from my understanding. I am also working on a summary of the current situation to send to Peter so that we all have the same information.

A couple of minor amendments in the proposed message below:

Folks:

I've talked to all the stakeholders about the June 15 deadlines requested by the FDA

1. The Expanded Access Program (EAP) has a Red Cap database of (b) (4) COVID patients which is used to prepare safety data and will be analyzed in the coming days for outcomes/efficacy measures. Amy Abernethy confirmed that Stephen Hahn and Peter Mark's focus for June 15 is this Red Cap database. Peter Marks has provided the EAP team with the analytics desired by the FDA and all is aligned for a June 15th delivery.

2. Next week we'll begin the process of collecting line-level patient data directly from Epic and Cerner sites to contribute to this effort.

This Epic/Cerner federated approach will be extremely valuable but does not need to part of the June 15 analysis. Amy Abernethy is also directly involved in this effort.

3. Epic and Cerner will also continue to work together in consultation with MSU and Mayo researchers to further analyze available consolidated data.

John

From: Halamka, John D., M.D., M.S. <Halamka.John@mayo.edu>
Sent: Friday, May 29, 2020 11:27 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: I think we have a plan

Before I send this email to Epic/Cerner, Mitre, Expanded Access Program, Mayo leadership and the two of you, are there any edits you'd like?

Thanks so much

Folks:

I've talked to all the stakeholders about the June 15 deadlines requested by the FDA

1. The Expanded Access Program (EAP) has a Red Cap database of (b) (4) COVID patients which is used to prepare safety data and will be analyzed in the coming days for outcomes/efficacy measures. Amy Abernathy confirmed that Stephen Hahn's focus for June 15 is this Red Cap database. Peter Marks has provided the EAP team with the analytics desired by the FDA and all is aligned for a June 15th delivery

2. Next week we'll begin the process of collecting line-level patient data directly from Epic and Cerner sites to contribute to this effort.

This Epic/Cerner federated approach will be extremely valuable but does not need to part of the June 15 analysis. Amy Abernathy is also directly involved in this effort.

3. Epic and Cerner will also continue to work together in consultation with MSU and Mayo researchers to further analyze available consolidated data.

John

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 1/19/2020 2:58:30 PM
To: Shah, Nilay D., Ph.D. [Shah.Nilay@mayo.edu]
CC: Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]
Subject: Re: Invitation to present the Plenary at the Mayo Clinic AI Symposium

Hi Nilay,

Thank you so much for the invitation. I am honored.

I am cc'ing Allison and team here to see what might be possible. We are trying to schedule a trip to Minnesota/Wisconsin & Mayo for several reasons so it is possible that we could align schedules, though there is already another meeting to which I have committed on 5/13 so it might still be tough. But let's see what we can do.

Thanks and take care,

Amy

From: "Shah, Nilay D., Ph.D." <Shah.Nilay@mayo.edu>
Date: Friday, January 17, 2020 at 3:54 PM
To: "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>
Subject: Invitation to present the Plenary at the Mayo Clinic AI Symposium

Dear Amy –

It was great to see you at the UCSF-Stanford meeting in San Francisco last weekend. I was reaching out to invite you to present at the Mayo Clinic AI Symposium which is being held on May 12-13. The goal of this meeting is focused on use of AI algorithms at the front lines of healthcare delivery and describe experiences of implementation in the EHR and impact of these algorithms on patient outcomes. I suspect that this will likely not work with your schedule, but I thought I would try.

If this does not work, we would love to have you visit Mayo Clinic as part of the CERSI to identify opportunities to further partner with the FDA. We can work around your schedule to find a time that might work in the future.

Thanks in advance for considering this.

Nilay

Nilay Shah, PhD
Chair, Division of Health Care Policy and Research
Robert E. and Patricia E. Kern Endowed Director for Research, Kern Center for the Science of Health Care Delivery
Associate Professor of Health Services Research
Mayo Clinic
Rochester, MN
Ph: 507-266-5130