

National Institutes of Health Freedom of Information Office Building 31, Room 5B-35 31 Center Drive, MSC 2107 Bethesda, Maryland 20892-2107 phone: (301) 496-5633 fax: (301) 402-4541

Via Email: petesorenson@gmail.com

December 28, 2022

C. Pete Sorenson Sorenson Law Office PO Box 10836 Eugene, Oregon, 97440

Re: NIH FOIA Case No.: 54696; US Right to Know v. NIH, Case No. 20cv3196

Dear Mr. Sorenson:

This is a partial response to the Freedom of Information Act (FOIA) request that is the subject of the complaint filed in US Right to Know v. NIH, Case No. 20cv3196, now pending in the U.S. District Court for the District of Columbia. Your FOIA request, dated July 10, 2020, was received by the National Institutes of Allergy and Infectious Diseases (NIAID) on the same day.

You requested three parts pertaining to the following employees:

- 1. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID)
- 2. Hugh Auchincloss, NIAID Principal Deputy Director
- 3. Paula Bryant, Director, Office of Biodefense, Research Resources and Translational Research, NIAID
- 4. F. Gray Handley, Associate Director for International Research Affairs
- 5. Gayle Bernabe, Regional Program Officer, East Asia-Pacific, NIAID
- 6. Heinz Ulrich Feldmann, Senior Investigator, Disease Modeling and Transmission Section, NIAID

"For this FOIA request we are seeking copies of records created, received and/or in the possession of NIH, including cross-references. Specifically, we are seeking records that reflect communications – whether in writing or verbal communications that were later reduced to writing (including any emails and their attachments, non-email correspondence, or other forms of communication) – to, from, or in the possession of the above-named individuals -- containing any of the following keywords or domains:

Part I of this request pertains to communications containing any of the following keywords or domains:

- East China Normal University
- Wuhan Institute of Virology OR WIV OR @wh.iov.cn
- Wuhan Center for Disease Control and Prevention

- Wuhan University Institute of Medical Virology
- EcoHealth Alliance OR EcoHealth OR @ecohealthalliance.org
- Christophe Mérieux Laboratory located in Beijing

Part II of this request pertains to communications containing any of the following combinations of keywords:

- "China" within 25 "biothreat"
- "China" within 25 "bioincident"
- "China" within 25 "Dual Use Research of Concern" OR "China" AND "DURC" OR "China" within 25 "GOF"
- "China" within 25 "biodefense"
- "China" within 25 "US Army Medical Research Institute of Infectious Diseases" OR "China" within 25 "USAMRIID"

For Part III, please search for all email correspondence to or from above listed employees—including attachments, CC and BCC – and the following person(s):

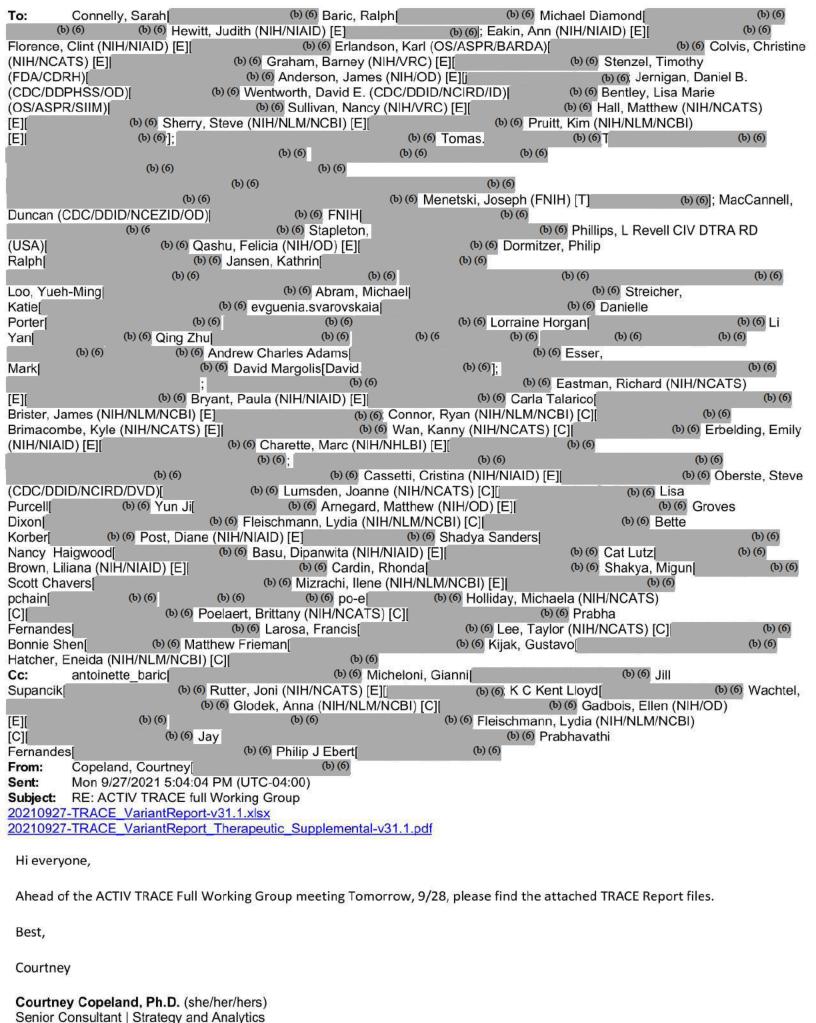
- Fang Li OR <u>lifang@umn.edu</u>
- George Gao OR gaof@im.ac.cn
- Linfa Wang OR linfa.wang@duke-nus.edu.sg
- Christian Bréchot OR <u>cbrechot@usf.edu</u>
- Ralph Baric OR <u>rbaric@email.unc.edu</u>
- Ian Lipkin OR wil2001@columbia.edu
- James Le Duc OR jwleduc@utmb.edu
- Thomas Ingelsby OR tinglesby@jhu.edu

In accordance with the Court's order dated September 30, 2021, we have processed 308 pages of responsive records this month. The information being withheld is protected from release pursuant to Exemptions 4 and 6 of the FOIA, 5 U.S.C. § 552 (b)(4) and (b)(6); and sections 5.31(d) and (f) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential Exemption 6 exempts from disclosure records the release of which would cause a clearly unwarranted invasion of personal privacy.

Please direct any questions regarding this response to Dedra Curteman of the Department of Justice, who can be reached at Dedra.Curteman@usdoj.gov, or (202) 252-2550.

Sincerely,

for Gorka Garcia-Malene Freedom of Information Act Officer, NIH



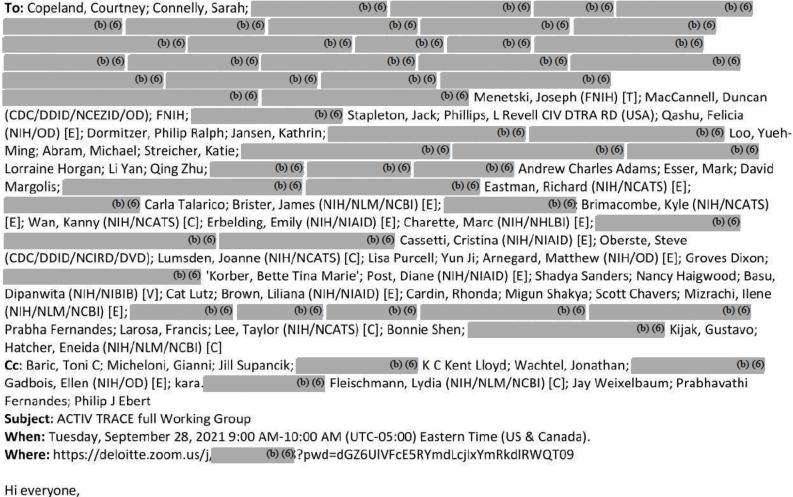
Deloitte Consulting LLP

200 Berkeley St 10th FI Boston, MA 02116 Tel/Direct: (b) (6) | Mobile:

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----Original Appointment----From: Copeland, Courtney

Sent: Friday, September 10, 2021 12:54 PM



Ahead of the ACTIV TRACE Full Working Group meeting Tomorrow, 9/28, please find the attached TRACE Report files.

Best,



Join Meeting

Join by Telephone	
Dial:	US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299
Meeting ID:	(b) (6)
Password:	(b) (6)
International numbers	
SIP:	(b) (6) @zoomcrc.com

(b) (6) or +16465189805.

(b)(6)

US: +13126266799,

(b) (6)

Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) <u>Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Tracking Resistance and Coronavirus Evolution (TRACE) Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at (b) (6) with any feedback, comments, or questions to help us improve this resource.</u>

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV TRACE, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

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The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- · From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the OpenData Portal Visualization Page Additional details on the visualized data are available on the NCATS OpenData Portal.

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New Pre-prints, Publications & Datasets:

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- 3. Safety and immunogenicity of SARS-CoV-2 variant mRNA vaccine boosters in healthy adults; an interim analysis [Journal Article]
- 4. Clinical Results with a B Cell Activating Anti-CD73 Antibody for the Immunotherapy of COVID-19 [Journal Article]

Updated Pre-prints and Publications:

1. Antibody evasion by the P.1 strain of SARS-CoV-2 [Journal Article]



Explore the latest Variants & Therapeutics data on OpenData Portal:

OpenData Portal | SARS-CoV-2 Variants & Therapeutics

Summary

Updated 09.24.21

105 data sources 4103 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

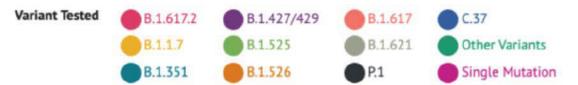
Click to explore variant data on OpenData Portal:

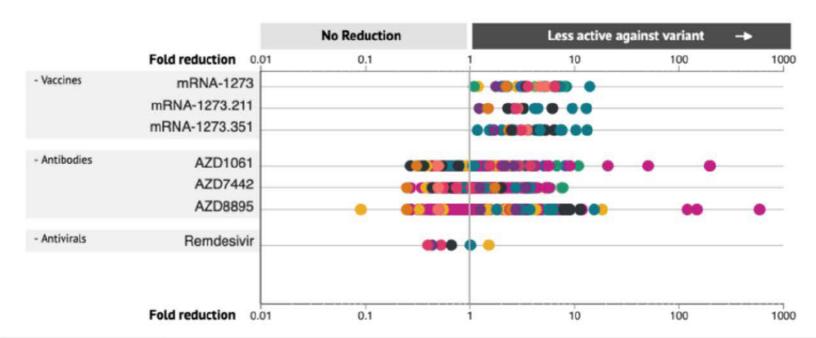
What's new in the last week? Data for All Variants B.1.617.2 AY.1/2 P.1 B.1.1.7 B.1.351 B.1.621 B.1.427/429 B.1.525 B.1.526 B.1.617 C.37 P.2 Other Variants Single Point Mutation Data





In vitro data added to NCATS OpenData Portal in last week







9.27.2021



(NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b) (6) (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)(b) (6) Lorraine Horgan; Li Yan; Qing Zhu; Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; Shakya, Migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; Kijak, Gustavo; Hatcher, Eneida (NIH/NLM/NCBI) [C]; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Jay Weixelbaum; Prabhavathi Fernandes; Philip J Ebert (b) (6) ?pwd=dGZ6UIVFcE5RYmdLcjIxYmRkdIRWQT09 Location: https://deloitte.zoom.us/j Normal Importance: ACTIV TRACE full Working Group Subject: Start Time: Tue 9/28/2021 9:00:00 AM (UTC-04:00) End Time: Tue 9/28/2021 10:00:00 AM (UTC-04:00) Required Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b)(6)(b) (6) (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) (b) (6); (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b)(6)(b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; (b) (6) po-e; Holliday, Shakya, Migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; Kijak, Gustavo; Hatcher, Eneida (NIH/NLM/NCBI) antoinette_baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Optional Attendees: Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];

Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Jay Weixelbaum; Prabhavathi Fernandes; Philip J Ebert

(b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann

20210927-TRACE VariantReport Therapeutic Supplemental-v31.1.pdf

20210927-TRACE VariantReport-v31.1.xlsx

From:

Attendees:

Copeland, Courtney

Connelly, Sarah; Baric, Ralph; Michael Diamond;

Hi everyone,

Ahead of the ACTIV TRACE Full Working Group meeting Tomorrow, 9/28, please find the attached TRACE Report files.

Best,



Join Meeting

Passcode: (b) (6)

Phone one-tap: US: <u>+13126266799</u>, (b) (6) or <u>+16465189805</u>, (b) (6)

Join by Telephone

Dial: US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299

Meeting ID: (b) (6)

Password: (b) (6)

International numbers

SIP: (b) (d) @zoomcrc.com

Passcode: (b) (6)

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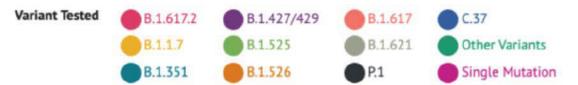
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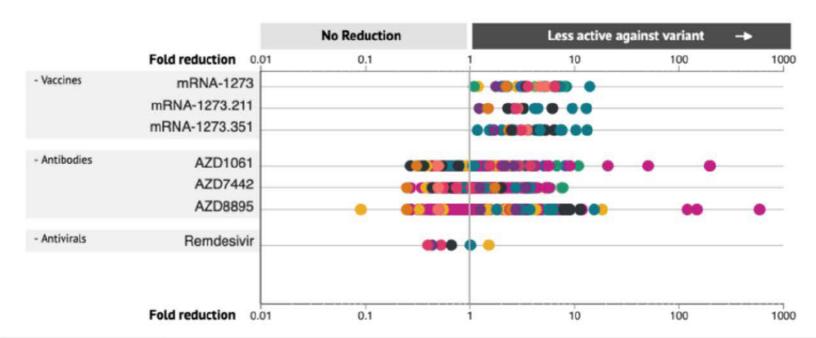
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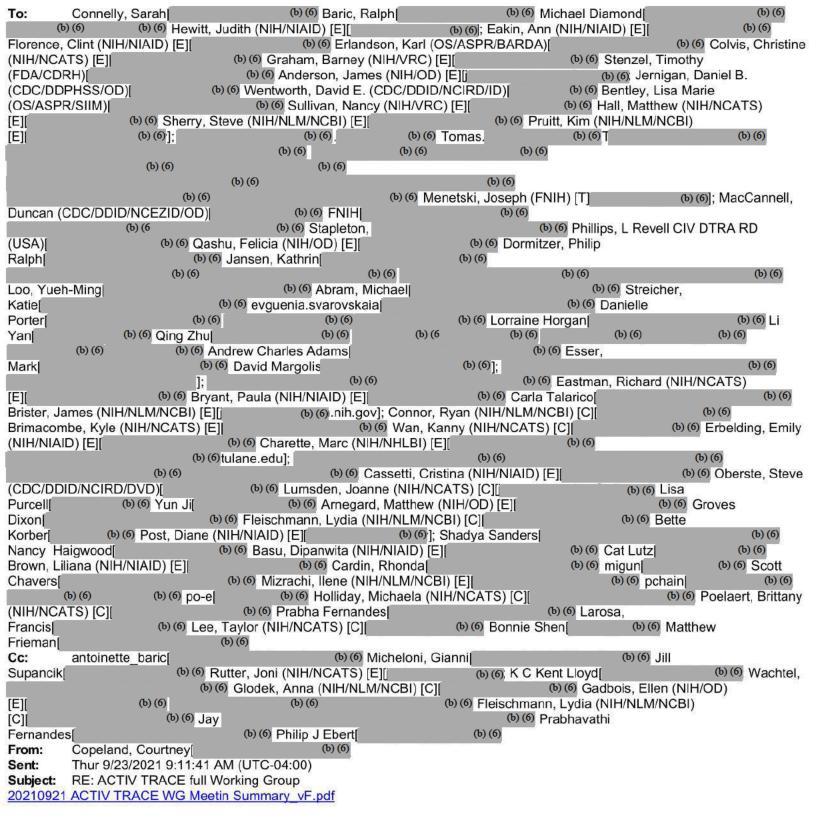






9.27.2021





Dear Working Group Members,

Thank you for attending the ACTIV TRACE Full Working Group meeting this Tuesday, 9/21. Attached are this week's meeting notes. Let us know if you all have any additions or amendments.

Warm Regards,

Courtney

Courtney Copeland, Ph.D. (she/her/hers) Senior Consultant | Strategy and Analytics Deloitte Consulting LLP

200 Berkeley St 10th FI Boston, MA 02116
Tel/Direct: (b) (6) | Mobile: + (b) (6) | www.deloitte.com

----Original Appointment-----From: Copeland, Courtney

Sent: Friday, September 10, 2021 12:54 PM

To: Copeland, Courtney; Conr	nelly, Sarah;		(b) (6)	(b) (6)	(b) (6)	(b) (6)
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(NIH/OD) [E]; Dormitzer, Phili	p Ralph; Janser	n, Kathrin;		(b) (6)		(b) (டி Loo, Yueh
Ming; Abram, Michael; Streic	her, Katie;		(b)	(6)	(b) (6)	(b) (6)
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Margolis;		(b) (6)		(b) (6) Eastmar	, Richard (NIH/	NCATS) [E];
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[E]; Wan, Kanny (NIH/NCATS)	[C]; Erbelding,	Emily (NIH/NI	AID) [E]; Chare	tte, Marc (NIH/I	NHLBI) [E];	(b) (6)
	(b) (6)		(b) (6) Casset	ti, Cristina (NIH)	NIAID) [E]; Obe	erste, Steve
(CDC/DDID/NCIRD/DVD); Lum	nsden, Joanne (NIH/NCATS) [C]; Lisa Purcell;	Yun Ji; Arnegar	d, Matthew (NI	H/OD) [E]; Groves Dixon;
(1)) (6) 'Korber, Be	ette Tina Mari	e'; Post, Diane	(NIH/NIAID) [E];	Shadya Sander	s; Nancy Haigwood; Basu,
Dipanwita (NIH/NIBIB) [V]; Ca	t Lutz; Brown, I	Liliana (NIH/N	IAID) [E]; Cardi	n, Rhonda; Migu	ın Shakya; Scot	t Chavers; Mizrachi, Ilene
(NIH/NLM/NCBI) [E];	(b) (6)	(b) (6)	(b) (6)		(b) (6)	(b) (6)
Prabha Fernandes; Larosa, Fra	ancis; Lee, Taylo	or (NIH/NCATS	S) [C]; Bonnie S	hen;		(b) (6)
Cc: Baric, Toni C; Micheloni, G	ianni; Jill Supar	ncik;	(р) (б) К (C Kent Lloyd; Wa	chtel, Jonathan	(b) (6)
Gadbois, Ellen (NIH/OD) [E]; k	ara.	(b) (б) Flei	schmann, Lydi	a (NIH/NLM/NCI	31) [C]; Jay Weix	celbaum; Prabhavathi
Fernandes; Philip J Ebert						
Subject: ACTIV TRACE full Wo	rking Group					
When: Tuesday, September 2	1, 2021 9:00 A	M-10:00 AM (UTC-05:00) Eas	stern Time (US 8	Canada).	
Where: https://deloitte.zoom	n.us/j, ((ው) (6) የpwd=dG	Z6UlVFcE5RYr	ndLcjlxYmRkdlR\	NQT09	

Hi everyone,

I am updating the meeting ownership.

Best,



Join Meeting

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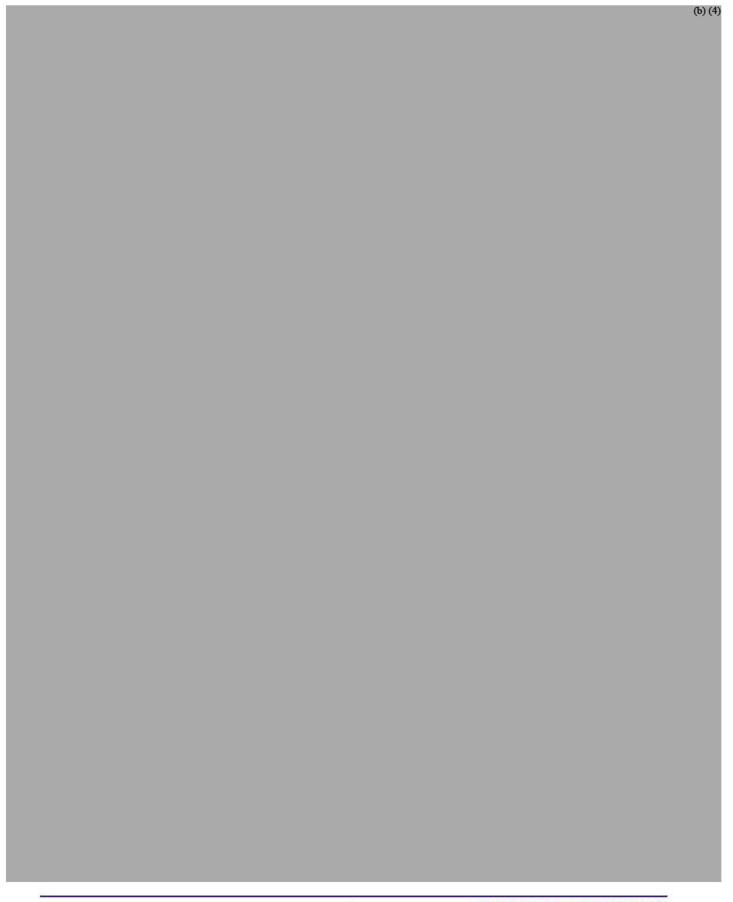
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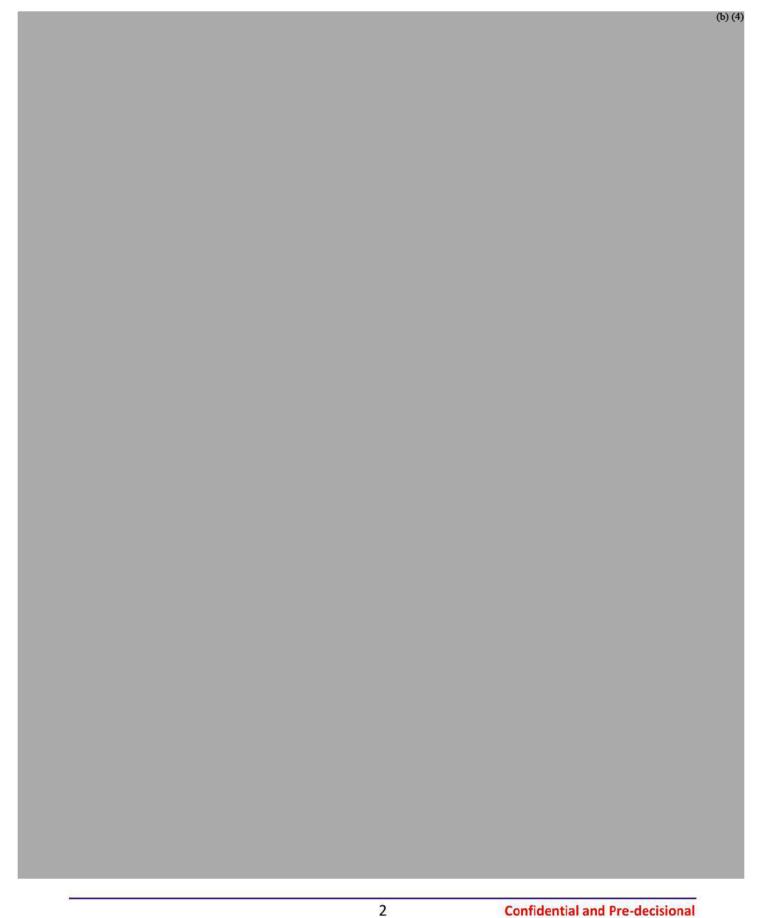
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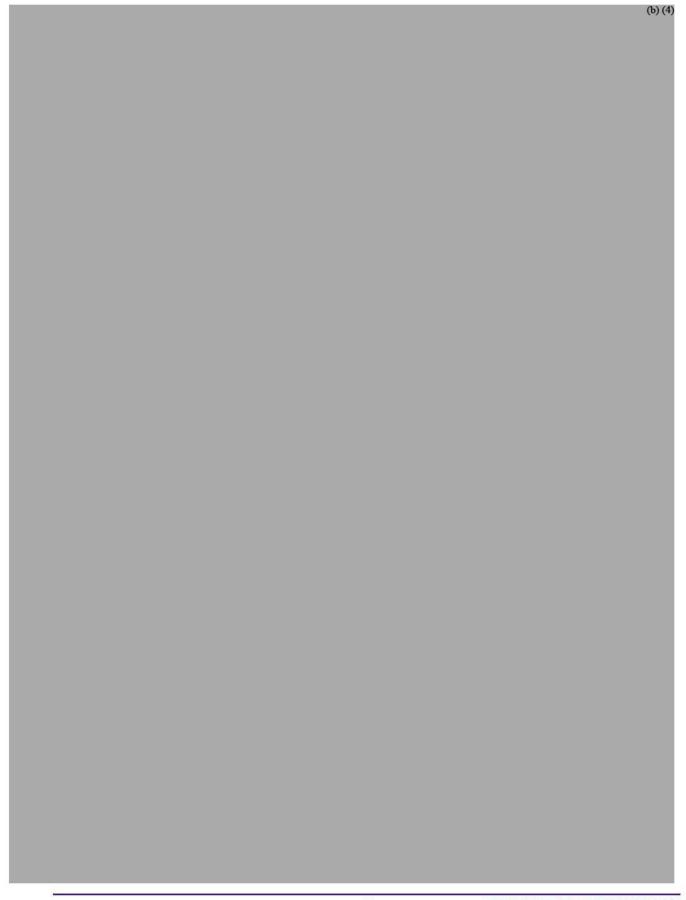
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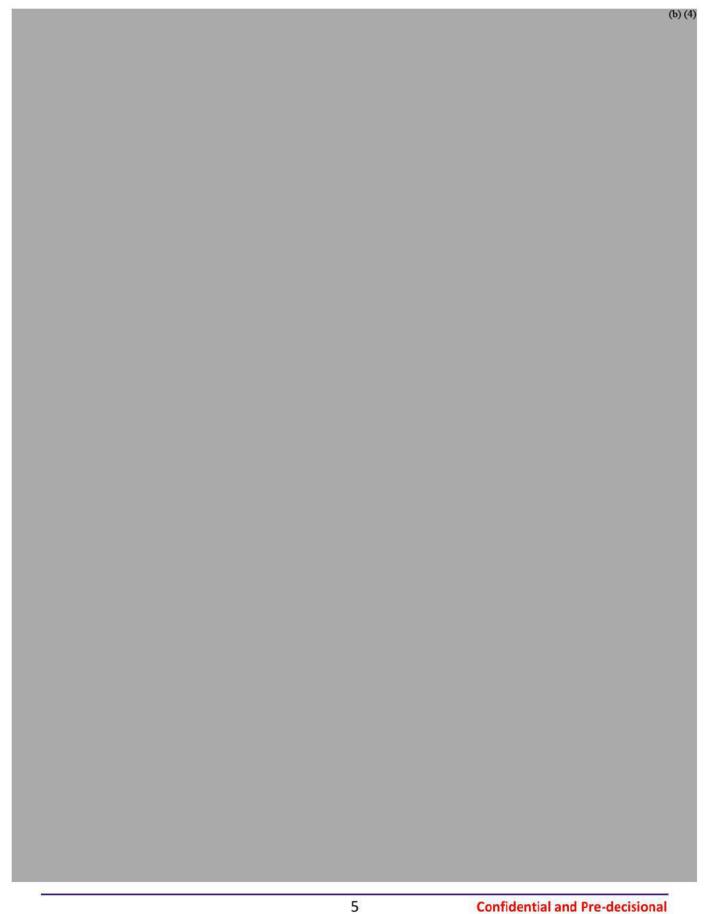
Join by Telephone

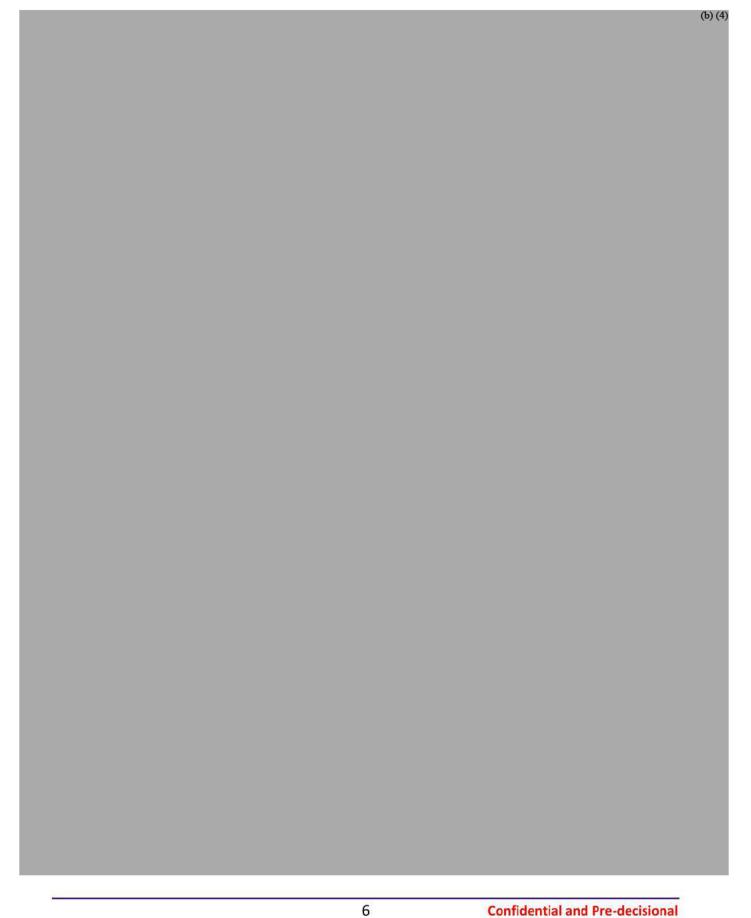




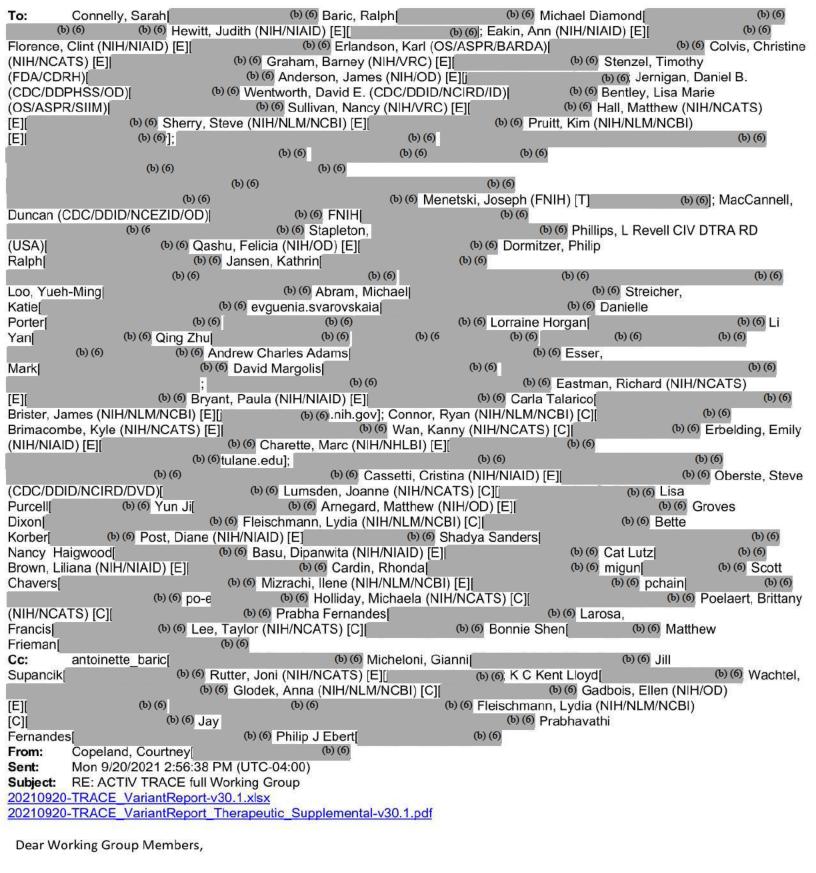












Ahead of tomorrow's meeting, please find attached this week's TRACE report and supplemental figures.

Warm Regards,

Courtney

Courtney Copeland, Ph.D. (she/her/hers) Senior Consultant | Strategy and Analytics Deloitte Consulting LLP 200 Berkeley St 10th FI Boston, MA 02116

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Sent: Friday, September 10, 2021 12:54 PM

To: Copeland, Courtney; Connelly, Sarah; (b) (6) (b) (6) (b)(6)(b) (6) (b) (6) (b)(6)(b)(6)(b) (6) (b)(6)(b)(6)(b)(6)(b) (6) (b) (6) (b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (b) (6) (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-(b)(6)(b)(6)(b)(6)Ming; Abram, Michael; Streicher, Katie; Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) (b)(6)(b) (6) Andrew Charles Adams; Esser, Mark; David (b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]; Margolis; (b) (6) Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; (b) (6) Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; (b) (6) 'Korber, Bette Tina Marie'; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIBIB) [V]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; Migun Shakya; Scott Chavers; Mizrachi, Ilene (b) (6) (NIH/NLM/NCBI) [E]; (b)(6)(b)(6)(b) (6) Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; (b)(6)(b) (6) Cc: Baric, Toni C; Micheloni, Gianni; Jill Supancik; (b) (6) K C Kent Lloyd; Wachtel, Jonathan; Gadbois, Ellen (NIH/OD) [E]; (b) (6) Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Jay Weixelbaum; Prabhavathi Fernandes; Philip J Ebert Subject: ACTIV TRACE full Working Group When: Tuesday, September 21, 2021 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada). (b) (6);?pwd=dGZ6UIVFcE5RYmdLcjlxYmRkdlRWQT09 Where: https://deloitte.zoom.us/

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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) <u>Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Tracking Resistance and Coronavirus Evolution (TRACE) Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at (b) (6) with any feedback, comments, or questions to help us improve this resource.</u>

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV TRACE, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- · From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the OpenData Portal Visualization Page Additional details on the visualized data are available on the NCATS OpenData Portal.

New to the OpenData Portal Variant Database this week:

New Pre-prints and Publications:

- 1. Clinical grade ACE2 as a universal agent to block SARS-CoV-2 variants [Pre-print]
- 2. BNT162b2-elicited neutralization of delta plus, lambda, and other variants [Pre-print]

Updated Pre-prints and Publications:

1. LY-CoV1404 (bebtelovimab) potently neutralizes SARS-CoV-2 variants [Pre-print]

Explore the latest Variants & Therapeutics data on OpenData Portal:

OpenData Portal | SARS-CoV-2 Variants & Therapeutics

Therapeutic Activity Explorer

Updated 09.17.2

101 data sources 3362 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

Click to explore variant data on OpenData Portal:

B.1.1.7	B.1.351	B.1.617.2	AY.1	AY.2	P.1
B.1.427/429	B.1.525	B.1.526	B.1.617	C.37	P.2

Data for All Variants

Other Variants

What's new in the last week?

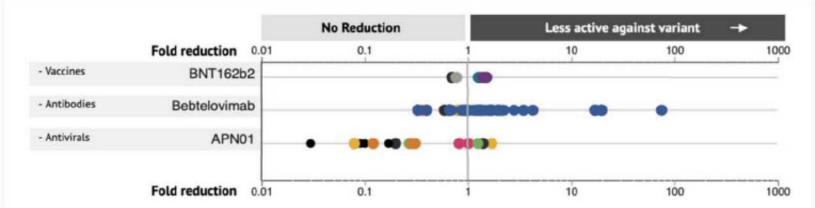
Single Point Mutation Data





In vitro data added to NCATS OpenData Portal in last week



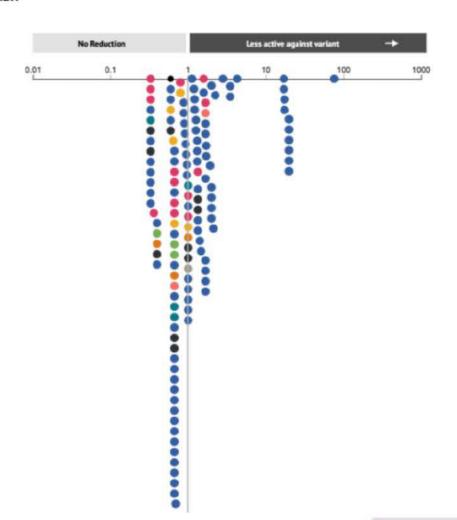




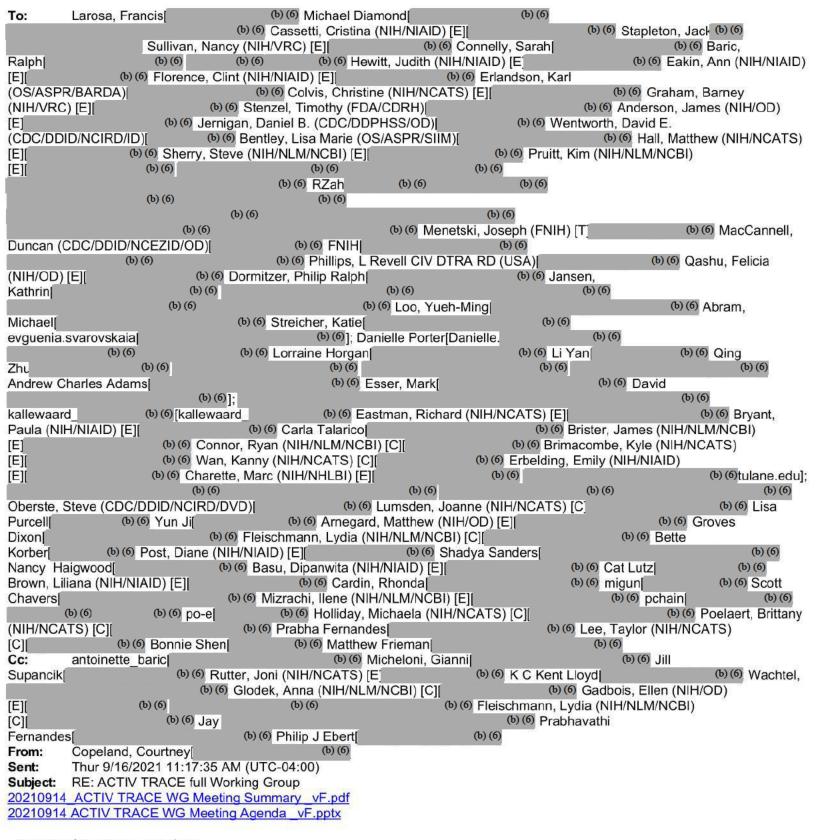
9.20.2021

EXPANDED THERAPEUTIC VIEW

Bebtelovimab







Dear Working Group Members,

Thank you for attending the ACTIV TRACE Full Working Group meeting this Tuesday, 9/14. Attached are this week's meeting notes and the agenda slides as we were unable to discuss updates in the ACTIV Variant Efforts due to time constraints. Let us know if you all have any additions or amendments.

Warm Regards,

Courtney

Senior Consultant | Strategy and Analytics
Deloitte Consulting LLP
200 Berkeley St 10th Fl Boston, MA 02116
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o: Larosa, Francis;	(b) (6)		(b) (6) Casset	ti, Cristina (NIH/N	IIAID) [E]; Stapleton, Ja	ack;
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Menetski, Joseph (FNI	H) [T]; MacCannell, Dunc	an (CDC/DDID/N	CEZID/OD); FNII	- 1;	(b) (6) Phillips, L R	evell CIV
DTRA RD (USA); Qashu	ı, Felicia (NIH/OD) [E]; Do	ormitzer, Philip R	alph; Jansen, Ka	thrin;	(b) (6)	
	(b) (б); Loo, Yueh-M	ng; Abram, Mich	ael; Streicher, K	atie;	(b) (6)	
	(b) (6)	(b) (6) Lorraine Ho	organ; Li Yan; Qi	ng Zhu;	(b) (6)	(6)
(b) (6) Andr	ew Charles Adams; Esse	r, Mark; David Ma	argolis;		(b) (6)	
	(b) (6) Eastman, Richard	d (NIH/NCATS) [E];	(b) (б) Carla Ta	larico; Brister, James	
NIH/NLM/NCBI) [E];	(b) (6); Br	imacombe, Kyle (NIH/NCATS) [E]	; Wan, Kanny (NII	H/NCATS) [C]; Erbeldin	g, Emily
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	(b) (6) Oberste, Steve (CDC/DDID/NCIRD	/DVD); Lumsde	n, Joanne (NIH/NO	CATS) [C]; Lisa Purcell;	Yun Ji;
Arnegard, Matthew (N	IIH/OD) [E]; Groves Dixo	n;	(b)	(6) 'Korber, Bette	Tina Marie'; Post, Dia	ne
NIH/NIAID) [E]; Shady	a Sanders; Nancy Haigw	ood; Basu, Dipan	wita (NIH/NIBIB) [V]; Cat Lutz; Bro	own, Liliana (NIH/NIAII	D) [E];
Cardin, Rhonda; Migu	n Shakya; Scott Chavers;	Mizrachi, Ilene (1	NIH/NLM/NCBI)	[E]; (1	b) (6) (b) (6)	(b
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Cc: Baric, Toni C; Mich	eloni, Gianni; Jill Supanc	ik;	(b) (6) K C Kent	Lloyd; Wachtel, Jo	onathan;	(b) (6)
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Subject: ACTIV TRACE	full Working Group					
When: Tuesday, Septe	mber 14, 2021 9:00 AM	-10:00 AM (UTC-0	05:00) Eastern T	ime (US & Canada	a).	
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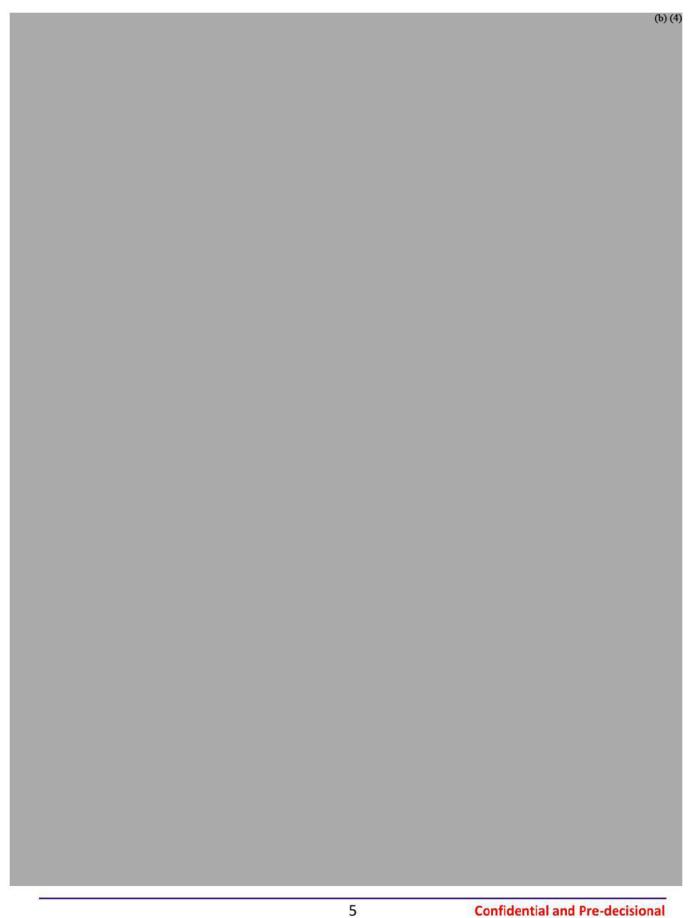
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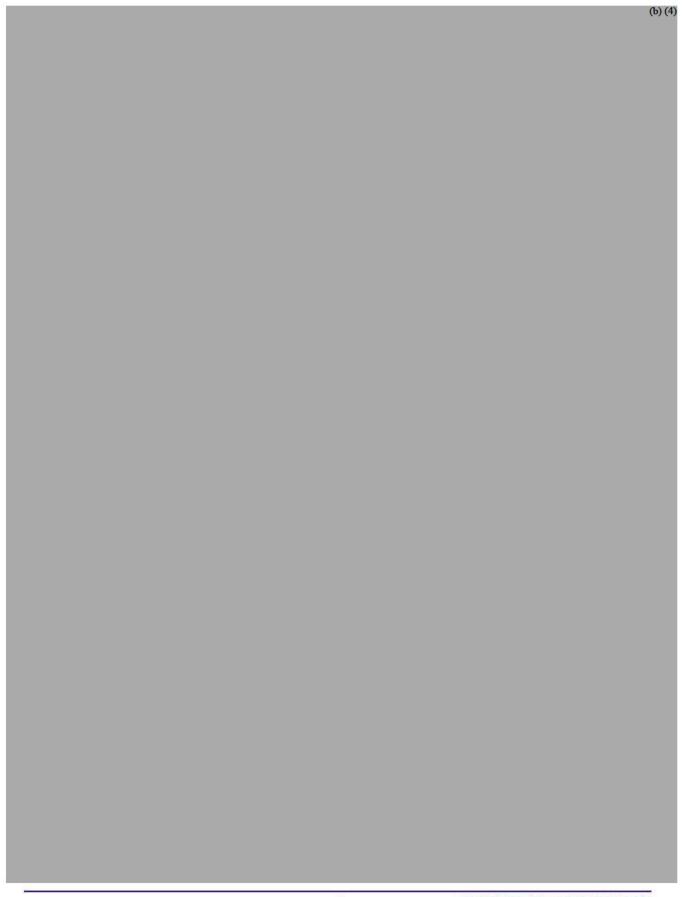
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ACTIV TRACE WG Meeting Summary	September 14, 2021		
	(b) (4		

(b) (4)



ACTIV Preclinical TRACE Working Group

September 14, 2021

Agenda for Today





TRACE: ACTIV Variant Efforts

09.14.2021 Update



New to the OpenData Portal Variant Database in the past week:

New Datasets, Pre-prints and Publications:

- 1. Neutralizing antibody responses to SARS-CoV-2 variants in vaccinated Ontario long-term care home residents and workers [Pre-print]
- 2. Neutralizing activity of sera from Sputnik V-vaccinated people against variants of concern (VOC: B.1.1.7, B.1.351, P.1, B.1.617.2, B.1.617.3) and Moscow Endemic SARS-CoV-2 variants [Peer-reviewed publication]
- 3. Neutralization of alpha, gamma, and D614G SARS-CoV-2 variants by CoronaVac vaccine-induced antibodies [Peer-reviewed publication]

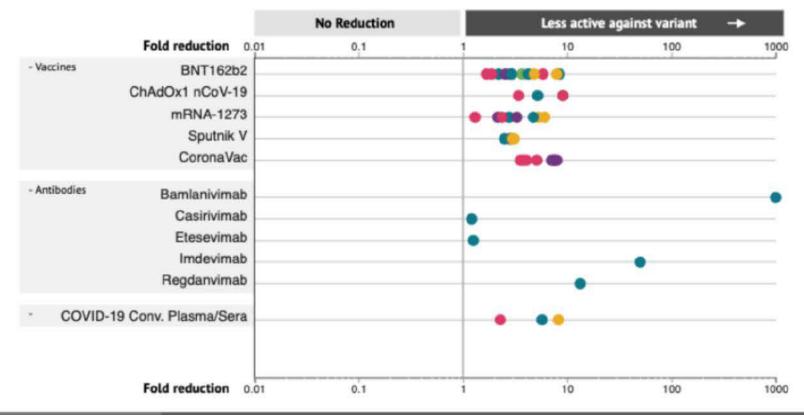
Updated Datasets, Pre-prints and Publications:

- 1. SARS-CoV-2 B.1.617.2 Delta variant replication and immune evasion [Peer-reviewed publication]
- 2. Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7): an exploratory analysis of a randomised controlled trial [Peer-reviewed publication]

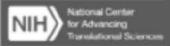


New to the OpenData Portal Variant Database in the past week:









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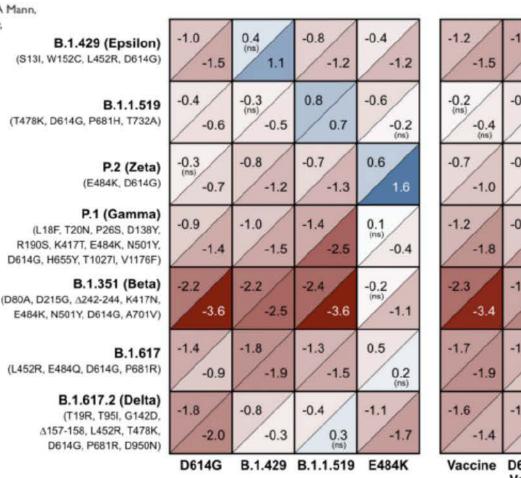
Exposures to different SARS-CoV-2 spike variants elicit neutralizing antibody responses with differential specificity towards established and emerging strains

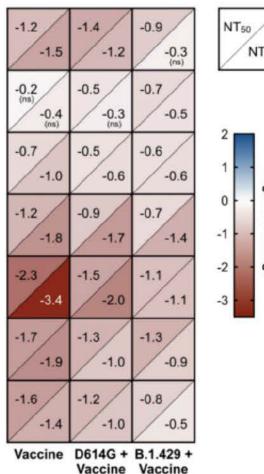
Joseph DeRisi

Matthew T Laurie, Jamin Liu, Sara Sunshine, James Peng, Douglas Black, Anthea M Mitchell, Sabrina A Mann, Genay Pilarowski, Kelsey C Zorn, Luis Rubio, Sara Bravo, Carina Marquez, Maya Petersen, Diane Havlir,

 Health care workers with 2 doses of Cc Vac in Thailand vs. naturally infect patients

Change in variant pseudovirus neutralization titer relative to D614G





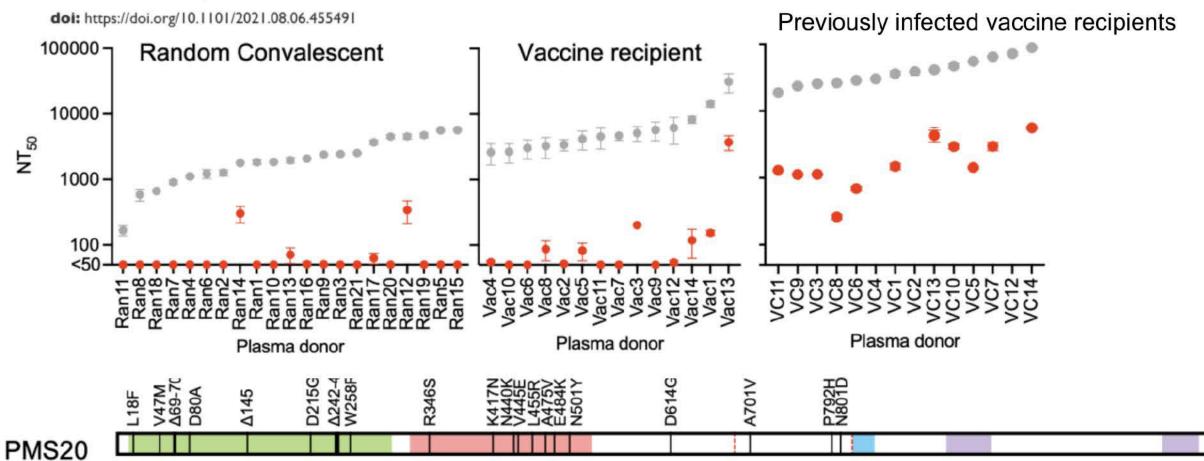
Conv. plasma

6 Vaccines (+ previous exposure)

Variant Data High ght (did not preet in setion cinteria)

High genetic barrier to escape from human polyclonal SARS-CoV-2 neutralizing antibodies

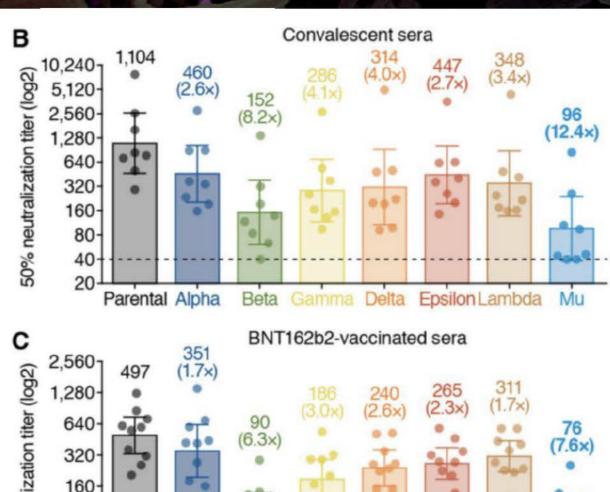
Fabian Schmidt, Yiska Weisblum, Magdalena Rutkowska, Daniel Poston, Justin Da Silva, Fengwen Zhang, Eva Bednarski, Alice Cho, Dennis J. Schaefer-Babajew, Christian Gaebler, Marina Caskey, Michel C. Nussenzweig, Theodora Hatziioannou, Paul D. Bieniasz

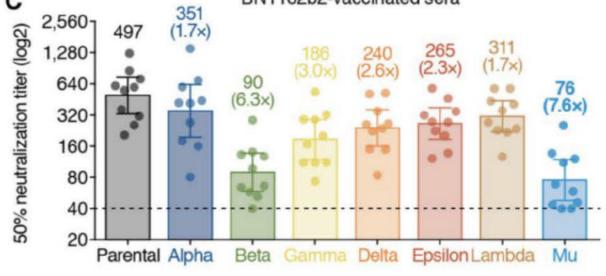


New Results

Ineffective neutralization of the SARS-CoV-2 Mu variant by convalescent and vaccine sera

Keiya Uriu, Izumi Kimura, Kotaro Shirakawa, Akifumi Takaori-Kondo, Taka-aki Nakada, Atsushi Kaneda, The Genotype to Phenotype Japan (G2P-Japan) Consortium, © So Nakagawa, © Kei Sato doi: https://doi.org/10.1101/2021.09.06.459005





Variant Resource ViewHut

https://view-hub.org/sites/default/files/2021-09/COVID19%20Vaccine%20Effectiveness%20Transmission%20%20Impact%20Studies%20-

%20Summary%20Tables_20210909.pdf

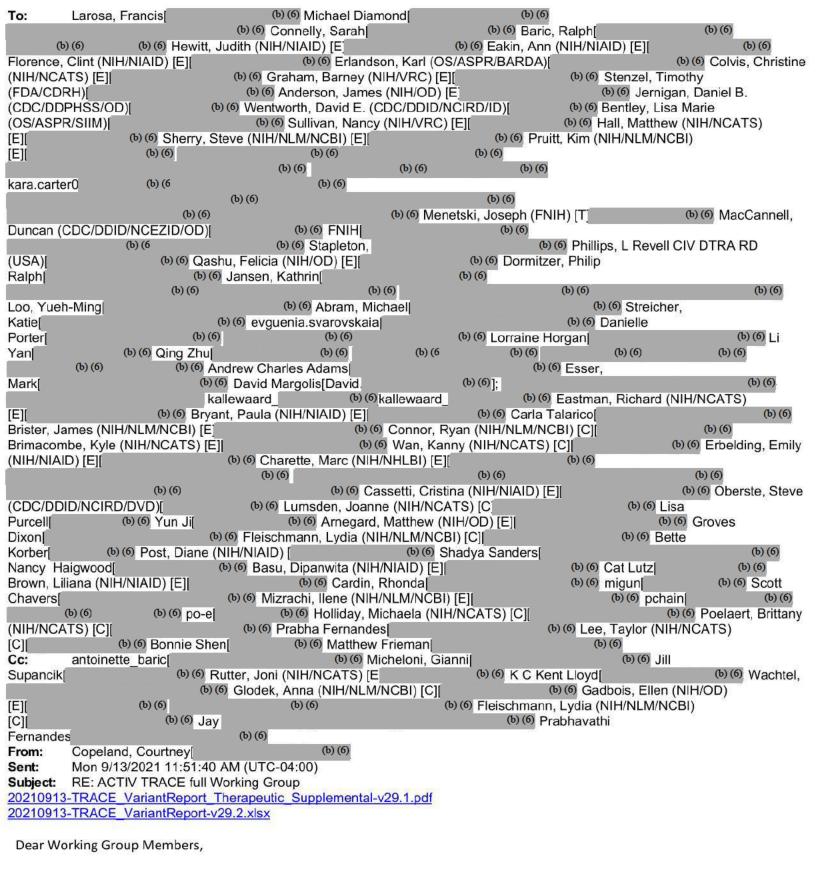


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6.	Review Papers and Meta-analyses	63

Max

		Reference (date)	Country	Design	Population	Dominant Variants	History of COVID	Vaccine Product	Outcome Measure	1st Dose VE % (95%CI)	Days post	2 nd Dose VE % (95% CI)	Days post 2nd dose	Duration of follow up after fully vaccinated																						
- [91	Thompson et al	USA	Test-negative	58,904 adults	Non-VOC,	Excluded	BNT162b2	Hospitalization	33 (18-46)	14+	87 (85-90)	14+	~22 weeks																						
		(September 8, 2021)		case control	aged 50+ with Covid-like illness	Alpha^††			Emergency department or urgent care visit	58 (46-68)		89 (85-91)																								
					who were			mRNA-1273	Hospitalization	68 (59-75)		91 (89-93)		20 weeks																						
					hospitalized or visited				Emergency department or urgent care visit	73 (64-79)		92 (89-94)																								
					emergency/ urgent care			Ad26.COV2.S	Hospitalization	68 (50-79)	1	-		14 weeks																						
					facilities				Emergency department or urgent care visit	73 (59-82)	1																									
								BNT162b2 & mRNA-1273	Hospitalization, patients with ≥ 1 chronic respiratory condition	56 (47-64)	88 (86-90) 86 (75-92)	90 (88-92)	14+ ~22	~22 weeks																						
									Hospitalization, patients with ≥ 1 chronic non- respiratory condition	54 (45-61)		88 (86-90)																								
									Hospitalization, Black patients	47 (10-69)		86 (75-92)																								
																															Hospitalization, Hispanic patients	56 (35-70)		90 (85-93)		
									Hospitalization, overall	-		88 (84-92)	14-27	~2 weeks																						
												86 (74-93)	112+	~22 weeks																						
									Emergency department or urgent care visit	-		92 (88-95)	14-27	~2 weeks																						
												86 (74-93)	112+	~22 weeks																						
Ì	90	Iliaki et al (September 6,	USA	Retrospective Cohort	4,317 HCWs	Alpha ^{††}	Excluded	BNT162b2 & mRNA-1273	Documented infection	80.2(57.5-90.8)	14+	95.2(80.0-98.8)	14+	~10 weeks																						
		2021)		Panel Harris				Ad26.COV2.S		95.5 (88.2-98.3)		-																								



Ahead of tomorrow's meeting, please find attached this week's TRACE report and supplemental figures.

Warm Regards,

Courtney

Courtney Copeland, Ph.D. (she/her/hers) Senior Consultant | Strategy and Analytics Deloitte Consulting LLP 200 Berkeley St 10th FI Boston, MA 02116

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----Original Appointment----

From: Copeland, Courtney

Sent: Friday, September 10, 2021 12:54 PM

To: Larosa, Francis;	(b) (6)		(р) (б) Сс	peland, Cour	tney; Connelly, Sarah	;
(b) (6);	(b) (6)	(b) (6)		(b) (6)	(b) (6)	(b) (6)
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	(b) (6)		(b)	(6) Menetsk	, Joseph (FNIH) [T]; N	1acCannell, Duncan
(CDC/DDID/NCEZID/OD); FN	IIH;	(b) (6) Sta	apleton, Jack; P	hillips, L Reve	ell CIV DTRA RD (USA)	; Qashu, Felicia
(NIH/OD) [E]; Dormitzer, Ph	ilip Ralph; Jansen,	Kathrin;		(b) (6)		(b) (6) Loo, Yue
Ming; Abram, Michael; Stre	icher, Katie;		(b) (6)		(b) (6)	(b) (6)
Lorraine Horgan; Li Yan; Qin	ng Zhu;	(b) (6)	(b) (6)	(b) (6) A	ndrew Charles Adams	s; Esser, Mark; David
Margolis;	((b) (6)		(b) (6) Eastma	n, Richard (NIH/NCAT	rs) [E];
(b) (6) Carl	a Talarico; Brister,	James (NIH/N	LM/NCBI) [E];		(b) (6) Brimacombe	e, Kyle (NIH/NCATS)
[E]; Wan, Kanny (NIH/NCAT	S) [C]; Erbelding, E	mily (NIH/NIA)	D) [E]; Charette	e, Marc (NIH)	NHLBI) [E];	(b) (6)
	(b) (6)		(b) (6) Cassetti,	Cristina (NIH	/NIAID) [E]; Oberste,	Steve
(CDC/DDID/NCIRD/DVD); Lu	ımsden, Joanne (N	IIH/NCATS) [C]	; Lisa Purcell; Yı	ın Ji; Arnegai	rd, Matthew (NIH/OD) [E]; Groves Dixon;
	(b) (6) 'Korber, Bet	te Tina Marie';	Post, Diane (N	IH/NIAID) [E]	; Shadya Sanders; Na	ncy Haigwood; Basu,
Dipanwita (NIH/NIBIB) [V]; (Cat Lutz; Brown, Li	liana (NIH/NIA	ID) [E]; Cardin,	Rhonda; Mig	un Shakya; Scott Cha	vers; Mizrachi, Ilene
(NIH/NLM/NCBI) [E];	(b) (6)	(b) (6)	(b) (6)		(b) (6)	(b) (6)
Prabha Fernandes; Lee, Tay	lor (NIH/NCATS) [0	C]; Bonnie Sher	1;		(b) (6)	
Cc: Baric, Toni C; Micheloni,	Gianni; Jill Supan	cik;	(p) (q) K C K	ent Lloyd; W	achtel, Jonathan;	(b) (6)
Gadbois, Ellen (NIH/OD) [E];	; kara.	(b) (6) Fleisc	hmann, Lydia (NIH/NLM/NC	BI) [C]; Jay Weixelbau	ım; Prabhavathi
Fernandes						
Subject: ACTIV TRACE full W	orking Group					
When: Tuesday, September	14, 2021 9:00 AM	1-10:00 AM (U	ГС-05:00) Easte	rn Time (US	& Canada).	

Hi everyone,

I am updating the meeting ownership.

Best,



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Passcode: (b) (6)

Phone one-tap: US: <u>+13126266799</u>, (b) (6) or <u>+16465189805</u>, (b) (6)

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Dial:	US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299
Meeting ID:	(b) (6)
Password:	(b) (6)
International numbers	
SIP:	(b) (6) @zoomcrc.com
Passcode:	(b) (6)

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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) <u>Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Tracking Resistance and Coronavirus Evolution (TRACE) Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at NCATSOpenDataPortal@nih.gov with any feedback, comments, or questions to help us improve this resource.</u>

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV TRACE, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- · From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the <u>OpenData Portal Visualization Page</u>
Additional details on the visualized data are available on the <u>NCATS OpenData Portal</u>.

New to the OpenData Portal Variant Database this week:

New Pre-prints and Publications:

- Neutralizing activity of sera from Sputnik V-vaccinated people against variants of concern (VOC: B.1.1.7, B.1.351, P.1, B.1.617.2, B.1.617.3) and Moscow Endemic SARS-CoV-2 variants [Peer-reviewed publication]
- 2. <u>Neutralizing antibody responses to SARS-CoV-2 variants in vaccinated Ontario long-term care home residents and workers [Pre-print]</u>
- 3. <u>Neutralization of alpha, gamma, and D614G SARS-CoV-2 variants by CoronaVac vaccine-induced antibodies [Peer-reviewed publication]</u>

Updated Pre-prints and Publications:

- 1. SARS-CoV-2 B.1.617.2 Delta variant replication and immune evasion [Peer-reviewed publication]
- 2. Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7): an exploratory analysis of a randomised controlled trial [Peer-reviewed publication]

Explore the latest Variants & Therapeutics data on OpenData Portal:

OpenData Portal | SARS-CoV-2 Variants & Therapeutics Therapeutic Activity Explorer Updated 09.10.21 98 data sources 3180 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

Click to explore variant data on OpenData Portal:

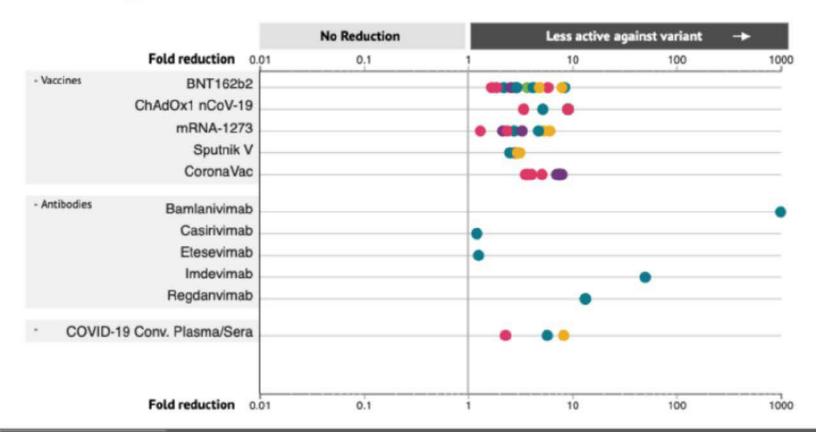
What's new in t	the last week?	Data for A	II Variants		
B.1.1.7	B.1.351	B.1.617.2	AY.1	AY.2	P.1
B.1.427/429	B.1.525	B.1.526	B.1.617	C.37	P.2
Other V	ariants	Single Point N	Mutation Data		





In vitro data added to NCATS OpenData Portal in last week







9.13.2021



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(b) (6) Connelly, Sarah
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To:
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(USA)
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Supancik
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[E][
                            (b) (6) Jay
                                                                                        (b) (6) Prabhavathi
(b) (6)
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From:
           Copeland, Courtney
           Fri 9/10/2021 3:21:00 PM (UTC-04:00)
Sent:
Subject:
           RE: ACTIV TRACE full Working Group
 Hi Everyone,
 At next Tuesdays full WG meeting, we will have invited speaker Matt Frieman Ph.D. present work using lung chips and transwell
 assays for SARS-CoV-2. We are looking forward to hearing about his research in complex organ models.
 Best,
 Courtney
 Courtney Copeland, Ph.D. (she/her/hers)
 Senior Consultant | Strategy and Analytics
 Deloitte Consulting LLP
```

200 Berkeley St 10th FI Boston, MA 02116

(b) (6) | Mobile:

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(b) (6)

Tel/Direct:

----Original Appointment----From: Copeland, Courtney

Sent: Friday, September 10, 2021 12:54 PM

To: Larosa, Francis; Copeland, Co	ourtney; Connelly	, Sarah;	(b) (6)		(b) (6) (b) (6)	1
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Margolis;	(b) (6)		(b) (6) Eas	stman, Richard	(NIH/NCATS) [E];	
(b) (6) Carla Tala	arico; Brister, Jam	es (NIH/NLM/NCI	3I) [E];	(b) (6) Br	imacombe, Kyle (N	IH/NCATS)
[E]; Wan, Kanny (NIH/NCATS) [C]	; Erbelding, Emily	(NIH/NIAID) [E];	Charette, Marc (NIH/NHLBI) [E];		(b) (6)
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(CDC/DDID/NCIRD/DVD); Lumsd	en, Joanne (NIH/I	NCATS) [C]; Lisa Pu	ırcell; Yun Ji; Arn	egard, Matthew	v (NIH/OD) [E]; Gro	ves Dixon;
(b) (6	Korber, Bette T	ina Marie'; Post, [Diane (NIH/NIAID) [E]; Shadya Sa	nders; Nancy Haig	wood; Basu,
Dipanwita (NIH/NIBIB) [V]; Cat Li	utz; Brown, Lilian:	a (NIH/NIAID) [E];	Cardin, Rhonda;	Migun Shakya;	Scott Chavers; Miz	rachi, Ilene
(NIH/NLM/NCBI) [E];	(b) (6)	b) (6)	(6)	(b) (6)		(b) (6)
Prabha Fernandes; Lee, Taylor (N	IIH/NCATS) [C]; B	onnie Shen;		(b) (6)		
Cc: Baric, Toni C; Micheloni, Giar	ıni; Jill Supancik;	(b)	6 K C Kent Lloy	d; Wachtel, Jona	ethan;	(b) (6)
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Fernandes						
Subject: ACTIV TRACE full Working	ng Group					
When: Tuesday, September 14, 3	2021 9:00 AM-10	:00 AM (UTC-05:0	0) Eastern Time	(US & Canada).		
Where: https://deloitte.zoom.us	;/j, (b) (6)	pwd=dGZ6UIVFcI	5RYmdLcjlxYmR	kdlRWQT09		
Hi everyone,						
Lam undating the meeting owner	rchin					

I am updating the meeting ownership.

Best,



Join Meeting

Passcode: (b) (6)

Phone one-tap: US: +13126266799,, (b) (6) or +16465189805, (b) (6)

Join by Telephone Dial: US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299 Meeting ID: (b) (6) Password: (b) (6) International numbers SIP: (b) (6) @zoomcrc.ccm

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Passcode:

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From:
                      Copeland, Courtney
Location:
                      https://deloitte.zoom.us/j/94985082196?pwd=cmR3dWo2ekZBK3k5Z2x2MIRRSFpEdz09
Importance:
                      Normal
Subject:
                      Canceled: ACTIV TRACE full Working Group
Start Time:
                      Tue 9/14/2021 9:00:00 AM (UTC-04:00)
                      Tue 9/14/2021 10:00:00 AM (UTC-04:00)
End Time:
                      Connelly, Sarah; Baric, Ralph; Michael Diamond;
Required Attendees:
                                                                           (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann
                      (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine
                      (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD)
                      [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                      (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                      (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
                                                         (b)(6)
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                      MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH;
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                      Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin;
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                      Katie; evguenia.svarovskaia; Danielle Porter;
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                      Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                      (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
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                                             (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD);
                      Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                      Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                      Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
                      Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
                                                                                      (b) (6) po-e; Holliday, Michaela
                      (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor
                      (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman
                      antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel,
Optional Attendees:
                      Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];
 Hi everyone,
 I am updating the meeting ownership.
 Best,
 Courtney
                                     Connelly, Sarah; Baric, Ralph; Michael Diamond;
        Required Attendees:
            (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl
      (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy
      (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E.
     (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew
       (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
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                                                                   (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD
 Duncan (CDC/DDID/NCEZID/OD); FNIH;
     (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin;
                               (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, Katie; evguenia.svarovskaia; Danielle
                                                                                                   (b) (6)
                                                                                                                     (b) (6)
                           (b) (6): Lorraine Horgan; Li Yan; Oing Zhu;
                                                                                 (b) (6)
  Porter:
              Andrew Charles Adams; Esser, Mark; David Margolis;
                             (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico;
   Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E];
          Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];
                                                               (b) (6)
                                                                                              (b) (6) Cassetti, Cristina
  (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun
   Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post,
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Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; 6) 6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman



Join Meeting

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Phone one-tap:	US: +13126266799 (b) (6) or +16465189805 (b) (6)
Join by Telephone	
Join by Telephone	
Dial:	US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299
Meeting ID:	(b) (6)
Password:	(b) (6)
International numbers	
SIP:	(b) (6) @zoomcrc.com
Passcode:	(b) (6)

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From:	Copeland, Courtney (b) (6)
Location:	https://deloitte.zoom.us/j/94985082196?pwd=cmR3dWo2ekZBK3k5Z2x2MIRRSFpEdz09
Importance:	Normal
Subject:	Canceled: ACTIV TRACE full Working Group
Start Time:	Tue 9/14/2021 9:00:00 AM (UTC-04:00)
End Time:	Tue 9/14/2021 10:00:00 AM (UTC-04:00)
Required Attendees:	Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NIAID) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OE) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Mari (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Km (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (c) (d) (e) (f) (f) (f) (f) (f) (f) (f) (f) (f) (f
	Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman
Optional Attendees:	antoinette_baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]; 6) (6)
Hi everyone,	

I am updating the meeting ownership.

Best,

Courtney

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v.E.1

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(b) (6)
From:
                       Copeland, Courtney
                                                                               (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann
Attendees:
                       Connelly, Sarah; Baric, Ralph; Michael Diamond;
                       (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine
                       (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD)
                       [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                       (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                       (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
                                                               (b) (6)
                                                            (b)(6)
                                                                                               (b) (6) Menetski, Joseph (FNIH) [T];
                       MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH;
                                                                                                (b) (6) Stapleton, Jack; Phillips, L
                       Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin;
                                                  (b)(6)
                                                                                  (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher,
                                                                                    (b) (6) Lorraine Horgan; Li Yan; Qing Zhu;
                       Katie; evguenia.svarovskaia; Danielle Porter;
                                                   (b)(6)
                                                                    (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis;
                                 (b) (6)
                                                                                      (b) (6) Eastman, Richard (NIH/NCATS) [E];
                                                        (b) (6); kallewaard
                       Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                       (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
                       (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];
                                                                                          (b)(6)
                                                                                                                              (b)(6)
                                               (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD);
                       Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                       Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                       Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
                       Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
                                                                                           (b) (6) po-e; Holliday, Michaela
                       (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor
                       (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter,
                       Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen
                                                        (b) (6)
                       (NIH/OD) [E];
Location:
                       https://deloitte.zoom.us/j
                                                          (b) (6) pwd=dGZ6UIVFcE5RYmdLcilxYmRkdIRWQT09
Importance:
                       Normal
Subject:
                       ACTIV TRACE full Working Group
Start Time:
                       Tue 9/14/2021 9:00:00 AM (UTC-04:00)
End Time:
                       Tue 9/14/2021 10:00:00 AM (UTC-04:00)
Required Attendees:
                       Connelly, Sarah; Baric, Ralph; Michael Diamond;
                                                                                (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann
                       (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine
                       (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD)
                       [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                        (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                       (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
                                          (b) (6)
                                                               (b)(6)
                                                            (b)(6)
                                                                                              (b) (6) Menetski, Joseph (FNIH) [T];
                       MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH;
                                                                                                (b) (6) Stapleton, Jack; Phillips, L
                       Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin;
                                                  (b)(6)
                                                                                  (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher,
                                                                                    (b) (6) Lorraine Horgan; Li Yan; Qing Zhu;
                       Katie; evguenia.svarovskaia; Danielle Porter;
                                 (b)(6)
                                                                    (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis;
                                                   (b)(6)
                                                         (b)(6)
                                                                                      (b) (6) Eastman, Richard (NIH/NCATS) [E];
                       Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                       (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
                       (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];
                                                                                          (b)(6)
                                               (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD);
                       Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                       Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                       Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
                       Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
                                                                                           (b) (6) po-e; Holliday, Michaela
                       (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor
                       (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman
Optional Attendees:
                       antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel,
                       Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];
Calendar Exception:
                       Untitled
```

(b)(6)

Organizer:

Hi everyone,

Copeland, Courtney

I am updating the meeting ownership.

Best,



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Join by Telephone

Dial: US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299

Meeting ID: (b) (6)

Password: (b) (6)

International numbers

SIP: (b) (6) @zoomcrc.com

Passcode: (b) (6)

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Organizer: Copeland, Courtney Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b)(6)(b) (6); (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)(b) (6) Lorraine Horgan; Li Yan; Qing Zhu; Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; Shakya, Migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; Kijak, Gustavo; Hatcher, Eneida (NIH/NLM/NCBI) [C]; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Jay Weixelbaum; Prabhavathi Fernandes; Philip J Ebert Start Time: Tue 9/28/2021 9:00:00 AM (UTC-04:00) End Time: Tue 9/28/2021 10:00:00 AM (UTC-04:00) Required Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b) (6) (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Andrew Charles Adams; Esser, Mark: David Margolis: (b) (6) (b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; Kijak, Gustavo; Hatcher, Eneida (NIH/NLM/NCBI) [C] Optional Attendees: antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]; (b) (6) Jay Weixelbaum; Prabhavathi Fernandes; Philip J Ebert

20210927-TRACE_VariantReport-v31.1.xlsx

20210927-TRACE VariantReport Therapeutic Supplemental-v31.1.pdf

Hi everyone,



Join Meeting

Passcode: (b) (6) (b) (6) or +16465189805... Phone one-tap: US: +13126266799, Join by Telephone US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299 Dial: (b) (6) Meeting ID: Password: (b)(6)International numbers SIP: (b) (6) @zoomcrc.com

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(b) (6)





How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) <u>Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Tracking Resistance and Coronavirus Evolution (TRACE) Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at with any feedback, comments, or questions to help us improve this resource.</u>

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV TRACE, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- · From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the OpenData Portal Visualization Page Additional details on the visualized data are available on the NCATS OpenData Portal.

New to the OpenData Portal Variant Database this week:

New Pre-prints, Publications & Datasets:

- 1. Remdesivir antiviral activity against SARS-CoV-2 variants of interest and variants of concern [Directly submitted data]
- AZD7442: AZD8895 (tixagevimab) and AZD1061 (Cilgavimab) mAbs for SARS-CoV-2 Antiviral Resistance Information [Directly submitted data]
- 3. Safety and immunogenicity of SARS-CoV-2 variant mRNA vaccine boosters in healthy adults; an interim analysis [Journal Article]
- 4. Clinical Results with a B Cell Activating Anti-CD73 Antibody for the Immunotherapy of COVID-19 [Journal Article]

Updated Pre-prints and Publications:

1. Antibody evasion by the P.1 strain of SARS-CoV-2 [Journal Article]



Explore the latest Variants & Therapeutics data on OpenData Portal:

OpenData Portal | SARS-CoV-2 Variants & Therapeutics

Summary

Updated 09.24.21

105 data sources 4103 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

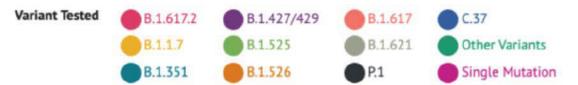
Click to explore variant data on OpenData Portal:

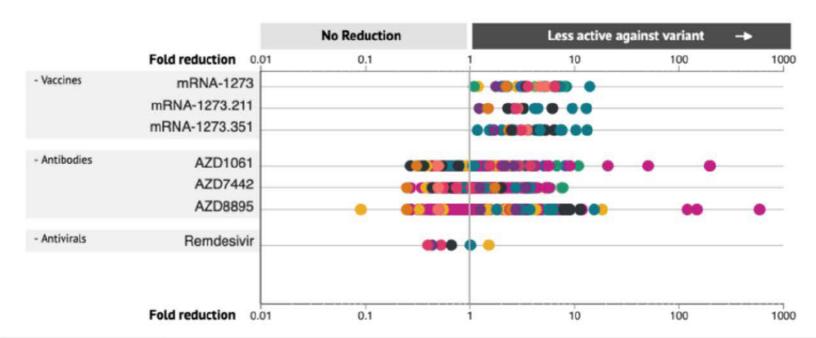
What's new in the last week? Data for All Variants B.1.617.2 AY.1/2 P.1 B.1.1.7 B.1.351 B.1.621 B.1.427/429 B.1.525 B.1.526 B.1.617 C.37 P.2 Other Variants Single Point Mutation Data





In vitro data added to NCATS OpenData Portal in last week







9.27.2021



Copeland, Courtney Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) jay (b) (6) (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6) (b) (6): (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (b)(6)(NIH/OD) [E]; Location: https://deloitte.zoom.us/j/ (b) (6) ?pwd=dGZ6UIVFcE5RYmdLcjIxYmRkdIRWQT09 Importance: Normal Subject: ACTIV TRACE full Working Group Start Time: Tue 9/14/2021 9:00:00 AM (UTC-04:00) Tue 9/14/2021 10:00:00 AM (UTC-04:00) End Time: Required Attendees: Connelly, Sarah: Baric, Ralph: Michael Diamond: (b) (6) Hewitt, Judith (NIH/NIAID) [E1: Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b)(6)(b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) (b) (6); (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood: Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; (b) (6) po-e; Holliday, Michaela Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Optional Attendees: Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];

I am updating the meeting ownership.

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From:



Join Meeting

Passcode: (b) (6)

Phone one-tap: US: <u>+13126266799</u>, (b) (6) or <u>+16465189805</u>, (b) (6)

Join by Telephone

Dial: US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299

Meeting ID: (b) (6)

Password: (b) (6)

International numbers

SIP: (b) (6) @zoomcrc.com

Passcode: (b) (6)

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Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b) (6) (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6) (b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (b) (6) (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]; Location: https://deloitte.zoom.us/j (b) (6) pwd=cmR3dWo2ekZBK3k5Z2x2MIRRSFpEdz09 Importance: Normal Subject: ACTIV TRACE full Working Group Start Time: Tue 9/14/2021 9:00:00 AM (UTC-04:00) Tue 9/14/2021 10:00:00 AM (UTC-04:00) End Time: Required Attendees: Connelly, Sarah: Baric, Ralph: Michael Diamond: (b) (6) Hewitt, Judith (NIH/NIAID) [E1: Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b)(6)(b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) (b) (6) (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood: Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; (b) (6) po-e; Holliday, Michaela Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Optional Attendees: Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];

I am updating the meeting ownership.

Hi everyone,

From:

Copeland, Courtney



Join Meeting

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Phone one-tap:	US: <u>+13126266799</u> , (b) (6) or <u>+16465189805</u> , (b) (6)
Join by Telephone	
Dial:	US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299
Meeting ID:	(b) (6)
Password:	(b) (6)
International numbers	
SIP:	(b) (6)
Passcode:	(b) (6)

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(b) (6) Baric, Ralph
                                                                                        (b) (6) Michael Diamond[
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To:
           Connelly, Sarah
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                       (b) (6) Hewitt, Judith (NIH/NIAID) [E][
                                                                              (b) (6); Eakin, Ann (NIH/NIAID) [E][
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Florence, Clint (NIH/NIAID) [E][
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(NIH/NCATS) [E]
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(OS/ASPR/SIIM)
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Duncan (CDC/DDID/NCEZID/OD)
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                                                                                 (b) (6) Dormitzer, Philip
(USA)
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Ralph
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Loo, Yueh-Ming
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Katie[
                                     (b) (6) evguenia.svarovskaia
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                    (b) (6) Qing Zhul
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                                  (b) (6) David Margolis
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Mark
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                                                                                           (b) (6) Eastman, Richard (NIH/NCATS)
                          (b) (6) Bryant, Paula (NIH/NIAID) [E]
                                                                                   (b) (6) Carla Talarico
[E][
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Brister, James (NIH/NLM/NCBI) [E][i
                                                   (b) (6).nih.gov]; Connor, Ryan (NIH/NLM/NCBI) [C][
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Brimacombe, Kyle (NIH/NCATS) [E]
                                                              (b) (6) Wan, Kanny (NIH/NCATS) [C]
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(CDC/DDID/NCIRD/DVD)[
                                           (b) (6) Lumsden, Joanne (NIH/NCATS) [C][]
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Purcell
                    (b) (6) Yun Ji
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Dixon
                                   (b) (6) Fleischmann, Lydia (NIH/NLM/NCBI) [C]
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                 (b) (6) Post, Diane (NIH/NIAID) [E][
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Korberl
                                                                     (b) (6); Shadya Sanders
                                     (b) (6) Basu, Dipanwita (NIH/NIAID) [E]
Nancy Haigwood
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Brown, Liliana (NIH/NIAID) [E]
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Chavers[
                                      (b) (6) Mizrachi, Ilene (NIH/NLM/NCBI) [E]
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                                         (b) (6) Prabha Fernandes
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Francis
                          (b) (6) Lee, Taylor (NIH/NCATS) [C]
                                                                               (b) (6) Bonnie Shen[
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           antoinette baric[
                                                                                                            (b) (6) Jill
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                                                                                                                             (b) (6) Wachtel,
Supancik
                                                                                  (b) (6) K C Kent Lloyd
                                  (b) (6) Glodek, Anna (NIH/NLM/NCBI) [C][
                                                                                               (b) (6) Gadbois, Ellen (NIH/OD)
                      (b)(6)
[E][
From:
           Copeland, Courtney
           Thur 9/9/2021 10:22:49 AM (UTC-04:00)
Sent:
           RE: CORRECTION ACTIV TRACE full Working Group
Subject:
20210907 ACTIV TRACE WG Meeting Summary vF.pdf
 Hi Everyone,
 Apologies, it was recently pointed out that I accidently attached the wrong set of notes to my email earlier. Attached please find
 the notes from our WG meeting on Tuesday and let us know if you all have any additions or amendments.
 Best,
 Courtney
 Courtney Copeland, Ph.D. (she/her/hers)
 Senior Consultant | Strategy and Analytics
 Deloitte Consulting LLP
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(b) (6)

200 Berkeley St 10th FI Boston, MA 02116
Tel/Direct: (b) (6) Mobile: (b) (6) | www.deloitte.com

From: Copeland, C	ourtney								
Sent: Thursday, Se	ptember 9, 2	.021 9:40 AM							
To: Connelly, Sarah	1 <	(b) (6)		(b) (6);		(b) (6)	(b) (6)		
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Subject: RE: ACTIV TRACE full Working Group

Dear Working Group Members,

Please find attached this week's TRACE report and supplemental figures and a summary of the Variant Prioritization Subgroup Meeting from Tuesday.

Warm Regards,

Courtney

Courtney Copeland, Ph.D. (she/her/hers) Senior Consultant | Strategy and Analytics Deloitte Consulting LLP 200 Berkeley St 10th FI Boston, MA 02116 Tel/Direct: (b) (6) Mobile: (b) (6) | www.deloitte.com

----Original Appointment----From: Connelly, Sarah < (b)(6)Sent: Friday, August 20, 2021 4:49 PM To: Connelly, Sarah; (b) (6) (b)(6)(b)(6)(b)(6)(b) (6) (b) (6) (b)(6)(b)(6)(b) (6) (b) (6) (b)(6)(b) (6) (b) (6) (b) (6) (b) (6) (b)(6)(b)(6)(b)(6)(b)(6)(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; (b) (6) Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b) (6) (b) (6) (b) (6); Lorraine Horgan; Li Yan; Qing Zhu; Katie; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6) (b) (6) (b) (6) Carla (b) (6); Eastman, Richard (NIH/NCATS) [E]; Talarico; Brister, James (NIH/NLM/NCBI) [E]; (b) (6) Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Bette Tina Marie'; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIBIB) [V]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; Migun Shakya; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; (b) (6) (b) (6) (b) (6) Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney; (b)(6)

Gadbois, Ellen (NIH/OD) [E]

Subject: Canceled: ACTIV TRACE full Working Group

Cc: Baric, Toni C; Micheloni, Gianni; Jill Supancik;

When: Tuesday, September 7, 2021 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada). Where: https://deloitte.zoom.us/j/ (b) (6) ?pwd=OFVIditub2M4V1hLckpHL2tzL0pXZz09

Updating the meeting name

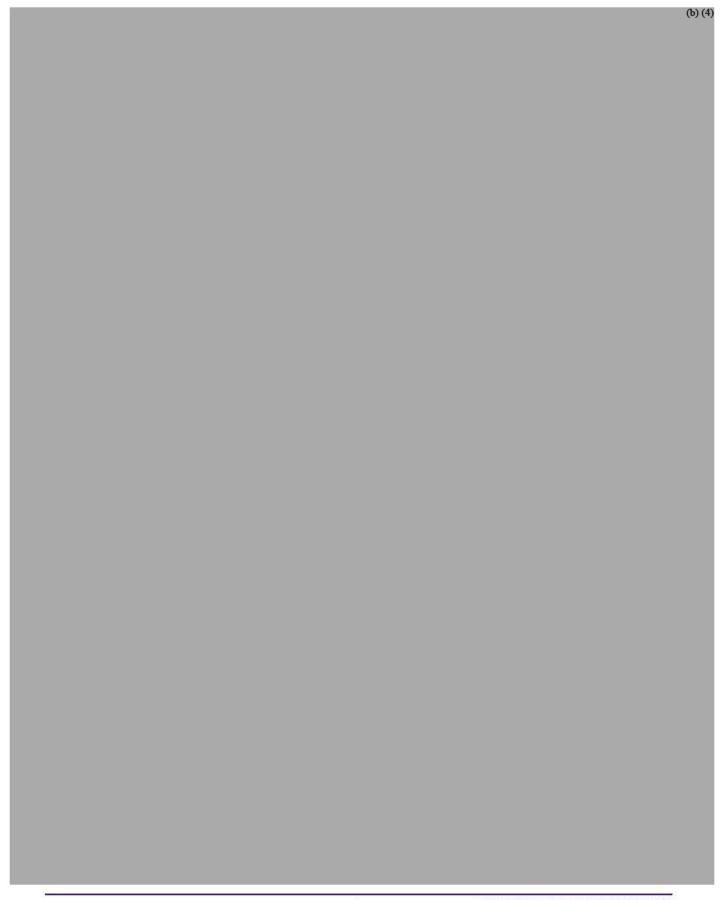
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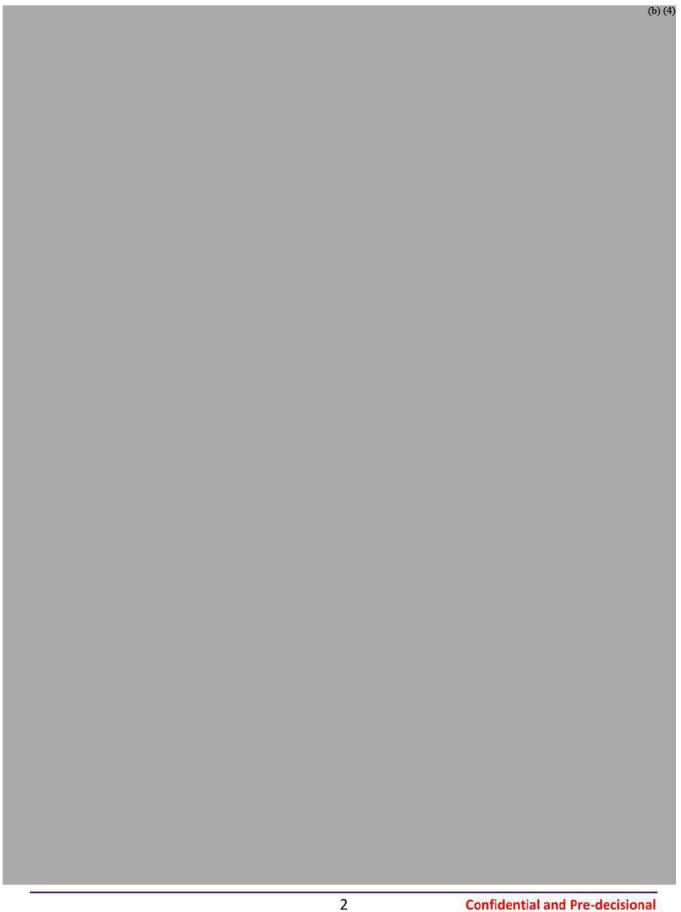
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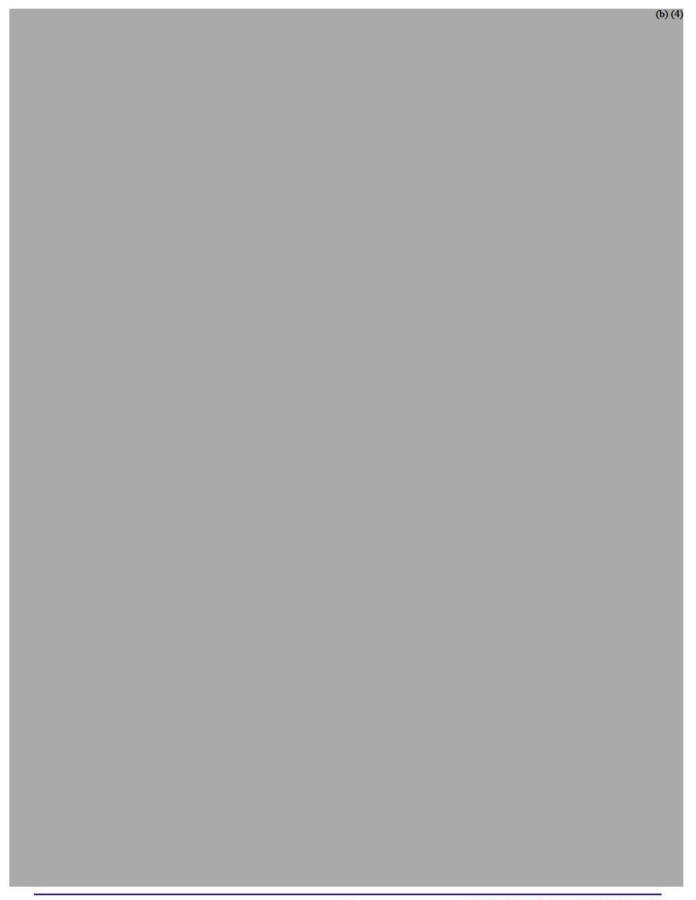
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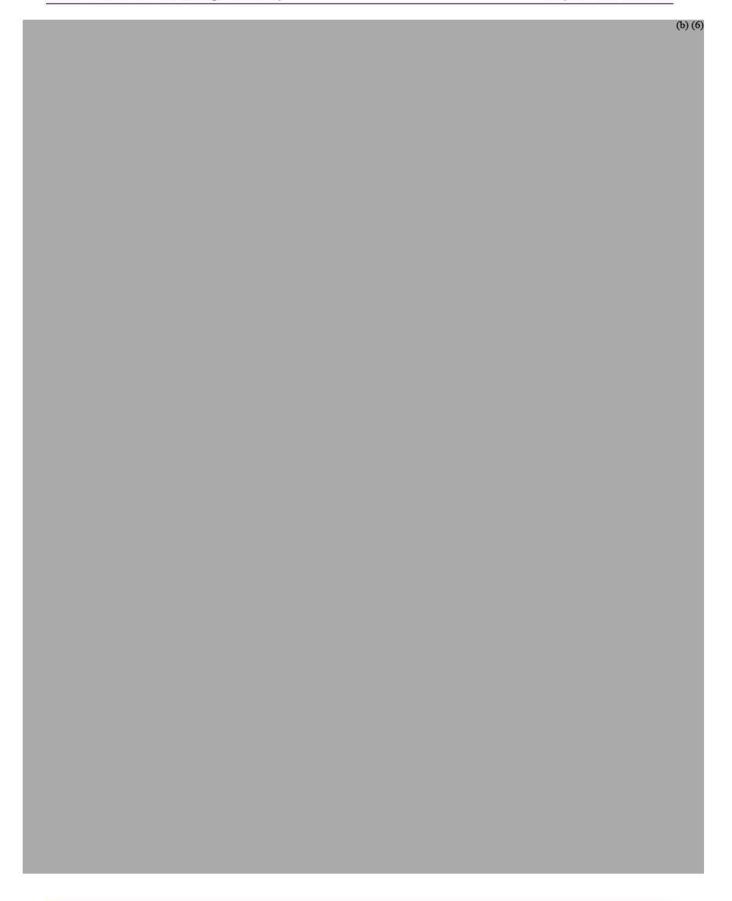




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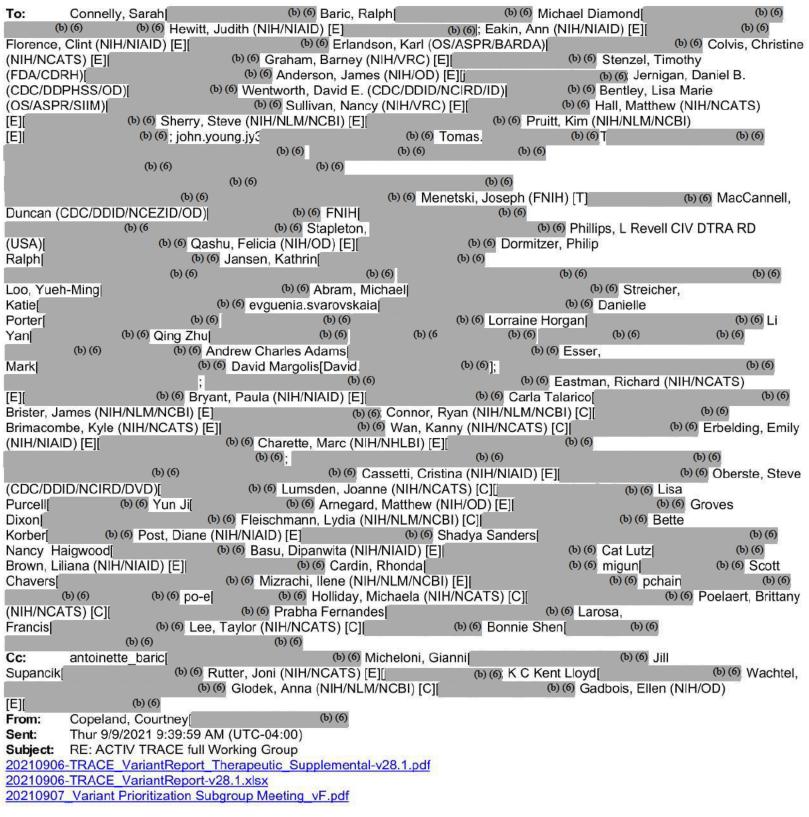






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Dear Working Group Members,

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Warm Regards,

Courtney

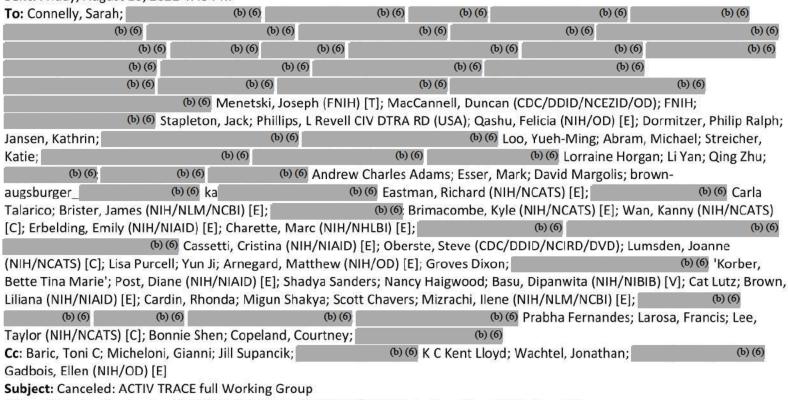
Courtney Copeland, Ph.D. (she/her/hers) Senior Consultant | Strategy and Analytics Deloitte Consulting LLP 200 Berkeley St 10th FI Boston, MA 02116

Tel/Direct:	(b) (6) Mobile:	(b) (6)
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-----Original Appointment-----

From: Connelly, Sarah < (b) (6)

Sent: Friday, August 20, 2021 4:49 PM



When: Tuesday, September 7, 2021 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: https://deloitte.zoom.us/ (b) (6) pwd=OFVIditub2M4V1hLckpHL2tzL0pXZz09

Updating the meeting name

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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Preclinical Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at MCATSOpenDataPortal@nih.gov with any feedback, comments, or questions to help us improve this resource.

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- · With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the OpenData Portal Visualization Page Additional details on the visualized data are available on the NCATS OpenData Portal.

New to the OpenData Portal Variant Database this week:

New Pre-prints and Publications:

1. <u>Durability of antibody responses elicited by a single dose of Ad26.COV2.S and substantial increase following late boosting [Pre-print]</u>

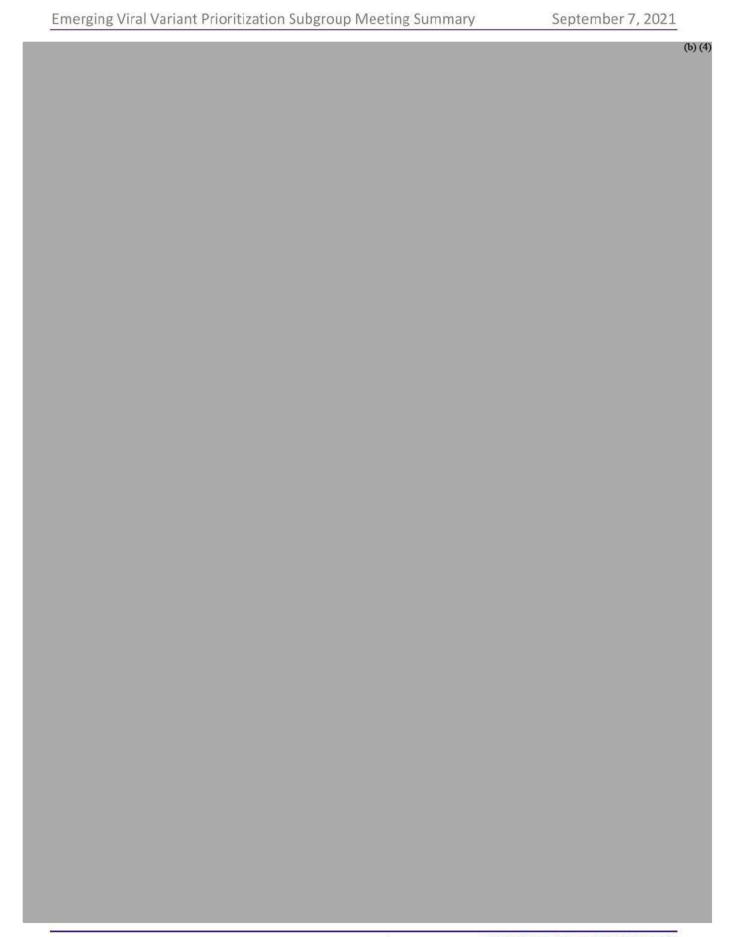
Explore the latest Variants & Therapeutics data on OpenData:



Click to explore variant data on OpenData Portal:

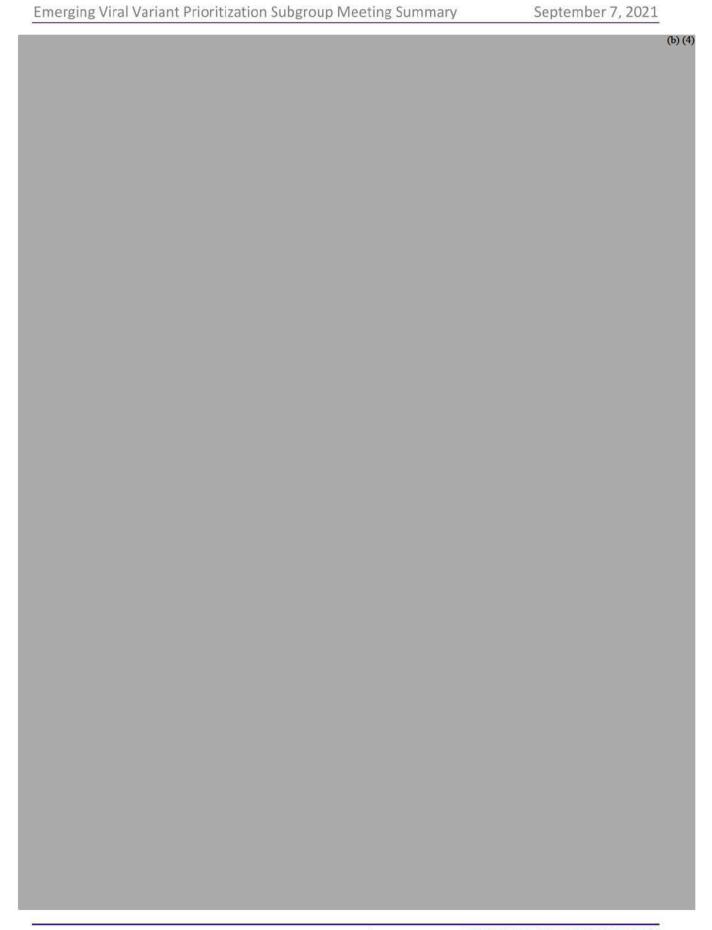
What's new in the last week?		Data for All Variants			
B.1.1.7	B.1.351	B.1.617.2	AY.1	AY.2	P.1
B.1.427/429	B.1.525	B.1.526	B.1.617	C.37	P.2
Other Variants		Single Point M	Mutation Data		







Emerging Viral Variant Prioritization Subgroup Meeting Summary	September 7, 2021
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Emerging Viral Variant Prioritization Subgroup Meeting Summary	September 7, 2021	
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Emerging Viral Variant Prioritization Subgroup Meeting Summary September 7, 2021	
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Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b) (6) (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6) (b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]; Location: https://deloitte.zoom.us/j (b) (6) pwd=cmR3dWo2ekZBK3k5Z2x2MIRRSFpEdz09 Importance: Normal Subject: ACTIV TRACE full Working Group Start Time: Tue 9/14/2021 9:00:00 AM (UTC-04:00) Tue 9/14/2021 10:00:00 AM (UTC-04:00) End Time: Required Attendees: Connelly, Sarah: Baric, Ralph: Michael Diamond: (b) (6) Hewitt, Judith (NIH/NIAID) [E1: Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b)(6)(b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) (b) (6) (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood: Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; (b) (6) po-e; Holliday, Michaela Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Optional Attendees: Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];

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Hi everyone,

From:

Copeland, Courtney



Join Meeting

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Join by Telephone	
Dial:	US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299
Meeting ID:	(b) (6)
Password:	(b) (6)
International numbers	
SIP:	(b) (6)
Passcode:	(b) (6)

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Copeland, Courtney Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b) (6) (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6) (b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (b)(6)(NIH/OD) [E]; Location: https://deloitte.zoom.us/j (b) (6) pwd=cmR3dWo2ekZBK3k5Z2x2MIRRSFpEdz09 Importance: Normal Subject: ACTIV TRACE full Working Group Start Time: Tue 9/14/2021 9:00:00 AM (UTC-04:00) Tue 9/14/2021 10:00:00 AM (UTC-04:00) End Time: Required Attendees: Connelly, Sarah: Baric, Ralph: Michael Diamond: (b) (6) Hewitt, Judith (NIH/NIAID) [E1: Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b)(6)(b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) (b)(6)(b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood: Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; (b) (6) po-e; Holliday, Michaela Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Optional Attendees: Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];

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From:



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Join by Telephone	
Dial:	US: +1 312 626 6799 or +1 646 518 9805 or +1 213 338 8477 or +1 720 928 9299
Meeting ID:	(b) (6)
Password:	(b) (6)
International numbers	
SIP:	(b) (6)
Passcode:	(b) (6)

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From:
                      Connelly, Sarah
                                                       (b) (6)
Location:
                      https://deloitte.zoom.us/j/
                                                      (b) (6) pwd=OFVIditub2M4V1hLckpHL2tzL0pXZz09
Importance:
                      Normal
                      Canceled: ACTIV TRACE full Working Group
Subject:
Start Time:
                      Tue 9/14/2021 9:00:00 AM (UTC-04:00)
                      Tue 9/14/2021 10:00:00 AM (UTC-04:00)
End Time:
Required Attendees:
                      Baric, Ralph; Michael Diamond;
                                                           (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E];
                      Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E];
                      Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan,
                      Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                      (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                      (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
                                                        (b)(6)
                                                                                        (b) (6) Menetski, Joseph (FNIH) [T];
                      MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH;
                                                                                          (b) (6) Stapleton, Jack; Phillips, L
                      Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin;
                                               (b) (6)
                                                                             (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher,
                                                                               (b) (6) Lorraine Horgan; Li Yan; Qing Zhu;
                      Katie; evguenia.svarovskaia; Danielle Porter;
                                                               (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis;
                                                                                (b) (6) Eastman, Richard (NIH/NCATS) [E];
                      Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                      (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
                                                                                                                      (b) (6)
                      (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];
                                            (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD);
                      Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                      Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                      Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
                      Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
                                                                                     (b) (6) po-e; Holliday, Michaela
                      (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor
                      (NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney; Matthew Frieman
                      antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel,
Optional Attendees:
                      Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];
 Updating the meeting name
                             Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann
 Required Attendees:
       (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine
  (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E];
      Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
  (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI)
       [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
                                                                                                       (b)(6)
                                 (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD);
                            (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E];
 FNIH;
  Dormitzer, Philip Ralph; Jansen, Kathrin;
                                                                                                         (b) (6) Loo, Yueh-
                                                                                                   (b) (6) Lorraine Horgan;
 Ming; Abram, Michael; Streicher, Katie; evguenia.svarovskaia; Danielle Porter;
                                                                     (b) (6) Andrew Charles Adams; Esser, Mark; David
    Li Yan; Qing Zhu;
                                                    (b) (6)
                                                                              (b) (6) Eastman, Richard (NIH/NCATS) [E];
  Margolis;
 Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI)
     [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E];
                                                                    (b)(6)
              Charette, Marc (NIH/NHLBI) [E];
                          (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden,
  Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia
      (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu,
     Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers;
                                                            (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert,
   Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
 Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Copeland,
                                               Courtney; Matthew Frieman
 Optional Attendees:
                             antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent
 Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];
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Password: (b) (6)

International numbers

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From: Connelly, Sarah (b) (6) Location: https://deloitte.zoom.us/ (b) (6) pwd=OFVIditub2M4V1hLckpHL2tzL0pXZz09 Normal Importance: Subject: Canceled: ACTIV TRACE full Working Group Start Time: Tue 1/5/2021 10:00:00 AM (UTC-04:00) **End Time:** Tue 1/5/2021 11:00:00 AM (UTC-04:00) Required Attendees: Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; jay (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (b) (6) (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD);

Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;

Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor

(NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney; (b) (6)

Optional Attendees: antoinette_baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel,

Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]

Updating the meeting name

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Copeland, Courtney Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b) (6) (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b) (6) (b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (b)(6)(NIH/OD) [E]; Location: https://deloitte.zoom.us/j (b) (6) pwd=cmR3dWo2ekZBK3k5Z2x2MIRRSFpEdz09 Importance: Normal Subject: ACTIV TRACE full Working Group Start Time: Tue 9/14/2021 9:00:00 AM (UTC-04:00) Tue 9/14/2021 10:00:00 AM (UTC-04:00) End Time: Required Attendees: Connelly, Sarah: Baric, Ralph: Michael Diamond: (b) (6) Hewitt, Judith (NIH/NIAID) [E1: Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b)(6)(b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b)(6)Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) (b)(6)(b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood: Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; (b) (6) po-e; Holliday, Michaela Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Optional Attendees: Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];

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From:

Best,



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(b) (6) From: Copeland, Courtney (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b)(6)(b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b) (6) kallewaard_ brown-augsburger patricia (b) (6) Eastman, Richard (NIH/NCATS) [E]; Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b)(6)(b)(6)(b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood: Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman; antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (b)(6)(NIH/OD) [E]: | Location: https://deloitte.zoom.us/j/ (b) (6)?pwd=cmR3dWo2ekZBK3k5Z2x2MIRRSFpEdz09 Importance: Normal Subject: Canceled: ACTIV TRACE full Working Group Start Time: Tue 9/14/2021 9:00:00 AM (UTC-04:00) End Time: Tue 9/14/2021 10:00:00 AM (UTC-04:00) Required Attendees: Connelly, Sarah; Baric, Ralph; Michael Diamond; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan, Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3; (b) (6) (b)(6)jay (b)(6)(b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin; (b) (6) (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; Katie; evguenia.svarovskaia; Danielle Porter; (b) (6) (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; (b)(6)(b)(6)(b) (6) Eastman, Richard (NIH/NCATS) [E]: Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain; (b) (6) po-e; Holliday, Michaela (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C]; Bonnie Shen; Matthew Frieman antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Optional Attendees: Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];

(b)(6)

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Hi everyone,

Organizer:

Copeland, Courtney

Best,

Courtney

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Hi everyone,

From:

Copeland, Courtney

Best,



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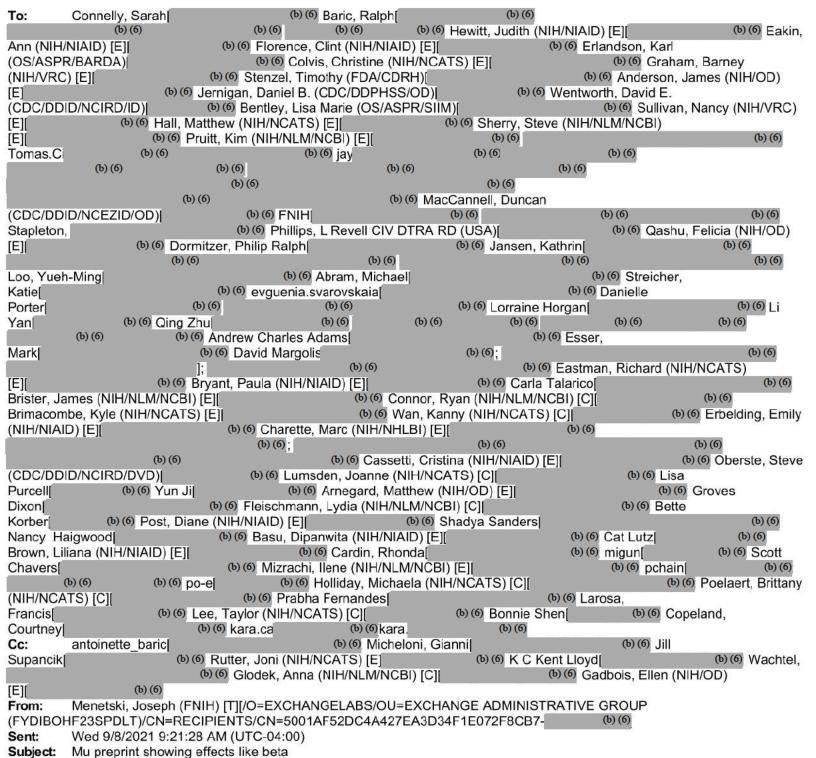
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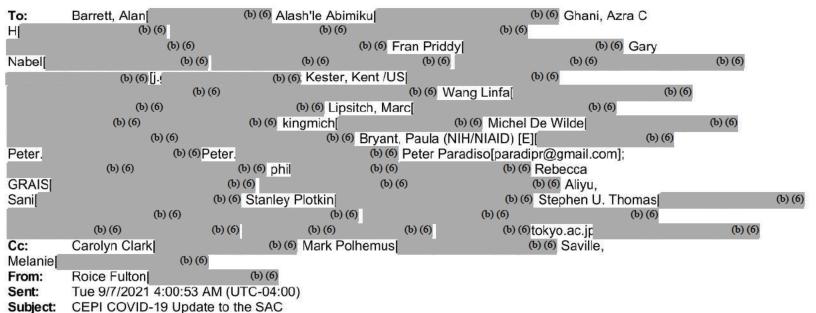
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Dear CEPI SAC members,

Please see the below COVAX update from Richard Hatchett. These reports are sent out regularly to CEPI governance and advisory bodies; SAC members may expect to receive these updates going forward.

Best,

Roice for the SAC Support Team

- COVAX deliveries continue to suffer from delays, in large part due to regulatory challenges with Clover and Novavax, and export
 restrictions impacting AstraZeneca/SII, Novavax, and Johnson & Johnson. In this context, a revised supply forecast is being developed
 and is anticipated to be communicated to participating economies and published in the first half of September.
- COVAX is developing its 2022 strategy, building on the WHO global vaccination strategy and scenarios. Dedicated workshops and
 targeted working sessions will culminate in deliverables in mid-September which will define the scope and role for COVAX in 2022 and
 each partner's contribution. A discussion on COVID/COVAX including the strategy, and CEPI's R&D objectives will be held at CEPI's
 September Board.

Announcements

- On 17th August CEPI announced a <u>funding agreement of up to \$20.6Mn with Gritstone bio</u> to support the development of a self-amplifying mRNA vaccine candidate against COVID-19 variants. This funding forms part of CEPI's programme to develop 'next generation' COVID-19 vaccines that are differentiated from those already in advanced development and can be used against variants.
- On 30th August CEPI partner SK Biosciences initiated a Ph3 clincial trial to compare their protein-based adjuvanted COVID-19 vaccine to the AstraZeneca COVID-19 vaccine, with results expected in the first half of 2022. The study, conducted using the GlaxoSmithKline pandemic adjuvant, will enroll 4,000 participants and compare safety and immunogenicity., It will be one of the first active comparator trials to be initiated in the current context in which randomized placebo-controlled trials have become increasingly difficult to conduct.
- On 2nd September <u>CEPI and IFC announced an MoU</u> agreeing to collaborate on unlocking opportunities for commercially viable vaccine production in LMICs. CEPI will support IFC to evaluate the technical aspects of potential projects and the capability requirements of its prospective investees and technology transfer partners. CEPI will be involved in assessing the technology capabilities of manufacturers, vaccine product portfolios, the versatility of suppliers in producing different kinds of vaccines, and will identify critical success factors required for sustainable local vaccine production.

Portfolio

- Review and investment decisions for CEPI's call for proposals for complimentary clinical trials (launched January 2021) have concluded, with 7 proposals approved for funding from a pool of 26 applicants. Agreements have been signed with Aurum Institute, University of Oslo Hospital and IVI.
 - Proposals address clinical research gaps in (1) vulnerable populations (i.e. elderly, HIV-positive, immunosuppressed), (2) mix and match vaccination strategies using vaccines available in-country. (3) efficacy of vaccines against variants in contexts with high rates of circulation.
 - · The majority of approved studies support capacity building in LMICs and are led by in-country partners, with the potential to

impact immunization strategies.

COVID-19/COVAX

- As of 2nd September, COVAX has shipped over 233.9Mn doses to 139 countries/territories. COVAX has allocated 414.2Mn doses (319.2Mn to AMCs), of which over 233.9Mn have been shipped (180Mn to AMCs).
- Of the COVAX doses that have been shipped, 101.8Mn are donated. Donated doses accounted for nearly 60% of COVAX delivered doses
 in August, and over 45% across all COVAX deliveries. Nearly 130Mn donated doses have been allocated.
- In mid-August, 3Mn doses (the first AstraZeneca doses) donated to COVAX by the UK arrived in 11 African countries. This shipment is
 part of a broader pledge from the UK to share 100Mn doses, of which 80% will be through COVAX. The first Danish and Canadian doses
 delivered through COVAX also arrived in Algeria, Nigeria, Kenya and Niger.
- As part of France's pledge to donate at least 60Mn doses to the world this year, a new arrangement between France and the African Union will see 10Mn doses provided through a partnership with COVAX and the Africa Vaccine Acquisition Trust (AVAT).
- On 31st August, CEPI's Centralized Lab Network partnered with BioPharmaceutical Emerging Best Practices Association (BEBPA) to host
 a <u>webinar</u> focused on the lessons learned during tech transfer of immunological assays. The webinar engaged a global network of
 laboratories with the aim of standardizing the evaluation of the immune response elicited by different SARS-CoV-2 vaccines.
- On 1st September, Dr Tedros and Chancellor Merkel hosted the inauguration of the new global WHO Hub for Pandemic and Epidemic Intelligence in Berlin. The Hub will bring together partners worldwide to collaborate and create the tools and data needed for all countries to prepare, detect and respond to pandemic and epidemic risks.
- The COVAX Manufacturing Taskforce continues to make progress on all workstreams:
 - WS0: Launch of a new study to understand in more detail the size of the COVID-19 vaccine market in the medium- and long-term, and country preferences for different vaccines. This is intended to help decision-making in key areas, such as market shaping, vaccine financing, and policy.
 - WS1: Onboarded COVAX Marketplace partners including vaccine manufacturers and consumables suppliers with offers posted for transaction. Aligned on role to support WTO free flow of goods to support raw materials supply chain (e.g. supply chain transparency, modified customs procedures and tariffs).
 - WS2: Finalization of manufacturing workforce training landscaping report to transfer activity to WS3.
 - WS3: Continued discussions with various donors regarding the hub, the selection process for identification of mRNA tech donors, and potential mRNA hubs.

COVAX Meetings:

- 19th August: COVAX Coordination Meeting covered shipment and donation status, delivery costing, COVAX 2022 strategy, and an update on the manufacturing and supply chain task force.
- 23rd August: ACT-Accelerator Facilitation Council Vaccine Manufacturing Working Group met with COVAX Manufacturing Taskforce leadership to discuss Taskforce plans and progress.

CEPI Governance:

The EIC met on 2nd September and discussed a proposal to spend MUSD8.5 on systems immunology work, which was endorsed.

Other Recent and Upcoming Events

- 3rd September: WHO R&D Blueprint Consultation on 'Will emerging data allow increased reliance on vaccine immune responses for public health and regulatory decision-making?'
- 15th September: CCM#13
- 16th-17th September: CEPI Board meeting

ROICE FULTON

Consultant Project Manager



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To: Connelly, Sarah <

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Subject: RE: Input Requested - Ideas for next NIH COVID Summit
     External Sender. Be aware of links, attachments and requests.
 Topics are still welcome for the fourth ACTIV-associated Workshop. Please respond directly to me or
                                                                                                                                  (b)(6)
 Jim Anderson
 NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives
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 From: Connelly, Sarah <
 Sent: Wednesday, September 1, 2021 9:44 AM
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Subject: Input Requested - Ideas for next NIH COVID Summit

Dear Working Group Members,

We write on behalf of Dr. Francis Collins to solicit your recommendations for the topic of a fourth ACTIV-associated Workshop. Previous Workshops provided timely research updates and recommendations that informed research needs to end the COVID-19 pandemic. Where at this point would a workshop help inform development of our collective research strategy? Information on previous workshops is listed below.

Please respond to Sarah Connelly (b) (6) by end of day today, Wednesday September 1 including why it is urgent to address your topic now and how the outcomes from the workshop would change the arc of the pandemic.

Thanks very much, Sarah

NIH Summit on Anti-SARS-CoV-2 Antibodies for Treatment and Prevention of COVID-19: Lessons Learned and Remaining Questions

June 15, 2021

11:00 a.m. - 4:00 p.m. ET

Description: The goal of this Summit is to summarize current knowledge and lessons learned on clinically relevant anti-SARS-CoV-2 antibodies for the treatment and/or prevention of COVID-19 and to identify key unanswered scientific questions to catalyze clinical development and implementation.

- Videocast
- Agenda
- Presentation (Forthcoming)

NIH SARS-CoV2 Antiviral Therapeutics Summit

November 6, 2020

Description: This summit will provide an overview of the current state of direct anti-coronaviral targets and therapeutics, available tools and challenges.

- Videocast
- Agenda
- Summit Report

Neutralizing Antibodies Scientific Summit

August 20, 2020

Description: Operation Warp Speed, in collaboration with the National Institutes of Health, is hosting a virtual scientific summit to explore the current state and future opportunities for neutralizing antibodies (nAbs) as a possible treatment for COVID-19.

- Videocast
- Agenda (for questions regarding this document, please contact the NIH News Media Branch(link sends e-mail))
- Summit Report

Sarah Connelly, PhD

Manager | GPS S&A
Deloitte Consulting, LLP

2200 Ross Ave. #1600, Dallas, TX 75201

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           Connelly, Sarah
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From:
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
           Fri 9/3/2021 2:58:59 PM (UTC-04:00)
Sent:
Subject:
          RE: Input Requested - Ideas for next NIH COVID Summit
                                                                                                                               (b)(6)
 Topics are still welcome for the fourth ACTIV-associated Workshop. Please respond directly to me or
 Jim Anderson
 NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives
 From: Connelly, Sarah <
 Sent: Wednesday, September 1, 2021 9:44 AM
                                       (b) (6)
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 To: Baric, Ralph <
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- Agenda (for questions regarding this document, please contact the NIH News Media Branch(link sends e-mail))
- Summit Report

Sarah Connelly, PhD

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Connelly, Sarah
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Attendees:
                       Baric, Ralph;
                                                                   (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E];
                       Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E];
                       Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan,
                       Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                       (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                       (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
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                       Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                       (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
                       (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];
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                       Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                       Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                       Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
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                       (NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney; Matthew Frieman; antoinette baric; Micheloni, Gianni;
                       Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna
                       (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];
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                       ACTIV TRACE full Working Group
                       Tue 9/14/2021 9:00:00 AM (UTC-04:00)
Start Time:
                       Tue 9/14/2021 10:00:00 AM (UTC-04:00)
End Time:
Required Attendees:
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                       Baric, Ralph:
                       Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E];
                       Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan,
                       Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                       (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
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                       Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                       Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                       Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
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                       (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor
                       (NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney; Matthew Frieman
                       antoinette_baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel,
Optional Attendees:
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 Required Attendees:
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From:

Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E];

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NTO(101THAI) 및 제공연기에 되었었으며 [1		. (25/4) Fig. 25/6/1 Fig. 26/6/1	H/NCATS) [C]; Erbelding,	(b) (6)	
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Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

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Connelly, Sarah
                                                      (b) (6)
Attendees:
                       Baric, Ralph;
                                                                    (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E];
                       Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E];
                       Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan,
                       Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                       (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                       (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
                       jay
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                                                            (b)(6)
                                                                                              (b) (6) Menetski, Joseph (FNIH) [T];
                       MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH;
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                       Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; Jansen, Kathrin;
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                                                                                  (b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher,
                                                                                    (b) (6) Lorraine Horgan; Li Yan; Qing Zhu;
                       Katie; evguenia.svarovskaia; Danielle Porter;
                                                                   (b) (6) Andrew Charles Adams; Esser, Mark; David Margolis;
                                                                                      (b) (6) Eastman, Richard (NIH/NCATS) [E];
                       Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                       (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
                       (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];
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                       Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                       Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                       Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
                       Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
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                       (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor
                       (NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney;
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                       Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel, Jonathan; Glodek, Anna
                       (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]
Location:
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Importance:
                       Normal
Subject:
                       ACTIV TRACE full Working Group
                       Tue 1/5/2021 10:00:00 AM (UTC-04:00)
Start Time:
                       Tue 1/5/2021 11:00:00 AM (UTC-04:00)
End Time:
Required Attendees:
                                                                   (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E];
                       Baric, Ralph:
                       Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E];
                       Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan,
                       Daniel B. (CDC/DDPHSS/OD); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                       (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                       (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
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                       Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                       (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
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                       (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];
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                       Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                       Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                       Haigwood; Basu, Dipanwita (NIH/NIAID) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
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                       Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
                       (NIH/NCATS) [C]; Poelaert, Brittany (NIH/NCATS) [C]; Prabha Fernandes; Larosa, Francis; Lee, Taylor
                       (NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney;
                       antoinette_baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel,
Optional Attendees:
                       Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E]
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                                Baric, Ralph;
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 Required Attendees:
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Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E]; Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E];

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Dormitzer, Philip Ralp	h; Jansen, Kathrin;		(b) (6)		(b) (6) Loo, Yue	h-
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(b) (6) Baric, Ralph
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To:
           Connelly, Sarah
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(NIH/NCATS) [C][
                                         (b) (6) Prabha Fernandes
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Francis
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[E][
From:
           Copeland, Courtney
Sent:
           Wed 9/1/2021 4:23:45 PM (UTC-04:00)
           RE: ACTIV TRACE full Working Group
Subject:
2021-08-31 ACTIV TRACE WG Meeting Summary vF.pdf
 Dear Working Group Members,
 Thank you all for attending our TRACE WG meeting on Tuesday. Please see the attached file for the notes from our discussion, and
 let us know if you all have any additions or amendments.
 Best,
 Courtney
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Courtney Copeland, Ph.D. (she/her/hers) Senior Consultant | Strategy and Analytics

200 Berkeley St 10th FI Boston, MA 02116

(b) (6) | Mobile:

(b) (6) www.deloitte.com

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Tel/Direct:

Original	Appointment						
From: Conn	elly, Sarah <	(b) (6)					
Sent: Friday	, August 20, 202	1 4:49 PM					
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[C]; Erbeldir	ng, Emily (NIH/NI	AID) [E]; Charette, Mar	c (NIH/NHLBI) [E];		(b) (6)		(b) (6)
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(NIH/NCATS) [C]; Lisa Purcel	l; Yun Ji; Arnegard, Mat	thew (NIH/OD) [E]	; Groves Dixon	;	(b)	(6) 'Korber,
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		in, Rhonda; Migun Shal	kya; Scott Chavers;				(b) (6)
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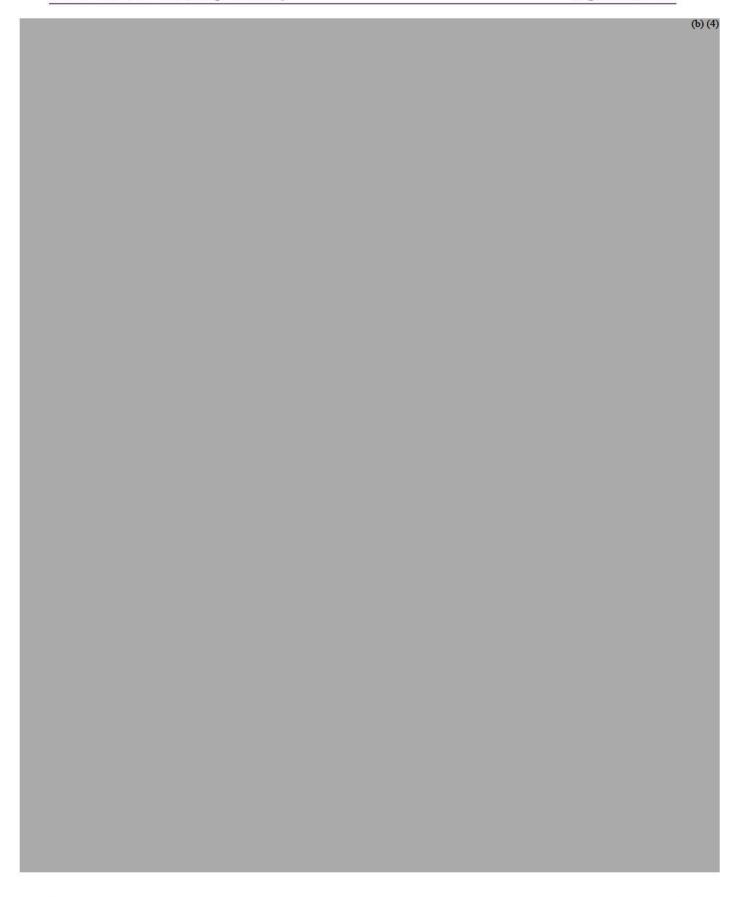
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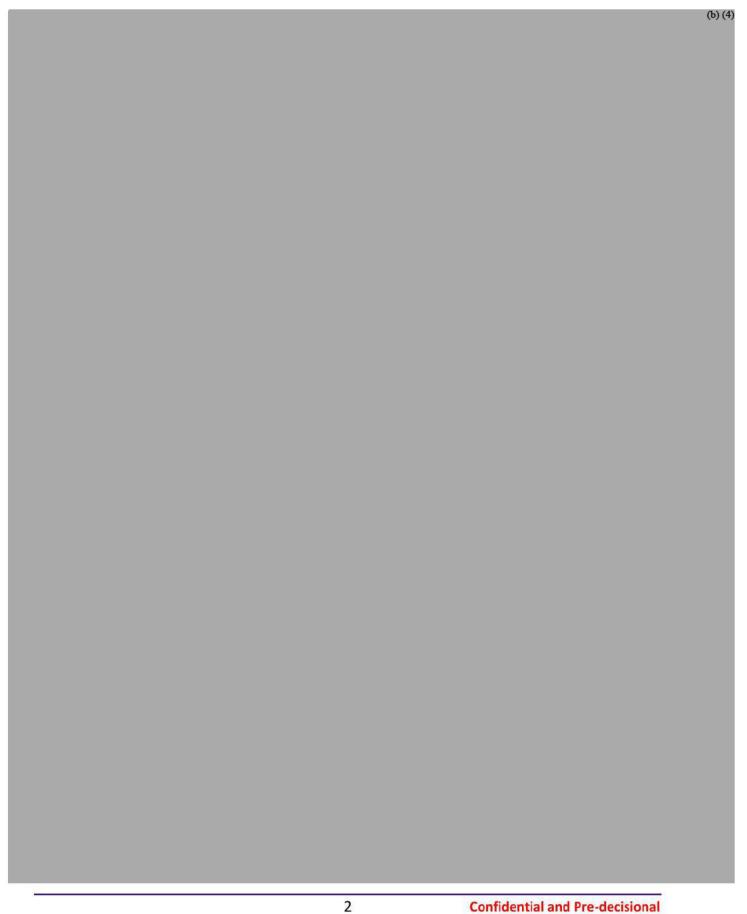
International numbers

Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

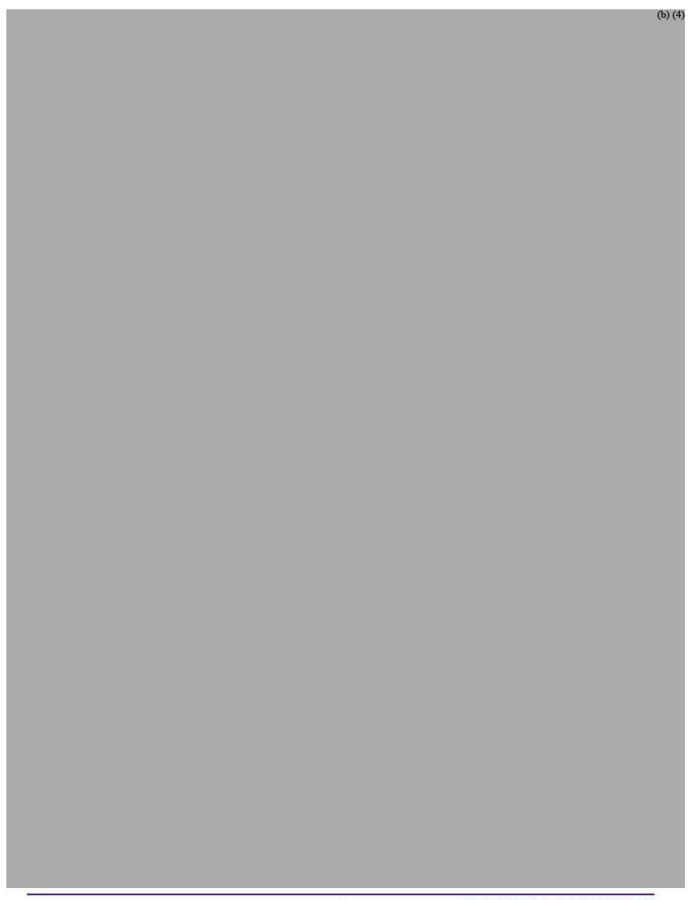
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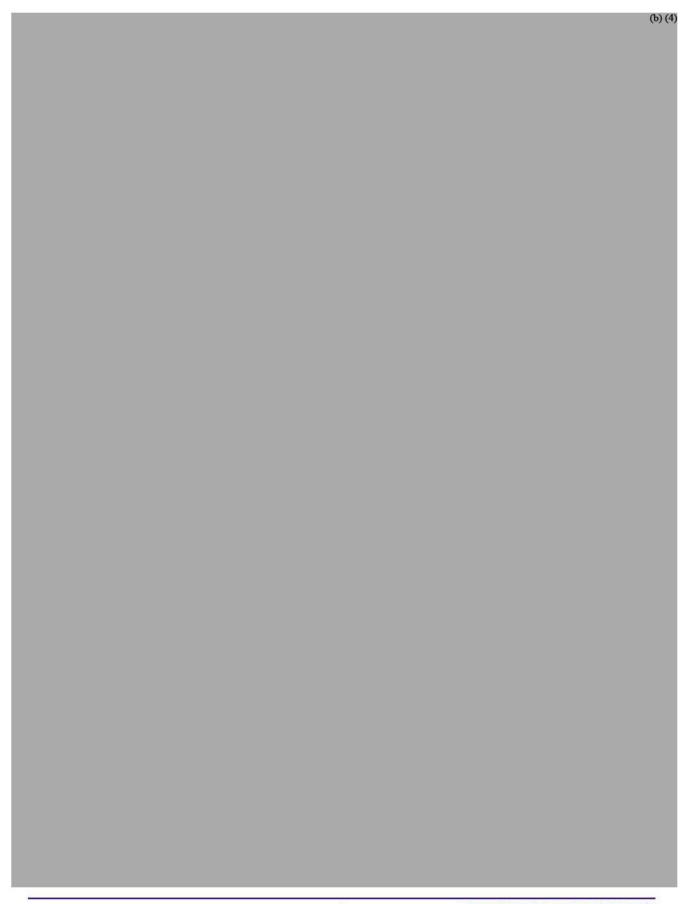
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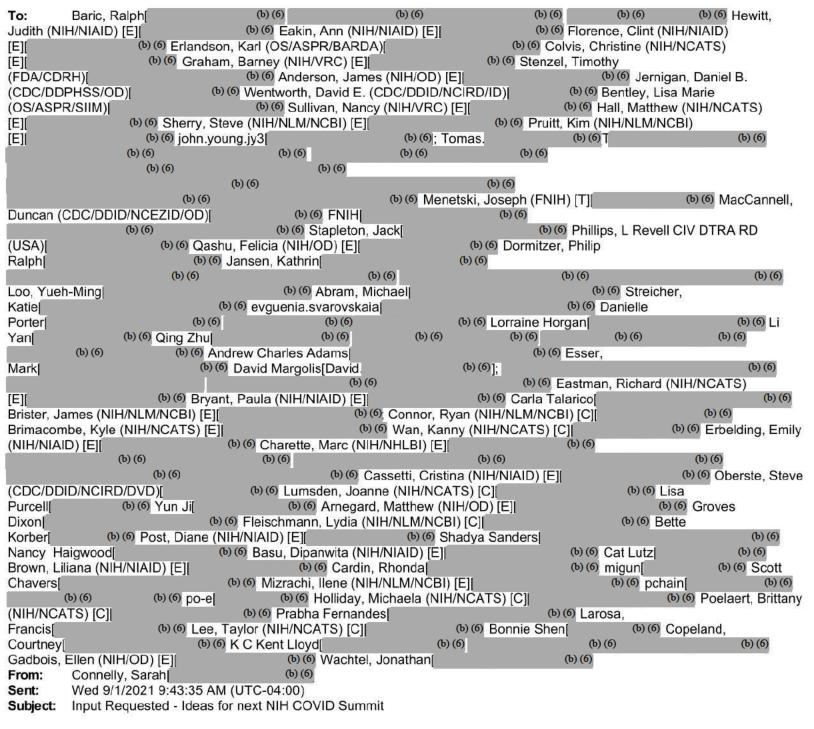






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ACTIV TRACE WG Meeting Summary	August 31, 2021		
	(b) (4		



Dear Working Group Members,

We write on behalf of Dr. Francis Collins to solicit your recommendations for the topic of a fourth ACTIV-associated Workshop. Previous Workshops provided timely research updates and recommendations that informed research needs to end the COVID-19 pandemic. Where at this point would a workshop help inform development of our collective research strategy? Information on previous workshops is listed below.

Please respond to Sarah Connelly (b) (6) by end of day today, Wednesday September 1 including why it is urgent to address your topic now and how the outcomes from the workshop would change the arc of the pandemic.

Thanks very much, Sarah

NIH Summit on Anti-SARS-CoV-2 Antibodies for Treatment and Prevention of COVID-19: Lessons Learned and Remaining Questions

11:00 a.m. - 4:00 p.m. ET

Description: The goal of this Summit is to summarize current knowledge and lessons learned on clinically relevant anti-SARS-CoV-2 antibodies for the treatment and/or prevention of COVID-19 and to identify key unanswered scientific questions to catalyze clinical development and implementation.

- Videocast
- Agenda
- Presentation (Forthcoming)

NIH SARS-CoV2 Antiviral Therapeutics Summit

November 6, 2020

Description: This summit will provide an overview of the current state of direct anti-coronaviral targets and therapeutics, available tools and challenges.

- Videocast
- Agenda
- Summit Report

Neutralizing Antibodies Scientific Summit

August 20, 2020

Description: Operation Warp Speed, in collaboration with the National Institutes of Health, is hosting a virtual scientific summit to explore the current state and future opportunities for neutralizing antibodies (nAbs) as a possible treatment for COVID-19.

- Videocast
- Agenda (for questions regarding this document, please contact the NIH News Media Branch(link sends e-mail))
- Summit Report

Sarah Connelly, PhD

Manager | GPS S&A Deloitte Consulting, LLP

2200 Ross Ave. #1600, Dallas, TX 75201

Tel/Direct: (b) (6) | Fax: +1 844 337 3590 | Mobile: (b) (6) (b) (6) | www.deloitte.com

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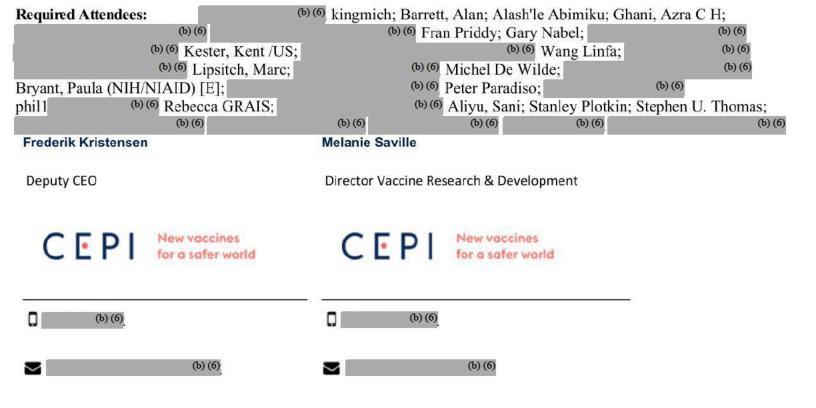
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Organizer:	CEPI Secretariat	(b) (6)			
From:	CEPI Secretariat	(b) (6)			
Attendees:	Kester, Kent /US; (b) (6) (b) (6)	(b) (6) Fran Priddy D Lipsitch, Marc; D) (6) Bryant, Paula (b) (6)	(b) (6) Wang Linfa; (b) (6) Mi (NIH/NIAID) [E]; Rebecca GRAIS;	(b) (6) (b) (6) chel De Wilde; (b) (6)	(b) (6) (b) (6) Peter Paradiso; Aliyu, Sani; Stanley
	Plotkin; Stephen U. Thom (b) (6)	nas; (b) (6)	(b) (6)	(b) (6)	(b) (6)
Location:	VTC - Details to follow				
Importance:	Normal				
Subject:	[SAVE THE DATE] CEPI	Portfolio Review n	neeting – 4-5 November	2021 - Day 2	
Start Time:	Fri 11/5/2021 9:00:00 AM	(UTC-04:00)			
End Time:	Fri 11/5/2021 1:00:00 PM	(UTC-04:00)			
Required Attendees:	Kester, Kent /US;	(b) (6) Fran Priddy (c) Lipsitch, Marc; (d) Bryant, Paula	(b) (6) Wang Linfa; (b) (6) Mi (NIH/NIAID) [E];	(b) (6) (b) (6) chel De Wilde;	(b) (6) (b) (6) (b) (6) Peter Paradiso;
	(b) (6) Plotkin; Stephen U. Thom (b) (6)		Rebecca GRAIS; (b) (6)	(b) (6) (b) (6)	Aliyu, Sani; Stanley (b) (6)
Dear invitees of the C	CEPI Portfolio Review meetii	ng,			
Followina the invitati	ion vou have received via e-	mail. please indica	te whether vou are able	to attend the Portf	olio Review meetina

Following the invitation you have received via e-mail, please indicate whether you are able to attend the Portfolio Review meeting through responding to the 'save-the-date' calendar invitation by 10th September.

Further details, agenda and presentation materials will be communicated in due course.

Best regards,



Organizer: CEPI Secretariat (b)(6)(b)(6)From: CEPI Secretariat (b)(6)Attendees: (b) (6) kingmich; Barrett, Alan; Alash'le Abimiku; Ghani, Azra C H; (b) (6) Fran Priddy; Gary Nabel; (b)(6)(b) (6) (b) (6) Wang Linfa; Kester, Kent /US; (b) (6) Lipsitch, Marc: (b) (6) Michel De Wilde: (b) (6) Bryant, Paula (NIH/NIAID) [E]; (b) (6) Peter Paradiso; (b) (6) Aliyu, Sani; Stanley (b)(6)(b) (6) Rebecca GRAIS; Plotkin; Stephen U. Thomas; (b) (6) tokyo.ac.jp; Christopher Viehbacher (Gurnet Point Capital); Seth Berkley; (b)(6)Subhash Kapre; Kiran Mazumdar/Corporate/BIOCON; Trevor Mundel; (b) (6) mariepaule.kieny; Derrick Sim Location: VTC - Details to follow Importance: Normal [SAVE THE DATE] CEPI Portfolio Review meeting - 4-5 November 2021 - Day 1 Subject: Start Time: Thur 11/4/2021 9:00:00 AM (UTC-04:00) End Time: Thur 11/4/2021 1:00:00 PM (UTC-04:00) (b)(6)(b) (6) kingmich; Barrett, Alan; Alash'le Abimiku; Ghani, Azra C H; Required Attendees: (b) (6) (b)(6)(b) (6) Fran Priddy; Gary Nabel; Kester, Kent /US; (b) (6) Wang Linfa; (b) (6) Michel De Wilde; (b) (6) Lipsitch, Marc; (b) (6) Bryant, Paula (NIH/NIAID) [E]; (b) (6) Peter Paradiso; (b) (6) Rebecca GRAIS; (b) (6) Aliyu, Sani; Stanley (b)(6)(b)(6)Plotkin; Stephen U. Thomas; (b) (6) tokyo.ac.jp; Christopher Viehbacher (Gurnet Point Capital); Seth Berkley; Subhash Kapre; Kiran Mazumdar/Corporate/BIOCON; Trevor Mundel; paule.kieny; Derrick Sim Dear invitees of the CEPI Portfolio Review meeting, Following the invitation you have received via e-mail, please indicate whether you are able to attend the Portfolio Review meeting through responding to the 'save-the-date' calendar invitation by 10^{th} September. SAC members are kindly requested to also join Day 2 of the Portfolio Review (separate calendar invitation). Further details, agenda and presentation materials will be communicated in due course. Best regards, (b) (6) kingmich; Barrett, Alan; Alash'le Abimiku; Ghani, Azra C H; Required Attendees: (b) (6) (b) (6) (b) (6) Fran Priddy; Gary Nabel; (b) (6) (b) (6) Kester, Kent /US; (b) (6) Wang Linfa; (b) (6) Lipsitch, Marc; (b) (6) Michel De Wilde; (b)(6)(b) (6) Peter Paradiso; Bryant, Paula (NIH/NIAID) [E]; (b) (6) Rebecca GRAIS; (b) (6) Aliyu, Sani; Stanley Plotkin; Stephen U. Thomas; (b) (6) (b)(6)(b)(6)(b) (6) tokyo.ac.jp; Christopher Viehbacher (Gurnet Point Capital); Seth Berkley; Subhash Kapre; Kiran Mazumdar/Corporate/BIOCON; (b) (6) marie-paule.kieny; Derrick Sim Trevor Mundel: Frederik Kristensen Melanie Saville Deputy CEO Director Vaccine Research & Development **New vaccines** CEPI New vaccines CEPI

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for a safer world

for a safer world

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Attendees:			h'le Abimiku; Ghani, A		(b) (6)
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Location:	VTC - Details to follow				
Importance:	Normal				
Subject:	[SAVE THE DATE] CEPI Po	ortfolio Review meetir	ıg – 4-5 November 202	1 - Day 2	
Start Time:	Fri 11/5/2021 9:00:00 AM (U	JTC-04:00)			
End Time:	Fri 11/5/2021 1:00:00 PM (L	JTC-04:00)			
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Dear invitees of the CE	PI Portfolio Review meeting,				
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Further details, agendo	a and presentation materials	will be communicate	ed in due course.		
Best regards,					
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Frederik Kristensen		Melanie Saville			oryo.ac.jp
Deputy CEO		Director Vaccine Re	search & Developmen	t	
CEPI	New vaccines for a safer world	CEPI	New vaccines for a safer world		
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From:

CEPI Secretariat

Attendees:	(b) (i	6) Fran Priddy; Gary (b) (6) Wang Linfa;	(b) (6) j (b) (6)	(b) (6) (b) (6)
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Importance:	Normal				
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Trevor Mundel; Frederik Kristensen		marie-paule.kieny; lelanie Saville		zumdar/Corporate/B	IOCON;
Deputy CEO	2	Director Vaccine Rese	earch & Development		
CEPI	New vaccines for a safer world	CEPI	New vaccines for a safer world		
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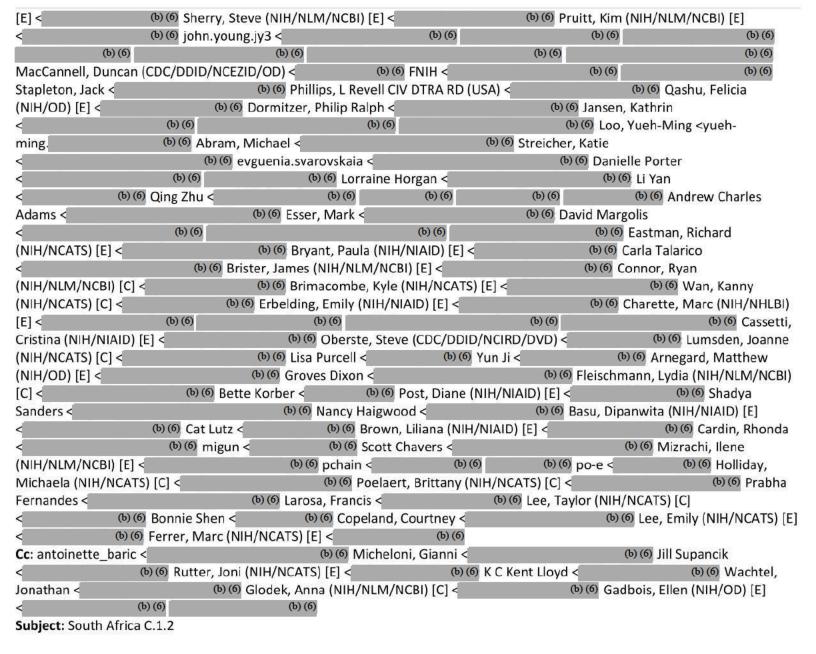
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CEPI Secretariat

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                                                                       (b) (6) 'Shadya Sanders'[
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Brown, Liliana (NIH/NIAID) [E]
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(NIH/NCATS) [C]
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'Bonnie Shen'
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Marc (NIH/NCATS) [E]
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                                                                                    (b) (б) 'K C Kent Lloyd'
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                                  (b) (6) Glodek, Anna (NIH/NLM/NCBI) [C][
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[E][
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From:
           Prabha Fernandes
Sent:
           Tue 8/31/2021 8:42:54 AM (UTC-04:00)
           RE: South Africa C.1.2
Subject:
C 1. 2. South Africa.pdf
 Hello Joe,
 Here is the paper.
 Regards,
 Prabha
                                                         (b)(6)
 From: Menetski, Joseph (FNIH) [T] <
 Sent: Tuesday, August 31, 2021 8:39 AM
                                              (b) (6) Baric, Ralph <
                                                                                                                                (b) (6) Hewitt,
                                                                                       (b)(6)
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 To: Connelly, Sarah <
 Judith (NIH/NIAID) [E] <
                                               (b) (6) Eakin, Ann (NIH/NIAID) [E] <
                                                                                                    (b) (6) Florence, Clint (NIH/NIAID) [E]
                       (b) (6) Erlandson, Karl (OS/ASPR/BARDA) <
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                         (b) (6) Graham, Barney (NIH/VRC) [E] <
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 (CDC/DDPHSS/OD) <
 (OS/ASPR/SIIM) <
                                              (b) (6) Sullivan, Nancy (NIH/VRC) [E] <
                                                                                                       (b) (6) Hall, Matthew (NIH/NCATS)
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I am guessing this will be an upcoming interest? We should at least have it on the radar.

https://www.reuters.com/world/africa/south-africa-detects-new-coronavirus-variant-still-studying-its-mutations-2021-08-30/

The continuous evolution of SARS-CoV-2 in South Africa: a new lineage with rapid accumulation of mutations of concern and global detection

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Abstract

SARS-CoV-2 variants of interest have been associated with increased transmissibility, neutralization resistance and disease severity. Ongoing SARS -CoV-2 genomic surveillance world-wide has improved our ability to rapidly identify such variants. Here we report the identification of a potential variant of interest assigned to the PANGO lineage C.1.2. This lineage was first identified in May 2021 and evolved from C.1, one of the lineages that dominated the first wave of SARS-CoV-2 infections in South Africa and was last detected in January 2021. C.1.2 has since been detected across the majority of the provinces in South Africa and in seven other countries spanning Africa, Europe, Asia and Oceania. The emergence of C.1.2 was associated with an increased substitution rate, as was previously observed with the emergence of the Alpha, Beta and Gamma variants of concern (VOCs). C.1.2 contains multiple substitutions (R190S, D215G, N484K, N501Y, H655Y and T859N) and deletions (Y144del, L242-A243del) within the spike protein, which have been observed in other VOCs and are associated with increased transmissibility and reduced neutralization sensitivity. Of greater concern is the accumulation of additional mutations (C136F, Y449H and N679K) which are also likely to impact neutralization sensitivity or furin cleavage and therefore replicative fitness. While the phenotypic characteristics and epidemiology of C.1.2 are being defined, it is important to highlight this lineage given its concerning constellations of mutations.

Main Text

More than a year into the COVID-19 pandemic, SARS-CoV-2 remains a global public health concern. Ongoing waves of infection result in the selection of SARS -CoV-2 variants with novel constellations of mutations within the viral genome ^{1–4}. Some emerging variants accumulate mutations within the spike region that result in increased transmissibility and/or immune evasion, making them of increased public health importance ^{2–4}. Depending on their clinical and epidemiological profiles, these are either designated as variants of interest (VOI) or variants of concern (VOC)⁵, and ongoing genomic surveillance is essential for early detection of such variants. There are currently four VOCs (Alpha, Beta, Gamma and Delta) and four VOIs (Eta, Iota, Kappa and Lambda) in circulation globally. Of these, Alpha, Beta and Delta have had the most impact globally in terms of transmission and immune evasion, with Delta rapidly displacing other variants to predominate globally, including in South Africa.

Ongoing genomic surveillance in South Africa also detected an increase in sequences assigned to C.1 during the third wave of SARS-CoV-2 infections in May 2021, which was unexpected since C.1, first identified in South Africa ^{6,7}, was last detected in January 2021. Upon comparison of the mutational profiles between these and older C.1 sequences (which only contain the D614G mutation within the spike), it was clear that these new sequences had mutated substantially. C.1 had minimal spread globally but was detected in Mozambique and had accumulated additional mutations resulting in the PANGO lineage C.1.1 ⁷. These new sequences, however, were also very distinct from C.1.1, resulting in the assignment of the PANGO lineage C.1.2 on 22 July 2021 ⁸. C.1.2 is highly mutated beyond C.1 and all other VOCs and VOIs globally with between 44-59 mutations away from the original Wuhan Hu-1 virus (**Fig. 1a**). While the VOI Lambda (C.37) is phylogenetically closest to C.1.2, the latter has distinct lineage-defining mutations.

The C.1.2 lineage was first detected in the Mpumalanga and Gauteng provinces of South Africa, in May 2021 (**Fig. 1b** and **Supplementary Fig. 1a**). In June 2021, it was also detected in the KwaZulu-Natal and Limpopo provinces of South Africa as well as in England and China (**Fig. 1b** and **Supplementary Fig. 1b**). As of August 13, 2021 the C.1.2 lineage has been detected in 6/9 South African provinces (including the Eastern Cape and Western Cape), the Democratic Republic of the Congo (DRC), Mauritius, New Zealand, Portugal and Switzerland (**Fig. 1b** and **Supplementary Fig. 1b** and **c**).

As of August 13, 2021 we have identified 63 sequences that match the C.1.2 lineage, of which 59 had sufficient sequence coverage to be used in phylogenetic analyses and/or spike

analysis. All C.1.2 sequences including those with poor coverage (from the DRC and Mpumalanga) can be found on GISAID (www.gisaid.org), the global reference database for SARS-CoV-2 viral genomes^{9,10}, and listed in **Supplementary Tables 1** and **2**. The majority of these sequences (n=53) are from South Africa. Though SARS-CoV-2 genomic surveillance is ongoing, there is normally a delay of 2-4 weeks between sampling and data being publicly available on GISAID. Provincial detection of C.1.2 to some extent mirrored the depth of sequencing across SA (**Supplementary Fig. 1a, c** and **d**), suggesting that it may be present in under-sampled provinces and these numbers are most likely an underrepresentation of the spread and frequency of this variant within South Africa and globally. Nevertheless, we see consistent increases in the number of C.1.2 genomes in South Africa on a monthly basis, where in May C.1.2 accounted for 0.2% (2/1054) of genomes sequenced, in June 1.6% (25/2177) and in July 2.0% (26/1326), similar to the increases seen in Beta and Delta in South Africa during early detection (**Supplementary Fig. 1e**).

Preliminary molecular clock estimates suggested that the overall rate of evolution of SARS -CoV-2 in 2020 was 8x10⁻⁴ substitutions/site/year, which equates to 24 substitutions per year ¹¹. The current global estimate (derived from global Nextstrain a build, https://nextstrain.org/ncov/gisaid/global, accessed August 15th 2021) including multiple variants of concern/interest suggests a similar rate of approximately 25.2 substitutions per year (8.4x10⁻⁴ substitutions/site/year). The global phylogeny, including C.1.2 sequences, gives a slightly higher clock rate of 26.6 substitutions per year (8.9x10⁻⁴ substitutions/site/year), with the C.1.2 sequences clearly having a higher substitution rate than the majority of other sequences (Fig. 1c). To obtain an estimate of the rate of C.1.2 specifically, we performed a root-to-tip regression of C.1.2 against C.1 sequences. This suggested that the emergence of the C.1.2 lineage resulted from a rate closer to 1.4x10⁻³, or ~41.8 mutations per year, which is approximately 1.7-fold faster than the current global rate and 1.8-fold faster than the initial estimate of SARS-CoV-2 evolution. This short period of increased evolution compared to the overall viral evolutionary rate was also associated with the emergence of the Alpha, Beta and Gamma VOCs^{2,3,12}, suggesting a single event, followed by the amplification of cases, which drove faster viral evolution 13.

C.1.2 shares some mutations with C.1 but has accumulated additional mutations within the ORF1ab, spike, ORF3a, ORF9b, E, M and N proteins (**Fig. 2a**). Of these mutations, 30 occur in >50% of the sequences. Several mutations were observed within the spike protein, with >50% of the viruses assigned to C.1.2 having 14 mutations, including five within the NTD (C136F, Y144del, R190S, D215G and 242-243del (L242 and A243 deletions)), three within the receptor binding motif (RBM) (Y449H, E484K and N501Y) and two adjacent to the furin

cleavage site (N679K and T716I). P9L, D614G, H655Y and T859N make up the remaining four major mutations. Though these mutations occur in the majority of C.1.2 viruses, there is additional variation within the spike region of this lineage (**Fig. 2b**), suggesting ongoing intralineage evolution. Approximately 44% of the viruses also contain a P25L m utation in the NTD, ~19% have L585F in S1, ~16% have T478K in the RBM, ~11% contain P681H adjacent to the furin cleavage site, 8% have D936H, and a further ~8% have H1101Q in S2. The majority of these mutations (P9L, C136F, R190S, D215G, L242del, A243del, Y449H, E484K, N501Y, H655Y, and T716I) appeared together early in the lineage evolution (**Fig. 3a**). Thereafter, the majority of sequences have also accumulated the mutations Y144del, N679K and T859N. The mutations P25L, W152R, R346K, T478K, L585F, N440K, P681H, A879T, D936H and H1101Q can be seen in some of the smaller clusters from more recent sequences, further highlighting continued evolution within the lineage.

Several (52%, 13/25) of the spike mutations identified in C.1.2 have previously been identified in other VOIs and VOCs (Fig. 3b). These include D614G, common to all variants 14, and E484K and N501Y which are shared with Beta and Gamma, with E4 84K also seen in Eta and N501Y in Alpha. The T478K substitution is seen in <50% of the C.1.2 viruses but is also observed in Delta. N440K and Y449H co-localize on the same outer face of C.1.2 RBD (Fig. 3c). While these mutations are not characteristic of current VOCs/VOIs, they have been associated with escape from certain class 3 neutralizing antibodies 15,16. The combination of these mutations presents a potentially novel antigenic landscape for C.1.2 variant specific antibodies. More striking, however, was the remodeling of NTD relative to the Wuhan Hu-1 sequence (blue, Fig. 3c). While Y144del and 242-244del cause frameshifts to the immunodominant N3 or N5 loops of NTD in the Alpha or Beta variants respectively 17, the deletion of both regions in C.1.2 (with a different N5 frameshift relative to Beta) likely contributes to evading NTD immune responses elicited by infection with either Alpha or Beta. Furthermore, the C136F mutation abolishes a disulphide bond with the N1 loop of NTD, and in combination with P25L likely contributes to immune escape by conformationally liberating the entire N -terminus of NTD. Mutations close to the furin cleavage site have also been observed in VOCs, H655Y has been seen in Gamma and P681R/H have been seen in Alpha, Delta, and Kappa (S1/S2 region in Fig. 3c). In the C.1.2 lineage, N679K and P681H are mutually exclusive (with N679K predominating) and may therefore perform a similar role by increasing the local, relative positive charge and improving furin cleavage. Evolution involving the introduction of N679K or P681H has recently been seen within Gamma (P.1)¹⁸. The identification of convergent evolution between C.1.2 and other VOIs and VOCs suggests that this variant may also share concerning phenotypic properties with VOCs.

We are currently assessing the impact of this variant on antibody neutralization following SARS-CoV-2 infection or vaccination against SARS-CoV-2 in South Africa.

Discussion/Conclusion

We have identified a new SARS-CoV-2 variant assigned to the PANGO lineage C.1.2. This variant has been detected throughout the third wave of infections in South Africa from May 2021 onwards and has been detected in seven other countries within Europe, Asia, Africa and Oceania. The identification of novel SARS-CoV-2 variants is commonly associated with new waves of infection. Like several other VOCs, C.1.2 has accumulated a number of substitutions beyond what would be expected from the background SARS-CoV-2 evolutionary rate. This suggests the likelihood that these mutations arose during a period of accelerated evolution in a single individual with prolonged viral infection through virus -host co-evolution ^{19–21}. Deletions within the NTD (like Y144del, seen in C.1.2 and other VOCs) have been evident in cases of prolonged infection, further supporting this hypothesis ^{22–24}.

C.1.2 contains many mutations that have been identified in all four VOCs (Alpha, Beta, Delta and Gamma) and three VOIs (Kappa, Eta and Lambda) as well as additional mutations within the NTD (C136F), RBD (Y449H), and adjacent to the furin cleavage site (N679K). Many of the shared mutations have been associated with improved ACE2 binding (N501Y) ^{25–29} or furin cleavage (H655Y and P681H/R)^{30–32}, and reduced neutralization activity (particularly Y144del, 242-244del, and E484K)^{17,33–39}, providing sufficient cause for concern of continued transmission of this variant. Future work aims to determine the functional impact of these mutations, which likely include neutralizing antibody escape, and to investigate whet her their combination confers a replicative fitness advantage over the Delta variant.

The C.1.2 lineage is continuing to grow. At the time of submission (20 August 2021) there were 80 C.1.2 sequences in GISAID with it now having been detected in Botswana and in the Northern Cape of South Africa.

Methods

Sampling of SARS-CoV-2 and Metadata

As part of monitoring the viral evolution by the Network for Genomics Surveillance of South Africa (NGS-SA)⁴⁰, seven sequencing hubs receive randomly selected samples for sequencing every week according to approved protocols at each site. These samples include remnant nucleic acid extracts or remnant nasopharyngeal and oropharyngeal swab samples from routine diagnostic SARS-CoV-2 PCR testing, from public and private laboratories in South Africa. Permission was obtained for associated metadata for the samples including date

and location (district and province) of sampling, and sex and age of the patients to offer additional insights about the epidemiology of the infection caused by the virus.

Ethical statement

The project was approved by the University of the Witwatersrand Human Research Ethics Committee (HREC) (ref. M180832, M210159, M210752), University of KwaZulu–Natal Biomedical Research Ethics Committee (ref. BREC/00001510/2020), Stellenbosch University HREC (ref. N20/04/008_COVID19) and the University of Cape Town HREC (ref. 383/2020) and the University of Pretoria, Faculty of Health human ethics committee, (ref H101 -2017). Individual participant consent was not required for the genomic surveillance. This requirement was waived by the Research Ethics Committees.

Whole-genome sequencing and genome assembly

RNA Extraction

RNA was extracted either manually or automatically in batches, using the QIAamp viral RNA mini kit (QIAGEN, California, USA) as per manufacturer's instructions or the Chemagic 360 using the CMG-1049 kit (PerkinElmer, Massachusetts, USA), respectively. A modification was done on the manual extractions by adding 280 μ l per sample, in order to increase yields. 300 μ l of each sample was used for automated magnetic bead-based extraction using the Chemagic 360. RNA was eluted in 60 μ l of the elution buffer. Isolated RNA was stored at -80°C prior to use.

PCR and library preparation

Sequencing was performed using the COVIDSeq or nCoV-2019 ARTIC network sequencing protocol (https://artic.network/ncov-2019), which is an amplicon-based next-generation sequencing approach (Illumina, Inc, USA)⁴¹. Briefly, the first strand synthesis was carried out on extracted RNA samples using random hexamers primers from the SuperScript IV reverse transcriptase synthesis kit (Life Technologies). The synthesized cDNA was amplified using two separate multiplex polymerase chain reactions (PCRs), producing 98 amplicons across the SARS-CoV-2 genome. The primer pool additionally had primers targeting human RNA, producing an additional 11 amplicons. The pooled PCR products underwent bead-based tagmentation where they get fragmented and tagged to the adapter sequences using the Nextera Flex DNA library preparation kit. The adapter-tagged amplicons were cleaned-up using AmpureXP purification beads (Beckman Coulter, High Wycombe, U and amplified using one round of PCR. The PCRs were indexed using the Nextera CD indexes (Illumina, Sand Diego, CA, USA) according the manufacturer's instructions. Tagged libraries were pooled and cleaned using the K). Pooled samples were quantified using Qubit 3.0 or 4.0 fluorometer

(Invitrogen Inc.) using the Qubit dsDNA High Sensitivity assay according to manufacturer's instructions. The fragment sizes were analyzed using TapeStation 4200 (Invitrogen). The pooled libraries were further normalized to 4nM concentration and 25 µl of each normalized pool containing index adapter sets 1, 2, 3, and 4 were combined in a new tube. The final library pool was denatured and neutralized with 0.2N sodium hydroxide and 200 mM Tris -HCL (pH7), respectively. 1.5 pM sample library was spiked with 2% PhiX. Libraries were loaded onto a 300-cycle NextSeq 500/550 HighOutput Kit v2 and run on the Illumina NextSeq 550 instrument (Illumina, San Diego, CA, USA).

Assembly, processing and quality control of genomic sequences

Raw reads from Illumina sequencing were assembled using the Exatype NGS SARS -CoV-2 pipeline v1.6.1, (https://sars-cov-2.exatype.com/) or Genome Detective 1.132/1.133 (https://www.genomedetective.com/) and the Coronavirus Typing Tool 42,43. Samples sequenced from Oxford Nanopore GridION were assembled according to the Artic -nCoV2019 novel coronavirus bioinformatics protocol (https://artic.network/ncov-2019/ncov-2019bioinformatics-sop.html). For these samples raw reads were base called and demultiplexed using Guppy. To guarantee accuracy of the base calls, we only used dual indexed reads (i.e. required barcodes both ends). A reference-based assembly and mapping was generated for each sample using Minimap2 and consensus calculated using Nanopolish. The reference genome used throughout the assembly process was NC 045512.2 (Accession number: MN908947.3). The initial assembly obtained was cleaned by aligning mapped reads to the references and filtering out low-quality mutations using the Geneious software v2021.0.3 (Biomatters). Quality control reports were obtained from Nextclade 44. The resulting consensus sequence was further manually polished by considering and correcting indels in homopolymer regions that break the open reading frame (probably sequencing errors) using Aliview v1.27, (http://ormbunkar.se/aliview/)⁴⁵. Mutations resulting in mid-gene stop codons and frameshifts were reverted to wild type. Regions with clustered mutations and deletions resulting in frameshifts where annotated as gaps and insertions where removed. Sequences with less than 80% coverage relative to the Wuhan-Hu-1 reference where discarded. All assemblies were deposited in GISAID (https://www.gisaid.org/)10 and the GISAID accession was included as part of Supplementary Table 1. Clade and lineage assignment was determined using Nextclade and Pangolin⁴⁶.

Classification of lineage, clade and associated mutations

The 'Phylogenetic Assignment of Named Global Outbreak Lineages' (PANGOLIN) software suite (https://github.com/hCoV-2019/pangolin) was used for the dynamic SARS-CoV-2 lineage classification ⁴⁶. The SARS-CoV-2 genomes in our dataset were also classified using

the clade classification proposed by NextStrain (https://nextstrain.org/) built for real-time tracking of the pathogen evolution⁴⁷. The PANGO lineage identified predominantly in South Africa in this study is now assigned to the lineage C.1.2 (Pangolin version v3.1.7, lineages version 2021-07-28); the corresponding Nextclade classification is 20D (Nextclade version v1.5.3, clades version 2021-07-28). The C.1.2 lineage and its associated mutations were further confirmed using the Stanford Coronavirus Antiviral & Resistance Database (CoVDB) (https://covdb.stanford.edu/) and Outbreak.info (https://outbreak.info/).

Dataset Compilation

At the time of writing, there were over 2.9 million SARS-CoV-2 genomes available on GISAID (https://www.gisaid.org). Due to the size of this dataset, sub-sampling was performed to obtain a representative but manageable sample of genomes. A preliminary dataset was downloaded from GISAID; the options 'complete', 'high coverage', and 'collection date complete' were selected to ensure that only genomes with complete date information and less than 5% N content were included. This contained all C.1.2 genomes, genomes from the C.1 lineage (the original lineage to which C.1.2 was assigned), the C.1.1 lineage (a Mozambican lineage that evolved from C.17, and South African. The global and African Auspice datasets were also downloaded (accessed 13 August 2021). This dataset was further down-sampled using a custom build of the Nextstrain SARS-CoV-2 pipeline⁴⁷ to produce a final dataset of 5,756 genomes. Of these, 54 are from lineage C.1.2. Due to the fact that C.1.2 was first detected and is most prevalent in South Africa, we chose to include a large proportion of South African sequences, resulting in 1,922 South African genomes. To include global context, there were an additional 946 sequences from the rest of Africa, 843 from Asia, 1,038 from Europe, 443 from South America, 376 from North America, and 188 from Oceania. This dataset included genomes from all Variants of Concern (VOC) and Variants of Interest (VOI) as defined by the WHO5.

Temporal Analysis

We conducted temporal analysis to ensure that C.1.2 possesses a strong enough temporal signal for dated phylogenetic analysis, as well as to get an estimate of the molecular clock rate for the C.1.2 lineage. To do this, 54 C.1.2 and 135 C.1 samples were extracted from the initial dataset and aligned within MAFFT⁴⁸. The alignment was manually inspected in AliView ⁴⁵ to ensure there were no errors. IQ-TREE⁴⁹ was used to construct an undated maximum likelihood phylogeny of C.1 and C.1.2 samples, using the HKY+I nucleotide substitution model. The resulting tree was analyzed in TempEst⁵⁰ for the presence of a temporal signal. Inspection of the tree revealed a small cluster of sequences from several countries that formed a monophyletic group distinct from other C.1 and C.1.2 samples. Further inspection of these

sequences with CoVDB (https://covdb.standford.edu/) showed that they contain several spike mutations not characteristic of either C.1 or C.1.2, suggesting they have been mis-assigned. There were also several samples that may violate the molecular clock assumption. These sequences were removed and the tree remade. The final tree showed a strong positive temporal signal, with a correlation coefficient of 0.97 and R² of 0.95. The slope of the regression suggested a preliminary clock rate estimate of 1.4x10⁻³.

Phylogenetic Analysis

Phylogenetic analysis was conducted with a custom Nextstrain SARS -CoV-2 build⁴⁷. Briefly, the pipeline filters sequences, aligns these sequences with (https://github.com/neherlab/nextalign), sub-samples the datasets (resulting in the dataset described above), constructs a phylogenetic tree with IQ-TREE⁴⁹, refines and dates the tree with TreeTime⁵¹, reconstructs ancestral states, and assigns Nextstrain clades to the sequences. The tree was visualized with Auspice to confirm the presence of a C.1.2 cluster. This revealed that several non-C.1.2 samples clustered with C.1.2. These sequences were inspected for the presence of the major C.1.2 mutations (dark purple mutations in Fig. 3b). All sequences possessed at least eight major mutations; this, along with the clustering, was used as evidence to re-assign the sequences to C.1.2, resulting in a set of 54 C.1.2 genomes.

SARS-CoV-2 Model

We modelled the spike protein on the basis of the Protein Data Bank coordinate set 7A94. We used the Pymol program (The PyMOL Molecular Graphics System, version 2.2.0) for visualization.

Data availability

All of the global SARS-CoV-2 genomes of the C.1.2 lineage generated and presented in this article are publicly accessible through the GISAID platform (https://www.gisaid.org/), along with all other SARS-CoV-2 genomes generated by the NGS-SA. The GISAID accession identifiers of the C.1.2 sequences analyzed in this study are provided as part of **Supplementary Tables 2** and **3**, which also contain the metadata for the sequences. The nextstrain build of C.1.2 and global sequences will be made available at https://nextstrain.org/groups/ngs-sa.

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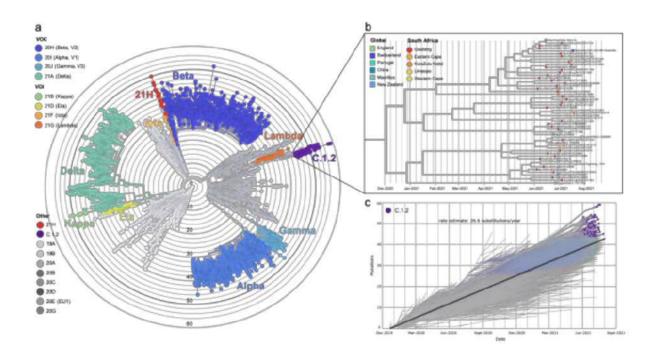


Fig. 1 | Global phylogenetic distribution of C.1.2

a, Phylogenetic tree of 5,756 global sequences including Variants of Concern (VOC), Variants of Interest (VOI), and the C.1.2 lineage, colored according to the key. Ofthese, 1,922 sequences are from South Africa. The tree is scaled by divergence (number of mutations) and colored by Nextstrain clade (shown in the key). The C.1.2 lineage (purple) forms a distinct, highly mutated cluster within clade 20D. b, Magnified time-scaled phylogenetic sub-tree of C.1.2 sequences with >=95% coverage data (n=54) detected across the globe, colored by province (circles for South African sequences) or by country (squares for non-South African sequences). c, Clock estimate of lineage evolution during the SARS-CoV-2 pandemic. C.1.2 samples are indicated by purple dots; all other samples are indicated by branches only. The regression line represents the average mutation rate of the SARSCoV-2 sequences in the tree (26.6 substitutions/year). C.1.2 sequences form a subcluster above the regression line, suggesting an increased substitution rate above the average.

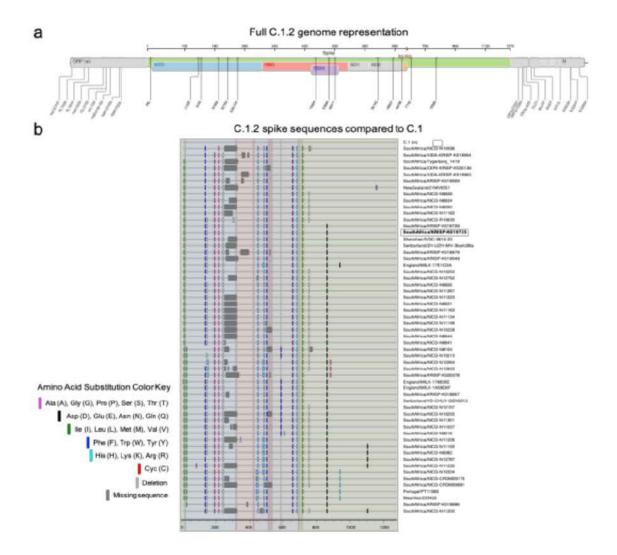


Fig. 2 | Mutational profile of C.1.2. a, Full genome representation of C.1.2 showing all mutations, with those in the spike (green) colored according to functional regions, including Nterminal domain (NTD, blue), receptor binding domain (RBD, red), receptor binding motif (RBM, purple), subdomain1 and 2 (SD1 or SD2, grey) and the cleavage site (S1/S2, yellow). Figure generated by covdb.stanford.edu. **b**, Highlighter plot of C.1.2 spike sequences with >=90% coverage of the spike region (n=57) identified across the globe, labelled according to the location identified and sequence name. Representative sequence shown ina, is labelled in bold. Mismatches compared to the C.1 strain are colored by Se-Al in hiv.lanl.gov highlighter tool as shown in the key. Large dark grey regions represent missing sequence data. Regions within the spike are colored as in panela.

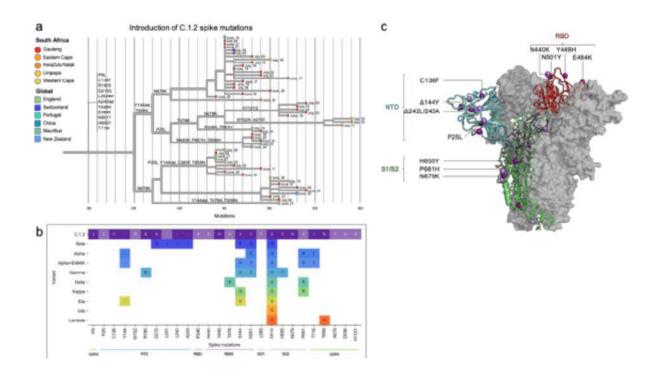
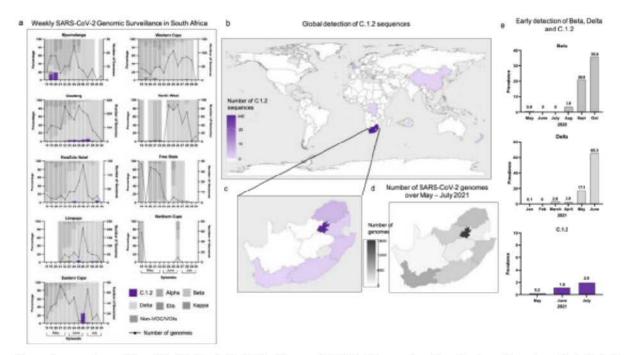


Fig. 3 | Location of C.1.2 mutations within functionally important spike domains. a, A phylogenetic tree highlighting the introduction of spike mutations in the different subclades of the C.1.2 lineage. The tree is annotated with date of collection and colored according to location (country or South African province as indicated in the key) (Figure generated from a Nextstrain Build of global C.1.2 sequences with >=95% coverage data).b, Visualization of C.1.2 lineage-defining mutations shared with Variants of Concern (VOC) and Variants of Interest (VOI). All C.1.2 mutations are shown, withthose present in >50% of C.1.2 sequences in dark purple and those present in <50% of C.1.2 sequences in light purple. For VOCs and VOIs only mutations present in at least 50% of sequences are shown (as determined by frequency information at outbreak.info) VOC and VOI mutations are colored by the Nextstrain clade. c, Schematic showing C.1.2 mutations on the RBD-down conformation of SARS-CoV-2 spike, with domains of a single protomer shown in cartoon view and colored cyan (Nterminal domain, NTD), red (C-terminal domain/receptor binding domain, CTD/RBD), grey (subdomain 1 and 2, SD1 and SD2), and green (S2). The adjacent protomers are shown in translucent surface view and colored shades of grey. Lineage-defining mutations (found in >50% of sequences) are cobred dark purple, with additional mutations (present in <50% of sequences) colored light purple. Key mutations known/predicted to influence neutralization sensitivity (C136F and P25L, Y144del, L242del/A243del, and E484K), or furin cleavage (H655Y and N679K) are indicated. Image was created using the PyMOL molecular graphic program.



Supplementary Fig. 1 | Global distribution of C.1.2. Maps showing the locations in which C.1.2 sequences have been detected, colored according to the number of C.1.2 sequences identified/sequenced. a, Percentage of genomes that are assigned to various SARS-CoV-2 lineages in South Africa for each of the provinces, with C.1.2 shown in purple, by epidemiological week (epiweek) for the months of May - July 2021. The number of genomes sequenced for each epiweek is shown by the black line. b, Global map highlighting South Africa, England, Portugal, Switzerland, China, the Democratic Republic of the Congo, Mauritius (shown in the magnified bubble) and New Zealand, across which 63 C.1.2 sequences have been detected. c, Map of South Africa highlighting the provinces in which C.1.2 has been detected, colored using the same color key as panel a. d, Map of South Africa showing the number of SARS-CoV-2 genomes (n=4,953 as of 13 August 2021) that have been sequenced by province in the months of May, June and July 2021, during which C.1.2 has been detected. e, Early prevalence rates of Beta, Delta and C.1.2 in South Africa based on the number of SARS-CoV-2 sequences generated for each month.

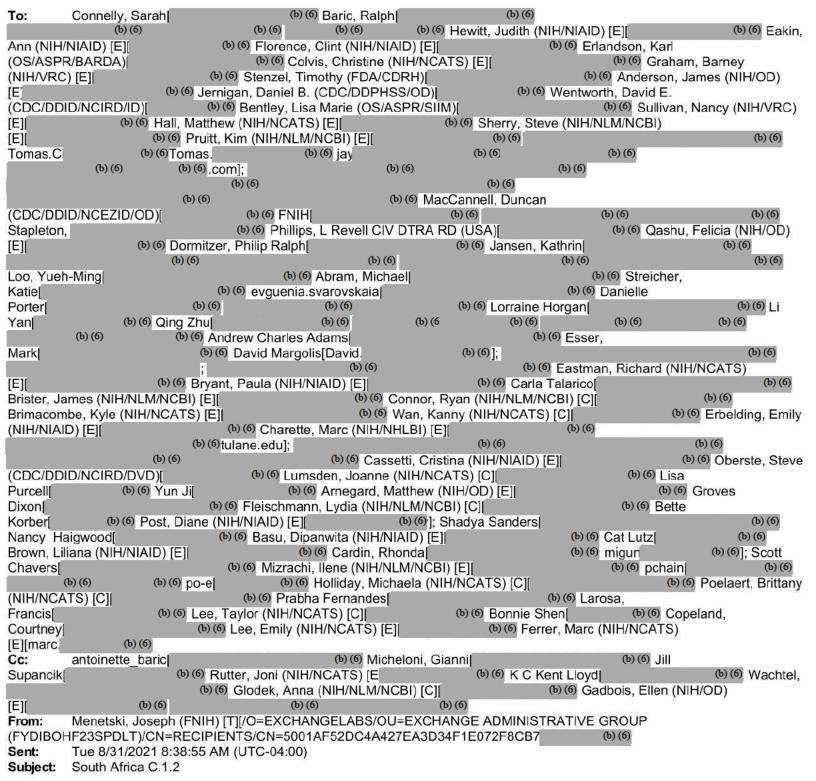
Supplementary Table 1 | Reference set of C.1.2 genomes on GISAID from South Africa.

Provided are the GISAID strain name and gisaid_epi_isl accession numbers for sequences with good quality used in the phylogenetic trees and highlighter plots and potentialC.1.2 sequences that have not been used due to poor sequence coverage (shown as None*).All sequences below were used in local distribution plots (Supplementary Fig. 1).

Strain Name	GISAID_EPI_ISL	Province	Use in Analysis
nCoV-19/South Africa/NICD-N12752/2021	EPI_ISL_3411463	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N12787/2021	EPI_ISL_3411467	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N12833/2021	EPI_ISL_3411457	Limpopo	Tree, highlighter plot
CoV-19/South Africa/NICD-N13250/2021	EPI_ISL_3411458	Limpopo	Tree, highlighter plot
CoV-19/South Africa/KRISP-K018657/2021	EPI_ISL_2726854	Gauteng	Tree, highlighter plot
CoV-19/South Africa/KRISP-K018679/2021	EPI_ISL_2726855	Gauteng	Tree, highlighter plot
CoV-19/South Africa/KRISP-K018739/2021	EPI_ISL_2770450	Gauteng	Tree, highlighter plot
CoV-19/South Africa/KRISP-K019509/2021	EPI_ISL_3132529	Gauteng	Tree, highlighter plot
CoV-19/South Africa/KRISP-K019549/2021	EPI_ISL_3132566	Gauteng	Tree, highlighter plot
CoV-19/South Africa/KRISP-K019696/2021	EPI_ISL_3132608	KwaZulu-Natal	Tree, highlighter plot
CoV-19/South Africa/KRISP-K019725/2021	EPI_ISL_3132623	Gauteng	Tree, highlighter plot
CoV-19/South Africa/KRISP-K020308/2021	EPI ISL 3261918	Gauteng	Tree, highlighter plot
CoV-19/South Africa/KRISP-K020378/2021	EPI ISL 3261970	KwaZulu-Natal	Tree, highlighter plot
CoV-19/South Africa/NICD-CRDM09081/2021	EPI ISL 3281601	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-CRDM09175/2021	EPI ISL 3281600	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N10213/2021	EPI ISL 2984801	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N10228/2021	EPI ISL 2988404	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N10255/2021	EPI ISL 2988405	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N10334/2021	EPI ISL 3149307	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11037/2021	EPI ISL 3149313	Limpopo	Tree, highlighter plot
CoV-19/South Africa/NICD-N11134/2021	EPI ISL 3237084	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11146/2021	EPI ISL 3237092	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11155/2021	EPI ISL 3237098	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11162/2021	EPI ISL 3237100	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11163/2021	EPI ISL 3236953		
		Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11200/2021	EPI_ISL_3101505	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11206/2021	EPI_ISL_3149299	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11223/2021	EPI_ISL_3149300	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11230/2021	EPI_ISL_3149301	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11267/2021	EPI_ISL_3074033	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N11301/2021	EPI_ISL_3149306	Gauteng	Tree, highlighter plot
hCoV-19/South Africa/NICD-N12157/2021	EPI_ISL_3237233	Eastern Cape	Tree, highlighter plot
nCoV-19/South Africa/NICD-N12264/2021	EPI_ISL_3237237	Limpopo	Tree, highlighter plot
nCoV-19/South Africa/NICD-N8831/2021	EPI_ISL_3342730	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N8834/2021	EPI_ISL_3342731	Gauteng	Tree, highlighter plot
nCoV-19/South Africa/NICD-N8841/2021	EPI_ISL_3342732	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N8844/2021	EPI_ISL_3342733	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N9216/2021	EPI_ISL_3342734	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N9250/2021	EPI_ISL_3342735	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N9382/2021	EPI_ISL_2828749	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N9628/2021	EPI_ISL_2827937	Limpopo	Tree, highlighter plot
nCoV-19/South Africa/NICD-N9826/2021	EPI_ISL_2942287	Gauteng	Tree, highlighter plot
nCoV-19/South Africa/NICD-R10630/2021	EPI_ISL_3219805	Gauteng	Tree, highlighter plot
CoV-19/South Africa/Tygerberg_1419/2021	EPI_ISL_3118719	Cape Town	Tree, highlighter plot
CoV-19/South Africa/VIDA-KRISP-K018954/2021	EPI_ISL_2841668	Gauteng	Tree, highlighter plot
CoV-19/South Africa/NICD-N13117/2021	EPI_ISL_3411459	Limpopo	Tree
CoV-19/South Africa/NICD-N10596/2021	EPI_ISL_2988409	Gauteng	Highlighter plot
CoV-19/South Africa/NICD-N8104/2021	EPI_ISL_2695610	Mpumalanga	Highlighter plot
CoV-19/South Africa/CERI-KRISP-K020136/2021	EPI_ISL_3267751	Eastern Cape	Highlighter plot
CoV-19/South Africa/VIDA-KRISP-K018963/2021	EPI_ISL_2841677	Gauteng	Highlighter plot
CoV-19/South Africa/NICD-N8127/2021	EPI_ISL_2695631	Mpumalanga	None*
hCoV-19/South Africa/NICD-N11018/2021	EPI ISL 3149312	Limpopo	None*
hCoV-19/South Africa/KRISP-K020179/2021	EPI_ISL_3267757	KwaZulu-Natal	None*

Supplementary Table 2 | Reference set of C.1.2 genomes on GISAID from other countries. We gratefully acknowledge the following authors from the originating laboratories responsible for obtaining the specimen, as well as the submitting laboratories where the genomes were generated and shared via GISAID, on which this research is based. All submitters of data may be contacted via www.gisaid.org. Authors are listed according to how they were provided on GISAID. Listed are those with good quality used in the phylogenetic trees and highlighter plots and potential C.1.2 sequences that have not been used due to poor sequence coverage (shown as None*). All sequences below were used in global distribution plots (Supplementary Fig. 1).

Use in Analysis	Vehua Tree, highlighter plot	Tree, highlighter plot	of K. John Tree, highlighter plot	rto d K. John Tree, highlighter plot	rto d K. John Tree, highlighter plot.	Mait reaz, avid savid filet free, highlighter plot ah noothy	on C. Tree, highlighter plot	Staire Highlighter plot	Claire Highlighter plot	naki, filko, as, None* None* ke,
Author List	National institute for Viral Disease Long Chen, Can Zhu,Xinyi Wei,Yue Li,Sharyu Deng and Yaqing He Wu,Yue Li,Sharyu Deng and Yaqing He	Borges et al	The Lighthouse Lab in Matton Regions and Associated Adeletion, Boberto Annalo, Jeffrey Barretti, School Goncalves, Eswan Harrison, Devolution, Jackson, lan Johnston, Dominic Kwalatkowskii, Cordella Langfords, John Silbos on behalf of the Weldermer Samper Institute COVID-19 States on behalf of the Weldermer Samper Institute COVID-19 Surveillance Team.	The Lighthouse Lab in Mistor Visions and New Adention, Roberto Annali, Jeffrey Berntt Sonia Goncalves, Ewan Harrison, David K. Jackson, Isan Johnson, David K. Missowski, Cordisia Langford, John Sillice on behalf of the Welstone Sanger Institute COVID-19 Surveillance Team.	The Lighthouse lab in Millon Warriers and New Adeltron, Roberto Annel, Jeffrey Berret, Sonis Concalves, Evan Harriero, Daniero Jackson, Isn Johnshin, Domeire Kwalstowskii, Cordella Langford, John Silboe on behalf of the Welderone Sanger Institute COVID-19 Surveillance Team.	Rachel Boyle, Salf-Ann Harbison, Olvis Stroeven, Xiaoyun Ren, Matt Storey, Nikki Freed, Muhammad Fasad, Jing Wang, Hermes Perez, Angi Wann, Adip van end Linder, Ado Upon, Ciris Marsalo, Bowl Harmer, Dragase Drincover, Gary MocAuffin, Haran Solia Anderson, James Usiser, Jil Sherwood, John Freeman, Julia Howard, Julier Boy, Mary Dakhmada, Matt Bakistin, Matthew Ropers, Max Biommield, Michael Addrés, Michele Baim, Saliy Roberts, Sarah Jellenes, Sharmin Mitanjay, Sanan Maydy, Timodhy Bellenes, Sharmin Marshy, Olin Slander, Jopey de Ligh.	Mantaj SS, Sonoo J, Pathoo M, Bahadoor BS, Mathur H, Sujeewon C, Jannoo N, Ramuth M	Trestan Pillonel, Damien Jacot, Sébastien Aaby, Gilbert Greub, Claire Berteill	Trestan Pillonel, Damien Jacol, Sébastien Aeby, Gilbert Greub, Claire Bertell	Piecio Menia Kopeleni, Elini Miverethe, Edrig Kopande, Lasannaki, Amuri Kzta, Frantisca Mayembe Miseneki, Emmanual Loide Luffeo, Jesen Claude Miskangara, Rapinsisi Limemine, Gabriel Kolammia, Casherin Mariansi Mariansi Apprisel, Limemine, Gabriel Kolammia, Casherin Mariansi Mariansi, Josephia Kales Mariansi Kalembara, Traver Bedrach, James Hodder, Landon Goodeladow, Andrew Rambatu, Nick, Loman, Victian Andrews Missel Wiley, Eden A Mariansul, Nick, Loman, Victian Andrews Mayember Tariffum
Submitting Laboratory	National Institute for Viral Disease Control and Prevention, China CDC	Instituto Nacional de Saude (INSA)	Welcome Sanger Institute for the COVID-19 Genomics UK (COG-UK) Consortum	Welcome Sanger Institute for the COVID-19 Genomics UK (COG-UK) Consortium	Welcome Sanger Institute for the COVID-19 Genomics UK (COG-UK) Consortium	Institute of Environmental Science and Research (ESR)	Virology Department, Central Health Laboratory, Victoria Hospital, Candos, Ministry of Health and Wellness, Mauritius	Laboratory of genomics and metagenomics	Institute of Medical Virology	Vra Respiratory Lab, National Pathogen Sequencing Lab, National Institute for Bornedical Research Institute for Bornedical Research (INRB)
Originating Laboratory	Shenzhen Center for Disease Control and Prevention	Sesaram	Lighthouse Lab in Million Keynes	Lighthouse Lab in Million Kaynesi	Lighthouse Lab in Million Keynes	Middemore Hospital	Airport Health Laboratory/Central Health Laboratory	Epizootic Haematopoletic Necrosis Virus (EHNV)	Stadtspital Triemli	Vrai Respiratory Lab. National Institute for Bonnedical Research (INRB)
Country	China	Portugal	United Kingdom	United Kingdom	United Kingdom	New Zealand	Mauritius	Switzeriand	Switzerland	Democratic Republic of the Congo
(Accession number)	EPI_ISL_2931281	EPI ISL 2989113	EPI_ISL_2803815	EPI ISL_2716062	EPI_ISL_3287712	EPI ISL. 3164100	EPI_ISL_3236186	EPI 1St_2868597	EPI 18L_3128775	EPI_ISL_3086831
Strain Name	hCoV-19/Sherzhen/IVDC-0610-33/2021	hCoV-19/Portugal/PT11580/2021	hCoV-19/England/MILK-17E1CDA/2021	hCoV-19/England/MILK-176835E/2021	hCoV-19/EnglandMILK-1A58D6F/2021	hCoV-19/NewZealand/21/MV0551/2021	hCoV-19/Maurikis/235422/2021	hCoV-19/Switzerland/vD-CHUV-GEN5512/2021	hCoV-19/Switzerland/ZH-UZH-IMV-3ba4c99a/2021	hCoV-190RC/INRB-RDC-587/2021



I am guessing this will be an upcoming interest? We should at least have it on the radar.

https://www.reuters.com/world/africa/south-africa-detects-new-coronavirus-variant-still-studying-its-mutations-2021-08-30/

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[C]
From:
           Connelly, Sarahl
           Mon 8/30/2021 2:02:55 PM (UTC-04:00)
Sent:
           RE: ACTIV TRACE full Working Group
Subject:
20210830-TRACE VariantReport-v27.1.xlsx
20210830-TRACE VariantReport Therapeutic Supplemental-v27.1.pdf
 Dear Working Group Members,
 Ahead of tomorrow's meeting, please find attached this week's TRACE report and supplemental figures.
```

Warm Regards, Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: +1 (b) (6)
www.deloitte.com

From: Connelly, Sarah

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

Sent: Wednesday To: Connelly, Sara	ah;	(b) (6)		(b) (6)	(b) (6)	(b) (6)	(b) (6)
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Subject: ACTIV TF	RACE full Worki	ng Group					
When: Tuesday,	August 31, 2021	9:00 AM-10:00	AM (UTC-05:0	00) Eastern Ti	me (US & Car	nada).	
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Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Preclinical Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at MCATSOpenDataPortal@nih.gov with any feedback, comments, or questions to help us improve this resource.

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- · With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the <u>OpenData Portal Visualization Page</u> Additional details on the visualized data are available on the <u>NCATS OpenData Portal</u>.

New to the OpenData Portal Variant Database this week:

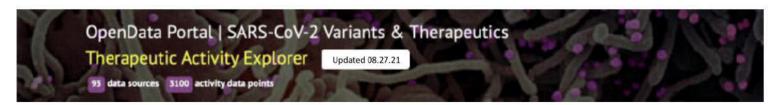
New Pre-prints and Publications:

1. Temporal Increase in Neutralization Potency of SARS-CoV-2 Antibodies and Reduced Viral Variant Escape after Sputnik V Vaccination [Pre-print]

Updated Pre-prints and Publications:

- XAV-19, a swine glyco-humanized polyclonal antibody against SARS-CoV-2 Spike receptorbinding domain, targets multiple epitopes and broadly neutralizes variants [Pre-print]
- TMPRSS2 and RNA-dependent RNA polymerase are effective targets of therapeutic intervention for treatment of COVID-19 caused by SARS-CoV-2 variants (B.1.1.7 and B.1.351) [Peer-reviewed publication]
- 3. Neutralization of ZF20001- elicited antisera to SARS-CoV-2 variants [Peer-reviewed publication]

Explore the latest Variants & Therapeutics data on OpenData:



Click to explore variant data on OpenData Portal:

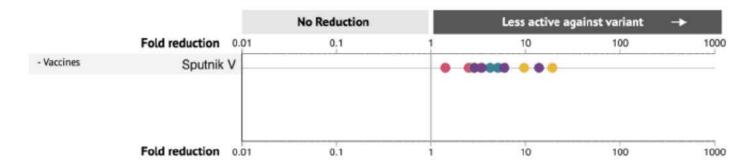
What's new in the last week?		Data for A	II Variants		
B.1.1.7	B.1.351	B.1.617.2	AY.1	AY.2	P.1
B.1.427/429	B.1.525	B.1.526	B.1.617	C.37	P.2
Other Variants		Single Point N	Mutation Data		





In vitro data added to NCATS OpenData Portal in last week





EXPANDED THERAPEUTIC VIEW

Sputnik V





8.30.2021



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Attendees:
                       Baric, Ralph;
                                                                    (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E];
                       Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E];
                       Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan,
                       Daniel B. (CDC/DDID/NCIRD/ID); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                       (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                       (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
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                       Katie; evguenia.svarovskaia; Danielle Porter;
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                       Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                       (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
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                       Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                       Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                       Haigwood; Basu, Dipanwita (NIH/NIBIB) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
                       Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
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                       (NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney; Lee, Emily (NIH/NCATS) [E]; Ferrer, Marc (NIH/NCATS)
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                       Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];
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Importance:
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Subject:
                       ACTIV TRACE full Working Group
                       Tue 8/31/2021 9:00:00 AM (UTC-04:00)
Start Time:
                       Tue 8/31/2021 10:00:00 AM (UTC-04:00)
End Time:
Required Attendees:
                                                                   (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E];
                       Baric, Ralph:
                       Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine (NIH/NCATS) [E];
                       Graham, Barney (NIH/VRC) [E]; Stenzel, Timothy (FDA/CDRH); Anderson, James (NIH/OD) [E]; Jernigan,
                       Daniel B. (CDC/DDID/NCIRD/ID); Wentworth, David E. (CDC/DDID/NCIRD/ID); Bentley, Lisa Marie
                       (OS/ASPR/SIIM); Sullivan, Nancy (NIH/VRC) [E]; Hall, Matthew (NIH/NCATS) [E]; Sherry, Steve
                       (NIH/NLM/NCBI) [E]; Pruitt, Kim (NIH/NLM/NCBI) [E]; john.young.jy3;
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                       Katie; evguenia.svarovskaia; Danielle Porter;
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                       Bryant, Paula (NIH/NIAID) [E]; Carla Talarico; Brister, James (NIH/NLM/NCBI) [E]; Connor, Ryan
                       (NIH/NLM/NCBI) [C]; Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily
                       (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];
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                       Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon;
                       Fleischmann, Lydia (NIH/NLM/NCBI) [C]; Bette Korber; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy
                       Haigwood: Basu, Dipanwita (NIH/NIBIB) [E]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; migun;
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                       Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; pchain;
                       (NIH/NCATS) [C]: Poelaert, Brittany (NIH/NCATS) [C]: Prabha Fernandes; Larosa, Francis; Lee, Taylor
                       (NIH/NCATS) [C]; Bonnie Shen; Copeland, Courtney; Lee, Emily (NIH/NCATS) [E]; Ferrer, Marc (NIH/NCATS)
                       [E]
                       antoinette baric; Micheloni, Gianni; Jill Supancik; Rutter, Joni (NIH/NCATS) [E]; K C Kent Lloyd; Wachtel,
Optional Attendees:
                       Jonathan; Glodek, Anna (NIH/NLM/NCBI) [C]; Gadbois, Ellen (NIH/OD) [E];
 Updating the meeting name
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Connelly, Sarah

From:

Required Attendees: Baric, Ralph; (b) (6) Hewitt, Judith (NIH/NIAID) [E]; Eakin, Ann (NIH/NIAID) [E]; Florence, Clint (NIH/NIAID) [E]; Erlandson, Karl (OS/ASPR/BARDA); Colvis, Christine

(NIH/NCATS) [E]; Gra		10, 10, 10, 10, 10, 10, 10, 10, 10, 10,	Γimothy (FDA/CDRH avid E. (CDC/DDID/1		
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	IIH/NLM/NCBI) [E];			b) (6)	(b) (6):
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FNIH;	(b) (6) Stapleton, Ja	ack; Phillips, L Rev	ell CIV DTRA RD (U	SA); Qashu, Felicia	(NIH/OD) [E];
Dormitzer, Philip Ralp	h; Jansen, Kathrin;	•	(b) (6)	(b)	6 Loo, Yueh-
Ming; Abram, Michael;	Streicher, Katie; evgi	uenia.svarovskaia;	Danielle Porter;	(p) (Q) L(C)	orraine Horgan;
Li Yan; Qing Zhu;	(b) (6)	(b) (6)	and the second s	arles Adams; Esser, l	385
Margolis;		(b) (6)		stman, Richard (NIH	
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Joanne (NIH/NCATS)					
			AID) [E]; Shadya San		
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Mizrachi, Ilene (NIH/)			po-e; Holliday, Mich	. [1] [1] [1] [1] [1] [1] [1] [1] [1] [1]	
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Join by Telephone

Dial: US: +1 213 338 8477 or +1 720 928 9299 or +1 312 626 6799 or +1 646 518 9805

Meeting ID: (b) (6)

Password: (b) (6)

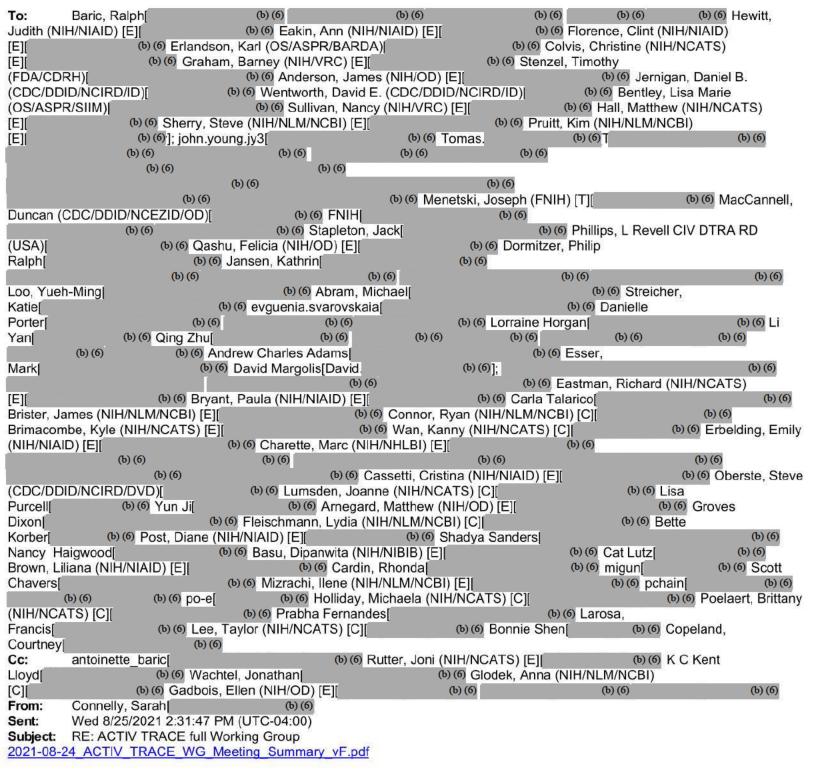
International numbers

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Dear Working Group Members,

Thank you all for attending our TRACE WG meeting on Tuesday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments.

Warm Regards,

Sarah

Sarah Connelly, PhD Deloitte Consulting, LLP Tel/Direct: +

(b) (6) www.deloitte.com

----Original Appointment----

From: Connelly, Sarah

Sent: Wednesday, December 23, 2020 11:12 AM

To: Connelly, Sarah;		(b) (6)		(b) (6)	(b) (6)	(b) (6)	(b) (6)
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International numbers

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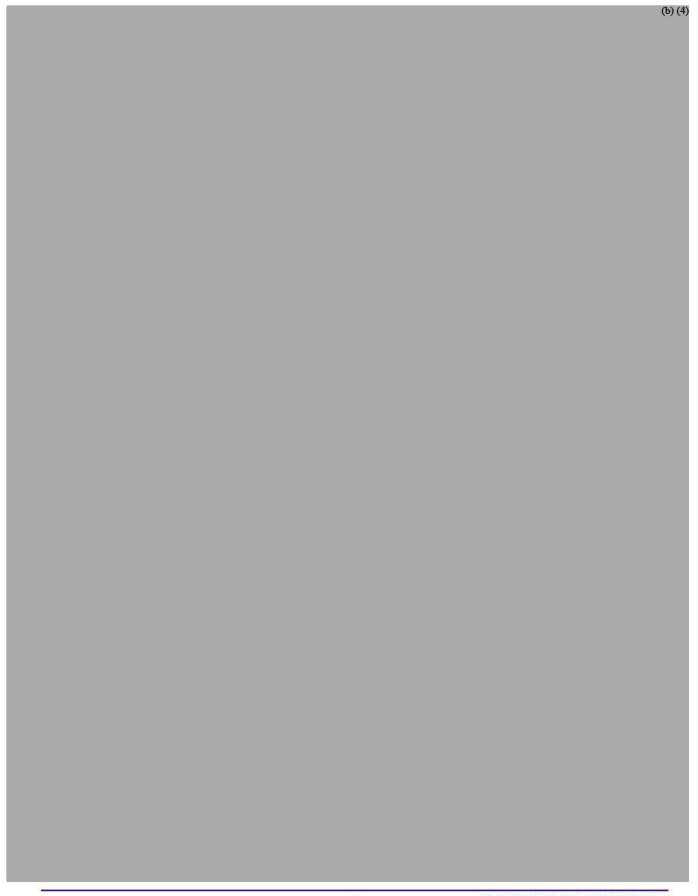
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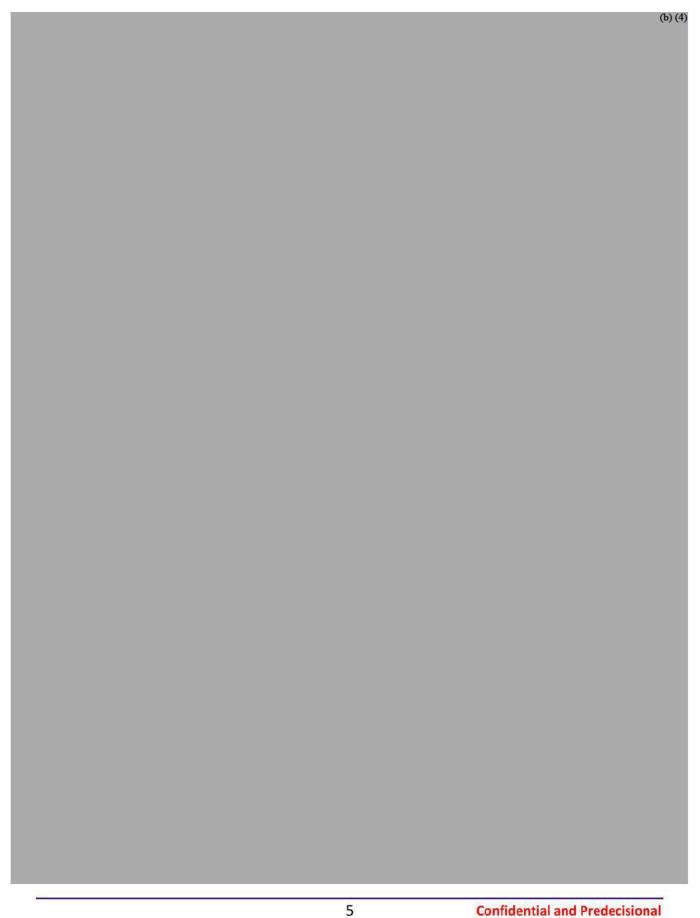
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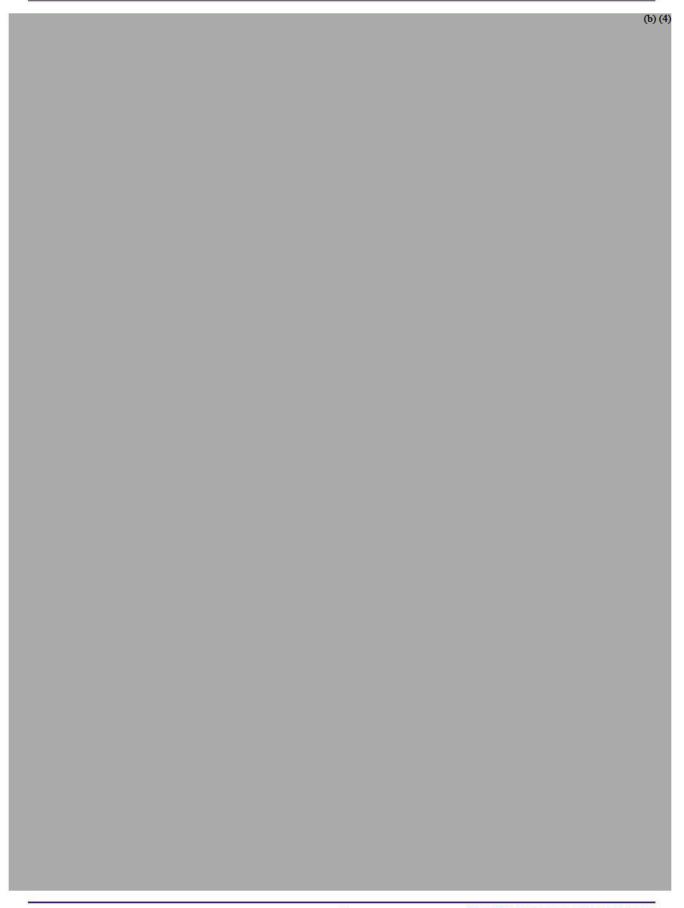




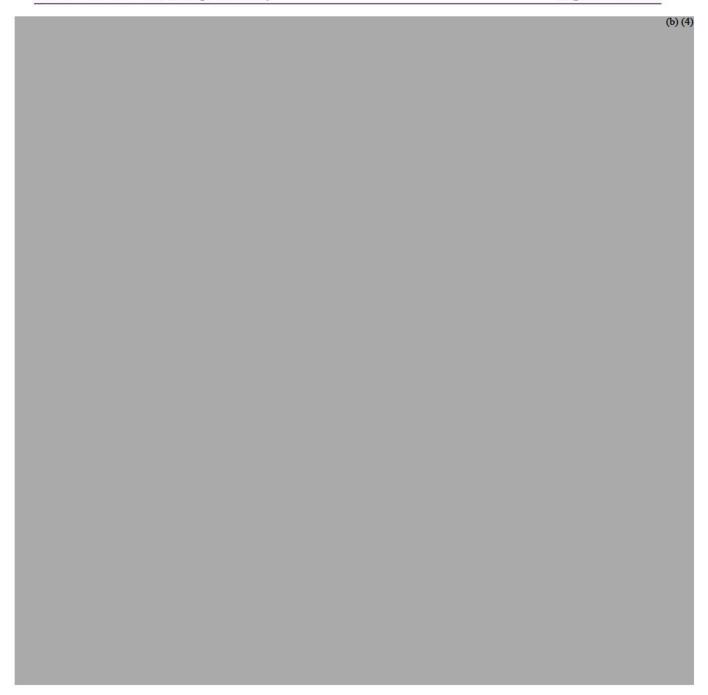








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		N=RECIPIENTS/CN=500				
Sent:		4:13:23 PM (UTC-04:00				
Subject:		uested - SARS-CoV-2 va		ise		
Dear All,						
It would	be very helpful	if you could all respond t	to this survey. The	addition of in vivo	data to the ODP w	ould increase its utility, but
we need	your input on h	now best to address the o	data.			
Please ta	ake a few minute	es and let us know what	you think.			
Thank yo	ou,					
Joe						
Subject	Innut Requeste	d - SARS-CoV-2 variant in	vivo database			

Thank you again for the discussion regarding the SARS-CoV-2 variant in vivo database during last Tuesday's meeting. This is a friendly reminder that we would greatly appreciate your participation in a very brief survey (link below) about the development

Dear Working Group Members,

of the in vivo database on the ODP site.

https://docs.google.com/forms/d/e/1FAIpQLScBAIFggNYxZFINJAxf9ao94YA3brb0blkz2-WwhH0-IZS99Q/viewform

Warm Regards, Sarah

Sarah Connelly, PhD Manager | GPS S&A

Deloitte Consulting, LLP 2200 Ross Ave. #1600.

2200 Ross Ave. #1600, Dallas, TX 75201

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           Connelly, Sarahl
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From:
           Mon 8/23/2021 4:07:33 PM (UTC-04:00)
Sent:
Subject:
           Input Requested - SARS-CoV-2 variant in vivo database
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Dear Working Group Members,

Thank you again for the discussion regarding the SARS-CoV-2 variant in vivo database during last Tuesday's meeting. This is a friendly reminder that we would greatly appreciate your participation in a very brief survey (link below) about the development of the in vivo database on the ODP site.

https://docs.google.com/forms/d/e/1FAIpQLScBAIFggNYxZFINJAxf9ao94YA3brb0blkz2-WwhH0-IZS99Q/viewform

Warm Regards,

Sarah

Sarah Connelly, PhD Manager | GPS S&A

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           Connelly, Sarah
From:
           Mon 8/23/2021 1:22:17 PM (UTC-04:00)
Sent:
           RE: ACTIV TRACE full Working Group
Subject:
20210823-TRACE VariantReport Therapeutic Supplemental-v26.1.pdf
20210823-TRACE VariantReport-v26.1.xlsx
 Dear Working Group Members,
 Ahead of tomorrow's meeting, please find attached this week's TRACE report and supplemental figures.
 Warm Regards,
```

Sarah

Sarah Connelly, PhD Deloitte Consulting, LLP Tel/Direct: +1 (b)(6)www.deloitte.com

----Original Appointment----From: Connelly, Sarah

Sent: Wednesday, December 23, 2020 11:12 AM

To: Connelly, Sarah;	(b) (6)		(b) (6)	(b) (6)	(b) (6)	(b) (6)
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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Preclinical Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at MCATSOpenDataPortal@nih.gov with any feedback, comments, or questions to help us improve this resource.

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- · From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- · With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the OpenData Portal Visualization Page Additional details on the visualized data are available on the NCATS OpenData Portal.

New to the OpenData Portal Variant Database this week:

New Pre-prints and Publications:

- 1. Molecular basis of immune evasion by the delta and kappa SARS-CoV-2 variants [Pre-print]
- 2. Preliminary Analysis of Safety and Immunogenicity of a SARS-CoV-2 Variant Vaccine
 Booster [Pre-print]
- 3. BNT162b2-Elicited Neutralization against New SARS-CoV-2 Spike Variants [Peer-reviewed publication]
- 4. BNT162b2 vaccine induces neutralizing antibodies and poly-specific T cells in humans [Peer-reviewed publication]

Updated Pre-prints and Publications:

1. <u>Durability of mRNA-1273 vaccine-induced antibodies against SARS-CoV-2 variants</u> [Peer-reviewed publication]

OpenData Portal | SARS-CoV-2 Variants & Therapeutics Therapeutic Activity Explorer Updated 8.20.21

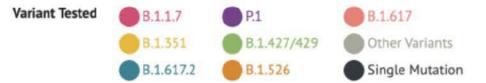
91 data sources 3073 activity data points

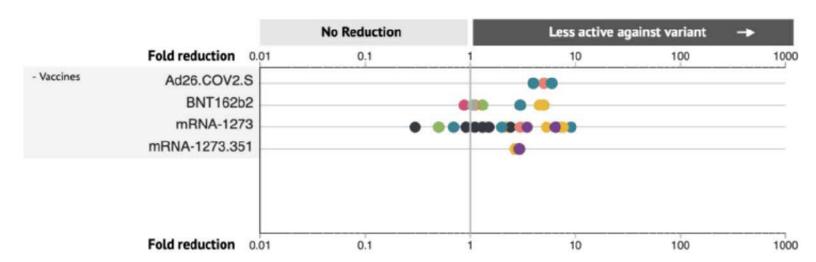
OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

Visualize and Explore the OpenData Portal Variant Data:

B.1.1.7	B.1.351	B.1.617.2	AY.1	AY.2	P.1
B.1.427/429	B.1.525	B.1.526	B.1.617	C.37	P.2
	Other Variants Single Point Mutation Data		Data for All	Variants	
			What's new in t	he last week?	

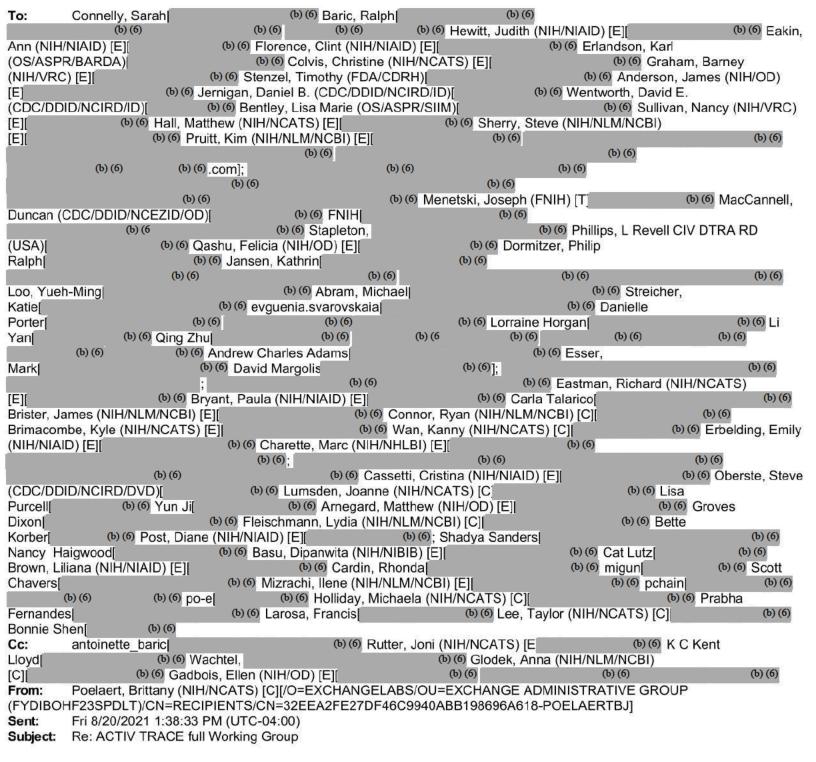
New in vitro neutralization data added to NCATS OpenData Portal last week







8.22.2021



Hello Working Group Members,

Thank you for the questions and discussion regarding the SARS-CoV-2 variant in vivo database during Tuesday's meeting. We would greatly appreciate your participation in a very brief survey. **Please click the link below to access the survey** (closure date: August 27,2021).

https://docs.google.com/forms/d/e/1FAIpQLScBAIFggNYxZFINJAxf9ao94YA3brb0blkz2-WwhH0-IZS99Q/viewform

Sincerely,

Brittany Poelaert, Ph.D.

Scientific Project Manager [C], Division of Preclinical Innovation

National Center for Advancing Translational Sciences (NCATS) National Institutes of Health 9800 Medical Center Drive



Connect with us!: https://ncats.nih.gov/connect

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Follow us on Twitter: https://twitter.com/ncats_nih_gov

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From: "Connelly, Sarah" <
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Date: Thursday, August 19, 2021 at 2:45 PM
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To: "Baric, Ralph" <
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Subject: RE: ACTIV TRACE full Working Group

Dear Working Group Members,

Thank you all for attending our TRACE WG meeting on Tuesday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments.

Also, we wanted to express our thanks for your attention and the wonderful discussion that resulted after the *in vivo* data presentation on Tuesday. The NCATS team has collated the comments and concerns from the discussion and has generated a survey. Your thoughts on the *in vivo* data subject are welcome and greatly appreciated. We look forward to receiving your feedback and help in this endeavor. Please click the link below to access the survey (closure date: August 27,2021).

https://docs.google.com/forms/d/e/1FAIpQLScBAIFggNYxZFINJAxf9ao94YA3brb0blkz2-WwhH0-IZS99Q/viewform

The NCATS team also delved deeper into the discussion points and questions and found that, of the 25 articles that fit our ingestion criteria (therapeutic in clinical trials or approved, government or pharmaceutic collaboration/authorship, and variant tested), 18 reports included a challenge study with a SARS-CoV-2 variant of concern. Of those 18 reports, 8 focused on pathogenicity of variant strains. The remaining studies detailed the use of therapeutic agents tested in SARS-CoV-2 variant challenge studies. These articles would fit a more stringent criteria that requires a variant of SARS-CoV-2 employed in a challenge study *in vivo*.

Warm regards, Sarah

Sarah Connelly, PhD Deloitte Consulting, LLP

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----Original Appointment----

From: Connelly, Sarah

Sent: Wednesday, December 23, 2020 11:12 AM

[C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E];

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           Connelly, Sarah
From:
Sent:
           Thur 8/19/2021 2:45:17 PM (UTC-04:00)
Subject:
           RE: ACTIV TRACE full Working Group
2021-08-17 ACTIV TRACE WG Meeting Summary vF.pdf
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Dear Working Group Members,

Thank you all for attending our TRACE WG meeting on Tuesday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments.

Also, we wanted to express our thanks for your attention and the wonderful discussion that resulted after the *in vivo* data presentation on Tuesday. The NCATS team has collated the comments and concerns from the discussion and has generated a survey. Your thoughts on the *in vivo* data subject are welcome and greatly appreciated. We look forward to receiving your feedback and help in this endeavor. Please click the link below to access the survey (closure date: August 27,2021).

https://docs.google.com/forms/d/e/1FAIpQLScBAIFggNYxZFINJAxf9ao94YA3brb0blkz2-WwhH0-IZS99Q/viewform

The NCATS team also delved deeper into the discussion points and questions and found that, of the 25 articles that fit our ingestion criteria (therapeutic in clinical trials or approved, government or pharmaceutic collaboration/authorship, and variant tested), 18 reports included a challenge study with a SARS-CoV-2 variant of concern. Of those 18 reports, 8 focused on pathogenicity of

variant strains. The remaining studies detailed the use of therapeutic agents tested in SARS-CoV-2 variant challenge studies. These articles would fit a more stringent criteria that requires a variant of SARS-CoV-2 employed in a challenge study *in vivo*.

Warm regards, Sarah

Sarah Connelly, PhD

Deloitte Consulting, LLP Tel/Direct: +1 (b) (6)

www.deloitte.com

----Original Appointment----

From: Connelly, Sarah

Sent: Wednesday, December 23, 2020 11:12 AM

To: Connelly, Sarah;	(b) (6)		(b) (6)	(b) (6)	(b) (6)	(b) (6)
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When: Tuesday, August 2	17, 2021 9:00 AM-10	0:00 AM (UTC-0	05:00) Eastern T	ime (US & Canada).	
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Join Meeting

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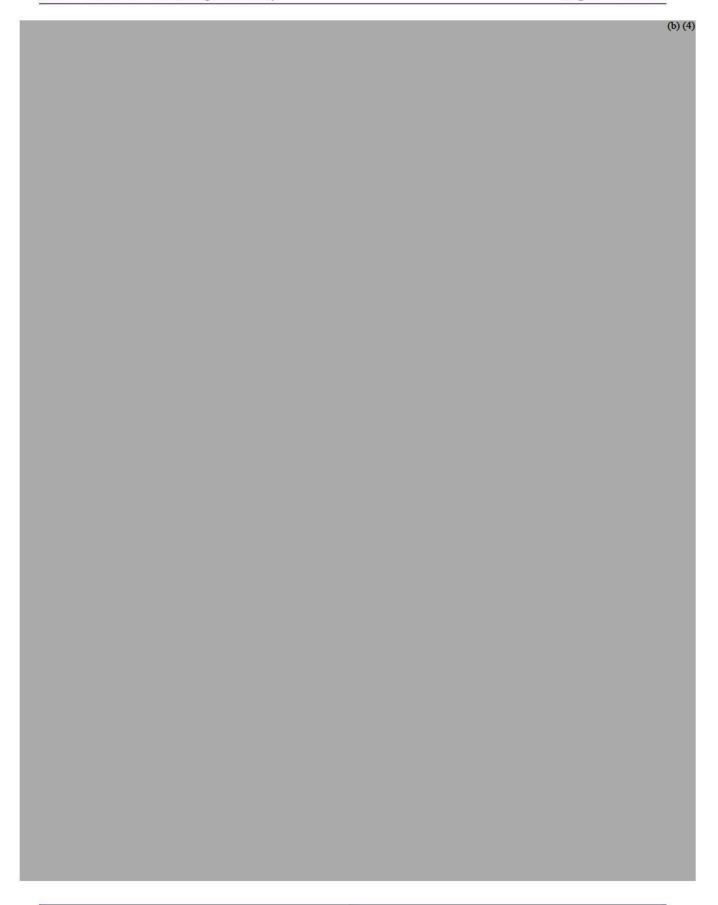
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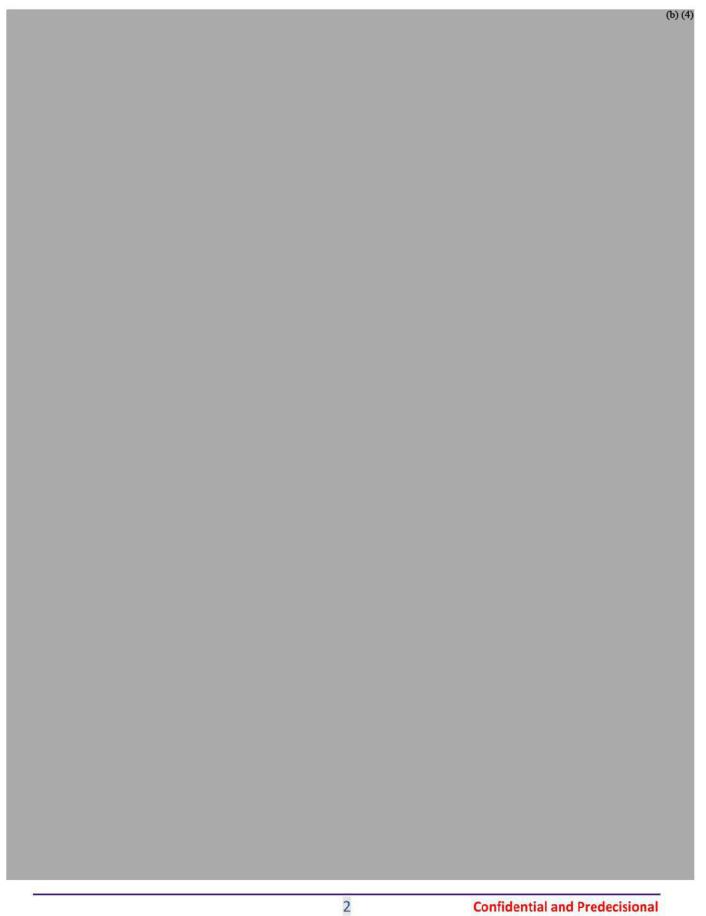
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Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

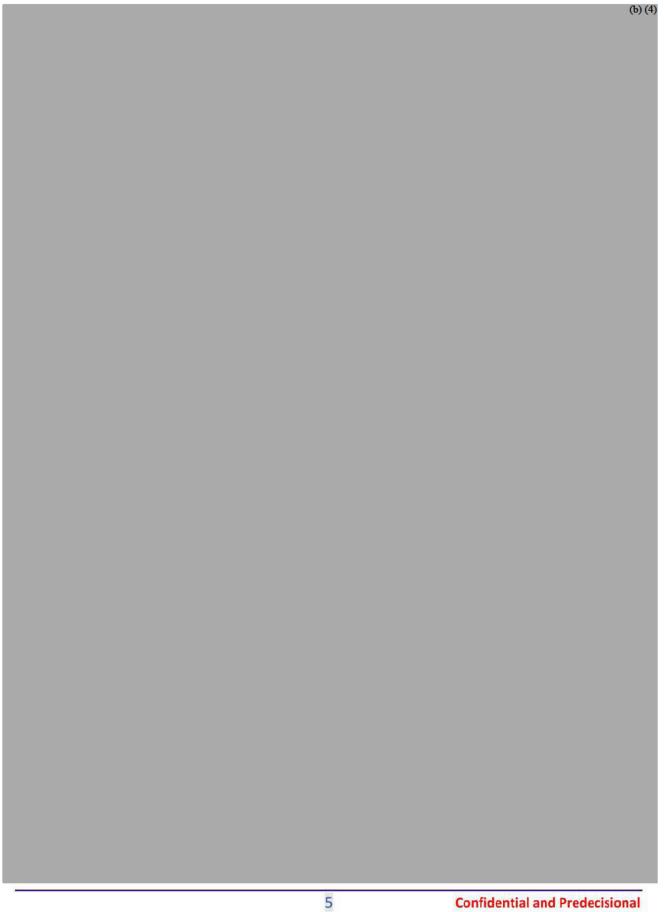
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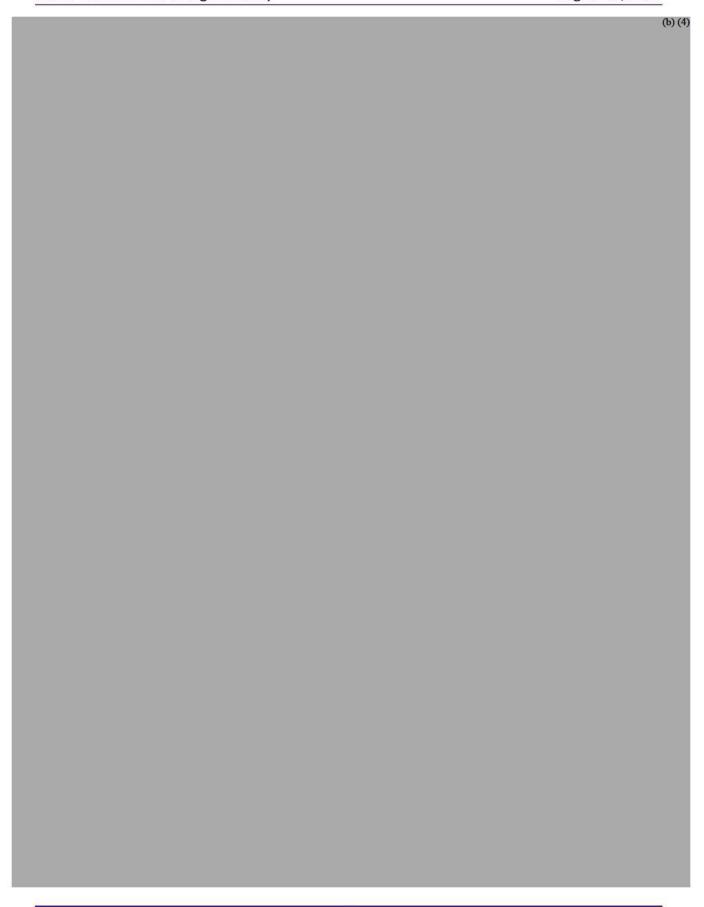
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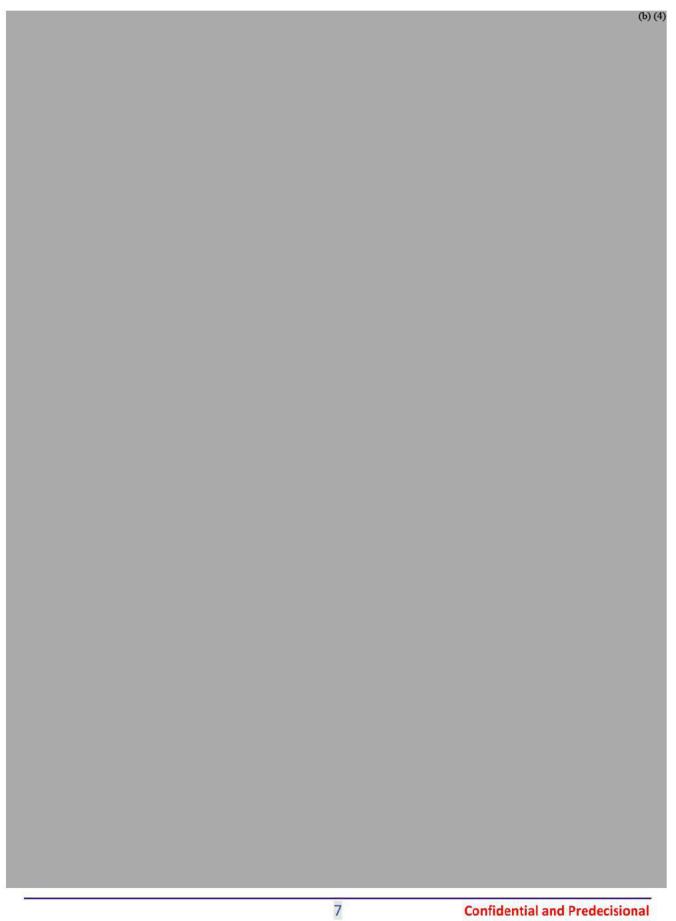
















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From:
           Connelly, Sarah
           Mon 8/16/2021 2:01:14 PM (UTC-04:00)
Sent:
           RE: ACTIV TRACE full Working Group
Subject:
20210816-TRACE VariantReport Therapeutic Supplemental-v25.1.pdf
20210816-TRACE VariantReport-v25.1.xlsx
 Dear Working Group Members,
 Ahead of tomorrow's meeting, please find attached this week's TRACE report and supplemental figures.
 Warm Regards,
 Sarah
 Sarah Connelly, PhD
 Deloitte Consulting, LLP
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Tel/Direct: +1

www.deloitte.com

----Original Appointment----

From: Connelly, Sarah

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Sent: Wednesday To: Connelly, Sar	and the return of the second second second	(b) (6)	(h)) (6)	(b) (6)	(b) (6)	(b) (6)
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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Preclinical Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at MCATSOpenDataPortal@nih.gov with any feedback, comments, or questions to help us improve this resource.

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- · From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- · With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the OpenData Portal Visualization Page Additional details on the visualized data are available on the NCATS OpenData Portal.

New to the OpenData Portal Variant Database this week:

New Therapeutics: Co-VLP (Vaccine); SAB-185 (Neutralizing antibody, polyclonal)

New Pre-prints and Publications:

- 1. Moderna Second Quarter 2021 Financial Results
- Serendipitous COVID-19 Vaccine-Mix in Uttar Pradesh, India: Safety and immunogenicity assessment of a heterologous regime [Pre-print]
- 3. <u>Durability and cross-reactivity of immune responses induced by an AS03 adjuvanted plant-based</u> recombinant virus-like particle vaccine for COVID-19 [Pre-print]
- 4. Fully human antibody immunoglobulin from transchromosomic bovines is potent against SARS-CoV-2 variant pseudoviruses [Pre-print]

Updated Pre-prints and Publications:

1. The dual function monoclonal antibodies VIR-7831 and VIR-7832 demonstrate potent in vitro and in vivo activity against SARS-CoV-2 [Pre-print]

OpenData Portal | SARS-CoV-2 Variants & Therapeutics Therapeutic Activity Explorer Updated 8.13.21

86 data sources 2995 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

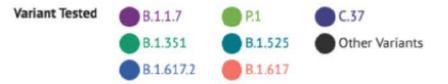
Visualize and Explore the OpenData Portal Variant Data:

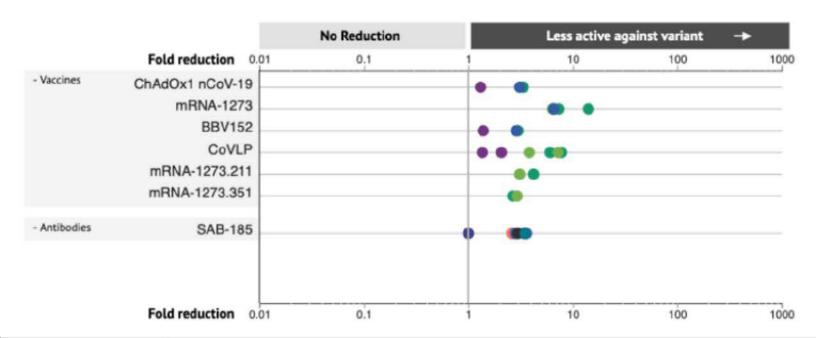
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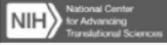
Single Point Mutation Data

What's new in the last week?

New in vitro neutralization data added to NCATS OpenData Portal last week







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Subject:
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08.10 ACTIV TRACE WG Meeting Agenda 20210809 v1.pptx
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Dear Working Group Members,

Thank you all for attending our TRACE WG meeting on Tuesday. Please see attached for the notes and slides from our discussion, and let us know if you all have any additions or amendments.

Warm regards, Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: +1 (b) (6)
www.deloitte.com

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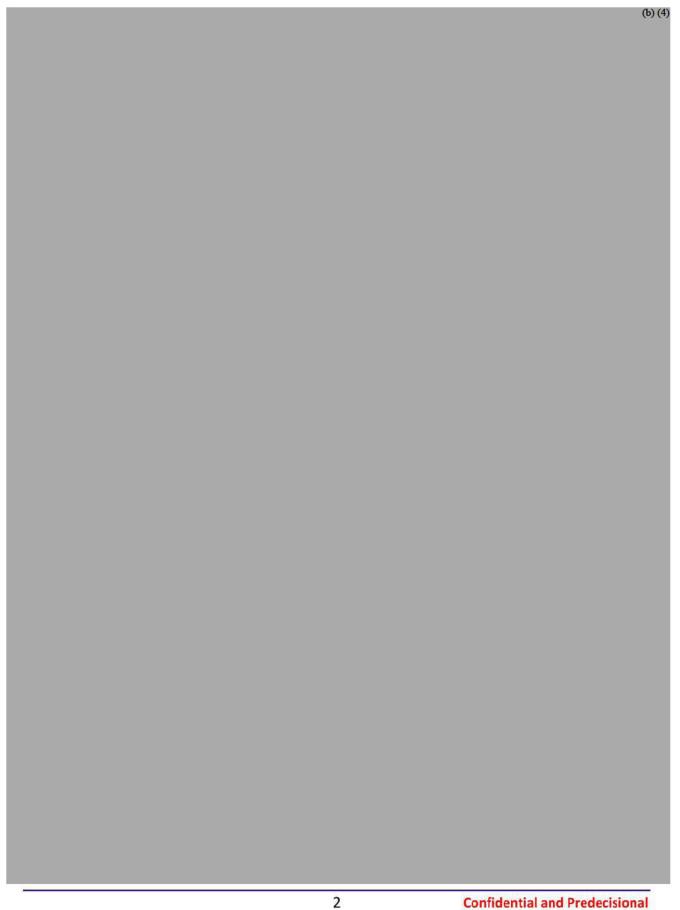
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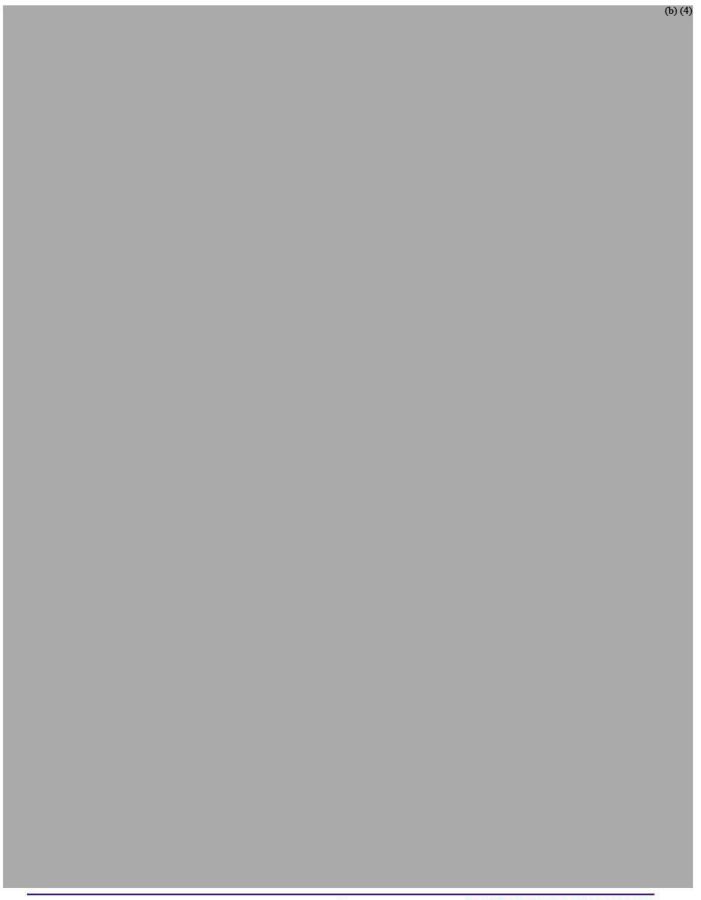
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/G Meeting Summary	August 10, 2021				
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ACTIV Preclinical TRACE Working Group

August 10, 2021

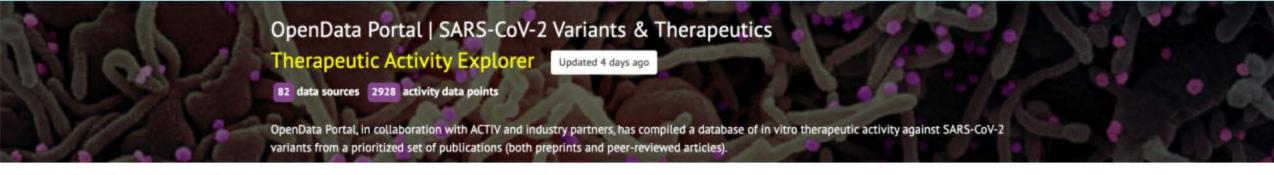
Agenda for Today





TRACE: ACTIV Variant Efforts

Update 08.10.2021



New to the OpenData Portal Variant Database in the past week:

New Datasets, Pre-prints and Publications:

- 1. Pfizer Second Quarter 2021 Earnings Report [press-release]
- 2. Prior infection with SARS-CoV-2 boosts and broadens Ad26.COV2.S immunogenicity in a variant dependent manner [Pre-print]
- 3. Comparable neutralization of SARS-CoV-2 Delta AY.1 and Delta in individuals sera vaccinated with BBV152 [Pre-print]
- 4. Neutralizing antibodies elicited by the Ad26.COV2.S COVID-19 vaccine show reduced activity against 501Y.V2 (B.1.351), despite protection against severe disease by this variant [Pre-print]

Updated Datasets, Pre-prints and Publications:

- 1. Neutralization of variant under investigation B.1.617 with sera of BBV152 vaccinees [Peer-reviewed publication]
- 2. <u>Neutralization of VUI B.1.1.28 P2 variant with sera of COVID-19 recovered cases and recipients of Covaxin an inactivated COVID-19 vaccine [Peer-reviewed publication]</u>
- 3. Neutralizing activity of Sputnik V vaccine sera against SARS-CoV-2 variants [Peer-reviewed publication]
- 4. Neutralization of Delta variant with sera of Covishield vaccinees and COVID-19 recovered vaccinated individuals [Peer-reviewed publications]



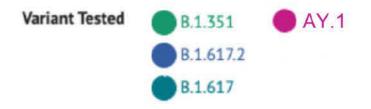
OpenData Portal | SARS-CoV-2 Variants & Therapeutics

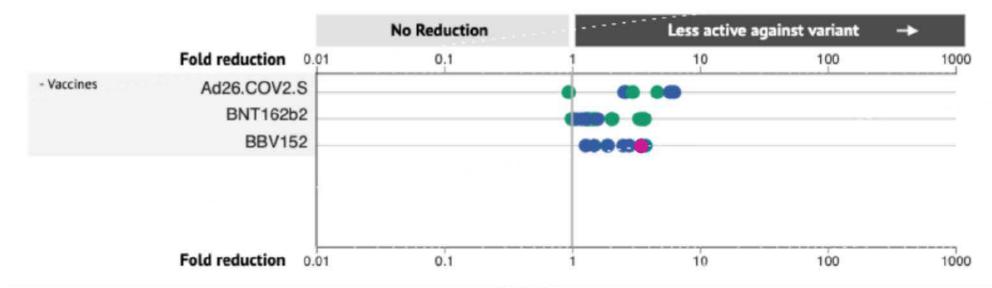
Therapeutic Activity Explorer Updated 4 days ago

79 data sources 2807 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

New to the OpenData Portal Variant Database in the past week:



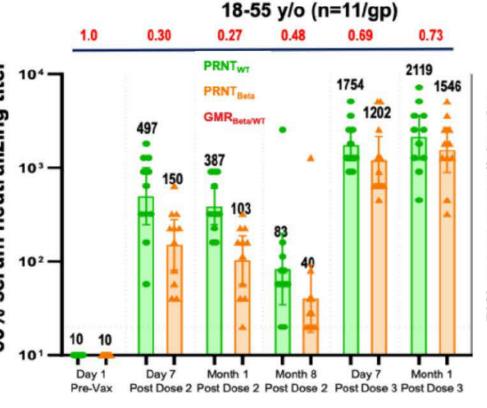


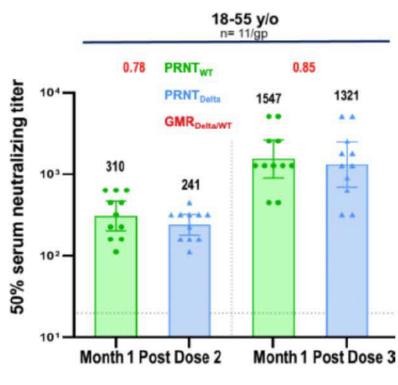




Pfizer vaccine 3rd dose neutralization data

- Booster dose (>6 mo. after 2nd dose of BNT162b2) has consistent tolerability profile & elicit titers >5-8X for WT and 15-21X for Beta variant vs. 2 doses
- Post dose 3 titers versus the Delta variant are >5-fold post dose 2 titers 18-55 y/o & >11-fold post dose 2 titers 65-85 y/o
- Estimated potential for up to 100-fold increase in Delta neutralization post-dose three compared to pre-dose three

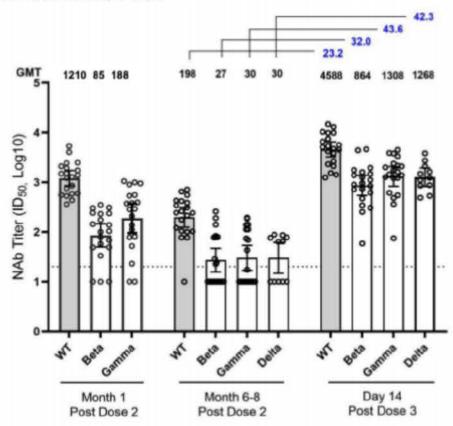




Moderna vaccine 3rd dose neutralization data

Dose 3 booster of 50 µg of mRNA-1273

Pseudovirus neutralization titers



Six months post second dose, neutralizing antibodies against wild-type (D614G) strain remained detectable

Neutralizing antibodies against VOC started lower, and waned substantially by six months after the second dose

Dose 3 (50 µg) booster of **mRNA-1273 significantly increased GMT for all VOC** Beta (B.1.351) by 32-fold, Gamma (P.1) by 43.6-fold and Delta (B.1.617.2) by 42.3-fold

The geometric mean neutralizing antibody titers with 95% confidence intervals are denoted. The titers for individual participants are shown by the circles. The geometric mean fold increase versus titers measured 6-8 months post dose 2 are shown for each variant. The horizonal dotted lines indicate the lower limit of quantification. N=20 participants per booster cohort; GMT, geometric mean titer; IDSO, 50% inhibitory dilution; NAb, neutralizing antibody





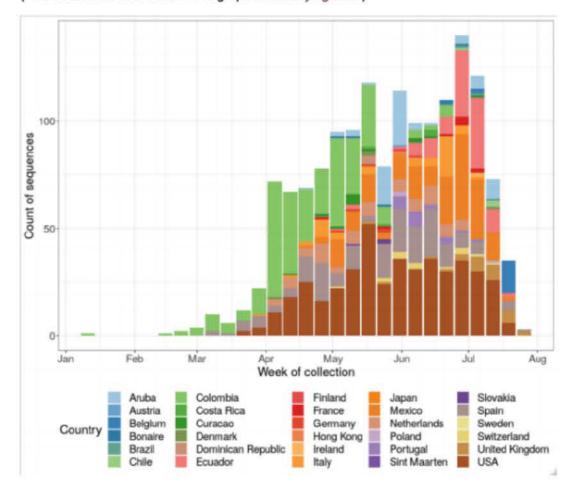
Emerging variants of interest/ cheern the pet met ingestion criteria)

B.1.621

VUI-21JUL-01 is characterised by the non-synonymous mutations NSP3; T237A, T720I. NSP4; T492I. NSP6; Q160R. NSP12; P323L. NSP13; P419S, T95I. S; R346K, E484K, N501Y, D614G, P681H, D950N. ORF3a; Q57H, ORF8; T11K, P38S, S67F, and N; T205I as well as an insertion in S at 144. Recent sequences identified as B.1.621 have also contained the spike K417N mutation.

GISAID by week as of 2 August 2021

(Find accessible data used in this graph in underlying data.)





Protecting and improving the nation's health



SARS-CoV-2 variants of concern and variants under investigation in England

Technical briefing 20

6 August 2021

This briefing provides an update on previous briefings up to 23 July 2021



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VUI-21JUL-01 is characterised by the non-synonymous mutations NSP3; T237A, T720I, NSP4; B.1.62 T492I. NSP6; Q160R. NSP12; P323L. NSP13; P419S, T95I. S; R346K, E484K, N501Y, D614G, P681H, D950N. ORF3a; Q57H, ORF8; T11K, P38S, S67F, and N; T205I as well as an insertion in S at 144. Recent sequences identified as B.1.621 have also contained the spike K417N mutation.



Protecting and improving the nation's health



1.8.1 Genotype to Phenotype (G2P) Consortium

Preliminary pseudovirus neutralisation data indicates that:

- sera from vaccinees shows decreased ability to neutralize B.1.621 compared to first wave virus and Alpha, with a magnitude of change similar to Beta
- sera from individuals who have been infected with Delta does not have strong neutralising activity against either Beta or B.1.621
- sera from individuals who have been vaccinated and have had subsequent recent Delta infection have a high level of neutralising activity against all variants tested (including beta and B.1.621)

SARS-CoV-2 variants of concern and variants under investigation in England

Technical briefing 20

6 August 2021

This briefing provides an update on previous briefings up to 23 July 2021



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From:
           Connelly, Sarahl
           Mon 8/9/2021 3:19:41 PM (UTC-04:00)
Sent:
           RE: ACTIV TRACE full Working Group
Subject:
20210809-TRACE VariantReport-v24.1.xlsx
20210809-TRACE VariantReport Therapeutic Supplemental-v24.1.pdf
 Dear Working Group Members,
 Ahead of tomorrow's meeting, please find attached this week's TRACE report and supplemental figures.
 Warm Regards,
 Sarah
 Sarah Connelly, PhD
 Deloitte Consulting, LLP
 Tel/Direct: +1
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www.deloitte.com

----Original Appointment----

From: Connelly, Sarah

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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Preclinical Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at MCATSOpenDataPortal@nih.gov with any feedback, comments, or questions to help us improve this resource.

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- · From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- · With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the OpenData Portal Visualization Page Additional details on the visualized data are available on the NCATS OpenData Portal.

New to the OpenData Portal Variant Database this week:

New Pre-prints and Publications:

- Pfizer Second Quarter 2021 Earnings Report
- 2. Prior infection with SARS-CoV-2 boosts and broadens Ad26.COV2.S immunogenicity in a variant dependent manner [Pre-print]
- 3. Comparable neutralization of SARS-CoV-2 Delta AY.1 and Delta in individuals sera vaccinated with BBV152 [Pre-print]
- Neutralizing antibodies elicited by the Ad26.COV2.S COVID-19 vaccine show reduced activity against 501Y.V2 (B.1.351), despite protection against severe disease by this variant [Pre-print]

Updated Pre-prints and Publications:

- 1. Neutralization of variant under investigation B.1.617 with sera of BBV152 vaccinees [Peer-reviewed publication]
- 2. Neutralization of VUI B.1.1.28 P2 variant with sera of COVID-19 recovered cases and recipients of Covaxin an inactivated COVID-19 vaccine [Peer-reviewed publication]
- 3. Neutralizing activity of Sputnik V vaccine sera against SARS-CoV-2 variants [Peer-reviewed publication]
- 4. Neutralization of Delta variant with sera of Covishield vaccinees and COVID-19 recovered vaccinated individuals [Peer-reviewed publications]

OpenData Portal | SARS-CoV-2 Variants & Therapeutics Therapeutic Activity Explorer Updated 8.5.21

82 data sources 2928 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

Visualize and Explore the OpenData Portal Variant Data:

B.1.1.7

B.1.351

B.1.617.2

P.1

B.1.427/429

B.1.525

B.1.526

B.1.617

C.37

P.2

Others

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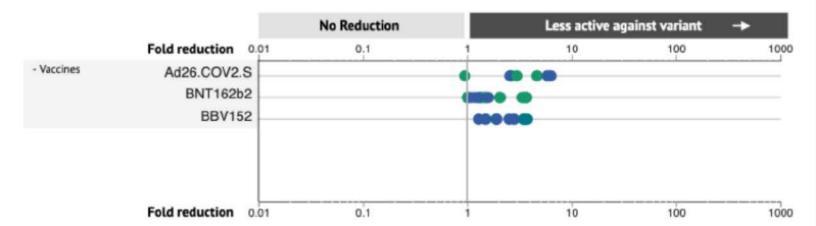
Data for All Variants

Single Point Mutation Data

What's new in the last week?

New in vitro neutralization data added to NCATS OpenData Portal last week



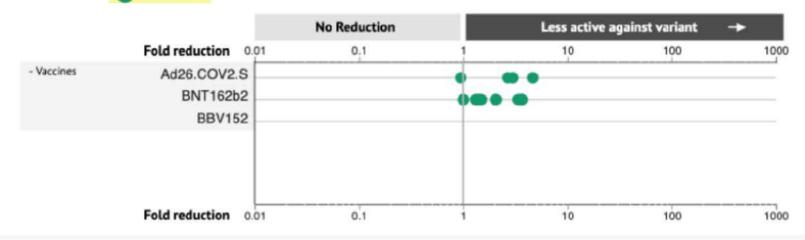




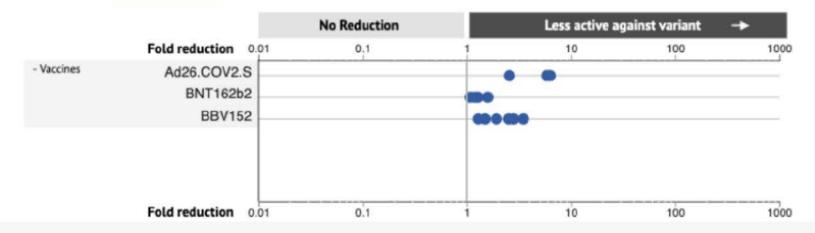
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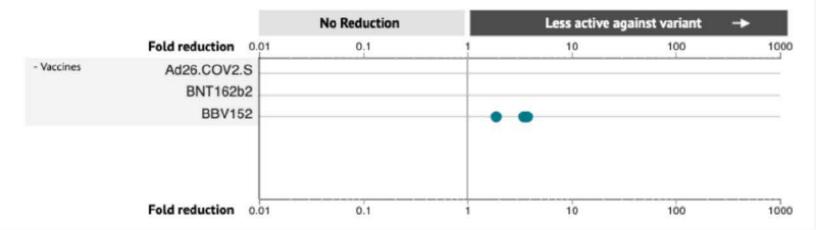
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Connelly, Sarah
From:
           Wed 8/4/2021 2:02:04 PM (UTC-04:00)
Sent:
           RE: ACTIV TRACE full Working Group
2021-08-03 ACTIV TRACE WG Meeting Summary vF.pdf
2021-07-30 ACTIV TRACE Delta Sub-Variant Discussion Meeting Summary vF.pdf
ACTIV 20210803 v2.pptx
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Dear Working Group Members,

Thank you all for attending our TRACE WG meeting on Tuesday. Please see attached for the notes and slides from our discussion, and let us know if you all have any additions or amendments.

If interested, also attached is the meeting summary from last Friday's meeting discussing the Delta sub-variants identified in the TRACE report.

Warm regards, Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: +1 (b) (6)
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----Original Appointment----From: Connelly, Sarah Sent: Wednesday, December 23, 2020 11:12 AM To: Connelly, Sarah; (b) (6) (b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b) (6) (b) (6) (b)(6)(b)(6)(b)(6)(b) (6) (b) (6) (b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b)(6)(b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; MacCannell, Duncan (CDC/DDID/NCEZID/OD); FNIH; (b) (6) Stapleton, Jack; Phillips, L Revell CIV DTRA RD (USA); Qashu, Felicia (NIH/OD) [E]; Dormitzer, Philip Ralph; (b)(6)(b) (6) Loo, Yueh-Ming; Abram, Michael; Streicher, Jansen, Kathrin; (b)(6)(b) (6) Katie: (b) (6) Lorraine Horgan; Li Yan; Qing Zhu; (b) (6) (b)(6)(b) (6) Andrew Charles Adams; Esser, Mark; David Margolis; brown-(b) (6) (b) (6) Eastman, Richard (NIH/NCATS) [E]: (b) (6) Carla augsburger Talarico; Brister, James (NIH/NLM/NCBI) [E]; (b) (6): Brimacombe, Kyle (NIH/NCATS) [E]; Wan, Kanny (NIH/NCATS) [C]; Erbelding, Emily (NIH/NIAID) [E]; Charette, Marc (NIH/NHLBI) [E]; (b) (6) Cassetti, Cristina (NIH/NIAID) [E]; Oberste, Steve (CDC/DDID/NCIRD/DVD); Lumsden, Joanne (NIH/NCATS) [C]; Lisa Purcell; Yun Ji; Arnegard, Matthew (NIH/OD) [E]; Groves Dixon; (b) (6) 'Korber, Bette Tina Marie'; Post, Diane (NIH/NIAID) [E]; Shadya Sanders; Nancy Haigwood; Basu, Dipanwita (NIH/NIBIB) [V]; Cat Lutz; Brown, Liliana (NIH/NIAID) [E]; Cardin, Rhonda; Migun Shakya; Scott Chavers; Mizrachi, Ilene (NIH/NLM/NCBI) [E]; (b) (6) (b)(6)(b) (6) (b) (6) Prabha Fernandes; Larosa, Francis; Lee, Taylor (NIH/NCATS) [C] (b) (6) K C Kent Lloyd; Wachtel, Jonathan; Cc: Baric, Toni C; Micheloni, Gianni; Jill Supancik; (b)(6)Gadbois, Ellen (NIH/OD) [E] Subject: ACTIV TRACE full Working Group When: Tuesday, August 3, 2021 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada). Where: https://deloitte.zoom.us/j/ (b) (6)?pwd=OFVIditub2M4V1hLckpHL2tzL0pXZz09 Updating the meeting name Join Meeting Password: (b) (6) Phone one-tap: US: +12133388477,, (b) (6) or +17209289299. (b)(6)Join by Telephone

Dial: US: +1 213 338 8477 or +1 720 928 9299 or +1 312 626 6799 or +1 646 518 9805

Meeting ID: (b) (6)

Password: (b) (6)

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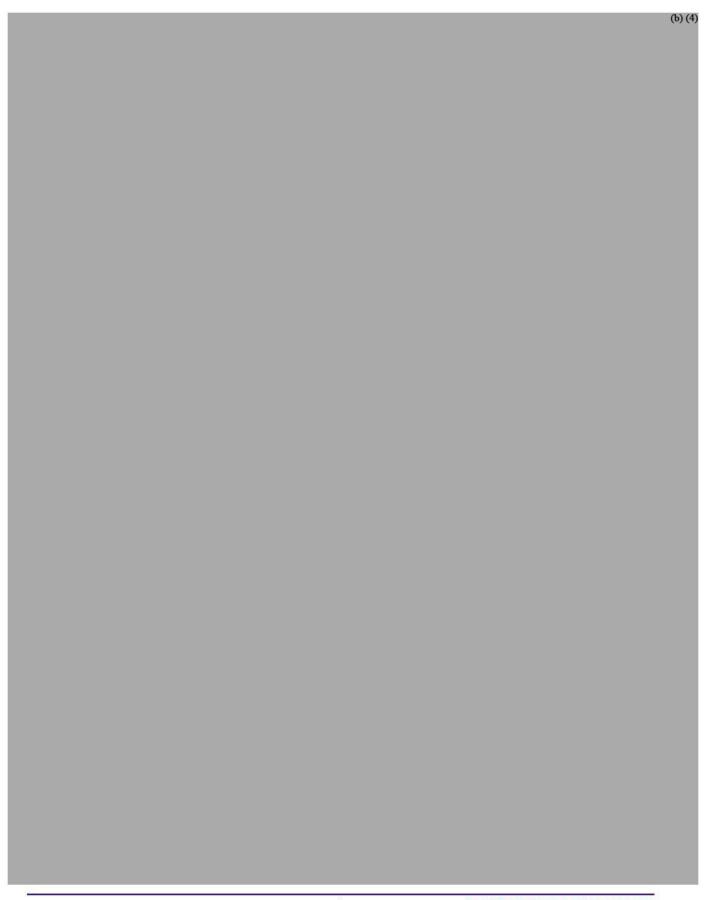
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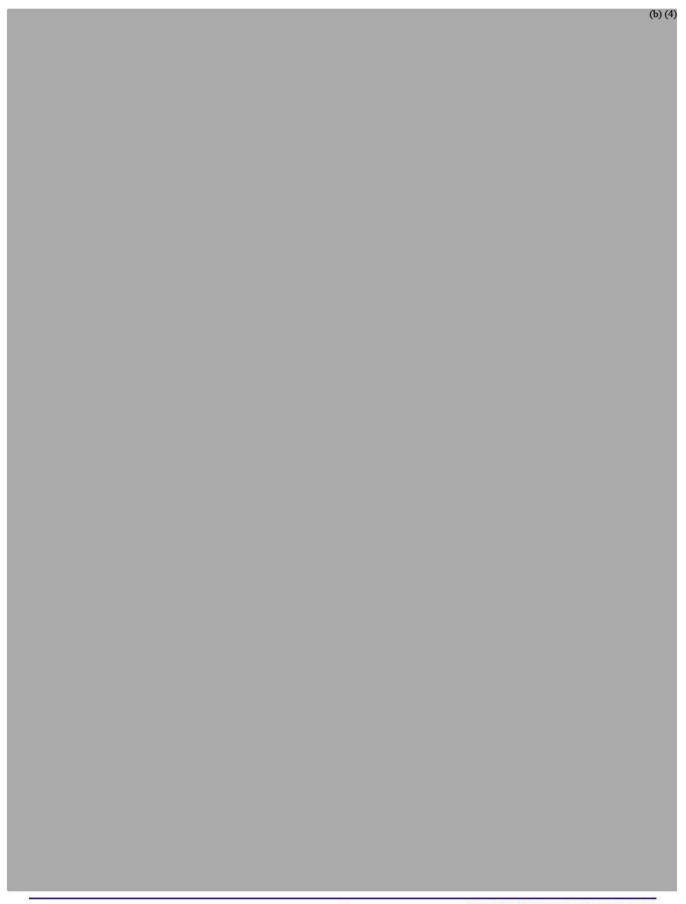
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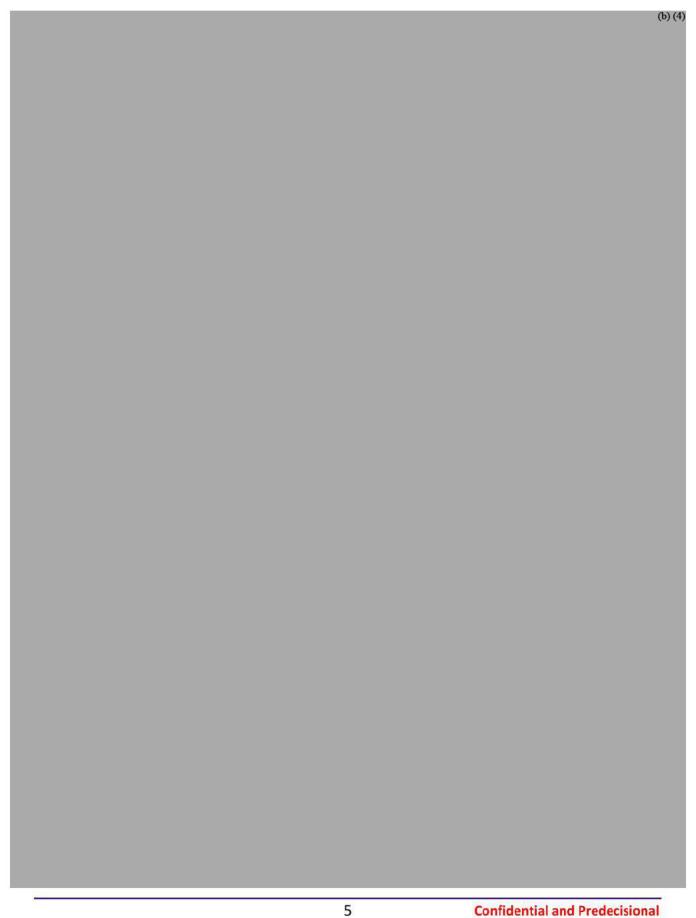
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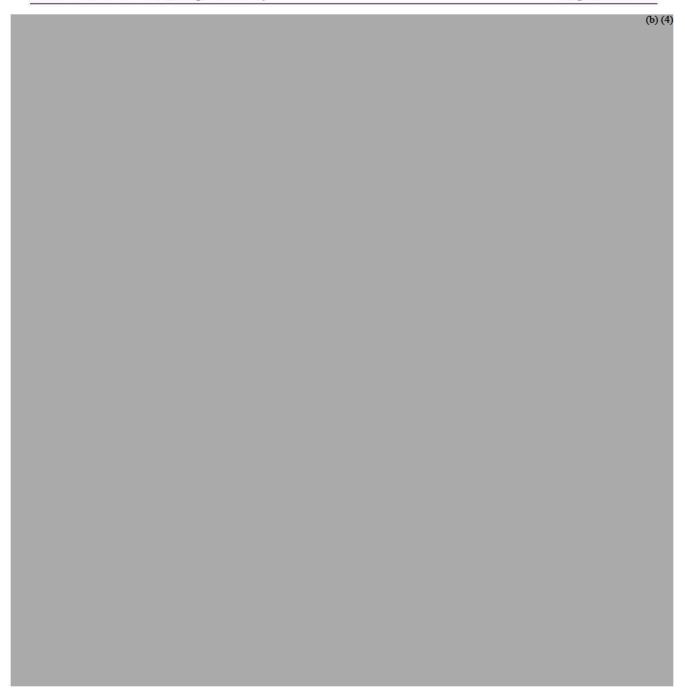
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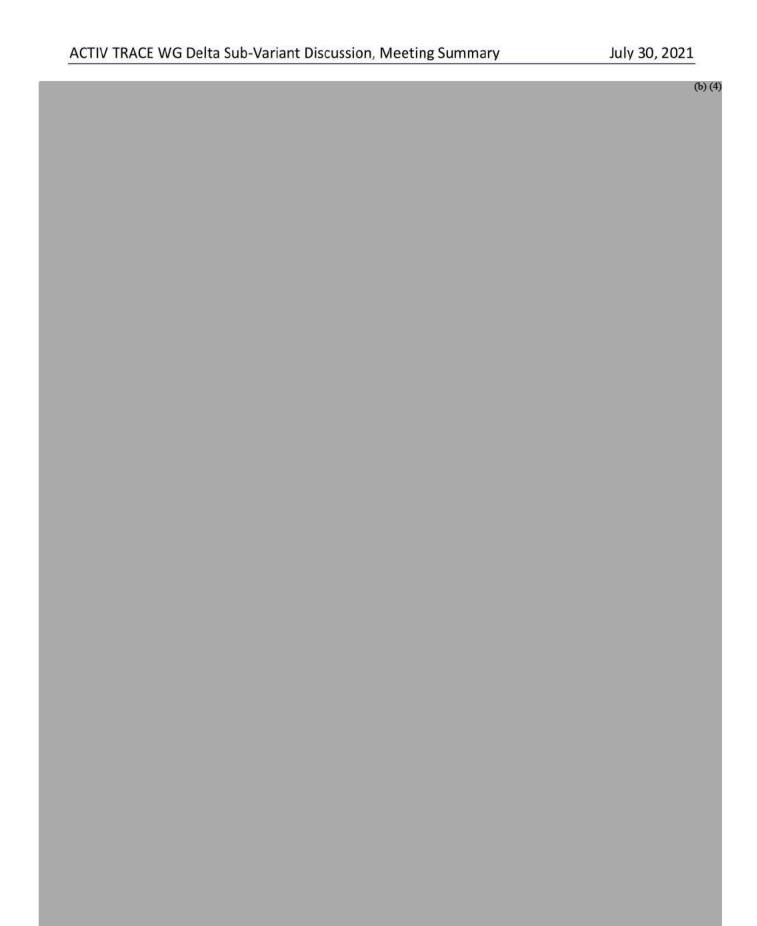


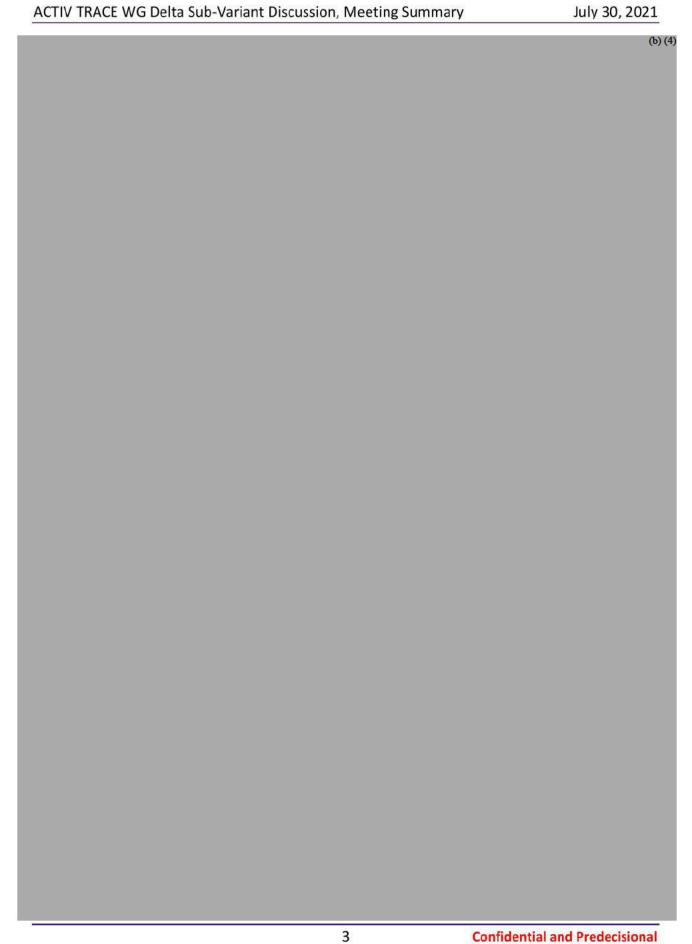


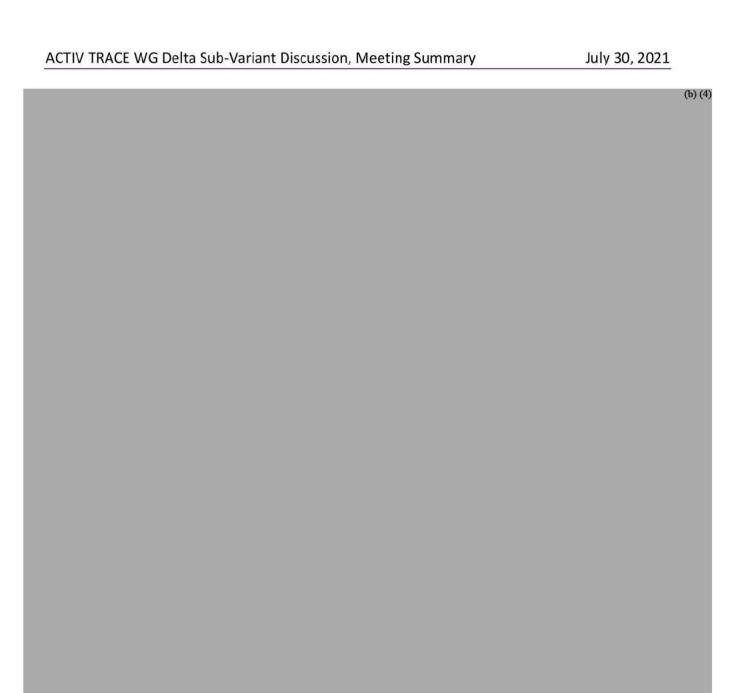
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ACTIV TRACE WG Delta Sub-Variant Discussion, Meeting Summary July 30, 2021	
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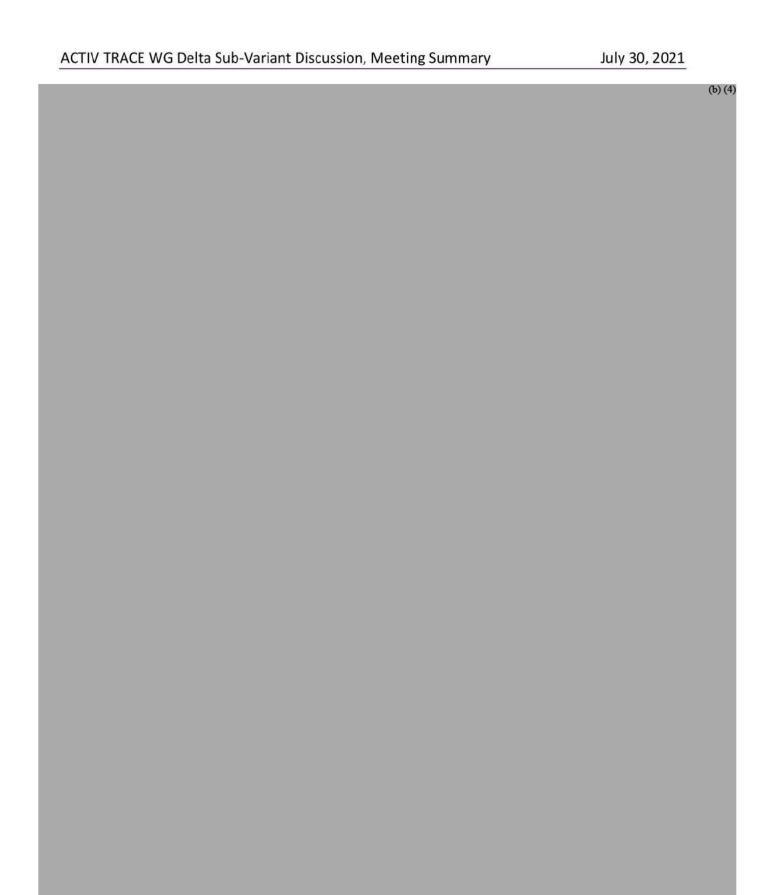


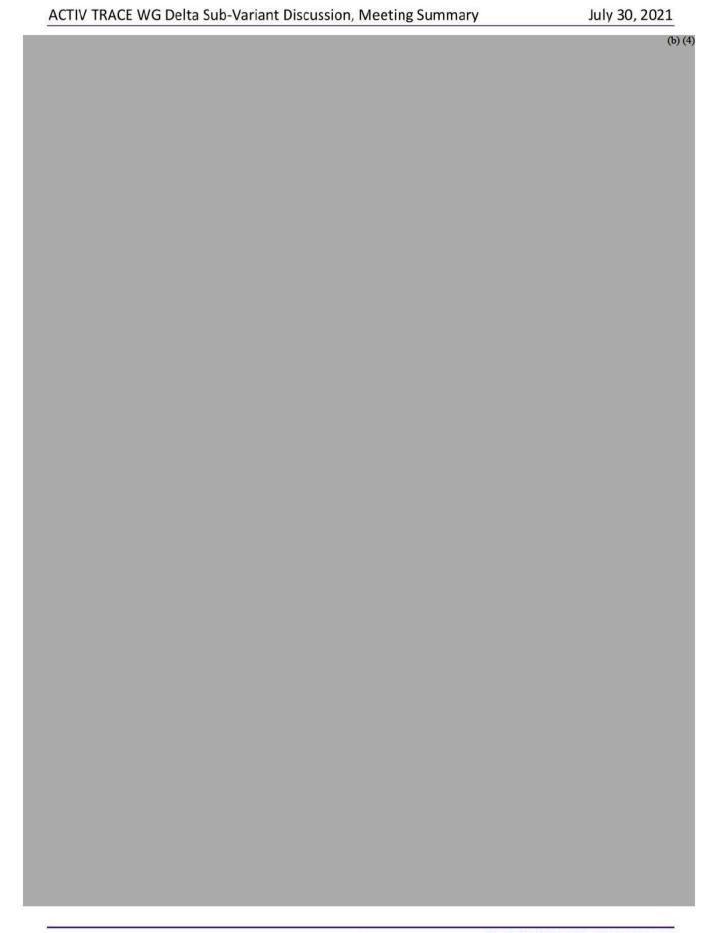




ACTIV TRACE WG Delta Sub-Variant Discussion, Meeting Summary	July 30, 2021
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ACTIV TRACE WG Delta Sub-Variant Discussion, Meeting Summary	July 30, 2021
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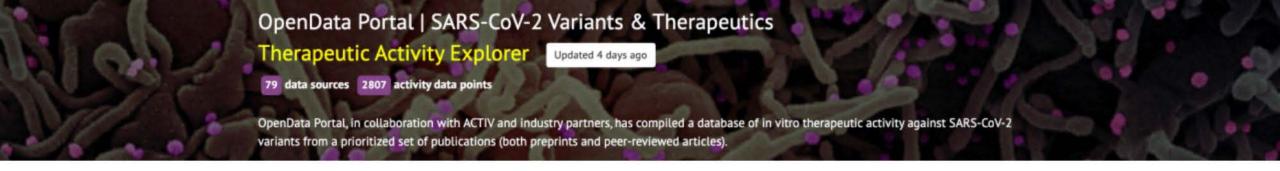






TRACE: ACTIV Variant Efforts

Update 08.03.2021



New to the OpenData Portal Variant Database in the past week:

New Datasets, Pre-prints and Publications:

1. AZD7442: AZD8895 (tixagevimab) and AZD1061 (Cilgavimab) mAbs for SARS-CoV-2 Antiviral Resistance Information

Data provided by

AstraZeneca

2. Ensovibep in vitro assay data against SARS-CoV-2 variants

Data provided by

Molecular Partners

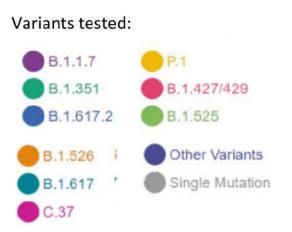
- 3. Safety and immunogenicity of nanocovax, a SARS-CoV-2 recombinant spike protein vaccine [Pre-print]
- 4. The in vitro and in vivo potency of CT-P59 against Delta and its associated variants of SARS-CoV-2 [Pre-print]

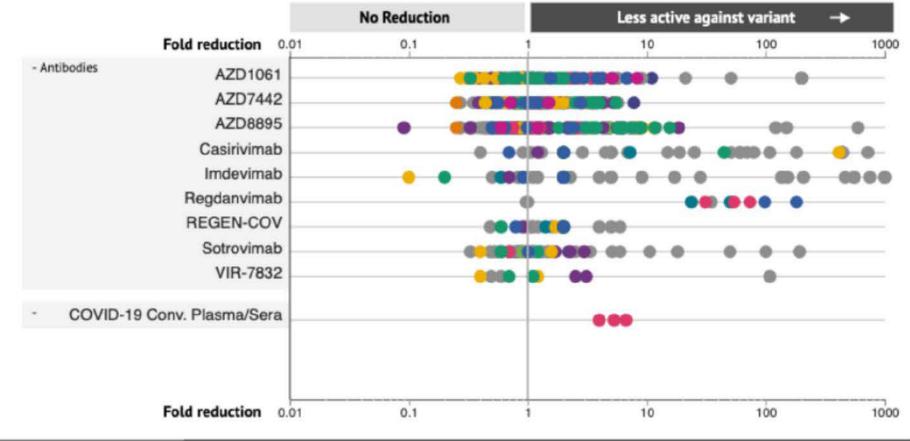
Updated Datasets, Pre-prints and Publications:

- 1. The dual function monoclonal antibodies VIR-7831 and VIR-7832 demonstrate potent in vitro and in vivo activity against SARS-CoV-2 [Pre-print]
- Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of REGEN-COV (Casirivimab and Imdevimab) (Revised 06/2021) [FDA Fact Sheet]
- 3. Transmission, infectivity, and neutralization of a spike L452R SARS-CoV-2 variant [Peer-reviewed publication]
- 4. Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab [FDA Fact Sheet]
- 5. SARS-CoV-2 variant B.1.1.7 is susceptible to neutralizing antibodies elicited by ancestral spike vaccines [Peer-reviewed publication]



New to the OpenData Portal Variant Database in the past week:











What's New? | Reported in vitro Therapeutic Activity

Therapeutic Activity Visualizati X



Viral Lineage: B.1.617.2

Full / Partial Variant: Full variant

Therapeutic Name: Regdanvimab

Data Source Type: Pre-print

Data Uploaded: 07/30/2021

Assay: Live virus replication assay

Spike Mutations: Not Reported

Therapeutic Class: Neutralizing antibody

Data Source: The in vitro and in vivo potency of CT-

P59 against Delta and its associated variants of

Viral Type: Live virus

Fold Change: 182.99

SARS-CoV-2

Dataset:

What's New? | Reported in vitro Therapeutic Activity

Therapeutic Activity Visualizal X

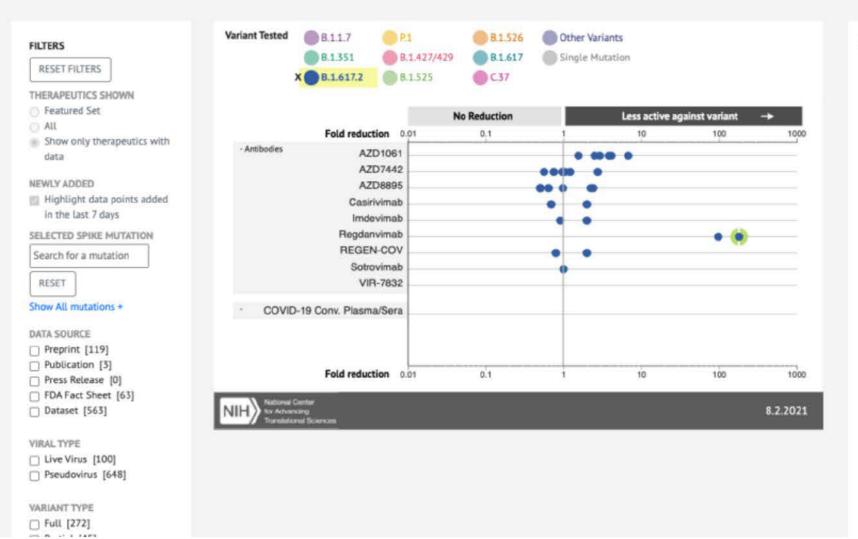
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What's New? | Reported in vitro Therapeutic Activity

Therapeutic Activity Visualizal X

opendata.ncats.nih.gov/variant/activity





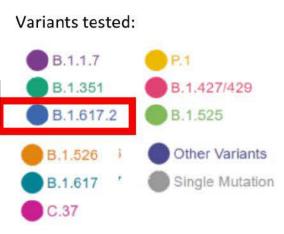
OpenData Portal | SARS-CoV-2 Variants & Therapeutics Updated 4 days ago

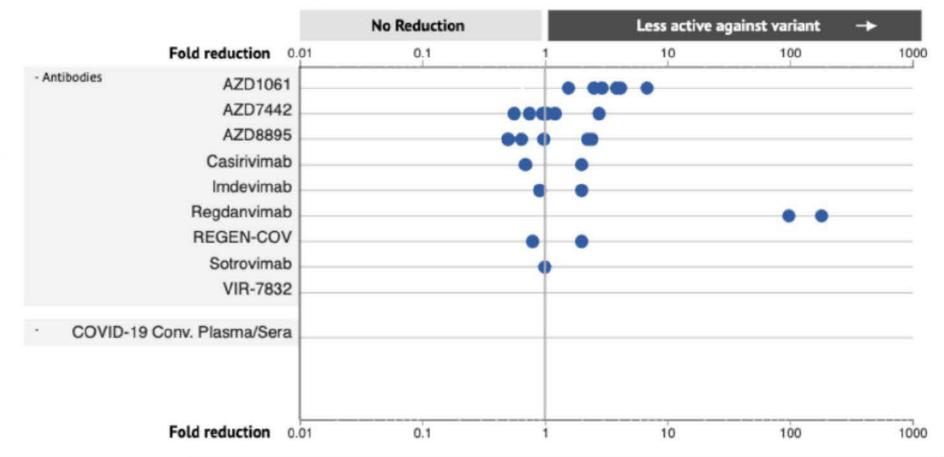
Therapeutic Activity Explorer

79 data sources 2807 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

New to the OpenData Portal Variant Database in the past week:







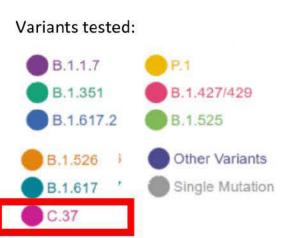


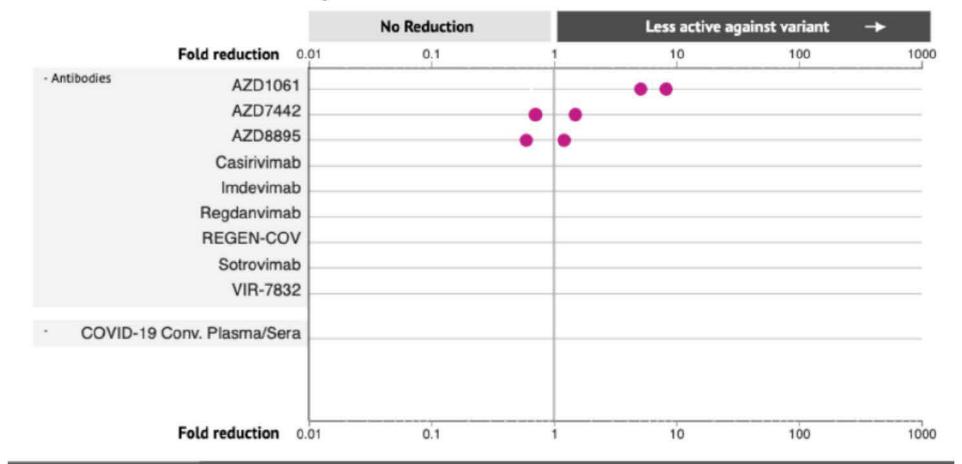
OpenData Portal | SARS-CoV-2 Variants & Therapeutics Therapeutic Activity Explorer Updated 4 days ago

79 data sources 2807 activity data points

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New to the OpenData Portal Variant Database in the past week:



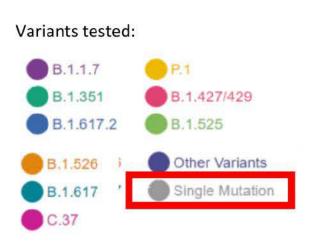


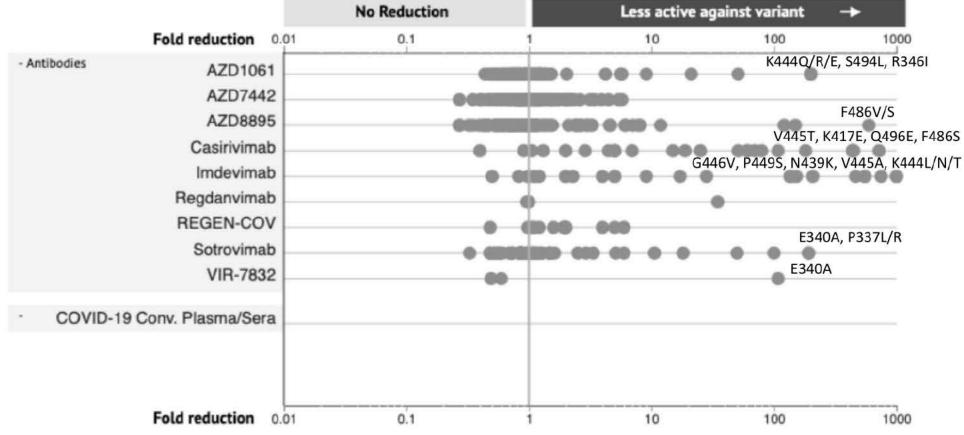




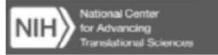
New to the OpenData Portal Variant Database in the past week:

variants from a prioritized set of publications (both preprints and peer-reviewed articles).









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New Results



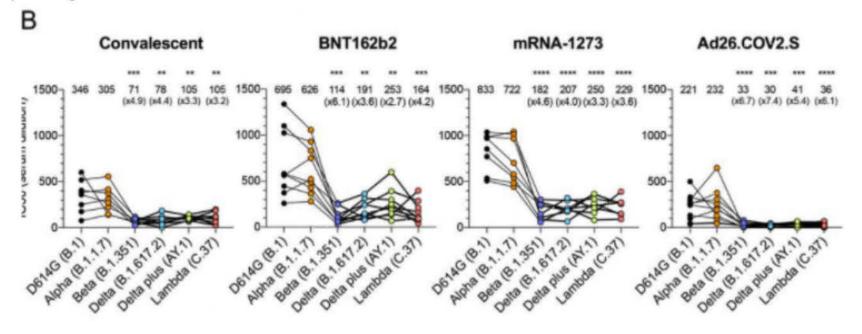


Comparison of Neutralizing Antibody Titers Elicited by mRNA and Adenoviral Vector Vaccine against SARS-CoV-2 Variants

Takuya Tada, Hao Zhou, Marie I. Samanovic, D Belinda M. Dcosta, Amber Cornelius, Mark J. Mulligan, Nathaniel R. Landau

doi: https://doi.org/10.1101/2021.07.19.452771

- Pfizer/Moderna vaccine & conv. plasma has modest neutralization resistance against Beta, Delta, Delta plus and Lambda variants
- J&J vaccine-elicited antibodies from a significant fraction of vaccinated individuals were of low neutralizing titer



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Brister, James (NIH/NLM/NCBI) [E
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Brimacombe, Kyle (NIH/NCATS) [E]
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Brown, Liliana (NIH/NIAID) [E]
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Scott Chavers
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Fernandes
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                                 (b) (6) Glodek, Anna (NIH/NLM/NCBI) [C][
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           Connelly, Sarah
From:
Sent:
           Mon 8/2/2021 6:38:11 PM (UTC-04:00)
           RE: ACTIV TRACE full Working Group
20210802-TRACE VariantReport Therapeutic Supplemental-v23.1.pdf
20210802-TRACE VariantReport-v23.1.xlsx
 Dear Working Group Members,
 Ahead of tomorrow's meeting, please find attached this week's TRACE report and supplemental figures.
 Warm Regards,
 Sarah
 Sarah Connelly, PhD
 Deloitte Consulting, LLP
 Tel/Direct: +1
                       (b)(6)
 www.deloitte.com
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----Original Appointment----

Sent: Wednesday, December 23, 2020 11:12 AM

From: Connelly, Sarah

To: Connelly, Sarah	;	(b) (6)		(b) (6)	(b) (6)	(b) (6)	(b) (6)
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Streicher, Katie; Qing Zhu;	(b) (6);	(b) (6)		Andrew Char	// // // // // // // // // // // // //	ms; Esser, Mark; David Margo	
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Taylor (NIH/NCATS)	[C]						
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Gadbois, Ellen (NIH	/OD) [E]						
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How to Read This Supplemental Report

The SARS-CoV-2 variant therapeutic data in this report have been curated in collaboration with the National Institutes of Health (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Preclinical Working Group with support from the Foundation for the National Institutes of Health (FNIH). New and updated information will be added on a weekly basis as more studies are shared. Please continue to check back as our curated database grows. Please contact us at MCATSOpenDataPortal@nih.gov with any feedback, comments, or questions to help us improve this resource.

What Data is Included?

The underlying data in these visualizations has been curated, in collaboration with ACTIV, from a prioritized set of publications (both preprints and peer-reviewed articles). To improve data accuracy, publications are limited to prominent therapeutic agents (both approved and in clinical trial), with an emphasis on studies conducted 1) by the sponsoring pharmaceutical company or 2) with a government partner. The OpenData Portal does not intend to serve as a comprehensive dashboard for all variant therapeutic data published in the literature.

How to Interpret the Visualizations

The visualization graphics are meant to provide a quick-glance summary of how **individual SARS-CoV-2 variants** may respond to known therapeutics, compared to reference strains. The displayed fold-change values represent data collected from published *in vitro* viral neutralization assays comparing variants to a reference strain.

Of important note, the data displayed were generated:

- · From different assay types and conditions
- · By different research laboratories
- · Using different reference strains
- · With test material from different sources/of potentially different grades, tested at different dose ranges

As a result, the visualizations **should not be used to conduct side-by-side comparisons** of therapeutics. Reported minimum fold reduction values (e.g. >1000-fold) may have greater actual fold change values than those displayed. Furthermore, the data shown are collected from *in vitro* assays, and it is not known how *in vitro* neutralization assay data correlate with clinical outcomes. It is worth noting that the experimental therapeutic concentrations are not necessarily correlated to clinical concentrations; thus therapeutics with large reported fold reductions in activity **may still be active against the variants in clinical settings**, as standard dosing/exposure in patients could exceed the required therapeutic window. Lastly, the data may be from preliminary reports that **have not been peer reviewed** and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Interactive versions of these graphics are available on the OpenData Portal Visualization Page Additional details on the visualized data are available on the NCATS OpenData Portal.

New to the OpenData Portal Variant Database this week:

New Therapeutic Agent: Nanovocax (vaccine)

New Datasets, Pre-prints and Publications:

AZD7442: AZD8895 (tixagevimab) and AZD1061 (Cilgavimab) mAbs for SARS-CoV-2
 Antiviral Resistance Information

Data provided by AstraZeneca

2. Ensovibep in vitro assay data against SARS-CoV-2 variants

Data provided by Molecular Partners

- 3. Safety and immunogenicity of nanocovax, a SARS-CoV-2 recombinant spike protein vaccine [Pre-print]
- 4. The in vitro and in vivo potency of CT-P59 against Delta and its associated variants of SARS-CoV-2 [Pre-print]

Updated Datasets, Pre-prints and Publications:

- 1. The dual function monoclonal antibodies VIR-7831 and VIR-7832 demonstrate potent in vitro and in vivo activity against SARS-CoV-2 [Pre-print]
- 2. Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of REGEN-COV (Casirivimab and Imdevimab) (Revised 06/2021) [FDA Fact Sheet]
- 3. Transmission, infectivity, and neutralization of a spike L452R SARS-CoV-2 variant [Peer-reviewed publication]
- 4. Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab [FDA Fact Sheet]
- 5. SARS-CoV-2 variant B.1.1.7 is susceptible to neutralizing antibodies elicited by ancestral spike vaccines [Peer-reviewed publication]

OpenData Portal | SARS-CoV-2 Variants & Therapeutics

Therapeutic Activity Explorer

Updated 7.30.23

79 data sources 2807 activity data points

OpenData Portal, in collaboration with ACTIV and industry partners, has compiled a database of in vitro therapeutic activity against SARS-CoV-2 variants from a prioritized set of publications (both preprints and peer-reviewed articles).

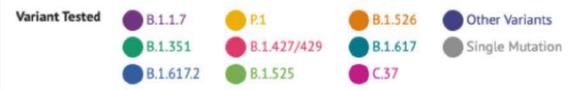
Visualize and Explore the OpenData Portal Variant Data:

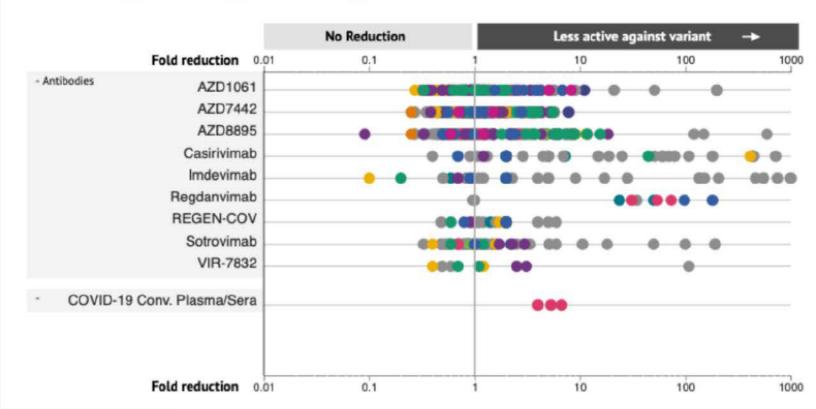
B.1.1.7 B.1.351 B.1.617.2 P.1 B.1.427/429 B.1.525

B.1.526 B.1.617 C.37 P.2 Others Mink

Data for All Variants Single Point Mutation Data What's new in the last week?

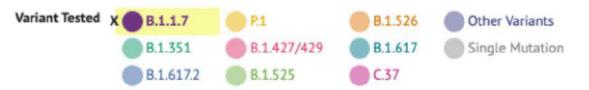
New in vitro neutralization data added to NCATS OpenData Portal last week

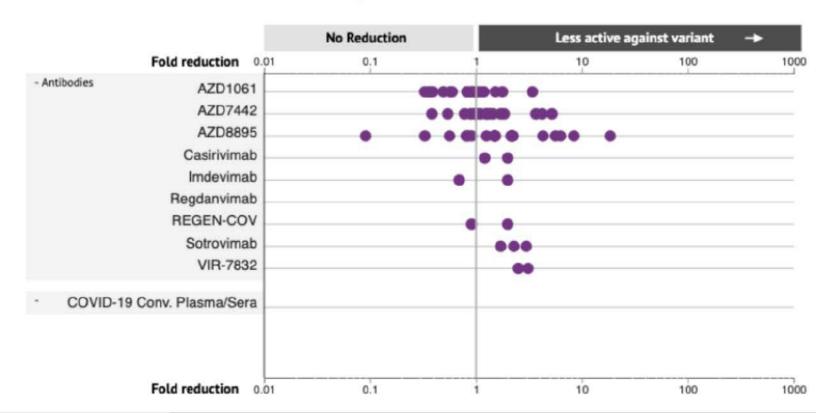




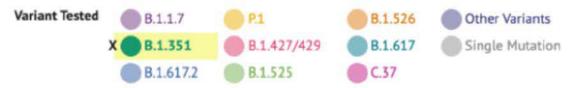


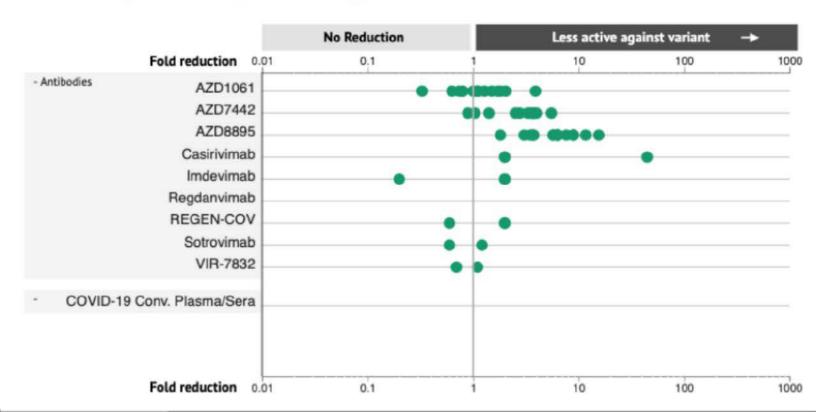
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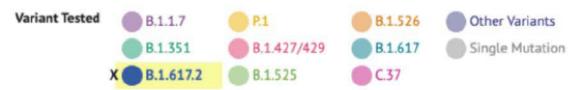


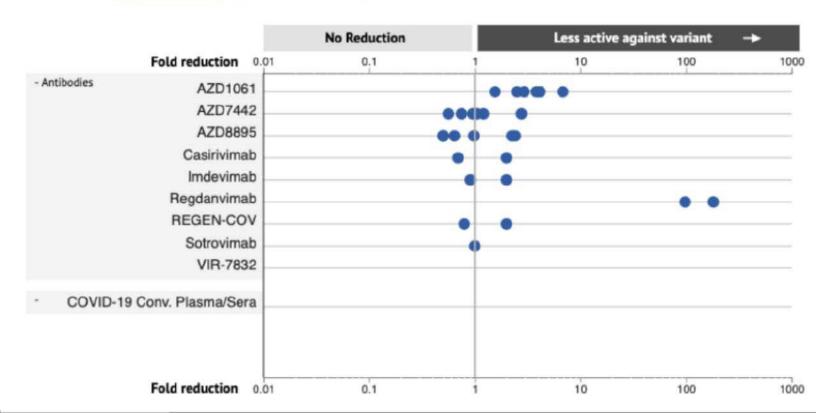




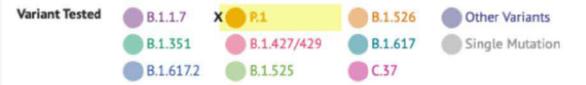


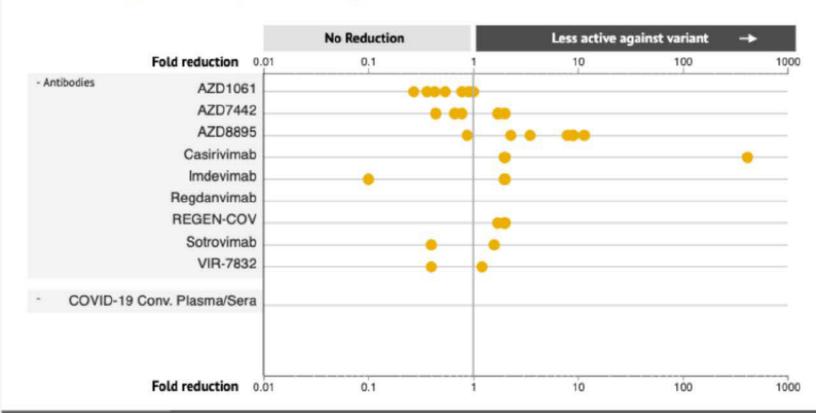




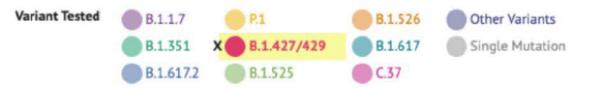


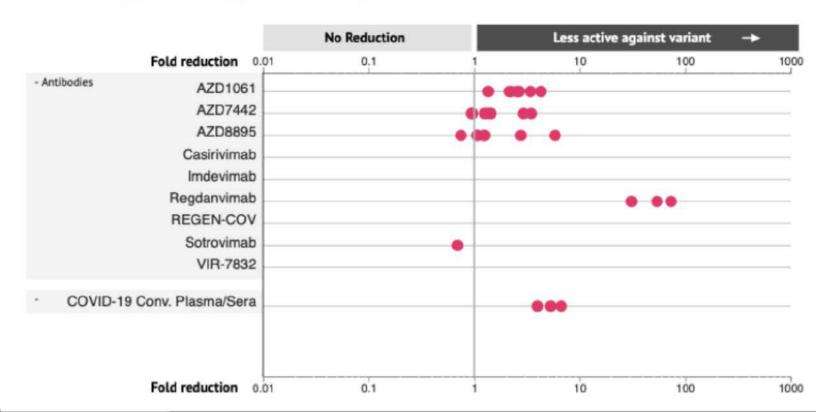




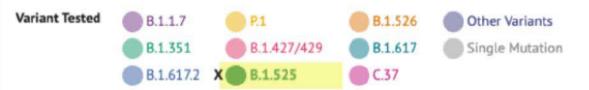


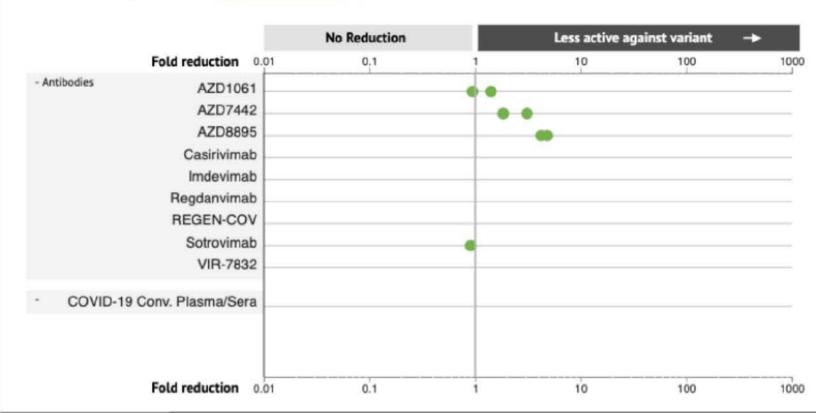




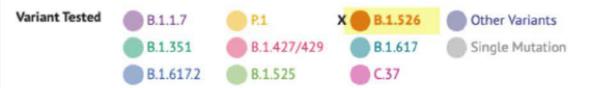


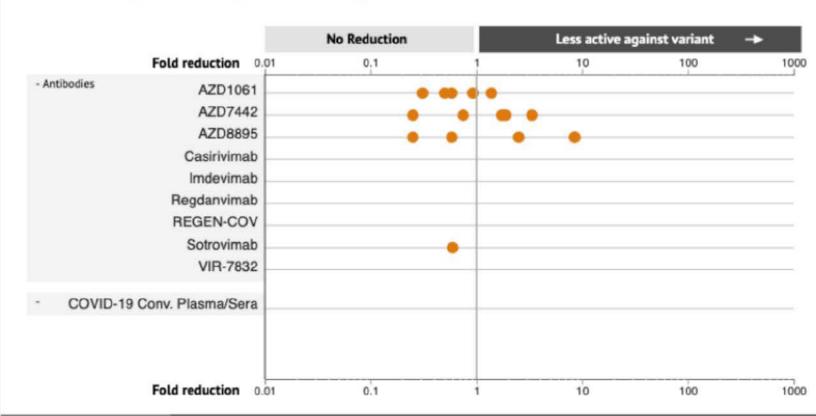




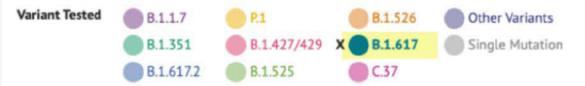


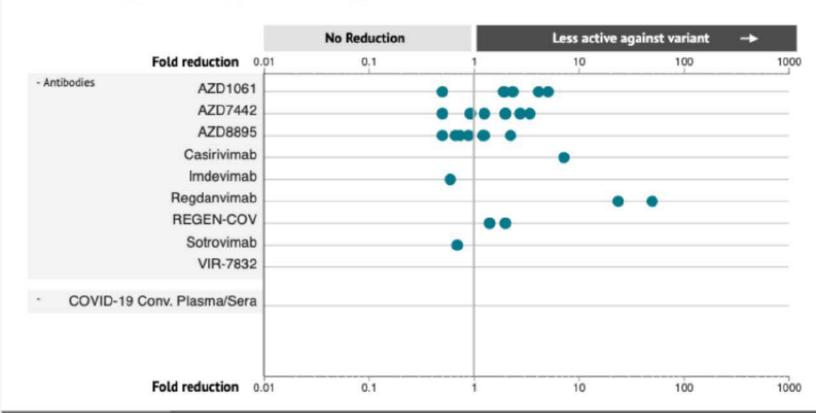




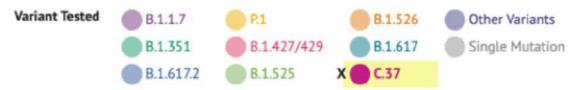


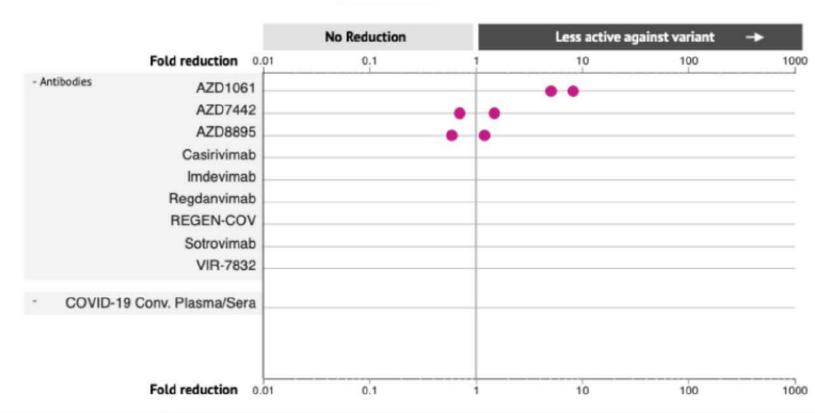




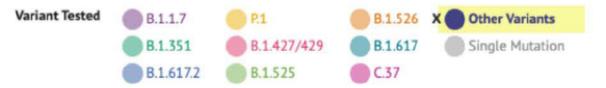


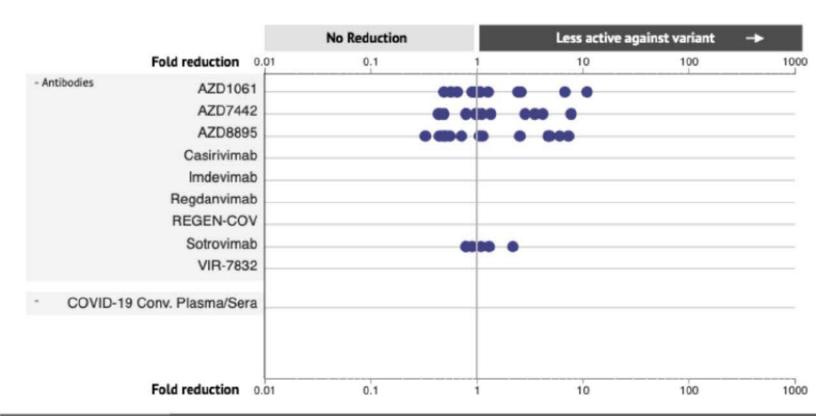




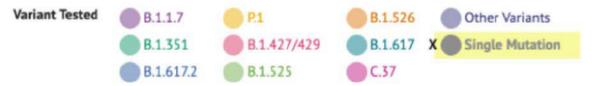


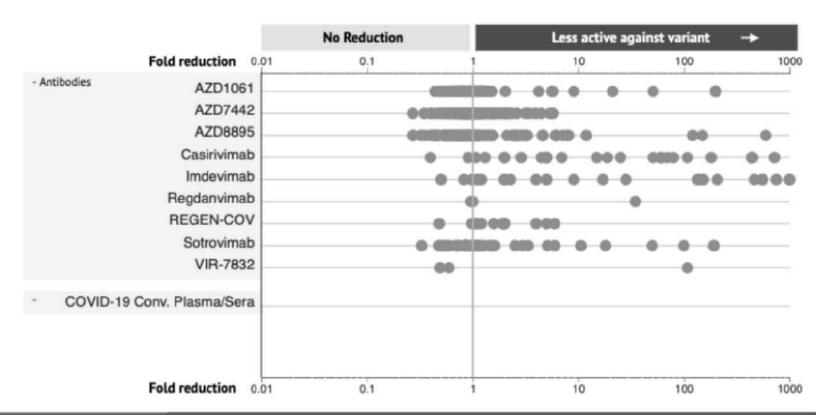


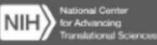












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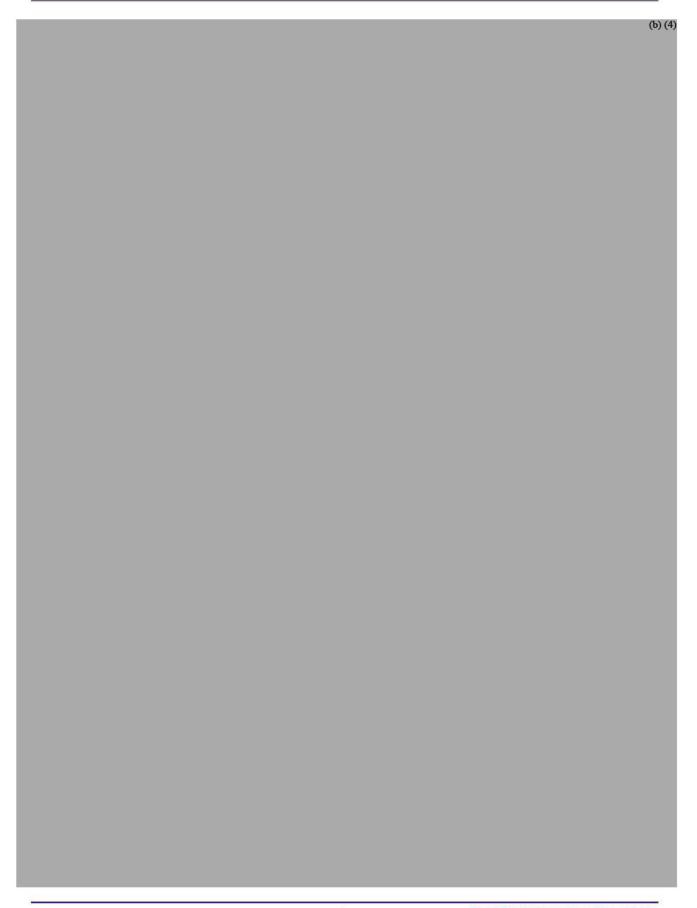
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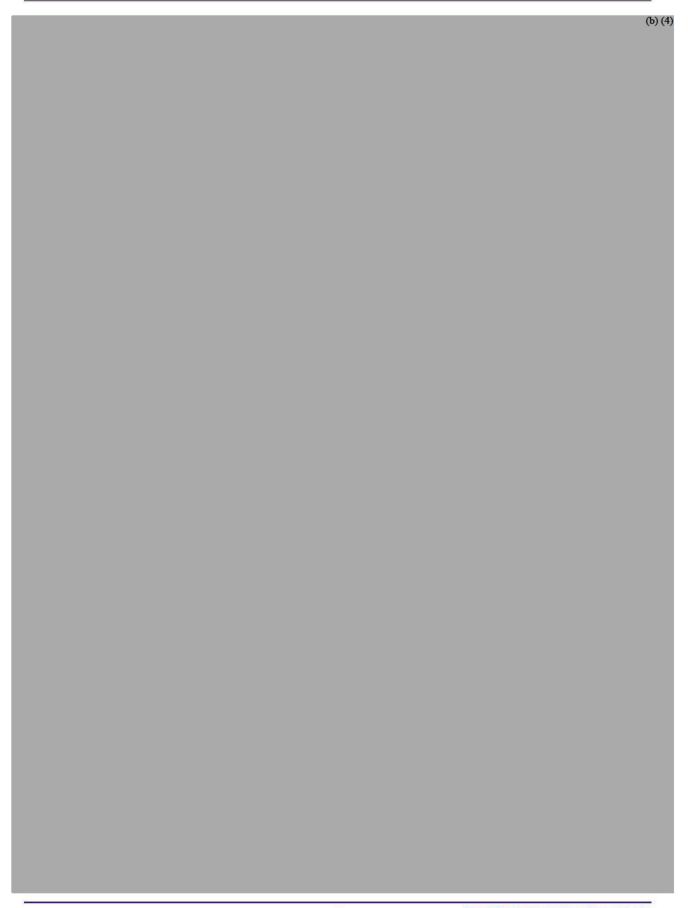
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