RADx-rad DCC

RADx-rad Discovery & Data Consortium Coordination Center (DCC)

Monthly All-Hands Meeting 14 June 2021 https://www.radxrad.org/



This meeting (video + chat) will be recorded.



DATE	TIME	ΤΟΡΙΟ
6/14/2021	10:00 - 10:05	Welcome – Lucila Ohno-Machado
	10:05 - 10:10	EAB Meeting Update – Lucila Ohno-Machado Update from EAB meeting held June 8th Q & A– Open discussion
	10:10 - 10:25	Awardee Anti-racism & Teamwork trainings - Cinnamon Bloss Information on trainings to be offered to awardees Q & A– Open discussion
	10:25 - 10:35	DCC Assessment Survey Results- Eliah Aronoff-Spencer Q & A- Open discussion
	10:35 – 10:45	Diagnostics Core Update – <i>Eliah Aronoff-Spencer</i> Q & A– Open discussion
	10:45 – 10:55	Date Core – Hua Xu Q & A– Open discussion
	10:55 – 11:00	Closing Remarks – Lucila Ohno-Machado Questions & Open Discussion Next All-Hands Meeting July 12, 2021

RADx-rad EAB Meeting Summary

Virtual EAB Meeting June 8th

EAB Members



Michael Busch M.D., Ph.D Vitalant Research Institute Laboratory Medicine



Gretchen Jackson, M.D., Ph.D IBM Biomedical Informatics



Genevieve Melton-Meaux, M.D., Ph.D University of Minnesota Population Health, Data Analytics & Informatics



Pilar Ossorio, Ph.D, J.D University of Wisconsin Research ethics and regulations & community consultation



Barbara Koenig, Ph.D, RN UC San Francisco Bioethical research for data informed policy



Guergana Savova, Ph.D Harvard Medical School, Boston Children's Hospital Computational Health Informatics



Mike Lochhead, Ph.D LightDeck Technical development & intellectual property strategies



Martin Were, M.D., MS Vanderbilt University Global Health Informatics

EAB Interests/Input in over

Impact of CDE development on IRB submissions

• Interest in how DCC is working with awardees through CDE changes to ensure studies are not delayed

Data collections standards, EAB interested in:

- How CDEs were defined
- Which standards were used for CDE development

Interests in level and engagement of participant involvement in oversight

• How will findings be reported back to the community and frequency

Linkage of datasets and ethical considerations

- Becoming more common
- Ethical Considerations and how DCC is approaching linkage
- How does DCC create the DCC Unique Participant IDs



Anti-Racism & Team Work Training

Cinnamon Bloss, PhD: Associate Professor of Psychiatry, Family Medicine & Public Health; Director of The Center of Empathy and Technology

 Research interests in societal impacts of emerging biomedical technologies impact empathy, compassion, and well-being for both provider and patient

Anti-Racism Training

Offered Year 1 – Year 4:

Training will be offered to provide Building Racial Equity. A collection of interactive trainings for those who wish to sharpen their skills and strategies to address structural racism and advance racial equity. Training emphasize:

- How to challenge institutional racial inequities
- How to change institutional racial inequities

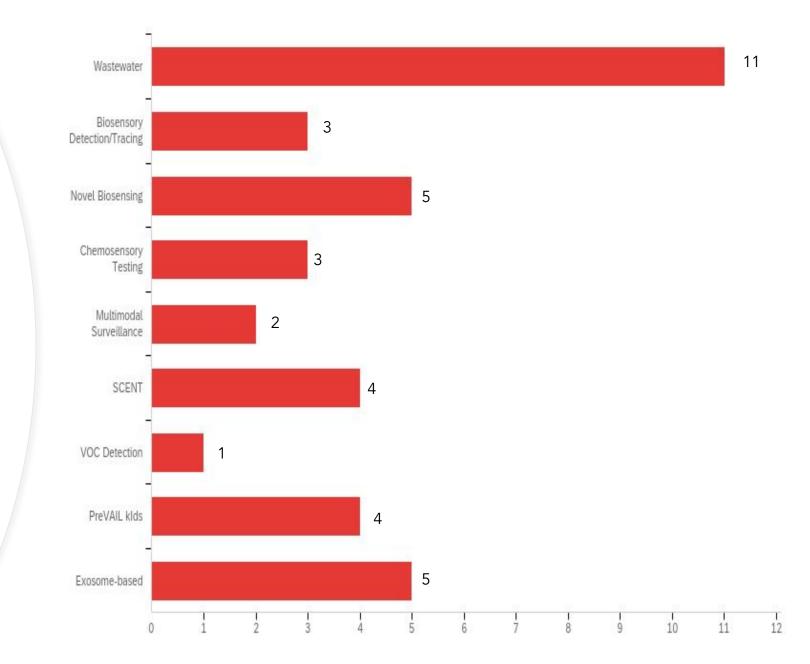
Team Work Training

Offered Year 1 – Year 4:

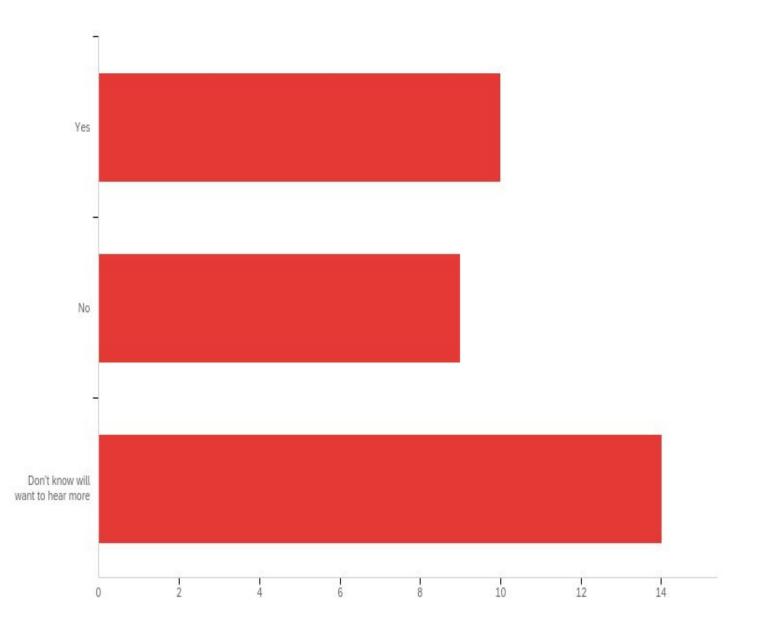
Attendees learn how to develop effective teams in the context of project management and how to implement communication and conversation strategies that help their team meet their project goals. Exploring common team-related issues:

- Team charter and team contracts
- Trust
- Culture
- Conflict resolution

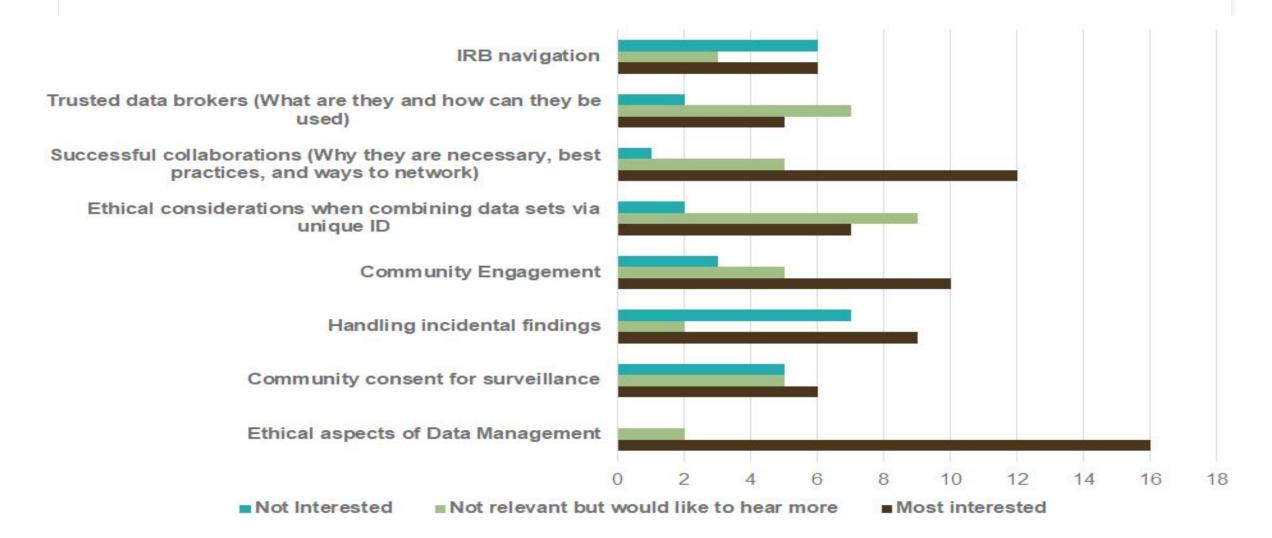
Awardee Group (N = 38)



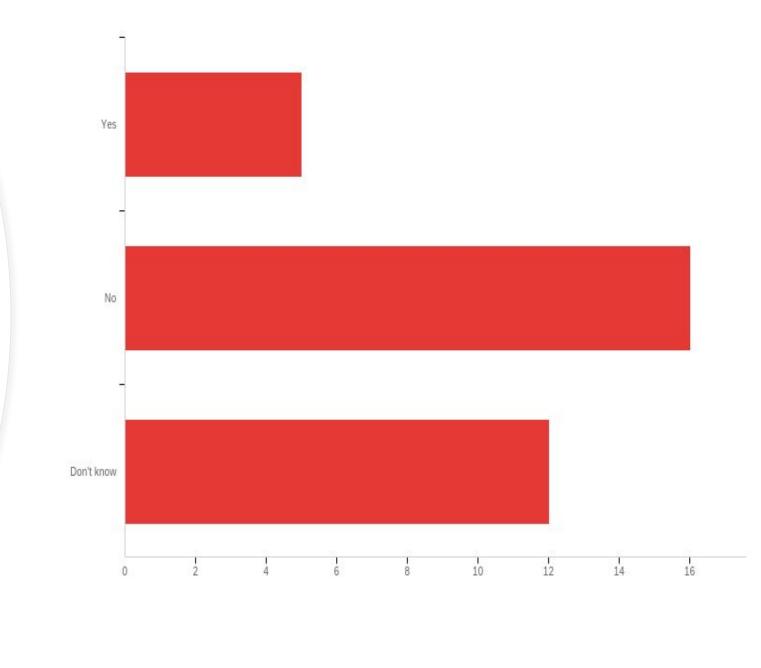
Would you like to attend Office Hours to discuss ethical dimensions of the RADx-rad research? (N=33)



Rank the following ELSI topics based on your interest and relevance to your study/project

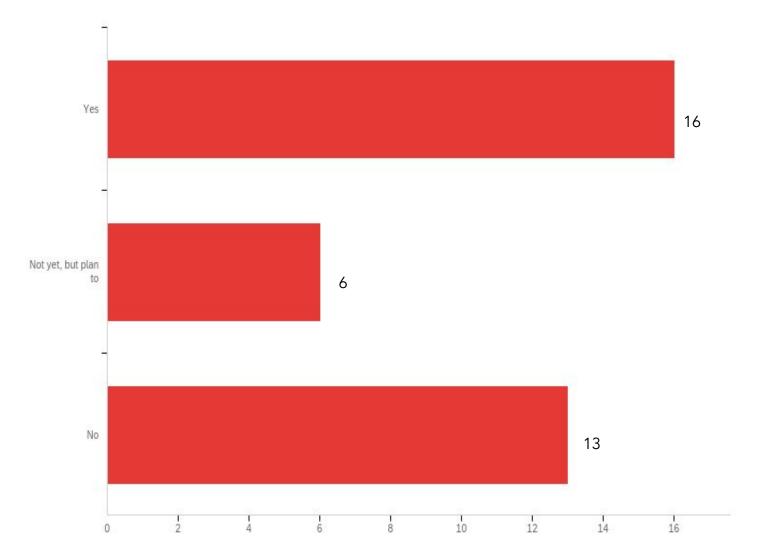


Would you like to consult with someone on your team about ethical aspects of your award? (N=33)

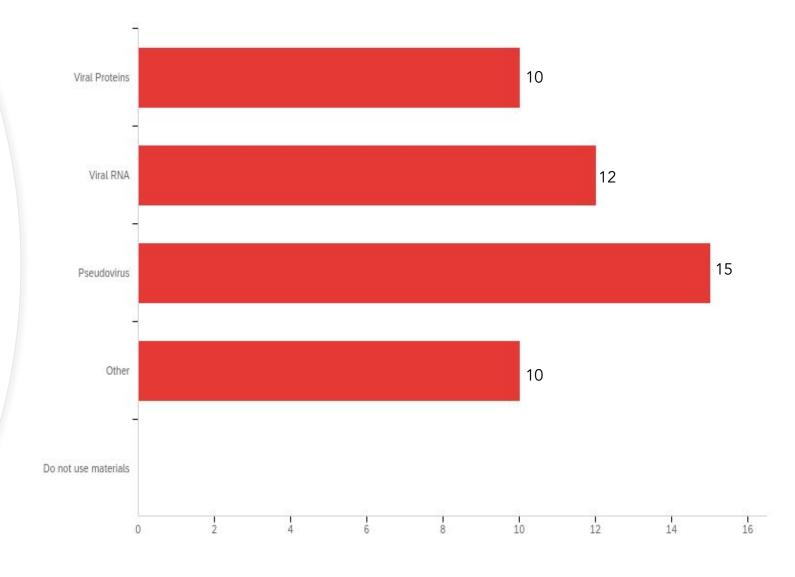


Diagnostics and Discovery Assessment

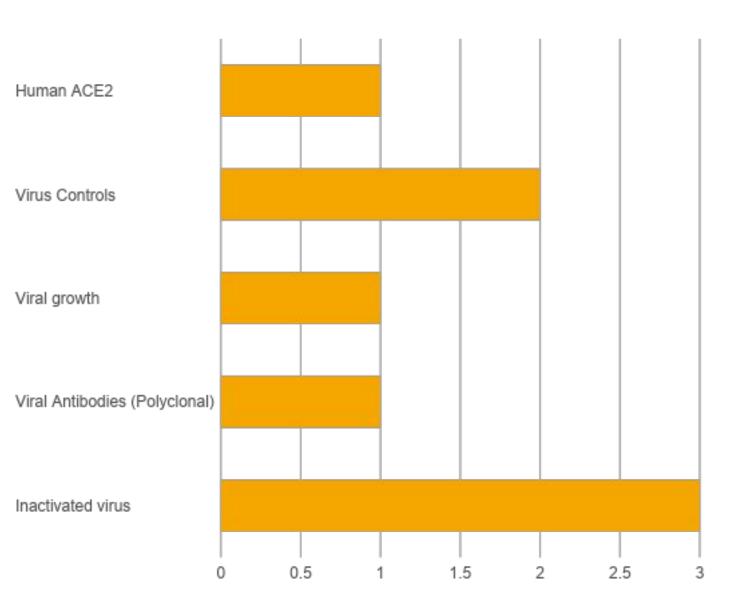
Given the changing landscape with coronavirus variants, the need to detect other circulating and emerging viruses, and new constraints on resource availability - Does your study use or order variants? (N = 35)



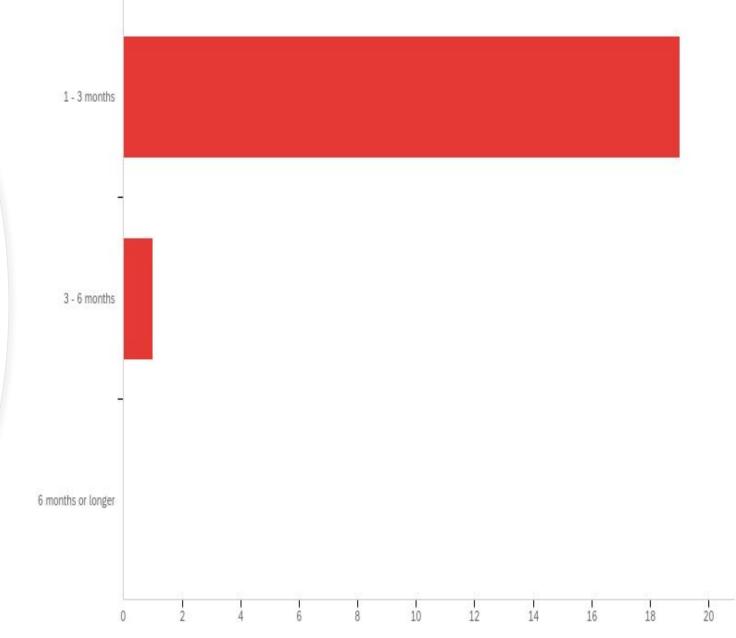
From the list of materials below, please select those you view as useful to your study/program (select all that apply)



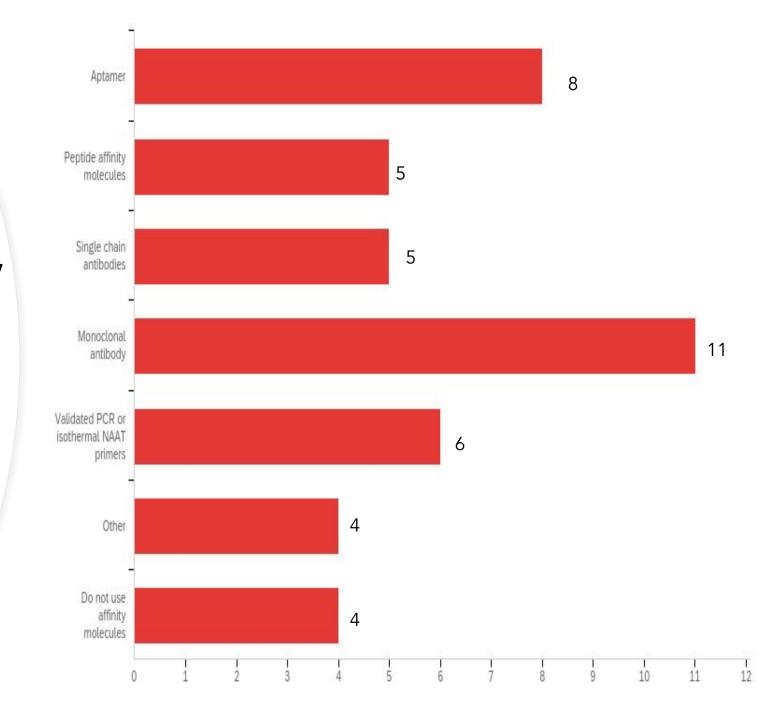
Materials "Other" response



What is the earliest date you would be able to use the materials selected? (N = 20)



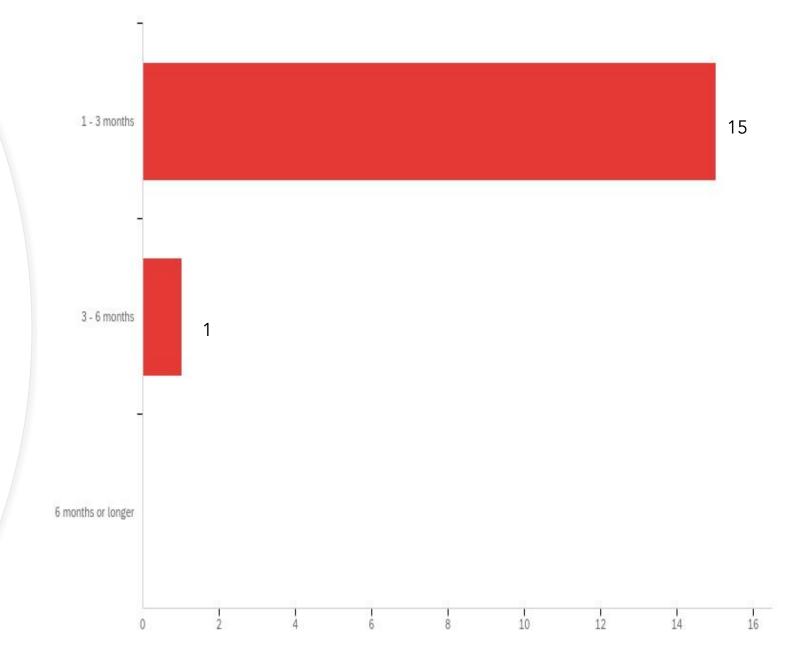
Please select useful affinity molecules from the list below (select all that apply)



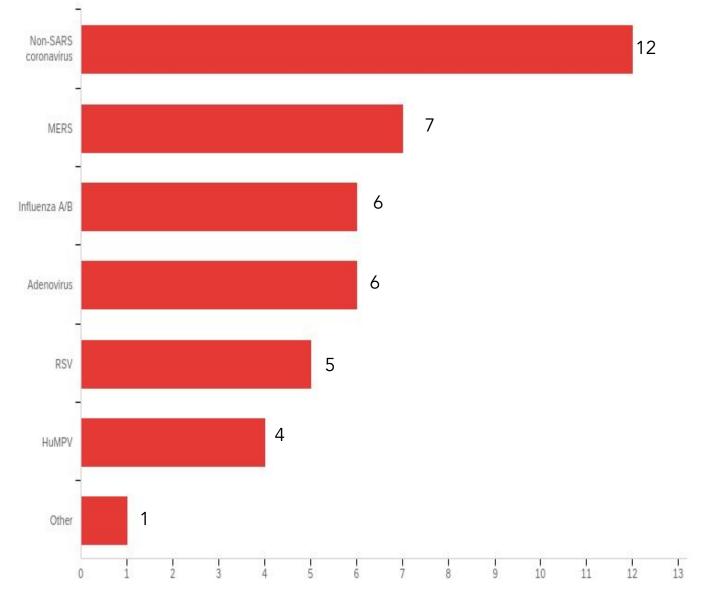
Affinity Molecule "Other" response (N=2)

- polyclonal viral antibodies
- ACE2

What is the earliest date you would be able to use the affinity molecules selected? (N = 16)

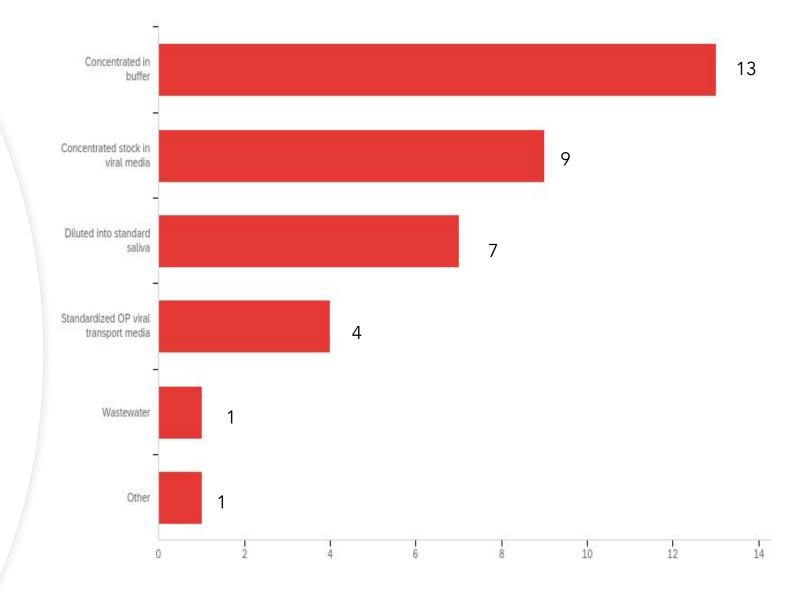


Testing specificities in your diagnostics, which virus do you think is the most useful from the list of Non-SARS-CoV2 viruses? (select all that apply)



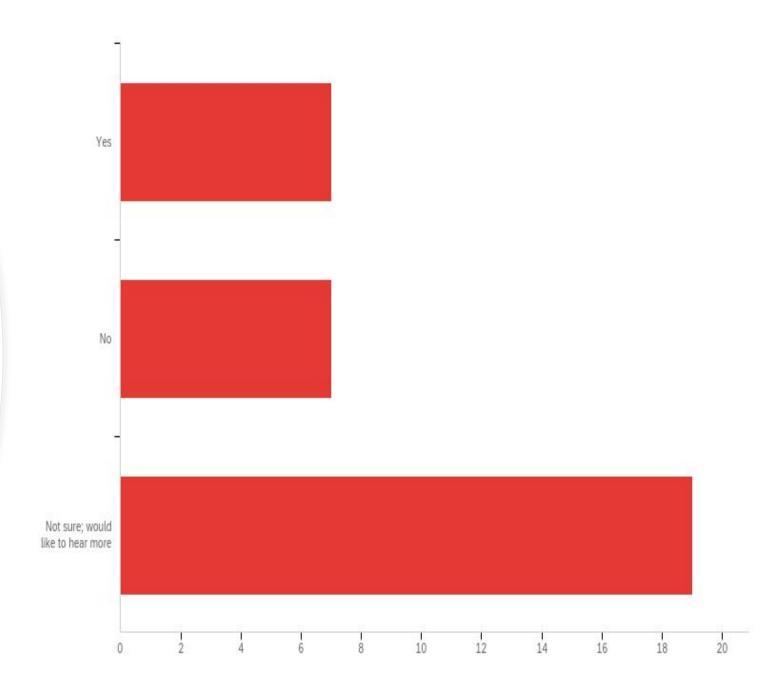
Other: Puro [internal standard (Spike), non-infectious retroviral (VLPs)

Please select the preferred matrix for shipping (select all that apply)

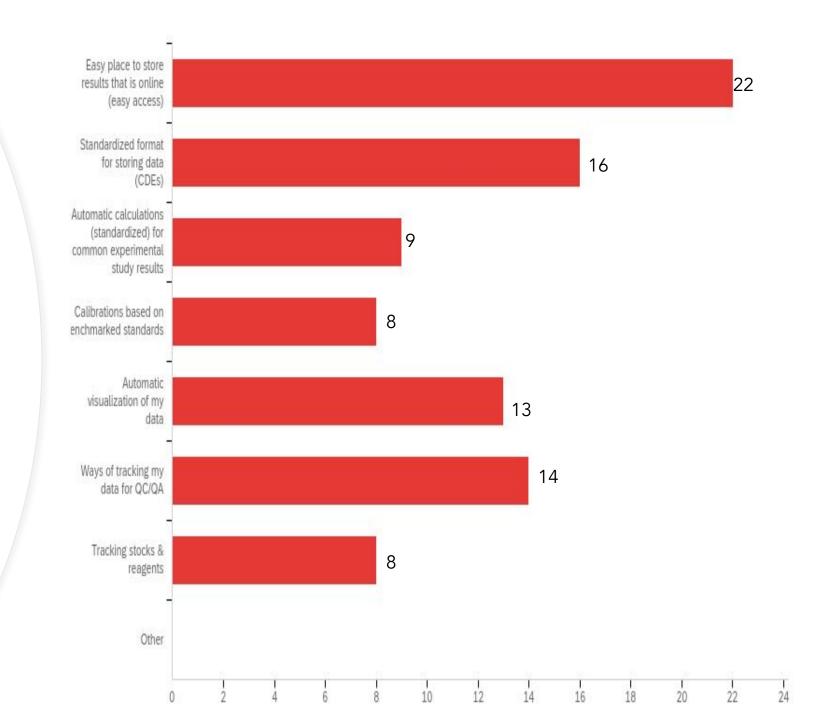


Other: Viral media with virus removed (ideally) or inactivated

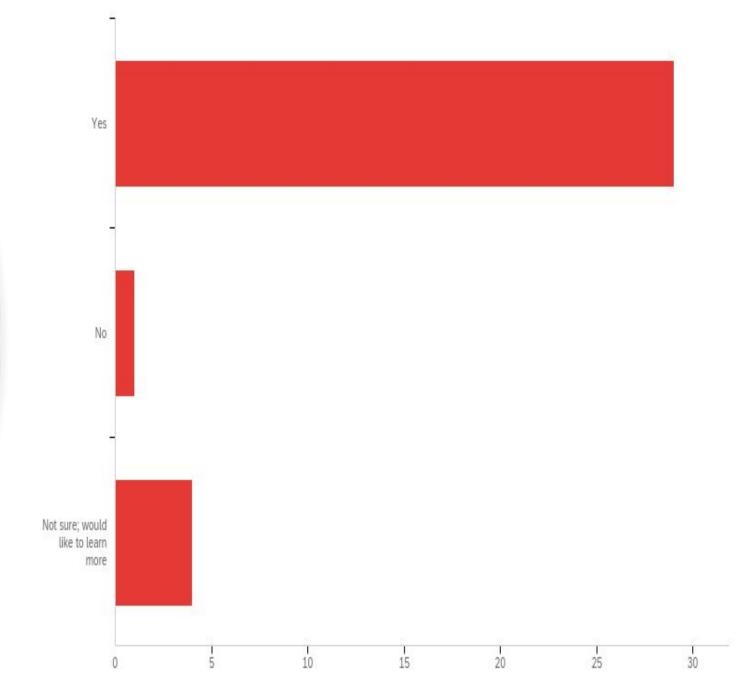
Would you use a free Laboratory Information Management System (LIMS) provided by RAD? (N = 33)



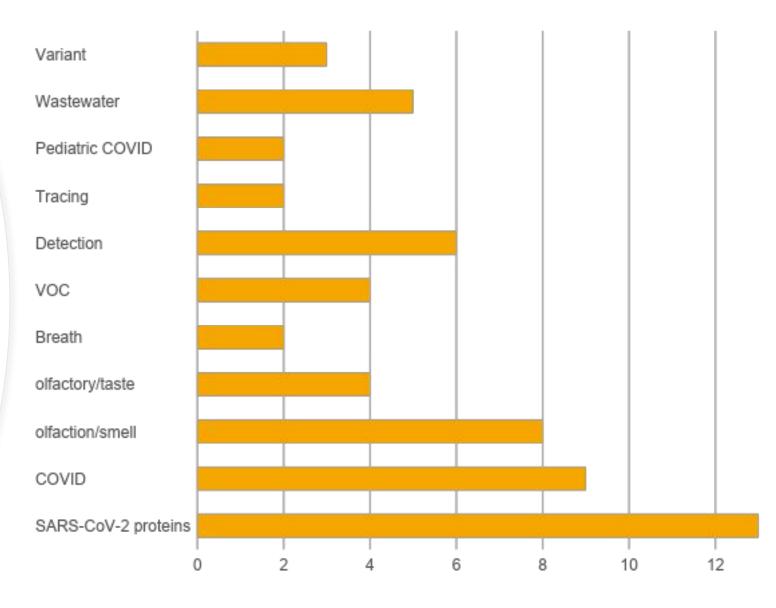
Which LIMS features would be most valuable for you? (select all that apply: N = 90)



We are building digests of literature and news that are tailored to your work. Would you be interested in using the digest?



What are the common key words you use/search for? (text entry) *Common responses



What are the common key words you use/search for? (text entry)

What are the common key words you use/search for? (text entry)

SARS-CoV-2 proteins

smell, olfaction, olfactory, post viral, COVID

antibody, intact virus, digital detection

Concentration, viral load, breath

volatile organic compounds, breath VOCs, skin VOCs, infectious disease, COVID-19

SARS-CoV-2, detection, inhibition, tracing

Multisystem inflammatory syndrome in children, MIS-C, Pediatric COVID-19, SARS-CoV-2 dysbiosis, SARS-CoV-2 antigen, Spike protein, biomarker

wastewater, clinical tests, surveillance, variants, lineages

Voc sensors, e-nose, organic binding peptides, olfactory sensors, graphene fET, chemfET, GFET, peptide discovery

covid detection technology, clinical utility, sensitivity and specificity

What are the common key words you use/search for? (text entry) (Continued)

What are the common key words you use/search for? (text entry)

wastewater, sars-cov-2

Breath analysis, VOCs, infectious disease, COVID-19, SARS-CoV-2

RT-qPCR, Variants, Wastewater, surveillance

biosensor, synthetic, electrochemical detection, infra red detection, SARS-Cov-2, coronavirus, limit of detection, spike, nucleocapsid, ORF1ab,

wastewater, SARS-CoV-2, variant

SARS-CoV-2, biosensor, electrochemical detection, aptamer, immunosensor, enzymatic biosensor, ACE2 biosensor, COVID-19 biosensor

MISC; PIMS; pediatrics

COVID-19, RADx

coronavirus, sars-cov-2, covid-19, AI, artificial intelligence, ML, machine learning

breath analysis, VOCs, dogs, scent, odor

What are the common key words you use/search for? (text entry) (Continued)

What are the common key words you use/search for? (text entry)

Olfaction, smell, COVID, SARS-COV-2, olfactory, taste

SARS-CoV-2 and wastewater

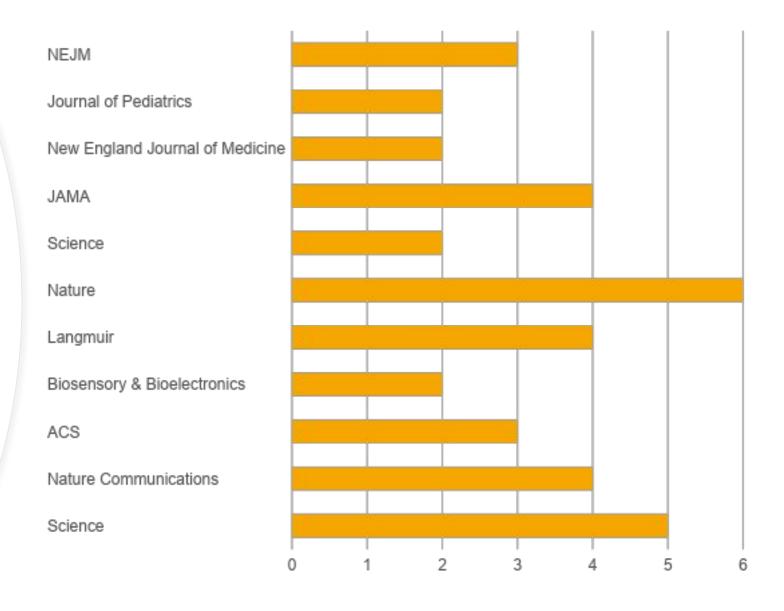
Kawasaki disease; MIS-C

COVID19

SARS-CoV-2, Exosomes, Immune Response,

aptamer, diagnostic

What are the most common journals and sources you use daily? (text entry) *Common responses



What are the most common journals and sources you use daily? (text entry)

What are the most common journals and sources you use daily? (text entry)

Chemical Senses, Nature Communications, The Laryngoscope

ACS, biosensors and bioelectronics, langmuir, nature, science

JAMA, New England Journal of Medicine

N/A

NA

Journal of Clinical Investigation, Journal of Pediatrics, NEJM, JAMA, Cell Reports Medicine, Nature, Cell, Mucosal Immunology

not many, biorxv

Acs Nano, Nature (various), Advanced Materials

scientist

none

Journal of Breath Research; Analytical Chemistry, Lung Cancer

What are the most common journals and sources you use daily? (text entry) (Continued)

What are the most common journals and sources you use daily? (text entry)

Science, Nature, Environmental Science and Technology

Not driven by journal but by topic

Advanced functional materials, Biosensors and Bioelectronics, Sensors and Actuators, Biosensors, Analyst, Electrochemical acta

JAMA (+subs), Pediatrics, Lancet (+subs)

NEJM, JAMA

daily pubmed search

mainstream media, specialty journals, broad journals

PubMed

Science of the Total Environment

NEJM, Cell, JCI, Science

google scholar

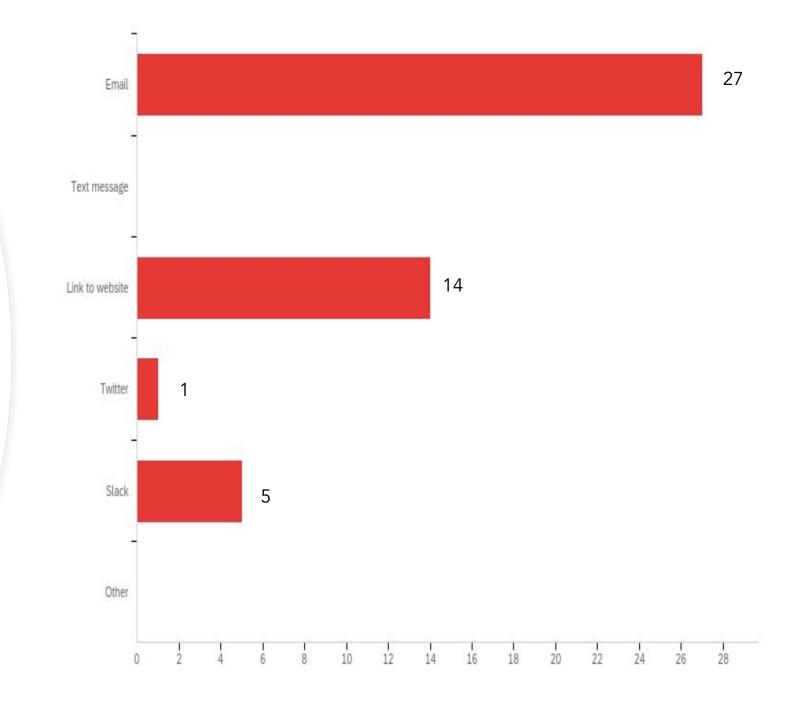
What are the most common journals and sources you use daily? (text entry) (Continued)

What are the most common journals and sources you use daily? (text entry)

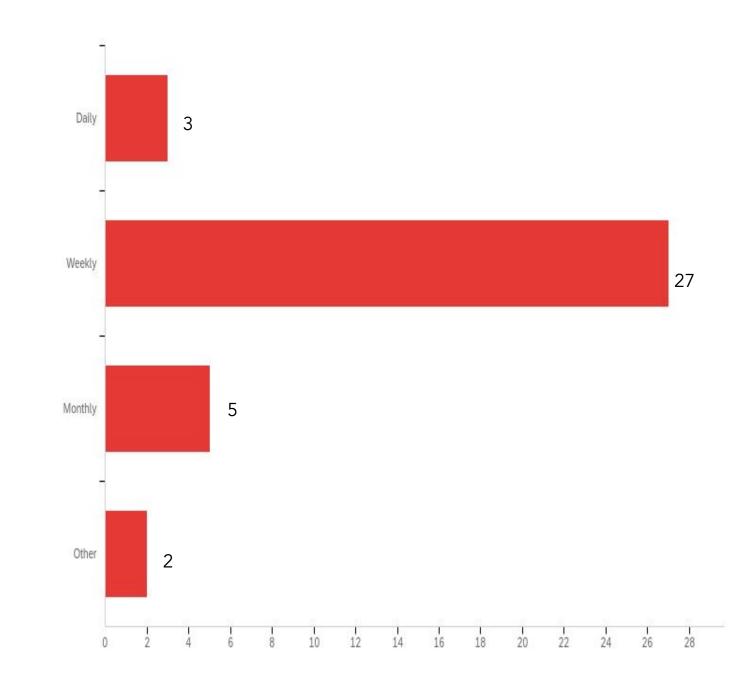
I use twitter and pubmed to find publications

acs journals, nature journals,

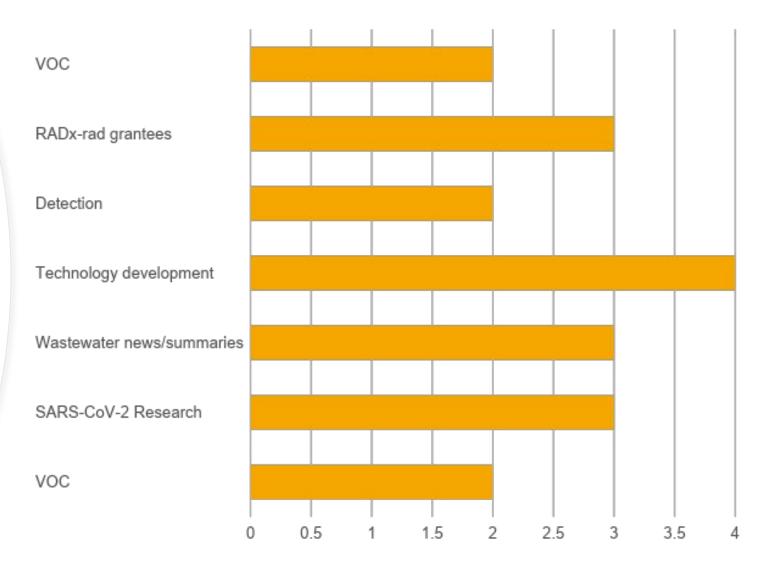
How would you like to receive digests? (select all that apply)



How often would you like to receive digests? (N = 37)



What would like to see in the RADx-rad digest? (text entry) *Common responses



What would like to see in the RADx-rad digest? (text entry)

What would like to see in the RADx-rad digest? (text entry)

Sample information, method, main result and significance

emerging technologies

Summaries of newly published literature pertaining to SARS-CoV-2

VOCs

NA

summary of wastewater detection nationwide, are even there public or sharable data?

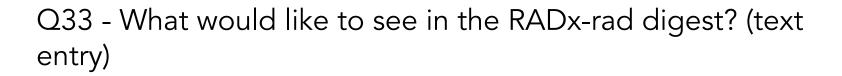
COVID gás phases sensing, VOC profiles.

technology development

wastewater-related SARS-CoV-2 research

COVID-19 detection

Method Developemnt, Method Comparsion



What would like to see in the RADx-rad digest? (text entry)

Coronavirus, Diagnostics, Surveillance, Monitoring

links to articles

Latest COVID-19 detection and tracing technologies

RADx technologies

citation and abstract

Curated press release, medRxiv, and bioRxiv data

Latest in terms of wastewater research. Highlight from RADx-rad groups. List of publications from RADx-rad group.

Short abstracts of articles

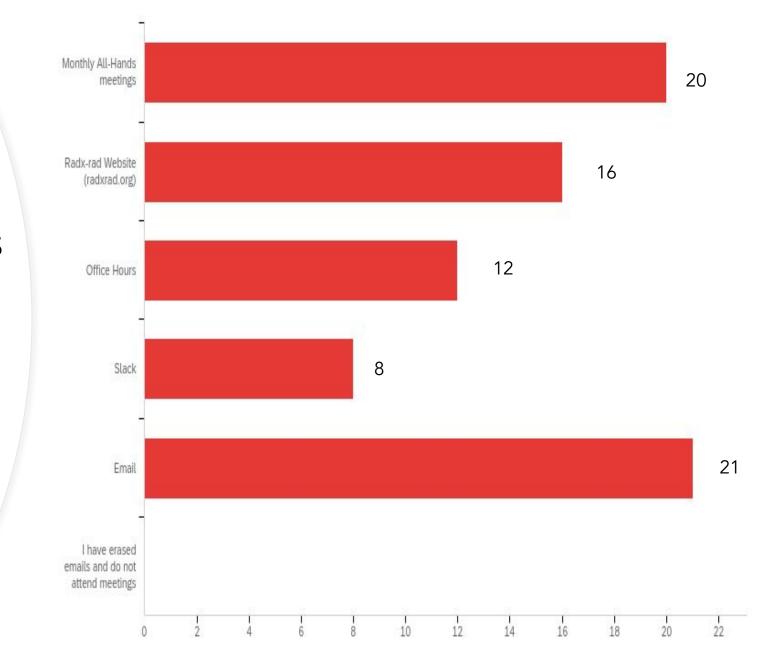
COVID19

Latest research, resources available to RADx-rad grantees, spotlights on other projects.

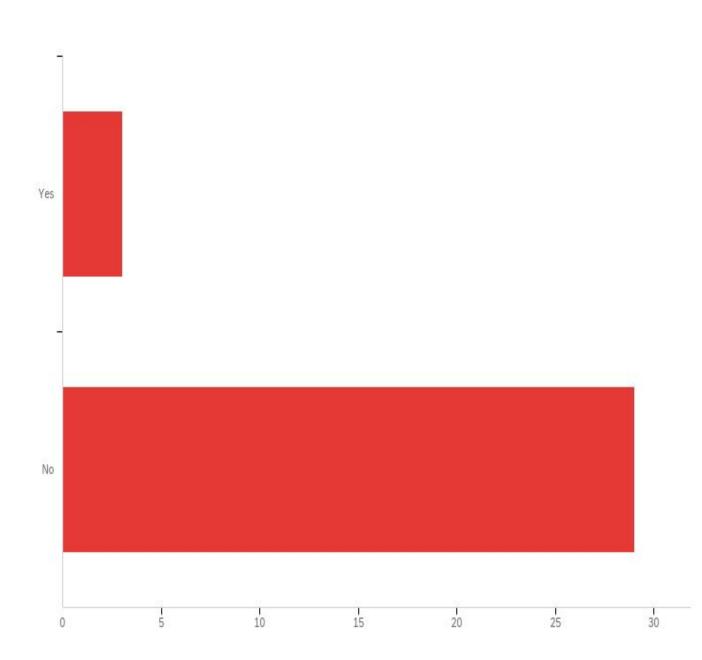
asd

DCC Assessment

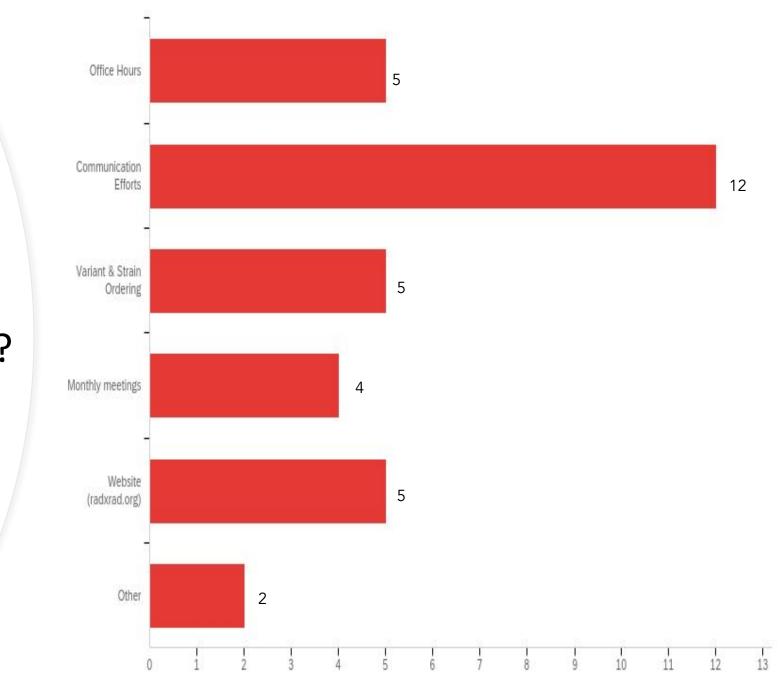
Are there any other forms of communication that would be helpful to your study/project? (N = 32)



Are there any other forms of communication that would be helpful to your study/project? (N = 32)



Which areas can the RADx-rad DCC improve on? (select all that apply)



How can the RADx-rad DCC better support your study/project? *Common responses

Data collection Meeting confusion Too many meetings Examples of forms & data dictionary 1.5 2 2.5 3 3.5 0.5 1 0

Communication efficiency

How can the RADx-rad DCC better support your study/project? (free text)

Post examples of forms, registration, data dictionary, etc. to avoid duplication of work. Thanks!

First - I support two projects (Selim Unlu and Mark Albers) so my answers attempt to cover both. Second - the DCC has been a terrific partner and provides great support! Individuals have been patient with all our questions and respond in a timely matter. They've made time for meetings and discussions for bigger issues, and those that are too specific to cover during Office Hours. Overall, I feel the support has been excellent. One area to improve might be communications - and I know that is difficult because there are so many non-PI people across different FOAs, and people like me who support different projects. I have a hard time figuring out whether or not the Office Hours are 'on' or not during a particular week, and ignore the Wastewater meeting invites that I get. While that could be better, the main thing is that when my teams have questions, we can get answers quickly. Nice job!

More information about RADx technology stack to facilitate our own data processing consistent with DCC protocols.

Simplify

NA

How can the RADx-rad DCC better support your study/project? (Continue)

How can the RADx-rad DCC better support your study/project? (free text)

The meeting invites do not easily forward, so I have to manage on my end, which was initially difficult as they kept changing. In addition, all of the collaborators on my project were overwhelmed with emails to meeting invites. As such, I spent quite a bit of time explaining what each meeting was for, and who should attend. Once I organized all of the meetings, an explanation of appropriate audience given the topic, and sent every team member what meetings they should attend, there was less confusion (but some still exists). Pritham and Sai were wonderful in assisting me by adding my team member's emails to the correct invitation list. There's still some confusion, and for some reason some of the invites don't play well with the University of Connecticut email system, so I still have to manage those individually.

DCC is doing great job!

More progress on VOC profiles

Nothing at the moment

Data format and communication

Reagents and clinical specimens

Need access to positive cohorts internationally.

How can the RADx-rad DCC better support your study/project? (Continue)

How can the RADx-rad DCC better support your study/project? (free text)

DCC is stellar and providing magnificent support. Thank you.

PreVAIL-kids communications from NIH still come as emails with attachments. Can they at least transition to emails with links to a file repository on the website?

Reducing redundancies of collected data

I find that when a short PPT is presented (including a short meeting agenda) the office hours tend to get start very interesting conversations. There needs to be a purpose to the office hours (something that needs to be communicated) and that leads to more productive conversations.

don't know

Less meetings and paperwork, more time to do the research (it is very hard to stay on top of all of the office hours, meetings, data reporting, etc).

asd

Diagnostic & Discovery Update

Diagnostic & Discovery Update

VARIANTS OF CONCERN

WHO label	Pango lineage	GISAID clade	Nextstrain clade	Earliest documented samples	Date of designation
Alpha	B.1.1.7	GRY	20I/S:501Y.V1	UK, Sept 2020	Dec 2020
Beta	B.1.351	GH/501Y.V2	20H/S:501Y.V2	South Africa, May 2020	Dec 2020
Gamma	P.1	GR/501Y.V3	20J/S:501Y.V3	Brazil, Nov 2020	Jan 2021
Delta	B.1.617.2	G/452R.V3	21A/S:478K	India, Oct 2020	May 2021

• WA1, B117(alpha), B1351 (beta) Shipping

- Heat /UV inactivated currently available
- Irradiated virus still TBD
- P1(gamma)/Non SARS-COV2 Corona Virus coming Next
- Delta On-deck

Steps to obtain virus

Request an MTA Virus should ship within 3 days of MTA

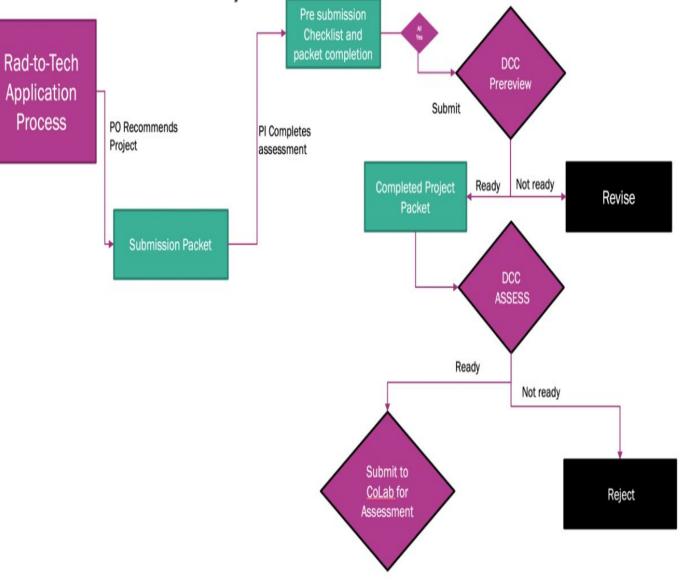
Source: WHO

RAD2Tech Coming June 2021 *Email update coming soon

- The Rad-to-Tech pathway offers a *three-stage process* to apply for a Tech transition work package:
 - 1) Brief Proposal which will be screened by the DCC.
 - 2) Full proposal to <u>Point-of-Care Technologies Research Network</u> (POCTRN) via the CoLab grants management portal.
 - 3) Deep Dive, preparation, proposal revision and screening for Work-Package by Tech Viability Panel
- There is limited availability of funding awards only mature technologies with a high chance of reaching market quickly will be selected for this process.
- There is a significant amount of documentation and preparation associated with this process. RADx-rad teams must be prepared to complete the documentation and have sufficient resources dedicated to the process.
- Applications will be processed by the RADx-rad DCC on a rolling basis, beginning on <u>June 16, 2021</u>, and will continue to be accepted until funds are spent.
 - Projects that pass DCC review will be invited to apply for RADx Tech funds via CoLab. These proposals will be assessed by the RADx Tech Viability panel.
 - Selected projects will then be awarded \$25,000 to support RADx Tech deep dive-assisted preparation of a full Work-Package submission to the RADx Tech Investment panel (Tech Viability).
 - For those projects that are recommended to proceed to the Work Package, funding amounts will vary between \$250,000-\$1M with
 4- to 6-month-long milestone timelines.

RAD2Tech Coming June 2021

RADX TO TECH PATHWAY (DCC TO TECH PRE-SUBMISSION)



FDA Questions

Next FDA Q&A session *Wednesday June 30*th

Any questions for FDA to be submitted to Alexandra Hubenko by COB Thursday June 24th ahubenko@ucsd.edu

Requests to include:

- PI Name
- Project
- FOA category (Exosome, SCENT, etc)
- Question for FDA

Data Core Update

FOA-specific Recommended CDEs Development

	Automatic Detection and Training	Chemo-sensory Testing	Exosome Based	Multimodal Surveillance	Novel Bio-sensing	PreVAIL kIds	SCENT and VOC	Wastewater
Minimum CDE communication	~	~	V	~	V	~	V	~
Data Standards Kick-Off	V	V	V	V	V	V	V	V
Data Dictionary Template sent out	✓ Draft Complete – In review with NIH/Data Hub (since 04/05)							
Received Data Dictionaries/ Input	✓ (1)	✔ (1)	✓ (1)	✓ (1)		✓ (3)	✓ (3)	✔ (4)
Data Standards Discussions	Monthly (2)	Ad Hoc (2)	Monthly (3)	Ad Hoc (1)	Ad Hoc (1)	Monthly (2), Weekly Pediatric working group	Ad Hoc (2)	Bi-weekly (7)
Progress Highlight for Data Standards	In Progress	In Progress	Advanced (~40 CDEs)	In Progress	In Progress	Advanced (Draft Kids CDEs)	In Progress (~10 CDEs)	Advanced (~120 CDEs)

IMI: A web-based CDE mapping tool

Beta-testing completed, will release this week

Interactive Mapping Interface **Collaborative Variable-CDE Mapping**

Log in		
Email *		
Password *		
Log in		
No account yet? Sig	ın Up	

test		Export	Share	Edit
inclusion	Variable Name racemoasianspec	Map	o Comme	ents O
essworker	Suggested CDEs			
enrollstudy stduiesenrolled otherstudyenroll	NIH Minimum CDEs Tace what is your race mark one or more boxes		Sele	ect
guid firstname	NH Covid CDE Race* what is your race		Sele	ect
 middlename lastname citybirth 	CINIH ALL CDE Person Biological Entity Race Code ACT I2B2 CDM Race Code		Sele	ect
dob gender ethmo	CANIH ALL CDE Child stop grow normal rate spec PhenX what happened if child stopped growing at a normal rate at any time since birth		Sele	ect
racemo racemoothr racemospcfy	CNIH ALL CDE Asian alone Census tract not hispanic or latino asian alone		Sele	ect
asianmo racemoasianspec ethfa	CNIH ALL CDE Other Asian Race Category Specify other asian other asian specify		Sele	ect
racefa racefaothr racefaspcfy	CNIH ALL CDE race_ethn_asian_detail null		Sele	ect
asianfaracefaasianspcfy				

Data Submission to DCC

dbGAP Study Registration Workflow:

Download forms from DCC website (will be sent to PIs by email too) R https://www.radxrad.org/resource/radx-rad-study-registration-institutional-AWS Transfer certification-and-study-sharing-and-submission-registration-documents-nih/ S3 Bucket Activitie RADx Data Sharing Plan & Submission Form 1 Incoming Files RADx Institutional Certification Form Approve (78) Approved Folder S3 User(s with the Tao 1 Scan' = "Par PI to set-up meeting with Vivian Ota Wang PI completes RADx Data PI completes RADx Questions Resolved Questions Resolved 76 Sharing Plan & Submission Institutional Certification Fail Folder with support from Erin Bailey at DCC: Oura Questions with the Form Form Questions elbailev@health.ucsd.edu (3) Files are tagged with 'Scan' = 'Pass' or 'Fai Upload event 7 PI to send to FOA PO for signature on Institution's Delegated Authorized Both completed forms are submitted to Notification sent email and http 5 completed RADx Data Sharing Plan & Signer (ex: Provost of Research) signs Vivian otawangv@mail.nih.gov endpoints Copy file from Message fanned to email **Submission Form** completed RADx Institutional and SQS guarantine cc: DCC elbailey@health.ucsd.edu & FOA PO Certification Amazi SNS Results written to (5a) run results table Vivian will register complete forms into the scan file 10 Amazon SQS ERS dbGaP registration database Form Form new file Complete Complete **Registration Complete** and Signed (4)and Signed Amazon EC delete message Message read by Read SNS details by 6 dbGaP Study ID emailed to PIs, DCC, FOA POs, and Data Hub project from DynamoDB ScanDetails Table scheduled polling

Development of Secure FTP for data submission (June 20th beta testing)

Data sharing – privacy protection tools

Subject ID generation tool: *beta testing commencing*

Name	Gender	DOB	Study ID	*		
VERONICA VILLANUEVA"	"F"	"12/31/1978"	ABCDBBJHI365648251		<u>^</u>	9 *
"ANNA JIMENEZ"	"F"	"01/24/2005"	ABCECAAFF713082796			
"MCKAYLA WILLIAMSON"	"F"	"02/23/2014"	ABEMCKAYL428879838			
"GIRL/ISLAMIAT BELLO"	"F"	"03/26/2020"	ACAGIRLIS308742729			Load Patient File
"JOANNE PROGESS"	"F"	"02/11/1939"	ACBBBJDJF803303417			
"John Harrington Jr."	"M"	"10/26/1977"	ACGBJHHJO836207239			
"PRINCEZZADEA DAVIS"	"F"	"01/26/2020"	ADAVISABC623207186			
"PEDRO PAEZ"	"M"	"01/03/1949"	ADBJEJMPE511088023			Generate Study ID(s)
"BETTY RINGER"	"F"	"03/24/1928"	ADCEBJCIF725960726			
"MICHAEL RUBY"	"M"	"03/24/1961"	ADCEBJGBM300542494			
"MIA SHIMAJ"	"F"	"04/03/1971"	AEADBJHBF447636651			Download Study ID(s)
"RAEANNE GILPIN"	"F"	"03/07/2012"	AEANNEGIL581702698			
"RAFAEL LOPEZ CASTRO"	"M"	"04/26/2016"	AFAELLOPE168664790			
"GIRL/QUANSHANIK TYLER"	"F"	"03/12/2020"	AGIRLQUAN217067749			
"OLLIE GATEWOOD"	"F"	"12/07/1938"	AHBJDIFOL856835170			
'GLADYS JESCHKE"	"F"	"02/07/1973"	AHBJHDFGL303998113			
"JAYCE MALVEAUX"	"M"	"05/07/2019"	AHCABJMJA922469628			
"RUSHAN ORAKZAI"	"M"	"03/07/2005"	AIADAHCAA535764405			
"James Russell Carter"	"M"	"08/16/1955"	AIBGBJFFJ015520399			
"N HINES"	"M"	"08/20/1948"	HINESAICA552094030			
"TAISHEA BUTLER"	"F"	"09/07/1988"	AISHEABUT775961344			
"KATHLEEN ELLWANGER"	"F"	"02/10/1950"	AKATHLEEN141332330			
"KYLE GATES"	"M"	"12/03/1990"	AKYLEGATE476773800		4	

Zip Code truncation tool: pending NIH decision

File Zipcode column index: 6	0						
zipcode		patient_id(1)	gender(2)	age(3)	city(4)	state(5)	zipcode(6)
data2.csv	1	314052616	female	30	Houston	ΤХ	27526
zipcode1_zipcodeResults	2	177415627	male	85	Houston	ΤХ	9839Z
data1_zipcodeModified.csv	3	773254168	male	30	Houston	ΤХ	865ZZ
data3_zipcodeModified.csv	4	344648736	female	60	Houston	ΧТ	2300Z
	5	519647883	female	19	Houston	ΤХ	60018
	6	631177921	female	22	Houston	ΤΧ	5536Z
	7	258930831	female	60	Houston	ΤΧ	55068
	8	917514677	female	80	Houston	ΤХ	513ZZ
	9	127965046	female	80	Houston	ΤΧ	516ZZ
	10	706701322	female	19	Houston	ΤХ	89183
	11	517088056	female	22	Houston	ΤХ	626ZZ
	12	164132868	male	70	Houston	ΤХ	9323Z

C:\Users\dpei2\Projects\uth\release\examples\dateshift.dts

File Subject ID column index: 1 Date column index list: 7,8

ateshift data1.csv data2.csv data2.csv		patient_id(1)	gender(2)	age(3)	city(4)	state(5)	zipcode(6)	login_date(7)
	1	559971937	female	30	Houston	тх	43701	12/05/2019
dateshift_dateResults	2	884807185	male	85	Houston	хт	95963	12/05/2019
data1_dateModified.csv	3	958233761	male	30	Houston	ΤХ	92648	12/07/2019
data3_dateModified.csv	4	678819532	female	60	Houston	ΤХ	15122	12/06/2019
	5	217316674	female	19	Houston	Χ	97501	12/08/2019
	6	722025475	female	22	Houston	ХТ	20621	12/06/2019
	7	113465010	female	60	Houston	ΤХ	25845	12/03/2019
	8	375098847	female	80	Houston	ΤХ	65068	12/04/2019
	9	341586032	female	80	Houston	ТХ	67418	12/09/2019
	10	695480258	female	19	Houston	ТХ	24360	12/12/2019

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Date-shifting tool: pending NIH decision

THANK YOU! To the NIH and RADx-rad Awardees

Announcements

 Don't forget to submit your dbGaP forms for registrations (Contact Dr. Vivian Ota Wang or Erin Bailey with any questions)

•Sign-up for RADx-rad Slack channel (invite has been sent out)

•Next All-Hands Meeting July 12, 2021