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.

Agenda

DATE	TIME	TOPIC
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** – *Eliah Aronoff-Spencer* 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

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

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

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

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

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

EAB Interests/Input

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

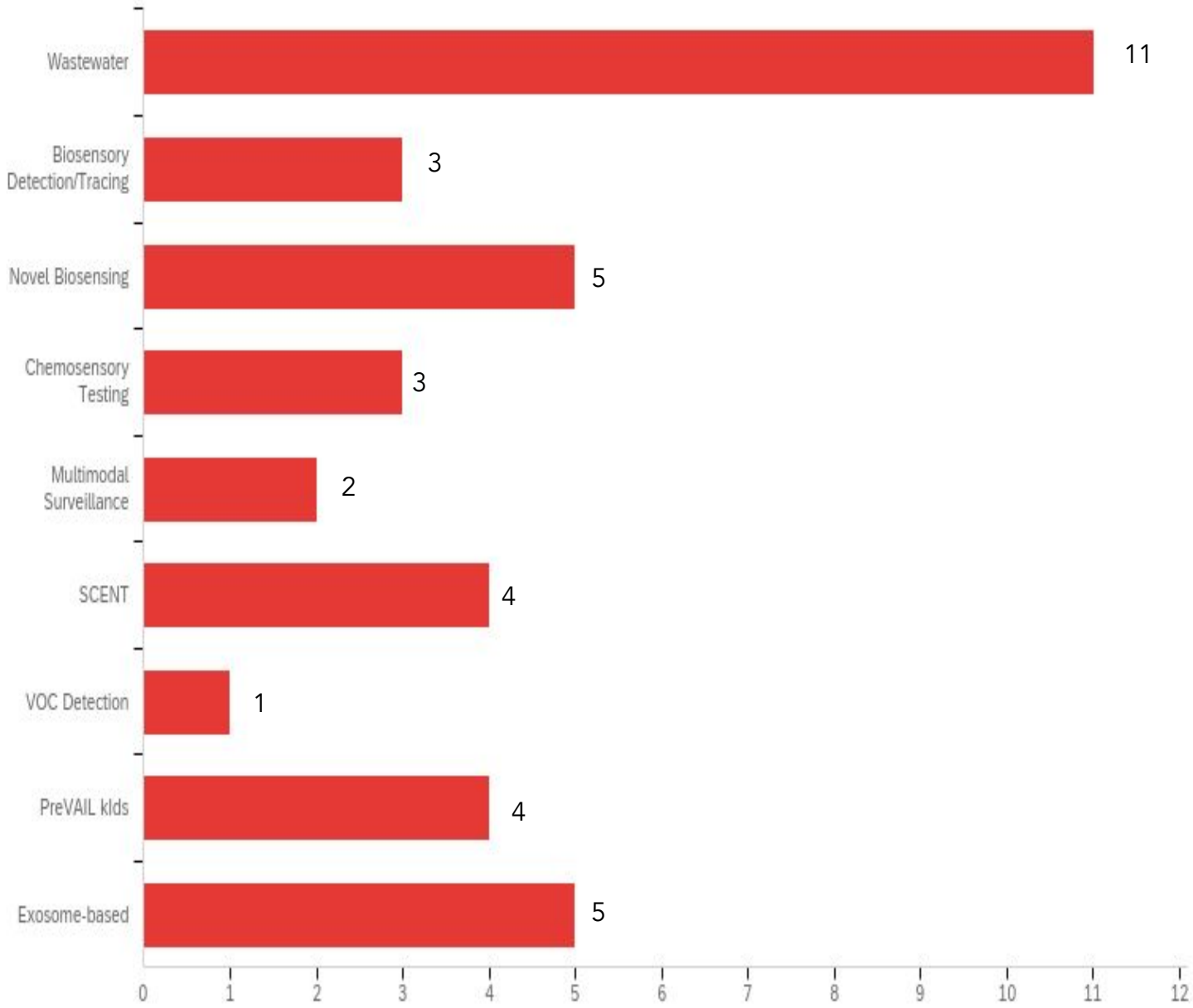
Team Work Training

Offered Year 1 – Year 4:

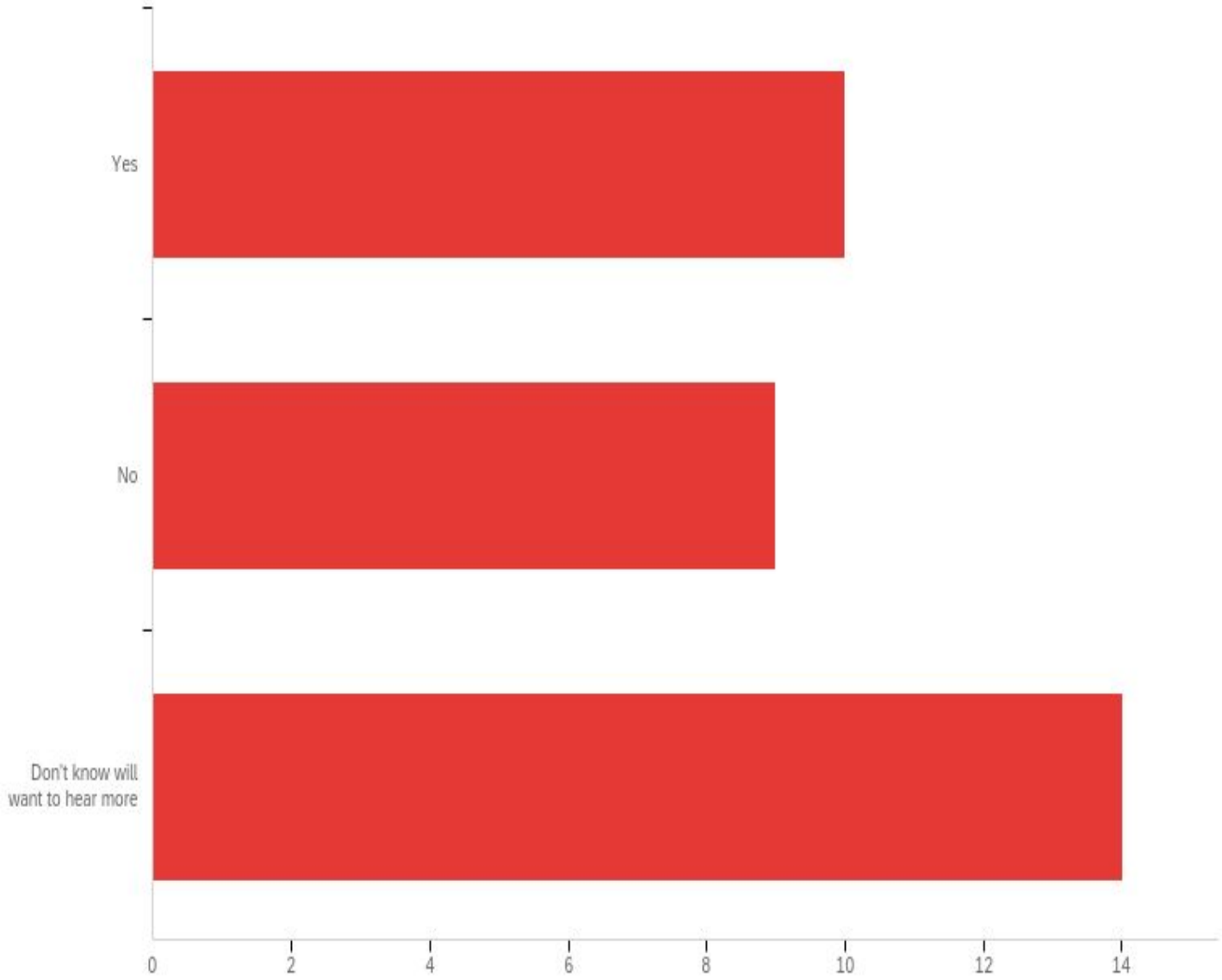
Attendees learn how to develop effective teams in the context of project management and how to implement communication and conversation strategies that help their team meet their project goals. Exploring common team-related issues:

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

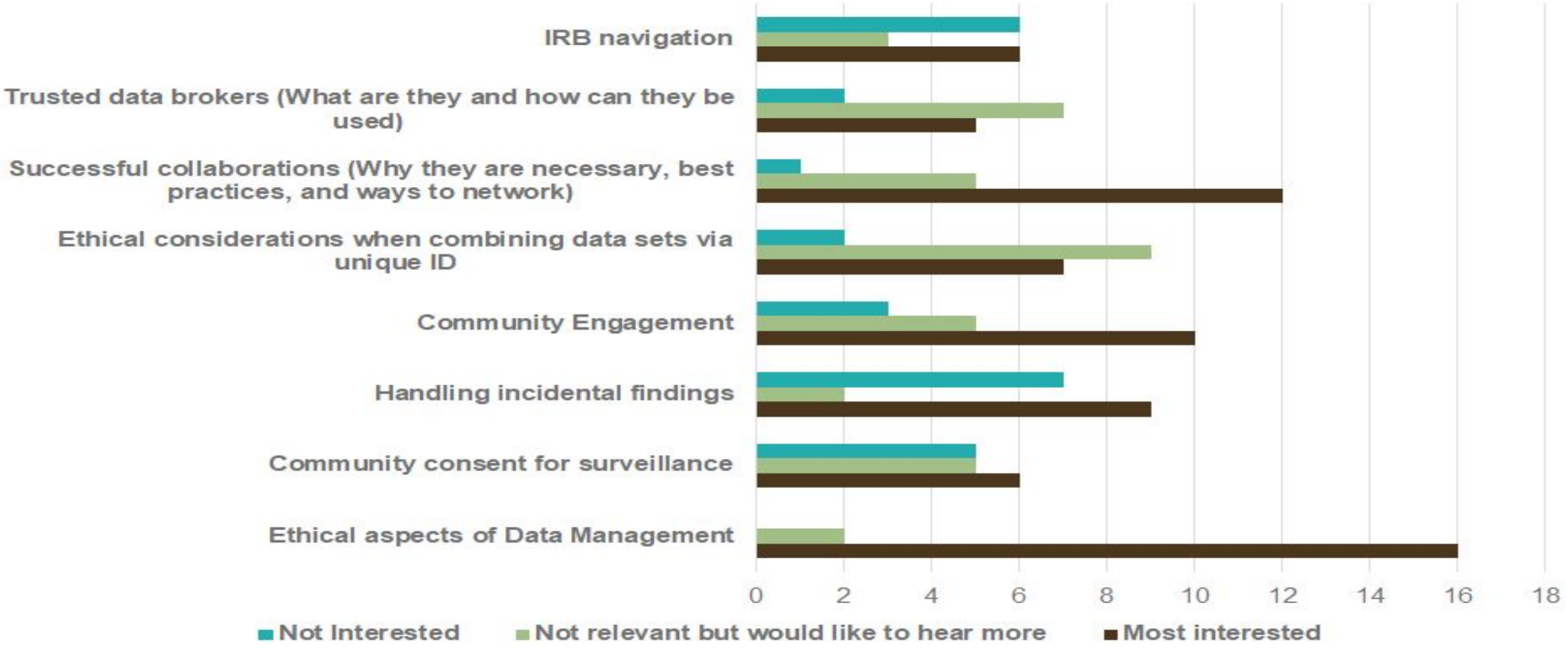
Awardee Group (N = 38)



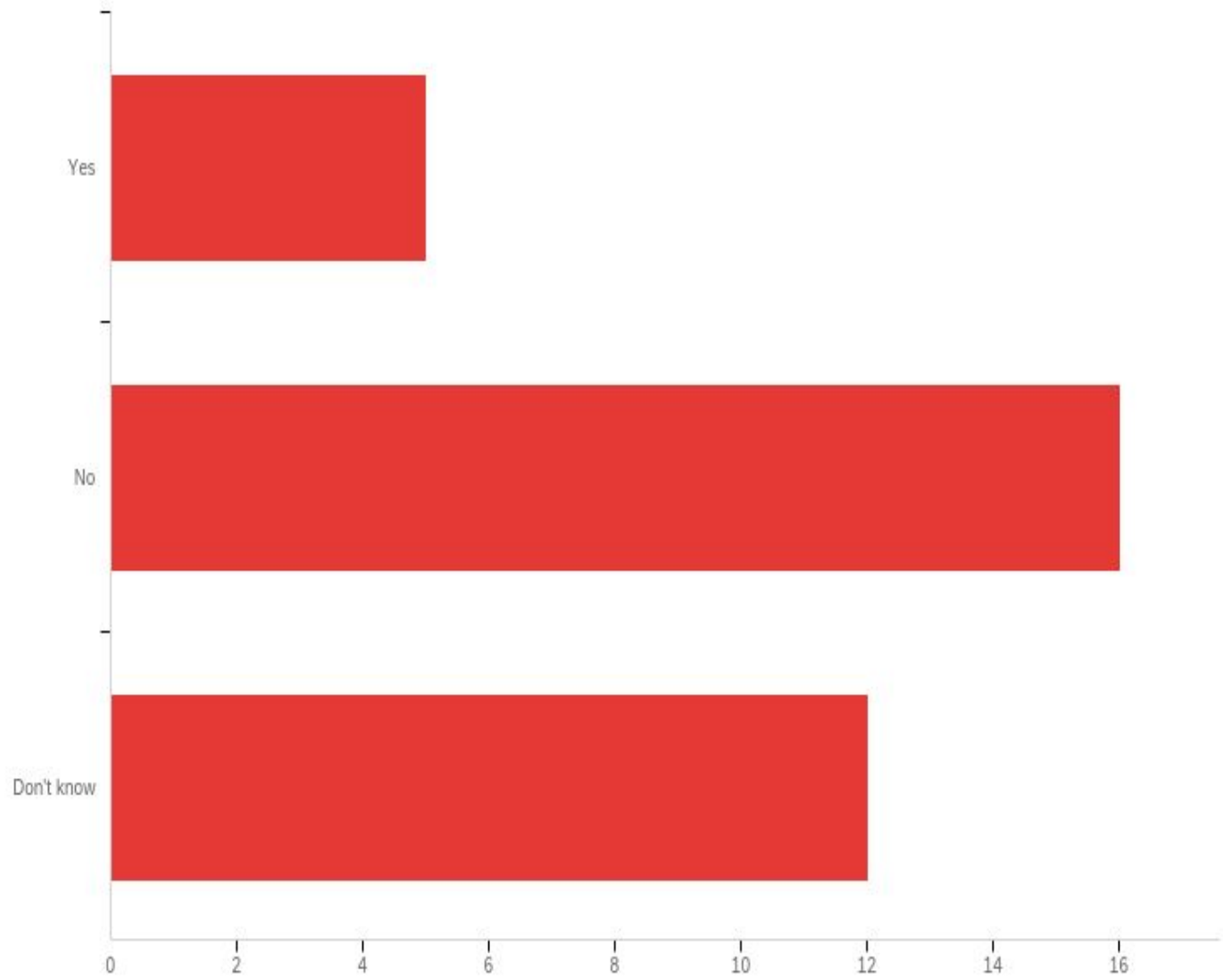
Would you like to attend Office Hours to discuss ethical dimensions of the RADx-rad research? (N=33)



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

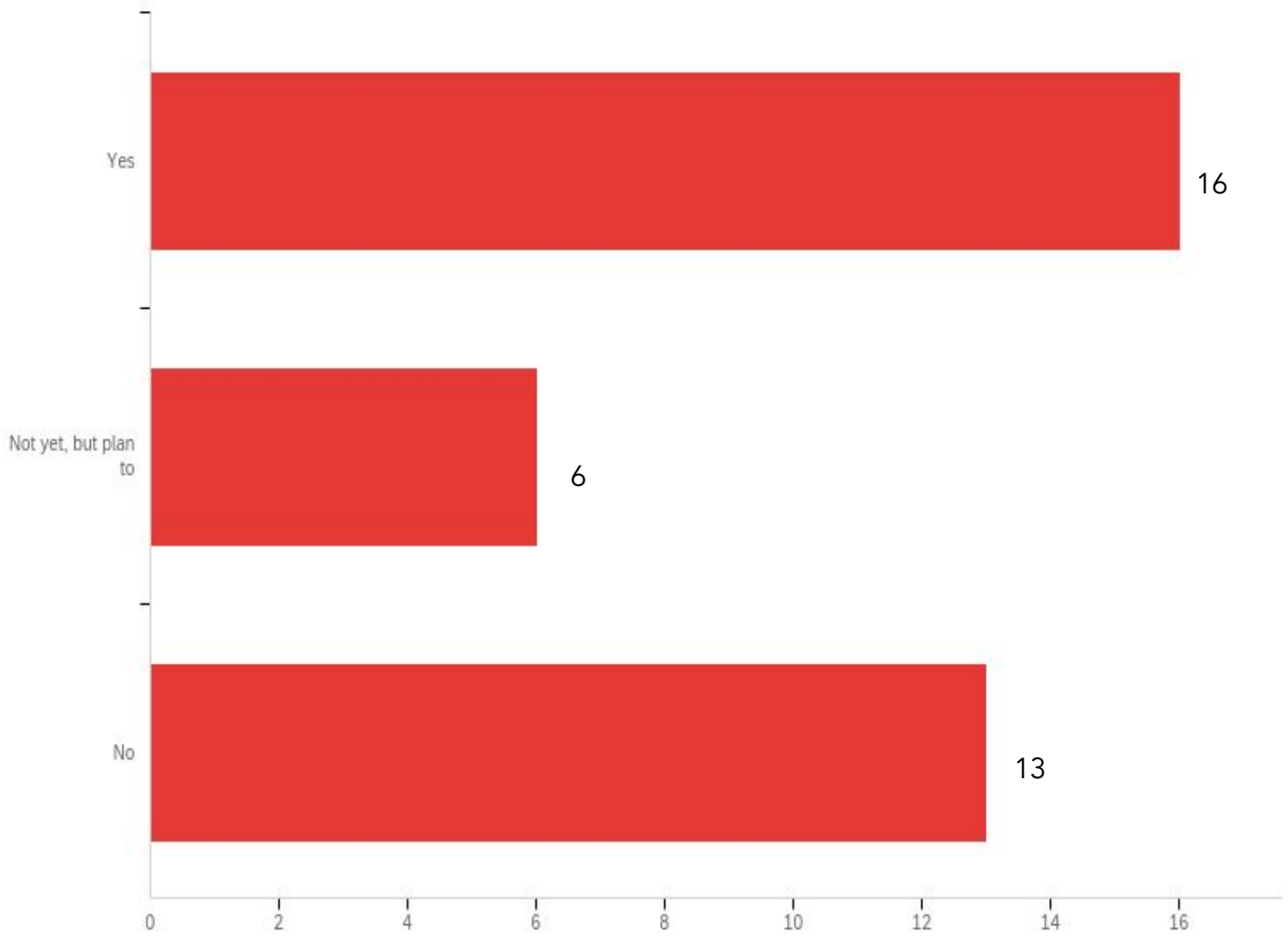


Would you like to consult with someone on your team about ethical aspects of your award? (N=33)

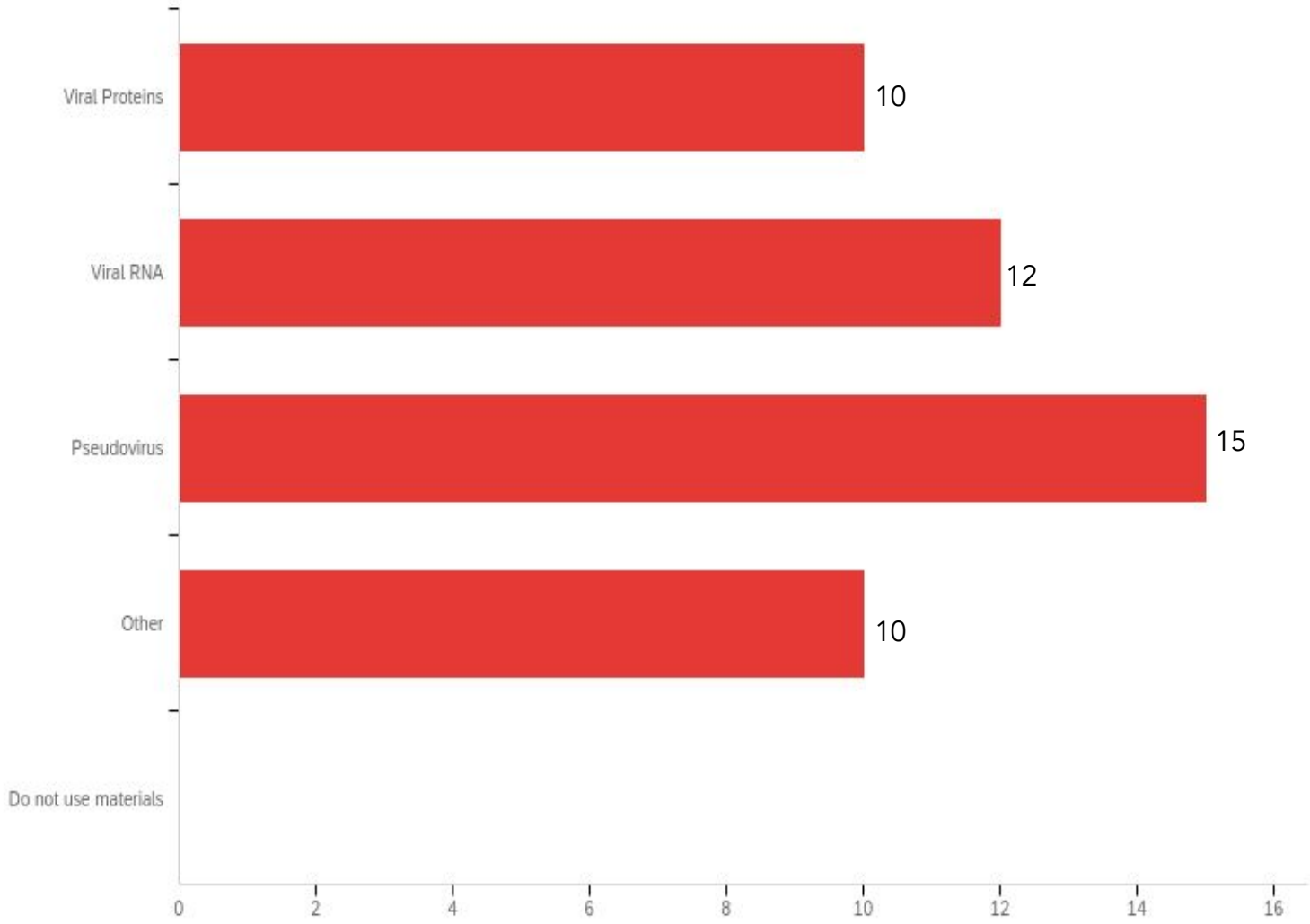


Diagnostics and Discovery Assessment

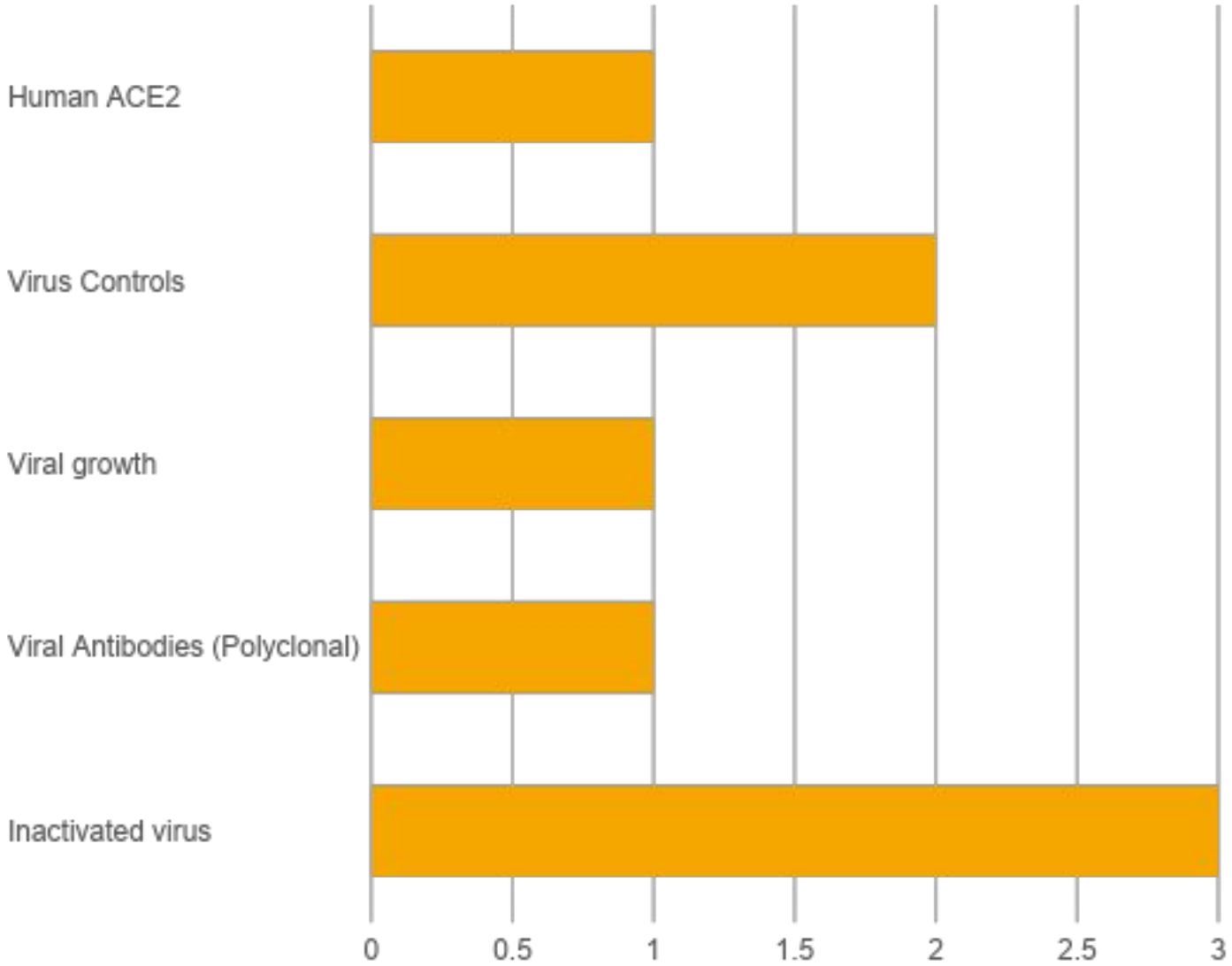
Given the changing landscape with coronavirus variants, the need to detect other circulating and emerging viruses, and new constraints on resource availability - Does your study use or order variants? (N = 35)



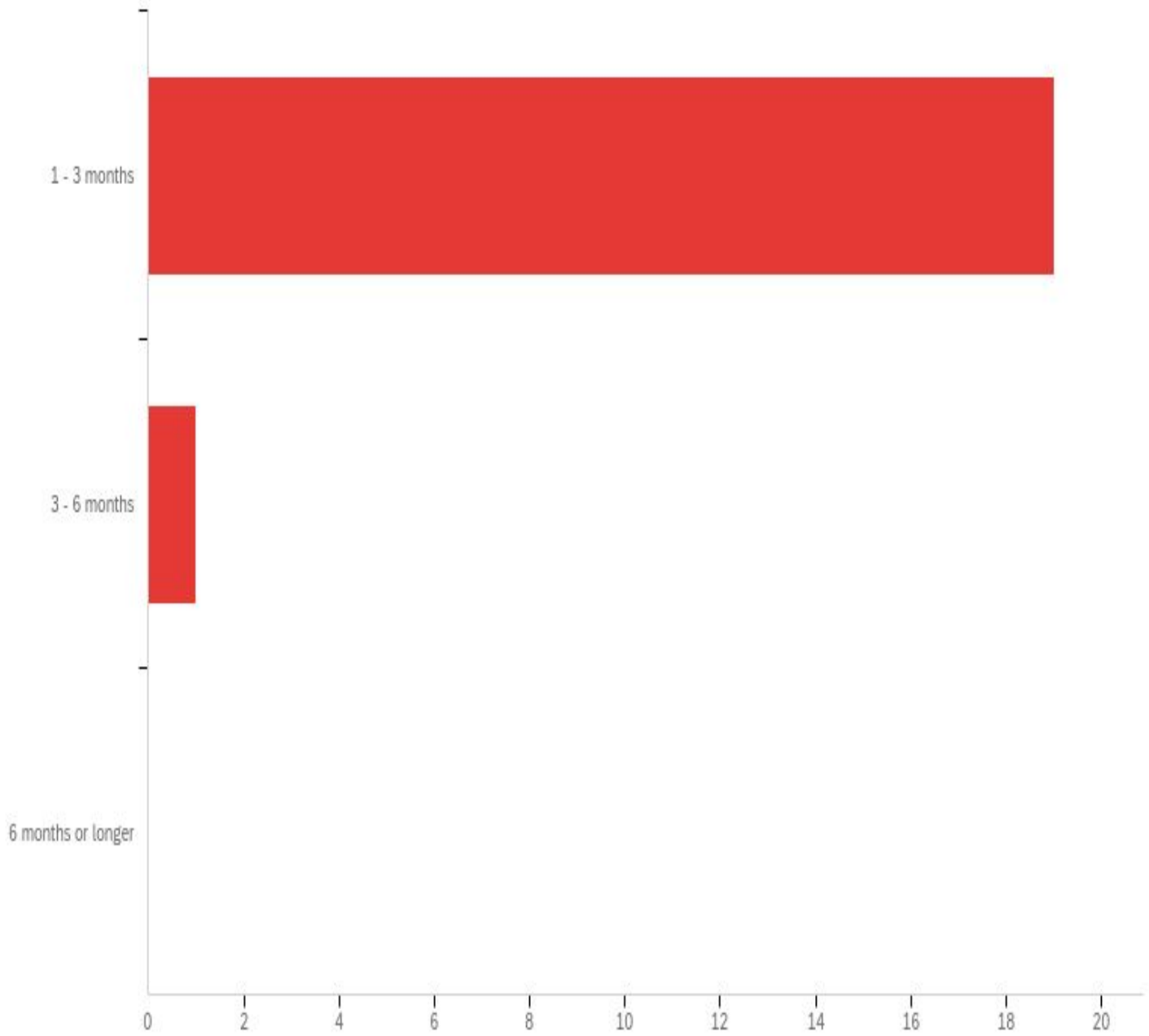
From the list of materials below, please select those you view as useful to your study/program (select all that apply)



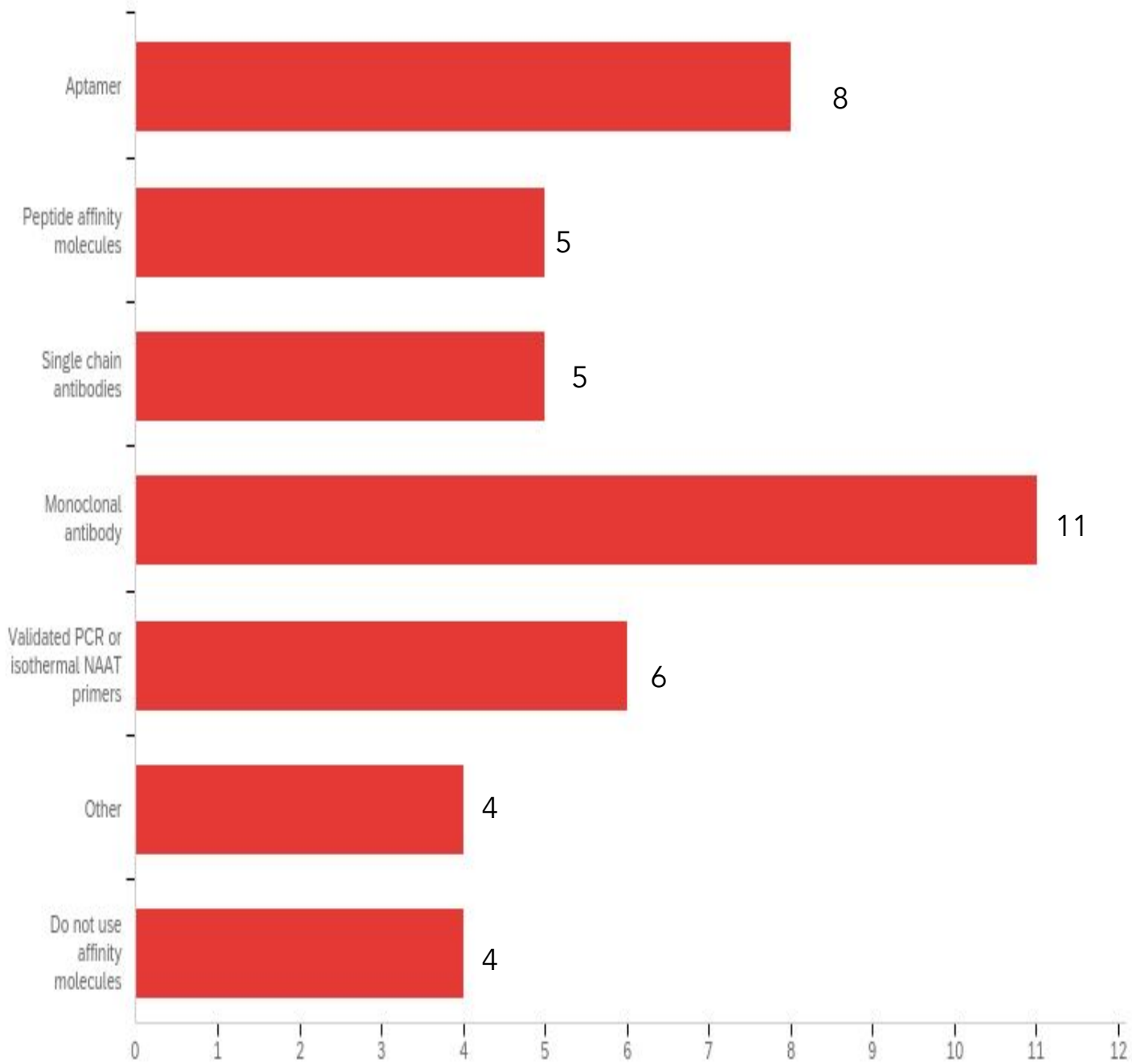
Materials “Other” response



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



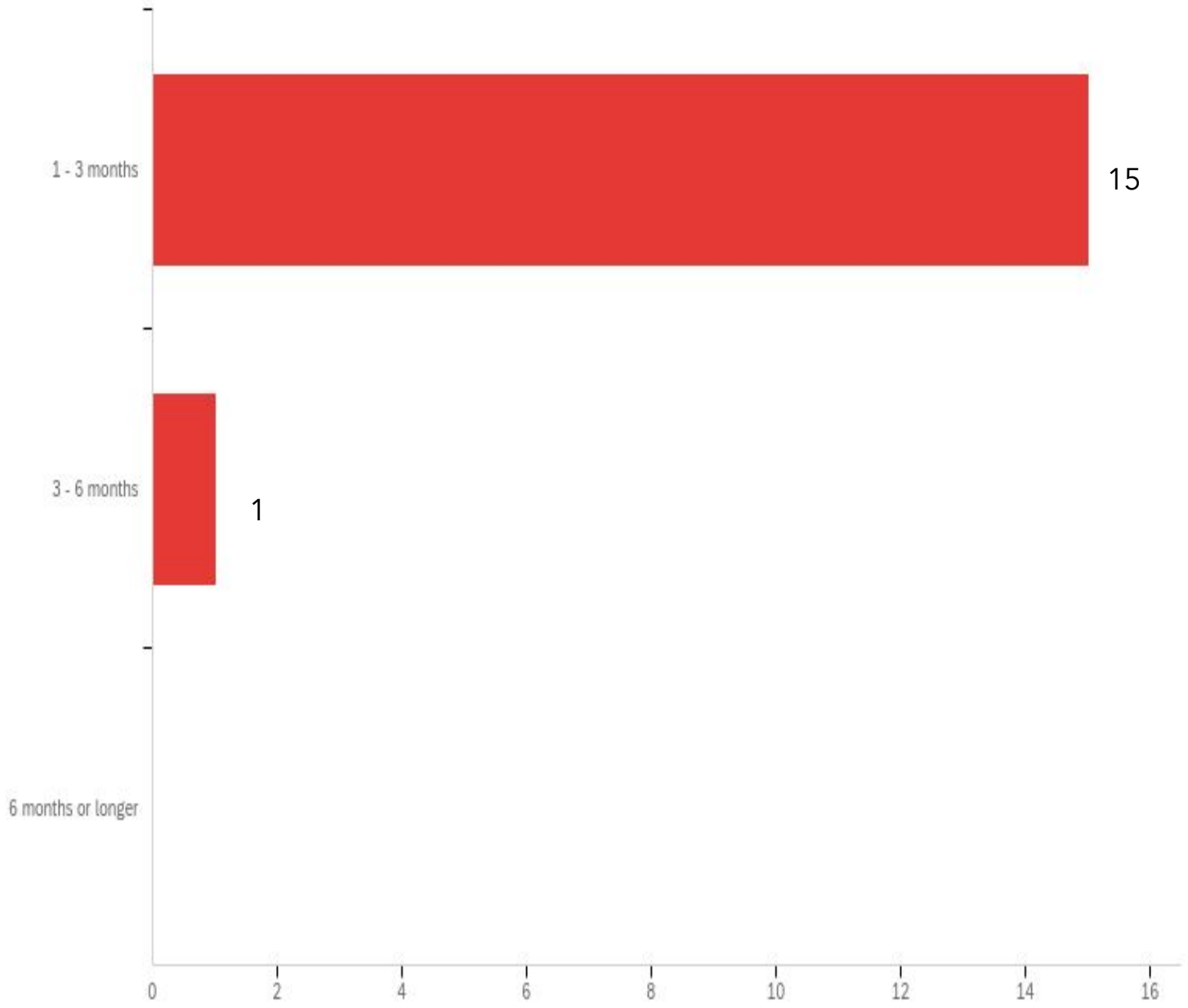
Please select useful affinity molecules from the list below (select all that apply)



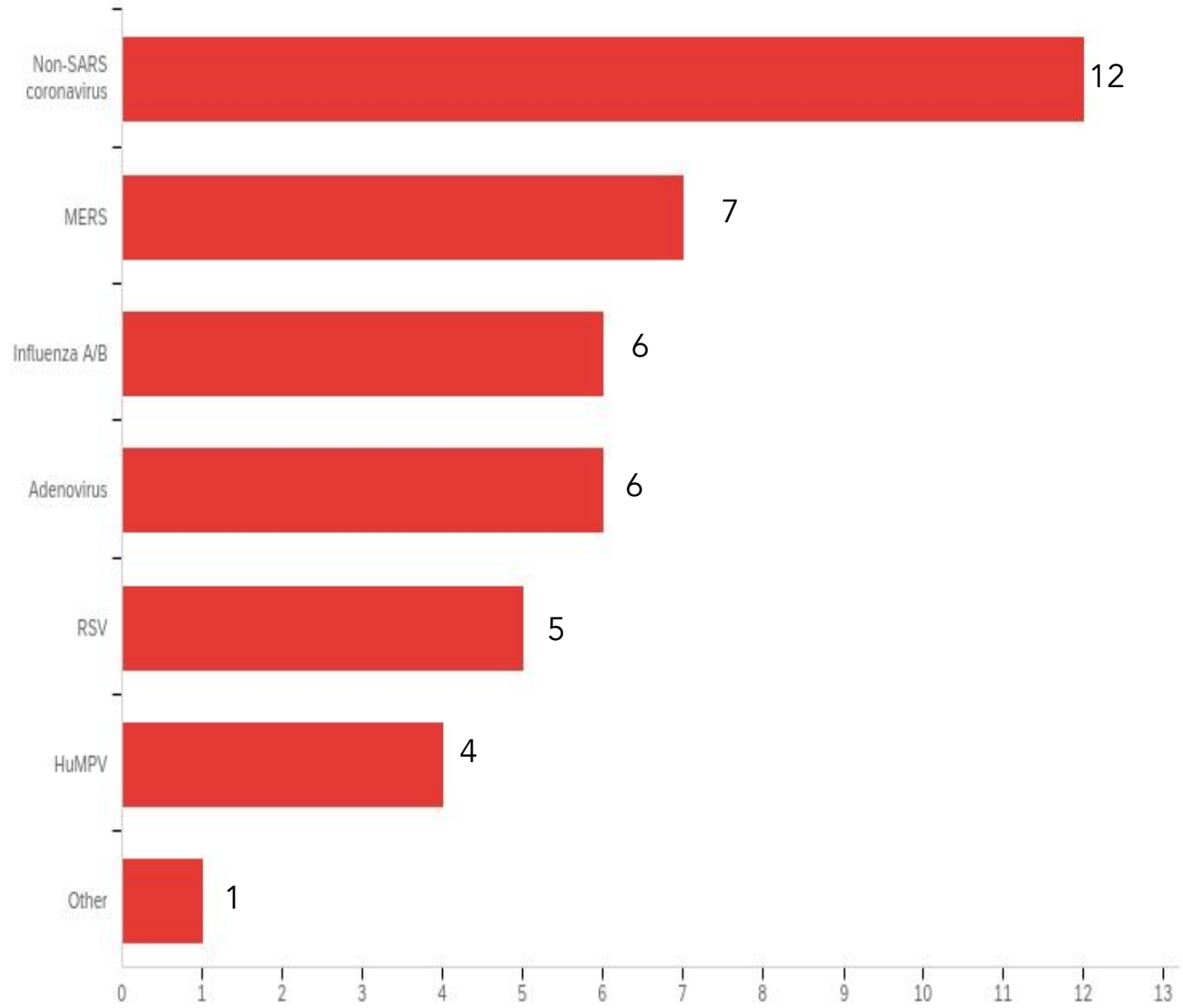
Affinity Molecule “Other” response
(N=2)

- polyclonal viral antibodies
- ACE2

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

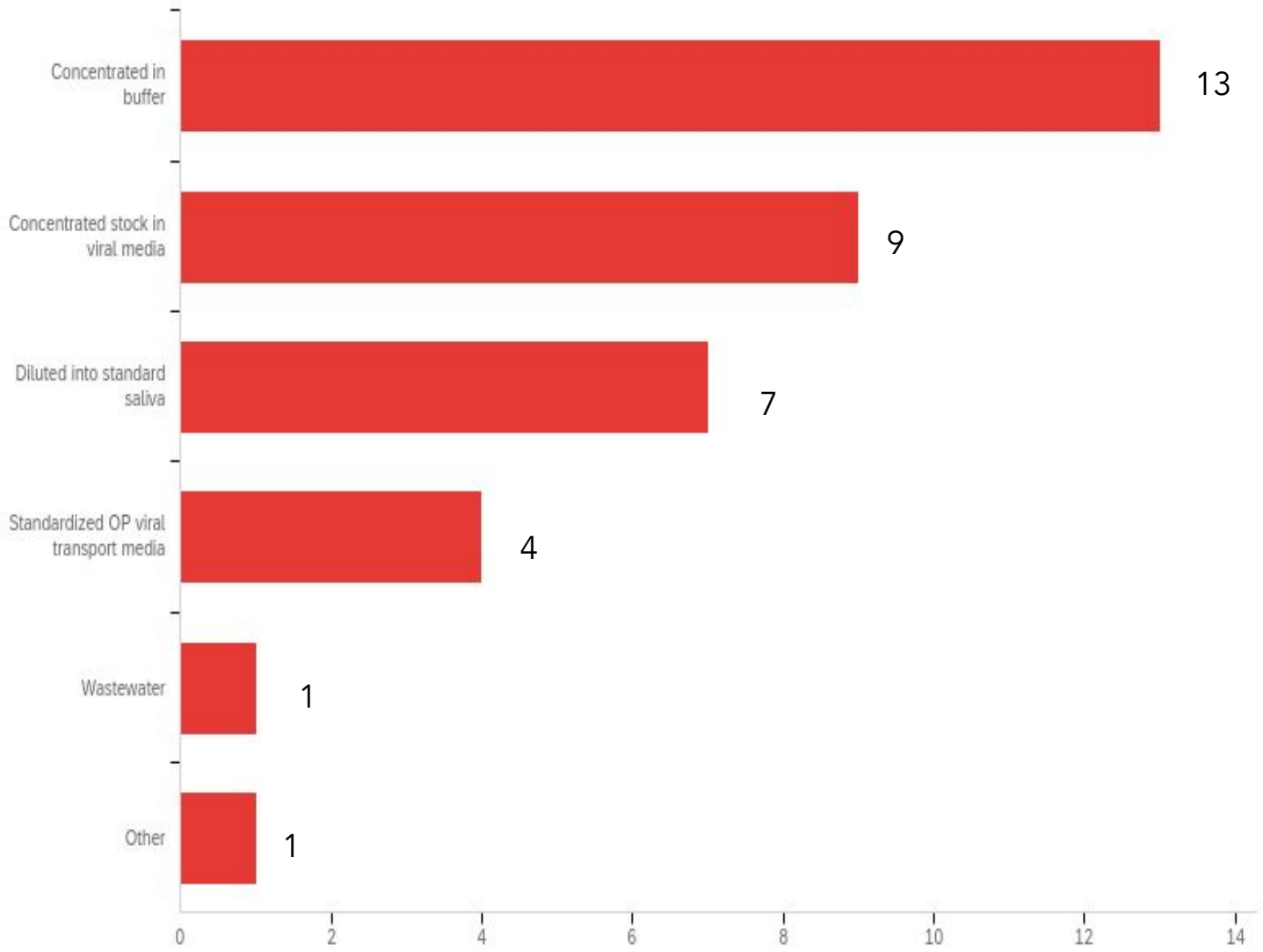


Testing specificities in your diagnostics, which virus do you think is the most useful from the list of Non-SARS-CoV2 viruses? (select all that apply)



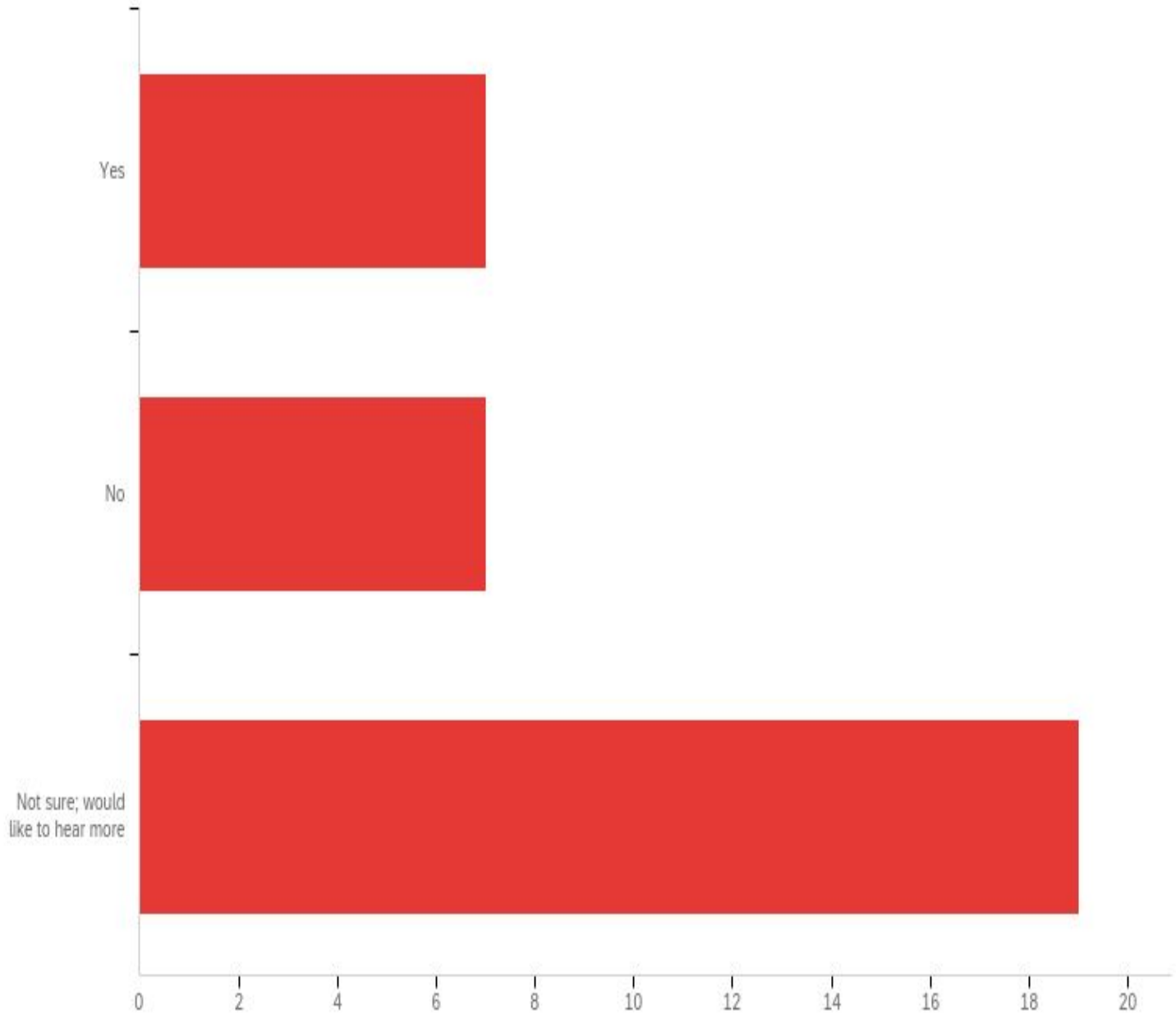
Other: Puro [internal standard (Spike), non-infectious retroviral (VLPs)

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

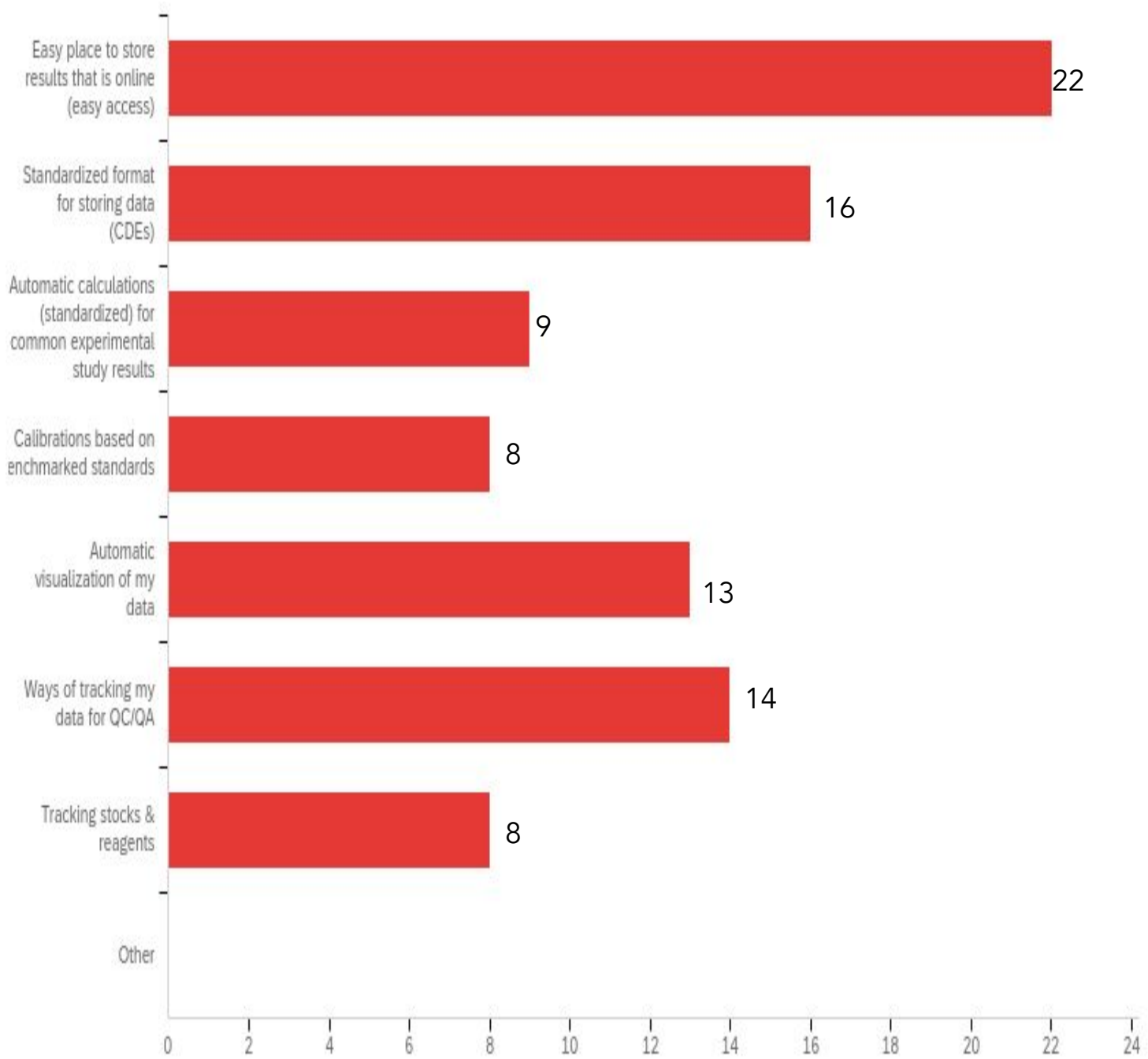


Other: Viral media with virus removed (ideally) or inactivated

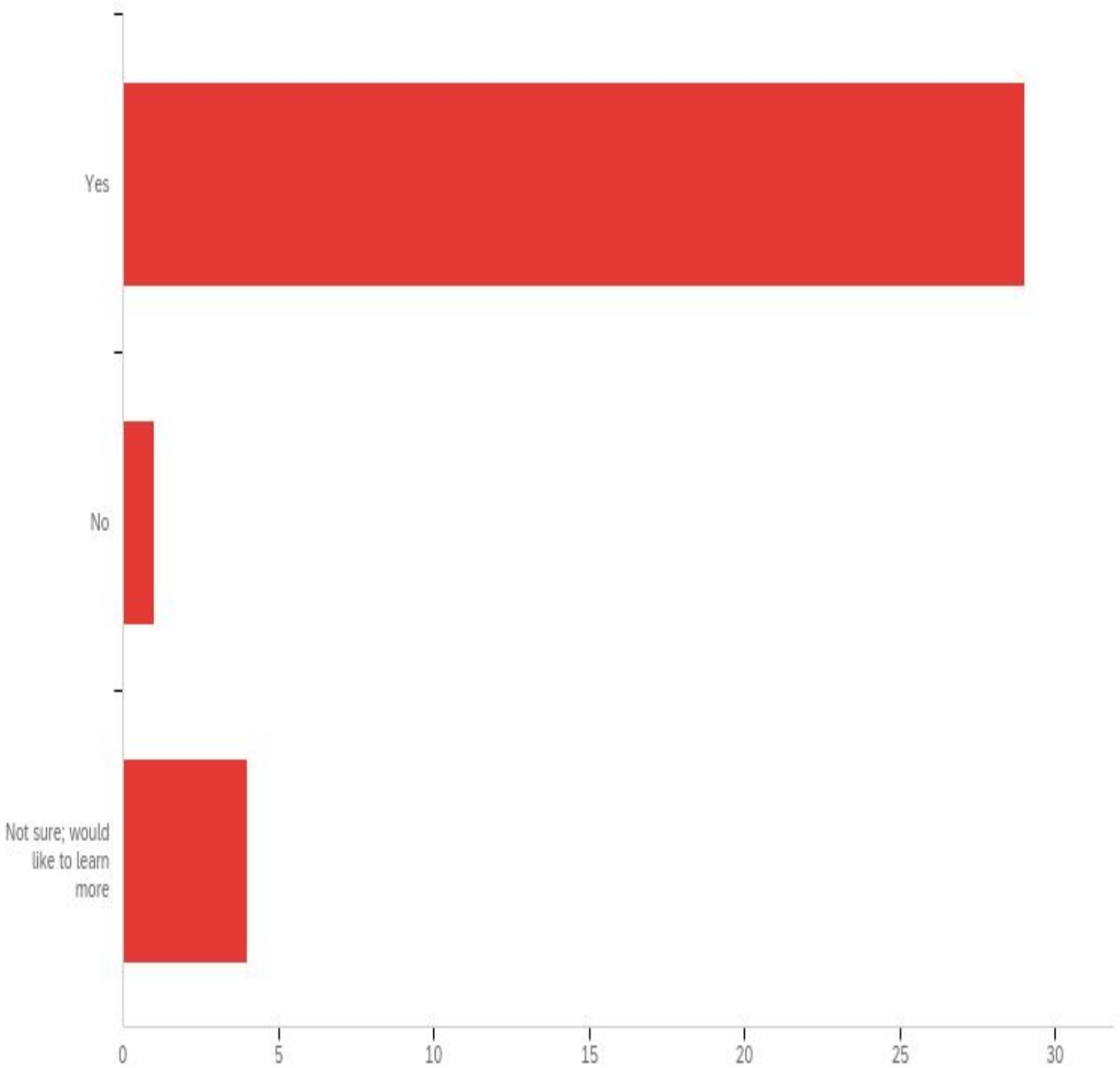
Would you use a free Laboratory Information Management System (LIMS) provided by RAD? (N = 33)



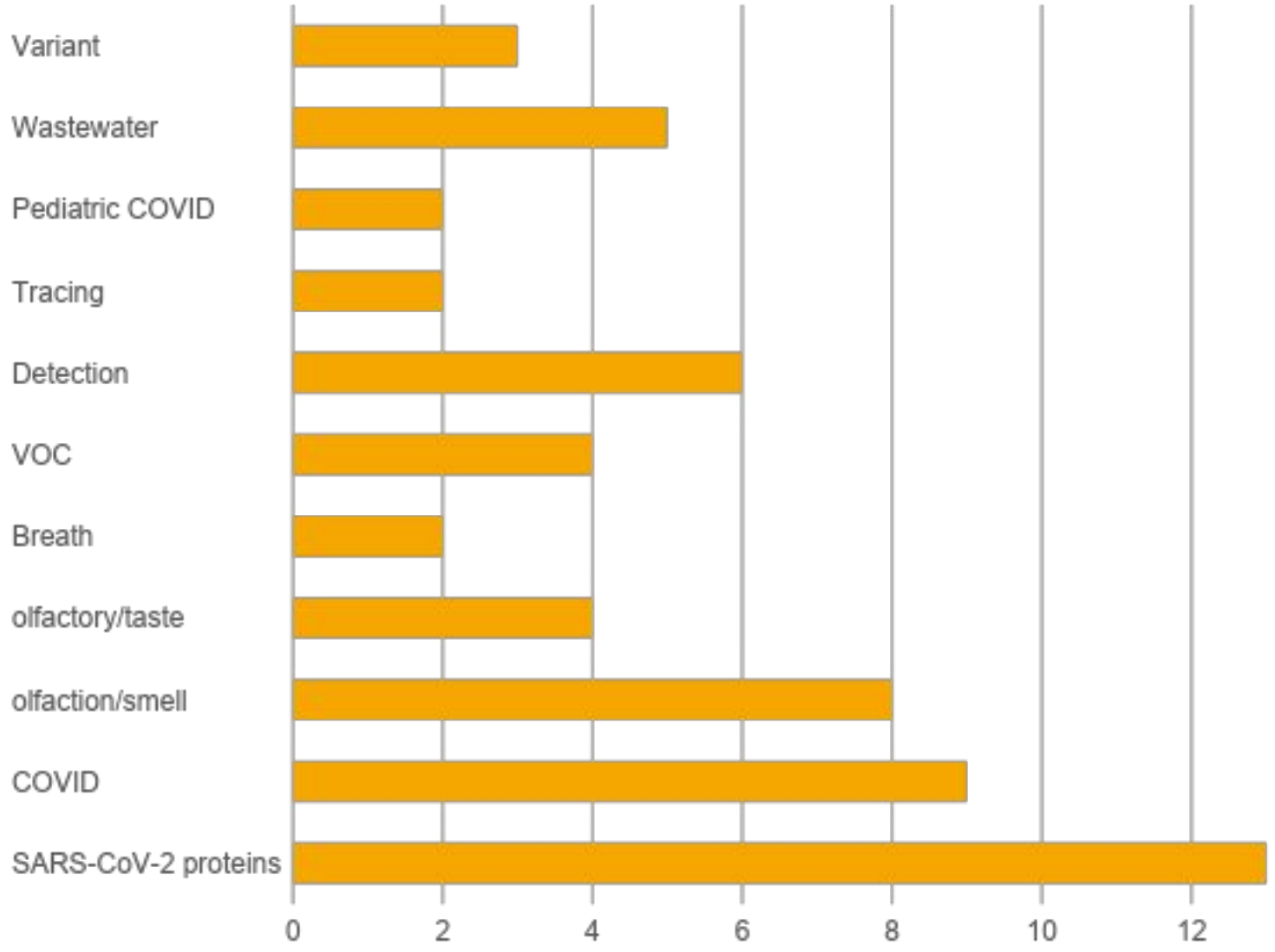
Which LIMS features would be most valuable for you? (select all that apply: N = 90)



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

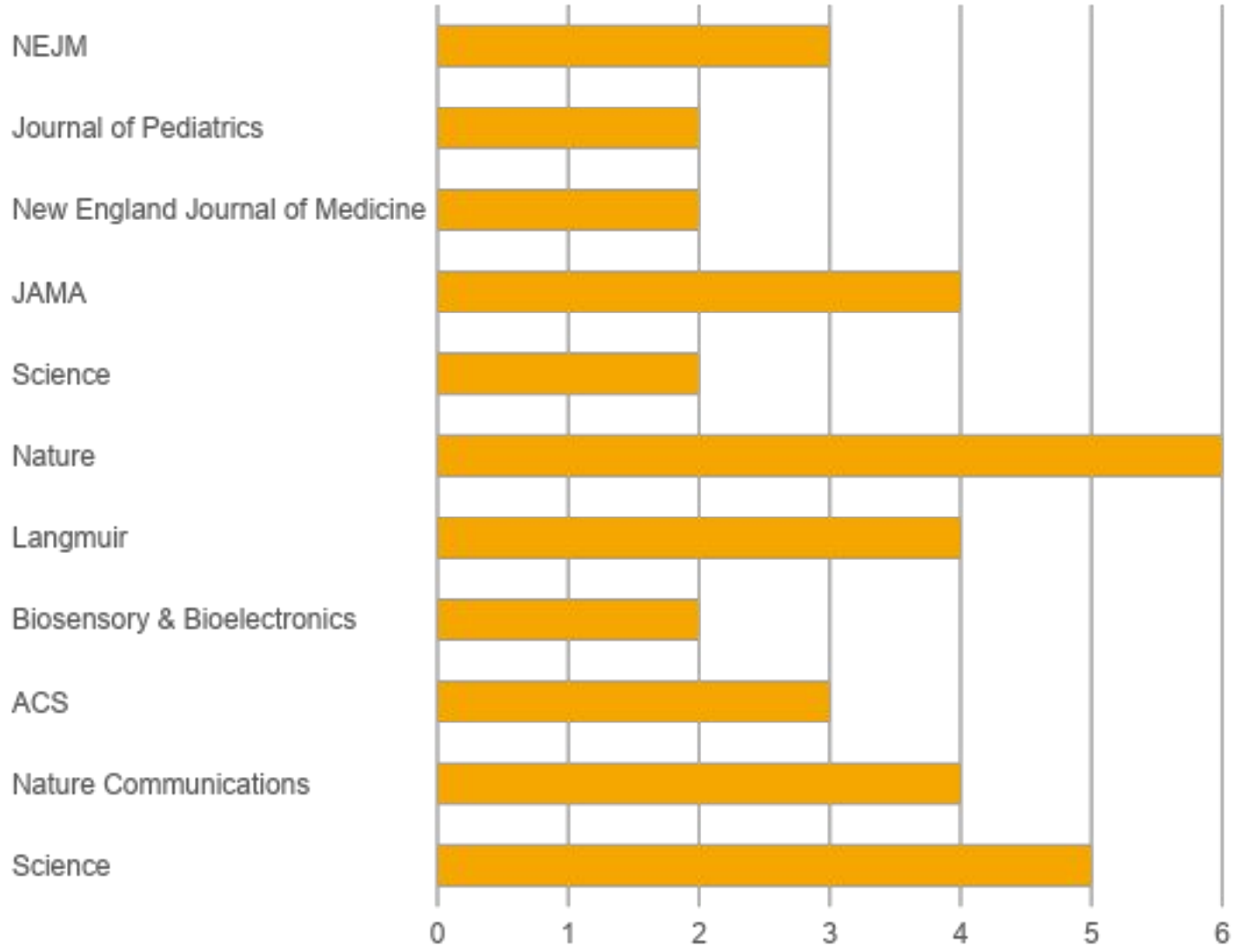
What are the common key words you use/search for? (text entry) (Continued)

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)

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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

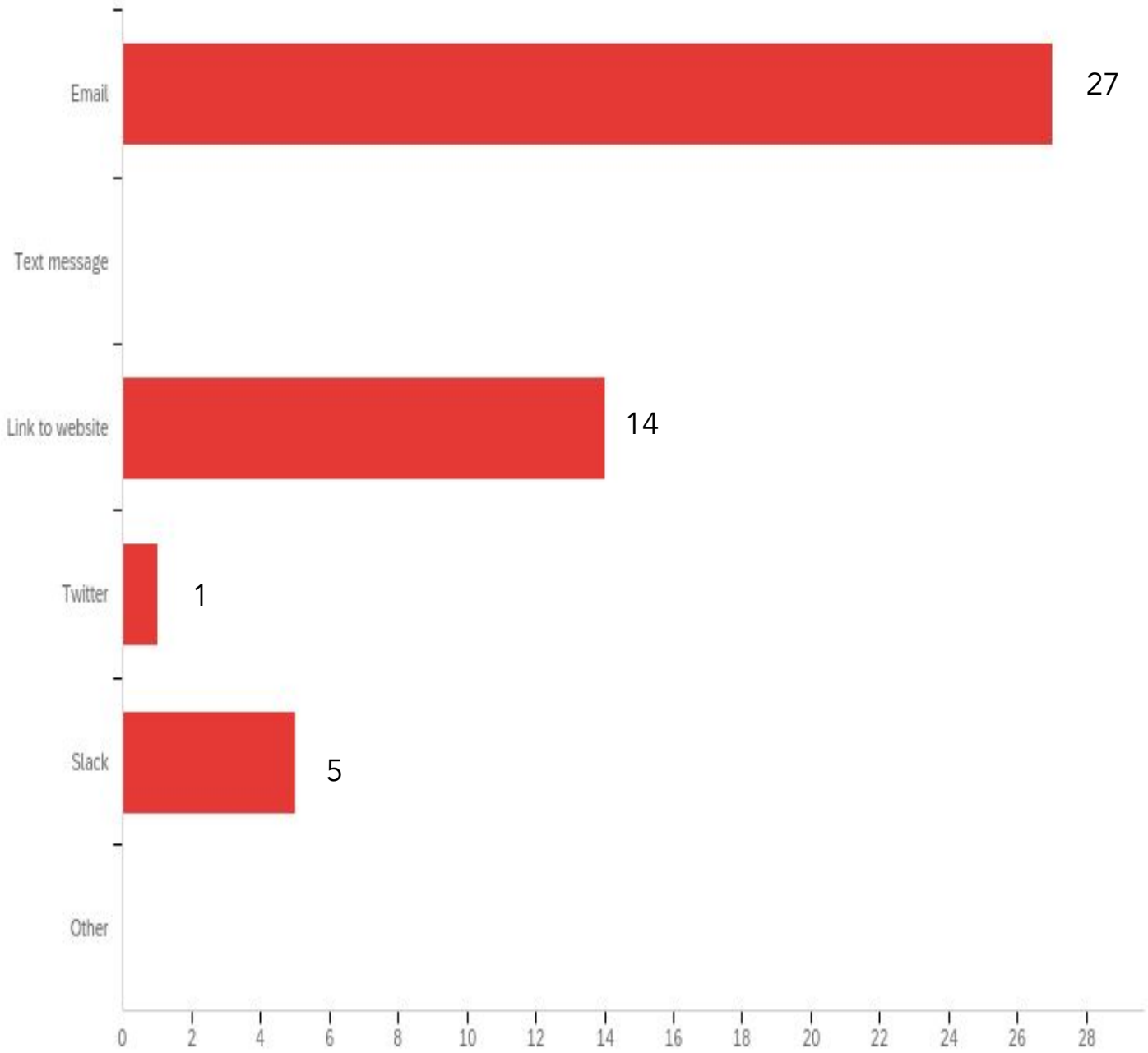
What are the most common journals and sources you use daily? (text entry) (Continued)

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

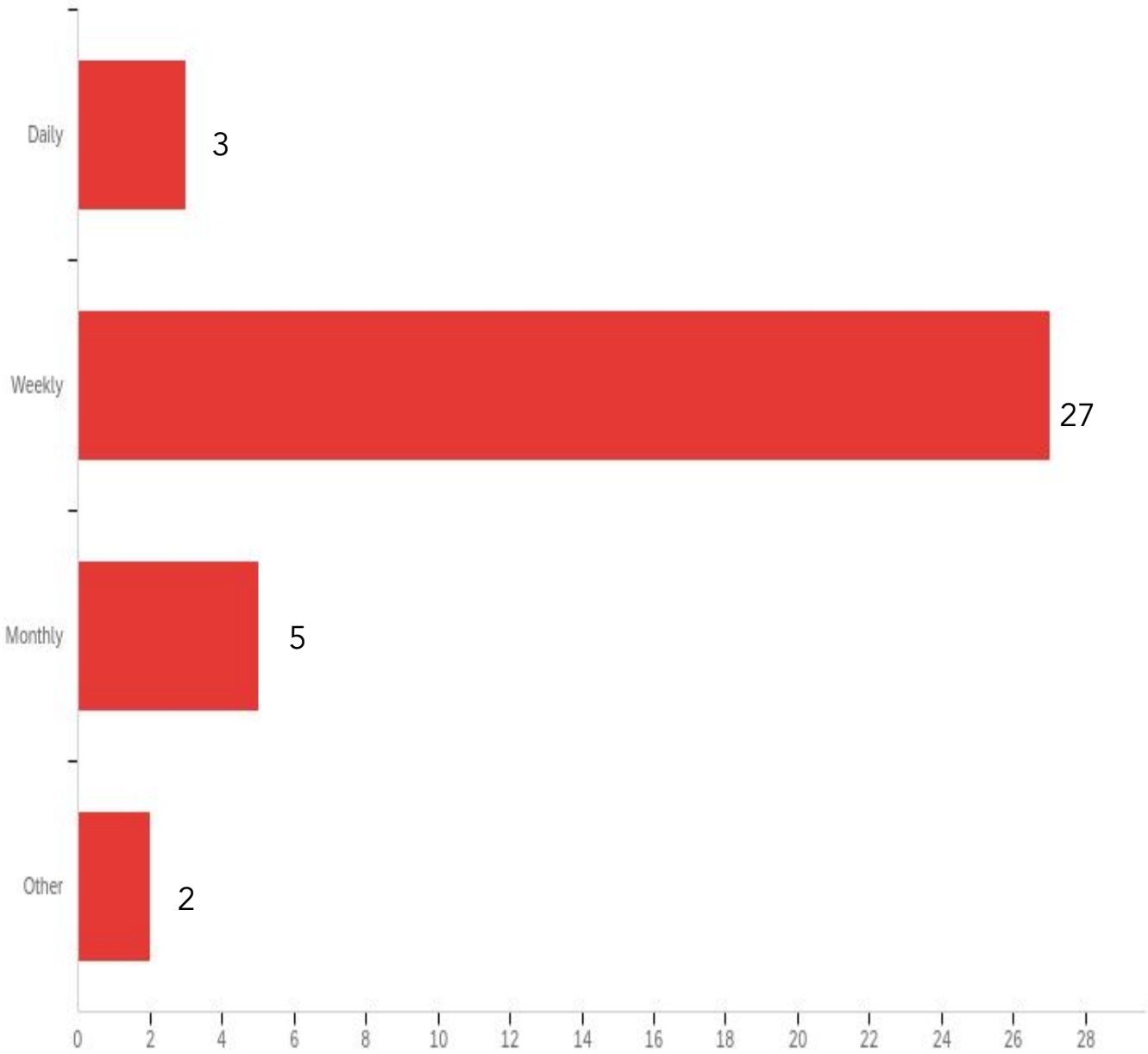
What are the most common journals and sources you use daily? (text entry) (Continued)

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,

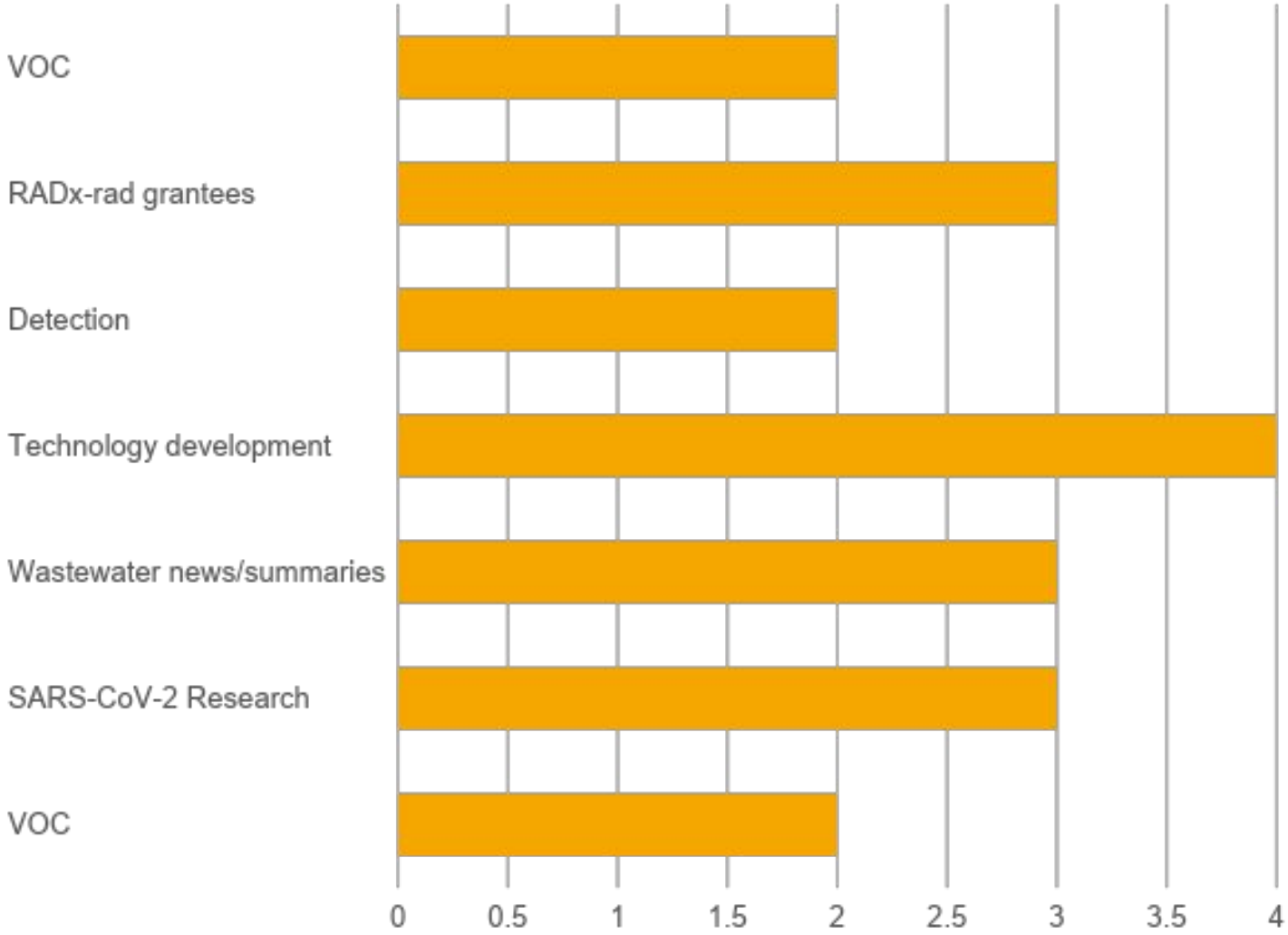
How would you like to receive digests? (select all that apply)



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)

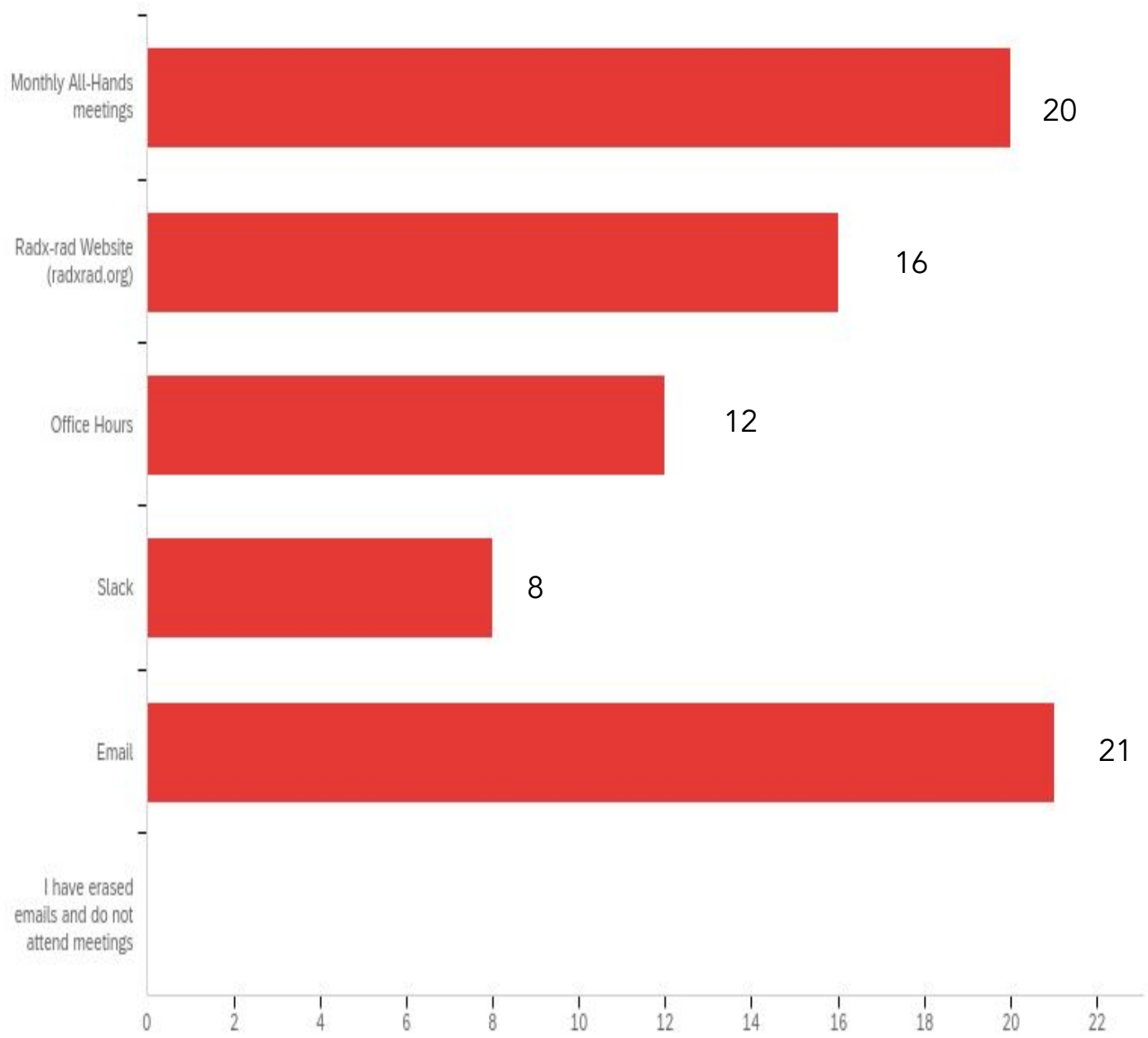
What would like to see in the RADx-rad digest? (text entry)
Sample information, method, main result and significance
emerging technologies
Summaries of newly published literature pertaining to SARS-CoV-2
VOCs
NA
summary of wastewater detection nationwide, are even there public or sharable data?
COVID gás phases sensing, VOC profiles.
technology development
wastewater-related SARS-CoV-2 research
COVID-19 detection
Method Developemnt, Method Comparsion

Q33 - What would like to see in the RADx-rad digest? (text entry)

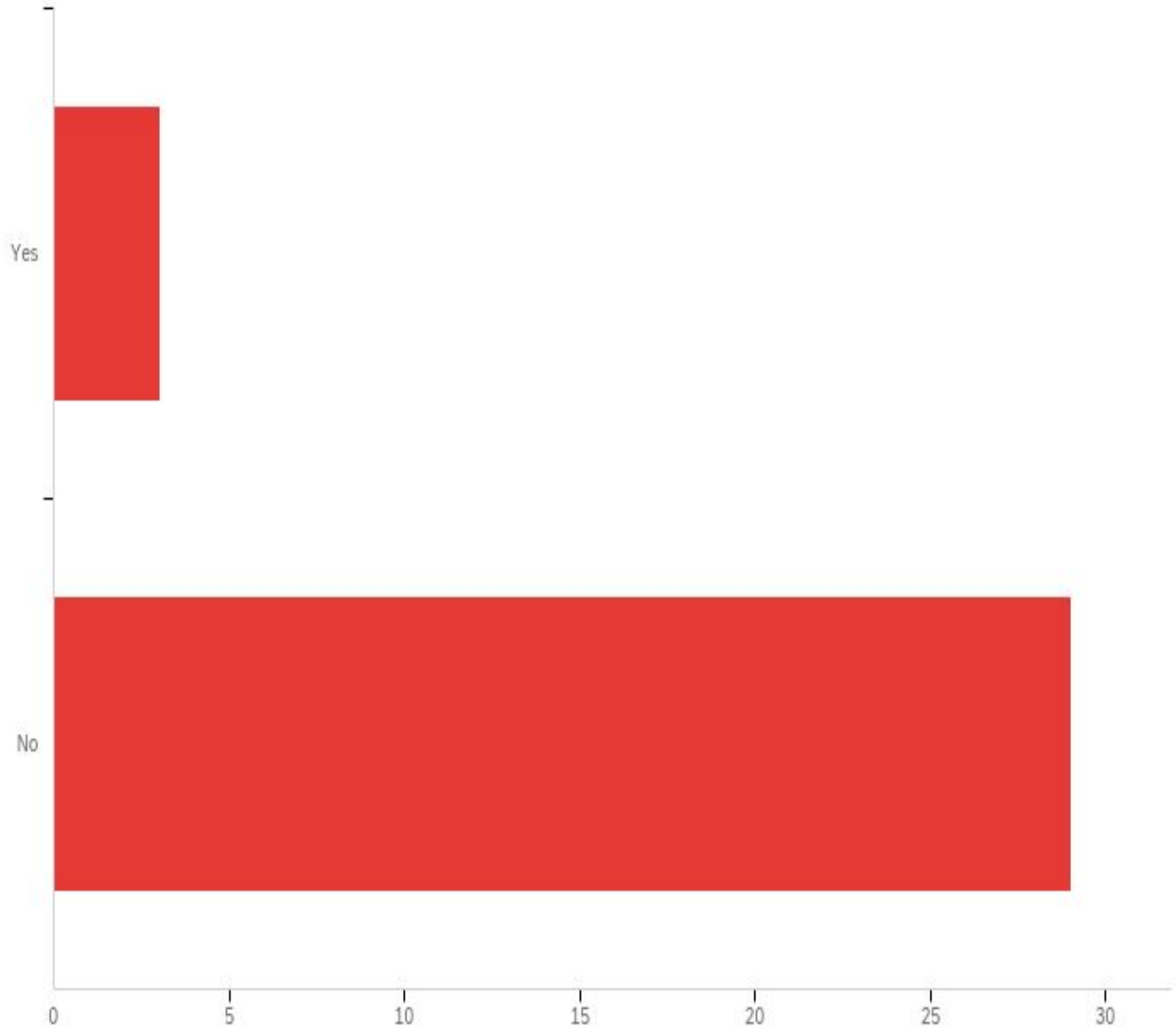
What would like to see in the RADx-rad digest? (text entry)
Coronavirus, Diagnostics, Surveillance, Monitoring
links to articles
Latest COVID-19 detection and tracing technologies
RADx technologies
citation and abstract
Curated press release, medRxiv, and bioRxiv data
Latest in terms of wastewater research. 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

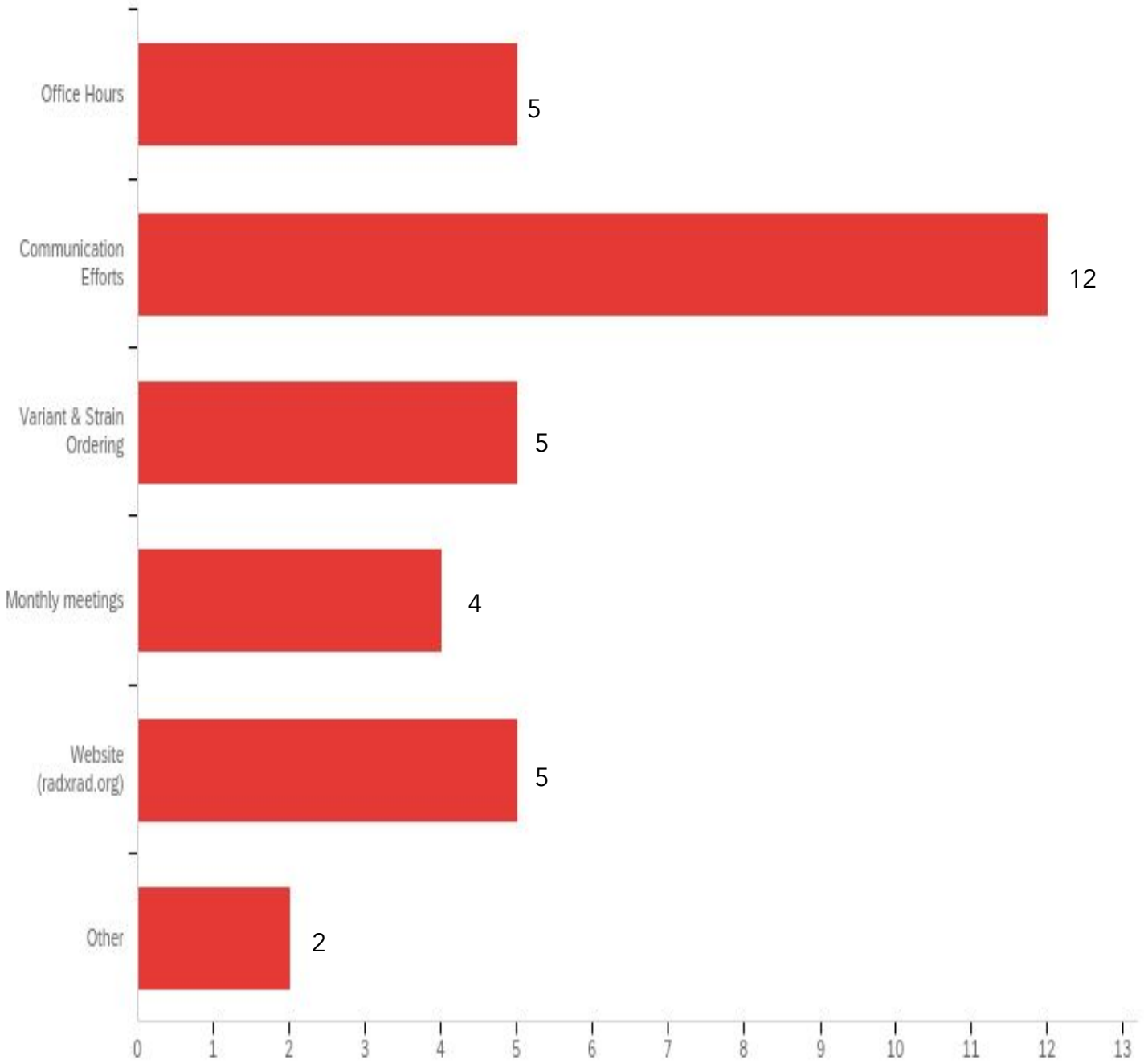
Are there any other forms of communication that would be helpful to your study/project? (N = 32)



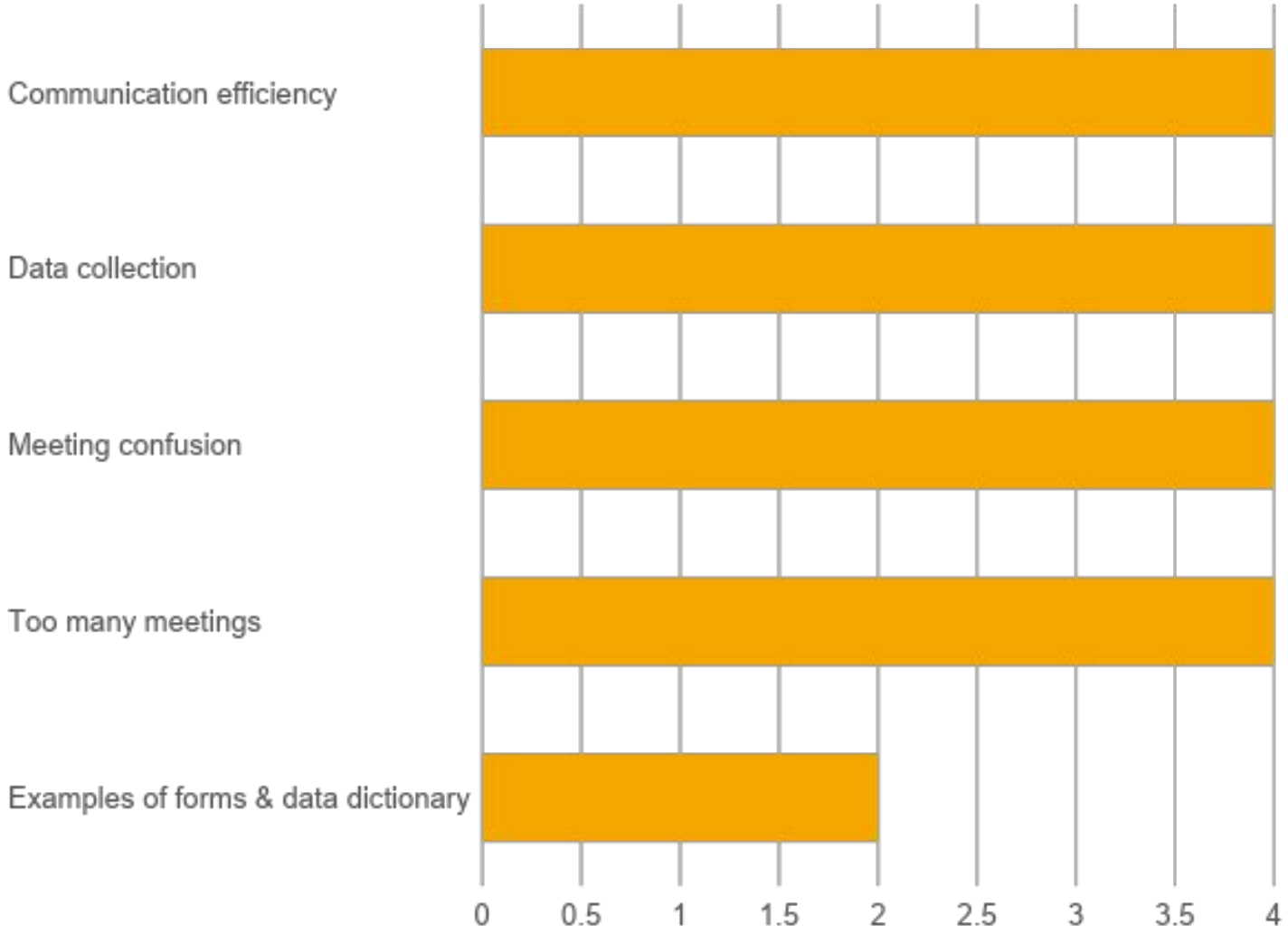
Are there any other forms of communication that would be helpful to your study/project? (N = 32)



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



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

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

Source: WHO

- 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

RAD2Tech Coming June 2021
*Email update coming soon

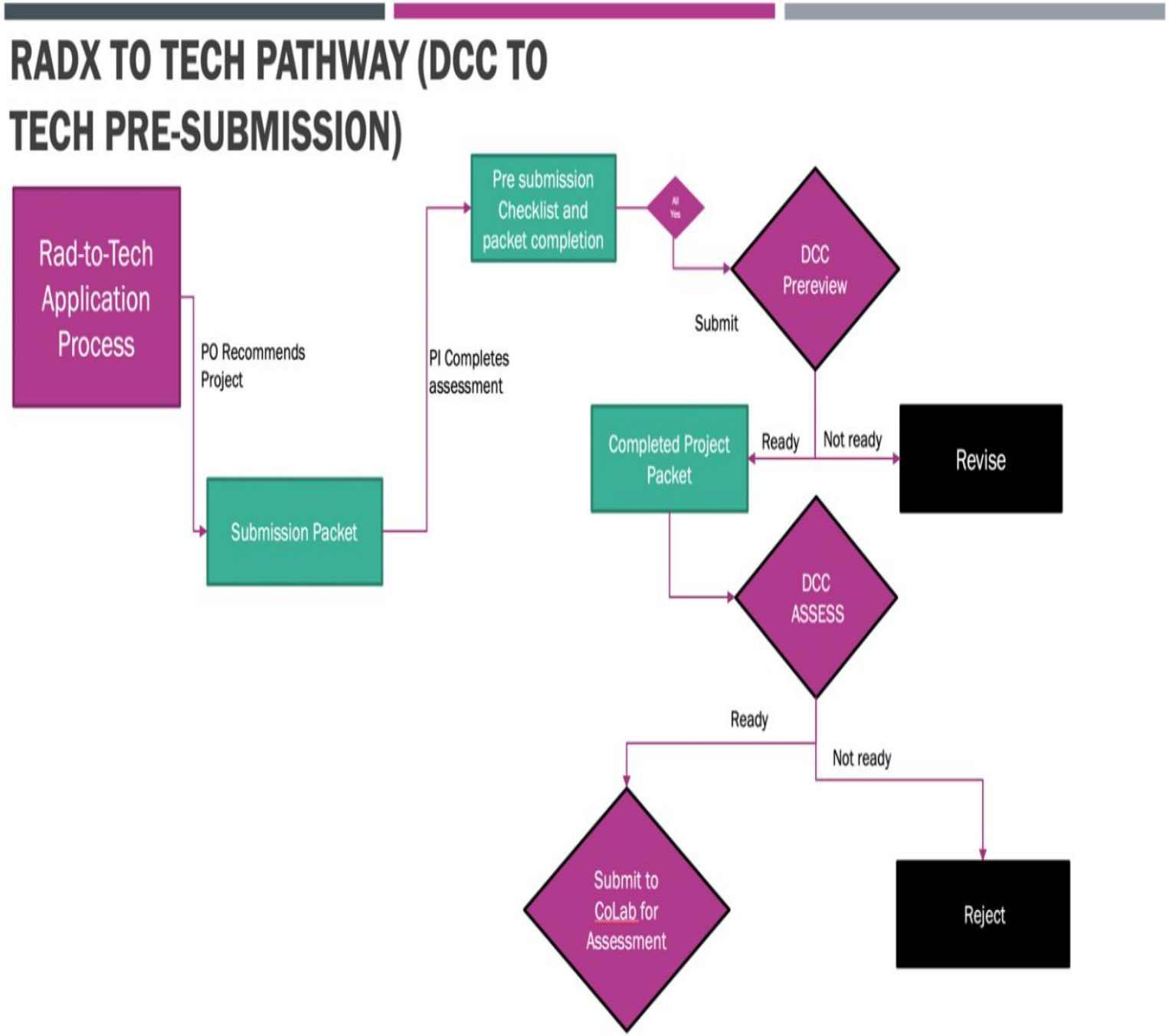
- The Rad-to-Tech pathway offers a ***three-stage process*** to apply for a Tech transition work package:
  1) Brief Proposal which will be screened by the DCC.
  2) Full proposal to Point-of-Care Technologies Research Network (POCTRN) via the CoLab grants management portal.
  3) Deep Dive, preparation, 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 ***June 16, 2021***, 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



FDA Questions

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

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

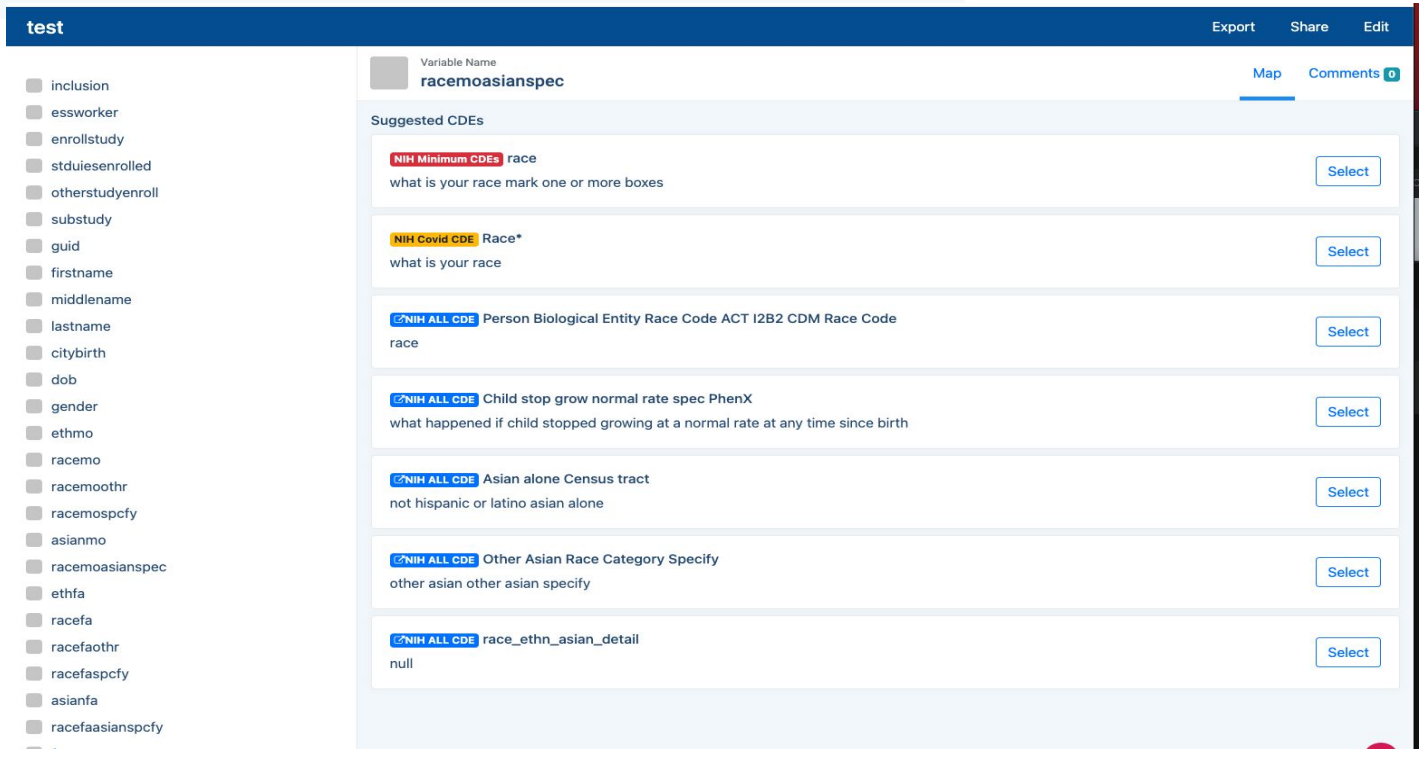
Data Core Update

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	✔	✔	✔	✔	✔	✔	✔	✔
Data Standards Kick-Off	✔	✔	✔	✔	✔	✔	✔	✔
Data Dictionary Template sent out	✔ Draft Complete – In review with NIH/Data Hub (since 04/05)							✔ (CDC NWSS)
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)

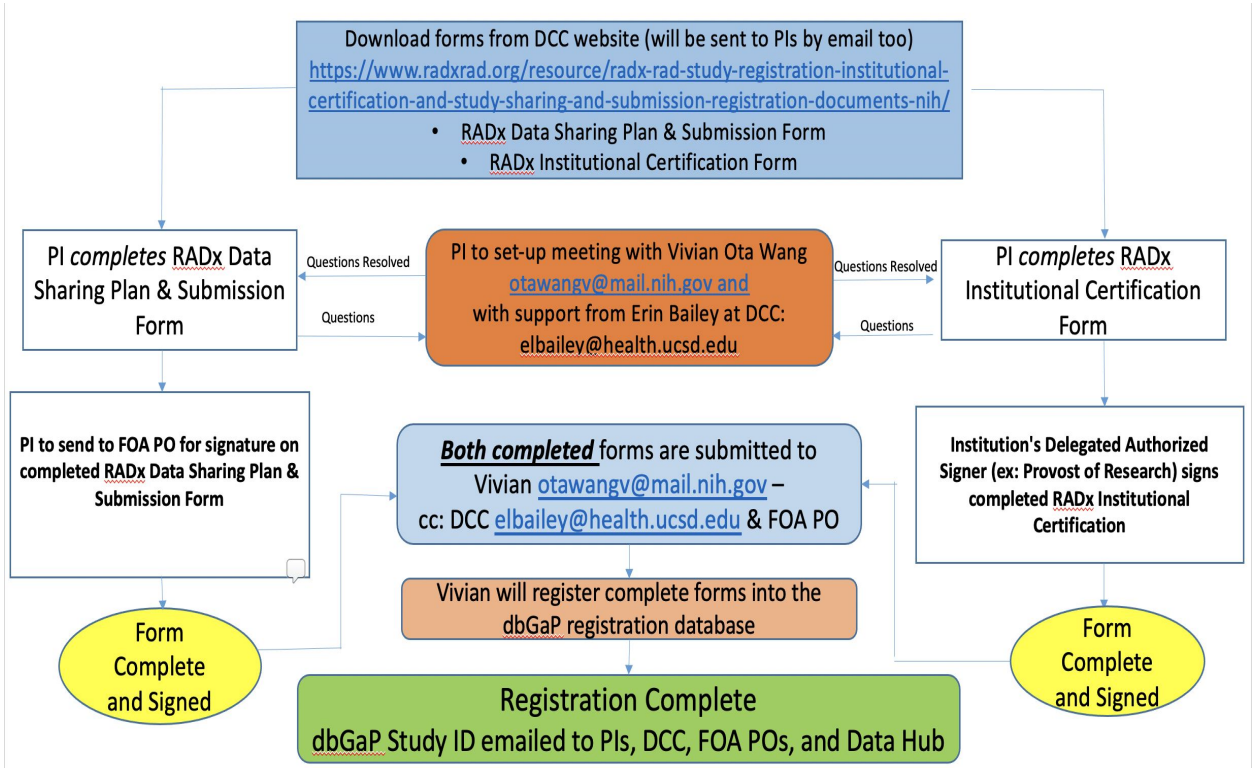
IMI: A web-based CDE mapping tool

- Beta-testing completed, will release this week

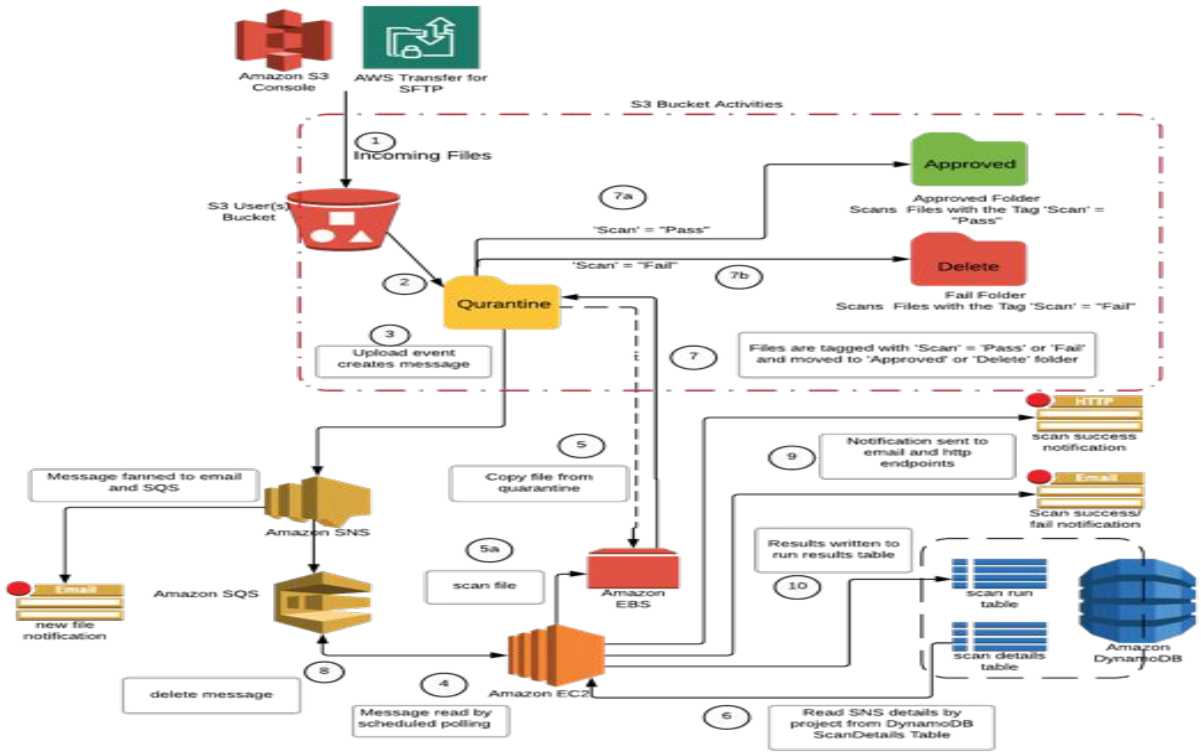


Data Submission to DCC

dbGAP Study Registration Workflow:

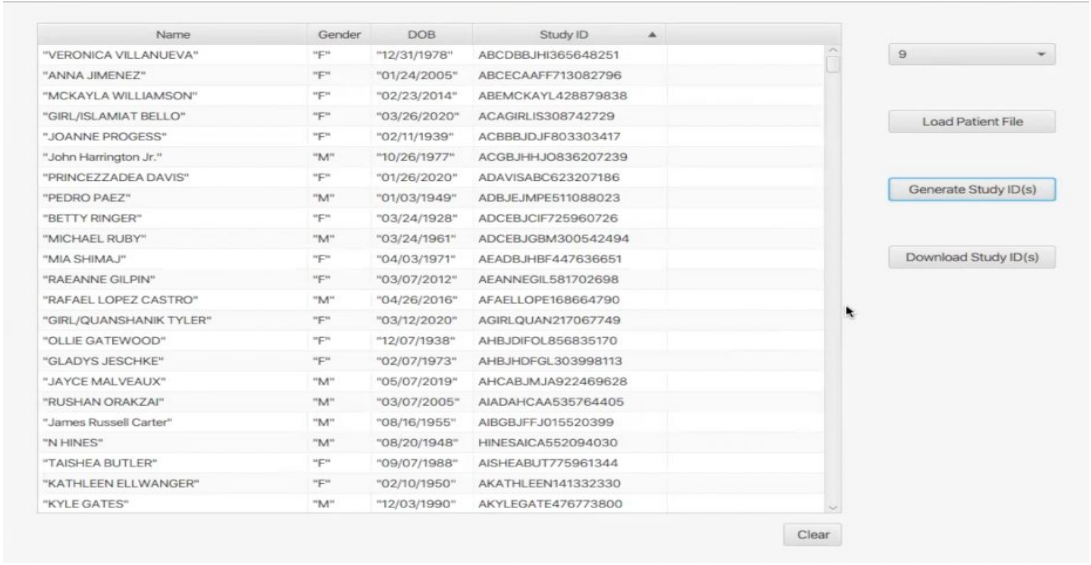


Development of Secure FTP for data submission
(June 20th beta testing)

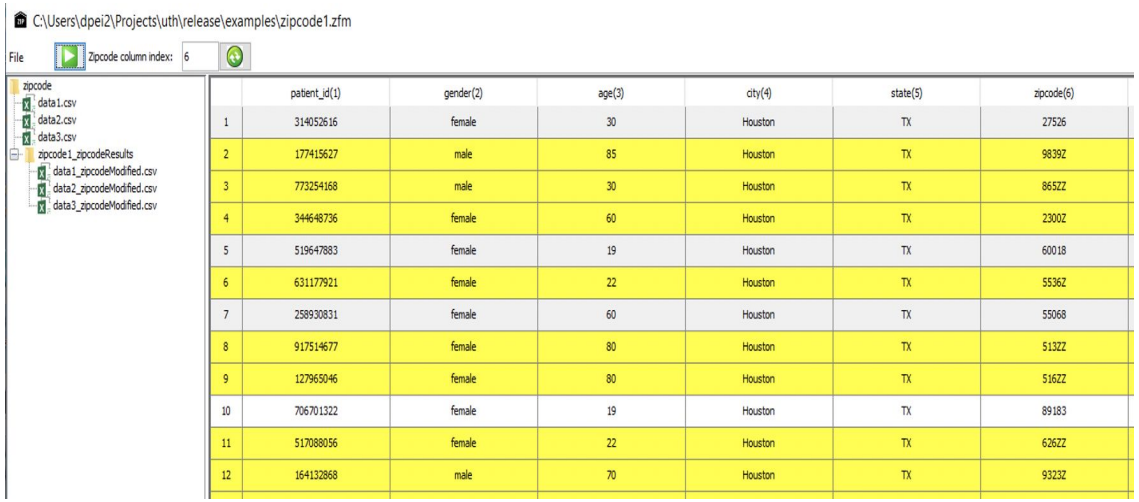


Data sharing – privacy protection tools

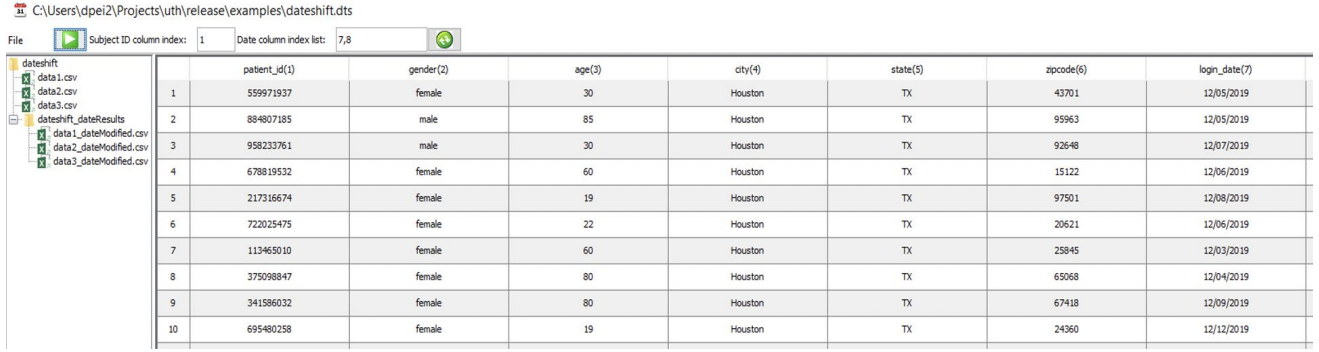
Subject ID generation tool: *beta testing commencing*



Zip Code truncation tool: *pending NIH decision*



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