



# RADx Rad Discovery & Data Consortium Coordination Center & Program Organization

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Introduction and Q&A





No Conflicts of  
Interest to Disclose

# CENTER FUNCTIONS

1

- Support IRB, trial design and protocol support
- Support production of *comparable* data
  - Develop Viral Quality Assurance panels with known viral concentrations including new variants
  - Provide Benchmarking Services for new diagnostic performance and usability
  - Validate new amplification and affinity-based tests with emerging variants
- Provide a preconfigured Laboratory Information Management System (LIMS) for data collection and sharing
- Advise on
  - Diagnostic test metrics, usability
  - Vendors and Resources
  - Regulatory questions & FDA submissions
  - Intellectual property issues

# CENTER FUNCTIONS 2

- Help awardees organize data for sharing
- Coordinate use of a common data model, data elements, other standards, and submission of data (when allowed) to the DCC Host and make available data (and code) for researchers
  - Manage Data Use Agreements, Users
  - Organize distributed computing if needed
  - Advise on statistics and AI methods
  - Support of data sharing between DCC and the NIH data hub
  - Offer training to enhance teamwork, anti-racism



CENTER ORGANIZATION

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# Multiple PIs

**Eli Aronoff-Spencer, MD, PhD**  
UC San Diego



Infectious Diseases, User Centered  
Design, Diagnostics & Informatics

**Lucila Ohno-Machado, MD, PhD**

**Hua Xu, PhD**  
 **UTHealth**  
The University of Texas  
Health Science Center at Houston



Privacy Technology, Predictive  
Modeling, Evaluation Methods

Data Representation, Biomedical  
Natural Language Processing

# NLM Team

## Program Officer:

Yanli Wang, PhD



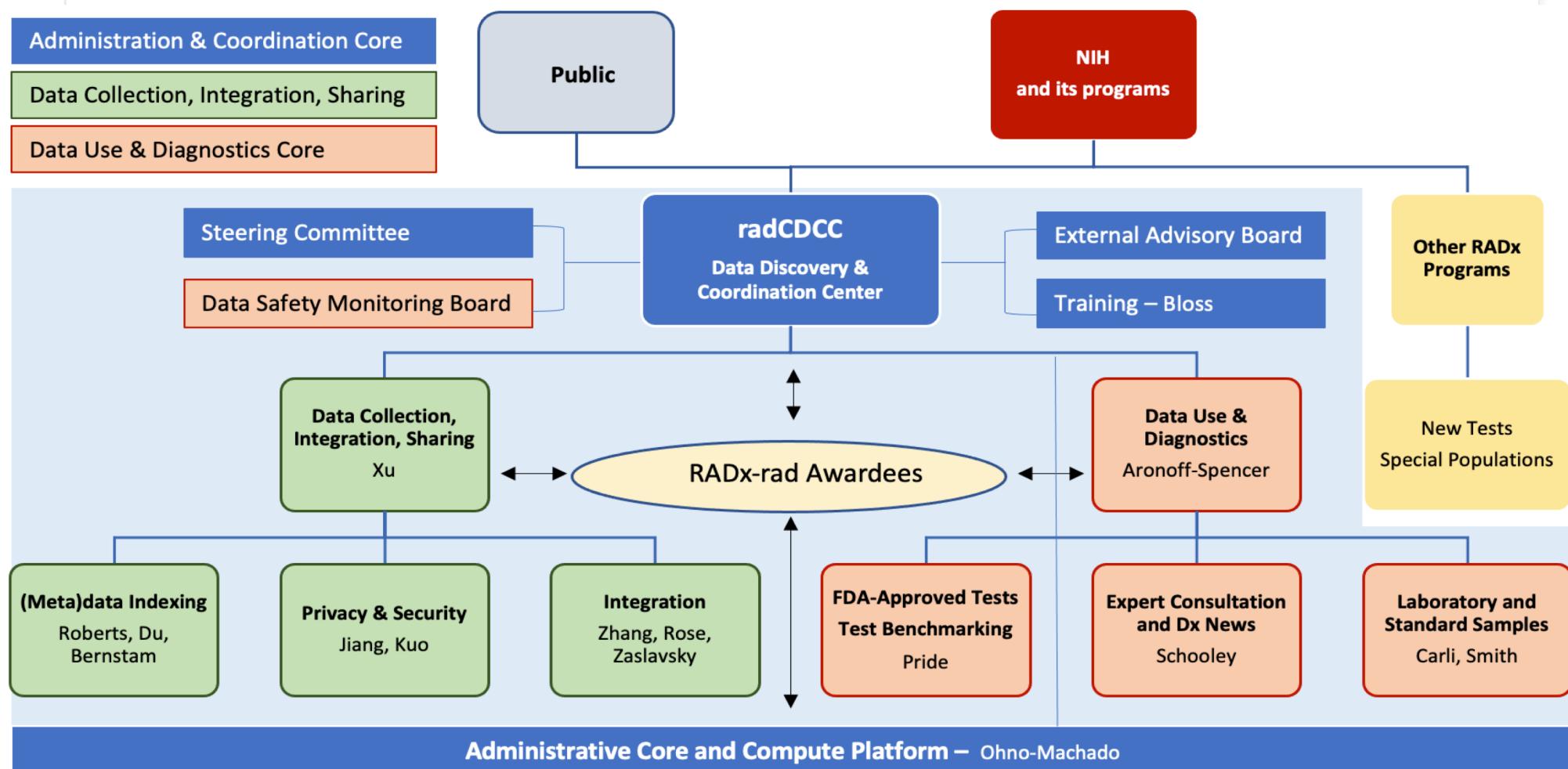
## Project Scientists:

Dina Demner-Fushman, MD, PhD

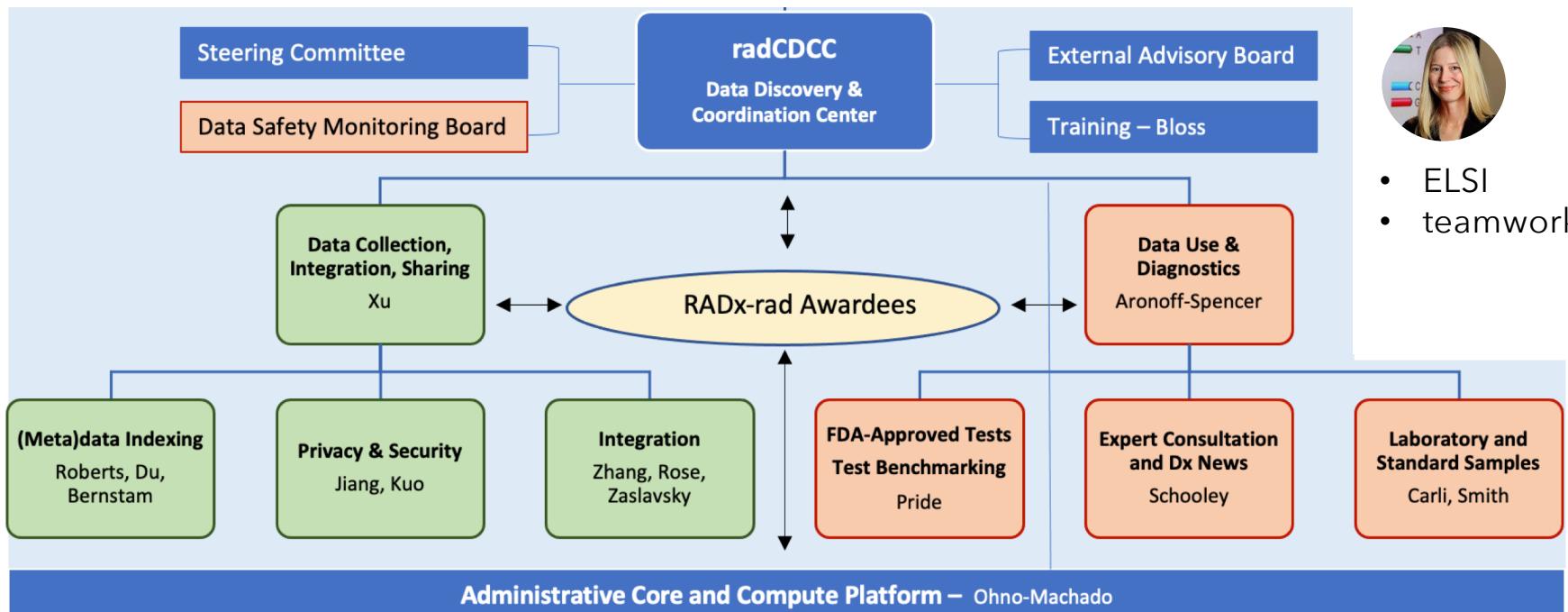
Leslie Derr, PhD

Anthony Kirilusha, PhD

Marie Gallagher



## Program Management



- ELSI
- teamwork

- data transformations
- standards



- "de-identification"
- ledger/auditing



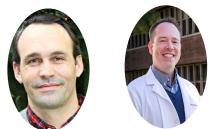
- data transfer
- integration



- test eval



- COVID expert



- send VQA
- test usage

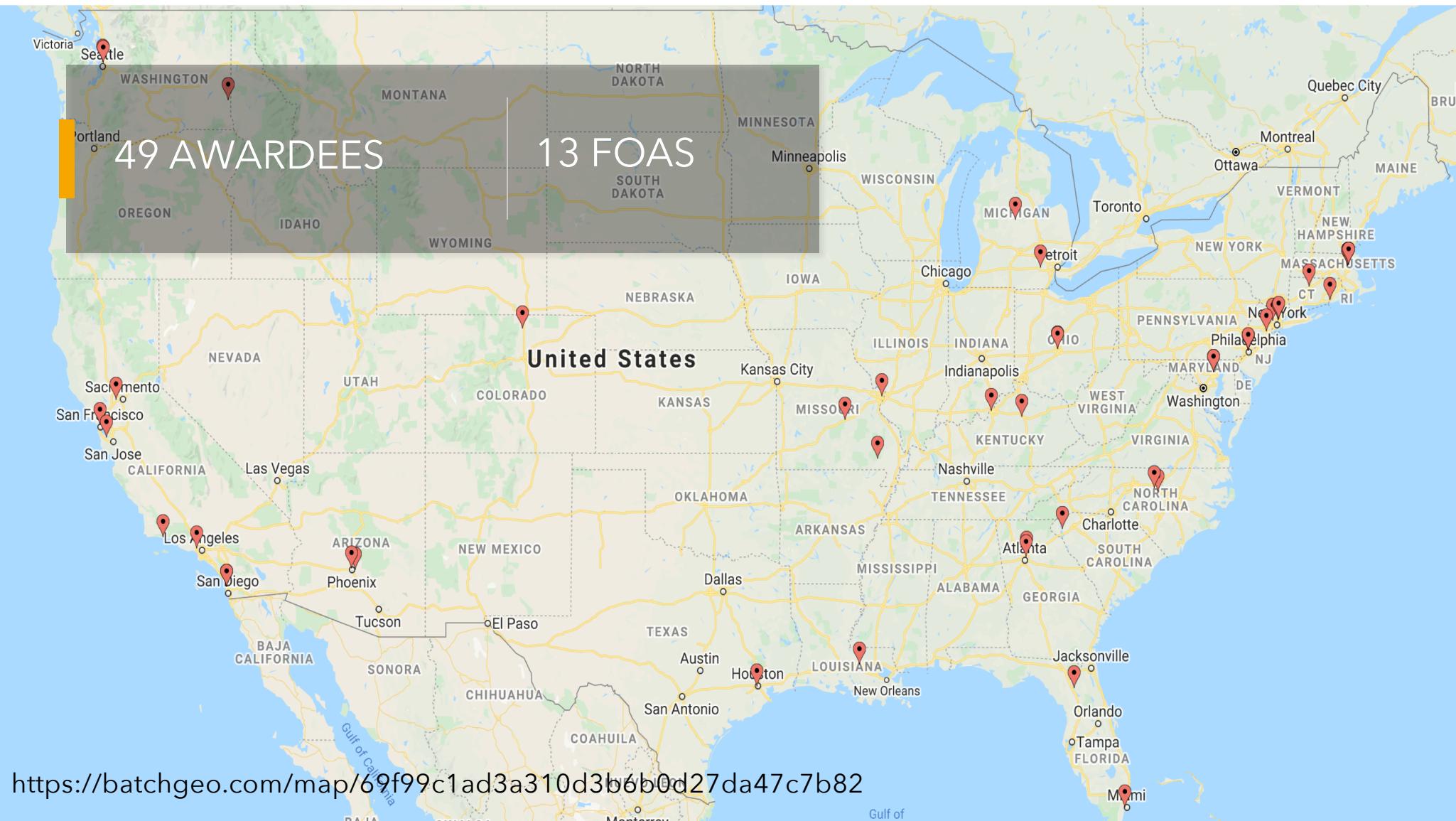
**49 AWARDDEES** | **13 FOAS**

PA-20-272 and NOT-OD-21-035	6	Virus Counter: Rapid and Sensitive Diagnostics Based on Digital Detection of Individual Pathogens	Boston University
PA-20-272 and NOT-OD-21-035	6	MOF-SCENT: Metal-organic Frameworks for Screening COVID-19 by Electronic-Nose Technology to Improve Selectivity and Time Response	Missouri University of Science and Technology
PA-20-272 and NOT-OD-21-035	6	Broad-spectrum Detection of VOC and Non-VOC Biomarkers from Patient Exhalant using Biomimetic Multiplexed eNose Biosensor for COVID-19 Diagnosis	University of Washington
PA-20-272 and NOT-OD-21-035	6	A Rapid Saliva Antigen Test for SARS-CoV-2 Detection	Brigham and Women's Hospital
PA-20-272 and NOT-OD-21-035	6	A Rapid Breathalyzer Diagnostics Platform for COVID-19	Rutgers University
PA-20-272 and NOT-OD-21-035	6	RADx-rad: A Rapid, Sensitive, Point-of-care, Antigen-based Diagnostics for SARS-CoV-2	Boston Biomedical Innovation Center (B-BIC)
RFA-OD-20-014	6	Nano-polymer-based Electrochemical Biosensor for Real-Time Detection of Aerosolized SARS-CoV-2	Washington University
RFA-OD-20-014	6	Design and Automatic Privacy-Protected Contact Tracing System Designed for COVID-19	Louisiana State Univ A&M Col Baton Rouge
RFA-OD-20-014	6	Rolosense: An Innovative Platform for Automatic Mobile Phone Readout of Active SARS-CoV-2 Particles	Emory University
RFA-OD-20-014	6	Minimal False-alarm Touch-based Detection of SARS-CoV-2 Virus Particles using Poly-aptamers	General Electric Global Research Center
RFA-OD-20-014	6	Touchscreen-compatible, Real-Time Electrochemical Sensing of SARS-CoV-2	University of Washington
RFA-OD-20-014	6	Development of an Automated Diagnostic Platform for SARS-CoV-2 Monitoring in Vulnerable Areas	Clemson University
RFA-OD-20-015	6	Development and Proof-of-Concept Implementation of the South Florida Miami RADx-rad SARS-CoV-2 Wastewater-Based Surveillance Infrastructure	University of Miami Coral Gables
RFA-OD-20-015	6	Wastewater Analysis of SARS CoV-2 in Tribal Communities	Arizona State University-Tempe
RFA-OD-20-015	6	Improved Scalability, Sensitivity, and Interpretability of Pathogen Detection, Including SARS-CoV-2, in Wastewater using High-Throughput, Highly Multiplexed Digital Array PCR Technology	University of North Carolina, Chapel Hill
RFA-OD-20-015	6	Wastewater Assessment for Coronavirus in Kentucky: Implementing Enhanced Surveillance Technology	University of Kentucky
RFA-OD-20-015	6	Wastewater Detection of COVID-19	Missouri State Dept/ Health & Senior Services
RFA-OD-20-015	6	Optimizing SARS-CoV-2 Wastewater Based Surveillance in Urban and University Campus Settings	Columbia University Health Sciences
RFA-OD-20-016	4	Marshallse: Alternate Surveillance for COVID-19 in a Unique Population	Washington State University
RFA-OD-20-016	4	Validation of Smart Masks for Surveillance of COVID-19	University of California, San Diego
RFA-OD-20-016	4	Multi-modal Wireless COVID Monitoring & Infection Alerts for Concentrated Populations	Stanford University
RFA-OD-20-016	4	Early Detection, Containment, and Management of COVID-19 in Dialysis Facilities Using Multi-Modal Data Sources	University of California, Santa Barbara
RFA-OD-20-017	4	Portable GC Detector for Breath-based COVID Diagnostics	University of California, Davis
RFA-OD-20-017	4	COVID-19 Detection through Scent Analysis with a Compact GC Device	University of Michigan at Ann Arbor
RFA-OD-20-017	4	A Handheld Microchip for GC Analysis of Breath to Screen for COVID-19	University of Louisville
RFA-OD-20-017	4	Effective, Reagent-free Detection of the Odor Signature of Covid-19 Infection Using a Nano-Enabled Sensor Array	University of Pennsylvania
RFA-OD-20-018	4	Multi-parametric Integrated Molecular Detection of SARS-CoV-2 from Biofluids by Adapting Single Extracellular Vesicle Characterization Technologies	Ohio State University
RFA-OD-20-018	4	AFS/SERS Saliva-based SARS-CoV-2 Earliest Infection and Antibodies Detection	University of California, Los Angeles
RFA-OD-20-018	4	Exosome-based Non-traditional Technologies Towards Multi-Parametric and Integrated Approaches for SARS-CoV-2	Johns Hopkins University
RFA-OD-20-018	4	Microfluidic Isolation and Characterization of SARS-CoV-2 and Virus Related Exosomes	Massachusetts General Hospital
RFA-OD-20-020	3	A Scalable Aptamer-based Electrochemical Biosensor for Rapid Detection of SARS-CoV-2 from Saliva	mPOD, Inc.
RFA-OD-20-020	3	Designer DNA Nanostructure Based Biosensing for Rapid COVID-19 Detection and Monitoring using Saliva Sample	Atom Bioworks, Inc.
RFA-OD-20-020	3	Direct Bioelectronic Detection of SARS-CoV-2 from Saliva using Single-molecule Field-effect Transistor Array	Quicksilver Biosciences, Inc.
RFA-OD-20-021	2	A Multimodal Platform for Oral Screening of COVID-19	Innotech, LLC
RFA-OD-20-021	2	A SARS-CoV-2 Breathalyzer for Direct Virus Detection	Aerosol Devices, Inc.
RFA-OD-20-022	3	SCENTinel: A Rapid Smell Test for COVID-19 Surveillance	Monell Chemical Senses Center
RFA-OD-20-022	3	Rapid Olfactory Tools for Telemedicine-friendly COVID-19 Screening and Surveillance	University of Florida
RFA-OD-20-022	3	Longitudinal at Home Smell Testing to Detect Infection by SARS-CoV-2	ADK Group, LLC

49 Awardees

13 FOAs

United States



# Awardees

## Wastewater

- Arizona State University
- University of Miami Coral Gables
- ASU-Tempe
- UNC Chapel Hill
- U Kentucky
- Missouri Dept/ Health & Senior Services
- Columbia University

## Biosensor Detection/Tracing

- Washington University
- Louisiana State Univ A&M Col Baton Rouge
- Emory University
- General Electric Global Research Center (GA)
- University of Washington
- Clemson University

## Novel Biosensing

- mPOD, Inc. (NY)
- Atom Bioworks, Inc. (NC)
- Quicksilver Biosciences, Inc. (NY)
- Innotech, LLC (RI)
- Aerosol Devices, Inc. (CO)

## Chemosensory Testing

- Ohio State University
- Monell Chemical Senses Center (PA)
- University of Florida
- ADK Group, LLC (MA)

## Multimodal Surveillance

- Washington State University
- UC San Diego
- Stanford
- UC Santa Barbara

# Awardees *(continued)*

## SCENT

- University of California, Davis
- University of Michigan at Ann Arbor
- University of Louisville
- University of Pennsylvania

## VOC Detection

- Boston University
- Missouri University of Science and Technology
- University of Washington
- Brigham and Women's Hospital
- Rutgers University
- Boston Biomedical Innovation Center (B-BIC)
  

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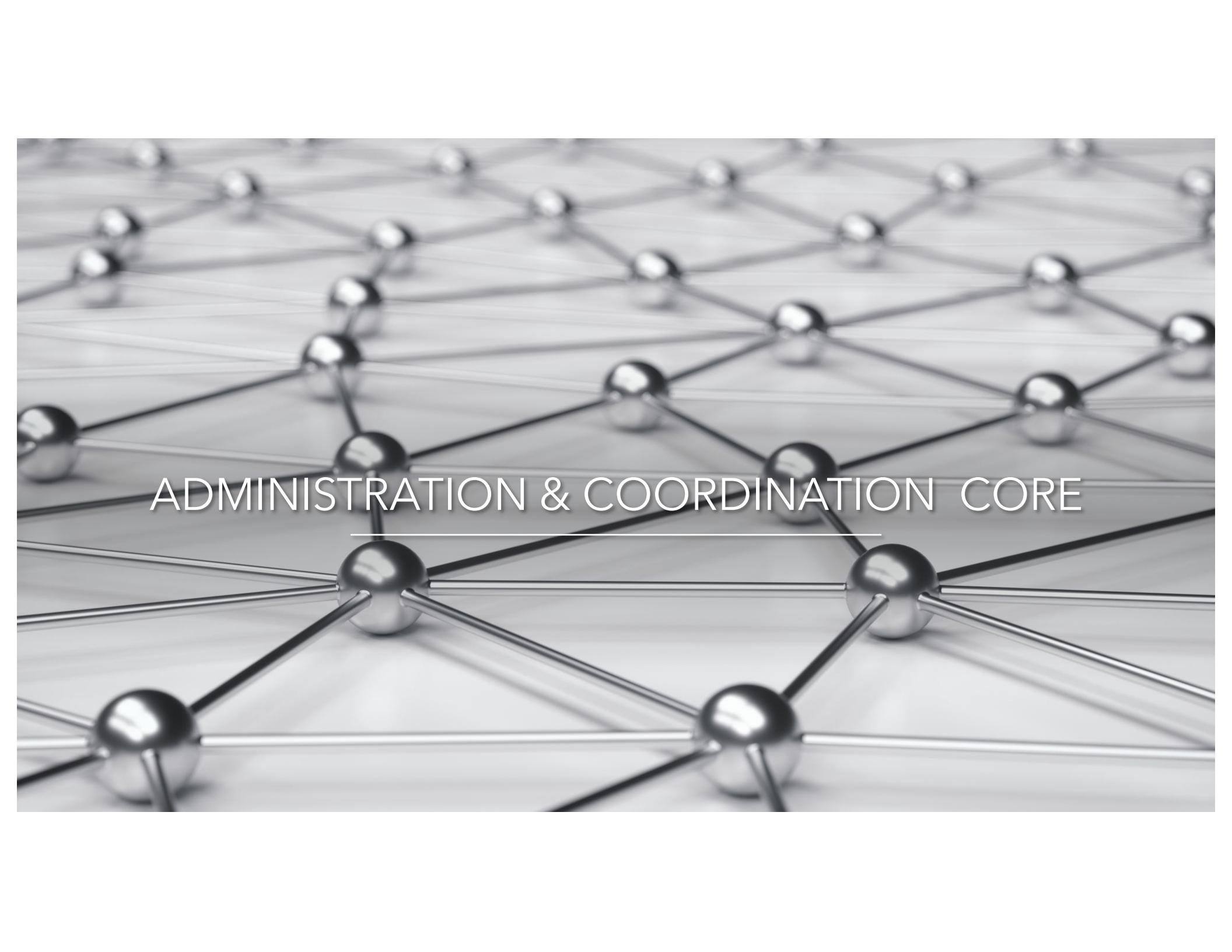
- National Institute of Environmental Health Sciences

## PreVAIL kIDS

- University of California, San Diego
- Johns Hopkins University
- Baylor College Of Medicine
- Children's Hospital of Philadelphia
- Central Michigan University
- Connecticut Children's Medical Center
- Robert Wood Johnson Medical School
- University of California, San Francisco

## Exosome-based

- Ohio State University
- University of California, Los Angeles
- Johns Hopkins University
- Massachusetts General Hospital



# ADMINISTRATION & COORDINATION CORE

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# Data Sharing to Accelerate Research



Large quantities of data are needed for statistical significance, AI models, etc.



Testing data can be sensitive, and 'de-identification' techniques do not always protect privacy



Research is competitive, and researchers want to quality control their data and be first to analyze the data



# Activities Planned

- Survey NIH and Awardees for Needs Analysis
- Advisory Board meetings
- Monthly all-hands calls
- Bi-Monthly Steering Committee call
- Help Desk & Weekly technical office-hours
- Training in Data Transformation, Teamwork, Anti-Racism
- Web portal with News, Awardee Highlights, Resource requests

# DATA CORE

```
    mirror object to mirror
    mirror_mod.mirror_object = ob
    if operation == "MIRROR_X":
        mirror_mod.use_x = True
        mirror_mod.use_y = False
        mirror_mod.use_z = False
    elif operation == "MIRROR_Y":
        mirror_mod.use_x = False
        mirror_mod.use_y = True
        mirror_mod.use_z = False
    elif operation == "MIRROR_Z":
        mirror_mod.use_x = False
        mirror_mod.use_y = False
        mirror_mod.use_z = True

    # selection at the end - add
    ob.select= 1
    mirror_ob.select=1
    context.scene.objects.active = selected
    print("Selected" + str(modifier))
    mirror_ob.select = 0
    copy.context.selected_objects = []
    data.objects[one.name].select = 1
    int("please select exactly one object")
    -- OPERATOR CLASSES --
    types.Operator:
        X mirror to the selected
        object.mirror_mirror_x"
        mirror X"
```

# Data Core



Assist in data collection

Help install LIMS if needed  
Develop APIs from awardees' LIMS  
Cloud hosting



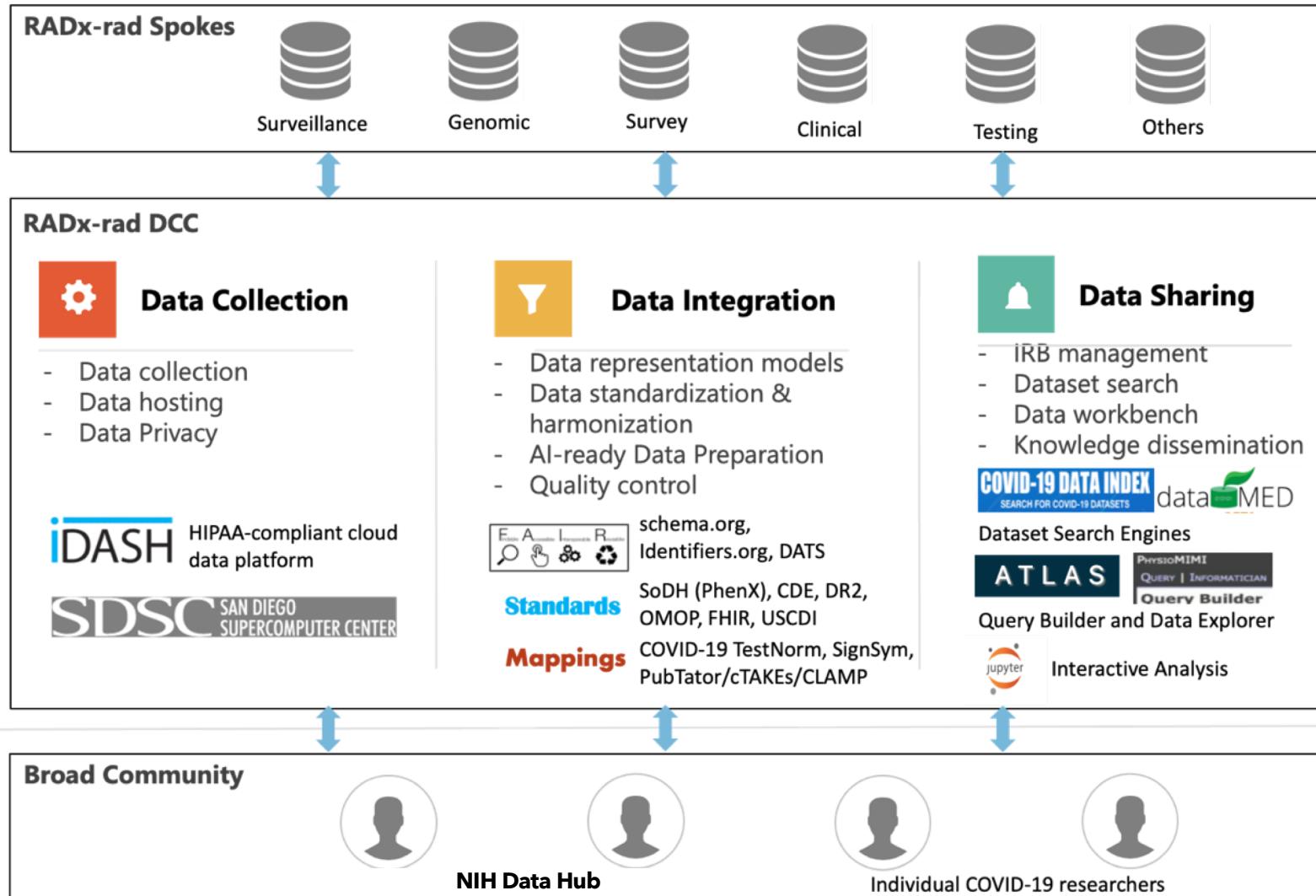
Data transformation and organization

OMOP  
CDE  
PhenX  
Metadata  
AI-ready



Data Sharing

Privacy technology  
IRB  
DUAs  
data analyses



# Initial Activities of Data Core

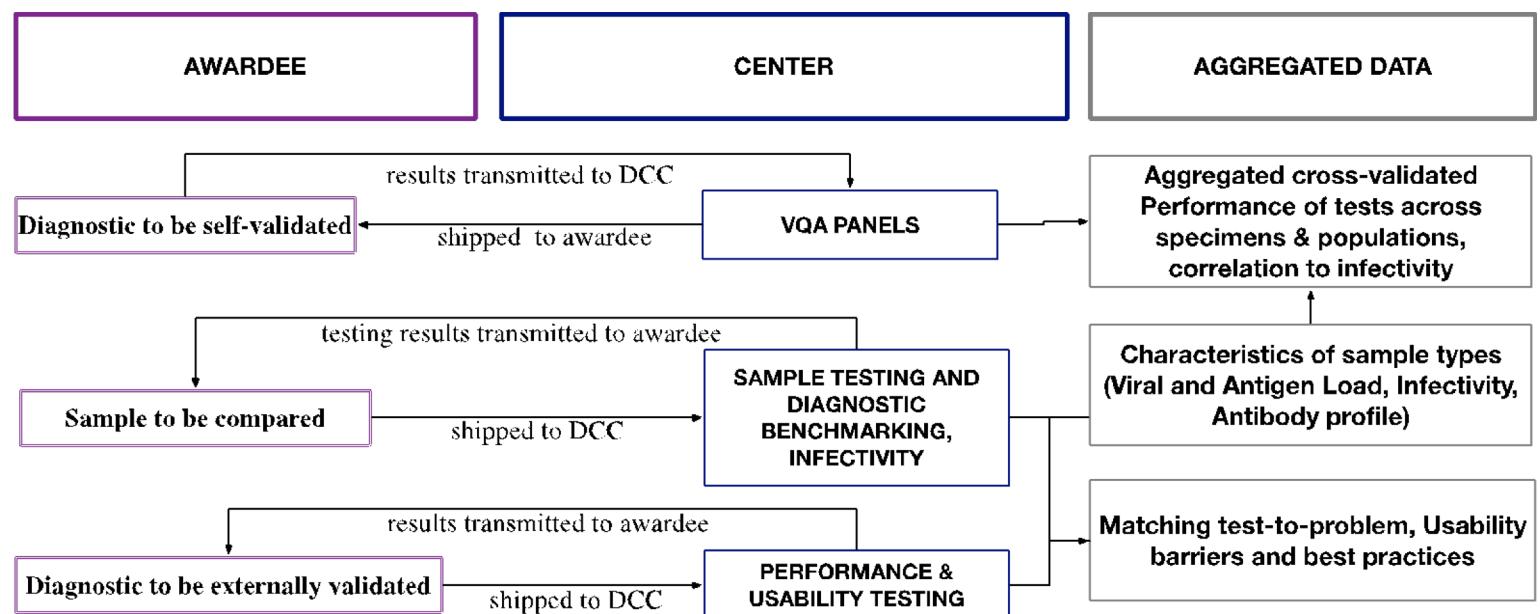
- Survey on datasets that will be generated from the RADx-rad program and other related efforts
- Communication structure with RADx-rad spokes (e.g., meetings, point of contact for with domain expertise for each data type)
- Resources for data collection, integration and sharing
  - Computational infrastructure setup
  - Standard specifications (e.g., CDEs)
  - Collection of tools (e.g., CDE mapping tool)

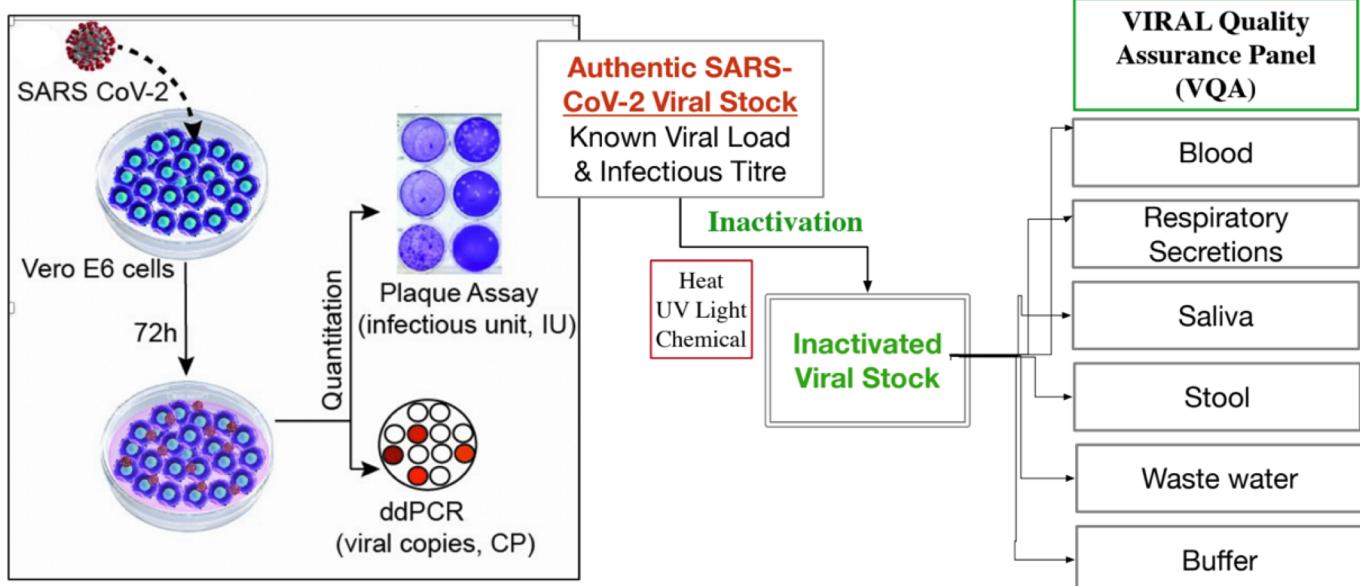
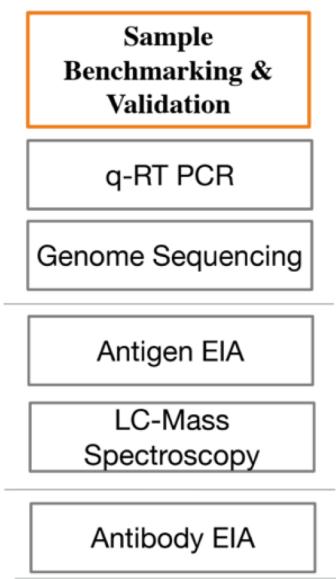


**DISCOVERY &  
DIAGNOSTICS  
CORE**

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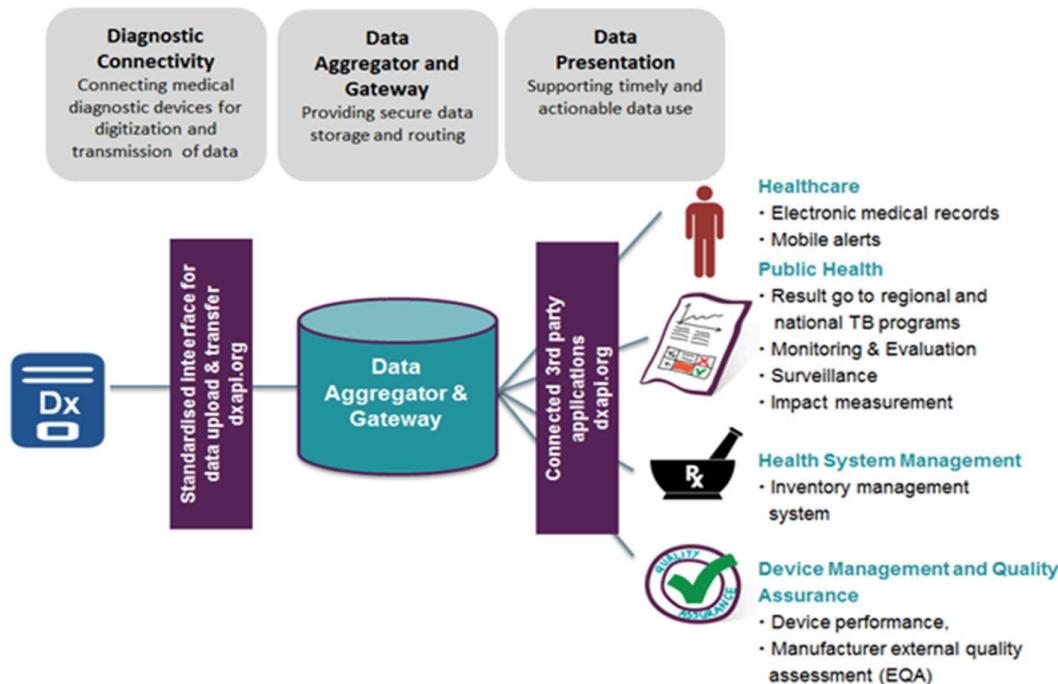
# Quality Assurance and Usability Support





## Native and Variant Viral Stocks

- Provide Viral Quality Assurance Samples including variants and nonSARS viruses to awardees so that they can test, generating standardized datasets
- Validate existing tests against SARS-COV2 & Variants
- Validate new affinity reagents & nucleic acid approaches
- Support Usability evaluation and improvement
- Assist with FDA submissions and Regulatory needs



## HOSTED LIMS (CDx)

- Connected Diagnostics (CDx) Platform makes it easy to collect and use diagnostic test data across multiple devices, tests, and disease verticals.
- Connects to common diagnostic platforms and add new ones easily
- Share data and aggregated results easily
- Free and Open Source Software

# RADx-rad PORTAL

member  
site 25

public  
portal

N

## NEWS & UPDATES

FDA presents updated guidance for development of novel diagnostics

"In the news, FDA updates guidance for home collection, rapid antibody and antigen diagnostics."

07/16/2020

Emerging insights into COVID-19 testing in underserved populations

" Reports issued today cast light on SARS-CoV-2 testing in underserved populations"

07/18/2020

COVID-19 disparities tackled by National Institutes of Health

"[RADx-UP] is designed to get at least \$200 million on the street by the end of December – record pace for NIH,"

07/20/2020

New Design Thinking for Community Driven Innovation

A new study using participatory design methods to develop connected cancer care solutions has published new findings. - L.A.U.N.C.H. project FCC Connect 2 Health Taskforce

07/14/2020

Cross validation of molecular diagnostics across specimens

Methods to develop connected cancer care solutions has published new findings. - L.A.U.N.C.H. project FCC Connect 2 Health Taskforce

07/14/2020

H

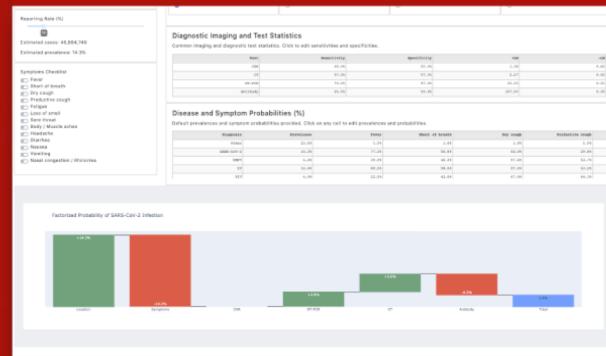
## HELP DESK

Search /Ask an Expert



P

## Performance Calculator



Interactive tool to assess the performance of diagnostics in high or low prevalence settings

Dx

## DIAGNOSTICS

① Request VQA Panel

② Send Sample to verify

③ Send Test to validate

④ Protocols & Usability

post data

pull data

mdi\_search



ROADMAP

# Immediate Steps

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DCC to meet with  
POs of every FOA



DCC to meet with  
PIs, and conduct  
needs analysis



Organize Steering  
Committee



Organize DSMB



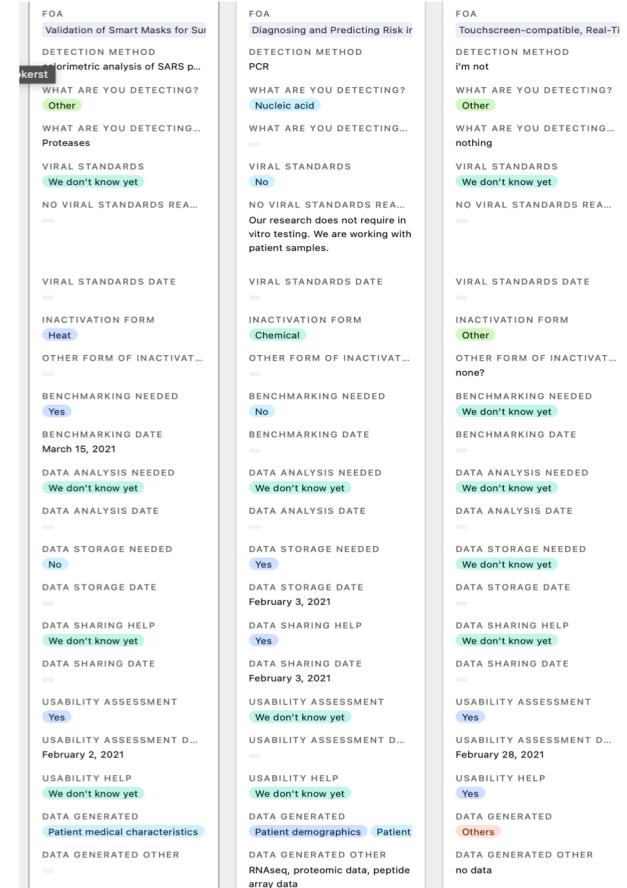
Organize cloud  
infrastructure for  
48 projects



Schedule monthly  
all-hands calls

# Needs Assessment Survey

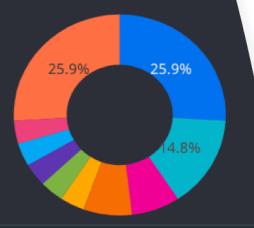
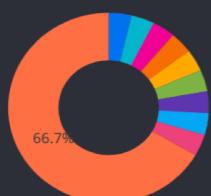
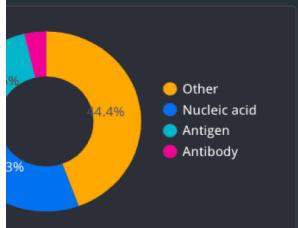
- With what method are you detecting SARS-CoV-2? What are you detecting?
- Will you need viral standards? What form of inactivation do you prefer?
- Would you like us to validate your assay?
- Do you need help analyzing the data?
- Do you need help with data storage?
- Do you need help with data sharing?
- What kind of data will your solution generate?
- What is your data format?
- What metadata standards do you use?
- What software/libraries do you use to process the data you generate?
- Will you be assessing usability of your test, and would you like help with that?
- What else would you like the DCC to help with? What do you NOT want our help with?



## AWARD INFO (n= 27/48)

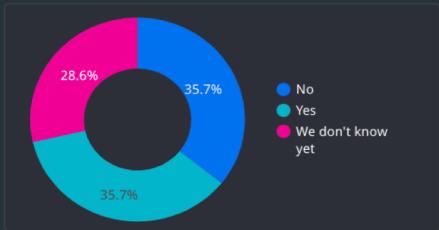
### RADx-RAD AWARDEE DIAGNOSTIC NEEDS

ON

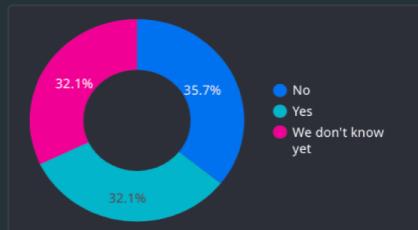


### STANDARDS AND MARKING

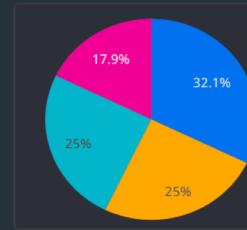
#### Viral Standards



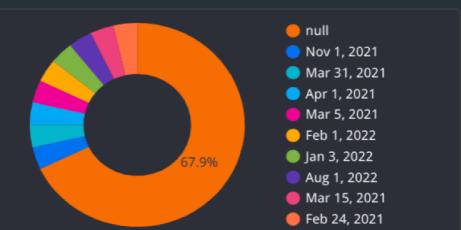
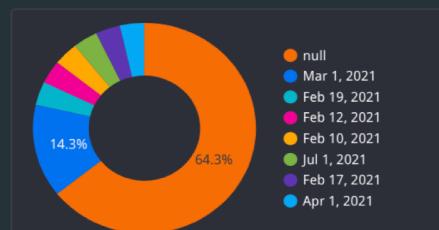
#### Benchmarking



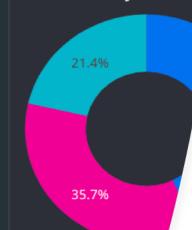
#### Preferred Inactivation



### BY



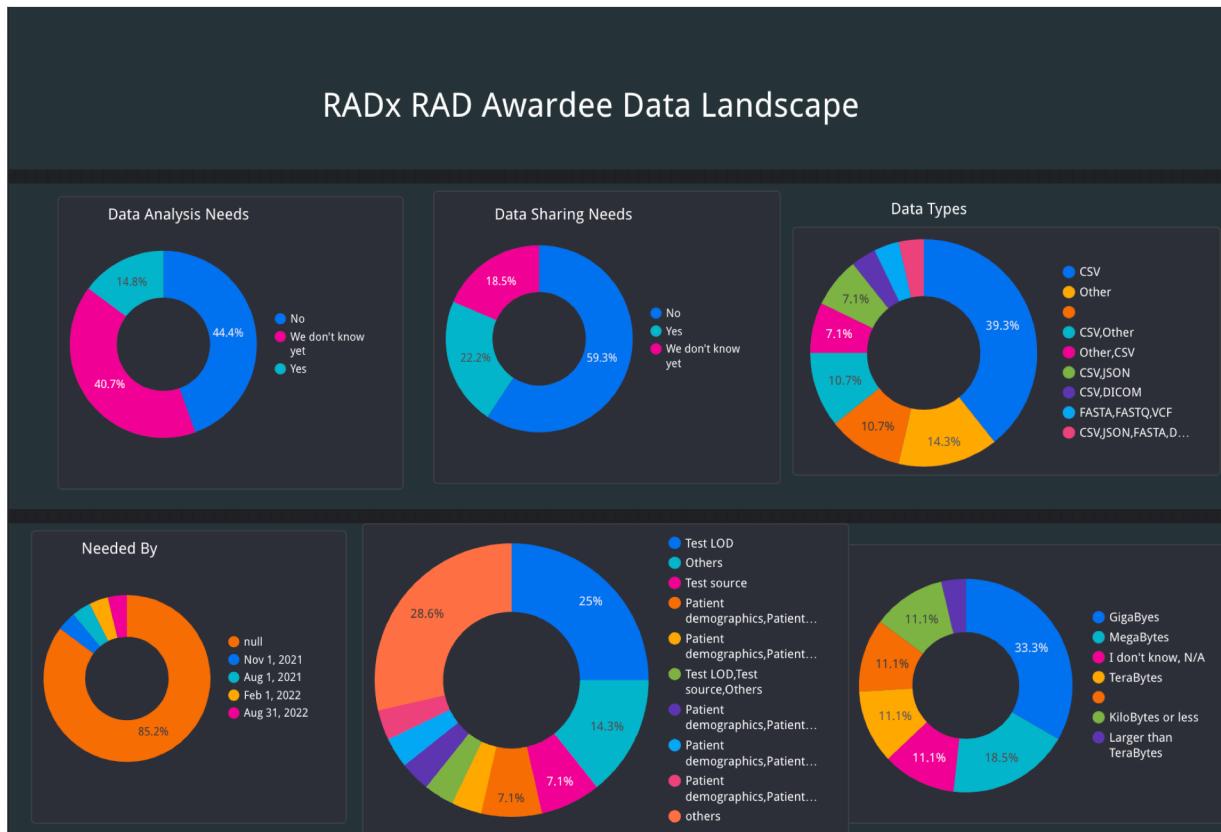
#### Usability Needs



## Diagnostics Needs: Preliminary results

- More than a third to a half of awardees will likely need viral standards, some as early as spring, others starting in summer 2021
- Those who need standards require multiple forms or inactivation in a diverse set of contrived specimens
- The most common detection method is nucleic acid testing followed by antigen, antibodies and then non-traditional approaches such as VOCs, Enzymes or bioinformatic methods.
- About a third will need help with benchmarking, many aren't sure yet. Those with standard diagnostics will mostly report LOD and TAT.
- About a third will need help with usability, many aren't sure yet.
- There are a diversity of data storage and sharing types and some opportunities for LIMS use

# Data needs: Preliminary results



- About a third of awardees anticipate needing help with data analysis, storage and sharing, many are not sure yet
- There is a diversity of data file types, though CSV and JSON are most prevalent
- Data size range from kilobytes to >terabytes
- Earliest data sharing dates start in late 2021
- There is a diversity of data types and analysis tools used: most common ones are Matlab (4), Python (3), R(2)

# We will help awardees be successful

(1)

**Peace of mind for diagnostic development, data quality, hosting and distribution**



**Resources & Support**



**Training for team success**



# THANK YOU!

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To the NIH and RADx-rad awardees