RADx-Radical (RADx-rad) Kickoff Meeting

February 22, 2021

National Institutes of Health
Turning Discovery into Health®

RADx-rad Kickoff Agenda

Topic	Description	Speaker	Time
Welcome & Logistics	• A welcome to the RADx-rad Initiative and explanation on how the presentation and subsequent Q&A session will flow	• Dr. Tara Schwetz	5 minutes
RADx Overview	• An introduction to the RADx Initiatives and its four programs: RADx-rad, -UP, and -Tech/ATP; as well as an explanation of coordination amongst the programs	• Dr. Francis Collins	10 minutes
RADx-rad Program Structure	• A presentation on the overall goals, research interests, and organizational structure of the RADx-rad initiative	• Dr. Judith Cooper • Dr. Patricia Powell	10 minutes
RADx Tech Collaboration	• A description of how RADx-rad projects can leverage RADx Tech infrastructure	• Dr. Bruce Tromberg	10 minutes
RADx Data Management and Common Data Elements (CDEs)	• A presentation on the plan for data management and CDEs across the RADx Initiative	• Dr. Susan Gregurick • Dr. Patti Brennan	10 minutes
RADx-rad DCC Overview	• A presentation by the principal investigators of the RADx-rad Data Coordination Center (DCC) explaining its data management plan, structure, and resources; as well as the responsibilities of RADx-rad awardees in working with the DCC	• Dr. Lucila Ohno-Machado • Dr. Hua Xu • Dr. Eliah Aronoff-Spencer	20 minutes
Briefing from FDA Representative	• An overview of FDA regulatory support available to RADx-rad awardees	• Dr. Sara Brenner	10 minutes
Q&A	• A session in which speakers answer questions from the audience via the Zoom chat or Q&A feature	• Dr. Rick Woychik	30 minutes

WELCOME & LOGISTICS

Speaker

Tara A. Schwetz, Ph.D.

Associate Deputy Director, National Institutes of Health (NIH)
tara.schwetz@nih.gov

Welcome & Logistics

Rules of the Road

- ✓ All **kickoff attendees will be "on mute"** for the duration of the kickoff.
- ✓ The webinar is **being recorded**; the recording and the presentation slides will be made available to attendees following the kickoff meeting.
- ✓ Please hold all questions until the very end of the meeting, at which time we will have a dedicated Q&A session. During this session, meeting participants can use the **Q&A function to submit their questions**.

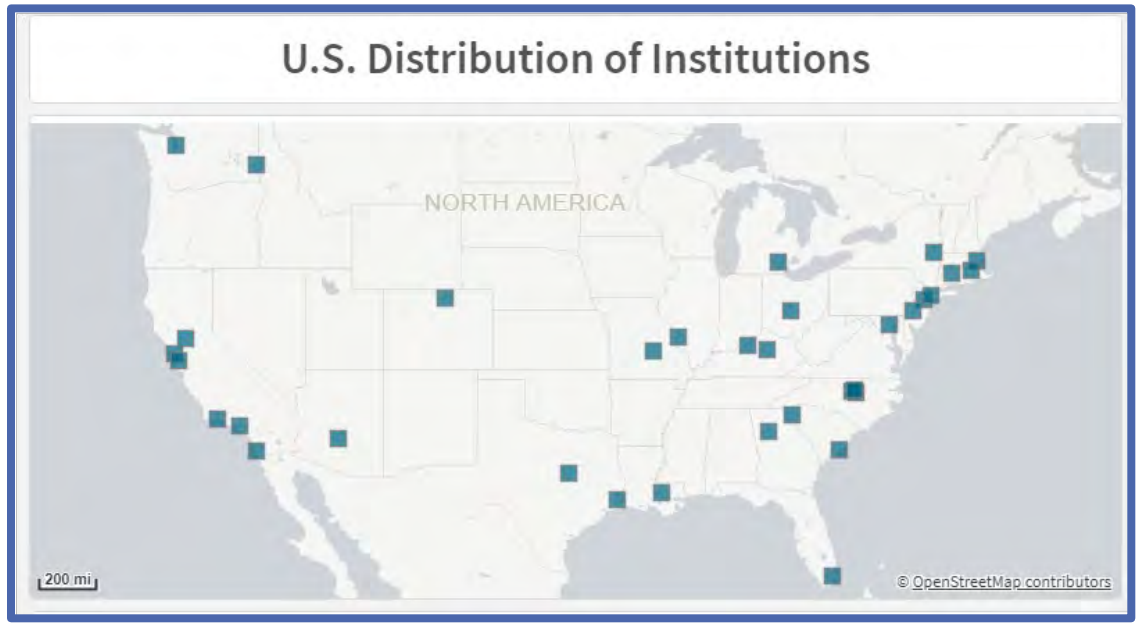
RADx-rad at a Glance

RADx – rad Phase I Highlights

$108M USD in Extramural Funding (approx.)
To support new, **non-traditional approaches** and **new applications** of existing tools

49 Extramural Awards
Issued to **45 unique institutions** in **20 states**

13 Funding Opportunity Announcements
Spanning **eight specific areas of research interest**



Geographic Distribution of Funded Projects

OVERVIEW OF RADx PROGRAM

Speaker

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health (NIH)

Rapid Acceleration of Diagnostics (RADx) Initiative

RADx Tech – $500M

Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Advanced Testing Program (RADx-ATP) – $230M

Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput — create ultra-high throughput laboratories and “mega labs”

RADx Underserved Populations (RADx-UP) – $500M

Interlinked community-engaged research projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

Data Management Support – $70M

Build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts

RADx Radical (RADx-rad) – $200M

Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Tech

Overarching Goal

Establish a robust pipeline of innovative diagnostic technologies to **increase national testing capacity**

Innovate Across the Testing Landscape

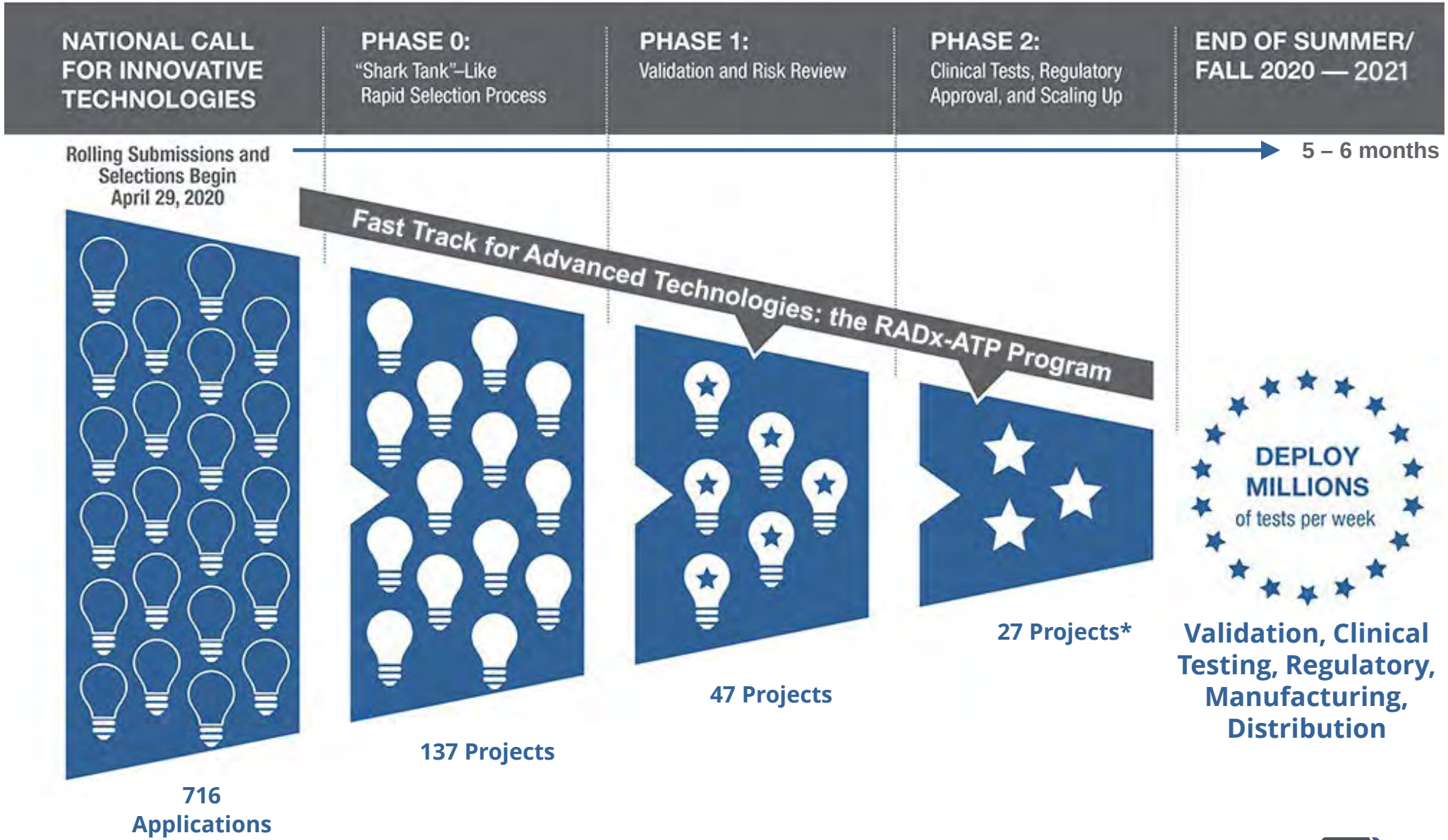
Expand the number, type, access, and throughput of testing technologies

Optimize Technology Performance

Develop technology for a range of essential “Use Cases”

- At-home
- Point of Care (POC)
- Hospital
- Testing Laboratory

RADx Tech "Shark Tank"



Note: *15 Tech/ATP projects have EUA, including first at home testing kit (Ellume test)

RADx-Advanced Technology Platforms (RADx-ATP)

Overarching Goal

Increase testing capacity and throughput by identifying existing and late-stage testing platforms to achieve **rapid scale-up or expanded geographical placement**

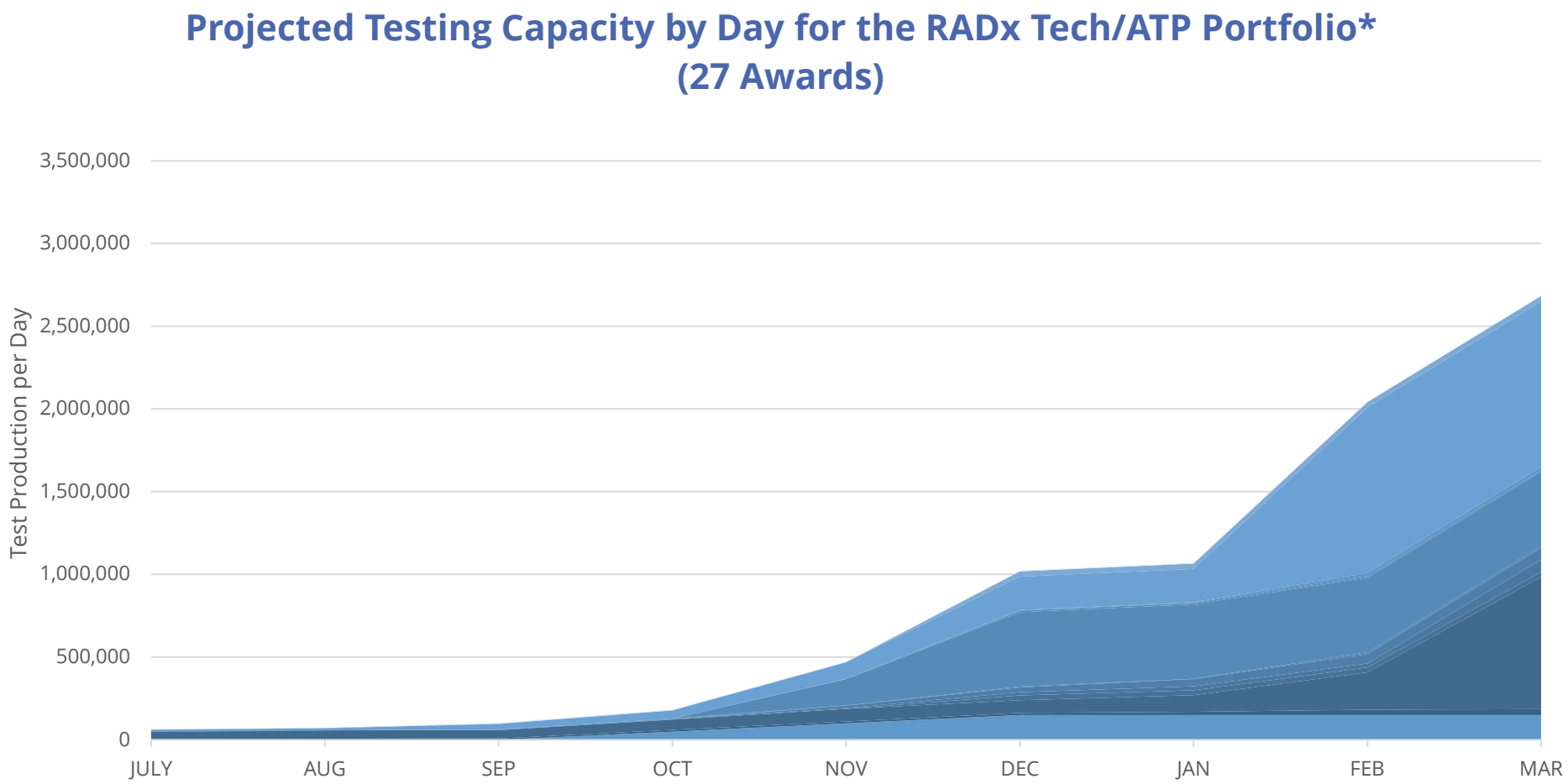
- Emphasize differential POC testing to distinguish SARS-CoV-2 vs. influenza
- Establish rapid collaborations with key industry partners

Scale-up Late-Stage Technologies

Support Scale-Up of High-Throughput Labs to Add Capacity

Contribution of RADx to the National Testing Capacity

It is projected that the 27 RADx awards will contribute over **2.5 million tests per day** to the National testing capacity by March 2021



Note: *Cumulative total of 94 million tests per day produced between Sept and Dec 2020

RADx-Underserved Populations (RADx-UP)

Overarching Goals

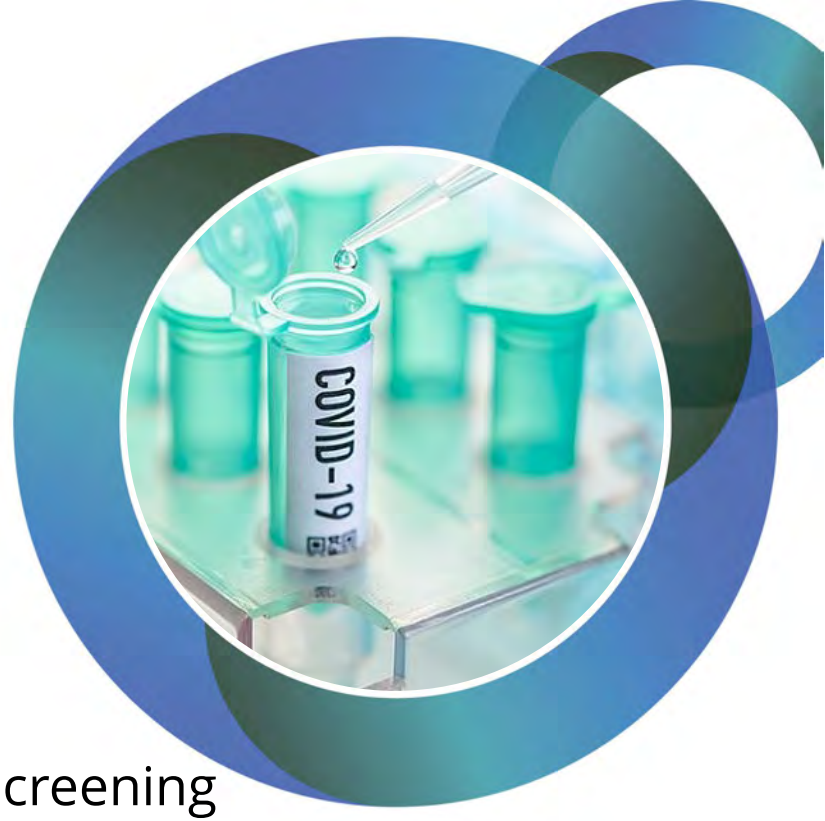
- Enhance COVID-19 testing among **underserved and vulnerable populations** across the US
- Develop/create a **consortium of community-engaged research projects** designed to rapidly implement testing interventions
- **Strengthen the available data** on disparities in infection rates, disease progression and outcomes, and **identify strategies to reduce these disparities** in COVID-19 diagnostics

September – November 2020 | **2021**

Phase I: $300M | **Phase II: $200M**

- *Build infrastructure*
- *Rapidly implement testing, other capabilities*
- *Integrate new advances*
- *Expand studies/ populations*

RADx-Radical (RADx-rad)



Overarching Goal

Support new, **non-traditional approaches** and **new applications of existing tools** that address gaps in COVID-19 testing and develop platforms that can be deployed in future outbreaks of COVID-19 and other, yet unknown, diseases

Example Research Technologies of Interest

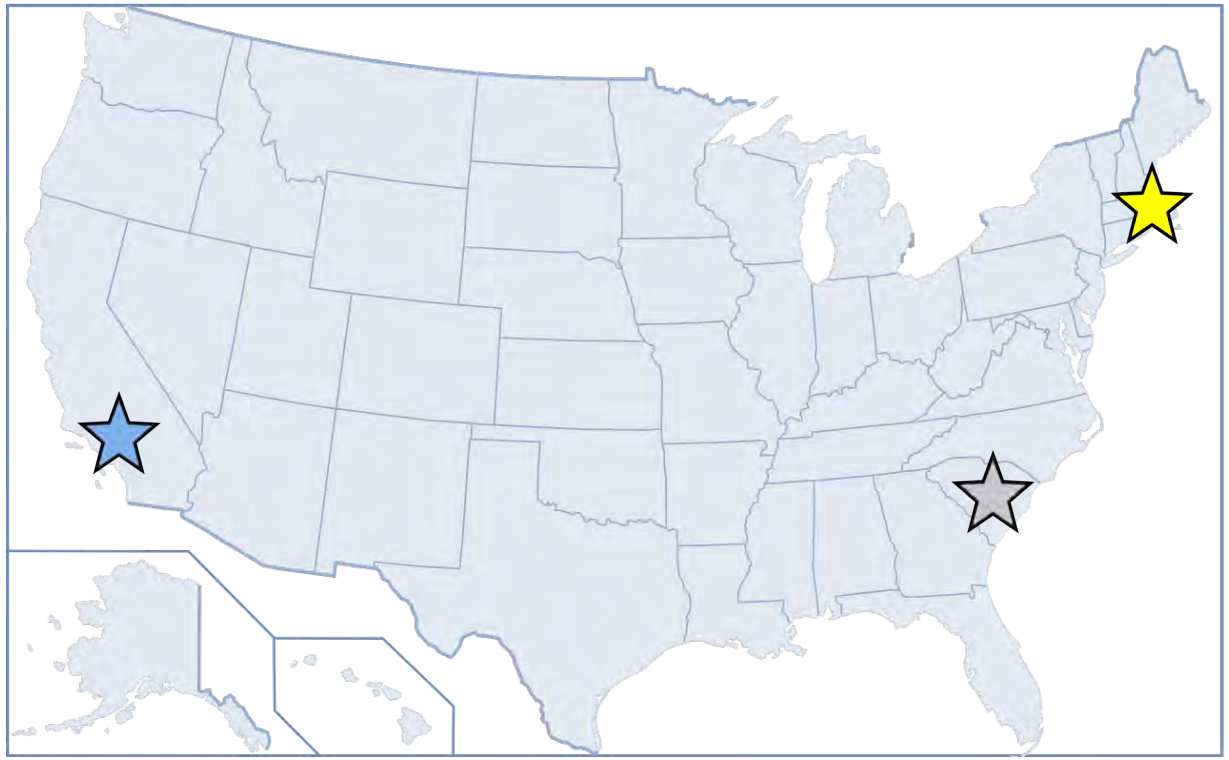
- **Novel biosensing and chemosensory testing** for COVID-19 screening
- **Single vesicle, exosome, and exRNA isolation** for the detection of SARS-CoV-2
- **Predicting viral-associated inflammatory disease severity** in children with laboratory diagnostics and artificial intelligence
- **Wastewater-based detection** of SARS-CoV-2
- **Multimodal COVID-19 surveillance** methods for high-risk populations

RADx Coordination

RADx is supported by unique coordinating centers that are collaborating with each other to enhance and optimize each program

- **Data Consortium Coordination Center & Program Organization** (D-C3PO) – UCSD, San Diego, CA (RADx-rad)
- **Consortia for Improving Medicine with Innovation & Technology** (CIMIT) – MGH, Boston, MA (RADx Tech/ATP)
- **Coordination & Data Collection Center** (CDCC) – Duke/UNC, Durham, NC (RADx-UP)

U.S. Distribution of RADx Coordination Centers



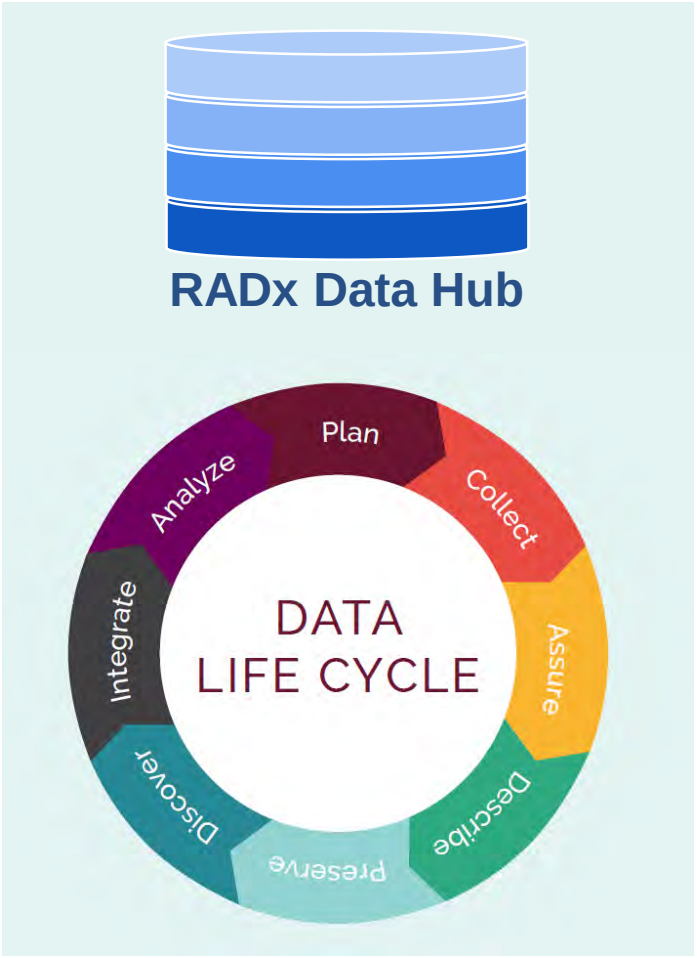
RADx Data Management

Overarching Goal

Develop platform to integrate data, on individuals and populations, from a variety of sources – including serology and genetic test results, output from smart sensors, self-reported clinical symptoms, and EHR data

- Support Common Data Elements
- Metadata & Data Repository
- Data Management
- Data Curation and Harmonization

Will provide access to deidentified RADx and related data, algorithms, and other capabilities generated by RADx programs and related technologies



RADx-rad PROGRAM STRUCTURE

Speakers

Judith Cooper, Ph.D.

Deputy Director, National Institute on Deafness and Other Communication Disorders (NIDCD)
cooperj@nidcd.nih.gov

Patricia A. Powell, Ph.D.

Deputy Director, National Institute on Alcohol Abuse and Alcoholism (NIAAA)
ppowell@mail.nih.gov

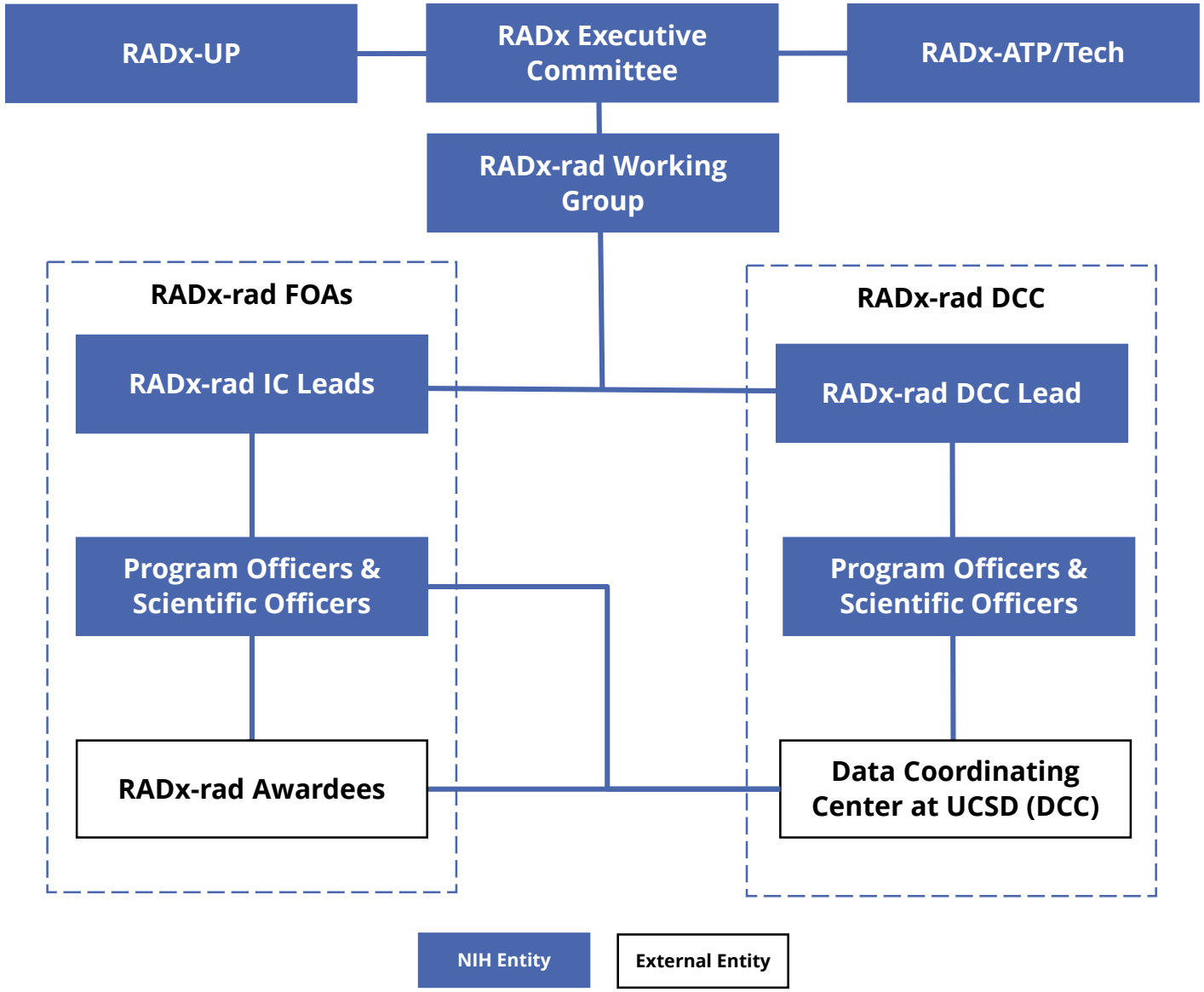
RADx-rad Overall Goals and Research Interests

Overall Goals

- Support **new, non-traditional approaches** and **applications of tools** to increase **COVID-19 testing and surveillance**.
- Develop platforms to **deploy in future outbreaks of COVID-19** and other diseases.
- Fund **49 projects across 13 FOAs** capturing **several areas of research interest**:

- ✔ **Studies Utilizing Wastewater Surveillance Methodologies for Detection of SARS-CoV-2**
- ✔ **Studies Specific for High-risk Clustered Populations**
- ✔ **Automatic Methodologies for Detection and Tracing Of The Virus**
- ✔ **Chemosensory Testing**
- ✔ **Novel Biosensing from Skin and The Oral Cavity**
- ✔ **Electronic-nose Technology**
- ✔ **Exosome-based Non-traditional Technologies**
- ✔ **Developing Tools to Predict Viral-Associated Inflammatory Disease Severity in Children with Laboratory Diagnostics And Artificial Intelligence**
- ✔ **Data Coordination Center**

RADx-rad Organizational Structure



Responsibilities

RADx Executive Committee: Oversees the strategic direction of all RADx programs and reports directly to NIH leadership.

RADx-rad Working Group (WG): Provides a forum to share major updates and issues across rad FOAs and the DCC.

RADx-rad IC Leads: Reports on major updates and issues for each rad FOA.

RADx-rad DCC Lead: Ensures the DCC and Awardees are coordinating appropriately.

Program Officers (POs): Report on the scientific progress and accomplishments of Awardees.

Scientific Officers (SOs): SOs are assigned as subject matter experts for RADx-rad Awardees of a specific FOA to help Awardees achieve their objectives.

RADx-rad Awardees: Achieve and report on key project milestones and provide scientific data to the DCC.

Data Coordinating Center at UCSD (DCC): Standardizes, integrates, and shares with the NIH the data provided by RADx-rad Awardees.

RADx-rad Leadership Team

RADx – rad CO-CHAIRS

Drs. Tara Schwetz and Rick Woychik

RADx – rad DATA COORDINATION CENTER

Program Officer

Dr. Yanli Wang

Principal Investigators

Drs. Lucila Ohno-Machado, Hua Xu, and Eliah Aronoff-Spencer

RADx – rad WORKING GROUP

Co-chairs

Drs. Judith Cooper and Patricia Powell

Members

Dr. Leonardo Angelone	Dr. Douglas Bell	Dr. Yanli Wang
Dr. Changhai Cui	Dr. Valerie Florance	Dr. Sai Majji
Dr. Bill Kapogiannis	Dr. Elena Koustova	Kristin Ta, MPH
Dr. Orlando Lopez	Dr. Amanda Melillo	Kasima Garst
Dr. Susan Sullivan	Dr. Danilo Tagle	Christopher Booher
	Dr. Joel Islam	

RADx TECH COLLABORATION

Speaker

Bruce Tromberg, Ph.D.

Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB)

bruce.tromberg@nih.gov

RADx Tech: Collaboration Opportunities

Bruce J. Tromberg, Ph.D.

Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB)

RADx Tech Team Leads: Tiffani Lash, Todd Merchak, Mike Wolfson, Doug Sheeley, David George, Gene Civillico, Bill Heetderks, Charles Anamelechi, Matt McMahon, Felicia Qashu, Tony Kirilusha, Mark Snyder, Andrew Weitz, Krishna Juluru, Taylor Gilliland, Kate Egan, Ray MacDougall, Patty Wiley, Jennifer Jackson

Rapid Acceleration of Diagnostics (RADx)

NIH Office of the Director


Francis Collins


Rachael Fleurance


Larry Tabak


Tara Schwetz

April 24, 2020: $1.5B to NIH
$500 Million to NIBIB

RADx Tech – $500M
Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Advanced Technology Platforms (RADx-ATP) – $230M
Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput – create ultra-high throughput machines and facilities

RADx Radical (RADx-Rad) – $200M
Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Underserved Populations (RADx-UP) – $500M
Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations


Jill Heemskerk


Bruce Tromberg

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

$307 M Partnership with BARDA

December 2020 Congress: *$100,000,000*

Tech/ATP Team Leads: Tiffani Lash, Todd Merchak, Taylor Gilliland, Kate Egan, Mike Wolfson, Doug Sheeley, Gene Civillico

OASH FDA CMS CDC

https://www.nih.gov/research-training/medical-research-initiatives/radx

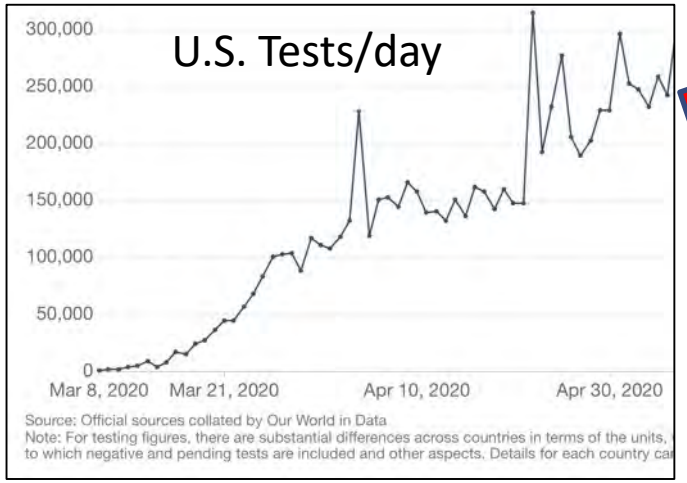
RADx Tech & -ATP Goals

1) Expand COVID-19 Testing Technologies: *Number, Type and Access*

2) Optimize Performance: *Technologic and Operational; Match Community Needs*

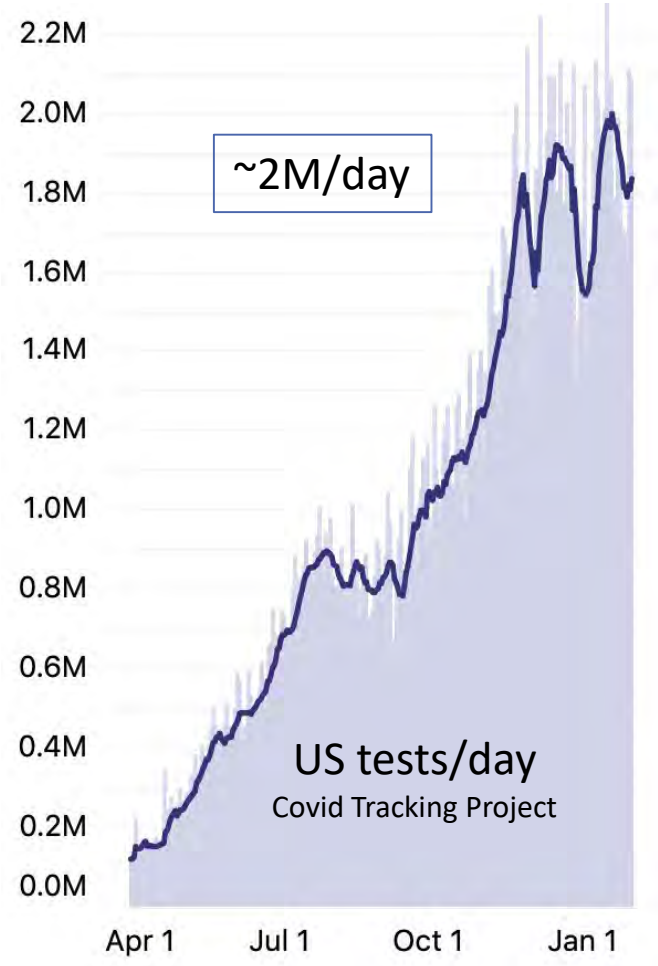
Test Settings

- Home-based
- Point of Care (POC)
- Laboratory (CLIA, research)



RADx Launch: *~250k/day*

Lab > POC



POC > Lab

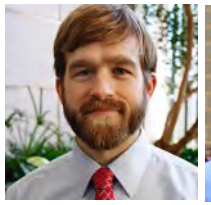
+ >4 million/day LFA antigen tests unreported

https://www.theatlantic.com/health/archive/2021/01/rapid-antigen-covid19-tests-unreported/617668/

Point-of-Care Technologies Research Network (POCTRN)

NIBIB National Network: *5-6 years for new POC technologies*

Established 2007, Expanded 2020: >1000 RADx experts & contributors




Todd Merchak Tiffany Lash

https://www.poctrn.org

VENTUREWELL™ idea to impact

GaTech/Emory
- ✓Engineering
- ✓Design/Prototype
- ✓Clinical Validation
- ✓Biobank samples
- ✓In-Home Validation

Johns Hopkins
- ✓Public Health/STD
- ✓Global Health
- ✓Clinical Validation
- ✓Biobank samples
- ✓Validation in LMICs

CIMIT/MGH
- ✓Coordinating Center
- ✓Collaboration/Management Platform
- ✓Business/Commercialization

Northwestern
- ✓HIV/AIDS
- ✓Engineering
- ✓Global Health
- ✓Clinical Validation
- ✓Validation in LMICs

UMass
- ✓Heart, lung, blood
- ✓Engineering
- ✓Clinical Validation
- ✓Biobank samples
- ✓Clinical Trials
- ✓Business/Commercialization

C BIO M C3i

Operations:

- Review & Fund
- Test & Validate
- Expert Guidance

Validation Core

>50 projects complete, ~2000 participants

Clinical Studies Core

Standard Trial Design, Digital Health Platform, Single IRB, Center Network

Deployment Core

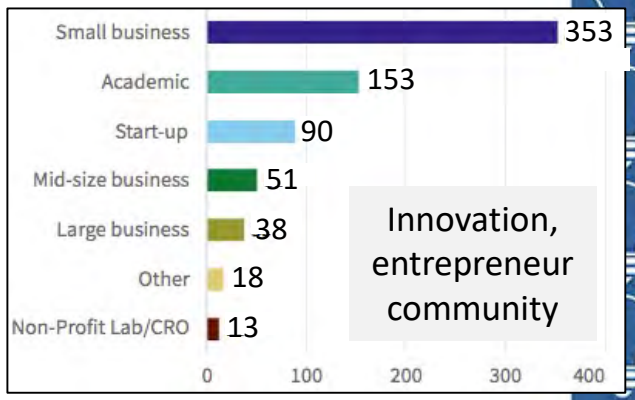
Supply chain, Manufacturing, User Community, End to end solutions

National Institute of Biomedical Imaging and Bioengineering

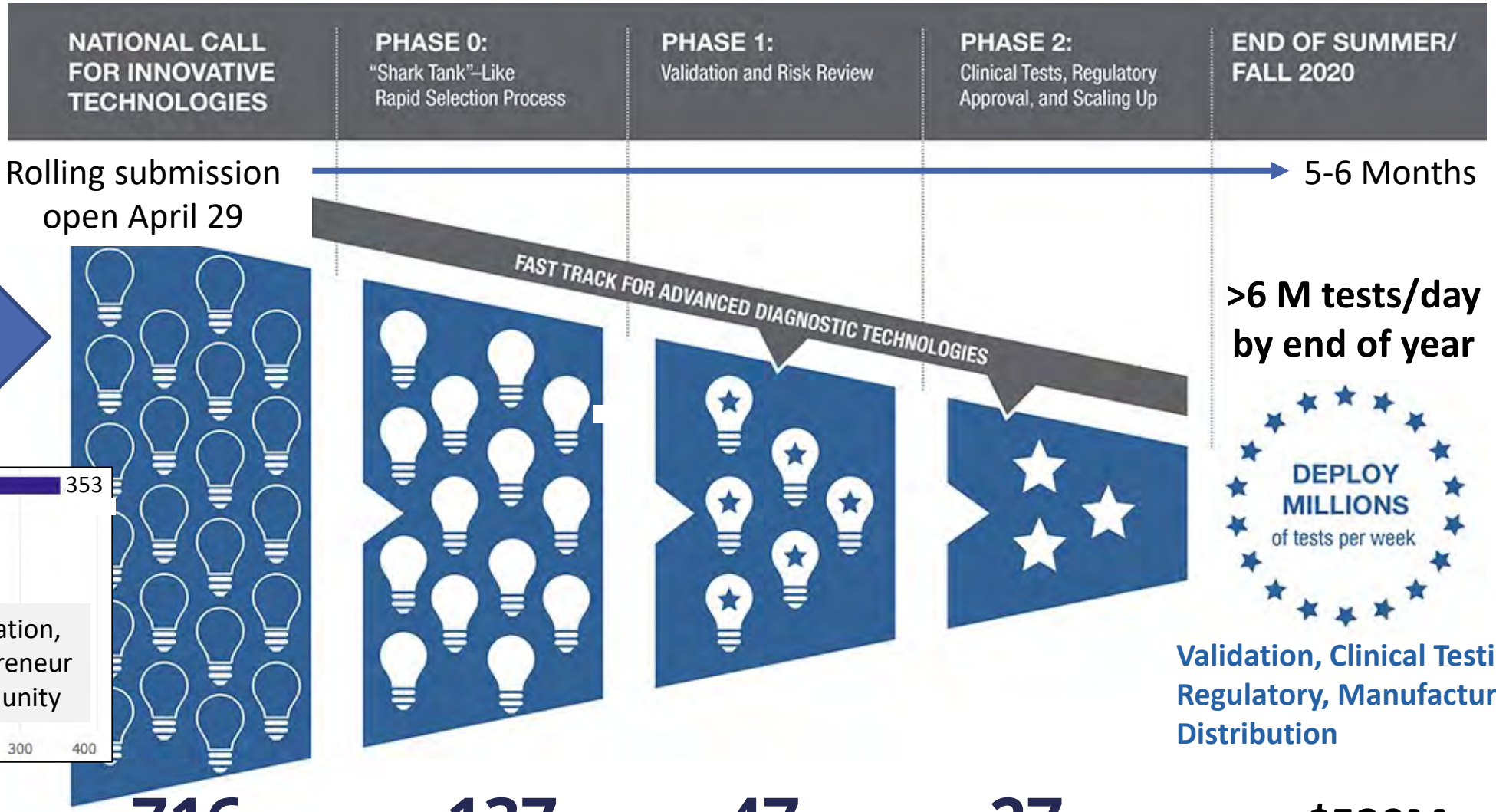
NIH National Institutes of Health *Turning Discovery into Health®*

RADx Tech/-ATP Innovation Funnel

~3000
Applications Started



Innovation, entrepreneur community



>6 M tests/day by end of year

DEPLOY MILLIONS of tests per week

Validation, Clinical Testing, Regulatory, Manufacturing, Distribution

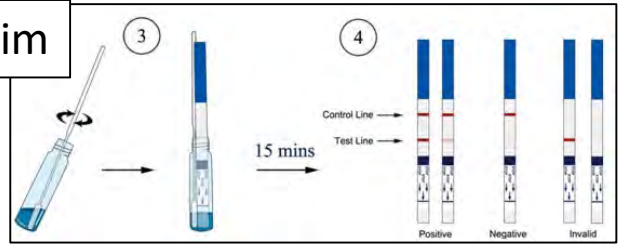
Projects in each Phase

716 | **137** | **47** | **27** (Tech + ATP)

~$520M

Mesa BioTech

Maxim



14 EUAs issued

Quidel Sophia

Yukon Swabs

Visby Medical

Ubiquitome

Ellume

Fluidigm

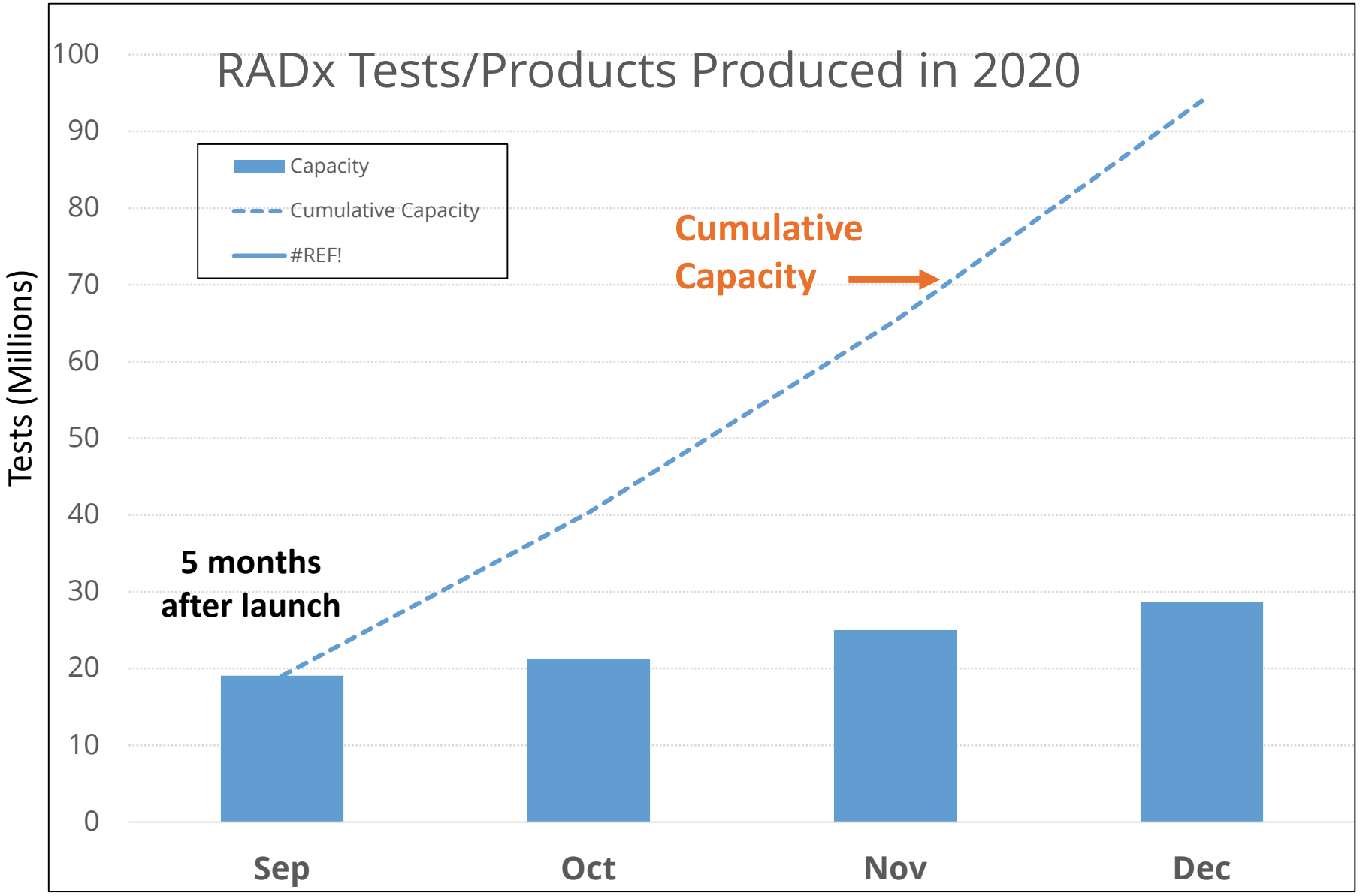
Luminostics

Flambeau

ANP

Point of Care & Home	
Visby	RTPCR
Mesa	RTPCR
Microgem	RTPCR
Talis	ISO-PCR
MatMaCorp	RTPCR
Ubiquitome	RTPCR
Meridian	RTPCR
GenBody	An-LFA
Quidel Sophia	An-LFA
Quidel QuickView	An-LFA
Luminostics	An-LFA
ANP	An-LFA
Ellume	An-LFA
Laboratory	
Flambeau	PCR-mobile
Fluidigm	RTPCR
Broad Inst	RTPCR
Illumina	NGS
Helix	NGS/RTPCR
Gingko	NGS/RTPCR
Sonic Healthcare	RTPCR
PathGroup	RTPCR
Aegis	RTPCR
Quanterix	SIMOA (An)
Lab Products	
Mammoth Biosci	CRISPR
Ceres Nanosciences	Beads/Conc
Yukon	Swabs

RADx Impact in 2020



- **~94 million capacity in 2020**
- ~950k tests/day Dec 2020
- ~14 EUAs and 1st OTC EUA
- ~150 Companies supported, 27 “Phase 2”
- **March 2021:** Project >2.5M tests/day

RADx Test Validation Core (Emory-Gtech)

>50 projects complete



Wilbur Lam Greg Martin. Oliver Brand

Feasibility

- Ensure positive control (provided or commercial) is positive
- Ensure negative matrix (i.e. saliva, patient sample or commercial) is negative
- Ensure negative matrix spiked with live and/or inactivated SARS-CoV-2 virus is positive

Contrived samples

- Verify the limit of detection (LOD) via live and/or inactivated SARS-CoV-2 virus by serial dilution using correct matrix
- Test non-SARS-CoV-2 coronaviruses (test specificity/cross-reactivity)
- Test different strains of SARS-CoV-2 (strain variation)

Patient samples

- Test banked patient samples (adult and pediatric) with concomitant testing on reference method to determine concordance
- Test prospective patient samples using collection sites >2,000 participants
- Calculate sensitivity, specificity, positive and negative predictive values with input from our biostatistical core

RADx Clinical Studies Core (UMass)

Mission: *Evaluate Phase 2 RADx platforms in clinical studies to develop "real world" guidance on tech use, performance, digital health integration.*

Laura Gibson, MD

David McManus, MD

- **LFA Multisite study:** ***UMass, UIUC, JHU in progress (n=100)***
  - Longitudinal sequential Lateral Flow Assay (LFA) assessment (2 weeks)
  - RTPCR, saliva, + viral infectiousness assay
- **LFA home testing study:** ***UMass and Northwestern, Jan 25 (n=100)***
  - At home, Self sampling, Digital health platforms
- **LFA large population study, planning w/public health (n>200,000)**
  - Regular frequent tests break chain of transmission?

COVID-19 Test US

COVID-19 SHIELD Target TEST Tell

UMassMemorial Health Care

UCSF Health

Northwestern Medicine

Eureka

Participant ID & Enrollment

JOHNS HOPKINS MEDICINE

EMORY HEALTHCARE

+

The CTSA Trial Innovation Network

Connecting: NIH Institutes, Industry, Researchers, and Participants

Investigators at CTSA Hubs across the U.S.

Trial Innovation Centers (TICs)

Request Support and Advice for Success

Recruitment Innovation Centers (RICs)

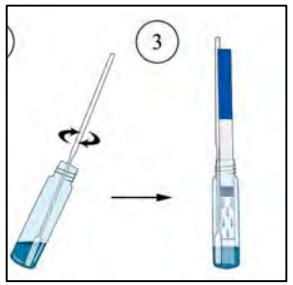
NIH National Institutes of Health

Turning Discovery into Health®

RADx Tech Digital Health Platforms

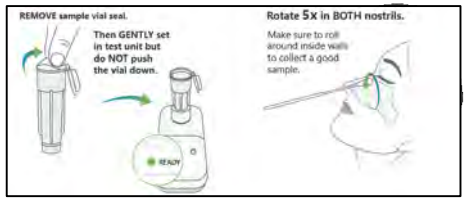
RADx POC Test

PCR



LFA

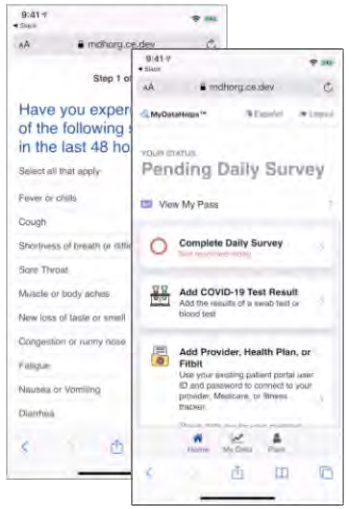
How to Use



Wearables

Digital Contact Tracing

Symptom Surveys



Cell Phone Reader

e.g. OpenRDT (Audere)

EHR & Claims

SYNC FOR SCIENCE

HL7 FHIR

Blue Button Download My Data

careevolution HEALTHCARE TECHNOLOGY

Proof of Health Status

GATES foundation

Andrew Weitz
NIBIB

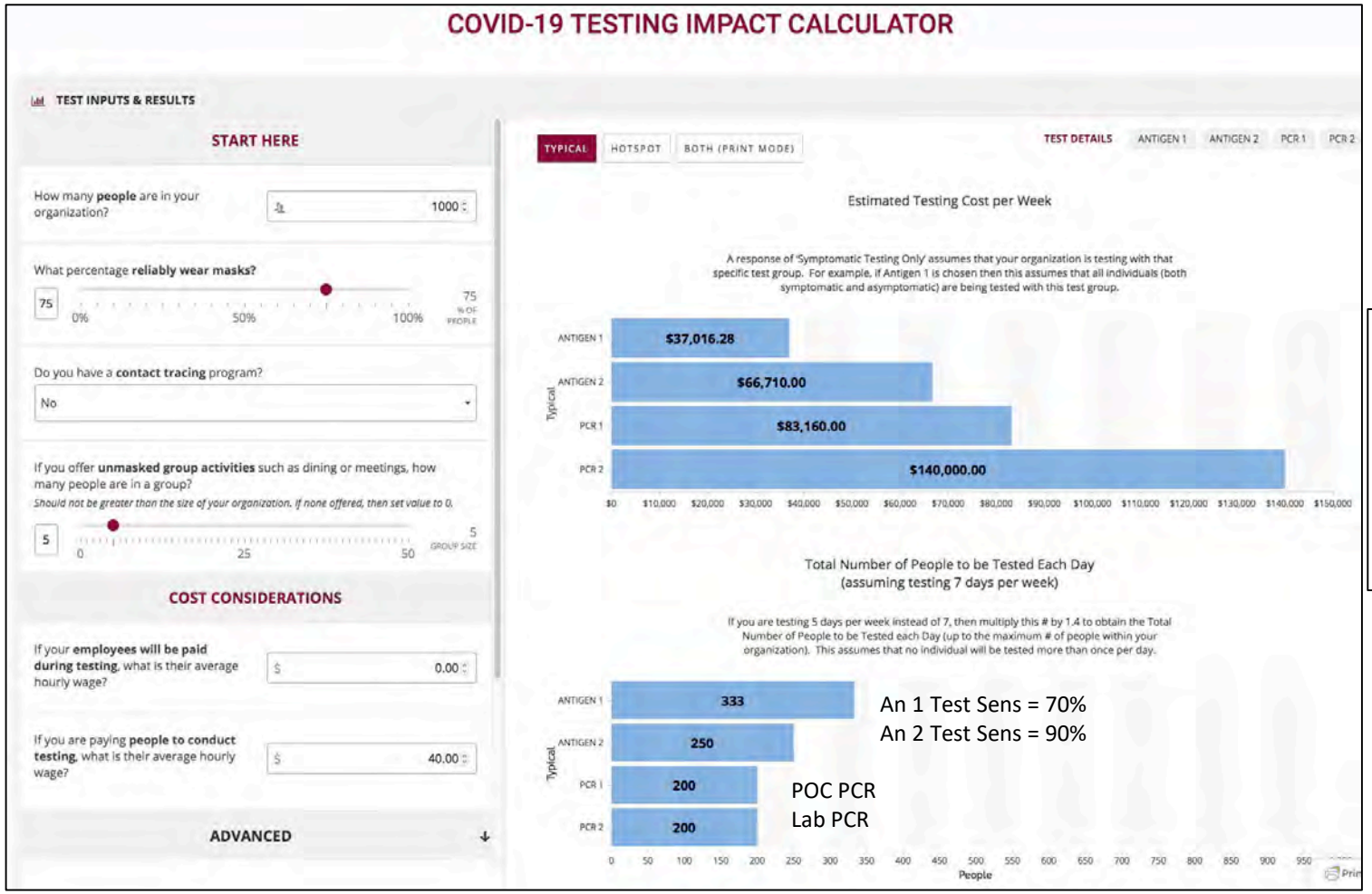
NIH NATIONAL CANCER INSTITUTE

https://www.nibib.nih.gov/news-events/newsroom/nih-awards-contracts-develop-innovative-digital-health-technologies-covid-19

RADx Tech Deployment Core: CIMIT/MGH

"When-to-Test" https://whentotest.org/ Match tests w/needs; evaluate impact of risk reducing activities.

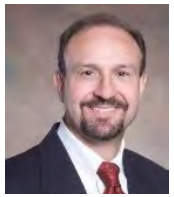
Bridging NIH/USG w/non-profits (Rockefeller, BMGF, FIND, APHL, APC) Academia, and Industry



Nancy Gagliano, MD
Deployment core lead
CIMIT/MGH

- **Create** Playbooks: *K-12, College/Uni, Business*
- **Connect** purchasers with vendors
- **Coordinate** supply chain solutions
- **Collaborate** with RADx UP
- **Organize** trans-RADx core task force on variants

Anette Hosoi, MIT



Paul Tessier, MGH

RADx Tech – RADx-rad Collaboration

Charles Anamelechi, Ph.D.
Deloitte

1) Coordination core connections:

Provide RADx-rad with guidance on how to establish internal core capabilities

- Technology validation
- Clinical studies
- Test deployment

Connect RADx Rad investigators with relevant people and resources in RADx Tech network

2) Innovation funnel access:

Conduct “deep dives” on select RADx-rad projects ready for acceleration

- Develop path for validation, regulatory approval, commercialization, manufacturing
- Potential for additional “Phase 1” funding to accelerate

DATA MANAGEMENT & COMMON DATA ELEMENTS (CDEs)

Speakers

Susan K. Gregurick., Ph.D.

Associate Director for Data Science, National Institutes of Health (NIH)
cooperj@nidcd.nih.gov

Patricia F. Brennan, RN, Ph.D.

Director, National Library of Medicine (NLM)
ppowell@mail.nih.gov

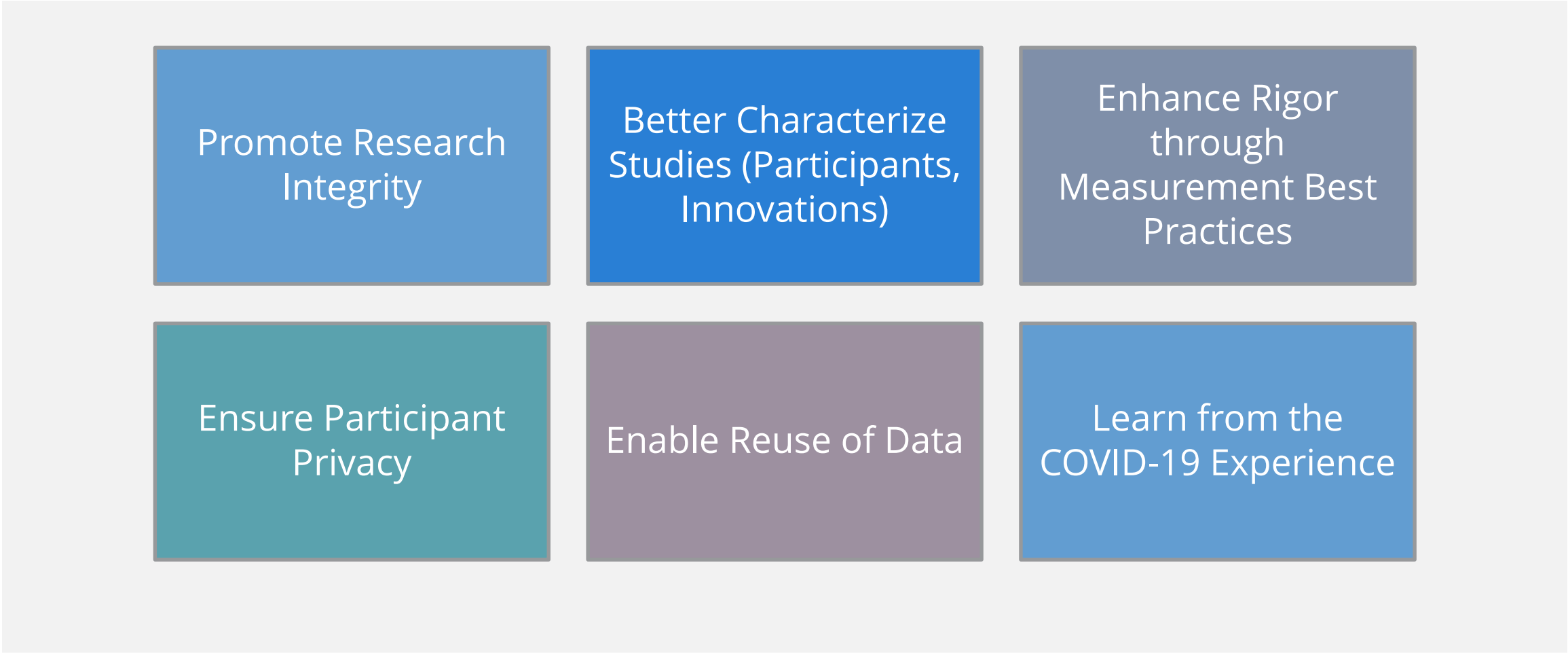
Background: Overall Vision

Researchers will need a single access point to de-identified RADx and related data, algorithms, and other capabilities generated by various digital health solutions and RADx technologies.

The RADx Data Hub is envisioned to work with RADx projects, through Data Coordination Centers to:

- **Provide a research data repository of curated and de-identified RADx data**, allowing researchers to find, aggregate, and perform analysis of these data, within a STRIDES cloud-enabled platform
- **Allow researchers the ability to share results of analyses**, citing relevant data, with collaborators and with the external community
- **Provide a portal for researchers to find additional curated and de-identified data** on NIH supported COVID resources
- Working with NIH supported COVID programs, **develop and/or implement standards**, CDEs, CDMs and best practices

Data management goals across the RADx RAD Programs



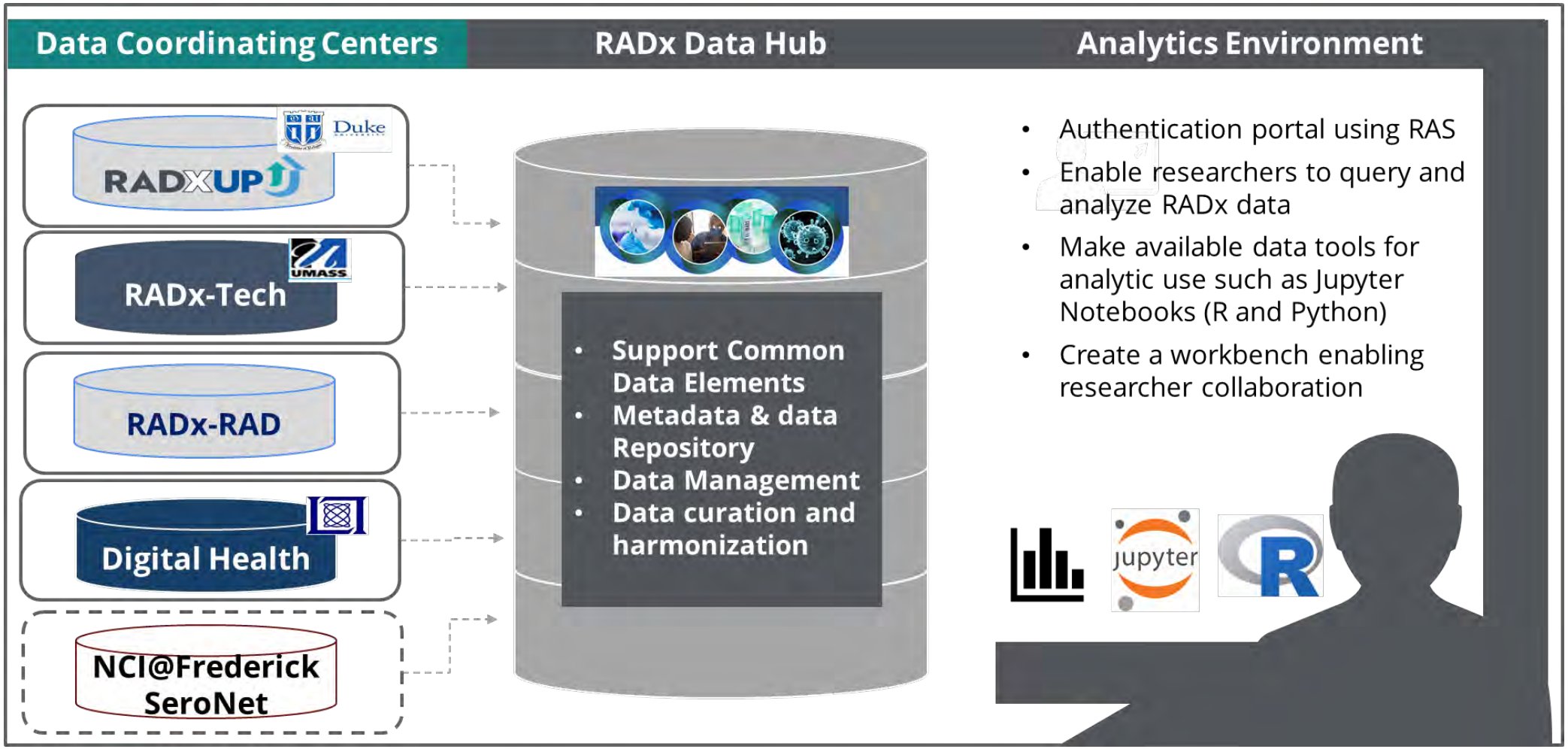
RADx Data Hub

Access to deidentified RADx and related data, algorithms, and other capabilities generated by RADx program and related technologies.

- Working with the RADx Data Coordinating Centers to keep as much of the data curation and management effort with the investigators

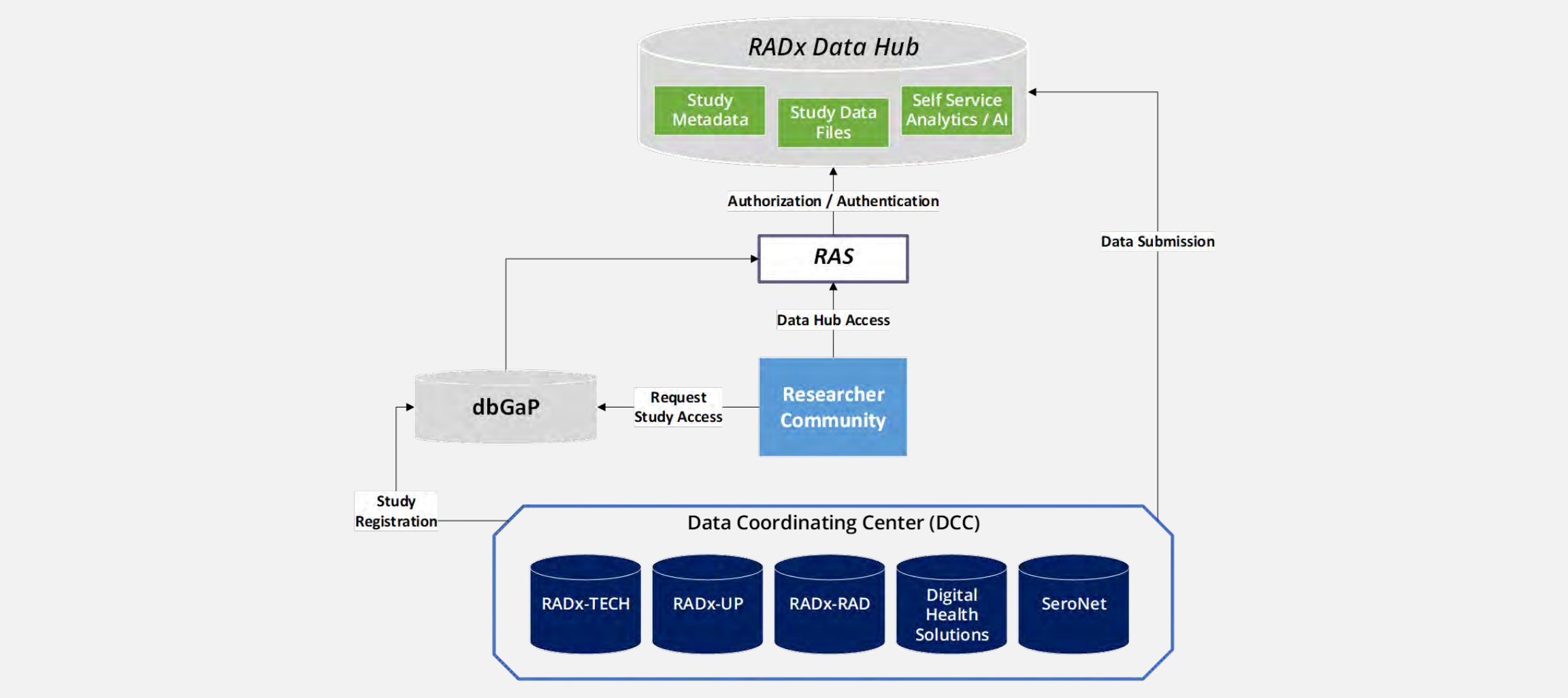
RADx Data Hub

RADx DCCs are working with their communities on CDEs, data management, de-identifying data, with NIH on developing metadata, and depositing this in the RADx data hub.



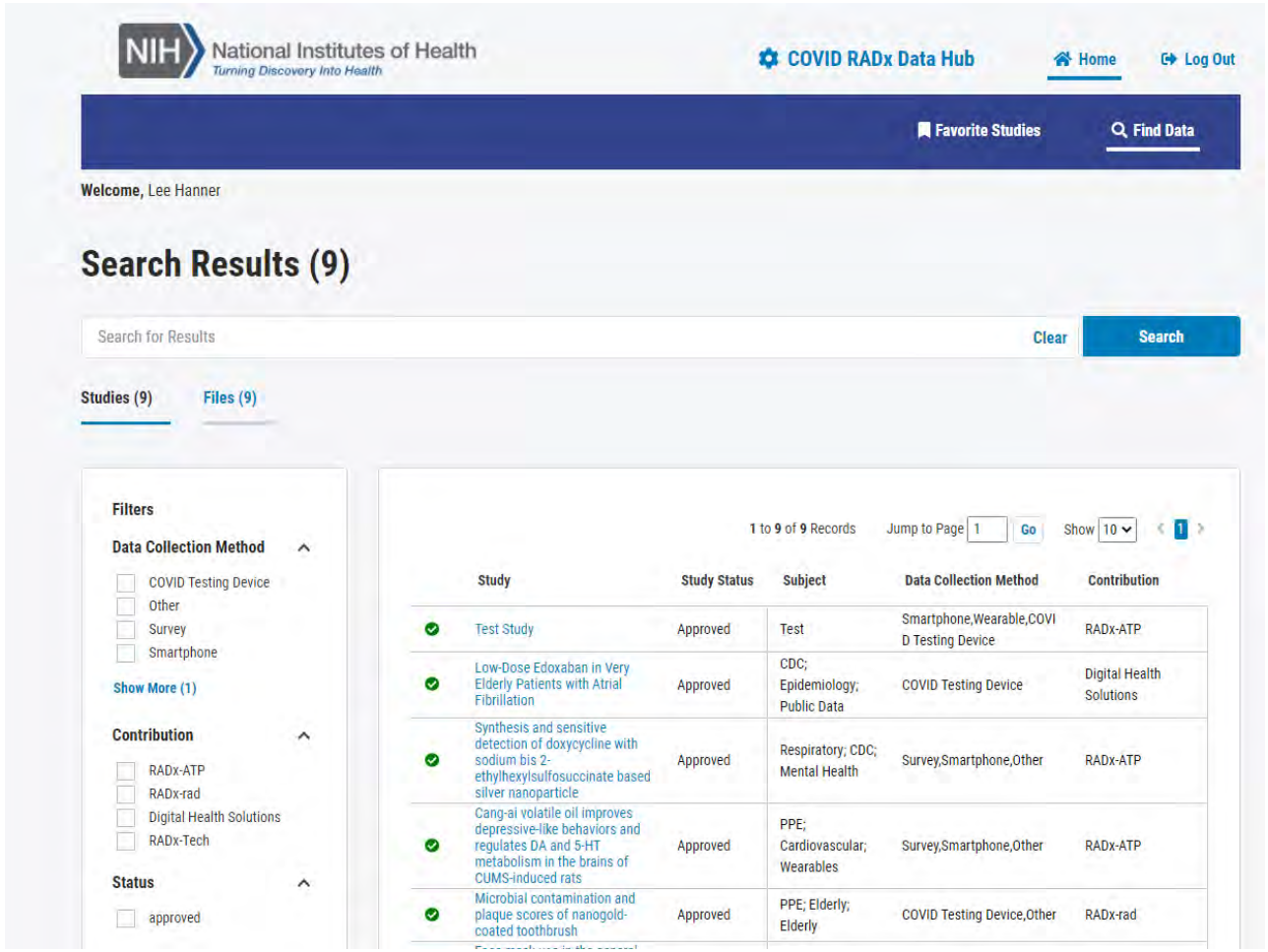
RADx Data Hub

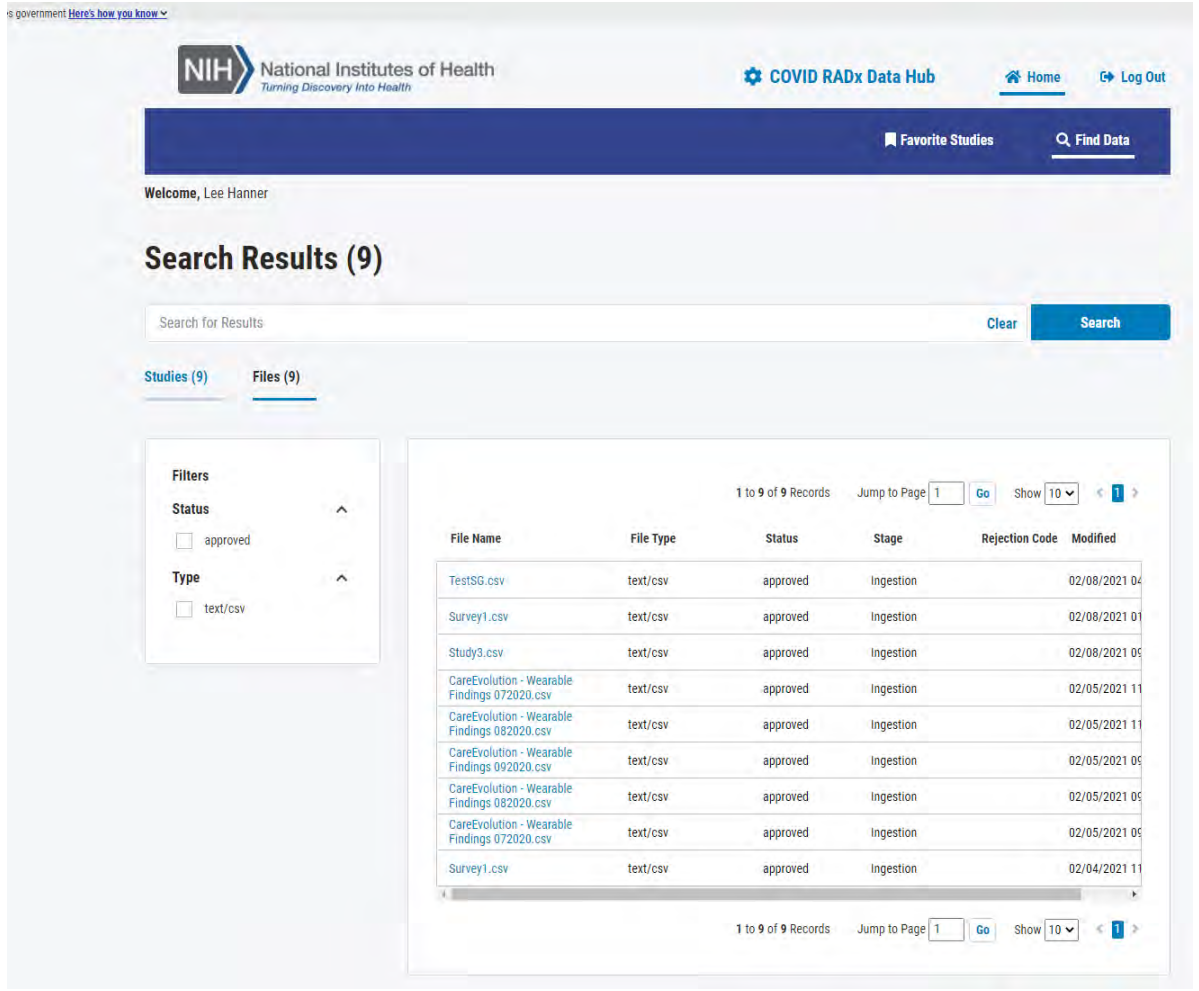
High-level Data Context Diagram



Researcher Workbench in the RADx Data Hub

The screenshots below demonstrate the features available to the Researcher to browse Studies and their associated Data files available within the RADx Data Hub.





Rigor and Reproducibility across RADx RAD project

We're paying attention to data security, participant privacy, and encouraging the use of common data elements across studies to enable future researchers to make use of the data.

- *Data Harmonization*
- *Security*
- *Common Data Elements*
- *Mapping to Data Models*

Data Harmonization

Data harmonization is the process of bringing together data of naming conventions and transforming it into one cohesive data set.

At the point of data deposit: Use Curation strategies.

At the point of data collection: Use Common Data Elements.

Common Data Elements "Question-Answer" Pair

- A combination of:
  - A defined variable or question
  - Paired with a specified set of similarly coded permissible responses to questions
- Designated for use in multiple data sets or used across different studies
- Structured as a:
  - Single data element
  - A collection of data elements to compute a survey score
- Captures essential features of participants, interventions, environments
- Not every variable, but critical variables:
  - Required, tier 1, minimum – for EVERY study
  - Recommended, tier 2, core – best practice for assessing specific variables

Common Data Element Resources

- Where can our team find measures?
  - NIH CDE repository (https://cde.Nlm.Nih.Gov/home)
  - PhenX (www.Phenxtoolkit.Org)
  - Disaster research response (https://dr2.Nlm.Nih.Gov)

- Is there one approved list of NIH CDEs?
  - No – CDEs must meet the measurement needs of projects and programs
  - Projects propose set of CDEs (items or scales) and psychometric support
  - NIH CDE governance group reviews project/program submissions

- Data coordination center provides technical support

CDE Expectations for RADx RAD Projects

Human Participants?

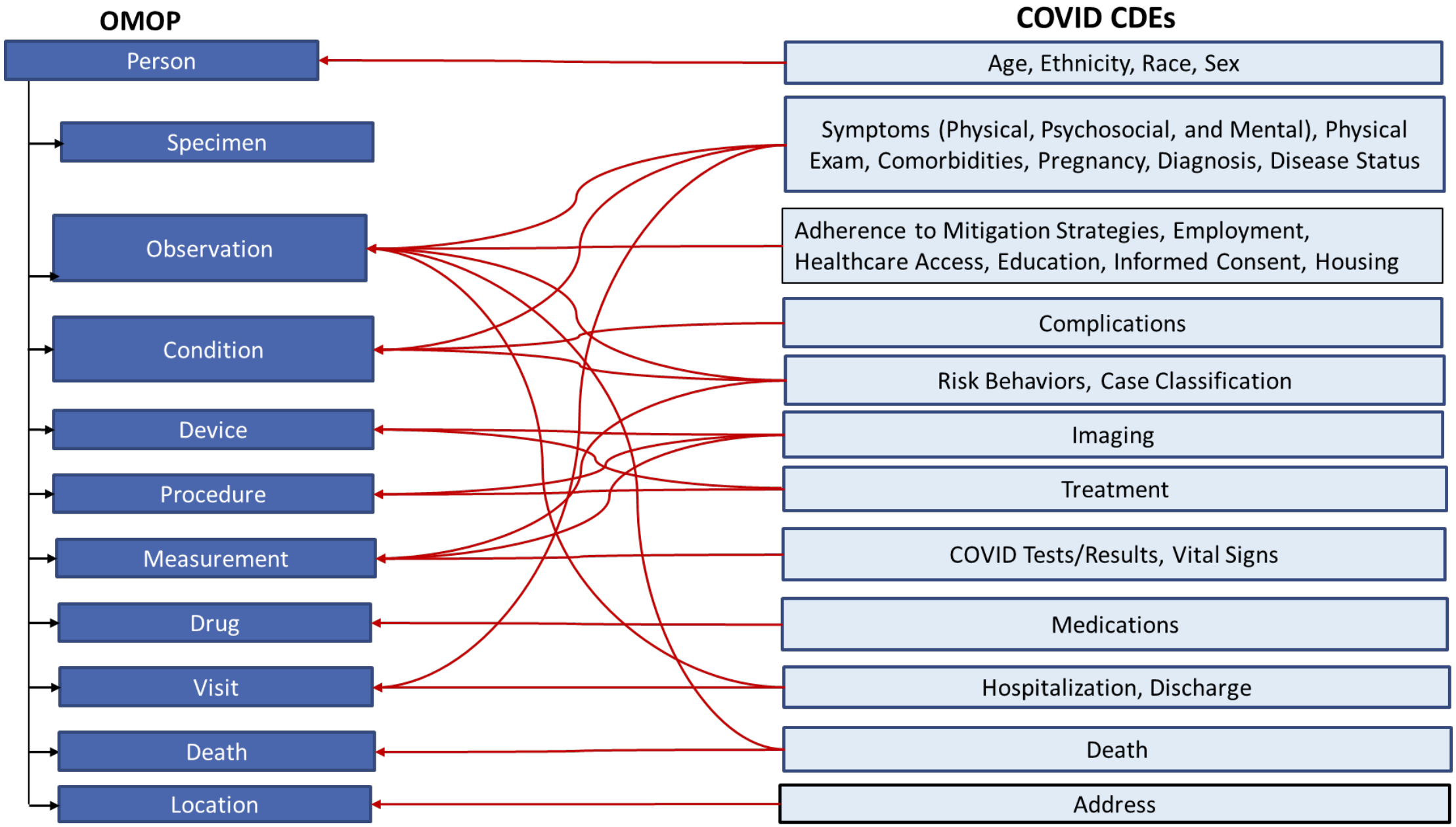
- Collect RADx executive required CDEs
- Work with dcc to identify:
  - Required CDEs unique to RADx-rad needs
  - Recommended CDEs relevant to RADx-rad needs

No Human Participants?

- Work with DCC to identify:
  - Required CDEs unique to RADx-rad needs
  - Recommended CDEs relevant to RADx-rad needs

RADx All Required (Tier 1, Minimum)

Concept	
Identity	
Race & Ethnicity	American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, More than one race, Unknown//Hispanic or Latino, Not Hispanic or Latino, Unknown
Age	Date of birth
Sex	Biological sex assigned at birth
Education	Formal years of education
Domicile	Current Address
Employment	Yes/no/temporary
Insurance Status	private/public/none
Disability status	Six-item Standard Disability Questions (CDC; hearing, seeing, making decisions, bathing…)
Medical history	Substance use including vaping; asthma; cancer; cardiovascular disease; chronic kidney disease; chronic lung disease; diabetes; hypertension; immunosuppressive condition; serious mental illness; sickle cell disease; pregnancy status
Symptoms	Cough, fever, difficulty breathing, headache; muscle ache, loss of taste or smell, chills, excessive fatigue; N/V, diarrhea, abdominal pain, skin rash, conjunctivitis
Health Status	BMI (weight and height), single-question (How good is your health?)


OMOP
Person
Specimen
Observation
Condition
Device
Procedure
Measurement
Drug
Visit
Death
Location
COVID CDEs
Age, Ethnicity, Race, Sex
Symptoms (Physical, Psychosocial, and Mental), Physical Exam, Comorbidities, Pregnancy, Diagnosis, Disease Status
Adherence to Mitigation Strategies, Employment, Healthcare Access, Education, Informed Consent, Housing
Complications
Risk Behaviors, Case Classification
Imaging
Treatment
COVID Tests/Results, Vital Signs
Medications
Hospitalization, Discharge
Death
Address

From Data Elements to COMMON Data Elements – Example

Data Elements

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. Protections
    a. Mask
    b. Social Distancing
10. Work location
11. Family
    a. Adults
    b. Children
12. Health Status
13. Symptoms
14. Disability
15. Medical History
16. Nicotine Use
17. Alcohol Use
18. Housing
19. Usual Place of Health Care
20. Chest exam

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19. Usual Place of Health Care
20. Chest exam

KEY: **RED** Data Elements = Data Elements Required Across All RADx Projects

From Data Elements to COMMON Data Elements – Example

RADx-Rad Project A

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. (9)Protections
    1. Mask
    2. Social Distancing
10. (11) Health Status
11. (14) Disability

Data Elements

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. Protections
    a. Mask
    b. Social Distancing
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11. Family
    a. Adults
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12. Health Status
13. Symptoms
14. Disability
15. Medical History
16. Nicotine Use
17. Alcohol Use
18. Housing
19. Usual Place of Health Care
20. Chest exam

KEY: **RED** Data Elements = Data Elements Required Across All RADx Projects
Blue Data Elements = Data Elements Included for RADx-Rad Project A

From Data Elements to COMMON Data Elements – Example

RADx-Rad Project A

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. (9)Protections
    1. Mask
    2. Social Distancing
10. (11) Health Status
11. (14) Disability

Data Elements

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. Protections
    a. Mask
    b. Social Distancing
10. Work location
11. Family
    a. Adults
    b. Children
12. Health Status
13. Symptoms
14. Disability
15. Medical History
16. Nicotine Use
17. Alcohol Use
18. Housing
19. Usual Place of Health Care
20. Chest exam

RADx-Rad Project B

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. (18) Housing
10. (10) Work location
11. (14) Disability
12. (20) Chest Exam

KEY: **RED** Data Elements = Data Elements Required Across All RADx Projects
Blue Data Elements = Data Elements Included for RADx-Rad Project A
Purple Data Elements = Data Elements Included for RADx-Rad Project B

From Data Elements to COMMON Data Elements – Example

RADx-Rad Project A

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. (9)Protections
    1. Mask
    2. Social Distancing
10. (11) Health Status
11. (14) Disability

Data Elements

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. Protections
    a. Mask
    b. Social Distancing
10. Work location
11. Family
    a. Adults
    b. Children
12. Health Status
13. Symptoms
14. Disability
15. Medical History
16. Nicotine Use
17. Alcohol Use
18. Housing
19. Usual Place of Health Care
20. Chest exam

RADx-Rad Project B

1. Sex
2. Age
3. Race
4. Ethnicity
5. Education
6. Domicile
7. Health Insurance
8. Employment
9. (18) Housing
10. (10) Work location
11. (14) Disability
12. (20) Chest Exam

KEY:

RED Data Elements = Data Elements Required Across All RADx Projects

Blue Data Elements = Data Elements Included for RADx-Rad Project A

Purple Data Elements = Data Elements Included for RADx-Rad Project B

Green Data Elements = Data Elements Included for both RADx-Rad Project A & B

RADx-RAD DCC OVERVIEW

Speakers

Lucila Ohno-Machado, M.D., Ph.D.

Professor of Medicine and Chair of the Department of Biomedical Informatics, University of California San Diego
lohnomachado@health.ucsd.edu

Hua Xu, Ph.D.

Professor and Director of Center for Computational Biomedicine, UTHealth
hua.xu@uth.tmc.edu

Eliah Aronoff-Spencer

Assistant Professor of Medicine, University of California San Diego
earonoffspencer@health.ucsd.edu

RADx Rad Discovery & Data Consortium Coordination Center & Program Organization

Introduction and Q&A

No Conflicts of Interest to Disclose

CENTER FUNCTIONS 1

- Support IRB and trial design
- 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
- Support production of *comparable* data
  - Provide protocol support
  - Provide Viral Quality Assurance panels with known viral concentrations
  - Provide Benchmarking Services for new diagnostic performance and usability
- Provide a preconfigured Laboratory Information Management System (LIMS) for data collection and sharing

CENTER FUNCTIONS 2

- 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
- Advise on:
  - Diagnostic test metrics, usability
  - Vendors and Resources
  - Regulatory questions & FDA submissions
  - Intellectual property issues
- Offer training to enhance teamwork, anti-racism

CENTER ORGANIZATION

Multiple PIs

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

Infectious Diseases, User Centered Design, Diagnostics & Informatics

Lucila Ohno-Machado, MD, PhD — UTHealth The University of Texas Health Science Center at Houston

Privacy Technology, Predictive Modeling, Evaluation Methods

Hua Xu, PhD

Data Representation, Biomedical Natural Language Processing

NLM Team

Program Officer:

Yanli Wang, PhD

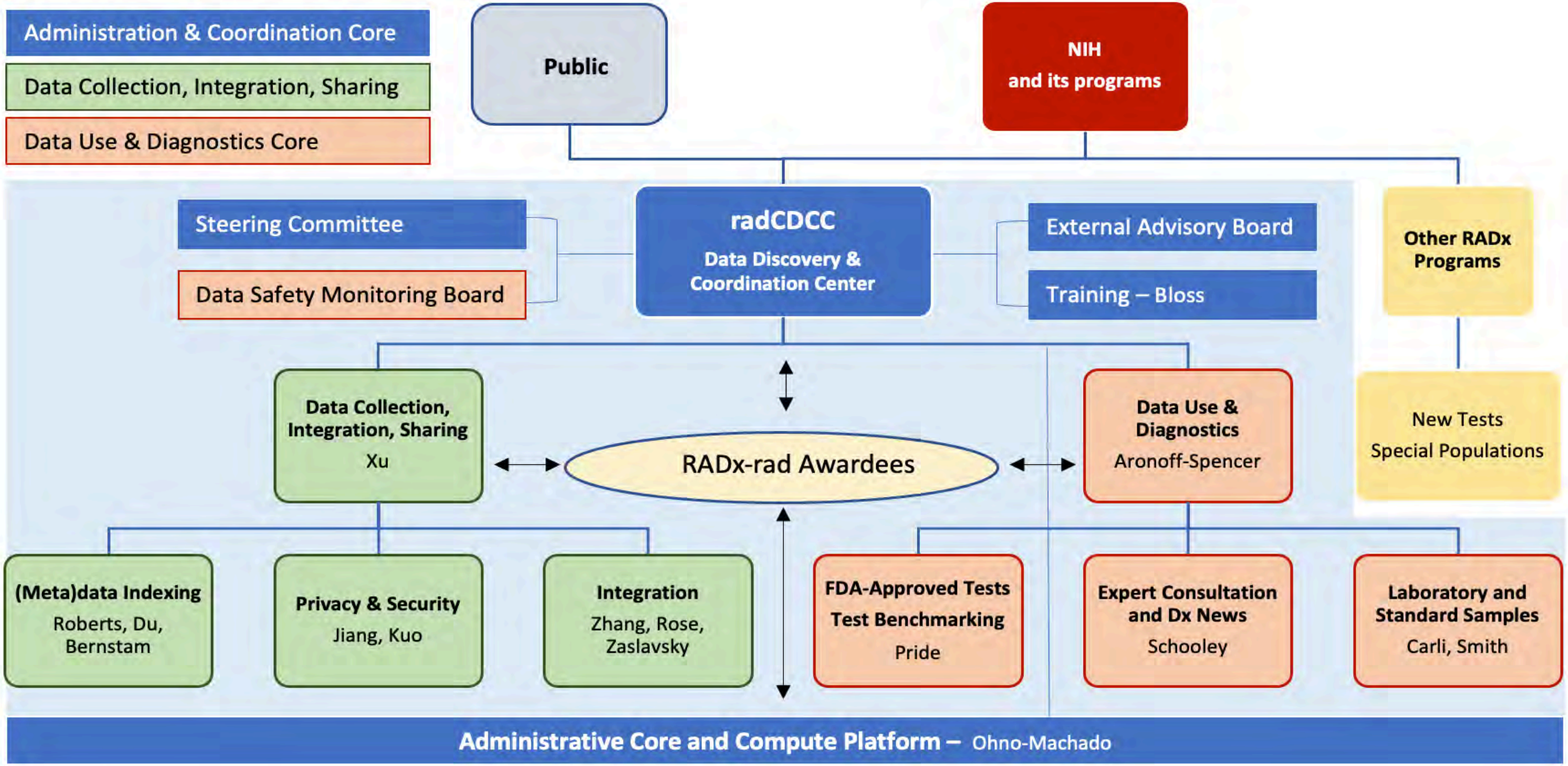
Project Scientists:

Dina Demner-Fushman, MD, PhD

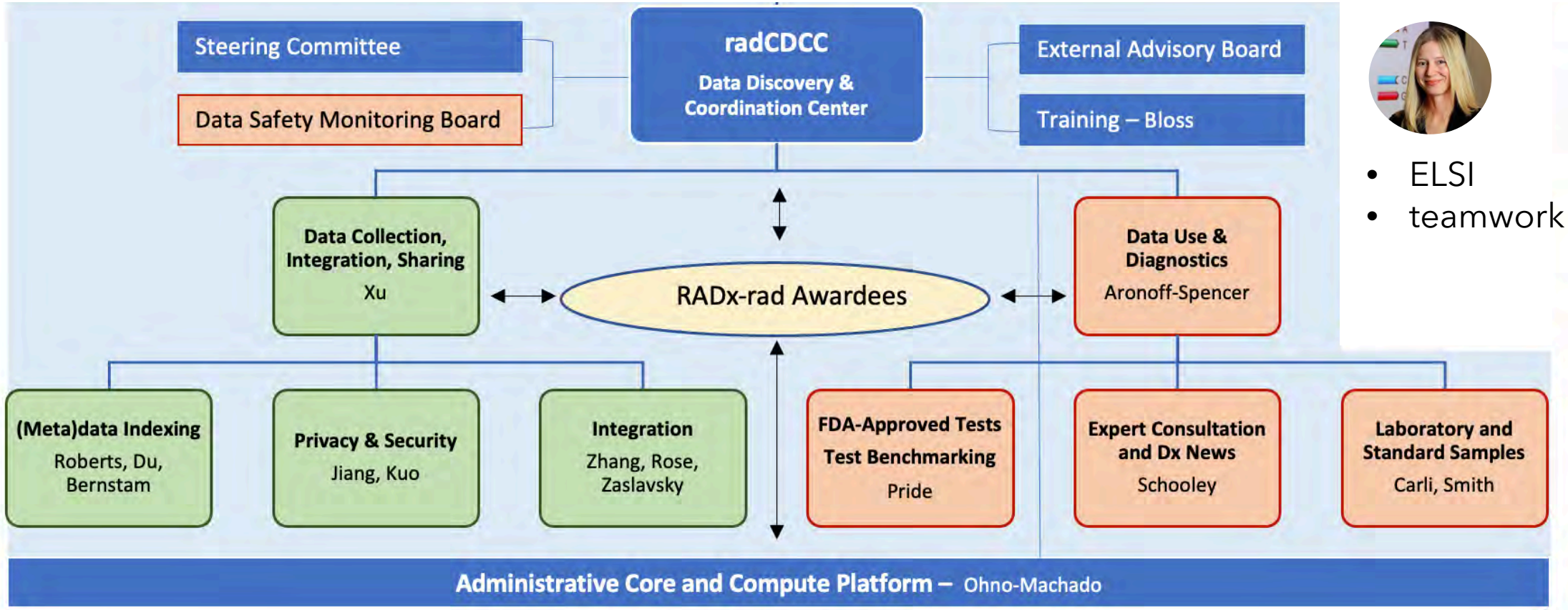
Leslie Derr, PhD

Anthony Kirilusha, PhD

Marie Gallagher


Administration & Coordination Core
Data Collection, Integration, Sharing
Data Use & Diagnostics Core
Public
NIH
and its programs
Steering Committee
Data Safety Monitoring Board
radCDCC
Data Discovery &
Coordination Center
External Advisory Board
Training – Bloss
Other RADx
Programs
Data Collection,
Integration, Sharing
Xu
RADx-rad Awardees
Data Use &
Diagnostics
Aronoff-Spencer
New Tests
Special Populations
(Meta)data Indexing
Roberts, Du,
Bernstam
Privacy & Security
Jiang, Kuo
Integration
Zhang, Rose,
Zaslavsky
FDA-Approved Tests
Test Benchmarking
Pride
Expert Consultation
and Dx News
Schooley
Laboratory and
Standard Samples
Carli, Smith
Administrative Core and Compute Platform – Ohno-Machado

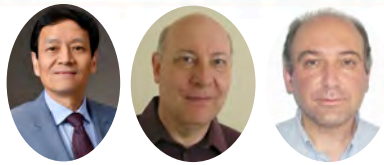
Program Management



- ELSI
- teamwork

- data transformations
- standards

- "de-identification"
- ledger/auditing



- data transfer
- integration

- test eval

- COVID expert

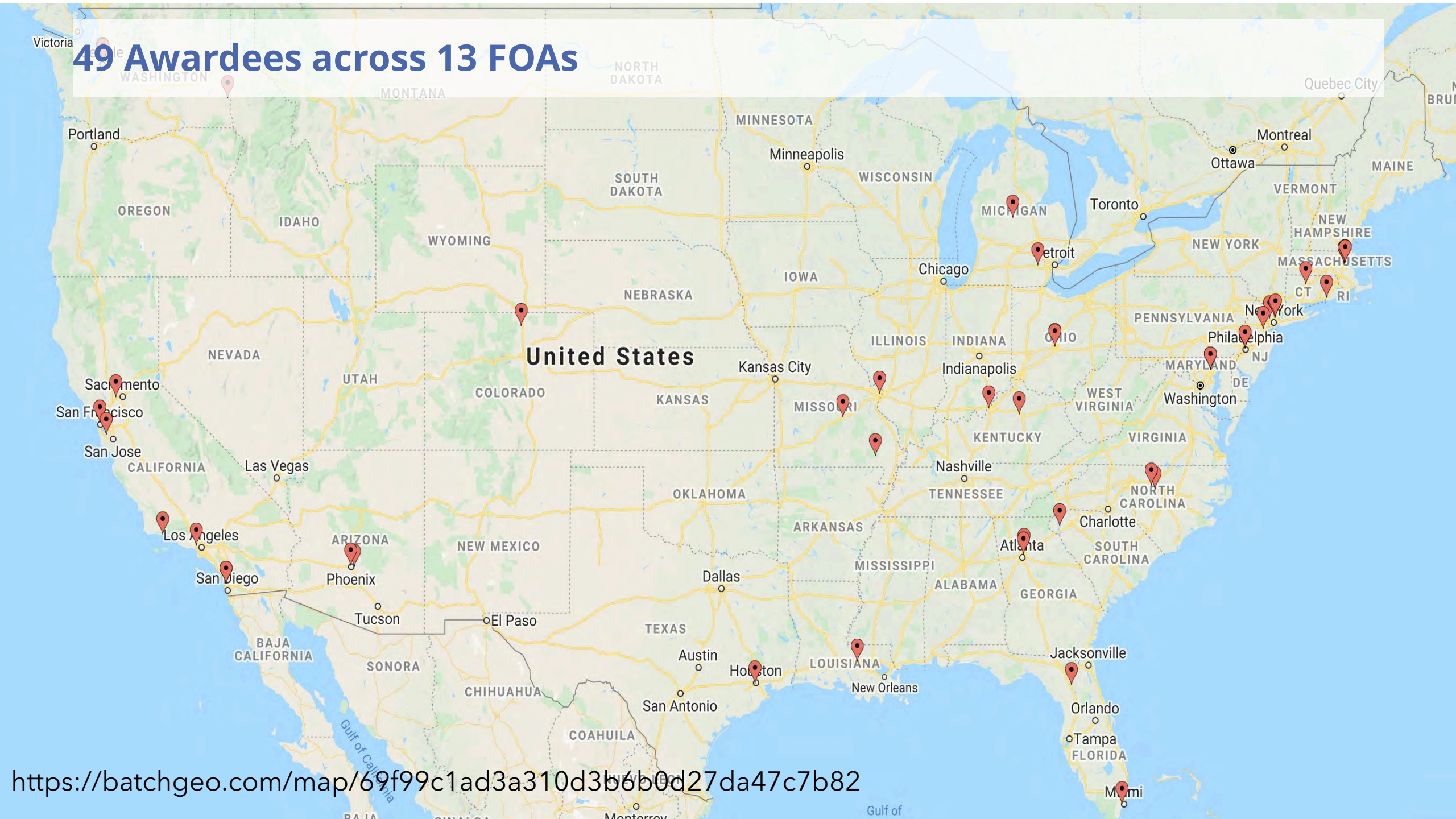
- send VQA
- test usage

49 Awardees

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	Nanobody-based Electrochemical Biosensor for Real-Time Detection of Aerosolized SARS-CoV-2	Washington University
RFA-OD-20-014	6	Detection 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	Marshallese: 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 Singlemolecule 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 across 13 FOAs



https://batchgeo.com/map/69f99c1ad3a310d3b6b0d27da47c7b82

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)

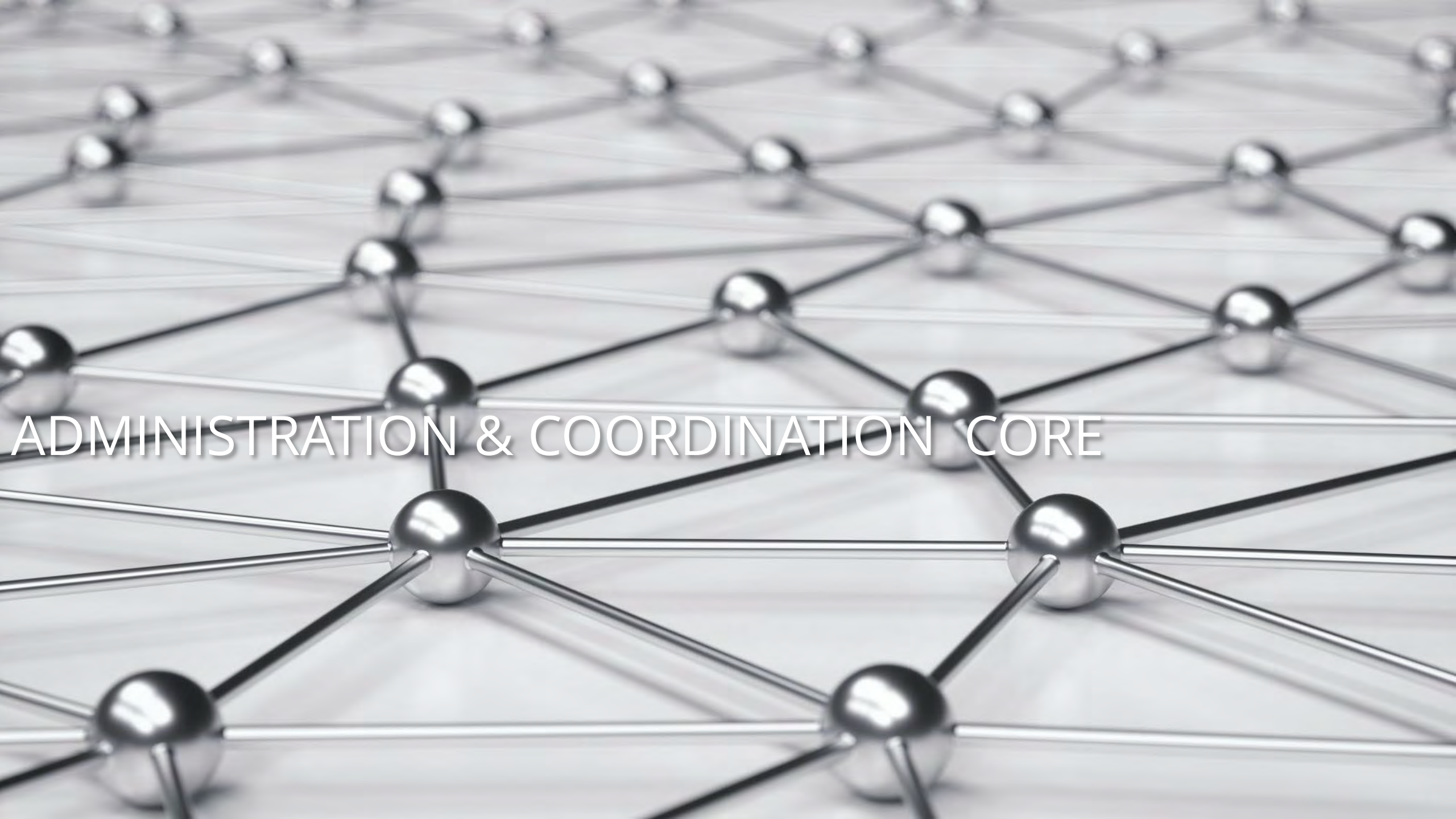
- National Institute of Environmental Health Sciences

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

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
- ✓ Organize DSMB
- ✓ 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

Data Core

Assist in Data Collection

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

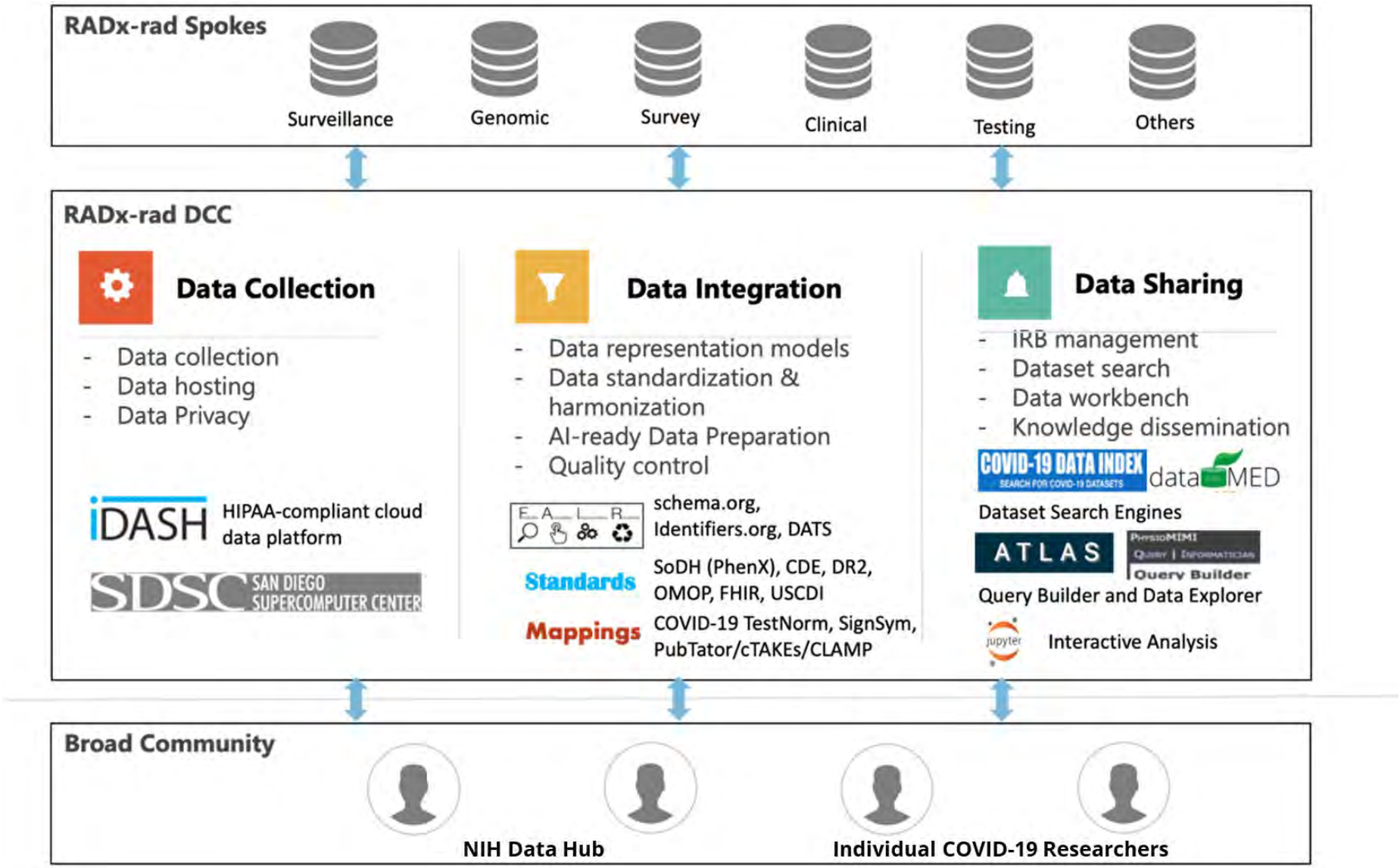
Data Transformation and Organization

OMOP
CDE
PhenX
Metadata
AI-ready

Data Sharing

Privacy technology
IRB
DUAs
data analyses

Data Core

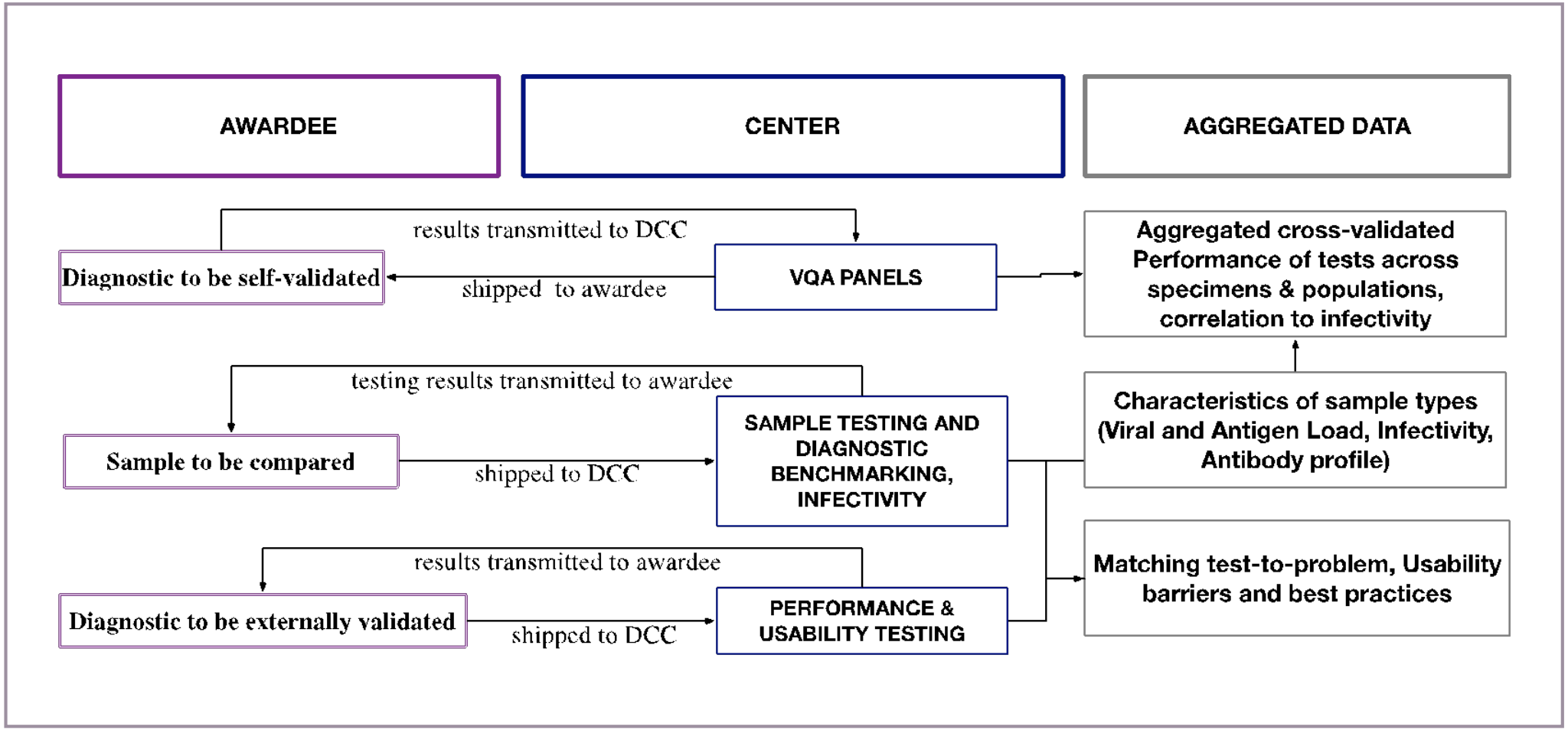

RADx-rad Spokes
Surveillance
Genomic
Survey
Clinical
Testing
Others
RADx-rad DCC
Data Collection
- Data collection
- Data hosting
- Data Privacy
iDASH
HIPAA-compliant cloud data platform
SDSC
SAN DIEGO SUPERCOMPUTER CENTER
Data Integration
- Data representation models
- Data standardization & harmonization
- AI-ready Data Preparation
- Quality control
FAIR
schema.org, Identifiers.org, DATS
Standards
SoDH (PhenX), CDE, DR2, OMOP, FHIR, USCDI
Mappings
COVID-19 TestNorm, SignSym, PubTator/cTAKEs/CLAMP
Data Sharing
- IRB management
- Dataset search
- Data workbench
- Knowledge dissemination
COVID-19 DATA INDEX
SEARCH FOR COVID-19 DATASETS
dataMED
Dataset Search Engines
ATLAS
PhysioMIMI
Query | Informatician
Query Builder
Query Builder and Data Explorer
jupyter
Interactive Analysis
Broad Community
NIH Data Hub
Individual COVID-19 Researchers

Initial Activities of Data Core

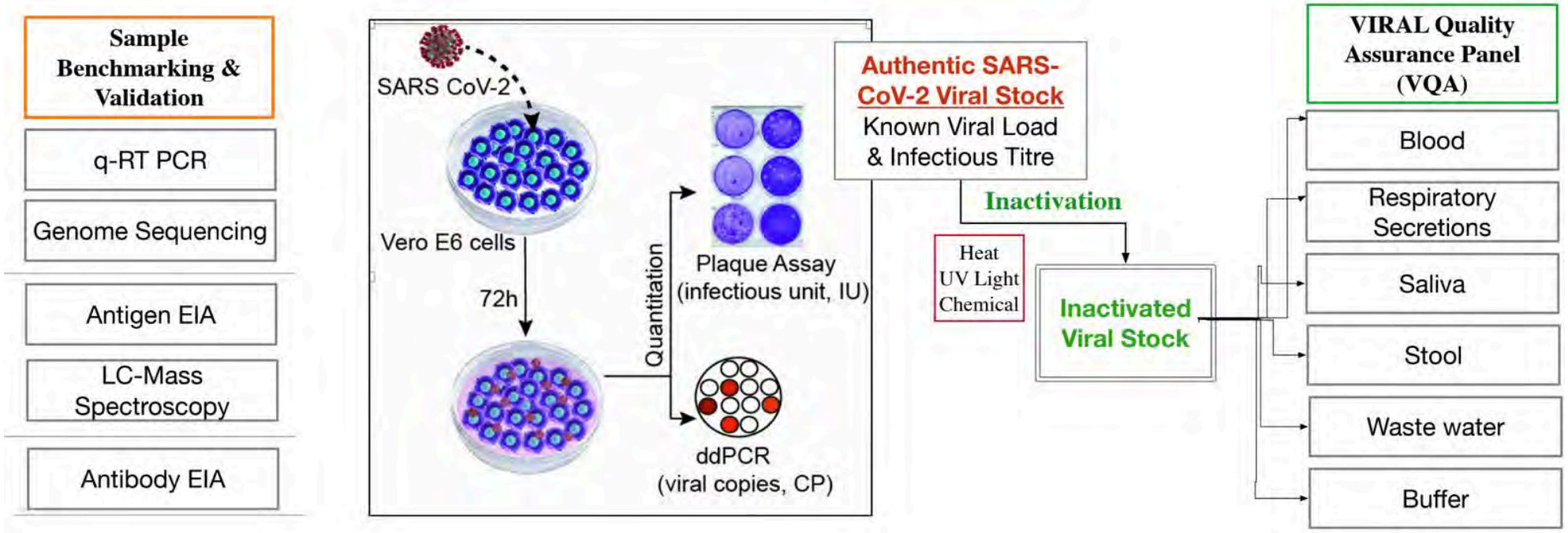
- ✓ Survey on datasets that will be generated from the RADx-rad program and other related efforts
- ✓ Communication structure with RADx-rad spokes (e.g., meetings, point of contact for with domain expertise for each data type)
- ✓ Resources for data collection, integration and sharing
  - Computational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

DISCOVERY & DIAGNOSTICS CORE

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

D-C3PO member Dashboard

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 valididation of molecular ostics across specimens

ethods to develop connected cancer care solutions has 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 a low prevalence settings

Dx DIAGNOSTICS

mdl_search

1 Request VQA Panel

2 Send Sample to verify

3 Send Test to validate

4 Protocols & Usability

post data

pull


ROADMAP

Immediate Steps

DCC to meet with POs of every FOA

DCC to meet with PIs, and conduct needs analysis

Organize Steering Committee

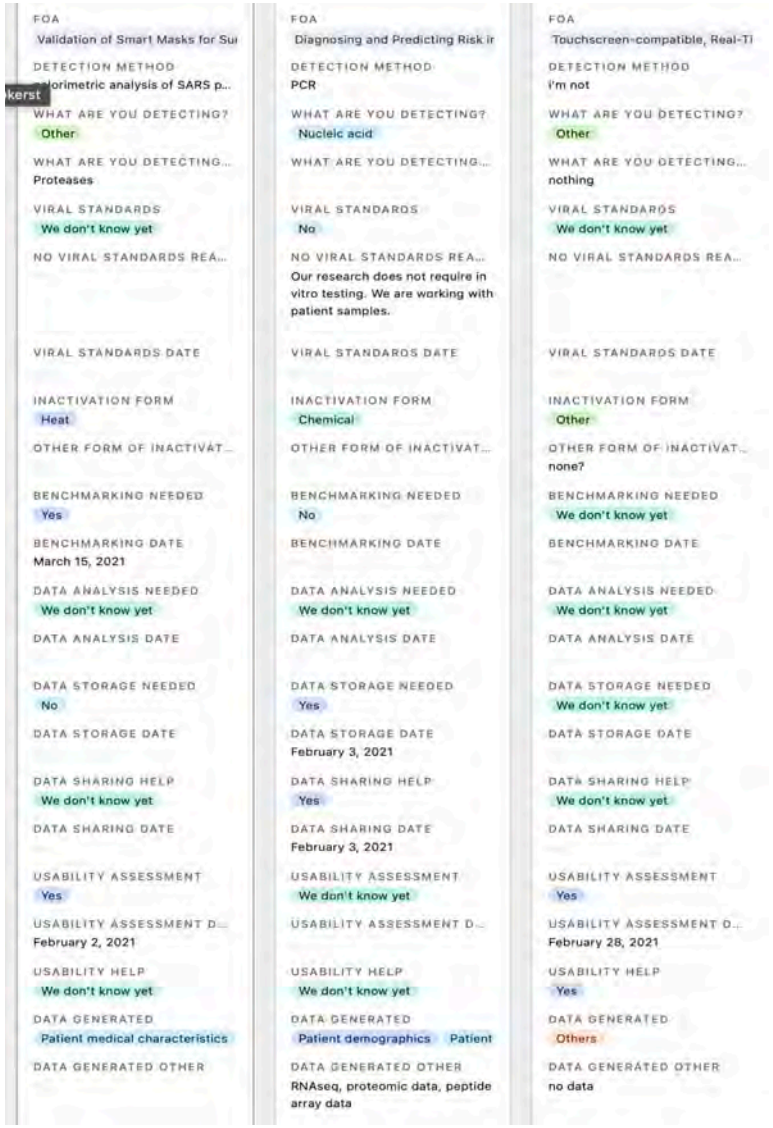
Organize DSMB

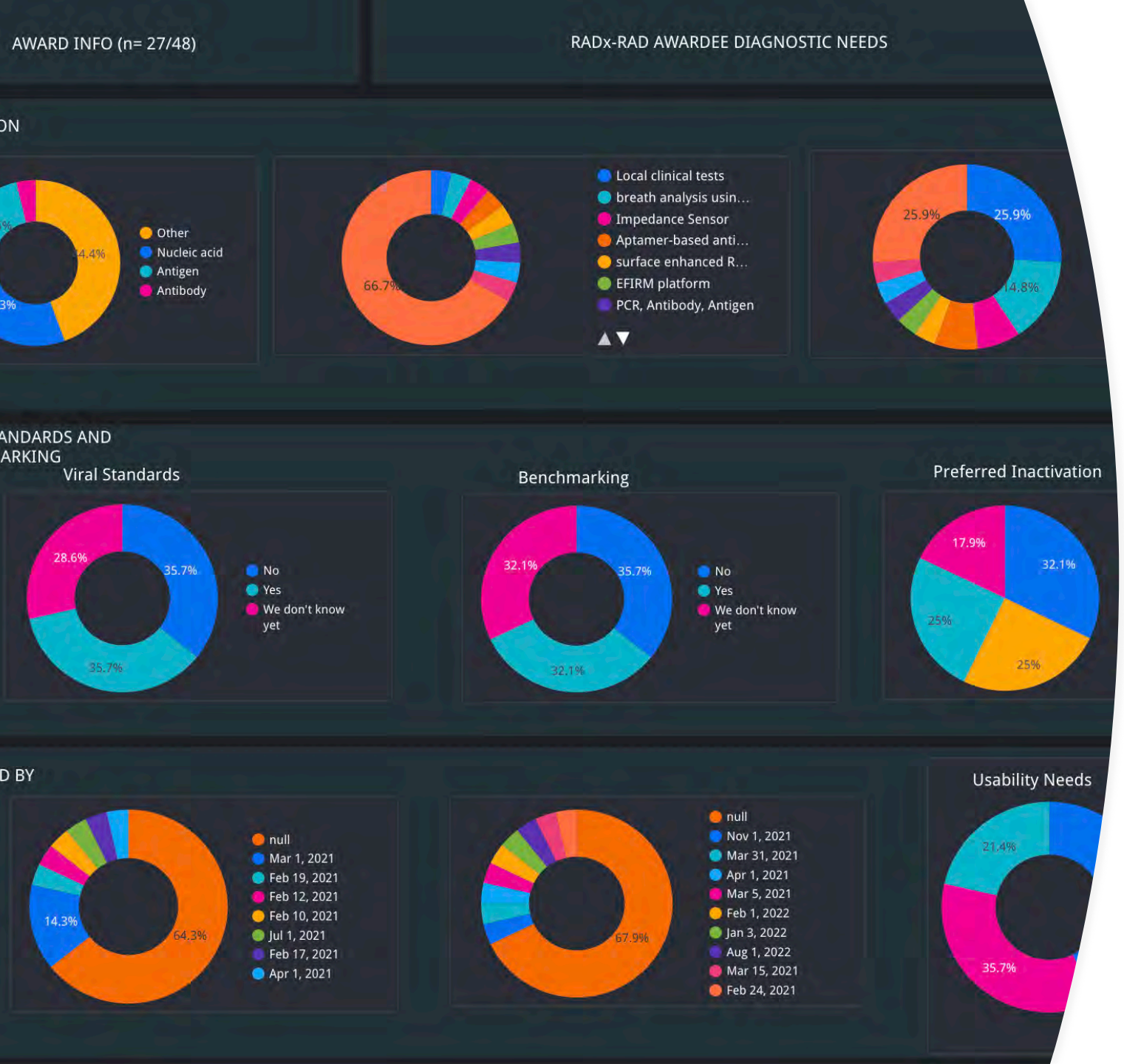
Organize cloud infrastructure for 48 projects

Schedule monthly all-hands calls

Needs Assessment Survey - the questions we're asking

- ✓ 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?

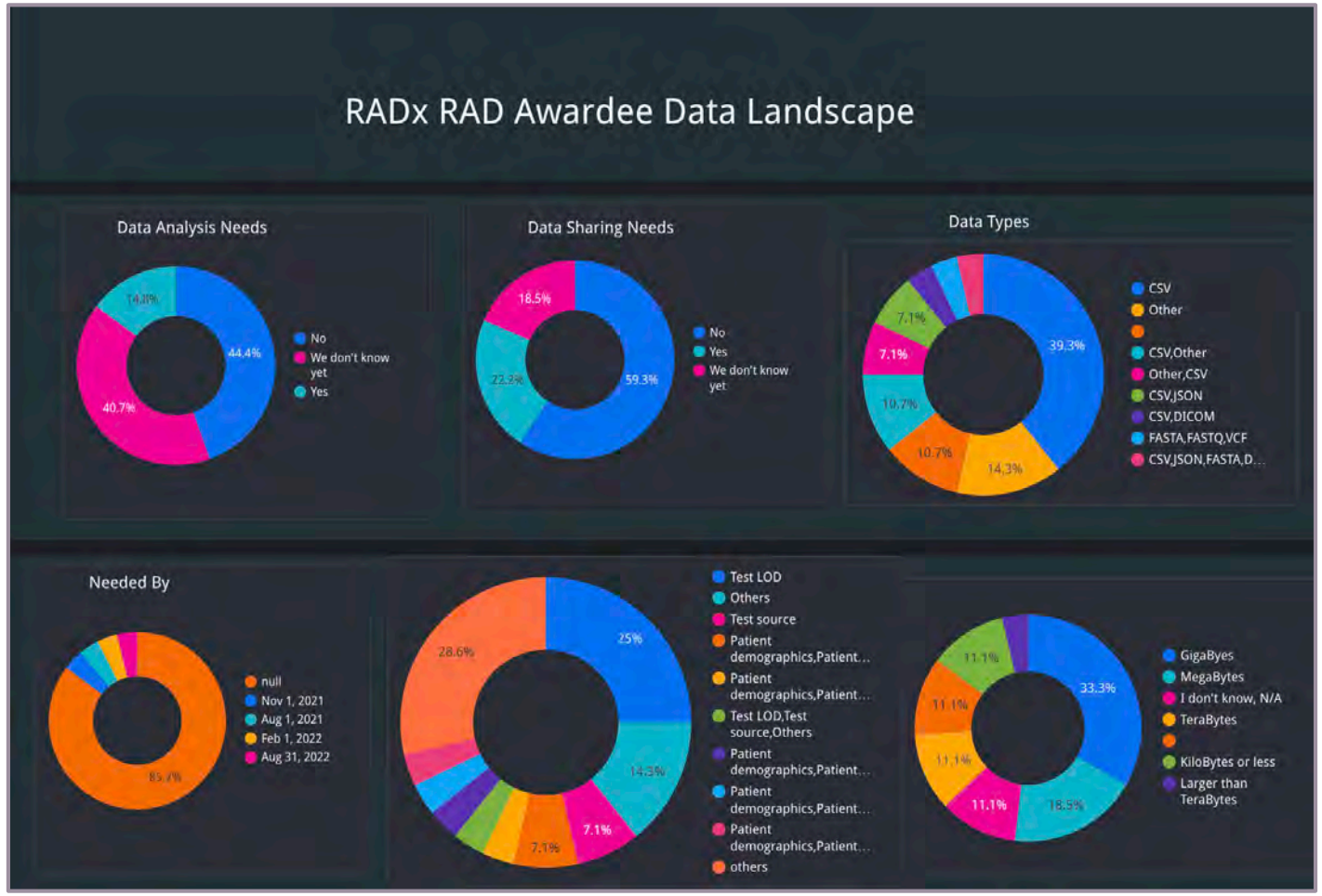




Diagnostics Needs: Preliminary results

- 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!
To the NIH and RADx-rad awardees

FDA BRIEFING

Speaker

Sara Brenner, M.D., MPH

Associate Director for Medical Affairs, Office of Health Technology, Food and Drug Administration (FDA)

Sara.brenner@fda.hhs.gov

COVID-19 Emergency Use Authorization and FDA-RADx Program Engagement

Sara Brenner, MD, MPH

Associate Director for Medical Affairs

Chief Medical Officer for In Vitro Diagnostics

Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA

Diagnostic Data Lead, Data Strategy and Execution Workgroup

COVID-19 National Response, U.S. Department of Health and Human Services

February 22, 2021

EUA Authority

Section 564 of the Federal Food, Drug and Cosmetic Act (FD&C Act)

- Amended by the Project Bioshield Act of 2004
- Amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)
- The 21st Century Cures Act of 2016
- Public Law 115-92 of 2017

EUA Authority

FDA can authorize:

- Use of unapproved MCMs (despite lacking the amount of data that would be necessary for approval)
- Unapproved use of approved MCMs (e.g., for a new indication) to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when certain criteria are met.

Emergency Use Authorizations: Diagnostics

Emergency Use Authorization

Emergency Use Authorization (EUA) information, and list of all current EUAs

Share | Tweet | Linkedin | Email | Print

Content current as of:

01/11/2021

RADx Focus

- COVID-19
- Federal not State specific EUAs
- Antigen & molecular (Viral RNA) not antibody (serology)

On this page:

- About Emergency Use Authorizations (EUAs)
- PREP Act
- EUA Guidance
- COVID-19 EUAs
  - In Vitro Diagnostic Products
  - Personal Protective Equipment and Related Medical Devices
  - Ventilators and Other Medical Devices
  - Drug and Biological Products
- Other Current EUAs
- Related Links

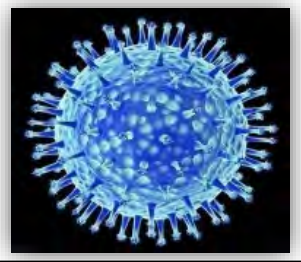
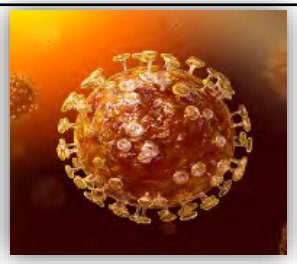
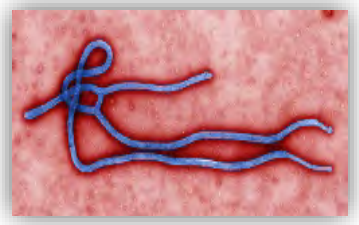
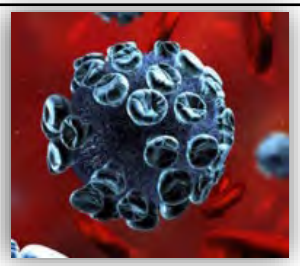
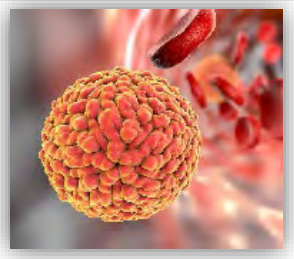
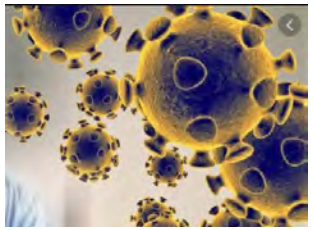
Photo Source: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

EUA and IVDs

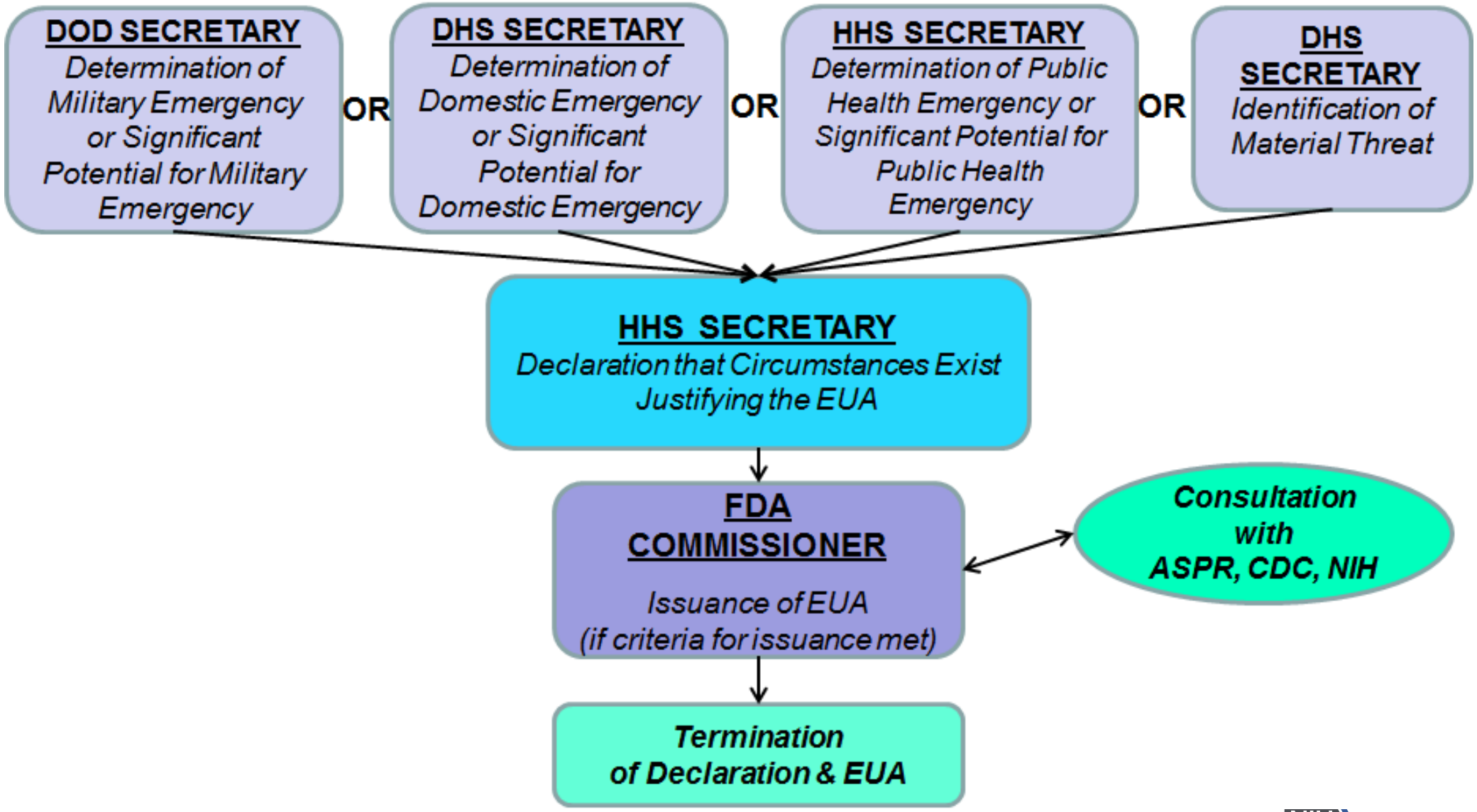
In vitro diagnostics play a very important role in any emergency response involving an emerging infectious disease - from initial outbreak detection, diagnosis, patient management and infection control.

In the absence of a cleared/approved FDA assay the EUA authority is a mechanism FDA can use to address a public health emergency.

HHS Secretary Declaration of Emergency or Threat

Influenza H7N9 Orthomyxoviridae	**MERS-CoV** Coronaviridae	**Ebola** Filoviridae	**Enteroirus D68** Picornaviridae	**Zika Virus** Flaviviridae	**2019-nCoV** Coronaviridae
					
April 19, 2013	May 29, 2013	August 4, 2014	February 6, 2015	February 26, 2016	January 31, 2020
Emergency Use of In Vitro Diagnostics for Detection of the Avian Influenza A (H7N9) Virus	Emergency Use of In Vitro Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus	Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus	Emergency Use of New In Vitro Diagnostics for Detection of Enterovirus D68	Emergency Use of In Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection	

EUA Determination and Declaration



Criteria for EUA

1. The agent causes a serious or life-threatening disease or condition.
2. Based on totality of scientific evidence, reasonable belief:
   - Product may be effective
   - Known/potential benefits outweigh known / potential risks
3. No adequate, approved, available alternative to the product

Types of EUAs: Diagnostics

Individual EUAs for **Molecular** Diagnostic Tests for SARS-CoV-2

Individual EUAs for **Antigen** Diagnostic Tests for SARS-CoV-2

RADx-Tech Focus

Umbrella EUAs for **Molecular** Diagnostic Tests for SARS-CoV-2 (*Developed And Performed By Laboratories Certified Under CLIA to Perform High Complexity Tests: LDTs)*

On occasion

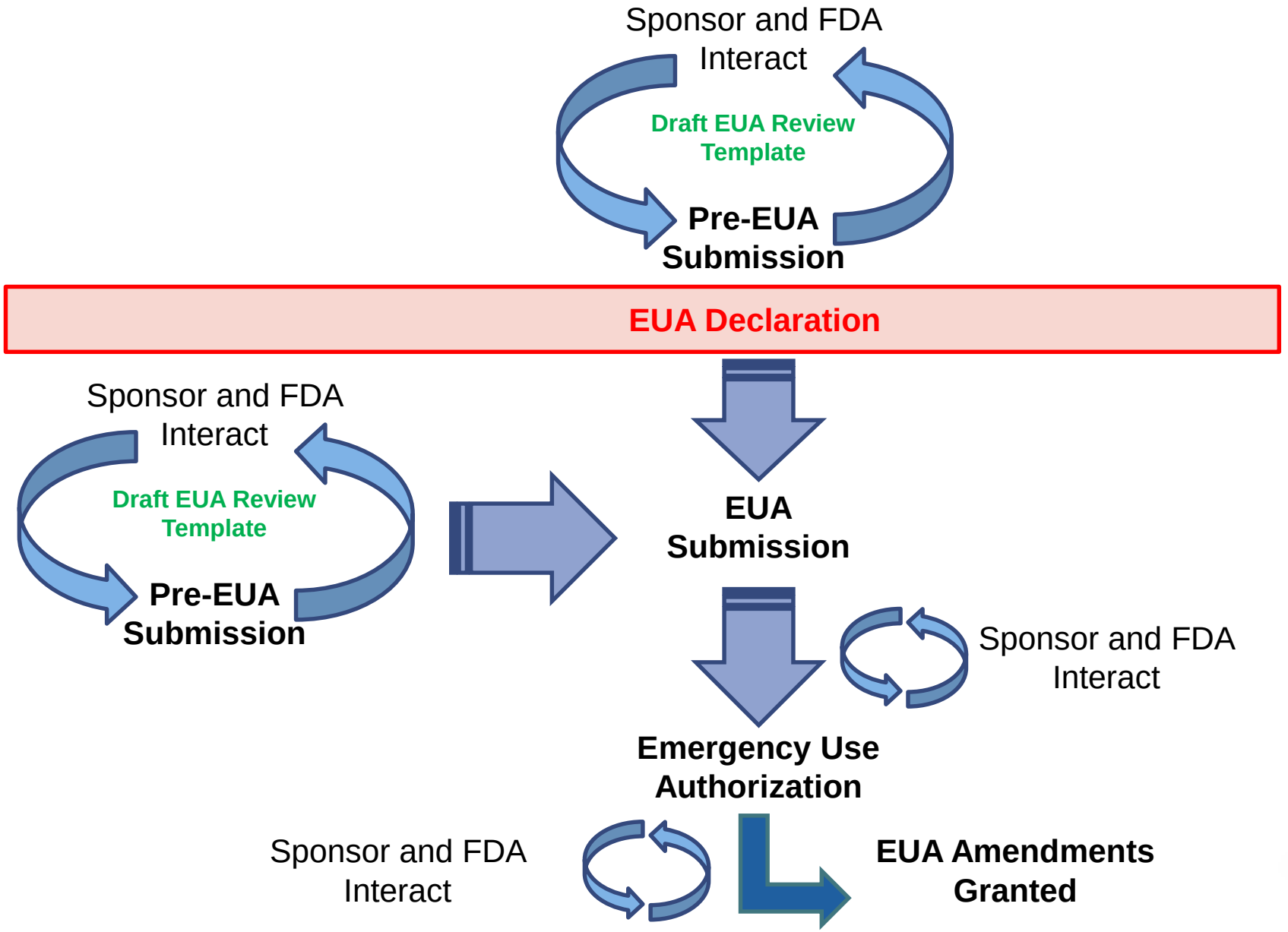
EUA Templates
As of February 2, 2021

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

- Molecular Diagnostic Template for Commercial Manufacturers (updated July 28, 2020)
- Molecular Diagnostic Template for Laboratories (updated July 28, 2020)
- Serology Template for Test Developers (November 24, 2020)
- Antigen Template for Test Developers (October 26, 2020)
- Home Specimen Collection Molecular Diagnostic Template (May 29, 2020)
- Home Specimen Collection Serology Template for Fingerstick Dried Blood Spot (November 24, 2020)
- Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (July 29, 2020)

Source: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

OPEQ/OHT7-OIR EUA Program



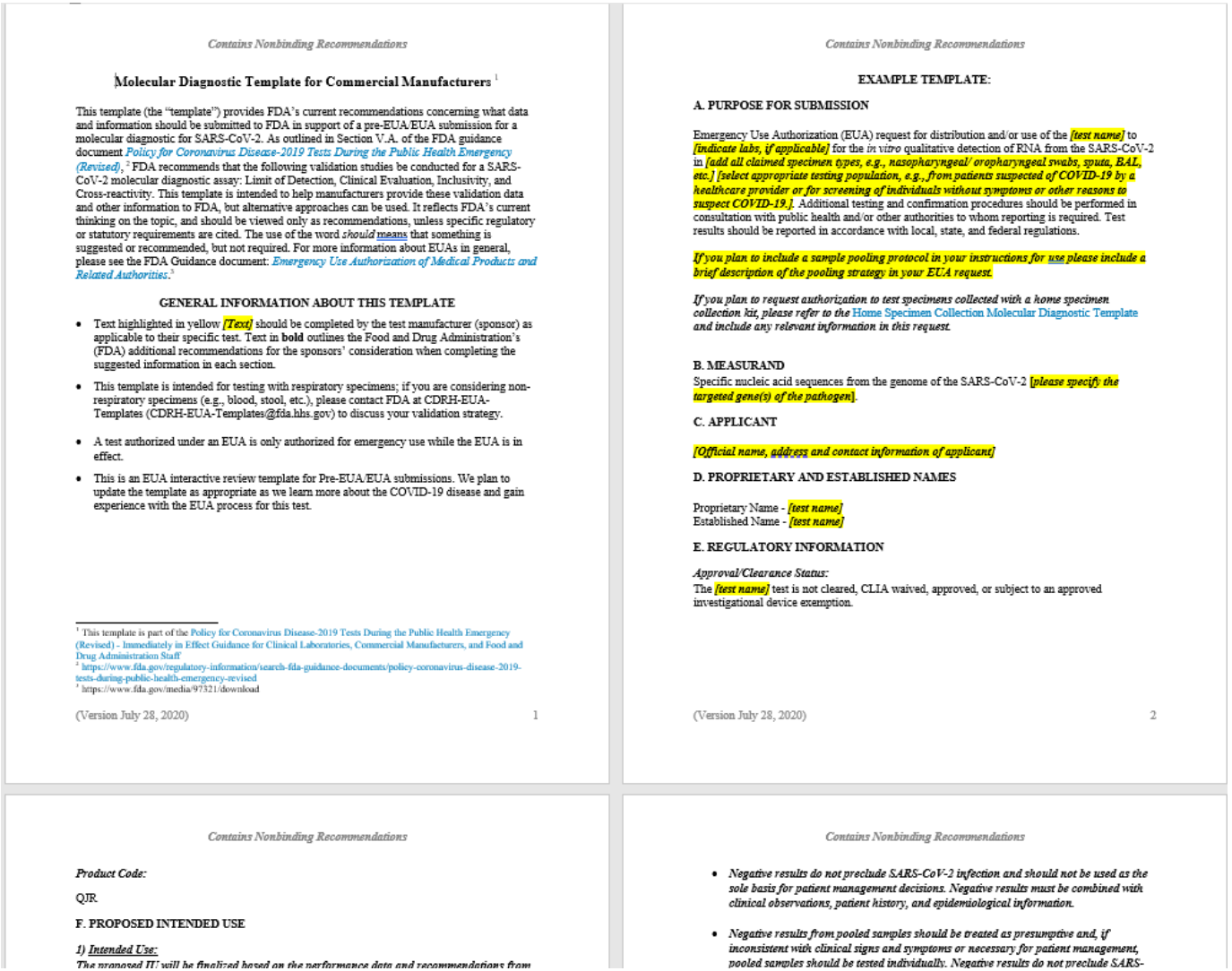
EUA Documents:

- EUA Review Template

Public Documents:

- Letter of Authorization
- Fact Sheets – Healthcare Providers and Patients
- Manufacturer Package Insert/Instructions for Use

Diagnostics: Example EUA Template



Contains Nonbinding Recommendations

Molecular Diagnostic Template for Commercial Manufacturers [1]

This template (the "template") provides FDA's current recommendations concerning what data and information should be submitted to FDA in support of a pre-EUA/EUA submission for a molecular diagnostic for SARS-CoV-2. As outlined in Section V.A. of the FDA guidance document *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, [2] FDA recommends that the following validation studies be conducted for a SARS-CoV-2 molecular diagnostic assay: Limit of Detection, Clinical Evaluation, Inclusivity, and Cross-reactivity. This template is intended to help manufacturers provide these validation data and other information to FDA, but alternative approaches can be used. It reflects FDA's current thinking on the topic, and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* means that something is suggested or recommended, but not required. For more information about EUAs in general, please see the FDA Guidance document: *Emergency Use Authorization of Medical Products and Related Authorities*. [3]

GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow *[Text]* should be completed by the test manufacturer (sponsor) as applicable to their specific test. Text in **bold** outlines the Food and Drug Administration's (FDA) additional recommendations for the sponsors' consideration when completing the suggested information in each section.
- This template is intended for testing with respiratory specimens; if you are considering non-respiratory specimens (e.g., blood, stool, etc.), please contact FDA at CDRH-EUA-Templates (CDRH-EUA-Templates@fda.hhs.gov) to discuss your validation strategy.
- A test authorized under an EUA is only authorized for emergency use while the EUA is in effect.
- This is an EUA interactive review template for Pre-EUA/EUA submissions. We plan to update the template as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for this test.

[1] This template is part of the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised
[3] https://www.fda.gov/media/97321/download

(Version July 28, 2020) 1

Contains Nonbinding Recommendations

EXAMPLE TEMPLATE:

A. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the *[test name]* to *[indicate labs, if applicable]* for the *in vitro* qualitative detection of RNA from the SARS-CoV-2 in *[add all claimed specimen types, e.g., nasopharyngeal/ oropharyngeal swabs, sputa, BAL, etc.] [select appropriate testing population, e.g., from patients suspected of COVID-19 by a healthcare provider or for screening of individuals without symptoms or other reasons to suspect COVID-19.]*. Additional testing and confirmation procedures should be performed in consultation with public health and/or other authorities to whom reporting is required. Test results should be reported in accordance with local, state, and federal regulations.

If you plan to include a sample pooling protocol in your instructions for use please include a brief description of the pooling strategy in your EUA request.

If you plan to request authorization to test specimens collected with a home specimen collection kit, please refer to the Home Specimen Collection Molecular Diagnostic Template *and include any relevant information in this request.*

B. MEASURAND

Specific nucleic acid sequences from the genome of the SARS-CoV-2 *[please specify the targeted gene(s) of the pathogen]*.

C. APPLICANT

[Official name, address and contact information of applicant]

D. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - *[test name]*
Established Name - *[test name]*

E. REGULATORY INFORMATION

Approval/Clearance Status:
The *[test name]* test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

(Version July 28, 2020) 2

Contains Nonbinding Recommendations

Product Code:

QJR

F. PROPOSED INTENDED USE

1) Intended Use:
The proposed IU will be finalized based on the performance data and recommendations from

Contains Nonbinding Recommendations

- *Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.*
- *Negative results from pooled samples should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Negative results do not preclude SARS-*

In Vitro Diagnostics EUAs (for COVID-19)

- Web search: "FDA + EUA + IVD"
- Test types & definitions (e.g., diagnostic, serology, etc.)
- Templates
- List of EUA Authorizations (date, entity, EUA letter and issue date, attributes, authorized setting, authorization documents)

Pre-EUA Packages

Diagnostics: Example EUA Template

Requirements	Emergency Use Authorization (EUA)	De Novo/510(k)
Special Circumstances	Requires declaration by the HHS Secretary that circumstances exist justifying the EUA; There is no adequate, approved, and available alternative to the product	No
Duration	Temporary - remains in effect for the duration of the declaration unless revoked sooner	Not Limited
Analytical Evaluation	Limited	Full validation
Clinical Evaluation	Limited	Full validation
cGMP	Expected but limits or waivers may be granted in an EUA on a case-by-case basis	Required

https://www.fda.gov/about-fda/cdrh-transparency/evaluation-automatic-class-iii-designation-de-novo-summaries

Studies EUA vs. De Novo/510(k) - NAAT

NAAT	Emergency Use Authorization (EUA)	De novo/510(k)
Limit of Detection (LoD)	Yes	Yes
Inclusivity	Yes Some *in silico*	Yes Some *in silico*
Exclusivity	Limited Some *in silico*	Full validation Some *in silico*
Interference	Situation specific	Yes
Precision	No	Yes - Multisite
Fresh vs. Frozen	Fresh specimens preferred	Fresh specimens preferred
Clinical Evaluation	Limited – natural clinical specimens	Full validation – natural clinical specimens

1. What Is A Pre-EUA Package? Should I Prepare One?

How to Submit a Pre-EUA for In vitro Diagnostics to FDA

Pre-EUA information for manufacturers of IVD tests

Share | Tweet | LinkedIn | Email | Print

This page is intended for manufacturers of *in vitro* diagnostic (IVD) tests.

About Pre-EUA

To help prepare for potential and current emergencies, FDA works with medical countermeasure developers to prepare Pre-EUA packages, when appropriate. A Pre-EUA package contains data and information about the safety, quality, and efficacy of the product, its intended use under a future or current EUA, and information about the emergency or potential emergency situation. The pre-EUA process allows FDA scientific and technical subject matter experts to begin a review of information and assist in the development of conditions of authorization, fact sheets, and other documentation that would be needed for an EUA in advance of an emergency and also helps to facilitate complete EUA requests during a current emergency declaration. Please note that a pre-EUA can only transition to an EUA if there is a current applicable emergency declaration.

It is highly advisable to prepare and submit a pre-Emergency Use Authorization (EUA) package – in particular, for new technologies (e.g., breath test) or if this is the first time submitting an EUA.

How to Submit a Pre-EUA for In vitro Diagnostics

FDA Pre-EUA processes and interactions differ from other regulatory interactions as there are no meetings held with FDA; the process is initiated via email

IVD for pathogen ***with*** current EUA Declaration:

- ❑Find applicable EUA review template or request copy via email (incl. description of IVD – target, technology type, etc.); COVID-19 IVD EUA templates can be found here
- ❑Populate draft EUA template with as much information/data as possible
- ❑Send the pre-EUA template package – including a brief description of the IVD, prepopulated EUA template, and any other helpful information about the IVD (and specific questions) – back to FDA via email indicating it is a "Pre-EUA submission"
- ❑After FDA receives the pre-EUA information, an FDA reviewer and a pre-EUA review number (PEUA******) is assigned
- ❑Additional Resources:
  - ➢FAQs on Testing for SARS-CoV-2
  - ➢COVID-19 Test Development and Review: FAQs on Testing for SARS-CoV-2

2. Do The New UK, South African, And Brazilian Variants Have An Impact On EUAs?

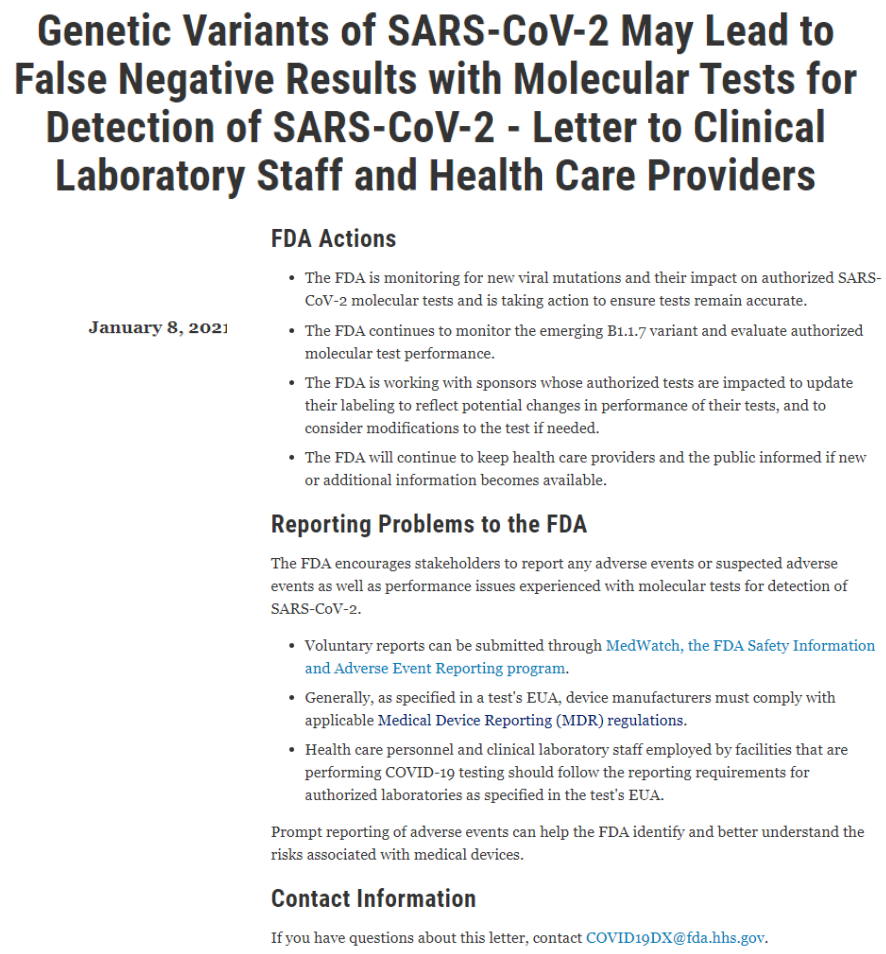
Yes! Templates have not yet changed BUT

FDA monitors the potential effects of genetic variation in molecular tests that have received EUAs…AND…

… is alerting labs and health care providers that false negative results may occur with any molecular test for the detection of SARS-CoV-2 if a mutation occurs in the part of the virus' genome assessed by that test.

The following test developers have already been contacted by FDA:

- Accula SARS-Cov-2 Test
- TaqPath COVID-19 Combo Kit
- Linea COVID-19 Assay Kit



Genetic Variants of SARS-CoV-2 May Lead to False Negative Results with Molecular Tests for Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers

January 8, 2021

FDA Actions

- The FDA is monitoring for new viral mutations and their impact on authorized SARS-CoV-2 molecular tests and is taking action to ensure tests remain accurate.
- The FDA continues to monitor the emerging B1.1.7 variant and evaluate authorized molecular test performance.
- The FDA is working with sponsors whose authorized tests are impacted to update their labeling to reflect potential changes in performance of their tests, and to consider modifications to the test if needed.
- The FDA will continue to keep health care providers and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

The FDA encourages stakeholders to report any adverse events or suspected adverse events as well as performance issues experienced with molecular tests for detection of SARS-CoV-2.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program.
- Generally, as specified in a test's EUA, device manufacturers must comply with applicable Medical Device Reporting (MDR) regulations.
- Health care personnel and clinical laboratory staff employed by facilities that are performing COVID-19 testing should follow the reporting requirements for authorized laboratories as specified in the test's EUA.

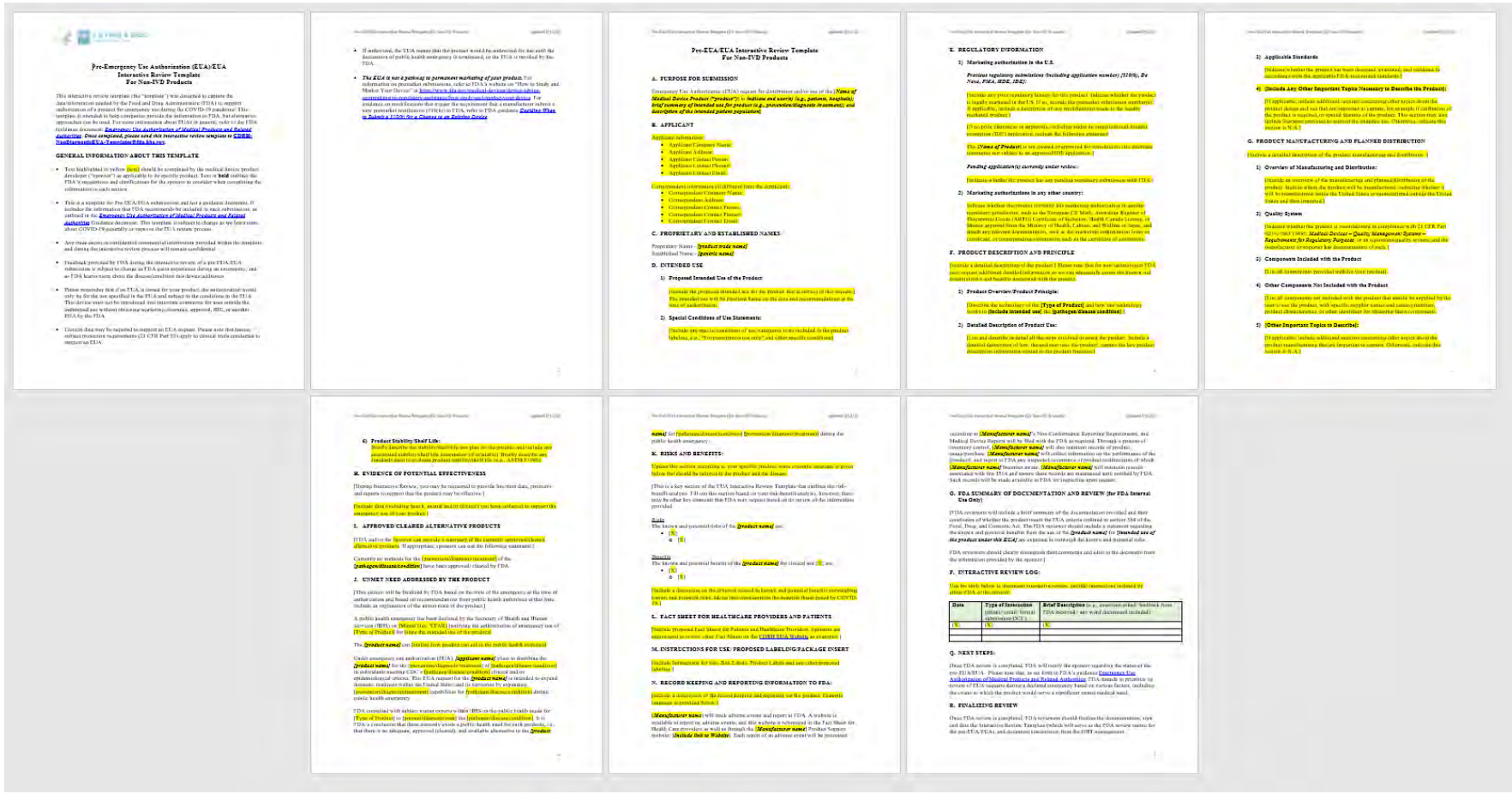
Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact COVID19DX@fda.hhs.gov.

Source: https://www.fda.gov/medical-devices/letters-health-care-providers/genetic-variants-sars-cov-2-may-lead-false-negative-results-molecular-tests-detection-sars-cov-2

EUA Template: Non-IVD Products



Other Medical Device EUAs (for COVID-19)

- EUA Template: Non-IVD Products
- Pre-EUA package

- ***Once completed, please send this interactive review template (as a pre-EUA or an EUA package) to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.***

Guidance for Industry: *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*

- RWD are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
- RWE is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.

Regulatory Context in Which RWE May be Used

- RWD used to generate the RWE are of sufficient quality
- May potentially be used as some or all of the evidence necessary for understanding medical device performance at different points in the Total Product Life Cycle (TPLC)

Characteristics of RWD

RWD must demonstrate:

- **Relevance** – is the RWD data adequate to address the applicable regulatory question or requirement
- **Reliability**
  - Data accrual: how the data were collected
  - Data assurance: data quality and integrity

Example Where RWE Might Be Used

- Expanded indications of use
- Postmarket surveillance studies
- Post-approval device surveillance as condition of approval
- Control group
- Supplementary Data
- Objective Performance Criteria and Performance Goals

RWE/RWD Questions

Can I use the data obtained for EUA authorization?

Yes, if no modifications to the device have been made since the EUA authorization. If modifications have been made, a risk assessment of the modifications is required to determine the extend of changes to the device and its influence on performance.

Can I use data generated outside the US in an FDA submission?

Yes, if the test procedure was performed according to the package insert with no deviations.

Diagnostic Data & Reporting

- Diagnostic Tests have two critical purposes during the pandemic:
  - **INDIVIDUAL: Deliver correct diagnostic result to the patient**
    - Guide appropriate clinical care
    - Inform personal decisions and behaviors
  - **POPULATION**: Deliver diagnostic data to public health officials
    - Guide local, state, and Federal public health decision-making based on data
    - Track, monitor, and mitigate viral spread and transmission (proactively)
    - Inform and evaluate impact of policies, interventions, and guidance
    - Early identification and intervention of outbreaks, resurgences
    - Target distribution of supplies, resources, and personnel
    - Predict and mitigate supply chain and testing shortages, critical hospital capacity
    - Identify underserved and disproportionately impacted populations
- COVID-19 Diagnostic Data Standards: FAQs
  - https://www.hhs.gov/coronavirus/testing/covid-19-diagnostic-data-reporting/index.html

Mandatory Minimum Core Data Elements for All COVID-19 Diagnostic Test Reporting

		FEDERAL		STATE		Source	
Data Element^	Field^	Mandatory	Requested	Mandatory	Requested	Lab-based	Non-lab-based
1	Test Ordered	X		X		Lab	Auto-populated
2	Test Result	X		X		Lab	Auto-populated
3	Result Date	X		X		Lab	Auto-populated
5	Test Ordered Date		X		X	Lab	Auto-populated
4	Report Date	X		X		Lab	Auto-populated
6	Specimen Collected Date	X		X		Lab	Auto-populated
7	Device Identifier	X		X		Lab	Auto-populated
20	Specimen Source	X		X		Lab	Auto-populated
8	Accession #/Specimen ID		X	X		Lab	N/A^^
18	Perf Facility Name; CLIA#	X		X		Lab	N/A^^
19	Perf Facility Zip Code		X	X		Lab	N/A
	Reporting Facility			X		Lab/Other	N/A^^
21	Patient Name (PII)			X		Patient/Provider	Patient
23	Patient Address (PII)			X		Patient/Provider	Patient
14	Patient Zip Code	X		X		Patient/Provider	Patient
15	Patient County	X		X		Patient/Provider	Auto-populated
24	Patient Phone (PII)			X		Patient/Provider	Patient
	Patient Email (PII)				X	Patient/Provider	Patient
9	Patient Age	X		X		Patient/Provider	Auto-populated
10	Patient DOB (PII)			X		Patient/Provider	Patient
11	Race		X	X		Patient/Provider	Patient
12	Ethnicity		X	X		Patient/Provider	Patient
13	Sex		X	X		Patient/Provider	Patient
22	Unique Patient Identifier*	X*	X	X*	X	Patient/Provider	Auto-populated
27-33	AOE questions		X		X	Patient/Provider	Patient
16	Provider Name; NPI ~	X		X		Provider	Provider**
25	Provider Address ~		X	X		Provider	Provider
17	Provider Zip Code ~		X	X		Provider	Provider
26	Provider Phone ~		X	X		Provider	Provider

^ per COVID-19 Data Reporting for Laboratory-Based Testing (August 31, 2020) - PDF **(Technical Specifications for Implementation)** and COVID-19 Data Reporting for Non-Laboratory-Based Testing (September 23, 2020) - PDF **(Technical Specifications for Implementation)**

* Mandatory for non-laboratory-based tests only

~ if by prescription; n/a for non-prescription tests

^^ enter "SA" for self-administered in these fields

** enter "OTC" for over-the-counter in these fields, if non-prescription

https://www.hhs.gov/sites/default/files/hhs-diagnostic-data-faqs.pdf

The Design-a-thon is a public-facing, open-innovation technology sprint with industry that aims to develop device-integrated software for automatic data capture and wireless transmission directly from in vitro diagnostic devices (IVDs).

HHS.gov
U.S. Department of Health & Human Services

GOAL 1: The Design-a-thon brings together **public and private sector innovators** to develop software/digital health tools that **integrate with IVDs.**

GOAL 2: Build an **HHS interface** that will exemplify the **design principles** and provide device/systems-agnostic "docking" between HHS Protect and various reporting systems, called **"Wireless Automated Transmission for Electronic Reporting Systems" (WATERS).**

- Future State: By setting the design principles, the Design-a-thon will establish and align diagnostics data reporting **standards** for **every single core data element defined under CARES**, which have been defined by HHS (including **technological specifications**) for lab-based and non-lab-based tests.

Participate in the TOPx (phase 2) at: Waters.Crowdicity.com

NIH National Institutes of Health
Turning Discovery into Health®

The COVID-19 TOPx Tech Sprint Teams Have Been Allocated into 3 Tracks

Track: Data Capture from Diagnostic Workflow

A

- **Net Medical Xpress Solutions, Inc:** Net Medical's Telemed for COVID-19 Wireless Data
- **Safe Health Systems:** Connected Diagnostics Platform
- **Lifepoint Informatics:** COVID-19 State Reporting Hub
- **DynamiCare Health & InfoWerks**: At-Home Tele-Lab: From Epidemic to Pandemic
- **Skyflow:** Privacy-First, Real-Time APIs for Collecting and Curating COVID-19 Data
- **UDoTest:** Simple Patient Testing Solution That's Live, Integrated and Comprehensive

Track: Severity/risk scoring and health passports

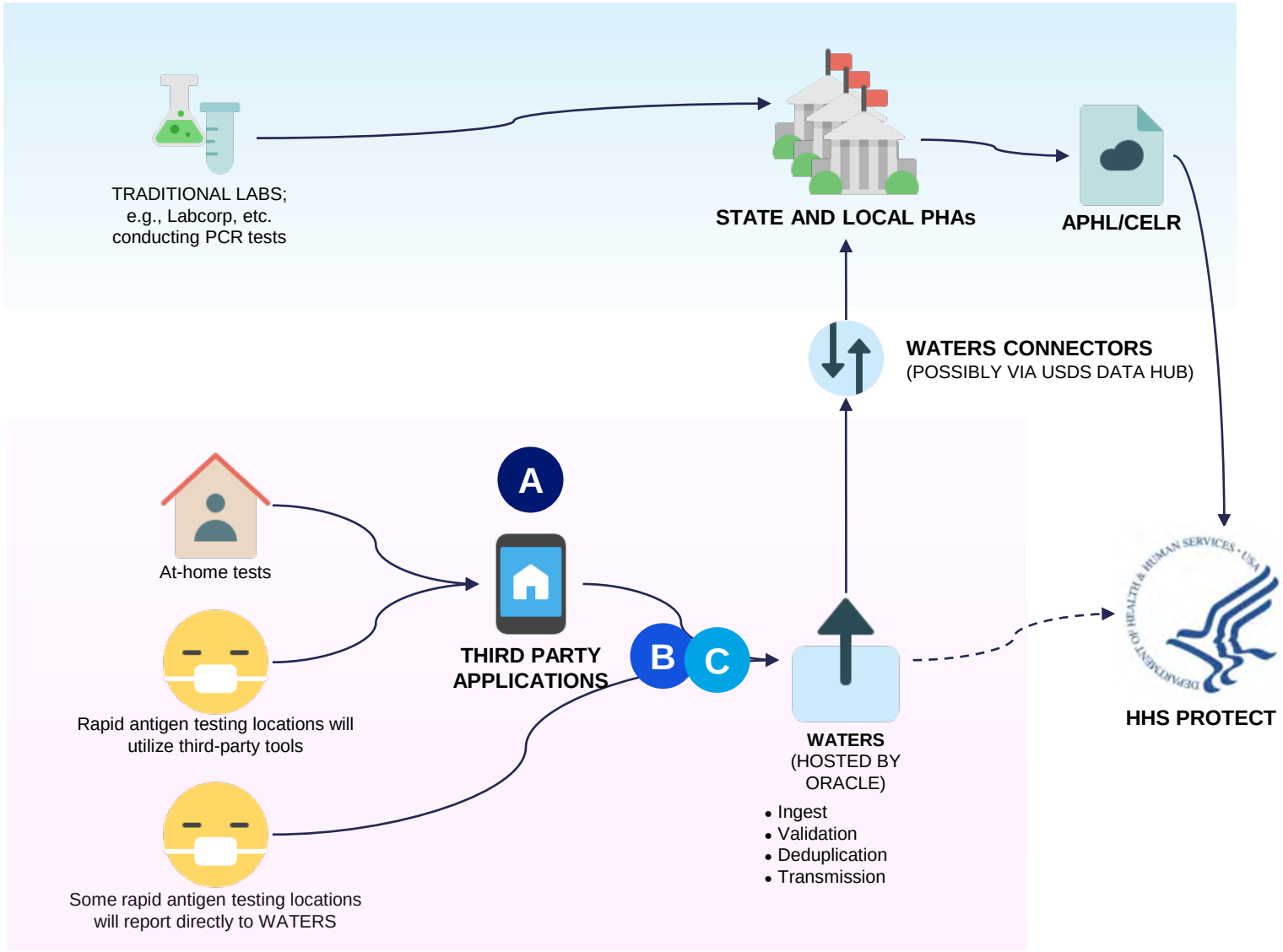
B

- **NYU:** Smart Diagnostics Ecosystem for COVID-19 Disease Management
- **VirusIQ**: VirusIQ Screening Platform > Virtual Lab Module
- **CURA Patient**: CuraPatient Digital Platform
- **Oasys**: One Country, One Data Standard, One Process for all
- **AIE Technology Solutions, Inc:** Mareedi Wellness App

Track: Secure data storage and exchange

C

- **Oracle**: COVID-19 Immutable Test Results Submission and Visualization
- **IBM**: Digital Health Pass for Citizen Reported COVID-19 Testing Data
- **DLC-Delta:** Co-Verify Solution
- **Interpret-COVID**: Consumer Dx Test App
- **Dovel Technologies:** Patient Health Surveillance Ecosystem Portal (PHSEP)



Participate in the TOPx (phase 2) at: Waters.Crowdicity.com

Participants Are Building an Ecosystem of Solution Functions

		Test kit ordering	Test scheduling	Test result input	Test result verification	Health passport	Patient risk scoring	Data ownership & exchange	Data harmonization & connectivity	Data security	API/SDK marketplace
UDOTest	A	●		●	●						
VirusIQ + AIE	B	●					●				●
Cura Patient	B		●			●					
Oasys	B		●								
Net Medical	A			●					●		
Safe Health	A			●	●	●					
DynamiCare	A			●	●	●					
Skyflow	A			●				●	●		
Interpret-COVID	C			●				●			
NYU	B					●	●				
IBM	C					●		●		●	
DLC-Delta	C					●		●			
Dovel	C							●			
Lifepoint	A								●		
Oracle	C									●	

Description of solution functions

- Test kit ordering: order test kits for delivery or pickup
- Test scheduling: schedule tests
- Test result input: manually or automatically input test results
- Test result verification: verify correctness and/or authenticity of inputted test results
- Health passport: proof that test was taken and result was negative
- Patient risk scoring: determining likelihood of having COVID-19
- Data ownership and exchange: hold and/or share individuals' data, e.g. through setting policies
- Data harmonization and connectivity: map and format data and create exchange mechanisms
- Data security: ensuring data authenticity, correctness, and no unauthorized reads
- API/SDK marketplace: place to find 3rd-party APIs, SDKs, code for data connectivity

Participate in the TOPx (phase 2) at: Waters.Crowdicity.com

Track A Focuses on Test Data Capture

Supports first at-home test

Data Capture from Diagnostic Workflow

A
- **Lifepoint Informatics**
- **Safe Health Systems**
- **Skyflow**
- **DynamiCare Health & InfoWerks**
- **Net Medical Xpress Solutions, Inc**
- **UDoTest**

Diagnostic Data Ecosystem, Analytics Utilization
Severity/risk scoring and health passports for patients

B
- NYU
- VirusIQ
- CURA Patient
- Oasys
- AIE Technology Solutions, Inc

Track: Data Security, Privacy, Exchange, Storage, Ownership
Secure data storage and exchange

C
- Oracle
- IBM
- DLC-Delta
- Interpret-COVID
- Dovel Technologies

Lifepoint Informatics: Transmits Ellume test results. Reporting hub receives test results and distributes normalized data; data connections to 300+ labs, 10K+ practice EMRs, Gov/State health orgs

Safe Health Systems: Test instructions and test strip interpretation. Working with manufacturers Quidel, ACON, and Osang. Developing health passport combining test results and vaccine credentials

Skyflow: Test results and patient questionnaire input. APIs and services to capture and harmonize data, and to create data feed to applications or data repositories. Individuals define data sharing policies

DynamiCare Health & InfoWerks: Test instructions, test strip pos/neg interpretation, patient data capture. Record selfie to prove identity and test strip belongs to patient. Provides health passport

Net Medical Xpress Solution: Wireless test data capture protocol and data harmonization

UDOTest: Test data capture via bluetooth, test verification through network of labs, group/employer test ordering

Track B Focuses on Risk Scoring and Health Passports

Data Capture from Diagnostic Workflow

Test data capture, combining it with medical records, and transmit for processing

A
- Lifepoint Informatics
- Safe Health Systems
- Skyflow
- DynamiCare Health & InfoWerks
- Net Medical Xpress Solutions, Inc
- UDoTest

Severity/risk scoring and health passports

B
- NYU
- VirusIQ
- CURA Patient
- Oasys
- AIE Technology Solutions, Inc

Track: Data Security, Privacy, Exchange, Storage, Ownership

Secure data storage and exchange

C
- Oracle
- IBM
- DLC-Delta
- Interpret-COVID
- Dovel Technologies

NYU: Patients receive COVID-19 severity score; algorithm uses patient demographics and diagnostic data. Provide health passport

VirusIQ: Find and order tests. Marketplace for API/SDK and software for labs to establish data connections and for capturing test results from devices. Health risk analytics

CURA Patient: Test scheduling and health passports

Oasys: Real-time analytics, including identifying hotspots and dispatching mobile lab. App/web solution to create and check-in to test appointments and enter test results. This team may decide not to participate in TOPx

AIE Technology Solutions: App for daily pass; patient inputs heart rate, respiratory sounds monitoring, self-reported symptoms, CDC COVID-19 questionnaire

Track C Focuses on Secure Data Storage and Exchange

Data Capture from Diagnostic Workflow
Test data capture, combining it with medical records, and transmit for processing

A
- Lifepoint Informatics
- Safe Health Systems
- Skyflow
- DynamiCare Health & InfoWerks
- Net Medical Xpress Solutions, Inc
- UDoTest

Diagnostic Data Ecosystem, Analytics Utilization
Severity/risk scoring and health passport for patients

B
- NYU
- VirusIQ
- CURA Patient
- Oasys
- AIE Technology Solutions, Inc

Secure data storage and exchange

C
- **Oracle**
- **IBM**
- **DLC-Delta**
- **Interpret-COVID**
- **Dovel Technologies**

WATERS will be deployed on Oracle blockchain gov cloud

Oracle: Permissioned blockchain solution; test results submitted to distributed ledger, automatic protection of PII

IBM: Facilitates health data exchange by individuals setting and implementing data sharing policies. Provide health passport

DLC-Delta: Individuals track test results and share them with entities needing proof of negative results. Employers track employee test results

Interpret-COVID: Individuals enter and track test results and provide answers to survey questions on their own vaccine status, demographics, and comorbidities

Dovel Technologies: Patient portal combines clinical supply chain and patient health data

FDA-RADx Rad Engagement

FDA CDRH POC

Sara Brenner, MD, MPH
Sara.Brenner@fda.hhs.gov

- Weekly/monthly cadence TBD
- Organized through CDRH OHT7 (Office of In Vitro Diagnostics & Radiological Health) with coordination across Center as needed

FDA Resources: IVDs

FDA In Vitro Diagnostics EUAs:

- https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

FDA FAQs on Testing for SARS-CoV-2

- https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

The FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov

HHS Diagnostic Data & Reporting FAQ:

- https://www.hhs.gov/coronavirus/testing/covid-19-diagnostic-data-reporting/index.html

FDA Resources: IVDs

FDA EUA Templated for IVDs

FDA FAQs for IVDs (with sub-sections)

Estimated National Testing Trends (HHS)

FDA Virtual Townhalls for SARS CoV-2 Test Developers

FDA EUA Removal List

FDA SARS-CoV-2 Reference Panel Comparative Data

HHS Announcement on FDA Premarket Review of Laboratory-Developed Tests (LDTs)

HHS FAQs on Laboratory Developed Tests (LDT)

FAQs on Diagnostic Testing for SARS-CoV-2 and CLIA and University Laboratory Testing FAQ (CMS)

FDA Resources: non-IVDs

Other Medical Device EUAs (for COVID-19)

EUA Template: Non-IVD Products

List of "Other Medical Devices" with EUAs

EUA for CLEWICU system (AI)

EUA for Dascena's COVID-19 Machine Learning Algorithm

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Office of the Commissioner and Office of Chief Counsel

Thank You!

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Diagnostic Data Lead, Data Strategy and Execution Workgroup

COVID-19 National Response, U.S. Department of Health and Human Services

February 22, 2021

Q&A

Moderator

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Thank You!