RADx Program Overview

December 2023

National Institutes of Health
Turning Discovery into Health®

Overview of RADx Program

Agenda

1. RADx Program Overview
   Program Chair: Dr. Tara Schwetz
2. RADx Tech
   Program Chair: Dr. Bruce Tromberg
3. RADx-UP
   Program Chairs: Dr. Eliseo Perez-Stable & Dr. Richard Hodes
4. RADx-rad
   Program Chair: Dr. Richard Woychik
5. RADx Data Hub
   Program Chair: Dr. Susan Gregurick
6. Conclusion

"Now is the time for that unmatched American ingenuity to bring the best and most innovative technologies forward to make testing for COVID-19 widely available."

— Former NIH Director Francis S. Collins, M.D., Ph.D.

E. Jason Wambsgans/Chicago Tribune via Getty Images

RADx Program

What?

The Rapid Acceleration of Diagnostics (RADx) Program was developed in 2020 to **speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing.**

Why?

The rapid worldwide spread and impact of COVID-19 created a need for **accurate, reliable, and readily accessible testing on a massive scale**.

How?

To meet this challenge, RADx created programs that made it possible to **rapidly scale-up testing across the country and enhance access to those most in need.**

Rapid Acceleration of Diagnostics (RADx) Program Objectives

RADx Tech

Accelerate innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. The RADx Tech/Advanced Testing Program (ATP) innovation funnel was designed to compress the customary technology development timeline from years down to just months.

RADx Underserved Populations (RADx-UP)

Study COVID-19 testing access and uptake to reduce disparities for underserved and vulnerable populations.

RADx Radical (RADx-rad)

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

Data Management Support

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

RADx Tech

RADx Tech: *Beginning*

April 20, 2020

<8M tests/month, *mainly in labs*

The Washington Post

Opinion: We need more covid-19 tests. We propose a 'shark tank' to get us there.

Opinion by **Lamar Alexander** and **Roy Blunt**

April 20, 2020 at 8:46 p.m. EDT

Lamar Alexander (R-Tenn.) is chairman of the Senate Health, Education, Labor and Pensions Committee. Roy Blunt (R-Mo.) is chairman of the Senate's health appropriations subcommittee.

There is no safe path forward to combat the novel coronavirus without adequate testing. To contain covid-19 and persuade

April 24, 2020

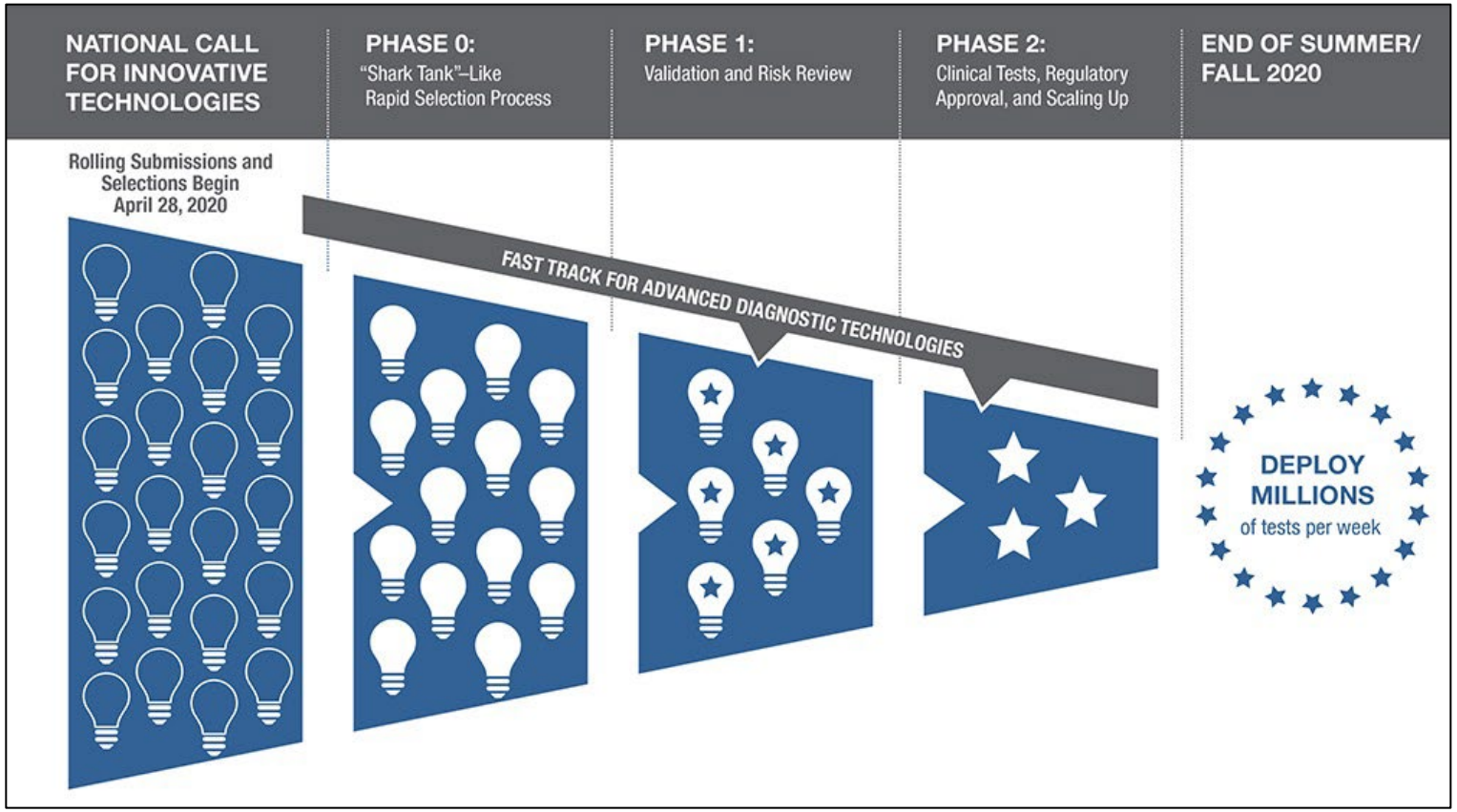
4th Congressional Supplement ($1.5B NIH)

April 29, 2020

RADx Launched; Goal: POC, OTC >> Lab

10s millions test/month by fall 2020

Innovation Funnel (Shark Tank)



RADx Tech: *Structure*

NIBIB Point of Care Tech Research Network (POCTRN U54)

Expanded April 29, 2020: >900 RADx experts & contributors: (USG, Academia, Industry, NFP)

RADx Tech Website

Innovation Funnel
(shark tank)

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

VENTUREWELL idea to impact

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

C BIO M C3i

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

100s projects complete >10,000 participants

Validation Core

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

Clinical Studies Core

Supply chain, Manufacturing, User Community, *whentotest.org*

My COVID Toolkit

Deployment Core

https://www.poctrn.org

RADx Tech: *Programs*

Innovation Funnel

NIBIB Point of Care Tech Research Network (POCTRN U54)

Expanded April 29, 2020: >900 RADx experts & contributors: (USG, Academia, Industry, NFP)

[RADx Tech Website]

RADx MARS
Digital Health

COVID-19 Test Us

Variant Task Force
Project Rosa

Independent Test Assessment (ITAP)

MAKE MY TEST COUNT
makemytestcount.org

HOME TEST TO TREAT PROGRAM

Test Accessibility

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

VENTUREWELL idea to impact

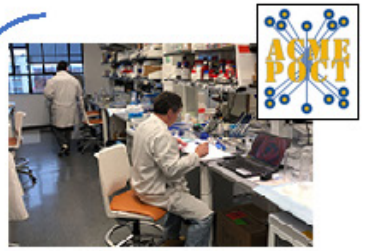
Johns Hopkins
- ✓ Public Health/STD
- ✓ Global Health
- ✓ Clinical Validation
- ✓ Biobank samples
- ✓ Validation in LMICs

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/Commer-cialization

C BIO M C3i



100s projects complete, >10,000 participants

Validation Core

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

Clinical Studies Core

Supply chain, Manufacturing, User Community, *whentotest.org* My COVID Toolkit

Deployment Core

https://www.poctrn.org

RADx Tech: *Accomplishments*

Innovation Funnel

1042 Applications→50 Phase 2

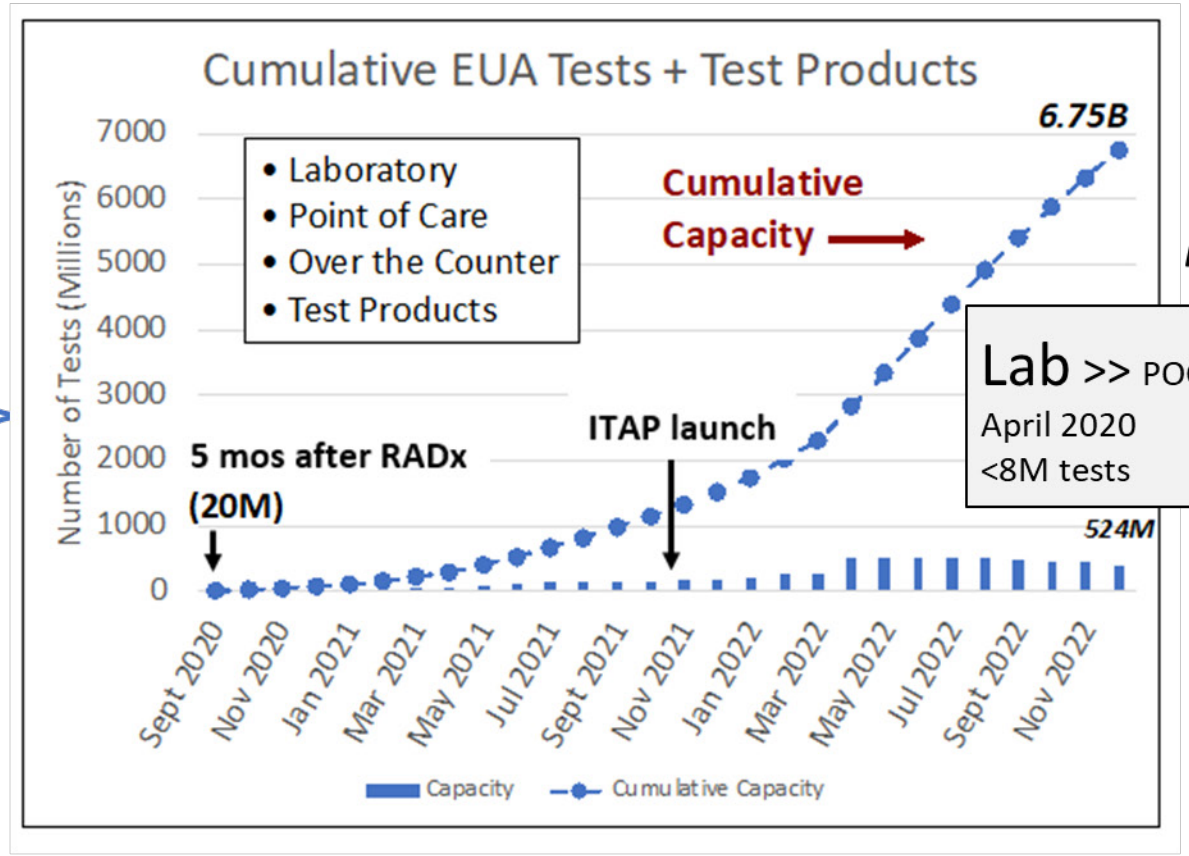
- **7.8 B tot capacity →March 2023**
- **56 EUAs**: *19 OTC, 17 POC*

Independent Test Assessment (ITAP)

EUA ~8-12 weeks

NIBIB Point of Care Tech Research Network (POCTRN U54)

Expanded April 29, 2020: >900 RADx experts & contributors: (USG, Academia, Industry, NFP)



Dx Paradigm Shift

Lab >> POC → OTC, POC >> Lab (~12%)

April 2020 <8M tests

Feb 2022 ~ 1B OTC tests

[RADx Tech Website]

RADx Tech: *Accomplishments (Continued)*

Process Innovation

Program Setup (4-6 weeks)

- Scope/Criteria
- Workflow
- Staffing
- Funding
- Contracts
- FDA Protocols /Template
- Application
- Bioinformatics
- MTAs
- Clinical Samples
- Biobank
- Solicitation

ITAP Week 0

Intro Meetings & Risk Assessment (2 weeks)

Independent Assessment (Emory, 3 weeks)

Analytical Studies (CRO, 3 weeks)

Clinical Trial (CRO/Emory/UMass, 1-4 weeks)

Modular EUA Submission (1-4 weeks)

ITAP Week 8-15

EUA Authorization (1 week after submission of final module)

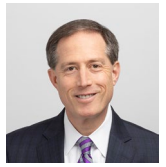
Launched 11/2021
to meet Omicron Surge

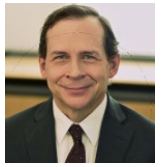
+ OHT7 team

NIBIB ITAP Team Leads


Eric Lai


Pam Miller


Jeff Shuren


Tim Stenzel


Kris Roth

- **Output:** *12 COVID EUAs, ~4B OTC LFAs*
- *2 OTC Multiplex EUA (NAT)*
- *1 POC Mpox EUA (NAT)*
- *FDA policy changes*

Emory Validation Core

UMass Clinical Studies Core

RADx Tech: *Accomplishments (Continued)*

Program Setup (4-6 weeks)

-Scope/Criteria -FDA Protocols /Template -Clinical Samples
-Workflow -Application -Biobank
-Staffing -Bioinformatics -Solicitation
-Funding
-Con

ITAP Week 0

Intro Meetings

1) Serial use labeling for rapid Ag tests
2) Link PPA to LOD in clinical trials
3) Standardized analytical measures
4) Pediatric self-swabbing
5) Accepted digital clinical trial data

Independent Assessment (Emory, 3 weeks)

Analytical Studies (CRO, 3 weeks)

Emory Validation Core

UMass Clin Studies Core

Clinical Trial (CRO/Emory/UMass, 1-4 weeks)

NIH FDA

Launched 11/2021
to meet Omicron Surge

NIBIB ITAP Team Leads

Eric Lai

Pam Miller

+ OHT7 team

Jeff Shuren

Tim Stenzel

Kris Roth

- **Output:** *12 COVID EUAs, ~4B OTC LFAs*
- *2 OTC Multiplex EUA (NAT)*
- *1 POC Mpox EUA (NAT)*
- *FDA policy changes*

ITAP Week 8-15

Modular EUA Submission (1-4 weeks)

EUA Authorization (1 week after submission of final module)

RADx Tech: *Next?*

NIBIB Point of Care Tech Research Network (POCTRN+)*

Expanding RADx concept/structure with partnerships

Innovation Funnel
(shark tank)

Independent Test Assessment (ITAP)

Projects

1) OTC/POC COVID multiplexed, high performance, accessible Dx
2) POC Mpox and multiplexed STD Dx
3) POC HCV Dx for Test to Treat
4) POC/OTC HIV + viral load Dx
5) Neurotechnologies
6) Maternal Health Technologies
7) Fetal Monitoring Technologies

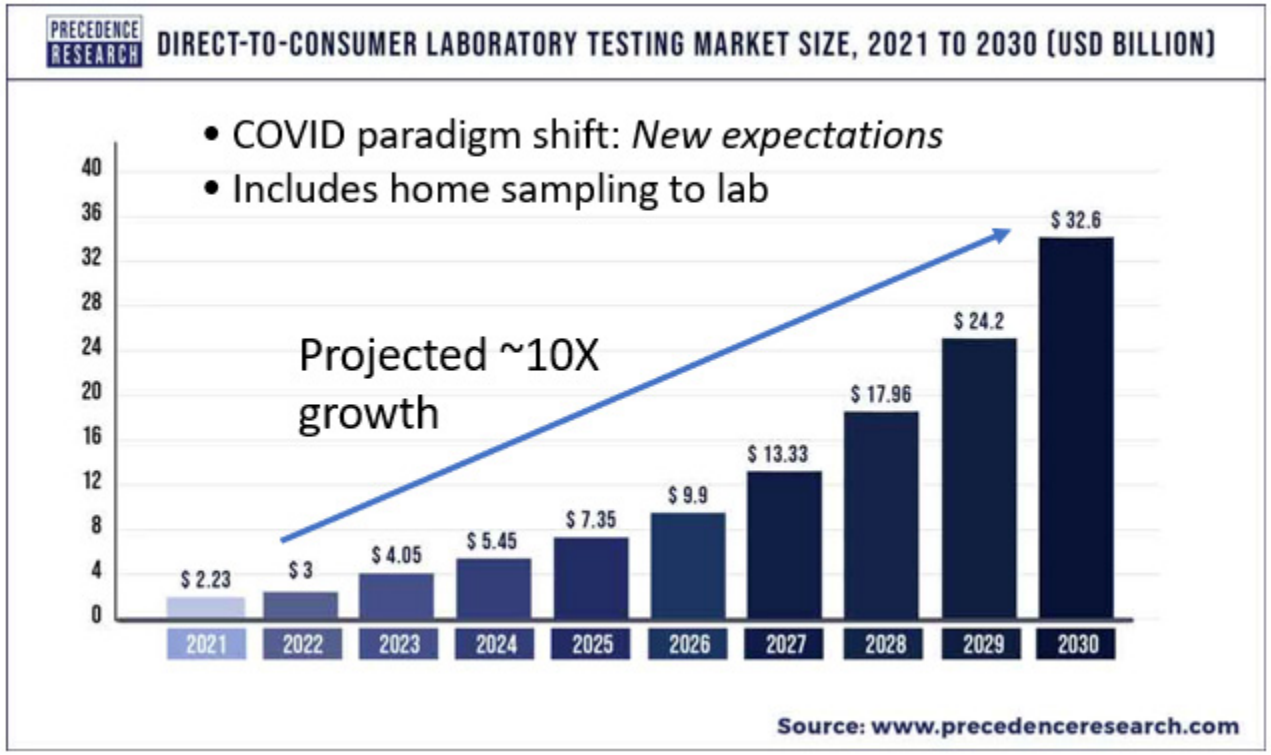
USG, NFP Partners

NIH OD, NIAID, NIDA, NICHD, ORWH, NINR, OAR, NIH BluePrint, CDC, FDA, ASPR, Gates Foundation

***2023 POCTRN+:** *NIBIB, + NHLBI, NCCIH, NIAID, FIC, OA, OBSSR, ODP* www.poctrn.org

RADx Tech: *Next?*

Consumers @home/POC are the new Dx Market



Drivers, Sustainability

1) Dx Tech advances/investments during COVID
2) Expansion of Telehealth: *better w/OTC Dx*
3) Other pathogens, chronic disease, prevention

Dx led precision medicine:

Better prevention & Tx management,
Improved access & outcome

Challenge: *How to use, report, standardize, & interpret tests, "invisible" to HealthCare (EHR, CMS, Drs., etc.)*

RADx-UP

Racial and Ethnic Minorities are Disproportionately Affected by COVID-19 - April 2021

Risk for COVID-19 Infection, Hospitalization, & Death by Race and Ethnicity

Rate ratios compared to White Persons	American Indian or Alaska Native	Asian	Black or African American	Hispanic or Latino
Cases	1.6x	0.7x	1.1x	2.0x
Hospitalized	3.5x	1.0x	2.8x	2.8x
Death	2.4x	1.0x	1.9x	2.3x

Table Source CDC as of April 23, **2021: Risk for COVID-19 Infection by Race/Ethnicity (CDC)**

Racial and Ethnic Minorities are Disproportionately Affected by COVID-19- December 2022

Risk for COVID-19 Infection, Hospitalization, and Death by Race and Ethnicity

Rate ratios compared to White Persons	American Indian or Alaska Native	Asian	Black or African American	Hispanic or Latino
Cases	1.6x	0.8x	1.1x	1.5x
Hospitalized	2.5x	0.7x	2.1x	1.8x
Death	2.0x	0.8x	1.6x	1.7x

Table Source KFF as of December 25, 2022: Cumulative Age-Adjusted Risk of COVID-19 Infection, Hospitalization, and Death, Compared to White People in the United States

RADx-UP and Community Engaged Research

- Research initiated in full partnership with community members
- Address the concerns and problems together and decide on research plan
- Partnerships based on trust, mutual benefits, complementary skills, and focus on health
- Expand capacity and deploy tests
- Mitigation strategies and deploy interventions
- Social, ethical, and behavioral factors

Phases of the RADx-UP Program: Focal Areas

Phase I

- ✓ Build COVID-19 testing *infrastructure*
- ✓ *Rapidly* implement testing and other capabilities to mitigate COVID-19 health disparities
- ✓ Investigate the social, ethical, and behavioral barriers to testing

Phase II

- ✓ Integrate *new* advances
- ✓ *Expand* studies and populations
- ✓ Add *school-based* studies focused on testing access and effectiveness for returning to schools
- ✓ Investigate the social, ethical, and behavioral barriers – testing & *vaccination*

Phase III

- ✓ Investigate the social, ethical, and behavioral barriers
- ✓ Emphasize *rapid testing*
- ✓ Build on school-based studies focused on testing access and effectiveness for *staying in school*

Phase IV

- ✓ *Analyze* existing RADx-UP data from multiple project sites to gain novel insights
- ✓ Investigate *dissemination and implementation* research focused on COVID-19 testing interventions

RADXUP at a glance

Data as of 11/29/2023

141
Phase I - IV

1
Coordination & Data Collection Center

53
States, territories, and D.C.

253
Community-engagement resources in the RADx-UP library

120
Projects submitting CDEs to CDCC

404,632
Enrolled participants (direct participants)

447,955
COVID-19 tests conducted (direct participants, CDEs only*)

13
Partnering for Impact writing teams

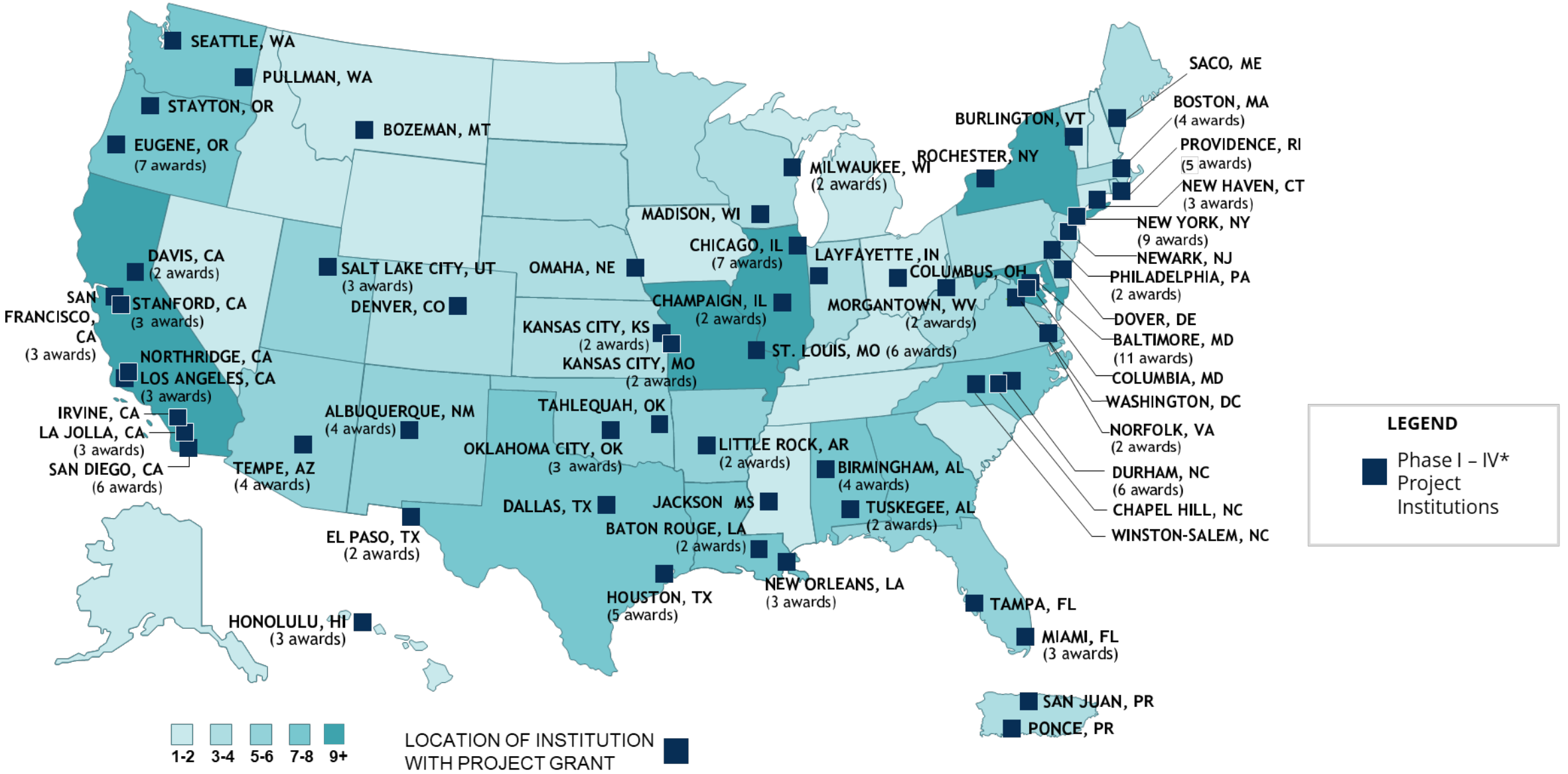
25
Rapid Research Pilot Awards

69
Community Collaboration Grants

265
Published research articles

*Count reflects common data elements data only, not actual tests conducted in the program (in the millions)

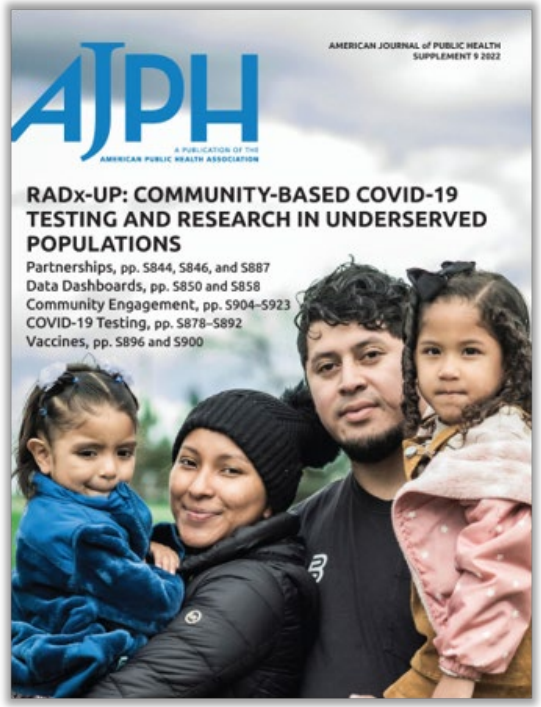
RADx-UP Awardee Locations (142 Projects Phase I-IV)



*Phase IV projects do not yet include awards for RFA-OD-23-051.

What's the Buzz around RADx-UP?

In 2022, a special issue "RADx-UP: Community-Based COVID-19 Testing and Research in Underserved Population" was published in the *American Journal of Public Health*.



In 2023, a supplement "Evidence for the Safe Return to School With COVID-19 Testing" was published in *Pediatrics*.

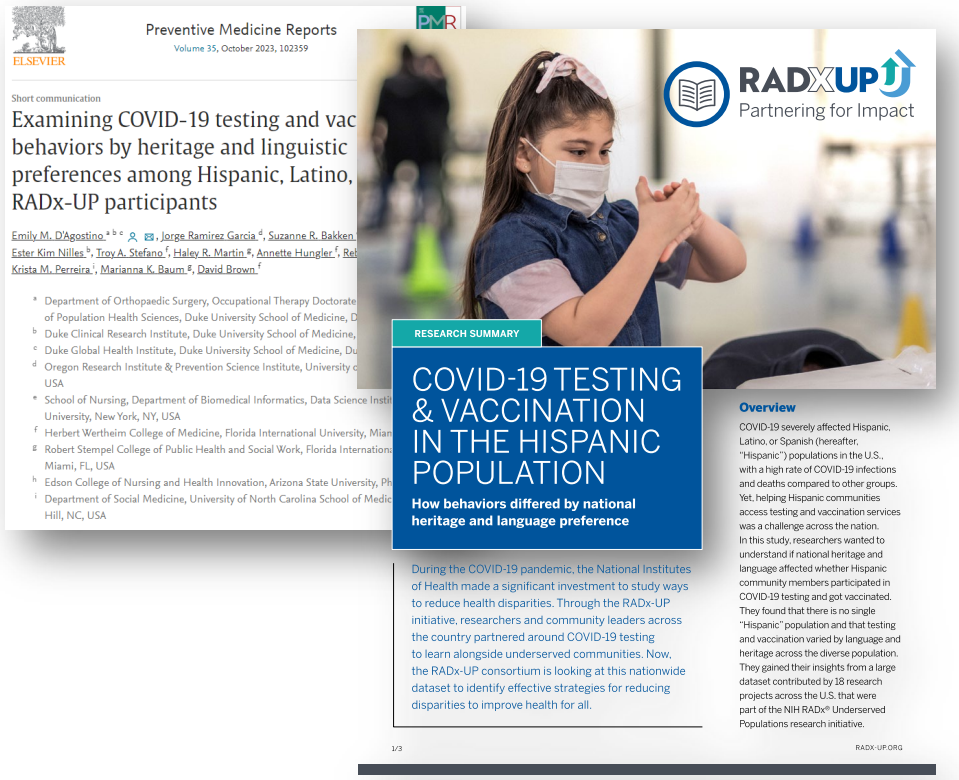
Keeping Children Safe in Schools

RADx-UP Principal Investigator
Dr. Kanecia Zimmerman
Publication in Pediatrics.

The ABC Science Collaborative concluded that:

- ✓ Offering in-school testing increased testing uptake of close contacts and allowed for shortened quarantine durations
- ✓ Nursing staff were critical to the success
- ✓ Where resources were limited, testing was more difficult
- ✓ *Motivations*: convenience, keeping others safe
- ✓ *Concerns*: implications of positive test

COVID-19 Testing and Vaccination Behaviors Among Hispanic/Latino Participants



RADx-UP CDCC Dr. Emily D'Agostino Publication in Preventive Medicine Reports.

- ✓ **n = 3308; mean age = 44.1 years [SD = 14.9], 60% women; 83% spoke other than English at home**
- ✓ **Reference population = Mexican participants**
- ✓ **Findings:**
  - ✓ **Puerto Rican or Dominican more likely to get tested for COVID-19**
  - ✓ **South American participants more likely to get tested and vaccinated**
- ✓ **Speaking Spanish (vs. English) or another language at home = more likely to get vaccinated**
- ✓ **Spanish-speaking participants with Mexican, Cuban, or Central American heritage = more likely to get vaccinated**
- ✓ **Highlights heterogeneity in testing and vaccination**
- ✓ **Culturally specific interventions that vary by heritage may be warranted**
- ✓ **Designing national public health services that are culturally appropriate for the wide range of Hispanic communities is challenging, largely because different Hispanic populations have settled in different parts of the U.S., have retained language and cultural norms in different ways, and participate in testing and vaccination**

Opportunities and Challenges from the RADx-UP initiative after 44 months

- NIH support for a community-engaged network of community-academic partnerships
- Developed and implemented common data elements across >80% of projects
- Data sharing in central repository for analyses
- Mechanism to disseminate science-based information and return of results to communities
- Continuous effort to sustain trust
- Sustainable financial support to CBOs

RADx-rad

RADx-rad Overview

Overarching Program Goals

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

Phase I

~$108M in Extramural Funding, including PreVAIL kIds, a research effort to study Multisystem Inflammatory Syndrome in Children (MIS-C)

49 Extramural Awards issued to **45 unique institutions** in **20 states;** also supported **2** intramural projects

Example Research Technologies

- **Predicting viral-associated inflammatory disease severity** in children with laboratory diagnostics and artificial intelligence
- **Novel biosensing and chemosensory testing** for COVID-19 screening
- **Wastewater-based** detection of SARS-CoV-2
- **Multimodal** surveillance methods for high-risk populations
- **Exosome-based** technologies towards multi-parametric and integrated approaches for SARS-CoV-2

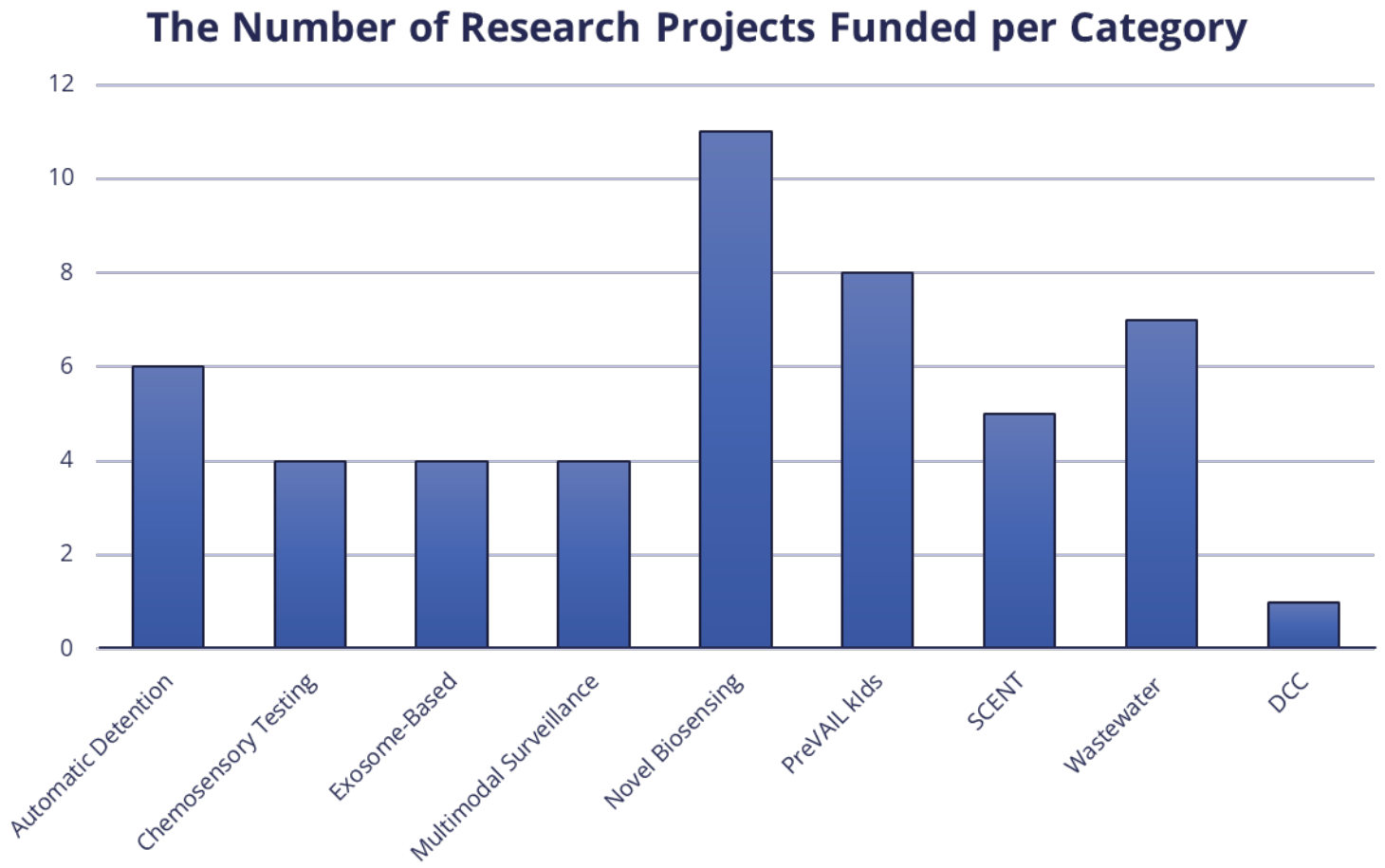
Phase II

Commercialization support provided in coordination with **SEED**

Long Covid Computational Challenge **(L3C)** which supported creative **data-driven solutions** that meaningfully advance the current understanding of the risks of developing PASC/Long COVID

RADx-rad Overview of Projects

Researchers from across the U.S. submitted creative applications, to fund 50 projects to 45 unique institutions in 20 states.



Examples of Funded Research

- Optimization and clinical validation of novel and repurposed technologies, such as **chemosensory approaches** and **exosome-based** detection technology **for SARS-CoV-2 detection**.
- Approaches to using **wastewater-based** and other environmental analysis for SARS-CoV-2 detection, to **provide real-time information and forewarning of disease spread**.
- Development of **prognostic algorithms** to stratify Multisystem Inflammatory Syndrome in Children (MIS-C) and severe COVID-19 in children.
- Support of a Computational Challenge **for creative data-driven solutions** to advance the current understanding of the risks of developing Long COVID.

Example Research Technologies – Phase I

WASTEWATER DETECTION

Wastewater analysis **observed and detected emerging variants** of COVID

HIGHLIGHTS:

Wastewater analysis **provided data that linked detection of COVID-19 variants in wastewater** with detection of the same variants in clinical samples from buildings/locations associated with the wastewater collection.

Wastewater detection **was shown to precede outbreaks of infection** as detected in the clinical samples.

FUTURE OPPORTUNITIES:

Commercialization efforts have been started with the creation of prototype testing equipment with industry backing.

Wastewater testing has started to **expand into testing for other viruses, bacteria, and drugs.**

Walter E. Lamar, Ph.D., executive director of Occupational Health, Safety and Compliance for the University of Miami Medical Campus, sets up an autosampler in a manhole on the University of Miami's campus. Image courtesy of Matthew Roca.

Example Research Technologies – Phase I

EXOSOME-BASED TECHNOLOGY

Researchers developed a **rapid saliva-based test** that can differentiate between gram positive and gram negative-bacterial infections as well as viral infections.

HIGHLIGHTS:

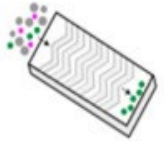
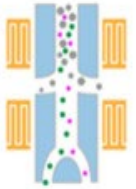
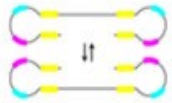
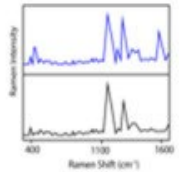
Developed saliva-based testing that **can be used to detect all variants of COVID-19** and other diseases ranging from viral and bacterial infections to cancer.

Developed testing methods with a rapid testing time, and several of the testing kits have a 90-day shelf life.

FUTURE OPPORTUNITIES:

Exosome based testing has been **licensed to external companies for the scalability of manufacturing** of the testing devices.

Development of **technologies to be used for detecting multiple viruses,** characterizing cancer biomarkers, and predicting response to therapies.

Awardee Institution	Johns Hopkins University	Mass General Hospital	Ohio State University	UCLA
Viral Separation Method				
	Simple Bind-Elute Microfluidics	Novel Microfluidic Chip	Novel Microfluidic Chip	Acoustofluidic Separation (AFS)
Viral Detection Method				
	Electrical Probe-Based Detection	Loop-Mediated Isothermal Amplification (LAMP)	Total Internal Reflection Fluorescence Microscopy	Surface Enhanced Raman Scattering (SERS)
Detection	SARS-CoV-2 RNA Exosome RNA	SARS-CoV-2 RNA Exosome RNA Exosome Protein	SARS-CoV-2 RNA SARS-CoV-2 Protein	SARS-CoV-2 RNA SARS-CoV-2 Protein Host Antibodies

Exosome Based Technology:

The RADx-rad Exosome research utilizes microfluidic based platforms for the viral separation and isolation. The steps are:

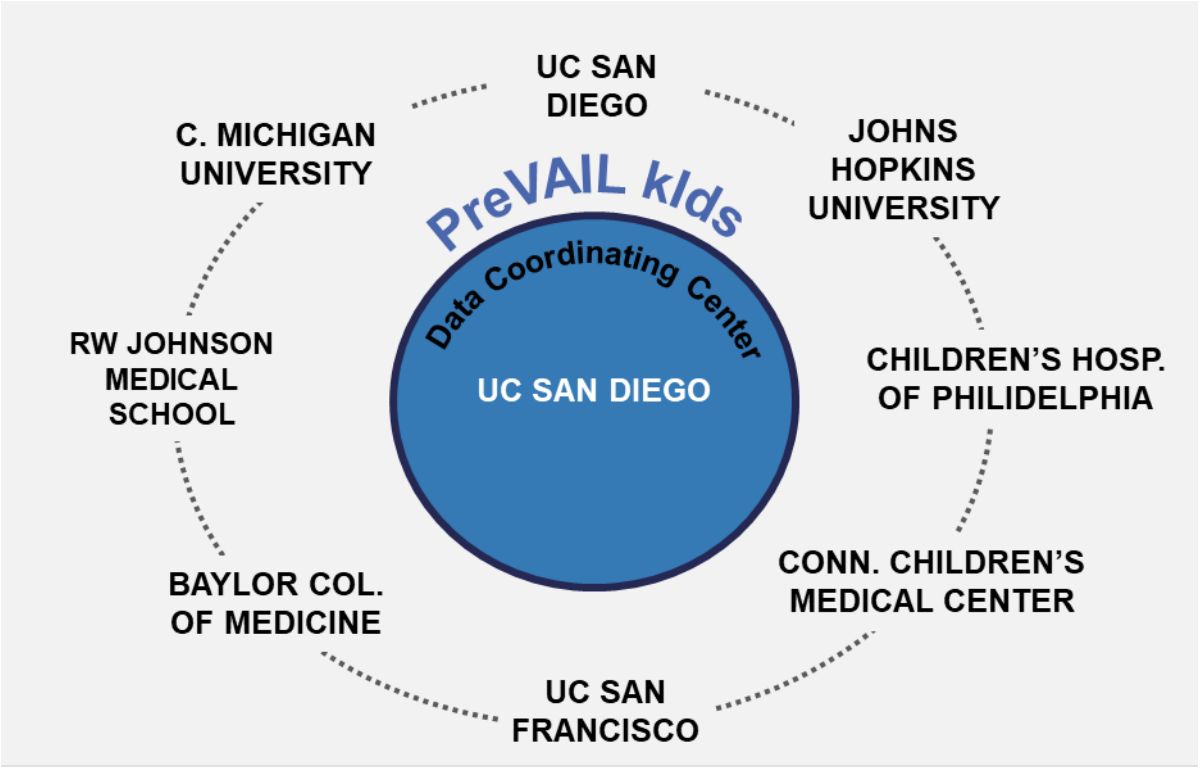
1. The Isolation of intact viral particles
2. Enrichment of intact viral particles
3. Detection of SARS-CoV-2 through electrical probe-based detection, loop-mediated isothermal amplification, total internal reflection fluorescence microscopy, and surface enhanced Raman spectroscopy

Source:
Happel C, Peñalber-Johnstone C, Tagle DA. Pivoting Novel Exosome-Based Technologies for the Detection of SARS-CoV-2. Viruses. 2022 May 18;14(5):1083. doi: 10.3390/v14051083. PMID: 35632824; PMCID: PMC9148162.

Predicting Viral-Associated Inflammatory disease severity in children with Laboratory diagnostics and artificial Intelligence

Program Goals and Structure

PreVAIL kIds supports innovative research to develop **novel, unique, and non-traditional approaches** to identify and **characterize the spectrum of SARS-CoV-2-associated illnesses**, such as multisystem inflammatory syndrome in children (**MIS-C**).



Program Highlights

- **All 8 Teams** successfully transitioned to **R33 phases** after fulfilling their R61 milestones
- Prospective Enrollment: **8024** individuals
- Retrospective Enrollment : **237766** individuals
- **93 research publications** and an additional **65** in preparation
- Broad patient populations from **>75 sites across 30 US states** and international collaborators in UK, Canada, South Africa, Asia, and South America
- **7 teams** have been funded for a supplemental study aimed to **validate assays and algorithms** developed in the R61 stage

Scientific Highlights

- **Developing and validating algorithms to differentiate MIS-C** from similarly presenting diseases to **optimize treatment**
- Determining **immune function biomarkers** that can **predict** COVID-19 **severity** through RNA and epigenomic analyses
- **Identifying RNA biomarkers** that distinguish MIS-C from non-MIS-C and severe COVID-19 from mild/asymptomatic COVID-19
- Developing **RNA and Proteomic signatures of MIS-C** and other inflammatory syndromes to develop new diagnostic tools

Phase II - L3C Summary

Research Question: If infected with SARS-CoV-2, who is more susceptible to developing PASC/Long COVID?

Challenge Scope: Develop, train, and test AI/ML models and algorithms using N3C data, creating open-source tools for using structured medical records to identify which patients infected with SARS-CoV-2 have a high likelihood of developing PASC/Long COVID

KEY STATS

35 Teams Submitted Complete Models - *High submission-per-team engagement level for a Challenge*

29 Models ran successfully and were scored in Technical Review

12 Federal Judges participating in Federal Review

10 Models evaluated in the Top 25% Federal Review Phase

Rank	Winners	Prize
First Place	Convalesco	$200k
Second Place	Geisinger AI Lab	$150k
Third Place	UC Berkeley	$100k
Hon. Mention	University of Wisconsin Madison BMI	$16.6k
Hon. Mention	Penn	$16.6k
Hon, Mention	Ruvos	$16.6k

Summary of Winner's Scientific Details: Team Convalesco, based out of the University of Chicago, designed a lightweight, portable model which achieved a 0.87 AUROC and uses 131 total features (100 temporal features and 31 static demographic features) and included a cumulative-risk-over-time visualization dashboard for the model interpretation. The model's features included:

- Conditions from the acute phase sometimes associated with PASC, as well as prior viral exposure of any type
- Oxygen saturation
- Bloodwork
- Certain drug exposures during the acute phase

RADx-rad Key Accomplishments

Program Accomplishments

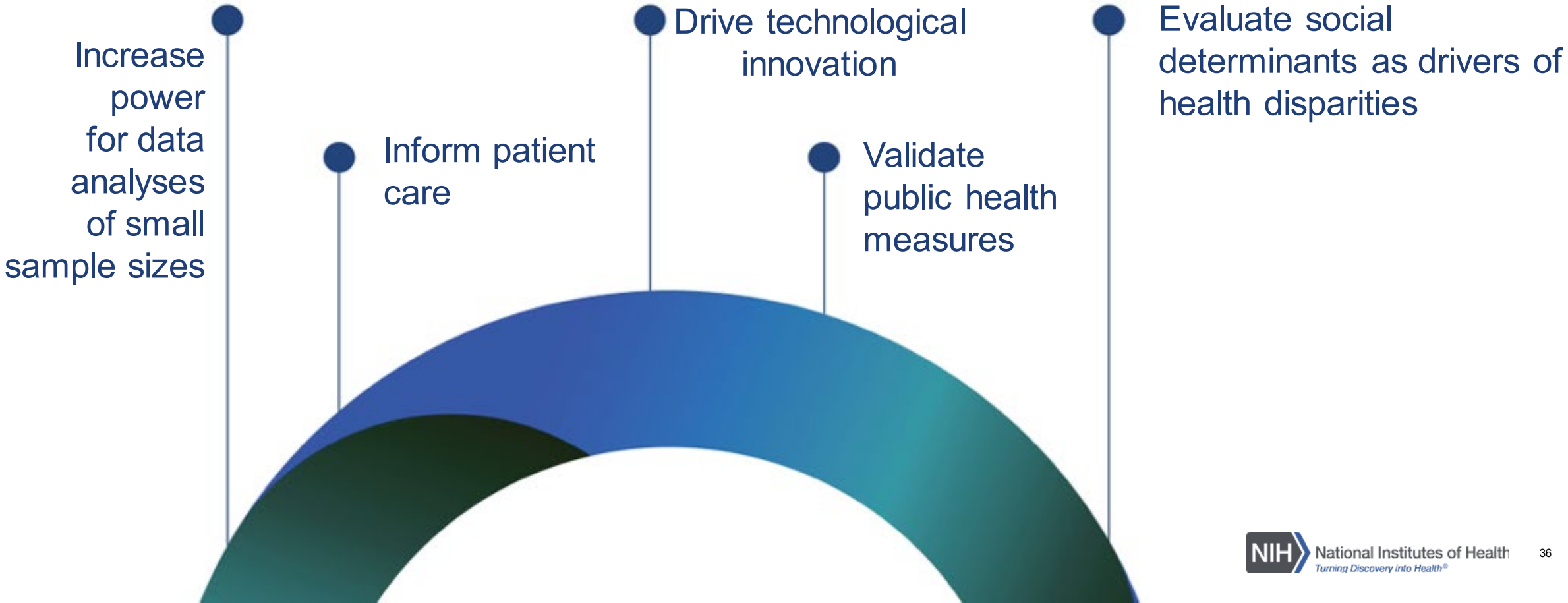
As of October 2023,…

- **7** Projects **submitted Pre-EUA** applications, **1** Project **submitted EUA** application
- **32 filed and granted patents** or **released as open source** tools
- **23 projects** met with the FDA
- **26** project teams submitted **Primary Publications**
- **10** projects were awarded **commercialization support**

RADx Data Hub

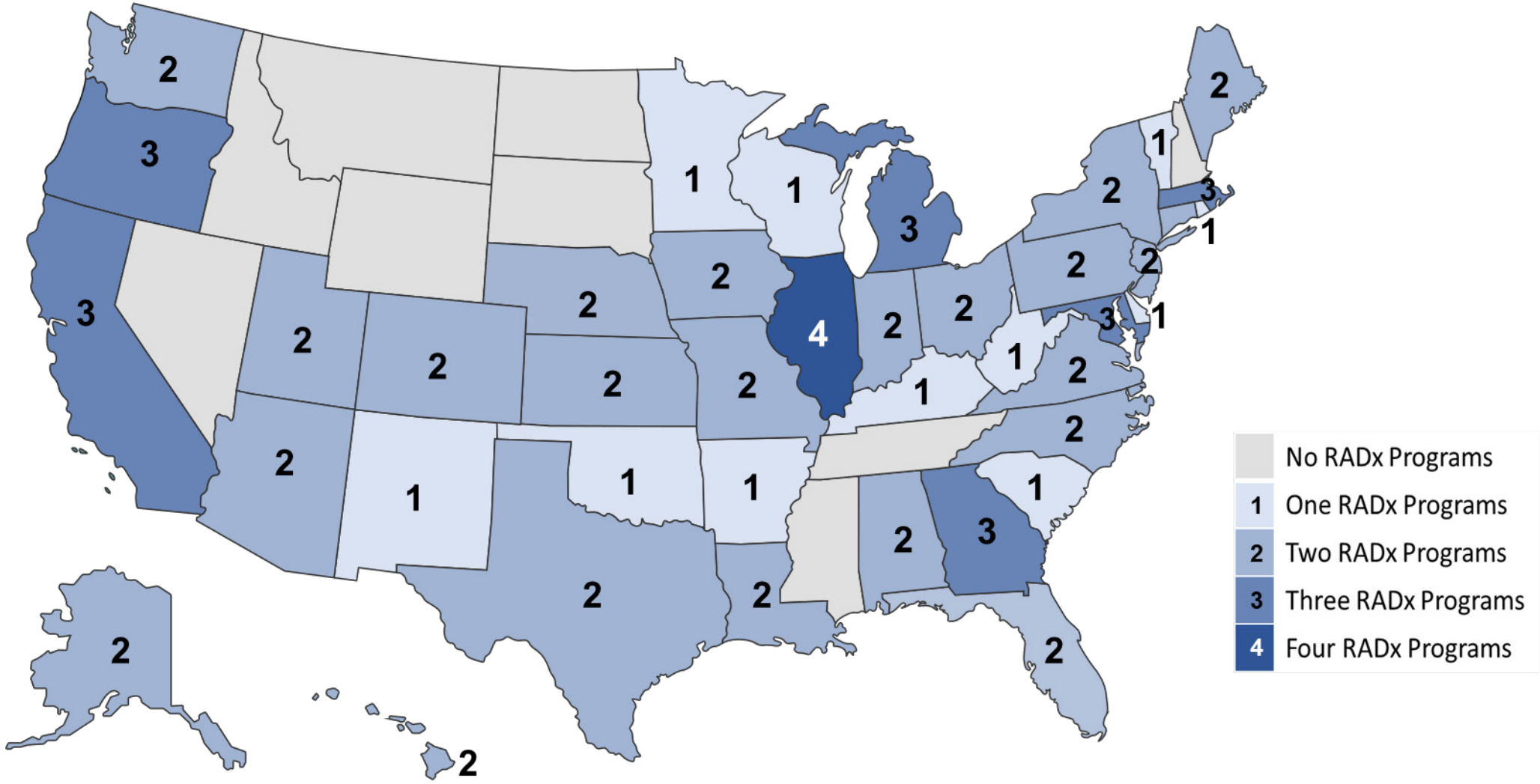
The Value of RADx Data

Provide researchers with data and tools to answer questions that may inform the COVID-19 response and better equip us to deal with future pandemics



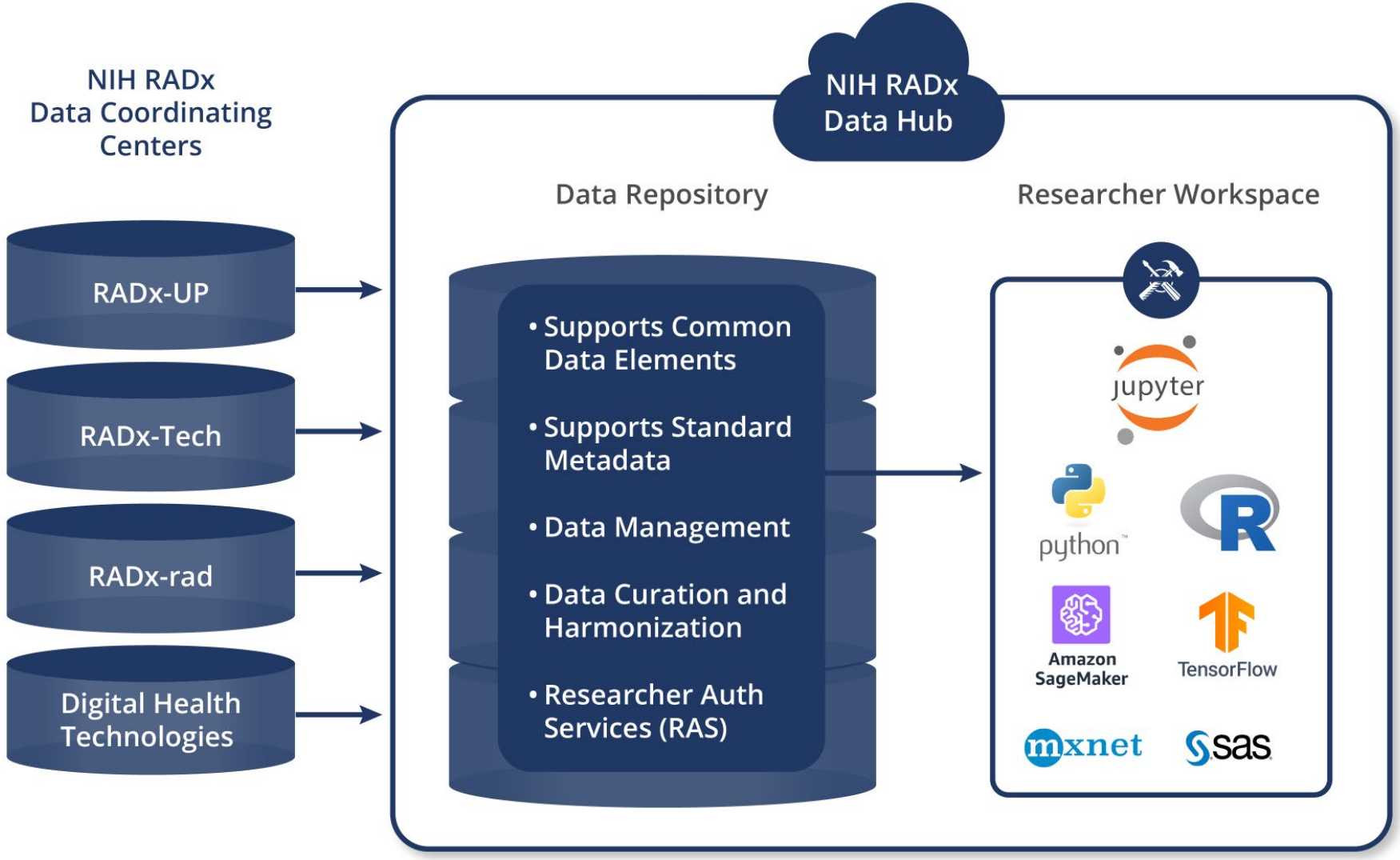
RADx Data Data Sources

The data collection of the participants in RADx Data Hub are spread across the country with many states represented by multiple RADx study programs.



RADx Data Hub Vision

The RADx Data Hub is a cloud-enabled data repository that provides curated and de-identified COVID-19 study data, algorithms, and other capabilities generated by the NIH-supported RADx programs



Current RADx Data Hub Features

Study Registration
Employs dbGaP for increased findability and simplified data access

Secure Data Access
Employs NIH Researcher Auth Service (RAS) for user authentication and authorization to approved studies and data files

Data Discoverability
Discover 138 studies across all four RADx programs using the Data Catalog

Cloud-based Workspaces
Analyze RADx data using cloud-based tools in a secure environment

Sharable and Reusable Tools
Use Jupyter notebooks to create or reuse Python or R analysis tools

Available Studies for Research Use (as of 11/27/2023)

	89 Studies RADx-UP	39 Studies RADx-rad	7 Studies RADx Tech	3 Studies RADx-DHT	138 Studies Total
Expected # of Studies	126 studies	49 studies	13 studies	10 studies	198 studies
# of Data Files Available	152 data files	960 data files	17 data files	N/A	1,129 data files
# of Variables Available	24,474 variables	19,551 variables	1,442 variables	N/A	45,467 variables
Data Types	*Studies include survey, clinical, diagnostic/ test, biological sample, and/or sequencing data*	*Studies include also provide survey, clinical, diagnostic/ test, biological sample, and/or sequencing data*	*Studies include also provide diagnostic/test data, sequencing data, and/or images*	*Studies include also include survey and wearable/sensor data*	*Studies include Social Determinates of Health*
Genomic Samples & Images	N/A	1,663 samples 0 images	233 samples 2,519 images	N/A	1,896 samples 2,519 images

Metadata Harmonization Challenges

Conflicting Standards

Different schemas and standards across diverse sources

Varying Quality

Usually incomplete, non-uniform, inaccurate, nor F.A.I.R. (Findable, Accessible, Interoperable, Reusable)

High Expertise Required

Requires combining technical proficiency, domain knowledge, and diverse metadata schema understanding

Achieved: RADx (C)DCCs adoption of RADx Metadata Specifications.
Most RADx (C)DCCs now submit harmonized metadata.

Next Steps: Determine future metadata submission expectations.
Provides unified start-to-finish solution.

Impact: New and improved data and metadata harmonization workflow.

Future RADx Data Hub Updates

Updates focus on increasing usability

Study Explorer

Metadata-driven advanced search, sort, and filtering across studies and datasets

- Faceted browsing: automatically updated after new study or data files released
- Search results in list or table view
- Enhanced study pages with information on datasets, documentation, and study variables
- Access to synthetic and training datasets

Metrics Reporting

Dynamic, on-demand reporting on content, harmonization, and user activity

Updated Researcher Workspace

Improved workspaces with scalable, automated, and collaborative tools

- Preconfigured, scalable compute instances with Jupyter 3 notebook using Python or R
- Ability to create fully-automated machine learning workflows
- Data manipulation, analysis, and visualization capabilities with SAS

Improved Data Ingest

Enhanced upload processes, file categorization, and validation

Improved User Management

Additional user and institution attributes, improved Support Request feature

RADx Data Accomplishments

Launched the RADx Data Hub website and cloud platform in Dec. 2022

- A secure workspace to combine authorized data use and analytics tools
- Enables researcher collaborations
- Ensures ability to share analyses results
- Created a framework for generating artificial intelligence-ready datasets

RADx® Tribal Data Repository (TDR): **Data for Indigenous Implementations, Interventions, and Innovations (D4I)**

- Enables researcher's access to RADx study data on COVID-19 and other health topics involving American Indian and Alaska Native participants.
- Objectives
  - **Administrative, Governance, and Tribal Consultation Logistics** – Adherence to the Tribal Nations laws & policies
  - **RADx TDR Build** – Adherence to NIH IT security standards
  - **Research Capacity & Education Resource Development & Implement**

Stanford University, Stanford, CA, Native BioData Consortium (NBDC), Eagle Butte, SD, University of Wisconsin, Madison, WI, Arizona State University, Phoenix, AZ, University of Washington, Seattle, WA, Ohio State University, Columbus, OH, University of California – Santa Cruz, CA

Conclusion

The Legacy and Future of RADx

RADx Tech

- **Accelerated development, accessibility, and availability** of COVID-19 diagnostic testing platforms.
- The RADx Tech infrastructure has been **used to address a range of other public health concerns**, such as fetal and maternal health, nervous system disorders, mpox, Hepatitis-C, and HIV.

RADx-UP

- **Built community engagement**, connecting underserved and vulnerable populations with COVID-19 mitigation resources; will continue to foster these relationships **for lasting impact**.
- Laid the foundation to **prepare for future public health emergencies** by successfully researching program implementation **focused on underserved and vulnerable populations**.

RADx-rad

- Provided a mechanism that **supports innovative projects** to complement other SARS-CoV-2 detection and testing research, and to better diagnose acute and long-term conditions associated with COVID-19.
- Using a wide variety of technologies, showed the various **ways informatics and technologies can be used to support future public health response** to pandemics.

RADx Data Hub

- Represents one of the largest collections of NIH COVID-19 testing data available to researchers.
- Will provide **harmonized data across ~200 RADx studies** that is findable, accessible, interoperable, reusable.
- The development of the **RADx Tribal Data Repository created a pathway for future collaboration** and data collection working with American Indian/Alaska Native communities.

Q&A