

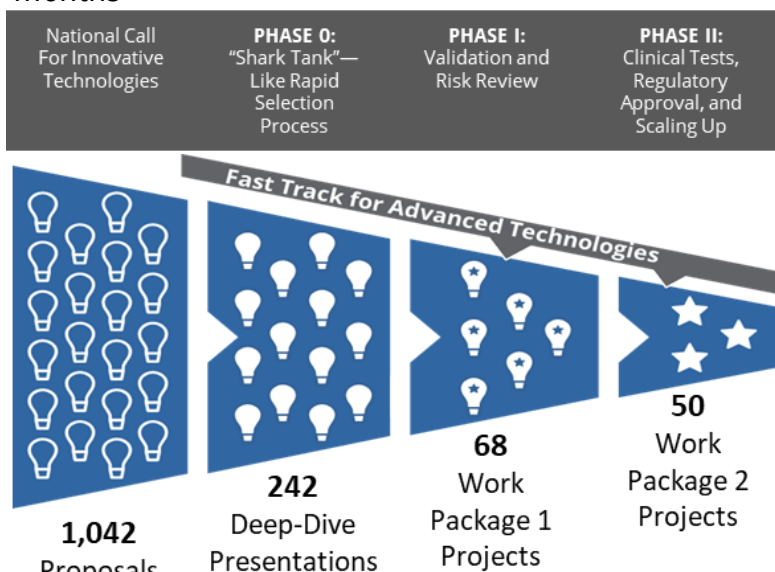
NIH RAPID ACCELERATION OF DIAGNOSTICS (RADX®) TECH | RADx® Tech



OVERVIEW: RADx Tech was created to generate a robust pipeline of innovative diagnostic technologies to increase national COVID-19 testing capacity. This effort was able to validate, de-risk, manufacture, scale-up, and deploy novel at-home and point-of-care tests through an optimized pipeline in less than eight months.

RADx Tech Innovation Funnel

This funnel was designed to compress the customary technology development timeline from years down to months



By the Numbers

PROJECT SUCCESSES (2020 – 2023)	
>7.8 billion tests and products produced	18 OTC EUAs and 1st OTC test for COVID-19
55 FDA authorized tests	125+ publications
>100 organizations supported	1,042 proposals from 47 states/territories and 23 countries
2 Multiplex COVID/Flu Test EUAs via ITAP	1 Mpx POC Test EUA & 1 Pending EUA for Mpx Home Collection Kit



What People are Saying

"The US RADx program has spawned a phalanx of diagnostic products to market in just 12 months. Its long-term impact on point-of-care, at-home and population testing maybe even more profound."
— Nature Biotechnology Editorial, April 2021

Independent Test Assessment Program (ITAP)

Accelerates regulatory review and availability of high-quality, accurate, and reliable diagnostic tests

- As a collaboration between RADx Tech and the FDA, ITAP support has produced 12 over-the-counter (OTC) Emergency Use Authorizations (EUAs) for COVID-19 diagnostic devices
- Current ITAP support focuses on validating multiplex diagnostic products for COVID-19 and Flu

Mobile At Home Reporting Through Standards (MARS)

Promotes a standards-based approach to reporting COVID-19 self-test results and establishes best practices for future reporting of remote diagnostics

- MARS site currently supports reporting for 10 COVID-19 diagnostic products
- Since launching in November 2022, over 123,000 test results have been self-reported
- MARS acts as the backbone for Make My Test Count, a website to anonymously report test results regardless of the type of test, which can then be assessed by local public health departments

Accessible Test Initiative

The effort to work with collaborators to develop at-home diagnostic tests for COVID-19 that can be used independently by people with disabilities

- Collaborated with the U.S. Access Board to develop a "Best Practices" document for the design of accessible, at-home tests
- The RADx Tech III funnel has recently funded five projects focused on developing accessible tests
- Achieved EUA for a simple, two-part, "pen" test that can be used independently by people with disabilities

Program Contacts: RADxInfo@nih.gov
www.nibib.nih.gov/covid-19/radx-tech-program

NIH RAPID ACCELERATION OF DIAGNOSTICS (RADx®) UNDERSERVED POPULATIONS | RADx®-UP



OVERVIEW: The RADx-UP program assesses and expands COVID-19 testing to reduce disparities for underserved and vulnerable populations.

RADx-UP Program Highlights

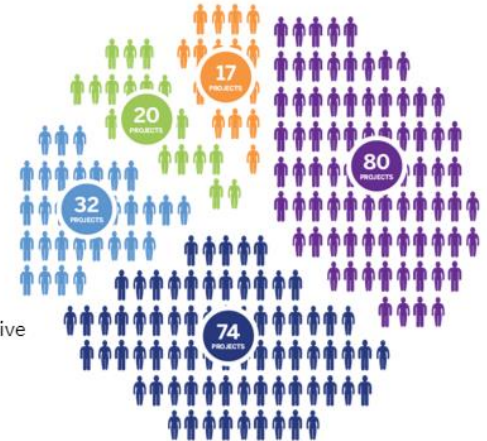
- The program strengthened the ability to distribute millions of diagnostic tests within underserved populations and reach different communities disproportionately affected by COVID-19
- Projects provided isolation and contact tracing strategies, as well as point of care, self and saliva-based testing to mitigate community transmission
- Publications indicate that mitigation strategies, including testing, can reduce COVID-19 transmission in settings such as schools, residential care facilities, and jails/prisons
- Community-engaged and directed research is integral to implementing testing and mitigation strategies, and requires time and attention to build trust, adequate compensation for community collaborators, and investment of full partnership among researchers, community participants, and NIH scientific staff

Primary Populations Engaged

By Race and Ethnicity

- Hispanic/ Latino
- Black/ African American
- Asian
- American Indian/ Alaska Native
- Hawaiian/ Pacific Islander

Data is self-reported by projects. Projects may serve more than one population.



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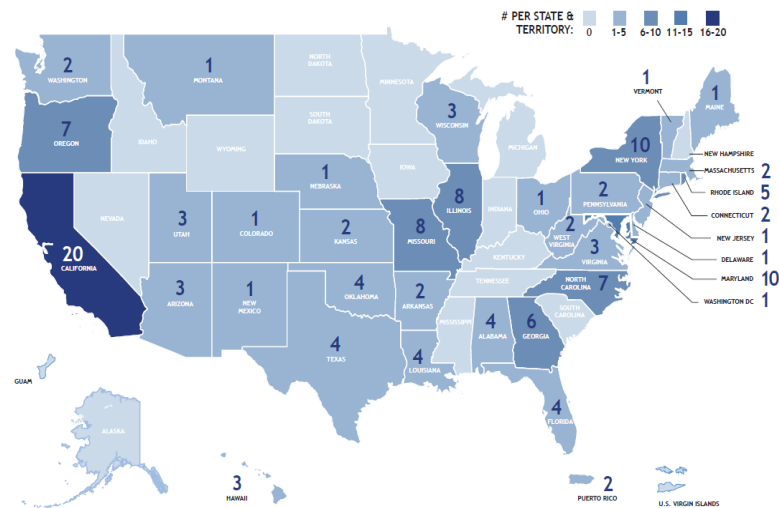
Accomplishments by the Numbers

PHASES I - IV (2020 - 2023)

142 Projects	1 Coordination & Data Collection Center (CDCC)	53 States, Territories, and DC
404,00+ Enrolled participants	447,000+ COVID-19 tests conducted	120 Projects submitting data to the CDCC
69 Community Collaboration Grants	25 Rapid Research Pilot Awards	265 Journal Articles

RADx-UP Project Locations

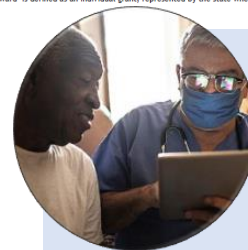
Below is a map of the number of RADx-UP projects across the U.S. and Territories from Phase I through Phase IV



*Award is defined as an individual grant, represented by the state where the primary recipient institution is located

Community Engagement's Impact

- Community engagement accelerated program goals and advanced equitable access to testing locally and nationally.
- Trusted partnerships quickly mobilized interventions, while enhancing community acceptance and readiness for research.
- Underserved populations want to collect, share, and disseminate their data – it is a key piece of community engagement - they also want to hear about results!



What Participants are Saying

“The idea here is to partner with communities and local health departments to help address inequities, beginning with inequities in testing, and the vast majority of these funds will go into these counties and directly into these at-risk communities.”

– **Edward Ellerbeck, M.D., MPH**
RADx-UP Principal Investigator
Chair, Department of Population Health
University of Kansas School of Medicine

NIH RAPID ACCELERATION OF DIAGNOSTICS (RADx®) RADICAL (RAD) | RADx®-RAD



OVERVIEW: The NIH's RADx-rad program supports new, non-traditional approaches that address current gaps in COVID-19 testing and surveillance, such as rapid detection devices, environmental surveillance and diagnosis of acute and long-term effects of COVID-19. These approaches may improve identification and tracking of SARS-CoV-2, as well as future pathogens, and provide information on acute and long-term effects of COVID-19.

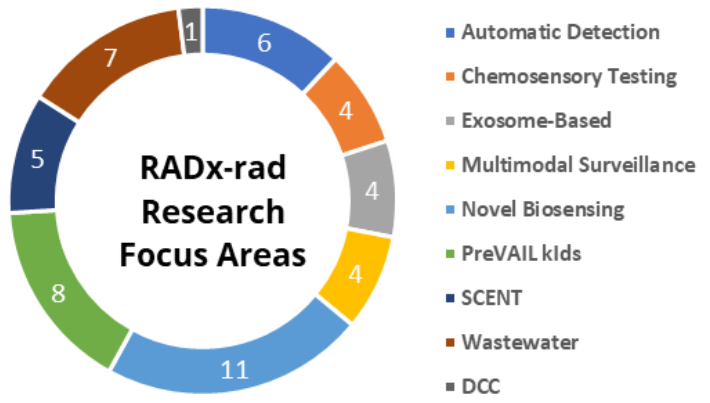
Program Highlights

- 49 Extramural Awards issued to 45 unique institutions in 20 states; also supported two intramural projects
- Beyond initial awards, ran a challenge prize which attracted 160 participants and resulted in six awards

Example Research Technologies:

- 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 SARS-CoV-2 in children
- Support of a Computational Challenge for creative data-driven solutions to advance the current understanding of the risks of developing Long COVID

Research Focus Areas

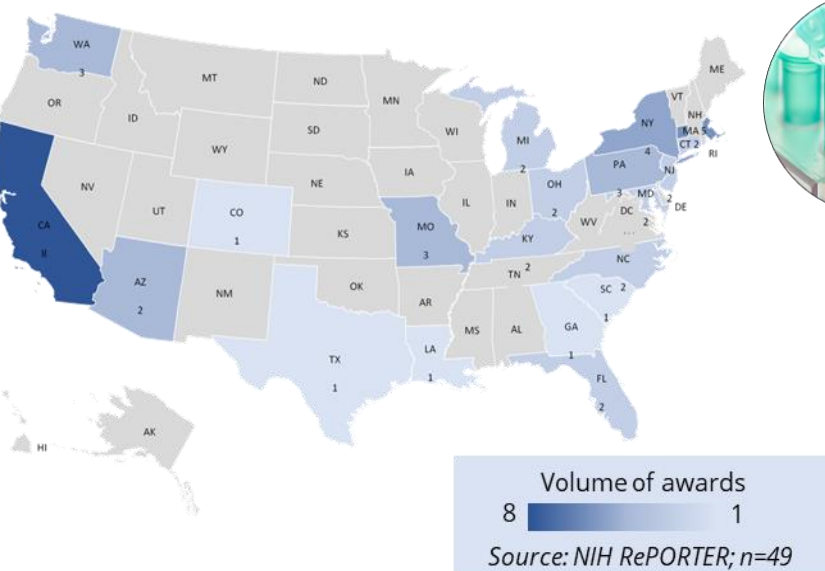


By the Numbers

INITIAL AWARDS (2020 – 2024)		
49 Projects awarded	12 Funding opportunities	45 Participating institutions
PROJECT SUCCESSES (REFLECTS 2020 – 2023)		
32 Filed patents or released as open source	7 Projects submitted Pre-EUAs	1 Project submitted Emergency Use Authorization (EUA)
23 Projects TEAMS met with FDA	26 Projects TEAMS submitted primary publications	10 Awarded commercialization support

RADx-rad Project Locations

U.S. Distribution of Institutions awarded in Phase I



What People are Saying

“These awards from the RADx-rad program provide superb examples of outside-the-box concepts that will help us overcome this pandemic and give us a cadre of devices and tactics to confront future outbreaks.”

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

Program Contact: RADxInfo@nih.gov
www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs#radx-rad

NIH RAPID ACCELERATION OF DIAGNOSTICS (RADX®) DATA HUB | RADx® Data Hub

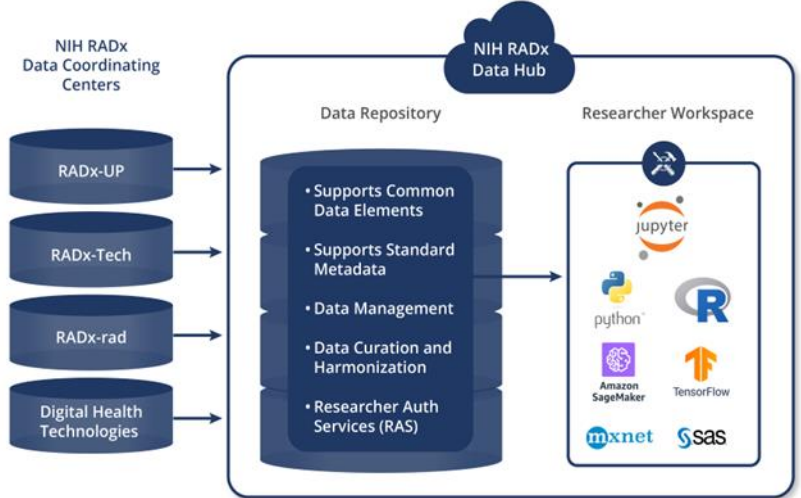


OVERVIEW: The RADx Data Hub is a cloud-enabled data repository that provides curated and de-identified COVID-19 study data, algorithms, and other capabilities generated by the NIH-supported RADx programs. It supports capabilities to find, aggregate, and analyze data to better understand COVID-19 and future pandemics including underserved populations and those disproportionately impacted by COVID-19.

Program Goals

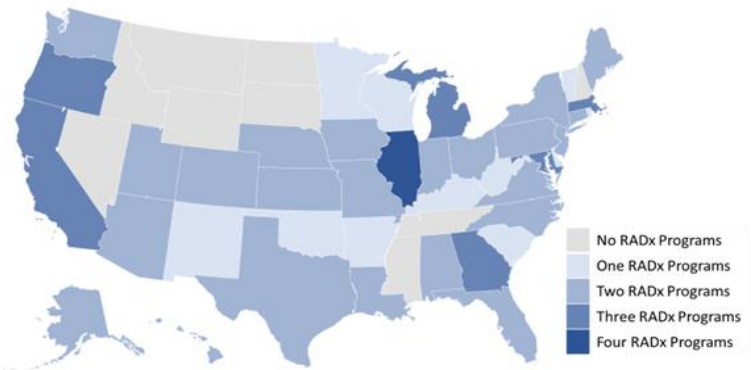
1. Develop a cloud-based data repository of **COVID-19 research data** – including clinical, behavioral, social determinants of health, survey, interview, diagnostic test results, viral sequencing, output from smart sensors, self-reported symptoms, and imaging data
2. Provide access to **de-identified RADx** study research data, **algorithms**, and other capabilities to expand testing and identify effective testing implementation strategies, especially for underserved populations and those disproportionately impacted by COVID-19

RADx Data Hub Architecture



RADx Data Hub Data Sources

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



By the Numbers

PROJECT SUCCESSES (2020 – 2023)	
138 Available Studies for Research Use	Harmonized 12 Common Data Elements & 133 Mapped Variables
1,129 Data Files	45,467 Total Data Variables Across All Studies
10+ Data Domains Collected	287 Metadata Files (Data Dictionaries, READMEs & Schema)
1,896 Viral Samples with Genomic Sequencing Data	2,519 Viral Images

Program Accomplishments

The RADx Data Hub:

- Provides 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**
- Creation of a **RADx Tribal Data Repository** for sovereignty-based data access and sharing of American Indian/Alaska Native RADx data



What People are Saying

"This marks a major milestone for the RADx Initiative...from our DHP partnership's efforts, the support of our colleagues across the NIH Institutes, Centers, and Offices who have committed countless hours to the RADx effort, research participants, and the tireless efforts of the RADx researchers across the nation." — Dr. Susan Gregurick, Director, Associate Director for Data Science, NIH

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