RADx Underserved Populations (RADx-UP)

Phase III: Rapid Testing and SEBI Pre-Application Webinar

March 15, 2022

NIH National Institutes of Health
Turning Discovery into Health®

Speaker

Welcome and Introductions

Elizabeth Walsh, Ph.D.
Office of the Director

Webinar Outline

Topic	Presenter	Time
Welcome & Introductions	Elizabeth Walsh Ph.D.	1:00-1:05pm
Overview of RADx	Elizabeth Walsh Ph.D.	1:05-1:15pm
Rapid Testing RFA-OD-22-006	Wilson Compton M.D., M.P.E.	1:15-1:35pm
SEBI RFA-OD-22-005	Nancy Jones Ph.D.	1:35-1:50pm
CDCC and Data Sharing	Dottie Castille Ph.D.	1:50-2:10pm
Question & Answer	Moderated by: Nancy Jones Ph.D. Panelists include: • Lisa Steele, CSR • Chris Lindsey Ph.D. • Jonathan King Ph.D. • Greg Greenwood Ph.D., M.P.H. • Brian Albertini	2:10-2:50pm

Housekeeping

- The webinar will be recorded.
- All participants except speakers and panelists will be muted.
- Please place questions in the Questions and Answers module; they will be answered either in the chat box or during the Q&A sessions.
- Immediately after each presentation, the speaker will answer a few questions; the extended Q&A session after all presentations will cover all questions.
- All questions and answers will be captured in an FAQ.
- The FAQ, the video, and the slides for today's webinar will all be posted on the NIH RADx website: https://www.nih.gov/research-training/medical-research-initiatives/radx/events

Presenters and Panelists

Presenters:

Dr. Elizabeth Walsh (Office of the Director, RADx-UP Governance Committee and Working Group Coordinator)

Dr. Wilson Compton (Deputy Director, NIDA, RADx-UP Working Group Co-Chair)

Dr. Nancy Jones (NIMHD, Division of Community Health and Population Science)

Dr. Dorothy Castille (NIMHD, RADx-UP Coordination and Data Collection Center Program Officer)

Additional Panelists:

- **CSR Review**
  Lisa Steele (Epidemiology and Population Health Branch)
- **Grants Management**
  Brian Albertini (NINR)
- **Rapid Testing FOA/Notice**
  Dr. Jonathan King (NIA)
  Dr. Greg Greenwood (NIMH)
- **SEBI**
  Dr. Nancy Jones (NIMHD)
- **Testing in Schools**
  Dr. Chris Lindsey (NICHD)

Speaker

Rapid Acceleration of Diagnostics (RADx) Overview

Elizabeth Walsh, Ph.D.
Office of the Director

Rapid Acceleration of Diagnostics (RADx) Initiative

RADx Tech – $908M*

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

RADx Underserved Populations (RADx-UP) – $533M

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

RADx Radical (RADx-rad) – $187M

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

RADx Advanced Testing Program (RADx-ATP) – $192M

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

Data Management Support – $70M

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

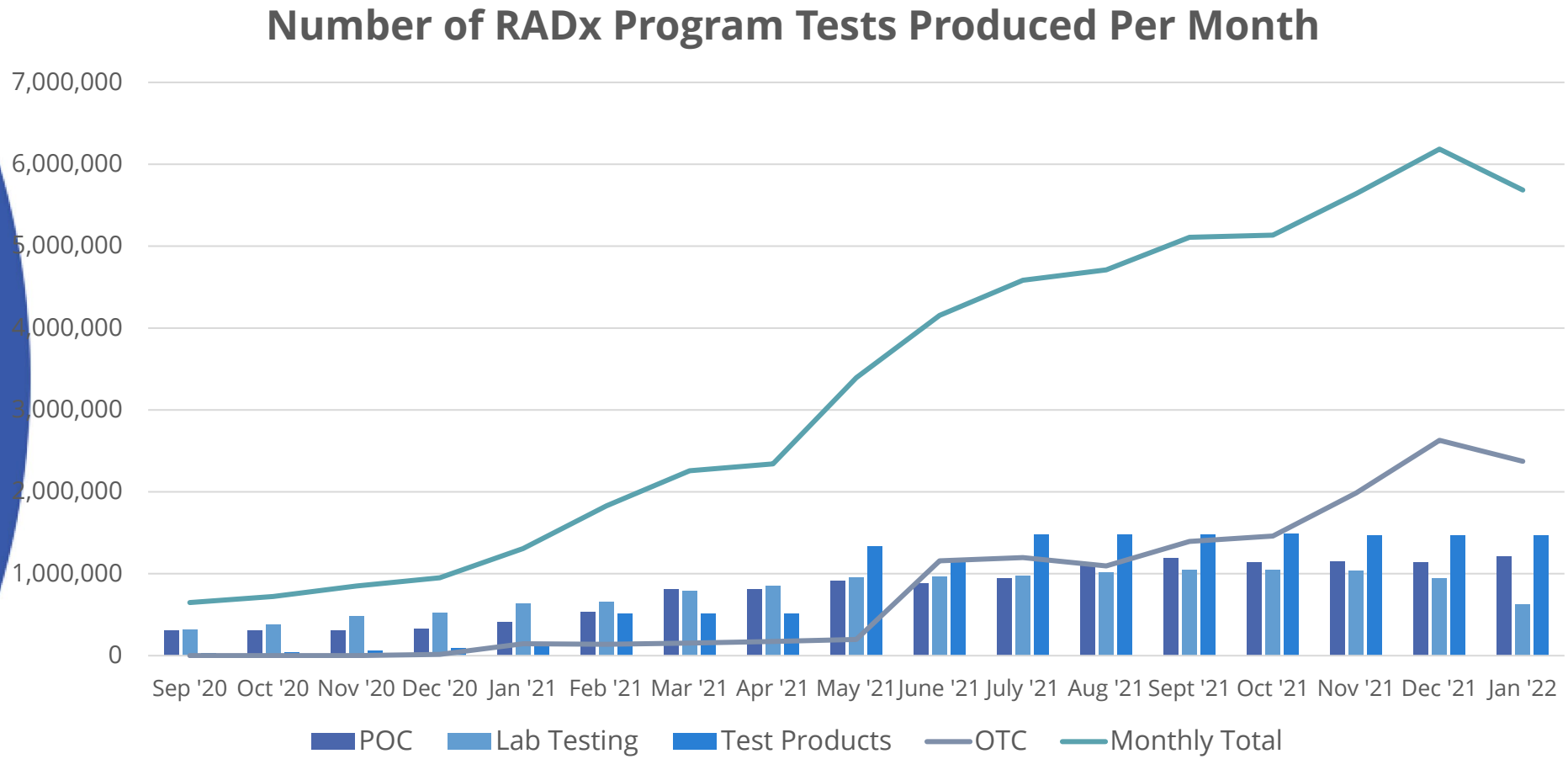
At-Home Diagnostic Testing– $20M

Evaluate the effectiveness of existing diagnostic technologies and platforms in at-home environments

* Includes $185M in BARDA funds for development of RADx tests (funds were not transferred to NIH)

Contribution of RADx to the National Testing Capacity

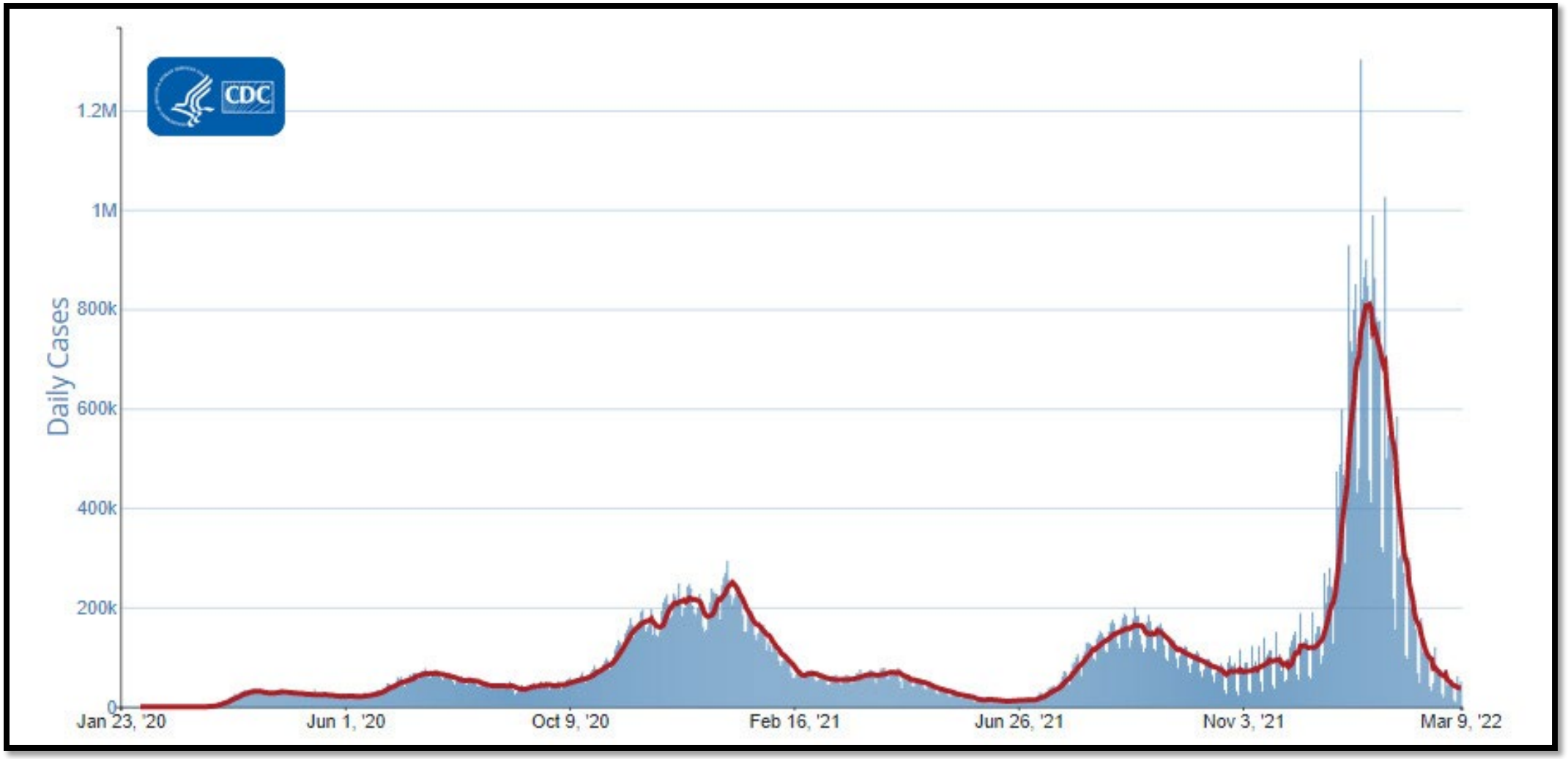
RADx awards contributed a cumulative **1.7B tests** to the National Testing capacity as of January 2022



* **Point-of-Care (POC)** is defined as a clinic, physician office, pharmacy, mass testing site, organization, or other location where test sample is collected and processed by a health care professional or trained individual. Considered a rapid test and results are provided at the time of testing in 30 minutes or less.

- **Lab/Test Products** - test kits, swabs, or technology that can help meet supply gaps or increase the number of tests that can be processed.

Daily Trends in COVID-19 Cases in the United States Reported to CDC



https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

March 9, 2022 – New cases: 48,868
7-day moving average: 37,147
Total Cases Reported: 79,248,406

Racial and Ethnic Minority Groups are Disproportionately Affected by COVID-19*

Risk for COVID-19 Infection, Hospitalization, & Death by Race/Ethnicity[1]

Rate ratios compared to White Persons	American Indian or Alaska Native	Asian	Black or African American	Hispanic or Latino
Cases	1.5x	0.7x	1.1x	1.5x
Hospitalization	3.1x	0.8x	2.5x	2.3x
Death	2.7x	0.8x	1.7x	1.9x

https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/infographic-cases-hospitalization-death.html

**Note that the CDC data shown does not include Pacific Islander populations which is another population disproportionately affected by COVID-19*

[1] Table Source CDC as of March 1, 2022: Risk for COVID-19 Infection by Race/Ethnicity (CDC)

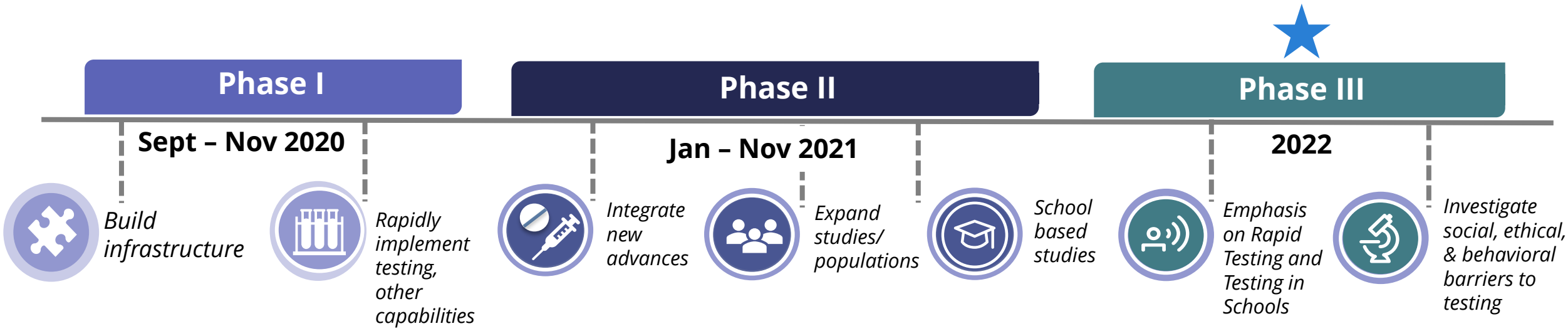
RADx-UP focuses on people who are experiencing a disproportionate burden of COVID-19

- **Underserved:** NIH-designated health disparity populations and other groups known to **experience barriers to accessing needed health care services** or have inadequate health care coverage. A full description can be found at https://www.nimhd.nih.gov/about/overview/
- **COVID-19 medically and socially vulnerable populations:** Specific populations included in this program thought to be specifically **vulnerable to the impact of COVID-19** due to specific medical conditions, social determinants, or living situations. A detailed list is provided in the FOA.

RADx-UP Phases and Timeline

Program Goals

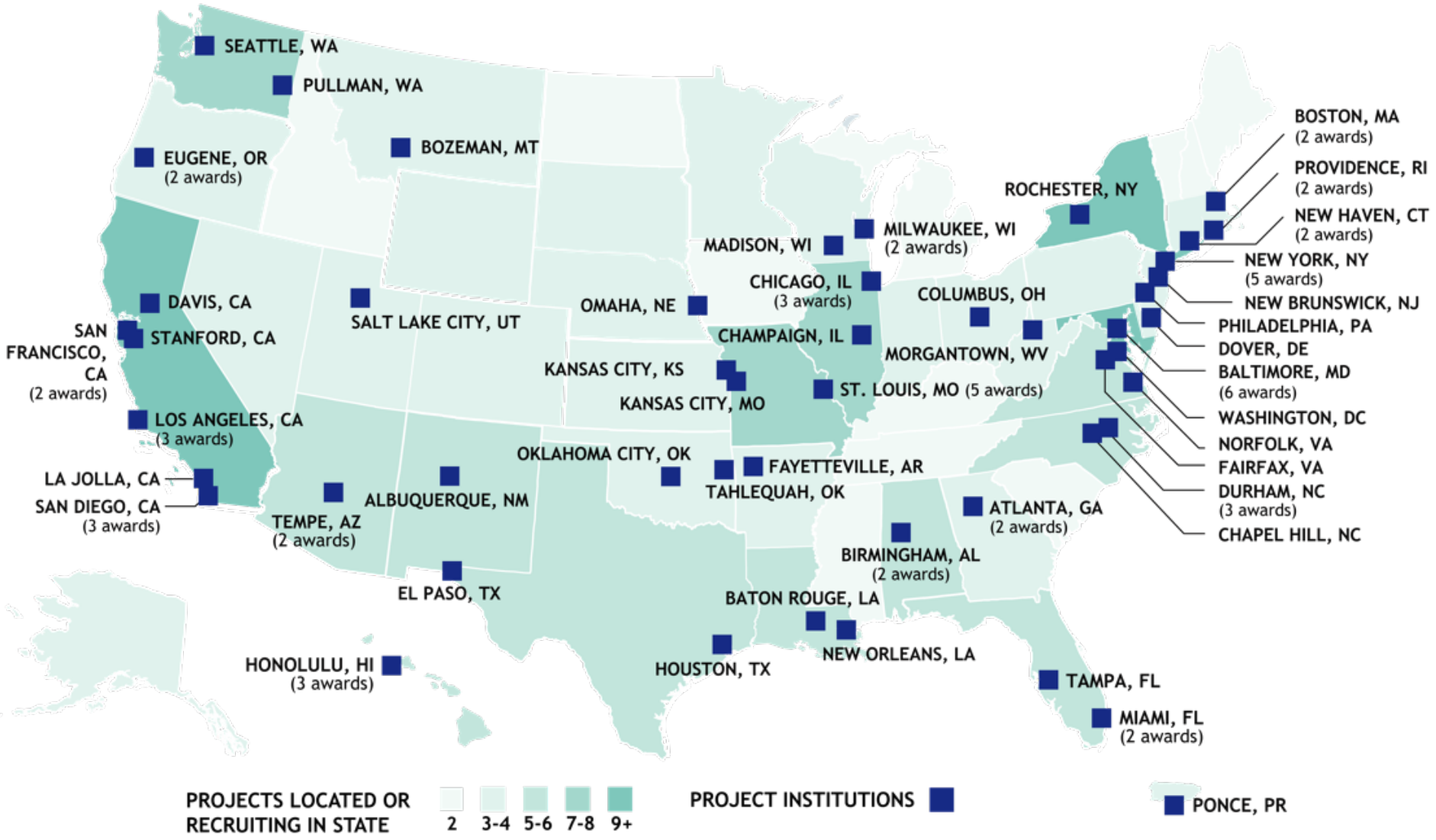
- Enhance COVID-19 testing among **underserved and vulnerable populations** across the US
- Develop/create a **consortium of community-engaged research projects** designed to rapidly implement testing interventions
- **Strengthen the available data** on disparities in infection rates, disease progression and outcomes, and **identify strategies to reduce disparities** in COVID-19 diagnostics
- Reduce barriers and increase access and utilization of COVID-19 tests combined with other mitigation strategies
- Expand the evidence base of **scalable** and **sustainable** approaches to safely maintain students in school



RADx-UP Strategies

- **Expand capacity to test broadly** for SARS-CoV-2 in highly affected populations, including asymptomatic persons.
- **Deploy validated point of care tests** as available, including self-test and saliva-based methods.
- **Inform implementation of mitigation strategies** based on isolation and contact tracing to limit community transmission.
- **Understand social, ethical and behavioral factors** that contribute to COVID-19 disparities and **implement interventions** to reduce these disparities.
- **Establish infrastructure** that could facilitate evaluation and distribution of vaccines and therapeutics.

Communities served by RADx-UP projects



Self-reported data reflects RADx-UP Phase I and II projects as of 10/20/2021

RADx-UP At a Glance

127
COVID-19 testing/SEBI/R2S projects

1
Coordination & Data Collection Center

56
States, Territories* and D.C.

>1.4 million
Participants
(from EHR data)

>1.5 million
COVID-19 tests** conducted

68
Projects submitting data to CDCC

40
Community Collaboration Mini Grants

13
Rapid Research Pilot Awards

66
Published research articles

Data as of 3/15/2022
** COVID-19 tests conducted' includes prospective, EHR, and YMCF
* Territories include sites in: Guam, American Samoa, US Virgin Islands, Northern Mariana Islands and Puerto Rico)

Key Outcomes per Target Population (Testing + SEBI)

Schools

- ✓ Participation in weekly testing increases conscious mitigation behavior
- ✓ When mitigation strategies are followed, in-school transmission is low (<1%)
- ✓ Participation in weekly testing wanes over time
- ✓ Universal Masking is associated with reduced secondary transmission compared to optional masking

Black and Latino Communities

- ✓ Latino populations present with greater proportions of asymptomatic cases as compared to national average
- ✓ Black/African Americans in rural areas have lower testing rates, biasing positivity rates
- ✓ Black and Latino community populations display greater vaccine hesitancy – Local leaders should be engaged to facilitate acceptance and uptake

Lower Socioeconomic Status

- ✓ Lower income populations have reduced motivation to self-test and distribute testing kits to contacts

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RADx-UP Phase III: New Funding Opportunities

	RFA-OD-22-005	RFA-OD-22-006
FOA Focus	Social, Ethical and Behavioral Implications-SEBI	Rapid Testing
Budget Mechanism	U01	U01
Direct costs per year	limited to $350,000	limited to $700,000
Application Receipt	May 02	May 02
Eligibility	Open	Open
Scientific Focus	Address SEBI implications of testing	Implement and evaluate SARS-CoV-2 rapid testing

Speaker

COVID-19 Rapid Testing

RFA-OD-22-006

Wilson Compton M.D, M.P.E
National Institute on Drug Abuse

Background and Goals

Apply scientific knowledge gained thus far to:

- Develop and evaluate interventions with the **goal of decreasing disparities**
- Quantify and address **the benefits, risks, and efficacy of testing** and mitigation strategies at multiple levels
- **Expand the reach, scope, and effectiveness** of rapid diagnostic tests for communities
- Improve **utilization of subsequent mitigation behaviors based on test results**
- **Address disparities in testing and the effects of testing combined with other mitigation strategies** (e.g., public health guidance) on infection rates, transmission, and outcomes

What's new in Phase III?

- Specific focus on implementation and evaluation of **rapid SARS-CoV-2 testing**, **contract tracing, surveillance, and mitigation** strategies in varied settings
- Opportunity to implement and evaluate testing for **variant emergence or community-level sources of spread**
- Includes **evaluations of testing and vaccination mandates**
- **Individual, community, and population-level interventions** to optimize testing and mitigation adherence
- Special attention to **groups who have not been consistently identified as vulnerable** and may have considerable barriers to testing and mitigation adherence
- Focus on **testing in school and childcare settings** to gain a better understanding of effective new testing models and strategies to keep people safe during in-person instruction

Definitions

Rapid SARS-CoV-2 Diagnostic Testing

Molecular or antigen tests used to diagnose infection performed at or near the place where a specimen is collected, usually outside of a laboratory setting and might be used to diagnose SARS-CoV-2 infections in various settings, including at home, community health clinics, schools, the workplace, etc.

*Tests must be **FDA Emergency Use Authorized (EUA)** or Approved or Cleared tests for the specific, on-label purpose for which they were developed and authorized/approved/cleared.*

Effective Use of rapid diagnostic SARS-CoV-2 tests

Effective use means that tests must be used for the specific, on-label purpose for which they were developed and authorized/approved/cleared (e.g., including serial administration of tests if part of the recommended approach) by the FDA.

Point-of-Care Testing

Medical testing done at or near the point of care that involves performing a diagnostic test.

CLIA Certification

Clinical Laboratory Improvement Amendments (CLIA) regulates and requires all labs that accept human samples for diagnostic testing be certified by the Center for Medicare and Medicaid Services (CMS)

Emergency Award: RADx-UP Community-Engaged Research on Rapid SARS-CoV-2 Testing among Underserved and Vulnerable Populations (U01 Clinical Trial Optional)

RFA-OD-22-006

- *New* U01 awards

Purposes

1. To evaluate **rapid testing interventions** to prevent and control COVID-19 transmission among underserved and vulnerable populations
2. To implement rapid SARS-CoV-2 testing in **school and childcare settings**
3. Develop **partnership-driven research** to implement and evaluate rapid testing and reduce COVID-19 disparities

Research Topic *Examples* for RFA-OD-22-006

Potential research topics include but are not limited to:

- Expanding ***rapid testing strategies*** and new technologies to ***digitalize the return of results***, with a focus on diverse settings/populations
- Examine the effects of ***rapid testing interventions*** across states and localities with ***varying testing and vaccination mandates***
- Research in ***school and childcare settings*** to determine appropriate and effective rapid testing implementation to ***identify testing cadence,*** also known as “Test to Stay”
- Research to examine and address ***disparities in the availability, ease of use, and accessibility of new rapid testing technologies***
- Evaluate ***home visit programs for rapid testing***
- Implement and evaluate rapid testing for ***identifying variant emergence*** and community level spread
- Evaluations of testing and vaccination ***mandates among healthcare workers and employers*** and their implications
- ***Use of rapid tests to promote effective contact tracing*** in underserved locations with high community transmission

Key Considerations

Below are some key components of the study design, community engagement, and testing specifications in the FOAs

- ❑ Focus must be on underserved or COVID-19 vulnerable populations
- ❑ Primary outcomes must focus on testing, however secondary aims can include vaccination
- ❑ Projects should leverage, expand, or strengthen community-engaged partnerships
- ❑ Tests must be FDA-Emergency Use Authorized/approved/cleared and results must be CLIA certified where appropriate
- ❑ Actively coordinate, collaborate, and rapidly share all project data with the RADx-UP Coordination and Data Collection Center (CDCC)
- ❑ Disseminate results rapidly to improve mitigation strategies in communities disproportionately impacted by COVID-19

Requirements: *Examples*

Documented infrastructure to collaborate with the **Coordinating and Data Collection Center (CDCC)**

Use of **FDA EUA/approved/cleared** rapid diagnostic tests and supplies

Testing as the primary outcome (**measured objectively**)

Provide project **sustainability descriptions, milestones** and **timelines**

Establish research **infrastructure** and research **plan**

Utilize research strategies that reflect the **evolving landscape of the pandemic**

Collaborate with RADx-UP consortium members where appropriate

Full integration of community partners

NIH RADx-UP common data elements/Data **Sharing**

(https://radx-up.org/learning-resources/cdes/)

Non-Responsive Factors (*see RFA for full list*)

The following are examples that would be considered non-responsive

- Populations that are not underserved or COVID-19 vulnerable
- Project focusing exclusively on vaccination where the study primary outcome is vaccine-related (secondary vaccine-related outcomes are acceptable)
- Lack of demonstrated community engagement with populations of interest
- Study populations or sites outside of the U.S. or the U.S. territories
- Exclusively qualitative research (mixed methods are acceptable)
- Inability to collect NIH RADx-UP Common Data Elements and align Informed Consent Forms with the appropriate Data Use Agreements and Data Transfer Agreements
- No testing plan/strategies or use of tests other than FDA-authorized/ approved/cleared tests and CLIA processes

Review Considerations

RFA-OD-22-006 (*U01 Emergency Award*)

Significance: *standard criteria*

Investigator(s): Do the key personnel have appropriate expertise in community engaged research?

- When considering experience of community engaged researchers and community partners, nontraditional indices of expertise such as years of work in the index community or successful delivery of health programs to underserved communities can be considered. This experience should be documented through letters of support from community stakeholders, Tribal leaders, or other key representatives of the community with the authority to speak to the collaboration and past accomplishments.

Innovation: *standard criteria*

Review Considerations

RFA-OD-22-006 (*U01 Emergency Award*)

Approach: *standard criteria plus FOA specific additional criteria*--

- How feasible and appropriate are the plans to collaborate with the existing RADx-UP field sites and future RADx-UP field sites? Where a network of subprojects are collaborating in a project, does each subproject include agreement with the requirements to collect NIH RADx-UP Tier 1 Common Data Elements, adhere to sharing of all data where not prohibited by Tribal sovereignty in the required format and on the NIH-directed timetable?
- Does the research team have the capability to adapt and respond quickly to the changing dynamics (e.g., variants, cases, hospitalizations, deaths, availability of tests and supplies, personal protective equipment, closures, public health guidance, population specific changes, etc.) of the COVID-19 pandemic?
- Where vaccination uptake is included as a topic, does the study of vaccination (within the context of rapid COVID-19 testing) clearly add value to the application's aims regarding rapid testing in underserved and vulnerable populations?
- Is the proposed approach dynamic and able to be responsive to evolving changes in COVID-19 diagnostics, vaccination, and treatment?
- How feasible and appropriate are the plans for integrating community partners into the study?

Review Considerations

RFA-OD-22-006 (*U01 Emergency Award*)

Environment: *standard criteria*

Resource Sharing Plan:

- Is the resource sharing plan timely and feasible? Does the plan make instruments, products, results, and data findable and accessible to the research and public health community, where not limited by Tribal data sovereignty? In instances involving Tribal data sovereignty, is there documentation of Tribal agreement with adapted data sharing plans? If school data are included, are there considerations of protections such as those included in the Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99)?

Additional Review Criteria:

- Study Timeline
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan

Budget for RFA-OD-22-006

Respondents can request a budget option limited to $700K in direct costs per year

Conditions

Study budgets should include funds to compensate community partners to participate in research design and implementation

Budgets should reflect active participation by community partners to the extent possible

Process

Reviewers will consider whether the budget and requested period of support are fully justified and reasonable in relation to the proposed research

The administrative and funding instrument used for this program will be the cooperative agreement

An assistance mechanism, rather than an acquisition, in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of activities

Key Dates

	Application Receipt	Review Process	Earliest Start Date
RFA-OD-22-006 (U01 Emergency Award Testing)	**May 2, 2022 – 5pm local time**	July-October 2022	December 2022

Questions?

Speaker

Social Ethical Behavioral Implications (SEBI)

RFA-OD-22-005

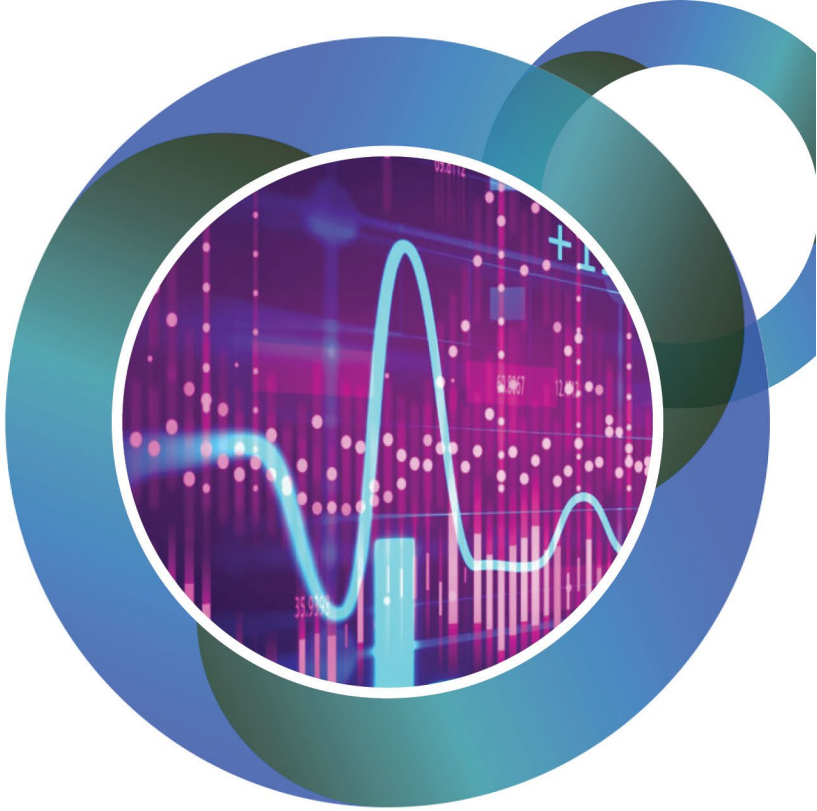
Nancy Jones, Ph.D. , M.A.

National Institute of Minority Health and Health Disparities

What's new in Phase III?

- SEBI projects should consider the **social, ethical, behavioral, communication, structural, environmental, historical, and policy-related barriers** that lead to disparities in access to and uptake of COVID-19 testing in underserved populations
- How the **availability of COVID-19 vaccines**, boosters, and therapeutics affects the **need for and propensity to seek COVID-19 testing**
- New focus on the challenges of COVID-19 **testing access and uptake**, including **rapid tests** at point-of-care locations
- The influences of **cultural beliefs, expectations, distrust, and communication** preferences and strategies on willingness to complete testing, prior to and after gatherings
- **Testing-related scientific inquiries** as the primary research question with **vaccination** and other mitigation strategies as secondary aims

Emergency Awards: RADx®-UP - Social, Ethical, and Behavioral Implications (SEBI) Research on Disparities in COVID-19 Testing among Underserved and Vulnerable Populations (U01 Clinical Trial Optional)



RFA-OD-22-005

- *New* U01 awards

Purposes:

1. Focus on the urgent need for social, ethical, and behavioral implications (**SEBI**) research to understand COVID-19 **disparities** arising from **barriers** to **testing** among **underserved** and **vulnerable populations**
2. **Psychological** and **communication science** interventions to improve **uptake** of **testing** and **vaccination**

Requirements

Address **social, ethical, and behavioral factors** associated with COVID-19 testing disparities

Establish research **infrastructure** and research **plan**

Flexible response to a **rapidly changing** pandemic environment

Inclusion of **community partners and stakeholders**; letters of support

Include descriptions of **project sustainability, milestones, partnership** and **timelines**

Work with **RADx-UP, CCDC, consortium members**

Collect **personal identifiers** where permitted & possible

NIH RADx-UP CDE/Data Sharing https://radx-up.org/learning-resources/cdes/-resources

Research Topic Examples for RFA-OD-22-005

The following list is not exhaustive

- Studies focused on **unintended positive and negative consequences** of COVID-19 testing, including factors that contribute to **vaccine and related booster uptake and reinforce protective behaviors**
- Research to examine and address the **effects of distrust of medical and public health research** on COVID-19 testing and vaccination programs
- Natural experiments across **states and localities with different testing and/or vaccination policies** to develop a stronger evidence base regarding how to address COVID-19 disparities
- **Variations in messaging and mitigation policies at the local, state, and federal levels** on COVID-19-related beliefs (e.g., trust) and behaviors (e.g. help-seeking, adherence to testing, quarantine, and vaccination recommendations)

Scientific Emphases

The following are examples of important considerations for SEBI projects

- Looking ahead to **future roles of/issues** with testing
- Testing in groups and areas where **vaccines have/have not reached**
- Vaccination effects on **adherence to other prevention** behaviors
- Effects of **structural racism**
- Effective **collection of testing data** and use in decision-making
- Impact on communities of **stacking COVID-19 research** on top of testing/vaccination services

Key Project Considerations

- ❑ Examine SEBI implications of testing among underserved and vulnerable populations
- ❑ Projects can conduct COVID-19 testing, but are not required
- ❑ Projects can examine SEBI of vaccination, but a major focus must be COVID-19 testing disparities
- ❑ Projects without quantitative components are acceptable
- ❑ Plan to collect CDE and share all data with NIH, where it is not prohibited
- ❑ Community engagement and collaboration
- ❑ Multi-level analysis (individual, interpersonal, institutional, community, policy)

Non-Responsive Factors

The following types of projects would generally not be appropriate

- Administer COVID-19 testing or vaccination as the primary activity (see RFA-OD-22-006)
- Do not have a primary focus on SEBI issues
- Do not focus on underserved and COVID-19 vulnerable populations
- Focus exclusively on vaccination
- Offer COVID-19 testing, or work with COVID-19 testing or vaccination programs that are not FDA emergency use authorized/approved/cleared, and not using CLIA certified labs
- Do not discuss generalizability and public health impact
- Do not demonstrate equitable relationships with populations and stakeholders
- Study populations or COVID-19 testing outside the United States
- Lack of structure and planning to coordinate with CDCC and other RADx-UP sites to align and share data
- **Applications must discuss consent for and collection of all NIH RADx-UP Common Data Elements**

Key Dates

	Application Receipt	Review Process	Earliest Start Date
RFA-OD-22-005 (U01 Emergency Award SEBI)	May 2, 2022 – 5pm	July-August 2022	November 2022

Questions?

Speakers

RADx-UP Coordination and Data Collection Center (CDCC) and Data Sharing

Dottie Castille, Ph.D.

Program Official for CDCC

National Institute of Minority Health and Health Disparities

RADx-UP CDCC

RADx-UP Coordination and Data Collection Center (CDCC)

- Serves as a hub for all RADx-UP funded projects
- Provides steadfast assistance to RADx-UP projects to optimize engagement, outreach, testing strategies, data collection and integration, and co-learning opportunities between and among projects and with the communities that we serve
- Led by the **Duke Clinical Research Institute (DCRI), the Center for Health Equity Research at UNC-Chapel Hill** with support from a key partner, **Community-Campus Partnerships for Health**

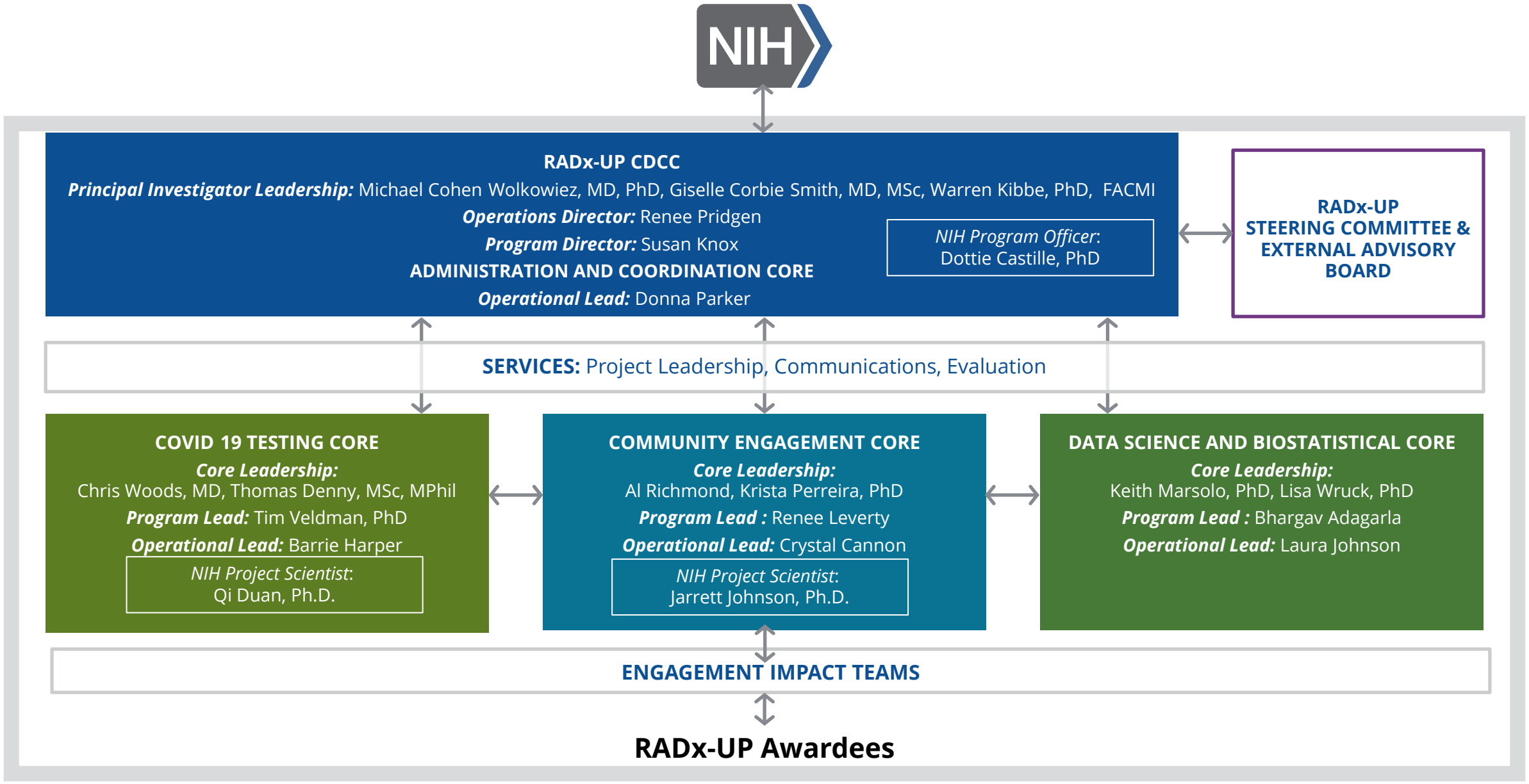
RADx-UP CDCC Goals

Accelerate COVID-19 community implementation science via an agile, flexible, participatory, transparent and sustainable CDCC.

Amplify and disseminate community best practices for successful implementation of COVID-19 testing strategies and vaccines.

Support data collection, integration, and sharing while preserving necessary data protections.

Utilize RADx-UP infrastructure to support COVID-19 research.



RADx-UP CDCC Resources can be viewed here: https://radx-up.org/learning-resources/

NIH Vision for RADx-UP Data

- Largest single NIH investment to **understand the factors that protect or harm** underserved communities
- NIH RADx-UP Common Data Elements (**CDEs**) to help **capture consistent data** for comparison across studies
- Alignment with requirements to make data findable, accessible, interoperable and reusable (FAIR)
- Resource for NIH, communities, and researchers to **understand the impact of COVID-19 on the well-being, risk, resilience, and disparities** in underserved and vulnerable communities

RADx-UP Scope

- **The scope for all RADx-UP projects must retain a primary focus on testing and testing interventions.**

- **All testing interventions must be completed with FDA EUA/approved/cleared certified tests AND be processed under CLIA certification.**

- **All projects must collect <u>all</u> NIH RADx-UP Tier 1 Common Data Elements.**

Data Sharing Policies

01

Weekly CDE Deposition

Based on project terms and conditions, all RADx-UP Projects are required to deposit NIH **RADx-UP Tier 1 CDEs on a weekly basis**

02

Quarterly Data Deposition

The NIH **requires** for all RADx projects is to **deposit ALL** relevant **project data** on a **quarterly** cadence

03

Data Sharing Plans

All RADx projects must have **clear data sharing plans** that are in alignment with the specifications in the FOA and the Terms and Conditions of Award

04

Clean Data

Data deposited to the CDCC required to be **anonymized and consented for general research re-use**

NIH RADx-UP Informed Consent Requirements

Informed Consent Form (ICF) language is required to include:

- Depositing de-identified data in the CDCC and NIH RADx Data Hub
- Sharing de-identified data with the CDCC and NIH for future scientific research
- Sharing identifiable data to permit re-contact for future follow-up and participation in future research

Refer to the RADx-UP CDCC Learning Resources webpage for Informed Consent Form Data Sharing Template Language in English and Spanish (when available).

Questions?