RADx[SM] Underserved Populations (RADx-UP)

Phase II: Testing/Vaccination and SEBI Pre-application Webinar

April 28, 2021

National Institutes of Health
Turning Discovery into Health®

Speaker

Welcome and Introductions

Ming Lei, Ph.D.

National Institute of General Medical Sciences

Webinar Outline

Topic	Presenter	Time
Welcome & Introductions	Ming Lei Ph.D.	1:00-1:05pm
Overview of RADx	Ming Lei Ph.D.	1:05-1:15pm
Testing and Vaccination & CR RFA-OD-21-008 & NOT-OD-21-103	Monica Webb Hooper Ph.D.	1:15-1:35pm
SEBI RFA-OD-21-009	Dave Kaufman Ph.D.	1:35-1:50pm
CDCC and Data Sharing	Dottie Castille Ph.D. Beda Jean-Francois Ph.D.	1:50-2:05pm
Question & Answer	Brian Albertini; Judy Arroyo Ph.D.; Alison Cernich Ph.D.; Wilson Compton M.D.; Nancy Jones Ph.D.; Tiffani Lash Ph.D.; Lindsey Martin Ph.D.;	2:05-2:50pm

Presenters and Panelists

Presenters:

Dr. Ming Lei (Director of the Division for Research Capacity Building, NIGMS, RADx-UP Working Group Co-Chair)

Dr. Monica Webb Hooper (Deputy Director, NIMHD, RADx-UP Working Group Co-Chair)

Dr. Dave Kaufman (Program Director, NHGRI, Division of Genomics and Society)

Dr. Beda Jean-Francois (Health Scientist Administrator, NIMDH, RADx-UP Coordination and Data Collection Center Program Officer)

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

Additional Panelists:

- **Grants Management**
  - Brian Albertini (NINR)
- **Testing-Vaccination FOA/Notice**
  - Dr. Wilson Compton (NIDA)
  - Dr. Lindsey Martin (NIEHS)
  - Dr. Tiffani Lash (NIBIB)
  - Dr. Judith Arroyo (NIMHD)
- **SEBI**
  - Dr. Nancy Jones (NIMHD)
- **Return to School**
  - Dr. Alison Cernich (NICHD)
  - Dr. Sonia Lee (NICHD)

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Housekeeping

- 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 webinar will be recorded.
- 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

Speaker

Rapid Acceleration of Diagnostics (RADx) Overview

Ming Lei, Ph.D.

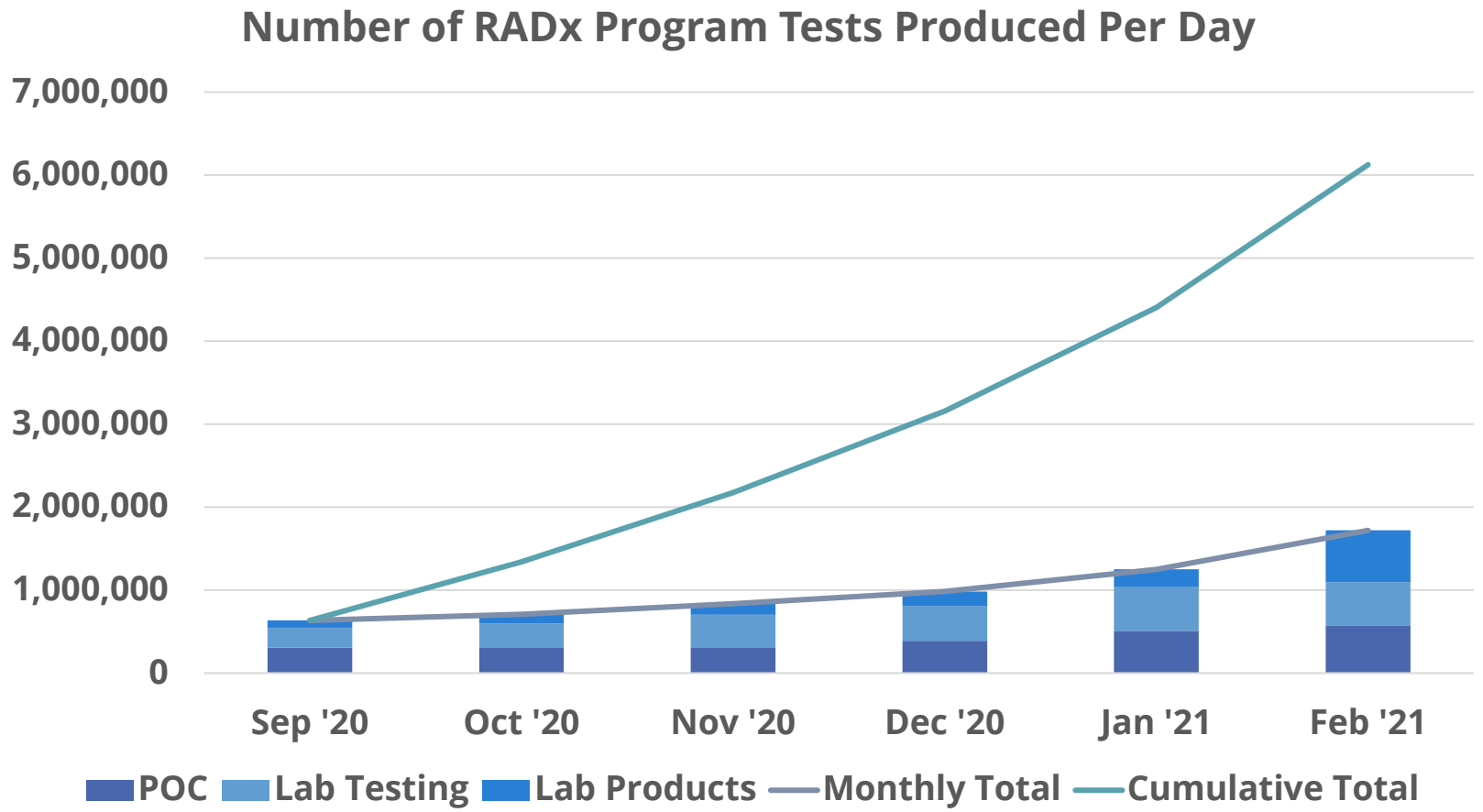
National Institute of General Medical Sciences

Rapid Acceleration of Diagnostics (RADx) Overview

Project	Description
RADx Tech	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)	Rapid scale-up of advanced POC technologies and laboratories to accelerate, enhance and validate utility of ultra-high throughput machines and facilities.
RADx-Radical (RADx-rad)	Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing.
RADx-Underserved Populations (RADx-UP)	Interlinked community-engaged projects focused on implementation strategies to enable and enhance testing of COVID-19 in underserved and/or vulnerable populations.

Contribution of RADx to the National Testing Capacity

RADx awards contributed a cumulative **6.1M tests per day** to the National Testing capacity as of February 2021



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

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/or 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 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.

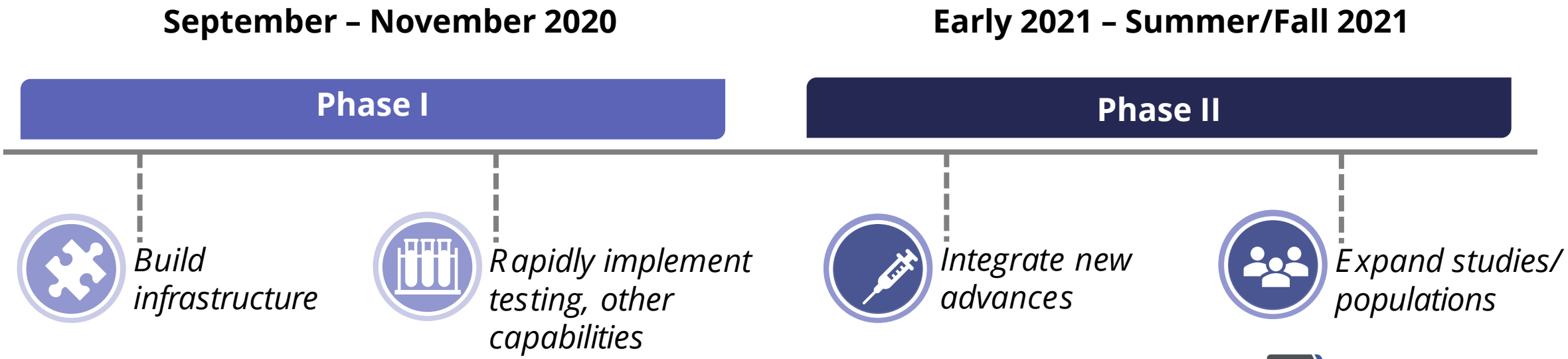
RADx-Underserved Populations (RADx-UP)

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 improve and implement testing interventions

Strengthen the available data on disparities in infection rates, disease progression and outcomes, and identify strategies and interventions to **reduce these disparities in COVID-19** diagnostics



RADx-UP Phase I

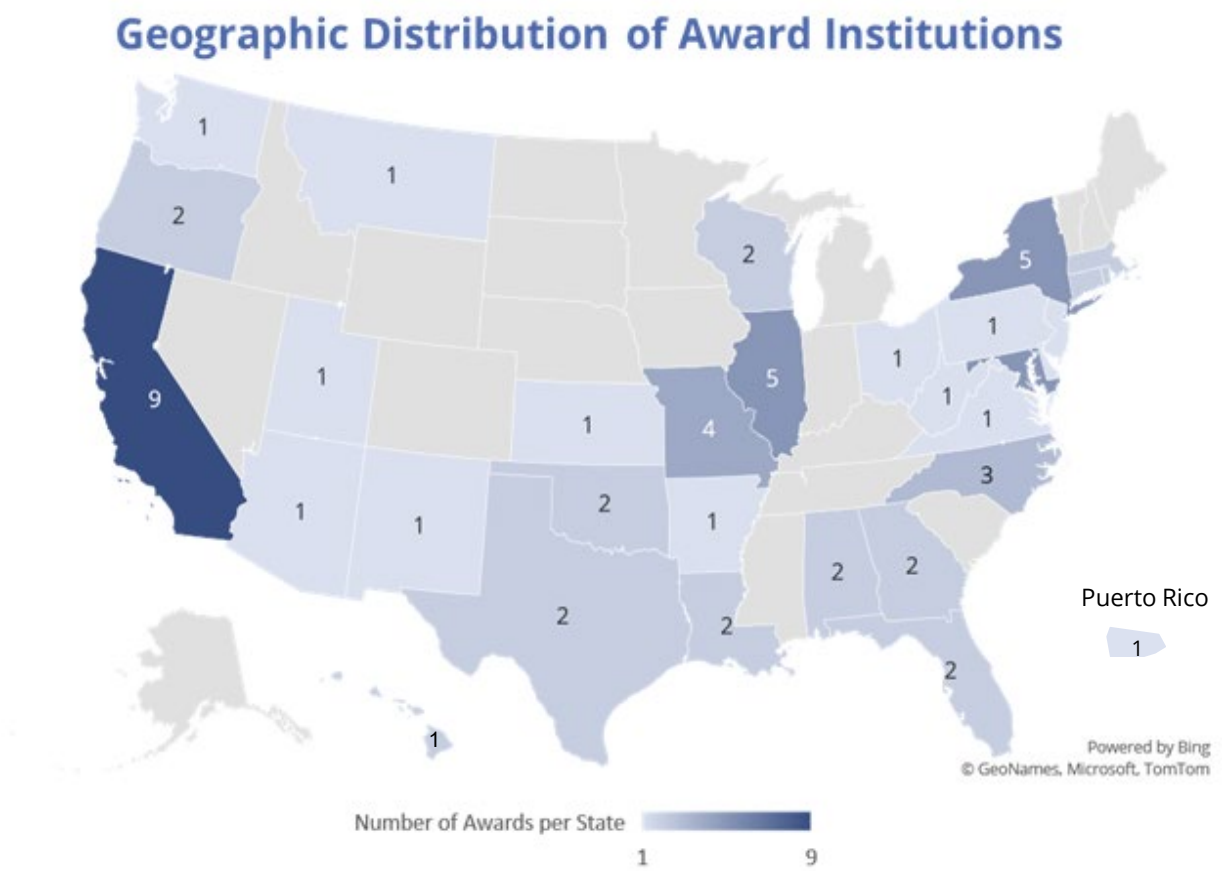
Awarded September & November 2020

- **Competitive revisions** to current NIH grantees to leverage **established research infrastructures and partnerships**
- Projects to **understand COVID-19 testing access/uptake patterns** and **implement strategies or interventions** to identify and address disparities
- Projects to **assess and address social, ethical, and behavioral factors** influencing acceptability and uptake
- **Coordination and Data Collection Center** New award to provide overarching support and guidance for 1) Operations and Logistics, 2) COVID-19 Testing Technology, 3) Community Engagement, and 4) Data Collection, Integration and Sharing

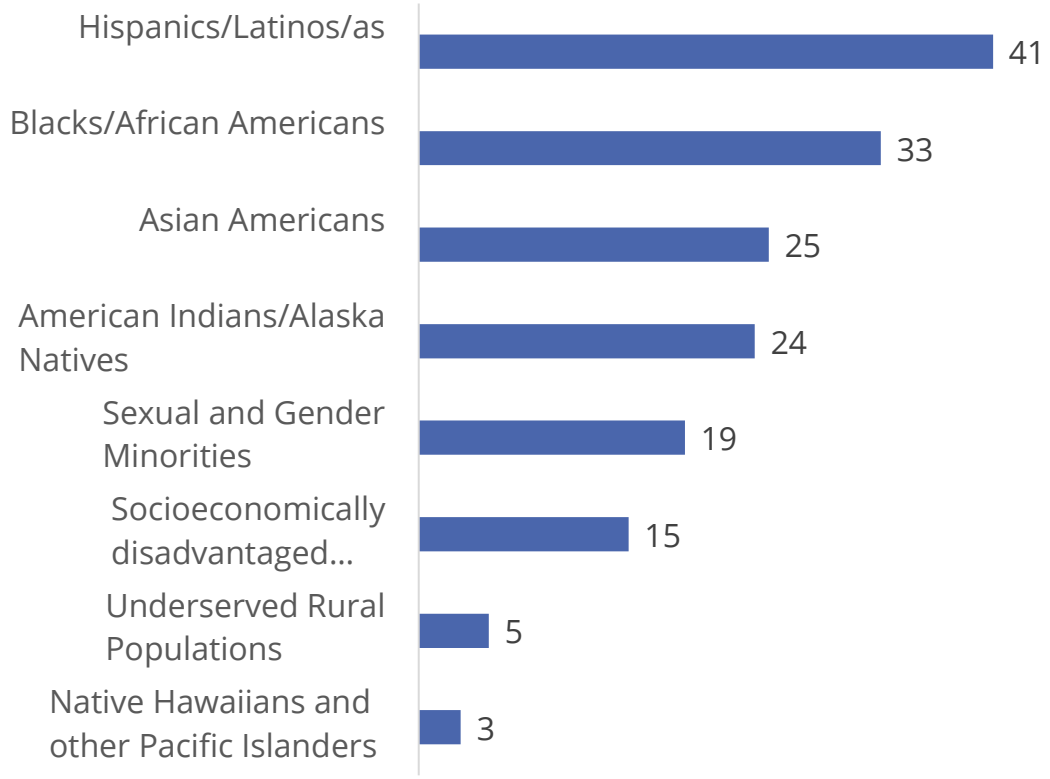
RADx-UP Phase I Snapshot: 69 Funded Research Projects and Coordination and Data Collection Center

NOT-OD-20-121, NOT-OD-20-120, NOT-OD-20-119

Funded sites and research projects span a total of **31 states** in addition to DC and Puerto Rico and include **55 institutions**.



Projects include diverse health disparity population affected by COVID-19.



RADx-UP Phase II: New Funding Opportunities

	NOT-OD-21-103	RFA-OD-21-008	RFA-OD-21-009	NOT-OD-21-101	OTA-21-007
	Testing / Vaccination	Testing/ Vaccination	Social, Ethical and Behavioral Implications-SEBI	Administrative Supplements for RADx-UP	Return to School Round II
Budget Mechanism	Competitive Revisions	U01	U01	Administrative Supplements	OTA
Total direct costs per year	$750,000	$750K-$1.5M	$400,000	$300,000	$3-5 million
Application Receipt	May 24	July 07	July 07	May 10	May 14
Eligibility	NIH grantees	Open	Open	RADx-UP Phase I	Invitees from LOI Phase
Scientific Focus	Testing interventions in environment of vaccine availability	Testing interventions in environment of vaccine availability	Address SEBI implications of testing	Address vaccine hesitancy within existing RADx-UP projects	COVID-19 testing access and effectiveness for safe return to school

Speaker

COVID-19 Testing and Vaccination

RFA-OD-21-008 & NOT-OD-21-103

Monica Webb Hooper, Ph.D.
National Institute on Minority Health and Health Disparities

What's new in Phase II?

What are the main differences between the Phase I and Phase II Awards?

1. Interventions to reduce COVID-19 disparities

2. Increasing SARS-CoV-2/COVID-19 testing access and uptake given the availability of vaccines

Emergency Awards: Community-Engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations – RADx-UP Phase II (U01 Clinical Trial Optional)

RFA-OD-21-008

- *New* U01 awards

Notice of Special Interest (NOSI): Emergency Competitive Revisions for Community-Engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations – RADx-UP Phase II (Emergency Supplement - Clinical Trial Optional)

NOT-OD-21-103

- *Competitive revisions* to existing awards

Scientific objectives are the same

Community-Engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations – RADx-UP Phase II (Clinical Trial Optional)

RFA-OD-21-008 and NOT-OD-21-103

Purposes

1. To expand the scope and reach of testing ***interventions*** to **reduce COVID-19 disparities** among underserved and vulnerable populations
2. Address questions on interventions to increase access to and uptake of COVID-19 testing given the **increasing availability of SARS-CoV-2 vaccines**.

COVID-19 Data At-A-Glance, April 27, 2021 (11:15AM)

CASES

148M
cases worldwide

32.1M
cases in U.S.

DEATHS

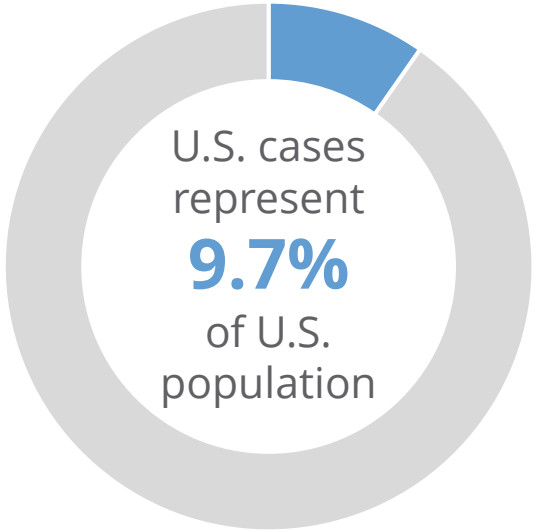
3.1M
deaths worldwide

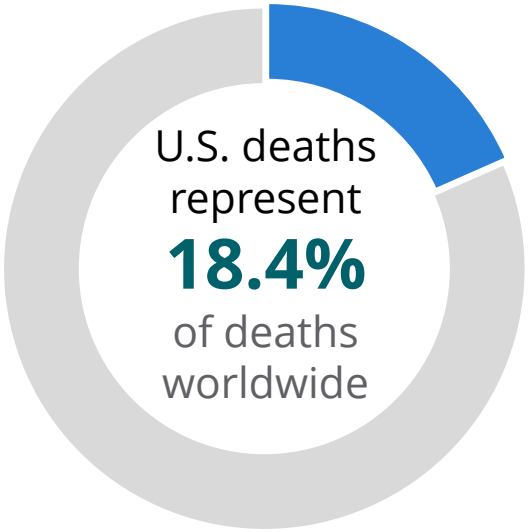
572.7K
deaths in U.S

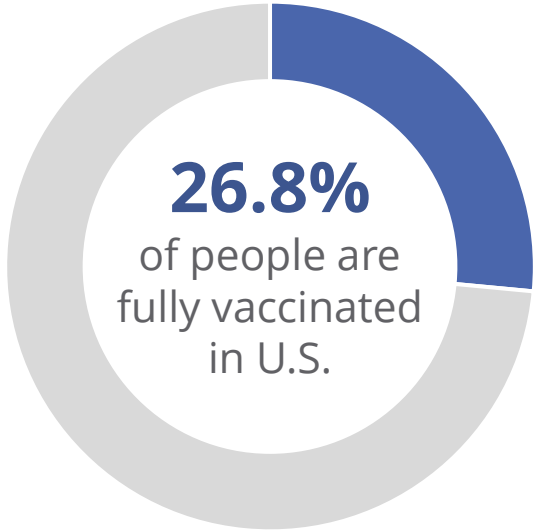
VACCINES

230.7M
doses administered in U.S.

87.9M
people fully vaccinated in U.S



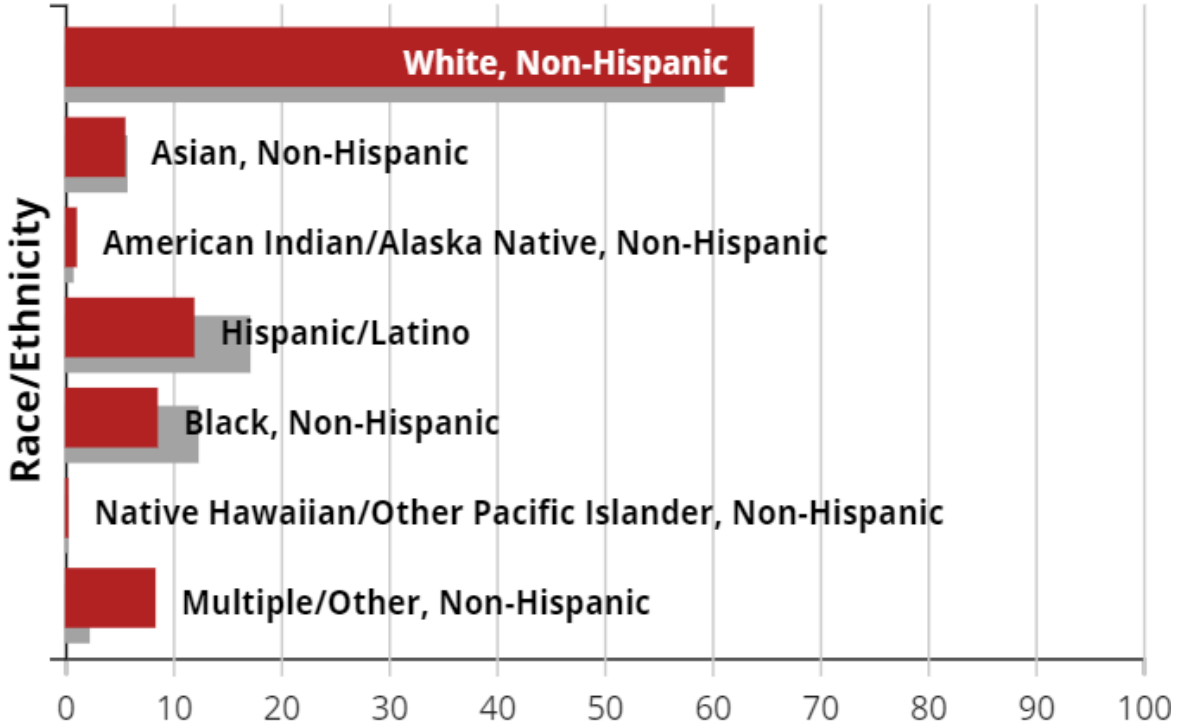




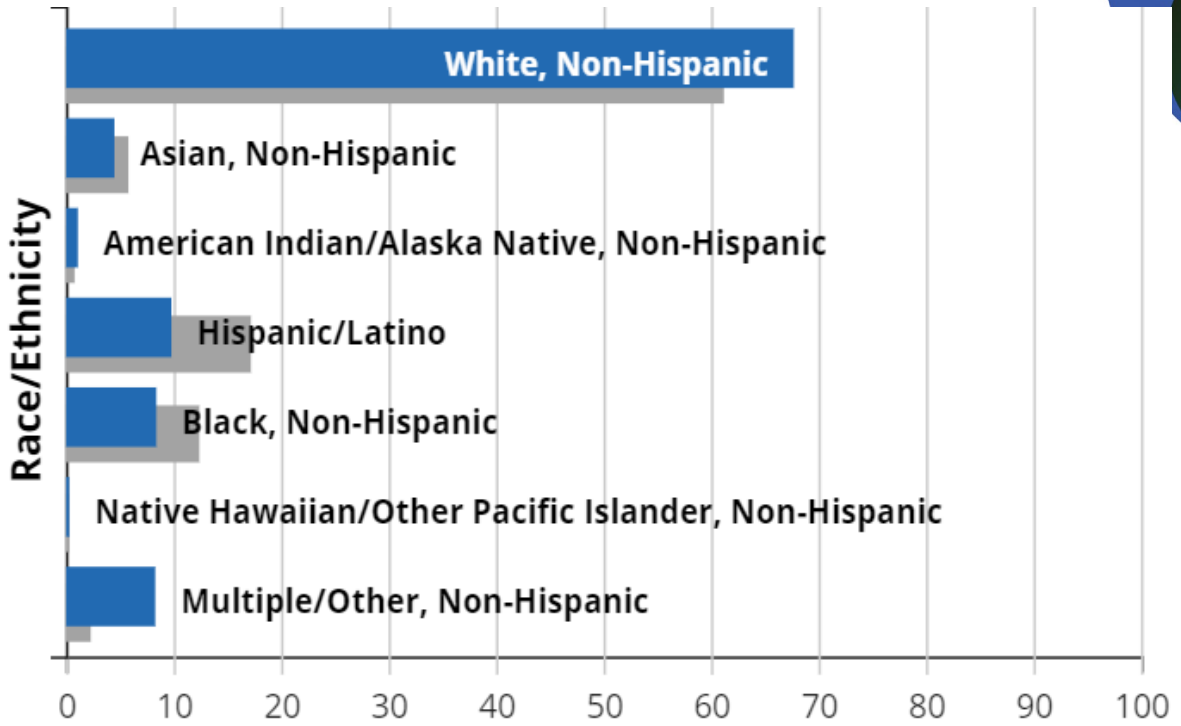
COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University
International Vaccination Efforts by Johns Hopkins University

Demographic Characteristics of People Receiving COVID-19 Vaccinations in the U.S., April 25, 2021 (6:00 AM)

Race/Ethnicity of People with 1+ Doses Administered



Race/Ethnicity of People with 2 Doses Administered



Grey denotes percentage of the US Population in the Demographic Category

Demographic Characteristics of People Receiving COVID-19 Vaccinations in the United States from CDC's COVID Data Tracker

Background and Goals

Apply scientific knowledge gained thus far to:

- Develop and evaluate interventions with the goal of decreasing disparities
- 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
- Propose innovative science to fill gaps and address new challenges

Research Topic Examples

The following list of possible research topics is not exhaustive

- Examine and address disparities in the availability, ease of use, and/or accessibility of at-home COVID-19 testing options
- Rapid cycle designs to examine testing technologies to improve uptake of testing, vaccination, and repeat testing
- Testing implementation strategies to increase the reach, access, uptake, and sustainability of testing in community-, workplace-, school-, or family-based settings (e.g., technology-based approaches, mobile health units)
- Modeling and/or simulation studies to understand drivers of COVID-19 disparities followed by interventions to reduce them

Key Considerations

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

- ❑ Focus must be on underserved *and* vulnerable populations
- ❑ Primary outcomes must focus on testing, however secondary aims can include vaccination
- ❑ Leverage, expand, or strengthen community partnerships
- ❑ Testing capacities used must be FDA-authorized and results must be CLIA certified
- ❑ Consistency and reproducibility by planning to collect NIH RADx-UP Common Data Elements (CDEs)
- ❑ Mixed methods research OK; qualitative only not accepted

Requirements

Work with the **Coordinating and Data Collection Center (CDCC)**

Have an established research **infrastructure**

Sustainability description including partnerships

Collaborate with RADx-UP consortium members where appropriate

Ability to **demonstrate impact** within 6 months of award

Milestones and **timelines**

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

Letters of support from and inclusion of community partners

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

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

The following are examples that would be considered non-responsive

- Populations that are not underserved *and* COVID-19 vulnerable
- Project focusing exclusively on vaccination; primary outcome vaccine-related
- Lack of demonstrated community engagement with populations of interest
- Study populations or sites outside of the U.S. or its territories
- Exclusively qualitative research (mixed methods are acceptable)
- Lack of structure and planning to coordinate with CDCC and other RADx-UP sites to align and share data
    - Must be able to collect NIH RADx-UP Common Data Elements and aligned Informed Consent Forms with the appropriate Data Use Agreements
- No testing plan/strategies or use of FDA-authorized or approved test

Review Considerations

NOT-OD-21-103 (*Competitive revisions* to existing awards)

Internal NIH staff review panel using standard criteria with additional criteria of:

1. Urgency and significance of research
2. Research feasibility and design
3. Investigators
4. Community partners
5. Data sharing plan
6. Coordination plans
7. Outcomes
8. Sustainability
9. Testing
10. Post-vaccination testing studies
11. Evaluation plan

Review Considerations

RFA-OD-21-008 (*New* U01 awards)

1. Overall Impact
2. Significance
3. Innovation
4. Investigators
5. Approach
6. Study Timeline
7. Environment
8. Protection of Human Subjects
9. Inclusion

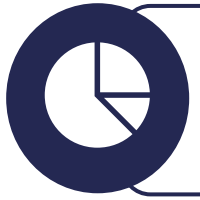
Please see RFA Announcement for additional detail

Budget Partnership Options for RFA-OD-21-008 (new U01 awards)

Respondents can request a budget option that exceeds $750K in direct costs per year

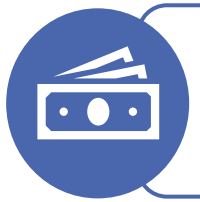
Conditions

Collaboration with 1 or more PIs from institutions that received specified maximum of NIH funding
FOA details partner institutions that have received no more than $6M average in NIH RPG funding per year from 2018-2020 are eligible to be multi-PIs or key collaborators



Collaborator Institution(s) will receive no less than 40% of award
A list of possible eligible applicants is available in the FOA, but range from American Indian Tribal governments to Public Institutions of Higher Education

Process



Higher Budget Requires Prior Approval
Submit a request for a budget exceeding $750,000 and up to $1.5M in direct costs per year no later than 6 weeks prior to application receipt date, or **May 26, 2021**

Applicants will be informed of the decision prior to application receipt date
An Institute Program Official will review the higher budget request and ensure they meet the two conditions and provide a decision no later than **June 16, 2021**

Key Dates

RFA-OD-21-008 & NOT-OD-21-103

	Application Receipt	Scientific Merit Review	Awards Distributed
RFA-OD-21-008 (New U01s)	July 7, 2021 5pm *Select Institute or Center based on relevance to scientific aims of your research	July-October 2021	October 2021
NOT-OD-21-103 (Competitive Revisions)*	May 24, 2021 5pm * Electronic submission to Institute or Center of **existing NIH grant**	May-August 2021	August 2021

*No higher budget option; $.75M/ year direct costs

Late applications will not be accepted for any of these funding opportunities

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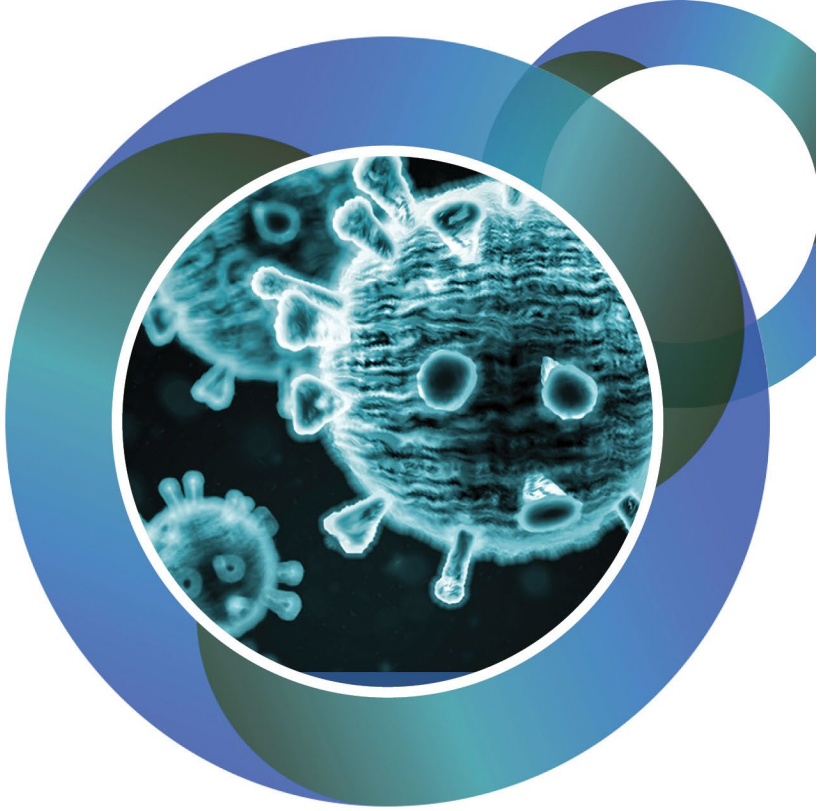
Questions?



Speaker

Social Ethical Behavioral Implications RFA-OD-21-009

Dave Kaufman, Ph.D.

National Human Genome Research Institute

Phase II Social Ethical and Behavioral Implications (SEBI)

RFA-OD-21-009

RADx-UP - Social, Ethical, and Behavioral Implications (SEBI) Research on Disparities in COVID-19 Testing among Underserved and Vulnerable Populations

Purpose:

To address actionable **social, ethical, behavioral, structural, environmental, historical and policy factors** that are sources of COVID-19 disparities, including inequities in testing access.

SEBI Overview

- Plan to fund 16 awards
- 2 years
- $400,000/year direct costs
- Community/stakeholder partnerships
- Emphasis on actionable findings
- One receipt date (July 7, 2021)
- U01 Mechanism – cooperative agreement

Requirements

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

Describe **sustainability**

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

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

Include milestones 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-21-009

The following list is not exhaustive

- Develop culturally competent communication about COVID-19 testing and vaccination
- Assess how the presence and prevalence of COVID-19 vaccination will affect societal views, roles, and uptake of SARS CoV-2 testing
- Assess testing and vaccination programs' resource allocation plans and determine characteristics that perpetuate or mitigate disparities

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**
- Impact and sequelae of **COVID-19 diagnostic tests and results**
- 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 Study Design Components

- ❑ Examine SEBI implications of testing among underserved and vulnerable populations
- ❑ Projects can conduct COVID-19 testing, but not the primary goal
- ❑ 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 Common Data Elements (CDEs) where appropriate
- ❑ 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-21-008)
- 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 authorized/approved, 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 NIH RADx-UP Common Data Elements**

Key Dates

RFA-OD-21-009

	Application Receipt	Scientific Merit Review	Awards Distributed
RFA-OD-21-009	**July 7, 2021 5pm** *Select Institute or Center based on relevance to scientific aims of your research Late applications will not be accepted	July-October 2021	October 2021

Questions?

Speakers

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

Dottie Castille, Ph.D.

Beda Jean-Francois, Ph.D.

Program Officials for CDCC

National Institute of Minority Health and Health Disparities

The 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 to the communities that we serve
- Is 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**

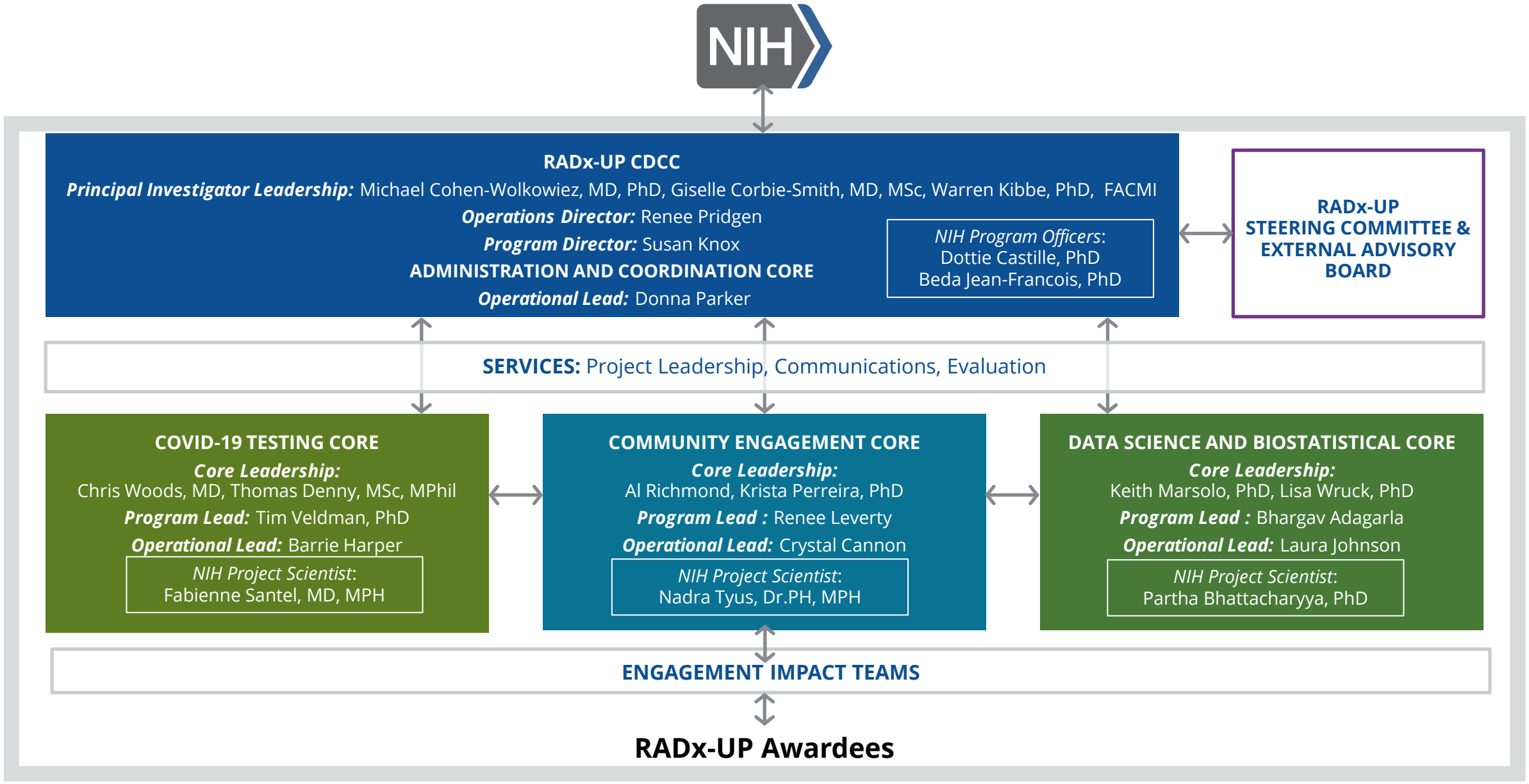
RADx-UP CDCC Goals

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.


NIH
RADx-UP CDCC
Principal Investigator Leadership: Michael Cohen-Wolkowiez, MD, PhD, Giselle Corbie-Smith, MD, MSc, Warren Kibbe, PhD, FACMI
Operations Director: Renee Pridgen
Program Director: Susan Knox
ADMINISTRATION AND COORDINATION CORE
Operational Lead: Donna Parker
NIH Program Officers:
Dottie Castille, PhD
Beda Jean-Francois, PhD
RADx-UP STEERING COMMITTEE & EXTERNAL ADVISORY BOARD
SERVICES: Project Leadership, Communications, Evaluation
COVID-19 TESTING CORE
Core Leadership:
Chris Woods, MD, Thomas Denny, MSc, MPhil
Program Lead: Tim Veldman, PhD
Operational Lead: Barrie Harper
NIH Project Scientist:
Fabienne Santel, MD, MPH
COMMUNITY ENGAGEMENT CORE
Core Leadership:
Al Richmond, Krista Perreira, PhD
Program Lead : Renee Leverty
Operational Lead: Crystal Cannon
NIH Project Scientist:
Nadra Tyus, Dr.PH, MPH
DATA SCIENCE AND BIOSTATISTICAL CORE
Core Leadership:
Keith Marsolo, PhD, Lisa Wruck, PhD
Program Lead : Bhargav Adagarla
Operational Lead: Laura Johnson
NIH Project Scientist:
Partha Bhattacharyya, PhD
ENGAGEMENT IMPACT TEAMS
RADx-UP Awardees

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

CDCC Role in the RADx Data Ecosystem

Data collected under RADx-UP will be anonymized and shared through the RADx-UP CDCC, and ultimately deposited into the COVID RADx Data Hub.

CDCC will coordinate across the consortium to ensure:

- Collection and reporting of NIH RADx-UP CDEs
- Consistent language in consent
  - General Research Use
  - Ability to re-contact participants for future research
  - Hash (Hash is usually a string of charecters and are generated by a formula)
- Return of Results
- **CDCC work with program staff to resolve special considerations for SEBI projects (NIH RADx-UP CDEs, Data Deposit)**

NIH RADx-UP CDE Requirements

Projects funded under the RADx-UP Initiative are **required** to collect the NIH RADx-UP Tier 1 CDEs

Permission to collect and share NIH RADx-UP CDEs will be solicited through specific language in the Informed Consent Form (ICF) on the following points:

1. Depositing de-identified data in the CDCC and NIH RADx Data Hub
2. Sharing de-identified data with the CDCC and NIH for future scientific research
3. Sharing identifiable data to permit re-contact for future follow-up and participation in future research
4. Sharing identifiable data to perform linkages with external data sets, such as the Centers for Medicare & Medicaid Services (CMS), electronic health records (EHR), or other identifiable datasets, to understand health outcomes of the COVID-19 pandemic among underserved and vulnerable populations

*NIH RADx-UP CDEs should be viewed in conjunction with the Informed Consent language. Refer to the **Informed Consent Data Sharing Template Language** found **here** in English and Spanish for guidance.*

Data

Data Sharing and Standards

- Data acquisition, collection, and curation strategies of Phase II projects shall be coordinated with:
    - CDCC guidance for annotation and benchmarking of data
    - Collection of standardized NIH Tier 1 Common Data Elements (CDEs)
    - Obtaining appropriate consent for data sharing
    - Linkage of data to external data sets, and recontact for future follow-up research
- If a clinical trial is proposed, data and safety monitoring plans, and, if needed, plans for a Data Safety Monitoring Board (DSMB)

Speaker

Question and Answer

Ming Lei, Ph.D.

National Institute of General Medical Sciences

Question & Answer

Please submit all questions in the Q&A box

- If you have questions today, please place them in the Questions and Answers module; the moderator will facilitate a discussion of them at the conclusion of the presentation or in the chat box
- All questions and answers will be captured in an FAQ that will be distributed after the webinar to all parties who received the solicitation.
- This meeting will be recorded and will be made available via a link that will be distributed after the webinar.