

# RADx-UP: Return To School Diagnostic Testing Approaches

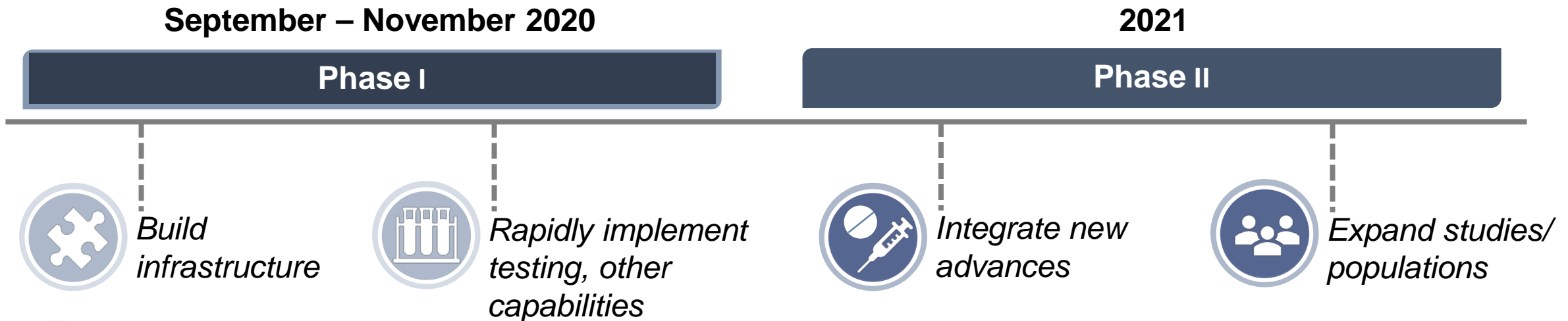
OTA-21-004 and OTA-21-007



# RADx-Underserved Populations (RADx-UP)

## Overarching Goals

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



# **Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP):**

*Return To School Diagnostic Testing Approaches  
(OTA-21-004 and OTA-21-007)*



# RADx-UP Return To School Diagnostic Testing Approaches

## Goal

Develop and test COVID-19 diagnostic testing approaches to safely return children and staff to the in-person school setting in underserved and vulnerable communities

## Mechanism

Other Transaction Authority to provide flexibility for changing circumstances and funding of non-traditional partners

## Budget

~\$50 million commitment from the OD congressional appropriation

# Return to School

## OTA-21-004 & OTA-21-007

**Program Information:** ~\$35M awarded for 16 sites

- Focus on children and adolescents below the age eligible for vaccination via Emergency Use Authorization (age 16) and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction
- Identify effective, scalable, and sustainable testing implementation strategies, including in-school testing, in community pediatric primary care clinics, childcare centers, preschool, and school settings serving primarily underserved or disadvantaged children and their families.

### Overview

- **Awarded 16 projects** in FY21
  - Phase I (2/3/21 concept initiated to award 8 projects on 4/16/2021, ~10 weeks)
  - Phase II (ROA posted 4/22/21 to award 8 projects on 6/30/2021, ~10 weeks)
- **Strategies for school-based settings** to combine frequent testing with proven safety measures to reduce the spread of COVID-19



# **Other Transactions Award Mechanism**



# Other Transactions (OT2)



- These are funding instruments which do not incorporate the standard terms and conditions of the OMB Circulars, NIH Grants Policy Statement, and FAR based Contract requirements but rather, all terms and conditions are negotiated between the federal sponsor (NIH) on a case-by-case basis with the Awardee.
  - Not a grant/cooperative agreement, not a contract
  - Substantial and active NIH program negotiation and management, before, during and at the end of the project
  - Milestone-driven projects with contingency plans
  - Special award terms
  - Flexibility to alter the course of the project (e.g., expanded, modified, discontinued) and to design unique collaborations with other partners and between awardees
- Address rapidly evolving research areas such as urgent public health situations



# Award Terms



## Example of rights with these awards

- Fund projects in increments and/or with options for continued work at the end of one or more phases;
- Fund projects of two or more entities (potentially across different applications) as part of a reorganized collaboration, teaming arrangement, or other means acceptable to the government;
- Reporting requirements;
- Request additional documentation (certifications, etc.); and
- Remove participants from award consideration should the parties fail to reach a finalized, fully executed agreement prior to a date determined by the NIH, or the proposer fails to provide requested additional information in a timely manner.





# Negotiation Process

## Highly interactive



- An electronic application that will include a formal statement of work, detailed budget information, and other certifications
- The applications can be negotiated prior to submission after a formal request for negotiations is issued by the OT official
- Negotiations will be recorded and documented by the NIH; the NIH will likely interact with multiple investigators
- The recipient of the award will be expected to comply with the regulatory requirements listed in the OTA
- The scope of work, milestones, and performance requirements will be finalized through negotiation and memorialized on the Notice of Award



# Requirements after Award



## Interactive Process

- All terms and conditions will be in the agreement; these can be amended during the course of the award
- Generally, payments align with achievement of milestones and a payment schedule will be negotiated prior to issuance of the award
- Frequent financial and progress reports are required
- Organizations will be asked to implement management controls and management roles for staff
- Future years will each be negotiated, contingent on funds available and satisfactory progress



# Just the Facts



Other Transactions are typically announced through Research Opportunity Announcements (ROAs) and may be published on NIH Institute, Center, Office, or program web pages as well as other non-traditional venues. All applications must be submitted to [eRA](#) per the specific instructions stated in the ROA as well as those provided for [eRA ASSIST](#). Once submitted, the applications will undergo a non-traditional, objective review, one that still promotes integrity, confidentiality, fairness, and transparency.

Though select NIH Institutes have had the authority to support Other Transactions for some time, NIH obtained the broad authority to use Other Transactions in 2020. NIH spent \$823.2 million on 137 Other Transactions in fiscal year (FY) 2020 and \$1.3 billion on 154 projects in FY 2021. But for perspective, grants still remain the predominant way to support biomedical and behavioral research, as evident by NIH spending \$23.3 billion on all research project grants in FY 2021.

	Number of OT Awards	OT Awards Total Funding
2020	137	\$823,156,431
2021	154	\$1,266,797,851



# Questions?

