Rapid Acceleration of Diagnostics (RADx)

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National Institutes of Health
Turning Discovery into Health®

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COVID-19 Key Facts

SNAPSHOT:

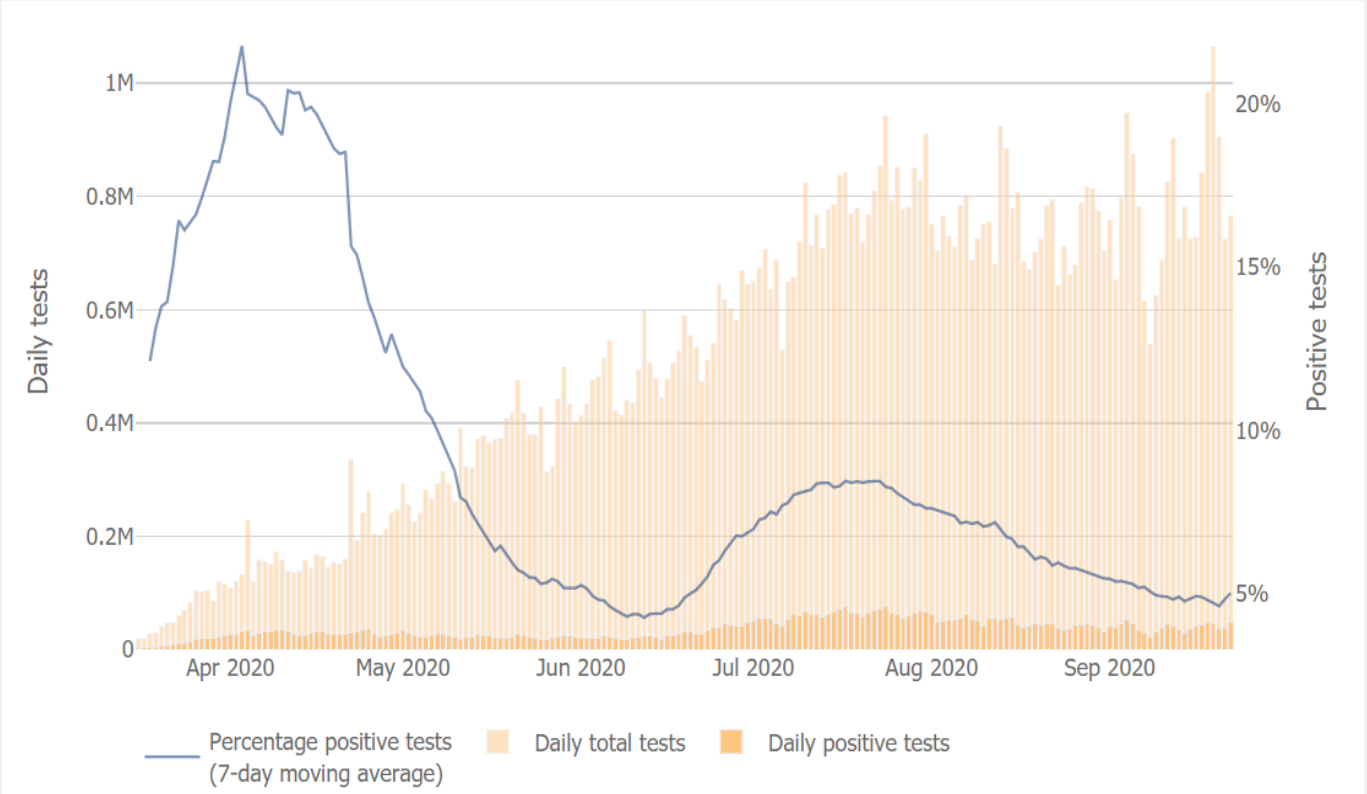
Total Cases: 6,899,272

Number of Deaths: 200,893

Tests Conducted: 96,612,436

Positivity Rate (7 Day Avg): ~5.05%

Daily State-by-state Testing Trends, JHU



Note: Data sourced (and graph excerpted) from the Johns Hopkins Coronavirus Resource Center; Data current as of 9/23/20

Different Types of COVID-19 Tests

	Lab-Based PCR Tests	Rapid Antigen Tests	At-Home Tests
Use	Indicates current infection through amplification/detection of **viral RNA**	Indicates current infection through detection of **viral antigens**	Currently home collection systems mailed to lab to be processed as lab-based **PCR tests**. Future will be **rapid antigen tests** with format similar to home pregnancy tests. Some may use a smartphone camera and app as a reader.
Accuracy	**Greater sensitivity** via detection of low levels of virus. Allows identification of infection early and late in course.	**Lower sensitivity** that requires greater viral load for detection. May miss some asymptomatic or very early or late infections.	**Sensitivity** will depend on type of test**.**
Time to Result	**Moderate**; ~24-48 hours (high tests volumes can significantly delay results, i.e. days)	**Fast**; ~15-30 minutes	**True home-based tests - Fast**; ~15-30 minutes Mail-in tests – Slow. Transit will add 1-2 days
Collection Setting	Point-of-Care	Point-of-Care	Point-of-Care
Processing Setting	Lab	Point-of-Care	Point-of-Care (true home-based tests) or Lab (mail-in tests)

Rapid Acceleration of Diagnostics (RADx) Initiative

Supplement Appropriations Language

…not less than **$1,000,000,000** shall be transferred to the "National Institutes of Health—Office of the Director" to **develop**, **validate**, **improve**, and **implement testing** and **associated technologies**; to accelerate research, development, and implementation of **point of care** and other **rapid testing**; and for **partnerships** with governmental and nongovernmental entities to research, develop, and implement the activities outlined in this proviso…

Signed into law, April 24, 2020

https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics

RADx Program Overview

	**RADx-tech** Highly competitive, rapid three-phase challenge to identify the best innovative technologies for at-home or point-of-care tests
	**RADx-Advanced Testing Program (RADx-ATP)** Rapid scale-up of existing point-of-care technologies and support of ultra-high throughput laboratories
	**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 in underserved and/or vulnerable populations

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SPECIAL REPORT

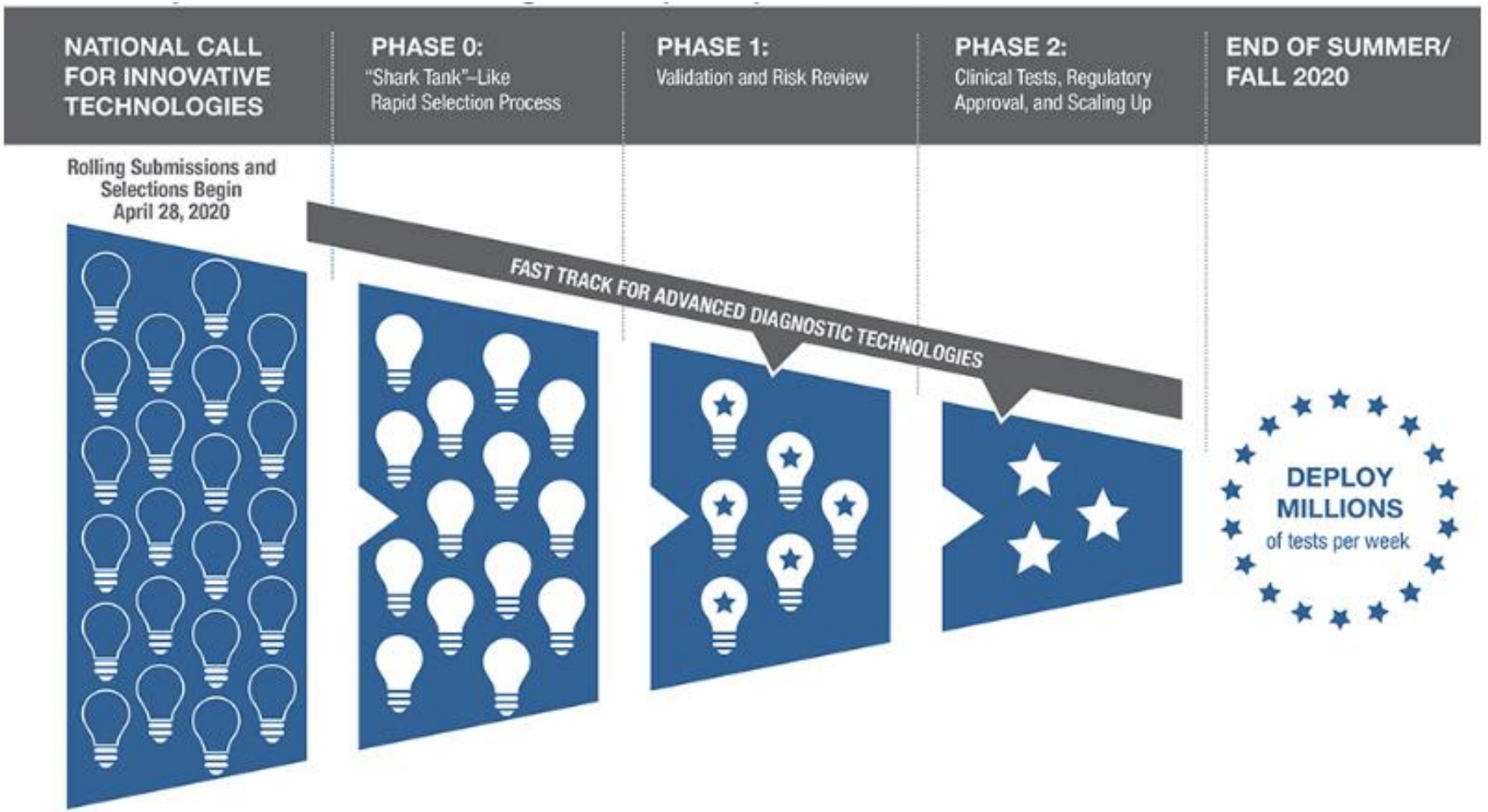
Rapid Scaling Up of Covid-19 Diagnostic Testing in the United States — The NIH RADx Initiative

Bruce J. Tromberg, Ph.D., Tara A. Schwetz, Ph.D., Eliseo J. Pérez-Stable, M.D., Richard J. Hodes, M.D., Richard P. Woychik, Ph.D., Rick A. Bright, Ph.D., Rachael L. Fleurence, Ph.D., and Francis S. Collins, M.D., Ph.D.

The first reports of an unusual cluster of pneumonia cases in the city of Wuhan, China, emerged in December 2019, heralding a global pandemic. As of July 13, 2020, more than 3.3 million U.S. residents have received a diagnosis of coronavirus disease 2019 (Covid-19), and more than 135,000 have died.[1] Of great concern are the data showing the disproportionate effect of Covid-19 on ethnic and racial minorities.[2,3] Since January 2020, the National Institutes of Health (NIH) has been involved in multiple wide-rang- of RADx and their goals, and we end with a review of the challenges ahead.

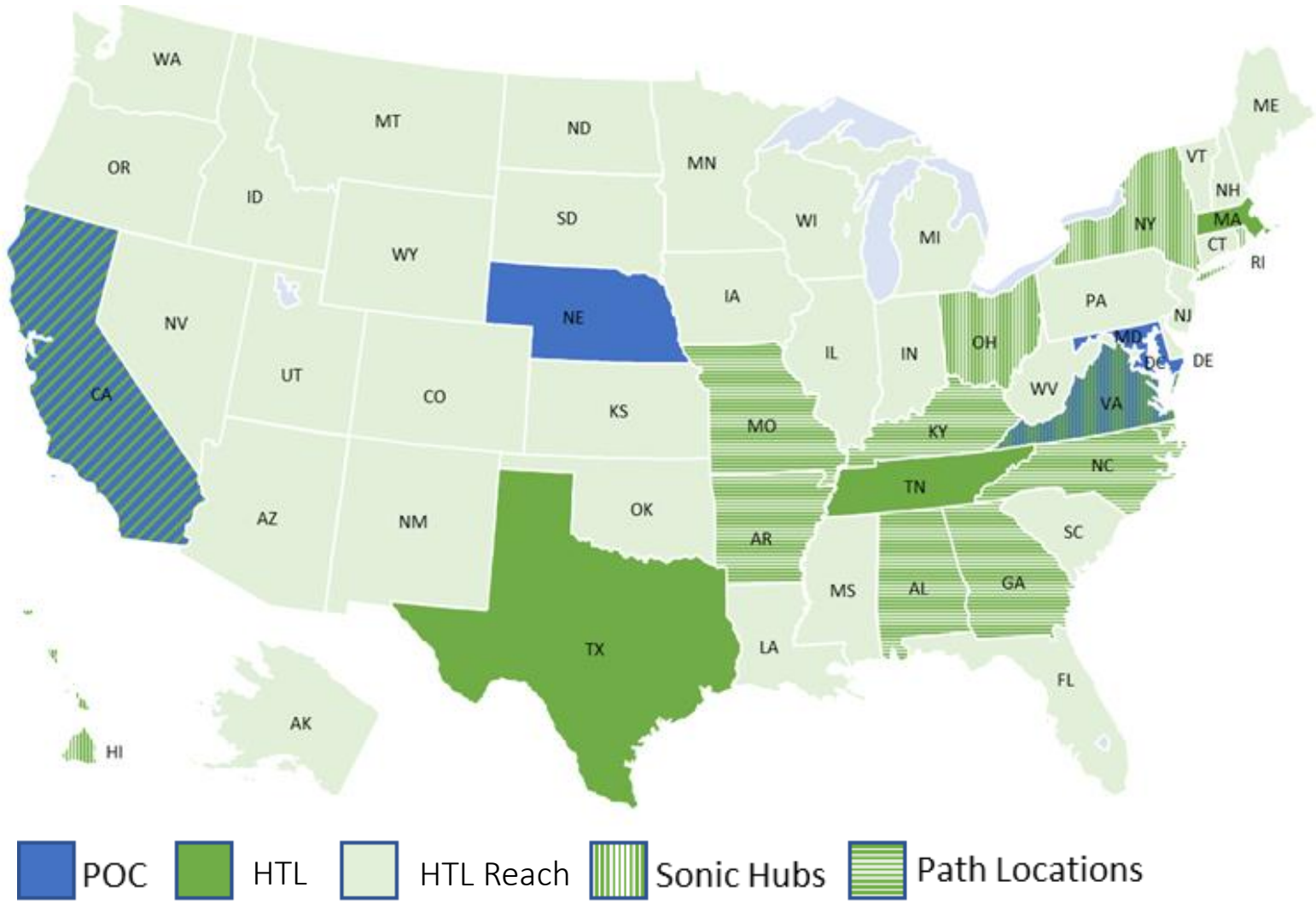
On April 24, 2020, Congress appropriated $1.5 billion, from the $25 billion provided in the Paycheck Protection Program and Health Care Enhancement Act for SARS-CoV-2 testing, to the NIH. Within 5 days after the legislation was signed into law, the NIH launched RADx to support the development, production scale-up, and deployment of accurate, rapid tests across the country. From a timing perspective, the RADx

RADx Shark Tank



Summary of RADx-Tech and RADx-ATP Awards

~$400 million as of September 2



9 High-Throughput Labs

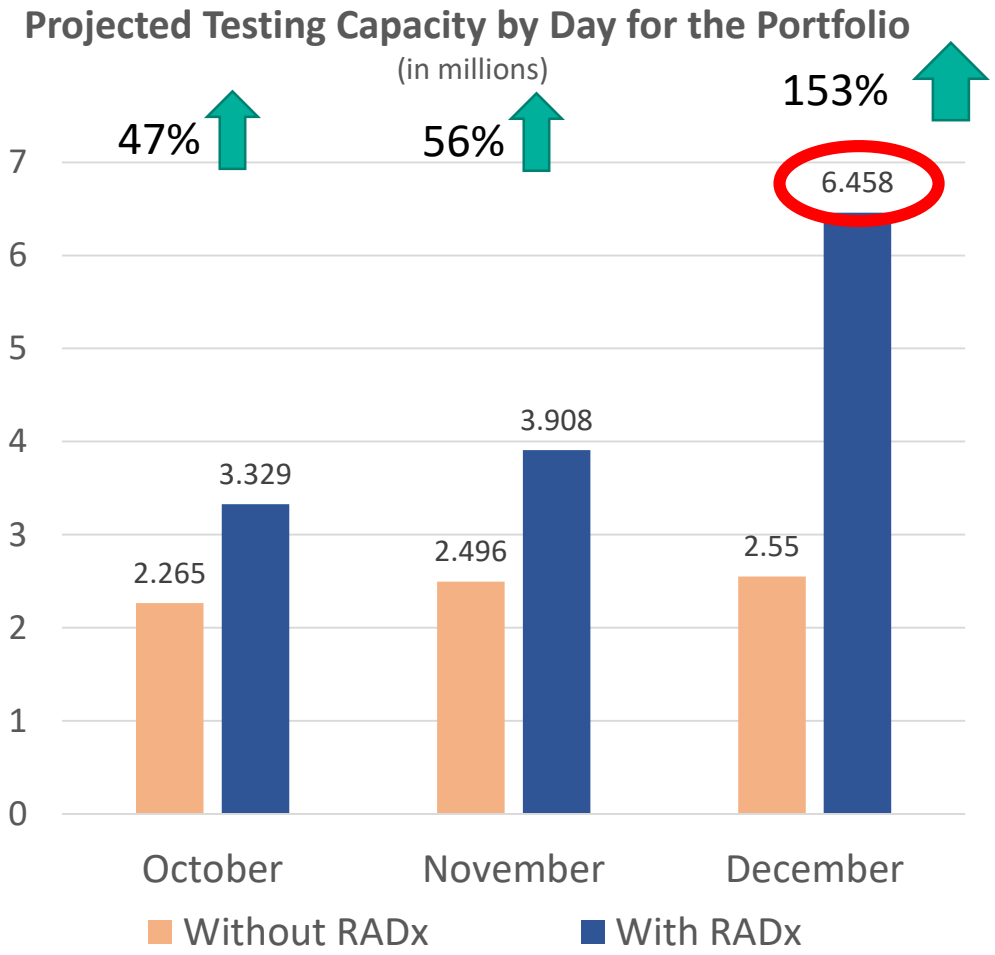
GINKGO BIOWORKS — THE ORGANISM COMPANY
PathGroup — Physician Centered. Patient Focused.
AEGIS Sciences Corporation
illumina
Helix
SONIC HEALTHCARE USA
BROAD INSTITUTE
Mammoth Biosciences
FLUIDIGM

7 Point-of-Care

mesabiotech
TALIS Biomedical
CERES NANO
MatMaCorp
Maxim Biomedical, Inc.
QUIDEL
MicroGEM

Full list of awards: https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-phase2-awards

Contribution of RADx to the National Testing Capacity

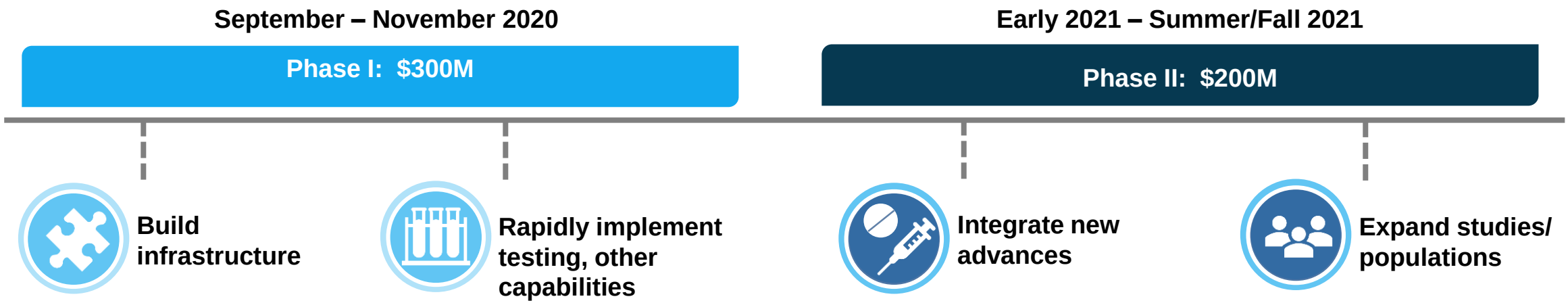


RADx Team will continue to provide awardees:

- Support for clinical, regulatory, manufacturing efforts
- Assistance with EUA approvals, by coordinating with FDA in the regulatory process – including concurrent **influenza A and B** testing, saliva collection, at-home tests
- Supply chain coordination with HHS, DoD, and BARDA to identify **shortages and solutions** for tips, reagents, robots, other items necessary for test production

RADx-Underserved Populations (RADx-UP) Overview

- Overarching Goal
  - Enhance testing among underserved and vulnerable populations
- Mechanism
  - Develop consortium of community-engaged research projects for rapid implementation of testing interventions
  - Strengthen available data on disparities in infection rates, disease progression, and outcomes; identify strategies to reduce these disparities in diagnostics



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 factors that contribute to COVID-19 disparities; implement interventions to reduce these disparities
- Establish infrastructure to facilitate evaluation and distribution of vaccines and therapeutics

RADx-Radical (RADx-rad) Overview

- Overarching Goal
  - Support new, non-traditional approaches in COVID-19 testing; develop platforms that can be deployed in future outbreaks of COVID-19 and other, yet unknown, diseases
- Timeline
  - FOAs published early August
  - Awards made by end of CY20
- Examples of RADx-rad Research Interests
  - Wastewater-based detection of SARS-COV-2
  - Chemosensory testing for COVID-19 screening
  - Predicting viral-associated inflammatory disease severity in children with laborato diagnostics and artificial intelligence
  - Multiplexed screening methods with next generation sequencing to detect SARS-COV-2 viral gRNA content

Areas for continued evidence generation

Need empirical evidence in the following areas:

- **Pooled testing**: evaluate different pooled testing techniques and protocols in real world settings in order to optimize sample collection, analysis, return of results, frequency of testing, cost-effectiveness of different pooling approaches.
- **Comparative performance** of different **testing modalities**, including comparing laboratory PCR tests, POC antigen tests and use of antibody tests as confirmatory tests.
- **High-risk settings testing modalities and protocols**: develop testing protocols (type of test, frequency of testing, sample collection logistics, return of results) in high-risk settings such as schools, colleges, nursing homes, essential worker settings, factories, prisons etc.
- Develop **assurance testing protocols** in low prevalence communities, such as low-risk workplaces, and settings where non distanced social activities are taking place such as restaurants, bars, sporting events.
- **Serial testing**: generate real world data on the optimal frequency of testing required for screening using lower sensitivity antigen tests.
- **Patient preferences**: generate patient preference data that could be used to accompany regulatory submissions to the FDA. The FDA has formerly expressed interest in evaluating real world data, including patient preference studies, in order to reduce uncertainty at the time of authorization/clearance/approval.

Key Areas to watch in COVID-19 Testing

Regulatory, logistical, data and reimbursement aspects

On the **regulatory** front: timing of the authorization of first at-home tests is unknown. At-home tests have the potential to be a disruptive tool in managing the COVID-19 pandemic.

On the **logistics'** front, supply chain challenges include: tips, re-agents, pipettes, robots, swabs. Matching test availabilities with areas in need.

On the **electronic data front**, need to collect test data and results and link to electronic health records to generate Real-World Evidence for research and surveillance purposes.

On the **reimbursement** front, the CARES act covers diagnostic tests with no co-pay for patients. Uncertainty about coverage for screening tests will need to be addressed.

Deploying the right tests at the right time to the right people will be critical to managing the pandemic until a vaccine is available and beyond. Testing will still be necessary after the vaccine become available.