Rapid Acceleration of Diagnostics (RADx): the NIH Response to Testing During the COVID-19 Pandemic

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Rapid Acceleration of Diagnostics (RADx) Initiative

Challenge

COVID-19 has created a need for accurate, reliable, and accessible testing on a massive scale. Testing must be:

- User friendly
- Widely accessible in a variety of settings and locations
- Able to detect people who are asymptomatic

Opportunity

RADx is creating programs to rapidly scale-up testing across the country and enhance access to those most in need.

Newer technologies offer user-friendly designs with lower cost and increased accessibility at home and at the point of care.

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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

Rapid Acceleration of Diagnostics (RADx) Initiative

Goal

Accelerate innovation in, development and commercialization of, and implementation of COVID-19 testing

Approach

- Fund early innovative diagnostic technologies
- Advance late-stage diagnostic technologies to expand testing infrastructure
- Identify effective testing implementation strategies in underserved populations
- Work closely with other government agencies (FDA, BARDA, CDC)

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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 to accelerate and enhance and validate throughput – and support 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
Data Management Support	Build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts

RADx Tech

RADx Tech Program – $500M

Overarching Goal

Establish a robust R&D pipeline of innovative diagnostic technologies to **increase national testing capacity**

Innovate across the testing landscape

Expanding the number, type, access, and throughput of testing technologies

Optimize technology performance

Develop technology for a range of essential "Use Cases"

- At-home
- Point of Care (POC)
- Hospital
- Testing Laboratory

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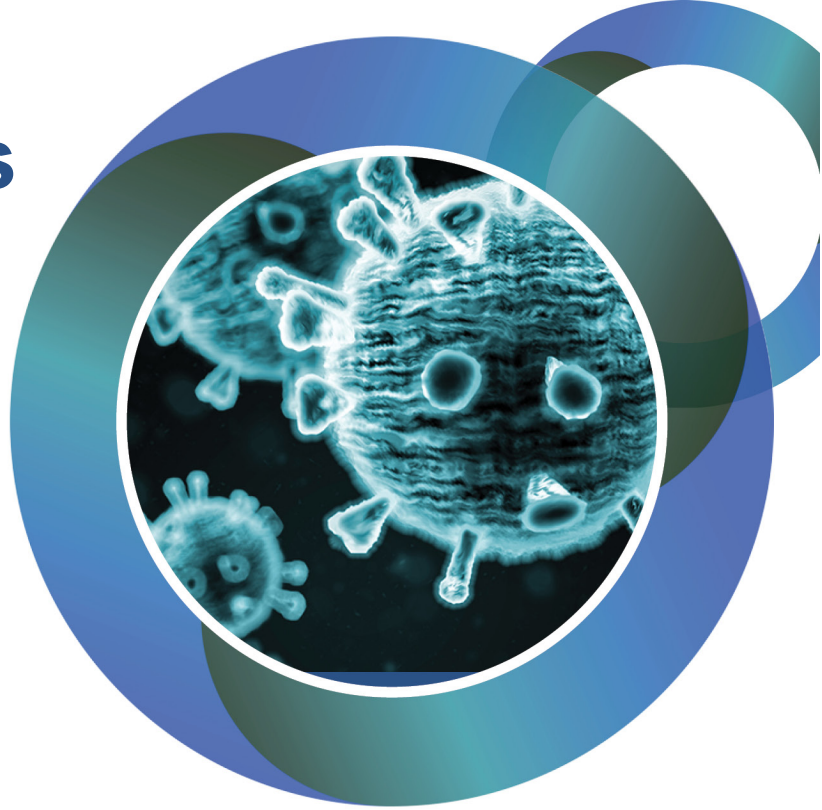
RADx-Advanced Technology Platforms (RADx-ATP)



RADx-ATP – $230M

Overarching Goal

Increase testing capacity and throughput by identifying existing and late stage testing platforms to achieve **rapid scale-up or expanded geographical placement**

- Emphasize differential POC testing to distinguish SARS-Cov-2 vs. influenza
- Establish rapid collaborations with key industry partners

Scale-up Late Stage Technologies → **Support Scale-Up of High-Throughput Labs to Add Capacity**

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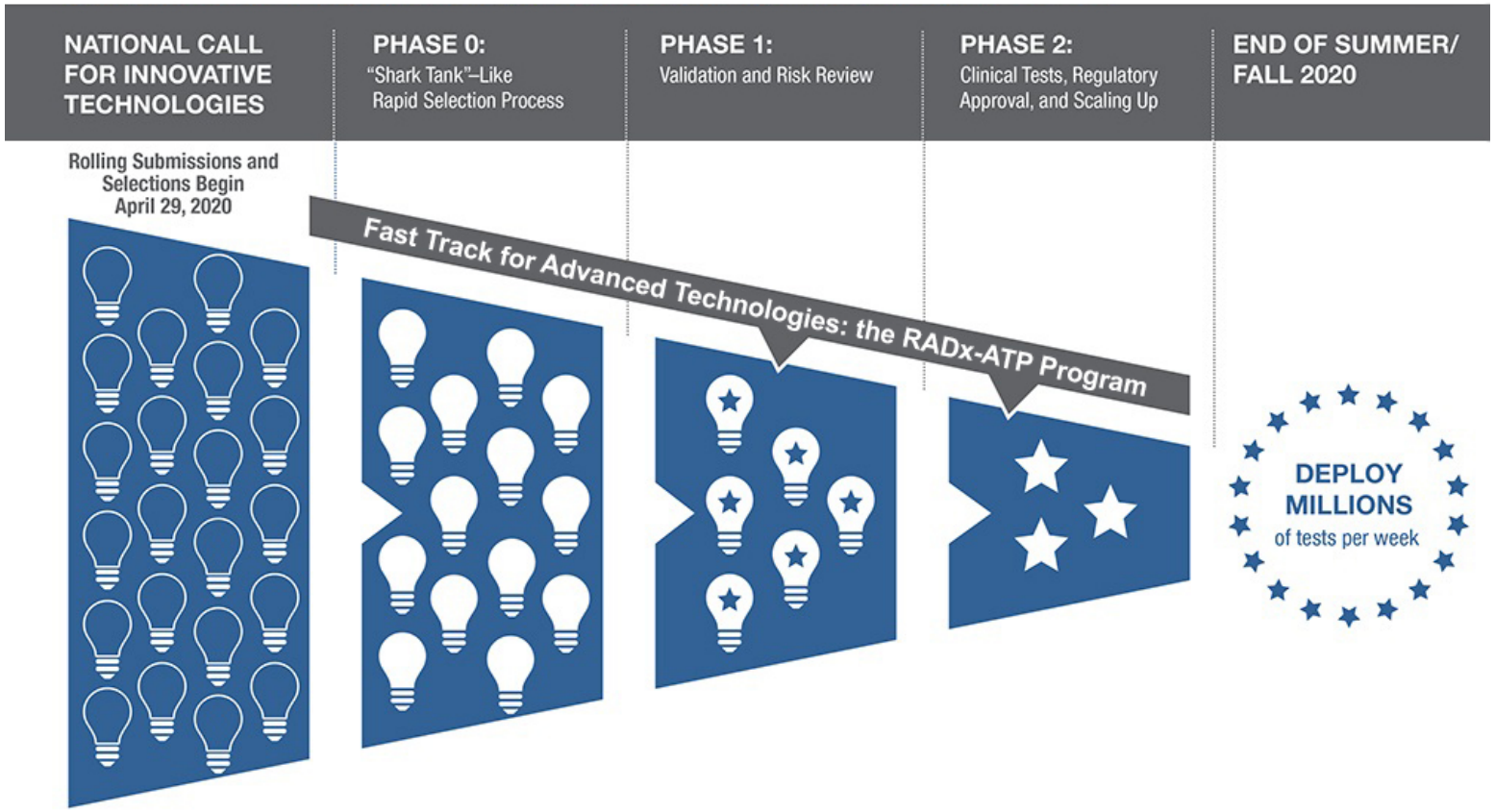
Strategy for RADx Tech

Approach

Part I (FY20)



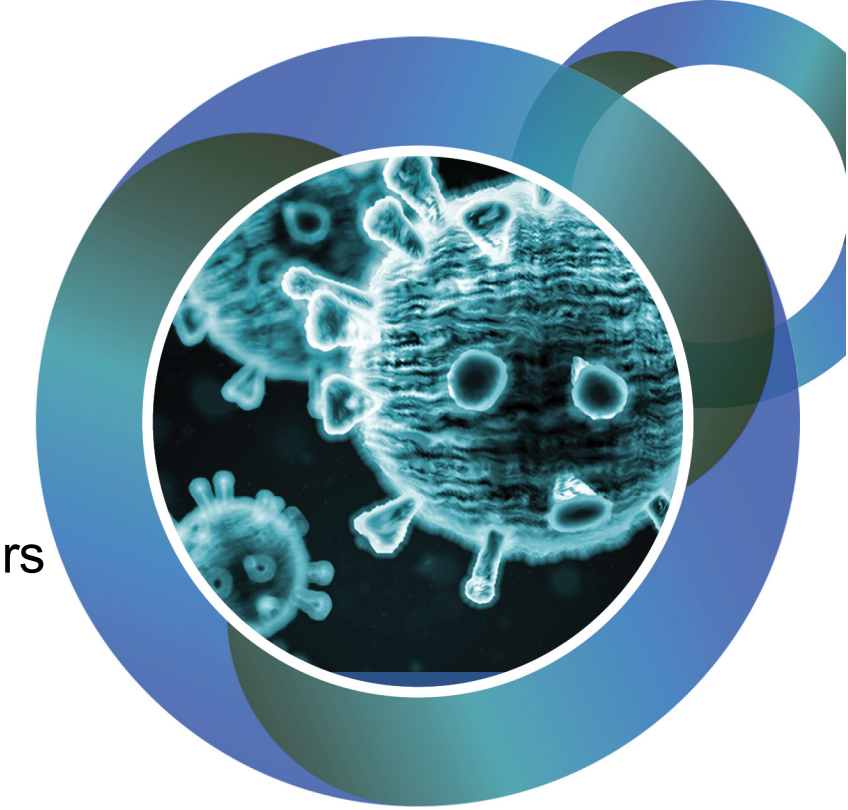
Part II (FY20, 21)

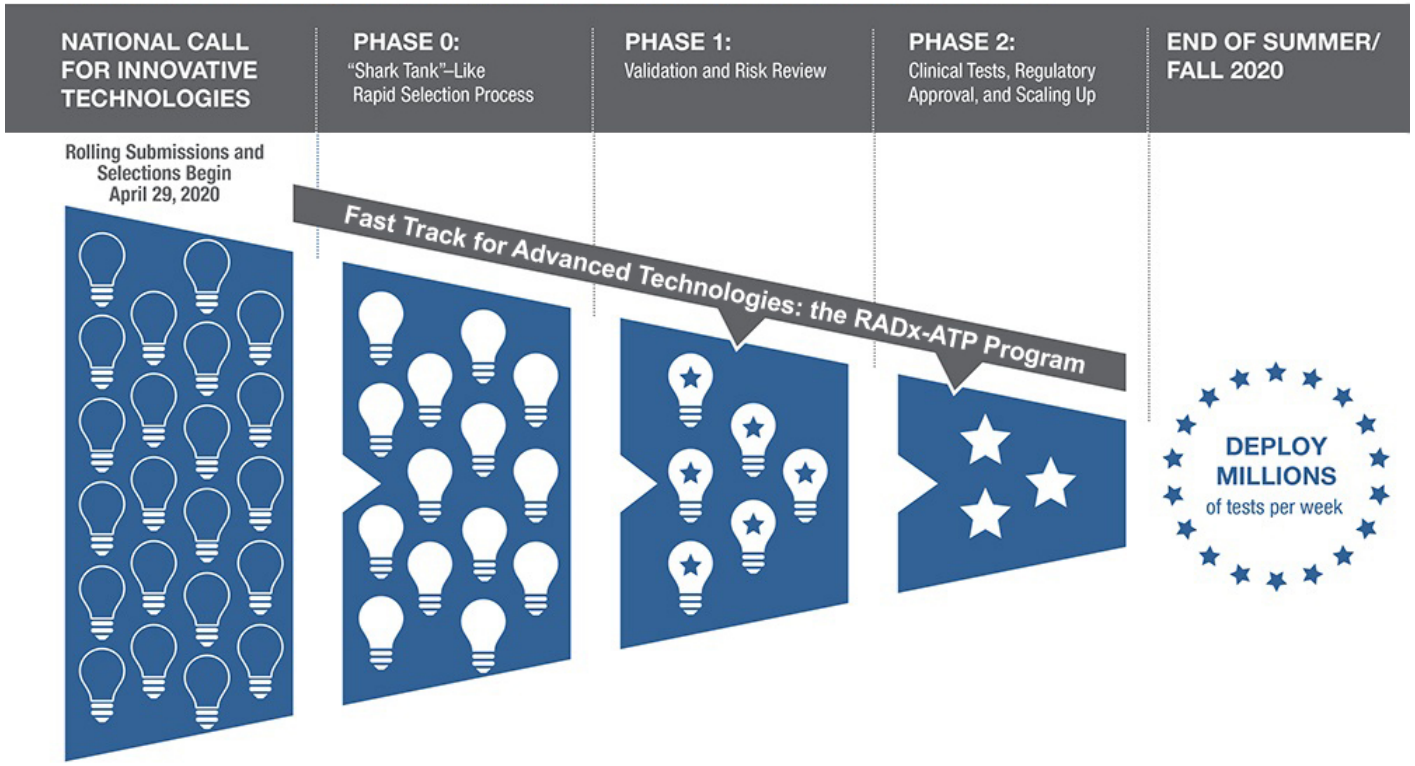
- Create POCTRN core resources and working groups for test validation, clinical, regulatory, and scale up/manufacturing challenges
- Continue manufacturing scale-up and distribution of current and additional tests

Strategy for RADx-ATP

Approach

- Leverages RADx Tech POCTRN project submission review infrastructure and market research to identify applicants of high potential
- Selection by ATP Team and coordination with federal collaborators





RADx-ATP remains on track to provide ~1M tests/day by the end of December 2020

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RADx Tech & ATP

Phase 2 Awards

A **broad range of technologies and approaches** have been supported through RADx Tech and ATP, including POC and lab-based tests and sample prep methods

Tests utilize a **range of sample types, methods, and techniques** such as RT-PCR, RT-LAMP, and CRISPR

Tests range from those nearing **FDA authorization** to those authorized and ready to be scaled

Diversifying the support for diagnostic technologies enhances the ability to innovate and develop **effective tests for many environments**

RADx awards also support programs designed to increase high-throughput testing with **established testing kits and distribution systems**

RADx Tech & ATP

Phase 2 Awards

Point-of-care tests

MatMaCorp
Lincoln, NE

Maxim Biomedical Inc
Rockville, MD

Mesa Biotech
San Diego, CA

MicroGEM International
Charlottesville, VA

Quidel
San Diego, CA

Talis Biomedical
Menlo Park, CA

Lab-based tests

Aegis Sciences
Nashville, TN

Broad Institute
Cambridge, MA

Ceres Nanoscience Inc
Manassas, VA

Fluidigm
San Francisco, CA

Ginkgo Bioworks
Boston, MA

Helix OpCo
San Mateo, CA

Illumina
San Diego, CA

Mammoth Biosciences, Inc
South San Francisco, CA

PathGroup
Nashville, TN

Sonic Healthcare USA
Austin, TX

More details are available here:
www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-phase2-awards

RADx-Radical (RADx-rad)

RADx-rad – $200M

Overarching Goal

Support new, **non-traditional approaches** and **new applications of existing tools** that address gaps in COVID-19 testing and develop platforms that can be deployed in future outbreaks of COVID-19 and other, yet unknown, diseases

Mechanism

Range of mechanisms including intramural projects, contracts, cooperative agreements, SBIR/STTR awards, RPGs, and competitive revisions to support 1-4 years awards

Timeline

- FOAs published early August
- Application receipt dates: Sept 15, 18, 30
- Awards made by end of CY20

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RADx-rad Research Interests

- **Wastewater-based detection** of SARS-COV-2
- **Single vesicle, exosome, and exRNA isolation** for the detection of SARS-CoV-2
- **Chemosensory testing** for COVID-19 screening
- **Predicting viral-associated inflammatory disease severity** in children with laboratory diagnostics and artificial intelligence

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RADx-rad Research Interests

- **Multimodal COVID-19 surveillance methods** for high risk populations
- **Novel biosensing** of biological or chemical signatures of COVID-19 from skin and the oral cavity
- Automatic, real-time detection and tracing of SARS-COV-2 with **aptamer biosensing and digital devices**
- Multiplexed screening methods with **next generation sequencing** to detect SARS-COV-2 viral gRNA content

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RADx-Underserved Populations (RADx-UP)

RADx-UP – $500M

Overarching Goal

Enhance COVID-19 testing among underserved and vulnerable populations

Mechanism

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

September – November 2020

Phase I: $300M

- **Build infrastructure**
- **Rapidly implement testing, other capabilities**

Early 2021 – Summer/Fall 2021

Phase II: $200M

- **Integrate new advances**
- **Expand studies/ populations**

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 and **implement interventions** to reduce these disparities
- **Establish infrastructure** that could facilitate evaluation and distribution of vaccines and therapeutics

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Components of RADx-UP

Collaborative Clinical Research Network

- Support research centers and consortia, grants across the country
- Test strategies for underserved and vulnerable populations

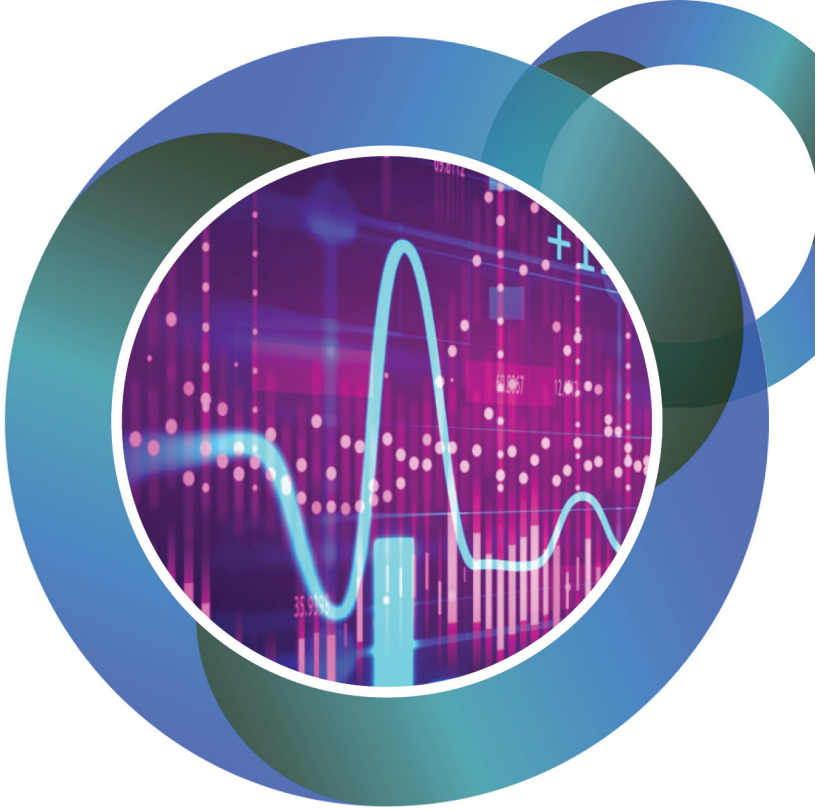
Social, Ethical, and Behavioral Implications (SEBI) Program

- Study range of issues that may influence access and uptake of COVID-19 testing

Coordination and Data Collection Center (CDCC)

- Coordinate administrative aspects of consortium
- Manage data collection, harmonization, storage, management
- Facilitate community engagement
- Offer expertise on testing technologies

RADx Data Management



Data Management Support – $70M

Goal

Develop a platform to integrate data, on individuals and populations, from a variety of sources, including serology and genetic test results, output from smart sensors, self-reported clinical symptoms, and EHR data

Mechanism

- Contract mechanisms — approximately 10 awards for 5 years; established as hub and spoke model

Timeline

- FOAs for 'spokes' published in summer 2020
- Awards made by end of FY20
- Data Hub awarded by end of CY20

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RAPID ACCELERATION OF DIAGNOSTICS (RADX)

RADx

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On this page

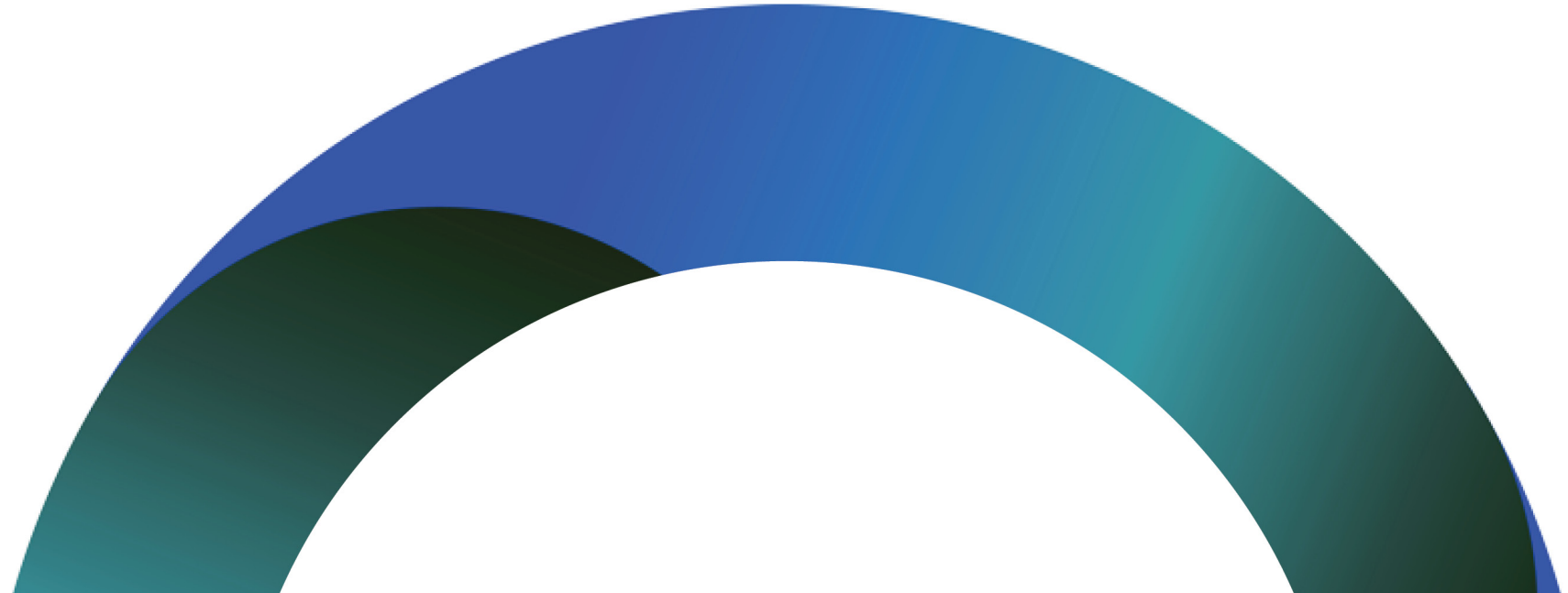
Overview | Challenge | Opportunity

Overview

The National Institutes of Health (NIH) launched the Rapid Acceleration of Diagnostics (RADx[SM]) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. Accurate, fast, easy-to-use, and widely accessible testing is required before the nation can safely return to normal life.

https://www.nih.gov/research-training/medical-research-initiatives/radx

Additional Slides



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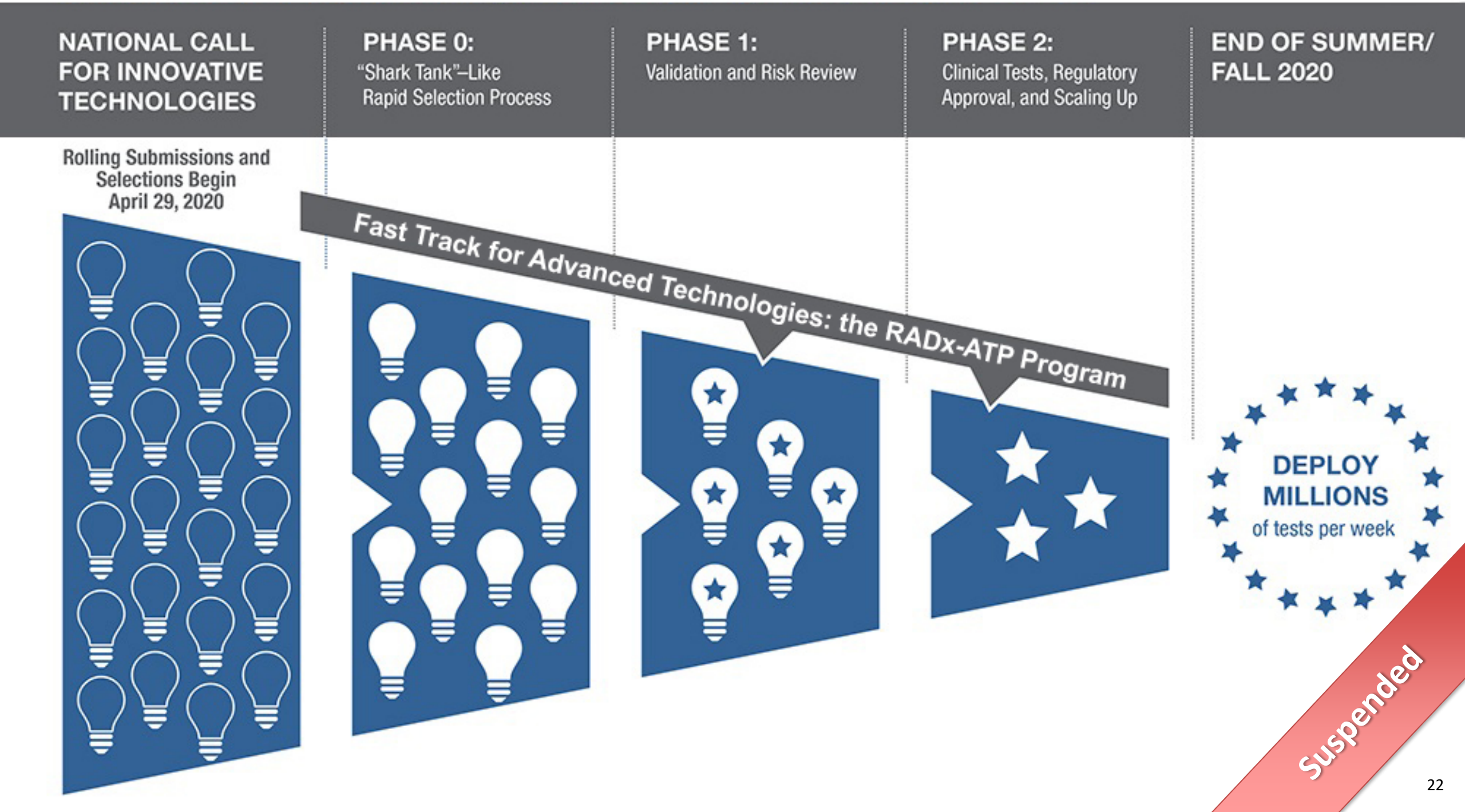
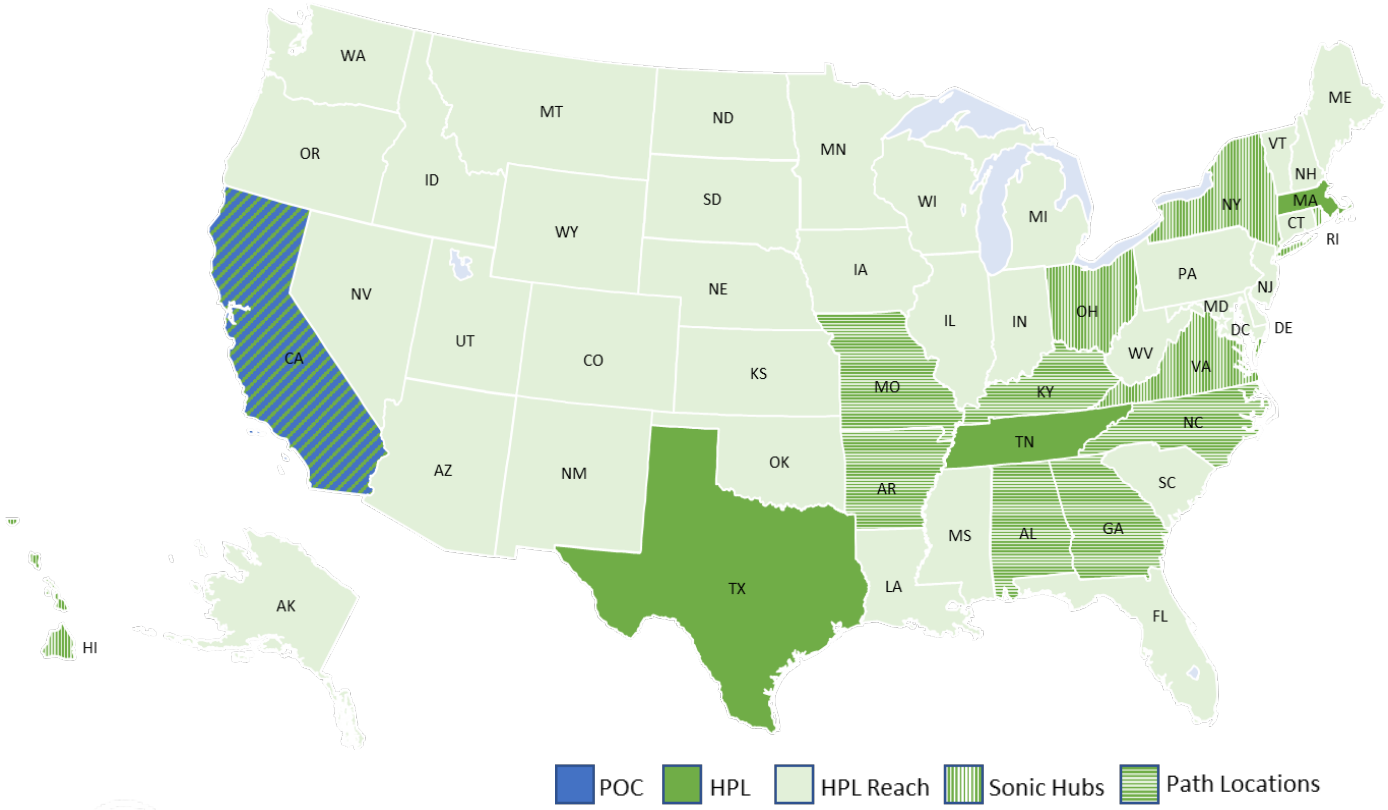

NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES
PHASE 0:
"Shark Tank"–Like Rapid Selection Process
PHASE 1:
Validation and Risk Review
PHASE 2:
Clinical Tests, Regulatory Approval, and Scaling Up
END OF SUMMER/ FALL 2020
Rolling Submissions and Selections Begin April 29, 2020
Fast Track for Advanced Technologies: the RADx-ATP Program
DEPLOY MILLIONS
of tests per week
Suspended

RADx-ATP

Phase 2 Awards

The ATP portfolio of POC and 7 high-throughput labs allows for a **wide geographical reach** of the different technologies and for **dynamic scale-up depending on regional needs.**



High-Throughput Labs

GINKGO BIOWORKS
THE ORGANISM COMPANY

AEGIS SCIENCES CORPORATION

illumina

Helix

SONIC HEALTHCARE USA

BROAD INSTITUTE

PathGroup
Physician Centered. Patient Focused.

Point-of-Care

QUIDEL

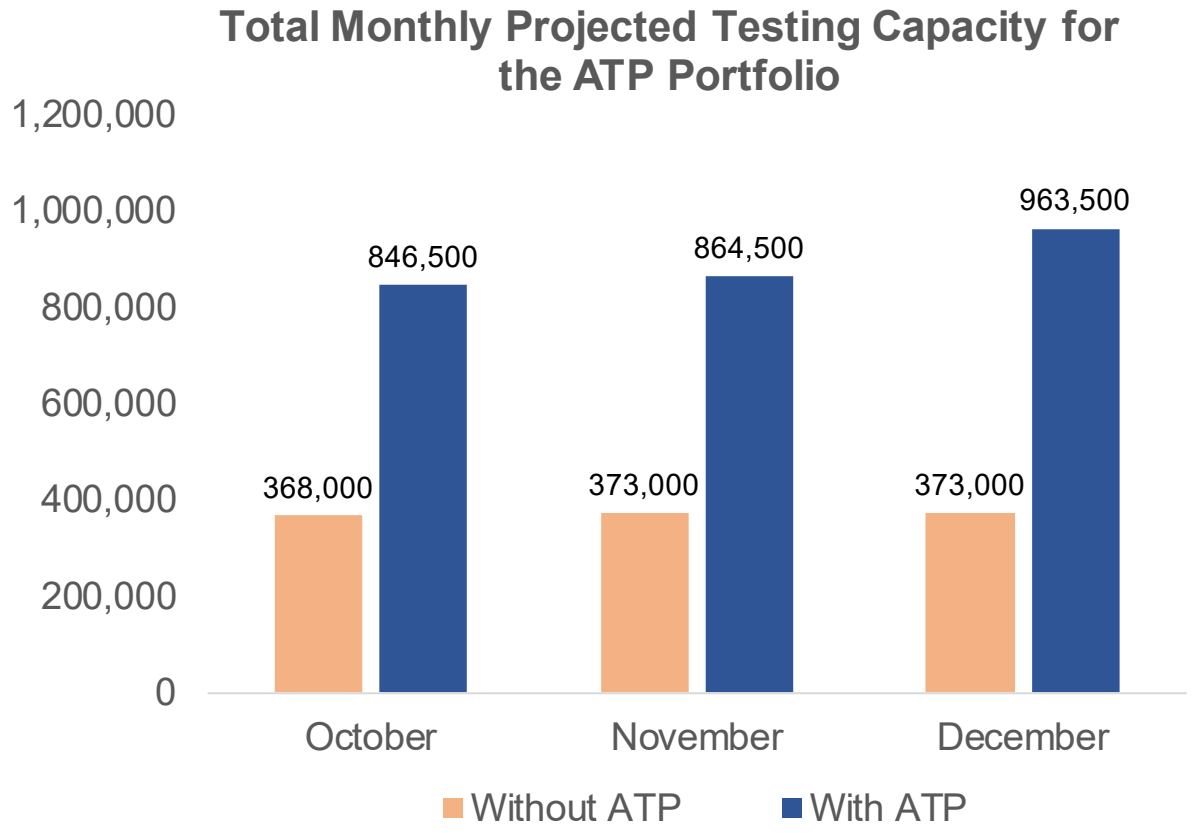
RADx-ATP Upcoming Milestones and Anticipated Challenges

ATP awardees and POs will continue to collaborate for proactive identification and resolution of risks and challenges

Goals for the upcoming months:

- **Continue to scale up testing efforts** throughout the fall and winter
- **Coordinate EUA approvals** for companies seeking to amend their EUAs to include saliva-based or at-home testing
- Support awardees as they **incorporate influenza A and B testing into COVID-19 testing kits**

RADx-ATP remains **on track to provide ~1M tests/day by the end of December 2020**



RADx-rad Strategies

- Identify **unique application** of existing strategies
- Support **unconventional** detection strategies
- Invest in novel technologies, strategies, and devices that require **additional development time**
- Enhance **access to or usability of** COVID-19 testing