FDA U.S. FOOD & DRUG ADMINISTRATION & Devices

# RADx Program

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# Operation Warp Speed

## Vaccines, Therapeutics, Diagnostics

- Operation Warp Speed's (OWS) goal is to produce and deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).
- OWS is a partnership among components of the Department of Health and Human Services (HHS)
  - Centers for Disease Control and Prevention (CDC)
  - National Institutes of Health (NIH)
  - Biomedical Advanced Research and Development Authority (BARDA)
  - Department of Defense (DoD).
  - OWS engages with private firms and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs.
- It will coordinate existing HHS-wide efforts, including the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, **NIH's Rapid Acceleration of Diagnostics (RADx)** initiative, and work by BARDA.
- OWS Video: https://www.youtube.com/embed/Z06JQhyZLUI?rel=0

# RADx Tech & ATP Program Overview

- The RADx$^{SM}$ Tech/ATP program is one component of the overarching RADx$^{SM}$ Initiative at NIH to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing.

| Program | Goal |
|---|---|
| RADx Tech ($500M) | Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or POC tests |
| RADx Advanced Technology Platforms ($230M) | Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput |
| RADx Radical ($200M) | Develop and advance novel, non-traditional approached or new applications of existing approaches for testing |
| RADx Underserved Populations ($500M) | Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of vulnerable populations |



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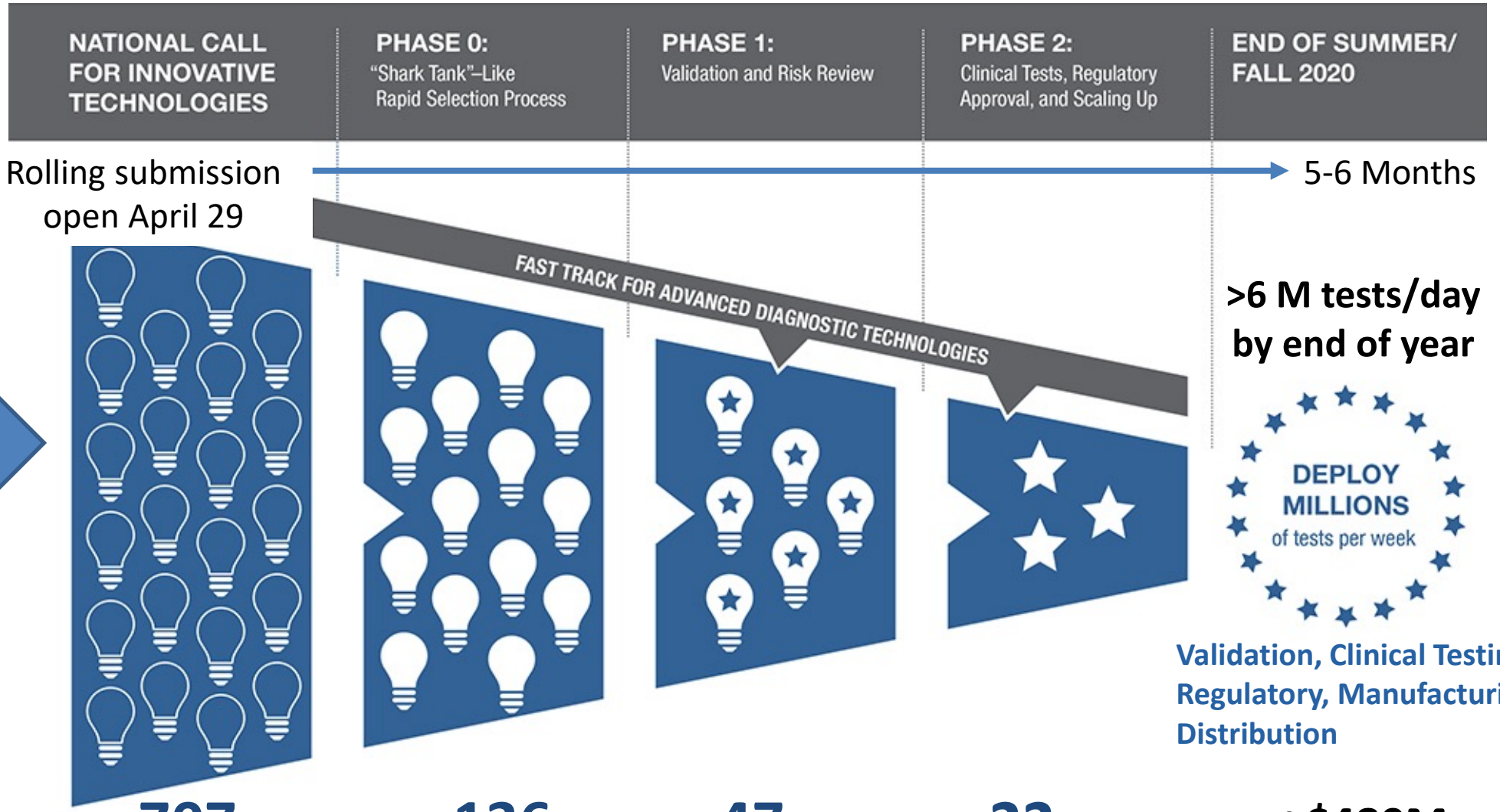
# RADx Tech & ATP

## High-level goals

- Expand COVID-19 Testing Technologies
- Optimize Performance
- De-risk innovation to commercialization pipeline
- Millions tests/day

Content from NIBIB

# Innovation Funnel (Tech & ATP)




Applications Started

**~3000**

**Projects in each Phase**

# Point-of-Care Technologies Research Network (POCTRN)

Content from NIBIB

https://www.poctrn.org

## NIBIB National Network

Established 2007, Expanded 2020: >1000 RADx experts & contributors

Project Tech:

1) Review
2) Funding
3) Expertise
4) Testing

VENTUREWELL™ idea to impact

**GaTech/Emory**
- ✓Engineering
- ✓Design/Prototype
- ✓Clinical Validation
- ✓Biobank samples
- ✓In-Home Validation

**Johns Hopkins**
- ✓Public Health/STD
- ✓Global Health
- ✓Clinical Validation
- ✓Biobank samples
- ✓Validation in LMICs

**CIMIT/MGH**
- ✓Coordinating Center
- ✓Collaboration/Management Platform
- ✓Business/Commercialization

**Northwestern**
- ✓HIV/AIDS
- ✓Engineering
- ✓Global Health
- ✓Clinical Validation
- ✓Validation in LMICs

**UMass**
- ✓Heart, lung, blood
- ✓Engineering
- ✓Clinical Validation
- ✓Biobank samples
- ✓Clinical Trials
- ✓Business/Commercialization

C BIO M C3i

**Validation Core**

>15 projects complete, >11 ongoing, >1500 participants

**Clinical Studies Core**

Standard Trial Design, Digital Health Platform, Single IRB, Center Network

**Deployment Core**

Supply chain, Manufacturing, User Community, End to end solutions

National Inst Biomedical Imaging and Bioengineering

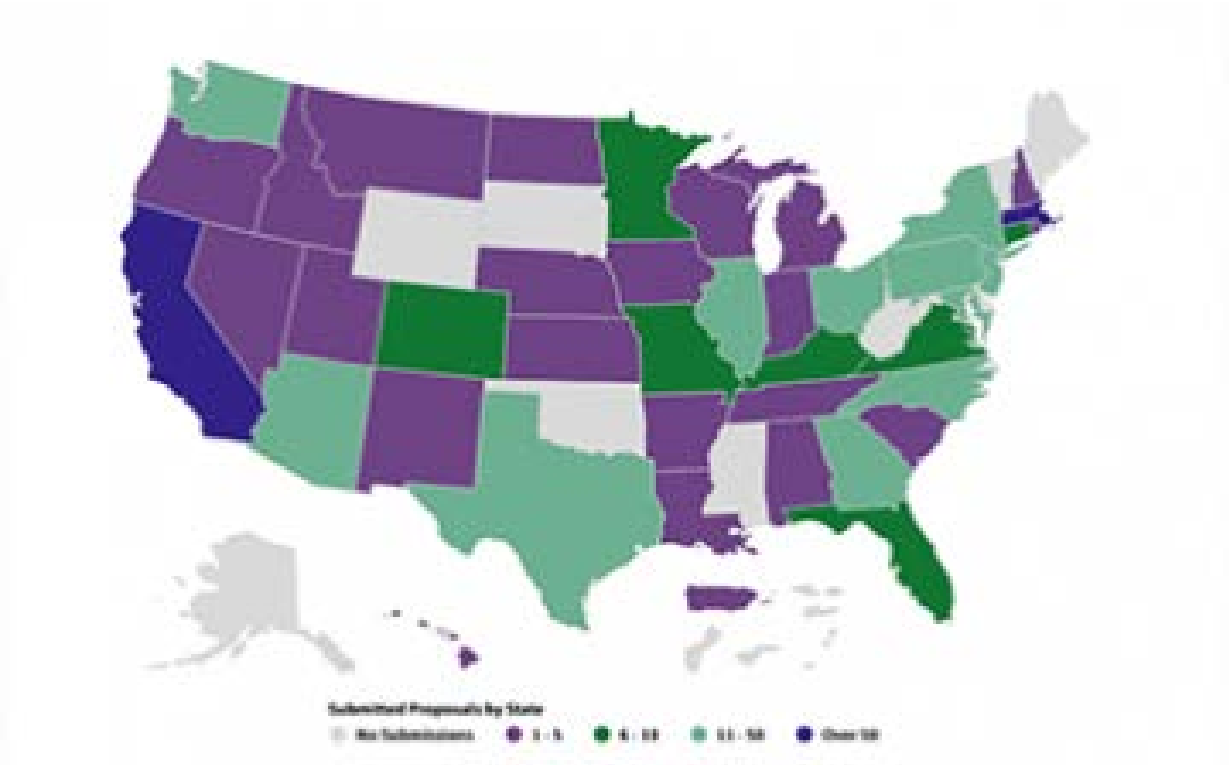
# Phase 2 Awards

*as of 11/16/20*

- Visby Medical
- Ubiquitome
- Flambeau Diagnostics
- Quanterix
- Luminostics, Inc
- Ellume USA LLC
- Sonic Healthcare USA
- PathGroup
- Ceres Nanosciences Inc
- Broad Institute
- Aegis Sciences
- MicroGem International
- Maxim Biomedical Inc
- MatMaCorp
- Mesa Biotech, Inc
- Talis Biomedical Corp
- Quidel Corp
- Mammoth Biosciences
- Fluidigm Corp, Inc
- Helix OpCo, LLC
- Illumina Inc
- Ginkgo Bioworks

# RADx$^{SM}$ Tech/ATP Dashboard

Information on this page provides a summary of proposals submitted, the stage of development, the type of testing samples proposed, and the types of organizations responding to these two programs that are part of the NIH RADx initiative (updated weekly).



*https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-dashboard*

# FDA CDRH Engagement

- Daily communication with RADx management teams at NIH, NIBIB, POCTRN, CIMIT
- Division review teams proactive and continual engagement with RADx staff, developers
- OIR participation in daily, weekly RADx All-Cores meetings, Q&A's, CLIA, emerging technologies

NIH National Institute of Biomedical Imaging and Bioengineering

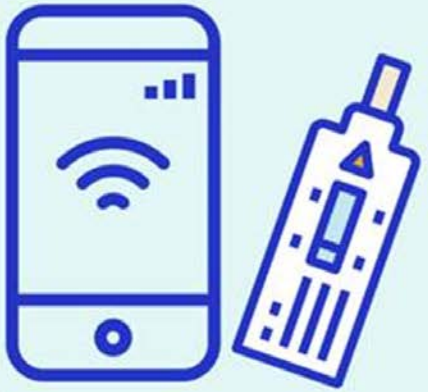
FDA

Center for Devices and Radiological Health CDRH

# COVID-19 AT-ANYWHERE DIAGNOSTICS

## Design-a-thon

**Developing digital solutions for data capture, harmonization, and reporting from diagnostic tests**



**#COVIDdesignathon**

*The Design-a-thon is a public-facing, open-innovation technology sprint with industry that aims to develop device-integrated software for automatic data capture and wireless transmission directly from in vitro diagnostic devices (IVDs).*

HHS.gov
U.S. Department of Health & Human Services

**GOAL 1:** The Design-a-thon brings together **public and private sector innovators** to develop software/digital health tools that **integrate with IVDs.**

**GOAL 2:** Build an **HHS interface** that will exemplify the **design principles** and provide device/systems-agnostic "docking" between HHS Protect and various reporting systems, called **"Wireless Automated Transmission for Electronic Reporting Systems" (WATERS).**

- Future State: By setting the design principles, the Design-a-thon will establish and align diagnostics data reporting **standards** for **every single core data element defined under CARES**, which have been defined by HHS (including **technological specifications**) for lab-based and non-lab-based tests.

*Happening NOW through Nov. 30*

**Participate in the Design-a-thon at: Waters.Crowdicity.com**

# RADx Contacts

**Program Contacts**

RADx$^{SM}$ Tech/ATP programmatic or technical inquiries: info.radx@poctrn.org

All other RADx$^{SM}$ Tech/ATP Applicants: RADxNIBIB@mail.nih.gov

SBIR/STTR Applicants: NIBIB-SBIR@mail.nih.gov

All others: COVID19NIBIB@nibib.gov

# RADx Resources

- NIH/NIBIB Program Overview
  - https://www.nibib.nih.gov/covid-19/radx-tech-program
- RADx Tech and ATP Phase 2 awards
  - https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-phase2-awards
- RADx Tech/ATP Dashboard
  - https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-dashboard
- Press Release (10/6/20) on POC contracts
  - https://www.nibib.nih.gov/news-events/newsroom/nih-radx-initiative-advances-six-new-covid-19-testing-technologies

# RADx Videos

- RADx Tech Video from NIBIB
  - https://www.youtube.com/watch?v=pD6q4Ul-Fdg&feature=youtu.be
- Dr. Bruce Tromberg's RADx presentation for the COVID-19 At-Anywhere Diagnostics Design-a-thon
  - https://www.youtube.com/watch?v=jqBbFEEXA-g&list=PLrl7E8KABz1HJPz2_-zi4i2YSotfUosk9&index=6

# Thank You