

RADx Projects



RADx Tech – \$500M

Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19



RADx Underserved Populations (RADx-UP) – \$500M

Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations



RADx Radical (RADx-Rad) – \$200M

Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing



RADx Advanced Testing Program (RADx-ATP) – \$230M

Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput – create ultra-high throughput machines and facilities



Data Management Support – \$70M

Build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts

Rapid Acceleration of Diagnostics: RADx Tech

June 11, 2020

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Director

National Institute of Biomedical Imaging and Bioengineering



Challenge: *Increase Testing Capacity*



Large Scale Semi-Contained

- High schools, manufacturing plants, large event gatherings
- Rapid deployment to aid in the investigation of a newly identified emerging cluster of cases, such as in response to an outbreak among workers at meatpacking plants.



Small-Medium Scale Semi-Contained

- Long-term care facilities or correctional institutions.
- Day care and elementary schools
- Closed to public businesses



Large Scale Public

- Large retail stores
- Transportation hubs or channels such as airports
- Large community building



Medium-Small Scale Public

- Small retail stores
- Restaurants
- Rural community buildings



Healthcare

- Rural hospitals, other sites (e.g. retail health, offices) w/o widely available testing.
- Public health dept testing sites; health care workers/1st responders
- Emergency departments for testing of high-priority specimens requiring a rapid result.



Home

- Home tests will allow people enter public spaces once confirmed negative

CDC: ~2.5M residents + staff
CMS: *baseline + weekly tests w/resident or staff Dx*

Rapid Acceleration of Diagnostics (RADx) Initiative

Signed into law, April 24 → Launched April 29 (2020)

Rapid Acceleration of Diagnostics (RADx)



\$500 Million to NIBIB

Innovate: *Expand Number, Type, Access, Throughput of Testing Technologies*

Optimize: *Technology Performance for Range of Essential “Use Cases”*

- Home-based
- Point of Care (POC)
- Hospital
- Testing Laboratory

<https://www.nibib.nih.gov/news-events/newsroom/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics>



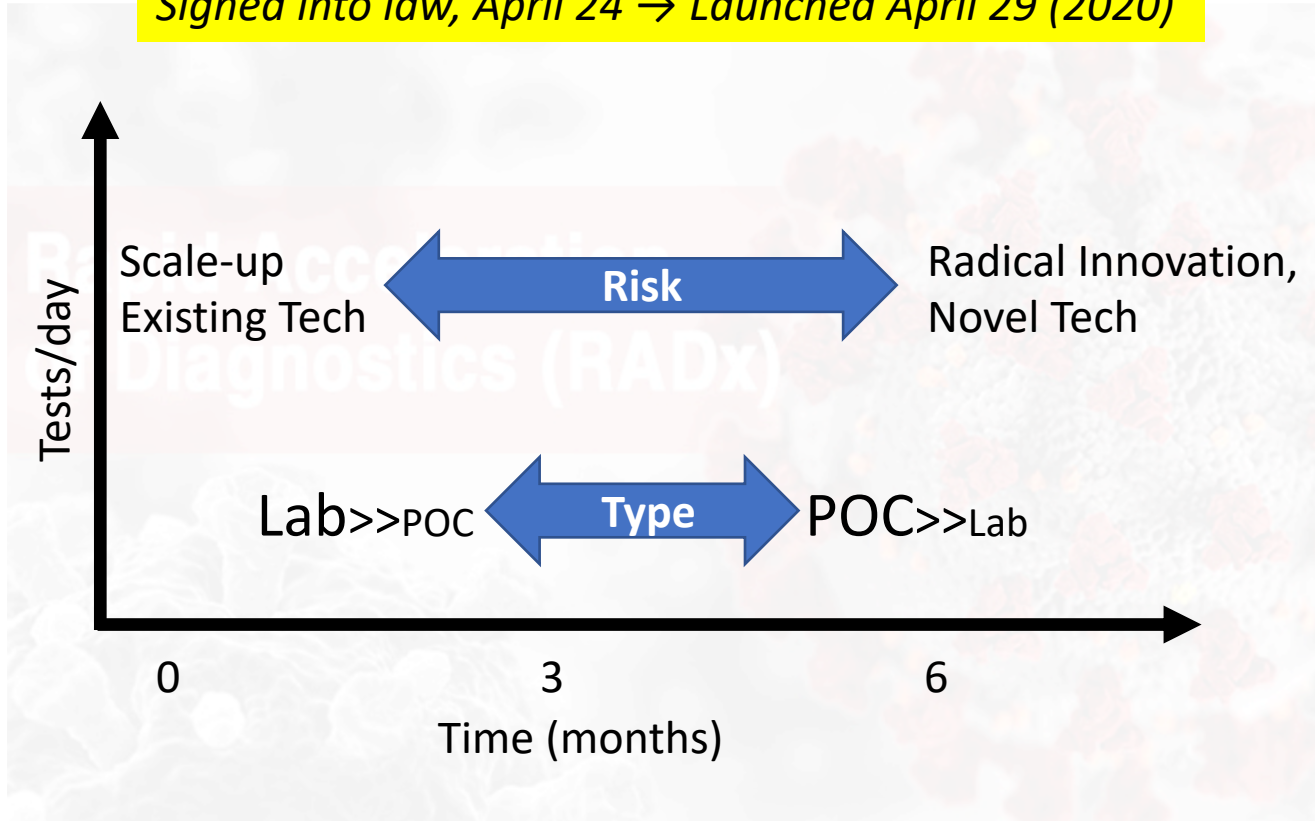
National Institute of Biomedical Imaging and Bioengineering

Creating Biomedical Technologies to Improve Health

and Bioengineering

Rapid Acceleration of Diagnostics (RADx) Initiative

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\$500 Million to NIBIB

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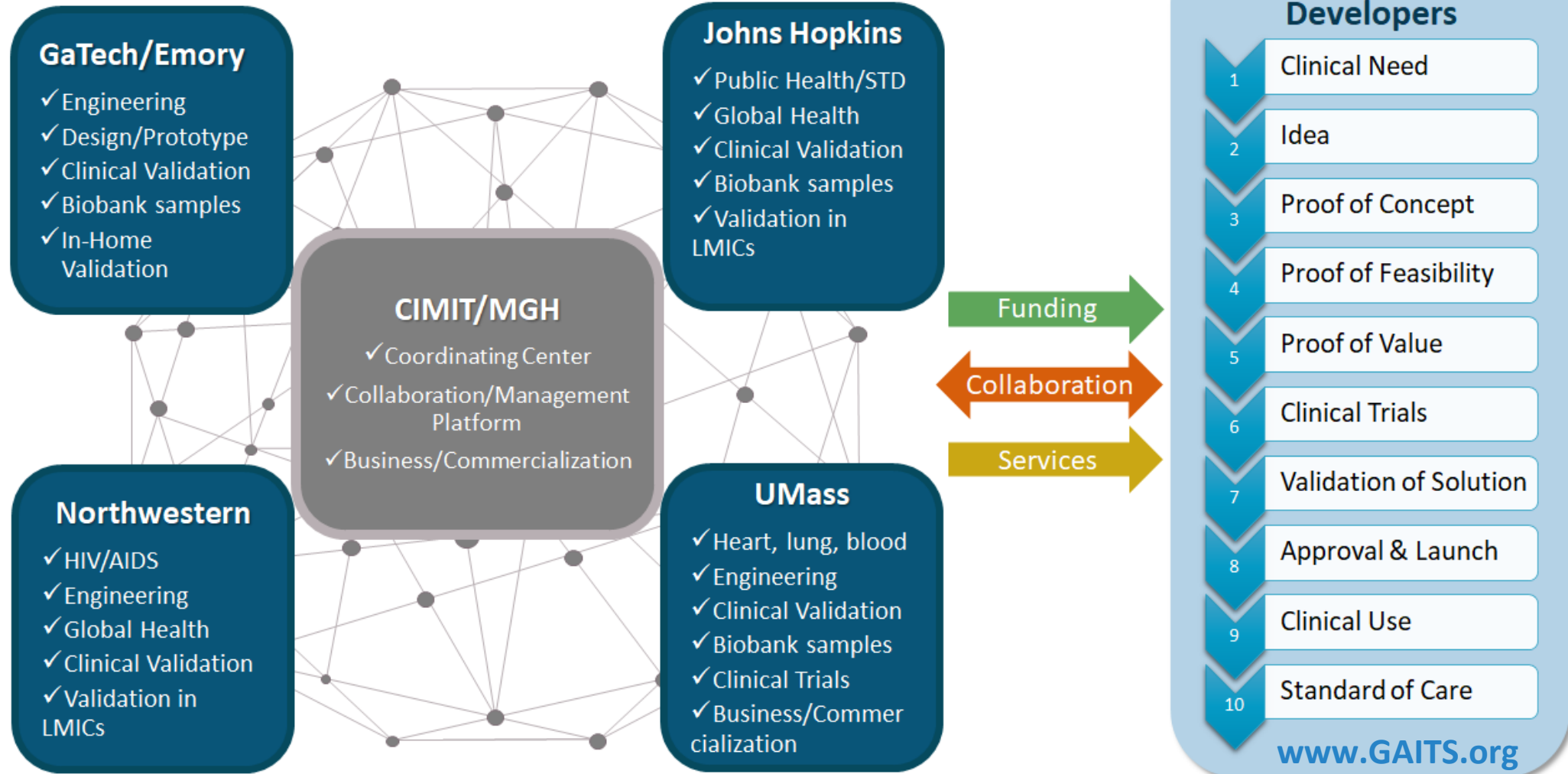
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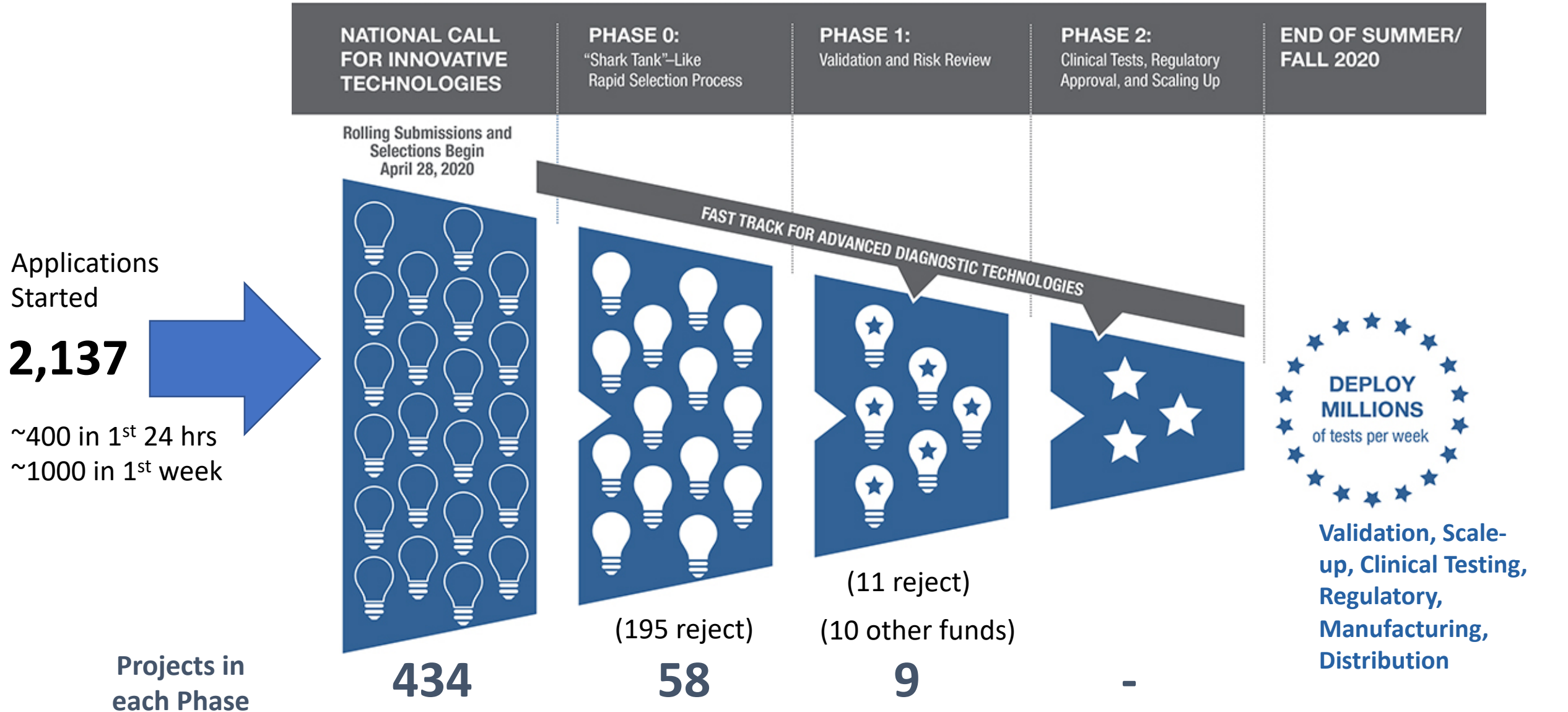
<https://www.nibib.nih.gov/news-events/newsroom/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics>

Point-of-Care Technologies Research Network (POCTRN)

NIBIB U54 National Network since 2007

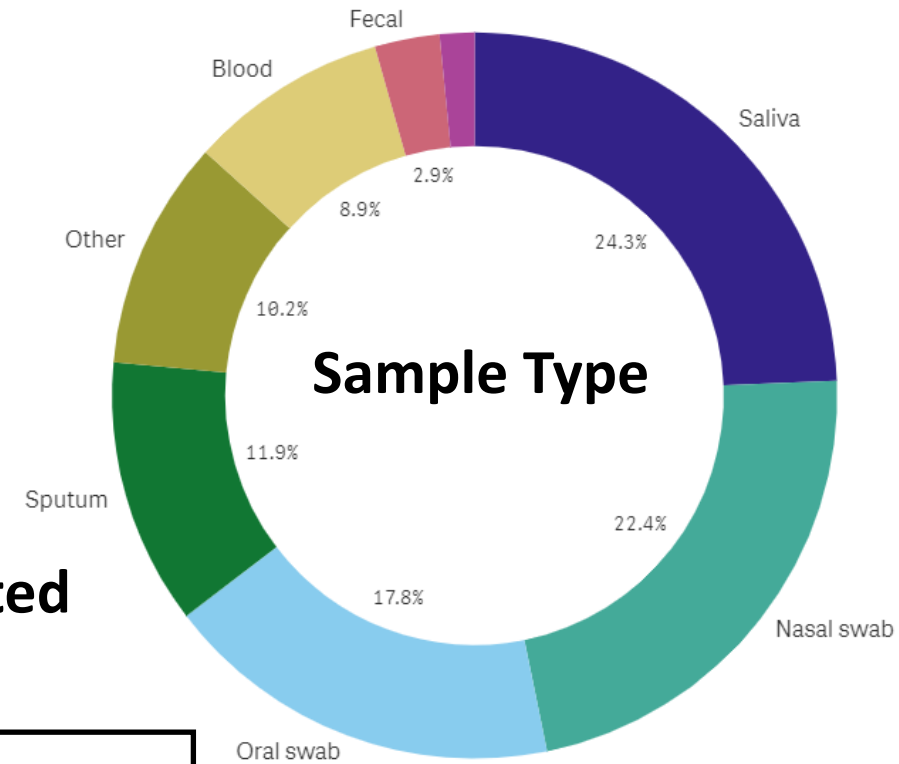
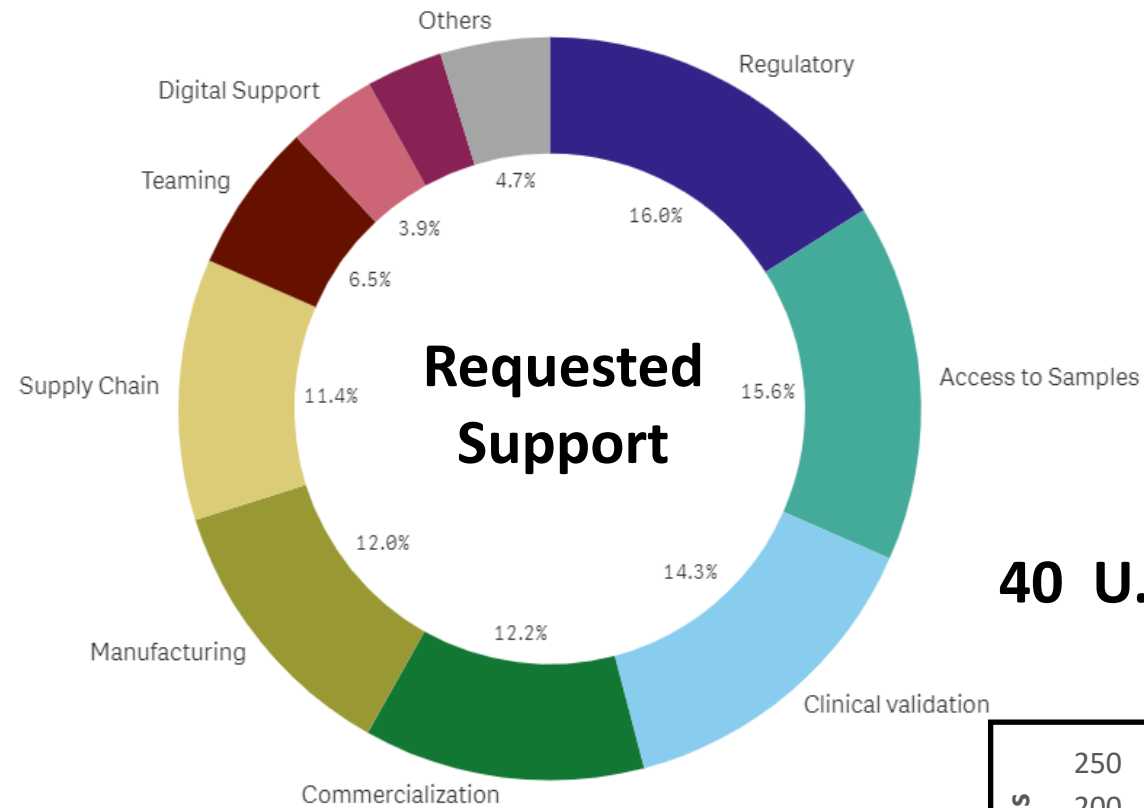


RADx Tech Innovation Funnel: Project Status



**As of 12:00 pm 6/7/20*

Landscape of RADx Tech Proposals

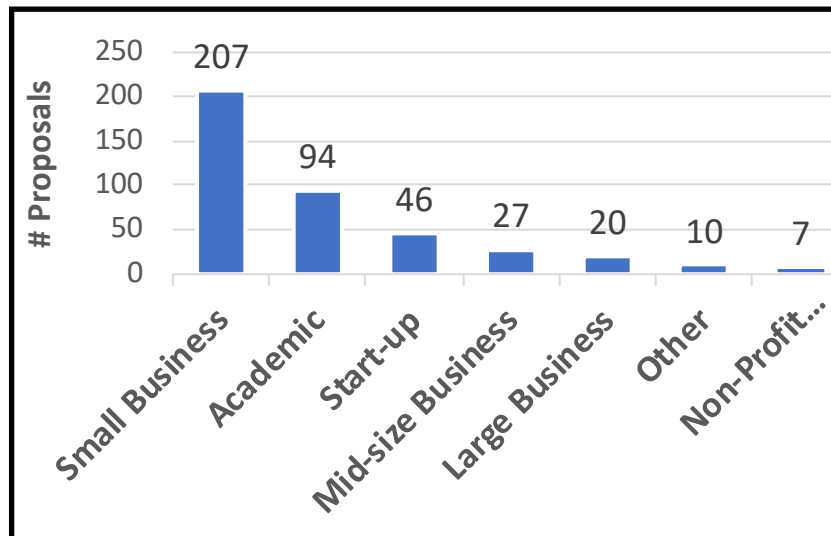


40 U.S. states represented



400+

Expert Volunteers to
Support RADx Project
Review & Management



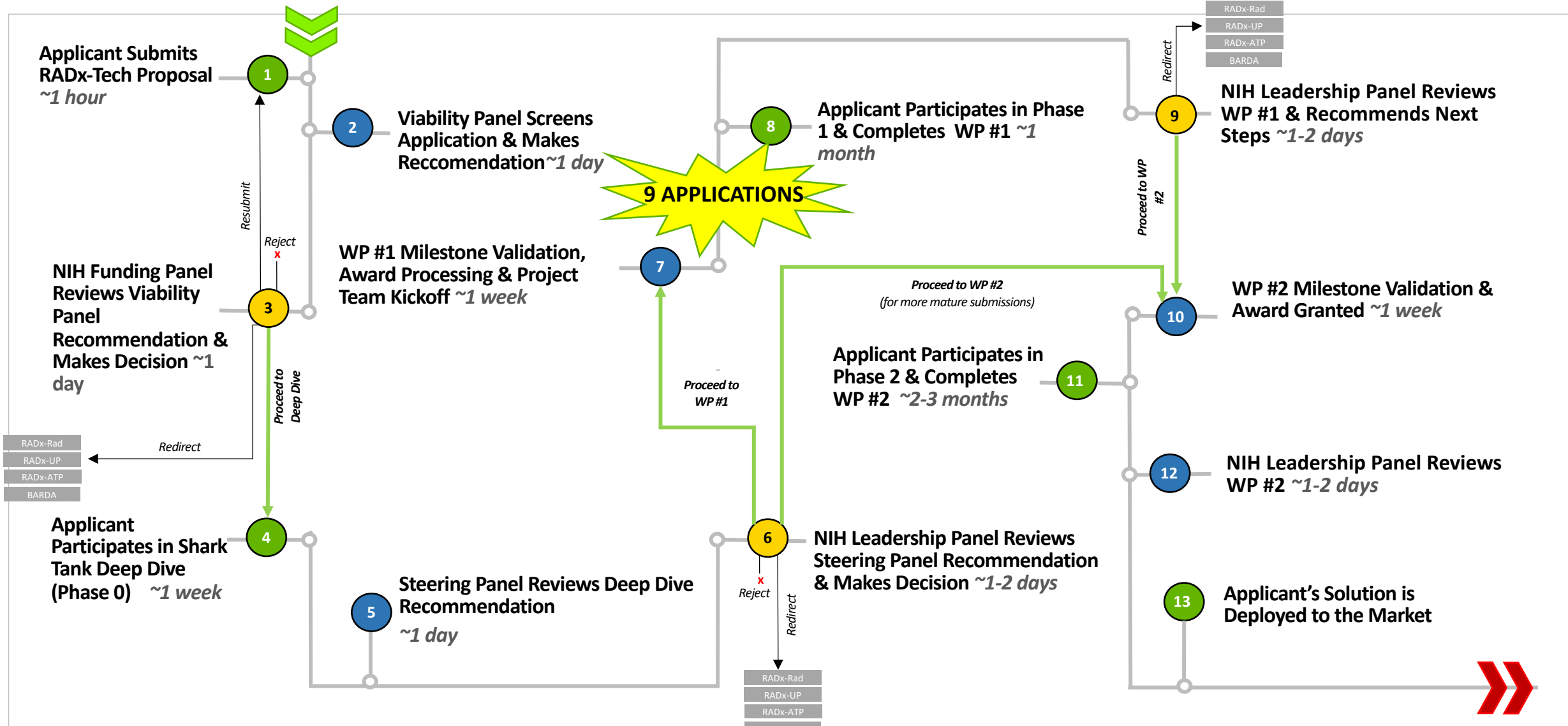
**As of 12:00 pm 6/4/20*

RADx Tech Applicant Journey Map

Overview Version

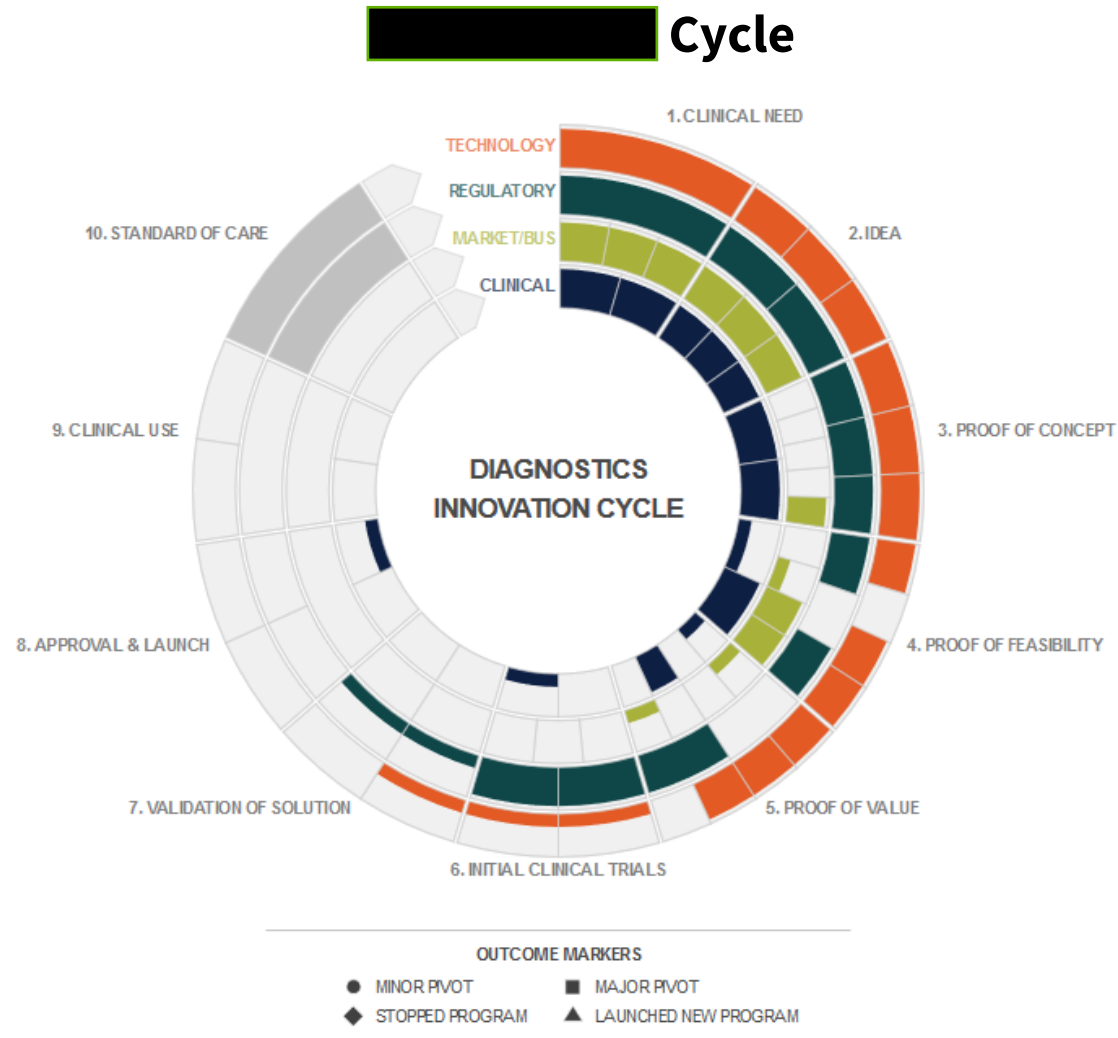
Month 0

Month 6



~May 12th- May 19th: [REDACTED] Participates in Shark Tank Deep Dive (2 of 3)

Each project is uploaded into CIMIT's GAITS platform in order to track its development and maturity throughout each phase. [REDACTED] GAITS platform is created during the Deep Dive and will now be used going forward by the Project Team.



CIMIT's **Guidance and Impact Tracking System (GAITS)** platform, a **secure, web-based project and portfolio management platform** designed to assist the commercialization of healthcare innovations by helping teams with innovative healthcare ideas, and the portfolio managers that support them, learn from the experiences of others to more efficiently speed innovative solutions to patient care.

The Healthcare Innovation Cycle captures CIMIT's experience facilitating more than 1,000 teams with innovative HealthTech solutions. It is composed of **a series of Deliverables grouped by maturity (10 Milestones) and topic areas (4 Domains) creating 40 Cells**. Each Cell is divided into Segments that represent a Deliverable. **As a Deliverable is being completed, the Segment grows radially to show its status**, providing a quick "diagnostic" for a project.

<https://www.gaits.org/public-plan-track>

RADx Tech Cores



	Test Validation Core	Clinical Trials Core	Large Scale Operations Core
Organization	Emory University & Georgia Tech	UMass Medical School & UMass Lowell	Led by Nancy Gagliano (former CVS Exec)
Description	<ul style="list-style-type: none"> Objective: provide independent validation of proposed tests and assess their relative promise <ul style="list-style-type: none"> Provide FDA confidence when evaluating results from clinical trials of the technology in question Evaluate each test across a variety of metrics, potentially including: sensitivity, specificity, positive predictive value, reproducibility, robustness under different environmental conditions, and resistance to operator error 	<ul style="list-style-type: none"> Objective: support the refinement and clinical testing of POC technologies for COVID detection in “real-world” environments Proposed elements of the Core: <ul style="list-style-type: none"> Biostatistics and Research Design Center (BERD) to provide access state-of-the-art statistical and study design considerations Regulatory Knowledge and Support (RKS) for key insights into regulatory methods and processes Data Safety/Ethics Core to evaluate proposed clinical studies and weigh key ethical considerations Community Engagement, Health and Policy core to increase community participation in the design and conduct of clinical research 	<ul style="list-style-type: none"> Objective: coordinate and manage the manufacturing, commercialization, and distribution process <ul style="list-style-type: none"> Describe the full pipeline and identify partners needed in the pathway from innovation to public dissemination, including scaleup for real-world testing, identifying manufacturing partners, and distribution approaches. Identify unmet needs and challenges along the pathway that can be addressed by expansion of POCTRN capabilities, by government agencies, or by industry partnerships. Consider parallel, ‘at risk’ approaches to achieve a minimal timeline.



Complementary Programs

