NATIONAL INSTITUTES OF HEALTH
Office of the Director
RADx Initiative
(Dollars in millions)

Activity	Amount
RADx-Underrepresented Populations (RADx-UP)	500.000
RADx-Radical Non-Traditional Approaches (RADx-Rad)	200.000
RADx-Accelerating Technology Platforms (RADx-ATP)	230.000
Data Management for Testing for Safe Release	70.000
Office of the Director Coronavirus Funding	**1,000.000**

The National Institutes of Health (NIH) will respond to the COVID-19 outbreak by speeding innovation in, development and commercialization of, and implementation of COVID-19 testing through the Rapid Acceleration of Diagnostics (RADx) initiative, a multi-component effort. RADx will infuse funding into early innovative technologies, including those using non-traditional approaches, to speed development of rapid and widely accessible COVID-19 testing. At the same time, NIH will seek opportunities to move more advanced diagnostic technologies swiftly through the development pipeline toward commercialization and broad availability. Efforts will also be undertaken to expand the testing infrastructure across the country by investigating, in real-time, a variety of testing methods and approaches to better understand the uptake, administration, and effectiveness in specific populations, areas, or settings. NIH will work closely with other agencies, including the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority (BARDA), to advance these goals.

Multiple components of RADx are described below. RADx-Tech, a sister effort run by NIBIB, is accelerating the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2, the virus that causes COVID-19. RADx-Tech is not being presented for concept clearance.

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

As part of the Rapid Acceleration of Diagnostics (RADx) initiative, NIH proposes to develop a series of interlinked community-engaged projects focused on implementation strategies to enhance COVID-19 testing for of health disparity populations (see https://www.nimhd.nih.gov/about/overview/), in addition to other underserved, under-resourced, rural, and/or vulnerable populations across the US. This initiative will develop an infrastructure to assess and expand evidence-based testing interventions and capacity for those populations that are disproportionately affected by, have the highest infection rates of, and/or are most at risk for adverse outcomes from contracting the virus, including African Americans, American Indians/Alaska Natives, rural populations, underserved urban areas, those in situations which facilitate transmission of the virus (e.g., nursing homes, jails/prisons), homeless people, those with underlying conditions, and pregnant women. RADx-UP will establish pragmatic clinical trials at multiple sites across the country to investigate, in real-time, a variety of testing methods and approaches to better understand the uptake, administration, and effectiveness in specific populations, areas, or settings. Sites

within RADx-UP will be strongly encouraged to leverage existing and develop new community partnerships to identify and address the unique needs of different communities. RADx-UP projects will create sustainable infrastructure for future crises, specify strategies to address social determinants of health that present barriers to test completion and follow-up, and conduct evidence-based outreach and dissemination activities to inform communities about the project and its findings.

This initiative will leverage the advances brought forth from the other RADx efforts and develop testing strategies to use them in real-world settings, such as distribution of at-home diagnostic kits. Additionally, given the expected rapid expansion of vaccine trials and the need for associated serological and other testing strategies, the demonstration projects associated with RADx-UP will serve as a resource for more routine testing once the vaccine trials accelerate. Additionally, fully appreciating the scope of the sensitivities associated with this disease and the disparate toll COVID-19 is taking on specific populations, this initiative will build a social, ethical, and behavioral implications (SEBI) program to understand the range of ethical and social issues associated with testing/diagnostic technologies and information/data collection and sharing (including the stigma associated with a positive test result) in research, clinical, or other settings. A Coordinating and Data Collection Center (CDCC) will provide leadership and project management and serve to facilitate connections across the initiative, including collection of common data elements, data storage, management, and harmonization, and epidemiological studies to understand factors contributing to disparities in infection rates and outcomes. The CDCC will serve as a spoke in the hub and spoke model for data management described below. It will also serve as a national resource to engage stakeholders – both from the scientists and community partners – across the initiative, facilitate study participant recruitment and retention, provide a central clearing house for documentation of unanticipated or adverse events and their remediation, and coordinate governance activities across the initiative (e.g., Steering Committee, External Advisory Committee).

Mechanisms, Budget, and Timeline:
This project will use a phased approach. The over-arching research objective of both Phase I and II is to collect high-quality testing data to understand prevalence, treatment, and the effects of public health measures and in an effort to address outcome disparities in the populations of interest. Specifically:

RADx-UP Phase I projects (FY20-22, $200M) will work closely with communities to develop and rapidly implement interventions to increase access and uptake of FDA-approved point-of-care tests for SARS-CoV-2 virus and antibody testing. Thus, Phase I consortium sites must have already established infrastructures and partnerships to demonstrate measurable impact within a short timeframe. The following projected award budgets include:
- Phase Ia:
  - Coordination and Data Collection Center (CDCC) – up to $30M for one site; U24 cooperative agreement
  - Collaborative network of clinical research centers and consortia across the country – up to $5M/site for ~25 sites; various mechanisms (e.g., P30, P50, U54)
- Phase Ib[1]:
  - Collaborative network of clinical research grants across the country – up to $1M/site for 30 sites; competitive revisions/new R01s

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[1] Phase Ia and Phase Ib will simultaneously release FOAs; however, Phase Ib will have a slightly later receipt date to allow for and promote self-assembly amongst various potential applicants

o   Social, Ethical, and Behavioral Implications (SEBI) program – up to $5M for 5-8 sites; competitive revisions/new R01s

RADx-UP Phase II projects (FY22-24, $300M) will apply scientific and technological advancements about the virus/pandemic acquired by currently ongoing research, including those from the Phase I studies and other components of the RADx initiative, to accelerate the rapid deployment of COVID-19 testing, and address barriers to implementation at the point-of-care using community engaged approaches. With the rapidly changing nature of the disease and anticipated rapid expansion of vaccine trials and the need for associated serological and other testing strategies, Phase II studies will serve as a resource for more routine testing once the vaccine trials accelerate. The launch of Phase II will occur within one year after the initiation of Phase I to allow opportunities for infrastructure enhancement and expanding multisector partnerships in communities with high need. The following projected award budgets include:

- CDCC – up to $50M for one site (renewal of Phase I CDCC)
- SEBI program – up to $5M for 5-8 sites; competitive revisions/new R01s
- Renewal or expansion of Phase I components with additional new awards to build the synthetic network of clinical research sites and centers across the country – up to $245M; competitive revisions/new awards

RADx-RAD (Radical Non-traditional Approaches) - ($200M)

This effort will support novel concepts that address current gaps in SARS-CoV-2 testing through non-traditional approaches. This effort will focus on non-traditional viral screening approaches, such as biological or physiological markers, new analytical platforms with novel chemistries or engineering, rapid detection schemes, point-of-care devices, and home-based testing technologies. In addition, novel or non-traditional applications of existing approaches to enhance usability, access, robustness, or accuracy will be encouraged. These ideas may take a bit longer to actualize, but could provide a range of novel approaches to identify the SARS-CoV-2 virus and may be applicable to other, as yet unknown, viruses.

Examples of novel approaches include monitoring of community waste-water, a noninvasive diagnostic device that detects Volatile Organic Compound (VOC) on the skin, novel oral biosensors, detection and measurement of the mucosal innate and adaptive immune response in easily accessible nasopharyngeal (NP) epithelial airway samples, and assessment of the microbiome to detect SARS-CoV-2.

Mechanism, Budget, and Timeline:
This effort will utilize grant mechanisms to award up to $200M by the end of CY20 (planned by November 2020), which will allow time to assess technologies that are currently in development. These 2-3 year projects will be implemented through a range of grant mechanisms, including cooperative agreements, SBIR awards (for small business research/research and development projects), R01s, and other mechanisms as needed. NIH intramural program projects will be considered for RADx-Rad, but will not constitute more than 10% of the RADx-Rad budget (i.e., $20M).

RADx-ATP (Accelerating Technology Platforms) - ($230M)

This effort will identify diagnostic testing approaches for COVID-19 that are currently advanced enough to enable and achieve rapid scale-up in a reasonably short period of time to address the pandemic in real-time. These efforts will focus on scaling up existing technologies to increase rapidity and enhance and validate through-put, including the creation of ultra-high throughput machines and facilities. Engineering innovations could be introduced to existing high-throughput machines to increase analytical and operational performance. Potential approaches could include scaling up testing and utilization through the creation of large capacity regional testing hubs that leverage large NIH clinical networks, such as CTSAs and Cancer Centers. Each of these approaches would require optimization and certification (*e.g.,* Clinical Laboratory Improvement Amendments (CLIA), but also have different throughput per machine and different technical specs matched to use cases.

Specific project examples may include:

- Build on or leverage Point of Care Technology Research Network (POCTRN) capabilities to validate and perform clinical tests and obtain needed regulatory approvals. This approach would leverage existing technologies to create solutions that target and reach certain design specifications and offer diverse challenges to rapidly advance and/or scale-up testing capacity across the country.
- Development of modular test panels for multiple infectious diseases (differential diagnosis), including viral agent and the immune response, bacteria, genetics, other syndromes.

Mechanism, Budget, and Timeline:
This 2 year effort will utilize contract mechanisms to be awarded by the end of FY20 (Fall 2020) for up to $230M.

Data Management for Testing for Safe Release - ($70M)

The Data Management for Testing for Safe Release Project will build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts. A primary initial focus will be on the development of 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. The platform will report deidentified information to ensure the privacy of individuals. It will also provide a resource of indexed and searchable data and incorporate some analytics tools. Deidentified data will be made publicly available to researchers through standard controlled access procedures. This initiative will leverage coordinated efforts with the CDC to include data from the National Death Index and health claims data.

Mechanism, Budget, and Timeline:
This 5 year effort will utilize contract mechanisms to be awarded by the end of FY20 (late Summer/early Fall 2020) and anticipates making approximately 10 awards using a hub and spoke model. The goal is to incorporate data from tens of thousands of people (~50,000) initially and exponentially increase to hundreds of thousands of people (~500,000) within a rapid timescale (i.e., months).