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Executive Summary

The COVID-19 pandemic presented a se

the initial group of proposals, the NIH leadership selected a subset of concepts to be further developed into funding announcements. Researchers from across the U.S. submitted creative applications, from which 49 awards were distributed in December of 2020. The RADx-rad program was divided into two phases, each of which is briefly described below in addition to a detailed list of all the RADx-rad funded projects.

During Phase I, an estimated $108 million was provided to support the development of new, non-traditional approaches for COVID-19 testing. These non-traditional approaches include unconventional screening, identification, and use of biological or physiological markers, development of point-of-care devices, and utilization of data science and artificial intelligence technologies. Further, RADx-rad provided an opportunity for researchers to explore and identify new approaches to understand SARS-CoV-2, which could potentially be used in the future to expedite the research response to new pathogens. These research projects were funded across the following eight categories including:

Automated Detection and Tracing of SARS-CoV-2: These projects consisted of the early-stage development of an innovative platform that integrates virus-sensing elements with touchscreens or other digital devices to achieve automatic, real-time detection and tracing of SARS-CoV-2.

Chemosensory: This approach consisted of the development of new, objective chemosensory tests to be used as COVID-19 screening tools for their use at home and in a wide variety of settings.

Exosome-based Selection: Newly developed technologies and approaches for single exosome and extracellular RNA (exRNA) isolation and analyses were deployed for the detection of SARS-CoV-2 virus RNA and/or protein, and detection of IgA, IgG, and IgM antibodies that are part of the host response to viral infection.

Multimodal Surveillance: These projects consisted of identifying existing surveillance technologies that could be rapidly deployed in communal living contexts. Additionally, this category included projects that explored novel methods of data collection, interpretation, and use of machine learning (ML) to facilitate broad-based, real-time assessment of the needs of high risk, vulnerable populations.

Novel Biosensing: This category was comprised of the development and integration of novel biosensing detection technologies with dedicated engineering and artificial intelligence (AI) systems. The goal of these technologies was to leverage the accessibility of human skin, breath, and the oral cavity to detect biological, chemical, and other biometric signatures of COVID-19.

Predicting Viral-Associated Inflammatory Disease Severity in Children with

The community wastewater analysis method served as a complementary approach to individual-level testing and screening.

In addition, RADx-rad was supported by a Data Coordination Center (DCC) which provided management, direction, and overall coordination across RADx-rad awardees in areas such as data collection and sharing (e.g., data upload to the NIH RADx Data Hub), data management standards and terminologies, and provided standardized viral samples and testing protocols.

Following the initial set of awards, the RADx-rad program launched Phase II in the spring of 2021, which provided an additional ~$75 million in NIH funding (including access to RADx core resources and entrepreneur consultation, as well as additional funding support for assistance to projects that demonstrated the potential for commercialization). The Long COVID

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enabled physicians to differentiate between serious childhood diseases such MIS-C, Typhus, Kawasaki disease, and other febrile diseases within a 24-hour period, thereby preventing discharge of individuals who require more intensive treatment.

Researchers developed a rapid saliva-based test that can differentiate between gram positive and gram negative-bacterial infections and viral infections. This test has broad implications for public health in combatting the emergence of antibiotic resistant pathogens by allowing clinicians to tailor the use of antibiotics for bacterial infections and eliminate the inappropriate provision of antibiotics for viral-based conditions.

RADx-rad researchers used AI and ML technologies to determine that VOC signatures in breath significantly differed in response to variants of COVID-19 in the host. Early results showed a difference in VOC biomarkers between children and adults with COVID technologies with multiplexing capabilities further towards commercialization for preparation for future pandemics.

During Phase II, L3C was a community-based challenge which supported the development of creative data-driven solutions that meaningfully advance the current understanding of the risks of developing PASC. The top three winners for the challenge were:

First Place:

Impact and the Path Moving Forward

As the post-pandemic world continues to take shape, it is important to apply the lessons learned over the past few years. Several processes have been proven beneficial to the ongoing success of the program. First, the RADx-rad program established a working group of committed Program Officers. Clear, early guidance helped resolve Common Data Elements (CDEs) in advance of application receipt which ensured data quality and consistent data collection. Second, the program tailored its support and funding to the needs of the investigators. The program partnered with the NIH Small Business Education and Entrepreneurial Development (SEED) Office to support the investigators as they worked to bring their products to market. Finally, the program provided opportunities for investigators to engage with the FDA prior to the submission of their applications for authorization. Some investigators are continuing to work with the SEED office as their projects move closer to commercialization. Lessons learned on navigating and expediting the regulatory process from FDA officials, and bringing a product to market from the SEED entrepreneurs in residence as well as the various core supports has positioned both individual investigators and the NIH as a whole to tackle future health emergencies. Overall, the RADx-rad program brought together academics, industry partners, and community members from across the U.S. to develop innovative approaches and reimagine uses of existing tools to detect and combat the SARS-CoV-2 virus, its variants, and emerging infectious diseases.
The project teams are continuing to collect longitudinal data and develop their technologies to be used in detecting other diseases. Notable among future plans are:

SCENT is exploring the use of breath analysis for rapid screening of illicit drugs, and for the detection of PASC, Diabetes, Respiratory Syncytial Virus (RSV), Influenza, and Lung Cancer

The Chemosensory Testing teams are assessing how to encourage the routine testing of loss of olfaction function, which can be a symptom of viral infections, brain injuries, and

The Exosome-Based project teams are working to develop technologies to be used for detecting multiple viruses, characterizing cancer biomarkers, and predicting response to therapies

The WBD teams are expanding their testing to other viruses, bacteria, and illicit drugs.

Multimodal Surveillance project teams are collecting longitudinal data on COVID-19 outcomes, including mortality and hospitalization rates

The Novel Biosensing teams are working to develop a multiplexing test for COVID-19, RSV, and Influenza

PreVAIL kIds teams are working to implement the new KIDMATCH algorithm which calculates a risk score for the development of MIS-C and Kawasaki disease

Automatic Detection and Tracing teams are improving the accuracy of the testing and are planning to expand to include the detection of other viruses such as Human Immunodeficiency Viruses, Influenza, RSV, and Dengue Fever

Overall, the novel concepts developed from the RADx-rad program will provide an array of devices and strategies to tackle the next pandemic as well as inform the detection and treatment of other health conditions.

Conclusion

In summary, the RADx-rad.028 0 Td[(Ar628-3 (o imTD[(I)13 (n s F-5.0 5 BDC CID Tw iion /TT0 152f-0.1 Tf the)