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Executive Summary

The Rapid Acceleration of Diagnostics (RADx ®) Tech program was launched in April 2020 as a collaboration between the Office of the Director (OD) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB). As a part of the overall RADx initiative, RADx Tech's focus was to generate a robust pipeline of innovative diagnostic technologies to provide tests for COVID-19 to the nation. This effort enabled the validation, de-risking, manufacturing, scale-up, and deployment of novel at-home and point-of-care (POC) tests through an optimized pipeline in as little as six months. As a result, RADx Tech produced a U.S. capacity of over 7.8 billion tests and test products during the pandemic and shifted testing from labs to home and POC. RADx Tech continues to develop tests that target unmet needs, such as multiplex tests for respiratory illnesses and more accessible home

innovative diagnostic technologies that could be readied for regulatory authorization within months. Subsequent solicitations to meet emerging needs has led to more than 1,000 submissions to date. Applications were evaluated by a diverse team of external consultants and experts from across the NIH.

Projects that were deemed promising by a panel based on proposed technical, clinical, regulatory, and commercial factors then underwent an intensive review process. The first step in this process was a two-week examination during which a team of RADx Tech experts worked closely with developers to understand all aspects of the technology and its promise for rapid deployment to the market. Technologies that were approved by the practitioners then moved into a de-risking phase, where detailed, milestone-

had two distinct solicitations that applicants could apply to. The first solicitation was for accessible OTC tests that can be used by persons with disabilities, specifically blindness, low vision, fine motor skill difficulties, and aging-related disabilities. The second solicitation focused on improving performance of OTC and POC tests as well as integrating universal design features to ensure ease of use. Tests should aim to minimize or eliminate the need for serial testing and performance should be unaffected by variants. RADx Tech III has recently completed application review and has funded a total of 25 Work Package 1 projects (WP1s).

RADx Tech adopted elements of the Innovation Funnel in 2021 to greatly expand the U.S. test market by accelerating FDA authorization of tests that were already being produced and sold in other countries. In close collaboration with the FDA, RADx Tech launched the Independent Test Acceleration Program (ITAP) to rapidly validate the performance of non-U.S. tests and shave weeks to months off the regulatory authorization timeline. ITAP independently conducted analytical and clinical analysis of tests according to protocols agreed upon by the FDA, allowing the FDA to authorize new tests in a matter of days after submission of the RADx data.

Program Accomplishments

Since launching in 2020, the RADx Tech program has yielded 55 FDA EUA tests and, as of April 2023, has produced a U.S. capacity of more than 1.8 billion tests and test products. By producing an abundance of OTC tests, RADx Tech enabled the shift of testing away from central

In addition to working closely with other federal agencies and advocacy groups, the RADx Tech program established musl.q n111herherah

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