New COVID-19 Diagnostics Evidence Accelerator Applies Real-World Data to Answer Urgent Questions on SARS-CoV-2 Testing

Washington, DC – Today, the Reagan-Udall Foundation for the FDA, in collaboration with Friends of Cancer Research, announce the COVID-19 Diagnostics Evidence Accelerator, a multi-stakeholder, collaborative project to leverage real-world data in the diagnostic test (e.g., nucleic acid or antigenic) and antibody test (e.g., serological) study space.

Bringing together device manufacturers, technology companies, government and academic researchers, professional societies, payers, and health systems, the Diagnostics Evidence Accelerator lets those on the forefront of testing review recent analyses of real-world data related to test performance, contemporaneous symptoms and presentation, real-time surveillance trends, and immunity.

"The Diagnostics Evidence Accelerator is a significant step toward harnessing the full potential of real-world data to tackle the COVID-19 pandemic," said Amy Abernethy, M.D., PhD., FDA Principal Deputy Commissioner. "Leveraging real-world data collected from patients can contribute to our scientific evaluation of viral diagnostic and antibody tests, gain a deeper understanding of the prevalence of SARS-CoV-2 in specific populations and potentially answer critical questions on immunity. The Accelerator will allow the community to collect and evaluate the data in a thoughtful way, continuing our standards for safety and efficacy when reviewing potential interventions for patients."

"We are at a pivotal point where testing and diagnostics are absolutely critical in understanding the spread of COVID-19 and how to best manage reopening the country," said Ellen V. Sigal, Chair of both the Reagan-Udall Foundation and Friends of Cancer Research. "Working alongside our partners at the FDA, we have brought together a collaborative effort that will truly help patients and physicians all across the country."

Nearly 50 organizations have participated in initial meetings to identify strategies to answer fundamental questions about test performance and the role that real-world data can contribute. The Diagnostics Evidence Accelerator builds on the framework and methodologies already in place for the COVID-19 Therapeutics Evidence Accelerator launched in April. Contributing researchers engage in weekly meetings to present and critically discuss findings from different data sources as well as work closely with the conveners to develop key research questions that multiple teams can address simultaneously. Initial activities include (1) rapidly finalizing a list of core data elements; (2) identifying those critical to answering the primary questions; and (3) establishing uniform collection parameters.

Diagnostic Evidence Accelerator meetings are held weekly with summaries posted at EvidenceAccelerator.org. FDA's announcement of the Diagnostics Evidence Accelerator can be found at https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-harness-real-world-data-inform-covid-19-response-efforts.

###

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed lifesaving treatments to patients. For more information, please visit www.focr.org.

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) created by Congress to advance regulatory science to help the U.S. Food and Drug Administration (FDA) accomplish its mission. The Foundation works to improve health and safety through stakeholder engagement and public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and polices to keep pace with today's rapidly evolving science.