

FDA Expands Support of C-Path CDRC to Automate EHR Data Extraction



Emory, Johns Hopkins Medicine, Infectious Disease Data Observatory/Oxford, Society of Critical Care Medicine and Mayo Clinic identified as primary institutional partners within CDRC

TUCSON, Ariz., November 1, 2022 — Critical Path Institute's (C-Path) CURE Drug Repurposing Collaboratory (CDRC) has received additional funds as part of a new U.S. Food and Drug Administration (FDA) Health and Human Services (HHS) grant. This funding will support the development of partnerships with clinical and technical consultants and data providers, to capture the most critical COVID-19 treatment data from electronic healthcare records (EHR) and registries.

FDA's Clinical Methodologies Group (ClinMeth) within the Center for Drug Evaluation and Research (CDER) Office of Medical Policy (OMP) received a \$8.3 million grant through the HHS Office of the Assistant Secretary for Planning and Evaluation's (ASPE) Patient Centered Outcomes Research Trust Fund. The grant will fund the expansion of CURE ID— FDA and NIH's National Center for Advancing Translational Sciences' (NCATS) web-based platform and mobile application that allows the global clinical community to share novel uses of existing drugs for challenging infectious diseases — to allow automated data collection from electronic health records (EHRs) worldwide and clinical disease registries for COVID-19 and other difficult-to-treat infectious diseases.

As part of this effort, C-Path's CDRC will manage the relationships with the primary institutional partners (PIPs). These include Emory School of Medicine, Johns Hopkins University School of Medicine, the Infectious Diseases Data Observatory (IDDO)/Oxford University Nuffield Department of Medicine, the Society of Critical Care Medicine (SCCM) and Mayo Clinic VIRUS Registry.

The partners have been identified based upon their expertise in clinical infectious disease management (including COVID-19), drug development and drug repurposing, experience in automated data extraction from EHRs/registries, and willingness to participate in this collaborative effort and share data from their health systems and partner institutions.

"The PIPs for this initiative are vital to the success of this endeavor and we're excited to get started with everyone," said CDRC Executive Director Marco Schito, Ph.D. "The extraction of data from their EHRs and registries, plus their support as the primary source of data collection from their own institutions and their many subsidiary and partner hospitals will provide rich and significant insight of existing drugs used in the fight against diseases such as COVID-19."

By enabling data extraction in a standardized and automated fashion and then making this data openly available, CURE ID may facilitate the clinical, research and regulatory communities to identify signals of potentially safe and effective therapies for infectious diseases. These treatments may then be candidates for additional study in randomized controlled trials.

"The CURE ID and CDRC data enhancement and partnership expansion will enable healthcare providers and researchers interested in patient-centered outcomes research for COVID-19 and other infectious diseases to have access to comprehensive, de-identified, case reports for tens of thousands of patients, including their treatment outcomes, such as recovery, deterioration, hospitalization, ICU admission and death," said Heather Stone, MPH, Office of Medical Policy, CDER.

Currently, CDRC facilitates access to clinician-submitted case reports via the CURE ID platform, provides academic input on the focus of the program, implements strategies to curate the data obtained, and leads disease-focused communities of users. Through the expansion of the program, CDRC has funded a pilot program in partnership with the SCCM's VIRUS Registry and the Johns Hopkins School of Medicine to test and refine the development of an automated extraction tool to enable data from several EHRs to be extracted and converted into a common data model.

CDRC will partner with hundreds of medical institutions to include EHR data in CURE ID. As part of the expansion, CDRC will work with a team from Johns Hopkins to use the tools they develop to automate the extraction of data elements from EHRs into the CURE ID case report form. "This funding allows the tools developed by this initiative to remain in the hospital systems, which can then be used to look for signals of efficacy for other diseases that have limited treatment options," said Society of Critical Care Medicine Director of Research & Quality Vishakha Kumar, M.D., MBA. Recently, these tools have been implemented and EHR data successfully extracted from the first pilot site. Although this infrastructure is being built for COVID-19, it will also be useful to employ for future outbreaks of existing and emerging infectious diseases as well as for rare and neglected infections lacking adequate approved treatments.

For more information or to inquire about becoming a partner with CDRC, please contact cdrc@c-path.org. To learn more about CURE ID, visit https://cure.ncats.io/home or download the "CURE ID" app from the Apple app or Google play store.



About Critical Path Institute

Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and hundreds of pharmaceutical and biotech companies. C-Path U.S. is headquartered in Tucson, Arizona, C-Path in Europe is headquartered in Amsterdam, Netherlands and C-Path Ltd. operates from Dublin, Ireland with additional staff in multiple other locations. For more information, visit c-path.org.

Critical Path Institute is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) and is 54.2% funded by the FDA/HHS, totaling \$13,239,950, and 45.8%

funded by non-government source(s), totaling \$11,196,634. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.

This work, "CURE ID: Aggregating and Analyzing COVID-19 Treatments from EHRs & Registries Globally" was supported by the Office of the Secretary Patient-Centered Outcomes Research Trust Fund under an Interagency Agreement.

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