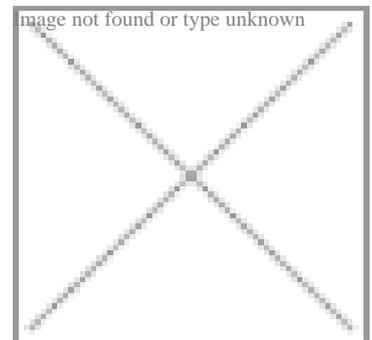

C-Path Launches CURE Drug Repurposing Collaboratory to Accelerate Identification of New Uses of Existing Drugs to Treat Infectious Diseases, Including COVID-19

Clinicians to report novel uses of existing drugs through FDA-NCATS CURE ID Mobile App.

TUCSON, Ariz., June 23, 2020 — As millions of patients struggle with diseases that lack adequate treatments, there is a critical need to understand how existing drugs can be used in new ways to improve clinical outcomes. Health care professionals use drugs in novel ways as a potential life-saving intervention when no specific approved therapies are available. However, without the ability to share these experiences in a systematic manner, the clinical and research communities cannot benefit from lessons learned.

To address the challenge, the Critical Path Institute (C-Path) today announced the launch of the CURE Drug Repurposing Collaboratory (CDRC) funded by the U.S. Food and Drug Administration (FDA), in collaboration with the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH). A public-private partnership, CDRC will provide a forum for the exchange of clinical practice data to inform potential new uses of existing drugs for areas of high unmet medical need, advancing research in these areas. The Collaboratory will also create a network connecting major treatment centers, academic institutions and researchers, private practitioners, government facilities and health care professionals around the world.



CDRC will focus on capturing relevant real-world clinical outcome data through the FDA-NCATS CURE ID platform. The objective is to accelerate the identification and development of potentially effective drugs for patients with diseases that lack adequate approved treatment options with the goal of helping identify drug candidates for additional study and potentially drug labeling in the future. Available on the web and as a mobile app, CURE ID serves as a centralized source of reliable, curated, clinician-submitted information.

“The CURE ID platform enables clinicians to provide data to a crowdsourced central repository where aggregated clinician experiences can be shared with the global scientific community to help drive innovation,” said NCATS Director Christopher P. Austin, M.D.

In a pilot project focused on COVID-19, CDRC will use data collected via the CURE ID platform to aggregate global clinician treatment experiences to identify existing drugs that demonstrate possible treatment approaches that should be studied further in randomized trials. Critical updates have been made to the CURE ID case report form for capturing relevant details related to COVID-19.

“This initiative led by C-Path, in partnership with multiple divisions and offices within the FDA as well as NCATS/NIH, will help address the scientific and regulatory challenges for drug repurposing,” said Amy Abernethy, M.D., Ph.D., FDA principal deputy commissioner. “For COVID-19 patients, time is of the essence and the contribution of cases reported directly by health care providers, followed by rapid analysis of data from the CURE ID platform, provides a much-needed accelerated strategy to generate hypotheses about the potential safety and efficacy of existing drugs and inform subsequent clinical trials.”

“While participation of patients in randomized clinical trials of potential COVID treatments is ideal, we recognize that many individuals with COVID-19 are unable to participate in trials,” said infectious disease physician and FDA Associate

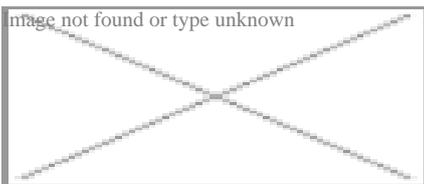
Director for Clinical Methodology in the Office of Medical Policy Leonard Sacks, M.D. “Broad data sharing of treatment successes and failures will provide information that can be used to inform new trials to find safe and effective therapies for COVID-19.”

The effort will rely on FDA’s experience and knowledge in the regulation of drugs and C-Path’s vast experience in regulatory innovation, as well as its proven model of creating successful and productive collaborations. C-Path Scientific Director Marco Schito, Ph.D., will serve as the Executive Director for the CDRC.

“We are encouraging health care professionals, researchers, clinicians and prescribers to download CURE ID and submit data regularly,” said C-Path President and CEO Joseph Scheeren, Pharm.D. “Clearly this is of immediate importance for global public health and we applaud the FDA and NCATS for developing the CURE ID app, which may accelerate the identification of treatments for COVID-19 and other diseases that can be further studied in randomized controlled trials.”

Visit <https://c-path.org/cdrc> for more information. To date, more than 5,500 health care professionals have registered on the CURE ID platform. Health care professionals who wish to download and use the CURE ID application should visit <https://cure.ncats.io> or download “CURE ID” from the App or Play Store. Institutions, organizations, and individuals interested in becoming CURE Drug Repurposing Collaboratory partners should email: CDRC@c-path.org.

The CURE Drug Repurposing Collaboratory is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award 2U18FD005320 totaling \$1,103,978 funded 100% by FDA/HHS. 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.



Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005. 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 dozens of pharmaceutical and biotech companies. C-Path US is headquartered in Tucson, Arizona and C-Path, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit www.c-path.org and c-path.eu.

Contact:

Kissy Black

C-Path

615.310.1894

kblack@c-path.org