

C-Path Joins New Coalition to Improve Patient Care and Address Unmet Medical Needs through Community-Level Clinical Trials

Tools being developed by C-Path's CURE Drug Repurposing Collaboratory will help incorporate adaptive platform trial protocols in clinical practice.



WASHINGTON and TUCSON, Ariz., November 9, 2021 — Launching today, the [Advancing Clinical Trials at the Point of Care \(ACT@POC\) Coalition](#) will generate quality clinical research evidence in real time to better evaluate treatments and therapeutics, including those to treat COVID-19. The Coalition will engage a broader, more diverse group of patients and providers and develop digital health tools that make clinical trials simpler to run and more accessible to patients.

C-Path's CURE Drug Repurposing Collaboratory (CDRC) is partnering with ACT@POC to assist in identifying and improving trial site resources that support trial execution. CDRC will be leveraging its current funded projects to implement digital tools that enable more automated and straightforward data collection, consent and enrollment, including an adaptable common data model to collect data from electronic medical record platforms and other data sources.

Currently, the complexity and cost of traditional clinical trials pose obstacles to patient and provider participation, identification of effective treatments for diseases, and the acceleration of new clinical insights and knowledge. This multi-stakeholder coalition aims to drive implementation of large-scale clinical trials at the community level — in the doctor's offices and care facilities where most of the U.S. population receives care.

The coalition's agenda and action steps aim to substantially augment the evidence generation capacity of the current clinical trial enterprise by working with patient groups, community hospitals and health centers, medical practices, research organizations, and biotechnology companies. In its work, the Coalition will target:

- **Engaging clinicians** in a broader range of care settings
- **Developing and adopting effective data collection tools**
- **Collaborating** with clinical trial design leaders, regulators, funders, and other stakeholders **to assure that clinical trial design features are fit for purpose**
- **Enrolling diverse trial participants** for broader participation in effective community-level trials
- **Addressing unmet medical needs** by reaching a critical mass of participation in existing and new clinical trials

- **Improving technology supports** and capabilities to conduct such studies over time

“The vast majority of patients and their providers do not participate in clinical trials,” said **Dr. Mark McClellan, director of the Duke-Margolis Center for Health Policy**. “Through its more accessible, cost-effective, and inclusive approach, the Advancing Clinical Trials at the Point of Care coalition will help the clinical trial enterprise answer priority research questions for COVID-19, prepare for future public health emergencies, and address common diseases where there is long-standing unmet medical need including, cardiovascular and neurological diseases.”

Founding members of the coalition include: Duke-Margolis Center for Health Policy, MITRE, CURE Drug Repurposing Collaboratory (C-Path + FDA), Duke University Health System, Emory-Morningside Center for Innovative and Affordable Medicine, Intermountain Healthcare, Mayo Clinic, University of California—Irvine, and The Broad Institute. Its [growing membership](#) will include health systems, community-based care organizations, health research organizations, and other collaborators.

“CDRC, a public-private partnership led by C-Path and funded by the FDA, is looking forward to partnering with the ACT@POC to assist in advancing the efficiency and inclusivity of clinical trials while reducing costs and additional time commitments from clinicians in community settings,” said C-Path Interim President and COO Kristen Swingle, M.S.

The consequences of inefficient, low-value COVID-related clinical research made the need for a coalition to support inclusive and efficient clinical trials apparent. One [analysis](#) found that, of 2,610 trials of existing drugs repurposed as COVID-19 therapeutics, only five percent had sufficient enrollment and key design features to yield actionable evidence to combat COVID-19. Further, only a tiny fraction of Americans diagnosed with COVID-19 participated in those trials.

“COVID-19 has required health systems and public health experts to rely on data for decision-making to quickly gain insights that could deliver better patient outcomes,” said **Dr. Brian Anderson, MITRE, chief digital health physician**. “The answers to many research questions can be found in the data and allow for engagement of patients in underserved communities who are often left out of traditional clinical research trials. By working with clinicians who are the trusted care givers of underserved communities, we hope to more fully engage and reach people through this collaboration to help yield new answers to many public health diseases.”

“The Coalition will make it possible for tools being developed by CDRC to be deployed in an actionable setting,” said C-Path Chief Science Officer Klaus Romero, M.D., M.S., F.C.P. “This will allow the automated extraction and curation of de-identified data from electronic health records, across different health systems and standards, contributing to the transformation of clinical research paradigms.”

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



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 dozens of pharmaceutical and biotech companies. C-Path U.S. is headquartered in Tucson, Arizona and CPath, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit c-path.org and c-path.eu.

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