C-Path and I-ACT Collaborate on EHR Data Transfer

A Major Milestone for Pediatric Real-World Data Project

TUCSON, Ariz., June 8, 2023 — Critical Path Institute's (C-Path) International Neonatal Consortium (INC) and the Institute for Advanced Clinical Trials for Children (I-ACT) have announced a collaboration to integrate patient-level data from Electronic Health Records (EHR) as part of a real-world data (RWD) project. This project aims to generate actionable real-world evidence (RWE) for pediatric drug development, marking this data transfer a significant milestone for both C-Path and I-ACT.

The first EHR dataset, obtained from several I-ACT sites including Lurie Children's Hospital, Children's Mercy Hospital, Driscoll Children's Hospital and University of New Mexico, is a testament to the cooperative effort to improve health outcomes for children. This initiative, focused on the clinical development of innovative therapeutic solutions, serves the pediatric community by ensuring timely access to the best therapy for every child with a medical need.

"This marks a major stride forward in our mission to enhance pediatric drug development using real-world data," said I-ACT Chief Medical Officer Gary J. Noel, M.D., FAAP, FIDSA, FPIDS. "The collaborative efforts of our I-ACT partners have been crucial in reaching this milestone. We believe that this data will substantially contribute to the development of innovative therapeutic solutions for critically ill newborns."

The EHR data will be integrated into the Real-World Data and Analytics Platform (RW-DAP), an integrated database and analytics hub developed by C-Path's Data Collaboration Center. The RW-DAP is designed to generate actionable RWE, significantly advancing our understanding of pediatric disease progression and clinical outcome measures.

"This collaboration with I-ACT represents a watershed moment in the pediatric drug development landscape," said C-Path INC Executive Director Kanwaljit Singh, M.D. MPH. "The integration of these datasets into our Real-World Data and Analytics Platform will provide unprecedented insights into pediatric disease progression and will be instrumental in our efforts to develop more effective treatments for children."

The RWD project, through the partnership between INC and I-ACT, aims to transform pediatric drug development by harnessing the combined strengths of these organizations. The data generated will provide valuable insights into disease progression, thereby informing optimal trial design and leading to improved treatments for this vulnerable population.

C-Path's INC is actively meeting and working with collaborators and new data contributors to integrate additional patient-level datasets. For more information on collaborating with INC, and how to contribute data, please email incinfo@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.

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.

About the Institute for Advanced Clinical Trials for Children
The Institute for Advanced Clinical Trials for Children (I-ACT) is an independent, nonprofit organization launched in 2017 through a collaborative effort led by C-Path. I-ACT advocates on behalf of children everywhere by working with all stakeholders involved in achieving the regulatory approval and labeling of new medicines and devices for use in infants and children. Since its launch, I-ACT has organized a clinical site network of 81 sites in 4 continents and has established advisory panels and hosted programs aimed at assisting sponsors in improving the efficiency of designing and conducting clinical trials involving children. I-ACT is headquartered in Rockville Maryland. For more information ,visit https://iactc.org.

Contact:
Kissy Black
C-Path
615.310.1894
kblack@c-path.org