

C-Path Announces Significant Expansion in Neonatal RWD Project

Details of the expansion will be a highlight of the Institute's Scientific Breakthrough Summit Oct. 26-27 in D.C.

TUCSON, Ariz., October 25, 2023 — Critical Path Institute's (C-Path) International Neonatal Consortium (INC) and the [Institute for Advanced Clinical Trials for Children](#) (I-ACT) are thrilled to announce a significant expansion of neonatal data in their Real-World Data (RWD) Project, thanks to new collaborative efforts. With the recent acquisition of five new datasets, the total number of datasets now stands at 28, marking a noteworthy expansion and strengthening the scope of the project to encompass RWD derived from approximately 386,000 neonates worldwide, encompassing clinical trials, registries, and electronic health records.

These additional datasets have been generously contributed by esteemed partners, including Yale Medical Center, Prentice, Rady Children's Hospital, University of Minnesota, and University of Utah, all of whom have joined forces with INC to advance the understanding of neonatal disease progression and clinical outcomes. The inclusion of these datasets represents a major step forward in INC's mission to advance neonatal drug development.

The RWD Project, an INC initiative with generous support from FDA's Office of Medical Policy, now boasts a comprehensive collection of neonatal data that will serve as a valuable resource for improving the lives of critically ill newborns. These datasets have been integrated into C-Path's Real-World Data and Analytics Platform (RW-DAP™), a robust database and analytics hub developed by C-Path's Data Collaboration Center.

Kanwaljit Singh, M.D., MPH, Executive Director of C-Path's INC, expresses the importance of this milestone, stating, "The growth of neonatal data through our collaboration with I-ACT and esteemed partners represents a significant advancement in the ability of INC to create drug development tools to advance neonatal drug development. These datasets will provide invaluable insights into neonatal disease progression and clinical trial optimization and will be instrumental in our ongoing efforts to develop more effective treatments for neonates."

In 2020, INC and I-ACT announced a collaboration to integrate patient-level data from EHRs as part of the RWD project, which aims to generate actionable real-world evidence for neonatal drug development.

"The continuous collaboration between INC, I-ACT, and our partner institutions exemplifies a shared commitment to improving health outcomes for children," said I-ACT Chief Medical Officer Albert J. Allen, M.D. "We believe that the knowledge gained from these datasets will substantially contribute to the development of innovative therapeutic solutions for critically ill newborns and pediatric patients."

RW-DAP is designed to generate actionable RWE, significantly advancing our understanding of neonatal disease progression and clinical outcome measures. The RWD Project continues to actively seek new collaborators and data contributors who share our vision for transforming pediatric drug development through real-world data.

To learn more about collaborating with INC and how to contribute data, please contact incinfo@c-path.org.

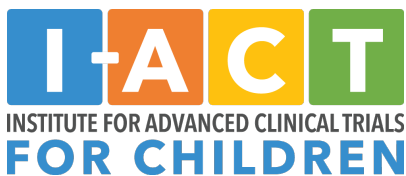
C-Path and INC will hold their upcoming Scientific Breakthrough Summit, October 26 -27, 2023, at the Westin Crystal City, Reagan National Airport, Arlington, Va. Learn more, [here](#).



About Critical Path Institute

Critical Path Institute (C-Path) is an independent, nonprofit established in 2005 as a public-private partnership, in response to the [FDA's Critical Path Initiative](#). **C-Path's mission is to lead collaborations that advance better treatments for people worldwide.** Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

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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