C-Path and NICHD to Share Real-world Data to Advance Neonatal Drug Development

TUCSON, Ariz., Dec. 1, 2021 — Critical Path Institute's (C-Path) International Neonatal Consortium (INC) today announced a seminal data-sharing collaboration with the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health, as a part of a U.S. Food and Drug Administration (FDA) sponsored project to generate actionable real-world evidence (RWE) for neonatal drug development from real-world neonatal data (RWD).

The is the first collaboration of its kind between NICHD, FDA and C-Path, the effort is centered on sharing 1,316 patient level data-points from the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT) study.

"It's an honor to work with NICHD on this very important project," said INC Executive Director Kanwaljit Singh, M.D., M.P.H. "I'm especially thankful to the NICHD data access committee who expeditiously approved our request to share the data from the SUPPORT study. NICHD-sponsored clinical trials are quality studies and the data acquired will go a long way to increasing our understanding of neonates and improve drug development for this underserved population."

Coordinated by INC, C-Path's Data Collaboration Center will develop the Real-World Data and Analytics Platform (RW-DAP) as an integrated database and analytics hub designed to be used in generating actionable RWE. In turn, such actionable RWE will be generated by C-Path's Quantitative Medicine Program, focusing on mathematical models of disease progression, laboratory values, clinical outcome measures and biomarkers that can be used to design optimal trials in this population. An additional benefit of the RW-DAP is the promotion of RWD sharing and the optimization of future RWD collection. By integrating relevant RWD in a format suitable for analytics, RW-DAP will accelerate the understanding.

"C-Path thanks Dr. Andrew Bremer at NICHD, who was key in making this collaboration possible so quickly," said C-Path Chief Science Officer, Klaus Romero, M.D., M.S., F.C.P. "C-Path's core competencies in data science, quantitative analytics, and regulatory science, will be leveraged to ensure the success of this effort, which is poised to help transform the lives of neonates in need of novel medical products."

"RW-DAP will be well-positioned to generate ideas for drug development solutions, which can be made publicly available to qualified researchers in industry, government, regulatory agencies and academia," said Bremer, Chief of the Pediatric Growth and Nutrition Branch within NICHD.

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 C-Path

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 C-Path, 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.

Contact:

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