C-Path Launches Global Collaborative to Advance Drug Development for Neonatal Brain Injury

TUCSON, Ariz., June 20, 2025 — =Critical Path Institute® (C-Path), through its International Neonatal Consortium (INC), is proud to announce the official launch of the Neonatal Brain Injury Collaborative (NBIC) — a global, pre-competitive initiative aimed at accelerating the development of safe and effective therapies for conditions such as hypoxic-ischemic encephalopathy (HIE) and neonatal white matter injury.

This collaborative brings together regulators, academic leaders, patient advocates, and industry scientists to co-develop regulatory-grade tools and frameworks that will streamline clinical trial design and reduce barriers to therapeutic innovation in this high-need area.

Founding industry members of the NBIC include ReAlta Life Sciences and Tellus Therapeutics, both of whom are pioneering work in neonatal neuro-protection and repair.

“HIE and related neonatal brain injuries represent some of the most challenging areas in pediatric drug development,” said Lynne Yao, M.D., Director of the Division of Pediatrics and Maternal Health at the U.S. FDA. “This initiative offers a valuable opportunity to align stakeholders and build the scientific and regulatory foundation needed to support meaningful therapeutic advances.”

“As a company dedicated to addressing life-threatening rare and acute inflammatory diseases, we are honored to serve as one of the founding members of NBIC, bringing our expertise in neonatal inflammatory pathways and our HIE development program,” said Paolo Martini, Ph.D., Chief Research & Development Officer at ReAlta Life Sciences. “Together, we can accelerate the development of better tools and trial designs — with the ultimate goal of improving outcomes for the most vulnerable patients and their families.”

“Neonatal white matter injury remains a vastly under-addressed therapeutic area, despite its profound lifelong impacts,” said Jason Kralic, Ph.D., Co-Founder and CEO of Tellus Therapeutics. “By participating in NBIC, we aim to help shape the infrastructure and standards needed to make future trials more efficient, feasible, and meaningful.”

“Hope for HIE has been a key driver in forming the NBIC with INC, working together with leadership and the many partners advancing important therapeutics for this underserved population,” said Betsy Pilon, Executive Director, Hope for HIE. “INC has built an impressive multistakeholder platform to tackle the most pressing issues and barriers in neonatal clinical trials. HIE babies and families cannot wait another decade for innovation, and the pipeline for HIE ready to launch. We are eager to have this group come together to tackle the many unmet needs of the population, and center patient-family perspectives and lived experiences in building meaningful endpoints and core outcome measures.”

The collaborative’s first priorities include advancing novel imaging biomarkers, exploring complementary approaches such as blood-based and physiologic measures, and building a trial simulation platform to enable smaller, faster, and more efficient clinical trials. A white paper outlining shared unmet needs and potential solutions will be released in the coming months.

C-Path welcomes additional partners from industry, academia, and advocacy groups to join the collaborative and shape the next phase of this initiative. For more information, please contact Kanwaljit Singh, M.D.,

MPH, at ksingh@c-path.org.

About Critical Path Institute

Founded in 2005, as a public-private partnership in response to the FDA's Critical Path Initiative, Critical Path Institute® (C-Path) celebrates its 20th anniversary as a vital, independent, nonprofit. 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.

Critical Path Institute is supported by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) and is 56% funded by the FDA/HHS, totaling $23,740,424, and 44% funded by non-government source(s), totaling $18,881,611. 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.

Media Contacts:

Roxan Triolo Olivas
C-Path
520.954.1634
rolivas@c-path.org

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