

C-Path Recognizes HIE Awareness Month, Calls for Global Collaboration to Accelerate Neonatal Drug Development

TUCSON, Ariz., April 22, 2025 — Critical Path Institute® (C-Path), through its International Neonatal Consortium (INC), joins families, clinicians, and researchers around the world in recognizing April as Hypoxic-Ischemic Encephalopathy (HIE) Awareness Month. Neonatal and pediatric-acquired HIE is a challenging condition that can cause lifelong neurological impairment or death in newborns and children — and despite significant research efforts, therapeutic development has not kept pace with the urgency of need and impact globally.

Neonatal HIE is the second leading cause of infant mortality in the world, and a significant cause of lifelong disability often resulting in cerebral palsy, epilepsy, and neurocognitive disabilities.

INC is pleased to share its intent to engage with stakeholders from industry, academia, regulatory agencies, and patient advocacy groups to explore the formation of a Neonatal Brain Injury Task Force. This initiative would aim to turn longstanding challenges in HIE drug development into actionable opportunities by:

- Validating biomarkers and early endpoints
- Optimizing clinical trial designs to ensure feasibility and scientific rigor
- Harmonizing fragmented approaches across sectors and regions
- Promoting early alignment with regulators to streamline development pathways
- Embedding patient-family perspectives into trial design, informed consent, and long-term engagement to reduce attrition and improve relevance



Seizing these opportunities demands global, pre-competitive collaboration — rooted in regulatory science and united by a shared commitment to improving outcomes for the most vulnerable patients and their families.

“As we observe HIE Awareness Month, we’re reminded not just of the urgency of this condition, but of the opportunity we have to remove persistent barriers to innovation,” said Kanwaljit Singh, M.D., MPH, MBA, Executive Director of the International Neonatal Consortium and Director of Pediatric Programs at C-Path. “We believe that by coming together across sectors — through open, collaborative frameworks — we can build the tools and consensus needed to accelerate progress in safe and effective HIE treatments.”

C-Path is actively engaging stakeholders from industry, academia, regulatory agencies, and the patient advocacy community to co-develop a unified approach for tackling drug development challenges. Plans are

underway to launch a multi-stakeholder Task Force focused on advancing regulatory-grade tools — such as imaging and blood-based biomarkers — that can support more effective HIE trial design.

Early contributions to this effort have come from ReAlta Life Sciences, a biopharmaceutical company focused on rare and life-threatening conditions, and Hope for HIE, the leading advocacy group representing families affected by neonatal and pediatric-acquired hypoxic-ischaemic encephalopathy.

“Families and children impacted by HIE have waited far too long for meaningful progress in safe and effective treatment options,” said Betsy Pilon, Executive Director of Hope for HIE. “We’re incredibly grateful to the leadership team at C-Path and founding partners who have listened to the unmet needs of our global community and have stepped forward to lead a collaborative effort grounded in the realities of drug development. Embedding the patient-family voice in this process is essential, and we’re proud to contribute to building a more hopeful future for these children and families.”

C-Path welcomes engagement from all stakeholders who share the vision of making HIE drug development more efficient, inclusive, and impactful. For more information on collaborative efforts in HIE, please contact Kanwaljit Singh, ksingh@c-path.org or Christine Barry, cbarry@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