CRITICAL PATH INSTITUTE

C-Path's International Neonatal Consortium Launches Groundbreaking Neonatal Lab Values GUI Tool to Standardize Reference Ranges in Neonatal Trials

TUCSON, Ariz., November 18, 2025 — Critical Path Institute's® (C-Path) International Neonatal Consortium (INC) today announced the public launch of its Neonatal Laboratory Values Graphical User Interface (Neo-LV) Tool, a first-of-its-kind platform designed to harmonize and standardize laboratory reference ranges in neonatal research and clinical trials.

Neonatal laboratory values are known to vary significantly by gestational and postnatal age, posing challenges for clinicians and researchers in interpreting lab results and assessing drug safety in the most vulnerable patient populations. Neo-LV provides a publicly accessible, interactive interface for exploring harmonized laboratory reference ranges derived from real-world neonatal data, enabling evidence-based decision-making in both clinical and regulatory settings.

"For decades, the absence of standardized laboratory reference ranges has hindered the interpretation of neonatal clinical trial data," said Kanwaljit Singh, M.D., MPH, MBA, Executive Director of INC and Director of Pediatric Programs at C-Path. "This new platform provides a scientifically rigorous and regulatory-aligned foundation for assessing laboratory data in neonatal trials and everyday care, helping accelerate the safe development of therapies for newborns."

Developed by INC, Neo-LV leverages curated real-world global data from neonatal intensive care units across multiple institutions. The tool enables users to visualize laboratory value distributions by gestational and postnatal age, and supports comparisons across multiple analytes relevant to neonatal physiology. Its interactive design allows researchers to identify physiologic patterns and contextualize abnormal findings without relying solely on data from non-neonatal populations (such as adult or pediatric reference standards).

"This innovative tool reflects C-Path's core strength — connecting the dots across data, science and collaboration to drive regulatory innovation," said C-Path CEO Klaus Romero, M.D., M.S., FCP. "By delivering a harmonized resource for neonatal laboratory data, we are helping ensure that every decision in neonatal research is informed by robust evidence and shared global insight."

The launch of Neo-LV represents a significant milestone in C-Path's INC broader mission to create regulatory-grade tools that improve the efficiency and reliability of neonatal clinical trials. Future versions of Neo-LV will continue to expand data coverage and functionality, integrating additional datasets and supporting natural history and endpoint development studies.

Neo-LV is now publicly available at: https://cpath.shinyapps.io/lvgui/

About International Neonatal Consortium
The International Neonatal Consortium (INC), established in 2015 and coordinated by Critical Path Institute, unites stakeholders from regulatory agencies, industry, academia, advocacy groups, and clinical networks to accelerate the development of safe and effective therapies for newborns. INC's collaborative approach ensures that the unique needs of neonates are represented in global regulatory and clinical research frameworks. For more information, visit c-path.org/inc.

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.

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