

Critical Path Institute Launches New Neonatal Consortium

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The International Neonatal Consortium (INC) aims to accelerate the development of safe, effective therapies for newborns.

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TUCSON, Ariz., May 19, 2015 — Today, the [Critical Path Institute \(C-Path\)](#), a pioneering non-profit organization dedicated to accelerating the pace and reducing the costs of medical product development by facilitating unique partnerships among a wide range of stakeholders, formed its ninth consortium, the International Neonatal Consortium (INC). The launch took place at the European Medicines Agency (EMA) during a widely attended workshop focused on the needs of the neonate. Dr. Jordi Llinares Garcia (Interim Head, Human Medicines Research & Development Support Division, EMA) welcomed the collaborative efforts to create novel and improved methods to evaluate treatments that will one day benefit a vulnerable and underserved population.

Dr. Janet Woodcock, Director of the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), added that "By uniting stakeholders from research institutions, drug developers, regulatory agencies, patient advocacy and other organizations, INC can develop practical tools that can be incorporated into clinical trials for neonates, which will then lead to more successful, efficient trials and provide this population with better treatments."

INC is the latest in a series of successful developments for C-Path, which include the celebration of its 10th anniversary and the opening of a new office in London.

"Individual organizations simply do not have the data, resources, or expertise to address the many gaps in regulatory science that exist for the neonatal population," explained C-Path President and CEO Dr. Martha Brumfield. "By utilizing our consensus science model and working directly with regulators, we will forge a more efficient regulatory pathway for much-needed neonatal treatments."

The C-Path-appointed Executive Director of the new consortium is Dr. Alan Bedrick, who will continue to serve as Chief of Neonatology and Developmental Biology at the University of Arizona College of Medicine – Tucson.

"The International Neonatal Consortium embodies the collaborative nature of the Arizona Health Sciences Center, which has major multi-disciplinary initiatives in health disparities, population health, pediatrics, translational medicine and many other areas," said Dr. Joe G.N. "Skip" Garcia, UA Senior Vice President for Health Sciences. "We welcome the opportunity to partner with C-Path to more rapidly develop better treatments for this vulnerable population."

INC will concentrate on conditions commonly observed in neonatal intensive care units (NICUs). Therapeutic areas include neonatal brain, lung, and gastrointestinal injury; neonatal sepsis; retinopathy of prematurity; and neonatal abstinence syndrome. Workshop participants prioritized an array of high-impact initiatives, such as developing clinical trial endpoints to assess efficacy of treatments. The workshop was supported in part by contributions from the Burroughs Wellcome Fund, the March of Dimes Foundation,

Graham's Foundation, and grant 1U18FD005320-01 from the FDA.

“The rapidly changing and unique physiology of neonates presents hurdles that often cause one-off approaches to falter,” concludes Bedrick. “Only by marshalling forces of the global neonatal community can we address the urgent needs for the care and treatment of neonates.”



C-Path (Critical Path Institute) is an independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the U.S. Food and Drug Administration (FDA). 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 eight global, public-private partnerships that currently include over 1,000 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.



Arizona Health Sciences Center at the University of Arizona is a network of health-related organizations and activities unique in the state and region. Arizona's academic health center, AHSC is based on the campus of the University of Arizona in Tucson and maintains a growing presence on the Phoenix Biomedical Campus in downtown Phoenix. From these vantage points, AHSC reaches across the state of Arizona and well beyond its borders to provide health-care education, research, patient care and service for Arizonans and their neighbors today and for the future. For more information, please visit ahsc.arizona.edu.

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