
Critical Path Institute Establishes The Global Pediatric Clinical Trials Network Pre-Launch Consortium

July 22, 2015

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The Pre-Launch Consortium aims to establish the first global, multi-specialty clinical trials network dedicated to the timely and efficient development of safe and effective therapies for children.

TUCSON, Ariz., July 22, 2015 — 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, has formed a new consortium, the Global Pediatric Clinical Trials Network Pre-Launch Consortium (“Pre-Launch Consortium”).

According to Dr. Janet Woodcock, Director of the U.S. Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER), “Health care providers must have high-quality, reliable data to inform treatment decisions for their pediatric patients. C-Path has leveraged its expertise and stakeholders to support the development of a first-of-its-kind pediatric clinical trial network. The Pre-Launch Consortium signals an important step toward efficient and sustainable pediatric data collection and development of better treatments for children. I strongly support this effort and look forward to working with this global consortium.”

The mission of the Pre-Launch Consortium will be the formation of an independent non-profit entity that will operate a novel global pediatric clinical trials network (“Network”). The Pre-Launch Consortium will establish the Network, create its organizational and operating framework, and identify its leadership team. This work will involve collaborators from academia, government scientific and regulatory agencies, industry, foundations, child health advocacy groups, and other important stakeholders.

The need and vision for the Network has been discussed and evaluated in a number of forums over the last 18 months, most notably at the landmark November 2014 Pediatric Clinical Trials Stakeholder Forum (“Forum”) hosted by the American Academy of Pediatrics (AAP) and funded by an unrestricted grant from the Pharmaceutical Research and Manufacturers of America (PhRMA). The Forum brought together an unprecedented number of international leaders with diverse backgrounds and interests, including clinicians, academicians, regulators, patient advocates, parents, AAP leadership, and representatives from the pharmaceutical industry and other disease-focused pediatric networks.

Parent and patient advocate Lindsey L. Elsaesser shared her reflections on the AAP Forum. “This meeting was monumental. To have such a comprehensive group of individuals in the same room with the main goal of developing better medicine and improving the quality of life for our children was both humbling and

magnificent.”

At the close of the Forum, those assembled unanimously passed the following resolution:

“The attendees of the Pediatric Clinical Trials Stakeholder Forum resolved to establish a Global Pediatric Clinical Trials Network and are committed to engage in the work to create and sustain it.”

This resolution was instrumental in setting the stage for this important next step, the formation of the Pre-Launch Consortium. Dr. Sam Maldonado, Vice President, Child Health Innovation Department at Janssen Research & Development, an attendee at the AAP Forum and a champion of the Network, commented: “We need a fundamentally different approach to serving the health and wellness needs of children, and are delighted that the Critical Path Institute has decided to be a catalyst in forming the Network. Through its research, evidence-based information will be generated to provide children, parents, and prescribers with the information required to safely use medicines and other therapies to help children.”

About the Global Pediatric Clinical Trials Network

The mission of the Network will be to facilitate the development of innovative and quality medicines according to the highest ethical and scientific standards to help extend and enhance the lives of infants, children, and adolescents. It will serve as a resource for pediatric product development strategy and will provide the sustainable global infrastructure needed to plan, start up, conduct, and close out pediatric studies. Its portfolio will span all sub-specialties, study types, phases, and sponsor types (industry, academia, government, non-profits, etc.). Quality will emanate from early, systematic, and integrative engagement with parents, children, academia, regulators, and sponsors. An emphasis on operational efficiency and network sustainability is anticipated to result in significant shortening of the time to plan and complete studies and a meaningful reduction in the administrative burden experienced today. This new paradigm will accelerate availability of innovative, safe, and effective medicines for children, improving health and wellness globally.

About C-Path



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 nine 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.