C-Path Awarded FDA Contract to Enhance the Assessment of Clinical Outcomes in Pediatric Asthma Treatment Trials

Resulting novel drug development tools will support patient-focused drug development for children with asthma

TUCSON, Ariz., April 21, 2020 — The Critical Path Institute (C-Path) announced today it has been awarded a U.S. Food and Drug Administration (FDA) contract in support of ongoing development of novel clinical outcome assessments for pediatric asthma. C-Path's Patient-Reported Outcome (PRO) Consortium will carry out this work through its Pediatric Asthma Working Group. Specifically, these assessments are intended to facilitate innovative patient-focused drug development and aid regulatory decision making by filling an unmet measurement gap.

The 5-year partnership has two aims. The first is to conduct qualitative research to confirm the content validity of a patient-reported outcome (PRO) measure for children from 8 through 11 years old with asthma and an observer-reported outcome (ObsRO) measure for caregivers of children from 4 through 11 years old with asthma. The second aim is to conduct quantitative research to generate evidence of cross-sectional measurement properties of the PRO and ObsRO measures to support their qualification under FDA's Clinical Outcome Assessment Qualification Program.

"We are honored to receive FDA support of, and collaboration on, this new project," said C-Path President and CEO Joseph Scheeren, Pharm.D. "FDA funding, in combination with the expertise of the PRO Consortium, will enable development of much-needed tools for the scientific community and, most importantly, will ultimately lead to improved medical outcomes for pediatric asthma patients."

Pediatric asthma is a chronic inflammatory disease of the airways and is the most common childhood condition worldwide. In the United States, asthma is twice as common in children as adults and is a leading cause of school absenteeism as well as the third ranking cause of hospitalization of children.

"Pediatric asthma treatment trials face challenges in the reliable assessment of lung function in young children leading to the need to assess self-reportable or observable signs and symptoms of asthma to evaluate the benefit of new therapies," said Stephen Joel Coons, Ph.D., Executive Director of the PRO Consortium. "These fit-for-purpose measures will significantly enhance the assessment of clinical benefit for children with asthma."

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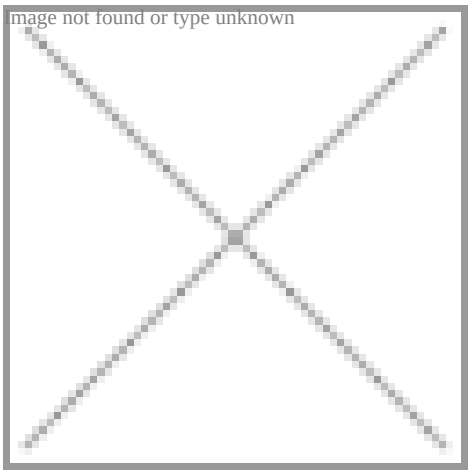
About Patient-Reported Outcome Consortium

The Patient-Reported Outcome (PRO) Consortium was formed in 2008 by Critical Path Institute in cooperation with the US Food and Drug Administration's Center for Drug Evaluation and Research and the pharmaceutical industry. The mission of the PRO Consortium is to establish and maintain a collaborative framework with appropriate stakeholders for the qualification of PRO measures and other clinical outcome assessment (COA) tools that will be publicly available for use in clinical trials where COA-based endpoints are used to support product labeling claims.



About Critical Path Institute

Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. 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 numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path US is headquartered in Tucson, Arizona and C-Path, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit c-path.org and c-path.eu.

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