

Pediatric IBD Foundation, ImproveCareNow, C-Path to Establish the Children's Registry for the Advancement of Therapeutics

TUCSON, Ariz., November 5, 2020 — The Pediatric IBD Foundation, ImproveCareNow, and the Critical Path Institute (C-Path) are proud to announce a collaboration establishing the Children's Registry for the Advancement of Therapeutics (CREATE™). CREATE™ is a drug-agnostic safety registry designed to support the completion of global post-marketing safety requirements, as well as collect safety information on all therapies used in pediatric IBD patients.

CREATE™ will facilitate collaboration between multiple industry sponsors to advance the development of the safety monitoring registry. Stakeholders contributing to the implementation of CREATE™ include universities, hospitals, health care providers, learning health networks, community organizations, the pharmaceutical industry and government agencies. With the endorsement and support of the IBD community, CREATE™ brings together key groups to advance new ideas in IBD treatment and safety.

“We are excited to partner with the Pediatric IBD Foundation and ImproveCareNow on this initiative,” says C-Path President and CEO, Joseph Scheeren, Pharm.D. “CREATE™ promotes collaboration and the safe data sharing processes that have long been needed to advance pediatric IBD treatments.”

The three partnering organizations will advance development of a post-marketing safety monitoring registry by jointly developing operational and business models aimed to gain the endorsement and support of pharmaceutical companies and regulatory agencies.

“With support of pediatric gastroenterologists, patients and families, to develop tools and processes and roll out strategy among pediatric GI sites for a regulatory compliant pediatric IBD safety registry, the capturing of important safety information for all therapies used in pediatric IBD patients will be realized,” said PIBDF Board Chair Eric Zuckerman, D.O. “Progress does take time but the spirit of collaboration is always critical to advancement of new ideas. The time is now to accelerate these plans for children with inflammatory bowel disease.”

“Establishment of long-term safety registry is the need of the hour, as increasing number of biologic therapies become available for treatment of pediatric onset inflammatory bowel diseases,” said ImproveCareNow Clinical Director Shehzad Saeed, M.D., F.A.A.P., A.G.A.F. “Collaboration between the relevant stakeholders is the key for realizing this important step. The ImproveCareNow community looks forward to this collaboration.”



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 www.c-path.org and c-path.eu.



The **Pediatric IBD Foundation's** mission is to improve the lives of children with Crohn's disease and ulcerative colitis through advocacy, education and research. The Foundation has been a leader in developing a much needed and groundbreaking effort to establish a public safety registry for medicines used to treat IBD. PIBDF has co-sponsored conferences with FDA, pharmaceutical companies and other IBD stakeholders to expedite drug development in children.



ImproveCareNow (ICN) is a Learning Health Network dedicated to transforming care, health and costs for all children and youth with Crohn's disease and ulcerative colitis (Inflammatory Bowel Disease or IBD) by building a sustainable collaborative chronic care network. ICN is enabling and empowering patients, families, clinicians and researchers to work together in a learning health care system to accelerate innovation, discovery and the application of new knowledge, and transform care and outcomes of children with IBD.

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