

Shaping the Global Innovation and Access Landscape for Better Paediatric Medicines: C-Path Becomes Official Partner of WHO



TUCSON, Ariz. and AMSTERDAM, June 7, 2023 — [Critical Path Institute \(C-Path\)](#), a leading global nonprofit committed to expediting drug development through the acceleration of regulatory-endorsed solutions, today announced an official partnership with the [World Health Organization's \(WHO\) Global Accelerator for Paediatric Formulations \(GAP-f\) project](#).



In 2016, the World Health Assembly identified the lack of suitable paediatric medicines and formulations as a significant obstacle, impeding the achievement of sustainable development goals and universal health coverage. This scarcity not only jeopardizes the health and well-being of children, but also hampers global efforts to ensure equitable access to healthcare. GAP-f's mission is to accelerate and remove barriers to developing and delivering appropriate, quality, affordable and accessible medicines for children.

C-Path's participation in the GAP-f project will be multi-faceted, including representation in the Clinical Research Working Group, along with contributions to the GAP-f Paediatric Data Hub designed to improve the availability, quality and use of real-world data to monitor and optimize treatments. GAP-f will leverage electronic medical records systems at various levels of maturity in countries and complement other more traditional sources of effectiveness and safety data such as the follow up of randomized controlled trials and observational cohorts.

Through its cumulative and collaborative experience from its partners, the Product Development and Regulatory Affairs Working Group (PDRA) can play a key role in helping to identify the most appropriate and effective regulatory tools in the whole product life cycle. C-Path will help navigate the global regulatory landscape using the most efficient pathways. The aim is to improve access to essential medicines and formulations for children.

C-Path's esteemed experts, Patrick O'Meara, European Lead for C-Path's Data Collaboration Centre based in Dublin, Ireland and Huong Huynh, Ph.D., C-Path Director of Regulatory Science, based in Tucson, Arizona, will serve as representatives in these respective groups, contributing their extensive knowledge and expertise to advance paediatric development.

C-Path Chief Science Officer Klaus Romero, M.D., M.S., FCP, expressed his enthusiasm regarding the partnership, “Becoming a partner in the WHO GAP-f project is a significant milestone for C-Path. We are dedicated to making a lasting impact on children’s health by accelerating the development of safe and effective medicines tailored to their needs. This collaboration aligns perfectly with our mission and presents a unique opportunity to drive positive change in global paediatric development.”

C-Path Chief Executive Officer Daniel Jorgensen, M.D., MPH, MBA, emphasized the importance of addressing the pressing challenges in paediatric drug development, “Children deserve the best possible medicines, specifically designed for them. By joining forces with the WHO GAP-f project, we can pool our collective expertise and resources to overcome obstacles and ensure that paediatric development is prioritized and accelerated.”

C-Path is eager to collaborate with GAP-f and its diverse network of partners to forge innovative pathways for paediatric development. By joining forces, the organizations will achieve the common goal of improving the health and well-being of children worldwide.



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 hundreds of pharmaceutical and biotech companies. C-Path U.S. is headquartered in Tucson, Arizona, [C-Path in Europe](#) is headquartered in Amsterdam, Netherlands and C-Path Ltd. operates from Dublin, Ireland with additional staff in multiple other locations. For more information, visit c-path.org.

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