
C-Path and Congenital Hyperinsulinism International Announce Data Sharing Agreement

TUCSON, Ariz., October 26, 2023 — [Critical Path Institute](#) (C-Path) and [Congenital Hyperinsulinism International](#) (CHI), a leading nonprofit dedicated to improving the lives of children and adults living with Congenital Hyperinsulinism (HI), today announced a data sharing agreement to incorporate rare disease patient-level data from CHI's HI Global Registry into C-Path's [Rare Disease Cures Accelerator-Data and Analytics Platform](#) (RDCA-DAP®).

HI is a life-threatening disorder that causes dangerously low blood sugar levels. Prolonged or severe low blood sugar can cause seizures, brain damage, and even death.

RDCA-DAP provides a centralized and standardized infrastructure to support and accelerate rare disease characterization targeted for clinical development. Additionally, the platform advances best practices to support the rigorous conduct of natural history studies, with attention to established data quality standards, in order to be most useful to clinical trial design and regulatory review. It includes a robust, integrated database and analytics hub that allows for the aggregation of rare disease data from various sources and the efficient and effective interrogation of that data.

CHI will contribute hyperinsulinism data from its HI Global Registry (HIGR). CHI [developed](#) the patient-reported registry to improve the understanding of HI, and advance research for better treatments and patient care. The registry consists of thirteen surveys made up of questions about the person's experience with HI over their lifetime. Additionally, [MaxHIGR](#) adds physicians' information to increase HI research opportunities by complementing patient-reported responses in the registry.

"This hyperinsulinism data are extremely valuable as we work to advance drug development in rare diseases," said RDCA-DAP Executive Director Alexandre Betourne, Pharm.D., Ph.D. "This is RDCA-DAP's inaugural dataset for this disease, a crucial resource bound to amplify breakthroughs in hyperinsulinism and unlock avenues for related conditions." RDCA-DAP remains dedicated to enhancing its database, including hormonal disorders, metabolic diseases, neuromuscular diseases and more. The database has more than 69 datasets spanning 30 different diseases to date.

The HI Global Registry is hosted on the IAMRARE® Platform which was developed and is owned by the [National Organization for Rare Disorders](#) (NORD). The IAMRARE Platform was created with input from patient, caregiver, and government stakeholders to ensure a safe and user-friendly system for study participation.

"There are so many unanswered questions in the rare disease space; the collaboration and infrastructure that RDCA-DAP provides is an amazing opportunity to help researchers begin to answer some of these pressing questions," said CHI Chief Research Officer Tai Pasquini, MPH, Ph.D. "CHI is thrilled to partner with C-Path and the other partners of this program to advance rare disease research."

Groups interested in contributing data to RDCA-DAP may visit c-path.org/rdca-dap or email rdcadap@c-path.org. The platform is now OPEN and accepting applications for use; visit portal.rdca.c-path.org to apply and learn more.



About Critical Path Institute

Critical Path Institute (C-Path) is an independent, nonprofit established in 2005 as a public-private partnership, in response to the [FDA's Critical Path Initiative](#). **C-Path's mission is to lead collaborations that advance better treatments for people worldwide.** Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

Critical Path Institute is supported by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) and is 55% funded by the FDA/HHS, totaling \$17,612,250, and 45% funded by non-government source(s), totaling \$14,203,111. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.



CHI is a leading nonprofit dedicated to improving the lives of children and adults living with Congenital Hyperinsulinism (HI). CHI provides a world of information, resources, and support to the HI community. CHI advocates on behalf of patients for better treatments and access to care. CHI is dedicated to increasing awareness of the disorder as it leads to more timely diagnosis and the best outcomes for patients. CHI supports medical research for improved therapies, potential cures, and timely diagnosis. CHI works globally because we are stronger as an international community. Cooperation across borders fosters important advances in medicine. We hope you will partner with us to prevent damage and death, search for better treatments, and improve the quality of life for all HI patients. Learn more: <https://congenitalhi.org>.

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