

C-Path's T1D Consortium New-onset Article Published in The Lancet Diabetes and Endocrinology

Research confirms immune-based therapies improve outcomes in new-onset T1D

TUCSON, Ariz., November 7, 2023 — Critical Path Institute's (C-Path) Type 1 Diabetes Consortium, along with external collaborators from Cardiff University and the University of Alberta, today announced the publishing of "[C-peptide and metabolic outcomes in trials of disease modifying therapy in new-onset type 1 diabetes](#)" in *The Lancet Diabetes and Endocrinology*.

The investigation showed that disease modifying therapy to support beta cell preservation can be helpful at improving metabolic outcomes in new-onset T1D. The article shows supporting evidence that improvements in HbA1c are directly proportional to the degree of C-peptide preservation, quantifying this relationship, and supporting the use of C-peptide as a surrogate endpoint in clinical trials.

The work was completed by the C-Path Trial Outcomes Markers Initiative (TOMI), a partnership between researchers from academic institutions, the pharmaceutical industry, and independent nonprofits. TOMI's mission was to accelerate drug development and optimize immune intervention trials in T1D through the development of a composite outcome measure. A worldwide inventory and dataset of completed clinical trials and observational studies, assembled and stored by C-Path, was used to support this project. C-Path is continuing additional analysis expected to generate further insights under its T1D Consortium New Onset workstream.

"We are thrilled to see the role of immunotherapy advance developments in type 1 diabetes treatments," added Joseph Hedrick, Ph.D., Executive Director of Critical Path Institute's T1D Consortium. "The enhanced therapies will improve the lives of those living with type 1 diabetes and is reflective of how collaborative efforts like these can create a safer, healthier world."

Senior author Colin Dayan, Ph.D., M.A., M.B.B.S., F.R.C.P., Cardiff University, highlighted, "This research supports the role of immunotherapy, focusing on preventing the autoimmune destruction of insulin producing cells, rather than simply relying on insulin to treat the resulting insulin deficiency. Potentially screening programs could also be undertaken to detect people at high risk of type 1 diabetes, and these treatments could be used even earlier with the ultimate aim of preventing childhood type 1 diabetes."

"This analysis has allowed us to extract vital information demonstrating that drugs which protect beta cells will make a meaningful difference for people with T1D," stated Peter Senior, Ph.D., BMedSci, MBBS, FRCP(E), FRCP, Director of the Alberta Diabetes Institute and Professor of Medicine at the University of Alberta. "For 100 years we have used insulin to treat a disability. This analysis paves the way for new drugs to treat the disease. It's a new paradigm for T1D."

C-Path and the additional TOMI project collaborators are excited to put this new information into the hands of researchers and industry to help accelerate drug development in T1D. This work was funded by JDRF and Diabetes UK.



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.

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