

C-Path Reaffirms Commitment to Advancing Regulatory Science for Disease-Modifying Therapies in Type 1 Diabetes

Regulatory milestone underscores opportunity for shared regulatory-science and evidence frameworks to support the next generation of therapies.

TUCSON, Ariz., June 15, 2026 — Critical Path Institute® (C-Path), through its Type 1 Diabetes Consortium, today reaffirmed its commitment to strengthening the regulatory-science and evidence infrastructure needed to enable the next phase of therapeutic innovation across multiple stages of type 1 diabetes (T1D). The announcement comes in response to the U.S. Food and Drug Administration's (FDA) accelerated approval last week of Tzield® as the first disease-modifying therapy for stage 3 type 1 diabetes, a milestone achieved by Sanofi, one of several long-standing [members](#) of C-Path's T1D Consortium.

C-Path is expanding the evidence base for C-peptide as a biomarker by increasing the number of trials under evaluation to 74. Through continued engagement with the FDA, this expanded data pool will support ongoing evaluation of C-peptide as a drug development tool that can help bring diverse classes of disease-modifying therapies to people living with T1D sooner.

Together, the approval and the expanded C-peptide evidence base represent significant progress for the field, while reinforcing the need for shared frameworks to define clinically meaningful benefit, generate confirmatory evidence and support development of future therapies utilizing different therapeutic approaches.

Most recently, the consortium's pivotal 2025 public workshop, 21st Century Trials in New-Onset Type 1 Diabetes, attended by more than 400 stakeholders, examined the scientific and regulatory considerations surrounding C-peptide and preserved beta-cell function as measures of disease modification and clinically meaningful benefit. The workshop brought together diverse perspectives at a critical moment in the evolution of the field, reinforcing the value of collaborative, precompetitive regulatory dialogue in addressing drug development challenges.

While the FDA's action focuses on recently diagnosed stage 3 T1D, it confirms the broader opportunity to develop regulatory-grade evidence frameworks that can inform therapeutic development across all stages of disease in which endogenous beta-cell function remains relevant. Establishing consistent approaches to defining clinically meaningful disease modification will become increasingly important as a growing number of therapies advance through the development pipeline.

C-peptide

is a surrogate endpoint that can help bring diverse classes of disease-modifying therapies to people living with T1D sooner.

“The June 12 announcement marks an important moment for type 1 diabetes drug development,” said Simi Ahmed, Ph.D., executive director of C-Path’s Type 1 Diabetes Consortium. “The opportunity now is to collaboratively build shared regulatory-science approaches that define and quantify the clinical relevance of preserved beta-cell function in relation to how a person feels, functions or survives. By bringing together regulators, academia, patient organizations and drug developers in a neutral, precompetitive environment, C-Path remains committed to strengthening the infrastructure needed to accelerate therapeutic innovation across multiple stages of type 1 diabetes.”

“Progress in regulatory science is collaborative and iterative,” said Joseph Hedrick, Ph.D., senior advisor of the T1D Consortium. “The questions that define clinically meaningful benefit and future development pathways are increasingly shared across sponsors and stakeholders. By convening diverse expertise and facilitating early regulatory dialogue in a neutral setting, C-Path is helping the field build evidence frameworks that can improve consistency, efficiency and confidence across ongoing development programs.”

“The FDA’s accelerated approval of the first disease-modifying therapy for stage 3 type 1 diabetes is a landmark for the field,” said Jeffrey A. Bluestone, Ph.D., distinguished professor emeritus at the University of California, San Francisco. “There is tremendous opportunity now for researchers and sponsors to work together to define clinically meaningful benefit and build the shared regulatory frameworks needed to accelerate development of these therapies, regardless of disease stage or therapeutic approach.”

Addressing these questions will require sustained alignment around regulatory expectations and evidence-generation strategies across the entire T1D drug development ecosystem. Through its neutral, precompetitive model, C-Path helps the field tackle foundational scientific and regulatory challenges that no single organization can efficiently address alone.

To learn more about C-Path’s Type 1 Diabetes Consortium and view the full list of member organizations, visit <https://c-path.org/program/type-1-diabetes-consortium/>.

About Critical Path Institute

Critical Path Institute® (C-Path) is an independent, nonprofit organization 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 in Tucson, Arizona; 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 56% funded by the FDA/HHS, totaling \$23,740,424, and 44% funded by non-government source(s), totaling \$18,881,611. 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.

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