C-Path Virtual Workshop to Feature Latest Advances in Clinical Trials for T1D

More than 300 Attendees and 20 Speakers Are Expected to Participate in the International Workshop, June 15-16

TUCSON, Ariz., May 25, 2021 — Critical Path Institute (C-Path) today announced its schedule for the **Design of Clinical Trials in New-Onset Type 1 Diabetes: Regulatory Considerations for Drug Development Workshop**, to be held virtually June 15-16. Together with the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and in collaboration with Benaroya Research Institute, INNODIA and JDRF, this 2-day public workshop will focus on the implementation of endpoints and outcome measures for clinical trials in new onset type 1 diabetes (T1D). More than 300 researchers, pharmaceutical representatives, academia members, investigators, T1D patients and regulatory experts from throughout the United States and Europe are expected to gather virtually to hear 15 presentations about T1D research and medical product development.

“An important element of C-Path’s work is to bring together leading researchers from academia and industry, alongside clinicians and patient advocates, to gather consensus on the latest scientific developments that can improve the lives of members of the T1D community,” said C-Path’s T1D Consortium Executive Director Inish O’Doherty, Ph.D. “By providing a forum for the community and regulators to publicly engage, our workshop seeks to bridge the gap between scientific understanding of outcome measures, such as C-peptide, and their implementation in registration studies for new onset T1D.”

As one main objective of the workshop, attendees can expect discussion on existing evidence regarding the role of C-peptide in clinical trials intended to support regulatory decision making, regulatory considerations from the FDA and EMA, and perspectives from the T1D drug development community.

“This meeting comes at a critical time in the development of disease-modifying therapies to address the significant unmet needs for people with type 1 diabetes,” says JDRF Vice President of Research Sanjoy Dutta, Ph.D. “We are excited to participate in this important discussion and thank the FDA, EMA, meeting organizers and presenters for bringing the community together to accelerate pathways to cures for T1D.”

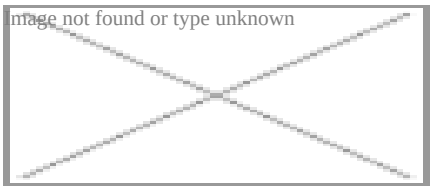
The conference will include scheduled live-broadcast sessions, live panel discussions and Q&A.

The preliminary agenda is as follows:

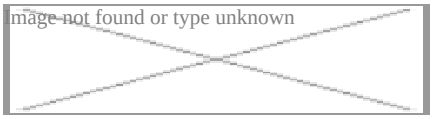
- Welcome and Introductory Remarks
- Session I: Regulatory Framework for Clinical Investigations in New/Recent Onset T1D
- Session II: Scientific Framework: The rationale for C-peptide preservation and use as a clinical trial endpoint
- Session III: Establishing/confirming clinical benefit
- Session IV: Overall Issues of Study Design: Considerations and panel discussion/open comment

Registration is free and open to the public. For more information and to receive additional updates leading up the event, visit the workshop event page.

Critical Path Institute is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) and is 55% funded by FDA/HHS, totaling $14,575,306, and 45% funded by non-government source(s), totaling $11,916,747. 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. For more information, please visit FDA.gov.



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 U.S. 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 c-path.org and c-path.eu.



JDRF's mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested more than $2.5 billion in research funding since our inception. We are an organization built on a grassroots model of people connecting in their local communities, collaborating regionally for efficiency and broader fundraising impact, and uniting on a national stage to pool resources, passion, and energy. We collaborate with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers throughout the United States and our five international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D. For more information, please visit jdrf.org or follow us on Twitter (@JDRF), Facebook (@myjdrf), and Instagram (@jdrfhq).

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