CRITICAL PATH INSTITUTE

WorkshopSummary

Introduction:

On June 15 and 16, 2021, the Critical Path Institute (C-Path) hosted a two-day public workshop titled "Design of Clinical Trials in New-Onset Type 1 Diabetes: Regulatory Considerations for Drug Development". C-Path is a not-for-profit 501(c)3 organization that operates as a trusted and neutral third-party that convenes pre-competitive public private partnerships. These collaborations include patient advocates, industry, academicians, clinicians, regulators, and others to accelerate and enhance medical product development. C-Path leverages its expertise in regulatory science, data science, quantitative methodologies and modeling, biomarkers, and clinical outcome assessments to put forth novel solutions that meet pressing unmet drug development needs.

This workshop was held in collaboration with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and had two primary objectives:

1. Provide a virtual workshop environment for type 1 diabetes drug developers, researchers, clinicians, patient organizations, and regulators to examine clinical trial design and regulatory considerations of drug development for new-onset T1D
2. Discuss amongst the T1D community the use of C-peptide as a primary endpoint in registration studies of therapeutic agents in new-onset T1D

A workshop planning committee was convened consisting of subject matter experts from FDA (CDER and CBER), EMA, INNODIA, TrialNet, and JDRF. The full workshop agenda is seen below.

In total, the workshop included 27 speakers or panelists from more than 15 organizations, and featured patient and caregiver perspectives during a roundtable discussion on clinically meaningful measures. The workshop was well attended with approximately 260 people attending virtually each day.

Recordings of the meeting's proceedings are publicly available, and a summary recap of the meeting's proceedings is provided here.

The presentations given by FDA employees (including their participation in panel sessions) reflect the views of the presenter and should not be construed to represent FDA's views or policies.