Critical Path Institute (C-Path) is a nonprofit, public-private partnership with the Food and Drug Administration (FDA) created under the auspices of the FDA’s Critical Path Initiative program in 2005. C-Path orchestrates the sharing of data, expertise, and knowledge among industry, regulatory authorities, government, patient advocacy groups, and academia in the pre-competitive space to generate the evidence needed to improve the drug development pathway. The result is a more efficient process that reduces the time and effort needed to bring safe, effective medical products to market. C-Path has established a network of nearly 1,000 scientists from 41 bioscience and pharmaceutical companies as well as regulatory agencies, disease-specific patient organizations, and research universities, participating in seven global consortia that focus on a variety of health challenges. Consensus science is the path that will lead to global answers sooner.

Mission
C-Path’s aim is to accelerate the pace and reduce the costs of medical product development through the creation of new data standards, measurement standards, and methods standards that aid in the scientific evaluation of the efficacy and safety of new therapies. C-Path’s consensus science improves medical product development efficiencies by identifying pathways that integrate new scientific advances into the regulatory review process. As a trusted, independent body, C-Path works closely with the FDA, EMA, and other regulatory agencies to ensure regulatory input specific to the new science is incorporated. When formal regulatory decisions are necessary (i.e., qualification or fitness-for-purpose determinations), C-Path gathers the necessary evidence. This involves the development of standards for data, measurement and methods, the aggregation of large volumes of data and the preparation of regulatory documentation of the evidence.

Consortium History

For a history of C-Path endeavors and initiatives, click here

Structure & Governance

C-Path is a non-profit public-private partnership with the FDA

Financing

As an independent 501(c)(3) not-for-profit organization, C-Path relies upon funding from a diverse array of funders who share a common belief: the path therapies travel to reach patients can be improved.

Intellectual Property
C-Path adheres to pre-competitive standards and approaches

Data Sharing

C-Path orchestrates the development of DDTs through an innovative, collaborative approach to the sharing of data and expertise. They build consensus among participating scientists from industry and academia with FDA participation and iterative feedback. The process culminates in a formal application to FDA for official “qualification” of the DDT for a given use in product development. Qualified DDTs then become open standards for the scientific community, which, in turn, may be assured both of the scientific rigor under which they were developed and of the FDA’s understanding and acceptance of their validity.

Impact/Accomplishment

For a full list of C-Path’s accomplishments and success’, click here

Links/Social Media Feed

Homepage  https://c-path.org/
Twitter  @CPathInstitute

Points of Contact

1730 E. River Rd.
Tucson, AZ 85718
520 547-3440
520 547-3456
info@c-path.org
Sponsors & Partners

Coalition Against Major Diseases (CAMD)
The Duchenne Regulatory Science Consortium (D-RSC)
Electronic Patient-Reported Outcome Consortium (ePRO Consortium)
Coalition For Accelerating Standards and Therapies (CFAST)
International Neonatal Consortium (INC)
Predictive Safety Testing Consortium (PSTC)
Critical Path For Parkinson’s (CPP)
Multiple Sclerosis Outcome Assessments Consortium (MSOAC)
Pediatric Trials Consortium (PTC)
Critical Path to TB Drug Regimens (CPTR)
Polycystic Kidney Disease Outcomes Consortium (PKD)
TB-Platform for Aggregation of Clinical TB Studies (TB-PACTS)
Data Collaboration Center (DCC)
Patient-Reported Outcome Consortium (PRO Consortium)

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