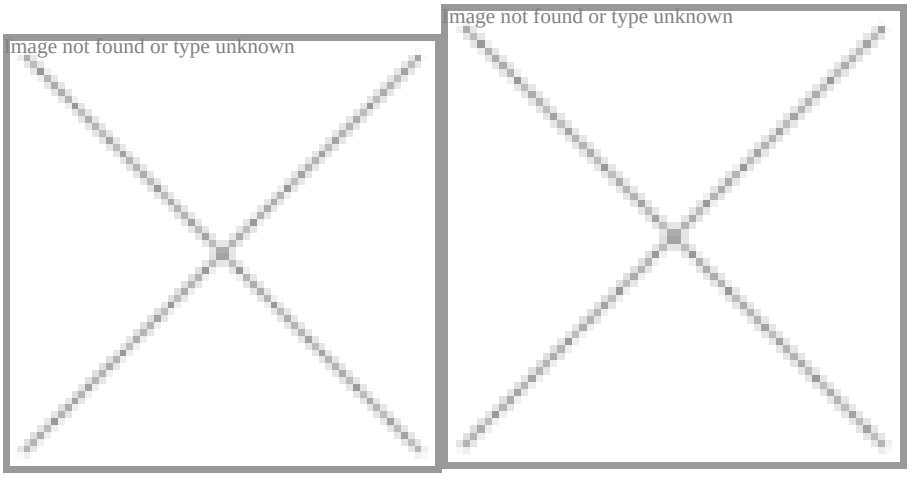
C-Path, CDISC Release Therapeutic Area Standard to Drive Research Forward for Clostridium Difficile Associated Diarrhea



TUCSON, Ariz. and AUSTIN, May 2, 2019 — The Critical Path Institute (C-Path) and CDISC are pleased to announce the release of a global Therapeutic Area Standard, which describes how to use CDISC standards to represent data in research studies pertaining to Clostridium difficile associated diarrhea (CDAD).

The standard, released in the form of a User Guide for data managers, statisticians, programmers and study managers, is freely available on the CDISC website. CDISC Therapeutic Area User Guides (TAUG) provide examples and guidance on implementing CDISC standards to drive operational efficiencies within the organizations that use them, expedite the regulatory review process and reduce time to market.

Caused by infection with the bacterial pathogen *C. difficile*, CDAD, also referred to as *Clostridium* difficile infection, is a major medical and infection control problem. It is particularly common among the elderly in long-term care or hospital facilities. A 2015 study from the US Centers for Disease Control and Prevention found that CDAD alone caused almost half a million infections among patients in a single year in the United States.

“CDAD is a serious public health issue, yet many are unaware of its existence, let alone its gravity,” said David R. Bobbitt, CDISC President and CEO. “This Therapeutic Area Standard will allow data that is critical to driving forward clinical research and improving public health become more accessible and reusable for research today and tomorrow.”

This CDISC Therapeutic Area standard for CDAD was developed through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, a partnership of CDISC and C-Path, with participation from the NIH National Cancer Institute Enterprise Vocabulary Services (NCI-EVS), the U.S. Food and Drug Administration (FDA), TransCelerate, the Japan Pharmaceutical and Medical Devices Agency (PMDA) and additional stakeholders. The goal of the CFAST initiative is to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research

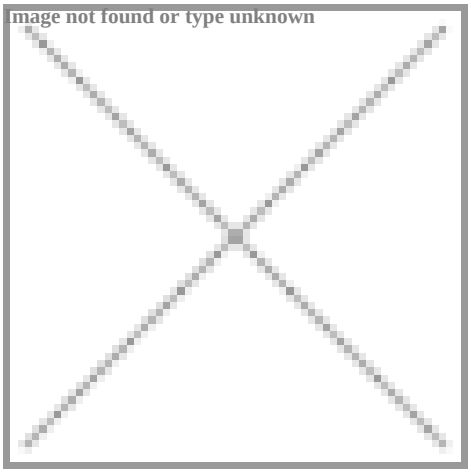
in therapeutic areas that are important to public health.

“The CFAST initiative continues to drive progress in developing therapeutic area standards for some of the world’s most pressing health concerns,” said C-Path President and CEO Joseph Scheeren, Pharm. D. “These standards are crucial to the clinical research and development community and we hope that this readily available information for CDAD can quickly be utilized to accelerate the development of treatments and tools that could improve outcomes for patients.”

This project has been funded in whole or in part with Federal funds from the FDA through grant 5U01FD005855-02.

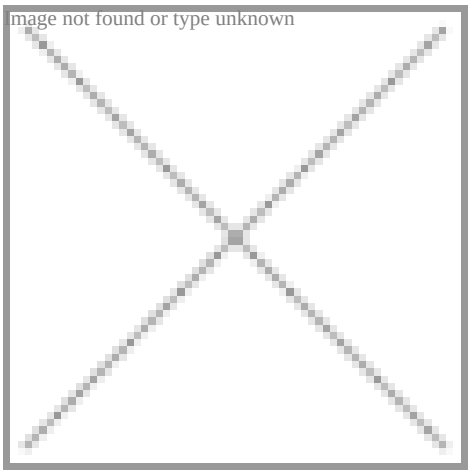
CDISC standards have been adopted and used in more than 90 countries. To date, TA standards have been developed for over 30 disease areas.

About C-Path



C-Path (Critical Path Institute) 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 over 1,500 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path is headquartered in Tucson, Arizona, with additional staff in multiple remote locations. For more information, visit www.c-path.org.

ABOUT CDISC



CDISC creates clarity in clinical research by convening a global community to develop and advance data standards of the highest quality. Required by the United States Food and Drug Administration (FDA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and adopted by the world's leading research organizations, CDISC standards enable the accessibility, interoperability, and reusability of data. With the help of CDISC standards, the entire research community can maximize the value of data for more efficient and meaningful research that has invaluable impact on global health. CDISC is a 501(c)(3) global nonprofit charitable organization and is headquartered in Austin, Texas, with hundreds of employees, volunteers, and member organizations around the world. www.cdisc.org.

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