

C-Path, CDISC Develop Therapeutic Area Standard to Foster More Efficient and Meaningful Research for HIV



TUCSON, Ariz. and AUSTIN, April 16, 2019 — The Critical Path Institute (C-Path) and CDISC are pleased to announce the release of a global Therapeutic Area Standard that specifies how to structure commonly collected data and outcome measurements in clinical trials for HIV. The standard, released in the form of User Guide for data managers, statisticians, programmers and study managers, covers the areas of prevention, vaccines and treatment and 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.

HIV, the virus that causes AIDS, is one of the world's most serious health and development challenges. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), there were approximately 36.9 million people worldwide living with HIV/AIDS at the end of 2017. Of these, 1.8 million were children (<15 years old).

Implementing this standard will allow HIV data to be structured effectively and easily analyzed, leaving more time for researchers to focus on discoveries that will have invaluable impact on clinical research and global public health. This standard will also promote data harmonization across a wide range of studies in HIV, which will facilitate collaboration and cross-study analyses to ensure the highest return on research investments.

“We were honored to be a part of the amazing team working on the development and publication of the new Therapeutic Area User Guide for HIV clinical trials,” said C-Path President and CEO Martha Brumfield, Ph.D. “The importance of these standards cannot be underscored enough. We encourage the research community to rapidly adopt this information in their studies, as structuring data in a common format is key to supporting the development of additional drug development tools and therapies for HIV/AIDS.”

“Collaboration and inclusivity have always been bedrocks of CDISC's culture. It's why we convene a global community of experts from across the research spectrum and facilitate the development of standards that are open and available to all, enabling data sharing around the world,” said David R. Bobbitt, CDISC President and CEO. “The development of this important standard has benefitted from the input of a diverse set of

collaborators to tackle a critical public health issue.”

This CDISC Therapeutic Area standard for HIV was developed through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, a partnership of CDISC and the Critical Path Institute (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 National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) was a major partner in the development of this User Guide. 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. This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201700078C and the US FDA through grant 1U01FD005876.

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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