C-Path and CDISC Announce Updated Therapeutic Area Standard for TB

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TUCSON, Ariz., and AUSTIN, Texas – 6 June 2016 – The Clinical Data Interchange Standards Consortium (CDISC) and the Critical Path Institute (C-Path) announce the open availability of an updated CDISC Therapeutic Area (TA) Standard for tuberculosis (TB). The tuberculosis v2.0 standard is an updated version of the original TB v1.0 standard and includes new content focused on pediatrics and drug susceptibility testing.

Tuberculosis kills 1.7 million people per year with one person dying of TB every 20 seconds. It is one of the world's deadliest diseases, exacerbated by global poverty, the AIDS epidemic, and drug resistance.

"The TB clinical trial data standard is an important tool that can help maximize the investment in clinical trials for TB drugs and regimens by streamlining data collection and enabling data to be integrated across multiple sources to enhance learnings from these important trials," says Debra Hanna, PhD, Executive Director of the Critical Path to TB Drug Regimens (CPTR) initiative.

With funding from the Bill & Melinda Gates Foundation, this standard was developed through the work of the CPTR Data Standards and Integration team and the Coalition for Accelerating Standards and Therapies (CFAST).

CFAST, a joint initiative of CDISC and C-Path, was formed to accelerate clinical research and medical product development by creating and maintaining data standards, tools, and methods for conducting research in therapeutic areas important to public health, with input and assistance from such organizations as the National Cancer Institute (NCI), Innovative Medicines Initiative (IMI), TransCelerate BioPharma Inc., and regulatory agencies including the US Food and Drug Administration (FDA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and the European Medicines Agency (EMA).

"CDISC is grateful to our partner, C-Path, for spearheading development of v2.0 of the Tuberculosis standard," stated Bron Kisler, CDISC VP, Strategic Alliances & Development. "This is a particularly meaningful milestone, as TB v1.0 was one of the first TA standards to be released, and now v2.0 represents the first TA standard with content covering use in pediatrics.

“Our continued collaboration through the CFAST initiative ensures we meet our mutual goal of improving medical research for all patients.”

TB v2.0 is available via the CDISC website, through User Guides, and Shared Health and Research Electronic Library (SHARE), CDISC’s metadata repository that facilitates electronic access to the standards and enables the reuse of common concepts across future TA standards.

CDISC standards have been adopted and used in more than 90 countries, and will soon be required by regulatory authorities in the US and Japan. To date, TA Standards have been developed for over 25 different disease areas, with most being developed under the CFAST program. Use of these standards from the start of clinical research programs has proven capable of saving both time and resources. Researchers working in the area of tuberculosis are encouraged to implement these standards into their processes.

About the organizations:

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C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US Food and Drug Administration (FDA). 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 12 global, public-private partnerships that currently include over 1,450 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.

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CDISC is a 501(c)(3) global nonprofit charitable organization that develops clinical research data standards to streamline research and enables connections to healthcare. The CDISC suite of standards is freely available on our website and makes it possible for data to speak the same language, empowering simple data collection and private sharing to make the most of the valuable information offered by patients participating in research studies around the globe. Implementing CDISC standards from the start of studies enables *Smarter Research to Unlock Cures (www.unlockcures.org)*, saving 70-90% time in the start-up of clinical research studies and ~60% overall in terms of time and resources to conduct research. CDISC is the patient’s advocate, creating therapeutic area data standards for over 25 different disease areas that advance medical product development and various types of clinical research.

CDISC membership is open to any organization interested in supporting the development and adoption of CDISC standards. To learn more about CDISC membership, please visit http://www.cdisc.org/membership.

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