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## **CDISC, C-Path and FDA Collaborate to Develop Data Standards to Streamline Path to New Therapies**

**Austin, TX – 21 June 2012** – The Clinical Data Interchange Standards Consortium (CDISC) and the Critical Path Institute (C-Path) announce the signing of a partnership agreement to establish the Coalition For Accelerating Standards and Therapies, or CFAST, an initiative 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.

Version 1.0 of an Alzheimer's data standard, used to develop the C-Path Coalition Against Major Diseases' (CAMD) groundbreaking Alzheimer's Disease data repository, was developed through the CDISC process and posted to the CDISC website in October 2011. Since this first major milestone, CDISC and C-Path and such partners as the Bill and Melinda Gates Foundation, the Michael J. Fox Foundation, the PKD Foundation, Tufts University, Rochester University, the National Institutes of Health (NIH) and others have continued to make advancements in a number of therapeutic areas. Tuberculosis, Pain, Parkinson's Disease, Polycystic Kidney Disease, Virology, Oncology, and Cardiovascular Disease are therapeutic areas for which standards are currently in development.

"We have enjoyed our collaboration to develop standards and research databases that are open to scientists around the world to seek new therapies," says Dr. Carolyn Compton, President and CEO of C-Path. "We need a means to scale the process and manage the development of a very large number of therapeutic area standards. The establishment of CFAST embodies our resolve to take what we have learned from the initial projects to formulate a new process that will be significantly more efficient while retaining the rigor that is essential to this work."

Also in 2011, the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) released a list of priority therapeutic areas that could benefit from the standardization of key study data specific to each area. The FDA website states: "FDA, CDISC and the Critical Path Institute [C-Path] are collaborating on efforts to support development of therapeutic area standards. [...] We encourage stakeholders to engage in and, where possible, support these data standardization efforts."

Therapeutic area standards development has been identified by the CDISC Board of Directors and the CDISC community as a key strategic goal for CDISC. "Our stakeholders have expressed that CDISC provides value to them through our free and open standards and that this value will be enhanced if we can extend the foundational standards to cover therapeutic areas," stated Dr. Rebecca Kush, CDISC

President and CEO. "CFAST is a major new initiative that will allow the industry to speed the delivery new therapies for patients, both in helping us gain more knowledge from past research and in improving the overall process for new studies, from protocol design through analysis and reporting."

The official launch of CFAST, including the roll out of the newly designed process and a Shared Health and Research Electronic Library (SHARE) environment to make the standards more accessible, will be on 24 October at the CDISC International Interchange in Baltimore, MD. To learn more about these therapeutic area standards, interested parties are invited to attend the session "Standards for Patients: Collaborations to Innovate Therapy Development," chaired by Bron Kisler, CDISC VP of Strategic Initiatives, taking place at the DIA Annual Meeting in Philadelphia on Monday morning, 25 June 2012.

#### **ABOUT CDISC**

CDISC is a 501(c)(3) global non-profit charitable organization, with ~300 supporting member organizations from across the clinical research and healthcare arenas. Through the efforts of volunteers around the globe, CDISC catalyzes productive collaboration to develop industry-wide data standards enabling the harmonization of clinical data and streamlining research processes from protocol through analysis and reporting, including the use of electronic health records to facilitate the collection of high quality research data. The CDISC standards and innovations can decrease the time and cost of medical research and improve quality, thus contributing to the faster development of safer and more effective medical products and a learning healthcare system. The CDISC Vision is *to inform patient care and safety through higher quality medical research.*

#### **ABOUT C-PATH**

An independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the U.S. Food and Drug Administration (FDA), C-Path's mission is to improve human health and well-being by developing new technologies and methods to accelerate the development and review of medical products. An international leader in forming collaborations, C-Path has established global, public-private partnerships that currently include 1,000+ scientists from government regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, AZ and has an office in Rockville, MD. Visit [www.c-path.org](http://www.c-path.org) for more information.

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