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Austin, TX – 12 October 2015 – The FDA recently awarded several grants to the Clinical Data Interchange Standards Consortium (CDISC) and the Critical Path Institute (C-Path) to fund development of additional Therapeutic Area (TA) standards through their joint initiative, the Coalition for Accelerating Standards and Therapies (CFAST).

CDISC and C-Path will develop CDISC standards for six key disease areas important to public health – Colorectal Cancer, Major Depressive Disorder, Diabetic Kidney Disease, Rheumatoid Arthritis, Solid Organ Transplantation (Kidney), and Cardiovascular Imaging. CDISC standards have been shown to significantly reduce time and resources associated with clinical research, while C-Path databases (with data aggregated using CDISC standard formats) provide researchers with high quality data for disease modeling and other scientific analyses that can lead to qualification of biomarkers and supporting opportunities for new therapies.

“FDA grants are proving to be a pivotal enabling mechanism, making development of important CDISC TA standards for therapeutic areas possible,” said Bron Kisler. “We greatly appreciate the ongoing support of the FDA, NCI, and the many other CFAST partner organizations.”

Signifying a continued investment by both organizations to advance the development of therapeutic area standards critical for public health, CDISC and C-Path formally renewed their Memorandum of Understanding (MOU). C-Path and CDISC have had a formal partnership for a decade, with the first MOU signed in 2006. The two organizations have complementary roles that are synergistic in advancing new therapies for patients globally.

“Our partnership, which was formed by CDISC President Dr. Rebecca Kush and C-Path’s founder, Dr. Raymond Woosley shortly after the Critical Path Institute was launched in Arizona, has now demonstrated the value of standards to enable meaningful collaboration based on fully aggregated data sets that inform new drug development tools,” said Dr. Martha Brumfield, current C-Path President and CEO. “Our joint work is built upon a unique sense of trust and a common interest in improving the lives of patients through higher quality data and enabling collaborative research. We are pleased that our partnership will continue and have no doubt it will become even stronger as we continue the work of CFAST and related C-Path consortia.”

CDISC and C-Path have partnered to date on the development and implementation of numerous CDISC therapeutic area standards, including those for Alzheimer's disease, Parkinson's disease, tuberculosis, polycystic kidney disease, multiple sclerosis, influenza, virology, traumatic brain injury, and more.

The recent grants will provide a portion of the funding necessary to develop new standards. The CDISC TA standards are available via the CDISC website and through the CDISC Shared Health and Research Electronic Library (SHARE). SHARE enables electronic access to the standards and facilitates re-use across future therapeutic area standards with common data elements.

The 2015 CDISC International Interchange, scheduled for 09-13 November 2015 in Chicago, Illinois, will include presentations by global regulators that highlight upcoming requirements for submissions data in CDISC standard format, as well as engaging and relevant sessions by representatives from CDISC, C-Path, and others describing the importance of TA standards development to support research.

About CFAST

CFAST, a joint initiative of CDISC and C-Path, was launched to accelerate clinical research and medical product development by facilitating the establishment and maintenance of data standards, tools, and methods for conducting research in therapeutic areas important to public health. CFAST collaborators include the U.S. Food and Drug Administration (FDA), TransCelerate BioPharma, Inc., and the National Cancer Institute Enterprise Vocabulary Services (NCI-EVS), with participation and input from many other organizations.

About CDISC

CDISC is a 501(c)(3) global non-profit charitable organization that streamlines research and enables connections to healthcare through the development of clinical research data standards. CDISC standards make it possible for data to speak the same language, empowering simple data collection and private sharing that makes the most of the valuable information offered by patients participating in research studies around the globe. Using CDISC standards from the start of studies enables Smarter Research to Unlock Cures, saving ~60% overall in terms of time and resources to conduct research. CDISC is the patient's advocate, creating therapeutic area data standards that advance medical product development and various types of clinical research.

About Critical Path Institute

Critical Path Institute (C-Path) is 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 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 now established twelve global, public-private partnerships that currently include over 1,000 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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