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CRITICAL PATH INSTITUTE AND CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM HOST INTERNATIONAL PROGRAM AT NEW TRAINING FACILITY

Joint effort to advance data standards and create public databases as means to accelerate medical product development

Tucson, Arizona, February 16, 2011 – On the heels of their announcement of an innovative partnership to set new clinical data standards that will facilitate more efficient development of new therapies for major diseases, Critical Path Institute (C-Path) and Clinical Data Interchange Standards Consortium (CDISC) have opened a state of the art, collaborative training facility in Tucson, Arizona, and there conducted the first in an ongoing series of classes aimed at data managers, clinical programmers, and others interested in learning and using U.S. Food and Drug Administration (FDA) sanctioned common data elements in biomedical research. The session took place on January 19-21, 2011 and included attendees from diverse professional backgrounds representing 14 organizations from three countries: South Korea, Canada, and the United States.

C-Path and CDISC are both non-profit organizations committed to forming collaborations to address process gaps responsible for delays and inefficiencies in medical product development. Both groups believe that the first step in accelerating the development of safe, innovative therapies lies in creating and promoting the use of data standards and building open databases of clinical research data that truly describe the progression of diseases. This will also enable the FDA to review new product applications more efficiently and effectively. In order to ensure that standards can be implemented globally, CDISC has developed an international training and education program that is delivered by CDISC qualified trainers.

According to Enrique Aviles, Director of Data Standards and Management for C-Path, "The data standards established by CDISC make it possible for research scientists to share data and collaborate more efficiently. This is critical to establishing faster, safer approaches to the development of new medicines. This course was the first of many in which clinicians, scientists, and technicians will learn how to implement CDISC data standards, and how to apply these standards to improve the qualification process for new medicines." Aviles also acknowledged

the ongoing public and private philanthropic support that allows C-Path to create new partnerships and initiatives like the one with CDISC, particularly noting the indispensible $12+ million in grants that has been awarded from Science Foundation Arizona (SFAz).

This training session focused on the Study Data Tabulation Model (SDTM) Theory and Application as well as the Clinical Data Acquisition Standards Harmonization (CDASH) Implementation. SDTM is the standard for clinical data tabulations, and is specified through the FDA electronic Common Technical Document (eCTD) Guidance as the model for submitting clinical data to the FDA in support of marketing applications. The Study Data Tabulation Model Implementation Guide (SDTMIG) provides a standardized, structured way to organize and submit subject data for regulatory approval. CDASH is the CDISC standard for case report forms (CRFs) that is harmonized with SDTM and other CDISC standards. CDASH focuses closely on the content used in CRFs to ensure greater accuracy and in order to create an environment where data can ultimately be shared within and across studies. The use of the CDASH standard up front in clinical studies has been demonstrated to save significant time and resources throughout a research study, whether preparing an eventual eSubmission or not.

Chris Tolk, CDISC Director for Terminology, who led the SDTM training stated, "Education around global standards implementation is vital to enable organizations working in medical research to deliver higher quality and more efficient processes. The new facility in Tucson will enhance the ability of CDISC to deliver education, and further sessions are being planned for 2011. This is an excellent benefit of our enhanced relationship with C-Path."

About Critical Path Institute (C-Path): An independent, non-profit organization established in 2005, C-Path is committed to transformational improvement of the drug development process. An international leader in forming collaborations around this mission, C-Path has established first-of-its-kind global partnerships that currently include over 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, and thirty major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland. For more information, visit www.c-path.org.

About CDISC: CDISC (Clinical Data Interchange Standards Consortium) operates to advance the continued improvement of public health by enabling efficiencies in medical research and related areas of healthcare. As a catalyst for productive collaboration, CDISC brings together individuals spanning the healthcare continuum to develop global, open, consensus-based medical research data standards. For more information, visit http://www.cdisc.org/.

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