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CRITICAL PATH INSTITUTE AND CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM ANNOUNCE INNOVATIVE PARTNERSHIP TO ADDRESS MAJOR DISEASES Global leaders join forces to establish data standards and create public databases as new means to accelerate medical product development



Tucson, Arizona, January 10, 2011 – Critical Path Institute (C-Path) and Clinical Data Interchange Standards Consortium (CDISC) have established a formal partnership to set new clinical data standards that will facilitate more efficient development of new therapies for major diseases. Raymond Woosley, MD, PhD, President/CEO of C-Path and Rebecca Kush, PhD, President/CEO of CDISC, signed the partnership agreement at C-Path's headquarters in Tucson, Arizona. CDISC, founded in Austin, Texas, has also opened an office in Tucson, adjacent to C-Path, to optimize this collaborative effort.

C-Path and CDISC are both non-profit organizations committed to forming precompetitive collaborations to address process gaps responsible for delays and inefficiencies in medical product development. After working together to build the landmark Alzheimer's disease clinical database launched publicly by C-Path's Coalition Against Major Diseases (CAMD) in June 2010. C-Path/CDISC will now take on other brain diseases (Huntington's disease, ALS, multiple sclerosis), as well as lung cancer, diabetes mellitus, and other diseases identified by the U.S. Food and Drug Administration (FDA) as high priority public health challenges.

Secretary of the U.S. Department of Health and Human Services, Kathleen Sebelius, commented on the new partnership, "To be successful, an enterprise has to establish a common language and tools that facilitate communication and learning. The important work being done by C-Path and CDISC is providing scientists around the world with the common data standards and qualified tools critically needed in clinical research and medical product development. The two organizations are natural partners in delivering this important service towards the advancement of public health."

Janet Woodcock, MD, Director, Center for Drug Evaluation and Research (CDER) at the FDA added, "Companies are struggling to develop new therapies to treat a variety of diseases and conditions. The lack of clinical data

standards and accurate databases that truly describe the progression of diseases is a major impediment to making rapid progress. C-Path and CDISC are two of FDA's most successful partners, and their joint effort to expand the scope of CAMD will make even greater strides possible."

As a keynote speaker at the recent CDISC Interchange North America conference in Baltimore, Dr. Woosley noted, "Today, as in the 1980s when the world lacked effective HIV/AIDs treatments, patients and the public are demanding collaborations to accelerate the development of safe and effective therapies for major diseases. In response, CAMD has united the efforts of global biopharmaceutical companies, research scientists, and governmental agencies such as the National Institutes of Health (NIH), the FDA, and its counterpart in Europe. The data standards established by CDISC make it possible for CAMD scientist to communicate and share data efficiently."

In launching the Alzheimer's disease database, CAMD, using CDISC data standards, combined patient data from eleven clinical trials that were openly shared by seven pharmaceutical companies. This database of over 4,000 patients is now available to qualified researchers around the world and provides a standardized platform on which they can design more efficient clinical trials to test new treatments for patients much earlier in their disease.

Woosley 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 indispensable \$12+ million in grants that has been awarded from Science Foundation Arizona (SFAz).

Data standards and better databases will also enable the FDA to review new applications more efficiently. Citing the critical importance of data standards, the FDA, in its draft document titled, "CDER Data Standards Plan Version 1.0," outlines a proposed comprehensive data standards program to be implemented within the agency. "With an increasing volume of submissions," the draft plan says, "CDER and the Center for Biologics Evaluation and Research (CBER) must transition to standardized electronic regulatory submissions in order to meet strict regulatory deadlines."

According to Dr. Kush, "We are excited about the synergy that comes from working with C-Path, an organization that shares our commitment to the basic principles of strength through collaboration and sharing knowledge to advance public health. Our new CDISC office in Tucson will facilitate this productive collaboration and aligns nicely with the CDISC vision of informing patient care and safety through higher quality medical research."

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 750 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. For more information on CAMD and the database, visit <http://www.c-path.org/CAMD.cfm>.

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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