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CDISC Announces the Keynote Speakers for the North American Interchange

Austin, TX – 12 October 2010 – **The CDISC North American Interchange is to be held in Baltimore, MD, 1 – 5 November 2010**. The CDISC Board of Directors and Dr. Rebecca Kush, President & CEO are pleased to announce three exceptional keynote speakers to introduce this year's event: Dr. Doug Fridsma, acting director of the Office of Interoperability and Standards in the Office of the National Coordinator for Health Information Technology; Dr. Theresa M. Mullin, Ph.D., Director, Office of Planning and Informatics, Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA) and Dr. Raymond L. Woosley, Founder and Chief Executive Officer of the Critical Path Institute (C-Path).

Dr. Fridsma completed his medical training at the University of Michigan in 1990, and his PhD in Biomedical Informatics from Stanford University in 2003. His research interests include the development of computational tools to study patient safety, clinical work processes, and methods to improve model-driven standards development processes. He has served on the Clinical Data Interchange Standards Consortium (CDISC) Board of Directors from 2005-2008, and was appointed to the HIT Standards Committee in 2009. He recently resigned from the HIT SC to become the acting director of the Office of Interoperability and Standards at ONC. He is currently on leave from the Department of Biomedical Informatics at Arizona State University and from his clinical practice at Mayo Clinic Scottsdale.

Dr. Mullin directs strategic planning and business informatics for FDA CDER. The Office of Planning and Informatics plays a lead role in CDER long-range planning, budget formulation, program analysis, and informatics operations. In addition, Dr. Mullin has been appointed lead negotiator for FDA for the 2012 PDUFA reauthorization. Dr. Mullin will speak at the CDISC Interchange on her leadership in the development of the CDER Data Standards Plan and other efforts that are coming into play within FDA to leverage the value of standards to improve the FDA review process.

Dr. Woosley founded C-Path, a non-profit corporation formed by the Food and Drug Administration, SRI International and the University of Arizona to develop scientific consensus on methods that accelerate the development of safe innovative medicines. He is currently on leave from the Department of Biomedical Informatics at Arizona State University and from his clinical practice at Mayo Clinic Scottsdale. In recent months, C-Path's Coalition Against Major Diseases (CAMD), a collaboration that includes CDISC and other organisations, released a database of more than 4,000 unidentified Alzheimer's disease patients who have participated in eleven industry-sponsored clinical trials. The CAMD collaboration is bringing greater speed, efficiency, safety and predictability to medical product development.

The Program for this year's event sees a new stream, 'Standards and the Patient' where CDISC is privileged to welcome Dr. Adam Clark (Faster Cures – formerly Lance Armstrong Foundation and NCI), Dr. Jeff Allen (Friends of Cancer Research) and Dr. Ron Perrone (Tufts University). They will be

speaking about the need for standards to work with healthcare, in a translational science setting to benefit human health. In addition, the FDA will have good representation through the FDA panel and Dr. Vicki Seyfert-Margolis, Office of the Commissioner, will be presenting in the session dedicated to the FDA's implementation plans.

This year's Interchange also sees the new Round Table Discussion Groups making their debut in North America, following their success in Europe in April, as well as the most up-to-date CDISC education. The latest version of the Protocol Representation course has been carefully restructured to appeal to a wider audience and a brand new course, CDISC: A Global Approach to Accelerating Medical Research, will be launched at this conference. It is designed to demonstrate the true value of 'implementing CDISC end to end' and educate attendees on the real business solutions that can benefit any organisation in this arena.

Full details of the conference, including courses, registration and hotel accommodation can be found on the CDISC website: www.cdisc.org/interchange

ABOUT CDISC

CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to ***develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.*** CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website. Additional information on CDISC can be found on the website at www.cdisc.org.