



## Press Release

### **CDISC Collaborates with FDA and ACRO in Open Forum on Standards for Clinical Data Collection**

Austin, TX – 27 January 2006 – A large group of stakeholders within the clinical research enterprise attended an open forum on 25 January entitled “Creating Clinical Trial Efficiencies through Standard Data Collection” to share updates on work accomplished to standardize the collection of clinical research and health care data. Sponsored by the Drug Information Association, the well-attended event in Washington DC featured perspectives from investigative sites, academic research organizations, clinical trial sponsors and the FDA.

A keynote presentation from Dr. Janet Woodcock, Deputy Commissioner for Operations and Chief Operating Officer, FDA, set the tone for the forum. Dr. Woodcock provided an update on the FDA’s Critical Path Initiative and cited two areas where modernization is expected to yield the greatest return on investment: biomarkers and the conduct, design and execution of clinical trials.

“The FDA has the largest pool of randomized clinical trial data in the world, but it cannot be analyzed now because it is inaccessible,” she said. There is a critical need to get data that can be easily pooled to permit cross-product analyses, particularly in the area of patient safety.” Dr. Woodcock added that “the FDA has now adopted the CDISC Study Data Tabulation Model (SDTM) for electronic submissions.” This standard data format will allow the agency to populate a cross-study database and do more comprehensive analyses for the benefit of patients. “FDA is here today to support your efforts in standardizing data collection,” said Dr. Woodcock. “We will do whatever we can to help move this initiative forward.”

During the forum, the Association of Clinical Research Organizations (ACRO) presented examples of standardized case report forms that it has developed to collect safety data and medication information. Case report forms are widely considered an area ripe for improvement in clinical research as multiple designs and approaches, with varying data collection requirements, create inefficiencies and frustration for site personnel and increase the risk of data transcription errors. The data fields from ACRO’s sample case report forms were mapped to CDISC’s SDTM, and an XML version using the CDISC transport standard, the Operational Data Model (ODM), was developed to collect the data electronically. Several vendors were able to then render electronic case report forms with standard data fields in a matter of hours. Site representatives, sponsors and FDA indicated their support to further this collaborative activity.

Dr. Woodcock concluded her keynote with reference to the importance of integrating electronic health records and electronic clinical trial data collection solutions: “There are important efforts taking place to bridge healthcare with clinical research through CDISC, NCI and HL7. I applaud these groups and other stakeholders in this work.”

**About CDISC**

CDISC is an open, multidisciplinary, non-profit organization committed 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. CDISC is made possible through the generous support of its members, sponsors, and volunteer participants. These include academia, biopharmaceutical companies, technology and service providers, HL7, NCI, institutional review boards and anyone interested in streamlining biopharmaceutical product development and clinical data quality.

Additional information on CDISC can be found on the CDISC website at [www.cdisc.org](http://www.cdisc.org).

**Contact:**

Shirley Williams  
Director of Finance and Operations  
Phone: 001.512.341-9885  
e-mail: [swilliams@cdisc.org](mailto:swilliams@cdisc.org)