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CDISC and Industry Collaborative Group Lead FDA Critical Path Initiative Opportunity for Data Collection Standards

Austin, TX – xx March 2007 – The Clinical Data Interchange Standards Consortium (CDISC) has agreed to lead a project to address one of the Food and Drug Administration (FDA) Critical Path Initiative Opportunities: Consensus on Standards for Case Report Forms (CRFs). “A wide array of different forms and formats are used to collect clinical trial information, and most data are submitted to the FDA on paper. Differences in case report forms across sponsors and trials creates opportunities for confusion and error,” states this document (http://www.fda.gov/oc/initiatives/criticalpath/reports/opp_list.pdf). The Clinical Data Acquisition Standards Harmonization (CDASH) project is designed to address this problem.

“From FDA’s perspective, the quality and integrity of the data is paramount. Common standards for case report forms can improve both, and are also a crucial enabler for the biomedical research of the future, for example, to support genotypic and phenotypic evaluation of each subject. We appreciate CDISC taking the leadership role to start now to create the data collections tools for the future,” states Dr. Janet Woodcock, Deputy Commissioner and Chief Medical Officer, FDA. The CDASH project follows the CDISC open consensus-based standards development procedure, which includes an internal cross-team CDISC review as well as external and public review stages. A Collaborative Group of (XX) organizations is contributing direction and resources.

This effort was initiated by the Association of Clinical Research Organizations (ACRO); “After a year of work and the development of several CRF templates, we knew the project needed to involve a broad range of stakeholders and be led by a global standards development organization,” said ACRO Executive Director, Douglas Peddicord, Ph.D. “We are extremely pleased that CDISC is directing the effort.” In addition to CDISC, ACRO and FDA, the Collaborative Group for CDASH is comprised of the Association of Clinical Research Professionals (ACRP); American Medical Informatics Association (AMIA); Baylor College of Medicine; the Critical Path Institute (C-Path); Duke Clinical Research Institute (DCRI); National Institutes of Health (NIH), whose participation is being coordinated through the Clinical Research Policy Analysis and Coordination Program; National Cancer Institute Enterprise Vocabulary Services (EVS); National Center for Research Resources (NCRR); National Cancer Institute Center for Bioinformatics (NCICB); National Library of Medicine (NLM); Pharmaceutical Research and Manufacturers Association (PhRMA); Biotechnology Industry Organization (BIO); Society for Clinical Data Management (SCDM).

“We salute CDISC for taking on this initiative; it is an important building block in the overall effort to enable an efficient end-to-end IT environment that is critically needed by the biopharmaceutical industry to help it meet the pressing challenge of developing medicines to improve patients’ health,” said Darrick Fu, Associate VP, Science & Regulatory Affairs, PhRMA.

One key goal of this initiative is to facilitate the participation of investigators and investigative site personnel in clinical trials by allowing them to enter data in a common format across trials. CDISC has a complementary project (Healthcare Link), which has just completed an important integration profile to bring case report forms into systems, such as electronic health records, that the investigators are already using in their practices; thus, clinical research is integrated into the basic patient care and work flow priorities of the site.

The CDASH standard will be harmonized with the standard that CDISC has already developed for submission of data to the FDA in the Common Technical Document and the evolving Regulated Product Submission. This harmonization will ensure that there is an integrated flow of data from site through submission and warehousing/archive. A recent Business Case project conducted by Gartner and PhRMA with CDISC has shown that the implementation of standards at the beginning of the clinical research development process can save as much as 60% of the overall cost and time. In addition, it improves team communication (including sites), re-use and integration of information, and data quality.

“The SCDM is very excited to be playing a role in this new standards venture. We feel that our expertise in the area of clinical data quality and management, coupled with CDISC’s expertise in data interchange standards, will lead to high quality deliverables from this group. There is more and more evidence that standards like this lead to faster drug development timelines and higher clinical data quality, said Anthony Costello, Chairman of the Board of Directors, SCDM and VP of Product Development, Nextrials.

The CDASH project is focusing on electronic data capture fields (vs. the layout of a paper CRF). CDASH is now well underway, with a mission to develop a set of ‘content standards’ (element name, definition, metadata) for a core set of global data collection fields that will support clinical research studies. The initial scope will be the ‘safety data/domains’ to support clinical trials. If additional funding can be secured, standards specific to therapeutic areas will become part of the extended CDASH scope. For further information on CDASH or to contribute to this initiative, please contact Rhonda Facile, CDASH Project Leader, CDISC (rfacile@cdisc.org).

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.

CDISC is made possible through the generous support of its members, sponsors, and volunteer participants. These include academia, biopharmaceutical companies, technology and service providers, institutional review boards and anyone interested in streamlining biopharmaceutical product development and improving clinical data quality and healthcare. CDISC also has joint memberships with HL7, HIMSS, AMIA and the C-Path Institute. Additional information on CDISC can be found on the CDISC website at www.cdisc.org.

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