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CDISC SHOWCASES INTEROPERABILITY PROTOTYPE BETWEEN MEDICAL RESEARCH AND HEALTHCARE

Austin, TX – 10 April 2007 – CDISC, the leading standards development organization for clinical trials research, presented a demonstration of a prototype designed to bridge healthcare data with clinical research, safety and surveillance data. The “New Directions Life Sciences” demonstration was shown as a part of the Interoperability Showcase at the HIMSS (Health Information and Management Systems Society) Annual meeting held in New Orleans the week of 25 February 2007.

The CDISC prototype, developed in collaboration with IHE (Integrating the Healthcare Enterprise), is accelerating interoperability between medical research systems and the healthcare EHR (electronic health record), using the IHE Remote Form for Data Capture (RFD) profile and the CDISC ODM model.

CDISC worked with key Pharmaceutical industry thought-leaders to develop use-case scenarios depicting how data can be transferred seamlessly between care provider’s EHR systems and systems used for safety surveillance, clinical research, disease registries and disease surveillance.

“We’re encouraged by what we’ve seen in the use-case scenarios. If adopted by the healthcare industry, it would allow us to collect safety data directly from a doctor’s EHR, at the point-of-care, and would make safety reporting part of the clinical workflow. Physicians and staff would no longer need to re-enter data into specialized forms, systems or websites. Avoiding this redundant data entry would reduce data errors and save the care provider’s valuable time. And as part of FDA’s ‘Sentinel System’ it could substantially improve the quality, number and timeliness of spontaneous reports, and so have a direct impact on public health.” observed Michael Ibara, Head of Pharmacovigilance Information Management at Pfizer.

Five interoperability scenarios were demonstrated at the New Directions Life Sciences showcase. Data and support was provided by the following companies for each corresponding scenario or usage case: Pfizer and Drug Safety reporting; Novartis and Lilly representing clinical trials lab and image data and clinical trials workflow respectively, and Genzyme and Disease Registries; and SAIC in collaboration with the CDC (Centers for Disease Control) representing Biosurveillance. Implementers who supported these scenarios are: Allscripts, Assero/IPL, Cerner, Digital Infuzion, IBM, Phase Forward, SAS, Sentrx, Relsys and University of Washington.

A final participant, SEC Associates, provided regulatory compliance oversight, addressing 21 CFR PART 11 and GCP records compliance issues for each of the use-case scenarios.

Landen Bain, CDISC Liaison to Healthcare and Program Manager for the CDISC/IHE-led effort reports that, "All the "New Directions Life Sciences" participants were highly pleased with the results, and particularly with the opportunity to raise awareness at HIMSS with healthcare IT and academic medical centers about the advantages of enabling interoperability from the EHR to secondary uses of these data in safety reporting, research and surveillance".

Following the showcase, IHE Director, Didi Davis added that "Interoperability of EHR systems and pharmaceutical systems will reduce error, reduce the cost of documentation and staffing, and streamline workflow".

CDISC plans to continue adding additional use-cases and identifying, through pilot programs, ways that CDISC standards and the RFD profile can continue to enable the expansion of the data integration between healthcare and medical research.

About CDISC

CDISC is a global, open, multidisciplinary, non-profit organization that has developed standards to support the acquisition, exchange, submission and archive of clinical trial 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 CPATH Institute.

Additional information on CDISC can be found on the CDISC website at www.cdisc.org.