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CDISC Partners with DIA and IHE to Demonstrate EHRs for Medical Research

Austin, TX – 15 June 2011 – The Clinical Data Interchange Standards Consortium (CDISC) is pleased to announce its collaboration with DIA and Integrating the Healthcare Enterprise (IHE) to bring a state-of-the-art demonstration of the implementation of electronic health records (EHRs) to streamline medical research. This process represents a simple yet powerful means towards shortening the current 17 year gap in translating research results into clinical care decisions.

“CDISC has been a leader in demonstrating the value of EHRs in the research arena,” stated Dr. Doug Fridsma, Director, Office of Interoperability & Standards at the U.S. HHS Office of the National Coordinator for Health IT (ONC). “Linking clinical care with clinical research sets the stage for novel ways of leveraging patient care information using more granular metadata approaches.”

The currently available solution is being demonstrated by EHR vendors along with clinical trial technology and service providers, CDISC and HIMSS at DIA 2011 in Chicago on June 19-23. DIA 2011 provides educational and networking opportunities to more than 8,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related health care products.

“We are very pleased to partner with DIA and CDISC to feature the profiles from the Quality Research and Public Health domain of IHE. This is a valuable opportunity to share the HIMSS Interoperability Showcase™ with research stakeholders,” said H. Stephen Lieber, CAE, HIMSS President and CEO of HIMSS.

CDISC has been working with the IHE Committee on Quality Research and Public Health (QRPH) for the past 7 years to develop the necessary integration profiles to implement global standards such as CDISC and HL7. The ANSI-sponsored Interoperability Specification (IS # 158), which provides a core standard research dataset from EHRs, was ratified by the Health Information Technology Standards Panel (HITSP) in 2010. The development of this IS was conducted in a manner to ensure compliance with regulatory requirements for electronic source data, electronic record retention, patient privacy and data security, audit trails and the global Good Clinical Practices (GCP). The concept behind this standards-based innovation is that data should be entered once for multiple purposes, thus improving quality and patient safety along with streamlining workflow such that a busy clinician can readily participate in research.
“This solution has the potential to revolutionize the research process,” said Landen Bain, CDISC Healthcare Liaison. “It is in use today, and the powerful simplicity includes the opportunity for medical sites with varying EHR systems (or even paper or EDC systems) to participate in the same research study, yet the resulting research data are provided in a standard format so that they can readily be aggregated into robust research databases to facilitate analysis, publications or eSubmissions to FDA in the preferred format to improve regulatory reviews.”

“We are excited to bring the HIMSS Interoperability Showcase to DIA so that those conducting research can appreciate this interesting and educational opportunity,” said Paul Pomerantz, Executive Director of DIA. “The event will include not only the continuous demonstration, but also presentations in the showcase area and an Interoperability Town Hall, moderated by CDISC President Dr. Rebecca Kush, with panelists from FDA and HHS/ONC.”

Participants

- **Premier Supporters:** Oracle and Quintiles
- **Contributor Network:** ASTER Safety Consortium, Duke Clinical Research Institute, HL7
- **Participant/Vendors:** Allscripts, Cerner Corporation, FDA/CDRH, Greenway Medical Technologies, IPL, Medidata Solutions, Nextrials, Oracle, Outcome, SAS Institute
- **Emerging Technology Participant:** CMIC Co., Ltd.

Visit the DIA Interoperability Showcase page for details.

ABOUT CDISC

**CDISC** is a global, open, multidisciplinary, neutral non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. CDISC Healthcare Link Initiative collaborates to link research and healthcare through standards-inspired innovation to further the CDISC mission and vision. 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. The CDISC Vision: Informing patient care and safety through higher quality medical research.** CDISC standards are global, vendor-neutral, platform-independent and freely available via the CDISC website. Additional information on CDISC can be found on the CDISC website at [www.cdisc.org](http://www.cdisc.org).

ABOUT DIA

**DIA** is a nonprofit, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies, and services to improve health and well being worldwide. Headquarters are in Horsham, PA, USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China. For more information visit: [www.diahome.org](http://www.diahome.org).

ABOUT HIMSS

**HIMSS** is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 50 years ago, HIMSS and its related organizations have offices in Chicago,
Washington, DC, Brussels, Singapore, Leipzig, and other locations across the United States. HIMSS represents more than 35,000 individual members, of which more than two thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 520 corporate members and more than 120 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote information and management systems’ contributions to improving the quality, safety, access, and cost-effectiveness of patient care. To learn more about HIMSS and to find out how to join us and our members in advancing our cause, please visit our website at www.himss.org. HIMSS Interoperability Showcases serve the healthcare community by promoting uptake of standards-based solutions that improve the potential for health information exchange between systems, providers, and organizations in order to optimize clinical care.

ABOUT IHE
IHE International, Inc. (www.ihe.net) is the global hub of the IHE initiative, a multi-stakeholder effort started in 1997 to promote the effective use of electronic health records and health information technology (HIT) by driving the adoption of standards-based solutions for interoperability. IHE International brings together HIT experts and stakeholders in more than a dozen clinical and operational domains to develop implementation guides called IHE Profiles that define the use of standards to address specific HIT interoperability needs. It also oversees a process of testing that fosters the adoption of IHE Profiles in real-world HIT products and care settings. IHE interoperability solutions are implemented in hundreds of products and in care sites around the world.