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HITSP Begins Harmonization Process for
Use of Electronic Health Records in Clinical Research

Thirty-five leading organizations from the clinical research
community have pledged support for new initiative

Washington, DC, June 15, 2009: The Healthcare Information Technology Standards Panel (HITSP), a cooperative partnership between the public and private sectors that works to ensure the interoperability of electronic health records (EHRs) in the United States, has begun work to identify global standards to support "core research data element exchange," specifically, a common set of information that can readily be exchanged between EHRs and clinical research systems.

As administrator of HITSP, the American National Standards Institute (ANSI) appreciatively acknowledges thirty-five organizations that have contributed their financial support to make this work effort possible, including:

- Abbott
- Accenture
- BioClinica, formerly Phoenix Data Systems
- Biogen Idec
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Cleveland Clinical and Translational Science Collaborative at Case Western Reserve University
    - Case Western Reserve University
    - Cleveland Clinic
    - MetroHealth System
    - University Hospitals
- Critical Path Institute
- Deloitte Consulting LLP
- Digital Infuzion
- Duke University
    - Duke Comprehensive Cancer Center
    - Duke Clinical Research Institute
- Eli Lilly and Company
- Genentech, Inc.
- Genetic Alliance

- Genzyme
- GlaxoSmithKline
- Greenway Medical Technologies
- HP
- JSS Medical Research Inc.
- McDougall Scientific Ltd.
- Medidata Solutions Worldwide
- MedXview
- Nextrials, Inc.
- Numoda Corporation
- Oracle
- Outcome
- Partners HealthCare
- Perceptive Informatics, a subsidiary of PAREXEL International
- PharmaNet Development Group, Inc.
- Pfizer
- Quintiles
- Schering-Plough Research Institute
- Target Health Inc.

"On behalf of ANSI, I thank these organizations for their generosity and forward thinking," said Frances Schrotter, ANSI senior vice president and chief operating officer. "These contributions have made it possible for HITSP to begin working toward a sustainable, interoperable infrastructure through which healthcare advances clinical research and in turn informs clinical care."

In addition to the contributions from the clinical research community, six U.S. federal agencies have demonstrated their support, including the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Cancer Institute, the National Center for Research Resources, the Office of the National Coordinator for Health Information Technology, the Department of Veterans Affairs, and the Assistant Secretary of Planning and Evaluation, Department of Health and Human Services.

The initiative began late last year when the U.S. Department of Health and Human Services (HHS) requested that ANSI convene a workgroup of experts to prioritize a value/use case for standards harmonization in this area. Co-chairs Dr. Rebecca Kush, president and CEO of the Clinical Data Interchange Standards Consortium (CDISC), and Dr. Gregory Downing, director of the Initiative on Personalized Health Care at the U.S. Department of Health and Human Services, are leading the workgroup effort. At an initial meeting in Washington, DC on November 10, 2008, the workgroup identified the need for a common set of information that can readily be exchanged between EHRs and clinical research systems to support research activities on a global scale.

With the initial priority "core research data element exchange" value case identified, HITSP convened a workgroup of technical experts and stakeholders in the clinical research space on June 9-11, 2009, in Arlington, Virginia. The final goal is to produce a streamlined electronic standards implementation guide that outlines the standards, how they support clinical research, and how they fit with existing HITSP guidelines – termed "Interoperability Specifications" – that are already in use within the clinical care environment.

"We are deeply appreciative of the many organizations who have committed their support and active participation to this initiative," said Dr. Kush. "Our work will help to streamline and enhance clinical research within the healthcare setting, providing the means to better assess such areas as efficacy, effectiveness and safety for the benefit of patients, investigators, clinicians, technology and service providers, and researchers alike."

About HITSP
Operating under contract to the U.S. Department of Health and Human Services (HHS), HITSP is administered by ANSI in cooperation with strategic partners including the Healthcare Information and Management Systems Society (HIMSS), the Advanced Technology Institute (ATI) and Booz Allen Hamilton.

About ANSI
ANSI is a private non-profit organization whose mission is to enhance U.S. global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. Its membership is comprised of businesses, professional societies and trade associations, standards developers, government agencies, and consumer and labor organizations. The Institute represents the diverse interests of more than 125,000 companies and organizations and 3.5 million professionals worldwide.

The Institute is the official U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC), and is a U.S. representative to the International Accreditation Forum (IAF). ANSI currently has offices in New York City and Washington, DC.

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