



**FOR IMMEDIATE RELEASE**

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**ANSI Seeks Funding to Ensure that Electronic Health  
Records Will Support Clinical Research Activities**

*Twenty-seven leading organizations from the clinical research  
community have already pledged support*

**Washington, DC, February 13, 2009:** The [American National Standards Institute](http://www.ansi.org) (ANSI), coordinator of the U.S. standards and conformity assessment system, is working to facilitate the use of electronic health information to support global clinical research activities. The Institute seeks the active engagement and financial support of the clinical research community to ensure that divergent and disparate standards do not inhibit the use of electronic health records (EHR) for future research and clinical decision support.

“We are faced with an important opportunity to ensure that clinical research needs are addressed in the work that is done to harmonize EHR standards,” said Frances Schrotter, ANSI senior vice president and chief operating officer. “Our immediate goal is to raise sufficient private-sector funds to cover the organizational costs needed to address this activity. In the long term, our objective is to create a sustainable, interoperable infrastructure through which healthcare advances clinical research and in turn informs clinical care.”

ANSI is pleased to announce that twenty-seven organizations have already stepped forward with contributions in support of the effort, including:

- Abbott
- 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
- Digital Infuzion
- Duke University
  - Duke Comprehensive Cancer Center
  - Duke Clinical Research Institute
- Genetic Alliance
- GlaxoSmithKline
- Greenway Medical Technologies
- HP
- JSS Medical Research Inc.
- McDougall Scientific Ltd.
- Medidata Solutions Worldwide
- MedXview
- Nextrials, Inc.
- Numoda Corporation
- Outcome
- Partners HealthCare
- PharmaNet Development Group, Inc.
- Pfizer
- Phoenix Data Systems, a division of Bio-Imaging Technologies
- Quintiles
- Target Health Inc.

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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.

In addition to the contributions from the clinical research community, six U.S. federal agencies have demonstrated their support through contributions to development of the workgroup's value/use case document; these agencies include 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.

With the initial priority value case identified, harmonization efforts will be undertaken by the Healthcare Information Technology Standards Panel (HITSP), a cross-sector initiative that is administered by ANSI. If sufficient funds are raised, HITSP will convene a workgroup of technical experts and stakeholders in the clinical research space to work through the Interoperability Specification (IS) development process, ultimately producing a document that outlines the standards, how they support clinical research, and how they fit with existing HITSP IS that are already recognized for EHR use in the clinical care environment.

Stakeholders in the clinical research community can expect the value case to result in an increased return on the investment of their research dollar, greater reliability and efficiency of clinical data interchange, greater numbers of clinicians and patients participating in research, and enhanced usability of this highly valuable patient information.

“The clinical research community must have a voice in the development of EHRs to ensure that globally accepted clinical research standards are recognized, leveraged, and included in the harmonization process,” said Dr. Kush. “We are deeply appreciative of the many organizations who have already committed their support to this initiative, but another \$100,000 is still needed to help fund the work effort. We ask that all stakeholders seriously consider supporting this vital initiative for the future of global clinical research.”

Interested parties are asked to offer their commitment of funds before Monday, March 2, 2009. For more information or to make a contribution, please contact Dr. Kush (512.791.7612; [rkush@cdisc.org](mailto:rkush@cdisc.org)) or Ms. Schrotter (212.642.4934; [fschrott@ansi.org](mailto:fschrott@ansi.org)).

### **[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.

### **[About HITSP](#)**

Operating under contract to the U.S. Department of Health and Human Services (HHS), the 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.