



Date: January 2009

Re: Global Clinical Research Standards

CDISC, the Clinical Data Interchange Standards Consortium is an international standards development organization whose 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"***.

As members and/or supporters of the Clinical Data Interchange Standards Consortium (CDISC) Global Expert Group, we wish to encourage the advocacy and adoption, along with continued collaborative development, harmonization and support of the CDISC global clinical data standards that facilitate the clinical research process while integrating it into the healthcare arena.

Over the past 11 years, CDISC has established a set of complementary standards that support the acquisition, exchange, submission/reporting and archive of clinical research data. These standards have wide-ranging support and implementation within the clinical research environment as well as support from regulatory authorities, the U.S. Food & Drug Administration being one. Additionally, and in keeping with its mission, CDISC led the development of a domain analysis model for the protocol-driven research domain (Biomedical Research Integrated Domain Group – BRIDG model) such that the CDISC standards can be harmonized with those of healthcare, specifically Health Level Seven (HL7) through its Reference Information Model (RIM). CDISC holds Liaison A status with the ISO TC 215 for Healthcare Standards and is a member of the Joint Initiative Council [International Standards Organization (ISO TC 215), European Committee for Standardization (CEN 251), Health Level Seven (HL7), CDISC and now the International Health Terminology Standards Development Organization (IHTSDO, i.e. SNOMED)]; the JIC is a collaborative group that works towards ensuring harmonized and interoperable standards globally.

CDISC has significant and growing presence in Japan, Europe, China as well as the United States, along with CDISC Coordinating Committees and self-established user networks within these areas of the world. In addition, CDISC has provided education in India, Australia, Brazil and Singapore. CDISC is collaborating with numerous different organizations to develop globally harmonized terminology to support the clinical research standards; these include (but are not limited to): FDA, ICH, EMEA, ISO, HL7, the US National Cancer Institute, the US Health Information Technology Standards Panel, and the Global Tuberculosis Alliance.

Use of disparate proprietary clinical research standards (which effectively means not having a real standard) leads to inefficiency and extra costs in clinical research. In contrast, the worldwide acceptance of a global set of interrelated and interoperable standards for the clinical research domain and the related areas of healthcare, such as what CDISC has developed, will benefit all stakeholders, including regulatory authorities, research sponsors, technology and service providers, investigators and most importantly, patients. There is flexibility that can be leveraged in the CDISC standards in terms of being able to support different languages and other local needs, without imposing the need to develop a new and different standard. The consensus-based and collaborative approach of CDISC in working with other organizations has been a key strength and an asset to achieving its respected position in the global standards community while supporting all stakeholders' interests.

We support the continued collaborative development and global adoption of CDISC standards and encourage others to join this effort to enhance the collective power of the standards community in advancing the improvement of public health by streamlining clinical research and healthcare through standards.

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