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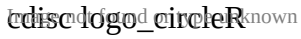

CDISC Announces Groundbreaking Clinical Trial Registry XML Standard

New CDISC CTR-XML standard enables submission of clinical research data to multiple global clinical trial registries

Austin, TX – 28 April 2016 – The Clinical Data Interchange Standards Consortium (CDISC) announces today the open availability of a new CDISC standard, Clinical Trial Registry (CTR) XML. Clinical trial registries are official platforms and catalogs for registering clinical trials. This innovative standard will make it possible to build applications that generate submissions for multiple, global clinical trial registries; specifically the World Health Organization (WHO), European Medicines Agency (EMA) and to the United States' ClinicalTrials.gov from a single file.

At its core, the CTR standard is inspired by the International Committee of Medical Journal Editors (ICMJE), and is based upon the 20-item WHO Trial Registration Data Set as well as EudraCT specific extensions. The CTR standard maximizes the re-use of existing CDISC transport standards by extending the Operational Data Model (ODM-XML) and including Study/Trial Design Model (SDM-XML) content. This makes the standard a more general solution that any trial registry could potentially use as the means to populate their registry with structured content from a clinical trial sponsor's systems.

"This standard will save the industry a lot of time in registering trials with multiple registries and is an essential step toward creating registries that house consistent, high-quality data, which will make them more useful to patients seeking research trials," stated Paul Houston, Head of the CDISC Europe Foundation.

"Efficient and high quality registry and results data are achieved when data can be mapped consistently to the sponsor systems that are used to plan and execute clinical trials," added Neil John Newman of the European Federation of Pharmaceutical Industries and Associations (EFPIA). "Using the clinical and data expertise of CDISC promotes harmonisation and demonstrates a concrete effort to address the demands of the public, clinical researchers and industry for access to consistent information concerning clinical research, globally. This CDISC standard for CTR-XML is a very positive first step."

Mr. Houston continued, "The next stage will extend the standard, creating an underlying structured protocol standard, results summaries and Identification of Medicinal Products (IDMP) compliance (an ISO standard),

to further increase the richness, reliability and traceability of registry information."

CDISC is looking for volunteers and sponsors to join the CTR team for stage two; please email phouston@cdisc.org for details. For more information about CTR-XML and to view organizations that have sponsored this effort, please visit the CTR-XML page on the CDISC website.

About the organizations:

cdisc logo_circleR

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CDISC is a 501(c)(3) global non-profit charitable organization that streamlines research and enables connections to healthcare through the development of clinical research data standards. CDISC has developed a suite of standards to support clinical research from protocol through analysis and reporting. CDISC standards make it possible for data to speak the same language, empowering simple data collection and private sharing that makes the most of the valuable information offered by patients participating in research studies around the globe. Using CDISC standards from the start of studies enables Smarter Research to Unlock Cures (www.unlockcures.org), saving ~60% overall in terms of time and resources to conduct research. CDISC is the patient's advocate, creating therapeutic area data standards for over 25 different disease areas that advance medical product development and various types of clinical research.

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