Unlocking a Global Language for Smarter Research

Overview: The opportunity to transform clinical research is at our fingertips with new technologies and global standards available. Still, we continue to struggle with a number of research-related activities including, but not limited to: a) preparing and implementing useful data-sharing plans when data are collected in different formats; b) readily exchanging and aggregating sufficient data to support biomarker identification; c) mapping data into standards at the end of a study; d) deploying EHRs with data stored in proprietary formats that do not readily support the data quality and breadth necessary for clinical research; e) storing data in silos that are not accessible; f) ensuring traceability, privacy and security of data from patients. These frustrations are widespread and prevent efficient and effective learning from evidence generated through research or healthcare.

CDISC standards support research, from protocol development and trial registration, to patient-level data collection and data aggregation across patients to tabulation, to analysis and publication or regulatory submissions. The global data standards used for clinical research support all types of research, including outcomes, observational, public health and the development of new therapies for patients. CDISC has led the consensus-based development of data standards for over 25 different therapeutic areas (TA), including standards for research in areas such as Vaccines, Nutrition, outbreaks/epidemiology, QT studies, Imaging and major disease areas such as Oncology, Cardiovascular disease, Diabetes, Alzheimer’s disease, Parkinson’s disease, Hepatitis C and others.

CDISC standards for data tabulations and analysis datasets will be required by FDA and Japan’s PMDA for aggregated patient data submitted to support the approval of new biopharmaceutical products. CDISC has also worked with HL7 and IHE to develop standards that enable the use of EHRs and other eSource tools such as smart phones to facilitate workflow from patient care to medical research, enabling a learning health system.

This Symposium will provide an overview of CDISC and its suite of harmonized and curated standards for clinical research. These standards are available electronically via the Shared Health and Research Electronic Library (SHARE), CDISC’s metadata repository. In terms of data quality and ROI, the value of using CDISC standards from the start of a research study will be discussed. Details on the process for developing TA standards and information on how researchers can actively participate in the development stages and/or the comment periods will also be provided.

Objectives

- Explore how beginning-to-end CDISC standards can enhance and streamline the process for any type of research study, from protocol through analysis and reporting, while enhancing innovation
- Learn how CDISC standards now support over 25 disease areas representing millions of patients worldwide
- Gain an awareness of approaching regulatory requirements for using CDISC standards, and what this could mean for your research
- Become familiar with the CDISC standards development process and how you can help shape emerging standards

Date: Friday, 30 September 2:00 pm – 5:00 pm

Pricing: Platinum Member and Academic/Gov/Non-profit - $75; Gold Members - $95; Non-Members - $150

Audience: Clinicians, clinical researchers and scientific investigators interested in ways to represent clinical research data to accelerate study start-up, enhance the value of research data and streamline research processes.

Presenters: Dr. Rebecca Kush, Founder and President/CEO, CDISC; Barrie Nelson, VP, Standards, Terminology and Technical Services, CDISC; Rhonda Facile, VP, Standards Development, CDISC

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