Strength through collaboration.

Collective Power

CDISC (Clinical Data Interchange Standards Consortium) operates to advance the continued improvement of public health by enabling efficiencies in medical research and related areas of healthcare. As a catalyst for productive collaboration, CDISC brings together individuals spanning the healthcare continuum to develop global, open, consensus-based medical research data standards.

Key industry leaders like yourself and CDISC’s vision for the future of healthcare are critical. Together, we can leverage a dynamic set of living standards to truly enable and empower the medical research community to better share and exchange information. The value—easily accessing shared knowledge and achieving data consistency across the spectrum, from discovery to clinical care—

Unique Insight

- Standardization removing drug development from discovery through market delivery for the biopharmaceutical industry to pivotal to this process, standards give us a common focus and encourage further collaboration with our peers. Together, we can guide the industry toward borderless innovation.

Standards provide a shared database of knowledge that ensures drug safety in an era of escalating safety concerns. In a clinical study site, an efficient standard method of data collection across studies can help site personnel do what they do best—apply their unique insight to provide advanced patient care.

Similarly, the service and technology industries are under mounting pressure to support methods and tools for safe product development and public health. Standardization streamlines the development process through collaborative research and solidifies data and product quality, productivity and customer satisfaction, yielding us all a competitive advantage.

At the forefront of biomedical research standards development since its inception in 1997, CDISC has helped guide the industry by enabling a collective voice. CDISC has leveraged best practices to develop and establish standards with the involvement of key leaders spanning the entire process from pre-clinical research to healthcare delivery.

Making History

In 1999, 32 global companies took action to establish a set of standards to maximize experiences and insight from all members of the medical research community by becoming charter sponsors of CDISC. The result was the establishment of a progressive, global, non-profit organization to support the electronic acquisition, exchange, submission and archive of clinical and pre-clinical study data.
You are Essential

- Here, your ideas know no boundaries. Your insight enables the power of CDISC. Without it, productive collaboration is impossible. For these reasons, we are actively seeking the membership and participation of industry influencers like you and your organization. To find out more about how you can affect industry change through CDISC, please visit us at www.cdisc.org. You may also contact us directly at 1-512-541-9885 to learn more about the value of membership and different membership types.

You are CDISC

CDISC is comprised of nearly 200 organizations spanning the globe. Our members include leading global biotechnology and pharmaceutical development companies, device and diagnostic companies, CROs and technology providers, as well as government institutions, academic research centers and other non-profit organizations.

You are hereby encouraged to seek the membership and participation of your organization in CDISC. Without it, productive collaboration is impossible. Here, your ideas know no boundaries.

CDISC is your voice. Your voice to affect change.

Setting the Global Standard for Medical Research

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Healthier

- We are all witnessing firsthand the evolution of healthcare and will be forced to make a decision on how we will respond. Through continued collaboration with leaders like you, we believe we have the ability to shape and guide the industry towards a better tomorrow.

Efficiency

Today

CDISC standards catalyze information flow through the entire pre-clinical and clinical research process, from study protocol and various sources of data collection to analysis and reporting through regulatory submission and electronic data archive.

Core Data Tabulation Model (SDTM)
The content standard for regulatory submission of case report form data extractions from clinical research studies.

Analysis Data Model (ADAM)
The content standard for regulatory submission of analysis datasets and associated files.

Operational Data Model (ODM)
The XML-based content and format standard for the acquisition, exchange, importing or submission, and archival of case report form (CRF)-based clinical research data.

Laboratory Data Model (LDM)
The content and format standard for the data transfer between clinical laboratories and study sponsors/CROs.

Case Report Tabulation Data Definition Specification (CDASH - eCRF Document)
The XML-based content and format standard referenced by the FDA as the specification for the data definitions for CDISC SDTM datasets. This standard, also known as define.xml, is an extension of the ODM.

Standardized Exchange of Nonclinical Data (SEND)
An extension of the ODM for submission of data from pre-clinical studies.

CDISC is always growing. Always evolving. Effective in 2001, the organization recognized the need to connect electronic data generated during the pre-clinical and clinical research process with that generated during healthcare delivery. To fulfill the industry need, CDISC entered into an original agreement with HL7 with the goal of forming a standards-based information bridge joining the efforts of HL7 with CDISC standards.

CDISC introduced the Biomedical Research Integrated Domain Group (BRIDG) Model-a clinical research domain analysis model to harmonize and connect the entire spectrum.

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Clinical Research Standards (CDISC)

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