

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.

Strength through collaboration.

Collective Power

→ More efficient time to market. Lower development cost. We hear the demands daily, but how can we as an industry deliver on these expectations? By learning from each other. Working together. Collaborating to achieve future goals for our organizations and the healthcare industry. Increased research and development costs threaten the safety and advancement of public health. Fortunately, you are in a position to help ensure that the integrity of clinical research is maintained for our organizations and the public — through the implementation of data standards, our industry can flourish.

CDISC standards implemented at the beginning of a clinical study can reap savings of 70-90% of the start-up stage time and cost, for an overall study resource savings of 60% (outside of the subject participation time). The resulting efficiencies would allow the industry as a whole to save billions of dollars and also to concentrate on developing products that meet escalating safety, public health and regulatory requirements.

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 streamlines drug development from discovery through market delivery. For the biopharmaceutical industry, 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 2000, 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 this reason, 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 919.419.7100 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.

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.

Study Data Tabulation Model (SDTM)

The content standard for regulatory submission of case report form data tabulations 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, reporting or submission, and archival of case report form (CRF)-based clinical research data.

Laboratory Data Model (LAB)

The content and format standard for data transfer between clinical laboratories and study sponsors/CROs.

Protocol Representation (PR)

The content and format standard supporting the interchange of clinical trial protocol information. This is a collaborative effort with Health Level Seven (HL7).

Trial Design Model (TDM)

The content standard that defines the structure for representing the planned sequence of events and the treatment plan of a trial. This is a subset of the SDTM and Protocol Representation.

Clinical Data Acquisition Standards Harmonization (CDASH)

A CDISC-led collaborative initiative to develop the content standard for basic data collection fields in case report forms. This standard is based upon the SDTM.

Case Report Tabulation Data Definition Specification (CRTDDS) – (define.xml)

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.

Standard for Exchange of Nonclinical Data (SEND)

An extension of the SDTM standard for submission of data from pre-clinical studies.

Terminology

The controlled standard vocabulary and code sets for the all CDISC models/standards.

Glossary

The CDISC dictionary of terms and their definitions, related to the electronic acquisition, exchange and reporting of clinical research information. Abbreviations and acronyms are also listed.

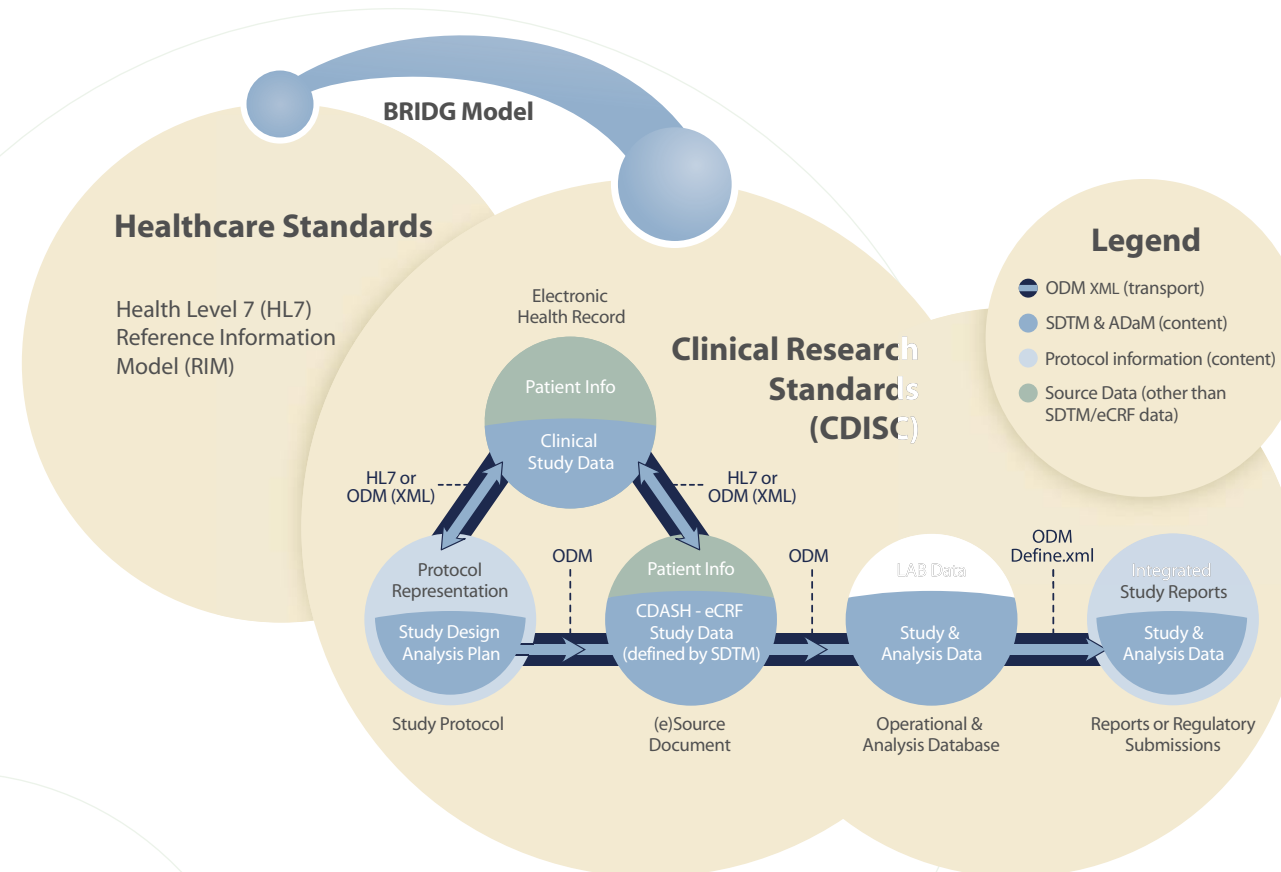
CDISC is always growing. Always evolving. In 2001, the organization recognized the need to connect electronic data gathered during the pre-clinical and clinical research process with that gathered during healthcare delivery. To fulfill the industry need, CDISC chartered an original agreement with HL7 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.



Setting the Global Standard for Medical Research

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Healthier Tomorrow

→ 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.

The collective power of our insight is helping to advance the FDA's proposal of a Critical Path to New Medical Products, challenging innovation vs. stagnation, and similar initiatives in other areas of the globe, such as the EU Innovative Medicines Initiative. Together our efforts to streamline clinical studies are being realized through the development and establishment of the CDISC standards. In particular, clinical data collection for sites and study sponsors, vendors and CROs through standard case report forms is catalyzed through the CDISC-led Clinical Data Acquisition Standards Harmonization (CDASH) initiative. True success requires that we work together as a larger scientific community to employ these solutions. Because of you, the value and innovation of a Critical Path to New Medical Products can be a reality.

Our goal is to provide you the platform from which you can apply innovative standards for the future — a set of standards that have been optimized and accounts for a combination of best practices in data collection, conduct and reporting to support the necessary communication required among all research partners in the application of clinical and translational sciences to improve the public health.

CDISC is your voice. Your voice to affect change.