

# Current status and future scope of CDISC standards



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## 1. Introduction

In translational research, research information is used to inform healthcare decisions, and healthcare information is used for research (Fig. 1). This cycle, however, is too long and inefficient and needs to be shortened, which is basically the vision of CDISC (Clinical Data Interchange Standards Consortium).

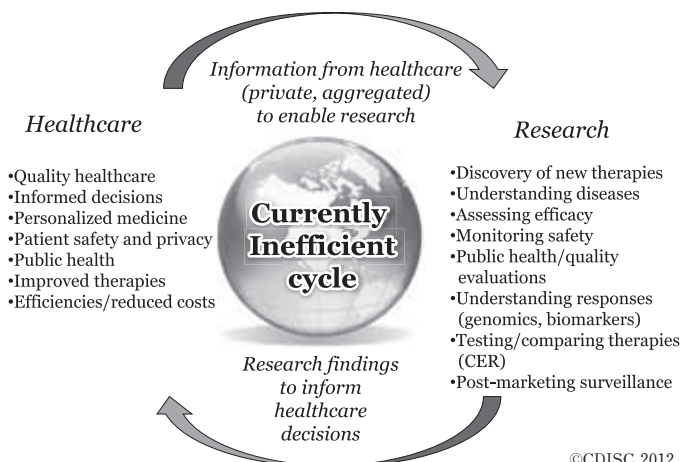
The CDISC vision is ‘to inform patient care and safety through higher quality medical research’. CDISC is a standards developing organization. It is global, open, multidisciplinary, vendor-neutral, and non-

profit, and it was founded in 1997. There are approximately 300 member organizations from academia, biopharmaceutical companies, device companies, technology and service providers and other companies.

CDISC develops and teaches educational courses around the world. It has active coordinating committees in Japan, China, Korea, and Europe, and about 20 user networks around the world. Individuals from about 90 different countries are downloading the CDISC standards around the globe (Fig. 2).

CDISC has established worldwide industry standards starting with protocol representation through

**Fig. 1 Healthcare-research information cycle**



analysis and reporting to support the electronic acquisition, exchange submission, and archiving of clinical research data and metadata. The idea was to improve the quality of research and to streamline the process. It uses a consensus-based standards development approach, documented in the CDISC Operating Policy (COP-001). CDISC has an IP (intellectual property) Policy that ensures the standards stay open and free.

CDISC has an agreement with Health Level Seven (HL7) and holds a Liaison A status with the

International Organization for Standardization (ISO) Technical Committee 215 for healthcare standards. CDISC is the current leader of Joint Initiative Council (JIC), which is a group of six different standards developing organizations that are committed to global harmonization of standards.

## 2. Global standards for protocol-driven research

The CDISC foundational standards support research planning, protocol development, study design, data collection, tabulation of data, and statistical data analysis (Fig. 3). The CDISC transport standards help move the standard CDISC content. Semantics has to do with the glossary and terminology. CDISC implementations include standards that support implementations for Therapeutic Area (TA) Standards; the foundational standards are mostly safety standards, and TA standards address efficacy. Innovation pertains to the use of standards such as integration profiles that improve workflow and processes improvements.

Fig. 2 CDISC around the globe

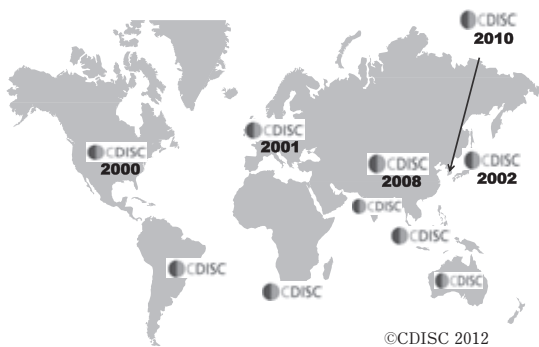
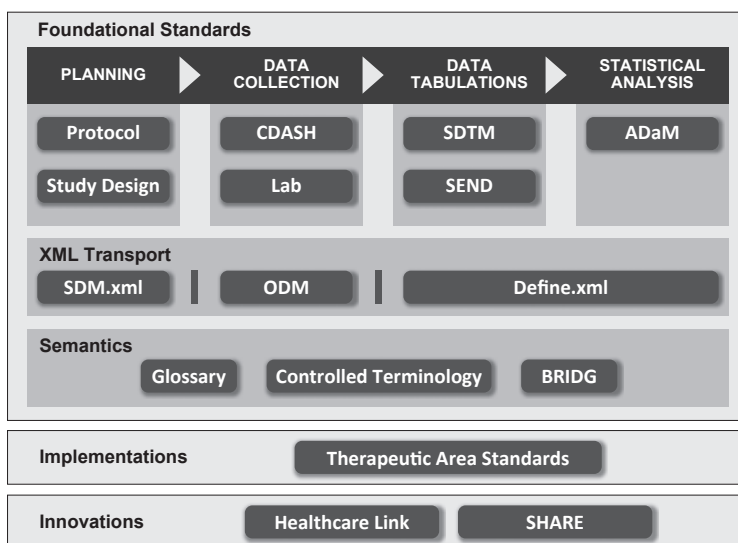


Fig. 3 Global standards for protocol-driven research



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### 3. Gartner-PhRMA-CDISC business case

CDISC has conducted a business case with Gartner to assess the business value of the standards. The value increases the further upstream in the process the standards are implemented. For example, standards can help reduce the startup time of a clinical study by 70% to 90% when used upfront in designing case record forms and developing the protocol. They improve the overall process by ~ 60%.

In addition to saving time and resources (including money), CDISC standards improve data quality. They enable the integration of data and enhance re-usability of the data. Standards facilitate data exchange from different partners and enable the use and choice of software tools. They improve communication amongst teams and facilitate regulatory reviews and audits.

### 4. Strategic goals: 2012-2015

The CDISC Board of 2011 developed a new set of five strategic goals for CDISC for the coming 3 years.

The first strategic goal is to achieve significant progress in the use of CDISC standards to allow scientifically sound data aggregation and support the secondary uses of research data for the purposes of scientific investigation and comparative effectiveness.

The second strategic goal is to achieve significant progress in enabling interoperability between clinical care and clinical research and explore the expansion from bench to bedside (translational research); accelerate the cycle through which healthcare informs research and research informs clinical decisions.

The third strategic goal is to expedite the development and rollout of therapeutic area standards, while continuing to refine, support, and educate on the existing foundational standards to ensure consistency in data capture and analysis related to efficacy in addition to patient safety.

The fourth strategic goal is to develop SHARE (Shared Health and Clinical Research Electronic Library), a global, accessible electronic library for CDISC content/semantics that will enable precise standardized data element definitions and richer metadata that can be reused within applications and across studies to improve biomedical research and its link with healthcare.

The fifth strategic goal is to leverage the global non-profit, vendor-neutral, independent status of CDISC to forge productive collaborations with and provide value to key stakeholder communities.

### 5. CDISC: Mission statement

The CDISC's mission statement is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

### 6. CDISC collaborations

CDISC has a number of very important collaborations in keeping with our motto of "Strength through Collaboration". This section describes key CDISC collaborations in terms of how they fit with the 2012-2015 strategic goals (productive collaborations being the fifth strategic goal).

One of these important collaborations is with the Critical Path Institute, which was formed after the FDA produced its document about the Critical Path Initiative 2004.

According to the Critical Path Institute, CDISC

standards provide efficient collaboration and exchange of information. They enable efficient collaboration, better science and regulatory efficiency. The Coalition Against Major Diseases (CAMD) was started by the Critical Path Institute. They received data from different companies and organizations from clinical research studies conducted with patients with Alzheimer’s Disease. The data was mapped into CDISC standards and aggregated into a database that currently has over 5,000 patients’ worth of Alzheimer’s Disease data. This database is open to public researchers for review and analysis to see if a cure can be found for Alzheimer’s Disease (Fig. 4).

Organizations can now leverage the Alzheimer’s Disease standard and collect data upfront in a standard format and make it more productive and of higher quality. (This is an example of the first CDISC strategic goal.)

With regards to other therapeutic area standards, CDISC has been partnering with different organizations on many such standards. The FDA


has posted 55 therapeutic area standards that they would like to see developed over the next 5 years. CDISC is currently working with C-Path to evaluate how best to develop such standards. (This is in line with CDISC’s third strategic goal.)


CDISC SHARE is another strategic goal. It is a globally-accessible electronic library which enables precise and standardized data element definitions, including value sets that can be used in applications and studies to improve biomedical research and its link with healthcare. Currently, SHARE does not exist. There is ongoing work in assessing partners and figuring out ways to build the infrastructure for SHARE.

In the meantime, CDISC has partnered with the National Cancer Institute (NCI) and uses their Enterprise Vocabulary Services (EVS) which is open and freely available to anyone around the globe, which was one of the requirements for CDISC controlled terminology. (The fourth strategic goal is to build and launch SHARE, and it is hoped that can happen this year.)

Fig. 4 Alzheimer’s Disease standard and database

**Press Release: June 10, 2010**





**CRITICAL PATH  
INSTITUTE**

***Initial database required mapping to a standard (CDISC); can now be leveraged to collect data using the standard***

**COALITION AGAINST MAJOR DISEASES**

**Public Announcement June 11, 2010**

*collaborate • innovate • accelerate*

**PUBLIC RELEASE OF ALZHEIMER’S CLINICAL TRIAL DATA BY PHARMACEUTICAL RESEARCHERS**  
**First Combined Pharmaceutical Trial Data on Neuro-degenerative Diseases;**  
**Shared Resource from Unique Public-Private Partnership Will Help Accelerate Alzheimer’s, Parkinson’s, and Other Brain Disease Research**

Washington, DC – A new database of more than 4,000 Alzheimer’s disease patients who have participated in 11 industry-sponsored clinical trials will be released today by the Coalition Against Major Diseases (CAMD). This is the first database of combined clinical trials to be openly shared by pharmaceutical companies and made available to qualified researchers around the world.

Another important collaboration is the Innovative Medicines Initiative (IMI), which is a partnership between the European Union and the pharmaceutical manufacturers of Europe (EFPIA: European Federation of Pharmaceutical Industries and Associations) to collaborate (along with the academic community and others) towards innovative medicines.

CDISC and IMI have signed a memorandum of understanding to communicate and identify areas of mutual interest, primarily around knowledge management from all the IMI projects. CDISC has been providing introductory courses to IMI participants, specifically a course called “A Global Approach to Accelerating Medical Research”. IMI will be using CDISC standards by default, if they exist. If the standards do not exist, then IMI would partner with CDISC in developing those standards.

There is ongoing work on IMI projects as well, including the use of Electronic Health Records for Clinical Research (EHR4CR), Drug Disease Model Resources (DDMoRe), Vaccine Safety, and a proposal for a European Translational Information and Knowledge Management Services (eTRIKS).

CDISC has collaborations with a number of regulatory authorities. The review community of the United States FDA is asking for electronic submissions to use CDISC standards in order to improve the quality of their reviews. FDA has awarded a grant to CDISC for virology standards and to improve and speed up developing therapeutic areas standards. The Office of Scientific Investigation is also looking at eSource opportunities based upon the CDISC eSource Data Interchange document, which is referenced by EMA (European Medicines Agency).

## 7. Supporting activities in Japan

CDISC has an important collaboration with the

Translational Research Informatics Center (TRI). TRI has translated CDISC’s glossary and standards into Japanese, and these are now posted on CDISC’s website and made available in Japan. TRI is also using the Alzheimer’s Disease standard in an international research study. There are other opportunities for CDISC and TRI to collaborate as well.

The Japan CDISC Coordinating Committee (J3C) is working also on collaborations for CDISC within Japan, e.g. with TRI, JPMA (Japan Pharmaceutical Manufacturers Association), PMDA (Pharmaceuticals and Medical Devices Agency) and MHLW (Ministry of Health, Labour and Welfare).

## 8. Optimizing the research process

One of the strategic goals of CDISC (the second) is to look at the link between healthcare and research and to optimize the research process. The idea is to use Electronic Health Records (EHR) as an electronic source of information for research, which can optimize the reconciliation between healthcare and research and streamline the process in addition to increasing the capacity of research clinicians and patients.

In 2006, FDA asked CDISC to help them encourage the use of electronic technology, such as electronic dairies or electronic source data within the context of their existing regulations. The goal was to make it easier for physicians to conduct a clinical research, to collect the data once in an industry standard format for multiple downstream uses, and to improve data quality and patient safety.

By 2006, CDISC had produced the eSource Data Interchange (eSDI) Document. This formed the basis for the Retrieve Form for Data Capture (RFD) Integration Profile. EMA references the CDISC requirements from the eSource Data Interchange Document and has published a docu-

ment called the “Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials,” which has become an EMA guidance that pertains to field audits of investigative sites.

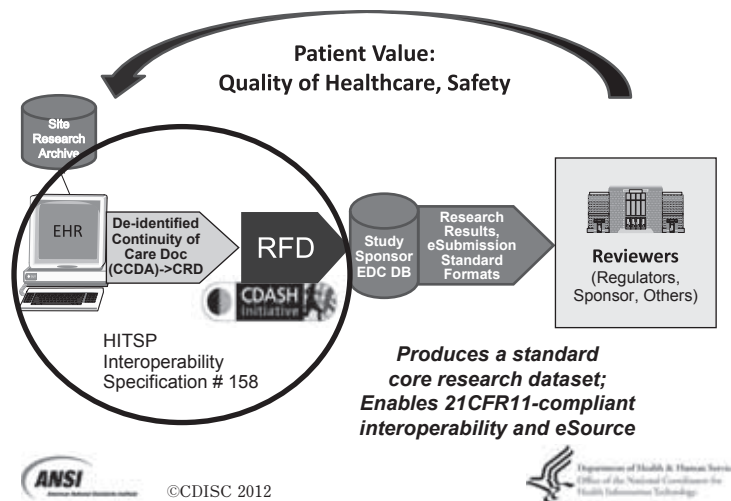
CDISC concurrently did a pilot called Single Source designed to bring patient care and research together using Electronic Health Records (EHR) for research. Landen Bain implemented the EHR at the Duke University Medical Center. Hence, CDISC worked with Mr. Bain and partnered with the Duke Clinical Research Institute (DCRI), Novartis, Merck, Johnson and Johnson, and Microsoft to do the pilot. After the pilot showed that this concept could be achieved, the next step was development of Retrieve Form for Data Capture (RFD), an integration profile, which was developed in collaboration with the IHE (Integrating the Healthcare Enterprise).

Through the U.S. Department of Health and Human Services (HHS), ANSI (American National Standards Institute) and Healthcare Information

Technology Standards Panel (HITSP), a use case was then developed and standards identified to enable the production of a core set of research data from EHRs. The idea was to take the clinical care data and electronic health record and produce a standard, common research dataset to be used for multiple downstream purposes, including research studies, registries, FDA reviews, publications, data safety monitoring boards.

The three ‘standards’ identified were the Continuity of Care Document (CCD), which is mapped to a Clinical Research Document (CRD); use of IHE RFD for workflow integration, and CDISC CDASH (Clinical Data Acquisition Standards Harmonization), which is the core data collection standard. This was called the Interoperability Specification # 158. There are now implementations using RFD for quality, clinical research, and public health. These are demonstrating its value in streamlining such processes for the secondary use of EHR data (Fig. 5).

**Fig. 5 Streamlining the research process using EHRs and standards**



## 9. BRIDG (Biomedical Research Integrated Domain Group) Model

Finally, about the BRIDG Model, it is a domain analysis model for the clinical research domain, with a scope of protocol-driven research. It has been developed with CDISC, HL7, FDA, and NCI as a collaborative project. It is now bridging organizations, bridging standards, and bridging research and healthcare. It is being linked with the NCI Life Sciences Domain Analysis Model and the HL7-CDISC Clinical Genomics Domain Analysis Model.

In this way, the BRIDG Model is helping to bridge translational research and clinical research.

BRIDG is ensuring harmonization of all of the CDISC standards and other standards relevant to protocol-driven research. BRIDG is a CDISC and an HL7 standard and is going through the Joint Initiative Council (JIC) process, which means that will also be an ISO standard and a CEN (Comité Européen de Normalisation, European Committee for Standardization) standard.

In conclusion, CDISC is more than just standards. It is about standards-inspired innovation, process redesign, workflow integration, and quality improvement for medical research.

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