CDISC Vision & Mission

The CDISC Vision is to inform patient care and safety through higher quality medical research.

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

CDISC is a 501(c)(3) non-profit charitable organization, with over 300 member organizations across the healthcare industry. Our organization and members are committed to maximizing the value of medical and research information, to streamlining the research process and to accelerating the translation of research findings into clinical decisions that benefit patients around the globe. CDISC has been made possible by the efforts and support of thousands of dedicated volunteers, collaborating to realize the CDISC vision and mission. CDISC global consensus-based standards for medical research and its link with healthcare are vendor-neutral, platform-independent and freely available via the CDISC website.

CDISC was initiated as a volunteer organization in 1997 and was incorporated as a non-profit organization in February 2000. In May of 2011, CDISC attained 501(c)(3) status, recognizing it as a charitable organization. Since 1997, teams of volunteers have ensured that efficient, consensus-based standards have been produced through the CDISC Standards Development process. The standards development process was updated in 2012 (using lessons learned from the development of a number of therapeutic area standards) to an improved, accelerated process that is now being implemented.

CDISC released its first production models in 2000 and has had a steady record of accomplishment ever since. In 2013, the U.S. Food and Drug Administration and the Japan Pharmaceuticals and Medical Devices Agency released documentation announcing the intent to require data in CDISC format in the coming years. Additionally, the European Medicines Agency, Korea Food and Drug Administration and China Food & Drug Administration are considering researching the use of CDISC standards.
The Organization

CDISC Timeline

<table>
<thead>
<tr>
<th>The Organization</th>
<th>1997-1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
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</thead>
<tbody>
<tr>
<td>Volunteer Group Initiated</td>
<td>Non-profit incorporation 501c6 (32 Charter Members)</td>
<td>100 Member Organizations</td>
<td>5-year Anniversary (~150 member orgs)</td>
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Teams

CDISC Standards and Innovations

<table>
<thead>
<tr>
<th>Modeling and Nomenclature Groups &gt; Glossary Group &gt; ODM (DAS) and SDS</th>
<th>ADaM and LAB Teams</th>
<th>SEND Team</th>
<th>Protocol Representation Group (CDISC-HL7)</th>
<th>Terminology Team; BRIDG Groups</th>
</tr>
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<tbody>
<tr>
<td>SDS v1.0 and ODM v0.8</td>
<td>SDS v1.1</td>
<td>ODM v1.1</td>
<td>LAB v1.0; SDTM v3.0; SEND 1.0; LAB V3 Message passed ballot</td>
<td></td>
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<tr>
<td>New versions annually thereafter</td>
<td>ODM v1.2; SDTM v3.1; ODM v1.2.1; SDTM v3.1.1; ODM mapped to HL7 RIM</td>
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Globalization

Collaborations

Foundational Standards

Protocol Representation Model
BRIDG-based model and tools for representing standard clinical research protocol elements and relationships.

CDASH
Clinical Data Acquisitions Standards Harmonization is a specification describing basic data collection domains and variables for CRF data with standard question text, implementation guidelines, and best practices.

LAB
Specification describing standard content for the acquisition and interchange of clinical laboratory data between central labs and sponsors or CROs.

ODM
Operational Data Model - XML Schema specification for the regulatory compliant acquisition, exchange and archive of clinical trials data and metadata.

Define-XML
XML Schema specification based on ODM to describe metadata for SDTM, SEND and ADaM submission datasets.

Dataset-XML
XML Schema specification based on ODM for representing study datasets associated with Define-XML metadata.

ADaM
Analysis Data Model describing fundamental principles and standards for representing analysis datasets and metadata.

ADaM Time to Event Model
ADaM Adverse Event Model

SDTM
Study Data Tabulation Model – general model for representing study tabulation data used in clinical research.

SEND
Standard for Exchange of Nonclinical Data: SDTM IG describing domains and variables for data from nonclinical studies.

Semantics

Glossary
Glossary with definitions of acronyms and terms commonly used in clinical research.

Controlled Terminology
A set of standard value lists, developed and maintained in partnership with NCI Enterprise Vocabulary Services (EVS) to support CDISC standards such as SDTM, CDASH, ADaM from data collection through submission.

CDISC SHARE
CDISC Metadata Repository source for all CDISC standard metadata and terminology.

CDISC SHARE
• Single, trusted, authoritative source for CDISC data standards
• Concepts, metadata, collections, relationships, value sets across the full spectrum of CDISC content
• Supports change control, impact analysis and inheritance, transformation logic and governance workflows.
• Aligned with NCI Semantic Systems
• Links research to healthcare concepts to support interoperability

BRIDG
Biomedical Research Integrated Domain Group (BRIDG) UML model of the semantics of protocol-driven clinical research.

Facilities Data Exchange

SHARE

BRIDG, ISO21090
Protocol, CDASH, SDTM, ADaM
Terminologies

Implements access to data standards
Facilitates traceability
Re-use of concepts
Accelerates development of standards

Improve access to data standards
Facilities

Traceability
Re-use of concepts
Accelerates development of standards
CDISC Timeline


- CDISC Team and Streams; eSDI Group
- ISO Liasions Awarded; ASTER launched
- Critical Path Institute/CAMO/Alzheimers; Tufts–PD; ACC–CV disease
- Additional IHE Profiles Proposed (e.g. RPE); Greenway EHR–Outcome Implementation of RFD
- CDISC accepted into Joint Initiative Council (JIC) for Global Harmonization of Healthcare Standards
- CDISC-IHE Quality, Research and Public Health (QRP) Launched
- User Networks initiated in Europe (5 languages)

CDASH Team and Streams: eSDI Group

2006

- CDASH v1.3: LAB & SDTM Aligned; CDISC-IHE RDF
- ODM v1.3: LAB & SDTM Aligned; CDISC-IHE RDF
- C3C Initiated
- BRIDG v1.0, v1.1; BRIDG posted as open source model
- TR (Japan) MOU Signed
- TR (Japan) MOU Signed
- BRIDG v2.0, v2.1, v2.2 CDOM v1.0: eSDI Document Published
- ODM v1.3: LAB & SDTM Aligned; CDISC-IHE RDF
- 1-year anniversary since incorporated; ~ 250 member orgs

2007

- HTSP: Use Case (ERBs for Core Research Data) – Clinical Research Tiger Team Initiated
- Devices Team; SHARE Teams
- Protocol Representation Model (PRM) v1.2; BRIDG v1.0; CDOM v1.3; IHE-ONC/MHTSP Interoperability Specification #158; CDISC-IHE RPE
- TR (Japan) MOU Signed
- Medical Devices Team; eSDI Group
- Essential Standards to Enable Learning (ESTEL) Initiative Launched; 7 New CFAST Teams Initiated

2008

- Therapeutic Area Standards projects
- Clinical Research Tiger Team
- Research and Practice Committee
- CDISC-IHE Quality, Research and Public Health (QRP)
- CDASH v1.1; SEND v3.0; Study Design XML v1.0;
- CDASH v1.1; SEND v3.0
- Alzheimer’s Disease
- Parkinson’s Disease
- Polycystic Kidney Disease
- Tuberculosis

2009

- CDASH v1.2; ADaM v2.1
- Imaging CRF + CDISC-IHE RDF and RPE
- Alzheimer’s Disease
- Parkinson’s Disease
- Tuberculosis
- Asthma
- Questionnaires

2010

- SDTM v1.2; ADAM v2.1
- Data Sharing and Facilitate Global Regulatory Submission. A list of available them into CDISC standards to improve semantic understanding, support area concepts and endpoints for targeted therapeutic areas and translate 1-day CDASH Implementation 1-day ADaM Implementation ½-day Controlled Terminology Implementation
- 16-year anniversary since incorporated; ~ 250 member orgs
- Alzheimer’s Disease
- Parkinson’s Disease
- Polycystic Kidney Disease
- Tuberculosis
- Alzheimer’s Disease
- Parkinson’s Disease
- Polycystic Kidney Disease
- Tuberculosis
- Asthma
- Questionnaires

2011

- Alzheimer’s Disease
- Parkinson’s Disease
- Polycystic Kidney Disease
- Tuberculosis
- Therapeutic Area Standards

2012

- CDASH v1.2; ADAM v2.1
- Imaging CRF + CDISC-IHE RDF and RPE
- Alzheimer’s Disease
- Parkinson’s Disease
- Polycystic Kidney Disease
- Tuberculosis
- Asthma
- Questionnaires

2013

- Alzheimer’s Disease
- Parkinson’s Disease
- Polycystic Kidney Disease
- Tuberculosis
- Asthma
- Questionnaires

Therapeutic Area Standards

The goal of the development of CDISC Therapeutic Area (TA) standards, under the CFAST initiative, is to identify a core set of clinical therapeutic area concepts and endpoints for targeted therapeutic areas and translate them into CDISC standards to improve semantic understanding, support data sharing and facilitate global regulatory submission. A list of available TA standards is below:

- Alzheimer’s Disease
- Parkinson’s Disease
- Tuberculosis
- Asthma
- Questionnaires

Healthcare Link Standards

The CDISC Healthcare Link Initiative has developed a suite of CDISC-inspired IHE standards and enablers to improve the workflow of clinicians doing research, leveraging electronic health records and research systems.

- Alzheimer’s Disease
- Parkinson’s Disease
- Polycystic Kidney Disease
- Tuberculosis
- Asthma
- Questionnaires

Learn CDISC from CDISC!

The CDISC education program provides the only courses for the CDISC standards that are developed under the authority of a CDISC Operating Procedure (COP-005). This ensures that the course materials are developed with the cooperation of the CDISC technical teams and delivered by instructors who are selected through a rigorous set of qualification criteria.

Developed to advance the CDISC mission and to ensure distribution of authoritative educational courses across the medical research continuum, CDISC authorized courses are identified by the Education logo and are only available through CDISC Education. Look for the logo to be sure that you are receiving authorized CDISC education.

CDISC Authorized Education Courses:

1-day ADaM Implementation
1-day CDASH Implementation
½-day Controlled Terminology Implementation
1-day Deep Dive BRIDG Workshop
½-day Introduction to BRIDG
1-day LAB Implementation
1-day ODM Implementation
½-day Protocol Representation
2-day SDTM Theory and Application
2-day SDTM Theory and Application for Medical Devices
1-day Healthcare Link
2-day SEND

In Development for 2014:

- Dataset-XML
- Pharmacogenomics
- Online Courses:
  - SDTM
  - CDASH
  - ADaM
  - Controlled Terminology
  - BRIDG
  - Therapeutic Areas
Gold Member Benefits

1. **NEW!** Webinars for Members ONLY starting in 2014
2. **NEW!** Opportunity to be CDISC ODM certified
3. Access to ‘Members Only’ area on the CDISC website for every employee of member organization
4. 20% discount for CDISC Education Courses and CDISC Events
5. Opportunity to be a CDISC Registered Solution Provider
6. Opportunity to participate in CDISC’s licensed training program
7. Personalized Gold Member plaque

Platinum Member Benefits

All the Gold Member Benefits PLUS the following:

1. **NEW!** Platinum members will have free access to CDISC SHARE content in 2014
2. Representation on the CDISC Advisory Council (CAC), with the following benefits:
   - Networking opportunities and face-to-face meetings with peers, clients and visionaries
   - Opportunity for representation on Board Committees (Strategy, Technical and Financial)
   - Opportunity to vote a Board Member onto the CDISC Board of Directors
   - Opportunity to participate in Town Hall meetings with regulators and CDISC Board members
3. Additional 20% Discount (i.e. 40% total) for CDISC Education Courses and CDISC Events
4. CDISC Overview course CDISC “Global Approach to Accelerating Medical Research” can be given at Member site upon request
5. Personalized Platinum Member plaque