

Clinical Data Interchange Standards Consortium (CDISC)

 consortiapedia.fastercures.org/consortia/cdisc/

Research Areas



Tool Development

Standard



Data-Sharing Enabler

At a Glance

- Status: **Active Consortium**
- Year Launched: **1997**
- Initiating Organization: **CDISC**
- Initiator Type: **Third-party organization**
- Location: **International**

Abstract

CDISC is a 501(c)(3) global non-profit charitable organization that streamlines research and enables connections to healthcare through the development of clinical research data standards. CDISC standards make it possible for data to speak the same language, empowering simple data collection and private sharing that makes the most of the valuable information offered by patients participating in research studies around the globe. Using CDISC standards from the start of studies enables Smarter Research to Unlock Cures, saving ~60% overall in terms of time and resources to conduct research. CDISC is the patient's advocate, creating therapeutic area data standards that advance clinical research and medical product development for over 28 disease areas, with many more to come.

Mission

CDISC is an open, multidisciplinary, nonprofit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. Its 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 standards are



vendor-neutral, platform-independent, and freely available via the CDISC website.

Structure & Governance

The CDISC Advisory Council, formerly known as the Industry Advisory Board (IAB) and CDISC Advisory Board (CAB), consists of a representative from each corporate sponsor company. Duties of the CAC representatives include participate in Advisory Council Meetings (at least two times/year); participate in working teams and task forces; develop task forces that have assigned tasks in specific areas; support the CDISC strategic plan by providing input and advice into its development and implementation; and help with fundraising. The Advisory Council members may choose to participate in the working team and/or assign someone from their organization to participate.

Intellectual Property

The full intellectual property (IP) document can be accessed here:

http://www.cdisc.org/system/files/all/article/application/pdf/cdisc_20ip_20policy_final.pdf

Because it leads the development of standards, CDISC must protect those standards to ensure that, to the extent practicable, they remain neutral, open, compensation (royalty)-free, and without encumbering ties to prior intellectual property.

The IP policy is designed to facilitate the activities of CDISC in promotion of such open standards, to maximize the adoption of such standards by protecting against the ownership of such standards by one party, and to protect the legitimate intellectual property rights of contributors.

The policy ensures that CDISC is in accordance with its bylaws, other policies, and basic principles. For more information on CDISC, its bylaws, strategic plan, other policies, and basic principles, see the CDISC website at www.cdisc.org.

Each participant agrees that, upon request and subject to Sections 5.1 and 8, it will grant, to all parties implementing a final standard developed by a CDISC group in which it was a participant, a



nonexclusive, compensation-free (i.e., no royalty or other fee), nontransferable, non-sublicensable, worldwide, and otherwise reasonable and nondiscriminatory license under such participant's necessary claims covering such final standard, solely to make, have made, use, import, offer to sell, sell, lease, and otherwise distribute and dispose of licensee's products that implement such final standard; provided, however, that such commitment to license shall not apply to any necessary claims for which the participant does not have the right to license without obligation of payment of royalties or other material consideration by such participant to an unaffiliated third party. The commitment to license arising under this section shall be effective as of the date the party was first deemed to be a participant in the applicable CDISC group.

Data Sharing

CDISC SHARE, a cornerstone of the CDISC technical roadmap, will be a global electronic repository for developing, integrating, and accessing CDISC metadata standards in electronic format. SHARE is envisioned to help users find, understand, and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently, and to improve integration and traceability of clinical data from protocol through analysis.

Links/Social Media Feed

Homepage <http://www.cdisc.org/>

Facebook <https://www.facebook.com/pages/Clinical-Data-Interchange-Standards-Consortium-CDISC/198245526939534>

Twitter <https://twitter.com/CDISC>

Other website <https://www.youtube.com/user/CDISCInc>

LinkedIn https://www.linkedin.com/groups/CDISC-56393?home=&gid=56393&trk=groups_most_popular-h-logo&goback=%2E%2Fpiv_12216389512*43_335546_bNa6_*1_*1%2Egdr_1336686088308_1_*2

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