In the ever-evolving clinical research landscape, CDISC provides critical clarity to amplify data’s impact. We achieve this through individual contributions from our tremendous volunteers, member organizations, government regulators, and staff, who come together across the globe to harness their collective power to drive more meaningful research. Among the achievements in 2018, were the finalization of CDISC Library and the initial planning phase of an ambitious new project, CDISC 360. CDISC is innovating clinical data standards to ensure they remain valuable and relevant into the future.

CDISC grew in 2018 to more than 40 professional staff and nearly 100 contractors supporting a global community of more than 3,300 volunteers. At CDISC, we believe that standards training for all should be considered an ongoing commitment in order to maximize program efficiencies and progress you up your career ladder. To make this possible, in 2018 we invested in a year-long migration to a new online learning system. This easy-to-use system features interactive tools and augments the fine training already available via CDISC Interchanges, public and private events, and webinars. As a fellow student of standards, I encourage you to check into our online learning system. This easy-to-use system features interactive tools and augments the fine training already available via CDISC Interchanges, public and private events, and webinars. As a fellow student of standards, I encourage you to check into our online learning system.

In order to keep abreast of the changing needs of organizations, researchers, and regulators, the CDISC Board of Directors, under the leadership of Chair Stephen Pyke, an executive at long-time CDISC member company GSK, launched a Blue Ribbon Commission, co-chaired by HIMSS executive and CDISC Board member Joyce Sensmeier, RN, and Dr. Robert Califf, former Commissioner of US FDA. The Blue Ribbon Commissioners served as a strategic think tank for CDISC. The Blue Ribbon Commission was charged with preparing CDISC for the next phase of growth and development with work scheduled for completion in early 2019. This vision, in the form of written insights, will guide CDISC for the next decade.

CDISC continues a period of growth as more organizations are utilizing the CDISC standards and accruing the benefits of standardization of data. Medical and disease focused charitable groups are also taking notice and continue to provide the much needed funding it takes to continue in our efforts. Notably, The Leona M. and Harry B. Helmsley Charitable Trust has awarded CDISC with a significant Innovation Grant, which will fund standards development for specific disease focused organizations. The CDISC continues a period of growth as more organizations are utilizing the CDISC standards and accruing the benefits of standardization of data. Medical and disease focused charitable groups are also taking notice and continue to provide the much needed funding it takes to continue in our efforts. Notably, The Leona M. and Harry B. Helmsley Charitable Trust has awarded CDISC with a significant Innovation Grant, which will fund standards development for specific disease focused organizations.

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In the ever-evolving clinical research landscape, CDISC provides critical clarity. We develop and advance data standards of the highest quality to transform compatible formats, inconsistent methodologies, and diverse perspectives into a powerful framework for generating clinical research data that is as accessible as it is illuminating.

CDISC harnesses the vision and insights of each volunteer, member organization, and partner to define a focused approach for capturing and analyzing clinical research data. Pg. 5

For over 20 years, we’ve taken a rigorous approach to developing and advancing data standards. Pg. 6

CDISC offers classroom and online training opportunities as well as webinars covering a wide range of topics and experience levels. Pg. 11

Attending an Interchange, meeting, or volunteer event provides face-to-face interaction with the CDISC community. Pg. 12

CDISC standards and related innovations would not be possible without the dedicated volunteer efforts and financial assistance of our member organizations. Pg. 16

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Diverse Perspectives

Collaboration and inclusivity have always been bedrocks of CDISC’s culture – and they remain central to our process today. It’s why we convene a global community of experts from across the research spectrum and facilitate the development of standards that are open and available to all, enabling data sharing around the world.

Our strength derives from the diverse perspectives of our community. Whether coming from a pharmaceutical organization, academic institution, regulatory agency, non-profit, or beyond, our contributors bring a range of experiences and backgrounds that drive more meaningful clinical research.

Incoming Chair Doug Peddicord and David R. Bobbitt thank amateur beekeeper Steve Pyke with a personalized beehive box for his term as chair.

Convening a Community

CDISC harnesses the vision and insights of each volunteer, member organization, and partner to define a focused approach for capturing and analyzing clinical research data. When the entire research community works together, we have the power to solve issues too complex for any one individual, team, or organization to address alone.

Thank you to every CDISC volunteer! Your contributions of talent, knowledge, and insight form the core of CDISC’s work and are critical to every success.

2018 Board of Directors

Stephen Pyke, Chair
GSK

Douglas Peddicord, PhD, Chair-Elect
Association of Clinical Research Organizations (ACRO)

C. David Hardison, PhD, Past-Chair
Déloite

Jonathan Chainey
F. Hoffman-La Roche

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ICON

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IQVIA

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Oracle

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Information and Management Systems Society (HIMSS)

Hirochimi Shirasawa, MD
MSD Japan/Mark

John Speakman
New York University Langone Medical Center

Masanori Fukushima, MD, PhD
Tri-Kobe

Pam Howard
ICON

Margaret Keegan
IQVIA

Steve Rosenberg
Oracle

Joyce Senesimer, ML, RN
Information and Management Systems Society (HIMSS)

Volunteer from South Korea visit the CDISC office in Austin, Texas to discuss the growing CDISC community in Korea.

Clear data is essential to the success of research and the development of new treatments and therapies. But far too often this data remains confined to one organization or one moment in time. When CDISC standards are applied, data is collected, organized, and analyzed in a clear and consistent manner so that all researchers can leverage and share information from individuals and studies around the world. For over 20 years, we’ve taken a rigorous approach to developing and advancing data standards for clinical research and beyond. Each standard is informed and shaped by the expertise of those at the forefront of research today, making them not just of the highest quality, but also attuned to the practicalities of their implementation.

An Urgent Need: Quality Standards

For over 20 years, we’ve taken a rigorous approach to developing and advancing data standards for clinical research and beyond. Each standard is informed and shaped by the expertise of those at the forefront of research today, making them not just of the highest quality, but also attuned to the practicalities of their implementation.


Data Exchange Standards facilitate the sharing of CDISC content and information among systems. Data Exchange Standards are optimized to represent CDISC content, and flexible enough to be applied by information systems that haven’t implemented the Foundational Standards (e.g., legacy, data academy, studies).

Central to the mission of CDISC is the sharing of CDISC content, so that data can be structured, efficient and cost effective of clinical research processes from beginning to end. CDISC Foundation Standards are the basis of a complete suite of data standards, enhancing the quality, efficiency, and cost effectiveness of clinical research processes.

PTSD

Protocol Representation Model (PRM) provides a standardized approach for the design of a research protocol with focus on study design, eligibility criteria, submittal requirements, and implementation. PRM is one of the required standards for data submission to the US FDA.

Study Data Tabulation Model (SDTM) establishes a way to collect data across studies so that formats and structures provide clear traceability of submission data into SDTM, delivering more transparency to regulators and others who conduct data review.

CTR-XML lets technology vendors implement tools that support a "write once, use many times" solution based on a single XML file. That has become the language of choice for representing case report form data, the metadata for human and animal model datasets using the SDTM standard. It has become the language of choice for representing case report form content in many electronic data capture (EDC) tools.


Therapeutic Area User Guides (TAUGs) Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. As of the end of 2018, CDISC had published over 32 TA standards.

Researchers spend a substantial amount of time deciphering, translating, and mapping unstandardized data. Implementing CDISC standards means that data can be structured effectively and easily analyzed, leaving more time to focus on discoveries that will have invaluable impact on clinical research and global health. The following Therapeutic Area Standards were released in 2018:

• Colorectal Cancer
• Huntington’s Disease
• PTSD
• Vaccines

Controlled Terminology is the set of standard expressions (values) used with data items within CDISC-defined datasets.

Choice in the spring of 2019, CDISC President and CEO David R. Bobbitt, with advice and consent of the CDISC Board of Directors under the leadership of Chair Stephen Pyke, appointed a Blue Ribbon Commission to serve as a strategic think tank for CDISC. The Blue Ribbon Commission was charged with preparing CDISC for the next decade of growth and change by considering what factors would most influence utilization of CDISC standards.

Commissioners were selected to reflect the geographic reach of CDISC standards as well as to represent the industries and users of CDISC standards. Joyce Semmens, HIMSS executive and CDISC Board member, and Dr. Robert Califf, former Commissioner of the US FDA, co-chaired the Commission. Over six months, Commissioner and dedicated experts generated more than 200 pages of thoughts and discussion. Their recommendations, as identified by staff comments, were incorporated into a high-level report.

Commissioners connected, as members of the CDISC community so often do, over their shared passions which are bringing clarity to data, reducing human suffering, curing diseases, supporting automation, enhancing medical research, and improving global health.

Summary of Insights
The Commissioners believe that CDISC standards are, and will remain, relevant for every aspect of the research enterprise; however, they also acknowledge that CDISC standards must be fine-tuned both to support implementation through better internal alignment and to better reflect the core biomedical concepts common to research protocols. As the use of real world data (RWD) in clinical research grows, CDISC standardization remains necessary to maintain the value of real world evidence (RWE) in research datasets. CDISC must fundamentally change its historically hands-off approach to implementation. One key opportunity to support implementation is to build a new content layer that will standardize the transformation of data across the CDISC foundational standards. The CDISC standards will become de facto one standard, evolving to one well-defined model on the back and foundational standards, and therapeutic area specific extensions, become views of data, while developing on the front and a more accessible profile so that non-experts can leverage the benefits of standardization. CDISC must be prepared for future global growth by supporting a robust clinical data standards ecosystem. Central to this ecosystem is the CDISC Library metadata repository. CDISC Library offers new ways to expose and implement the CDISC standards as well as a new technology-based platform from which to build and update CDISC standards. As part of this robust ecosystem, CDISC as an organization will continue to support and extend efforts beyond the sponsor-regulator focus to include the broader research landscape, with a renewed emphasis on support for academic researchers’ efforts beyond the sponsor-regulator focus to include the broader research community.

Strategic Themes

**Broad Theme #1: Better standards from inception**

**Refine the model**

Commissioners unanimously agreed that CDISC must align all foundational standards around one core model so that CDISC-based data can be instantaneously accessed and used consistently. The core model will help ensure the sustainability of CDISC standards and their ability to evolve, as the CDISC vision is to become the model as its highest priority. This is the overarching theme of the Blue Ribbon Commission work. In many cases, Commissioners agreed to other priorities yet emphasized that the core model theme must come first over other considerations.

**Improve implementation consistency**

Commissioners recognized that CDISC sought to build standards that are even more implementable from inception and that CDISC must implementers through training and education as well as through key partnerships.

**Broad Theme #2: Optimizes the volunteer labor above**

CDISC has been, and will remain, a volunteer-driven organization. Commission has changed over the past 20 years of CDISC’s existence and will likely continue to evolve; yet the core commitment of volunteer’s passion and expertise to fundamentally improve human health and well-being standards will remain unchanged in the coming decade.

**Broad Theme #3: Focus and clarity**

CDISC is a small nonprofit organization with an enormous mission. Commissioners agreed that CDISC must be focused and clear in articulating goals and strategies in order to be successful, especially to achieve success in influencing the mighty powerful enterprise that CDISC must regularly engage.

**Broad Theme #4: Build a strong standards ecosystem**

While this theme was not identified in response to an exhaustive survey, it is generally perceived CDISC need a strong standards ecosystem to build a critical mass of CDISC contributors, both from academia and industry, that will help ensure the sustainability of CDISC standards. The Commission acknowledges that CDISC must support further adoption of the standards. Yet the Commission cautioned that CDISC standards should not be used for quality more than mandates. CDISC should be open and willing to work in a close relationship with CDISC.

**Broad Theme #5: Leverage models for membership and revenue while maintaining current strategy**

Commissioners generally perceived CDISC as doing a good job in building an effective membership model, supporting current CDISC membership and revenue while maintaining current strategy. Commissioners recognized that CDISC must support further adoption of the standards. Yet the Commission cautioned that CDISC standards should not be used for quality more than mandates. Commissioners agreed that the most important use case for CDISC is to support further adoption of the standards. Yet the Commission cautioned that CDISC standards should not be used for quality more than mandates. CDISC should be open and willing to work in a close relationship with CDISC.

**Broad Theme #6: Growth**

The Commission recommended growth from two perspectives: use cases and geographic.

Grow Use Case
The Commission acknowledged CDISC standards are growing in use cases beyond the original use cases and regulatory adoption. Commissioners agreed that the most important use case for CDISC is to support adoption while the growth in use cases beyond the original use cases and regulatory adoption. Commissioners agreed that the most important use case for CDISC is to support adoption while the growth in use cases beyond the original use cases and regulatory adoption. Commissioners agreed that the most important use case for CDISC is to support adoption while the growth in use cases beyond the original use cases and regulatory adoption.

Grow geographically
The Commission recognizes that CDISC standards are used globally and that mandates are useful to support further adoption of the standards. Yet the Commission cautioned that CDISC standards should not be used for quality more than mandates. CDISC should be open and willing to work in a close relationship with CDISC.

Special Thanks to Our Blue Ribbon Commissioners
- Jayne Beaumont, MSc, Co-Chair | EMA
- Dr. Robert Califf, Co-Chair | US FDA, Commissioner, former Commissioner, CDISC
- Dr. Ken Gersing | National Institutes of Health
- Dr. Dr. Lynn Hudson | Critical Path Institute, CFAST
- Dr. Joanne G. Kurtzberg | Duke University, MRTC, Vivli
- Dr. Yuki Ando | PMDA
- Pilgrims Health Care Institute
- Dr. Robert Califf, Co-Chair | US FDA, Commissioner, former Commissioner, CDISC
- Dr. Ken Gersing | National Institutes of Health
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- Dr. Yuki Ando | PMDA
- Pilgrims Health Care Institute

Blue Ribbon Commission

Dr. James Scoville, NHS, Co-Chair | ISPOR
- Dr. Robert Califf, Co-Chair | US FDA, Commissioner, former Commissioner, CDISC
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CDISC Library

Behind the scenes throughout 2018, the CDISC Data Science team, under the leadership of Dr. Sam Hume, developed the new CDISC Library. CDISC Library, at launch, will be a first-in-class metadata repository (MDR) to include a new API, an expanded metadata model, and new and updated content with additional levels of granularity and features previously unavailable.

CDISC Library uses a new linked data technology stack. Over the year, the Data Science team transformed all existing metadata into formats compatible with the new system. This work included representing more than 1 million metadata elements, linked via 6 million relationships. The team also continued to develop tools that the Standards Development Teams can use to expedite standards’ availability.

The Data Science team transformed all existing metadata into formats compatible with the new system. CDISC Library was designed to become the single source of truth for CDISC standards. It represents a significant investment of time and money to reduce attaining the full benefit of standardization.

CDISC is committed to regulators and sponsors as well as healthcare providers and researchers through the implementation of CDISC standards to further automate clinical research processes.

CDISC Library is the successor to CDISC SHARE, an early innovation in the community. In listening to the feedback from CDISC’s community and the Blue Ribbon Commission, CDISC leadership decided to rename CDISC SHARE as CDISC Library at launch, to align with our new and improved ability to recognize the significant improvements and new capacities in the MDR. CDISC leadership decided to update and expand the offerings of CDISC SHARE to its current, renamed CDISC Archives. Throughout the year, CDISC Archives were available to all members, providing CDISC metadata, metadata available for download in a variety of electronic formats. In addition to the standards and controlled terminology metadata files, CDISC Library Archives provides access to novel metadata sources such as Diff (Difference) files and thesauric area metadata.

CDISC staff benefited from our partnership with Nurocor to develop and launch CDISC Library and the thought leadership provided by Nurocor staff members Fredrik Malfati and Saimi Nelson. At the end of 2018, President and CEO David R. Bobbitt announced the CDISC Library API would provide all CDISC members at no additional charge as a benefit of membership. CDISC leadership is developing new, simplified EULAs for component access to standards specified in the FDA’s Data Standards Catalog and the PMDA’s Data Standards Catalog. Classroom training is available across the globe, in multiple languages, and with multiple capacities for adding new and updated content.

Online Classes

Convenience is the key to taking online courses through CDISC. Class offerings cover the complete range of clinical data standards topics and releases, such as our Library program. Each webinar is led by a CDISC expert and designed to increase knowledge and improve workflow.

CDISC holds global events annually on three continents with hundreds of attendees gathering to network, share their expertise, best practices, and lessons learned about implementing CDISC standards to bring efficiencies and clarity to data.

**Highlights of 2018**

- Launched New Branding at US Interchange
- Regulator panelists included US FDA, Japan PMDA, China NMPA, and EU EMA

*95% of survey respondents state that they would recommend CDISC Interchanges to others!*

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**Europe | Berlin, Germany**

23 – 27 April 2018

“Well organised with many interesting tracks and inspiring speakers.”

**Japan | Tokyo | 10 - 11 July 2018**

“The speakers were very clear, and it was easy to understand common issues.”

**China | Beijing | 6 – 7 September 2018**

“The conference had opportunities to share experiences, process improvements and innovations.”

**US | Bethesda, Maryland**

10 – 11 October 2018

“Great job. Very engaging topics - probably the best Interchange that I’ve been to in terms of content.”

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In 2018, CDISC embarked on an ambitious project to improve user experience through a redesigned website and complete rebrand which were both ready in time for an exciting launch at the 2018 US Interchange in Bethesda, MD. Both projects took diligent effort from all areas of the organization.

The background pattern found throughout the new website has 50% overlap—a visual representation of the theme of collective power (the CDISC community) and the framework for generating and connecting clinical research data.

The significance of the new logo and pattern

The geometric, clean, and bold typographic element of the logo supports the brand essence, “Clear Data. Clear Impact.” The logo’s data represent planning, collection, organisation, and analysis, the four clinical research data points. These data are integrated with the letters CDISC, symbolising that CDISC is a global environment. Better access to who we are and how we work in a global environment is possible to turn information into invaluable impact for clinical research and global health.

“Clear Data. Clear Impact.” The new CDISC tag line, concisely relays that in the ever-evolving and complex clinical research landscape, CDISC provides critical clarity by developing and advancing data standards of the highest quality to transform incompatible formats, inconsistent methodologies, and diverse perspectives into the accessibility, interoperability, and reusability of clinical data, helping the entire field of clinical research unlock its potential.

A New Look for CDISC.org

As a leader in global standards development, it is important for CDISC to make information regarding clinical data standards and our array of services, education, and events easily accessible for our current and prospective members and volunteers. The 2018 release of the updated and rebranded CDISC website helped in this effort by providing our community with the most accurate, up-to-date information about our shared knowledge and expertise in the field clinical research.
Membership

Membership by Industry

CDISC Member Benefits

CDISC Standards and related innovations would not be possible without the dedicated volunteer efforts and financial assistance of our member organizations. Our members’ support ensures standards remain open and free, and that they are sustainable into the future. We sincerely appreciate the continuing support and advocacy of our members. By working together, we will achieve the CDISC mission.

CDISC serves 16 industry segments and has 457 member organizations globally!

Membership by Country

Throughout history, groups have come together to achieve benefits far greater than anything they’d be able to accomplish solo. CDISC, through minded individuals so they can enjoy the benefits of a larger presence. In the end, the more people who come together, the more possibilities exist our member organizations, brings together like-to find solutions that reduce human suffering.

United States 49%
China 5%
Germany 5%
Japan 11%
Belgium 3%
Canada 3%
France 4%
United Kingdom 4%
Denmark 3%
India 1%
South Korea 2%
Sweden 1%
Ireland 1%
Spain 1%
Switzerland 3%
All Others 5%

China National Medical Products Administration

CDISC Increases Interactions with China National Medical Products Administration

CDISC executive David R. Bobbitt, Peter Van Reusel, and Sheila Leaman had a productive meeting with officials in Beijing at the offices of the Center for Drug Evaluation (CDE), which is part of the China National Medical Products Administration (NMPA) during the week of the China Interchange. Later in the fall, Special Advisor to the CEO, Dr. Steve Wilson, represented CDISC at a meeting of Chinese stakeholders organized by NMPA to discuss how adoption of global data standards helps meet the needs of the Chinese people to provide domestic pharmaceutical discovery and manufacturing.

Peter Van Reusel Named Chief Standards Officer

In 2018, CDISC named long-time standards advocate, skilled instructor, and European Liaison, Peter Van Reusel, as the organization's Chief Standards Officer. Peter brings over 20 years’ experience in senior roles in pharma and related industries, including CDISC standards and carrying out other standards work in a multitude of organizational settings. He has been a CDISC-authorized instructor for over 11 years, and has helped significantly in developing CDISC training courses. For the past two years, Peter has served as CDISC’s European Liaison, shepherding relationships with key European regulatory, academic, and biopharma stakeholders. He is also an active PhUSE working group leader.

Complete Competency in CDISC Standards

The Leona M. and Harry B. Helmsley Charitable Trust provided $5.4 million in funding to CDISC in 2018, and the Helmsley Charitable Trust also supported work to standardize clinical data to ease the process of people to grow domestic pharmaceutical discovery and manufacturing.

US FDA CDER Requires Medical Reviewers to Complete Competency in CDISC Standards

With mounting clinical research skills and passion in India, a CDISC User Group was launched in 2018 to serve as a support system to connect and keep up with the fast-paced industry in the country.

CDISC India User Group Launches

Milestones

CDISC is a non-profit, educational organization that facilitates research and development of new medical therapies and procedures by supporting work to standardize clinical data. Key milestones for 2018 include:

• New Online Learning Management System Released

CDISC continued to invest in technology and tools to enhance implementer experience as well as help our community unlock the benefits of data standardization. One such improvement was launching a new learning platform to access our authorized online training courses. The new platform features:

- Interactive tools that foster active and engaging learning
- Assessment diagnostics to monitor your progress as you go
- Ease of enrollment with the capability to register a team of any size quickly
- Full integration with the CDISC website, allowing single sign on

• SDTM v1.7

In 2018, CDISC released SDTM v 1.7, which describes the general conceptual model for representing clinical study data submitted to regulatory authorities. SDTM v3 provides specific domain models, assumptions, and examples for preparing standard tabulation datasets that are based on the SDTM.

• SDTMIG v3.3

Along with the release of SDTM v1.7, CDISC released SDTMIG v3.3, which provides specific domain models, assumptions, business rules, and examples for preparing standard tabulation datasets that are based on the SDTM.

• Glossary v12.0

Glossary v12.0 included a more robust and frequently used repository process for new terms since Glossary activity is better integrated into Controlled Terminology to support the exchange of digital information. The team updated approximately 50 existing terms, reviewed close to 100 new terms, and updated or added more than 150 acronyms/abbreviations/initals not included in 2017. In addition, sources for definitions from new guidelines are provided as a tab for ease of use in the Excel file.

• Therapeutic Area User Guide – Colorectal Cancer

Colorectal cancer is the second most commonly occurring cancer in women and third most commonly occurring cancer in men, according to the World Cancer Research Fund International. There were over 1.8 million new cases in 2018.

Version 1.0 of the Colorectal Cancer Therapeutic Area User Guide (TAUG-C) was developed under the CDISC Standards Development Process and describes the most common biomedical concepts relevant to colorectal cancer and the necessary metadata to represent data consistently with Terminology and SDTM.

• Therapeutic Area User Guide – Vaccines

VAX) was developed under the CDISC Standards Development Process and describes the most common biomedical concepts relevant to vaccines, and the necessary metadata to represent such data consistently with Terminology and SDTM.
CDISC experienced strong growth in 2018, with revenue increasing by 8% over 2017. This dynamic performance was driven in particular by a strong support from our community, as evidenced by the increase in membership and above all project funding.

This strong growth has allowed us to significantly increase our net revenue for 2018, ensuring the long-term sustainability of our mission. Our internal organization was also significantly remodeled, and our staffing increased, particularly in the standards and data science teams. The impact of these changes has already been positively felt, and we expect this to continue as we advance several key projects in 2019.
CDISC creates clarity in clinical research by convening a global community to develop and advance data standards of the highest quality. Required by the United States Food and Drug Administration (FDA) and Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) and adopted by the world’s leading research organizations, CDISC standards enable the accessibility, interoperability, and reusability of data.

With the help of CDISC standards, the entire research community can maximize the value of data for more efficient and meaningful research that has invaluable impact on global health. CDISC is a 501(c)(3) global nonprofit charitable organization and is headquartered in Austin, Texas, with hundreds of employees, volunteers, and member organizations around the world.