Clear Data.
Clear Impact.

2018 Annual Report

Letter from the CEO

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, members, partner 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 2,300 volunteers.

At CDISC, we believe that standards training for all should be considered an ongoing commitment in order to maximize program efficiencies and progress 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 educational opportunities today.

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 diseases as well as improvements that are aimed at speeding up the research process through technological advancements.

It is a privilege to lead a small but mighty staff team that sits at the intersection of so much good work. It is clear that our community is in a period of significant change. Yet it is equally clear this community is confident in our commitment to quality data standards, effective implementation, and clear data.

Sincerely,

David R. Bobbitt, MSc, MBA
President and CEO

What we do:

Create Clarity.

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

How we do it:

Individual Contributions. Collective Power.

CDISC convenes a global community of research experts representing a range of experiences and backgrounds. Each brings a vision, we bring the blueprint. They develop the data, we develop the platform. They provide the insights, we provide the focus. With everyone contributing their unique strengths, we're able to harness our collective power to drive more meaningful clinical research.

Why We Do It:

To Amplify Data's Impact.

CDISC is driven by the belief that the true measure of data is the impact it has, but for far too long, its full potential wasn't being realized. So, we enable the accessibility, interoperability, and reusability of data, helping the entire field of clinical research tap into—and amplify—its full value. From greater efficiency to unprecedented discoveries, we make it possible to turn information into invaluable impact for clinical research and global health.

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. Pg. 5

Standards

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

Education

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

Events

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

Membership

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

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.

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	Deloitte
Jonathan Chainey	F. Hoffman-La Roche
Charles Cooper, MD	BD Diagnostics
Chris Decker	d-wise
David Evans, MS	Accenture
Masanori Fukushima, MD, PhD	Tri-Kobe
Pam Howard	ICON
Margaret Keegan	IQVIA
Steve Rosenberg	Oracle
Joyce Sensmeier, MS, RN	Information and Management Systems Society (HIMSS)
Hirochimi Shirasawa, MD	MSD Japan/Merck
John Speakman	New York University Langone Medical Center
Névine Zariffa, M. Math	AstraZeneca
Jonathan Zung, PhD	Covance

2018 CDISC Board Members

Thank You Chairman Pyke

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.

CDISC staff and volunteers enjoyed some much deserved relaxation at the end of the 2018 Working Group Meeting.

A lively discussion during the German User Group Face-to-Face meeting.

CDISC Board Member Chris Decker gives an inspirational talk on innovation.

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

Dave Scocca from CDISC Gold Member, Rho, proudly encouraging attendees.

Yoshiteru Chiba welcomes CDISC staff to the UMIN office at Tokyo University.

CDISC SHARE Workshop

J3C members and Japan Interchange sponsors shared the week's events on social media.

An Urgent Need: Quality Standards

CDISC Standards in the Clinical Research Process

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.

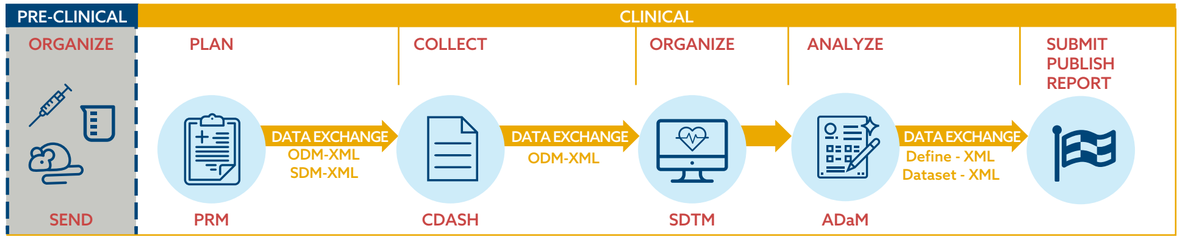
CDISC Foundational Standards are the basis of a complete suite of data standards, enhancing the quality, efficiency and cost effectiveness of clinical research processes from beginning to end.

Protocol Representation Model (PRM) provides a standard for planning and designing a research protocol with focus on study design, eligibility criteria, submittal requirements, and automating CRF creation and EHR configuration to support research data sharing.

Standard for Exchange of Nonclinical Data* (SEND) is an implementation of the SDTM standard to collect and present nonclinical data in a consistent format, and is one of the required standards for data submission to the US FDA.

Clinical Data Acquisition Standards Harmonization (CDASH) 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.

Clinical Research Process



Study Data Tabulation Model* (SDTM) provides a standard for organizing and formatting clinical study data to streamline processes in collection, management, analysis and reporting.

Analysis Data Model* (ADaM) defines dataset and metadata standards that support efficient generation, replication, and review of clinical trial statistical analyses, and traceability among analysis results, analysis data, and data represented in SDTM.

***Submission** - The FDA (US) and PMDA (Japan) require the use of SDTM, ADaM and Define-XML for new drug applications. The FDA also requires the use of SEND.

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

Data Exchange Standards facilitate the sharing of structured data across different information systems. Data Exchange Standards are optimized to represent CDISC content, and flexible enough to be used by information systems that haven't implemented the Foundational Standards (e.g., legacy data, academic studies).

CTR-XML lets technology vendors implement tools that support a "write once, use many times" solution based on a single XML file that holds the information needed to generate submissions for multiple clinical trials for clinical trial registry submissions primarily to the World Health Organization (WHO), European Medicines Agency (EMA) EudraCT Registry and United States ClinicalTrials.gov.

Dataset-XML supports exchanging tabular data in clinical research applications using ODM-based XML technologies, enabling the communication of study datasets for regulatory submissions.

Define-XML* transmits metadata that describes any tabular dataset structure. When used with the CDISC content standards, it provides the metadata for human and animal model datasets using the SDTM and/or SEND standards and analysis datasets using ADaM.

LAB provides a standard model for the acquisition and exchange of laboratory data, primarily between labs and sponsors or CROs. The LAB standard was specifically designed for the interchange of lab data acquired in clinical trials.

ODM-XML is a vendor-neutral, platform-independent format for exchanging and archiving clinical and translational research data, along with their associated metadata, administrative data, reference data, and audit information. ODM-XML facilitates the regulatory-compliant acquisition, archival and exchange of metadata and data. It has become the language of choice for representing case report form content in many electronic data capture (EDC) tools.

SDM-XML is an extension of ODM-XML and allows organizations to provide rigorous, machine-readable, interchangeable descriptions of the designs of their clinical studies, including treatment plans, eligibility and times and events. SDM-XML defines three key sub-modules – Structure, Workflow, and Timing – permitting various levels of detail in any representation of a clinical study's design.

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

Therapeutic Area Standards Published and In Development

Blue Ribbon Commission

Context

In the spring of 2018, 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 Sensmeier, HIMSS executive and CDISC Board member, and Dr. Robert Califf, former Commissioner of the US FDA, co-chaired the Commission. Over six months Commissioners met frequently, and these dedicated experts generated more than 200 pages of thoughts and discussion. Their recommendations, augmented by some 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 interoperability, 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 concluded CDISC must be prepared for significant changes as the research world is undergoing substantial changes. New technologies combined with data from new sources will require CDISC to become nimbler and more rapidly responsive to change. The core CDISC foundational standards model 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 maximize the value of real world evidence (RWE) in research datasets. CDISC must fundamentally change its historically hands-off approach to implementation. One key effort to support implementation is to build a new content layer that standardizes the transformation of data across the CDISC foundational standards. The CDISC standards will become de facto one standard, evolving to one well-refined model on the back end where foundational standards, and therapeutic area specific extensions, become views of data, while developing on the front end 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 should build on and extend efforts beyond the sponsor-regulator focus to include the broader research landscape, with a renewed emphasis on support for academic researchers' effective utilization of the CDISC standards.

Above all, CDISC must remain a focused and productive global community, providing and demonstrating value for its members and stakeholders. This community is a welcoming place for volunteers where each member of the community can bring their personal gifts and talents. This community builds solid partnerships with other stakeholders and entities: there is much work to do, and more hands and minds to do this work will always be a gift.

Strategic Themes

Broad Theme #1: Better standards from inception

Refine the model
Commissioners agreed unanimously that CDISC should align all foundational standards around one core model so that CDISC becomes de facto one standard. Foundational standards (e.g., SDTM, ADaM, etc.) become views of data that can be accessed and assembled by users according to their requirements. This "refine the model" theme will help ensure the sustainability of CDISC standards. CDISC must address 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 refining the model must come first over other considerations.

Improve implementation consistency
Commissioners agree that CDISC ought to build standards that are even more implementable from inception and that CDISC must support implementers through training and education as well as through key partnerships.

Broad Theme #2: Optimize the volunteer labor force

CDISC has been, and will remain, a volunteer-driven organization. Volunteering has changed over the first 20 years of CDISC's existence and will likely continue to evolve; yet the core commitment of volunteers pooling their expertise and knowledge to fundamentally improve human health through well-crafted 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 mightily powerful entities that CDISC must regularly engage.

Broad Theme #4: Build a strong standards ecosystem

While this theme was not identified in response to any discrete question, Commissioners generally perceive CDISC standardization to be a critical resource, which like any resource must be deployed judiciously and sustained. Commissioners agreed that a strong standards ecosystem grows from a healthy community of standards creators and standards implementers. Each member of this community has a critical role. CDISC is central to a healthy standards ecosystem.

Broad Theme #5: Rely on key partnerships

CDISC is not an island. Everything CDISC does affects others. Commissioners encouraged CDISC to be a good partner and to cultivate key partnerships. Commissioners noted certain partnerships, which are core to CDISC's future vision.

Broad Theme #6: Growth

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

Grow Use Case
Commissioners acknowledged CDISC standards are growing in use cases beyond the original use case of regulatory approvals. Commissioners agreed that the most important use case for CDISC to support above and ahead of all others in the foreseeable future is standardization of academic research, observational research, patient-reported outcomes, and real world evidence.

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 be chosen for quality more than merely mandated. CDISC should be opportunistic whenever a regulatory agenda is interested in a closer relationship with CDISC.

Broad Theme #7: Explore new models for membership and revenue while maintaining current strengths

Commissioners generally perceived CDISC as doing a good job in building an effective membership model and supporting the community through a well-staffed and well-managed organization. Commissioners recognized that CDISC must reassess membership offerings from time to time to ensure relevance, and that CDISC in the course of good management ought to consider new and additional revenue streams. Commissioners provided a range of advice on these matters.

Special Thanks to Our Blue Ribbon Commissioners

Joyce Sensmeier, RN, Co-Chair | HIMSS
Dr. Robert Califf, Co-Chair | Duke University, former Commissioner, US FDA
Dr. Yuki Ando | PMDA
Scott Bahlavooni | d-Wise, PhUSE
Dr. Wenjun Bao | JMP Life Sciences, | SAS Institute Inc.
Dr. Barbara Bierer | Harvard University, Brigham and Women's Hospital, MRTC, Vivli
Dr. Jeffrey Brown | Harvard University Medical School, Harvard Pilgrims Health Care Institute
Dr. Alison Cave | EMA
Jonathan Chainey | Roche, CDISC Advisory Council
Sherry Chou | Parexel
Dave Evans | Accenture
Paul Franson | Medtronic
Dr. Ken Gersing | National Institutes of Health
Hugh Glover | Blue Wave Informatics
Dr. C. David Hardison | Deloitte
Dr. Lynn Hudson | Critical Path Institute, CFAST
Dr. Georgina S. Humphries | Wellcome Trust
Dave Iberson-Hurst | Assero, former CTO CDISC
Scott Kahn | Helmsley Charitable Trust
Dr. Stephen Kern | Bill and Melinda Gates Foundation
Joanna Koft | Biogen
Dr. Laura Merson | Oxford University
Hidetoshi Misawa | Pfizer, J3C
Jennifer O'Callaghan | Eisai Worldwide
Dr. Ülo Palm | Allergan
Maria Picone | TREND Community, patient advocate
Phil Pochon | Covance
Dr. Lyubov Remennik | NIH National Cancer Institute Enterprise Vocabulary Services
Dr. Frank Rockhold | Duke University
Dr. Lilliam Rosario | US FDA
John Speakman | New York University
Dr. Sam Volchenboum | University of Chicago, Litmus Health
Dr. Anita Walden | University of Arkansas for Medical Sciences
Dr. Zibao Zhang | dMed Pharmaceuticals, AP3C, C3C
David R. Bobbitt, MSc, MBA | CDISC
Anthony Chow | CDISC
Rhonda Facile, MS | CDISC
Dr. Sam Hume | CDISC
Marine Laurent | CDISC
Bess Leroy, MPH | CDISC
Peter Van Reusel | CDISC

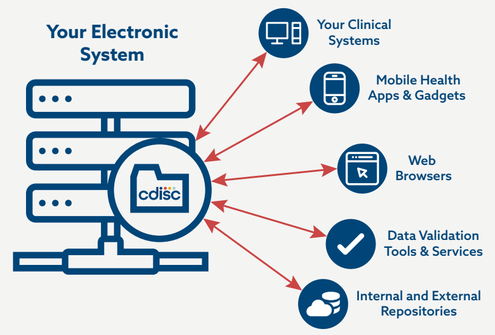
Behind the scenes throughout 2018, the CDISC Data Science team, under the leadership of Dr. Sam Hume, developed the new CDISC Library. CDISC Library, at launch, will be a first-in-class metadata repository (MDR) to include a new API, an expanded metadata model, and new standards content with additional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

Throughout the year, the CDISC Data Science team held workshops at Interchanges and periodic webinars to inform the community of the many benefits of CDISC Library and its ecosystem of tools as well as provide progress updates toward Library's next iteration. The team and colleagues also published the article "CDISC SHARE, a Global, Cloud-based Resource of Machine-Readable CDISC Standards for Clinical and Translational Research" in the American Medical Informatics Association Joint Summits on Translational Science Proceedings.

New hires augmented the talent already working in Data Science. CDISC volunteer and former SDS team leader Mike Hamidi joined CDISC as Head of Data Science. Long-time CDISC volunteer and well-known authorized instructor, Sally Cassells, joined as Senior Director, Data Exchange Standards.

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 the heterogeneity of standards implementations. CDISC is committed to regulators and sponsors attaining the full benefit of standardization. The API allows real-time access to standards in a variety of formats (JSON, XML, Excel/CSV) for programmatic use by developers to create CDISC metadata libraries within their metadata repositories, support CDISC standards in electronic case report forms, and use within clinical research and learning health systems. The API facilitates the implementation of CDISC standards to further automate clinical research processes.



CDISC Library is the successor to CDSIC 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 branding and to recognize the significant improvements and new capacities in the MDR. CDISC continued to update and expand the offerings of CDISC SHARE Exports, renamed CDISC Library Archives, throughout the year. CDISC Library Archives, available to all members, provides CDISC standards 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 therapeutic 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 Frederik Malfait and Barrie Nelson.

At the end of 2018, President and CEO David R. Bobbitt announced the CDISC Library API would be available to all CDISC members at no additional charge as a benefit of membership. CDISC leadership is developing new, simplified EULAs (End User License Agreements) that encouraged open source and commercial software developers to develop products using the API.

Greater Clarity Starts with CDISC Education

New Learning Management System

In 2018, CDISC continued to innovate in ways we deliver educational opportunities completing a year-long migration to a new online learning management system (LMS). This LMS features interactive tools and an easy-to-use learner portal integrated with the CDISC website.

The clean design of the CDISC LMS interface was designed for ease of use.

Online Classes

Convenience is the key to taking online classes through CDISC. Class offerings cover the complete range of clinical data standards topics and new and updated content is always just a click away. Plus, CDISC's new LMS system keeps track of your progress.

Classroom Training

CDISC classroom training courses provide expert-led training sessions for individuals and organizations of all experience levels and cover material from 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 taught by our authorized instructors.

Public Training

Opportunities to attend CDISC Public Training sessions occur in a variety of locations throughout the year. A convenient way to join us for Public Training is to attend a CDISC Interchange, where multiple classes are available before and after the event.

CDISC public and private training provide learning and networking opportunities.

Private Training

On-site training is an ideal opportunity to get multiple staff members up to speed on the clinical data standards that are specifically important to your organization - all in the comfort of your offices or the location of your choosing.

Webinars

Our webinar series provides ongoing training and discussion on hot topics in research. These expert-led discussions can be attended at home or in the office, and past offerings are available for review with membership access.

In 2018, more than 90 subject matter experts provided CDISC Education content via 201 events to 5,553 learners across 36 countries!

Workshops

CDISC Workshops bring in elements to ground participants in a variety of topics, from the fundamentals of standards used to connect healthcare and research and to sessions covering the latest advancement of CDISC's technical releases, such as our Library program.

Each webinar is led by a CDISC expert and designed increase knowledge and improve workflow.

Interchanges & Events

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.

"Well organised with many interesting tracks and inspiring speakers."

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

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

"Great job. Very engaging topics – probably the best Interchange that I've been to in terms of content."

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!

Interchanges & Events

Clear Data. Clear Impact.

Alliances

CDISC is not an island. Our impact as an organization is multiplied by our collaborations with our global partners. Through partnership, we can continue to advance interoperable standards across a wide range of therapeutic areas so greater clarity is achieved, more powerful research is conducted, and more meaningful connections are discovered. And as our dedication and collaboration continue to grow, so too will our collective impact on global health.

A few of our key partners and collaborative efforts over the year are highlighted here:

CRITICAL PATH INSTITUTE

The Critical Path Institute (C-Path) is a nonprofit, public-private partnership with the FDA created under the auspices of the FDA's Critical Path Initiative program. C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. CDISC and C-Path long-standing collaborations have resulted in the development of over 30 Therapeutic Area User Guides.

phuse

CDISC and PhUSE PhUSE partner to further the mission of each organization, with CDISC focusing on developing global, platform-independent data standards, and PhUSE focusing on implementing CDISC standards. **PhUSE is CDISC's preferred partner** for implementation questions and issues.

NIH NATIONAL CANCER INSTITUTE Enterprise Vocabulary Services

NCI EVS is a founding partner in the development, maintenance, and production of Controlled Terminology content, tools, and services to accurately code, analyze, share, and integrate clinical, translational, and public health data for cancer research and other biomedical fields. CDISC and NCI EVS work together to create Controlled Terminology that is linked to other common research semantics through EVS tools for CDISC Foundational and Therapeutic Area Standards. NCI EVS is an active participant throughout CDISC's global community, providing subject matter expertise on many steering committees to implement strategic goals. CDISC and EVS released four quarterly Controlled Terminology packages in 2018.

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

The Leona M. and Harry B. Helmsley Charitable Trust committed $5.4 million in funding to CDISC to support work to standardize clinical data to ease data sharing among research scientists and to improve medical research around the globe.

Helmsley's support will enable CDISC to create data standards for type 1 diabetes (T1D) and Crohn's disease (CD) research, building CDISC's infrastructure, tools, and training for academic researchers. In time, these interoperable data will foster better medical decision-making, drug discovery, and healthcare for T1D and CD patients worldwide. Benefitting both the T1D and CD communities, the new CDISC standards will allow for more seamless information sharing across research centers, improve the quality, usefulness, and consistency of clinical data, and support the evaluation of the effectiveness of emerging treatments.

Helmsley's commitment also enables CDISC to continue following time-tested, consensus-based processes to consolidate and transform standards into real-world-data compatible standards, and ensure optimal data quality, validity, and use. Once harmonized and accessible via open-source and web-based tools, the transformed standards will help researchers who are not experts in data standards build clinical datasets that can be shared with others. This, along with educational support, aims to promote ethical data sharing.

CDISC Rebrand

New Look, New Experience

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.

New CDISC Look, Consisting of Logo, Pattern and Tag Line

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 dots represent planning, collection, organization, and analysis, the four clinical research data points. These dots are integrated with the letters of CDISC to convey the idea that our Standards are interconnected and interoperable. Aligned horizontally they suggest the collective power and forward thinking of the CDISC global community.

The background pattern found throughout CDISC's website, emails, and collateral continues the theme of collective power (the CDISC community) and the framework for generating and connecting clinical research data.

David R. Bobbitt and Nicole Harmon launch the CDISC re-branding initiative. Dr. Harmon led the rebranding initiative, which developed from workshops and interviews with staff members, volunteers, and the Board of Directors.

Clear Data. Clear Impact.

"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 a powerful framework for generating clinical research data that is as accessible as it is illuminating.

CDISC is driven by the belief that the true measure of data is the impact it has. We enable the accessibility, interoperability, and reusability of data, helping the entire field of clinical research tap into—and amplify—its full value. From greater efficiency to unprecedented discoveries, we make it possible to turn information into invaluable impact for clinical research and global health.

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 event opportunities 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.

Our goal with the new website was to provide our visitors an easier way to learn about standards and to browse information based on their areas of interest. We believe that the new website gives better access to who we are and how we work in a global environment.

Membership

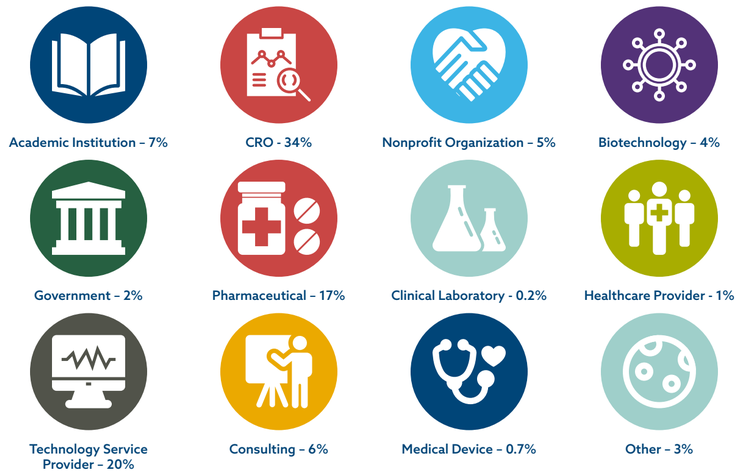
Throughout history, groups have come together to achieve benefits far greater than anything they'd be able to accomplish solo. CDISC, through our member organizations, brings together like-minded individuals so they can enjoy the benefits of a larger presence. In the end, the more people who come together,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

CDISC Member Benefits

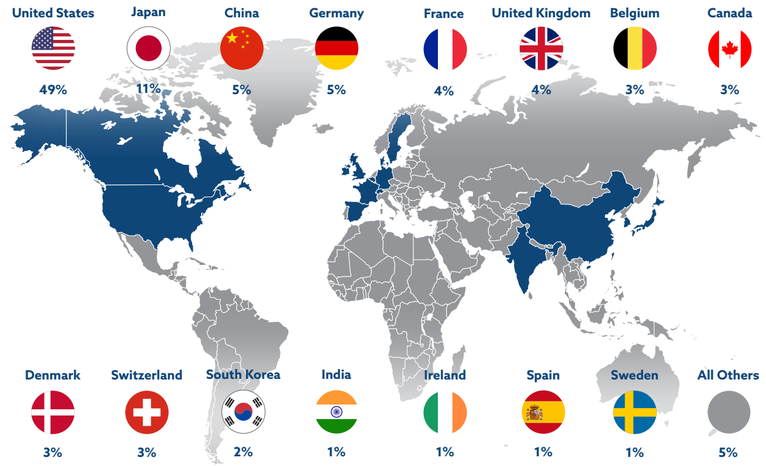
- Significant Discounts on Training and CDISC Interchanges
- Exclusive Access to CDISC Library and CDISC Library Archives
- Credit for Online Training Courses
- Free Monthly Members-Only Mini Training Webinars
- Postings on the CDISC Industry Job Board
- Unlimited access to the Members Only Area
- Community Growth
- Plus MORE!

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.

Membership by Industry



Membership by Country



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

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The Helmsley Charitable Trust

The Leona M. and Harry B. Helmsley Charitable Trust provided $5.4 million in funding to CDISC in 2018, supporting work to standardize clinical data to ease the process of data sharing among research scientists and to improve medical research around the globe.

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 at CROs, leading the development and implementation of 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.

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

Completing competency in CDISC Standards, among other competencies, is required for reviewers to move from Level 1 (Associate) Medical Reviewer to Level 2 (Career Conditional) Medical Reviewer.

CDISC India User Group Launches

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.

China National Medical Products Administration

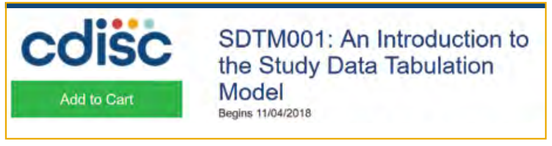
CDISC Increases Interactions with China National Medical Products Administration

CDISC executives 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 grow domestic pharmaceutical discovery and manufacturing.

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. SDTMIG v3.3 provides specific domain models, assumptions, business rules, 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 request process for new terms since Glossary activity is better integrated into Controlled Terminology to support the exchange of digital information.

The team updated about 50 existing terms, reviewed close to 100 new terms, and updated or added more than 150 acronyms/abbreviations/initials 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-CrCa) 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 CDASH, SDTM, and ADaM.

Therapeutic Area User Guide – Huntington Disease

The Huntington's Disease Regulatory Science Consortium (HD-RSC), launched in March 2018 by the Critical Path Institute (C-Path) and CHDI Foundation, along with the CDISC, provided the open availability of a newly developed Huntington's Disease Therapeutic Area User Guide (TAUG-HD). The guide was developed to describe the most broadly utilized clinical concepts for data acquisition and analysis in Huntington's disease (HD) clinical studies using the CDISC standard format. The user guide defines parameters for data collection and allows datasets from different sources to be compared or combined for sharing and analysis.

Therapeutic Area User Guide – PTSD

CDISC and Cohen Veterans Bioscience collaborated to establish a new CDISC Therapeutic Area Data Standard for post-traumatic stress disorder (PTSD).

The CDISC and Cohen Veterans Bioscience collaboration maps the most common data elements and biomedical concepts used in PTSD to establish uniform clinical research and terminology standards. This will be accomplished by collecting, tabulating, analyzing and then standardizing data for PTSD medical research and clinical care, collected within the US National Institutes of Health, Department of Defense, Veterans Affairs and other key organizations.

Therapeutic Area User Guide – Vaccines

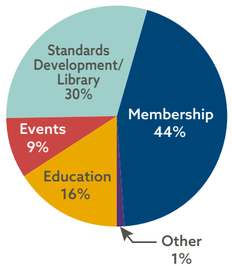
Version 1.1 of the Vaccines Therapeutic Area User Guide (TAUG-Vax) was developed under the CDISC Standards Development Process and describes the most common biomedical concepts relevant to vaccines, and the necessary metadata to represent such data consistently with Terminology and SDTM.

2018 Income vs. Expenses

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.

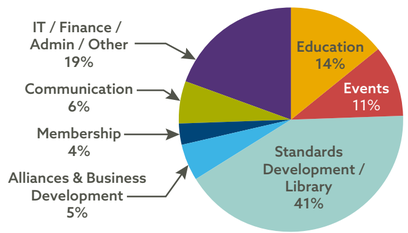
2018 Income

Income		
Education	$1,336,000	16%
Events	$730,000	9%
Standards Development / Library	$2,509,000	30%
Membership	$3,759,000	44%
Other	$84,000	1%
Gross Income	$8,418,000	



2018 Expenses

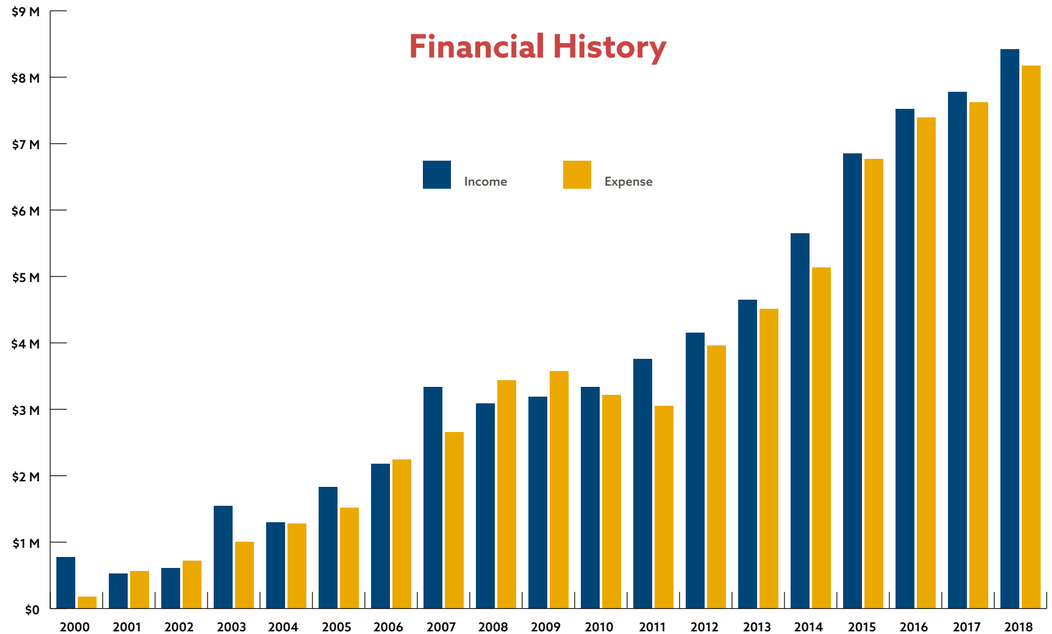
Expenses		
Education	$1,169,000	14%
Events	$853,000	11%
Standards Development / Library	$3,383,000	41%
Alliances & Business Development	$430,000	5%
Membership	$276,000	4%
Communication	$492,000	6%
IT / Finance / Admin / Other	$1,572,000	19%
Total Expenses	$8,175,000	



2018 Financial Information

Long-term Growth

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.



Clear Data. Clear Impact.

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.

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