

COISC Clear Data. Clear Impact.

2019 Annual Report

Letter from the CEO



If I can summarize 2019 for CDISC in one word that word would be "achievement." Through the individual contributions and collective power of our global community and staff, CDISC accomplished many great things.

To begin, CDISC made significant progress on our pathway of change. Based on the long-term vision of the CDISC Blue Ribbon Commission, our Board of Directors, under the leadership of Chair Dr. Douglas Peddicord, approved a three-plus-year strategic plan for CDISC to evolve so that we can build a future where data standardization facilitates good science to help reduce human suffering.

Another achievement highlighted in this Annual Report is the launch of CDISC 360, an ambitious project geared toward innovating clinical data standards to ensure they remain valuable and relevant into the future. I am amazed by the incredible commitment of talent our member companies have made under the leadership of CDISC Chief Standards Officer, Peter Van Reusel, to see this automation pilot become reality.

We were delighted to release CDISC Library via an API and data standards browser to our Platinum and Gold members as well open source developers.

By the end of 2019, CDISC Library achieved 100+ organizations in just eight months. The diversity of CDISC Library customers by industry and geographic region was, and continues to be, impressive.

2019 was also the year that CDISC Standards became the preferred standards for electronic data submission in China with the release of the requirements of clinical trial data submission in the electronic common technical document by the Center for Drug Evaluation of the National Medical Products Administration. This achievement represents a strengthening of the relationship between NMPA and CDISC, while supporting continued positive development of the Chinese pharmaceutical industry.

CDISC enjoyed a highly productive year of achievement. It remains a privilege to lead a small but mighty staff team that sits at the intersection of so much good work.

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 and 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:

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.

Contents



Collective Power

Convening a Community

CDISC harnesses the vision and insights of each volunteer, member organization, employee, 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.











2019 Board of Directors

Douglas Peddicord, Chair	Association of Clinical Research Organizations (ACRO)
Jonathan Zung, PhD, Chair Elect	WCG
Stephen Pyke, Past Chair	GSK
Chris Decker, MS	d-Wise
David Evans, MS	Accenture Research and Development Services
Pandu Kulkarni, PhD	Eli Lilly and Co.
Zhengqing Li, PhD	MSD
Masanori Fukushima, PhD	Tri Kobe
C. David Hardison, PhD	ConvergeHEALTH by Deloitte
Pam Howard, MS	ICON
Margaret Keegan	PRAHS
Hiroshi Masumoto, PhD	Daiichi Sankyo
Steve Rosenberg	Oracle
Joyce Sensmeier, RN	Healthcare Information and Management Systems Society
Névine Zariffa, M. Math	AstraZeneca

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.

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.



















A Global Need: Quality Standards

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 Standards in the Clinical Research Process



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.



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.



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.



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 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

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.

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).

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 User Guides extend the Foundational Standards to represent data that pertains to specific disease areas. As of the end of 2019, CDISC had published over 35 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.

TAUGS are Currently Available for the Following General Disease Categories

Autoimmune	Neurology	
Cardiovascular	Oncology	
Endocrine	Rare Diseases	
Gastrointestinal	Respiratory	
Infectious	Treatments	
Mental Health	Other	

The following Therapeutic Area Standards were released in 2019:

- C. Difficile-Associated Disease (CDAD)
- HIV
- Lung Cancer
- Nutrition
- Traditional Chinese Medicine Coronary Artery Disease-Angina

A Complete List of Therapeutic Area Standards Published and In Development is Located at: cdisc.org/standards/therapeutic-areas



Strategic Plan 2019-2022

In 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. This 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.

In 2019 the insights of the Blue Ribbon Commission were adopted into the CDISC Strategic Plan which will guide this organizaition's evolution and journey of change over the coming years in preparation for the new sources of data and new technology platforms that will require CDISC standards to evolve as clinical, non-clinical, observational science and continues to evolve.

Change and innovation are not easy, and no particular outcome is guaranteed. Yet the CDISC community and CDISC, as a nonprofit entity led by an allvolunteer Board of Directors, are committed to engaging with this change in a transparent and mutually supportive culture.

CDISC has established five highlevel goals to help guide this organization, and the global community it supports so that together we build a future where data standardization facilitates good science to help reduce human suffering.



I. Transform

Transition to a multidimensional representation of CDISC standards and support automation.

CURRENT STATE:

CDISC foundational standards are built in a two-dimensional model. There is no significant CDISC support for automation of foundational standards in the research enterprise.

I.A: Develop multi-Goal dimensional standards in an open, transparent manner that allows community members to transition with as little disruption to their research as possible while unlocking greater benefits of standardization. Engage in concrete steps to achieve end-toend standardization.

Goal 1.B: Transition to a model where volunteers develop standards first for CDISC Library. Build a new paradigm where community ata that can become de facto a part of the CDISC standards or where that metadata can be designated as fit for a specific use case.



II. Expand

Identify and prioritize adjacent research areas that can benefit from data standardization.

CURRENT STATE:

Many stakeholders in adjacent research areas recognize the benefits of standardizing data including support for collaboration; data sharing; and rendering data findable and interoperable. CDISC has limited capacity to incentivize these stakeholders to standardize their data at this time. What CDISC can do is reduce the barriers to utilizing CDISC standards as one way to support promulgation of standardization.

Goal II.A: Evaluate the following opportunities and determine whether it is ready for significant investment. Monitor, prioritize, choose, and seek external funding as appropriate. As a consequence of the evolution of the model. selectively extend CDISC standards to support new data types and / or new technologies

Goal II.B: Pilot extension of the CDISC standards to better support academic investigators. Provide those researchers the knowledge and tools they need to support good science.

- Joyce Sensmeier, RN, Co-Chair | HIMSS Dr. Robert Califf, Co-Chair | Duke University, former
- 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 Dr. Ken Gersing | National Institutes of Health

III. Support

Ensure that this vibrant global community is heard and wellserved.

CURRENT STATE:

A vibrant global community composed of those who make and utilize standards exists and requires CDISC to continue to support their aspirations and to understand their needs even as changes including new sources of data and new technologies continue at a significant pace.

Goal III.A: Ensure a positive culture and utilize technology tools so volunteers can be recruited, onboarded, and retained so the global CDISC community can benefit from their expertise and skills.

Goal III.B: Operate globally, building greater local visibility and impact in growing markets while maintaining in established markets.



IV. Include

Reduce the barriers to entry and use for those who utilize CDISC standards.

CURRENT STATE:

There are high barriers to entry and use including (1.) CDISC standards and documentation are largely only available in English; (2.) it is expensive for most entities initially to standardize comprehensively with CDISC standards (although most entities later experience cost savings related to standardization); and (3.) standards implementers must become standards experts in order to attain significant benefits of standardization.

GoalIV.A:Facilitatethedevelopment of quality tools to help unlock the benefits of standardization to a variety of community members/ stakeholders.

Goal IV.B: Provide high-quality training and education so that the global community can benefit from CDISC standards.



V. Engage

Raise awareness of the benefits of data standardization among key stakeholder

CURRENT STATE:

CDISC is a small organization and thus relies on many partners to complete aspects of our mission. At the same time, partners change over time as other organizations begin and end and as the many industries touched by CDISC evolve. CDISC must be vigilant to identify the current optimal mix of partners to best ensure our goals are achieved.

In addition, not all stakeholders industries among the and stakeholders CDISC touches are aware of the benefits of standardization.

Goal V.A: Be an excellent partner.

The complete strategic plan and associated webinar are available for review or download at www.cdisc.org/about.

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

Marine Laurent | CDISC Bess Leroy, MPH | CDISC Peter Van Reusel | CDISC

Technology & CDISC Standards



CDISC launched CDISC 360, an ambitious project geared toward innovating clinical data standards to ensure they remain valuable and relevant into the future. CDISC 360 aims to support standards-based, metadata-driven automation across the end-to-end clinical research data lifecycle and represents a significant next step toward realizing an increased return on investment in standards implementation that our stakeholders expect – substantially improved efficiency, consistency, and re-usability.

CDISC 360 seeks to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata drivenautomation across the end-to-end clinical research data lifecycle. New software tools will consume this new metadata to ease standards implementations while increasing data processing efficiencies.

CDISC 360 will demonstrate the feasibility of standards-based metadata-driven automation as a start towards realizing the full benefits expected of the CDISC standards: substantially improved efficiency, consistency, and reusability across the clinical research data lifecycle. These benefits drive the return on investment in the CDISC standards implementations expected by CDISC stakeholders.

Tremendous Participation

67 individuals from 29 member companies are actively contributing the project across to six workstreams. They are a global group from Asia, Europe, and North America. Their companies cover the industry spectrum, including pharmaceuticals, biotechs, CROs, technology firms, and solutions providers. The US FDA also serves as participant to ensure that the concept-based standards model developed in the project will meet FDA reviewers' needs for safety analyses.

A series of collaboration tools have been provided to support workstream teams as members work remotely worldwide. These tools include shared environments for document content (Wiki), issue tracking (Jira), concept mapping (Cmap Cloud), instant messaging (Slack), and metadata management (CDISC Library). In addition, Microsoft, as a project participant, is providing its Azure platform to further support collaboration, including but not limited to support for data storage and script execution in multiple scripting languages as the project team executes the use cases.

CDISC 360 at the US Interchange

CDISC 360 presentations Six were delivered at the 2019 US Interchange, CDISC Board Members Chris Decker and Dave Evans challenged the audience to imagine the possibilities of a new clinical trials future powered by the kind of linked metadata being modeled by the CDISC 360 team. CDISC CSO Peter Van Reusel provided a project overview and status, and a live User Experience simulation to portray what future clinical trial design, build, and execution, might look like. Dr. Sam Hume, CDISC VP, Data Science, took the podium to provide a snapshot and demo of the technical progress made to date in the project.

CDISC also held a breakout session titled "CDISC 360 Use Cases -Industry Perspectives", featuring presentations about each of the three industry-centric 360 project use cases, delivered by the project workstream leads. Additionally, about 25 project participants gathered to take a deeper look at the technical demo provided in the Plenary by Sam Hume, to explore how to best communicate the project meaning and results to the CDISC community.



Data Science

CCISC 53 LIBRARY

In April of 2019, CDISC Library, our standards metadata repository, became freely available to members.

The single, trusted, authoritative source of CDISC content, and the only platform for creating, maintaining, and publishing CDISC standards and terminology metadata. CDISC Library uses linked data and a REST API to deliver CDISC standards metadata to software applications that automate standards-based processes. CDISC Library provides access to new relationships between standards as well as a substantially increased number of versioned CDISC standards and controlled terminology packages.

CDISC Library Browser

In September of 2019, CDISC launched the CDISC Library Data Standards Browser at the US Interchange in San Diego. The Data Standards Browser allows wider stakeholder access via an intuitive, user friendly interface to the same normative metadata found in a Rest API. Users can simply select the CDISC standard (e.g., CDASH, SDTM, ADaM, etc.) they wish to review in more detail. Traversing the standards via the CDISC Library Browser includes access to all associated metadata (i.e., models, classes, domains, variables, controlled terminology, etc.). The data standards browser also provides explicit relationships acrossproducts, such as identifying the model to an implementation guide or controlled terminology association(s). This content can be further filtered at its result level (e.g., by keywords), which makes the data standards browser an ideal querying mechanism. Additional key features include search capabilities via elasticsearch and export functionality (e.g., CSV, XLSX). We continue to refine CDISC Library to include additional features and new content as it becomes available.

By the end of 2019, CDISC Library achieved 100+ organizations in just 8 months after its initial soft release. More importantly, the diversity of CDISC Library customers by industry and geographic region was and continues to be impressive.



Your Clinical Systems Mobile Health Apps & Gadgets Web Browsers Data Validation Tools & Services

CDISC Library Benefits

Platform

- New Semantic Technology Stack
- Resource Description Framework
 (RDF) Model
- Expanded RESTful API
- Simplification of Standards Integration for Automation
- Elasticsearch for Greater Metadata
 Search Functionality

Content

- Authoritative Source for Machine-Readable Normative CDISC Standards & Terminology Metadata
- Version Traceability
- Model-Based Standards Metadata
 for Greater Quality
- Relationship Lineage Identification
- Future Novel Metadata (e.g., CT Code Tables & Relationships, QRS Supplements, Conformance Rules, TAUGs, etc.)
- Ongoing Loading of New Content
- Available Media Types (JSON, XML, CSV, Excel

Innovation

- Agile Development Methodology for Quicker Release Cadence
- Continuous Exploration of New Functionality via R&D
- Data Standards Web Browser
- Future Media Types (ODM-XML, Define-XML, JSON-LD)
- Requirements Gathering & Alignment with CDISC 360 Project
- User Product Feedback & Enhancement Requests

Snapshot

- 85+ Versioned Standards
- 1+ Million Resources (100k+ Controlled Ter111s, ·1 .2k CDASH Fields, 2k+ SDTM Variables, 740 ADaM Variables)
- 6+ Million Relationships
- 1.5k CDASH-to-SDTM Mapping
 Statements
- 35 Regulatory Support Statements

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.



Japan | Tokyo 10-12 July 2019





South Korea | Daegu 7 November 2019

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

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

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

2019 Highlights

- First Korea Summit hosted over 200 participants
- Regulator panelists included US FDA, Japan PMDA, China NMPA, and EU EMA

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

Interchanges & Events









CDISC KOREA SUMMIT 2019. 11. 07. THU.





















CDISC Education

Greater Clarity Starts with CDISC Education

New Learning Management System

In 2019, CDISC continued to innovate in ways to deliver educational opportunities by updating all existing content on the CDISC learning management system (LMS). These updates included interactive tools to further engage the learner and help increase interest and retention.



The clean design of the CDISC LMS interface provides industry-leading user experience.

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 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.

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

In 2019, CDISC provided 12,118 sessions of learning via online and in-person training to the global CDISC community encompassing over 25 countries on 5 continents.

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 to sessions covering the latest advancement of CDISC's technical releases, such as our Library program.

CDISC Partners

CDISC is not an island. Our impact as an organization is multiplied by 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. A few of our key partners and collaborative efforts over the year are highlighted here:



The Critical Path Institute (C-Path) is a nonprofit, publicprivate partnership with the FDA created under the auspices of the FDA's Critical Path Initiative program. In 2019, CDISC and C-Path collaborated on the development and release of Therapeutic Area Guides for HIV and CDAD.



The Innovative Medicines Initiative (IMI) joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The IMI and CDISC are working together to enhance the use of information gathered for the purpose of developing safer, more effective innovative medicines for patients.



The Joint Initiative Council on SDO Global Health Informatics Standardization is formed to enable common, timely health informatics standards. The Council includes: CDISC, CEN Health Informatics TC251, DICOM, GS1, HL7, IHE, ISO TC215, and SNOMED.



Mapi Research Trust is the largest curator of Clinical Outcomes Assessments (COA) and their translations. CDISC and Mapi Research Trust work together to ensure copyrighted instruments are available to CDISC.



NCI EVS is a founding partner in the development, maintenance, and production of Controlled Terminology content, tools, and services. CDISC and EVS released four quarterly Controlled Terminology packages in 2019.



In 2019, CDISC announced a collaboration with the **Pancreatic Cancer Action Network (PanCAN)** to establish the first-ever data standards specifically for pancreatic cancer.



CDISC and 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.



SCDM was created to advance the discipline of Clinical Data Management in all regions of the world. CDISC and SCDM share many members and volunteers and have aligned missions of improving global clinical data management.



TransCelerate BioPharma's mission is to collaborate across the global biopharmaceutical research and development community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines. CDISC, with support from TransCelerate Biopharma, is developing version 2.0 of the CDASH SAE Supplement.among research scientists and to improve medical research around the globe.

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.

With CDISC membership you build and nurture your organization's culture for quality standards with the support of an organization dedicated to bringing clarity to data.

As a CDISC member, you get access to tools, knowledge, discounts and networking opportunities with others passionate about clinical standards and technology the world uses to amplify the power of data.



CDISC Member Benefits

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

Membership by Segment



460+ members around the globe, representing many ind

Membership



In 2019, each member received a framed certificate to display in lobbies, offices, or at standardsrelated events.



The Member Portal provides access to members-only benefits and a wealth of standards resources.

All CDISC Platinum and Gold Members are listed in the back cover of this report. Please check to see if your organization is listed, and start using your many 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.



Membership by Country

ustries, united to pursue the benefits of data standards.

2019 was undoubtedly a year of innovation, progress and forward movement in the standards community. Over the past year at CDISC, we have seen new trending topics such as Real World Data, we have made inroads into new geographies such as South Korea, and have planned a strategy to take us through the next decade of delivering standards that bring clarity to clinical research data. Throughout the year, we were quick to provide you with these compelling insights through our always-expanding website content, emails, press releases, social platforms, events, and education resources.

As CDISC prepares for more exciting milestones to come, we want to revisit some of the most significant events that occurred over the past year.

Strategic Plan

CDISC released our 2019-2022 Strategic Plan with its five goals: Transform, Expand, Support, Include, and Engage. The Strategic Plan guides CDISC and our global community to evolve so that data standardization facilitates more meaningful and efficient research that has greater impact on global health.

As 2019 came to a close, CDISC began working to convert these goals into work plans. Ultimately, we aim to make concrete strides toward better, more accessible data standards, resulting in more cures.

Knowledge Base

CDISC revealed the new Knowledge Base at our US Interchange in October. Available on our website, the Knowledge Base features in-depth articles written by CDISC staff and teams about implementing CDISC standards. Visitors can filter by standard, search by key word, and sort by proficiency level and audience to find the information they are looking for.

CDISC Publishes First Traditional Chinese Medicine Standard

Developed in partnership with CDISC volunteers, Xiyuan Hospital of China Academy of Chinese Medical Sciences, National Cancer Institute Enterprise Vocabulary Services (NCI-EVS), and supported by the China CDISC coordinating committee (C3C) and other TCM Institutions in China, the standard describes how to use CDISC standards to represent data pertaining to coronary artery disease for the treatment of angina. It is CDISC's first standard to be released for Traditional Chinese Medicine as well as the first standard published in Chinese and English.

The standard would not have come to fruition without the support of the Chinese reviewers from industry and the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) for participating, reviewing and providing useful feedback during the Internal and Public Review periods.

Helmsley Innovation Grant

The Leona M. and Harry B. Helmsley Charitable Trust made significant investments to modernize and innovate CDISC Standards in 2019. The Helmsley Charitable Trust invests in critical projects: the development of new data standards for type 1 diabetes (T1D) and Crohn's disease (CD) research as well as a new set of innovative activities designed to help us move significantly forward in developing the types of standards that can be utilized by non-standards experts. Because of Helmsley's support, CDISC standards will be opened up as never before to academic researchers, the open source community, and others who can benefit from data standardization and interoperability, but also face a high threshold to implementation of CDISC.

Over time, the newly developed CDISC standards will benefit the T1D and CD communities by allowing more seamless information sharing across research centers as well as improving quality, usefulness, and consistency of clinical data. Once in place, these standards are also expected to provide researchers with the ability to evaluate the effectiveness of emerging treatments. In time, this interoperable data will foster better medical decisions, drug discovery, and healthcare considerations for T1D and CD patients worldwide.

First Korea Summit

CDISC held our first Summit in Daegu, South Korea in November. CDISC staff, David R. Bobbitt, Rhonda Facile, Mike Hamidi, Bess LeRoy and Sheila Leaman, traveled to Daegu to meet with local and national officials and presented a wide-range of CDISC-focused topics. As the implementation of CDISC standards is an exciting new topic for many interested parties in South Korea, the Summit focused on providing an essential overview of the standards and tools CDISC offers. The Summit was quite popular for a first-time event, with 200 attendees. Participating staff were impressed by the prominent conference backdrop and pyrotechnics during the event! Local leaders who spoke during the Summit included the Vice Mayor of Daegu, Young-jin Kwon; Dr. Soondo Cha, Medicity Daegu Chairman, and Seonghyup Lee, Director of the Daegu Digital Industry Promotion Agency. The event was emceed by Gihwan Kim of Clupea. Dr. Ron Fitzmartin, FDA-CBER; Dr. Yuki Ando, PMDA; and Dr. Frank Pétavy, EMA also participated virtually on behalf of their fellow global regulatory agencies.

K3C Launched

A Korean CDISC Coordinating Committee (K3C) was launched at the 2019 CDISC Korea Summit. Long-time CDISC advocate Dr. Maria Im Hee Shin of Daegu Catholic University Medical Center serves as K3C Chair. The K3C joined other CDISC coordinating committees in the Europe, China, Japan, and the Asia-Pacific region.

CDISC Coordinating Committees (3Cs) support global CDISC initiatives within specific regions of the world and provide regional feedback to the central CDISC organization. 3Cs represent CDISC around the globe and help strengthen relationships with international and local entities as well as organizations in their respective regions. Their primary aim is to promote the value of implementing CDISC standards to bring clarity to clinical research data.

China NMPA Recommends CDISC Standards

CDISC standards are now the preferred standards for electronic data submission in China. A new electronic common technical document (eCTD) released by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) stipulates the use of SDTM, CDISC's standard for formatting and organizing study data, and ADaM, CDISC's standard for data analysis, for pharmaceutical sponsors submitting datasets in clinical trial databases and related materials. Going forward, CDISC standards are the only global data standard the CDE has recommended.

The NMPA joins the US FDA and Japan PMDA in recognizing the centrality of global CDISC standards to be used for submission of clinical research study data. Requiring standardized data enables regulators to modernize the review process with a more consistent use of analysis tools to better view drug data and highlight areas of concern.

Since 2012, the community of CDISC users in China has grown significantly as members of the Chinese CDISC Coordinating Council (C3C) promote awareness and support the implementation of CDISC standards.

RWD Connect

CDISC initiated "CDISC RWD Connect" to engage the academic community in a conversation around how CDISC standards can be effectively and efficiently deployed in Real World Data (RWD) settings. The benefits of connecting RWD to CDISC standards are myriad and include improvements in data sharing, crossstudy analysis and meta-analysis of data for all clinical researchers.

CDISC is collecting information primarily from academic researchers and will produce one or more articles that discuss methodology, what we learned about current CDISC standards utilization for RWD, and outline the emerging strategy and recommendations for fostering the use of CDISC standards to connect academic research.

CDISC has employed a phased approach to this initiative which involves: 1) listening to better understand the barriers to implementing CDISC standards for RWD and getting a picture of what tools and guidance may be needed to more easily implement CDISC standards; 2) focusing on creating a strategy for fostering consistent implementation of CDISC standards within the academic community; 3) making the tools and guidance we agree are needed a reality.

2019 Working Group Meeting

CDISC staff and volunteers gathered again 12-14 June in Silver Spring, Maryland for the annual Working Group Meeting. The Working Group Meeting focuses on crossteam sessions devoted to accomplishing 2019 CDISC team goals and addressing common topics of interest among all CDISC teams. Foundational teams also devoted a full day to within team meetings to make progress on team deliverables. Over 90 volunteers were in attendance to participate in face-to-face meetings with the teams they work with virtually throughout the year. They tackled a robust agenda that included such topics as SEND & SDS Team Development Principles, Redesigned Metadata Specifications & Conformance Rules,SDS & Lab/CT Updates to Lab-related Domains, Examples Collection Development, and Fundamental Definitions of CDISC Documents.



Log on and sign up for CDISC news and events today!

2019 Income vs. Expenses

2019 was once again a year of strong growth for CDISC, with an annual gross revenue almost 20% higher than in 2018. This strong performance was driven in particular by our events and training activities, as well as an extremely dynamic year in terms of standards and technical developments.

This allows us to increase our reserves and strengthens our sustainability moving forward.

Financial Performance

Income		
Education	\$1,594,000	15%
Events	\$ 963,000	9 %
Standards Development / Library	\$ 3,729,000	36%
Membership	\$ 4,066,000	39 %
Other	\$ 138,000	1%
Gross Income	\$10,490,000	

2019 Revenue



Expenses		
Education	\$1,101,000	11%
Membership & Events	\$1,319,000	14%
Standards Development / Library	\$4,662,000	48%
Alliances & Business Development	\$520,000	5%
Communication	\$336,000	4%
IT / Finance / Admin / Other	\$1,707,000	18%
Total Expenses	\$9,645,000	

2019 Expenses



Long-term Growth

Over many years, CDISC has grown to meet the needs of an expanding global community of clinical data standards users. Recent growth has fueled advances in technology interdependencies and new outreach. CDISC thanks every member, volunteer, donor, and partner for your ongoing support.







October's staff retreat gathered team members from North America and Europe to begin planning for 2020!

PLATINUM MEMBERS

1mdata AbbVie** Abond CRO, Inc.** Accenture, LLC** Acorda Therapeutics, Inc* Alexion Pharmaceuticals* Amgen*** Argenx ARO Council Asahi Kasei Pharma Corporation* Ashermed Astellas Pharma, Inc.** AstraZeneca AB** Baxter Healthcare Corporation** Bayer Pharma AG** BeiGene, Inc. Bioclinica, Inc.** Biogen, Inc.** Boehringer Ingelheim Pharmaceuticals*** Bristol Myers Squibb*** Business & Decision Life Sciences** Catalyst Clinical Research Celgene Corporation** Center for Biostatistics in AIDS Research Centers for Disease Control / National Center for HIV/ AIDS, Viral Hepatitis, STD and TB Prevention Certara*** **Clinical Trial Data Services** Clinipace³ CLUPEA, Inc. Cohen Veterans Bioscience CompleWare Corporation*** Covance** Critical Path Institute** **CRScube Inc.*** d-Wise Technologies** Daegu Catholic University Medical Center* Daiichi Sankyo, Inc.** Danone Nutricia Research Deep Intelligent Pharma Co., Ltd. Deloitte Consulting, LLC* Digital Infuzion** dMed Biopharmaceutical Co., Ltd. eClinical Solutions, LLC* **EDETEK Inc*** Eisai, Inc.** Eli Lilly and Company*** EORTC* ERT Pharmaceuticals** F. Hoffmann-La Roche Ltd** Food & Drug Administration* Forte Research Systems, Inc.** **Fujitsu Limited*** Galapagos NV Gilead Sciences** **GSK***** ICON Clinical Research** Incyte Corporation* Innovative Medicines Initiatives* **Innovion BVBA** Institut de Recherche Pierre Fabre* Intercept Pharmaceuticals, Inc. IOVIA** Japan Agency for Medical Research and Development Jazz Pharmaceuticls, Inc.* Johnson & Johnson***

L7 Informatics, Inc. LinkDoc Technology (Beijing) Co., Ltd. LLX Solutions Lung Biotechnology, Inc.* LYSĂRC Massachusetts General Hospital - CIB Massachusetts Veterans Epidemiology Research and Information Center** McDougall Scientific Ltd.** Medidata Solutions Worldwide** Medtronic, Inc.* Mel Consulting Merck & Co., Inc.*** Merck KGaA** Microsoft Corporation Mitsubishi Tanabe Pharma Corporation** Montreal Health Innovations Coordinating Center National Cancer Center* National Cancer Institute* National Institute of Allergy & Infectious Diseases (NIAID) National Library of Medicine Navitas Data Sciences* New York University School of Medicine NHMRC Clinical Trials Centre, Sydney University Northwest Ehealth Novartis Pharmaceuticals Corporation*** Novo Nordisk** Novum Pharmaceutical Research Services Nurocor Ono Pharmaceutical Co., Ltd.* Oracle Corporation** Otsuka Pharmaceutical Development and Commercialization, Inc.** PAREXEL** Pfizer, Inc.*** Pharmaceuticals & Medical Devices Agency* Philip Morris Products SA* Pinnacle 21 LLC.** PointCross Life Sciences, Inc.** Population Health Research Institute PPC Group **PPD***** PRA Health Sciences** Premier Research Group*** **PROMETRIKA, LLC*** Sanofi*** Santen, Inc.* SAS** SCRI Development Innovations (SCDI)* Servier* SGS** Shionogi & Co., Ltd* Shire Pharmaceuticals, Inc.** Sumitomo Dainippon Pharma Co., Ltd** Syneos Health Inc.* Takeda Pharmaceutical Company Limited*** Target Health, Inc.** Teva Pharmaceutical Industries Ltd** The Helmsley Charitable Trust The University of Tokyo Hospital Theravance Biopharma, Inc.** Trifecta Clinical* UCB Biosciences, Inc.** University of Oxford University of Southampton Clinical Informatics Research Unit Xclinical**

GOLD MEMBERS

A2 Healthcare Corporation** AC Medical, Inc.* Acceleron Pharma Accord Research s.r.o. ACI Clinical** aCROnordic** Acumen Information & Technology Co., Ltd. AdClin* Advance Research Associates, Inc.* Advanced Clinical** Agati Clinical Informatics AIXIAL* Akebia Therapeutics Akros Pharma, Inc.* ALK-Abello A/S Alkermes Allergan** Almirall, S.A.* Alnylam Pharmaceuticals Alpha Clinical Systems Altasciences Clinical Research American Medical Informatics Association (AMIA)** Amphastar Pharmaceuticals Inc* AnalysisMate LLC ASKA Pharmaceutical Co., Ltd. Assign Data Management and **Biostatistics GmbH** Association of Clinical Research Organizations* Atlant Clinical Ltd. Basilea Pharmaceutica International Ltd.3 Battelle Memorial Institute Becton Dickinson **Beijing Bioknow Information** Technology Co., Ltd. Beijing BioVoice Technology Co., Ltd. Beijing Data Science Express Consulting Co., Ltd Beijing Farinfo Technology Co. Ltd. Beijing Huayi Internet Technology Co., Ítď Beijing Improve-Quality Technology Co., Ltd. Beijing Natureself Technology Co., Ltd. Beijing Trust Medical Consulting Co. Ĺtď. Bioforum Ltd.* BioMarin Pharmaceutical Inc.** BioOperations Consulting bioskin GmbH* **BioStata ApS* Biotrial Biometrics*** bluebird bio Bogier Clinical & IT Solutions, Inc.* Bracket Global Brightech International LLC* C&R Research CAC Croit Corporation** Cancer Insight, LLC Cancer Research And Biostatistics* Capish Nordic AB* Cardiovascular Clinical Science Foundation Castor EDC Ce3, Inc.* CEBIS International Center for International Blood and Marrow Transplant Research Center of Excellence for Biomedical and Public Health Informatics* Children's Oncology Group Chonbuk National University Hospital CHU Sainte-Justine* ClinDART, Inc. Clindata Insight Inc.* ClinDatrix, Inc. Clinical Solutions Group (CSG), Inc. Clinical Trial Center at Asan Medical Center Clinical Trials Statistical and Data Management Center at the University of Iowa* CliniOps, Inc. Clinvest Research CMIC Holdings Co. Ltd.** Cognigen Corporation Cognitive Research Corporation*

Commonwealth Informatics

*** CDISC Charter Member

Corbus Pharmaceuticals Corcept Therapeutics Cota Enterprises, Inc. CPC Clinical Research* CR Medicon US, Inc. CRC Oncology Corp CRC Pharma CROMSOURCE* CROS NT s.r.l.* Cross Research SA* CRS Clinical Research Services Mannheim GmbH* CSL Behring* CTEP (RealWorldEDC) Ltd** Cytel, Inc.** Dacima Software Inc* Data MATRIX, Ltd. Data Standards Decisions Aps DATAMAP GmbH Datametrix Densuke Systems Co. Ltd.* DF/Net Research, Inc.* Dicore Group, LLC* DOT WORLD CO., LTD.* DP Clinical* DSG, Inc.* DSG, Inc." DT & SanoMedics Duke Clinical Research Institute*** DZS Clinical Services EA Pharma Co., Ltd.* Edgerton Data Consulting, LLC. Edwards Lifesciences LLC **EFFI-STAT** Elligo Health Research EMB Statistical Solutions, LLC* Emergent Biosolutions Ennov Clinical Entimo AG** Ephicacy Consulting Group, Inc.* EPS Corporation* ethica CRO European Clinical Research Infrastructure Network EVAMED Everest Clinical Research** Exelixis, Inc.* eXYSTAT Fast-Track Drugs & Biologics, LLC* Ferring Pharmaceuticals** Fiverings Co., Ltd. FMD K & L, Inc.* ForceClouds Software Co., Ltd. Formedix USA** Foundry Health* Fred Hutchinson Cancer Research Center* Frontier Science Foundation* GCP ClinPlus Co., Ltd. GCP-MB GCP-Service International Ltd. & Co. KG* GEM Programming Solutions Ltd. GenInvo, Inc.* Genmab A/S* Genomedia Inc. Gossamer Bio Grunenthal GmbH** Grupo Español de Investigación en Cáncer de mama (GEIČAM) GWU Biostatistics Center H. Lundbeck A/S* H2O Clinical, LLC* Halozyme Therapeutics, Inc. Hands-on GmbH** Health Decisions Helpclin Data Service Co., Ltd. Helsinn Healthcare SA* HERAX* HIMSS* HMS Analytical Software GmbH Hua Medicine, Inc. Icahn School of Medicine at Mount Sinai ICRC-Weyer GmbH* IDDI* Imbrium Therapeutics** InClin, Inc.* Inductive Quotient Analytics India Pvt Ltd. Inference Inc. Innovative Analytics Inc. Instat Instem LSS**

INTAGE Healthcare Inc.* Integrated Clinical Systems, Inc. Intellim Corporation iOMEDICO AG* Ionis Pharmaceuticals, Inc.* IPSEN Innovation* Jiaxing Clinflash Computer Technology Co., Ltd Jiaxing Taimei Medical Technology Co., Ltd JSC Almedis JSS Medical Research JUUL Labs Inc KAI Research, Inc.** Kaiser Permanente* Kaleidoscope I T Kanazawa University Kantar GmbH KCR KCT Data, Inc. Keyrus Biopharma KOEHLER eClinical GmbH** Kyoto University Hospital* Kyowa Kirin Co., Ltd* Kyushu University Hospital* La Jolla Pharmaceutical Lab Data Concepts Lambda-Plus SA* Larix ApS* LATIS SRL LEO Pharma A/S* Liaoning Yeedo Medical Data Co., Ltd. Liminal R&D BioSciences Inc. Linical LSK Global Pharma Services MacroGenics, Inc.* MacroStat (China) Clinical Research Co., Ltd Marcus Institute for Aging Research, Hebrew SeniorLife Maruho Co., Ltd.* MaxiVAX SA Mayo Clinic Foundation Medical Excellence Inc.³ Medical Research Institute of New Zealand Mediqual-Sprl MEDISCIENCE PLANNING, Inc. MedNet Solutions* Medpace, Inc.* Medrio Metronomia Clinical Research GmbH** Midda MKS Incorporated* MMS Holdings, Inc.** Mosim Co., Ltd. Multi-Regional Clinical Trials Center at Harvard* Nagoya Medical Center* National Institute of Public Health Neurocrine Biosciences, Inc. Nippon Shinyaku Co., Ltd. Nordic Bioscience A/S* Novotech Pty Ltd.** NRG Oncology Foundation Nubilaria Srl Nuventra, Inc.* OCS Life Sciences* Omeros Corporation* OmniComm Systems** Orion OXMO CDM Oy 4Pharma Ltd P1vital Products Ltd PCG Solutions AB PDS Life Sciences* Peachtree BioResearch Solutions Pentara Corporation PerkinElmer Pharm-Olam International Ltd. Pharma Medica Research Inc.* PharmaStat LLC** **Plus-Project** Poseida Therapeutics Prevail Infoworks PROCURATIO Profil Institut fuer Stoffwechselforschung** Progenics Pharmaceuticals* Prothena Biosciences Inc. PSI CRO AG Puma Biotechnology, Inc. Quadratek Data Solutions** Quality Data Services, Inc.**

Quartesian LLC* Quotient Sciences Quretec, Ltd. R-Square, Inc.* Rakuten Medical RCTs REGENXBIO Research Mentor Co. Ltd. ResearchPoint Global Rho, Inc.** Robarts Clinical Trials Robertson Centre for Biostatistics* S-cubed ApS** Saama Technologies Sage Therapeutics SanaClis s.r.o. Sanford Health Sarepta Therapeutics, Inc. SCIAN Services Inc.* SCSK Corporation* Seattle Children's Seattle Conditions Seattle Genetics Senju Pharmaceutical Co., Ltd. Seven to One, Inc. Shanghai KNOWLANDS MedPharm Shanghai KNOWLANDS MedPha Consulting Co.,Ltd. Shanghai Mudi Biotech Co., Ltd SHYFT Analytics Signifikans Aps* SimulStat Incorporated Soladis Clinical Studies StatisticaMedica Statistics and Data Corporation** Sumptuous Data Sciences, LLC Sycamore Informatics SymBio Pharmaceuticals Limited Symyoo Co.,Ltd. Syne qua non Limited* Synteract** Systex, Inc* Taisho Pharmaceutical Co., Ltd.* Takumi Information Technology Inc.** TalentMine, LLC Tamr* TELEMEDICINE TECHNOLOGIES S.A.S Texas e-Health Alliance* TFS The EMMES Corporation* The Griesser Group* Theradex Oncology Therapeutics, Inc. TMF - Technology, Methods, and Infrastructure for Networked Medical Research** Toray Industries, Inc* TradeCraft Clinical Research Trial Data Pharmaceutical Technology (Shanghai) Co., Ltd. Turning Point Therapeutics Ultragenyx Pharmaceutical* University Hospital Medical Information Network** University of Alabama at Birmingham University of California, San Diego University of Luxembourg University of Tsukuba* University of Utah - Center for Clinical and Translational Science UniWeb Uppsala Clinical Research Center* Uppsala Monitoring Centre* US Army MRMC** Venn Life Sciences Veristat, Inc.* Vertex Pharmaceuticals** Vita Data Sciences, a division of Softworld Inc. Wake Forest Baptist Medical Center Westat Winicker Norimed GmbH* World Programming* Worldwide Clinical Trials* X-act Cologne Clinical Research GmbH³ Xi'an Riehen Life Science Technology Co. Ltd. Xinghui Medtech (Shanghai) Co. Ltd. Xiyuan Hospital of China Academy of Chinese Medical Sciences XML4 Pharma* Xybion Corporation* YPrime Zifo RnD Solutions* Zymeworks, Inc.

**** Member for 10 years and Longer**

Institut Paoli-Calmettes

Quanticate International Ltd*

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.









