



SHARING

*Sharing saves lives
Standards save lives*

President's Letter

*"A candle loses nothing by lighting another candle."
—Father James Keller*

Dear Colleagues:

CDISC saw a pivotal year in 2013. We owe this unprecedented progress to our loyal member organizations, our diligent volunteers, our keen supporters and our growing staff. One should be able to get a flavor of the CDISC 2013 activities over the course of the year in the following pages, although limited space meant we had to choose only major highlights from the numerous CDISC accomplishments and milestones of 2013.

One key accomplishment in 2013 was the official launch of the long-awaited Shared Health and Research Electronic Library (SHARE). This acronym is nicely aligned with the theme of this year's Annual Public Report: SHARING. As the cover image indicates, the world has changed since CDISC was founded in 1997. In that year, we were just embarking on a new way to collect clinical research data – electronic data capture, rather than the well-known 3-part NCR paper method that many of us found comforting. At that time in 1997, I had already spent two decades in the area of clinical research, including bench science, hands-on NIH research studies with the Pima Indians in Arizona, publication/document preparation with a Japanese biopharmaceutical company and project management for numerous research sponsors through a global CRO. Still, I drew a blank when asked, "What are the electronic data interchange (EDI) standards in your Industry?" This question spawned the

origin of CDISC. By 1999, CDISC had developed a small Glossary and the initial versions of SDTM (Study Data Tabulation Model) and ODM (Data Acquisition Standard); these were done completely through volunteer efforts, and I am pleased that many of these original volunteers are still engaged and playing key roles in CDISC.

Today CDISC offers a harmonized suite of global standards for the exchange of clinical research information from protocol through analysis and reporting, including links with healthcare standards through BRIDG and CDISC-Inspired IHE Profiles that support the use of EHRs for prospective research studies. These standards can support seamless data sharing across studies, cross-study comparisons and ready aggregation. In turn, they bring opportunities in the form of workflow efficiencies and the creation of large high-quality datasets for disease modeling and biomarker qualification to stimulate the development of new therapies for patients. Without standard data formats, these opportunities are either lost or they require far more resources than are warranted.

CDISC is unique among standards developing organizations in the life sciences/healthcare arena in that the standards must complement one another and not compete with or 'break' another CDISC standard. SHARE will facilitate this complementarity as well as the re-use of common components among and across the standards, which is

particularly important as we enhance the foundational standards to support specific therapeutic areas (TA) through our Coalition For Accelerating Standards and Therapies. In addition, CDISC SHARE will improve accessibility to a reference set of industry standards for clinical research in electronic format, which could significantly reduce the resources that individual organizations spend on standards development and maintenance.

As we consider the benefits of standards for data sharing, we look to our Gartner-supported Business Case, which has stood the test of time (7 years), especially with respect to emphasizing the value of implementing standards from the start. Unfortunately, there has been a concurrent increase in the complexity of research protocols, which emphasizes not only the need for data standards for data sharing but also for focus on the truly important data. CFAST, although initially targeting reporting standards, must expand to include the whole suite of CDISC standards, including protocol and data collection (i.e. CDASH as a core essential set of data elements for global clinical research), to bring the greatest value to all stakeholders, including patients.

In 2014, children cannot fathom a world without electronic tablets, smartphones and computers. During the past 3 decades, new technologies have created a 'smaller world' with connectivity at our fingertips, yet the clinical research process has lagged behind with automation of paper-

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based processes and point solutions. Regulatory Guidance on eSource encourages electronic data from beginning to end, yet researchers continue to manually transcribe and re-enter data, thus increasing the chance of error and the burden on site personnel and monitors. The CDISC standards and CDISC Healthcare Link products, however, are poised for a breakthrough to transform the way research is conducted. Embracing them for their flexibility and their potential to drive innovation could bring what we all sorely need – a far more efficient research process with a focus on key information. In a world of “Big Data,” CDISC is about **SUPER Data: Data that is Suitable, Useful, Prudent, Exchangeable and Re-usable.**

Responsible data sharing is what research participants and patients expect; we must derive the most value from the precious contributions these patients make towards the development of new therapies that are now possible through scientific advances. We must also make the leap to using eSource and engage electronic health records for prospective research so that research results can be derived more directly from patient data and more rapidly be applied to clinical care decisions. We envision a world where clinical research data can be shared as seamlessly as two children might share music in our modern age.

We hope that you enjoy this Annual Public Report and that you will let us know your thoughts on what caught your attention and what you feel should be included next year. Our CDISC Communications channels are open and continuously expanding; email Communications@cdisc.org and be sure to visit our upgraded website (www.cdisc.org) for a wealth of information about CDISC and our collaborative activities.

As always, we cannot adequately thank all of you who make CDISC possible through the many ways that you contribute each day. To our members and supporters, we offer our sincerest appreciation.

Kind regards,



Becky Kush

CDISC Vision & Mission

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



Vision

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

Mission

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

CDISC Principles

The CDISC Core Principles are:

1. Lead the development of standards that improve efficiency while supporting the scientific nature of clinical research.
2. Recognize the ultimate goal of creating regulatory submissions that allow for flexibility in scientific content and are easily interpreted, understood, and navigated by regulatory reviewers.
3. Acknowledge that the data content, structure and quality of the standard data models are of paramount importance, independent of implementation strategy and platform.
4. Maintain a global, multidisciplinary, cross-functional composition for CDISC and its working groups.
5. Work with other professional groups to encourage that there is maximum sharing of information and minimum duplication of efforts.
6. Provide educational programs about CDISC standards, models, values and benefits.
7. Accomplish the CDISC goals and mission without promoting any individual vendor or organization.

CDISC Values

The CDISC values were developed by CDISC Operations between December 2008 and April 2009. They represent CDISC Business Ethics and are based on the principles from the Economy of Communion (EoC), which inspires a “culture of giving” versus a “culture of having.”

The CDISC Core Value is to foster an understanding that the CDISC community is an altruistic organization contributing to the advancement of global healthcare.



Strategic Themes 2013–2015

- Continue to refine, support and educate about existing/foundational CDISC standards, achieving significant progress in the use of CDISC standards to streamline research, build quality into the beginning of the research process and promote scientifically sound data aggregation for the purposes of scientific investigation, comparative effectiveness and patient safety.
- Expedite the development and rollout of new therapeutic area standards to ensure consistency in data capture and analysis related to efficacy in addition to patient safety.
- Achieve significant progress in enabling interoperability between clinical care and clinical research and explore expansion from bench to bedside (translational research); accelerate the cycle through which healthcare informs research and research informs clinical decisions.
- Develop CDISC SHARE, a global, accessible, electronic library for CDISC content/semantics that will enable precise and standardized data element definitions and richer metadata that can be reused within applications and across studies to improve biomedical research and its link with healthcare.
- Leverage our global, nonprofit, vendor neutral, independent status to forge productive collaborations, to communicate well and to provide value to key stakeholder communities.

CDISC History & Standards

CDISC was initiated as a volunteer organization in 1997 and was incorporated as a non-profit organization in February 2000. In May of 2011, CDISC attained 501(c)(3) status, recognizing it as a charitable organization. Since 1997, teams of volunteers have ensured that efficient, consensus-based standards have been produced through the CDISC Standards Development process. The standards development process was updated in 2012 (using lessons learned from the development of a number of therapeutic area standards) to an improved, accelerated process that is now being implemented. CDISC released its first production models in 2000 and has had a steady record of accomplishment ever since. In 2013, the U.S. Food and Drug Administration and the Japan Pharmaceuticals and Medical Devices Agency released documentation announcing the intent to require data in CDISC format in the coming years. Additionally, the European Medicines Agency, Korea Food and Drug Administration and China Food & Drug Administration are considering researching the use of CDISC standards.

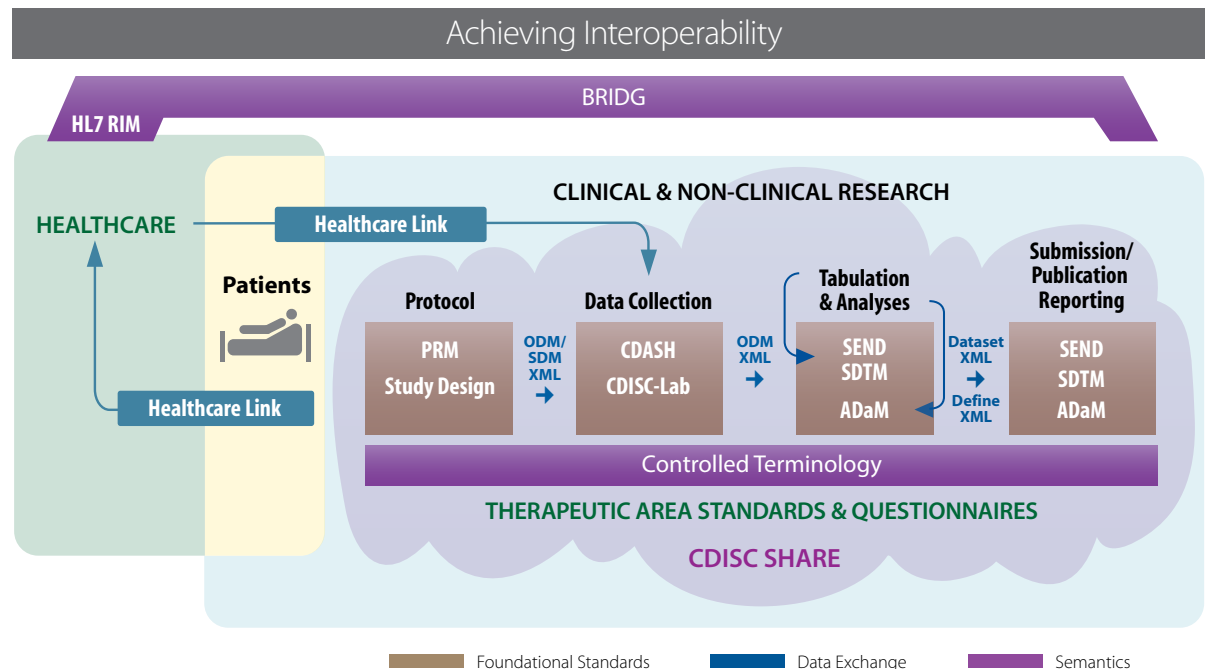
“The importance of a standard for the exchange of clinical trial data cannot be overstated. FDA reviewers spend far too much valuable time simply reorganizing large amounts of data submitted in varying formats. Having the data presented in a standard structure will improve FDA’s ability to evaluate the data and help speed new discoveries to the public.”

–Former FDA Commissioner

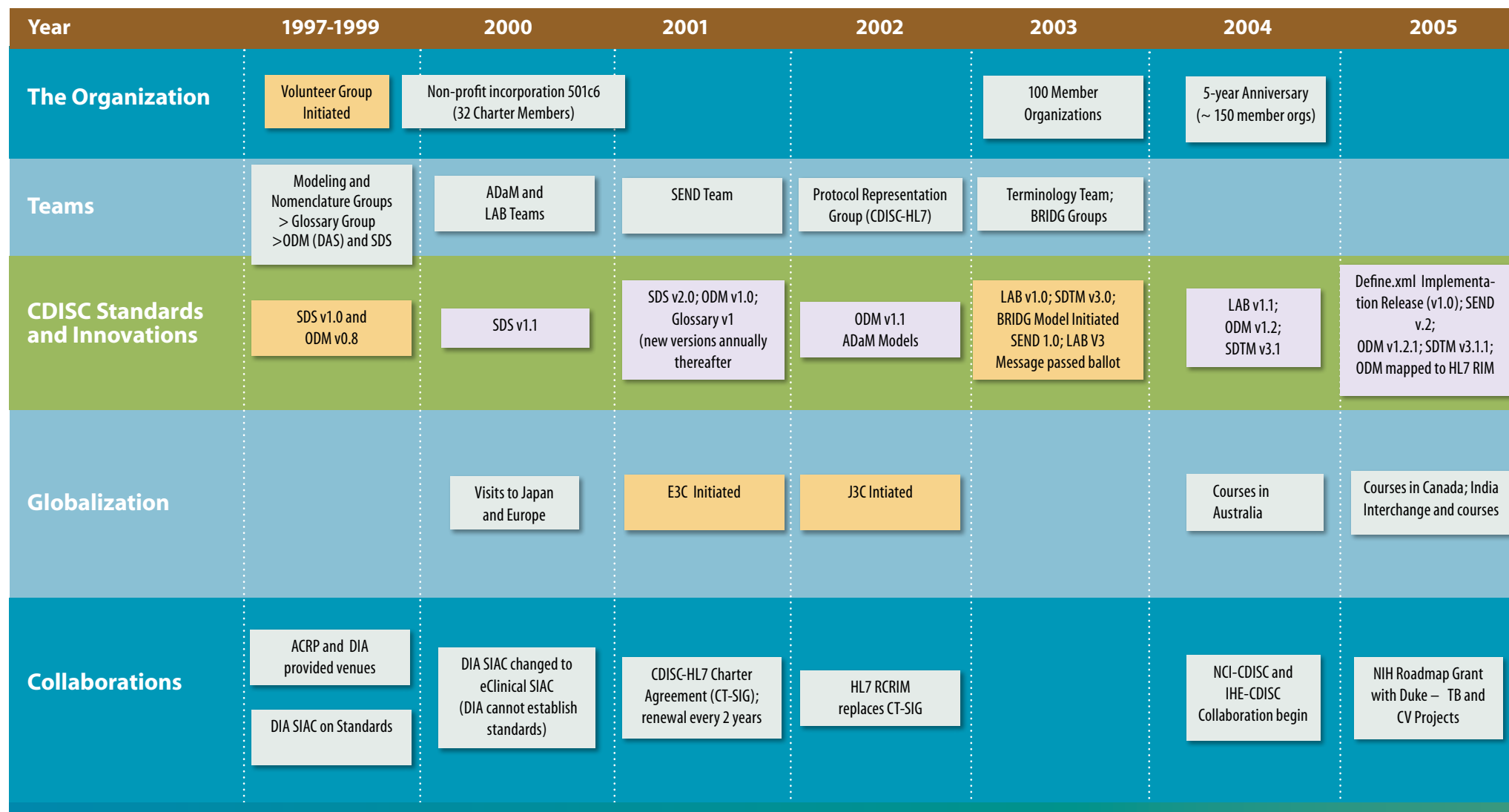
Why Data Standards? What Can Standards Do for Us?

The word “standards” brings up many different connotations, depending on who hears it and in what context. In this case, semantics are important. The CDISC suite of data standards have been designed to support various stages of the clinical research process while conforming to common research business processes and regulatory guidelines. However, taken collectively, they can streamline the medical research process, saving time and cost while improving quality. Use of data standards can increase the value and reusability of data while preserving meaning as data passes through various stages of the research process. Standards bring order to complexity. Here are some of the many benefits that users of CDISC global industry standards can expect:

- Support more streamlined research processes from protocol through analysis and reporting
- Facilitate consistent and efficient data aggregation
- Increase ability to share information among systems and organizations
- Decrease the time to initiate a new research study
- Improve and maintain consistent data quality and improve traceability across the research value chain
- Improve team interactions and communications
- Support easier adoption of a variety of standards-based tools and technologies
- Contribute toward the development of a learning healthcare system where research informs clinical care decisions and healthcare data are used for ongoing research



The CDISC Timeline



2012 CDISC Standards Releases

ADaM AE v1.0	CDASH User Guide v1.0	Terminology Packages 10, 11 & 12
ADaM TTE v1.0	Medical Device Supplement to SDTM v1.0	CDISC SHARE RFI
ADaM Sample Data	PRM Toolset v1.0	Define.xml v2.0
ADaM v1.2 Validation Checks	SDTM v1.3	Parkinson's Disease Therapeutic Area User Guide v1.0
BRIDG v3.2	SDTM Implementation Guide v3.1.3	

2006	2007	2008	2009	2010	2011	2012	2013
				10-year anniversary since incorporated, ~ 250 member orgs	501c3 status (charitable) approved by US IRS; CDISC Europe Foundation launched	300 Member Mark Achieved; Austin Office Established; CFAST TA Program Steering Committee Established	CFAST Scientific Advisory Committee Established; >320 Members; CFAST Grant Awarded by FDA; CDISC Grows to >20 Employees
CDASH Team and Streams; eSDI Group		HITSP: Use Case (EHRs for Core Research Data) – Clinical Research Tiger Team Initiated	Devices Team; SHARE Teams	Therapeutic Area Standards projects		CFAST TA Standards Teams	Essential Standards to Enable Learning (ESTEL) Initiative Launched; 7 New CFAST TA Teams Initiated
ODM v1.3: LAB & SDTM Aligned; CDISC-IHE RFD	BRIDG v1.0, v1.1; BRIDG posted as open source model	BRIDG v2.0, v2.1, v2.2 CDASH v1.0; eSDI Document Published	SDTM v3.1.2; ADam v2.1 Imaging CRFs CDISC-IHE RFD and RPE	Protocol Representation Model (PRM) v1.0; BRIDG v3.0; ODM v1.3.1; HHS-ONC/HITSP Interoperability Specification #158; CDISC-IHE RPE	Alzheimers Disease TA Package CDASH v1.1; SEND v3.0; Study Design XML v1.0;	Updates to Foundational Standards; Updates to XML Data Exchange Standards; Updates to Semantics Updates to Implementations <i>For detailed description of standards released in 2012-13, please see below</i>	
User Networks initiated in Europe (5 languages)	C3C Initiated Courses in Brazil	Courses in China; RFD Training in Japan	K3C Initiated Courses in Thailand and Singapore	South Africa initiates User Network	10th Anniversary for CDISC Japan; CDISC Workshops with AmCham in China; WHO Forum on Health Data Standardization and Interoperability; EMA Workshop on Clinical-trial Data and Transparency; European Commission Projects Convergence Round Table		Global Regulatory Authorities Announce Intent to Require CDISC Standards in Near Future; First CDISC Asia-Pacific Interchange Held in Singapore; Asia-Pacific CDISC Coordinating Committee (AP3C) Established; CDISC User Groups started in India
CDISC-IHE Quality, Research and Public Health (QRPH)	ISO Liaison A Status Awarded; ASTER Launched	CDISC accepted into Joint Initiative Council (JIC) for Global Harmonization of Healthcare Standards Additional IHE Profiles Proposed (e.g. RPE); Greenway EHR-Outcome Implementation of RFD	Critical Path Institute/ CAMD–Alzheimers; Tufts–PKD; ACC–CV disease	TRI (Japan) MOU Signed EMA cites CDISC eSDI requirements; SHARPN Project with ONC/Mayo; JIC Leadership; Rockefeller/FDA –Pain and Analgesics	IMI (Europe) MOU Signed C-Path MOU Signed; Gates Foundation-TB	Endorsed core values of the Learning Health System; CDISC engaged in 3 IMI Consortia projects; NIH/ FDA Grants; Leading role in JIC; One Mind for Research Workshop	IMI, NCI EVS & C-Path Relationships Strengthened; Learning Health Community MOU; <i>For further details, please see Page 12, Collaborations</i>

2013 CDISC Standards Releases	SDTM v1.4	Polycystic Kidney Disease Therapeutic Area User Guide v1.0
	SDTM Implementation Guide v3.2	Asthma Therapeutic Area User Guide v1.0
CDISC SHARE Officially Launched, R1 Completion Anticipated Early 2014	SDTM Implementation Guide for Associated Persons Data v1.0	Alzheimer's Disease Therapeutic Area User Guide v2.0
	Dataset-XML v1.0 Draft	CDISC-inspired IHE Data Element Exchange (DEX) Profile
Define.xml v2.0	Terminology Packages 13, 14, 15 & 16	CDISC-inspired IHE Research Matching (RM) Profile
CDASH Serious Adverse Events v1.0	Periodic Questionnaire Updates	

About Our Global Organization

CDISC Board of Directors: The role of the Board of Directors is to define the CDISC strategy and assure fiduciary responsibility. CDISC Board of Directors is made up of 12-15 members, each serving a three-year term. Elections are held annually for vacant seats and new directors begin their terms on 1 January.

CDISC Advisory Council: The CDISC Advisory Council (CAC) is comprised of a representative from each CDISC Platinum Member organization. The CAC representatives participate in Advisory Council meetings, teleconferences and task forces; supports the CDISC Strategic Plan; and enhances the organization's public image.

CDISC Coordinating Committees: CDISC Coordinating Committees support global CDISC initiatives within specific regions of the world and provide regional feedback to the central CDISC organization. CDISC 3Cs help to strengthen relationships with international and local entities as well as organizations in their respective regions. They may also assist in planning CDISC Interchanges.

CDISC Technical Leadership Committee: The Technical Leadership Committee is composed of CDISC Team Leaders. Their primary responsibility is to ensure that each team develops and follows a Charter with a plan for activities aligned with the CDISC Technical Roadmap.

CDISC Teams: CDISC teams are composed of hundreds of volunteers from around the globe who develop and maintain the CDISC standards, and assist with the development of educational courses.

CDISC User Networks: CDISC User Networks enable face-to-face interactions in specific regions or languages. They are self-formed groups that encourage the adoption and understanding of the value of CDISC standards.

CDISC Members, Stakeholders, Supporters, Adopters and Volunteers: It would not be possible to develop the CDISC standards without the incredible support we have had from this increasingly large network of people from over 90 countries around the world.

For more information about CDISC bylaws, policies, charters, operating procedures and related information, please visit the CDISC website: cdisc.org/mission-and-principles.

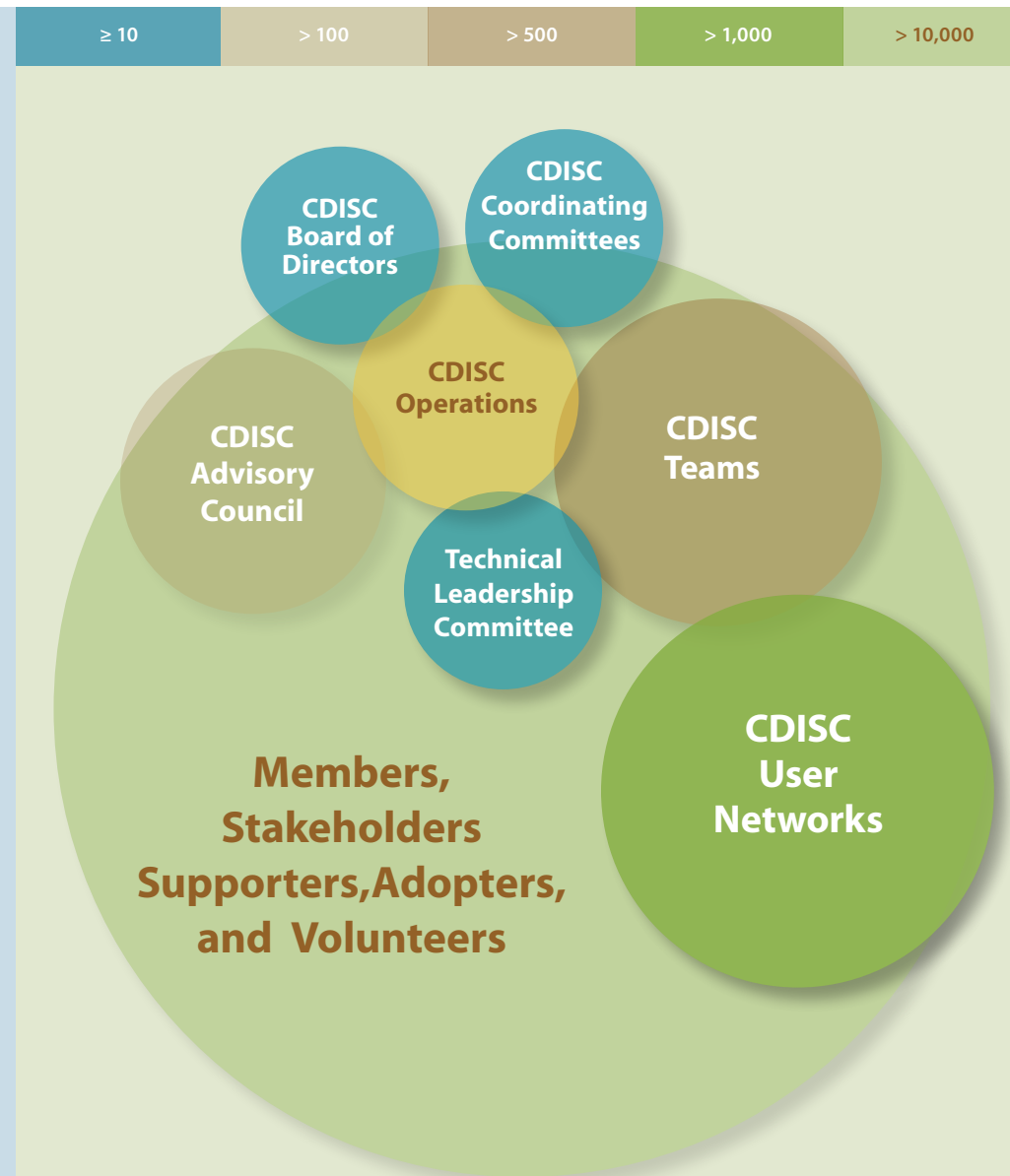


Diagram above illustrates the relationship between and different sizes of the varied groups that represent CDISC.

2013 Milestones

Global Regulatory Authorities Announce Intent to Require CDISC Standards in Near Future

FDA: On 13 September 2013, the U.S. Food and Drug Administration (FDA) released a position statement, recognizing the efforts of a great number of CDISC volunteers over the last decade and verified publicly that the FDA will soon “require study data in conformance to CDISC standards.” The statement also announced that the FDA would soon publish guidance on these requirements.

EMA: On 24 June 2013, the European Medicines Agency (EMA) released the draft policy on the publication and access to clinical trial data for a three-month public consultation. The draft contained the following language: “Wherever technically possible, analyzable, de-identified raw CT data should be made available for downloading in the format in which they were analysed by the applicant, submitted and evaluated. For the time being, this can be according to CDISC or other appropriate standard. In future, CDISC shall be the required standard, in line with future guidance from the Agency.” The final version is anticipated in early 2014.

PMDA: The Japan Pharmaceuticals and Medical Devices Agency (PMDA) released a statement on 2 September 2013, requesting that companies participate in a pilot, submitting electronic clinical study data to PMDA that had been “amassed and summarized according to the CDISC standards.” PMDA officials, including PMDA Senior Executive Director, Dr. Taisuke Hojo, spoke at the 2013 Japan Interchange in December, stating, “The PMDA wishes to promote medical innovation and shorten the time from early development to approval. PMDA has been communicating with the U.S. FDA, and will soon begin a special project using CDISC.”

CFDA: CFDA has formed a joint standards committee with the C3C to evaluate standards for clinical research.”

FDA Pilot Project to Test Dataset-XML as New Transport Format: At the end of 2013, the U.S. FDA announced that it was seeking sponsors to participate in a pilot project to test the new Dataset-XML standard for the submission of clinical study data as an alternative to the legacy SAS V5 transport format (XPORT). This replacement for XPORT is expected to eliminate many technical limitations of the 30-year-old XPORT format and enable many new efficiencies and capabilities for both FDA and sponsors.



2013 CDISC Asia-Pacific Interchange



CDISC Asia-Pacific Coordinating Committee December 2013 Meeting

Asia-Pacific CDISC Coordinating Committee (AP3C) Established: As a result of the positive outcome of the Asia-Pacific Interchange (top photo), many who attended the event voiced their support of the development of an Asia-Pacific CDISC Coordinating Committee (AP3C) to continue efforts to develop and support cross-country collaborations in this large region. After the completion of the Interchange, Drs. Kiyoteru Takenouchi of the CDISC Board and Ken Toyoda, J3C Chair, created a draft business plan to develop a working AP3C. With representatives from around the Asia-Pacific region, a follow up meeting was held in December 2013 in Hong Kong (bottom photo). Those in attendance were voted into the committee and followed Operating Procedure 014, which serves as a Charter for all global CDISC Coordinating Committees. The AP3C was thus established, and plans were made to have monthly meetings and another Asia-Pacific Interchange (in tandem with the Japan Interchange) in July 2014 in Tokyo.

“Dataset-XML is a relatively simple, ODM-based transport standard that complements Define-XML v2.0. It is really the first step in eliminating restrictions in the CDISC standards that carry over from the legacy SAS transport format. Dataset-XML was designed to support the standards as they exist today, but also to enable innovative enhancements to the standards going forward.”

- Sam Hume, CDISC Vice President of SHARE Technology and Services

Data Sharing for the Benefit of Patients

Data Sharing has become a topic of keen interest recently. These two words tend to elicit a broad array of reactions. Typical concerns often start with privacy, security and confidentiality; these are followed by questions about the ownership of the data and the intentions of potential recipients. The integrity of the data and the interpretations or analyses thereof can have everything to do with the success or failure of a hypothesis. Science is indeed complicated, especially when the human body is concerned; hence, clinical research requires very careful processes and management of the output—the data. Hans Joerg Eichler (EMA) commented at a recent Institute of Medicine (IOM) of the National Academy of Science workshop on the topic of “Strategies for Responsible Sharing of Clinical Trial Data,” stating, “Data are like children. You like your own best and you don’t want others to play with them.”

In the interim, the New England Journal of Medicine published a series of articles on this topic and a chapter on Data Sharing was included in a recent Clinical Research Informatics book. Journal editors are not accepting articles unless the clinical trials are registered publicly and results are shared, and federal funding is coming with requirements for “data sharing plans.” The CEO Roundtable on Cancer has been encouraging a data sharing project in oncology (DataSphere). Finally, at the end of 2012, the EU declared, “clinical trial data is not commercial confidential information.” Consequently, the EMA has been gathering public input and taking additional steps to make clinical trial data more accessible.

CDISC has played a role in the majority of these activities, with a conviction that data sharing cannot be

accomplished responsibly if the data are not collected and exchanged in globally recognized standard formats. These formats should facilitate clinical research and promote data integrity and high quality. It is interesting how many times we have been the lone voice amongst those who either assume that data just naturally flows when shared and do not really think about the impact of collecting data in a variety of formats (until it is too late) or believe that “big data” is the answer. The big data approach assumes that if one has enough data, the standard formats are not necessary and that computer algorithms will address this deficiency. Unfortunately, in clinical research studies, the data may be comparatively sparse. Patients who contribute their data in the name of science consider it precious; they make sacrifices to contribute their data, even a small bit, and they find it unacceptable and irresponsible if it is not used and shared responsibly.

Other organizations share a similar view. The Critical Path Institute (C-Path) has demonstrated what can be done when data are shared using CDISC standards. Its Coalition Against Major Diseases (CAMD) is enabling data aggregation, analyses and disease modeling that were never possible within one individual organization gathering data from only a small number of patients per study. The Innovative Medicines Initiative (IMI) in Europe is encouraging the use of CDISC standards for their eTRIKS repository, which will house the data from multiple IMI projects.

The CDISC Strategy focuses on the development of harmonized standards, not only to streamline clinical research studies from protocol through analysis and reporting, but also upstream to eSource, including the use of electronic health records. The insertion of

eSource, such that data are captured electronically from the beginning and never transcribed from paper or into different electronic systems can save significant time and resources, in addition to improving data quality and integrity. 2013 saw an unprecedented output of CDISC standards as well as CDISC-inspired IHE standards, complementing the existing foundational CDISC standards and the new CDISC therapeutic area standards, developed under the CFAST initiative. The synergistic use of these standards has the potential to transform research, bringing it closer to the patients themselves by making it easier for clinicians to conduct research and patients to receive the promising potential benefits sooner.

One final consideration on the topic of Data Sharing brings up the value of CDISC’s Shared Health and Clinical Research Electronic Library (SHARE). SHARE is a tool that will improve accessibility to the CDISC standards while providing a reference standard and a means to accelerate

“As a Parkinson’s patient who has participated in clinical research studies, I don’t have any issue with my data being used (and re-used) as long as it is done responsibly and in a way that protects my privacy. I do have a problem if my data is not used (and re-used). I participate in clinical research to advance knowledge to improve health and, hopefully, to bring new treatments to market sooner. It is a disservice to patients like me when data are collected in proprietary or non-standard formats and cannot be compared or aggregated without conversion.”

– Sue Dubman, former CDISC Board member and current CDISC Advisory Council Chair-elect,

Dare to SHARE! CDISC SHARE

the development of therapeutic area standards. With this tool and our open, end-to-end suite of harmonized and synergistic standards, we have provided tools for a more efficient clinical research process that can drive informed health care decisions earlier. Use of these tools will ensure that data is used responsibly and that patients will see the benefits in a timely fashion.

CDISC SHARE: Unlocking the Standards for the Betterment of Research

In 2013, CDISC officially launched the Shared Health and Clinical Research Electronic Library (SHARE), a global, electronic repository for developing, integrating and accessing CDISC metadata standards in electronic format. The launch of this project was the culmination of the long-held vision of the CDISC Board of Directors and the efforts of many CDISC stakeholders and volunteers. By the end of 2013, the first phase of the project, themed Machine Readable Standards, was nearly complete.

SHARE helps users find, understand and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently to improve the integration and traceability of clinical data from protocol through analysis.

Individual CDISC standards were originally provided as PDF documents. These standards address discrete areas of the clinical research process, focusing on the most commonly used data elements that appear in most clinical studies – primarily safety data. As the use of standards matured, it became clear that the value of CDISC standards would be increased by extending CDISC data standards to incorporate efficacy data elements and enhancing access to CDISC metadata beyond the current PDF format. CDISC

SHARE will eventually make all CDISC metadata standards electronically accessible to computer applications in an integrated system. SHARE will increase the availability of machine-readable metadata, providing additional opportunities for metadata-driven process automation and reuse of standards across therapeutic areas. SHARE will also provide a collaborative standards development environment that will improve the quality, integration, reach and consistency of CDISC standards.

CDISC SHARE will guide an advanced information-based approach to standards definition and metadata development. This new process will involve consistent, unambiguous definition of clinical research concepts in the context of the BRIDG model, tracing the use of these concepts from protocol through data collection, tabulation and analysis, and binding them to specific controlled terminologies. This will both accelerate the standards development process and reduce the cost of standards development and maintenance. Use of CDISC standards through SHARE will also facilitate aggregation of data to gain new insights to inform the research process and will improve interoperability with healthcare by aligning research concepts with external healthcare concepts. By providing a more complete set of machine-readable metadata for the foundational as well as the therapeutic area standards, SHARE will eliminate the need for individual organizations to re-create this standards-based metadata on their own. SHARE will help CDISC realize the promise of defining data standards once so data can be reused many times for multiple research purposes.

Looking into 2014, CDISC SHARE will meet many milestones. In the next calendar year, after the completion of the first phase of the project (R1), a number of electronic



metadata downloads will soon become available, and the second phase of the project, R2, will also be complete by the end of the year. The theme of R2 is the SHARE Concept Model, and will focus on developing the SHARE concept model, as well as loading the remaining CDISC standards metadata in to the production library.

The development of CDISC SHARE is nothing less than the most ambitious project upon which CDISC has ever embarked. Its creation thus far has been aided by the generous contributions of numerous stakeholders and volunteers. Should you like to take an active role in the development of SHARE, please visit the CDISC website to complete a volunteer form to pledge your time to work with the SHARE implementation and content development teams, donate toward this project, ensure your organization is a member of CDISC, or support the use of CDISC standards throughout your organization and among your partners. The benefits of CDISC standards will be realized and the promise of CDISC SHARE delivered when an ever-increasing number of organizations use standards, consistently and effectively, from the start of their research projects.

“The ability to retrieve metadata and terminologies in electronic format enables anyone, not just those focused on data management, to understand and utilize the standards.”

Collaborations

CDISC believes in “Strength through Collaboration!” The development of Therapeutic Area Standards offers a particularly ripe opportunity to collaborate with many different organizations, including academia and patient advocacy groups. The collaborations listed here represent vital relationships. Unfortunately, due to space limitations, we could only list an example of the many collaborations of which CDISC is a part. For more information, please visit the CDISC website (cdisc.org).

Innovative Medicines Initiative (IMI)



CDISC has had a memorandum of understanding in place with IMI since 2011 and continued an extremely valuable partnership with IMI in 2013. On 10 July 2013, the European Commission released its proposal for IMI 2 with the goal of developing next generation vaccines, medicines and treatments. IMI 2 will build on the successes and lessons learned under IMI. CDISC and IMI seek to expand their partnership under IMI 2 and through CFAST. CDISC is currently a partner on three major IMI project consortia.

The EHR4CR project (Electronic Health Records for Clinical Research <http://www.ehr4cr.eu>) is in its fourth year and CDISC is contributing to the semantic interoperability and pilot work packages to ensure supplemental use of data from Electronic Health Record systems for Clinical Research.

The BioVacSafe project (Biomarkers for Enhanced Vaccine ImmunoSafety <http://www.biovacsafe.eu>) is entering its third year. The goal of BioVacSafe is to develop cutting edge tools to speed up and improve the testing and monitoring of vaccine safety. CDISC is working closely

with Charité University (Germany), University of Surrey (UK), and global vaccine manufacturers on a data standards package.

The eTRIKS project (European Translational Information & Knowledge Management Services <http://www.etriks.org>) is now in its second year. CDISC is leading the data standards work package with Roche and IDBS. Building upon the open source tranSMART system, eTRIKS will provide a sustainable Knowledge Management Platform and Service to support Private/Public Translational Research across IMI, bringing curated data together from key IMI project consortia.

The Coalition for Accelerating Standards and Therapies (CFAST)



The Coalition For Accelerating Standards and Therapies (CFAST) is an initiative formed to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health. CFAST was initiated

“IMI is committed to collaborating with partners like CDISC to share data, ideas and experience to avoid the duplication of effort. Only by working together in this way can we hope to speed up the development of new treatments to tackle deadly and debilitating diseases.”

—Michel Goldman, IMI Executive Director

as a partnership between CDISC and the Critical Path Institute (C-Path). Since launching CFAST, CDISC and C-Path have worked to expand the TA Program Steering Committee (TAPSC) to ensure input from US FDA, the National Cancer Institute Enterprise Vocabulary Services (NCI EVS) and TransCelerate BioPharma. CDISC also initiated the CFAST Scientific Advisory Committee, which brings advice from the TAPSC organizations and also IMI and the Association of Clinical Research Organizations (ACRO). Through the CFAST initiative, 7 new therapeutic area standards projects were launched in 2013 and 3 were completed. For more information on the standards developed through the CFAST initiative, please visit pages 6-7, the CDISC Timeline.

The Critical Path Institute (C-Path)



C-Path and CDISC remain strong strategic partners. C-Path helps ensure CDISC standards are clinically relevant by testing them through development of valuable disease specific research databases within clinical community consortia that include patient foundations. CDISC data standards are used to enable data aggregation and comparability, thus facilitating analysis and complex modeling that would otherwise not be possible.

TransCelerate BioPharma (TCB)



Formed in 2012, TCB is a non-profit organization founded by 10 global pharmaceutical companies with the goal of improving the quality of clinical studies and enabling new medicines to reach patients faster by facilitating the collaboration necessary to solve challenges encountered

“Hiding within those mounds of data is knowledge that could change the life of a patient, or change the world.”

–Atul Butte, Stanford

in the clinical trial process. TCB now includes 19 member organizations. One of the initial five TCB projects is to develop standards for therapeutic areas; TCB is partnering with CDISC through CFAST to accelerate development of these standards. TCB is providing resources for standards development and SHARE.

National Cancer Institute Enterprise Vocabulary Services (NCI EVS)



NCI EVS has been providing CDISC with expert services to develop and maintain its controlled terminology since 2005. This invaluable and essential partnership has continued to expand in 2014 with NCI EVS providing critical terminology support and resources for CFAST therapeutic area projects as well as SHARE. NCI EVS also provides terminology services to other key partners such as US FDA and NIH Institutes. NCI is also a key stakeholder organization (along with CDISC, HL7 and FDA) for the BRIDG model.

The Learning Health Community

CDISC was involved in the planning of the first Learning Health System Summit, which was held in May 2012 at the National Press Club and was sponsored by the Joseph H. Kanter Family Foundation. The outcome of this Summit was a set of Core Values for a Learning Health System (which CDISC has endorsed along with 59 other organizations) and a growing Learning Health Community (LHC). The LHC aims to mobilize and empower multiple and diverse stakeholders to collaboratively realize a national-scale (and ultimately global), person-centered, continuous and rapid learning health system (LHS). The

Essential Standards to Enable Learning (ESTEL) initiative, led by CDISC, was launched in the CDISC Offices in Austin, TX in February 2013 and held another face-to-face meeting at Duke in September 2013. CDISC was invited to host the LHC in terms of providing a non-profit tax-deductible mechanism for their fund-raising and a link to their website; we were honored to sign such an MOU with the LHC this year in addition to continuing to lead the ESTEL Initiative.

CDISC Healthcare Link Collaborations



One of the five CDISC 2013-15 Strategic Goals is to enable interoperability between clinical care and clinical research, in such as way as to accelerate the cycle through which healthcare informs research and research informs clinical decisions. CDISC has been working with Integrating the Healthcare Enterprise (IHE) and the IHE Quality, Research and Public Health (QRPH) group (led by Landen Bain, CDISC Healthcare Liaison), to develop a number of CDISC-inspired IHE profiles. By the end of 2013, CDISC and IHE developed a total of eight CDISC-inspired IHE profiles, and the relationship between CDISC and IHE continues to grow.

To further accomplish this strategic goal, CDISC has been fortunate to have representation both on the U.S. Health IT Standards Committee and the Structured Data Capture (SDC) Initiative, an initiative of the Health and Human Services (HHS) Office of the National Coordinator for Health IT. Through collaborative efforts on the SDC initiative, it was determined to develop an SDC/IHE Profile under QRPH in 2013. This profile will specify Retrieve Form for Data Capture (RFD) and allows Data Element Exchange (DEX) as an option. It appears that CDISC SHARE will be

considered an SDC-compliant metadata repository, and ODM and CDASH are well positioned to be SDC-compliant forms.

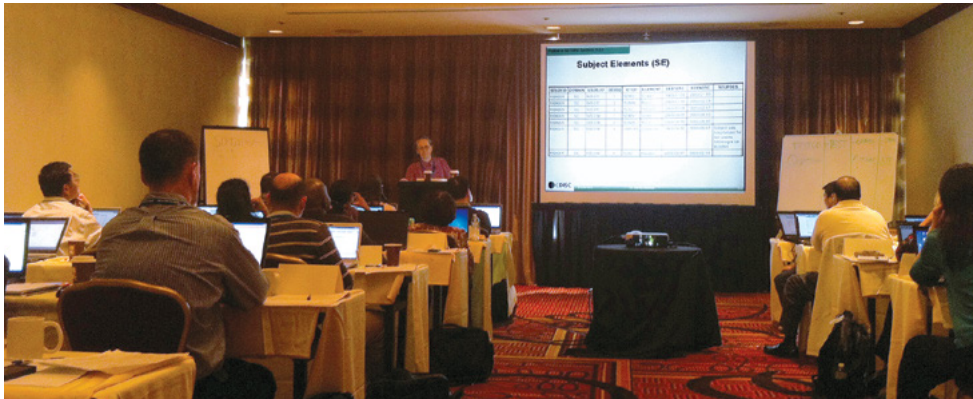
Furthermore, another attempt to create linkages between the worlds of healthcare and research has been through our collaboration with the PhUSE Computational Science Symposium (CSS). This collaboration brings together CDISC with the PhUSE CSS group, and has created the opportunity for a new semantic web-oriented project, keyCRF, which was presented and approved by the CSS group in 2013.

Another project in this area has been to demonstrate the alignment of CDISC standards and CDISC-inspired IHE profiles with the IMI EHR4CR clinical study execution and drug safety scenarios. The goal of this effort has been to express, through this collaboration, the availability of standards-based EHR-enabled applications for clinical research and patient safety.

Through these initiatives, CDISC and the LHC will continue to align with and support movement toward informed healthcare IT.

“TransCelerate is happy to participate in the development of therapeutic area data standards via the CFAST initiative,” said Dalvir Gill, PhD, Chief Executive Officer of TransCelerate. “The efficient, consensus-based development of such standards is aligned with our goal of collaborating to improve data flow, quality and interoperability in and across clinical trials – ultimately bringing new therapeutics to patients.”

Authorized CDISC Education & Member Benefits



Learn CDISC from CDISC!

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

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



Meeting the Challenges of the Future

The CDISC Education team recognizes the need to address global training needs both now and in the future. To meet those needs in a sustainable and responsible way, our teams are actively deploying online training courses. Our goal is to provide consistency in the presentation of course materials, provide a cost-effective alternative to classroom training, and include a mechanism for assessing student comprehension of the material prior to issuing a certificate.

2013 CDISC Training Milestones

Authorized CDISC Education courses were conducted worldwide in 2013 in multiple locations across the continents of Asia, Europe, and North America. CDISC issued 1,528 certificates for all public and private education courses held throughout the year. In addition, FDA employees participated in training courses at FDA-CDER and FDA-CBER, in addition to standard courses delivered to FDA-CBER. CDISC currently has 27 qualified instructors delivering authorized CDISC training globally. For more information, please visit the CDISC website (cdisc.org).

Gold Member Benefits

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

Platinum Member Benefits

All the Gold Member Benefits PLUS the following:

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

CDISC Authorized Education Courses:

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

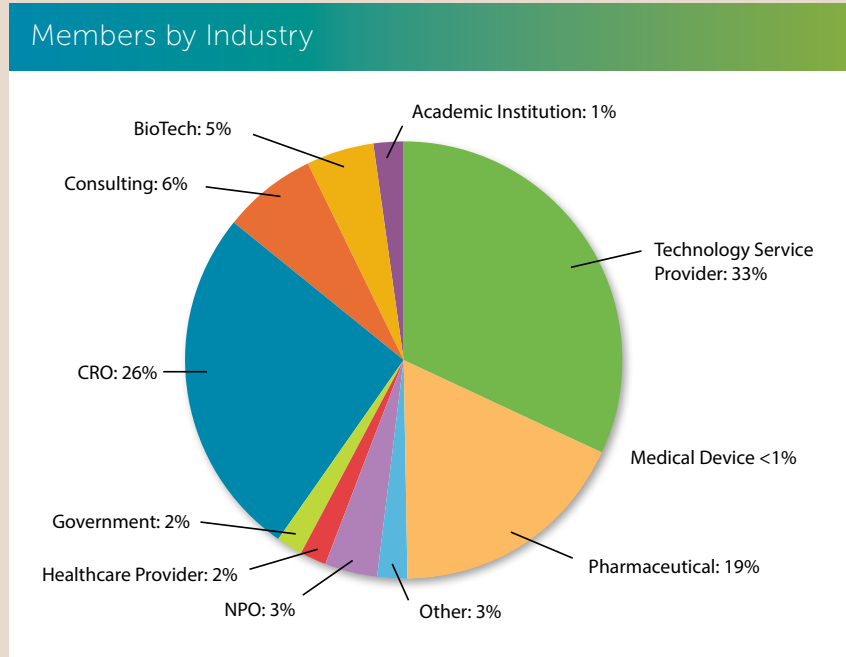
- 2-day SDTM Theory and Application for Medical Devices
- 1-day Healthcare Link
- 2-day SEND

In Development for 2014:

- DataSet-XML
- Pharmacogenomics
- Online Courses: SDTM, CDASH, ADaM, Controlled Terminology, BRIDG, Therapeutic Areas

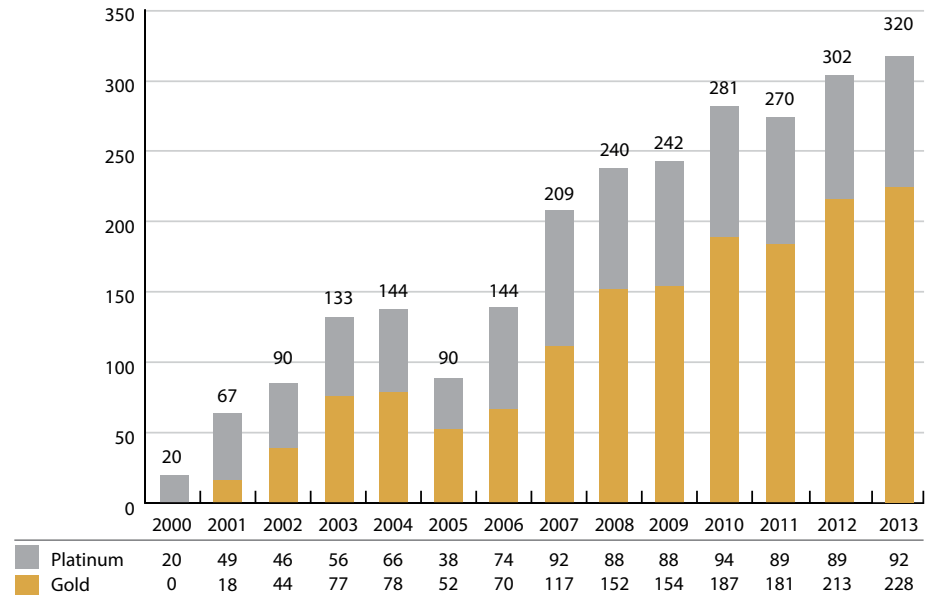
CDISC Membership

CDISC standards and related innovations would not be possible without the dedicated volunteer efforts and financial assistance of a great number of CDISC members and supporters across the healthcare industry. In 2013, CDISC officially reached more than 320 members. Our members are located in 25 countries and across 12 different industry categories.



One of the benefits of CDISC Platinum Membership is representation on the elite CDISC Advisory Council. Pictured here is the yearly exclusive brainstorming session between the CDISC Board of Directors, regulators, and the CAC during the International Interchange

CDISC Membership Trend 2000-2013



Members by Country

Australia	3	India	4	South Korea	1
Belgium	9	Ireland	3	Spain	1
Canada	5	Israel	2	Sweden	5
China	1	Italy	1	Switzerland	13
Denmark	8	Japan	29	Thailand	1
Finland	1	Lithuania	1	United Kingdom	17
France	9	Netherlands	1	United States	180
Germany	22	Norway	1		
Hungary	1	South Africa	1		

*"Numbers have an important story to tell. They rely on you to give them a clear and convincing voice."
– Stephen Few, Founder of Perceptual Edge*

The CDISC Communications Team had another exciting year in 2013, seeing markedly improved visibility across the numerous communications mediums we provide. We offer our sincere thanks to our CDISC members and supporters who access our information and materials on a regular basis, and help to spread the good word about CDISC to new individuals and markets.

To support the increasing development and achievements CDISC has realized in 2013, the Communications Team released press releases, blog posts, provided case studies and success stories, and initiated a new eNewsletter format.

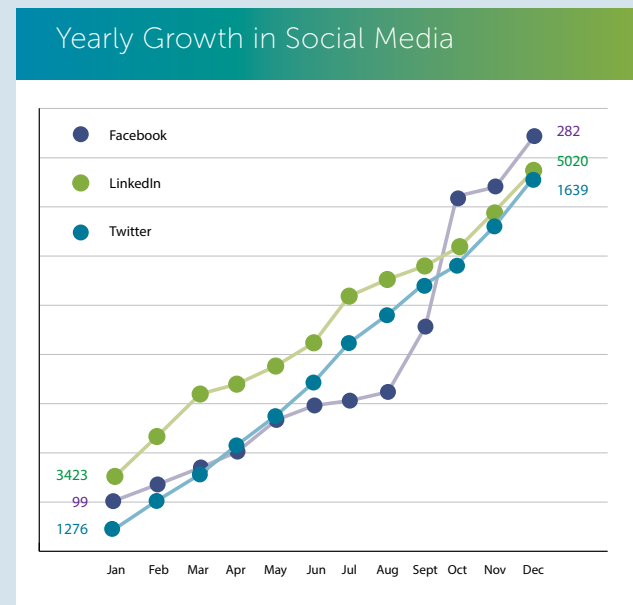
In addition to this, our team assisted in the development and release of an informational video for the newly-launched CDISC SHARE metadata repository, created and managed the first CDISC Social Media Challenge, developed and vetted all website content, reached out to our CDISC User Networks to gain invaluable feedback, and designed and developed a large number of email marketing messages to make our CDISC supporters aware of upcoming CDISC events, education courses, surveys and more.

The 2014 year looks to be even more exciting for CDISC Communications, with plans underway for a new website, a number of new marketing materials to express the value of our organization and the standards we openly provide, and expanded use of our various social media platforms to encourage and strengthen interaction with and amongst the CDISC community.

Website Activity

Visitor Type	Date Range	Visits
Returning Visitors	Jan 2, 2013 – Dec 31, 2013	140,755
	Jan 1, 2012 – Dec 31, 2012	125,361
New Visitors	Jan 2, 2013 – Dec 31, 2013	140,939
	Jan 1, 2012 – Dec 31, 2012	118,059
Total Visitors	Jan 2, 2013 – Dec 31, 2013	281,694
	Jan 1, 2012 – Dec 31, 2012	243,421

% change for returning visitors	12.4%
% change for new visitors	19.3%



CDISC Website

SHARE Video

SHARE video available at cdisc.org

2013 Financial Information

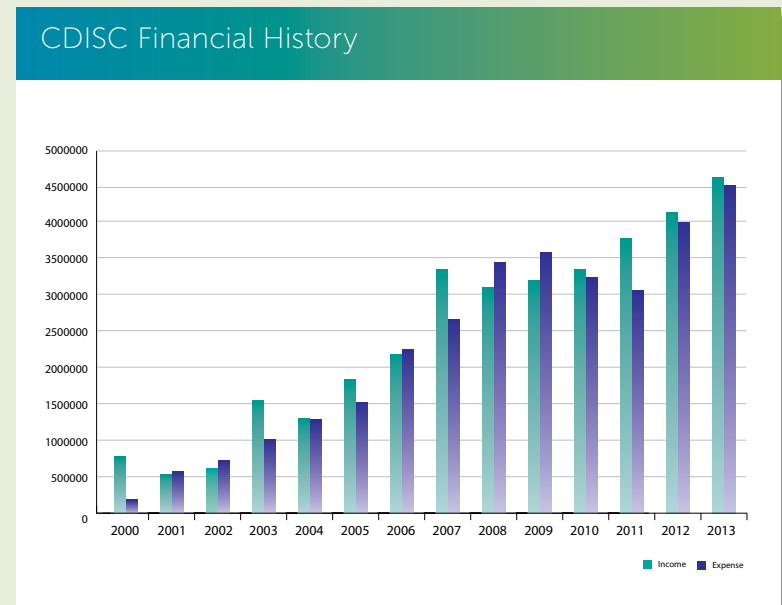
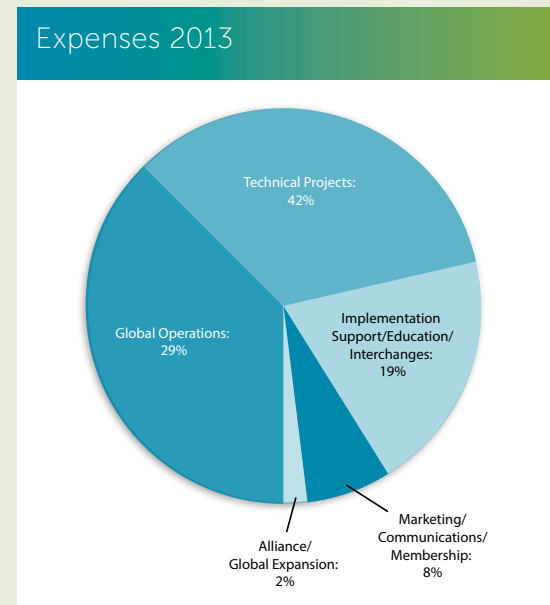
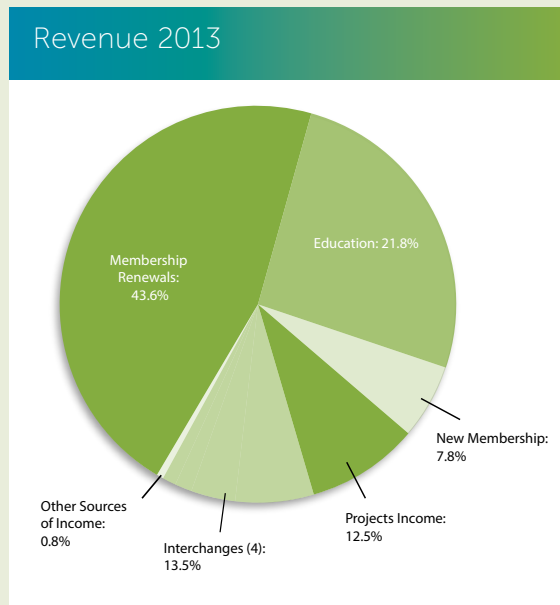
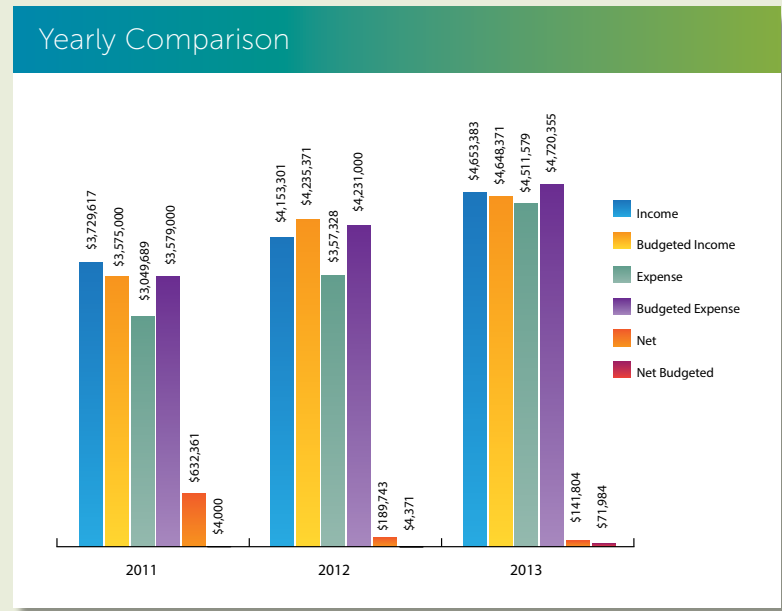
In 2013, CDISC again successfully managed expenditures against revenue, ensuring that income is invested in CDISC standards and initiatives that align with the CDISC Vision, Mission and Strategic Goals.

Revenue 2013: Revenue of \$4,653,383 was \$5,012 more than the budgeted \$4,648,371 and was \$497,492 more than the \$4,150,879 revenue in 2012, an increase of 12%. The areas that had the most impact on revenue were membership dues, education and events. The following chart illustrates the percentage of revenue from the different sources ("other" consists of revenue from donations, primers, interest, Certification, IntraChange and Registered Solution Providers).

Expenses 2013: Expenses of \$4,511,587 were \$208,768 (4%) below the budgeted \$4,720,355, resulting in a net positive \$141,796 at the end of 2013. This will help support CDISC SHARE expenditures in 2014.

Yearly Comparison: The graph reflects the comparison from the last three years of financial actual versus budget results.

CDISC Financial History: The historical picture of CDISC's financial outcomes since it was incorporated in February 2000.



2013-2014 CDISC Board of Directors

Paula Brown Stafford <i>Chair</i>	<i>Quintiles</i>
Sue Dubman	<i>Sanofi</i>
Michael Glickman	<i>Computer Network Architects</i>
David Handelsman	<i>SAS</i>
Dr. David Hardison	<i>Recombinant by Deloitte</i>
Dr. Rebecca Kush	<i>CDISC</i>
Dr. Pierre-Yves Lastic	<i>Sanofi</i>
Dr. Douglas Peddicord	<i>ACRO</i>
Stephen Pyke	<i>GlaxoSmithKline</i>
Dr. Frank Rockhold	<i>GlaxoSmithKline</i>
Dr. Eliot Siegel	<i>University of Maryland School of Medicine</i>
John Speakman	<i>NYU Langone Medical Center</i>
Dr. Kiyoteru Takenouchi	<i>CMIC</i>

2014 CDISC Board of Directors

Dr. Pierre-Yves Lastic, <i>Chair</i>	<i>Sanofi</i>
Dr. Charles Cooper	<i>Becton Dickinson Diagnostics</i>
Michael Glickman	<i>Computer Network Architects</i>
David Handelsman*	<i>SAS</i>
Dr. David Hardison	<i>Recombinant by Deloitte</i>
Dr. Dipak Kalra	<i>University College London</i>
Wayne Kubick*	<i>CDISC</i>
Dr. Rebecca Kush	<i>CDISC</i>
Dr. Douglas Peddicord	<i>ACRO</i>
Stephen Pyke	<i>GlaxoSmithKline</i>
Joyce Sensmeier	<i>HIMSS</i>
John Speakman	<i>NYU Langone Medical Center</i>
Paula Brown Stafford	<i>Quintiles</i>
Dr. Kiyoteru Takenouchi	<i>Medical Front Corporation</i>
Névine Zariffa	<i>AstraZeneca</i>

* ex-officio members of the Board of Directors

CDISC Leadership



REBECCA DANIELS KUSH Ph.D.

CDISC President and CEO

Rebecca Daniels Kush, Ph.D. is a Founder and the current President and CEO of CDISC. Dr. Kush has over 30 years of experience in the area of clinical

research. She has worked for the U.S. National Institutes of Health, academia, a global contract research organization and global pharmaceutical companies based in the U.S. and Japan. Dr. Kush has published numerous articles in key journals, including New England Journal of Medicine and Science Translational Research and has been cited in a number of publications of the National Academy of Sciences Institute of Medicine. She was appointed by the head of HHS/ONC to represent Research on the Health Information Technology (HIT) Standards Committee; she has served on the boards of DIA, HL7 and ACRES; and, she currently serves on the National Cancer Advisory Board Informatics Work Group. Dr. Kush holds a B.S. in Chemistry and Biology from the University of New Mexico and a Ph.D. in Physiology and Pharmacology from the University of California San Diego (UCSD) School of Medicine.



WAYNE R. KUBICK Chief Technical Officer

Wayne R. Kubick, MBA, has over 25 years of experience in clinical research and drug safety, including executive management and strategy development. Prior to his CDISC role, Mr. Kubick worked for Oracle Health Sciences

as Sr. Director of Product Strategy. Preceding this, he was Senior Vice President and Chief Quality Officer of Lincoln Technologies, Inc. where he served as the Principal Investigator for its Cooperative Agreement with the FDA to develop tools for receiving, assessing and reviewing eSubmissions data in CDISC standard format. Mr. Kubick has served as Chief Information Officer and Vice President for IT at PAREXEL International, and as Manager of Information Systems at BBN Software Products. He is a frequent speaker at industry conferences, and holds a BA degree from the University of Illinois and an MBA in MIS and Public Management from Boston University.



SAM HUME

Vice President, SHARE
Technology and Services

Sam Hume, MS, has over 20 years experience in clinical research informatics, eight of these specializing in the development of global clinical information standards. At CDISC, he

leads the CDISC SHARE project and co-leads the XML Technologies team. Previously, he worked as Director of IS Architecture at AstraZeneca, where, amongst his many varied functions, he was instrumental as the IS leader of a team charged with creating a standards metadata repository to drive interoperability, and developed a global CDISC implementation strategy and roadmap for AZ. Prior to this, Mr. Hume held the position of VP of Technical Operations at Phoenix Data Systems and Chief Technology Officer at CB Technologies. Sam has an MS in Information Science, MS in Telecommunications, and is completing his doctorate in Healthcare Informatics.



SHANNON LABOUT, CCDM

Vice President, Education

Shannon Labout, CCDM, has over 20 years experience working in healthcare technology and clinical research organizations in the US and EU. She is a clinical data management and standards leader with a career reputation of

pursuing and achieving excellence through affirmative team leadership. During her career, she has developed expert knowledge of ICH clinical development processes, and implementation of industry standards (CDISC, GCDMP and ICH GCP). Prior to her current position at CDISC, Ms. Labout held the positions of Senior Director of Education at CDISC, Director of Data Management at Statistics & Data Corporation, and Manager of Clinical Data Management at both Astellas Pharma Europe and Tyco Healthcare Mallinckrodt. She currently serves on the Board of Trustees for the Society for Clinical Data Management. Ms. Labout is a Certified Clinical Data Manager (CCDM), and received her BA in Organizational Leadership from Maryville University.

SHIRLEY WILLIAMS

Executive VP, Finance and Administration

Shirley Williams was privileged to be the first CDISC employee and has been a part of its growth and success since its inception. She has over 25 years experience in the clinical research industry and was instrumental in the startup of CDISC and the CDISC Europe Foundation. Her extensive experience is in the areas of financials, metrics, reengineering and process improvement and project coordination. She has been responsible for CDISC's financial and legal viability, ensuring that CDISC has always used its funds appropriately to establish and support the



CDISC Staff

While the majority of CDISC staff are based out of Austin, Texas, others in CDISC Operations are located and work in and around the globe.

Pictured above, from left to right. Back Row: Eloise Sepeda, Paul Houston, Wayne Kubick, Anthony Chow, Shirley Williams, Bron Kisler, Dana Booth, Joe Ben Clark, Sam Hume, Alana St. Clair, and Pamela Harvey. Front Row: Andrea Vadakin, Sheila Leaman, Amy Palmer, Ella Kamona, Saad Yousef, Landen Bain, Shannon Labout, Kit Howard, Rhonda Facile, Jyoti Pillay, Diana El-Harakeh, and Rebecca Kush. Not pictured: Julie Evans, Steve Kopko, and Bernice Yost

CDISC standards and initiatives. Her responsibilities for CDISC include legal, financial, human resources, support for the CDISC Board and its Financial Oversight and Governance Committees, and coordination of the financial aspects of all of CDISC projects and events. Shirley is the official CDISC Treasurer and Clerk and provides financial oversight for the CDISC Europe Foundation.



BRON KISLER

Vice President, Strategic Initiatives

Bron Kisler is a Co-Founder of CDISC and currently serves as Vice President, Strategic Initiatives. Within this role, he is responsible for identifying new growth opportunities

for CDISC, steering the organization into new clinical and geographic markets, and managing key strategic alliances. Bron has 25 years of technical and business experience from both the public and private sectors, and has worked in the pharmaceutical industry for 18 years, developing innovative clinical research solutions. He successfully spearheaded the CDISC Terminology Program in 2005 and launched CDISC's initial Therapeutic Area projects, leading Therapeutic Area standards to become a priority in the US, Europe as well as with global biopharmaceutical companies and key patient foundations. Bron served as Chair of the Joint Initiative Council (JIC) for global standards harmonization and on the BRIDG Board of Directors. He is a graduate of the University of Central Florida and holds 3 Bachelor of Science degrees in Mathematics, Computer Science and Statistics.

PLATINUM

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 Absolute Systems Clinical Data
 Accenture*
 Accovion GmbH**
 Acorda Therapeutics Inc
 Alexion Pharmaceuticals
 Amgen***
 AMIA*
 Assero Limited**
 Astellas Pharma, Inc.*
 AstraZeneca AB**
 Bayer Healthcare LLC**
 BioClinica, Inc.**
 Biogen Idec, Inc.**
 Boehringer Ingelheim Pharmaceuticals***
 Booz Allen Hamilton
 Bristol Myers Squibb***
 Business & Decision*
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 Clinical Ink
 Clinical Research Support Center (CRS) Kyushu
 CompuWare Corporation***
 Computer Sciences Corporation*
 Covance**
 Critical Path Institute*
 CTTI*
 d-Wise Technologies*
 Daegu Catholic University Medical Center
 Daiichi Sankyo, Inc.*
 Dainippon Sumitomo Pharma Co., Ltd
 DataTrak International, Inc.***
 Digital Infuzion
 Dr. Oestreich + Partner, GmbH*
 Eisai, Inc*
 Eli Lilly and Company***
 EORTC
 eResearch Technology**
 F. Hoffmann-La Roche Ltd**
 Formedix USA**
 Forte Research Systems, Inc.*
 Foundation for Biomedical Research and Innovation
 FUJITSU LIMITED
 Gilead Sciences**
 GlaxoSmithKline***

HCL America, Inc.
 IBM**
 INC Research
 Innovative Medicines Initiatives
 Integrated Clinical Systems, Inc.
 inVentiv Health Clinical*
 Johnson & Johnson***
 Massachusetts Veterans Epidemiology**
 McDougall Scientific Ltd.*
 Medidata Solutions Worldwide**
 Medtronic, Inc.
 Merck & Co., Inc.***
 Merck KGaA*
 Mitsubishi Tanabe Pharma Corporation**
 National Cancer Institute
 Next Step Clinical Systems LLC
 Novartis Pharmaceuticals Corporation***
 Novo Nordisk**
 Onyx Pharmaceuticals
 Oracle Corporation
 Perceptive Informatics, Inc.***
 Pfizer***
 Pharsight Corporation***
 Pinnacle 21, Inc.*
 PointCross Life Sciences, Inc.*
 PPD***
 PRA International*
 Premier Research Group***
 Quintiles Transnational Corporation***
 S-cubed Aps*
 Sanofi-Aventis***
 Santen, Inc.
 SAS Institute, Inc.**
 SCRI Development Innovations
 SGS Life Sciences Services*
 Shionogi & Co., Ltd.
 Shire Pharmaceuticals, Inc.
 SOA Software
 TAKE Solutions
 Takeda Pharmaceuticals International Co.***
 TEVA Pharmaceutical Industries Ltd
 Texas e-Health Alliance
 Theravance, Inc.*
 Trifecta Clinical
 UCB Biosciences, Inc.*
 UsualCare LLC

GOLD

AAC Medical Inc.
 ACM Medical Laboratory
 Acronet Corp.*
 aCROnordic
 Actelion Pharmaceuticals Ltd*
 Active Biotech AB
 Acucela, Inc.
 AdClin
 Advance Research Associates, Inc.
 Advanced Clinical
 Adware Research Kft
 Akros Pharma Inc
 Allergan**
 Almirall, S.A.
 AMAG Pharmaceuticals
 Amphastar Pharmaceuticals Inc
 Applied Clinical Intelligence LLC*
 Aptiv Solutions
 ArisGlobal LLC
 ASKLEP Inc.*
 Association of Clinical Research
 ATLANSTAT
 Axio Research LLC*
 Basilea Pharmaceutica International Ltd.*
 Baxter Healthcare Corporation*
 Bell Medical Solutions, Inc.
 Bioforum Ltd.
 BioMarin Pharmaceutical Inc.*
 Biomedical Systems Co.*
 Bioskin GmbH
 BioStat International, Inc.
 BioStata ApS
 Biotrial Biometrics
 BITech Factory GmbH
 Brightech International LLC
 CAC EXiCARE Corporation
 Cancer Research and Biostatistics
 Capish!
 Cerafor Ltd
 CD3 Inc.
 Celgene Corporation
 Center of Excellence for Biomedical and Public Health Informatics
 Children's Hospital & Regional Medical Coordinating Center*
 ClinData International
 Clinical Data Integration
 Clinical DataFAX Systems Inc.
 Clinipace Worldwide
 Clinovo, Inc.
 ClinPharma Clinical Research LLC
 CMIC Co. Ltd.*
 CNI Professional Services, LLC
 Cognitive Research Corporation
 Cognizant Technology Solutions, Inc.
 Colorado Prevention Center
 Comprehend Systems

CRC Pharma
 CROMSOURCE
 CROS NT s.r.l.
 Cross Metrics SA
 CRS Clinical Research Services Mannheim GmbH
 CSL Behring
 CTEP Ltd.*
 Cubist Pharmaceuticals*
 Cytel, Inc.
 Dart NeuroScience, LLC
 DataCeutics, Inc.**
 Datalytics Pty Ltd
 Deloitte Consulting, LLC
 Destiny Corporation
 DF/Net Research, Inc.
 Dlcore Group, LLC
 DM-STAT, Inc.
 DOT International Co., Ltd.
 DP Clinical
 DSG CDM, LLC
 Duke Clinical Research Institute***
 DynPort Vaccine Company LLC
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 e-Trial Co., Ltd.
 eClinical Solutions, LLC
 ECRON ACUNOVA GmbH
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 Eliassen Group*
 EMB Statistical Solutions, LLC
 Emboma Corporation
 Entimo AG**
 Epihacy Consulting Group, Inc.
 EPS Corporation
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 Evado Clinical Software
 Everest Clinical Research Services Inc.
 Exelixis, Inc.
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 Feinstein Institute
 Ferring Pharmaceuticals*
 Forest Laboratories**
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 GCP-Service International Ltd. & Co. KG
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 H. Lundbeck A/S*
 H2O Clinical, LLC
 Hands-on LLC*
 Health Level Seven*
 Helsinn Healthcare SA*
 HERAX
 HIMSS*
 Hurley Consulting Associates
 Icahn School of Medicine at Mount Sinai
 ICON Clinical Research*
 ICRC-Weyer GmbH
 IDBS*
 IDDI*
 Illumina Interactive**

Infinity Pharmaceuticals
 Innovative Analytics Inc.
 Instem LSS*
 Institut de Recherches Internationales Servier
 Institut Jules Bordet, The BrEAST Group
 Intralinks, Inc
 IPSEN Innovations
 Isis Pharmaceuticals, Inc.
 Itrica
 Itwell
 Jazz Pharmaceuticals, Inc.
 Judy King
 K & L Consulting Services, Inc.
 KAI Research, Inc.*
 Kestrel Consultants
 Kinship Technologies Private Limited
 KOEHLER eClinical GmbH
 Kyoto University Hospital
 Kyushu University Hospital
 Lambda-Plus SA
 Larix ApS
 LEO Pharma A/S
 LFB (Laboratoire français du Fractionnement)
 Liaison Technologies*
 LINK Medical Research AS
 M.A.R.C.O. GmbH & Co., KG*
 MacroGenics, Inc.
 MaxisIT, Inc.*
 MedNet Solutions*
 Medpace, Inc.
 Metronomia Clinical Research GmbH
 MKS Incorporated
 MMS Holdings, Inc*
 Nagoya Medical Center
 National Cancer Center
 Nestle Clinical Development Unit
 Nextrials, Inc.*
 Novella Clinical
 Novotech Pty Ltd.
 NPS Pharmaceuticals
 nSpire Health
 Nth Analytics
 OCS Consulting BV
 Ofni Systems
 Omeros Corporation
 OmniComm Systems*
 OncoGenex Pharmaceuticals, Inc.
 Optimer Pharmaceuticals, Inc.
 Orion Pharma
 Otsuka Pharmaceutical Development and Commercialization, Inc.**
 PDS Preclinical Data Systems, Inc.
 PEGUS Research Inc.
 Pharm-Olam International Ltd.
 Pharma Consulting Group AB
 Pharma Medica Research Inc.
 PharmaStat LLC*
 PHASTAR
 Philip Morris Products SA

Pierre Fabre Biometrie
 Profil Institut fuer Stoffwechselforschung*
 Prometrika, LLC
 Purdue Pharma L.P.*
 Q2 Business Intelligence*
 QST Consultants, Ltd
 Quadratek Data Solutions
 Quality Data Services, Inc.*
 Quanticate International Ltd
 Quartesian LLC
 Quartz Bio
 R-Square, Inc.**
 REGISTRAT-MAPI
 Rho, Inc.*
 Robertson Centre for Biostatistics
 SAIC*
 Salix Pharmaceuticals, Inc.
 SAM GmbH
 Samvit Solutions, LLC
 SciAn Services Inc.
 ScientiaBio
 Scope Baltija*
 Simbec Research Ltd
 Statistics and Data Corporation*
 Sucampo AG
 Syne qua non, Ltd*
 Synergy
 SynteractHCR, Inc.
 Takumi Information Technology Inc.
 TalentMine, LLC
 Target Health, Inc.*
 The EMMES Corporation
 The Uppsala Monitoring Centre
 Theorem Clinical Research*
 Therapeutics, Inc.
 Threshold Pharmaceuticals
 TIBCO Software, Inc., Spotfire Division
 Toray Industries, Inc
 Toyama Chemical Co., Ltd.
 Trium Analysis Online GmbH
 United BioSource Corporation*
 University Hospital Medical Information Network*
 University of California, San Diego
 University of Tsukuba
 Uppsala Clinical Research Center
 US Army MRMCM*
 US Center for Disease Control and Prevention
 Veristat, Inc.*
 Vertex Pharmaceuticals*
 Winicker Norimed GmbH
 World Programming
 Worldwide Clinical Trials
 X-act Cologne Clinical Research GmbH
 XClinical**
 XML4 Pharma*
 XOMA
 Xyberion Corporation
 Zifo Technologies Private Ltd.

***CDISC Charter Members **Member for over 10 years *Member for over 5 years



info@cdisc.org
 cdisc.org