Letter from the President

2015 was a transformative year for CDISC, and 2016 holds new promise that has not previously been possible in the clinical research arena. We (and by this I mean the CDISC staff and our hundreds of wonderful volunteers and partners around the world) have worked diligently to develop ways for data to “speak the same language” to help unlock cures for patients with many different types of diseases. Our work is also helping to identify biomarkers that enable earlier treatment, such as the one recently approved for polycystic kidney disease, and improve research in areas intended to keep those without disease healthy, such as vaccines and nutrition.

The SHARE metadata repository has now been populated with the CDISC standards and metadata in machine-readable format such that they can be used electronically instead of being “locked” inside PDF documents. SHARE is now ready to be leveraged to streamline and automate research processes from data collection to trial management systems to data aggregation for producing tables and analysis datasets that can go to regulators in a way they can readily review for approval of new therapies. The value of SHARE is being realized through re-use of prior therapeutic area work into new and related therapeutic areas, for example, different types of cancers and viral diseases. And, SHARE can help facilitate the use of electronic health records for clinical research, using new eSource methodologies, to enable a learning health system through which research should more readily inform medical decisions for patients.

To support the CDISC community, CDISC has a team of knowledgeable leaders who continue to catalyze productive collaboration among volunteers to achieve our new Roadmap and cross-functional goals. These leaders have proven expertise in Standards Development and Implementation, Bioinformatics, Terminology, Education, Member Relations, Communications, Finance and Fund Development, and Strategic Alliances. To be successful, we must continue to serve all of our various stakeholders around the globe, including but not limited to academia, biopharmaceutical organizations, service and technology providers, regulators, patient research and advocacy groups, and our many valued partners.

We sincerely thank all of you who support our work through memberships. We are excited to be paving the way and breaking new ground to accelerate learning from research and healthcare information and to enable meaningful data sharing through a common “data language” for the benefit of all.

Dr. Rebecca Kush
CDISC President & CEO

Letter from the COO

As we look back over 2015, we can be proud of many CDISC successes, which are highlighted in this report, and led to opportunities for continued learning and improvement. To better understand how we are doing to serve our global community, CDISC staff made a point to focus on conducting internal and external qualitative assessments to evaluate the needs and goals of our members and users. Specifically, we held “listening tours” to learn more about implementation issues, conducted a member survey on adding value to memberships and interviewed all staff and contractors on their role and value in the future of the organization. In response to these assessments, we developed plans for how CDISC as an organization can operate more efficiently and how our teams can work more seamlessly together. Results from these evaluations will be highlighted throughout our Annual Report and have helped us focus our goals throughout 2015 and to create a roadmap for 2016. Examples of focus areas that have shaped our CDISC activities include:

1. Reducing Silos in Research
2. Facilitating Cross-Functional Projects and Goals
3. Improving Communication
4. Enhancing Onboarding and Recognition of our Volunteers
5. Making Standards More Accessible through SHARE and APIs
6. Expanding Therapeutic Area Standards
7. Supporting “Beginning to End” Standards Implementation
8. Evaluating and Improving Versioning and Terminology Processes
9. Expanding Interoperability with Healthcare
10. Increasing Outreach to Academia

Additionally this year, our organization set a goal of ensuring that the work that CDISC does to improve clinical research be understood by patient advocacy organizations and clinicians. This is being addressed through the launch of our UnlockCures.org website and marketing campaign with the tagline of “Smarter Research to Unlock Cures.” We hope you will visit this ‘sister website’ and share with your colleagues, family and friends so that when they invest or participate in research for the diseases that effect them or those close to their hearts, they will ask that CDISC standards be utilized to ensure the data can be shared and compared and their donation goes further, leading to cures being unlocked.

As we look into 2016, we are thrilled with the opportunities ahead. Our growing class of Fellows and continuous increase in members tells us that the work we are doing is essential to clinical research and, therefore, the CDISC organization must be sustainable. We will work to continue to diversify our funding sources to ensure stability with new partners, new types of events, broader adoption in new countries and new types of companies, additional education courses and expanded branding to broaden the scope of people who understand the need for standardized clinical research data that speaks a common language. Thank you for your interest, involvement and continued support!

Dr. Nicole Harmon
CDISC COO
WHEN CLINICAL RESEARCH IS DONE IN SILOS, WE CAN’T HARVEST CURES.

When we don’t share findings in clinical research, it’s as if billions of dollars get buried. When that happens, we all lose out on finding cures to diseases that affect people we love.
What is CDISC?

The Clinical Data Interchange Standards Consortium (CDISC) is a 501(c)(3) global non-profit charitable organization that streamlines research and enables connections to healthcare through the development of clinical research data standards. CDISC has developed a suite of standards to support clinical research from protocol and data collection through analysis and reporting. CDISC standards make it possible for data to speak the same language, empowering data collection and sharing that makes the most of the valuable information offered by patients participating in research studies around the globe. CDISC standards are consensus-based, developed over the past 18 years by thousands of volunteers around the world; as such, CDISC standards are vendor neutral. They are also freely available via the CDISC website. Using these standards from the start of studies enables Smarter Research to Unlock Cures, saving ~60% overall in terms of time and resources to conduct research. CDISC is the patient's advocate, having already developed therapeutic area specific standards for over 25 disease areas, with more in progress.

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.

“There are no more blockbuster drug categories coming down the pike. Collaboration and data sharing is the new competitive edge. The strength of your innovation is equal to the strength of industry collaboration.”

– Dr. Kald Abdallah, Project Data Sphere
CDISC and our Board of Directors developed the following strategic goals in 2014 in the interest of our focusing on bringing all areas of our organization together and ensuring the continued future growth of CDISC in three specific areas:

- Promote and support the continued global adoption of harmonized data standards throughout the clinical research lifecycle by engaging regulatory agencies, research sponsors, academia and other stakeholders through education, advocacy and collaboration.
- Implement clinical research standards that are complementary to standards in the broader healthcare ecosystem and thus add value for clinical researchers, healthcare providers and patients.
- Leverage the Shared Health And Research Electronic Library (SHARE) and other tools to further expedite the development and facilitate the implementation of harmonized standards for clinical research.

### Strategic Goals 2015–2017

In 2015, CDISC developed a new Roadmap, with the vision to show how CDISC will bring the CDISC Strategic Goals to reality in 2016 and beyond. Through this Roadmap, CDISC visually expresses how CDISC will offer computable data standards that will enable organizations to automate and streamline the entire research process for all major disease areas. Widespread adoption of these standards has the potential to dramatically reduce costs and speed the development of therapies for patients.

### CDISC Roadmap

- **Foundational CDISC Standards**
  - Focus on Governance, Controlled Terminology Process, Version Control and Validation Rules

- **Coalition For Accelerating Standards and Therapies (CFAST)**
  - Continue to develop Therapeutic Area (TA) Standards to support Beginning to End Automation with SHARE-generated TA Standards

- **Adoption**
  - Education, Survey and Implementation Calls, SHARE Roll-out, IntraChanges, Interchanges, CFAST TA Standards Workshops, New Messaging & Publications

- **Healthcare Link**
  - Launch eSource Stakeholders Group and projects to provide direct links between healthcare and research

- **Shared Health and Research Electronic Library (SHARE)**
  - Support “Beginning to End” Automation and use of Standards in Therapeutic Areas, Support Healthcare Link and eSource Projects, Demonstrate and Publish on Value of SHARE

Compatible data standards to enable automation and streamlining of the entire research process to dramatically reduce costs and speed the development of therapies for patients.
Japan PMDA Releases Several Guidance Documents in 2015, Adding to Binding Guidance Documents Released Prior by FDA

During 2015, the Japan PMDA issued a Technical Notification for Electronic Data Submission, Technical Conformance Guide, Data Standards Catalog and Study Data Validation Rules. The PMDA technical notification states that the Ministry of Health Labour and Welfare (MHLW) will require drug makers to submit electronic data in CDISC standard format beginning 01 October 2016, with a 3.5 year transitional period. This, added to the binding guidance documents released by the U.S. FDA in December 2014, which stated that they would also be requiring submission in CDISC format by December 2016, has demonstrated an ever-growing trend for global regulatory agencies to require submissions of clinical trial data in CDISC standard format. Please visit the CDISC website for links to the guidance documents. www.cdisc.org.

BRIDG Model for Research Published as Final ISO Standard

On 24 April 2015, the International Organization for Standardization (ISO) recognized the Biomedical Research Integrated Domain Group (BRIDG) Model v3.2 as a published, Final International Standard for clinical research and its link with healthcare. The BRIDG Model was initiated by CDISC in 2003 to support harmonization among the CDISC standards for clinical research and to bridge between research and healthcare. This effort has also been joined by the National Cancer Institute (NCI), Health Level Seven (HL7), and the U.S. Food and Drug Administration (FDA), who collaborate on development and maintenance of the model.

“Pharmacogenomics is key to realizing the power of translational medicine’s ability to match each patient with the most effective and safe treatment,” stated Joyce Hernandez, leader of the CDISC Pharmacogenomics team and Clinical Data Standards Manager at Eliassen Group. “Our CDISC team is very excited and proud to provide the research community with a standard that helps integrate pharmacogenomics with clinical data to gain insights on treatment options.”

CDISC Releases Standard for Pharmacogenomics/Genetics

In June 2015, CDISC released a groundbreaking standard for pharmacogenomics/genetics, supporting the industry’s transformation to Precision Medicine. Since the completion of the Human Genome Project in 2003, there has been a significant rise in the use of Pharmacogenomic data for both research and clinical care. The use of this new type of data, which can explain the relationship between genetic variations and drug response in patients, allows for the crucial opportunity to adjust therapies on a patient-by-patient basis, offering for the first time a glimpse at truly personalized and precise medicine, where treatments have been perfectly aligned for each patient’s genetic make up.

“Pharmacogenomics is key to realizing the power of translational medicine’s ability to match each patient with the most effective and safe treatment,” stated Joyce Hernandez, leader of the CDISC Pharmacogenomics team and Clinical Data Standards Manager at Eliassen Group. “Our CDISC team is very excited and proud to provide the research community with a standard that helps integrate pharmacogenomics with clinical data to gain insights on treatment options.”
CDISC and C-Path Continue CFAST Partnership through Awarded FDA Grants

In October 2015, the U.S. FDA awarded several grants to CDISC and the Critical Path Institute (C-Path) to fund development of additional Therapeutic Area standards through their joint initiative, the Coalition for Accelerating Standards and Therapies (CFAST). With these grants, CDISC and C-Path are collaborating to develop CDISC standards for six further key disease areas—Colorectal Cancer, Major Depressive Disorder, Diabetic Kidney Disease, Rheumatoid Arthritis, Solid Organ Transplantation (Kidney), and Cardiovascular Imaging—important to public health. CDISC standards have been shown to significantly reduce time and resources associated with clinical research, while C-Path databases (with data aggregated using CDISC standard formats) provide researchers with high quality data for disease modeling and other scientific analyses that can lead to qualification of biomarkers and supporting opportunities for new therapies. CDISC standards recently enabled the discovery of a new biomarker for Polycystic Kidney Disease, an effort which was published in October 2015 in the American Journal of Kidney Diseases.

Signifying a continued investment by both organizations to advance the development of therapeutic area standards critical for public health, CDISC and C-Path formally renewed their Memorandum of Understanding (MOU). The two organizations have complementary roles that are synergistic in advancing new therapies for patients.

“Our partnership, which was formed by CDISC President Dr. Rebecca Kush and C-Path’s founder, Dr. Raymond Woosley shortly after the Critical Path Institute was launched in Arizona, has now demonstrated the value of standards to enable meaningful collaboration based on fully aggregated data sets that inform new drug development tools,” said Dr. Martha Brumfield, current C-Path President and CEO. “Our joint work is built upon a unique sense of trust and a common interest in improving the lives of patients through higher quality data and enabling collaborative research. We are pleased that our partnership will continue and have no doubt it will become even stronger as we continue the work of CFAST and related C-Path consortia.”

CDISC Celebrates 15th Anniversary with New, Patient-Focused Campaign and Website

In November, CDISC commemorated our 15th anniversary at the 2015 CDISC International Interchange in Chicago, Illinois, introducing a new, patient-centered messaging campaign. CDISC and our numerous volunteers have worked diligently for a decade and a half to develop a suite of beginning-to-end, consensus-based standards that enable data sharing and reuse through the entire clinical research process in numerous disease areas, thus supporting the themes of having clinical research data speak the same global language to unlock cures for patients.

The new campaign, Smarter Research to Unlock Cures, and campaign website, UnlockCures.org, were developed with the intent to reach out to clinicians and the research-based patient advocacy community, in order to bring awareness to the advantages of using CDISC standards in clinical research, especially when a research study is initiated.

“The adoption of the CDISC standards has been steadily increasing as users, including regulators, continue to appreciate their value in streamlining data sharing and paving the way to new treatments for patients,” Dr. Rebecca Kush, CDISC President and CEO asserted. “We are effectively ‘unlocking’ a world of cures, some of which could be missed without standards that allow that data to speak the same language.”
CDISC Timeline

**ORGANIZATIONS:** These are major organizational achievements that CDISC has experienced since our inception in 1997. Examples include the initiation of our original volunteer group, achieving 501(c)(3) status, the launch of our CDISC Europe Foundation.

**TEAMS:** Each dot in the associated color represents the inauguration of a new CDISC standards development team. Examples include the original modeling and nomenclature groups, all the way to our current Foundational, SHARE and Therapeutic Area Standards teams.

**CDISC STANDARDS AND ADOPTION:** These are new or updated versions of the standards and innovations developed by CDISC since our founding.

**GLOBALIZATION:** Globalization represents major global accomplishments that CDISC has realized over our 18-year history. Examples include the initiation of CDISC Coordinating Committees (3Cs), CDISC Authorized Education courses held for the first time around the world, CDISC Interchanges and other CDISC events held across the globe, as well as many others.

**COLLABORATIONS:** These represent significant partnerships and relationships with organizations in the industry that have assisted CDISC in our standards development efforts throughout the years.

**CDISC MEMBERSHIP:** This black line represents the increase in members that have joined CDISC since our founding. As can be gleaned from this chart, the increasing work that CDISC is able to do would not be possible without the incredible support of our growing membership base. To all of our members, we thank you for your support; it is what makes this work possible.
When clinical research doesn’t talk, the conversation can turn deadly.

When we don’t share findings in clinical research, it’s as if billions of dollars get buried. When that happens, we all lose out on finding cures to diseases that affect people we love.
CDISC Standards in 2015 – Foundational & Therapeutic Area Standards

**CDISC Foundational Standards:** The CDISC Foundational Standards are the backbone of all CDISC standards development, offering the basis for a complete suite of standards that allow data for both clinical and non-clinical research to speak the same language from the beginning to end of the clinical research process. In 2015, our Foundational Standards teams were responsible for developing new and updated standards for eight different Foundational Standards areas, including a new standard for clinical trial registries, CTR-XML. By mapping information among different messages to populate several international registries, this standard will reduce human error and increase the quality of registry information. More information about the Foundational Standards can be found on the CDISC website at cdisc.org/foundational-standards.

**Therapeutic Area Standards:** CDISC Therapeutic Area (TA) Standards are extensions of the Foundational Standards, in that they extend the Foundational Standards to cover specific disease areas.

The following CDISC Therapeutic Area Standards have been published as of the end of 2015:

- Traumatic Brain Injury, v1.0
- ADaM Supplement for Diabetes v1.0
- Tuberculosis v2.0
- Chronic Hepatitis C v1.0
- Dyslipidemia v1.0
- Schizophrenia v1.0
- Alzheimer's Disease v1.0; v2.0
- Parkinson's Disease v1.0
- Polycystic Kidney Disease v1.0
- Asthma v1.0
- Pain v1.0
- Tuberculosis v1.0
- Virology v1.0
- Multiple Sclerosis v1.0
- Diabetes v1.0
- Cardiovascular v1.0
- Influenza v1.0
- QT Studies v1.0

Previously published Therapeutic Area Standards:

- Breast Cancer v1.0
- COPD v1.0
- Diabetic Kidney Disease v1.0
- Rheumatoid Arthritis v1.0
- Cardiovascular Imaging v1.0
- Prostate Cancer v1.0
- Major Depressive Disorder v1.0
- General Anxiety Disorder v1.0
- Bi-Polar Disorder v1.0
- Solid Organ (Kidney) Transplant v1.0

The following CDISC TA Standards were in development at the end of 2015:

- Breast Cancer v1.0
- COPD v1.0
- Diabetic Kidney Disease v1.0
- Rheumatoid Arthritis v1.0
- Cardiovascular Imaging v1.0
- Prostate Cancer v1.0
- Major Depressive Disorder v1.0
- General Anxiety Disorder v1.0
- Bi-Polar Disorder v1.0
- Solid Organ (Kidney) Transplant v1.0
CDISC Standards in 2015 – Healthcare Link & SHARE

Healthcare Link

The CDISC Healthcare Link project began in 2005 and focuses on the interoperability between healthcare (the EHR) and clinical research.

eSource Project

CDISC is working closely with the FDA and other innovative organizations to demonstrate benefits for clinical research of data sourced electronically from electronic health records (EHR) and related clinical technologies.

In response to the FDA Federal Register Notice “Source Data Capture from Electronic Health Records: Using Standardized Clinical Research Data,” CDISC began working with biopharma, electronic health record (EHR) and electronic data capture (EDC) vendors, academic medical centers and the FDA to move forward with this effort. The project kicked off in 2015 with an open, informational meeting of the eSource Stakeholders Group at the 2015 CDISC International Interchange. The first formal eSource Stakeholders Forum will be held in Silver Spring, Maryland in March 2016.

American College of Cardiology (ACC) Registry Project

This project seeks to apply CDISC standards to streamline the data entry process for sites to populate ACC registries. In 2015, the project was conducted at Duke Medical Center.

E2C Project

The Electronic Health Record to CDASH (E2C) Team demonstrated the real-word capability of CDISC standards to streamline the design and data collection in clinical research from healthcare by proving it possible to map data from Continuity of Care Documents (CCD) to CDASH using the CDISC/IHE Retrieve Form for Data Capture (RFD) Integration Profile. The CDASH standard is a crucial step in beginning clinical research, in that it describes the basic recommended data collection fields, including demographics, adverse events and other common domains that are typical to most therapeutic areas and phases of clinical research. The E2C Project links data from EHRs to research.

Previously Published CDISC/IHE Profiles and Demonstration Projects:

1. Retrieve Form for Data Capture (RFD)
2. Structured Data Capture CDISC/IHE Profile
3. Clinical Research Document (CRD)
4. Drug Safety Content (DSC)
5. Redaction Services
6. Retrieve Process for Execution (RPE)
7. Clinical Research Process Content (CRPC)
8. Research Matching
9. Data Element Exchange (DEX)

CDISC SHARE

CDISC SHARE is a metadata repository for developing, integrating and accessing CDISC standards in electronic format. SHARE dramatically improves quality, reusability and integration across the CDISC standards and controlled terminologies, and it improves interoperability with healthcare.

SHARE API Implementation

In 2015, the SHARE team began an application program interface (API) Pilot Project with six companies. The API makes it possible for sponsor organizations to automatically load content from SHARE into their own metadata repositories as information is published in SHARE. The intent is to make the API available to additional companies in Q3 2016.

RDF Export

In 2015, the SHARE team began work on a Resource Description Framework (RDF) export capability from CDISC SHARE. This work was based on the associated reference and user guides published in 2015, with an expected delivery date of Q2 2016. RDF is a framework for representing information on the Web, and provides a common way to describe information so it can be read and understood by computer applications. RDF is a W3C semantic web standard. The original development work was part of the FDA/PhUSE Semantic Technology project.

End-to-End Standards Mapping

Beginning in 2015, the SHARE Team began adding the mapping relationships between CDASH and SDTM in the SHARE environment, as well as adding links from SDTM to many ADaM variables. In 2016, further work will be done to add elements of a Protocol standard and Biomedical Concepts. This will enable the beginning of coverage from Protocol through Analysis, effectively creating end-to-end functionality within SHARE. Through a grant from the FDA, CDISC is also innovating the use of SHARE in standards development by piloting its use for the development of a Prostate Cancer standard. This is anticipated to give CDISC information on how best to modify the standards development process to prepare for the generation of computable standards within SHARE.
WHEN CLINICAL TRIAL DATA ISN’T SHARED, WE LOSE OUR PATIENTS.

When we don’t share findings in clinical research, it’s as if billions of dollars get buried. When that happens, we all lose out on finding cures to diseases that affect people we love.
Billions of dollars are spent on clinical research, but when data isn’t shared, results get buried. Along with patients needing cures.
CDISC Fellows Program

The goal of the CDISC Fellows program is to increase knowledge and expertise on CDISC standards throughout the global research community, while at the same time, contributing to the efficient development and enhancement of CDISC standards. CDISC Fellows receive training on the process, roles and skills needed to efficiently develop CDISC standards on an essentially full-time basis for a year. The program develops a new generation of CDISC experts whose knowledge can be leveraged internally within their sponsoring companies as well as externally as an ongoing volunteer participant in the CDISC collaboration community. CDISC Fellows have the unique opportunity and perspective to learn, and contribute to, innovative approaches to developing “beginning-to-end” concept-based standards that will be included in the CDISC SHARE metadata repository.

The 2014-2015 class of Fellows included Sherwood Barbee (Quintiles), Christine Fleeman (UCB), Gloria Jones (J&J), Ina Assfalg (Boehringer-Ingelheim), Tasneem Shahmalak (Theorem), Carolyn Famatiga-Fey (Independent), and Kathy Mellers (Independent).

“My participation in the CDISC Fellows program has enriched my CDISC knowledge and provided me with opportunities I might not have been offered otherwise. I am immensely grateful for the kindness and patience shown to me by my CDISC colleagues and would recommend this experience to those who are willing to learn and enjoy the spirit of collaboration.”

—Christine Fleeman, CDISC Fellow and Senior Standards Curator, UCB BioSciences Inc.

“I was delighted to have the opportunity to be a CDISC Fellow [...] I believe that the standard developed through this project will benefit data exchange and sharing of Traditional Chinese Medicine (TCM) clinical trial information, and play a positive role in introducing TCM to the world in the future.”

—Joy Qingna Li, CDISC Fellow and Clinical Data Manager, Xiyuan Hospital of China Academy of Chinese Medical Sciences

The 2015-2016 class CDISC Fellows come from the United States, India and China and are listed and pictured below:

Mikenlette Avent (UCB), Cliff Reinhardt (UCB), Dany Guerendo (STATProg Inc.), Kapila Patel (InventiveHealth), Philip Ho (Rundo International Pharmaceutical Research & Development Co.), Ruiling Peng (Beijing Improve-Quality Technology Ltd. Co.), and Joy Qingna Li (Xiyuan Hospital, China Academy of Chinese Medical Sciences). Not pictured are: Sandeep Sawant (InventiveHealth), Junchao Chen (Shanghai University of Traditional Chinese Medicine), Sharon Powell, and Helen Sile (FDA).

Membership Survey

In 2015, CDISC reached out to our entire membership base to conduct a survey on the value of CDISC Membership. Surveys like these are just one way that CDISC evaluates our members’ needs. Results from the 2015 Membership Survey are below.

Top 5 Reasons Members Join CDISC:
• To support CDISC in the development of global standards
• To access resources in the Members Only Area of the CDISC website
• To gain visibility in the marketplace
• To ensure the CDISC standards remain open and free
• To impact the development of regulatory requirements for submissions

Top 5 Most Valuable CDISC Resources Provided to CDISC Platinum Members:
• CDISC Website
• Interchanges
• CDISC Authorized Education Classroom Courses
• Members Only Webinars
• Public Webinars

Top 5 Most Valuable Sections of the Members Only Area of the CDISC Website:
• eSHARE Downloads
• SDTMIG v3.1.2 Amendment 1
• Presentations from past Interchanges and Events
• Business Case for the Use of CDISC Standards and documents on adoption of standards
• Archived Public Webinars
CDISC Membership and Benefits

CDISC standards and related innovations would not be possible without the dedicated volunteer efforts and financial assistance of a great number of CDISC member organizations and efforts from those that volunteer for CDISC activities and Fellowships. Our members’ support ensures that CDISC standards remain open and free and that they are sustainable into the future. We sincerely appreciate the continuing support and advocacy of our members for the CDISC standards. By working together, we will achieve the CDISC vision, strategic goals and Roadmap.

**CDISC Advisory Council**

One of the benefits of CDISC Platinum Membership is representation on the CDISC Advisory Council (CAC). CAC members are invited to face-to-face meetings during the Interchanges in Europe and US to meet with CDISC Leadership, Board of Directors and global regulators in addition to quarterly teleconferences with featured speakers, and a listserv for updates on standards development. CAC members also have the opportunity to help determine the future direction of CDISC and our initiatives, as well as have the opportunity to network with other CAC members. Additionally, there are openings for CAC representatives to serve on four Board Committees (Financial Oversight, Strategy, Fund Development and Technical Advisory) and the CAC Leaders are ex-officio members of the CDISC Board. The new mission statement for the CAC is “A Unified Voice of the Membership to Influence and Support CDISC Strategic Goals.”

**Gold Member Benefits**

1. Access to eSHARE, our online global repository for developing, integrating and accessing CDISC metadata standards to improve dataflow, quality, speed, efficiency and capabilities in clinical trials. File formats include excel, XML, RDF, Define-XML, ODM, PDF, CSV.

2. Unlimited access to the CDISC Members Only Area for all employees to leverage a variety of resources and tools.

3. Monthly Members Only Mini-training webinars that address industry hot topics.

4. 20% discount off of CDISC education courses and CDISC Events

5. Opportunity to become a CDISC Registered Solution Provider; RSPs serve as subject matter experts to organizations that want to implement CDISC Standards

6. Participation in the CDISC Licensed Training Program, allowing your staff to become authorized instructors to train fellow staff on CDISC standards.

7. Opportunity for database tools to be Operational Data Model (ODM) certified to improve the quality of metadata and data interchange throughout the clinical development process.

8. Personalized Gold Member plaque.

**Platinum Member Benefits**

Platinum Members receive all benefits of Gold Membership PLUS the following:

1. 40% discount off of CDISC training courses and events

2. Representation on the CDISC Advisory Council (CAC) with opportunities to actively engage in CDISC by:
   - Serving on Board Committees
   - Voting a Board Member onto the CDISC Board of Directors
   - Participating in Town Hall meetings with regulators and CDISC Board Members
   - Networking with peers, clients and visionaries at CAC Face-to-Face meetings
   - Attending teleconferences that include implementation experiences from peers and updates from CDISC Operations staff.

3. Overview course, “CDISC Global Approach to Accelerating Medical Research” given at member site during mutually convenient time at no charge

4. Personalized Platinum Member plaque.

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**2015 Members by Industry**

- Pharmaceutical 19%
- Technology Service Providers 22%
- CRO 30%
- Academic Institutions 6%
- Clinical Labs 5%
- Biotechnology 5%
- Consulting 7%
- Non-profit 4%
- Medical Device 1%
- Other 3%
- Healthcare Provider 1%
- Government 2%

**2015 Members by Global Regions**

- North America: 213
- Europe: 115
- Asia: 65
- Central America: 1
- Africa: 1
- Australia: 2

**2000-2014 Membership Trend**

- Platinum Members
- Gold Members
CFAST & Therapeutic Area Partnerships

CDISC collaborates with many organizations to develop Therapeutic Area (TA) standards for multiple disease areas through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, as well as other partnerships.

Regulatory Collaborations

CDISC works closely with regulators around the world to ensure that CDISC standards will 1) streamline research from protocol/study design and trial registration through analysis and reporting; 2) facilitate the eSubmission review process; 3) ensure that clinical research is high quality; and 4) support the approvals of safe and efficacious medicines for patients.

Standards Development Organizations (SDO) Collaborations

CDISC collaborates with other SDOs to develop standards that are synergistic to support a learning health system based upon high quality research.

CDISC and PhUSE partner to further the mission of each organization collectively, with CDISC focusing on the development of global, platform-independent data standards, and PhUSE focusing on the implementation and use of the CDISC standards. The two organizations work to combine efforts on key initiatives around end-to-end standards, TA standards, and semantics, strengthening an interdependent process.
Authorized CDISC Education

The CDISC Education team works directly with our teams of CDISC standards experts to create training materials and qualify the instructors who will teach the standards consistently and accurately. Our only mission is to advance the knowledge of the standards to help organizations implement them in a reliable and conformant way. There are four reasons that CDISC Education is important to the global CDISC community:

1. CDISC Education ensures that implementers will be trained in the same way, using the same materials, by our global team of authorized instructors who are all qualified and trained under standard procedures and are supported by our Education staff. Education is an integral part of the standards development process, and a training certificate from CDISC has the authority of the CDISC teams behind it.

2. Training from CDISC facilitates consistency among implementers. Consistency is a primary goal of standardized data, and it benefits all of the stakeholders. Implementers can build standard case report forms and programming allowing them to set up and close out studies faster, to leverage software that has been developed using the standards, and to aggregate and learn more from their own data. Consistent, conformant implementation across sponsors benefits the regulators who will receive data, and enhances their review process. Consistency also supports aggregating and sharing data in meaningful ways across organizations, supporting unexpected breakthroughs in health science.

3. CDISC Education provides financial support to continue the mission and goals of the overall CDISC organization. Revenue received from training dollars supports the ongoing development of global standards to help us unlock treatments and cures for other deadly diseases.

4. When our instructors lead classroom training, they have the opportunity to bring feedback from implementers back to our standards development teams, allowing that feedback to be considered earlier in the process of developing new and updating existing standards.

Building a Sustainable Future for CDISC Education: CDISC Education has been maturing over the past few years, and we have achieved a level at which our instructor team is able to support the global demand for authorized training on the CDISC standards. We have local teams of instructors in North America, Europe, Japan and China, and we will continue to expand our instructor team to other high priority regions over the next few years.

Please refer to the education tab at www.cdisc.org for more details on courses offered.
CDISC Events

CDISC Interchanges
CDISC hosted three global conferences in 2015. These conferences, called “Interchanges,” were held in Europe, Japan, and the United States, and were attended by a record total number of 1,060 people. CDISC would like to thank the many sponsors that have helped to support our global Interchanges in 2015, namely: Accenture, Oracle, SAS, Akana, OmniComm, Instem, Navitas, PPD and Tamr.

CDISC IntraChanges
CDISC IntraChanges are an opportunity for those involved in our standards development teams to meet face-to-face for knowledge sharing, discuss lessons learned, and to work collaboratively across teams to further standards development efforts. CDISC held two CDISC IntraChanges in 2015.

CDISC Days
CDISC Days are opportunities to gain insights into the latest CDISC accomplishments and global collaborations, and network with experts and representatives in the clinical research industry attending and presenting their latest experiences with the CDISC standards. These are one-day events held in different locations around the world. In 2015, CDISC Days were held in Copenhagen, Denmark; Milan, Italy; and Vienna, Austria.
TELL THE GIRL IN 324 WHY CLINICAL RESEARCH DATA DOESN’T GET SHARED. TOO LATE. YOU’LL HAVE TO TELL HER PARENTS.

Billions of dollars are spent on clinical research, but when data isn’t shared, results get buried. Along with patients needing cures.
Overview: 2015 was a year of both investment and growth for CDISC. Expenses increased by 26% compared to last year, mostly due to the increase of staff to support planned growth, while gross income increased by 15%, reaching over $6.5M. This allowed CDISC to end up with a net income of $34K, almost $100k better than the budgeted loss of $58K.

This positive net result strengthens CDISC’s independence and sustainability, further improving our ability to deliver current and new standards development projects and initiatives. CDISC is endlessly grateful to our members and supporters for making this work possible.

Financial History through 2015

FY2015 Revenue

FY2015 Expenses
# CDISC Leadership

## Board of Directors

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Pierre-Yves Lastic</td>
<td>Chair, Sanofi</td>
</tr>
<tr>
<td>Dr. David Hardison</td>
<td>Chair-elect, ConvergeHEALTH by Deloitte</td>
</tr>
<tr>
<td>Paula Brown Stafford</td>
<td>Past-Chair, Quintiles</td>
</tr>
<tr>
<td>Dr. Charles Cooper</td>
<td>Becton Dickinson Diagnostics</td>
</tr>
<tr>
<td>Michael Glickman</td>
<td>VP, Finances, Computer Network Architects</td>
</tr>
<tr>
<td>Sue Dubman*</td>
<td>University of California, San Francisco</td>
</tr>
<tr>
<td>Dr. Dipak Kalra</td>
<td>University College London</td>
</tr>
<tr>
<td>Dr. Rebecca Kush</td>
<td>President, CDISC</td>
</tr>
<tr>
<td>Dr. Douglas Peddicord</td>
<td>VP, Standards, Terminology and Technical Services</td>
</tr>
<tr>
<td>Stephen Pyke</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Joyce Sensmeier, RN</td>
<td>IHE America/HIMSS</td>
</tr>
<tr>
<td>John Speakman</td>
<td>NYU Langone Medical Center</td>
</tr>
<tr>
<td>Dr. Kiyoteru Takenouchi</td>
<td>Translational Research Institute</td>
</tr>
<tr>
<td>Névine Zariffa</td>
<td>AstraZeneca</td>
</tr>
<tr>
<td>Dr. Jonathan Zung</td>
<td>UCB</td>
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**Newly Elected 2016 Board Members**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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</thead>
<tbody>
<tr>
<td>Margaret Keegan</td>
<td>Quintiles</td>
</tr>
<tr>
<td>Dr. Hiro Shirasawa</td>
<td>Merck</td>
</tr>
</tbody>
</table>

*CAC Chair

## Operations Leadership

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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</thead>
<tbody>
<tr>
<td>Rebecca Kush, PhD</td>
<td>President and CEO</td>
</tr>
<tr>
<td>Nicole Harmon, PhD</td>
<td>COO</td>
</tr>
<tr>
<td>Lauren Becnel, PhD</td>
<td>Senior Director, Bioinformatics</td>
</tr>
<tr>
<td>Rhonda Facile</td>
<td>VP, Standards Development</td>
</tr>
<tr>
<td>Sam Hume</td>
<td>Head of Data Exchange Technologies</td>
</tr>
<tr>
<td>Michael Ibara, PhD</td>
<td>Head of Digital Healthcare</td>
</tr>
<tr>
<td>Bron Kisler</td>
<td>VP, Strategic Alliances</td>
</tr>
<tr>
<td>Shannon Labout</td>
<td>VP, Education</td>
</tr>
<tr>
<td>Marine Laurent, CPA</td>
<td>VP, Finances</td>
</tr>
<tr>
<td>Barrie Nelson</td>
<td>VP, Standards, Terminology and Technical Services</td>
</tr>
<tr>
<td>Diane Wold, PhD</td>
<td>Senior Director, Standards Modeling</td>
</tr>
</tbody>
</table>
The CDISC Members

PLATINUM
AbbVie **
Absolute Systems Clinical Data
Accenture *
Acorda Therapeutics Inc
Akebia
Alexion Pharmaceuticals
Amgen ***
ARO Council
Asahi Kasei Pharma Corporation
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AcornBio, Inc.
AstraZeneca AB **
Bayer Pharma AG **
Becton Dickinson
Biontech Immunobiology, Inc.
Biogen Idec, Inc. **
Boehringer Ingeheim Pharmaceuticals ***
Bristol-Myers Squibb **
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Celgene Corporation *
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Certa ***
Chiltern *
Clinical Ink
Clinical Research Support Center (CReS) Kyushu *
Clinispace Worldwide *
Covance
Covance Corporation
Critical Path Institute *
di Wisconsin Technologies
Duke Catholic University Medical Center
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Danoone Nutricia Research
Dart Neuroscience, LLC
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Cancer Research and Biostatistics
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China South-JinRui
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ClinData International
ClinDatix, Inc.
ClinDox Ltd.
Clinical Trials Statistical and Data Management Center at the University of Iowa
ClinOps, Inc.
Clinove, Inc.
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CN Professional Services, LLC
Cognizant Corporation
Cognizant Technology Solutions, Inc. *
Commonwealth Informatics
CPC Clinical Research
CPC Clinical Trial Hospital
CPRD-Clinical Practice Research Datalink
CRC Pharma

CROMSOURCE
CROSS INT.s.r.l.
CRSS Metrics SA
CRS Clinical Research Services Mannheim GmbH
CScube Inc.
CSL Behring
CTEP (RealWorldRDC) Ltd *
CTI *
Cyter, Inc. *
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Data Standards Decisions ApS
Datameet
DataNeuro, Inc.
DataDriven, Inc.
Datametrics
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DP/Net Research, Inc.
Dicore Group, LLC
DOT International Co., Ltd.
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DOS, Inc.
Duke Clinical Research Institute ***
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ethica.info *
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Forneda USA **
FORUM Biomedical Solutions
Foundry Health
Fred Hutchinson Cancer Research Center
Frontier Science *
GCE Solutions

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GEOSS-MIB
GEOSS-Service International Ltd. & Co. KG
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Grunenthal GmbH *
H. Lundbeck A/S **
H2D Clinical, LLC
Hands-on GmbH *
Health Level Seven **
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Helsinn Healthcare SA *
HERAX
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JDDI *
JIncIn, Inc.
Innovative Analytics Inc.
Instem LSS *
Institut Jules Bordet, The BEAST Group *
Institute for Drug Development
Iranis LifeSciences GmbH
iMEDICO AG
Ionis Pharmaceuticals, Inc.
Ipsen *
Jazz Pharmaceuticals, Inc.
JRI Research, Inc.
Kaiser Permanente
Kanazawa University
Kantar Health
KCO Data, Inc.
KOHLEFELT eClinical GmbH *
Kyoto University Hospital
Kyowa Hakko Kirin Co., Ltd.
Kyushu University Hospital
Lambda-Plus SA *
Laris ApS *
LEO Pharma A/S *
LFB (Laboratoire francais du Fracturation)
Liaison Technologies *
Lincoln
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Ludwig Institute for Cancer Research
MA.R.C.O. GmbH & Co., KG *
M.E.D. Technical Consulting
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Maruho Co., Ltd.
MassIT, LLC
Mayo Clinic Foundation *
Medical Excellence
MEDICROSS CO LTD
MEDICISCIENCE PLANNING, Inc.
Medivation, Inc.
MedNet Solutions *
Medpace, Inc. *
Meta Clinical Technology
Metronomia Clinical Research GmbH *
MXS Incorporated
MXL Goods, Inc *
MobilisMD System (iasking) Co., Ltd.
Multiple Regional Clinical Trials Center at Harvard
MULTITEL
Nagoya Medical Center
Nerestar Clinical Improvement Unit
Nextri, Inc. *
Nordic Biosciences A/S
Novartis Pharmaceuticals Corporation ***
Nuventra, Inc.
numerics
Nuvanc A/S
OCS Consulting *
OncoRoad Corporation
OnnCom Systems *
Onyx Pharmaceuticals, Inc.
Pfizer
Peckslin Inc
Pharma Consulting Group AB *
Pharma Medica Research Inc.
PharmaStat LLC **
PHASTAR
Philip Morris Products SA
Pierre Fabre Biométrie
Profil Institut fuer Stoffwechselforschung
Progenics Pharmaceuticals
PRONETRIKA, LLC
Purdue Pharma L.P.
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QST Consultations, Ltd *
Quadrato Data Solutions *
Quanticate International Ltd
Quartesian LLC
Quartz Bio
Quotient Clinical
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RA-eClinical Solutions *
REGISTRAR-MAP
ResearchPoint Global
RhO, Inc. *
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SAM GmbH *
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Schröter Children’s *
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Synergy
SyntecNEXTER, Inc. *
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Takumi Research Technology Inc.
TalentMine, LLC
TELEMEDICINE TECHNOLOGIES S.A.S
Texas e-Health Alliance +
TIPS
The EMES Corporation
The Grieser Group
The Uppala Monitoring Centre
Theraxed
Therapeutics, Inc.
Threshold Pharmaceuticals
TMR - Technology, Methods, and Infrastructure for Networked Medical Research **
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Tory Industries, Inc.
Toyama Chemical Co., Ltd.
Trium Analysis Online GmbH
Ultragenyus Pharmaceutical
United Biocore Corporation
University Hospital Medical Information Network *
University of California, San Diego
University of Michigan
University of Tokushima
Uppala Clinical Research Center
US Army MIRC *
Virtali, Inc. *
Vervet Pharmaceuticals *
Wake Forest Baptist Medical Center
Winchker Nordinmed
Worldwide
Worldwide Clinical Trials
X-cell Analysis Clinical Research
Xcellerator Clinical Research
XLMDA Pharma **
XOMA
Xyphon Corporation *
Zilo Technologies Private Ltd.