cdisc®

2024 Annual Report

Clear Data. Clear Impact.

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2024 Annual Report

Letter From The CEO

As I reflect on my first year leading CDISC, I am filled with gratitude for the incredible community that has embraced our shared mission of amplifying data's impact. It has been an honor to lead an organization at the forefront of advancing global data standards for clinical research. The passion and dedication of our volunteers, members, staff, regulators, and partners inspire me every day as we work together to shape the future of clinical research.

In 2024, we achieved significant progress toward our new Vision and Strategic Roadmap, setting the stage for transformative advancements that will redefine the clinical research standards paradigm. Building on the success of initiatives like CDISC 360, we are now preparing to embark on the next phase with 360i—the implementation of lessons learned from 360, with the goal of expanding and connecting our standards to drive automation across the study information lifecycle, from study design through analysis results. This ambitious evolution will unify CDISC standards from study design through submission analysis, enabling stakeholders with innovative tools and methodologies that enable automation, minimize variability, and elevate data quality.

Our achievements this year reflect the strength of our partnerships and their impact on the global research ecosystem. Our collaboration with TransCelerate has advanced a digital protocol standard that will drive and accelerate protocol-driven research, enhancing efficiency and interoperability.

We partnered with the FDA and PHUSE to deliver a successful pilot evaluating the new Dataset JSON model for submission, which is now under formal review by the FDA. We launched the first version of our eTFL portal, which combines a set of standard reports with analysis results metadata to support automated reporting. We published our first set of biomedical concepts, marking the foundation for connecting our standards end to end. We also celebrated the release of Tobacco Implementation Guide v1.0.

Additionally, our work with FDA Business Rules has established a framework for integrating regulatory guidance into open-source rules libraries, further simplifying implementation.

We were honored to collaborate with TransCelerate, ICH, Vulcan, and industry leaders to support the ICH M11 initiative, specifically signing an MOU to maintain and govern M11 Controlled Terminology. We also partnered with WHODrug to improve interoperability between CDISC standards and patient safety datasets. These collaborations underscore the trust and shared purpose that position CDISC as a cornerstone of global research.

Thank you for your continued investment in CDISC and for being part of this dynamic community. Together, we are shaping the future of clinical research, one standard at a time.

Chris Decker, CEO

Leadership Team

Chris Decker, MS

President and Chief Executive Officer

Chris is an expert in technology and standards for complex process and technology solutions and has extensive experience in executive roles across software development, clinical research, and consulting. Chris was previously at Instem (d-wise) for 15 years, most recently as Vice President, Clinical Solutions.

Peter Van Reusel

Chief Standards Officer

Peter provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans. He has over 20 years of experience in senior roles in pharma and at CROs, providing standards expertise in various organizational settings.

Nicole Harmon, Ph.D

Chief Operating Officer

Nicole is a distinguished leader with over 20 years of experience across nonprofit, healthcare, research, and technology sectors. She brings a wealth of expertise in operational excellence, strategic partnerships, and financial sustainability. She oversees CDISC's operational strategies, furthering its mission to amplify data's impact to advance research.

Sam Hume, DSc.

Principal Consultant, Data Science

Sam leads the Data Science team to develop tools and standards that support clinical and translational research. Sam directs delivery of the CDISC Library, co-leads the Data Exchange Standards team, and serves as a leader of CDISC's Open Rules Engine initiative.

Sheila Leaman

Vice President, Global Relations

Sheila focuses on membership recruitment, seeking out new opportunities as well as ensuring membership retention, providing a high level of membership satisfaction.

Board Of Directors

The CDISC Board of Directors plays a vital role in guiding the organization's mission to advance global clinical data standards and improve research efficiency worldwide. Comprised of leaders from diverse sectors of clinical research, technology, and healthcare, the Board provides strategic oversight and expertise to drive innovation, collaboration, and the adoption of CDISC standards across the industry.

CDISC CEO Chris Decker presents a token of appreciation to Dr. Eric Pulkstenis as he concludes his tenure as Board Chair and continues his service on the CDISC Board.

Leadership

Erik Pulkstenis, Ph.D., Board Chair
Vice President, AbbVie Data and Statistical Sciences

Brooke Hinkson, Chair-Elect
Executive Director of Global Clinical Data Standards, Merck

Board Of Directors

Wenjun Bao, Ph.D.
Chief Scientist and Sr. R&D Manager for JMP Life Sciences, SAS Institute Inc.

Karen Curran, MBA
Chief Strategic Officer, Veramed

David Hardison, Ph.D.
Vice President of Health Sciences (Retired), ConvergeHEALTH by Deloitte

Pam Howard
VP Biostatistics & Programming, Medical Writing, ICON

Pandu Kulkarni, Ph.D
CEO, Aparito

Dominic Labriola
Chief Data and Analytics Officer, Madrigal

Lisa Lin, MBA
Study Data Standards Manager, FDA CBER

Hiroshi Masumoto
Corporate Officer, Daiichi Sankyo

Mihoko Okada, Ph.D
President, Institute of Health Data Infrastructure for All

Rhona O'Donnell, BSc
Vice President of Data Management Systems and Standards, Novo Nordisk

Christina Reith, BSc, MBChB, PhD, FRCP, FFPM Senior Clinical Research Fellow, NDPH

Jonathan Chainey, BSc
Executive Director and Global Head, Data Standards & Governance within Data Sciences, Product Development, Roche

What We Do

Clinical Data Interchange Standards Consortium (CDISC) creates clarity in clinical research by convening a global community to develop and advance data standards of the highest quality. Required by the United States Food and Drug Administration (FDA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), recommended by the European Medicines Agency (EMA) and China National Medical Products Administration (NMPA) and adopted by the world's leading research organizations, CDISC standards enable the accessibility, interoperability, and reusability of data.

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

Vision

Amplify Data's Impact to Advance Research

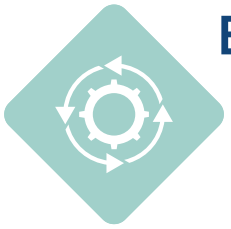
Mission

Create connected standards across the study information lifecycle to enable accessible, interoperable, and reusable data for more meaningful and effective research.

CDISC STRATEGY

Expand & Connect

- Embrace and adopt digital study design
- Expand and connect standards across the clinical research information lifecycle
- Define clear pipeline for integration of new data sources



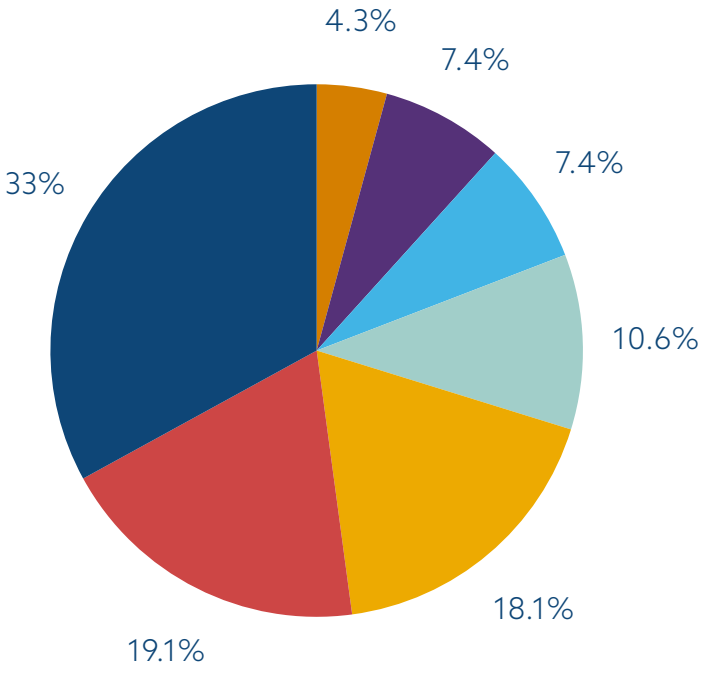
Enable & Automate

- Develop ready to use implementation standards
- Create open-source technology enabled standards
- Establish and manage a conformance framework

Engage & Adopt

- Establish a continuous feedback loop across the CDISC community
- Shift focus to producers/consumers needs and lower the barrier to use
- Prioritize communication to enable our stakeholders

Membership



Membership By Segment

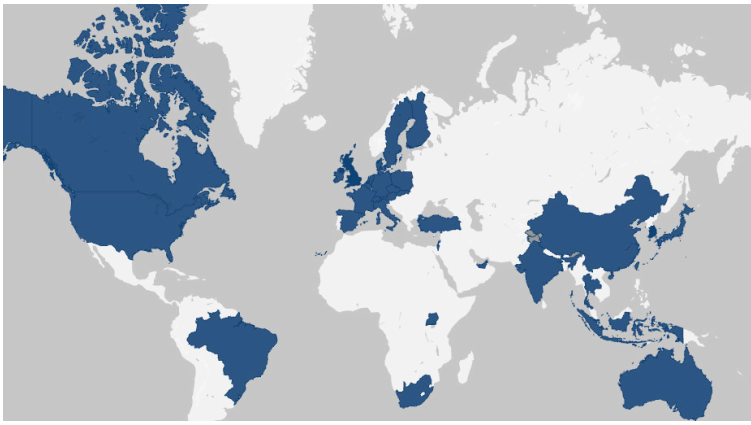
Together we bring clarity to data, amplify its impact, and help expedite regulatory review.

CDISC convenes a community of global experts to help shape emerging research standards. Learn from global experts from Pharmaceutical and Biotechnology companies, Government Regulators, CROs, Technology Service Providers, Clinical Laboratories, Medical Device companies, and increasingly Academia and Healthcare Providers.

CDISC membership provides a global platform for you to bring cutting-edge approaches and methodologies back to your organization while impacting the shape of future research standards.

450 ORGANIZATIONS

Membership By Region



Membership in CDISC represents:

31 Countries dedicated in advancing global clinical data standards.

450 Members drive transformation, innovation and impact across the clinical research ecosystem.

Be a Part of CDISC and play a critical part in amplifying the value of data for all our stakeholders worldwide

Platinum Members

Abbott
AbbVie
Alcon (Biometrics)
Alimentiv, Inc.
Alnylam Pharmaceuticals
American Thrombosis and Hemostasis Network
Amgen
Arcus Biosciences
Argenx
Asahi Kasei Pharma Corporation
Astellas Pharma, Inc.
AstraZeneca AB
Axiom Real-Time Metrics
Baxter Healthcare Corporation
Bayer HealthCare Pharmaceuticals, Inc.
BeiGene, Inc.
Bioforum Ltd.
Biogen, Inc.
bluebird bio, Inc.
Blueprint Medicines Corporation
Boehringer Ingelheim Pharmaceuticals
Bristol Myers Squibb
Business & Decision Life Sciences
Caidya
Catalyst Clinical Research
Center for Biostatistics in AIDS Research
Centers for Disease Control / National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Clario
ClinChoice
Clinpharma Clinical Research LLC
CLUPEA, Inc.
Cohen Veterans Bioscience
Critical Path Institute
Daegu Catholic University Medical Center
Daiichi Sankyo, Inc.
Danone Nutricia Research
Data4Knowledge
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Digital Infuzion
DNDi
eClinical Solutions, LLC
EDETEK, Inc.
Eisai, Inc.
Eli Lilly and Company
Embleema
F. Hoffmann-La Roche Ltd
Food & Drug Administration
Fortrea
Fosun Pharma
Fujitsu Limited
Galapagos NV
Gilead Sciences
GSK
H. Lundbeck A/S
ICON Clinical Research
IDDI
Incyte Corporation
Innovative Medicines Initiatives
Innovion BVBA
Institut de Recherche Pierre Fabre
Iovance Biotherapeutics
IQVIA
Japan Agency for Medical Research and Development
Jazz Pharmaceuticals, Inc.
JNPMEDI, Inc.
Johnson & Johnson
LYSARC
Medidata Solutions Worldwide
Medtronic, Inc.
Merative
Merck & Co., Inc.
Merck KGaA
Microsoft Corporation
MITRE
Moderna Therapeutics
Montreal Health Innovations Coordinating Center
National Cancer Institute
National Institute of Allergy & Infectious Diseases (NIAID)
National Library of Medicine
Navitas Life Sciences
New York University School of Medicine
Northwest Ehealth
Noumena Solutions
Novartis Pharmaceuticals Corporation
Novo Nordisk
Novotech Pty Ltd.
Nurocor
Ono Pharmaceutical Co., Ltd.
Oracle Corporation
Organon
Otsuka Pharmaceutical Development and Commercialization, Inc.
Pacira Biosciences
PAREXEL
Pfizer, Inc.
Pharmaceuticals & Medical Devices Agency
Philip Morris Products SA
Pinnacle 21 by Certara
PointCross Life Sciences, Inc.
Population Health Research Institute
PPD
Premier Research Group
PROMETRIKA, LLC
Regeneron
Sanofi
SAS
Servier
SGS
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Shanhu Health
Shionogi & Co., Ltd
Sumitomo Pharma Co., Ltd
Syneos Health Inc.
Takeda Pharmaceutical Company Limited
TCS Life Sciences ADD
Teva Pharmaceutical Industries Ltd
The Helmsley Charitable Trust
Theravance Biopharma, Inc.
TransPerfect Life Sciences
UCB Biosciences, Inc.
University of Southampton Clinical Informatics Research Unit
Veeva Systems
Vertex Pharmaceuticals

Gold Members

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aCROnordic
Acumen Information & Technology Co., Ltd.
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Advanced Clinical
Agati Clinical Informatics
Agios Pharmaceuticals
Akebia Therapeutics
Akros Pharma, Inc.
Alcedis GmbH
AliraHealth
ALK-Abello A/S
Alkermes
Almirall, S.A.
Altair
Altasciences Company Inc.
Alvotech Swiss AG
Amphastar Pharmaceuticals Inc
Arcellx
Ark Medical Solutions, Inc.
Arkivum
Arvinas
Assign Data Management and Biostatistics GmbH
Association of Clinical Research Organizations
Asymchem Clinical (Clin-nov)
Atlantic Research Group, Inc.
Atorus Research
Avenzo Therapeutics
Avidity Biosciences
Basilea Pharmaceutica International Ltd.
Beijing Bioknow Information Technology Co., Ltd.
Beijing BioVoice Technology Co., Ltd.
Beijing ClinFunction Co., Ltd.
Beijing Data Science Express Consulting Co., Ltd
Bethesdasoft
Biocomputing Platforms Ltd Oy
BioInformatiCo
BioMarin Pharmaceutical Inc.
BioOperations Consulting
BioStata ApS
Biotrial Biometrics
Bloqcube
Blueballon
C&R Research
Calian
Canadian Center for Vaccinology
Capish Nordic AB
Celerion
Center of Excellence for Biomedical and Public Health Informatics
Children's Oncology Group
Chungbuk National University Hospital Osong Clinical Trial Center
ClinDART, Inc.
ClinDatrix, Inc.
Clinical Trial Service (Guangzhou) Co., Ltd
Clinical Trials Statistical and Data Management Center, University of Iowa
CliniOps, Inc.
ClinSearch
Clinvia
Clymb Clinical
CMIC Holdings Co. Ltd.
Codex Scientific Co., Ltd.
Cogent Biosciences
Cogitars GmbH
Cognitive Research Corporation
Corcept Therapeutics
Cota Enterprises, Inc.
CPC Clinical Research
CR-CHUM
CRC Pharma
CRISALIS
CRISPR Therapeutics
Cross Research SA
CRS Clinical Research Services Mannheim GmbH
CRScube Inc.
CSL Behring
CTEP (RealWorldEDC) Ltd
Curadel
Cytel, Inc.
Dacima Software Inc
Data Standards Decisions Aps
DATAMAP GmbH
DF/Net Research, Inc.
DIcore Group, LLC
DP Clinical
Droice Labs
DT&CRO
EA Pharma Co., Ltd.
Edgerton Data Consulting, LLC.
Editas Medicine
Edwards Lifesciences LLC
EFFI-STAT
Elderbrook Solutions GmbH
Eliassen Group
EMB Statistical Solutions, LLC
Emergent Biosolutions
Ennov Clinical
Entimo AG
Ephicacy Consulting Group, Inc.
EPS Corporation
Estimondo GmbH
etera solutions
ethica CRO
Eurofins bioskin GmbH
European Clinical Research Infrastructure Network
Everest Clinical Research Corporation
EvidentIQ Germany GmbH
Evotec / Aptuit
Exelixis, Inc.
eXYSTAT
Faro Health Inc.
Fast-Track Drugs & Biologics, LLC
Ferring Pharmaceuticals
Fiverings Co., Ltd.
Formation Bio
Formedix USA
Foundation for Biomedical Research and Innovation at Kobe
Fred Hutchinson Cancer Research Center
Frontier Science Foundation
Frontier Science Scotland
GCP-MB
GCP-Service International Ltd. & Co. KG
GEM Programming Solutions Ltd.
GenInvo, Inc.
Genmab A/S
Genomedia Inc.
Gossamer Bio
Grunenthal GmbH
Guangdong Provincial Hospital of Chinese Medicine
H2O Clinical, LLC
Heidelberg Institute of Global Health

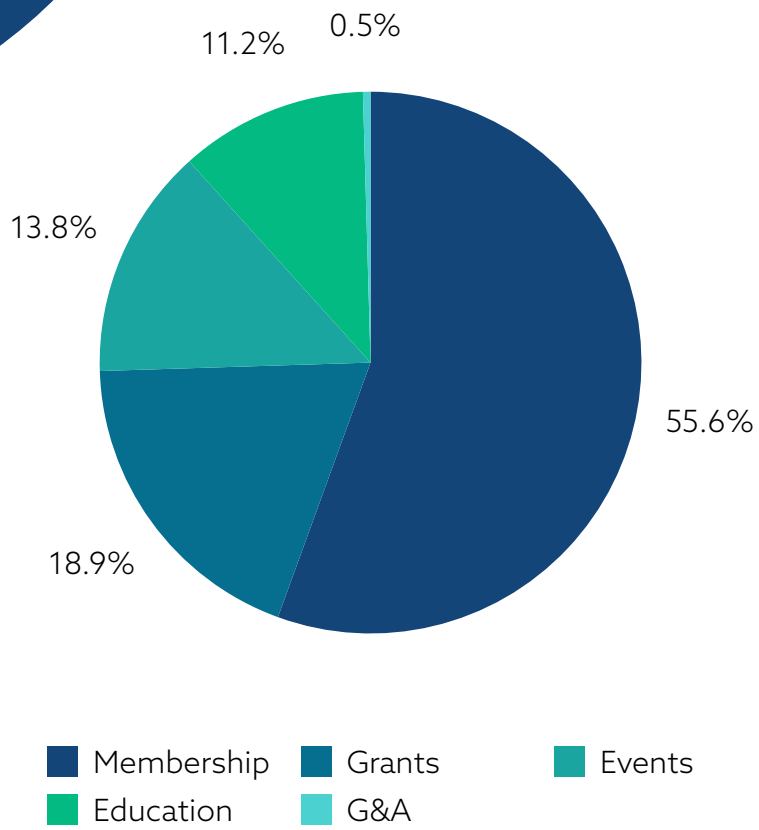
ICRC-Weyer GmbH
Illumina
InClin, Inc.
Inductive Quotient Analytics India Pvt Ltd.
Inference Inc.
inSeption Group
Insight Clinical Consulting, LLC
Instem LSS
Institut Paoli-Calmettes
Institute of Health Data Infrastructure for All
Intego Clinical
Intellia Therapeutics, Inc.
Intellim Corporation
Ionis Pharmaceuticals, Inc.
IPSEN Innovation
Jeonbuk National University Hospital
Jerion Consulting Group
JMP Clinical
JSS Medical Research
Just in Time GCP
Kapadi
KCR
KCT Data, Inc.
Keyrus Biopharma
Kiniksa Pharmaceuticals
Korea Institute of Toxicology
Kyoto University Hospital
Kyowa Kirin Co., Ltd
Kyushu University Hospital
Lantheus Holdings
Leap Therapeutics
LEO Pharma A/S
LFB Biotechnologies
Liaoning Yeedo Medical Data Technology Co., Ltd.
Lifebit Biotech Ltd
Lotus Clinical Research, LLC
LSK Global Pharma Services
Lumabridge
MAC Clinical Research
MacroGenics, Inc.
MacroStat (China) Clinical Research Co., Ltd
Mainanalytics GmbH
Marcus Institute for Aging Research, Hebrew SeniorLife
Maruho Co., Ltd.
Massachusetts General Hospital - CIB
Maxis Clinical Sciences LLC
Medable
Medical Excellence Inc.
Medical Research Institute of New Zealand
Mediqual-Sprl
MEDISCIENCE PLANNING, Inc.
Meditrial USA Inc.
MedNet Solutions
Medpace, Inc.
Medrio
Memorial Sloan Kettering Cancer Center
Menarini Ricerche s.p.a.
Metronomia Clinical Research GmbH
MKS Incorporated
MMS Holdings, Inc.
Montrium
Morphic Therapeutic
MRC/UVRI & LSHTM
Multi-Regional Clinical Trials Center at Harvard
N-Power Medicine, Inc.
Nanumspace
Narrativa
National Cancer Center East - Japan
National Institute of Public Health
NBCD A/S
NHO Nagoya Medical Center
Nippon Shinyaku Co., Ltd.
NORD
NRG Oncology Foundation
Nubilaria Srl
OCS Life Sciences
Omeros Corporation
Omicron ApS
Openclinica, LLC
Orion
OXMO CDM
P1vital Products Ltd
Patel Kwan Consultancy
Pentara Corporation
Pharma Medica Research Inc.
Pharmaron (US) Clinical Services, Inc.
PHARMASEAL International Limited
PharmaStat LLC
Plus-Project
PMV Pharmaceuticals
Poseida Therapeutics
Prevail Infoworks
PROCURATIO
Profil Institut fuer Stoffwechselforschung
Prothena Biosciences Inc.
PSI CRO AG
PT Labdha Teknika Nusantara
Puma Biotechnology, Inc.
Q-Square Business Intelligence, Corp.
Quadratek Data Solutions
Quanticate International Ltd
Quantics Consulting Ltd.
Quotient Sciences
R-Square, Inc.
Rakuten Medical
Ravis Technology
RCTs
REDCap Cloud
REGENXBIO
Relay Therapeutics
Research Organisation (KC), Ltd.
Resolutum Global
Revolution Medicines
Rho, Inc.
Rocket Pharmaceuticals
RTI International
S-cubed Biometrics Ltd
SafeSoft
Sage Therapeutics
SanaClis s.r.o.
Sarepta Therapeutics, Inc.
SCiAN Services Inc.
SCRI Development Innovations (SCDI)
SCSK Corporation
Senju Pharmaceutical Co., Ltd.
Seoul National University Hospital
SFJ Pharma
Shanghai Henlius Biotech, Inc
Shanghai OrigiMed Co., Ltd.
Shanghai Yaocheng Health Technology Co., Ltd.
Siemens-Healthineers
Signifikans Aps
Sinocelltech Group Limited
Soladis Clinical Studies
Sotio Biotech
StatisticaMedica
Statistics and Data Corporation
Sycamore Informatics
SymBio Pharmaceuticals Limited
Systex, Inc
T-TOP Clinical Research Co., Ltd.
Taisho Pharmaceutical Co., Ltd.
Takumi Information Technology Inc.
TELEMEDICINE TECHNOLOGIES S.A.S
TFS Healthscience
The EMMES Corporation
The Griesser Group
Theradex Oncology
Therapeutics, Inc.
Thrive Informatix, Inc.
Technology, Methods, and Infrastructure for Networked Medical Research
Toray Industries, Inc
TradeCraft Clinical Research
Trial by Fire Solutions
Trial Data Pharmaceutical Technology (Shanghai) Co., Ltd.
Trialwise
Triumph Research Intelligence Ltd

Turnstone Biologics
Union Laiya (Shanghai) Data Technology Co., Ltd.
United BioSource Corporation
Unither Bioengineering
University Hospital Medical Information Network
University of Alabama at Birmingham
University of Arkansas for Medical Sciences (UAMS)
University of California, San Diego
University of Leipzig
University of Oxford
Unlearn.AI
Uppsala Monitoring Centre
US Army MRMC
USWM
Vanderbilt University Medical Center (VUMC)
Vanguard Clinical
Venn Life Sciences
Veramed
Veristat, Inc.
Verve Therapeutics
Viatris
Viedoc Technologies AB
Vita Data Sciences, a division of Softworld Inc.
Voyager Therapeutics
Wakayama Medical University Hospital
WCG Clinical
WDB COCO Co. Ltd.
Wemedoo Clinical
Westat
Winicker Norimed GmbH
Worldwide Clinical Trials
WriteSource Medical Pty Ltd.
X-act Cologne Clinical Research GmbH
X4 Pharmaceuticals
Xiyuan Hospital of China Academy of Chinese Medical Sciences
XML4 Pharma
Xybion Corporation
Y-mAbs Therapeutics A/S
YPrime
Yseop
Zai Laboratory
Zifo RnD Solutions

Financial Report

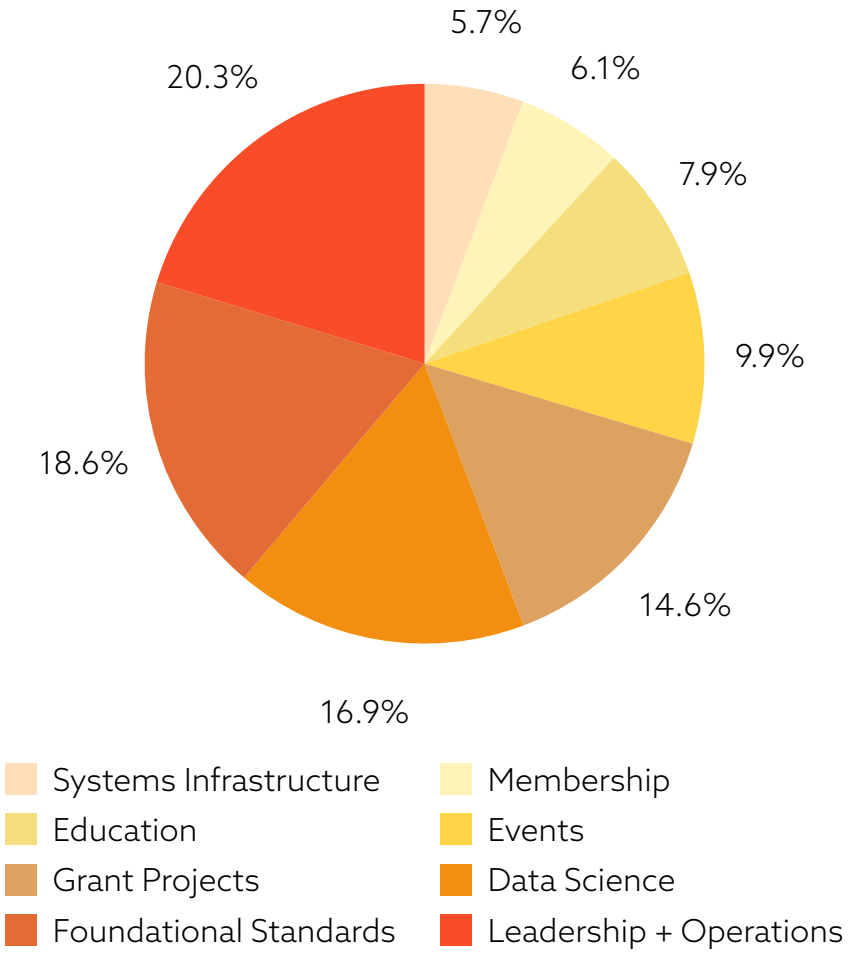
Revenue: $9,437,801

Membership	$5,243,161
Grants	$1,788,319
Events	$1,304,724
Education	$1,059,010
General & Administrative	$42,587



Expenses: $9,347,796

Systems Infrastructure	$535,190
Membership	$571,618
Education	$737,003
Events	$925,003
Grant Projects	$1,366,569
Data Science	$1,580,709
Foundational Standards	$1,734,794
Leadership & Operations	$1,896,910



2024 Milestones

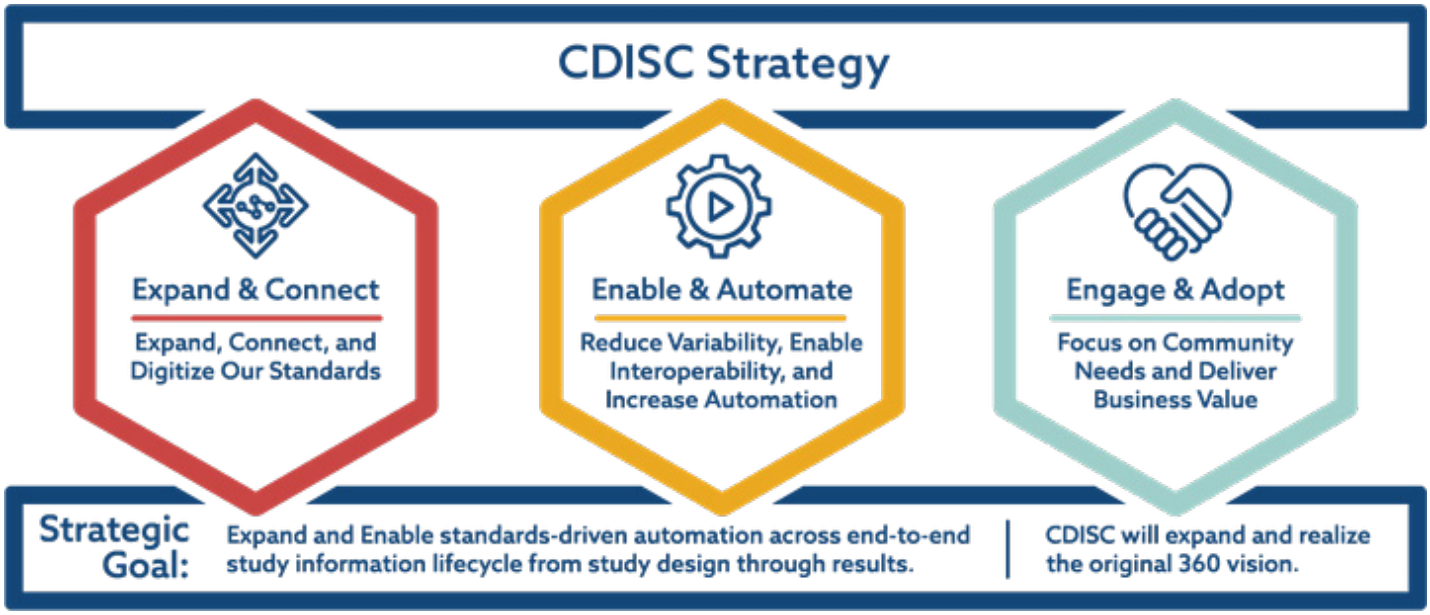
In 2024, CDISC introduced a Strategic Roadmap to expand and enable standards driven automation across the end-to-end study information lifecycle from study design through results.

To realize this vision, CDISC is mobilizing its work around three key pillars: Expand & Connect, Enable & Automate, and Engage & Adopt. These three strategic pillars position CDISC and the industry for future innovation and transformation.

With **Expand & Connect**, we aim to embrace and adopt digital study design, creating connected standards across the clinical research information lifecycle while defining a clear pipeline for integrating new data sources.

Through **Enable & Automate**, we will develop ready-to-use implementation standards that are enabled through technology, reduce variability and focused on interoperability and automation.

Finally, **Engage & Adopt** will establish a continuous feedback loop across the CDISC Community, prioritizing the needs of producers and consumers to lower the barrier to standards use, and increasing communication to better enable our stakeholders.



2024 Milestones

Analysis Results Standard v1.0

Introduced the Analysis Results Standard (ARS) v1.0 to tackle the inefficiencies in generating machine-readable analysis results. ARS enables automation, reproducibility, traceability, and reusability, transforming how analysis results are described, organized, and applied.

Biomedical Concepts Browser

Launched a new Biomedical Concepts (BC) browser to simplify access to the latest BCs and SDTM Dataset Specializations. The browser features search and filter tools, user-friendly video guides, and options to download files via Excel or retrieve data through CDISC Library APIs.

Observational Studies Guide v1

Released the Observational Studies Guide v1 to provide strategies for using SDTM with observational studies and real-world data. Developed collaboratively with the DRAGON consortium, CJUG, and global industry experts, the guide helps investigators represent data concepts in a CDISC-reviewed approach.

eTFL Portal Launch

Launched the eTFL Portal in Partnership with Clymb Clinical providing ready-to-use, ARS-compliant packages to streamline TFL generation. Each package includes display shells, ADaM datasets and metadata, analysis results metadata, and analysis outputs, promoting the adoption of ARS across the industry.

SDTM v2.1

Introduced Version 2.1 of Study Data Tabulation Model (SDTM) which includes new dataset and variable standards to meet the need for domain models described in the Tobacco Implementation Guide Version 1.0 (TIG v1.0).

Tobacco Implementation Guide v1.0

In collaboration with FDA CTP, launched Foundational Standard for collecting, analyzing, and exchanging tobacco product data. The TIG standardizes submissions using CDASH, SDTM, and ADaM models to support research, review, and harm reduction efforts.

USDM v3.0

Expanded protocol digitalization with full Protocol coverage in the USDM 3 model, enhancing downstream connectivity, aligning with ICH M11, and exploring the use of the CDISC Open Rule Engine for USDM conformance checks.

Define-XML v2.1.7 Package Update

Updated the define-enumerations schema file that reflects the release of Controlled Terminology Package 58.

{sdtm.oak} v0.1 Release

Introduced an open-source R package designed to facilitate the creation of Study Data Tabulation Model (SDTM) datasets. Developed through a collaboration among pharmaceutical companies and sponsored by the CDISC Open Source Alliance (COSA), {sdtm.oak} offers a modular framework with reusable algorithms to automate SDTM dataset creation.

eCRF Portal

Introduced the eCRF Portal, offering ready-to-use, CDASH-compliant annotated eCRFs in PDF, HTML, and XML formats. These eCRFs can be used as-is or imported into EDC systems for customization, providing flexible examples for data collection.

Coordinating Commitees

European Coordinating Committee (E3C)

"The CDISC E3C has been instrumental in advancing the adoption of CDISC standards across the region in 2024 by organizing the CDISC+TMF Interchange in Berlin.

400+ participants convened with prominent regulatory speakers, industry thought leaders, included a lineup of hands-on trainings and workshops – the event included networking opportunities and an exhibition showcasing the latest innovations from the standards community.

These efforts have strengthened European regional alignment, enhanced knowledge-sharing, and empowered stakeholders to implement CDISC standards effectively."

Nick De Donder E3C Chairman

Korea Coordinating Committee (K3C)

"In 2024, the CDISC K3C proudly hosted the second CDISC Korea Interchange in Seoul, welcoming over 100 participants from regulatory agencies, academia, and industry. This event built on the success of the first Interchange, fostering collaboration and advancing the adoption of CDISC standards across Korea.

By bringing together key stakeholders and providing targeted education, the K3C continues to drive progress in standardized clinical research practices and strengthen Korea's contributions to global harmonization efforts."

Park Byeong Kwan K3C Chairman

China Coordinating Committee (C3C)

"In 2024, the CDISC C3C made significant strides in advancing CDISC standards in China, including the Chinese translations of CDISC Standards, updates to commonly used Controlled Terminology, and hosting three impactful user group activities across Beijing, Guangzhou, and Shanghai.

These efforts culminated in the successful CDISC China Interchange, further driving the adoption of global data standards in the region."

Victor Wu C3C Chairman

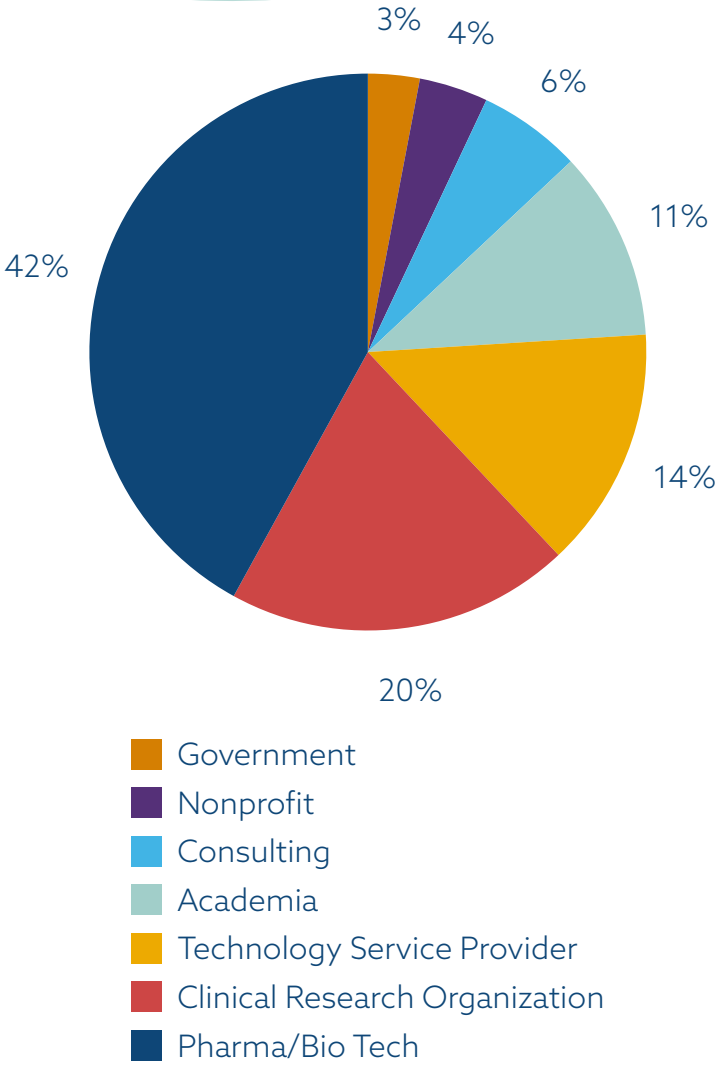
Japan Coordinating Committee (J3C)

"Reflecting on 2024, the J3C advanced the adoption of CDISC standards in Japan through key initiatives, including the Japan CDISC Interchange at Oracle Tokyo on June 12–13 and in-person training sessions at EPS on June 10–11. These efforts engaged industry professionals and introduced new initiatives like USDM, Dataset JSON, and enhanced TMF.

The virtual Japan Academic Workshop on November 15 further supported knowledge-sharing within academic circles".

Akira Soma J3C Chairman

Events



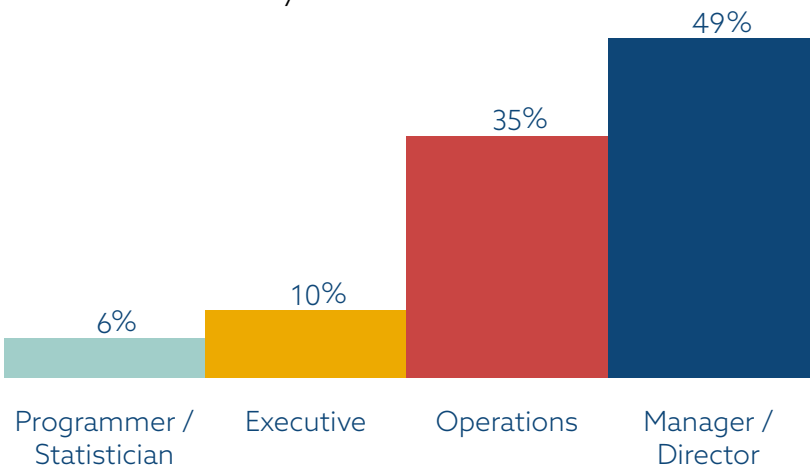
Diverse Sectors + Experience Represented Across Industry

2024 Interchange Attendees

CDISC held 7 global events across three continents with **more than 1,200 attendees** gathering to network, share their expertise, best practices, and lessons learned about leveraging CDISC standards to bring efficiencies and clarity to data.'

2024 brought together professionals from a wide range of roles, including managers, directors, operations experts, and executives.

This diverse attendee base reflects our ability to engage leaders and practitioners alike, fostering meaningful dialogue and collaboration across all levels of the industry.



2024 Interchanges

Thank you to everyone who attended an event in 2024. Here's to another year of excellence and innovation!

Engagement

Education

Total Trainees	940+
Instructor-Led Trainings	100+
Hours Of New Materials	30+
Countries Hosting Education Events	20
First Time Contributor SMEs	6
New Translations	2

Volunteers

Active Volunteers	1,200+
New Volunteer Requests	760+
Average Participants (Monthly)	370

Communications Reach

Email Community Subscribers	43,000+
LinkedIn Followers	18,000+

New Trainings

In-Person Hands-On
ARS Implementation
CDISC Open Rules Implementation
Dataset-JSON Implementation
ADaM Advanced Implementation
SDTM Advanced Implementation

Virtual
NORD Rare Diseases TAUG
SDTM Medical Devices
Tobacco Implementation Guide v1
TMF Excellence

On-Demand
Intro to TMF module

Partnership Highlights

Our impact as an organization is multiplied by our collaborations with our global partners. Through partnership, we can continue to advance interoperable standards across a wide range of therapeutic areas so greater clarity is achieved, more powerful research is conducted, and more meaningful connections are discovered. And as our dedication and collaboration continue to grow, so too will our collective impact on global health.

Transcelerate

Driving digital protocol standards to enhance research efficiency and interoperability

Our continued collaboration with TransCelerate has advanced a digital protocol standards that will drive and accelerate protocol driven research enhancing efficiency and interoperability. USDM v3.0 was released enhancing downstream connectivity, aligning with ICH M11, and exploring the use of the CDISC Open Rule Engine for USDM conformance checks.

Uppsala Monitoring Centre

Improving the interoperability of CDISC Standards

CDISC formalized a strategic partnership with Uppsala Monitoring Centre (UMC) to advance interoperability between CDISC standards and WHODrug Global, the world's leading drug dictionary. Together, CDISC and UMC will deliver joint projects, training, and resources to empower the healthcare community and ensure seamless utilization of clinical and safety data worldwide.

ICH M11 and Vulcan

Advancing harmonized clinical protocols

CDISC, HL7 Vulcan, and ICH M11 have partnered to advance the digital transformation of clinical protocols, improving automation and interoperability across research and healthcare. This project builds on ICH M11's work to develop a FHIR-based exchange standard aligned with CDISC standards, creating a structured and harmonized approach to protocol data.

PHUSE

Partnered with FDA and PHUSE on a successful release of the Dataset-JSON v1.1 model

CDISC partnered with the FDA and PHUSE to deliver a successful pilot evaluating the new Dataset JSON model for submission which is now under formal review by the FDA.

FDA Center for Tobacco Products (FDA CTP) *Partnered to develop Tobacco Implementation Guide v1.0 in partnership with the*

The Tobacco Implementation Guide (TIG) v1.0 is a Foundational Standard that serves as a comprehensive resource for the collection, tabulation, analysis, and exchange of tobacco product data for regulatory submissions. The TIG v1.0 implements the CDASH Model v1.2, SDTM v2.1 and ADaM v2.1, with references to standards such as the Define-XML v2.1, to standardize data for submission and facilitate tobacco product research, scientific review, and harm reduction.

U.S. Food and Drug Administration's Office of Translational Sciences *Initiated research collaboration to incorporate FDA Business Rules into CDISC's Open Rules Engine*

CDISC announced a research collaboration with the U.S. Food and Drug Administration's Office of Translational Sciences in the Center for Drug Evaluation and Research and Office of Regulatory Operations in the Center for Biologics Evaluation and Research to incorporate FDA Business Rules into CDISC's Open Rules Engine.

CDISC's Open Rules project provides an open-source version of the CDISC Conformance Rules in a machine-executable format. These rules, published and managed by CDISC, create a single source for conformance rules and allow external vendors and sponsor companies to implement and extend these rules within their tools.

National Organization for Rare Disorders

CDISC and NORD® have partnered to develop global data standards for rare disease research, ensuring data is structured for better analysis and regulatory review. These standards were released in a Therapeutic Area User Guide (TAUG), freely available on the CDISC website.

By aligning CDISC standards with NORD's IAMRARE® registry platform, this collaboration enhances data consistency, supports research efficiencies, and accelerates treatment development for rare diseases.

Trial Master File

The TMF Reference Model provides standardized taxonomy and metadata and outlines a reference definition of TMF content using standard nomenclature. The goal of the TMF Reference Model is to provide a single, unified interpretation of the regulations via document listing which would be accepted across the industry. The TMF Reference Model initiative is governed by the rules and procedures of CDISC but the work products are a Public Domain work.

The TMF Reference Model Is A Valuable Tool For:

- Biopharmaceutical sponsors of any size, both commercial and institutional, involved in clinical studies
- Clinical study team members, including trial and data management, clinical supplies, biostatistics, etc.
- Contract Research Organizations and vendors servicing TMFs, including technology providers TMF consultants, Site staff, including investigators and coordinators
- Regulators who wish to overcome the challenges of different TMF terminology and file structures that create inefficiency and a higher degree of variability during sponsor audits
- Clinical study team members, including trial and data management, clinical supplies, biostatistics, etc.

TMF Course Launched: The Critical Role of Data Managers, Biostatisticians, & Programmers in Achieving TMF Excellence

This half-day training provides an overview of Trial Master File (TMF) management with a focus on Data Management, Biostatistics, and Clinical Programming. Participants will learn about regulatory requirements, audit readiness, and how their roles contribute to TMF compliance.

The session reviews the CDISC TMF Reference Model, highlighting Zones 10 (Data Management) and 11 (Biostatistics), with deeper dives into key data and record types. Attendees explore the intersection of TMF with Digital Data Flow, gaining insights to enhance compliance and data integrity.

Looking Forward:

As we move from 2024 into 2025, we are excited to celebrate 25 years of CDISC's impact and look forward to a transformative year ahead.

The coming year will focus on advancing the 360i initiative, with the goal of expanding and connecting our Standards from design through analysis, expanding technical capabilities to support automation and AI-driven processes, creating resources that lower the barriers to standards adoption, and fostering a more connected community through tools and methodologies that empower researchers and organizations worldwide.

These efforts will further our mission to amplify data's impact, driving meaningful advancements in clinical research and delivering value to patients, sponsors, and the broader research ecosystem.

Together, we will continue to build on the strong foundation established over the past 25 years, shaping a future where standards drive innovation and accelerate the pace of progress. As we celebrate this 25th Anniversary, we invite you to be part of our next chapter. Support our mission, become a member, volunteer, and help shape the future of clinical research!

25 Years of Innovation, Collaboration, and Impact.