ANNUAL REPORT 2025

cdisc®

The Future is Connected

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LETTER FROM THE CEO

Status quo is safe, status quo is comfortable, but maintaining the status quo is actually one of the riskiest things we can do. We are trying to make a choice and a change.

We want to break through the status quo to involve our standards as a powerful enabler linking information from the beginning of a clinical trial - protocol and master file - all the way through to the results of the trial.

As we close out 2025, I reflect on a meaningful year for CDISC, one that marked our 25th anniversary and underscored the enduring power of collaboration, standards, and shared purpose in connecting and advancing clinical research.

This milestone year offered an opportunity not only to look back on what we have built together, but also to consider how our work continues to evolve to meet the needs of a rapidly changing research ecosystem. The progress captured in our 2025 Annual Report reflects the collective efforts of a global community committed to improving how clinical research data are structured, shared, and used.

Connection remained central to our work throughout the year. In 2025, CDISC convened seven global events that brought together more than 1,400 participants and delivered over 75 training sessions, strengthening collaboration across the CDISC and TMF communities. These engagements reinforced the importance of shared learning and consistent implementation of standards worldwide.

One of our most significant advances this year was the launch and rapid development of our 360i initiative.

With contributions from community members across design, build, and implementation, this initiative moves us closer to an ecosystem where standardized and semantically linked information enables greater automation, interoperability, and efficiency.

The foundation being established through 360i positions CDISC, and the broader research community, to responsibly leverage emerging technologies, including AI, in ways that accelerate the delivery of therapies while maintaining scientific rigor.

Thank you for your continued engagement, expertise, and trust. Your contributions make CDISC's work possible. I look forward to building on this momentum together as we move into 2026.

Sincerely,

Chris Decker, President & CEO, CDISC

LEADERSHIP TEAM

Chris Decker, President and CEO

Chris Decker, MS, President and Chief Executive, 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.

Nicole Harmon, Chief Operating Officer

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

Peter Van Reusel, Chief Standards Officer

Peter Van Reusel provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans, working closely with the President and CEO, as well as CDISC staff and stakeholders. He has over 20 years' experience in senior roles in pharma and at CROs, providing standards expertise and carrying out other standards work in various organizational settings. A long-time, CDISC-authorized instructor, Peter has helped significantly in developing CDISC training courses.

Julie Smiley, Chief Information Officer

Throughout her career, Julie has held leadership roles overseeing large-scale technology portfolios and pioneering solutions that bridge the gap between technology and business strategy. She has been actively engaged with CDISC for 25 years as a member, volunteer, and industry collaborator, contributing to the development of the CDISC Library and driving initiatives that improve interoperability across clinical research.

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. Our Board strengthens CDISC's connections across the clinical research community.

Board Leadership

Board Chair
Brooke Hinkson
Executive Director, Head Global Clinical Data Standards
Merck

Chair Elect
Jonathan Chainey
Executive Director, Global Head, Data Governance & Operations, PD Data Science & Analytics
Roche

Board Members

Wenjun Bao
Chief Scientist and Director
Advanced Analytics R&D
JMP

Catherine Chronaki
Secretary General
HL7 Europe Foundation

Karen Curran
Chief Strategy Officer
Veramed

David Hardison
Member Industry Advisory
CDISC

Lisa Lin
Study Data Standards Manager
U.S. FDA CBER

Patrick Nadolny
Global Head of
Clinical Data Management
Sanofi

Rhona O'Donnell
VP, Data Standards &
Integration
Novo Nordisk

Mihoko Okada
President
IDIAL

Erik Pulkstenis
Senior VP, Biometrics
Annexon Biosciences

Christina Reith
Associate Professor
University of Oxford

CDISC COORDINATING COMMITTEES (3CS)

CDISC's Coordinating Committees (3Cs) connect regional stakeholders with CDISC. They advance CDISC's mission by promoting standards within their regions and facilitating a global network of collaboration. By gathering and sharing regional insights, they bridge diverse perspectives and foster unity, supporting CDISC events that resonate across borders. Through these efforts, they strengthen relationships across global and local communities, creating interconnection that drives progress worldwide.

E3C Europe

Organized and planned the 2025 CDISC + TMF Europe Interchange in Geneva, which brought together a record-breaking audience of life sciences leaders to discuss standards, TMF processes, AI innovations, and best practices.

NA3C North America

Organized and planned the 2025 CDISC + TMF US Interchange in Nashville, bringing together a record-breaking audience of North American stakeholders and clinical data leaders to advance CDISC standards, regulatory readiness, and best practices across the region.

C3C China

CDISC China Day in Beijing at the Merck Research campus included sessions on CDISC implementation and China-specific regulatory expectations.

I3C India

Success with CDISC's first India Day in 2025, held in Bengaluru and hosted by Eli Lilly, paved the way for launching our inaugural I3C in 2026.

J3C Japan

CDISC Japan Interchange, held at the Oracle Aoyama Building with on-site public trainings in Tokyo, continued J3C's work to advance CDISC Standards in Japan. Japan Academic Workshop highlighted collaboration and practical academic use of CDISC Standards.

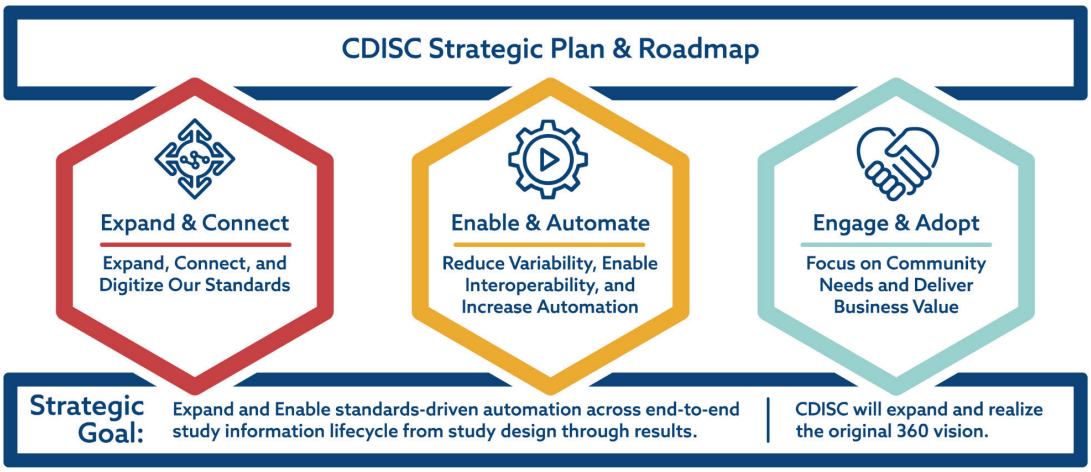
K3C Korea

Led Korea CDISC Day at Seoul National University Hospital's CMI Seosunghwan Hall, organizing sessions on CDISC updates and implementation, with K3C leadership chairing several key parts of the program.

Connect

Connecting
Community
For 25 Years

VISION + MISSION



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 an 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

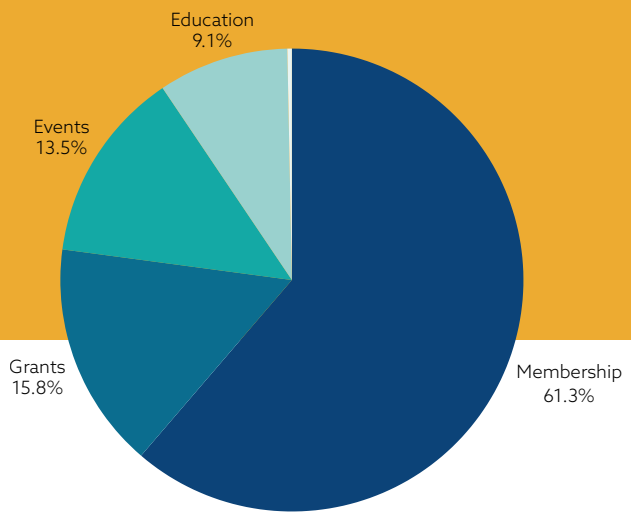
Amplify data's impact to advance research.

Mission

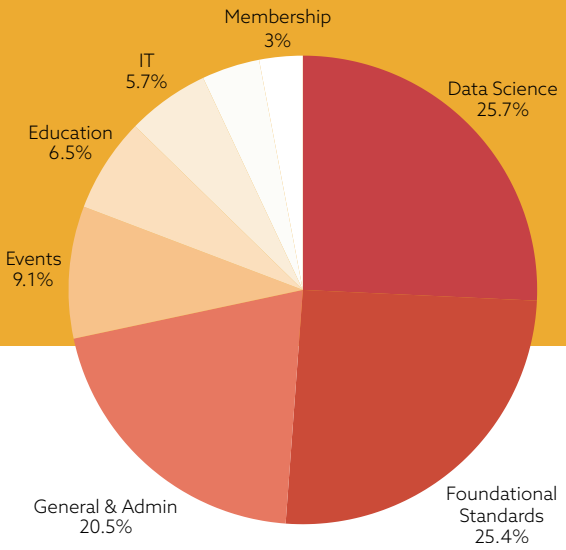
Create connected standards across the study information lifecycle to enable accessible, interoperable, and reusable data for more meaningful and effective research.

FINANCE

Revenues



Expenses



Revenues

Membership	$	5,334,578
Grants	$	1,377,508
Events	$	1,171,027
Education	$	793,462
Other Revenues	$	27,460
Total Revenues	$	8,704,035

Expenses

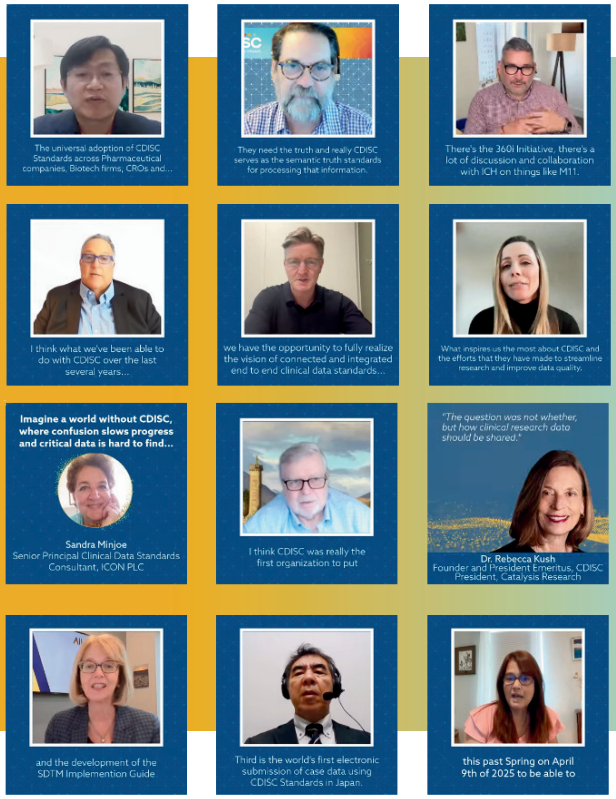
Data Science	$	2,237,965
Foundational Standards	$	2,212,718
General & Admin	$	1,782,338
Events	$	792,945
Education	$	567,747
IT	$	495,470
Communications & Alliances	$	348,158
Membership	$	260,325
Total Expenses	$	8,697,664

25TH ANNIVERSARY

CDISC marked its 25th Anniversary with a year-long celebration highlighting our global impact on clinical research. CDISC released a series of video interviews featuring community leaders, regulators, volunteers, and longtime contributors, sharing reflections on CDISC's evolution and influence.

CDISC also published multiple historical timelines, offering a visual look back at key milestones across its 25-year history.

We celebrated throughout CDISC's in-person 2025 Interchange events, with videos woven into gatherings in the U.S., Europe, Japan, and China. We honored CDISC's legacy while inviting the global community to help shape the next chapter of standards-driven clinical research.



1997-1999

The Beginning...

Dedicated volunteers work to develop a common standard for clinical research.

2000

Incorporation

CDISC incorporates as a Non-Profit Organization with 32 charter members.

2001

Study Data Tabulation Model (SDTM)

Operational Data Model (ODM)

Launched the first CDISC Standards - SDTM and ODM to standardize the content and the exchange of the content.

2003

FDA Endorsement

Marked significant step towards standardizing clinical trial data submissions, facilitating efficient and consistent regulatory reviews.

First International Interchange

Baltimore, Maryland, USA

2005-2006

Controlled Terminology

Analysis Data Model (ADaM)

Established CDISC Controlled Terminology in partnership with NCI/EVS and rolled out ADaM model to support analyses.

2009

Global Growth

250 Member Orgs

CDISC Coordinating Committees:

Europe (E3C) Japan (J3C) China (C3C) Korea (K3C)

Standard for Exchange of Nonclinical Data (SEND)

CDISC expanded beyond clinical data with the SEND model, standardizing nonclinical study data, facilitating data sharing and regulatory reviews.

2012

Therapeutic Area User Guides (TAUGs)

Introduced TAUGs, representing data pertaining to specific disease areas. (In collaboration with Critical Path Institute (C-Path), FDA, National Cancer Institute (NCI), TransCelerate BioPharma, and patient foundations, supported by Coalition for Accelerating Standards and Therapies (CFAST) Therapeutic Area (TA) Standards Teams.)

2014

Define-XML Standard

Introduced to provide a machine-readable format for study metadata and data definitions, crucial for regulatory submissions.

2015

Global Regulatory Recognition

Regulatory bodies worldwide, including European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), recognized and began adopting CDISC standards, solidifying CDISC's global role.

2016

CDISC Standards Mandated for Regulatory Submissions (FDA)

The FDA made CDISC standards mandatory for certain types of clinical and nonclinical data submissions.

2017

CDISC Advisory Council (CAC)

Established CAC, playing a crucial role in shaping CDISC's development and direction.

2020

CDISC 360: Driving Digital Study Design and Automation

Developed our digital protocol model in collaboration with TransCelerate demonstrating how end-to-end data standards can be used to streamline study processes, improve data accuracy, and reduce manual data entry.

Rapid Response: COVID-19

CDISC collaborated to develop and release COVID-19 Interim User Guide, showcasing CDISC's agility in addressing urgent health crises.

CDISC Open Source Alliance (COSA)

Open-source developers created and shared free tools for implementing CDISC standards.

2022

Trial Master File (TMF) Reference Model

CDISC officially affiliated with the TMF Reference Model, allowing volunteers to contribute to the development and maintenance of this model.

2024

CDISC 360i

In response to community feedback, CDISC expanded the scope of CDISC 360, launching the 360i initiative to implement end-to-end data standards for more efficient, automated study workflows.

Present

Worldwide Milestones

450+ Members in 31 Countries

Support from CDISC Coordination Committees (3Cs) in 6 Regions

User groups across Asia, Africa, Europe, and North America

Join

Donate

Volunteer

Adopt

Connecting
Present to Future

PUBLICATIONS + RELEASES

CDISC strengthened the global clinical research ecosystem by advancing standardized, interoperable data models that accelerated regulatory review, improved data quality and reusability, and enabled greater collaboration across industry, academia, and regulators. CDISC also moved forward digital and AI-enabled trial innovation by supporting machine-readable metadata, automating study design workflows, and expanding global training and community engagement.

CDISC Open Source Alliance (COSA) COSA partners across the global community met quarterly throughout the year to showcase their open-source solutions. Ranging from COSA Hackathons and winners' presentations to more than 15 open source solution demos and 8 OSS additions to the repository. The meetings also featured focused discussions on topics such as how 360i aligns with and supports the open-source community, highlighting continued collaboration and innovation across the clinical research ecosystem.

CDISC Open Rules Engine (CORE) v0.14.0
Enables JSONata rules (USDM conformance rules).

Unified Study Definitions Model v4.0
Includes an Implementation Guide, Logical Model, Controlled Terminology, API specifications, and Conformance Rules to support usage of USDM.

Unified Study Definitions Model v3.0 Conformance Rule Specs
Provides the technical guidance used to assert that any given Study Definition solution conforms to USDM v3.0.

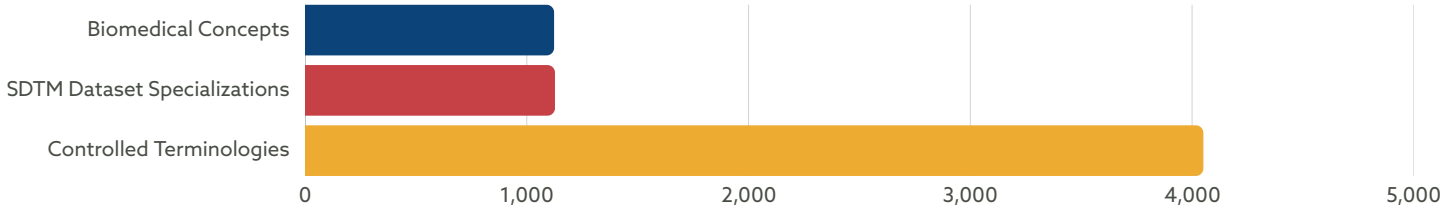
Cardiac Imaging Supplement to the Duchenne Muscular Dystrophy TA User Guide v1.0
Developed in partnership with the C-Path Duchenne Regulatory Science Consortium (D-RSC), the Supplement to the DMD TAUG includes new Controlled Terminology, and SDTM and ADaM examples for cardiovascular tests.

Define-XML v2.1.8 & v2.1.9 Releases
Includes the define-enumerations schema file that reflects the release of CT P59.

CT Relationships v1.0 for SDTM v1.7, SDTMIG v3.3, SDTMIG-MD v1.1
Defines relationships between published CT codelists/terminology subsets and the CDISC variables, tests, parameters, and non-standard variables (NSVs) published in SDTMIGs, TAUGs, and regulatory documents.

PUBLICATIONS + RELEASES

CDISC Library Expansion



Biomedical Concepts (BCs) Browser

In 2025, the CDISC Biomedical Concepts Browser expanded dramatically in content, strengthening its role as the primary access point for machine-readable BC metadata, and became a central enabler of CDISC's 360i digital transformation strategy.

QRS Portal

The QRS Portal was launched in 2025! Developed to provide Questionnaires, Ratings & Scales (QRS) content in a machine-readable format, each QRS Package contains:

- Biomedical Concepts
- Controlled Terminology
- SDTM Dataset Specializations
- CDISC Collection Dataset Specializations (draft)
- ODM Files with HTML Renditions

eCRF Portal

In 2025, the eCRF Portal continued to expand its library of CDASH-compliant, annotated eCRFs, offering ready-to-use forms in PDF, HTML, and XML formats to better support streamlined study startup and standardized data collection.

TRIAL MASTER FILE (TMF)

TMF's Transition to a Digital Standard: Advancing Clinical Trial Documentation

Introduction to the New TMF Era
In 2025, TMF announced its entry into a new era, marking a pivotal transformation in clinical trial documentation. The TMF community revealed that work was underway on a new version of the TMF Reference Model. This initiative represents the first fully digital TMF standard, characterized by digital-first records, improved interoperability, and expanded standardized metadata.

From Guidance to Governance: Evolution of the TMF Reference Model
TMF highlighted a strategic shift from providing "guidance" to establishing formal governance. This involved evolving the Reference Model into what is now known as the TMF Standard Model (TMF SM). Key developments included the introduction of new terminology, such as replacing artifacts with record groups, updating structural frameworks, and enhancing regulatory alignment.

Introducing TMF SM V1: A Leap Forward
The new standard, designated as TMF SM V1, represents a significant advancement. It solidifies a consistent, interoperable foundation for clinical trial documentation, ensuring greater clarity and reliability across the industry.

2025 Workstreams and Future Release
With the full release targeted for 2027, major workstreams commenced in 2025. These included expanding record types, aligning metadata, and preparing for the governance changes necessary for the new standard's implementation.

Building a Collaborative Community
The TMF Reference Model community is transitioning into the collaborative "CDISC TMFCommunity." This new collective is united by cutting-edge standards and a shared commitment to digital innovation in clinical trial documentation.

Impact and Outlook for Clinical Trials
2025 ushered in more than an update to TMF; it brought a profound shift in approach. The focus moved towards delivering data-driven, fully interoperable, and machine-readable TMFs. These advancements will support decentralized trials, enable real-time oversight, and streamline regulatory compliance, powering the future of clinical research.

Transforming Clinical Research

CDISC 360i is an initiative to transform clinical research by digitalizing study design through analysis, making metadata interoperable across the entire study lifecycle.

With connected standards and end-to-end automation, 360i eliminates manual tasks, enables AI, ensures traceability and consistency, and empowers the industry to deliver results faster, with better quality, and at a lower cost, accelerating the delivery of new therapies to patients.

Together with our global community, we launched and advanced the 360i vision through the tactical work of the 360i Operational Team, the "Art of the Possible" prototype, an AI Innovation Challenge, and our Technology Vendor Roundtable.

The 360i Team set out to transform the clinical research process into a dynamic, non-linear model - one where steps and phases can run in parallel rather than in sequence, and data flows seamlessly from one stage to the next.

360i Operational Team

The 360i Team fostered extensive industry collaboration, bringing together over 80 individuals across several project teams (Design, Build, and Run, along with an Operational Steering Committee, Reviewers, and Parallel groups to work on key outcomes, including CDISC open rules, biomedical concepts, and analysis concepts).

Phase 1	Achievements	Lessons Learned
Design	Developed several detailed user stories spanning from study design through study amendment - an important step toward aligning roles across our industry. From these user stories and through the use of open source tools and utilities, generated a USDM-JSON 4.0 file with associated biomedical concepts. This confirmed that standardizing study definitions linked to biomedical concepts is highly effective, and provides clear evidence of how these connections enable downstream use cases.	• Concept groupings are needed for improved usability • Robust tools are needed that support association of concept groups to activities for proving out semantic interoperability across the clinical data lifecycle
Build	Successfully utilized biomedical concepts linked to USDM to generate eCRF specifications, ODM.xml, SDTM annotated CRFs (aCRFs), SDTM dataset specializations, SDTM trial design domains, define.xml, and SDTM shell data sets.	• Additional operational metadata is required to close gaps and drive automation • Interim utilities were created to fill tooling and metadata gaps
Run	Demonstrated ability to process data from a wide range of sources and automate generation and validation of SDTM datasets, as well as exploring the use of AI/ML to help support development.	• Limited raw source data available to test multiple scenarios • Again, various gaps in missing operational metadata required to robustly drive automation

AI Innovation Challenge

The 2025 CDISC AI Innovation Challenge directly supported the 360i initiative by serving as a catalyst for its vision of an automated, modern clinical research lifecycle. Leveraging AI, Machine Learning, and CDISC Standards, the Challenge focused on three targeted use cases to advance the digitization and automation of clinical research.

Use Case #1 - Protocol Library:
Participants created a USDM-centric repository by extracting legacy protocol content using AI/ML, with thirteen submissions making it the most popular use case. Winner: Faro | Runner Up: Zifo

Use Case #2 - BC Acceleration:
This challenge showcased AI/ML-driven approaches to accelerate the development and curation of Biomedical Concepts, receiving five strong submissions. Winner: Saama | Runner Up: Lindus Health

Use Case #3 - Automated Traceability:
Participants demonstrated semantic traceability from statistical analyses back to source data using CDISC standards, resulting in four compelling submissions for this complex use case. Winner: Merck | Runner Up: Zifo

The 2025 CDISC AI Innovation Challenge underscored growing momentum and creativity surrounding the use of AI and ML in clinical research. Participants from across the globe demonstrated technical excellence, forward thinking, and a shared commitment to advancing standards-driven innovation for the benefit of the entire research ecosystem.

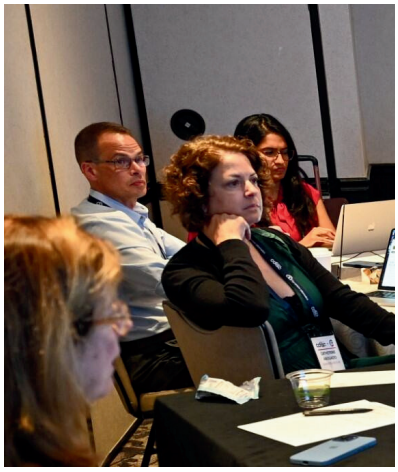
Technology Vendor Roundtable

This group strengthened connection across the CDISC community by uniting leading innovators to accelerate the development and adoption of CDISC Standards. Through ongoing virtual sessions and an in-person meeting at the US Interchange in Nashville, the group created a shared space for collaboration and strategic alignment. These connections helped build a more unified ecosystem of tools that support automation, enhance data quality, and reduce inefficiencies across the research lifecycle.

Engage

Community is Connection

EDUCATION



Educating our global community on the standards we develop is an essential connection and vital to our mission. CDISC delivered trainings across 35 countries, reaching 130+ organizations and more than 800 trainees through a total of 77 training sessions. By investing in a human-centered learning culture, we strengthened a thriving community across the entire clinical research lifecycle. Eight new training sessions focused on 360i digital transformation concepts like USDM and digital protocols, and prepared learners to implement end-to-end automation central to the 360i vision.

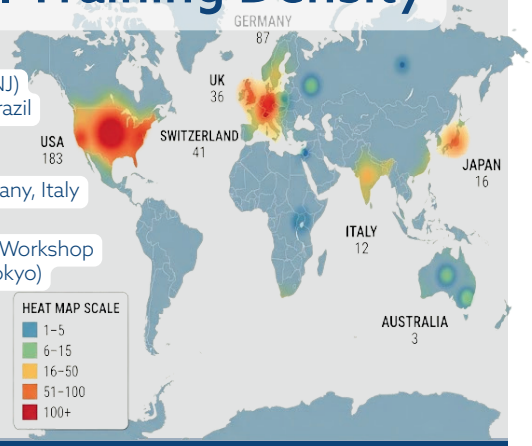
Global Training Density

Americas
80 In-Person Trainees (TN, MA, NJ)
New Private Training Location: Brazil

Europe
62 In-Person Trainees (Geneva)
Private Trainings: Belgium, Germany, Italy

Asia/Pacific
270 Attendees: Japan Academic Workshop
20 In-Person Trainees (Beijing, Tokyo)
Private Training: India

Africa
New Private Training Location: Uganda



8 New Trainings

- Biomedical Concepts Hands-On Implementation
- Designing TRUE Research (In partnership with LHEA)
- Pediatrics User Guide v1.0 On-Demand Training
- SDTM in Action Bundle (On-Demand)
- TIG Conformance Rules v1.0 OnDemand Training
- Understanding USDM: Digital Design and Schedule of Activities
- Understanding USDM: On-Demand
- USDM Onboarding Package

8 New Instructors

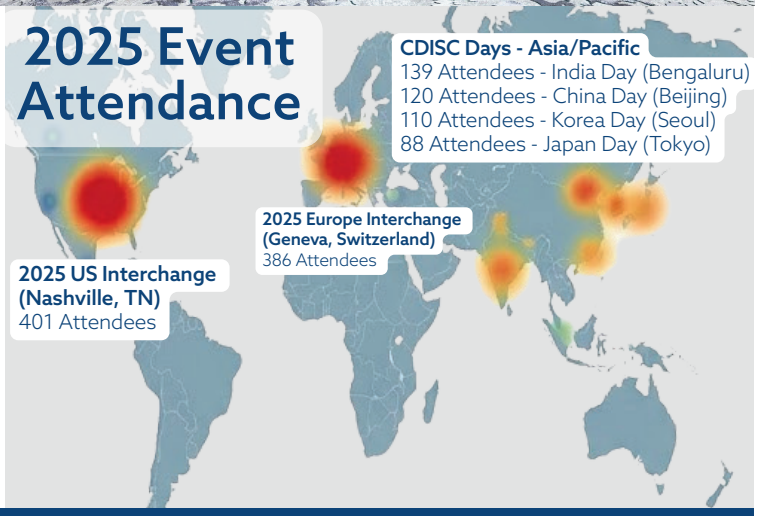
- Berber Snoeijer
- Bhavin Busa
- Carlo Radovsky
- Dagmar Kottig-Roth
- Els Janssens
- Linda Lander
- Richard Marshall
- Todd Georgieff

EVENTS

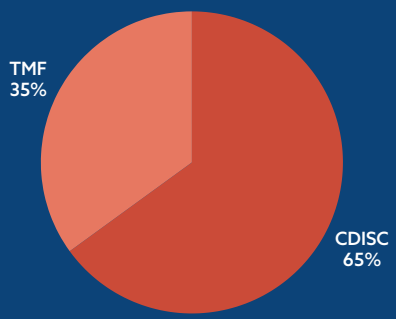
CDISC Events brought together innovators, experts, partners, and community members from across clinical research. CDISC Events are more than meetings; they are dynamic hubs where connection sparks ideas and collaborations to accelerate the transformation of data into meaningful health outcomes.

We welcomed 1,400+ attendees across our 7 global events. These attendees represented a range of professional levels and clinical research industry sectors. This diverse attendee base reflects our ability to engage leaders and practitioners alike, fostering meaningful dialogue and collaboration across all levels of the industry.

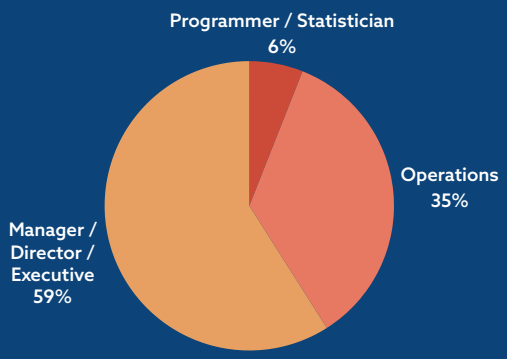
2025 Event Attendance



Attendee Interest Areas



Attendee Roles



2025 EVENT SPONSORS

Diamond + Ruby

ORACLE
Domino
cencora PharmaLex
凯莱英临床(凯诺) Asymchem Clinical (Clin-nov)
PINNACLE 21
sas
TCS TATA CONSULTANCY SERVICES
IQVIA TECHNOLOGIES
caidya
Just in Time GCP
康龙化成 PHARMARON

Sapphire + Emerald

CLUPEA Accelerating Clinical Trials
CRScube Clinical Research Solutions
JNPMEDI
LSK Global PS
inSeption GROUP
ClinChoice
BASE LIFE SCIENCE An Infosys company
PHLEXGLOBAL A PHARMALEX Company
inno.N
rednucleus
eNNOV Software for Life
INTEGO CLINICAL

Exhibitors

montrium
Arkivum
EGNYTE
CLYMB CLINICAL
TRANSPERFECT LIFE SCIENCES
PHARMASEAL
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EPHICACY
Zifo
Uppsala Monitoring Centre
EDETEK LIFE SCIENCE
nurocor
TCS TATA CONSULTANCY SERVICES
cdisc
Veeva
CMIC
phuse
CONNECT
NNIT
formedix
Cytel
BioForum
main analytics
OCS LIFE SCIENCES
PHLEXGLOBAL A PHARMALEX Company
EPISTA LIFE SCIENCES
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PINNACLE 21
Pharma SUG
Just in Time GCP
凯莱英临床(凯诺) Asymchem Clinical (Clin-nov)
IQVIA TECHNOLOGIES
caidya
ORACLE
康龙化成 PHARMARON
CLUPEA Accelerating Clinical Trials
CRScube Clinical Research Solutions
JNPMEDI
SGS
LSK Global PS
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ClinChoice
sas
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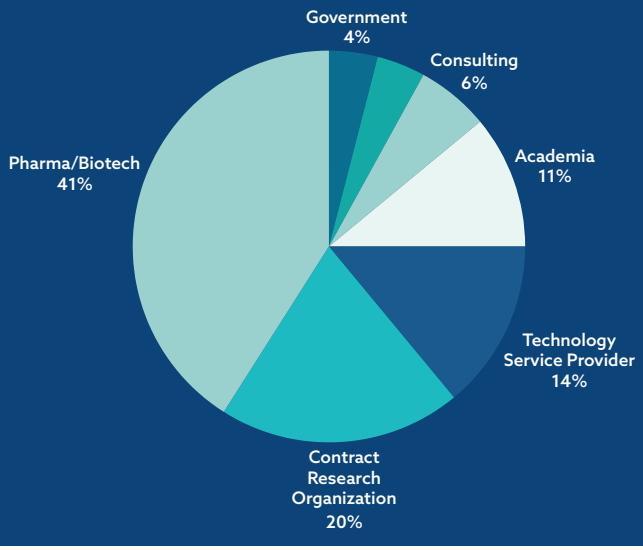
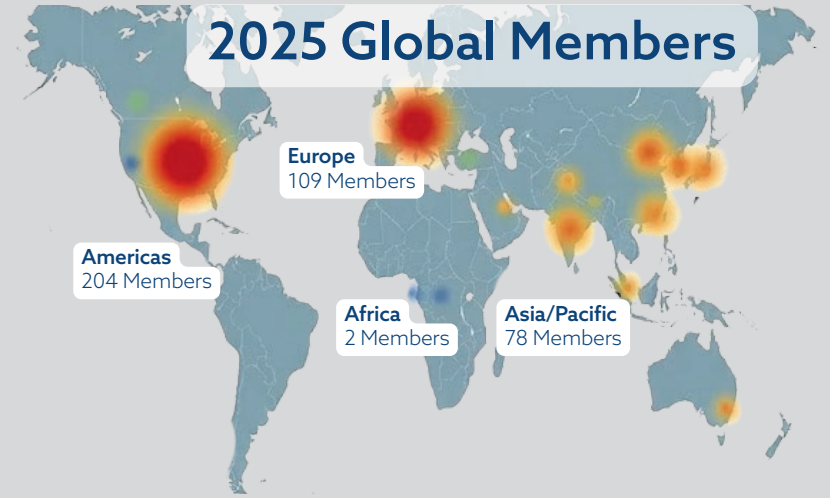
inno.N
Sycamore Informatics
rednucleus
eNNOV Software for Life
INTEGO CLINICAL

Attendee Industry Sectors

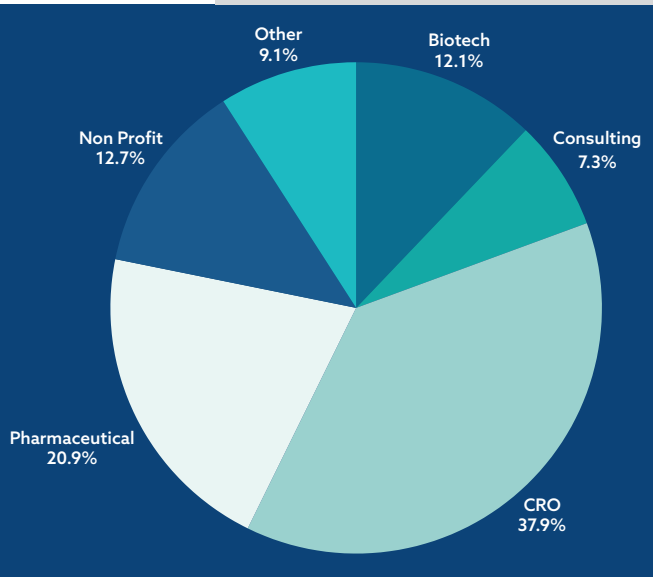


MEMBERSHIP

CDISC's 390+ member organizations span 30 countries, networking and helping shape emerging research standards and tools. Member companies range from Pharmaceutical and Biotechnology companies, Government Regulators, CROs, Technology Service Providers, Clinical Laboratories, Medical Device companies, and increasingly Academia and Healthcare Providers. CDISC membership sustains current standards and tools while investing in future innovation.



Member Industry Sectors



PLATINUM MEMBERS

Abbott
AbbVie
Agios Pharmaceuticals
Alcon (Biometrics)
Alnylam Pharmaceuticals
American Thrombosis and Hemostasis Network
Amgen
Arcus Biosciences
argenx BV
Asahi Kasei Pharma Corporation
Astellas Pharma, Inc.
AstraZeneca AB
Baxter Healthcare Corporation
Bayer HealthCare Pharmaceuticals, Inc.
BeOne Medicines
Bioforum Ltd.
Biogen, Inc.
Blueprint Medicines Corporation
Boehringer Ingelheim Pharmaceuticals
Bristol Myers Squibb
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
Cooperative Studies Program, U. S. Department of Veterans Affairs
Critical Path Institute
Daiichi Sankyo
Danone Nutricia Research
Data4Knowledge
Digital Infuzion
eClinical Solutions, LLC
EDETEK, Inc.
Eisai, Inc.
Eli Lilly and Company
Enovalife
Epista Life Sciences
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
inSeption Group
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
Moderna Therapeutics
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
Otsuka Pharmaceutical Development and Commercialization, Inc.
Pacira Biosciences
PAREXEL
Pfizer, Inc.
Pharmaceuticals & Medical Devices Agency
Pinnacle 21 By Certara
PointCross Life Sciences
Population Health Research Institute
PPD
Premier Research Group
PROMETRIKA, LLC
Regeneron
Sanofi
SAS
Servier
SGS
Shanghai Ruiyida Life Technology Co., Ltd.
Shionogi & Co., Ltd
Syneos Health Inc.
Takeda Pharmaceutical Company Limited
TCS Life Sciences ADD
The Helmsley Charitable Trust
Theravance Biopharma US, LLC
TransPerfect Life Sciences
UCB Biosciences, Inc.
University of Southampton Clinical Informatics Research Unit
Vertex Pharmaceuticals

GOLD MEMBERS

A2 Healthcare Corporation
AB Cube Germany GmbH
aCROnordic
Acumen Information & Technology Co., Ltd.
AdClin
Advanced Clinical
AI Lens
Akebia Therapeutics
Alcedis GmbH
Alimentiv, Inc.
AliraHealth
ALK-Abello A/S
Alkermes
Almirall, S.A.
AlphaLife Sciences
Altair
Altasciences Company Inc.
Alvotech Swiss AG
Amphastar Pharmaceuticals Inc
Arcellx
Ark Medical Solutions, Inc.
Arkivum
Arslan Munir
Arvinas
Assign Data Management and Biostatistics GmbH
Association of Clinical Research Organizations
Asymchem Clinical
Atorus Research
Avenzo Therapeutics
Avidity Biosciences
Basilea Pharmaceutica International Ltd.
BC Platforms AB
Beijing BioVoice Technology Co., Ltd.
Beijing Data Science Express Consulting Co., Ltd
Bethesdasoft
BioCytics
Bioinformatico (Pty) LTD
BioMarin Pharmaceutical Inc.
BioStata ApS
Biotrial Biometrics
Bloqcube
Bollinside Programming Services
C&R Research
Calian
Canadian Center for Vaccinology
Capish Nordic AB
Care Access
CDISC
Celerion
Center of Excellence for Biomedical and Public Health Informatics
Chungbuk National University Hospital Osong Clinical Trial Center
ClinDART, Inc.
Clinical Trial Service (Guangzhou) Co., Ltd
Clinical Trials Statistical and Data Management Center - University of Iowa
CliniOps, Inc.
ClinSearch
Clinvia
CLUPEA, Inc.
Clymb Clinical
CMIC Holdings Co. Ltd.
COG Research Foundation, LLC
Cogent Biosciences
Cogitars GmbH
Cognitive Research Corporation
Corcept Therapeutics
Cota Enterprises, Inc.
CPC Clinical Research
CRC Pharma
CRISALIS
CRISPR Therapeutics
Cross Research SA
CRS Clinical Research Services Mannheim GmbH
CRScube Inc.
CSL Behring
Curadel
Cytel
Dacima Software Inc
Daegu Catholic University Medical Center
Data Santander, SL
Data Standards Decisions Aps
DATAMAP GmbH
DF/Net Research, Inc.
DIcore Group, LLC
DNDi
Droice Labs
DT&CRO
EA Pharma Co., Ltd.
Edgerton Data Consulting, LLC.
Edwards Lifesciences LLC
Elderbrook Solutions GmbH
Eliassen Group
Ellen Stewart
EMB Statistical Solutions, LLC
Emergent Biosolutions
Ennov SAS
Entimo AG
Ephicacy Consulting Group, Inc.
EPS Corporation
Ergomed Group
Estimondo GmbH
etera solutions
ethica CRO
Eurofins bioskin GmbH
Everest Clinical Research Corporation
Evestia Clinical
Evotec / Aptuit
Exelixis
eXYSTAT
Faeth Therapeutics
Faro Health Inc.
Fast-Track Drugs & Biologics, LLC
Ferring Pharmaceuticals
Fiverings Co., Ltd.
Foundation for Biomedical Research and Innovation at Kobe
Fred Hutchinson Cancer Research Center
Frontier Science Foundation
Frontier Science Scotland
GCP-Service International Ltd. & Co. KG
GEM Programming Solutions Ltd.
Genmab A/S
Gossamer Bio
Grunenthal GmbH
Guangdong Provincial Hospital of Chinese Medicine
Hexal AG
HumanTrue
ICRC-Weyer GmbH
InClin, Inc.
Inductive Quotient Analytics India Pvt Ltd.
Inference Inc.
Inferential Premium Biometry
Insight Clinical Consulting, LLC
Instem LSS
Institut de Recherche Pierre Fabre
Institut Paoli-Calmettes
Institute of Health Data Infrastructure for All
Intego Clinical
Intellia Therapeutics, Inc.
IPSEN Innovation
JMP Clinical
JSS Medical Research
Just In Time GCP
Kapadi
KCT Data, Inc.
Kestrel Standards
Keyrus Biopharma
Kiniksa Pharmaceuticals
Korea Institute of Toxicology
Kyoto University Hospital
Kyowa Kirin Co., Ltd
Kyushu University Hospital
Labcorp
Lantheus Holdings
Leap Therapeutics
LFB Biotechnologies
Liaoning Yeedo Medical Data Technology Co., Ltd.
Lindus Health
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
Mediqual-Sprl
MEDISCIENCE PLANNING, Inc.
Meditrial USA Inc.
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
Nanumspace
Narrativa
National Cancer Center East - Japan
National Institute of Public Health
NBCD A/S
Nestlé Research and Development
NHO Nagoya Medical Center
Nippon Shinyaku Co., Ltd.
NORD
N-Power Medicine, Inc.
NRG Oncology Foundation
Nubilaria Srl
OCS Life Sciences
Omeros Corporation
Openclinica, LLC
Orion
OXMO CDM
Pentara Corporation
Pharma Medica Research Inc.
Pharmaron (US) Clinical Services, Inc.
PHARMASEAL International Limited
PharmaStat LLC
Philip Morris Products SA
Plus-Project
PMV Pharmaceuticals
Poseida Therapeutics
Prevail Infoworks
Profil Institut fuer Stoffwechselforschung
ProSum Consulting
PSI CRO AG
Puma Biotechnology, Inc.
Q-Square Business Intelligence, Corp.
Quanticate International Ltd
Quantics Consulting Ltd.
Quotient Sciences
Rakuten Medical
RCTs
REDCap Cloud
REGENXBIO
Relay Therapeutics
Resolutum Global
Revolution Medicines
Rho, Inc.
Rocket Pharmaceuticals
SafeSoft
Sage Therapeutics
SanaClis s.r.o.
Sarepta Therapeutics, Inc.
SCiAN Services Inc.
Scientific Toolbox Consulting
SCRI Development Innovations (SCDI)
SCSK Corporation
S-cubed Biometrics Ltd
Senju Pharmaceutical Co., Ltd.
Seoul National University Hospital
Seriant
Shanghai Henlius Biotech, Inc
Siemens-Healthineers
Signifikans Aps
Simple Trials
Soladis Clinical Studies
StatGPT LLC
StatisticaMedica
Statistics and Data Corporation
Sycamore Informatics
SymBio Pharmaceuticals Limited
Synovah Healthtech Private Limited
Systex, Inc
Taisho Pharmaceutical Co., Ltd.
Takumi Information Technology Inc.
TELEMEDICINE TECHNOLOGIES S.A.S
Test
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 Data Pharmaceutical Technology (Shanghai) Co., Ltd.
Trialwise
T-TOP Clinical Research Co., Ltd.
Union Laiya (Shanghai) Data Technology Co., Ltd.
United BioSource Corporation
University Hospital Medical Information Network
University of Alabama at Birmingham
University of Leipzig
University of Oxford
Uppsala Monitoring Centre
US Army MRMC
Vanderbilt University Medical Center (VUMC)
Vanguard Clinical
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
Xiyuan Hospital of China Academy of Chinese Medical Sciences
XML4 Pharma
Y-mAbs Therapeutics A/S
YPrime
Yseop
Zai Laboratory
Zifo RnD Solutions

VOLUNTEERS

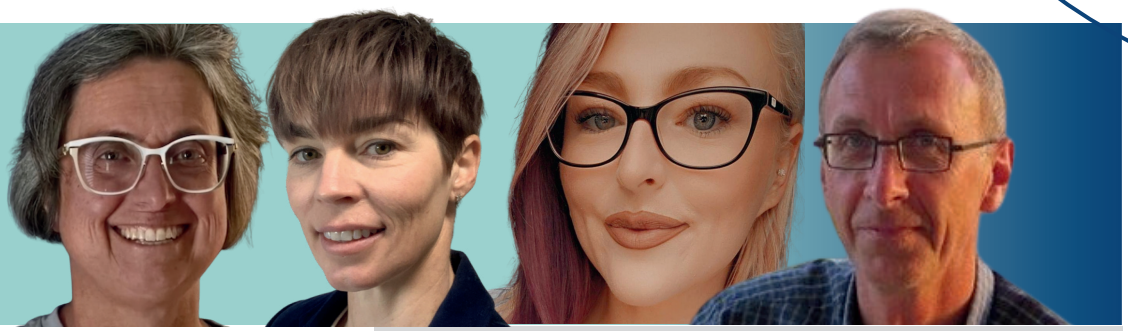
Volunteer Spotlights

Tatiana Sotingco
Associate Director
Johnson & Johnson

Jennie Walker
Statistical Programmer II
Novotech

Chloe Bosworth
SEND Specialist
Inotiv

Dr. Guido Claes



CDISC harnesses the vision and insights of each volunteer to define a focused approach for capturing and analyzing clinical research data. When the entire research community works together, we have the power to solve issues too complex for any one individual, team, or organization to address alone.

CDISC honors the memory of Dr. Guido Claes, who joined the CDISC Glossary Group in 2017 and quickly became an invaluable contributor.

A Belgian physician and longtime leader in Master Data Management, he brought deep medical, clinical, and semantic expertise to our work. His thoughtful guidance shaped our approach to defining critical clinical research terms, including the development of our "cluster" methodology.

Guido's wisdom, kindness, and gentle humor enriched every discussion, and his dedication continued well into his retirement. We are grateful for his many contributions and celebrate his lasting impact on the CDISC community.

"You develop a deeper knowledge of the intent behind the standards and gain the opportunity to influence future development."

-Tatiana Sotingco

New Volunteers	Active Volunteers	Volunteers Per Month	360i Volunteers
600+	1,100+	50+	93

PARTNERSHIPS

Our impact is multiplied through strong global collaboration, as partnerships with regulatory agencies, academic institutions, industry leaders, and patient advocates enable us to advance interoperable data standards across therapeutic areas. Together, we create greater clarity, empower more meaningful research, and build the connected future of clinical research - one where aligned standards drive interoperability across trials, regions, and markets, amplifying our shared impact on global health.

ICH
harmonisation for better health

In partnership with TransCelerate, CDISC collaborated with ICH to align the CDISC Unified Study Definition Model (USDM) with the newly adopted ICH M11 Guideline, ensuring a globally harmonized, machine-readable structure for clinical trial protocols. This partnership also includes CDISC's role in maintaining and governing M11 controlled terminology, supporting transparency, interoperability, and consistent global implementation.

MDIC
Medical Device
Innovation Consortium

Our partnership with MDIC advances interoperability and regulatory efficiency in the in vitro diagnostics (IVD) space through standardized, harmonized data that supports innovation, data reuse, AI-enabled insights, and improved patient outcomes globally.

TransCelerate BIOPHARMA INC.

Continued collaboration with TransCelerate advanced both USDM and DDF, driving greater efficiency and interoperability in clinical research. We have strengthened the development of structured, machine-readable study definitions, enabling smoother data exchange, reducing redundancy, and supporting faster, higher-quality delivery of therapies worldwide.

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Multi-year collaboration with the MRCT Center and Vivli advances the development of new Controlled Terminologies aligned with MRCT's Plain Language Glossary, strengthening clear, consistent, and patient-centered communication in clinical research.

phuse

Ongoing collaboration with PHUSE advances the adoption and application of global data standards through thought leadership, joint workshops, and shared resources to improve the use of CDISC Standards across the clinical research community.

SCDM

Continued partnership with SCDM strengthens the clinical data management community's understanding and application of global data standards. Through shared thought leadership and conference engagement, CDISC and SCDM work together to advance high-quality, standards-driven data practices across the clinical research lifecycle.

What we do

In the ever-evolving and complex clinical research landscape, CDISC provides critical clarity through the individual contributions and collective power to amplify data's impact.

Why we do it

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

How we do it

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

cdisc®

Annual Report 2025
The Future Is Connected