COISC 2024 Impact Summary





Amplify Data's Impact to Advance Research

CDISC MISSION

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

Amplifying Data's Impact in 2024 With...

93 eCRFs

4-61 Biomedical Concepts

439 SDTM Dataset Specializations Analysis Results Standard v1.0 Biomedical Concepts Browser Dataset-JSON v1.1 Define-XML v2.1.7 USDM v3.0 eTLF Portal Observational Studies Guide v1.0 OAK v1.0 Rare Diseases Therapeutic User Guide

> SDTM v2.1 SOGI eCRF Tobacco Implementation Guide v1.0

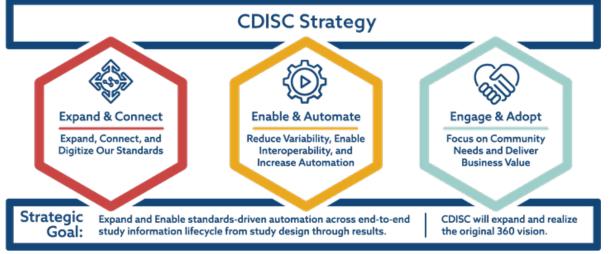
QRS Supplements

861 QRS Terminologies

1,961 Add'l Terminologies Including TMF

CDISC Strategic Roadmap Pillars & Objectives

Expanding Standards, Enabling Automation, and Engaging the Community









Leadership CDISC Welcomes New CEO

CDISC is proud to welcome Chris Decker as our new President and CEO. With over 20 years of experience in clinical research, technology, and standards, Chris has been a long-time supporter of CDISC, serving as a volunteer, implementer, and former Board member.

His deep industry expertise and passion for innovation make him uniquely qualified to lead CDISC into its next chapter. Under Chris's leadership, we look forward to expanding the breadth and depth of our work, advancing digital transformation, and driving meaningful progress in clinical research worldwide.

Implementing 360i:

From Proof of Concept to Implementation



Building on the success of initiatives like CDISC 360, we are now preparing to embark on the next phase with 360i, the implementation of the 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 analysis, equipping stakeholders with innovative tools and methodologies that enable automation, minimize variability, and elevate data quality.

CDISC Membership

Membership in CDISC represents nearly 500 organizations dedicated in advancing global clinical data standards. Our members' collaboration drives transformation, enabling innovation and impact across the clinical research ecosystem.

Together, Members play a critical part in amplifying the value of data for all our stakeholders worldwide.



<u>Partnerships</u>



Ongoing collaboration with TransCelerate to drive digital protocol standards that enhance research efficiency and interoperability

Initiated research collaboration to incorporate FDA Business Rules into CDISC's Open Rules Engine (CORE)





Partnered with Uppsala Monitoring Centre to improve interoperability of CDISC Standards and WHODrug Global

Advancing harmonized clinical protocols through and ICH M11 and Vulcan collaboration





Developed Tobacco Implementation Guide v1.0 in partnership with the U.S. Food and Drug Administration Center for Tobacco Products (FDA CTP)

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



Thank You to All Our Volunteers

We are deeply grateful to all the incredible volunteers who dedicated their time, expertise, and passion to advancing CDISC's mission in 2024.

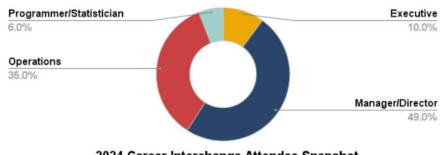
Your contributions are the backbone of our efforts to develop and promote global data standards, ensuring they benefit the entire clinical research community. Whether through creating impactful training, supporting standards development, or fostering collaboration, your efforts inspire and drive progress.



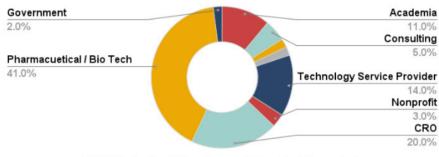


CDISC & TMF Events Highlights

We welcomed over 1,300 attendees in 5 countries at 7 CDISC Events in 2024, representing a range of professional levels and clinical research industry sectors.



2024 Career Interchange Attendee Snapshot



2024 Industry Interchange Attendee Snapshot

It was truly invigorating to witness the flourishing state of biotechnologies and pharmaceuticals. The presentations and discussions highlighted not only the current advancements but also the evolving needs and demands within the industry.



Education Highlights

10

New Education Trainings Launched

Co-hosted or collaborative training events held

31+ hrs

On-demand and Instructor-led Training Material Published

In-Person Training Events Held

The instructor was highly knowledgeable about the subject and did speak with a clear and easy tense. I really appreciated concrete real job experience examples coming from instructor. Also, quite a lot of rationale have been provided on why standards is done the way it is done.