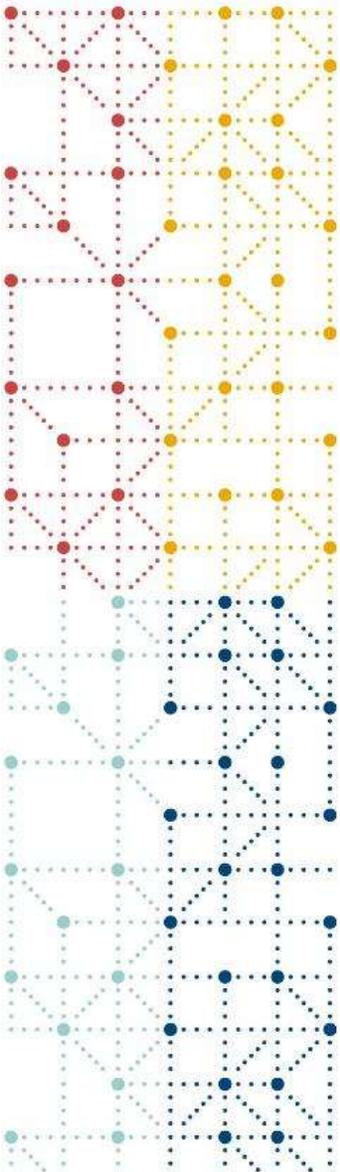


Leveraging AI with CDISC USDM to Drive Innovation : Readout from CDISC AI Challenge

Julie Smiley, CIO, CDISC

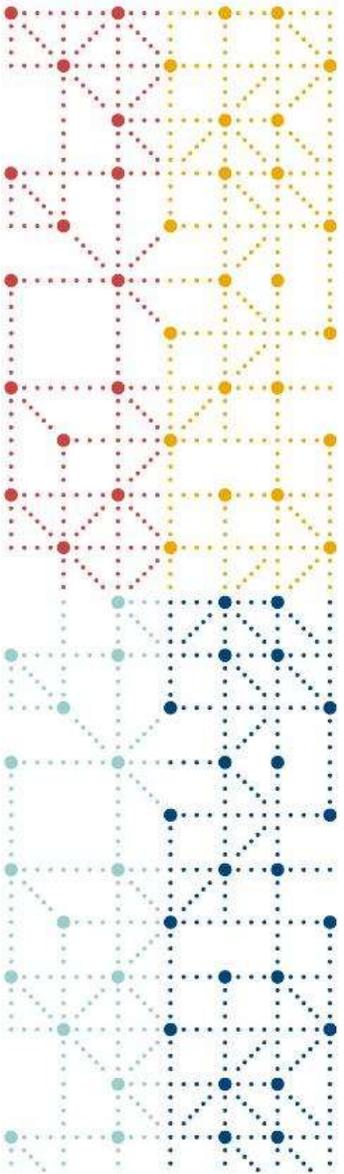
February 10, 2026





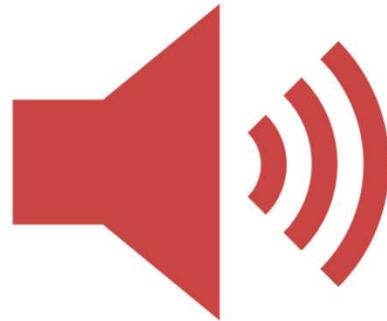
Agenda

1. Digital Data Flow Overview and How AI Can Accelerate the Work
2. Summary of the AI Protocol Challenge and Lessons Learned
3. Faro demonstration
4. Zifo Presentation
5. Q&A



Housekeeping

Housekeeping



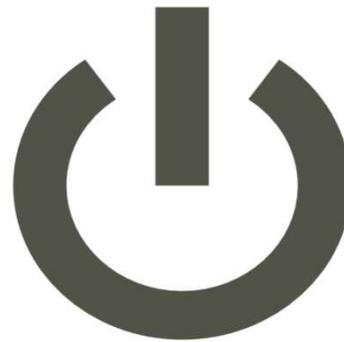
You will remain on **mute**

Housekeeping



Submit questions at any time via the Q&A section on your Teams app

Housekeeping



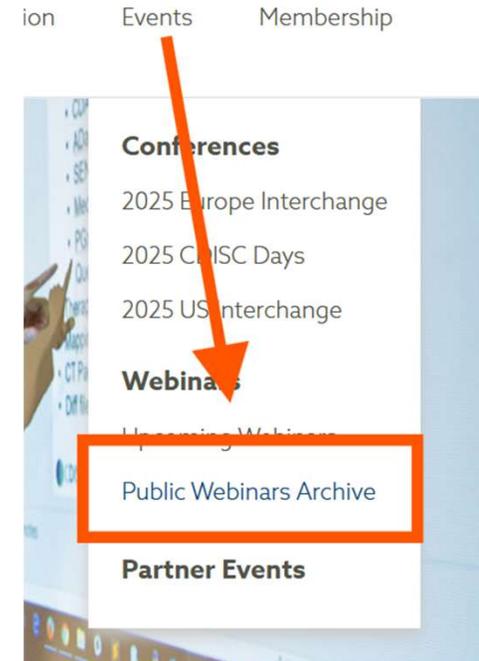
Audio Issues?

First, close and restart your Teams App
Second, check your local internet connection strength

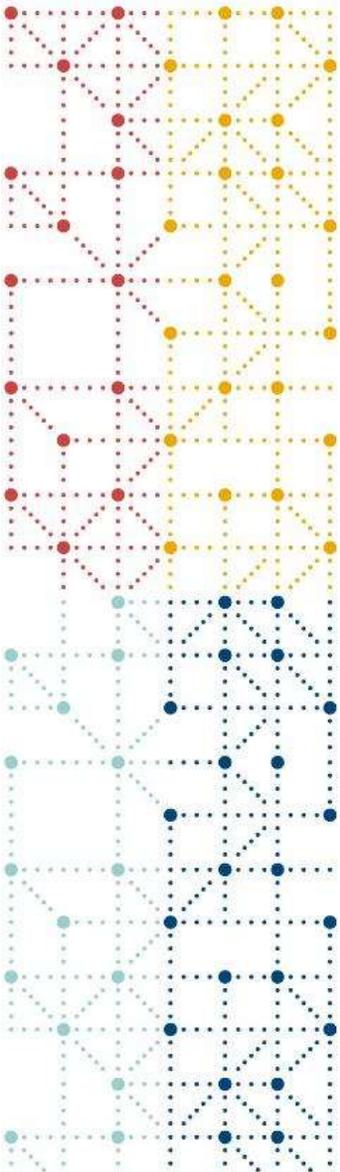
Housekeeping



Webinar Recording



A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.



Meet the Speakers



Julie Smiley

Title: Chief Information Officer

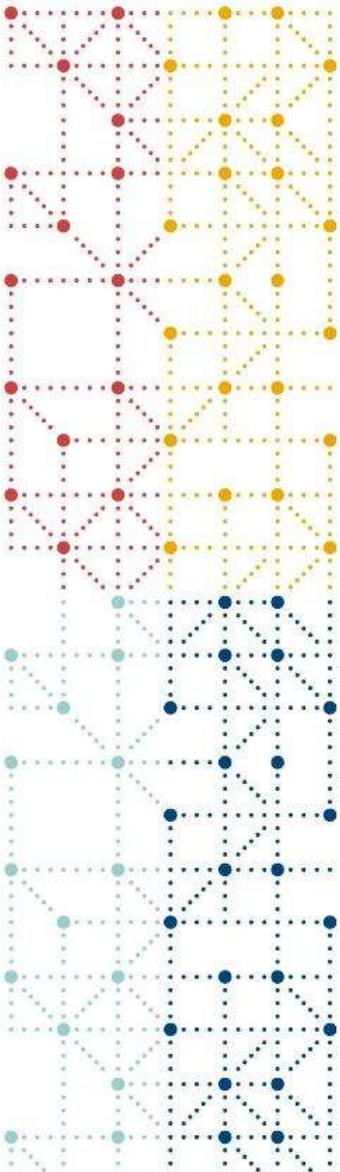
Organization: CDISC



William "Bill" Illis

Title: Executive Director, Technology & Scientific Computing, Drug Development

Organization: Novartis



Meet the Speakers



Maxine Chan

Title: Head of Product

Organization: Faro Health Inc.



Deepak Ananthan

Title: Vice President, Service Delivery

Organization: Zifo RnD Solutions



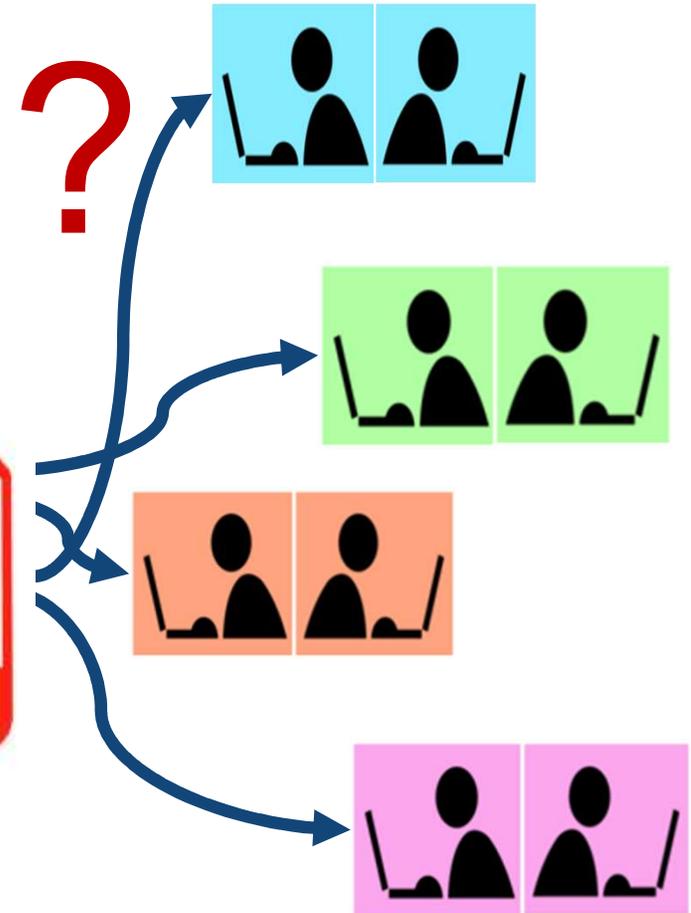
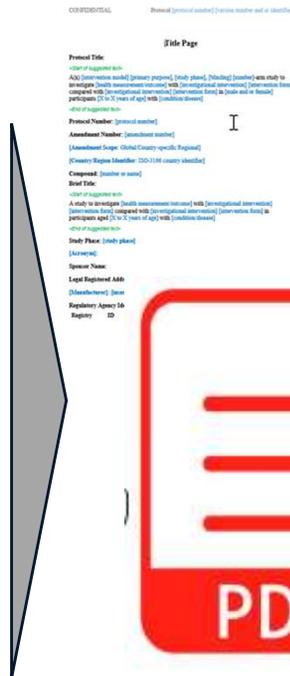
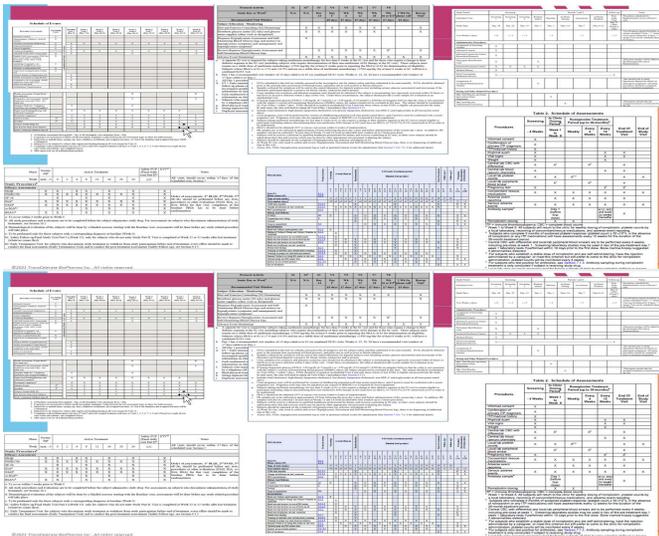
Digital Data Flow Overview How AI and Standards Can Partner to Enable Study Design

William Illis

Novartis & TransCelerate



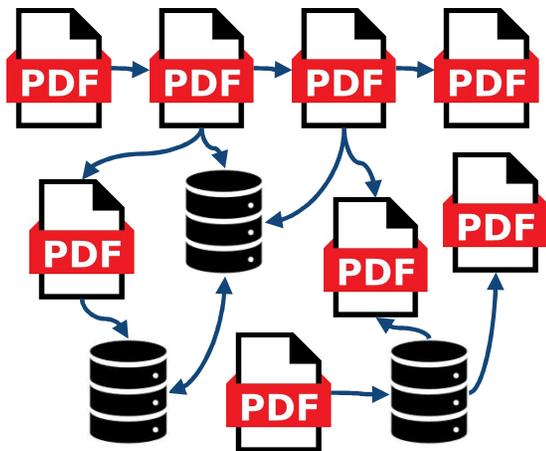
Clinical Study Protocols Broken...



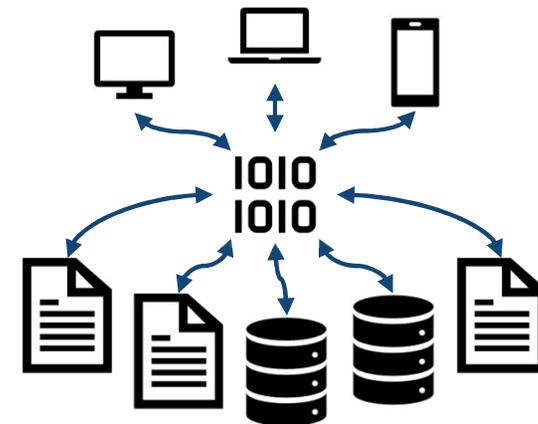
Why Digital Data Flow? – The Vision

Break the Document Paradigm

From document-first



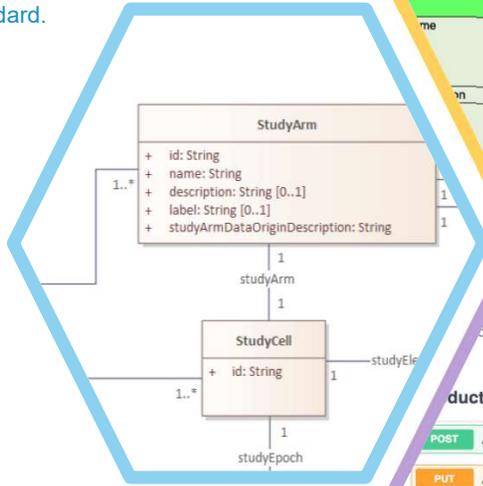
To data-first



The USDM Standard

Logical Model

The UML logical model (a class diagram) that provides the basis for the USDM standard.



API Specification

Provides the means to exchange a single study between machines using a JSON API

CDISC Controlled Terminology

Provides further semantics, complementing the UML model. Includes the definition of classes, attributes, and value sets

	C174447	Study Arm
	C170984	Study Arm Name
	C93728	Study Arm Description
	C188827	Study Arm Type
dataOriginDescription	C188828	Study Arm Data Origin Description
dataOriginType	C188829	Study Arm Data Origin Type
label	CNEW	Study Arm Label
studyEpoch	C71738	Study Epoch
name	C93825	Study Epoch Name
description	C93824	Study Epoch Description
type	C188830	Study Epoch Type
label	CNEW	Study Epoch Label

CORE Rules

Specification of the rules that define USDM compliance

Rule ID	Warning/ Error	Entity	Applies
1	ERROR	All	All
2	ERROR	All	All
3	ERROR	All	All
4	ERROR	All	All
5	ERROR	All	All
6	ERROR	All	All
7	ERROR	All	All
8	ERROR	All	All
9	ERROR	All	All
10	ERROR	All	All
11	ERROR	All	All
12	ERROR	All	All
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100	ERROR	All	All

API for DDF

Celerate Digital Data Flow (DDF) Study Definitions Repository API.

Introduction Routes that form the production specification.

POST	/v3/studyDefinitions	Create a study
PUT	/v3/studyDefinitions/{studyId}	Update a study
GET	/v3/studyDefinitions/{studyId}	Return a study
GET	/v3/studyDefinitions/{studyId}/history	Returns the study history
POST	/v3/studyDesigns	Study designs for a study

Implementation Guide

Guidance on using the USDM model and ensuring conformance with the standard

Examples

Example protocols implemented in the USDM with associated JSON files and visualisations

```

studyArms: [
  {
    "id": "StudyArm_1",
    "name": "Placebo",
    "label": "",
    "description": "Placebo",
    "type": {
      "id": "Code_61",
      "code": "C174268",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Placebo Comparator Arm"
    }
  },
  {
    "studyArmDataOriginDescription": "Data collected within study",
    "dataOriginType": {
      "id": "Code_62",
      "code": "C188866",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Data Generated Within Study"
    }
  },
  {
    "id": "StudyArm_2",
    "name": "Xanomeline Low Dose",
    "label": "",
    "description": "Active Substance",
    "type": {
      "id": "Code_63",
      "code": "C174267",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Xanomeline Comparator Arm"
    }
  }
]
  
```

on 2.0 Draft for Internal Review)

Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 2.0 (Draft for Internal Review)

Prepared by the DDF Team

Notes to Readers

- This is the draft version 2.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v2.0). It is intended for Internal Review only and is not a final version.

History

Version	Notes
2.0 Draft for Internal Review	

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Digital Data Flow Progress and Plans

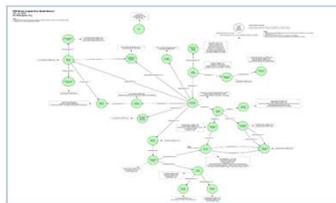


2025

2026



USDM 4.0



Model Updates USDM 4.1



Study Definition Repository



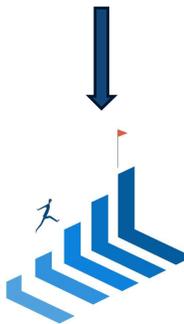
Executable Conformance Rules



USDM Extensions Registry



Adoption Stories



More Adoption Stories



Use Case Library



Use Case Handbooks



Solution Collaboration Forum and Showcase Webinar Series & Challenge Events

Overall Goals for Governance

Category	Conform/Maintain Standards	Enable/Platform's Tech	Enable Customisation	Enable Community
Purpose	Enable and maintain CDISC's USDM Reference Architecture (RA) USDM 4.0, CDISC's Controlled Terminology and Implementation Guide to ensure interoperability and consistency with the USDM Reference Architecture.	Enable and maintain CDISC's USDM Reference Architecture (RA) USDM 4.0, CDISC's Controlled Terminology and Implementation Guide to ensure interoperability and consistency with the USDM Reference Architecture.	Provide a mechanism for sponsors, CROs, tech vendors and others to demonstrate a fully conformant production use case to the USDM Reference Architecture, for ability to bring on-plate.	Secure, activate & create ongoing support to the community, collectively support the future success of USDM assets and standards.
Relevance/Timing	Relevant during full lifecycle of standard use.	Relevant during early to mid stages of adoption across ecosystem.	Relevant during full lifecycle of standard use.	Relevant during full lifecycle of standard use.

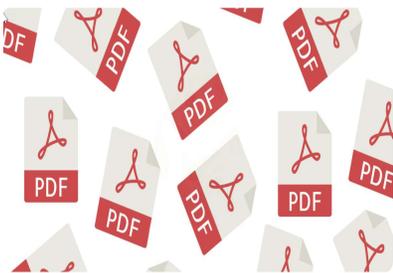
Design, Goals & Capabilities



USDM Governance Group DDF Advisory Board



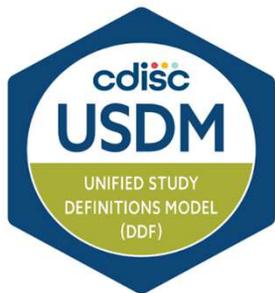
Better Data, Better AI



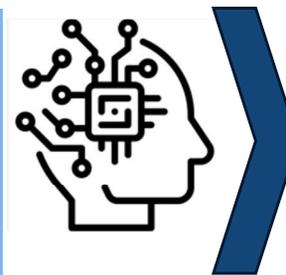
Unstructured, free text
Inconsistent naming
One-off interpretations
Missing information



- Plausible Inferences
- AI Assistants
- Helpful, sometimes impressive
- Limited, sometimes wrong
- Incremental gains



Structured objects
Defined relationships
Controlled terminology
Machine readable

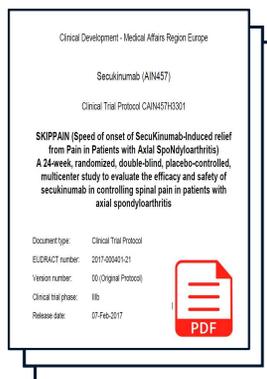


- Trusted outcomes that can be explained and defended
- Improved performance, accuracy and reliability
- Transformational gains

Using AI to Produce USDM Protocol Outputs



+



```
{  
  "protocolDefinition": {  
    "id": "PROT-123",  
    "studyTitle": "A Phase 2 Study of X in  
Patients with Y",  
    "epochs": [  
      {  
        "id": "Screening",  
        "type": "Screening"  
      },  
      {  
        "id": "Treatment",  
        "type": "Treatment"  
      }  
    ],  
    "scheduleOfActivities": {  
      "timepoints": [  
        { "id": "V1", "description": "Day 1" },  
        { "id": "V2", "description": "Week 4" }  
      ],  
      "activities": [  
        { "id": "ACT1", "name": "Vital Signs" },  
        { "id": "ACT2", "name": "Blood Draw" }  
      ],  
      "scheduledActivityInstances": [  
        { "timepoint": "V1", "activity": "ACT1"  
        },  
        { "timepoint": "V1", "activity": "ACT2"  
        }  
      ]  
    }  
  }  
}
```



USDM + AI: Study Design and Execution Examples

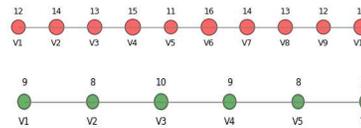
```

{
  "protocolDefinition": {
    "id": "PROT-123",
    "subTitle": "A Phase 2 Study of X in Patients with Y",
    "epochs": [
      {
        "id": "Screening",
        "type": "Screening",
        "activities": [
          {
            "id": "Treatment",
            "type": "Treatment"
          }
        ]
      },
      {
        "id": "Treatment",
        "type": "Treatment"
      }
    ],
    "scheduledActivities": [
      {
        "timepoint": [
          { "id": "M1", "description": "Day 1" },
          { "id": "M2", "description": "Week 4" }
        ],
        "activities": [
          { "id": "ACT1", "name": "Vital Signs" },
          { "id": "ACT2", "name": "Blood Draw" }
        ]
      },
      {
        "scheduledActivityInstances": [
          { "timepoint": "M1", "activity": "ACT1" },
          { "timepoint": "M1", "activity": "ACT2" }
        ]
      }
    ]
  }
}
    
```

+



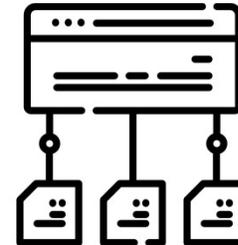
SoA Optimization



Amendment Impact



Downstream Config

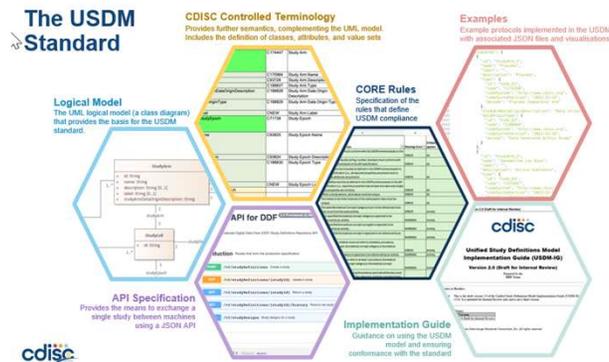


- ✓ Analyze activity density per visit
- ✓ Flag high-burden visits
- ✓ Make visit consolidation recommendations

- ✓ Identify affected activities changed visits, impacted cohorts
- ✓ Generate site-specific change lists, updated ICF language

- ✓ Translate USDM activities → EDC forms, eCOA screens
- ✓ Map USDM visits → EDC visit structure
- ✓ Alignment, Auto-configuration
- ✓ Self-assembling SDTM, ADaM, TFL's

CDISC Standards Provide Data That Is AI Ready

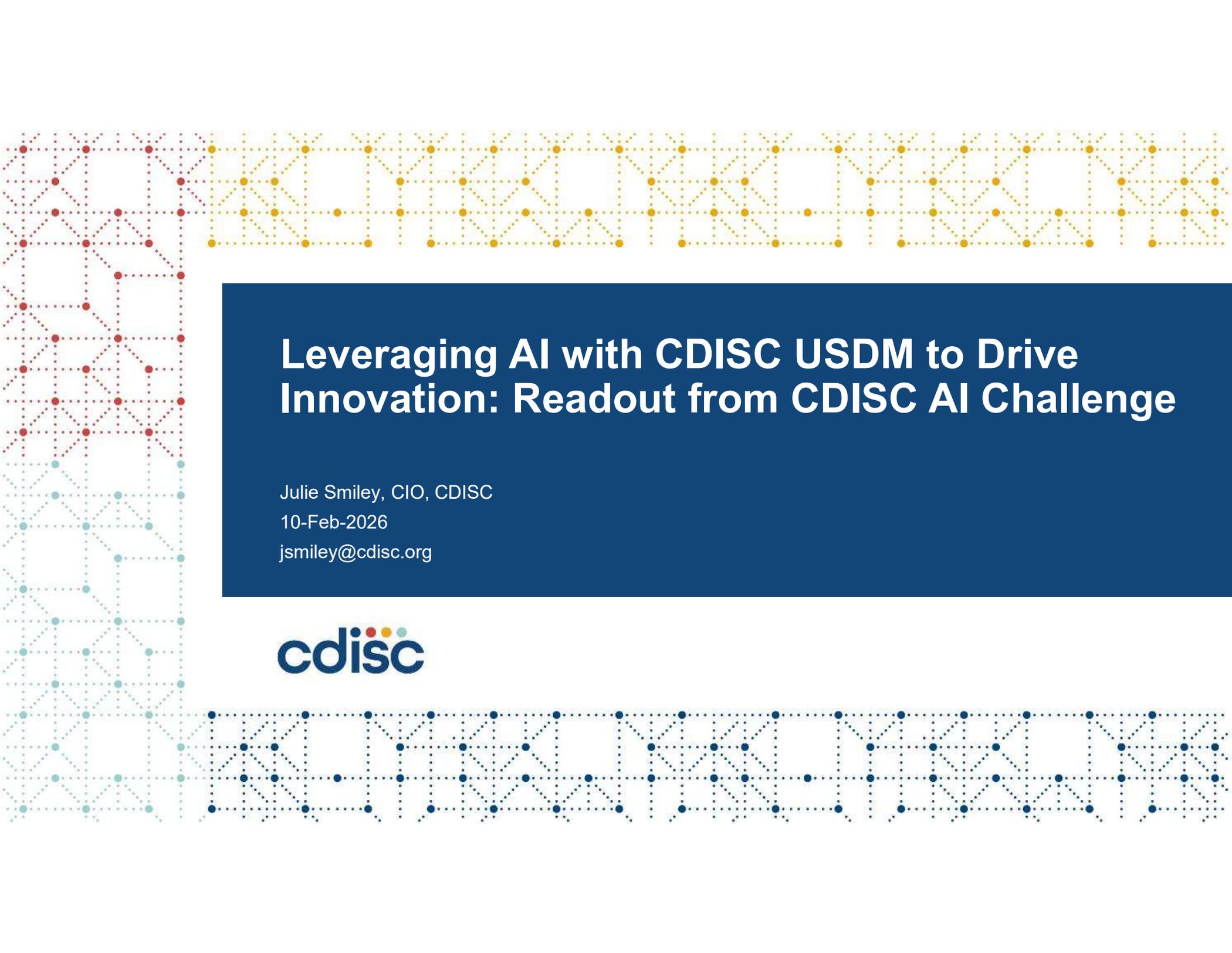


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Without USDM AI guesses

With USDM AI understands



Leveraging AI with CDISC USDM to Drive Innovation: Readout from CDISC AI Challenge

Julie Smiley, CIO, CDISC

10-Feb-2026

jsmiley@cdisc.org





Why the CDISC AI Innovation Challenge?

- Global call to apply AI/ML + CDISC standards
- Focused on implementation, not theory
- Designed to test how AI can accelerate a digital data flow, starting with USDM





Challenge Scope & Focus

- Three targeted use cases:
 - Digital Protocols (USDM)
 - Biomedical Concepts
 - Semantic Traceability
- 22 submissions from 40+ organizations
- Mix of commercial, hybrid, and open approaches





What emerged across solutions?

- Solutions were closer to production than expected
- Standards worked best when they were structured and executable
- AI helped with scale, linkage, and interpretation
- Trust, validation, and explainability mattered more than novelty

We didn't ask for these themes — they surfaced independently across solutions.



Use Case 1: Key Results

- Most popular use
- AI used to:
 - Extract legacy protocols into USDM
 - Enable search, reuse, comparison
 - Support downstream automation
- Demonstrated value beyond a digital document

Winners:

- Faro Health
- Zifo RnD Solutions



PROBLEM

Study design is manual, error prone, and time consuming and creates limited access to legacy study information



SOLUTION

USDM-centric digital library of legacy study definitions



CHALLENGE

Demonstrate AI extraction of legacy study information in USDM and interface for searching and downloading content



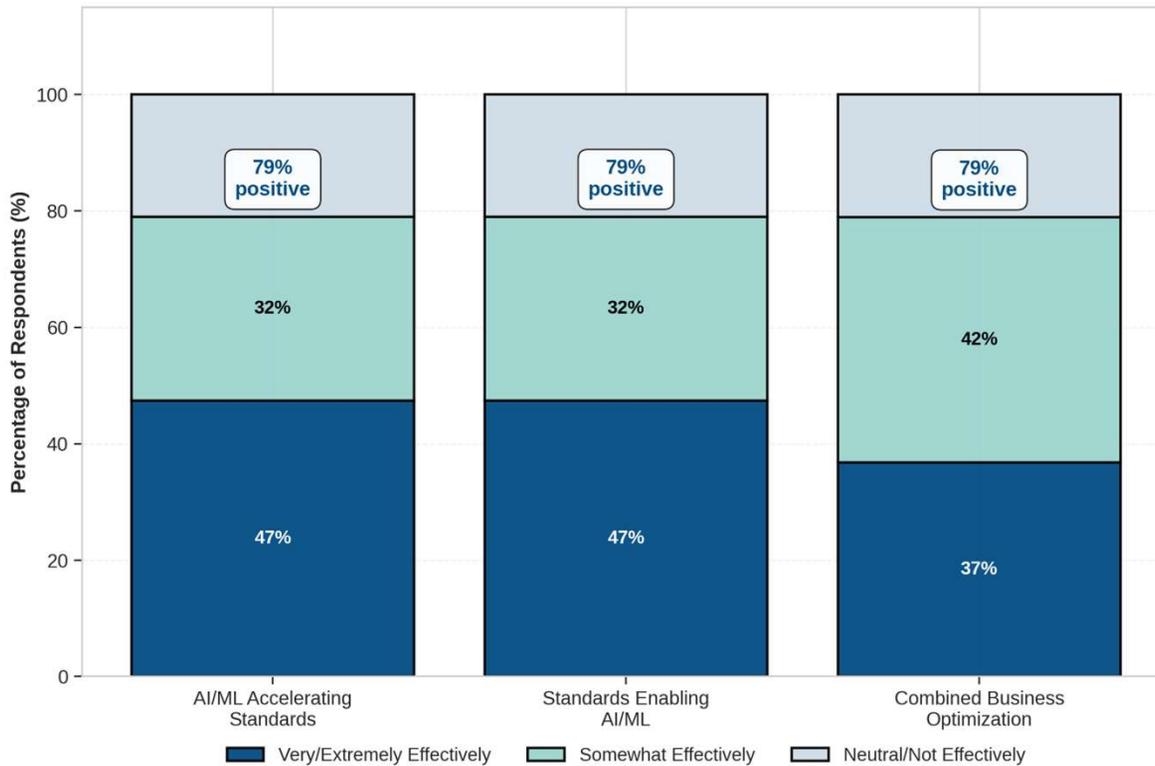
What We Learned

- Standards are no longer passive – They are AI enablers
- Digital protocols are the natural starting point for AI
- AI + standards enable end-to-end traceability (not just speed)
- Open and standards-aligned approaches drive trust and adoption
- AI can accelerate standards development (not just use them)
- The challenge validated 360i as an execution strategy





Bidirectional AI ↔ Standards Value
~80% Positive Agreement Across All Dimensions



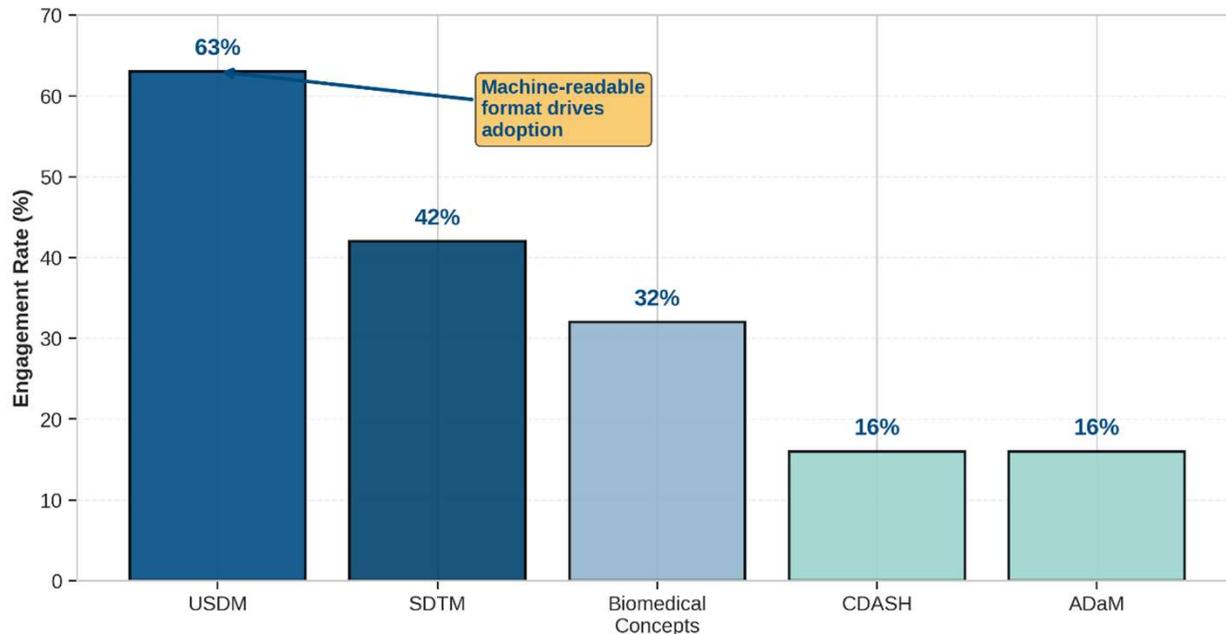
Key Finding: Symmetric ~80% positive ratings prove mutual reinforcement—not one-way dependency

Source: Post-challenge survey (n=19: 12 participants, 7 judges) | Scale: 1-5 (Very/Extremely=4-5, Somewhat=3)

AI doesn't replace standards — it amplifies them. And standards don't limit innovation — they make it scalable.”



Standards Engagement Hierarchy
Machine-readable USDM drives highest adoption



84% of solutions engaged multiple standards simultaneously — interoperability works in practice

When study design is structured, everything downstream becomes possible.



From Insight to Implementation

- Next: live demonstrations from Use Case 1 winners
- Focus on:
 - How AI works with USDM
 - What's production-ready today
 - Where value shows up in real workflows



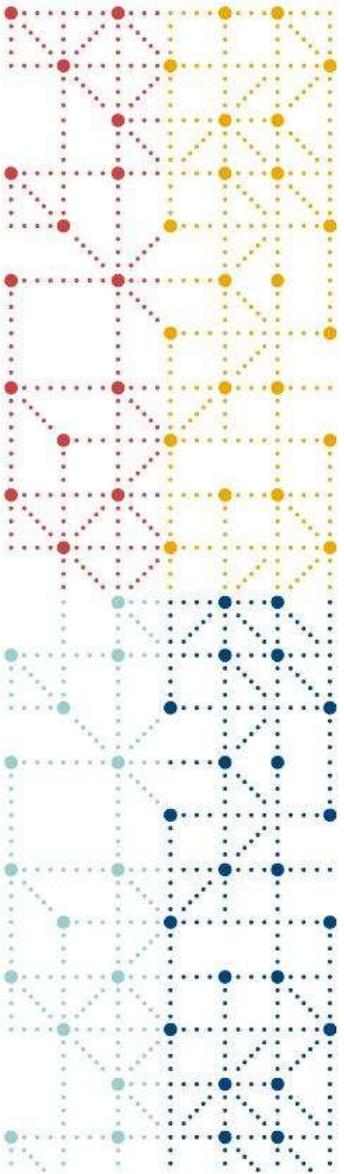


Upcoming Events

2026 Events	Date / Time	Format
PHUSE US Connect 2026 Learn more: PHUSE US Connect 2026 - Austin, Texas	22-26 March 2026	In-Person Event
Webinar: TransCelerate DDF Solution Showcase Learn more: View past solution showcases	23 April 2026 9:00 – 10:00 AM ET	Webinar
European Medical Writers Association Learn more: EMWA 2026 Conference – Barcelona, Spain	5 – 8 May 2026	In-Person Event
Digital Data Flow Mission Possible – India <i>Registration link coming soon...</i>	13 May 2026	In-Person Event
2026 CDISC Europe Interchange Learn more: 2026 Europe Interchange – Milan, Italy	20 -21 May 2026	In-Person Event
DIA – 2026 Global Annual Meeting Learn more: DIA Global 2026 - Philadelphia, PA	14 – 18 June 2026	In-Person Event
Digital Data Flow In-Person Event – United States & Europe <i>Registration link coming soon...</i>	Fall 2026	In-Person Event

Audience Questions





CDISC Resources

CDISC Education Training Courses

Information available at:
<https://www.cdisc.org/education>

Partnerships Education Events

- CDISC Learning System**
- My Learning Account
- Training Options**
- Course Catalog
- Virtual
- In-Person
- On-Demand
- Resources**
- Information for Learners
- Authorized Instructors
- Contact Us



In-Person Trainings
SHANGHAI, CHINA
 28-29 August 2024

Shanghai



In-Person Trainings
SCOTTSDALE, ARIZONA
 21-25 October 2024

Scottsdale



In-Person Trainings
SEOUL, KOREA
 11, 14, 15 November 2024

Seoul



Virtual Event



CDISC Newcomers Virtual



TMF Virtual / On-Demand



CT Virtual / On-Demand



SEND Virtual / On-Demand



CDASH Virtual / On-Demand



SDTM Virtual / On-Demand



ADaM Virtual / On-Demand



ODM Virtual / On-Demand



Define-XML Virtual / On-Demand

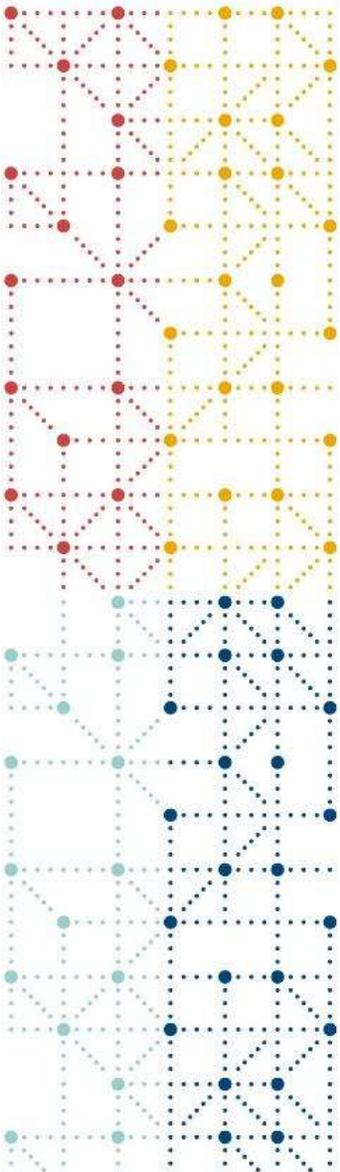


Coming Soon
 LHEA On-Demand



On-Demand Trainings





Free CDISC Courses

<http://learnstore.cdisc.org>



**TAUGs & Free
Trainings**

CDISC MEMBERSHIP

Become a Member!

Join nearly 500 member organizations that contribute to bringing clarity to data.

Already a Member?

Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.



cdisc.org/contact

Why Become a Member?

Events Membership

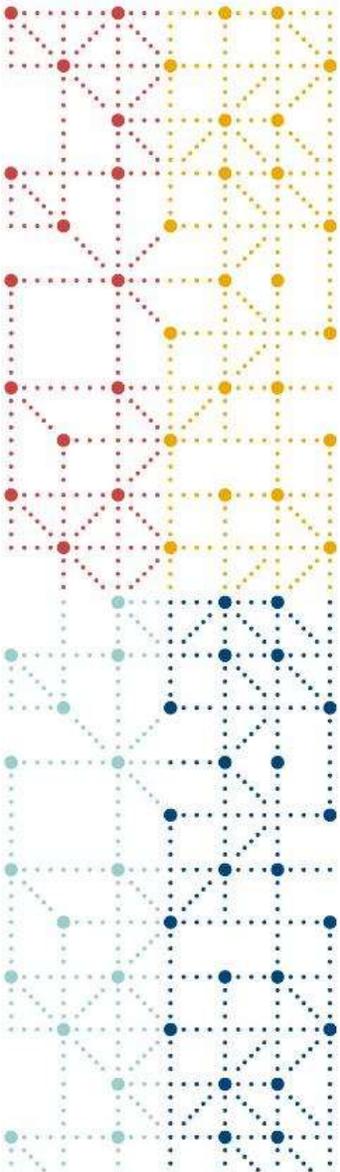
Why Become a Member

Membership Application

Rates & Benefits

Our Members

- To ensure the CDISC standards remain open and free
- To support CDISC in the development and maintenance of global standards
- To work with the CDISC community and be a voice in the development of clinical research standards
- To impact the development of regulatory requirements for submissions
- To access members only resources and benefits
- To gain visibility in the marketplace



Thank You!

cdisc