

Realizing the CDISC Mission



CDISC Strategic Plan & Roadmap



Expand & Connect

Expand, Connect, and Digitize Our Standards



Enable & Automate

Reduce Variability, Enable Interoperability, and Increase Automation



Engage & Adopt

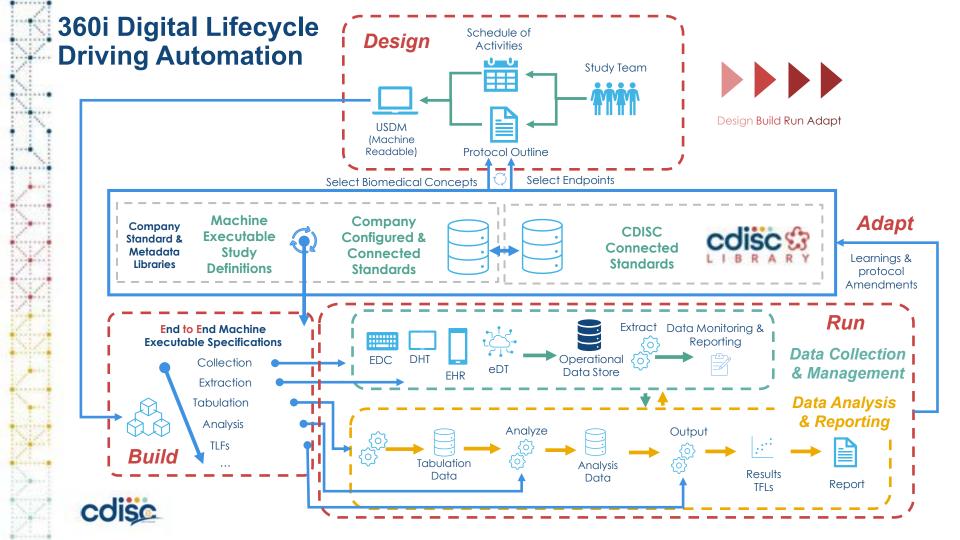
Focus on Community Needs and Deliver Business Value

Strategic Goal:

Expand and Enable standards-driven automation across end-to-end study information lifecycle from study design through results.

CDISC will expand and realize the original 360 vision.





Use Cases 360i Can Enable

Potential Al

Initial 360i Focus Potential future uses

Protocol Design & Study Planning



Study Conduct & Data Collection



Data
Aggregation &
Standardization



Analysis and Reporting



Regulatory Submission

Protocol Authoring



Study Build





ADaM Generation



Past Protocols

Electronic Data Transfers



Digital Analysis Plan



Digital SOA

Patient Recruitment

Tobul

Tabulation & Analysis Specs

Clickable Submission

Data Transfer Specifications

> Protocol Feasibility



Safety Monitoring eTMF

And many more use cases exist...

Governance & Reusability

Artifact Recommendations



Semantic Interoperability

Built In Traceability

Standards Conformance



Overview

Goal

 Engage community to advance standards through innovation

Outcome

 Winner and runner-up for each use case invited to showcase solution at 2025 CDISC US Interchange in Nashville

Rules/Framework

- Open to CDISC Member Organizations
- Solution may be open-source or commercial
- Open-source encouraged for community impact
- Submissions may be from individual, company, or through partnership(s)
- CDISC will not commit to adopt or endorse submitted solutions
- Submission will be a recorded demo no longer than 6 minutes
- Judges will be identified by CDISC
- Solution development, registration, and travel to Interchange are at your own expense



Timelines

Jun 12

 Al Innovation Challenge Announcement Jul 11-Sep 5

• Every other Friday Q&A Sessions Aug 31

Submission deadline

Sep 22-26

Winners announced

















Jul 1

 Al Innovation Challenge Webinar July 31

Submit your intent to participate

Sep 1-15

• Submission judging

Oct 13-14

 Showcase at CDISC US Interchange



Use Case 1: Protocol Library

Build a USDM-Centric Repository of Study Definitions from Existing Protocols

Problem

- Study design is manual, error prone, and time consuming
- 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
- UI for searching and downloading content



Use Case 2: BC Acceleration

Accelerate Development of Biomedical Concepts to Drive CDISC Transformation and Automation

Problem

 Siloed standards require manual interpretation and mappings

Solution

 Connect standards from design through analysis semantically with biomedical concepts (BCs)

Challenge

 Demonstrate accelerating creation and curation of BCs through use of legacy content



Use Case 3: Automated Traceability

Semantic Traceability from Analysis back to Study Design

Problem

 Clinical development artifacts are created through manual programming at each stage of the lifecycle and are often siloed, with limited traceability between them

Solution

 Enable reverse mapping from analytical outputs back to study definitions and collection elements demonstrating traceability

Challenge

- Demonstrate analyzing statistical analyses and derived data to create semantic linkage back to design
- Leverage USDM, dataset specializations and/or BCs
- Visualize lineage across standards layers
- Demonstrate how artifacts could be dynamically generated or traced using semantics



Submit Your Intent to Participate

- Why this matters
 - Helps us understand which use cases are being pursued
 - Allows CDISC to coordinate support, resources, and visibility
 - Ensures your organization is formally recognized as a challenge participant
- Deadline to submit intent
 - July 31st
 - Early submission encouraged
- Benefits to submitting
 - Official participation recognition
 - Access to CDISC support during solution development
 - Priority visibility in progress reports and community updates (e.g., details on how to submit final recorded demo)







Submitting Your Final Recorded Demo

- Submission requirements
 - Format: MP4 (preferred), MOV, or AVI
 - Video length: max 6 minutes (note: if we only have a few submissions, we may extend this time)
- Content to include in recording
 - Overview of use case addressed
 - Demo of your AI solution
 - · Highlight how CDISC standards were applied
 - Clarification if open-source or commercial
- Optional materials
 - 1-slide visual summary (for promotion/showcase)
 - Links to GitHub repo or product website (if applicable)
 - Short written description of your solution (250 words max)

- How to submit
 - Upload your video/optional materials to <TBD>
 - Link will be distributed to those who submit their intent to participate
- Submission deadline
 - August 31st at midnight PST
- Next steps after submission
 - Submissions will be reviewed by the evaluation panel
 - Selected solution key contacts will be notified by Sept 26th
 - Winners will be invited to present at the 2025 CDISC US Interchange



Bi-Weekly Q&A Sessions

- Occurs every other Friday, starting July 11th from 10-11am EST
- Purpose
 - Open forum to ask questions, share ideas, and clarify expectations
 - Get guidance on use cases, CDISC standards, or solution design
 - Opportunity to hear what others are working on (if they wish to share it)
- Who Should Join
 - Any Al Innovation Challenge participants
 - Those seeking clarification on deliverables, use case scope, or available CDISC resources
- Format
 - Brief updates (if any)
 - Live Q&A
 - Open discussion

Microsoft Teams Join the meeting now

Meeting ID: 280 772 229 676 9 Passcode: Zc29Pu3F







Thank You!

Questions?

