



AI Innovation Challenge 2026 Kickoff Webinar

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1. Housekeeping
2. Challenge Overview
3. Use Cases
4. Submission Process
5. Judging Criteria
6. Q&A

Housekeeping

- Audience will be on mute during this session.

Shhhh...



- Please submit via Q&A in the Teams App.

Questions?



- First, restart Teams.
- Second, check your local internet connection strength

Audio Issues?



- A recording of this webinar and slides will be available on Public Webinar Archive on CDISC website.

Recording



Overview

Goal

- Engage community to advance standards through innovation

Outcome

- Winner and runner-up for each use case invited to showcase solution at 2026 CDISC US Interchange in Denver
- Note: solution development, registration, and travel to Interchange are at your own expense

Rules/Framework

- Open to CDISC Member Organizations
- Solution may be open-source or commercial (open-source encouraged for community impact)
- Submissions may be from individuals, 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



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





2025 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 in 2025?

- 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.

Timeline for 2026 AI Innovation Challenge





Use Case 1: AI enabled Synthetic Data Generation for Automation Testing



PROBLEM

Limited access to clinical data for testing requires manual effort and makes validation of systems and workflows difficult.



SOLUTION

Use AI/ML-driven approaches to generate synthetic SDTM and/or ADaM datasets from digital protocol or other data sources (e.g., raw, DHT, EHR, or real-world data) to reduce reliance on manual data preparation.



CHALLENGE

Demonstrate AI-enabled generation of synthetic SDTM and ADaM datasets with traceable linkage to source inputs and metadata.





Use Case 2: AI-Driven Generation of Statistical Analysis Plans (SAP)

PROBLEM

SAPs are created manually, leading to inefficiencies, delays, and limited traceability to study design.

SOLUTION

Use AI/ML-driven methods to automate generation of SAPs from protocol and metadata inputs, improving efficiency, consistency, and traceability.

CHALLENGE

Demonstrate AI-enabled generation of SAP content that is accurate, consistent, and traceable to study design and analysis requirements.





Use Case 3: AI-Driven Tables, Figures, and Listings (TFL) Generation



PROBLEM

TFLs are generated manually, requiring repeated effort and limiting traceability from objective to result.



SOLUTION

Use AI/ML-driven approaches to automate the generation of TFLs, ensuring traceability from objective → endpoint → result and reducing manual effort.



CHALLENGE

Demonstrate AI-enabled generation of TFLs with end-to-end traceability from objective through analysis to final outputs.





Submit Your Intent to Participate

- <https://tinyurl.com/CDISC-AI-Challenge> or the QR code to the right
- Why this matters
 - Helps us understand which use cases are being pursued
 - Allows CDISC to coordinate support, judging, resources, and visibility
 - Ensures your organization is formally recognized as a challenge participant
- Deadline to submit intent
 - **May 29, 2026**
 - Early submission encouraged
- Benefits to submitting your intent to participate
 - 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)





How to submit

- How to submit
 - Upload your video to a public share site (e.g., YouTube)
 - Submit your final solution via the AI Challenge Submission form (link will be provided in advance) with links to your submission video by **July 31st** at midnight PDT
- Next steps after submission
 - Submissions will be reviewed by the evaluation panel
 - Selected solution key contacts will be notified by **mid-Sept**
 - Winners will be invited to present at the 2026 CDISC US Interchange in Denver (note: travel to the Interchange is at the participant's own expense)



Demo requirements

- Publish video to a publicly accessible site
 - Provide a link to your video using a platform such as:
 - YouTube (recommended – can set to 'Unlisted' if you don't want it publicly searchable)
 - Vimeo
 - Google Drive
 - OneDrive/SharePoint with public access enabled)
 - The video must be accessible without login or special permissions. Set permissions to "Anyone with the link can view" and test your links before submission .
 - Video length: no longer than 6 minutes
 - Content to include in recording
 - Overview of use case addressed
 - Demo of your AI solution
 - How CDISC standards and metadata were applied
 - Key capabilities and value (e.g., automation, traceability, interoperability)
- Optional Materials
 - One slide summary
 - Written description (<= 300 words) highlighting the use case, key capabilities, and value delivered.





New for 2026 Challenge Participants

- Longer time to prepare and submit
- Greater transparency in judging
 - Presenting scoring criteria up front
 - Providing written feedback summary to participants





Weighted Scoring Criteria

Criteria	Notes
Innovation & Relevance 30%	<ul style="list-style-type: none">• How effectively does the solution apply AI/ML to the use case?• Does it clearly address a meaningful industry problem?• Is the approach novel or does it significantly advance current capabilities?• Bonus consideration: Does it apply, promote, or accelerate development of standards in a new or impactful way?
Technical Quality & Feasibility 30%	<ul style="list-style-type: none">• Is the technical approach sound, scalable, and reproducible?• Can the solution be realistically adopted in a production environment?• Does it handle complexity (e.g., edge cases, variability in data or inputs)?• Bonus consideration: Is there clear documentation, transparency, validation, or human-in-the-loop support?
Standards Integration, Traceability, and Impact 40%	<ul style="list-style-type: none">• How well does the solution integrate CDISC standards?• Does it demonstrate traceability across the data lifecycle?• What is the potential to accelerate standards-driven automation and interoperability?• Does it deliver measurable or visible impact (efficiency, quality, reuse, conformance)?• Bonus consideration: Is the solution interoperable, reusable, or standards-aligned in a way that increases ecosystem value?

All submissions must demonstrate the use of AI/ML in combination with CDISC standards and metadata-driven approaches.

Scoring Matrix for Each Criteria

Scoring Scale	Descriptor	Explanation
1-3	Weak	Minimal relevance to the use case, limited or unclear use of AI. Weak technical feasibility and little evidence of standards alignment or impact.
4-6	Adequate	Addresses the basics of the use case with some use of AI. Feasible approach but limited innovation, standards integration, or clear impact.
7-8	Strong	Well-executed solution with meaningful use of AI. Demonstrates solid technical approach, clear standards integration, and tangible benefits or use case alignment.
9-10	Outstanding	Breakthrough or highly differentiated solution. Demonstrates strong AI application, deep standards integration, end-to-end traceability, and high potential for real-world adoption and impact.





Judging

- 5 or more judges per use case
- Judges selected to ensure no conflict of interest
- CDISC staff and external partner and advisory stakeholders
- Independent scoring by each judge
- 1-2 sentence comments to help summarize feedback





Bi-Weekly Q&A Sessions

- Schedule will be announced
- 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 AI 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





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 <p>Europe Interchange</p>	 <p>US Interchange</p>	 <p>2025 Event</p>	 <p>2025 Virtual Event</p>	 <p>India Day Training</p>	 <p>ARS Trainings</p>	 <p>Dataset-JSON Trainings</p>
 <p>China Day Trainings</p>	 <p>Newcomers Trainings</p>	 <p>CT Trainings</p>	 <p>SEND Trainings</p>	 <p>CDASH Trainings</p>	 <p>LHEA: Designing TRUE Research</p>	 <p>FREE TIG Training</p>
 <p>SDTM Trainings</p>	 <p>ADaM Trainings</p>	 <p>ODM Trainings</p>	 <p>Define-XML Trainings</p>	 <p>TMF Trainings</p>	 <p>TAUGs & Free Trainings</p>	 <p>Miscellaneous/Other</p>



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