Closing the Loop: Automated Semantic Traceability from Study Design to Analysis - Insights from the CDISC AI Innovation Challenge

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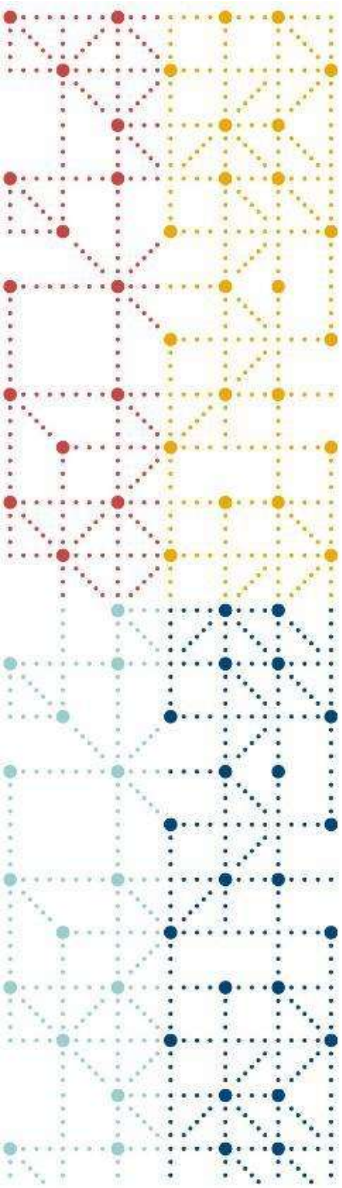
June 9, 2026



Agenda

1. Summary of the AI Protocol Challenge and Lessons Learned
2. Merck Demo
3. Zifo RnD Solutions Demo
4. Q&A

Housekeeping

Shhhh...

- Audience will be on mute during this session.

Questions?

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

Audio Issues?

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

Recording

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

Lessons Learned from the AI Innovation Challenge

Why the CDISC AI Innovation Challenge?

- Global call to apply AI/ML + CDISC standards
- Focused on implementation, not theory
- Designed to test how standards can support AI and how AI can accelerate standards development

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.

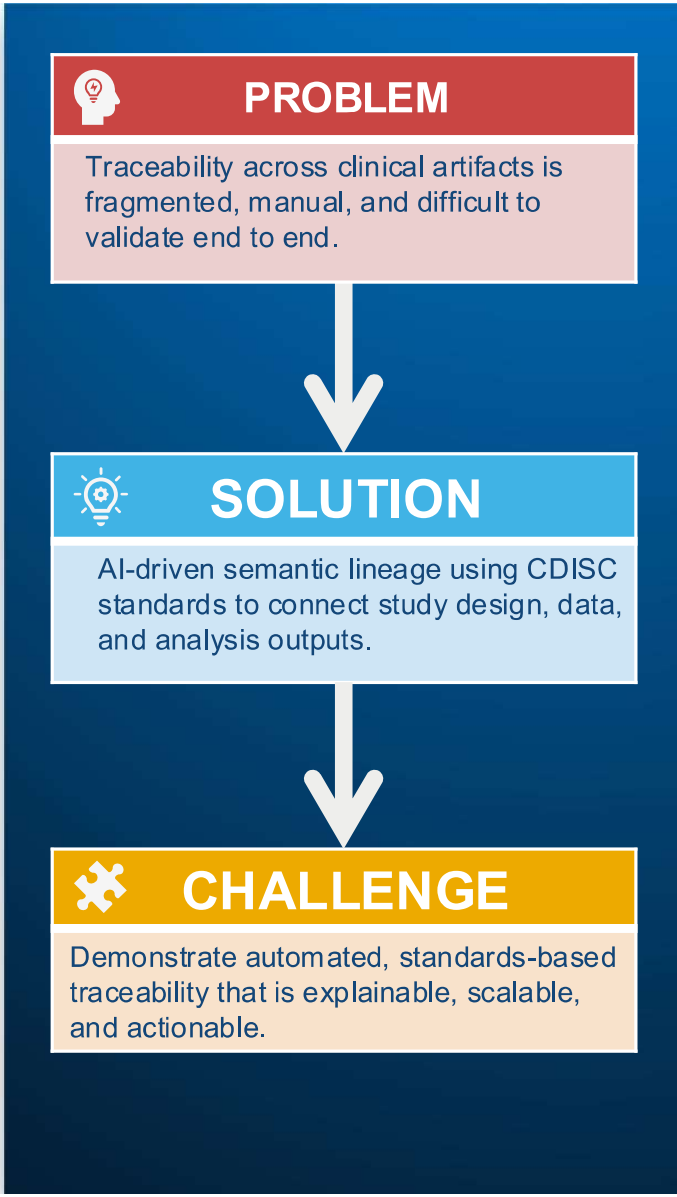
Use Case 3: Key Results

Submissions: 4

Winners:

- Merck
- Zifo RnD Solutions

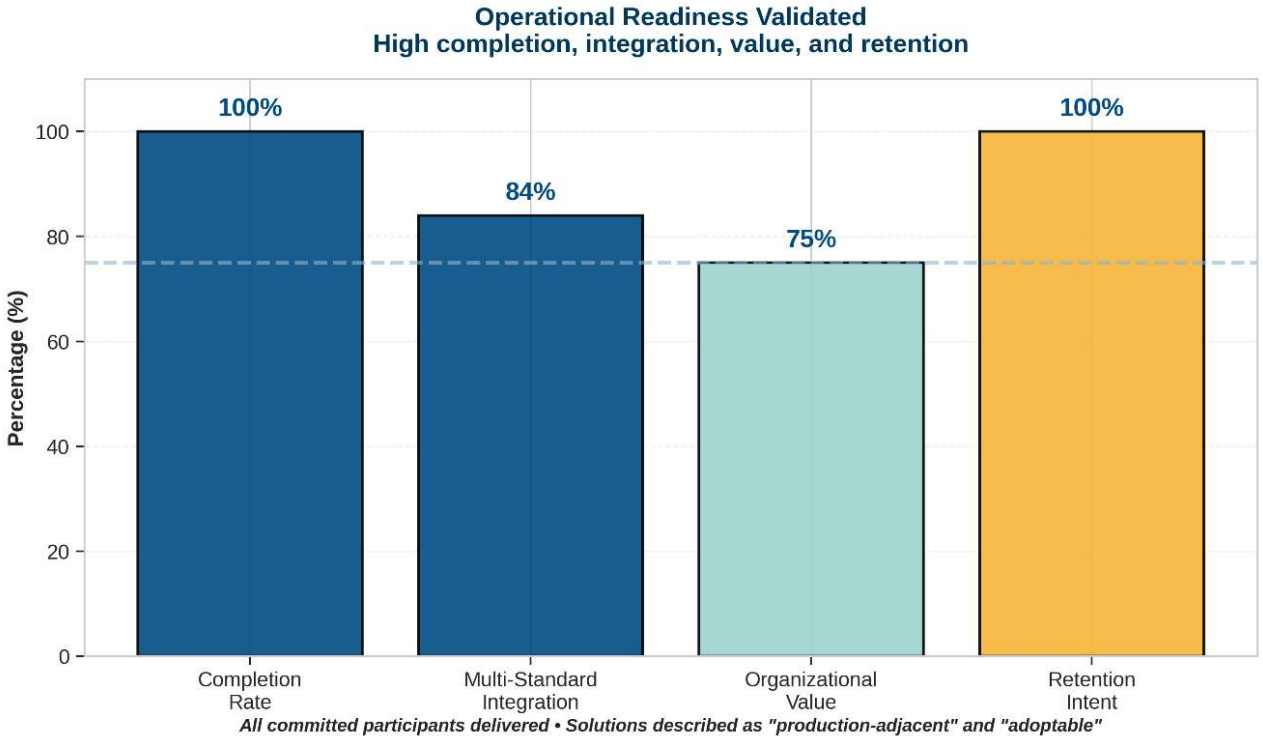
- Most technically complex and nuanced use case
- AI used to:
  - Establish semantic traceability from analysis back to study design
  - Link protocol, CRFs, SDTM, ADaM, TLFs, and results using standards
  - Visualize lineage and impact across the clinical data pipeline
- Demonstrated value beyond point-to-point mappings
- Showed AI's potential to enable explainable, end-to-end traceability



What We Learned – Semantic Traceability Use Case

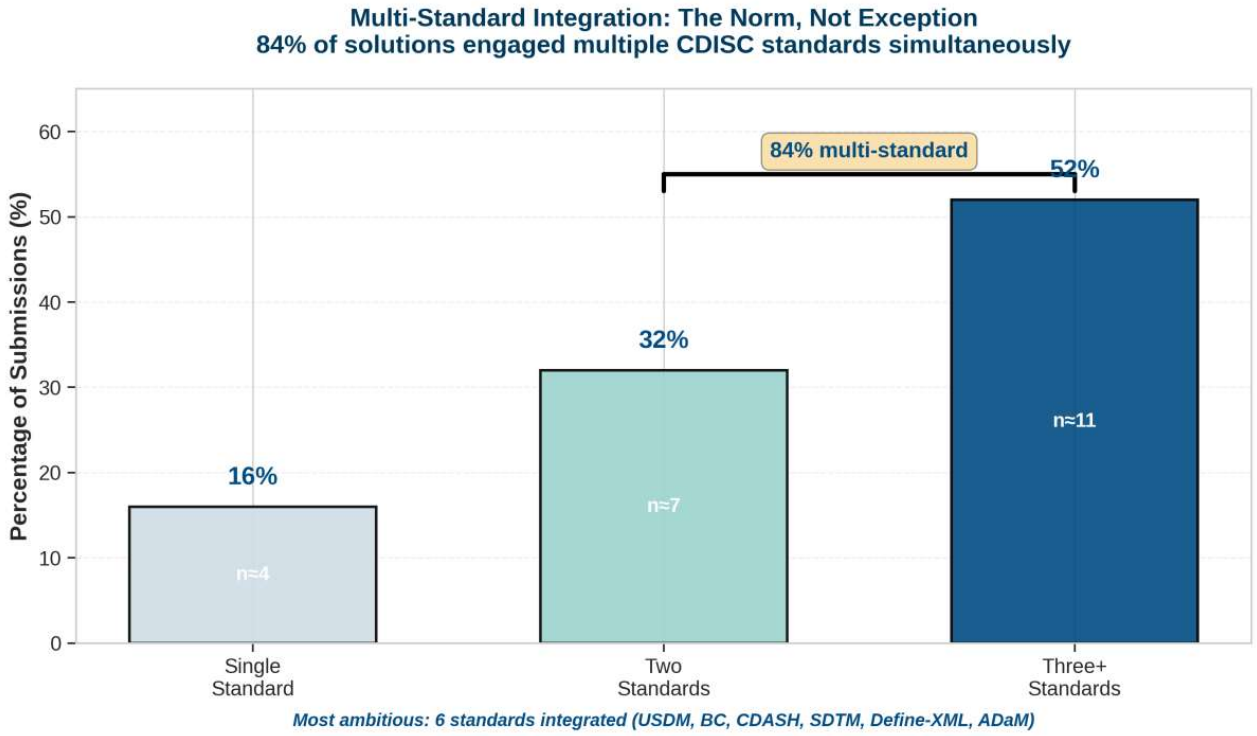
- Traceability is a metadata problem, not a documentation problem
- Connected standards enable end-to-end lineage across the study lifecycle
- AI helps discover, explain, and navigate relationships at scale
- Semantic traceability is more sustainable than manually maintained mappings
- Human-in-the-loop validation remains essential for trust and regulatory confidence
- AI-enabled traceability validates the 360i vision of connected standards

Traceability is Operationally Feasible Today



- **Question:** Can AI work with standards in production environments?
- **Answer:** Yes. 84% multi-standard integration, solutions described as "production-adjacent."
- **What Changed:** The barrier is no longer feasibility—it's enablement.

AI Proves Multi-standard Interoperability



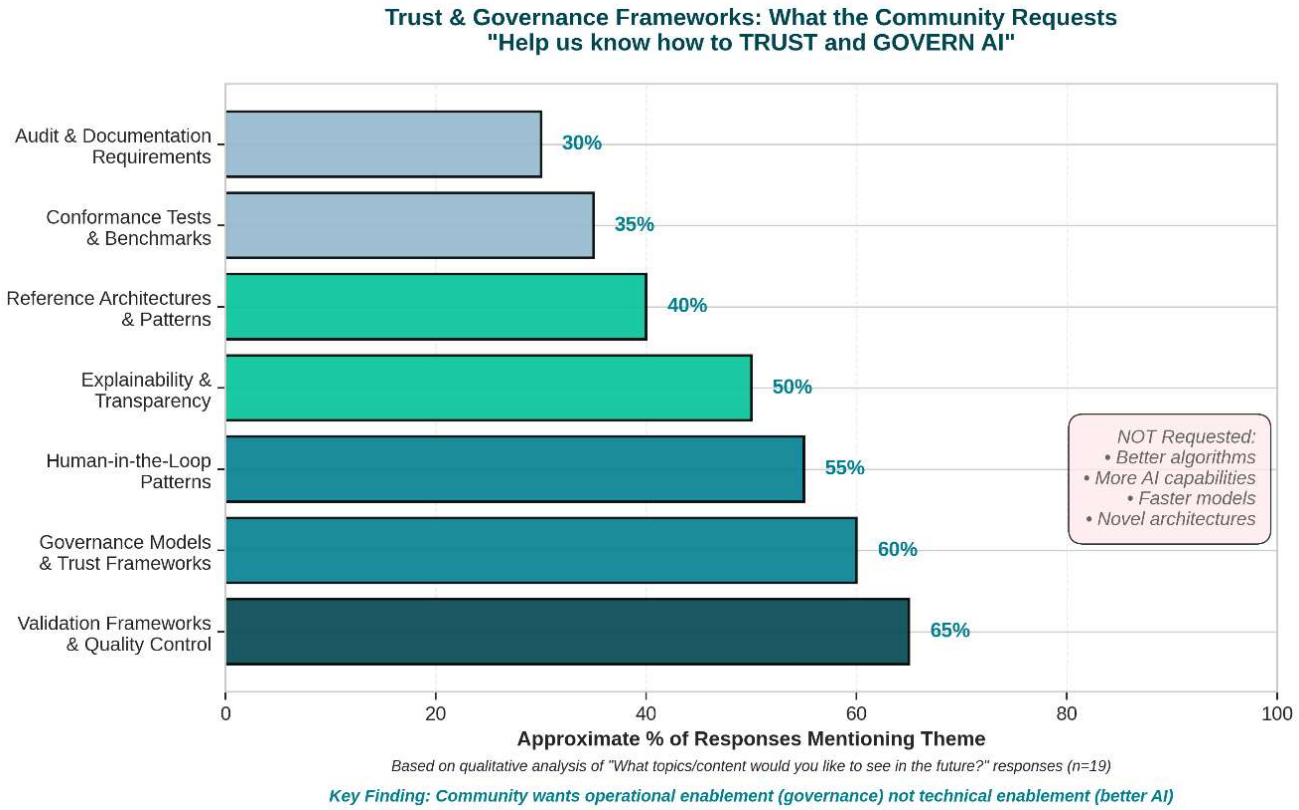
"The challenge proved that AI can master the complex, cross-standard relationships required for modern research—integrating multiple standards (USDM, BC, CDASH, SDTM, Define-XML and ADaM).

We are deeply committed to building an end-to-end, AI-enabled clinical data pipeline where data flows seamlessly across standards with absolute traceability.

Our goal is to ensure that from protocol to submission, every data point is standards-anchored and science-driven."

— Deepak Ananthan, VP Clinical Services at Zifo.

Trust Frameworks Explicitly Requested



"The challenge with AI is no longer building it, but governing it.

Faro's current investment is centered on evaluation, quality, and governance as prerequisites for enterprise adoption,"

— Vivian DeWoskin, Chief Commercial Officer at Faro, UC1 winner.

Timeline for 2026 AI Innovation Challenge

2026 Challenge Scope & Focus

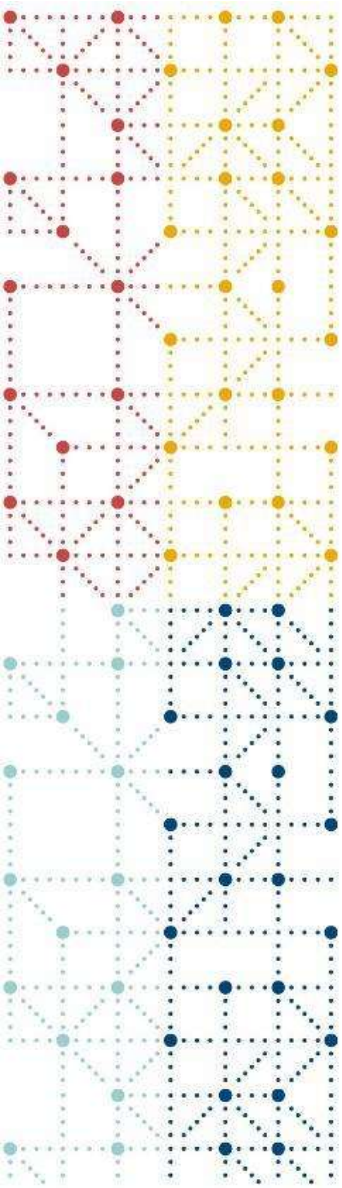
Three targeted use cases:

Use Case	#
AI-enabled Synthetic Data Generation for Automation Testing	39
AI-Driven Generation of Statistical Analysis Plans (SAP)	31
AI-Driven Tables, Figures, and Listings (TFL) Generation	32
Unique Submissions (69 submitters)	102

From Insight to Implementation

- Next: live demonstrations from Use Case 2 winners
- Focus on:
  - How AI helps to with semantic traceability
  - What's production-ready today
  - Where value shows up in real workflows

Audience Questions



Thank You!

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