



Enabling Innovation: Lessons from the CDISC AI Innovation Challenge (DS11)

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Agenda

1. AI Challenge Overview
2. Lessons Learned
3. Key Insights

Speakers



Julie Smiley
CIO
CDISC

- Julie Smiley is the Chief Information Officer (CIO) at CDISC with over 25 years of experience in pharmaceutical data management, standards, and digital transformation. She leads CDISC's technology and data science strategy, focusing on interoperability, automation, and AI-enabled standards to modernize clinical research data flows. Julie holds an MS in Computer Information Systems from Boston University.



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





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

Submissions: 13

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



Use Case 2: Key Results

- Moderate participation, highly specialized use case
- AI used to:
 - Accelerate creation of Biomedical Concepts
 - Leverage existing standards, terminologies, and legacy content
 - Reduce manual effort in BC curation and maintenance.
- Demonstrated value beyond manual standards authoring
- Highlighted AI's role in scaling semantically across studies

Submissions: 5

Winners:

- Saama
- Lindus Health



PROBLEM

Biomedical Concept development is manual, time-intensive, and difficult to scale consistently across studies.



SOLUTION

AI-assisted generation and curation of Biomedical Concepts aligned to CDISC standards and controlled terminology.



CHALLENGE

Demonstrate how AI can accelerate BC creation while preserving semantic accuracy, traceability, and governance.



Use Case 3: Key Results

- 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

Submissions: 4

Winners:

- Merck
- Zifo RnD Solutions



PROBLEM

Traceability across clinical artifacts is fragmented, manual, and difficult to validate end to end.



SOLUTION

AI-driven semantic lineage using CDISC standards to connect study design, data, and analysis outputs.



CHALLENGE

Demonstrate automated, standards-based traceability that is explainable, scalable, and actionable.



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.



Where the Hard Work Still Lies

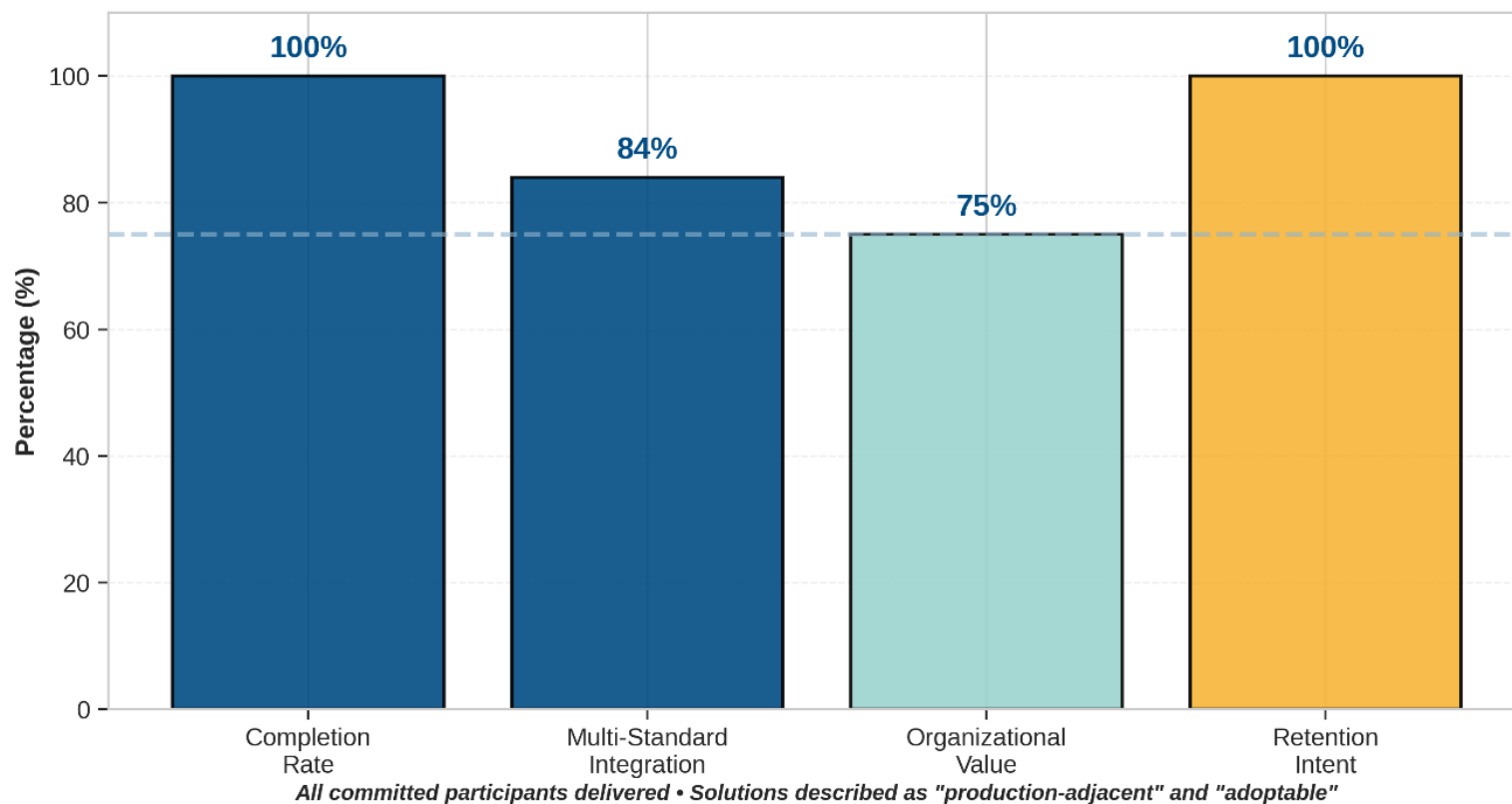
- How do we build confidence and trust in AI-assisted outputs?
- What makes solutions adoptable beyond pilots?
- Where does openness help — and where does it get complicated?
- What support does the ecosystem need (beyond standards themselves)?





Operational Readiness Validated

Operational Readiness Validated
High completion, integration, value, and retention



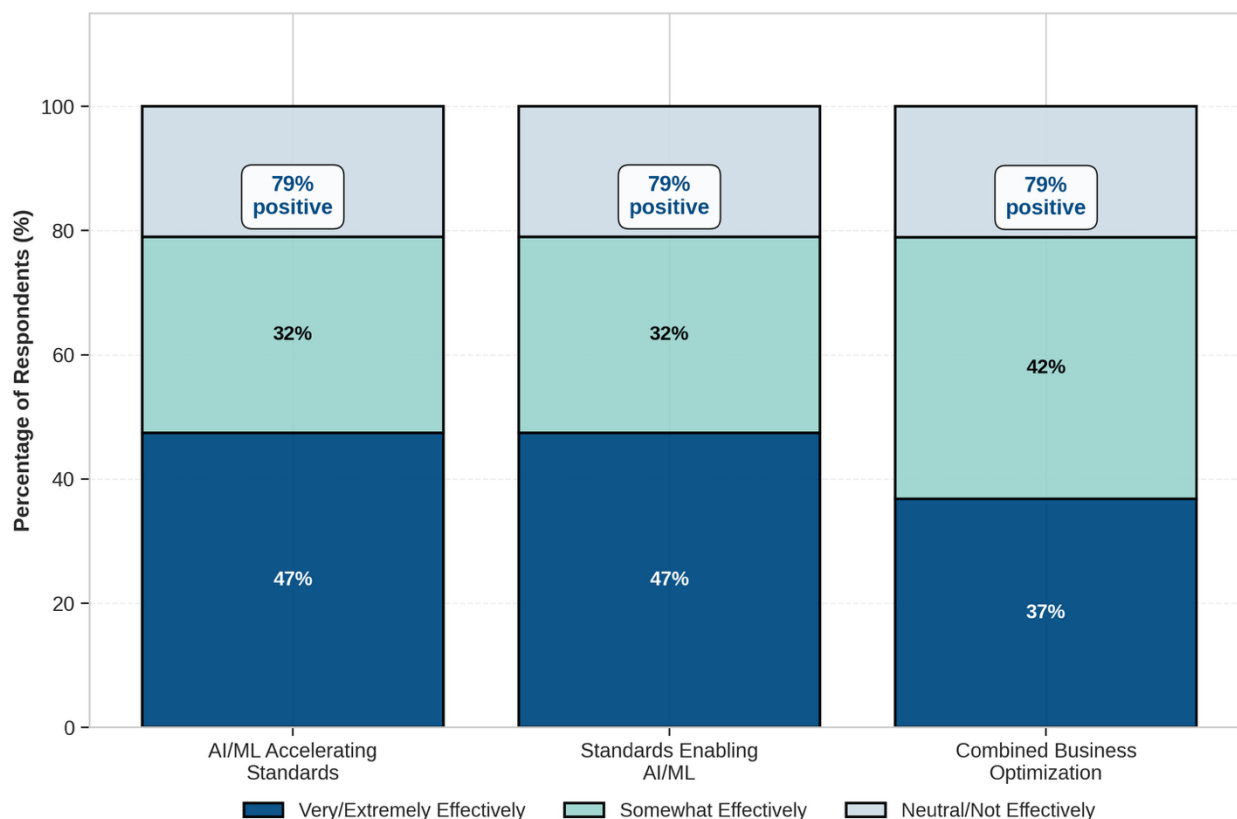
Insight #1

- **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.



Bidirectional AI <=> Standards Value

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)

Insight #2

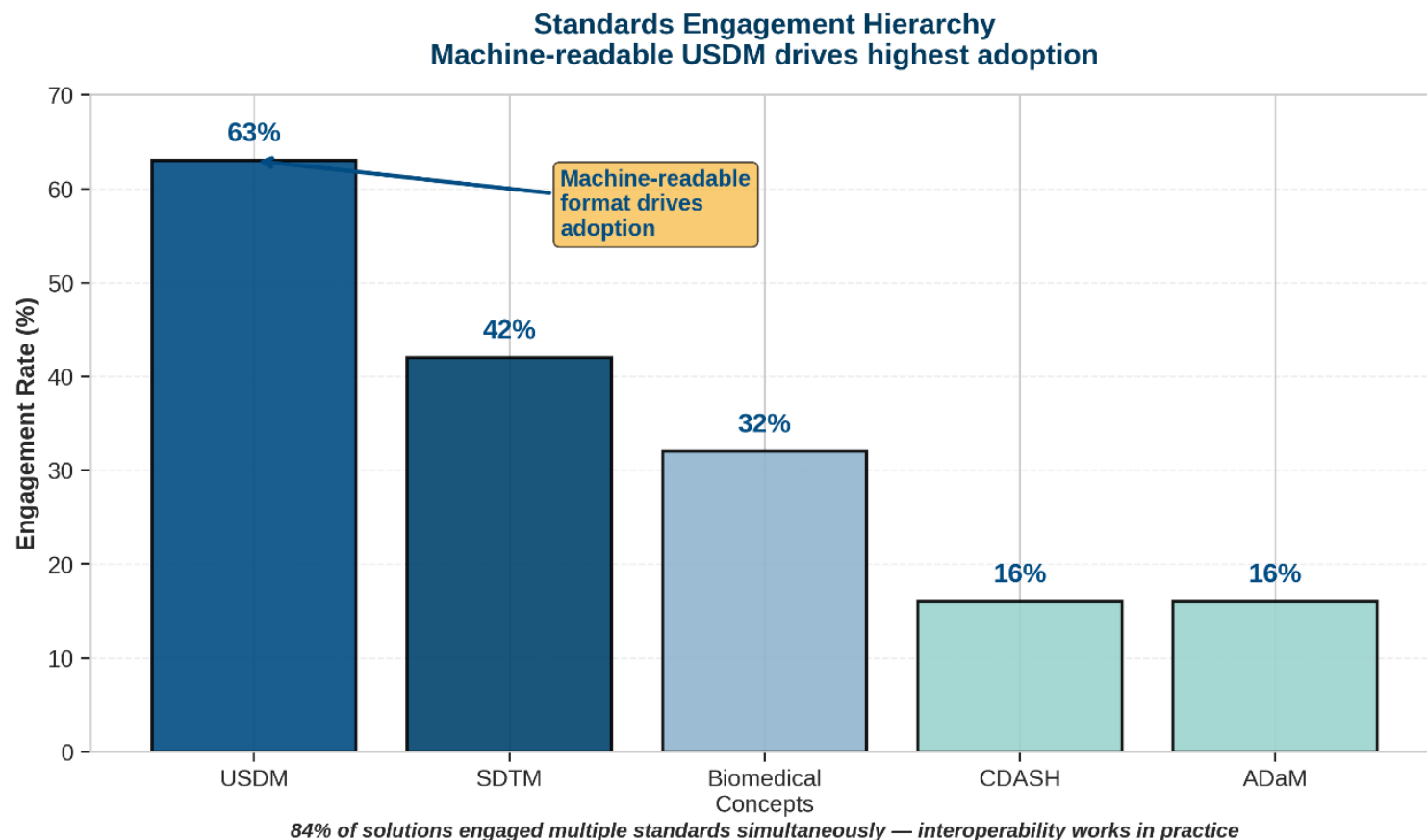
"The challenge isn't just adopting standards, but making them scalable for modern trial complexities. Saama's investment is focused on AI-driven enrichment, where our Agentic Frameworks turn static guidelines into dynamic tools."

This creates a bi-directional flywheel that solves for data variability in real-time, ensuring that traceability and operability are prerequisites, not just afterthoughts."

— Prasanna Rao, Chief Products and Innovation Officer, Saama



Executable Standards Drive Adoption



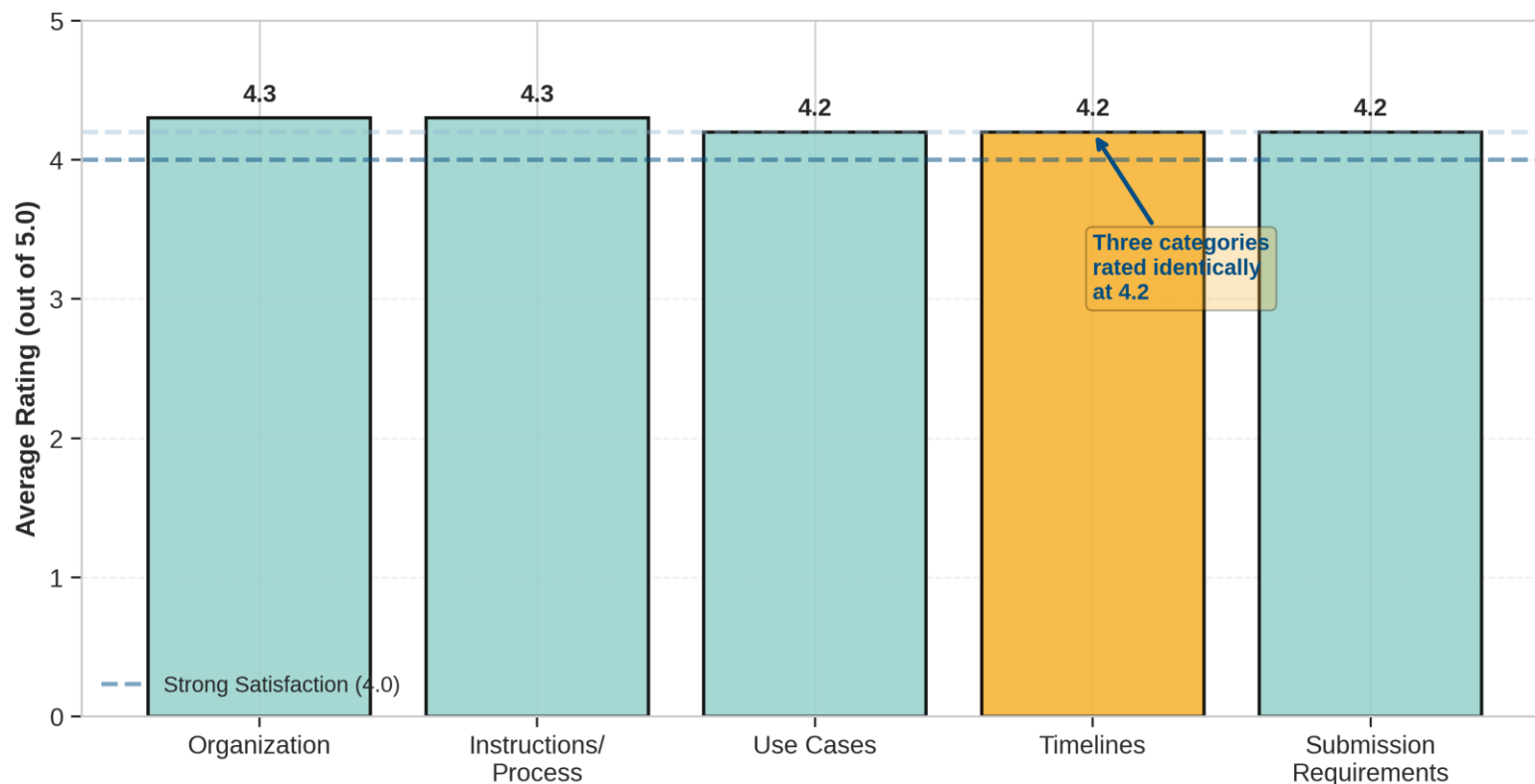
Insight #3

- **The Pattern:**
 - USDm (machine-readable): 63% engagement
 - Other standards: Lower engagement
- **The Lesson:** Give developers machine-readable formats, and they'll use them. PDFs don't cut it.



Timeline Signals Ambition

Satisfaction Ratings Across Challenge Dimensions
Timeline rated 4.2/5—on par with Use Cases and Submission Requirements



Participant ratings (n=12) | Timeline rated same as Use Cases and Requirements—not a constraint

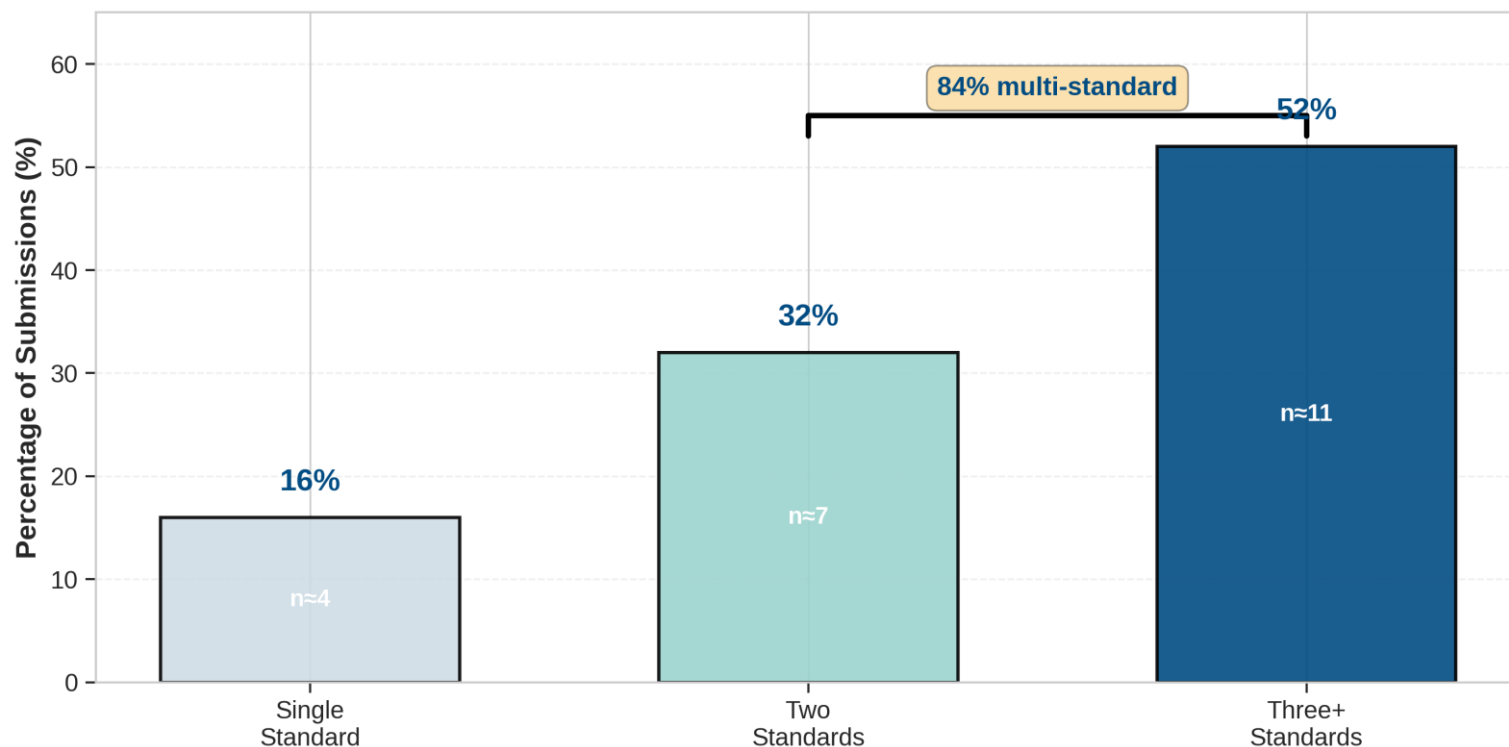
Insight #4

- **What Participants Said:** Timeline was fine, I just wanted MORE time to build MORE features.
- **What We Learned:** Not a constraint. Not unfair. Ambition. Scale accordingly.



AI Proves Multi-standard Interoperability

Multi-Standard Integration: The Norm, Not Exception
84% of solutions engaged multiple CDISC standards simultaneously



Most ambitious: 6 standards integrated (USDM, BC, CDASH, SDTM, Define-XML, ADaM)

Insight #5

“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.

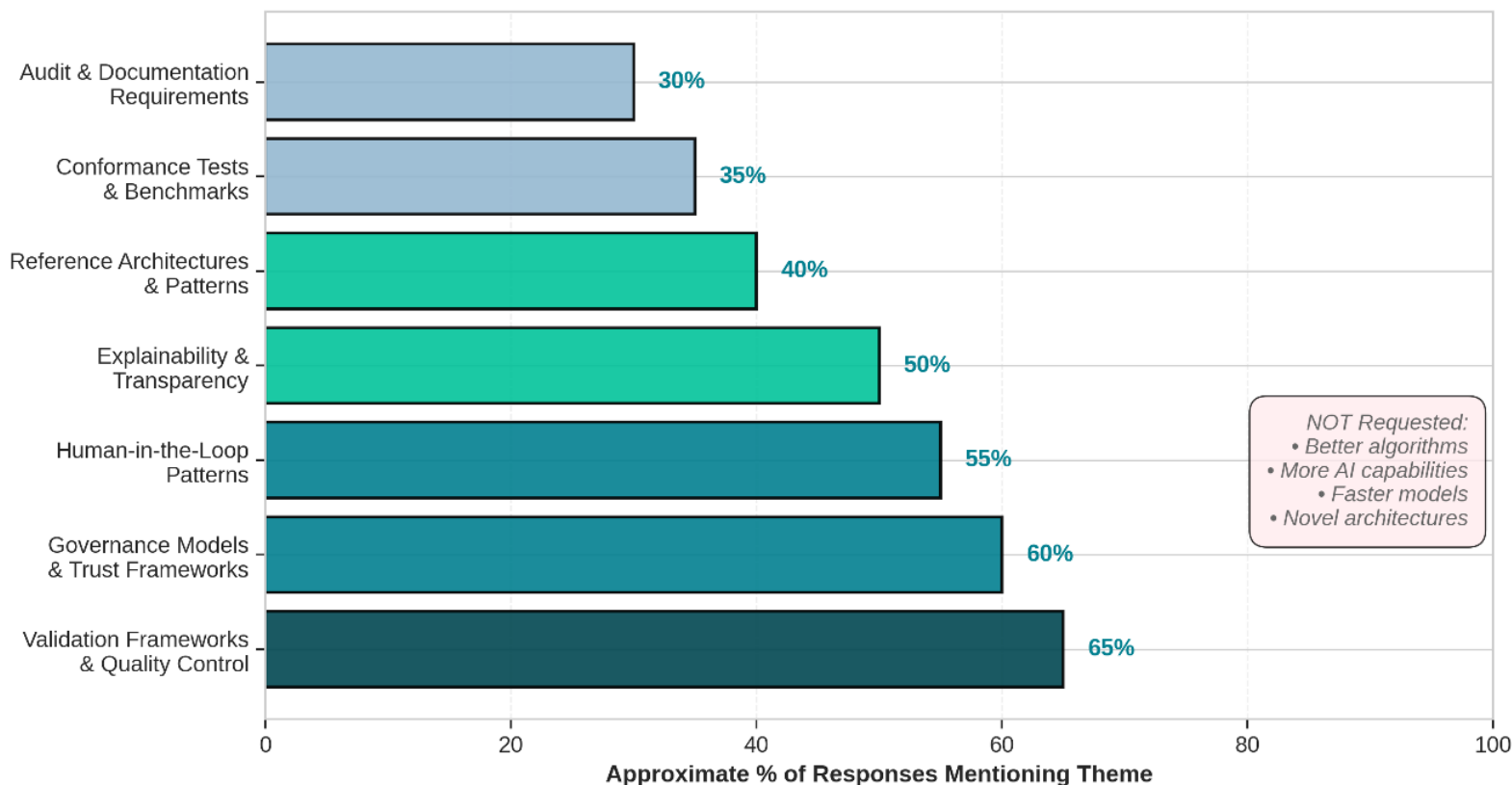
Our goal is to ensure that from protocol to submission, every data point is standards-anchored and science-driven.”

— Deepak Ananthan, VP Clinical Services at Zifo.



Trust Frameworks Explicitly Requested

Trust & Governance Frameworks: What the Community Requests
"Help us know how to TRUST and GOVERN AI"



Based on qualitative analysis of "What topics/content would you like to see in the future?" responses (n=19)

Key Finding: Community wants operational enablement (governance) not technical enablement (better AI)

Insight #6

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

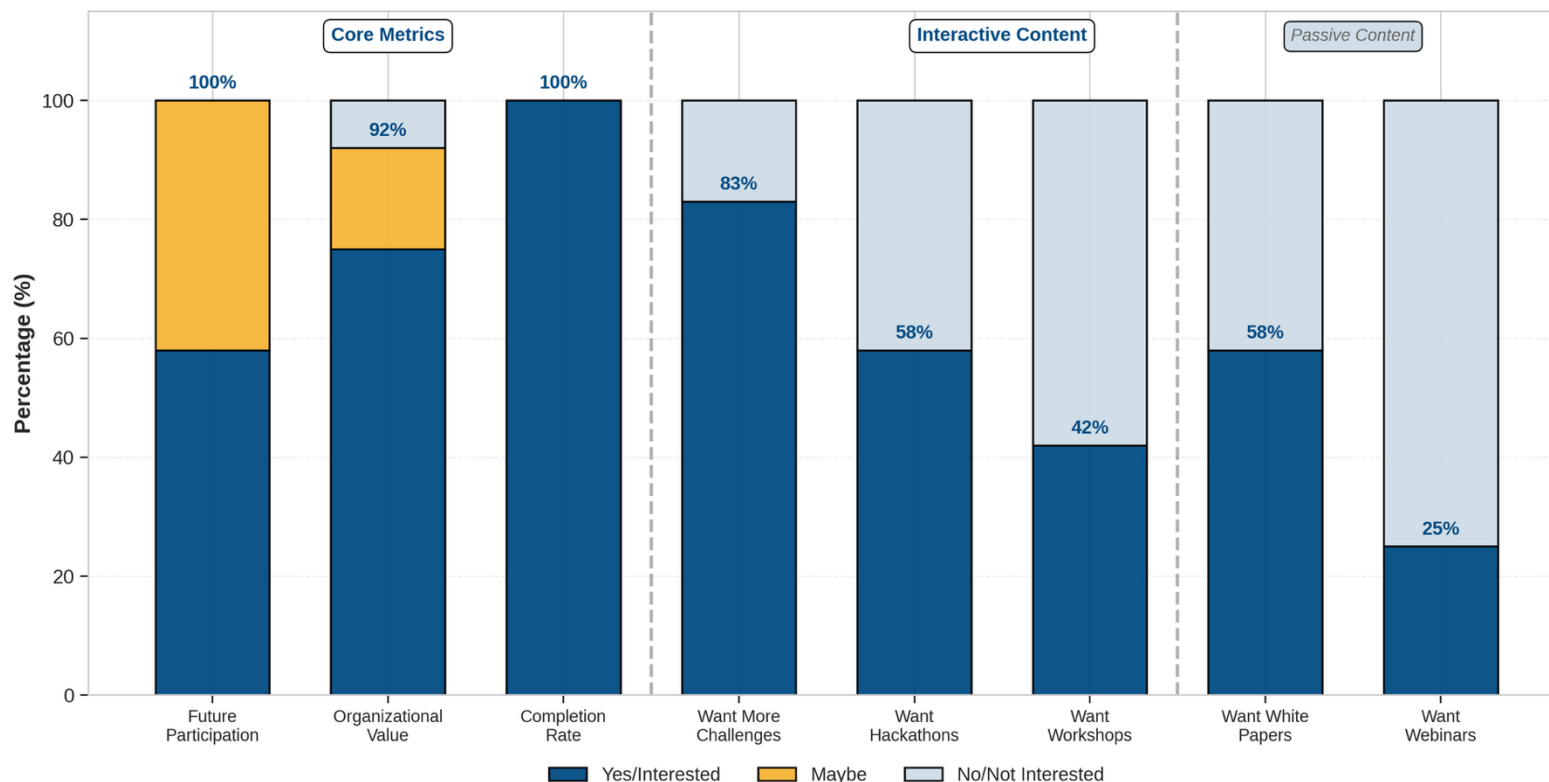
Faro's current investment is centered on evaluation, quality, and governance as prerequisites for enterprise adoption,"

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



Challenge Catalyzed Organizational Change

Strong Ecosystem Appetite: Retention, Value, and Future Engagement
100% willing to participate again • 83% want more challenges



Source: Post-challenge survey (n=12 participants) | Future content preferences from "What would you like to see?" question

Zero "No" responses for future participation—extraordinary commitment • Interactive formats dominate preferences

Insight #7

• The Numbers

- 100% retention intent
- 83% want more challenges
- 75% organizational value

• The Opportunity

- One-time events create spikes.
- Ongoing programs create transformation.



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





Questions?





Thank You!

