

Enabling Innovation: Lessons from the CDISC AI Innovation Challenge

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ABSTRACT

As artificial intelligence becomes an integral part of clinical research, standardized, interoperable data is essential to unlock its full potential. In this panel session, we showcase insights and outcomes from CDISC's first AI Innovation Challenge, a global call to action inviting technology innovators to build AI/ML solutions that use or accelerate development of CDISC standards. Panelists will reflect on what worked and what didn't, from data accessibility to the maturity of AI approaches, and discuss lessons learned for future innovation.

The session will also examine insights gleaned from the submitted use cases: where value was generated, what patterns emerged across solutions, and how these technologies might reshape study design, data transformation, and regulatory workflows. This conversation will offer a candid look at the opportunities and barriers in aligning open standards with AI-driven tools and explore what's needed next to drive meaningful adoption across the ecosystem.

EXECUTIVE SUMMARY

The CDISC AI Innovation Challenge, launched in June 2025, was a global call to action for vendors, researchers, and innovators to develop AI/ML solutions accelerating clinical research digitization through CDISC standards. The initiative drew interest from over 40 organizations and received 22 impressive submissions across three use cases.

Post-challenge survey validation: Participants rated overall satisfaction with the challenge at 4.2/5, and 80% agreed that CDISC standards effectively contributed to AI/ML acceleration. Survey analysis validates that the industry is operationally ready to deploy AI with standards today and that standards are essential to accelerate AI enablement.

CHALLENGE OUTCOMES

- Winners and runners-up presented at CDISC US Interchange (Nashville, October 2025)
- Open-source solution providers invited to contribute to COSA (CDISC Open-Source Alliance)
- Additional webinars and showcase sessions planned in 2026 to share learnings
- Participants expressed interest in more hands-on challenges and activities

STRATEGIC INSIGHTS

- Operational readiness validated – many production/production-adjacent solutions submitted
- Bidirectional value confirmed - AI accelerates standards AND standards enable AI
- Executable standards drive adoption - majority of solutions used multiple standards
- Strong community engagement - all respondents want to participate in future events
- AI proves multi-standard interoperability – majority of solutions utilized multiple standards within solution
- Trust frameworks requested - community asking for governance, validation patterns, and reference architectures

PART 1: THE CDISC AI INNOVATION CHALLENGE

CHALLENGE OVERVIEW

Launched in June 2025, the CDISC AI Innovation Challenge was a global initiative inviting vendors, researchers, and innovators to develop solutions that accelerate clinical research digitization through AI, machine learning, and CDISC standards. The challenge addressed real-world problems spanning the clinical research lifecycle, from protocol design to end-to-end metadata traceability.

- **Participation:** Over 40 organizations expressed interest, ranging from innovative startups to established industry leaders. Despite a brisk timeline, 22 impressive submissions were received. Several organizations tackled multiple use cases, a remarkable achievement given the short timeline and technical complexity.
- **Evaluation Process:** Each use case was reviewed independently by expert judges, ensuring fair and objective evaluation. Solutions were assessed on innovation and relevance, technical quality and feasibility, and overall impact and value in alignment with CDISC's 360i strategy.
- **Survey Response:** Post-challenge surveys achieved a 54.5% response rate from and 100% from judges, providing robust feedback on the challenge experience and strategic insights on AI-standards integration.

CONNECTION TO 360i

The Challenge directly supported CDISC's 360i initiative—'i' for 'implementation'—a multi-year strategy transitioning the industry from static, document-based standards and processes to a dynamic, digital data flow beginning with digital protocols.

360i focuses on:

- Transforming static standards into dynamic, executable assets (e.g., digital protocols, reusable biomedical concepts (BC))
- Enabling consistency, interoperability, and intelligent automation from study design through submission
- Reducing manual effort while increasing traceability, transparency, and data quality

The AI Innovation Challenge brought 360i to life by fostering AI solutions that digitize protocols, accelerate standards development, and enable traceability, transforming vision into real-world, scalable solutions.

THE 3 USE CASES

Use Case #1: Protocol Library

- **Objective:** Create a USDM-centric repository of study definitions by extracting legacy protocol content using AI/ML.
- **Submissions:** with 13 submissions, this was the most popular use case. Participants demonstrated intelligent extraction into USDM with user interfaces for searching and downloading structured study definitions.

Use Case #2: Biomedical Concept (BC) Acceleration

- **Objective:** Demonstrate how AI/ML can streamline BC development and curation by leveraging standards and data.
- **Submissions:** 5 strong submissions, each offering unique approaches to accelerating AI-based biomedical concept creation and curation.

Use Case #3: Automated Traceability

- **Objective:** Demonstrate semantic traceability from statistical analyses back to each data point's source and definition within the digital protocol using AI/ML.
- **Submissions:** with 4 compelling submissions, participants leveraged USDM, CDASH, SDTM, ADaM, BCs, and dataset specializations to visualize lineage and demonstrate how artifacts could be dynamically traced. As the most complex use case, it attracted sophisticated solutions.

CHALLENGE OUTCOMES & NEXT STEPS

- **Live Showcases:** Winners and runners-up presented their solutions at the CDISC US Interchange in Nashville, Tennessee (October 2025), providing the community with live demonstrations and Q&A opportunities.
- **COSA Invitation:** Open-source solution providers were invited to contribute their solutions to the CDISC Open-Source Alliance (COSA), accelerating community access to reference implementations.
- **Webinar Series:** Additional webinars are planned in 2026 to showcase solutions, share technical learnings, and facilitate broader adoption of AI + standards approaches across the industry.
- **Continued AI Innovation Challenges:** A new challenge aligned with CDISC 360i Phase 2 goals will be launched leading up to the CDISC EU Interchange in May.
- **Community Impact:** The Challenge served as a proof point for CDISC's role in enabling responsible, interoperable, and scalable AI adoption. Survey feedback confirmed 80% of respondents agreed CDISC standards effectively contributed to AI/ML acceleration.

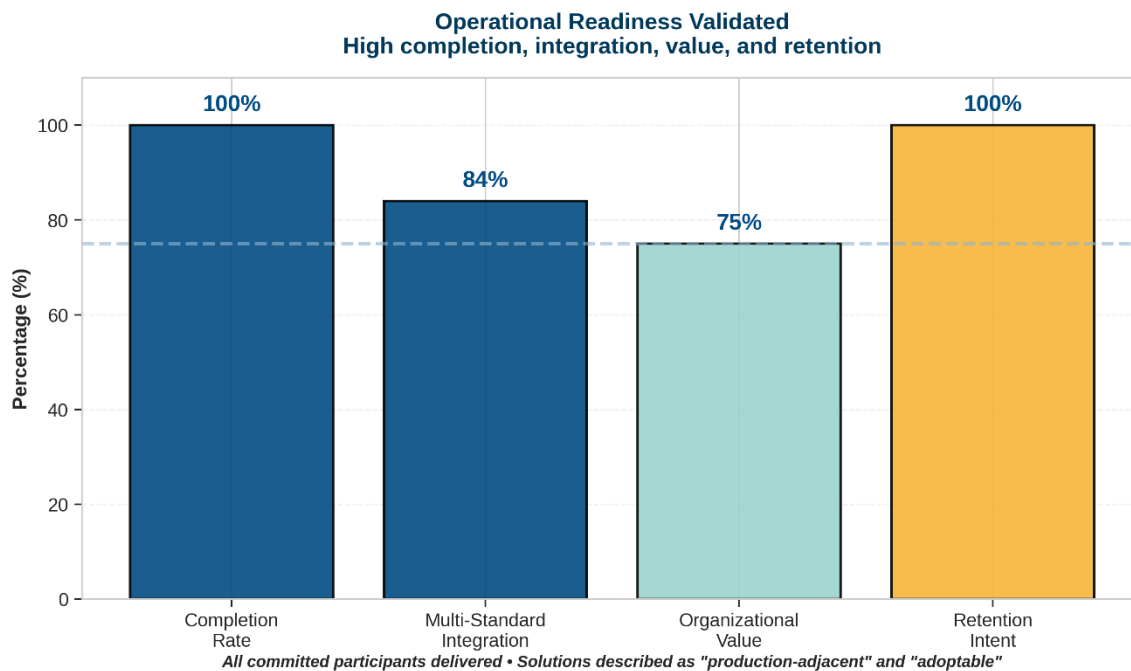
PART 2: SEVEN STRATEGIC INSIGHTS FROM SURVEY ANALYSIS

MEHTODOLOGY

Post-challenge surveys were distributed to all participants and judges. Response rates: 12 participants and 7 judges totaling 19 respondents. Surveys included quantitative (Likert scale 1-5) and qualitative (open-ended) questions covering satisfaction, effectiveness, standards engagement, organizational value, and future participation.

INSIGHT #1: OPERATIONAL READINESS VALIDATED

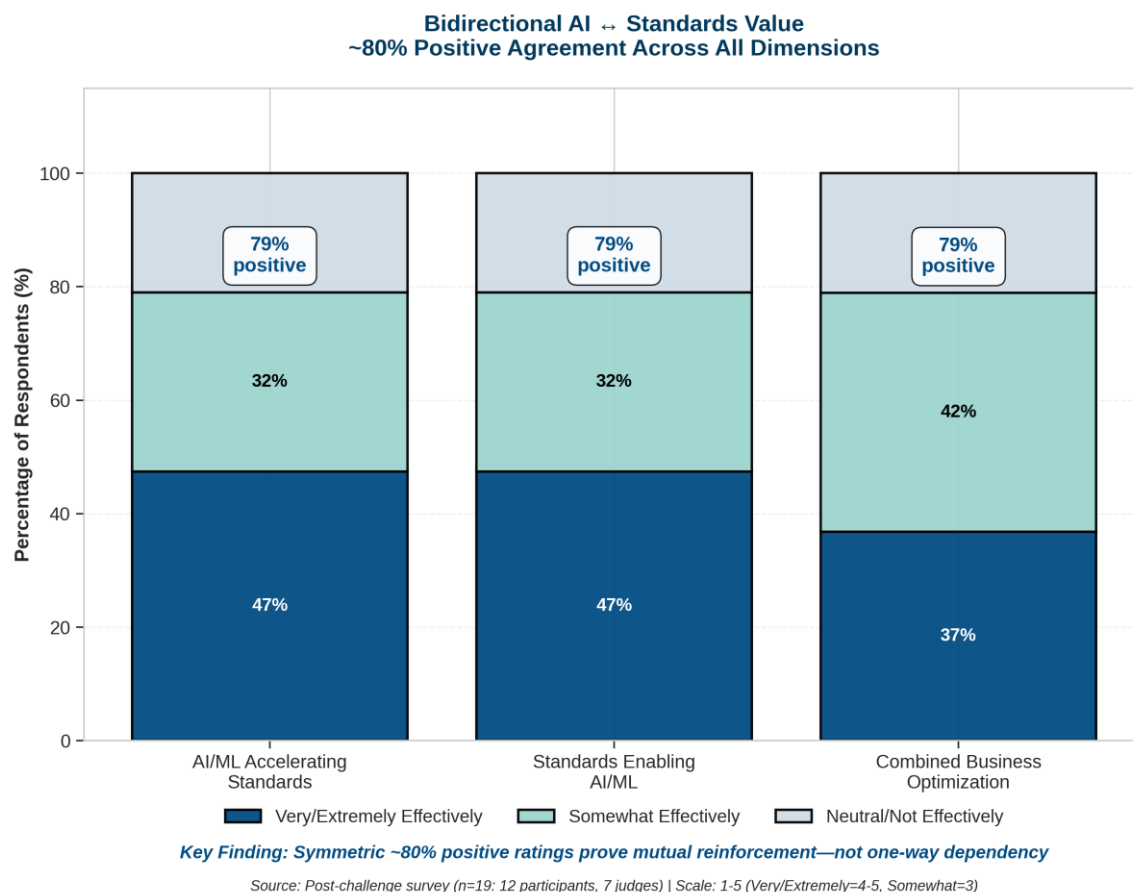
The Challenge demonstrated operational readiness, not proof-of-concept exploration. Of all participant surveys, 100% delivered solutions and some even tackled multiple use cases. These solutions were not merely prototypes, but many were described as “production-adjacent”, “adoptable”, and “realistic”. Participants and judges overall were very satisfied with the challenge process (90% satisfaction), as well as the use cases (100% satisfaction).



Strategic Implication: CDISC's role has shifted from proving feasibility to enabling adoption. The market is technically ready, but it is seeking governance frameworks, reference architectures, and validation patterns.

INSIGHT #2: BIDIRECTIONAL AI ↔ STANDARDS VALUE

Approximately 80% of respondents positively validated bidirectional value, rating both 'AI accelerating standards' and 'standards enabling AI' as effective. This symmetric agreement proves mutual reinforcement—better standards enable better AI, which drives better standards adoption, creating a virtuous cycle.



Participants consistently described this as a reinforcing cycle rather than a linear input-output relationship.

Participant perspectives:

- "CDISC standards provide the foundational structure that enables AI models to work effectively and responsibly with clinical data"
- "Having standard data is critical for good data feeding AI models"
- "CDISC Standards provided a clear framework for structuring clinical data, allowing AI and ML technologies to interpret and map information consistently"

As Prasanna Rao, Chief Products and Innovation Officer at Saama, articulated:

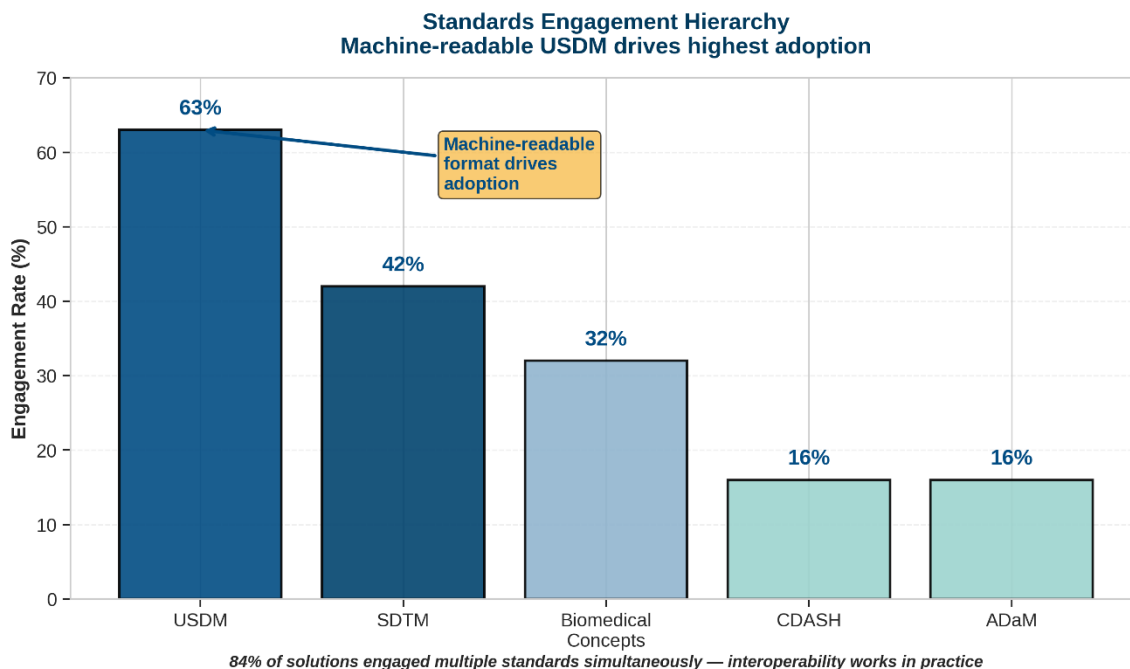
"The challenge isn't just adopting standards, but making them scalable for modern trial complexities. Saama's investment is focused on AI-driven enrichment, where our Agentic Frameworks turn static guidelines into dynamic tools. This creates a bi-directional flywheel that solves for data variability in real-time, ensuring that traceability and operability are prerequisites, not just afterthoughts."

Strategic Implication: Standards are not passive constraints but active AI amplifiers. This creates a flywheel model where better standards enable better AI, which accelerates standards adoption and refinement.

INSIGHT #3: EXECUTABLE STANDARDS DRIVE ADOPTION

AI adoption accelerates where standards are machine-readable and implementation-ready. 84% of solutions used multiple standards simultaneously, demonstrating that interoperability works in practice. USDM's 63% usage rate reflects its characteristics as an executable standard with a machine-readable JSON format, clear semantic model, defined relationships, a digital-first design, and implementation examples.

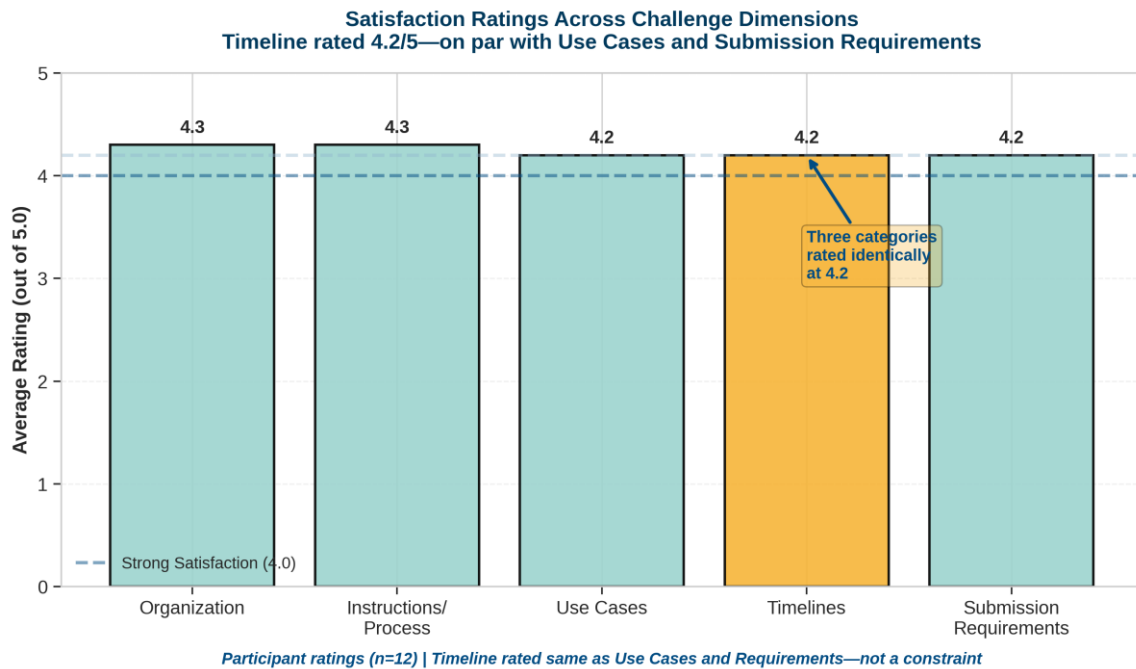
Participant feedback consistently emphasized "machine-readable," "structured," "automation-ready," and "clear framework for structuring clinical data." This pattern validates that Use Case 1 (Protocol Library) attracted 59% of submissions precisely because USDM provides the most mature, executable standard.



Strategic Implication: The 360i vision of digital, executable standards is not aspirational, it is the future for AI enablement. Where standards exist as PDFs requiring human interpretation, AI adoption stalls. Where standards provide machine-readable formats and clear semantic models, AI adoption accelerates.

INSIGHT #4: TIMELINE SIGNALS AMBITION

Timeline satisfaction rated 4.2/5 (strong but slightly lower than other categories). Qualitative feedback revealed participants wanted "more time" not because deadlines were unfair, but because they had "more features to build" and "deeper exploration" they wanted to pursue. One participant noted "difficult summer timing."



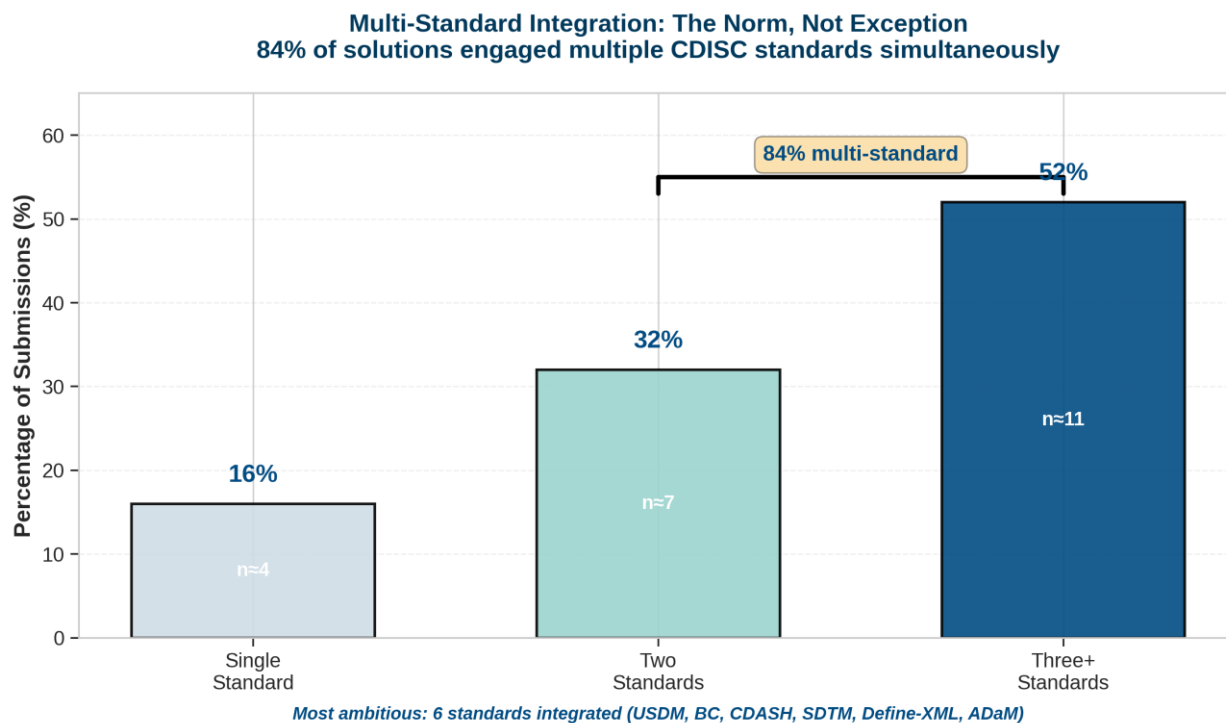
Strategic Implication: CDISC should scale scope and duration to match participant ambition, recognizing that the limiting factor is no longer participant capacity but CDISC's ability to support and evaluate complex submissions.

INSIGHT #5: AI PROVES MULTI-STANDARD INTEROPERABILITY

84% of solutions engaged multiple CDISC standards simultaneously, with some integrating 5-6 standards. AI successfully navigates complex cross-standard relationships—proving interoperability isn't just theoretical, it's operational.

The most ambitious submissions demonstrated end-to-end integration across the entire data lifecycle. *"Zifo is proud to have contributed to this landmark CDISC AI initiative. 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),"* noted Deepak Ananthan, VP Clinical Services at Zifo. *"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."*

This represents a fundamental shift in how the industry approaches standards implementation. Rather than treating each standard as an isolated specification, participants demonstrated that AI can understand and maintain relationships between standards, enabling true downstream automation from protocol to submission.



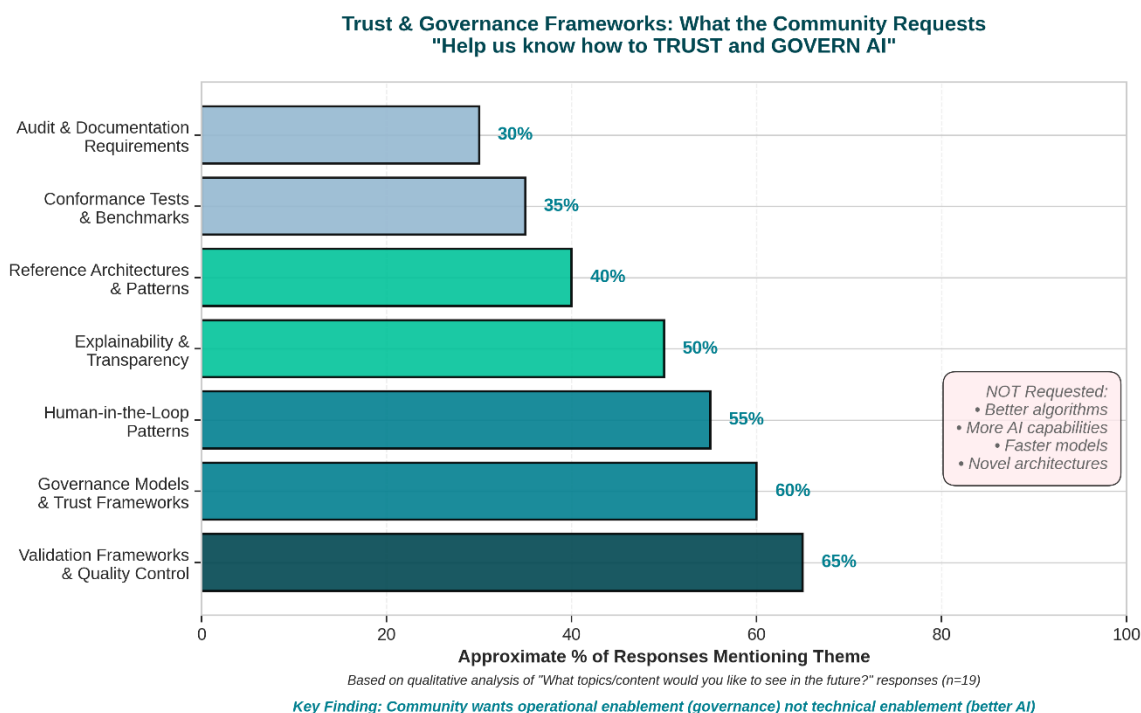
Strategic Implication: Cross-standard integration capabilities and reference architectures that show how standards connect should be prioritized going forward, not just showing how each standard works independently.

INSIGHT #6: TRUST FRAMEWORKS EXPLICITLY REQUESTED

The most consistent "what's next" requests centered on validation patterns, quality control approaches, governance models, and human-in-the-loop frameworks. Better algorithms, more AI capabilities, faster models, and novel architectures were not requested. The message is clear: Help us know how to trust and govern AI, not how to build it.

This sentiment was echoed by challenge winners: *"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,"* noted Vivian DeWoskin, Chief Commercial Officer at Faro, UC1 winner.

This represents a fundamental shift from feasibility to operationalization—the community has moved past "can we do this?" to "how do we do this responsibly?"

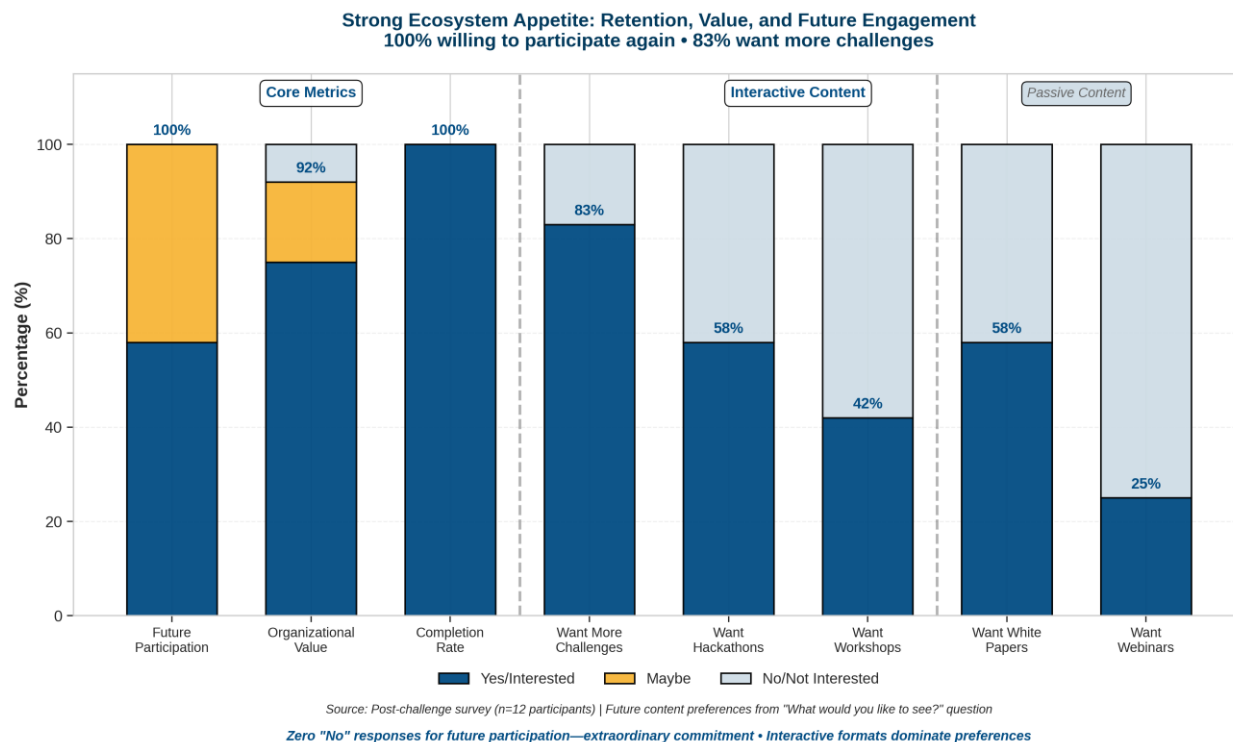


Strategic Implication: CDISC should consider collaborating through a cross-industry group for AI governance in clinical research by publishing practical trust frameworks that answer, "how do we know this AI is good enough?" rather than "how do we build better AI."

INSIGHT #7: CHALLENGE CATALYZED ORGANIZATIONAL CHANGE

75% of respondents confirmed organizational value, with high ratings for these challenge submissions contributing to their organizational goals (92%), influencing their product roadmaps (92%), and 100% willingness to participate in a future challenge (74% 'Yes', 26% 'Maybe').

Further, future content preferences heavily favor interactive formats: 83% want more challenges, 58% want hackathons, 42% want workshops, but only 25% want webinars. Qualitative feedback emphasized "learning," "mindset shifts," "reframing standards," "professional growth," and "cross-industry collaboration." The challenge functioned as a community-building mechanism and capability development program, not just a competition.



Strategic Implication: CDISC should consider holding regular "challenges" and other interactive, hands-on events to enhance community engagement and capability development, recognizing that these formats deliver far greater ecosystem value than passive content delivery.

CONCLUSION

The CDISC AI Innovation Challenge validated a fundamental industry transition: from *Can we do AI with standards?* to *How do we do it right and at scale?* This represents CDISC's evolution from proving value to enabling adoption.

The data reveals that operational readiness is validated, bidirectional value is real, executable standards drive adoption, the ecosystem appetite is strong, and trust frameworks are needed (community requests governance, not algorithms).

Winners and runners-up showcased their solutions at CDISC US Interchange, open-source providers were invited to COSA, and additional webinars will share learnings across the community. These outcomes transform the Challenge from a one-time event into an ongoing catalyst for AI + standards innovation.

The opportunity for the CDISC community is clear: provide the governance frameworks, validation patterns, and reference architectures the ecosystem explicitly requests. Success means AI + standards solutions become routine, trusted, and scalable, with CDISC frameworks making that possible.

ACKNOWLEDGMENTS

The CDISC AI Innovation Challenge would not have been possible without the extraordinary commitment and expertise of our participants and judges. This analysis draws upon insights from 22 submissions across three use cases, representing months of dedicated effort from innovative teams worldwide.

CHALLENGE PARTICIPANTS

We extend our deepest gratitude to all challenge participants who invested significant time and creativity into developing innovative AI solutions that demonstrate the power of standards-driven innovation. Your willingness to share not only your solutions but also your candid feedback has been instrumental in shaping both this analysis and the future direction of AI+standards innovation at CDISC. The survey response rate and extraordinary retention intent speaks to the collaborative spirit of this community.

CHALLENGE JUDGES

We are equally grateful to our expert judges who volunteered their time and expertise to evaluate submissions across three demanding use cases. Your thoughtful evaluation, constructive feedback, and strategic insights helped identify not only the winning solutions but also the broader patterns that have informed our understanding of where the industry stands in AI+standards maturity.

SPECIAL RECOGNITION

We particularly thank Prasanna Rao, Chief Products and Innovation Officer at Saama, for articulating the bi-directional flywheel between AI and standards. His perspective on operationalizing standards through AI-driven enrichment underscores the importance of scalability and real-time traceability in modern clinical research.

We also extend special recognition to Deepak Ananthan, VP Clinical Services at Zifo, for articulating the vision of end-to-end, AI-enabled clinical data pipelines. His perspective on multi-standard integration exemplifies the ambitious cross-standard thinking that characterized the most successful challenge submissions and points toward the future of standards-driven automation from protocol to submission.

We further acknowledge Vivian DeWoskin of Faro Health for contributing insights that capture the fundamental shift from "building AI" to "governing AI", a theme that emerged consistently across our analysis and reflects the growing maturity of the AI+standards ecosystem.

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