360i Roundtable Discussion

Agenda

1. Overview of the Roundtable Topics (15 min)
2. Breakout and Roundtable Discussions (40 min)
3. Each Group Summarize their Feedback (10 min)
4. Readout from each Group (25 min)

Roundtable Goal and Topics

Goal: To provide an open and collaborative forum for CDISC community to share perspectives, exchange ideas, and explore solutions on a range of topics for 360i, with the aim of fostering stronger engagement, enhancing community impact, and identifying actionable steps for future work

TOPICS:

- Identifying the Value Proposition and Elevator Pitch for Connected Standards
- Understand and Accelerate Development and Use of Biomedical Concepts
- Understanding, Developing, and Leveraging Analysis Concepts
- Accelerating Tool Development to Enable Digital Standards
- Leverage AI to help develop and use the Connected Standards

Identifying the Value Proposition and Elevator Pitch for Connected Standards

Facilitator: Chris Decker

Scribe: Sabine Zimmer

Future CDISC Standards provide the foundation to reinvent the development process and enable automation

Accelerates Clinical Study Start-Up & Reduces Time to Insight

- Automated workflows and error prone tasks results in moving from **months long setup to streamlined processes** in weeks
- Faster, machine-readable digital study information **improves speed and accuracy**,

Drives Quality & Consistency Across the Data Lifecycle

- Standards driven automation **ensures clinical data is consistent, traceable, and reusable**
- Real-time, embedded validation **reduces risk of costly errors and regulatory compliance issues**

Enables Seamless Interoperability & Future-Proofed Data Ecosystem

- Connected protocol to analysis standards in a single framework **empowers industry for greater interoperability**
- Supports growing complexity of trials with **scalable and future-ready data architectures** based on connected standard

Improves Stakeholder Engagement & Regulatory Compliance

- **Industry benefits from faster & smarter study designs**, improved cross-functional alignment, and a streamlined data flow
- Regulatory agencies **receive more consistent, high-quality 'clickable' data submissions**

CDISC 360i Elevator Pitch…

CDISC 360i is transforming clinical research by digitizing study design and making metadata interoperable across the entire study lifecycle. With reusable standards and end-to-end automation, 360i eliminates manual tasks, increases data quality, enables AI, ensures traceability and consistency, and empowers the industry to deliver clinical trial results faster, more efficiently, and at a lower cost streamlining the data flow and accelerating the delivery of new therapies to patients.

Roundtable Discussion Questions

- Who are the key stakeholder groups to whom we need to provide the message?
- What are the 2-3 key messages those stakeholders want to hear? (*How is the message different across these stakeholders?*)
- What is missing in helping your management understand the value proposition of E2E connected standards?

Accelerate Development and Operationalization of Biomedical Concepts

Facilitator: Bess LeRoy

Scribe: Erin Muhlbradt

Biomedical Concepts

Part of the overarching CDISC vision enabling **connected standards**

Facilitates **accurate** and **more consistent implementation** by reducing unnecessary variability

Facilitates **metadata-driven automation**

Increases **quality and efficiency** throughout end-to-end study delivery process

Enables **data reuse**

Round Table Discussion Questions

- CDISC has presented the case for “Why Biomedical Concepts” over the past several years, however, some stakeholders are still reluctant to adopt this approach. How does CDISC promote adoption?

- Until this point, Biomedical Concepts have been developed by a small curation team. How do we scale the development of Biomedical Concepts without having content thrown “over the wall” to developers?

- Biomedical Concepts can be retrieved from the CDISC Library or through downloadable spreadsheets. Without tools, there can be a barrier to adoption. What can CDISC do to help organizations operationalize Biomedical Concepts?

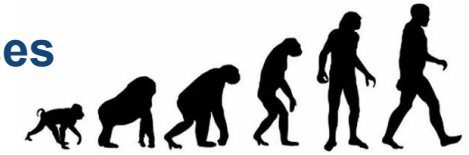
Understanding, Developing, and Leveraging Analysis Concepts

Facilitator: Peter Van Reusel

Scribe: Edwin Van Stein

Analysis Concepts – Elevator Pitch

Missing link: structured metadata for describing analyses



Analysis Concepts aim to fill this gap:

- Framework for expressing clinical questions > analysis data and results
- Support the creation of a digital Statistical Analysis Plan (eSAP)
- Inform programming logic for analyses

Analysis Concepts cover:

- Handling of subject-level data prior to analysis (from SDTM to ADaM)
- Analysis and creation of non-subject-level date (from ADaM to ARS)

Goals: interchange, automation and reuse of analyses, reduced ambiguity, increased traceability and streamlined collaboration

Roundtable Questions

- How do you believe standardizing analysis concepts will help us advance automation and traceability?
- What is the level of granularity we should define analyses while maintaining flexibility for the sciences?
- At what level should we stop defining standards and only provide a framework? Conceptual layer vs. implementation layer
- How do we make this understandable for a broad audience? Extending USDM to include everything or smaller standards that refer to each other?
- How do we encourage the community to engage in this topic?
- What education can we provide to help inform different stakeholders?

Accelerating Tool Development to Enable Digital Standards

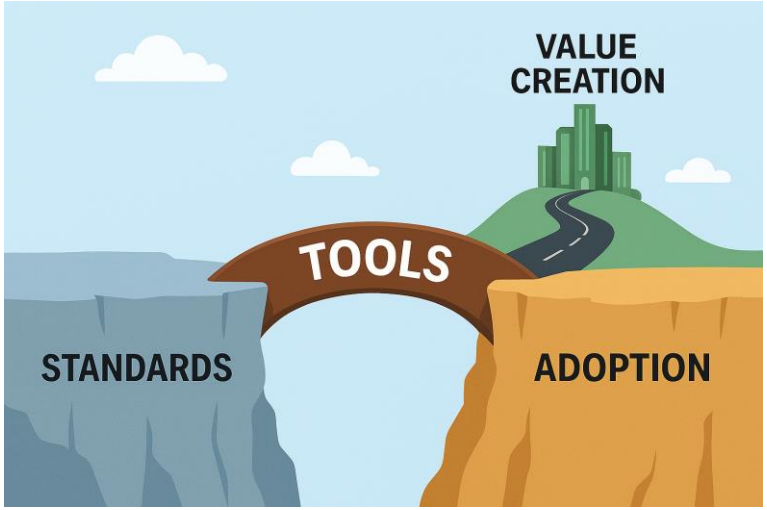
Facilitator: Darren Moreland

Scribe: Charles Shadle

Accelerating Tool Development: Enabling Connected Standards

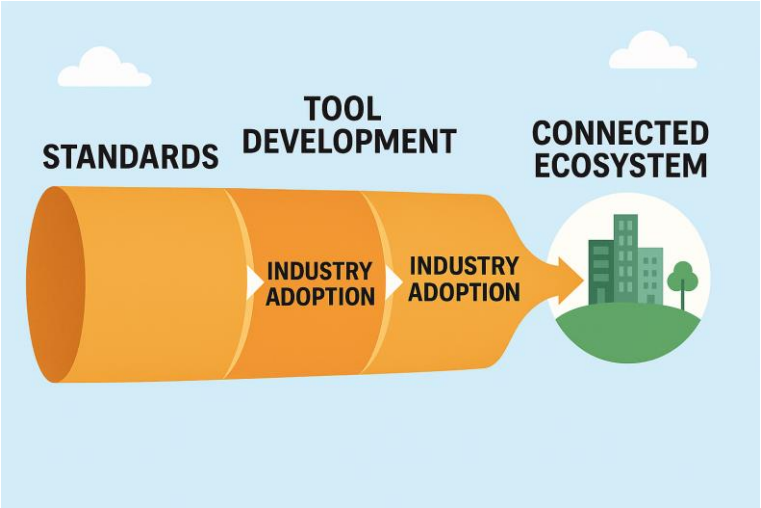
- Tools are the backbone for implementing and scaling connected standard
- Without robust tooling, adoption and interoperability slow down

- **Goal**: Identify strategies to accelerate tool creation and engagement



Accelerating Tool Development: Why it matters

- Challenges:
  - Fragmented ecosystem of tools
  - Limited incentives for open-source contributions
  - High development cost vs unclear ROI
- Opportunities:
  - Shared tooling reduces duplication
  - Open-source accelerates innovation
  - Community-driven development ensures relevance



Questions

- Current State & Gaps
  - How much does your organization use open-source tools within your operational work?
- Incentives & Engagement
  - How do we incentivize companies and individuals to develop open tools for standards?
- Collaboration & Governance
  - How do we ensure interoperability and avoid tool fragmentation?
- Adoption & Impact
  - How can we encourage community engagement and adoption?
- Community Education & Collaboration
  - How to best inform stakeholders and encourage collaboration?

How can we leverage AI to help drive standards?

Facilitator: Julie Smiley

Scribe: Dianna DiRusso

How Can We Leverage AI to Help Drive Standards?

- The industry is generating data faster than ever, but standards adoption and implementation often lag behind or are perceived as only needed when required for submissions.
- AI and automation can help close that gap from interpreting protocols to harmonizing study metadata and even producing submission artifacts.
- **Goal**: Explore how AI can accelerate the creation, application, and evolution of CDISC standards responsibly, transparently, and collaboratively.

How can AI augment, not replace our role in developing, maintaining, and applying data standards?

CDISC 360i – What we are doing with AI

- AI Innovation Challenge: Invited innovators to build AI/ML solutions that use or accelerate CDISC standards.
  - Use cases included: USDM-centric protocol repositories, Biomedical Concept acceleration, and reverse mapping from analysis to collection.
  - Winners and runners-up presented at the Innovation Showcase on Monday afternoon
- AI in Standards Development: Exploring NLP and generative models for automating rule generation, metadata extraction, and mapping and transformation across standards.
- AI + Standards in Practice: Assessing how AI can assist in conformance, study design automation, and transformation between data models.
- Goal: Build a framework for how AI can safely and transparently assist in standards-driven automation without compromising governance or neutrality.

Discussion Questions

- Theme 1 – Driving Efficiency (10 min)
  - Where can AI most effectively reduce manual effort in standards development or implementation?
  - What tasks should remain human-led to ensure quality, context, and trust?
- Theme 2 – Ensuring Quality & Transparency (10 min)
  - How do we maintain traceability and explainability when AI is used in standards development?
  - How can AI tools help validate adherence to standards rather than create bias or drift?
- Theme 3 – Industry Readiness & Collaboration (15 min)
  - What are the biggest barriers to AI adoption in standards-driven workflows today (technical, cultural, regulatory)?
  - How can CDISC and the broader community work together to responsibly pilot and share AI learnings?

Breakout Group Logistics

Roundtable Next Steps

- We'll now break into the following groups. Join the one of interest to you.
  - Identifying the Value Proposition and Elevator Pitch for Connected Standards
  - Understand and Accelerate Development and Use of Biomedical Concepts
  - Understanding, Developing, and Leveraging Analysis Concepts
  - Accelerating Tool Development to Enable Digital Standards
  - Leverage AI to help develop and use the Connected Standards
- There are signs around the room identifying the location of each group
- Join the group and start chatting!
- We'll have 40-45 minutes of discussion
- Will regroup after for an informal readout of the group discussions
- GO AND COLLABORATE!

Summary of Breakout Sessions

Topic: Identifying the Value Proposition and Elevator Pitch for Connected Standards

Key Messages:

- Text

Opportunities:

- Text

Challenges:

- Text

Topic: Understand and Accelerate Development and Use of Biomedical Concepts

Key Messages:

- Text

Opportunities:

- Text

Challenges:

- Text

Topic: Understanding, Developing, and Leveraging Analysis Concepts

Key Messages:

- Text

Opportunities:

- Text

Challenges:

- Text

Topic: Accelerating Tool Development to Enable Digital Standards

Key Messages:

- Text

Opportunities:

- Text

Challenges:

- Text

Topic: Leverage AI to help develop and use the Connected Standards

Key Messages:

- Text

Opportunities:

- Text

Challenges:

- Text