The AI Imperative: Accelerating the Pace of Standards Development

Presented by Sarah Jamal, Strategic Client Advisor,
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Meet the Speaker

Sarah Jamal

Title: Strategic Client Advisor

Organization: Oracle Health and Life Sciences

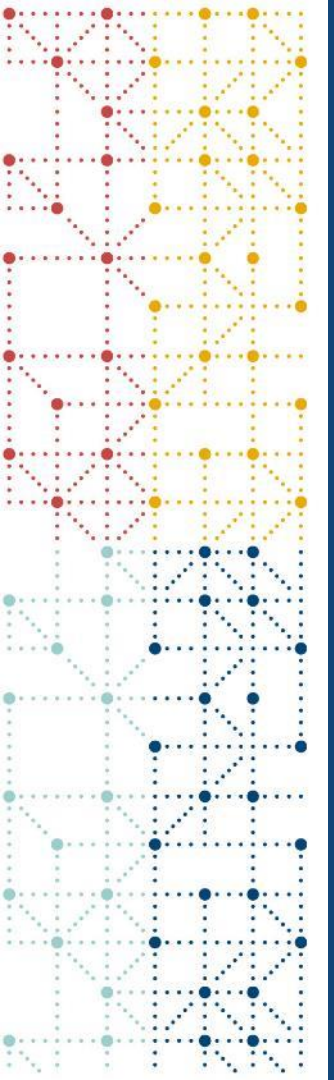
Sarah started her career in Clinical Data Management where she learnt CDISC standards by building CDASH libraries and validating SDTM datasets. For the past 5 years, she has leveraged this expertise at Oracle to deliver demonstrations, proposals and presentations to Life Sciences customers. As the current representative of Oracle's CDISC membership, she is involved in moving forward collaboration initiatives, promoting standards internally, and advocating for Oracle's presence at CDISC events globally.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. Challenge & Opportunity
2. What Can Be Done?
3. How Can It Be Done?
4. Key Takeaways

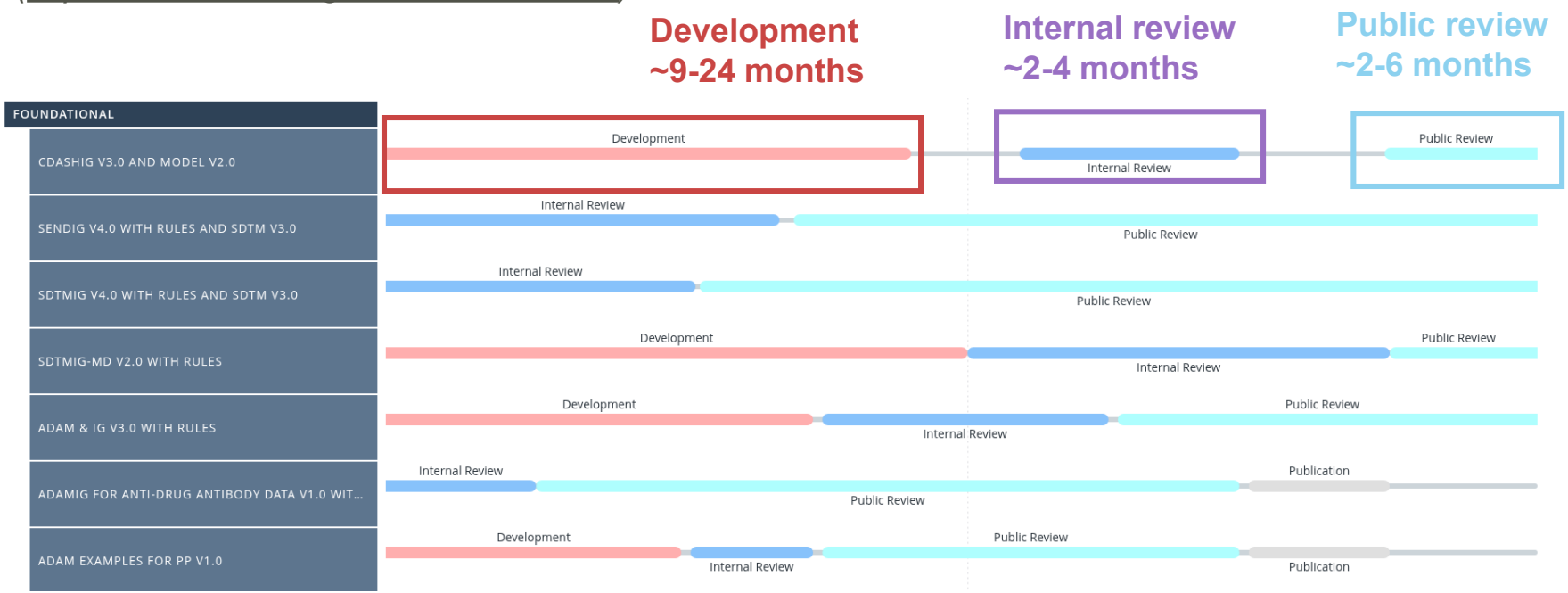


Challenge & Opportunity

The critical juncture

Currently, standards are developed through lengthy manual processes

*CDISC **timeline** for CDISC Foundational Standards in development, updated quarterly (https://www.cdisc.org/standards/timeline)*



The critical juncture

Challenge:

Standards development is lengthy and laborious

Opportunity:

Compute power to analyze billions of data points in minutes;

Intelligence to generate content

How do YOU see it

Quick round of 'show of hands'

1. (Raise your hand if) **You believe data standards development can become a bottleneck in clinical research**

2. (Raise your hand if) **You believe AI can accelerate the pace of standards development**

3. (Keep your hand raised if) **You believe AI can accelerate the pace of standards development without compromising its quality**

A perfect example of the critical juncture

Between the call for abstracts and the Interchange, this happened:

CDISC AI Innovation Challenge

Use Case 1: Protocol Library	Use Case 2: Biomedical Concepts Acceleration	Use Case 3: Automated Traceability
Build a USDM-centric repository of study definitions from existing protocols	**Accelerate development of biomedical concepts to drive CDISC transformation and automation**	Semantic traceability from analysis back to study design

What Can Be Done?

A few use cases

- Closing gaps in **controlled terminology**
- Developing new **therapeutic area user guides**
- Enhancing **SDTM domains**
- Automating **cross-standard mapping**

AI-powered review to close gaps in controlled terminology

Current state

- Manual request by users through submission form
- Manual review by volunteer team of experts
- Development and publication carried in spreadsheet-like document
- Publication of new terminology typically done quarterly

Strategic Direction

- AI-powered gap analysis to identify missing terminology
- Rule-based automated review of new suggested terms
- Human-in-the-loop through a final manual review of AI outputs

Fast forwarding the development of new therapeutic area user guides

Current state

- New TAUG project kick-off meetings with SME to identify variables, CT, etc
- Content is drafted in word-like documents, which go through public review cycles

Strategic Direction

- Use GenAI to get a preliminary draft of new TAUGs, based on BCs and TA-specific literature
- SMEs review scope and proposed examples, and request iterations where needed
- Final SME review, followed by public review

Smart enhancing and creation of SDTM domains

Current state

- Manual check of existing domains for new or non-standard data types
- Existing domains are regularly reviewed and updated to provide greater clarity
- New domains require thorough review of protocols, CRFs and current SDTM domains.
- Development of corresponding Implementation Guide

Strategic Direction

- AI can suggest appropriate domain for new variables based on its metadata.
- AI can propose a new domains' structure, based on patterns from existing domains and for variables that do not fit existing domains.
- Human experts can go from AI-suggested content

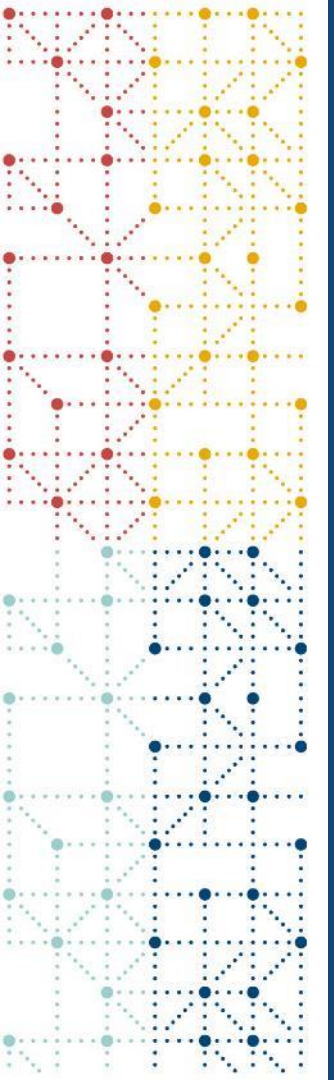
Expediting cross-standard mapping for continuous consistency

Current state

- Small group of experts with deep knowledge of both standards
- One-to-one mappings between standards
- Mappings are static snapshots in time

Strategic Direction

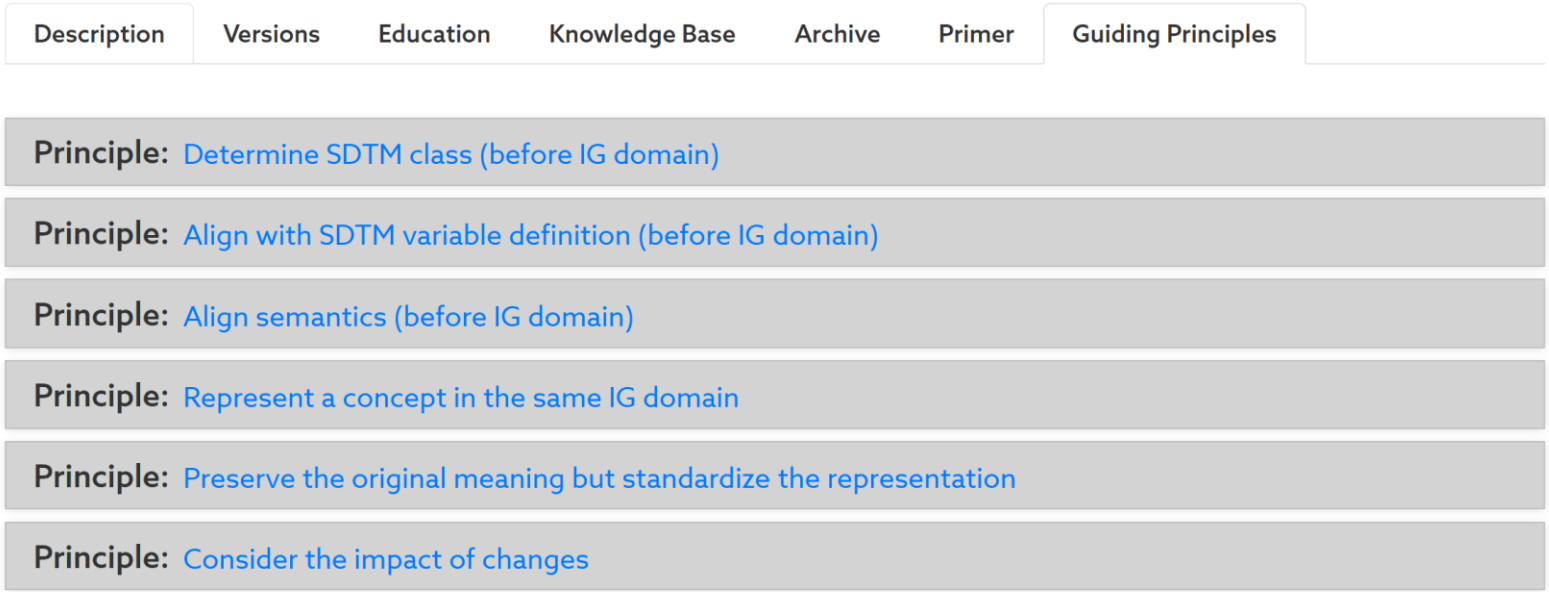
- Intelligent mapping, based on AI matched concepts
- Rule-based consistency check and flagging of complex mapping for human review
- Final review by expert



How Can It Be Done?

CDISC has well established processes that can serve as the foundational steps

*Example of **guiding principles** for SDTM (https://www.cdisc.org/standards/foundational/sdtm; all guiding principles here: https://www.cdisc.org/guiding-principles)*



The right ingredients to make it work

Outlining measurable **business goals**

- Address a need, *e.g. accelerate new TAUG development*
- Define measurable KPIs (quantitative or qualitative) for each goal, *e.g. reduce time for new TAUG first draft in 70%*

Upskilling with the **right expertise**

- Create an AI-expert team of volunteers

Choosing the **optimal methodology**

- Rule-based automation vs Machine Learning models vs Generative AI (incld. RAG)

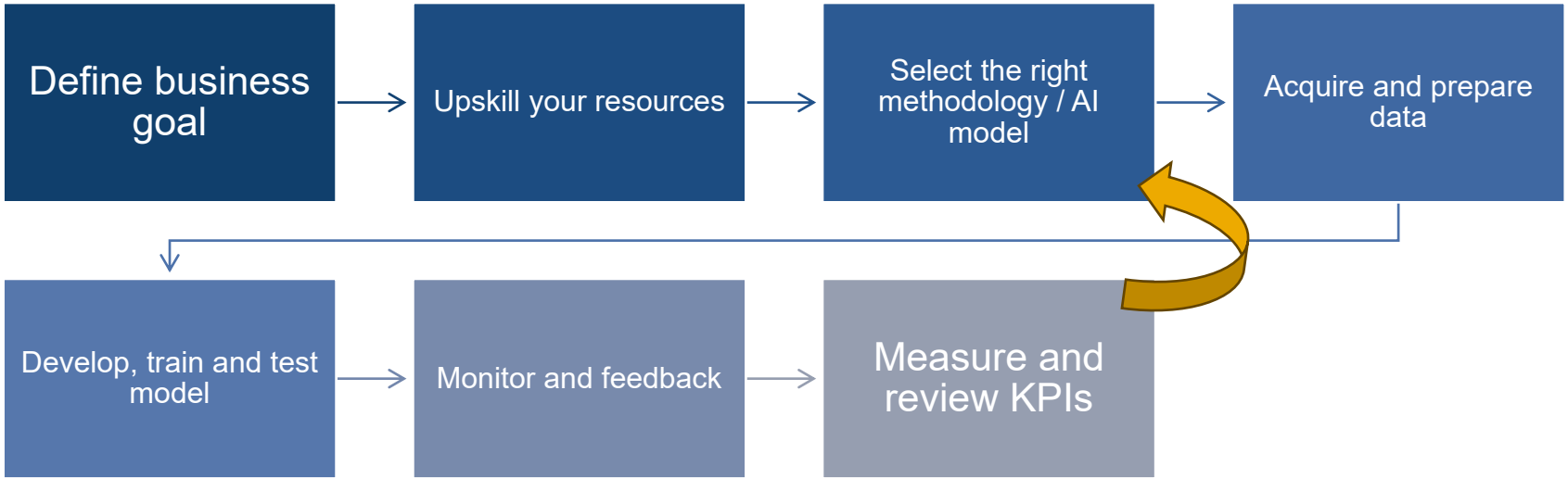
Finding the **right (meta)data**

- CDISC foundational standards, including implementation guides, and other recognized standards and ontologies, *e.g. HL7, MedDRA*
- Other reliable literature sources, *e.g. publications on PubMED and information from professional medical societies*

Looping in **risk management**

- Quality over quantity – start 'small'

The right steps to make it successful and sustainable



The ideal future state leverages an orchestrated AI agentic system

Artificially generated image, with Deep AI's 3d cartoon generator model.
Prompt: "team of AI agents working together in a library"

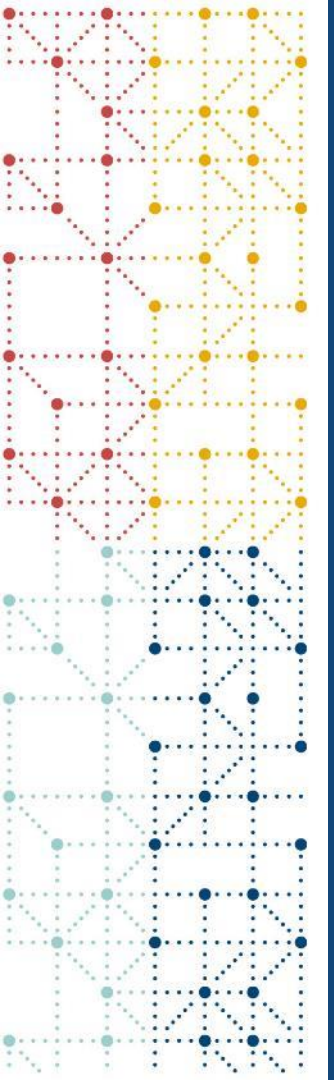
Imagine if…

What it looks like

- Goal-oriented & connected agents
- Real-time monitoring of relevant sources

What it unlocks

- Standards frequently updated
- Consistency across all CDISC & third-party standards



Key Takeaways

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LIFE SCIENCES

Accelerate and optimize legacy processes

CDISC COMMUNITY

Amplifying the work of CDISC volunteer experts

Measurable goals,

right methodology,

right expertise

right data,

& risk mngmt.

Thank You!

Reach me through https://www.linkedin.com/in/sarahkochjamal/

Let’s help the CDISC community to continue to serve Life Sciences at a fast pace!