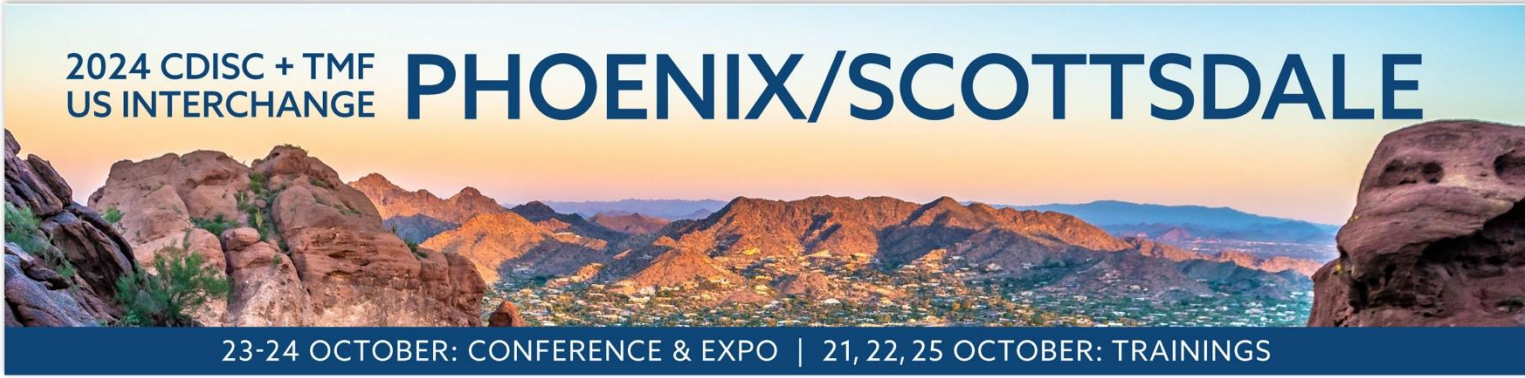


Embracing Metadata Management with Artificial Intelligence

Presented by Prasoon Sangwan, Program Manager, TATA Consultancy Services
Mayank Bhatia, Portfolio Head, TATA Consultancy Services

Meet the Speakers

Prasoon Sangwan

Title: Program Director

Organization: Tata Consultancy Services

Prasoon Sangwan has over 17 years of experience in clinical domain. She has led major clinical transformation programs like SDTM & ADaM automation, RBQM, safety monitoring and reporting, and protocol digitization initiatives. She has authored multiple papers in clinical space along with a book on SAS Grid. She also holds a patent on high performance computing environment

Mayank Bhatia

Title: Head of Product Strategy and Management

Organization: Tata Consultancy Services

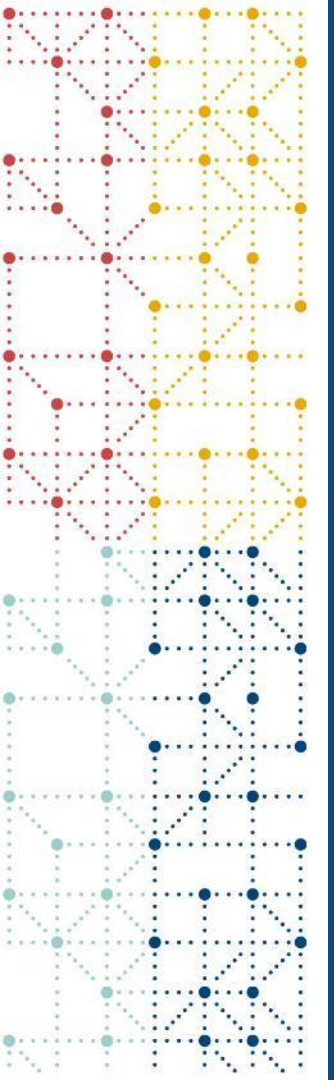
Mayank has more than 22 years of experience in clinical domain. His expertise span across building products, leading cross functional teams, bringing operational excellence, and driving change for transformational programs to bring efficiency at scale. Successfully led and delivered many large scale and highly critical transformational programs

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.*

Agenda

1. Data Standards Governance
2. Metadata Discovery
3. Connecting Disintegrated Standards
4. AI Enabled SDTM Generation
5. Conclusion



Data Standards Governance

Data Standards maintenance scope and objectives

Data Standards Governance

Study Design Standards

- Study Definition Standards*

Data Acquisition Standards

- CRF Elements
- Non- CRF Elements
- Data Verification rule
- Data collection Instructions

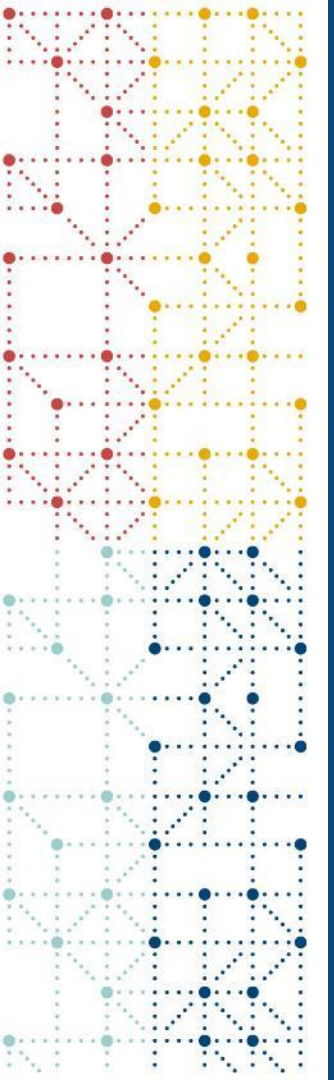
Analysis Standards

- SDTM Domain & Variables
- ADaM Datasets & Variables
- Analysis Results Standards

Terminology

Controlled Terminology, Glossary, Reference data

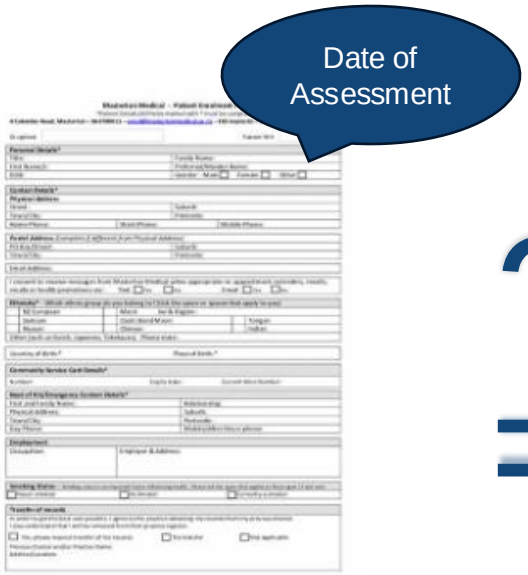
*Early evolution phase



Metadata Discovery

Ensuring Accurate and consistent metadata using AI

Same or Different?



CRF1

?

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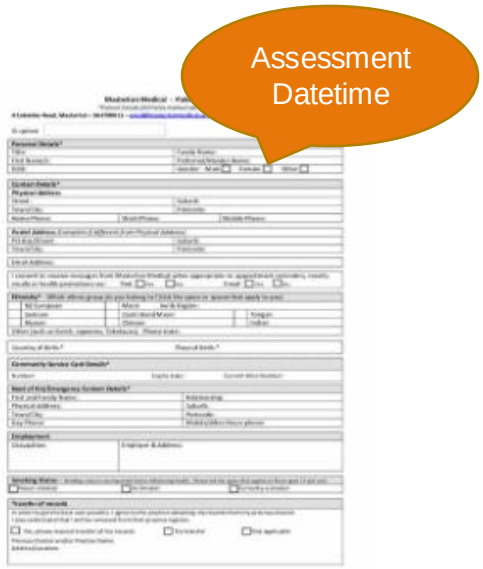
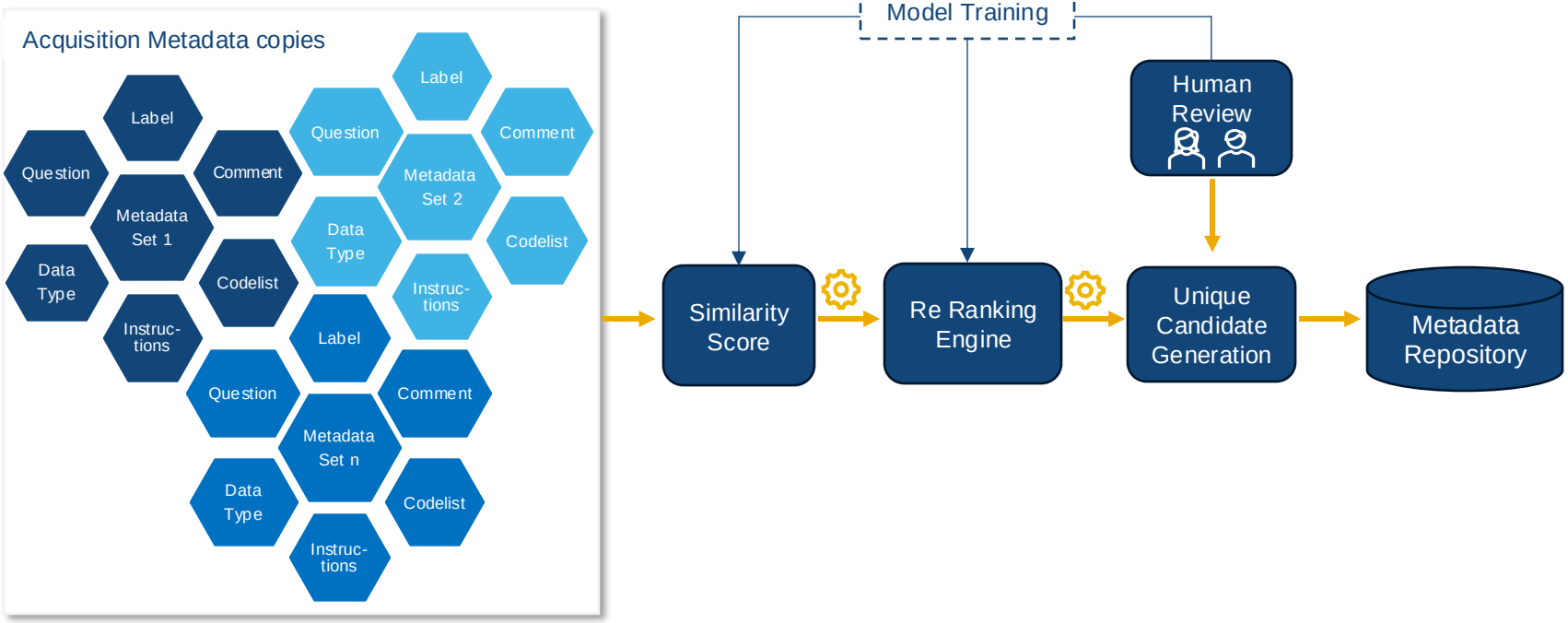
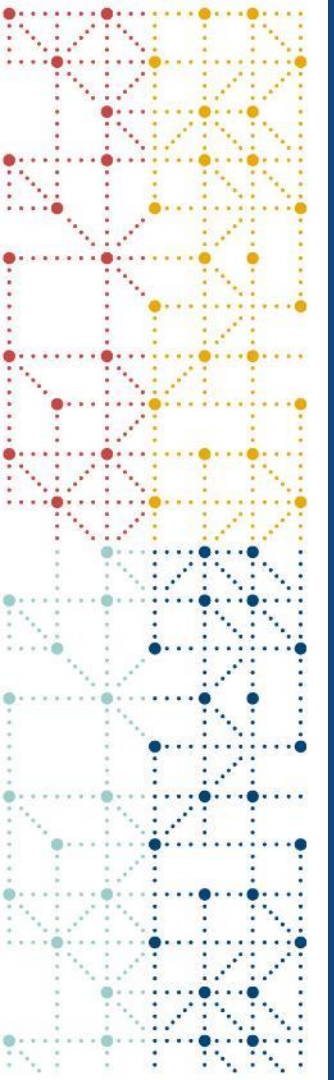


CRF2

Building Metadata Repository with AI

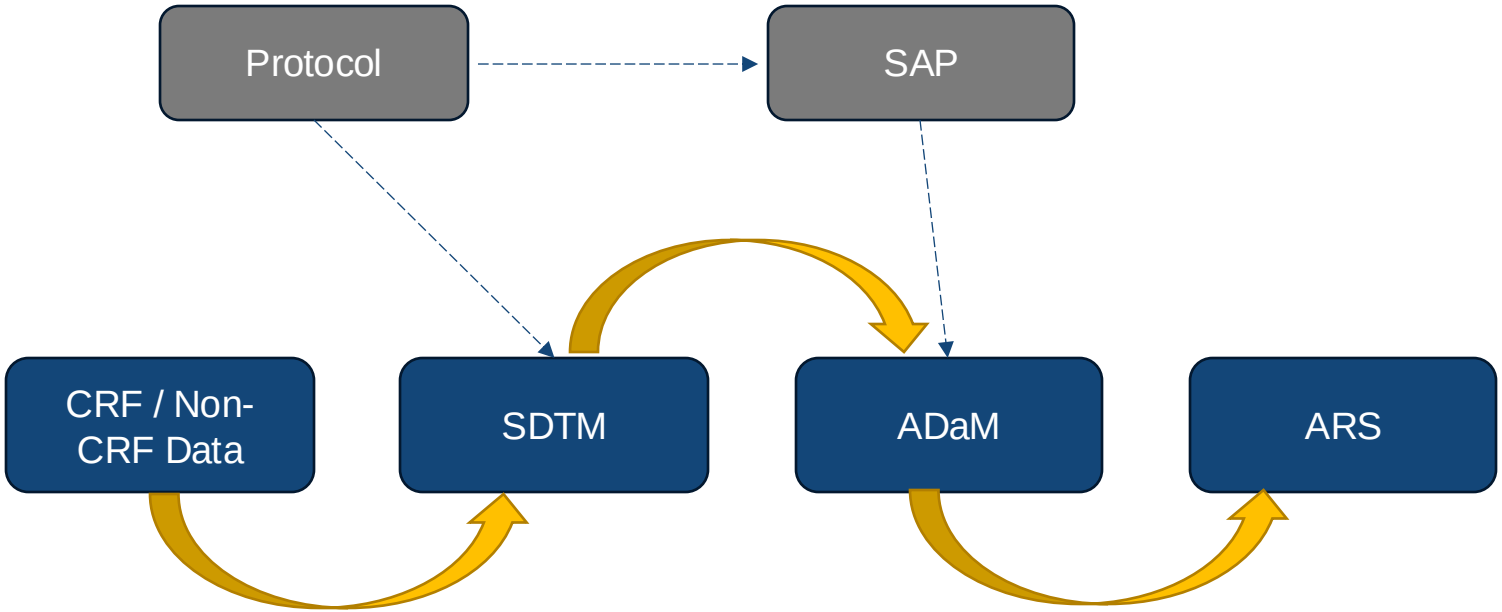




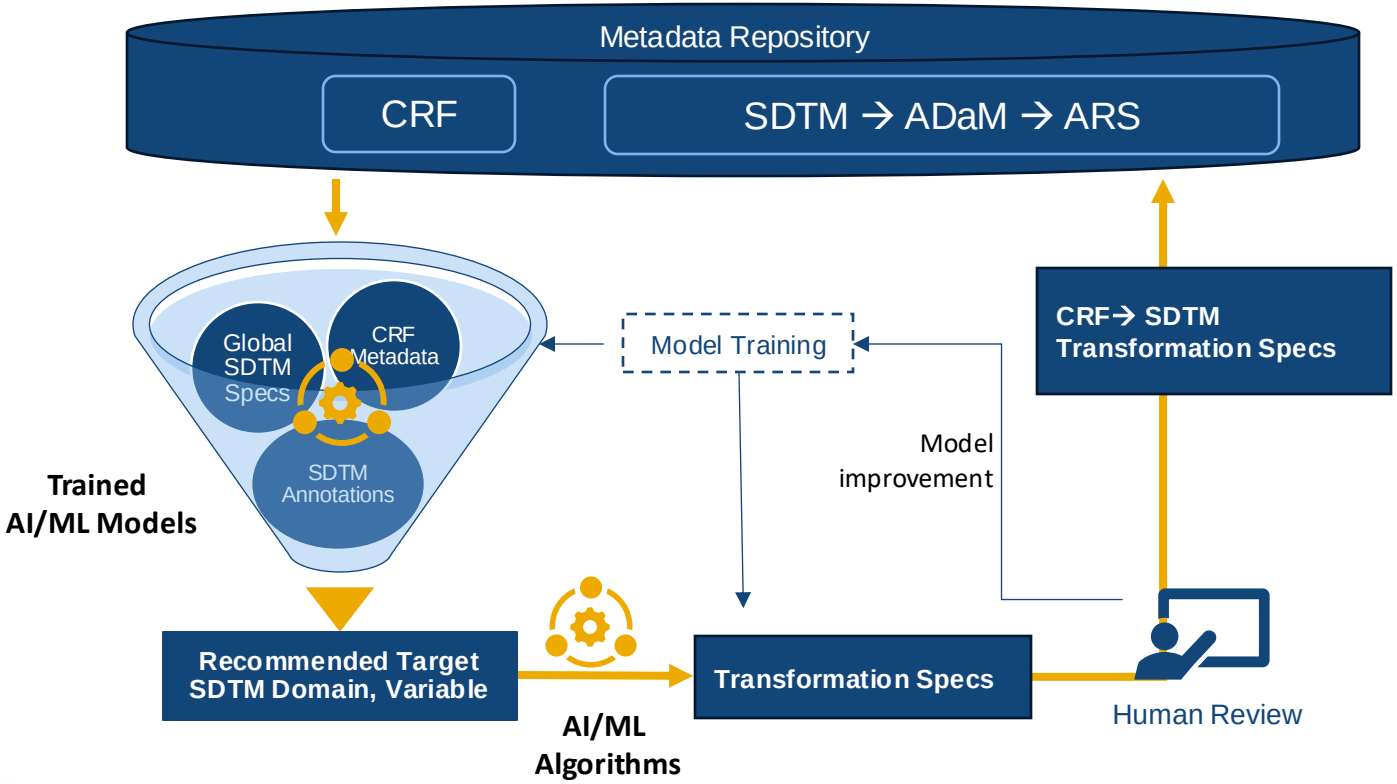
Connecting Disintegrated Standards

Generating End to End Lineage with AI

Are your standards connected?

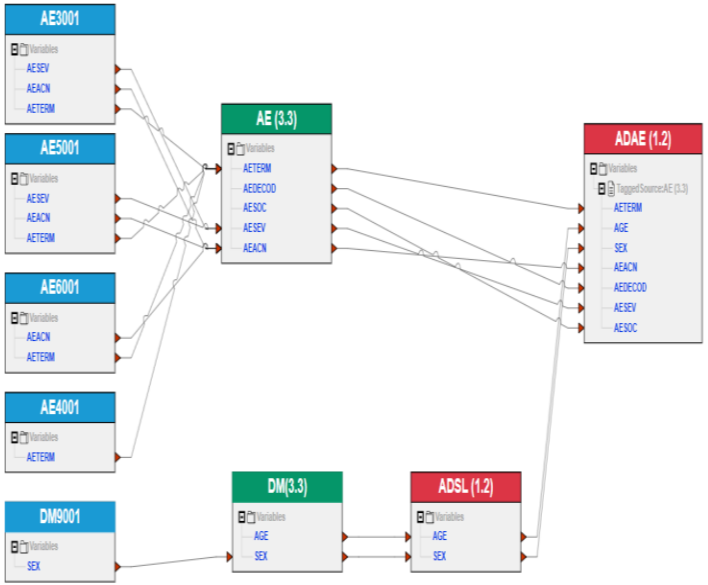


AI enabled End-to-End Lineage

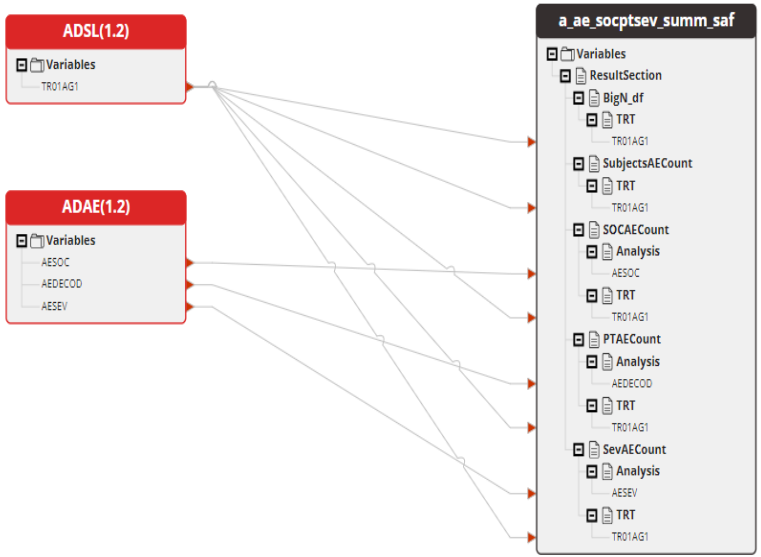


Traceability Snapshot from MDR

Forms → SDTM → ADaM

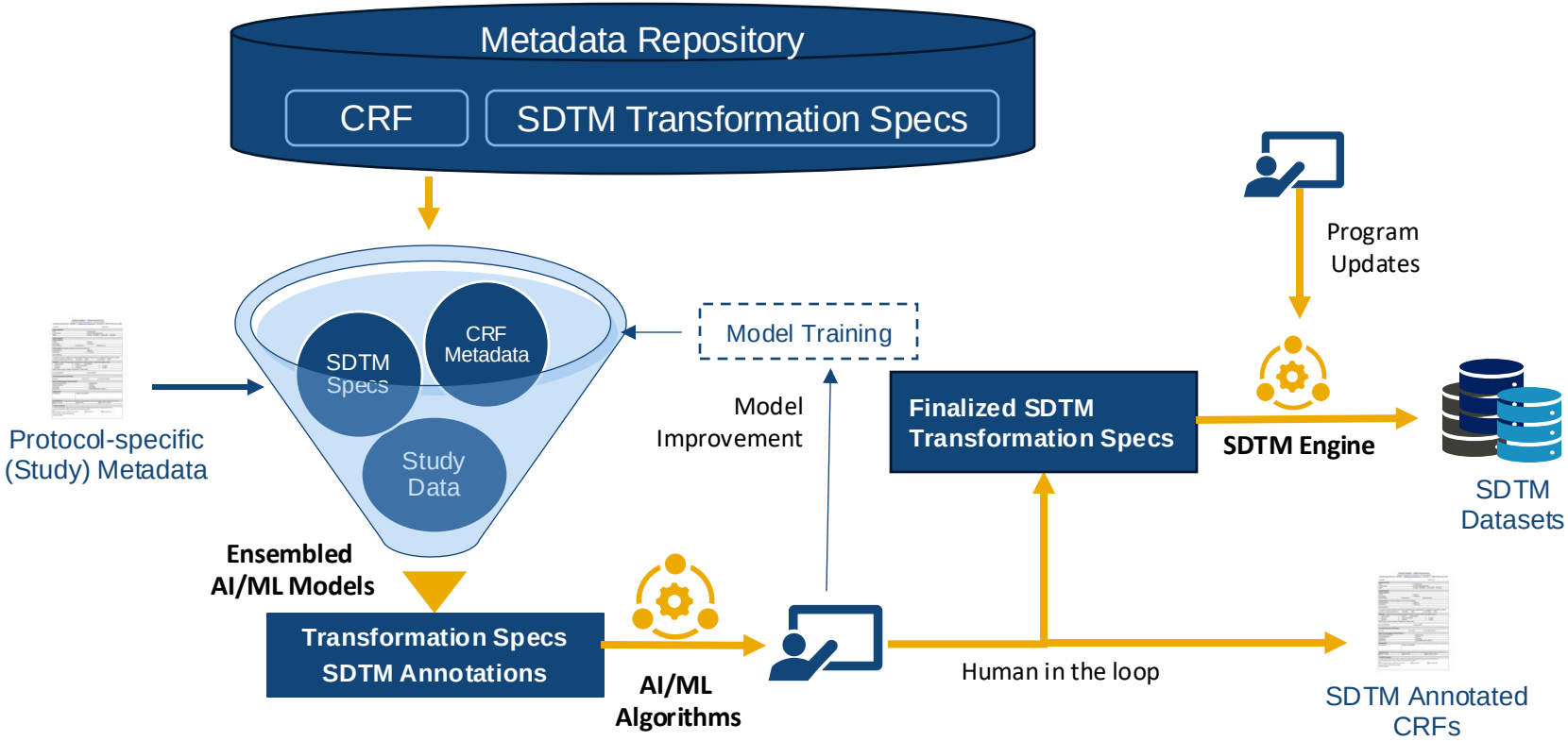


ADaM → ARDS



AI Enabled SDTM Generation

AI Enabled SDTM Generation



Conclusion

Benefits

Streamlined Digital Data Flow

Metadata Discovery

Robust Connected Standards

Metadata Up-versioning

Impact Analysis

Empowering Enormous Automations

Thank You!

Let’s standardize, harmonize and automate!!