Accelerating Digital Data Flow through Connected Standards-Driven Automation and AI

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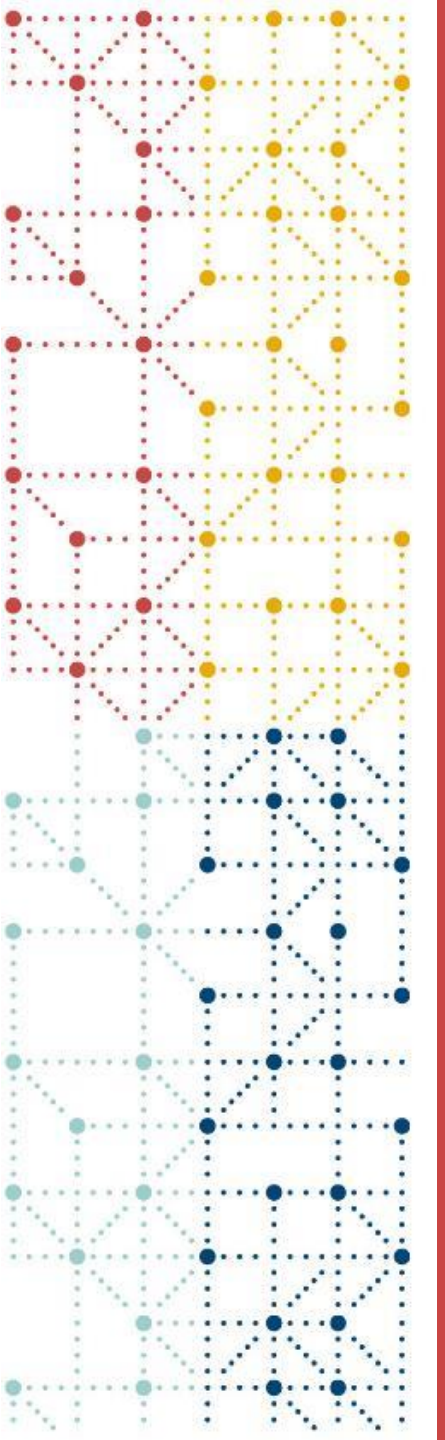

Agenda

1. Connected Standards – Digital Data Flow Backbone
2. Agentic AI driven Protocol – Unstructured to Structured
3. AI Driven Evolution of Standards Life Cycle
   - Automated Standards Generation
   - AI Assisted Standard Maintenance
   - Automated Lineage Across Standards
   - Seamless Standard Up-Versioning
4. AI Driven Process Benefits

Connected Standards – Digital Data Flow Backbone

Study Definition Metadata (USDM) → Data Acquisition Standards (CDASH) → Data Analysis Standards (SDTM →ADaM) → Analysis Reporting Standards (ARDS)

Key Benefits

- Streamline the clinical trial process, from design to submission
- Improves interoperability, data consistency and quality
- Empowers early decision making with accelerated data analysis and insights
- Reduce cost by promoting reusability and automation of various processes
- Ease of review and approval by regulatory bodies

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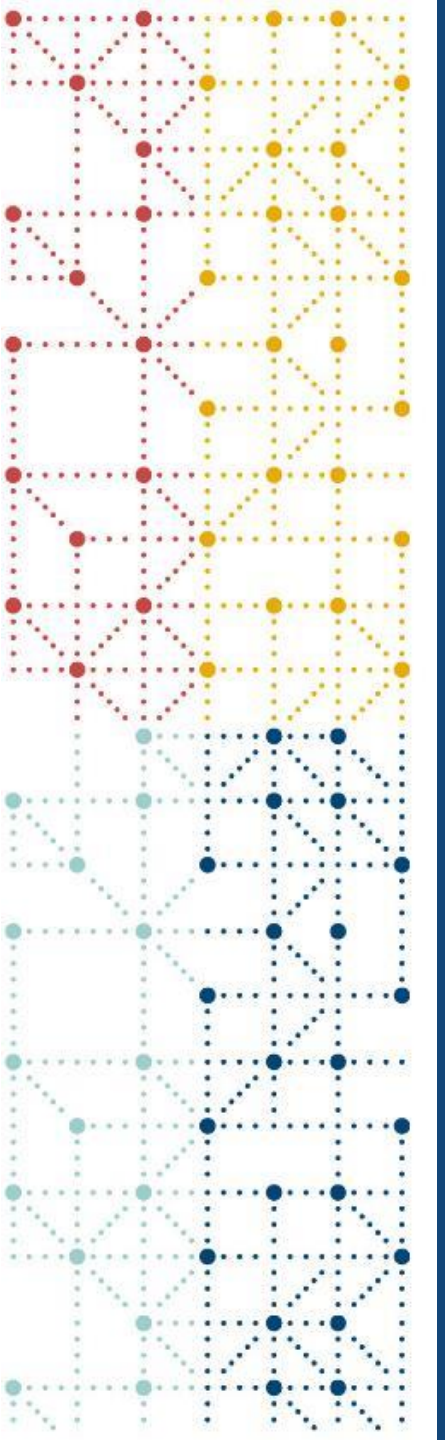
Agentic AI driven Protocol – Unstructured to Structured



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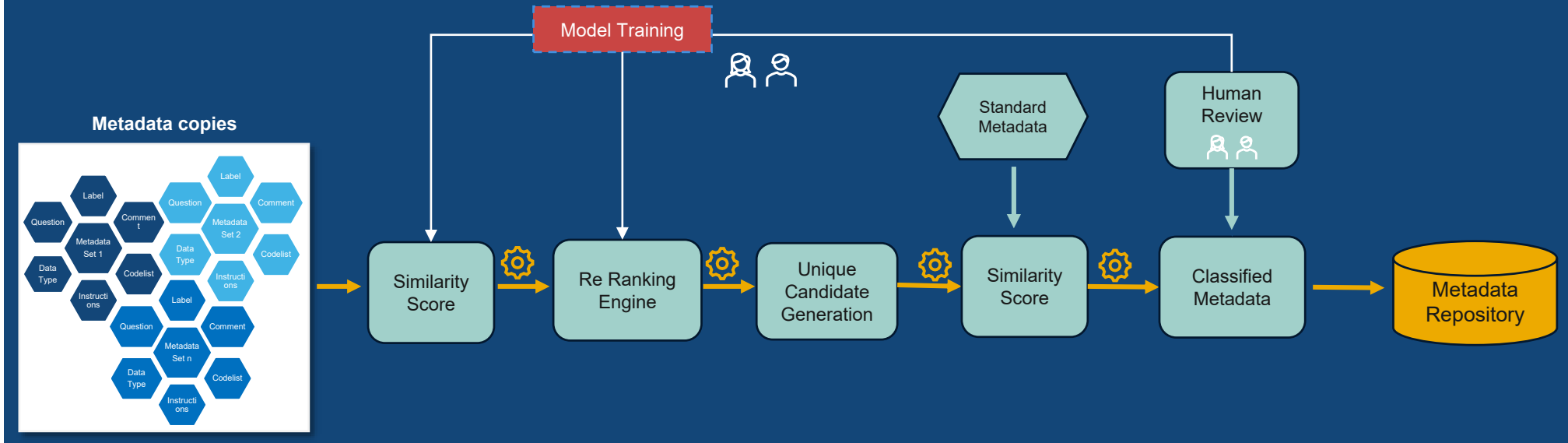
Automated Standards Generation



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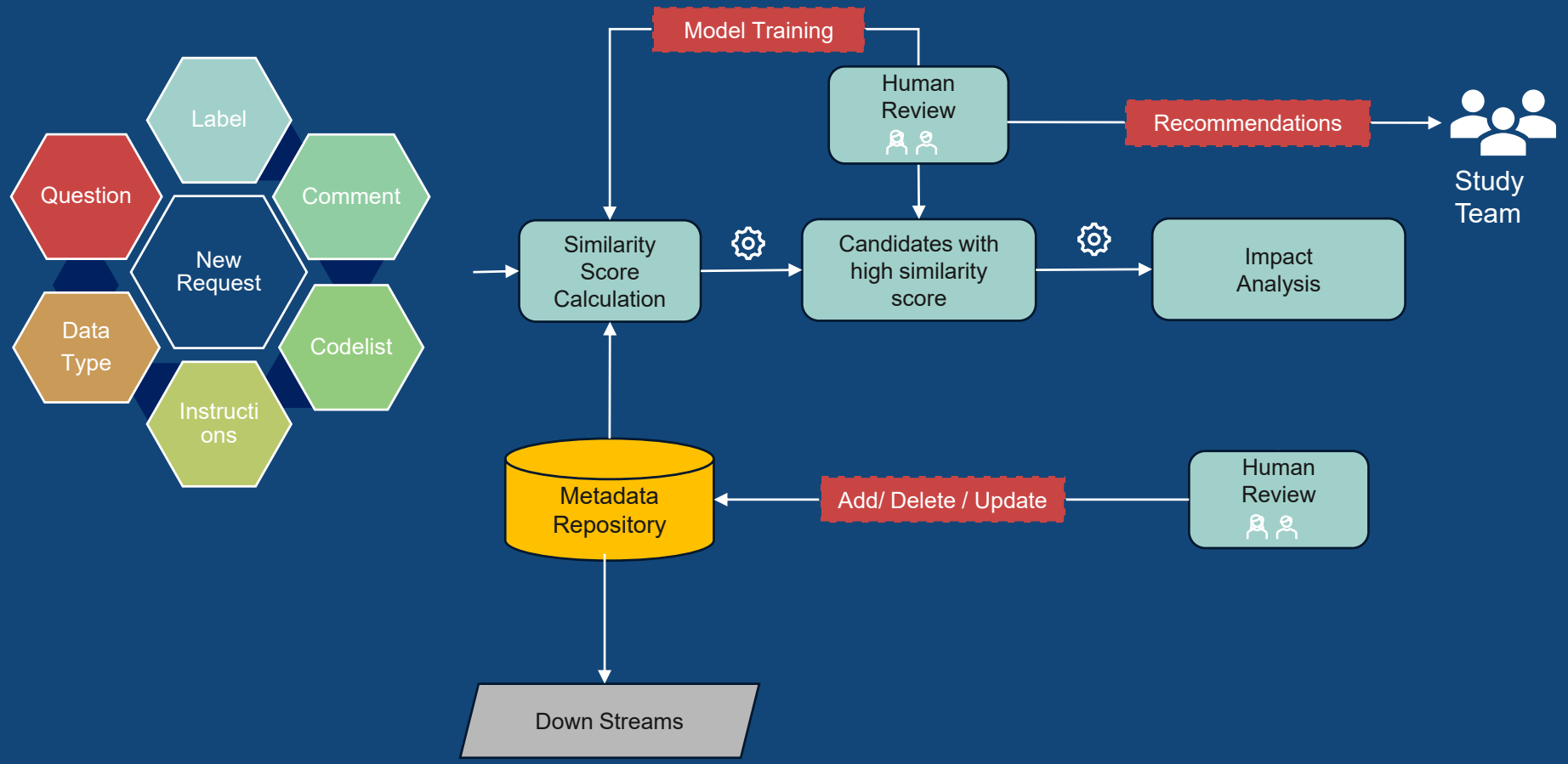
AI Assisted Standard Maintenance



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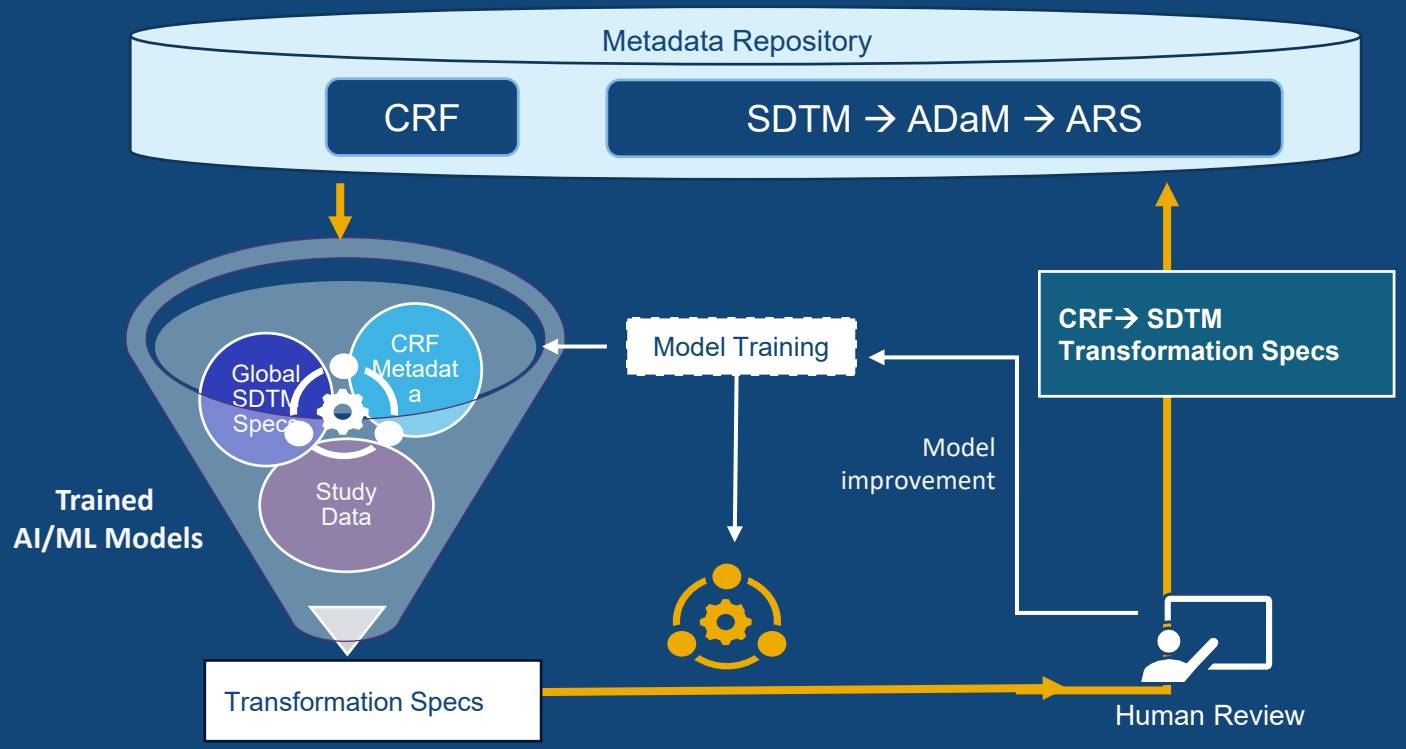
Automated Lineage Across Standards



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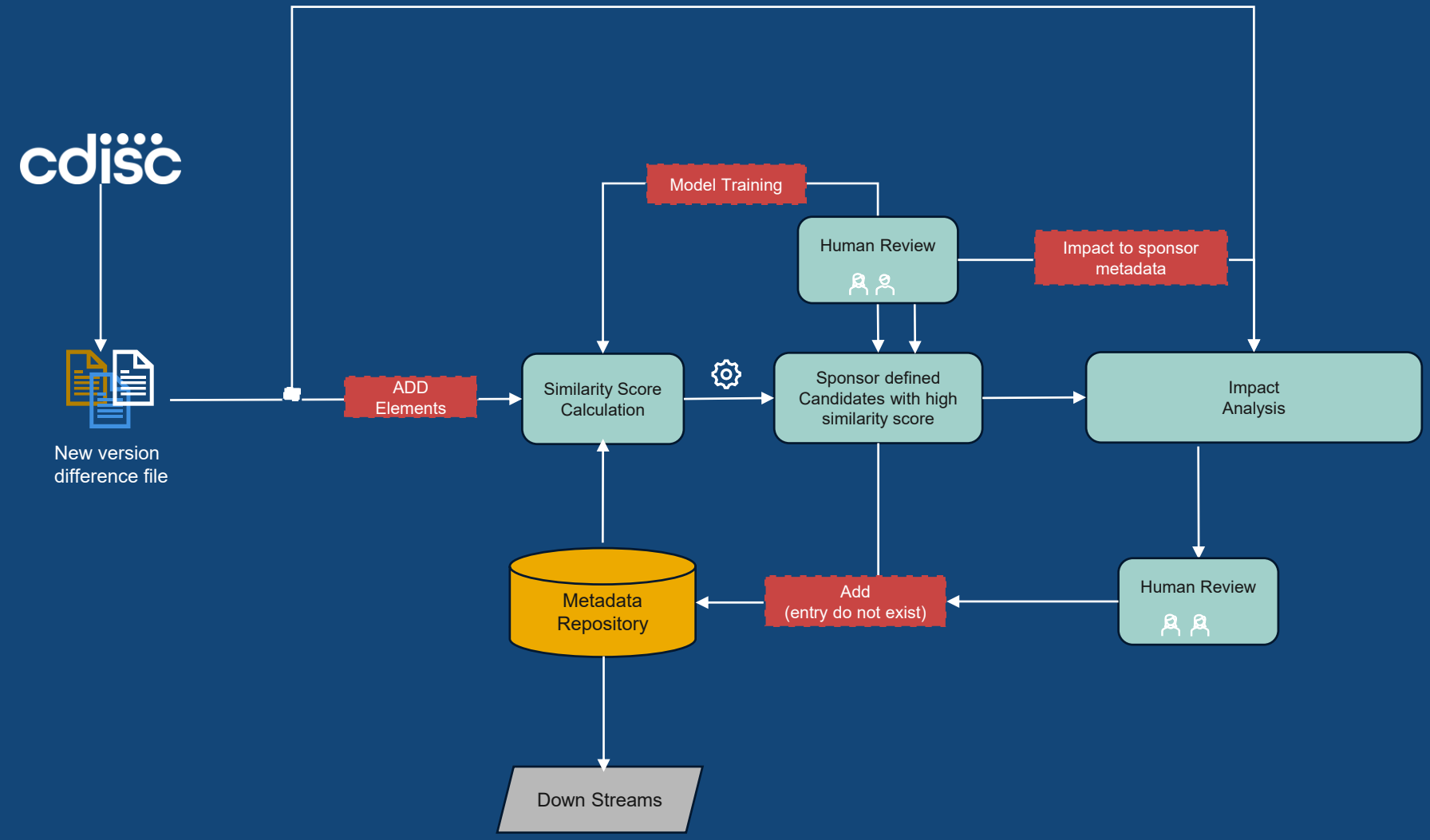
Seamless Standard Up-Versioning



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AI Driven Process Benefits

- **Enhanced Accuracy**: Leveraging advanced AI/ML models ensures more accurate and meaningful comparisons.
- **Efficiency**: Automated processes reduce manual effort and speed up the review process.
- **Continuous Improvement**: Regular feedback and periodic reviews ensure the repository evolves and improves over time.
- **Compliance**: The automated process helps in approval of right study metadata departures from the standards, increasing compliance with standards.
- **Interoperability**: Robust standards and high compliance with standards foster in interoperability between applications, paving the way for digital data flow. This open opportunities for enhanced operational efficiencies, improved data quality, cost savings, and reduced effort, ultimately accelerating time to market.

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Thank You!