



SPA MDR CDR SCE

DS18

Metadata-Driven TFL Generation: End-to-End Automation from Protocol to Output

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About the Presenter



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For more than 30 years, Bill has helped lead digital transformation in clinical analysis and reporting, driving automation, interoperability, and technology adoption to improve speed, quality, and efficiency. He is particularly focused on the role of AI, reuse, and metadata driven solutions in reshaping how the industry designs protocols, executes studies, and delivers reporting. Through next generation analytics and automation, he helps pharmaceutical companies and CROs accelerate clinical development and improve outcomes.



Agenda

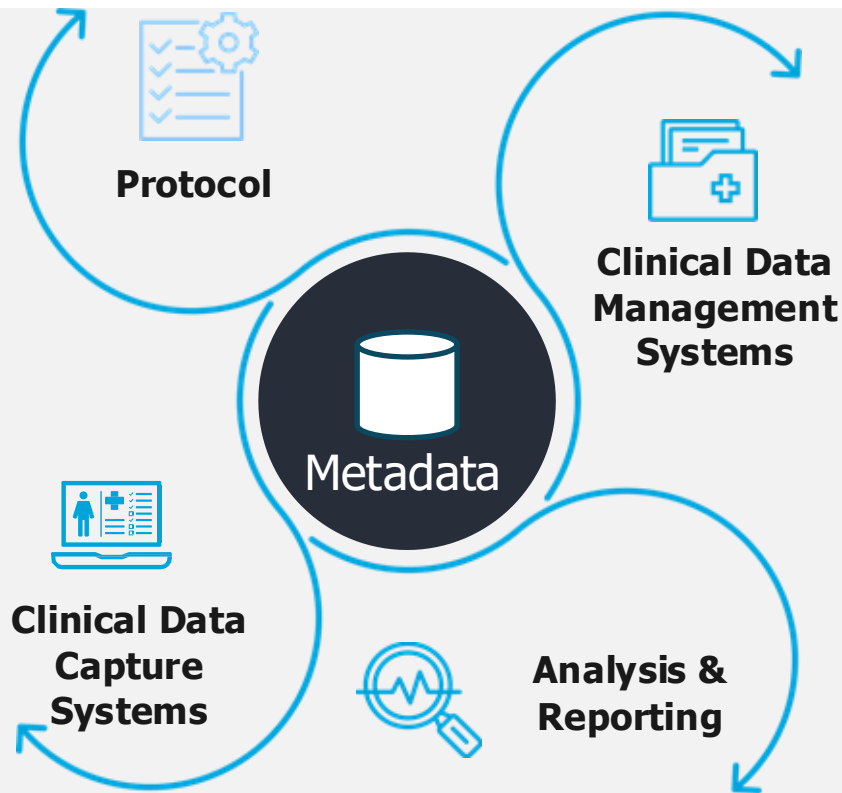
- What “Metadata-Driven” Means in Practice
- Metadata-First High-Level Architecture
- Metadata Repository Backbone
- Table Driven Code Generation
- Roles, Responsibilities, & Artifact Ownership
- Solution Evaluation Checklist



What is at the Center of Your Universe?

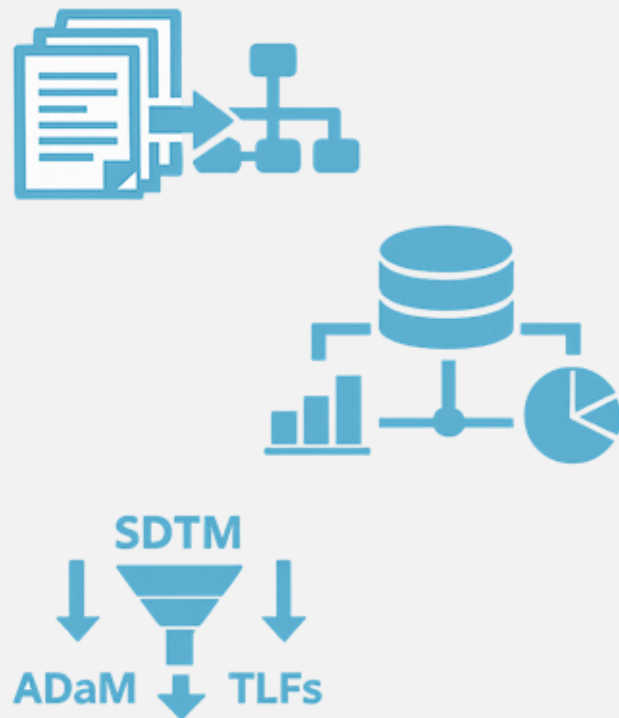
How Much Efficiency Are You Leaving on the Table?

- Protocols are narrative documents
- Analysis intent is restated in SAPs and specifications
- Programmers reinterpret specs into code and so on
- Relies on manual consumption, translation and interpretation
- Each hand-off introduces ambiguity, spec drift, and risk
- **The answer:** a metadata first operating model that drives the entire process



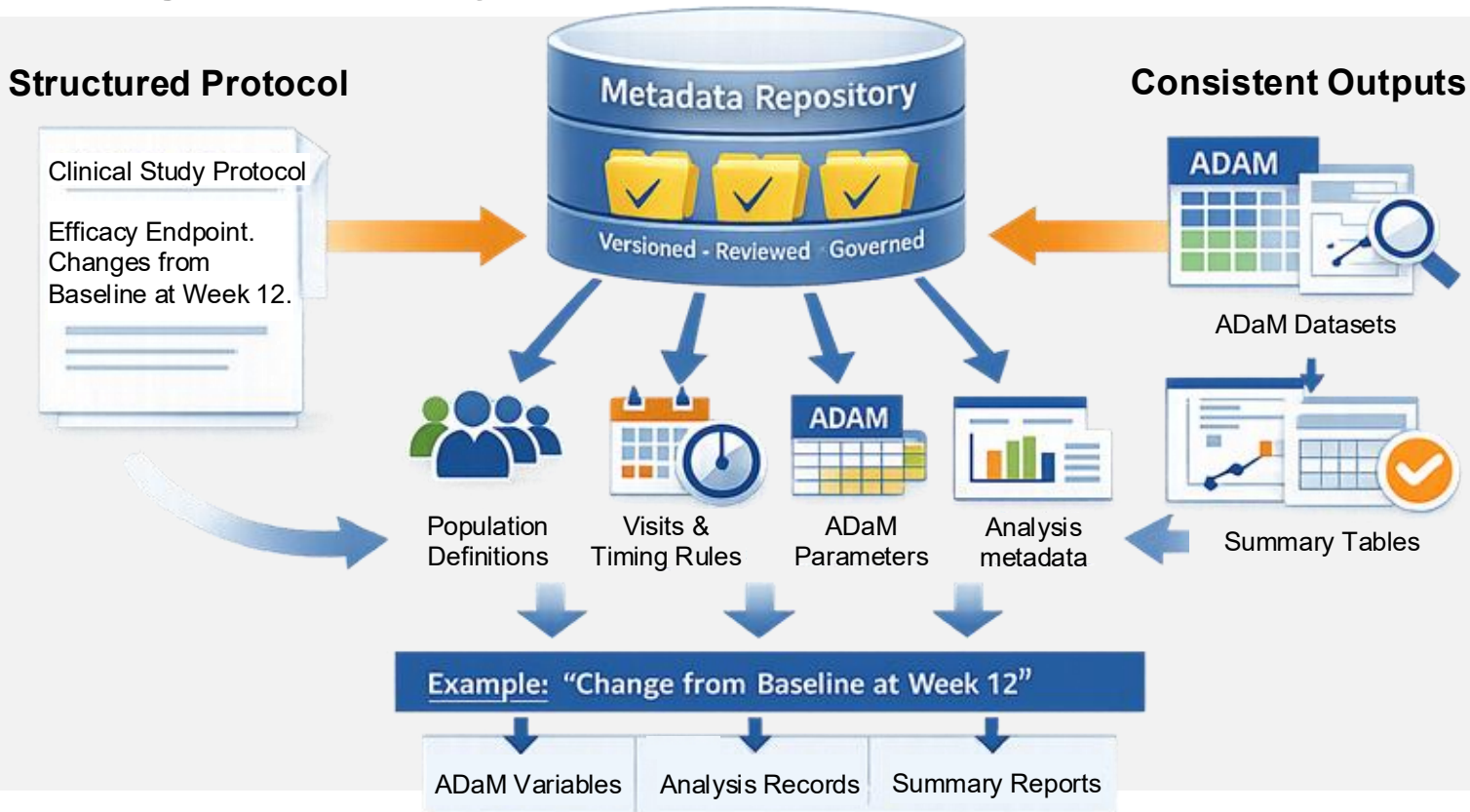
What “Metadata-Driven” Means in Practice

- Transition from Documentation to Executable Definitions
- Defined and Managed Core Metadata for Clinical Reporting
- Elimination of Reinterpretation Across SDTM, ADaM, and TLFs
- Table Driven Code Generation
- Defined Governance and Accountability
- Change Management and Impact Assessment & Control



Metadata-First High-Level Architecture:

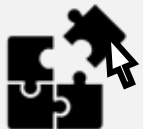
Ensuring consistency end-to-end



Structured Protocol: A Starting Point



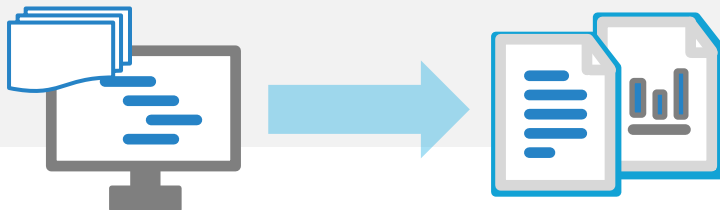
Study Protocol elements in **machine-readable** and **actionable** form



Stored within MDR as the **single source** of truth

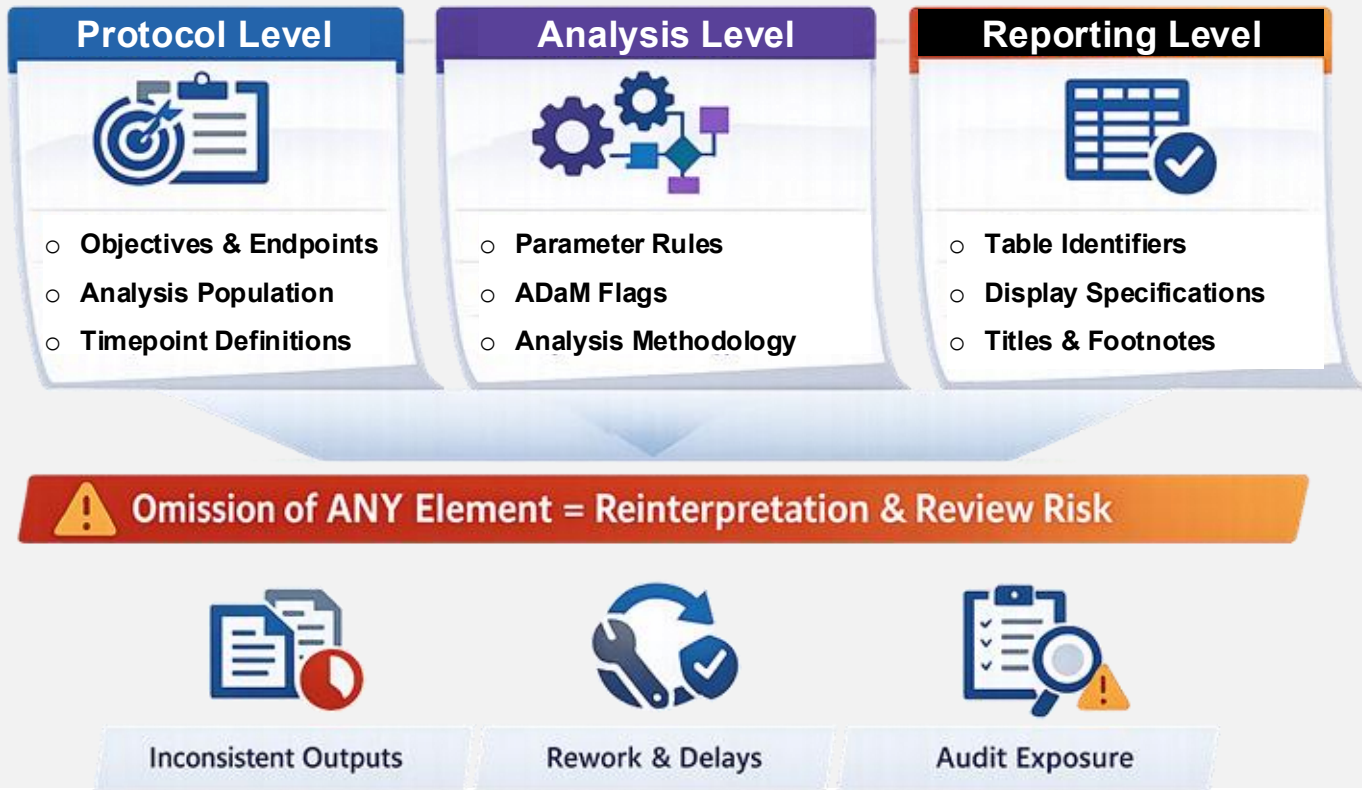


Drives and **automates** downstream clinical operations **processes** (e.g., EDC Builds) and production of key documentation (e.g., CRFs, SAP, Programming Specifications)

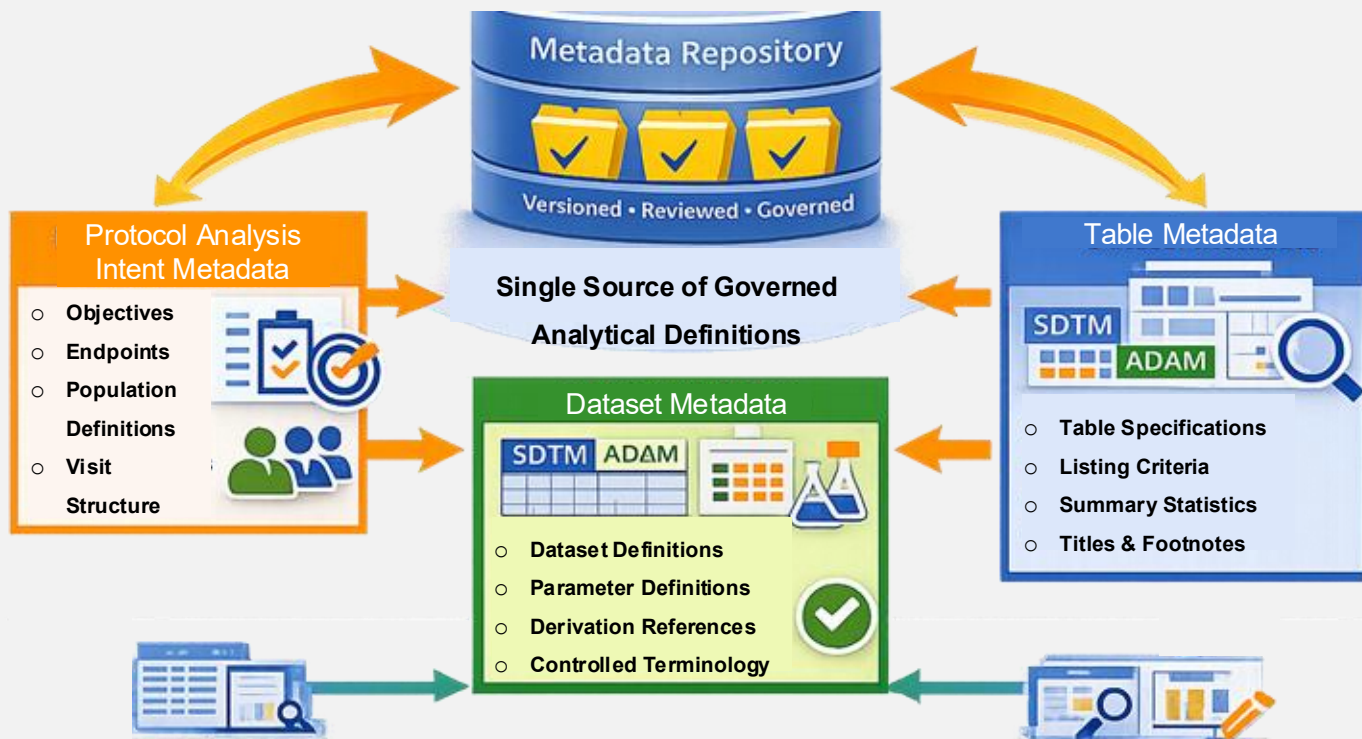


Non-Negotiable Metadata for CSR Reporting

Partial/incomplete definitions invite reinterpretation risk. Governed metadata is essential across all aspects.

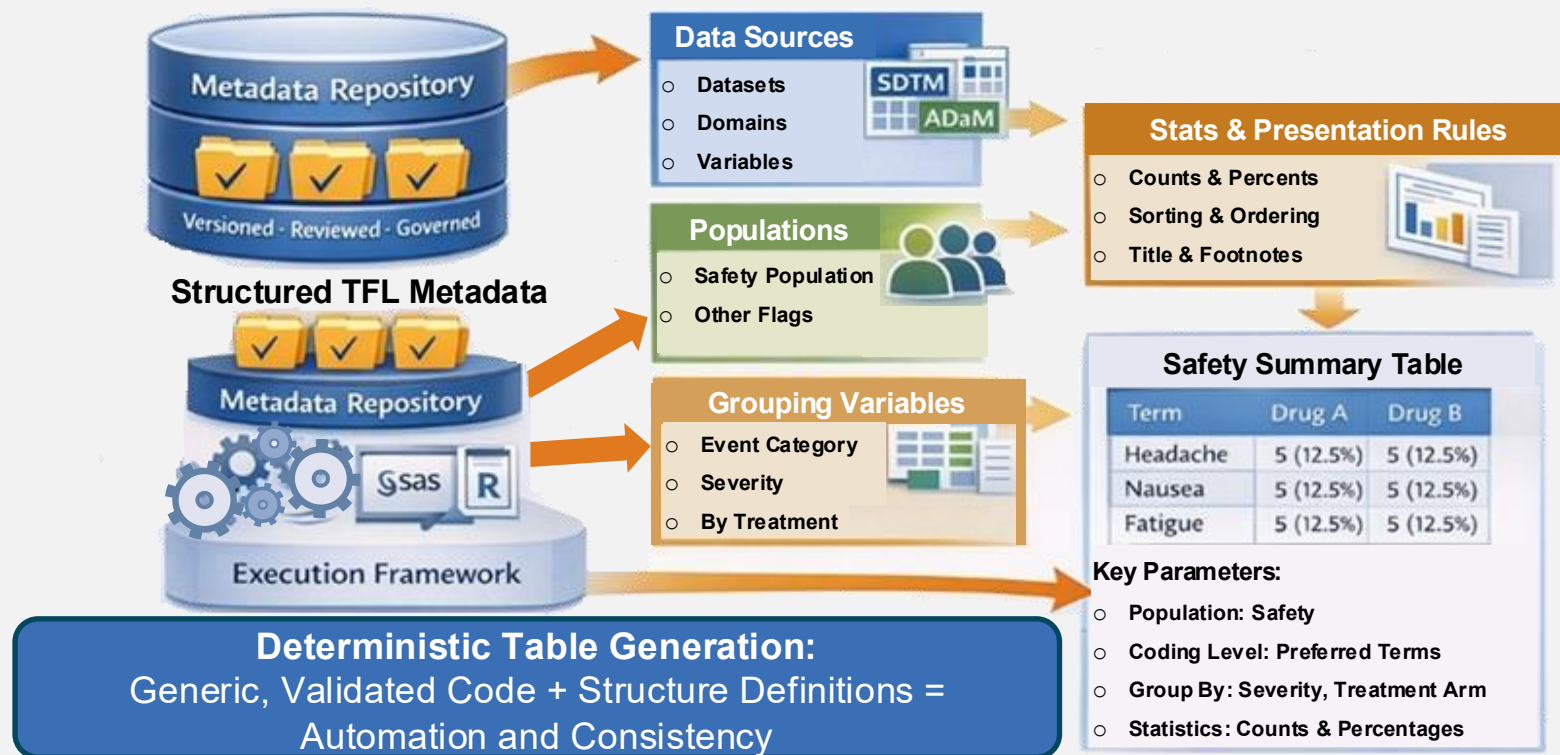


Metadata Repository Backbone: Managing Essential Metadata Domains for Clinical Reporting

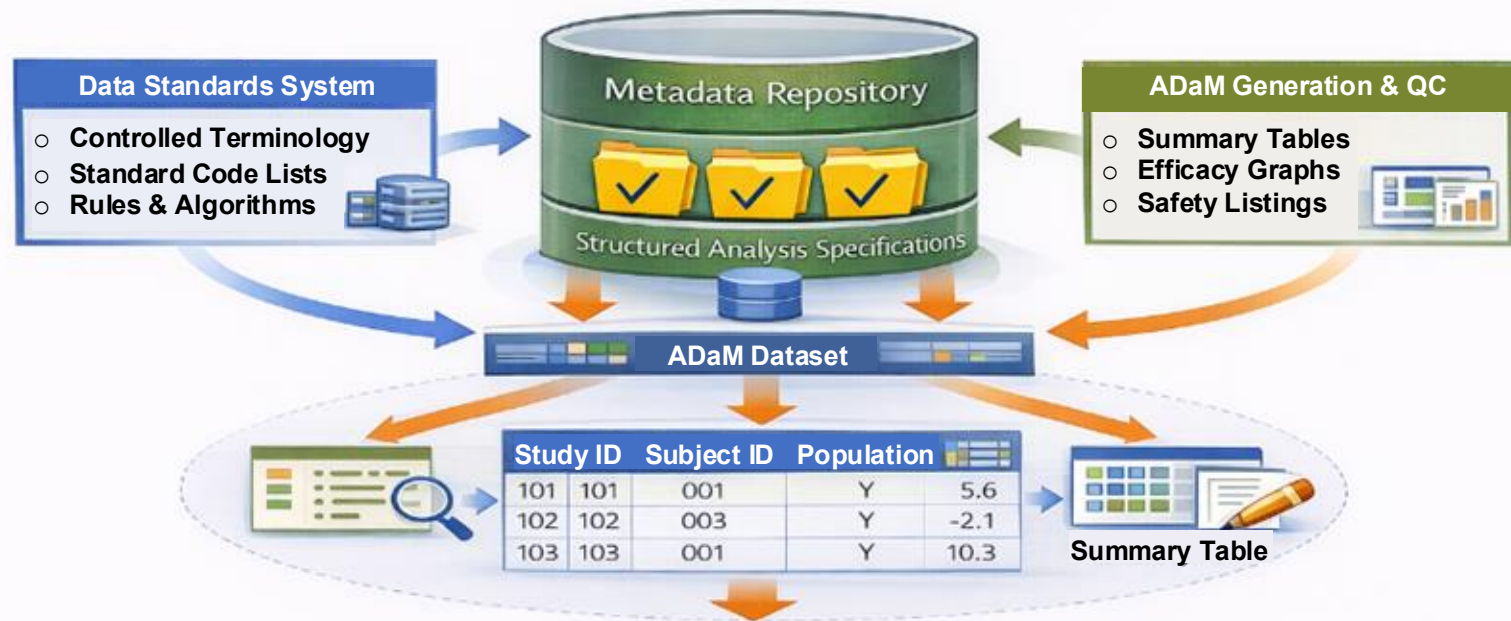


Consumption Systems; Dataset Processing; Statistical Programming; CSR Production

Table Driven Code Generation: Parameterizing Execution for Automated, Consistent Tables



Required Traceability: Establishing Governed Relationships to Address Review Needs



1 Table Derivation Logic

- Trace ADaM variables and specific derivation rules used to compute results.

2 Analysis Population

- Trace governed and versioned ADaM flags used to filter records.

3 Parameter Definitions

- Trace parameter labels, identifiers, and rules used to summarize data points.



Benefits of a Table-Driven Execution Model

Table driven generation replaces bespoke, table specific programming with **deterministic execution** controlled by metadata. In **traditional macro** centric or copy forward approaches, logic is duplicated across programs, **increasing the risk** of divergence between tables that are intended to be consistent.

01

Determinism. Each TLF is produced by executing the same validated routines against approved metadata.

02

Inspectability. Reviewers inspect what the system is instructed to do; no reverse engineering from code.

03

Scalability. Adding a new table requires defining metadata, not writing new programs.



Statistician. Owns analytical intent (defines endpoints, analysis populations, etc.). Approves analysis metadata before any CSR bound generation occurs.

Statistical Programmer. Owns execution design and technical correctness. Implements and validates the reusable derivation and reporting routines.

Clinical Data Manager. Owns data meaning and standards alignment and ensures controlled terminology is applied consistently.

Roles & Responsibilities

Medical Writer. Owns narrative alignment with outputs and consistency of terminology in the CSR.

System Owner. Owns the platform, access control, configuration, and operational reliability. Ensures environment qualification, role-based access, segregation of duties, etc.

QA. Owns process compliance. Approves governance model, metadata lifecycle controls, execution framework val approach & adherence to approval gates.



Artifact Ownership

Protocol Metadata

Owned by clinical and statistics with operational support from standards.



Analysis Metadata

Owned by statistics with strong partnership from programming and standards.



TLF Specifications

Co-owned by programming and statistics. Statistics owns the intent and Programming owns executability.



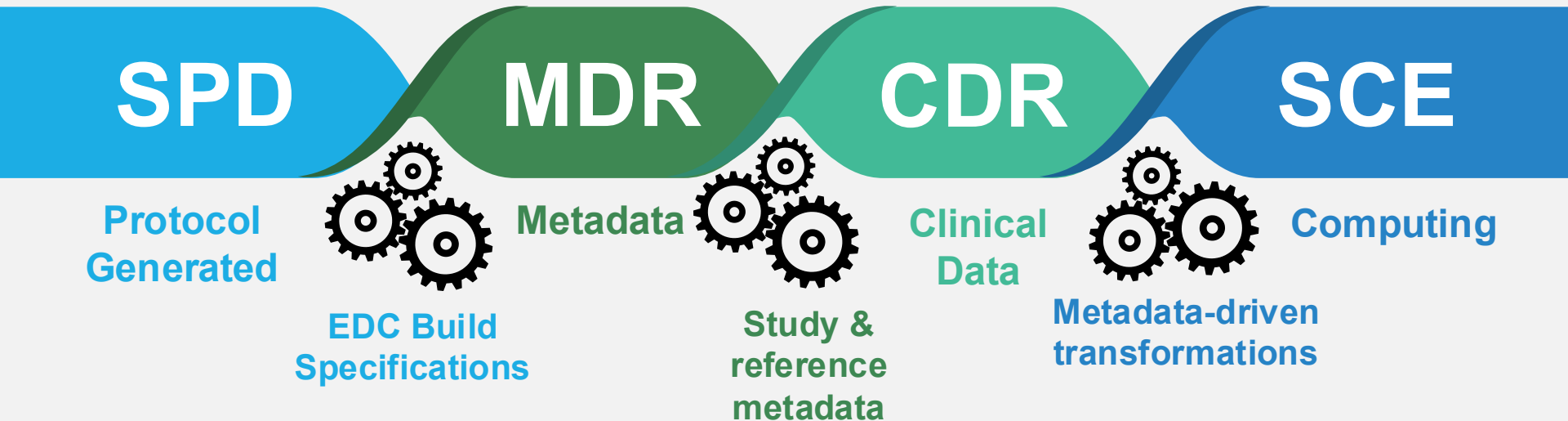
Outputs

Programming = generation & correctness; Statistics = scientific signoff; Medical writing CSR consistency.



End-to-End Facilitation of Processes is within Reach Today (SPD, MDR, CDR & SCE)

- Study Builder and Designer
- Protocol Writer
- Study Definitions Repository (SDR)
- Metadata Repository
- Clinical Data Repository
- Security, etc.
- Programs
- Data Processing
- Analysis



Solution Evaluation Checklist:

Buyers should evaluate end-to-end metadata solutions through the lens of intent continuity, controlled execution, and inspection-grade evidence.

01

Single Authoritative metadata repository that interoperates across ecosystem, functions, and deliverables.

02

End-to-end metadata continuity that traces protocol elements, analysis end-points, execution definitions across artifacts with governance.

03

Native traceability, lineage, and version control from analysis specifications to outputs (TLFs).

04

Demonstratable Inspection Readiness. Proven recovery of definitions, run history, audit trails, etc. without manual reconstruction.

05

Governance and validation must be enforced by the system; with approval gates (e.g., Metadata, TLF generation).



Putting it All Together...

- Governed **System of Record** is MDR
- In the Agentic AI world, standards are even more important as metadata provides the necessary context
- Executable metadata changes the **operating model**
- Metadata-Driven TLF generation results in a more predictable and defensible CSR production
- **Bottomline:** Improved consistency, accelerated delivery, and strengthened traceability from study definitions to final outputs



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