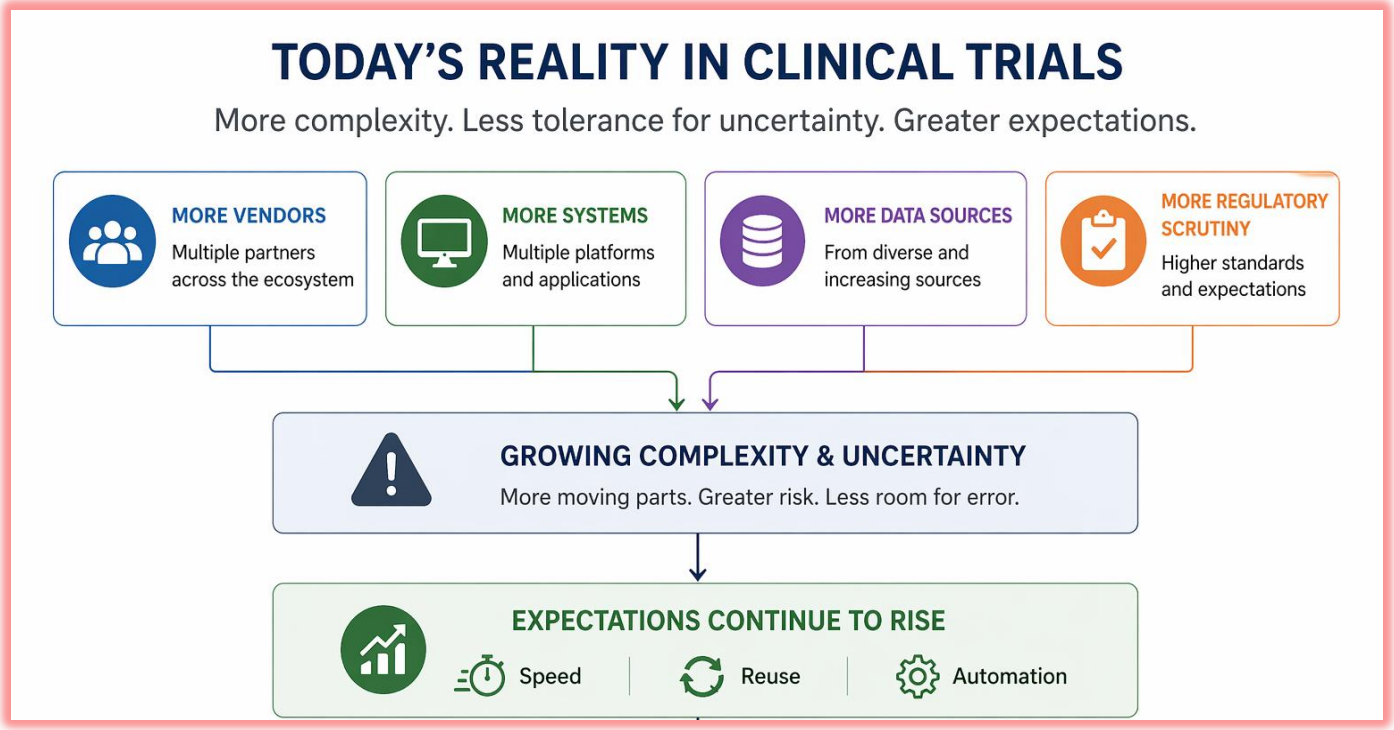
Engineering Trust in Clinical Data Through Metadata, Transparency, and Human Stewardship

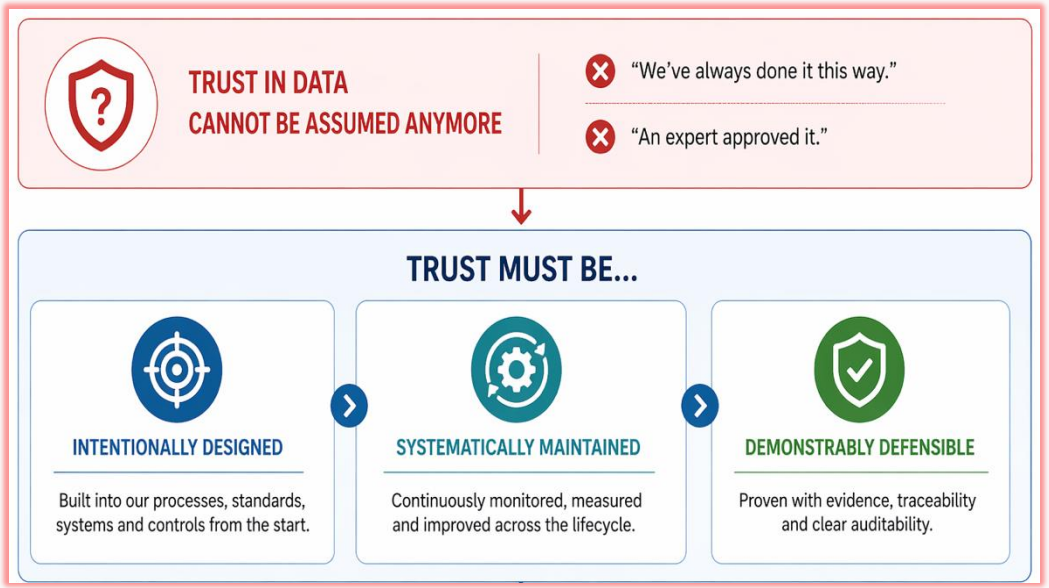
Rajesh Saha | June 2026

CERTARA

Engineering Trust in Clinical Data



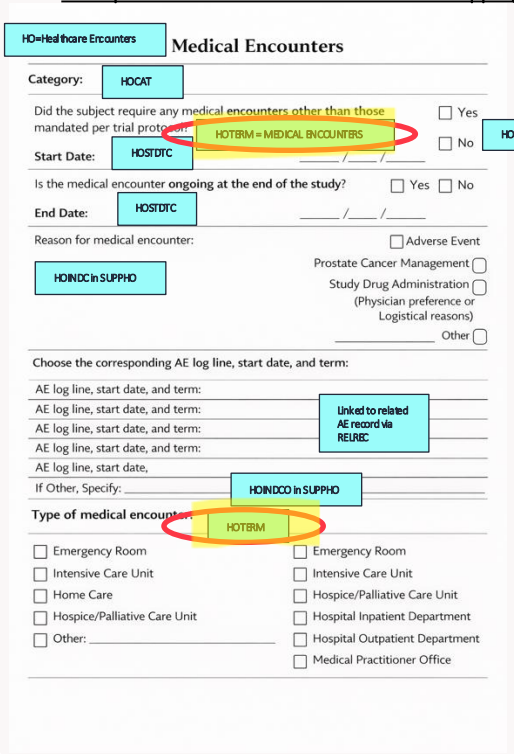
Engineering Trust in Clinical Data

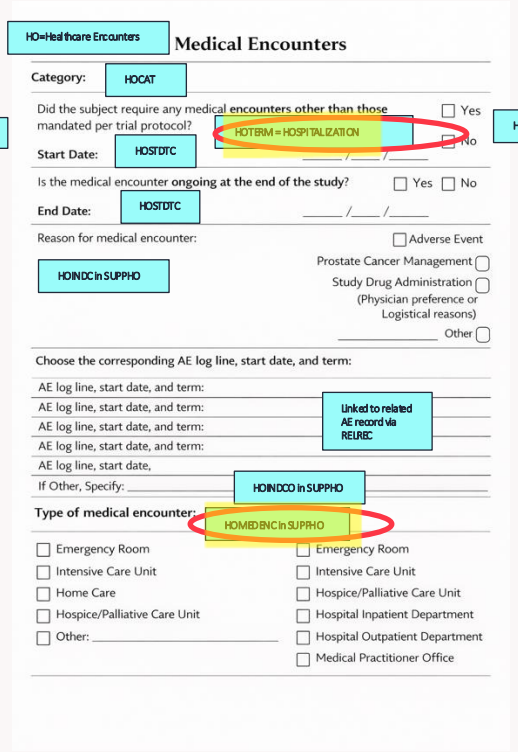


- Metadata is Foundational
- MDR - Single Source Of Truth
- Engineering Trust through Transparency
- Engineering Trust through Traceability
- Engineering Trust through Metadata Stewardship

How Data Loses Trust?

Example 1: Inconsistent Annotation or Mapping





Example 2: Controlled Terminology Override (AESEV)

What happened

Standard CDISC CT for AESEV is overridden to allow an additional value “LIFE THREATENING”)

Inspection question

“Why does AESEV include a non-standard value?”

Reality

- Teams know it was “agreed at the time”
- No documentation of the agreement
- Looks like uncontrolled deviation

With MDR

- Centralized management of standards annotations and mapping specifications to ensure consistent mapping across studies.
- CT deviation logged as metadata decision
- Rationale captured and linked to SDTMIG

Outcome:

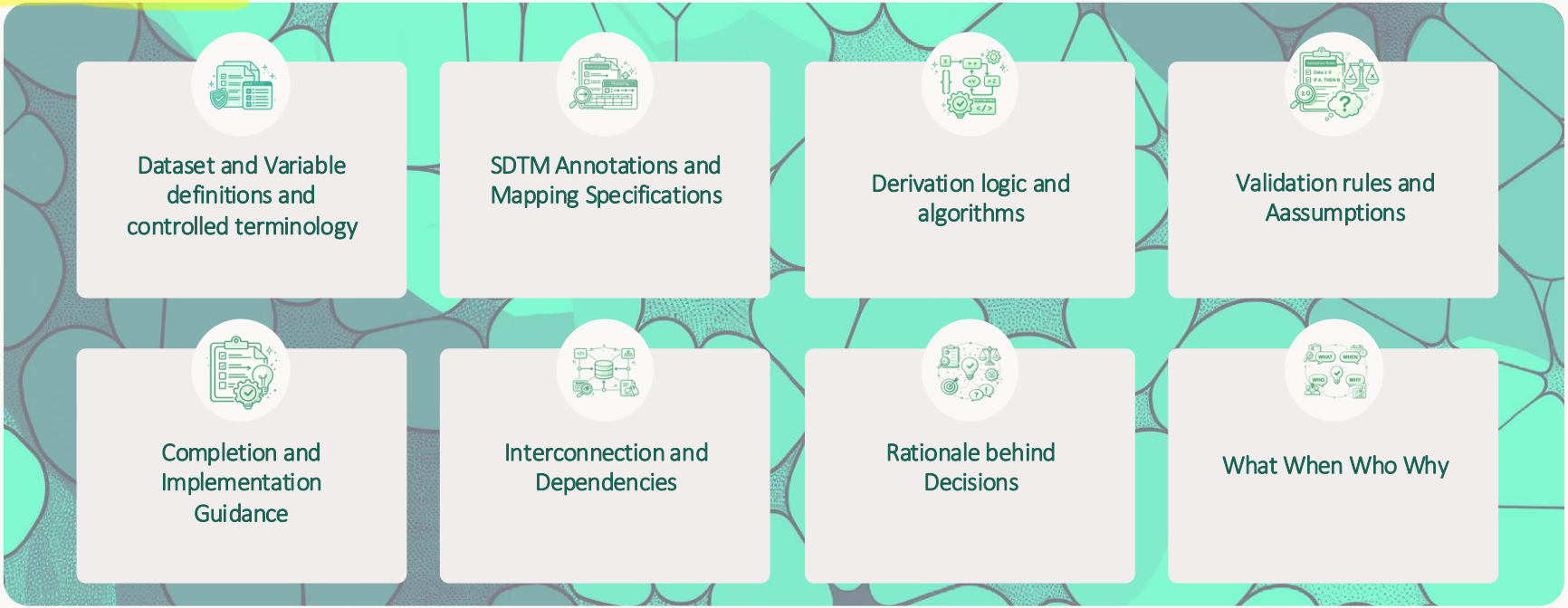
- Clear consistent approach
- Deviation is controlled, auditable, and defensible.

CERTARA

Metadata –is Foundational

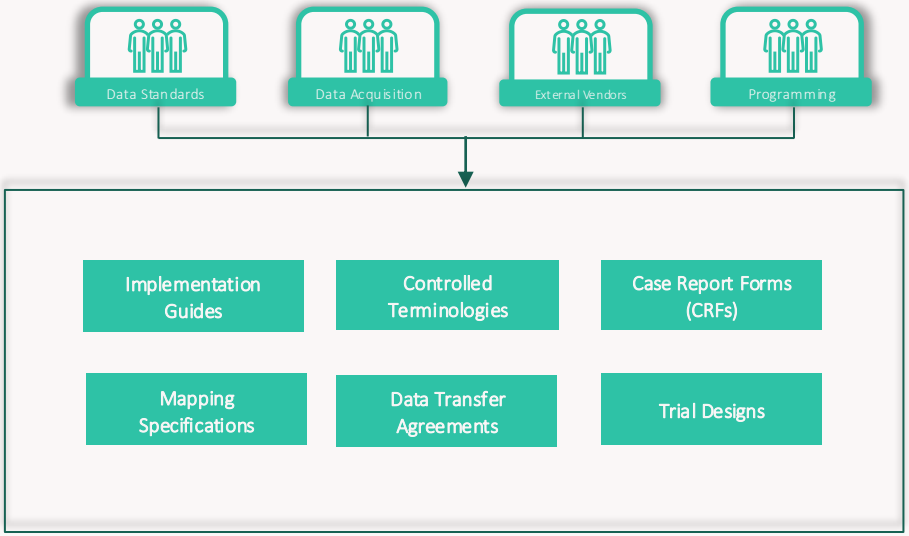
Clinical metadata is the **structured information that defines, explains, and governs clinical trial data** — not the data values themselves, but the meaning, rules, and context behind those values. When we say “metadata,” many people immediately think of standards libraries or variable lists. But that view is incomplete.

Clinical metadata includes:



CERTARA

Clinical MDR- Single Source Of Truth

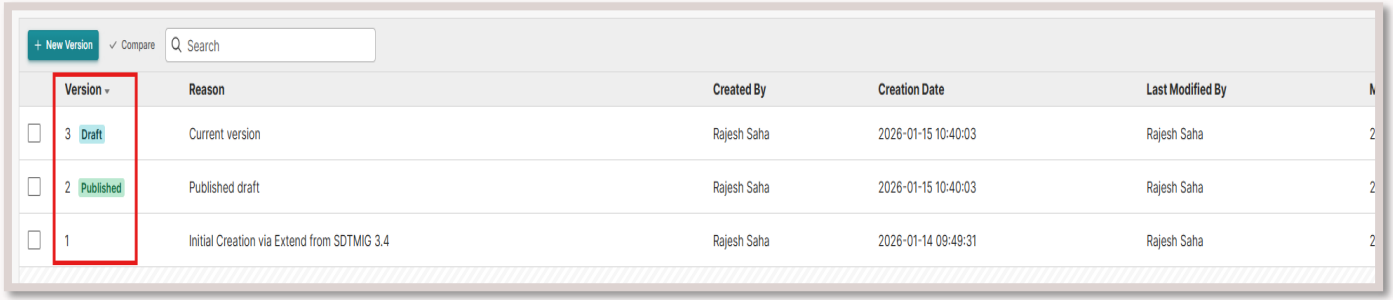


A clinical MDR host all kind of metadata and make it accessible to all stakeholders

MDR becomes the Single Source of Truth
Metadata becomes its foundation

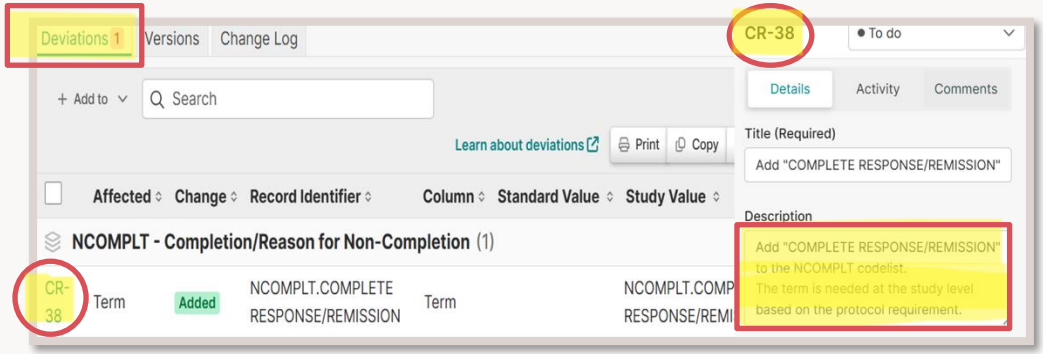
Engineering Trust through Transparency

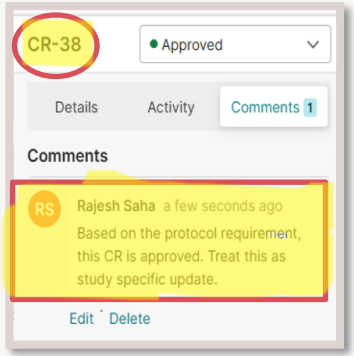
For Better Standards Governance and Accurate Standards Implementation



VERSIONING

MDR is a governed, version-controlled system of record for all study and standards metadata





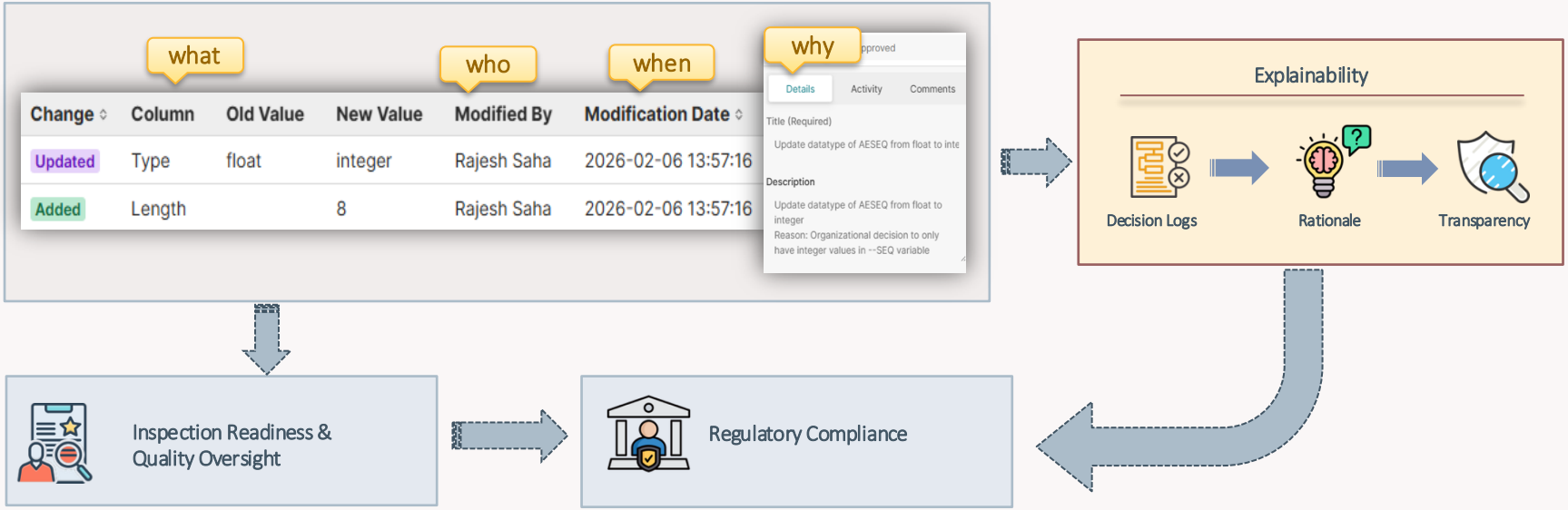
CHANGE MANAGEMENT

In MDR, study-level deviations should be highlighted, with change requests enabling easy documentation and approval.

CERTARA

Engineering Trust through Traceability

Audit trails in an MDR record who changed what, when, and why.

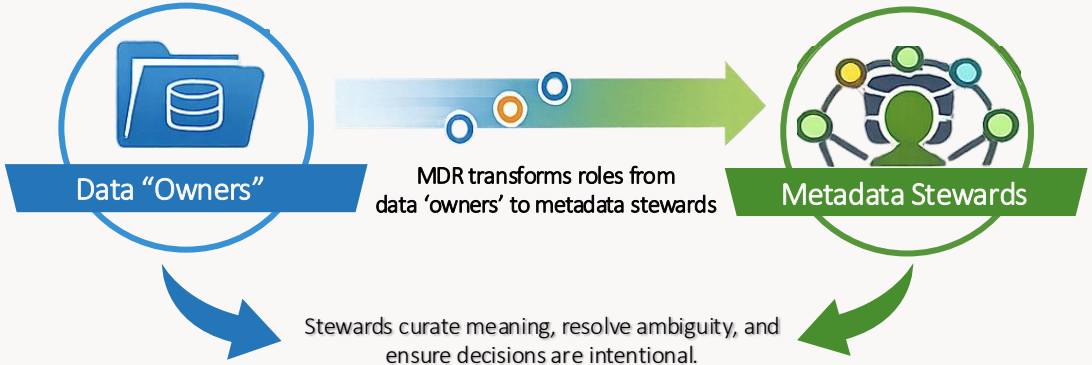


As automation and AI expand, explainability is becoming a regulatory expectation. An MDR provides the foundation to meet it.

CERTARA

Engineering Trust through Metadata Stewardship

Technology enables trust—but people sustain it.



Curate Meaning	Resolve Ambiguity	Document Decisions
Add context with metadata to provide clarity and value	Eliminate inconsistencies and ensure data make sense	Ensure all decisions are intentional and traceable

Use Case Example

Without MDR : “Data Owner” Behavior

Owns and updates their EDC forms, focuses on their study, communicates changes informally, and is typically not responsible for downstream impacts beyond the EDC system.

With MDR: “Metadata Steward” Behavior

That same person now:

- Registers EDC metadata in the MDR
- Cannot change metadata without versioning and governance
- Must review impact analysis before approval
- Knows their changes affect:
  - SDTM automation
  - ETL pipelines
  - AI models
  - Regulatory outputs
- Approves changes as part of a controlled workflow

Their accountability now extends to the **enterprise metadata ecosystem**.

Embedding MDR Across the Clinical Data Lifecycle

- Standards Management (SM)

Trusted, governed standards, ensuring consistency & traceability

MDR

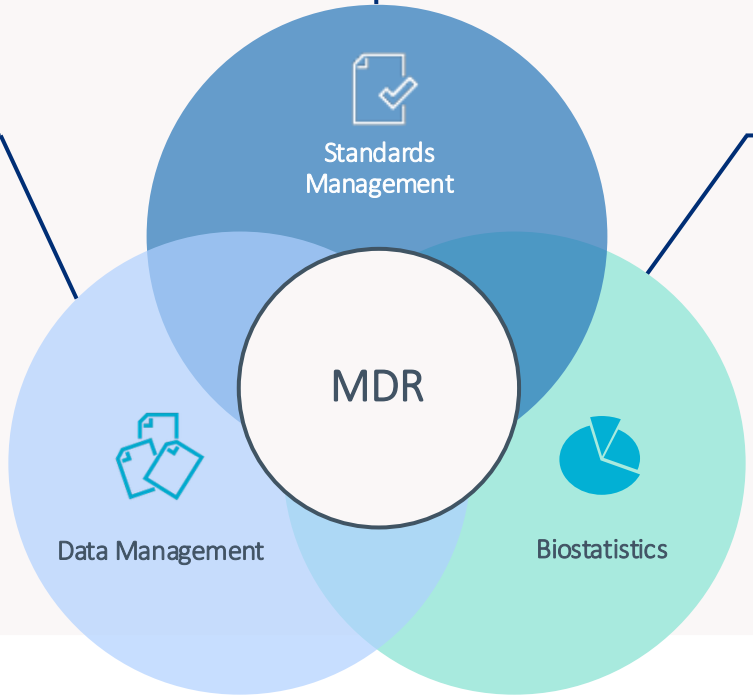
Enabling Trust In Data

- Data Management (DM)

Transparent, reusable, and standards-driven data collection

- Biostatistics

Traceable transformations enabling confident submissions



CERTARA

Questions?