





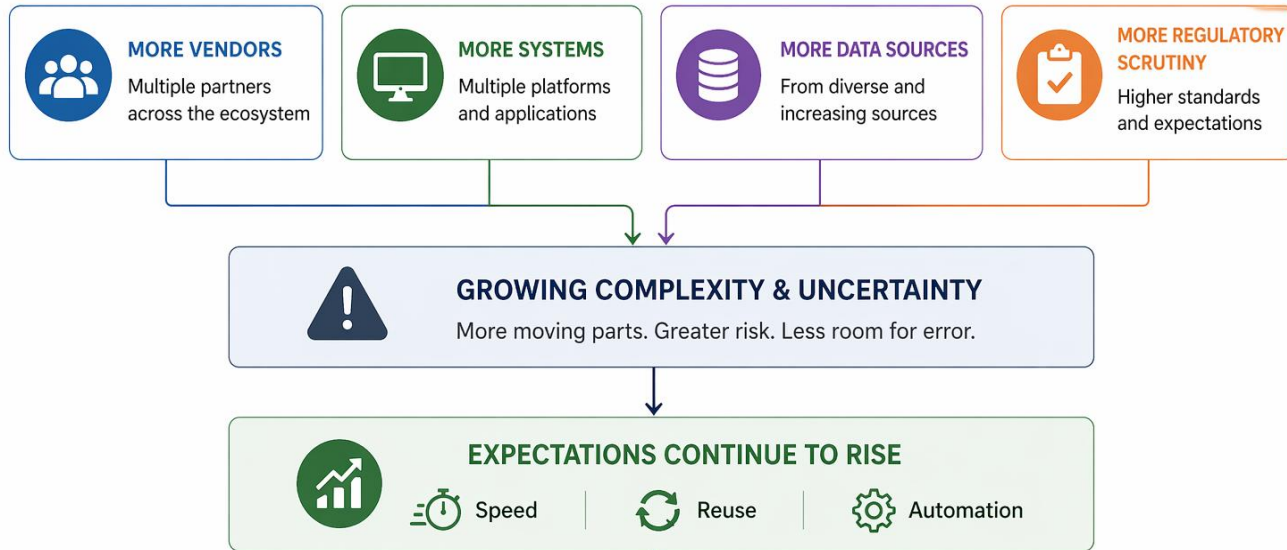
Engineering Trust in Clinical Data Through Metadata, Transparency, and Human Stewardship

Rajesh Saha | June 2026

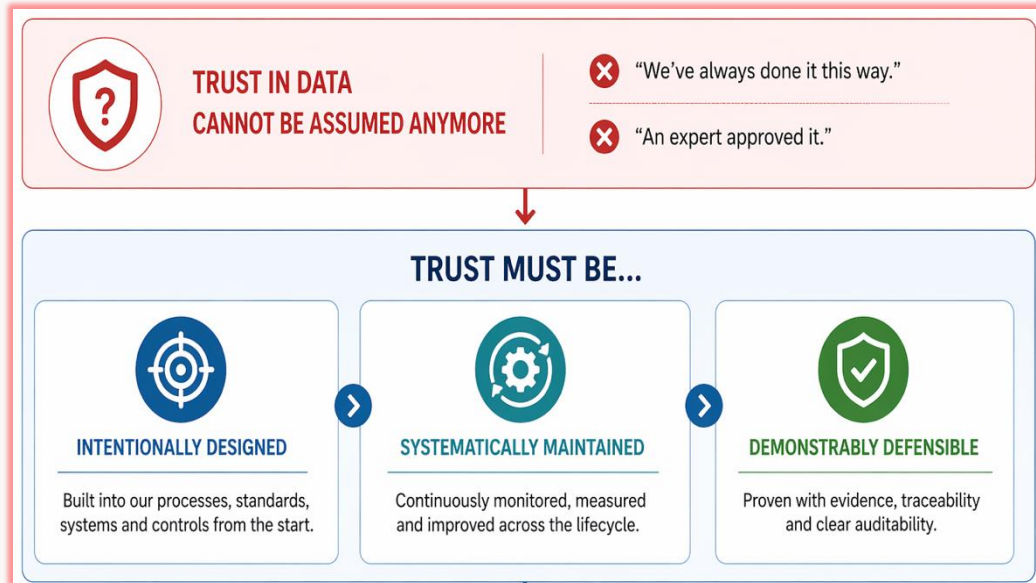
Engineering Trust in Clinical Data

TODAY'S REALITY IN CLINICAL TRIALS

More complexity. Less tolerance for uncertainty. Greater expectations.



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

HO=Healthcare Encounters

Medical Encounters

Category: **HOCAT**

Did the subject require any medical encounters other than those mandated per trial protocol? ☐ Yes ☐ No

Start Date: **HOSDTFC** **HOTIRM = MEDICAL ENCOUNTERS**

Is the medical encounter ongoing at the end of the study? ☐ Yes ☐ No

End Date: **HOSDTFC**

Reason for medical encounter: ☐ Adverse Event

HOINDC in SUPPHD

Prostate Cancer Management ☐
Study Drug Administration (Physician preference or Logistical reasons) ☐
Other ☐

Choose the corresponding AE log line, start date, and term:

AE log line, start date, and term: **Linked to related AE record via RELIRC**

AE log line, start date, and term: **HOINDC in SUPPHD**

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AE log line, start date, and term: **HOINDC in SUPPHD**

If Other, Specify: **HOINDC in SUPPHD**

Type of medical encounter: **HOTIRM**

☐ Emergency Room ☐ Emergency Room
☐ Intensive Care Unit ☐ Intensive Care Unit
☐ Home Care ☐ Hospice/Palliative Care Unit
☐ Hospice/Palliative Care Unit ☐ Hospital Inpatient Department
☐ Other: ☐ Hospital Outpatient Department
☐ Medical Practitioner Office

HO=Healthcare Encounters

Medical Encounters

Category: **HOCAT**

Did the subject require any medical encounters other than those mandated per trial protocol? ☐ Yes ☐ No

Start Date: **HOSDTFC** **HOTIRM = HOSPITALIZATION**

Is the medical encounter ongoing at the end of the study? ☐ Yes ☐ No

End Date: **HOSDTFC**

Reason for medical encounter: ☐ Adverse Event

HOINDC in SUPPHD

Prostate Cancer Management ☐
Study Drug Administration (Physician preference or Logistical reasons) ☐
Other ☐

Choose the corresponding AE log line, start date, and term:

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AE log line, start date, and term: **HOINDC in SUPPHD**

If Other, Specify: **HOINDC in SUPPHD**

Type of medical encounter: **HOMEDBNC in SUPPHD**

☐ Emergency Room ☐ Emergency Room
☐ Intensive Care Unit ☐ Intensive Care Unit
☐ Home Care ☐ Hospice/Palliative Care Unit
☐ Hospice/Palliative Care Unit ☐ Hospital Inpatient Department
☐ Other: ☐ Hospital Outpatient Department
☐ Medical Practitioner Office

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.

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:



Dataset and Variable
definitions and
controlled terminology



SDTM Annotations and
Mapping Specifications



Derivation logic and
algorithms



Validation rules and
Assumptions



Completion and
Implementation
Guidance



Interconnection and
Dependencies

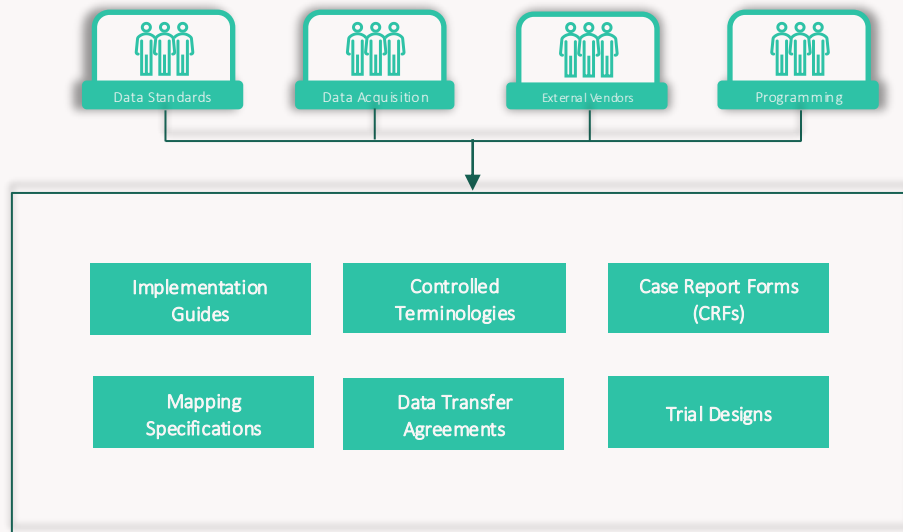


Rationale behind
Decisions



What When Who Why

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

+ New Version ✓ Compare Q Search					
Version	Reason	Created By	Creation Date	Last Modified By	
☐ 3 Draft	Current version	Rajesh Saha	2026-01-15 10:40:03	Rajesh Saha	2
☐ 2 Published	Published draft	Rajesh Saha	2026-01-15 10:40:03	Rajesh Saha	2
☐ 1	Initial Creation via Extend from SDTMIG 3.4	Rajesh Saha	2026-01-14 09:49:31	Rajesh Saha	2

Deviations 1

Versions

Change Log

+ Add to

Q Search

[Learn about deviations](#)

Print

Copy

Affected

Change

Record Identifier

Column

Standard Value

Study Value

NCOMPLT - Completion/Reason for Non-Completion (1)

CR-38	Term	Added	NCOMPLT.COMPLETE RESPONSE/REMISSION	Term	NCOMPLT.COMP RESPONSE/REMI
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CR-38

To do

Details

Activity

Comments

Title (Required)

Add "COMPLETE RESPONSE/REMISSION"

Description

Add "COMPLETE RESPONSE/REMISSION" to the NCOMPLT codelist.
The term is needed at the study level based on the protocol requirement.

CR-38

Approved

Details

Activity

Comments 1

Comments

RS

Rajesh Saha · a few seconds ago

Based on the protocol requirement, this CR is approved. Treat this as study specific update.

Edit

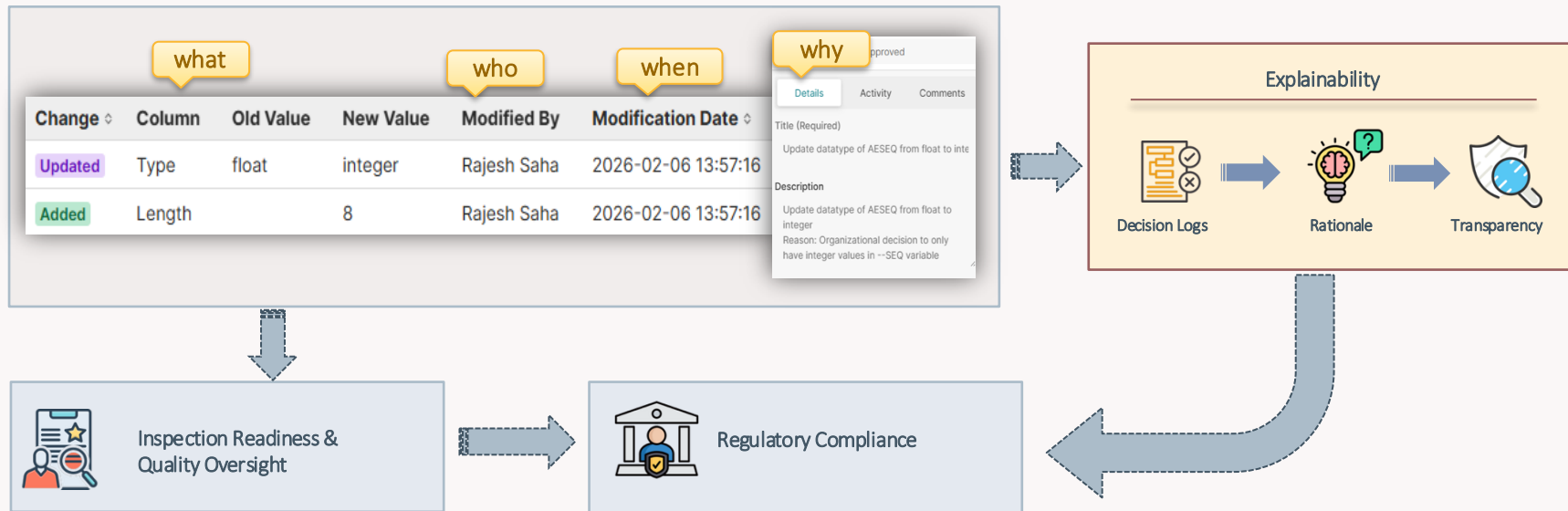
Delete

CHANGE MANAGEMENT

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

Engineering Trust through Traceability

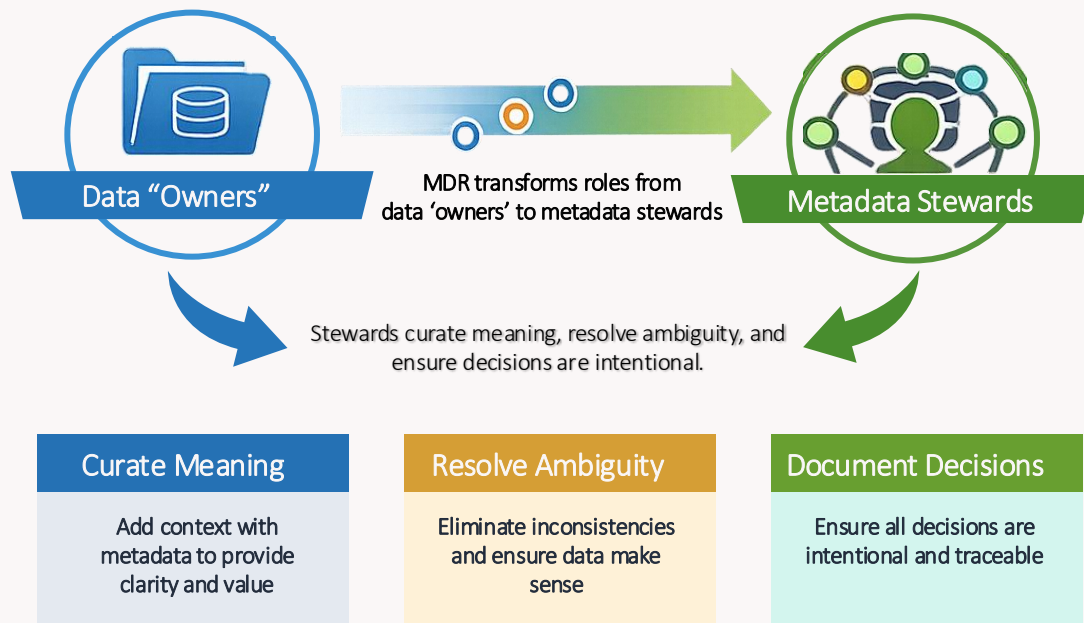
Audit trails in an MDR record who changed what, when, and why.



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

Engineering Trust through Metadata Stewardship

Technology enables trust—but people sustain it.



Use Case Example

Without MDR : "Data Owner" Behavior

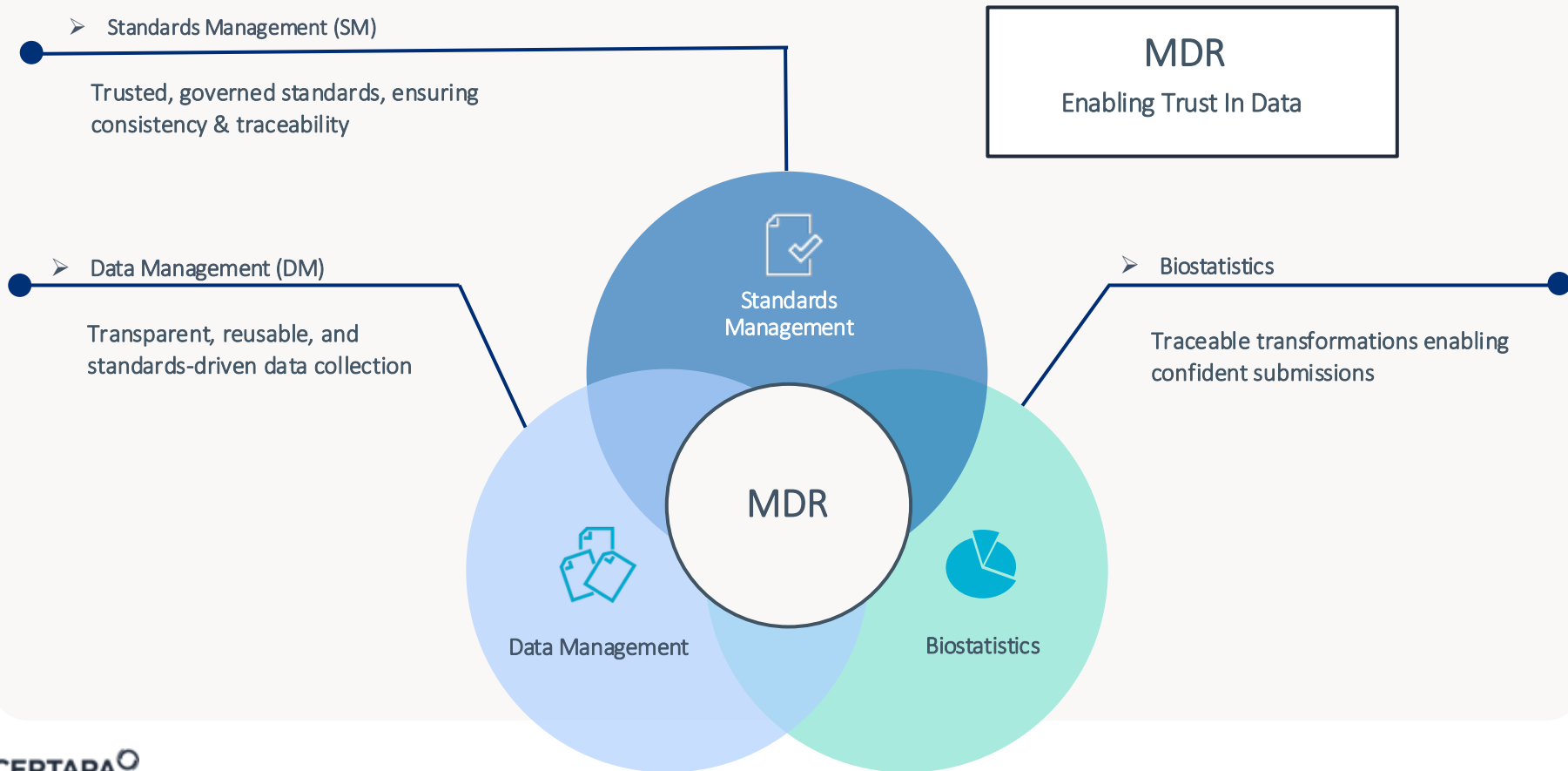
Owns and updates their EDC forms, focuses on their study, communicates changes informally, and is typically not responsible for downstream impacts beyond the EDC system.

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



Questions?

