

Bridging Operational Gaps in Data Standards to Power Agentic Orchestration

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Existing Clinical Data Standards Excel at Defining Final End-States

The Foundational Standards

- **USDM:** Structures clinical protocol.
- **CDASH:** Standardizes data collection instruments (EDC).
- **SDTM:** Governs submission data models.
- **Biomedical Concepts:** Associates data collection items into groupings, types, and formats.

Standards Lack Business Logic

The Gap

- Collection instruments require continuous design, testing, approval, and amendments.
- Collection processes require ongoing review, reconciliation, and cleaning.
- Confirmed but anomalous data requires documentation and remediation.
- Regulators focus on the business logic as much as the submission data.

Clinical Data Must Pass Through Complex Lifecycles

- Data requires continuous review and source-level discrepancy routing.
- Some data has special workflows (protocol deviations, safety case reporting, payments processing).
- Access requires dynamic blinding controls by role/individual (e.g., PK/Safety unblinding).
- Some data is more important (HbA1c efficacy data vs. Serious AE vs. physical exam).
 - Which discrepancy should the data manager, site staff, CRA, and medical reviewer prioritize?

What Do I Need to Know to Review a Prohibited Medication?

Subject		Form Sequence N	Concomitant Medication Name	Concomitant Medication Preferred Na f(x)	Concomitant Medication Raw Start Date f(x)
SCR-0003		1	Hydrocortisone	HYDROCORTISONE	14-Sep-2023
SCR-0003		2	Hydrocorticone/Cinchocaine	HYDROCORTISONE	19-Sep-2023
SCR-0003		6	Hydrocortisone	HYDROCORTISONE	15-Sep-2023

SCR-0003 | LOGS | CMTRT

SDV DMR Signed Frozen Not Locked EDC.CM

Create Query

SDV Not Completed

Query VV-003176: This verbatim doesn't match the indication

Closed | Sep 29, 2025

Message Details*

D Data Manager | Opened: This verbatim doesn't match the indication

Sep 29, 2025 2:19 PM

D Data Manager | Closed: Matches source

Latest Sep 29, 2025 2:20 PM

Item | PDV-000193: prohibited med

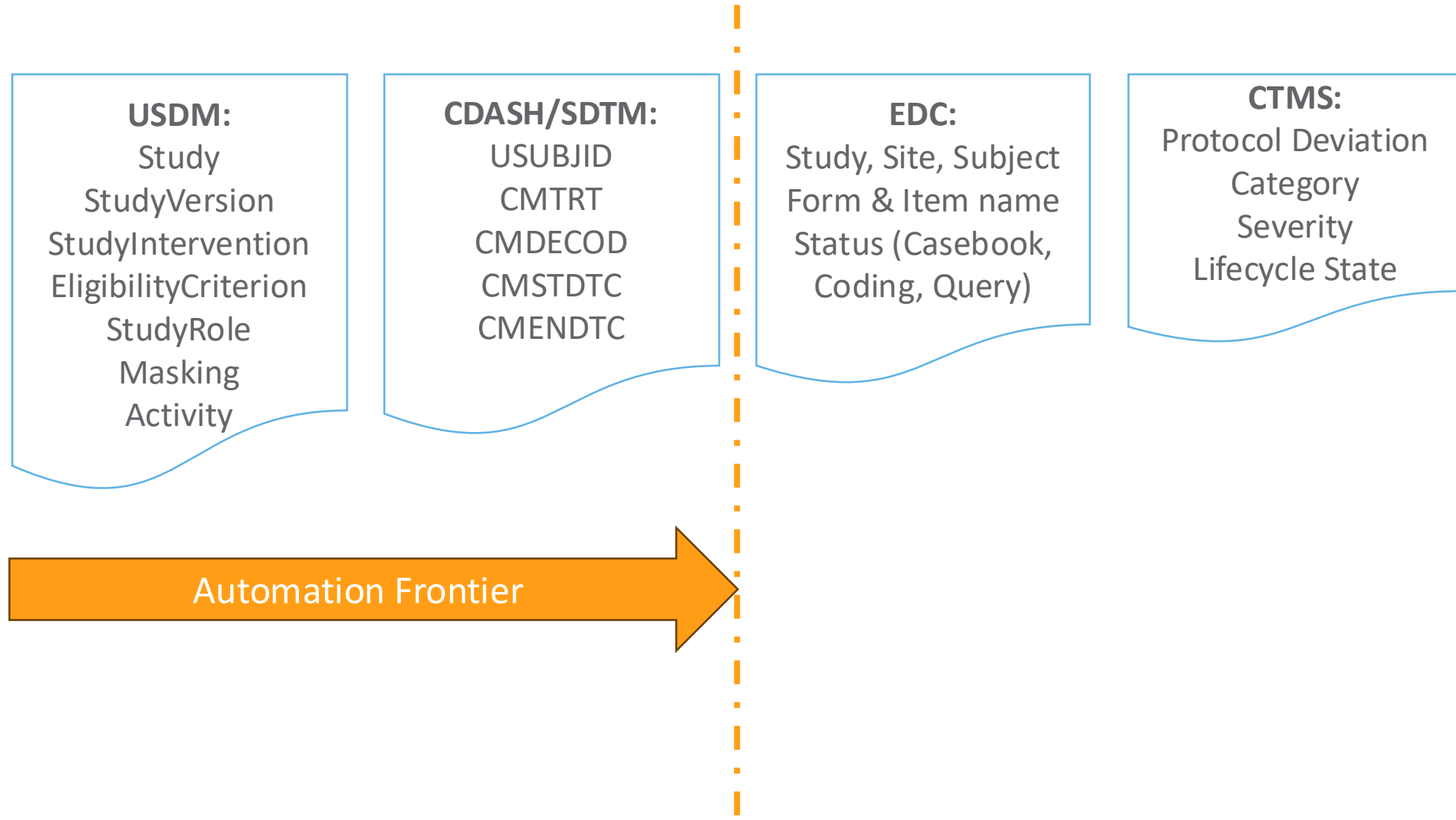
Prohibited Medications 7.1 Prohibited Medications taken Origin: Prohibited Medications Date of Deviation: Sep 15, 2023 Identified: Mar 27, 2026 Major Escalated

subject took prohibited medication

Created: Mar 27, 2026 1:21 PM by Dan Crawford (veeva.com) Modified: May 27, 2026 by Dan Crawford (veeva.com), Updated information



What Do I Need to Know to Review a Prohibited Medication?



Preserving Raw Data Unlocks Operational Context for Automation

The Approach

- Avoid early transformation to SDTM to retain operational metadata.
- Associate raw data with clinical concepts in a semantic classification layer.
- Semantic association enables automated surveillance and backward translation to take actions.
- Risk-based criticality targets highest-priority data for human/agent review.



Classification Enables AI to Execute Source-System Actions

Data Flow



Experts, Agents, MCP, and APIs Keep You Inspection Ready

Action Flow



Human Expert + AI Agent

- Who am I?
- What am I trained to do?
- What do I need to do next?
- Where / when do I need to do it?



MCP / API Gateway

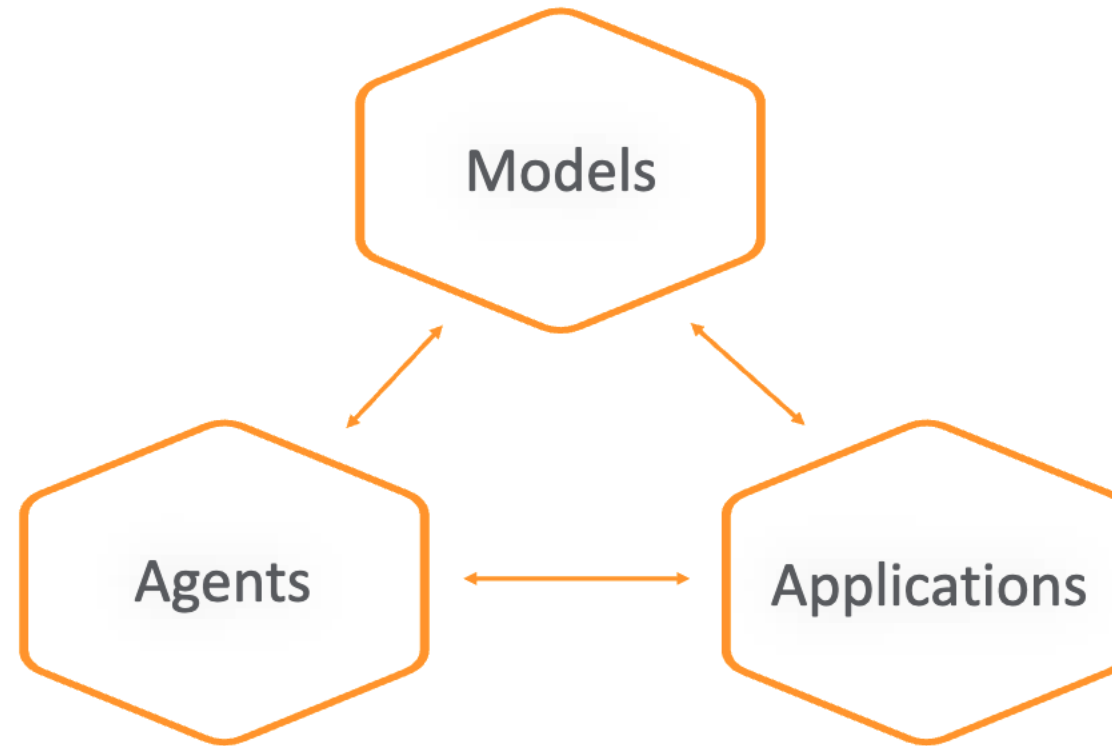
- Who are you?
- What are you allowed to do?
- How do you do it?
- What happened when you did it?



System of Record

- Who is everyone?
- What can everyone do?
- In what order must things be done?
- What was done? When? By whom?

MAAP Architecture



What Is Preventing Rapid Scaling?

The Obstacles

- Poor design of data collection instruments (e.g. multi-domain CRFs).
- Non-standard business logic (important PD vs. major PD).
- System-of-record functional differences (candidate query, observation vs. deviation).
- Opaque regulatory requirements (audit trail review).

AI-Ready Apps Must Bridge Static Models and Active Orchestration

Conclusion

- Existing standards define destinations; orchestration requires a map for the journey.
- Classification + process governance enables safe, scalable AI integration.
- Touching source data as little as possible maintains ALCOA+ principles, inspection-readiness, and speed





Questions?