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Bridging the Divide: Harmonizing HL7 FHIR, OMOP, and CDISC Standards for Regulatory-Grade Real-World Evidence

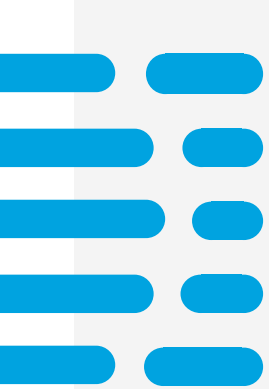
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Agenda

- A Complete Journey from Challenge to Strategic Action
- + The Challenge & Opportunity
 - Understanding fragmented workflows and the vision for integration
- + Foundation: Understanding the Standards
 - Deep dive into HL7 FHIR, OMOP CDM, and CDISC with comparative analysis
- + The Integrated Framework
 - Three stages of data transformation: Ingestion, Analytics, Submission
- + Implementation & Governance
 - Critical success factors, cross-functional teams, and ecosystem building
- + Outlook & Strategic Action
 - Evolving landscape and imperatives for moving forward

The Challenge: Fragmented Data Workflows



Multiple Standards

RWD generated and managed using OMOP for analytics, CDISC for regulatory submissions, and HL7 FHIR for data capture



Disconnected Processes

Data flows are fragmented with resource-intensive transformations happening at late stages



Regulatory Pressure

FDA and agencies increasingly demand RWD in submissions but emphasize data quality, traceability, and transparency

The Opportunity: Integrated Standards Framework

By harmonizing three powerful healthcare data standards, we can create an efficient, traceable pathway for transforming raw real-world data into submission-ready regulatory evidence.



Disparate Data Sources

Multiple unconnected healthcare data streams with varying formats and standards



Integrated Framework

Unified system combining three key healthcare data standards into one cohesive structure



Regulatory-Grade RWE

Processed, validated real-world evidence ready for regulatory submission and decision-making

Understanding the Three Standards

Foundation for Integration

Each standard brings unique strengths. Together, they create a complete solution for capturing, analyzing, and submitting regulatory-grade real-world evidence efficiently and with full traceability.



HL7 FHIR

Modern interoperability standard for real-time, granular clinical data exchange via APIs. Acts as the data ingestion layer, providing standardized access to diverse source systems.



OMOP CDM

Harmonizes diverse healthcare data into a common analytical structure. Enables scalable observational research and analytics across heterogeneous data sources.

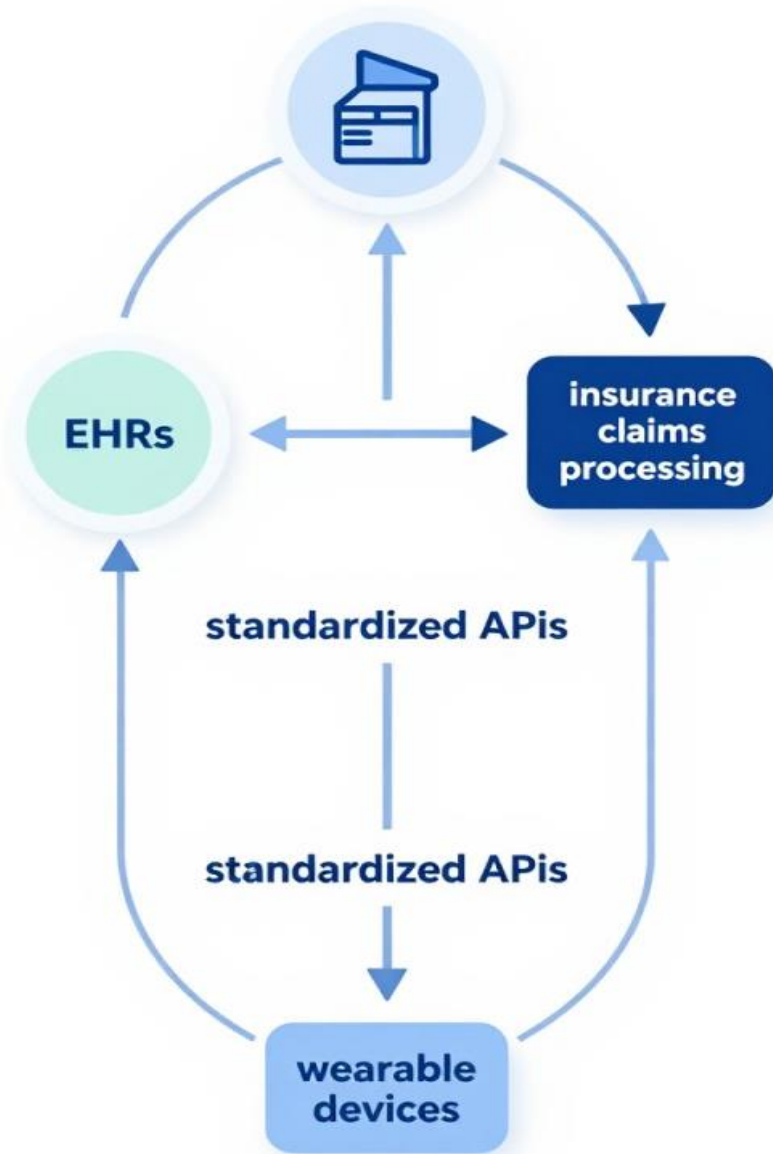


CDISC Standards

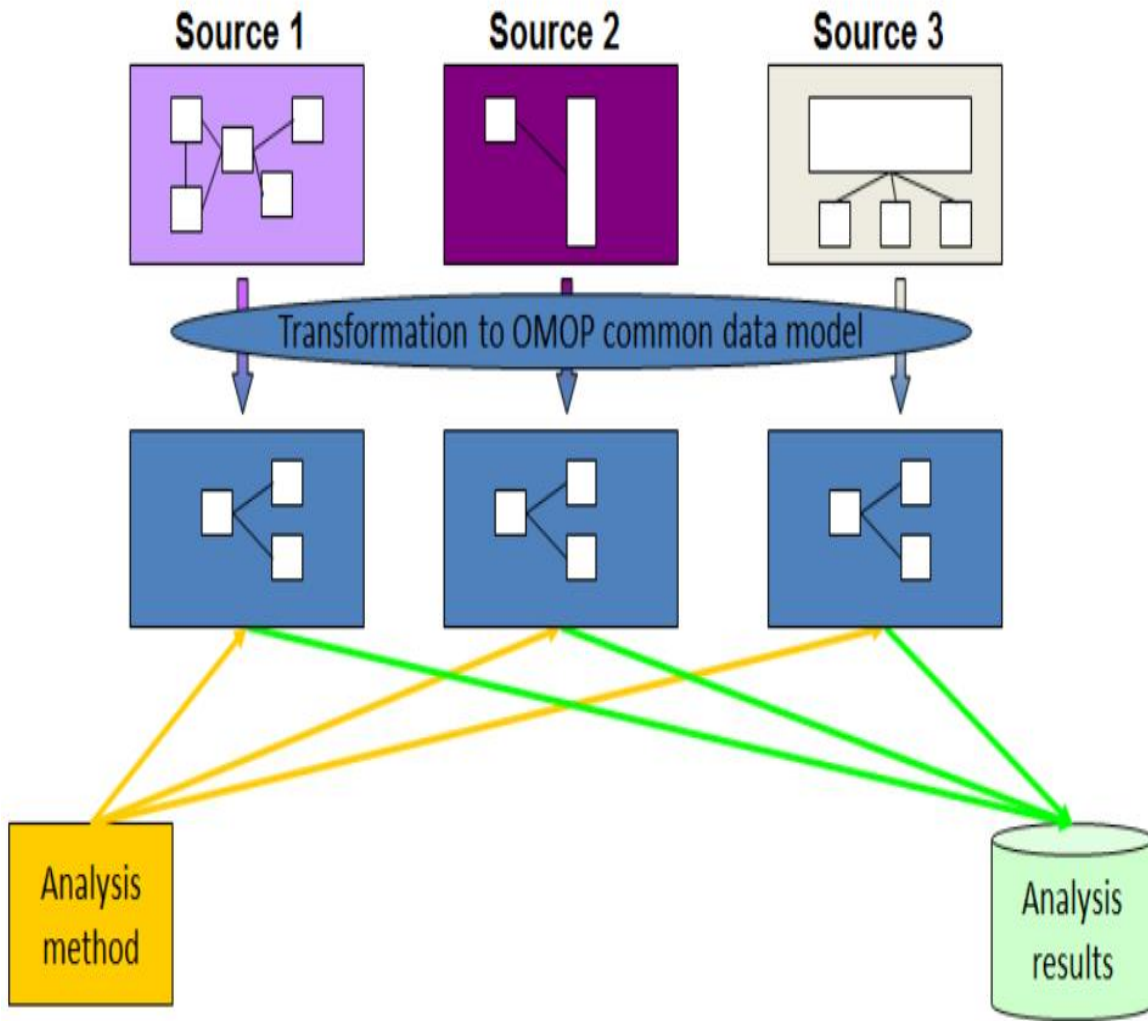
Mandated for regulatory submissions (SDTM, ADaM). Ensures consistency, auditability, and reproducibility. Guarantees analysis-ready, traceability-rich datasets for agencies.

HL7 FHIR: The Data Bridge

- **Strength:** Real-time, API-driven access to granular clinical data
- **Key capability:** Modular resource organization (Patient, Observation, Medication resources)
- **Role statement:** Serves as the upstream component for standardized data ingestion and exchange.
- **Important limitation:** Not designed as an analytical or submission model, but as an interoperability enabler.



OMOP CDM: The Analytical Engine



Primary strength - "Harmonizes diverse data into a unified structure for scalable analytics"

Key capability

Standardized schema with tables like PERSON

OBSERVATION

CONDITION_OCCURRENCE

DRUG_EXPOSURE

VISIT_OCCURRENCE

Use case

Enables longitudinal analyses and population-level research across heterogeneous healthcare datasets.

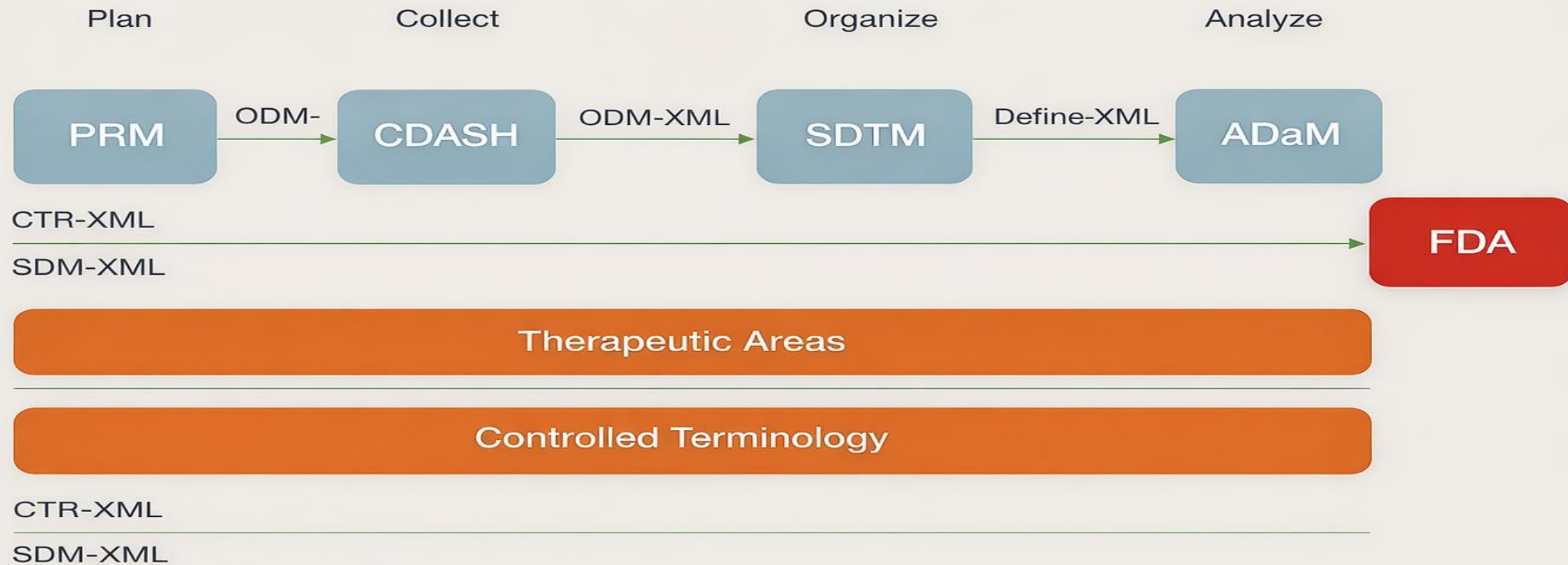
Supports reuse of standardized analytics commonly used in regulatory-supporting RWE studies

Current limitation

Lacks native regulatory traceability and analysis-ready datasets like ADaM.

CDISC Standards in the Clinical Research Process

Clinical study



Expected or required in most regulatory submissions, ensures auditability and reproducibility across the entire clinical research lifecycle.

Comparative Overview of Standards

HL7 FHIR

Real-time, granular clinical data. API-driven interoperability. Not analysis or submission ready. Serves as upstream data ingestion component.



OMOP CDM

Scalable, reusable analytics across diverse data. Harmonizes heterogeneous healthcare data. Limited regulatory traceability and reproducibility.



Integration Synergy

Combined framework leverages each standard's unique strength. FHIR ingestion → OMOP analytics → CDISC submission. Creates traceable, efficient RWE pathway.



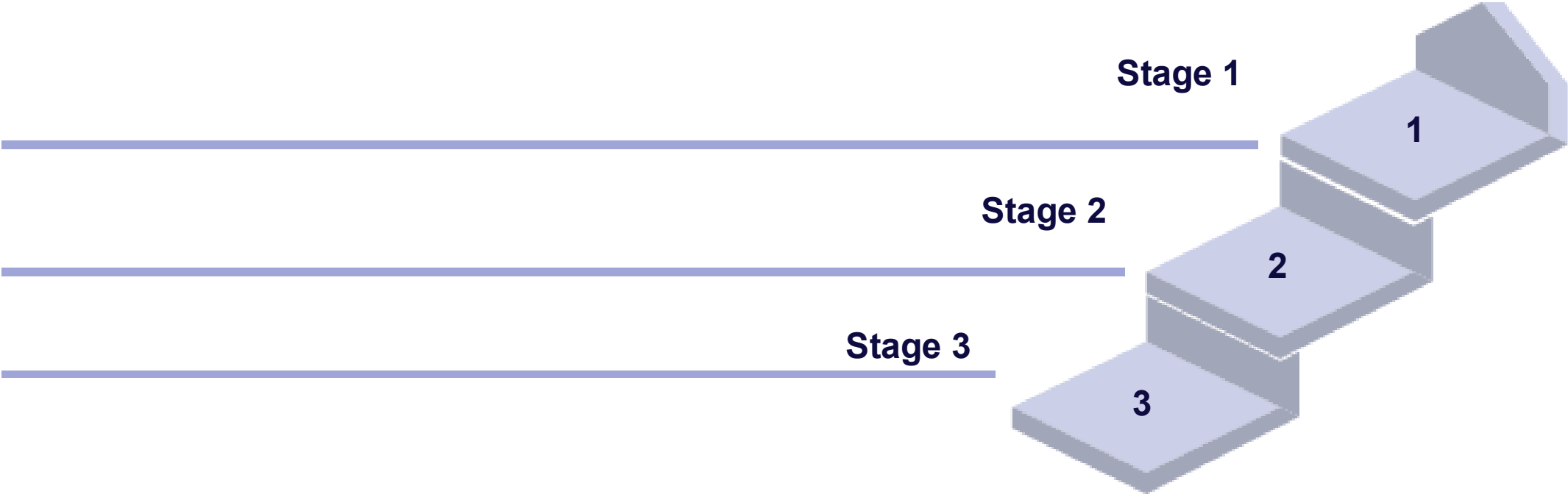
CDISC Standards

Ensures auditability and reproducibility for regulatory submissions. Mandated by agencies like FDA. High transformation effort from raw data.



The Integrated Framework

Three Stages to Regulatory-Grade RWE



Stage 1: Data Ingestion via HL7 FHIR



Objective: Standardize and unify data from diverse sources while preserving traceability and clinical granularity.

Stage 2: Analytical Processing via OMOP CDM



FHIR-Derived Data

- Standardized, clinically granular data from Stage 1



Transform to OMOP CDM

- Map to OMOP schema
- Standardize clinical concepts
- Build longitudinal records



Analytical Outputs

- Longitudinal Analyses
- Scalable Analytics
- Population-level Research

Enables robust observational research while maintaining governance controls for data provenance.

Stage 3: Regulatory Submission via CDISC



OMOP-Based Analytical Outputs

Initial research datasets formatted in OMOP Common Data Model structure



Map to SDTM

Conversion of OMOP data to Study Data Tabulation Model standards



Create ADaM Datasets

Generation of Analysis Data Model datasets for statistical analysis



Generate Define.xml Metadata

Creation of machine-readable metadata documentation for datasets

Regulatory-Compliant Datasets Ready for Submission

Critical Success Factors



Key Challenges

- **Semantic Alignment - Mapping concepts across different standards**
- **Preserving Traceability - Maintaining clear audit trails through multiple transformations**
- **Managing Complexity - Handling operational requirements and resource needs**



Solutions

- **Robust Metadata Management with metadata, source IDs, transformation logs**
- **Automation & Standardization with transformation pipelines, reusable mappings**
- **Organizational Alignment with cross-functional teams**

Building the Ecosystem

Cross-Functional Collaboration & Governance



Teams

- Clinical, Data Engineering, Biostatistics, Regulatory roles working together



Tooling

- Version control, mapping specifications, validation frameworks, automated transformation pipelines



Governance

- Data quality oversight, provenance tracking, compliance monitoring

"Successful implementation requires integrated collaboration across all disciplines and investment in scalable, interoperable infrastructure."

Strategic Imperatives: Moving Forward

Proactive investment in interoperable, standards-aligned architectures will enable organizations to adapt to evolving regulatory expectations and leverage real-world data effectively.

1

Align infrastructure with interoperability standards (FHIR, OMOP, CDISC)

2

Invest in automation and governance frameworks

3

Foster cross-functional collaboration and continuous learning

The time to integrate is now. Real-world evidence is the future of regulatory submissions.

References

- U.S. Food and Drug Administration. [Framework for FDA's Real-World Evidence Program.](#)
- Clinical Data Interchange Standards Consortium (CDISC). [Study Data Tabulation Model Implementation Guide.](#)
- Clinical Data Interchange Standards Consortium (CDISC). [Analysis Data Model Implementation Guide.](#)
- Observational Health Data Sciences and Informatics (OHDSI). [The OMOP Common Data Model.](#)
- Health Level Seven International. [FHIR Release Documentation.](#)

Acknowledgement

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THANK YOU

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