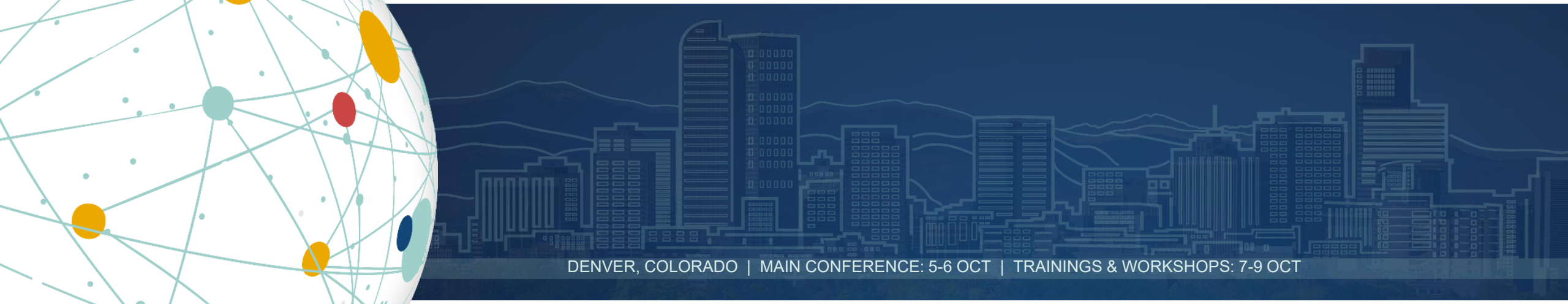


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Reimagining Clinical Trials with FHIR-to-CDISC Interoperability

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Long before a trial asks for them, a patient's diagnoses, medications, and lab results already live in the EHR . A data with nowhere to go until someone comes looking.

Someone will. The submission needs SDTM. It always has.

The bridge exists. CDISC and HL7 have drawn the blueprints. The tools were never the problem.

What's missing is the discipline to walk that path.

Agenda

1. What areas of clinical trial can EHR enrich
2. Benefits we can achieve
3. Challenges we encounter
4. Conceptual Reference Architecture
5. Considerations
6. Examples

Introduction

FHIR speaks the language of care. SDTM speaks the language of evidence. Together, they turn clinical data into clinical trials evidence.

- **EHR** is a care record. Authored during treatment, to guide treatment and support billing. Coded, timestamped, and complete for that purpose.
- **FHIR:** An HL7 standard for designed for real-time interoperability between EHRs, apps, devices, etc.
  - Key components
    - Resource – Encompasses ~150 resources including Clinical summary, diagnostics and Medication linked to each other in a graph like format.
    - Profile – constrains a resource for a use case. US Core is the US baseline.
    - Implementation Guide- Multiple IGs to handle country regulations and use cases
    - Coded elements – LOINC, SNOMED CT and RxNorm ride along inside the resource.

FHIR standardizes access, not content

- **Clinical trial record** is a research record. Authored to a protocol, to answer a pre-specified question and support a regulatory decision.
- **SDTM:** A CDISC standard designed for regulatory submission and analysis of clinical trial data.
  - Key components
    - Domain – A dataset holding one class of observation. LB, AE, CM. Records link through USUBJID and sequence numbers, not references.
    - Implementation Guide – constrains the model for submission. SDTMIG is the baseline.
    - Controlled Terminology – CDISC CT, MedDRA, and WHODrug supply the permitted values.

SDTM standardizes content, not access

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What areas of clinical trial can EHR enrich



Before the Trial

Check eligibility criteria, pick sites with enough patients

At Screening

Labs, vitals, history & concomitant meds already recorded

During the Trial

Visit assessments + outside labs & care the site never sees

At the Endpoint

Hospitalizations, deaths, emergency visits

After the Trial

Survival & status — no need to bring patients back

From screening onward, EHR data feeds the submission — where the full framework becomes necessary.

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Benefits we can achieve

Faster Study Timelines

Cuts weeks off site activation and data lock

Improved Data Accuracy

Removes manual re-entry and transcription errors

Real-Time Data Visibility

Sponsors see clinical data as it's captured

Reduced Site Burden

Sites spend less time on redundant data entry

Standardized, Submission-Ready Data

Structured to CDISC standards from the start

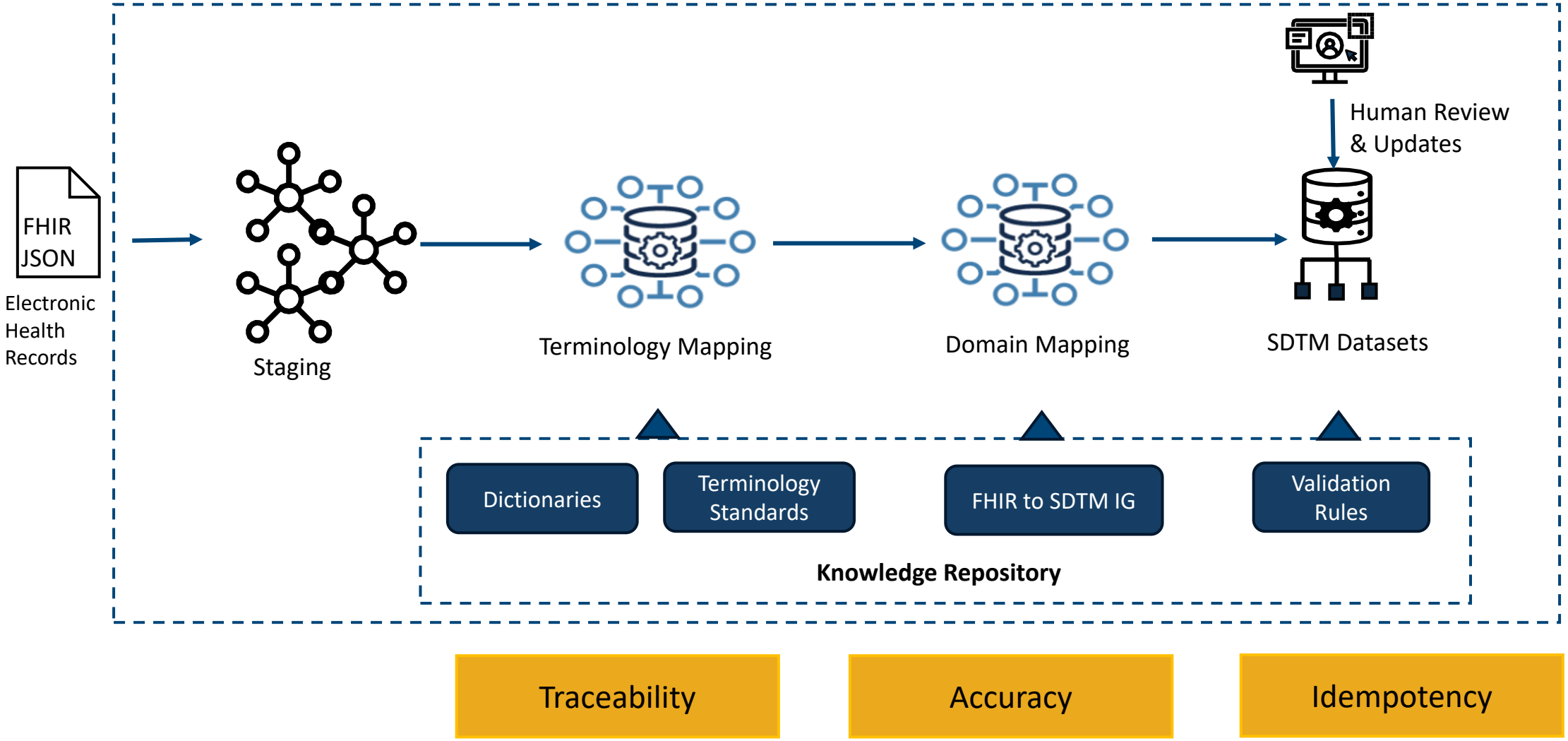
Eliminates Double Data Entry

One capture, one source of truth

Challenges we encounter

	Resource–Domain Many-to-Many Relationship	01
	Structural Mismatch: Graph to Table Conversion	02
	Terminology Harmonization	03
	Reconciling Visit Schedules with Clinical Encounters	04
	Processing Non-Standard / Extension Data	05
	Heterogeneity Across Source Systems	06

Conceptual Reference Architecture



Considerations

- **Not every domain is equally tractable**

STRONG FIT	WORKABLE WITH RECONCILIATION	ASSIST ONLY
Observation, Patient	Medication, Procedure	Condition, Encounter
LB, VS, EG, DM	CM, EX, PR	AE, MH, DS, SV
The clinical fact means the same thing in both worlds.	Mappable, but needs coding review and concordance checks against site-entered data.	Information gap in the collection of data fields required for clinical analysis

- **Traceability enables transparency & auditability**
- **A persistent, versioned mapping repository brings reusability and automation with study specificity plugin**
- **Treat extensions cautiously since ModifierExtentions may hold the contexts, while specific extension URLs may have SUPPQUAL record**

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Worked example: Observation to LB

FHIR	SDTM	WATCH FOR
Observation.code (LOINC)	**LBTESTCD / LBTEST**	*Via a curated crosswalk*
code.coding.code	**LBLOINC**	*Retain the source code — free provenance*
valueQuantity.value	**LBORRES**	*Preserve the comparator*
valueQuantity.code (UCUM)	**LBORRESU**	*Keep the code, not just the display*
referenceRange.low / .high	**LBORNRLO / LBORNRHI**	*Which range applies needs a rule*
effectiveDateTime	**LBDTC**	*Collection time — not "issued"*
dataAbsentReason	**LBSTAT / LBREASND**	*Not performed is not a null result*

Routing first: exclude entered-in-error and cancelled. Decide preliminary explicitly. Category absent happens — flag it as inferred.

Constraints with Adverse Events and Visit data

AN ADVERSE EVENT RECORD NEEDS

- Relationship to study treatment
- Seriousness against protocol criteria
- Action taken with study drug
- Outcome assessed against protocol definitions

These are clinical judgments an investigator makes, usually captured via a separate eCRF or eCOA form, not derivable from EHR data

A SUBJECT VISIT RECORD NEEDS

- Protocol Visit Schedule
- Relationship with Epochs
- One to one relationships
- Unscheduled vs. scheduled visit determination

EHR data is not the primary source of Subject Visit and used only as a secondary cross-check or to backfill actual visit dates when the CTMS date is missing or disputed.

Summary

Engineering solves the structure and terminology while clinical judgment decides meaning; getting this balance right is what makes real-world data trial-ready.

It lets sponsors move faster by automating the bulk of the mapping, while preserving the accuracy and traceability regulators require by directing judgment calls to human review.

Let Real World EHR data rightly empower clinical trials

Thank You!

