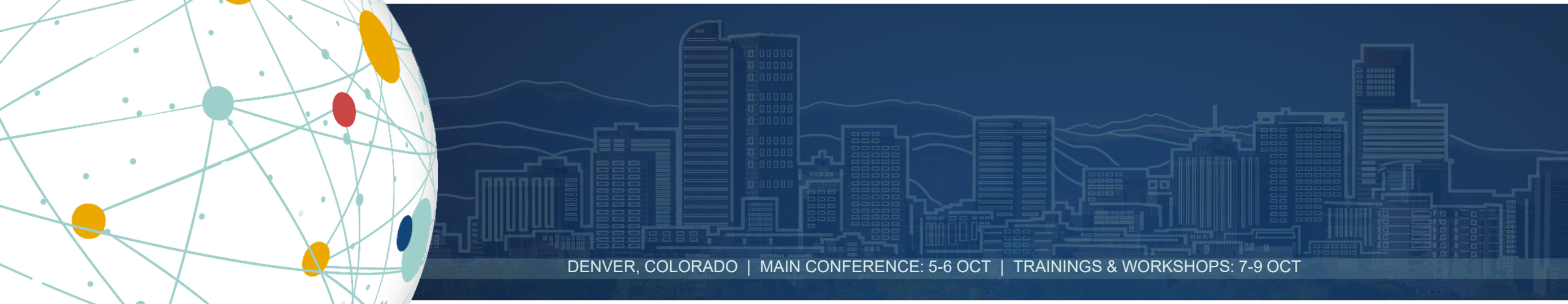


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Closing the Digital Data Flow Gap

AI-Powered Protocol Digitalization with Pluggable EDC Adapters for Automated Study Builds

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Agenda

1. Why protocol-to-study-build remains a Digital Data Flow gap?
2. How does a multi-agent pipeline work?
3. Traceability and human review in regulated workflows
4. Pluggable EDC adapters for operational study builds
5. Lessons Learned

Part 1

The gap between protocol finalization and study build readiness



The Digital Data Flow Gap



Clinical study builds still begin with static protocol documents



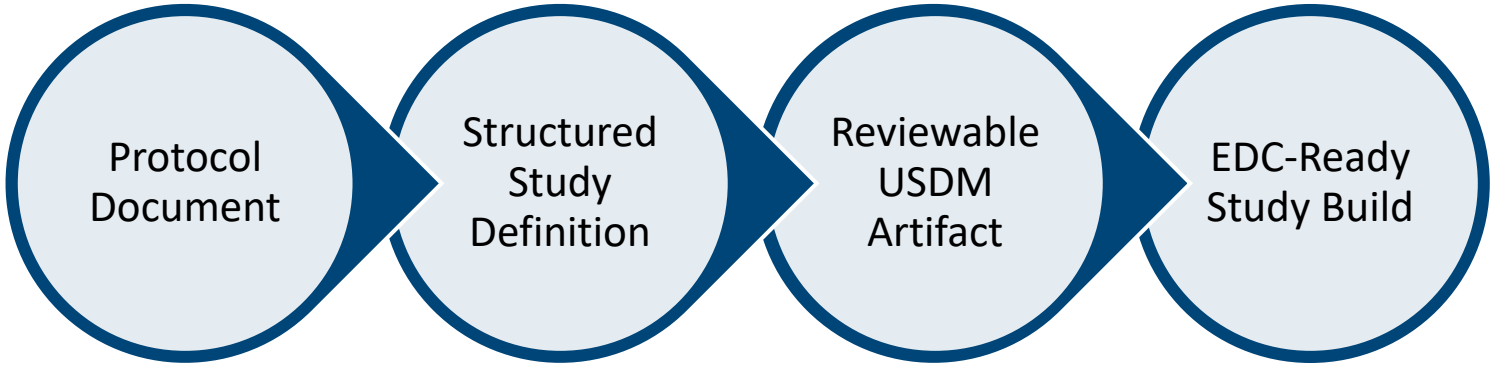
Teams repeatedly interpret study design, visits, activities, assessments, schedules, footnotes, and eligibility criteria



This creates repeated effort, inconsistent interpretation, limited reuse, and delays between protocol finalization and study activation

Static protocols contain study design knowledge, but that knowledge is not yet machine-actionable.

The Problem Is Not Just Extraction!



Most automation efforts stop once protocol content has been extracted

The operational gap is larger than document understanding

The real need is structured, traceable, reusable study design metadata that can move downstream

Part 2

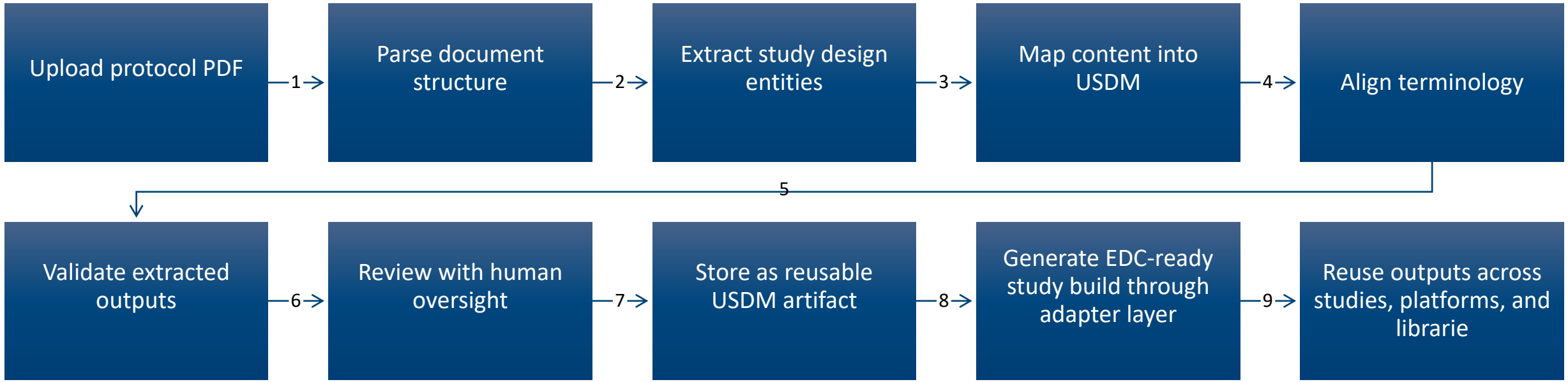
A standards-led AI pipeline for protocol digitalization

Solution Overview

Multi-agent document understanding for protocol text, tables, schedules, and appendices
Semantic extraction of study design elements from protocol content
USDM mapping of extracted entities and relationships
Terminology alignment using NCIt, MedDRA, and CDISC Controlled Terminology
Source-level traceability and human-in-the-loop review before downstream use
Pluggable EDC adapter layer for automated study build readiness

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Protocol PDF to EDC-Ready Build



Multi-Agent Architecture

Vision / Document Agent

- Reads protocol content, tables, schedules, and section structure

Section Classification Agent

- Identifies protocol sections and routes content

USDM Mapping Agent

- Maps extracted entities into USDM components

Ontology Agent

- Aligns terms with NCIt, MedDRA, CDISC CT, and related terminology sources

Validation Agent

- Checks completeness, consistency, and quality expectations

Lead Agent

- Orchestrates handoffs and controls the end-to-end workflow

USDM as the Study Design Backbone

- USDM provides the machine-actionable structure needed to turn protocol content into reusable study design metadata
- Current extraction focus includes study identifiers, versions, organizations, populations, objectives, endpoints, eligibility, arms, epochs, activities, and interventions
- USDM creates a structured bridge between protocol authoring and downstream operational systems
- The output becomes searchable, comparable, reusable, and ready for further automation

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Traceability and Human Review

Traceability

- Links each extracted element to its protocol source location
- Shows source context: narrative, table, schedule, or appendix
- Surfaces conflicts before downstream use

Human Review

- Compare AI output with highlighted protocol evidence
- Validate clinical intent and sponsor conventions
- Approve, correct, or reject before reuse

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Pluggable EDC Adapters

- The adapter layer converts reviewed USDM output into EDC-ready study build artifacts
- Adapters can support platform-specific formats and sponsor-specific form libraries
- Therapeutic-area-specific eCRF design patterns can be reused instead of recreated
- New EDC platforms require new adapters, without a new protocol digitalization pipeline

Extraction creates structured knowledge.

Adapters turn that knowledge into operational study build output.

Part 3

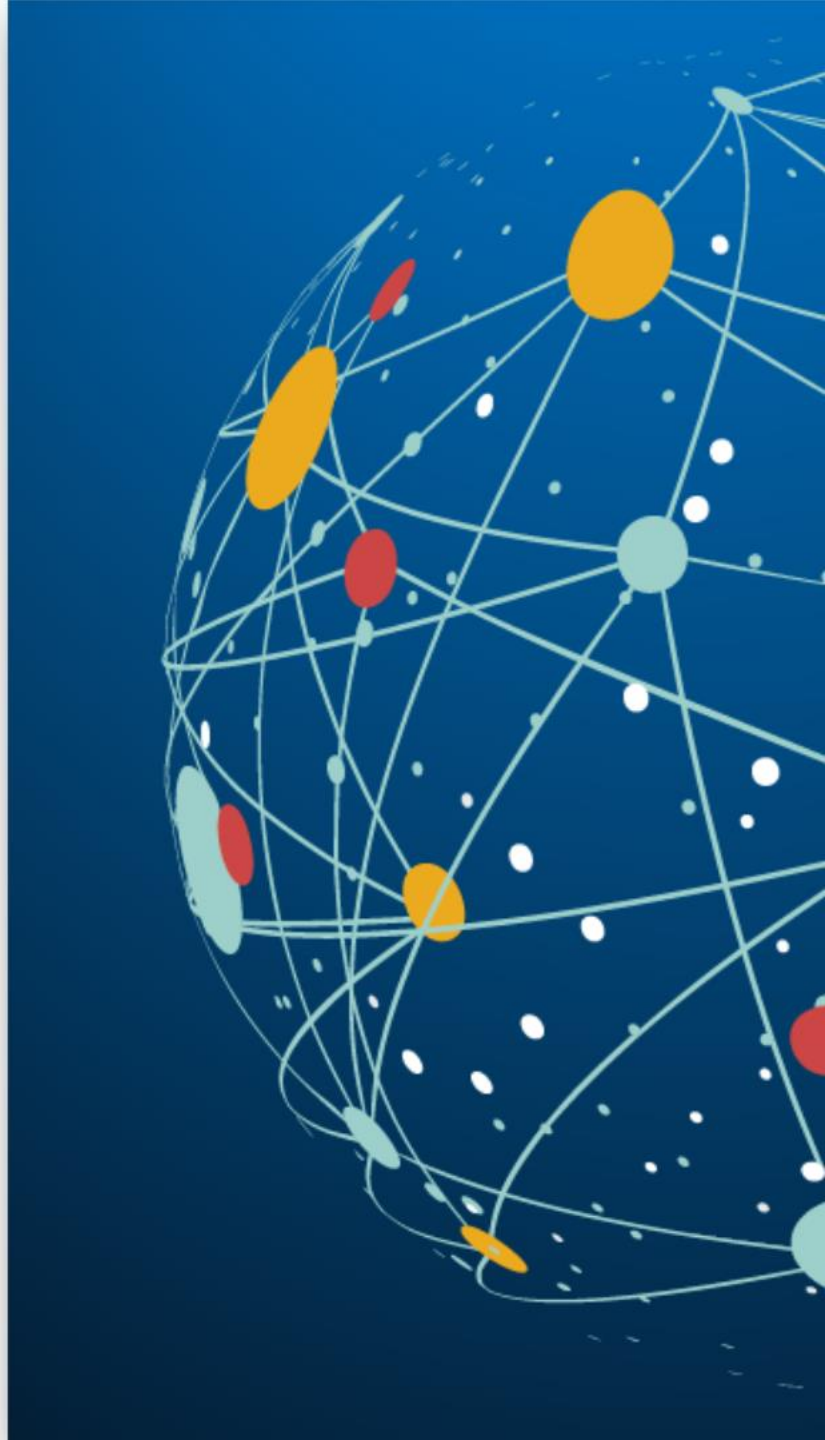
Demonstration, challenges, and lessons learned

Demonstration



Real-World Challenges Encountered

- Conflicts across narrative text, schedules, and appendices
- Dense schedules with footnote-driven logic
- Conditional procedures and visit-dependent assessments
- Legacy protocols missing modern metadata
- Sponsor-specific terminology and assessment conventions
- Broad clinical terms requiring domain interpretation
- Amendments requiring version-aware reprocessing
- Governance expectations for AI-derived artifacts



Lessons Learned

- AI accelerates first drafts; **experts** validate final interpretation
- USDM provides the interoperability backbone for downstream automation
- Traceability builds trust in source-linked extraction
- Adapters convert digitalization into operational study build value
- Governance must cover review, versions, amendments, and approval

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Closing Message

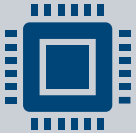
From static protocols to digital study blueprints.



Protocol knowledge should become reusable, standards-based, machine-actionable study assets



The practical path: Protocol PDF to USDM Study Definition to Human Review to EDC-Ready Build



AI, USDM, traceability, and adapters turn protocol digitalization into operational Digital Data Flow

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Questions?

