

2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



DENVER, COLORADO | MAIN CONFERENCE: 5-6 OCT | TRAININGS & WORKSHOPS: 7-9 OCT

Smart ClinSAP

AI Driven Generation of Statistical Analysis Plans

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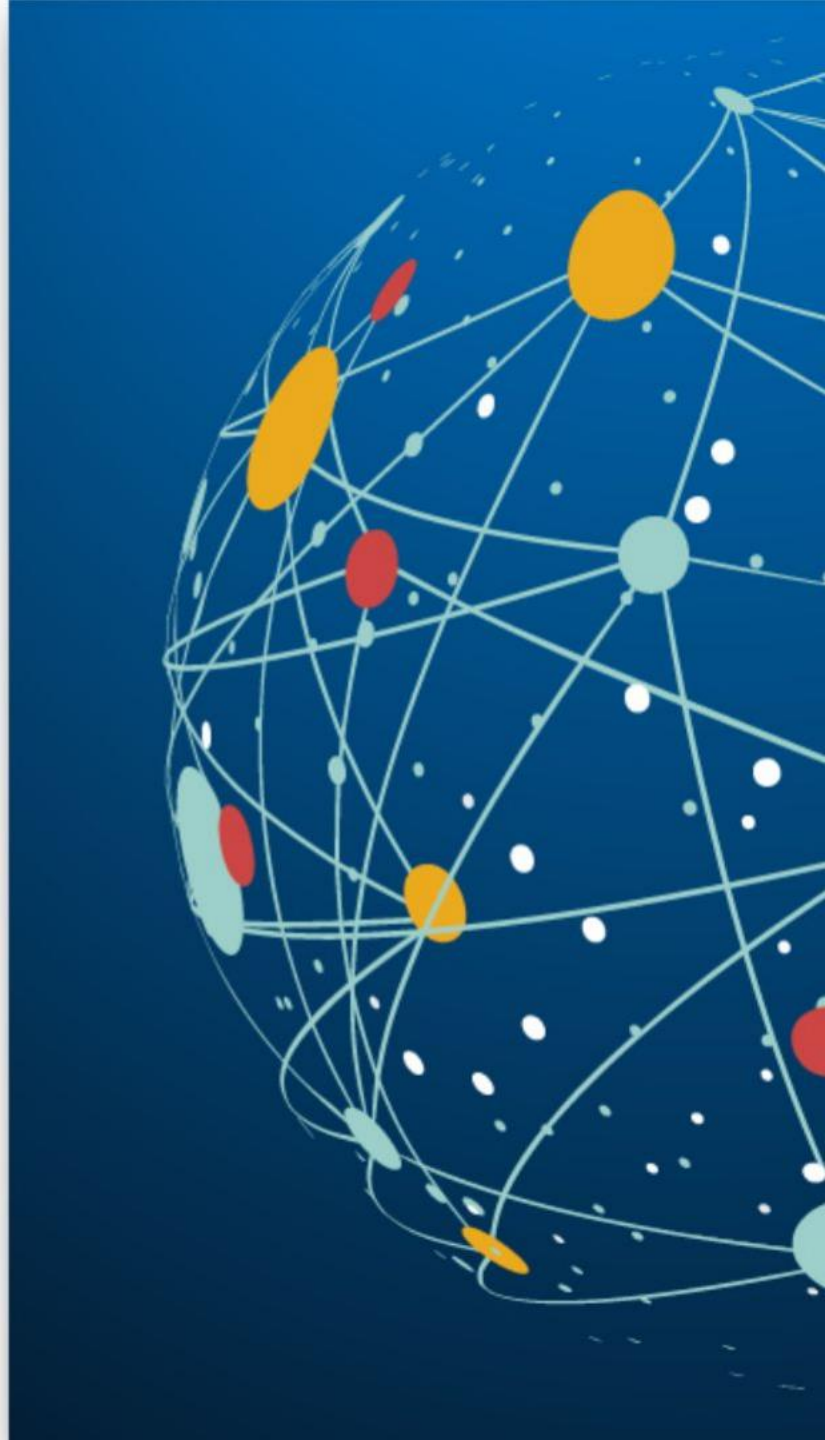
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The Manual SAP Bottleneck

- **Prolonged Drafts**
  - Manual fragmentation creates a 4-to-6-week SAP generation bottleneck.
- **Traceability Gap**
  - No structural link exists between the clinical protocol and the SAP.
- **Execution Disconnect**
  - Translating study definitions into code demands heavy manual intervention.



Meet SADM

- **CDISC USDM**
  - The external standard for clinical study design.
- **Proprietary SADM**
  - Our explicit extension translating USDM into computable statistical rules.
- **Resolved Pipeline**
  - USDM →SADM →TransCelerate SAP →Executable Code

Study Analysis Definition Model (SADM) – a natural extension of USDM for Statistical Analysis Plan's…

SADM: Built on USDM

Reused from USDM (18)	Added by SADM for the analysis (24)	
StudyDefinitionDocument	StatisticalAnalysisApproach	AlphaTransferRule
VersionHistoryEntry	StratificationFactor	MissingDataStrategy
StudyDesign	SubgroupAnalysis	DataHandlingConvention
Objective	SubgroupCategorization	ProtocolDeviationHandling
Endpoint	AnalysisSoftware	SampleSizeDetermination
Estimand	AssumptionCheck	InterimAnalysisDefinition
IntercurrentEvent	CensoringRule	DerivationConcept
AnalysisPopulation	SensitivityAnalysis	AnalysisConcept
PopulationDefinition	SupplementaryAnalysis	SafetyAnalysisFramework
StudyArm	StatisticalHypothesis	AdverseEventDefinition
StudyEpoch	MultiplicityAdjustment	ExposureCalculationRule
StudyIntervention	TestingFamily	ClinicalSignificanceCriteria
NarrativeContent		
CommentAnnotation		
Abbreviation		
Condition		
Activity		
Procedure		

Source: SADM Implementation Guide v1.0, §5 (R. Ravichandran)

Reuse the standard.

Add only what a statistical analysis plan needs.

The Knowledge Graph

- **Oncology Foundation**
  - Built on 97 Oncology Protocol-to-SAP pairs with ~15,000 analysis instances.
- **Extensible Architecture**
  - Anyone can feed in digitized protocols or SAPs to enrich the graph and expand domain coverage.
- **Plug-and-Play Rules**
  - Easily adapts to non-Oncology ontologies and sponsor-specific templates.

Deep in Oncology. Digitally extensible to any therapeutic area.

Production-Ready

- **End-to-End Traceability**
  - Complete lineage from SAS/R code back to the source protocol.
- **Continuous Evaluation**
  - Drift checks and gold-standard release gates on validation studies.
- **Measured Accuracy**
  - Quantitative tracking of structural fidelity and semantic similarity.

Every derivation is explicitly traced. Every release is quantitatively checked against historical ground truth.

Live Demo

“From Unstructured Protocol to Executable Artifacts”



Click to play the demo · 2:53

Thank You!

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Questions?

Smart ClinSAP

clinsap.airesearch.lsac-dev.com

Explore the demo site (view-only)

