



CDISC India Day

Analysis Concepts: From Concept to Execution

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Speaker



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Edwin has over 20 years' experience in different roles in pharma, biotech, CRO, non-profit and academia. His expertise includes standards development, end-to-end metadata-driven programming, process improvement, and tool development.

He is currently self-employed at Raccoon Consulting and senior consultant for CDISC. He is an active CDISC member as their USDM Content Owner, Analysis Concepts Workstream Lead and an ADaM and ARS team member.

He is also an active PHUSE member, contributing to PHUSE EU Connect as frequent presenter, stream chair, conference chair, and is currently a permanent member of the planning committee. He was also a working group lead on Optimizing the Use of Data Standards and part of the PHUSE Computational Science Symposium organizing committee.

Agenda

1.Approach, Theory and Design

2.Building and Executing an eSAP in Practice



Approach, Theory and Design





Problem Statement

Statistical Analysis Plan (SAP) is a plain-text document:

- Ambiguous by design
 - Incomplete
 - Open to interpretation
- Limited reuse of prior work
- Not machine-readable (or executable)
- Fragile traceability

The primary analysis of the ADAS-Cog (11) at Week 24 will use the efficacy population with LOCF imputation for any missing values at Week 24.

An ANCOVA model will be used with the baseline score, site, and treatment included as independent variables.

Treatment will be included as a continuous variable, and results for a test of dose response will be produced.

Solution

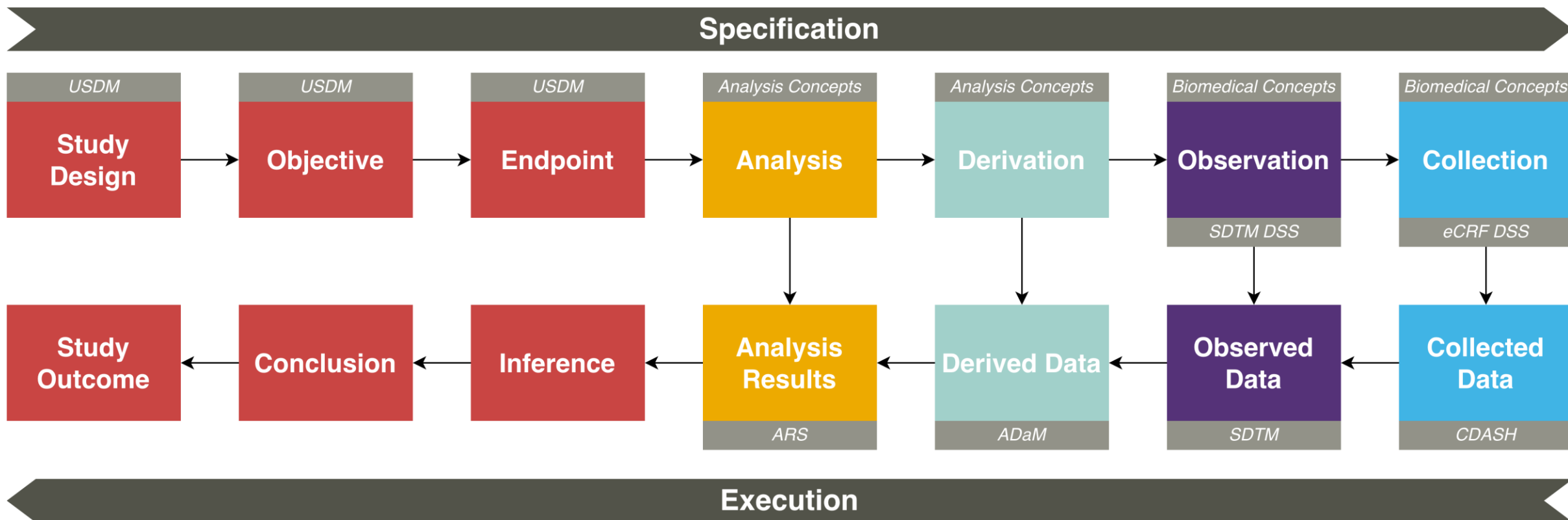
Replace unstructured, narrative SAP with an executable, standards-based specification built on CDISC USDM and the Analysis Concepts Model



Benefits

- Allows **interchange** of analysis specifications between systems and organizations
- Machine-readable specifications directly linked to code allows **automation** and reuse
- Reduced ambiguity by **enforcing precision**
- Increased traceability by **clear linkage** from results to USDM and vice versa
- Common language for expressing derivations and analyses streamlines **collaboration**

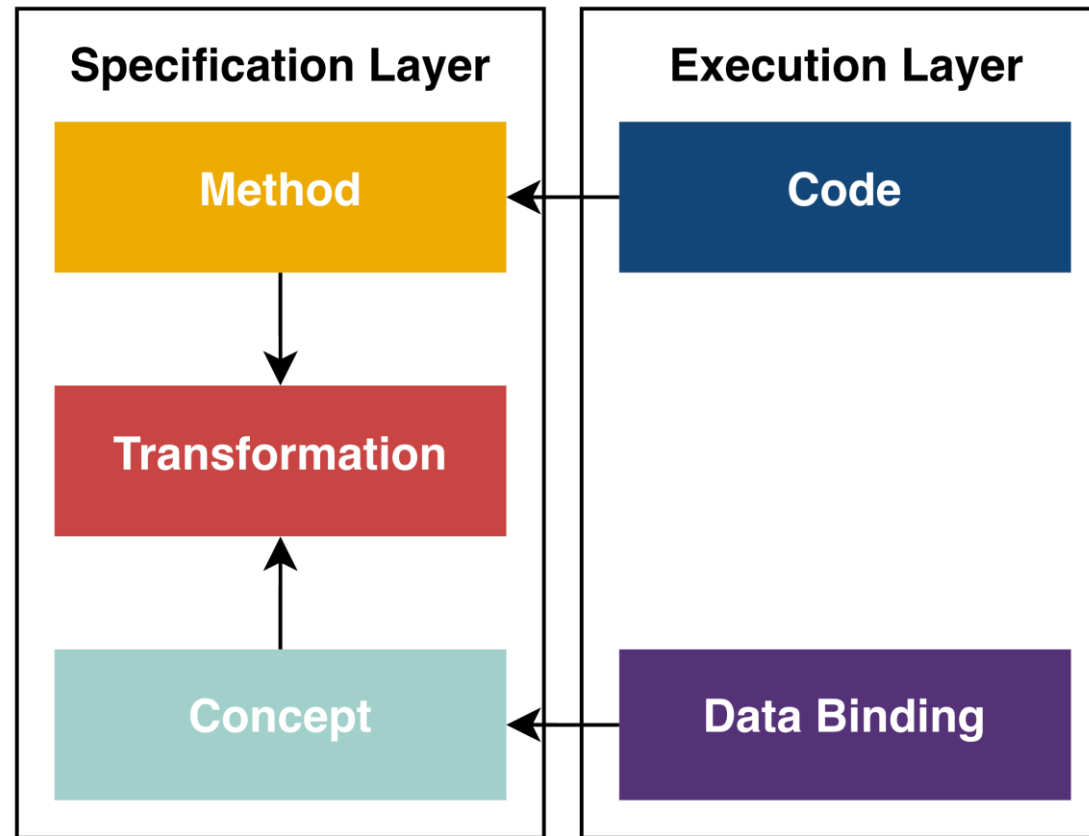
End to end specification and execution



Strict separation of layers

Specification Layer	Execution Layer
• Human-readable • Abstract, semantic, logical • Has meaning in the real world • Independent of data (standards) • Language-agnostic • Normative standard • CDISC Library	• Machine-readable and executable • Concrete, syntactic, physical • Implementation of specification • Binds data (standards) to specification • Binds code to specification • Reference implementation • CDISC Analysis Concepts Portal

High-level components



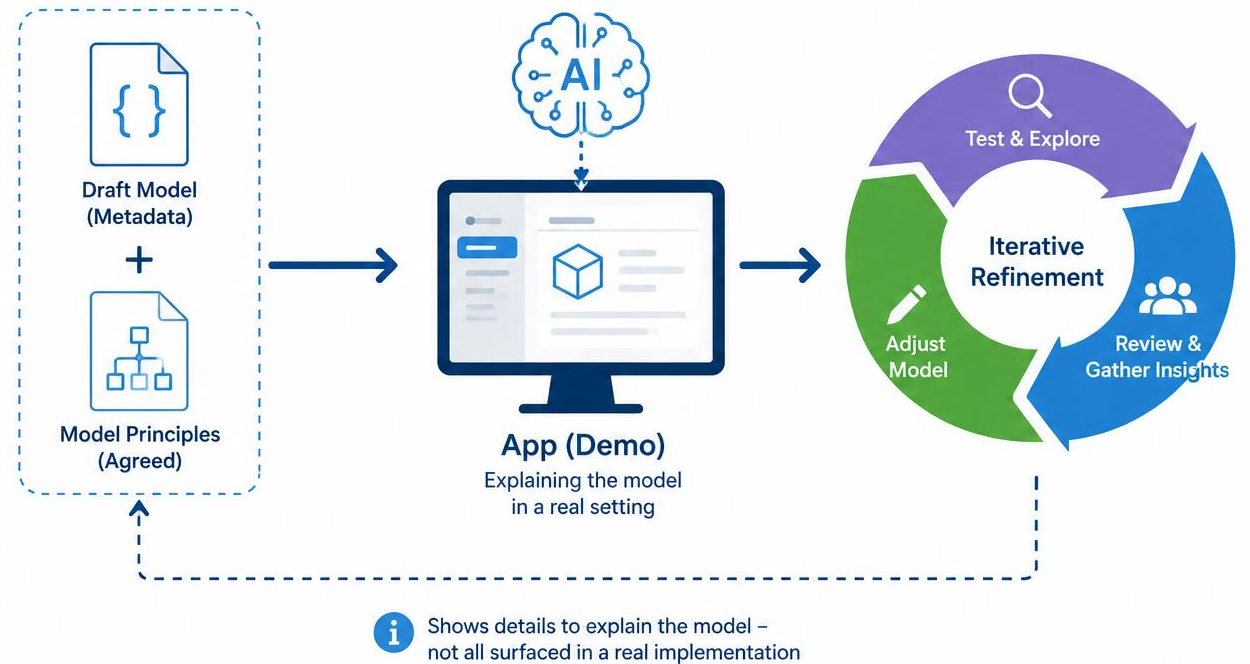


Building and Executing an eSAP in Practice



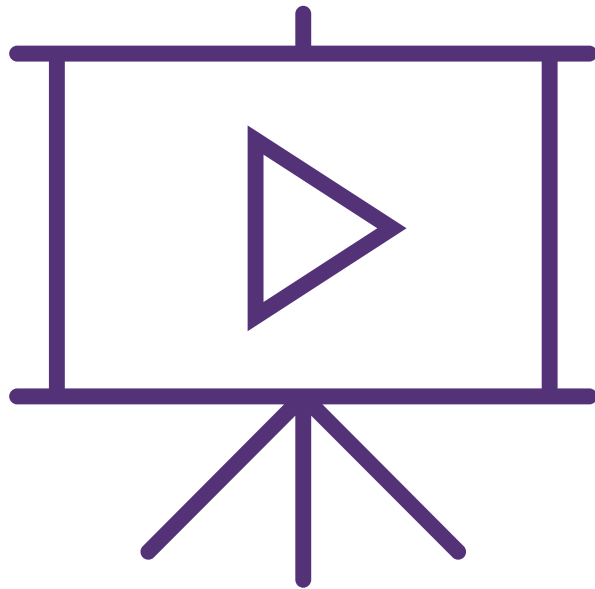
Demo Introduction

- Used AI to help build an app to show and tell
- Made according to draft model
- App helps to test adjustment to model
- App displays details a real implementation may not show to end-users





Demo



*Draft model
framework for
eSAP*



WORKFLOW STEPS

SPECIFICATION LAYER

- 1 Select Study**
Choose a study from USDM
- 2 Study Overview**
Objectives, endpoints & design
- 3 Endpoint**
Variable of interest
- 4 Analysis**
Summary measure
- 5 Summary**
Review all endpoints
- 6 Derivations**
Dependent derivation pipeline
- 7 eSAP Builder**
Generate analysis plan

EXECUTION LAYER

- 8 Execute**
Run analysis via WebR
-
- Configuration**
Variable mappings

AC/DC Framework

Select a study to begin building your electronic Statistical Analysis Plan

Available Studies

CDISC PILOT - LZZT - USDM aligned

H2Q-MC-LZZT

Phase II Trial **Alzheimer's disease**

The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought ...

3

Arms

6

Objectives

11

Endpoints

Breast Cancer Study

Oncology USDM study

TBD

A breast cancer study is available in a future update.

COMING
SOON

Arms

Objectives

Endpoints

Takeaway



Before

SAP = document
Interpretation required
Traceability manual
No linkage to USDM
Reimplementation every study



After

SAP = executable specification
Machine & AI -readable & testable
Traceability by design
Linked to USDM
Reuse built-in



Thank You!

