

Analysis Concepts: From Concept to Execution

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Speakers



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Agenda

1. Approach, Theory and Design - Edwin
2. Building and Executing an eSAP in Practice
- Kirsten

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

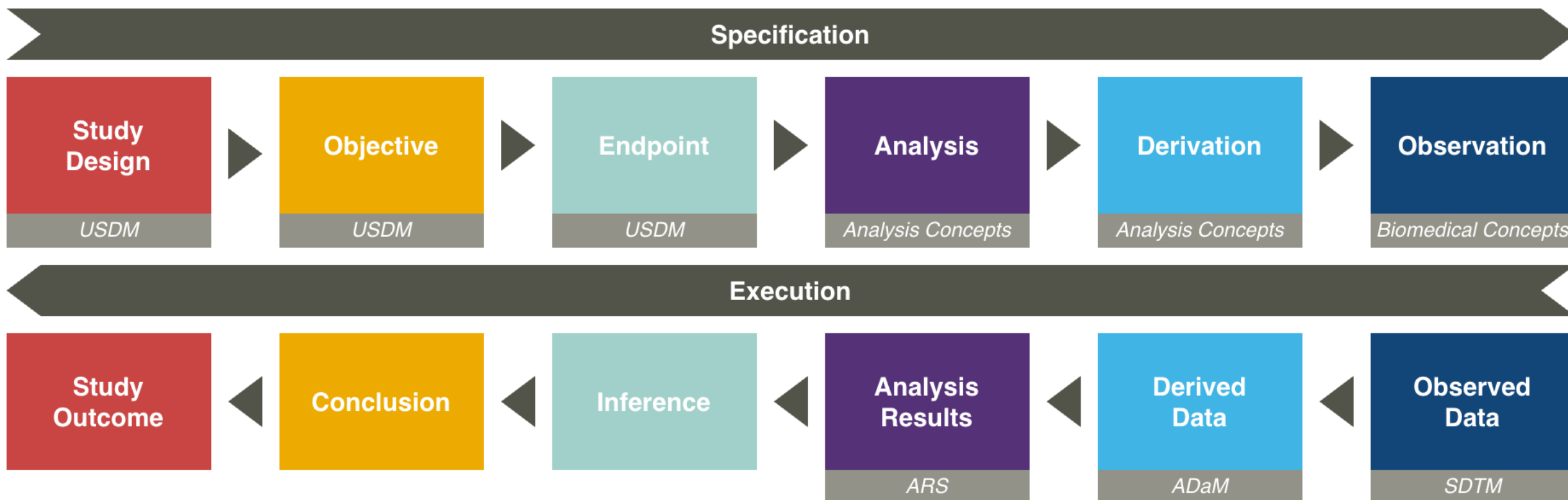
Replace unstructured, narrative SAP with an executable, standards-based specification built on CDISC USDM and the Analysis Concepts Model



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**

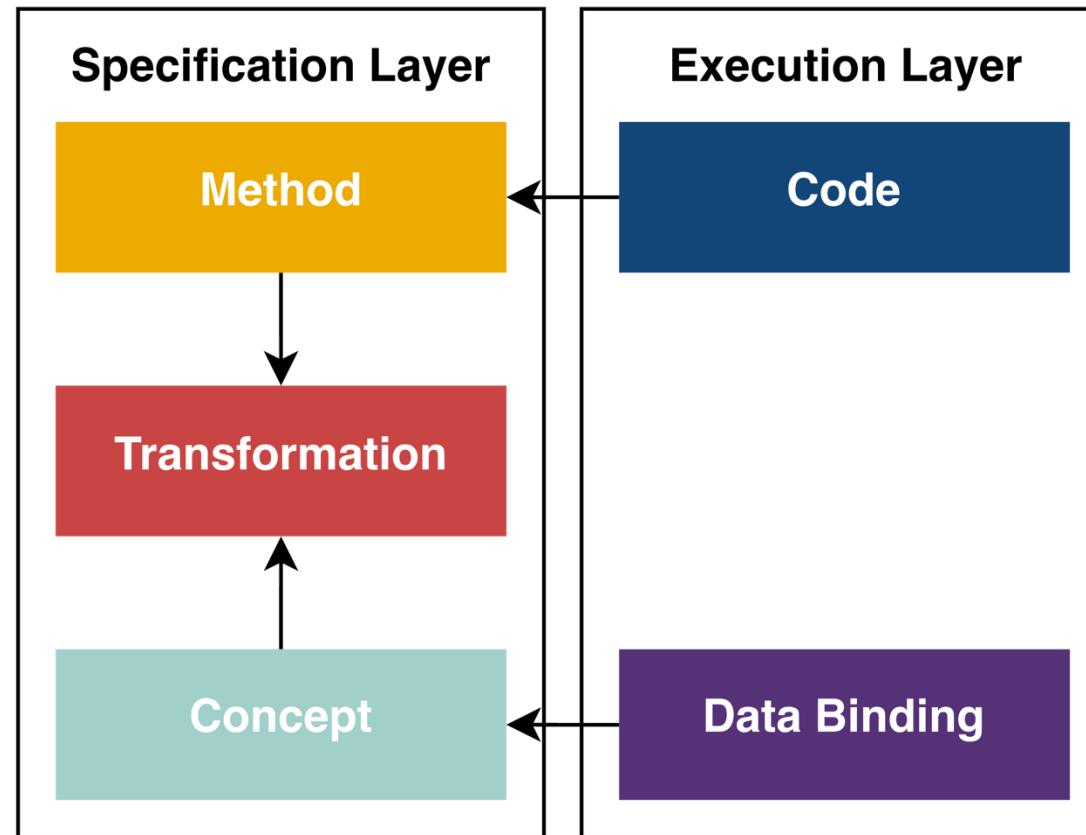
End to end specification and execution



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

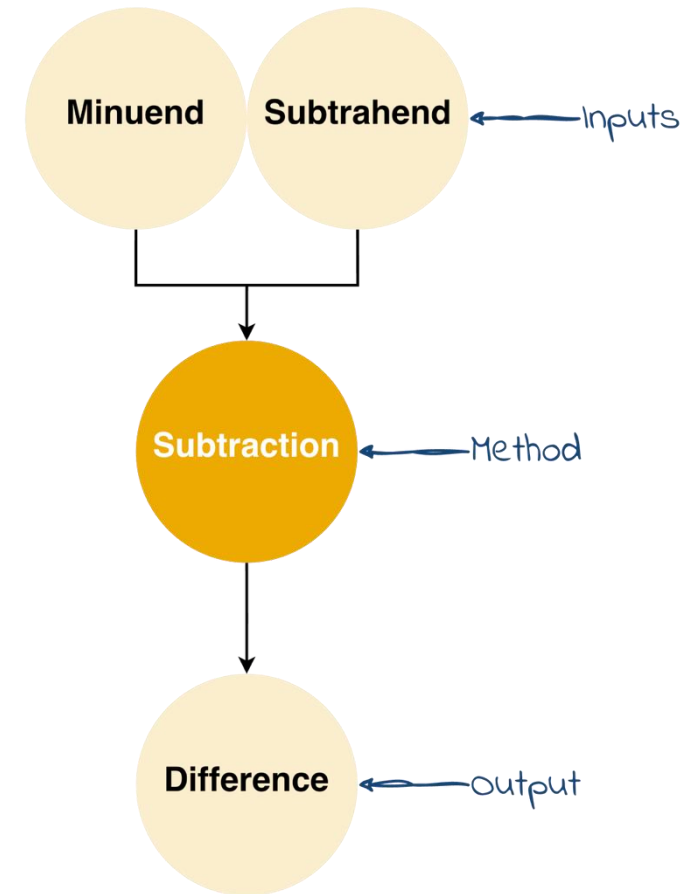
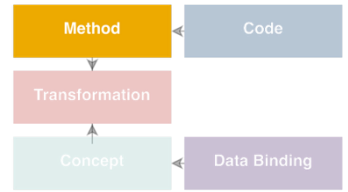
High-level components



Methods

Operation with inputs and outputs

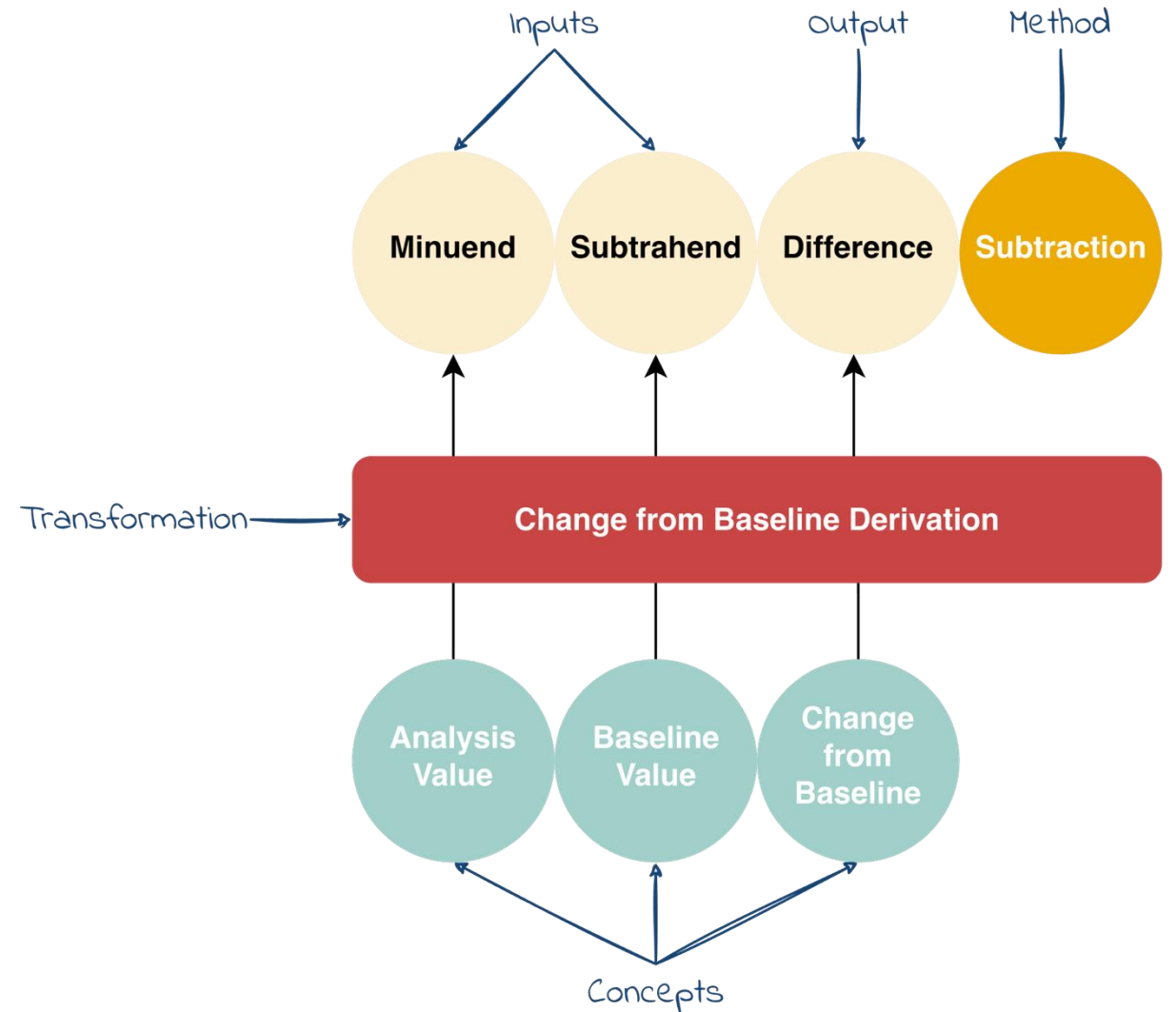
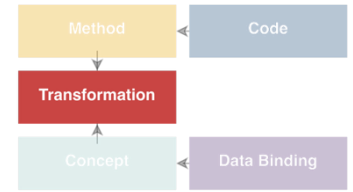
- Inputs and outputs have roles
- Knows nothing of concepts
- Language-agnostic
- One method can be referred to by many transformations



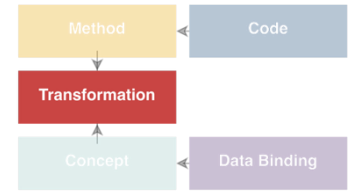
Transformations

Applied method binding concepts to roles

- Independent of data standards
- Language-agnostic
- Smartphrase as user-facing attribute



Transformations - Smartphrases



User-facing attribute of a transformation

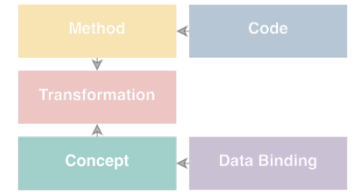
- Independent of data standards
- Language-agnostic
- Build and describe transformations in a human-readable way

Analysis of Covariance of {Response} of {Biomedical Concept} at {Timepoint} using {Covariate} as independent variable and {Fixed Effect} as fixed effect.



Analysis of Covariance of **Change from Baseline** of **ADAS-Cog Total Score (11)** at **week 24** using **Baseline value** and **Site Identifier** as independent variables and **Actual Treatment** as fixed effect

Concepts



Has meaning in the real world

- Independent of data standards
- Independent of where it sits in actual data
- One concept can have multiple roles in different transformations

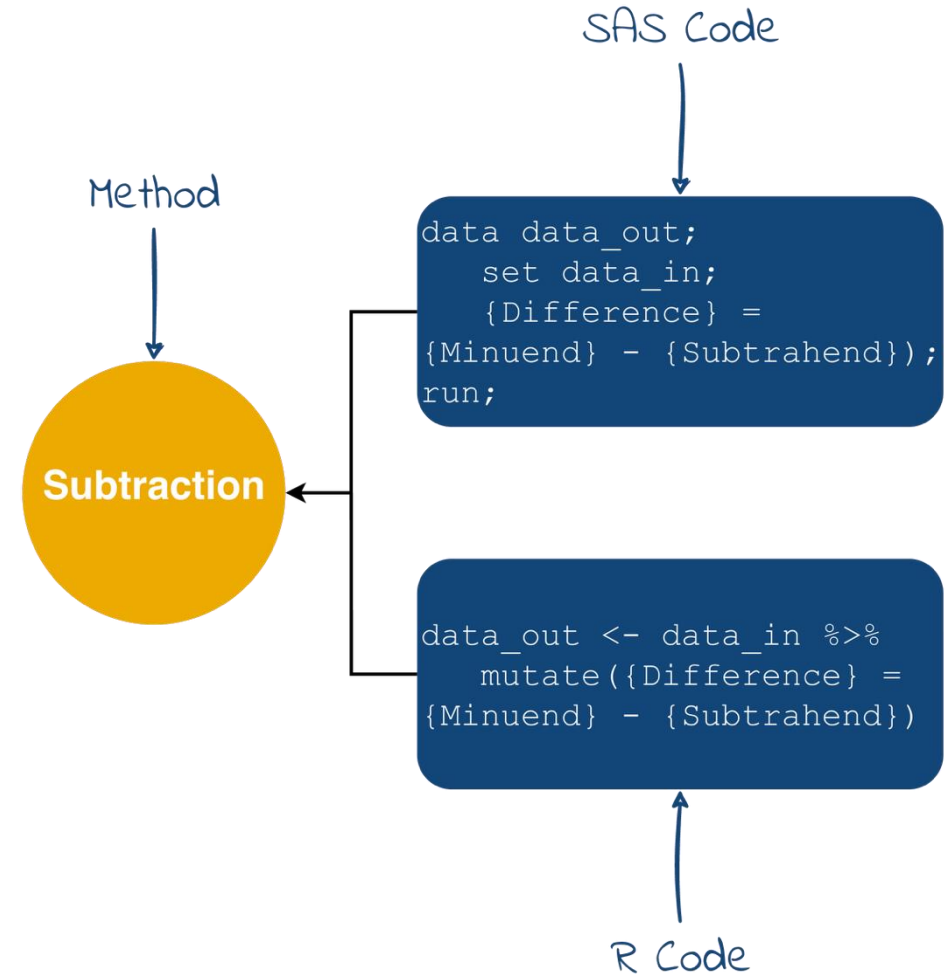
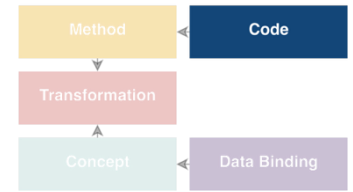
Examples:

- Analysis Value
- Baseline Value
- Analysis Visit
 - Week 24
- ADAS-Cog Total Score (11)
- Site Identifier

Code

Actual code in SAS, R, Python, etc.

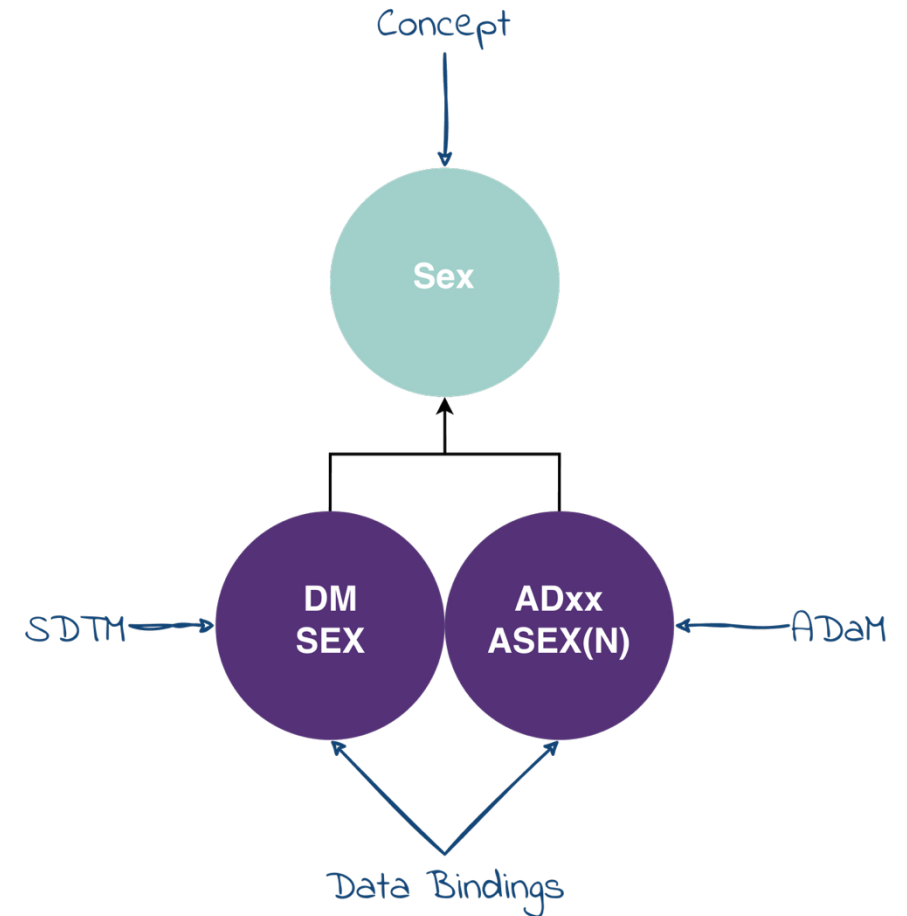
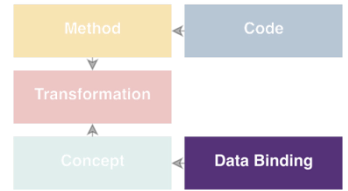
- Refers to a method
- One method can be referred to by many pieces of code (e.g. different languages to accomplish the same)



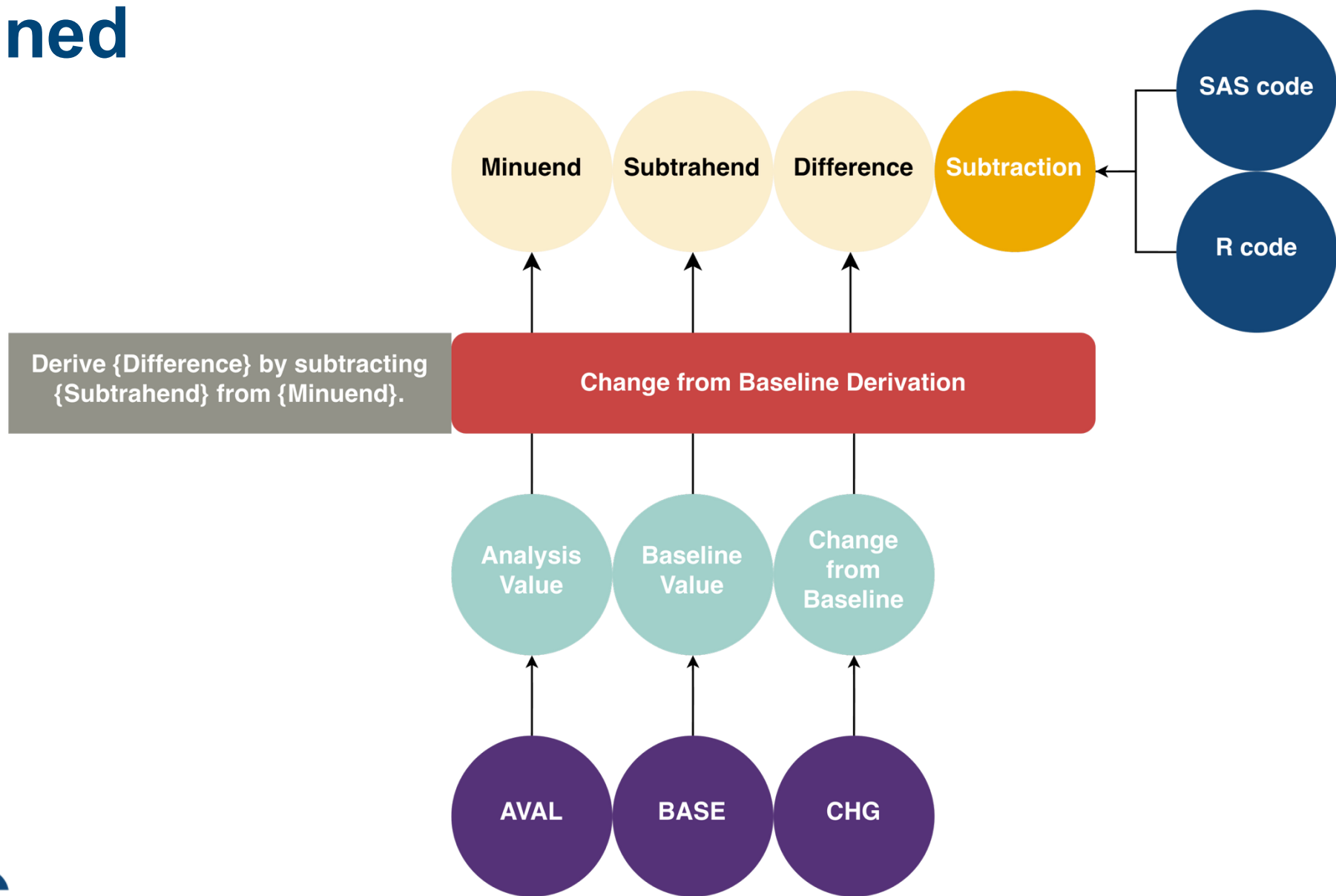
Data Bindings

Implementation of a concept in data

- Maps concepts to data in a standard (SDTM, ADaM)
- One concept can be referred to by many bindings (e.g. implementation in different data standards of the same concept)



Combined





Building and Executing an eSAP in Practice

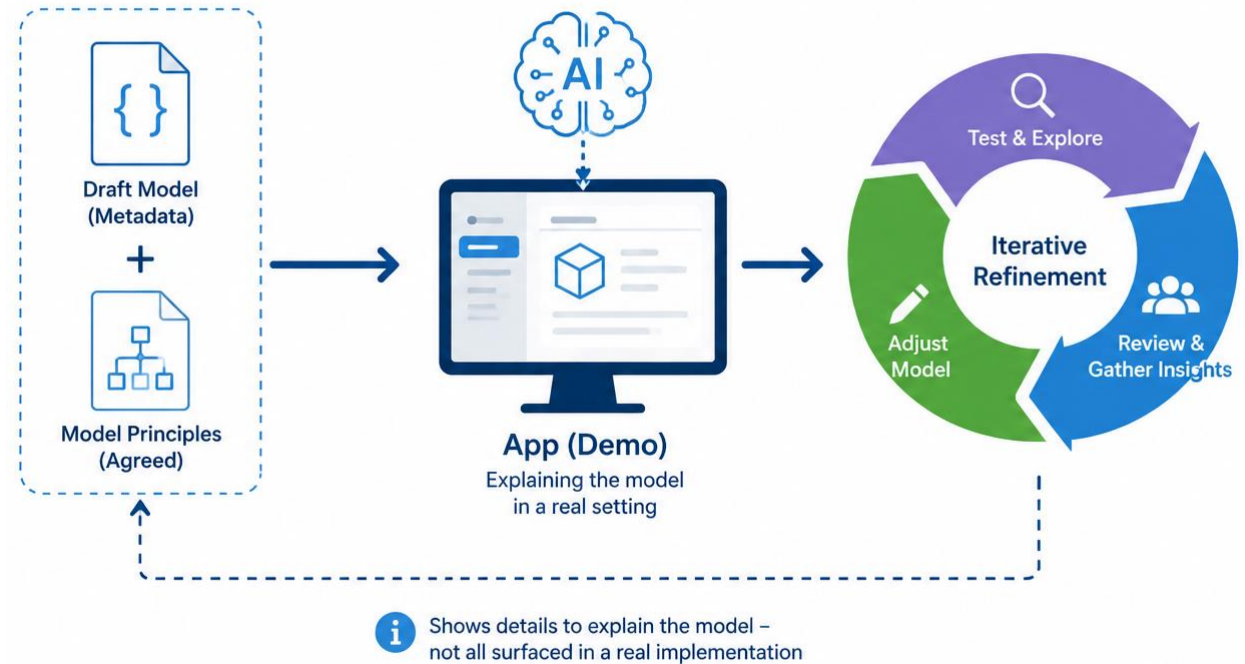
Demo - introduction

In supplement to creation of JSON metadata files and UML model diagrams we have used AI to help build an app that shows how the model works

App has been built on and uses metadata made according to a **draft model** – but the overall principles shown in the earlier slides are agreed upon by the AC working group

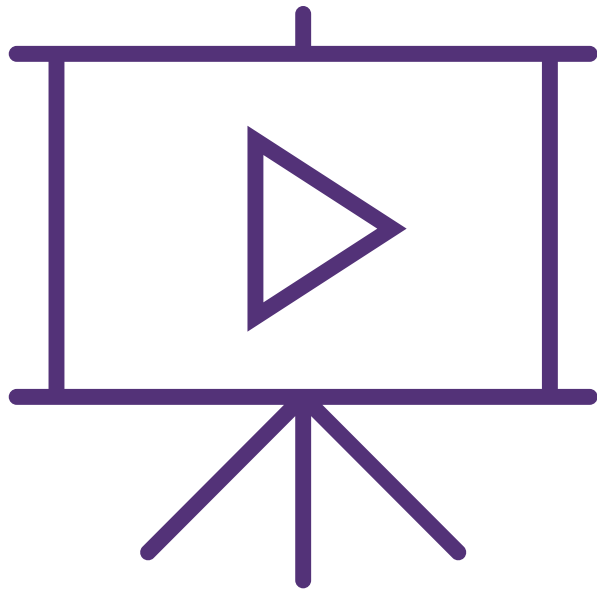
We are in the process of adjusting the details of the model framework and testing it in the app helps that process

The app displays details that a real implementation may not surface to the user. This is to done to 'explain' the model in a 'real' setting





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 will be available in a future update.

COMING
SOON

Arms

Objectives

Endpoints

Takeaway



Before

SAP = document
Interpretation required
Traceability manual
Reimplementation every study



After

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



Thank You!

