2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

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**

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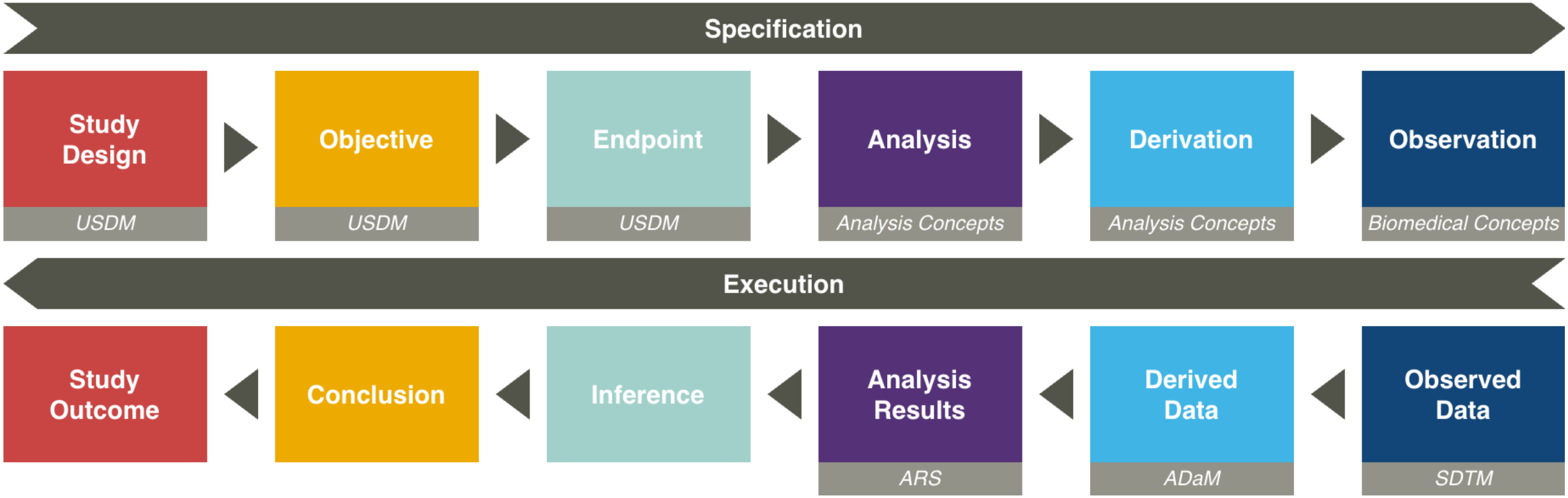
End to end specification and execution



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

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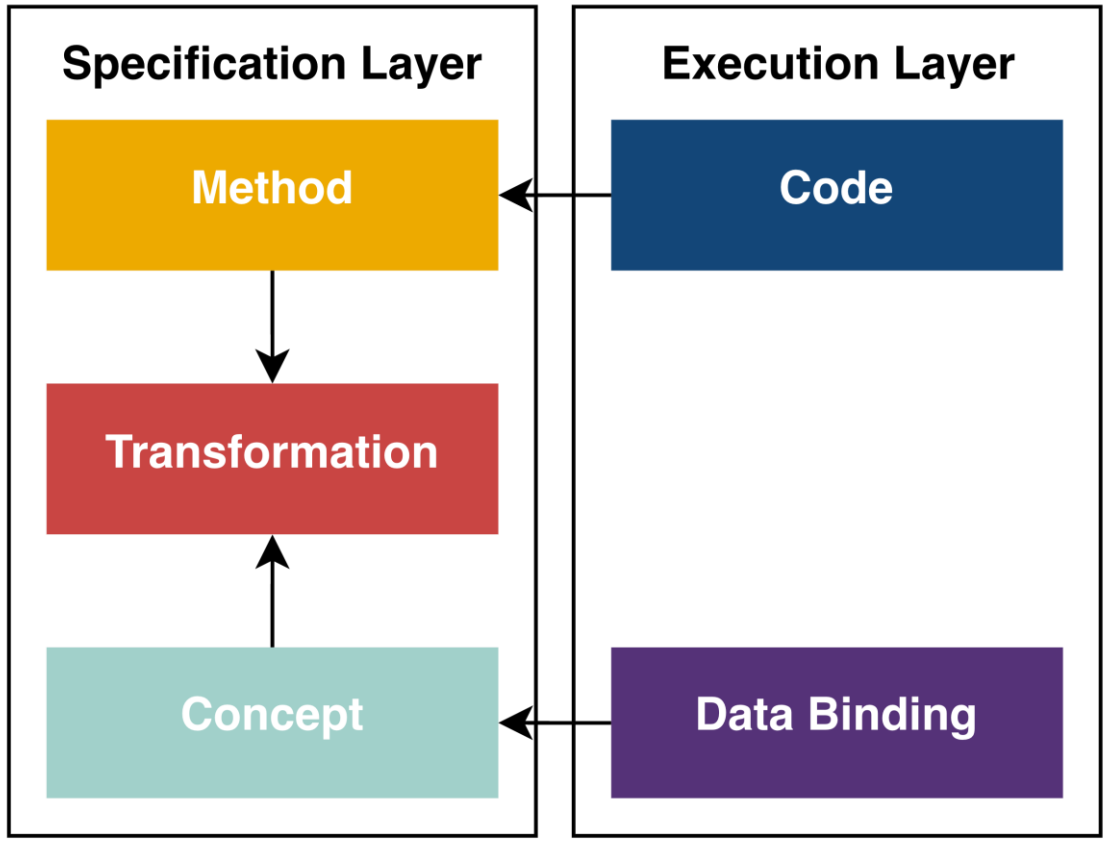
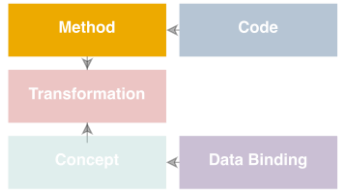
High-level components

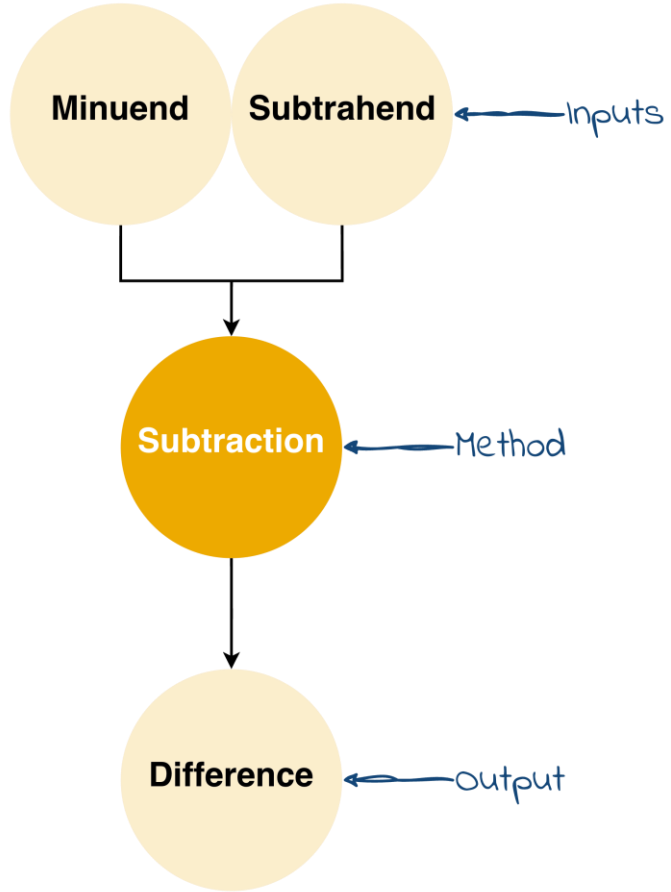


Methods



Operation with inputs and outputs

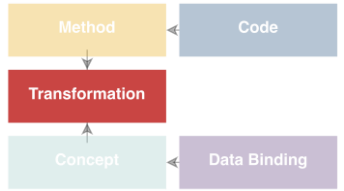
- Inputs and outputs have roles
- Knows nothing of concepts
- Language-agnostic
- One method can be referred to by many transformations

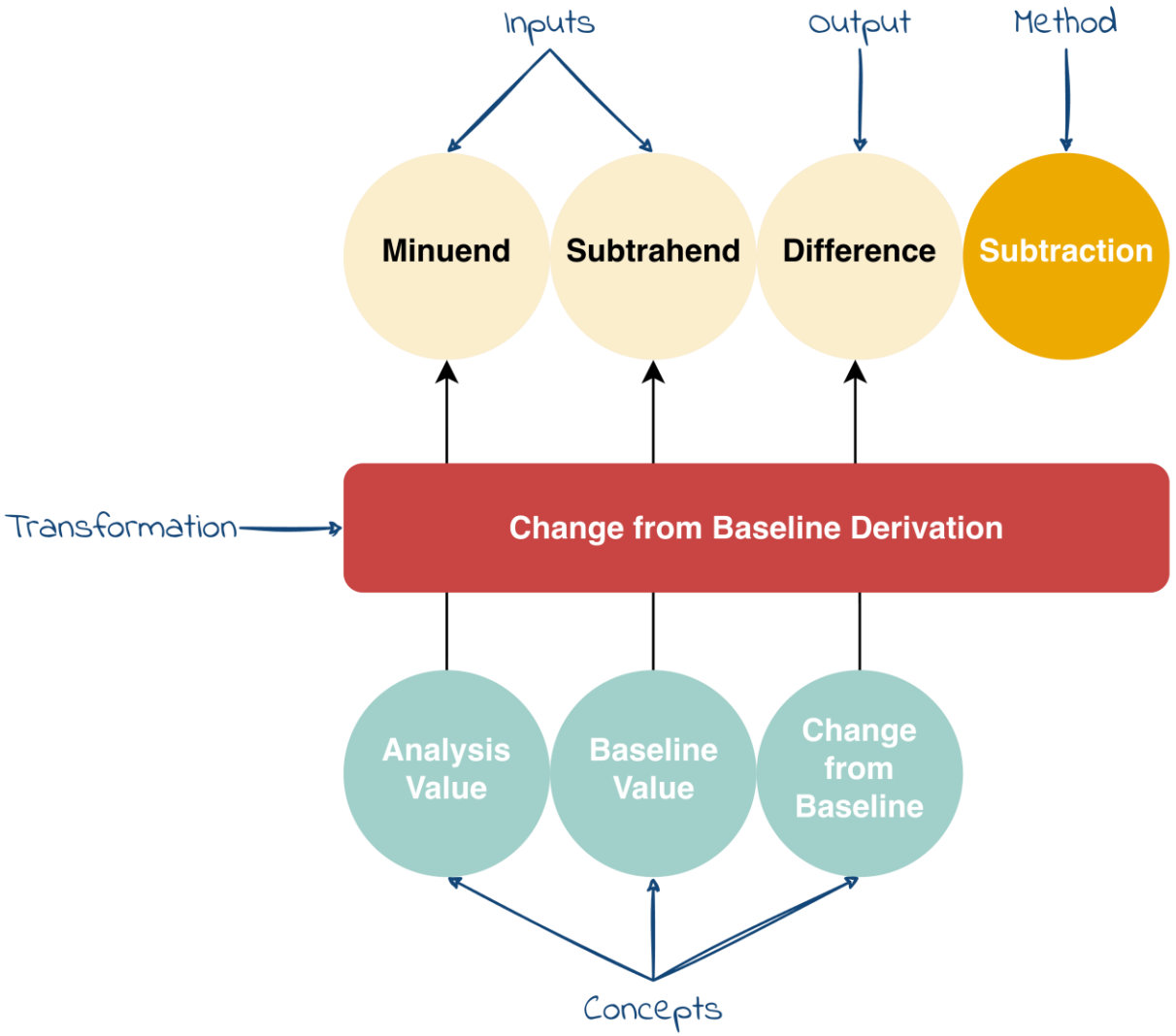


Transformations

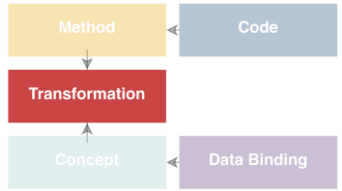
Applied method binding concepts to roles

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





Transformations - Smartphrases



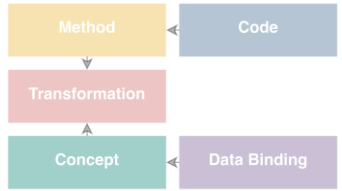
User-facing attribute of a transformation

- 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

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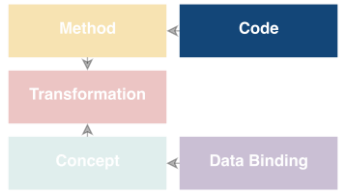
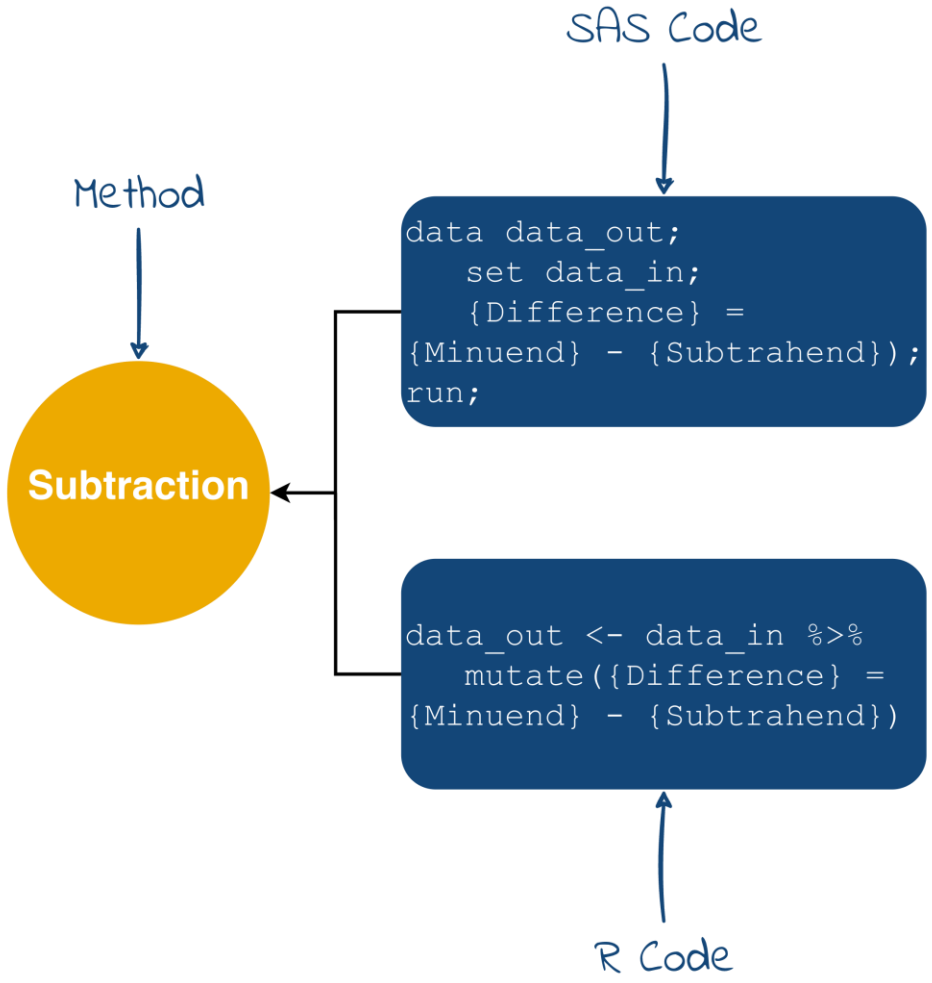
Code

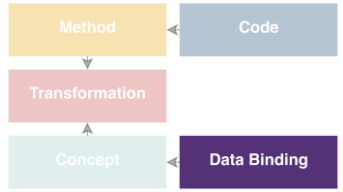


Actual code in SAS, R, Python, etc.

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

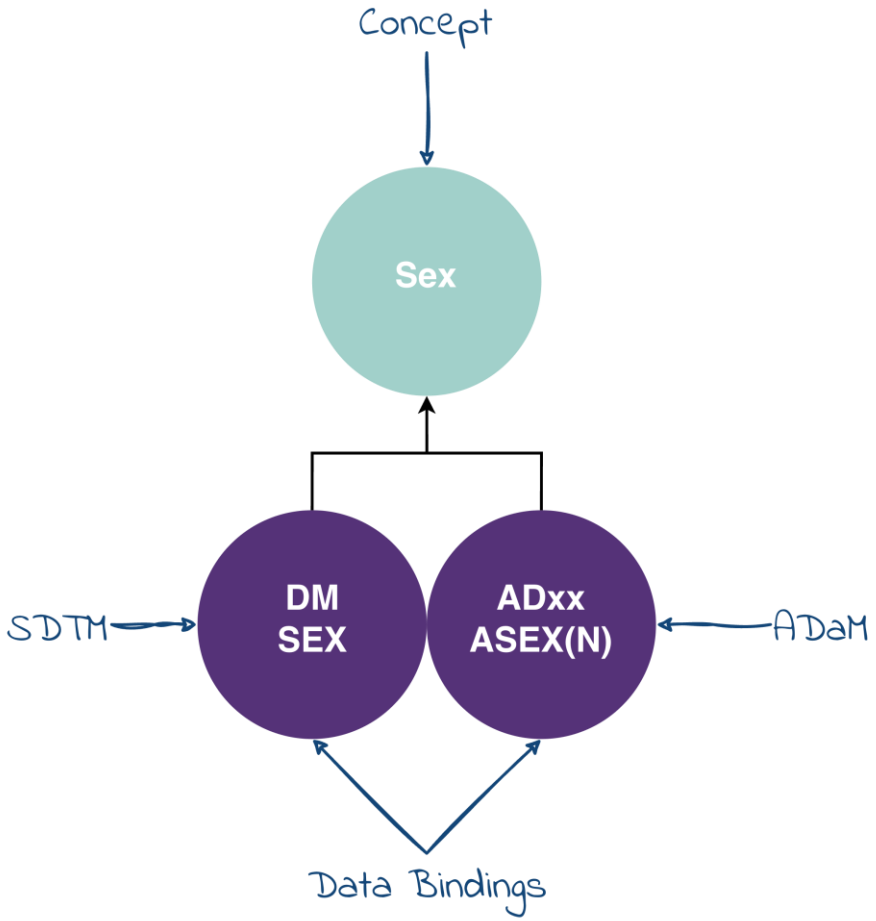


Data Bindings

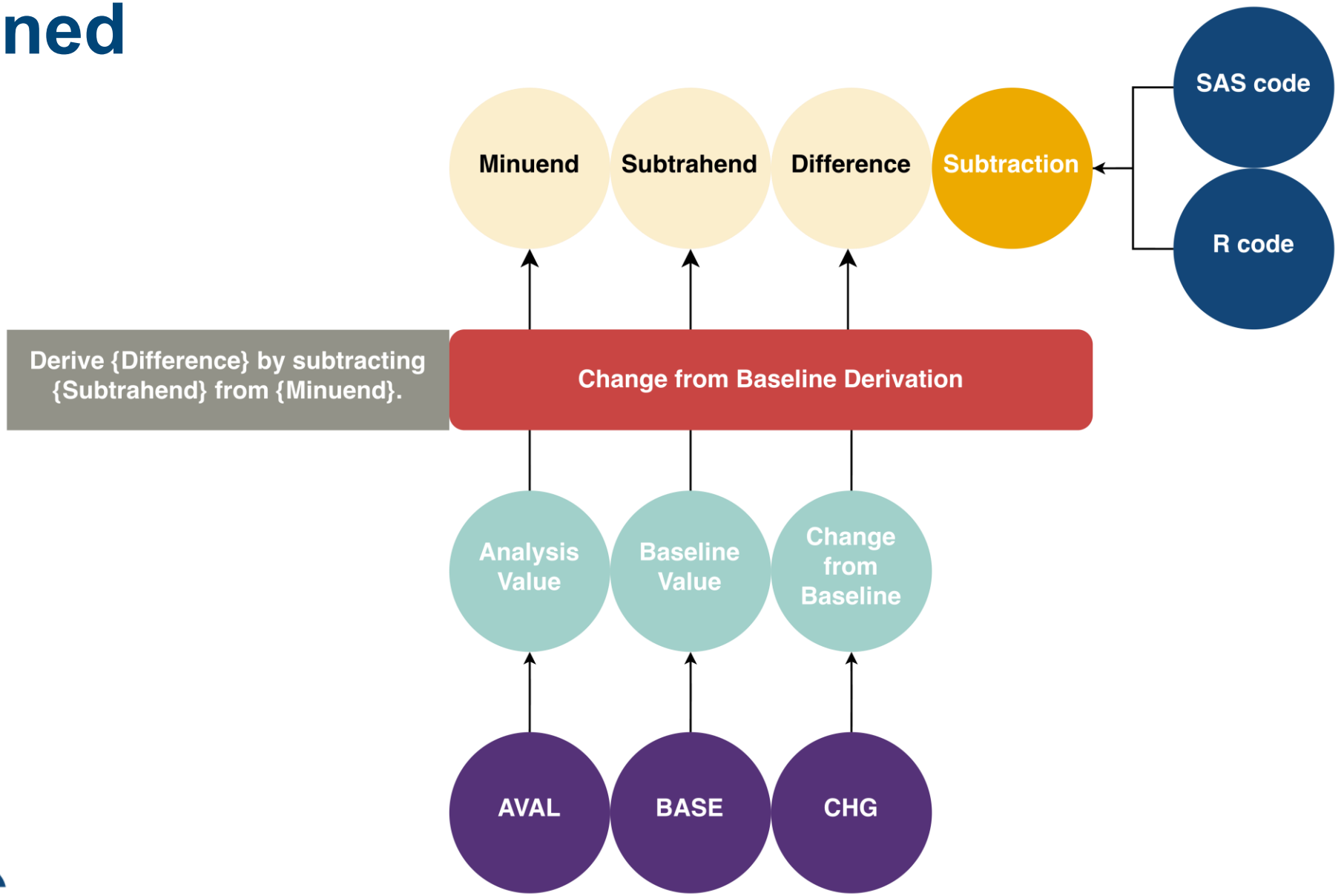


Implementation of a concept in data

- 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


SAS code
R code
Minuend
Subtrahend
Difference
Subtraction
Derive {Difference} by subtracting {Subtrahend} from {Minuend}.
Change from Baseline Derivation
Analysis Value
Baseline Value
Change from Baseline
AVAL
BASE
CHG

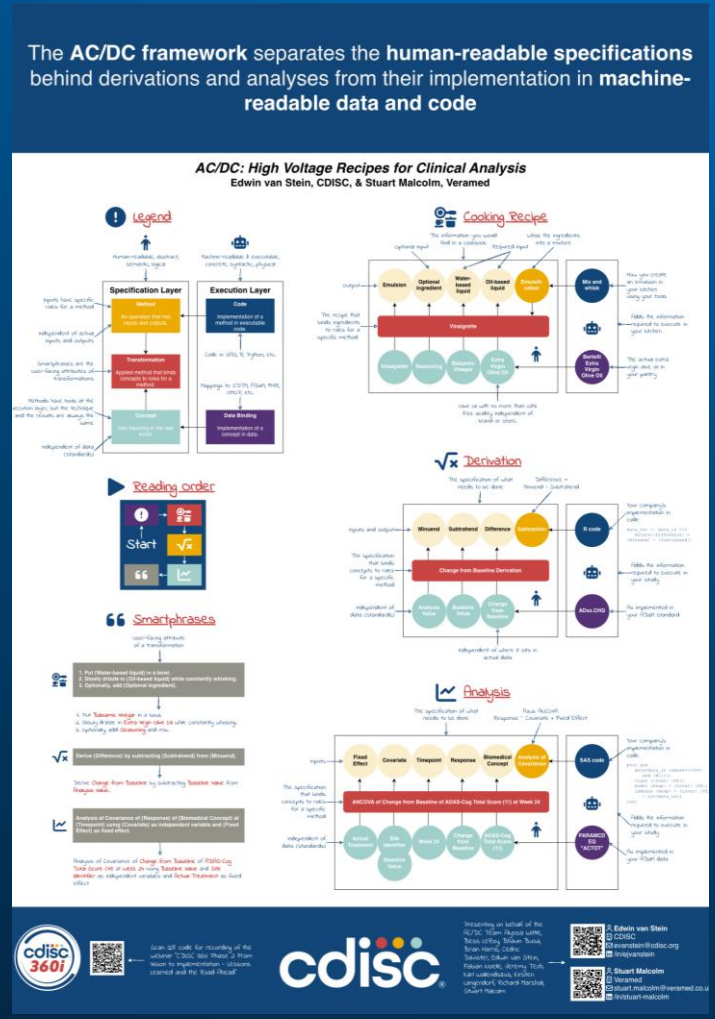
Come talk to us

Poster with high-level examples of the model components

Poster Session 12:30 – 13:30

AC/DC: High Voltage Recipes for Clinical Analysis

Edwin van Stein, CDISC & Stuart Malcolm, Veramed



Building and Executing an eSAP in Practice

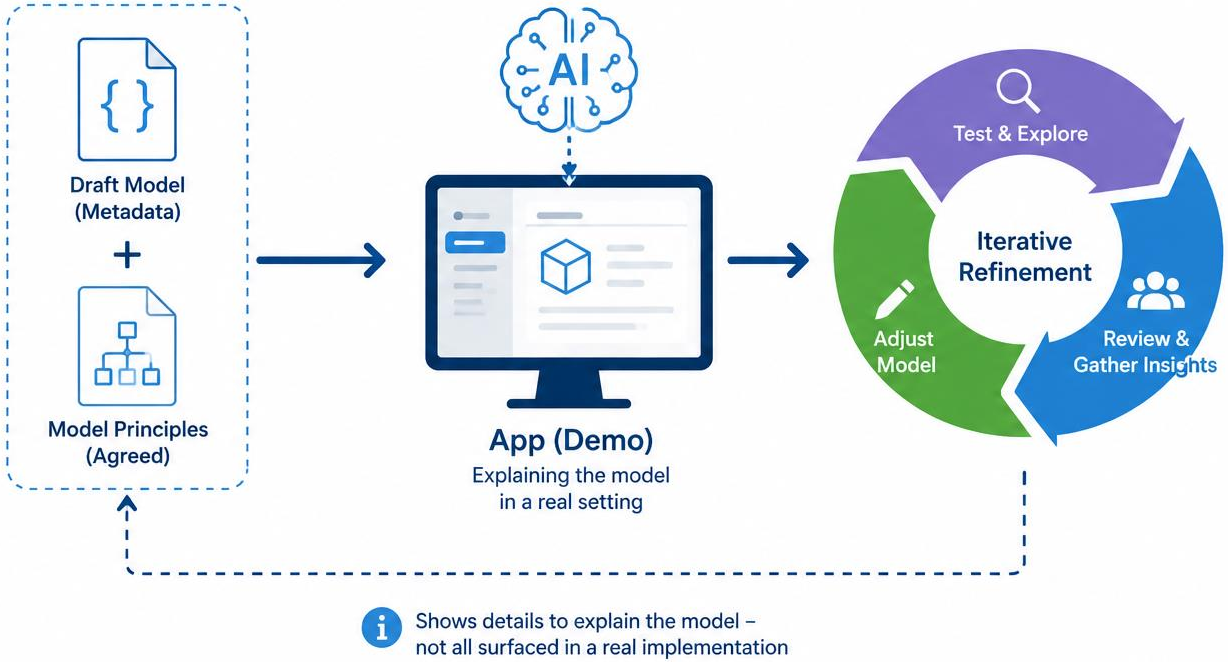
Demo - introduction

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

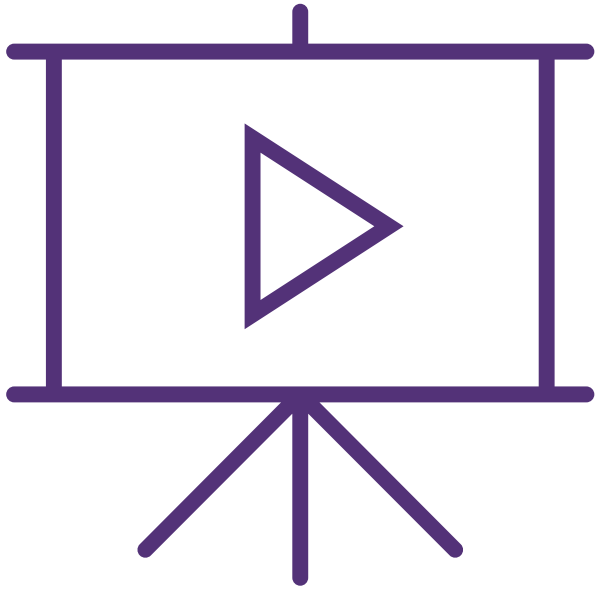
App has been built on and uses metadata made according to a **draft model** – but the overall principles shown in the earlier slides are agreed upon by the AC working group

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	6	11
Arms	Objectives	Endpoints

Breast Cancer Study

Oncology USDM study

TBD

A breast cancer study will be available in a future update.

COMING SOON

-	-	-
Arms	Objectives	Endpoints

Voice Powered by ElevenLabs

Takeaway

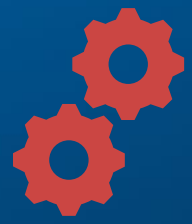
Before

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!