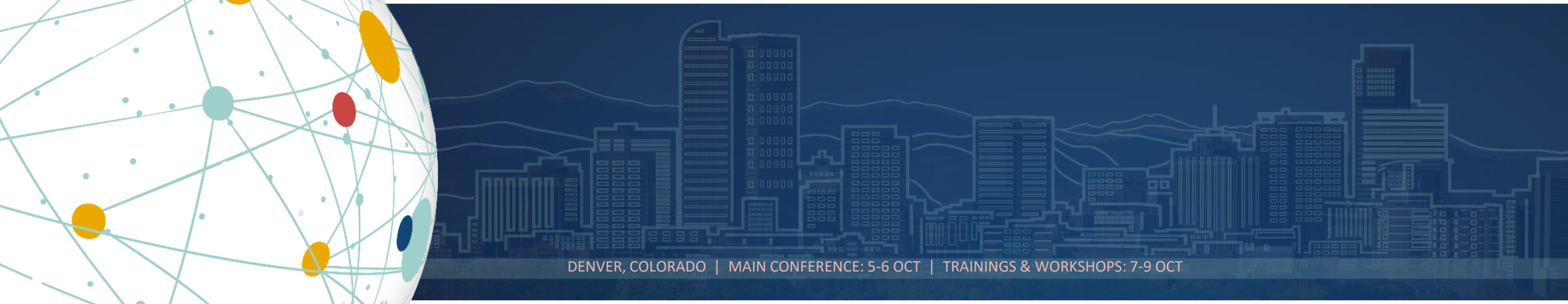


2026 US Interchange

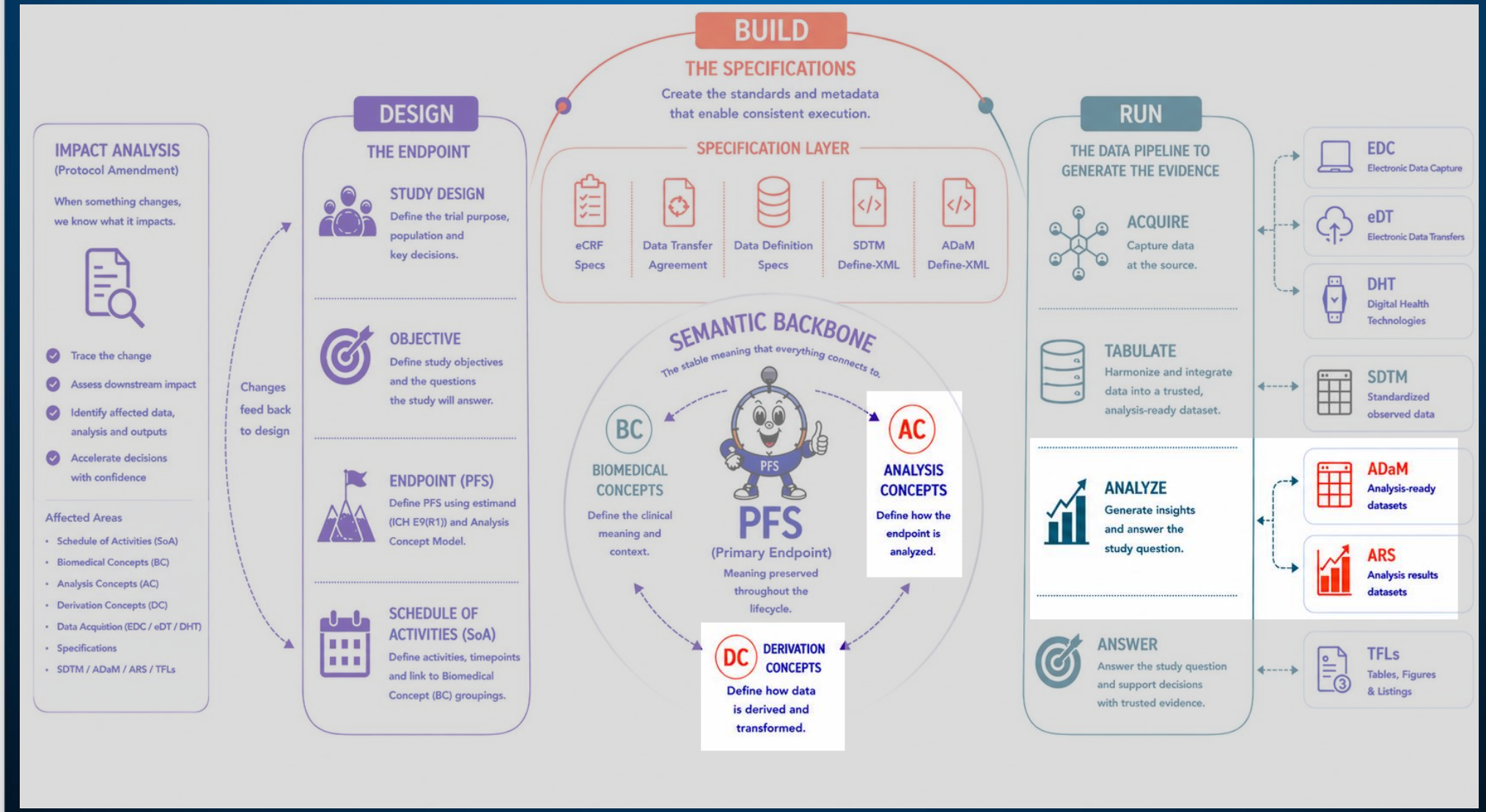
THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Analysis Concepts
A Standard for Executable Clinical Analysis

Edwin van Stein, Senior Consultant Data Standards, CDISC

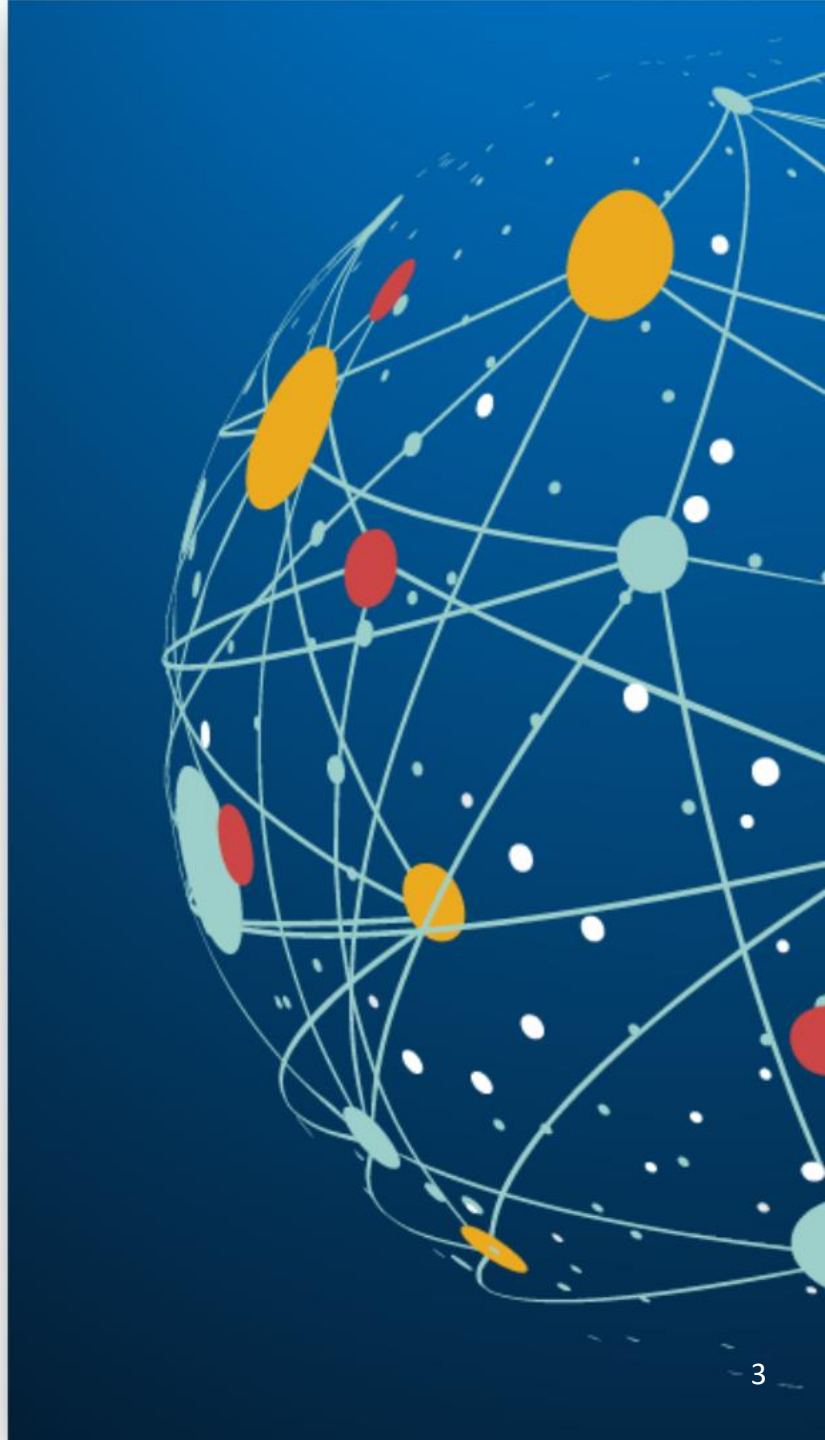
In Focus: Analysis Concepts



Problem Statement

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

- **Ambiguous by design**
- **Limited reuse of prior work**
- **Not machine-readable (or executable)**
- **Fragile traceability**



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



Common language for expressing derivations and analyses streamlines **collaboration**

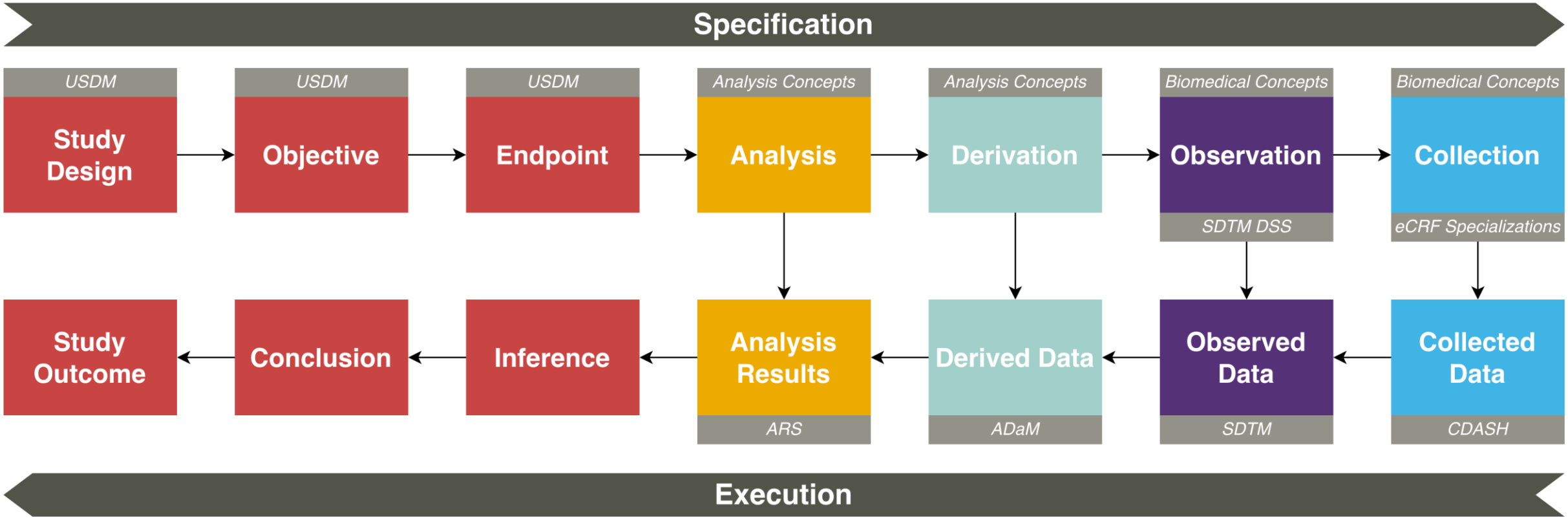


Reduced ambiguity by **enforcing precision**



Increased traceability by **clear linkage** from results to USDM and vice versa

Where It Sits



Strict Separation of Layers

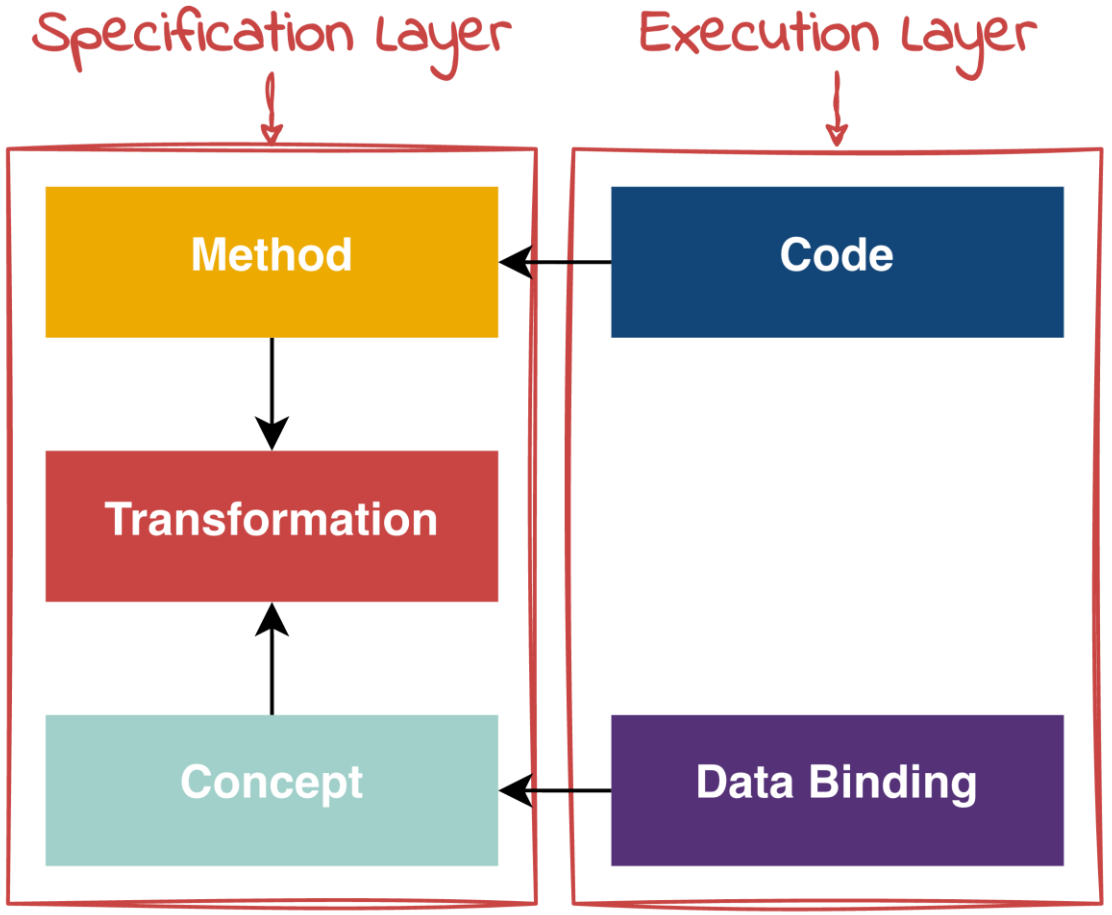
Specification Layer

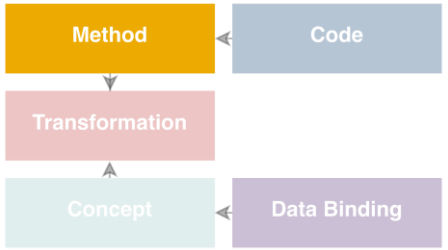
- Human-readable
- Abstract, semantic, logical
- Has meaning in the real world
- Independent of data (standards)
- Language-agnostic
- Normative standard
- CDISC Library

Execution Layer

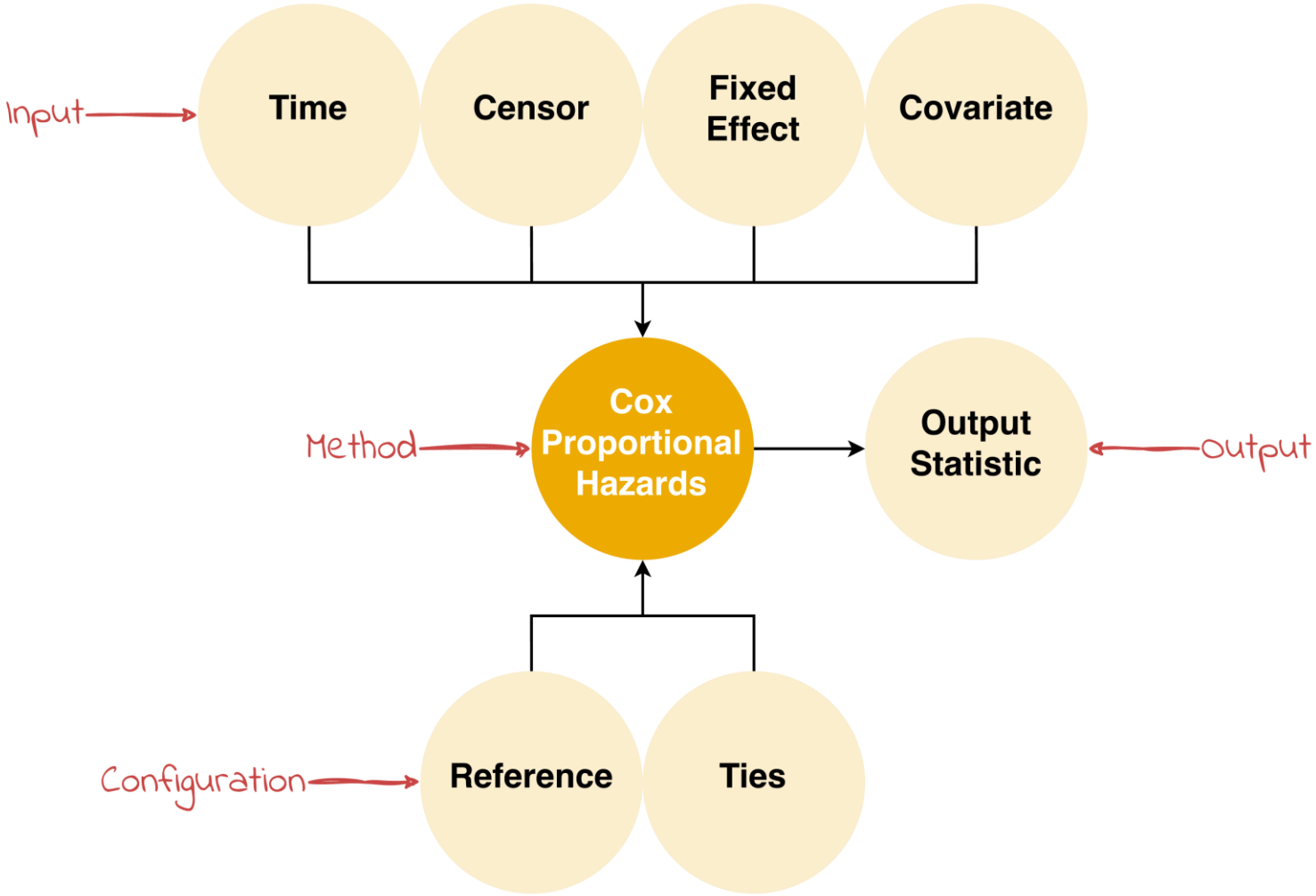
- Machine-readable and executable
- Concrete, syntactic, physical
- Implementation of specification
- Binds data (standards) to specification
- Binds code to specification
- Reference implementation
- CDISC Analysis Concepts Portal

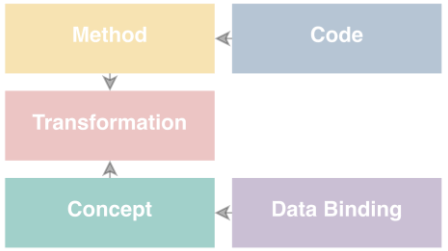
High-level Components



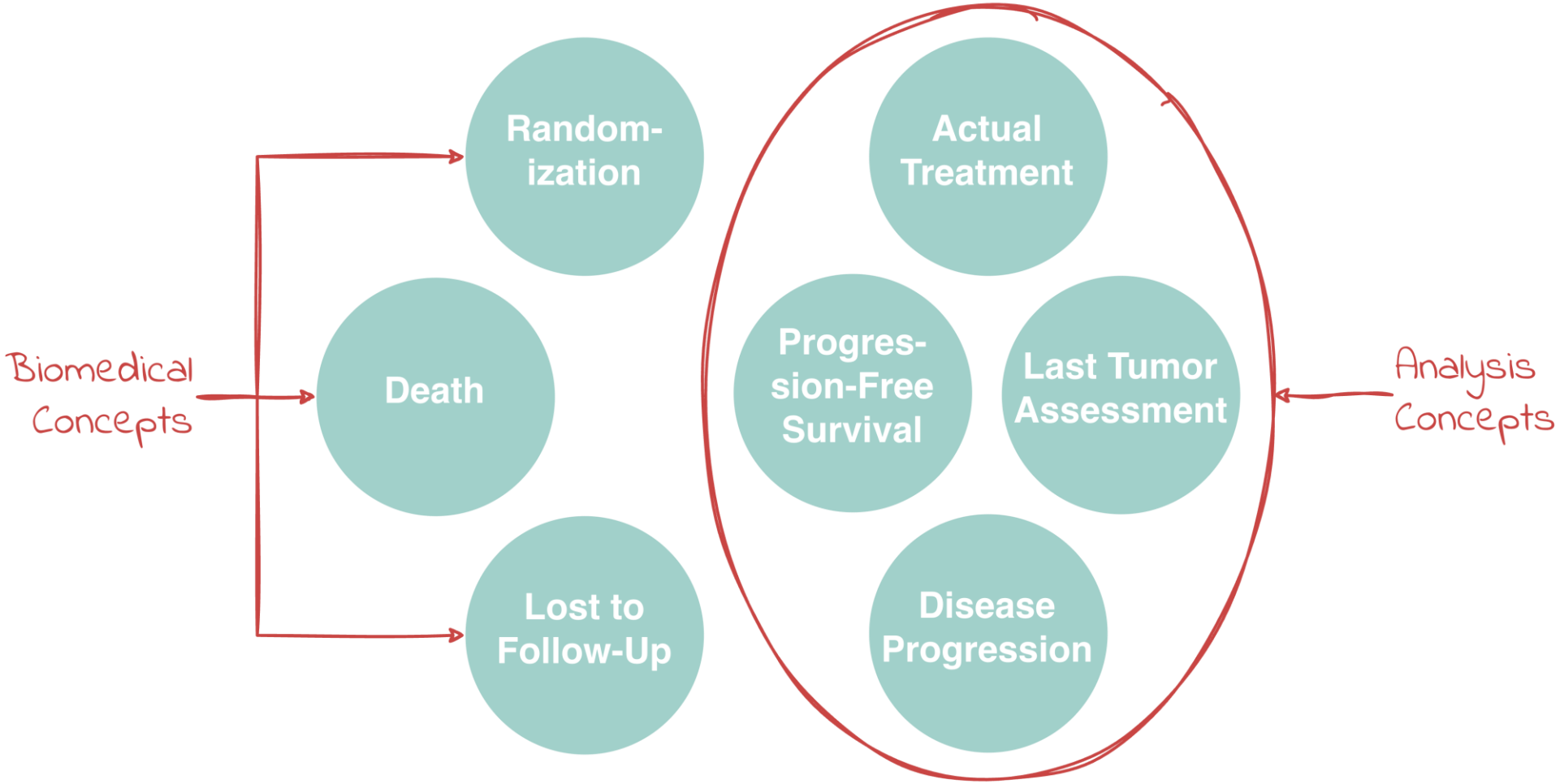

Method
Code
Transformation
Concept
Data Binding

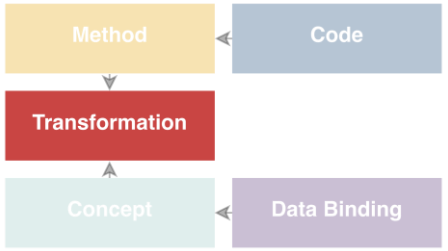
Methods


Input
Time
Censor
Fixed Effect
Covariate
Method
Cox Proportional Hazards
Output Statistic
output
Configuration
Reference
Ties

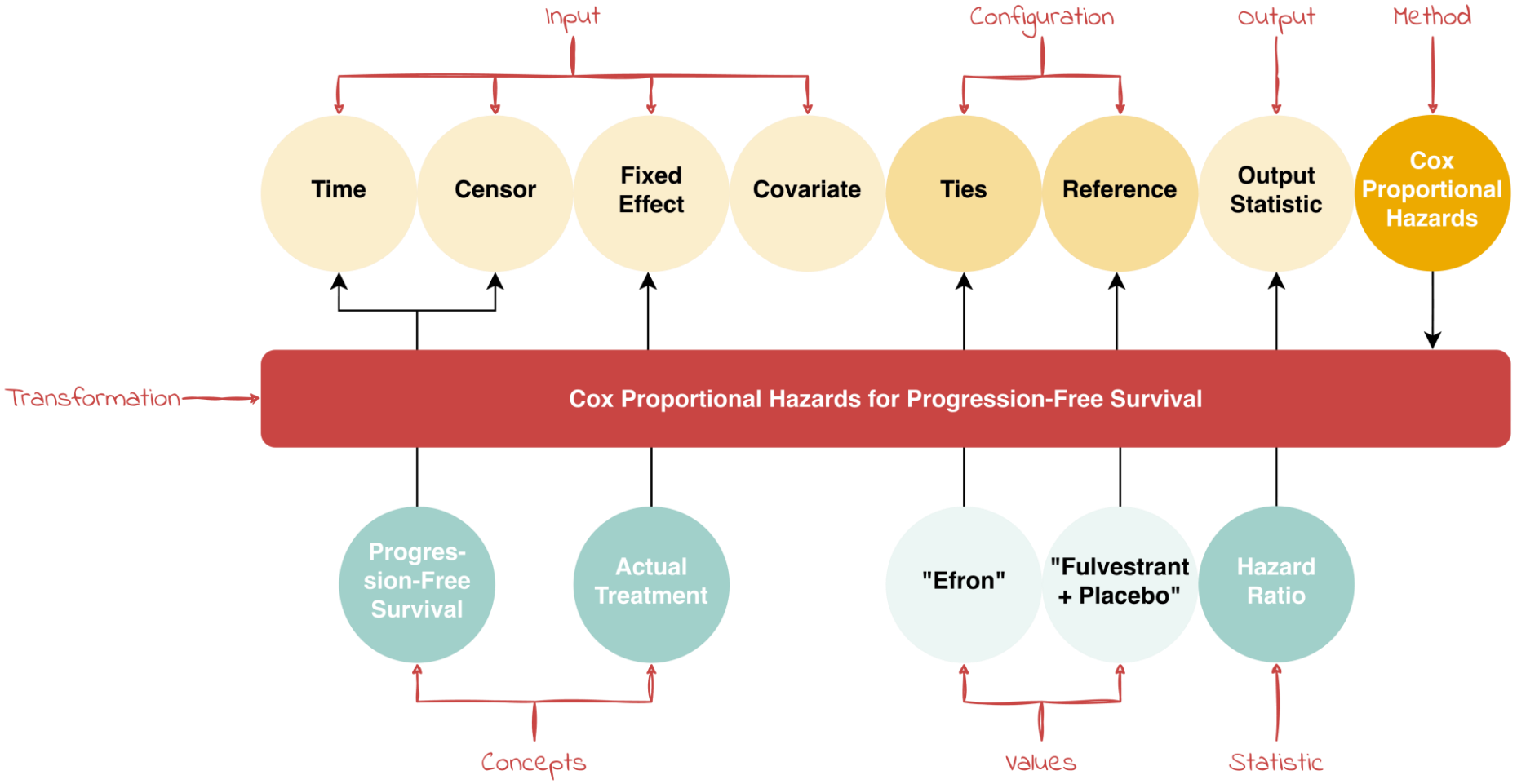

Method
Code
Transformation
Concept
Data Binding

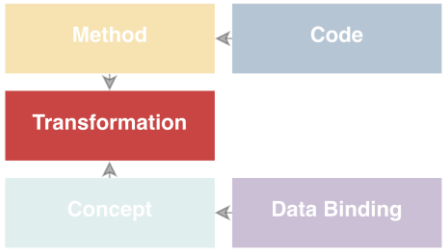
Concepts


Biomedical Concepts
Random-ization
Death
Lost to Follow-Up
Actual Treatment
Progres-sion-Free Survival
Last Tumor Assessment
Disease Progression
Analysis Concepts

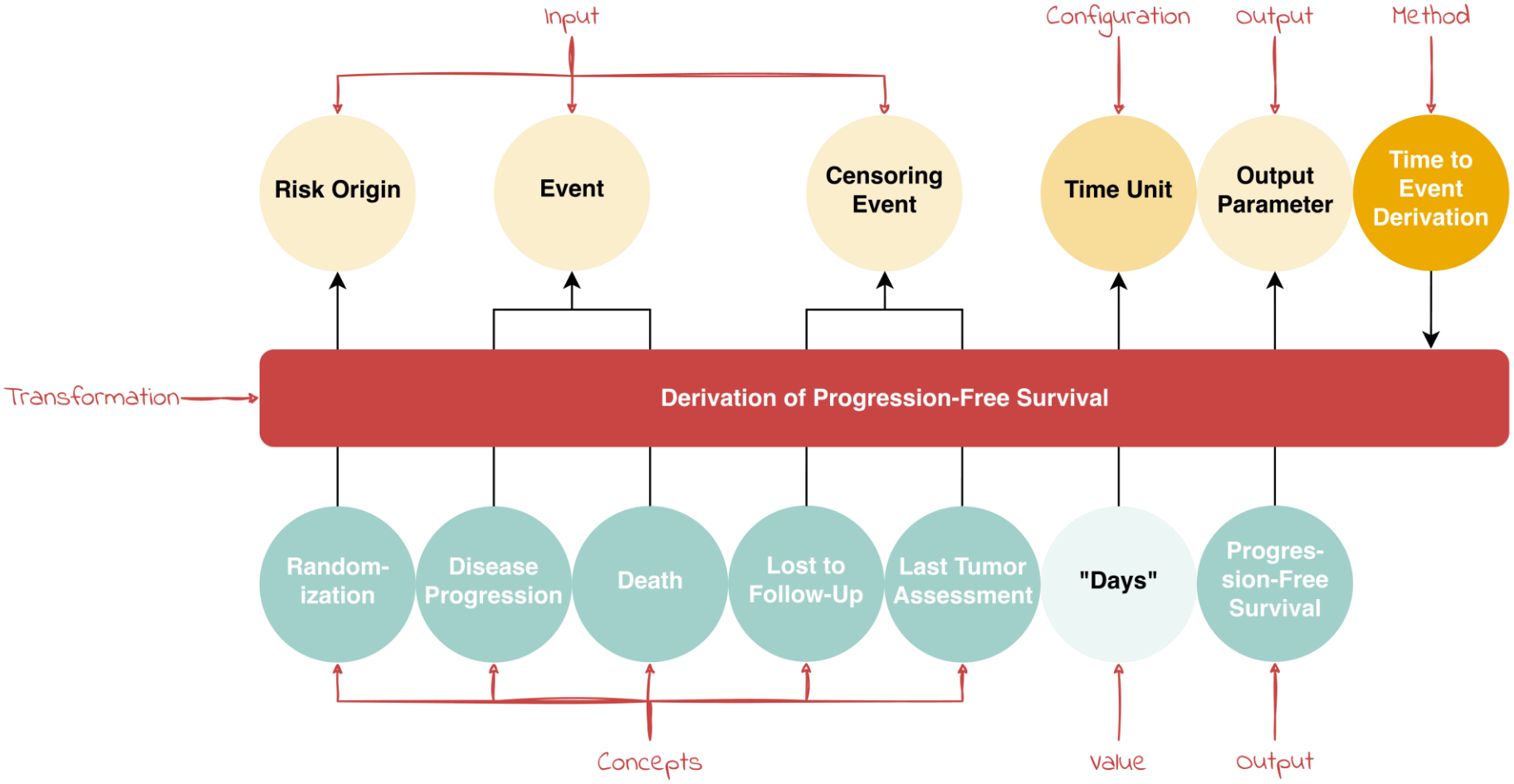


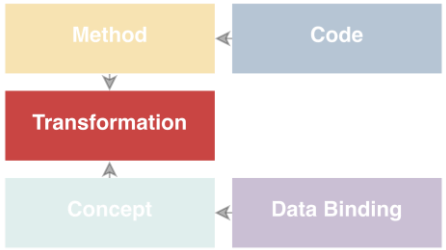
Transformations





Transformations



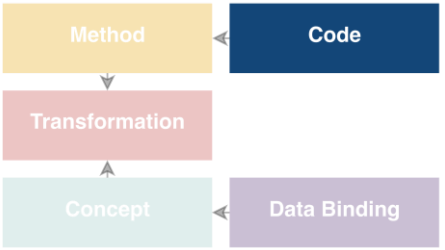


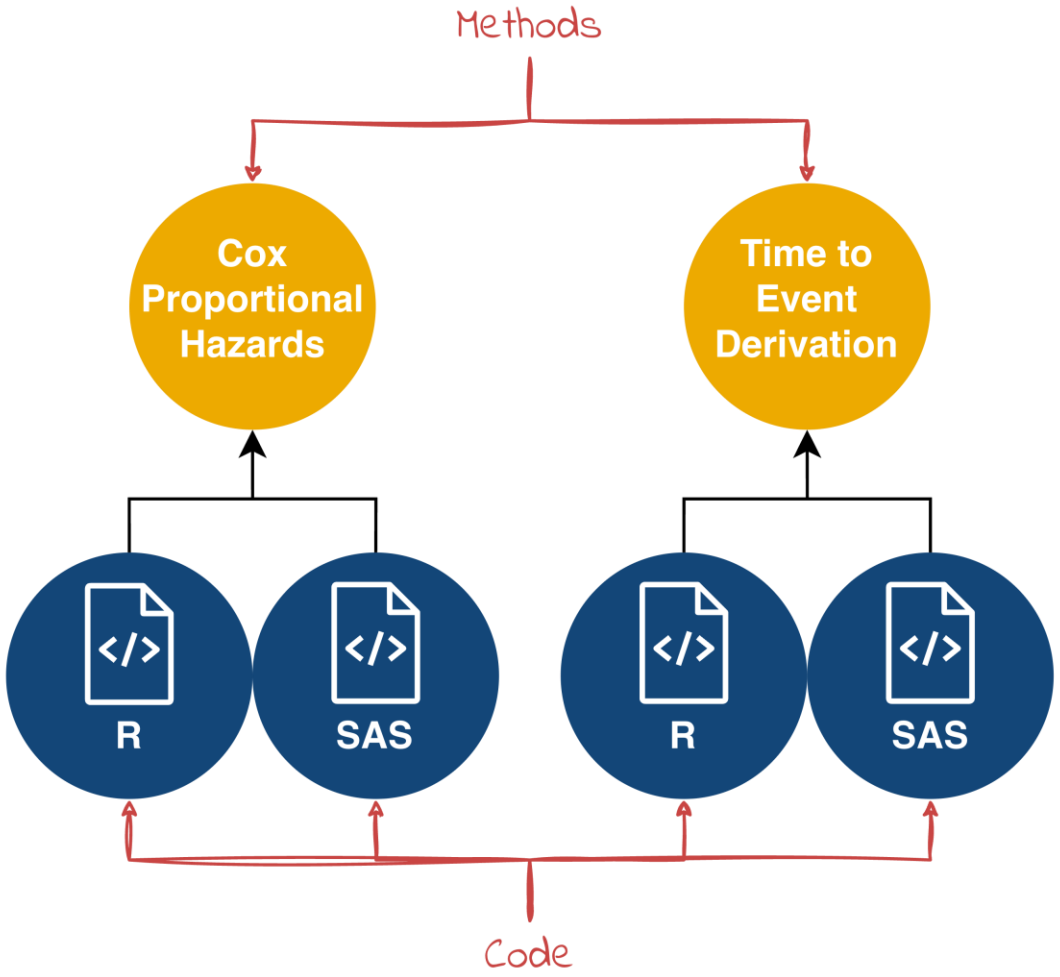
Transformations - Smartphrases

{Output Parameter} is defined as the time, in {Time Unit}, from {Risk Origin} to {Event}. Subjects are censored at {Censoring Event}.

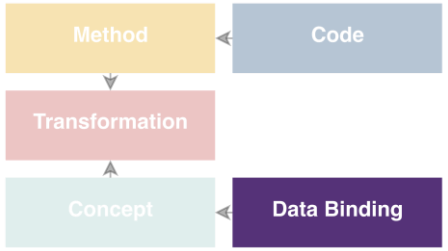
Progression-Free Survival is defined as the time, in Days, from Randomization to Disease Progression or Death. Subjects are censored at Lost to Follow-Up and Last Tumor Assessment.

Code


Method
Code
Transformation
Concept
Data Binding


Methods
Cox Proportional Hazards
Time to Event Derivation
R
SAS
R
SAS
Code

Data Bindings



Concepts

Actual Treatment

Progres-sion-Free Survival

Random-ization

Death

```
first of
   TRTA
   and ADSL.TRTA
   and ADSL.TRT01A
```

```
ADTTE.AVAL
and ADTTE.CNSR
   where
      ADTTE.PARAM EQ "Progression-Free Survival"
```

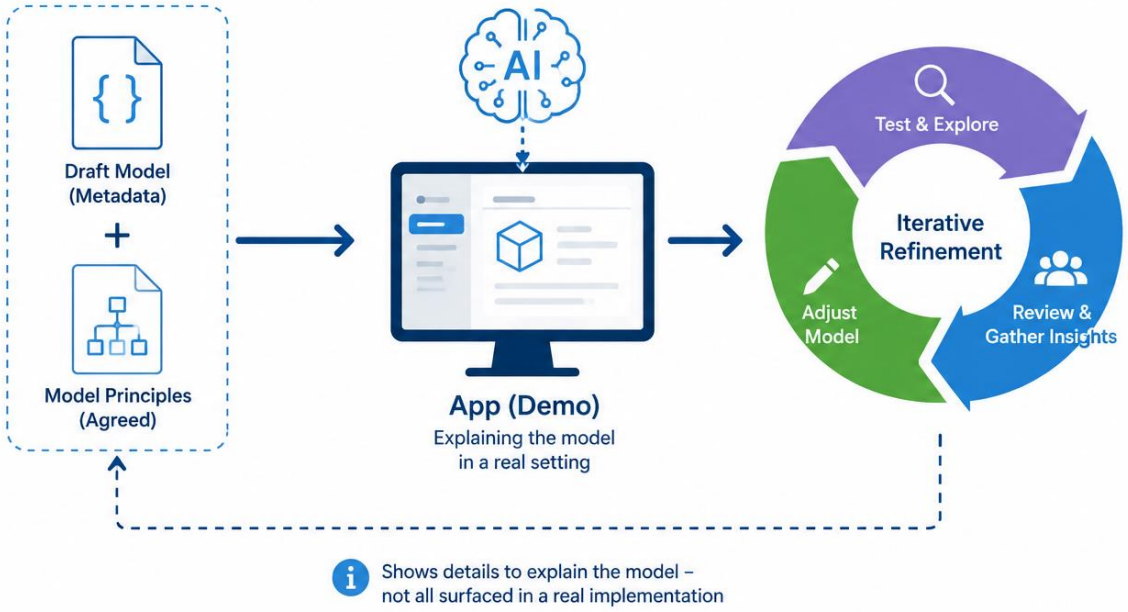
```
DS.DSSTDTC
   where
      DS.DSSCAT EQ "RANDOMIZED"
```

```
DS.DSSTDTC
   where
      DS.DSDECOD EQ "DEATH"
```

Data Bindings

Demo Introduction

- Used AI to help build an app to show and tell
- Made according to draft 0.7 model
- App helps to test adjustments to model
- App displays details a real implementation may not show to end-users



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

Loading data...

Demo Takeaway

Before



- SAP is a document
- Interpretation required
- Traceability manual
- No linkage to USDM
- Reimplementation every study

After



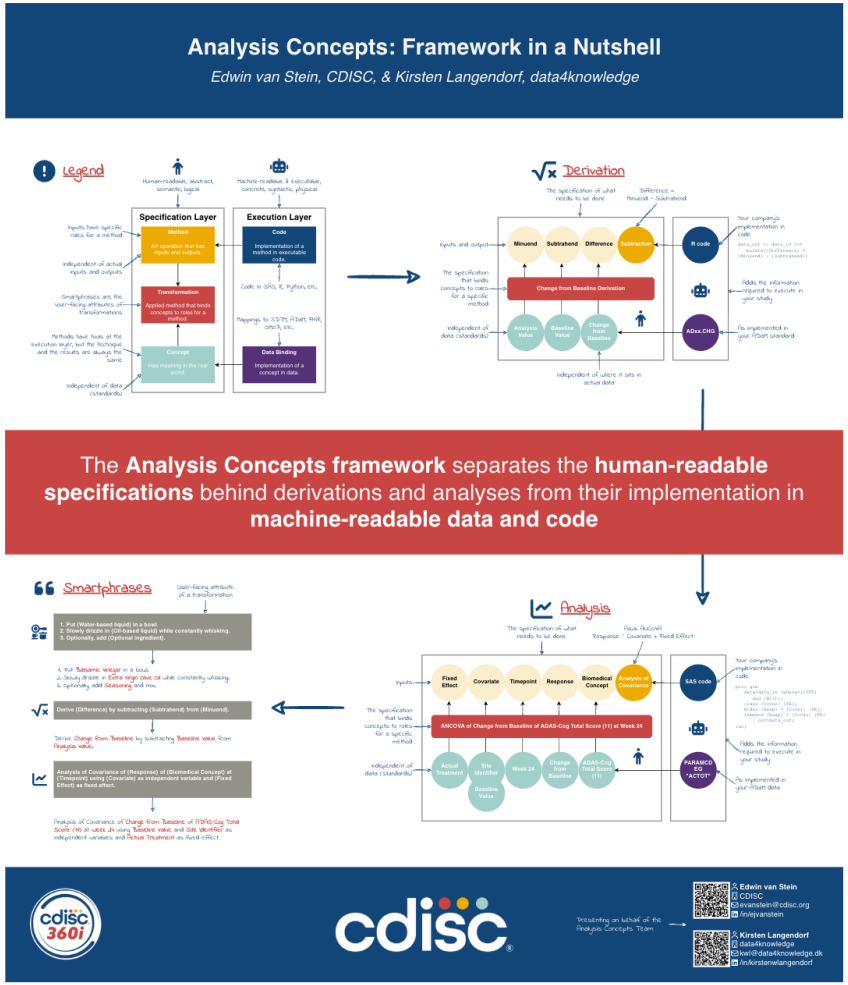
- SAP is an executable specification
- Machine & AI-readable & testable
- Traceability by design
- Linked to USDM
- Reuse built-in

Come Talk to Us

Poster Session 13:00 – 14:00

Analysis Concepts: Framework in a Nutshell

Edwin van Stein, CDISC & Kirsten Langendorf, data4knowledge



Looking Ahead – Short Term

- Finishing model version 1.0
- Documentation
- Public review to get feedback from the industry
- Publishing Controlled Terminology with NCI
- Publishing instantiated examples

Thank You!

