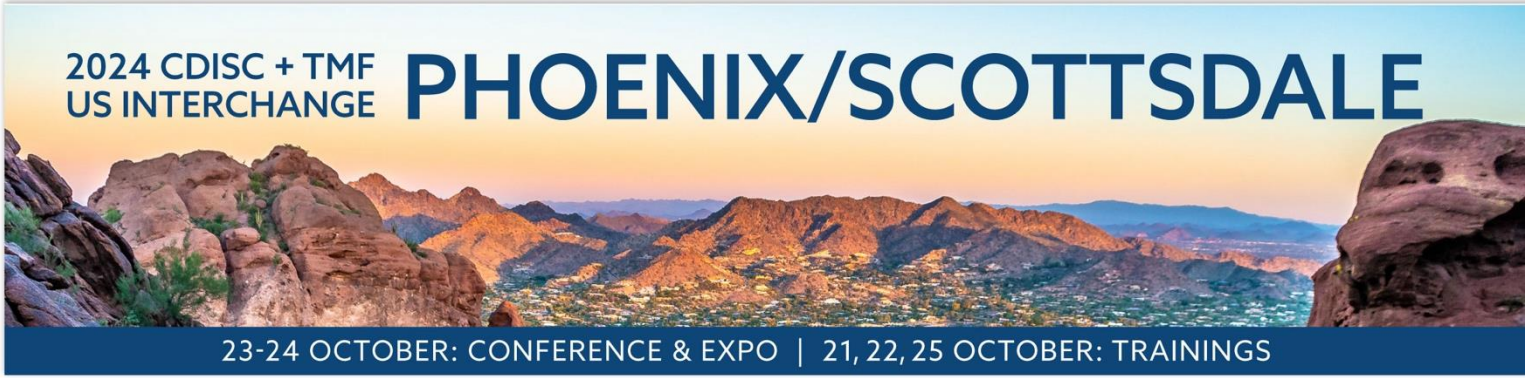


Analysis Concepts at Roche

Presented by Chris Price, Technical Strategy Lead, PD Data Sciences, Roche

Meet the Speaker

Chris Price

Title: Technical Strategy Lead

Organization: Roche

Chris Price has nearly twenty years' experience in the pharmaceutical industry. He is currently a Technical Strategy Lead within the Analytical Data Science group at Roche in Welwyn Garden City, UK where he leads and supports various projects relating to tools, systems, process and mindsets. During his career, Chris has spent many years leading the design and governance of biomedical data standards as part of Roche's Data Standards & Governance group as well as consulting across the organisation on the implementation of these data standards and how metadata can drive automation. Additionally, Chris is also the Working Groups Director at PHUSE responsible for the non-competitive, collaborative framework discussing topics and solutions relating to the advancement of computational science in medical research.

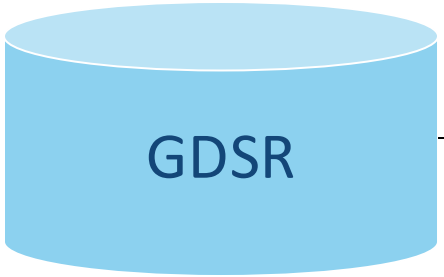
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author have no real or apparent conflicts of interest to report.*

Introductions

Key elements for our work



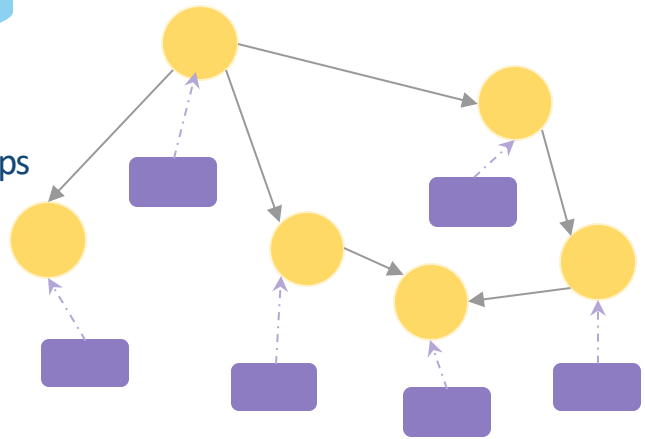
Roche MDR
Clinical Data Standards

Integration of (reference) metadata

Enables easy query through pre-defined catalog of SPARQL queries

Ontology - “schema”

- Concepts, relationships
- Definitions



Knowledge Graph - Metadata

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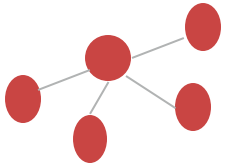
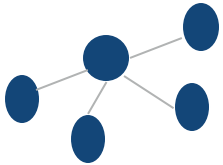
Current Data Standards Models

Data Collection

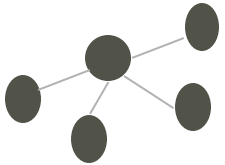
SDTM



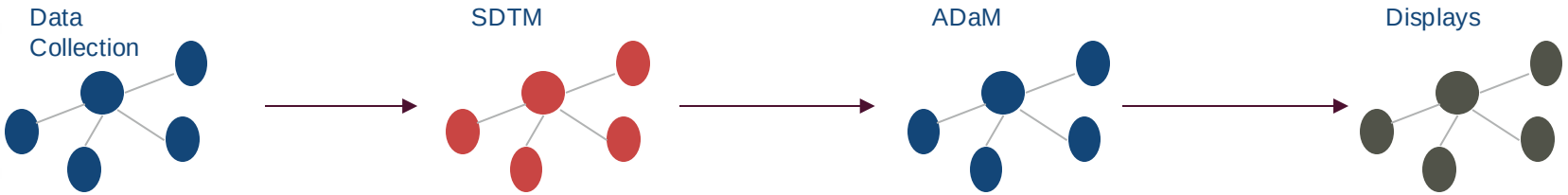
ADaM



Displays



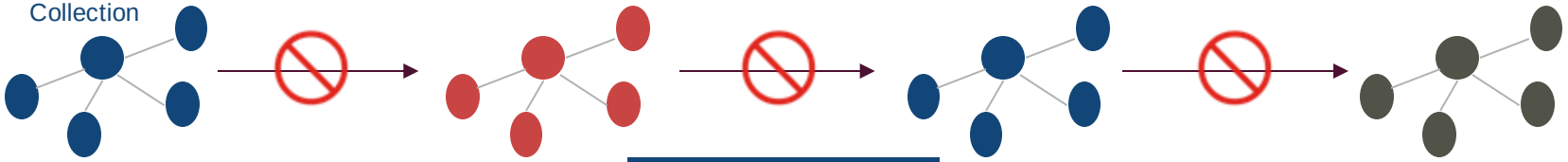
Current Data Standards Models



Current Data Standards Models

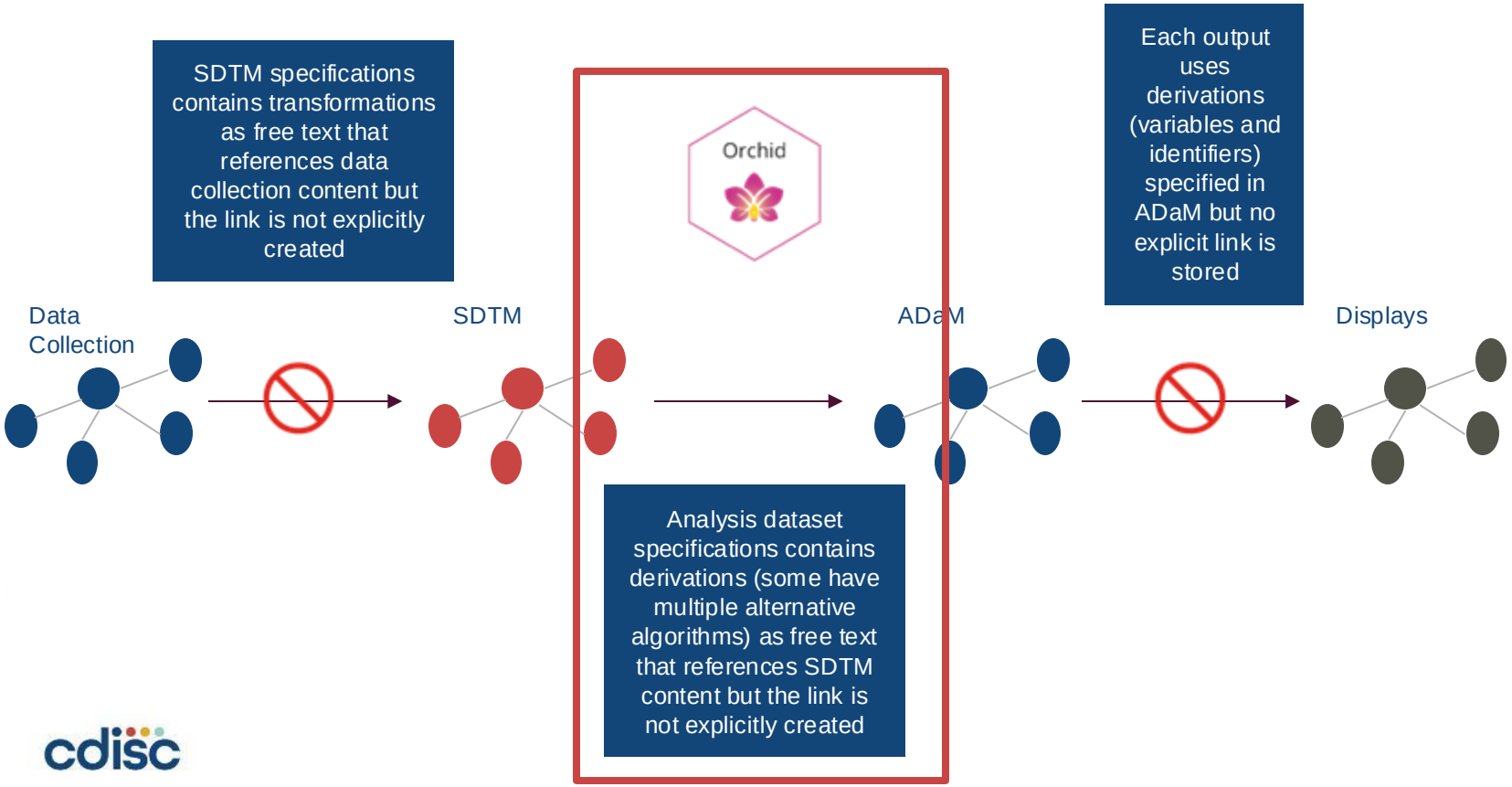
SDTM specifications contains transformations as free text that references data collection content but the link is not explicitly created

Each output uses derivations (variables and identifiers) specified in ADaM but no explicit link is stored



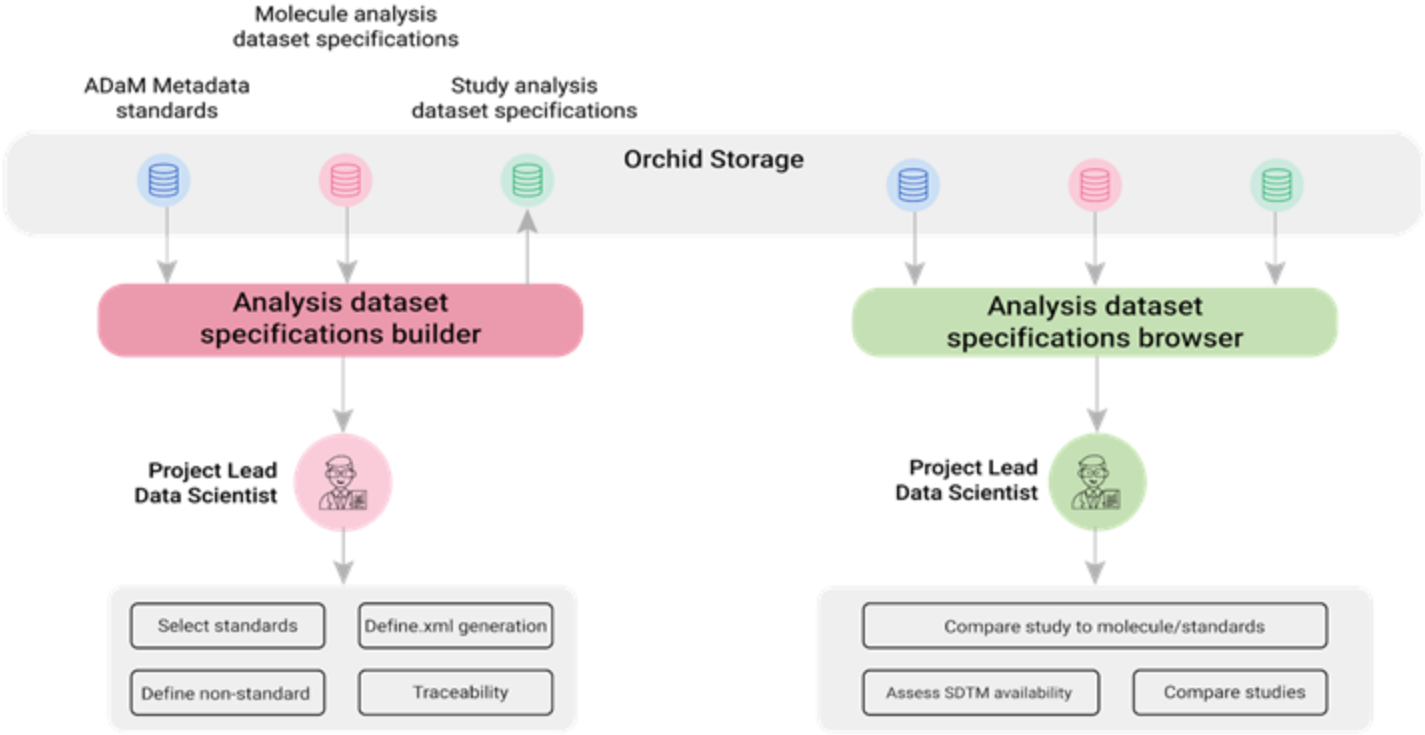
Analysis dataset specifications contains derivations (some have multiple alternative algorithms) as free text that references SDTM content but the link is not explicitly created

Current Data Standards Models



Orchid Garden Elements

Application, Connectivity and Graphs



Ontology Development

- **Key Competency Questions**
  - What are all the SDTM variables that impact an ADaM derivation?
  - What are the Admiral functions needed for generating derivation X?
  - What are all ADaM variables and parameters required for a derivation?

- **Requirements**
  - Definition of the input for a derivation
  - Definition of the output of a derivation
  - Definition of a link to the code implementation of the derivation
  - Support of multiple algorithms to derive the same analysis concept
  - Provision of persistent URIs for derivations

Analysis Concepts

- **What is an Analysis Concept**
  - Derivation
    - Unique definition of an algorithm with the same input, output and derivation rules
  - Derivation Concept
    - Conceptual grouping of algorithms that can all be used to derive a single outcome
  - Generic Derivation Concept
    - Conceptual Grouping of derivations and/or derivation concepts that have identical algorithms (e.g. change from baseline)
  - Input Value
    - The collection of inputs used in the algorithm including both collected data and derived data
  - ADaM Implementation
    - The variables and identifiers populated in ADaM to store the concept
  - Code Implementation
    - The Admiral function required to derive an individual derivation or generic derivation

- **What an Analysis Concept <u>is not</u>**
  - A machine readable algorithm from which raw code can be generated
  - A new data model for how analysis data should be stored
  - A single standard algorithm describing how an outcome is derived

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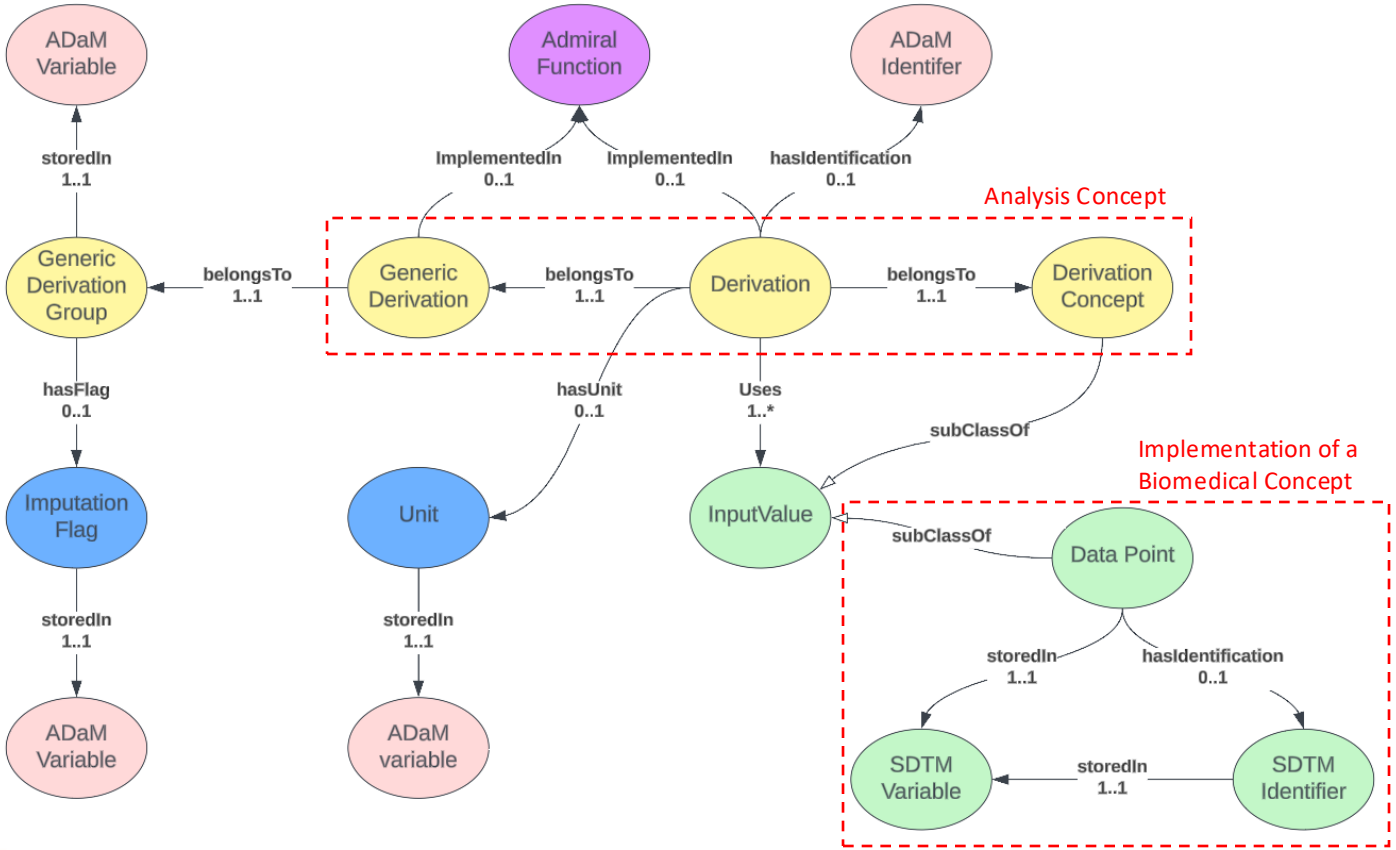
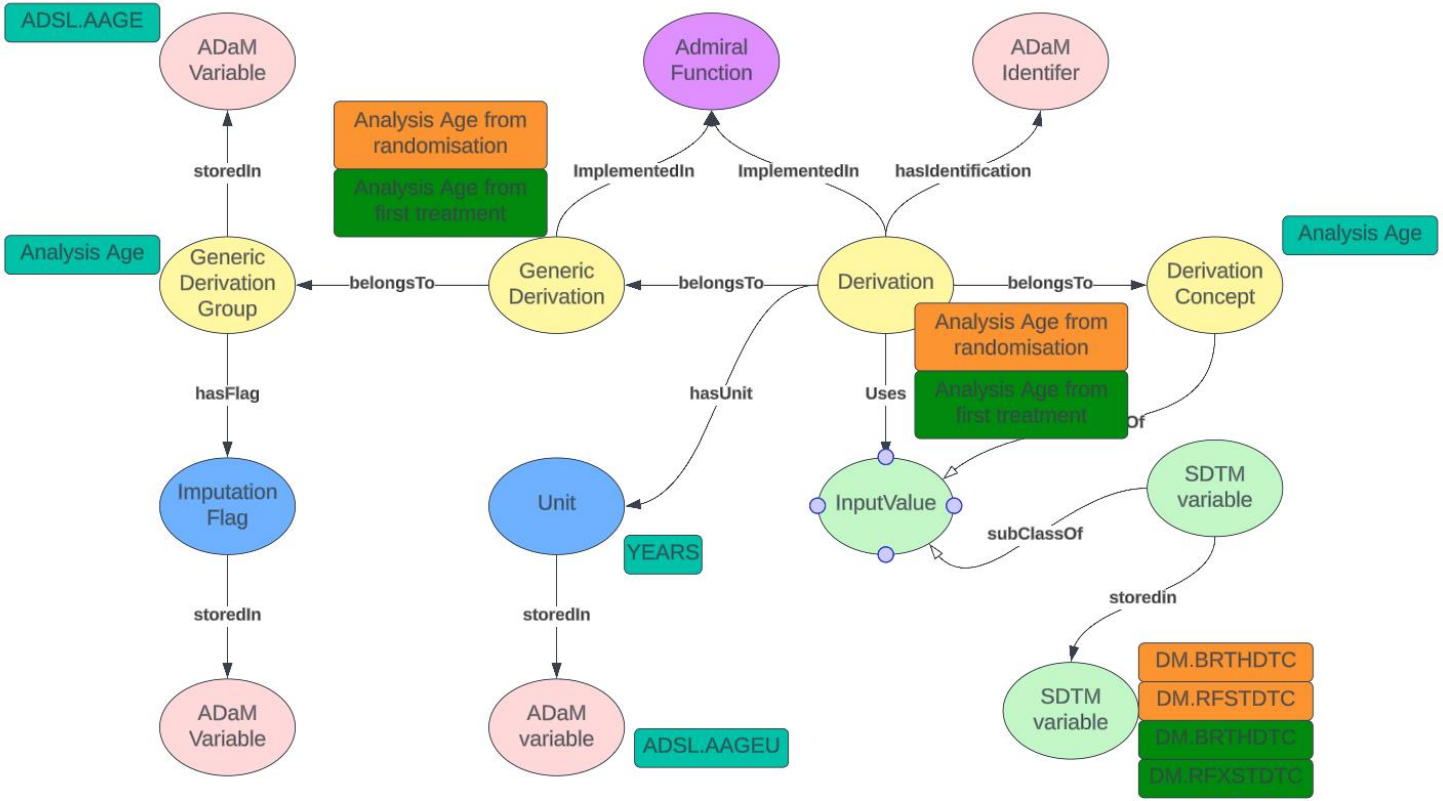
Ontology Development



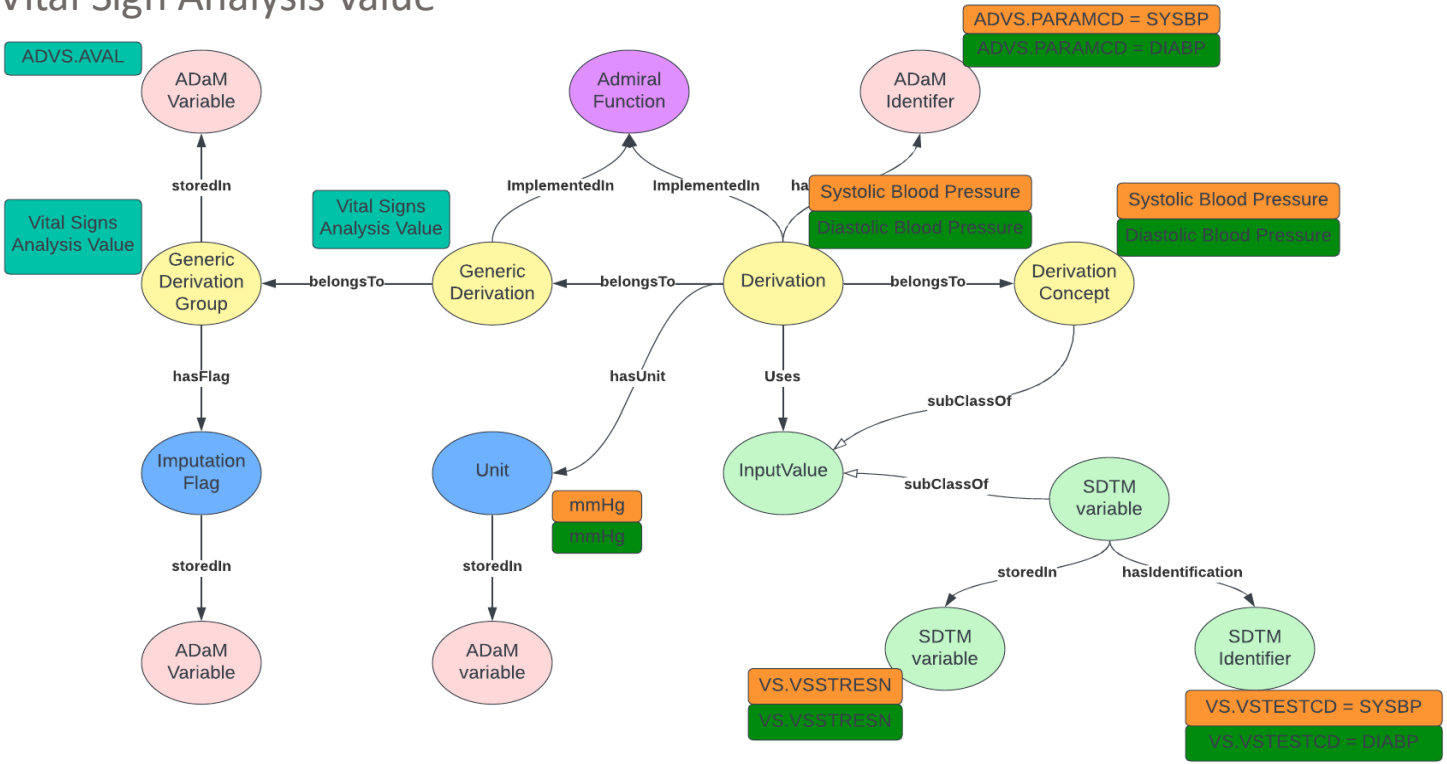
Ontology Development

Example - Analysis Age



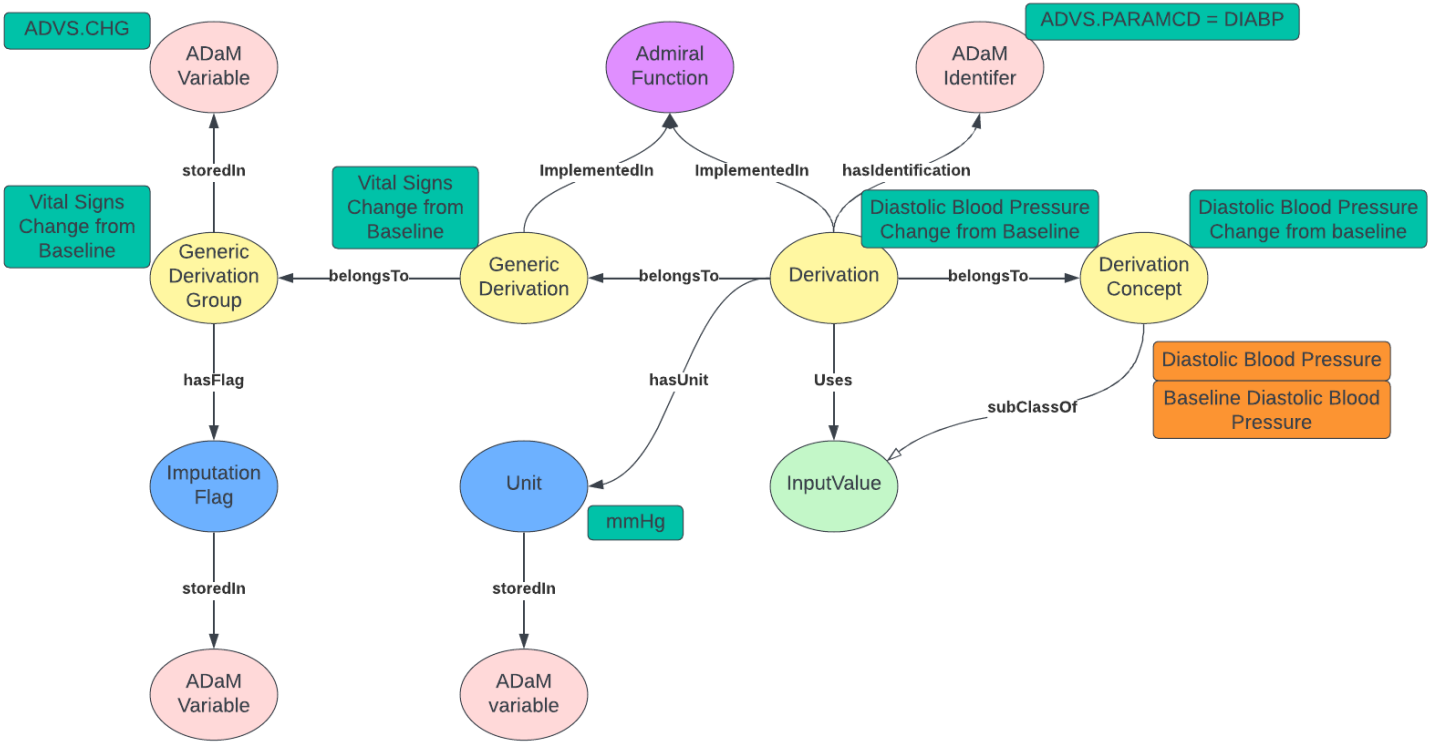
Ontology Development

Example - Vital Sign Analysis Value



Ontology Development

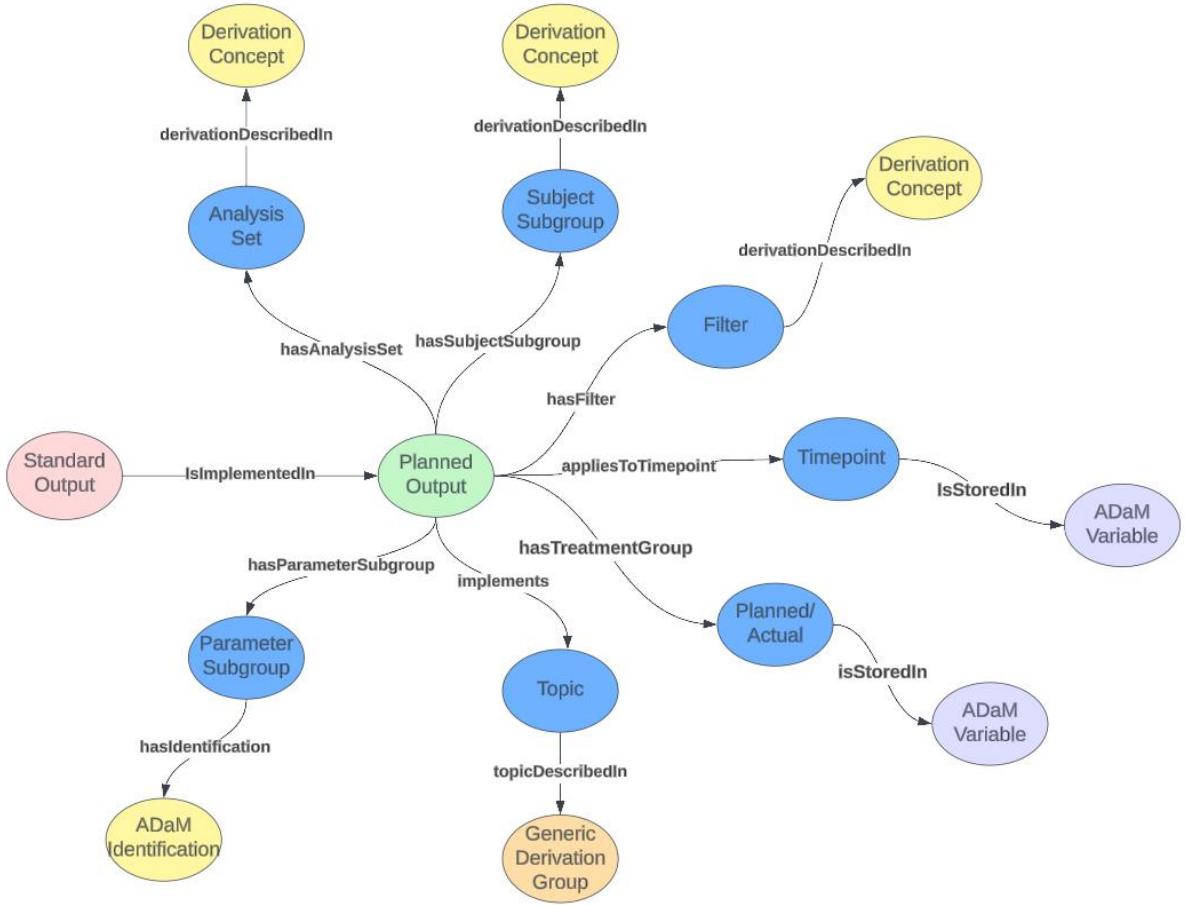
Example - Vital Signs Change from Baseline

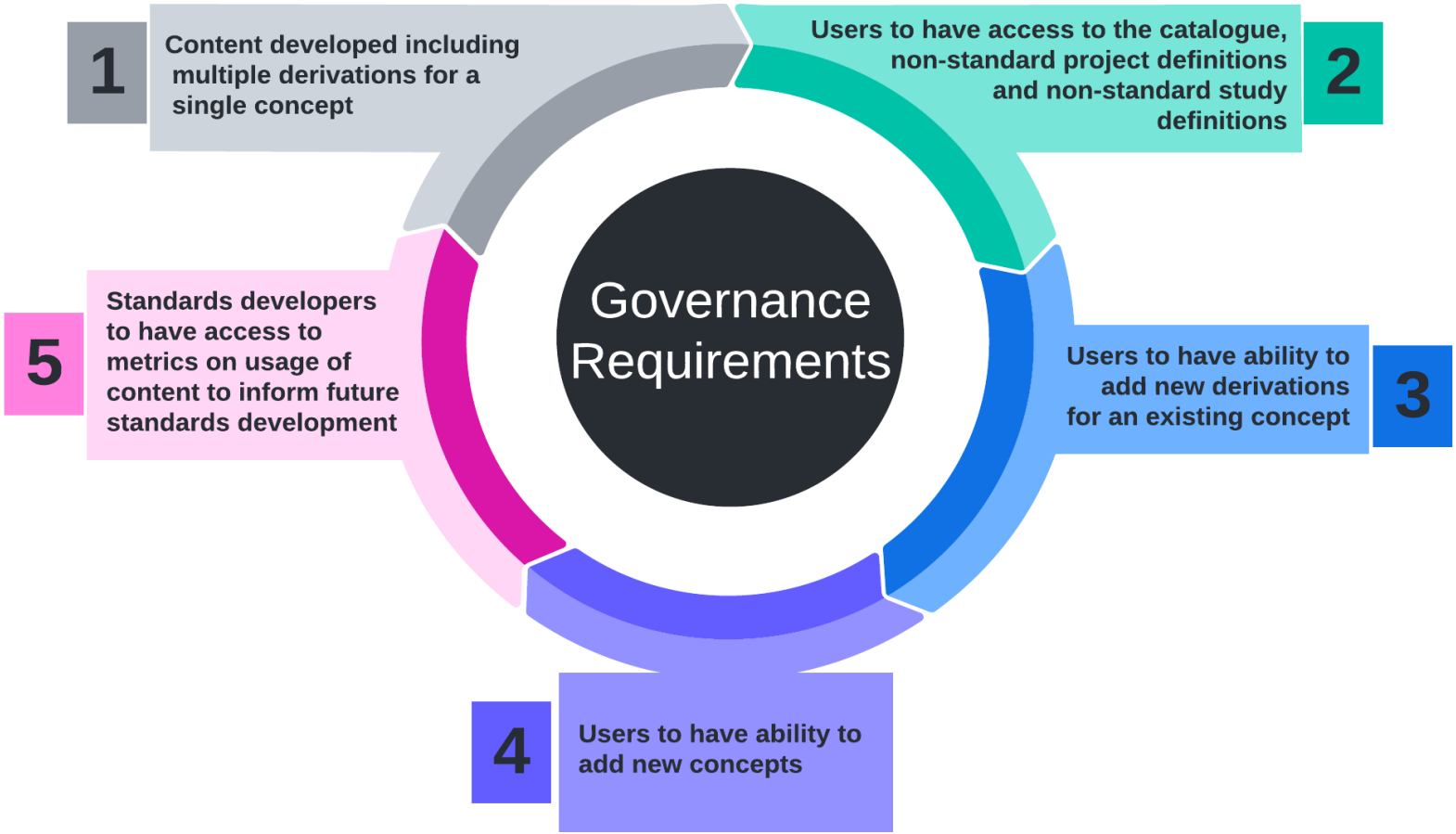


Connecting ADaM to Displays

Requirements

- Ability to link to persistent URIs for derivations described in Orchid
- Ability to link to ADAM variables that are not analysis concepts described in Orchid




Governance Requirements
1
Content developed including multiple derivations for a single concept
2
Users to have access to the catalogue, non-standard project definitions and non-standard study definitions
3
Users to have ability to add new derivations for an existing concept
4
Users to have ability to add new concepts
5
Standards developers to have access to metrics on usage of content to inform future standards development

Thank You!