

COSA – BC & OpenStudyBuilder Workshop @ EU Interchange 2023

Introduction

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Lex Jansen

Linda Lander

Mikkel Traun, Novo Nordisk A/S

Sujit Khune, Novo Nordisk A/S

17. October 2023

8:30 – 9:00 Coffee

9:00 – 9:30 Welcome and introduction

9:30 -10:50 BC use cases

11:00 – 12:15 Group work part 1

12:15 – 13:00 Lunch

13:00 – 14:00 How to get BCs

14:00 – 15:00 Group work part 2

15:00 – 17:00 Sharing in plenum

Workshop drivers:

- Dave Ibersen-Hurst
- Kirsten Langendorf
- Lex Jansen
- Linda Lander
- Mikkel Traun
- Sujit Khune

Workshop Description

COSA Biomedical Concept & OpenStudyBuilder Workshop

At this workshop we will dive into what Biomedical Concepts (BC) is, and how they can be applied within a MDR data standards repository and a SDR study definitions repository – illustrated within the OpenStudyBuilder (OSB) solution and others.

We will relate to how BC's are defined in different models : CDISC COSMoS, DDF/USDM, OpenStudyBuilder. There will be a shared introduction followed by 2 group work sessions, leading to a shared reflection and discussion on how we can support and bring these initiatives forward. The 2 group work sessions are currently defined as:

- Try study setup with BCs
 - Using OpenStudyBuilder
 - Using DDF/USDM excel
- Browse BCs
 - Using OpenStudyBuilder neoDash report
 - Using neoDash report for CDISC COSMos BCs

OpenStudyBuilder: A MDR and SDR open source project ([//novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/](https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/))

COSMoS: Conceptual and Operational Standards Metadata Services CDISC project ([//www.cdisc.org/cosmos](https://www.cdisc.org/cosmos))

DDF: TransCelerate Digital Data Flow project ([//transcelerate.github.io/ddf-home/](https://transcelerate.github.io/ddf-home/))

USDM: CDISC Unified Study Definitions Model ([//github.com/cdisc-org/DDF-RA](https://github.com/cdisc-org/DDF-RA))

Workshop Goals for the COSA BC & OpenStudyBuilder

For **CDISC & COSA**

- Promote COSA as the Open Source community enabling use and sharing of Open Source projects within the CDISC community
- Promote collaboration on the COSMoS initiative – defining BC's in CDISC Library
- Promote COSA initiatives supporting COSMoS
- Promote CDISC as a standards organisation not only defining data standards, but also facilitating tool development and sharing of these

For **Vendors**

- Explore and get insights into new business opportunities supporting open source initiatives with a focus on Biomedical Concepts as enabling end-2-end consistency and automation

For **Participants**

- Be **Trained** and **Explore** how Biomedical Concepts can enable end-2-end consistency and automation
- **Get Insights** into possibilities in using the OpenStudyBuilder tool for defining and applying Biomedical Concepts
- Learn opportunities in **accessing** and **sharing** Biomedical Concepts

For **Novo Nordisk**

- Promote development of shared open source tools providing general value for pharma industry
- Acknowledgement for actively contributing to new CDISC standards and tool development
- Get contributions from other pharma companies and technology providers to ensure better IT tools for Novo Nordisk

Detailed Agenda – Shared Introduction

- Recap what is a BC (Kirsten)
 - BC examples – different models
 - How can they facilitate breaking down data silos
- BC use cases
 - In DDF/USDM (Dave)
 - How are BCs used in USDM SoA
 - In A3 (Johannes)
 - How are BCs used on Forms
 - Use of BCs on Forms (core rules check) (Johannes)
 - Same information, different perspectives
 - In OSB (Mikkel)
 - BCs used in Protocol
 - Using SDTM Specializations for creating define (Lex)
- Group- work
 - Try OSB study setup
 - Try DDF/USDM study excel setup
- How do I get BC's
 - From COSMoS (Lex/Linda)
 - From legacy data (Linda/Mikkel/Kirsten)
 - From OSB (Mikkel/Kirsten)
- Group work
 - Browse BC via neoDash in OSB (Mikkel/Kirsten)
 - Browse via neoDash on CDISC BCs (Linda/Lex)
- Compare BC models (Dave)
 - Link to COSMoS-BC Model + NCI Terminology
 - Link to DDF-BC Model
 - Link to d4k Model
 - Link to OSB Model
 - Many representations exist, having different focus, context and purpose + discussion
- Perspectives on BCs (Dave)
- Group work
 - SWOT –Which Strengths, Weaknesses, Opportunities, and Threats do we see for BC's supporting our clinical data flows?
- Wrap-up – present SWOT and wrap-up the day

Recap what is a BC (Kirsten)

What is a Biomedical Concept?

and how do they help us in the data flow

Definition

A BC is a unit of knowledge created by a unique combination of characteristics. As noted above, BCs complement the existing standards, but omit the operationalization of the standards. That is, BCs exist independent of any given standards implementation, such as SDTMIG v3.2 or CDASHIG v2.0. A BC specifies an observation concept, or what should be observed for a specific subject assessment in a clinical study, but not how to capture the data or how to group observations together

Sam Hume

A Biomedical Concept is the recording, in data, of a single activity within a clinical study.

Dave Ibersen-Hurst

An action, undertaking, or event, which is anticipated to be performed or observed, or was performed or observed, according to the study protocol during the execution of the study.

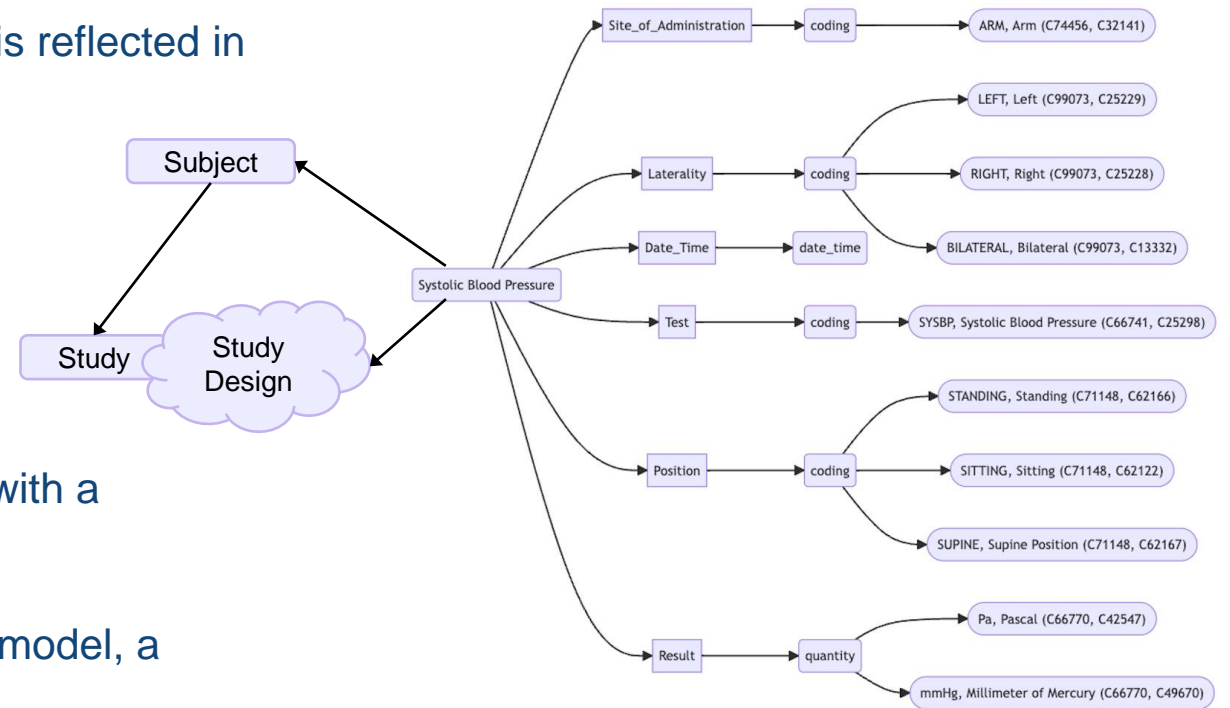
CDISC Glossary

An activity concept made to support both the protocol specification (electronically) as well as the down-stream data flow (Forms, SDTM). An activity in the OpenStudyBuilder can be a clinical recording (like the definition by Dave Ibersen-Hurst), but it can also be an activity performed during the study that is not leading to collection of data, for example the administration of study drug

OpenStudyBuilder,

A Biomedical Concept is ...

- A small model that defines a clinical concept in a standardized and reusable manner
- Atomic:
 - If it is split it loses meaning
 - Refers more to the data based on a BC but is reflected in the model
- Identifiable:
 - Has an identifier, unique
 - Find it, Reference it, Deploy it
- Complete:
 - Everything is defined
- Data Specification
 - Specification of the data, not how it is used with a particular technology
- Context:
 - A BC needs context, i.e the rest of the DDF model, a study, the encounters, activities, timing ...



The grocery list analogue – getting milk

Schedule of Events for Protocol H2Q-MC-LZZT(c)

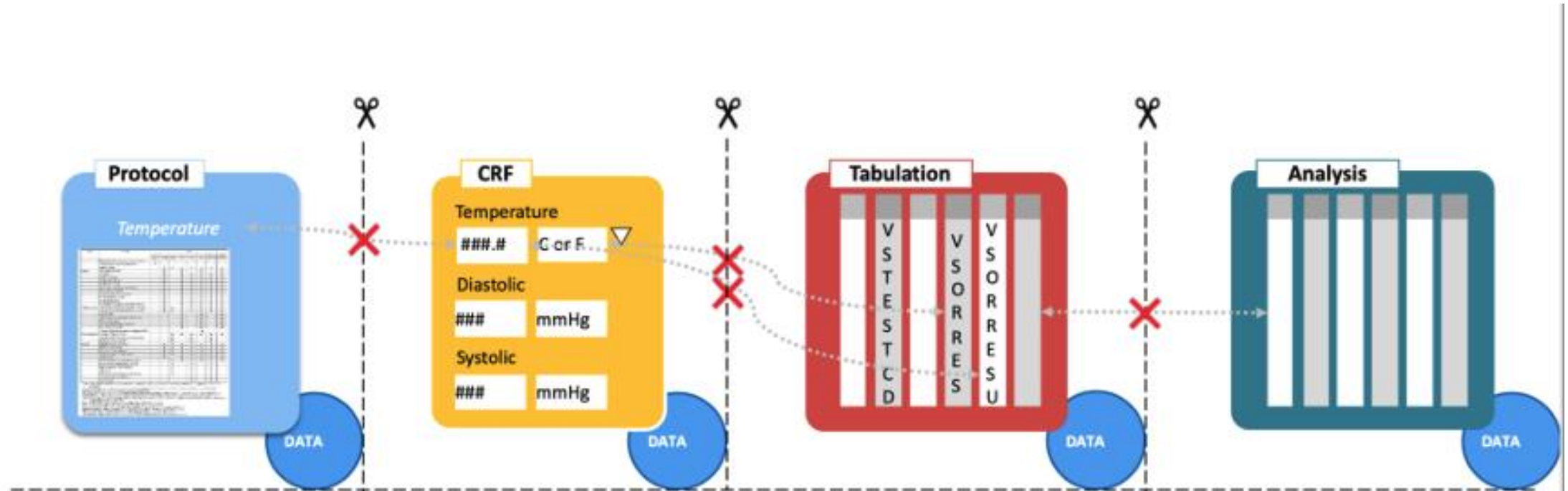
	VISIT	1	2	3	4	5	7	8
ACTIVITY	WEEK	-2	-.3	0	2	4	6	8
Informed consent		X						
Patient number assigned		X						
Hachinski ≤ 4		X						
MMSE 10-23		X						
Physical examination		X						
Medical History		X						
Habits		X						
Chest x-ray		X						
Apo E genotyping					X			
Patient randomized				X				
Vital signs/Temperature		X	X	X	X	X	X	X
Ambulatory ECG placed			X					

Detailed definition of what we collect is needed for down-stream processes, automation and data pooling



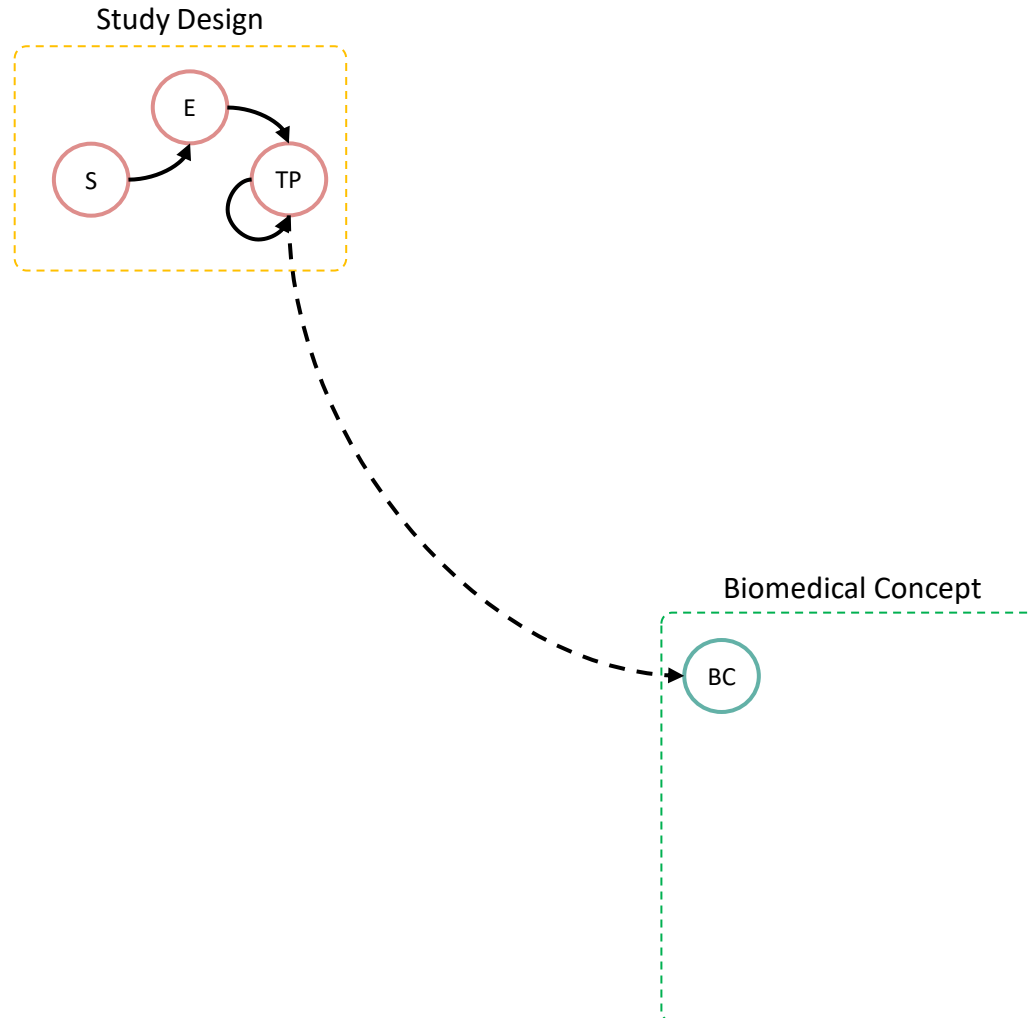
Plasma Specimen (Xanomeline)				X	X	X		X
Hemoglobin A _{1c}		X ^a						
Study drug record				X	X	X		X
Medications dispensed								
Medications returned								
TTS Acceptability Survey								
IDE C--		D		X				X
TTS Acceptability Survey								
Medications returned								
Medications dispensed								
Study drug record				X	X	X		X
Hemoglobin A _{1c} (Xanomeline)		X ^a						

Typical data flow



- We create silos of data
- It is hard to link (trace / map) it all after the event

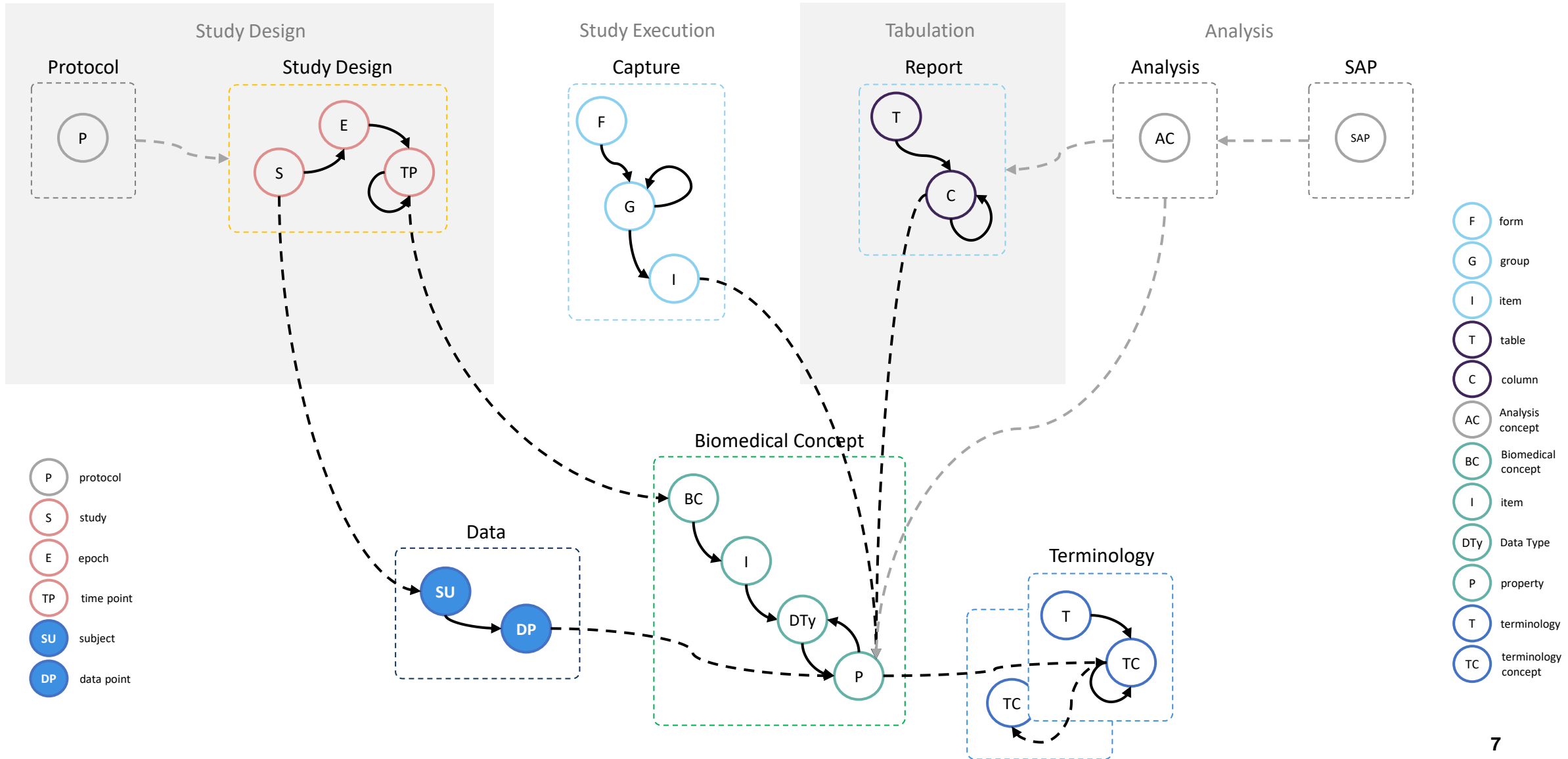
Study SoA is a list of BC at timepoints



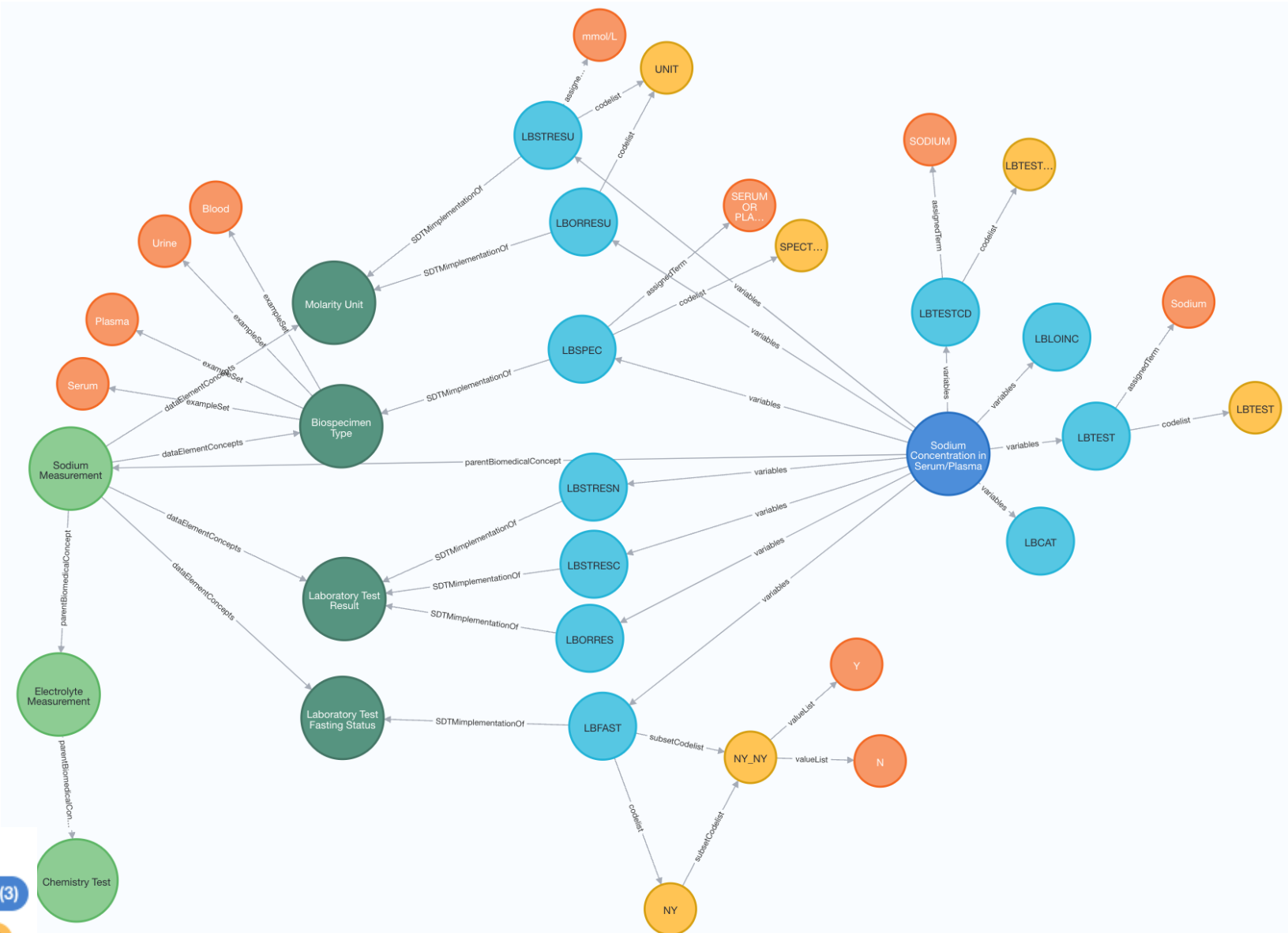
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	VISIT	1	2	3	4	5	7	8
ACTIVITY	WEEK	-2	-3	0	2	4	6	8
Informed consent		X						
Patient number assigned		X						
Hachinski ≤4		X						
MMSE 10-23		X						
Physical examination		X						
Medical History		X						
Habits		X						
Chest x-ray		X						
Apo E genotyping					X			
Patient randomized				X				
Vital signs/Temperature		X	X	X	X	X	X	X
Ambulatory ECG placed			X					
Ambulatory ECG removed				X				
ECG		X			X	X	X	X
Placebo TTS test		X						
CT Scan (if not within last year and patient passes all other screens)		X						
Concomitant Medications		X		X	X	X	X	X
Laboratory (Chem/Hemat):		X			X	X	X	X
Laboratory (Urinalysis)		X			X			
Plasma Specimen (Xanomeline)				X	X	X	X	
Hemoglobin A _{1c}		X ^a						
Study drug record				X	X	X	X	X
Medications dispensed								
Medications returned								
TTS Acceptability Survey								
† D † E C - -		D		X				X
† T † S † A † C † E † R † I † T † T †								
† M † E † D † I † C † I † O † N † S †								
† M † E † D † I † C † I † O † N † S †								
† S † I † M † P † L † E †				X	X	X	X	X
† H † E † M † O † G † L † O † B † I † N †		X ^b						
(Xanomeline)								

The end-to-end view



Sodium – CDISC COSMoS



Node labels

- * (67) BiomedicalConcept (3) DataElementConcept (4) SDTMGroup (3) Chemistry Test
- SDTMVariable (33) CodeList (5) AssignedTerm (6) subsetCodelist (3)
- Term (10)

Sodium – OpenStudyBuild er

Node labels

* (53) ActivityGrouping (1)

ActivityValidGroup (1) ActivityGroupValue (1)

ConceptValue (3)

TemplateParameterTermValue (3)

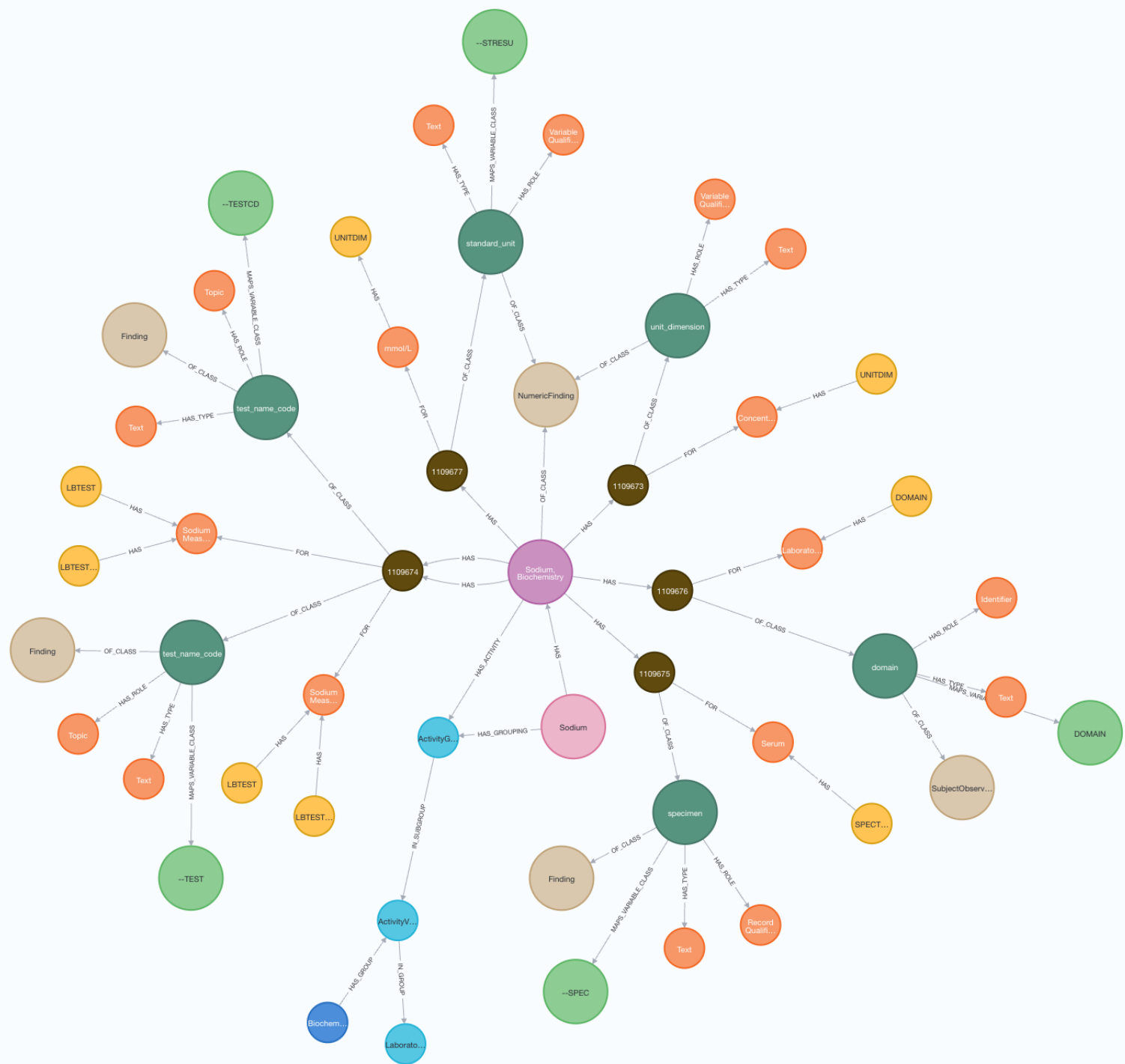
ActivitySubGroupValue (1) ActivityValue (1)

ActivityInstance (1) ActivityInstanceClass (5)

ActivityItem (5) ActivityItemClass (6)

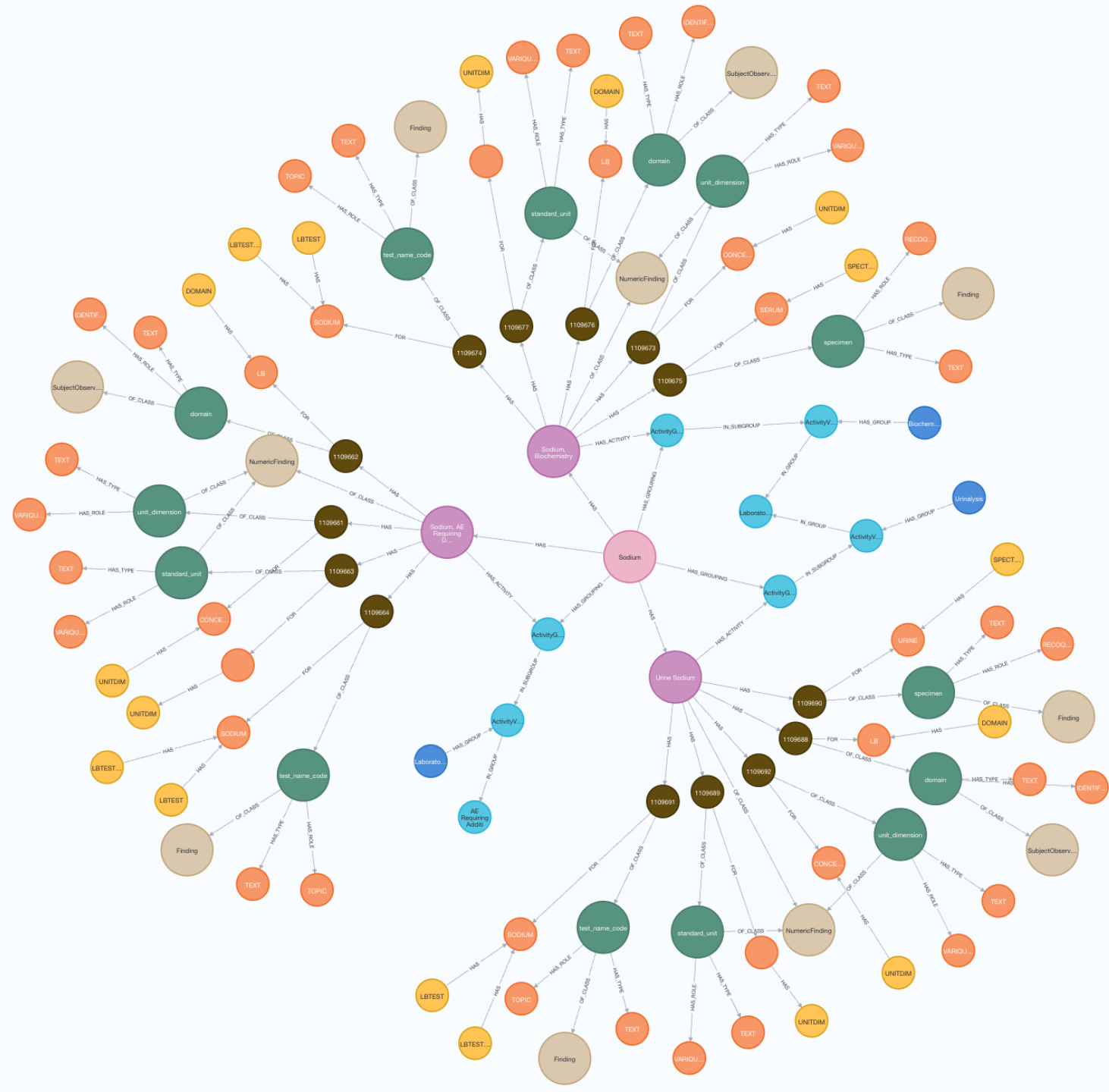
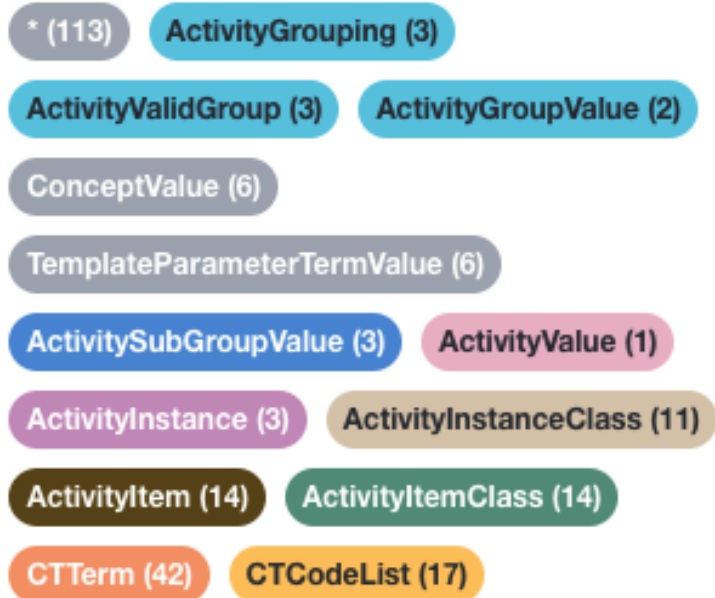
CTTerm (18) CTCCodeList (8)

VariableClass (5)



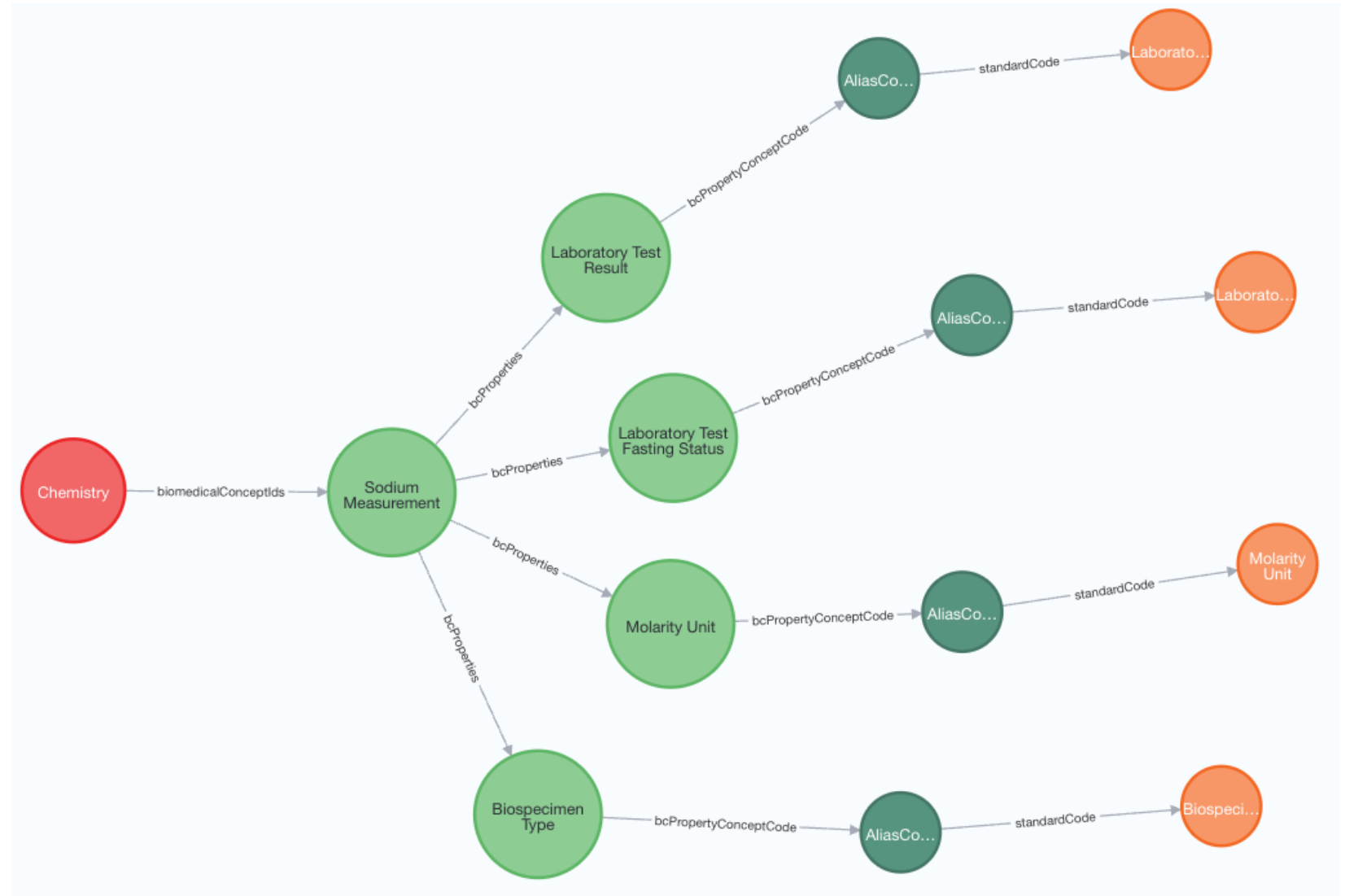
Sodium – OpenStudyBuild er

Node labels

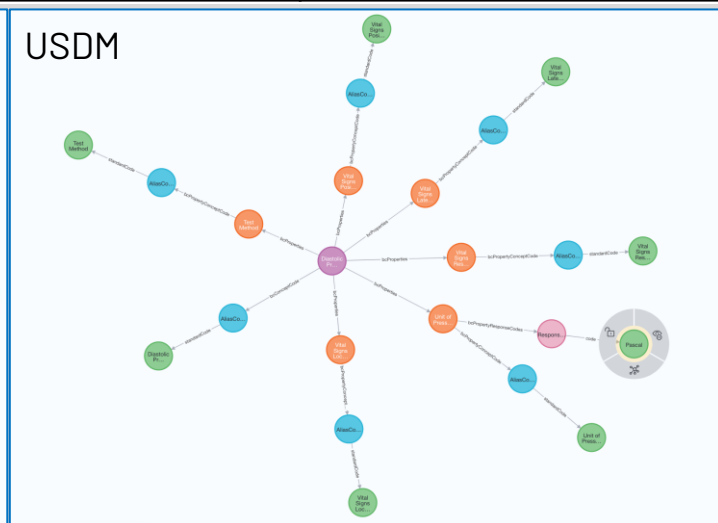
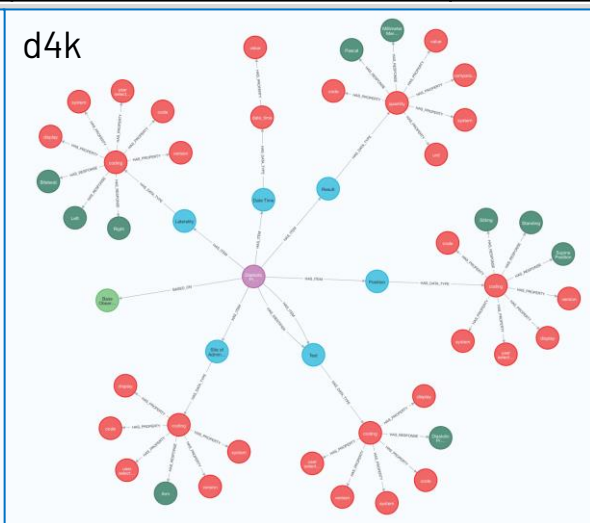
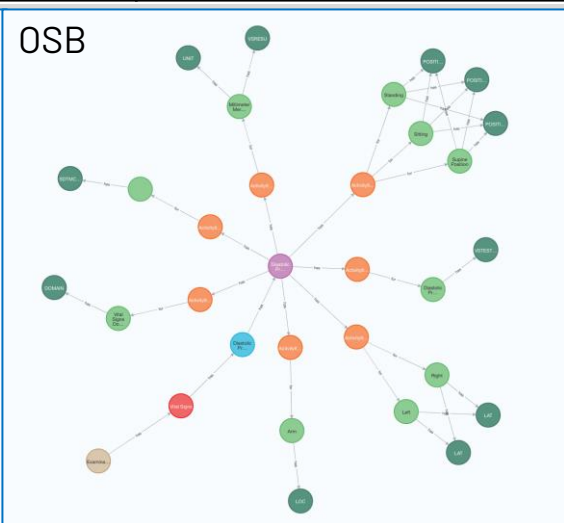
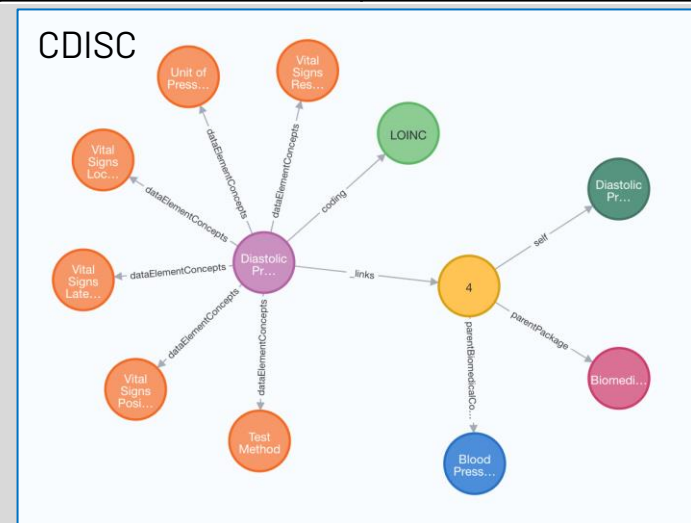


Sodium – USDM

Node labels



Perspective	A measure of the content of a BC. Inclusion or exclusion is not a mark of quality of fitness for purpose, the table is to show differences in approach	CDISC (Conceptual Layer)	OSB	d4k	USDM (Based on CDISC Model)
Central Node	Has a central node from which all BC information can be found				
Properties	Is the BC built up from a set of properties				
Identification	Does the BC have a unique identifier				
Version Managed	Is the BC explicitly version managed	Not currently explicit			Based on CDISC BC
Controlled Terms	Controlled terms defined as part of the BC and which CT used	CDISC CT	CDISC CT	CDISC CT	CDISC CT
Complete	Is the definition complete, everything needed for deployment	CT references			CT references
Equivalence	Does the BC allow for equivalence to other systems to be made		No?		
Hierarchy	Can the BCs be placed into a hierarchy		Yes (fixed)		
Configurable	Can the BCs be configured using attributes within the BC	Not designed to be	Planned		
Data Types	Do the BCs use complex data types in their design, if so which ones		Simple data types	FHIR	
Templated	Are the BC instances based on a template	No?	Yes, by Class concept		Based on CDISC BC



BC use case (Johannes)

Why do a Core rule from a BC?

- Proof of concept
- Different perspectives on the same data
- Core rule
 - Designed to check conformance, that the correct metadata is stored together on a row in a dataset
- Biomedical Concept
 - Identifiable: Has an identifier, unique
 - Complete: Everything is defined
 - Atomic: If it is split it loses meaning
 - Data Specification
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Why do a Core rule from a BC?

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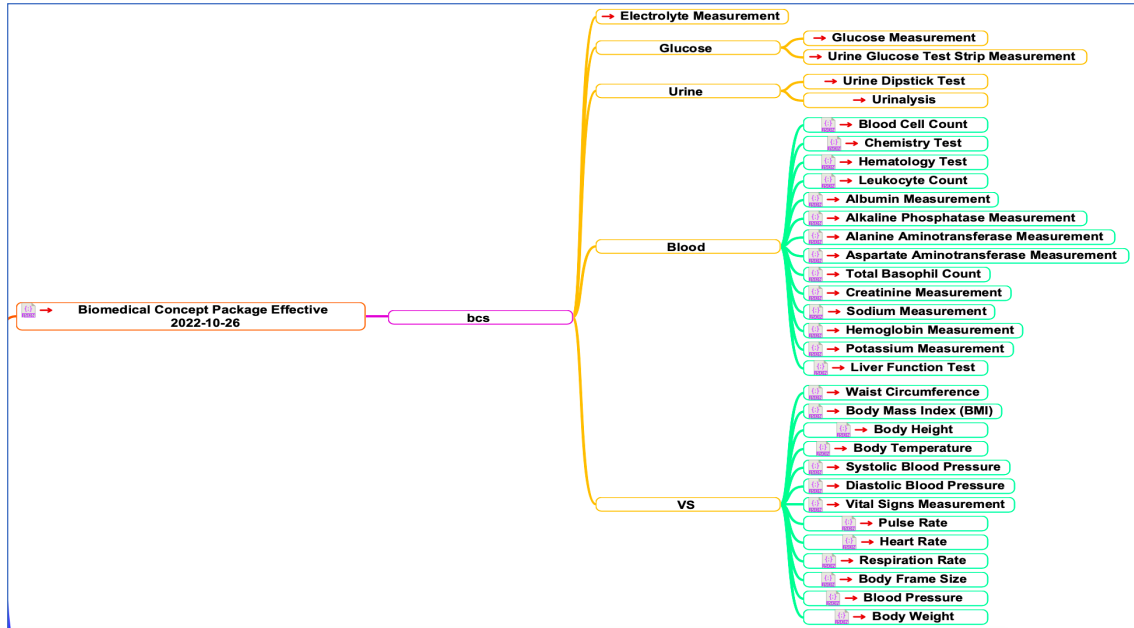
So the Core rule should be inside the BC?

Process

- 2022-10-26: First set of BC's available via CDISC Library API
 - Downloaded BC's as JSON from the CDISC Library API
 - Using python
- 2022-11-14: Attended Core Workshop at Phuse, Belfast
- On the bus trip from the conference to the airport (around 2 hours)
 - Converted the downloaded BC's to Core rules
 - Using Groovy/Java
 - Add some additional info linked from the BC (NCI concepts)
 - Created some test data
 - In csv format

When I got internet again...

- Uploaded Core rules and test data to Core test server
- I had working Core Rules for all BC's specifying --UNIT and --SPEC



Take a step back: Why do we need Core rules?

Example: Height – and the current state of definitions

Data

VSTESTCD	VSTEST	VSCAT	VSORRES	VSORRESU	VSPOS
HEIGHT	Height	BODY	70	in	

Specification

<u>(VSTESTCD)</u>	<u>(VSTEST)</u>	*	No terminology requirement	<u>(VSRESU)</u>	<u>(POSITION)</u>
ABSKNF	<i>Too long to show, but you know them</i>	* Sponsor defined		m	SITTING
BMI				beats/min	STANDING
BMR				breaths/min	DECUBITUS
BSA				C	FOWLERS
WEIGHT				cm	LATERAL
HEIGHT				cmHg	DECUBITUS
PULSE				in	LEFT LATERAL
SYSBP				mmHg	DECUBITUS
DIABP				Pascal	...
...				...	

Core rule

Systolic Blood Pressure vs Biomedical Concept

```

---
Authority:
  Organization: "CDISC"
Check:
  all:
    - name: "VSTESTCD"
      operator: "equal_to"
      value: "SYSBP"
    - name: "VSORRESU"
      operator: "is_not_contained_by"
      value:
        - "cmHg"
        - "mmHG"
        - "Pascal"
Citations: ...
Core: ...
Description: "Systolic BP unit is incorrect"
Outcome:
  Message: "SYSBP unit is not allowed"
  Output Variables:
    - "VSTESTCD"
    - "VSORRESU"
References: ...
Rule Type: "Data Pattern and Format"
Scopes:
  Classes:
    Include:
      - "Findings"
  Domains:
    Include:
      - "VS"
  Standards: ...
Sensitivity: "Record"
Severity: "Warning"
  
```

VSTESTCD = SYSBP

VSORRESU is not:
 - cmHg
 - mmHg or
 - Pascal

Output the error

(VSTESTCD)	(VSTEST)	*	No terminology requirement	(VSRESU)
ABSKNF	<i>Too long to show, but you know them</i>	Sponsor defined		m
BMI				beats/min
BMR				breaths/min
BSA				C
WEIGHT				cm
HEIGHT				cmHg
PULSE				in
SYSBP				mmHg
DIABP				Pascal
...				...

Core rule

Systolic Blood Pressure vs Biomedical Concept

```
---
Authority:
  Organization: "CDISC"
Check:
  all:
    - name: "VSTESTCD"
      operator: "equal_to"
      value: "SYSBP"
    - name: "VSORRESU"
      operator: "is_not_contained_by"
      value:
        - "cmHg"
        - "mmHG"
        - "Pascal"
Citations: ...
Core: ...
Description: "Systolic BP unit is incorrect"
Outcome:
  Message: "SYSBP unit is not allowed"
  Output Variables:
    - "VSTESTCD"
    - "VSORRESU"
References: ...
Rule Type: "Data Pattern and Format"
Scopes:
  Classes:
    Include:
      - "Findings"
  Domains:
    Include:
      - "VS"
  Standards: ...
Sensitivity: "Record"
Severity: "Warning"
```

```
{
  "conceptId": "C25298",
  "href": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C25298",
  "category": [
    "Vital Signs"
  ],
  "shortName": "Systolic Blood Pressure",
  "synonym": [
    "SYSBP"
  ],
  "href": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C173522",
  "dataElementConcepts": [
    {
      "conceptId": "C173522",
      "href": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C173522",
      "shortName": "Vital Signs Result",
      "dataType": "integer"
    },
    {
      "conceptId": "C49669",
      "href": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C49669",
      "shortName": "Unit of Pressure",
      "dataType": "string",
      "exampleSet": [
        "cmHg",
        "mmHG",
        "Pascal"
      ]
    }
  ]
}
```

Identifier

SYSBP is a synonym identifier

List of variables

Unit of Pressure = VSORRESU

List of units for Unit of Pressure

Let's visualize differently

Core rule YAML

editor.herowand.com

YAML Import View Tools Cloud Download

```
1 ---
2 Authority:
3   Organization: "CDISC"
4 Check:
5   all:
6     - name: "VSTESTCD"
7       operator: "equal_to"
8       value: "SYSBP"
9     - name: "VSORRESU"
10      operator: "is_not_contained_by"
11      value:
12        - "cmHg"
13        - "mmHG"
14        - "Pascal"
15 Citations:
16   Cited Guidance: "BC ID"
17   Item: "BC"
18   Document: "CDISC BC Working"
19   Section: "Somewhere"
20 Core:
21   Id: "CDISC.BC.SYSBP_UNITS"
22   Version: "1"
23 Description: "Systolic BP unit is incorrect"
24 Outcome:
25   Message: "SYSBP unit is not allowed"
26 Output Variables:
27   - "VSTESTCD"
28   - "VSORRESU"
29 References:
30   Origin: "CDISC BC C25298"
31   Version: "1.0"
32 Rule Identifier:
33   Id: "BC00001"
34   Version: "1.0"
35 Rule Type: "Data Pattern and Format"
36 Scopes:
37   Classes:
```

Authority (1) ∞ → Organization: "CDISC"

Check (1) ∞ → all (2) ∞ → name: "VSTESTCD" operator: "equal_to" value: "SYSBP"

Check (1) ∞ → all (2) ∞ → name: "VSORRESU" operator: "is_not_contained_by" value (3) ∞ → cmHg, mmHG, Pascal

Citations (1) ∞ → Cited Guidance: "BC ID", Item: "BC", Document: "CDISC BC Working", Section: "Somewhere"

Core (1) ∞ → Id: "CDISC.BC.SYSBP_UNITS", Version: "1"

Outcome (2) ∞ → Message: "SYSBP unit is not allowed"

Outcome (2) ∞ → Output Variables (2) ∞ → VSTESTCD, VSORRESU

References (2) ∞ → Origin: "CDISC BC C25298", Version: "1.0"

References (2) ∞ → Rule Identifier (1) ∞ → Id: "BC00001", Version: "1.0"

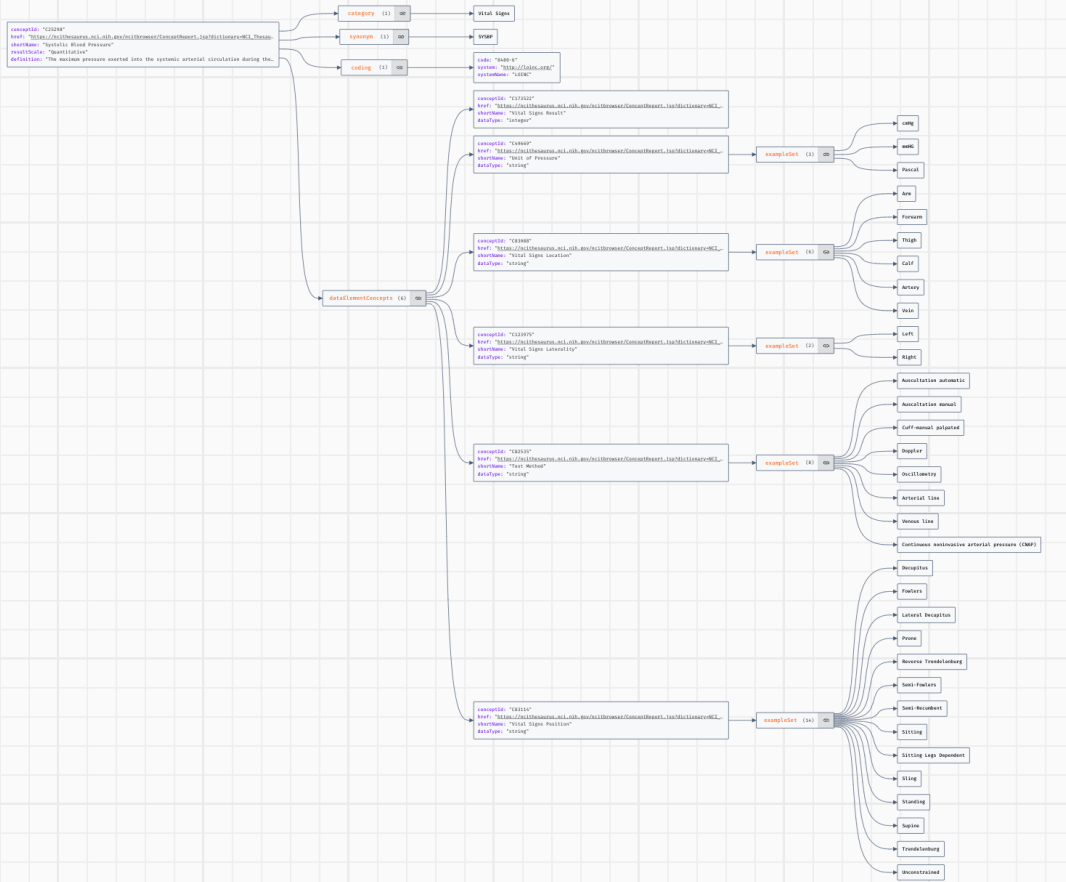
Scopes (1) ∞ → Classes (3) ∞ → Include (1) ∞ → Findings

Scopes (1) ∞ → Classes (3) ∞ → Domains (1) ∞ → Include (1) ∞ → VS

Scopes (1) ∞ → Classes (3) ∞ → Standards (1) ∞ → Name: "BC", Version: "1.0"

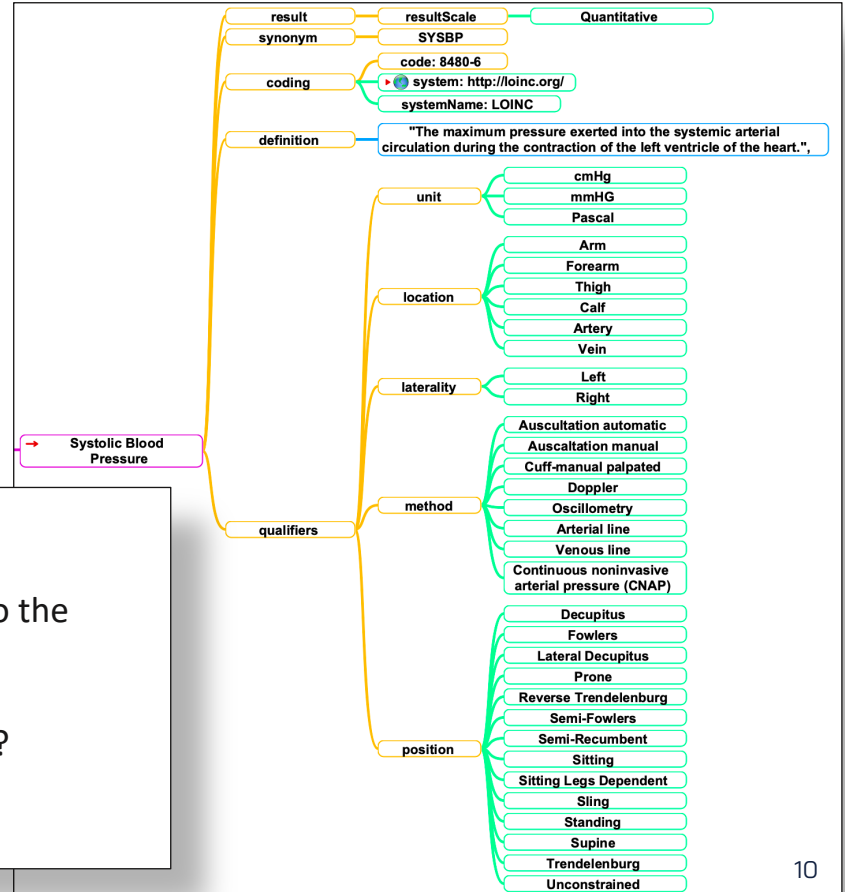
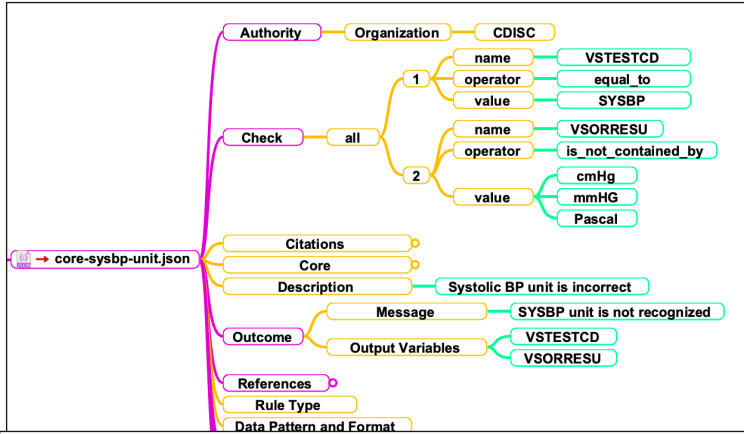
Powered by Altos

```
1 {
2   "conceptId": "C25298",
3   "href": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptBrowser.do?concept=C25298",
4   "category": [
5     "Vital Signs"
6   ],
7   "shortName": "Systolic Blood Pressure",
8   "synonym": [
9     "SYSBP"
10  ],
11  "resultScale": "Quantitative",
12  "definition": "The maximum pressure exerted into the arteries during the systole.",
13  "coding": [
14    {
15      "code": "8480-6",
16      "system": "http://loinc.org/",
17      "systemName": "LOINC"
18    }
19  ],
20  "dataElementConcepts": [
21    {
22      "conceptId": "C173522",
23      "href": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptBrowser.do?concept=C173522",
24      "shortName": "Vital Signs Result",
25      "dataType": "integer"
26    },
27    {
28      "conceptId": "C49669",
29      "href": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptBrowser.do?concept=C49669",
30      "shortName": "Unit of Pressure",
31      "dataType": "string",
32      "exampleSet": [
33        "cmHg",
34        "mmHG",
35        "Pascal"
36      ]
37    }
38  ]
39 }
```



Core rule

Systolic Blood Pressure vs Biomedical Concept



The Biomedical Concept

- contains all qualifiers and associated terminology
- Core rules can be deduced from the relationships to the qualifiers and their associated terminology

Should we trigger the Core engine from the BC directly?

Can the BC also be displayed as a form?

BC -> SDTM aCRF and create SDTM

Form Form 1
Render Hide

Systolic Blood Pressure, Supine Unit mmHg Position Supine Location Arm

VSTESTCD=SYSBP VSORRES VSORRESU VSPOS VSLOC

Pulse Unit beats/min Position Standing Location Leg

VSTESTCD=PULSE VSORRES VSORRESU VSPOS VSLOC

Race Subject self reports one or many

DM.RACE

American Indian or Alaska Native

Asian

Black or African American

White

Native Hawaiian or Other Pacific Islander

Collected view Save Collected Hide

id	result	location	position
EXAMPLE-TEMPLATE	100	C32141	
PULSE	65	C32974	C62166
Race	C41260,C41261		

References resolved Resolve Hide

```

{
  "EXAMPLE-TEMPLATE": {
    "type": "test",
    "identifier": {
      "name": "SYSBP",
      "domain": "VS",
      "display": "Systolic Blood Pressure, Supine",
      "label": "Systolic Blood Pressure",
      "submission_value": "SYSBP",
      "cat": "Vital Signs"
    }
  }
}
                
```

SDTM view Make SDTM Hide

STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSCAT	VSPPOS	VSORRES	VSORRESU	VSLOC	VSLAT	VISITNUM	VISIT	VSDTC	VSDY
PILOT01	VS		1	SYSBP	Systolic Blood Pressure	Vital Signs	SUPINE	100	mmHg	ARM					
PILOT01	VS		2	PULSE	Pulse Rate	PULSE AND BLOOD PRESSURE	STANDING	65	beats/min	LEG					

STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	INVID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	RACE1	RACE2
PILOT01	DM											MULTIPLE		ASIAN	WHITE

BC use case in OpenStudyBuilder := Activity Concepts (Mikkel)

*Slides in this section is sample set
reused from internal training
material*

BC in OSB := Activity Concepts

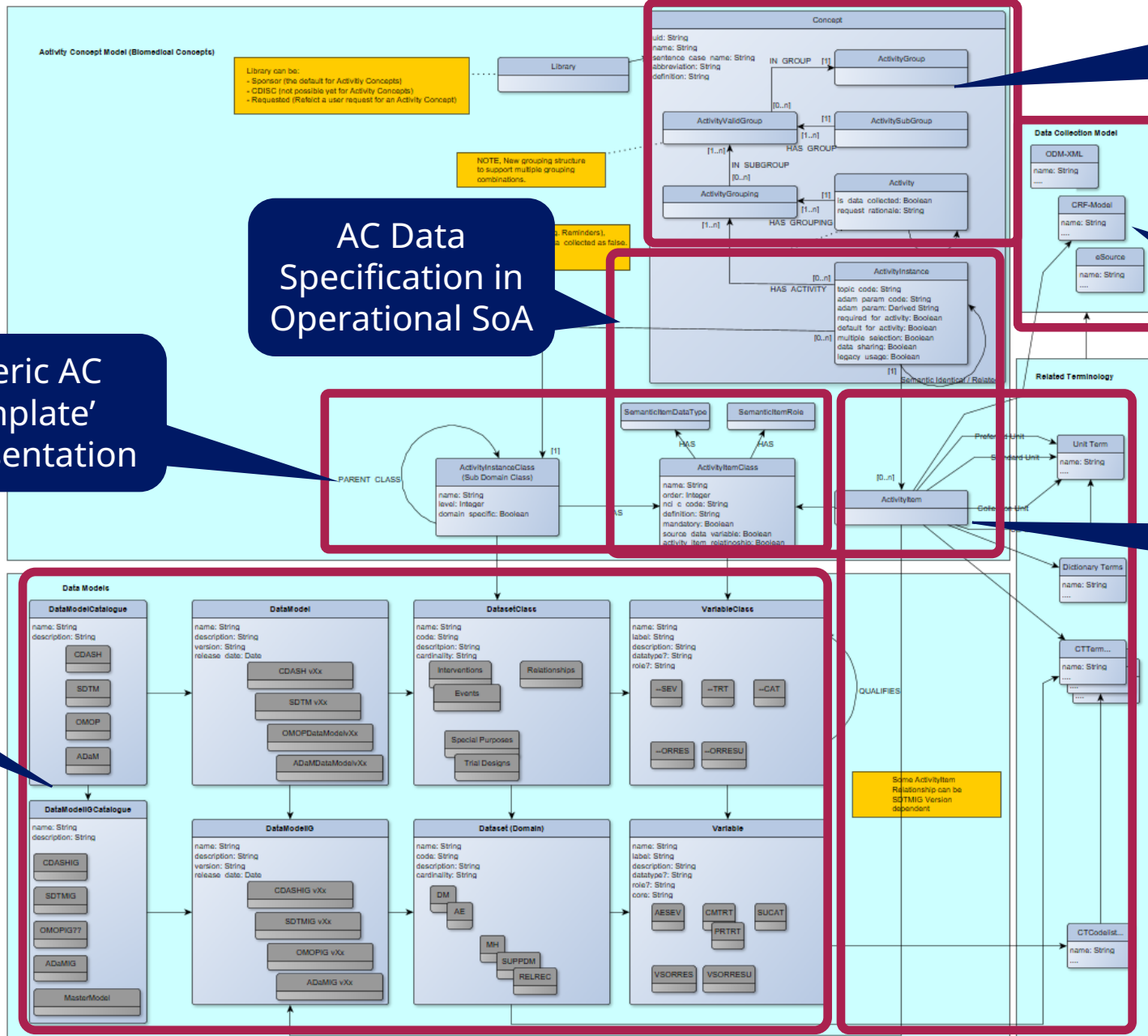
- OpenStudyBuilder is based on **Concept based Data Standards**
 - These are structures with more complex relationships
 - I.e. not only code-value pairs
 - They are applied for many different types of data, Activities (Clinical Procedures and Assessments), Compounds (linked to IDMP), Unit Definitions, Data Collection forms
- **Biomedical Concepts** (BC's) is generally defined as Activities (Clinical Procedures and Assessments)
- In OpenStudyBuilder we therefore use the general term **Concepts** and the specific term **Activity Concept := BC**

Activity Concept (AC) data model in StudyBuilder

17 October 2023

CCSA-AC & OpenStudyBuilder Workshop

Novo Nordisk®



Generic AC 'Template' Representation

AC Data Specification in Operational SoA

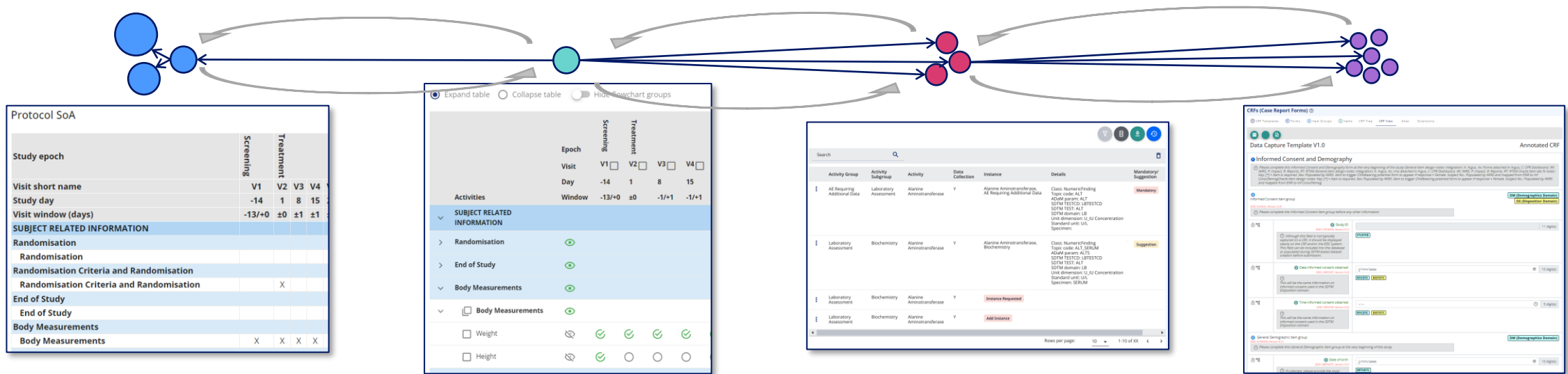
AC Representation in Detailed and Protocol SoA

AC Representation in Data Collection

AC Relationship to Terminologies

AC Representation in Data Models

Schedule of Activities (SoA) at multiple levels



Protocol SoA

- For the high level SoA in protocol section 1.2
- Main purpose is for the investigator and site staff to get an overview of the operational schedule

Detailed SoA

- Specifying the semantic data observations to be collected in the study – but not specific to representation in ADaM, SDTM or data collection
- Will be part of protocol section 8 and appendixes or other supplementary documents

Operational SoA

- The data specification to support data collection specification
- Correspond to our existing legacy BCs (Topic Codes)
- Will also related to specific ADaM PARAM/PARAMCD

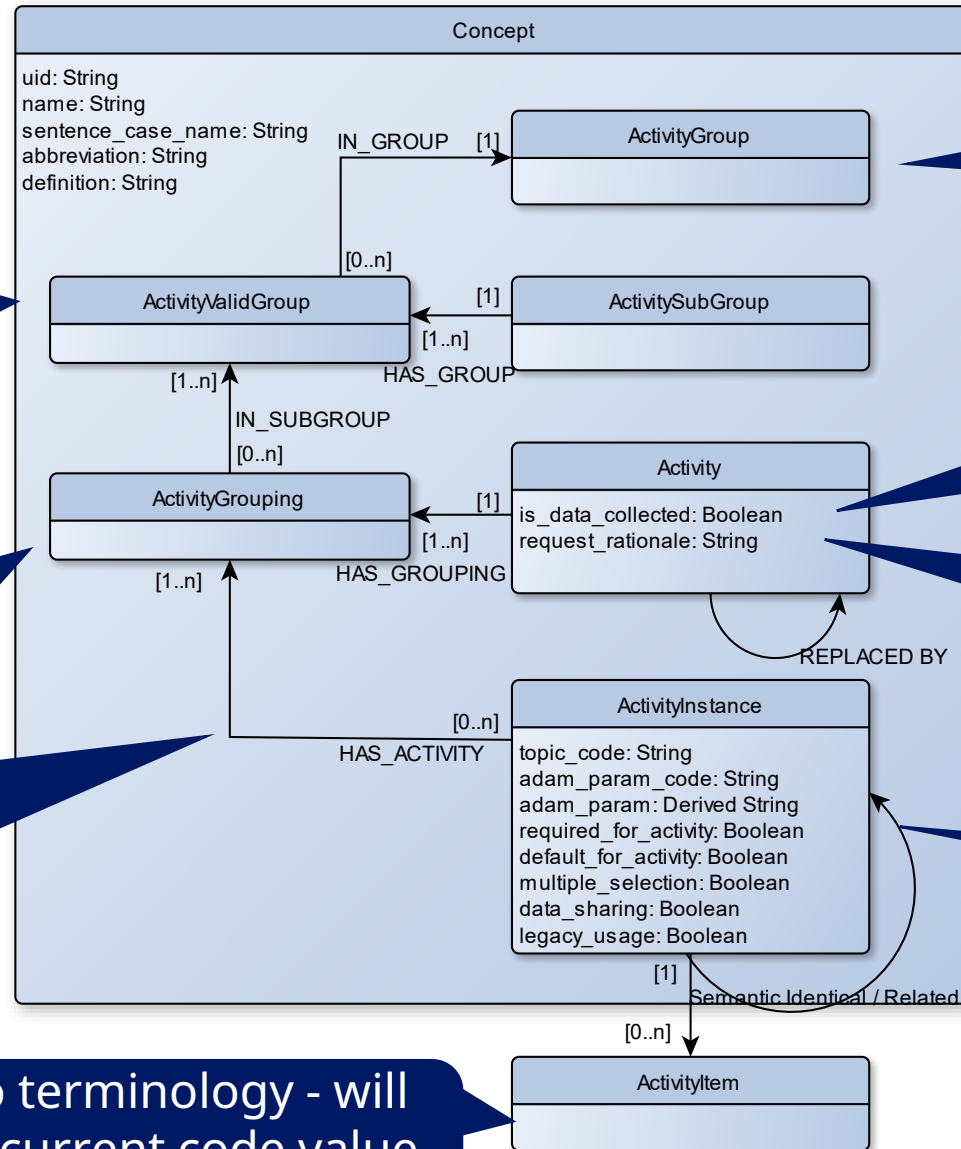
Data Capture / Collection Specification

- How data is to be collected in the study and when
- What is pre-set, what is collected and how

Light OpenStudyBuilder demo

- Browse Activity Concept in Library -> Activity Concepts
 - Display details – will be CDISC COSMoS compatible
- Refer to Activity Concepts in Syntax Templates
- Apply as Endpoint Selection selecting Activity in Study Purpose
- Apply as Activity selection in SoA
- Bring to Protocol Document
 - Activity Concepts in endpoints based on syntax templates and SoA
- Drive metadata for SDTM
 - Both study design datasets as well as SDTM Define specification including value level metadata
- DDF SDR Compatibility

Logical data model for Activity Instance



Valid hierarchy for ActivityGroup to ActivitySubgroup

Valid hierarchy for Activity in ActivitySubgroup and ActivityGroup

Valid hierarchy for ActivityInstance as a subset of valid groupings for Activity

Links to terminology - will replace current code value linkage in MMA.

Activity Groups and Subgroups will be maintained and versioned individually

Activity can be related to data collection or be a reminder in SoA without data collection

Activity can also be a placeholder/request - in this case the rationale will be defined

See next slide

Intended to link semantic identical who can replace e.g. a retired instance

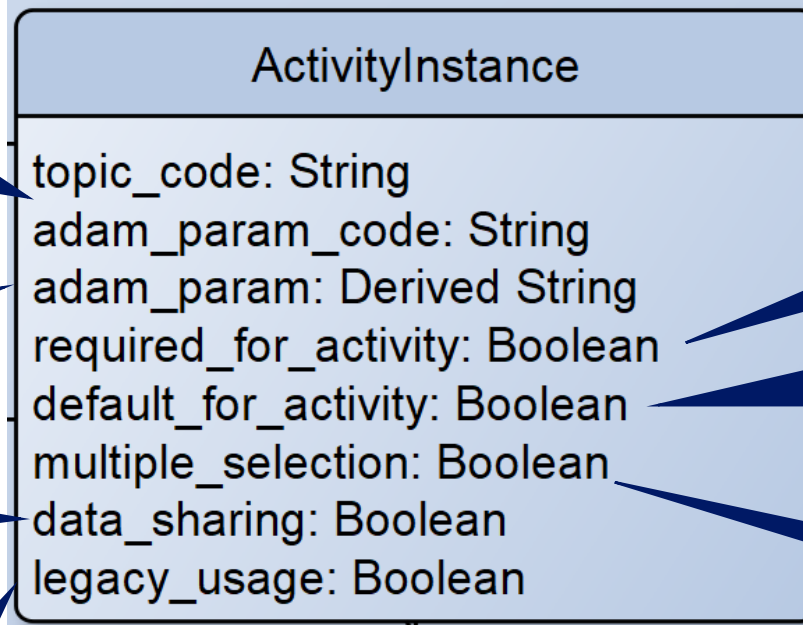
Logical data model for Activity Instance

```

uid: String
name: String
sentence_case_name: String
abbreviation: String
definition: String

```

Activity Instance correspond to our existing Topic Code, ADaM PARAM / PARAMCD. Specific to specimen, unit, SDTM Domain, Identify semantic observations



Topic Code and ADaM PARAMCD act as alternative identifiers

Concatenate 'name' with std unit

Activity Instance can be shared externally

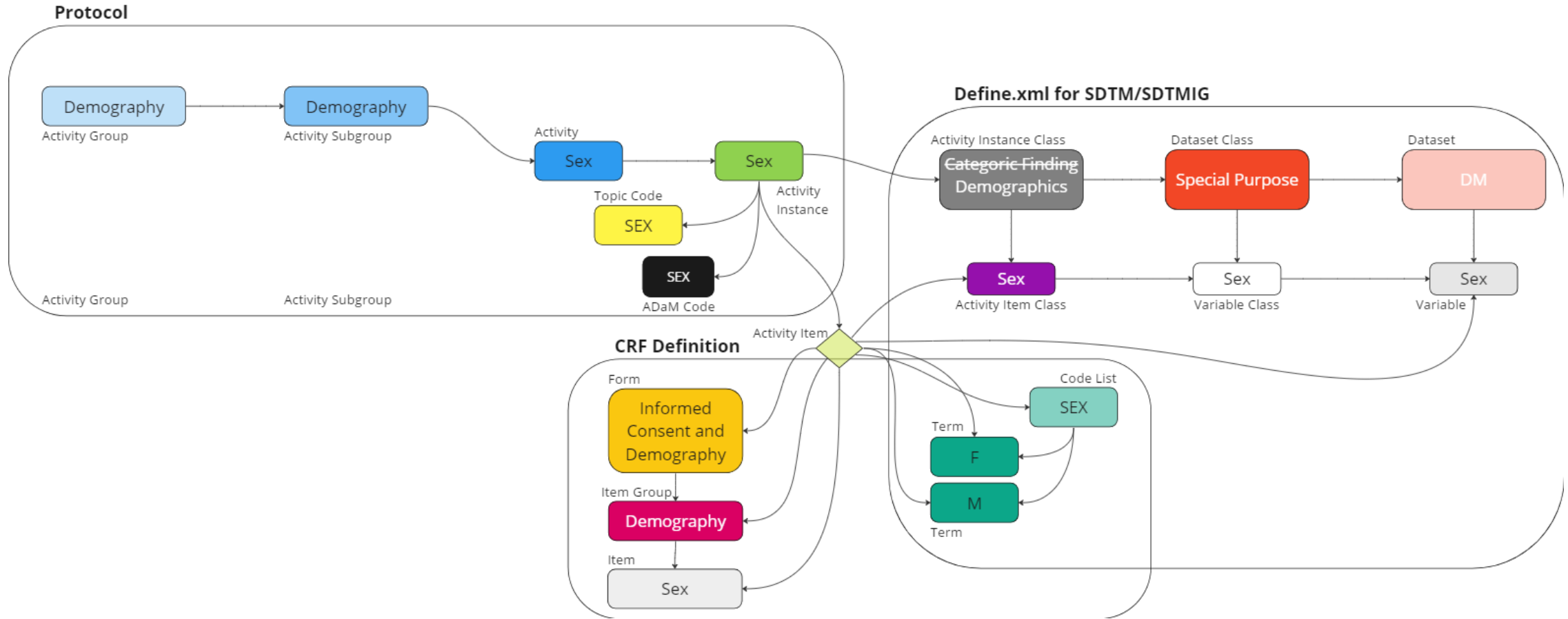
Activity Instance should only be used for legacy studies. This could be achieved by a dedicated 'legacy' library - To be discussed

The Activity Instance is required for the related Activity

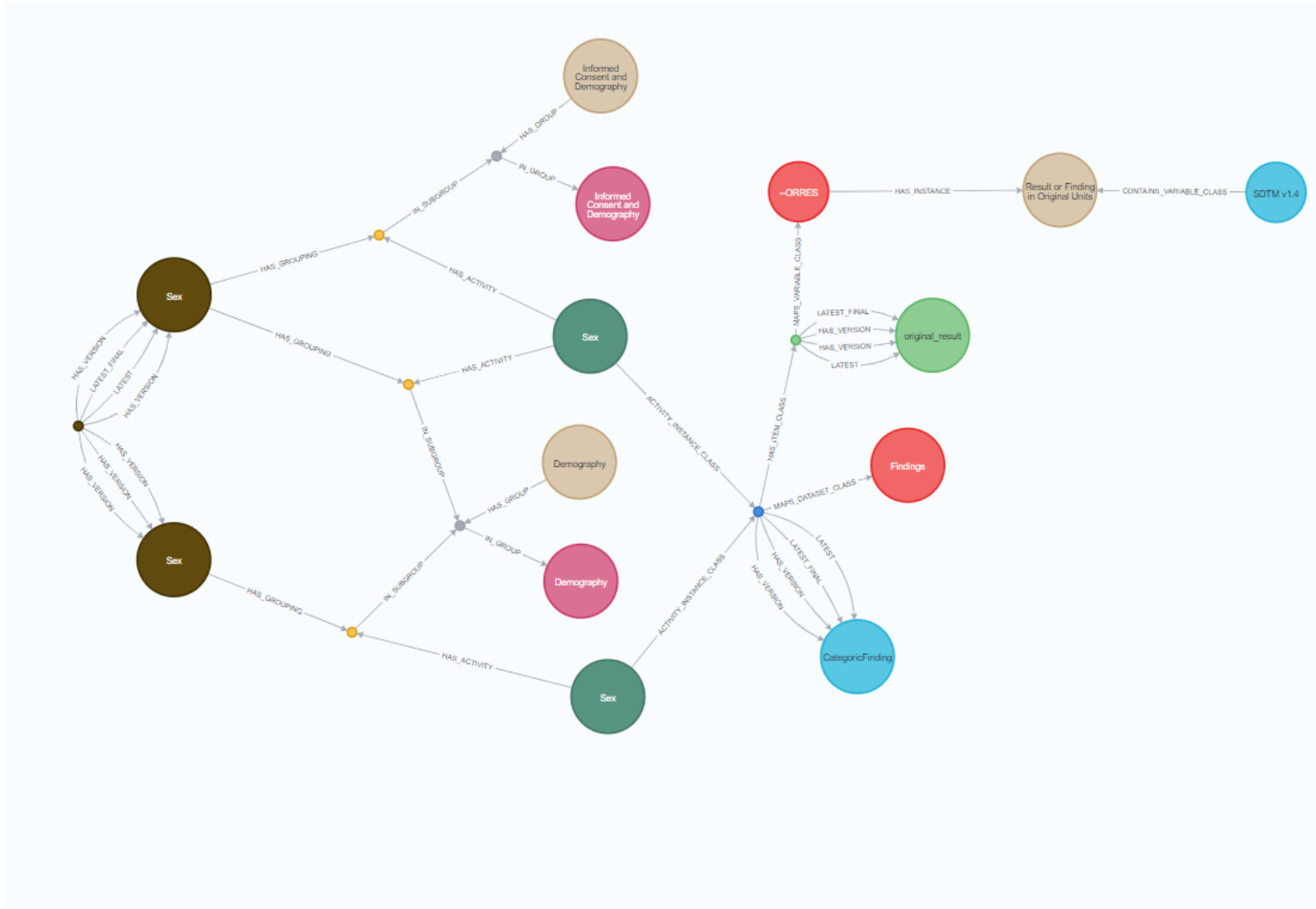
The Activity Instance is default selected for the related Activity

Multiple Activity Instance can be selected for the related Activity

A Concrete Activity Concept in StudyBuilder



The same Activity Concept in the Neo4j database



Overview

Node labels

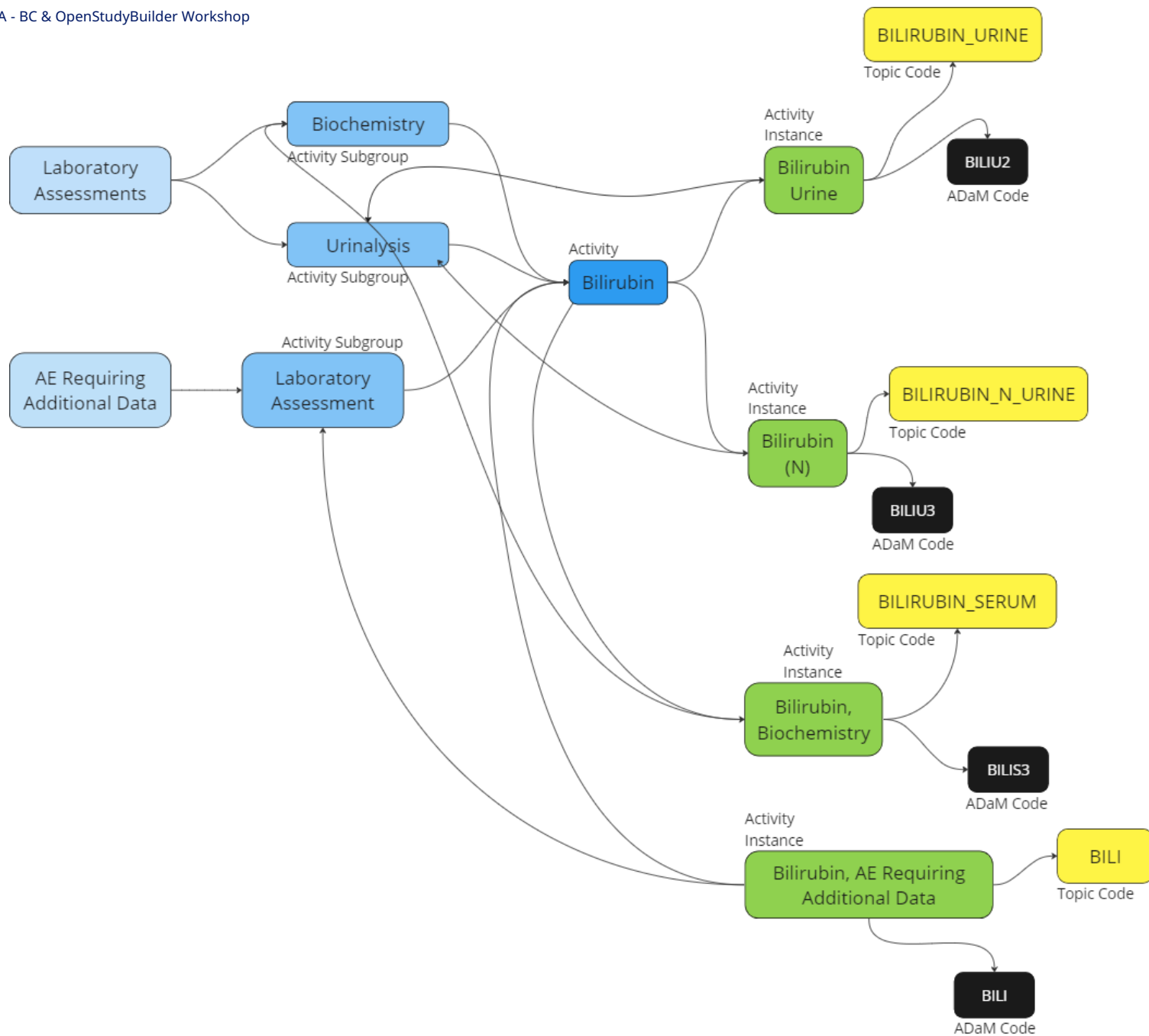
- * (22) **TemplateParameterTermRoot (1)**
- ConceptRoot (1)** **ActivityRoot (1)** **DatasetClass (1)**
- ActivityItemClassRoot (1)** **ActivityItemClassValue (1)**
- VariableClass (1)** **VariableClassInstance (1)**
- DataModelVersion (1)**
- TemplateParameterTermValue (8)** **ConceptValue (8)**
- ActivityValue (2)** **ActivityGrouping (3)**
- ActivityInstanceValue (2)** **ActivityValidGroup (2)**
- ActivityGroupValue (2)** **ActivitySubGroupValue (2)**
- ActivityInstanceClassRoot (1)**
- ActivityInstanceClassValue (1)**

Relationship types

- * (35) **HAS_VERSION (9)** **HAS_ITEM_CLASS (1)**
- LATEST_FINAL (3)** **MAPS_VARIABLE_CLASS (1)**
- HAS_INSTANCE (1)**
- CONTAINS_VARIABLE_CLASS (1)**
- HAS_GROUPING (3)** **HAS_ACTIVITY (3)**
- IN_SUBGROUP (3)** **IN_GROUP (2)**
- HAS_GROUP (2)** **ACTIVITY_INSTANCE_CLASS (2)**
- LATEST (3)** **MAPS_DATASET_CLASS (1)**

Displaying 22 nodes, 35 relationships.

Bilirubin Activity Concept



Read more in our BC article on our GitLab site

The screenshot shows the OpenStudyBuilder website interface. At the top, there is a blue header with the OpenStudyBuilder logo, a search bar, and navigation links for Description, Info, Guides, and FAQ. The main content area features a sidebar on the left with a 'Guides' section containing links for Introduction, Overview, Environments, Codelists, CRF, Study Structure, Activity Concept (highlighted), and API. The main article title is 'Biomedical Concepts & OSB Activity Concept' (created 2023-02-17). The article text states: 'In the library part of the OpenStudyBuilder various kinds of concept definitions are available:' followed by a dark blue menu titled 'Concepts' with options for Activities, Units, CRFs, and Compounds. Below this is a caption: 'Figure 1: The OpenStudyBuilder Library Part'. The article continues with text about standard concepts and their use in specifying study metadata. A 'Table of contents' is listed on the right side of the page.

OpenStudyBuilder Search

Description Info Guides FAQ

Guides
Introduction
Overview
Environments
Codelists
CRF
Study Structure
Activity Concept
API

Biomedical Concepts & OSB Activity Concept

(created 2023-02-17)

In the library part of the OpenStudyBuilder various kinds of concept definitions are available:

Concepts ^

- Activities
- Units
- CRFs
- Compounds

Figure 1: The OpenStudyBuilder Library Part

These standard concepts are used when specifying study metadata which allows a high degree of reusability and conformance checks. This article focusses on the "Activities" (Activity Concepts) which are like Biomedical Concepts (BCs).

First, we will give a brief overview of what a Biomedical Concept is and how OpenStudyBuilder Activity Concepts fit into the definition. Then we will focus on describing the use of the Activity Concepts in a study definition. Finally, we will share the conceptual model used for the Activity Concepts in the OpenStudyBuilder.

Biomedical Concept (BC)

Definition

Table of contents

- Biomedical Concept (BC)
 - Definition
 - Example
- Definition Activity Concept
- Usage of Activity Concepts
 - Define Activities for a Study
 - Visualize Activities (Protocol Flowchart)
- Activity Concepts Data Model
 - High-level Logical Activity Concepts Model
 - Logical Activity Concepts Entity Attribute Model
- Example Activity Concept
- OpenStudyBuilder Data Model
- References

How does the Activity Concepts data model relate to the class model and data model representations

Activity Concepts Class Model

ActivityInstanceClass represent the generic data response type. These are defined hieratically as sub domain classes of general purpose domain classes

ActivityItemClass represent the generic data variable. These define the generic semantic information recorded for a logical observation independent of the data model representation.

A specific ActivityInstance is of an ActivityInstanceClass

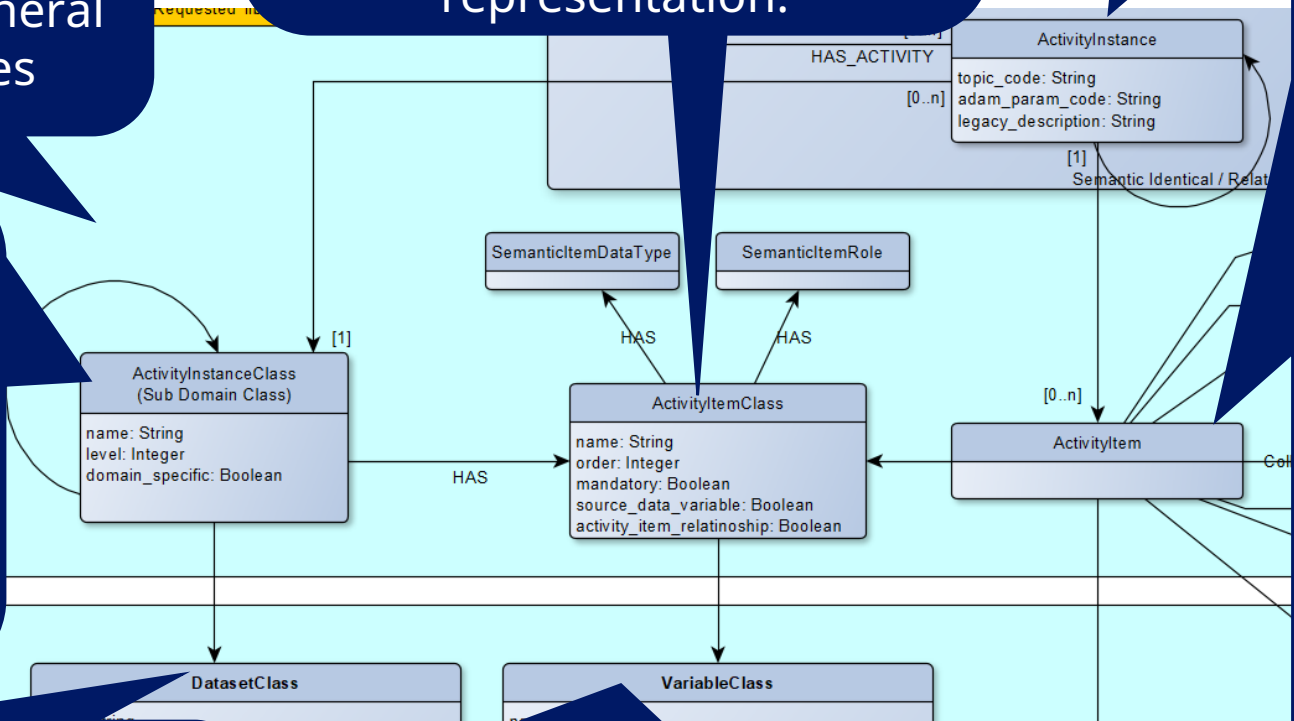
A specific ActivityItem represent the relationship from a specific ActivityInstance to the related ActivityItemClass (the generic variables) as well as the relationship to terminologies when applicable.

ActivityInstanceClass's correspond to the dataset response class's in the CDW legacy system. Global mappings was made to these dataset class's via Topic Code Types (e.g. Numeric Findings)

Dataset Class's can be based on an ActivityInstanceClass's at a specific level linking the data model datasets to the generic Activity Concept

Variable Class's is based on an ActivityItemClass linking the data model variables to the generic Activity Concept.

The ActivityItem can also include relationships to specific data model IG versions when e.g. terms a version specific (like SDTM data domains can be version specific)



Samples of Activity Instance and Item Class's

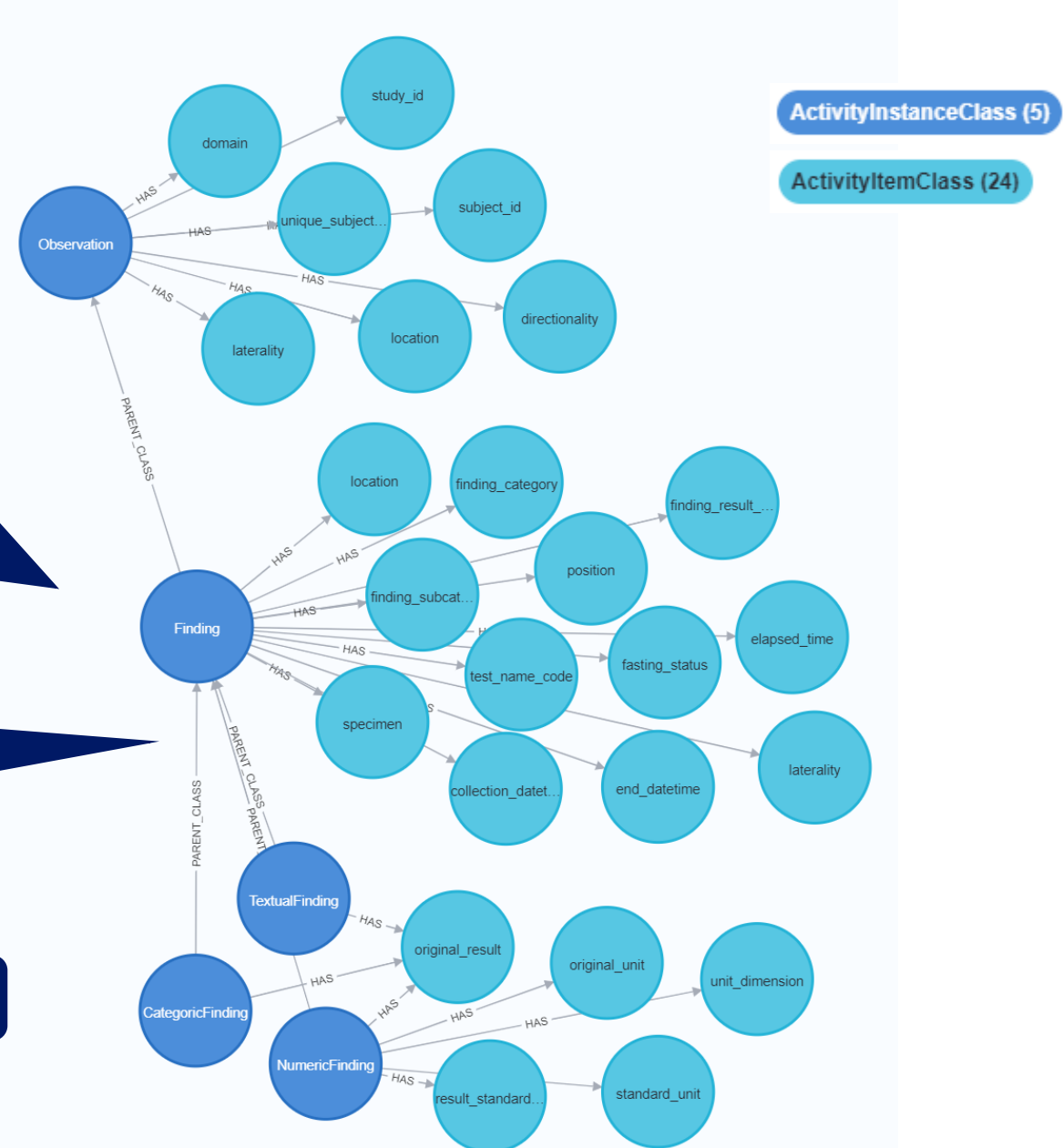
The ActivityInstanceClass's are here illustrated by:

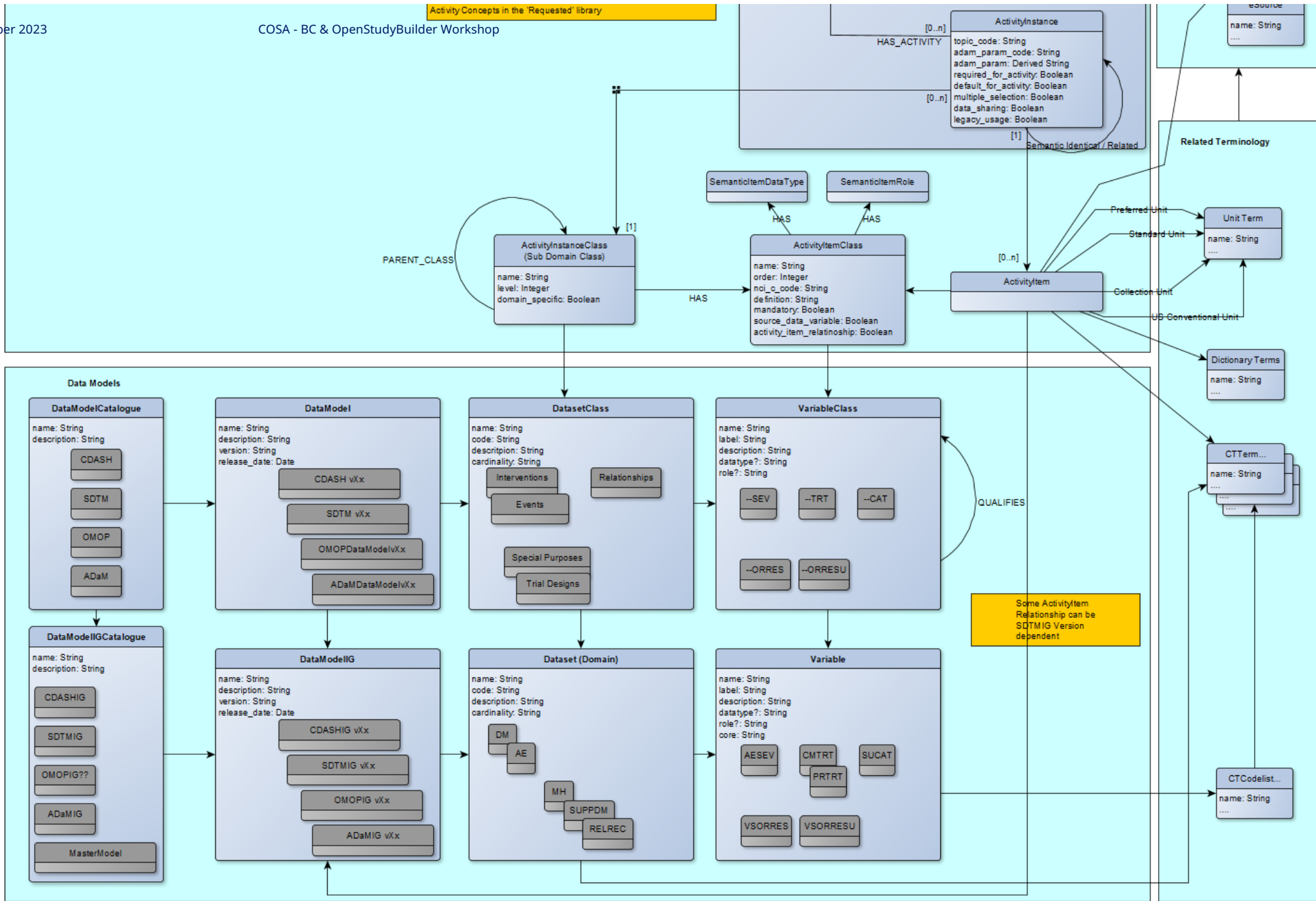
- **Observation**
 - **Finding**
 - **Numeric Finding**
 - **Categoric Finding**
 - **Textual Finding**

Each representing a class level having shared relationships to ActivityItemClass's

The ActivityItemClass's are illustrating generic variables related to an activity class at a specific level

Note, this is just an illustrative sample





How to use in Detailed and Operational SoA

Selection process of Activities for SoA

For Protocol Outline / Protocol

- Select Activities in relevant grouping
- When selecting an Activity within a specific grouping, then this will drive ActivityInstance – this should be visible for Protocol Writers (like a COL)
 - Some ActivityInstances can be mark as default for an Activity, and will then be pre-selected
 - Some ActivityInstances can be marked as mandatory – and cannot be un-selected
- Select what to display or hide in high-level Protocol SoA

For Operational Data Specification

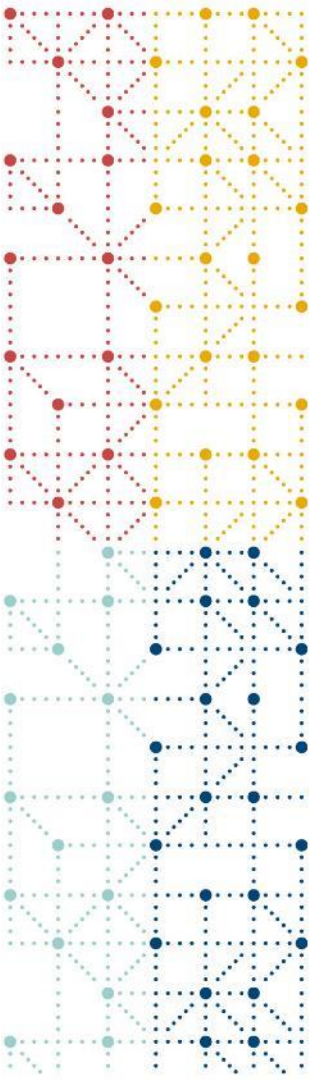
- Confirm or Select Activity Instances for each selected Activity
- If the correct ActivityInstance will change Grouping – this will require a change to the Protocol SoA – this will then

For Data Collection Specification

- The data collection specification
 - Lab specs
 - CRF
 - Other eSources
 - What is pre-set

Using SDTM specializations to create define

(Lex)



CDISC Biomedical Concepts and SDTM Dataset Specializations

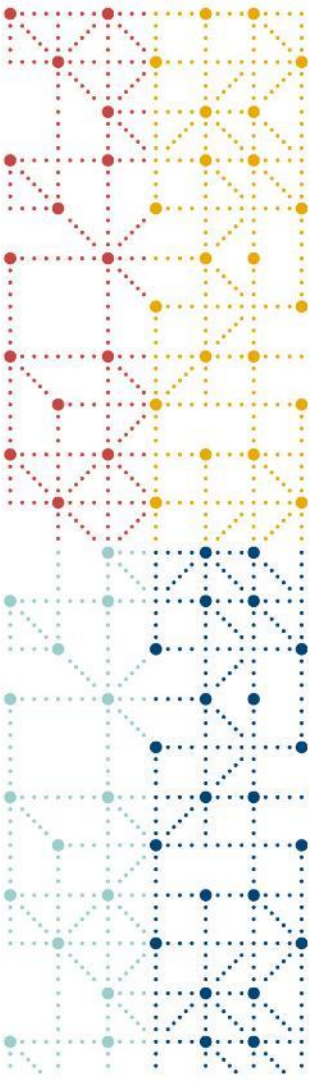
Background and Introduction

CDISC Biomedical Concepts and SDTM Dataset Specializations

Developing Biomedical Concepts allows accurate and **more consistent implementation** of the *conceptual content* being implemented

3 Key pieces of the **Pragmatic Implementation**:

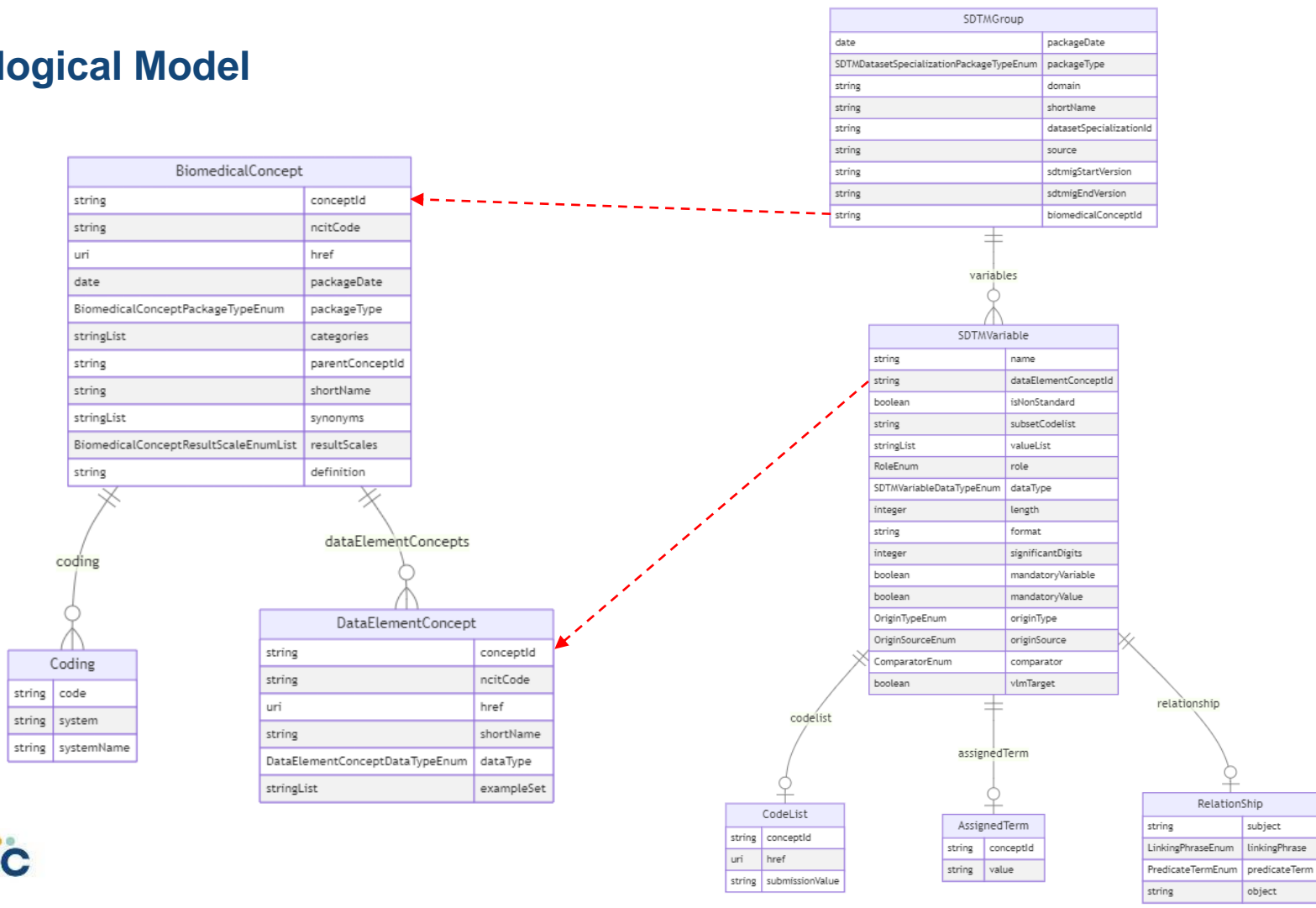
- Extend foundational standards
 - Add explicit relationships between variables
 - Additional operational metadata, e.g., data type, etc.
- Conceptual Layer – abstract BC's
 - Provides semantics - aligned with NCI terminology
 - Supports study design, Schedule of Activities (SOA)
- Implementation Layer - Dataset Specializations with VLM definitions
 - Supports programmers
 - Pre-configured building blocks for Define-XML
 - Tailored to BCs to link with unambiguous semantics & definitions
 - Dataset specializations as an extended dataset structure



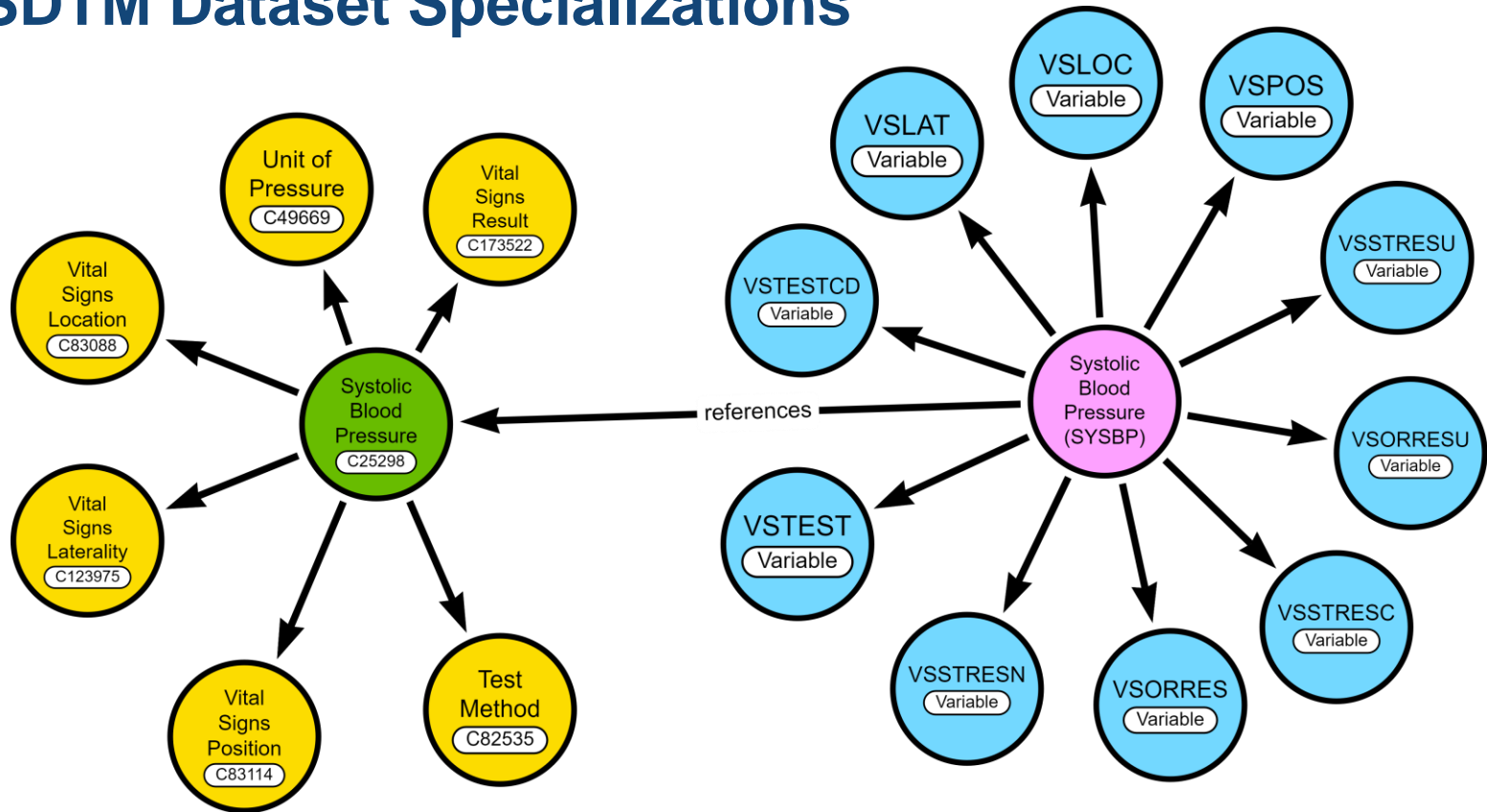
SDTM Dataset Specializations

Building Blocks for Define-XML

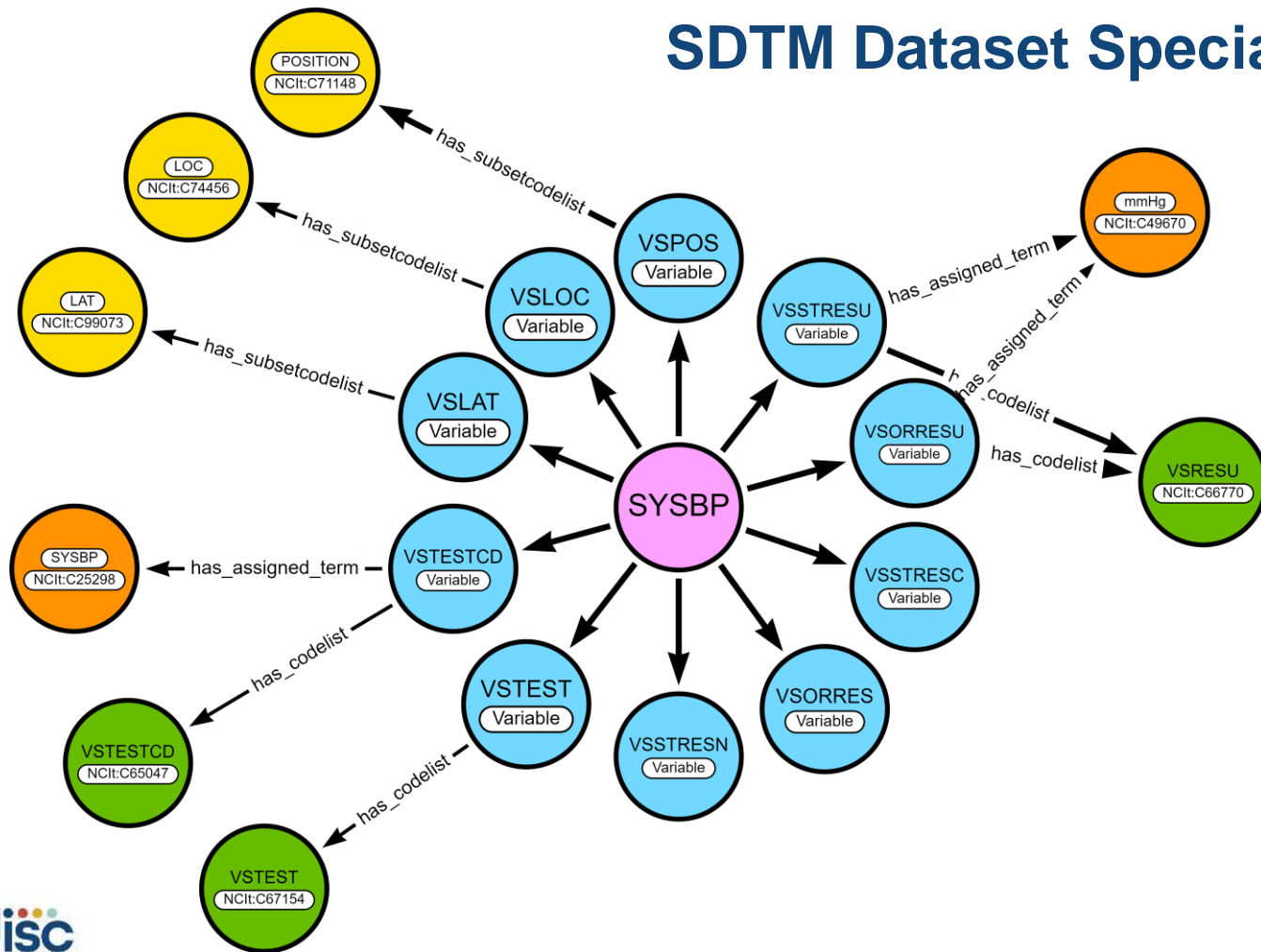
The logical Model



CDISC Biomedical Concepts and SDTM Dataset Specializations



SDTM Dataset Specializations



SDTM Dataset Specializations

Attribute	Description
datasetSpecializationId	Identifier for SDTM Value Level Metadata group
domain	Domain for the SDTM specialization group
shortName	SDTM group short name which provides a user friendly and intuitive name for the datasetSpecializationId
source	SDTM VLM Source which categorizes VLM groups by topic variable
sdtmigStartVersion	The earliest SDTMIG version applicable to the SDTM dataset specialization
sdtmigEndVersion	The last SDTMIG version that is applicable to the SDTM dataset specialization
biomedicalConceptId	Biomedical Concept identifier

SDTM Dataset Specializations

Attribute		Description
Name		Name of the variable included in the SDTM dataset specialization
dataElementConceptId		Biomedical Concept Data Element Concept identifier
isNonStandard		Flag that indicates if the variable is a non-standard variable
codelist	conceptId	C-code for a codelist in NCI
	href	Link to NCI for the codelist
	submissionValue	CDISC submission value for the codelist
subsetCodelist		Subset codelist short name
valueList		List of SDTM submission values used if subset codelist is not applicable
assignedTerm	conceptId	C-code for assigned term in NCI
	value	Submission value for assigned term in NCI if it exists, or an assigned value which will be the default value
role		SDTM variable role

SDTM Dataset Specializations

Attribute		Description
relationship	Subject	Subject in a variable relationship
	linkingPhrase	Variable relationship descriptive linking phrase
	predicateTerm	Short variable relationship linking phrase for programming
	object	Object in a variable relationship
datatype		Variable data type
length		Variable length
format		Variable display format
significantDigits		Variable significant digits
mandatoryVariable		Indicator that variable must be present within the SDTM group
mandatoryValue		Indicator that variable must be populated within the SDTM group
originType		Variable origin type (Assigned, Collected, Derived, Protocol, Predecessor)
originSource		Variable origin source (Investigator, Sponsor, Subject, Vendor)
comparator		Comparison operator for SDTM group variables included in VLM (EQ, IN)
vlmTarget		Target variable for VLM (true/false)

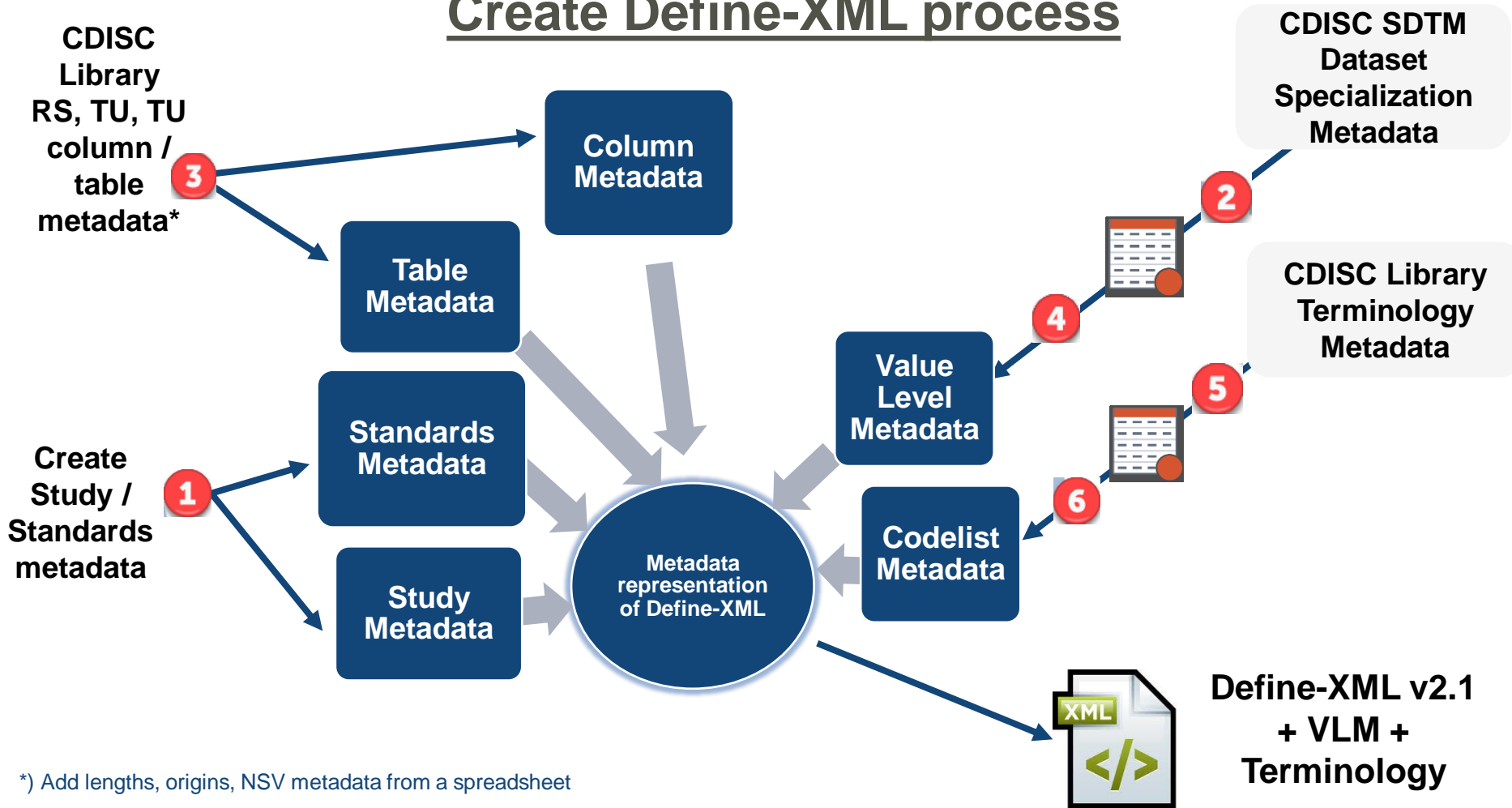
Define-XML v2.1 document with SDTM Dataset Specialization:

- Value Level Metadata and

- Controlled Terminology metadata for the RS, TR, and TU domains

- SDTM Dataset Specializations are considered pre-configured building blocks, from which end-users can select and configure to build Define-XML Value Level Metadata
- Exercise: present Oncology RECIST 1.1 SDTM Dataset Specializations as Value Level Metadata in Define-XML v2.1
- Oncology RECIST 1.1
 - 13 Biomedical Concepts
 - 13 SDTM Specializations (RS, TR, TU))
- REST API:
 - GET Biomedical Concepts:
`/mdr/bc/biomedicalconcepts?category=RECIST 1.1`
 - GET SDTM Specializations:
`/mdr/specializations/sdtm/datasetsspecializations?domain=RS`

Create Define-XML process



*) Add lengths, origins, NSV metadata from a spreadsheet

Define-XML v2.1 document with SDTM Dataset Specialization:

- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains

CDISC01

Standards

▼ Datasets

RS (Disease Response and Clin Class)

TR (Tumor/Lesion Results)

TU (Tumor/Lesion Identification)

► Controlled Terminology

Expand all VLM

Collapse all VLM

Date/Time of Define-XML document generation: 2023-10-11T14:27:04-04:00

Define-XML version: 2.1.6

Define-XML Context: Submission

Stylesheet version: 2019-02-11

Study Name	CDISC01
Study Description	CDISC Test Study
Protocol Name	CDISC01
Metadata Name	Study CDISC01_1, Data Definitions V-1
Metadata Description	Data Definitions for CDISC01-01 SDTM datasets

This Define-XML document is based on RS, TR and TU dataset and column metadata extracted from the CDISC Library. Value level metadata (VLM) and codelists were programmatically created by extracting metadata from CDISC SDTM Dataset Specializations and the CDISC Library.

Standards for Study CDISC01

Standard	Type	Status	Documentation
SDTMIG 3.3	IG	Final	
CDISC/NCI SDTM 2023-09-29	CT	Final	
CDISC/NCI DEFINE-XML 2023-06-30	CT	Final	

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
RS [SDTMIG 3.3]	Disease Response and Clin Classification	FINDINGS	One record per response assessment or clinical classification assessment per time point per visit per subject per assessor per medical evaluator	Tabulation	STUDYID, RSDTC, USUBJID, RSTESTCD, RSNAM, RSEVAL, RSEVALID, RSRGPID, VISITNUM		rs.xpt 🔗
TR [SDTMIG 3.3]	Tumor/Lesion Results	FINDINGS	One record per tumor measurement/assessment per visit per subject per assessor	Tabulation	STUDYID, VISITNUM, TRDTC, USUBJID, TRTESTCD, TRMETHOD, TRNAM, TREVAL, TREVAlID, TRLNKID		tr.xpt 🔗
TU [SDTMIG 3.3]	Tumor/Lesion Identification	FINDINGS	One record per identified tumor per subject per assessor	Tabulation	STUDYID, TUEVALID, TULNKID, VISITNUM, TUDTC, USUBJID, TUTESTCD, TULOC, TULAT, TUMETHOD, TUNAM, TUEVAL		tu.xpt 🔗

Define-XML v2.1 document with SDTM Dataset Specialization:

- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains

CDISC01

Standards

▼ Datasets

RS (Disease Response and Clin Cla

TR (Tumor/Lesion Results)

TU (Tumor/Lesion Identification)

▼ Controlled Terminology

▼ CodeLists

Directionality

Epoch, subset

Evaluator, subset

Laterality

Anatomical Location

Medical Evaluator Identifier

Method, subset

Not Done

No Yes Response, subset

No Yes Response, subset for Non

No Yes Response, subset for Targ

No Yes Response, subset for Non

No Yes Response, subset for Targ

Category of Oncology Response /

Oncology Response Assessment /

Oncology Response Assessment /

Oncology Response Assessment /

RSSCAT		Subcategory	text	Grouping Qualifier	200		Collected (Source: Investigator)
RSORRES VLM		Result or Finding in Original Units	text	Result Qualifier	200		Collected (Source: Investigator)
	EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and RSEVAL = "INVESTIGATOR" and RSTESTCD = "NEWLPROG" (New Lesion Progression)	New Lesion Progression	text	Qualifier		Oncology Response Assessment Result, subset for New Lesion Progression - Original (Res) <ul style="list-style-type: none"> "EQUIVOCAL" = "Equivocal" "UNEQUIVOCAL" = "Unequivocal" 	Collected (Source: Investigator)
	EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and RSEVAL = "INVESTIGATOR" and RSTESTCD = "NTRGRES" (Non-target Response)	Non-Target Response	text	Qualifier		Oncology Response Assessment Result, subset for Non-Target Response - Original (Res) <ul style="list-style-type: none"> "CR" = "Complete Remission" "NE" = "Unevaluable" "NON-CR/NON-PD" = "Non Complete Response/Non Progressive Disease" "PD" = "Progressive Disease" 	Collected (Source: Investigator)
	EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and RSEVAL = "INVESTIGATOR" and RSTESTCD = "OVRRESP" (Overall Response)	Overall Response	text	Qualifier		Oncology Response Assessment Result, subset for Overall Response - Original (Res) [7 Terms]	Collected (Source: Investigator)
	EPOCH = "TREATMENT" and RSCAT = "RECIST 1.1" and	Target Response	text	Qualifier		Oncology Response Assessment Result, subset for Target Response - Original (Res)	Collected (Source: Investigator)

Define-XML v2.1 document with SDTM Dataset Specialization:

- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains

CDISC01

- Standards
- ▼ Datasets
 - RS (Disease Response and Clinical Response)
 - TR (Tumor/Lesion Results)
 - TU (Tumor/Lesion Identification)
- ▼ Controlled Terminology
 - ▼ CodeLists
 - Directionality
 - Epoch, subset
 - Evaluator, subset
 - Laterality
 - Anatomical Location
 - Medical Evaluator Identifier
 - Method, subset
 - Not Done
 - No Yes Response, subset
 - No Yes Response, subset for
 - No Yes Response, subset for
 - No Yes Response, subset for
 - No Yes Response, subset for
 - Category of Oncology Response
 - Oncology Response Assessment
 - Oncology Response Assessment
 - Oncology Response Assessment
 - Oncology Response Assessment
 - Oncology Response Assessment

TRSTRESC VLM		Character Result/Finding in Std Format	text	Result Qualifier	200	Tumor or Lesion Properties Test Result [22 Terms]	Derived (Source: Sponsor)
	<p>EPOCH IN ("SCREENING", "TREATMENT") and</p> <p>TREVAL IN ("ADJUDICATOR", "INDEPENDENT ASSESSOR", "INVESTIGATOR") and</p> <p>TRMETHOD IN ("CALIPER MEASUREMENT METHOD", "CT SCAN", "ENDOSCOPY", "LYMPHANGIOGRAPHY", "MAMMOGRAPHY", "MRI", "NUCLEAR RADIOLOGY", "PET SCAN", "PET/CT SCAN", "PET/MRI SCAN", "PHOTOGRAPHY", "SCINTIGRAPHY", "TOTAL BODY RADIOGRAPHY", "ULTRASOUND", "X-RAY") and</p> <p>TRTESTCD = "LNSTATE" (Lymph Node State)</p>	Lymph Node State	text	Qualifier		<p>Tumor or Lesion Properties Test Result, subset for Lymph Node State - Standardized (Char Res)</p> <ul style="list-style-type: none"> "NON-PATHOLOGICAL" "PATHOLOGICAL" 	Derived (Source: Sponsor)

Define-XML v2.1 document with SDTM Dataset Specialization:

- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains

CDISC01

- Standards
- ▼ Datasets
 - RS (Disease Response and Clin
 - TR (Tumor/Lesion Results)
 - TU (Tumor/Lesion Identifier
- ▼ Controlled Terminology
 - ▼ CodeLists
 - Directionality
 - Epoch, subset
 - Evaluator, subset
 - Laterality
 - Anatomical Location
 - Medical Evaluator Identifier
 - Method, subset
 - Not Done
 - No Yes Response, subset
 - No Yes Response, subset for
 - No Yes Response, subset for
 - No Yes Response, subset for
 - No Yes Response, subset for
 - Category of Oncology Respor
 - Oncology Response Assessm
 - Oncology Response Assessm
 - Oncology Response Assessm
 - Oncology Response Assessm

TUSTRESC VM		Tumor/Lesion ID Result Std. Format	text	Result Qualifier	200	Tumor or Lesion Identification Test Results [28 Terms]	Derived (Source: Sponsor)
	EPOCH = "SCREENING" and TUEVAL = "INVESTIGATOR" and TUTESTCD = "NTIND" (Non-Target Indicator)	Non-Target Indicator	text	Qualifier	24	No Yes Response, subset for Non-Target Indicator - Standardized (Char Res) <ul style="list-style-type: none"> "N" = "No" "U" = "Unknown" "Y" = "Yes" 	Derived (Source: Sponsor)
	EPOCH = "SCREENING" and TUEVAL = "INVESTIGATOR" and TUTESTCD = "TIND" (Target Indicator)	Target Indicator	text	Qualifier	24	No Yes Response, subset for Target Indicator - Standardized (Char Res) <ul style="list-style-type: none"> "N" = "No" "U" = "Unknown" "Y" = "Yes" 	Derived (Source: Sponsor)
	EPOCH = "TREATMENT" and TUEVAL IN ("ADJUDICATOR", "INDEPENDENT ASSESSOR", "INVESTIGATOR") and TUMETHOD IN ("CALIPER MEASUREMENT METHOD", "CT SCAN", "ENDOSCOPY", "LYMPHANGIOGRAPHY", "MAMMOGRAPHY"	Tumor Merged	text	Qualifier	24	Tumor or Lesion Identification Test Results, subset for Tumor Merged - Standardized (Char Res) <ul style="list-style-type: none"> "TARGET" 	Derived (Source: Sponsor)

- Oncology Response Assessment Portion/Totality
- Relation to Reference Period
- Tumor or Lesion Properties Tr
- Tumor or Lesion Properties Tr
- Tumor or Lesion Properties Tr
- Tumor or Lesion Properties Tr

"TOTAL BODY RADIOGRAPHY", "ULTRASOUND", "X-RAY") and [TUTESTCD](#) = "TUMERGE" (Tumor Merged)



Conclusion

- SDTM Dataset Specializations can be represented as Value Level Metadata definitions in Define-XML v2.1.
- These definitions contain detailed metadata, including Controlled Terminology subsets.
- The SDTM Dataset Specializations can be considered pre-configured building blocks, from which end-users can select and configure to build Define-XML Value Level Metadata
- SDTM dataset specializations are ready to be used as building blocks for Define-XML.
- This provides immediate benefits to SDTM programmers and opens the door to efficient programming and automation

- Group- work
 - Try OSB study setup
 - Try DDF/USDM study excel setup

- How do I get BC's
 - From COSMoS

(Lex/Linda)



Retrieval of Biomedical Concepts and SDTM Dataset Specializations

Using CDISC Library APIs

API Endpoints in CDISC Library

- Biomedical Concepts and SDTM Specialization are published in packages
- Packages have **new content** and **updates to existing content**
- Not cumulative!

2022-10-26

API request template for Biomedical Concepts

2023-02-13

`/mdr/bc/packages`

2023-03-31

`/mdr/bc/packages/{package}/biomedicalconcepts`

2023-07-06

`/mdr/bc/packages/{package}/biomedicalconcepts/{biomedicalconcept}`

2023-10-03

API request template for SDTM Specializations

`/mdr/specializations/sdtm/packages`

`/mdr/specializations/sdtm/packages/{package}/datasetspecializations`

`/mdr/specializations/sdtm/packages/{package}/datasetspecializations/{datasetspecialization}`

API Endpoints in CDISC Library

- Biomedical Concepts and SDTM Specialization can now also be requested through the API (**v2 only**) with all the **latest versions**

API request template for Biomedical Concepts	API v2 Only?	Return Latest Version Only?
<code>/mdr/bc/biomedicalconcepts</code>	✓	✓
<code>/mdr/bc/biomedicalconcepts/{biomedicalconcept}</code>	✓	✓
<code>/mdr/bc/categories</code>	✓	
<code>/mdr/bc/biomedicalconcepts?category={category}</code>	✓	✓

API Endpoints in CDISC Library

- Biomedical Concepts and SDTM Specialization can now also be requested through the API (**v2 only**) with all the **latest versions**

API request template for SDTM Specialization	API v2 Only?	Return Latest Version Only?
<code>/mdr/specializations/sdtm/datasetspecializations</code>	✓	✓
<code>/mdr/specializations/sdtm/datasetspecializations/{datasetspecialization}</code>	✓	✓
<code>/mdr/specializations/sdtm/domains</code>	✓	
<code>/mdr/specializations/sdtm/datasetspecializations?domain={domain}</code>	✓	✓

API request template for Specializations	API v2 Only?	Return Latest Version Only?
<code>/mdr/specializations/datasetspecializations?biomedicalconcept={biomedicalconcept}</code>	✓	✓


API Requests in SAS


```
%let ApiKey=<your_personal_api_key>;
%let baseUrl=https://library.cdisc.org/api/cosmos/v2;


filename json_out temp;
proc http
  method = 'GET'
  url="&baseUrl/mdr/specializations/sdtm/datasetsspecializations/SYSBP"
  out=json_out;
  headers
    "api-key" = "&ApiKey"
    "Accept" = "application/json";
run;


filename json_map temp;
libname json_out json map=json_map automap=create fileref=json_out;


proc copy in = json_out out = work;
run;
```


 _links_parentbiomedicalconcept.sas7bdat


 _links_self.sas7bdat


 root.sas7bdat


 variables_assignedterm.sas7bdat


 variables_relationship.sas7bdat

 _links_parentpackage.sas7bdat

 alldata.sas7bdat

 variables.sas7bdat

 variables_codelist.sas7bdat

 variables_valuelist.sas7bdat

- How do I get BC's
 - From legacy data

(Linda/Mikkel/Kirsten)

- How do I get BC's
 - From OSB

(Mikkel)

What is a CDISC COSMoS compatible solution

- Conceptual and Operational Standards Metadata Services (COSMoS)
 - Biomedical Concepts (BCs) in a two-layered definition:
 - Conceptual/abstract layer that provides standards-agnostic, unambiguous semantic definition largely based on NCIt concepts.
 - Implementation layer based on valid CDISC dataset specializations that provide value level metadata definitions that facilitate metadata-driven automation.



What is the key elements of OpenStudyBuilder

- Library holding BCs
 - Named as Activity Concepts in OSB
- Study Module supporting Study Design and SoA
- SoA is key component in supporting the Digital Data Flow (DDF) vision
- In OSB we seek to achieve this by defining the SoA at different levels for dedicated parts of the Digital Data Flow



Concepts: Activities and Activity Instances

Library / Concepts / Activities / List of Activities /

Activities

List of Activities Activities by Grouping Activities Instances Requested Activities

Select rows

Search: bilirubin

Library	Activity group	Activity subgroup	Activity Name	Sentence case name	Abbreviation	Modified	Status
Sponsor	Contraceptive Counseling	Contraceptive Counseling	Bilateral Tubal Occlusion	bilateral tubal occlusion		Jul 4, 2023, 2:54 PM	Final
Sponsor	Laboratory Assessments	Biomarkers	Bile Acid	bile acid		Jul 4, 2023, 2:54 PM	Final
Sponsor	Laboratory Assessments	Biochemistry	Bilirubin	bilirubin		Jul 4, 2023, 2:54 PM	Final
Sponsor	AE Requiring Additional Data	Pancreatitis	Dilated Common Bile Duct	dilated common bile duct		Jul 4, 2023, 2:55 PM	Final
Sponsor	Laboratory Assessments	Biochemistry	Direct Bilirubin	direct bilirubin		Jul 4, 2023, 2:54 PM	Final
Sponsor	Eligibility Criteria	Eligibility Criteria	Eligibility Criteria Met	eligibility criteria met			
Sponsor	AE Requiring Additional Data	Gallbladder Disease	Gallbladder Dilated Common Bile Duct	gallbladder dilated common bile duct...			
Sponsor	AE Requiring Additional Data	Gallbladder Disease	Gallstone in Bile	gallstone in bile duct			

Library / Concepts / Activities / List of Activities / Bilirubin

Bilirubin

Overview COSMoS YAML

Name Bilirubin

Sentence Case Name bilirubin

Definition

Abbreviation Library Sponsor

Activity groupings

Activity group	Activity subgroup
Laboratory Assessments	Biochemistry

Activity instances

Name	Definition	Activity instance class	Topic code	ADaM parameter code
Bilirubin (N)		NumericFinding	BILIRUBIN_N_URINE	BILIU3
Bilirubin Urine		CategoricFinding	BILIRUBIN_URINE	BILIU2
Bilirubin, AE Requiring Additional Data		NumericFinding	BILI	BILI
Bilirubin, Biochemistry		NumericFinding	BILIRUBIN_SERUM	BILIS3

Library / Concepts / Activities / Activities Instances / Bilirubin Urine

Bilirubin Urine

Overview COSMoS YAML

Name Bilirubin Urine

Sentence Case Name bilirubin urine

Definition

Activity instance class CategoricFinding

Abbreviation Library Sponsor

ADaM parameter code BILIU2 Topic code BILIRUBIN_URINE

Activity groupings

Activity group	Activity subgroup
Laboratory Assessments	Biochemistry

Activity

Name	Definition	Library
Bilirubin		Sponsor

Activity items

Name	CT term name	Unit name	Activity item class
BILI	Total Bilirubin Measurement		test_name_code
LB	Laboratory Data Domain		domain
URINALYSIS	Urinalysis		finding_category
URINE	Urine		specimen

Activity

=

Biomedical Concept
(COSMoS project from CDISC)

NeoDash reports to view Activity to SDTM Variables

neo4j Labs neo4j://vm-db-fv7zbjhkegyw.clinicalmldr-dev.corp.azure.novonordisk.com:7687

StudyBuilder Activity Library Dashboard

ReadMe Activity Lib (search top-down) Activity Lib (search bottom-up) **Activity to SDTM** Activity in COSMOS format Activities used in Studies

Select Activity Instance

ActivityGroup	ActivitySubGroup	Activity	ActivityInstance
Adverse Event	Adverse Event	Adverse Event	AE
Laboratory Assessments	Biochemistry	Alanine	ALAP
AE Requiring Additional Data	Laboratory Assessment	Alanine Aminotransferase	ALT
Laboratory Assessments	Biochemistry	Alanine Aminotransferase	ALTS
AE Requiring Additional Data	Laboratory Assessment	Albumin	ALBU2

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Select SDTM version

Click	IG	Description	Effective Date	Version Number
SELECT	SDTMIG v3.4	This is the implementation guide for human clinical trials corresponding to Version 2.0 of the CDISC Study Data Tabulation Model.	2021-11-29	3.4
SELECT	SDTMIG v3.3	CDISC Version 3.3 (V3.3) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to guide t	2018-11-20	3.3
SELECT	SDTMIG v3.2	CDISC Version 3.2 (V3.2) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to guide t	2013-11-26	3.2
SELECT	SDTMIG v3.1.3	CDISC Version 3.1.3 (V3.1.3) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to gu	2012-07-16	3.1.3
SELECT	SDTMIG v3.1.2	CDISC Version 3.1.2 (V3.1.2) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to gu	2008-11-12	3.1.2

1-5 of 5

Activity mapped to SDTM

Activity	Activity Instance	Activity Item Class	Variable Class	SDTMIG Variable	SDTMIG Dataset
Albumin	Urinary Albumin Excretion	domain	DOMAIN	Domain Abbreviation	Labs
Albumin	Urinary Albumin Excretion	test_name_code	--TESTCD	Lab Test or Examination Short	Labs
Albumin	Urinary Albumin Excretion	test_name_code	--TEST	Lab Test or Examination Name	Labs
Albumin	Urinary Albumin Excretion	specimen	--SPEC	Specimen Type	Labs

Rows per page: 5 1-4 of 4

Activity with links to SDTM

- Group work
 - Browse BC via neoDash in OSB (Mikkel/Kirsten)
 - Browse via neoDash on CDISC BCs (Linda/Lex)

- Compare BC models
 - Link to COSMoS-BC Model + NCI Terminology
 - Link to DDF-BC Model
 - Link to d4k Model
 - Link to OSB Model
 - Many representations exist, having different focus, context and purpose + discussion

(Dave)

- Perspectives on BCs

(Dave)

- **Group work**
 - **SWOT –Which Strengths, Weaknesses, Opportunities, and Threats do we see for BC's supporting our clinical data flows?**

SWOT and Mind Map for next steps

- Use this framework to capture discussions and reflections at table groups
- Present for all in last plenum session

- SWOT
 - How do we see this for BC's supporting our clinical data flows
 - What tools do you see as needed

- Mind Map for next steps
 - How can we contribute and support the adoption of BC's in tools and our use supporting digital data flows

SWOT – Applying BC's in digital data flows

Strengths

BC's

- Generic representation independent of source and target data models
- Support end-2-end lineage across data standards
- Initial BC definitions shared and curated by CDISC

Tools

- Hide complexity of BC's from end users
- Will support usage across skill areas
- Initial tools shared as open-source

Opportunities

BC's

- Influence future industry standards via BC adoption
- Consistency in how CDISC standards are applied cross pharma

Tools

- Improved business insight through linking related elements via modern graph database allowing for intelligent dashboards and search functionality
- FAIR based data sharing through transparent API-based architecture

Weaknesses

BC's

- Perception of current state not reflecting actual status
- Pharma companies can manage with less
- Evolution of standards with BC's incompatibility

Tools

- Higher expectations than what is realistic to deliver due to business process complexity

Threats

BC's

- Too few SME resources and high dependency on few resources
- Limited sharing of BC definitions and curation of these
- Insufficient cross organisational/skill area allocation/commitment
- Dependency with other projects and initiatives

Tools

- Lack of integration capabilities in consumer systems preventing realisation of business benefits
- Currently only custom solutions and not as a commercial system

- **Wrap-up**
 - present SWOT and wrap-up the day