

COSA – BC & OpenStudyBuilder Workshop @ EU Interchange 2023

Introduction

Mikkel Traun, Novo Nordisk A/S

25th April 2023

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.

We will as well relate to how BC's are defined within COSMoS, DDF, d4k and other models. There will be a shared introduction followed by 4 breakout sessions, leading to a shared reflection and discussion on how we can support and bring these initiatives forward. The 4 breakout sessions are currently defined as:

- Setup BC's in OSB SoA for a new study, run various queries to learn how BC's can be utilised
- Learn and understand the BC model in OSB versus the COSMoS, DDF, d4k and other models
- Create and curate OpenStudyBuilder BC content via the OSB Library and NeoDash reports and mining BC's from existing data sources like SDTM.

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/))

d4k: data4knowledge BC model ([//d4k.dk](https://d4k.dk))

COSA – BC & OpenStudyBuilder Workshop @ EU Interchange 2023

9:00 – 9:30 Coffee and welcome

9:30 -11:00 Shared Introduction

11:00 – 12:00 Break-out part 1

12:00 – 13:00 Lunch

13:00 – 14:00 Break-out part 2

14:00 – 15:00 Sharing in plenum

Workshop drivers:

- Anja Lundgreen
- Katja Glass
- Dave Iberson-Hurst
- Lex Jansen
- Mikkel Traun
- Marius Conjeaud
- Kirsten Langendorf
- Chandrakant J S
- Nicolas de Saint Jorre
- Linda Lander

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

- Learn and get feedback from our community
- Promote development of shared open source tools providing general value for pharma industry
- 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 (Dave)
- BC in OSB := Activity Concepts (Mikkel)
 - OSB definition, why,
 - Overview of OSB model
 - Demo in App
 - Demo in NeoDash report (Kirsten)
- OSB model versus other models
 - Link to COSMoS-BC Model + Terminology (Kirsten, Linda)
 - Link to DDF-BC Model (Dave)
 - Link to d4k Model (Dave)
 - Many representations exist, having different focus, context and purpose + discussion
- Present initial SWOT and Mind Map as input to break-out sessions
- Present break-outs, adjust participation as relevant

Recap what is a BC (Dave)

Biomedical Concepts

Dave Iberson-Hurst
Partner, data4knowledge ApS & CDISC DDF Product Owner

25th April 2023



Collections ...

FDA's STUDY DATA TECHNICAL CONFORMANCE GUIDE

Contains Nonbinding Recommendations

Appendix: Data Standards and Interoperable Data Exchange

This appendix provides some of the guiding principles for the Agency's long-term study data standards management strategies. An important goal of standardizing study data submissions is to achieve an acceptable degree of *semantic interoperability* (discussed below). This appendix describes different types of interoperability and how data standards can support interoperable data exchange now and in the future.

At the most fundamental level, study data can be considered a collection of data elements and their relationships. A data element is the smallest (or *atomic*) piece of information that is useful for analysis (e.g., a systolic blood pressure measurement, a lab test result, a response to a question on a questionnaire).

A data value is by itself meaningless without additional information about the data (so called *metadata*). Metadata is often described as *data about data*. Metadata is structured information that describes, explains, or otherwise makes it easier to retrieve, use, or manage data.⁴⁸ For example, the number 44 itself is meaningless without an association with Hematocrit and the unit of measurement (e.g. "%"). Hematocrit in this example is metadata that further describes the data.

Just as it is important to standardize the representation of data (e.g., M and F for male and female, respectively), it is equally important to standardize the metadata. The expressions Hematocrit = 44, Hct = 44, or Hct Lab Test = 44 all convey the same information to a human, but an information system or analysis program will fail to recognize that they are equivalent because the metadata is not standardized. It is also important to standardize the definition of the metadata, so that the meaning of a Hematocrit value is constant across studies and submissions.

In addition to standardizing the data and metadata, it is important to capture and represent relationships (also called associations) between data elements in a standard way. Relationships between data elements are critical to understand or interpret the data. Consider the following information collected on the same day for one subject in a study:

Systolic Blood Pressure = 90 mmHg
 Position = standing
 Systolic Blood Pressure = 110 mmHg
 Time = 10:23 a.m.
 Time = 10:20 a.m.

⁴⁸ Metadata is said to "give meaning to data" or to put data "in context." Although the term is now frequently used to refer to XML (extensible markup language) tags, there is nothing new about the concept of metadata. Data about a library book such as author, type of book, and the Library of Congress number, are metadata and were once maintained on index cards. SAS labels and formats are a rudimentary form of metadata, although they have not historically been referred to as metadata.

December 2014

31

Contains Nonbinding Recommendations



Appendix A: Data Standards and Interoperable Data Exchange

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Systolic Blood Pressure = 90 mmHg
 Position = standing
 Systolic Blood Pressure = 110 mmHg
 Time = 10:23 a.m.
 Time = 10:20 a.m.
 Position = lying

⁷⁹ Metadata is said to "give meaning to data" or to put data "in context." Although the term is now frequently used to refer to XML (extensible markup language) tags, there is nothing new about the concept of metadata. Data about a library book such as author, type of book, and the Library of Congress number, are metadata and were once maintained on index cards. SAS labels and formats are a rudimentary form of metadata, although they have not historically been referred to as metadata.

U.S. Food & Drug Administration
 10903 New Hampshire Avenue
 Silver Spring, MD 20903
www.fda.gov

Page 56 of 72

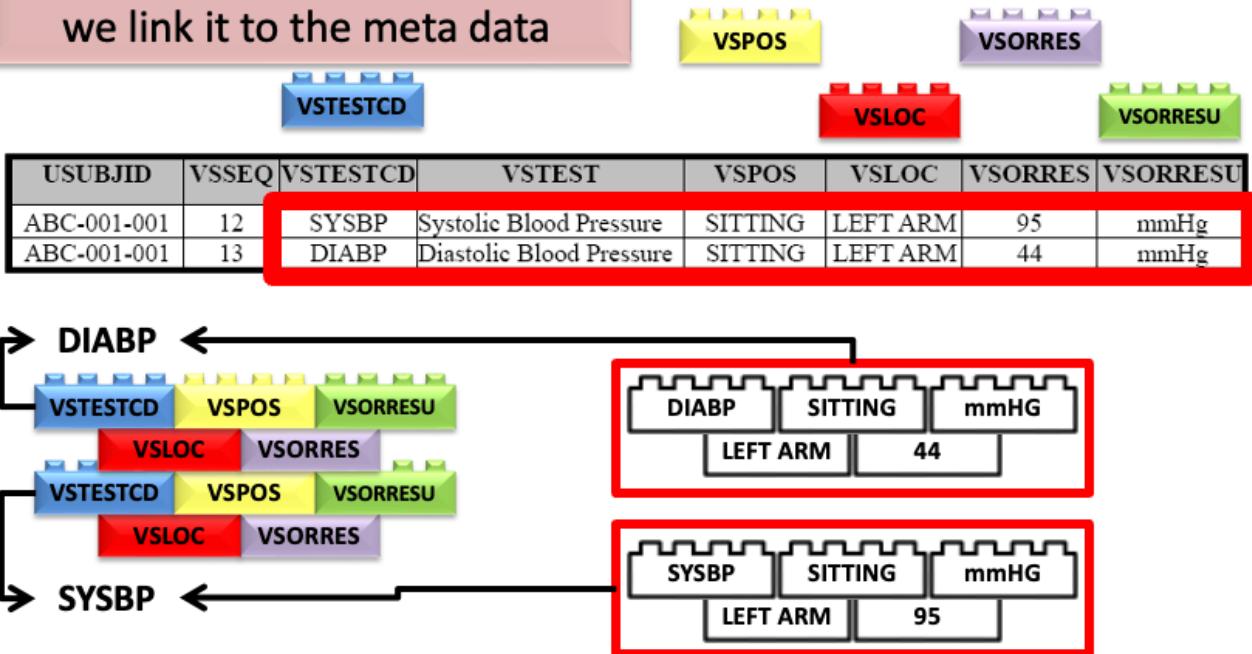
March 2023

March 2023

Collections ...

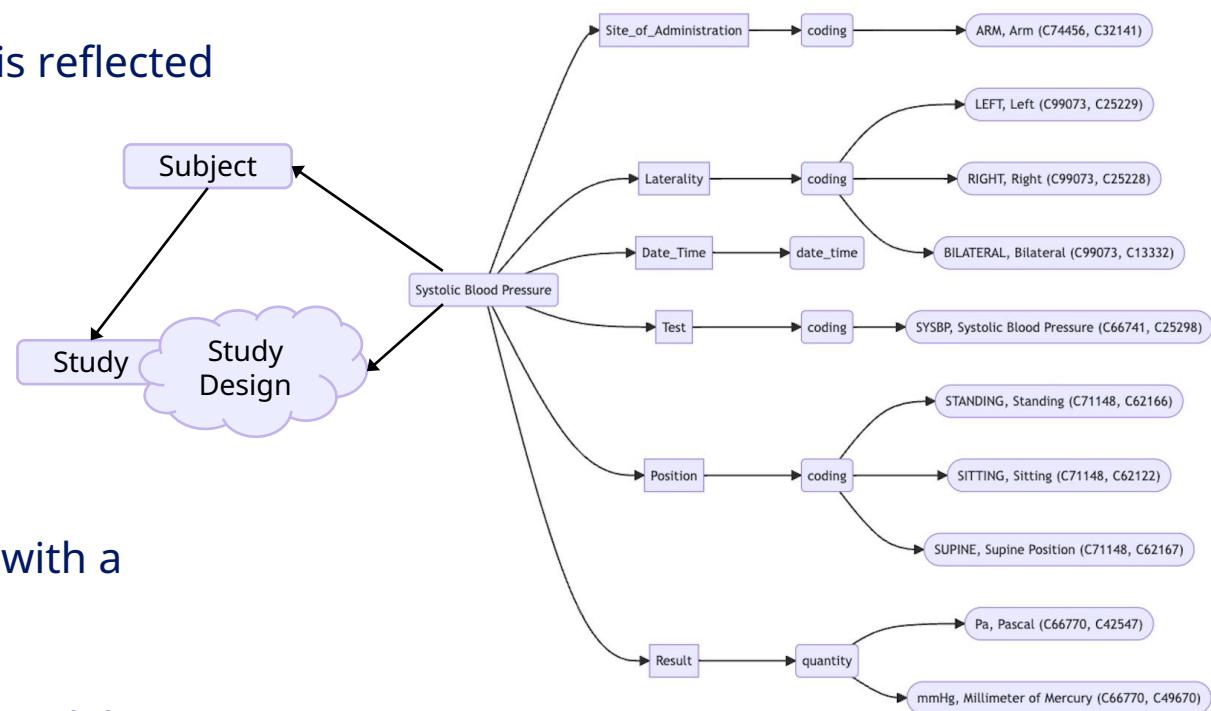
... and the data ...

The data only make sense when we link it to the meta data



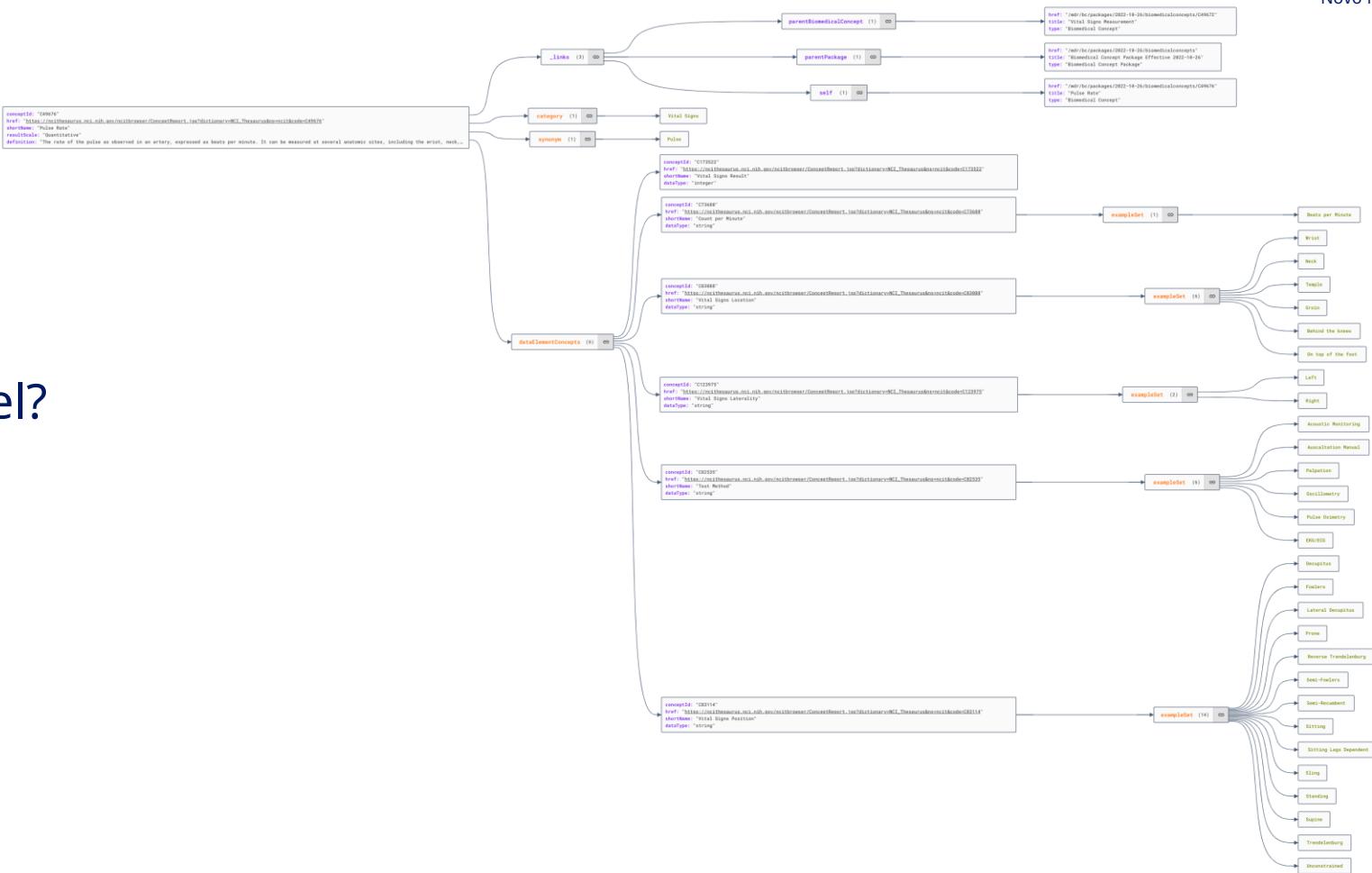
A Biomedical Concept is ...

- 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 ...



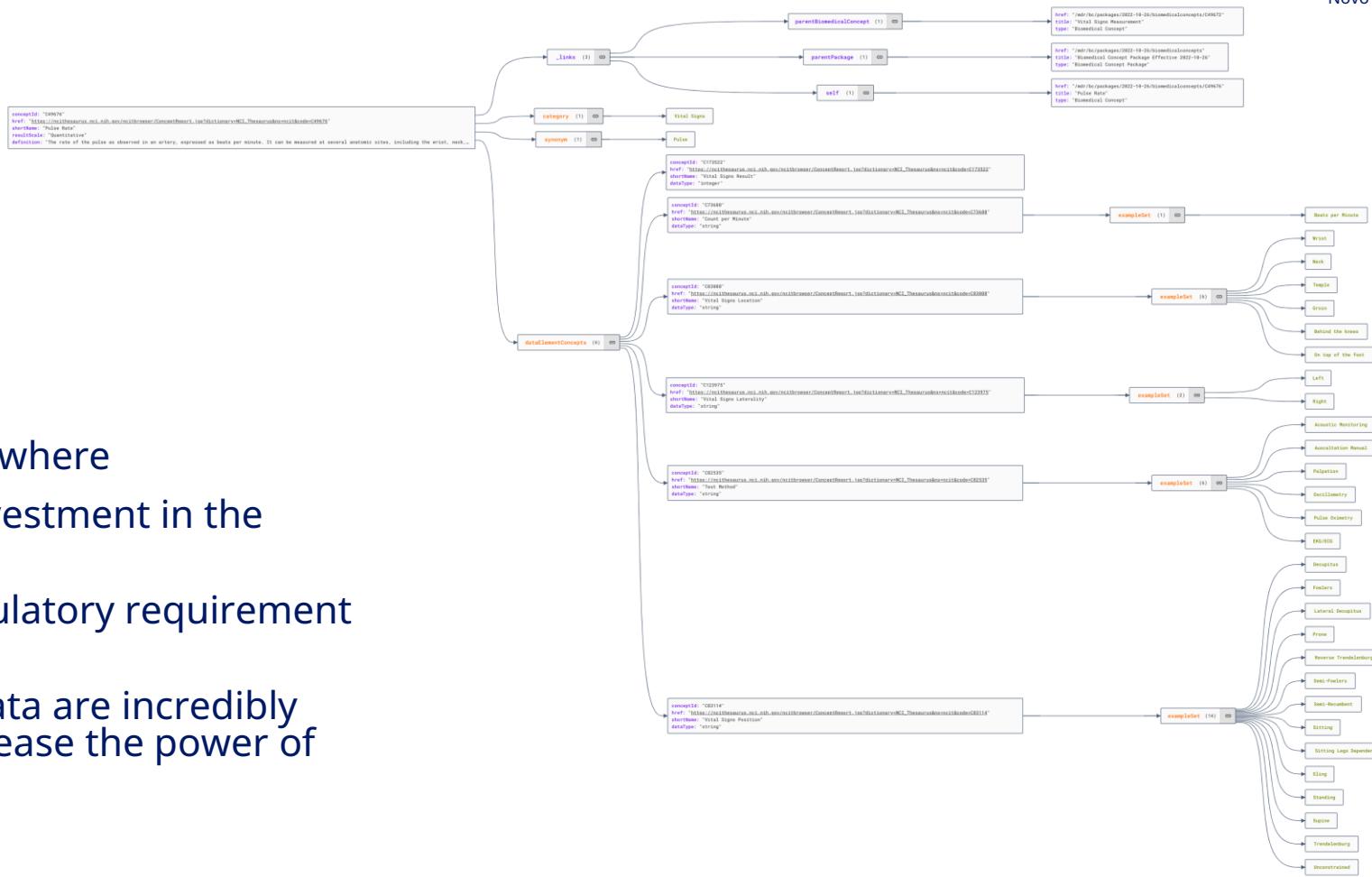
BC Design

- Are CDISC BCs Unique?
- Are we reinventing the wheel?



BC Design

- Are CDISC BCs Unique?
 - No
- Are we reinventing the wheel?
 - Yes and No
 - Clinical Models exist elsewhere
 - But ... Industry has a big investment in the current CDISC standards
 - SDTM Standard: Is a regulatory requirement for submission
 - SDTM Datasets: These data are incredibly valuable and BCs can release the power of all this “old” data
- CT is a major challenge
 - SDTM based on CDISC CT
 - Healthcare and Research have different needs
 - In charge of your own destiny



OHDSI

- Observational Health Data Sciences and Informatics
- Using SNOMED CT
- Hierarchy

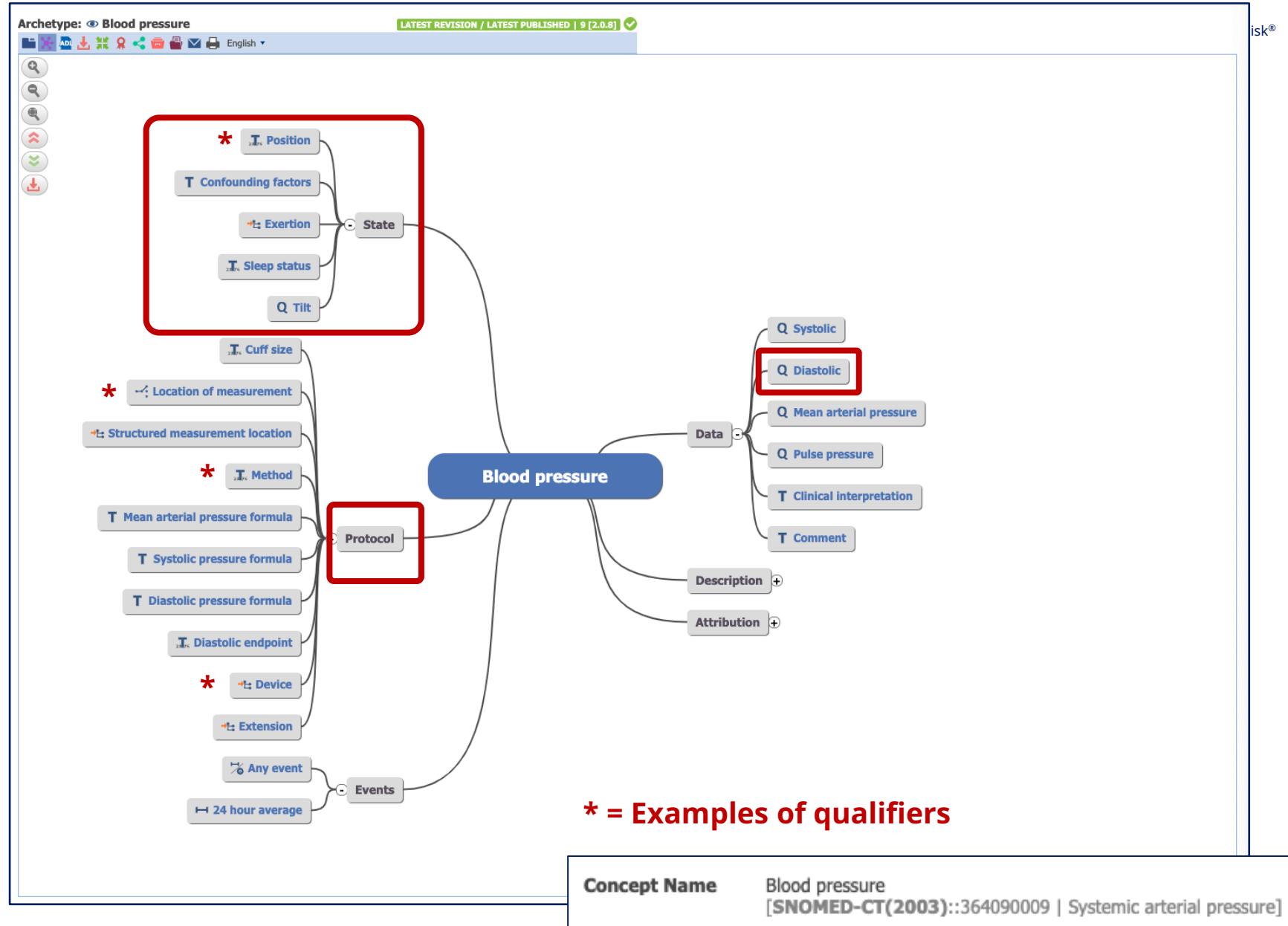
ATHENA

Diastolic blood pressure

DETAILS		TERM CONNECTIONS (32)	
		RELATIONSHIP	RELATED TO
Domain ID	Measurement	RELATES TO	CONCEPT ID VOCABULARY
Concept Class ID	Observable Entity	Active possibly_equivalent_to inactive (SNOMED)	Non-invasive diastolic arterial pressure 40454826 SNOMED
Vocabulary ID	SNOMED	Active same_as inactive (SNOMED)	Diastolic arterial pressure 40620464 SNOMED
Concept ID	4154790	Characterizes (SNOMED)	Diastolic phase 36716961 SNOMED
Concept code	271650006	Has Module	SNOMED CT core 40642539 SNOMED
Validity	Valid	Has property	Pressure 36716283 SNOMED
Concept	Standard	Has scale type	Quantitative 4149267 SNOMED
Synonyms	Diastolic blood pressure (observable entity) DAP - Diastolic arterial pressure Diastolic arterial pressure DBP - Diastolic blood pressure	Has status	Defined 40642537 SNOMED
Valid start	31-Jan-2002	Inheres in (SNOMED)	Structure of cardiovascular system 4014241 SNOMED
Valid end	31-Dec-2099	Interprets of (SNOMED)	Abnormal diastolic arterial pressure 4177952 SNOMED
			Decreased diastolic arterial pressure 4175340 SNOMED
			Increased diastolic arterial pressure 4047613 SNOMED
			Normal diastolic arterial pressure 4204973 SNOMED
		Is a	Blood pressure 4326744 SNOMED
			Vascular measure 4092664 SNOMED
		Non-standard to Standard map (OMOP)	Diastolic blood pressure 4154790 SNOMED
		Standard to Non-standard map (OMOP)	Diastolic arterial pressure 3162060 Nebraska Lexicon
			Diastolic arterial pressure 3464102 Nebraska Lexicon
			Diastolic arterial pressure 40620464 SNOMED
			Diastolic blood pressure 4154790 SNOMED
			Diastolic blood pressure 45906295 CIEL

openEHR

- Using SNOMED CT
- Strong content



HL7 FHIR Resource

- Using various CTs
 - LOINC
 - UCUM
 - SNOMED
 - Others ...
 - Uses FHIR data types
 - Binding of result value and units
 - Strong structure, less content focused

```
79 "component": [
80   {
81     "code": {
82       "coding": [
83         {
84           "system": "http://loinc.org",
85           "code": "8462-4",
86           "display": "Diastolic blood pressure"
87         }
88       ]
89     }
90   },
91   "valueQuantity": {
92     "value": 60,
93     "unit": "mmHg",
94     "system": "http://unitsofmeasure.org",
95     "code": "mm[Hg]"
96   },
97   "interpretation": [
98     {
99       "coding": [
100         {
101           "system": "http://terminology.hl7.org/CodeSystem/v3-ActRelationship-Subj",
102           "code": "L",
103           "display": "low"
104         }
105       ],
106       "text": "Below low normal"
107     }
108   ]
109 }
```

```
1 {  
2   "resourceType": "Observation",  
3   "id": "blood-pressure",  
4   "meta": {  
5     "profile": [  
6       "http://hl7.org/fhir/StructureDefinition/vitalsigns"  
7     ]  
8   },  
9   "text": {  
10    "identifier": [  
11      ],  
12      "basedOn": [  
13        ],  
14      "status": "final",  
15      "category": [  
16        ],  
17      "code": {  
18        "coding": [  
19          {"system": "http://loinc.org",  
20            "code": "85354-9",  
21            "display": "Blood pressure panel with all children optional"  
22          }  
23        ],  
24        "text": "Blood pressure systolic & diastolic"  
25      },  
26      "subject": [  
27        ],  
28      "effectiveDateTime": "2012-09-17",  
29      "performer": [  
30        ],  
31      "interpretation": [  
32        ],  
33      "bodySite": {  
34        "coding": [  
35          {"system": "http://snomed.info/sct",  
36            "code": "368209003",  
37            "display": "Right arm"  
38          }  
39        ],  
40        "component": [  
41          {"  
42            "code": {  
43              "coding": [  
44                {"system": "http://loinc.org",  
45                  "code": "8462-4",  
46                  "display": "Diastolic blood pressure"  
47                }  
48              ],  
49              "valueQuantity": {  
50                "value": 60,  
51                "unit": "mmHg",  
52                "system": "http://unitsofmeasure.org",  
53                "code": "mm[Hg]"  
54              },  
55              "interpretation": [  
56                {"coding": [  
57                  {"system": "http://terminology.hl7.org/CodeSystem/v3-ObservationInterpretation",  
58                    "code": "1",  
59                    "display": "low"  
60                  }  
61                ],  
62                "text": "Below low normal"  
63              }  
64            ]  
65          ]  
66        ]  
67      }  
68    }  
69  }
```

LOINC

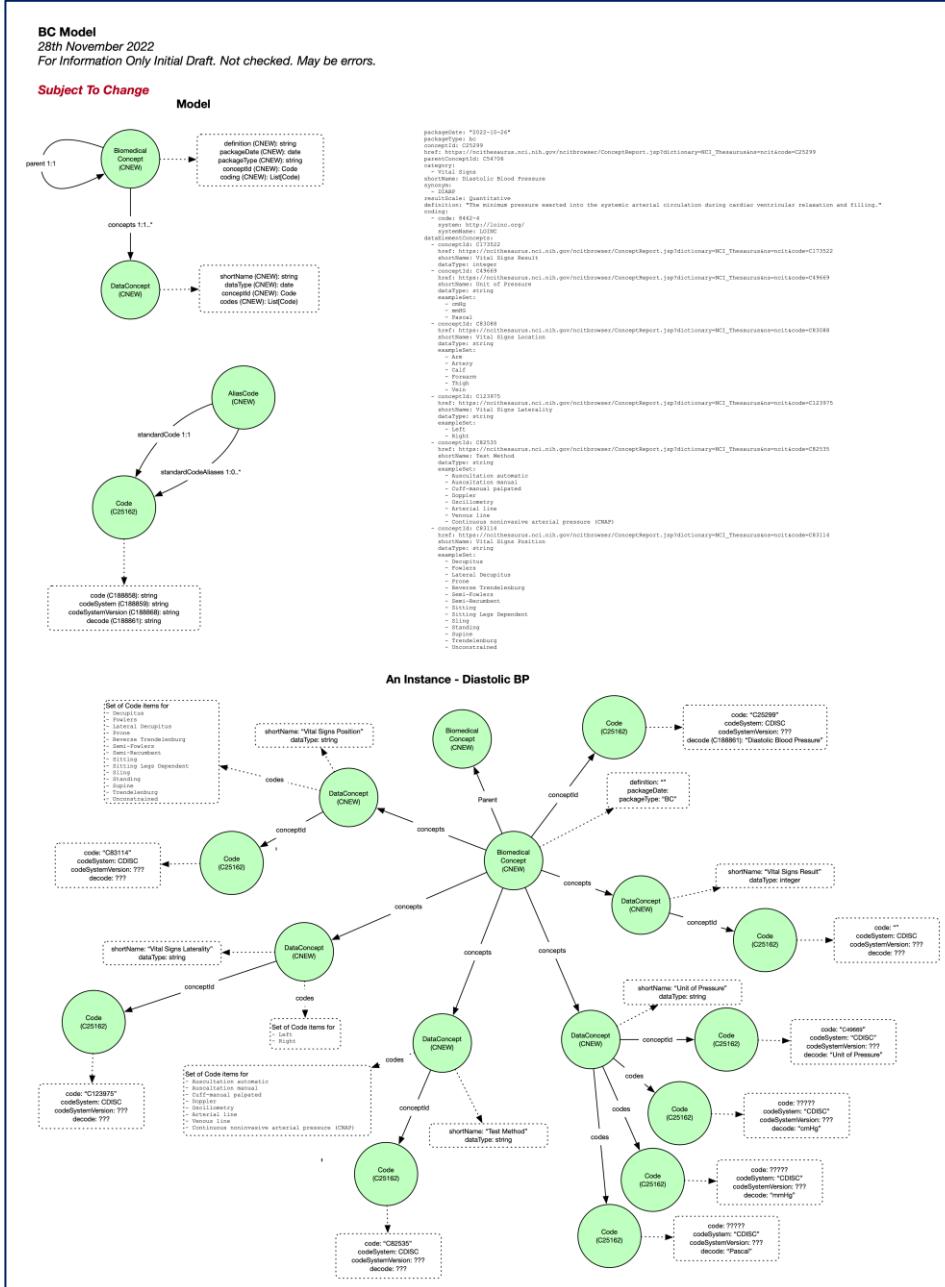
- Uses LOINC codes
- Precoordinated qualifiers
- Hierarchy

LOINC CODE 8454-1	LONG COMMON NAME Diastolic blood pressure--standing
LOINC CODE 8453-3	LONG COMMON NAME Diastolic blood pressure--sitting
LOINC CODE 8455-8	LONG COMMON NAME Diastolic blood pressure--supine

LOINC CODE 8462-4	LONG COMMON NAME Diastolic blood pressure	LOINC STATUS Active
Fully-Specified Name		
Component	Intravascular diastolic	
Property	Pres	
Time	Pt	
System	Arterial system	
Scale	Qn	
Method		
Additional Names		
Short Name	BP dias	
Associated Observations		
This panel contains all of the "Special circumstances" LOINC codes that are used to report the specific context during which a particular measurement was taken, where that context may affect the measurement value. Circumstances that can affect measurement of certain variables include when the patient is asleep, in pain, crying, febrile, or during a period of apnea. This panel is attached to the generic LOINC code for each measurement so that the circumstance under which the measurement was taken can be reported along with the primary result.		
LOINC	Name	R/O/C Cardinality Example UCUM Units
89263-8	Special circumstances associated observations panel	
10224-4	Hemodynamic method special circumstances	
55285-1	Glasgow coma score special circumstances	
55416-2	Oxymetry special circumstances	
8304-8	Body height special circumstances	
8337-8	Body weight special circumstances	
9278-3	Breath rate special circumstances	
9848-3	Body temperature special circumstances	
9855-8	Blood pressure special circumstances	
89299-2	Heart rate special circumstances	

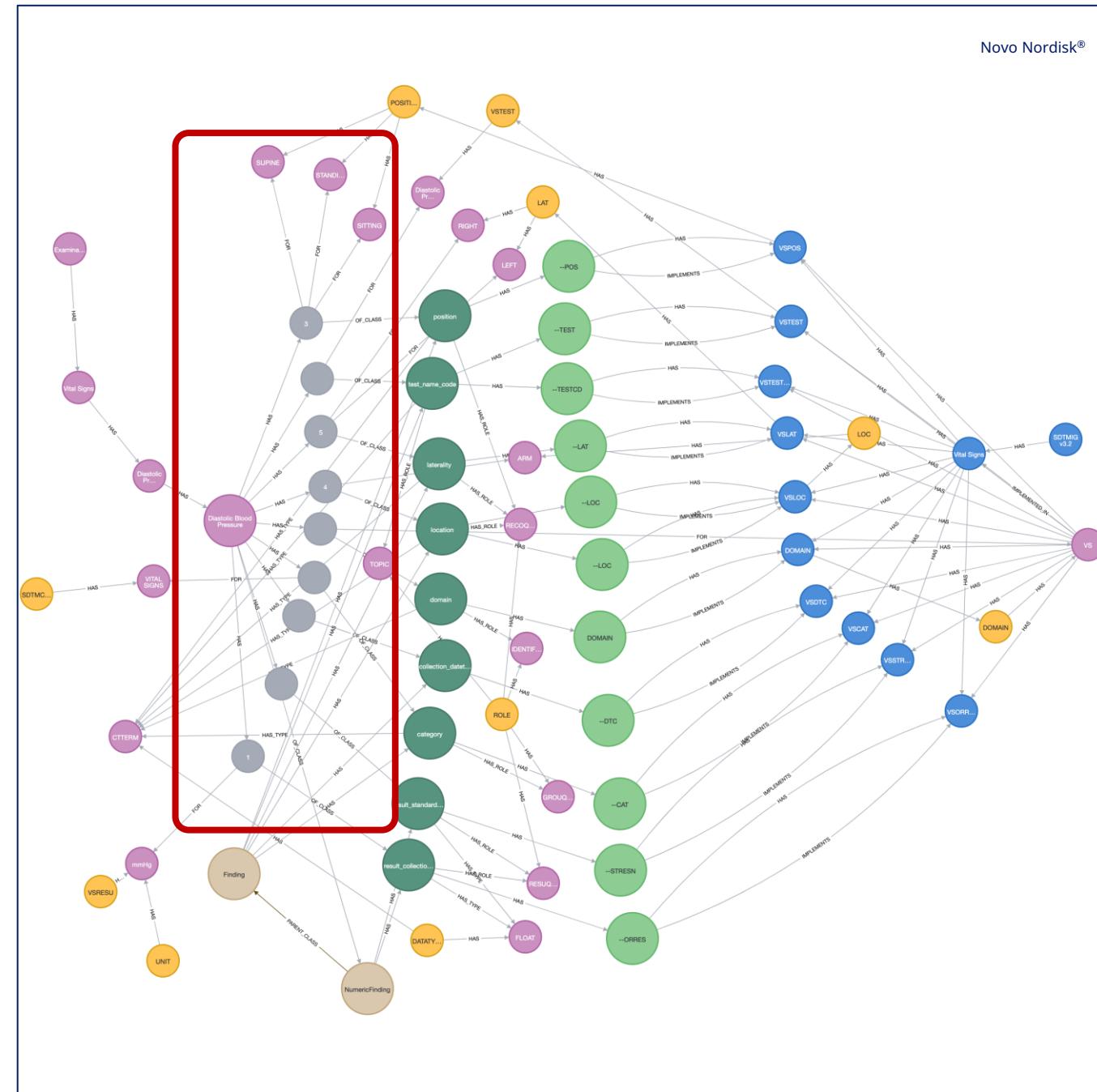
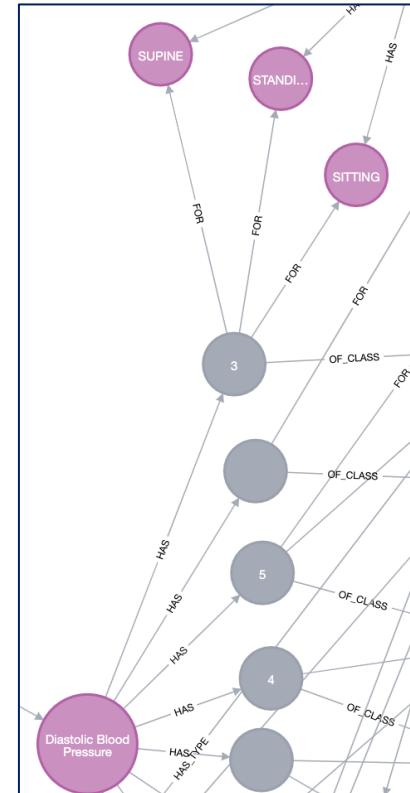
CDISC

- This is draft, new
 - Uses CDISC CT
 - No strong data types



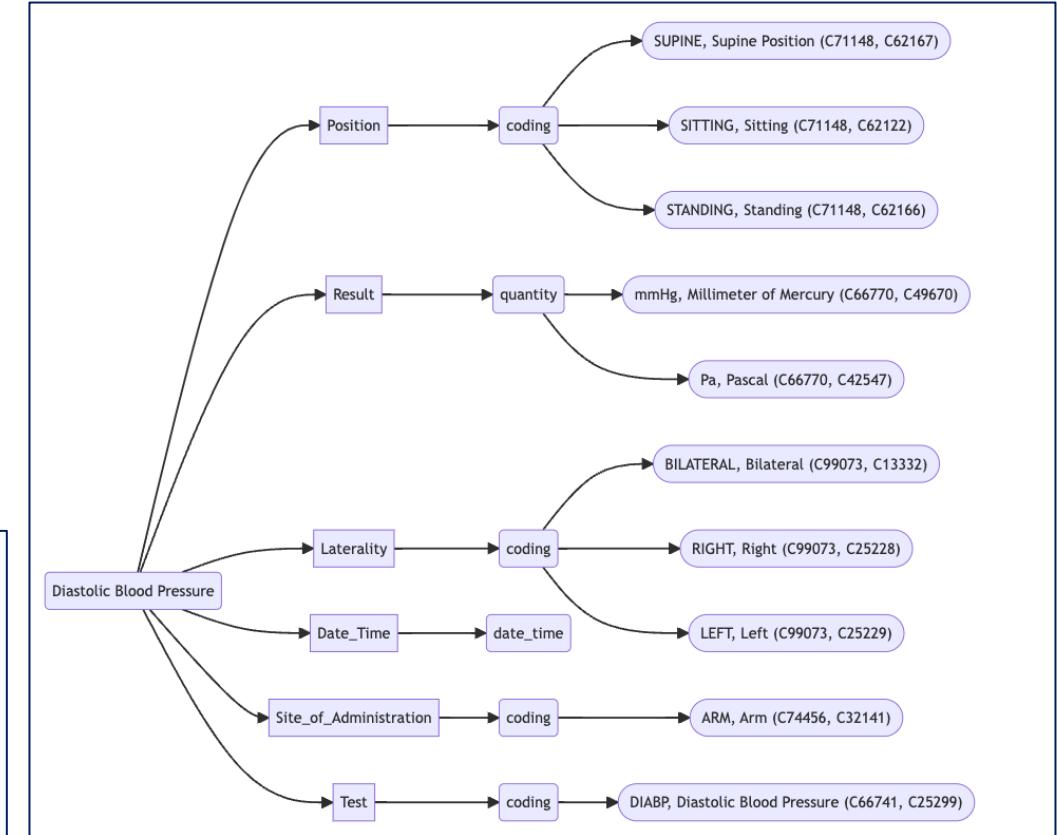
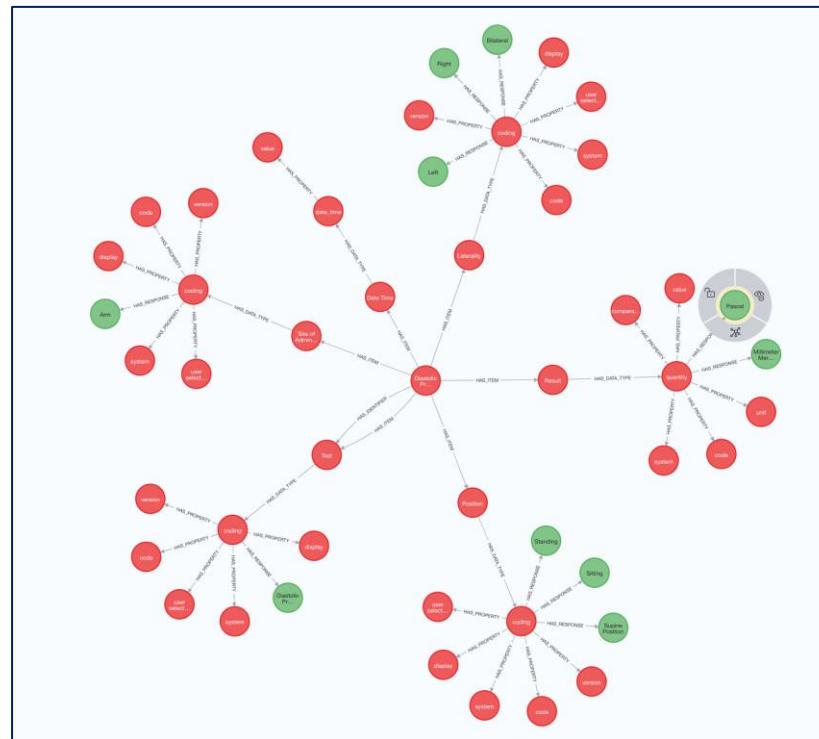
Open Study Builder

- Unit of knowledge and properties
- Attached CT, using CDISC



d4k

- Uses CDISC CT
 - Uses FHIR data types

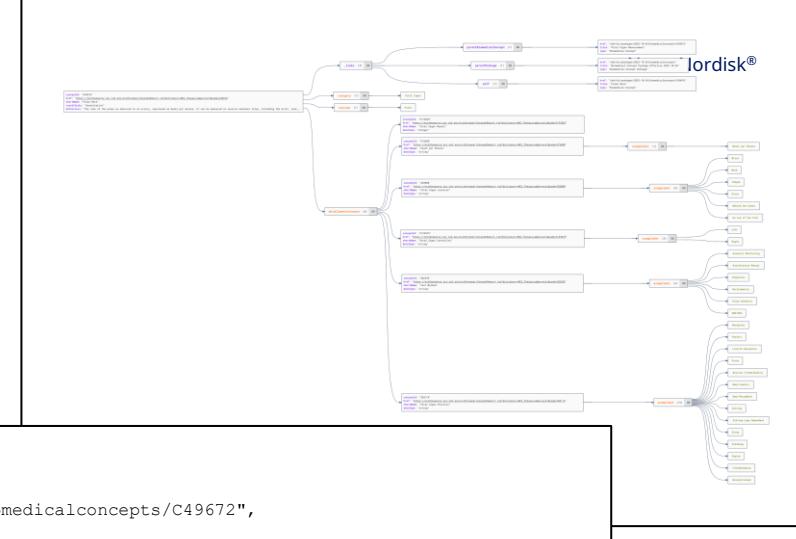


Item Name	Identifier	Data Type	Terms
Position		coding	SUPINE, Supine Position (C71148, C62167) SITTING, Sitting (C71148, C62122) STANDING, Standing (C71148, C62166)
Result		quantity	mmHg, Millimeter of Mercury (C66770, C49670) Pa, Pascal (C66770, C42547)
Laterality		coding	BILATERAL, Bilateral (C99073, C13332) RIGHT, Right (C99073, C25228) LEFT, Left (C99073, C25229)
Date Time		date_time	
Site of Administration		coding	ARM, Arm (C74456, C32141)
Test	▼	coding	DIABP, Diastolic Blood Pressure (C66741, C25299)

So ...

- A central node, the root of the BC
- Identification
 - Unique (UUID, URI ...)
 - Resolvable would be nice
- Version managed
- A set of properties
 - Some must be there, e.g. result
- Controlled Terms defined
 - CDISC CT
- Complete
 - Everything we need defined
- Equivalence
 - Links to equivalent models in other systems
- Hierarchy
 - Subclass, membership type capabilities
- Configurable
 - Select properties and / or CT values

```
{
  "_links": {
    "parentBiomedicalConcept": {
      "href": "/mdr/bc/packages/2022-10-26/biomedicalconcepts/C49672",
      "title": "Vital Signs Measurement",
      "type": "Biomedical Concept"
    },
    "parentPackage": {
      "href": "/mdr/bc/packages/2022-10-26/biomedicalconcepts",
      "title": "Biomedical Concept Package Effective 2022-10-26",
      "type": "Biomedical Concept Package"
    },
    "self": {
      "href": "/mdr/bc/packages/2022-10-26/biomedicalconcepts/C49676",
      "title": "Pulse Rate",
      "type": "Biomedical Concept"
    }
  },
  "conceptId": "C49676",
  "href": "https://ncitthesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C49676",
  "category": [
    "Vital Signs"
  ],
  "shortName": "Pulse Rate",
  "synonym": [
    "Pulse"
  ],
  "resultScale": "Quantitative",
  "definition": "The rate of the pulse as observed in an artery, expressed as beats per minute. It can be measured at several anatomic sites, including the wrist, neck, temple, groin, behind the knees, or on top of the foot.",
  "dataElementConcepts": [
    {
      "conceptId": "C173522",
      "href": "https://ncitthesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C173522",
      "shortName": "Vital Signs Result",
      "dataType": "integer"
    },
    ...
  ]
}
```



Definition

- A small model that defines a clinical concept in a standardized and reusable manner
- A unit of knowledge
- Independent of technology or means of collection
- A specification of the data

Structure

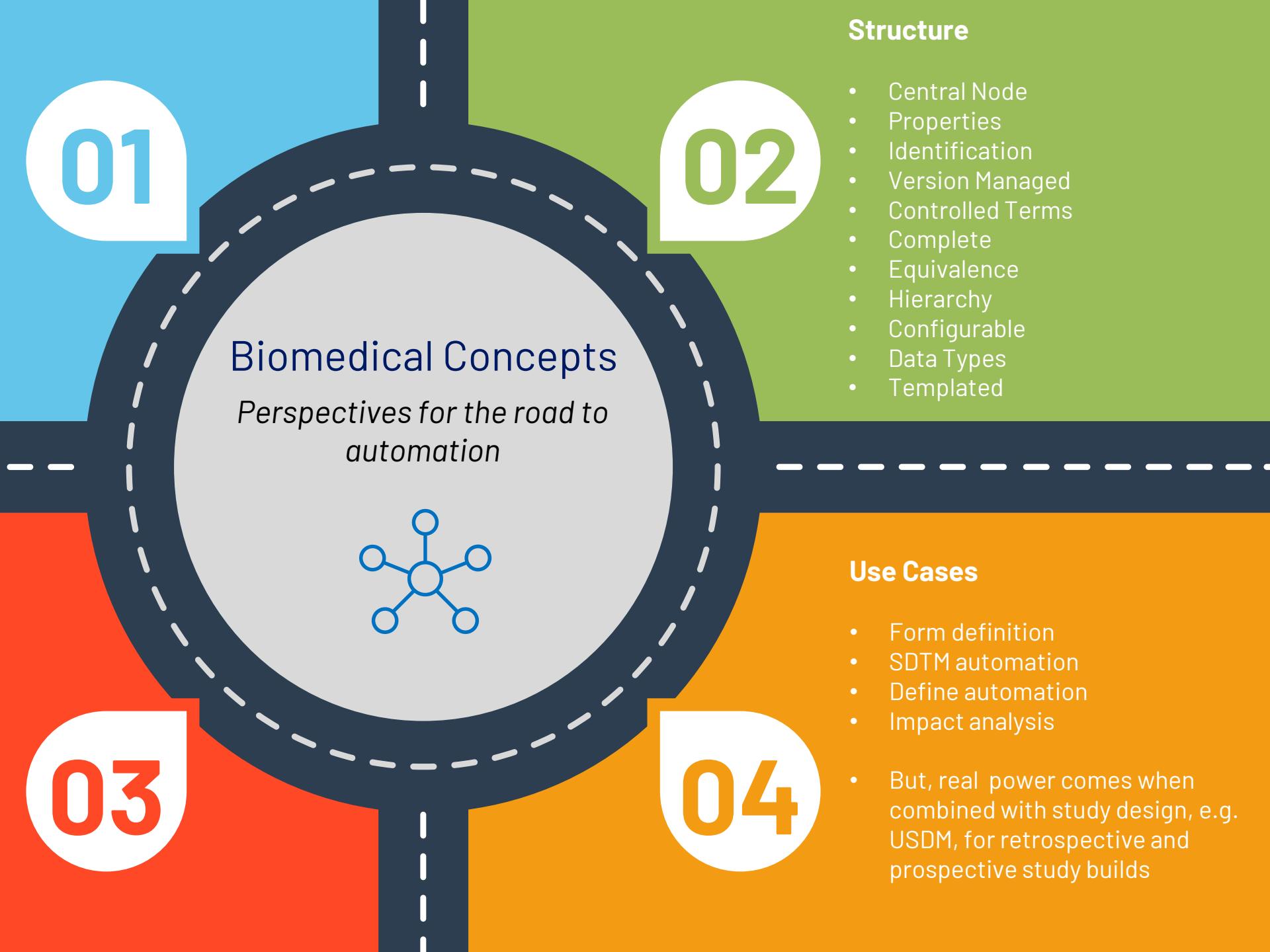
- Central Node
- Properties
- Identification
- Version Managed
- Controlled Terms
- Complete
- Equivalence
- Hierarchy
- Configurable
- Data Types
- Templated

Adoption

- Don't initially seek perfection
- Iterate and learn
- Question every assumption
- Think data not presentation, a data-centric approach
- Consider linking to DDF USDM to bring ultimate power

Use Cases

- Form definition
- SDTM automation
- Define automation
- Impact analysis
- But, real power comes when combined with study design, e.g. USDM, for retrospective and prospective study builds



Example Deployment

The image displays two screenshots illustrating the deployment of Biomedical Concepts (BCs) in a system.

Top Screenshot: Form Editor

This screenshot shows the 'Form Editor' interface in 'Development A3 MDR (v3.9.5)'. The left sidebar includes links for Dashboard, System Admin, Import/Export, Utilities, Terminology, Biomedical Concepts, Forms, SD TM SDTM, AD aM ADaM, and Managed Collections. The main area shows a hierarchical tree of Biomedical Concepts under 'BC Demonstration'. A node labeled 'Group for BCs' branches into 'Systolic Blood Pressure' and 'Diastolic Blood Pressure'. Each of these further branches into specific concepts like 'POS', 'LOC', 'LAT', 'DTC', 'ORRES', and 'ORRESU', each associated with clinical contexts such as 'Standing', 'Sitting', 'Supine Position', 'Arm', 'Left', 'Right', 'Bilateral', and units like 'Millimeter of Mercury' and 'Pascal'.

Bottom Screenshot: BC Demonstration

This screenshot shows the 'BC Demonstration' page. It includes a search bar with the placeholder 'VS=Vital Signs'. The page lists 'Common group' and 'Date and time' sections. Under 'Date and time', there are two dropdown menus for 'VSDTC where VTESTCD=DIABP' and 'VSDTC where VTESTCD=SYSBP', each with fields for Day (D), Month (M), Year (Y), and Hour (H). Below this is a 'Body Position' section with dropdown menus for 'VSPOS where VTESTCD=DIABP' and 'VSPOS where VTESTCD=SYSBP', each with radio buttons for 'Standing', 'Sitting', and 'Supine Position'. At the bottom, there is a 'Systolic Blood Pressure' section with a dropdown menu for 'VTESTCD' and a radio button for 'Systolic Blood Pressure'.

BC in OpenStudyBuilder := Activity Concepts (Mikkel)

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**

Read more in our BC article on our GitLab site

OpenStudyBuilder

Description Info Guides FAQ

Search

OpenStudyBuilder ☆ 9 1

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:

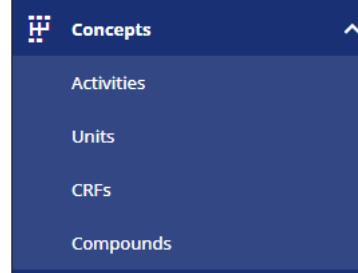


Figure 1: The OpenStudyBuilder Library Part

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.

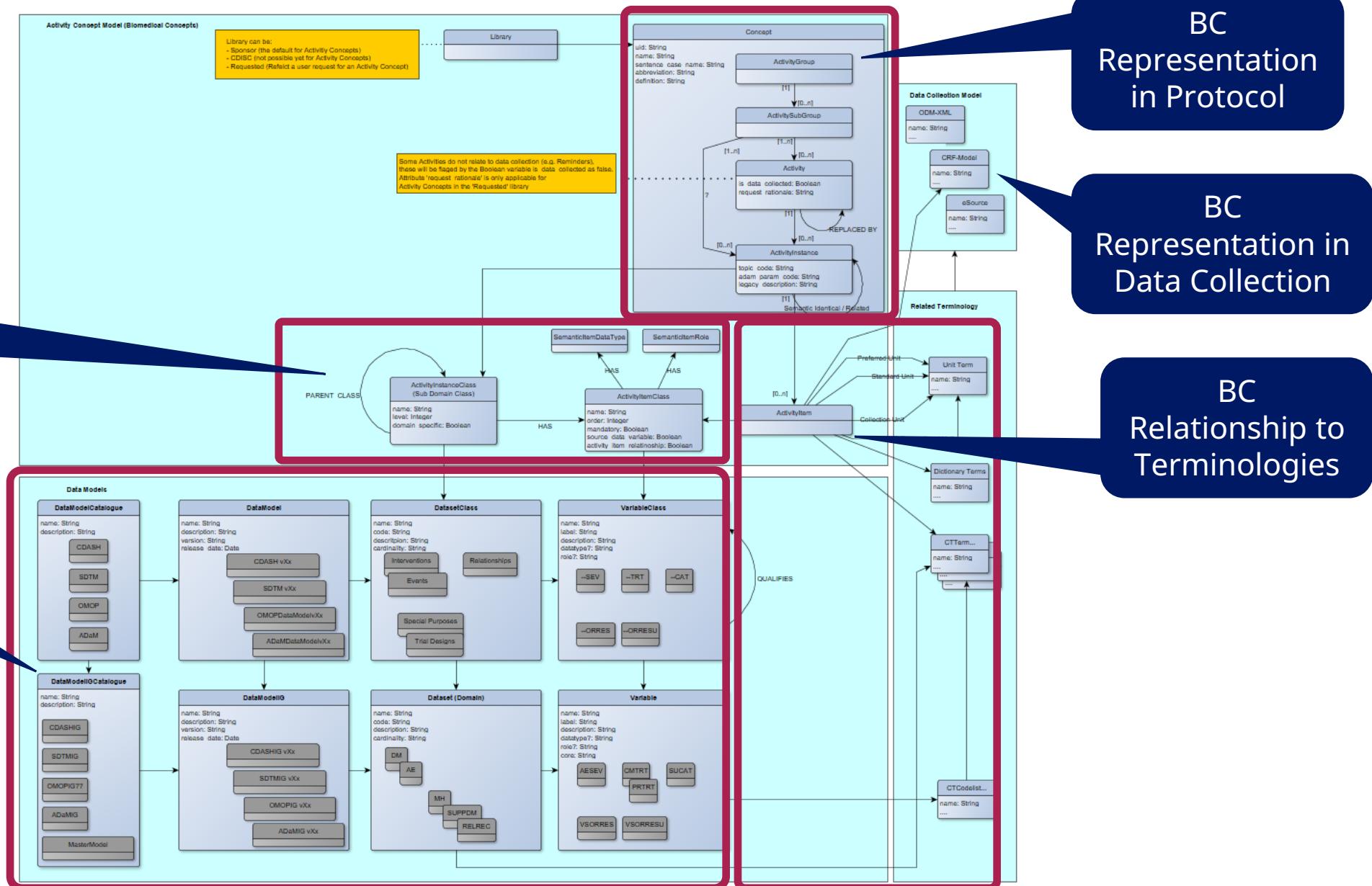
Biomedical Concept (BC)

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

Discussion on BC data model in OpenStudyBuilder versus others



- [About Library](#)
- [Process Overview](#)
- [Code Lists](#)
- [Dictionaries](#)
- [Concepts](#)
- [Activities](#)
- [Units](#)
- [CRFs](#)
- [Compounds](#)
- [Syntax Templates](#)
- [Template Instantiations](#)
- [Template Collections](#)
- [Data Exchange Standards](#)
- [List](#)

CRFs (Case Report Forms)

[CRF Templates](#) [Forms](#) [Item Groups](#) [Items](#) [CRF Tree](#) [ODM View](#) [Alias](#) [Extensions](#)[RELOAD](#)

ODM version 1.3.2 with DoB

Annotated CRF [MSG2.0]

Adverse Event

One AE should be reported per form. During conduct of the study, please transcribe data to EDC as soon as possible. The AE diagnosis, causality, seriousness and severity should be evaluated by the investigator or sub-investigator with physician background.

1: Any conditions / illnesses ?

MH (Medical History Domain)

[OID=G.MH.NS, Version=0.1]

Please state if there was any conditions / illnesses

2: Medical History item group

MH (Medical History Domain)

[OID=G.MH.CM, Version=0.1]

Please complete this Medical History item group before starting the treatment

Black label are Mandatory (otherwise Green)



Lock

* Data Entry Required

Informed Consent and Demography

Please complete this Informed Consent and Demography form at the very beginning of the study General item design notes: Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM General item design notes: Integration: A: Argus, Ax: rms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM Oracle item des N notes: Key: [*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/DemogOracle item design notes: Key: [*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/Demog

1: Informed Consent item group

DM (Demographics Domain)

[OID=G.DM.IC, Version=0.1]

Please complete the Informed Consent item group before any other information

	Study ID [OID=I.STUDYID, Version=0.1] <p> Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during SDTM-based dataset creation before submission.</p>	<input type="text" value="STUDYID"/> 11 digit(s)
	Time informed consent obtained [OID=I.RFICTIME, Version=0.1] <p> This will be the same information on informed consent used in the SDTM Disposition domain</p>	<input type="text" value="RFICDTCTIME"/> --::-- 5 digit(s)

2: General Demographic item group

DM (Demographics Domain)

[OID=G.DM.DM, Version=0.1]

Light OpenStudyBuilder demo

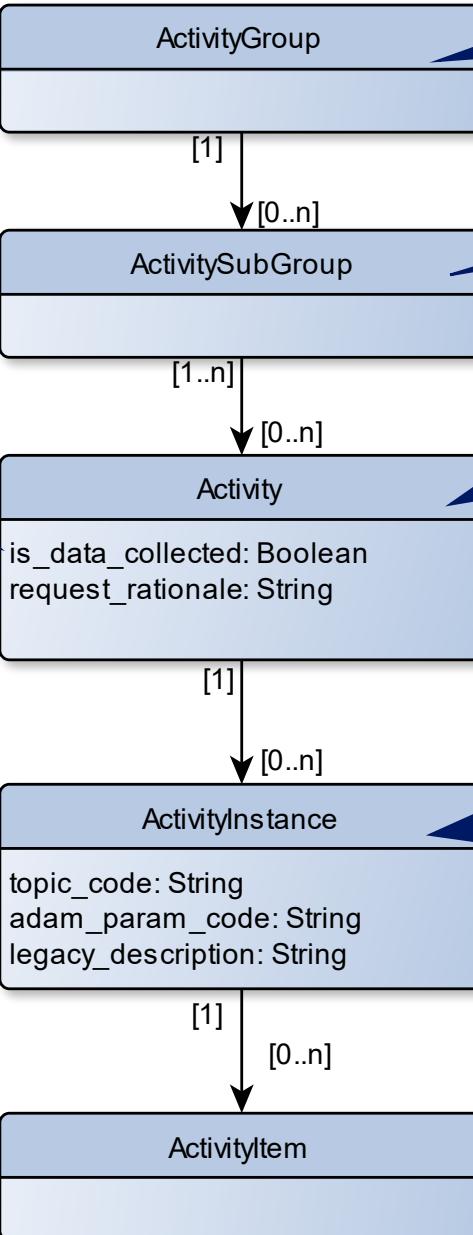
- Browse Activity Concept in Library -> Activity Concepts
 - Display details – will be CDISC COSMoS compatible
- Refer to Activity Concepts in Syntax Templates
- Apply as Endpoint Selection selecting Activity in Study Purpose
- Apply as Activity selection in SoA
- Bring to Protocol Document
 - Activity 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

We generally use the term '**Activity**' to cover both Assessments based Activities as well as Activities without Assessments (like procedures, reminders, etc.)

Things in the flowchart related or not to data collection

Links to Generic Activity Instance Class model – as an Activity Instance Template

Links to Generic Activity Item Class model – as an Activity Item Template



Grouping of Activities, optionally only the grouping can be shown in the protocol SoA

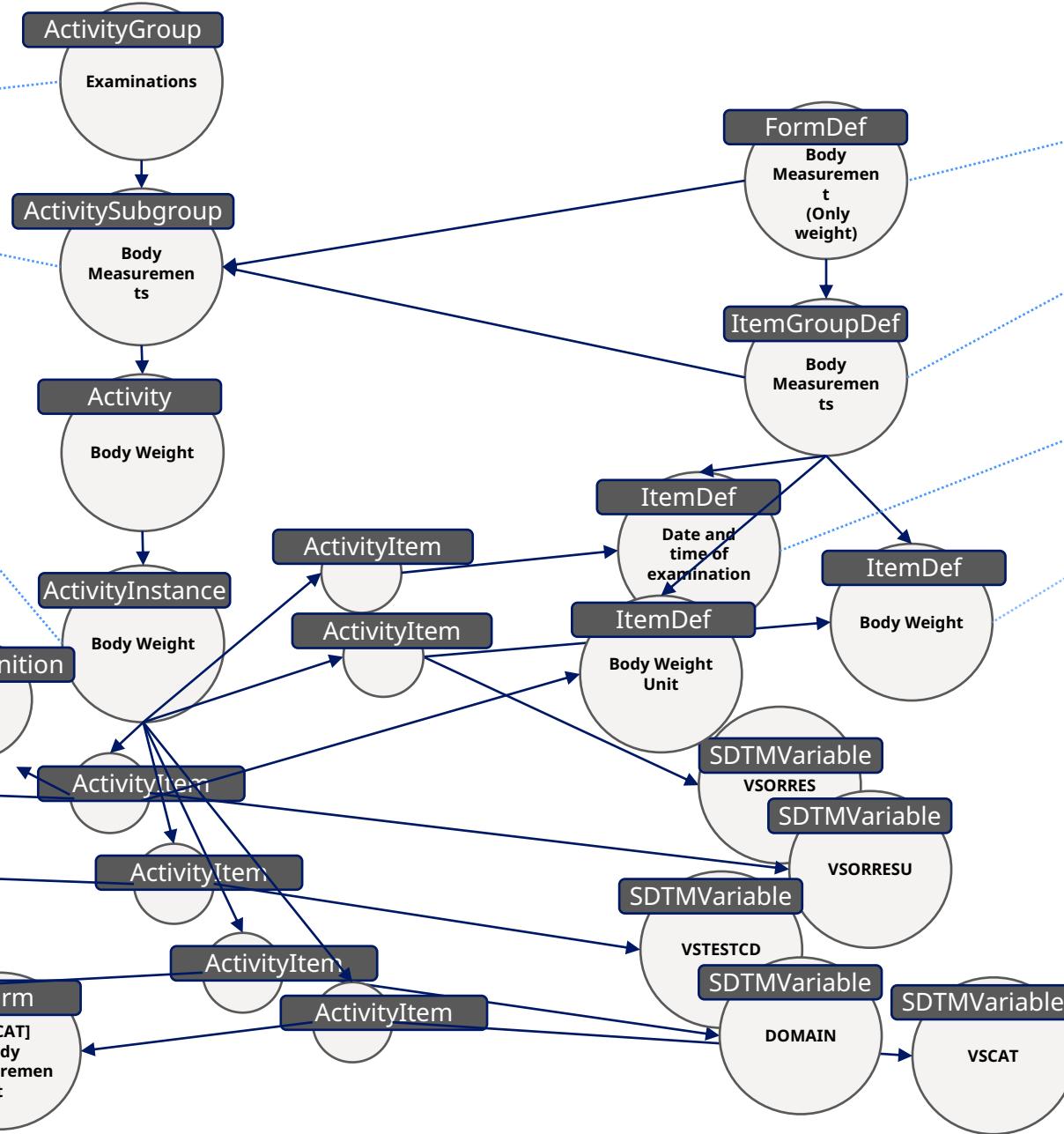
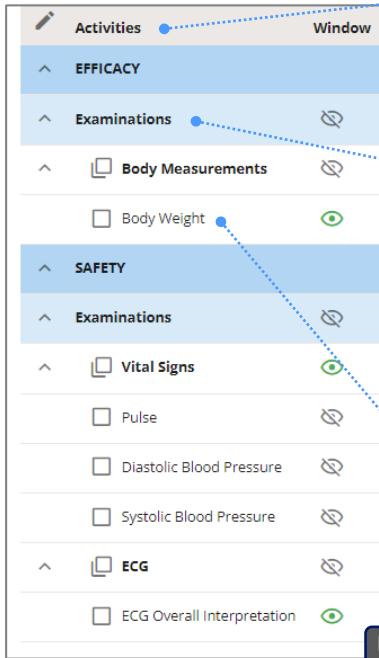
The specific level in the hierarchy for protocol SoA. Independent on e.g. specimen, unit, SDTM Domain, ADaM PARAM, ...

Correspond to our existing Topic Code, ADaM PARAM/PARAMCD. Specific to specimen, unit, SDTM Identify semantic observations

Links to terminology and cross data model variables

Activity Concept data model sample – Body Weight

Study Flowchart



CRF

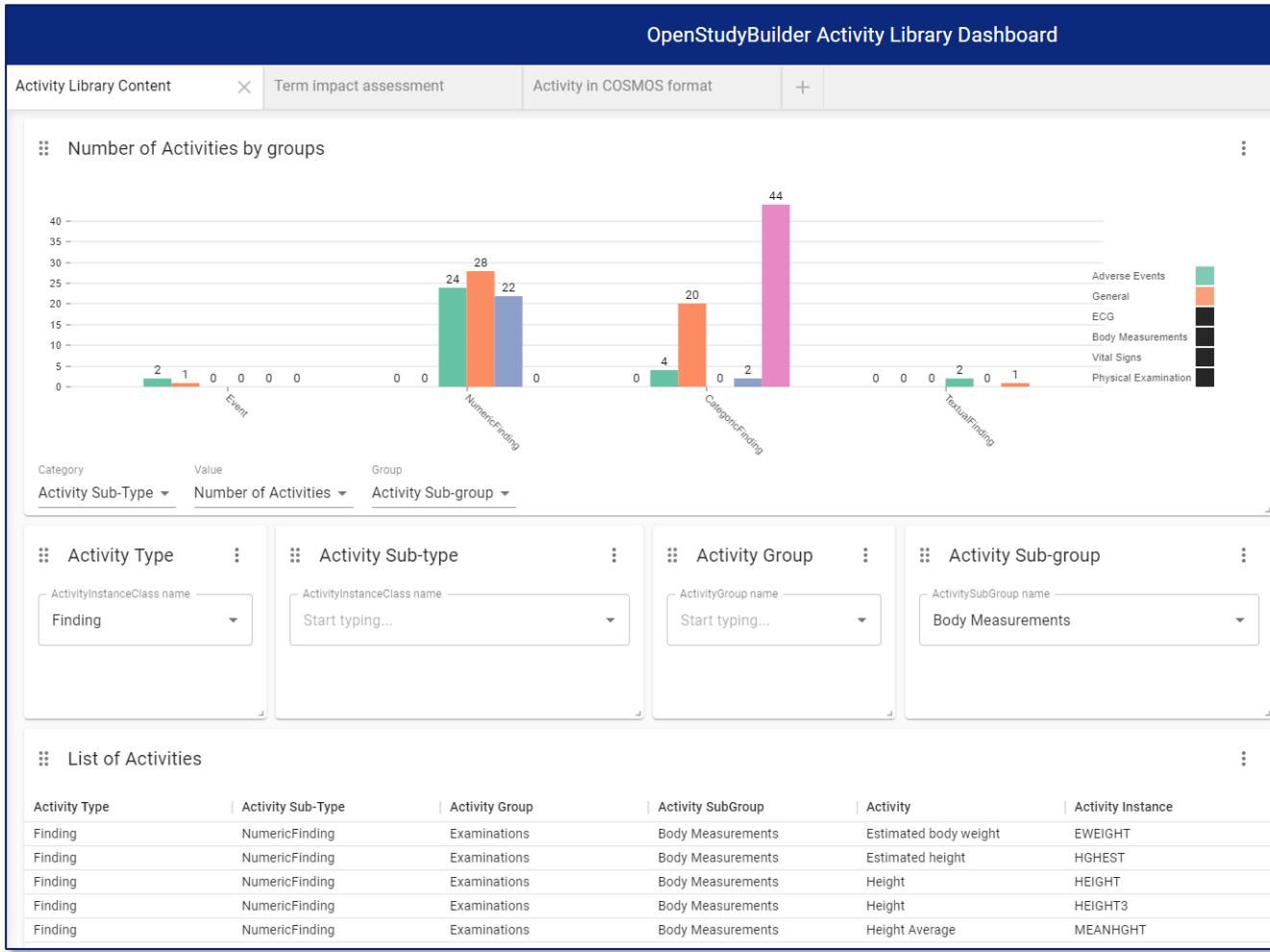
Body Measurements

Body Measurements

Study: XX-XXXX

Date and time of examination	Req/Unk	Req/Unk	24-hour clock
Body weight	xxxx.	0 kg	0 lb

Browse and curate BC content in OSB model



OpenStudyBuilder Activity Library Dashboard

Activity Library Content | Term impact assessment | Activity in COSMOS format | +

Select Activity Instance

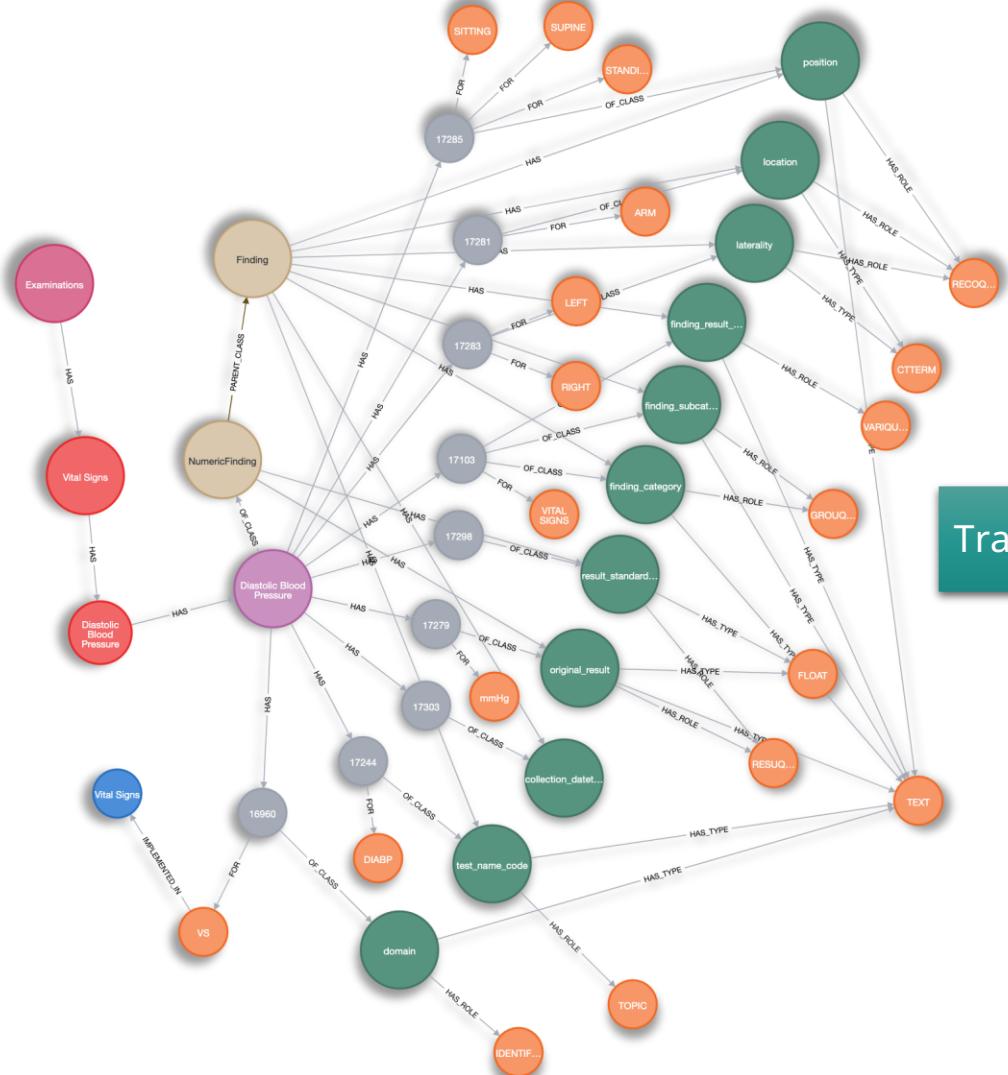
```
- ActivityInstance adam_param_code
  WEIGHT
```

Display Activity in CDISC Cosmos YAML format

Variable	Variable Name	Value	Detail
packageDate		2022-11-13	
packageType		SDTM	
datasetSpecialisationID		BODY_WEIGHT	
domain		VS	
shortName		Body Weight	
source		VS.VSTESTCD	
sdtmigStartVersion		3.2	
sdtmigEndVersion			
biomedicalConceptID		C25208	
variables	VSORRES	name : VSORRES	
variables		codelist	(submissionValue=VSRESU, conceptId=C66770, href=https://ncithesaurus.nci.nih.gov/ncit/)
variables		role : Result Qualifier	
variables		dataType : FLOAT	
variables		originType : Collected	
variables		mandatoryVariable : Yes	
variables	VSORRES	name : VSORRES	
variables		codelist	(submissionValue=UNIT, conceptId=C71620, href=https://ncithesaurus.nci.nih.gov/ncit/)
variables		role : Result Qualifier	
variables		dataType : FLOAT	
variables		originType : Collected	
variables		mandatoryVariable : Yes	
variables	VSORRES	name : VSORRES	
variables		codelist	(submissionValue=PKUNIT, conceptId=C85494, href=https://ncithesaurus.nci.nih.gov/ncit/)
variables		role : Result Qualifier	
variables		dataType : FLOAT	
variables		originType : Collected	

OSB model versus other models

OpenStudyBuilder Activity Model mapped to COSMoS-BC Model



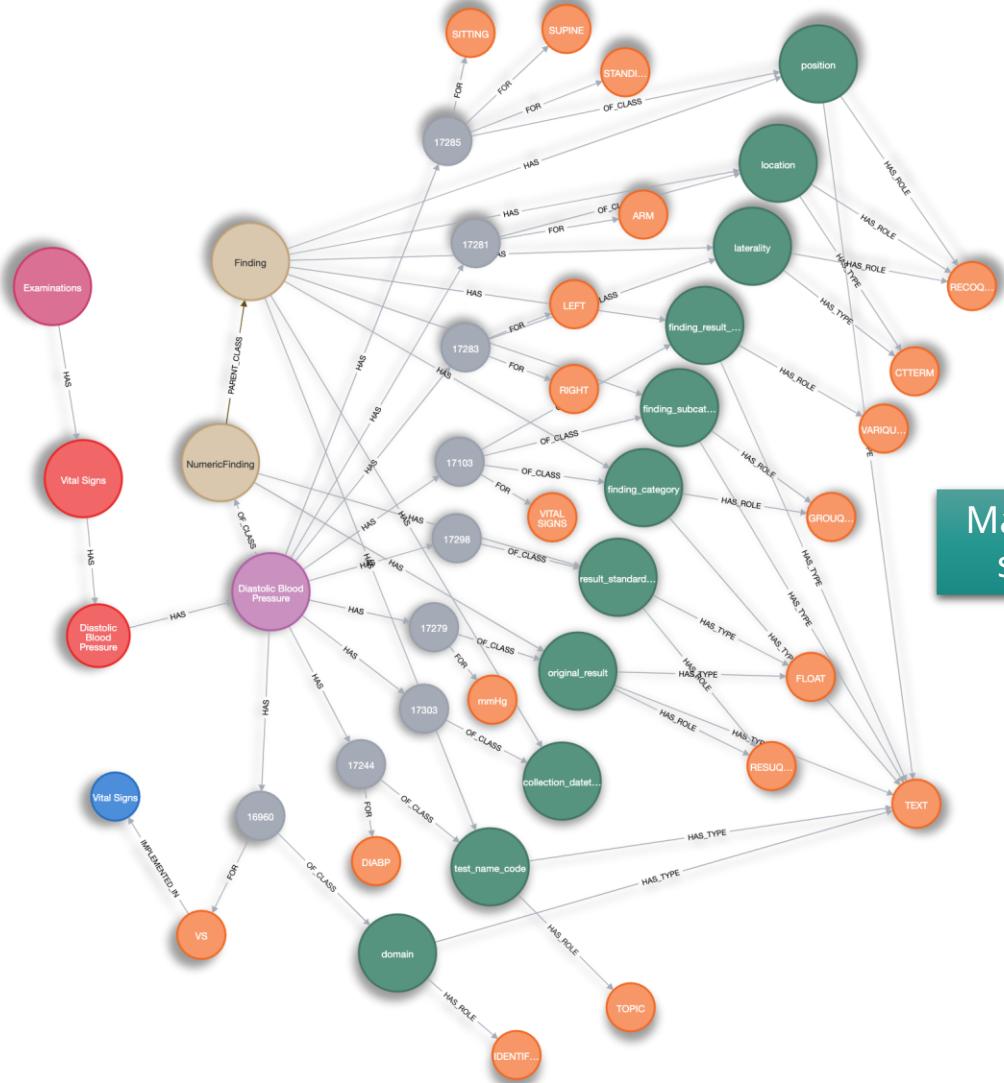
Transform

```

packageDate: "2022-10-26"
packageType: bc
conceptID: C25299
1   - packageDate: '2022-11-13'
2   packageType: bc
3   conceptID: C25299
4   href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI\_Thesaurus&ns=ncit&code=C25299
5   parentConceptId: C54706
6   category:
7     - Vital Signs
8   shortName: Diastolic Blood Pressure
9   synonym:
10    - DIABP
11   resultScale: Quantitative
12   definition: The minimum pressure exerted into the systemic arterial circulation
13   during cardiac ventricular relaxation and filling.
14   coding:
15     - code: LOINC-CODE TO BE FOUND
16       system: http://loinc.org/
17       systemName: LOINC
18   dataElementConcepts:
19     - conceptID: C83466
20       href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI\_Thesaurus&ns=ncit&code=C83466
21       shortName: VSTESTCD
22       dataType: CTTERM
23     - conceptID: C49672 ...
24     - conceptID: C83454 ...
25     - conceptID: C83452 ...
26     - conceptID: C83114 ...
27     - conceptID: C83088 ...
28     - conceptID: C123975 ...
29     - conceptID: C83108 ...
30     - conceptID: C83108 ...
31     - conceptID: C83464 ...
32   >
33   >
34   >
35   >
36   >
37   >
38   >
39   >
40   >
41   >
42   >
43   >
44   >
45   >
46   >
47   >
48   >
49   >
50   >
51   >
52   >
53   >
54   >
55   >

```

OpenStudyBuilder Activity Model mapped to COSMoS-BC Model



Mapping steps

```
apoc.map.fromPairs([
  'packageType', dmig.name],
  ['datasetSpecializationId', ai.topic_code],
  ['domain', ds.code],
  ['shortName', ai.name],
  ['source', ds.code+'.'+ds.code+'TESTCD'],
  ['sdtmigStartVersion', dmig.version],
  ['Variables', vars],
  ['category', asgrp.name],
  ['resultScale', aiclass]
]) as activity
```

Conversion

```
CASE when aic.name='NumericFinding' THEN 'Quantitative' ELSE
CASE WHEN aic.name='CategoricFinding' THEN 'Ordinal' ELSE
null END END as aiclass
```

OpenStudyBuilder Activity Model mapped to COSMoS-BC Model - finding terminology

```
def nci_service_get_concept_code_from_term(term):
    url = 'https://api-evsrest.nci.nih.gov/api/v1/concept/search?fromRecord=0&include=synonyms&pageSize=10&
synonymSource=CDISC&term=' + term + '&terminology=ncit&type=match'
    r = requests.get(url)
    concept_info = r.json()
    #avoid getting the CDASH one
    for concept in concept_info['concepts']:
        if 'CDASH' not in concept['name']:
            code = concept['code']
    return code

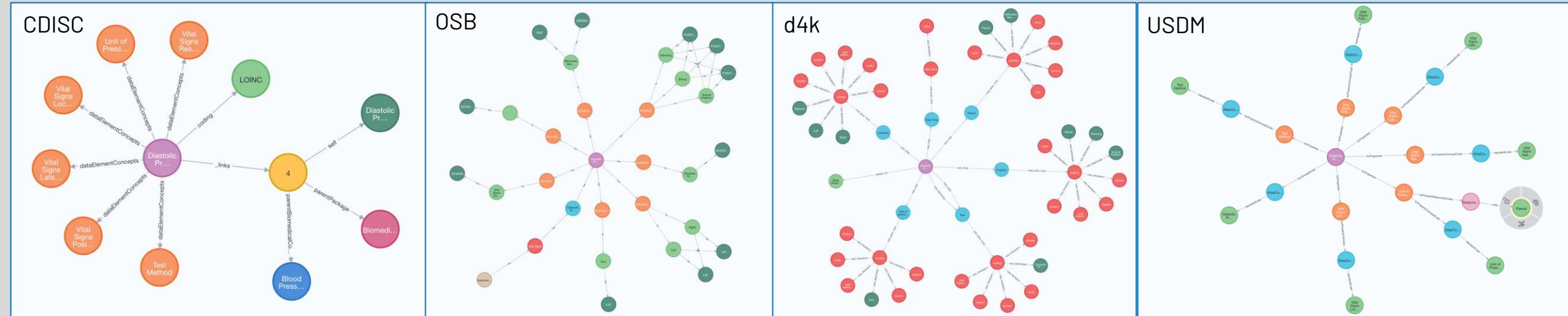
def get_testcd_subm_from_test_code(ccode):
    url = 'https://api-evsrest.nci.nih.gov/api/v1/concept/search?fromRecord=0&include=summary%2Csynonyms&
pageSize=10&synonymSource=CDISC&synonymTermType=PT&term=' + ccode + '&terminology=ncit&type=match'
    r = requests.get(url)
    concept_info = r.json()

    #Get the SDTM TESTCD term based on test (i.e. get DIAP from 'Diastolic Blood Pressure' term)
    for concept in concept_info['concepts'][0]['synonyms']:
        if "code" in concept:
            if 'TESTCD' in concept['code'] and 'SDTM' in concept['code']:
                testcd = concept['name']
    return testcd
```

Using NCI API

```
1  - packageDate: '2022-11-13'
2  packageType: bc
3  conceptID: C25299
4  href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C25299
5  parentConceptId: C54706
6  category:
7      - Vital Signs
8  shortName: Diastolic Blood Pressure
9  synonym:
10     - DIABP
11  resultScale: Quantitative
12  definition: The minimum pressure exerted into the systemic arterial circulation
13      during cardiac ventricular relaxation and filling.
14  coding:
15     - code: LOINC-CODE TO BE FOUND
16     system: http://loinc.org/
17     systemName: LOINC
18  dataElementConcepts:
19     - conceptID: C83466
20     href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C83466
21     shortName: VSTESTCD
22     dataType: CTTERM
23     - conceptID: C49672...
24     - conceptID: C83454...
25     - conceptID: C83452...
26     - conceptID: C83114...
27     - conceptID: C83088...
28     - conceptID: C123975...
29     - conceptID: C83108...
30     - conceptID: C83108...
31     - conceptID: C83464...
```

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



Present initial SWOT and Mind Map
as input to break-out sessions

Initial SWOT and Mind Map for next steps

- Use this framework to capture discussions and reflections during break-outs
- Present for all in last plenum session

- SWOT
 - How do we see this for BC's supporting our clinical data flows
- 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-to-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

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

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

Threats

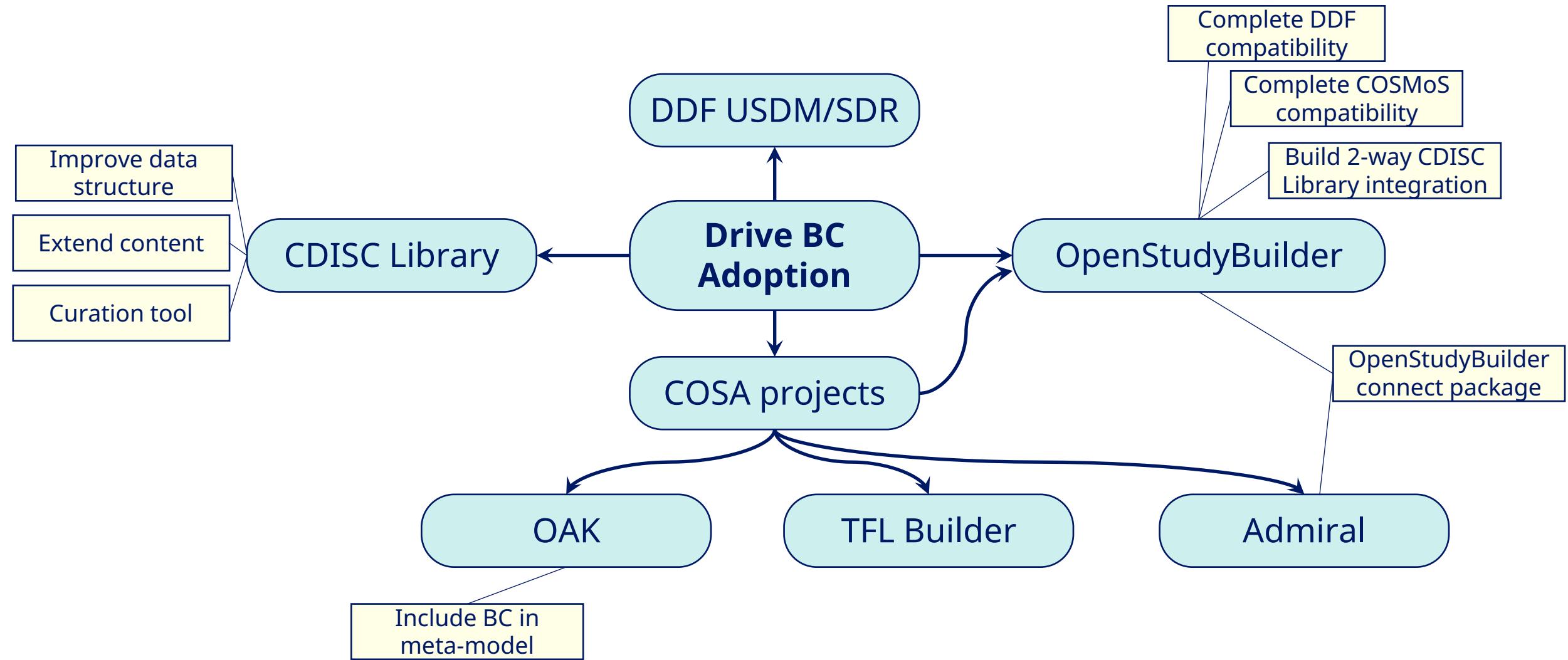
BC's

- 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

Mind Map for next steps in driving BC adoption



Breakout sessions

11:00 – 12:00 Break-out part 1

12:00 – 13:00 Lunch

13:00 – 14:00 Break-out part 2

14:00 – 15:00 Sharing in plenum

Breakout sessions

- Setup BC's in OSB SoA for a new study, run various queries to learn how BC's can be utilised
 - *BC beginners and those who want to see BCs applied in the OpenStudyBuilder*
- Learn and understand the BC model in OSB versus the COSMoS, DDF, d4k and other models
 - *BC engineers and for data modeling*
- Create and curate OpenStudyBuilder BC content via the OSB Library and NeoDash reports and mining BC's from existing data sources like SDTM.
 - *Modelling BCs from other sources and working with BCs, for example through dashboards*

- Room
 - Anja, Katja

- Room
 - Dave, Lex, Marius, Mikkel

- Room
 - Kirsten, Chandrakant, Nicolas, Linda

Recap

Breakout 1 – BCs in OpenStudyBuilder
Breakout 2 – BC Models
Breakout 3 – Curation
Final words

Final Words

- Hope you enjoyed the workshop and learned a lot of BC
 - Thanks for your input & discussions – all material will be shared
 - Please give us feedback on the workshop – mail to Charles
 - Looking forward to further collaborate
-
- OpenStudyBuilder Meet & Demo during Interchange (COSA Booth)

Wednesday

10:30-11:00	Talk
12:00-13:00	Demo
13:00-13:30	Talk
13:30-14:00	Demo
17:00-18:00	Demo

Thursday

9:00-10:00	Demo
12:00-13:00	Demo
13:00-13:30	Talk
13:30-14:00	Demo

Final Words

- Links (also in COSA mail)

OpenStudyBuilder Homepage	https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/
COSA Homepage	https://cosa.cdisc.org/
CDISC Cosmos	https://www.cdisc.org/cdisc-biomedical-concepts
TransCelerate DDF	https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/
D4K detailed BC paper	https://github.com/data4knowledge/biomedical_concepts/blob/main/docs/bc_treatise/Biomedical Concepts Treatise.pdf
OpenStudyBuilder	
Slack	Join OpenStudyBuilder Slack
LinkedIn Newsletter	Subscribe to our newsletter here
Guides	Various guides are available here