

COSA – BC & OpenStudyBuilder Workshop @ EU Interchange 2023

Breakout 1 – Setup BCs in OSB SoA

25 April 2023, Copenhagen

- Welcome & Introduction
- Short recap
- Show activity concept in database/Nicolas
- Browse Activity Concepts in Library/Anja
- Try out on your own & discussions/all
- Apply Activity Concepts in Study Setup/Anja
- Try out on your own & discussions/all
- Demo of pulling activities to the Protocol/Anja
- SWOT & wrapping up/Katja

Welcome to break-out 1

– Setup BCs in OSB SoA

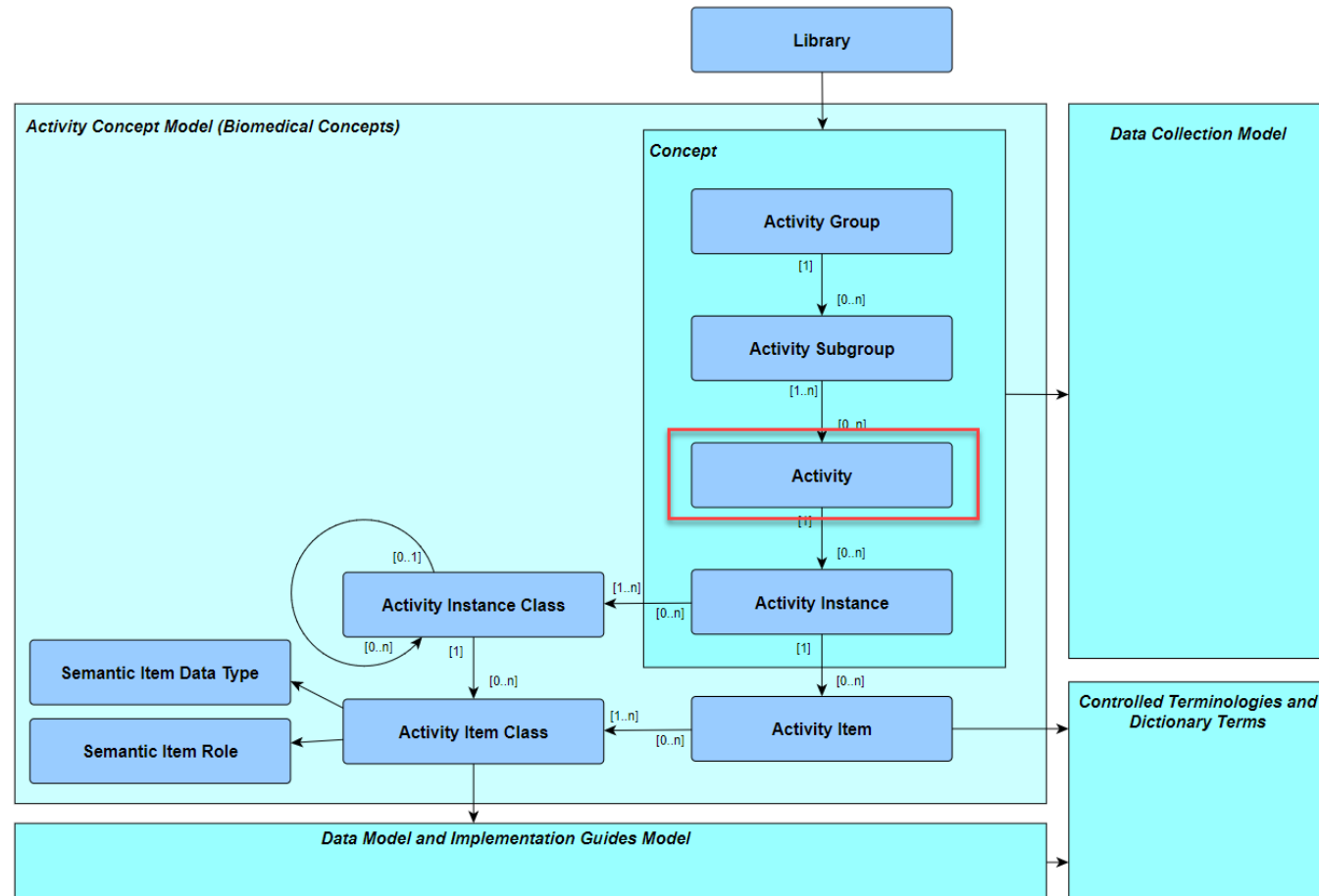
Who are we?

- Katja Glass, Open-Source Ambassador. Part time consultant & community manager
- Nicolas de Saint Jorre, Product Architect. Working at Novo Nordisk for 1 month – and several years as consultant within data management, EDC specialist, OSB and CDISC
- Anja Lundgreen, Principal Standards Specialist. Working at Novo Nordisk for 10+ years. Standards Governance and SDTM

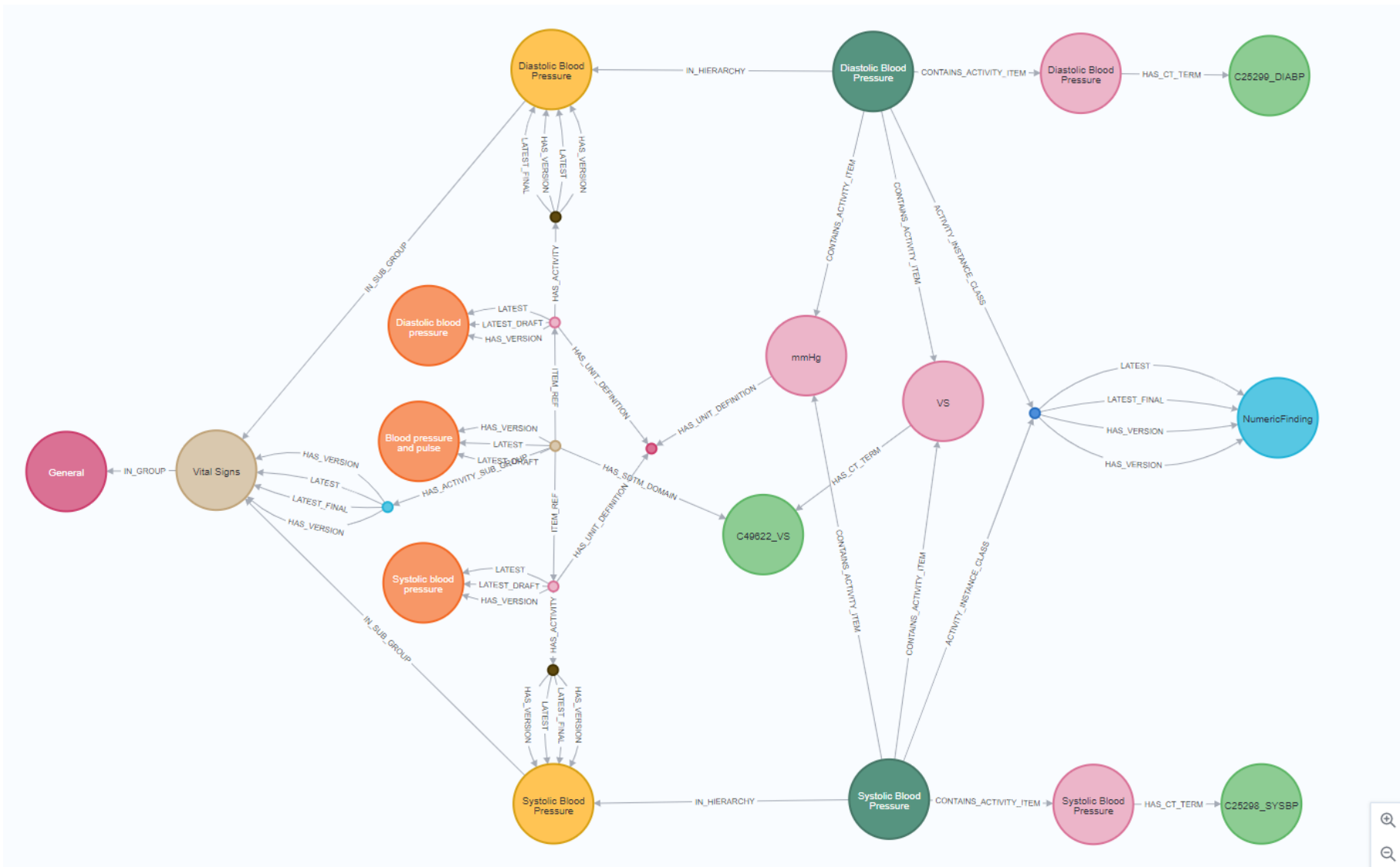
Goal for break-out

- Learn how to recognise and apply BC's (Activities) for a study in OSB
- Discuss SWOT (strengths, weaknesses, opportunities, threats) and next (collaboration) steps

Short recap: Biomedical concept in OpenStudyBuilder is **Activity** Concept



Activity Concept in the database



Overview



Node labels

- * (51)
- ActivityGroupValue (1)
- ConceptValue (9)
- TemplateParameterTermValue (6)
- ActivitySubGroupValue (1)
- ActivityValue (2)
- ActivityInstanceValue (2)
- ActivityItemValue (4)
- ActivityInstanceClassRoot (1)
- ActivityInstanceClassValue (1)
- ActivitySubGroupRoot (1)
- ConceptRoot (7)
- TemplateParameterTermRoot (4)
- OdmItemGroupRoot (1)
- OdmItemGroupValue (1)
- OdmItemRoot (2)
- OdmItemValue (2)
- ActivityRoot (2)
- UnitDefinitionRoot (1)
- CTTermRoot (3)

Relationship Types

- * (50)
- IN_GROUP (1)
- IN_SUB_GROUP (2)
- CONTAINS_ACTIVITY_ITEM (6)
- ACTIVITY_INSTANCE_CLASS (2)
- IN_HIERARCHY (2)
- HAS_UNIT_DEFINITION (3)
- LATEST (7)
- LATEST_FINAL (4)
- HAS_VERSION (11)
- ITEM_REF (2)
- HAS_ACTIVITY_SUB_GROUP (1)
- HAS_SDTM_DOMAIN (1)
- LATEST_DRAFT (3)
- HAS_ACTIVITY (2)
- HAS_CT_TERM (3)

Displaying 25 nodes, 50 relationships.



Activity Concept in the database

```
// Display VS ActivitySubGroup, Activity and ActivityInstance with SBP and DBP with CT and CRF metadata
MATCH (n2:ActivityGroupValue)<-[]-(n4:ActivitySubGroupValue)<-[]-(n6:ActivityValue)<-[]-(n8:ActivityInstanceValue)-[]->(n10:ActivityItemValue)
MATCH (n8)-[]->(n12:ActivityInstanceClassRoot)-[]->(n14:ActivityInstanceClassValue)
MATCH (n12)-[]->(n16:ActivityInstanceClassValue)
WHERE n2.name = 'General' AND n4.name = 'Vital Signs' AND n6.name CONTAINS 'Blood Pressure'
    OPTIONAL MATCH (n10)-[]->(n18:CTTermRoot)
    OPTIONAL MATCH (n4)<--(n19:ActivitySubGroupRoot)<--(n20:OdmItemGroupRoot)-->(n21:OdmItemGroupValue)
    OPTIONAL MATCH (n20)-->(n22:OdmItemRoot)-->(n23:OdmItemValue)
    OPTIONAL MATCH (n22)-->(n24:ActivityRoot)
    OPTIONAL MATCH (n22)-->(n25:UnitDefinitionRoot)<--(n10)
RETURN n2,n4,n6,n8,n10,n12,n14,n16,n18,n19,n20,n21,n22,n23,n24,n25;
```

Browse Activity Concepts in Library



- Activity concept
- Groupings
- Template parameters

Demo & try out

Apply Activity Concepts in Study Setup

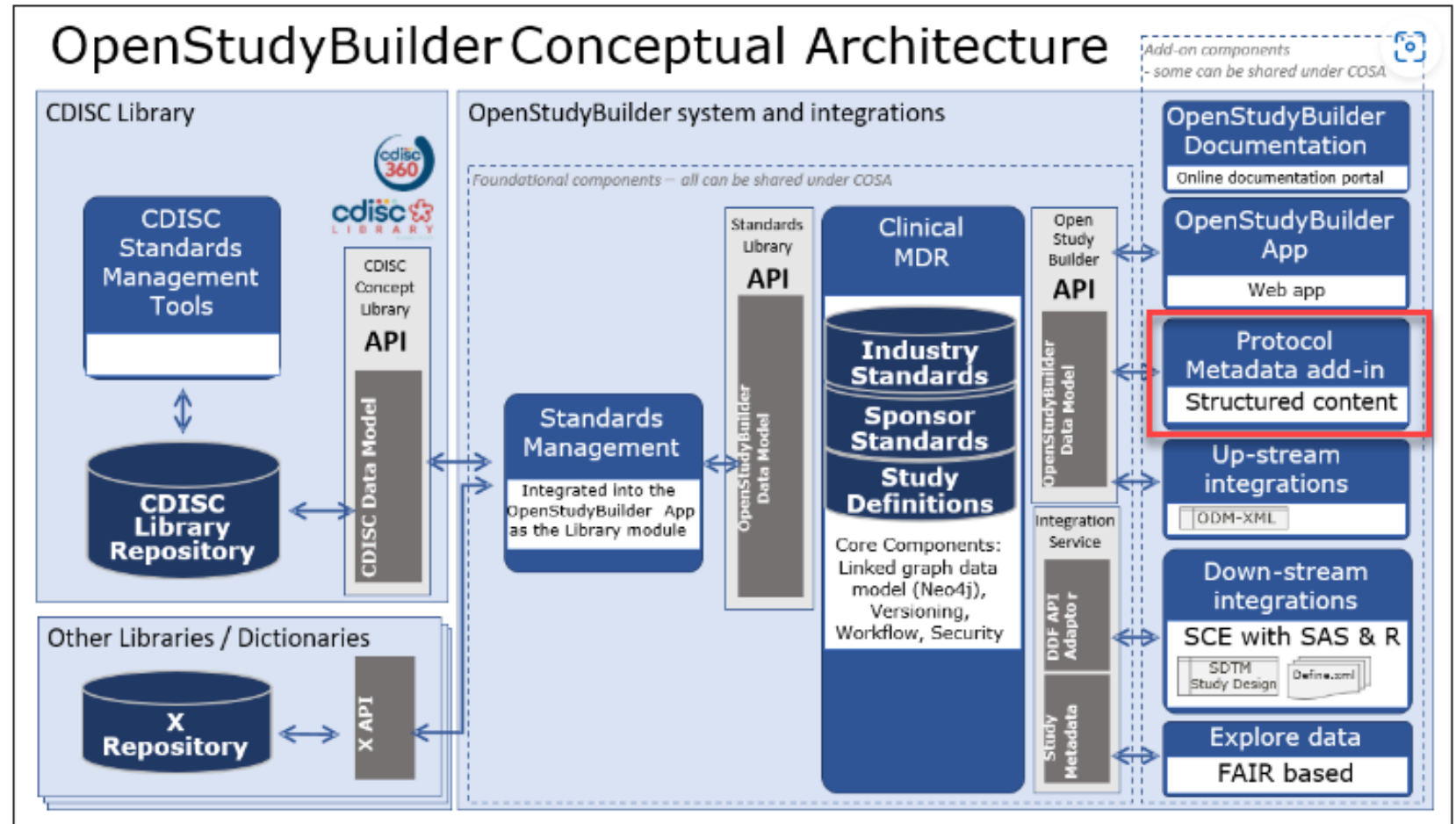


- Use in syntax templates
- Use in flowchart

Demo & try out

Demo display in Word add-in

Using the Novo Nordisk Word add-in



Demo

Please add 😊

SWOT – Setup BCs in OSB SoA

<p>Strengths</p> <p>BC's</p> <p>Tools</p>	<p>Weaknesses</p> <p>BC's</p> <p>Tools</p>
<p>Opportunities</p> <p>BC's</p> <p>Tools</p>	<p>Threats</p> <p>BC's</p> <p>Tools</p>

Discussion & SWOT

Discussion Notes

- Standardization crashed with real world flexibility requests
 - User understanding of arbitrary concepts like „Epoch“ / „Elements“
 - Difficult study design ideas
 - Non-interventional studies
- Objective Templates
 - Understanding of “terms”, we think “model-wise”, not end-user-wise
 - Easily go confusing, using wrong level
 - Workaround, select content -> derive level/type from this
 - Once template are available -> much less issues
- Protocol amendment
 - If metadata needs to change -> change in OSB
 - Milestones -> study lock (final protocol, amendment etc. -> currently just one lock)
- User collaboration
 - Commenting feature requested
 - Needs training, MW & different roles have different knowledge (currently MW & clinical operational lead)

Discussion Notes

- Hard to get an overview
 - How much am I done
 - Basic understanding issues
 - Very hard, culture change, being more standardized
 - Ideally have references / available stuff
- Why we need to standardize
 - Selling standards -> mind shift
 - Difficult to people who wants to invent new things
- Too complex
 - Reduce visibility (remove "studies" or things from screen)
 - Create own/reduces UI
 - All functionalities available through API
- Parallel editing
 - How to see/avoid concurrent conflicts

SWOT – Applying BC's in digital data flows

Strengths

- Reuse the same metadata
- Open source and being open (developer, user)
 - Generic by design, changeable and adoptable
- Define concept once, reuse it everywhere
- One platform for different skillsets (no translation loss)
- Collaboration platform
- Knowledge sharing
- Open concepts, for newcomers, easier also for academia to collaborate
- Graph database: FAIR
- DDF API Adapter

Weaknesses

- Reuse metadata too much (complicated)
- Who would be the best to define a concept
 - Divided by Therapeutic Areas
- Wording/concepts must be understood
- Need maturity on functionality
- Technical and function expensive
- Clarity on how/what to extend (documentation)
- Documentation / Training

Opportunities

- Look more towards FHIR
 - More studies from HER
 - Another level of transformation -> difficult otherwise
- Extend – where does this information comes from, who approved, origin
- Metadata about metadata
- Moving away from sponsor systems, better interoperability
- Customization
- Innovation
- Workflow could help understanding / processes
- Metadata validation checks
- Usage for Analysis, SAP, ADAM

Threats

- Never ending task to link to existing other things (UCUM, LOINC, more and more)
 - Generic way of handling new dicts/standards / dynamic integration
- Adoption when “everything is ready” is too late
- Big walls – much information not accessible
- Adoption takes time
- Technical issues, bugs, performance could impact adoption
- Disclosure of metadata not acceptable by some companies
- Language adoption (English for tool & documentation)

Thank you