

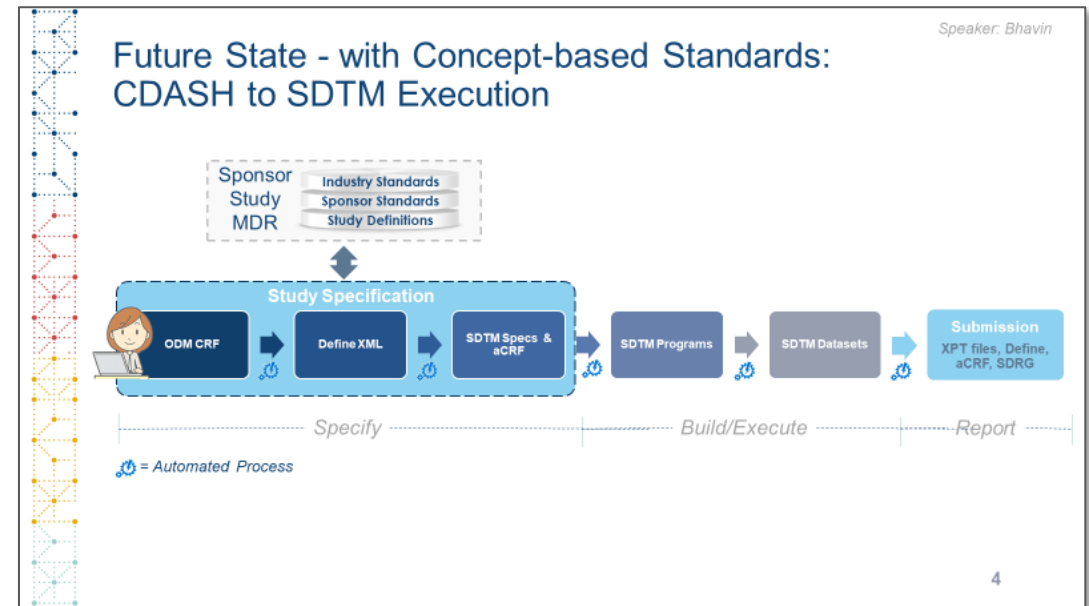
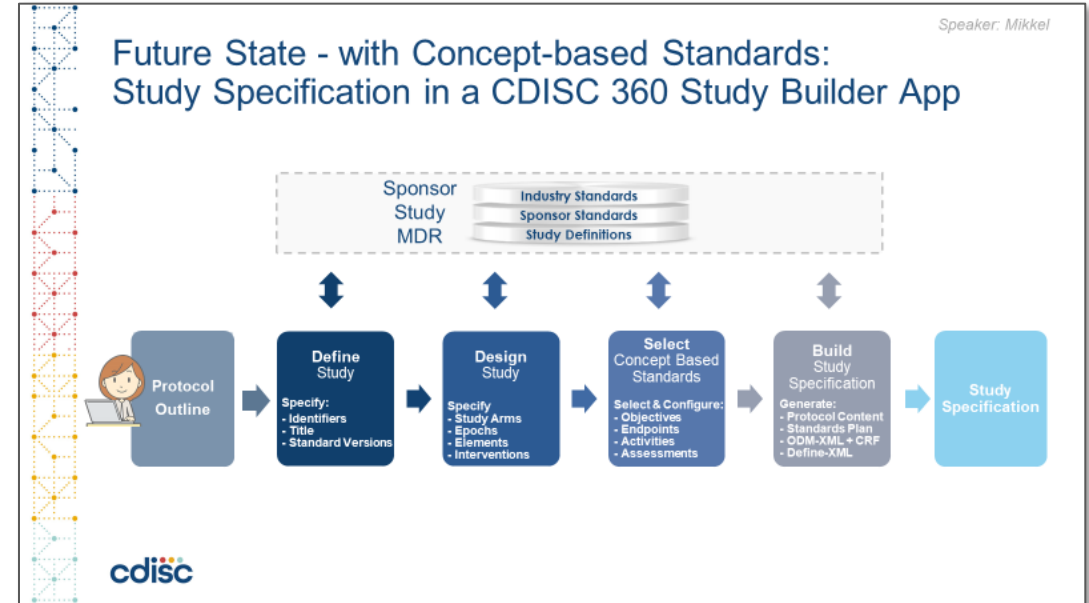
Use concept-based standards in OpenStudyBuilder

Use concept-based standards in OpenStudyBuilder

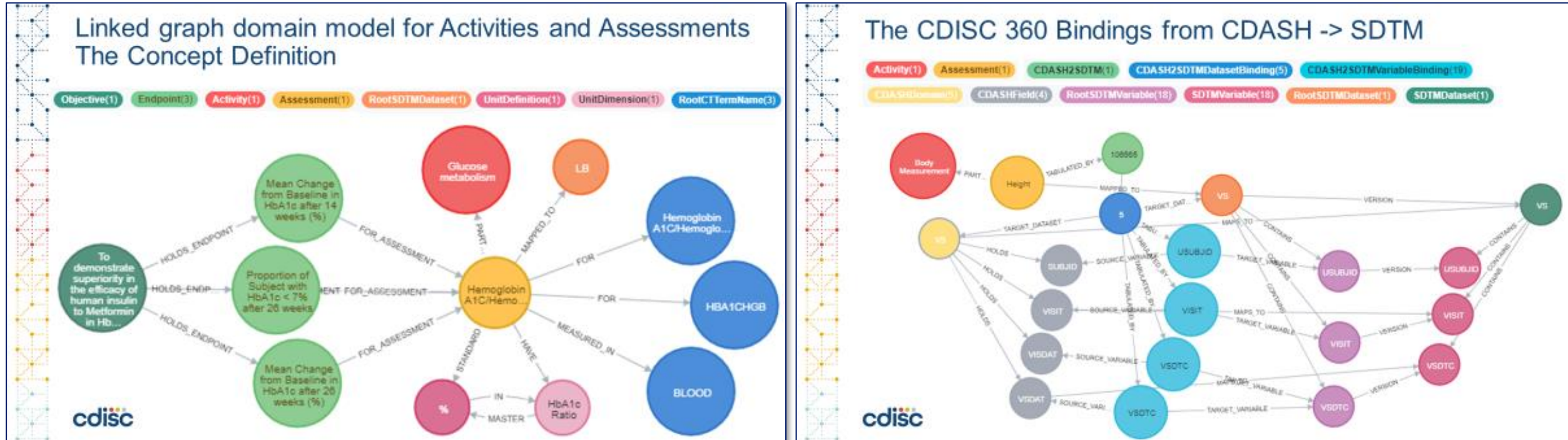
- Recap Concept definition from CDISC 360
 - Slides, white paper
- Demonstrate concept definitions in OpenStudyBuilder sandbox part 1
 - The Assessment Instance, linked to SDTM and CRF definitions
- Explain draft linked graph data model
- Time to play and explore, make screen dumps with call-out statements
 - Niels available on separate online meeting to give support
- Break
- Demonstrate concept definitions in OpenStudyBuilder sandbox part 2
 - Objective – Endpoint – Assessment – Assessment Instance
- Brainstorm session on SWOT analysis for use of concept-based standards
- Plan presentation for plenum

Apply concept-based data standards end-to-end

- From protocol preparation through study conduct to reporting and submission of applications to health authorities
 - and with reference to externally-compliant concept-based data standards and terminology
- Ensuring build-in compliance, and enabling more automation, efficient reuse across studies and projects, and aggregation of study specification details for insights



Concept model from CDISC 360 WS4



- We have used this as the basis – and are ongoingly continuing the model development
- See more info in [CDISC 360 Project White Paper.pdf](#)

OpenStudyBuilder Concepts model

- Currently not visible from within the app
- Some parts are in the development database
 - But simpler to illustrate from our sandbox database
 - Let's have a look via NeoDash and the Browser

Note:

Only these have linkage in the sandbox:

- Body Weight
- Height
- Pulse
- Diastolic Blood Pressure
- Systolic Blood Pressure

Demo Dashboard

Introduction

Browse Concepts

Control Terminology

Select Assessment Instance

AssessmentInstance name

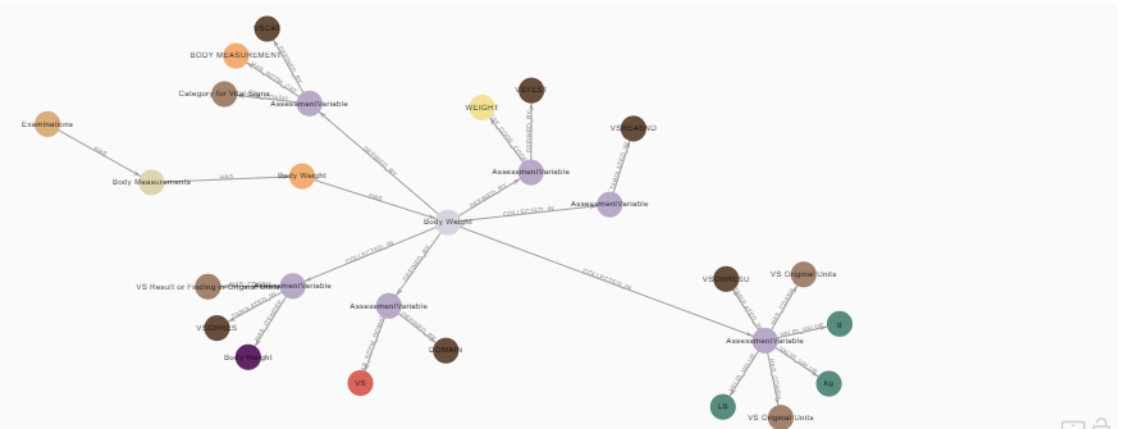
Body Weight

Assessment Instance

| Field | Value |
|--------------------|-------------------|
| ActivityGroup | Examinations |
| ActivitySubGroup | Body Measurements |
| Activity | Body Weight |
| AssessmentInstance | Body Weight |
| SDTMDomain | VS |

1-5 of 5 < >

Concept Graph



SDTM Column Level Metadata

| Domain | Variable | Label | Core | Role | sdmvar.xmlcodelist |
|--------|----------|-------------------------------------|------|-------------------|--------------------|
| VS | VSORRES | Result or Finding in Original Units | Exp | ResultQualifier | |
| VS | VSORRESU | Original Units | Exp | VariableQualifier | VSRESU |
| VS | VSREASND | Reason Not Performed | Perm | RecordQualifier | |
| VS | VSTEST | Vital Signs Test Name | Req | SynonymQualifier | VSTEST |
| VS | VSCAT | Category for Vital Signs | Perm | GroupingQualifier | VSCAT |

1-5 of 6 < >

SDTM Value Level Metadata



| Domain | Variable | Label | sdmvar.xmlcodelist | Value |
|--------|----------|--------------------------|--------------------|------------------|
| VS | VSORRESU | Original Units | VSRESU | LB |
| VS | VSORRESU | Original Units | VSRESU | kg |
| VS | VSORRESU | Original Units | VSRESU | g |
| VS | VSTEST | Vital Signs Test Name | VSTEST | WEIGHT |
| VS | VSCAT | Category for Vital Signs | VSCAT | BODY MEASUREMENT |

1-5 of 6 < >

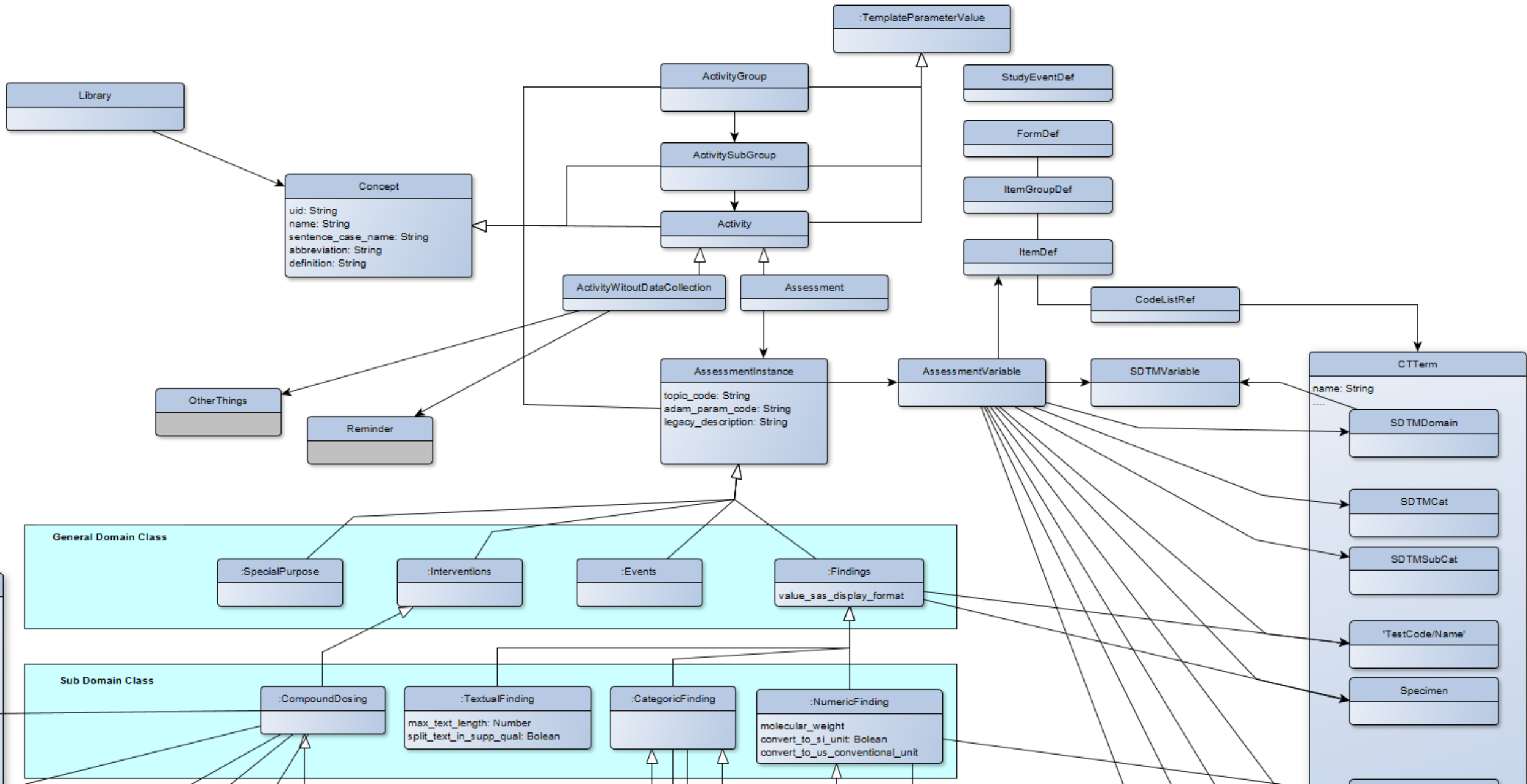
Concept Metadata



| ActivityGroup | ActivitySubGr... | AssessmentI... | TopicCode | AdamParamC... | Order | ODMItemDef... | ODMItemDefL... | ODMItemDefT... | SDTMVariable | SDTMLabel | SDTMRole | SDTMCore | Codelist | SubmissionV... | PreferredName | ConceptID |
|---------------|------------------|----------------|-------------|---------------|-------|---------------|----------------|----------------|--------------|------------------|------------------|----------|----------|----------------|---------------|-----------|
| Examinations | Body Measurem | Body Weight | BODY_WEIGHT | WEIGHT | 1 | I.WEIGHT | Body Weight | Num | VSORRES | Result or Findin | ResultQualifie | Exp | | null | null | null |
| Examinations | Body Measurem | Body Weight | BODY_WEIGHT | WEIGHT | 2 | | | | VSORRESU | Original Units | VariableQualifie | Exp | VSRESU | null | null | null |
| Examinations | Body Measurem | Body Weight | BODY_WEIGHT | WEIGHT | 2 | | | | VSORRESU | Original Units | VariableQualifie | Exp | VSRESU | null | null | null |
| Examinations | Body Measurem | Body Weight | BODY_WEIGHT | WEIGHT | 2 | | | | VSORRESU | Original Units | VariableQualifie | Exp | VSRESU | null | null | null |
| Examinations | Body Measurem | Body Weight | BODY_WEIGHT | WEIGHT | 3 | | | | VSREASND | Reason Not Per | RecordQualifier | Perm | | null | null | null |

1-5 of 5 < >

Graph model for concepts in OpenStudyBuilder



Use concept-based standards in OpenStudyBuilder

Strengths

- Concepts will connect standards end-2-end
- Change workflow
 - Select Concepts for your study
 - Configure possible data collections
 - No longer make data collection specs and mappings!
- Enable automation
- Support use of better tools, benefitting all skill areas

Weaknesses

- Will limit CRF form layout options
- Lack of flexibility
- New skill areas must learn to work with concepts
 - Motivated by using data faster and in new ways
- Governance will be very critical

Opportunities

- Link to other models, like FIHR, OMOP, ...
- Link to comparing with other studies on clinicaltrials.gov
- Tools is needed for working with Concepts

Threats

- Manual created CRF's may not fit
- Resistance to learn the way to work with Concepts
- Lacking clear and shared definitions for concepts
 - BC versus Activity versus Assessment

The roadmap ahead for concept based standards

Novo Nordisk StudyBuilder

- Migrate concepts from legacy MDR
- Complete model for Findings
- Complete model for CRF with linkage to assessment model
- Extend model for Interventions and Compounds
- Extend model for Events related data

OpenStudyBuilder

- Share data models
- Share test data
- Evaluation environments
- Join hackathons and workshops

CDISC Library

- Mine Define.xml
- Build CDISC Library model
- TA linkage
- Shared curation and collaboration

Other initiatives