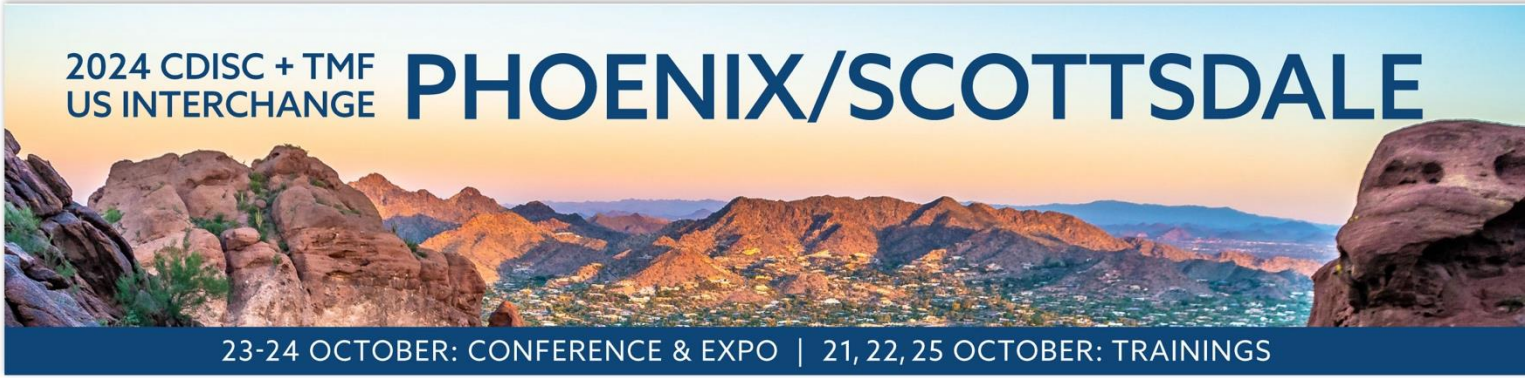
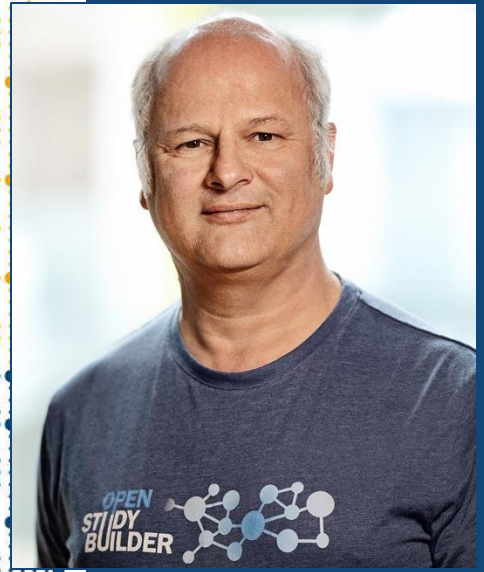


Activity Concepts in OpenStudyBuilder

Mikkel Traun, Solution Architect, Novo Nordisk A/S

Meet the Speakers



Mikkel Traun

Title: Solution Architect

Organization: Novo Nordisk A/S

Mikkel is solution architect for the next generation study builder and data standards repository solution at Novo Nordisk. Mikkel is also an active member of the TransCelerate and CDISC Digital Dataflow project, and previously the CDISC 360 project. He has worked as a principal system developer supporting the clinical data warehouse solution and the CDISC implementation at Novo Nordisk. Previously he has worked on several projects in pre-clinical, clinical and outcome research.

Disclaimer and Disclosures

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

- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
- *The author(s) have no real or apparent conflicts of interest to report.*

The data landscape is disconnected

Many Data Sources

***MDR and SDR** (Digital Protocol)*
Dictionaries, unit conversion rules, objectives, endpoints, in-/exclusion criteria, schedule of activities, arms, interventions, etc

CTMS
Study ID, sites, investigators, milestones, metrics, protocol deviations

External Standards
CDISC CT, MedDRA, SNOMED CT, WHO Drug, ISO …

IWRS/RTSM
Randomisation number and batch numbers

EDC
Informed consent obtained, subject status, demographics, medical history, concomitant medication, dose and compliance, adverse events, vital signs, body measurements, hypoglycaemic episodes, ECG interpretation, pregnancy test results, queries, etc.

Safety
SAE & pregnancy reporting

Laboratories
Biochemistry, hematology, glucose metabolism, antibodies, trial product concentrations, serology, drug tests, pregnancy test, proteomic and genomic sample tracking, etc.

CGM
Date, time, glucose, visit

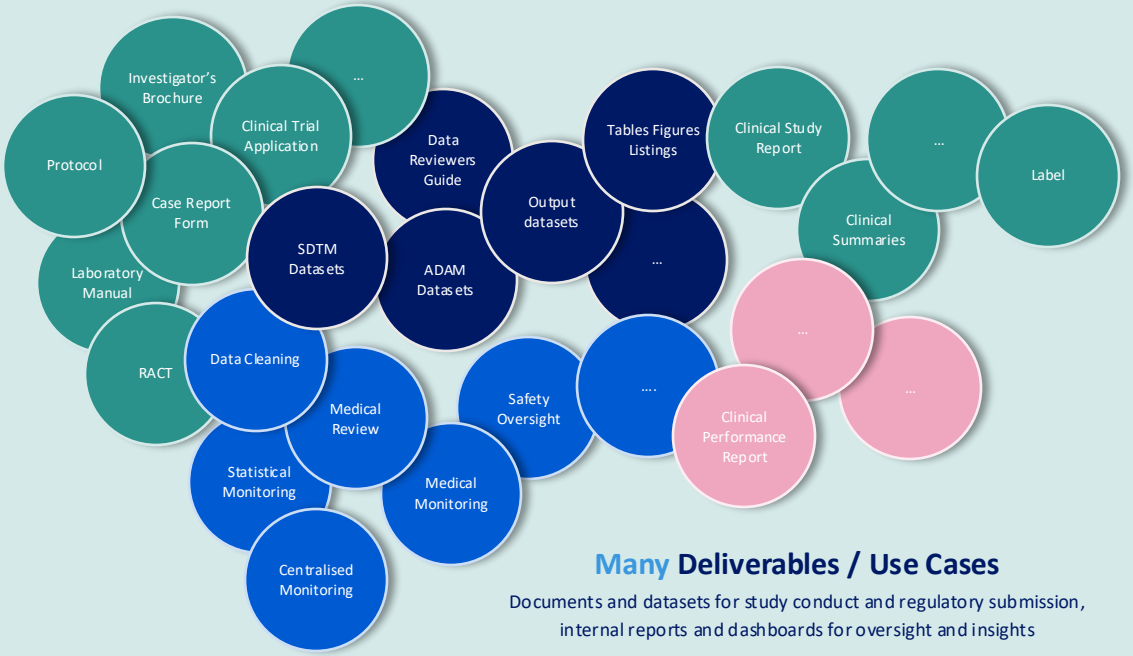
eCOAs
Questionnaires e.g. SF36, CSSRS, PHQ9
Diaries e.g. dose/compliance, hypoglycaemic episode, AE, bleeding event, BG meter readings
Sit and stand test

Imaging
Dexa scan, X-ray, MR

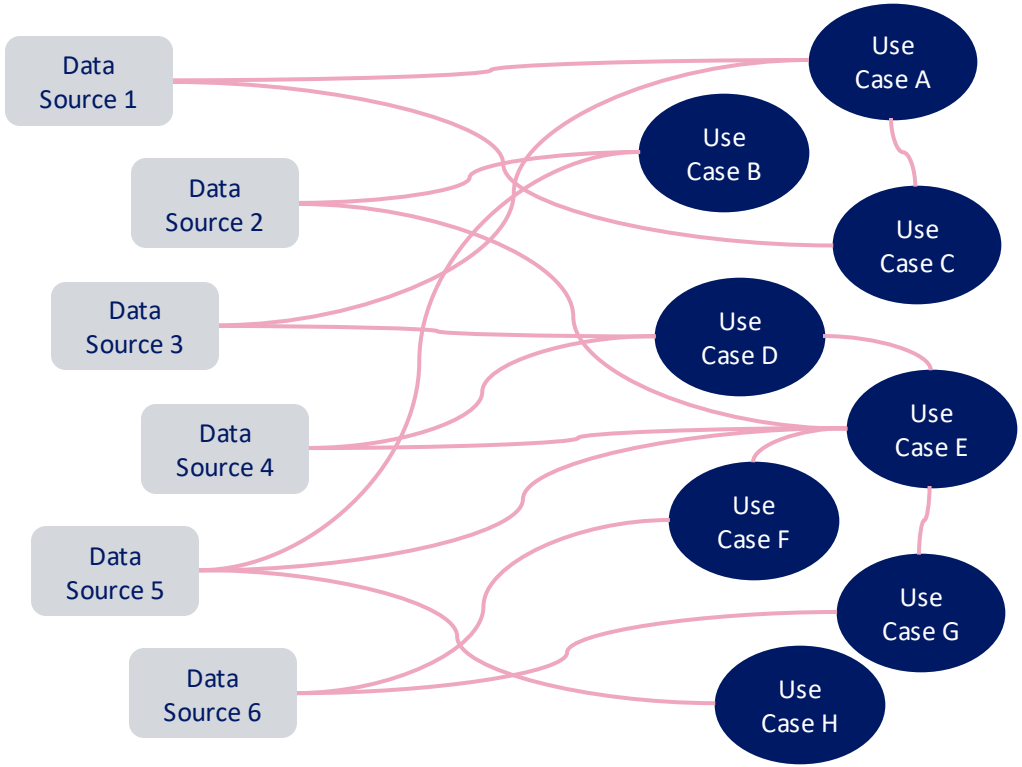
Data Lakes
Harmonized historic study data

Master Data
Medicinal product data

Other data
…



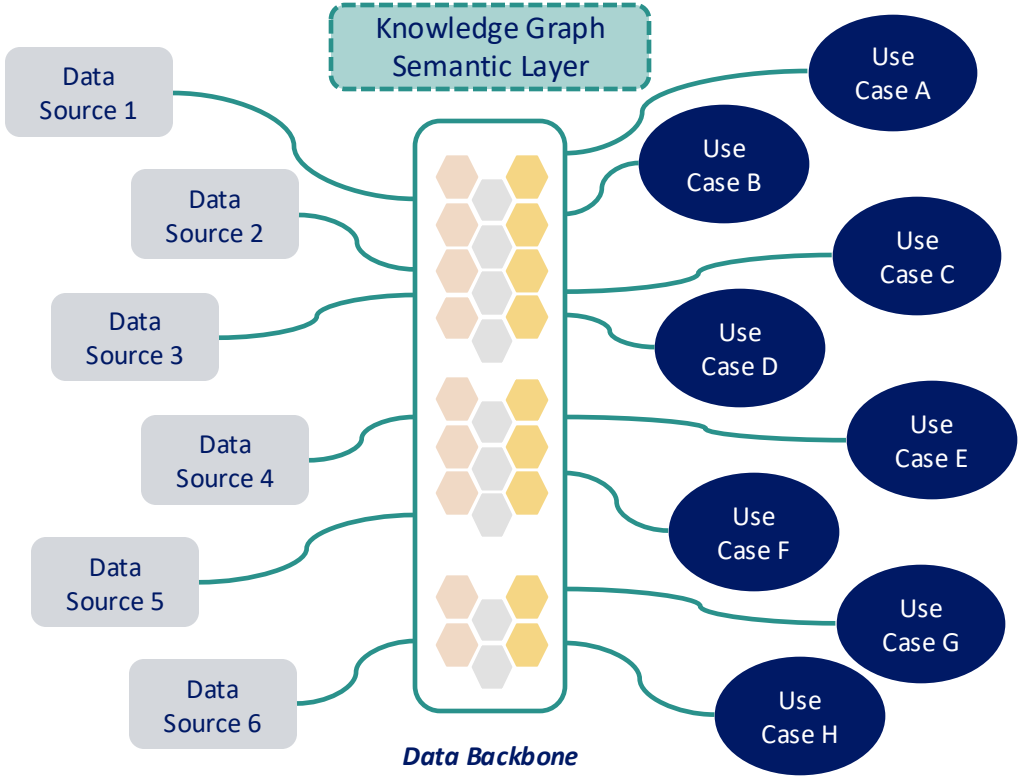
Today's **barrier** for efficiency and speed



Many to **Many** to **Many**

- Limited overview and transparency
- High-risk of inconsistencies
- Inefficiency due to re-do rather than reuse
- Lag-time between data availability and data ready for use

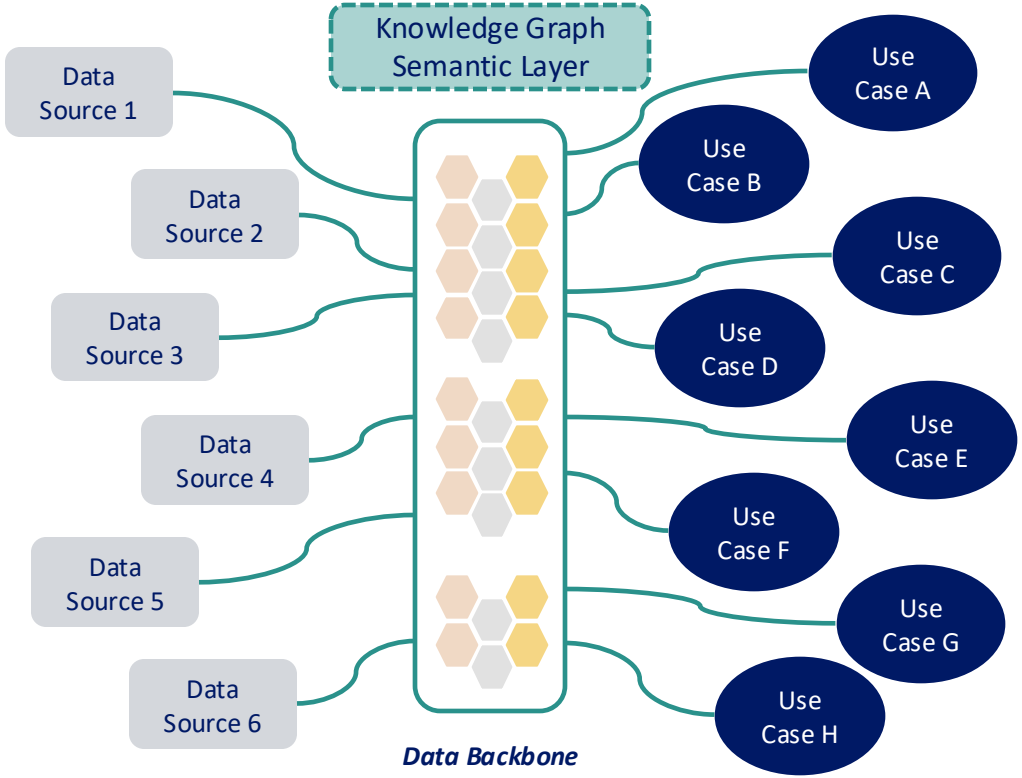
Tomorrow's **opportunity** for efficiency and speed

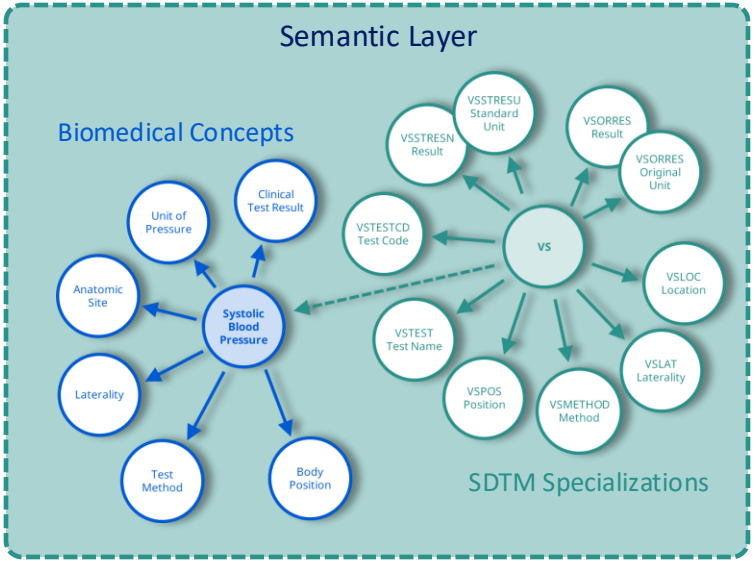


Many to **One** to **Many**

- Overview and transparency
- End-to-end consistency
- Efficiency through reuse
- Faster from data availability to data readiness

Tomorrow's **opportunity** for efficiency and speed





What is the OpenStudyBuilder?…

A NEW APPROACH TO STUDY SPECIFICATION

- Compliance with external and internal standards
- Facilitates automation and content reuse
- Ensures a higher degree of end-to-end consistency

3 ELEMENTS OF OpenStudyBuilder

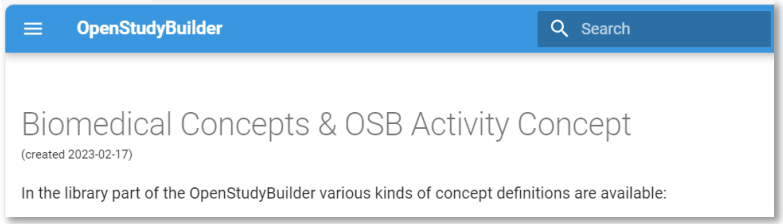
- **Clinical Metadata Repository (clinical MDR)**
  (central repository for all study specification data)
- **OpenStudyBuilder application / Web UI**
- **API layer**
  (allowing interoperability with other applications)
  (DDF API Endpoint – enabling DDF SDR Compatibility)

clinical **MDR**

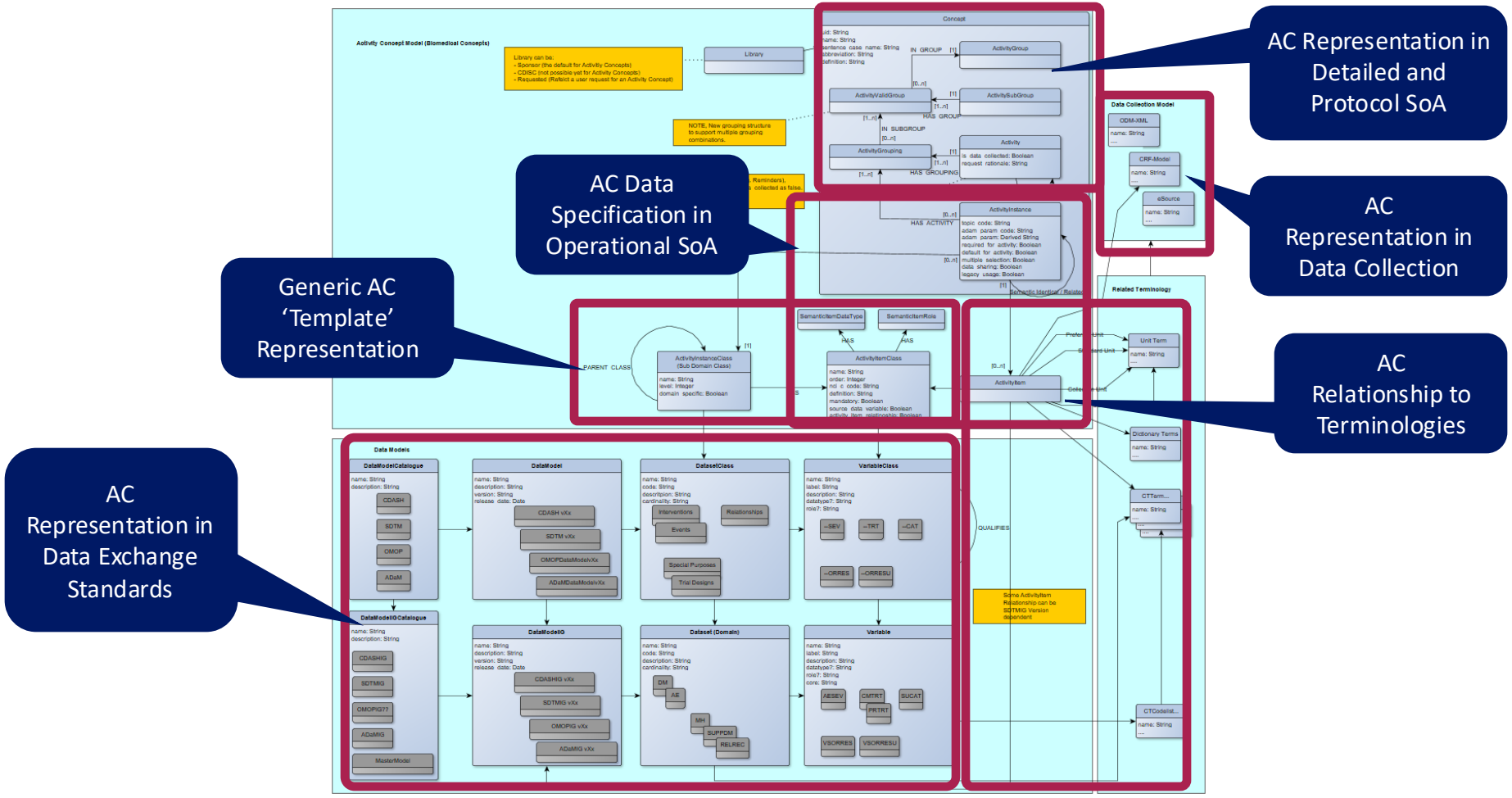
BC in OpenStudyBuilder := Activity Concepts

- 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 :=** current CDISC **Biomedical Concepts**

https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_activity_concept/



Activity Concept (AC) data model in StudyBuilder



OpenStudyBuilder Activity Concept data model (BC)

ActivityGroup ActivitySubgroup	***CDISC BC:*** Seem to be similar a parent BC at a high level. Often demoed as a CRF form name. ***OSB AC:*** Grouping of activities. The activity group or subgroup level can be what you decide to show in the protocol schedule of activities. May be like a CRF form names, but not necessarily, the clinical term relevant to show in the protocol.
Activity	***CDISC BC:*** 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. ***OSB AC:*** If relating to data collection, resulting in a semantic logical observation, this can depending on context and qualifiers have different identifications. If not related to data collection then to a semantic specific activity. At the most detailed level as needed in protocol SoA
ActivityInstance	***CDISC BC:*** Similar to a SDTM specialisation (but for an ADaM PARAM). ***OSB AC:*** The specific identification of the semantic logical observation, this includes reference to context and qualifier values. Primary identification is for ADaM BDS PARAM/PARAMCD or column name in ADSL. Also include internal uid identification as well as internal topic code.
ActivityItem	***CDISC BC:*** Similar to SDTM Variable but can be connected to any data exchange standards. ***OSB AC:*** Linking to related data model variables as well as terminology codes.

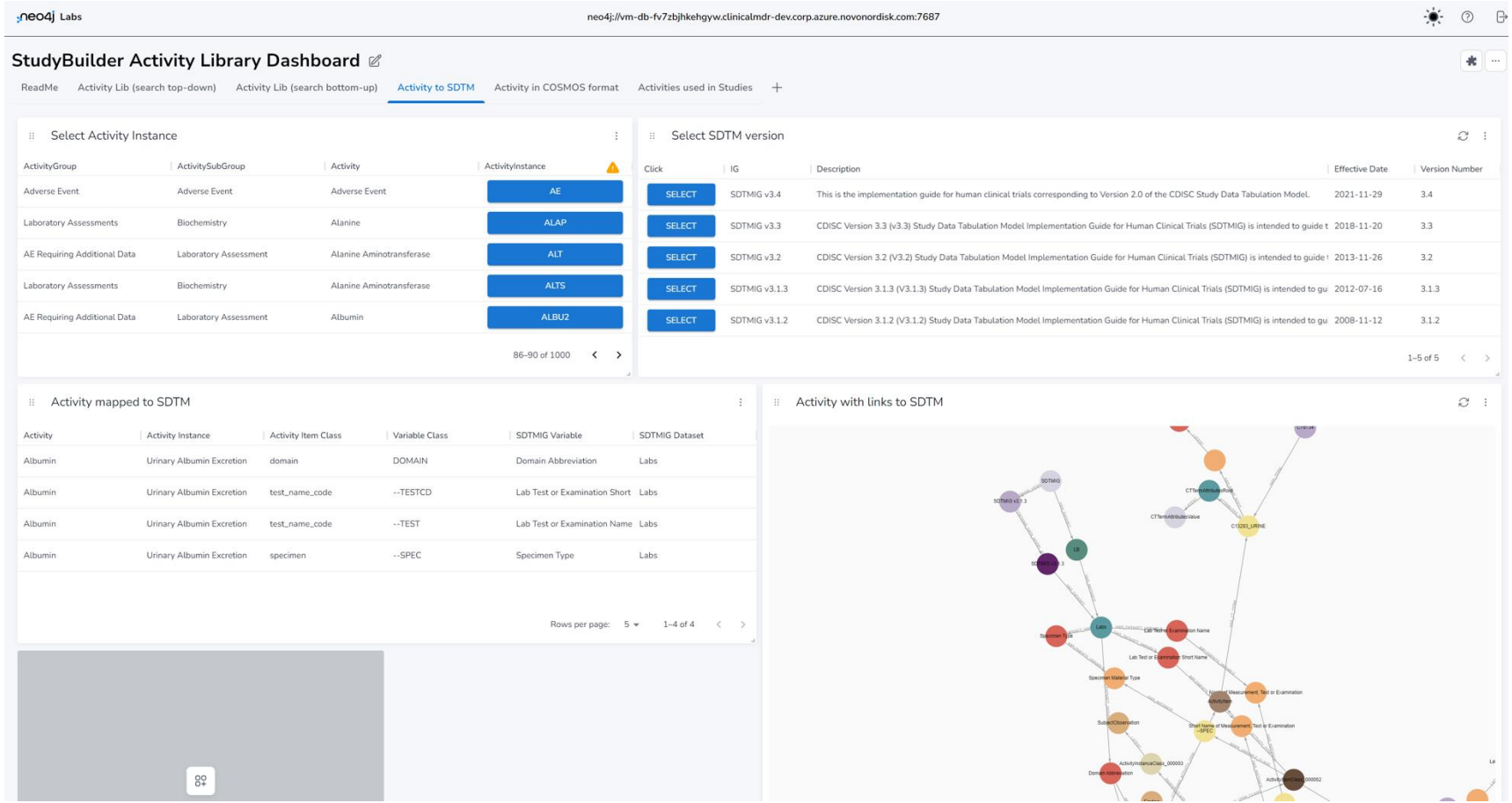
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Activities
Units
CRFs
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
Admin Definitions
List

Systolic Blood Pressure

Overview | OSB YAML | COSMoS YAML

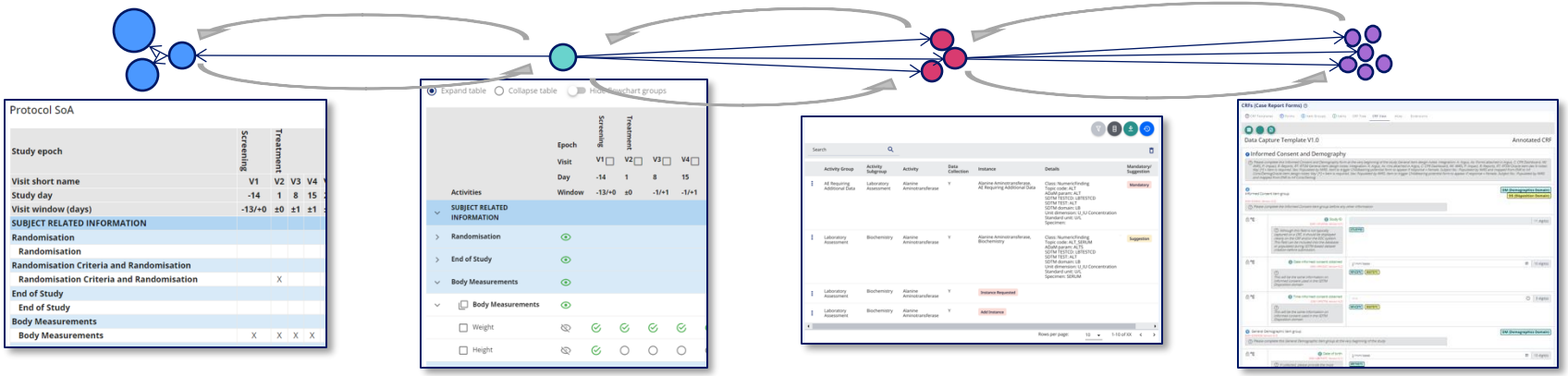
Name	Systolic Blood Pressure		
Sentence case name	systolic blood pressure		
Version	1.0	**Status**	Final
Start date	Apr 22, 2024, 1:15 PM	**End date**	None
Definition			
Activity instance class	NumericFinding		
Abbreviation		**Library**	Sponsor
NCI Concept ID			
ADaM parameter code	SYSBP	**Topic code**	BP_SYSTOLIC

NeoDash reports to view Activity to SDTM Variables




OPEN STUDY BUILDER
Studies
Library
Reports
SELECT STUDY
MT (MIKKEL TRAUN)
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Activities
Units
CRFs
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
Admin Definitions
List
Library / Concepts / Activities / Activities Instances / Systolic Blood Pressure
Systolic Blood Pressure
Overview
OSB YAML
COSMoS YAML
OSB Activity Concepts is made compatible with COSMoS model
categories:
- Vital Signs
conceptId: null
dataElementConcepts:
- conceptId: C117221
dataType: string
exampleSet: []
href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C117221
ncitCode: C117221
shortName: original_result
- conceptId: C82586
dataType: string
exampleSet:
- mmHg
href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C82586
ncitCode: C82586
shortName: original_unit
- conceptId: C82515
dataType: Date time
exampleSet: []
href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C82515
ncitCode: C82515
shortName: collection_datetime

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

Activity Concepts := Biomedical Concepts

- **Can be linked to from:**
  - Objectives
  - Endpoints
  - Criteria
  - Analysis Concepts
- **Will link to**
  - Protocol representation
  - Data Specification
  - Data Collection Specification

- **Will support automation in**
  - Protocol Document Generation
  - Data Collection system setup
  - Data ingestion verification
  - SDTM generation
  - ADaM generation

Thank You!

Questions or need more information?

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OpenStudyBuilder contact: OpenStudyBuilder@gmail.com