



2024 CDISC + TMF
US INTERCHANGE

PHOENIX/SCOTTSDALE

23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS

Activity Concepts in OpenStudyBuilder

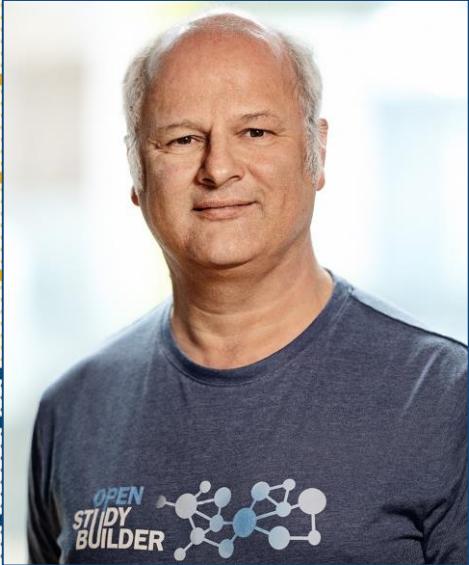
Mikkel Traun, Solution Architect, Novo Nordisk A/S

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.



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- *{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.*

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

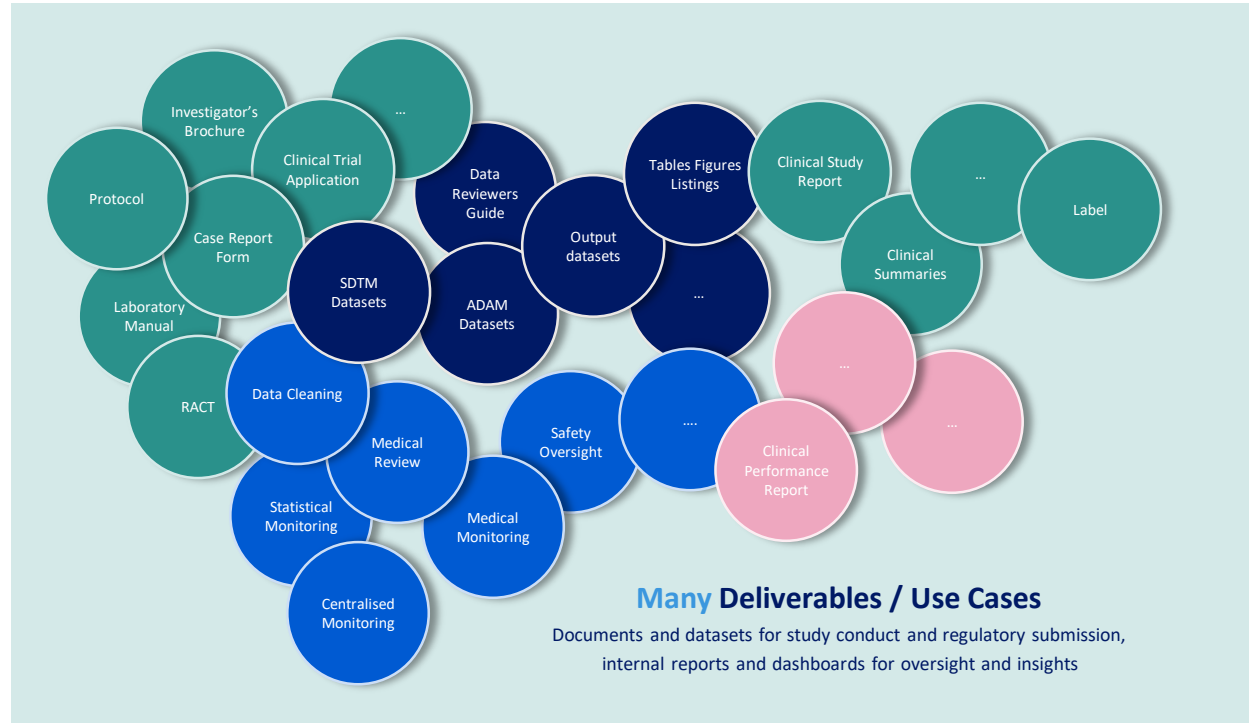
Master Data

Medicinal product data

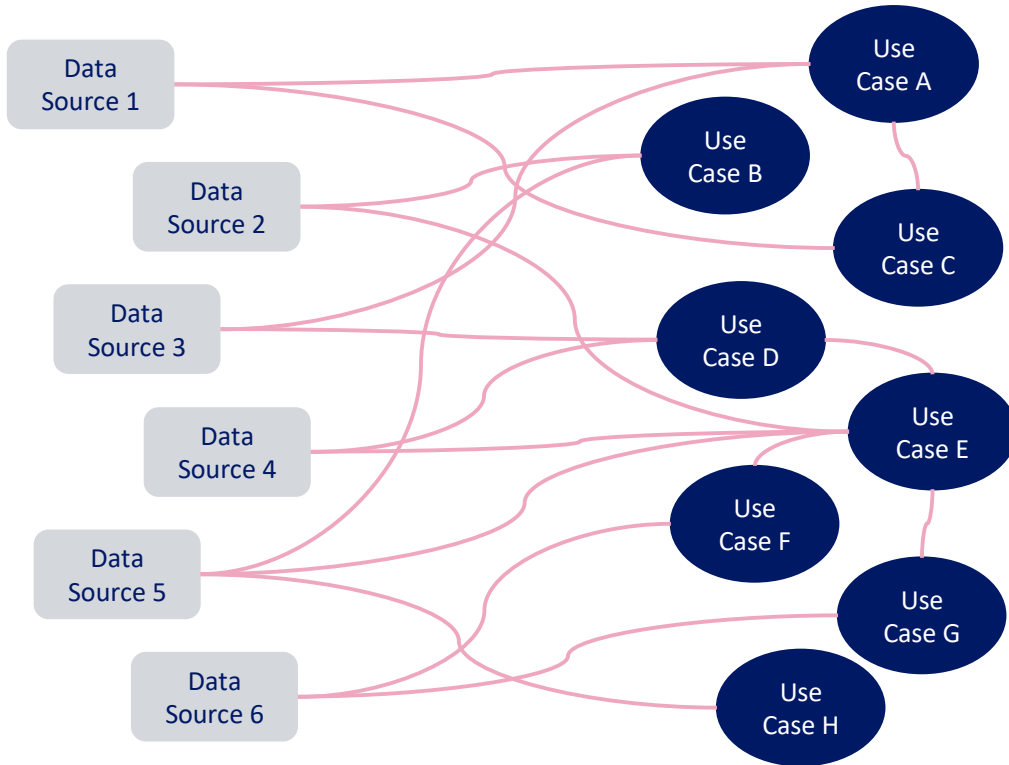
Other data

...

The data landscape is disconnected



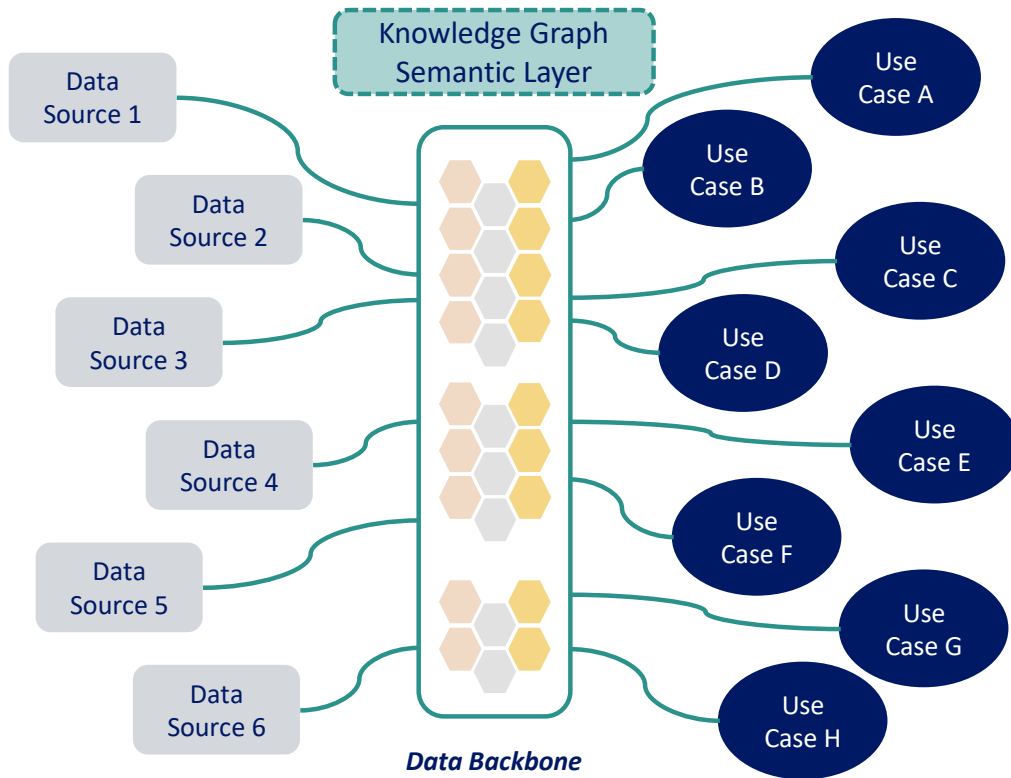
Today's **barrier** for efficiency and speed



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

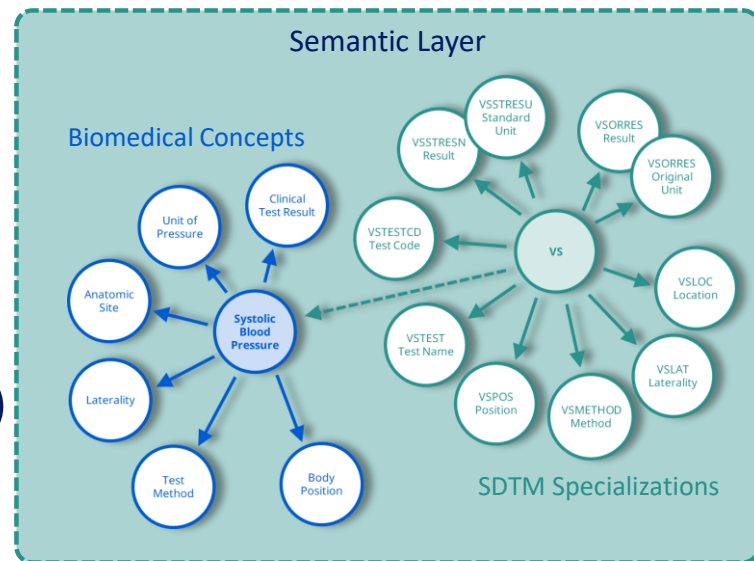
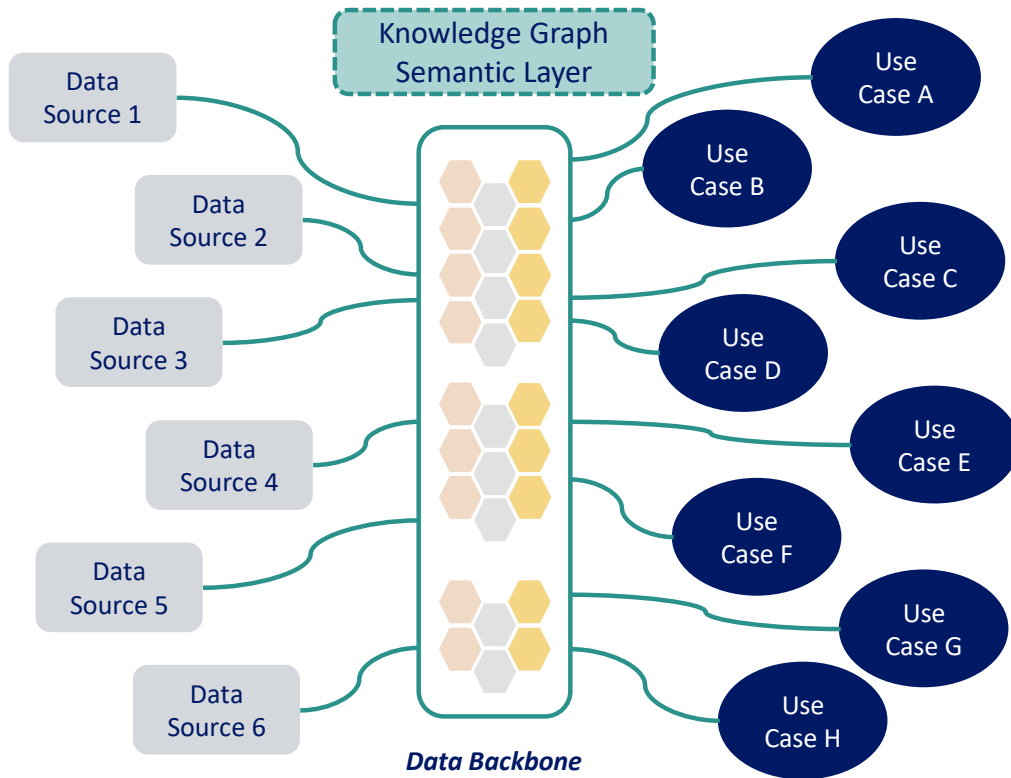
Tomorrow's **opportunity** for efficiency and speed



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

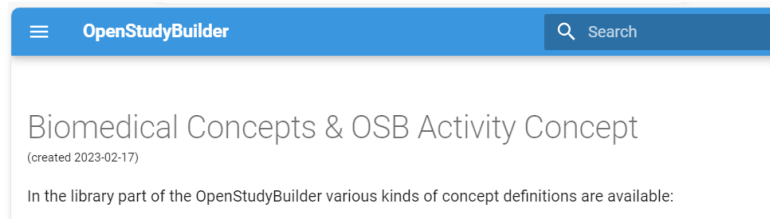
- **Clinical Metadata Repository (clinical MDR)**
(central repository for all study specification data)
- **OpenStudyBuilder application / Web UI**
- **API layer**
(allowing interoperability with other applications)
(DDF API Endpoint – enabling DDF SDR Compatibility)



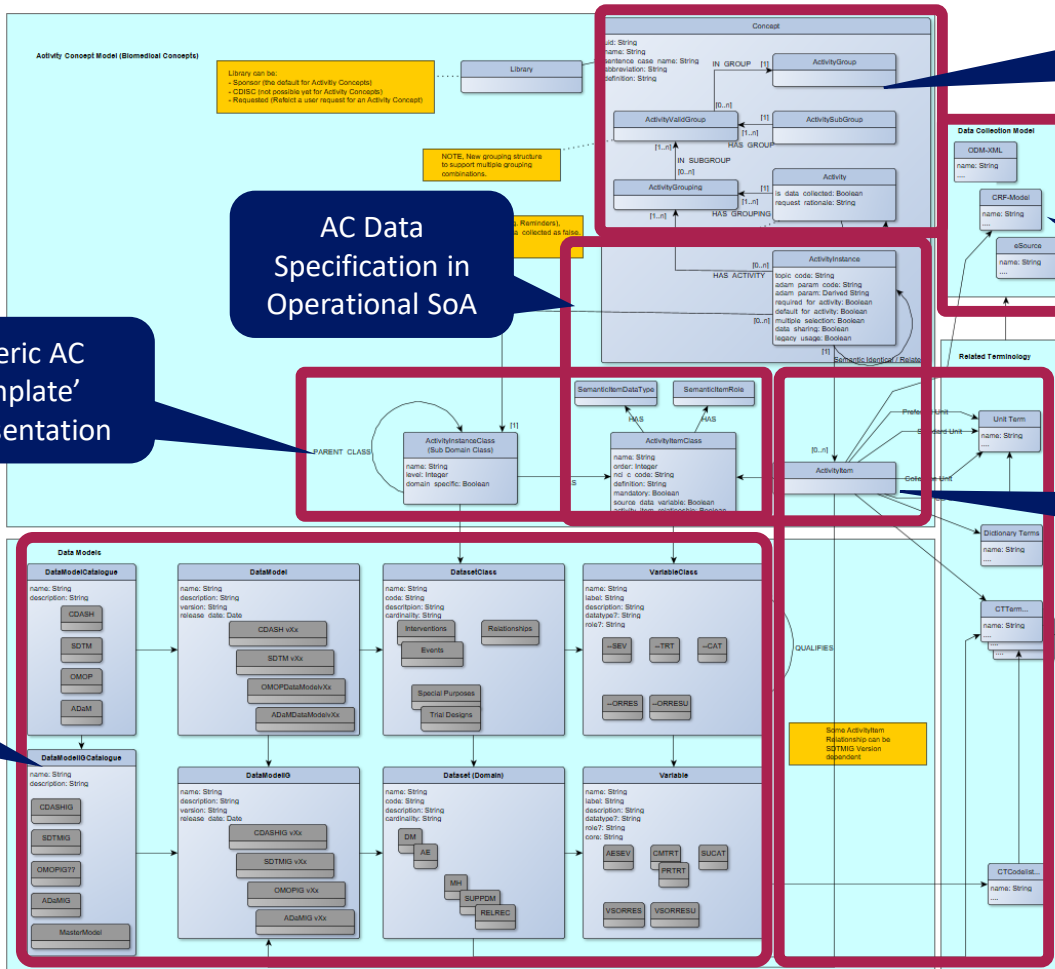
BC in OpenStudyBuilder := Activity Concepts

- 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



AC Representation in Detailed and Protocol SoA

AC Representation in Data Collection

AC Relationship to Terminologies

Generic AC 'Template' Representation

AC Data Specification in Operational SoA

AC Representation in Data Exchange Standards

OpenStudyBuilder Activity Concept data model (BC)

ActivityGroup

CDISC BC: Seem to be similar a parent BC at a high level. Often demoed as a CRF form name.

ActivitySubgroup

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

Library / Concepts / Activities / Activities Instances / Systolic Blood Pressure

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

neo4j Labs
neo4j://vm-db-fv7zjhkegyw.clinicalmdr-dev.corp.azure.novonordisk.com:7687

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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	ALBUZ

86-90 of 1000 ⏪ ⏩

⌵ 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

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
```



About Library



Process Overview



Code Lists



Dictionaries



Concepts



Activities

Units

CRFs



Syntax Templates



Template Instantiations



Template Collections



Data Exchange Standards



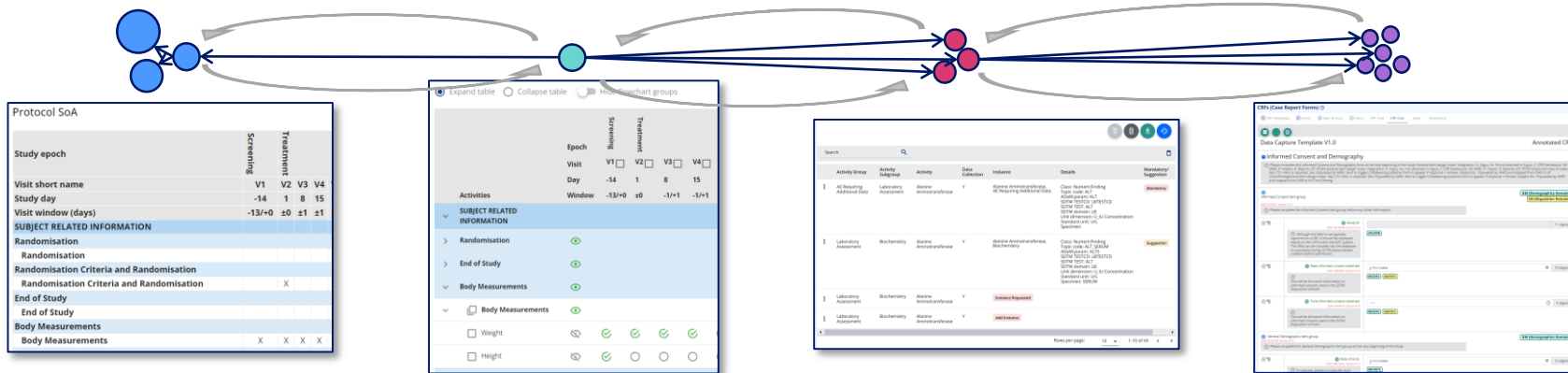
Admin Definitions



List



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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