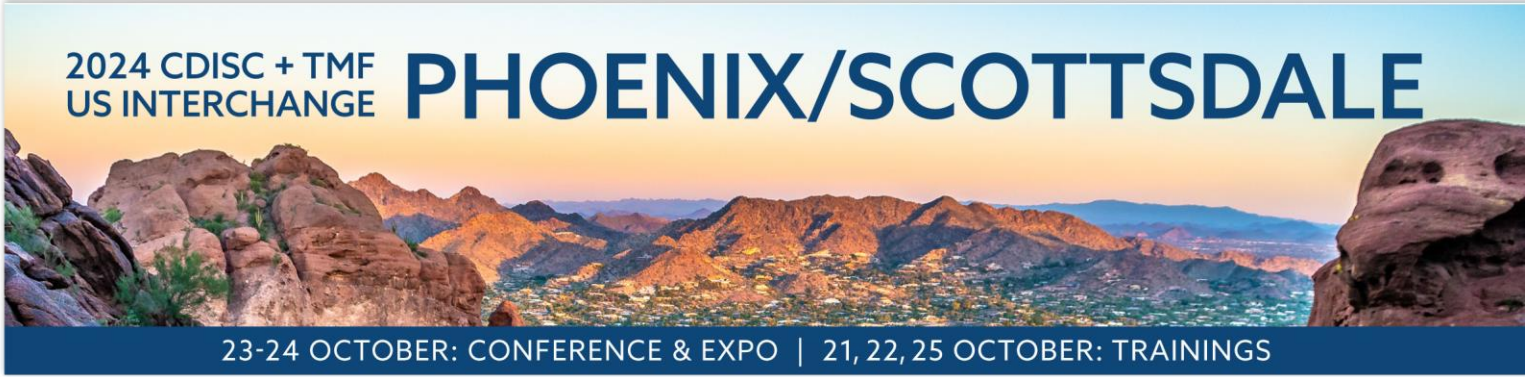
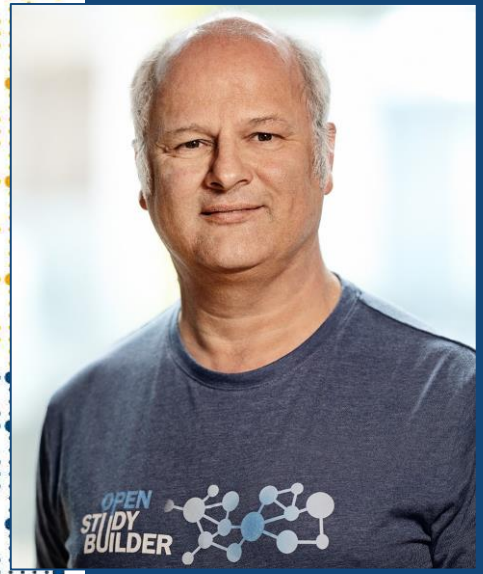


Schedule of Activities in OpenStudyBuilder

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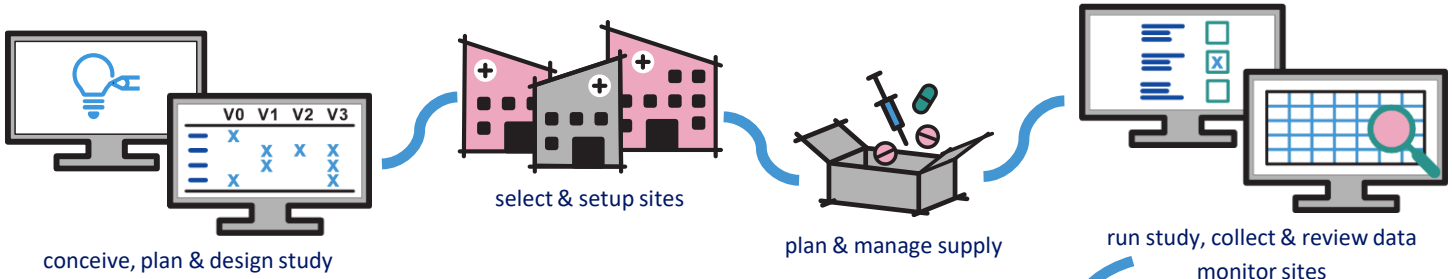
- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
- *The author(s) have no real or apparent conflicts of interest to report.*

ONE study journey



An efficient and scalable study journey connected by **one digital data flow** and simplified by **one common data model**§

§ *Modular and extensible interconnected domain-centric models with semantic metadata (incl taxonomies) and relations*

ONE Common Data Model

A schematic definition of **modular** and **extensible business entities** with **semantic metadata** that simplify integrations and application development

Biomedical Concepts is the foundation for this model

The common semantic data model does not contain the actual data but shows how the data should be structured, the terminology to use, and how things can be linked (combined)

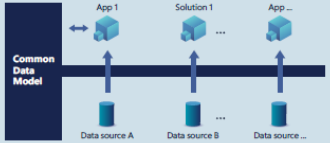
[CDISC Biomedical Concepts | CDISC]

Pharma Context

INTEGRATE & DISAMBIGUATE DATA WITH
THE COMMON DATA MODEL

An **open-sourced** definition of modular and extensible **business entities** with **semantic metadata** that **simplify the challenges of application development and data integration.**

The Common Data Model unifies data in a well-known schema with semantic consistency.



App developers and backend integrators can develop **independently.**

Enables quick application deployment and development, out-of-the-box intelligence, and much more.

Apps, reports, augmentation of AI (incl. ML) ..

COMMON DATA MODEL SCHEMA

external models, taxonomies & document/documentation structures

CDISC BRIDGE	ICH MedDRA	ICH M11
CDISC USDM	CDISC CT	CDISC TMF
CDISC CDASH	ISO 8601	ICH E3
CDISC SDTM	ISO 3166	ICH M4
CDISC ADAM	UCUM	ICH M8
OMOP CDM	WHO DRUG	
ISO IDMP		

additional internal
... other external models and taxonomies

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

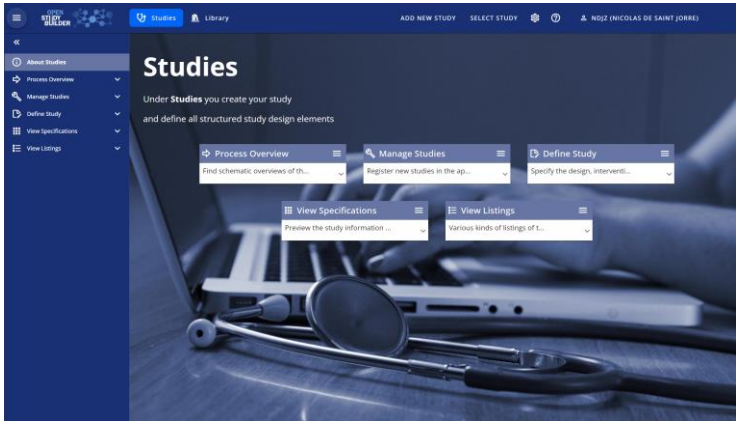
3 ELEMENTS OF OpenStudyBuilder

- **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 Adaptor – enabling DDF SDR Compatibility)

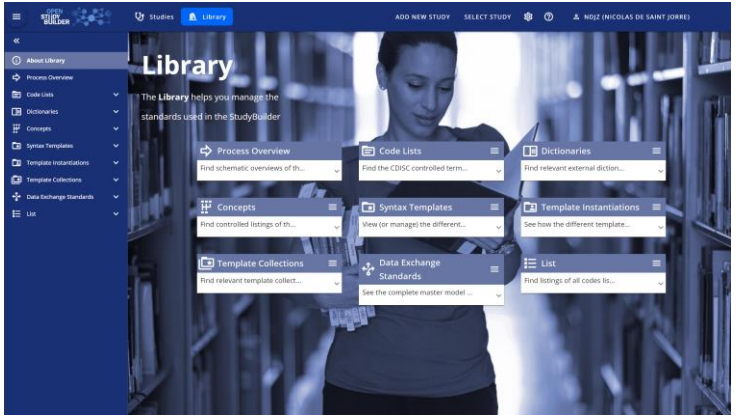
clinical **MDR**

OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES



LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	



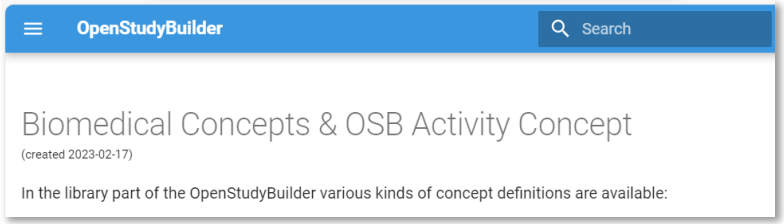
What is the key elements of OpenStudyBuilder

- Library holding BCs
  - Named as Activity Concepts in OSB
- Study Module supporting Study Design and SoA
- SoA is key component
  - Linking to BCs
  - Supporting the Digital Data Flow (DDF) vision
- In OSB we seek to achieve this by defining the SoA at different levels for dedicated parts of the Digital Data Flow

Clinical **MDR**

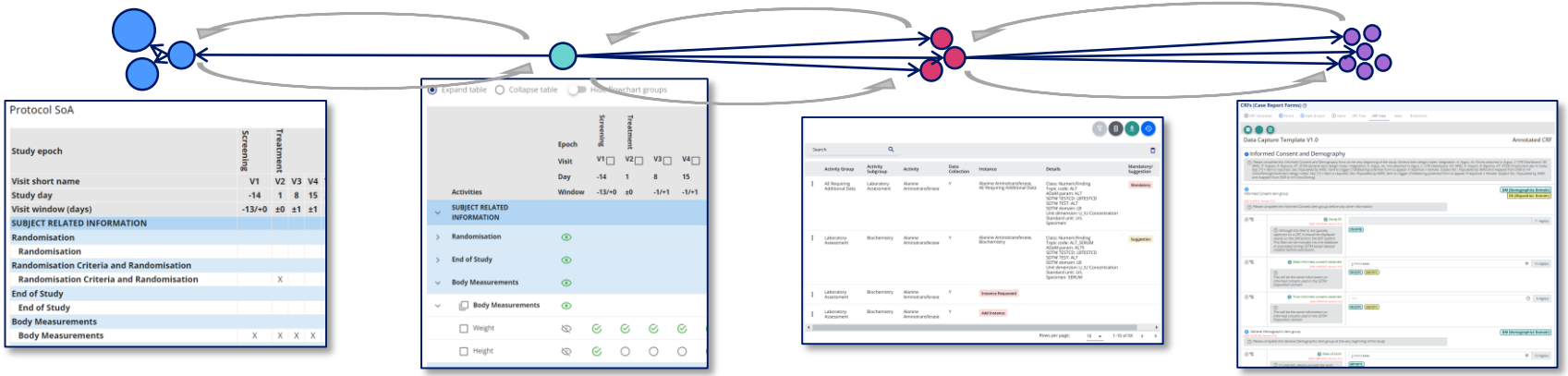
BC in OpenStudyBuilder := Activity Concepts

- 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/

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

Selection process of Activities for SoA

For Protocol Outline / Protocol

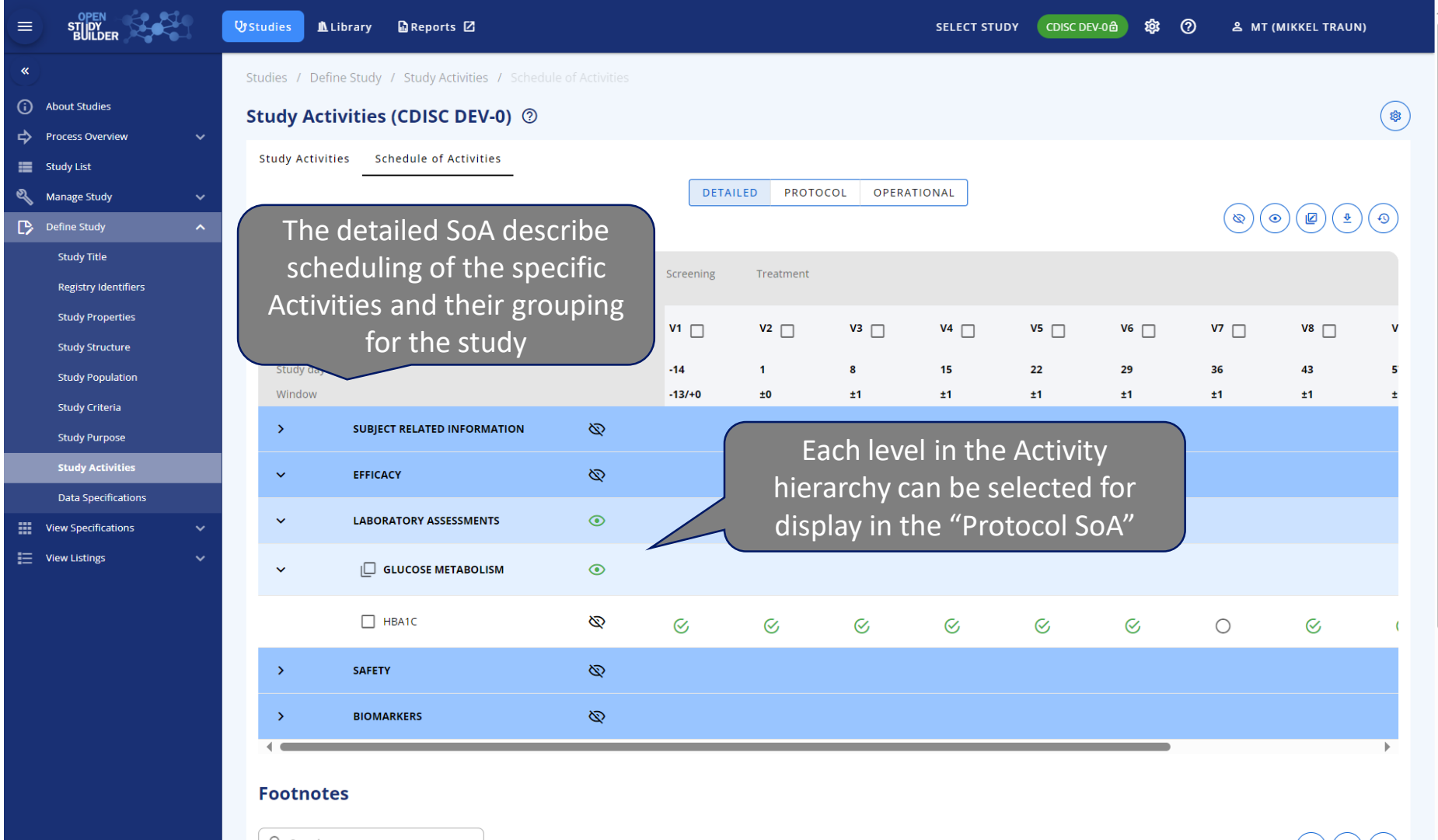
- Select Activities in relevant grouping
- When selecting an Activity within a specific grouping, then this will drive ActivityInstance – this should be visible for Protocol Writers (like a COL)
  - Some ActivityInstances can be mark as default for an Activity, and will then be pre-selected
  - Some ActivityInstances can be marked as mandatory – and cannot be un-selected
- Select what to display or hide in high-level Protocol SoA

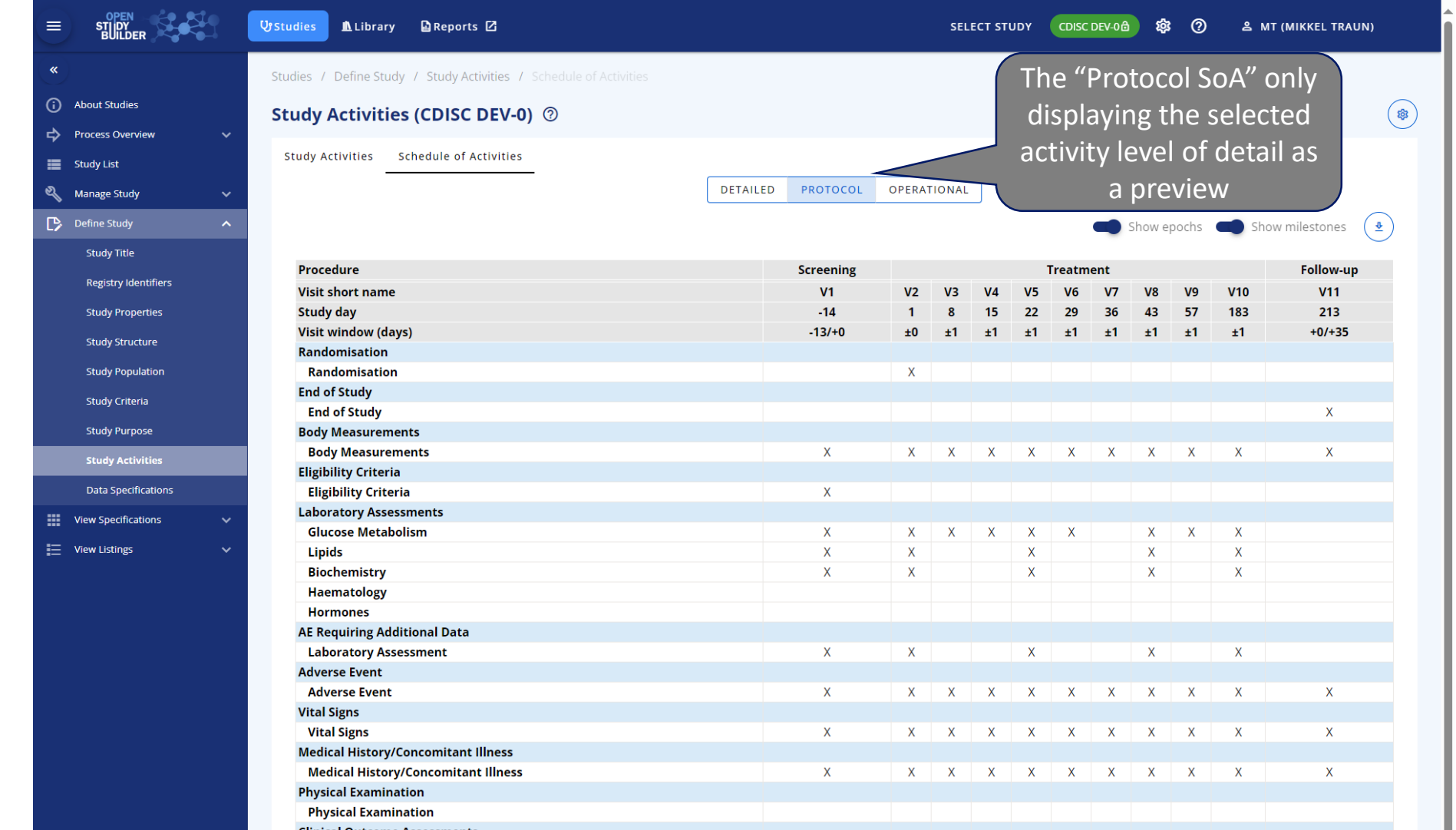
For Operational Data Specification

- Confirm or Select Activity Instances for each selected Activity
- If the correct ActivityInstance will change Grouping – this will require a change to the Protocol SoA – this will then

For Data Collection Specification

- The data collection specification
  - Lab specs
  - CRF
  - Other eSources
  - What is pre-set
- The data collection specification will be linked to:
  - Study Data Contracts
  - Activity Instance ‘Connector Model’ – and OAK transformation rules


Studies
Library
Reports
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Studies
Process Overview
Study List
Manage Study
Define Study
Study Title
Registry Identifiers
Study Properties
Study Structure
Study Population
Study Criteria
Study Purpose
Study Activities
Data Specifications
View Specifications
View Listings
Studies / Define Study / Study Activities / Schedule of Activities
Study Activities (CDISC DEV-0)
Study Activities
Schedule of Activities
DETAILED
PROTOCOL
OPERATIONAL
The detailed SoA describe scheduling of the specific Activities and their grouping for the study
Screening
Treatment
V1
V2
V3
V4
V5
V6
V7
V8
Window
-14
1
8
15
22
29
36
43
-13/+0
±0
±1
±1
±1
±1
±1
±1
SUBJECT RELATED INFORMATION
EFFICACY
LABORATORY ASSESSMENTS
GLUCOSE METABOLISM
HBA1C
SAFETY
BIOMARKERS
Each level in the Activity hierarchy can be selected for display in the “Protocol SoA”
Footnotes



Procedure	Screening	Treatment									Follow-up
Visit short name	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
Study day	-14	1	8	15	22	29	36	43	57	183	213
Visit window (days)	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35
Randomisation											
Randomisation		X									
End of Study											
End of Study											X
Body Measurements											
Body Measurements	X	X	X	X	X	X	X	X	X	X	X
Eligibility Criteria											
Eligibility Criteria	X										
Laboratory Assessments											
Glucose Metabolism	X	X	X	X	X	X		X	X	X	
Lipids	X	X			X			X		X	
Biochemistry	X	X			X			X		X	
Haematology											
Hormones											
AE Requiring Additional Data											
Laboratory Assessment	X	X			X			X		X	
Adverse Event											
Adverse Event	X	X	X	X	X	X	X	X	X	X	X
Vital Signs											
Vital Signs	X	X	X	X	X	X	X	X	X	X	X
Medical History/Concomitant Illness											
Medical History/Concomitant Illness	X	X	X	X	X	X	X	X	X	X	X
Physical Examination											
Physical Examination											

1.2 Flowchart

Schedule of Activities

Structured content including SoA will be transferred to the content controls Word based Protocol Template

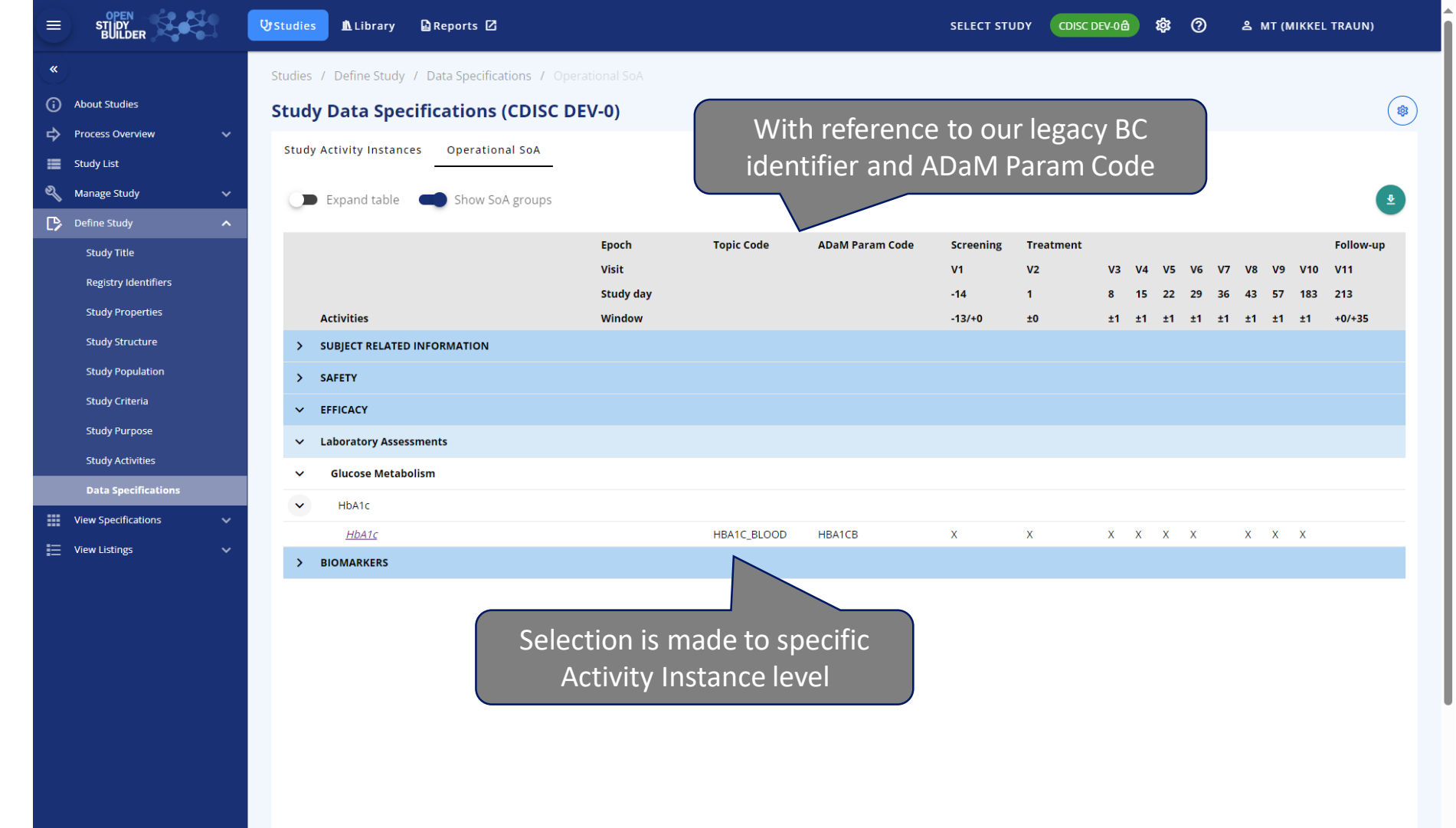
Procedure	Screening	Treatment									Follow-up
Visit short name	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**
Study day	**-14**	**1**	**8**	**15**	**22**	**29**	**36**	**43**	**57**	**183**	**213**
Visit window (days)	**-13/+0**	**±0**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**+0/+35**
Randomisation											
Randomisation		X									
End of Study											
End of Study											X
Body Measurements											
Body Measurements	X	X	X	X	X	X	X	X	X	X	X
Eligibility Criteria											
Eligibility Criteria	X										
Laboratory Assessments											
Glucose Metabolism	X	X	X	X	X	X	X	X	X	X	
Lipids	X	X			X			X		X	
Biochemistry	X	X			X			X		X	
AE Requiring Additional Data											

Get Data

Currently saved: CDISC DEV-(

Select all
- Protocol Title
- Protocol Short Title
- Universal Trial Number
- EudraCT Number
- IND Number
- Schedule of Activities
- Objectives & Endpoints
- Inclusion Criteria
- Exclusion Criteria

Update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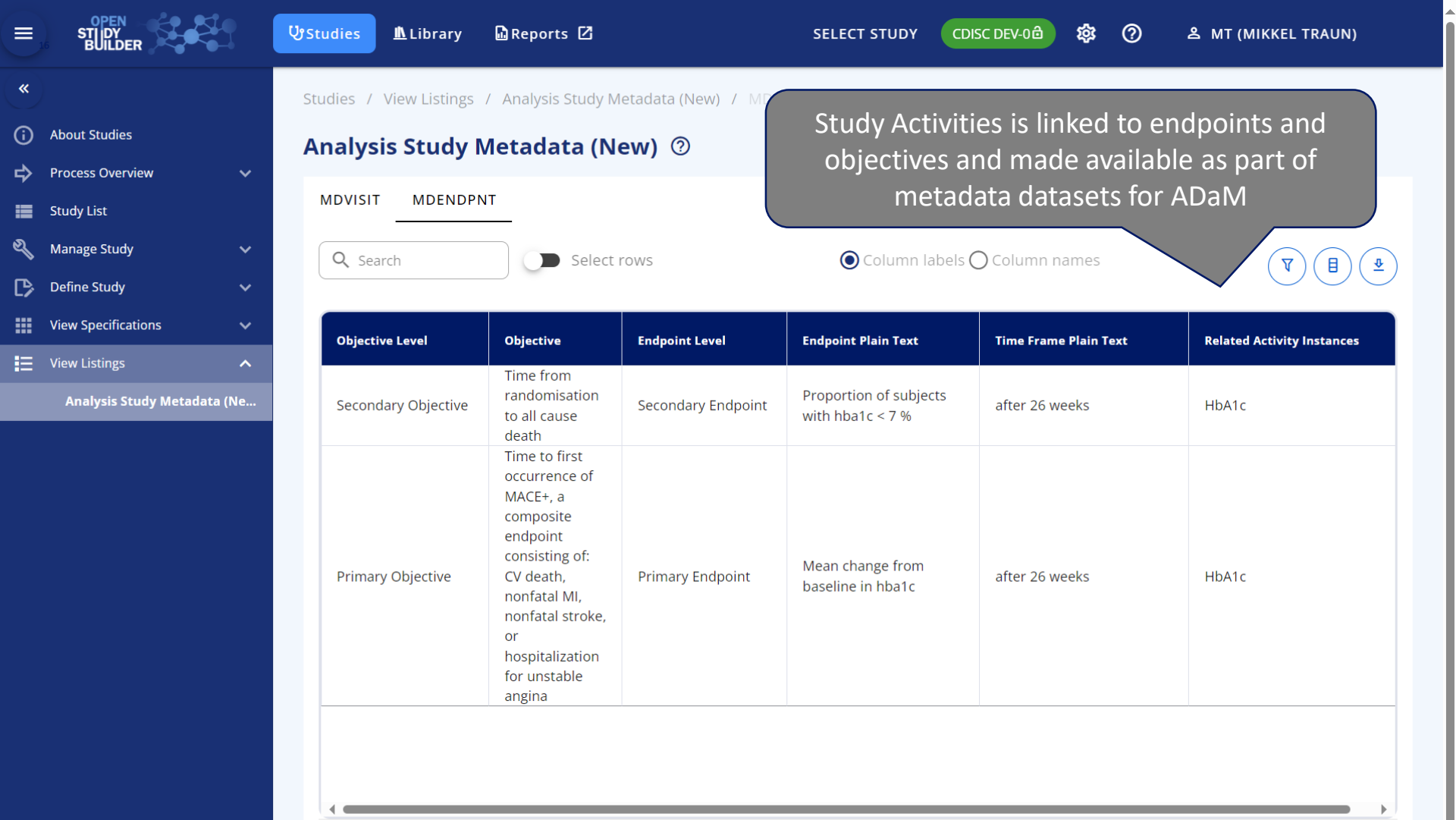
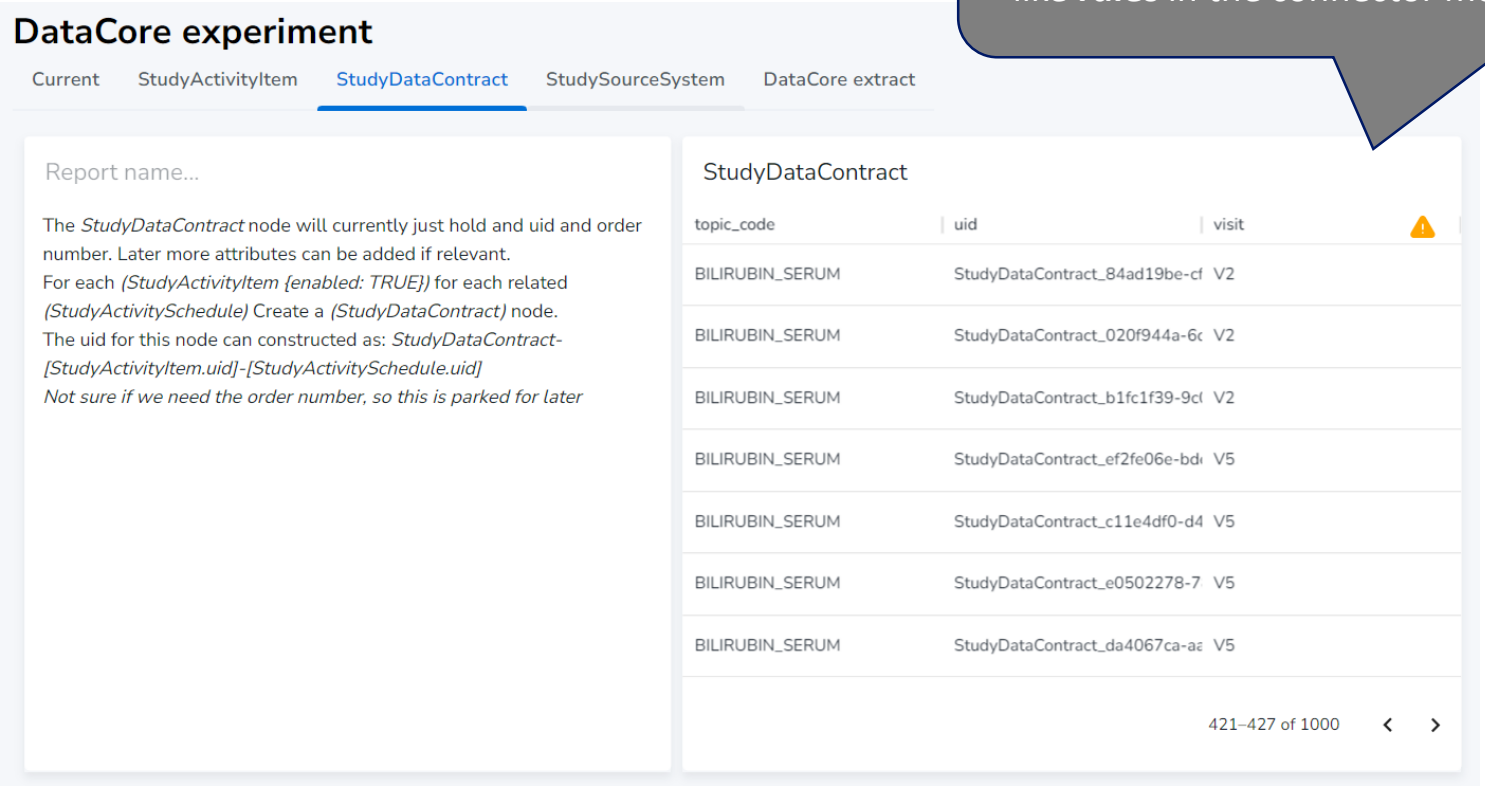
Registry Identifiers
Study Properties
Study Structure
Study Population
Study Criteria
Study Purpose
Study Activities
Data Specifications
View Specifications
View Listings
Studies / Define Study / Data Specifications / Operational SoA
Study Data Specifications (CDISC DEV-0)
With reference to our legacy BC identifier and ADaM Param Code
Study Activity Instances
Operational SoA
Expand table
Show SoA groups
Epoch
Topic Code
ADaM Param Code
Screening
Treatment
Follow-up
Visit
V1
V2
V3
V4
V5
V6
V7
V8
V9
V10
V11
Study day
-14
1
8
15
22
29
36
43
57
183
213
Activities
Window
-13/+0
±0
±1
+0/+35
SUBJECT RELATED INFORMATION
SAFETY
EFFICACY
Laboratory Assessments
Glucose Metabolism
HbA1c
HbA1c
HBA1C_BLOOD
HBA1CB
X
BIOMARKERS
Selection is made to specific Activity Instance level



Objective Level	Objective	Endpoint Level	Endpoint Plain Text	Time Frame Plain Text	Related Activity Instances
Secondary Objective	Time from randomisation to all cause death	Secondary Endpoint	Proportion of subjects with hba1c < 7 %	after 26 weeks	HbA1c
Primary Objective	Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina	Primary Endpoint	Mean change from baseline in hba1c	after 26 weeks	HbA1c

Study Activities is linked to **Study Data Contracts** – will include **OAK** like **rules** in the connector model



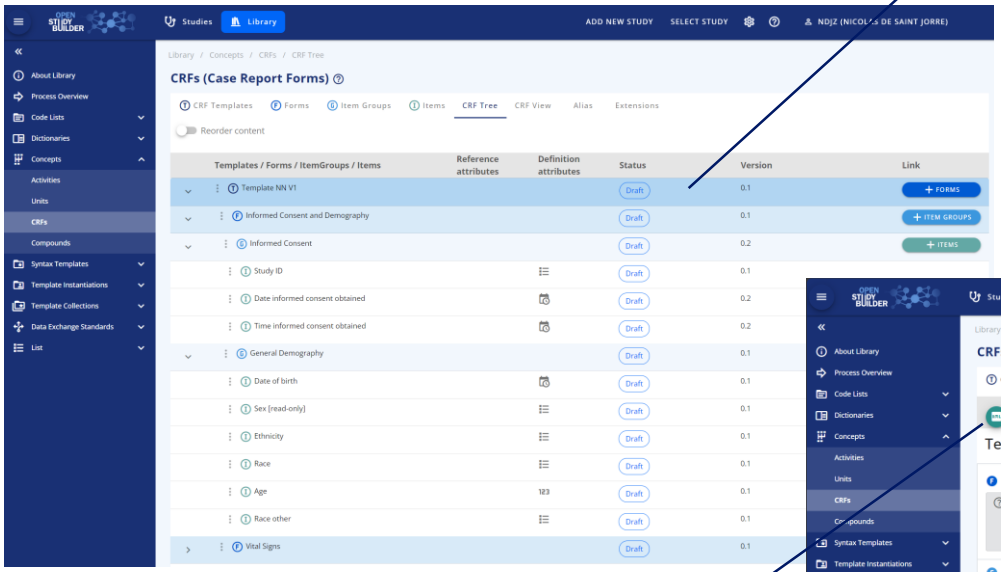
Concept: CRFs

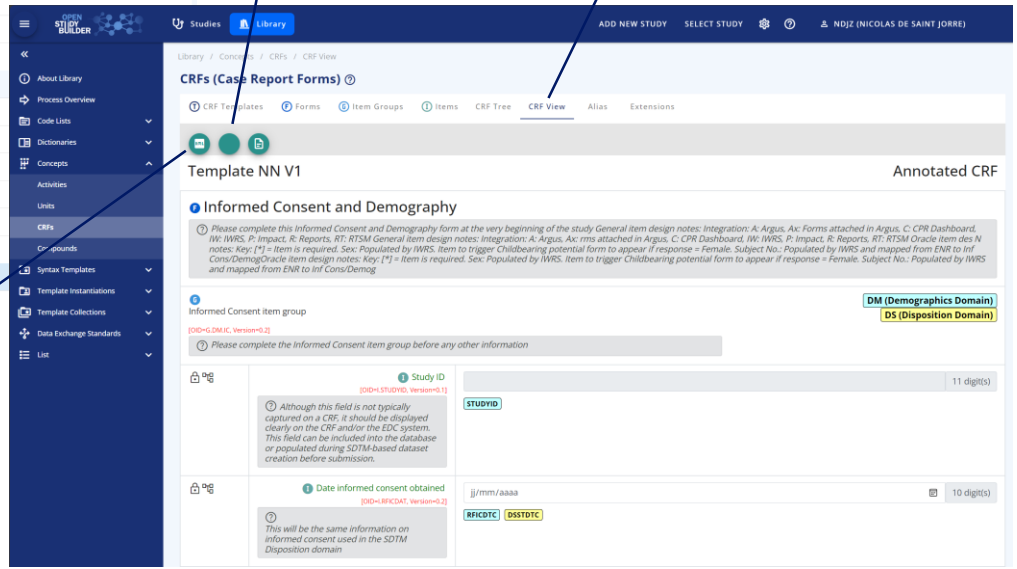
Templates used to defined multiple CRF version

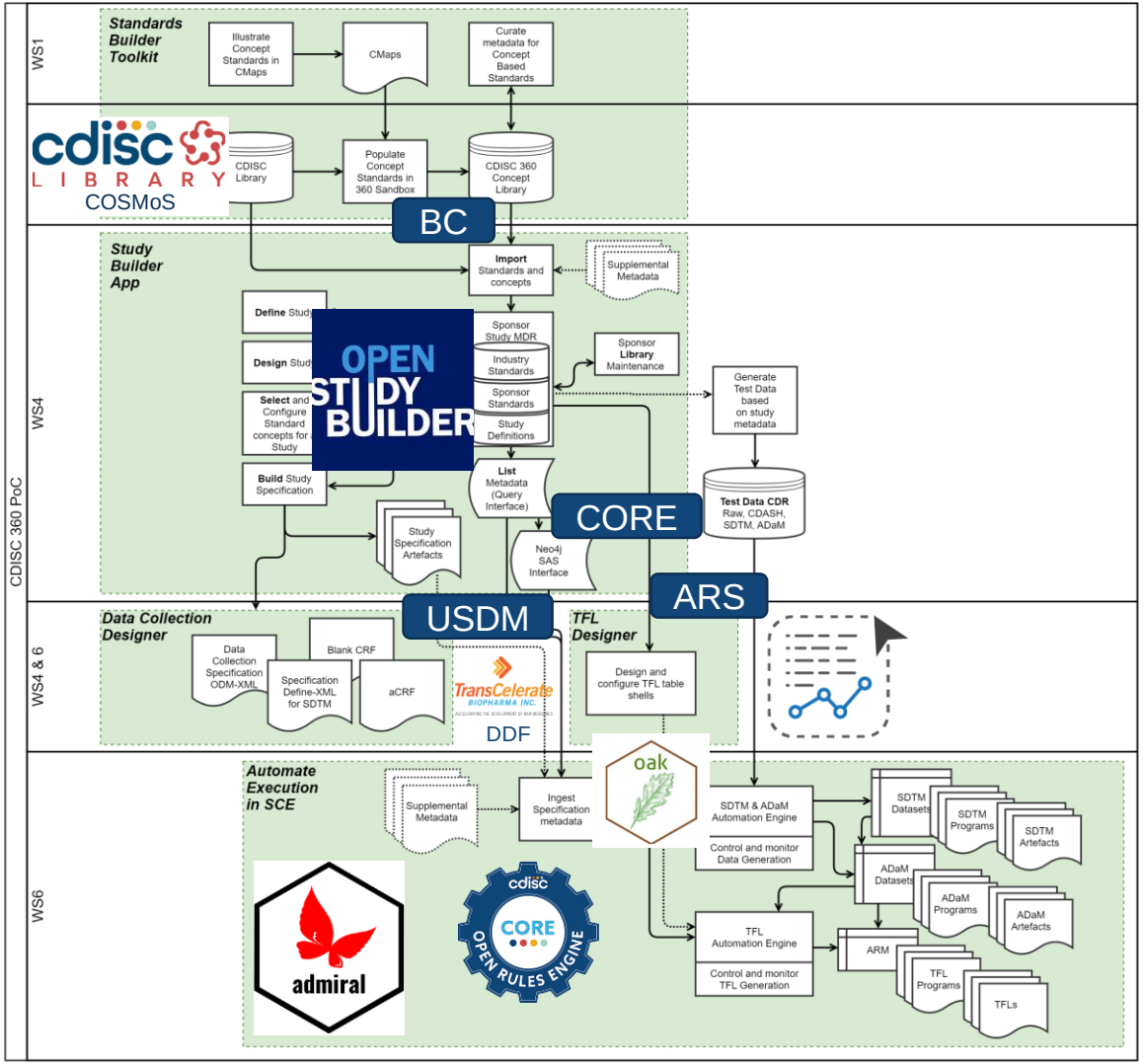
PDF format

Annotated CRF following MSG 2.0 standard

ODM.xml with vendor extensions (or CSV)







cdisc LIBRARY COSMoS

cdisc 360

Define

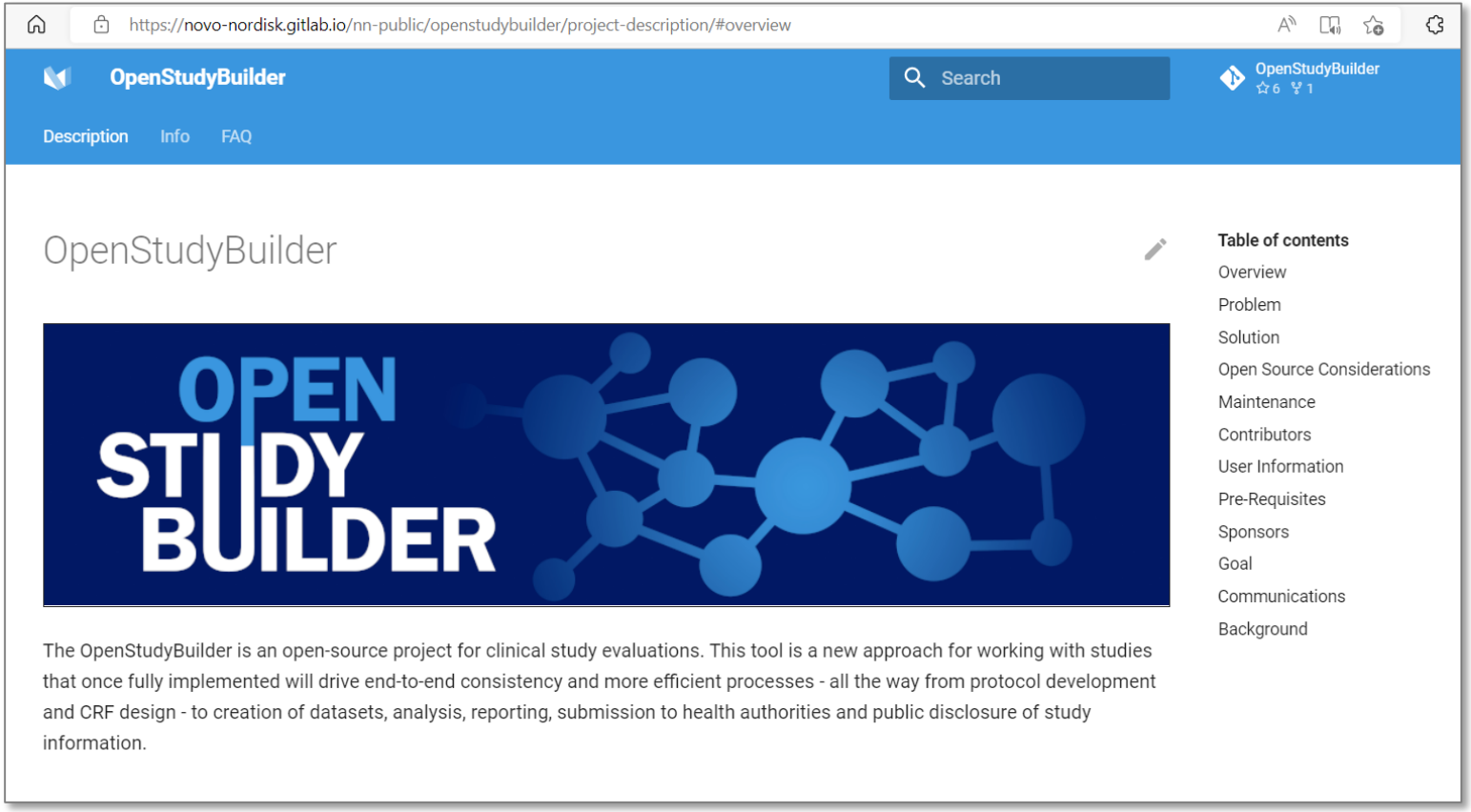
Design

Build

Execute

cdisc

How do I get started on OpenStudyBuilder?



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

Thank You!

Questions or need more information?

Mikkel Traun, Solution Architect, mt@novonordisk.com

OpenStudyBuilder contact: OpenStudyBuilder@gmail.com

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