cdisc

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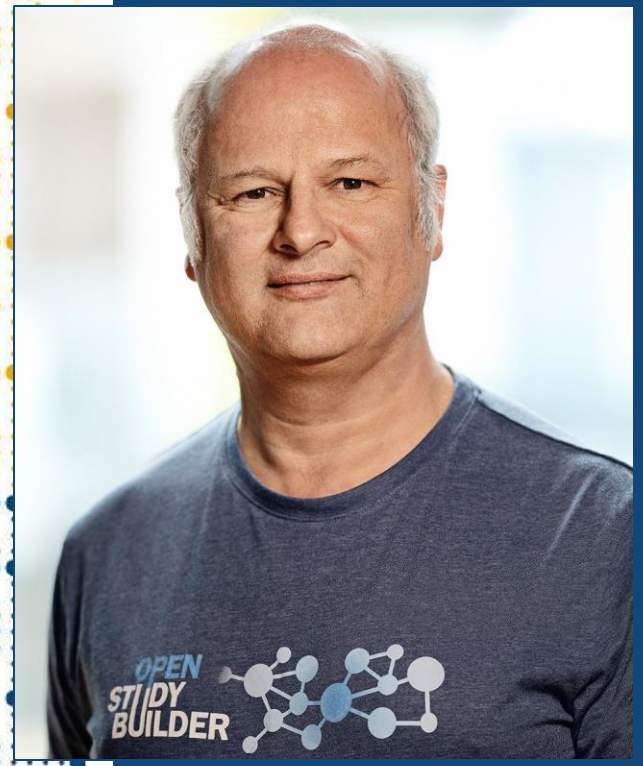
OpenStudyBuilder – an open-source DDF and COSMoS compatible solution

Mikkel Traun, Principal System Developer, Novo Nordisk A/S

Meet the Speakers



Mikkel Traun

Title: Principal System Developer

Organization: Novo Nordisk A/S

Mikkel is one of the product owners 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.

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

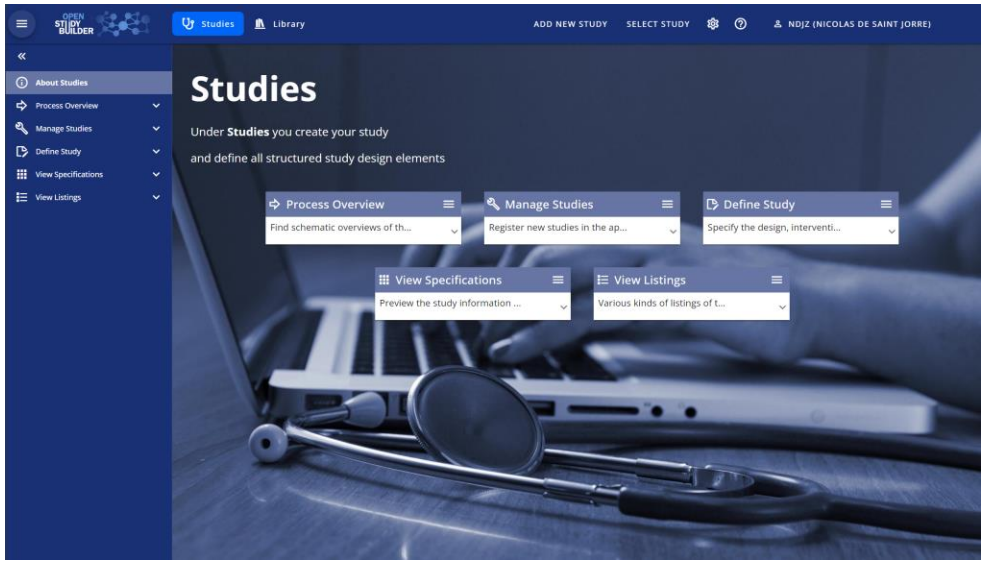
3 ELEMENTS OF OpenStudyBuilder

- **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)

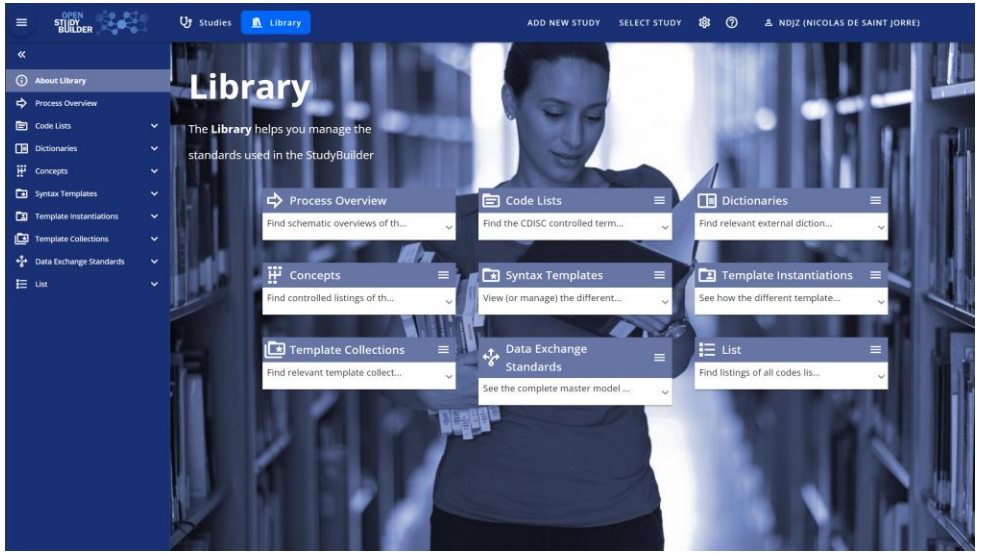
clinical **MDR**

OpenStudyBuilder Components

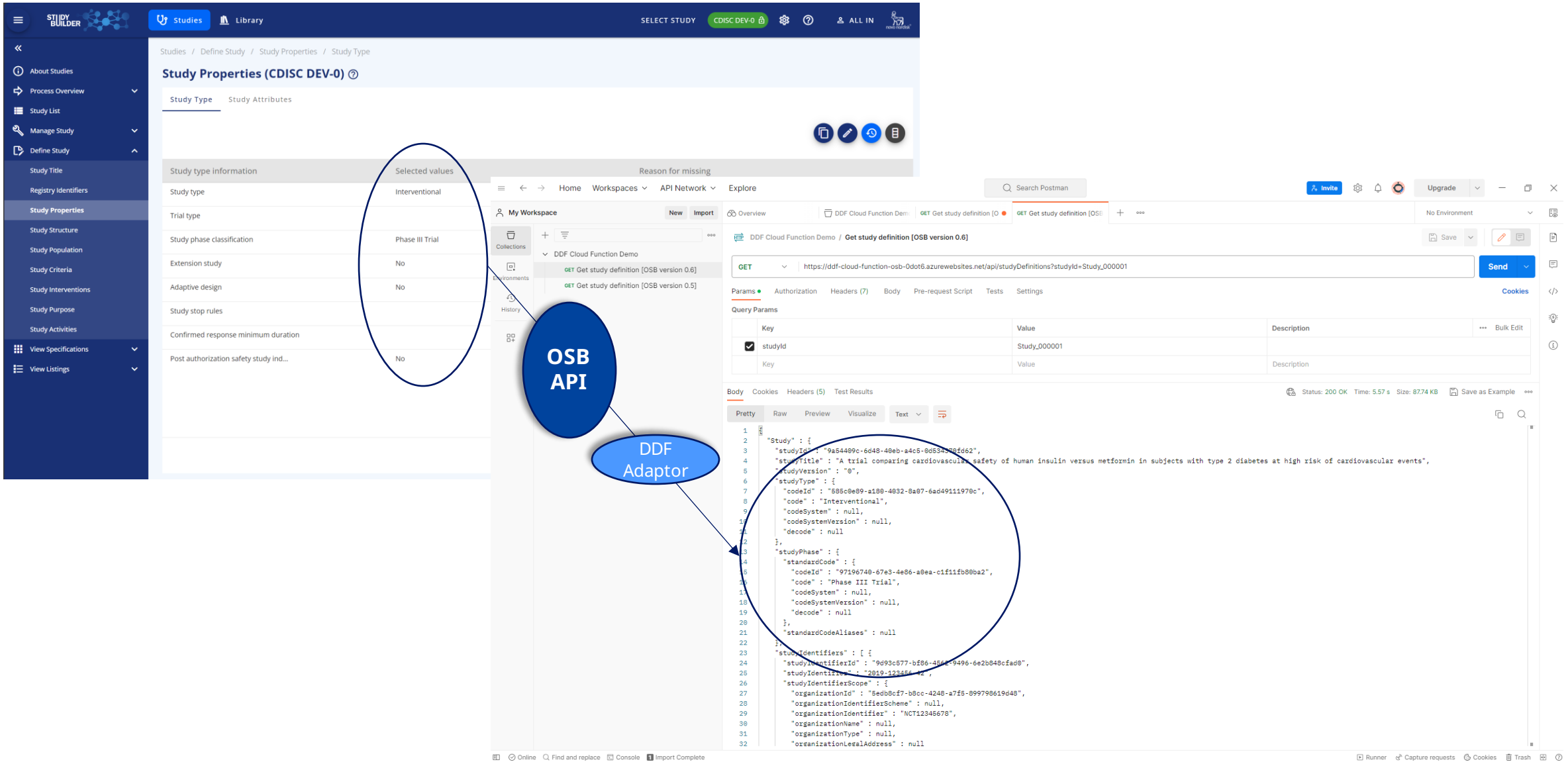
STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES



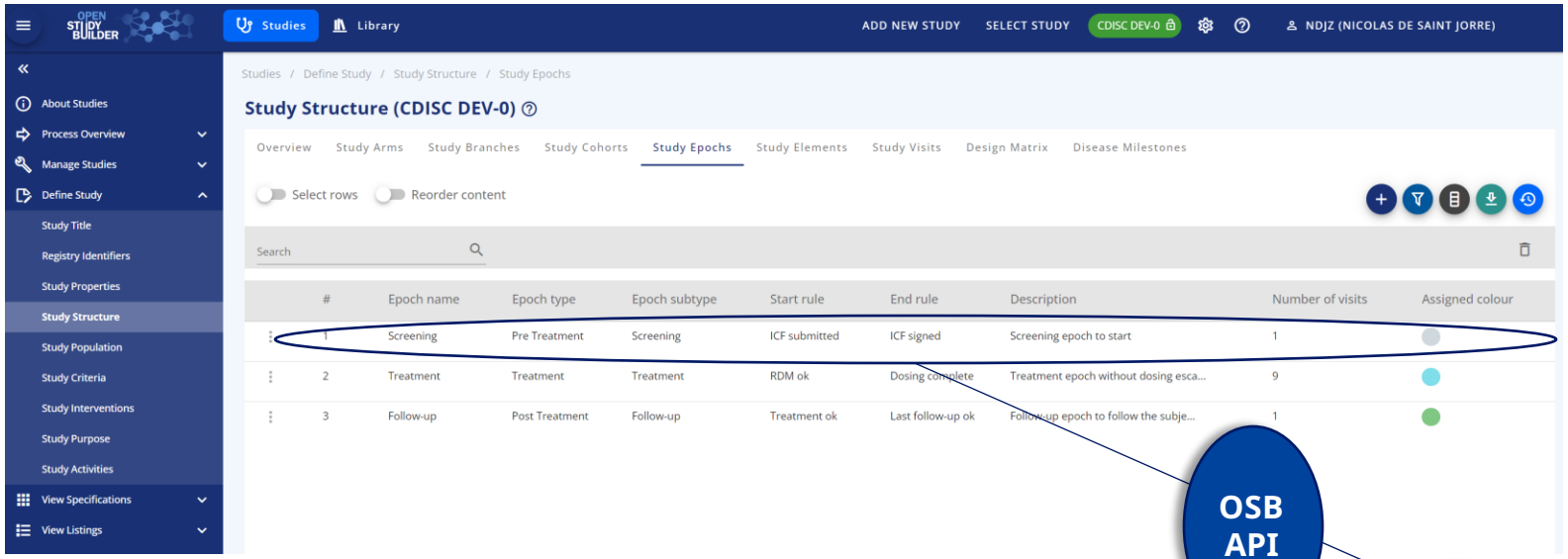
LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	



Digital Data Flow Adaptor (1/2)

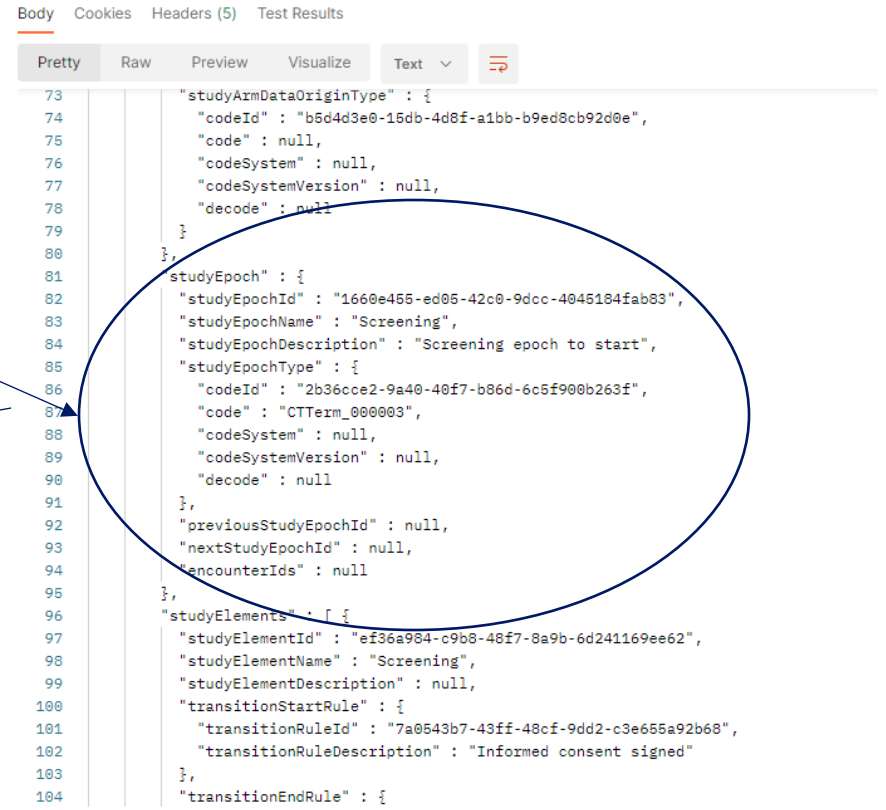


Digital Data Flow Adaptor (2/2)



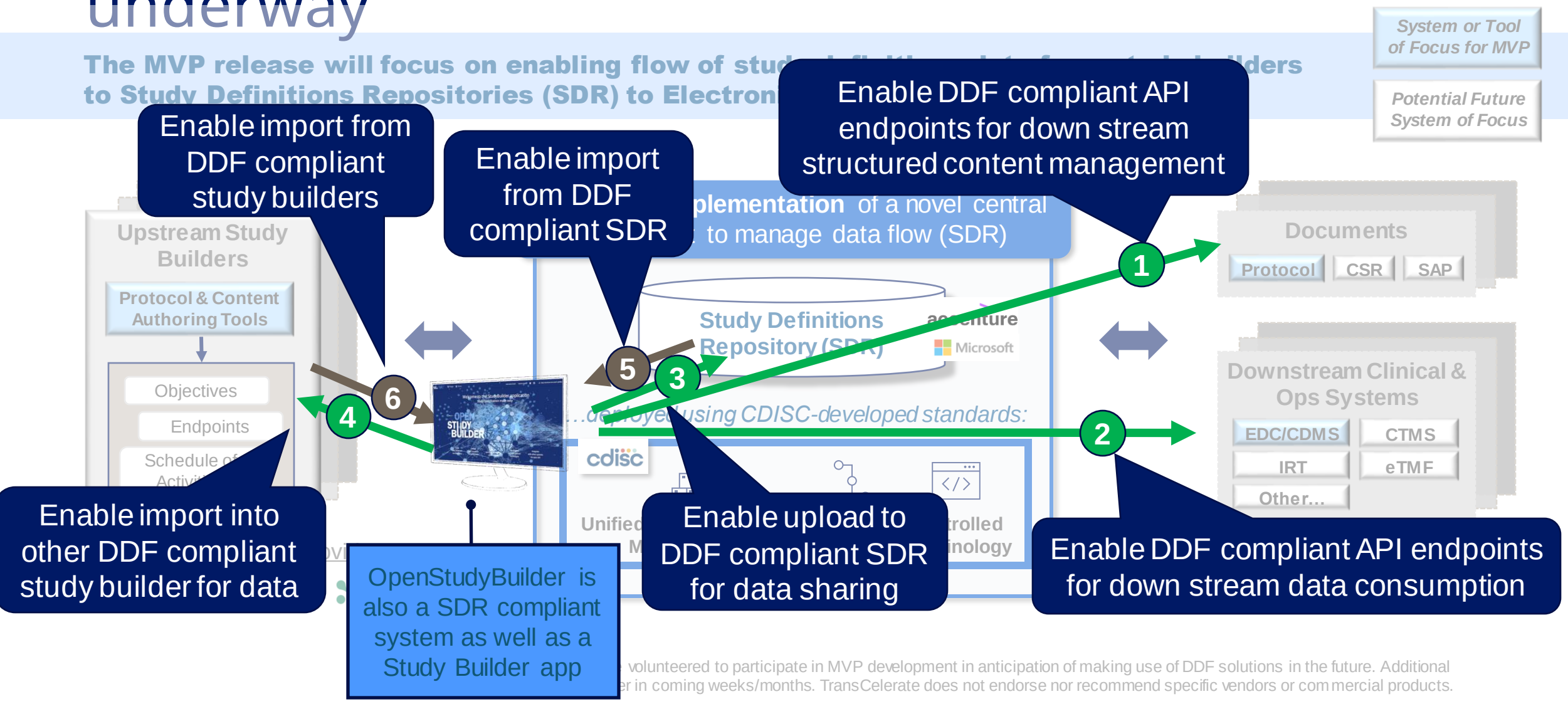
accenture

Microsoft



Minimum Viable Product (MVP) development underway

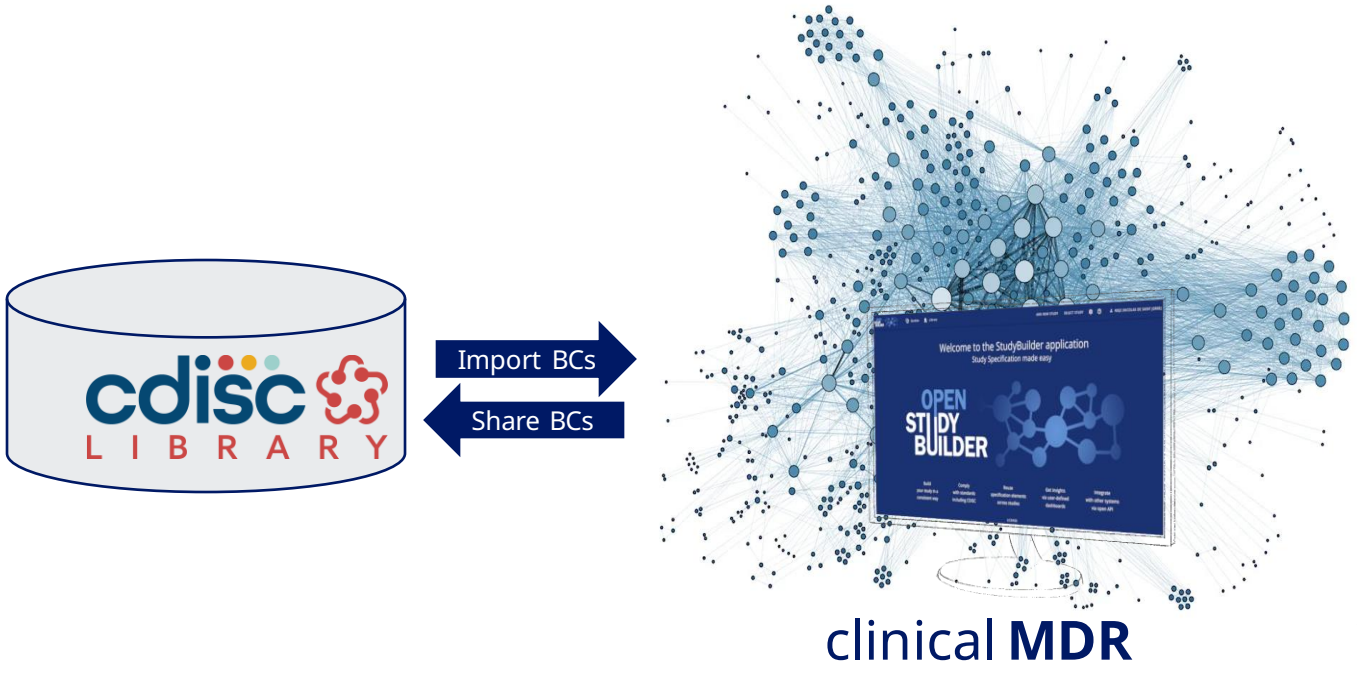
The MVP release will focus on enabling flow of stud… …ilders to Study Definitions Repositories (SDR) to Electroni…



…volunteered to participate in MVP development in anticipation of making use of DDF solutions in the future. Additional …er in coming weeks/months. TransCelerate does not endorse nor recommend specific vendors or commercial products.

What is a CDISC COSMoS compatible solution

- Conceptual and Operational Standards Metadata Services (COSMoS)
  - Biomedical Concepts (BCs) in a two-layered definition:
    - Conceptual/abstract layer that provides standards-agnostic, unambiguous semantic definition largely based on NCIt concepts.
    - Implementation layer based on valid CDISC dataset specializations that provide value level metadata definitions that facilitate metadata-driven automation.



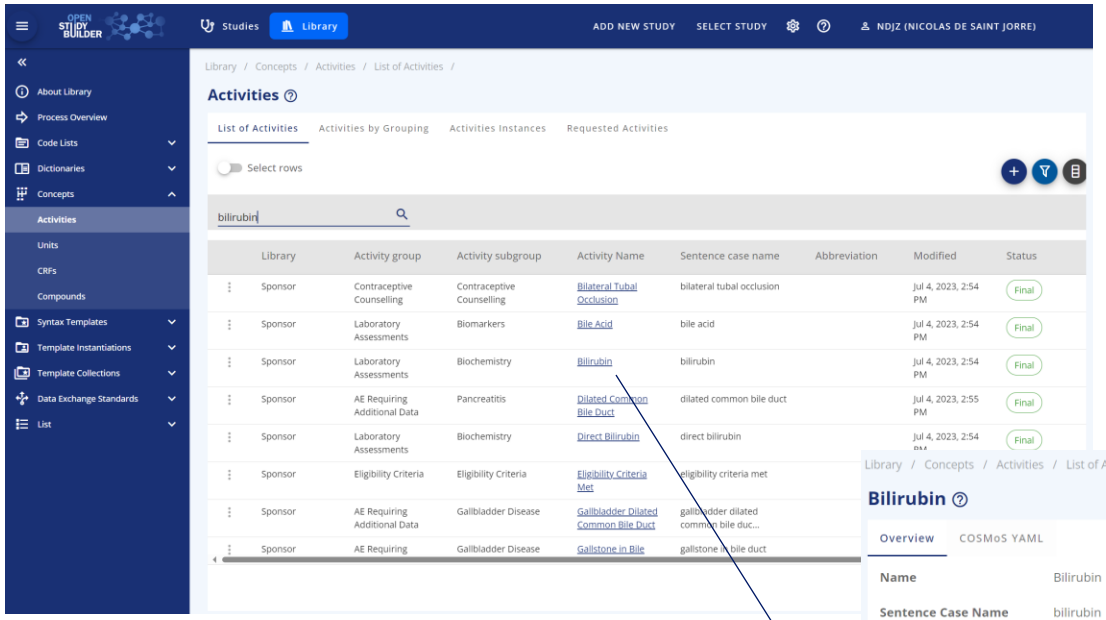
CDISC Biomedical Concepts | CDISC

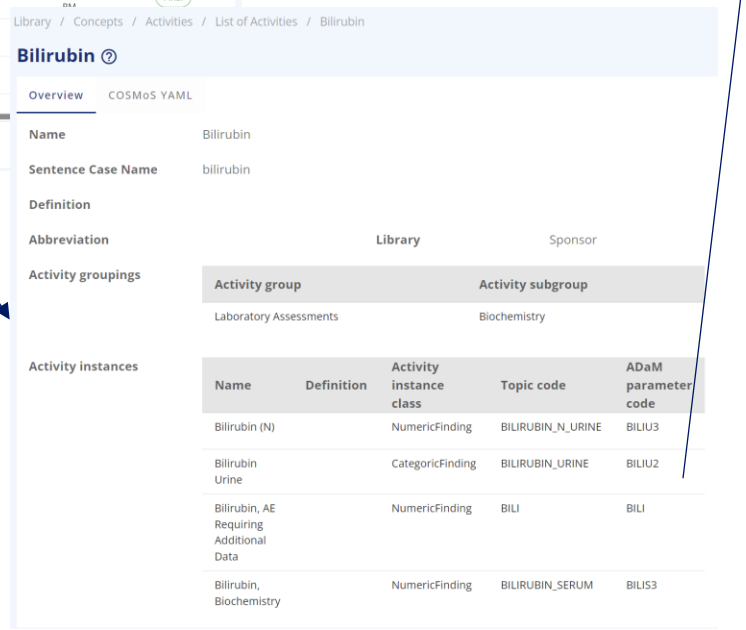
What is the key elements of OpenStudyBuilder

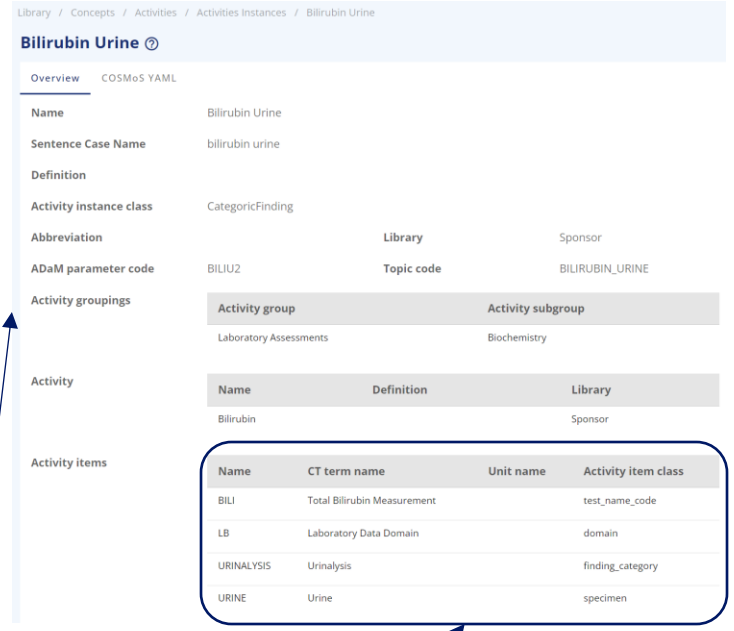
- Library holding BCs
  - Named as Activity Concepts in OSB
- Study Module supporting Study Design and SoA
- SoA is key component in supporting the Digital Data Flow (DDF) vision
- In OSB we seek to achieve this by defining the SoA at different levels for dedicated parts of the Digital Data Flow

clinical **MDR**

Concepts: Activities and Activity Instances







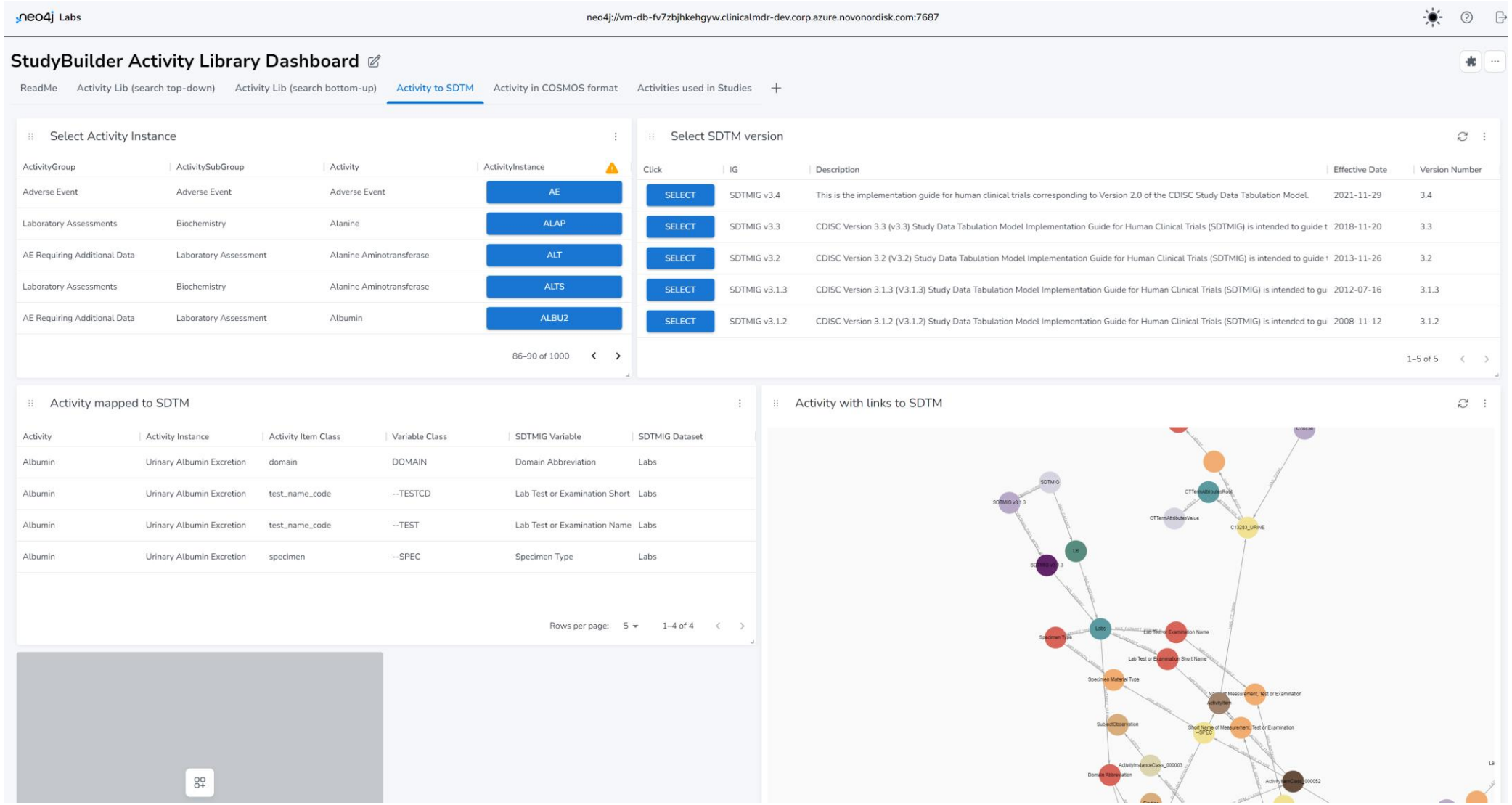
Activity

=

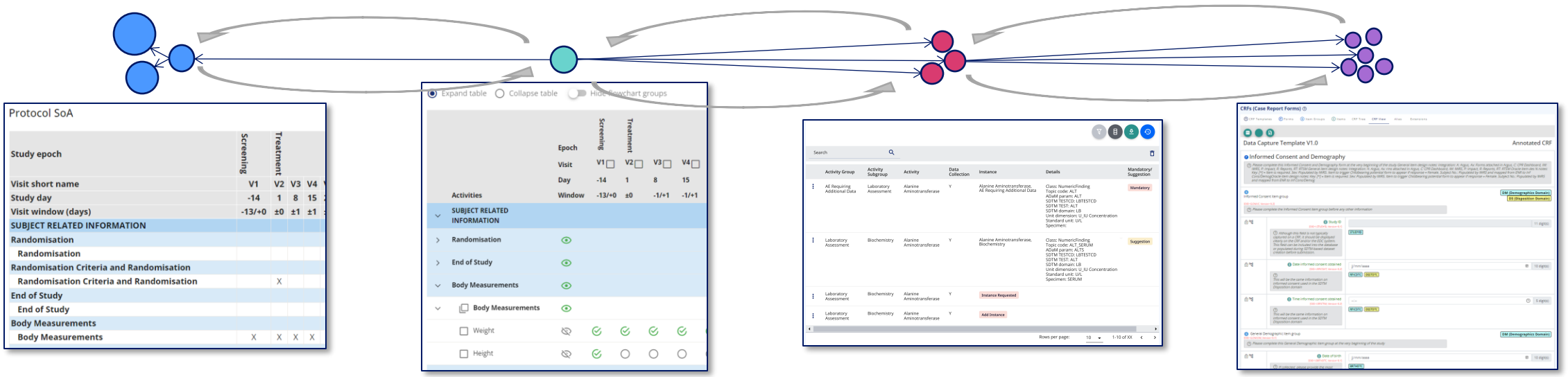
Biomedical Concept

(COSMoS project from CDISC)

NeoDash reports to view Activity to SDTM Variables



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

Studies / Define Study / Study Activities / Detailed SoA

About Studies
Process Overview
Manage Studies
Define Study
Study Title
Registry Identifiers
Study Properties
Study Structure
Study Population
Study Criteria
Study Interventions
Study Purpose
Study Activities
View Specifications
View Listings

Study Activities (CDISC DEV-0)

Study Activities | Study Activity Instances | Detailed SoA | SoA footnotes | Protocol SoA | Activity Instructions

The detailed SoA describe scheduling of the specific Activities and their grouping for the study

roups

		Screening	Treatment									Follow-up
		V1 ☐	V2 ☐	V3 ☐	V4 ☐	V5 ☐	V6 ☐	V7 ☐	V8 ☐	V9 ☐	V10 ☐	V11 ☐
		-14	1	8	15	22	29	36	43	57	183	213
Activities	Window	-13/+0	±0	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	0/+35
SUBJECT RELATED INFORMATION												
EFFICACY												
Laboratory Assessments												
Glucose Metabolism												
HbA1c		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	○
Self Measured Plasma Glucose												
Self Measured Plasma Glucose												
Mean Plasma Glucose		○	○	○	○	○	○	○	○	○	○	○
SAFETY												

Each level in the Activity hierarchy can be selected for display in the “Protocol SoA”

Studies / Define Study / Study Activities / Protocol SoA

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Study Activities | Study Activity Instances | Detailed SoA | SoA footnotes | Protocol SoA | Activity Instructions

The "Protocol SoA" only displaying the selected activity level of detail as a preview

Protocol SoA

DOWNLOAD DOCX

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											
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

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

1.2 Flowchart

Schedule of Activities

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
- [x] Schedule of Activities
- [ ] Objectives & Endpoints
- [ ] Inclusion Criteria
- [ ] Exclusion Criteria

Update

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Selection is made to specific Activity Instance level

Search

	Activity Group	Activity Subgroup	Activity	Data Collection	Instance	Details	Mandatory/ Suggestion
⋮	AE Requiring Additional Data	Laboratory Assessment	Alanine Aminotransferase	Y	Alanine Aminotransferase, AE Requiring Additional Data	Class: NumericFinding Topic code: ALT ADaM param: ALT SDTM TESTCD: LBTESTCD SDTM TEST: ALT SDTM domain: LB Unit dimension: U_IU Concentration Standard unit: U/L Specimen:	Mandatory
⋮	Laboratory Assessment	Biochemistry	Alanine Aminotransferase	Y	Alanine Aminotransferase, Biochemistry	Class: NumericFinding Topic code: ALT_SERUM ADaM param: ALTS SDTM TESTCD: LBTESTCD SDTM TEST: ALT SDTM domain: LB Unit dimension: U_IU Concentration Standard unit: U/L Specimen: SERUM	Suggestion
⋮	Laboratory Assessment	Biochemistry	Alanine Aminotransferase	Y	Instance Requested		

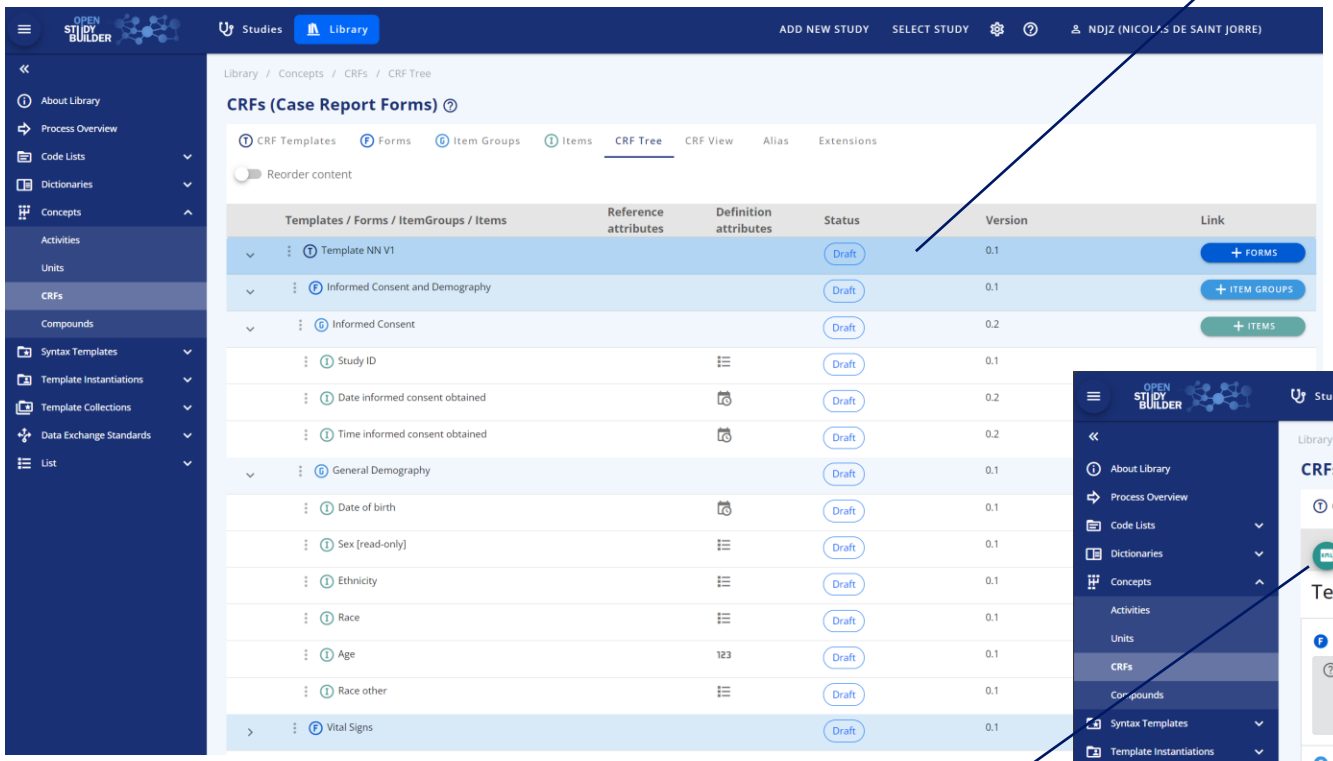
Concept: CRFs

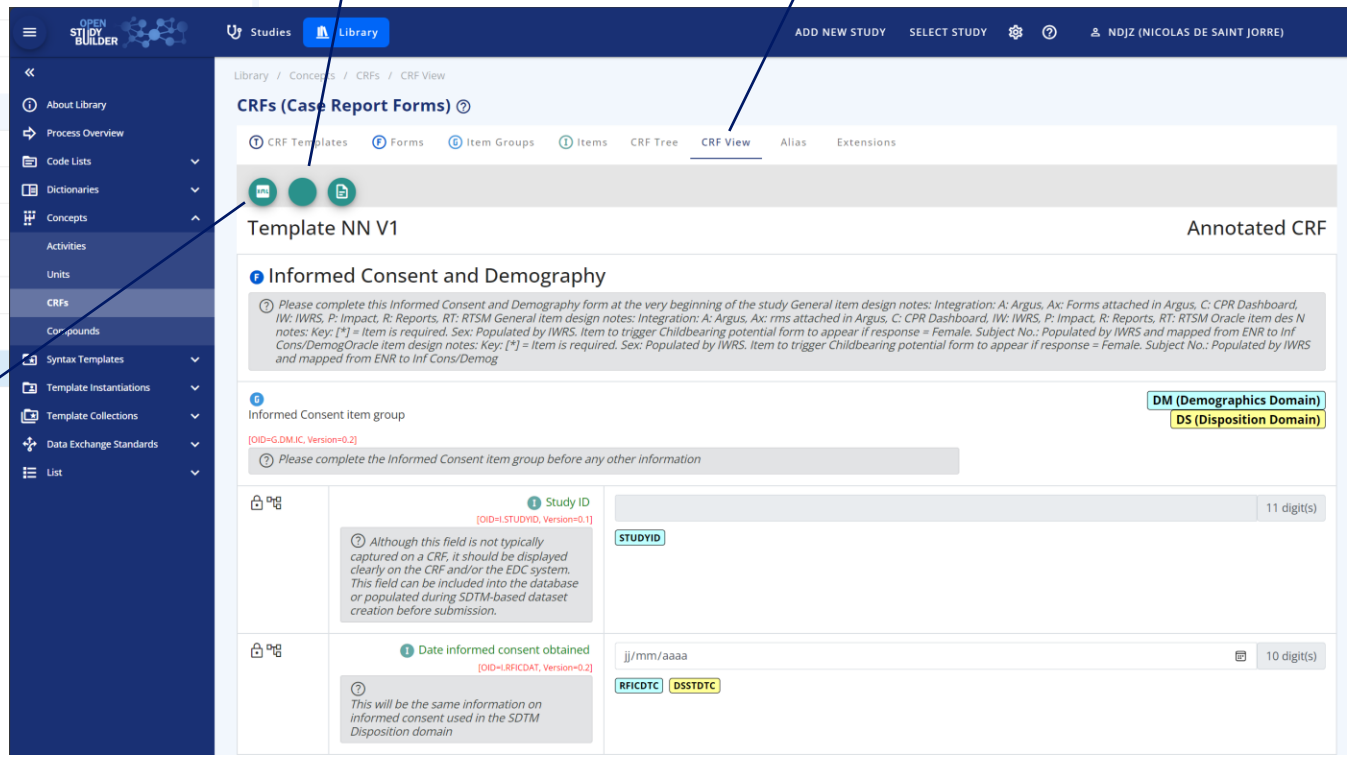
Templates used to defined multiple CRF version

PDF format

Annotated CRF following MSG 2.0 standard

ODM.xml with vendor extensions (or CSV)



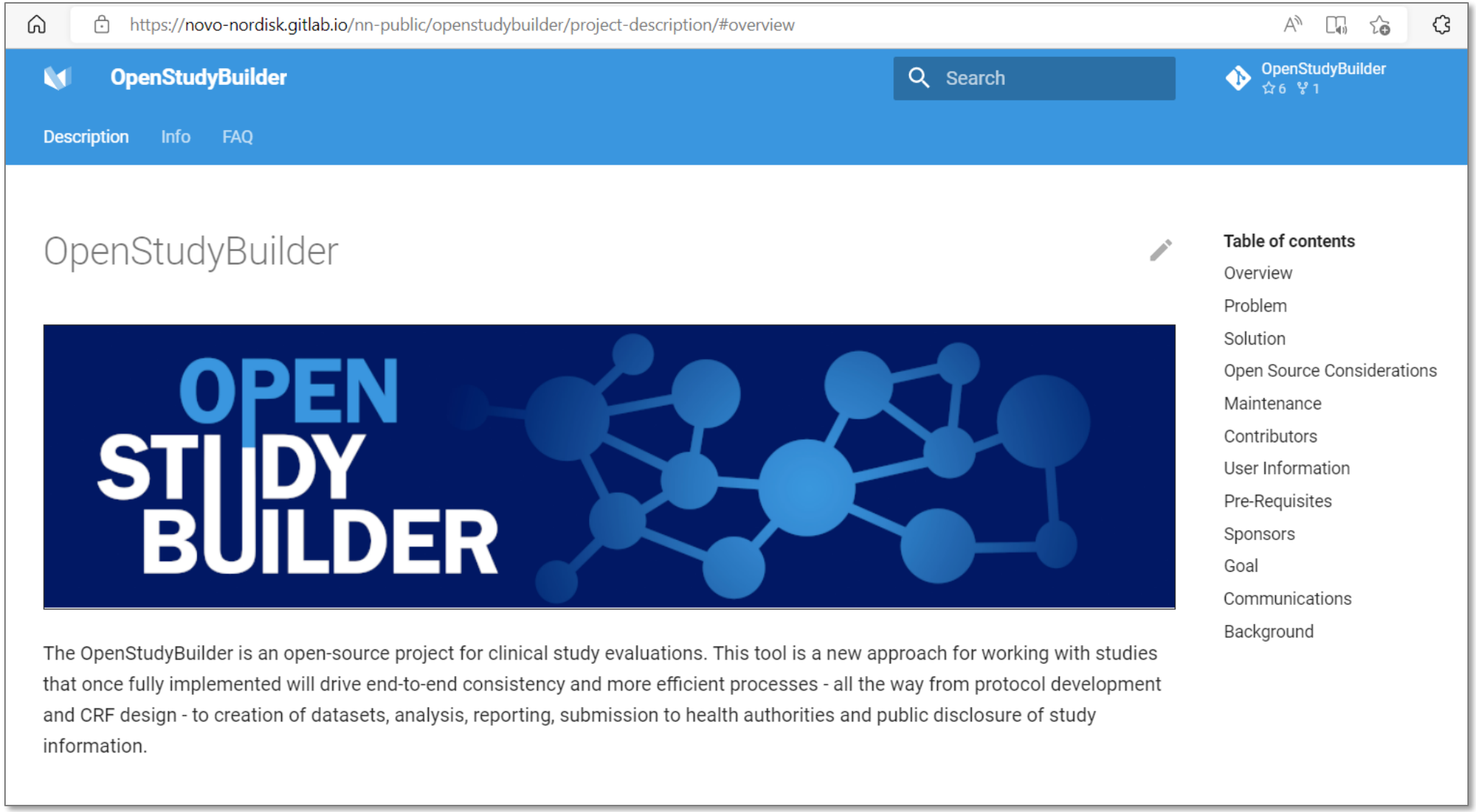


OpenStudyBuilder next steps

- Non-GCP MVP released internally at Novo Nordisk in September 2022 for pilots
- Business go-live November 2023 for phase 2-4 studies with protocol outline kickoff
- Share as open source project under COSA
  - https://cosa.cdisc.org/directory/openStudyBuilder
  - https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/

  Currently only containing a project description
- Seek to actively collaborate with CDISC, TransCelerate DDF, peers and vendors

How do I get started on OpenStudyBuilder?



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

Thanks!
Questions?