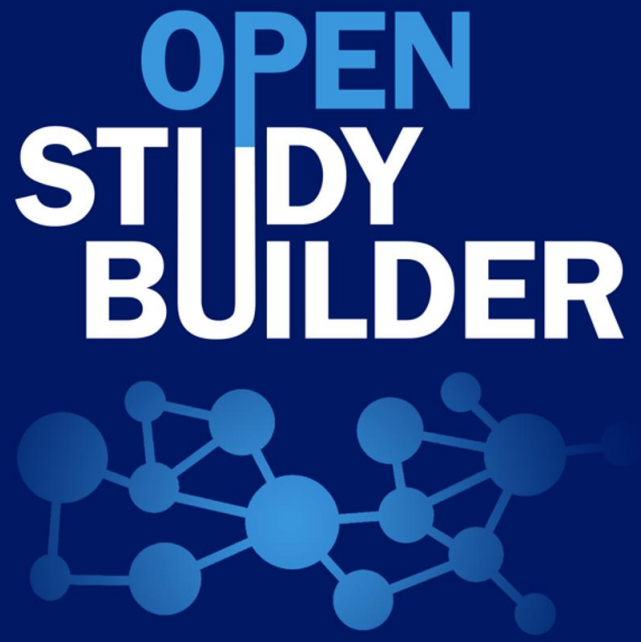
OpenStudyBuilder – Status & Workshop on EDC Integrations



COSA Spotlight Q1 – 26 March 2024

Nicolas de Saint Jorre

Introduction

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

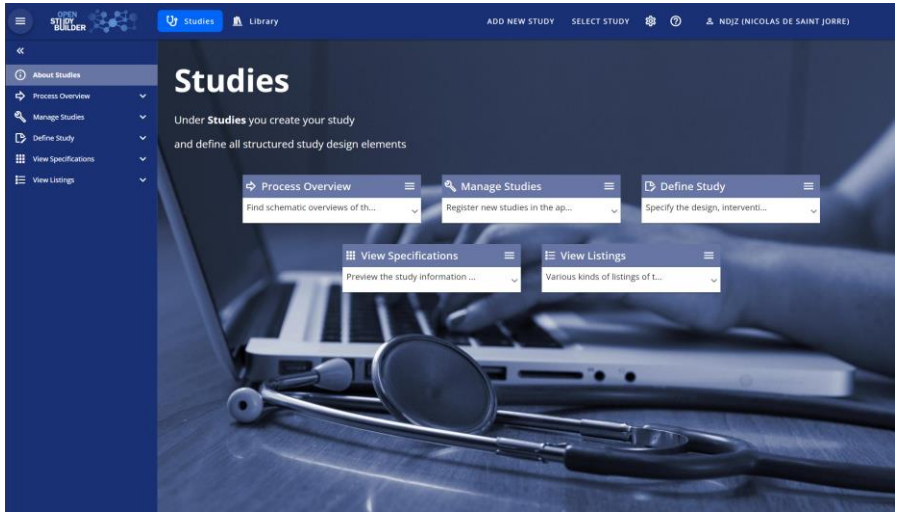
3 ELEMENTS OF OpenStudyBuilder

- **Clinical Metadata and Study Definition Repository**
  (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)

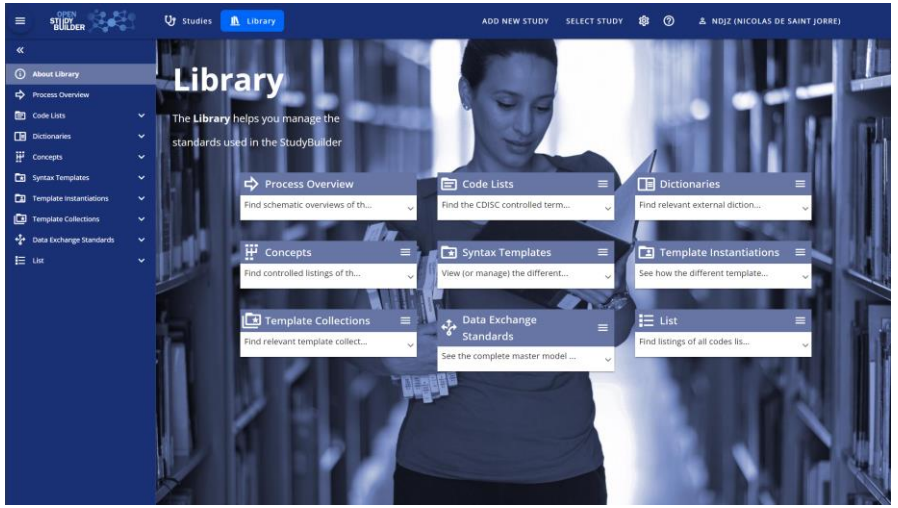
clinical **MDR**

OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES



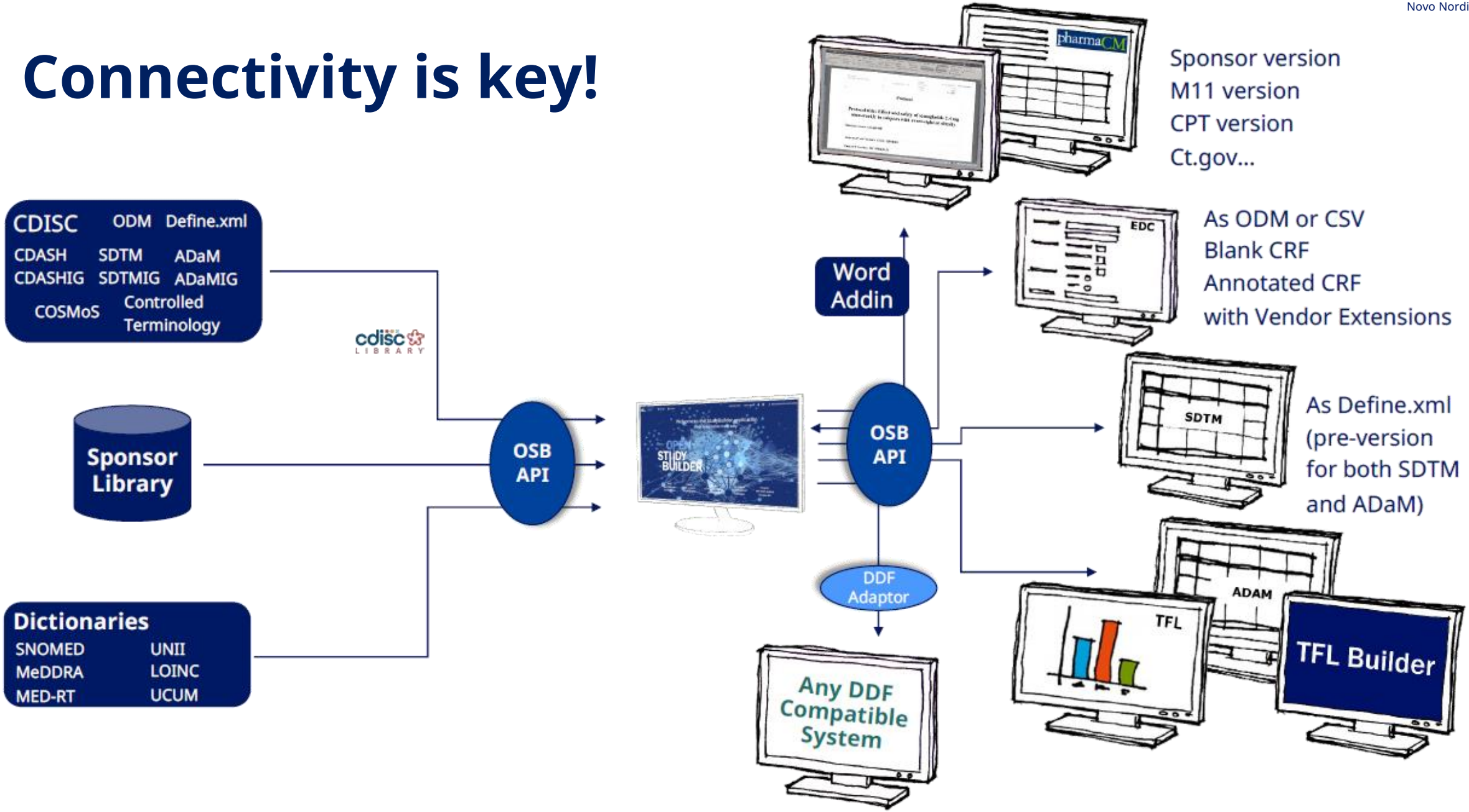
LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	



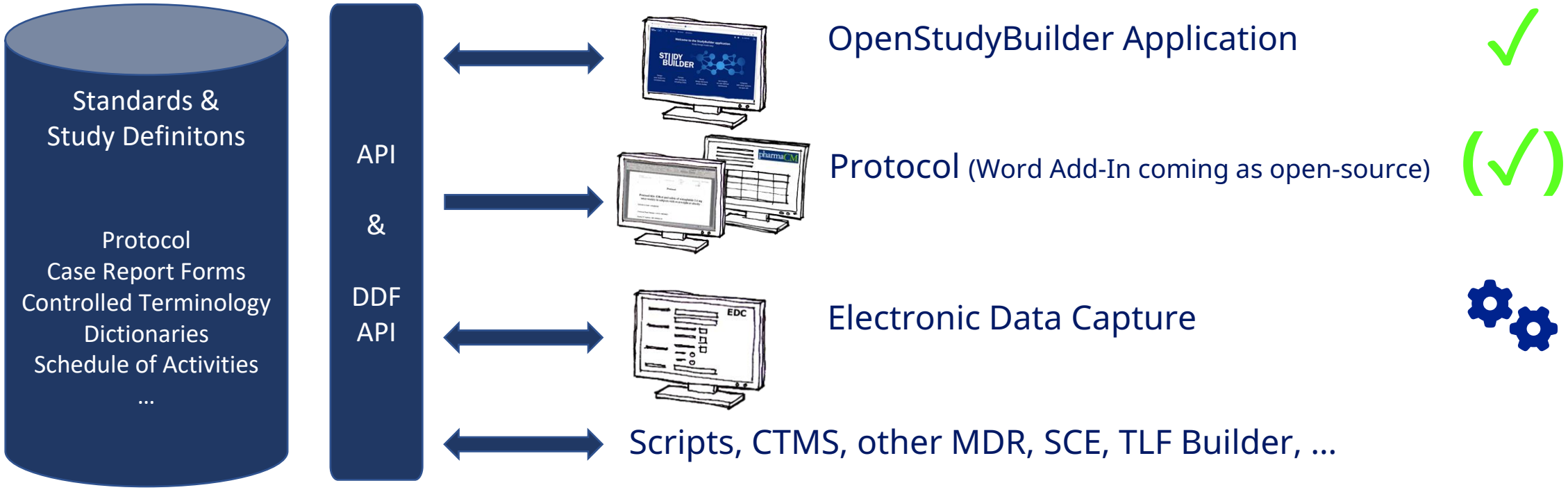
Goal of OpenStudyBuilder

Metadata driven
End-2-End Automation!

Connectivity is key!



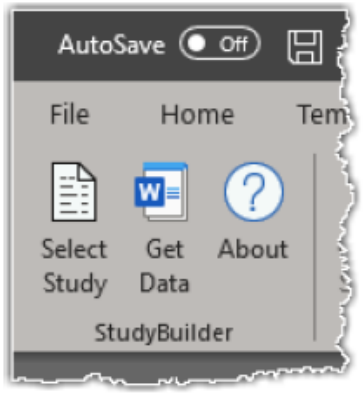
Connectivity is key!



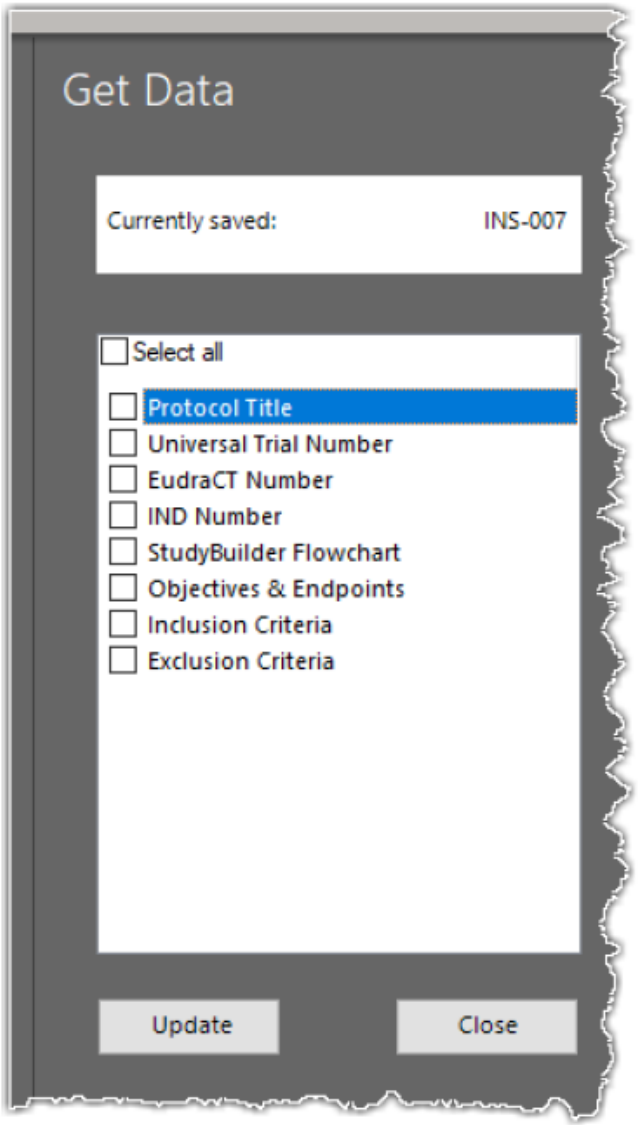
Protocol Generation

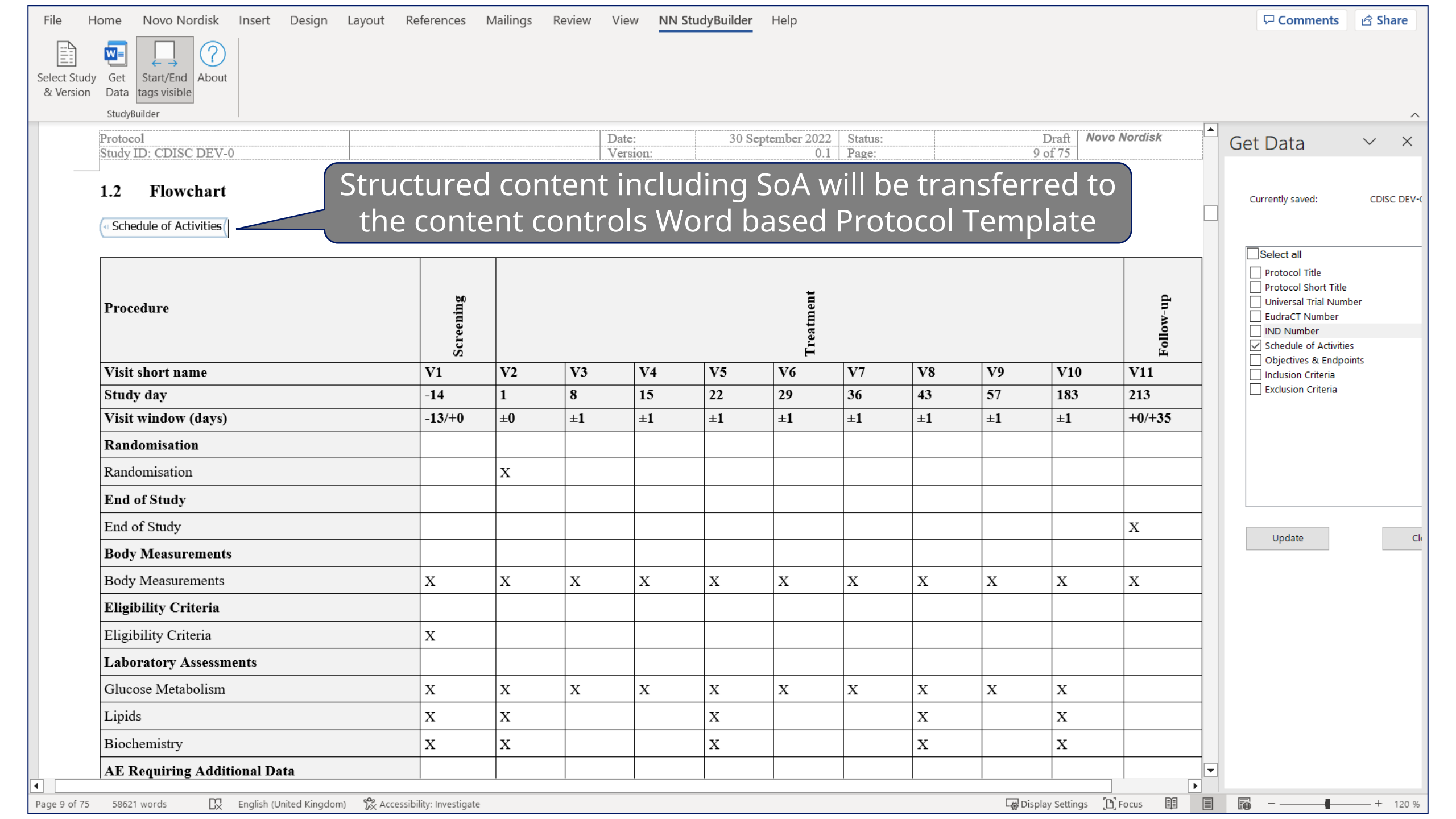
StudyBuilder ribbon
(Word add-in)

- ✓ One-way connection
- ✓ Code recognizes the document type
- ✓ User-friendly ribbon and 'fly-out' in Word
- ✓ Styles ensure proper formatting in Word



Protocol





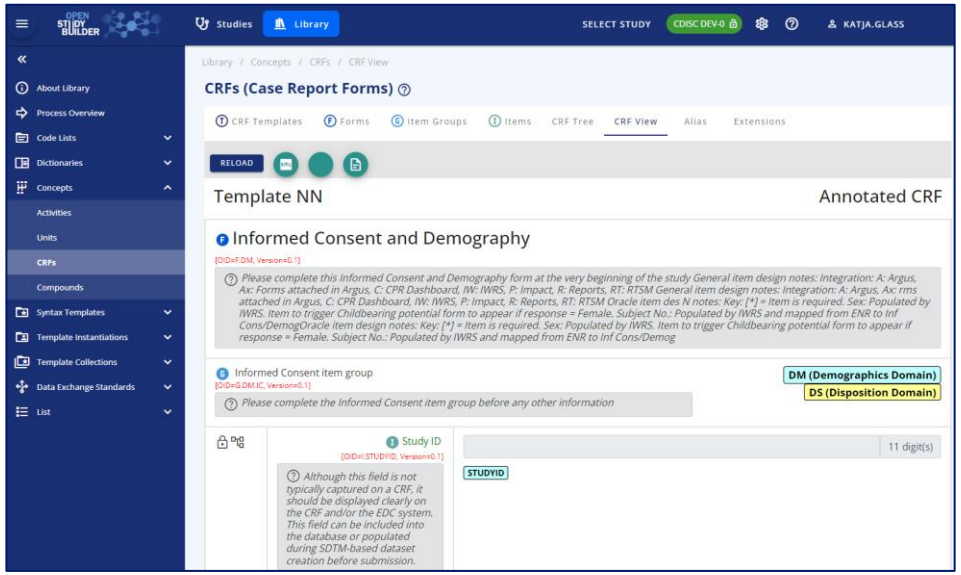
1.2 Flowchart

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											

CRF Standards & Metadata

Manage
Standard & Study CRF



EDC Setup, Test,
Execution

ORACLE
Health Sciences
Clinical One

Veeva Vault EDC

marvin
by EvidentIQ

...

Including rules, checks
Support vendor extensions

Finetuning, Layout

OpenStudyBuilder to drive EDC setup

A COSA Workshop

CDISC Interchange 2024

Use OpenStudyBuilder to drive EDC setup - a COSA Workshop

23 April 2024 9:00-16:00, Berlin, Germany

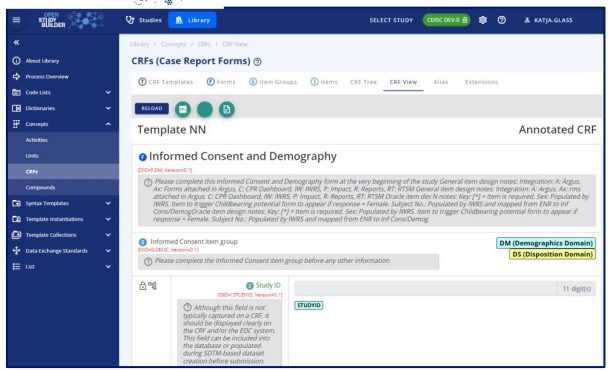
Problem Statement

Data Exchange Formats

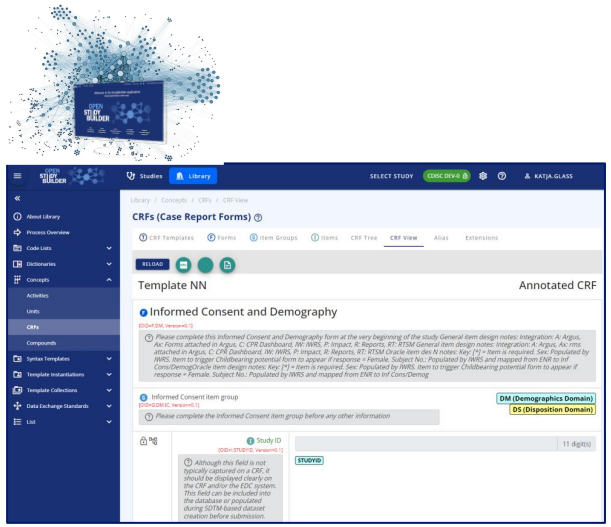
- CDASH
- ODM.XML
- USDM
- Biomedical Concepts

Implementation

- Native formats
- Limited interface capabilities
- Limited selection of standards
  - Custom extensions

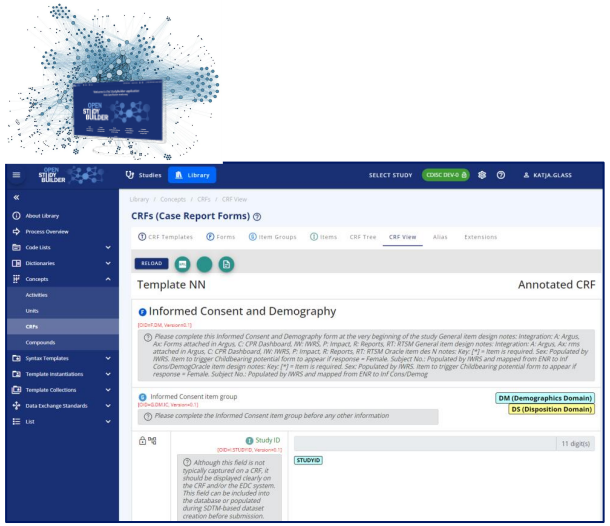


Workshop Focus



- Challenges & Opportunities
  - ODM.XML integrations
  - API based integrations
- Knowledge exchange
  - OpenStudyBuilder functionality
  - Integration status, challenges and opportunities from EDC vendors
- Discussion
  - Integration strengths, weaknesses, opportunities & threats
  - Options and next steps

Workshop Agenda



- Information Exchange
  - Introduction
  - OpenStudyBuilder status with CRF & SoA for EDC & plans
  - EvidentIQ ODM.xml integration (Marvin EDC)
  - Veeva EDC integration via SDS files and future API integration
  - Oracle ClinicalOne API integration & EvidentIQ ePRO API integration
  - The potential future of API standards
- Breakouts
  - Discuss strengths, weaknesses, opportunities & threats
  - Options and next steps
- Share and discuss in plenum

CRF for EDC Status & Questions

eCRF API endpoints

- ODM Study Events
- ODM Forms
- ODM Item Groups
- ODM Item
- ODM Conditions
- ODM Methods
- ODM Formal Expressions
- ODM Descriptions
- ODM Aliases
- ODM Vendor Namespaces
- ODM Vendor Attributes
- ODM Vendor Elements
- ODM Metadata Import/Export

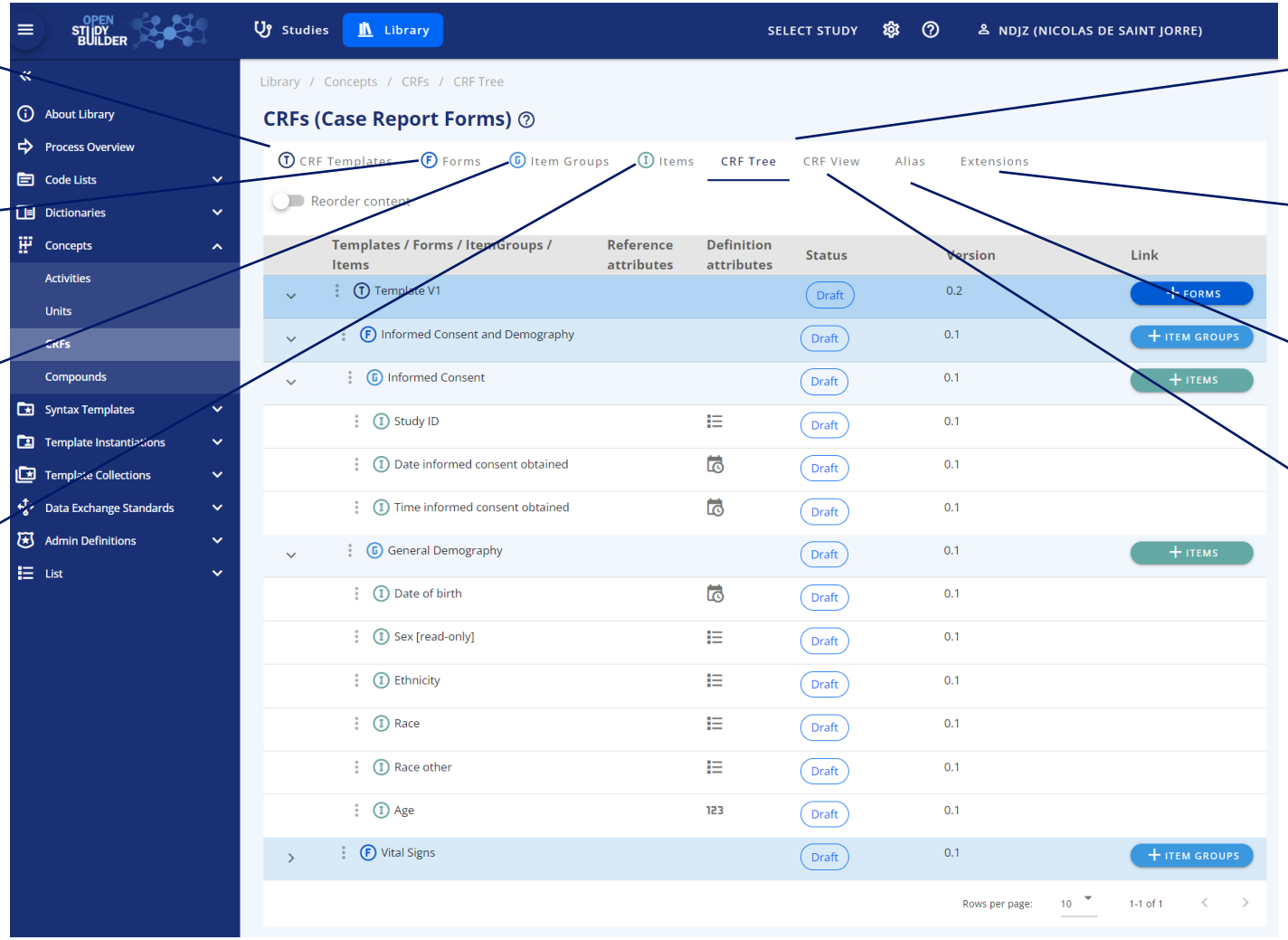
CRF Specification in the Library

Study Events

Forms

ItemGroups

Items



eCRF specs

Vendor Extensions

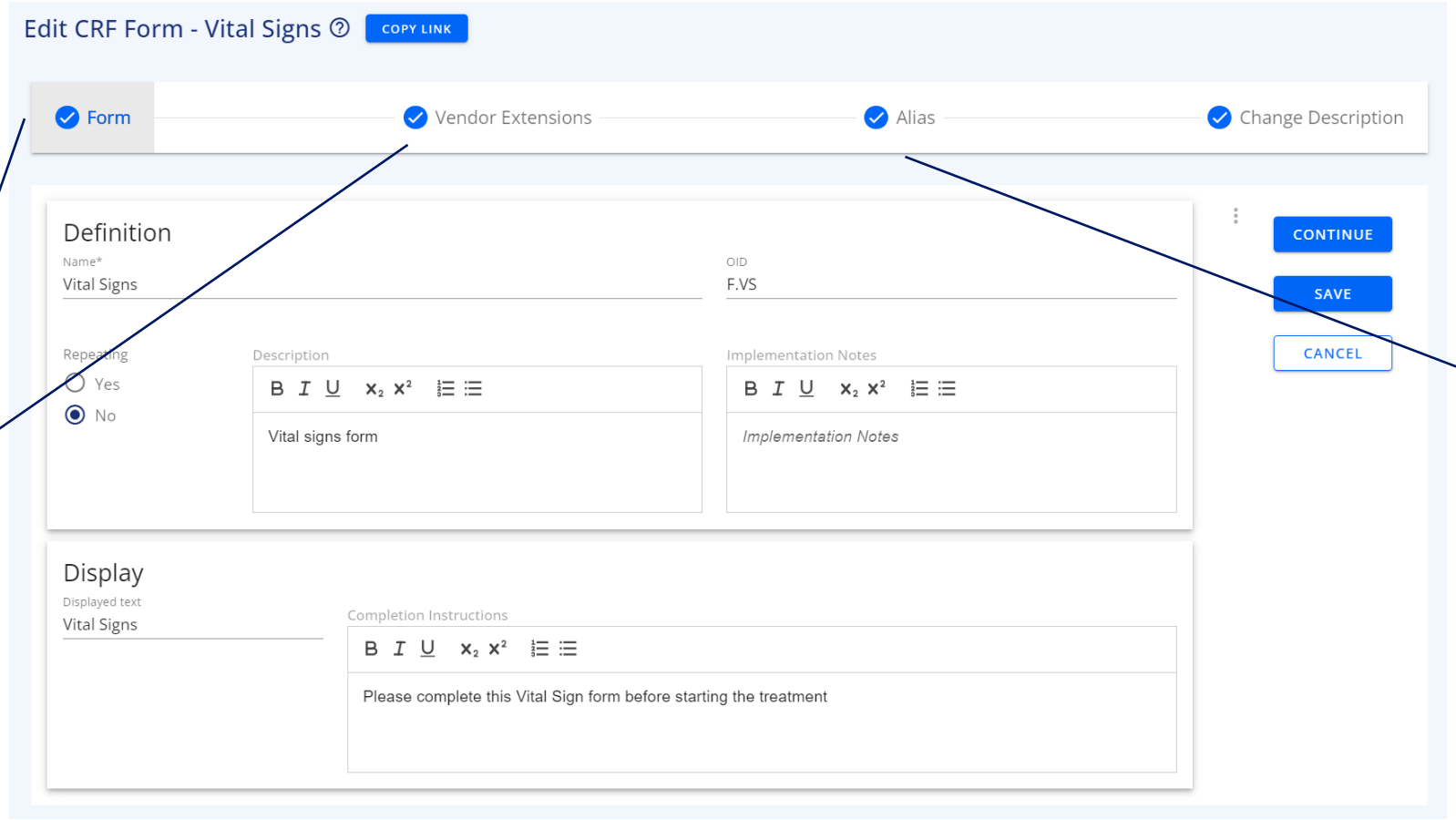
Alias

eCRF views

Form def. as ODM (Vendor Extensions + Alias)

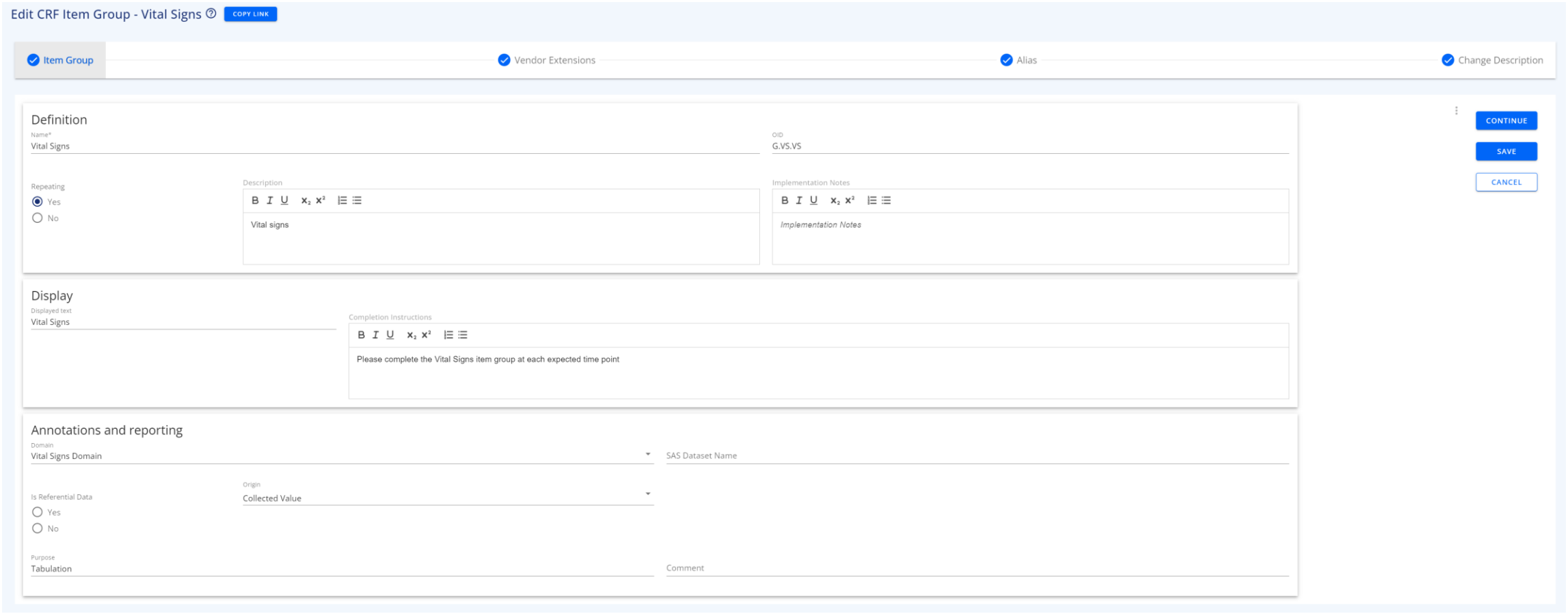
Form Definition

Vendor Extensions

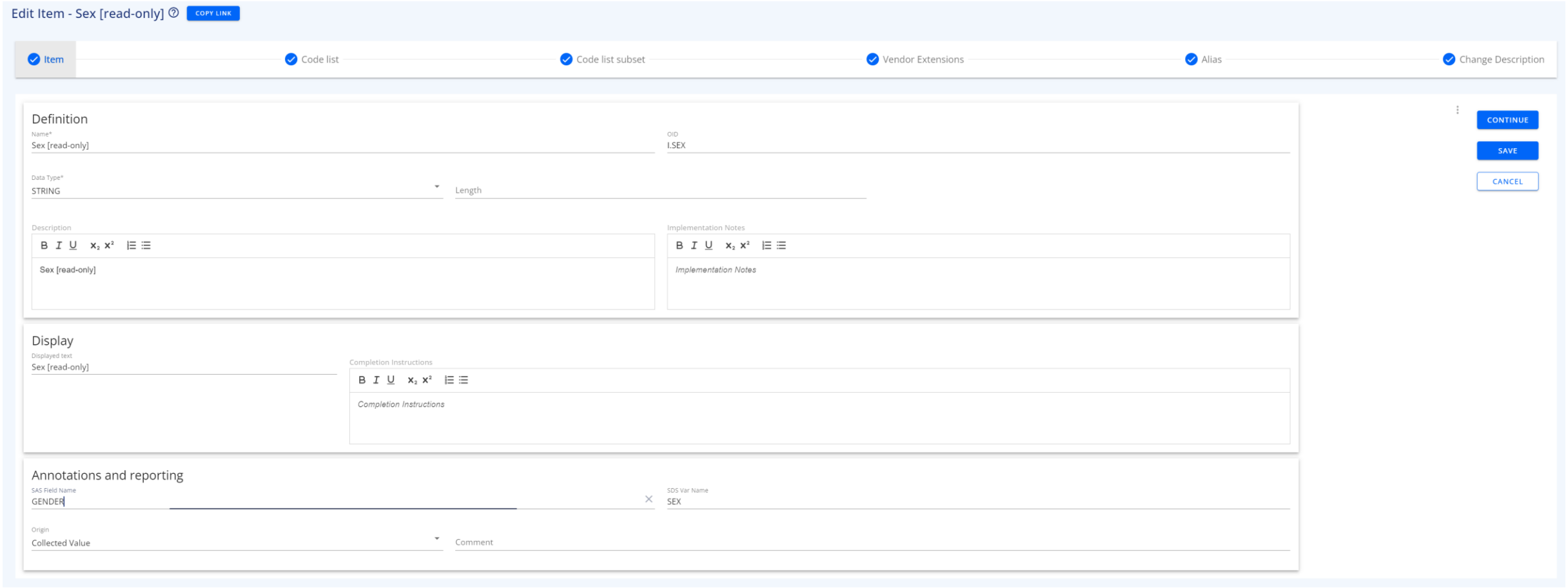


Alias

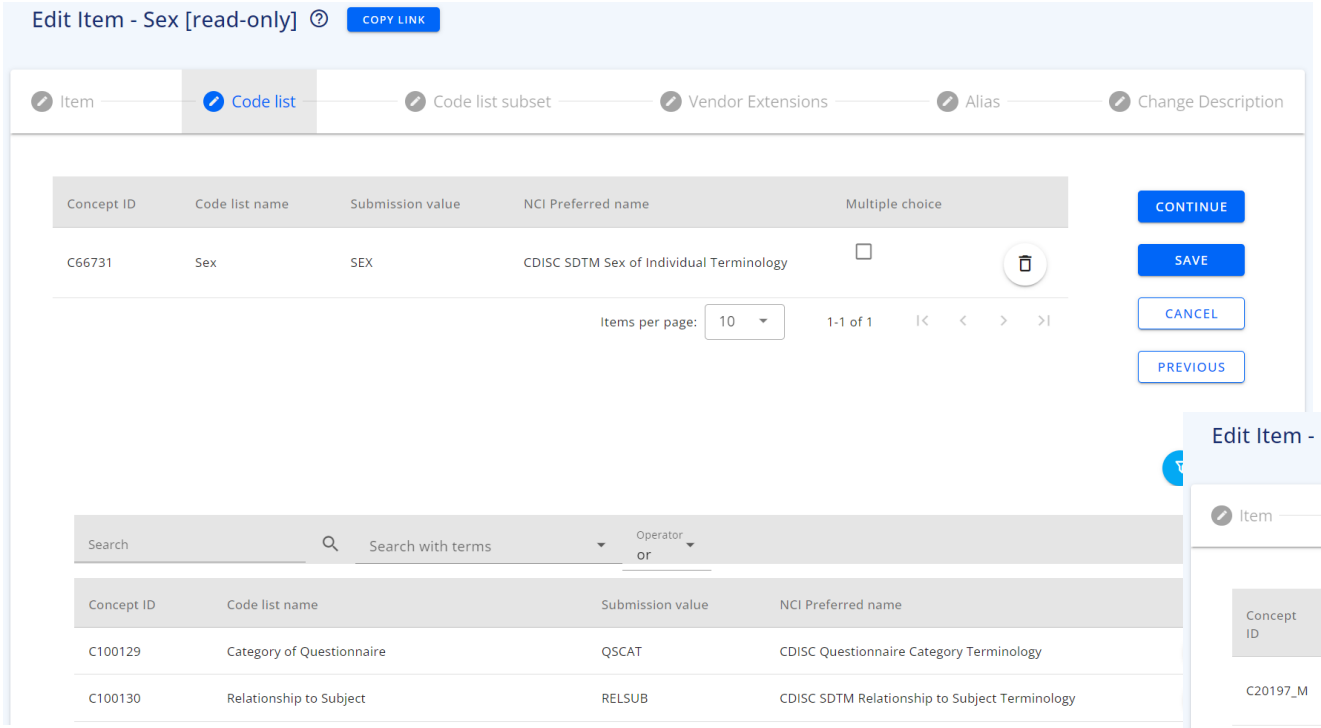
ItemGroup def. as ODM (Vendor Extensions + Alias)

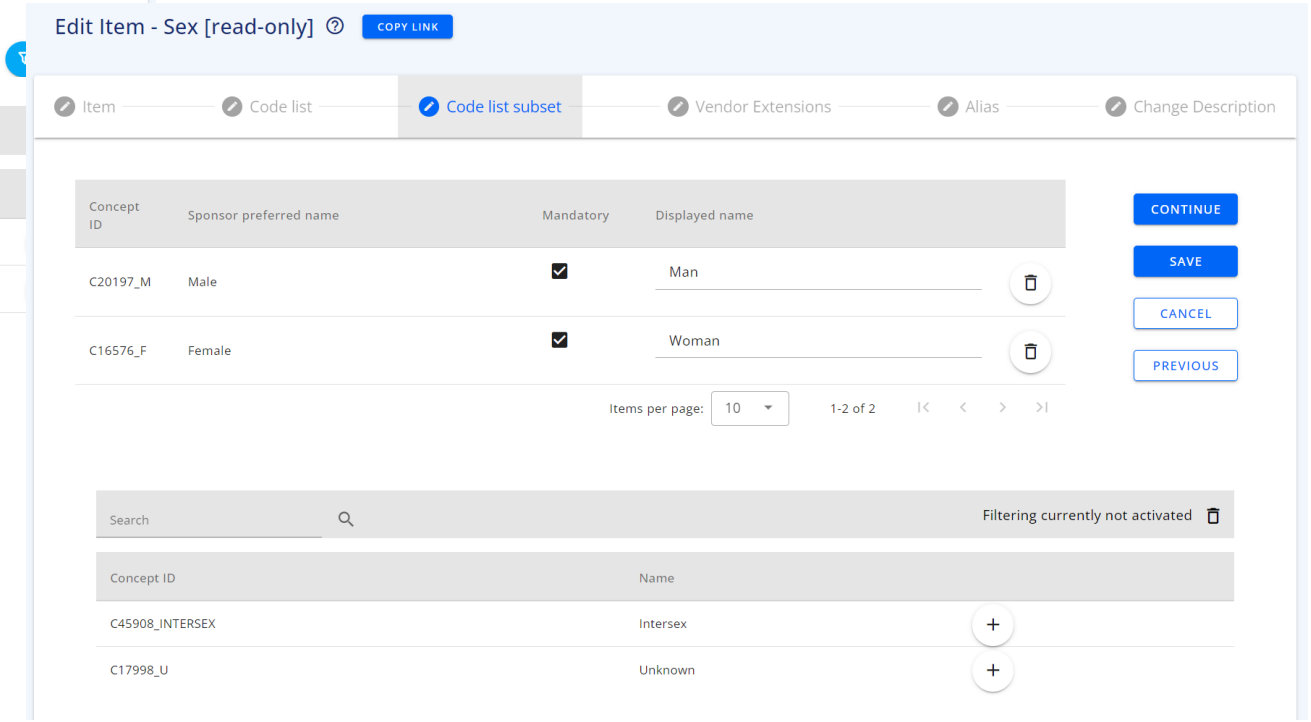


Item def. as ODM (Vendor Extensions + Alias) 1/2

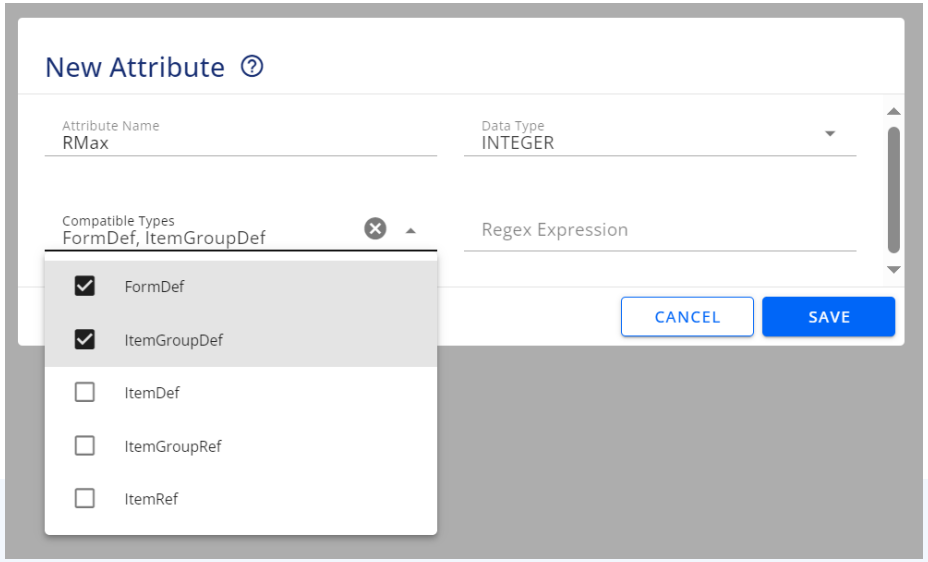


Item def. as ODM (Vendor Extensions + Alias) 2/2





Vendor Extensions



Edit CRF Item Group - Vital Signs COPY LINK

Item Group | Vendor Extensions | Alias | Change Description

Namespace	Parent	Name	Type	Data Type	Value
OpenStudyBuilder	OpenStudyBuilder	RMax	Attribute	INTEGER	Value 10

CONTINUE
SAVE
CANCEL
PREVIOUS

Search

Filtering currently not activated

Name	Namespace	Data Type
displayAsTable	OpenStudyBuilder	string
RMax	OpenStudyBuilder	INTEGER

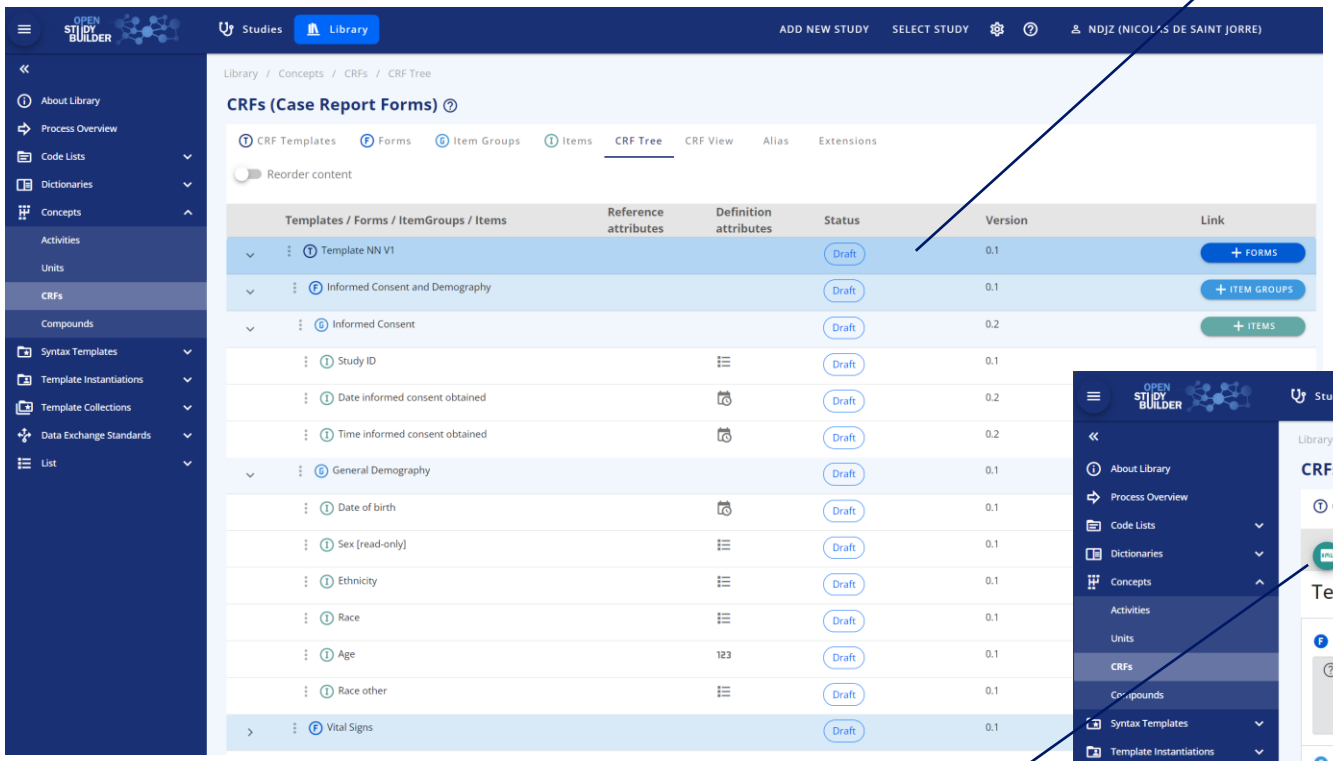
Concept: CRFs

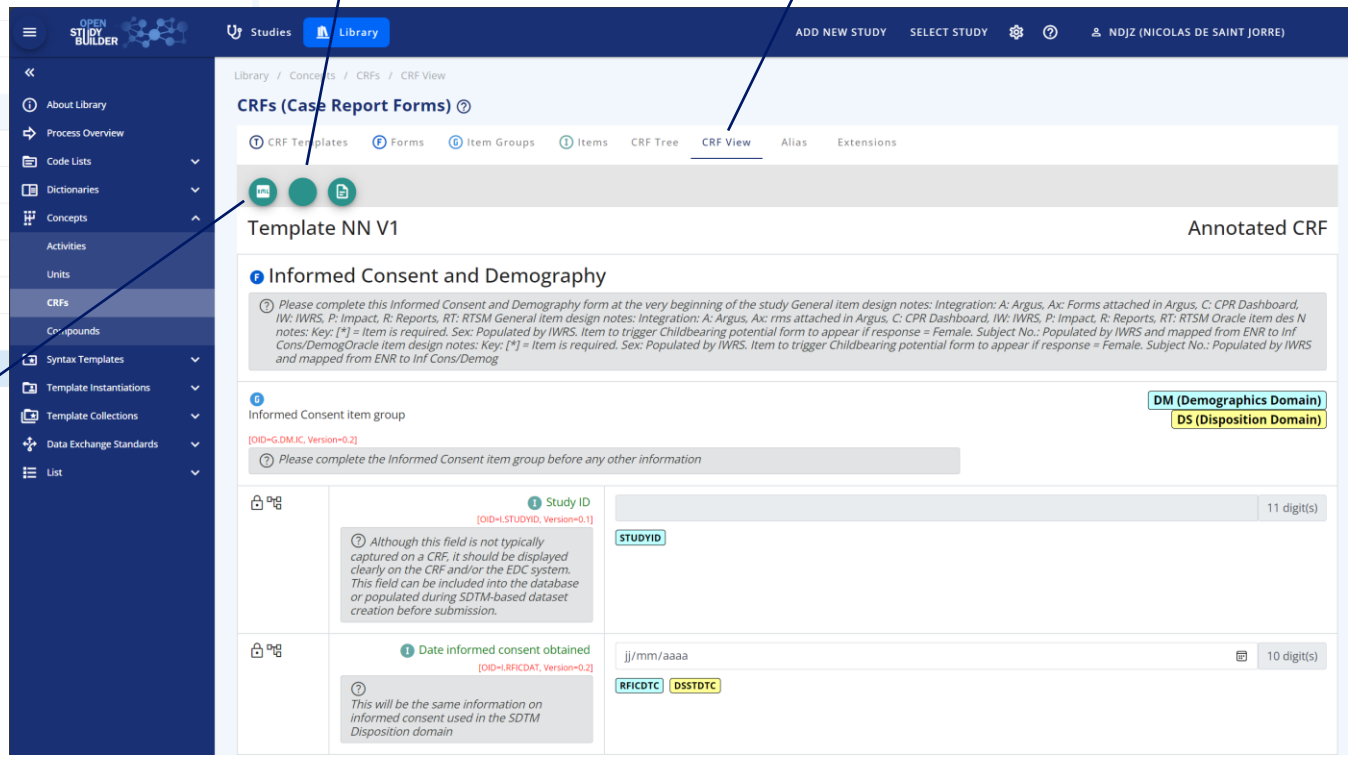
Templates used to defined multiple CRF version

PDF format

Annotated CRF following MSG 2.0 standard

ODM.xml with vendor extensions (or CSV)





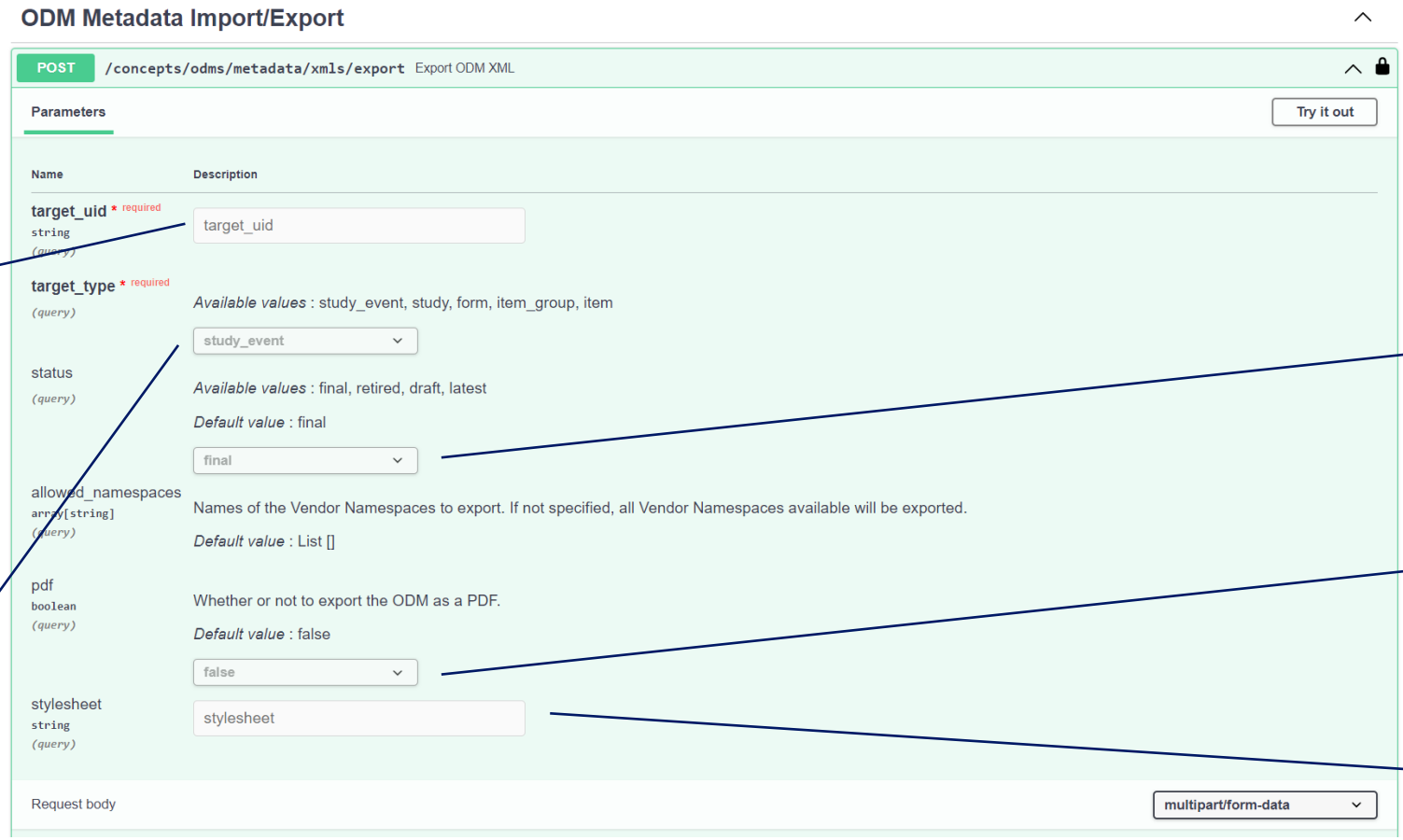
Vendor Extension in ODM

```
<MetaDataVersion OID="MDV.0.1" Name="MDV.0.1" Description="Draft version">
    <FormDef OID="F.VS" Name="Vital Signs" Repeating="No" osb:version="0.1"
    osb:instruction="Please complete this Vital Sign form before starting the treatment">
        <Description>
            <TranslatedText xml:lang="en" osb:version="0.1">Vital signs form</TranslatedText>
        </Description>
        <ItemGroupRef ItemGroupOID="G.VS.VS" Mandatory="No" OrderNumber="0"/>
    </FormDef>
    <ItemGroupDef OID="G.VS.VS" Name="Vital Signs" Repeating="Yes" Purpose="Tabulation"
    SASDatasetName="VITALSIGNS" Domain="VS:Vital Signs Domain" osb:version="0.5"
    osb:instruction="&lt;p&gt;Please complete the Vital Signs item group at each expected
    time point&lt;/p&gt;" osb:RMax="10">
        <osb:DomainColor>VS:#bfffff;</osb:DomainColor>
        <Description>
            <TranslatedText xml:lang="en" osb:version="0.1">&lt;p&gt;Vital signs&lt;/p&gt;</
            TranslatedText>
        </Description>
        <ItemRef ItemOID="I.PULSE" Mandatory="No" OrderNumber="0" MethodOID="null"/>
    </ItemGroupDef>
    <ItemDef OID="I.PULSE" Name="Pulse" Origin="Collected Value" DataType="integer"
    Length="3" SASFieldName="PULSE" SDSVarName="VSORRES/VSORRESU when VSTESTCD=PULSE"
    osb:version="0.1">
        <Question>
            <TranslatedText xml:lang="en" osb:version="0.1">Pulse</TranslatedText>
        </Question>
        <Description>
            <TranslatedText xml:lang="en" osb:version="0.1">Pulse</TranslatedText>
        </Description>
        <MeasurementUnitRef MeasurementUnitOID="beats/min"/>
    </ItemDef>
</MetaDataVersion>
```

Odm.xml API endpoint

Level of Metadata in the ODM (uid):
- StudyEvent
- Form
- ItemGroup

Target Type:
- StudyEvent
- Form
- ItemGroup

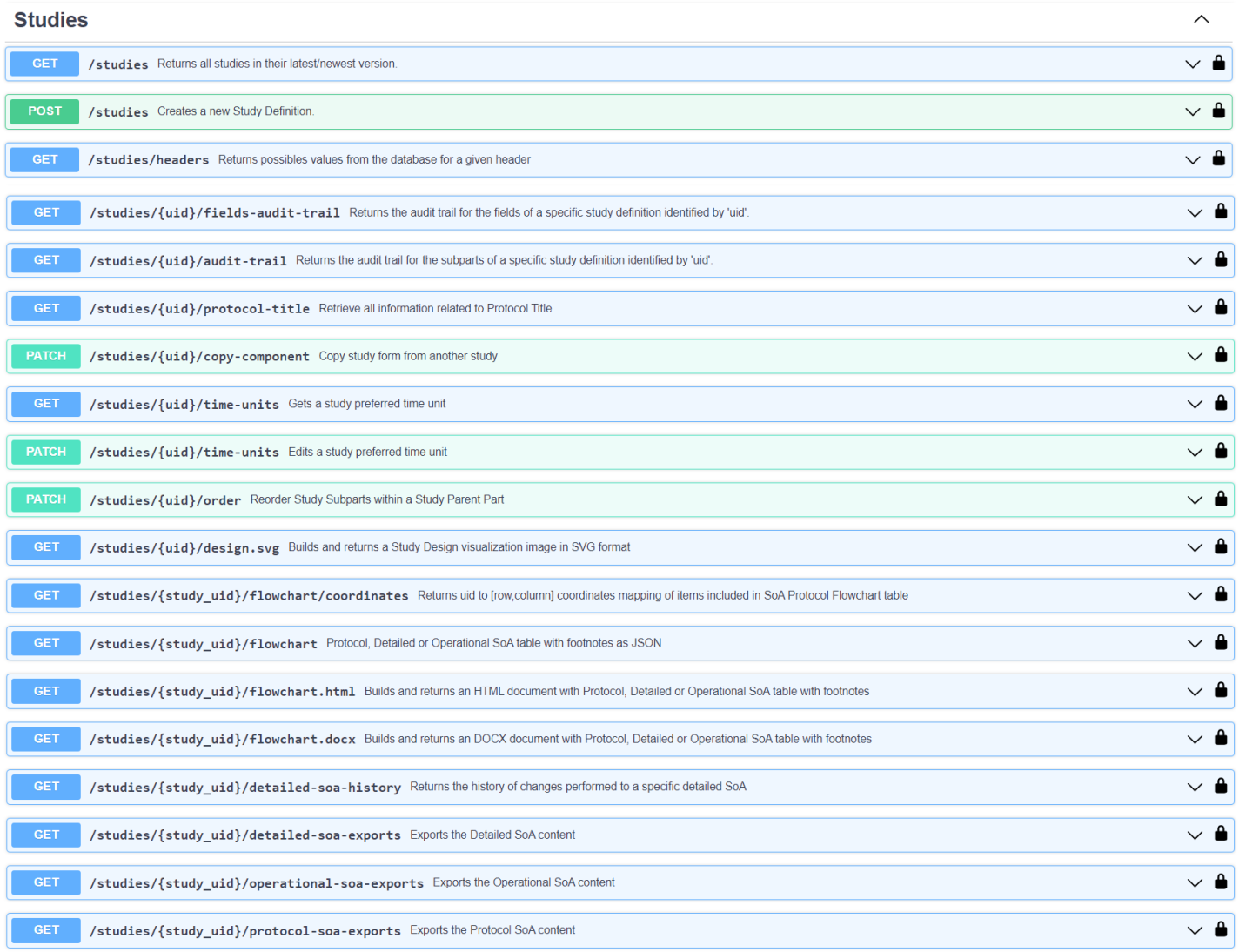


Status of the metadata

PDF or CSV

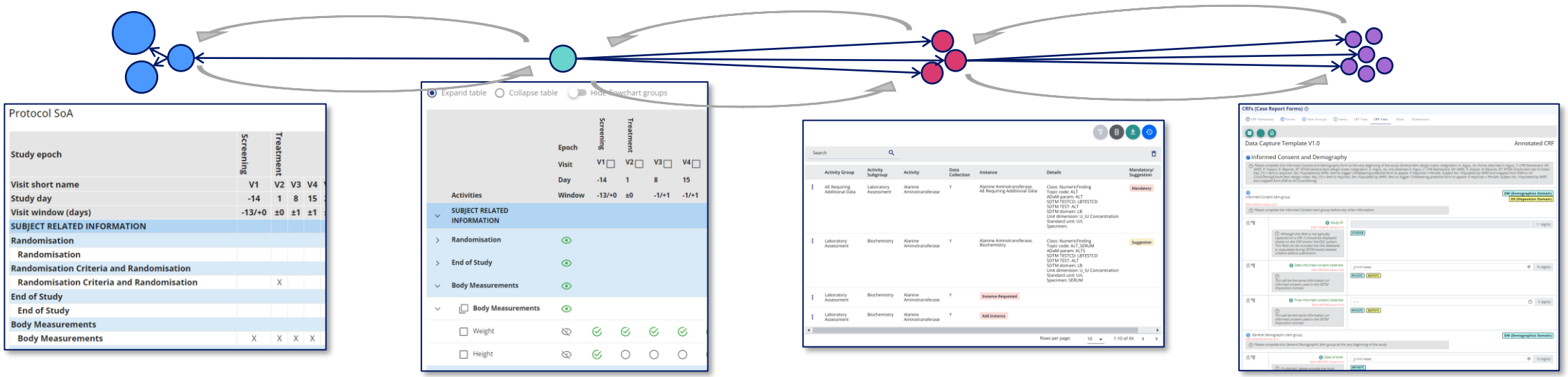
Stylesheet ref.

API Endpoints to work with the SoAs...



SoA and Biomedical Concepts…

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

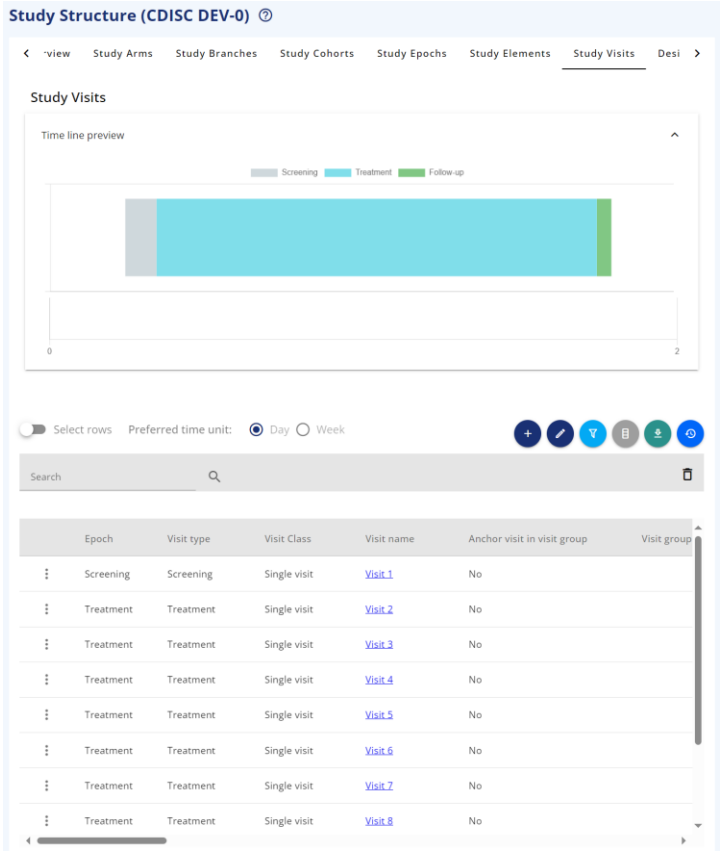
Operational SoA

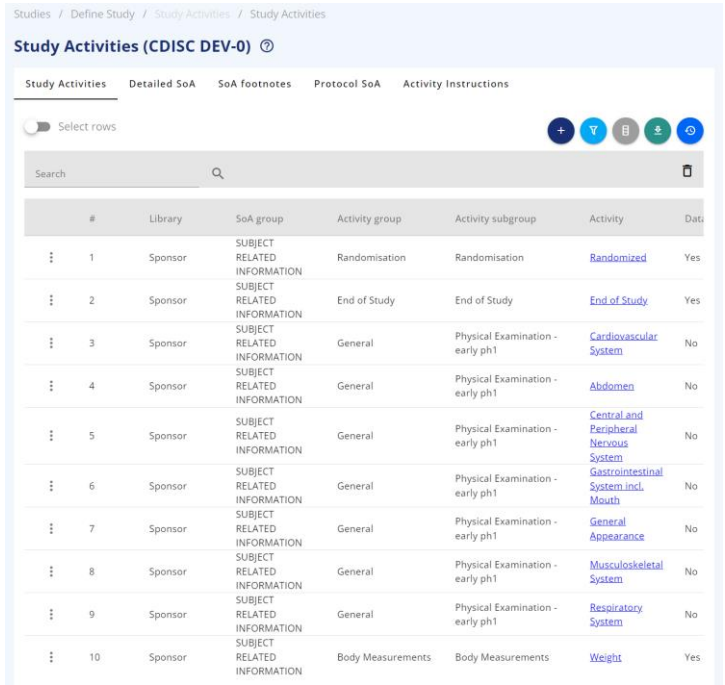
- The data specification to support data collection specification
- Correspond to our existing legacy BCs (Topic Codes)
- Will also related to specific ADaM PARAM/PARAMCD

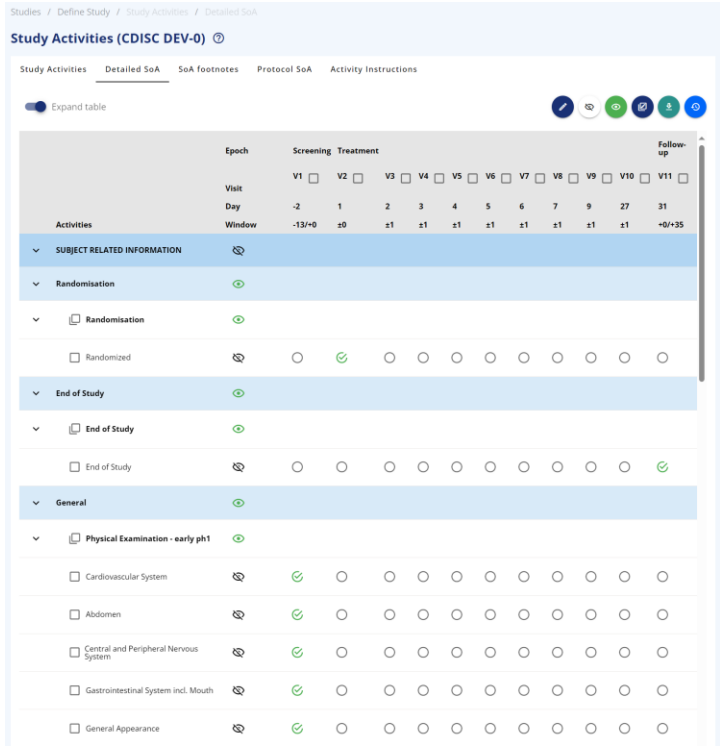
Data Capture / Collection Specification

- How data is to be collected in the study and when
- What is pre-set, what is collected and how

Detailed SoA







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

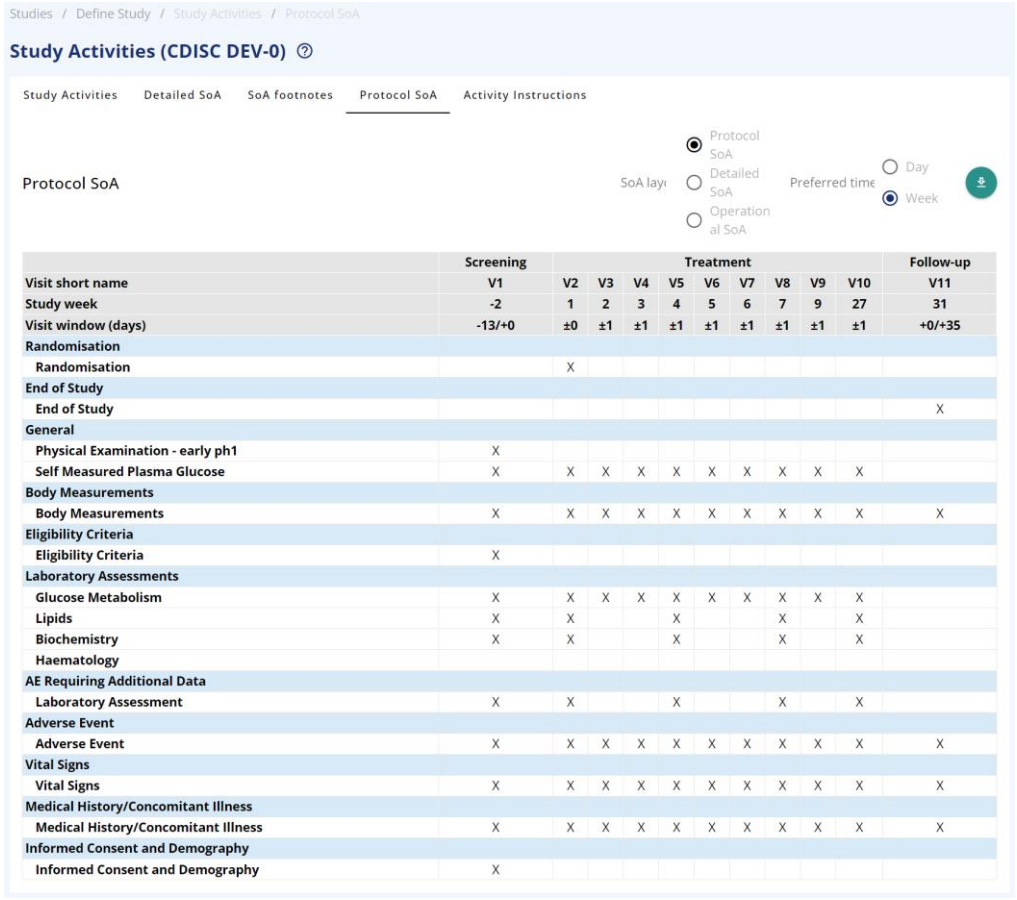
The detailed SoA describe scheduling of the specific Activities and their grouping for the study

roups

Activities	Window	Screening V1	Treatment V2	V3	V4	V5	V6	V7	V8	V9	V10	Follow-up V11
		-14	1	8	15	22	29	36	43	57	183	213
		-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”

Protocol and Operational SoA



Studies / Define Study / Study Activities / Protocol SoA

Study Activities (CDISC DEV-0)

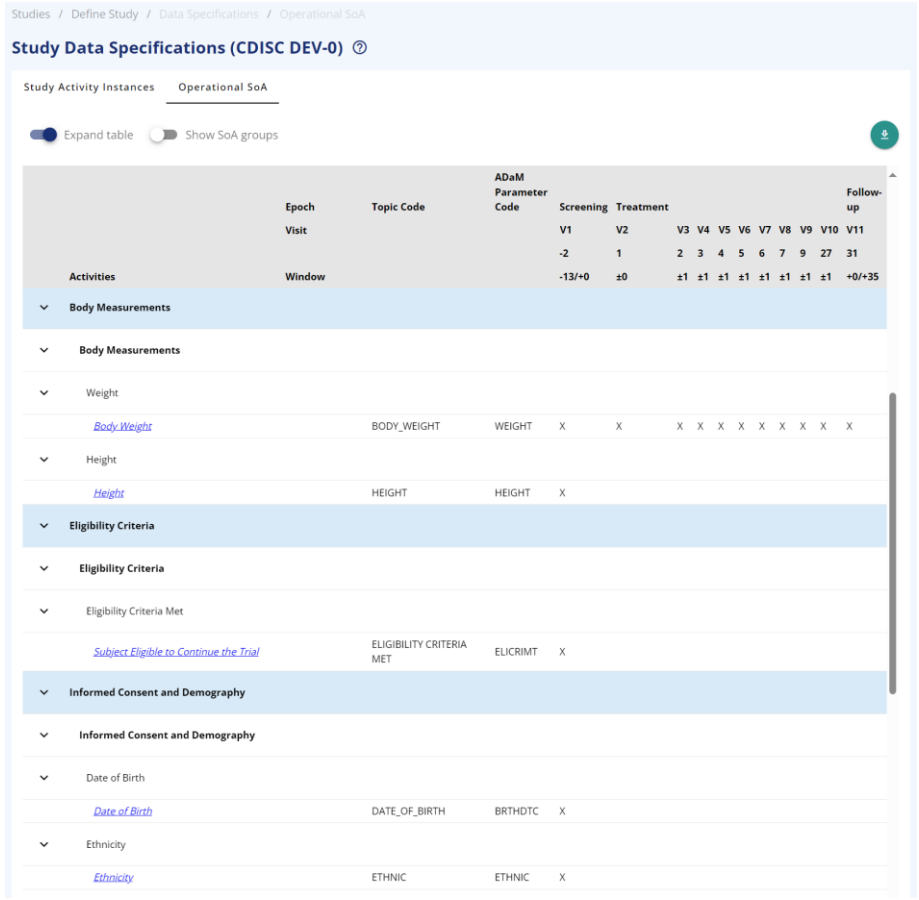
Study Activities | Detailed SoA | SoA footnotes | Protocol SoA | Activity Instructions

Protocol SoA

SoA layer: Protocol SoA / Detailed SoA / Operational SoA

Preferred time: Day / Week

	Screening	Treatment									Follow-up
Visit short name	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**
Study week	**-2**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**9**	**27**	**31**
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
General											
Physical Examination - early ph1	X										
Self Measured Plasma Glucose	X	X	X	X	X	X	X	X	X	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	
Haematology											
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
Informed Consent and Demography											
Informed Consent and Demography	X										



Studies / Define Study / Data Specifications / Operational SoA

Study Data Specifications (CDISC DEV-0)

Study Activity Instances | Operational SoA

Expand table | Show SoA groups

Activities	Epoch / Visit / Window	Topic Code	ADaM Parameter Code	Screening V1 -2 -13/+0	Treatment V2 1 ±0	V3 2 ±1	V4 3 ±1	V5 4 ±1	V6 5 ±1	V7 6 ±1	V8 7 ±1	V9 9 ±1	V10 27 ±1	Follow-up V11 31 +0/+35
Body Measurements														
Body Measurements														
Weight														
Body Weight		BODY_WEIGHT	WEIGHT	X	X	X	X	X	X	X	X	X	X	
Height														
Height		HEIGHT	HEIGHT	X										
Eligibility Criteria														
Eligibility Criteria														
Eligibility Criteria Met														
Subject Eligible to Continue the Trial		ELIGIBILITY CRITERIA MET	ELICRIMT	X										
Informed Consent and Demography														
Informed Consent and Demography														
Date of Birth														
Date of Birth		DATE_OF_BIRTH	BRTHDTC	X										
Ethnicity														
Ethnicity		ETHNIC	ETHNIC	X										

Study Activities (CDISC DEV-0)

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

Protocol SoA

SoA layout: Protocol SoA / Detailed SoA / Operational SoA

Preferred time unit: Day / Week

	Topic Code	ADaM Parameter Code	Screening	Treatment								Follow-up
Visit short name			V1	V2	V3	V4	V5	V6	V7	V8	V9	V11
Study week			-2	1	2	3	4	5	6	7	9	31
Visit window (days)			-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	+0/+35
SUBJECT RELATED INFORMATION												
Randomisation												
Randomisation												
Randomized												
Randomisation Date	RANDOMISATION_DATE	RANDDT		X								
End of Study												
End of Study												
End of Study												
End of Study	END_OF_TRIAL	EOT										X
General												
Physical Examination - early ph1												
Cardiovascular System												
Abdomen												
Central and Peripheral Nervous System												
Gastrointestinal System incl. Mouth												
General Appearance												
Musculoskeletal System												
Respiratory System												
Body Measurements												
Body Measurements												
Weight												
Body Weight	BODY_WEIGHT	WEIGHT	X	X	X	X	X	X	X	X	X	X
Height												
Height	HEIGHT	HEIGHT	X									
Eligibility Criteria												
Eligibility Criteria												
Eligibility Criteria Met												
Subject Eligible to Continue the Trial	ELIGIBILITY CRITERIA MET	ELICRIMT	X									

Produce a copy of the SoA compatible with Word

The “Protocol SoA” displaying the selected activity level of detail as a preview

M11 – Section 8 = Detailed SoA

1. Protocol summary
2. Introduction
3. Trial objectives, endpoints and estimands
4. Trial design
5. Trial population
6. Trial intervention and concomitant therapy
7. Discontinuation of trial intervention and participant withdrawal from trial
8. Trial assessments and procedures
9. Statistical considerations
10. General considerations: regulatory, ethical, and trial oversight
11. GENERAL CONSIDERATIONS: RISK MANAGEMENT AND QUALITY assurance
12. Appendix: adverse events and serious adverse events – definitions, severity, and causality
13. Appendix: definitions and supporting operational details
14. Appendix: glossary of terms
15. Appendix: references

ICH M11 Template

- Include guidelines for the management of relevant laboratory or other safety assessment abnormalities.

[Safety Assessments and Procedures]

8.3.1 Physical Examination

Include any specific instructions for the collection and interpretation of physical examinations.

[Physical Examination]

8.3.2 Vital Signs

Include any specific instructions for the collection and interpretation of vital signs.

[Vital Signs]

8.3.3 Electrocardiograms

Include any specific instructions for the collection, interpretation, and archiving of ECGs.

[Electrocardiograms]

8.3.4 Clinical Laboratory Assessments

Include any specific instructions for the collection and interpretation of clinical laboratory assessments.

- Specify if and when the use of local laboratories is allowed.
- Specify which laboratory parameters should be included in each panel (for example, for haematology, chemistry, urinalysis).

[Clinical Safety Laboratory Assessments]

8.3.5 Suicidal Ideation and Behaviour Risk Monitoring

If the trial meets any of the criteria requiring suicidal ideation and behaviour risk monitoring by the guidance/guideline in each region, include any specific instructions for the collection and interpretation of the assessment

[Suicidal Ideation and Behaviour Risk Monitoring]

8.4 Adverse Events and Serious Adverse Events

No text is intended here (header only).

8.4.1 Definitions of AE and SAE

Specify the AE and SAE definitions.

[AE definition]

[SAE definition]

Additional details and clarifications for AEs and SAEs are in Appendices 12.1 and 12.2.

Selection process of Activities for SoA

For Protocol Outline / Protocol

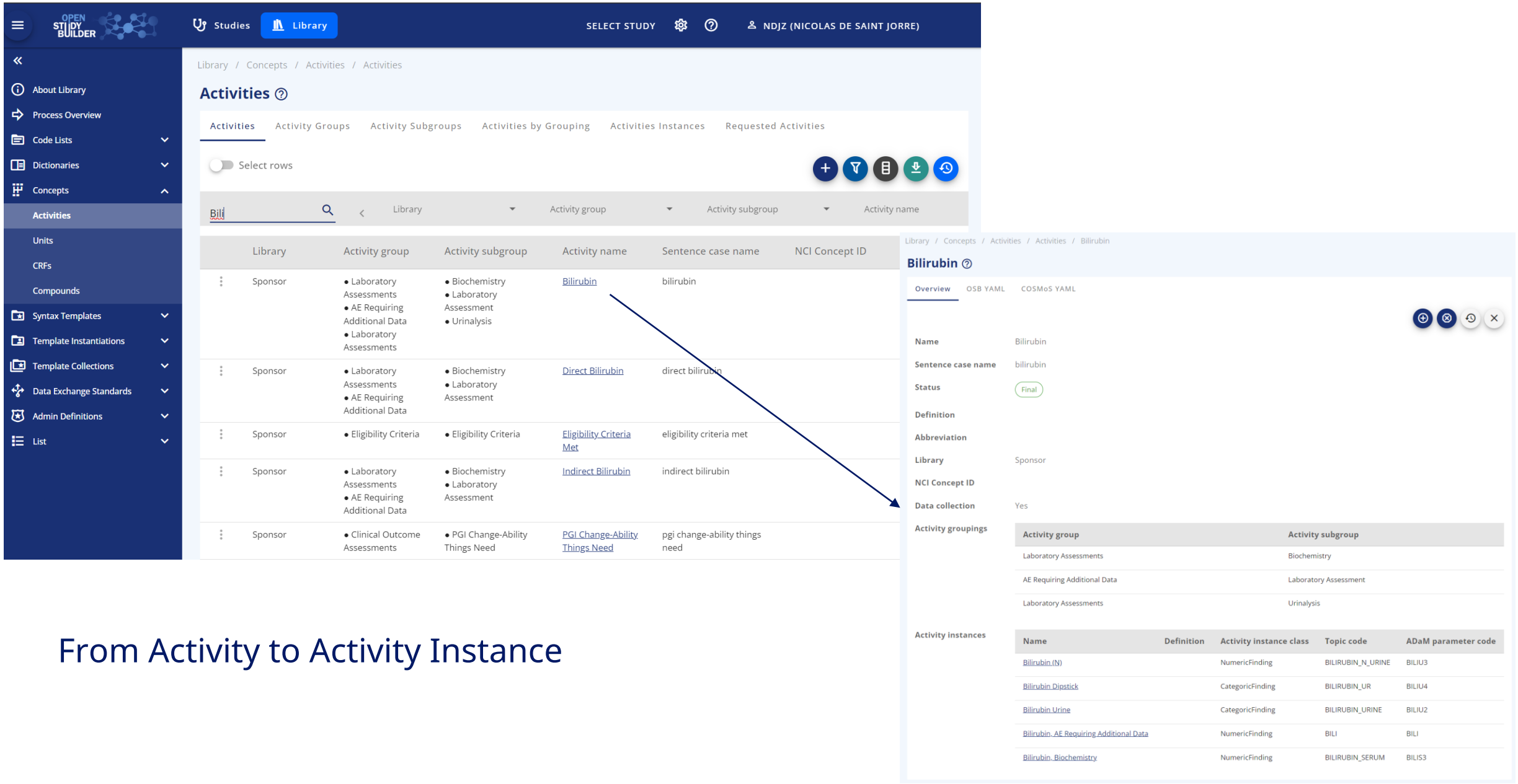
- Select Activities in relevant grouping
- When selecting an Activity within a specific grouping, then this will drive ActivityInstance – this should be visible for Protocol Writers (like a COL)
  - Some ActivityInstances can be mark as default for an Activity, and will then be pre-selected
  - Some 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

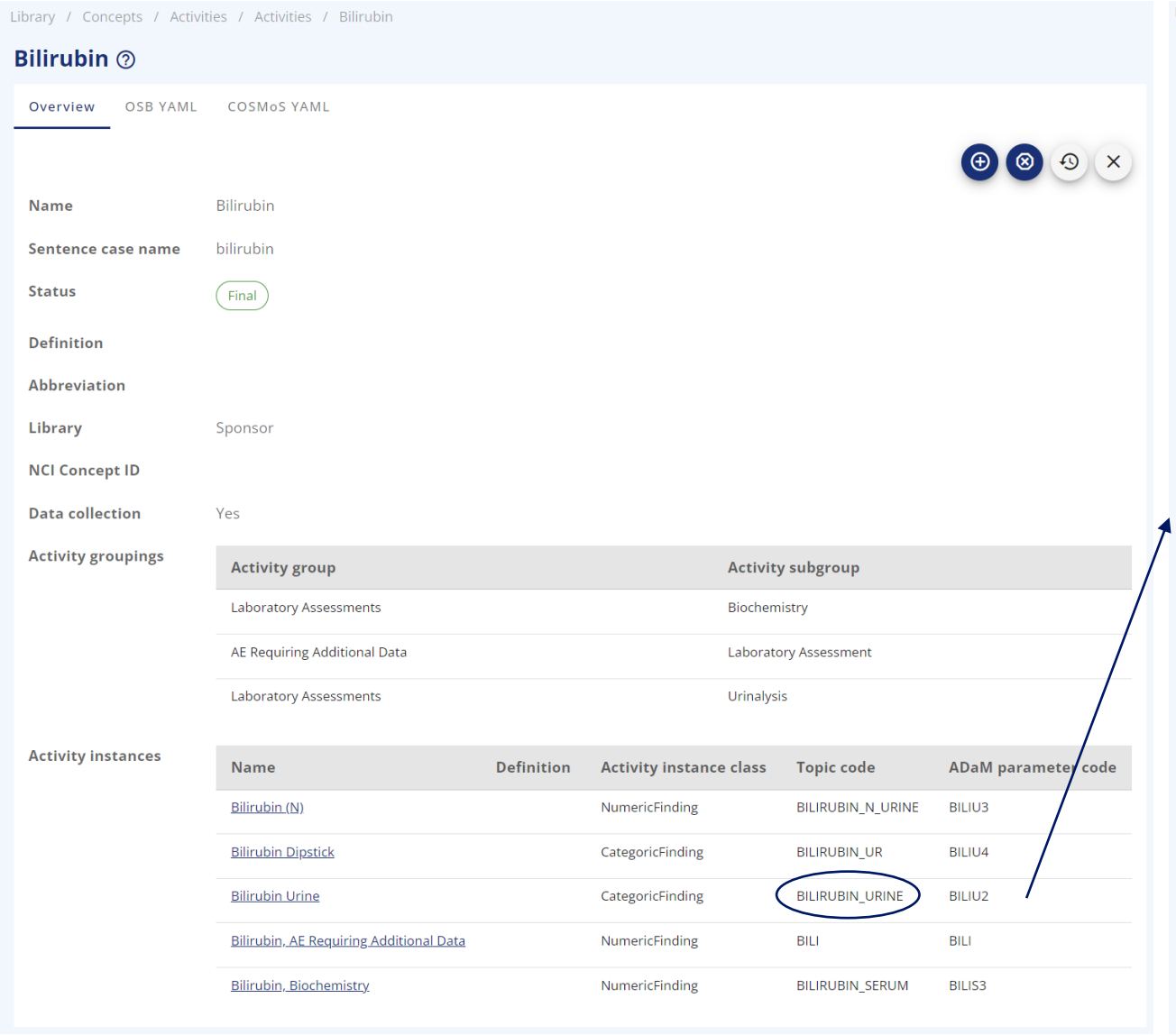
- Confirm or Select Activity Instances for each selected Activity
- If the correct ActivityInstance will change Grouping – this will require a change to the Protocol SoA – this will then

For Data Collection Specification

- The data collection specification
  - Lab specs
  - CRF
  - Other eSources
  - What is pre-set



From Activity to Activity Instance



Library / Concepts / Activities / Activities / Bilirubin

Bilirubin

Overview | OSB YAML | COSMoS YAML

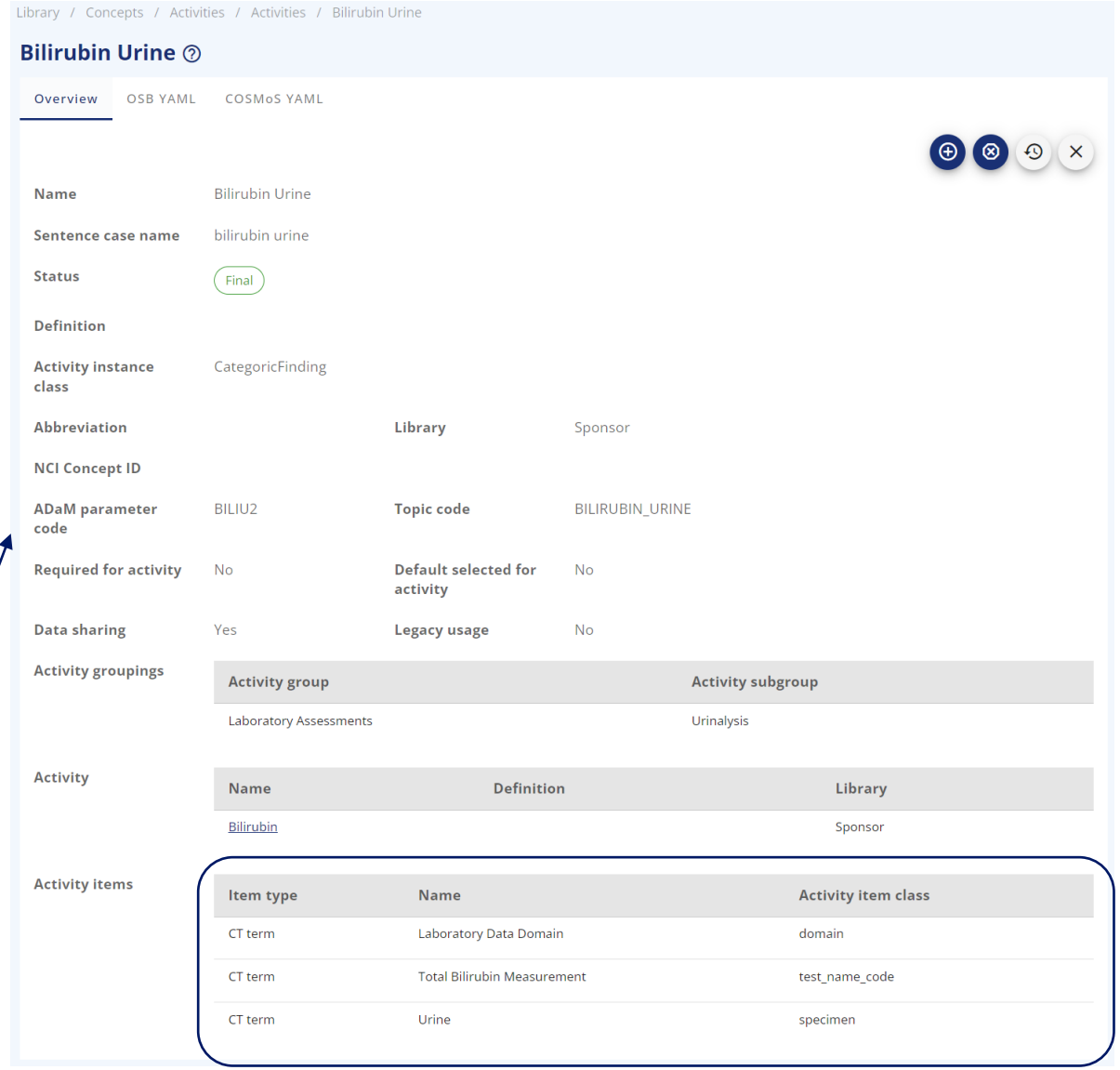
Name	Bilirubin
Sentence case name	bilirubin
Status	Final
Definition	
Abbreviation	
Library	Sponsor
NCI Concept ID	
Data collection	Yes

Activity groupings

Activity group	Activity subgroup
Laboratory Assessments	Biochemistry
AE Requiring Additional Data	Laboratory Assessment
Laboratory Assessments	Urinalysis

Activity instances

Name	Definition	Activity instance class	Topic code	ADaM parameter code
Bilirubin (N)		NumericFinding	BILIRUBIN_N_URINE	BILIU3
Bilirubin Dipstick		CategoricFinding	BILIRUBIN_UR	BILIU4
Bilirubin Urine		CategoricFinding	BILIRUBIN_URINE	BILIU2
Bilirubin, AE Requiring Additional Data		NumericFinding	BILI	BILI
Bilirubin, Biochemistry		NumericFinding	BILIRUBIN_SERUM	BILIS3



Library / Concepts / Activities / Activities / Bilirubin Urine

Bilirubin Urine

Overview | OSB YAML | COSMoS YAML

Name	Bilirubin Urine		
Sentence case name	bilirubin urine		
Status	Final		
Definition			
Activity instance class	CategoricFinding		
Abbreviation		Library	Sponsor
NCI Concept ID			
ADaM parameter code	BILIU2	Topic code	BILIRUBIN_URINE
Required for activity	No	Default selected for activity	No
Data sharing	Yes	Legacy usage	No

Activity groupings

Activity group	Activity subgroup
Laboratory Assessments	Urinalysis

Activity

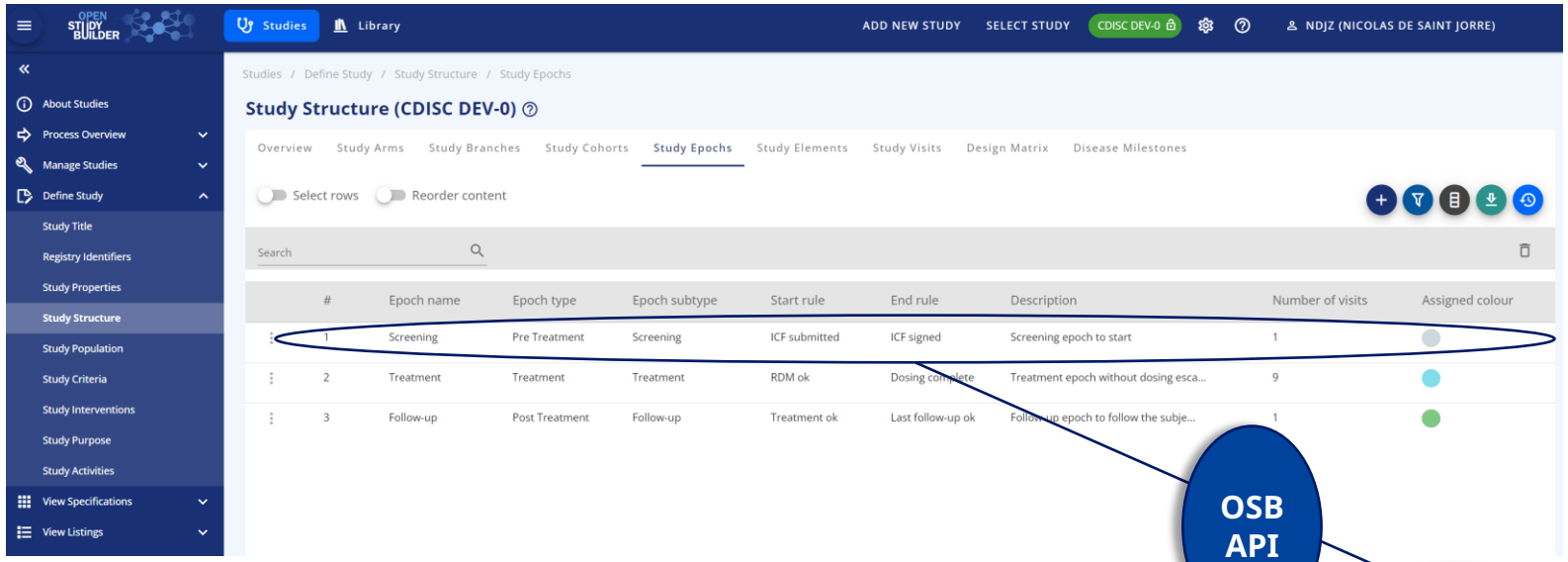
Name	Definition	Library
Bilirubin		Sponsor

Activity items

Item type	Name	Activity item class
CT term	Laboratory Data Domain	domain
CT term	Total Bilirubin Measurement	test_name_code
CT term	Urine	specimen

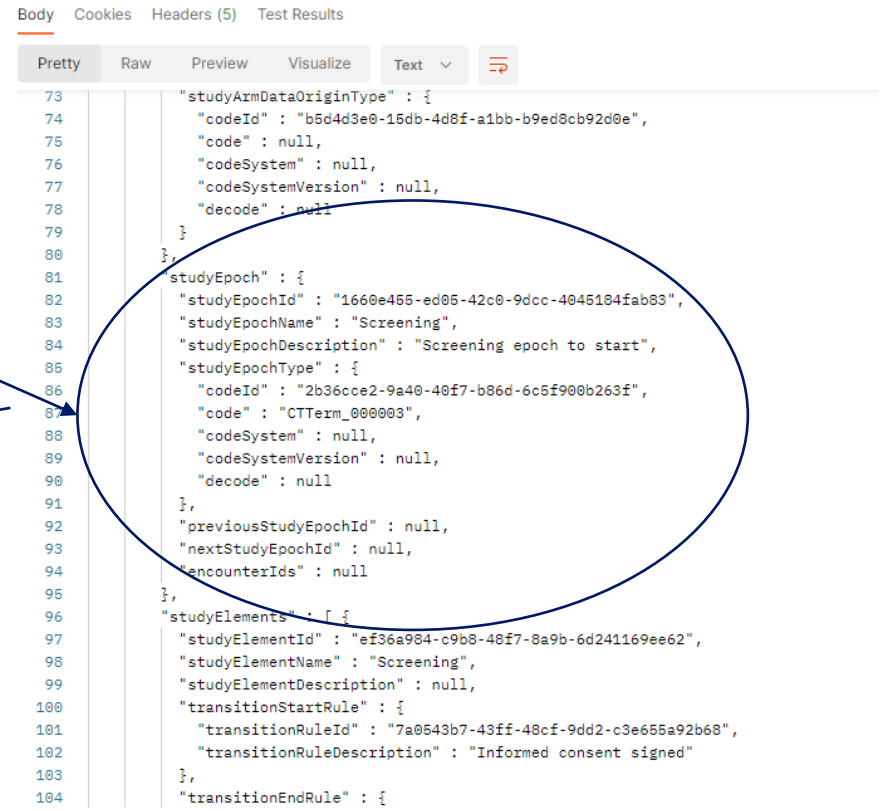
Activity to Activity Instance to Activity Item – As Biomedical Concept (COSMOS project from CDISC)

Digital Data Flow Adaptor (TransCelerate DDF)



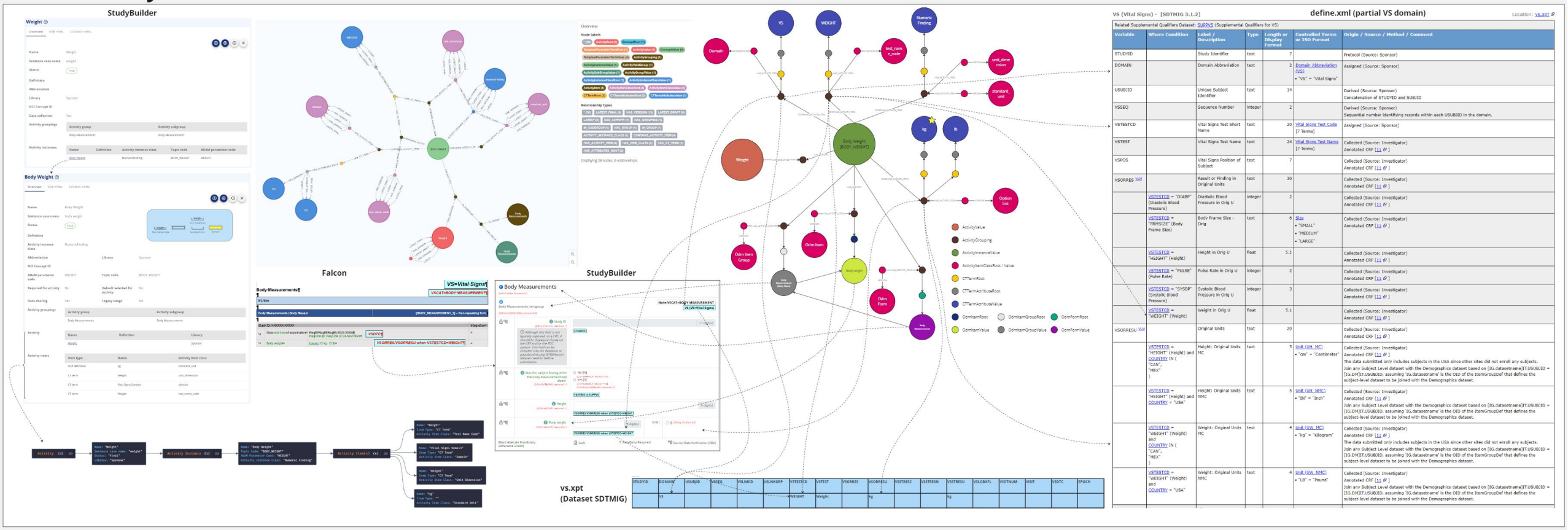
accenture

Microsoft

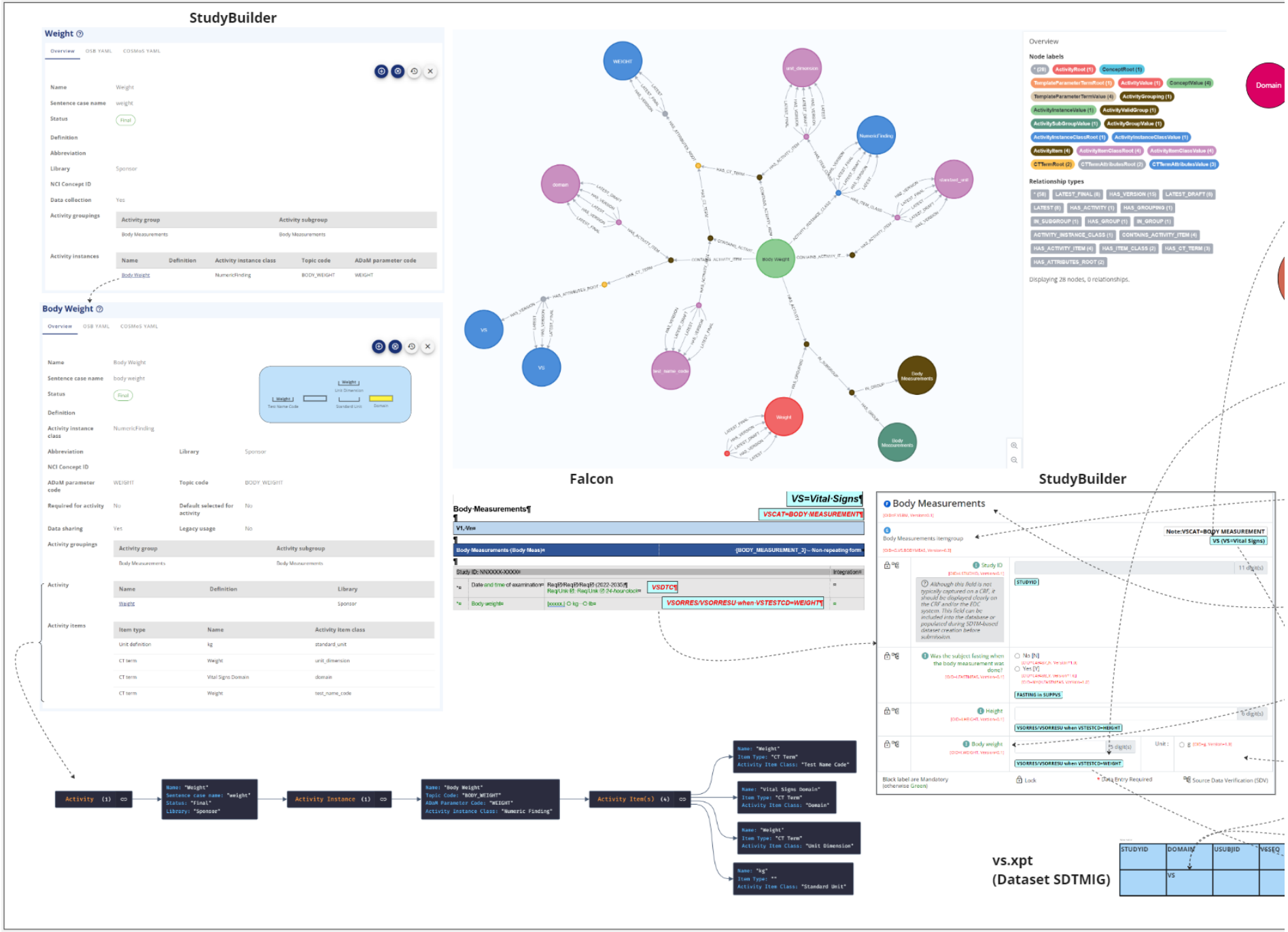


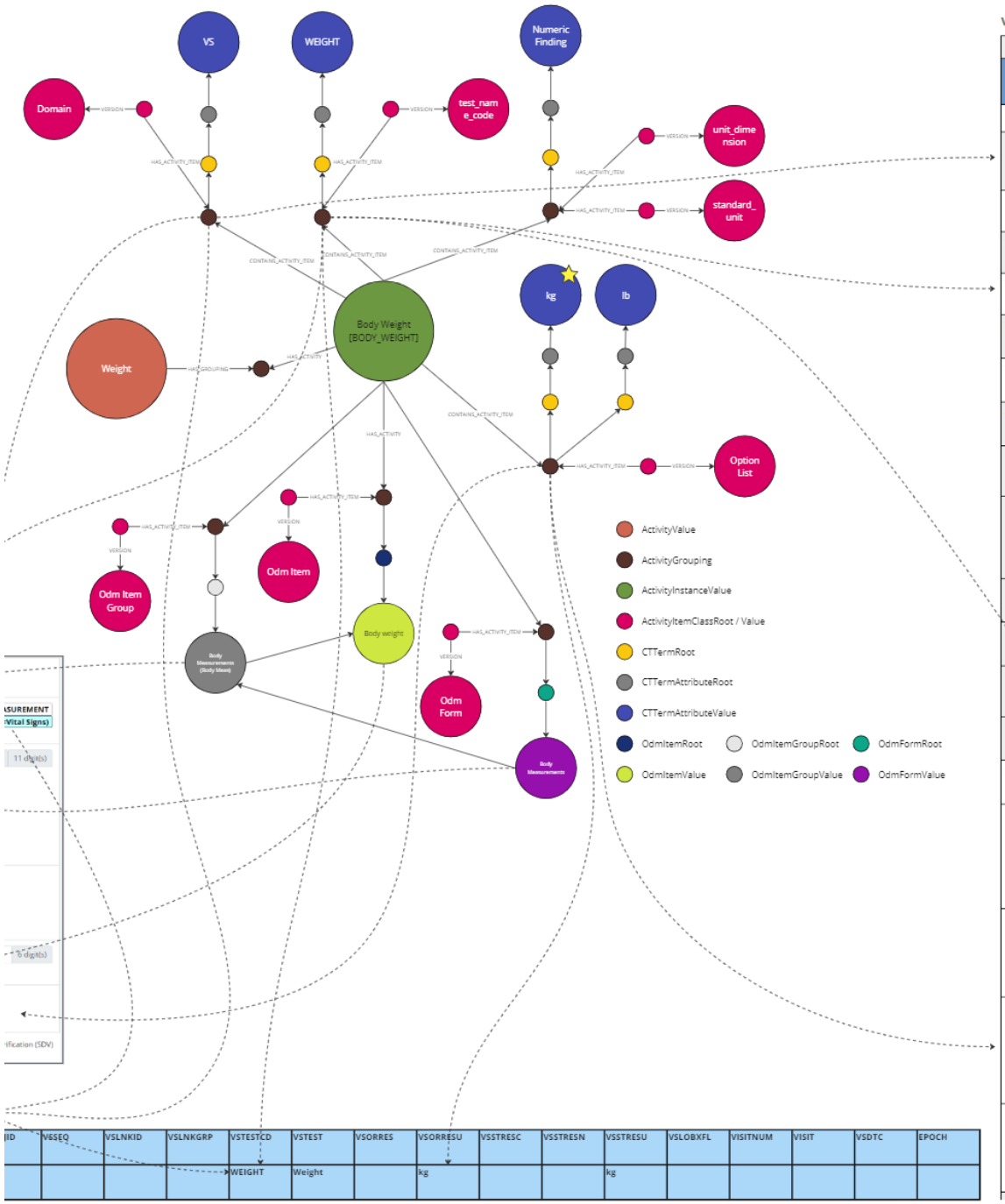
Our vision

From Activity to CRF and Define…



From Activity to CRF and Define…





ID	VSSEQ	VSLNKID	VSLNKGRP	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSLOBXFL	VISITNUM	VISIT	VSDTC	EPOCH
				WEIGHT	Weight		kg			kg					

define.xml (partial VS domain)

VS (Vital Signs) - [SDTMIG 3.1.2]

Location: vs.xpt

Related Supplemental Qualifiers Dataset: SUPPVS (Supplemental Qualifiers for VS)

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN		Domain Abbreviation	text	2	Domain Abbreviation (VS) • "VS" = "Vital Signs"	Assigned (Source: Sponsor)
USUBJID		Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
VSSEQ		Sequence Number	integer	2		Derived (Source: Sponsor) Sequential number identifying records within each USUBJID in the domain.
VSTESTCD		Vital Signs Test Short Name	text	20	Vital Signs Test Code [7 Terms]	Assigned (Source: Sponsor)
VSTEST		Vital Signs Test Name	text	24	Vital Signs Test Name [7 Terms]	Collected (Source: Investigator) Annotated CRF [11]
VSPOS		Vital Signs Position of Subject	text	7		Collected (Source: Investigator) Annotated CRF [11]
VSORRES VLM		Result or Finding in Original Units	text	30		Collected (Source: Investigator) Annotated CRF [11]
	VSTESTCD = "DIABP" (Diastolic Blood Pressure)	Diastolic Blood Pressure in Orig U	integer	2		Collected (Source: Investigator) Annotated CRF [11]
	VSTESTCD = "FRMSIZE" (Body Frame Size)	Body Frame Size - Orig	text	6	Size • "SMALL" • "MEDIUM" • "LARGE"	Collected (Source: Investigator) Annotated CRF [11]
	VSTESTCD = "HEIGHT" (Height)	Height in Orig U	float	5.1		Collected (Source: Investigator) Annotated CRF [11]
	VSTESTCD = "PULSE" (Pulse Rate)	Pulse Rate in Orig U	integer	2		Collected (Source: Investigator) Annotated CRF [11]
	VSTESTCD = "SYSBP" (Systolic Blood Pressure)	Systolic Blood Pressure in Orig U	integer	3		Collected (Source: Investigator) Annotated CRF [11]
	VSTESTCD = "WEIGHT" (Weight)	Weight in Orig U	float	5.1		Collected (Source: Investigator) Annotated CRF [11]
VSORRESU VLM		Original Units	text	20		Collected (Source: Investigator) Annotated CRF [11]
	VSTESTCD = "HEIGHT" (Height) and COUNTRY IN ("CAN", "MEX")	Height: Original Units MC	text	5	Unit (UH_MC) • "cm" = "Centimeter"	Collected (Source: Investigator) Annotated CRF [11] The data submitted only includes subjects in the USA since other sites did not enroll any subjects. Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.
	VSTESTCD = "HEIGHT" (Height) and COUNTRY = "USA"	Height: Original Units NMC	text	5	Unit (UH_NMC) • "IN" = "Inch"	Collected (Source: Investigator) Annotated CRF [11] Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.
	VSTESTCD = "WEIGHT" (Weight) and COUNTRY IN ("CAN", "MEX")	Weight: Original Units MC	text	4	Unit (UW_MC) • "kg" = "Kilogram"	Collected (Source: Investigator) Annotated CRF [11] The data submitted only includes subjects in the USA since other sites did not enroll any subjects. Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.
	VSTESTCD = "WEIGHT" (Weight) and COUNTRY = "USA"	Weight: Original Units NMC	text	4	Unit (UW_NMC) • "LB" = "Pound"	Collected (Source: Investigator) Annotated CRF [11] Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.

Status of the OpenStudyBuilder

- Already working:
  - Protocol SoA
  - Detailed SoA
  - eCRF in the Library
  - Vendor Extensions
  - Alias
  - Models integration (like SDTM/SDTMIG with version control in the Library)
- Work in progress:
  - Operational SoA
  - Connection between Activity Instances with Activity Items to eCRF, SDTM domains and variables, ADaM domains and variables with a sharing CT management and units
  - Integration of external data like Labs
- What is planned:
  - eCRF at the Study level (with integration to the Operational SoA
  - Production of the define.xml (pre version) based on the Protocol SoA and Detailed SoA

Questions to discuss

- Extensions / configurations required for vendors
  - Additional attributes, e.g. to link to systems & versions
  - ODM.xml additional information
  - API endpoints, additional requirements

- General aspects
  - API versioning
  - Continuous development challenges, up versioning
  - Adoptions & implications according license

- Standards
  - Additional standard requirements, recommendations, wishes

Additional Information

CDISC Interchange 2024

Use OpenStudyBuilder to drive EDC setup - a COSA Workshop

23 April 2024 9:00-16:00, Berlin, Germany

CDISC Interchange 2024

Use OpenStudyBuilder as MDR Meetup

23 April 2024 17:00-18:00, Berlin, Germany

- Reach out to OpenStudyBuilder@gmail.com

Meet us at the Interchange

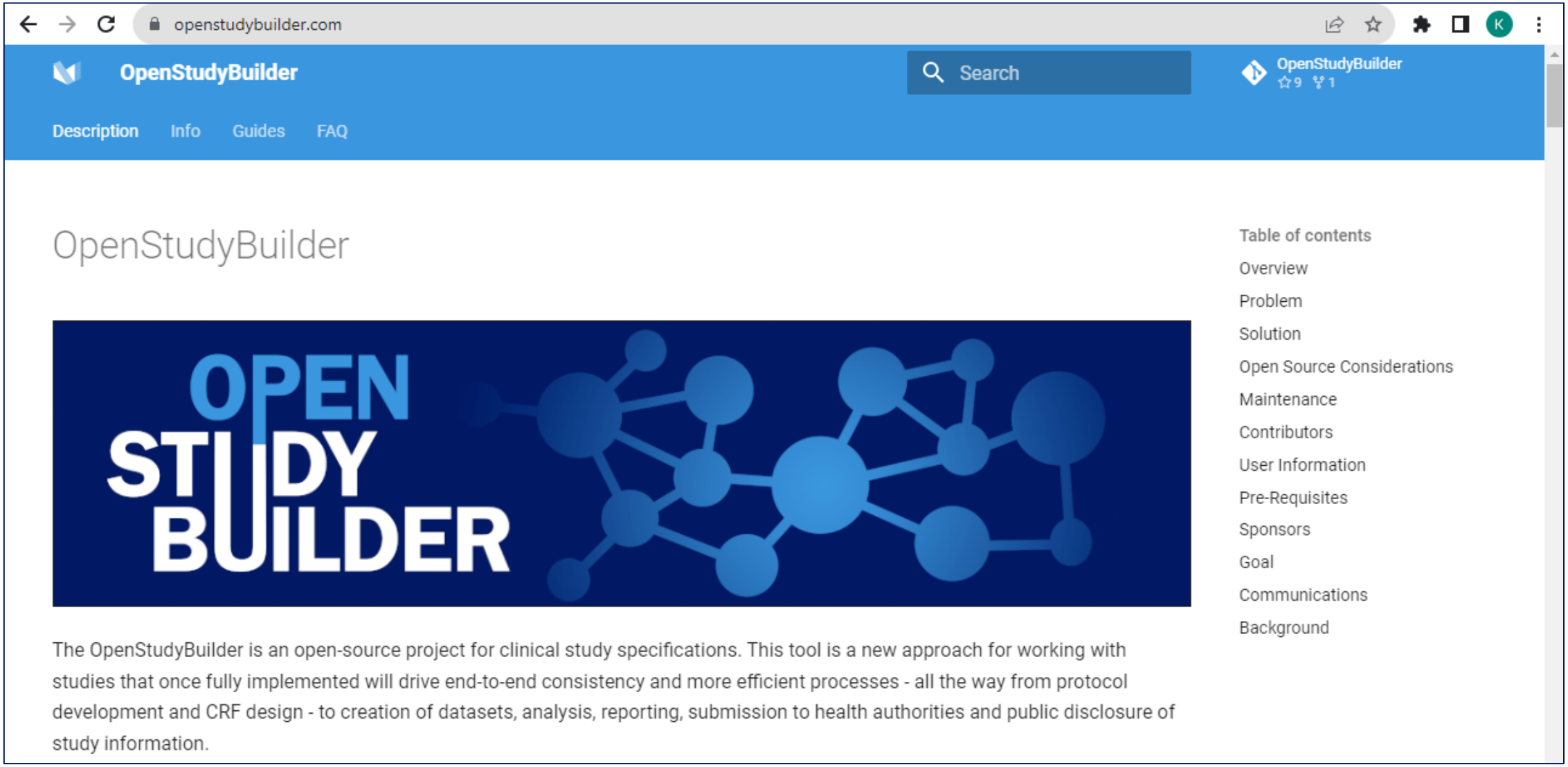
24-25 April 2024

- Reach us at the COSA booth for demonstration and exchange

From OpenStudyBuilder to the Digital Data Flow - USDM Format

15 April 2024 – 14:40-15:00, Presentation

Project Homepage



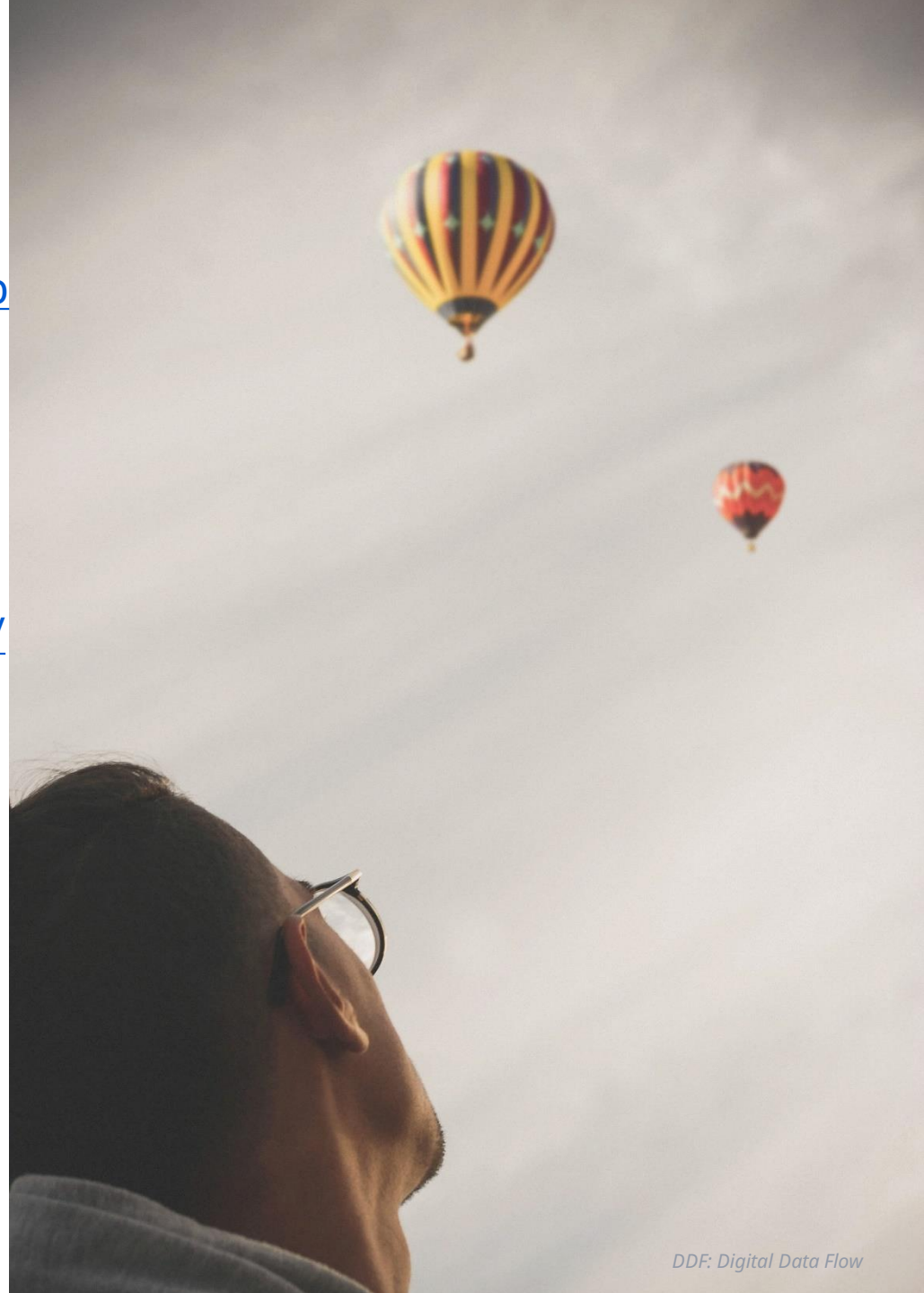
https://openstudybuilder.com/

Links

- Project Homepage: https://openstudybuilder.com/
- Newsletter: https://www.linkedin.com/newsletters/openstudybuilder-6990328054849916928/
- YouTube Demonstration (30’): https://youtu.be/dL5CY0BwfEs
- GitLab (Solution, Description): https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder
- Slack: https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyiIvB1Wsw
- E-Mail: openstudybuilder@gmail.com

Sandbox:

- Mail openstudybuilder@neotechnology.com – Subject “Request Sandbox access”
- Note: when add/modify/delete, you mail might be exposed in the version history



DDF: Digital Data Flow

Thanks!
Questions?