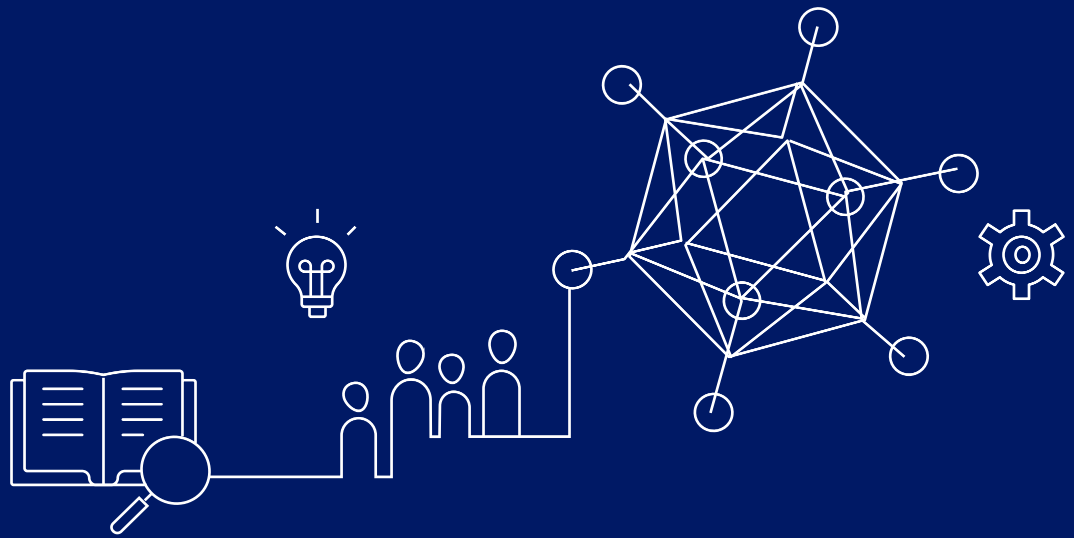
Digitalizing the study setup process from Protocol to Data Collection Specifications using

OpenStudyBuilder

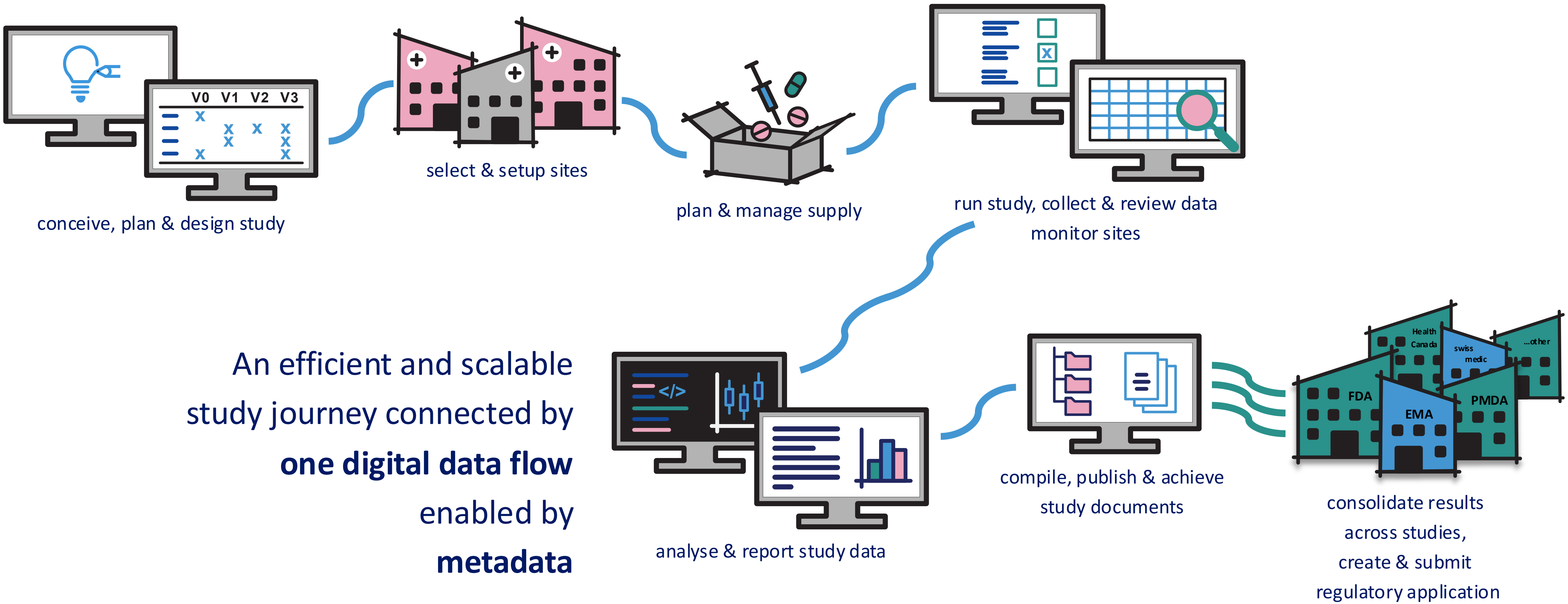


Camilla Kehler, Product Owner, Novo Nordisk

Ana Calduch Arques, Product Owner, Novo Nordisk

04th March, 2025

ONE study journey



An efficient and scalable study journey connected by **one digital data flow** enabled by **metadata**

Why OpenStudyBuilder?

The **Data Manager** specifies the study design and Schedule of Activities (SoA*) in the **Metadata mgt. sys**

The **Medical Center of Expertise** maintains the catalogue of in- & exculsion criteria in the **Quality mgt. sys**

The **Disclosure Specialist** enters study design and endpoints for public disclosure into **PharmaCM**

The **Medical Specialist** estimates study cost and feasibility in a **Study Design application**

The **Medical Writer** enters the SoA, endpoints, objectives and in- & exclusion criteria into the **Protocol Template (Word)**

The **Data Manager** translates the SoA and in- & exclusion criteria into the **Electonic Data Collection sys (EDC, Lab, eDiary etc.)**

The **Data Manager** enters the study design and endpoints into the **SDTM TS dataset**

Similar content handled in isolated IT solutions…

…. leads to **re-creation of content** resulting in double work, heavy need for QC and lack of alignment

Protocol

4.2.1 Primary endpoint

- Subjects who after 68 weeks achieve (yes/no):
  - Body weight reduction ≥ 5% from baseline at week 0

SDTM – trial summary (ts)

Parameter Value
Subjects who after 68 weeks achieve (yes/no) - Body weight reduction >=5%. Time frame: From baseline at week 0 to week 68.

PharmaCM (for upload to CT.gov)

Primary Outcome Measures:

- Subjects who achieve 5 or more percent body weight reduction (yes/no) [Time Frame: Week 68]
  Number of subjects.

SDTM: study data tabulation model

*SoA = Schedule of Activities

What is OpenStudyBuilder?

- A **new** and **digital approach** to study specifications
- An **OpenSource** project
- Aligned with **TransCelerate**’s Digital Data Flow initiative
- Based on the **CDISC** standards
- Allowing for **governance** of internal and external **standards**
- Facilitating **automation**

OpenSource project

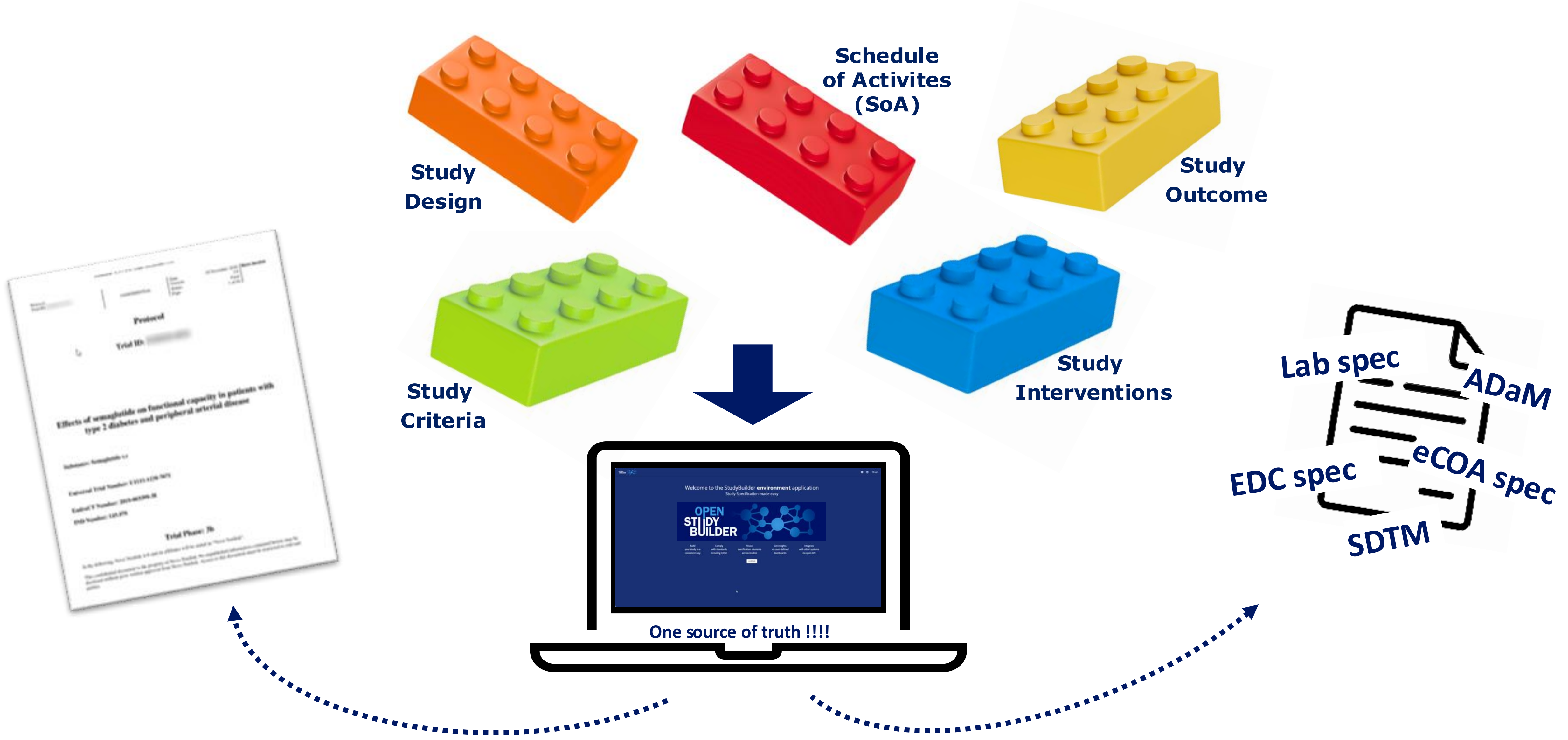
Link: [Visit the OpenStudyBuilder GitHub Repository for more info] slido

Please download and install the Slido app on all computers you use

Where would you use metadata in clinical trials?

ⓘ Start presenting to display the poll results on this slide.

How OpenStudyBuilder enables a Digital Data Flow.....

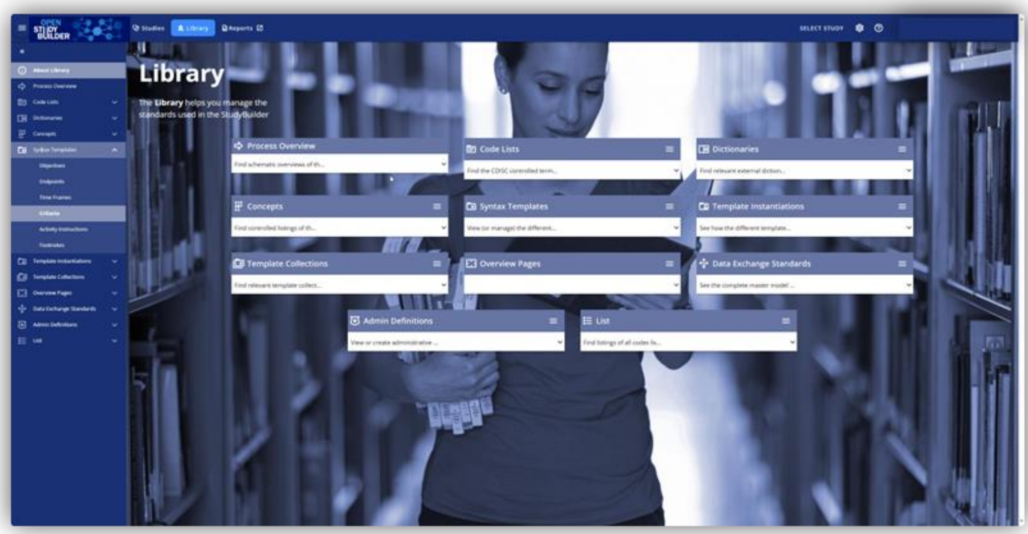


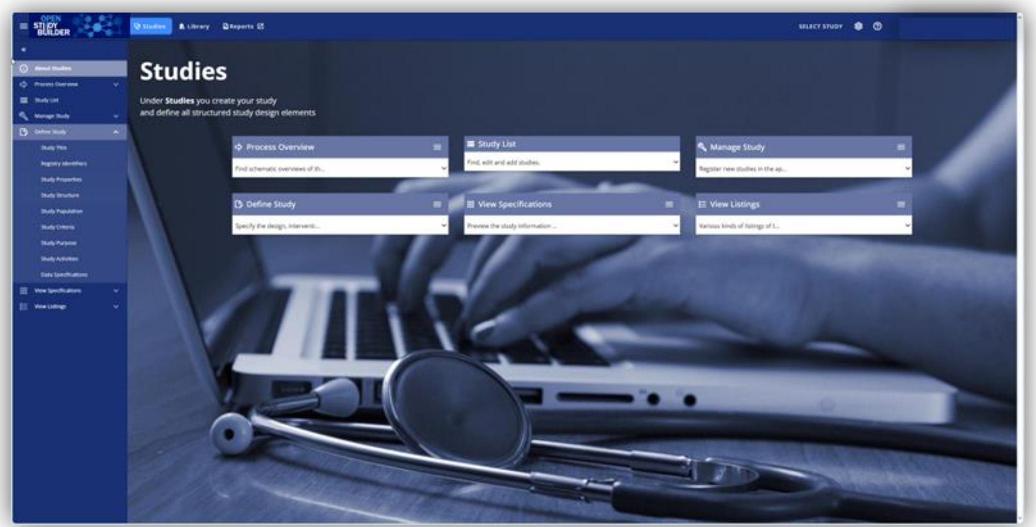
OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES

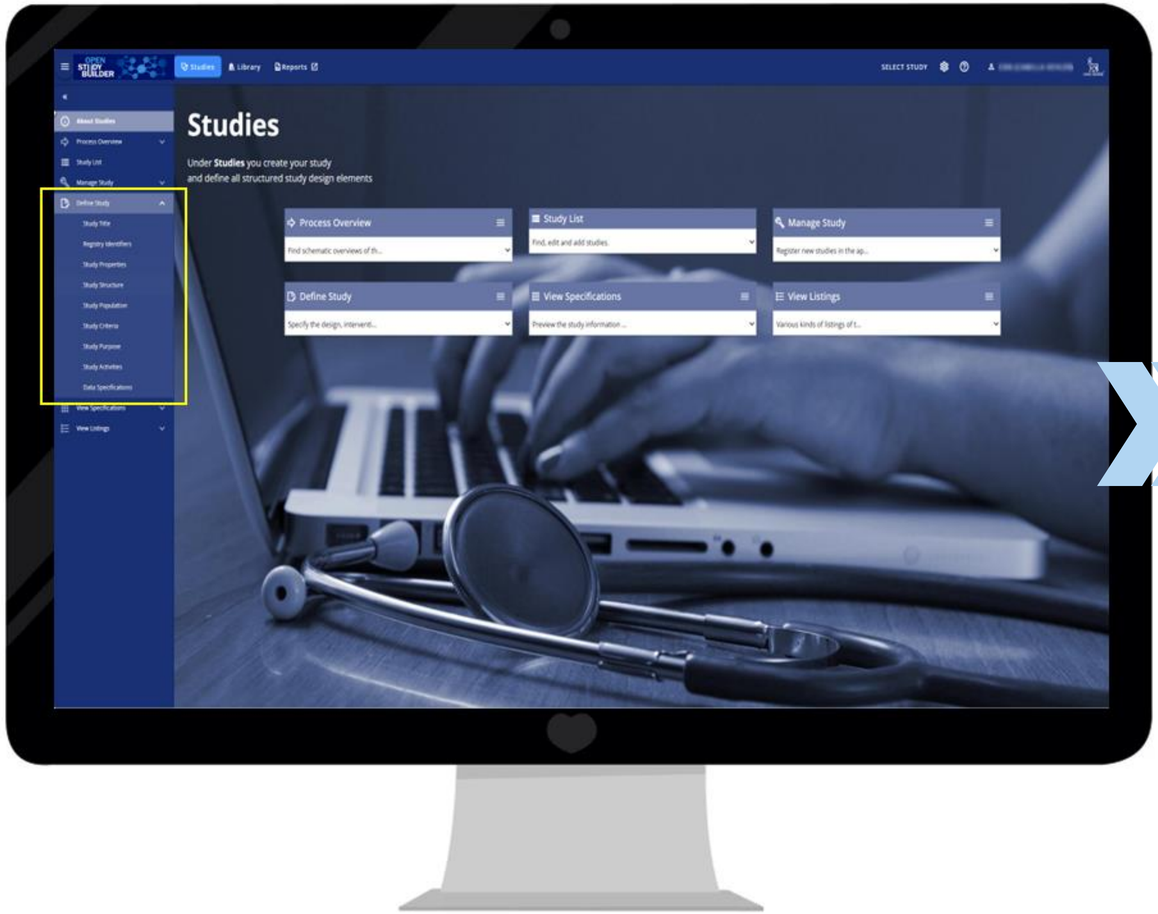
LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	

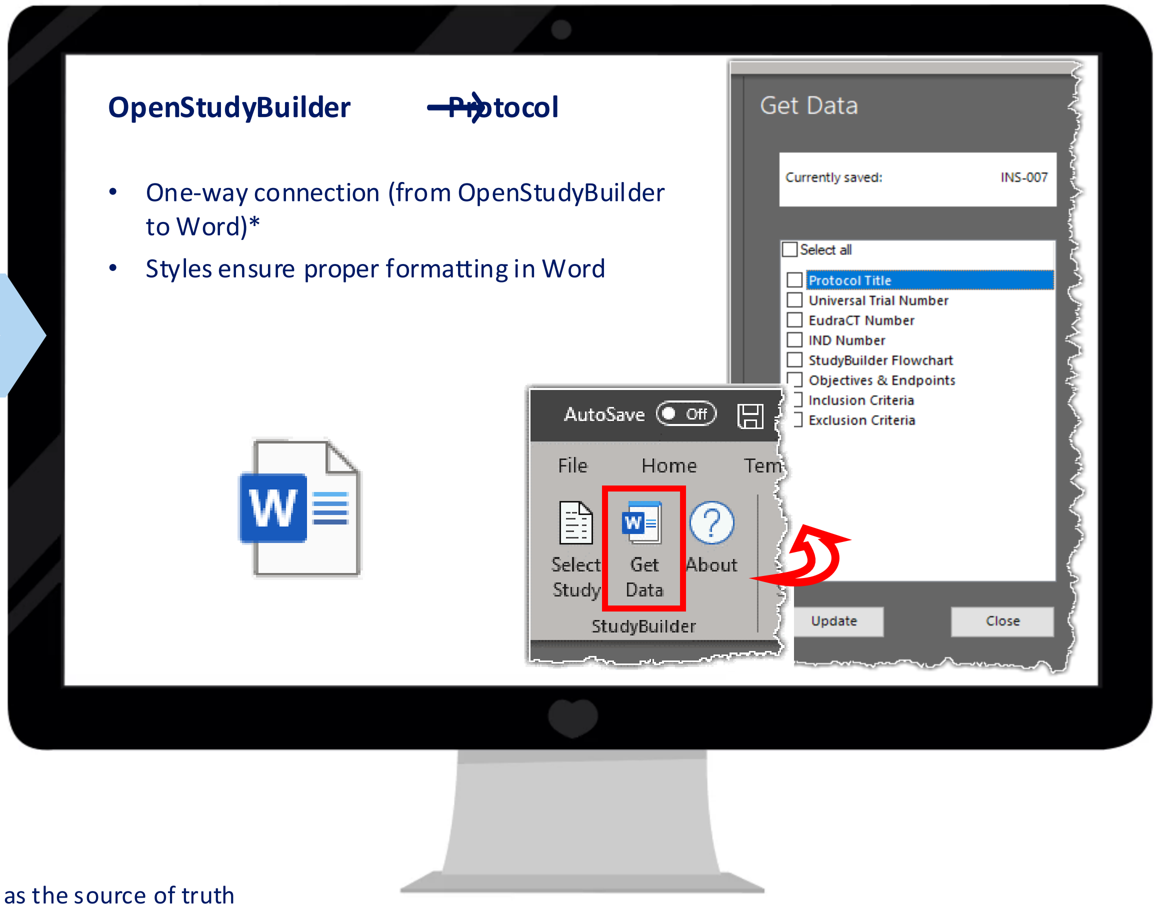
REPORTS	
DASHBOARDS OF ACTIVITIES/ASSESSMENTS	STUDY COMPARE REPORT
OVERVIEW OF STUDY CRITERIA, ENDPOINTS & OBJECTIVES	





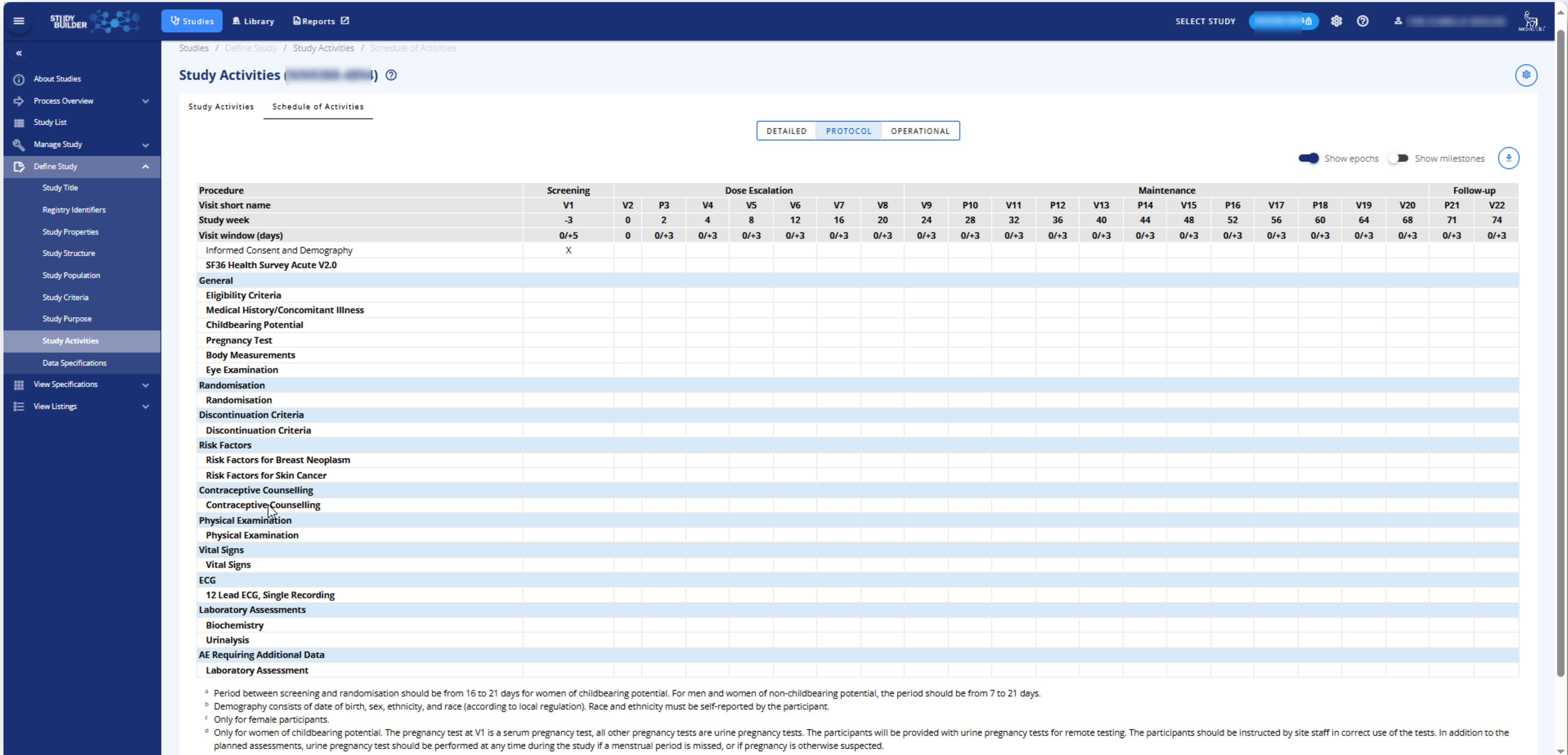
The integration from OpenStudyBuilder to protocol…





* Any updates to the study specification should ALWAYS be done in OpenStudyBuilder, to ensure it served as the source of truth

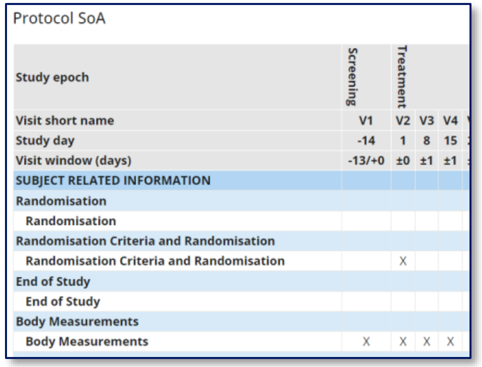
OpenStudyBuilder – Schedule of Activities (SoA)

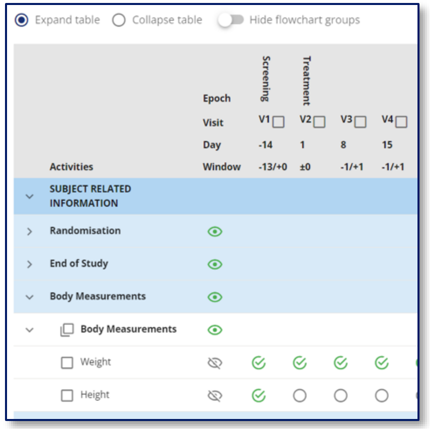


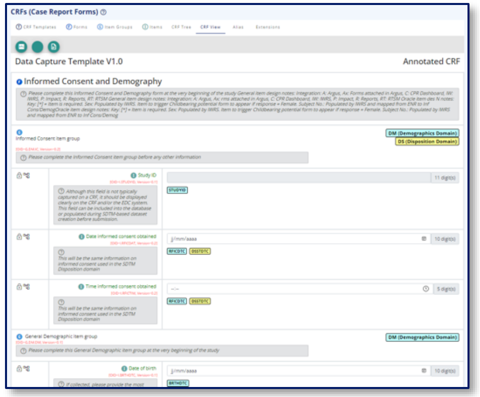
Procedure	Screening	Dose Escalation							Maintenance												Follow-up	
Visit short name	V1	V2	P3	V4	V5	V6	V7	V8	V9	P10	V11	P12	V13	P14	V15	P16	V17	P18	V19	V20	P21	V22
Study week	-3	0	2	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	64	68	71	74
Visit window (days)	0/+5	0	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3	0/+3
Informed Consent and Demography	X																					
SF36 Health Survey Acute V2.0																						
General																						
Eligibility Criteria																						
Medical History/Concomitant Illness																						
Childbearing Potential																						
Pregnancy Test																						
Body Measurements																						
Eye Examination																						
Randomisation																						
Randomisation																						
Discontinuation Criteria																						
Discontinuation Criteria																						
Risk Factors																						
Risk Factors for Breast Neoplasm																						
Risk Factors for Skin Cancer																						
Contraceptive Counselling																						
Contraceptive Counselling																						
Physical Examination																						
Physical Examination																						
Vital Signs																						
Vital Signs																						
ECG																						
12 Lead ECG, Single Recording																						
Laboratory Assessments																						
Biochemistry																						
Urinalysis																						
AE Requiring Additional Data																						
Laboratory Assessment																						

[a] Period between screening and randomisation should be from 16 to 21 days for women of childbearing potential. For men and women of non-childbearing potential, the period should be from 7 to 21 days.
[b] Demography consists of date of birth, sex, ethnicity, and race (according to local regulation). Race and ethnicity must be self-reported by the participant.
[c] Only for female participants.
[d] Only for women of childbearing potential. The pregnancy test at V1 is a serum pregnancy test, all other pregnancy tests are urine pregnancy tests. The participants will be provided with urine pregnancy tests for remote testing. The participants should be instructed by site staff in correct use of the tests. In addition to the planned assessments, urine pregnancy test should be performed at any time during the study if a menstrual period is missed, or if pregnancy is otherwise suspected.

Schedule of Activities (SoA) at multiple levels







Protocol SoA

- For the high level SoA in protocol
- Main purpose is for the investigator and site staff to get an overview

Detailed SoA

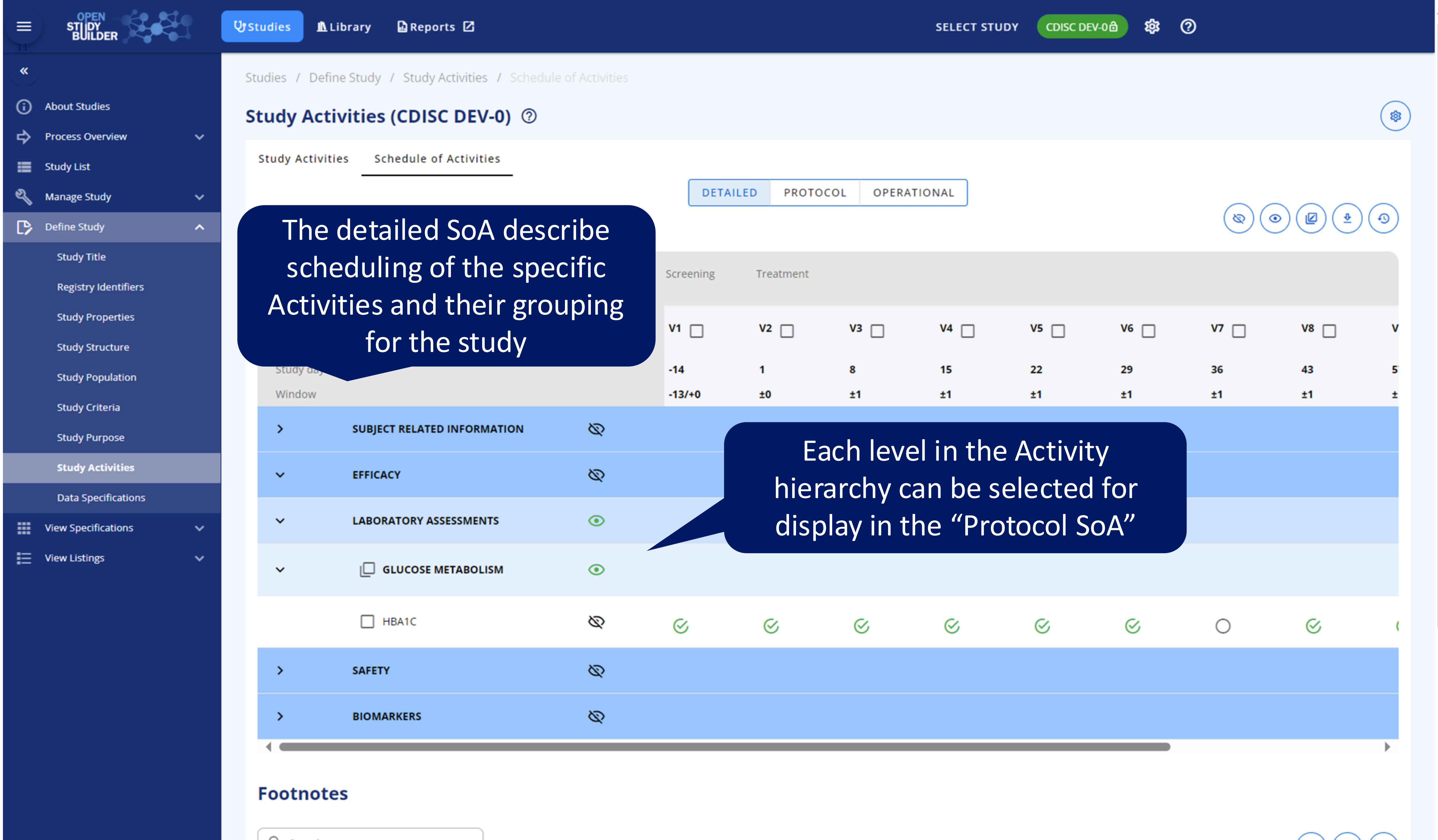
- Specifying the semantic data observations to be collected in the study – but not specific to representation in ADaM, SDTM or data collection
- This information will be included in different parts of the protocol

Operational SoA

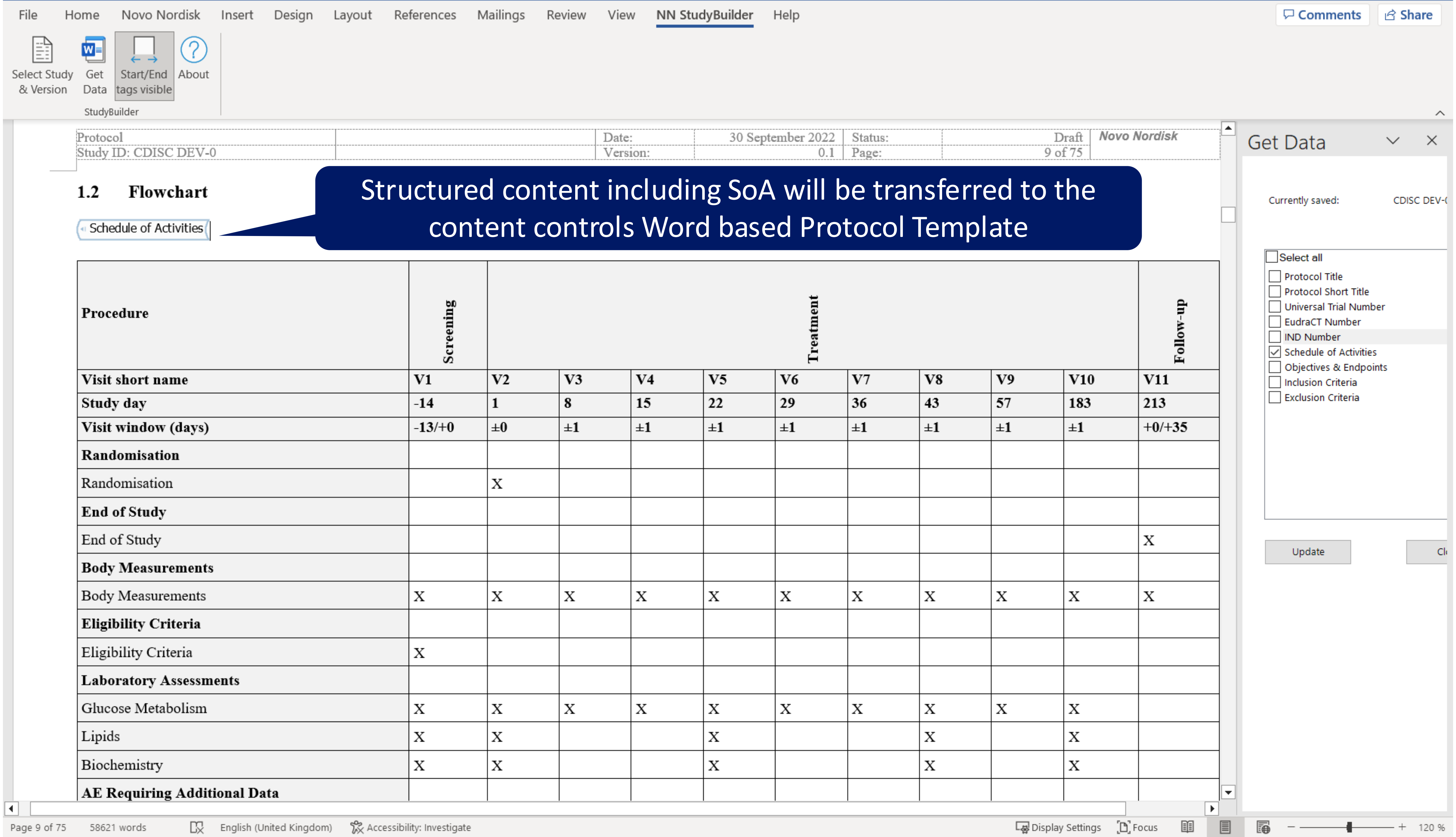
- The data specification to support external data transfers
- Correspond to NN existing legacy BCs
- Will also relate to specific ADaM PARAM/PARAMCD

Data Capture / Collection Specification

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


Studies
Library
Reports
SELECT STUDY
CDISC DEV-0
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

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



Protocol		Date:	30 September 2022	Status:	Draft	Novo Nordisk
Study ID: CDISC DEV-0		Version:	0.1	Page:	9 of 75	

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											

Studies | Library | Reports | SELECT STUDY | CDISC DEV-0

- 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 / Data Specifications / Operational SoA

Study Data Specifications (CDISC DEV-0)

Study Activity Instances | Operational SoA

Expand table | Show SoA groups

With reference to our legacy BC identifier and ADaM Param Code

Activities	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
	Window			-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35
SUBJECT RELATED INFORMATION														
SAFETY														
EFFICACY														
Laboratory Assessments														
Glucose Metabolism														
HbA1c														
HbA1c		HBA1C_BLOOD	HBA1CB	X	X	X	X	X	X		X	X	X	
BIOMARKERS														

Selection is made to specific Activity Instance level

Operational SoA supporting laboratory data specification

Data file specification for laboratory findings

LAB data description: Laboratory data such as haematology, biochemistry, urinalysis and laboratory biomarkers.
• All columns listed in the table below should be present in the data file and their order should not be changed.
• For columns that are not applicable, the column header should remain, and the content in the column should be set to NULL (i.e. left blank) in each record in the file.
• The data file header line with the pipe-delimited column headers is shown for your reference below.
• The instructions in 'Mandatory/optional' specify if it is mandatory to populate a column. **[Exceptions from this can, in rare cases, be agreed with the supplier while preparing the data specification.]**
[Addition of study-specific data file columns to the specification should be discussed in an Implementation Group meeting. If additional data file columns are required, e.g. QNAMs, please add the additional columns as new rows at the end of this table and ensure to add the extra columns to the relevant tables in DMW for the study. If an added column should be compliant with a codelist, please add the data file column to the content sheet so that relevant codelist submission values can be communicated to the supplier.
In Phase I studies, it can be relevant to add SEX for the subject's gender and DOB for the date of birth, which can be partial depending on the country. These columns can be used for checks in CDMS and will not be mapped to SDTM.]
• For codelist-controlled columns, supplier values should be mapped to the corresponding CDISC codelist values or to Novo Nordisk-defined additions to the codelists that are extensible. See the relevant codelist values as well as study-specific file content in the 'LAB, content' sheet.
• The data types specified in the table below are the Oracle database data types that the data will be loaded into. VARCHAR2 stores alphanumeric strings. The maximum length is specified for each column. Data type NUMBER stores numeric data.

Data file header line:

STUDYID|DOMAIN|SITE|SUBJID|FSUBJID|VISIT|LBREFID|TOPICCD|SUPTEST|LBORRES|UNITCOLL|LBORNRLO|LBORNRHI|LBNRIND|LBSTAT|LBREASND|LBNAM|LBLOINC|LOINCVER|LBSPEC|LBSPCCND|LBMETHO

Column position in data file	Column header in data file	Data type	Max length of character values	Content description	Mandatory/optional
1	STUDYID	VARCHAR2	40	Study ID. Default to 'XX9999-9999'.	Mandatory
2	DOMAIN	VARCHAR2	8	SDTM domain. Default to 'LB'.	M
3	SITE	VARCHAR2	20	Site identifier, e.g. '101'.	M
4	SUBJID	VARCHAR2	20	Subject identifier, e.g. '101201'.	M
5	FSUBJID	VARCHAR2	20	Scrambled subject ID. [If scrambling is not needed:] Default to NULL.	M
6	VISIT	VARCHAR2	64	Visit name, see 'Visits' sheet.	M
7	LBREFID	VARCHAR2	80	Unique sample identifier: Sample ID, requisition number or barcode, e.g. 'AB124578'.	M
8	TOPICCD	VARCHAR2	80	Topic code, see 'Lab, content' sheet.	M
9	SUPTEST	VARCHAR2	100	Supplier assessment name.	O
10	LBORRES	VARCHAR2	200	Result. LBORRES should be NULL if a result is not obtained. If the result is categorical, the LBORRES value should be compliant with CDISC CT codelist LBSTRESC (e.g. 'NEGATIVE')	M

"Traditional" Excel based data transfer specifications

Digitalized data transfer specifications automatically created from OpenStudyBuilder SoA L3

External Data File Specifications

Instructions | Dynamic text replacement | Visit / Time points | LAB Structure | LAB Content | LAB Range | PK Structure | PK Content | AB Structure | AB Content | Parameters

Data file specification for laboratory findings

LAB data description: Laboratory data such as haematology, biochemistry, urinalysis and laboratory biomarkers.

- All columns listed in the table below should be present in the data file and their order should not be changed.
- For columns that are not applicable, the column header should remain, and the content in the column should be set to NULL (i.e. left blank) in each record in the file.
- The data file header line with the pipe-delimited column headers is shown for your reference below.
- The instructions in 'Mandatory/optional' specify if it is mandatory to populate a column. [Exceptions from this can, in rare cases, be agreed with the supplier while preparing the data specification.] [Addition of study-specific data file columns to the specification should be discussed in an Implementation Group meeting. If additional data file columns are required, e.g. QNAMs, please add the additional columns as new rows at the end of this table and ensure to add the extra columns to the relevant tables in DMW for the study. If an added column should be compliant with a codelist, please add the data file column to the content sheet so that relevant codelist submission values can be communicated to the supplier. In Phase I studies, it can be relevant to add SEX for the subject's gender and DOB for the date of birth, which can be partial depending on the country. These columns can be used for checks in CDMS and will not be mapped to SDTM.]
- For codelist-controlled columns, supplier values should be mapped to the corresponding CDISC codelist values or to Novo Nordisk-defined additions to the codelists that are extensible. See the relevant codelist values as well as study-specific file content in the 'LAB, content' sheet.
- The data types specified in the table below are the Oracle database data types that the data will be loaded into. VARCHAR2 stores alphanumeric strings.

The maximum length is specified for each column. Data type NUMBER stores numeric data.

Data file header line: STUDYID|DOMAIN|SITE|SUBJID|FSUBJID|VISIT|LBREFID|TOPICCD|SUPTEST|LBORRES|UNITCOLL|LBORNRLO|LBORNRHI|LBNRIND|LBSTAT|LBREASND|LBNAM|LBLOINC|LOINCVER|LBSPEC|LBSPCCND|LBMETHOD|LBANMETH|LBFAST|LBDTC|LBTPT|SUBEVNUM|COMMENTALL

LAB, structure

Position	Column Header	Data type	Max Length	Content Description	Mandatory	Examples
1	STUDYID	VARCHAR2	40	Study ID. Default to 'XX9999-9999'.	Req	NN8640-4467
2	DOMAIN	VARCHAR2	8	SDTM domain. Default to 'LB'.	Req	
3	SITE	VARCHAR2	20	Site identifier, e.g. '101'.		
4	SUBJID	VARCHAR2	20	Subject identifier, e.g. '101201'.	Req	
5	FSUBJID	VARCHAR2	20	Scrambled subject ID. [If scrambling is not needed:] Default to NULL.		
6	VISIT	VARCHAR2	64	Visit name, see 'Visits' sheet.	Perm	V1,V2,V3,V4,V5,V6,V7,V9,V11,V13,V15,V15A,V16
7	LBREFID	VARCHAR2	80	Unique sample identifier: Sample ID, requisition number or barcode, e.g. 'AB124578'.		
8	TOPICCD	VARCHAR2	80	Topic code, see 'Lab, content' sheet.		
9	SUPTEST	VARCHAR2	100	Supplier assessment name.		
10	LBORRES	VARCHAR2	200	Result. LBORRES should be NULL if a result is not obtained. If the result is categorical, the LBORRES value should be compliant with CDISC CT codelist LBSTRESC (e.g. 'NEGATIVE') or sponsor-defined extensions.	Exp	
11	UNITCOLL	VARCHAR2	40	Collected unit. UNITCOLL should be compliant with CDISC CT codelist UNIT (e.g. 'mmol/L') or sponsor-defined extensions. Supplier should not perform unit-based conversion of results. UNITCOLL should be NULL for unitless data, e.g.		
12	LBORNRLO	VARCHAR2	40	Lower limit of supplier reference range applicable to the subject in same unit as the result. LBORNRLO should be NULL if there is not a lower limit.	Exp	
13	LBORNRHI	VARCHAR2	40	Upper limit of supplier reference range applicable to the subject in same unit as the result. LBORNRHI should be NULL if there is not an upper limit.	Exp	
14	LBNRIND	VARCHAR2	20	Reference range indicator. Indicates where the result falls with respect to reference range defined by LBORNRLO and LBORNRHI: - 'LOW' - 'NORMAL' - 'HIGH'	Exp	
15	LBSTAT	VARCHAR2	40	Completion status. Populate with 'NOT DONE' if LBORRES is NULL, otherwise NULL.	Perm	
16	LBREASND	VARCHAR2	200	Reason why result could not be obtained.	Perm	
17	LBNAM	VARCHAR2	40	Short name of the laboratory that performed the assessment. Default to 'LAB X'. [Short name as specified in 'List of MFT suppliers'. Note that if the supplier is delivering results from assessments performed by other labs, the red text at	Perm	
18	LBLOINC	VARCHAR2	200	LOINC code.	Perm	
19	LOINCVER	VARCHAR2	20	LOINC code version.		
20	LBSPEC	VARCHAR2	80	Specimen type. LBSPEC should be compliant with CDISC CT codelist SPECTYPE (e.g. 'PLASMA', 'SERUM', 'URINE') or sponsor-defined extensions.	Perm	
21	LBSPCCND	VARCHAR2	40	Specimen condition. Used in cases where a result is obtained, but the sample is less than optimal. LBSPCCND should be compliant with CDISC CT codelist SPECCOND (e.g. 'HEMOLYZED') or sponsor-defined extensions.	Perm	
22	LBMETHOD	VARCHAR2	80	Method of assessment or examination. LBMETHOD should be compliant with CDISC CT codelist METHOD (e.g. 'ELISA') or sponsor-defined extensions.	Perm	
23	LBANMETH	VARCHAR2	80	Analysis method. Describes the method of secondary processing applied to a complex observation result, e.g. 'CREATININE 2021 CKD-EPI FORMULA'.	Perm	
24	LBFAST	VARCHAR2	2	Fasting status. - If subject was fasting: 'Y' - If subject was not fasting: 'N' - If not relevant: NULL	Perm	
25	LBDTC	VARCHAR2	64	Datetime of specimen collection in ISO 8601 format: YYYY-MM-DDTHH:MM:SS, e.g. 2020-10-12T14:30:15.	Exp	
26	LBTPT	VARCHAR2	80	Planned time point name, e.g. '10 MIN AFTER', see 'Time points' sheet.	Perm	
27	SUBEVNUM	NUMBER		Subevent number, which is used to distinguish unplanned resampling. Resampling is done when the original sample cannot be used. - If no resampling: SUBEVNUM should be 0. - If resampling is done for the same VISIT, SUBJID and T		
28	COMMENTALL	VARCHAR2	200	Comments that do not fit into other columns.		

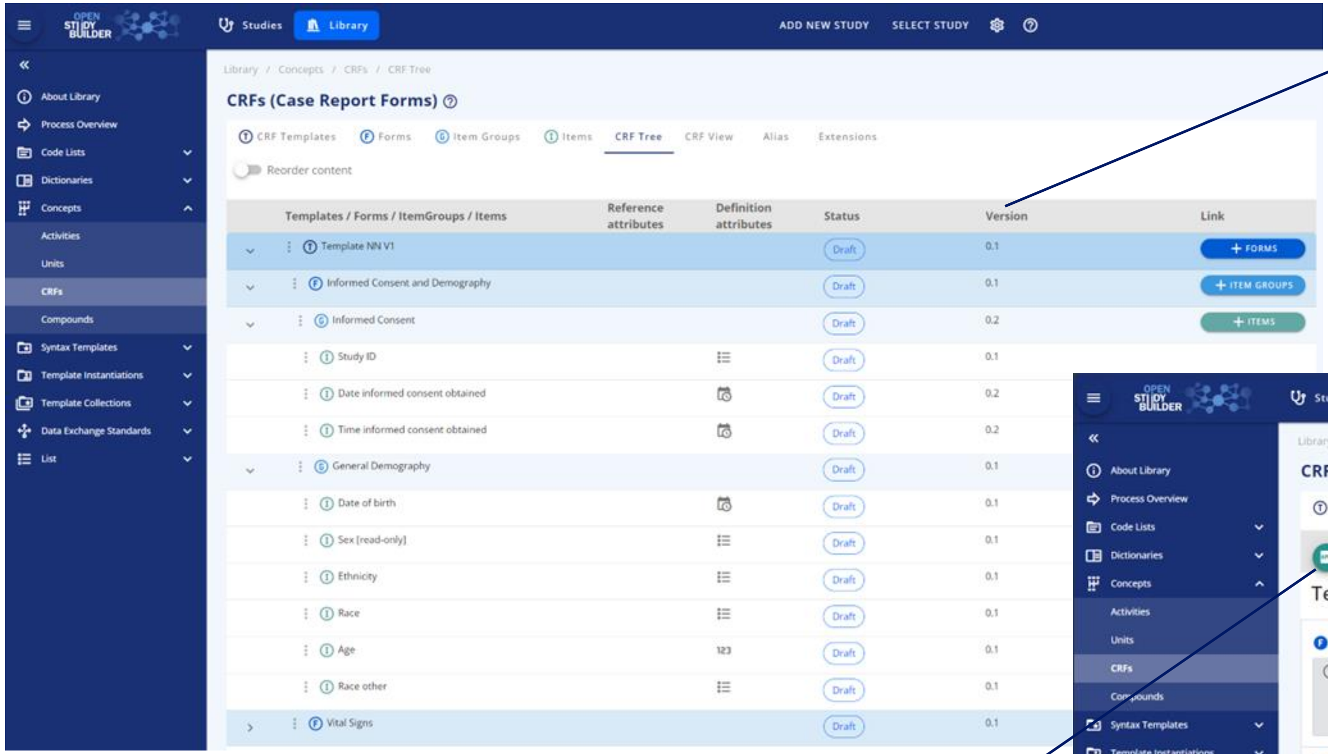
slido

Please download and install the Slido app on all computers you use

Are you working on something similar in your company?

ⓘ Start presenting to display the poll results on this slide.

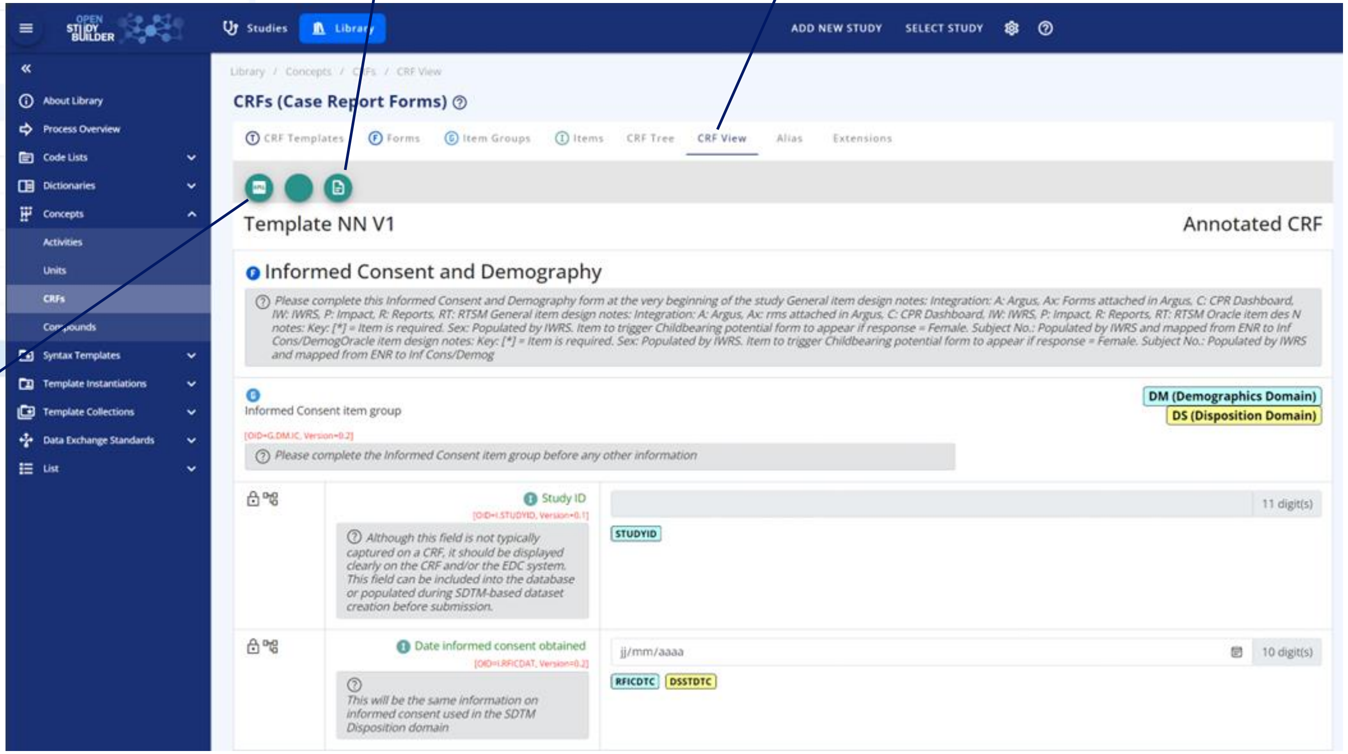
L4 SoA *(work in progress)* - Concept: CRFs



Templates used to defined multiple CRF version

PDF format

Annotated CRF following MSG 2.0 standard

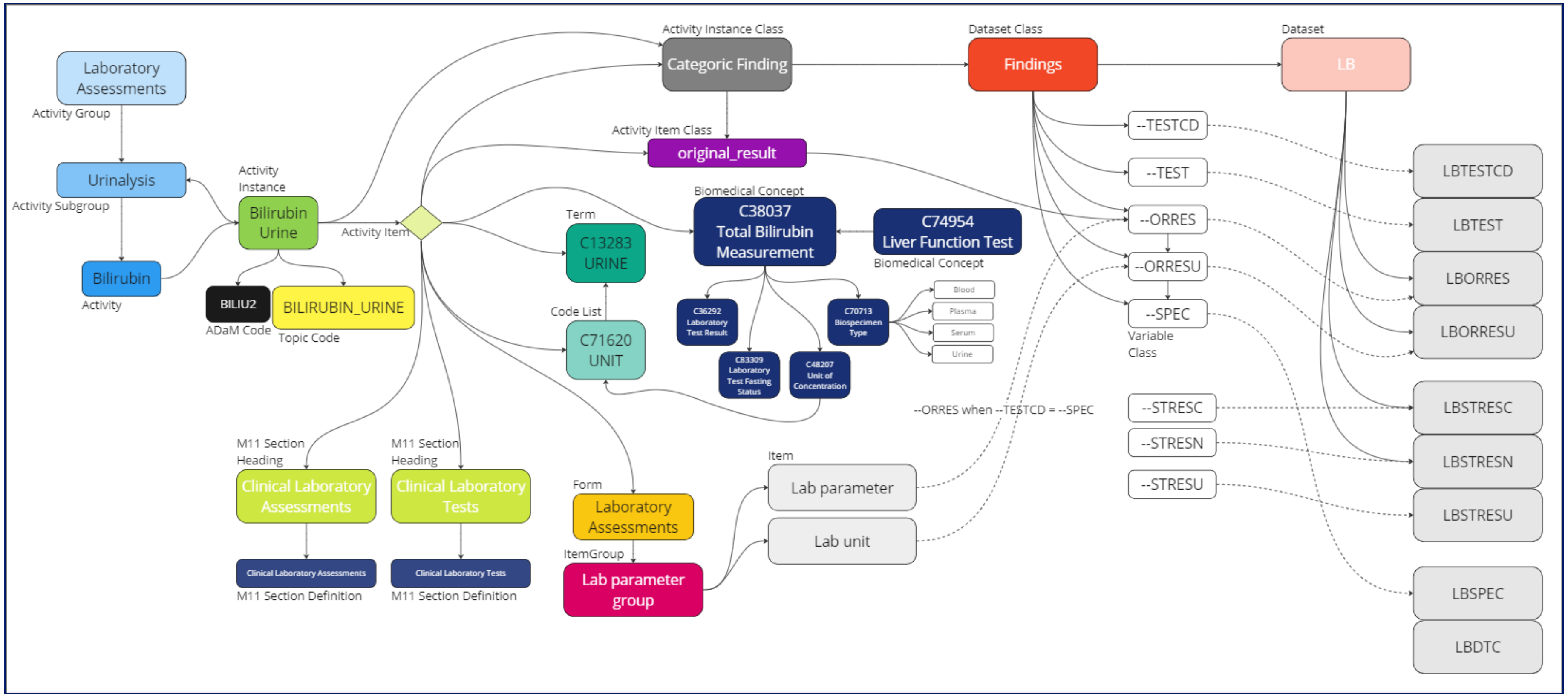


ODM.xml with vendor extensions (or CSV)

Biomedical Concepts drive Digital Data Flow

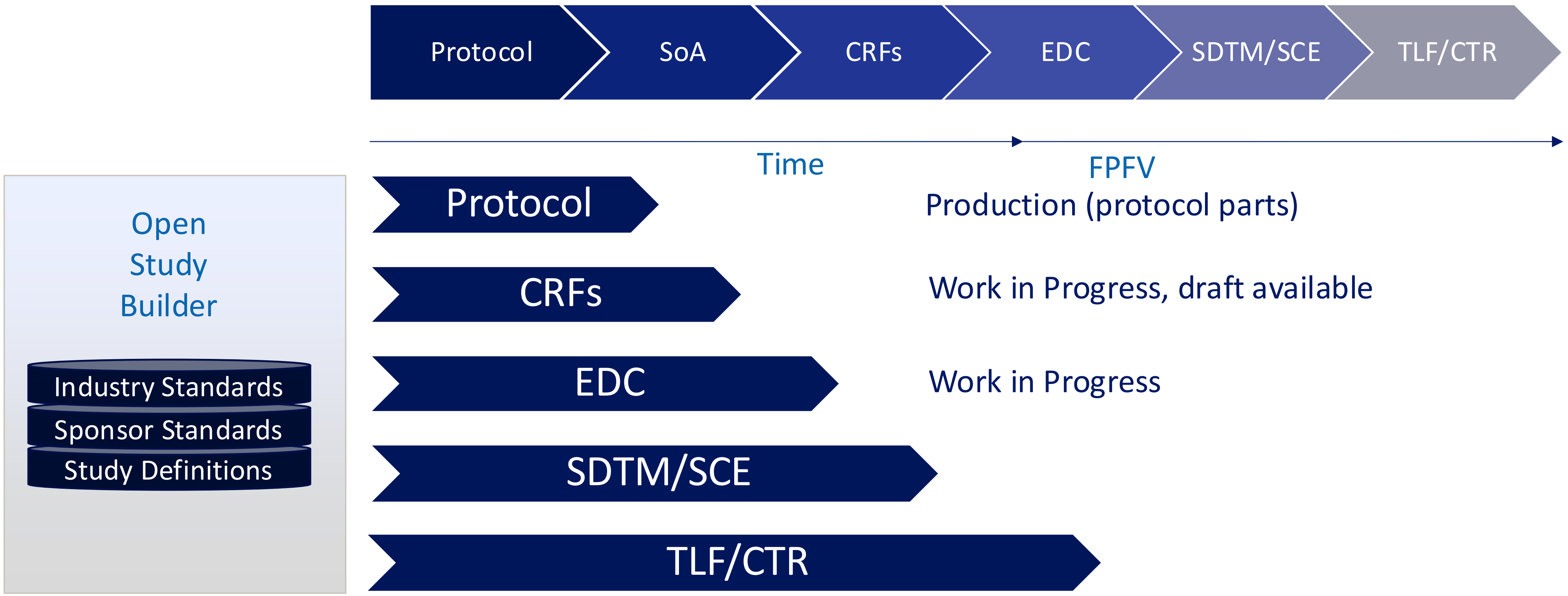
Connect to **Flow** - define once & use many

- Protocol definition
- CRF utilization
- EDC specification
- SDTM definition
- ADAM definition



Transitioning from a sequential to a parallel work flow

- Digitized Processes Over Manual Processes



Enable Parallelization

- 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