

Open-Source MDR and SDR

The OpenStudyBuilder as a new
Metadata Repository solution

OPEN
STUDY
BUILDER



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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)



What's in ?

Application

The screenshot shows a study application interface. On the left, a sidebar lists various study components like About Studies, Project Overview, Manage Studies, Define Study, View Specifications, Protocol Elements, CTD Specifications, Pharmacopedia Specifications, Trial Supplier Specifications, IOM Specifications, SDTM Specifications, SDTM Study Design Datasets, ADAM Specification, and View Logins. The main area displays 'Protocol Elements (CDISC DEV-0)'. It includes a 'Protocol Flowchart' and a 'Study epoch' table with columns for Visit short name (V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12) and Visit duration (days). A 'SUBJECT RELATED INFORMATION' section contains fields for Randomization, End of Study, Physical Examination - early pH, Body Measurements, Eligibility Criteria, and EFFICACY. At the bottom, there are sections for Laboratory Assessments and Disease Metabolism.

Neo4j database
- Including example data



API

The screenshot shows an API response titled 'Responses'. It includes a 'Call' section with a curl command, a 'Request URL' (https://openstudybuilder.southorange.cloudapp.azure.com/api/studies), and a 'Server response' section. The response body is a JSON object with an array of 'Items' containing details about a study element.

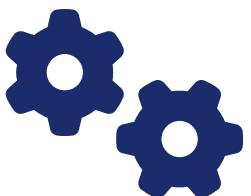
```

    "Items": [
      {
        "id": "1",
        "name": "Diabetes",
        "type": "Assessment",
        "studyId": "CDISC DEV-0",
        "version": "1.0.0",
        "projectName": "CDISC DEV-0",
        "status": "Active",
        "currentVersion": 1
      }
    ]
  
```

DB Browser

The screenshot shows a Neo4j DB Browser interface. On the left, a 'Database Information' panel shows 'sandbox' as the active database. Below it, a 'Node Labels' list includes Activity, ActivityGroup, ActivitySubGroup, Assessment, AssessmentInstance, AssessmentVariable, CTDInstrument, COASVariable, CTMeasurement, CTTime, ConceptMapping, Criteria, CriteriaImploded, CriteriaType, Event, Finding, FormCode, Item, Itemized, NumericalFinding, Operator, and SDTMVariable. The main area is a graph visualization with nodes colored by their labels (e.g., pink for Assessment, blue for COASVariable, green for Item). Nodes include 'Diabetes', 'Mean', 'Body Mass Index', 'Blood Glucose', 'HbA1c', 'Vital Signs', 'VS Result or Finding in Origin', 'AssessmentVariable', 'AssessmentInstance', 'Criteria', 'CriteriaImploded', 'Event', 'Finding', 'FormCode', 'Item', 'Itemized', 'NumericalFinding', 'Operator', and 'SDTMVariable'.

Scripts



Documentation

- // Documentation
- Project Homepage
- Tool documentation
- GitLab documentation
 - Database design
 - Architecture design
 - Instructions

Neo4j dashboard*

The screenshot shows a 'Study Dashboard' interface. It features a 'Concept Graph' for 'Diabetic Blood Pressure' with nodes like 'Diabetic Blood Pressure', 'AssessmentVariable', 'AssessmentInstance', 'Criteria', 'CriteriaImploded', 'Event', 'Finding', 'FormCode', 'Item', 'Itemized', 'NumericalFinding', 'Operator', and 'SDTMVariable'. Below the graph, sections for 'Select Assessment' and 'Select Assessment inst' are shown, both currently set to 'Diabetic Blood Pressure'.

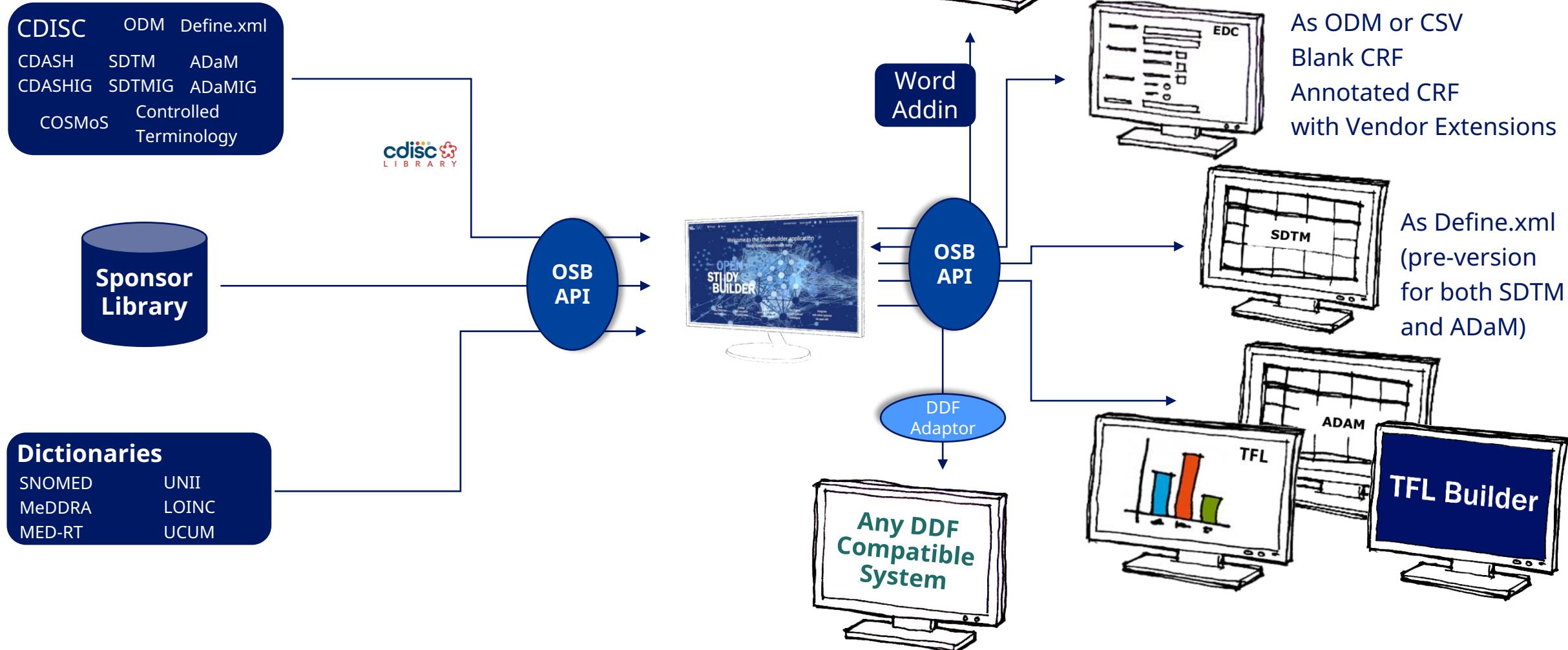
*available in sandbox, can be installed on other environments

OpenStudyBuilder Components

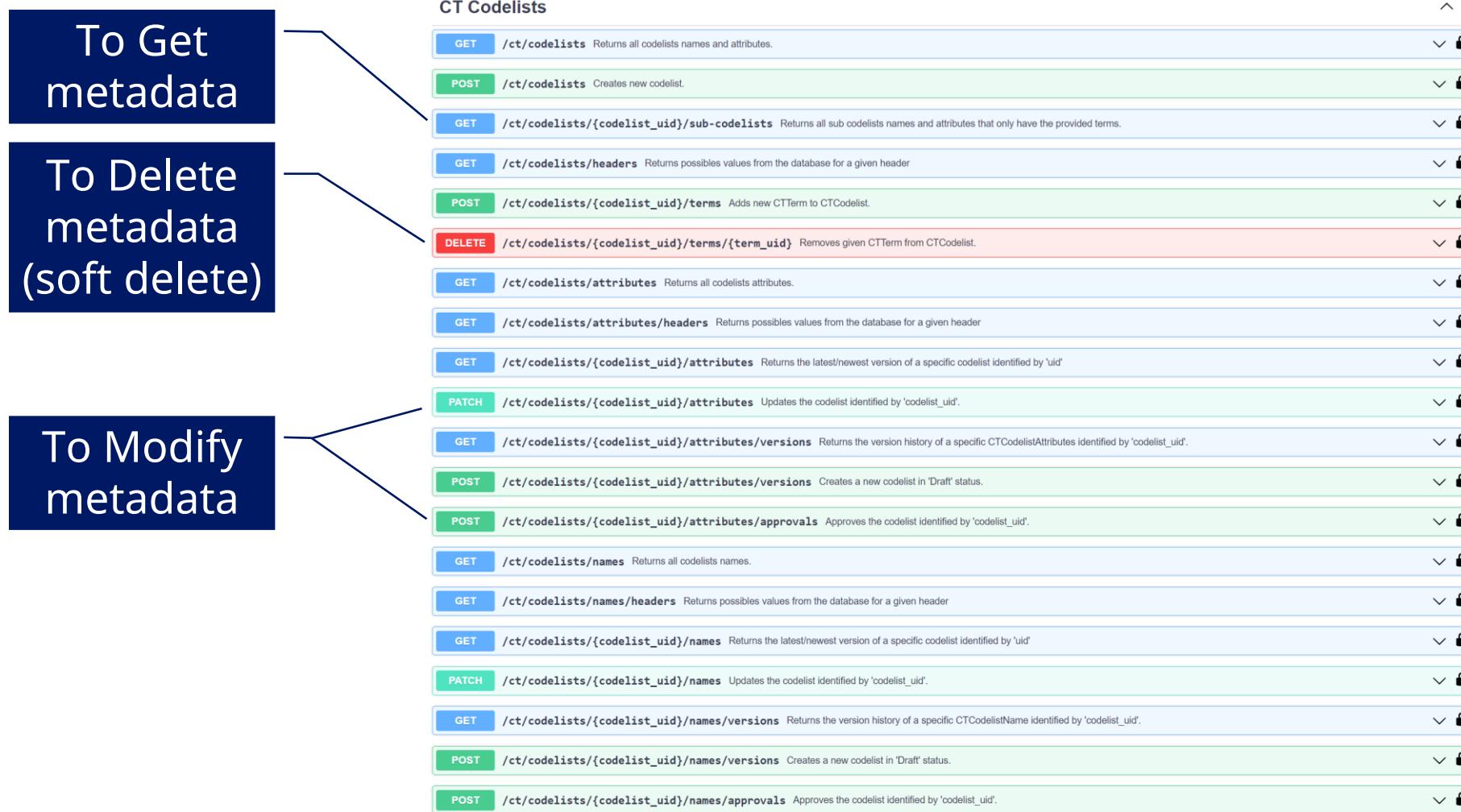
STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES

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

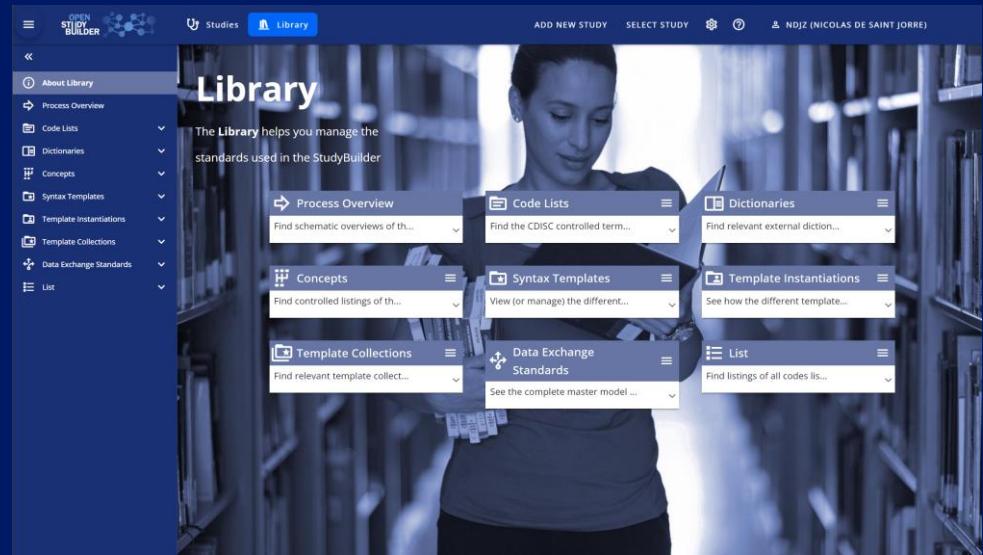
The vision...



Example of API endpoints to manage CDISC CT

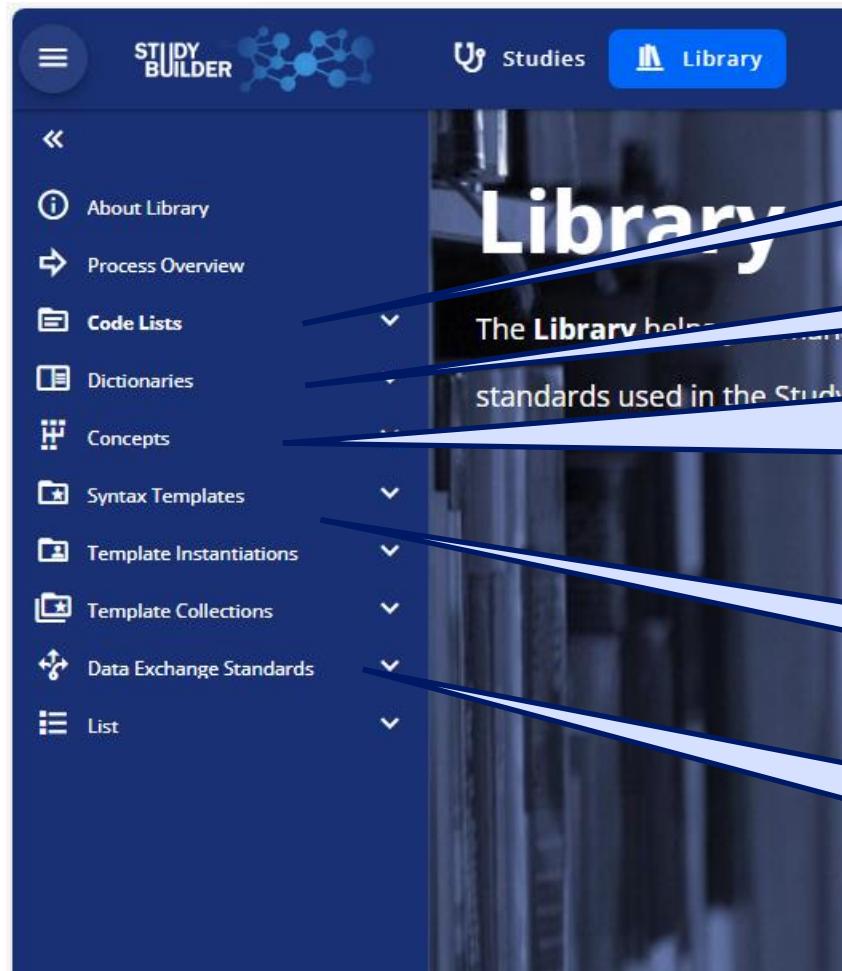


Library



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

Library content



Code Lists := CTerm
CDISC + Sponsor

Dictionaries
Subset of values & dictionaries

Concepts
Activities, Compounds and Units
(legacy migration)
CRF (PoC)

Syntax Templates
Objectives, Endpoints, Criteria,
Activities, Footnotes

Data Exchange Standards
From CDISC Library + Sponsor extensions



Code list C66737 - TPHASE / Term Detail (Concept ID: C15602_PHASE_III_TRIAL)

For all terminologies we include the option to define the sponsor preferred name, in UK spelling, in Title and sentence case

Code List Summary					
For the term sponsor values					
CT Identifiers	Selected values	Status	Modified	Version	Actions
Sponsor Preferred Name	3	Final	Oct 19, 2023, 11:06 PM	2.0	
Sentence case name	3				
Order	3				

In this case, we can use Arabic numbers as a synonym in the protocol template for study phase

Code List Summary					
For the code list attributes values					
CT Identifiers	Selected values	Status	Modified	Version	Actions
Concept ID	C15602_PHASE_III_TRIAL	Final	Mar 31, 2023, 2:00 AM	2.0	
Name submission value					
Code submission value	PHASE III TRIAL				
NCI preferred name	Phase III Trial				
Definition	Phase that includes the controlled clinical trials intended to confirm safety and effectiveness, evaluate the overall benefit-risk relationship, and to provide substantial evidence for marketing approval. NOTE: Phase 3 studies usually include f...				

Dictionaries

Library / Dictionaries / SNOMED

SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms) for Diseases and Disorders

SNOMED ID	Preferred synonym	Preferred synonym (lower case)	Abbreviation	Definition	Status	Version	Modified
64572001	Disease	disease		Disease (disorder)	Final	1.0	Jul 4, 2 PM
362965005	Disorder of body system	disorder of body system		Disorder of body system (disorder)	Final	1.0	Jul 4, 2 PM
609564002	Pre-existing type 1 diabetes mellit...	pre-existing type 1 diabetes mellit...		Pre-existing type 1 diabetes mellit...	Final	1.0	Jul 4, 2 PM
446221000	Heart failure with normal ejection ...	heart failure with normal ejection ...	HFpEF	Heart failure with normal ejection ...	Final	1.0	Jul 4, 2 PM
442685003	Nonalcoholic steatohepatitis	nonalcoholic steatohepatitis	NASH	Nonalcoholic steatohepatitis (disor...	Final	1.0	Jul 4, 2 PM
441190003	Severe hereditary factor IX deficie...	severe hereditary factor IX deficie...		Severe hereditary factor IX deficie...	Final	1.0	Jul 4, 2 PM
440993008	Severe hereditary factor VIII defic...	severe hereditary factor VIII defic...		Severe	Final	1.0	Jul 4, 2 PM

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Library / Dictionaries / MED-RT

MED-RT (Medication Reference Terminology) for Pharmacologic Class (PCLASS)

MED-RT ID	Class name	Class name (lower case)	Abbreviation	Definition	Status	Version	Modified
N0000029185	ORAL HYPOGLYCEMIC AGENTS	oral hypoglycemic agents		ORAL HYPOGLYCEMIC AGENTS	Final	1.0	Jul 4, 2023, 3:08 PM
N0000191730	PCSK9 Inhibitors	pcsk9 inhibitors		PCSK9 Inhibitors	Final	1.0	Jul 4, 2023, 3:08 PM
	Ziltivekimab	ziltivekimab		Ziltivekimab	Final	1.0	Jul 4, 2023, 3:08 PM
N0000175945	I-Thyroxine	i-thyroxine		I-Thyroxine	Final	1.0	Jul 4, 2023, 2:43 PM
N0000175848	Tubulin Inhibiting Agent	tubulin inhibiting agent		Tubulin Inhibiting Agent	Final	1.0	Jul 4, 2023, 2:43 PM
N0000180190	Thiazolidinedione	thiazolidinedione		Thiazolidinedione	Final	1.0	Jul 4, 2023, 2:43 PM
N0000175608	Sulfonylurea	sulfonylurea		Sulfonylurea	Final	1.0	Jul 4, 2023, 2:43 PM
N0000175880	Sulfonamide	sulfonamide		Sulfonamide	Final	1.0	Jul 4, 2023, 2:43 PM
N0000187940	Cadmium Gluconate	cadmium gluconate enterosolvent		Cadmium Gluconate	Final	1.0	Jul 4, 2023, 2:43 PM

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Library / Dictionaries / UNII

UNII (Unique Ingredient Identifier) for Active Substances

UNII ID	Substance name	Substance name (lower case)	Abbreviation	Status	Version	Modified
Q51B043MG4	LEVOTHYROXINE	levothyroxine		Final	1.0	Jul 4, 2023, 3:08 PM
U188XYD42P	MOXIFLOXACIN	moxifloxacin		Final	1.0	Jul 4, 2023, 3:08 PM
SX6K58TVWC	GLYBURIDE	glyburide		Final	1.0	Jul 4, 2023, 3:08 PM
QFP0P1DV7Z	SITAGLIPTIN	sitagliptin		Final	1.0	Jul 4, 2023, 3:08 PM
1Y17CTI55R	INSULIN HUMAN	insulin human		Final	1.0	Jul 4, 2023, 2:45 PM
36209ITL9D	PARACETAMOL	paracetamol		Final	1.0	Jul 4, 2023, 2:45 PM
9100L32L2N	METFORMIN	metformin		Final	1.0	Jul 4, 2023, 2:45 PM
WTT295HSY5	DULAGLUTIDE	dulaglutide		Final	1.0	Jul 4, 2023, 3:08 PM
X7WD795NSC	GLIPIZIDE	glipizide		Final	1.0	Jul 4, 2023, 3:08 PM
X40V7IU42S	PIOGLITAZONE	piglitazone		Final	1.0	Jul 4, 2023, 3:08 PM

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Library / Dictionaries / UCUM

UCUM (Unified Code for Units of Measure)

UCUM code	UCUM description	Status	Version	Modified
g/wk	gram per week	Final	1.0	Jul 4, 2023, 2:44 PM
{GLOBULE}	globule unit	Final	1.0	Jul 4, 2023, 2:45 PM
{PUFF}	puff dosing unit	Final	1.0	Jul 4, 2023, 2:45 PM
kBq/uL	kilobecquerel per microliter	Final	1.0	Jul 4, 2023, 2:45 PM
{DROP}	drop	Final	1.0	Jul 4, 2023, 2:45 PM
{SPRAY}	spray dosing unit	Final	1.0	Jul 4, 2023, 2:45 PM
{Capsule}	capsule dosing unit	Final	1.0	Jul 4, 2023, 2:45 PM
{CAN}	can dosing unit	Final	1.0	Jul 4, 2023, 2:45 PM
{Pack}	pack dosage form	Final	1.0	Jul 4, 2023, 2:45 PM
{Tablet}	tablet dosing unit	Final	1.0	Jul 4, 2023, 2:45 PM

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About Library
Process Overview
Code Lists
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Compounds
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List

Library / Concepts / Activities / Activities Instances / Bilirubin_Biochemistry

Bilirubin, Biochemistry

Overview OSB YAML

Biomedical Concepts in OpenStudyBuilder is named as Activity Concepts

Name	Bilirubin, Biochemistry												
Sentence case name	bilirubin, biochemistry												
Status	Final												
Definition													
Activity instance class	NumericFinding												
Abbreviation	Library Sponsor												
NCI Concept ID													
ADAM parameter code	BILIS3 Topic code BILIRUBIN_SERUM												
Required for activity	No Default selected for activity No												
Data sharing	Yes Legacy usage No												
Activity groupings	<table border="1"><thead><tr><th>Activity group</th><th>Activity subgroup</th></tr></thead><tbody><tr><td>Laboratory Assessments</td><td>Biochemistry</td></tr></tbody></table>	Activity group	Activity subgroup	Laboratory Assessments	Biochemistry								
Activity group	Activity subgroup												
Laboratory Assessments	Biochemistry												
Activity	<table border="1"><thead><tr><th>Name</th><th>Definition</th><th>Library</th></tr></thead><tbody><tr><td>Bilirubin</td><td></td><td>Sponsor</td></tr></tbody></table>	Name	Definition	Library	Bilirubin		Sponsor						
Name	Definition	Library											
Bilirubin		Sponsor											
Activity items	<table border="1"><thead><tr><th>Item type</th><th>Name</th><th>Activity item class</th></tr></thead><tbody><tr><td>CT term</td><td>Laboratory Data Domain</td><td>domain</td></tr><tr><td>CT term</td><td>Total Bilirubin Measurement</td><td>test_name_code</td></tr><tr><td>CT term</td><td>Serum</td><td>specimen</td></tr></tbody></table>	Item type	Name	Activity item class	CT term	Laboratory Data Domain	domain	CT term	Total Bilirubin Measurement	test_name_code	CT term	Serum	specimen
Item type	Name	Activity item class											
CT term	Laboratory Data Domain	domain											
CT term	Total Bilirubin Measurement	test_name_code											
CT term	Serum	specimen											

The Activity Concepts is what you will select for the SoA - and include end to end definitions

Concept: CRFs

The screenshot shows the 'CRF Tree' tab selected in the top navigation bar. The main area displays a tree structure of study components. At the top level are 'Template NN V1', 'Informed Consent and Demography', and 'Informed Consent'. Below 'Informed Consent' are 'Study ID', 'Date informed consent obtained', 'Time informed consent obtained', 'General Demography', 'Date of birth', 'Sex [read-only]', 'Ethnicity', 'Race', 'Age', 'Race other', and 'Vital Signs'. Each node has a status (Draft), version (e.g., 0.1, 0.2), and a 'Link' button.

ODM.xml
with vendor
extensions
(or CSV)

Templates used
to define
multiple CRF
version

PDF format

The screenshot shows the 'CRF View' tab selected. The main area displays the 'Informed Consent and Demography' form. It includes a section for 'Informed Consent item group' with a note: 'Please complete the Informed Consent item group before any other information'. Below it is a section for 'Date informed consent obtained' with a note: 'This will be the same information on informed consent used in the SDTM Disposition domain'. A legend on the right indicates 'DM (Demographics Domain)' and 'DS (Disposition Domain)'.

Blank or
Annotated
CRF following
MSG 2.0
standard



About Library

Process Overview

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Concepts

Syntax Templates

Objective Templates

Endpoint Templates

Time Frame Templates

Criteria Templates

Activity Templates

Footnote Templates

Template Instantiations

Objective Instances

Endpoint Instances

Time Frame Instances

Activity Instruction Instances

Criteria Instances

Footnote Instances

Template Collections

Data Exchange Standards

List

Endpoints

 Select rows

Search



Syntax Templates in OpenStudyBuilder is used to manage structured text with references to Activity Concepts and Controlled Terminology for library items

Template	Endpoint	Status	Version
Safety and tolerability of [Compound] + [Compound] cohort measured by number and grade of toxicity events	Safety and tolerability of azd6738 + olaparib cohort measured by number and grade of toxicity events	Final	1.0
Safety and tolerability of [Compound] + [Compound] cohort measured by number and grade of toxicity events	Safety and tolerability of azd6738 + durvalumab cohort measured by number and grade of toxicity events	Final	1.0
Disease control rate of [Compound] + [Compound] cohort	Disease control rate of azd6738 + olaparib cohort	Final	1.0
Disease control rate of [Compound] + [Compound] cohort	Disease control rate of azd6738 + durvalumab cohort	Final	1.0
Mean change from baseline in [ActivityInstance]	Mean change from baseline in body weight	Final	1.0
Proportion of subjects with [ActivityInstance] [Operator] [NumericValue] [Unit]	Proportion of subjects with hba1c < 7 %	Final	1.0
Mean change from baseline in [ActivityInstance]	Mean change from baseline in hba1c	Final	1.0

Manage Protocol Standard Texts

- Objectives
- Endpoints
- Criteria

- Re-usability
- Standardization
- Search capabilities

Objective

To compare the effect of [Compound] relative to [Comparator] on [ActivityInstance]

Endpoint

Occurrence of [Activity] (yes/no)

Endpoint

Mean change from baseline in [ActivityInstance]

Criteria

Age [NumericValue] [Age Unit] or above at the time of signing the informed consent.

Syntax Templates and Instantiations

Library / Syntax Templates / Criteria Templates / Inclusion / Parent

Criteria Templates ⓘ

Inclusion Exclusion Run-in Randomisation Dosing Withdrawal

Parent Pre-instance User Defined

Select rows

Sequence number	Indication or disorder	Criterion category	Criterion sub-category	Parent template
CI3	Nonalcoholic steatohepatitis	Body Measurements	Not Applicable	must be Activity
CI2	Not Applicable	Not Applicable	Not Applicable	Diagnosed with DiseaseDisorder Operator NumericValue Age Unit before screening.
CI1	Not Applicable	Not Applicable	Not Applicable	Age NumericValue Age Unit or above at the time of signing the informed consent.

Library / Template Instantiations / Objective Instances

Objective instantiations ⓘ

Select rows

Library	Template	Objective	Modified ↓	Status	Version	Number of studies
Sponsor	To assess the safety of [Compound] and [Compound] combination or [Compound] and [Compound] combination in biliary tract cancer patients	To assess the safety of azd6738 and durvalumab combination or azd6738 and olaparib combination in biliary tract cancer patients	Jul 4, 2023, 3:11 PM	Final	1.0	1
Sponsor	To assess the effect of [Compound] and [Compound] or [Compound] and [Compound] combination in biliary tract cancer patients who have failed to 1st-line chemotherapy	To assess the effect of azd6738 and durvalumab or azd6738 and olaparib combination in biliary tract cancer patients who have failed to 1st-line chemotherapy	Jul 4, 2023, 3:11 PM	Final	1.0	1
Sponsor	To compare the effect of [Compound] relative to [Comparator] on [ActivityInstance]	To compare the effect of metformin relative to npn insulin on body weight	Jul 4, 2023, 3:11 PM	Final	1.0	1
User Defined	Time from randomisation to all cause death	Time from randomisation to all cause death	Jul 4, 2023, 3:09 PM	Final	1.0	1
User Defined	Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina	Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina	Jul 4, 2023, 3:09 PM	Final	1.0	1

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Data Exchange Standards – CDISC Models

Library / Data Exchange Standards / SDTM

SDTM/SDTMIG ⓘ

SDTM Models SDTM Implementation Guide SDTMIG AP SDTMIG MD SENDIG SENDIG AR SENDIG DART SENDIG GENETOX

Status: Final Effective date: 2021-11-29 Implements: SDTM v2.0

Classes

Class	Name	Ordinal	Description
BS	Laboratory Test Results	24	A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.
CV			
DA			
DD			
EG			
FT			
GF			
IE			
IS			
LB			
MB			
MI			
MK			
MS			
NV			
OE			
PC			
PE			
PP			
QS			

Fields

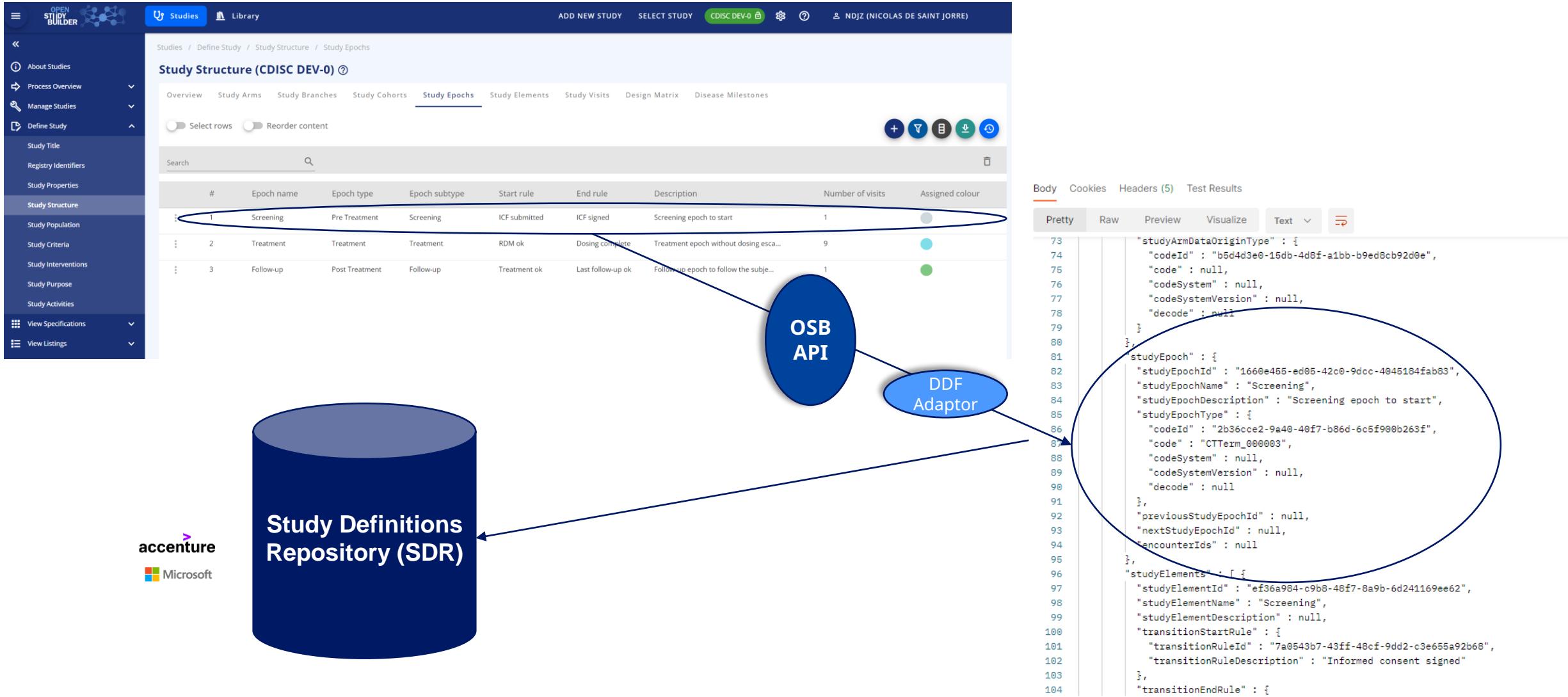
Field	Name	Label	Data Type	Role	Core	Codelist	Described Value Domain	Implements	Value List	Description
1	STUDYID	Study Identifier	Char	Identifier	Req			STUDYID		Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	Req			DOMAIN	LB	Two-character abbreviation for the domain.
3	USUBJID	Unique Subject Identifier	Char	Identifier	Req			USUBJID		Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	LBSEQ	Sequence Number	Num	Identifier	Req			SEQ		Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
5	LBGRPID	Group ID	Char	Identifier	Perm			GRPID		Used to tie together a block of related records in a single domain for a subject.
6	LBREFID	Specimen ID	Char	Identifier	Perm			REFID		Internal or external specimen identifier. Example: specimen ID.
7	LBSPID	Sponsor-Defined Identifier	Char	Identifier	Perm			SPID		Sponsor-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on the Lab page.
8	LBTESTCD	Lab Test or Examination Short Name	Char	Topic	Req	C65047		TESTCD		Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "ALT", "LDH".

CDASH and ADaM Models
will be added soon...

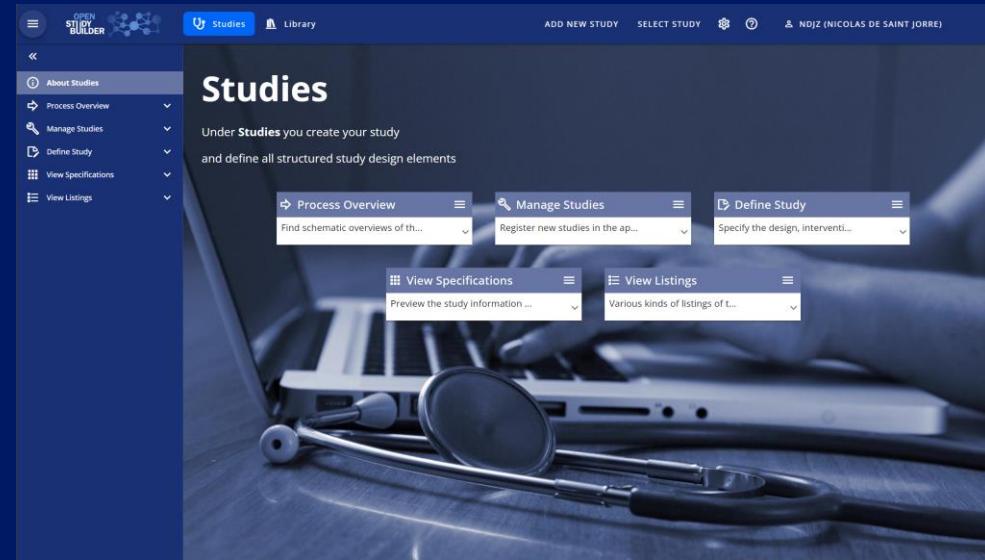
Importing
Models from
the CDISC
Library with
Version
Control +
Sponsor
additional
metadata

NeoDash reports to view Activity to SDTM Variables

Digital Data Flow Adaptor (TransCelerate DDF)



Study Protocol



STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES

Manage Studies

- Enter study information
 - Title, Description, Objectives, Endpoints, Criteria, Schedule of Activities ...
- Reuse in Protocol (and more)

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About Studies

Process Overview

Manage Studies

Define Study

View Specifications

Protocol Elements

SDTM Study Design Datasets

View Listings

Studies / View Specifications / Protocol Elements / Title Page

Protocol Elements (CDISC DEV-0)

[Title Page](#) [Protocol SoA](#) [Objectives and Endpoints](#) [Study Design](#) [Study Population](#) [Study Interventions](#) [Study Activities](#)

Title Page Information

Title page elements	Values
Protocol title	My first study
Protocol short title	my first study short title
Substance name	NPH Insulin
Universal Trial Number	
EudraCT number	2019-123456-42
IND number	
Study phase	3

The Studies module support

- general study attributes
- study design
- study criteria
- study SoA

And preview of structured protocol content

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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

Studies / Define Study / Study Activities / Detailed SoA

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



Screening	Treatment	Follow-up								
V1 <input type="checkbox"/>	V2 <input type="checkbox"/>	V3 <input type="checkbox"/>	V4 <input type="checkbox"/>	V5 <input type="checkbox"/>	V6 <input type="checkbox"/>	V7 <input type="checkbox"/>	V8 <input type="checkbox"/>	V9 <input type="checkbox"/>	V10 <input type="checkbox"/>	V11 <input type="checkbox"/>
-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

Activities Window

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"

Study Activities (CDISC DEV-0)

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

Protocol SoA

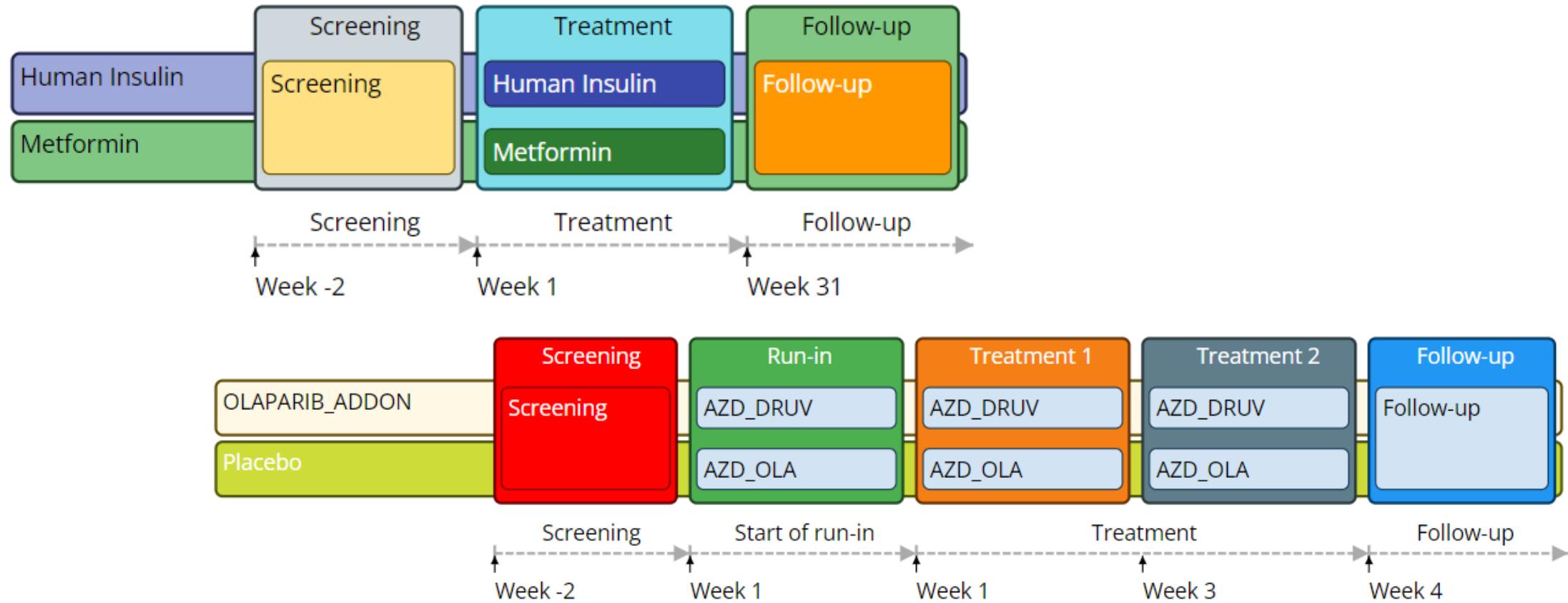
The “Protocol SoA”
only displaying the
selected activity level
of detail as a preview

DOWNLOAD DOCX

Procedure	Screening		Treatment								Follow-up
	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
Visit short name	-14	1	8	15	22	29	36	43	57	183	213
Study day	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35
Visit window (days)											
Randomisation											
Randomisation							X				
End of Study											
End of Study											X
Body Measurements											
Body Measurements		X	X	X	X	X	X	X	X	X	X
Eligibility Criteria					X						
Eligibility Criteria											
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	X
Adverse Event											
Adverse Event		X	X	X	X	X	X	X	X	X	X
Vital Signs											
Vital Signs		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

Produce a copy of
the SoA compatible
with Word

Study Design

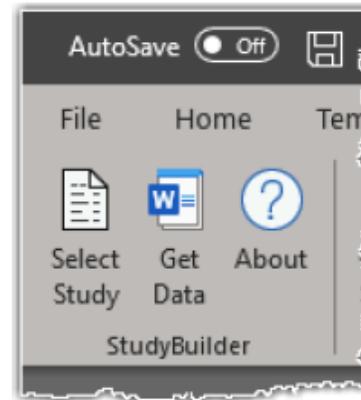




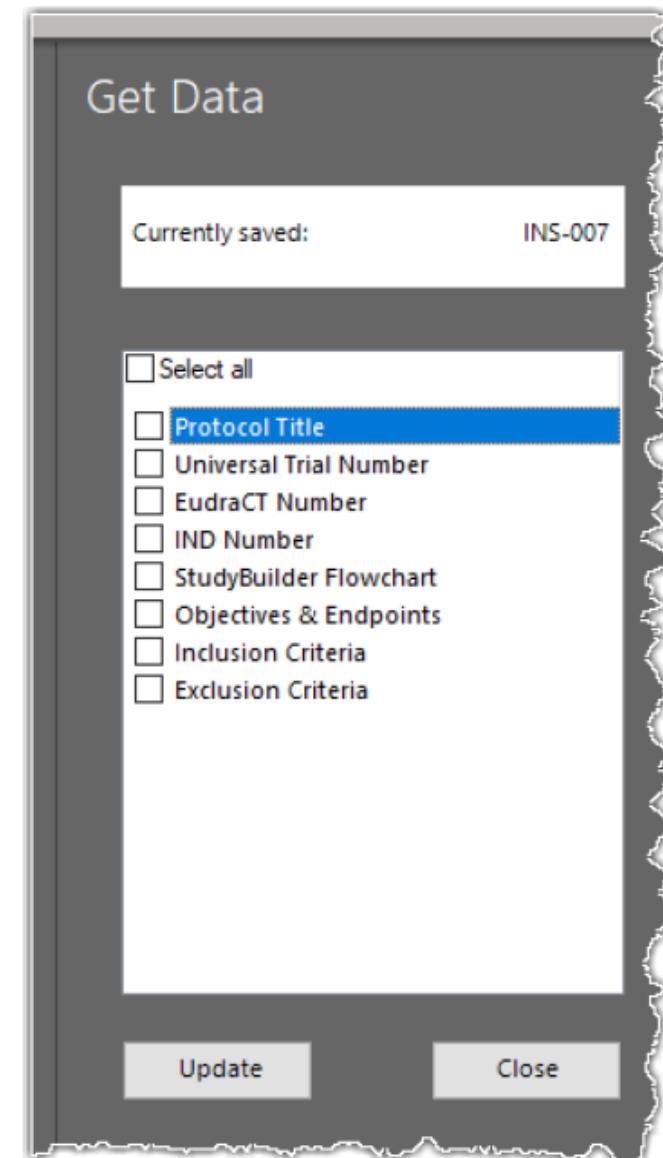
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- ✓ One-way connection
- ✓ Code recognizes the document type
- ✓ User-friendly ribbon and 'fly-out' in Word
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Protocol



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NLMU (Nils Müllenborn)

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		Version: 0.1	
		Status: Open	
		Page: 1 of 73	

Protocol

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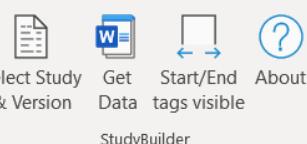
The title must include the name of the investigational intervention(s), the condition being studied, the study population included and the primary purpose, and should not be longer than 300 characters, including spaces. Two studies must not have identical titles.
Study intervention name(s) must be consistent throughout the protocol and protocol-related documents. The investigational medicinal product name must comply with document Q145046. Consult HQ Regulatory Affairs and/or project vice president/project director for correct use of product/substance name(s)/devices.
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Protocol Version Number: Version X.0 (add the version number that the protocol ultimately will

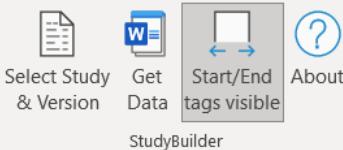


Protocol Study ID: CDISC DEV-0	CONFIDENTIAL	Date:	30 September 2022	<i>Novo Nordisk</i>
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1.2 Flowchart

[Schedule of Activities](#)

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

Procedure	Screening	Treatment										Follow-up
		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	
Visit short name	V1											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												

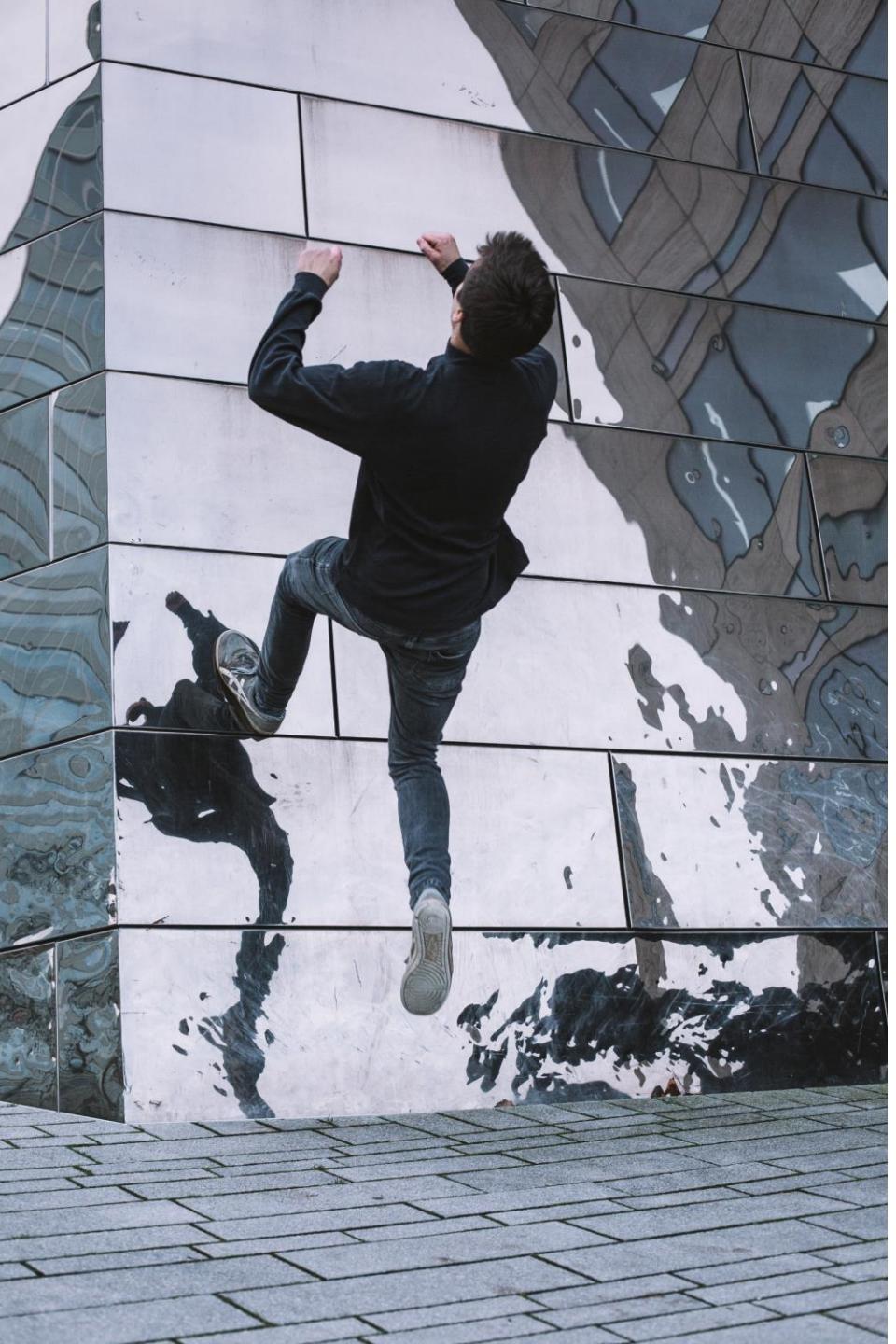
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Conclusion



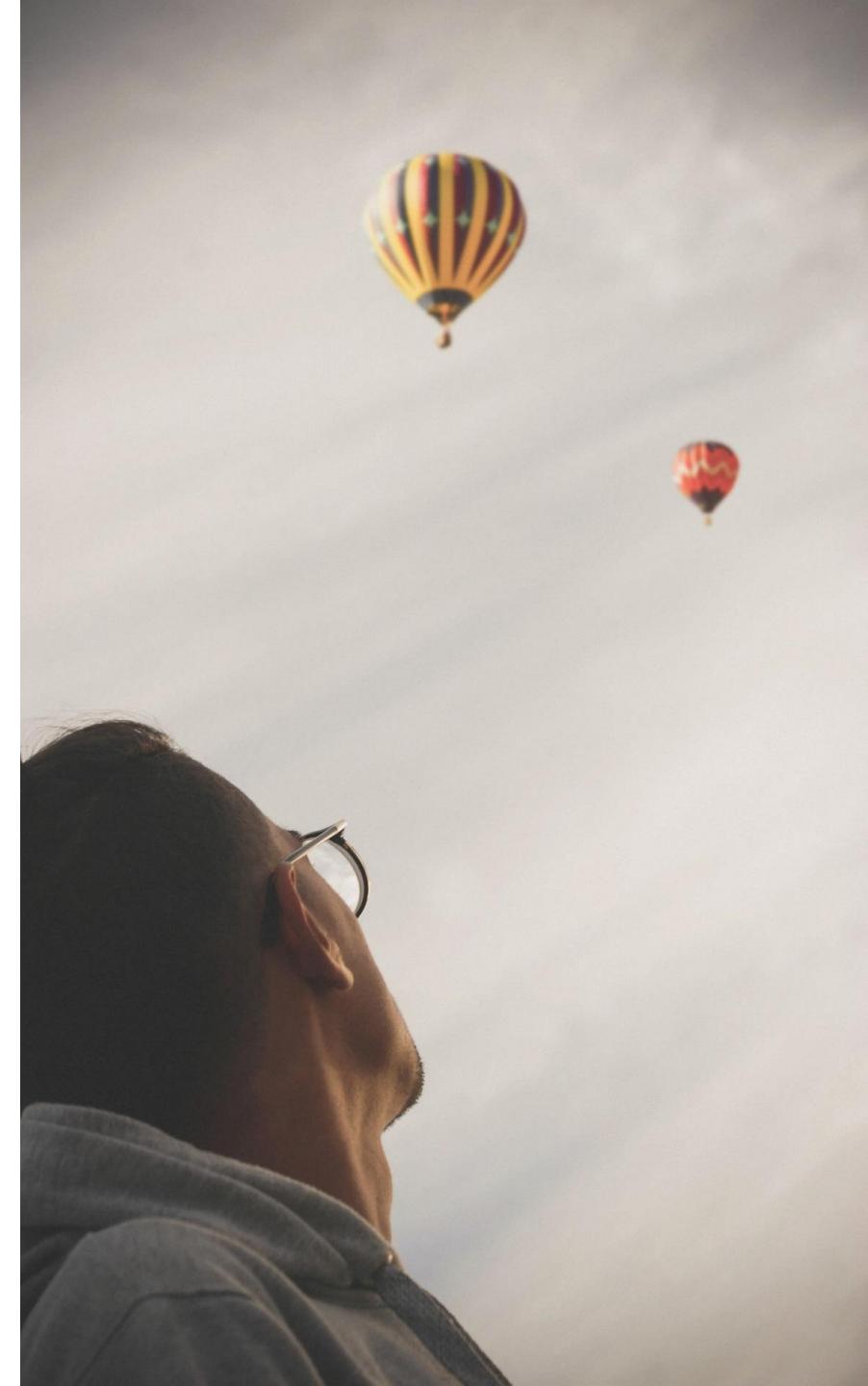
OpenStudyBuilder next steps

- 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://openstudybuilder.com/>
- Word Addin planned to be released as open source
- Seek to actively collaborate with CDISC, TransCelerate DDF, peers and vendors

Links

- [LinkedIn Newsletter](#)
- Project Homepage: <https://openstudybuilder.com/>
 - Information
 - Guides
 - References
 - Events
- Demonstration Video ([YouTube](#))
- [GitLab Source Code](#)
- Slack ([invite Link](#))
- E-Mail: openstudybuilder@gmail.com

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





Getting along

➤ Support

- Documentation
- Newsletter (LinkedIn)
- OpenStudyBuilder Q&A sessions (LinkedIn)
- Slack & Mail
- Commercial support options of vendors

➤ Share

- Documentation, Feedback, Ideas
- Enhancements, connected tools
- Biomedical Concepts discussions & additions

Thanks!

Questions?

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