

Open-Source MDR and SDR

The OpenStudyBuilder as a new
Metadata Repository solution



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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

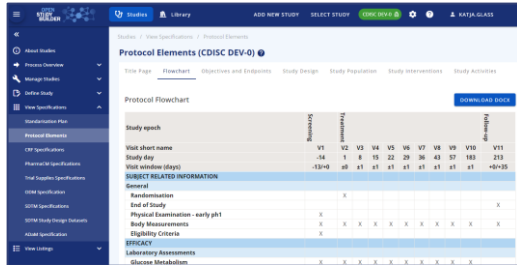
3 ELEMENTS OF OpenStudyBuilder

- **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

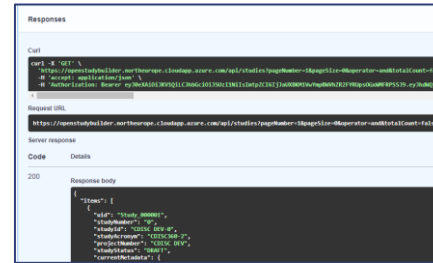


Neo4j database

- Including example data



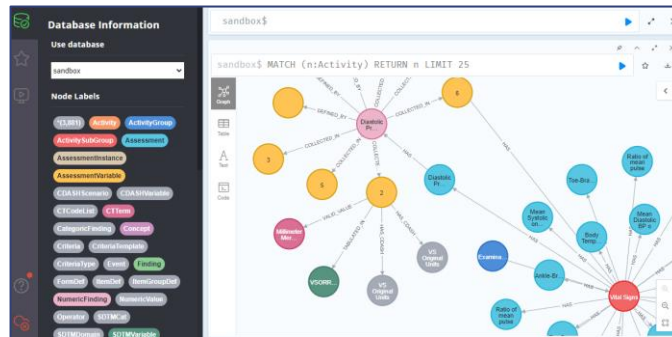
API



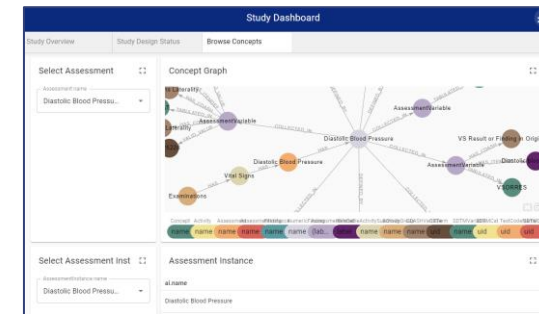
Documentation

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

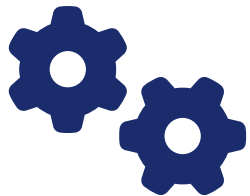
DB Browser



Neo4j dashboard*



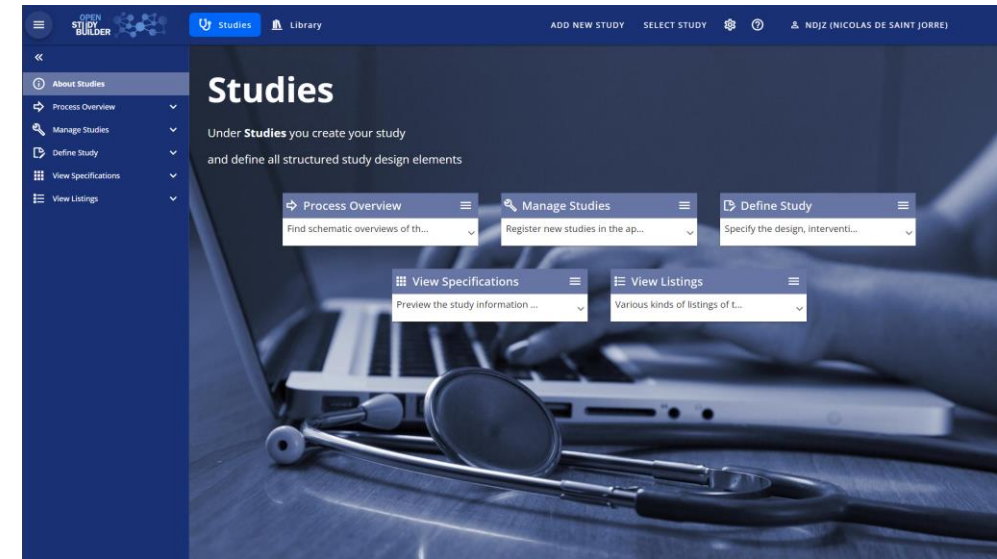
Scripts



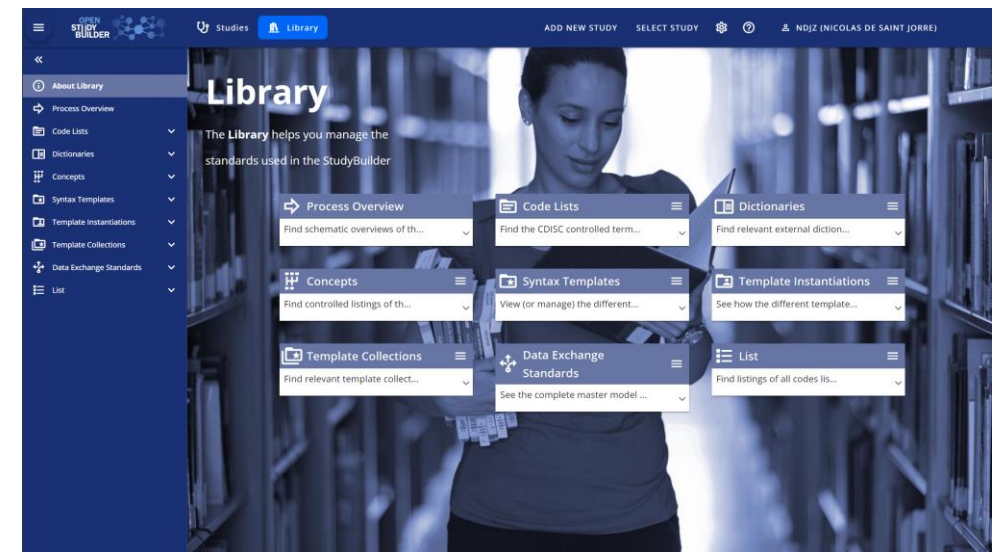
*available in sandbox, can be installed on other environments

OpenStudyBuilder Components

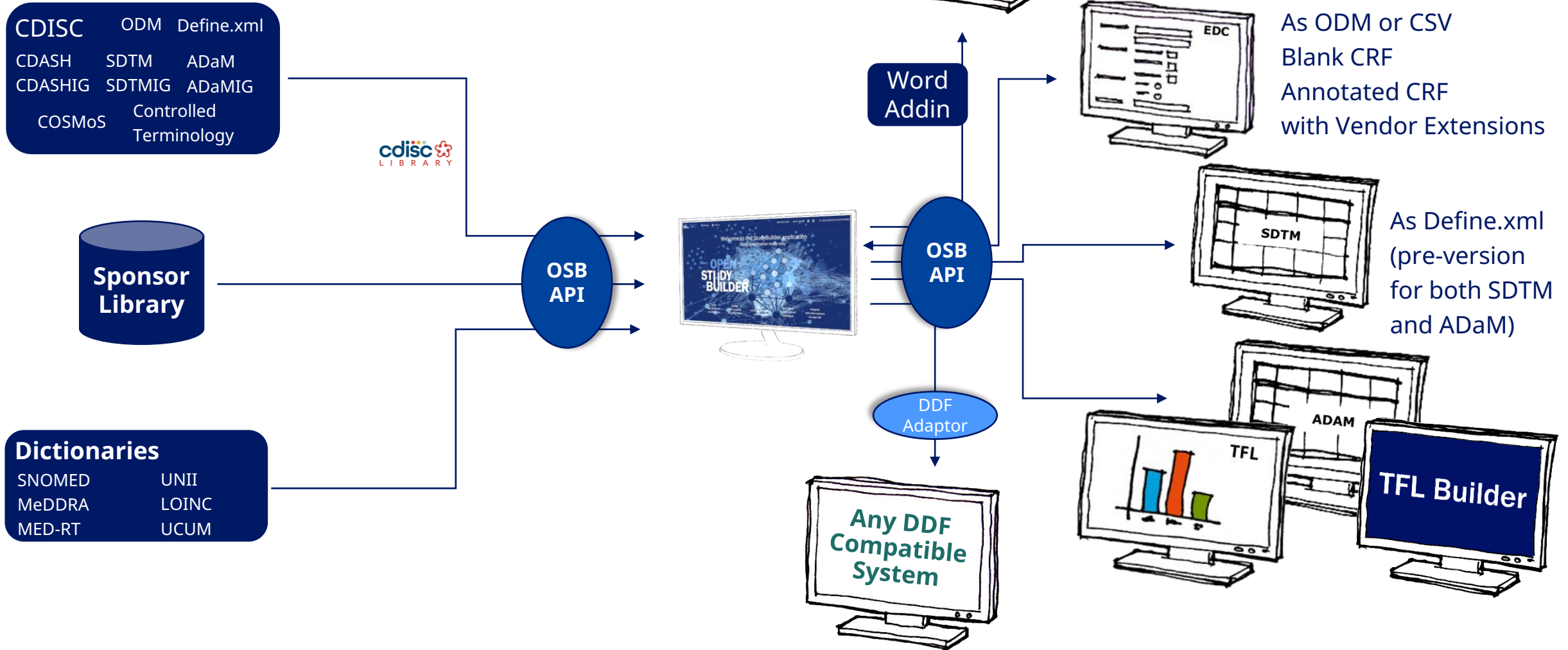
STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



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

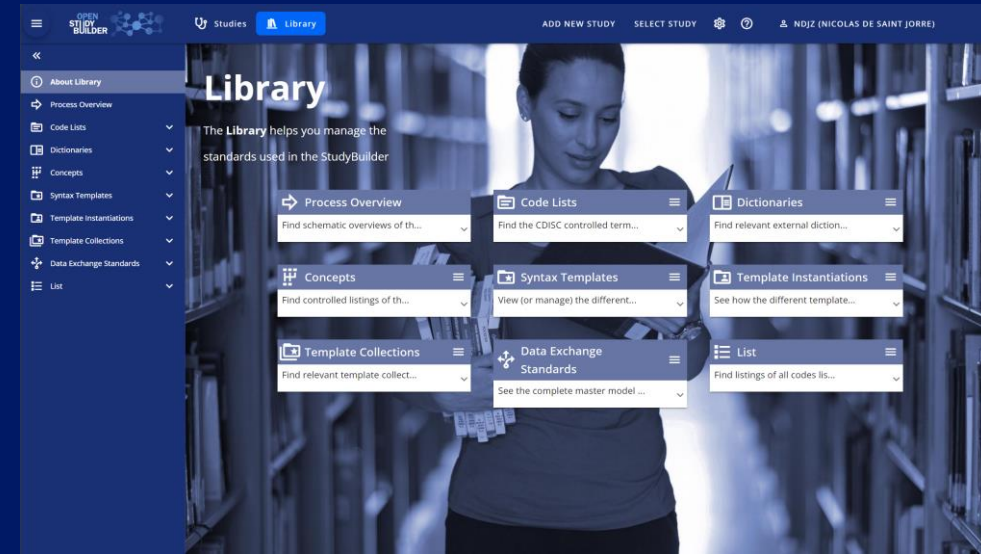
To Get
metadata

To Delete
metadata
(soft delete)

To Modify
metadata

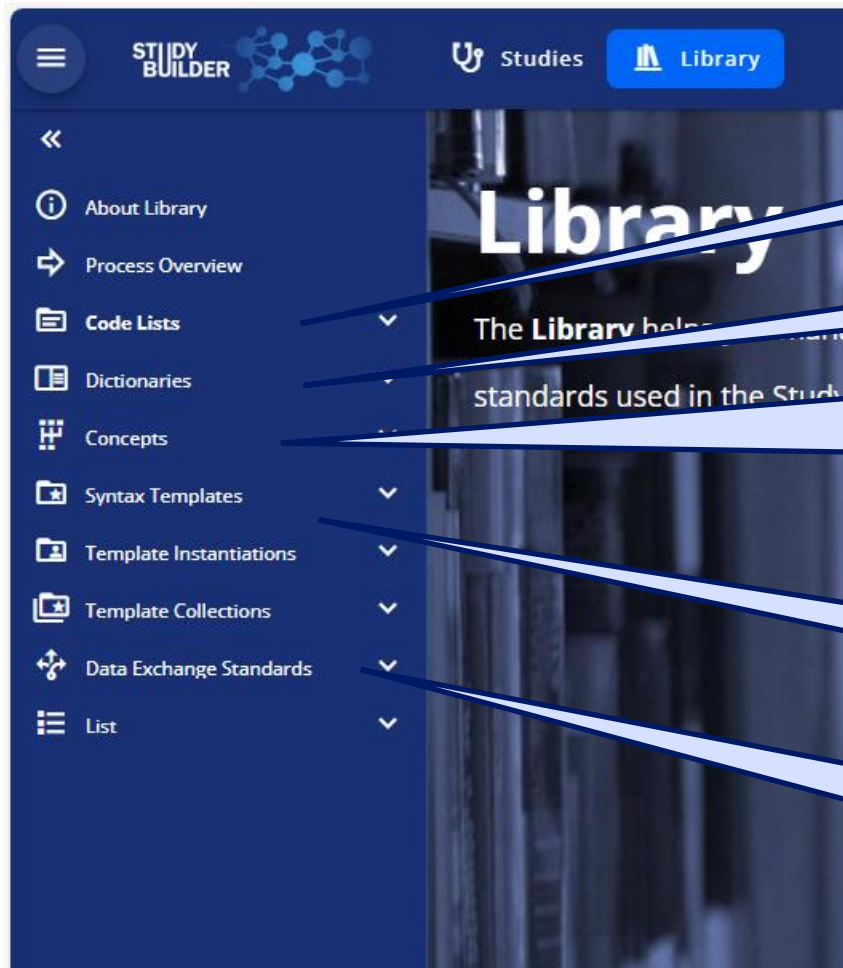
CT Codelists		^
GET	/ct/codelists	Returns all codelists names and attributes.
POST	/ct/codelists	Creates new codelist.
GET	/ct/codelists/{codelist_uid}/sub-codelists	Returns all sub codelists names and attributes that only have the provided terms.
GET	/ct/codelists/headers	Returns possible values from the database for a given header
POST	/ct/codelists/{codelist_uid}/terms	Adds new CTTerm to CTCodelist.
DELETE	/ct/codelists/{codelist_uid}/terms/{term_uid}	Removes given CTTerm from CTCodelist.
GET	/ct/codelists/attributes	Returns all codelists attributes.
GET	/ct/codelists/attributes/headers	Returns possible values from the database for a given header
GET	/ct/codelists/{codelist_uid}/attributes	Returns the latest/newest version of a specific codelist identified by 'uid'
PATCH	/ct/codelists/{codelist_uid}/attributes	Updates the codelist identified by 'codelist_uid'.
GET	/ct/codelists/{codelist_uid}/attributes/versions	Returns the version history of a specific CTCodelistAttributes identified by 'codelist_uid'.
POST	/ct/codelists/{codelist_uid}/attributes/versions	Creates a new codelist in 'Draft' status.
POST	/ct/codelists/{codelist_uid}/attributes/approvals	Approves the codelist identified by 'codelist_uid'.
GET	/ct/codelists/names	Returns all codelists names.
GET	/ct/codelists/names/headers	Returns possible values from the database for a given header
GET	/ct/codelists/{codelist_uid}/names	Returns the latest/newest version of a specific codelist identified by 'uid'
PATCH	/ct/codelists/{codelist_uid}/names	Updates the codelist identified by 'codelist_uid'.
GET	/ct/codelists/{codelist_uid}/names/versions	Returns the version history of a specific CTCodelistName identified by 'codelist_uid'.
POST	/ct/codelists/{codelist_uid}/names/versions	Creates a new codelist in 'Draft' status.
POST	/ct/codelists/{codelist_uid}/names/approvals	Approves the codelist identified by 'codelist_uid'.

Library



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

Library content



Code Lists := CTTerm
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

- About Library
- Process Overview
- Code Lists
- Dashboard
- CT Catalogues
- CT Packages
- CDISC
- Sponsor
- Dictionaries
- Concepts
- Syntax Templates
- Template Instantiations
- Template Collections
- Data Exchange Standards
- List

Library / Code Lists / CT Catalogues / / C66737 / Terms / C15602_PHASE_III_TRIAL

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

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	+ x ↻
Sentence case name	3				
Order	3				

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

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

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 a treatment approach. NOTE: Phase 2 studies will include a				

Dictionaries

Library / Dictionaries / SNOMED

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

Select rows

Search

SNOMED ID	Preferred synonym	Preferred synonym (lower case)	Abbreviation	Definition	Status	Version	Modified
64572001	Disease	disease		Disease (disorder)	Final	1.0	Jul 4, 2023, 3:08 PM
362965005	Disorder of body system	disorder of body system		Disorder of body system (disorder)	Final	1.0	Jul 4, 2023, 3:08 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, 2023, 3:08 PM
446221000	Heart failure with normal ejection ...	heart failure with normal ejection ...	HFpEF	Heart failure with normal ejection ...	Final	1.0	Jul 4, 2023, 3:08 PM
442685003	Nonalcoholic steatohepatitis	nonalcoholic steatohepatitis	NASH	Nonalcoholic steatohepatitis (disor...	Final	1.0	Jul 4, 2023, 3:08 PM
441190003	Severe hereditary factor IX deficie...	severe hereditary factor IX deficie...		Severe hereditary factor IX deficie...	Final	1.0	Jul 4, 2023, 3:08 PM
440993008	Severe hereditary factor VIII defici...	severe hereditary factor VIII defici...		Severe hereditary factor VIII defici...	Final	1.0	Jul 4, 2023, 3:08 PM

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Library / Dictionaries / UNII

UNII (Unique Ingredient Identifier) for Active Substances

Select rows

Search

UNII ID	Substance name	Substance name (lower case)	Abbreviation	Status	Version	Modified
Q51B043MG4	LEVOTHYROXINE	levothyroxine		Final	1.0	Jul 4, 2023, 3:08 PM
U188YD42P	MOXIFLOXACIN	moxifloxacin		Final	1.0	Jul 4, 2023, 3:08 PM
SX6KS5TWWC	GLYBURIDE	glyburide		Final	1.0	Jul 4, 2023, 3:08 PM
QFF0P1DV7Z	SITAGLIPTIN	sitagliptin		Final	1.0	Jul 4, 2023, 3:08 PM
1Y17CT15SR	INSULIN HUMAN	insulin human		Final	1.0	Jul 4, 2023, 2:45 PM
362O9ITL9D	PARACETAMOL	paracetamol		Final	1.0	Jul 4, 2023, 2:45 PM
9100L32L2N	METFORMIN	metformin		Final	1.0	Jul 4, 2023, 2:45 PM
WTT295SHYS	DULAGLUTIDE	dulaglutide		Final	1.0	Jul 4, 2023, 3:08 PM
X7WDT95NSC	GLIPIZIDE	glipizide		Final	1.0	Jul 4, 2023, 3:08 PM
X4OV71U42S	PIOGLITAZONE	pioglitazone		Final	1.0	Jul 4, 2023, 3:08 PM

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Library / Dictionaries / MED-RT

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

Select rows

Search

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
N0000187060	Erdofium Glucuronate	erdofium glucuronate		Erdofium Glucuronate	Final	1.0	Jul 4, 2023, 2:43 PM

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Library / Dictionaries / UCUM

UCUM (Unified Code for Units of Measure)

Select rows

Search

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
- Dictionaries
- Concepts
- Activities**
- Units
- CRFs
- Compounds
- Syntax Templates
- Template Instantiations
- Template Collections
- Data Exchange Standards
- List

Library / Concepts / Activities / Activities Instances / Bilirubin Biochemistry

Bilirubin, Biochem

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

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

Activity groupings	Activity group	Activity subgroup
	Laboratory Assessments	Biochemistry

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	Serum	specimen

Concept: CRFs

Templates / Forms / ItemGroups / Items	Reference attributes	Definition attributes	Status	Version	Link
Template NN V1			Draft	0.1	+ FORMS
Informed Consent and Demography			Draft	0.1	+ ITEM GROUPS
Informed Consent			Draft	0.2	+ ITEMS
Study ID			Draft	0.1	
Date informed consent obtained			Draft	0.2	
Time informed consent obtained			Draft	0.2	
General Demography			Draft	0.1	
Date of birth			Draft	0.1	
Sex (read-only)			Draft	0.1	
Ethnicity			Draft	0.1	
Race			Draft	0.1	
Age		123	Draft	0.1	
Race other			Draft	0.1	
Vital Signs			Draft	0.1	

Templates used to defined multiple CRF version

Blank or Annotated CRF following MSG 2.0 standard

PDF format

ODM.xml with vendor extensions (or CSV)

Template NN V1 Annotated CRF

Informed Consent and Demography

Please complete this Informed Consent and Demography form at the very beginning of the study. General Item design notes: Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM General item design notes: Integration: A: Argus, Ax: rms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM Oracle item des N notes: Key: [*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/DemogOracle item design notes: Key: [*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/Demog

DM (Demographics Domain)
DS (Disposition Domain)

Informed Consent item group
[OID=GDM.IC, Version=0.2]

Please complete the Informed Consent item group before any other information

Study ID [OID=LSTUDYID, Version=0.1] 11 digit(s)
STUDYID

Date informed consent obtained [OID=LRFICDAT, Version=0.2] 10 digit(s)
jj/mm/aaaa
RFICDTC DSSTDTC

Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during SDTM-based dataset creation before submission.

This will be the same information on informed consent used in the SDTM Disposition domain

- «
- About Library
- Process Overview
- Code Lists
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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

Library / Template Instantiations / End

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

Search

Sequence number	Indication or disorder	Criterion category	Criterion sub-category	Parent template
⋮ C3	Nonalcoholic steatohepatitis	Body Measurements	Not Applicable	must be Activity
⋮ C2	Not Applicable	Not Applicable	Not Applicable	Diagnosed with DiseaseDisorder Operator NumericValue Age Unit before screening.
⋮ C1	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

Search

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 nph 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

3.4 Status Final Effective date 2021-11-29 Implements [SDTM v2.0](#)

Classes

< Comments Demographics Events **Findings** Findings About Interventions Non-host Organism Identifiers Related Records Related Specimens Related Subjects Subject Disease Milestones Subject Elements >

< BS CP CV DA DD EG FT GF IE IS **LB** MB MI MK MS NV OE PC PE PP QS >

3.1.3

3.1.2

Ordinal	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".

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

CDASH and ADaM Models will be added soon...

NeoDash reports to view Activity to SDTM Variables

neo4j Labs neo4j://vm-db-fv7zbjkehgyw.clinicalmdr-dev.corp.azure.novonordisk.com:7687

StudyBuilder Activity Library Dashboard

ReadMe Activity Lib (search top-down) Activity Lib (search bottom-up) **Activity to SDTM** Activity in COSMOS format Activities used in Studies

Select Activity Instance

ActivityGroup	ActivitySubGroup	Activity	ActivityInstance
Adverse Event	Adverse Event	Adverse Event	AE
Laboratory Assessments	Biochemistry	Alanine	ALAP
AE Requiring Additional Data	Laboratory Assessment	Alanine Aminotransferase	ALT
Laboratory Assessments	Biochemistry	Alanine Aminotransferase	ALTS
AE Requiring Additional Data	Laboratory Assessment	Albumin	ALBU2

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Select SDTM version

Click	IG	Description	Effective Date	Version Number
SELECT	SDTMIG v3.4	This is the implementation guide for human clinical trials corresponding to Version 2.0 of the CDISC Study Data Tabulation Model.	2021-11-29	3.4
SELECT	SDTMIG v3.3	CDISC Version 3.3 (v3.3) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to guide t	2018-11-20	3.3
SELECT	SDTMIG v3.2	CDISC Version 3.2 (V3.2) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to guide t	2013-11-26	3.2
SELECT	SDTMIG v3.1.3	CDISC Version 3.1.3 (V3.1.3) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to gu	2012-07-16	3.1.3
SELECT	SDTMIG v3.1.2	CDISC Version 3.1.2 (V3.1.2) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to gu	2008-11-12	3.1.2

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Activity mapped to SDTM

Activity	Activity Instance	Activity Item Class	Variable Class	SDTMIG Variable	SDTMIG Dataset
Albumin	Urinary Albumin Excretion	domain	DOMAIN	Domain Abbreviation	Labs
Albumin	Urinary Albumin Excretion	test_name_code	--TESTCD	Lab Test or Examination Short	Labs
Albumin	Urinary Albumin Excretion	test_name_code	--TEST	Lab Test or Examination Name	Labs
Albumin	Urinary Albumin Excretion	specimen	--SPEC	Specimen Type	Labs

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Activity with links to SDTM

Digital Data Flow Adaptor (TransCelerate DDF)

OPEN STUDY BUILDER

Studies / Define Study / Study Structure / Study Epochs

ADD NEW STUDY SELECT STUDY CDISC DEV-0

Study Structure (CDISC DEV-0)

Overview Study Arms Study Branches Study Cohorts **Study Epochs** Study Elements Study Visits Design Matrix Disease Milestones

Select rows Reorder content

Search

#	Epoch name	Epoch type	Epoch subtype	Start rule	End rule	Description	Number of visits	Assigned colour
1	Screening	Pre Treatment	Screening	ICF submitted	ICF signed	Screening epoch to start	1	
2	Treatment	Treatment	Treatment	RDM ok	Dosing complete	Treatment epoch without dosing esca...	9	
3	Follow-up	Post Treatment	Follow-up	Treatment ok	Last follow-up ok	Follow-up epoch to follow the subje...	1	

Body Cookies Headers (5) Test Results

Pretty Raw Preview Visualize Text

```

73   "studyArmDataOriginType" : {
74     "codeId" : "b5d4d3e0-15db-4d8f-a1bb-b9ed8cb92d0e",
75     "code" : null,
76     "codeSystem" : null,
77     "codeSystemVersion" : null,
78     "decode" : null
79   },
80 },
81 "studyEpoch" : {
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83   "studyEpochName" : "Screening",
84   "studyEpochDescription" : "Screening epoch to start",
85   "studyEpochType" : {
86     "codeId" : "2b36cce2-9a40-40f7-b86d-6c5f900b263f",
87     "code" : "CTTerm_000003",
88     "codeSystem" : null,
89     "codeSystemVersion" : null,
90     "decode" : null
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93   "nextStudyEpochId" : null,
94   "encounterIds" : null
95 },
96 "studyElements" : [ {
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103  },
104  "transitionEndRule" : {

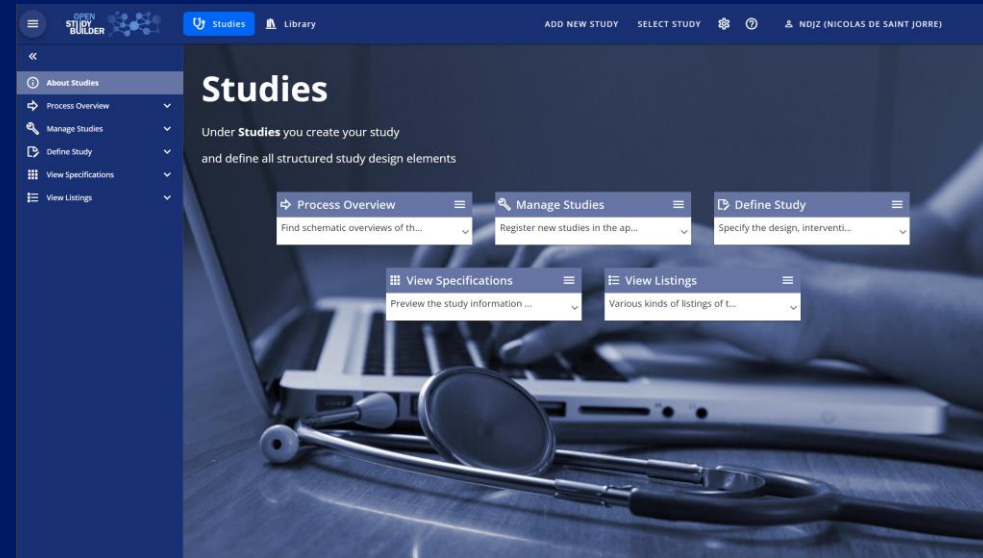
```



OSB
API

DDF
Adaptor

Study Protocol



STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES

Manage Studies

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



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

- ←
- 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) ?

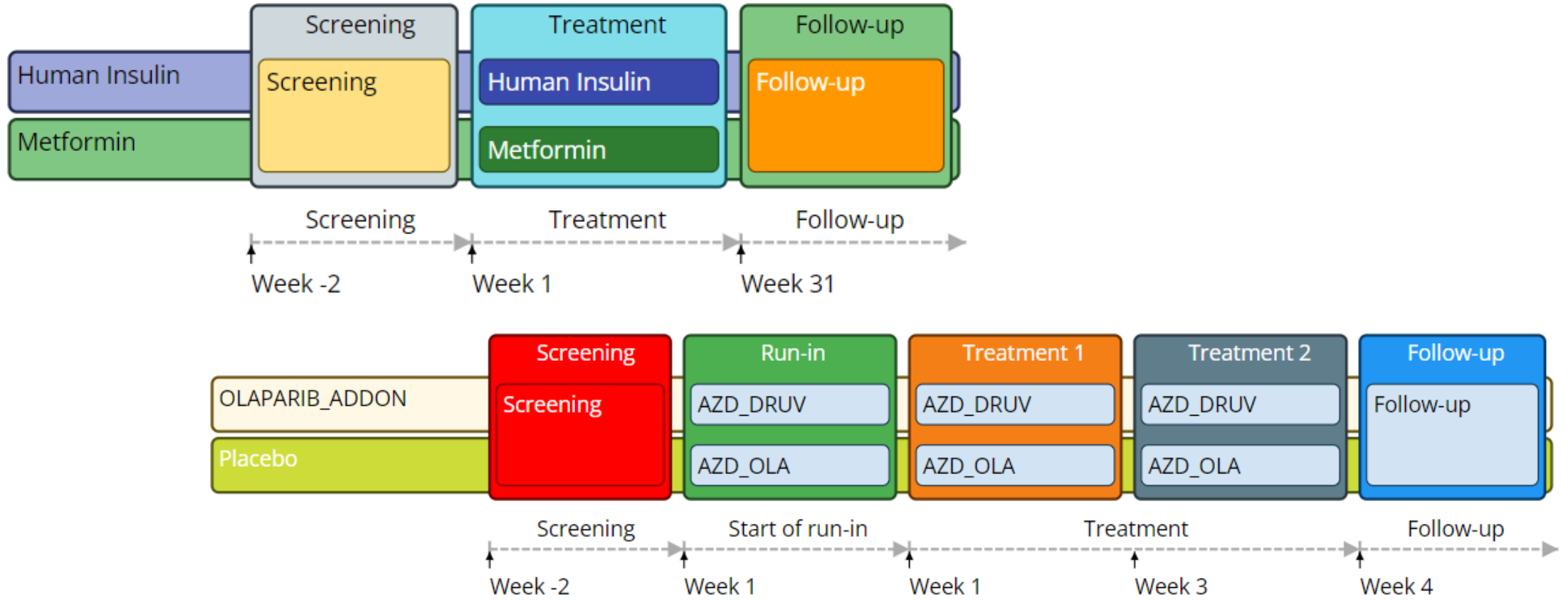
Study Activities | Study Activity Instances | Detailed SoA | SoA footnotes | Protocol SoA | Activity Instructions

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

Activities	Window	Screening										Follow-up
		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	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	👁️											
▼ <input type="checkbox"/> Glucose Metabolism	👁️											
<input type="checkbox"/> HbA1c	🗑️	✅	✅	✅	✅	✅	✅	✅	✅	✅	✅	○
▼ Self Measured Plasma Glucose	👁️											
<input type="checkbox"/> Self Measured Plasma Glucose	🗑️											
<input type="checkbox"/> Mean Plasma Glucose	🗑️	○	○	○	○	○	○	○	○	○	○	○
> SAFETY	🗑️											

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

Study Design

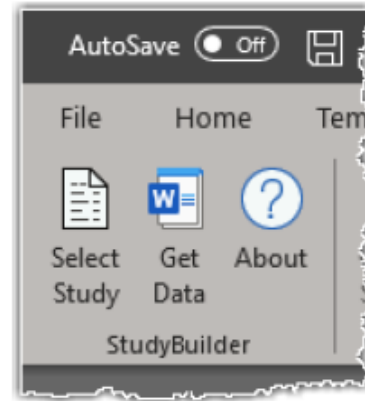




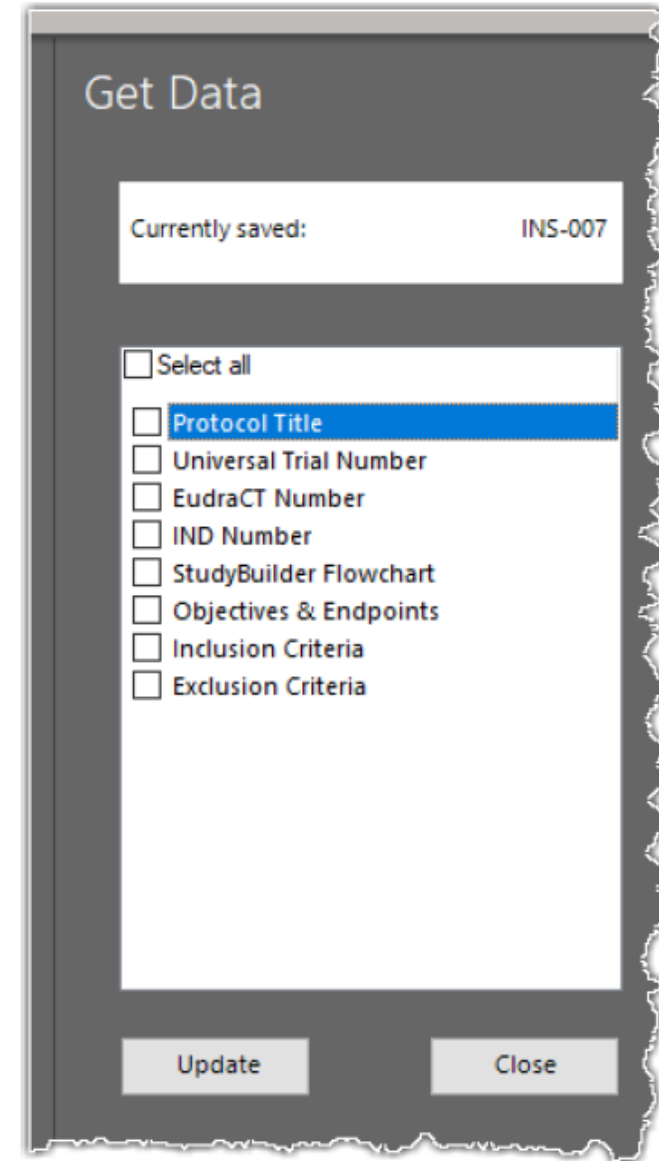
StudyBuilder ribbon (Word add-in)

✓ One-way
connection

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



Protocol



Select Study & Version
Get Data
Start/End tags visible
About
StudyBuilder

Protocol	CONFIDENTIAL	Date:	30 September 2022	Novo Nordisk
Study ID:		Version:	0.1	
		Status:	Draft	
		Page:	1 of 73	

Protocol

This template is based on the *NN Authoring Master Template* and requires the **NN Authoring ribbon**, which you install (once) from the Software portal.
 To remove this guidance text, click it and tap Delete **twice**. To bulk remove all guidance text boxes in the document, use the NN Authoring ribbon: Document Fix > Remove Guidance Text.
 For template support and more information type: [TemplateSupport/](#) in your browser

For explanation of the formatting and text conventions, see Instructions for Protocol Templates on page 2.
 To remove this guidance text box, click it and tap Delete **twice**.

Protocol Title: Insert via the StudyBuilder ribbon.
 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.
 To remove this guidance text box, click it and tap Delete **twice**.

Short Title: Insert via the StudyBuilder ribbon.
 Include a short title in lay language, to be aligned with the participant information/informed consent (PI/IC) title. Maximum 300 characters. For guidance on lay language titles please refer to the User guide on lay language titles in the [PI/IC toolbox on SharePoint](#).
 To remove this guidance text box, click it and tap Delete **twice**.

Substance Number / Name (as applicable):

Protocol Version Number: Version *X.0* (add the version number that the protocol ultimately will

Select Study & Version | Get Data | Start/End tags visible | About

StudyBuilder

Protocol		Date:	30 September 2022	<i>Novo Nordisk</i>
Study ID: CDISC DEV-0		Version:	0.1	
	CONFIDENTIAL	Status:	Draft	
		Page:	4 of 73	

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Select Study & Version

Template type: InterventionalStudyProtocol Saved: CDISC DEV-0_I

Type Project number, Study ID, or Study acronym (min 3 characters):

cdi

Project Number	Study ID	Status	Study Acronym	Study Number
CDISC DEV	CDISC DEV-0	DRAFT	CDISC360-2	0
CDISC DEV	CDISC DEV-0001	DRAFT	DDF-SampleData-...	0001

Refr

Version	Status	VersionDate
	DRAFT	2023-10-18

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Get T

Select Study & Version | Get Data | Start/End tags visible | About

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

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	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-0

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

Update

Conclusion

OpenStudyBuilder next steps

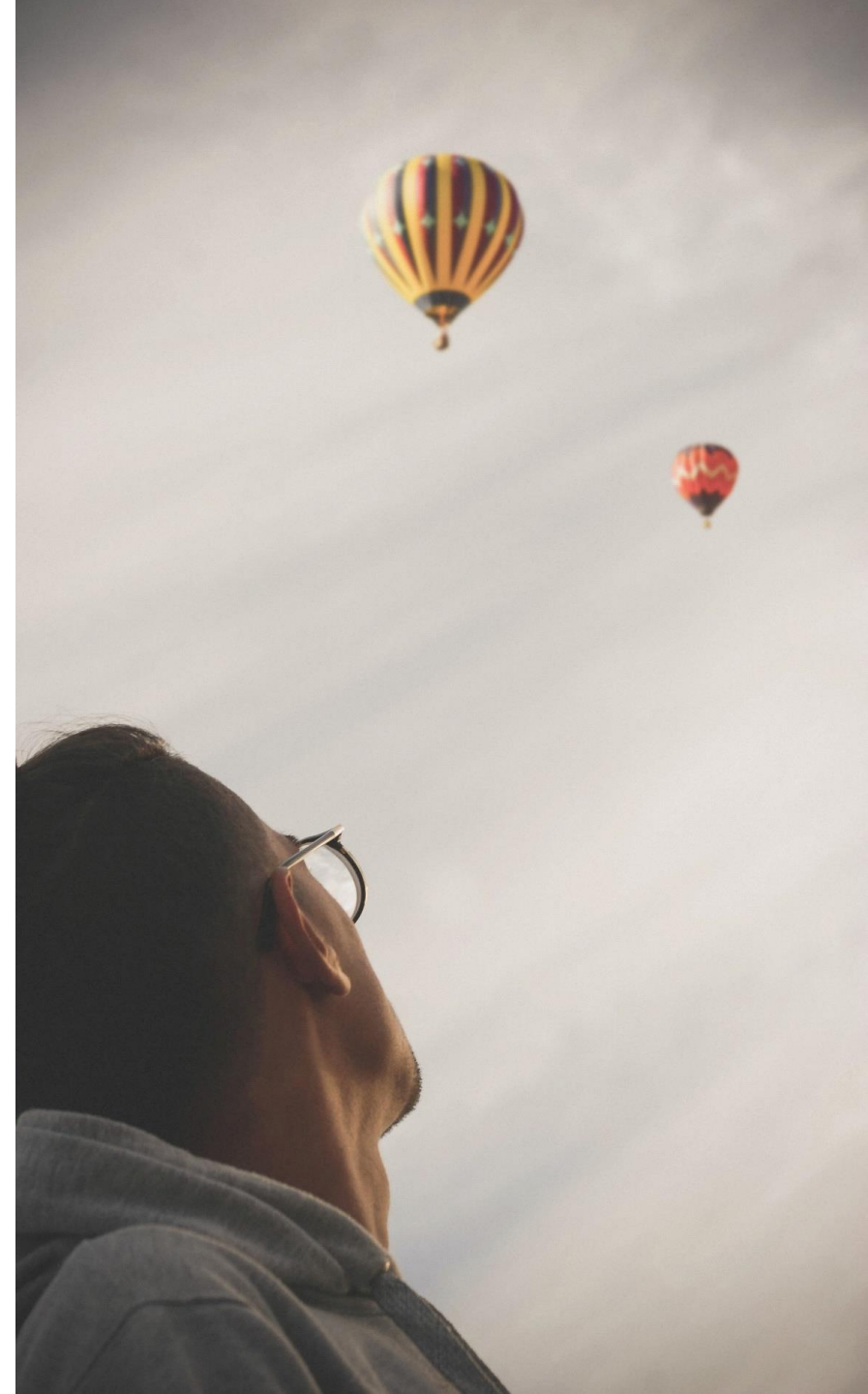
- Non-GCP MVP released internally at Novo Nordisk in September 2022 for pilots
- Business go-live November 2023 for phase 2-4 studies with protocol outline kickoff
- Share as open source project under COSA
 - <https://cosa.cdisc.org/directory/openStudyBuilder>
 - <https://openstudybuilder.com/>
- Word 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”
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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?

OPEN
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