

Open-Source MDR and SDR

Managing Your Standards with the OpenStudyBuilder



Birmingham, Monday 6 November 2023

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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)



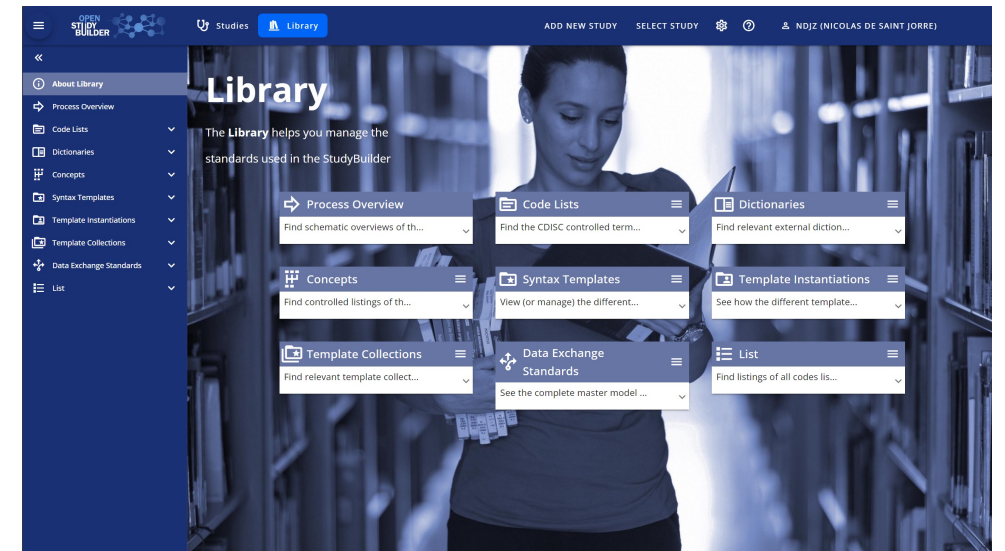
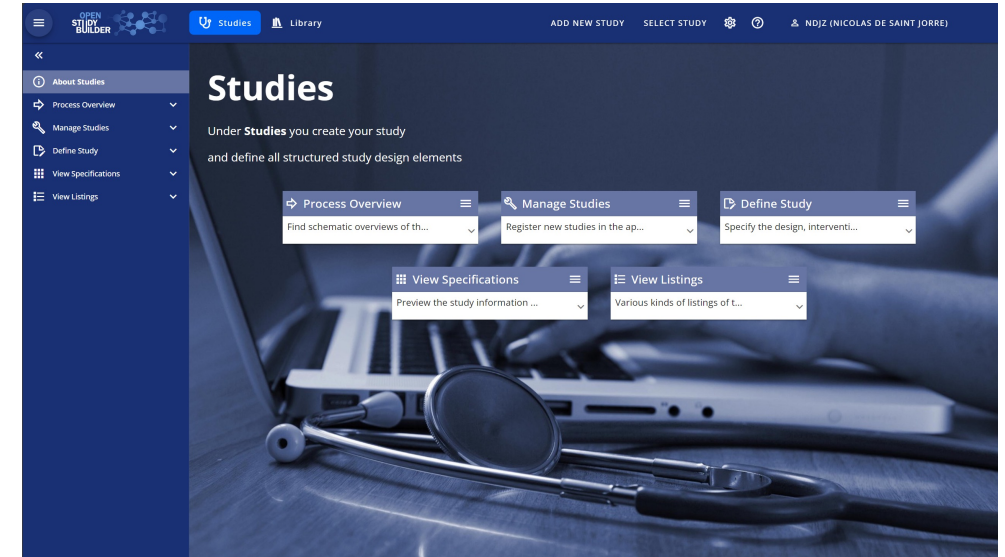
OpenStudyBuilder Components

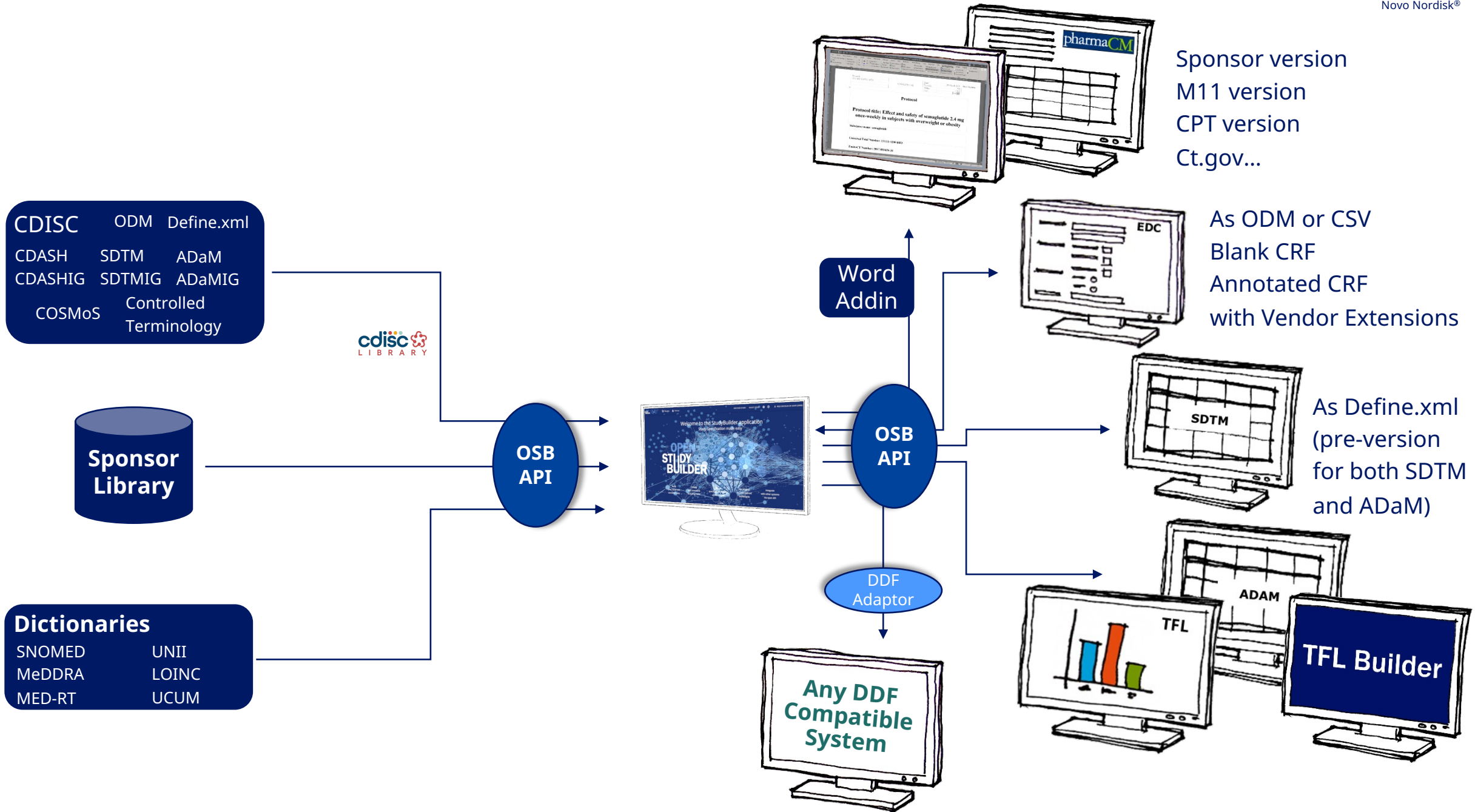
STUDIES

TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES

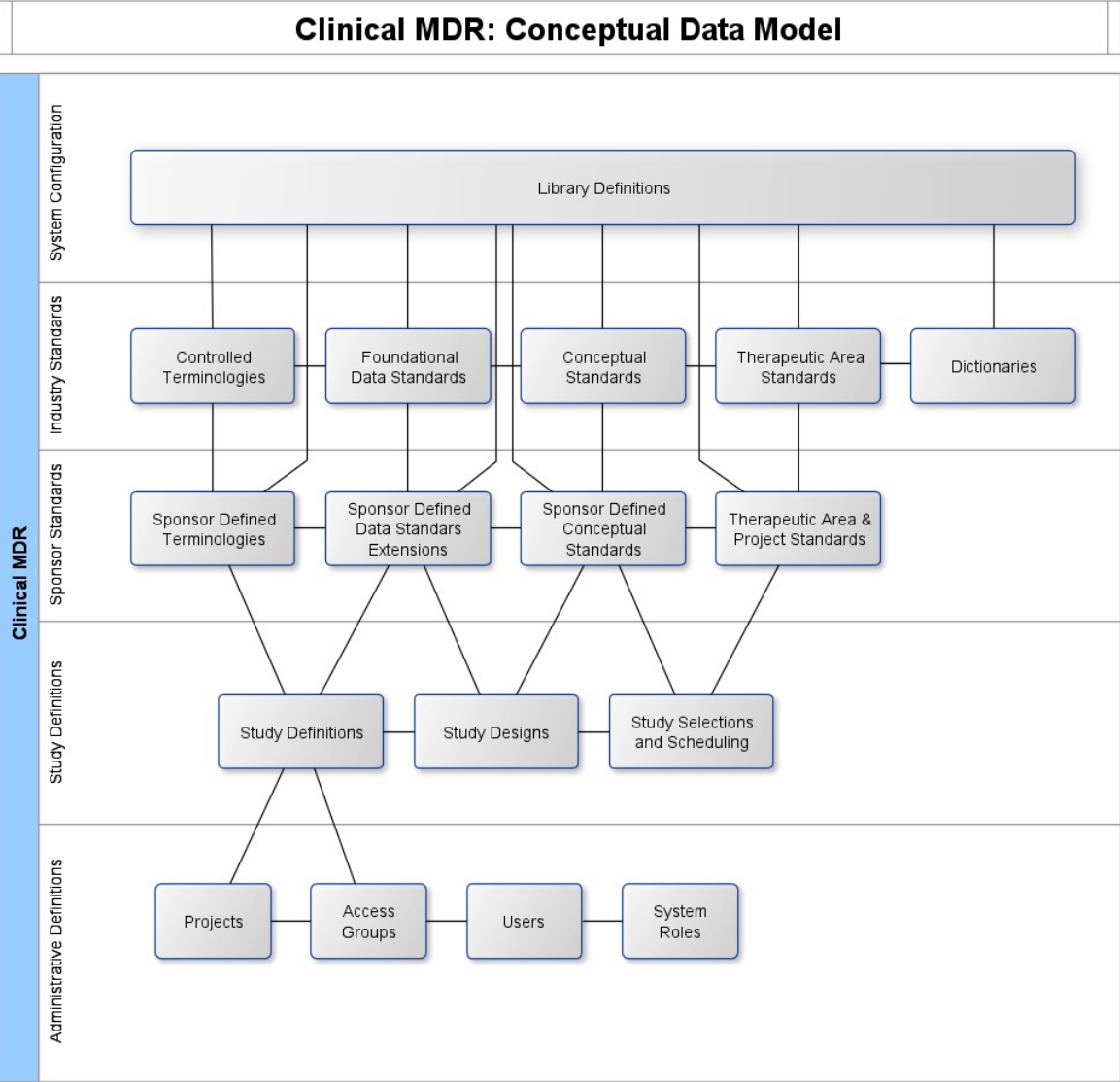
LIBRARY

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





Conceptual Data Model and the OSB API



Clinical MDR API 3.0.28 OAS3

/api/openapi.json

NOTICE

This license information is applicable to the swagger documentation of the clinical-mdr-api, that is the openapi.json.

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Authentication

Supports OAuth2 [Authorization Code Flow](#), at paths described in the OpenID Connect Discovery metadata document (whose URL is defined by the `OAUTH_METADATA_URL` environment variable).

Microsoft Identity Platform documentation can be read [\(here\)](#).

Authentication can be turned off with `OAUTH_ENABLED=false` environment variable.

When authentication is turned on, all requests to API endpoints must provide a valid bearer (JWT) token inside the `Authorization` http header.

When authentication is turned off, all endpoints accept (optional) custom header `X-Test-User-Id` which allows any request to specify any user id value. If the `X-Test-User-Id` header is missing, the default value of `unknown-user` is assumed.

System information:

System information is provided by a separate [System Information](#) sub-app which does not require authentication.

Servers

/api

Authorize

ODM Study Events

ODM Forms

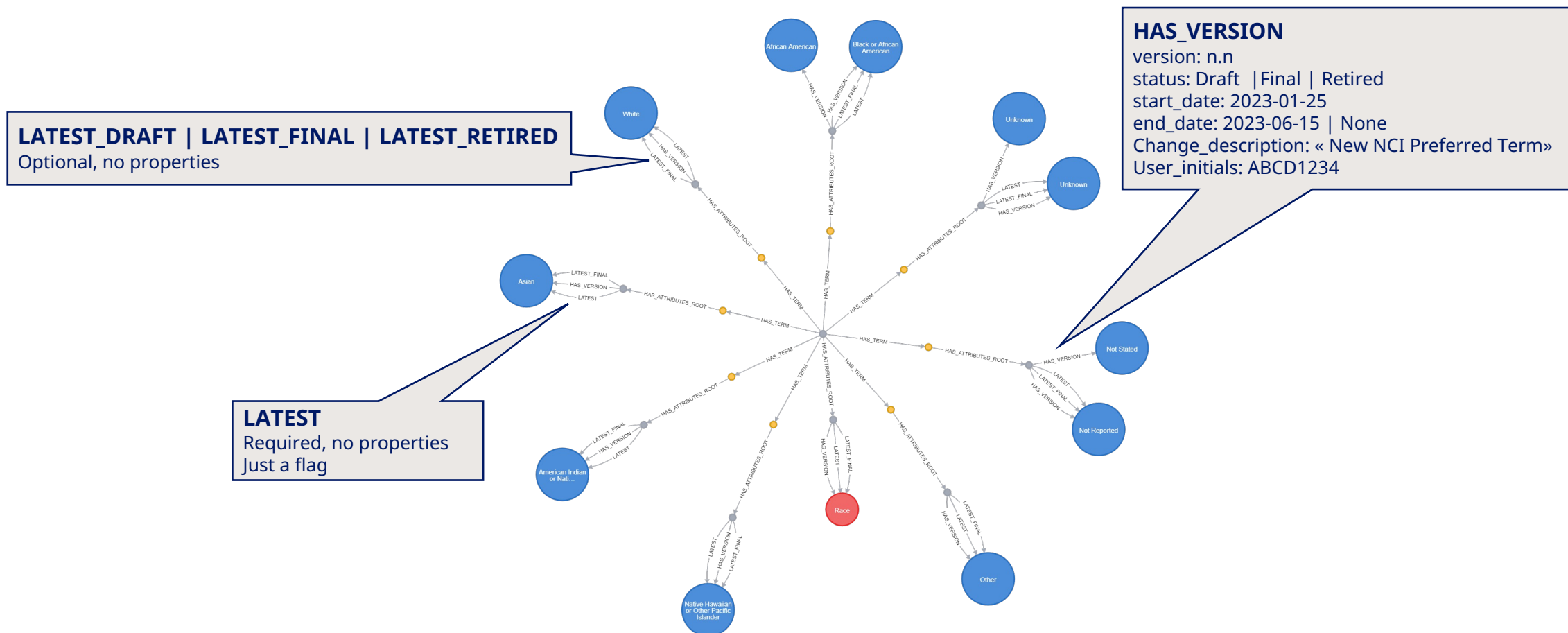
ODM Item Groups

ODM Item

ODM Conditions

ODM Methods

Version control over our Standard Metadata



The Controlled Terminology in OSB

Library / Code Lists / CT Catalogues

CT Catalogues

All ADAM CT CDASH CT COA CT DDF CT DEFINE-XML CT GLOSSARY CT PROTOCOL CT QRS CT QS-FT CT SDTM CT SEND CT

Select rows

Search Search with terms Operator or

Library	Sponsor preferred name	Template parameter	Code list status	Name modified	Concept ID	Submission value
CDISC	Category of Questionnaire	No	Final	Apr 13, 2023, 3:30 PM	C100129	QSCAT
CDISC	Relationship to Subject	No	Final	Apr 13, 2023, 3:30 PM	C100130	RELSUB
CDISC	QS-Alzheimer's Disease Assessment S...	No	Final	Apr 13, 2023, 3:30 PM	C100131	ADCTN
CDISC	QS-Alzheimer's Disease Assessment S...	No	Final	Apr 13, 2023, 3:30 PM	C100132	ADCTC
CDISC	QS-Brief Psychiatric Rating Scale-A...	No	Final	Apr 13, 2023, 3:30 PM	C100133	BPRS11TN
CDISC	QS-Brief Psychiatric Rating Scale-A...	No	Final	Apr 13, 2023, 3:30 PM	C100134	BPRS11TC
CDISC	QS-European Quality of Life Five Di...	No	Final	Apr 13, 2023, 3:30 PM	C100135	EQSD01TN
CDISC	QS-European Quality of Life Five	No	Final	Apr 13, 2023, 3:30	C100136	EQSD01TC

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Library / Code Lists / CT Packages / ADAM CT / History

Controlled Terminology Packages History

ADAM CT CDASH CT COA CT DDF CT DEFINE-XML CT GLOSSARY CT PROTOCOL CT QRS CT QS-FT CT SDTM CT SEND CT

2023-03-31 2022-06-24 2021-12-17 2020-11-06 2020-06-26 2020-03-27 2019-12-20 2019-09-29 2018-12-21 2017-09-29 2017-03-31 2016-12-16 2016-0

Show: ☒ Submission value (default) ☐ Code list code ☐ Sponsor name

From 2022-06-24 To 2023-03-31

New code list 1

2023-03-31
NEWS1PN

Changed code lists 3

2023-03-31
NEWS1PC NEWS1PN

Deleted code lists 0

Library / Code Lists / CT Packages

CT Packages

ADAM CT CDASH CT COA CT DDF CT DEFINE-XML CT GLOSSARY CT PROTOCOL CT QRS CT QS-FT CT SDTM CT SEND CT

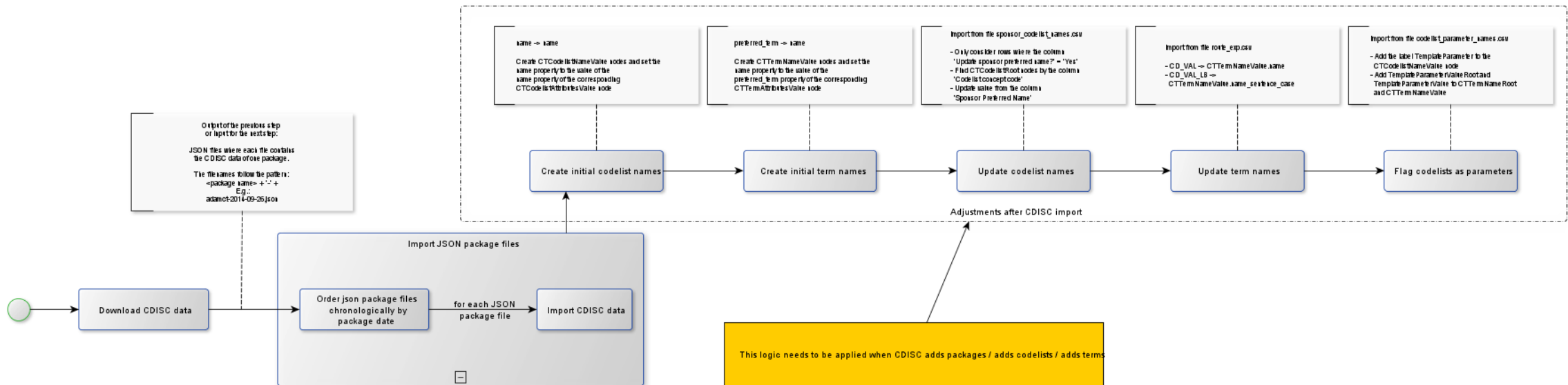
Select rows

Search Search with terms Operator or

Library	Sponsor preferred name	Template parameter	Code list status	Name modified	Concept ID	Submission value
CDISC	Subject Trial Status	No	Final	Apr 13, 2023, 3:35 PM	C124296	SI
CDISC	Geriatric Depression Scale Short Fo...	No	Final	Apr 13, 2023, 3:57 PM	C158114	G
CDISC	Geriatric Depression Scale Short Fo...	No	Final	Apr 13, 2023, 3:57 PM	C158115	G
CDISC	Pool for Integration	No	Final	Apr 13, 2023, 4:02 PM	C165644	PH
CDISC	Generalized Anxiety Disorder - 7 Ve...	No	Final	Apr 13, 2023, 4:06 PM	C172334	G
CDISC	Generalized Anxiety Disorder - 7 Ve...	No	Final	Apr 13, 2023, 4:06 PM	C172335	G
CDISC	Hamilton Depression Rating Scale - ...	No	Final	Apr 13, 2023, 4:23 PM	C187455	H

Rows per page: 10 1-10 of 16

Workflow used to download CDISC CT...



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'.	✓	🔒

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, 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	severe hereditary factor VIII defic...		Severe	Final	1.0	Jul 4, 2

Rows per page: 101-10 of 39<>

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
⋮	SX6K58TVWC	GLYBURIDE	glyburide		Final	1.0	Jul 4, 2023, 3:08 PM
⋮	QFFOP1DV7Z	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
⋮	36Z09ITL9D	PARACETAMOL	paracetamol		Final	1.0	Jul 4, 2023, 2:45 PM
⋮	9100L32L2N	METFORMIN	metformin		Final	1.0	Jul 4, 2023, 2:45 PM
⋮	WTT295SH5Y	DULAGLUTIDE	dulaglutide		Final	1.0	Jul 4, 2023, 3:08 PM
⋮	X7WDT95N5C	GLIPIZIDE	glipizide		Final	1.0	Jul 4, 2023, 3:08 PM
⋮	X4OV71U4Z5	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
⋮	N0000187069	Sodium Glucos...	sodium glucos...		Sodium Glucos...	Final	1.0	Jul 4, 2023, 2:43

Rows per page: 101-10 of 30<>

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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Concepts: Activities and Activity Instances

CDISC
STUDY
BUILDER

Studies Library

ADD NEW STUDY SELECT STUDY

NDJZ (NICOLAS DE SAINT JORRE)

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 / List of Activities /

Activities

List of Activities Activities by Grouping Activities Instances Requested Activities

Select rows

bilirubin

	Library	Activity group	Activity subgroup	Activity Name	Sentence case name	Abbreviation	Modified	Status
	Sponsor	Contraceptive Counselling	Contraceptive Counselling	Bilateral Tubal Occlusion	bilateral tubal occlusion		Jul 4, 2023, 2:54 PM	Final
	Sponsor	Laboratory Assessments	Biomarkers	Bile Acid	bile acid		Jul 4, 2023, 2:54 PM	Final
	Sponsor	Laboratory Assessments	Biochemistry	Bilirubin	bilirubin		Jul 4, 2023, 2:54 PM	Final
	Sponsor	AE Requiring Additional Data	Pancreatitis	Dilated Common Bile Duct	dilated common bile duct		Jul 4, 2023, 2:55 PM	Final
	Sponsor	Laboratory Assessments	Biochemistry	Direct Bilirubin	direct bilirubin		Jul 4, 2023, 2:54 PM	Final
	Sponsor	Eligibility Criteria	Eligibility Criteria	Eligibility Criteria Met	eligibility criteria met			
	Sponsor	AE Requiring Additional Data	Gallbladder Disease	Gallbladder Dilated Common Bile Duct	gallbladder dilated common bile duc...			
	Sponsor	AE Requiring	Gallbladder Disease	Gallstone In Bile	gallstone in bile duct			

Library / Concepts / Activities / List of Activities / Bilirubin

Bilirubin

Overview COSMoS YAML

Name Bilirubin

Sentence Case Name bilirubin

Definition

Activity instance class CategoricFinding

Abbreviation Library Sponsor

ADaM parameter code BILIU2 Topic code BILIRUBIN_URINE

Activity groupings

Activity group	Activity subgroup
Laboratory Assessments	Biochemistry

Activity

Name	Definition	Library
Bilirubin		Sponsor

Activity items

Name	CT term name	Unit name	Activity item class
BILI	Total Bilirubin Measurement		test_name_code
LB	Laboratory Data Domain		domain
URINALYSIS	Urinalysis		finding_category
URINE	Urine		specimen

Activity = Biomedical Concept (COSMoS project from CDISC)

Concepts: Units (with conversion rules)

Relationship
to UCUM
Units

And to CT
Units

OPEN
STUDY
BUILDER

StudiesLibrary

ADD NEW STUDYSELECT STUDYNDJZ (NICOLAS DE SAINT JORRE)

Library / Concepts / Units

Units

Select rows

Search

Library	Name	Master unit	Display unit	Unit subsets	UCUM unit	CT Unit terms	Convertible unit	SI unit	US convention
Sponsor	keV	No	Yes			keV	Yes	No	Yes
Sponsor	RATIO	No	Yes		{Ratio}	RATIO	Yes	No	Yes
Sponsor	IU/kg	No	Yes	Dose Unit	[IU]/kg	IU/kg	Yes	No	Yes
Sponsor	PA	No	Yes		/a	PA	Yes	No	Yes
Sponsor	LB	No	Yes		[lb_av]	LB	Yes	No	Yes
Sponsor	weeks	No	Yes	Age Unit, Study Time, Time Unit	wk	WEEKS	Yes	No	Yes
Sponsor	week	No	Yes	Age Unit, Study Preferred Time Unit, Study Time, Time Unit	wk	WEEKS	Yes	No	Yes
Sponsor	years	No	Yes	Age Unit, Study Time, Time Unit	a	YEARS	No	No	No
Sponsor	months	No	Yes	Age Unit	mo	MONTHS	No	No	No
Sponsor	hours	No	Yes	Age Unit, Time	h	HOURS	Yes	Yes	Yes

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Concept: CRFs

Library / Concepts / CRFs / CRF Tree

CRFs (Case Report Forms) ⓘ

CRF Templates Forms Item Groups Items CRF Tree CRF View Alias Extensions

Reorder content

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

PDF format

Annotated CRF following MSG 2.0 standard

ODM.xml with vendor extensions (or CSV)

Library / Concepts / CRFs / CRF View

CRFs (Case Report Forms) ⓘ

CRF Templates Forms Item Groups Items CRF Tree CRF View Alias Extensions

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

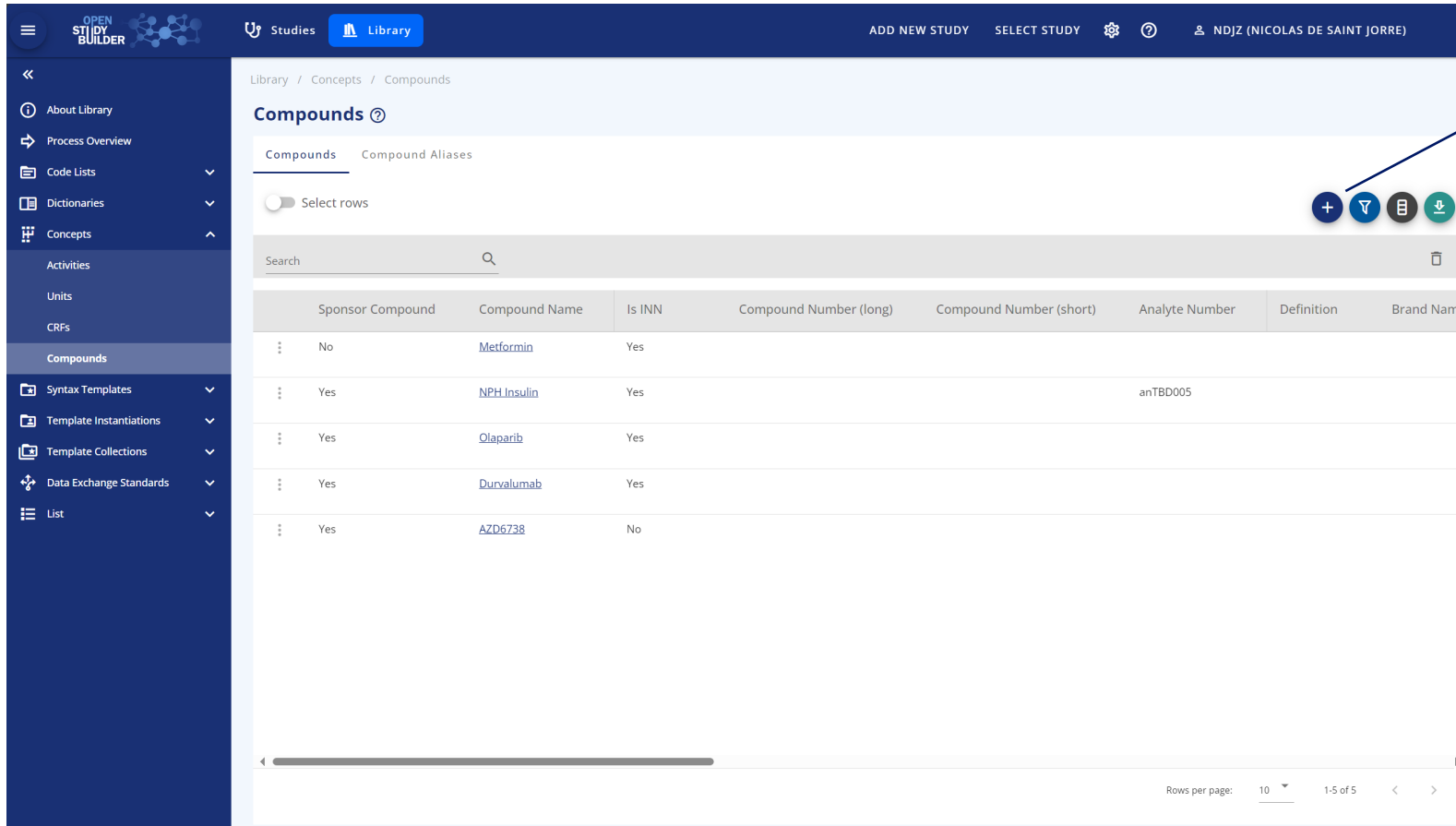
Informed Consent item group

[OID=G.DM.IC, Version=0.2]

Please complete the Informed Consent item group before any other information

Study ID	[OID=LSTUDID, Version=0.1]	11 digit(s)
Date informed consent obtained	[OID=LRFICDAT, Version=0.2]	10 digit(s)

Concepts: Compounds...



Library / Concepts / Compounds

Compounds ?

Compounds Compound Aliases

☐ Select rows

Search

	Sponsor Compound	Compound Name	Is INN	Compound Number (long)	Compound Number (short)	Analyte Number	Definition	Brand Name
⋮	No	Metformin	Yes					
⋮	Yes	NPH Insulin	Yes			anTBD005		
⋮	Yes	Olaparib	Yes					
⋮	Yes	Durvalumab	Yes					
⋮	Yes	AZD6738	No					

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Sponsor can
add every
compound as
needed

They are
then
available for
every Studies

Syntax Templates

Objectives, Endpoints, Time Frame, Criteria, Activity, Footnotes

Harmonisation

Library / Syntax Templates / Objective Templates / Parent

Objective Templates

Parent Pre-instance User Defined

Select rows

Search

Sequence number	Indication or disorder	Objective category	Confirmatory testing	Parent template	Modified ↓	Status	Version
O9	Heart failure	Not Applicable	Yes	To compare the effect of Compound relative to Comparator on ActivityInstance when something	Jul 4, 2023, 3:08 PM	Final	1.0
O8	Not Applicable	Not Applicable	Yes	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, 3:08 PM	Final	1.0

Add objective template pre-instantiation

1 Set template parameter values

2 Index template

To compare the effect of metformin relative to nph insulin on diabetic retinopathy - cataract when something

Compound metformin X Comparator nph insuli... X ActivityInstance diabetic r... X

Unformatted plain text representation

To compare the effect of metformin relative to nph insulin on diabetic retinopathy - cataract when something

CONTINUE CANCEL

Templates are using 'parameters' (in Green) that will be replaced when used at Study level

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
⋮ 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

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

3.3

3.2

3.1.3

3.1.2

Status

Final

Effective date

2021-11-29

Implements

[SDTM v2.0](#)

Classes

<

Comments

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QS

>

Name

Ordinal

Description

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.

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-fv7bjhkehgyw.clinicalmldr-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	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

Rows per page: 5 1-4 of 4

Activity with links to SDTM

Digital Data Flow Adaptor (1/2)

The image displays a screenshot of the Study Builder interface, specifically the 'Study Properties (CDISC DEV-0)' section. The interface is divided into a left sidebar with navigation options and a main content area. The 'Study Properties' section is currently selected, showing a table of study attributes. A blue oval highlights the 'Selected values' column, which lists 'Interventional' for Study type, 'Phase III Trial' for Trial type, 'No' for Extension study, 'No' for Adaptive design, 'No' for Study stop rules, 'No' for Confirmed response minimum duration, and 'No' for Post authorization safety study ind....

Below the table, a blue oval labeled 'OSB API' points to a 'My Workspace' section. This section contains a 'New' button and a list of collections. A blue oval labeled 'DDF Adaptor' points to a specific collection named 'DDF Cloud Function Demo'. This collection contains two API endpoints: 'GET Get study definition [OSB version 0.6]' and 'GET Get study definition [OSB version 0.5]'. The 'GET Get study definition [OSB version 0.6]' endpoint is selected, and its details are shown in the right pane.

The right pane displays the API call details for 'GET Get study definition [OSB version 0.6]'. The URL is 'https://ddf-cloud-function-osb-0dot6.azurewebsites.net/api/studyDefinitions?studyId=Study_000001'. The 'Query Params' section shows a table with the following data:

Key	Value	Description
studyId	Study_000001	

The 'Body' section shows the JSON response of the API call. A blue oval highlights the 'studyType' field, which is an object with the following properties:

```
{
  "codeId": "885c0e09-a198-4032-8a07-6ad4911970c",
  "code": "Interventional",
  "codeSystem": null,
  "codeSystemVersion": null,
  "decode": null
}
```

The 'studyPhase' field is also highlighted, showing the following properties:

```
{
  "standardCode": {
    "codeId": "97196740-67e3-4e86-a0ea-c1f1fb80ba2",
    "code": "Phase III Trial",
    "codeSystem": null,
    "codeSystemVersion": null,
    "decode": null
  },
  "standardCodeAliases": null
}
```

Digital Data Flow Adaptor (2/2)

OPEN STUDY BUILDER

StudiesLibrary

ADD NEW STUDYSELECT STUDYCDISC DEV-0NDJZ (NICOLAS DE SAINT JORRE)

Studies / Define Study / Study Structure / Study Epochs

Study Structure (CDISC DEV-0)

OverviewStudy ArmsStudy BranchesStudy CohortsStudy EpochsStudy ElementsStudy VisitsDesign MatrixDisease Milestones

Select rowsReorder 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	



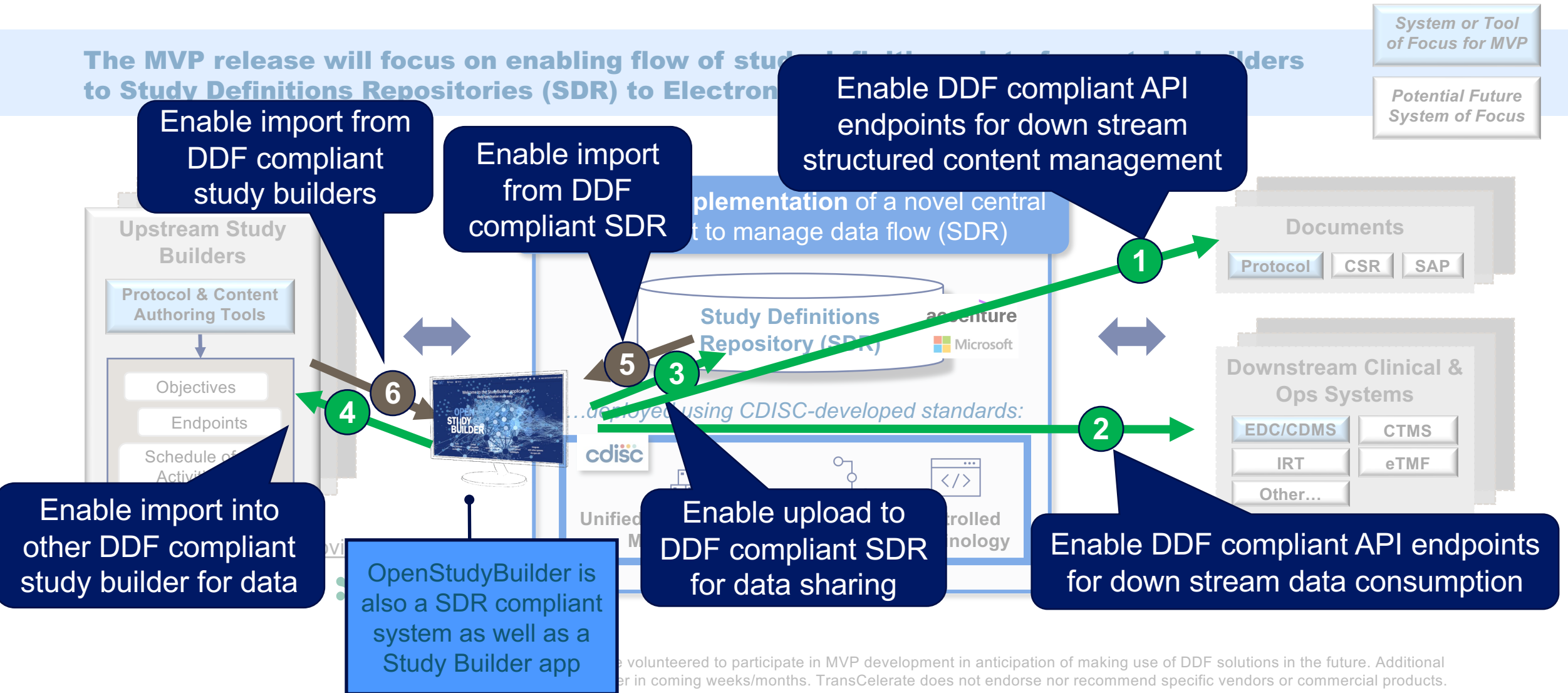
BodyCookiesHeaders (5)Test Results

PrettyRawPreviewVisualizeText

```
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" : {
82    "studyEpochId" : "1660e455-ed05-42c0-9dcc-4045184fab83",
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
91    },
92    "previousStudyEpochId" : null,
93    "nextStudyEpochId" : null,
94    "encounterIds" : null
95  },
96  "studyElements" : [ {
97    "studyElementId" : "ef36a984-c9b8-48f7-8a9b-6d241169ee62",
98    "studyElementName" : "Screening",
99    "studyElementDescription" : null,
100    "transitionStartRule" : {
101      "transitionRuleId" : "7a0543b7-43ff-48cf-9dd2-c3e655a92b68",
102      "transitionRuleDescription" : "Informed consent signed"
103    },
104    "transitionEndRule" : {
```

Minimum Viable Product development underway

The MVP release will focus on enabling flow of study definitions from Upstream Study Builders to Study Definitions Repositories (SDR) to Electronic Data Capture (EDC) systems.



Thanks!

Questions?

