

# Open-Source MDR and SDR Managing Your Standards with the OpenStudyBuilder

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## ABSTRACT

The OpenStudyBuilder (OSB) is an open-source project for clinical study specifications. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.

The OpenStudyBuilder contains:

- Standards and templates used for study specification
- Individual versioning of standard elements in the library
- Real-time team collaboration around study design by study team
- Central storage of study design data for multiple down-stream usages ('one source of truth')
- Versioning and full audit trail of study definitions

In the library section you can browse all kinds of standards, like for CDISC the SDTM, ADAM, SEND, CDASH and many more. Also, other dictionaries like SNOMED, LOINC, UCUM are available. MedDRA could be loaded as well of course. You can see different SDTM versions! As everything is FAIR, concepts can be created and maintained, so these can easily be reused. A core feature is the usage of syntax templates, for example for objectives and endpoints. Here general standard wordings and types are defined, which can then be instantiated with a concrete compound or comparator.

The OpenStudyBuilder, as an outcome of the CDISC 360° project and related to the TransCelerate Digital Data Flow project, is meant to be the core component for all study related activities and tools, managing and providing standards and study metadata. The solution comes along with tools, scripts and a graph database for industry and sponsor standards as well as study definitions.

We have close collaborations with other standard initiatives. The solution imports standards data through the CDISC library. For the TransCelerate DDF, we provide (and enhance) an API adapter to support the DDF API. And we are also working with CDISC on the COSMoS model and integration as well as being a CDISC Open Source Alliance (COSA) member.

## INTRODUCTION

Why do we need to have every standard metadata in an efficient metadata system? As they are evolving over time and as they are driving the way we manage our Studies, having them in one tool ensures the accuracy in an efficient manner.

In the OpenStudyBuilder we can manage different types of standards:

- Controlled Terminologies
  - Code Lists. These can be defined by external organization (e.g., CDISC) or sponsor defined,
  - Dictionary Terminologies. These are a code submission value, an identifier and a definition defined by other standards organizations than CDISC (e.g., SNOMED, MED-RT, UNII, UCUM - MedDRA, LOINC etc.),
- Concept based standards. We refer to concept-based standards as data standards defined in more complex structures than code-value pairs. In the OpenStudyBuilder we have grouped the ones we currently cover into the following groups related to their scope:
  - Activities. These refer to our definition of Biomedical Concepts which cover clinical procedures and assessments with or without data collection,
  - Units. These refer to unit definitions including relationship to UCUM and CDISC CT as well as metadata supporting unit conversions,
  - CRFs. These generally refer to data collection instruments with reference to Activity Concepts as well as representation in CDISC ODM.XML format,

- Compounds. These refer to representations of medicinal products in the protocol as well as the data collection and submission datasets. This model is in alignment with the ISO IDMP standard.
- Syntax Templates. These are templates for textual representation of the main structured elements in the protocol e.g., study objectives, endpoints, time frames, criteria and activity instructions. The syntax template will support use of easily readable sentences with reference to template parameter values being linked to controlled terminologies and concept-based standards,
- CDISC Models and Implementation Guides with Sponsor metadata added to them.

## OPENSTUDYBUILDER AS A METADATA REPOSITORY

In the library area of the frontend of the OpenStudyBuilder, you will be able to manage different types of standards. Metadata can be browsed, updated and retired. Additionally, new metadata can be created and maintained; they can easily be reused for example specially in studies managed inside the OpenStudyBuilder. This harmonized our metadata for better transversal management.

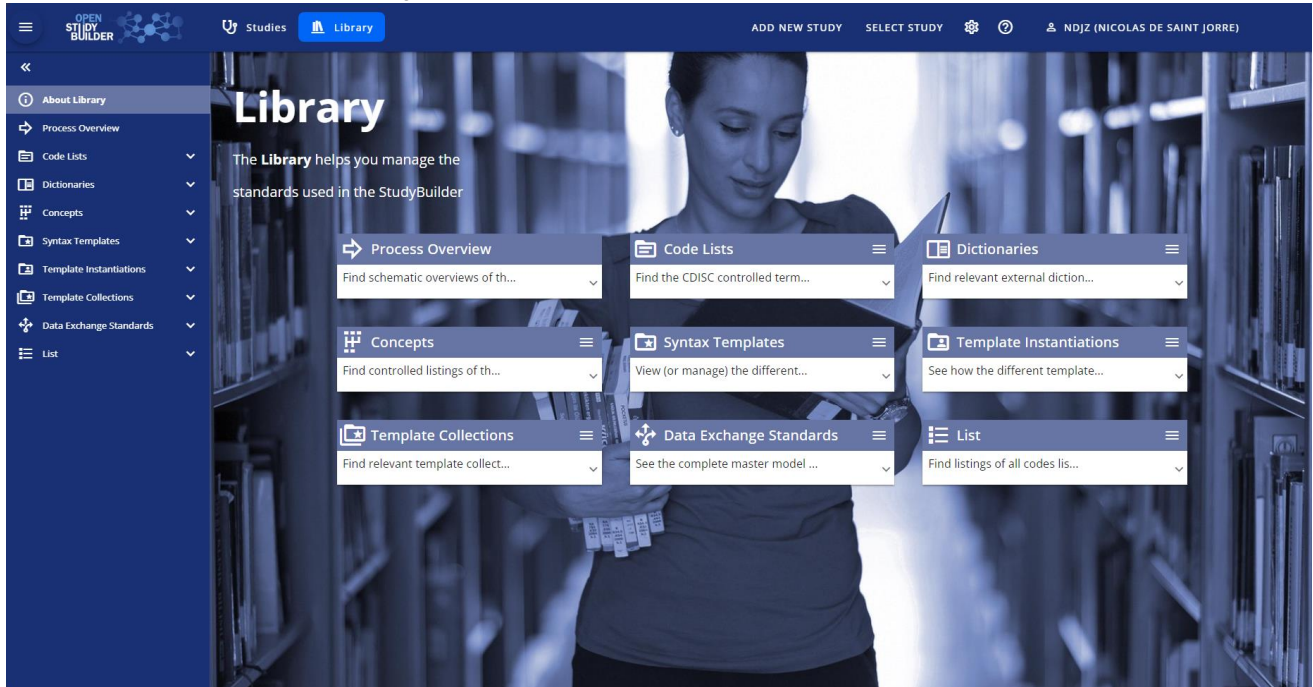


Figure 1: OpenStudyBuilder Library welcome page

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

Figure 2: List of Metadata available in the library zone

The metadata coming from Standards like the CDISC organization or from dictionaries are loaded using the OpenStudyBuilder Application Programming Interface (hereafter called API) directly from JSON files (like for CDISC CT) or via a migration process with CSV files (see Figure 3).

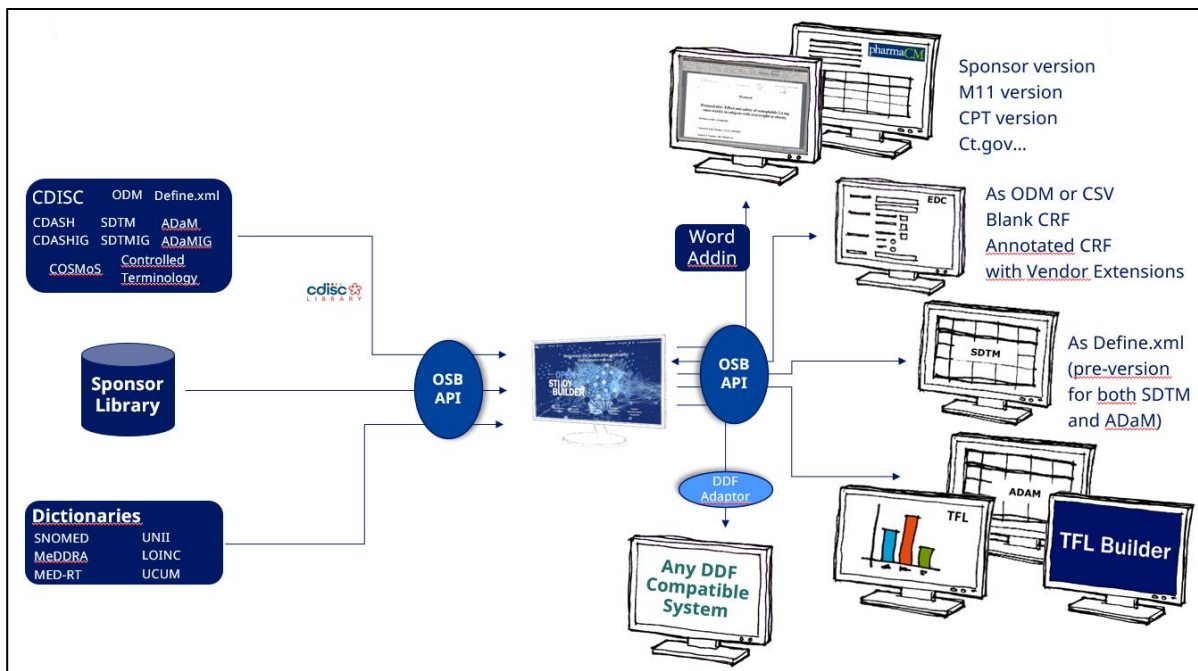


Figure 3: External workflow to and from OSB

This metadata is needed to create a complete and consistent set of concepts. This allows the creation of a protocol, for example following a sponsor's format, the ICH M11 guideline, the Common Protocol Template from TransCelerate, or others. This metadata is also used to create blank or annotated Case Report Form with or without vendor extension. We could also produce a pre-define.xml for both SDTM and ADaM, as TFL when needed! And we can already think of additional metadata usages.

It is already possible to convert some metadata from the OpenStudyBuilder into the Unified Study Definition Model (USDM) from TransCelerate via the OpenStudyBuilder API and a Digital Data Flow (DDF) Adaptor to produce standard metadata to be used by external compatible systems (as illustrated in Figure 3).

### CONCEPTUAL MODEL OF THE OPENSTUDYBUILDER

The OpenStudyBuilder is defining the metadata repository with 5 layers of information at the library level (see Figure 4):

- The System Configuration where we have the Library Definition itself,
- The Industry Standards where we have the Controlled Terminology, the Foundational Data Standards from CDISC for example, the Conceptual Standards, the Therapeutic Area Standards and the external Dictionaries,
- The Sponsor Standards with the Sponsor Defined Terminologies, the Sponsor Defined Data Standards Extensions, the Sponsor Defined Conceptual Standards and the Therapeutic Area and the Project Standards,
- The Study Definitions where we are using the metadata managed by the two previous level to have the Study Definitions, the Study Designs and the Study Selections and Scheduling,
- And the Administrative Definition with the Projects, the Access groups, the Users and the System Roles.

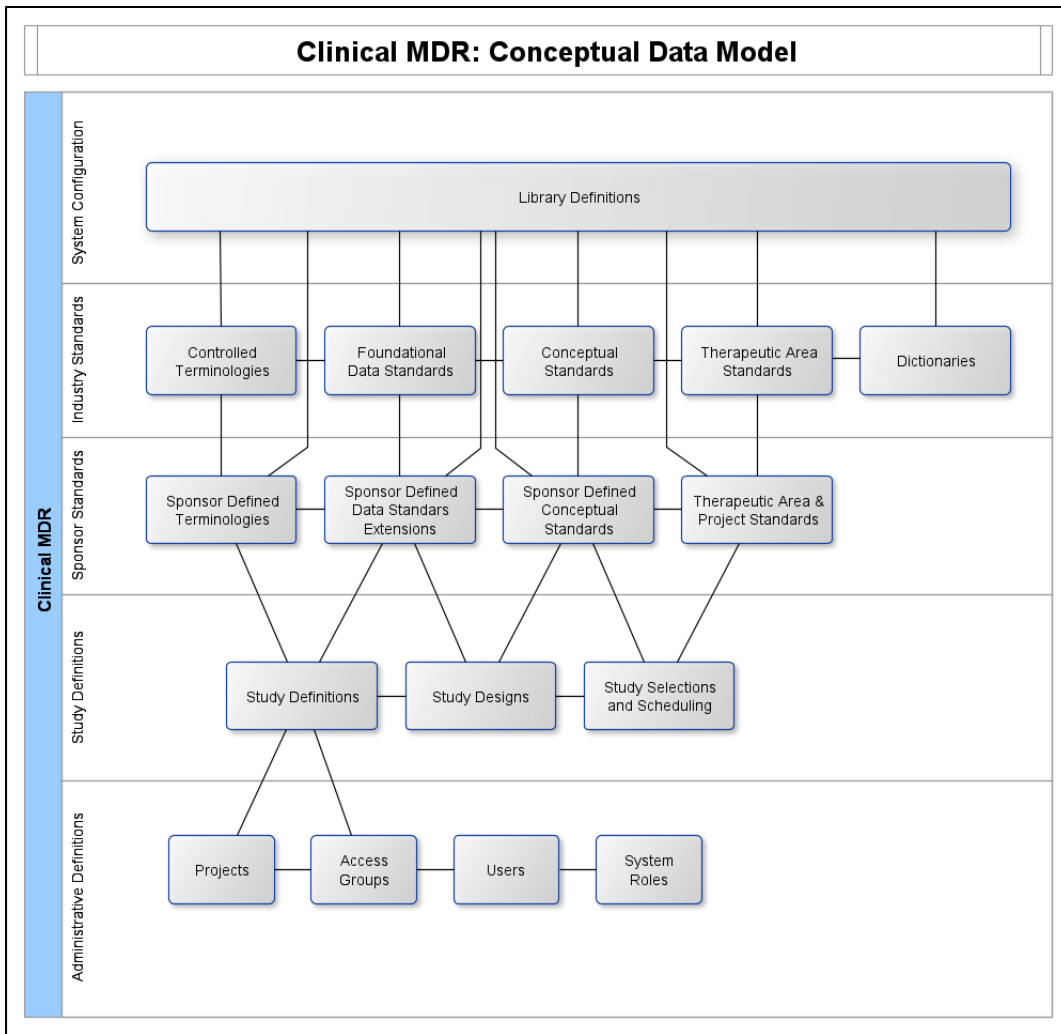


Figure 4: Conceptual Data Model

## THE API OF THE OPENSTUDYBUILDER

The OpenStudyBuilder is using a Graph database to store every metadata.

What is a Graph Database? It is a database that uses graph structures for semantic queries with nodes, edges, and properties to represent and store data. A key concept of the system is the graph (or edge or relationship). The graph relates the data items in the store to a collection of nodes and edges, the edges representing the relationships between the nodes.

On top of this, the OpenStudyBuilder is having an interface (API) with multiples Endpoints (see Figure 5):

- The HTTP GET request is used to fetch a resource from the Graph database,
- The HTTP POST request is used to post data or create a resource in the Graph database,
- The PATCH request updates a resource but requires only the field(s) which is being updated in the payload,
- The DELETE request is used to delete a resource from the Graph database (here it is a soft delete always, we are not deleting any record).

**Clinical MDR API** 3.0.28 OAS3  
swaggerapi.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  
 Authorize

- ODM Study Events
- ODM Forms
- ODM Item Groups
- ODM Item
- ODM Conditions
- ODM Methods

Figure 5: Swagger documentation of the OSB API (using Fast API)

### VERSION CONTROL OVER OUR STANDARD METADATA

The OpenStudyBuilder is using a sophisticated version control solution to track the evolution of standards. For example, the Controlled Terminology can be updated 4 times a year, with addition, modification and even deletion – See Figure 6. This version Control is insuring the non-duplication of metadata. Here, for example the node "Unknown" is shared with every other codelist using it.

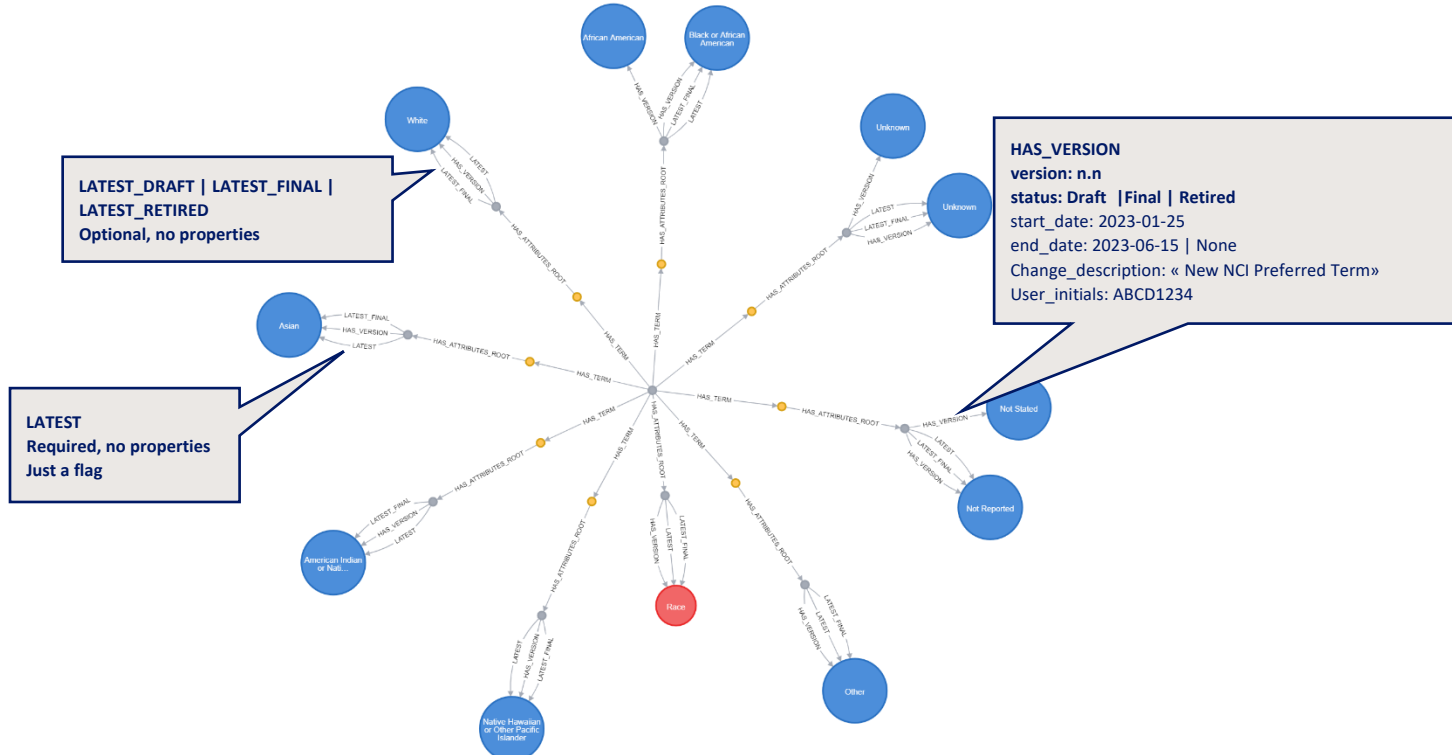


Figure 6: Version Control on the Codelist RACE

## THE CONTROLLED TERMINOLOGY IN OPENSTUDYBUILDER

One of the first data loaded into the OpenStudyBuilder is directly coming from the CDISC Organization: The API is used to download JSON files from the CDISC Library and then injected into an intermediate database where we remove duplicates. Then the API shifts that metadata into the OpenStudyBuilder database, where this is flagged as 'CDISC' in the library. It is possible to browse the Codelists by catalogues (model) or by packages (date) and catalogues (model).

As soon as this metadata is available, it is possible to add sponsor information like a dedicated name. It is also possible to add sponsor codelists and terms, but again, here the API is re-using the existing metadata, preventing duplication – see figure 7 and 8.

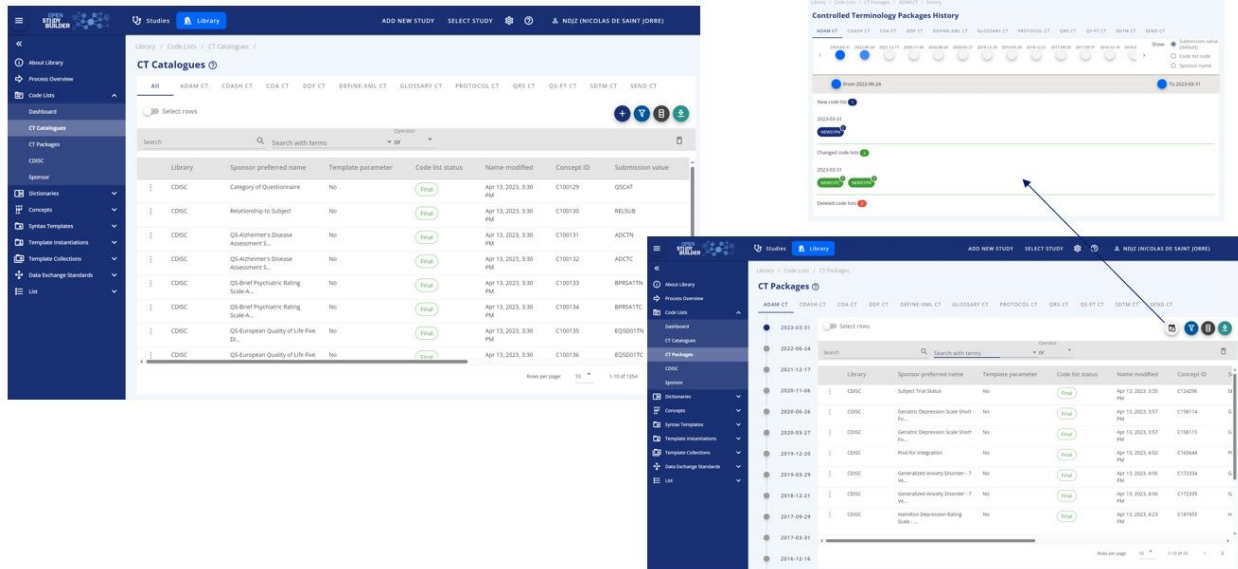


Figure 7: Controlled Terminology with metadata history

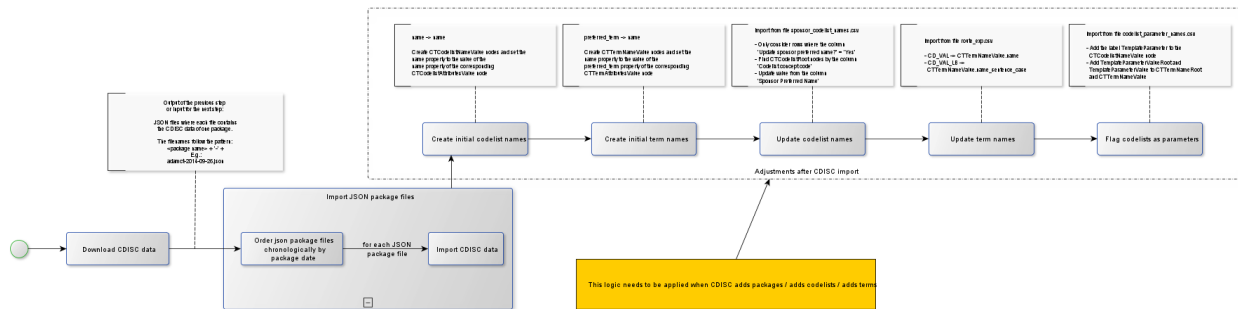


Figure 8: Controlled Terminology upload workflow

## THE DICTIONARIES IN THE OPENSTUDYBUILDER

In the Library of the OpenStudyBuilder, you have access to dictionaries. You will find here the following metadata (see Figure 9):

- The SNOMED CT - Systematized Nomenclature of Medicine - Clinical Terms,
- The MED-RT - Medication Reference Terminology for Pharmacologic Class (PCLASS)
- The UNII - Unique Ingredient Identifier for Active Substances
- UCUM - Unified Code for Units of Measure

Here also, the metadata are loaded with a version control track. And for each dictionary, it is possible for the end user to add terms inside the sponsor library.

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
44572001	Disease	disease		Disease (disorder)	Final	1.0	Jul 4, 2023, 9:08 PM
362965005	Disorder of body system	disorder of body system		Disorder of body system (disorder)	Final	1.0	Jul 4, 2023, 9:08 PM
605964002	Pre-existing type 1 diabetes mellit...	pre-existing type 1 diabetes mellit...		Pre-existing type 1 diabetes mellit...	Final	1.0	Jul 4, 2023, 9:08 PM
446225005	Heart failure with normal ejection...	heart failure with normal ejection...	HFrEF	Heart failure with normal ejection...	Final	1.0	Jul 4, 2023, 9:08 PM
44285003	Nonalcoholic steatohepatitis	nonalcoholic steatohepatitis	NASH	Nonalcoholic steatohepatitis (diseas...	Final	1.0	Jul 4, 2023, 9:08 PM
44179003	Severe hereditary factor II defici...	severe hereditary factor II defici...		Severe hereditary factor II defici...	Final	1.0	Jul 4, 2023, 9:08 PM
44079008	Severe hereditary factor VII defici...	severe hereditary factor VII defici...		Severe hereditary factor VII defici...	Final	1.0	Jul 4, 2023, 9:08 PM

Rows per page: 10 | 1 to 6 of 6

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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
0018043M54	LEVOTHYROXINE	levothyroxine		Final	1.0	Jul 4, 2023, 9:08 PM
U78810D4P	MOXIFLOXACIN	moxifloxacin		Final	1.0	Jul 4, 2023, 9:08 PM
5A8AS7YWC	GLYBURIDE	glyburide		Final	1.0	Jul 4, 2023, 9:08 PM
Q95F-DV72	STAGMURIN	stagmurin		Final	1.0	Jul 4, 2023, 9:08 PM
1Y1707054	INSULIN HUMAN	insulin human		Final	1.0	Jul 4, 2023, 2:45 PM
3L20R7L5D	PARACETAMOL	paracetamol		Final	1.0	Jul 4, 2023, 2:45 PM
910L3L2N	METFORMIN	metformin		Final	1.0	Jul 4, 2023, 2:45 PM
W722595Y5	DULAGLUTER	dulaglutide		Final	1.0	Jul 4, 2023, 9:08 PM
X766F6R6C	SULPISIDE	sulpiside		Final	1.0	Jul 4, 2023, 9:08 PM
440714425	PROGLUTAZONE	proglutazone		Final	1.0	Jul 4, 2023, 9:08 PM

Rows per page: 10 | 1 to 10 of 10

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
N000021845	ORAL ANTIDIABETIC AGENTS	oral hypoglycemic agents		ORAL ANTIDIABETIC AGENTS	Final	1.0	Jul 4, 2023, 9:08 PM
N000011750	PCSK9 INHIBITORS	pcsk9 inhibitors		PCSK9 INHIBITORS	Final	1.0	Jul 4, 2023, 9:08 PM
	Zilvestromab	zilvestromab		Zilvestromab	Final	1.0	Jul 4, 2023, 9:08 PM
N000075045	L-Thyroxine	l-thyroxine		L-Thyroxine	Final	1.0	Jul 4, 2023, 2:45 PM
N000075048	Tubulin-inhibiting Agent	tubulin-inhibiting agent		Tubulin-inhibiting Agent	Final	1.0	Jul 4, 2023, 2:45 PM
N000081100	Thiazolidinedione	thiazolidinedione		Thiazolidinedione	Final	1.0	Jul 4, 2023, 2:45 PM
N000075048	Sulfarylurea	sulfarylurea		Sulfarylurea	Final	1.0	Jul 4, 2023, 2:45 PM
N000075048	Sulfonamide	sulfonamide		Sulfonamide	Final	1.0	Jul 4, 2023, 2:45 PM
N000007600	Anti-infective agent	anti-infective agent		Anti-infective agent	Final	1.0	Jul 4, 2023, 9:08 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
gww	gram per week	Final	1.0	Jul 4, 2023, 2:45 PM
USL286L3	gigawatt	Final	1.0	Jul 4, 2023, 2:45 PM
PLU75	gulf-blasting unit	Final	1.0	Jul 4, 2023, 2:45 PM
M3QAL	microwatt per microcoulomb	Final	1.0	Jul 4, 2023, 2:45 PM
DRDP	drop	Final	1.0	Jul 4, 2023, 2:45 PM
SPR605	spray blasting unit	Final	1.0	Jul 4, 2023, 2:45 PM
USL286L5	capacitor blasting unit	Final	1.0	Jul 4, 2023, 2:45 PM
USL286L6	can blasting unit	Final	1.0	Jul 4, 2023, 2:45 PM
PH00	park message form	Final	1.0	Jul 4, 2023, 2:45 PM
USL286L7	tablet blasting unit	Final	1.0	Jul 4, 2023, 2:45 PM

Rows per page: 10 | 1 to 10 of 10

Figure 9: Dictionaries available in the OpenStudyBuilder

## CONCEPTS: ACTIVITIES AND ACTIVITY INSTANCES

In OpenStudyBuilder we use the term ActivityConcept for the implementation of a Biomedical Concept with the following definition:

*We differentiate between two different types of activity concepts: a semantic logical observation and a semantic specific activity. If the activity is related to data collection, then the activity corresponds to a logical data observation; otherwise, it's a semantic specific activity.*

*The activity related to a logical data observation is defined at a level of granularity where it will match an observation: an example can be Systolic blood pressure measured sitting, in unit of mmHg, at a specific point in time.*

*The semantic specific activity not related to data collection can e.g., be dosing instructions for the subject.*

The OpenStudyBuilder has functionality to create an electronic "protocol". As a user you can define the study design, the visits and what is to be performed/collected at each visit (called Schedule of Activities (SoA) in OpenStudyBuilder, others may call it Flowchart). The Activity Concepts are the activities in the protocol Schedule of Activities.

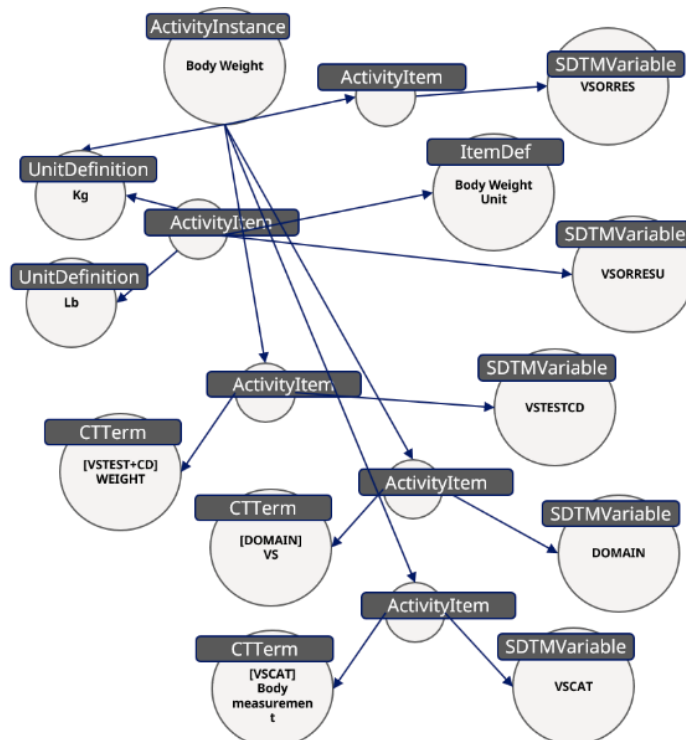


Figure 10: Body Weight Example Activity Concept

Browsing the library will allow the end user to manage activities and activity instances with activity items as in Figure 11.

**Activity Instances Table:**

Library	Activity group	Activity subgroup	Activity Name	Sentence Case Name	Abbreviation	Modified	Status
Sponsor	Comprehensive Counseling	Comprehensive Counseling	Bilirubin [Unit]	Bilirubin urine		Jul 4, 2023, 2:54 PM	new
Sponsor	Laboratory Assessments	Biochemistry	Bilirubin [Unit]	Bilirubin		Jul 4, 2023, 2:54 PM	new
Sponsor	AD Requiring Additional Data	Pharmacokinetics	Bilirubin [Unit]	Bilirubin	direct common bile duct	Jul 4, 2023, 2:55 PM	new
Sponsor	Laboratory Assessments	Biochemistry	Bilirubin [Unit]	direct bilirubin		Jul 4, 2023, 2:54 PM	new
Sponsor	Eligibility Criteria	Eligibility Criteria	Bilirubin [Unit]	eligibility criteria met		Jul 4, 2023, 2:54 PM	new
Sponsor	AD Requiring Additional Data	Gettable Disease	Bilirubin [Unit]	gettable disease		Jul 4, 2023, 2:55 PM	new
Sponsor	AD Requiring Additional Data	Gettable Disease	Bilirubin [Unit]	gettable disease		Jul 4, 2023, 2:55 PM	new

**Activity Items Table:**

Name	CT term name	Unit name	Activity item class
BLU	Total Bilirubin Measurement	test_name_code	
LB	Laboratory Data Domain	domain	
URANALYSIS	Urinalysis	finding_category	
URSE	Urine	specimen	

Figure 11: From Activity to Activity Instance to Activity Items

**CONCEPTS: UNITS WITH CONVERSION RULES**

Next to the activities, the OpenStudyBuilder is equipped with 374 units that are linked, when applicable, to the UCUM and the Controlled Terminology Codelist UNIT of CDISC.



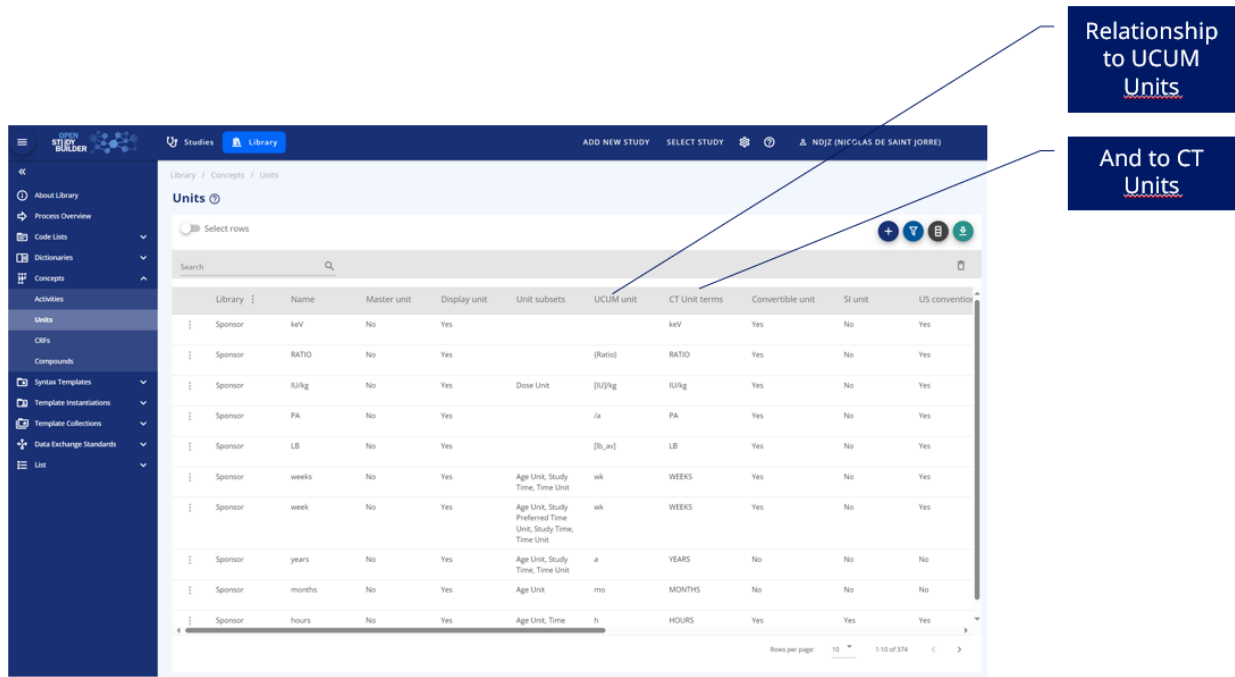


Figure 12: Unit listing with UCUM and CT mapping

**CONCEPTS: CASE REPORT FORM**

In addition to the library, we offer a comprehensive Case Report Form (CRF) management system that adheres to the CDISC Operational Data Model (ODM) for terminology, structure, and import/export format. This industry-standard approach ensures optimal connectivity and interoperability.

Our CRF management system empowers end-users to create Forms, Item Groups, and Items, which can be bound within a template. This template can be validated and reused, and its metadata can be linked to the activities available in the library. This integration enables seamless usage by the protocol (refer to Figure 13).

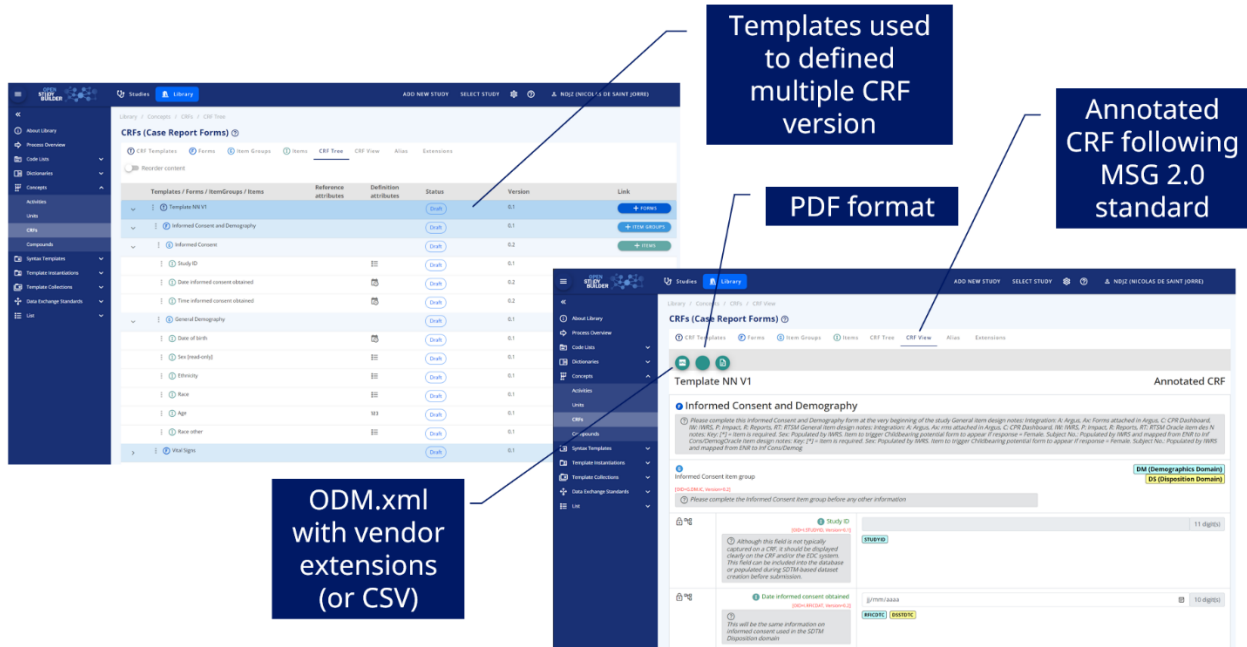
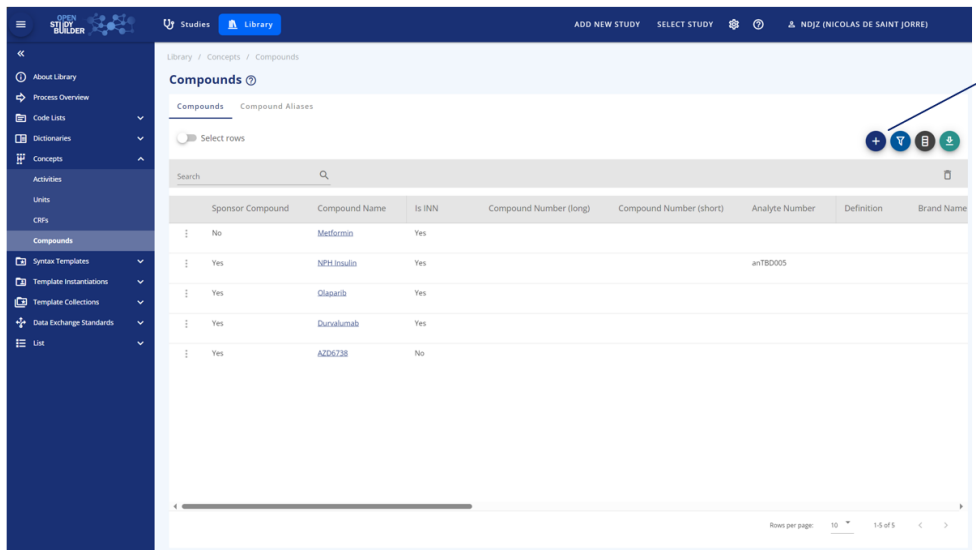


Figure 13: Case Report Forms with Annotated version

**CONCEPTS: COMPOUNDS**

These refer to the representations of medicinal products in the protocol, as well as the datasets used for data collection and submission. Our model aligns with the ISO Identification of Medicinal Products (IDMP) standard, ensuring consistency and interoperability.



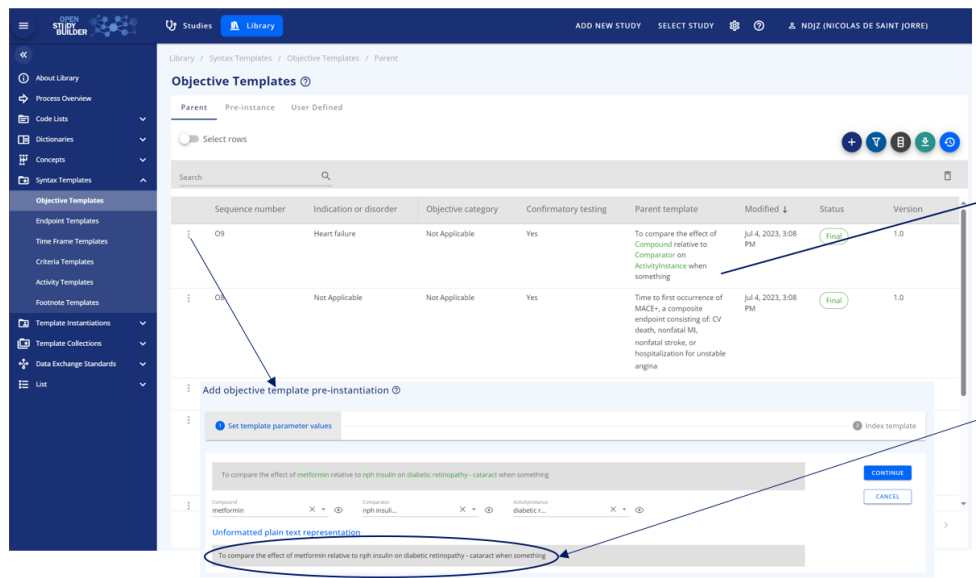
Sponsor can add every compound as needed

They are then available for every Studies

Figure 14: Compounds in the Library

**SYNTAX TEMPLATE: OBJECTIVES, ENDPOINTS, TIME FRAME, CRITERIA, ACTIVITY, FOOTNOTES**

Our syntax templates provide a textual representation of the main structured elements in the protocol, such as study objectives, endpoints, time frames, criteria, and activity instructions. These templates use easily readable sentences that reference template parameter values linked to controlled terminologies and concept-based standards. References to template parameters are displayed between square brackets, as shown in figure 14.

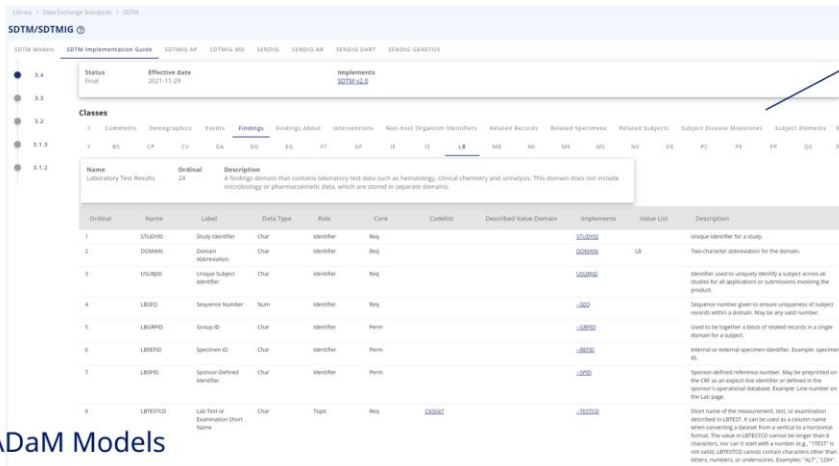


Templates are using 'parameters' (in Green) that will be replaced when used at Study level

Figure 14: Example of Objective Template with reference to template parameter

**DATA EXCHANGE STANDARDS – CDISC MODELS**

In our latest release, the library now manages Models and Implementation Guides for the Study Data Tabulation Model (SDTM/SDTMIG), complete with version control similar to that of the Controlled Terminology. This set of metadata offers internal connections, enabling end-users to browse the Models and Implementation Guides by packages and navigate to the Controlled Terminology (refer to Figure 15, accessible via the link in the Codelist column).



CDASH and ADaM Models will be added soon...

Figure 15: SDTM/SDTMIG in the OpenStudyBuilder

### THE OPENSTUDYBUILDER COME WITH VISUALISATION TOOL: NEODASH

NeoDash is a low-code, open-source Dashboard Builder designed for Neo4j, the Graph database used by the OpenStudyBuilder. With NeoDash, users can easily create interactive dashboards featuring tables, graphs, bar charts, line charts, maps, and more, using the data available in the database (refer to Figure 16).

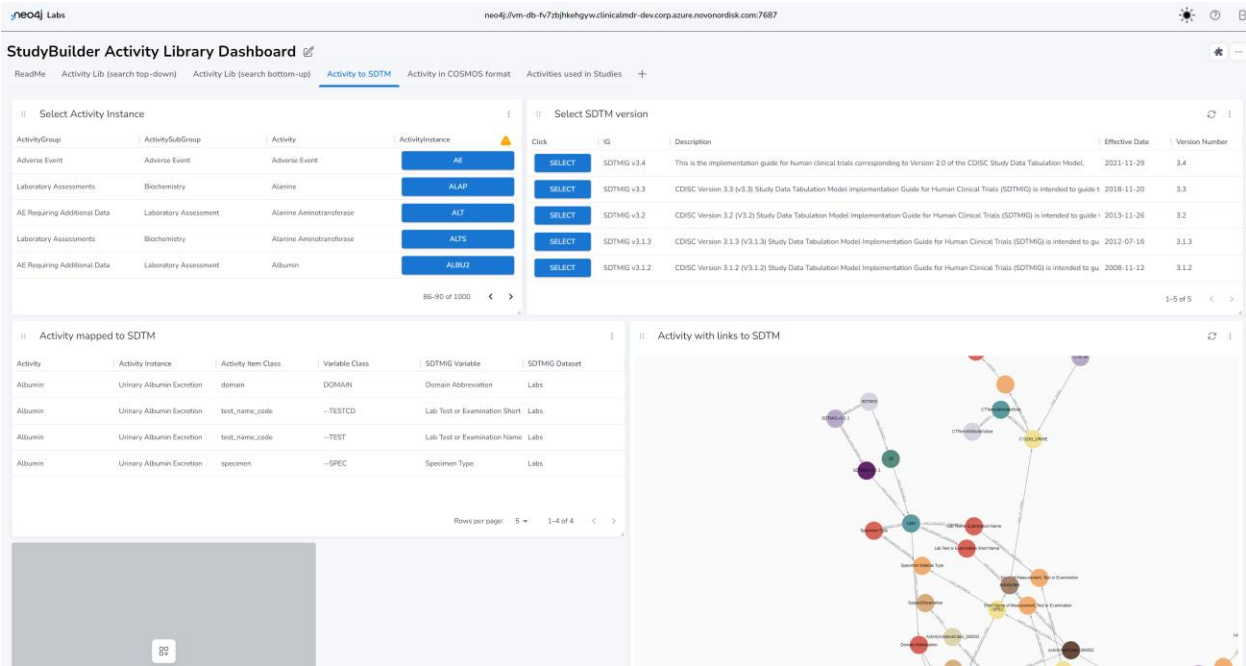


Figure 16: NeoDash in action

### DIGITAL DATA FLOW ADAPTOR

Finally, the OpenStudyBuilder aims to become a reference implementation for Digital Data Flow (DDF), offering a range of features to support this goal. As such, any tools that support DDF will be able to work seamlessly with the OpenStudyBuilder.

The TransCelerate DDF envisions a future state of fully automated, dynamic study start-up readiness, which is also the goal of the OpenStudyBuilder. Within the context of DDF, the OpenStudyBuilder serves as a Study Definition Repository (SDR).

One of the main advantages of DDF is its standard API, which enables the connection of diverse up- and downstream systems. As the OpenStudyBuilder supports the same APIs, all tools that support the DDF project through their standard APIs should also be usable with the OpenStudyBuilder.

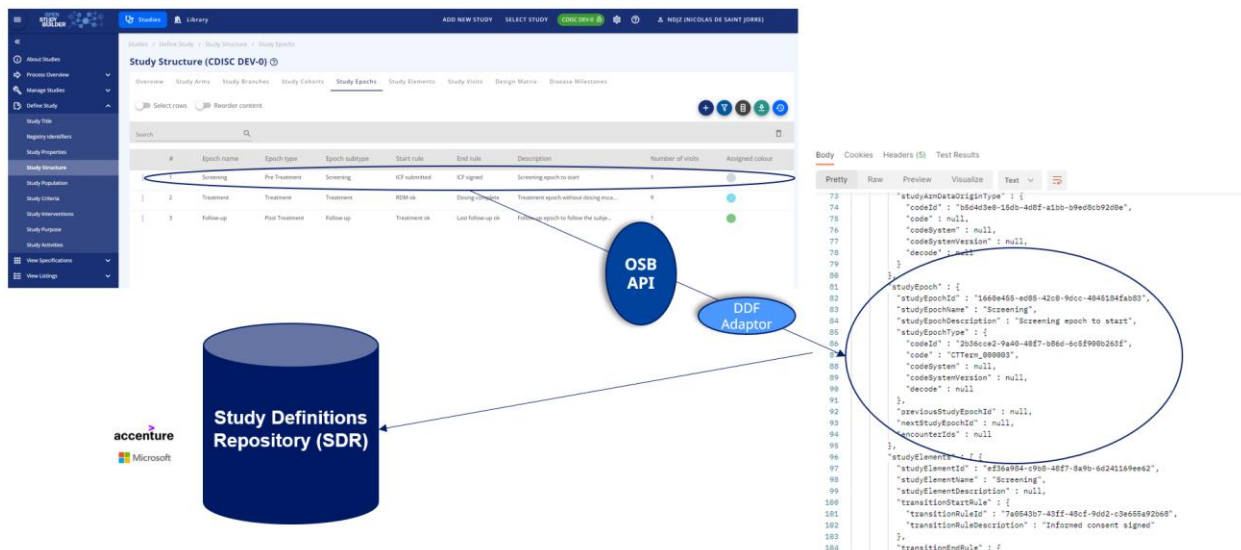


Figure 17: From OpenStudyBuilder to Digital Data Flow example

## CONCLUSION

Currently, the OpenStudyBuilder provides a wealth of metadata in the library section, complete with a full version management workflow. End-users can consume this data in every study, ensuring harmonization of information and increasing interoperability between the protocol, CRF, SDTM define.xml specifications and more. This metadata can be cleverly connected, creating a concrete platform that heavily utilizes biomedical concepts to enhance end-to-end processes for clinical trials.

## ACKNOWLEDGMENTS

We would like to thank Novo Nordisk for sharing this project as an open-source solution. Additionally, we would like to thank the complete OpenStudyBuilder team which is a squad of around 30 highly skilled professionals who work together in a dynamic environment to deliver and enhance the amazing OpenStudyBuilder solution.

We are looking forward to collaborations, so if you are interested in joining the OpenStudyBuilder project, please reach out to us.



Figure 18: OpenStudyBuilder team

## RECOMMENDED READING

1. Project Homepage, detailed project information, guides and more is available on the OpenStudyBuilder homepage: <https://openstudybuilder.com/>
2. Project Resources, if you would like to see various information resources available, you can check out the resource-list: [https://openstudybuilder.com/info\\_resources/](https://openstudybuilder.com/info_resources/)
3. OpenStudyBuilder demonstration video, we have a 30' demonstration video available showing the functionality of the OpenStudyBuilder in version 0.4: <https://www.youtube.com/watch?v=dL5CY0BwfEs>
4. GitLab repository, the complete solution is available in GitLab. A docker setup is available as well: <https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder/OpenStudyBuilder-Solution/>
5. Newsletter, our newsletter is getting out through linkedIn: <https://www.linkedin.com/newsletters/openstudybuilder-6990328054849916928/>
6. Slack channel, we do have a slack space available where you can ask any question: [https://join.slack.com/t/openstudybuilder/shared\\_invite/zt-19mtauzic-Jvrhtmy7hGstgyilvB1Wsw](https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyilvB1Wsw)

## CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

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