From OpenStudyBuilder to the Digital Data Flow - USDM Format

Presented by Maurizio Mazzei, Engineer, Neo4j
And Nicolas de Saint Jorre, Lead Product Architect, Novo Nordisk

Meet the Speakers

Maurizio MAZZEI

Title: Consulting Engineer

Organization: Neo4j

Maurizio is a software developer based in Rome, Italy. His career started in academia, where his efforts went towards the creation of a big data integration benchmark, then he moved to the industry, working as a Software Engineer developing APIs and ML models for different products, and now helps people make sense of their data with Neo4j, from database data modeling to web API development. He's currently collaborating with Novo Nordisk on the OpenStudyBuilder as a consulting software engineer.

Nicolas de SAINT JORRE

Title: Lead Product Architect

Organization: Novo Nordisk

29-year career in Data Management and Clinical Research. From pioneering EDC systems in 2000 to advancing CDISC-compliant solutions with EvidentIQ in 2005, I've been at the forefront of innovation in our field. In 2018, I contributed to the CDISC360 project, developing a metadata-centric 'Study Builder' prototype. Furthering this path, I collaborated with Novo Nordisk on the OpenStudyBuilder since 2019 and recently joined their team as Lead Product Architect in 2023.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. The OpenStudyBuilder as a Metadata Repository
2. The Word Add-in as a first editing solution
3. The Digital Data Flow Adaptor (DDF Adaptor)
4. Challenges…

The OpenStudyBuilder as a Metadata Repository

How do we create an electronic version of the Protocol?

What is the OpenStudyBuilder?...

A NEW APPROACH TO STUDY SPECIFICATION

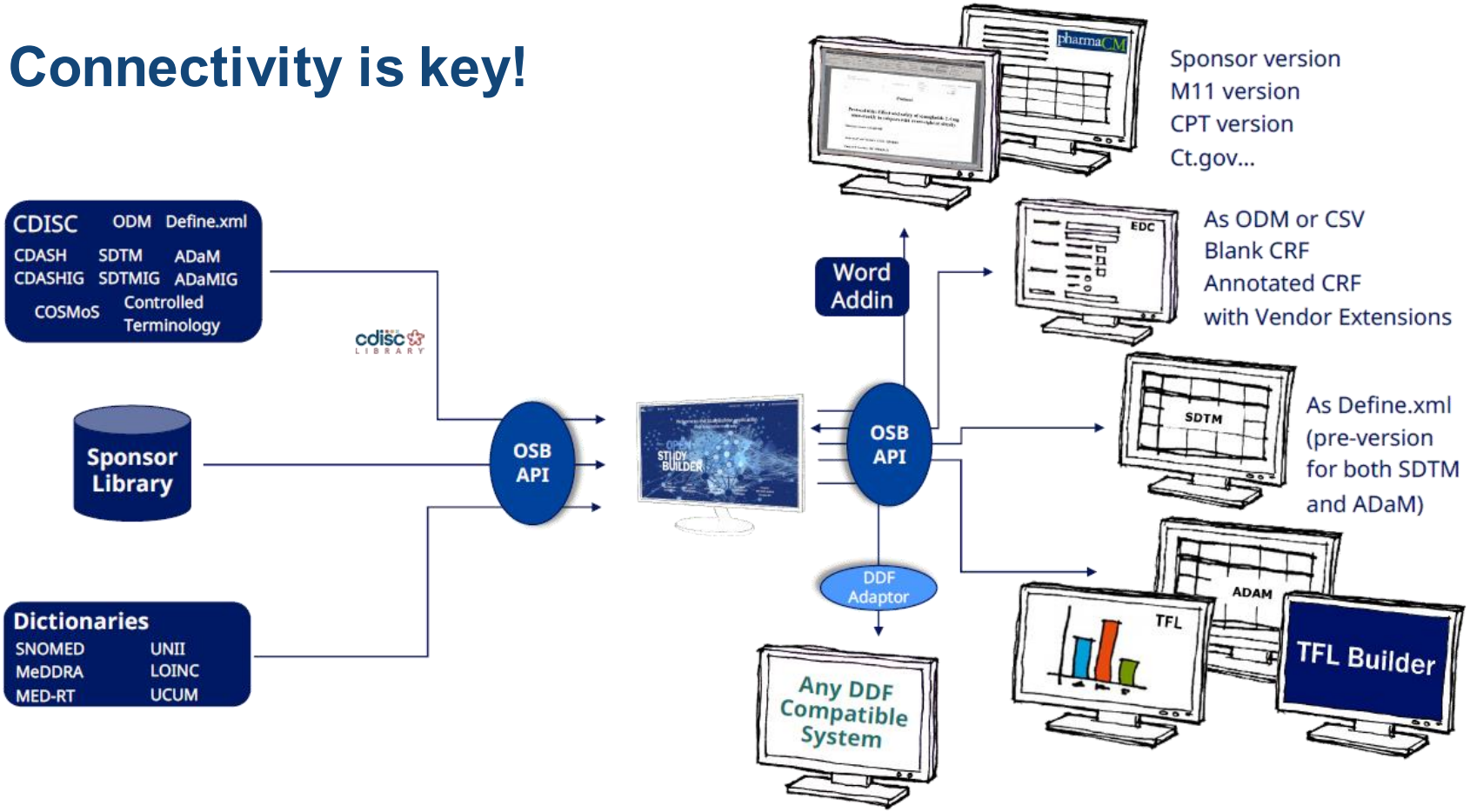
- Compliance with external and internal standards
- Facilitates automation and content reuse
- Ensures a higher degree of end-to-end consistency

3 ELEMENTS OF OpenStudyBuilder

- **Clinical Metadata and Study Definition Repository**
  (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)

clinical **MDR**

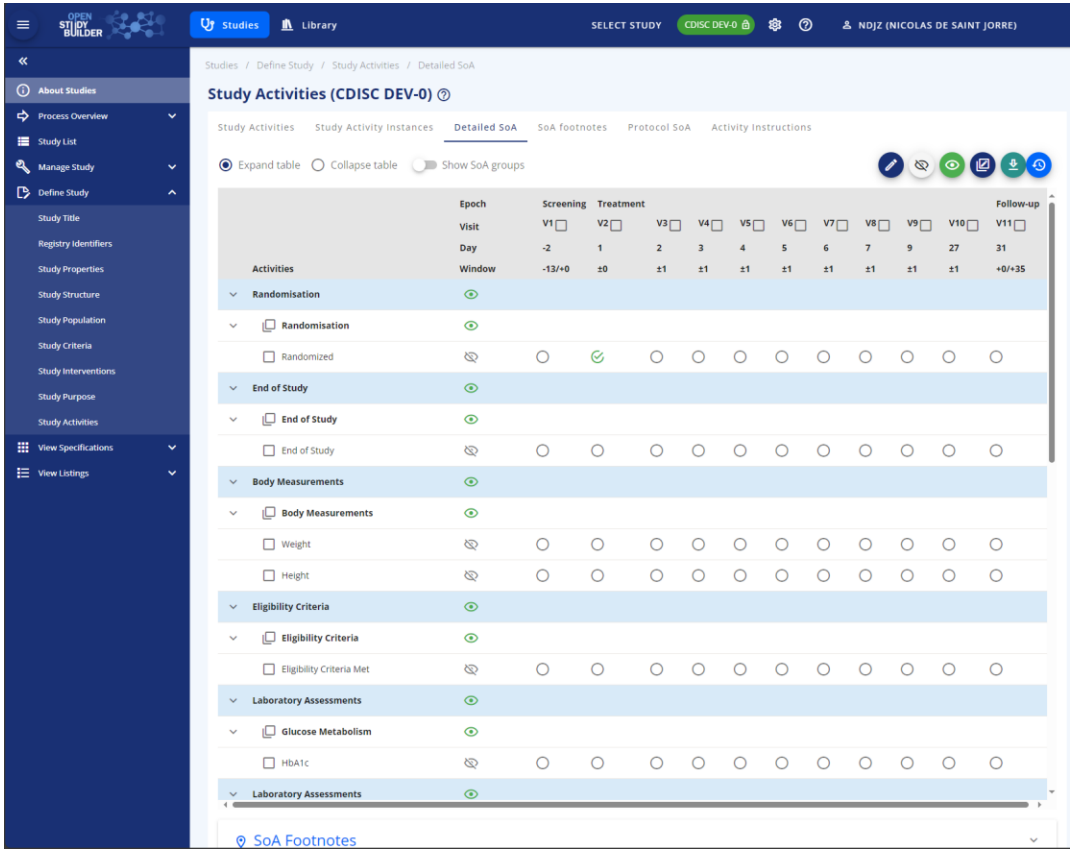
Connectivity is key!



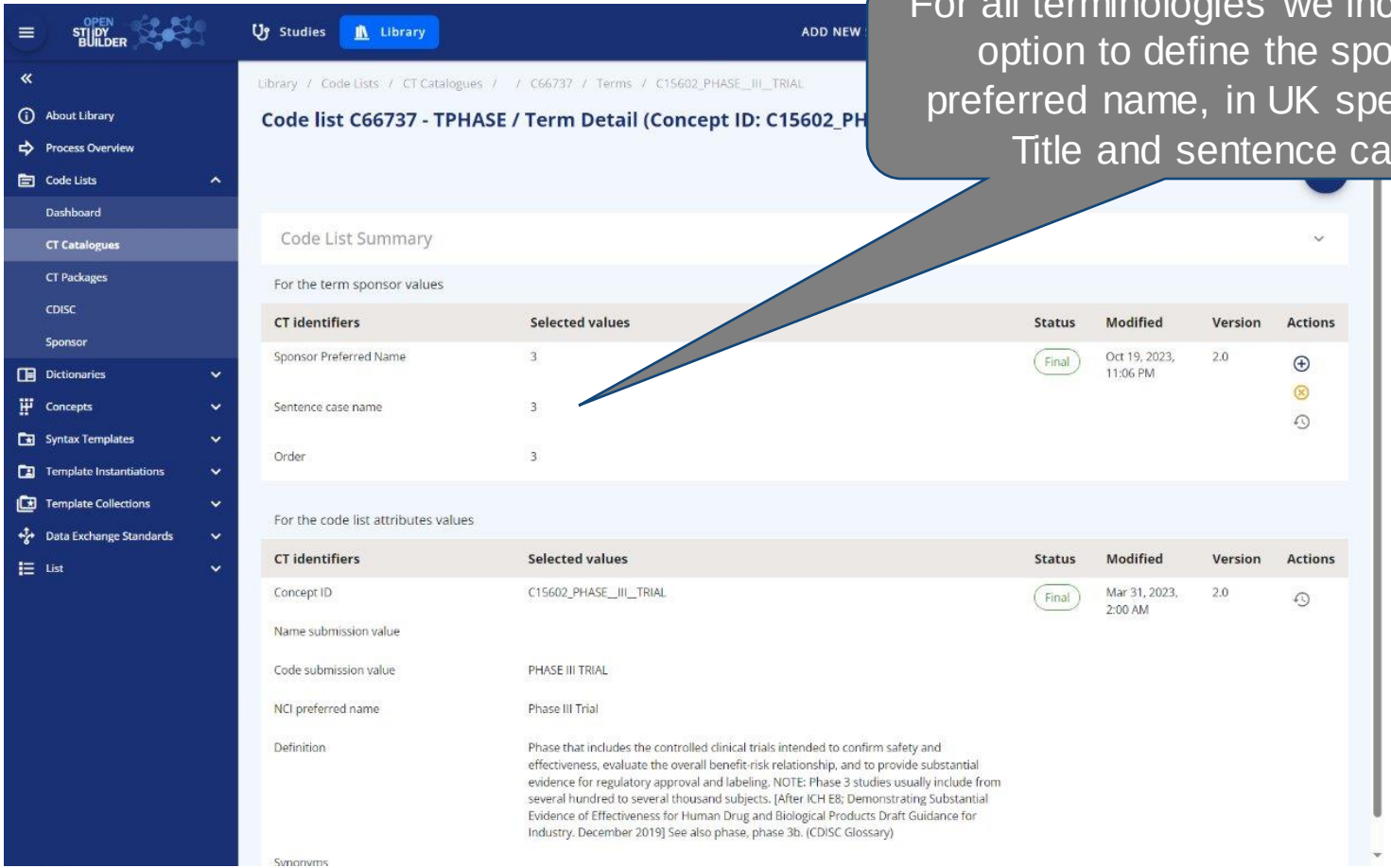
How to Specify our Electronic Protocol?

- In the « Studies »:
  - Study title
  - Registry Identifiers
  - Study Properties
  - Study Structure
  - Study Population
  - Study Criteria
  - Study Interventions
  - Study Purpose
  - Study Activities

- Many data are using the metadata coming from the Library



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



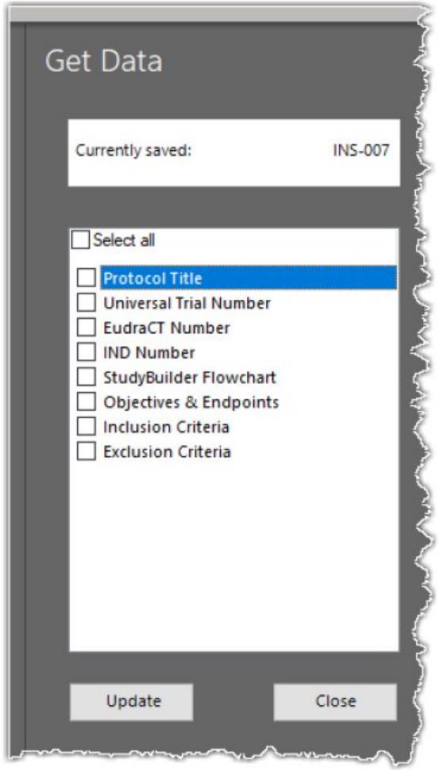
The Word Add-in as a first editing solution

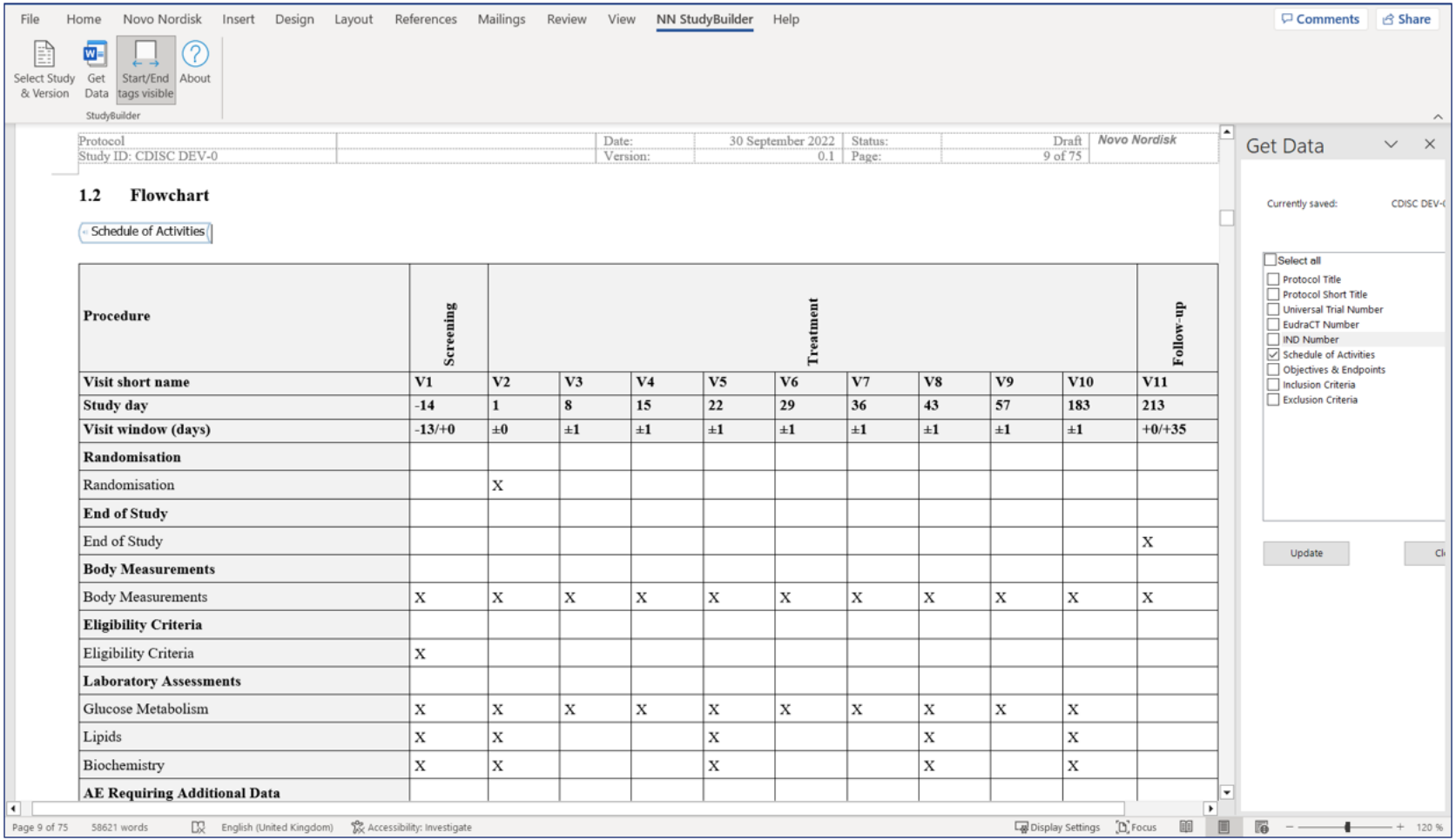
Authors can work in the Word editor to complete the Protocol…

Protocol Generation

StudyBuilder ribbon (Word add-in)

- ✓ One-way connection
- ✓ Code recognizes the document type
- ✓ User-friendly ribbon and ‘fly-out’ in Word
- ✓ Style ensure proper formatting in Word
- ✓ Using the API to generate the Word content



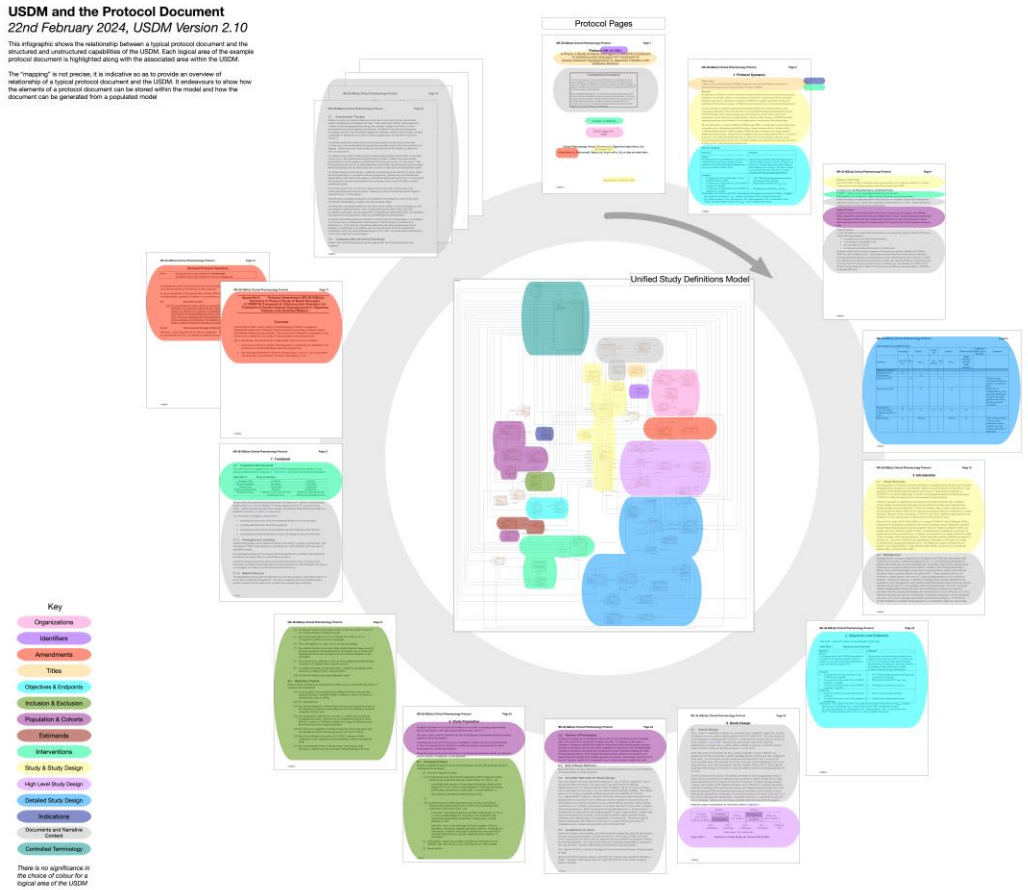


Procedure	Screening	Treatment									Follow-up
Visit short name	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**
Study day	**-14**	**1**	**8**	**15**	**22**	**29**	**36**	**43**	**57**	**183**	**213**
Visit window (days)	**-13/+0**	**±0**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**+0/+35**
Randomisation											
Randomisation		X									
End of Study											
End of Study											X
Body Measurements											
Body Measurements	X	X	X	X	X	X	X	X	X	X	X
Eligibility Criteria											
Eligibility Criteria	X										
Laboratory Assessments											
Glucose Metabolism	X	X	X	X	X	X	X	X	X	X	
Lipids	X	X			X			X		X	
Biochemistry	X	X			X			X		X	
AE Requiring Additional Data											

The Digital Data Flow Adaptor

A dedicated module enables OpenStudyBuilder to convert our metadata into the Unified Study Definition Model (USDM) and exposes the result through DDF-compliant API

USDM: The big Protocol Picture



Key

- Organizations
- Identifiers
- Amendments
- Titles
- Objectives & Endpoints
- Inclusion & Exclusion
- Population & Cohorts
- Estimands
- Interventions
- Study & Study Design
- High Level Study Design
- Detailed Study Design
- Indications
- Documents and Narrative Content
- Controlled Terminology

There is no significance in the choice of colour for a logical area of the USDM

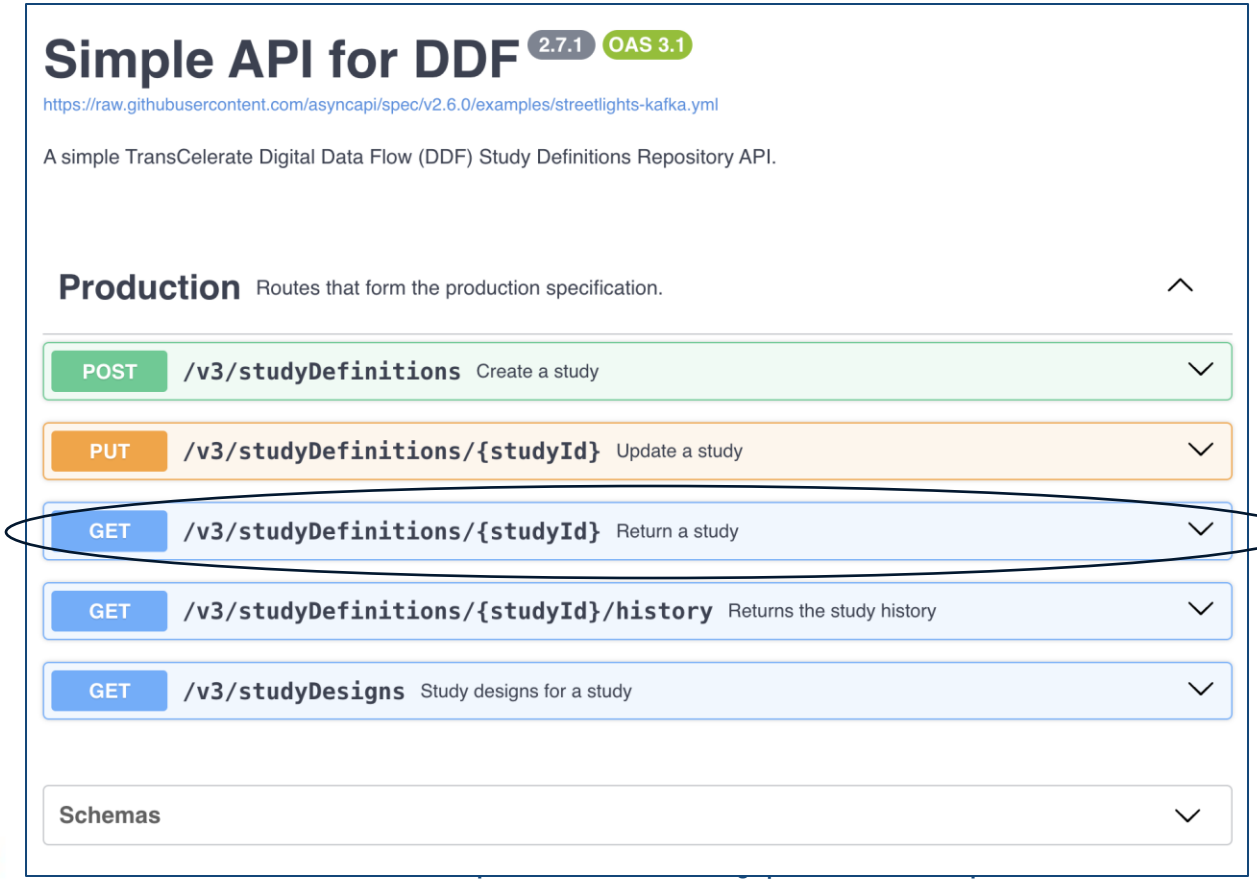
DDF Adaptor enables new use cases

- The DDF Adaptor enables:
  - Downstream structured content management
    - For documents: Protocol, SAP…
  - Downstream data consumption
    - Clinical & Ops Systems
      - EDC/CDMS, CTMS, …
  - Upload to DDF-compliant SDR for data sharing

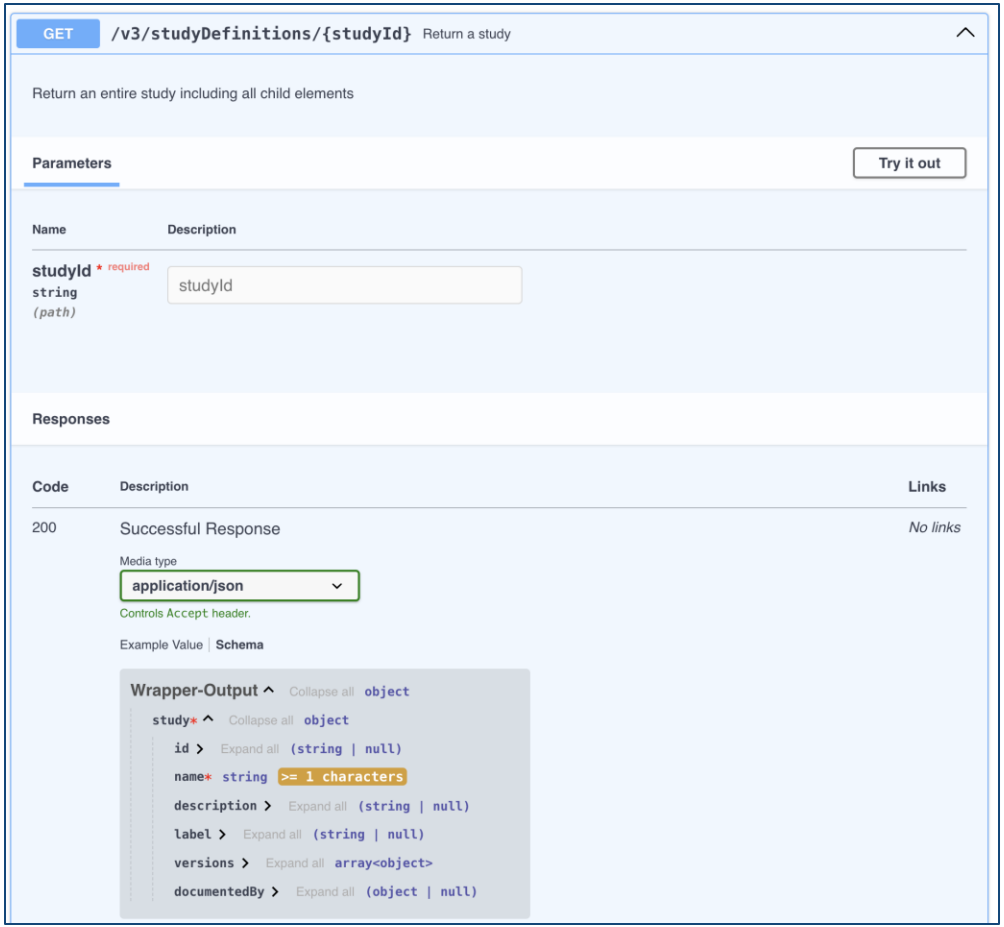
Mapping matrix between OSB and DDF

	A	B	C	D	E	F	G	H	I	J	K
1	Row	Entity Name	Role	Logical Data Model Name	NCI C-code	CT Item Preferred Name	Synonym(s)	Definition	Has Value List	Codelist URL	OpenStudyBuilder Mapping
112	111	Encounter	Entity	Encounter	C142427	Clinical Encounter		Contact between subject/patient and healthcare practitioner/researcher, during	N		uuid4
113	112	Encounter	Relationship	transitionStartRule					N/A		entity "TransitionRule" {id: uuid4, name: 'TransitionStartRule', text: StudyVisit->start_rule}
114	113	Encounter	Relationship	transitionEndRule					N/A		entity "TransitionRule" {id: uuid4, name: 'TransitionEndRule', text: StudyVisit->end_rule}
115	114	Encounter	Relationship	scheduledAt					N/A		/
116	115	Encounter	Attribute	name	C171010	Clinical Encounter Name		The literal identifier (i.e., distinctive designation) for a protocol-defined clinical encounter.	N		StudyVisit->visit_name
117	116	Encounter	Attribute	description	C188836	Clinical Encounter Description		A narrative representation of the protocol-defined clinical encounter.	N		StudyVisit->description
118	117	Encounter	Attribute	label	CNEW	Encounter Label		The short descriptive designation for the encounter.	N		/
119	118	Encounter	Relationship	previous					N/A		
120	119	Encounter	Relationship	next					N/A		
121	120	Encounter	Attribute	type	C188839	Clinical Encounter Type		A characterization or classification of contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed	Y (C188728)	https://ncit.nci.nih.gov/ncitbrowser/ajax?action=create_src_vs_tree	entity "Code" {id: uuid4, code: StudyVisit->visit_type_uid, codeSystem: 'openstudybuilder.org', decode: StudyVisit->visit_type_name}
122	121	Encounter	Attribute	environmentalSetting	C188840	Environmental Setting		The environment/setting where the event, intervention, or finding occurred.	Y (SDTM Terminolog	https://ncit.nci.nih.gov/ncitbrowse	/
123	122	Encounter	Attribute	contactModes	C188841	Contact Mode		The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device).	Y (SDTM Terminology Codelist C171445)	https://ncit.nci.nih.gov/ncitbrowser/ajax?action=create_src_vs_tree&vsd_uri=http://	list of entity "Code" {id: uuid4, code: StudyVisit->visit_contact_mode_uid, codeSystem: 'openstudybuilder.org', decode: StudyVisit->visit_contact_mode_uid}

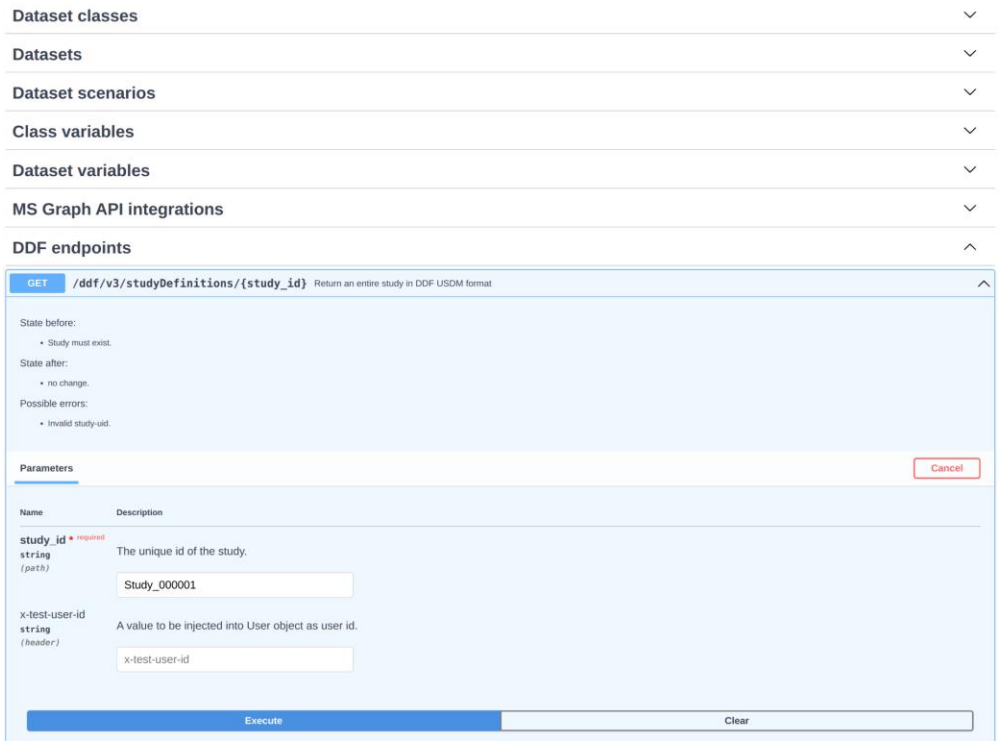
DDF API specification



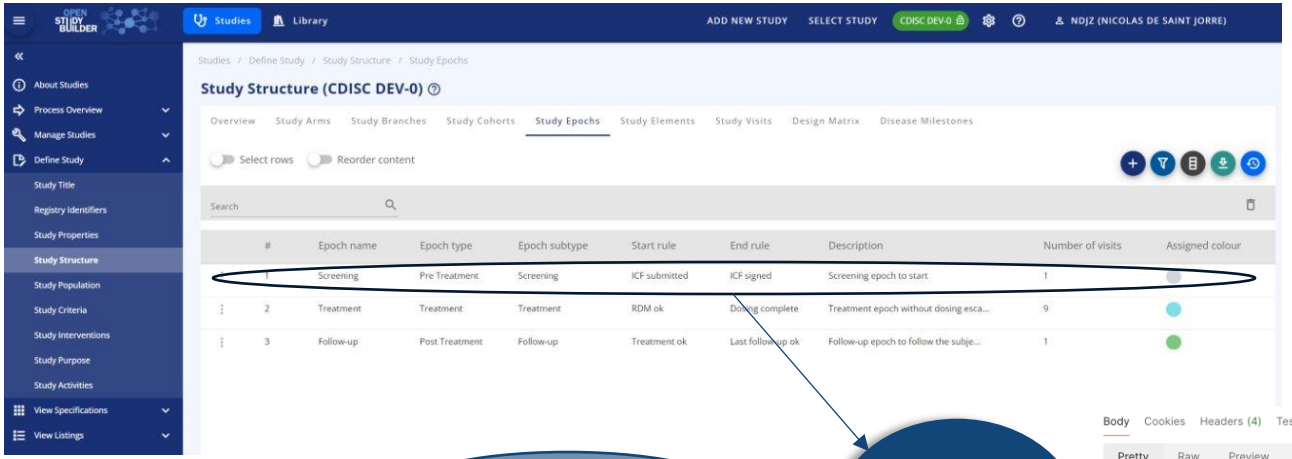
DDF API specification

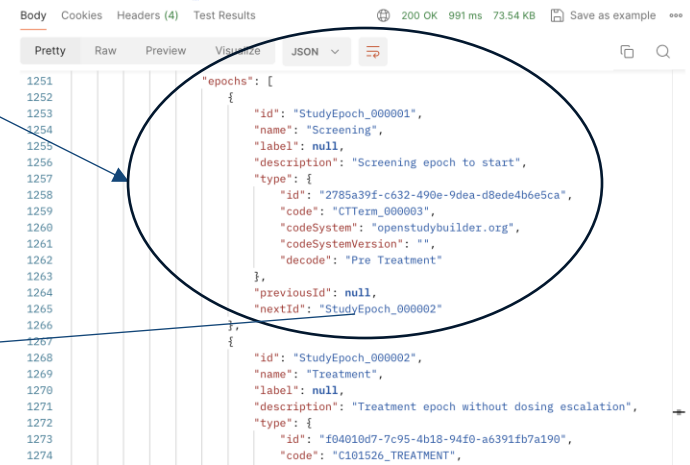


DDF is now in the OpenStudyBuilder API!



Digital Data Flow Adaptor (in the OpenStudyBuilder)





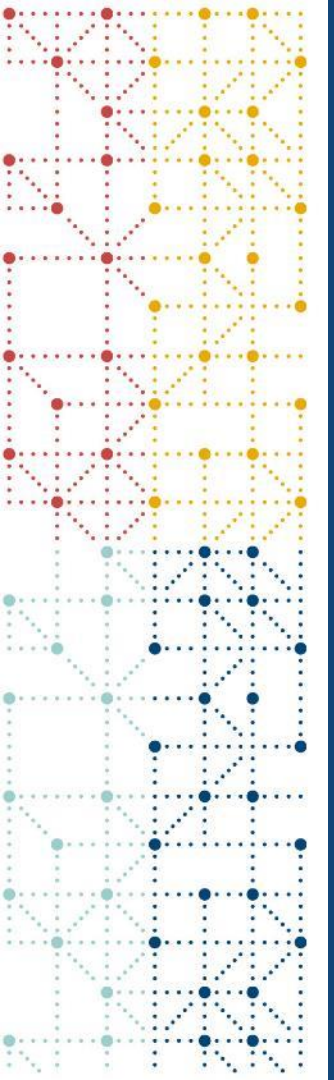
OSB with DDF Adaptor

DDF Study Definitions Repository (SDR)

accenture

Microsoft

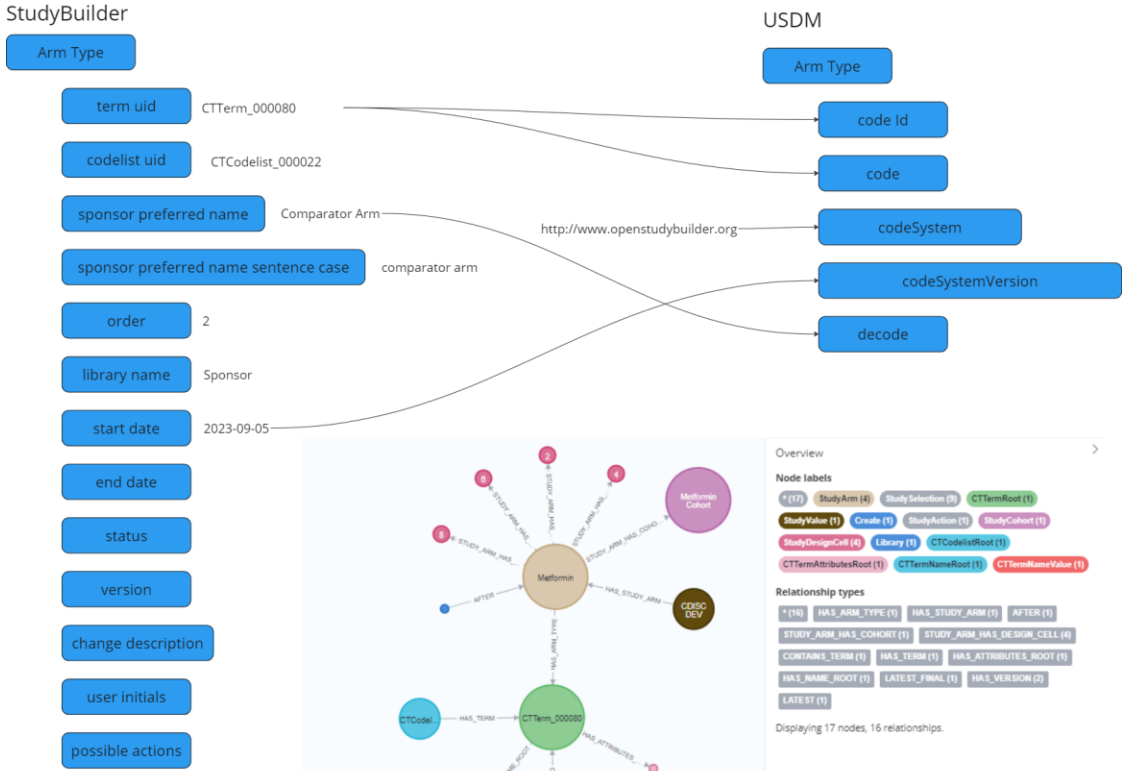
cdisc



Challenges?

Evolution of the OpenStudyBuilder and the DDF-USDM

- OpenStudyBuilder started before DDF…
- OpenStudyBuilder is still in version 0.8.1 / DDF is looking at version 3.0…
- OpenStudyBuilder is defining metadata differently



Objectives using Template versus Blob Text…

Study Purpose (CDISC DEV-0)

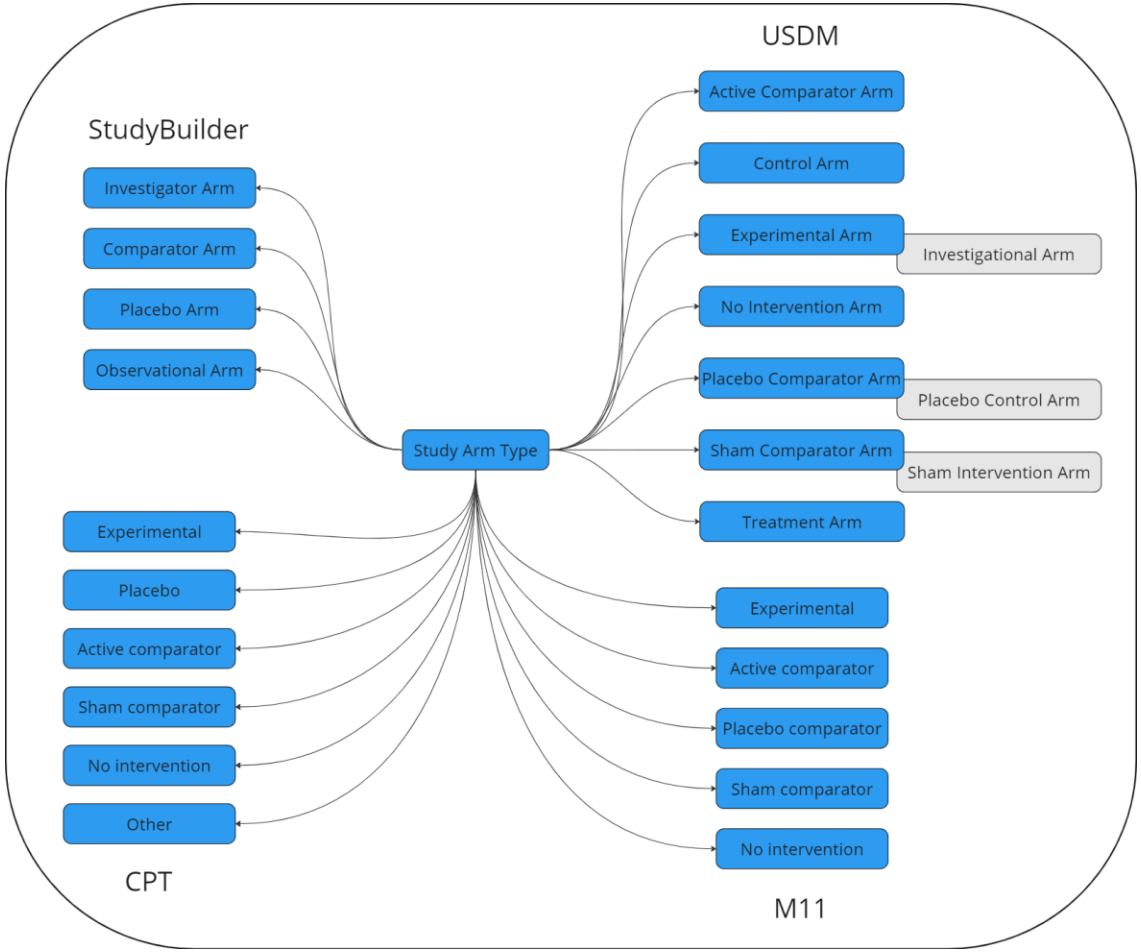
Study Objectives | Study Endpoints | Study Estimands

Select rows

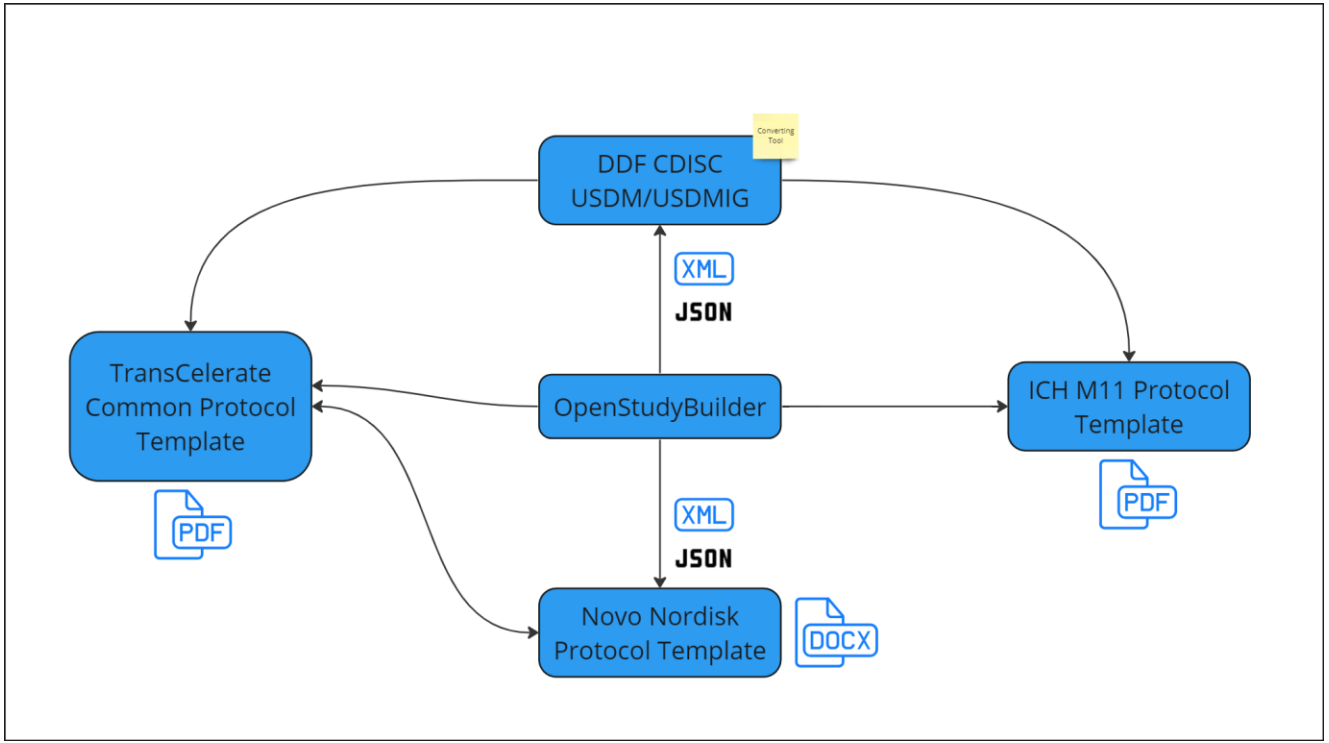
Search

	#	Objective level	Objective
⋮	1	Primary Objective	Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina
⋮	2	Secondary Objective	Time from randomisation to all cause death


```
"objectives": [
  {
    "id": "2bc878b4-3317-42c5-b51c-be23fcd43679",
    "name": "Objective_000004",
    "label": null,
    "description": "<p>Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI,</p><p>nonfatal stroke, or hospitalization for unstable </p><p>angina</p>",
    "instanceType": "OBJECTIVE",
    "text": "",
    "dictionaryId": null,
    "level": {
      "id": "2c71d89c-47b6-48c8-bf9a-43350ce4bd0b",
      "code": "C85826_OBJPRIM",
      "codeSystem": "openstudybuilder.org",
      "codeSystemVersion": "",
      "decode": "Primary Objective"
    },
    "endpoints": [
      {
        "id": "cb9a5d33-6863-4551-8190-40e6da8958ac",
        "name": "Endpoint_000001",
        "label": null,
        "description": "<p>Mean change from baseline in hba1c</p>",
        "instanceType": "ENDPOINT",
        "text": "",
        "dictionaryId": null,
        "purpose": "",
        "level": {
          "id": "c6076db7-708c-42a0-9b4a-4e39bfc96023",
          "code": "C98772_OUTMSPRI",
          "codeSystem": "openstudybuilder.org",
          "codeSystemVersion": "",
          "decode": "Primary Endpoint"
        }
      }
    ]
  },
```


USDM
StudyBuilder
Investigator Arm
Comparator Arm
Placebo Arm
Observational Arm
Study Arm Type
Active Comparator Arm
Control Arm
Experimental Arm
Investigational Arm
No Intervention Arm
Placebo Comparator Arm
Placebo Control Arm
Sham Comparator Arm
Sham Intervention Arm
Treatment Arm
Experimental
Placebo
Active comparator
Sham comparator
No intervention
Other
CPT
Experimental
Active comparator
Placebo comparator
Sham comparator
No intervention
M11

OpenStudyBuilder as a multisource system



Thank You!

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