

Phuse EU Connect 2024 - DH08

Leveraging the USDM Standard for Enhanced Data Exchange

OPEN
STUDY
BUILDER



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Disclaimer and Disclosures

The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the position of any company.

1. The OpenStudyBuilder as a Metadata Repository
2. What is the DDF - USDM
3. The USDM in the OpenStudyBuilder
4. Export and import...
5. Integration of the ICH – M11 Template

The OpenStudyBuilder as a Metadata Repository

How do we create an electronic version of the Protocol?



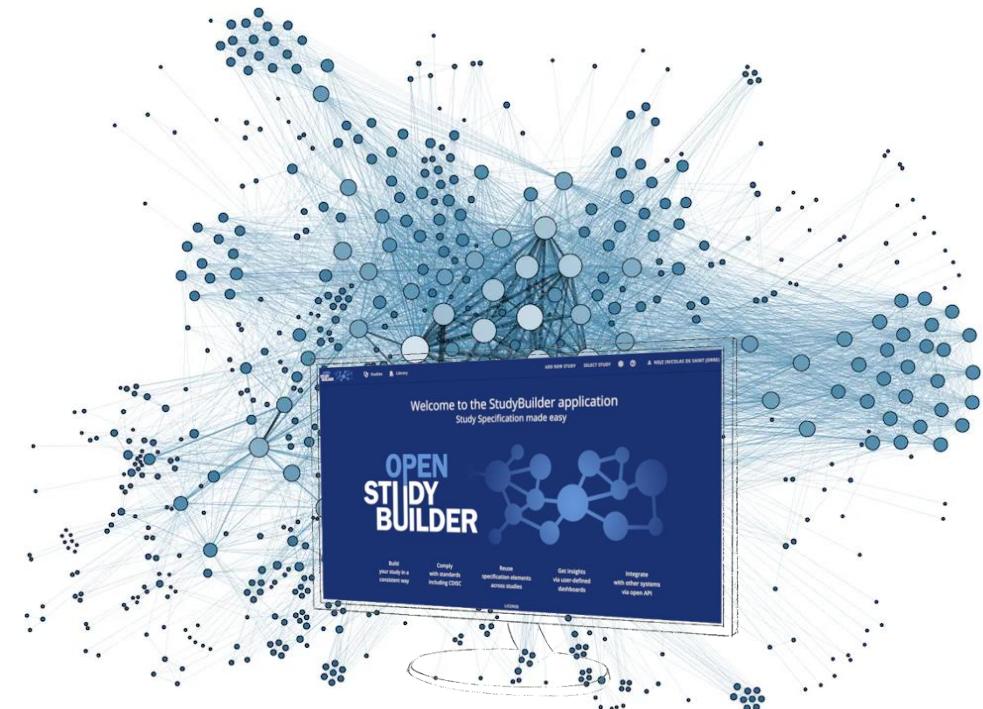
What is the OpenStudyBuilder?...

A NEW APPROACH TO STUDY SPECIFICATION

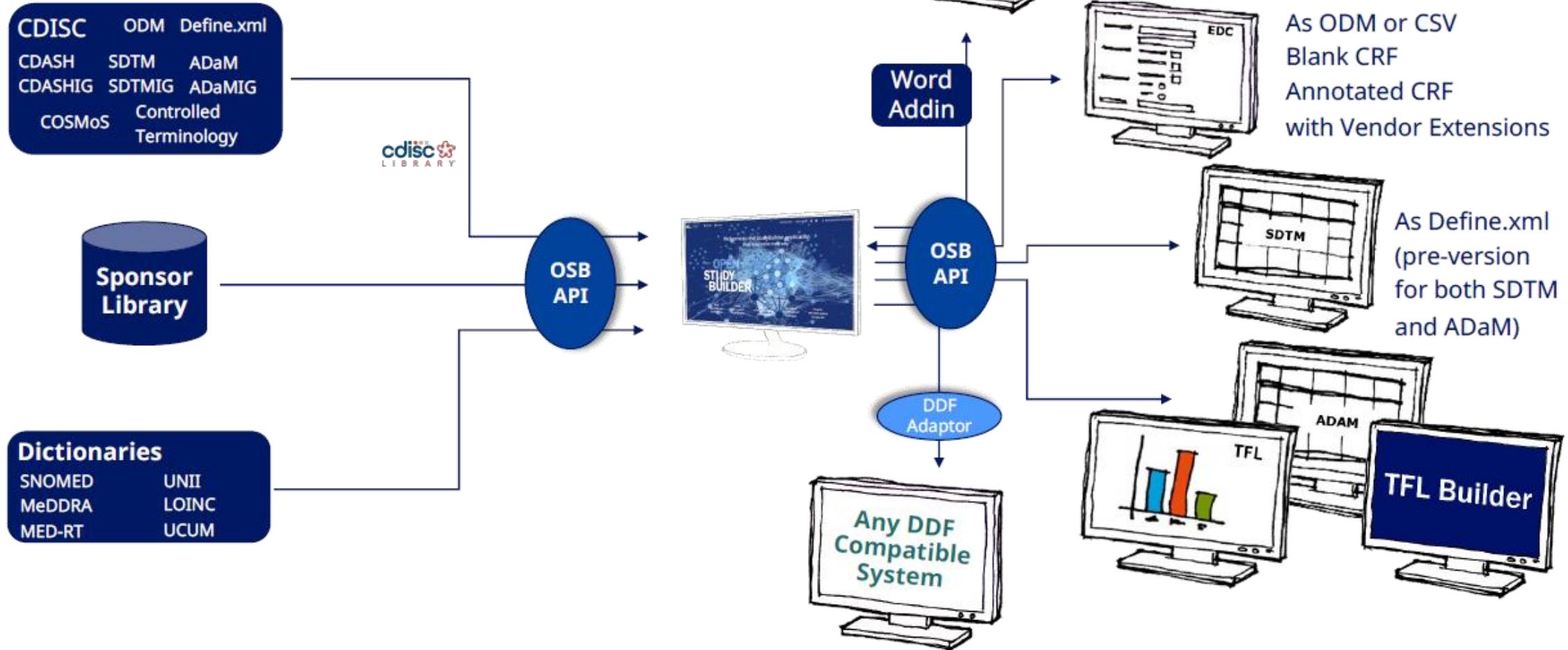
- Compliance with external and internal standards
- Facilitates automation and content reuse
- Ensures a higher degree of end-to-end consistency

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)



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

Code List Summary

For the term sponsor values

CT identifiers	Selected values	Status	Modified	Version	Actions
Sponsor Preferred Name	3	Final	Oct 19, 2023, 11:06 PM	2.0	+
Sentence case name	3				X
Order	3				🕒

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 regulatory approval and labeling. NOTE: Phase 3 studies usually include from several hundred to several thousand subjects. [After ICH E8; Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products Draft Guidance for Industry. December 2019] See also phase, phase 3b. (CDISC Glossary)				

Synonyms

What is the DDF - USDM

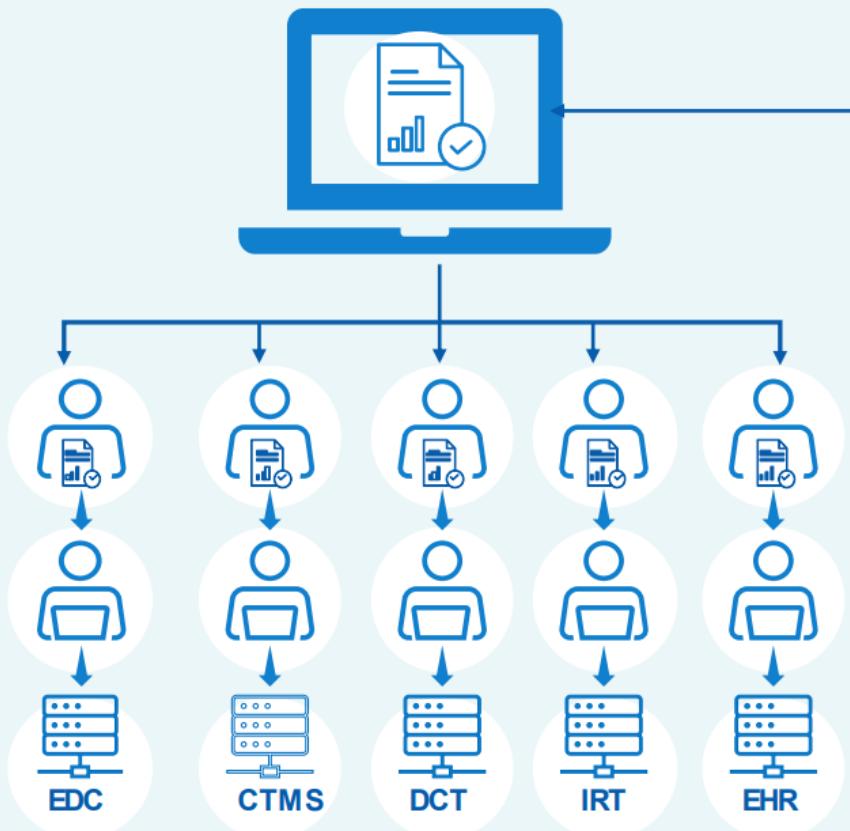
TransCelerate is specifying the Digital Data Flow Unified Study Definition Model ...



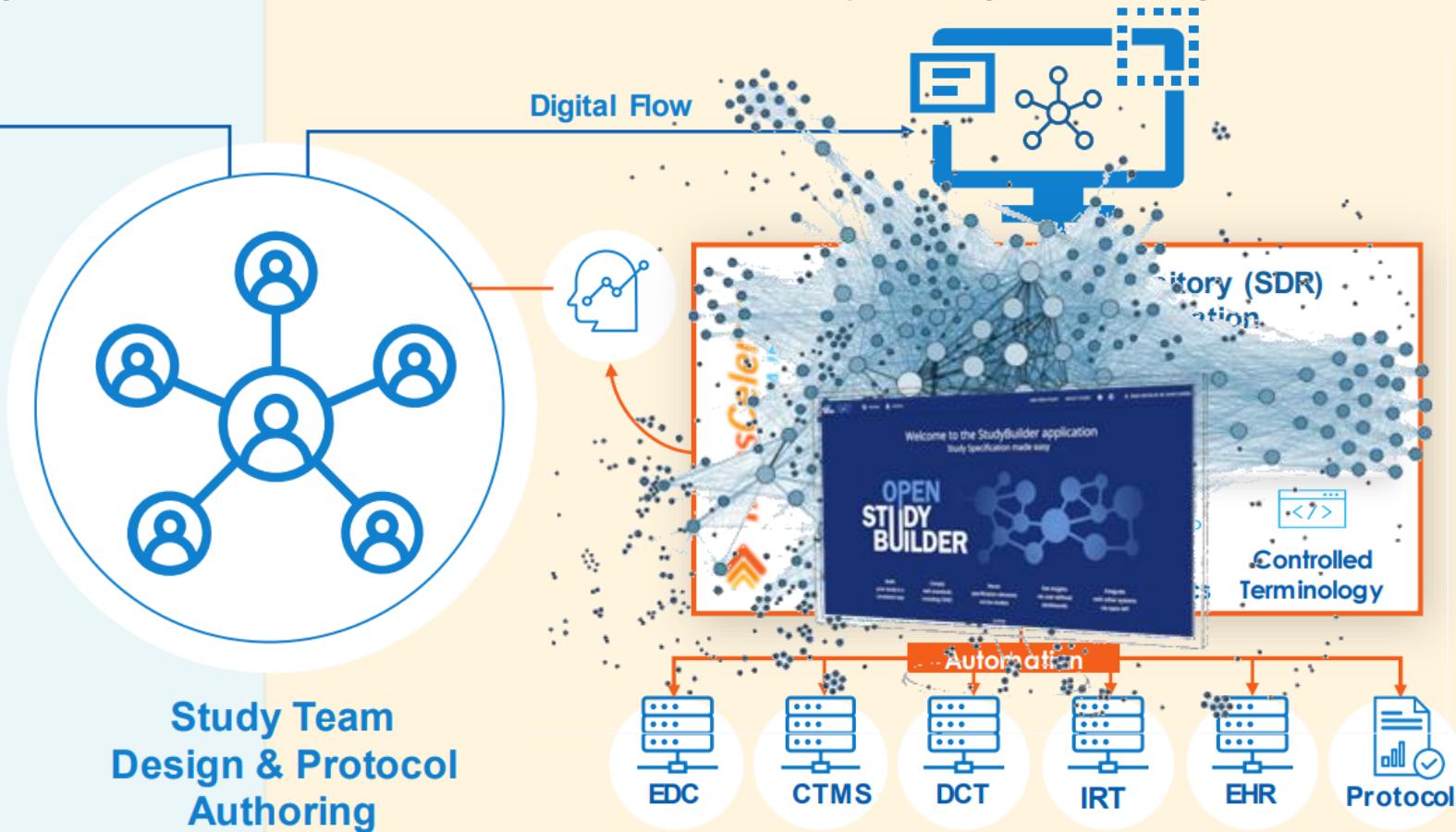
TransCel erate Digital Data Flow (DDF) Ambition

Write Once, Read Many

TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems



TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



The USDM in the OpenStudyBuilder

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

USDM and the Protocol Document 22nd February 2024, USDM Version 2.10

This infographic shows the relationship between a typical protocol document and the structured and unstructured capabilities of the USDM. Each logical area of the example protocol document is highlighted along with the associated area within the USDM.

The “mapping” is not precise; it is indicative so as to provide an overview of relationship of a typical protocol document and the USDM. It endeavours to show how the elements of a protocol document can be stored within the model and how the document can be generated from a populated model.



DDF USDM API Endpoint

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

DDF API specification

Simple API for DDF 2.7.1 OAS 3.1

<https://raw.githubusercontent.com/asyncapi/spec/v2.6.0/examples/streetlights-kafka.yml>

A simple TransCelerate Digital Data Flow (DDF) Study Definitions Repository API.

Production Routes that form the production specification.



POST /v3/studyDefinitions Create a study



PUT /v3/studyDefinitions/{studyId} Update a study



GET /v3/studyDefinitions/{studyId} Return a study



GET /v3/studyDefinitions/{studyId}/history Returns the study history



GET /v3/studyDesigns Study designs for a study



Schemas



DDF API specification

GET /v3/studyDefinitions/{studyId} Return a study ^

Return an entire study including all child elements

Parameters Try it out

Name	Description
studyId * required string (path)	studyId

Responses

Code	Description	Links
200	Successful Response	No links

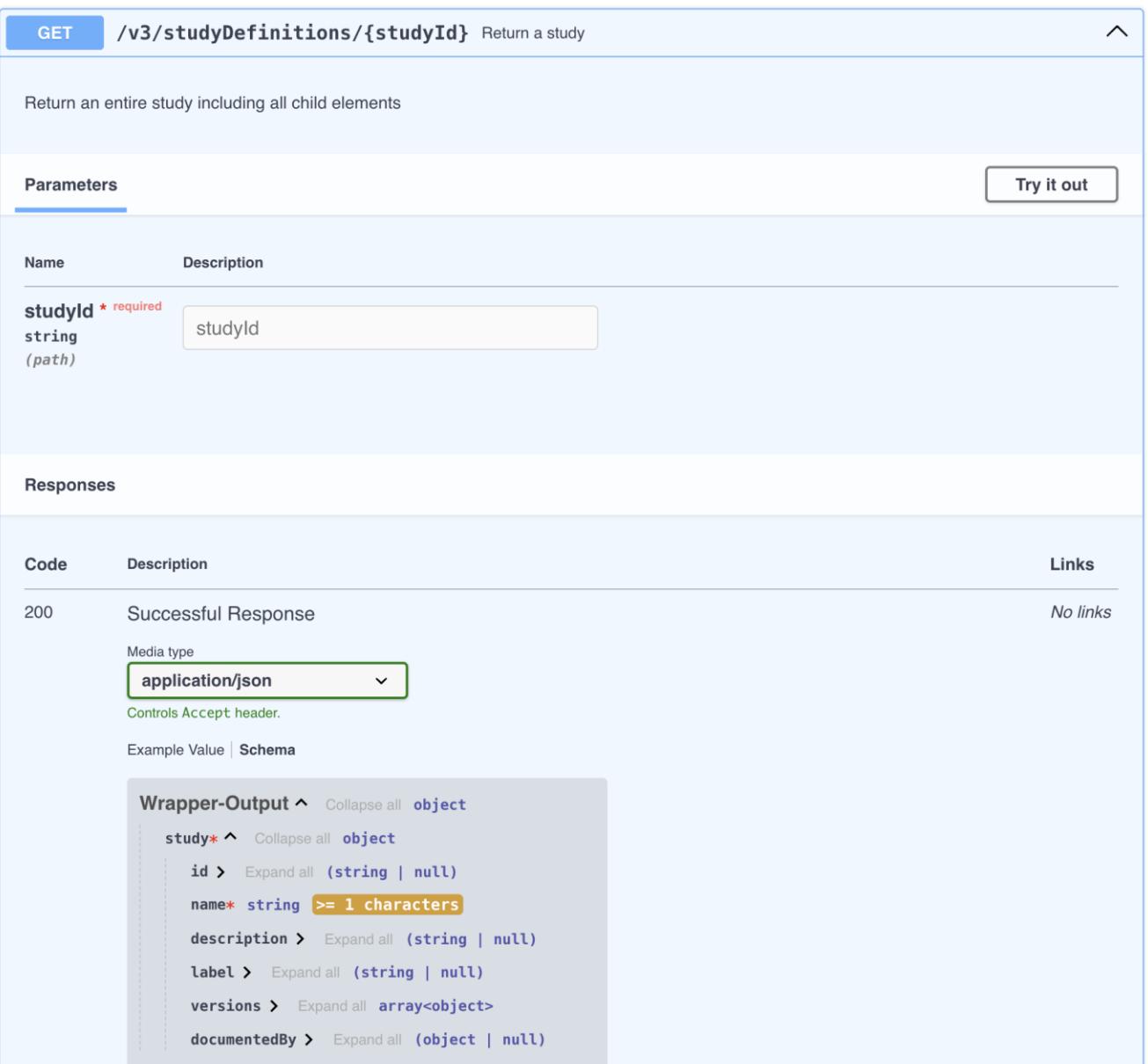
Media type application/json ▾
Controls Accept header.
[Example Value](#) | [Schema](#)

Wrapper-Output ^ Collapse all object

study* ^ Collapse all object

id > Expand all (string | null)
name* string >= 1 characters

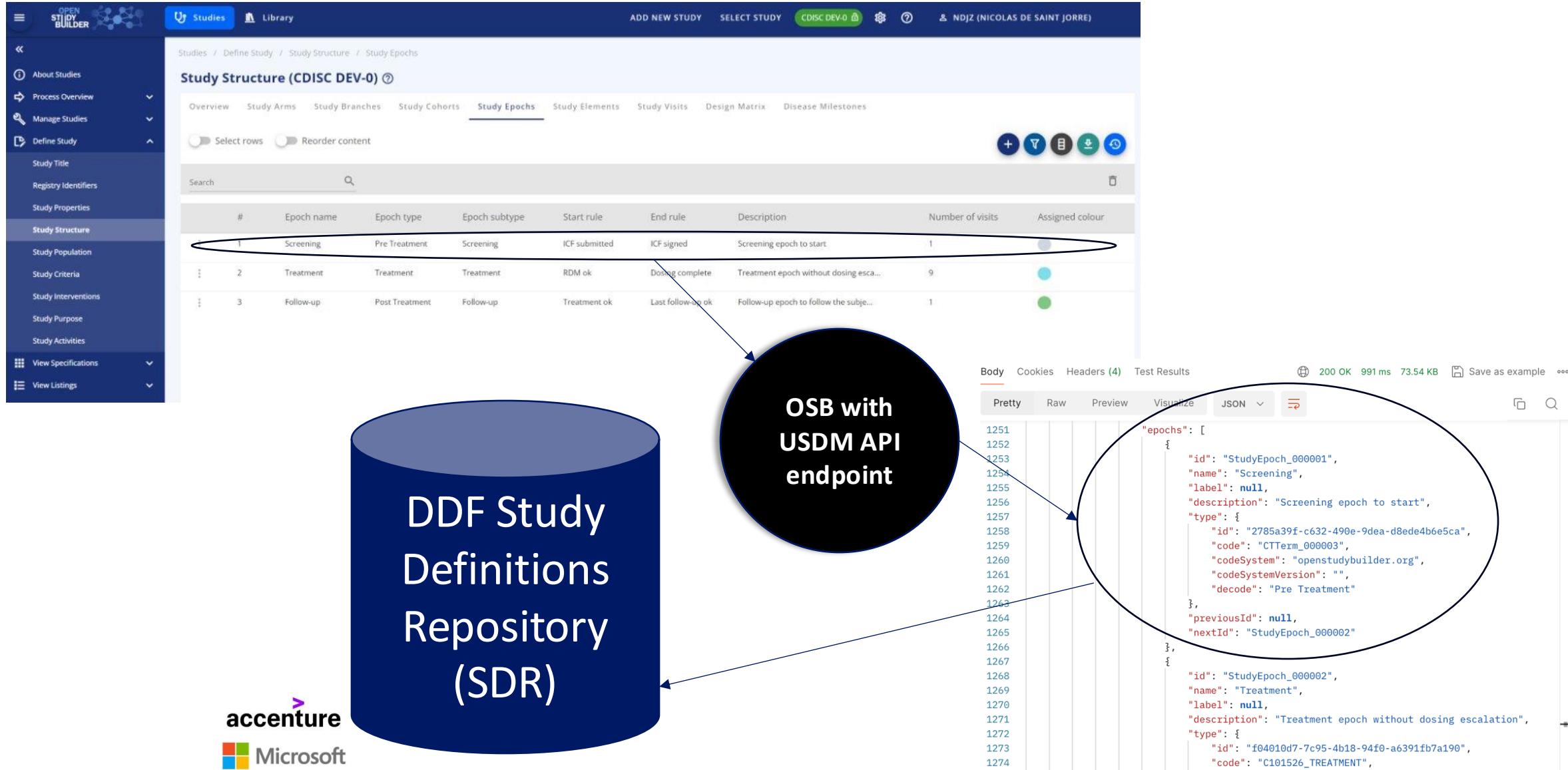
description > Expand all (string | null)
label > Expand all (string | null)
versions > Expand all array<object>
documentedBy > Expand all (object | null)



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_type	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 Terminology)	https://ncit.nci.nih.gov/ncitbrowser/ajax?action=create_src_vs_environment	/
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_contact_modes	list of entity "Code" {id: uuid4, code: StudyVisit->visit_contact_mode_uid, codeSystem: 'openstudybuilder.org', decode: StudyVisit->visit_contact_mode_name}

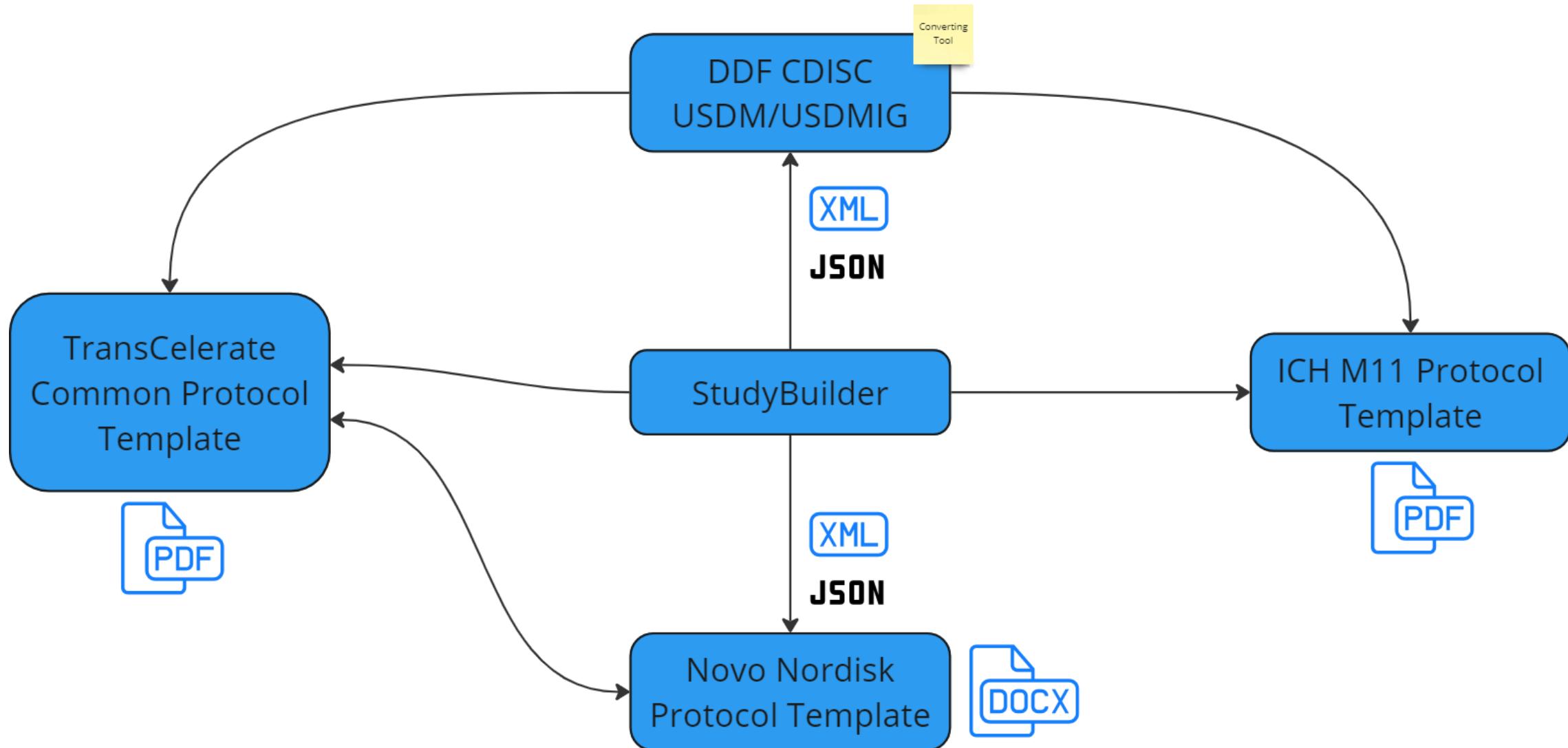
Digital Data Flow Adaptor (in the OpenStudyBuilder)



Export and Import ?



OpenStudyBuilder as a multisource system

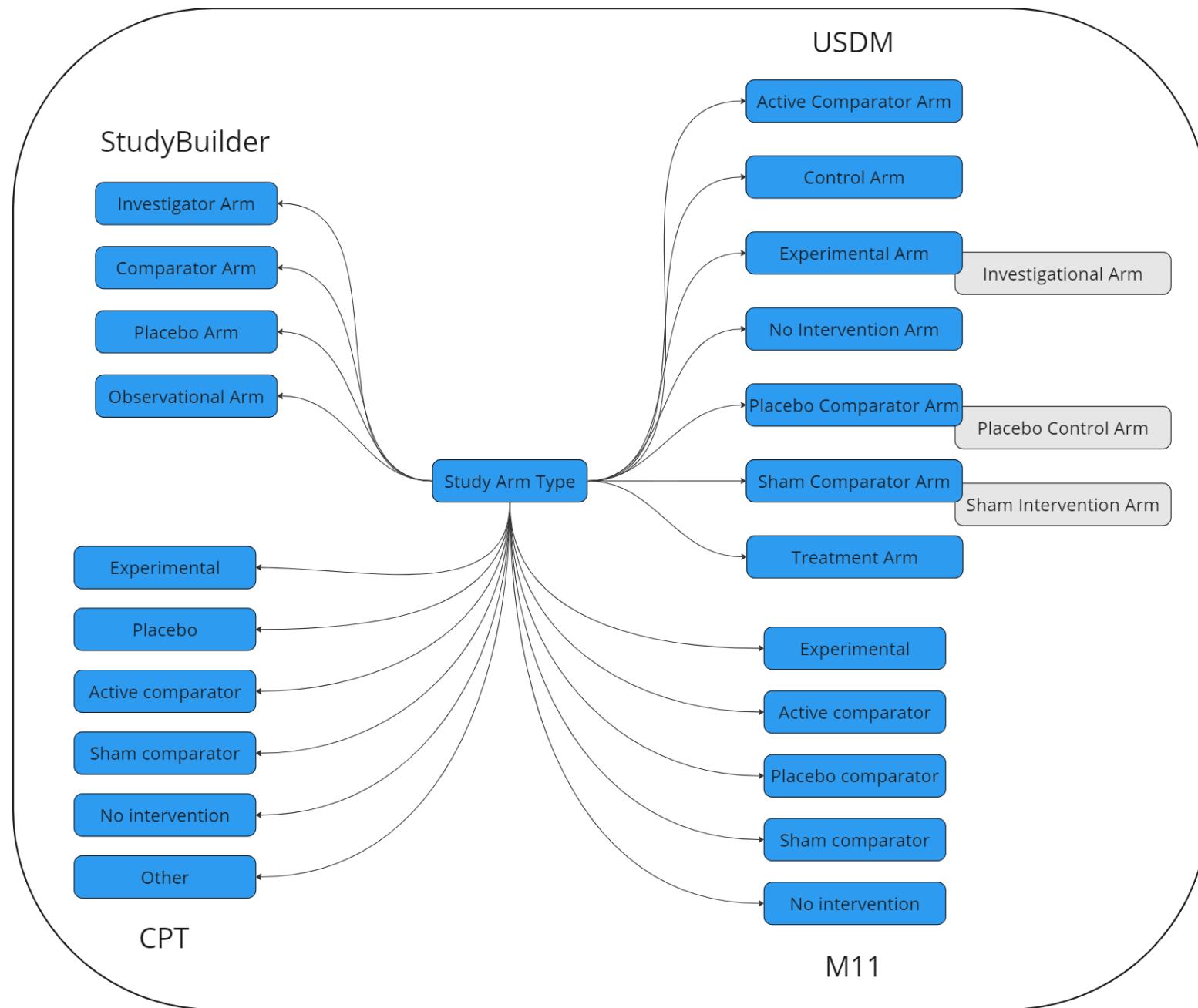


USDM in the Front-end application

The screenshot shows the Open Study Builder interface. The left sidebar has a navigation menu with items like About Studies, Process Overview, Study List, Manage Study, Define Study, View Specifications (which is expanded), Protocol Elements, SDTM Study Design Datasets, and USDM (which is selected). The main content area shows the 'Studies / View Specifications / USDM' path. The title is 'USDM version of the Protocol'. Below the title is a JSON representation of a USDM protocol specification, with the 'studyPhase' section highlighted by a red box.

```
{
  "id": "6369f3b8-1461-42f6-a7ac-e31bb4bb781f",
  "description": null,
  "label": null,
  "versions": [
    {
      "id": "4dce76f6-e755-434e-aaa0-dd65329a9770",
      "versionIdentifier": "None",
      "rationale": "",
      "studyType": {
        "id": "21729659-87a0-4e91-9cde-705e74a35bd7",
        "code": "C98388_INTERVENTIONAL",
        "codeSystem": "openstudybuilder.org",
        "codeSystemVersion": "",
        "decode": "Interventional",
        "instanceType": "Code"
      }
    }
  ],
  "studyPhase": {
    "id": "3f7bee89-f1a4-42a4-b689-9d1cf05234d",
    "standardCode": {
      "id": "3508d81e-826a-423b-8597-f0a885cd1b97",
      "code": "C15602_PHASE_III_TRIAL",
      "codeSystem": "openstudybuilder.org",
      "codeSystemVersion": "",
      "decode": "Phase III Trial",
      "instanceType": "Code"
    }
  }
},
```

Some challenges...



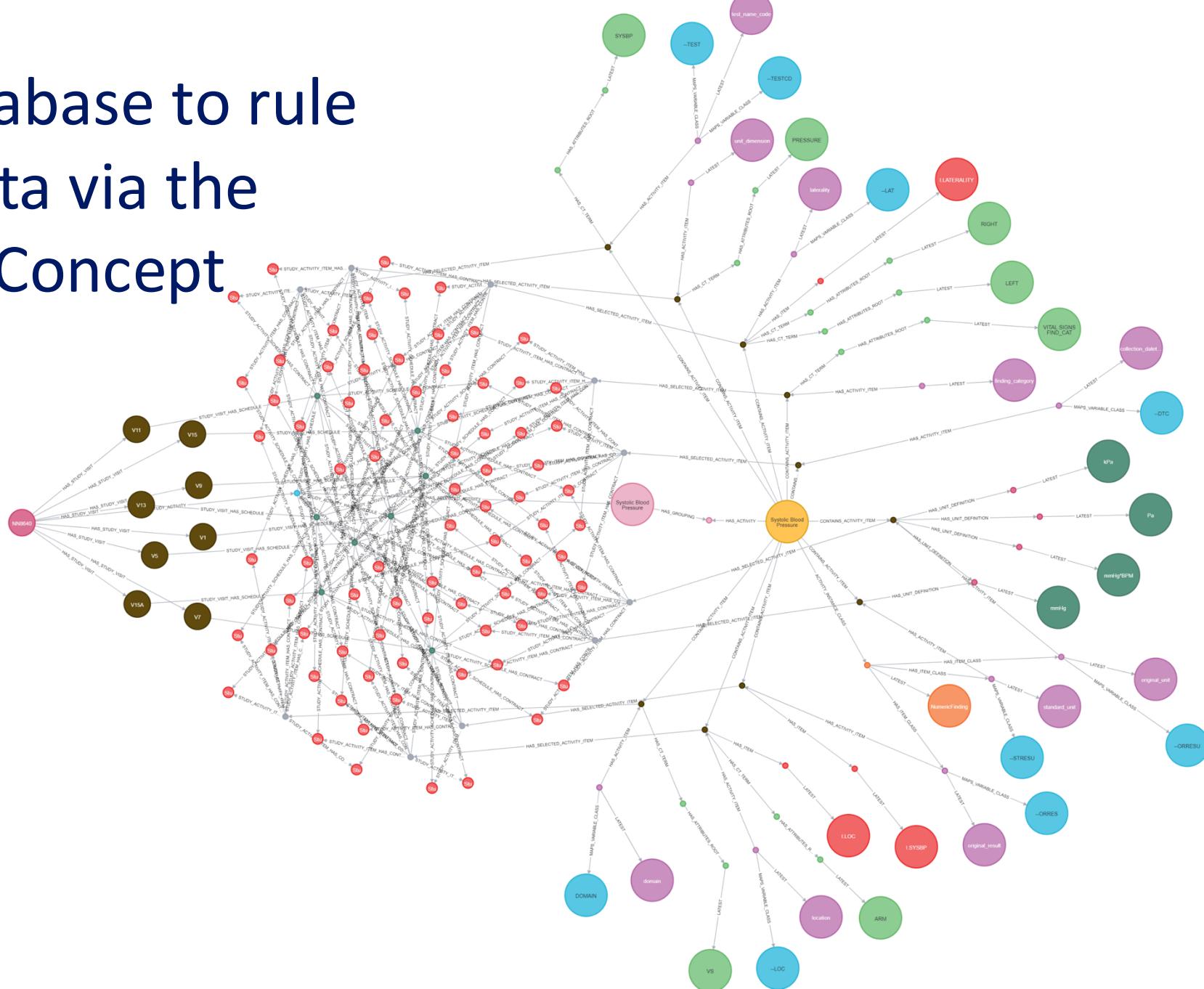
USDM to ICH - M11

Integration of ICH - M11 Template in OpenStudyBuilder:

- Leverages USDM JSON metadata
- Generates HTML version of M11 protocol
- Conversion to PDF document
- Aligns with industry standards
- Enhances efficiency, accuracy, and compliance
- Empowers researchers and stakeholders

ICH M11 Template	
Protocol Full Title:	[Protocol Full Title] Coming from the OpenStudyBuilder
	The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet searches.
Sponsor Confidentiality Statement:	[Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
Protocol Number:	[Protocol Number] A unique alphanumeric identifier for the trial, designated by the Sponsor, is a standard part of trial data, and should be included for most trials.
Version:	[Version] An optional field for use by the Sponsor at their discretion.
Amendment Number:	[Amendment Number] Enter the amendment number. If this is the original instance of the protocol, indicate Not Applicable.
Amendment Scope:	[Amendment Scope] [Country/Region Identifier] Acceptable entries for amendment scope are: "global" or "Country-specific/Regional" Use the ISO-3166 region or country identifier (for example, DE or EU). For global trials delete the Country/Region Identifier field.
Compound Number(s):	[Compound Number] Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.

A graph database to rule our Metadata via the Biomedical Concept



Conclusion

Advancements in Metadata Management

- Successful generation of JSON aligned with USDM
- Highlights the efficacy of OpenStudyBuilder's approach
- Neo4j Graph database orchestrates metadata interconnections
- Planned USDM import function to enhance data integration
- Future focus on integrating M11 display for industry-standard protocols

Thank You!



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