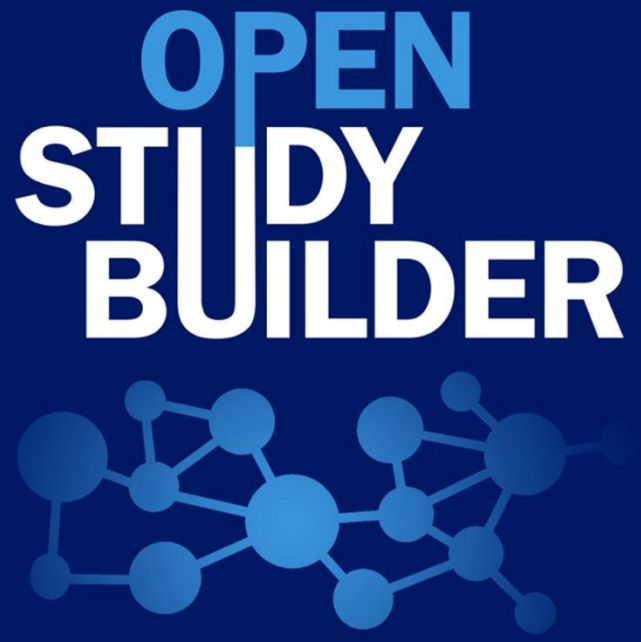
Phuse EU Connect 2024 - DH08

Leveraging the USDM Standard for Enhanced Data Exchange



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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.

Agenda

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

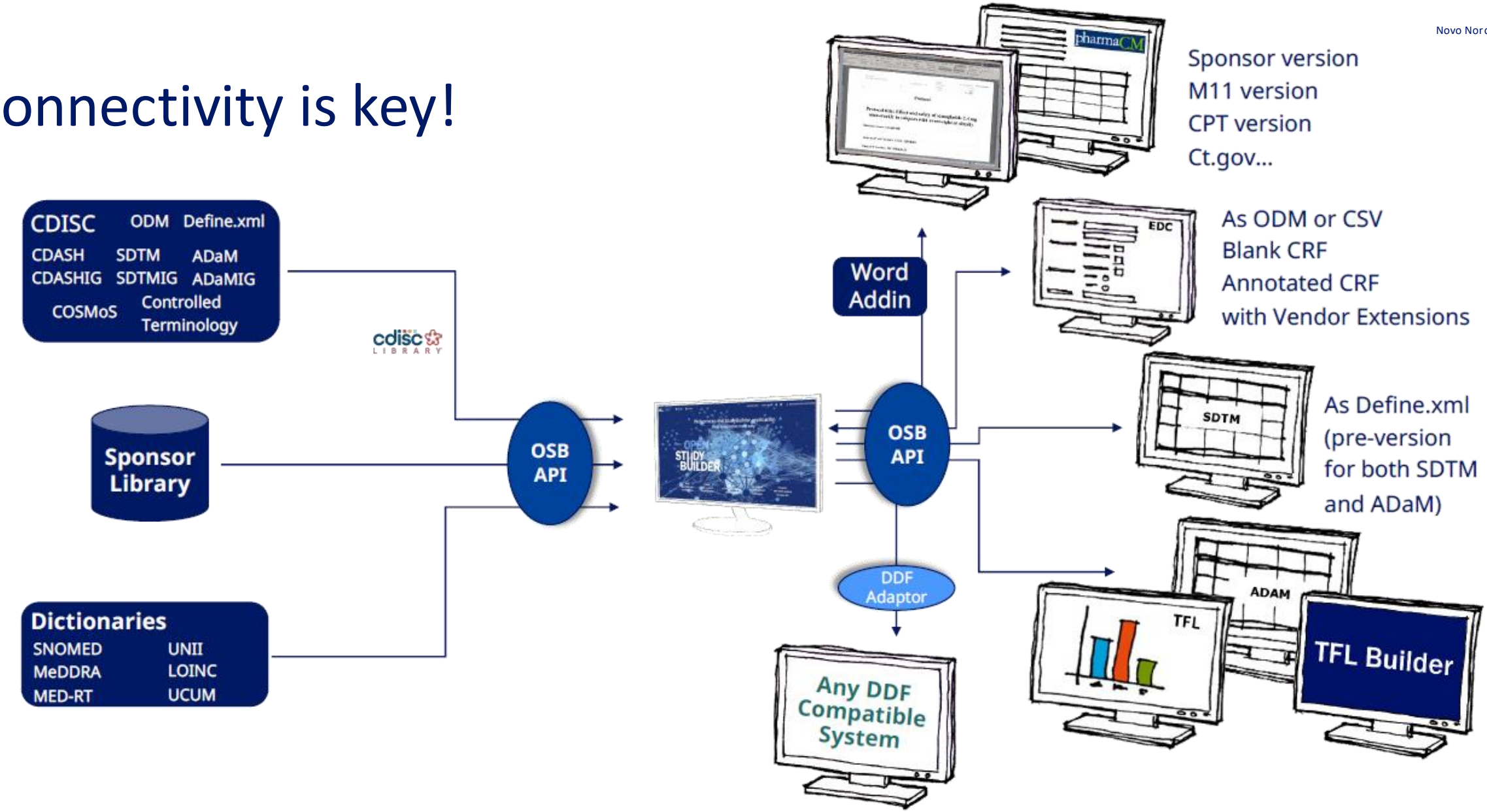
- Compliance with external and internal standards
- Facilitates automation and content reuse
- Ensures a higher degree of end-to-end consistency

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)

clinical **MDR**

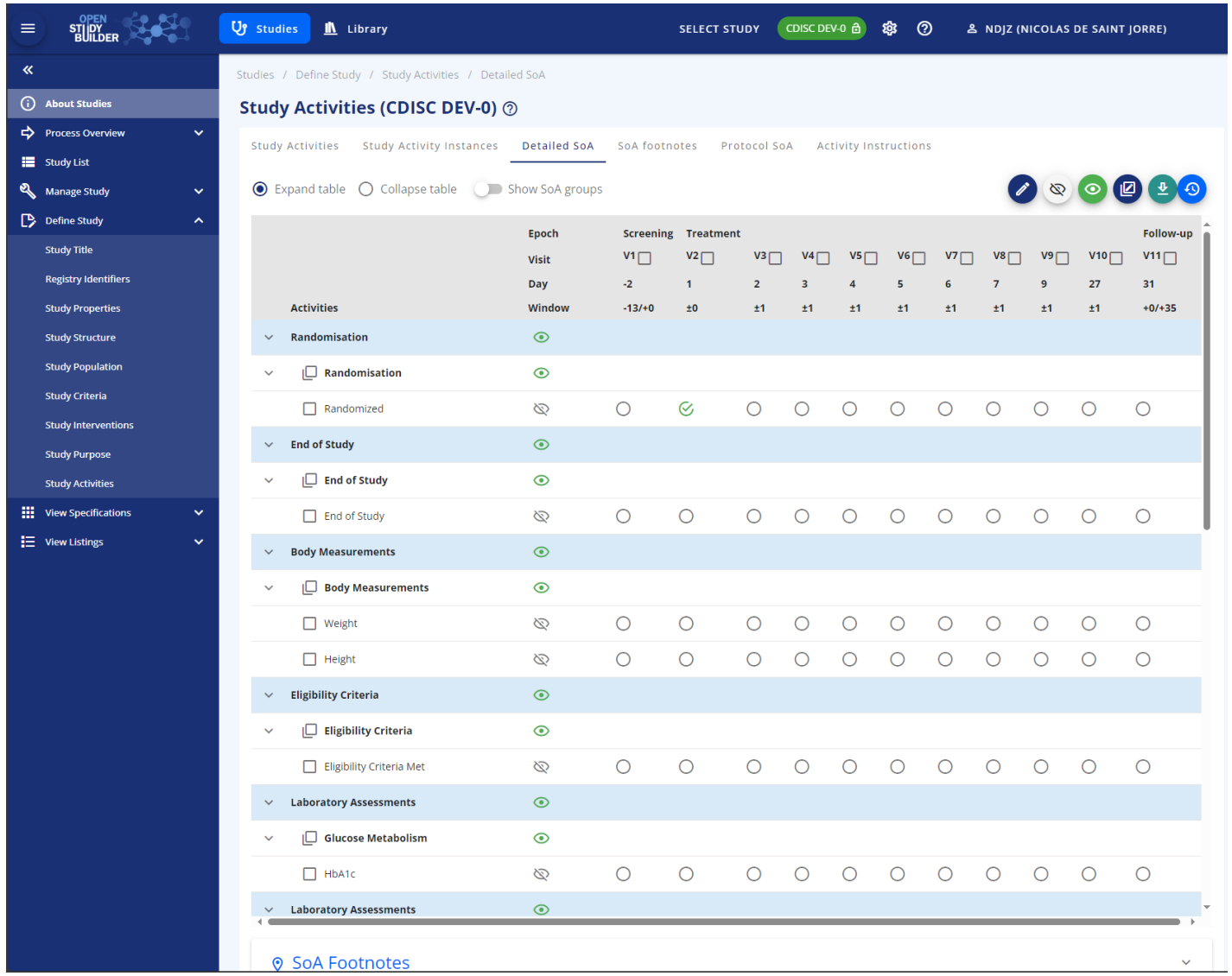
Connectivity is key!

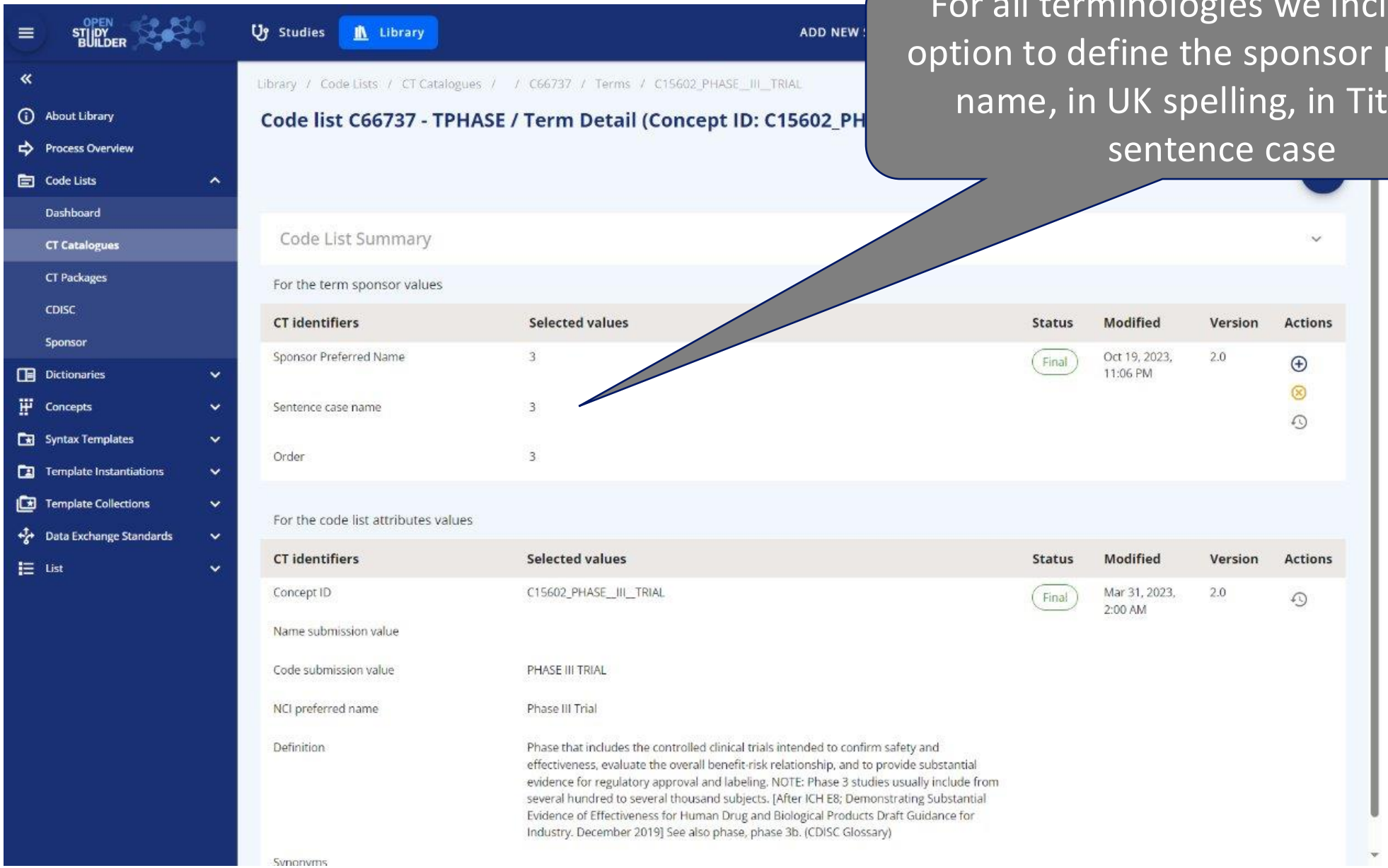


How to Specify our Electronic Protocol?

- 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

What is the DDF - USDM

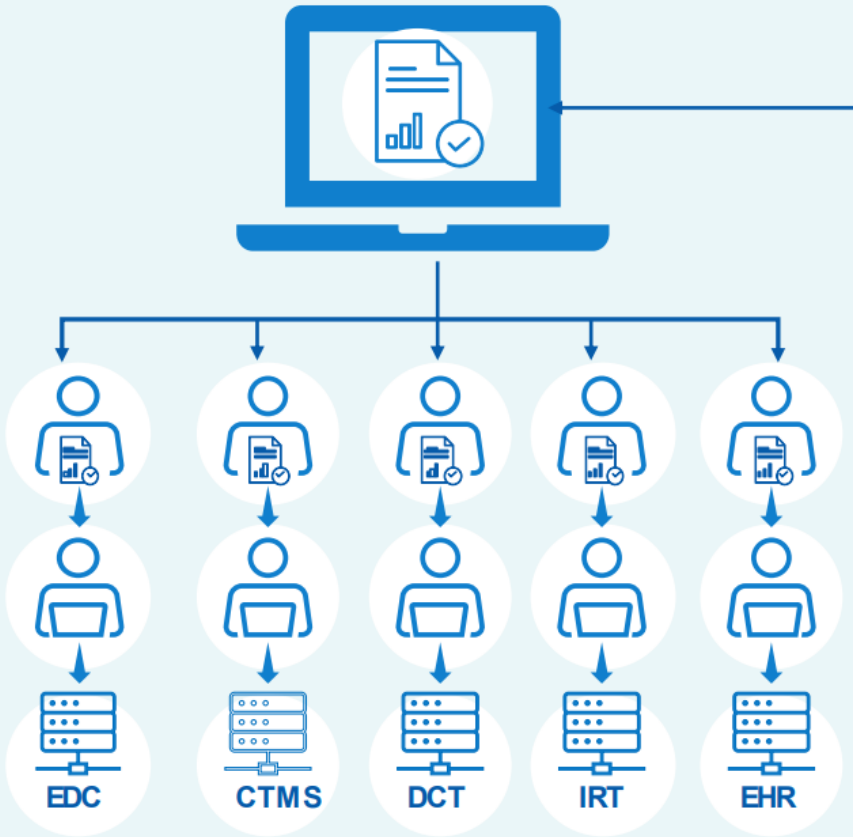
TransCelerate is specifying the Digital Data Flow Unified Study Definition Model …

https://www.transceleratebiopharmainc.com/assets/digital-data-flow-solutions/

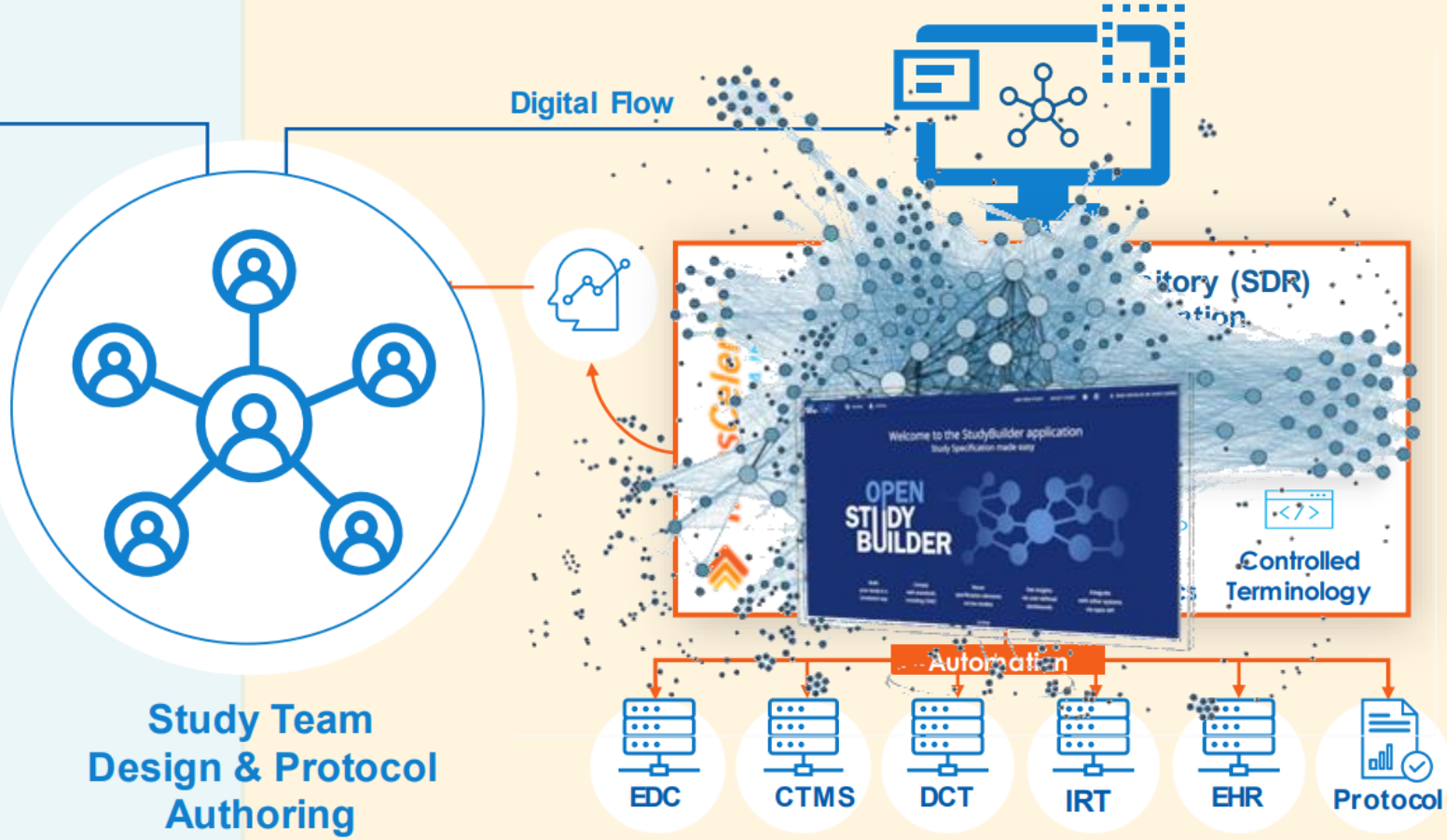
TransCelerate Digital Data Flow (DDF) Ambition

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



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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

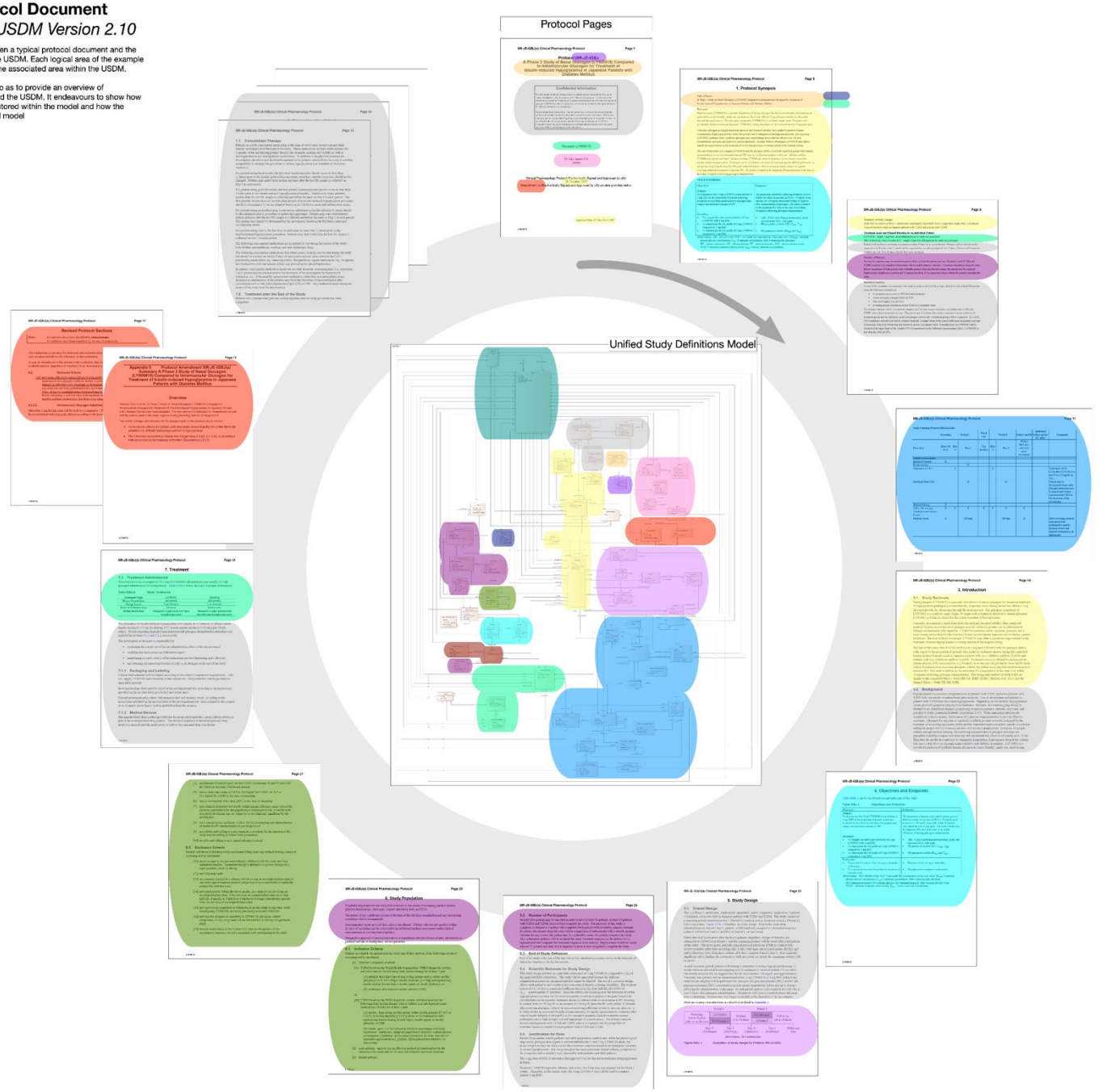
USDM

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



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

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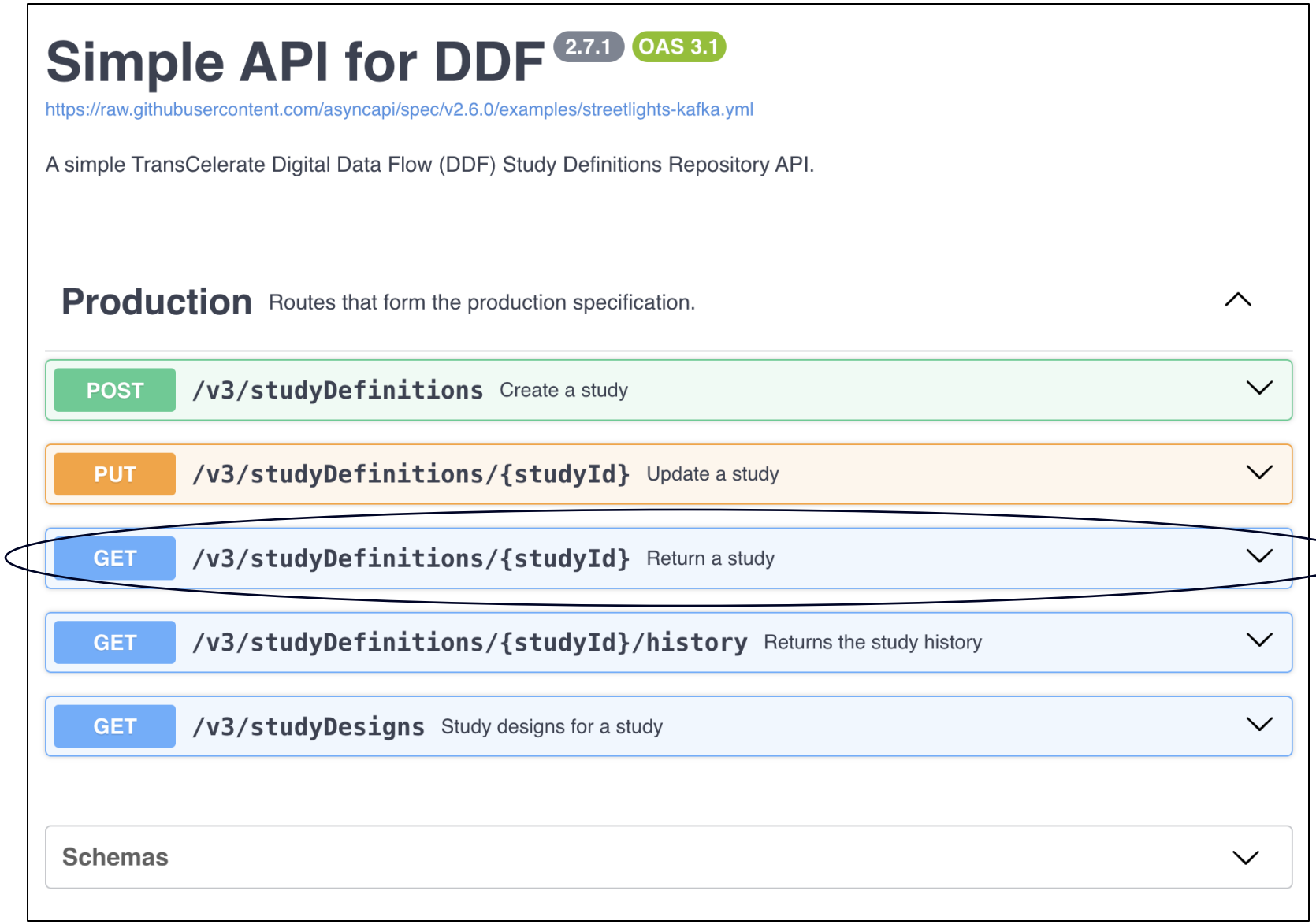
DDF USDM API Endpoint

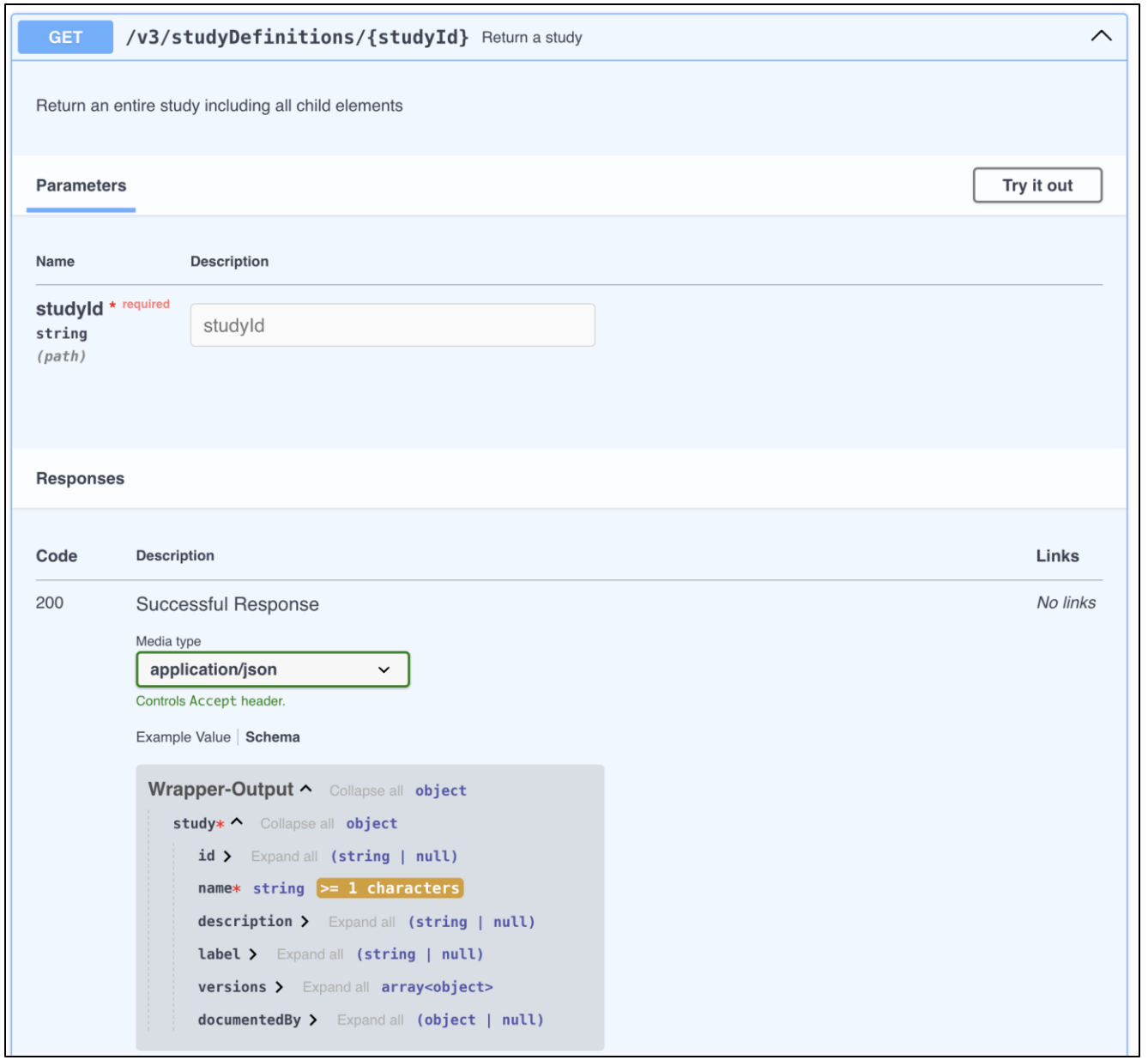
The DDF Adaptor enables:

- 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



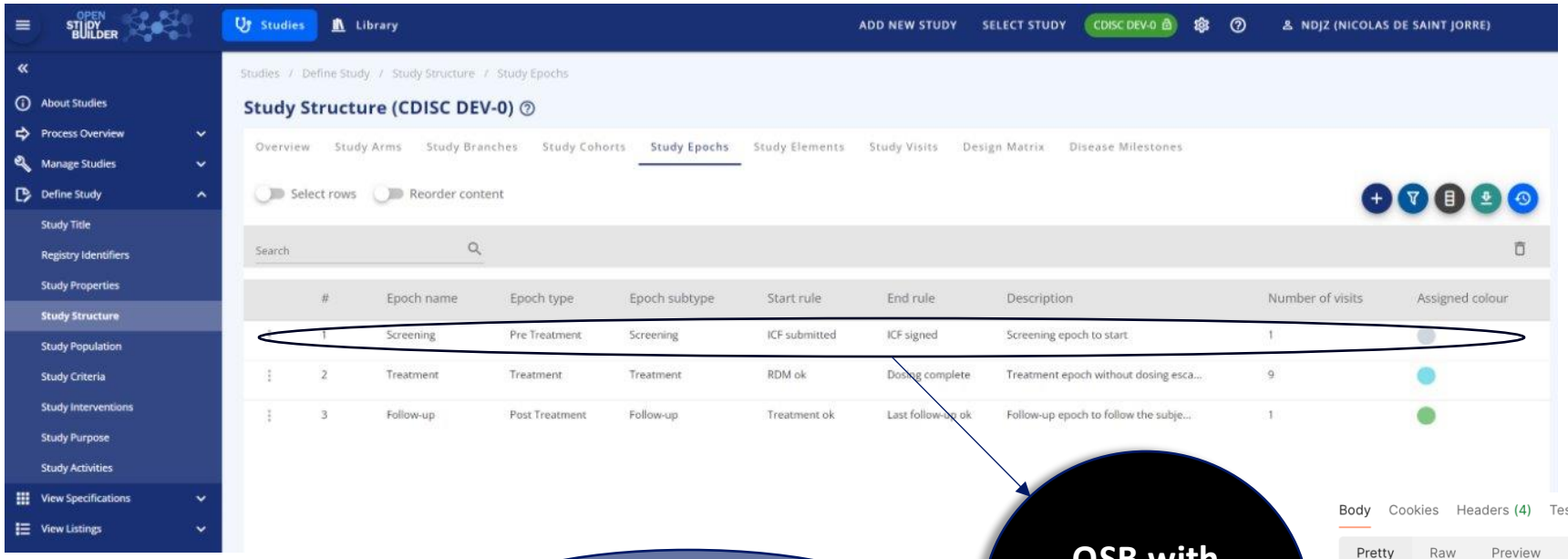
DDF API specification

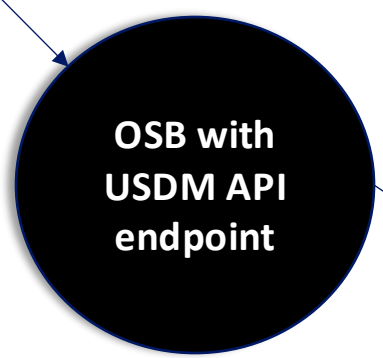


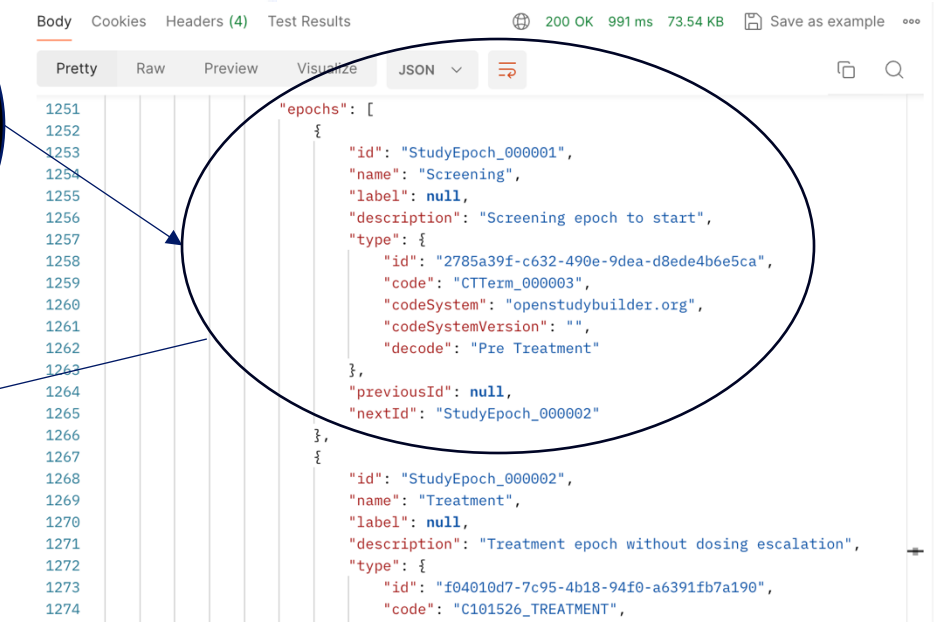
Mapping matrix between OSB and DDF

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
111	Encounter	Entity	Encounter	C142427	Clinical Encounter		Contact between subject/patient and healthcare practitioner/researcher, during	N		uuid4
112	Encounter	Relationship	transitionStartRule					N/A		entity "TransitionRule" {id: uuid4, name: 'TransitionStartRule', text: StudyVisit->start_rule}
113	Encounter	Relationship	transitionEndRule					N/A		entity "TransitionRule" {id: uuid4, name: 'TransitionEndRule', text: StudyVisit->end_rule}
114	Encounter	Relationship	scheduledAt					N/A		/
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
116	Encounter	Attribute	description	C188836	Clinical Encounter Description		A narrative representation of the protocol-defined clinical encounter.	N		StudyVisit->description
117	Encounter	Attribute	label	CNEW	Encounter Label		The short descriptive designation for the encounter.	N		/
118	Encounter	Relationship	previous					N/A		
119	Encounter	Relationship	next					N/A		
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}
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	/
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}

Digital Data Flow Adaptor (in the OpenStudyBuilder)





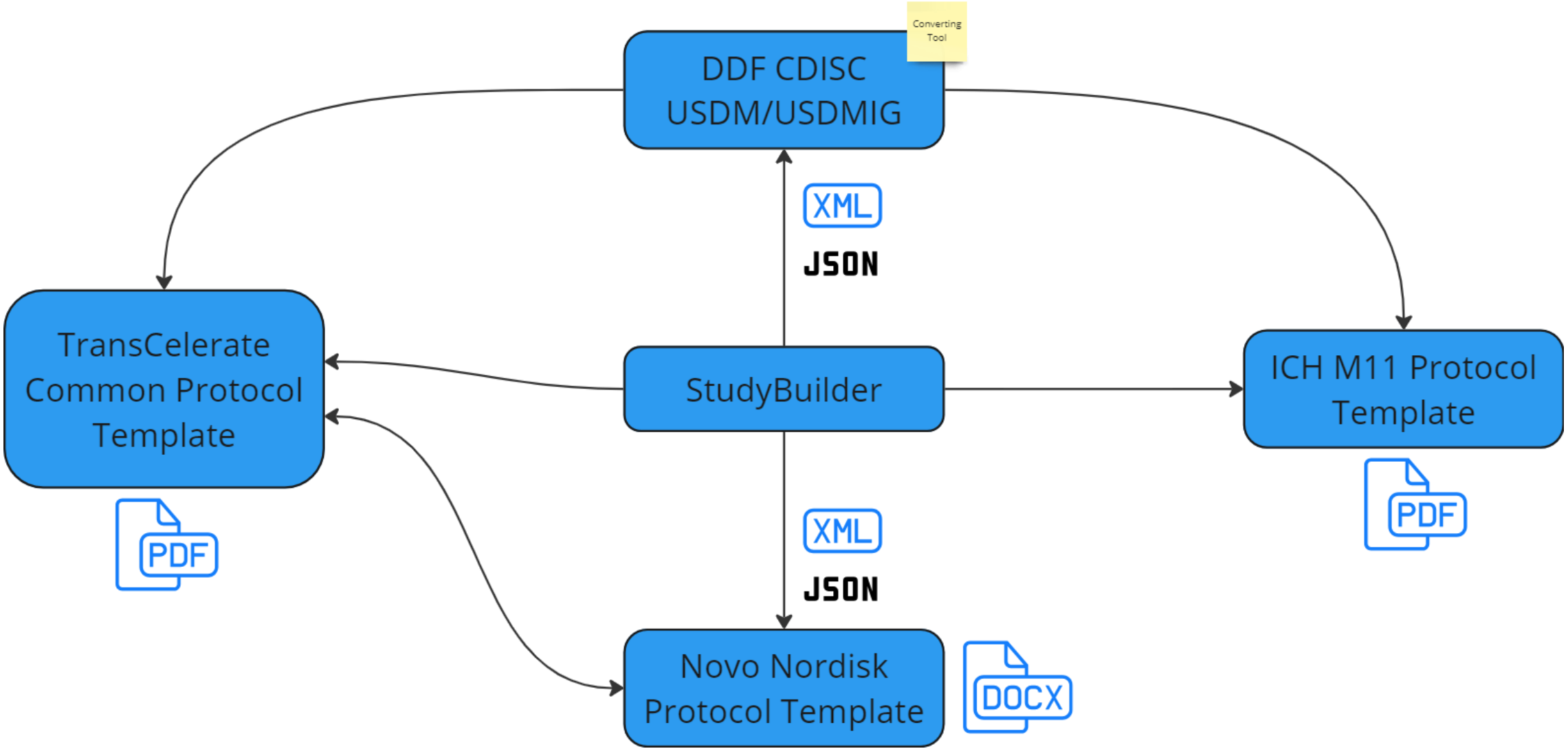


accenture

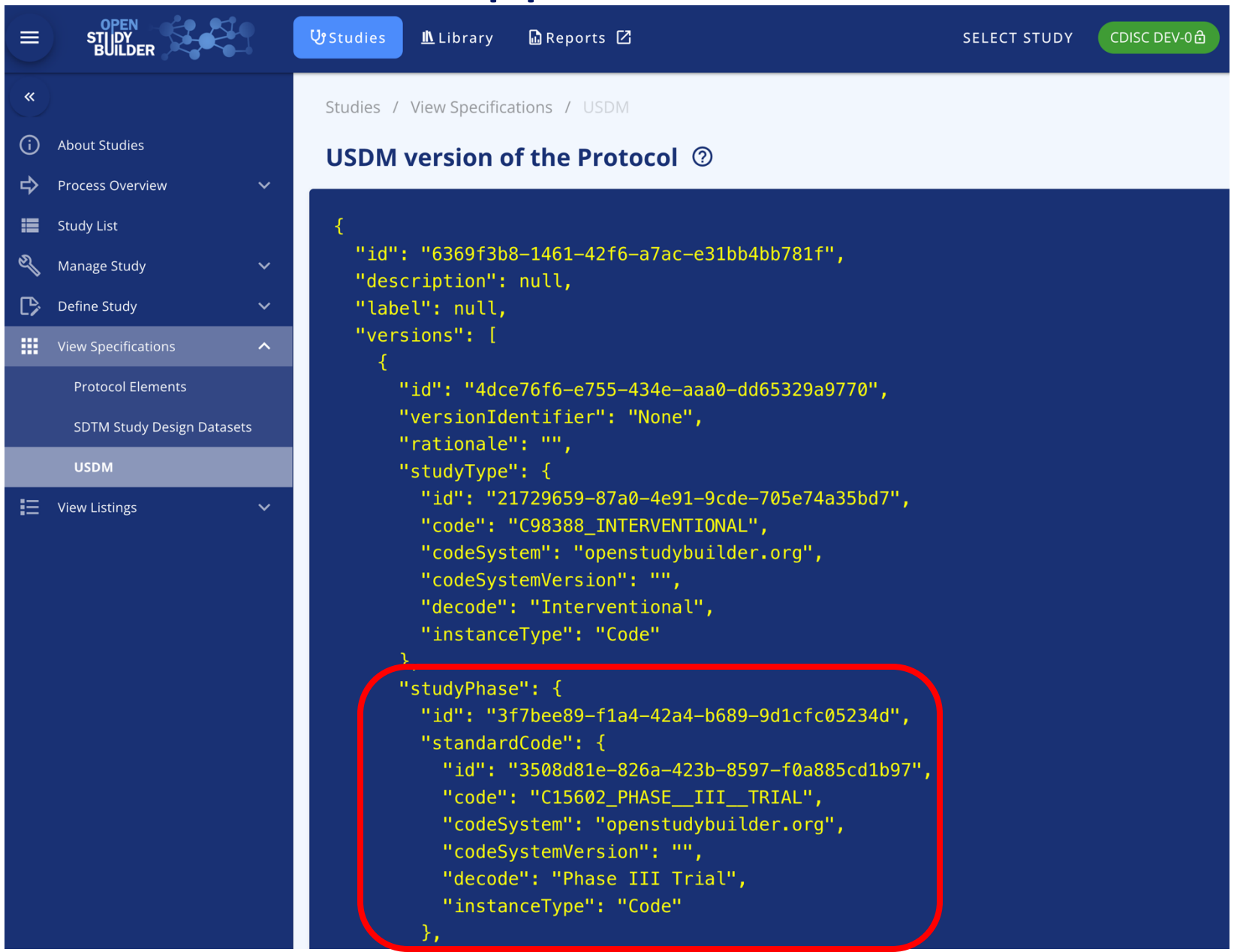
Microsoft

Export and Import ?

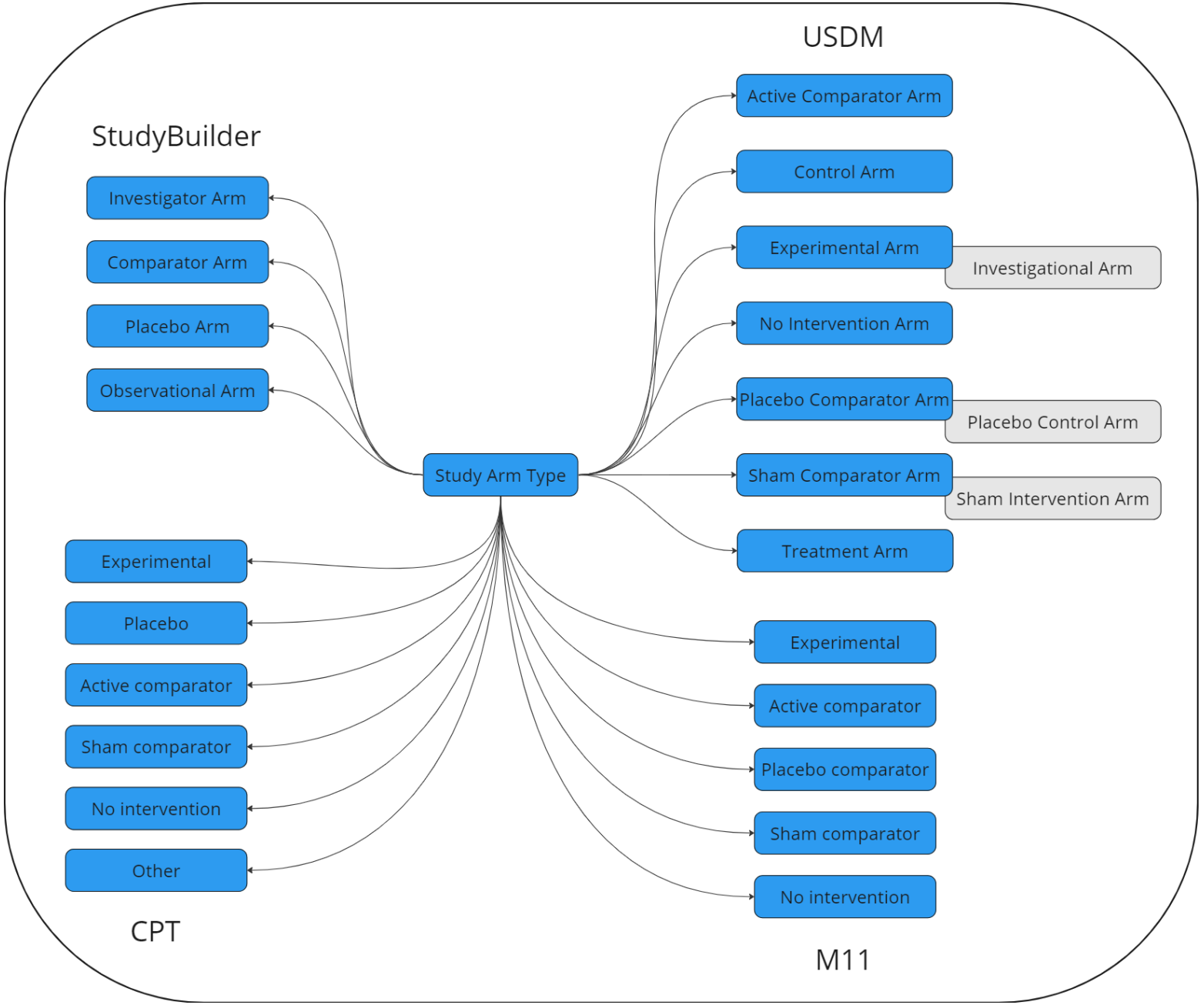
OpenStudyBuilder as a multisource system



USDM in the Front-end application



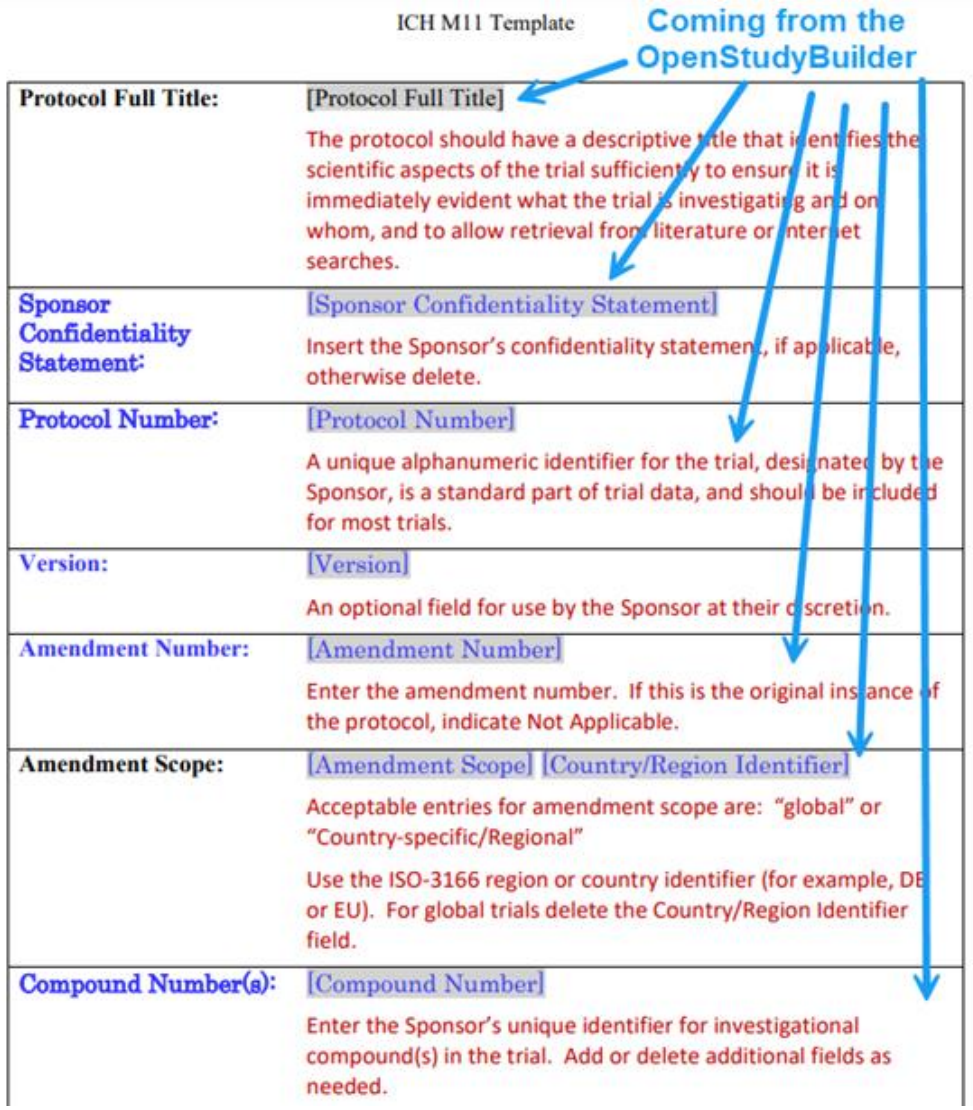
Some challenges…



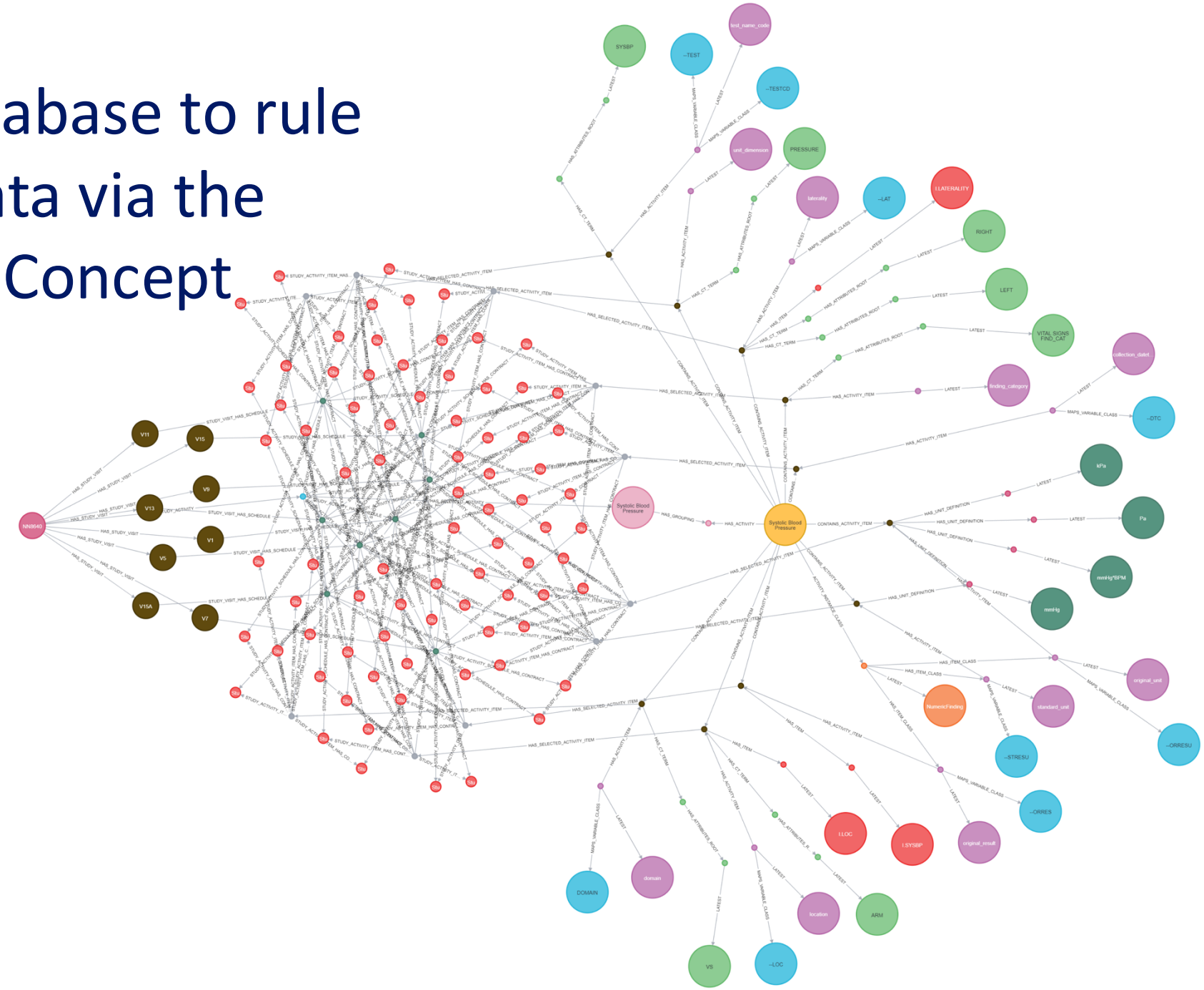
USDM to ICH - M11

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



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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