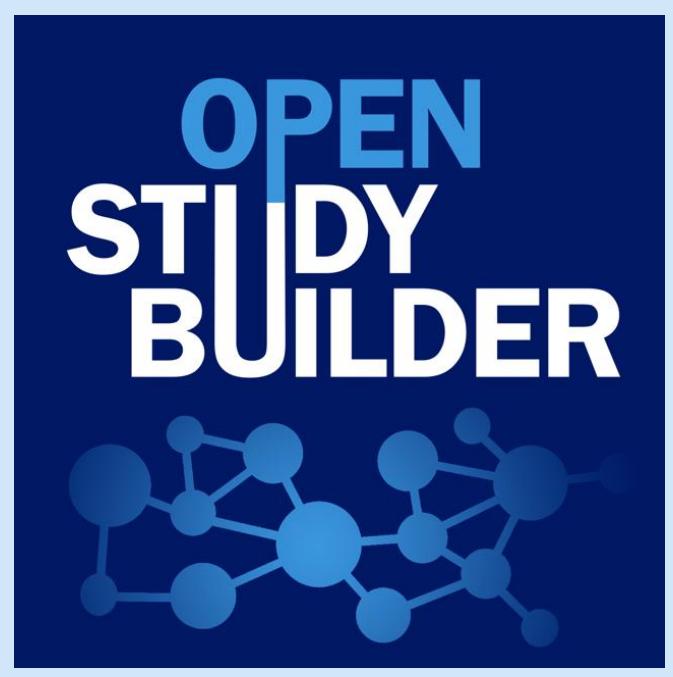




USDM & Digital Data Flow

OpenStudyBuilder Project
as Enabler

Agenda

The logo for Open Study Builder, featuring the text "OPEN STUDY BUILDER" in white on a dark blue rectangular background, with a stylized molecular or network structure icon at the bottom.

- Introduction
- USDM in OSB
- Adoption



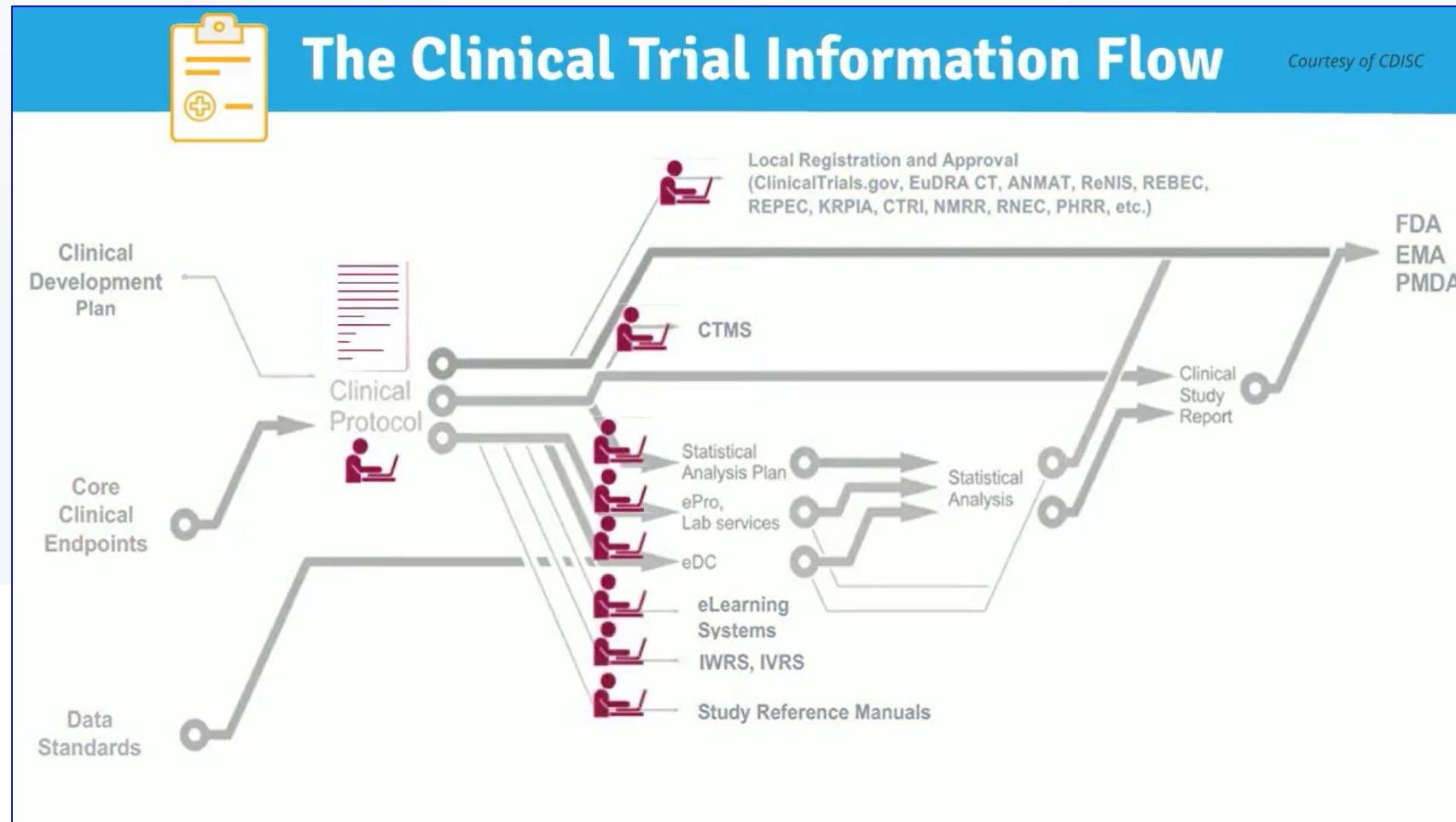
Introduction

Why do we need DDF
and the USDM Model?

Process Automation



Digital Data Flow – Problem 1



Documents
instead
Data

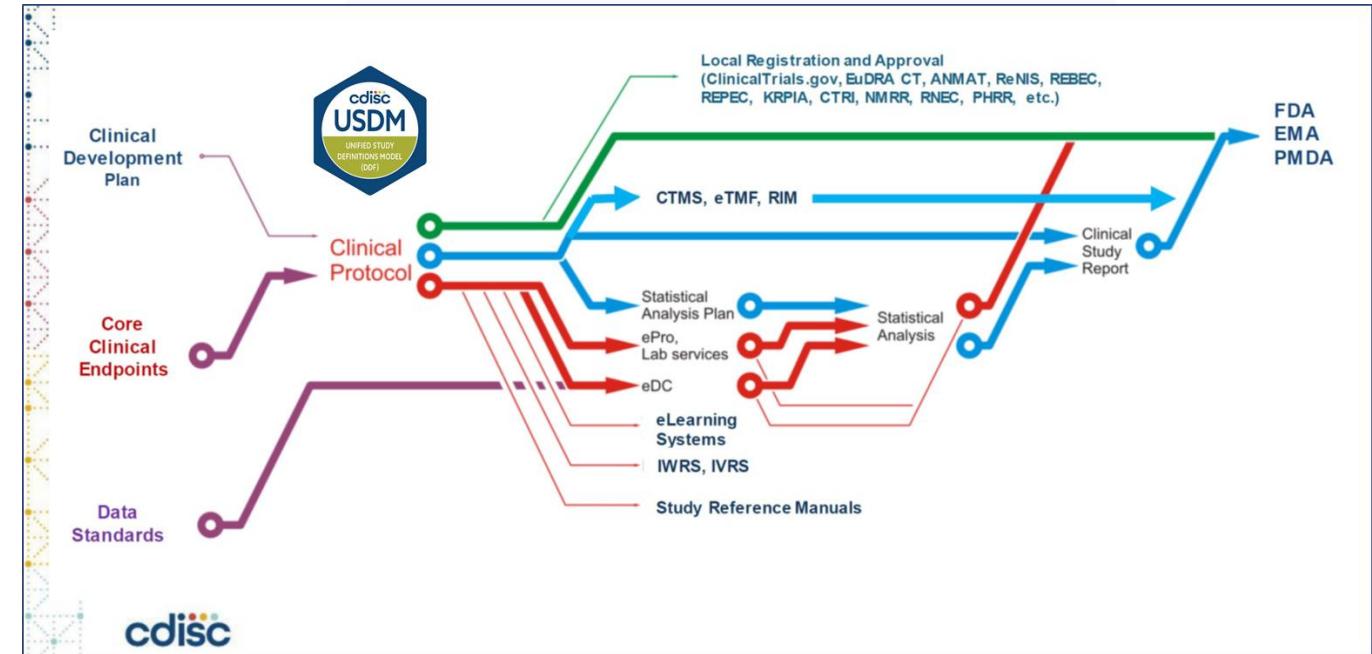
Digital Data Flow – Problem 2



Digital Data Flow – Solution

Data instead
Documents

- Data Exchange Standard (USDM)



- Electronic Protocol (ICH M11)



Digital Data Flow – Solution

Graph Database with Semantic Information

- Biomedical Concepts (CDISC)
- Linked Data Model





Way to Connected Data Landscape

A Metadata Data Repository and a Study Definition Repository

End-to-end automation from structured protocol
to submission deliverables using
concept-based standards

Core Elements

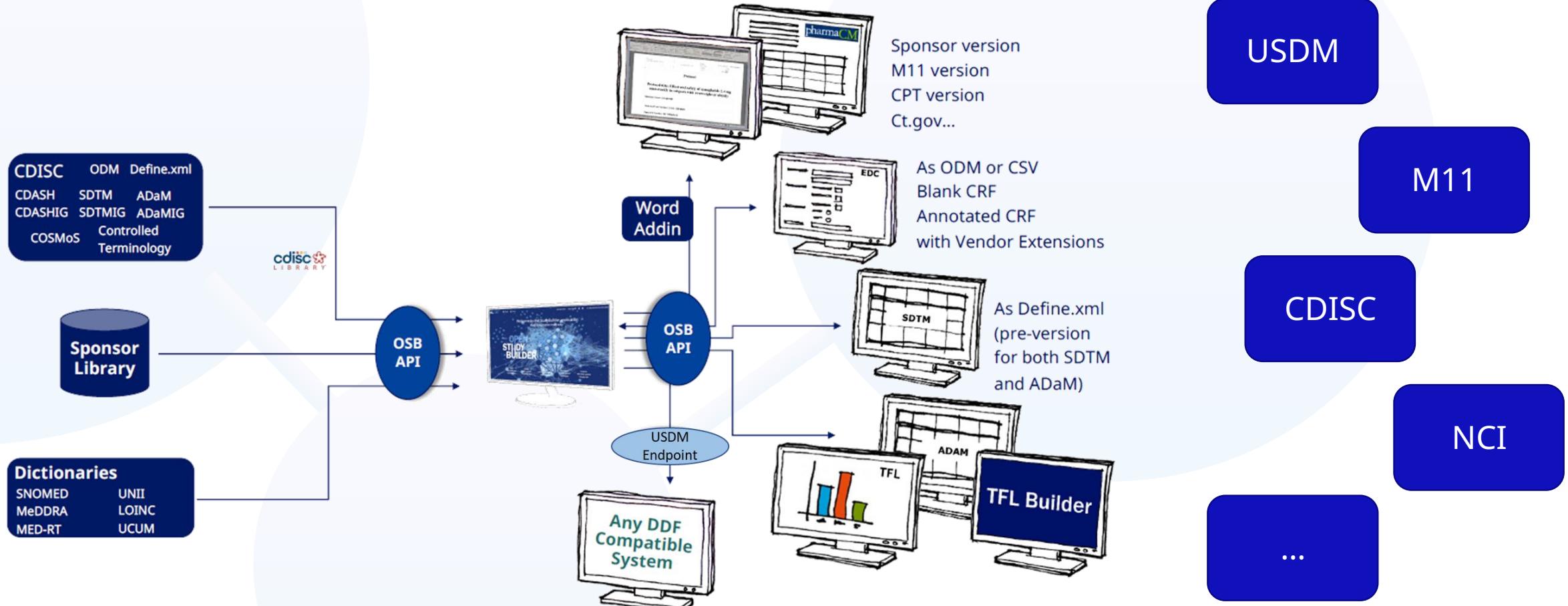
- Clinical Metadata and Study Definition Repository
- API layer
- OpenStudyBuilder application / Web UI



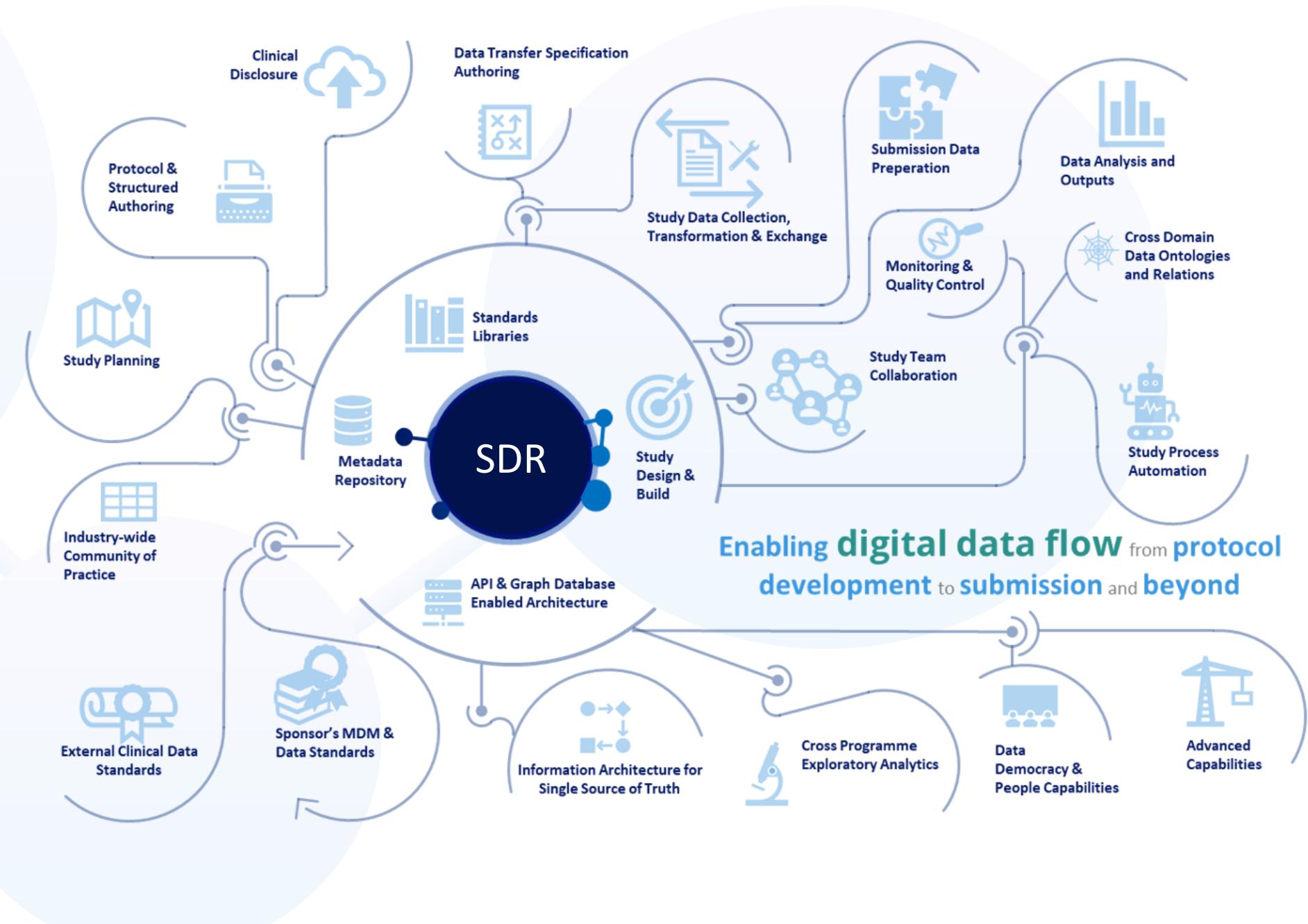
Open Source



Connectivity & Standards are Key



Opportunity Map



USDM & M11 Enabling Protocol Automation

Protocol content built in SDR

- **Population** (disease area, indication, sex, ...)
- **Study type** (interventional, observational, ...)
- **Study design** (random., blinding, arms, ...)
- **Schedule of Activities** (naming, timing, type, windows)
- **Study purpose** (objectives, endpoints)
- **Selection criteria** (eligibility, withdrawal, ...)
- **Interventions** (drug, dose, route, other ...)

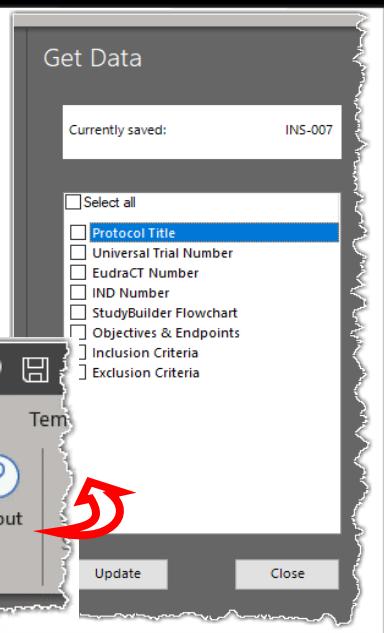
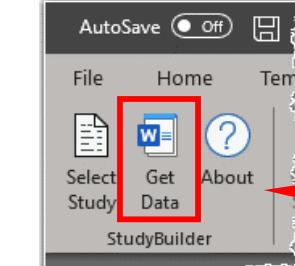
Supported by library capabilities for endpoints, eligibility criteria and assessments.

Define Study

- Study Title
- Registry Identifiers
- Study Properties
- Study Structure
- Study Population
- Study Criteria
- Study Interventions
- Study Purpose
- Study Activities

Word Add-in in Protocol Template

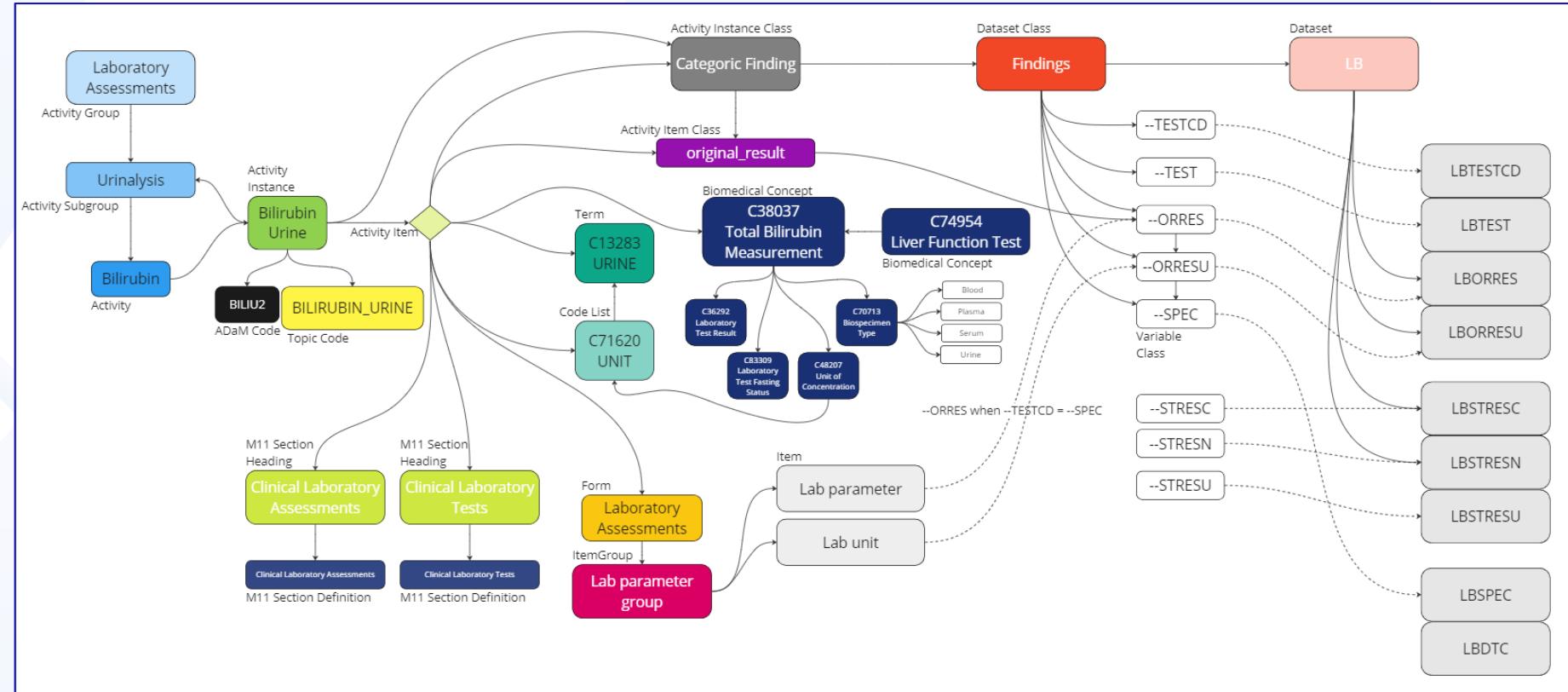
- One-way connection
- Code recognizes the document type
- User-friendly ribbon and 'fly-out' in Word
- Styles ensure proper formatting in Word



Biomedical Concepts drive Digital Data Flow

Connect to Flow - define once & use many

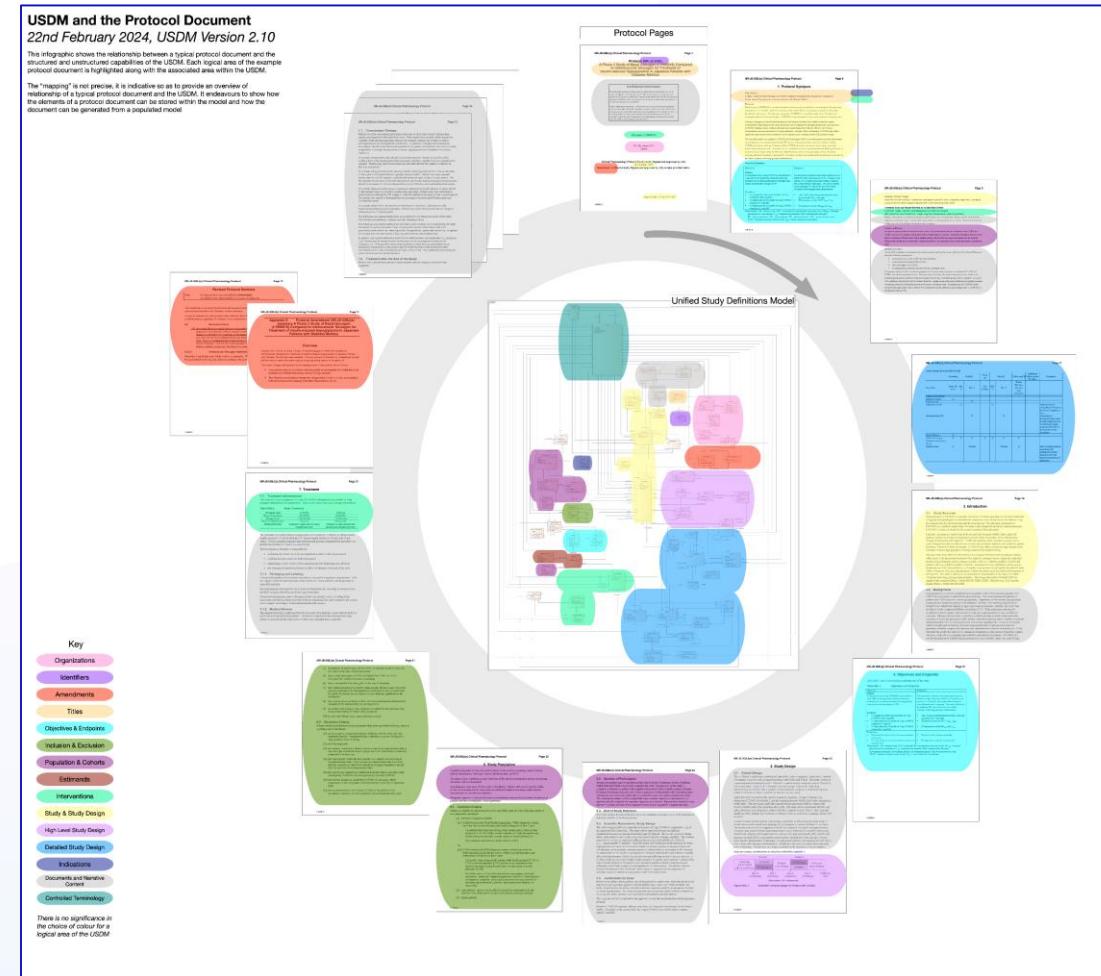
- Protocol definition
- CRF utilization
- EDC specification
- SDTM definition
- ADAM definition





USDM in
OpenStudyBuilder

The USDM Model

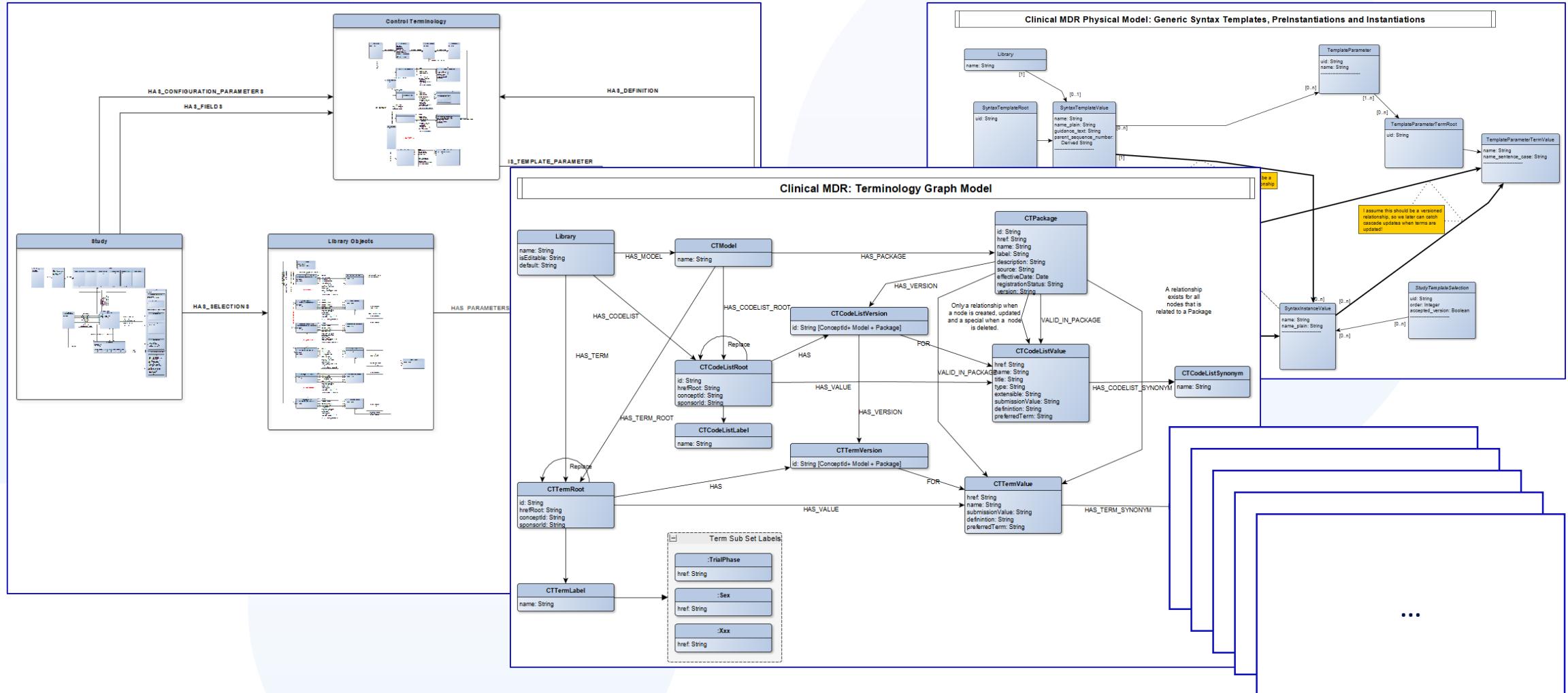


Key

- 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

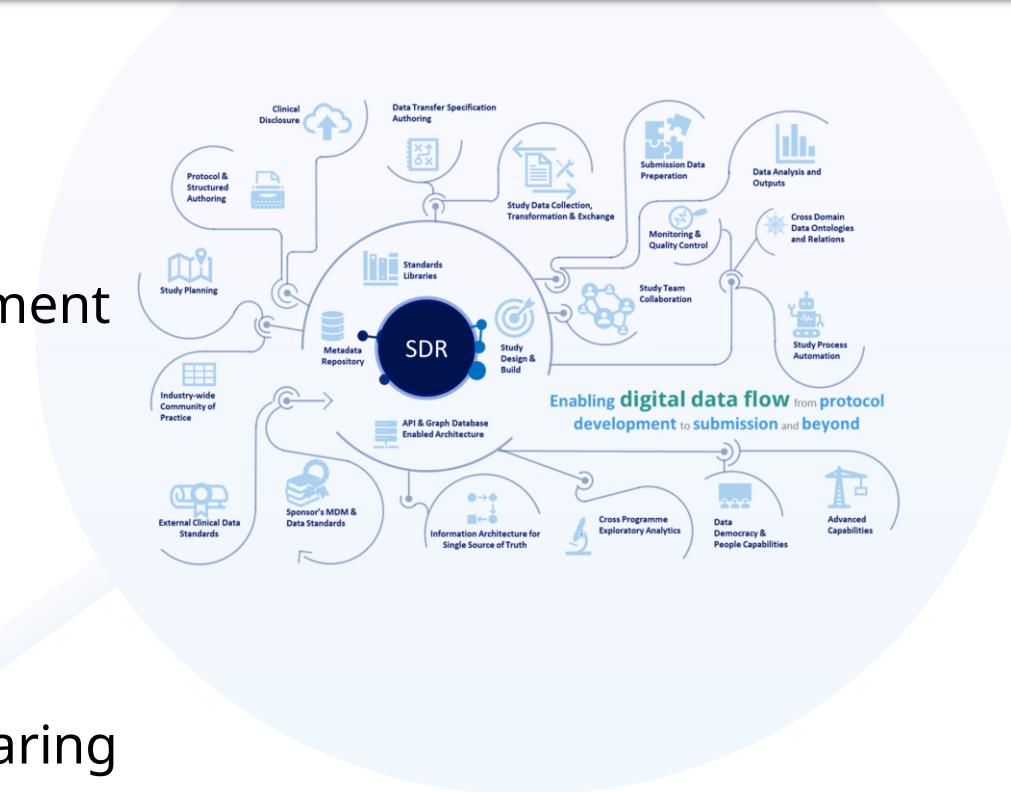
The OSB Model



USDM Endpoint Enabling new Use Cases

USDM Export 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

	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	Synonyms(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 Terminolog	https://ncit.nci.nih.gov/ncitbrowser/ajax?action=create_src_vs_type&uri=http://evsd.uri	/
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 Terminolog y Codelist C171445)	https://ncit.nci.nih.gov/ncitbrowser/ajax?action=create_src_vs_type&uri=http://evsd.uri	list of entity "Code" {id: uuid4, code: StudyVisit->visit_contact_mode_uid, codeSystem: 'openstudybuilder.org', decode: StudyVisit->visit_contact_mode_uid}

API – The DDF Endpoint

DDF endpoints

GET /ddf/v3/studyDefinitions/{study_uid} Return an entire study in DDF USDM format

State before:

- Study must exist.

State after:

- no change.

Possible errors:

- Invalid study-uid.

Parameters

Try it out

Name	Description
study_uid * required	The unique uid of the study. string (path)
study_uid	

Responses

Curl

```
curl -X 'GET' \
  'https://openstudybuilder.northeurope.cloudapp.azure.com/api/ddf/v3/studyDefinitions/Study_000001' \
  -H 'accept: application/json' \
  -H 'Authorization: Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsImtpZCI6IjNQYUs0RWZ5Qk5RdTNDdGpZc2EzMW1oUTVFMCIiLCJodHRwOi8vY2FsbGVjdW1lbnQuY29udmVydC5hZG1pbi5jb20iOiJodHRwOi8vY2FsbGVjdW1lbnQuY29udmVydC5hZG1pbi5jb20vY29udmVydC9v393LzIiLCJ9' --insecure
```

Request URL

https://openstudybuilder.northeurope.cloudapp.azure.com/api/ddf/v3/studyDefinitions/Study_000001

Server response

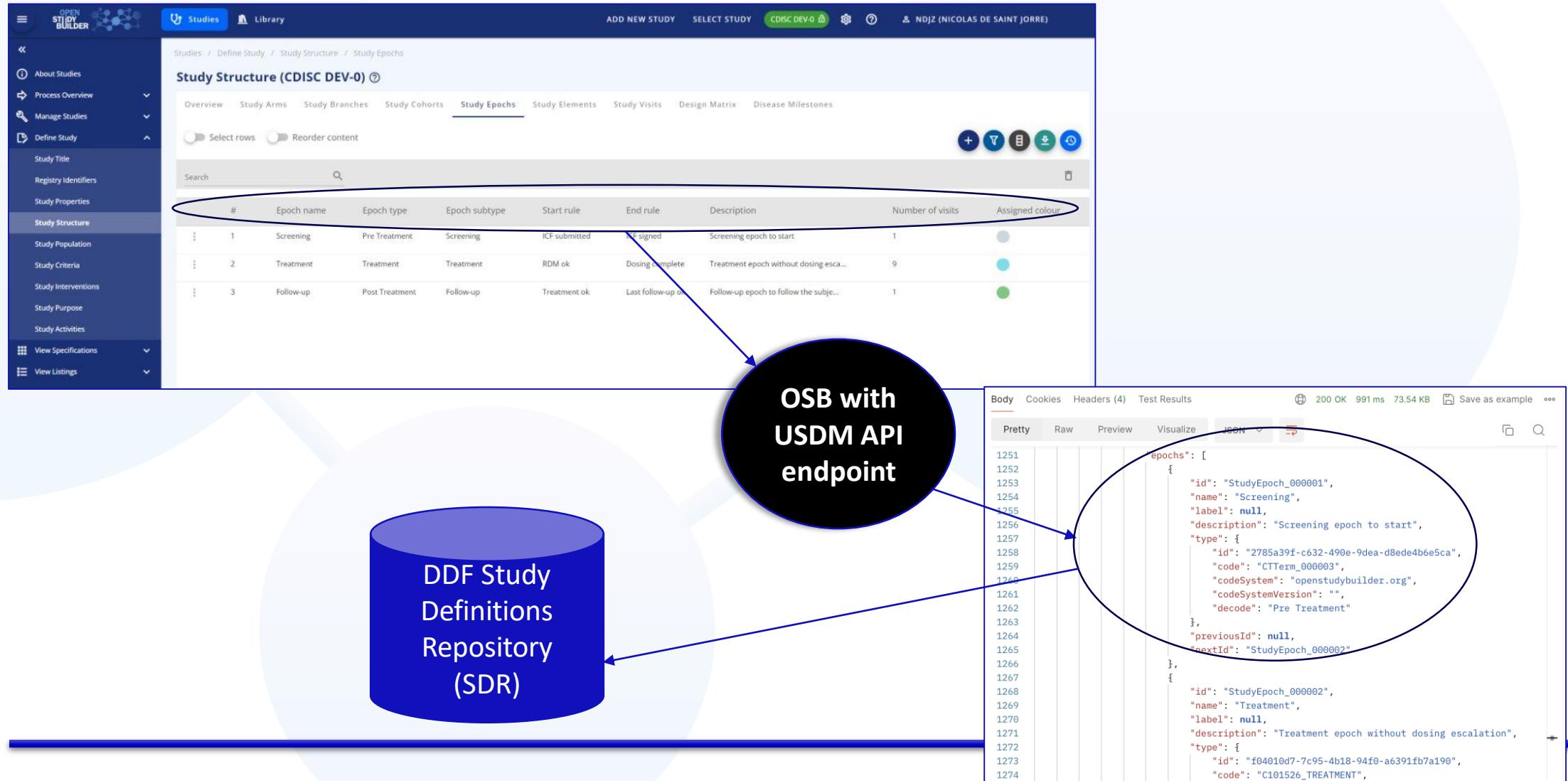
Code Details

200 Response body

```
{
  "id": "483e94ee-1c13-4d27-a09d-8cad4751be47",
  "description": null,
  "label": null,
  "versions": [
    {
      "id": "41c68aa1-1424-4cff-a05c-d15be56c977f",
      "versionIdentifier": "None",
      "rationale": "",
      "studyType": {
        "id": "70a6fb49-f23a-4991-b49a-188364fe120e",
        "code": "C98388_INTERVENTIONAL",
        "codesystem": "openstudybuilder.org",
        "codesystemVersion": "",
        "decode": "Interventional",
        "instanceType": "Code"
      },
      "studyPhase": {
        "id": "db765cd8-0c0f-464d-8ccd-9372101d8370",
        "standardCode": {
          "id": "7360a2be-b088-4698-a22d-7d4143bbfa84",
          "code": "C15602_PHASE_III_TRIAL",
          "codesystem": "openstudybuilder.org",
          "codesystemVersion": "",
          "decode": "Phase III Trial",
          "instanceType": "Code"
        }
      }
    }
  ]
}
```

Download

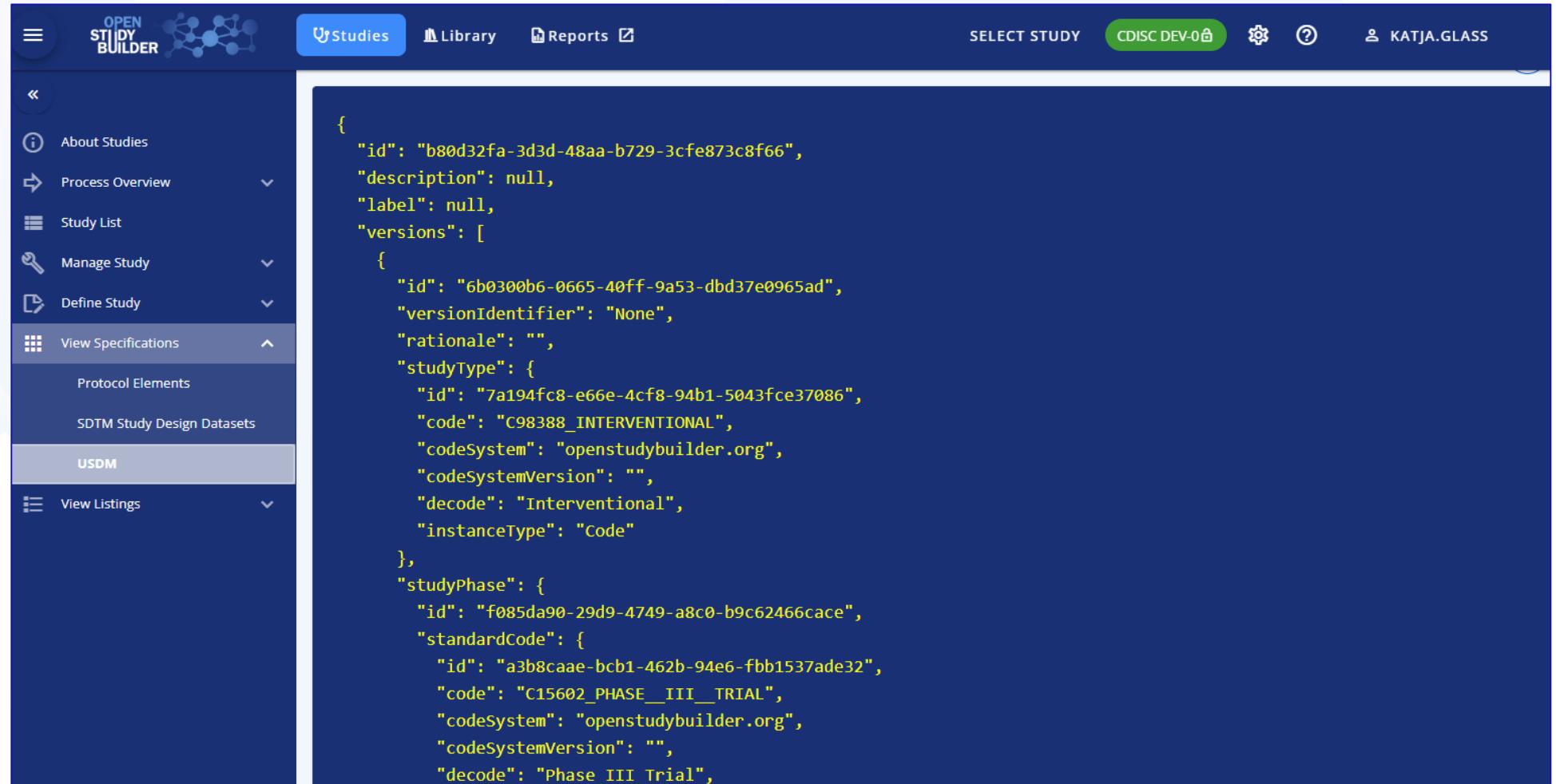
API – The DDF Endpoint



DDF Endpoint in UI

Raw USDM
display

M11
Rendering



The screenshot shows the Open Study Builder application interface. The top navigation bar includes links for 'Studies', 'Library', 'Reports', 'SELECT STUDY' (set to 'CDISC DEV-0'), and user information ('KATJA.GLASS'). The left sidebar menu has sections like 'About Studies', 'Process Overview', 'Study List', 'Manage Study', 'Define Study', 'View Specifications' (which is expanded to show 'Protocol Elements' and 'SDTM Study Design Datasets'), 'USDM' (which is selected and highlighted in grey), and 'View Listings'. The main content area displays a raw JSON object representing a study specification:

```
{
  "id": "b80d32fa-3d3d-48aa-b729-3cfe873c8f66",
  "description": null,
  "label": null,
  "versions": [
    {
      "id": "6b0300b6-0665-40ff-9a53-dbd37e0965ad",
      "versionIdentifier": "None",
      "rationale": "",
      "studyType": {
        "id": "7a194fc8-e66e-4cf8-94b1-5043fce37086",
        "code": "C98388_INTERVENTIONAL",
        "codeSystem": "openstudybuilder.org",
        "codeSystemVersion": "",
        "decode": "Interventional",
        "instanceType": "Code"
      },
      "studyPhase": {
        "id": "f085da90-29d9-4749-a8c0-b9c62466cace",
        "standardCode": {
          "id": "a3b8caae-bcb1-462b-94e6-fbb1537ade32",
          "code": "C15602_PHASE_III_TRIAL",
          "codeSystem": "openstudybuilder.org",
          "codeSystemVersion": "",
          "decode": "Phase III Trial",
        }
      }
    }
  ]
}
```



DDF Controlled Terminology

Library / Code Lists / CT Catalogues / DDF CT

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

Search Search with terms or Select rows

	Library	Sponsor preferred name	Template parameter	Code list status	Name modified	Concept ID	Submission value	Code list name	NCI Preferred name	Extensible	Attributed
...	CDISC	Environmental Setting	No	Final	Apr 18, 2024, 9:45 AM	C127262	SETTING	Environmental Setting	CDISC SDTM Environmental Setting Terminology	Yes	Fhir
...	CDISC	Mode of Subject Contact	No	Final	Apr 18, 2024, 9:53 AM	C171445	CNTMODE	Mode of Subject Contact Terminology	CDISC SDTM Mode of Subject Contact Terminology	Yes	Fhir
...	CDISC	Study Arm Type Value Set Terminology	No	Final	Apr 18, 2024, 9:53 AM	C174222	Study Arm Type Value Set Terminology	Study Arm Type Value Set Terminology	CDISC Protocol Study Arm Type Value Set Terminology	No	Fhir
...	CDISC	DDF Entity Terminology	No	Final	Apr 18, 2024, 9:58 AM	C188698	DDF Entity Terminology	DDF Entity Terminology	CDISC DDF Entities Terminology	No	Fhir
...	CDISC	DDF Clinical Study Attribute Terminology	No	Final	Apr 18, 2024, 9:58 AM	C188699	DDF Clinical Study Attribute Terminology	DDF Clinical Study Attribute Terminology	CDISC DDF Clinical Study Attribute Terminology	No	Fhir
...	CDISC	DDF Study Protocol Version Attribute Terminology	No	Final	Apr 18, 2024, 9:58 AM	C188700	DDF Study Protocol Version Attribute Terminology	DDF Study Protocol Version Attribute Terminology	CDISC DDF Study Protocol Version Attribute Terminology	No	Fhir
DDF Study Identifier											

Rows per page: 10 | 1-10 of 54 | < < > >

USDM to ICH M11

Integration of ICH M11 Template in OBS:

- 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		Coming from the OpenStudyBuilder
Protocol Full Title:	[Protocol Full Title]	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.



DDF Adoption

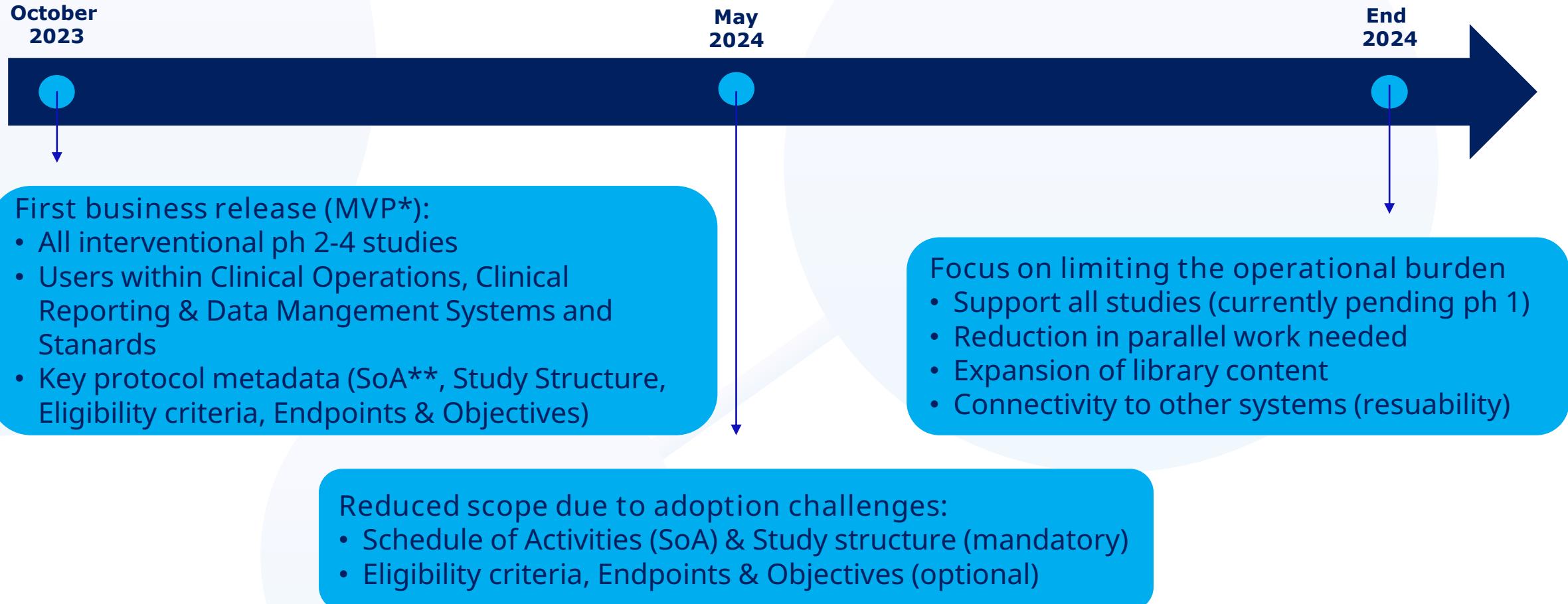
DDF Adoption



Structured Protocol vs. Free Text Flexibility

- Adopt to predefined template blocks instead of free writing
- Select and manage template blocks in another tool (not Word)
- Loss of writing flexibility for the purpose of standardization & reuse
- Complex study design modelling in standard context difficult
- Adoption for Protocol Writers need time, understanding and continuous enhancements based on feedback

DDF Adoption - Scoping



* MVP = Minimal Viable Product

** SoA = Schedule of Activities

DDF Adoption – Lessons Learned

People

- Early **involvement** of end users is key
- Data instead of documents requires a large **change management** effort
- Sufficient **resources** within management, product team and impacted business areas is crucial
- Continuous **user feedback** is essential

Process

- **Standardization** and sharing of meta data is needed, but difficult to implement
- Keeping releases **small** and **frequent**
- **Pilot** studies speed up the identification of issue, but might prolong the first release
- Clear project **ownership** is important when implementing a cross functional product

Technology

- Clear **business value** – short term and long term – is essential
 - System **performance** key
-



DDF Adoption – Key to Success

Address Challenges

Share Opportunities

Integration Support

Gather Feedback

Harmonize Standards

Collaborate on Open Source

DDF Adoption – Key to Success





Community
OpenStudyBuilder@gmail.com

Community manager
katja.glass@glacon.eu

Developer (Nicolas)
ndjz@novonordisk.com

Thanks!





OpenStudyBuilder Links

- Project Homepage: <https://openstudybuilder.com/>
- Newsletter: <https://www.linkedin.com/newsletters/openstudybuilder-6990328054849916928/>
- YouTube Demonstration (30'): <https://youtu.be/dL5CY0BwfEs>
- GitLab (Solution, Description): <https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder>
- Slack: https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyilvB1Wsw
- E-Mail: openstudybuilder@gmail.com

Sandbox:

- Mail openstudybuilder@neotechnology.com – Subject “Request Sandbox access”
 - Note: when add/modify/delete, your mail might be exposed in the version history
-