



Digital Data Flow (DDF) Solution Showcase

December 05, 2024

Presenting Organizations:
Risklick and Novo Nordisk



Agenda

Topic

Welcome, Background, Webinar Logistics & Ground Rules

Presenting company 1: Risklick – 30 mins

Presenting company 2: Novo Nordisk – 30 mins

Q & A with Panelists

Closing

Today's Presenters

Risklick and Novo Nordisk



Poorya Amini

Founder & CEO
Risklick



Nicolas de Saint Jorre

Lead Product Architect
Novo Nordisk

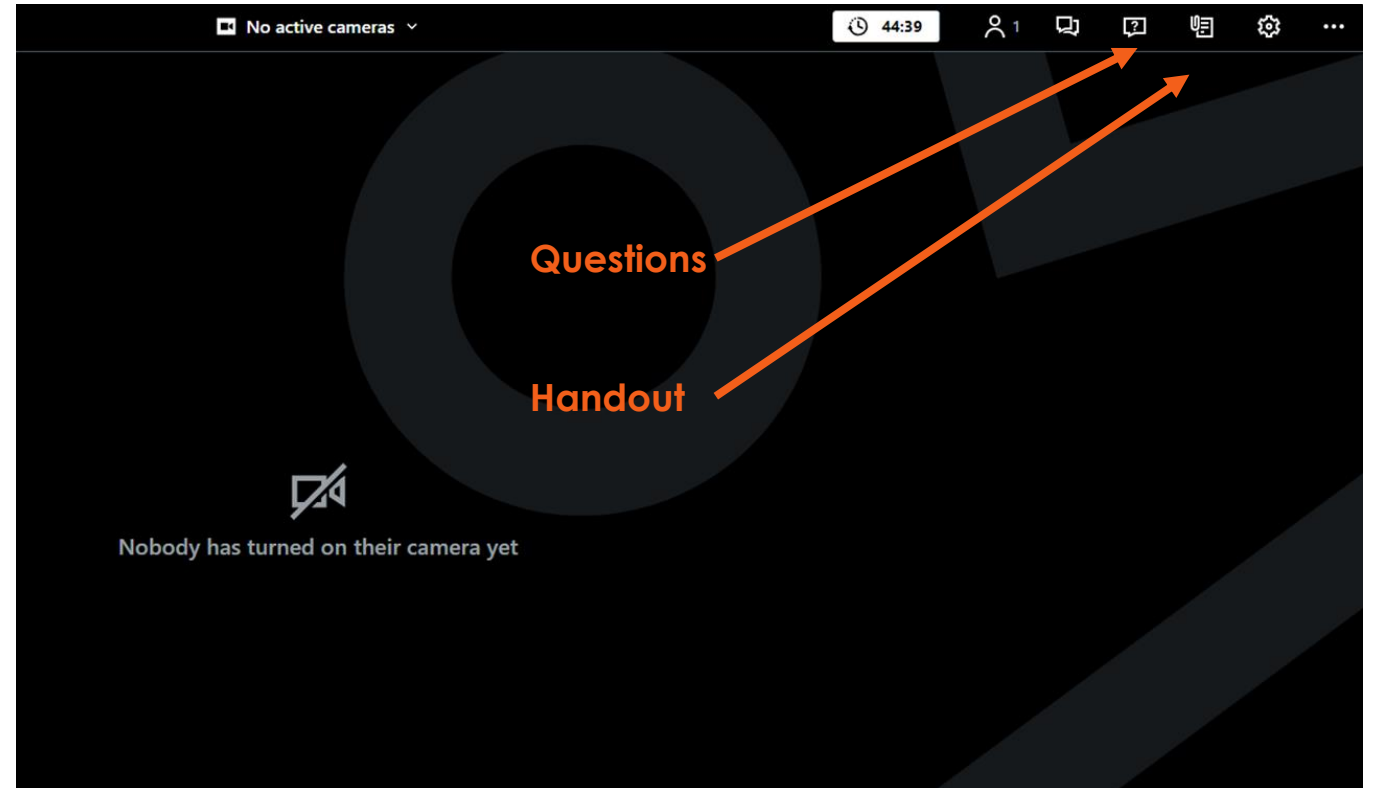


Katja Glaß

Open-Source Ambassador,
Consultant
Novo Nordisk (Contractor)

Logistics for the Webinar

- **All participants will be muted for this call.**
- **For audio:** Connect to audio to listen to presentations via your computer or phone
- **To submit a question to the presenters:**
 - Type your question in the Questions panel and click Send.



Reminder: This webinar may be recorded in whole or in part.

Ground Rules

- **We want to make this discussion helpful and answer as many of your questions as we can, so here are some quick ground rules:**
 - Participation is voluntary, as is using TransCelerate assets/tools
 - The responsibility for compliance with laws and regulations is owned by the solution adopter
 - You don't have to identify what company you work for
- **Things we would ask you not to post questions on:**
 - For clinical trial sponsors, what vendors/sites/CROs a company is working with or not working with
 - For tech companies, vendors, CROs, & others, what pharma companies you work with or don't work with
 - Any issues/criticisms companies have with any vendors, tech company, sites, CROs, or sponsors
 - Future and long-term development plans
 - Anything related to pricing or costs -- what you pay for the purchase of or receive for the sale of any goods or services
- **We can't answer questions about:**
 - Specific vendors or other business partners with whom member companies are working
 - Costs of using/implementing TransCelerate assets/tools
 - Which member companies are using or going to use any TransCelerate solution or any commercial product or service

TransCelerate is a Not-for-Profit Entity Created to Foster Collaboration

Our mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design, and facilitate the implementation of solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.



CDISC Standards

By bringing together a global community of experts to develop and advance data standards of the highest quality, CDISC creates clarity in clinical research.

Together, we enable the accessibility, interoperability, and reusability of data for more meaningful and efficient research that has greater impact on global health.



- Consensus-based standards development
- Standards for clinical and translational research
- Standards are freely available at www.cdisc.org
- IP Policy ensures open standards
- Ongoing global research support in the Americas, Europe, Japan, China, India, Korea and other regions
- Standards downloaded in 90+ countries

About This Webinar Series

TransCelerate and CDISC are co-sponsors of this webinar series:

- TransCelerate leads the Digital Data Flow (DDF) initiative
- CDISC develops the USDM data standard for digitized protocols



Objective(s)

- Bring together DDF solution providers, sponsors, and industry stakeholders to witness innovative solutions
- Provide a platform to showcase different approaches to protocol digitalization (utilizing the USDM standard)
- Foster knowledge sharing relative to protocol digitalization



Solution Showcase Presentations

▶ The Power of Digital Protocols



Dr. Poorya Amini

Founder & CEO

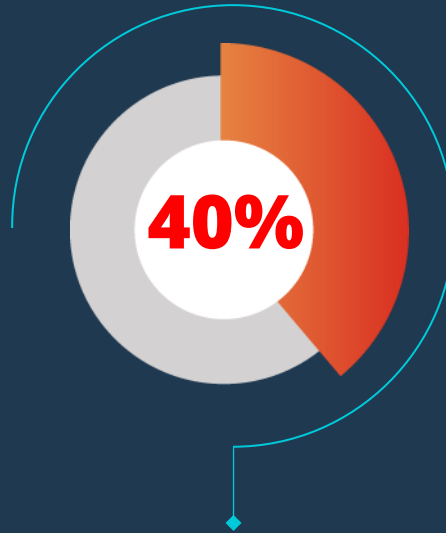
poorya.amini@risklick.ch



▶ **Each protocol amendment costs \$400k and delays the trial by 4 months**



Amendments per trials

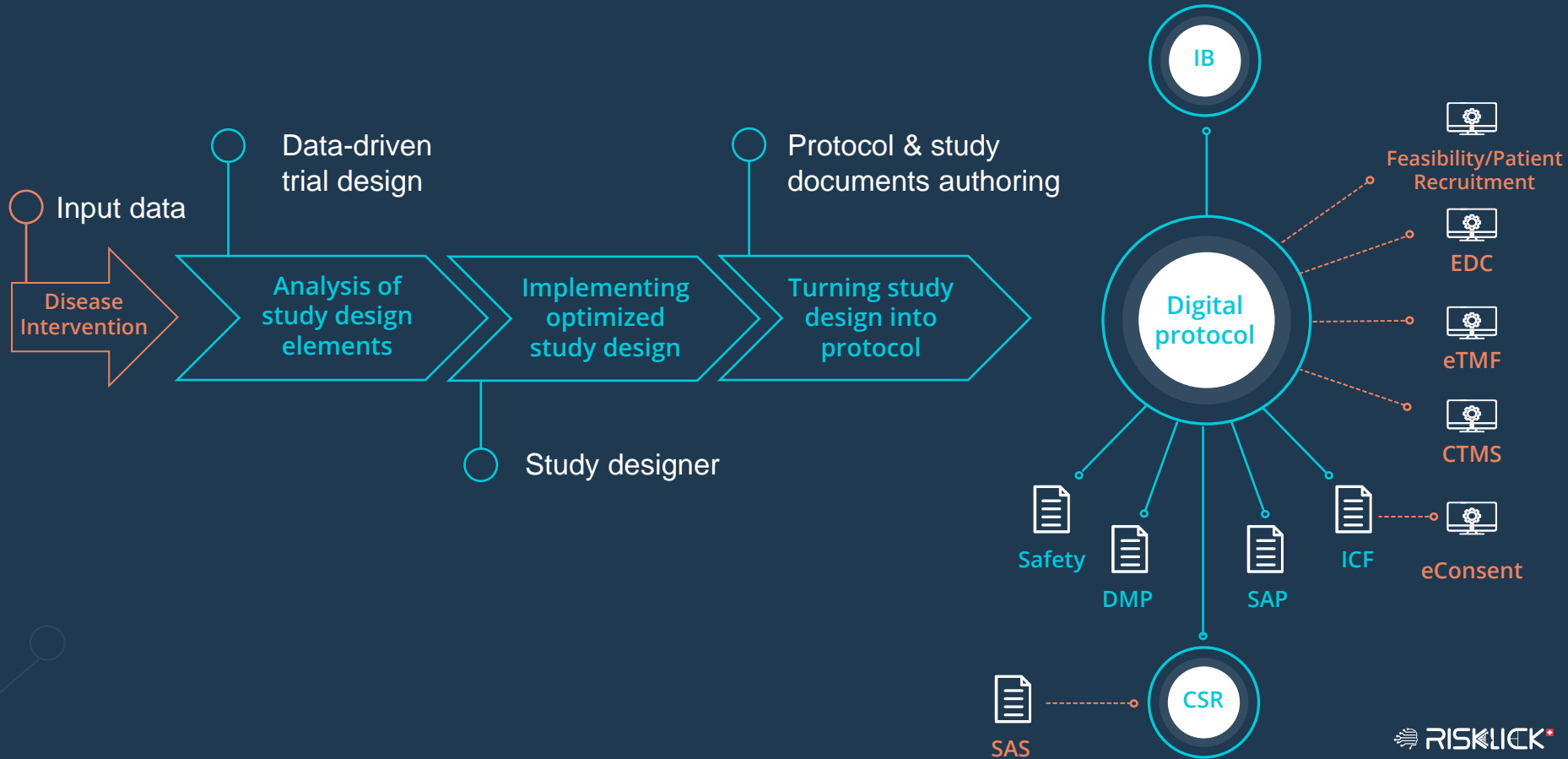


Trials undergoing amendments before the first patient is enrolled



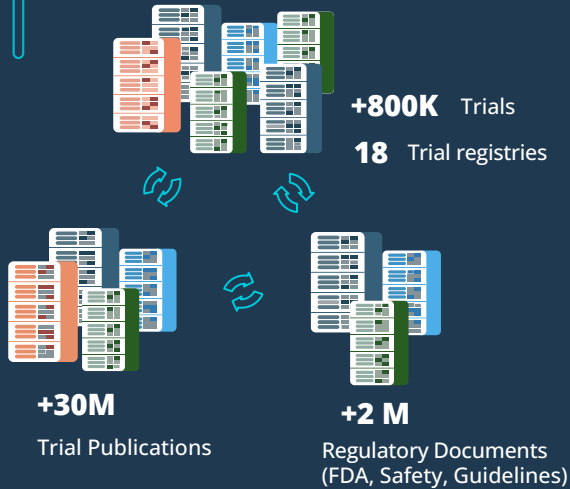
Amendments deemed avoidable by better protocol design

▶ Protocol AI™ : An End-to-End solution for protocol and study documents

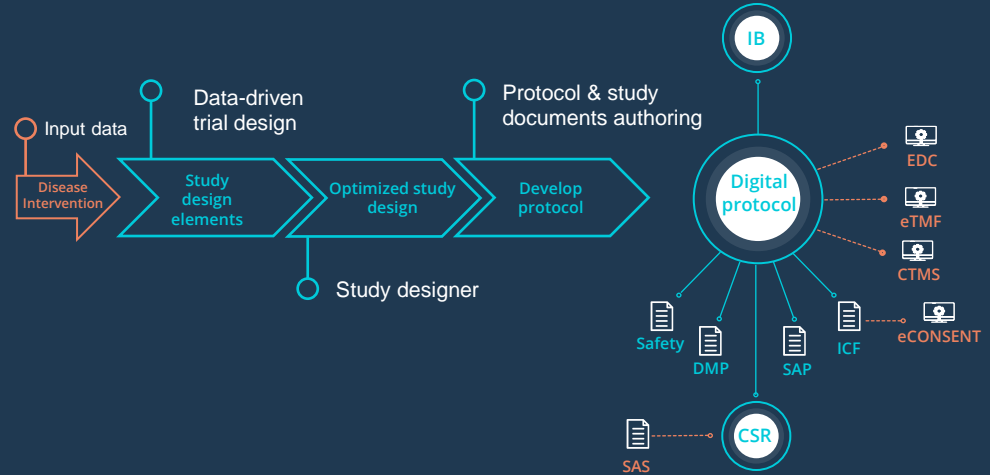


▶ Protocol AI™: Clinical trial data and publications from all countries

Linkage of Protocols, Publications & Regulatory



Weekly Data Collection & Update



▶ Developing a USDM and ICH M11-compliant protocol from scratch

- ✓ Collaborative work on one platform
- ✓ Build digital protocols with USDM compliance from scratch
- ✓ Capture all USDM requirements during development
- ✓ No word/PDF conversion: time-saving & error-free
- ✓ Download in MS Word, USDM JSON, or Excel format any time
- ✓ Use USDM JSON to connect the protocol to all study documents and external systems

▶ Ensure USDM compliance with any protocol template

- ✓ Easy, user-friendly protocol template creation
- ✓ Apply USDM requirements to any protocol template
- ✓ Tag additional USDM requirements and make them optional
- ✓ Guidance for mandatory info before computer-readable export
- ✓ User instructions to address USDM mandatory information

▶ **Let's make trials faster, cheaper, and safer for the benefit of all**





USDM & Digital Data Flow

OpenStudyBuilder Project
as Enabler

Agenda



- Introduction
- USDM in OSB
- Adoption



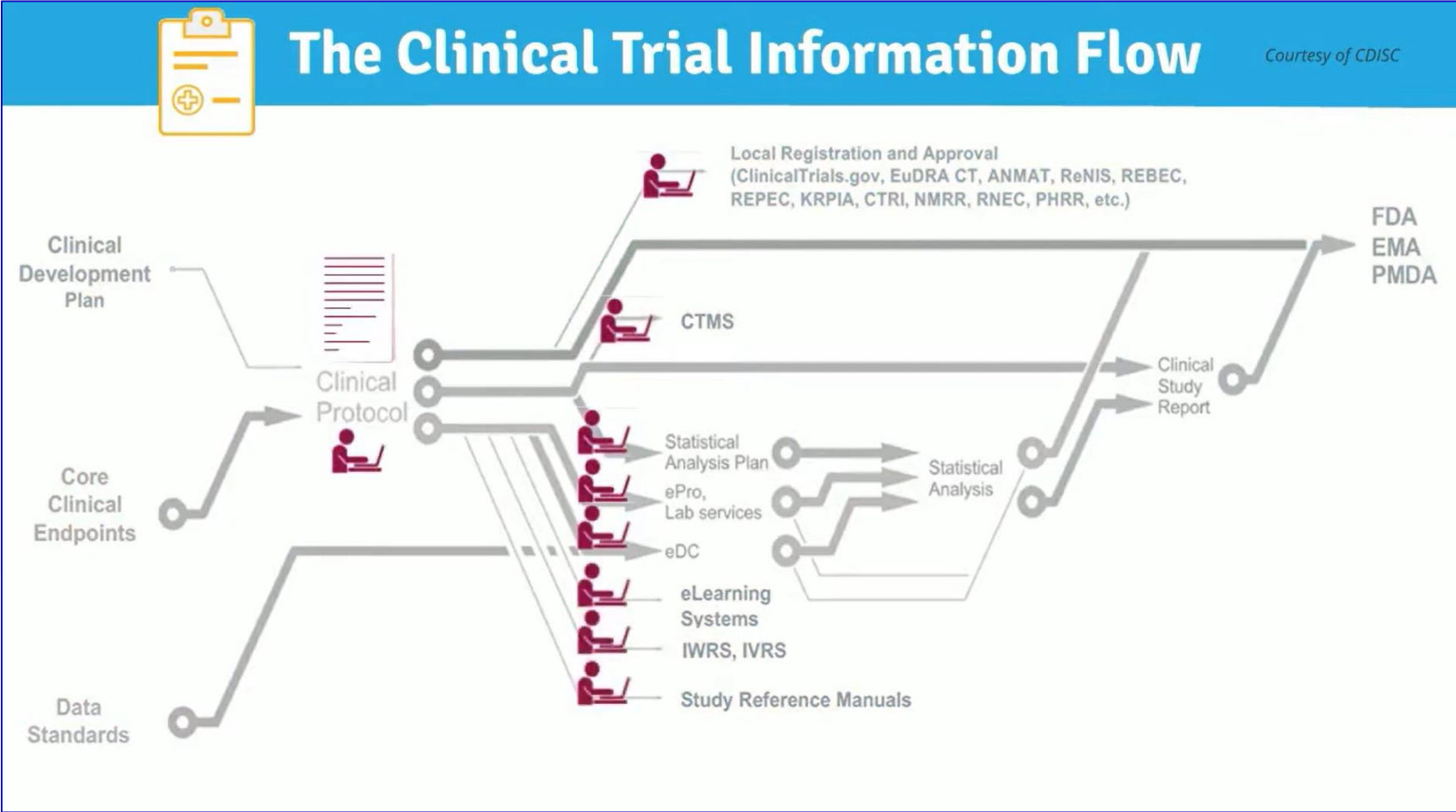
Introduction

Why do we need DDF
and the USDM Model?

Process Automation



Digital Data Flow – Problem 1



Documents
instead
Data

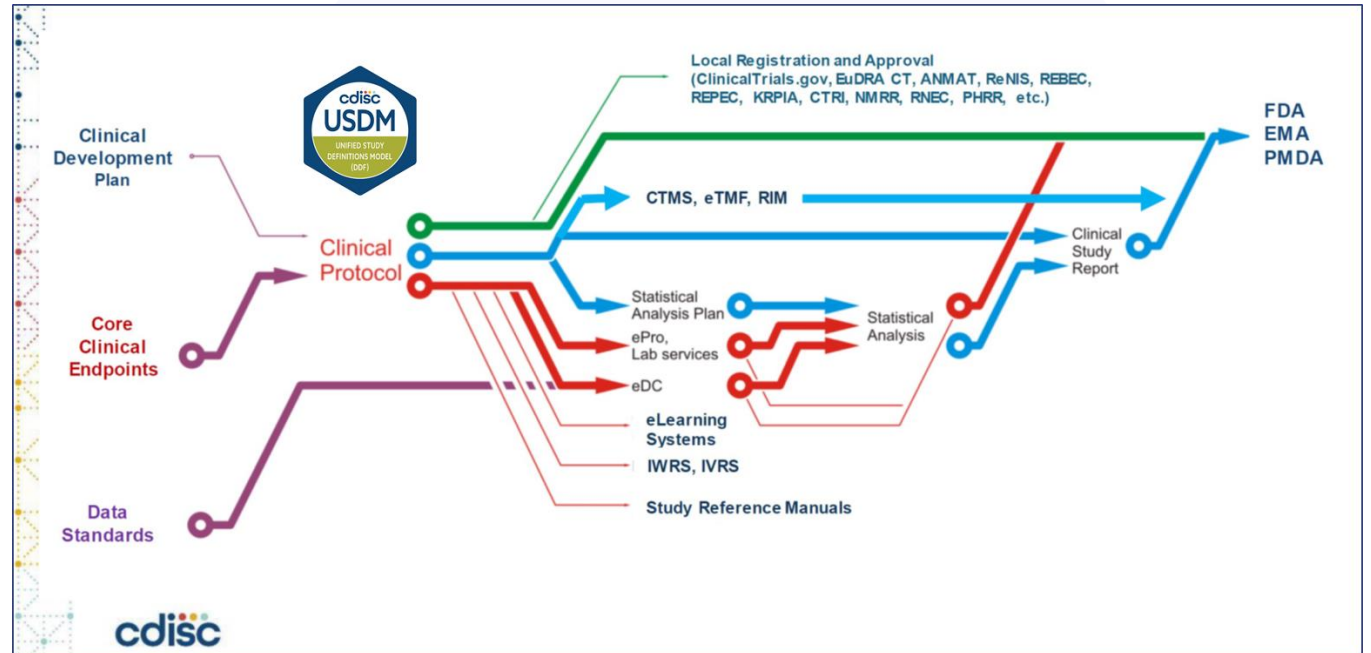
Digital Data Flow – Problem 2



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

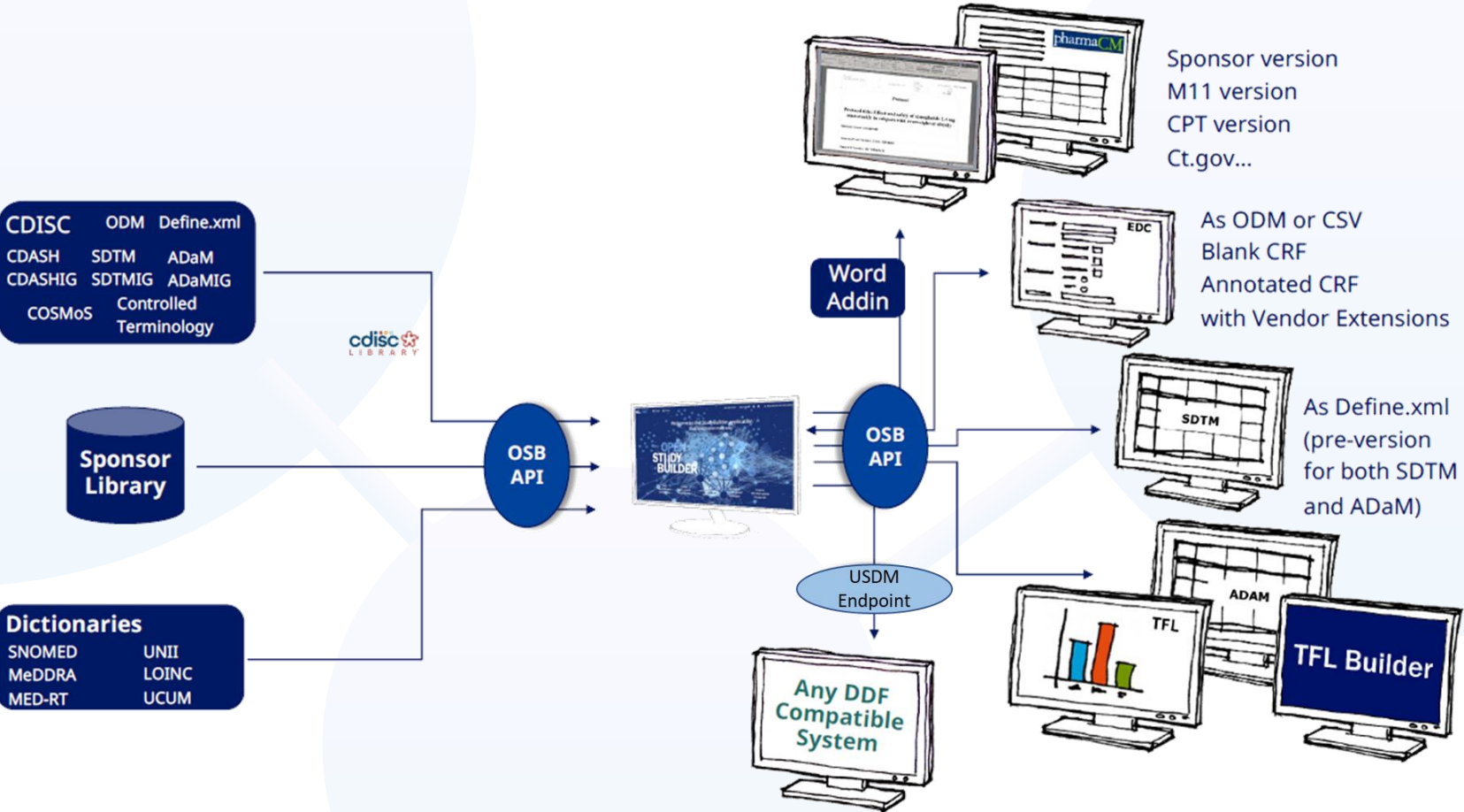


Open Source



MDR & SDR

Connectivity & Standards are Key



USDm

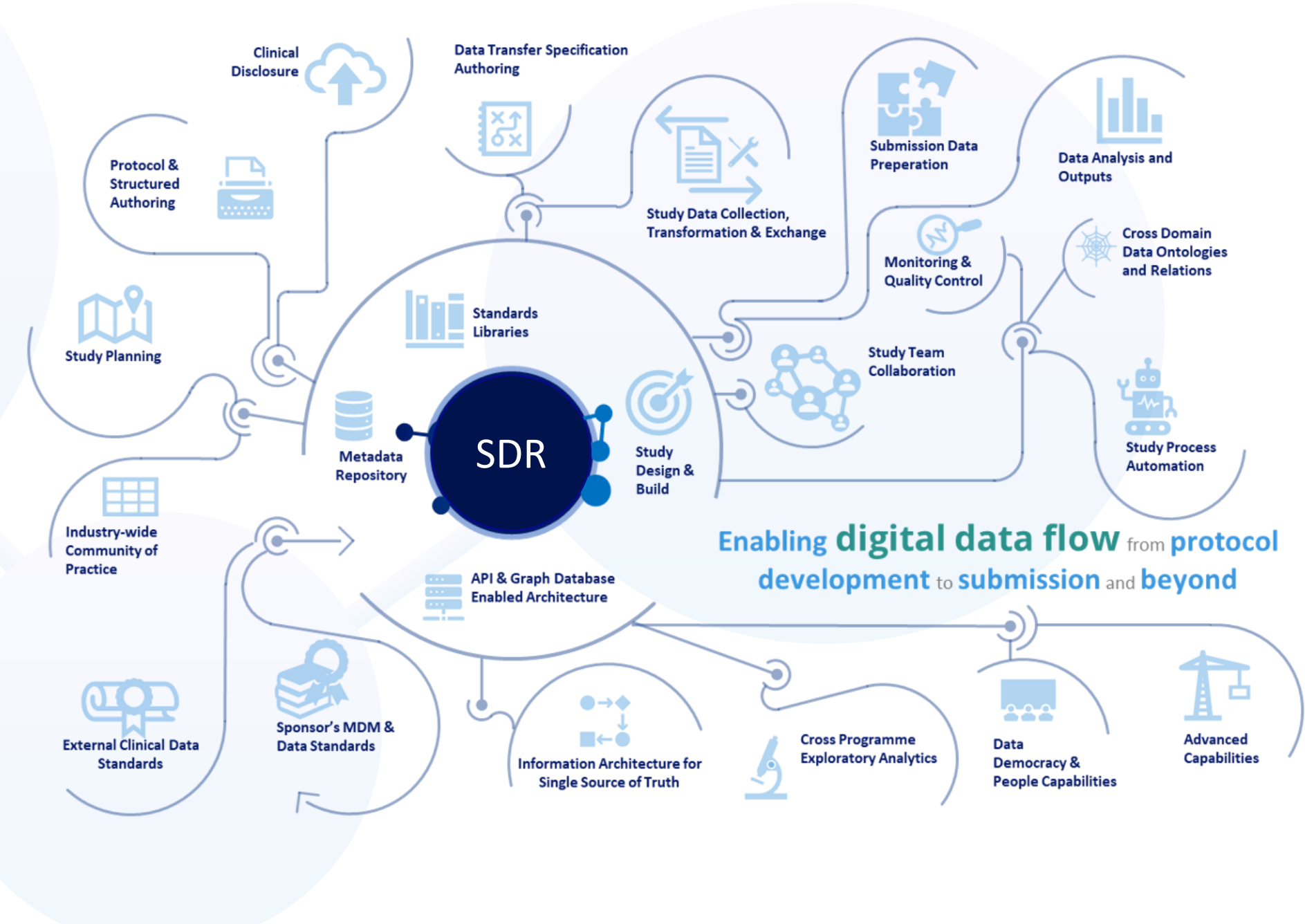
M11

CDISC

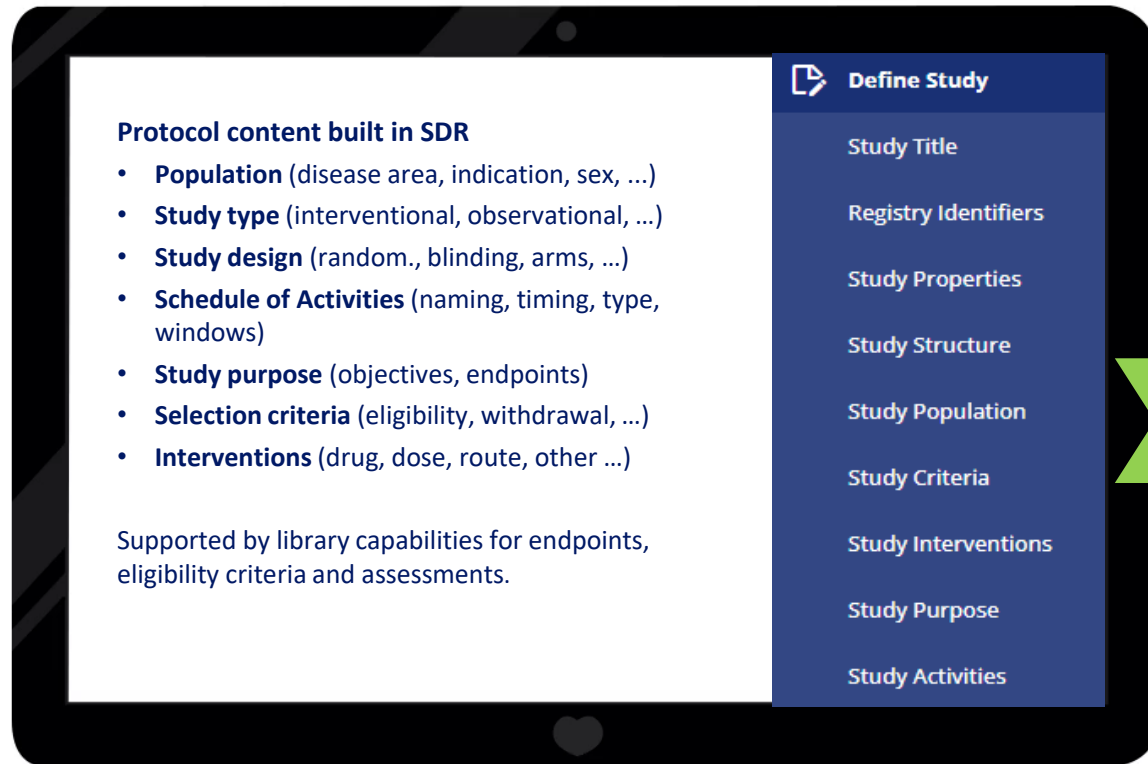
NCI

...

Opportunity Map



USDM & M11 Enabling Protocol Automation



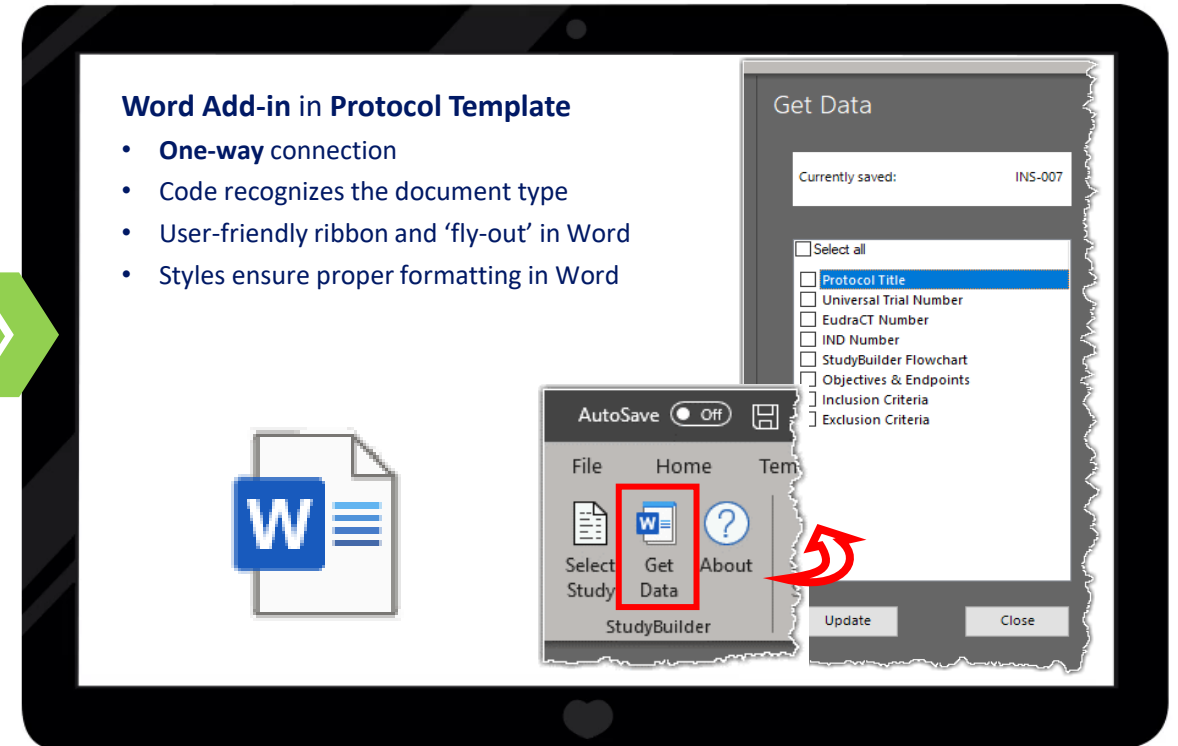
Define Study

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

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.



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

Get Data

Currently saved: INS-007

Select all

- Protocol Title
- Universal Trial Number
- EudraCT Number
- IND Number
- StudyBuilder Flowchart
- Objectives & Endpoints
- Inclusion Criteria
- Exclusion Criteria

AutoSave Off

File Home Tem

Select Study **Get Data** About

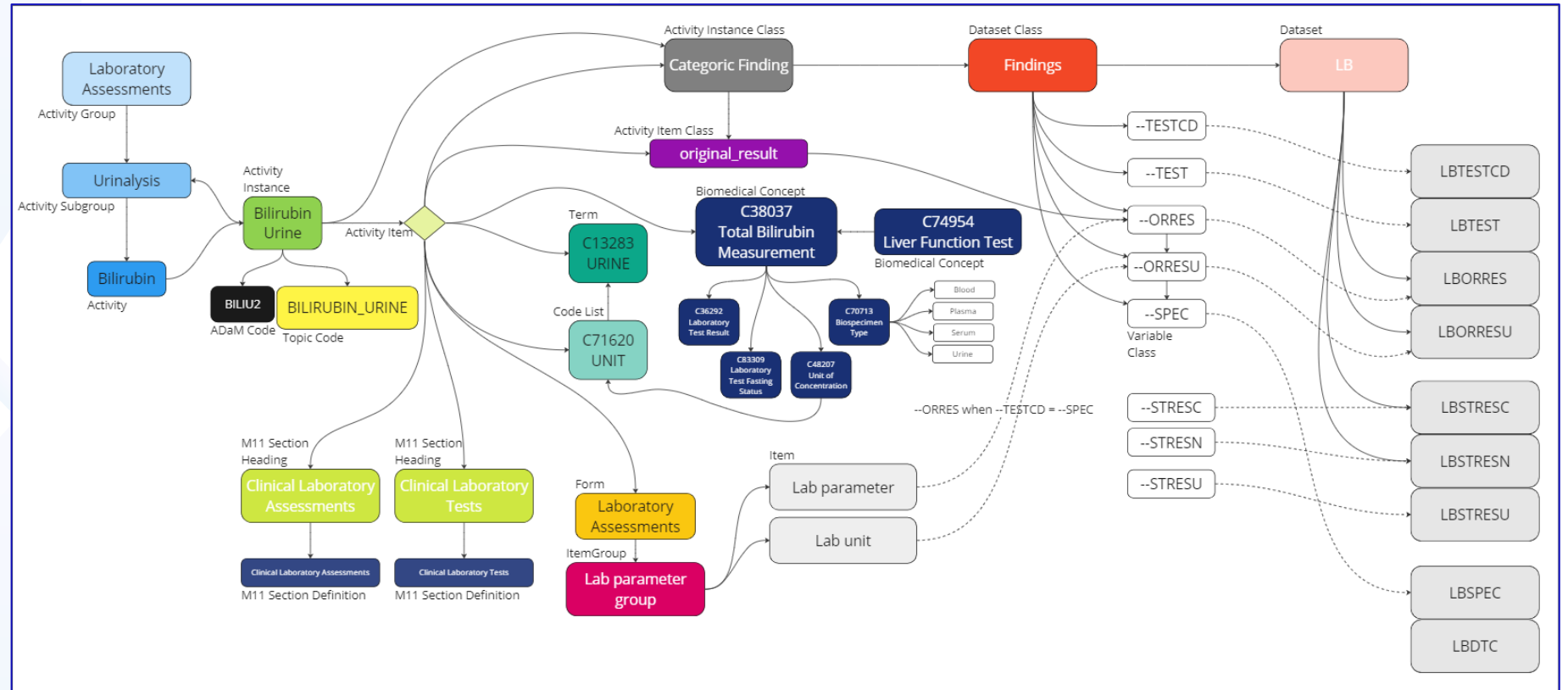
StudyBuilder

Update Close

Biomedical Concepts drive Digital Data Flow

Connect to **Flow** - define once & use many

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



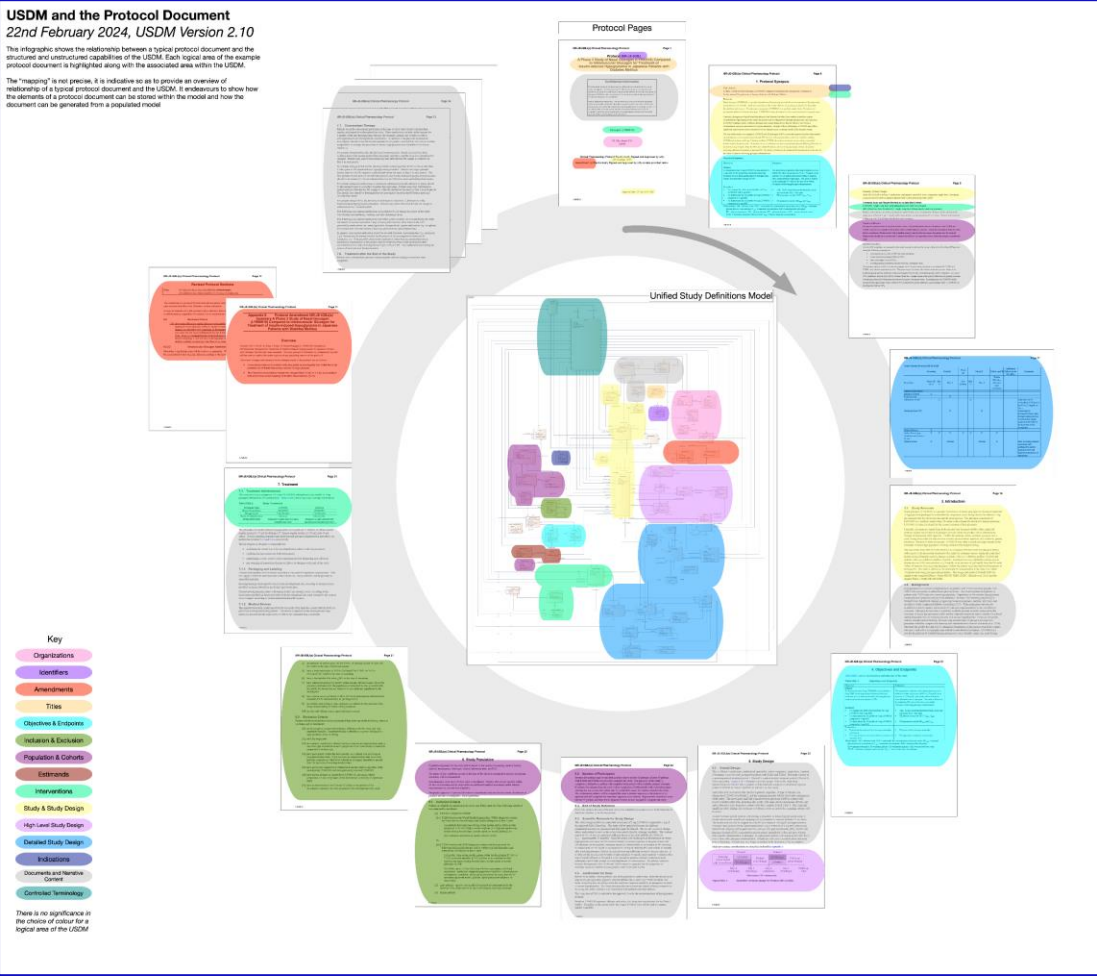


USDM in OpenStudyBuilder

The USDM Model



ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

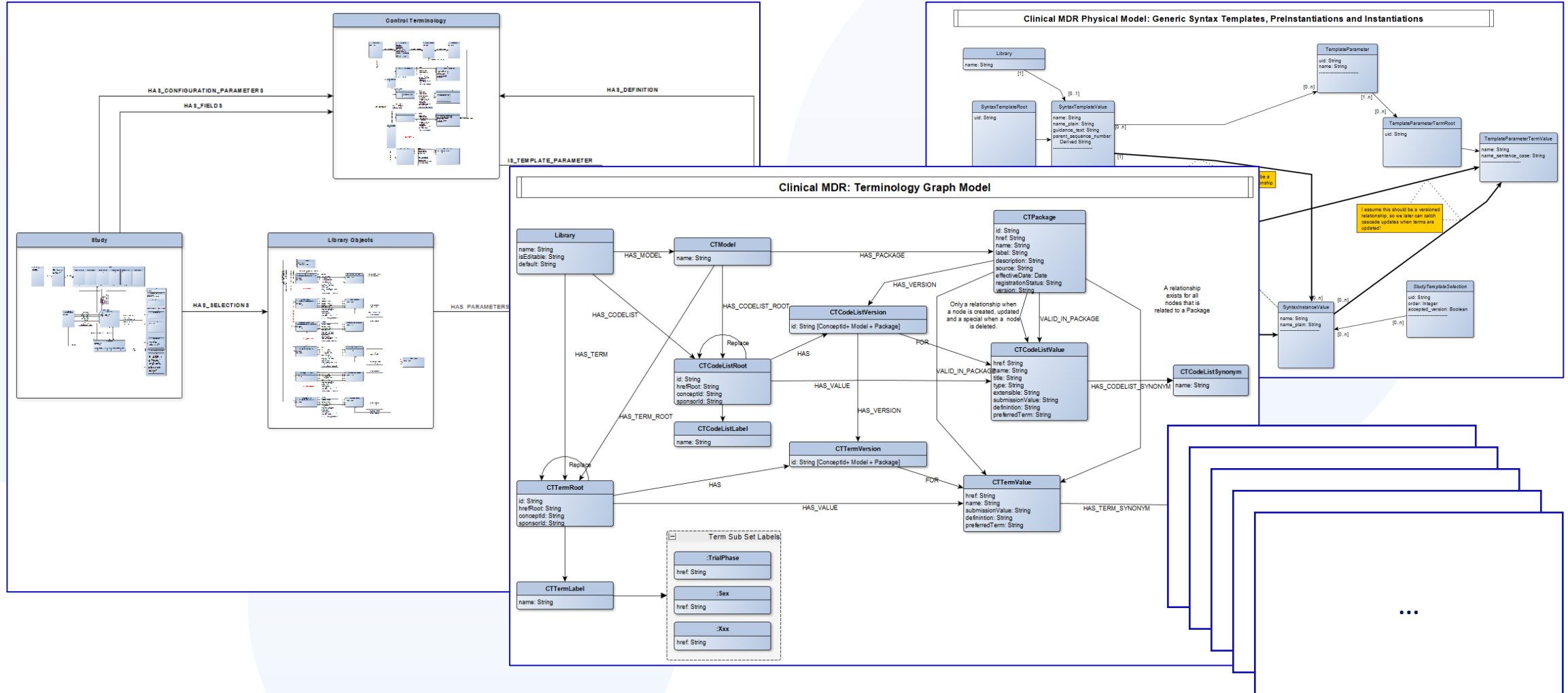


Key

- 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	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/ncitbrowse/r/ajax?action=create_src_vs_tree&src=C188839&target=C188839	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 Codelist C171445)	https://ncit.nci.nih.gov/ncitbrowse/r/ajax?action=create_src_vs_tree&src=C188840&target=C188840	/
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/ncitbrowse/r/ajax?action=create_src_vs_tree&src=C188841&target=C188841	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)	<input type="text" value="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 eyJ0eXAiOiJKV1QiLCJhbGciOiJIUzI1NiIsImtpZCI6IjNjYU50RmZ5Qk5rdTNDdGpZC2EzZW1oUTVFMCI
```

Request URL

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

Server response

Code	Details
200	<p>Response body</p> <pre>{ "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" } } }] }</pre> <p>Download</p>

API – The DDF Endpoint

#	Epoch name	Epoch type	Epoch subtype	Start rule	End rule	Description	Number of visits	Assigned colour
1	Screening	Pre Treatment	Screening	ICF submitted	ICF signed	Screening epoch to start	1	Grey
2	Treatment	Treatment	Treatment	RDM ok	Dosing complete	Treatment epoch without dosing esca...	9	Light Blue
3	Follow-up	Post Treatment	Follow-up	Treatment ok	Last follow-up ok	Follow-up epoch to follow the subje...	1	Green

OSB with USDM API endpoint

DDF Study Definitions Repository (SDR)

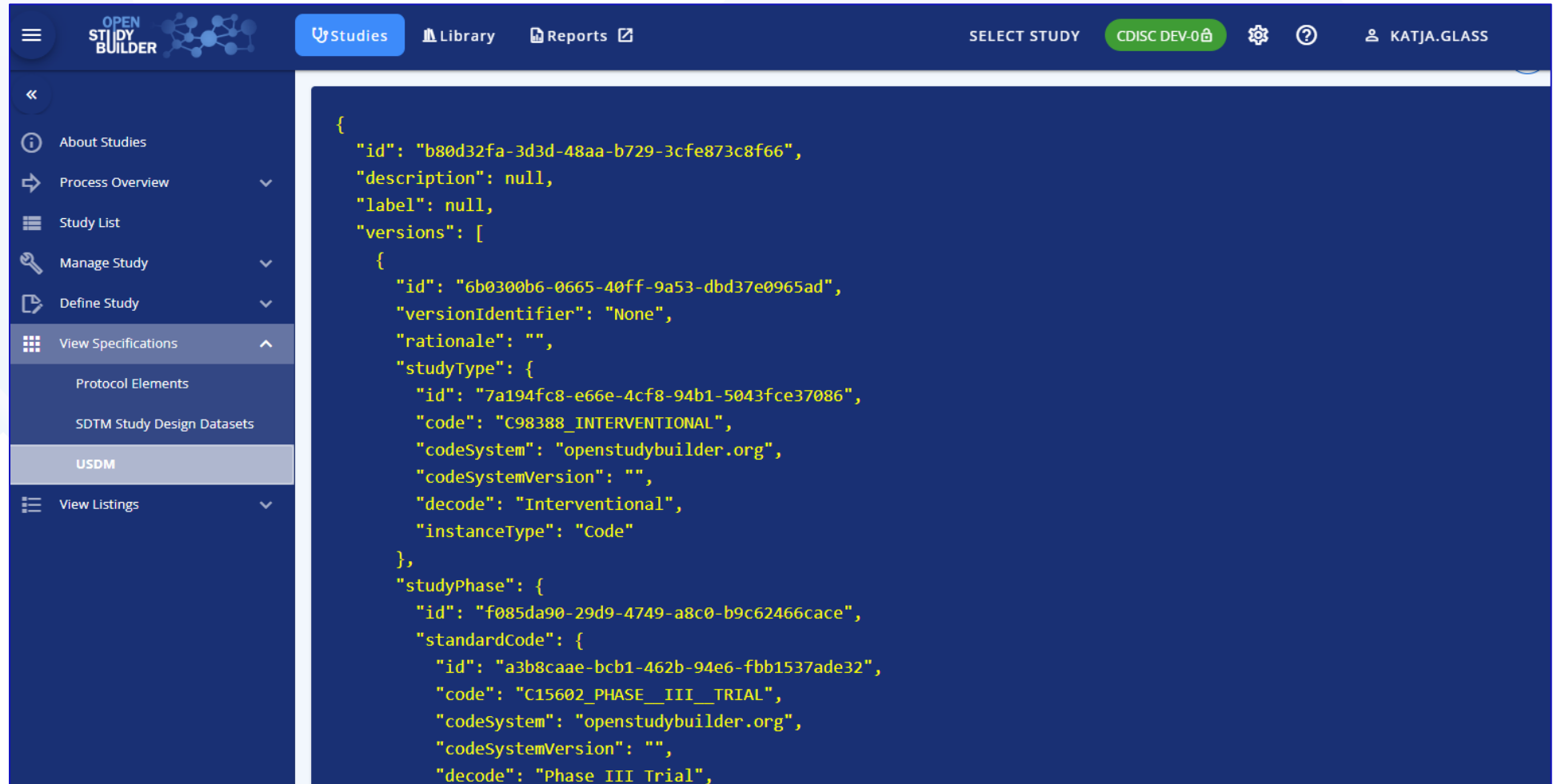
```
epochs: [
  {
    "id": "StudyEpoch_000001",
    "name": "Screening",
    "label": null,
    "description": "Screening epoch to start",
    "type": {
      "id": "2785a39f-c632-490e-9dea-d8ede4b6e5ca",
      "code": "CTTerm_000003",
      "codeSystem": "openstudybuilder.org",
      "codeSystemVersion": "",
      "decode": "Pre Treatment"
    },
    "previousId": null,
    "nextId": "StudyEpoch_000002"
  },
  {
    "id": "StudyEpoch_000002",
    "name": "Treatment",
    "label": null,
    "description": "Treatment epoch without dosing escalation",
    "type": {
      "id": "f04010d7-7c95-4b18-94f0-a6391fb7a190",
      "code": "C101526_TREATMENT",

```

DDF Endpoint in UI

Raw USDM
display

M11
Rendering



The screenshot shows the Open Study Builder interface. The top navigation bar includes the logo, 'Studies' tab, 'Library', 'Reports', and user information 'KATJA.GLASS'. The left sidebar has a menu with 'View Specifications' selected. The main content area displays a JSON object representing a DDF endpoint.

```
{
  "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"
      },
    },
    {
      "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



[Studies](#)
[Library](#)
[Reports](#)

[SELECT STUDY](#)
CDISC DEV-006

 NDJZ (NICOLAS DE SAINT JORRE)

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](#)

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	Attri
⋮	CDISC	Environmental Setting	No	Final	Apr 18, 2024, 9:45 AM	C127262	SETTING	Environmental Setting	CDISC SDTM Environmental Setting Terminology	Yes	Fir
⋮	CDISC	Mode of Subject Contact	No	Final	Apr 18, 2024, 9:53 AM	C171445	CNTMODE	Mode of Subject Contact	CDISC SDTM Mode of Subject Contact Terminology	Yes	Fir
⋮	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	Fir
⋮	CDISC	DDF Entity Terminology	No	Final	Apr 18, 2024, 9:58 AM	C188698	DDF Entity Terminology	DDF Entity Terminology	CDISC DDF Entities Terminology	No	Fir
⋮	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	Fir
⋮	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	Fir
⋮	CDISC	DDF Study Identifier	No	Final	Apr 18, 2024, 9:58 AM	C188701	DDF Study Identifier	DDF Study Identifier	CDISC DDF Study Identifier	No	Fir

Rows per page 10 1-10 of 54 < >

USDM to ICH M11

Integration of ICH M11 Template in OBS:

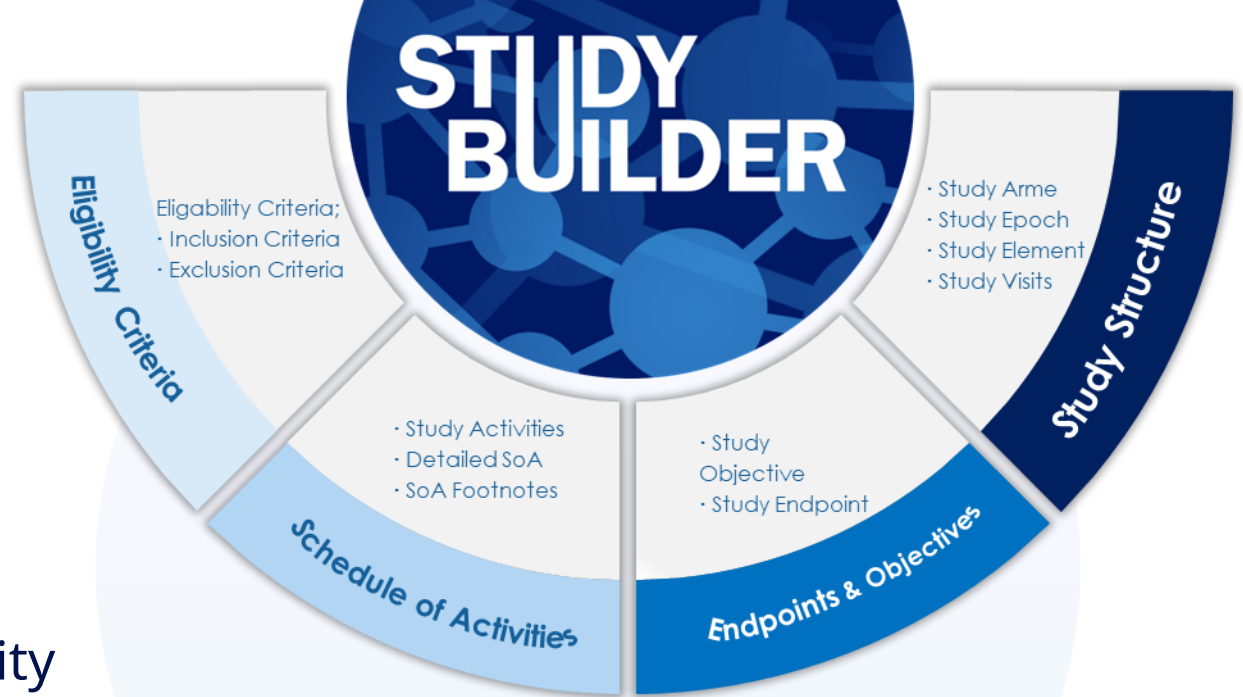
- Leverages USDM JSON metadata
- Generates HTML version of M11 protocol
- Conversion to PDF document
- Aligns with industry standards
- Enhances efficiency, accuracy, and compliance
- Empowers researchers and stakeholders

ICH M11 Template	
Protocol Full Title:	<p>[Protocol Full Title] ← Coming from the OpenStudyBuilder</p> <p>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.</p>
Sponsor Confidentiality Statement:	<p>[Sponsor Confidentiality Statement]</p> <p>Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.</p>
Protocol Number:	<p>[Protocol Number]</p> <p>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.</p>
Version:	<p>[Version]</p> <p>An optional field for use by the Sponsor at their discretion.</p>
Amendment Number:	<p>[Amendment Number]</p> <p>Enter the amendment number. If this is the original instance of the protocol, indicate Not Applicable.</p>
Amendment Scope:	<p>[Amendment Scope] [Country/Region Identifier]</p> <p>Acceptable entries for amendment scope are: "global" or "Country-specific/Regional"</p> <p>Use the ISO-3166 region or country identifier (for example, DE or EU). For global trials delete the Country/Region Identifier field.</p>
Compound Number(s):	<p>[Compound Number]</p> <p>Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.</p>



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

October
2023

May
2024

End
2024

First business release (MVP*):

- All interventional ph 2-4 studies
- Users within Clinical Operations, Clinical Reporting & Data Management Systems and Standards
- Key protocol metadata (SoA**, Study Structure, Eligibility criteria, Endpoints & Objectives)

Focus on limiting the operational burden

- Support all studies (currently pending ph 1)
- Reduction in parallel work needed
- Expansion of library content
- Connectivity to other systems (resuability)

Reduced scope due to adoption challenges:

- Schedule of Activities (SoA) & Study structure (mandatory)
- Eligibility criteria, Endpoints & Objectives (optional)

* 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



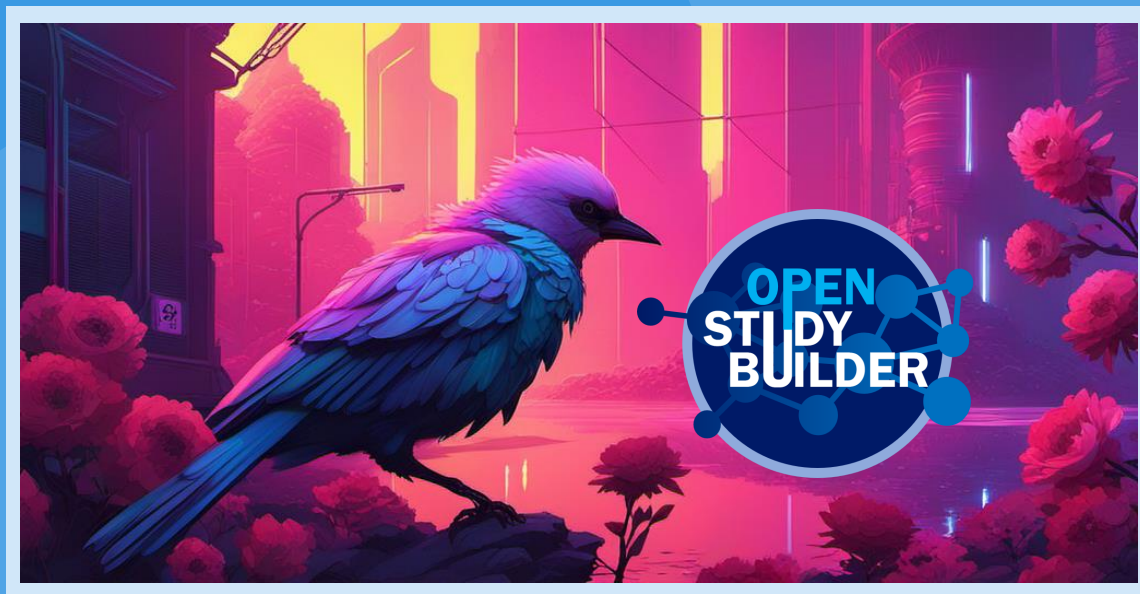


Community
OpenStudyBuilder@gmail.com

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, you mail might be exposed in the version history
-

Presenter Q&A

Q&A Panel



Belinda Griffin
Digital Data Flow
Program Manager



Poorya Amini

Founder & CEO
Risklick



**Nicholas de Saint
Jorre**

Lead Product Architect
Novo Nordisk



Katja Glaß

Open-Source
Ambassador, Consultant
Novo Nordisk (Contractor)



Dave Iberson-Hurst

USDM Product Owner
CDISC

If you have a question, **please denote to whom** the question is directed.
Note: depending on time, we will not be able to answer all questions

As a reminder, we can't answer questions about:

- Specific vendors or other business partners with whom organizations are working
- Costs of using/implementing TransCelerate assets/tools
- Which member companies are using or going to use any TransCelerate solution or any commercial product or services

Tools & Resources



Visit us, for more information:
www.TransCelerateBioPharmaInc.com



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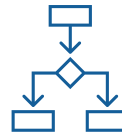


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