# 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



TransCelerate BIOPHARMA INC.

# Today's Presenters

*Risklick and Novo Nordisk*

**Poorya Amini**

Founder & CEO
**Risklick**

**Nicolas de Saint Jorre**

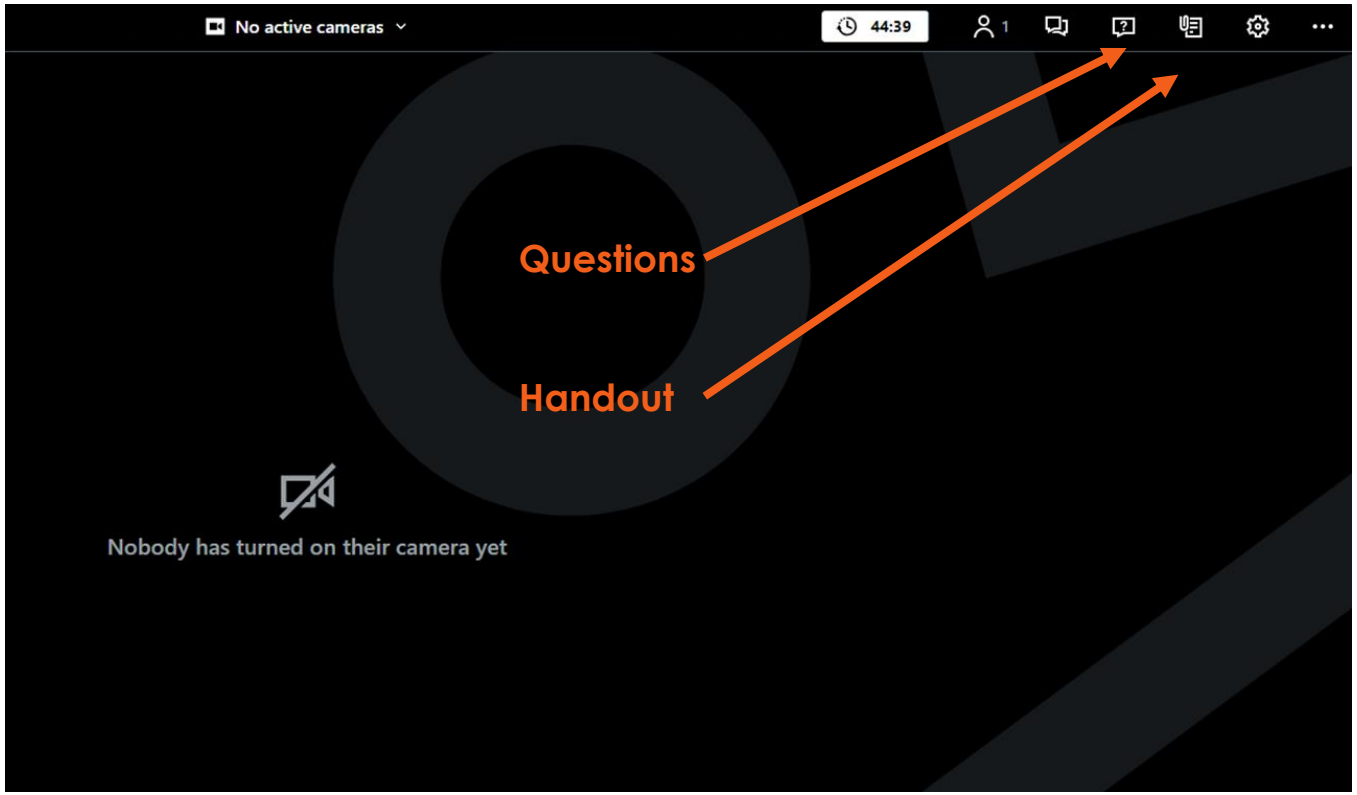
Lead Product Architect
**Novo Nordisk**

**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.



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# 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 <u>not to post questions on</u>:**
  - 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 off 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

RISKLICK

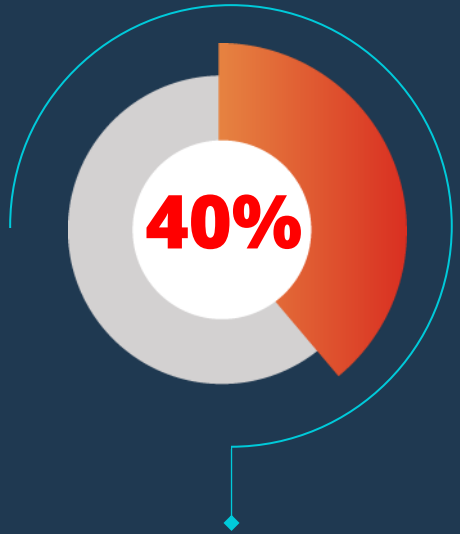
# The Power of Digital Protocols

**Dr. Poorya Amini**
Founder & CEO

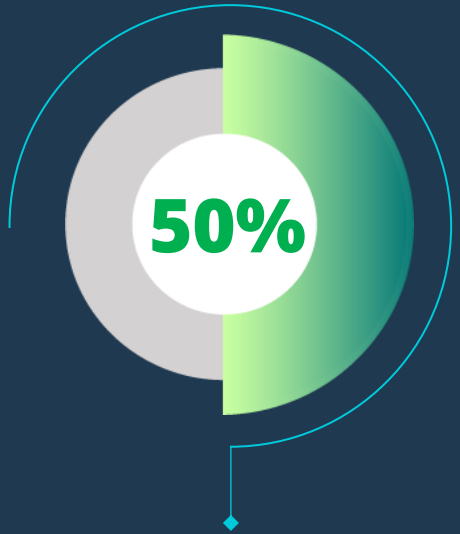
poorya.amini@risklick.ch

# Each protocol amendment costs $400k and delays the trial by 4 months


Amendments per trials




Trials undergoing amendments before the first patient is enrolled

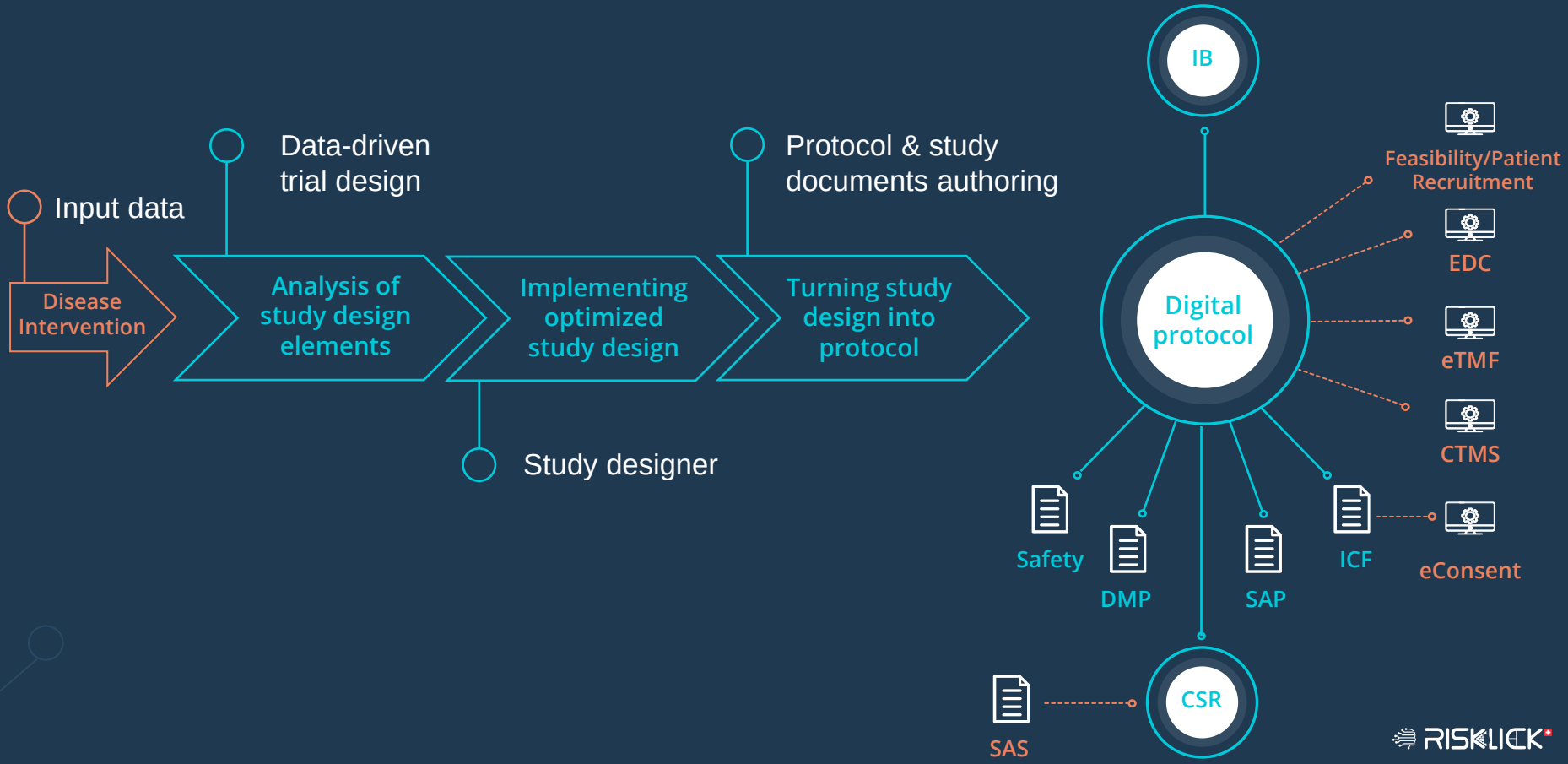



Amendments deemed avoidable by better protocol design

Kenneth Getz et al. New Benchmarks on Protocol Amendment Practices, Trends, and Their Impact on Clinical Trial Performance, Science, 2024

RISKLICK

# 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

**+800K** Trials

**18** Trial registries

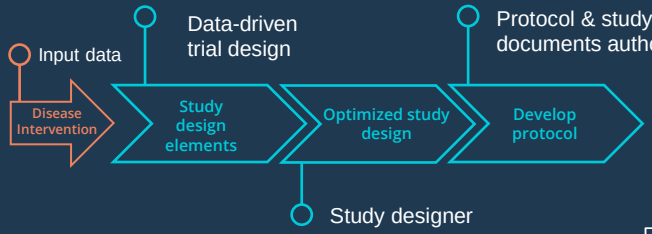
**+30M**

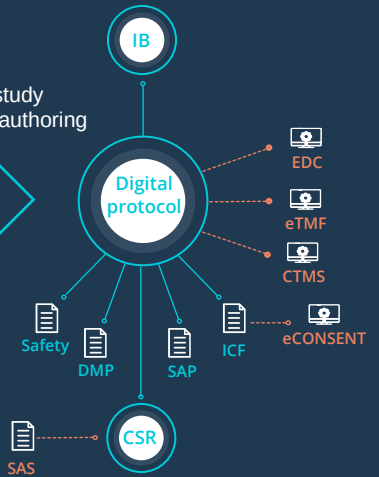
Trial Publications

**+2 M**

Regulatory Documents (FDA, Safety, Guidelines)

Weekly Data Collection & Update




RISKLICK

# 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

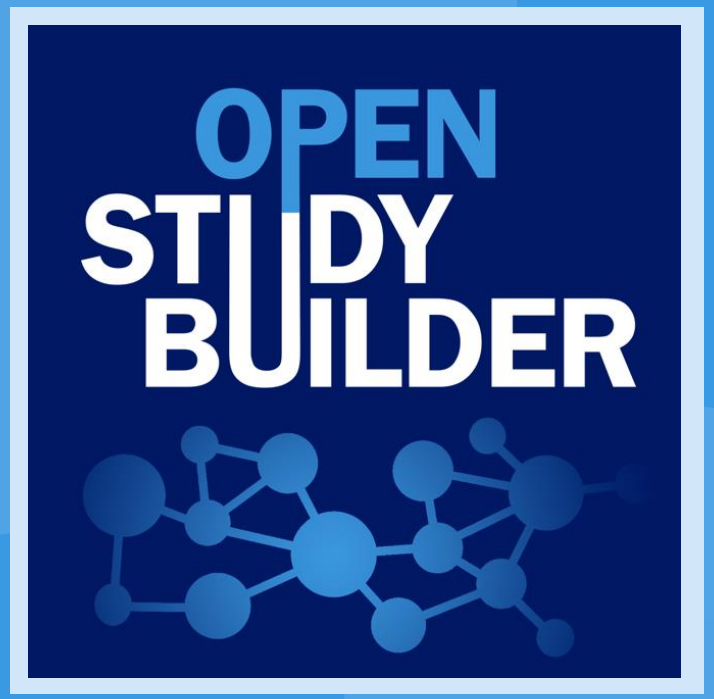
- ✓ Easy, user-friendly protocol template creation
- ✓ Apply USDM requirements to any protocol template
- ✓ Tag additional USDM requirements and make them optional
- ✓ Guidance for mandatory info before computer-readable export
- ✓ User instructions to address USDM mandatory information

# Let’s make trials faster, cheaper, and safer for the benefit of all

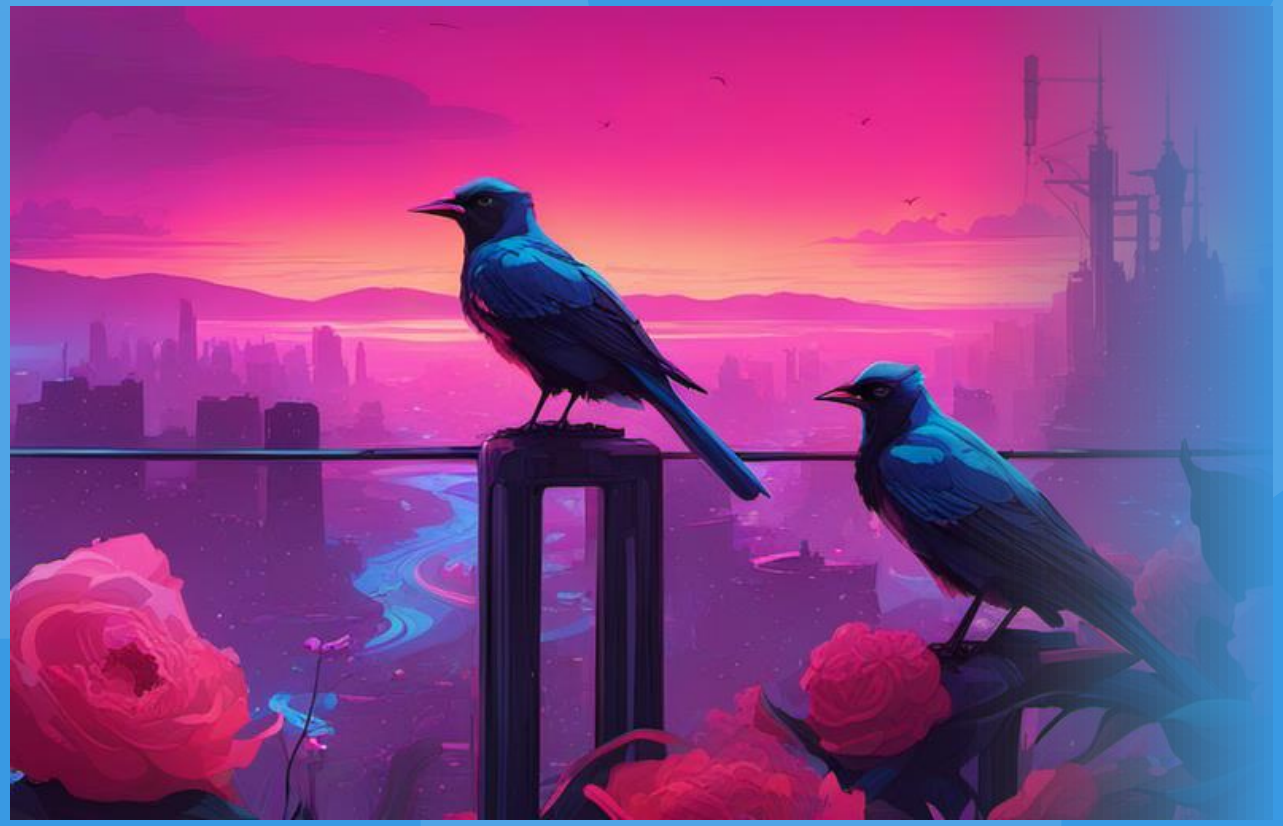

# USDM & Digital Data Flow

## OpenStudyBuilder Project as Enabler

# Agenda



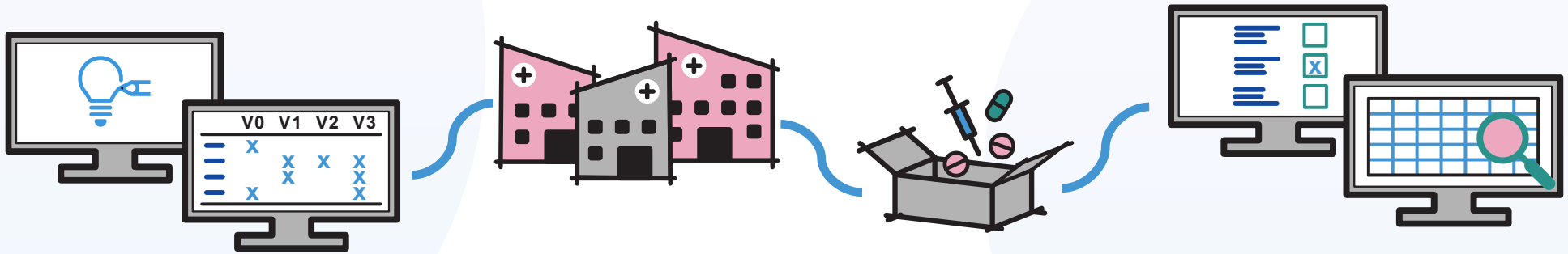

- Introduction
- USDM in OSB
- Adoption



# Introduction

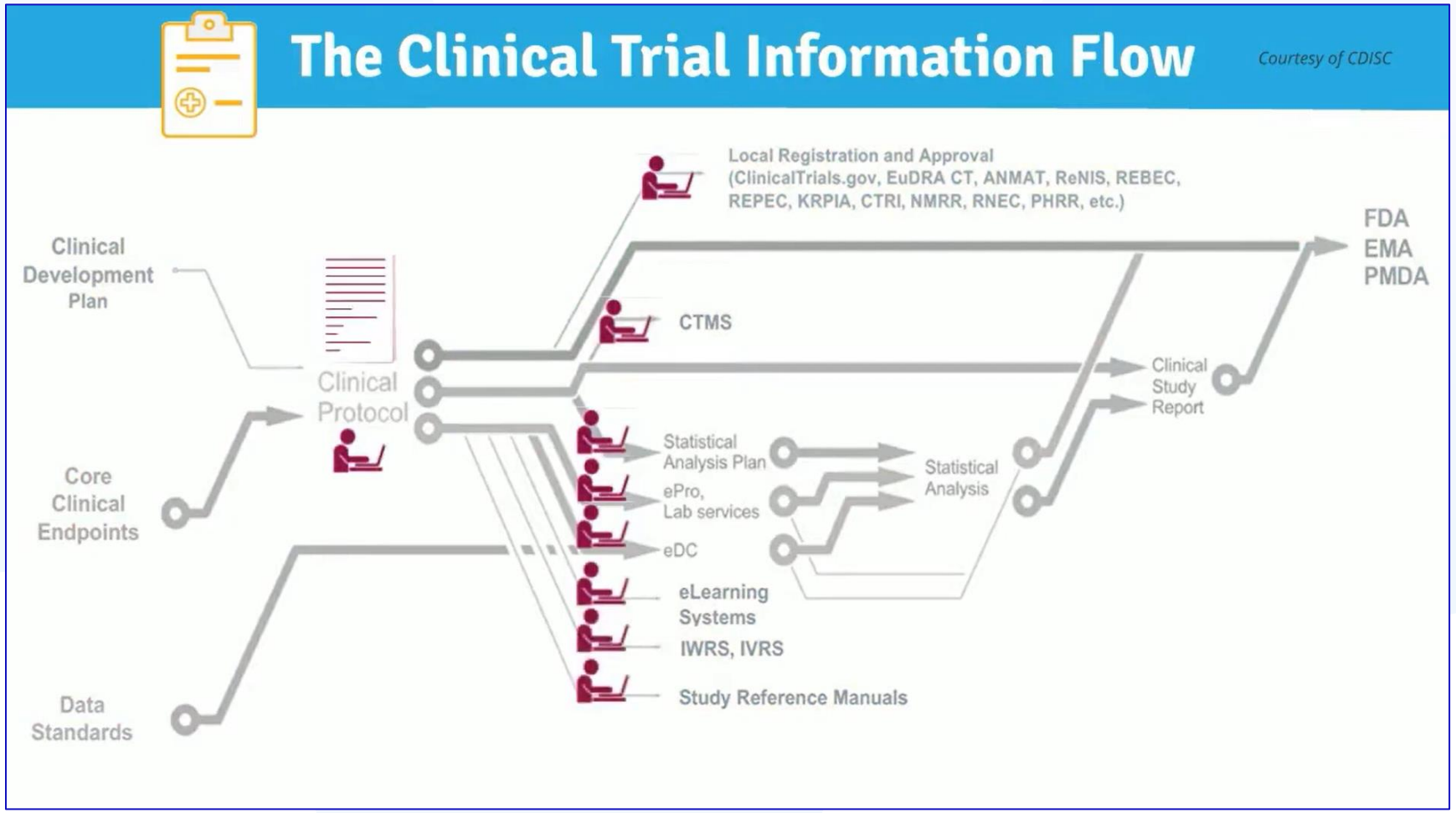
Why do we need DDF and the USDM Model?

# Process Automation




An efficient and scalable study journey connected by **one digital data flow** and simplified by **one common data model.**

# Digital Data Flow – Problem 1




**Documents**
instead
Data

https://www.youtube.com/watch?v=Otg0d2385is

# Digital Data Flow – Problem 2

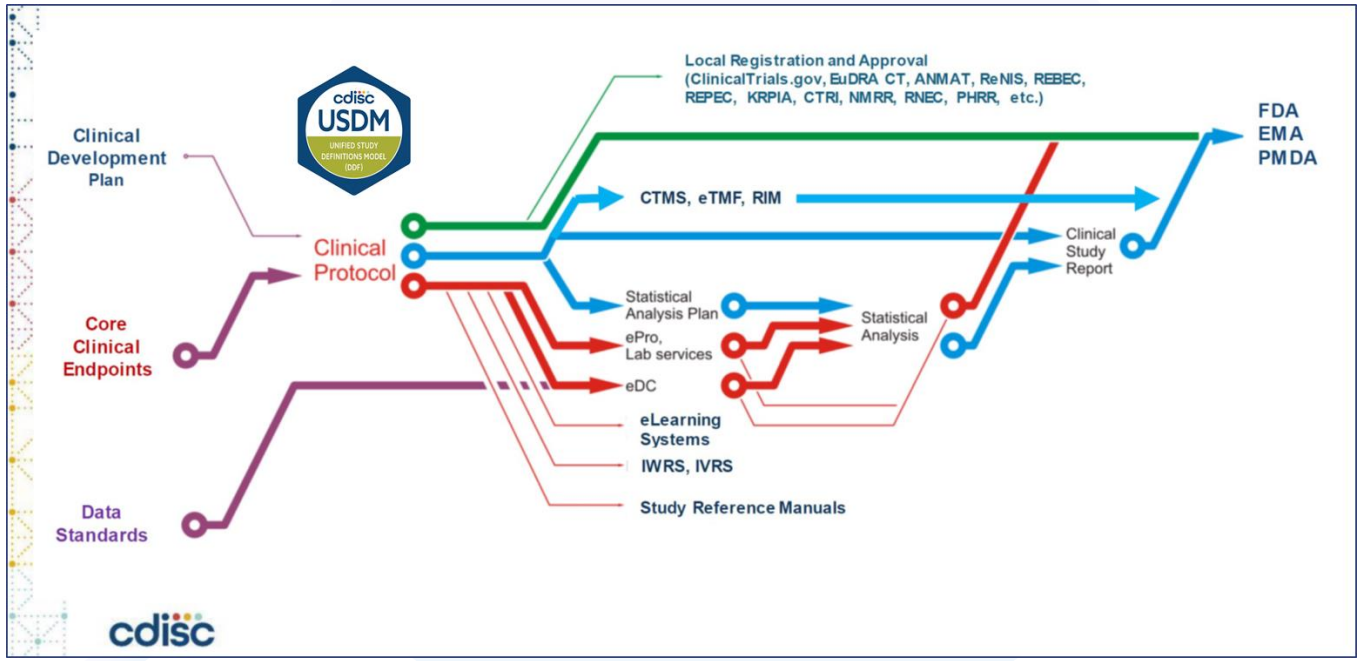

**Disconnected**

Data

# Digital Data Flow – Solution

**Data** instead Documents

- Data Exchange Standard (USDM)
- Electronic Protocol (ICH M11)




ICH harmonisation for better health

# 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

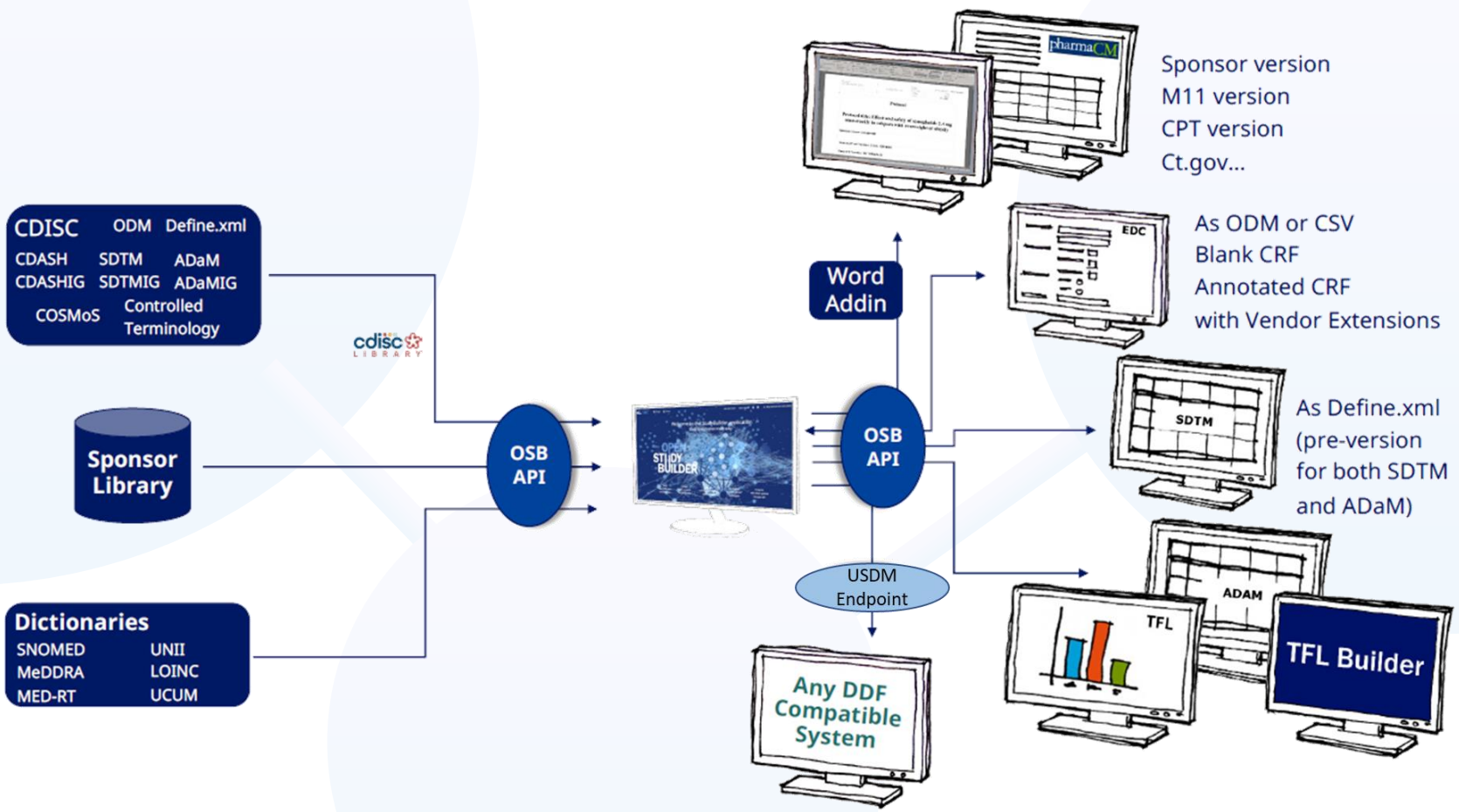
## Core Elements

- 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

**Protocol content built in SDR**

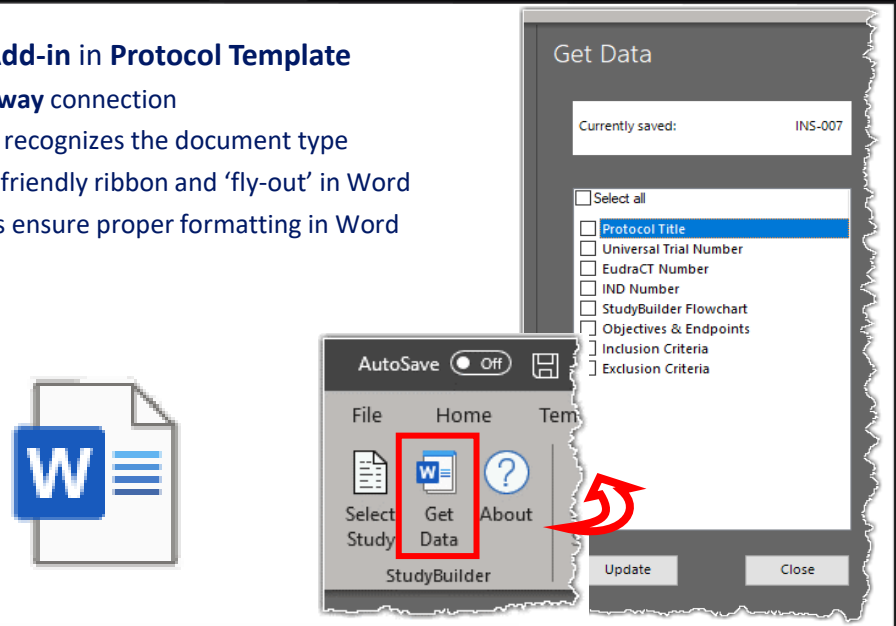
- **Population** (disease area, indication, sex, …)
- **Study type** (interventional, observational, …)
- **Study design** (random., blinding, arms, …)
- **Schedule of Activities** (naming, timing, type, windows)
- **Study purpose** (objectives, endpoints)
- **Selection criteria** (eligibility, withdrawal,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

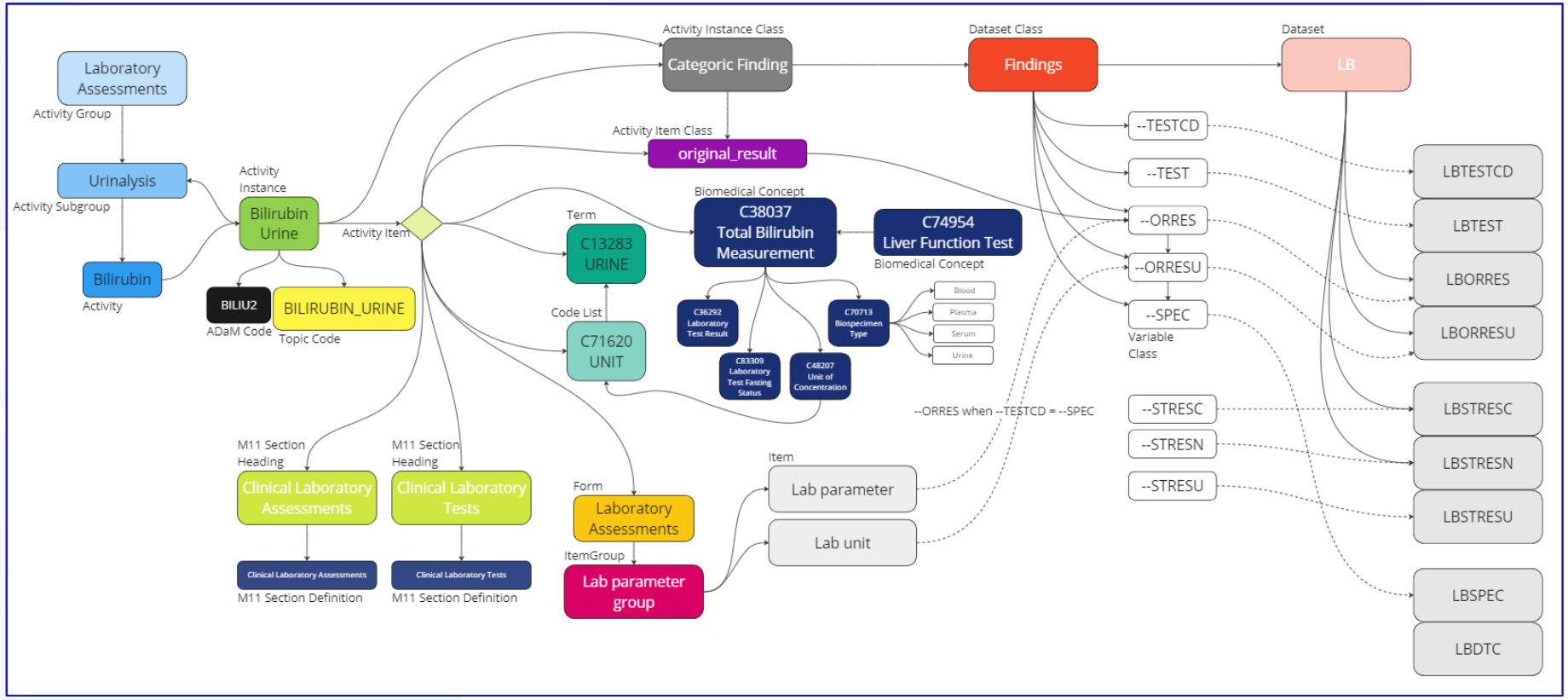
- **One-way** connection
- Code recognizes the document type
- User-friendly ribbon and ‘fly-out’ in Word
- Styles ensure proper formatting in Word



# Biomedical Concepts drive Digital Data Flow

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

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



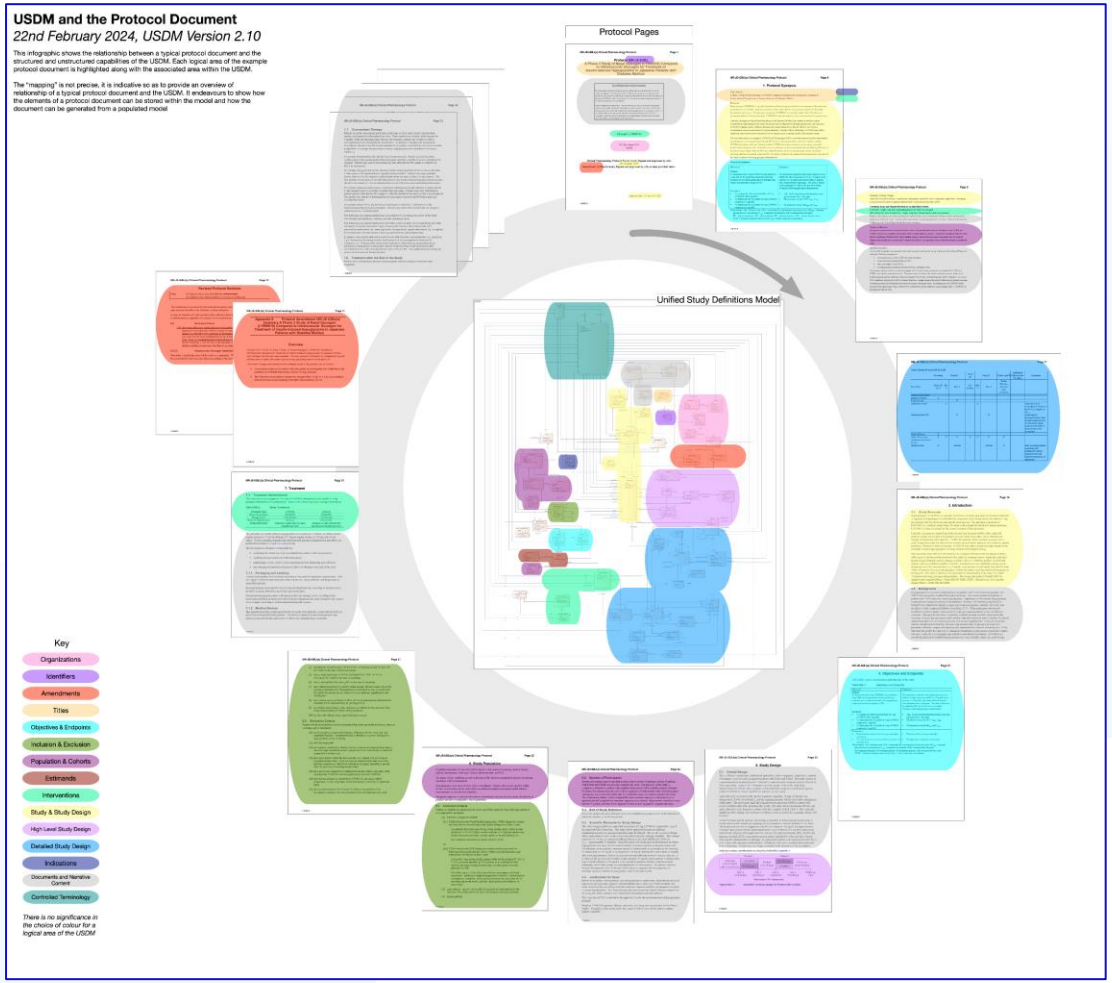
# USDM in OpenStudyBuilder

# The USDM Model

TransCelerate BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

cdisc

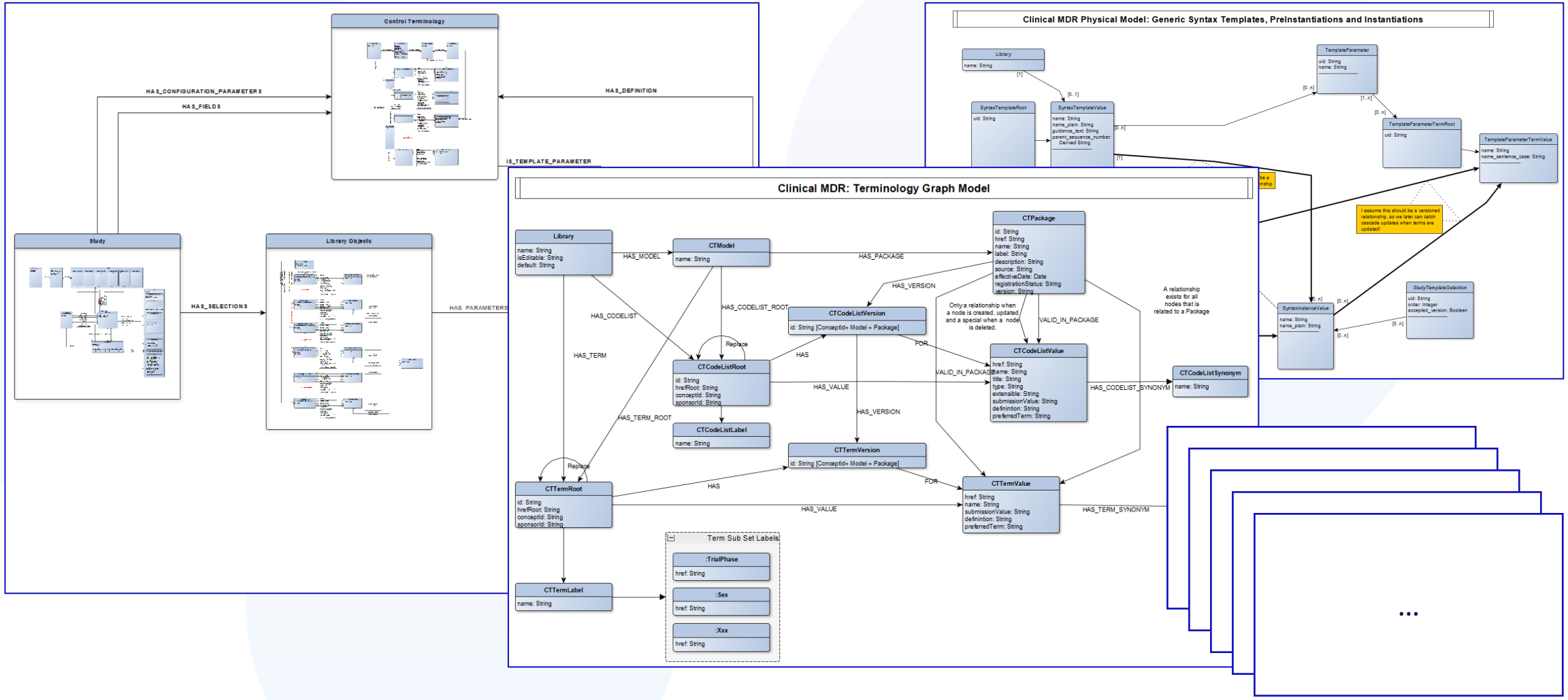



Key

- 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

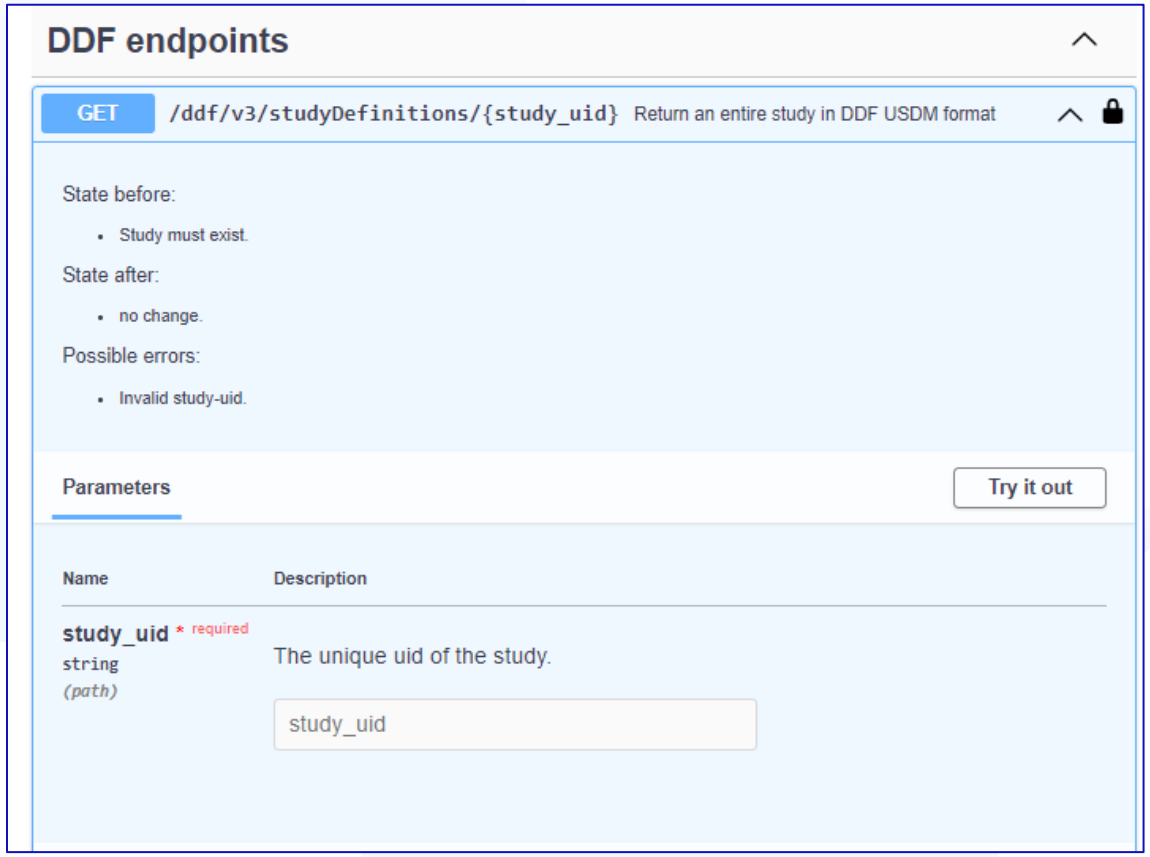
**USDM Export enables:**

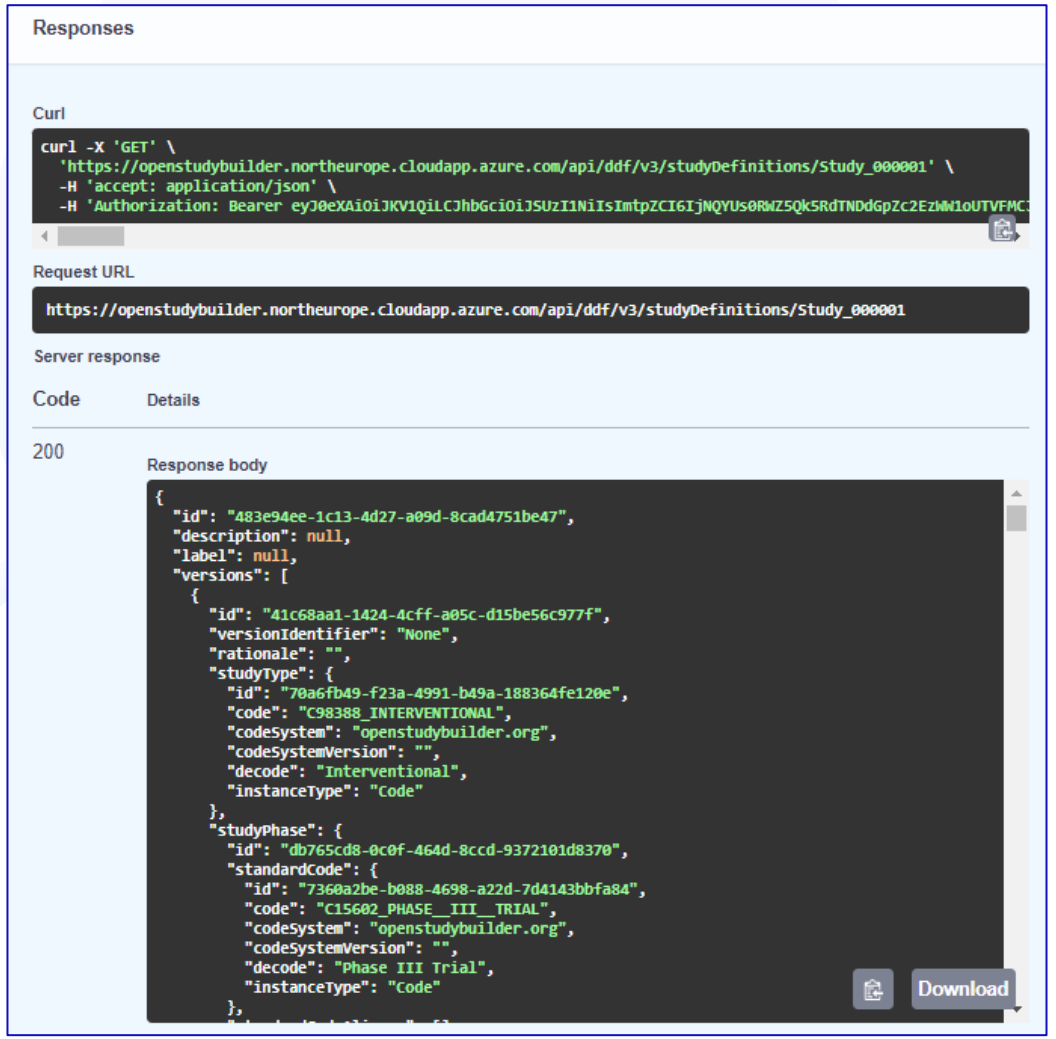
- Downstream structured content management
  - For documents: Protocol, SAP…
- Downstream data consumption
  - Clinical & Ops Systems
    - EDC/CDMS, CTMS, …
- Upload to DDF-compliant SDR for data sharing

# Mapping Matrix

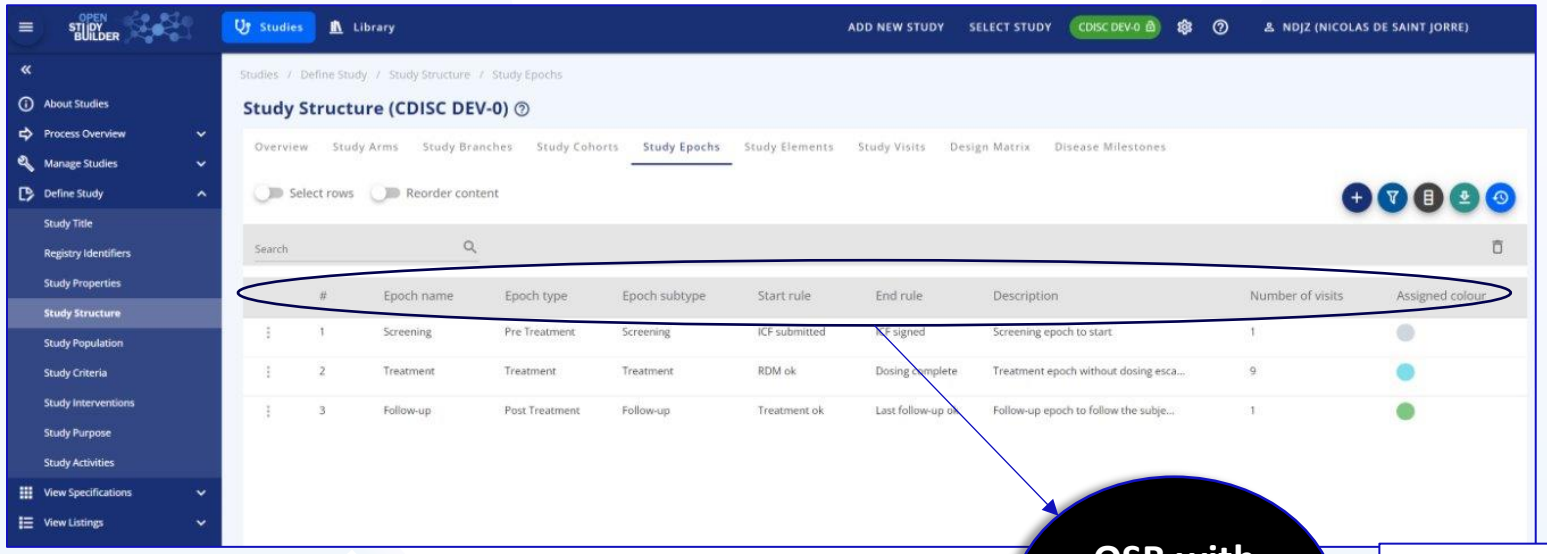
| | A | B | C | D | E | F | G | H | I | J | K |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Row | Entity Name | Role | Logical Data Model Name | NCI C-code | CT Item Preferred Name | Synonym(s) | Definition | Has Value List | Codelist URL | OpenStudyBuilder Mapping |
| 112 | 111 | Encounter | 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/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} |

# API – The DDF Endpoint



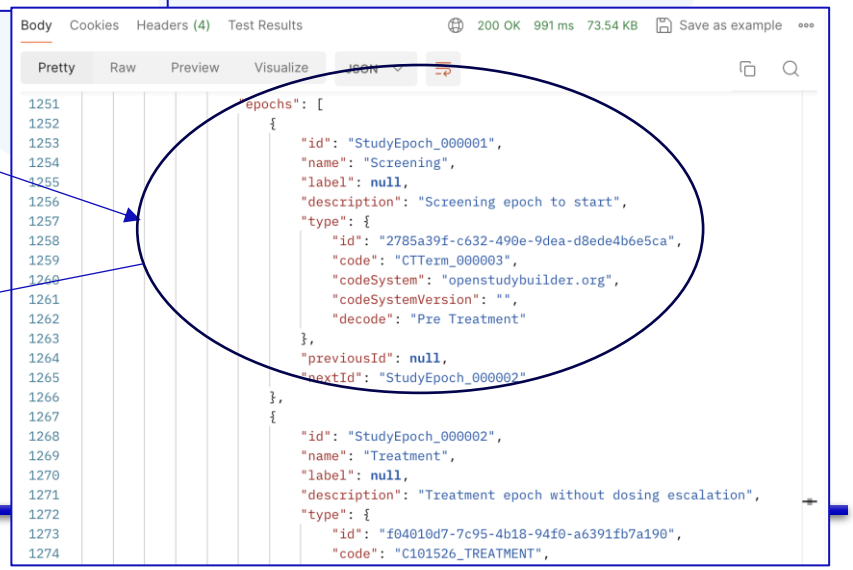



# API – The DDF Endpoint




**OSB with USDM API endpoint**

DDF Study Definitions Repository (SDR)



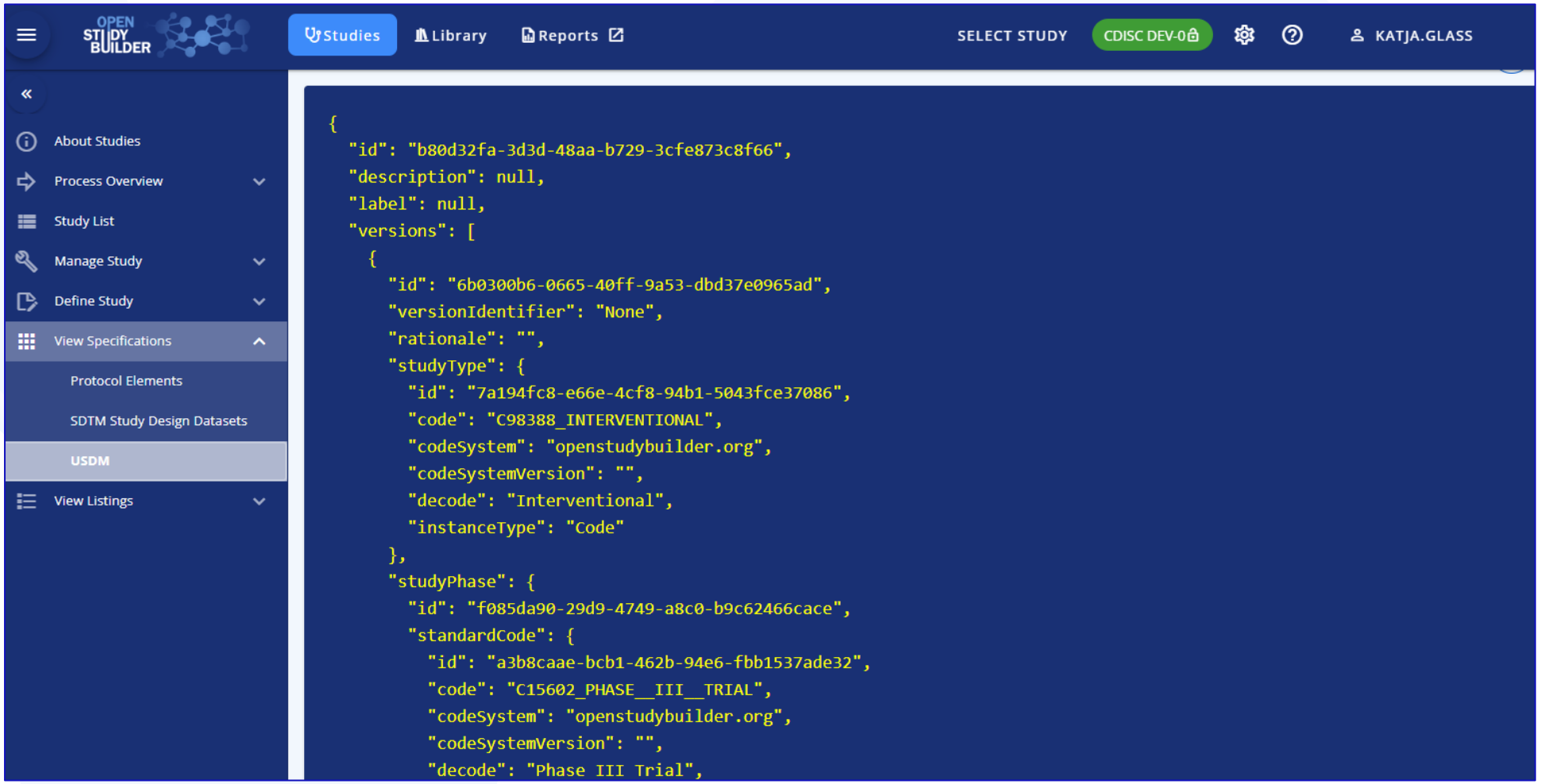
# DDF Endpoint in UI

Raw USDM

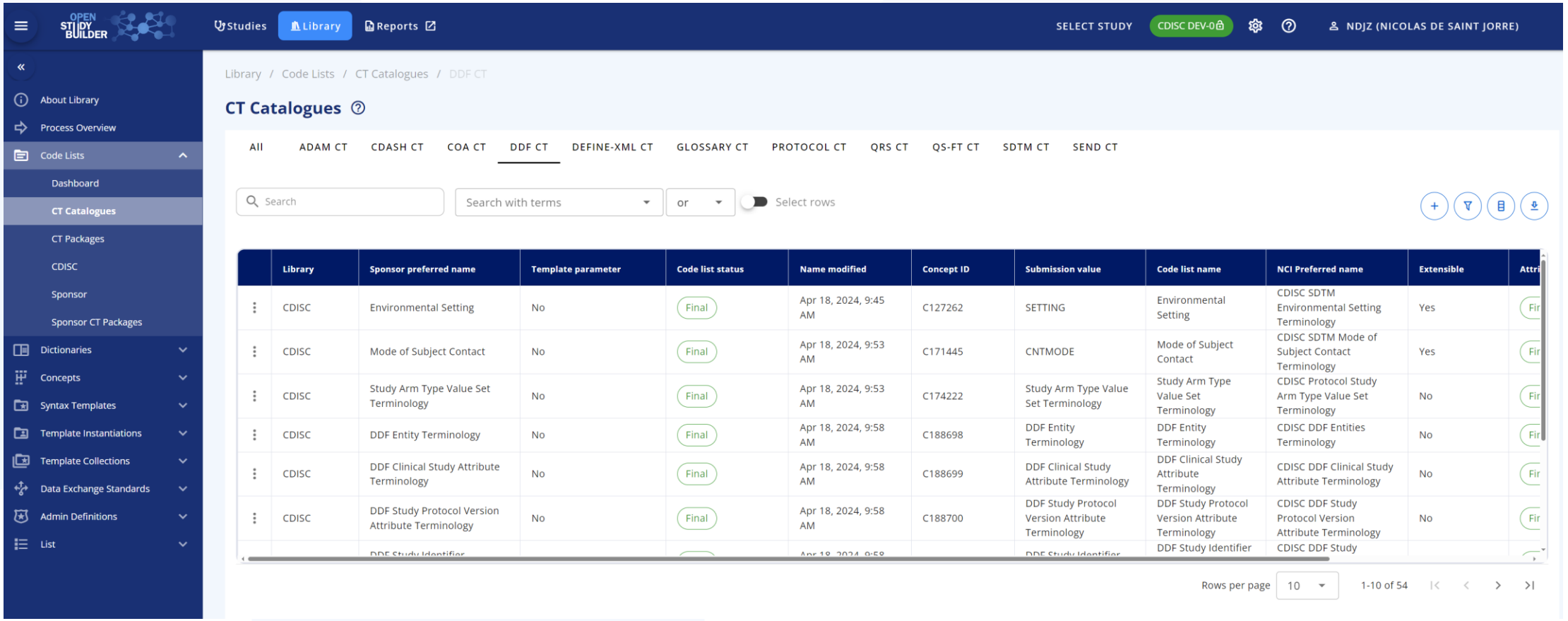
**display**

**M11**

Rendering



# DDF Controlled Terminology

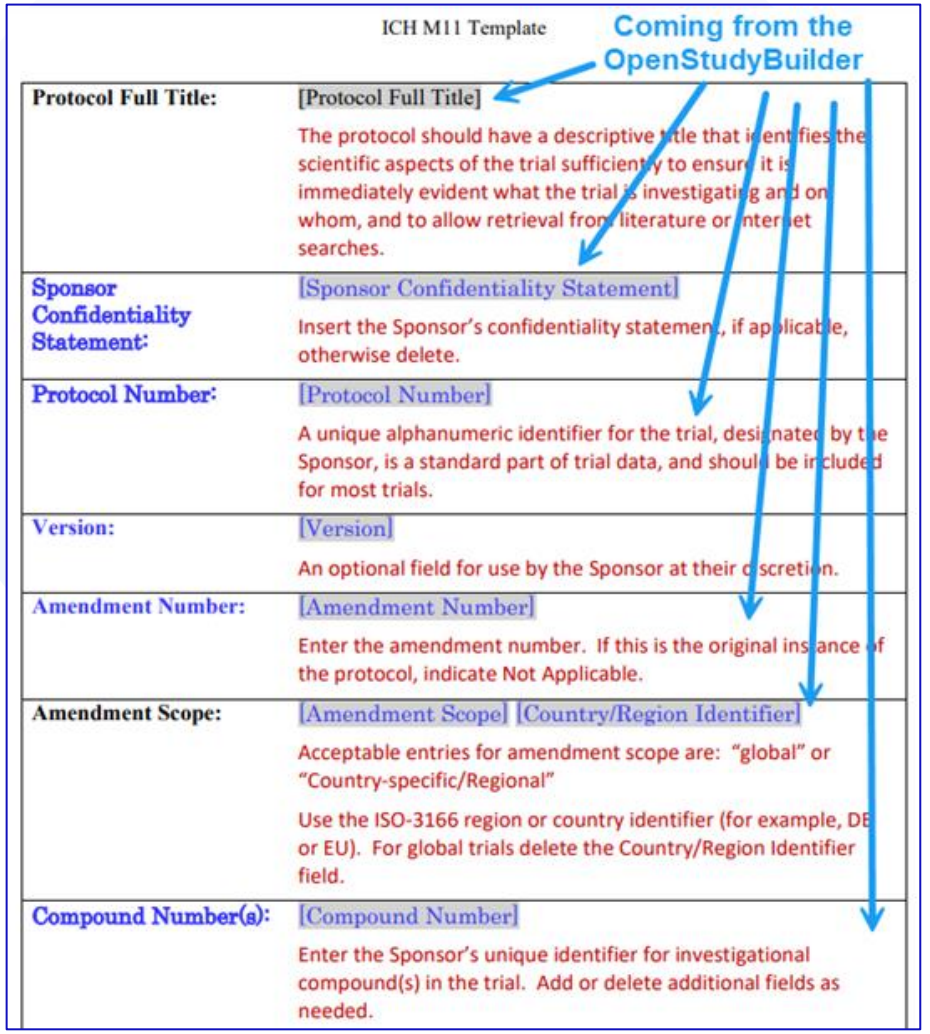



| Library | Sponsor preferred name | Template parameter | Code list status | Name modified | Concept ID | Submission value | Code list name | NCI Preferred name | Extensible |
|---|---|---|---|---|---|---|---|---|---|
| CDISC | Environmental Setting | No | Final | Apr 18, 2024, 9:45 AM | C127262 | SETTING | Environmental Setting | CDISC SDTM Environmental Setting Terminology | Yes |
| 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 |
| 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 |
| CDISC | DDF Entity Terminology | No | Final | Apr 18, 2024, 9:58 AM | C188698 | DDF Entity Terminology | DDF Entity Terminology | CDISC DDF Entities Terminology | No |
| 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 |
| 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 |
| | | | | | | | DDF Study Identifier | CDISC DDF Study | |

# USDM to ICH M11

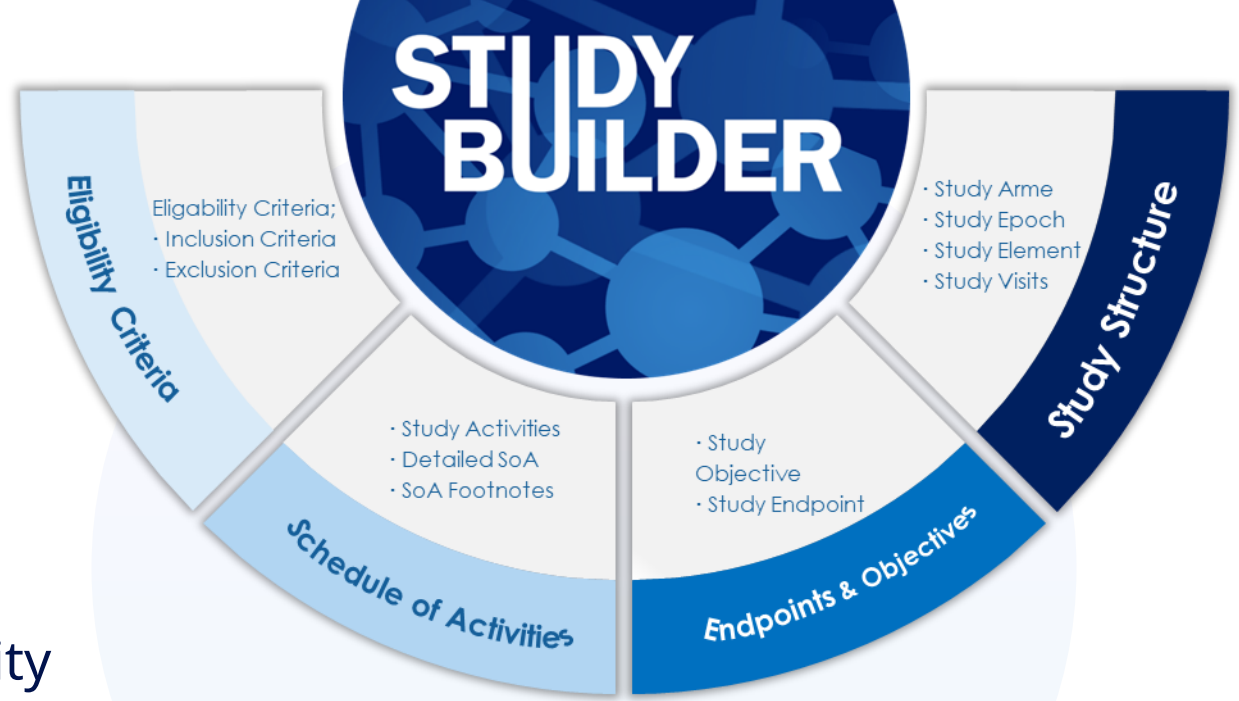
Integration of **ICH M11** Template in OBS:

- 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



# 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


**First business release (MVP*):**
- All interventional ph 2-4 studies
- Users within Clinical Operations, Clinical Reporting & Data Mangement Systems and Stanards
- 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-Jvrhtmy7hGstgyiIvB1Wsw
- 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



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# Tools & Resources

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# Thank you!

**Please reach out with any additional questions:**
**ddf@transcelerateBiopharmainc.com**