

From Documents to Connected Metadata

Graphs in Clinical Trials

Neo4j Meetup

11. November 2026

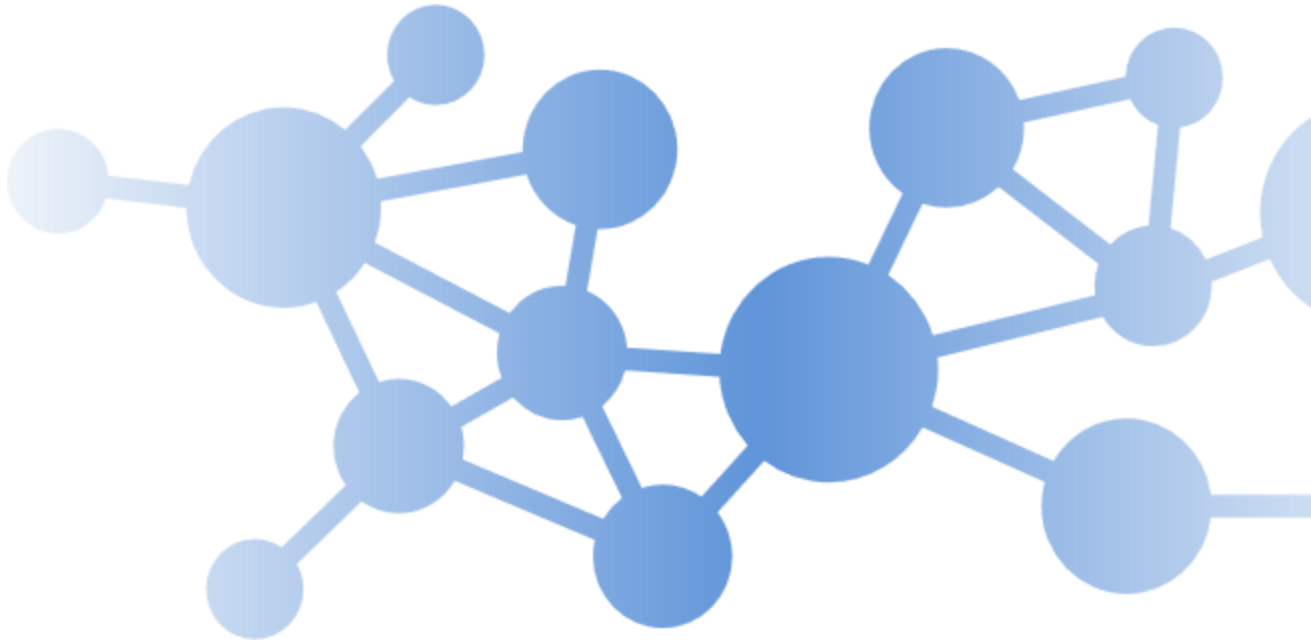
Katja Glaß, OpenStudyBuilder Community Manager

Agenda

01 Introduction

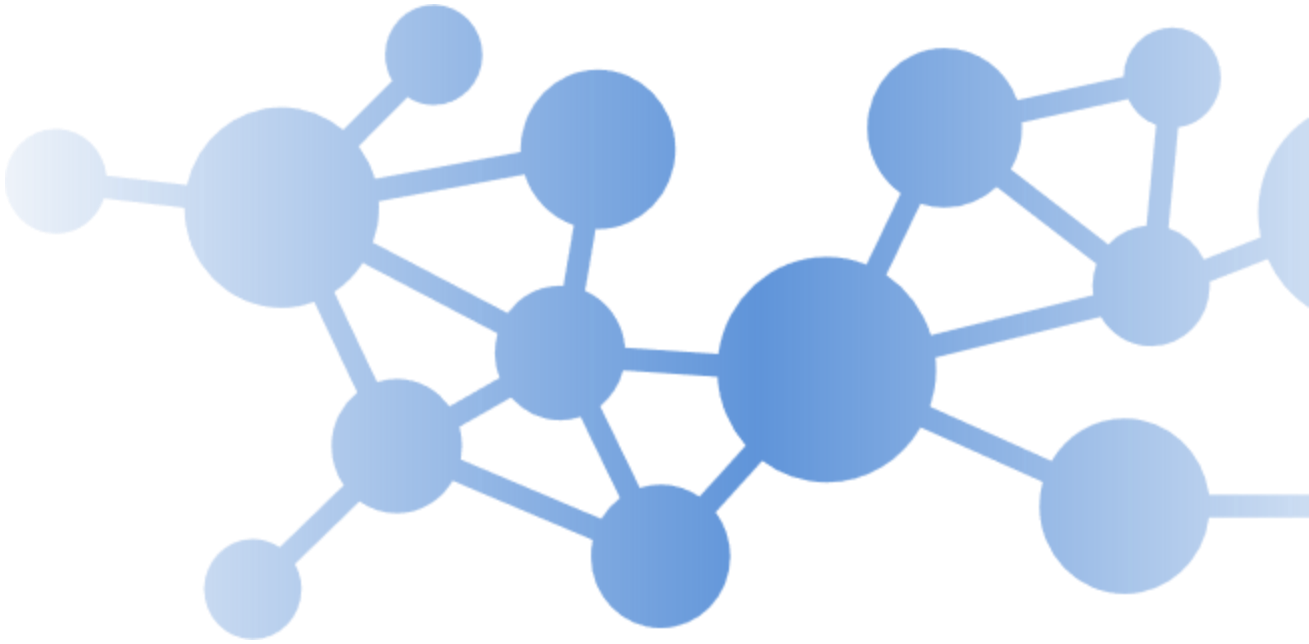
02 Graph in OSB

03 Outlook of OSB

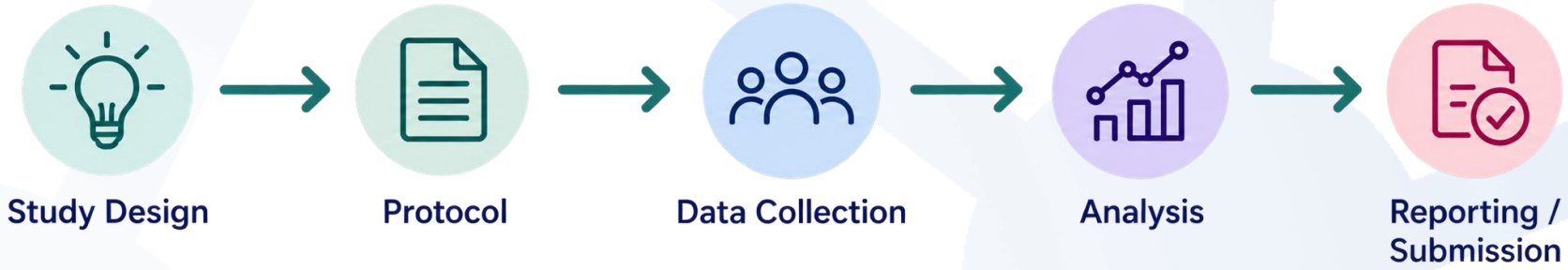


Introduction

What is OpenStudyBuilder?

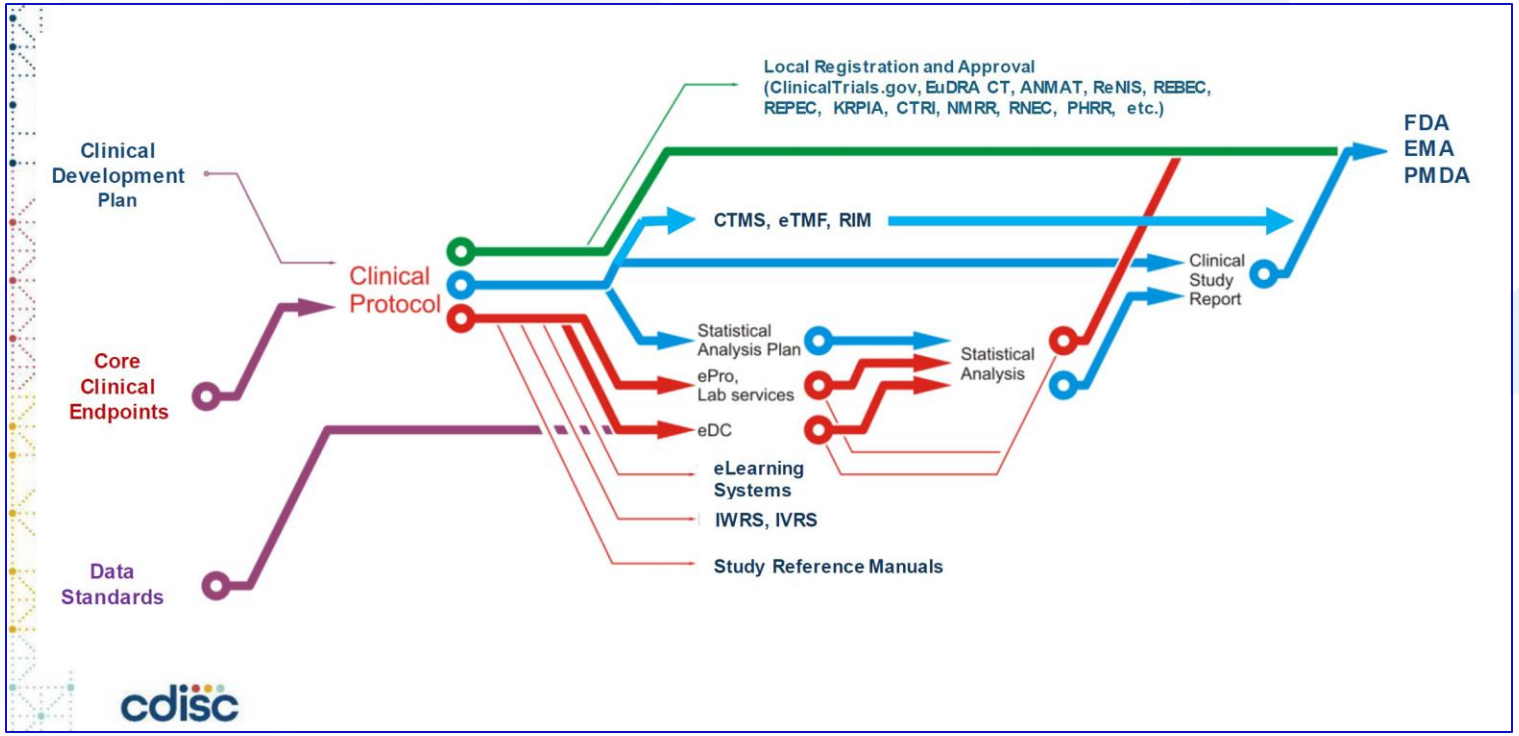


Clinical Studies Process Flow



Simplified. Heavily.

Clinical Studies Process Flow



Complex. **Connected.**

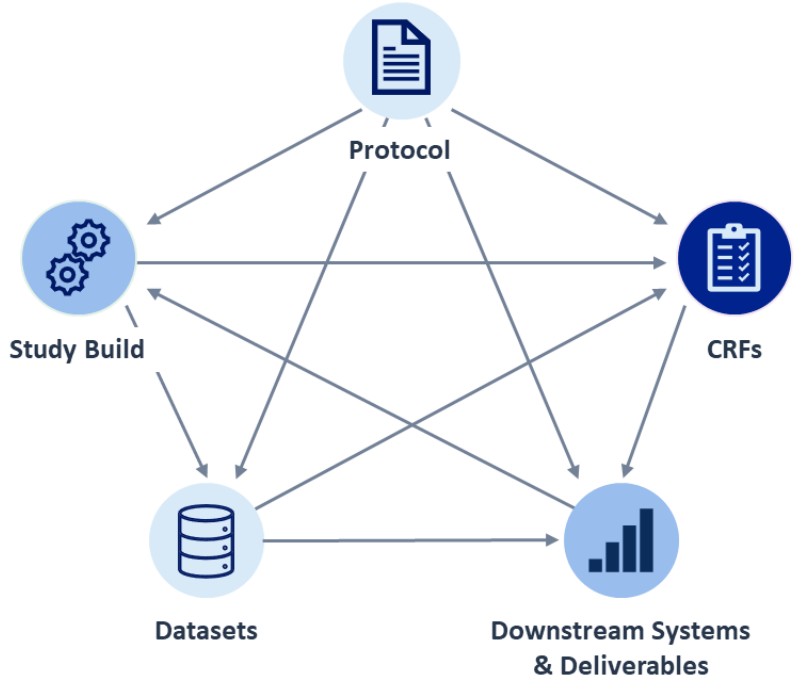
https://phuse.s3.eu-central-1.amazonaws.com/Archive/2024/Connect/US/Bethesda/PRE_SM12.pdf

Digital Data Flow Ambition

Before OSB

Same information, multiple places.

Study information is repeatedly created and maintained across documents and systems.



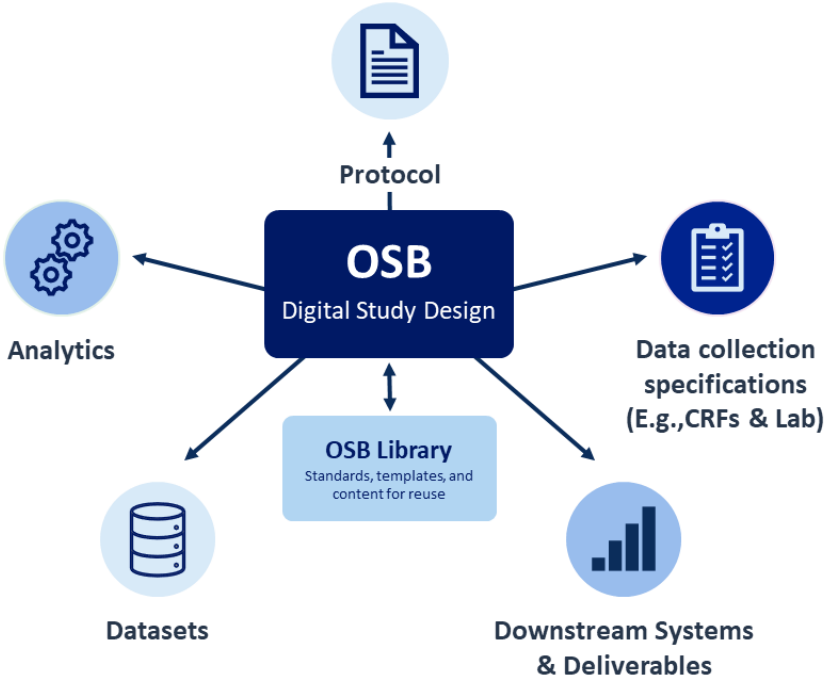
Define multiple times

Rework, inconsistencies, errors and delays

With OpenStudyBuilder

Define once. Reuse everywhere.

Structured study metadata is defined in OSB and reused across downstream outputs and systems.



- Consistent study metadata
- Reduced manual work
- Faster study delivery

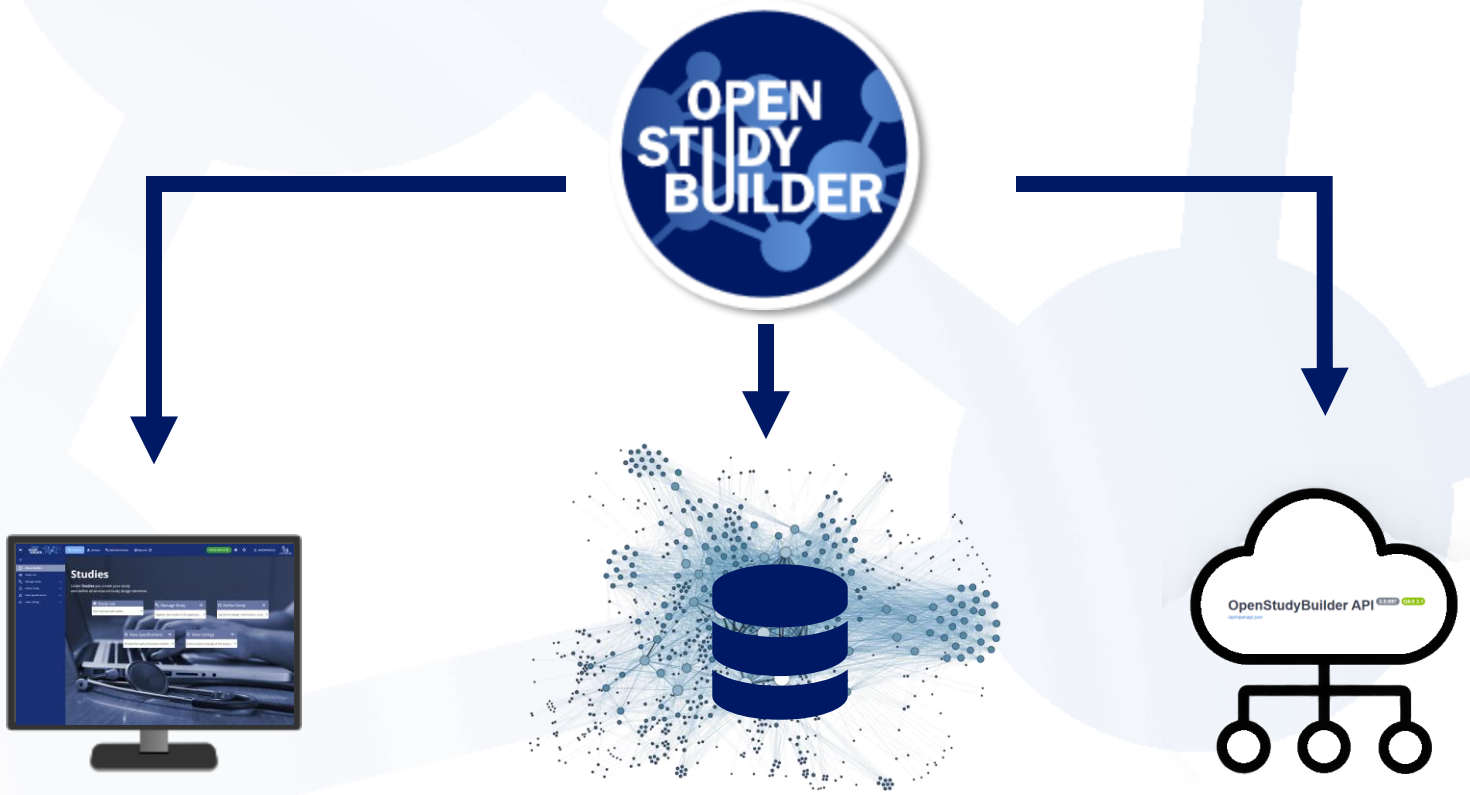
What is OpenStudyBuilder?

- A new **digital approach** to study specifications
- An **open source** project
- Aligned with **TransCelerate**'s Digital Data Flow initiative
- Based on the **CDISC** standards
- Allowing for central **governance** of internal and external **standards**
- Facilitating **automation** and **interoperability** with other systems



Metadata & Study Definition Repository
(MDR & SDR)

The Architecture



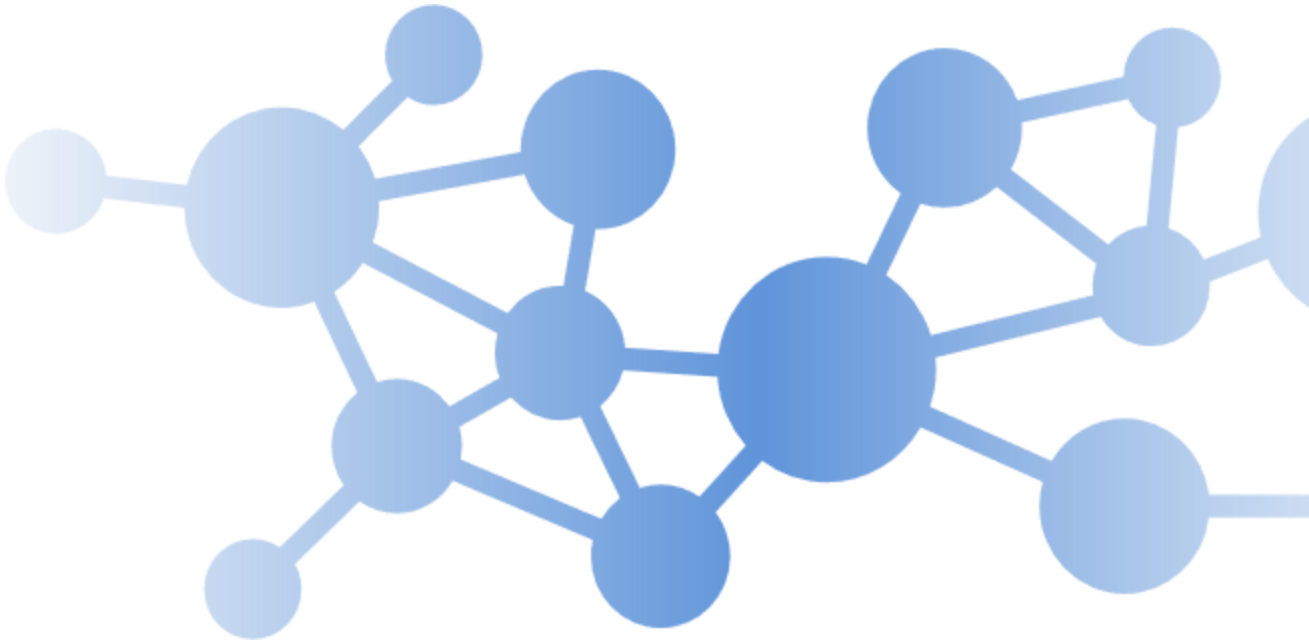
Web based user interface

Metadata and Study Definition Repository

API

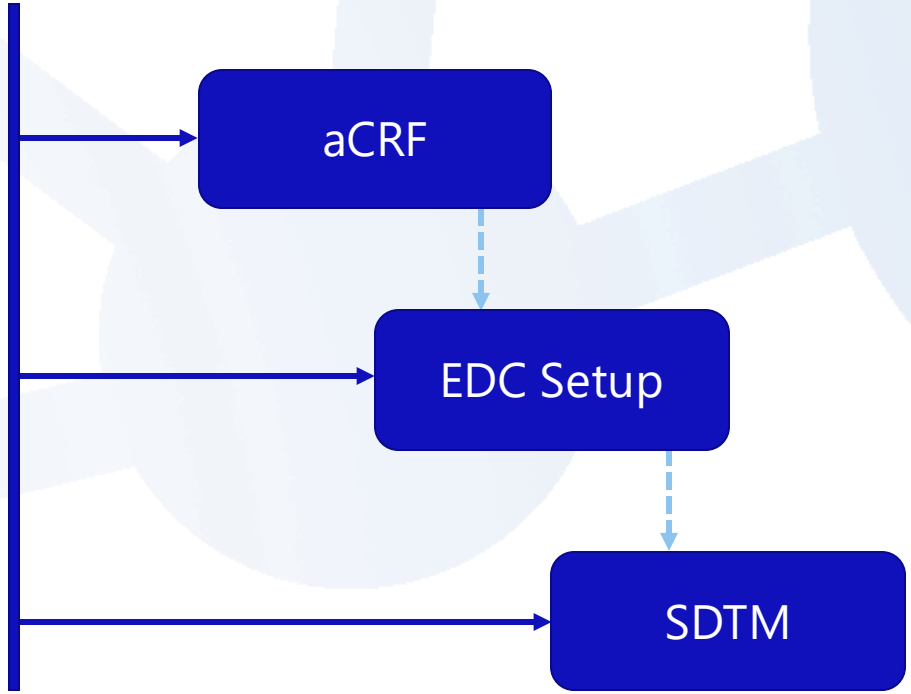
Graph in OSB

Study definitions and metadata as a graph



From SoA to aCRF, EDC & SDTM

Epoch		Screening	Treatment	
Visit		V1 ☐	V2 ☐	V3 ☐
Study week		-2	0	1
Visit window (days)		-13/0	0	±1
VITAL SIGNS				
VITAL SIGNS				
☐ Pulse Rate		☑	☑	☑
☐ Diastolic Blood Pressure		☑	☑	☑
☐ Systolic Blood Pressure		☑	☑	☑
MEDICAL HISTORY/CONCOMITANT ILLNESS				



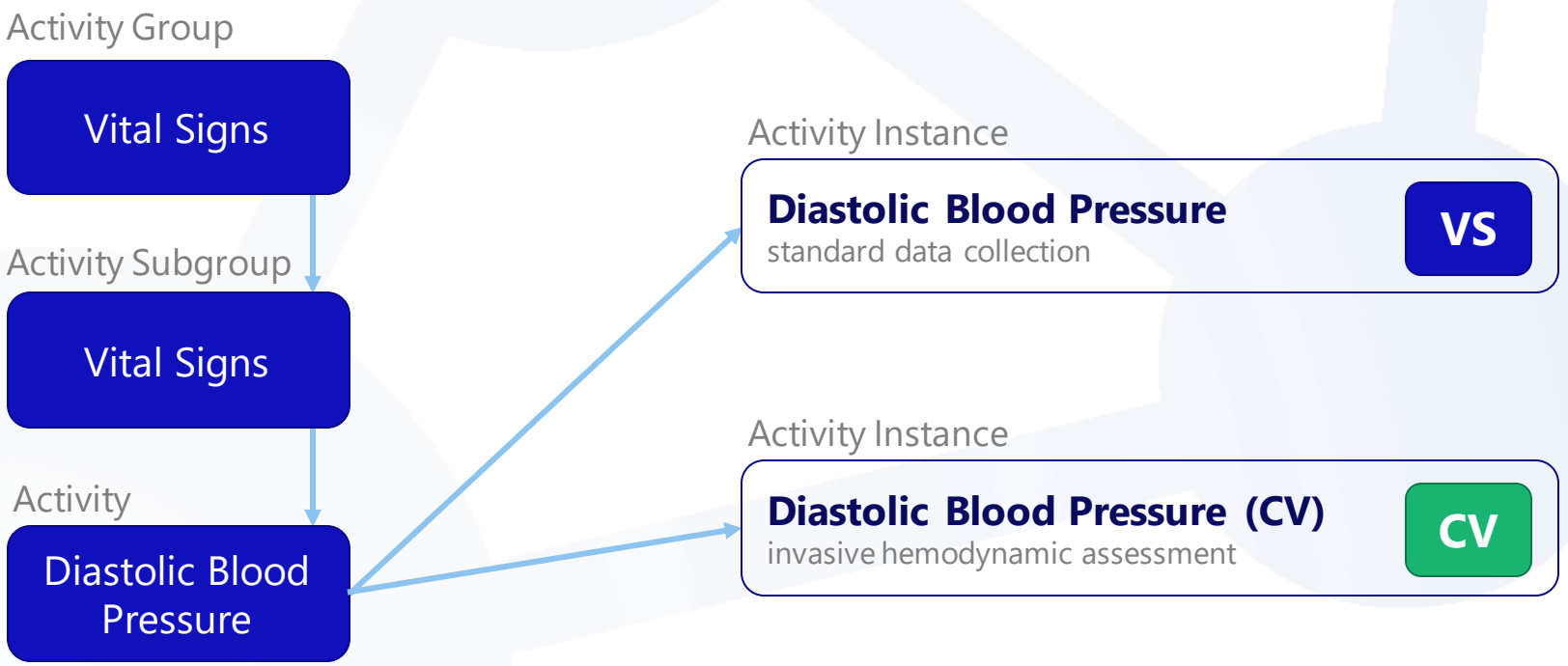
From SoA to aCRF, EDC & SDTM



Protocol

VITAL SIGNS	
VITAL SIGNS	
Diastolic Blood Pressure	

From SoA to aCRF, EDC & SDTM



Same activity. Different meaning.

From SoA to aCRF, EDC & SDTM

Activity Instance

Diastolic Blood Pressure
standard data collection

VS

Attributes	
Library	Sponsor
Status	Final
Version	2.0
Activity instance class	NumericFindings
ADaM parameter code	DIABP
Topic Code	BP_DIASTOLIC

Attributes Item Classes

ITEM CLASS	VALUE	Submission Value
domain	Vital Signs Domain	VS
unit_dimension	Pressure	PRESSURE
laterality	Right, Left	RIGHT, LEFT
location	Arm	ARM
standard_unit	mmHG	
...		

From SoA to aCRF, EDC & SDTM

Activity Instance

Diastolic Blood Pressure
standard data collection

VS

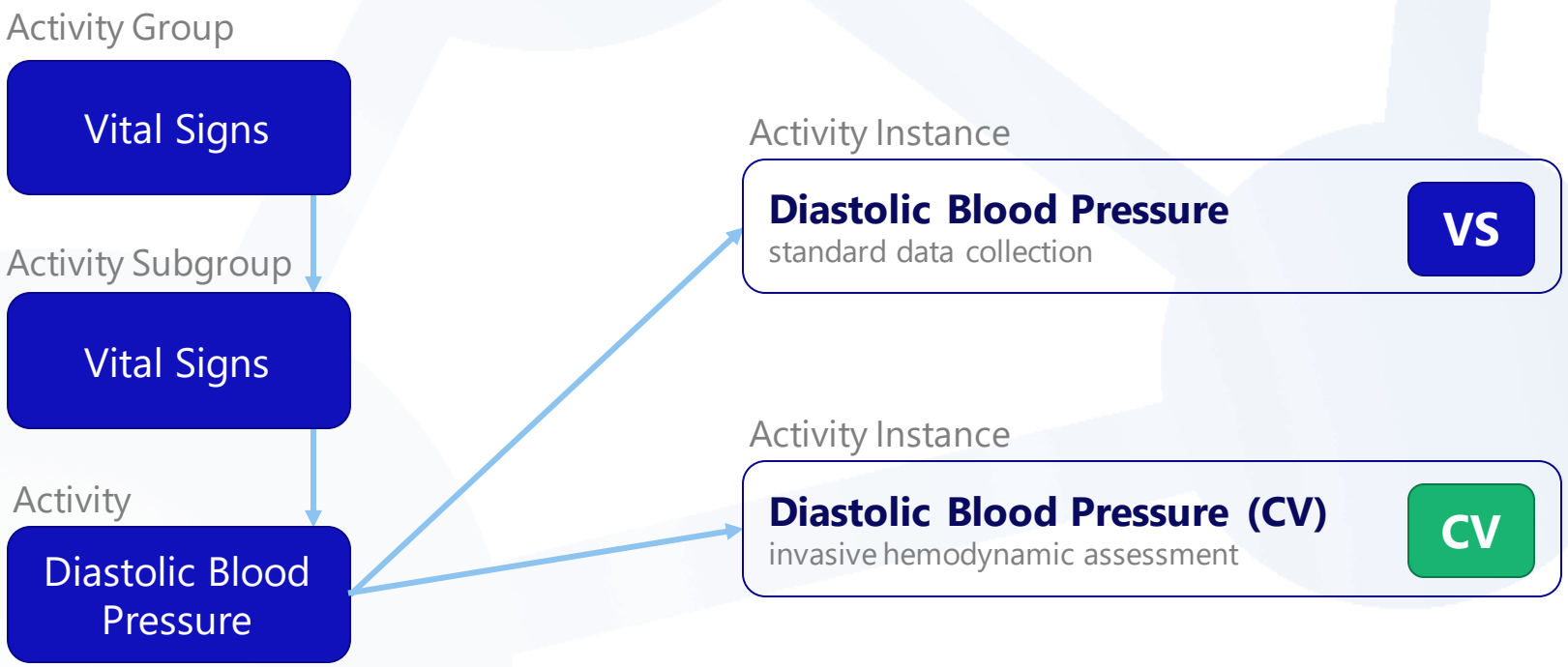
Attributes Item Classes

ITEM CLASS	VALUE	Submission Value
domain	Vital Signs Domain	VS
unit_dimension	Pressure	PRESSURE
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...		

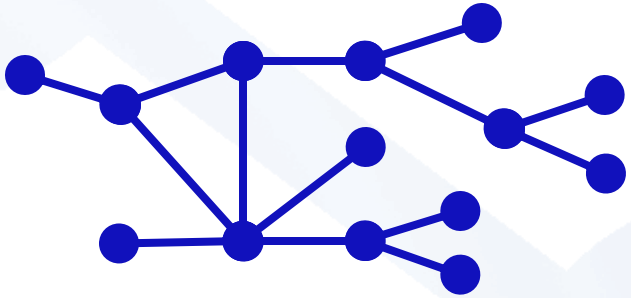
CRF – ODM Items

	Blood pressure and pulse *	
*	Diastolic blood pressure	○ mmHg ○ Pa
*	Position	○ Sitting ○ Supine Position ○ Standing
*	Laterality	○ Right ○ Left
*	Anatomical Location	○ Arm

Data Specification

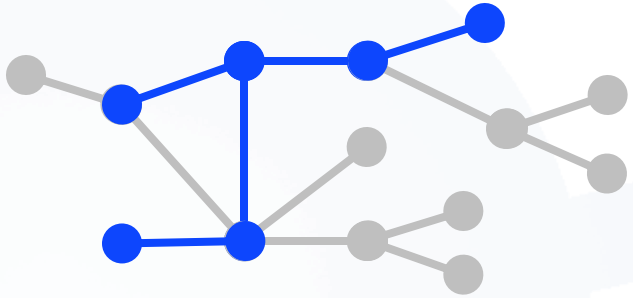


One Graph. Three Views.

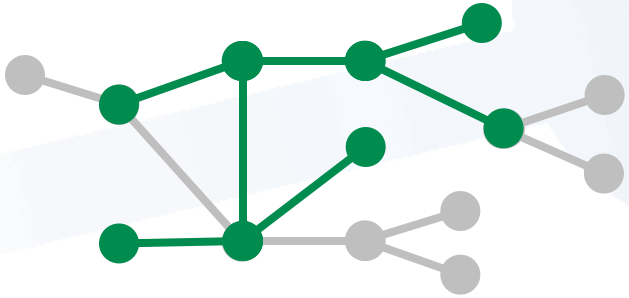


Library - Activity Instance Items
Connected Standards

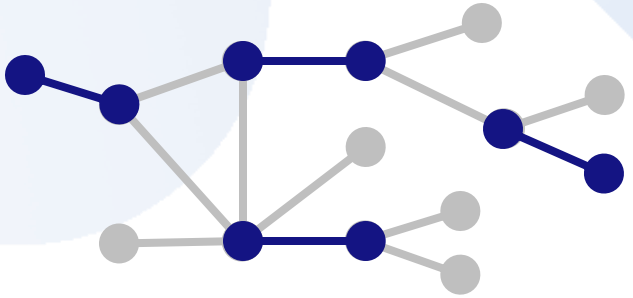
Study Data Specifications
within Schedule of Activities



aCRF.html
for humans



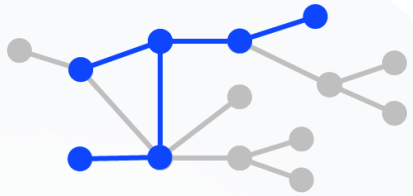
ODM.xml
for EDC Systems



Pre Define.xml
SDTM Structure

aCRF – SDTM Mapping

- Manual mapping via items
- Automated mapping through Activity Instances



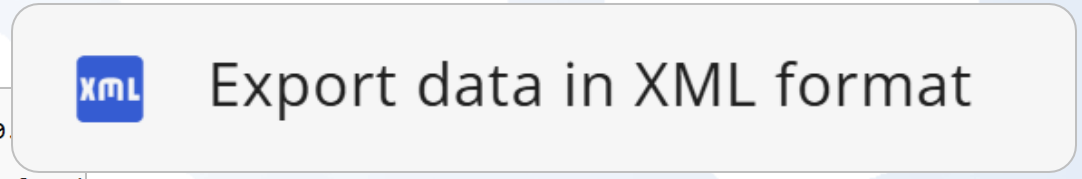
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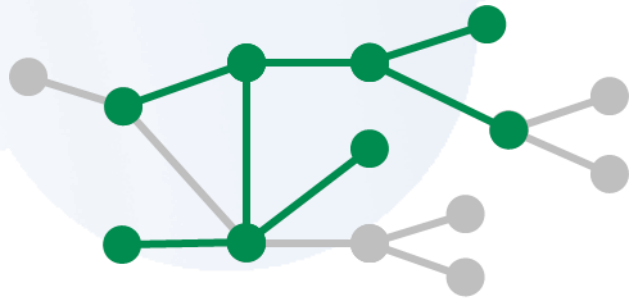
			VS (Vital Signs Domain)	VS (Vital Signs Domain) Ⓐ	Integration
	Blood pressure and pulse *				
*	Systolic blood pressure **ACTIVITY INSTANCE: Systolic Blood Pressure** Topic Code *BP_SYSTOLIC* ADaM Param Code *SYSBP* Activity Item Class *numeric_finding_original_result, numeric_finding_original_result_unit, domain*	○ mmHg	VSORRES Ⓐ VSORRESU Ⓐ VSORRES where VSTESTCD=SYSBP VSORRESU where VSTESTCD=SYSBP		

ODM.xml

- Export a CRF into ODM.xml (v1.3.2)

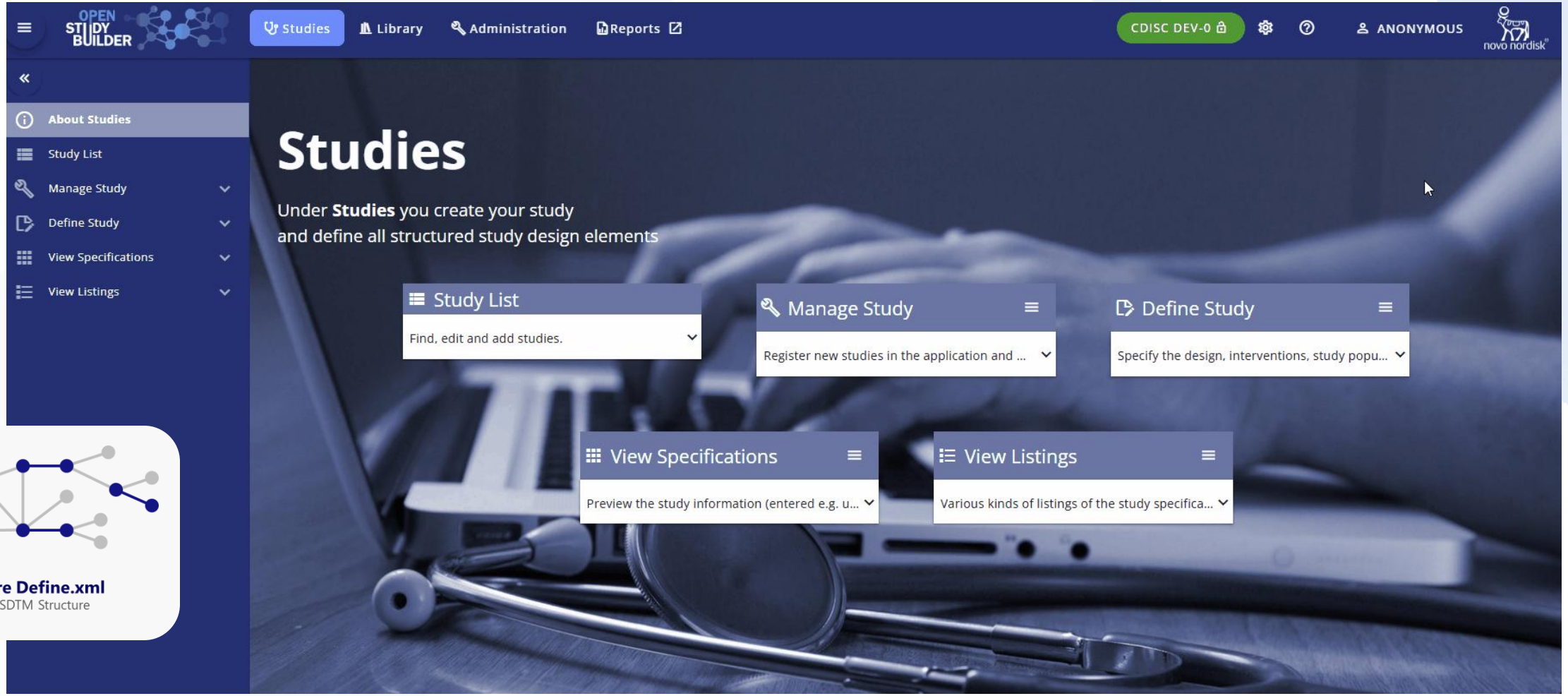
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        <FormDef OID="F.VS" Name="Vital Signs" Repeating="No" osb:version="0.
                <Description>
                        <TranslatedText xml:lang="en">Vital signs form</Translated
                </Description>
                <osb:CompletionInstructions>
                        <TranslatedText xml:lang="en">Please complete this Vital S
                </osb:CompletionInstructions>
                <ItemGroupRef ItemGroupOID="G.VS.VS" Mandatory="Yes" OrderNumber="
                <ItemGroupRef ItemGroupOID="G.VS.BPP" Mandatory="Yes" OrderNumber=
        </FormDef>
        <ItemGroupDef OID="G.VS.BPP" Name="Blood pressure and pulse" Repeating="No
                <osb:DomainColor>VS:#bfffff !important;</osb:DomainColor>
                <Description>
                        <TranslatedText xml:lang="en">Blood pressure and pulse</Tr
                </Description>
                <osb:CompletionInstructions>
                        <TranslatedText xml:lang="en">Please complete the Blood pr
                </osb:CompletionInstructions>
                <ItemRef ItemOID="I.SYSBP" Mandatory="Yes" OrderNumber="1"/>
                <ItemRef ItemOID="I.DIABP" Mandatory="Yes" OrderNumber="2"/>
                <ItemRef ItemOID="I.POSITION" Mandatory="Yes" OrderNumber="3"/>
                <ItemRef ItemOID="I.LATERALITY" Mandatory="Yes" OrderNumber="4"/>
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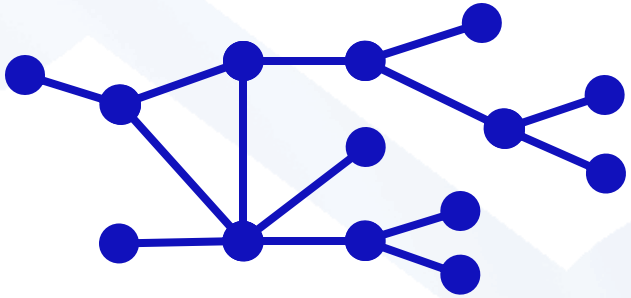
ODM.xml
for EDC Systems

SDTM Structure



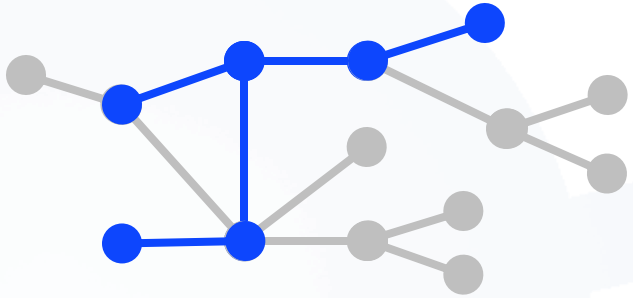
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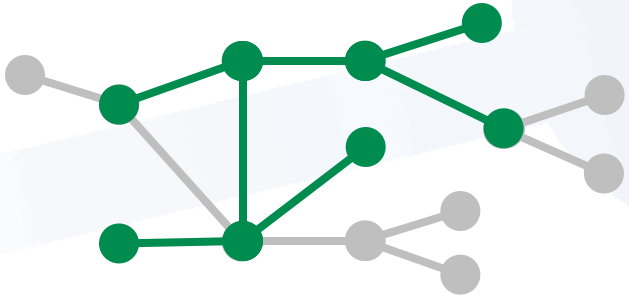


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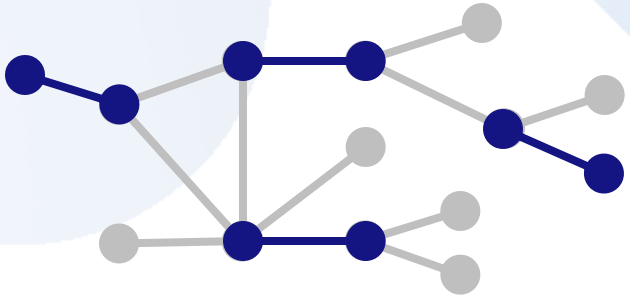
Study Data Specifications
within Schedule of Activities



aCRF.html
for humans

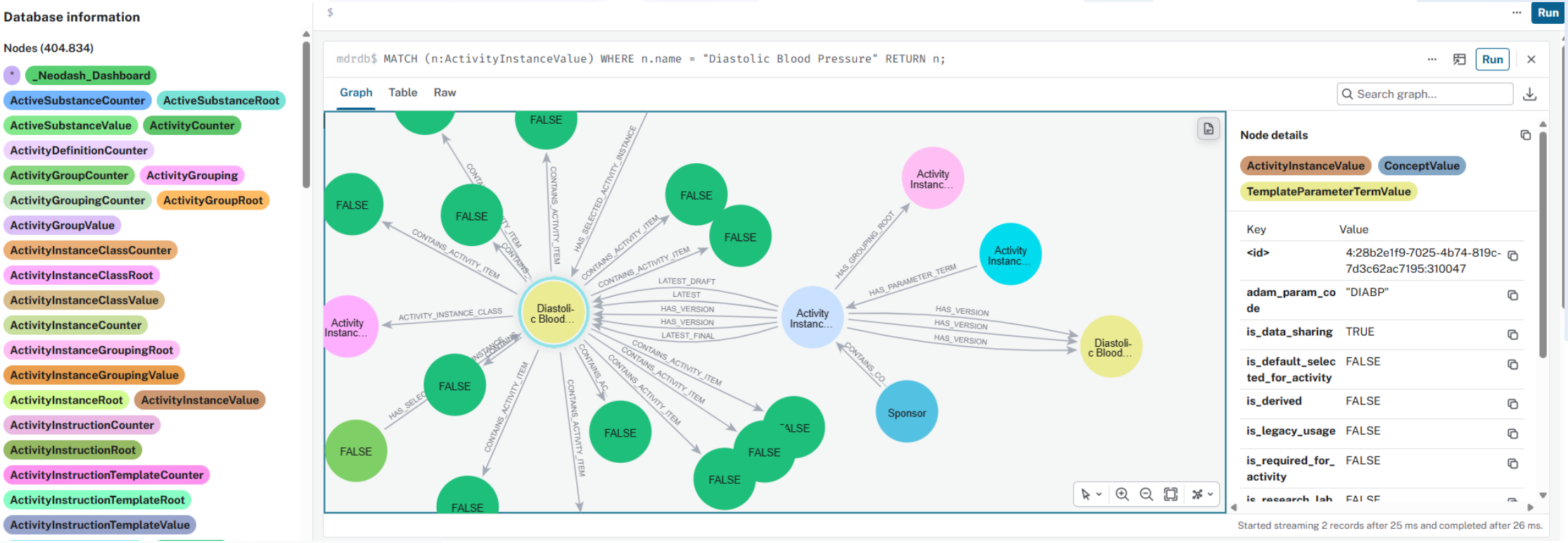


ODM.xml
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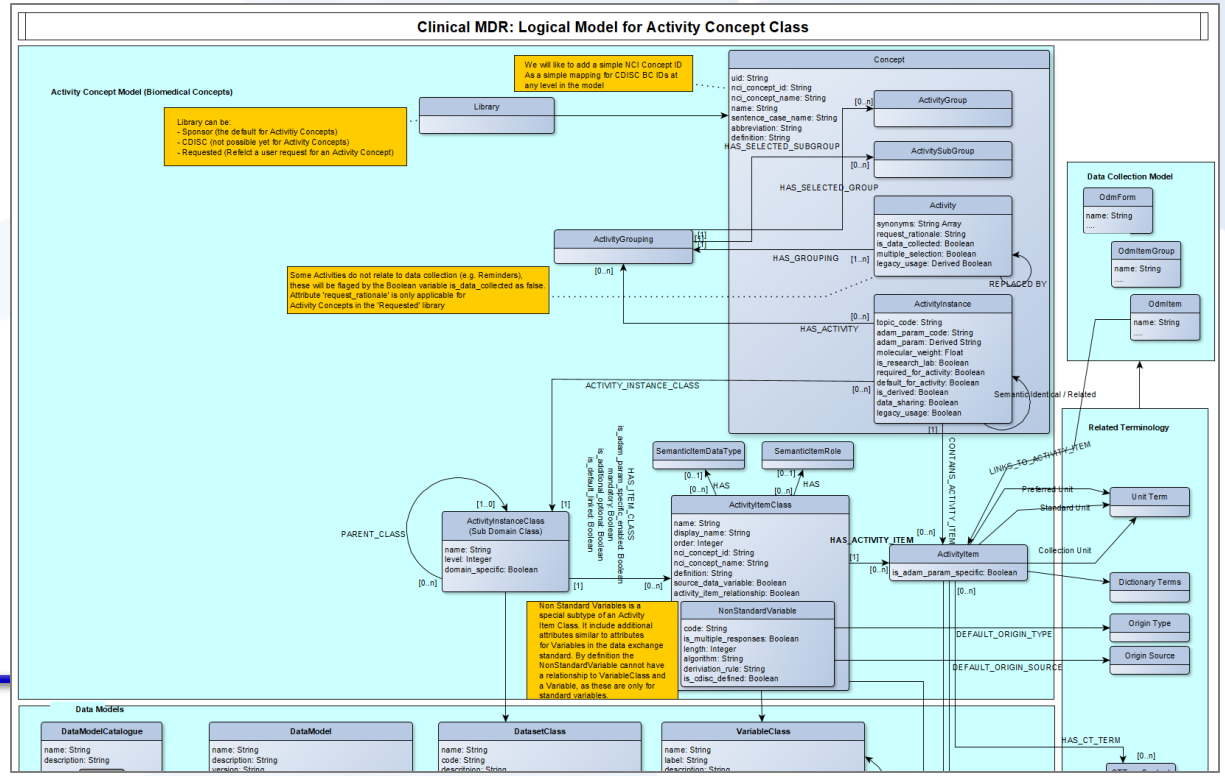
Pre Define.xml
SDTM Structure

Graph Database Insides



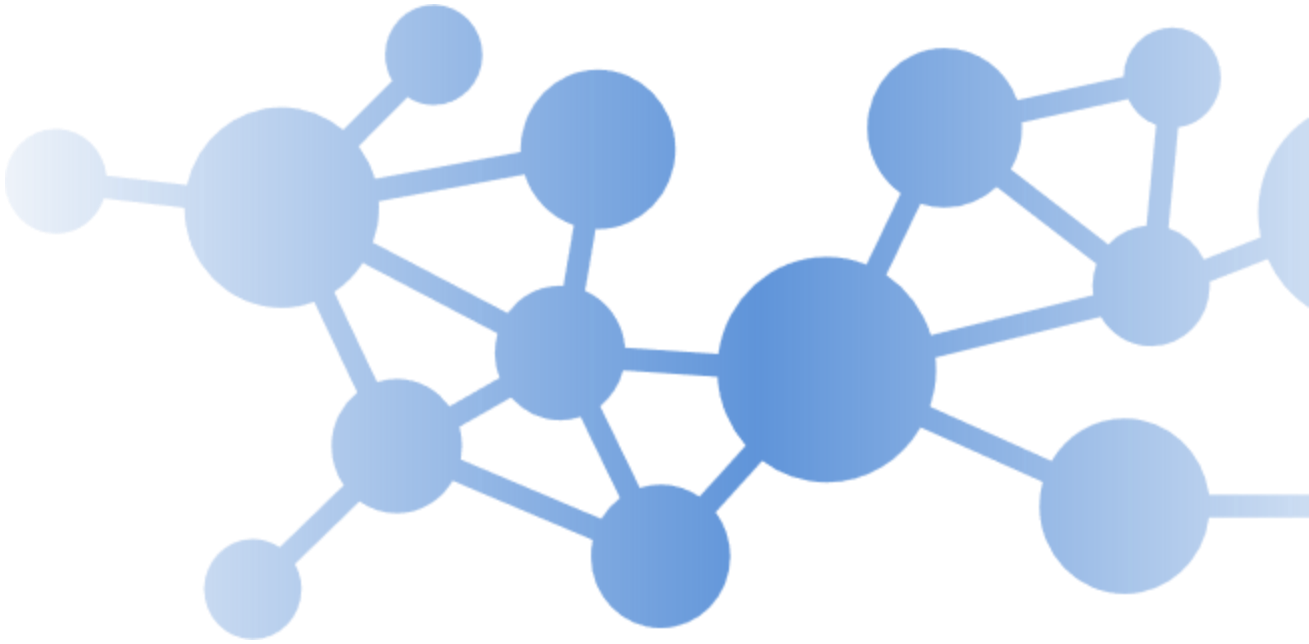
Graph Database Insides

- High complexity
- Includes versioning and audit trail
- OSB coming along with Neo4j browser and different DB views

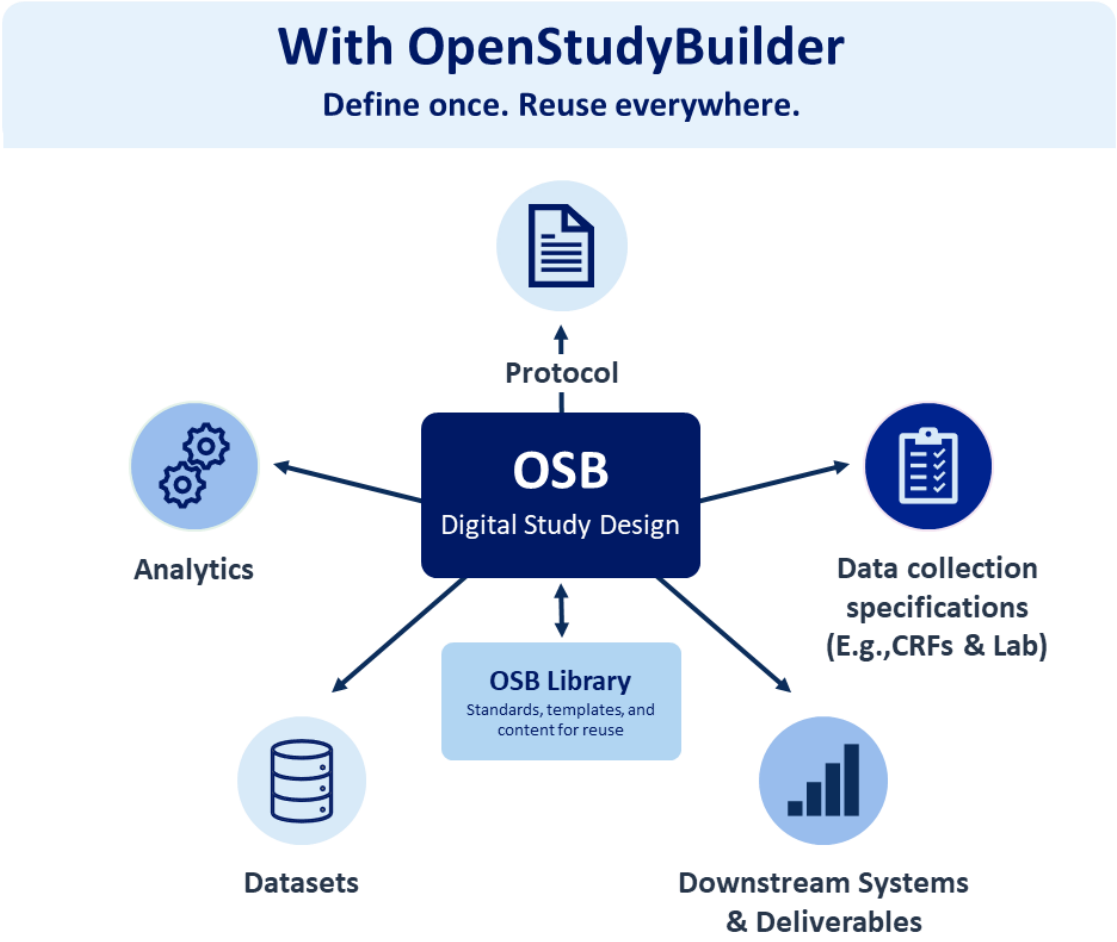


https://github.com/NovoNordisk-OpenSource/openstudybuilder-solution/tree/main/db/model/logical_data_model

Outlook of OSB



Graph technology enabling the digital data flow



Benefits of OpenStudyBuilder

One source of truth

Create study design information in a centralized, structured environment, and reused across processes, documents, and systems, improving consistency and traceability.

Standards by Design

Built-in alignment with CDISC and other standards helps ensure compliance and harmonization across studies and in downstream processes.

Automation and Efficiency:

Structured metadata, reusable templates, APIs, and integrations help reduce manual work, speed study setup, and support downstream automation.



Upcoming OSB Webinars

OSB WEBINAR · 1 OF 2

OpenStudyBuilder in Action

From Study Design to Downstream Automation

Wed, 25 November 2026

16:00 to 17:30 CET · Online via Teams · Free

Register here!

OSB WEBINAR · 2 OF 2

OpenStudyBuilder Collaboration

Where Open Source Meets Industry Collaboration

Thu, 3 December 2026

16:00 to 17:30 CET · Online via Teams · Free

Register here!

Get Started

Getting Started

- Project website: https://openstudybuilder.com
- Newsletter: LinkedIn
- Demonstration Videos: Overview (2025), Details (2023)
- Demonstration Flow: Homepage
- Repository: GitHub
- Slack: Join
- Email: openstudybuilder@gmail.com
- Request sandbox access: Sandbox
- Status Page: Status



https://openstudybuilder.com/status/

Questions?



OPEN STUDY BUILDER

Thank you for joining!