

# Use OpenStudyBuilder to drive EDC setup - a COSA Workshop



Mikkel Traun, Novo Nordisk

Sarah Jamal, Oracle

Charles Shadle, CDISC

08:45 – 09:00 Coffee and welcome

09:00 – 10:30 Introductions

11:00 – 13:30 Discussion & Lunch

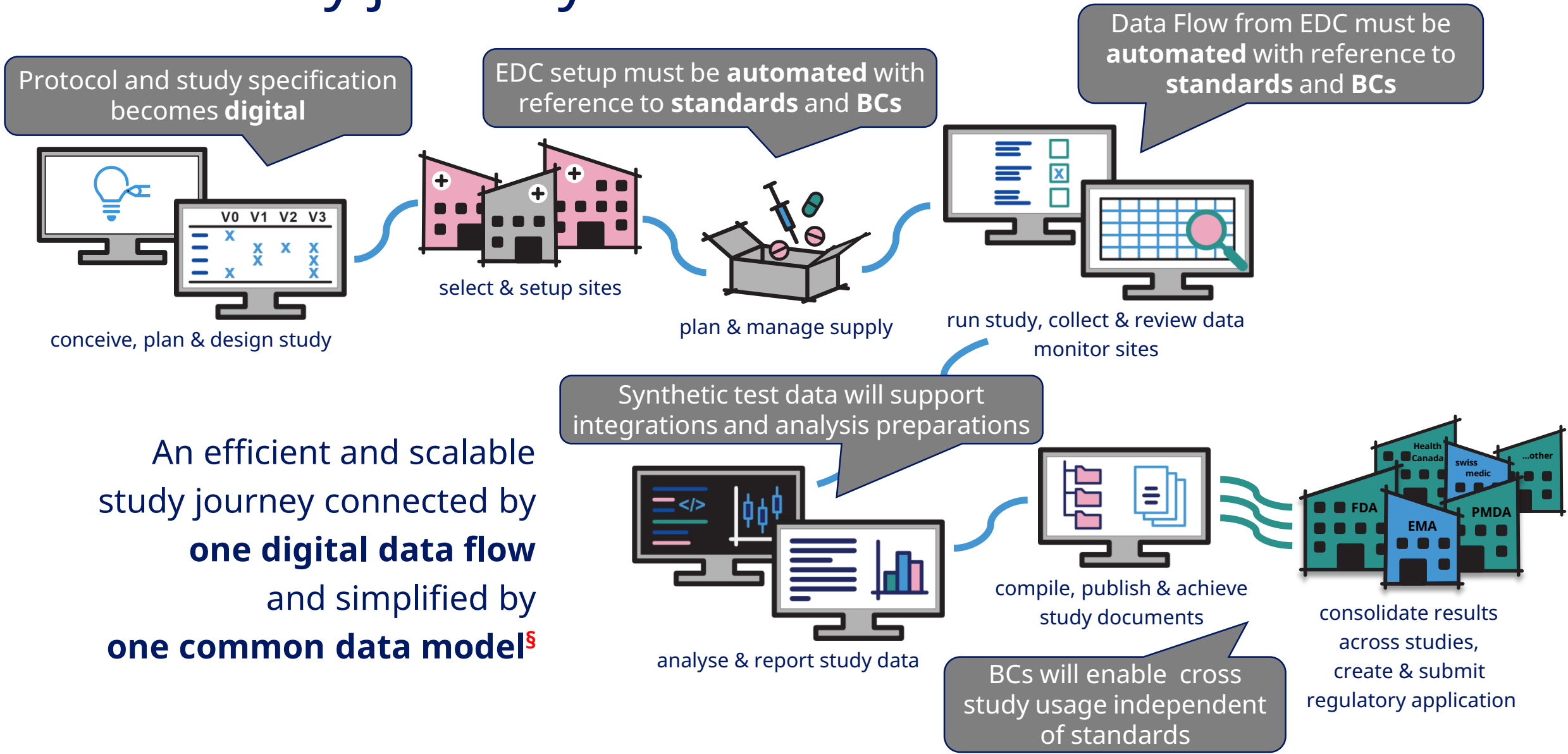
13:30 – 14:00 Summary and Closing

# Agenda

# Introduction



# ONE study journey



An efficient and scalable study journey connected by **one digital data flow** and simplified by **one common data model**<sup>§</sup>

<sup>§</sup> Modular and extensible interconnected domain-centric models with semantic metadata (incl taxonomies) and relations

# Introductions

Who are we today?

What brought you here?

Do you see opportunities in improved  
MDR/SDT <-> EDC Integrations?

# 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

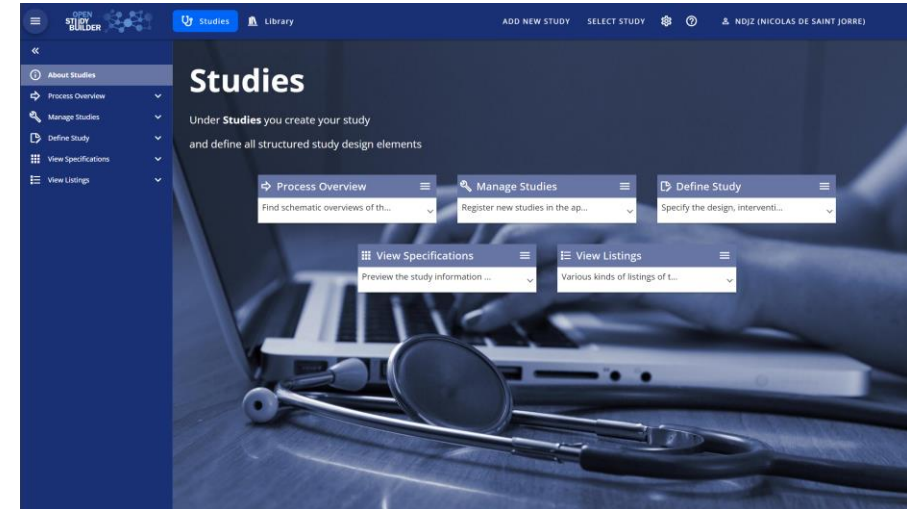
## 3 ELEMENTS OF OpenStudyBuilder

- **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)

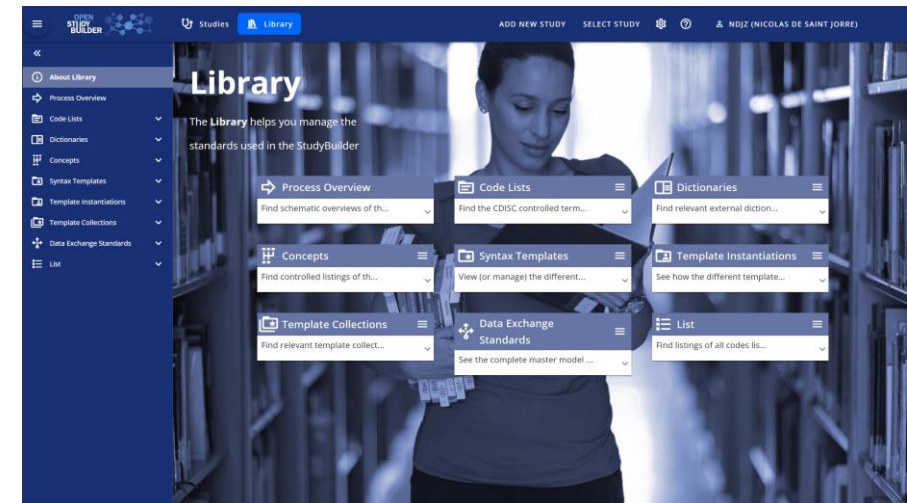


# OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	



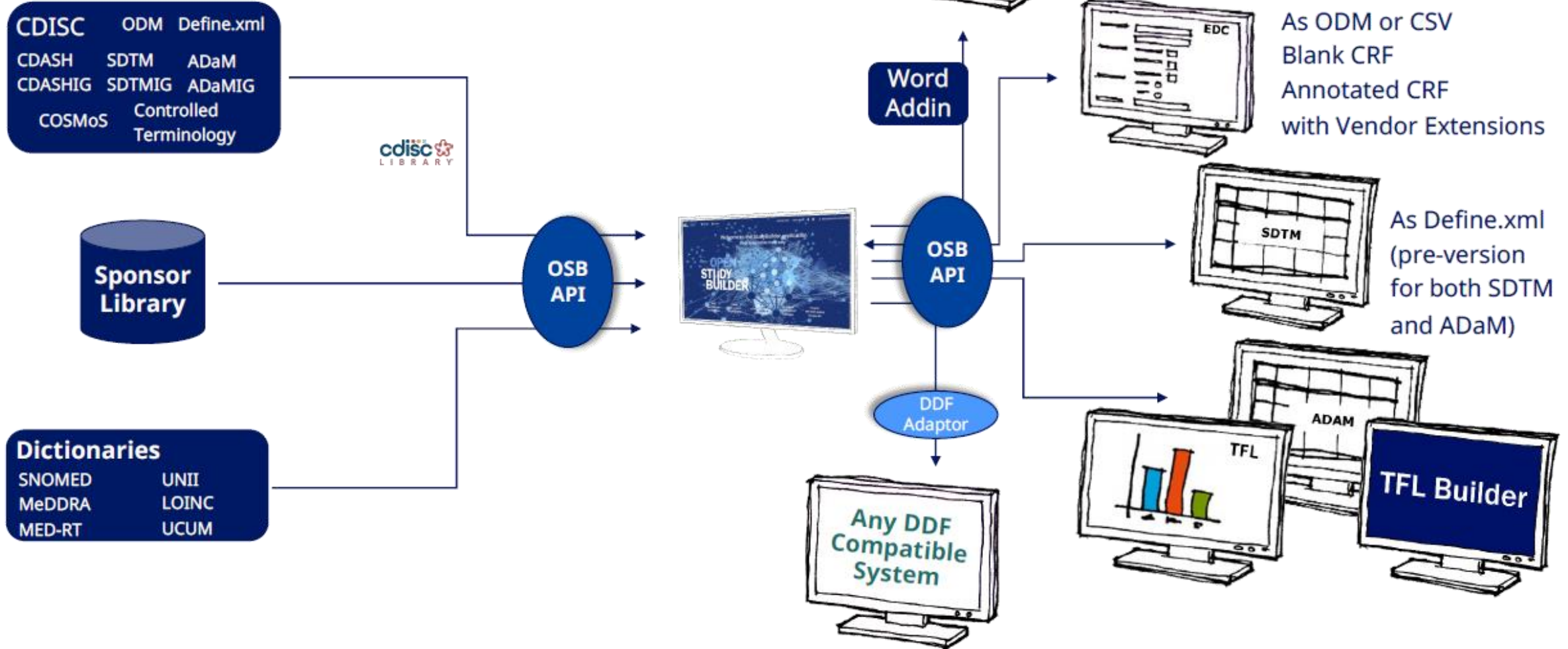
# Goal of OpenStudyBuilder

Metadata driven  
End-2-End Automation!





# Connectivity is key!

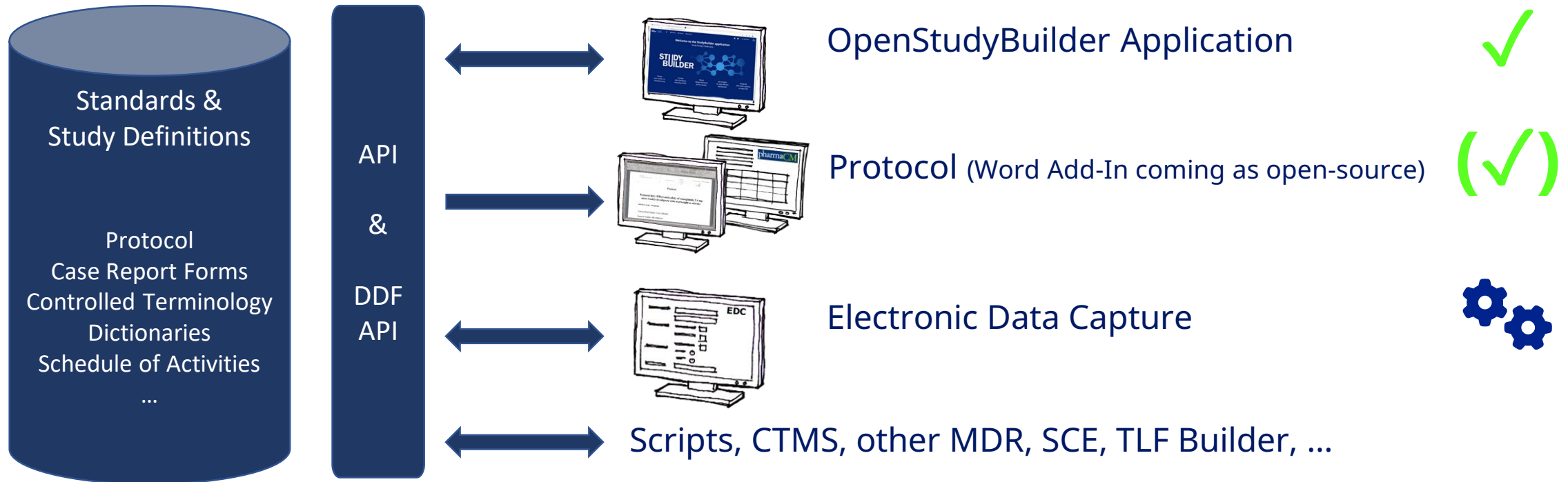


# Connectivity is key! - USDM Representation

The screenshot displays the Open Study Builder web application. The top navigation bar includes a hamburger menu, the logo 'OPEN STUDY BUILDER', and tabs for 'Studies', 'Library', and 'Reports'. On the right, there are buttons for 'SELECT STUDY', 'CDISC DEV-01', a settings gear, a help icon, and a user profile labeled 'ANONYMOUS'. The left sidebar contains a navigation menu with options like 'About Studies', 'Process Overview', 'Study List', 'Manage Study', 'Define Study', 'View Specifications', 'Protocol Elements', 'SDTM Study Design Datasets', 'USDM', and 'View Listings'. The main content area shows the breadcrumb 'Studies / View Specifications / USDM' and the title 'USDM version of the Protocol'. A download icon is visible in the top right of the content area. The central focus is a dark blue box containing a JSON representation of the USDM version of the Protocol.

```
{
  "id": "7b4fb61a-3378-4d87-972f-32897a4b6dda",
  "description": null,
  "label": null,
  "versions": [
    {
      "id": "1ba5ced7-dd7f-471d-9c3a-a588b1c4ef16",
      "versionIdentifier": "None",
      "rationale": "",
      "studyType": {
        "id": "83192125-80ad-4797-b276-df8a4747f90f",
        "code": "C98388_INTERVENTIONAL",
        "codeSystem": "openstudybuilder.org",
        "codeSystemVersion": "",
        "decode": "Interventional",
```

# Connectivity is key!



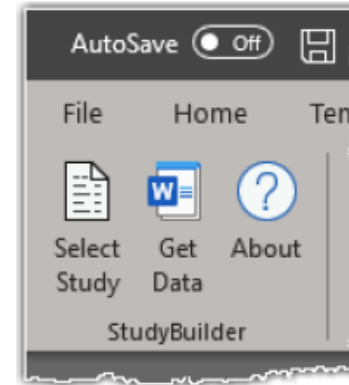
# Protocol Generation



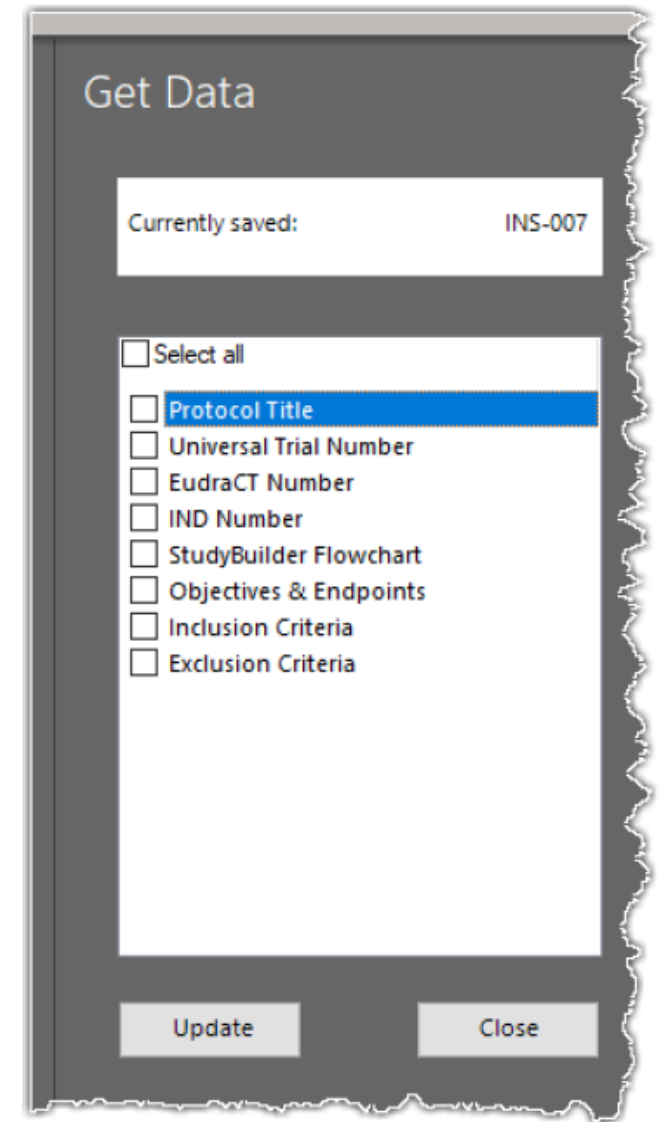
## StudyBuilder ribbon (Word add-in)



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



**Protocol**



Select Study & Version Get Data Start/End tags visible About StudyBuilder

Protocol Study ID: CDISC DEV-0	Date: Version:	30 September 2022 0.1	Status: Page:	Draft 9 of 75	Novo Nordisk
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## 1.2 Flowchart

Schedule of Activities

Structured content including SoA will be transferred to the content controls Word based Protocol Template

Procedure	Screening	Treatment									Follow-up
		V1	V2	V3	V4	V5	V6	V7	V8	V9	
<b>Visit short name</b>	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
Study day	-14	1	8	15	22	29	36	43	57	183	213
Visit window (days)	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35
<b>Randomisation</b>											
Randomisation		X									
<b>End of Study</b>											
End of Study											X
<b>Body Measurements</b>											
Body Measurements	X	X	X	X	X	X	X	X	X	X	X
<b>Eligibility Criteria</b>											
Eligibility Criteria	X										
<b>Laboratory Assessments</b>											
Glucose Metabolism	X	X	X	X	X	X	X	X	X	X	
Lipids	X	X			X			X		X	
Biochemistry	X	X			X			X		X	
<b>AE Requiring Additional Data</b>											

### Get Data

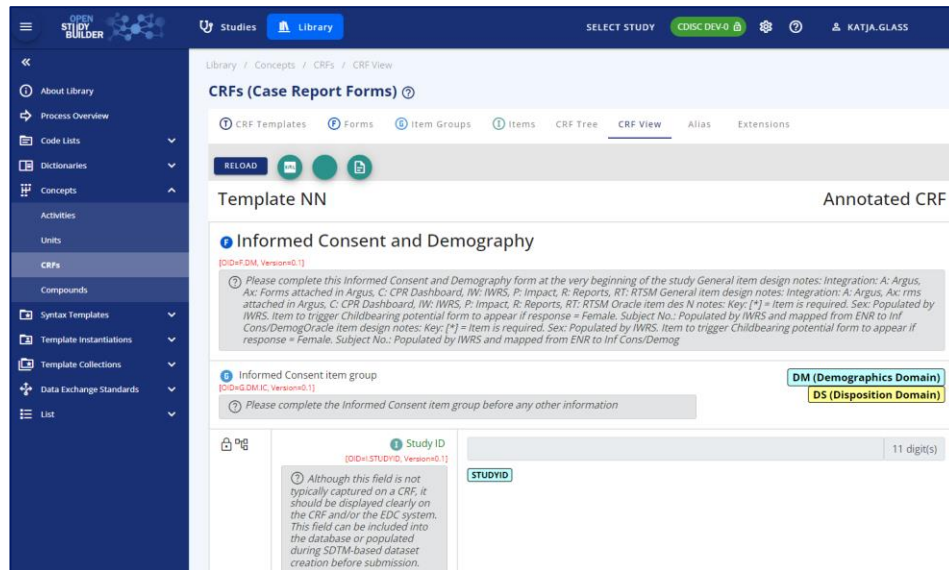
Currently saved: CDISC DEV-0

- Select all
- Protocol Title
- Protocol Short Title
- Universal Trial Number
- EudraCT Number
- IND Number
- Schedule of Activities
- Objectives & Endpoints
- Inclusion Criteria
- Exclusion Criteria

Update Cl

# CRF Standards & Metadata

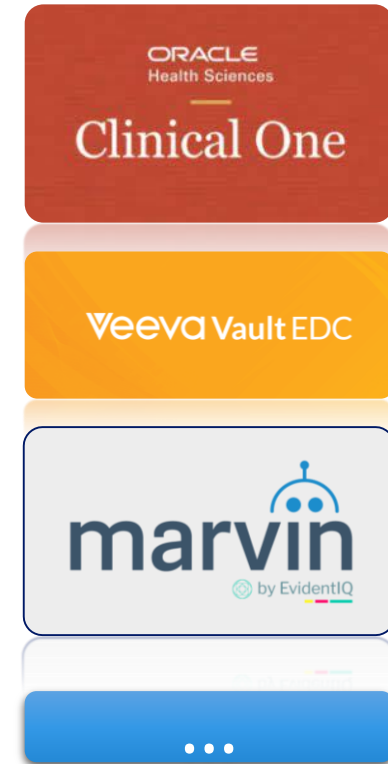
Manage  
Standard & Study CRF



Including rules, checks  
Support vendor extensions



EDC Setup, Test,  
Execution



Finetuning, Layout

# OpenStudyBuilder to drive EDC setup

A COSA Workshop



# Problem Statement

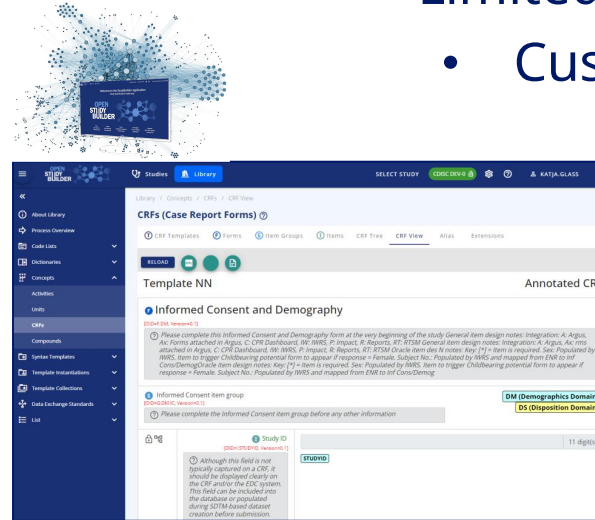
## Data Exchange Formats

- CDASH
- ODM.XML
- USDM
- Biomedical Concepts



## Implementation

- Native formats
- Limited interface capabilities
- Limited selection of standards
  - Custom extensions





# Workshop Focus

- Challenges & Opportunities
  - ODM.XML integrations
  - API based integrations
- Knowledge exchange
  - OpenStudyBuilder functionality
  - Integration status, challenges and opportunities from EDC vendors
- Discussion
  - Integration strengths, weaknesses, opportunities & threats
  - Options and next steps



# Opportunities – OpenStudyBuilder to EDC

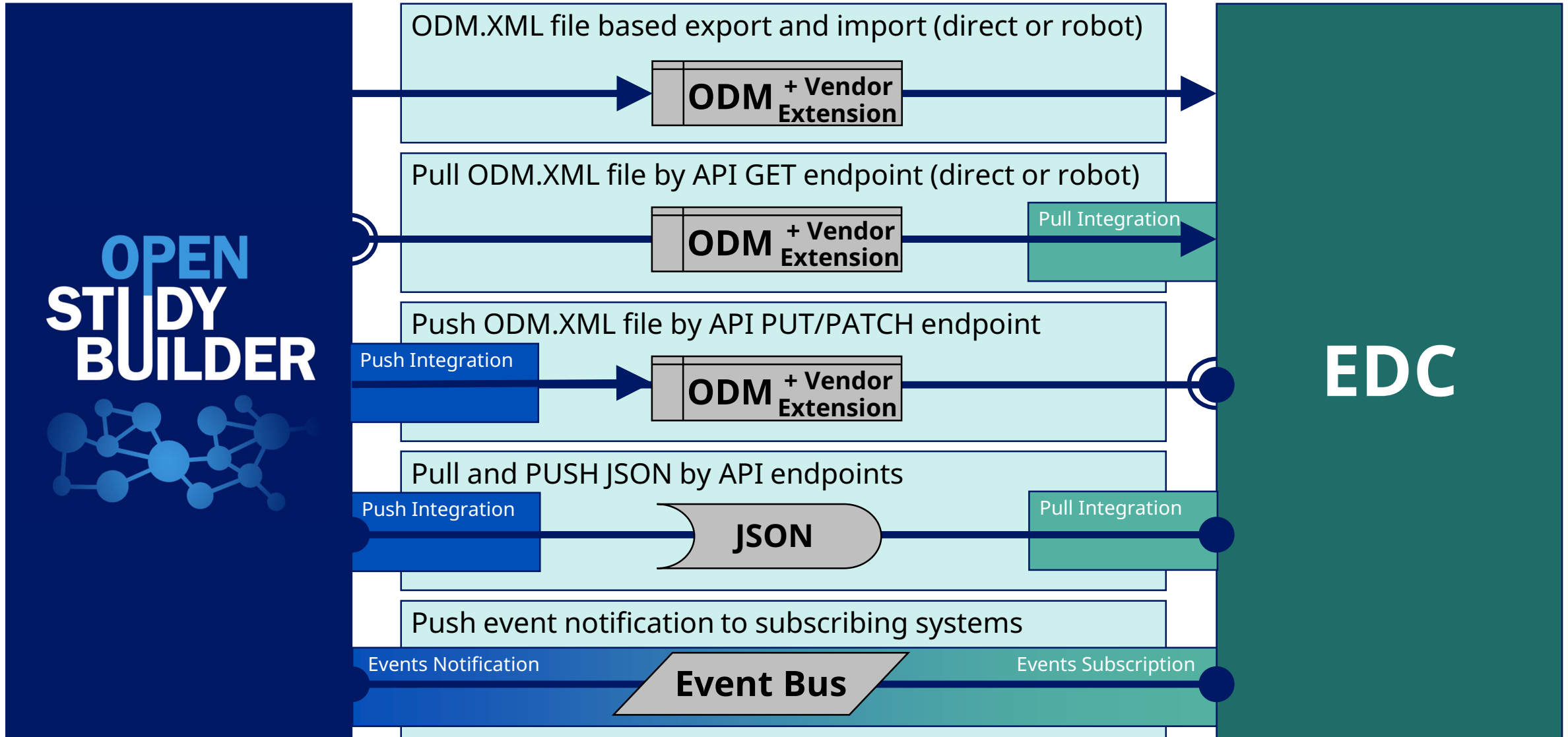
## Selection and Configuration of Standard Library Forms

- Standard Forms Defined in OSB Library
  - Include vendor extensions
- Standard Forms implemented in the EDC
  - Include vendor extensions and capabilities not supported by OSB
- Study selections of standard forms with configurations in OSB, this + study specification send to EDC
  - Shared vendor extensions in ODM.XML
  - APIs

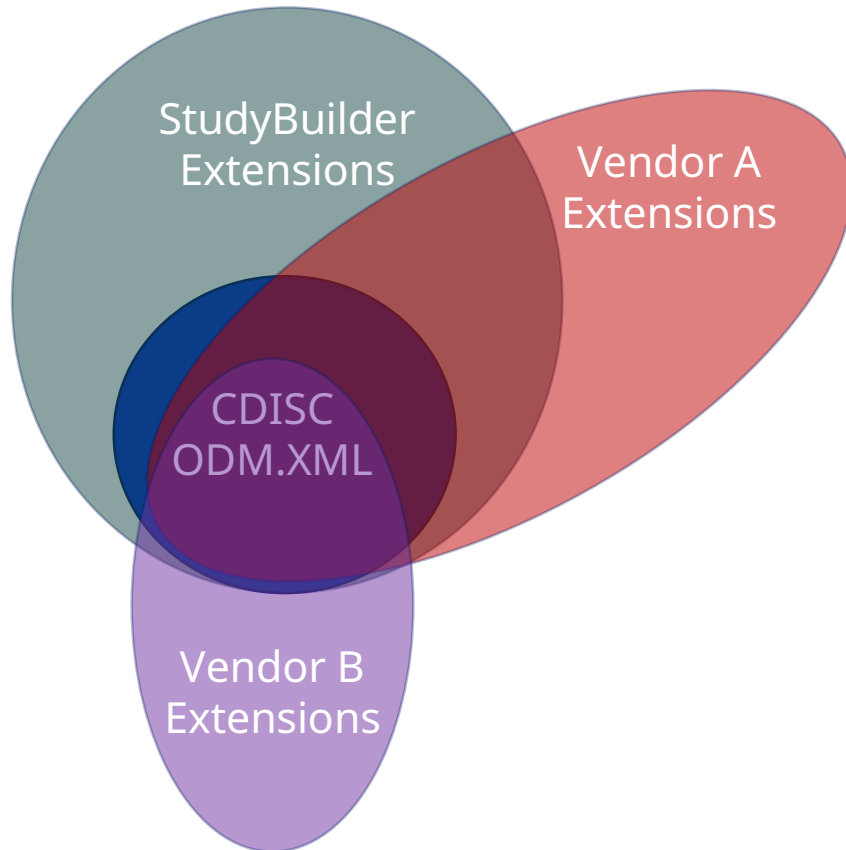
## Dynamic build of Study Specific Forms

- OSB Library include reusable form elements and structures supporting custom build of study specific forms
- Linked to Activity Concepts and relationship to data model representations including SDTM
- The study specific forms can be build including 'shared' vendor extensions and imported into the study setup in EDC
  - This will require some additional EDC setup of EDC specific capabilities (like display logic, edit checks, etc.)

# OpenStudyBuilder to EDC Options



# Scope of ODM Vendor Extensions



- OpenStudyBuilder with ODM extensions
  - OpenStudyBuilder generic
    - Activity Instance IDs (BC IDs)
    - SDTM annotations
  - Common extensions
    - Reference to standard forms (in OSB and EDC library)
  - EDC Vendor specific extensions
    - Enables by OSB to support specific EDC
  - Option to provide subset of basic ODM.XML (for vendors with limited support)
  - Other exchange formats (datasets, json, ...)

# Use Cases for EDC Integrations

**1**

## Sharing OpenStudyBuilder and EDC Library forms

- Create standard forms in OSB
- Include vendor specific extension
- Import into EDC Library
- Add EDC specific capabilities in library forms
- Change management between OSB and EDC libraries

**2**

## Support study level selection and configuration of standard library forms in EDC build

- Design how reference to standard forms can be provided to the EDC system via ODM.XML extensions or via references in direct API responses
- Evaluate data delivered from EDC system including reference to StudyBuilder extensions

**3**

## Making study specific forms in StudyBuilder linked to study SoA

- Design how we link from the protocol SoA into the detailed operational SoA linked to data collection specification
- Explore how our Activity Concept model (Biomedical Concept) can be utilised in the best possible way in the end-to-end data lineage

**4**

## Support import and operational setup of study specific forms

- Design how we can improve the build of study specific forms including ODM extensions supporting load into the EDC system
- Evaluate data delivered from EDC system including reference to StudyBuilder extensions

# CRF for EDC Status



- ←
- About Library
- Process Overview
- Code Lists
- Dictionaries
- Concepts
- Activities
- Units
- CRFs
- Compounds
- Syntax Templates
- Template Instantiations
- Template Collections
- Data Exchange Standards
- Admin Definitions
- List

Library / Concepts / CRFs / CRF View

### CRFs (Case Report Forms) ?

CRF Templates Forms Item Groups Items CRF Tree CRF View Alias Extensions

RELOAD

## Template V1

Annotated CRF

### Informed Consent and Demography

[OID=F.DM, Version=0.1]

Please complete this Informed Consent and Demography form at the very beginning of the study General item design notes: Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM General item design notes: Integration: A: Argus, Ax: rms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM Oracle item des N notes: Key: [\*] = Item is required, Sex: Populated by IWRS, Item to trigger Childbearing potential form to appear if response = Female, Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/Demog Oracle item design notes: Key: [\*] = Item is required, Sex: Populated by IWRS, Item to trigger Childbearing potential form to appear if response = Female, Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/Demog

#### Informed Consent item group

[OID=G.DM.IC, Version=0.1]

DM (Demographics Domain)

DS (Disposition Domain)

Please complete the Informed Consent item group before any other information

<p>Study ID</p> <p>[OID=I.STUDYID, Version=0.1]</p> <p>Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during SDTM-based dataset creation before submission.</p>	<p>11 digit(s)</p> <p>STUDYID</p>
<p>Date informed consent obtained</p> <p>[OID=I.RFICDAT, Version=0.1]</p> <p>This will be the same information on informed consent used in the SDTM Disposition domain</p>	<p>10 digit(s)</p> <p>jj/mm/aaaa</p> <p>RFICDTC DSSTDTC</p>
<p>Time informed consent obtained</p> <p>[OID=I.RFICTIM, Version=0.1]</p> <p>This will be the same information on informed consent used in the SDTM Disposition domain</p>	<p>5 digit(s)</p> <p>--:--</p> <p>RFICDTC DSSTDTC</p>

#### General Demographic item group

[OID=G.DM.DM, Version=0.1]

DM (Demographics Domain)

Please complete this General Demographic item group at the very beginning of the study

<p>Date of birth</p> <p>[OID=I.BRTHDTC, Version=0.1]</p> <p>If collected, please provide the most complete Date of birth</p>	<p>10 digit(s)</p> <p>jj/mm/aaaa</p> <p>BRTHDTC</p>
<p>Sex [read-only]</p> <p>[OID=I.SEX, Version=0.1]</p>	<p>Female [F]</p> <p>[OID=C16576_F, Version=1.0]</p> <p>Male [M]</p> <p>[OID=C20197_M, Version=1.0]</p> <p>[OID=SEX@I.SEX, Version=1.0]</p> <p>SEX</p>

# eCRF API endpoints

<b>ODM Study Events</b>	∨
<b>ODM Forms</b>	∨
<b>ODM Item Groups</b>	∨
<b>ODM Item</b>	∨
<b>ODM Conditions</b>	∨
<b>ODM Methods</b>	∨
<b>ODM Formal Expressions</b>	∨
<b>ODM Descriptions</b>	∨
<b>ODM Aliases</b>	∨
<b>ODM Vendor Namespaces</b>	∨
<b>ODM Vendor Attributes</b>	∨
<b>ODM Vendor Elements</b>	∨
<b>ODM Metadata Import/Export</b>	∨



# CRF Specification in the Library

The screenshot shows the 'Library / Concepts / CRFs / CRF Tree' view. The main content is a table of CRF specifications:

Templates / Forms / ItemGroups / Items	Reference attributes	Definition attributes	Status	Version	Link
Template V1			Draft	0.2	+ FORMS
Informed Consent and Demography			Draft	0.1	+ ITEM GROUPS
Informed Consent			Draft	0.1	+ ITEMS
Study ID			Draft	0.1	
Date informed consent obtained			Draft	0.1	
Time informed consent obtained			Draft	0.1	
General Demography			Draft	0.1	+ ITEMS
Date of birth			Draft	0.1	
Sex [read-only]			Draft	0.1	
Ethnicity			Draft	0.1	
Race			Draft	0.1	
Race other			Draft	0.1	
Age		123	Draft	0.1	
Vital Signs			Draft	0.1	+ ITEM GROUPS

Callout boxes on the left side of the image point to the following elements:

- Study Events (points to the top navigation bar)
- Forms (points to the 'Forms' tab in the CRF Tree)
- ItemGroups (points to the 'Item Groups' tab in the CRF Tree)
- Items (points to the 'Items' tab in the CRF Tree)

Callout boxes on the right side of the image point to the following elements:

- eCRF specs (points to the 'CRF Tree' tab)
- Vendor Extensions (points to the 'Extensions' tab)
- Alias (points to the 'Alias' tab)
- eCRF views (points to the 'CRF View' tab)

# Form def. as ODM (Vendor Extensions + Alias)

Form  
Definition

Vendor  
Extensions

Edit CRF Form - Vital Signs [COPY LINK](#)

Form  Vendor Extensions  Alias  Change Description

**Definition**

Name\*  OID

Repeating  Yes  No

Description

Implementation Notes

**Display**

Displayed text

Completion Instructions

**Buttons:** CONTINUE, SAVE, CANCEL

Alias

# ItemGroup def. as ODM (Vendor Extensions + Alias)

Edit CRF Item Group - Vital Signs COPY LINK

Item Group
 Vendor Extensions
 Alias
 Change Description

### Definition

Name* Vital Signs	OID G.VS.VS
Repeating <input checked="" type="radio"/> Yes <input type="radio"/> No	Description <div style="border: 1px solid #ccc; padding: 2px; font-family: monospace; font-size: 0.9em;"> <b>B I U</b> x<sub>2</sub> x<sup>2</sup> ≡ ≡         </div> Vital signs
	Implementation Notes <div style="border: 1px solid #ccc; padding: 2px; font-family: monospace; font-size: 0.9em;"> <b>B I U</b> x<sub>2</sub> x<sup>2</sup> ≡ ≡         </div> Implementation Notes

### Display

Displayed text Vital Signs	Completion Instructions <div style="border: 1px solid #ccc; padding: 2px; font-family: monospace; font-size: 0.9em;"> <b>B I U</b> x<sub>2</sub> x<sup>2</sup> ≡ ≡         </div> Please complete the Vital Signs item group at each expected time point
-------------------------------	---

### Annotations and reporting

Domain Vital Signs Domain	SAS Dataset Name
Is Referential Data <input type="radio"/> Yes <input type="radio"/> No	Origin Collected Value
Purpose Tabulation	Comment

CONTINUE
SAVE
CANCEL

# Item def. as ODM (Vendor Extensions + Alias) 1/2

Edit Item - Sex [read-only] [COPY LINK](#)

Item  Code list  Code list subset  Vendor Extensions  Alias  Change Description

---

### Definition

Name\* Sex [read-only] OID I.SEX

Data Type\* STRING Length \_\_\_\_\_

Description Sex [read-only] Implementation Notes Implementation Notes

**B I U x<sub>2</sub> x<sup>2</sup> ☰ ☷**

---

### Display

Displayed text Sex [read-only] Completion Instructions Completion Instructions

**B I U x<sub>2</sub> x<sup>2</sup> ☰ ☷**

---

### Annotations and reporting

SAS Field Name SEX SDS Var Name SEX

Origin Collected Value Comment \_\_\_\_\_

**CONTINUE**  
**SAVE**  
CANCEL

# Item def. as ODM (Vendor Extensions + Alias) 2/2

Edit Item - Sex [read-only] ⓘ [COPY LINK](#)

Item
  **Code list**
 Code list subset
  Vendor Extensions
  Alias
  Change Description

Concept ID	Code list name	Submission value	NCI Preferred name	Multiple choice
C66731	Sex	SEX	CDISC SDTM Sex of Individual Terminology	<input type="checkbox"/>

CONTINUE  
 SAVE  
 CANCEL

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

Search  Search with terms  Operator  or

Concept ID	Code list name	Submission value	NCI Preferred name
C100129	Category of Questionnaire	QSCAT	CDISC Questionnaire Category Terminology
C100130	Relationship to Subject	RELSUB	CDISC SDTM Relationship to Subject Terminology

Edit Item - Sex [read-only] ⓘ [COPY LINK](#)

Item
  Code list
  **Code list subset**
 Vendor Extensions
  Alias
  Change Description

Concept ID	Sponsor preferred name	Mandatory	Displayed name
C20197_M	Male	<input checked="" type="checkbox"/>	<input type="text"/>
C16576_F	Female	<input checked="" type="checkbox"/>	<input type="text"/>
C20197_M	Male	<input type="checkbox"/>	<input type="text"/>
C16576_F	Female	<input type="checkbox"/>	<input type="text"/>

CONTINUE  
 SAVE  
 CANCEL  
 PREVIOUS

Rows per page: 10 1-4 of 4 < >

Search

Concept ID	Name
C45908_UNDIFFERENTIATED	Intersex +
C17998_U	Unknown +

# Vendor Extensions

### New Attribute ?

Attribute Name: **RMax**      Data Type: **INTEGER**

Compatible Types: **FormDef, ItemGroupDef**      Regex Expression: \_\_\_\_\_

- FormDef
- ItemGroupDef
- ItemDef
- ItemGroupRef
- ItemRef

[CANCEL](#) [SAVE](#)

## Edit CRF Item Group - Vital Signs ? [COPY LINK](#)

[Item Group](#)      **[Vendor Extensions](#)**      [Alias](#)      [Change Description](#)

Namespace	Parent	Name	Type	Data Type	Value	
OpenStudyBuilder	OpenStudyBuilder	RMax	Attribute	INTEGER	Value 10	

[CONTINUE](#)  
[SAVE](#)  
[CANCEL](#)  
[PREVIOUS](#)

Search       Filtering currently not activated

Name	Namespace	Data Type	
displayAsTable	OpenStudyBuilder	string	+
RMax	OpenStudyBuilder	INTEGER	+

# Concept: CRFs

Library / Concepts / CRFs / CRF Tree

CRFs (Case Report Forms) ②

CRF Templates Forms Item Groups Items CRF Tree CRF View Alias Extensions

Reorder content

Templates / Forms / ItemGroups / Items	Reference attributes	Definition attributes	Status	Version	Link
① Template NN V1			Draft	0.1	+ FORMS
② Informed Consent and Demography			Draft	0.1	+ ITEM GROUPS
③ Informed Consent			Draft	0.2	+ ITEMS
④ Study ID			Draft	0.1	
⑤ Date informed consent obtained			Draft	0.2	
⑥ Time informed consent obtained			Draft	0.2	
⑦ General Demography			Draft	0.1	
⑧ Date of birth			Draft	0.1	
⑨ Sex (read-only)			Draft	0.1	
⑩ Ethnicity			Draft	0.1	
⑪ Race			Draft	0.1	
⑫ Age		123	Draft	0.1	
⑬ Race other			Draft	0.1	
⑭ Vital Signs			Draft	0.1	

Templates used to defined multiple CRF version

PDF format

Annotated CRF following MSG 2.0 standard

ODM.xml with vendor extensions (or CSV)

Library / Concepts / CRFs / CRF View

CRFs (Case Report Forms) ②

CRF Templates Forms Item Groups Items CRF Tree CRF View Alias Extensions

Template NN V1 Annotated CRF

④ Informed Consent and Demography

Please complete this Informed Consent and Demography form at the very beginning of the study General Item design notes: Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM General item design notes: Integration: A: Argus, Ax: rms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM Oracle item des N notes: Key: [\*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/Demog/Oracle Item design notes: Key: [\*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/Demog

DM (Demographics Domain)  
DS (Disposition Domain)

Informed Consent item group  
[OID=G.DM.IC, Version=0.2]  
Please complete the Informed Consent item group before any other information

① Study ID [OID=L.STUDYID, Version=0.1]	11 digit(s)
② Date informed consent obtained [OID=L.RFICDAT, Version=0.2]	10 digit(s)

## Vendor Extension in ODM

```

<MetaDataVersion OID="MDV.0.1" Name="MDV.0.1" Description="Draft version">
  <FormDef OID="F.VS" Name="Vital Signs" Repeating="No" osb:version="0.1"
  osb:instruction="Please complete this Vital Sign form before starting the treatment">
    <Description>
      <TranslatedText xml:lang="en" osb:version="0.1">Vital signs form</TranslatedText>
    </Description>
    <ItemGroupRef ItemGroupOID="G.VS.VS" Mandatory="No" OrderNumber="0"/>
  </FormDef>
  <ItemGroupDef OID="G.VS.VS" Name="Vital Signs" Repeating="Yes" Purpose="Tabulation"
  SASDatasetName="VITALSIGNS" Domain="VS:Vital Signs Domain" osb:version="0.5"
  osb:instruction="&lt;p&gt;Please complete the Vital Signs item group at each expected
  time point&lt;/p&gt;" osb:RMax="10">
    <osb:DomainColor>VS:#bfffff;</osb:DomainColor>
    <Description>
      <TranslatedText xml:lang="en" osb:version="0.1">&lt;p&gt;Vital signs&lt;/p&gt;</
      TranslatedText>
    </Description>
    <ItemRef ItemOID="I.PULSE" Mandatory="No" OrderNumber="0" MethodOID="null"/>
  </ItemGroupDef>
  <ItemDef OID="I.PULSE" Name="Pulse" Origin="Collected Value" DataType="integer"
  Length="3" SASFieldName="PULSE" SDSVarName="VSORRES/VSORRESU when VSTESTCD=PULSE"
  osb:version="0.1">
    <Question>
      <TranslatedText xml:lang="en" osb:version="0.1">Pulse</TranslatedText>
    </Question>
    <Description>
      <TranslatedText xml:lang="en" osb:version="0.1">Pulse</TranslatedText>
    </Description>
    <MeasurementUnitRef MeasurementUnitOID="beats/min"/>
  </ItemDef>
</MetaDataVersion>

```



# Odm.xml API endpoint

## ODM Metadata Import/Export

POST /concepts/odms/metadata/xmls/export Export ODM XML

Try it out

Name	Description
target_uid * required string (query)	target_uid
target_type * required (query)	Available values : study_event, study, form, item_group, item study_event
status (query)	Available values : final, retired, draft, latest Default value : final final
allowed_namespaces array[string] (query)	Names of the Vendor Namespaces to export. If not specified, all Vendor Namespaces available will be exported. Default value : List []
pdf boolean (query)	Whether or not to export the ODM as a PDF. Default value : false false
stylesheet string (query)	stylesheet

Request body multipart/form-data

Level of Metadata in the ODM (uid):

- StudyEvent
- Form
- ItemGroup

Target Type:

- StudyEvent
- Form
- ItemGroup

Status of the metadata

PDF or CSV

Stylesheet ref.


# API Endpoints to work with the SoAs...

Studies		^
GET	<code>/studies</code> Returns all studies in their latest/newest version.	▼ 🔒
POST	<code>/studies</code> Creates a new Study Definition.	▼ 🔒
GET	<code>/studies/headers</code> Returns possible values from the database for a given header	▼ 🔒
GET	<code>/studies/{uid}/fields-audit-trail</code> Returns the audit trail for the fields of a specific study definition identified by 'uid'.	▼ 🔒
GET	<code>/studies/{uid}/audit-trail</code> Returns the audit trail for the subparts of a specific study definition identified by 'uid'.	▼ 🔒
GET	<code>/studies/{uid}/protocol-title</code> Retrieve all information related to Protocol Title	▼ 🔒
PATCH	<code>/studies/{uid}/copy-component</code> Copy study form from another study	▼ 🔒
GET	<code>/studies/{uid}/time-units</code> Gets a study preferred time unit	▼ 🔒
PATCH	<code>/studies/{uid}/time-units</code> Edits a study preferred time unit	▼ 🔒
PATCH	<code>/studies/{uid}/order</code> Reorder Study Subparts within a Study Parent Part	▼ 🔒
GET	<code>/studies/{uid}/design.svg</code> Builds and returns a Study Design visualization image in SVG format	▼ 🔒
GET	<code>/studies/{study_uid}/flowchart/coordinates</code> Returns uid to [row,column] coordinates mapping of items included in SoA Protocol Flowchart table	▼ 🔒
GET	<code>/studies/{study_uid}/flowchart</code> Protocol, Detailed or Operational SoA table with footnotes as JSON	▼ 🔒
GET	<code>/studies/{study_uid}/flowchart.html</code> Builds and returns an HTML document with Protocol, Detailed or Operational SoA table with footnotes	▼ 🔒
GET	<code>/studies/{study_uid}/flowchart.docx</code> Builds and returns a DOCX document with Protocol, Detailed or Operational SoA table with footnotes	▼ 🔒
GET	<code>/studies/{study_uid}/detailed-soa-history</code> Returns the history of changes performed to a specific detailed SoA	▼ 🔒
GET	<code>/studies/{study_uid}/detailed-soa-exports</code> Exports the Detailed SoA content	▼ 🔒
GET	<code>/studies/{study_uid}/operational-soa-exports</code> Exports the Operational SoA content	▼ 🔒
GET	<code>/studies/{study_uid}/protocol-soa-exports</code> Exports the Protocol SoA content	▼ 🔒

# Schedule of Activities and Biomedical Concepts...



# Biomedical Concepts?!



**TransCelerate**  
BIOPHARMA INC.  
Accelerating Answers.

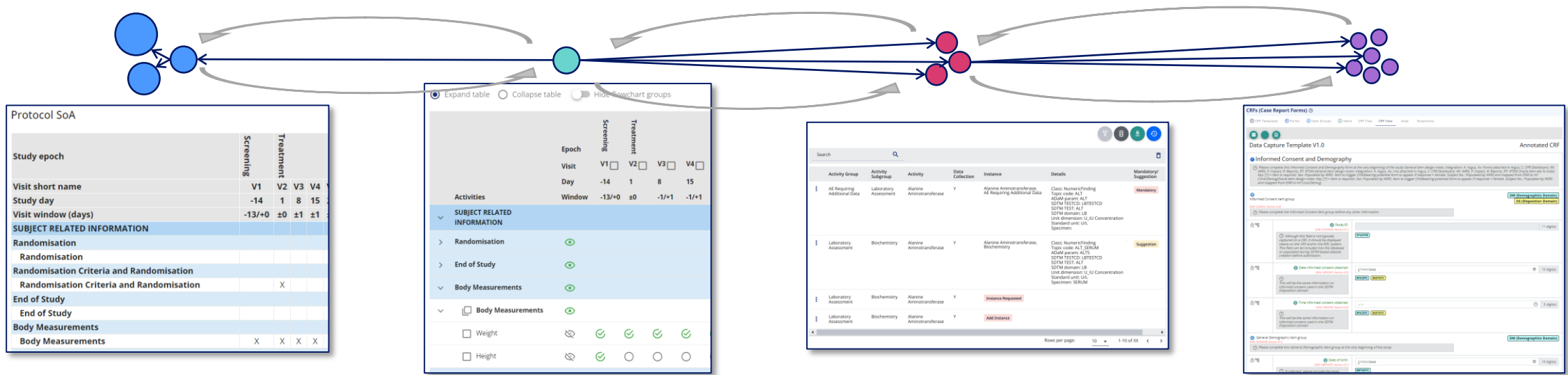
---

**Supporting Automation of  
Case Report Forms Using  
Biomedical Concepts**

0:08 / 3:45

⏪ ⏩ 🔊 ⏸ ⚙️ 📄 🖥️ 🗑️

# Schedule of Activities (SoA) at multiple levels



## Protocol SoA

- For the high level SoA in protocol section 1.2
- Main purpose is for the investigator and site staff to get an overview of the operational schedule

## Detailed SoA

- Specifying the semantic data observations to be collected in the study – but not specific to representation in ADaM, SDTM or data collection
- Will be part of protocol section 8 and appendixes or other supplementary documents

## Operational SoA

- The data specification to support data collection specification
- Correspond to our existing legacy BCs (Topic Codes)
- Will also related to specific ADaM PARAM/PARAMCD

## Data Capture / Collection Specification

- How data is to be collected in the study and when
- What is pre-set, what is collected and how



- ←
- About Studies
- Process Overview
- Manage Studies
- Define Study
- Study Title
- Registry Identifiers
- Study Properties
- Study Structure
- Study Population
- Study Criteria
- Study Interventions
- Study Purpose
- Study Activities**
- View Specifications
- View Listings

Studies / Define Study / Study Activities / Detailed SoA

## Study Activities (CDISC DEV-0) ?

The detailed SoA describe scheduling of the specific Activities and their grouping for the study

		Screening	Treatment								Follow-up	
		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
		-14	1	8	15	22	29	36	43	57	183	213
Activities	Window	-13/+0	±0	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	-1/+1	0/+35
> SUBJECT RELATED INFORMATION	🗑️											
▼ EFFICACY	🗑️											
▼ Laboratory Assessments	👁️											
▼ <input type="checkbox"/> Glucose Metabolism	👁️											
<input type="checkbox"/> HbA1c	🗑️	✅	✅	✅	✅	✅	✅	✅	✅	✅	✅	○
▼ Self Measured Plasma Glucose	👁️											
<input type="checkbox"/> Self Measured Plasma Glucose	🗑️											
<input type="checkbox"/> Mean Plasma Glucose	🗑️	○	○	○	○	○	○	○	○	○	○	○
> SAFETY	🗑️											

Each level in the Activity hierarchy can be selected for display in the "Protocol SoA"





## Study Activities (CDISC DEV-0001)

Study Activities Schedule of Activities

DETAILED PROTOCOL **OPERATIONAL**



Produce a copy of the SoA compatible with Word

	Topic Code	ADaM Param Code	Screening	Run-in			Treatment 1			Treatment 2			Follow-up
Visit short name			V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
Study week			-2	0	0	0	0	0	0	2	2	2	3
Visit window (days)			±0	±0	±0	±0	±0	±0	±0	±0	±0	±0	±0
<b>SUBJECT RELATED INFORMATION</b>													
<b>Informed Consent and Demography</b>													
Informed Consent and Demography													
Informed Consent Obtained													
Date of Birth													
<b>Eligibility Criteria</b>													
Eligibility Criteria													
Eligibility Criteria Met													
<b>Medical History/Concomitant Illness</b>													
Medical History/Concomitant Illness													
Medical History/Concomitant Illness													
<b>Body Measurements</b>													
Body Measurements													
Height													
Height	HEIGHT	HEIGHT	X				X						
Weight													
Body Weight	BODY_WEIGHT	WEIGHT	X	X			X	X		X	X		X
<b>Laboratory Assessments</b>													
<b>Haematology</b>													
Erythrocytes													
Erythrocytes	ERCS_BLOOD	RBCB	X			X	X			X			X
<b>Vital Signs</b>													
Vital Signs													
Systolic Blood Pressure													
Systolic Blood Pressure	BP_SYSTOLIC	SYSBP	X	X	X	X	X	X	X	X	X	X	X
Diastolic Blood Pressure													
Diastolic Blood Pressure	BP_DIASTOLIC	DIABP											

The "Protocol SoA" displaying the selected activity level of detail as a preview

# Selection process of Activities for SoA

## For Protocol Outline / Protocol

- Select Activities in relevant grouping
- When selecting an Activity within a specific grouping, then this will drive ActivityInstance – this should be visible for Protocol Writers (like a COL)
  - Some ActivityInstances can be mark as default for an Activity, and will then be pre-selected
  - Some ActivityInstances can be marked as mandatory – and cannot be un-selected
- Select what to display or hide in high-level Protocol SoA

## For Operational Data Specification

- Confirm or Select Activity Instances for each selected Activity
- If the correct ActivityInstance will change Grouping – this will require a change to the Protocol SoA – this will then

## For Data Collection Specification

- The data collection specification
  - Lab specs
  - CRF
  - Other eSources
  - What is pre-set

# From Activity to Activity Instance

Library / Concepts / Activities / Activities

Activities

Activities Activity Groups Activity Subgroups Activities by Grouping Activities Instances Requested Activities

Search:  Select rows

	Library	Activity group	Activity subgroup	Activity name	Sentence case name	NCI Concept ID
	Sponsor	• AE Requiring Additional Data	• Laboratory Assessment	<a href="#">Direct Bilirubin</a>	direct bilirubin	
	Sponsor	• Laboratory Assessments • AE Requiring Additional Data • Laboratory Assessments	• Biochemistry • Laboratory Assessment • Urinalysis	<a href="#">Bilirubin</a>	bilirubin	
	Sponsor	• AE Requiring Additional Data	• Laboratory Assessment	<a href="#">Indirect Bilirubin</a>	indirect bilirubin	
	Sponsor	• Eligibility Criteria	• Eligibility Criteria	<a href="#">Eligibility Criteria Met</a>	eligibility criteria met	
	Sponsor	• Laboratory Assessments • Laboratory Assessments • Laboratory Assessments	• Urinalysis • Urinalysis - Urine Dipstick • Urine Dipstick	<a href="#">Urobilinogen</a>	urobillinogen	
	Sponsor	• Eligibility Criteria	• Subgroup 41 updated	<a href="#">Sponsor Activity 147</a>	sponsor activity 147	
	Sponsor	• Eligibility Criteria	• Eligibility Criteria	<a href="#">Sponsor Activity 177</a>	sponsor activity 177	

Rows per page: 10 1-10 of 11

Library / Concepts / Activities / Activities / Bilirubin

Bilirubin

Overview OSB YAML COSMoS YAML

Name: Bilirubin

Sentence case name: bilirubin

Version: 1.0 Status: Final

Start date: Oct 10, 2024, 7:02 PM End date: None

Definition

Abbreviation

Library: Sponsor

NCI Concept ID

Data collection: Yes

Activity groupings

Activity group	Activity subgroup
AE Requiring Additional Data	Laboratory Assessment
Laboratory Assessments	Urinalysis
Laboratory Assessments	Biochemistry

Activity instances

Name	Definition	Version	Status	Activity instance class	Topic code	ADaM parameter code
<a href="#">Bilirubin Urine</a>		1.0	Final	CategoricFinding	BILIRUBIN_URINE	BIU2
<a href="#">Bilirubin Urine</a>		0.1	Draft	CategoricFinding	BILIRUBIN_URINE	BIU2
<a href="#">Bilirubin_AE Requiring Additional Data</a>		1.0	Final	NumericFinding	BILI	BILI
<a href="#">Bilirubin_AE Requiring Additional Data</a>		0.1	Draft	NumericFinding	BILI	BILI
<a href="#">Bilirubin_Biochemistry</a>		1.0	Final	NumericFinding	BILIRUBIN_SERUM	BIU3

Library / Concepts / Activities / Activities / Bilirubin

### Bilirubin

Overview OSB YAML COSMoS YAML

**Name** Bilirubin

**Sentence case name** bilirubin

**Version** 1.0 **Status** Final

**Start date** Oct 10, 2024, 7:02 PM **End date** None

**Definition**

**Abbreviation**

**Library** Sponsor

**NCI Concept ID**

**Data collection** Yes

**Activity groupings**

Activity group	Activity subgroup
AE Requiring Additional Data	Laboratory Assessment
Laboratory Assessments	Urinalysis
Laboratory Assessments	Biochemistry

**Activity instances**

Name	Definition	Version	Status	Activity instance class	Topic code	ADaM parameter code
<a href="#">Bilirubin Urine</a>		1.0	Final	CategoricFinding	BILIRUBIN_URINE	BILIU2
<a href="#">Bilirubin Urine</a>		0.1	Draft	CategoricFinding	BILIRUBIN_URINE	BILIU2
<a href="#">Bilirubin_AE Requiring Additional Data</a>		1.0	Final	NumericFinding	BILI	BILI
<a href="#">Bilirubin_AE Requiring Additional Data</a>		0.1	Draft	NumericFinding	BILI	BILI
<a href="#">Bilirubin_Biochemistry</a>		1.0	Final	NumericFinding	BILIRUBIN_SERUM	BILIS3

Library / Concepts / Activities / Activities Instances / Bilirubin Urine

### Bilirubin Urine

Overview OSB YAML COSMoS YAML

**Name** Bilirubin Urine

**Sentence case name** bilirubin urine

**Version** 1.0 **Status** Final

**Start date** Oct 10, 2024, 7:04 PM **End date** None

**Definition**

**Activity instance class** CategoricFinding

**Abbreviation** **Library** Sponsor

**NCI Concept ID**

**ADaM parameter code** BILIU2 **Topic code** BILIRUBIN\_URINE

**Required for activity** No **Default selected for activity** No

**Data sharing** Yes **Legacy usage** No

**Activity groupings**

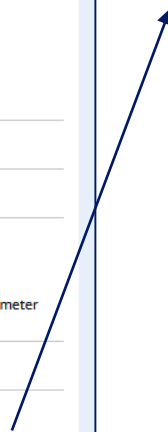
Activity group	Activity subgroup
Laboratory Assessments	Urinalysis

**Activity**

Name	Definition	Version	Status	Library
<a href="#">Bilirubin</a>		1.0	Final	Sponsor

**Activity items**

Item type	Name	Activity item class
CT term	Urine	specimen
CT term	Total Bilirubin Measurement	test_name
CT term	Laboratory Data Domain	domain
CT term	Total Bilirubin Measurement	test_code



Activity to Activity Instance to Activity Item – As Biomedical Concept (COSMOS project from CDISC)

# Operational SoA – part of Data Specification

OPEN STUDY BUILDER

Studies Library Reports

SELECT STUDY CDISC DEV-0

ANONYMOUS

Studies / Define Study / Data Specifications / Study Activity Instances

## Study Data Specifications (CDISC DEV-0)

Study Activity Instances Operational SoA

Search Select rows

	Library	SoA group	Activity group	Activity subgroup	Activity	Data collection	Activity instance	Topic code	State/Actions	ADaM
⋮	Sponsor	RELATED INFORMATION	Randomisation	Randomisation	Randomized	Yes	Add Instance		Missing selection	
⋮	Sponsor	SUBJECT RELATED INFORMATION	End of Study	End of Study	End of Study	Yes	Add Instance		Missing selection	
⋮	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	Cardiovascular System	No	Add Instance		Not required	
⋮	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	Abdomen	No	Add Instance		Not required	
⋮	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	Central and Peripheral Nervous System	No	Add Instance		Not required	
⋮	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	Gastrointestinal System incl. Mouth	No	Add Instance		Not required	
⋮	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	General Appearance	No	Add Instance		Not required	
⋮	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	Musculoskeletal System	No	Add Instance		Not required	
⋮	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	Respiratory System	No	Add Instance		Not required	
⋮	Sponsor	SUBJECT	Body							

No action needed Notification Action needed

Rows per page 10 1-10 of 32

# StudyBuilder to Veeva SDS Specification



- Summary
- Schedule - Grid
- Schedule - Tree
- Repeating Event Groups
- Form Definitions**
- Rules
- Comparison Rules
- Casebook Variables
- Codelist
- Unit Codelists
- Study Settings

Report name...

Form_Label	Form_Short_La...	Status	Linked_Forms	Linked_Forms_...	Item_Group_N...	Item_Group_Label	Item_Name	External_ID	Label	Data_Type	Codelist	Unit_Codelist	IGO	IO
1713839979899	99	In Progress											0	0
Administration of <Investigational medicinal product>	IM	In Progress											0	0
Adverse Event	AE	In Progress											0	0
CRFFNAME	ID	In Progress											0	0
ECG	EG	In Progress											0	0
Informed Consent & Demography	DM	In Progress											0	0
Informed Consent & Demography	DM	In Progress			17138400878 37 Edited	Informed Consent							0	0
Informed Consent & Demography	DM	In Progress			G.DM.IC	Informed Consent							0	0
Informed Consent & Demography	DM	In Progress			17138400878 37 Edited	Informed Consent	1713840136028 Edited	I.STUDYID	StudyID	STRING			0	0
Informed Consent & Demography	DM	In Progress			G.DM.IC	Informed Consent	1713840136028 Edited	I.STUDYID	StudyID	STRING			0	0
Informed Consent & Demography	DM	In Progress			17138400878 37 Edited	Informed Consent	Study ID	I.STUDYID	StudyID	STRING			0	0
Informed Consent & Demography	DM	In Progress			G.DM.IC	Informed Consent	Study ID	I.STUDYID	StudyID	STRING			0	0
Informed Consent & Demography	DM	In Progress			17138400878 37 Edited	Informed Consent	Date informed consent obtained	I.RFICDAT	Date informed consent obtained	DATE			0	1
Informed Consent & Demography	DM	In Progress			G.DM.IC	Informed Consent	Date informed consent obtained	I.RFICDAT	Date informed consent obtained	DATE			0	1
Informed Consent & Demography	DM	In Progress			17138400878 37 Edited	Informed Consent	Time informed consent obtained	I.RFICTIM	Time informed consent obtained	TIME			0	2
Informed Consent & Demography	DM	In Progress			G.DM.IC	Informed Consent	Time informed consent obtained	I.RFICTIM	Time informed consent obtained	TIME			0	2
Informed Consent & Demography	DM	In Progress			G.DM.DM	General Demography							1	0
Informed Consent & Demography	DM	In Progress			G.DM.DM	General Demography	Date of birth	I.BRTHDTC	DOB	DATE			1	0



# Mapping a Veeva SDS specification to ODM-XML



The banner features a dark blue background with diagonal teal stripes on the right side. On the left, the 'phuse·connect' logo is displayed in white, with the tagline 'connect·share·advance' below it. Underneath the logo, the text 'The Clinical Data Science Conference' is written in white. To the right of the logo, the text 'EU 2024' is prominently displayed in large white letters. Below this, the dates '10-13 November' and the location 'Strasbourg Convention Centre' are listed in white. On the far right, there is a stylized illustration of the Strasbourg Cathedral in light green and white, with a white box containing the text 'Strasbourg Cathedral' overlaid on it.

**phuse·connect**  
connect·share·advance

The Clinical Data  
Science Conference

**EU 2024**

**10-13 November**  
Strasbourg Convention Centre

Strasbourg Cathedral

SI04 – Monday 10<sup>th</sup> November – 13:30 – 14:00

Paper & Presentation will be available afterwards

# Activity – CRF Linkage





# Status of the OpenStudyBuilder

- Already working:
  - Protocol SoA
  - Detailed SoA
  - eCRF in the Library
  - Vendor Extensions
  - Alias
  - Models integration (like SDTM/SDTMIG with version control in the Library)
- Work in progress:
  - Operational SoA
  - Connection between Activity Instances with Activity Items to eCRF, SDTM domains and variables, ADaM domains and variables with a sharing CT management and units
  - Integration of external data like Labs
- What is planned:
  - eCRF at the Study level (with integration to the Operational SoA)
  - Production of the define.xml (pre version) based on the Protocol SoA and Detailed SoA

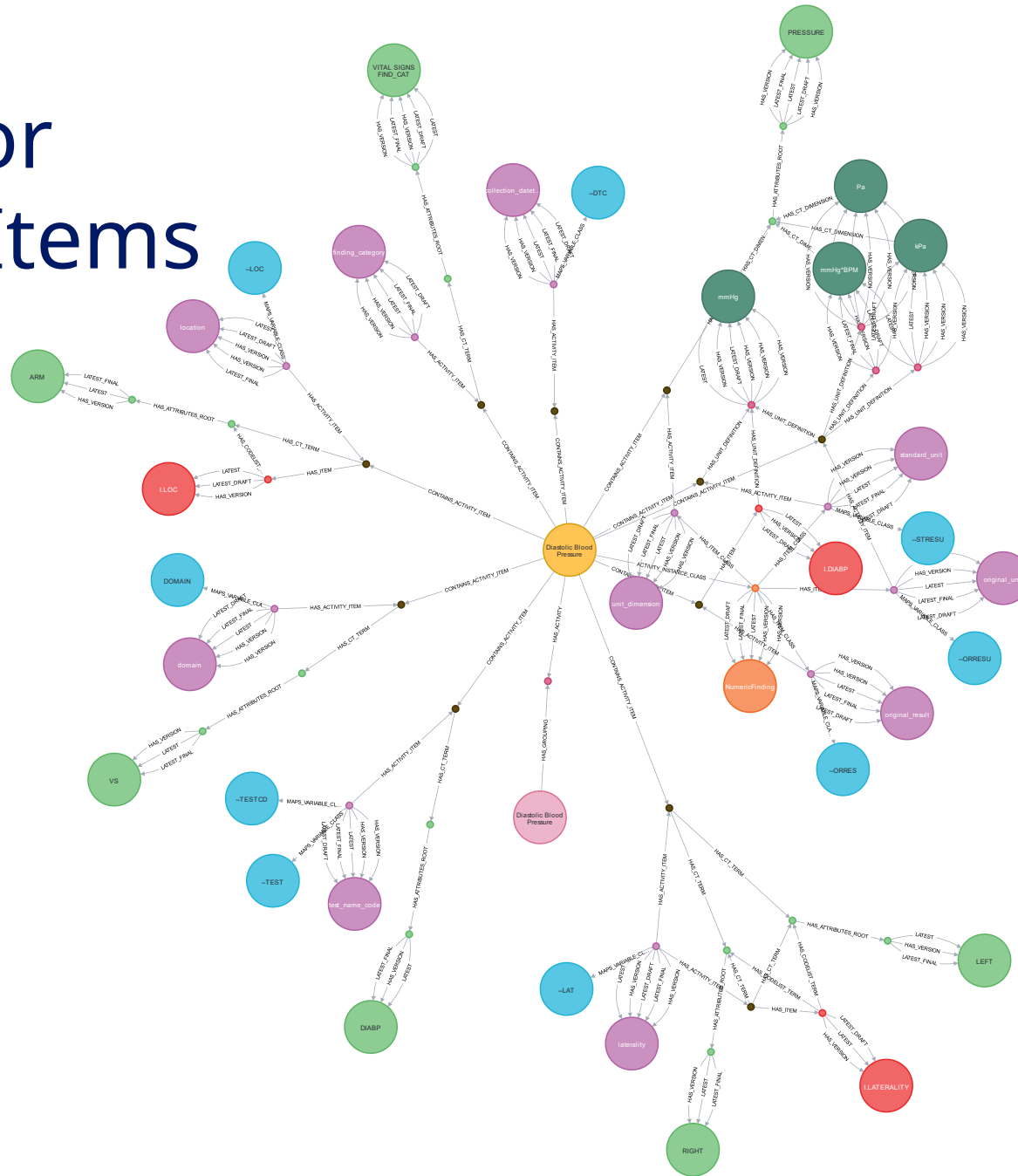
# Mapping plan for Activity Instance CF Items

## Node labels

- ^(80) ActivityValue (1) ConceptValue (9)
- TemplateParameterTermValue (6) VariableClass (9)
- ActivityInstanceClassRoot (1)
- ActivityInstanceClassValue (1)
- ActivityItemClassRoot (10) ActivityItemClassValue (10)
- ConceptRoot (7) OdmItemRoot (3) ActivityItem (11)
- ActivityGrouping (1) OdmItemValue (3)
- ActivityInstanceValue (1)
- TemplateParameterTermRoot (4) UnitDefinitionRoot (4)
- UnitDefinitionValue (4) CTermRoot (7)
- CTermAttributesRoot (7) CTermAttributesValue (7)

## Relationship types

- ^(181) HAS\_ITEM (3) HAS\_GROUPING (1)
- HAS\_VERSION (48) LATEST (25)
- LATEST\_FINAL (19) LATEST\_DRAFT (20)
- HAS\_ITEM\_CLASS (4) HAS\_ACTIVITY\_ITEM (11)
- MAPS\_VARIABLE\_CLASS (9)
- HAS\_UNIT\_DEFINITION (6) HAS\_CODELIST\_TERM (3)
- HAS\_CT\_TERM (9) CONTAINS\_ACTIVITY\_ITEM (10)
- HAS\_ACTIVITY (1) ACTIVITY\_INSTANCE\_CLASS (1)
- HAS\_CT\_DIMENSION (4) HAS\_ATTRIBUTES\_ROOT (7)



# Questions to discuss

- Extensions / configurations required for vendors
  - Additional attributes, e.g. to link to systems & versions
  - ODM.xml additional information
  - API endpoints, additional requirements
- General aspects
  - API versioning
  - Continuous development challenges, up versioning
  - Adoptions & implications according license
- Standards
  - Additional standard requirements, recommendations, wishes



# Vendor Experiences & Views

