

# Use OpenStudyBuilder to drive EDC setup - a COSA Workshop

OPEN  
STUDY  
BUILDER



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& Collaborators

08:45 - 09:00 Coffee and welcome

09:00 - 11:00 Shared Introduction

11:00 - 12:00 Break-out part 1

12:00 - 13:00 Lunch

13:00 - 14:00 Break-out part 2

14:00 - 16:00 Sharing and discussion in plenum

# Agenda

- Introduction
- OSB status with CRF & SoA for EDC & plans
- EvidentIQ ODM.xml integration (Marvin EDC)
- Oracle ClinicalOne API integration & EvidentIQ ePRO API integration
- Veeva EDC integration via SDS files, future API integration
- CDISC, The potential future of API standards

# Agenda

# Introduction



# 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

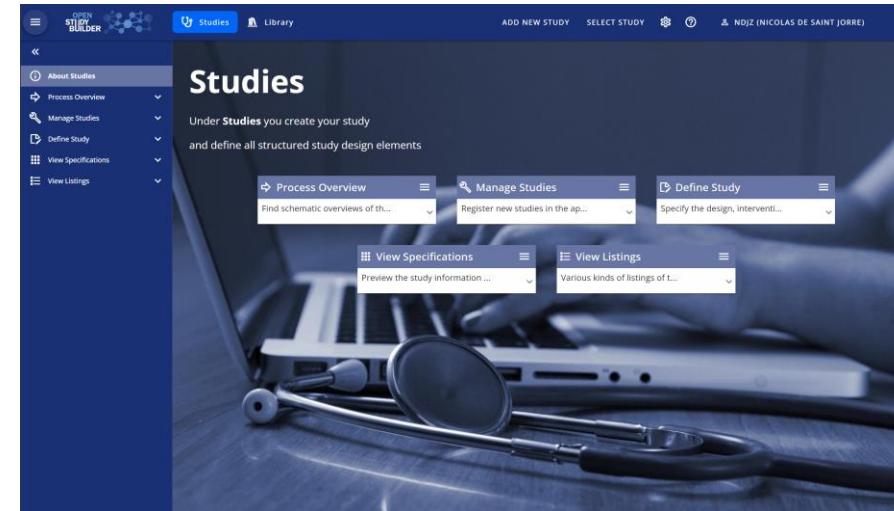
## 3 ELEMENTS OF OpenStudyBuilder

- **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)

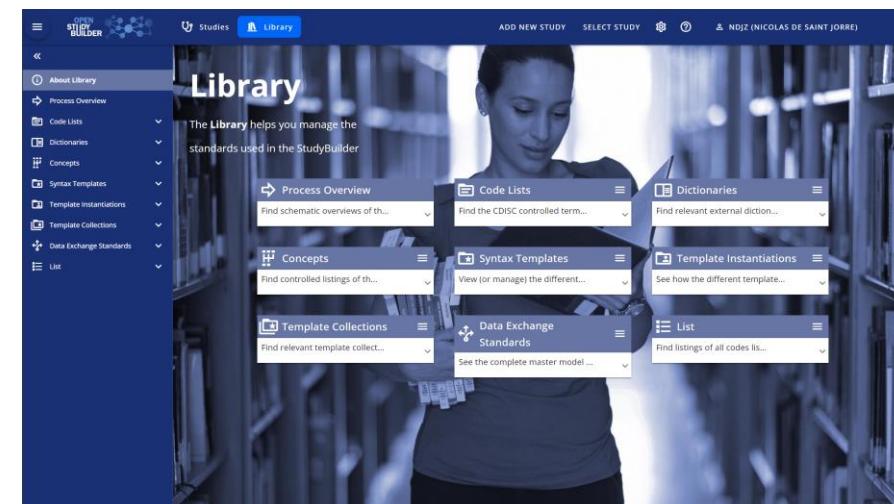


# OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES



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

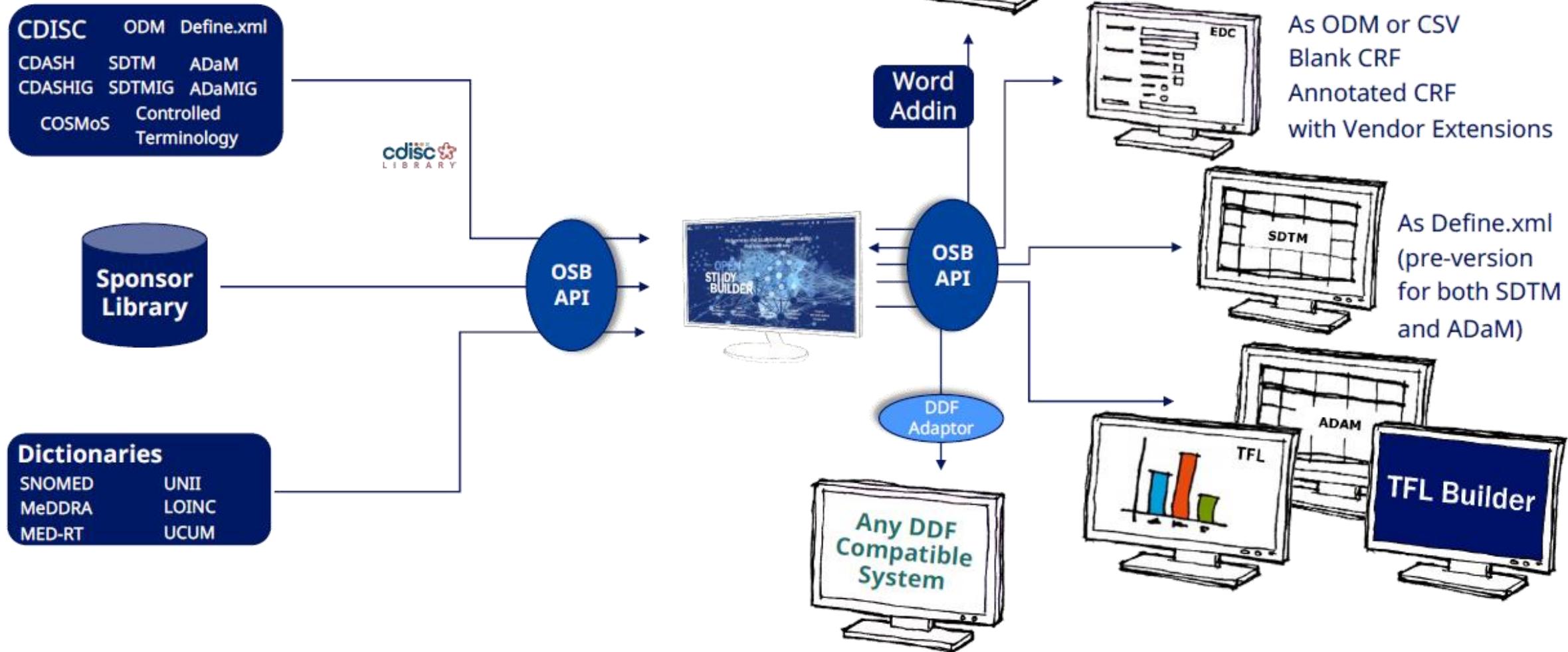


# Goal of OpenStudyBuilder

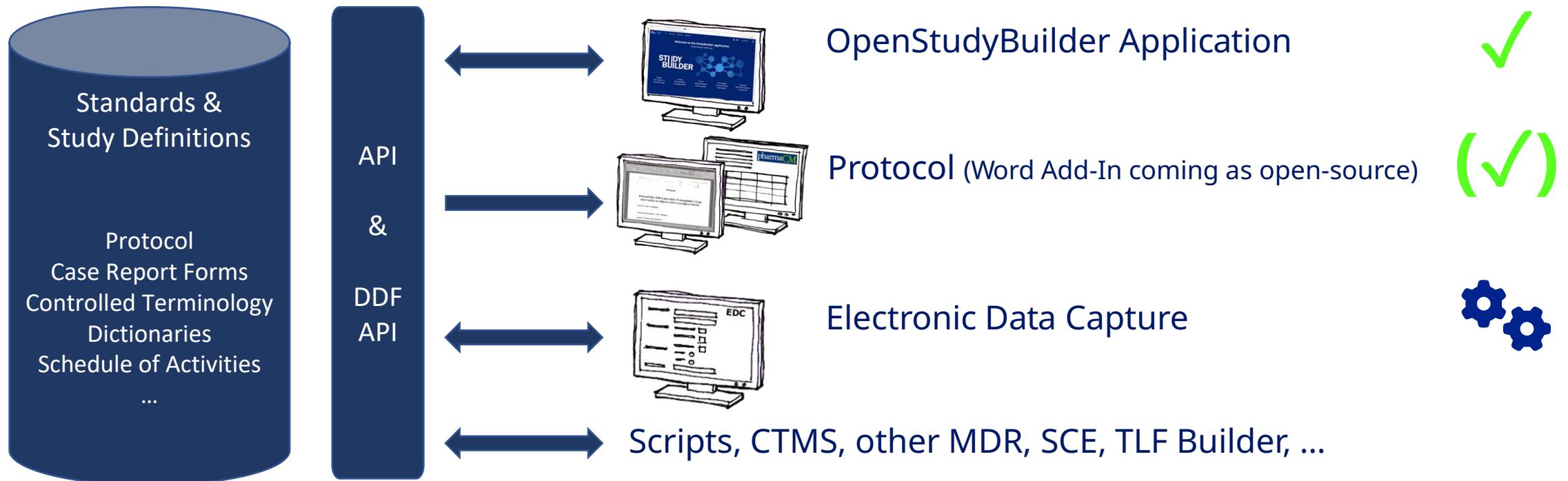
Metadata driven  
End-2-End Automation!



# Connectivity is key!



# Connectivity is key!



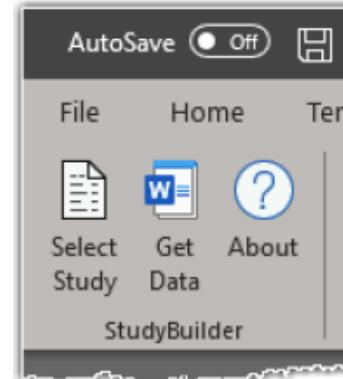
# Protocol Generation



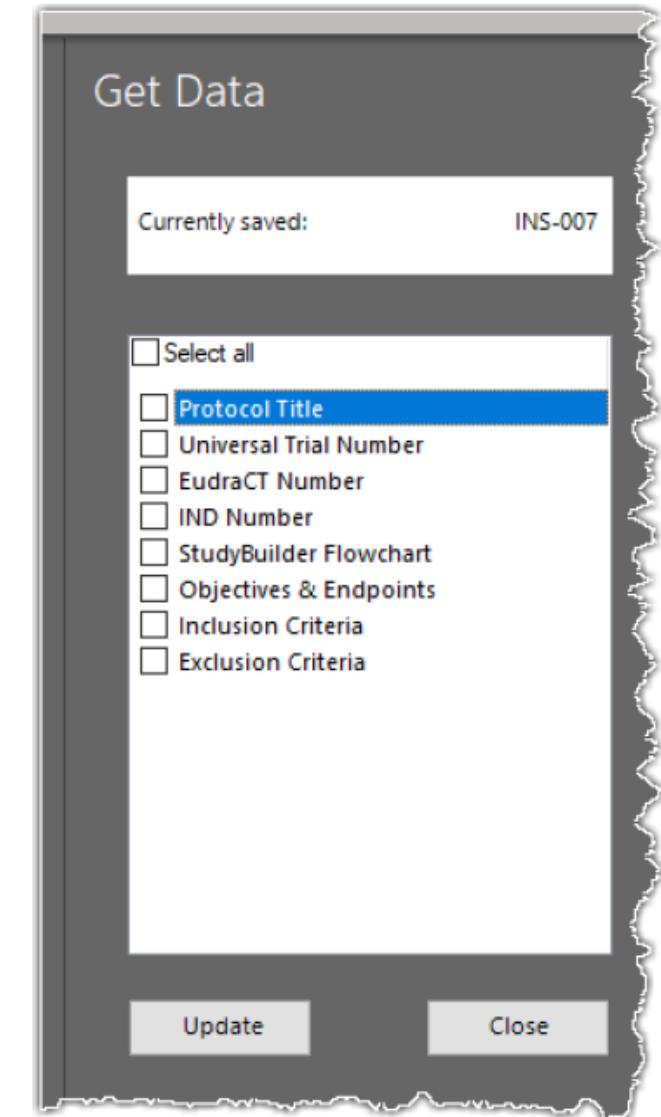
## StudyBuilder ribbon (Word add-in)

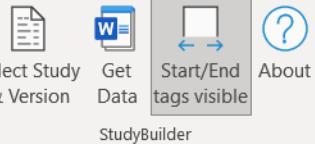
✓ One-way connection

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



Protocol





StudyBuilder

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

## 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	V10	
Visit short name	V1											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	±1	+0/+35
Randomisation												
Randomisation		X										
End of Study												X
End of Study												
Body Measurements												
Body Measurements	X	X	X	X	X	X	X	X	X	X	X	
Eligibility Criteria												
Eligibility Criteria	X											
Laboratory Assessments												
Glucose Metabolism	X	X	X	X	X	X	X	X	X	X		
Lipids	X	X			X		X		X		X	
Biochemistry	X	X			X			X		X		
AE Requiring Additional Data												

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

Close

# CRF Standards & Metadata

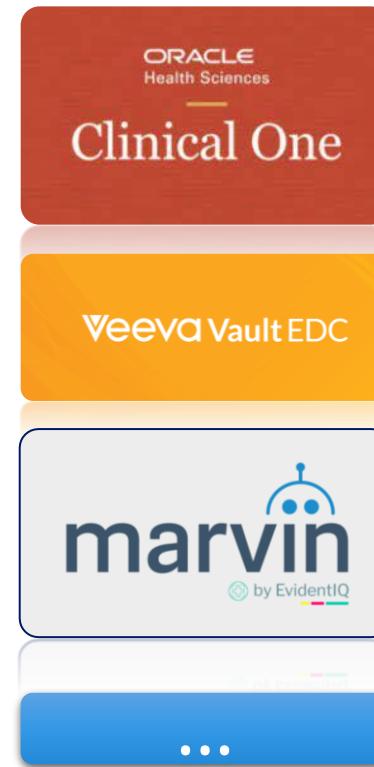
Manage  
Standard & Study CRF

The screenshot shows the 'CRFs (Case Report Forms)' section of the Open Study Builder application. The left sidebar is filled with navigation links for 'About Library', 'Process Overview', 'Code Lists', 'Dictionaries', 'Concepts', 'Activities', 'Units', 'CRFs', 'Compounds', 'Syntax Templates', 'Template Instantiations', 'Template Collections', and 'Data Exchange Standards'. The main panel displays a template titled 'Template NN' under the heading 'Annotated CRF'. The template content includes sections for 'Informed Consent and Demography' and 'Informed Consent item group'. A note at the bottom of the template states: '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.' At the bottom right of the main panel, there are two yellow buttons labeled 'DM (Demographics Domain)' and 'DS (Disposition Domain)'. The top of the screen shows the application title 'OPEN STUDY BUILDER', the study name 'CDISC DEV-0', and the user 'KATJA.GLASS'.

Including rules, checks  
Support vendor extensions



EDC Setup, Test,  
Execution



Finetuning, Layout

# OpenStudyBuilder to drive EDC setup

## A COSA Workshop



# Problem Statement

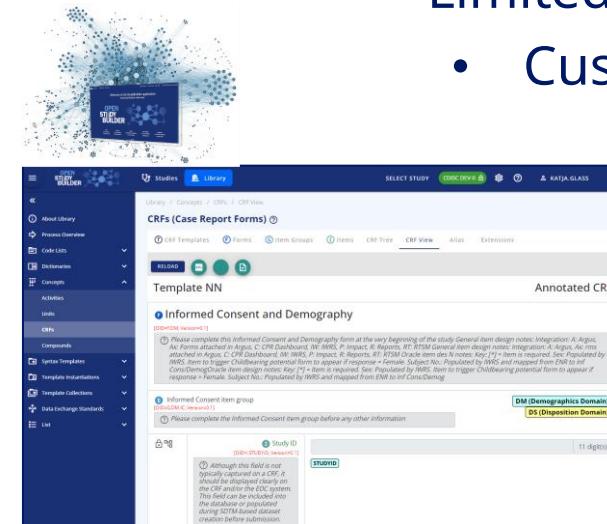
## Data Exchange Formats

- CDASH
- ODM.XML
- USDM
- Biomedical Concepts



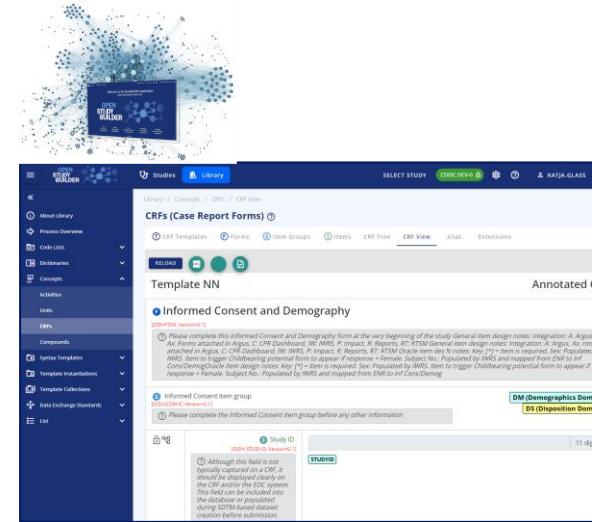
## Implementation

- 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

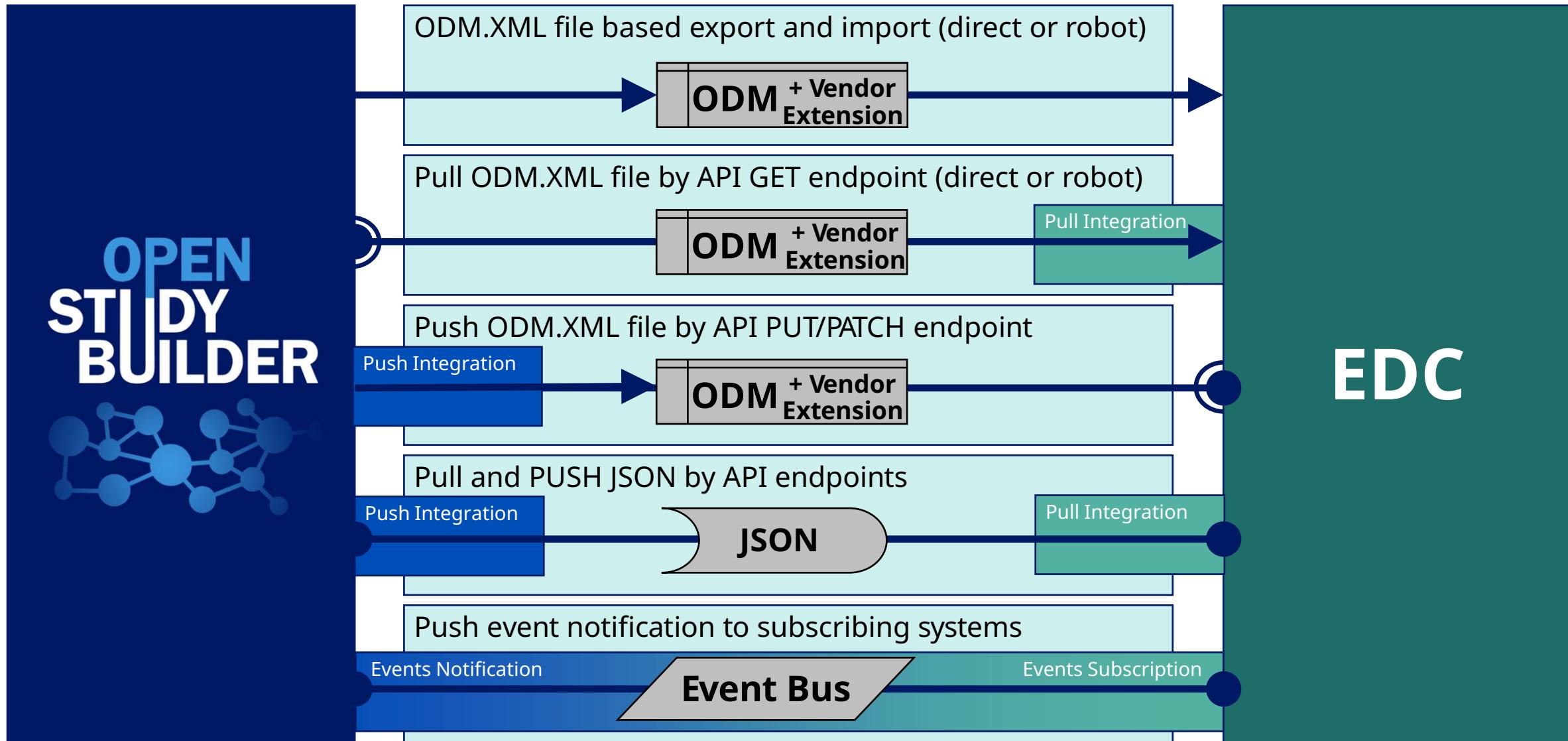
## Selection and Configuration of Standard Library Forms

- 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

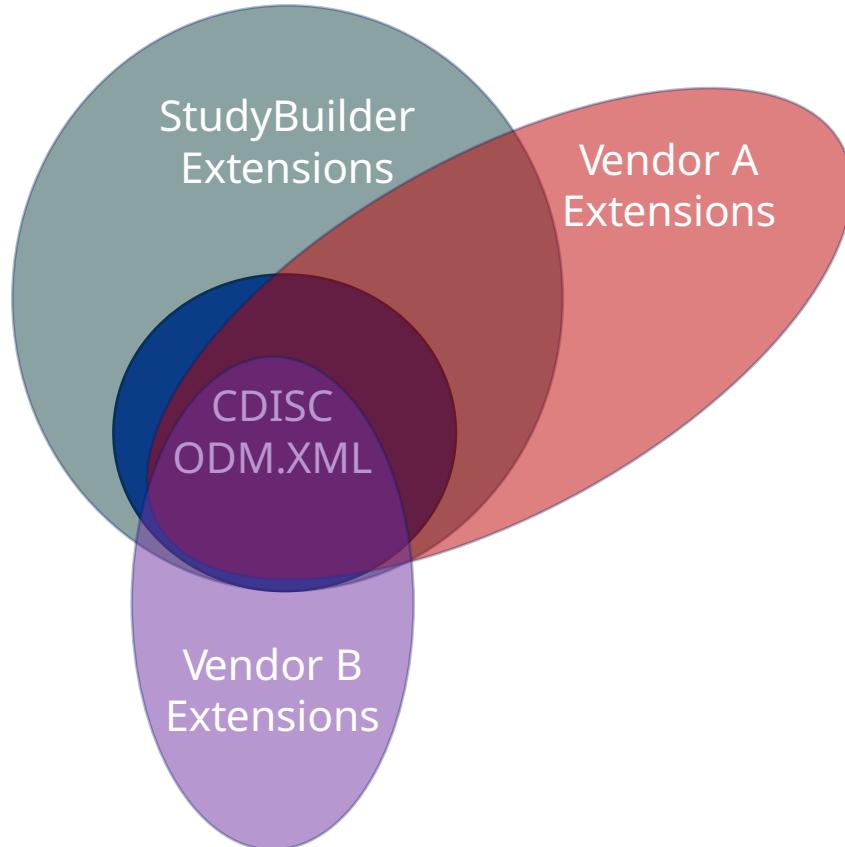
## Dynamic build of Study Specific Forms

- 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

**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

**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

**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](#)

## 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

[\[OID=I.F.DM, Version=0.1\]](#)

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/DemogOracle 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

[\[OID=I.G.DM.IC, Version=0.1\]](#)

Please complete the Informed Consent item group before any other information

**DM (Demographics Domain)**
**DS (Disposition Domain)**

	Study ID <a href="#">[OID=I.STUDYID, Version=0.1]</a> <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>	<input type="text" value="STUDYID"/> 11 digit(s)
--	---	--

	Date informed consent obtained <a href="#">[OID=I.RFICDAT, Version=0.1]</a> <p> This will be the same information on informed consent used in the SDTM Disposition domain</p>	<input type="text" value="jj/mm/aaaa"/> 10 digit(s)
--	--	---

	Time informed consent obtained <a href="#">[OID=I.RFICTIM, Version=0.1]</a> <p> This will be the same information on informed consent used in the SDTM Disposition domain</p>	<input type="text" value="--::--"/> 5 digit(s)
--	--	--

	General Demographic item group <a href="#">[OID=I.G.DM.DM, Version=0.1]</a> <p> Please complete this General Demographic item group at the very beginning of the study</p>	<b>DM (Demographics Domain)</b>
--	---	---------------------------------

	Date of birth <a href="#">[OID=I.BRTHDTC, Version=0.1]</a> <p> If collected, please provide the most complete Date of birth</p>	<input type="text" value="jj/mm/aaaa"/> 10 digit(s)
--	--	---

	Sex [read-only] <a href="#">[OID=I.SEX, Version=0.1]</a> <p> Female [F] <a href="#">[OID=C16576_F, Version=1.0]</a>  <input type="radio"/>            Male [M] <a href="#">[OID=C20197_M, Version=1.0]</a>  <a href="#">[OID=SEX@I.SEX, Version=1.0]</a></p>	<input type="text" value="SEX"/>
--	---	----------------------------------

# eCRF API endpoints

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

# CRF Specification in the Library

Study Events

Forms

ItemGroups

Items

The screenshot shows the 'CRFs (Case Report Forms)' section of the library. The left sidebar lists various study components: Study Events, Forms, ItemGroups, and Items. The main area displays a table of CRF components:

Template / Form / ItemGroup / Item	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

Navigation and search controls are at the bottom of the table.

eCRF specs

Vendor Extensions

Alias

eCRF views

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

Form  
Definition

Vendor  
Extensions

Alias

Edit CRF Form - Vital Signs ⓘ COPY LINK

Form     Vendor Extensions     Alias     Change Description

**Definition**

Name\*  
Vital Signs

Repeating  
 Yes     No

Description  
B I U x<sub>2</sub> x<sup>2</sup> ≡ ≡  
Vital signs form

OID  
F.VS

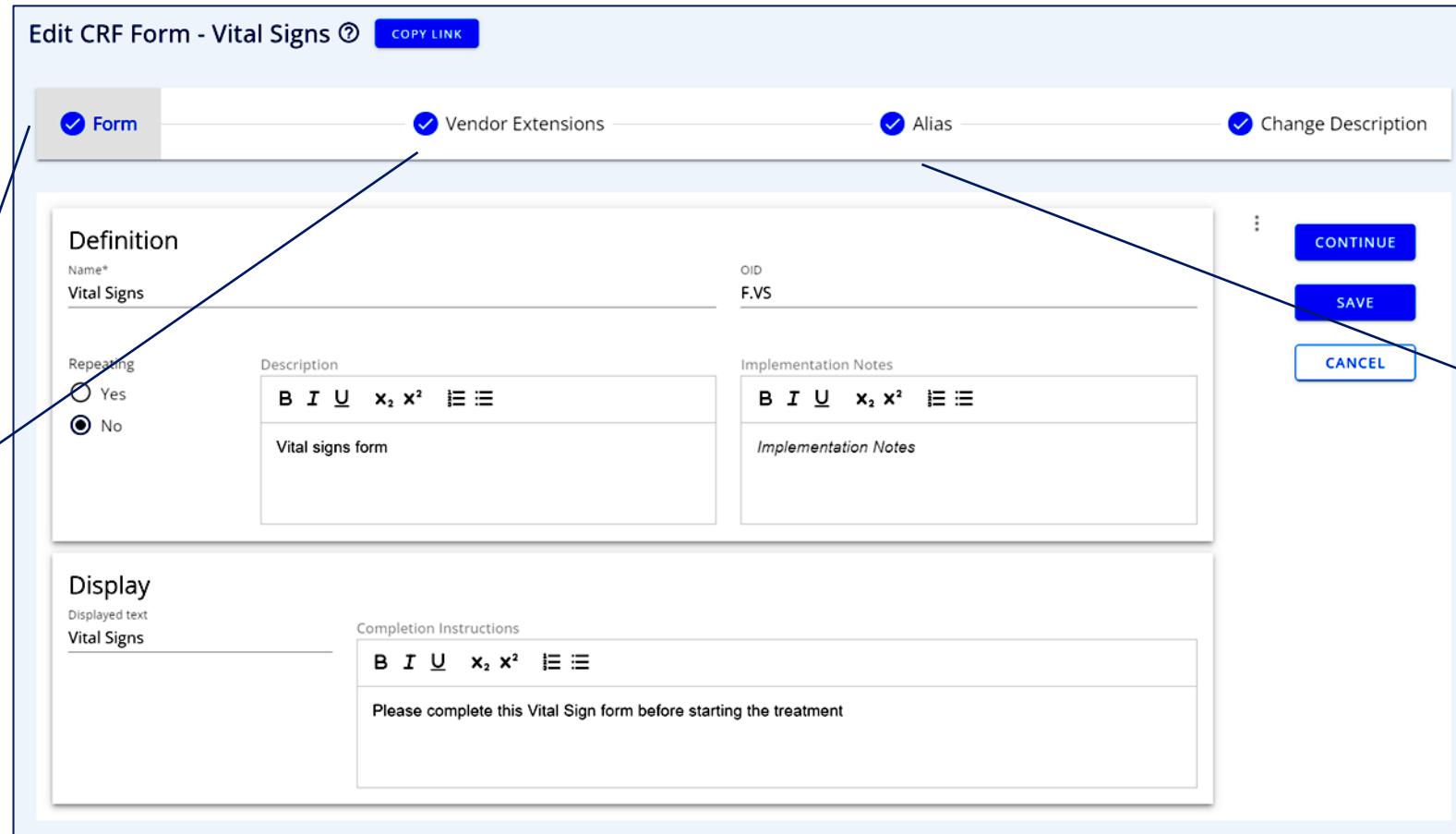
Implementation Notes  
B I U x<sub>2</sub> x<sup>2</sup> ≡ ≡  
Implementation Notes

**Display**

Displayed text  
Vital Signs

Completion Instructions  
B I U x<sub>2</sub> x<sup>2</sup> ≡ ≡  
Please complete this Vital Sign form before starting the treatment

...    CONTINUE    SAVE    CANCEL



# 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  
 Yes  
 No

Description  
**B I U x<sub>2</sub> x<sup>2</sup> ≡ ≡**  
Vital signs

Implementation Notes  
**B I U x<sub>2</sub> x<sup>2</sup> ≡ ≡**  
Implementation Notes

**Display**

Displayed text  
Vital Signs

Completion Instructions  
**B I U x<sub>2</sub> x<sup>2</sup> ≡ ≡**  
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  
 Yes  
 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  
ISEX

Data Type\*  
STRING

Length

Description  
**B I U x, x<sup>2</sup> ≡ ≡**  
Sex [read-only]

Implementation Notes  
**B I U x, x<sup>2</sup> ≡ ≡**  
Implementation Notes

**Display**

Displayed text  
Sex [read-only]

Completion Instructions  
**B I U x, x<sup>2</sup> ≡ ≡**  
Completion Instructions

**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"/>

Rows per page: 10    1-1 of 1    CONTINUE    SAVE    CANCEL

**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"/>

Rows per page: 10    1-4 of 4    CONTINUE    SAVE    CANCEL    PREVIOUS

Search

Concept ID	Name
C45908_UNDIFFERENTIATED	Intersex
C17998_U	Unknown

# Vendor Extensions

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

New Attribute ⓘ

Attribute Name RMax Data Type INTEGER

Compatible Types FormDef, ItemGroupDef

FormDef  
 ItemGroupDef  
 ItemDef  
 ItemGroupRef  
 ItemRef

Regex Expression

CANCEL SAVE

# Concept: CRFs

ODM.xml  
with vendor  
extensions  
(or CSV)

Templates used to  
define multiple  
CRF version

PDF format

**Annotated CRF**

**DM (Demographics Domain)**  
**DS (Disposition Domain)**

**Informed Consent item group**  
[OID=6.G.DMIC, Version=0.2]  
Please complete the Informed Consent item group before any other information

**STUDYID**  
Study ID  
[OID=1.STUDYID, Version=0.1]  
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.

**Date informed consent obtained**  
[OID=1.RFICDAT, Version=0.2]  
This will be the same information on informed consent element in the SDTM Disposition domain  
jj/mm/aaa  
RFICDT  
DSSTDTC

## 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="<p>Please complete the Vital Signs item group at each expected
    time point</p>" osb:RMax="10">
    <osb:DomainColor>VS:#bfffff;</osb:DomainColor>
    <Description>
      <TranslatedText xml:lang="en" osb:version="0.1"><p>Vital signs</p></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 VTESTCD=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

Level of Metadata in the ODM (uid):

- StudyEvent
- Form
- ItemGroup

Target Type:

- StudyEvent
- Form
- ItemGroup

**ODM Metadata Import/Export**

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

**Parameters**

Name	Description
target_uid * required (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

Try it out

Status of the metadata

PDF or CSV

Stylesheet ref.

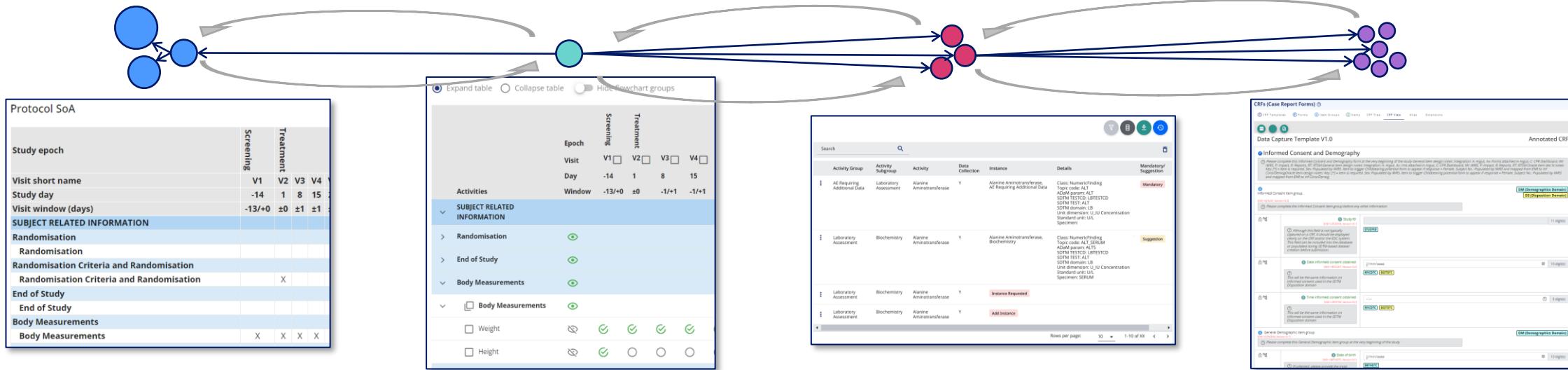
# API Endpoints to work with the SoAs...

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

# Schedule of Activities and Biomedical Concepts...



# 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 relate 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

## Detailed SoA

## Study Structure (CDISC DEV-0) ⓘ

< View Study Arms Study Branches Study Cohorts Study Epochs Study Elements Study Visits Desi >

### Study Visits

Time line preview

Screening Treatment Follow-up

0 2

Select rows Preferred time unit: Day Week

+ 🖊️ 📈 ⚡ 🗑️

Epoch	Visit type	Visit Class	Visit name	Anchor visit in visit group	Visit group
⋮	Screening	Screening	Single visit	<a href="#">Visit_1</a>	No
⋮	Treatment	Treatment	Single visit	<a href="#">Visit_2</a>	No
⋮	Treatment	Treatment	Single visit	<a href="#">Visit_3</a>	No
⋮	Treatment	Treatment	Single visit	<a href="#">Visit_4</a>	No
⋮	Treatment	Treatment	Single visit	<a href="#">Visit_5</a>	No
⋮	Treatment	Treatment	Single visit	<a href="#">Visit_6</a>	No
⋮	Treatment	Treatment	Single visit	<a href="#">Visit_7</a>	No
⋮	Treatment	Treatment	Single visit	<a href="#">Visit_8</a>	No

Study Activities (CDISC DEV-0) 						
Study Activities		Detailed SoA	SoA footnotes	Protocol SoA	Activity Instructions	
<input checked="" type="checkbox"/> Select rows						
<input type="text" value="Search"/> <span>🔍</span>						
#	Library	SoA group	Activity group	Activity subgroup	Activity	Date
1	Sponsor	SUBJECT RELATED INFORMATION	Randomisation	Randomisation	<a href="#">Randomized</a>	Yes
2	Sponsor	SUBJECT RELATED INFORMATION	End of Study	End of Study	<a href="#">End of Study</a>	Yes
3	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	<a href="#">Cardiovascular System</a>	No
4	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	<a href="#">Abdomen</a>	No
5	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	<a href="#">Central and Peripheral Nervous System</a>	No
6	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	<a href="#">Gastrointestinal System incl. Mouth</a>	No
7	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	<a href="#">General Appearance</a>	No
8	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	<a href="#">Musculoskeletal System</a>	No
9	Sponsor	SUBJECT RELATED INFORMATION	General	Physical Examination - early ph1	<a href="#">Respiratory System</a>	No
10	Sponsor	SUBJECT RELATED INFORMATION	Body Measurements	Body Measurements	<a href="#">Weight</a>	Yes

&lt;

 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)

Study Activities

Study Activity Instances

Detailed SoA

SoA footnotes

Protocol SoA

Activity Instructions

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



Screening	Treatment										Follow-up
V1 <input type="checkbox"/>	V2 <input type="checkbox"/>	V3 <input type="checkbox"/>	V4 <input type="checkbox"/>	V5 <input type="checkbox"/>	V6 <input type="checkbox"/>	V7 <input type="checkbox"/>	V8 <input type="checkbox"/>	V9 <input type="checkbox"/>	V10 <input type="checkbox"/>	V11 <input type="checkbox"/>	
-14	1	8	15	22	29	36	43	57	183	213	

Activities	Window
> SUBJECT RELATED INFORMATION	
▼ EFFICACY	
▼ Laboratory Assessments	
▼ Glucose Metabolism	
<input type="checkbox"/> HbA1c	
▼ Self Measured Plasma Glucose	
▼ 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-0) ②**

Study Activities	Detailed SoA	SoA footnotes	Protocol SoA	Activity Instructions
<input type="radio"/> Protocol SoA <input type="radio"/> SoA layout <input type="radio"/> Detailed SoA    Preferred time unit: <input type="radio"/> Day <input checked="" type="radio"/> Week <input checked="" type="radio"/> Operational SoA				
<b>Protocol SoA</b>				
Topic Code	ADaM Parameter Code	Screening	Treatment	Follow-up
Visit short name		V1	V2 V3 V4 V5 V6 V7 V8 V9 V10	V11
Study week		-2	1 2 3 4 5 6 7 9 27	31
Visit window (days)		-13/+0	±0 ±1 ±1 ±1 ±1 ±1 ±1 ±1 ±1	+0/+35
<b>SUBJECT RELATED INFORMATION</b>				
<b>Randomisation</b>				
Randomisation	RANDOMISATION_DATE	RANDDT	X	
<b>End of Study</b>				
End of Study	END_OF_TRIAL	EOT		X
<b>General</b>				
Physical Examination - early ph1				
Cardiovascular System				
Abdomen				
Central and Peripheral Nervous System				
Gastrointestinal System incl. Mouth				
General Appearance				
Musculoskeletal System				
Respiratory System				
<b>Body Measurements</b>				
Body Measurements				
Weight	BODY_WEIGHT	WEIGHT	X X X X X X X X X X X X X	
Height	HEIGHT	HEIGHT	X	
<b>Eligibility Criteria</b>				
Eligibility Criteria				
Eligibility Criteria Met	ELIGIBILITY CRITERIA MET	ELICRIMT	X	
Subject Eligible to Continue the Trial				

Produce a copy of the SoA compatible with Word

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 marked 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**

The screenshot illustrates the process of creating activity instances from a general activity definition. On the left, the 'Activities' section shows a list of activities grouped by sponsor, including Laboratory Assessments, Biochemistry, and AE Requiring Additional Data. A specific row for 'Bilirubin' is highlighted. A blue arrow points from this row to the right panel, which displays the detailed configuration of the 'Bilirubin' activity instance.

**Activities Overview:**

- Library / Concepts / Activities / Activities
- Activities tab selected
- Search bar: Bil
- Filter: Select rows
- Toolbar: +, 🔍, ⏷, ⏷, ⏷, ⏷

Library	Activity group	Activity subgroup	Activity name	Sentence case name	NCI Concept ID
Sponsor	Laboratory Assessments • AE Requiring Additional Data • Laboratory Assessments	Biochemistry • Laboratory Assessment • Urinalysis	<a href="#">Bilirubin</a>	bilirubin	
Sponsor	Laboratory Assessments • AE Requiring Additional Data	Biochemistry • Laboratory Assessment	<a href="#">Direct Bilirubin</a>	direct bilirubin	
Sponsor	Eligibility Criteria	Eligibility Criteria	<a href="#">Eligibility_Criteria_Met</a>	eligibility criteria met	
Sponsor	Laboratory Assessments • AE Requiring Additional Data	Biochemistry • Laboratory Assessment	<a href="#">Indirect Bilirubin</a>	indirect bilirubin	
Sponsor	Clinical Outcome Assessments	PGI Change-Ability Things Need	<a href="#">PGI_Change-Ability_Things_Need</a>	pgi change-ability things need	

**Bilirubin Activity Instance Details:**

- Overview tab selected
- Name: Bilirubin
- Sentence case name: bilirubin
- Status: Final
- Definition: (empty)
- Abbreviation: (empty)
- Library: Sponsor
- NCI Concept ID: (empty)
- Data collection: Yes
- Activity groupings:

  - Laboratory Assessments → Biochemistry
  - AE Requiring Additional Data → Laboratory Assessment
  - Laboratory Assessments → Urinalysis

- Activity instances:

Name	Definition	Activity instance class	Topic code	ADaM parameter code
<a href="#">Bilirubin (N)</a>	NumericFinding	BILIRUBIN_N_URINE	BILIU3	
<a href="#">Bilirubin Dipstick</a>	CategoricFinding	BILIRUBIN_UR	BILIU4	
<a href="#">Bilirubin Urine</a>	CategoricFinding	BILIRUBIN_URINE	BILIU2	
<a href="#">Bilirubin_AE_Requiring_Additional_Data</a>	NumericFinding	BILI	BILI	
<a href="#">Bilirubin_Biochemistry</a>	NumericFinding	BILIRUBIN_SERUM	BILIS3	

Library / Concepts / Activities / Activities / Bilirubin

### Bilirubin ⓘ

[Overview](#) [OSB YAML](#) [COSMoS YAML](#)

Name	Bilirubin																														
Sentence case name	bilirubin																														
Status	<span style="border: 1px solid green; border-radius: 50%; padding: 2px;">Final</span>																														
Definition																															
Abbreviation																															
Library	Sponsor																														
NCI Concept ID																															
Data collection	Yes																														
Activity groupings	<table border="1"> <thead> <tr> <th>Activity group</th> <th>Activity subgroup</th> </tr> </thead> <tbody> <tr> <td>Laboratory Assessments</td> <td>Biochemistry</td> </tr> <tr> <td>AE Requiring Additional Data</td> <td>Laboratory Assessment</td> </tr> <tr> <td>Laboratory Assessments</td> <td>Urinalysis</td> </tr> </tbody> </table>	Activity group	Activity subgroup	Laboratory Assessments	Biochemistry	AE Requiring Additional Data	Laboratory Assessment	Laboratory Assessments	Urinalysis																						
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Laboratory Assessments	Urinalysis																														
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<a href="#">Bilirubin_Biochemistry</a>	NumericFinding	BILIRUBIN_SERUM	BILIS3																												

+ X S U X

Library / Concepts / Activities / Activities / Bilirubin Urine

### Bilirubin Urine ⓘ

[Overview](#) [OSB YAML](#) [COSMoS YAML](#)

Name	Bilirubin Urine												
Sentence case name	bilirubin urine												
Status	<span style="border: 1px solid green; border-radius: 50%; padding: 2px;">Final</span>												
Definition													
Activity instance class	CategoricFinding												
Abbreviation													
Library	Sponsor												
NCI Concept ID													
ADaM parameter code	BILI2												
Topic code	BILIRUBIN_URINE												
Required for activity	No												
Default selected for activity	No												
Data sharing	Yes												
Legacy usage	No												
Activity groupings	<table border="1"> <thead> <tr> <th>Activity group</th> <th>Activity subgroup</th> </tr> </thead> <tbody> <tr> <td>Laboratory Assessments</td> <td>Urinalysis</td> </tr> </tbody> </table>	Activity group	Activity subgroup	Laboratory Assessments	Urinalysis								
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Item type	Name	Activity item class											
CT term	Laboratory Data Domain	domain											
CT term	Total Bilirubin Measurement	test_name_code											
CT term	Urine	specimen											

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

# Operational SoA – part of Data Specification

The screenshot shows the Novo Nordisk Study Builder interface. The top navigation bar includes 'STUDY BUILDER' with a molecular icon, 'Studies' (selected), 'Library', 'SELECT STUDY' (set to 'CDISC DEV-0'), and various icons for settings, help, and user profile.

The left sidebar has a tree view under 'Define Study': About Studies, Process Overview, Study List, Manage Study, and Define Study (expanded). Under Define Study, the 'Data Specifications' section is selected, showing 'View Specifications' and 'View Listings'.

The main content area is titled 'Study Data Specifications (CDISC DEV-0)'. It shows two tabs: 'Study Activity Instances' and 'Operational SoA' (selected). Below these are two toggle buttons: 'Expand table' and 'Show SoA groups'.

The 'Operational SoA' table has columns: Epoch, Topic Code, ADaM Parameter Code, Screening, and Follow-up. The rows show Visit (Epoch: Day, Topic Code: Day, ADaM Parameter Code: V0, Screening: -4, Follow-up: -2, 1, 1, 31), Window (Epoch: Activities, Topic Code: Window, ADaM Parameter Code: ±0, Screening: -13/+0, Follow-up: -4/+1, ±0, +0/+35), AE Requiring Additional Data, AE Requiring Additional Data, Medical History/Concomitant Illness, Vital Signs, Vital Signs, Systolic Blood Pressure (Topic Code: BP\_SYSTOLIC, ADaM Parameter Code: SYSBP, Screening: X), and Diastolic Blood Pressure.

## StudyBuilder to Veeva SDS Specification

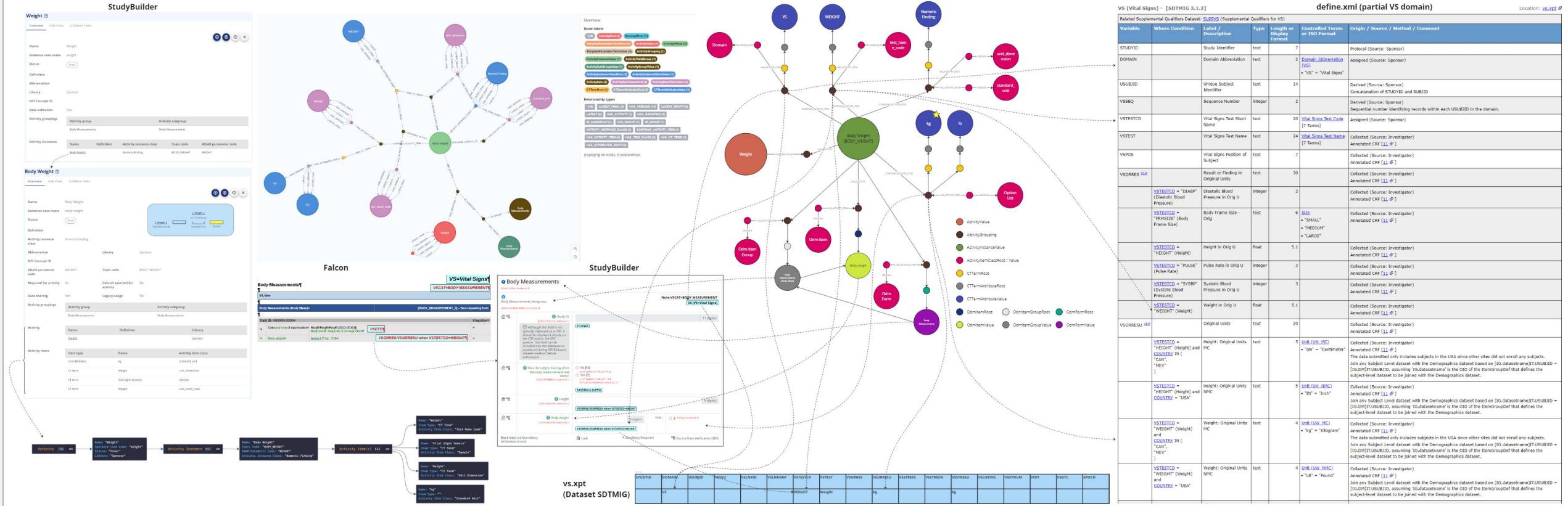
[Summary](#) [Schedule - Grid](#) [Schedule - Tree](#) [Repeating Event Groups](#) [Form Definitions](#) [Rules](#) [Comparison Rules](#) [Casebook Variables](#) [Codelist](#) [Unit Codelists](#) [Study Settings](#)

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.BRTHDT	DOR	DATE			1	0

# Our vision

From Activity to CRF and Define...



# 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

# 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

