

# OpenStudyBuilder – Status & Workshop on EDC Integrations

OPEN  
STUDY  
BUILDER



**COSA Spotlight Q1 – 26 March 2024**

Nicolas de Saint Jorre

# 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

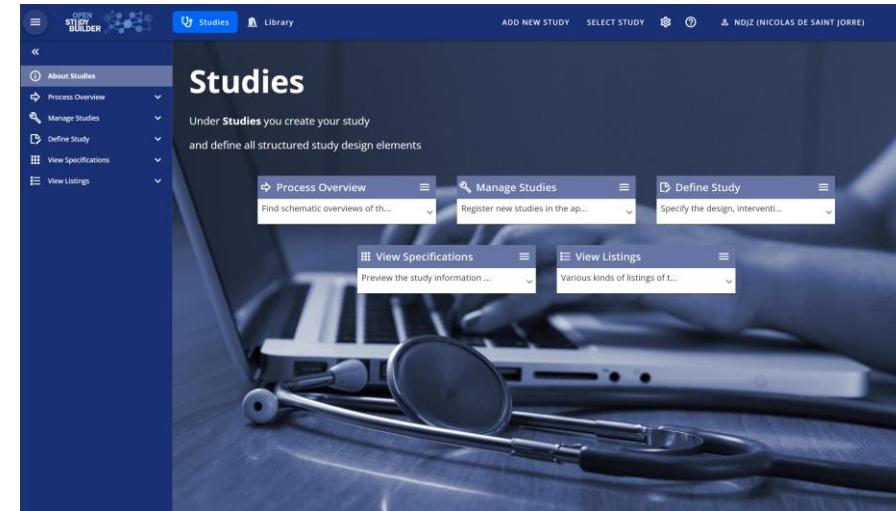
## 3 ELEMENTS OF OpenStudyBuilder

- **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)

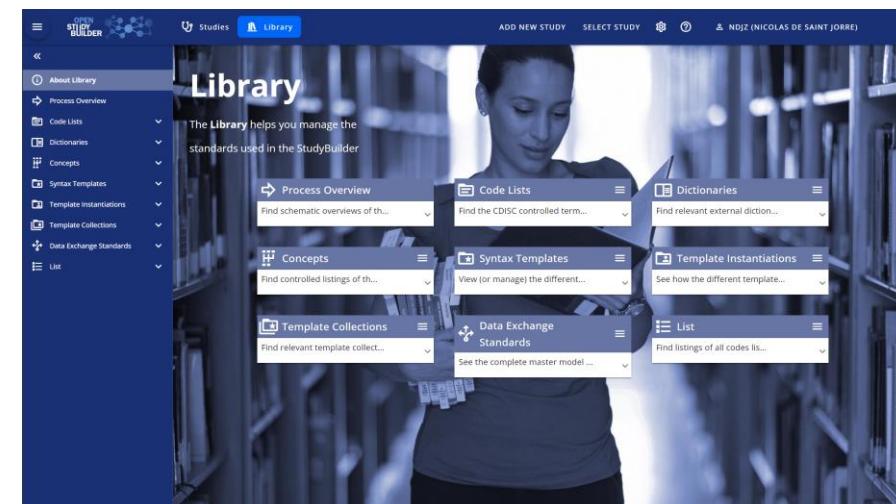


# OpenStudyBuilder Components

| STUDIES              |               |
|----------------------|---------------|
| TITLE                | CRITERIA      |
| REGISTRY IDENTIFIERS | INTERVENTIONS |
| STRUCTURE            | PURPOSE       |
| POPULATION           | ACTVITIES     |



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

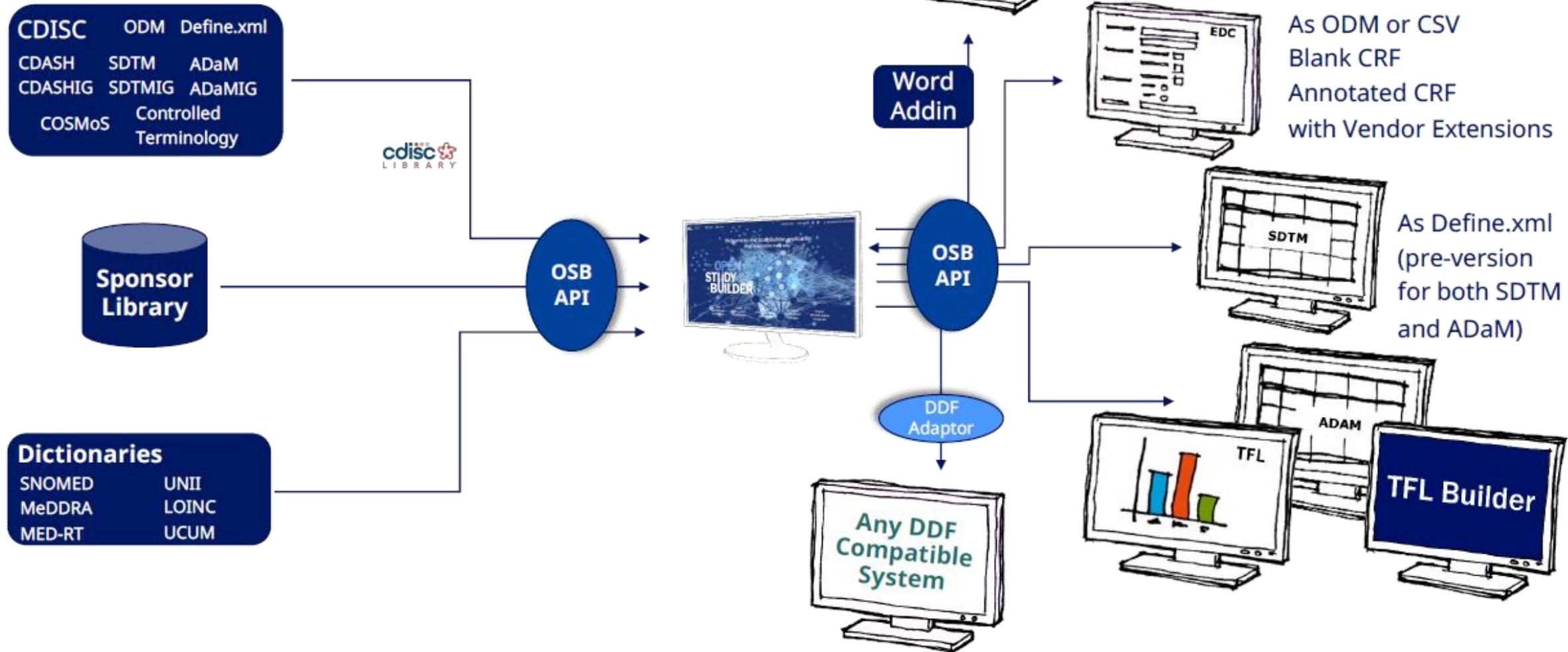


# Goal of OpenStudyBuilder

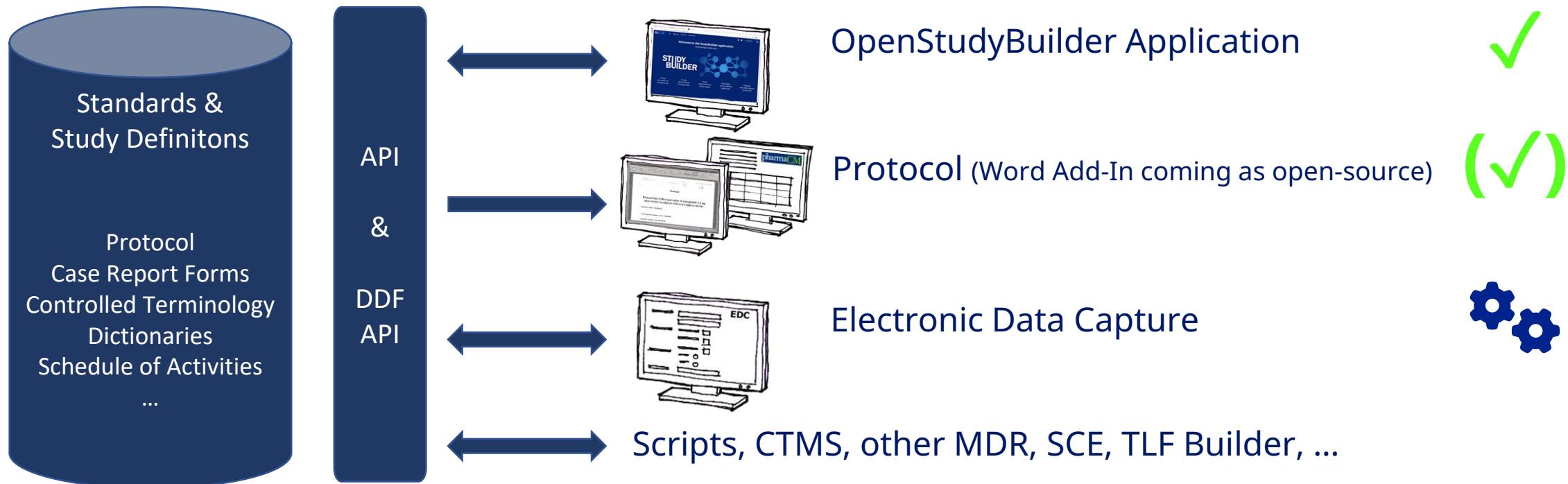
Metadata driven  
End-2-End Automation!



# Connectivity is key!



# Connectivity is key!



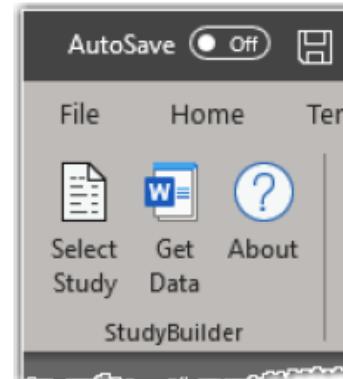
# Protocol Generation



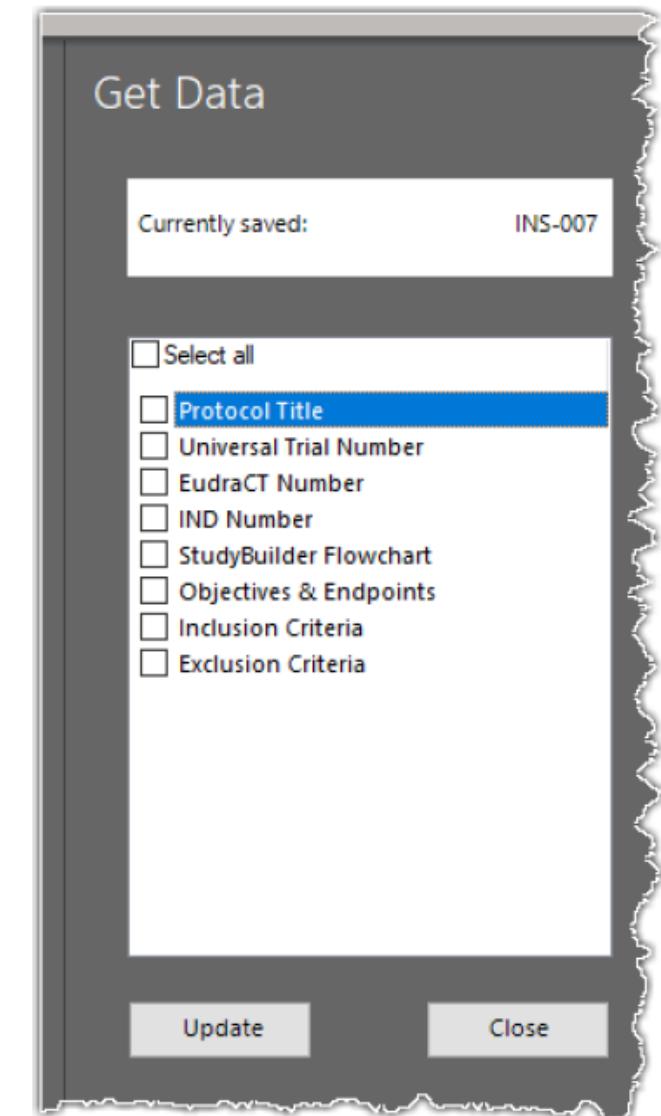
## StudyBuilder ribbon (Word add-in)

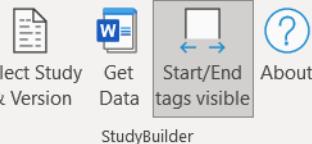
✓ One-way connection

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



Protocol





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

StudyBuilder

Protocol  
Study ID: CDISC DEV-0

Date: 30 September 2022 Status: Draft  
Version: 0.1 Page: 9 of 75 Novo Nordisk

## 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         |
| 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

# CRF Standards & Metadata

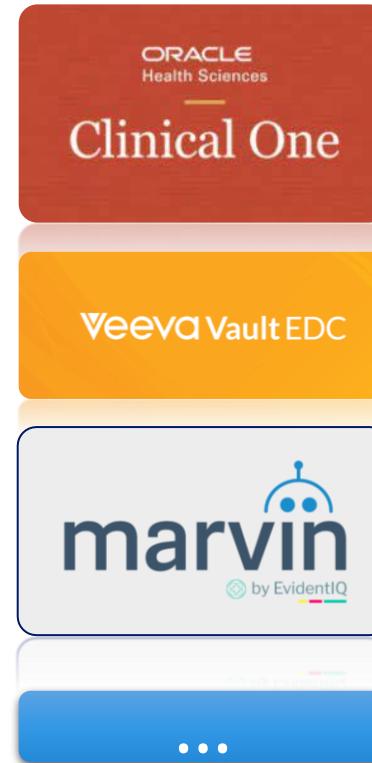
Manage  
Standard & Study CRF

The screenshot shows the 'Open Study Builder' application's interface. On the left is a sidebar with navigation links like 'About Library', 'Process Overview', 'Code Lists', 'Dictionaries', 'Concepts', 'Activities', 'Units', 'CRFs', 'Compounds', 'Syntax Templates', 'Template Instantiations', 'Template Collections', and 'Data Exchange Standards'. The main area is titled 'CRFs (Case Report Forms)'. It displays a section for 'Template NN' with a heading 'Annotated CRF' and a sub-section 'Informed Consent and Demography'. Below this, there are two buttons: 'DM (Demographics Domain)' and 'DS (Disposition Domain)'. A note at the bottom left says: '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.'

Including rules, checks  
Support vendor extensions



EDC Setup, Test,  
Execution



Finetuning, Layout

# OpenStudyBuilder to drive EDC setup

## A COSA Workshop



# CDISC Interchange 2024

**Use OpenStudyBuilder to drive EDC setup - a COSA Workshop**

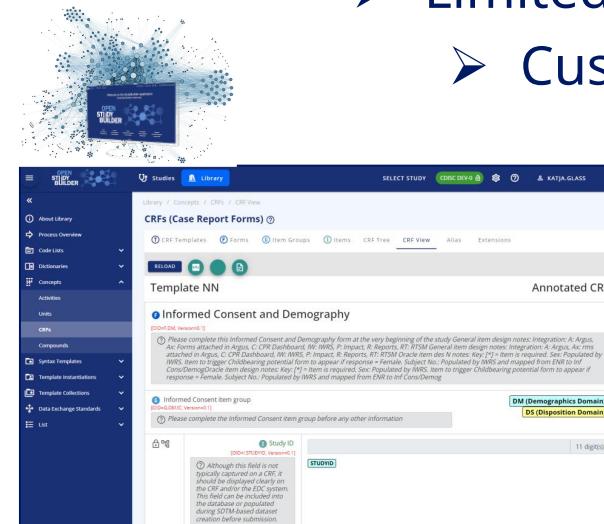
23 April 2024 9:00-16:00, Berlin, Germany



# Problem Statement

## Data Exchange Formats

- CDASH
- ODM.XML
- USDM
- Biomedical Concepts



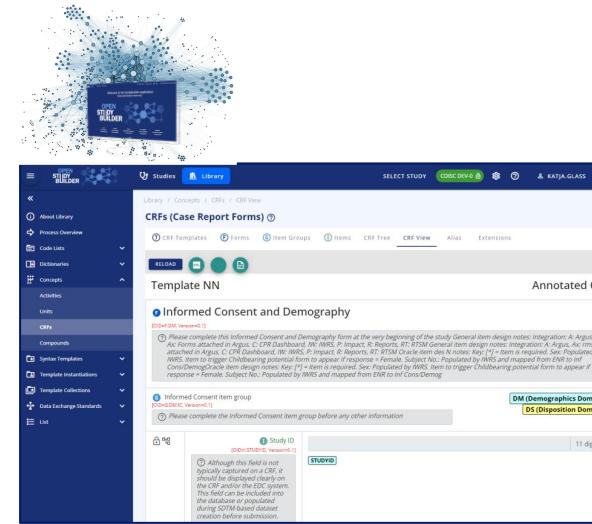
## Implementation

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



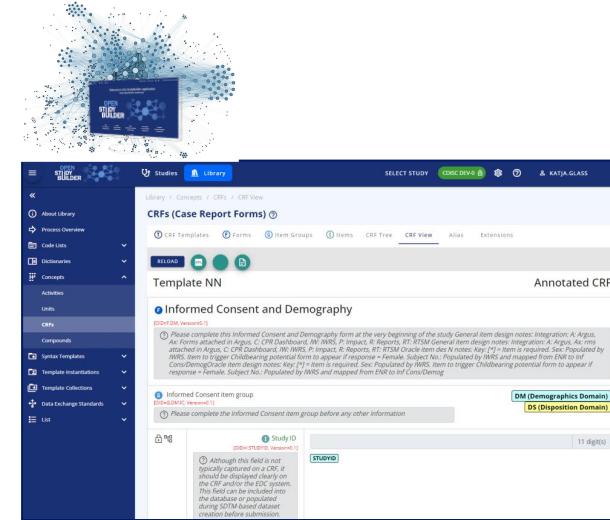
# Workshop Focus

- 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



# Workshop Agenda

- Information Exchange
  - Introduction
  - OpenStudyBuilder status with CRF & SoA for EDC & plans
  - EvidentIQ ODM.xml integration (Marvin EDC)
  - Veeva EDC integration via SDS files and future API integration
  - Oracle ClinicalOne API integration & EvidentIQ ePRO API integration
  - The potential future of API standards
- Breakouts
  - Discuss strengths, weaknesses, opportunities & threats
  - Options and next steps
- Share and discuss in plenum



# CRF for EDC Status & Questions



# 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 | ▼ |

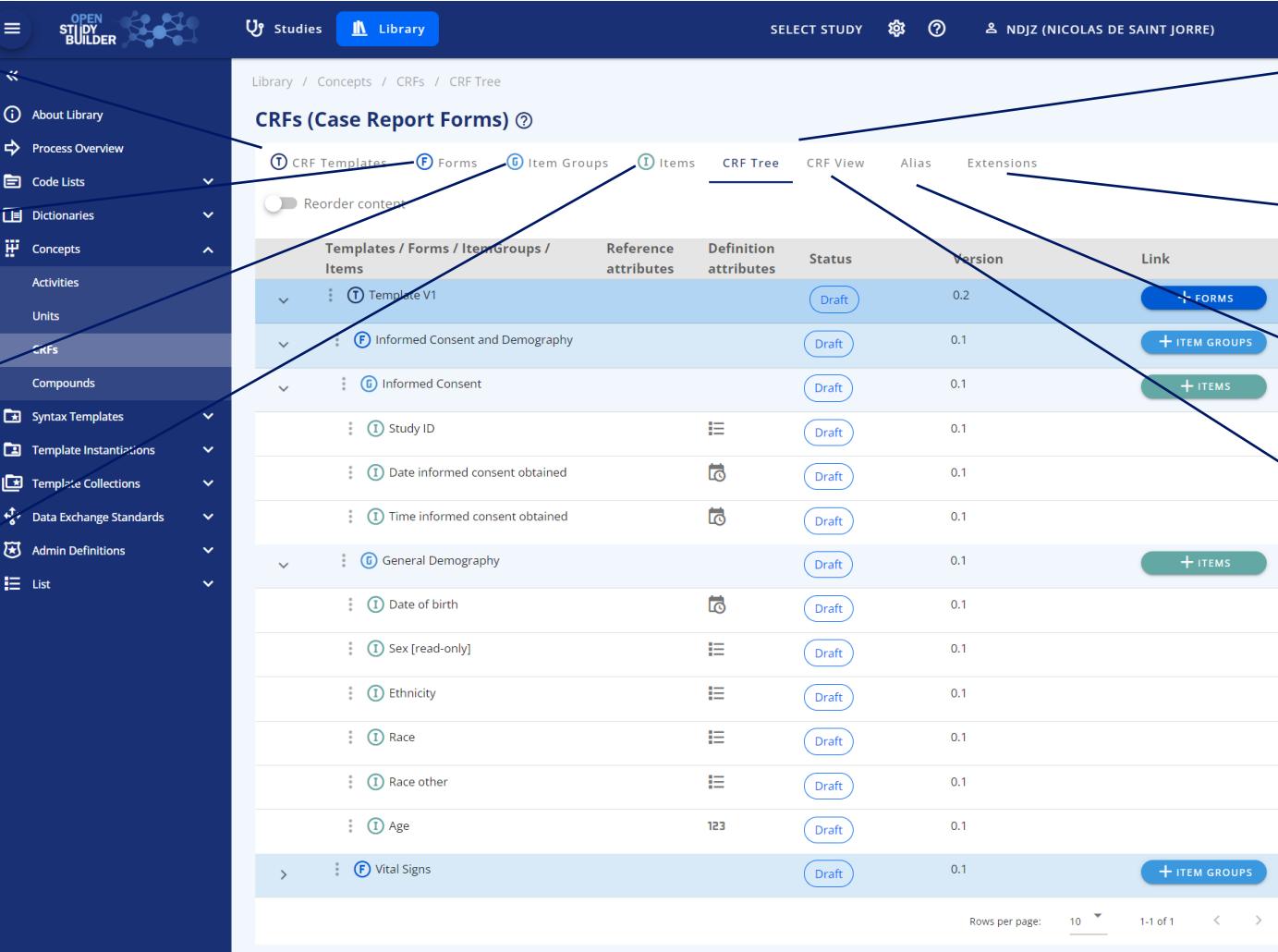
# CRF Specification in the Library

**Study Events**

**Forms**

**ItemGroups**

**Items**



The screenshot shows the 'CRFs (Case Report Forms)' section of the library. It displays a table with columns: Reference attributes, Definition attributes, Status, Version, and Link. The table lists various items under 'Template V1' and other sections like 'Informed Consent and Demography'. Each item has a 'FORMS' button, an 'ITEM GROUPS' button, and an 'ITEMS' button.

| Reference attributes            | Definition attributes | Status | Version | Link                        |
|---------------------------------|-----------------------|--------|---------|-----------------------------|
| Template V1                     |                       | Draft  | 0.2     | <a href="#">FORMS</a>       |
| Informed Consent and Demography |                       | Draft  | 0.1     | <a href="#">ITEM GROUPS</a> |
| Informed Consent                |                       | Draft  | 0.1     | <a href="#">ITEMS</a>       |
| Study ID                        |                       | Draft  | 0.1     |                             |
| Date informed consent obtained  |                       | Draft  | 0.1     |                             |
| Time informed consent obtained  |                       | Draft  | 0.1     |                             |
| General Demography              |                       | Draft  | 0.1     | <a href="#">ITEMS</a>       |
| 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     | <a href="#">ITEM GROUPS</a> |

**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

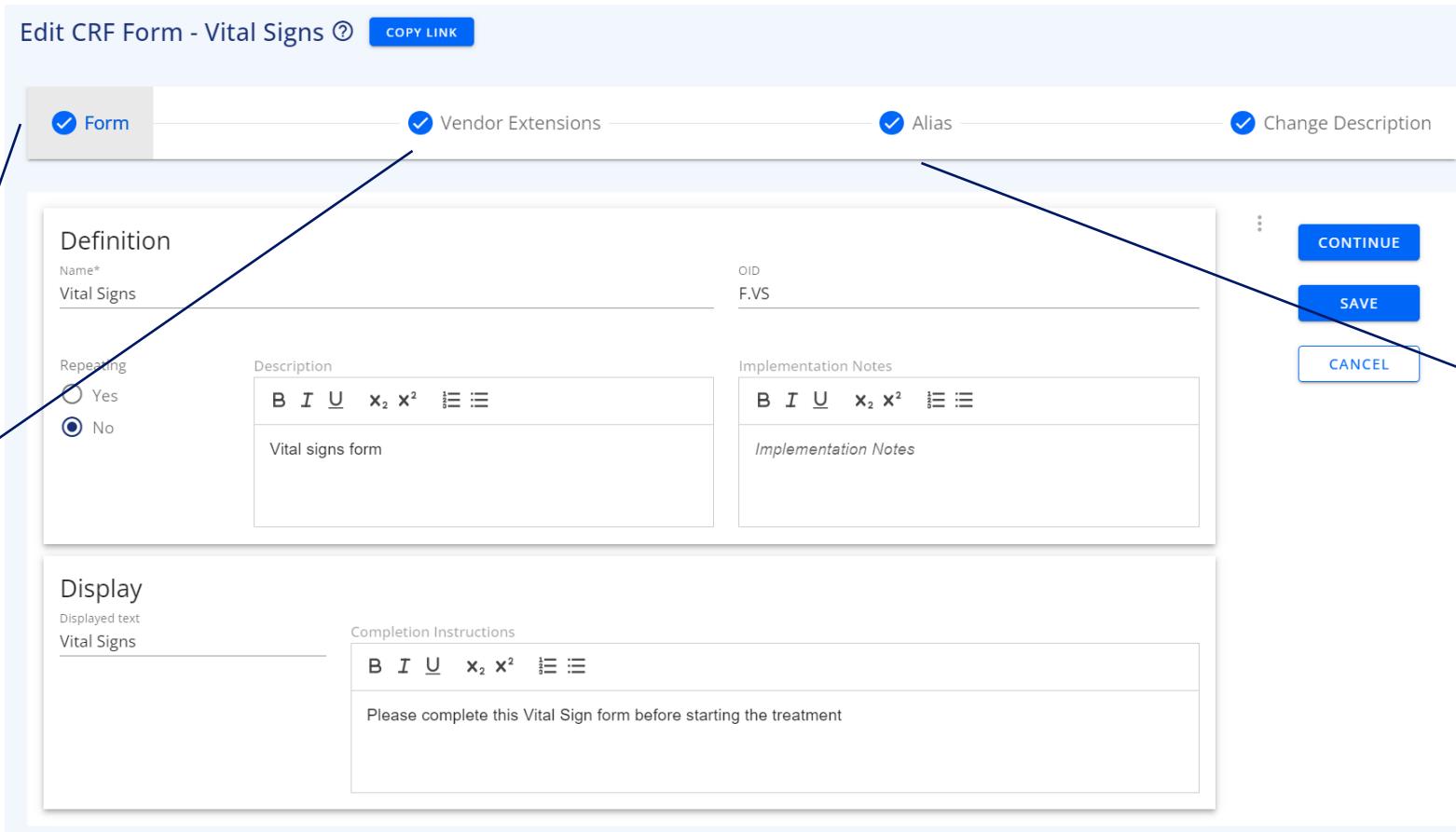
Completion Instructions  
B I U x<sub>2</sub> x<sup>2</sup> ≡ ≡

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

Repeating  
 Yes  
 No

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

OID  
G.VS.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 the Vital Signs item group at each expected time point

**Annotations and reporting**

Domain  
Vital Signs Domain

Is Referential Data  
 Yes  
 No

Origin  
Collected Value

SAS Dataset Name

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

B I U x<sub>2</sub> x<sup>2</sup> |≡≡≡

Implementation Notes

B I U x<sub>2</sub> x<sup>2</sup> |≡≡≡

Implementation Notes

[CONTINUE](#)

[SAVE](#)

[CANCEL](#)

**Display**

Displayed text  
Sex [read-only]

Completion Instructions

B I U x<sub>2</sub> x<sup>2</sup> |≡≡≡

Completion Instructions

**Annotations and reporting**

SAS Field Name  
GENDER

SDS Var Name  
SEX

Origin  
Collected Value

Comment

# 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"/> <a href="#">Delete</a> |

Items per page: 10 | 1-1 of 1 | < < > >|

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

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"/> | Man <a href="#">Delete</a>   |
| C16576_F   | Female                 | <input checked="" type="checkbox"/> | Woman <a href="#">Delete</a> |

Items per page: 10 | 1-2 of 2 | < < > >|

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

Search [Filtering currently not activated](#)

| Concept ID      | Name                            | Add               |
|-----------------|---------------------------------|-------------------|
| C45908_INTERSEX | Intersex <a href="#">Delete</a> | <a href="#">+</a> |
| C17998_U        | Unknown <a href="#">Delete</a>  | <a href="#">+</a> |

# 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<br>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 following  
MSG 2.0  
standard

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

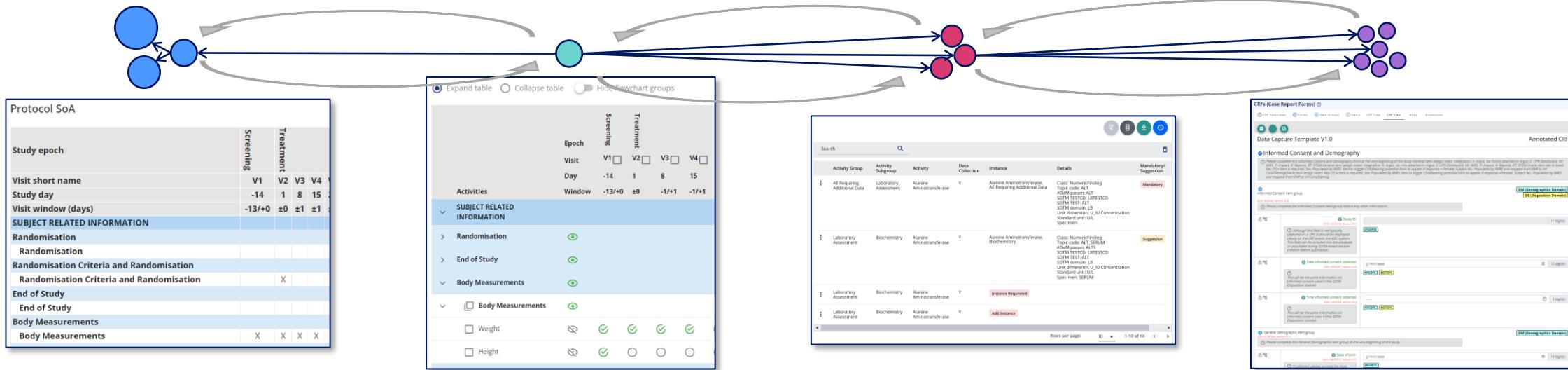
## Studies

|                    |   |   |   |   |
|--------------------|---|---|---|---|
| <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  | ✓ | 🔒 |

# SoA 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 Design  

### Study Visits

Time line preview



Select rows Preferred time unit:  Day  Week     

Search  

| Epoch     | Visit type | Visit Class  | Visit name | Anchor visit in visit group | Visit group |
|-----------|------------|--------------|------------|-----------------------------|-------------|
| Screening | Screening  | Single visit | Visit_1    | No                          |             |
| Treatment | Treatment  | Single visit | Visit_2    | No                          |             |
| Treatment | Treatment  | Single visit | Visit_3    | No                          |             |
| Treatment | Treatment  | Single visit | Visit_4    | No                          |             |
| Treatment | Treatment  | Single visit | Visit_5    | No                          |             |
| Treatment | Treatment  | Single visit | Visit_6    | No                          |             |
| Treatment | Treatment  | Single visit | Visit_7    | No                          |             |
| Treatment | Treatment  | Single visit | Visit_8    | No                          |             |

Studies / Define Study / Study Activities / Study Activities

**Study Activities (CDISC DEV-0) **

Study Activities Detailed SoA SoA footnotes Protocol SoA Activity Instructions

Select rows         

Search  

| #  | Library | SoA group                   | Activity group    | Activity subgroup                | Activity                              | Date |
|----|---------|-----------------------------|-------------------|----------------------------------|---------------------------------------|------|
| 1  | Sponsor | SUBJECT RELATED INFORMATION | Randomisation     | Randomisation                    | Randomized                            | Yes  |
| 2  | Sponsor | SUBJECT RELATED INFORMATION | End of Study      | End of Study                     | End of Study                          | Yes  |
| 3  | Sponsor | SUBJECT RELATED INFORMATION | General           | Physical Examination - early ph1 | Cardiovascular System                 | No   |
| 4  | Sponsor | SUBJECT RELATED INFORMATION | General           | Physical Examination - early ph1 | Abdomen                               | No   |
| 5  | Sponsor | SUBJECT RELATED INFORMATION | General           | Physical Examination - early ph1 | Central and Peripheral Nervous System | No   |
| 6  | Sponsor | SUBJECT RELATED INFORMATION | General           | Physical Examination - early ph1 | Gastrointestinal System incl. Mouth   | No   |
| 7  | Sponsor | SUBJECT RELATED INFORMATION | General           | Physical Examination - early ph1 | General Appearance                    | No   |
| 8  | Sponsor | SUBJECT RELATED INFORMATION | General           | Physical Examination - early ph1 | Musculoskeletal System                | No   |
| 9  | Sponsor | SUBJECT RELATED INFORMATION | General           | Physical Examination - early ph1 | Respiratory System                    | No   |
| 10 | Sponsor | SUBJECT RELATED INFORMATION | Body Measurements | Body Measurements                | Weight                                | Yes  |

Studies / Define Study / Study Activities / Detailed SoA

**Study Activities (CDISC DEV-0) **

Study Activities Detailed SoA SoA footnotes Protocol SoA Activity Instructions

Expand table         

| Epoch  | Screening                   | Treatment                   | Follow-up                   |                             |                             |                             |                             |                             |                             |                              |                              |  |
|--|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|------------------------------|------------------------------|--|
| Visit  | 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"/> |  |
| Day  | -2                          | 1                           | 2                           | 3                           | 4                           | 5                           | 6                           | 7                           | 9                           | 27                           | 31                           |  |
| Window                                       | -13/+0                      | +0                          | +1                          | +1                          | +1                          | +1                          | +1                          | +1                          | +1                          | +0/+35                       |                              |  |
| <b>SUBJECT RELATED INFORMATION</b>           |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>Randomisation</b>                         |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>Randomized</b>                            |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>End of Study</b>                          |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>End of Study</b>                          |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>General</b>                               |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>Physical Examination - early ph1</b>      |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>Cardiovascular System</b>                 |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>Abdomen</b>                               |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>Central and Peripheral Nervous System</b> |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>Gastrointestinal System incl. Mouth</b>   |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |
| <b>General Appearance</b>                    |                             |                             |                             |                             |                             |                             |                             |                             |                             |                              |                              |  |

&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                          |
| -13/+0                      | ±0                          | -1/+1                       | -1/+1                       | -1/+1                       | -1/+1                       | -1/+1                       | -1/+1                       | -1/+1                       | -1/+1                        | 0/+35                        |

Activities Window

SUBJECT RELATED INFORMATION

EFFICACY

Laboratory Assessments

Glucose Metabolism

 HbA1c 

Self Measured Plasma Glucose

Self Measured Plasma Glucose

 Mean Plasma Glucose 

&gt; SAFETY

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



# Protocol and Operational SoA

Studies / Define Study / Study Activities / Protocol SoA

## Study Activities (CDISC DEV-0) ⓘ

Study Activities   Detailed SoA   SoA footnotes   Protocol SoA   Activity Instructions

Protocol SoA    Detailed SoA    Operational SoA   SoA layer: Day   Preferred time: Week

|                                     | Screening | Treatment |    |    |    |    |    |    |    | Follow-up |        |
|-------------------------------------|-----------|-----------|----|----|----|----|----|----|----|-----------|--------|
|                                     | V1        | V2        | V3 | V4 | V5 | V6 | V7 | V8 | V9 | V10       | V11    |
| Visit short name                    |           |           |    |    |    |    |    |    |    |           |        |
| 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 |
| Randomisation                       |           |           |    |    |    |    |    |    |    |           |        |
| Randomisation                       | X         |           |    |    |    |    |    |    |    |           |        |
| End of Study                        |           |           |    |    |    |    |    |    |    |           | X      |
| General                             |           |           |    |    |    |    |    |    |    |           |        |
| Physical Examination - early ph1    | X         |           |    |    |    |    |    |    |    |           |        |
| Self Measured Plasma Glucose        | X         | X         | X  | X  | X  | X  | X  | X  | X  | X         |        |
| Body Measurements                   | X         | X         | X  | X  | X  | X  | X  | X  | X  | X         |        |
| Body Measurements                   |           |           |    |    |    |    |    |    |    |           |        |
| 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  | X  |           |        |
| Biochemistry                        | X         | X         |    | X  |    | X  |    | X  | X  |           |        |
| Haematology                         |           |           |    |    |    |    |    |    |    |           |        |
| AE Requiring Additional Data        |           |           |    |    |    |    |    |    |    |           |        |
| Laboratory Assessment               | X         | X         |    | X  |    | X  |    | X  | X  |           |        |
| Adverse Event                       |           |           |    |    |    |    |    |    |    |           |        |
| Adverse Event                       | X         | X         | X  | X  | X  | X  | X  | X  | X  | X         |        |
| Vital Signs                         |           |           |    |    |    |    |    |    |    |           |        |
| Vital Signs                         | X         | X         | X  | X  | X  | X  | X  | X  | X  | X         |        |
| Medical History/Concomitant Illness |           |           |    |    |    |    |    |    |    |           |        |
| Medical History/Concomitant Illness | X         | X         | X  | X  | X  | X  | X  | X  | X  | X         |        |
| Informed Consent and Demography     |           |           |    |    |    |    |    |    |    |           |        |
| Informed Consent and Demography     | X         |           |    |    |    |    |    |    |    |           |        |

Studies / Define Study / Data Specifications / Operational SoA

## Study Data Specifications (CDISC DEV-0) ⓘ

Study Activity Instances   Operational SoA

Expand table    Show SoA groups

| Epoch Visit                                   | Topic Code | ADaM Parameter Code |           |    |    |    |    |    |    |    |        | Follow-up |
|---|------------|---------------------|-----------|----|----|----|----|----|----|----|--------|-----------|
|   |            | Screening           | Treatment | V1 | V2 | V3 | V4 | V5 | V6 | V7 | V8     |           |
| -2  | 1          | 2                   | 3         | 4  | 5  | 6  | 7  | 9  | 27 | 31 |        |           |
| -13/+0  | ±0         | ±1                  | ±1        | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | ±1 | +0/+35 |           |
| <b>Activities</b>                             |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Body Measurements</b>                      |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Weight</b>                                 |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Height</b>                                 |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Eligibility Criteria</b>                   |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Eligibility Criteria</b>                   |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Subject Eligible to Continue the Trial</b> |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Informed Consent and Demography</b>        |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Informed Consent and Demography</b>        |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Date of Birth</b>                          |            |                     |           |    |    |    |    |    |    |    |        |           |
| <b>Ethnicity</b>                              |            |                     |           |    |    |    |    |    |    |    |        |           |

## Study Activities (CDISC DEV-0) ?

[Study Activities](#)   [Detailed SoA](#)   [SoA footnotes](#)   [Protocol SoA](#)   [Activity Instructions](#) Protocol SoA

SoA layout

 Detailed SoAPreferred time unit:  Day  Week Operational SoA

### Protocol SoA

|   | 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                           |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Randomized                              |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Randomisation Date                      | RANDOMISATION_DATE       | RANDDT              | X         |           |    |    |    |    |    |    |    |     |        |           |
| <b>End of Study</b>                     |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| <b>End of Study</b>                     |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| End of Study                            |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| End of Study                            | END_OF_TRIAL             | EOT                 |           |           |    |    |    |    |    |    |    |     |        | X         |
| <b>General</b>                          |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| <b>Physical Examination - early ph1</b> |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Cardiovascular System                   |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Abdomen                                 |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Central and Peripheral Nervous System   |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Gastrointestinal System incl. Mouth     |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| General Appearance                      |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Musculoskeletal System                  |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Respiratory System                      |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| <b>Body Measurements</b>                |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| <b>Body Measurements</b>                |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Weight                                  |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Body Weight                             | BODY_WEIGHT              | WEIGHT              | X         | X         | X  | X  | X  | X  | X  | X  | X  | X   | X      | X         |
| Height                                  |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Height                                  | HEIGHT                   | HEIGHT              | X         |           |    |    |    |    |    |    |    |     |        |           |
| <b>Eligibility Criteria</b>             |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| <b>Eligibility Criteria</b>             |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Eligibility Criteria Met                |                          |                     |           |           |    |    |    |    |    |    |    |     |        |           |
| Subject Eligible to Continue the Trial  | ELIGIBILITY CRITERIA MET | ELICRIMT            | X         |           |    |    |    |    |    |    |    |     |        |           |

Produce a copy of  
the SoA compatible  
with Word

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

# M11 – Section 8 = Detailed SoA

ICH M11 Template

1. Protocol summary
2. Introduction
3. Trial objectives, endpoints and estimands
4. Trial design
5. Trial population
6. Trial intervention and concomitant therapy
7. Discontinuation of trial intervention and participant withdrawal from trial
8. Trial assessments and procedures
9. Statistical considerations
10. General considerations: regulatory, ethical, and trial oversight
11. GENERAL CONSIDERATIONS: RISK MANAGEMENT AND QUALITY assurance
12. Appendix: adverse events and serious adverse events – definitions, severity, and causality
13. Appendix: definitions and supporting operational details
14. Appendix: glossary of terms
15. Appendix: references

- 833 • Include guidelines for the management of relevant laboratory or other safety assessment abnormalities.
- 834 [Safety Assessments and Procedures]
- 835 **8.3.1 Physical Examination**
- 836 Include any specific instructions for the collection and interpretation of physical examinations.
- 837 [Physical Examination]
- 838 **8.3.2 Vital Signs**
- 839 Include any specific instructions for the collection and interpretation of vital signs.
- 840 [Vital Signs]
- 841 **8.3.3 Electrocardiograms**
- 842 Include any specific instructions for the collection, interpretation, and archiving of ECGs.
- 843 [Electrocardiograms]
- 844 **8.3.4 Clinical Laboratory Assessments**
- 845 Include any specific instructions for the collection and interpretation of clinical laboratory assessments.
- 846 • Specify if and when the use of local laboratories is allowed.
- 847 • Specify which laboratory parameters should be included in each panel (for example, for haematology, chemistry, urinalysis).
- 848 [Clinical Safety Laboratory Assessments]
- 849 **8.3.5 Suicidal Ideation and Behaviour Risk Monitoring**
- 850 If the trial meets any of the criteria requiring suicidal ideation and behaviour risk monitoring by the guidance/guideline in each region, include any specific instructions for the collection and interpretation of the assessment
- 851 [Suicidal Ideation and Behaviour Risk Monitoring]
- 852 **8.4 Adverse Events and Serious Adverse Events**
- 853 No text is intended here (header only).
- 854 **8.4.1 Definitions of AE and SAE**
- 855 Specify the AE and SAE definitions.
- 856 [AE definition]
- 857 [SAE definition]
- 858 Additional details and clarifications for AEs and SAEs are in Appendices 12.1 and 12.2.
- 859
- 860
- 861
- 862
- 863
- 864

# 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 defining an activity instance based on a selected activity. A blue arrow points from the 'Bilirubin' activity entry in the main table to its detailed view on the right.

**Main Interface (Left):**

- Header:** OPEN STUDY BUILDER, Studies, Library, SELECT STUDY, NDJZ (NICOLAS DE SAINT JORRE)
- Sidebar:** About Library, Process Overview, Code Lists, Dictionaries, Concepts, Activities, Units, CRFs, Compounds, Syntax Templates, Template Instantiations, Template Collections, Data Exchange Standards, Admin Definitions, List.
- Current Path:** Library / Concepts / Activities / Activities
- Table Headers:** Library, Activity group, Activity subgroup, Activity name, Sentence case name, NCI Concept ID.
- Table Rows:**
  - Sponsor: Laboratory Assessments, Biochemistry, Bilirubin, bilirubin
  - Sponsor: Laboratory Assessments, Biochemistry, Direct Bilirubin, direct bilirubin
  - Sponsor: Eligibility Criteria, Eligibility Criteria Met, Eligibility\_Criteria\_Met, eligibility criteria met
  - Sponsor: Laboratory Assessments, Biochemistry, Indirect Bilirubin, indirect bilirubin
  - Sponsor: Clinical Outcome Assessments, PGI Change-Ability Things Need, PGI\_Change-Ability\_Things\_Need, pgi change-ability things need

**Right Panel (Activity Details):**

- Bilirubin (Activity Detail):** Overview, OSB YAML, COSMoS YAML.
- Properties:**
  - Name: Bilirubin
  - Sentence case name: bilirubin
  - Status: Final
  - Definition: (empty)
  - Abbreviation: (empty)
  - Library: Sponsor
  - NCI Concept ID: (empty)
  - Data collection: Yes
- Activity groupings:**

| Activity group               | Activity subgroup     |
|------------------------------|-----------------------|
| Laboratory Assessments       | Biochemistry          |
| AE Requiring Additional Data | Laboratory Assessment |
| Laboratory Assessments       | Urinalysis            |
- Activity instances:**

| Name                                   | Definition       | Activity instance class | Topic code | ADaM parameter code |
|--|------------------|-------------------------|------------|---------------------|
| Bilirubin(N)                           | NumericFinding   | BILIRUBIN_N_URINE       | BILI3      |                     |
| Bilirubin_Dipstick                     | CategoricFinding | BILIRUBIN_UR            | BILI4      |                     |
| Bilirubin_Urine                        | CategoricFinding | BILIRUBIN_URINE         | BILI2      |                     |
| Bilirubin_AE_Requiring_Additional_Data | NumericFinding   | BILI                    | BILI       |                     |
| Bilirubin_Biochemistry                 | NumericFinding   | BILIRUBIN_SERUM         | BILIS3     |                     |

Library / Concepts / Activities / Activities / Bilirubin

## Bilirubin ⓘ

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

Name Bilirubin

Sentence case name bilirubin

Status Final

Definition

Abbreviation

Library Sponsor

NCI Concept ID

Data collection Yes

Activity groupings

| Activity group               | Activity subgroup     |
|------------------------------|-----------------------|
| 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 Urine

## Bilirubin Urine ⓘ

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

Name Bilirubin Urine

Sentence case name bilirubin urine

Status Final

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 | Library |
|---------------------------|------------|---------|
| <a href="#">Bilirubin</a> |            | Sponsor |

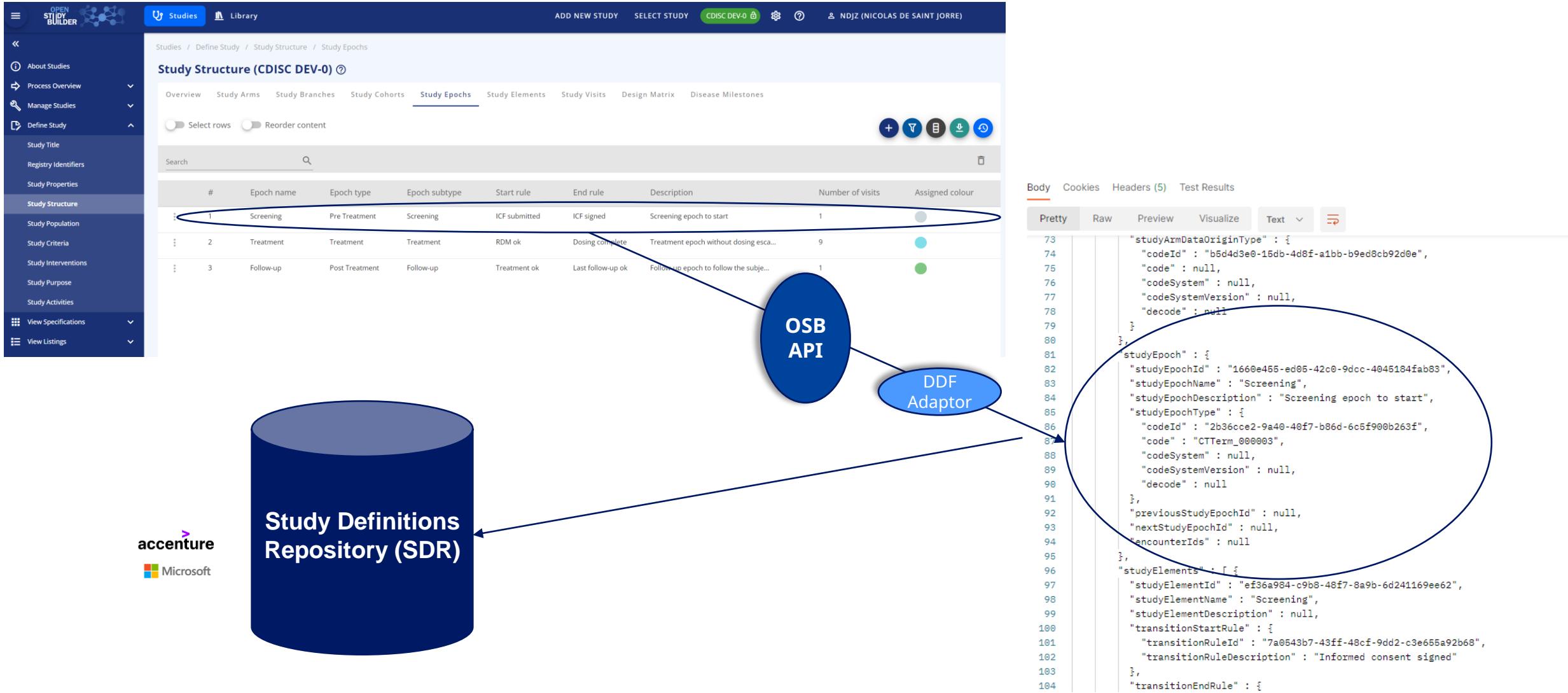
Activity items

| Item type | Name                        | Activity item class |
|-----------|-----------------------------|---------------------|
| CT term   | Laboratory Data Domain      | domain              |
| CT term   | Total Bilirubin Measurement | test_name_code      |
| CT term   | Urine                       | specimen            |



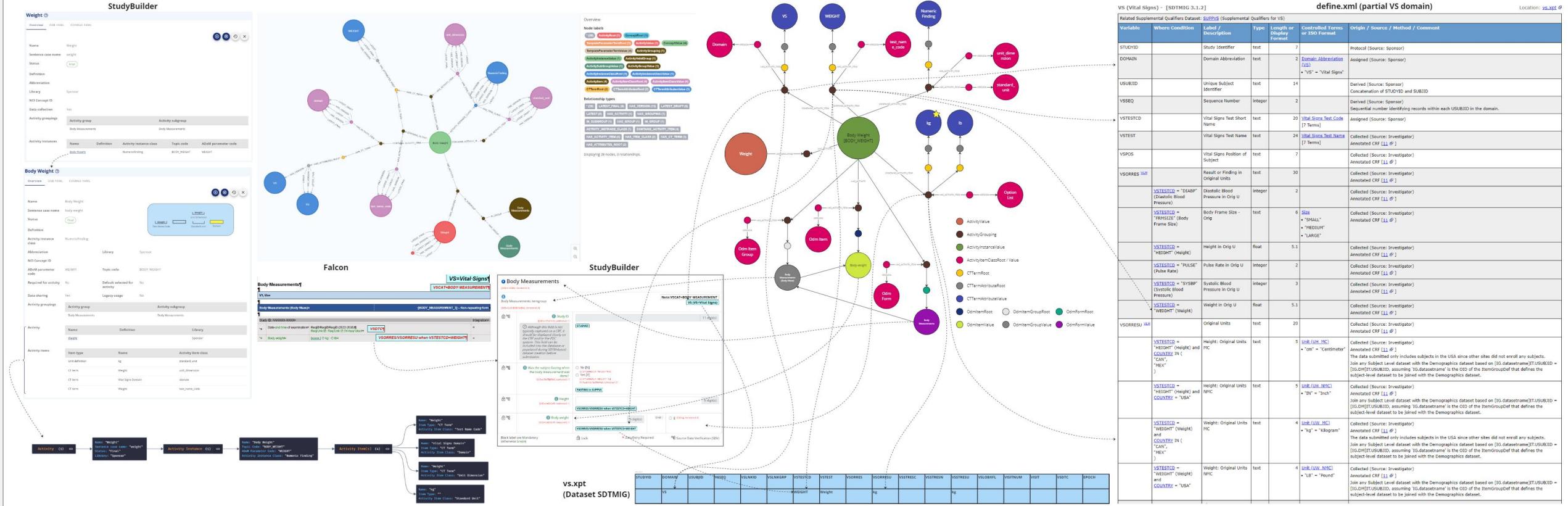
Activity to Activity Instance to Activity Item – As Biomedical Concept (COSMOS project from CDISC)

# Digital Data Flow Adaptor (TransCelerate DDF)



# Our vision

From Activity to CRF and Define...



# From Activity to CRF and Define...

40

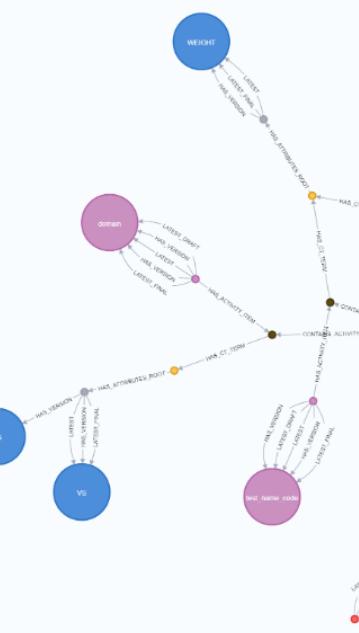
Novo Nordisk®

**StudyBuilder**

**Weight**

**Body Weight**

**Activity**

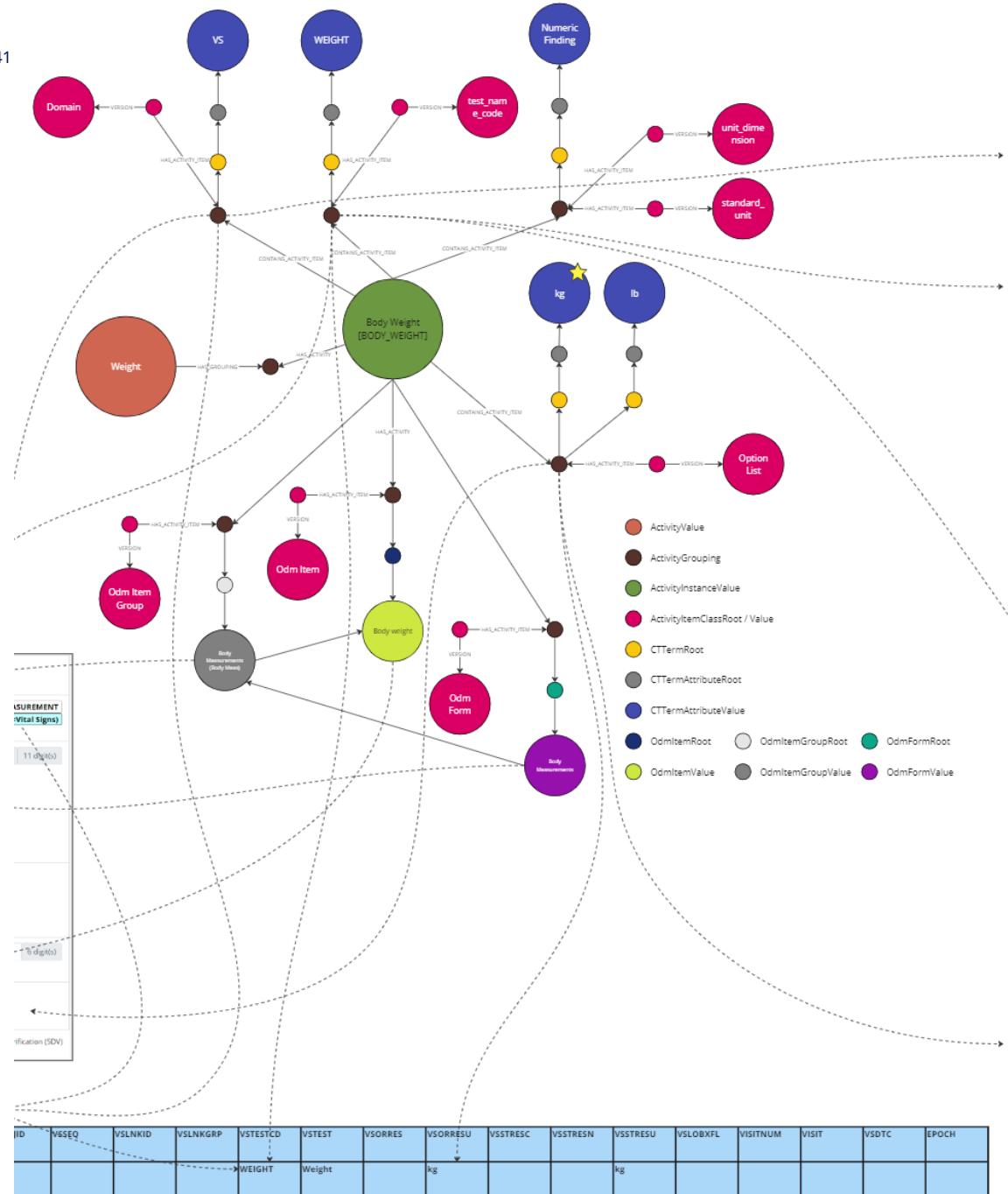


**Falcon**

**Body Measurements**

**StudyBuilder**

**vs.xpt (Dataset SDTMIG)**



## VS (Vital Signs) - [SDTMIG 3.1.2]

Related Supplemental Qualifiers Dataset: SUPPVS (Supplemental Qualifiers for VS)

## define.xml (partial VS domain)

Location: vs.xpt ↗

| Variable                   | Where Condition   | Label / Description                                | Type    | Length or Display Format | Controlled Terms or ISO Format                     | Origin / Source / Method / Comment   |
|----------------------------|---|--|---------|--------------------------|--|--|
| STUDYID                    |   | Study Identifier                                   | text    | 7                        |  | Protocol (Source: Sponsor)   |
| DOMAIN                     |   | Domain Abbreviation                                | text    | 2                        | Domain Abbreviation (VS)<br>• "VS" = "Vital Signs" | Assigned (Source: Sponsor)   |
| USUBJID                    |   | Unique Subject Identifier                          | text    | 14                       |  | Derived (Source: Sponsor)<br>Concatenation of STUDYID and SUBJID   |
| VSEQ                       |   | Sequence Number                                    | integer | 2                        |  | Derived (Source: Sponsor)<br>Sequential number identifying records within each USUBJID in the domain.  |
| VTESTCD                    |   | vital Signs Test Short Name                        | text    | 20                       | Vital Signs Test Code<br>[7 Terms]                 | Assigned (Source: Sponsor)   |
| VTEST                      |   | Vital Signs Test Name                              | text    | 24                       | Vital Signs Test Name<br>[7 Terms]                 | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
| VSPOS                      |   | vital Signs Position of Subject                    | text    | 7                        |  | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
| VSORRES <small>VLM</small> |   | Result or Finding in Original Units                | text    | 30                       |  | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
|                            | VTESTCD = "DIABP"   | Diastolic Blood Pressure in Orig U                 | integer | 2                        |  | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
|                            | VTESTCD = "FRMSIZE"                                       | Body Frame Size - Orig                             | text    | 6                        | Size<br>• "SMALL"<br>• "MEDIUM"<br>• "LARGE"       | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
|                            | VTESTCD = "HEIGHT"  | Height in Orig U                                   | float   | 5.1                      |  | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
|                            | VTESTCD = "PULSE"   | Pulse Rate in Orig U                               | integer | 2                        |  | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
|                            | VTESTCD = "SYSBP"   | Systolic Blood Pressure in Orig U                  | integer | 3                        |  | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
|                            | VTESTCD = "WEIGHT"  | Weight in Orig U                                   | float   | 5.1                      |  | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
|                            | VSORRESU <small>VLM</small>                               | Original Units                                     | text    | 20                       |  | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]   |
|                            | VTESTCD = "HEIGHT" (Height) and COUNTRY IN ("CAN", "MEX") | Height: Original Units MC<br>• "cm" = "Centimeter" | text    | 5                        | Unit (UH_MC)                                       | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]<br>The data submitted only includes subjects in the USA since other sites did not enroll any subjects.<br>Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset. |
|                            | VTESTCD = "HEIGHT" (Height) and COUNTRY = "USA"           | Height: Original Units NMC<br>• "IN" = "Inch"      | text    | 5                        | Unit (UH_NMC)                                      | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]<br>Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.  |
|                            | VTESTCD = "WEIGHT" (Weight) and COUNTRY IN ("CAN", "MEX") | Weight: Original Units MC<br>• "kg" = "Kilogram"   | text    | 4                        | Unit (UW_MC)                                       | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]<br>The data submitted only includes subjects in the USA since other sites did not enroll any subjects.<br>Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset. |
|                            | VTESTCD = "WEIGHT" (Weight) and COUNTRY = "USA"           | Weight: Original Units NMC<br>• "LB" = "Pound"     | text    | 4                        | Unit (UW_NMC)                                      | Collected (Source: Investigator)<br>Annotated CRF [11 ↗]<br>Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.  |

# 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



# Additional Information



# CDISC Interchange 2024

**Use OpenStudyBuilder to drive EDC setup - a COSA Workshop**

23 April 2024 9:00-16:00, Berlin, Germany



# CDISC Interchange 2024

## Use OpenStudyBuilder as MDR Meetup

23 April 2024 17:00-18:00, Berlin, Germany

- Reach out to [OpenStudyBuilder@gmail.com](mailto:OpenStudyBuilder@gmail.com)



## Meet us at the Interchange

24-25 April 2024

- Reach us at the COSA booth for demonstration and exchange

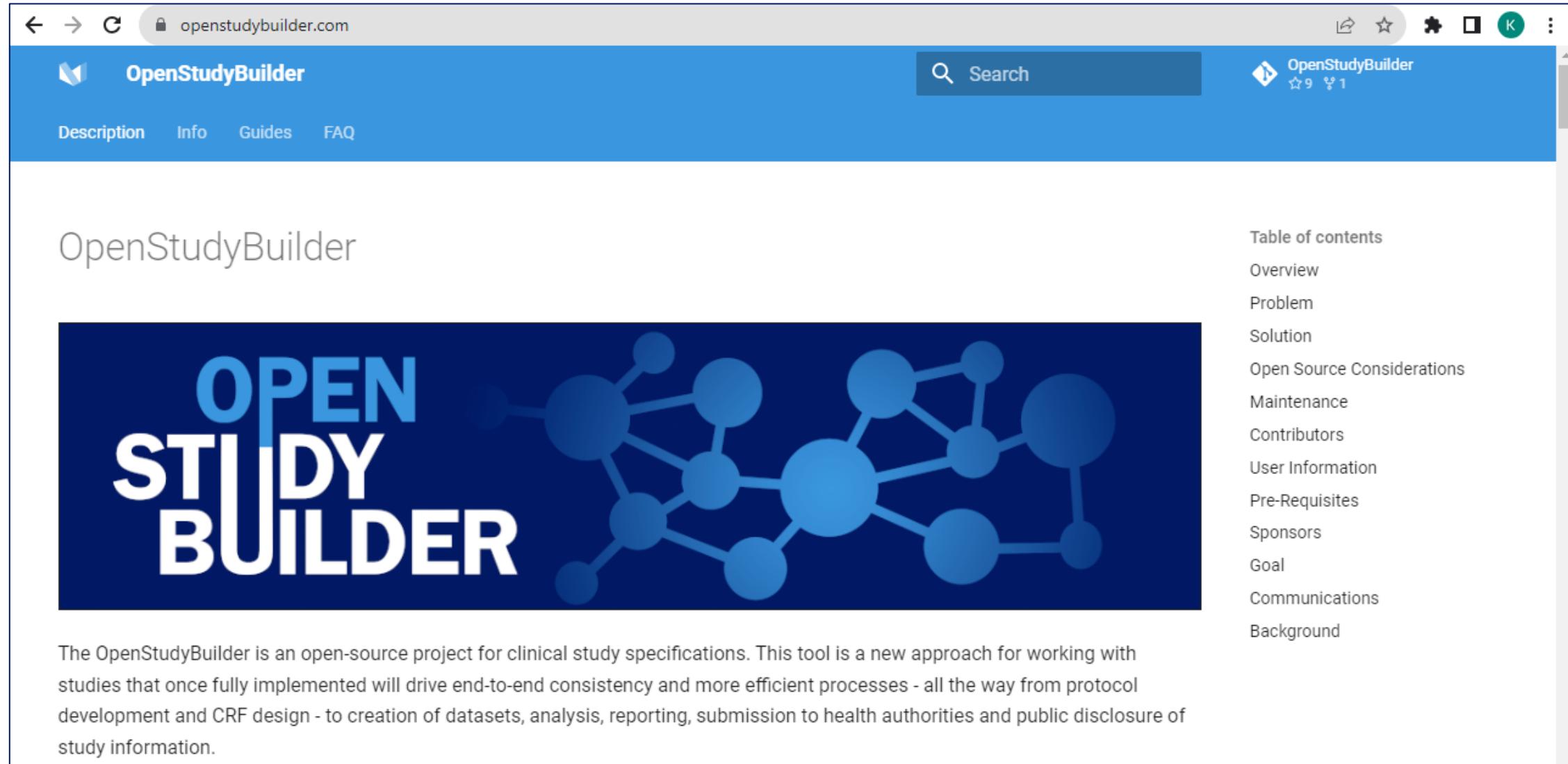


## From OpenStudyBuilder to the Digital Data Flow - USDM Format

15 April 2024 – 14:40-15:00, Presentation



# Project Homepage



The screenshot shows a web browser displaying the OpenStudyBuilder project homepage. The URL in the address bar is [openstudybuilder.com](https://openstudybuilder.com/). The page has a blue header with the project logo and navigation links for Description, Info, Guides, and FAQ. A search bar is also present in the header. The main content area features the "OPEN STUDY BUILDER" logo on the left and a network graph icon on the right. To the right of the main content, there is a sidebar with a vertical list of project documentation sections: Table of contents, Overview, Problem, Solution, Open Source Considerations, Maintenance, Contributors, User Information, Pre-Requisites, Sponsors, Goal, Communications, and Background.

OpenStudyBuilder

Table of contents

Overview

Problem

Solution

Open Source Considerations

Maintenance

Contributors

User Information

Pre-Requisites

Sponsors

Goal

Communications

Background

The OpenStudyBuilder is an open-source project for clinical study specifications. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.

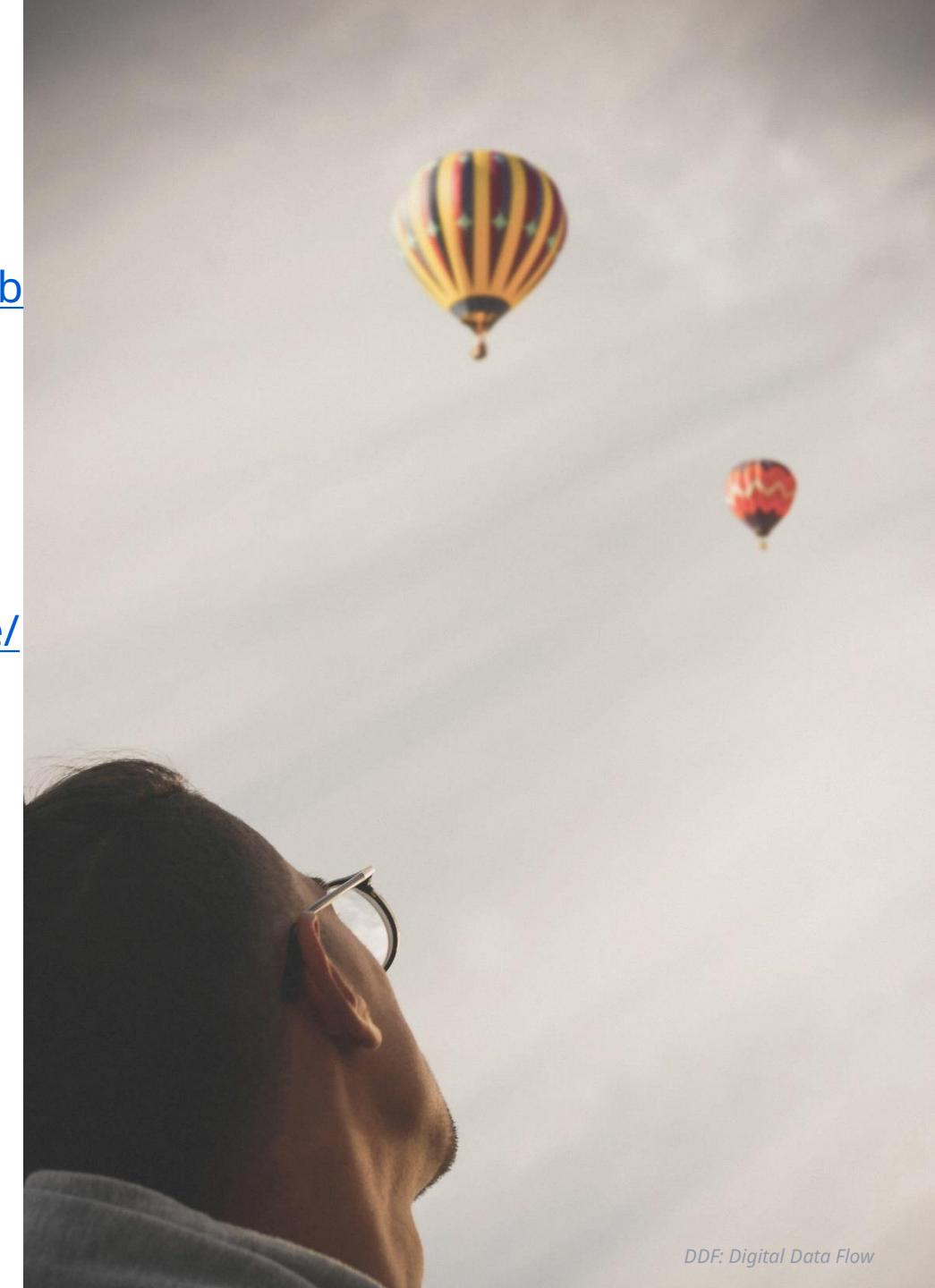
<https://openstudybuilder.com/>

# Links

- Project Homepage: <https://openstudybuilder.com/>
- Newsletter: <https://www.linkedin.com/newsletters/openstudybuilder-6990328054849916928/>
- YouTube Demonstration (30'): <https://youtu.be/dL5CY0BwfEs>
- GitLab (Solution, Description): <https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder>
- Slack: [https://join.slack.com/t/openstudybuilder/shared\\_invite/zt-19mtauzic-Jvrhtmy7hGstgyiIvB1Wsw](https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyiIvB1Wsw)
- E-Mail: [openstudybuilder@gmail.com](mailto:openstudybuilder@gmail.com)

Sandbox:

- Mail [openstudybuilder@neotechnology.com](mailto:openstudybuilder@neotechnology.com) – Subject  
“Request Sandbox access”
- Note: when add/modify/delete, your mail might be exposed in  
the version history



Thanks!  
Questions?

OPEN  
STUDY  
BUILDER

