

# OpenStudyBuilder – Status & Workshop on EDC Integrations



**COSA Spotlight Q1 – 26 March 2024**

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# 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

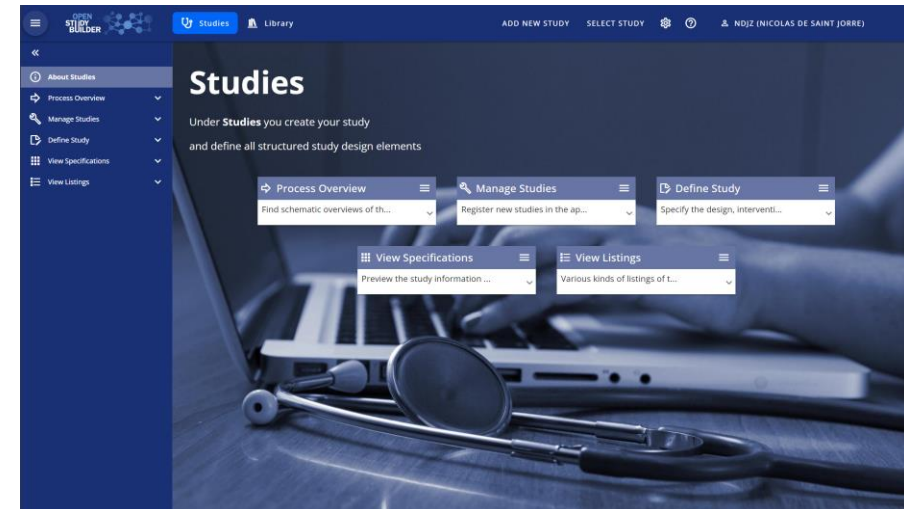
## 3 ELEMENTS OF OpenStudyBuilder

- **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)

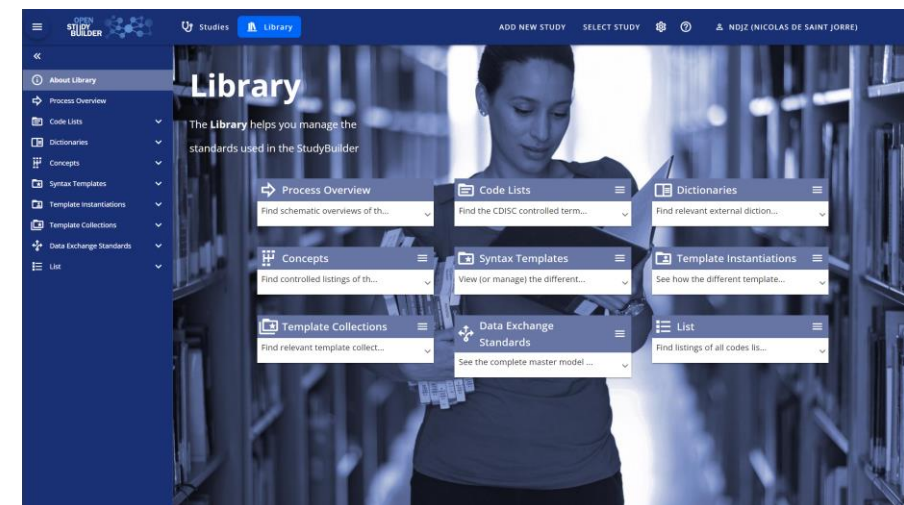


# OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



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



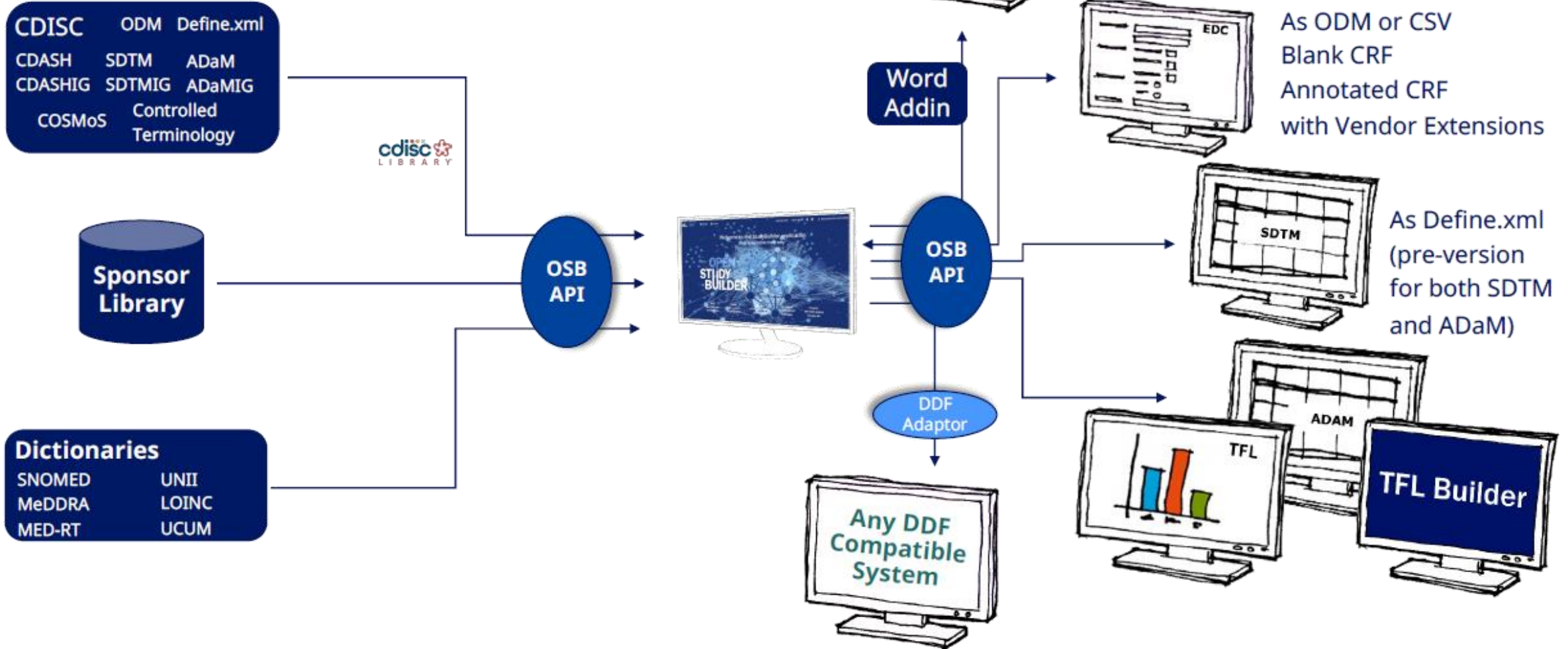
# Goal of OpenStudyBuilder

Metadata driven  
End-2-End Automation!

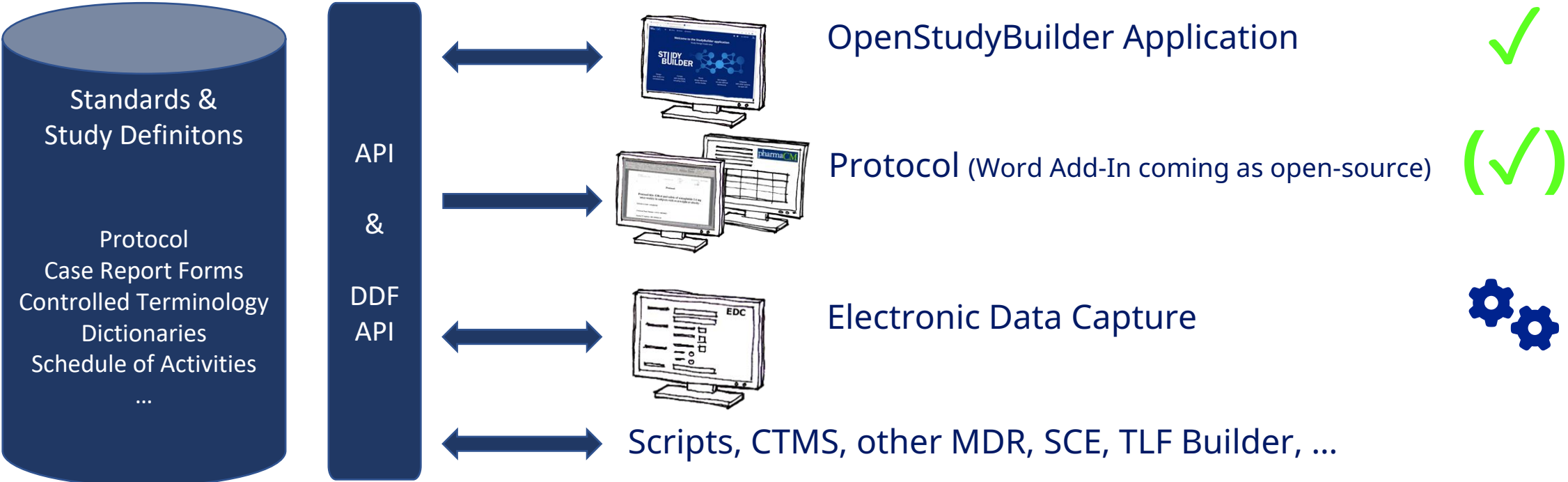




# Connectivity is key!



# Connectivity is key!



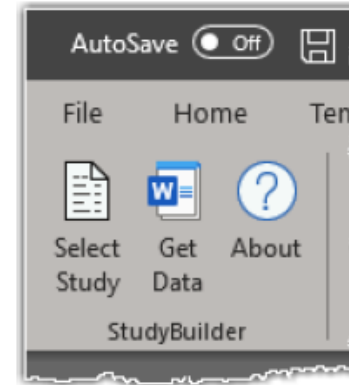
# Protocol Generation



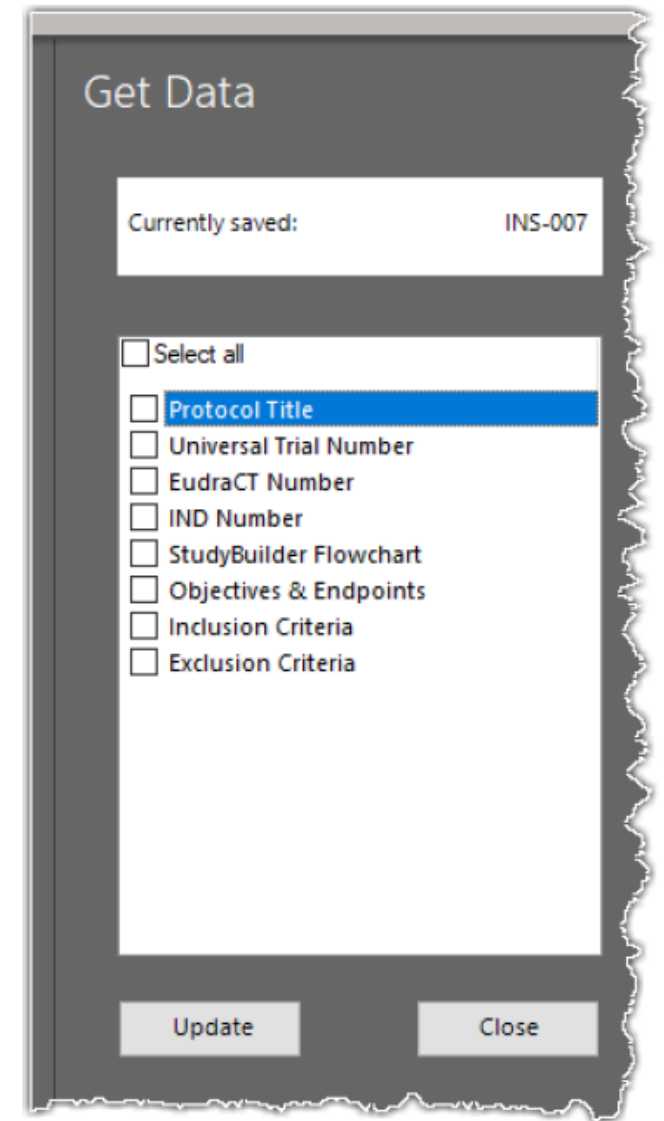
## StudyBuilder ribbon (Word add-in)



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



**Protocol**





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

StudyBuilder

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

### Get Data

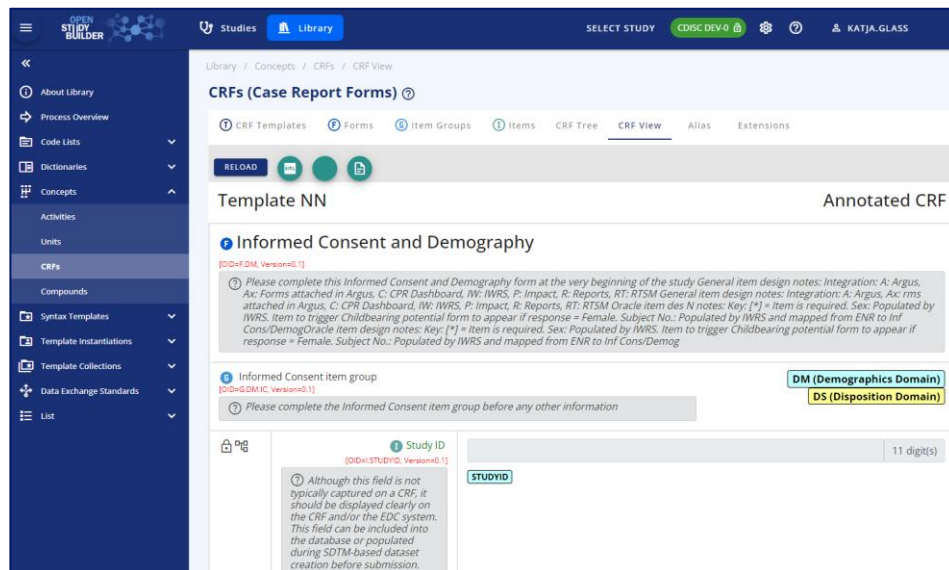
Currently saved: CDISC DEV-0

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

Update | Cancel

# CRF Standards & Metadata

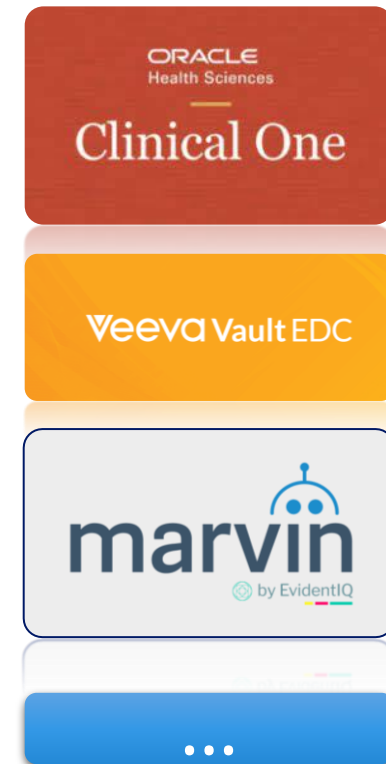
Manage  
Standard & Study CRF



Including rules, checks  
Support vendor extensions



EDC Setup, Test,  
Execution



Finetuning, Layout

# OpenStudyBuilder to drive EDC setup

A COSA Workshop



# CDISC Interchange 2024

Use OpenStudyBuilder to drive EDC setup - a COSA Workshop

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





# Problem Statement

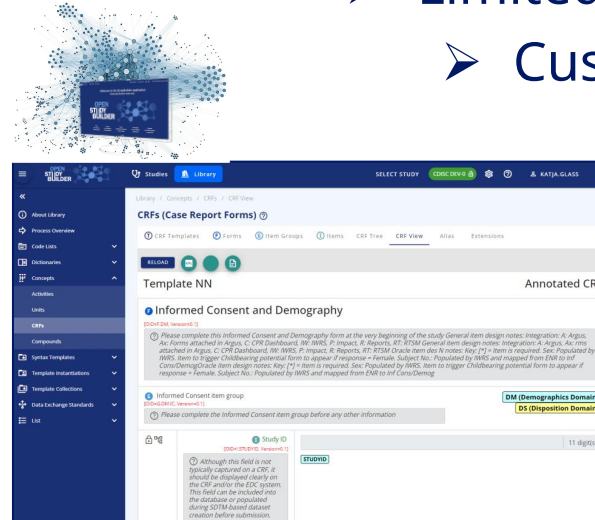
## Data Exchange Formats

- CDASH
- ODM.XML
- USDM
- Biomedical Concepts



## Implementation

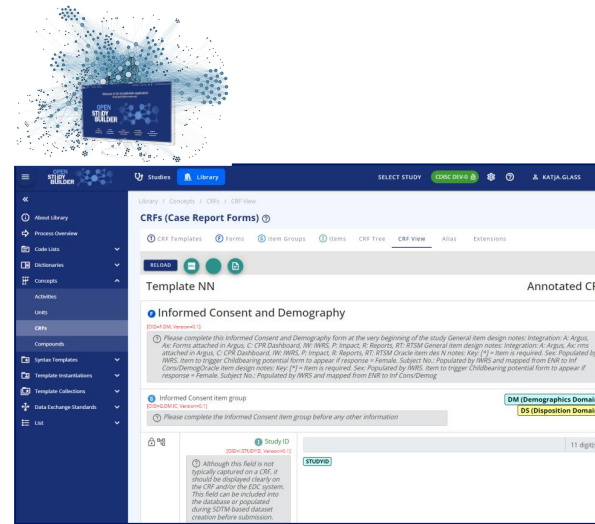
- Native formats
- Limited interface capabilities
- Limited selection of standards
- Custom extensions





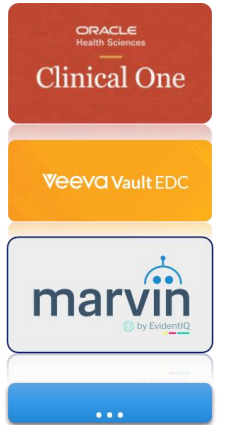
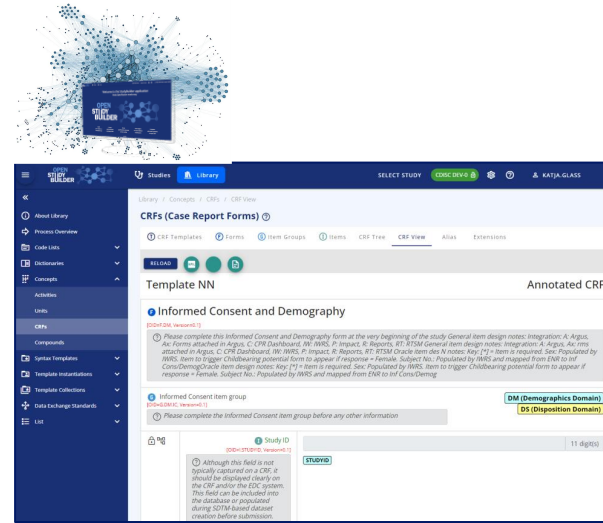
# Workshop Focus

- 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

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

# CRF Specification in the Library

The screenshot shows the 'Library / Concepts / CRFs / CRF Tree' view. The table below represents the data shown in the interface:

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

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

- Study Events
- Forms
- ItemGroups
- Items

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

- eCRF specs
- Vendor Extensions
- Alias
- eCRF views



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

The screenshot shows the 'Edit CRF Form - Vital Signs' interface. At the top, there are four tabs: 'Form', 'Vendor Extensions', 'Alias', and 'Change Description', all of which are checked. The 'Form' tab is currently active. The interface is divided into two main sections: 'Definition' and 'Display'. The 'Definition' section includes fields for 'Name\*' (Vital Signs), 'OID' (F.VS), 'Repeating' (Yes/No), 'Description' (Vital signs form), and 'Implementation Notes' (Implementation Notes). The 'Display' section includes 'Displayed text' (Vital Signs) and 'Completion Instructions' (Please complete this Vital Sign form before starting the treatment). On the right side, there are three buttons: 'CONTINUE', 'SAVE', and 'CANCEL'. Three callout boxes are present: 'Form Definition' points to the 'Form' tab, 'Vendor Extensions' points to the 'Vendor Extensions' tab, and 'Alias' points to the 'Alias' tab.

**Form Definition**

**Vendor Extensions**

**Alias**

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

Form  Vendor Extensions  Alias  Change Description

**Definition**

Name\*  
Vital Signs

OID  
F.VS

Repeating  
 Yes  
 No

Description  
Vital signs form

Implementation Notes  
Implementation Notes


**Display**

Displayed text  
Vital Signs

Completion Instructions  
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>1</sub> x<sub>2</sub>**  

Vital signs



Implementation Notes  
**B I U x<sub>1</sub> x<sub>2</sub>**  

Implementation Notes

Implementation Notes


**Display**

Displayed text  
Vital Signs


Completion instructions  
**B I U x<sub>1</sub> x<sub>2</sub>**  

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\*  OID

Data Type\*  Length

Description  Implementation Notes

---

### Display

Displayed text  Completion Instructions

---

### Annotations and reporting

SAS Field Name  SDS Var Name

Origin  Comment

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

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

Edit Item - Sex [read-only] ⓘ

[COPY LINK](#)

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

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

[CONTINUE](#)

[SAVE](#)

[CANCEL](#)

[PREVIOUS](#)

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

Search  Search with terms

Operator or

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

Edit Item - Sex [read-only] ⓘ

[COPY LINK](#)

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

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

[CONTINUE](#)

[SAVE](#)

[CANCEL](#)

[PREVIOUS](#)

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

Search

Filtering currently not activated

Concept ID	Name
C45908_INTERSEX	Intersex
C17998_U	Unknown

# Vendor Extensions

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

**Vendor Extensions** | Item Group | Alias | Change Description

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

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](#)

[CONTINUE](#)

[SAVE](#)

[CANCEL](#)

[PREVIOUS](#)



# Concept: CRFs

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

Templates used to defined multiple CRF version

PDF format

Annotated CRF following MSG 2.0 standard

ODM.xml with vendor extensions (or CSV)

**Template NN V1** Annotated CRF

**Informed Consent and Demography**

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

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

Informed Consent item group  
[OID=GDM.IC, Version=0.2]

Please complete the Informed Consent item group before any other information

**Study ID** [OID=LSTUDYID, Version=0.1] 11 digit(s)  
STUDYID

**Date informed consent obtained** [OID=LRFCIDAT, Version=0.2] 10 digit(s)  
jj/mm/aaaa  
RFLCDDTC DSSTDTCT

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.

This will be the same information on informed consent used in the SDTM Disposition domain

## Vendor Extension in ODM

```

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

```

# Odm.xml API endpoint

## ODM Metadata Import/Export

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

Try it out

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

Request body multipart/form-data

Level of Metadata in the ODM (uid):

- StudyEvent
- Form
- ItemGroup

Target Type:

- StudyEvent
- Form
- ItemGroup

Status of the metadata

PDF or CSV

Stylesheet ref.

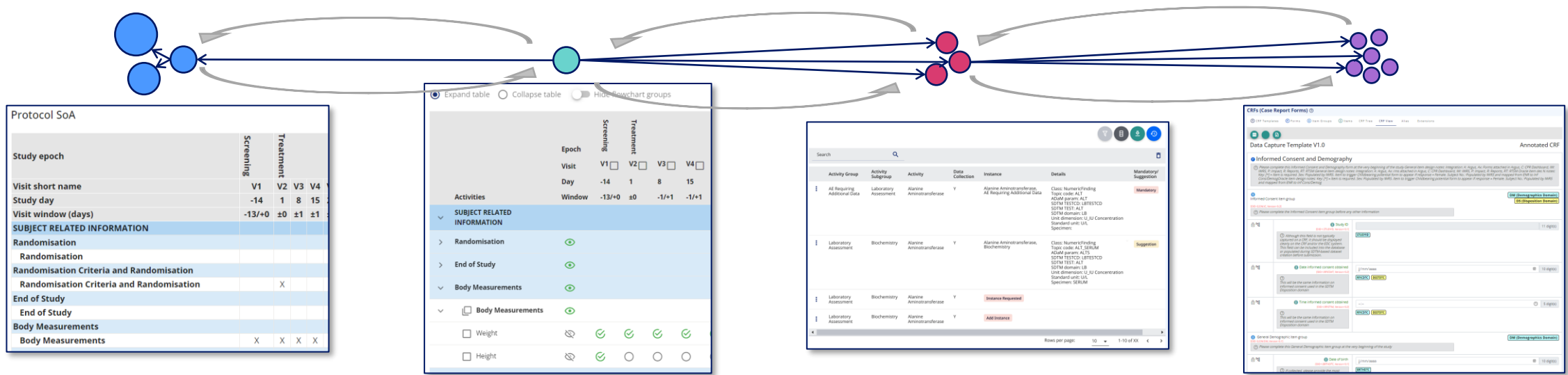
# API Endpoints to work with the SoAs...

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

# 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 related to specific ADaM PARAM/PARAMCD

## Data Capture / Collection Specification

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





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

Studies / Define Study / Study Activities / Detailed SoA

### Study Activities (CDISC DEV-0) ?

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


Activities	Window	Screening										Follow-up
		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
		-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
> SUBJECT RELATED INFORMATION	🗑️											
▼ EFFICACY	🗑️											
▼ Laboratory Assessments	👁️											
▼ <input type="checkbox"/> Glucose Metabolism	👁️											
<input type="checkbox"/> HbA1c	🗑️	✅	✅	✅	✅	✅	✅	✅	✅	✅	✅	○
▼ Self Measured Plasma Glucose	👁️											
<input type="checkbox"/> Self Measured Plasma Glucose	🗑️											
<input type="checkbox"/> Mean Plasma Glucose	🗑️	○	○	○	○	○	○	○	○	○	○	○
> SAFETY	🗑️											

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



## Study Activities (CDISC DEV-0) ?

Study Activities   Detailed SoA   SoA footnotes   Protocol SoA   Activity Instructions

Protocol SoA   SoA layout   Preferred time unit:  Day  Week 

Protocol SoA  
 Detailed SoA  
 Operational SoA

Produce a copy of the SoA compatible with Word

	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>														
Randomised														
<i>Randomisation Date</i>	RANDOMISATION_DATE	RANDDT		X										
<b>End of Study</b>														
End of Study														
<i>End of Study</i>	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														
<i>Body Weight</i>	BODY_WEIGHT	WEIGHT	X	X	X	X	X	X	X	X	X	X	X	
Height														
<i>Height</i>	HEIGHT	HEIGHT	X											
<b>Eligibility Criteria</b>														
<b>Eligibility Criteria</b>														
Eligibility Criteria Met														
<i>Subject Eligible to Continue the Trial</i>	ELIGIBILITY CRITERIA MET	ELICRIMT	X											

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

# M11 – Section 8 = Detailed SoA

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

ICH M11 Template

833	• Include guidelines for the management of relevant laboratory or other safety
834	assessment abnormalities.
835	[Safety Assessments and Procedures]
836	<b>8.3.1 Physical Examination</b>
837	Include any specific instructions for the collection and interpretation of physical examinations.
838	[Physical Examination]
839	<b>8.3.2 Vital Signs</b>
840	Include any specific instructions for the collection and interpretation of vital signs.
841	[Vital Signs]
842	<b>8.3.3 Electrocardiograms</b>
843	Include any specific instructions for the collection, interpretation, and archiving of ECGs.
844	[Electrocardiograms]
845	<b>8.3.4 Clinical Laboratory Assessments</b>
846	Include any specific instructions for the collection and interpretation of clinical laboratory
847	assessments.
848	• Specify if and when the use of local laboratories is allowed.
849	• Specify which laboratory parameters should be included in each panel (for example, for
850	haematology, chemistry, urinalysis).
851	[Clinical Safety Laboratory Assessments]
852	<b>8.3.5 Suicidal Ideation and Behaviour Risk Monitoring</b>
853	If the trial meets any of the criteria requiring suicidal ideation and behaviour risk monitoring by
854	the guidance/guideline in each region, include any specific instructions for the collection and
855	interpretation of the assessment
856	[Suicidal Ideation and Behaviour Risk Monitoring]
857	<b>8.4 Adverse Events and Serious Adverse Events</b>
858	No text is intended here (header only).
859	<b>8.4.1 Definitions of AE and SAE</b>
860	Specify the AE and SAE definitions.
861	[AE definition]
862	[SAE definition]
863	Additional details and clarifications for AEs and SAEs are in Appendices 12.1 and 12.2.
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 mark as default for an Activity, and will then be pre-selected
  - Some ActivityInstances can be marked as mandatory – and cannot be un-selected
- Select what to display or hide in high-level Protocol SoA

## For Operational Data Specification

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

## For Data Collection Specification

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

OPEN STUDY BUILDER

Studies Library

SELECT STUDY ? NDJZ (NICOLAS DE SAINT JORRE)

Library / Concepts / Activities / Activities

### Activities

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

Select rows

Bill Library Activity group Activity subgroup Activity name

Library	Activity group	Activity subgroup	Activity name	Sentence case name	NCI Concept ID
Sponsor	<ul style="list-style-type: none"> <li>Laboratory Assessments</li> <li>AE Requiring Additional Data</li> <li>Laboratory Assessments</li> </ul>	<ul style="list-style-type: none"> <li>Biochemistry</li> <li>Laboratory Assessment</li> <li>Urinalysis</li> </ul>	<a href="#">Bilirubin</a>	bilirubin	
Sponsor	<ul style="list-style-type: none"> <li>Laboratory Assessments</li> <li>AE Requiring Additional Data</li> </ul>	<ul style="list-style-type: none"> <li>Biochemistry</li> <li>Laboratory Assessment</li> </ul>	<a href="#">Direct Bilirubin</a>	direct bilirubin	
Sponsor	<ul style="list-style-type: none"> <li>Eligibility Criteria</li> </ul>	<ul style="list-style-type: none"> <li>Eligibility Criteria</li> </ul>	<a href="#">Eligibility Criteria Met</a>	eligibility criteria met	
Sponsor	<ul style="list-style-type: none"> <li>Laboratory Assessments</li> <li>AE Requiring Additional Data</li> </ul>	<ul style="list-style-type: none"> <li>Biochemistry</li> <li>Laboratory Assessment</li> </ul>	<a href="#">Indirect Bilirubin</a>	indirect bilirubin	
Sponsor	<ul style="list-style-type: none"> <li>Clinical Outcome Assessments</li> </ul>	<ul style="list-style-type: none"> <li>PGI Change-Ability Things Need</li> </ul>	<a href="#">PGI Change-Ability Things Need</a>	pgi change-ability things need	

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

From Activity to Activity Instance

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	<b>BILIRUBIN_URINE</b>	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)

#	Epoch name	Epoch type	Epoch subtype	Start rule	End rule	Description	Number of visits	Assigned colour
1	Screening	Pre Treatment	Screening	ICF submitted	ICF signed	Screening epoch to start	1	Grey
2	Treatment	Treatment	Treatment	RDM ok	Dosing complete	Treatment epoch without dosing esca...	9	Light Blue
3	Follow-up	Post Treatment	Follow-up	Treatment ok	Last follow-up ok	Follow-up epoch to follow the subje...	1	Green

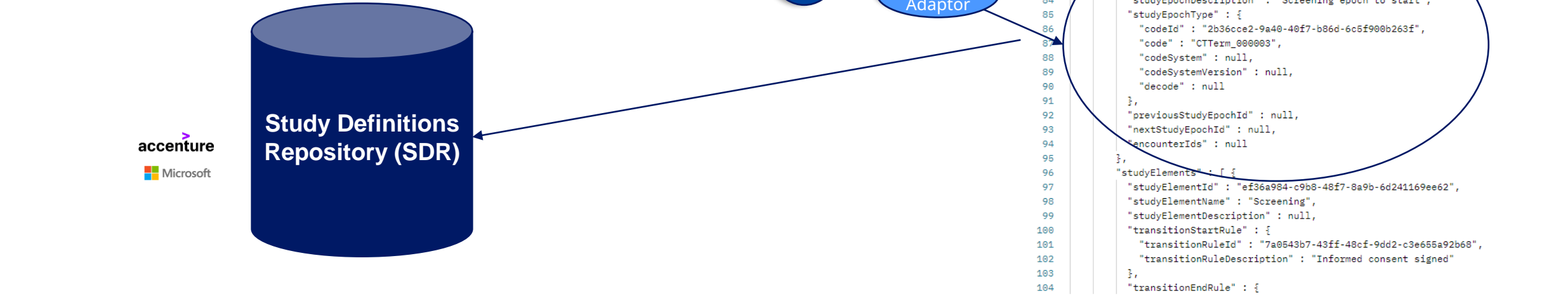
Body Cookies Headers (5) Test Results

```

73   "studyArmDataOriginType" : {
74     "codeId" : "b5d4d3e0-15db-4d8f-a1bb-b9ed8cb92d0e",
75     "code" : null,
76     "codeSystem" : null,
77     "codeSystemVersion" : null,
78     "decode" : null
79   },
80 },
81 "studyEpoch" : {
82   "studyEpochId" : "1660e455-ed05-42c0-9dcc-4045184fab83",
83   "studyEpochName" : "Screening",
84   "studyEpochDescription" : "Screening epoch to start",
85   "studyEpochType" : {
86     "codeId" : "2b36cce2-9a40-40f7-b86d-6c5f900b263f",
87     "code" : "CTTerm_000003",
88     "codeSystem" : null,
89     "codeSystemVersion" : null,
90     "decode" : null
91   },
92   "previousStudyEpochId" : null,
93   "nextStudyEpochId" : null,
94   "encounterIds" : null
95 },
96 "studyElements" : [ {
97   "studyElementId" : "ef36a984-c9b8-48f7-8a9b-6d241169ee62",
98   "studyElementName" : "Screening",
99   "studyElementDescription" : null,
100  "transitionStartRule" : {
101    "transitionRuleId" : "7a0543b7-43ff-48cf-9dd2-c3e65a92b68",
102    "transitionRuleDescription" : "Informed consent signed"
103  },
104  "transitionEndRule" : {
  
```

OSB API

DDF Adaptor





# From Activity to CRF and Define...

### StudyBuilder

**Weight**

Overview OSB YAML COSMOS YAML

Name: Weight

Sentence case name: weight

Status: Final

Definition: [ ]

Abbreviation: [ ]

Library: Sponsor

NCI Concept ID: [ ]

Data collection: Yes

Activity groupings: Activity group, Activity subgroup

Activity instances: [Table with columns: Name, Definition, Activity instance class, Topic code, ADaM parameter code]

**Body Weight**

Overview OSB YAML COSMOS YAML

Name: Body Weight

Sentence case name: body weight

Status: Final

Definition: [ ]

Activity instance class: Numeric Finding

Abbreviation: [ ]

Library: Sponsor

NCI Concept ID: [ ]

ADaM parameter code: WEIGHT

Required for activity: No

Data sharing: Yes

Activity groupings: Activity group, Activity subgroup

Activity items: [Table with columns: Item type, Name, Unit definition, CT term]

### Falcon

### StudyBuilder

**Body Measurements**

Body Measurements Itemgroup

Study ID: [ ]

Was the subject fasting when the body measurement was done? [ ]

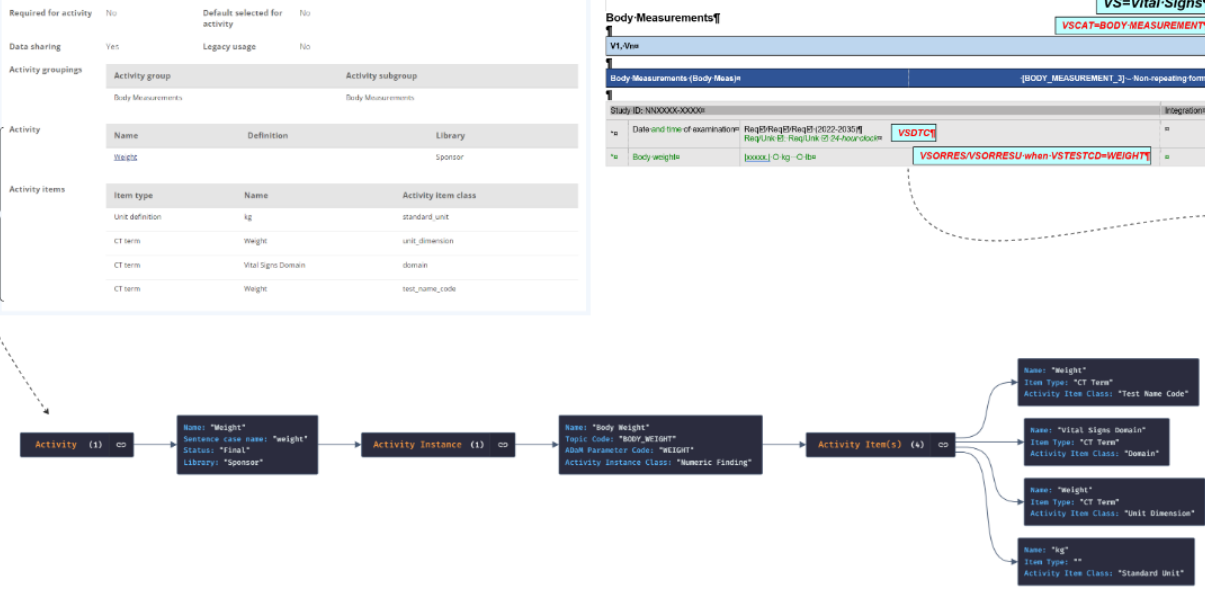
Height: [ ]

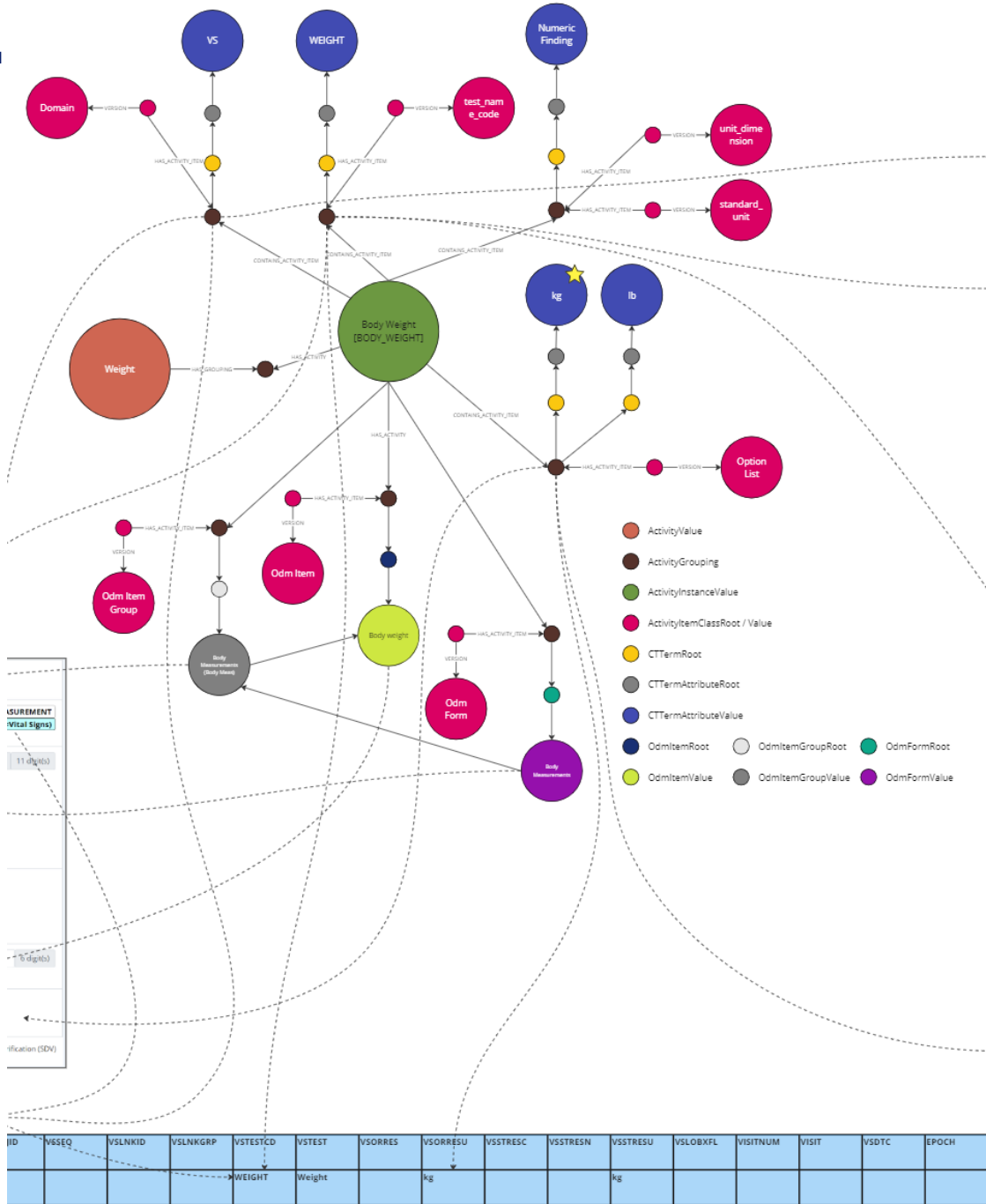
Body weight: [ ]

Block label are Mandatory (otherwise Green)

**vs.xpt (Dataset SDTMIG)**

STUDYID	DOMAIN	USUBJID	VSEQ
	VS		





Related Supplemental Qualifiers Dataset: SUPPYVS (Supplemental Qualifiers for VS)						
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) • "VS" = "Vital Signs"	Assigned (Source: Sponsor)
USUBJID		Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
VSSEQ		Sequence Number	integer	2		Derived (Source: Sponsor) Sequential number identifying records within each USUBJID in the domain.
VSTESTCD		Vital Signs Test Short Name	text	20	Vital Signs Test Code [7 Terms]	Assigned (Source: Sponsor)
VSTEST		Vital Signs Test Name	text	24	Vital Signs Test Name [7 Terms]	Collected (Source: Investigator) Annotated CRF [11] [9]
VSPOS		Vital Signs Position of Subject	text	7		Collected (Source: Investigator) Annotated CRF [11] [9]
VSORRES <i>VLM</i>		Result or Finding in Original Units	text	30		Collected (Source: Investigator) Annotated CRF [11] [9]
		<i>VSTESTCD</i> = "DIABP" (Diastolic Blood Pressure in Orig U)	Integer	2		Collected (Source: Investigator) Annotated CRF [11] [9]
		<i>VSTESTCD</i> = "FRMSIZE" (Body Frame Size - Orig)	text	6	Size • "SMALL" • "MEDIUM" • "LARGE"	Collected (Source: Investigator) Annotated CRF [11] [9]
		<i>VSTESTCD</i> = "HEIGHT" (Height)	float	5.1		Collected (Source: Investigator) Annotated CRF [11] [9]
		<i>VSTESTCD</i> = "PULSE" (Pulse Rate)	integer	2		Collected (Source: Investigator) Annotated CRF [11] [9]
		<i>VSTESTCD</i> = "SYSBP" (Systolic Blood Pressure in Orig U)	integer	3		Collected (Source: Investigator) Annotated CRF [11] [9]
		<i>VSTESTCD</i> = "WEIGHT" (Weight)	float	5.1		Collected (Source: Investigator) Annotated CRF [11] [9]
VSORRESU <i>VLM</i>		Original Units	text	20		Collected (Source: Investigator) Annotated CRF [11] [9]
		<i>VSTESTCD</i> = "HEIGHT" (Height) and <i>COUNTRY</i> IN ("CAN", "MEX")	Height: Original Units MC	text	5	Unit (UH_MC) • "cm" = "Centimeter" The data submitted only includes subjects in the USA since other sites did not enroll any subjects. 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.
		<i>VSTESTCD</i> = "HEIGHT" (Height) and <i>COUNTRY</i> = "USA"	Height: Original Units NMC	text	5	Unit (UH_NMC) • "IN" = "Inch" 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.
		<i>VSTESTCD</i> = "WEIGHT" (Weight) and <i>COUNTRY</i> IN ("CAN", "MEX")	Weight: Original Units MC	text	4	Unit (UW_MC) • "kg" = "Kilogram" The data submitted only includes subjects in the USA since other sites did not enroll any subjects. 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.
		<i>VSTESTCD</i> = "WEIGHT" (Weight) and <i>COUNTRY</i> = "USA"	Weight: Original Units NMC	text	4	Unit (UW_NMC) • "LB" = "Pound" 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.

ID	VSSEQ	VSLNKID	VSLNKGRP	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSTRESC	VSTRESN	VSTRESU	VSLOBXFL	VISITNUM	VISIT	VSDTC	EPOCH
				WEIGHT	Weight		kg			kg					

# 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

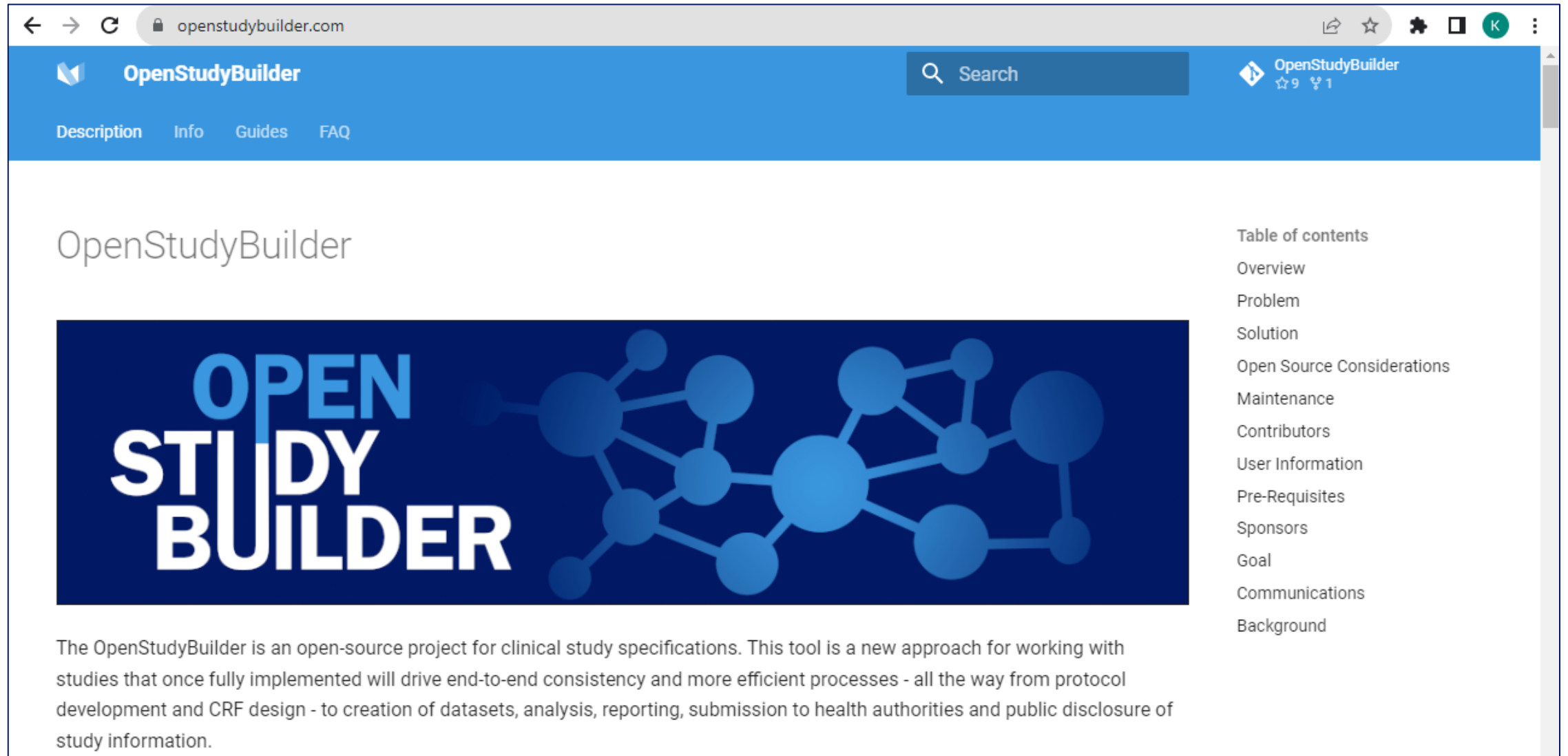


## From OpenStudyBuilder to the Digital Data Flow - USDM Format

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



# Project Homepage



The screenshot shows a web browser window with the URL [openstudybuilder.com](https://openstudybuilder.com). The page features a blue header with the OpenStudyBuilder logo, a search bar, and navigation links for Description, Info, Guides, and FAQ. The main content area includes the title "OpenStudyBuilder", a large blue banner with the project logo and a network diagram, and a paragraph describing the project as an open-source tool for clinical study specifications. A table of contents is listed on the right side of the page.

OpenStudyBuilder

**OPEN  
STUDY  
BUILDER**

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.

Table of contents

- Overview
- Problem
- Solution
- Open Source Considerations
- Maintenance
- Contributors
- User Information
- Pre-Requisites
- Sponsors
- Goal
- Communications
- Background

<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, you mail might be exposed in the version history



**Thanks!**  
Questions?

**OPEN**  
**STUDY**  
**BUILDER**

