

Use OpenStudyBuilder to drive EDC setup - a COSA Workshop

OPEN
STUDY
BUILDER



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08:45 - 09:00 Coffee and welcome
09:00 - 10:30 Introductions
11:00 - 13:30 Discussion & Lunch
13:30 - 14:00 Summary and Closing

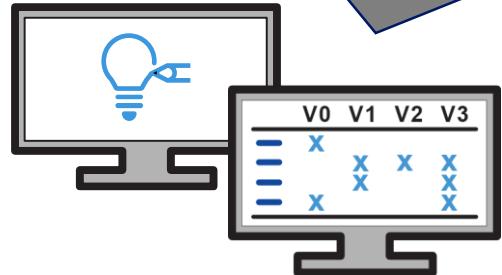
Agenda

Introduction



ONE study journey

Protocol and study specification becomes **digital**



conceive, plan & design study

EDC setup must be **automated** with reference to **standards** and **BCs**



plan & manage supply

Data Flow from EDC must be **automated** with reference to **standards** and **BCs**



run study, collect & review data
monitor sites

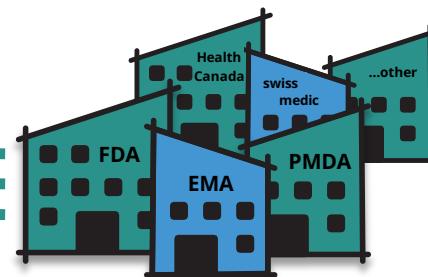
Synthetic test data will support integrations and analysis preparations



analyse & report study data

BCs will enable cross study usage independent of standards

An efficient and scalable study journey connected by **one digital data flow** and simplified by **one common data model^s**



consolidate results across studies, create & submit regulatory application

Introductions

Who are we today?

What brought you here?

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

What is the OpenStudyBuilder?...

A NEW APPROACH TO STUDY SPECIFICATION

- Compliance with external and internal standards
- Facilitates automation and content reuse
- Ensures a higher degree of end-to-end consistency

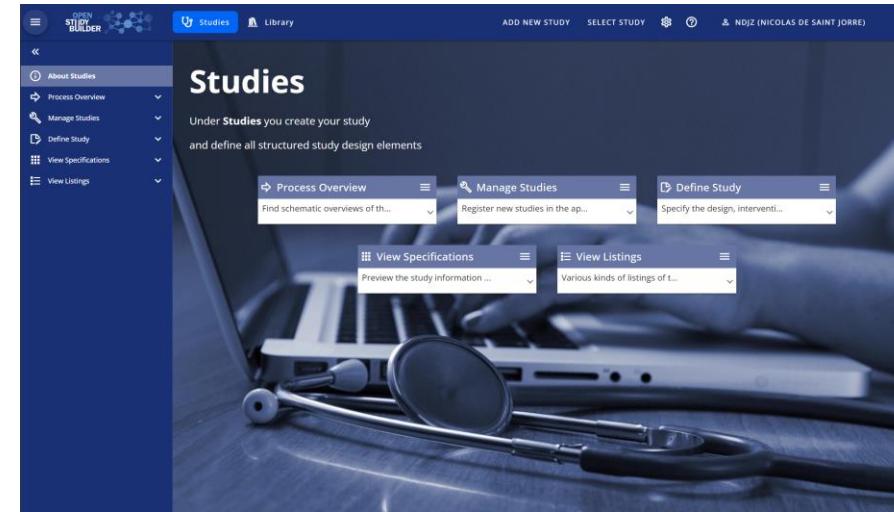
3 ELEMENTS OF OpenStudyBuilder

- **Clinical Metadata and Study Definition Repository**
(central repository for all study specification data)
- **OpenStudyBuilder application / Web UI**
- **API layer**
(allowing interoperability with other applications)
(DDF API Adaptor – enabling DDF SDR Compatibility)

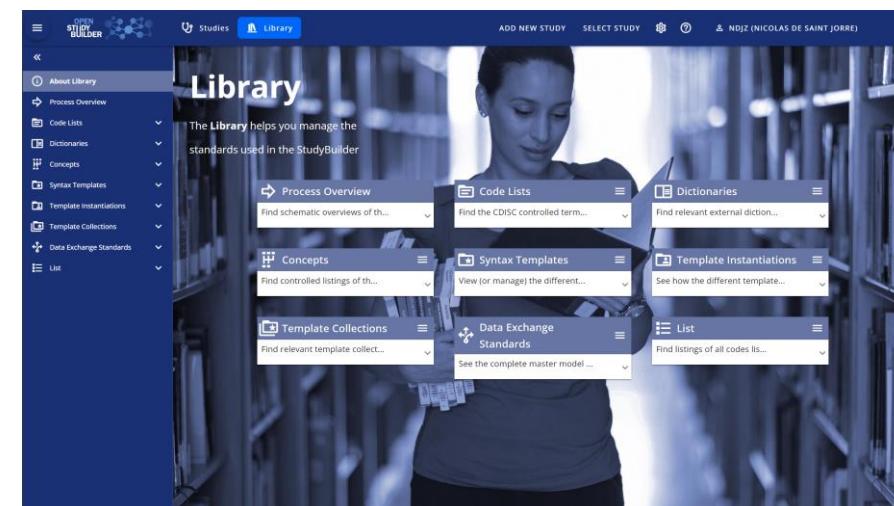


OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES



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

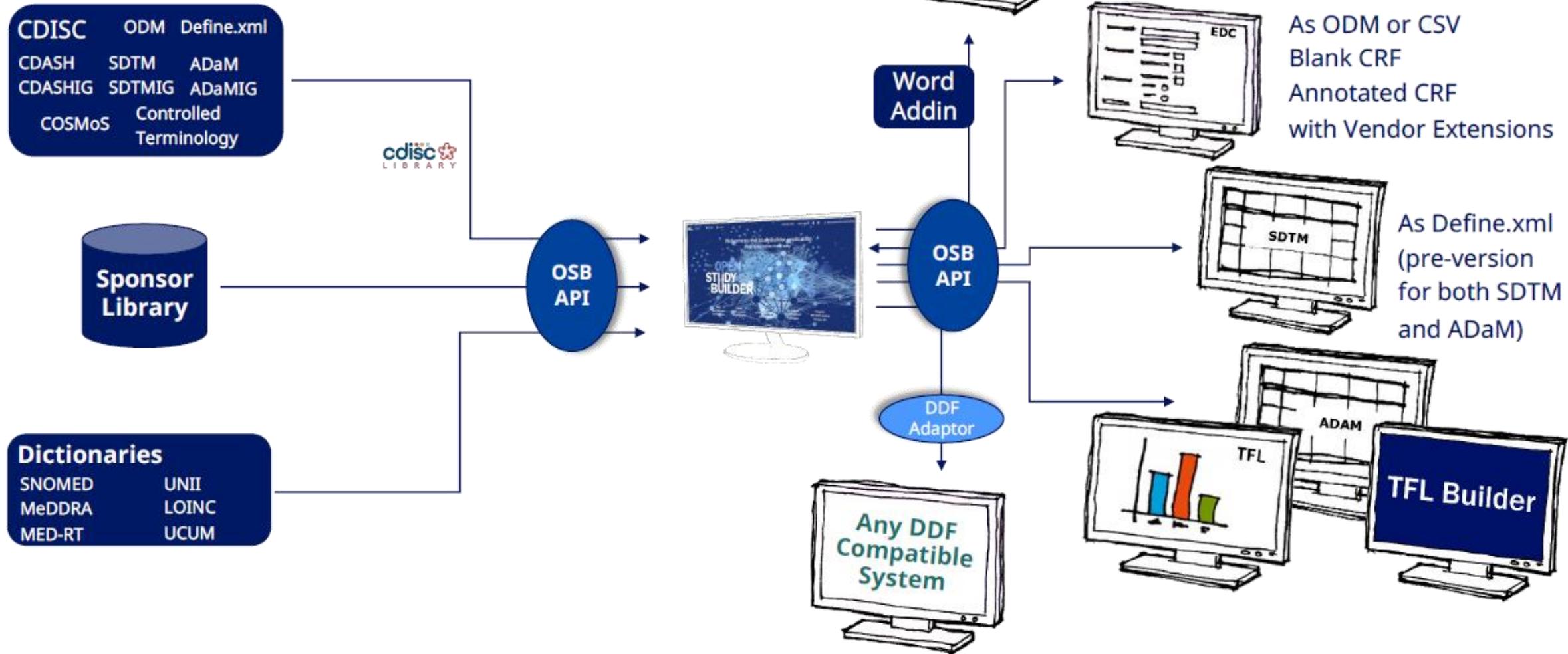


Goal of OpenStudyBuilder

Metadata driven
End-2-End Automation!



Connectivity is key!

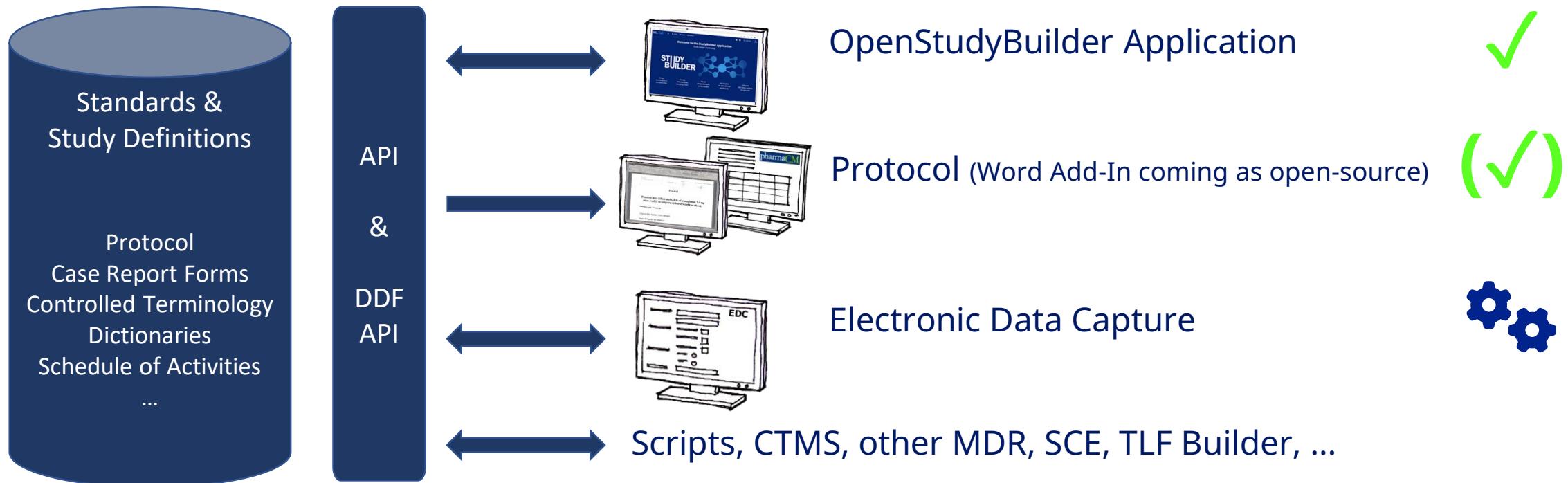


Connectivity is key! - USDM Representation

The screenshot shows the Open Study Builder application interface. The top navigation bar includes links for 'OPEN STUDY BUILDER' (with a network icon), 'Studies' (highlighted in blue), 'Library', 'Reports', 'SELECT STUDY' (set to 'CDISC DEV-0'), and user options ('ANONYMOUS'). The left sidebar has a tree view with nodes like 'About Studies', 'Process Overview', 'Study List', 'Manage Study', 'Define Study', 'View Specifications' (selected), 'Protocol Elements', 'SDTM Study Design Datasets', 'USDM' (selected), and 'View Listings'. The main content area displays the 'USDM version of the Protocol' with a download icon. Below it is a JSON representation of the protocol specification:

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

Connectivity is key!



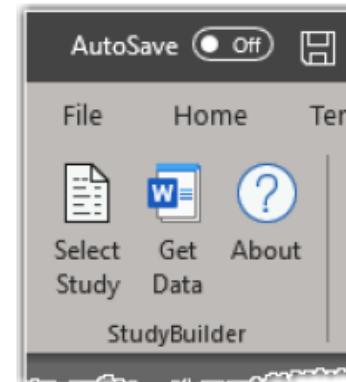
Protocol Generation



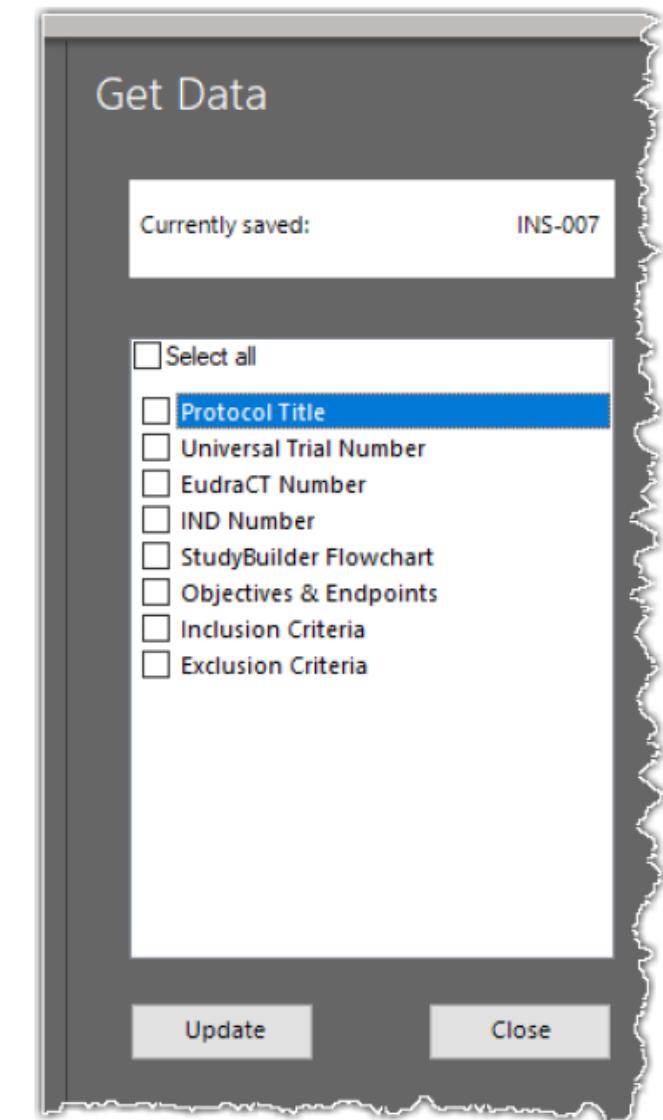
StudyBuilder ribbon (Word add-in)

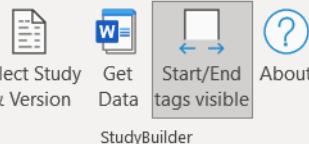
✓ One-way connection

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

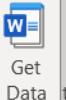


Protocol





Select Study & Version



StudyBuilder

Protocol
Study ID: CDISC DEV-0Date:
Version:

30 September 2022

Status:
0.1Draft
9 of 75

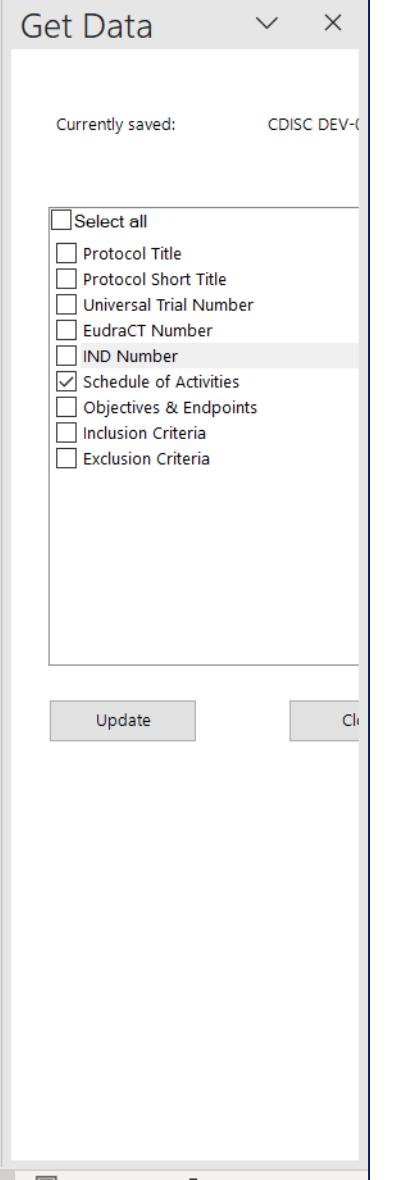
Novo Nordisk

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											
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												



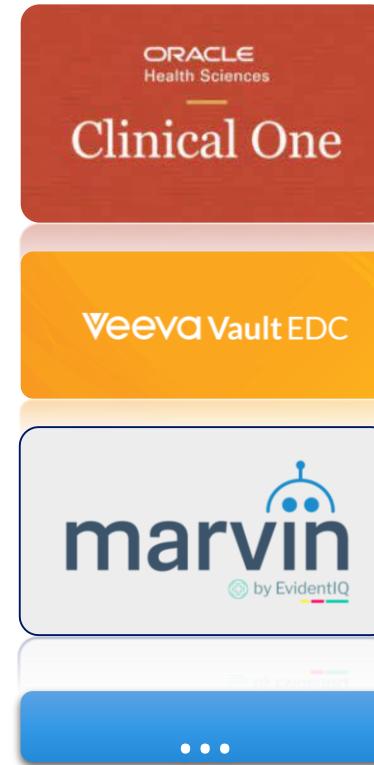
CRF Standards & Metadata

Manage
Standard & Study CRF

The screenshot shows the 'CRFs (Case Report Forms)' section of the Open Study Builder application. The left sidebar includes options like 'About Library', 'Process Overview', 'Code Lists', 'Dictionaries', 'Concepts', 'Activities', 'Units', 'CRFs' (selected), 'Compounds', 'Syntax Templates', 'Template Instantiations', 'Template Collections', and 'Data Exchange Standards'. The main panel displays a template titled 'Template NN' under the heading 'Annotated CRF'. It contains sections for 'Informed Consent and Demography' and 'Informed Consent item group'. A note at the bottom of the first section states: 'Although this field is not typically centered 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.' Buttons for 'DM (Demographics Domain)' and 'DS (Disposition Domain)' are visible.



EDC Setup, Test,
Execution



Including rules, checks
Support vendor extensions

Finetuning, Layout

OpenStudyBuilder to drive EDC setup

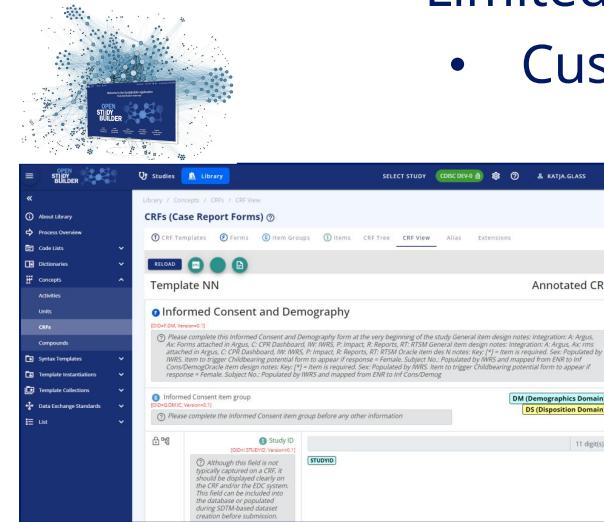
A COSA Workshop



Problem Statement

Data Exchange Formats

- CDASH
- ODM.XML
- USDM
- Biomedical Concepts



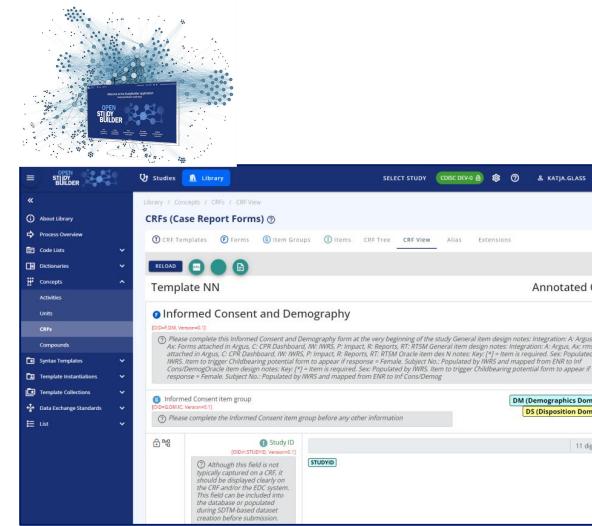
Implementation

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



Workshop Focus

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



Opportunities – OpenStudyBuilder to EDC

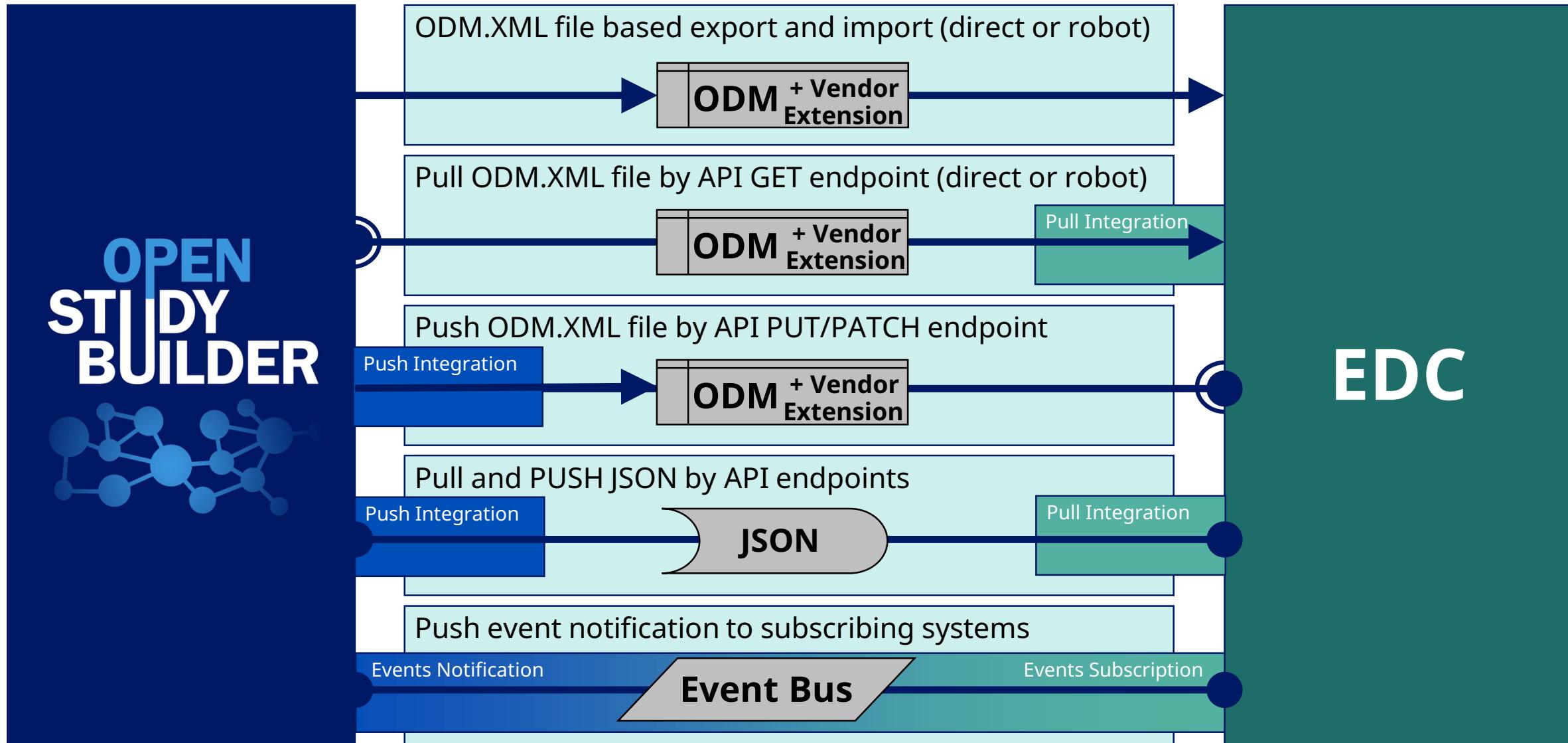
Selection and Configuration of Standard Library Forms

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

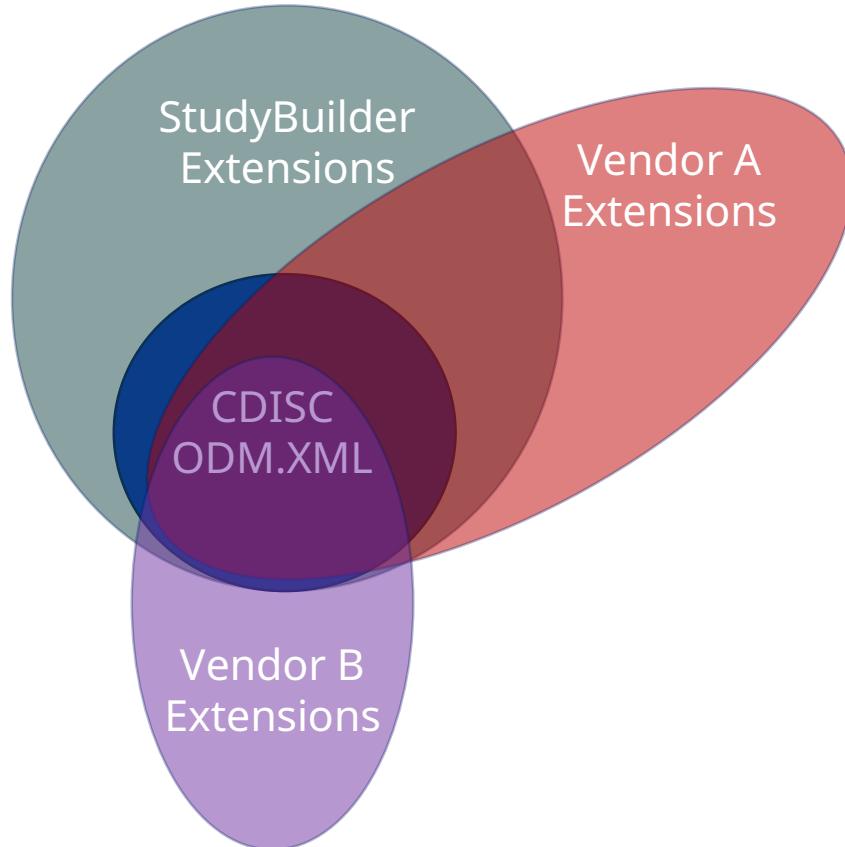
Dynamic build of Study Specific Forms

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

OpenStudyBuilder to EDC Options



Scope of ODM Vendor Extensions



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

Use Cases for EDC Integrations

1

Sharing OpenStudyBuilder and EDC Library forms

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

3

Making study specific forms in StudyBuilder linked to study SoA

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

2

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

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

4

Support import and operational setup of study specific forms

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

CRF for EDC Status



«

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

Library / Concepts / CRFs / CRF View

CRFs (Case Report Forms)

(T) CRF Templates (F) Forms (G) Item Groups (I) Items (CRF Tree) **CRF View** Alias Extensions

Template 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/Demog Oracle item design notes: Key: [*] = Item is required. Sex: Populated by IWRs. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRs and mapped from ENR to Inf Cons/Demog

G Informed Consent item group

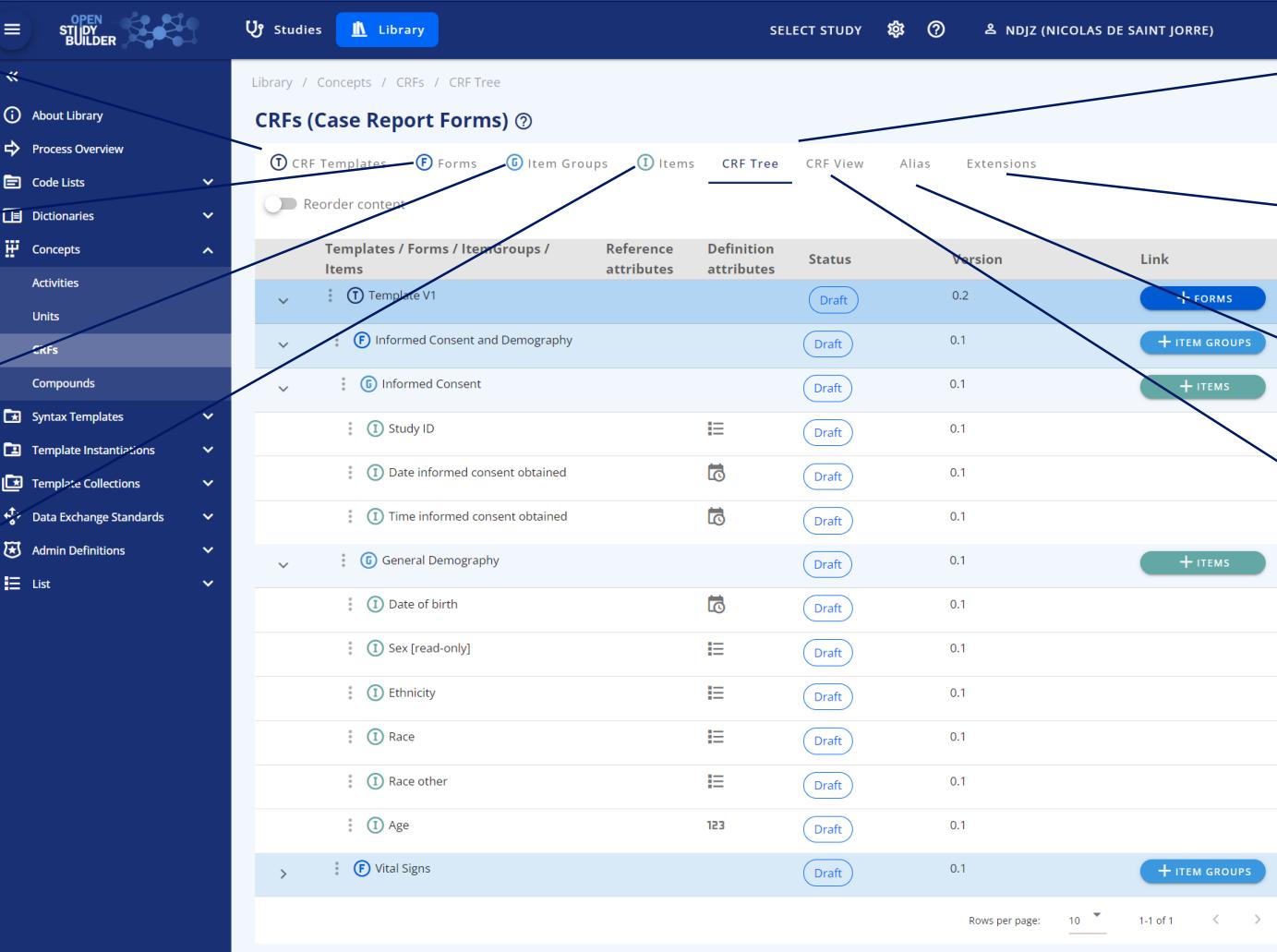
Please complete the Informed Consent item group before any other information

	Study ID 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.	STUDYID jj/mm/aaaa RFICDTC DSSTDTC --:-- RFICDTC DSSTDTC
	Date informed consent obtained This will be the same information on informed consent used in the SDTM Disposition domain	jj/mm/aaaa RFICDTC DSSTDTC
	Time informed consent obtained This will be the same information on informed consent used in the SDTM Disposition domain	--:-- RFICDTC DSSTDTC
	General Demographic item group Please complete this General Demographic item group at the very beginning of the study	jj/mm/aaaa BRTHDTC SEX
	Date of birth If collected, please provide the most complete Date of birth	jj/mm/aaaa BRTHDTC
	Sex [read-only] Female [F] Male [M]	SEX

eCRF API endpoints

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

CRF Specification in the Library



The screenshot shows the 'CRFs (Case Report Forms)' section of the library. The left sidebar has sections for Study Events, Forms, ItemGroups, and Items, each with a corresponding callout box. The main area displays a table of CRF templates, forms, item groups, and items. The table columns include Reference attributes, Definition attributes, Status, Version, and Link. Buttons for 'FORMS', '+ ITEM GROUPS', and '+ ITEMS' are visible.

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:

- Study Events**: Points to the 'Study Events' section in the sidebar.
- Forms**: Points to the 'Forms' section in the sidebar.
- ItemGroups**: Points to the 'ItemGroups' section in the sidebar.
- Items**: Points to the 'Items' section in the sidebar.
- eCRF specs**: Points to the 'Link' column in the table.
- Vendor Extensions**: Points to the '+ ITEM GROUPS' button.
- Alias**: Points to the '+ ITEMS' button.
- eCRF views**: Points to the '+ ITEMS' button.

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 x₂ x² ≡ ≡
Vital signs form

OID
F.VS

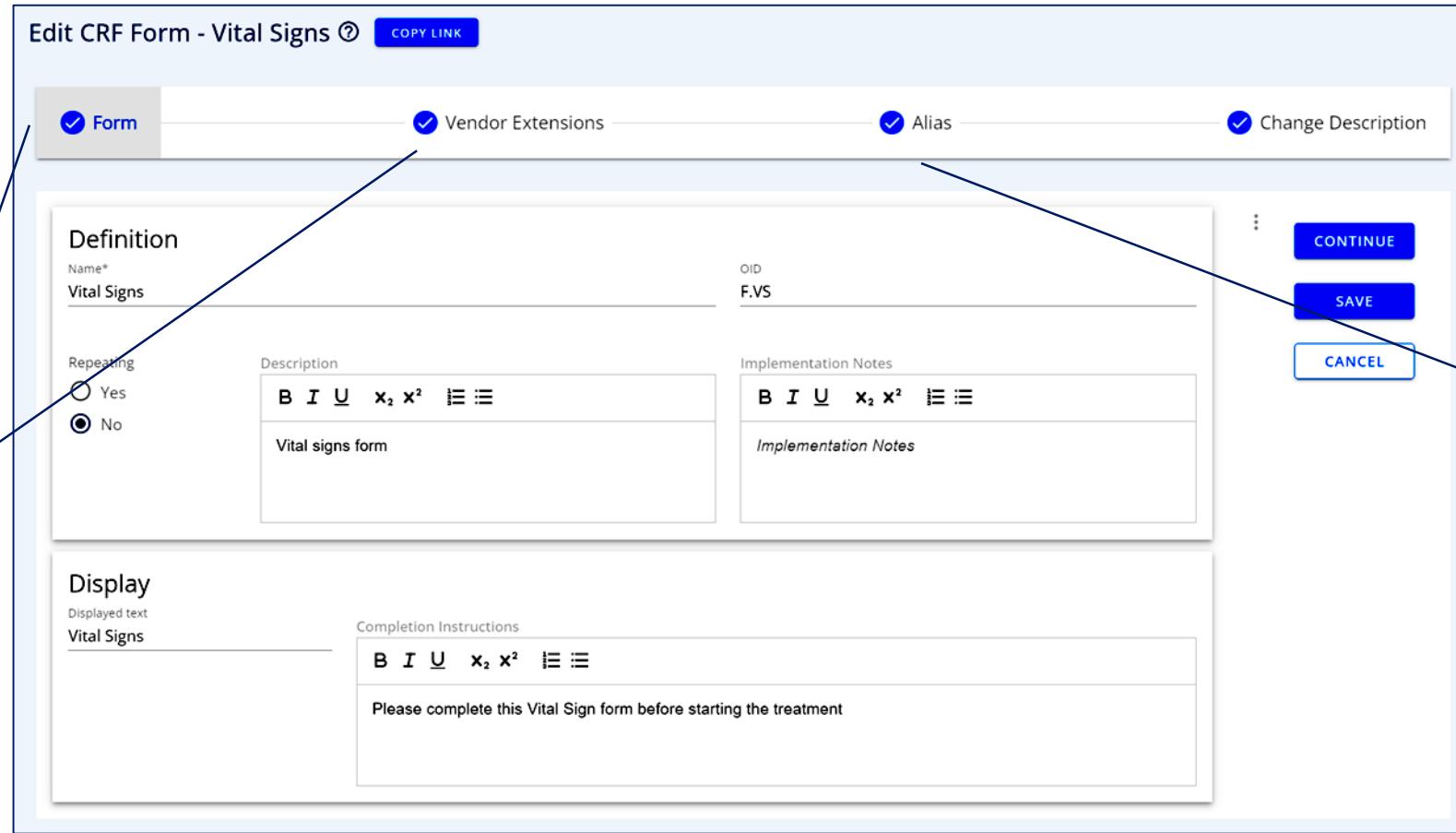
Implementation Notes
B I U x₂ x² ≡ ≡
Implementation Notes

Display

Displayed text
Vital Signs

Completion Instructions
B I U x₂ x² ≡ ≡
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 x₂ x² ≡ ≡
Vital signs

Implementation Notes
B I U x₂ x² ≡ ≡
Implementation Notes

Display

Displayed text
Vital Signs

Completion Instructions
B I U x₂ x² ≡ ≡
Please complete the Vital Signs item group at each expected time point

Annotations and reporting

Domain
Vital Signs Domain

SAS Dataset Name

Is Referential Data
 Yes
 No

Origin
Collected Value

Purpose
Tabulation

Comment

⋮ CONTINUE SAVE CANCEL

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

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

Item Code list Code list subset Vendor Extensions Alias Change Description

Definition

Name*
Sex [read-only]

OID
ISEX

Data Type*
STRING

Length

Description
B I U x₂ x² ≡ ≡

Implementation Notes
B I U x₂ x² ≡ ≡

Implementation Notes

Display

Displayed text
Sex [read-only]

Completion Instructions
B I U x₂ x² ≡ ≡

Completion Instructions

Annotations and reporting

SAS Field Name
SEX

SDS Var Name
SEX

Origin
Collected Value

Comment

⋮ [CONTINUE](#) [SAVE](#) [CANCEL](#)

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

Edit Item - Sex [read-only] ⚭ COPY LINK

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

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

Rows per page: 10 | 1-1 of 1 | < > | **SAVE** | **CANCEL**

Search Search with terms Operator: or

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

Edit Item - Sex [read-only] ⚭ COPY LINK

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

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

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

Search

Concept ID	Name
C45908_UNDIFFERENTIATED	Intersex
C17998_U	Unknown

Vendor Extensions

The screenshot illustrates the process of creating a new attribute within a CRF Item Group. A modal window titled "New Attribute" is open, showing the attribute name "RMax" and data type "INTEGER". Below these fields is a section for "Compatible Types" which includes "FormDef, ItemGroupDef" and other options like "FormItemDef", "ItemGroupRef", and "ItemRef". The "ItemGroupDef" checkbox is selected. The "Vendor Extensions" tab is highlighted in the main interface, indicating the context of the operation.

Edit CRF Item Group - Vital Signs ⚭ COPY LINK

Item Group Vendor Extensions Alias Change Description

Namespace Parent Name Type Data Type Value

OpenStudyBuilder	OpenStudyBuilder	RMax	Attribute	INTEGER	Value 10
------------------	------------------	------	-----------	---------	-------------

CONTINUE SAVE CANCEL PREVIOUS

Search Filtering currently not activated

Name	Namespace	Data Type
displayAsTable	OpenStudyBuilder	string
RMax	OpenStudyBuilder	INTEGER

Concept: CRFs

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

Request body

multipart/form-data

Try it out

Status of the metadata

PDF or CSV

Stylesheet ref.

API Endpoints to work with the SoAs...

Studies

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

Schedule of Activities and Biomedical Concepts...



Biomedical Concepts?!

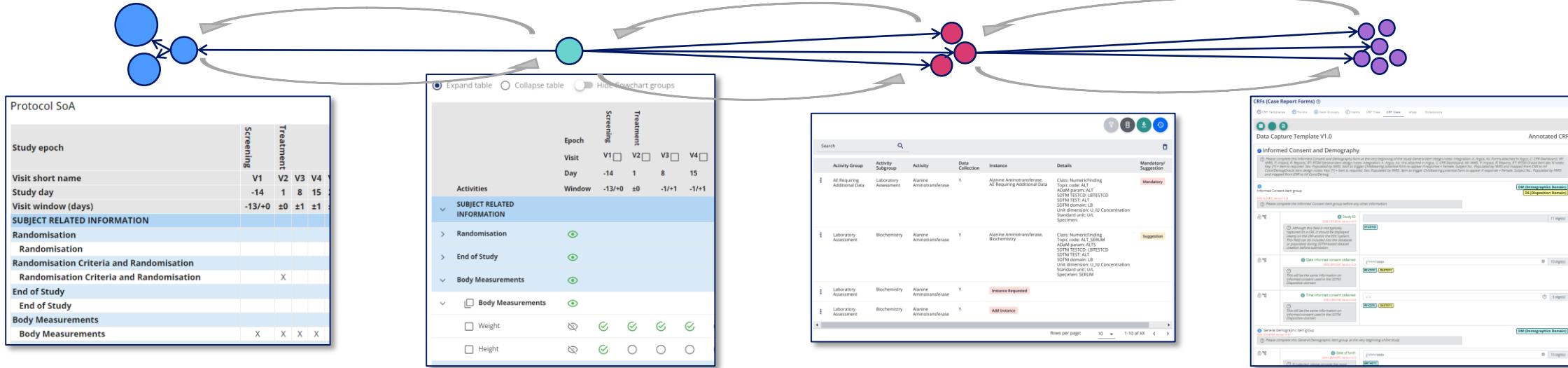


TransCelerate
BIOPHARMA INC.
Accelerating Answers.

Supporting Automation of Case Report Forms Using Biomedical Concepts

0:08 / 3:45

Schedule of Activities (SoA) at multiple levels



Protocol SoA

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

Detailed SoA

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

Operational SoA

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

Data Capture / Collection Specification

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

Detailed SoA

Study Structure (CDISC DEV-0) ⓘ

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

Study Visits

Time line preview

Screening Treatment Follow-up

0 2

Select rows Preferred time unit: Day Week

+ 🖊️ 🔍 ⏷ ⏵ ⏴ ⏵

Epoch	Visit type	Visit Class	Visit name	Anchor visit in visit group	Visit group
⋮ Screening	Screening	Single visit	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	Q				
#	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	

<

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

> SAFETY

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

Protocol and Operational SoA

Study Activities (CDISC DEV-0001) ②

Study Activities Schedule of Activities

DETAILED PROTOCOL OPERATIONAL

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

Produce a copy of
the SoA compatible
with Word

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

Selection process of Activities for SoA

For Protocol Outline / Protocol

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

For Operational Data Specification

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

For Data Collection Specification

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

From Activity to Activity Instance

The diagram illustrates the process of creating an activity instance from a general activity definition. A blue arrow points from the 'Activities' page on the left to the 'Bilirubin' activity instance page on the right.

Activities Page (Left):

- Header:** OPEN STUDY BUILDER, Studies, Library (highlighted), Reports, SELECT STUDY (CDISC DEV-0001), ANONYMOUS.
- Left Sidebar:** About Library, Process Overview, Code Lists, Dictionaries, Concepts (selected), Activities, Units, CRFs, Syntax Templates, Template Instantiations, Template Collections, Data Exchange Standards, Admin Definitions, List.
- Content:** Activities tab selected. Search bar: Bili. Filter: Select rows. Buttons: +, ⌂, ⌂, ⌂, ⌂, ⌂.
- Table:**| | Library | Activity group | Activity subgroup | Activity name | Sentence case name | NCI Concept ID |
| --- | --- | --- | --- | --- | --- | --- |
| ⋮ | Sponsor | • AE Requiring Additional Data | • Laboratory Assessment | Direct Bilirubin | direct bilirubin | |
| ⋮ | Sponsor | • Laboratory Assessments • AE Requiring Additional Data • Laboratory Assessments | • Biochemistry • Laboratory Assessment • Urinalysis | Bilirubin | bilirubin | |
| ⋮ | Sponsor | • AE Requiring Additional Data | • Laboratory Assessment | Indirect Bilirubin | indirect bilirubin | |
| ⋮ | Sponsor | • Eligibility Criteria | • Eligibility Criteria | Eligibility Criteria Met | eligibility criteria met | |
| ⋮ | Sponsor | • Laboratory Assessments • Laboratory Assessments • Laboratory Assessments | • Urinalysis • Urinalysis - Urine Dipstick • Urine Dipstick | Urobilinogen | urobilinogen | |
| ⋮ | Sponsor | • Eligibility Criteria | • Subgroup 41 updated | Sponsor Activity 147 | sponsor activity 147 | |
| ⋮ | Sponsor | • Eligibility Criteria | • Eligibility Criteria | Sponsor Activity | sponsor activity 177 | |

Rows per page: 10 | 1-10 of 11 | < < > >>

Bilirubin Activity Instance Page (Right):

 - Header:** Library / Concepts / Activities / Activities / Bilirubin.
 - Buttons:** Overview (highlighted), OSB YAML, COSMoS YAML.
 - Information:**
 - Name: Bilirubin
 - Sentence case name: bilirubin
 - Version: 1.0, Status: Final
 - Start date: Oct 10, 2024, 7:02 PM
 - End date: None
 - Definition: (empty)
 - Abbreviation: (empty)
 - Library: Sponsor
 - NCI Concept ID: (empty)
 - Data collection: Yes
 - Activity groupings:
 - Activity group: (empty)
 - Activity subgroup: (empty)
 - AE Requiring Additional Data: Laboratory Assessment
 - Laboratory Assessments: Urinalysis
 - Laboratory Assessments: Biochemistry - Activity instances:

Name	Definition	Version	Status	Activity instance class	Topic code	AdaM parameter code
Bilirubin_Urine		1.0	Final	CategoricFinding	BILIRUBIN_URINE	BILIU2
Bilirubin_Urine		0.1	Draft	CategoricFinding	BILIRUBIN_URINE	BILIU2
Bilirubin_AE Requiring Additional Data		1.0	Final	NumericFinding	BILI	BILI
Bilirubin_AE Requiring Additional Data		0.1	Draft	NumericFinding	BILI	BILI
Bilirubin_Biochemistry		1.0	Final	NumericFinding	BILIRUBIN_SERUM	BILIS3

Library / Concepts / Activities / Activities / Bilirubin

Bilirubin ?

Overview OSB YAML COSMoS YAML

Name	Bilirubin						
Sentence case name	bilirubin						
Version	1.0	Status	Final				
Start date	Oct 10, 2024, 7:02 PM	End date	None				
Definition							
Abbreviation							
Library	Sponsor						
NCI Concept ID							
Data collection	Yes						
Activity groupings	Activity group		Activity subgroup				
	AE Requiring Additional Data		Laboratory Assessment				
	Laboratory Assessments		Urinalysis				
	Laboratory Assessments		Biochemistry				
Activity instances	Name	Definition	Version	Status	Activity instance class	Topic code	ADaM parameter code
	Bilirubin Urine		1.0	Final	CategoricFinding	BILIRUBIN_URINE	BILIU2
	Bilirubin Urine		0.1	Draft	CategoricFinding	BILIRUBIN_URINE	BILIU2
	Bilirubin_AE Requiring Additional Data		1.0	Final	NumericFinding	BILI	BILI
	Bilirubin_AE Requiring Additional Data		0.1	Draft	NumericFinding	BILI	BILI
	Bilirubin_Biochemistry		1.0	Final	NumericFinding	BILIRUBIN_SERUM	BILIS3

Library / Concepts / Activities / Activities Instances / Bilirubin Urine

Bilirubin Urine ?

Overview OSB YAML COSMoS YAML

Name	Bilirubin Urine					
Sentence case name	bilirubin urine					
Version	1.0	Status	Final			
Start date	Oct 10, 2024, 7:04 PM	End date	None			
Definition						
Activity instance class	CategoricFinding					
Abbreviation	Library		Sponsor			
NCI Concept ID						
ADaM parameter code	BILIU2	Topic code	BILIRUBIN_URINE			
Required for activity	No	Default selected for activity	No			
Data sharing	Yes	Legacy usage	No			
Activity groupings	Activity group		Activity subgroup			
	Laboratory Assessments		Urinalysis			
Activity	Name	Definition	Version	Status	Library	
	Bilirubin			1.0	Final	Sponsor
Activity items	Item type	Name		Activity item class		
	CT term	Urine		specimen		
	CT term	Total Bilirubin Measurement		test_name		
	CT term	Laboratory Data Domain		domain		
	CT term	Total Bilirubin Measurement		test_code		

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

Operational SoA – part of Data Specification

OPEN STUDY BUILDER

studies Library Reports

SELECT STUDY CDISC DEV-0 ANONYMOUS

Studies / Define Study / Data Specifications / Study Activity Instances

Study Data Specifications (CDISC DEV-0)

Study Activity Instances Operational SoA

Search Select rows

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

No action needed Notification Action needed

Rows per page 10 1-10 of 32 < < > >

neo4j Labs <neo4j+s://vm-db-fv7zbjhkehgyw.clinicalmdr-dev.corp.azure.novonordisk.com:7687>

StudyBuilder to Veeva SDS Specification

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

Report name...

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

1-27 of 37

Mapping a Veeva SDS specification to ODM-XML



The banner features the phuse·connect logo with the tagline "connect.share.advance". The main title "EU 2024" is prominently displayed in large white letters. Below it, the dates "10-13 November" and the location "Strasbourg Convention Centre" are listed. To the right, there is an illustration of the Strasbourg Cathedral and a text box identifying it as such.

phuse·connect
connect.share.advance

EU 2024

10-13 November
Strasbourg Convention Centre

Strasbourg Cathedral

SI04 – Monday 10th November – 13:30 – 14:00

Paper & Presentation will be available afterwards

Activity – CRF Linkage



Status of the OpenStudyBuilder

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

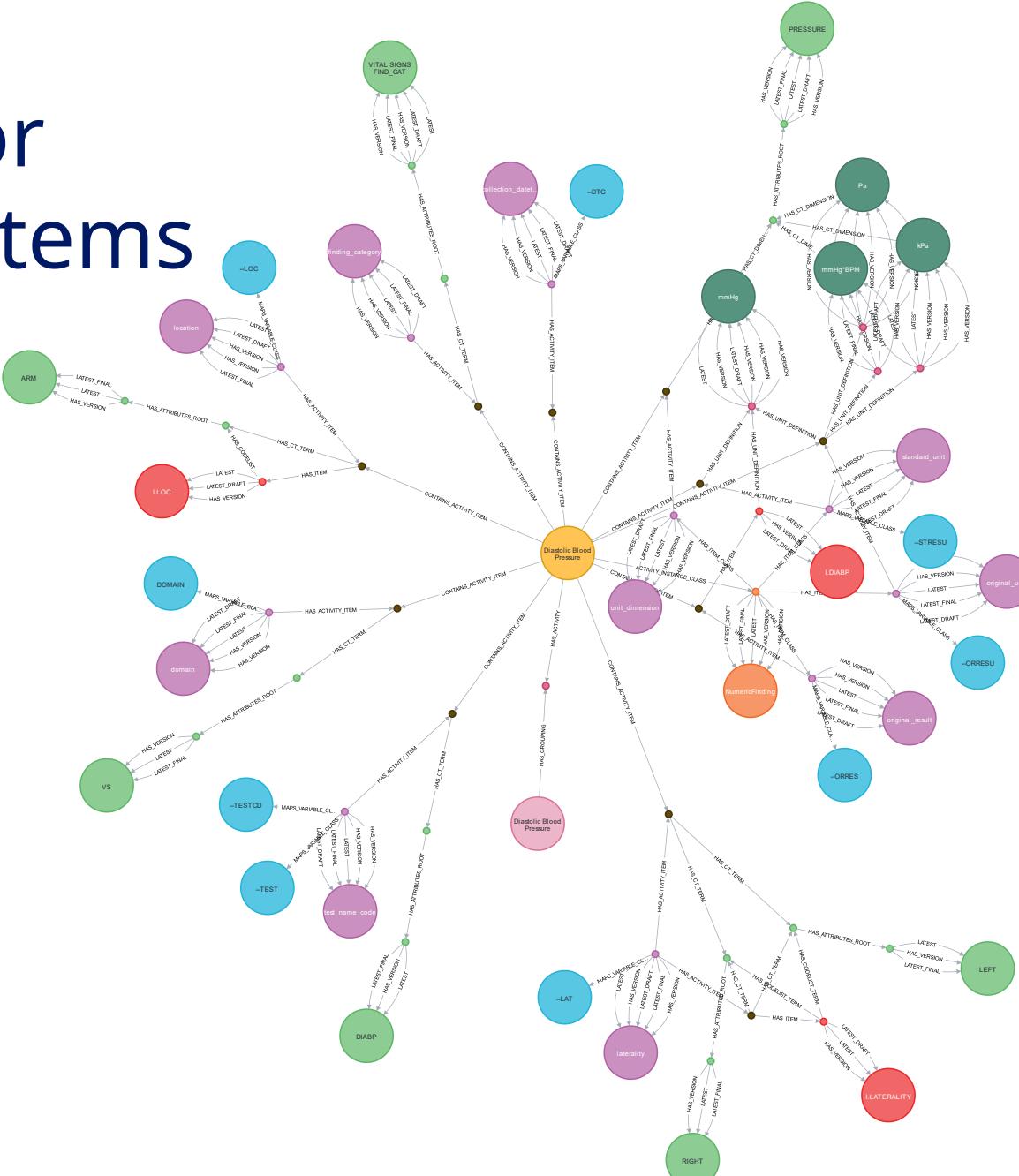
Mapping plan for Activity Items

Node labels

* (80)	ActivityValue (1)	ConceptValue (9)
TemplateParameterTermValue (6)	VariableClass (9)	
ActivityInstanceClassRoot (1)		
ActivityInstanceClassValue (1)		
ActivityItemClassRoot (10)	ActivityItemClassValue (10)	
ConceptRoot (7)	OdmitemRoot (3)	ActivityItem (11)
ActivityGrouping (1)	OdmitemValue (3)	
ActivityInstanceValue (1)		
TemplateParameterTermRoot (4)	UnitDefinitionRoot (4)	
UnitDefinitionValue (4)	CTTermRoot (7)	
CTTermAttributesRoot (7)	CTTermAttributesValue (7)	

Relationship types

* (181)	HAS_ITEM (3)	HAS_GROUPING (1)
HAS_VERSION (48)	LATEST (25)	
LATEST_FINAL (19)	LATEST_DRAFT (20)	
HAS_ITEM_CLASS (4)	HAS_ACTIVITY_ITEM (11)	
MAPS_VARIABLE_CLASS (9)		
HAS_UNIT_DEFINITION (6)	HAS_CODELIST_TERM (3)	
HAS_CT_TERM (9)	CONTAINS_ACTIVITY_ITEM (10)	
HAS_ACTIVITY (1)	ACTIVITY_INSTANCE_CLASS (1)	
HAS_CT_DIMENSION (4)	HAS_ATTRIBUTES_ROOT (7)	



Questions to discuss

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



Vendor Experiences & Views

