

Use OpenStudyBuilder to drive EDC setup - a COSA Workshop



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& Collaborators

08:45 – 09:00 Coffee and welcome

09:00 – 11:00 Shared Introduction

11:00 – 12:00 Break-out part 1

12:00 – 13:00 Lunch

13:00 – 14:00 Break-out part 2

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

Agenda

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

Agenda

Introduction



What is the OpenStudyBuilder?...

A NEW APPROACH TO STUDY SPECIFICATION

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

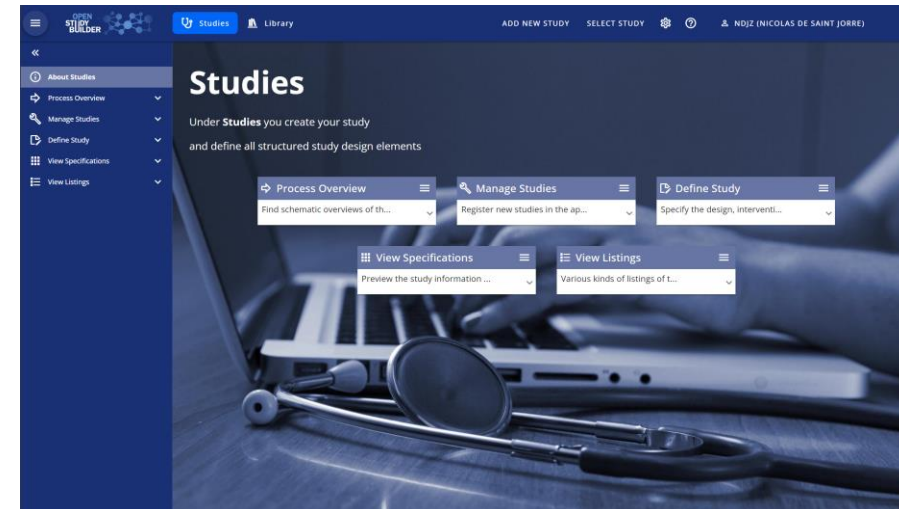
3 ELEMENTS OF OpenStudyBuilder

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

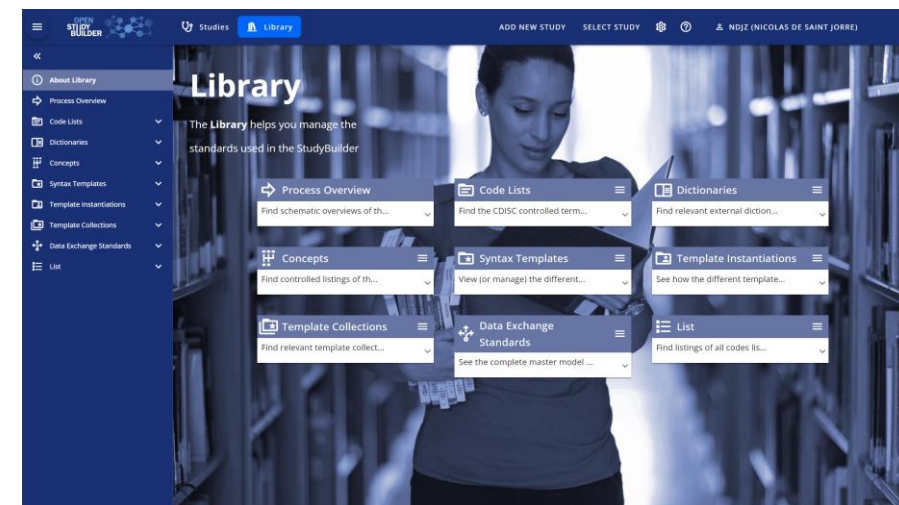


OpenStudyBuilder Components

STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



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

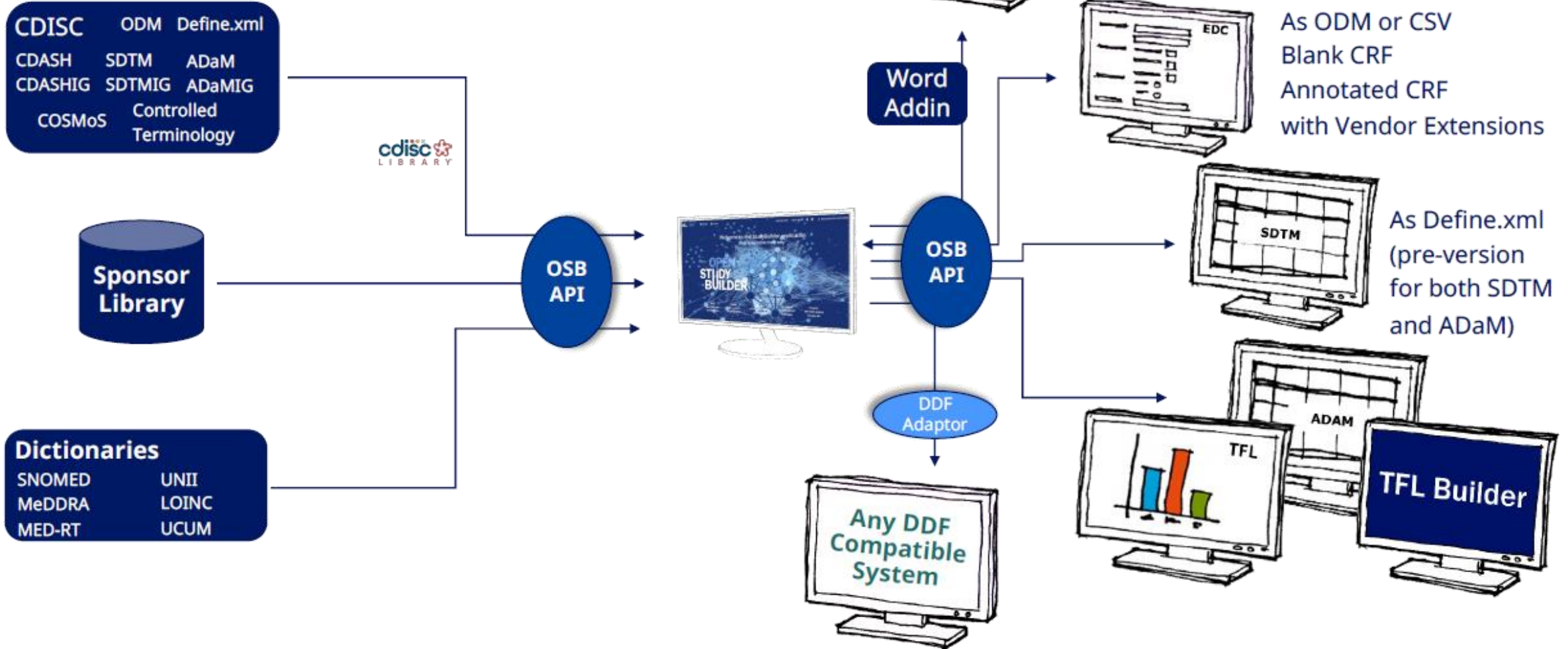


Goal of OpenStudyBuilder

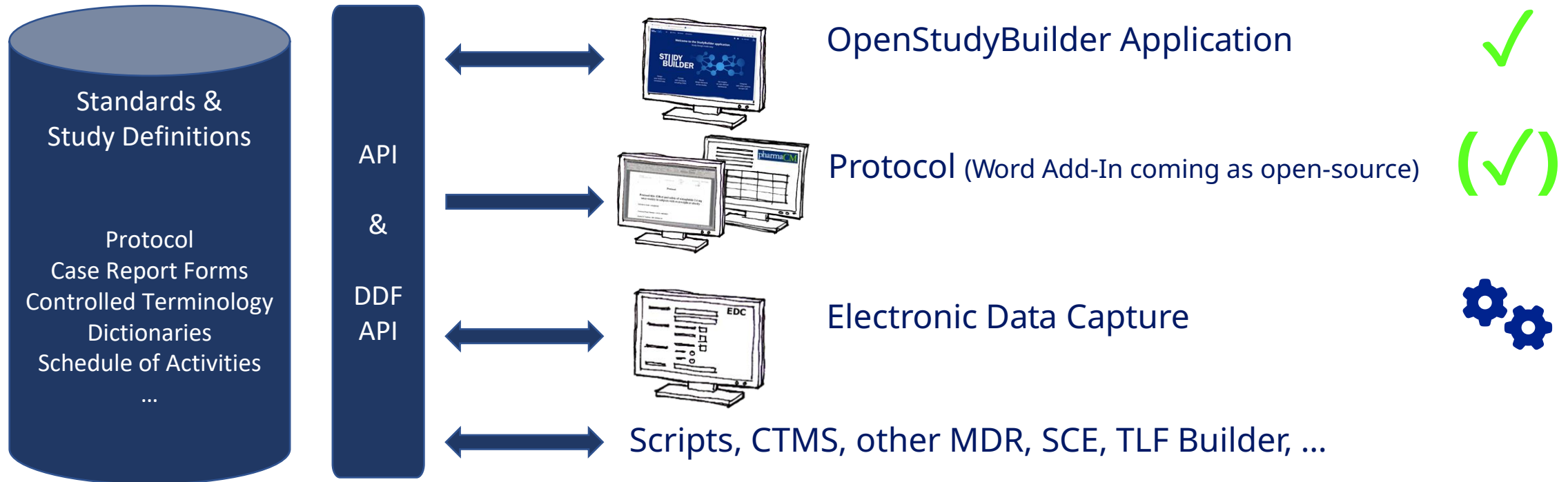
Metadata driven
End-2-End Automation!



Connectivity is key!



Connectivity is key!



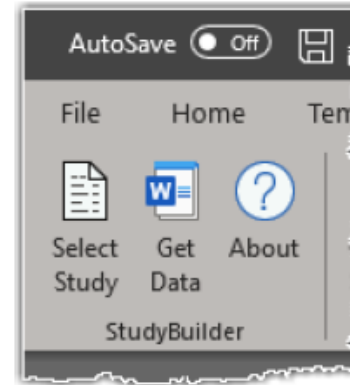
Protocol Generation



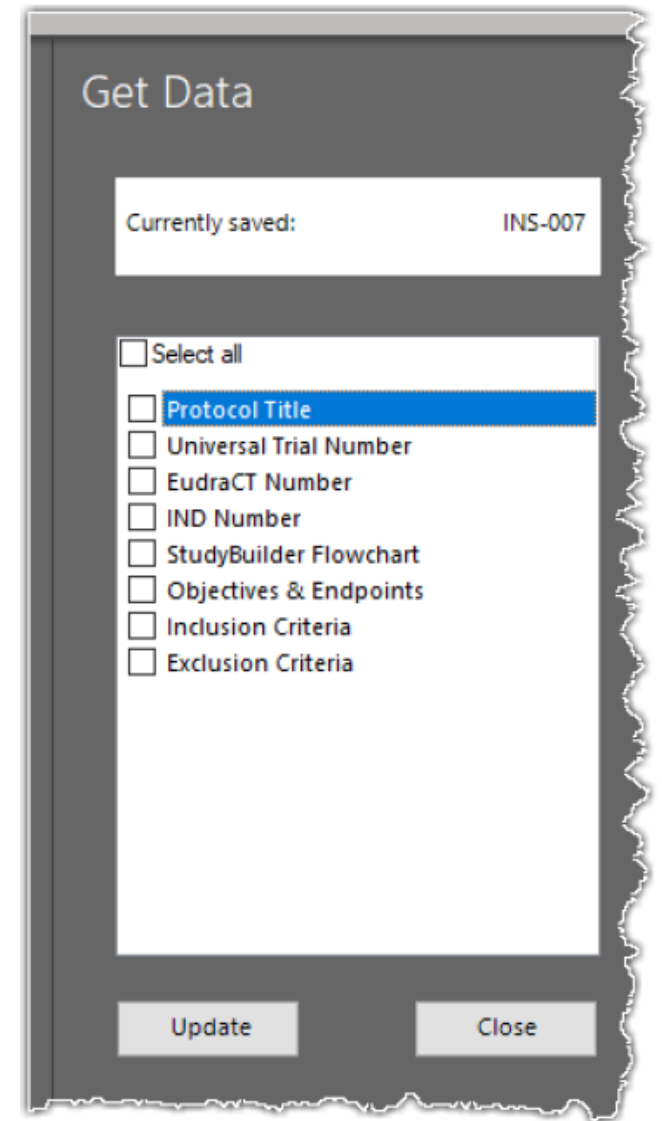
StudyBuilder ribbon (Word add-in)



- ✓ 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	
Visit short name	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
Randomisation											
Randomisation		X									
End of Study											
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	
Biochemistry	X	X			X			X		X	
AE Requiring Additional Data											

Get Data

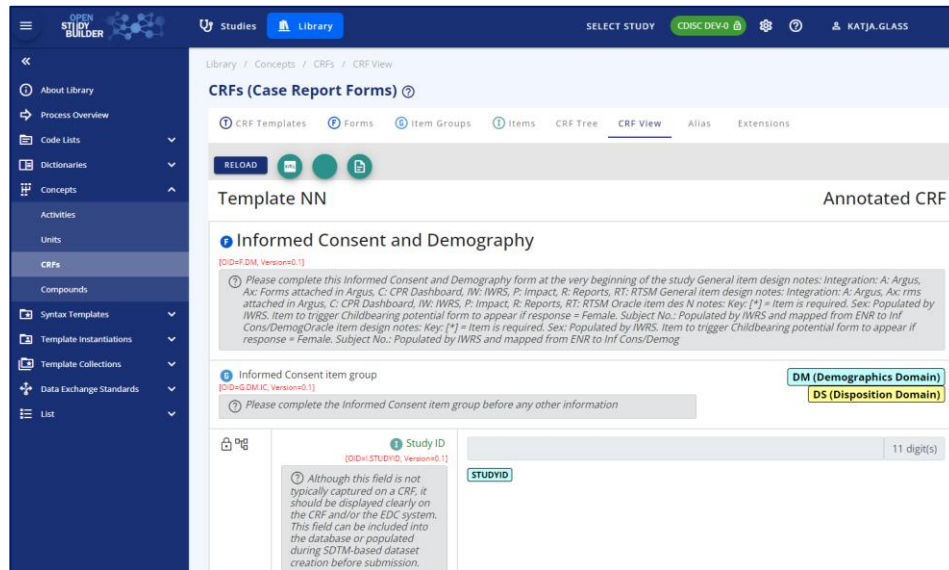
Currently saved: CDISC DEV-0

- 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



EDC Setup, Test, Execution



Including rules, checks
Support vendor extensions

Finetuning, Layout

OpenStudyBuilder to drive EDC setup

A COSA Workshop



Problem Statement

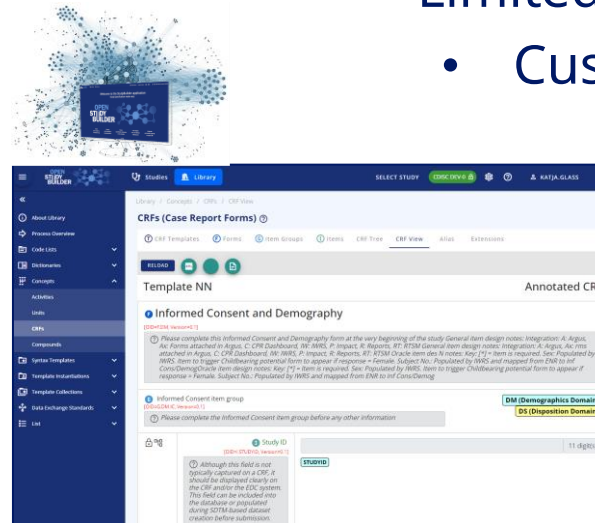
Data Exchange Formats

- CDASH
- ODM.XML
- USDM
- Biomedical Concepts



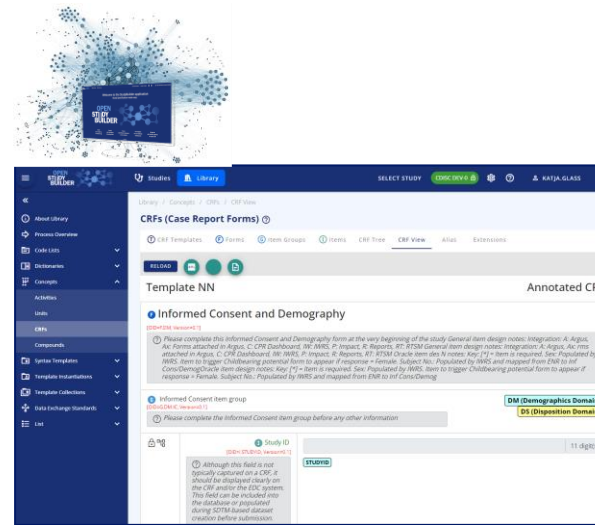
Implementation

- 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

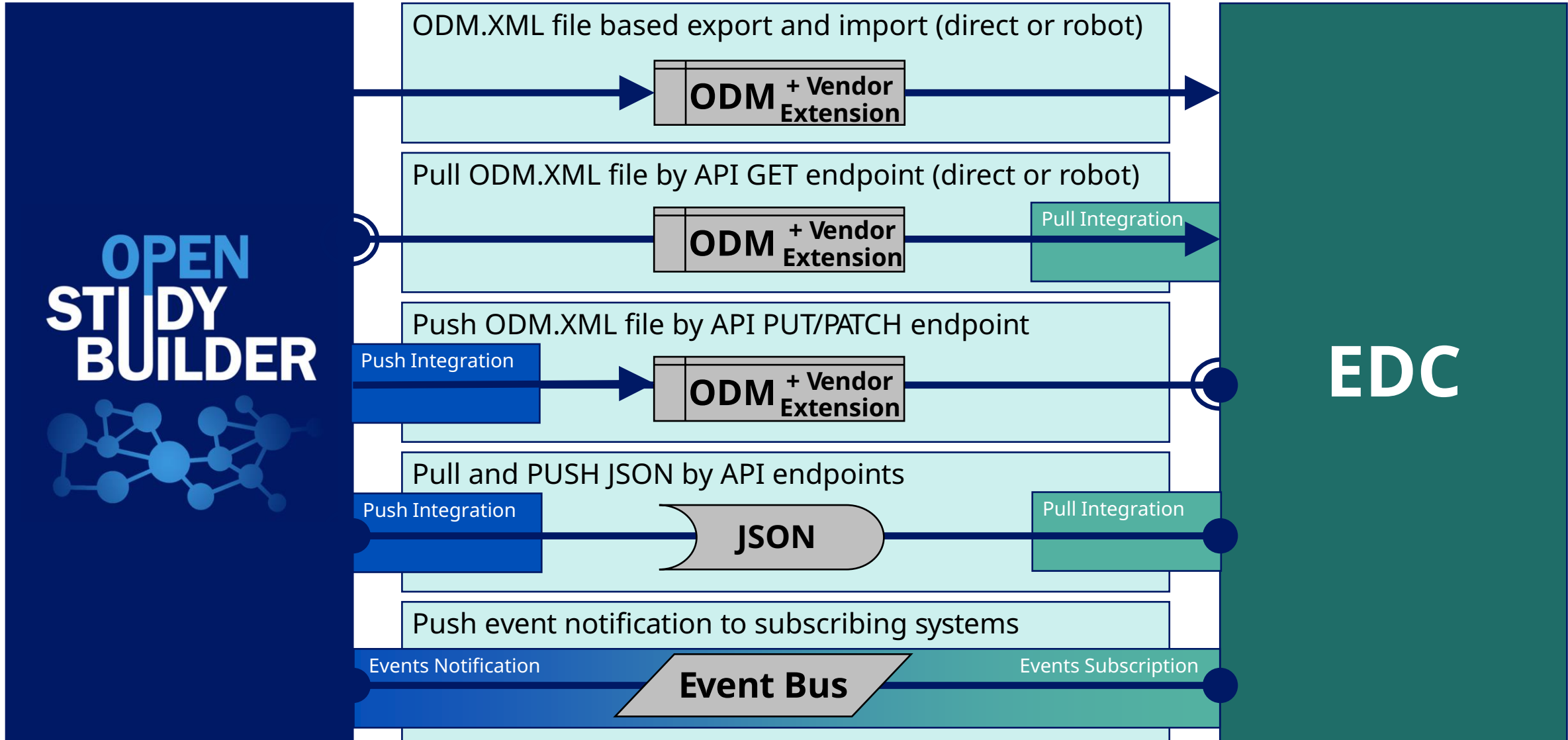
Selection and Configuration of Standard Library Forms

- 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

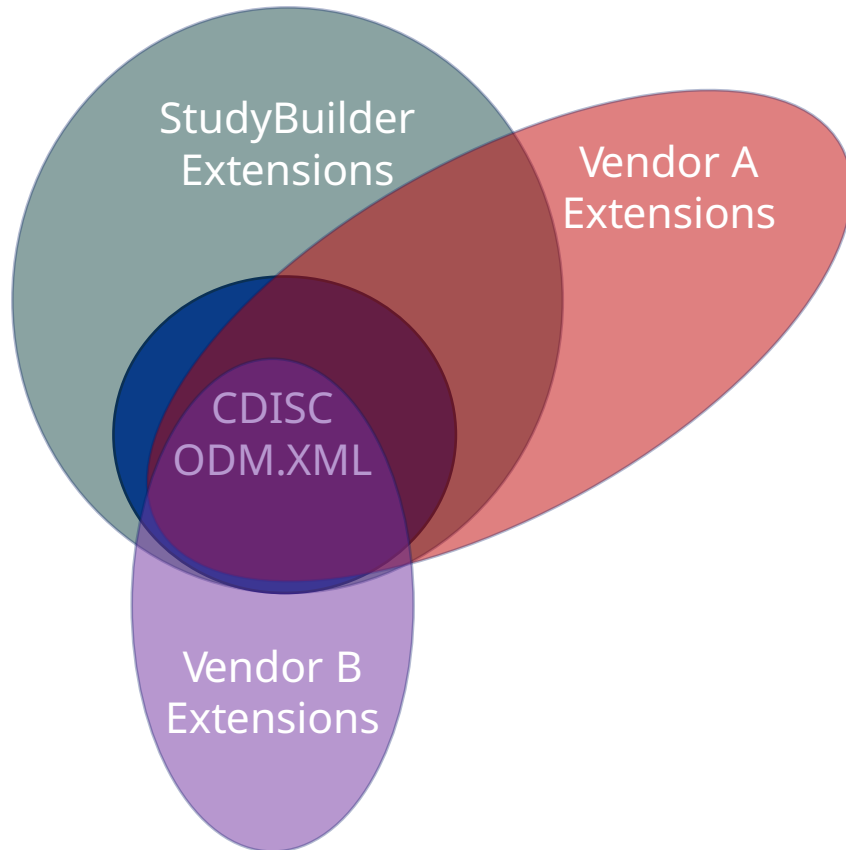
Dynamic build of Study Specific Forms

- 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) ?

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

RELOAD [Icons]

Template V1

Annotated CRF

Informed Consent and Demography

[OID=F.DM, Version=0.1]

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

Informed Consent item group

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

DM (Demographics Domain)

DS (Disposition Domain)

Please complete the Informed Consent item group before any other information

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

General Demographic item group

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

DM (Demographics Domain)

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

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

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

Library / Concepts / CRFs / CRF Tree

CRFs (Case Report Forms)

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

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

Rows per page: 10 1-1 of 1

eCRF specs

Vendor Extensions

Alias

eCRF views

Form def. as ODM (Vendor Extensions + Alias)

Form
Definition

Vendor
Extensions

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

Form Vendor Extensions Alias Change Description

Definition

Name* 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](#)

Alias

ItemGroup def. as ODM (Vendor Extensions + Alias)

Edit CRF Item Group - Vital Signs COPY LINK

Item Group
 Vendor Extensions
 Alias
 Change Description

Definition

Name* Vital Signs	OID G.VS.VS
Repeating <input checked="" type="radio"/> Yes <input type="radio"/> No	Description <div style="border: 1px solid #ccc; padding: 2px; font-family: monospace; font-size: 0.9em;"> B I U x₂ x² ≡ ≡ Vital signs </div>
	Implementation Notes <div style="border: 1px solid #ccc; padding: 2px; font-family: monospace; font-size: 0.9em;"> B I U x₂ x² ≡ ≡ Implementation Notes </div>

Display

Displayed text Vital Signs	Completion Instructions <div style="border: 1px solid #ccc; padding: 2px; font-family: monospace; font-size: 0.9em;"> B I U x₂ x² ≡ ≡ Please complete the Vital Signs item group at each expected time point </div>
-------------------------------	--

Annotations and reporting

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

CONTINUE

SAVE

CANCEL

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

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

Item Code list Code list subset Vendor Extensions Alias Change Description

Definition

Name* 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"/>

Rows per page: 10 1-1 of 1

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

Search Search with terms Operator

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

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

Item
 Code list
 Code list subset
 Vendor Extensions
 Alias
 Change Description

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

Rows per page: 10 1-4 of 4

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

Search

Concept ID	Name
C45908_UNDIFFERENTIATED	Intersex +
C17998_U	Unknown +

Vendor Extensions

New Attribute ?

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

Compatible Types: **FormDef, ItemGroupDef** Regex Expression: _____

- FormDef
- ItemGroupDef
- ItemDef
- ItemGroupRef
- ItemRef

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

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

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

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

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

 Filtering currently not activated

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

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

Informed Consent item group DM (Demographics Domain)
DS (Disposition Domain)

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

Study ID [OID=L.STUDYID, Version=0.1] 11 digit(s)
STUDYID

Date informed consent obtained [OID=L.RFICDAT, Version=0.2] 10 digit(s)
jj/mm/aaaa
RFICDTIC DSSTDTIC

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

Schedule of Activities and Biomedical Concepts...



Schedule of Activities (SoA) at multiple levels



Protocol SoA

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

Detailed SoA

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

Operational SoA


- The data specification to support data collection specification
- Correspond to our existing legacy BCs (Topic Codes)
- Will also 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

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	
SUBJECT RELATED INFORMATION														
Randomisation														
Randomised														
<i>Randomisation Date</i>	RANDOMISATION_DATE	RANDDT		X										
End of Study														
End of Study														
<i>End of Study</i>	END_OF_TRIAL	EOT											X	
General														
Physical Examination - early ph1														
Cardiovascular System														
Abdomen														
Central and Peripheral Nervous System														
Gastrointestinal System incl. Mouth														
General Appearance														
Musculoskeletal System														
Respiratory System														
Body Measurements														
Body Measurements														
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											
Eligibility Criteria														
Eligibility Criteria														
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

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"> Laboratory Assessments AE Requiring Additional Data Laboratory Assessments 	<ul style="list-style-type: none"> Biochemistry Laboratory Assessment Urinalysis 	Bilirubin	bilirubin	
Sponsor	<ul style="list-style-type: none"> Laboratory Assessments AE Requiring Additional Data 	<ul style="list-style-type: none"> Biochemistry Laboratory Assessment 	Direct Bilirubin	direct bilirubin	
Sponsor	<ul style="list-style-type: none"> Eligibility Criteria 	<ul style="list-style-type: none"> Eligibility Criteria 	Eligibility Criteria Met	eligibility criteria met	
Sponsor	<ul style="list-style-type: none"> Laboratory Assessments AE Requiring Additional Data 	<ul style="list-style-type: none"> Biochemistry Laboratory Assessment 	Indirect Bilirubin	indirect bilirubin	
Sponsor	<ul style="list-style-type: none"> Clinical Outcome Assessments 	<ul style="list-style-type: none"> PGI Change-Ability Things Need 	PGI Change-Ability Things Need	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
Bilirubin (N)		NumericFinding	BILIRUBIN_N_URINE	BILIU3
Bilirubin Dipstick		CategoricFinding	BILIRUBIN_UR	BILIU4
Bilirubin Urine		CategoricFinding	BILIRUBIN_URINE	BILIU2
Bilirubin_AE Requiring Additional Data		NumericFinding	BILI	BILI
Bilirubin_Biochemistry		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
Bilirubin (N)		NumericFinding	BILIRUBIN_N_URINE	BILIU3
Bilirubin Dipstick		CategoricFinding	BILIRUBIN_UR	BILIU4
Bilirubin Urine		CategoricFinding	BILIRUBIN_URINE	BILIU2
Bilirubin AE Requiring Additional Data		NumericFinding	BILI	BILI
Bilirubin Biochemistry		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
Bilirubin		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)

Operational SoA – part of Data Specification

STUDY BUILDER
SELECT STUDY CDISC DEV-0 ⚙️ ? 👤 ALL IN

Studies / Define Study / Data Specifications / Operational SoA

Study Data Specifications (CDISC DEV-0)

Study Activity Instances Operational SoA

Expand table Show SoA groups
↓

	Epoch	Topic Code	ADaM Parameter Code	Screening			Follow-up	
	Visit			V0	V1	P2	V3	V4
	Day			-4	-2	1	1	31
Activities	Window			±0	-13/+0	-4/+1	±0	+0/+35
>	AE Requiring Additional Data							
>	AE Requiring Additional Data							
>	Medical History/Concomitant Illness							
∨	Vital Signs							
∨	Vital Signs							
∨	Systolic Blood Pressure							
		Systolic Blood Pressure	BP_SYSTOLIC	SYSBP		X		X
>	Diastolic Blood Pressure							

- ←
- ⓘ About Studies
- ➔ Process Overview
- ☰ Study List
- 🔑 Manage Study
- 📄 Define Study
- Study Title
- Registry Identifiers
- Study Properties
- Study Structure
- Study Population
- Study Criteria
- Study Interventions
- Study Purpose
- Study Activities
- Data Specifications
- ☰ View Specifications
- ☰ View Listings

StudyBuilder to Veeva SDS Specification



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

Report name...

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



Our vision

From Activity to CRF and Define...

The image illustrates the data pipeline from study design to data collection and analysis. It features several key components:

- StudyBuilder:** Two screenshots showing the configuration of 'Weight' and 'Body Weight' activities. The 'Weight' activity is linked to 'Activity Instance Class' and 'Activity Parameter Code'. The 'Body Weight' activity is linked to 'Activity Instance Class' and 'Activity Parameter Code'.
- Falcon:** A network diagram showing relationships between various entities like 'Activity', 'Activity Group', 'Activity Instance', and 'Activity Parameter Code'.
- StudyBuilder:** A detailed view of the 'Body Measurements' activity, showing its configuration and the associated 'VS-Vital Signs' activity.
- define.xml (partial VS domain):** A table listing variables for Vital Signs, including their conditions, labels, types, lengths, and origins.

Variable	Where	Condition	Label / Description	Type	Length or Display Format	Controlled Terms or SDO Format	Origin / Source / Method / Comment
STUDID			Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN			Domain Abbreviation	text	2	Domain.Abbreviation (3)	Assigned (Source: Sponsor)
USUBID			Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDID and SUBID
VSSEQ			Sequence Number	integer	2		Derived (Source: Sponsor) Sequential number identifying records within each USUBID in the domain.
VSTESTCD			Vital Signs Test Short Name	text	20	Vital.Sigs.Test.Code (7 Terms)	Assigned (Source: Sponsor)
VSTEST			Vital Signs Test Name	text	24	Vital.Sigs.Test.Name (7 Terms)	Collected (Source: Investigator) annotated CRF [1] (P)
VSPOS			Vital Signs Position of Subject	text	7		Collected (Source: Investigator) annotated CRF [1] (P)
VSORRES			Result or Finding in Original Units	text	30		Collected (Source: Investigator) annotated CRF [1] (P)
			VSTESTCD = "D1ABP" (Diastolic Blood Pressure)	integer	2		Collected (Source: Investigator) annotated CRF [1] (P)
			VSTESTCD = "FRHSIZE" (Body Frame Size)	text	6	Size • "SMALL" • "MEDIUM" • "LARGE"	Collected (Source: Investigator) annotated CRF [1] (P)
			VSTESTCD = "HEIGHT" (Height)	float	5.1		Collected (Source: Investigator) annotated CRF [1] (P)
			VSTESTCD = "PULSE" (Pulse Rate)	integer	2		Collected (Source: Investigator) annotated CRF [1] (P)
			VSTESTCD = "SYSBP" (Systolic Blood Pressure)	integer	3		Collected (Source: Investigator) annotated CRF [1] (P)
			VSTESTCD = "WEIGHT" (Weight)	float	5.1		Collected (Source: Investigator) annotated CRF [1] (P)
VSORRESU			Original Units	text	20		Collected (Source: Investigator) annotated CRF [1] (P)
			VSTESTCD = "HEIGHT" (Height) and COUNTRY IN ("CAN", "MEX")	text	5	Line (UH_HIC) • "cm" = "Centimeter"	Collected (Source: Investigator) annotated CRF [1] (P) The data submitted only includes subjects in the USA since other sites do not enroll any subjects. Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]ITUSUBID = [IG.DM]ITUSUBID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.
			VSTESTCD = "HEIGHT" (Height) and COUNTRY IN ("CAN", "MEX")	text	5	Line (UH_HIC) • "IN" = "Inch"	Collected (Source: Investigator) annotated CRF [1] (P) The data submitted only includes subjects in the USA since other sites do not enroll any subjects. Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]ITUSUBID = [IG.DM]ITUSUBID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.
			VSTESTCD = "WEIGHT" (Weight) and COUNTRY IN ("CAN", "MEX")	text	4	Line (UH_HIC) • "kg" = "kilogram"	Collected (Source: Investigator) annotated CRF [1] (P) The data submitted only includes subjects in the USA since other sites do not enroll any subjects. Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]ITUSUBID = [IG.DM]ITUSUBID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.
			VSTESTCD = "WEIGHT" (Weight) and COUNTRY IN ("CAN", "MEX")	text	4	Line (UH_HIC) • "LB" = "pound"	Collected (Source: Investigator) annotated CRF [1] (P) The data submitted only includes subjects in the USA since other sites do not enroll any subjects. Join any Subject Level dataset with the Demographics dataset based on [IG.datasetname]ITUSUBID = [IG.DM]ITUSUBID, assuming 'IG.datasetname' is the OID of the ItemGroupDef that defines the subject-level dataset to be joined with the Demographics dataset.
- vs.xpt (Dataset SDTMIG):** A table showing the structure of the data export, with columns for variables like STUDID, DOMAIN, USUBID, VSSEQ, etc.

Status of the OpenStudyBuilder

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

Questions to discuss

- Extensions / configurations required for vendors
 - Additional attributes, e.g. to link to systems & versions
 - ODM.xml additional information
 - API endpoints, additional requirements

- General aspects
 - API versioning
 - Continuous development challenges, up versioning
 - Adoptions & implications according license

- Standards
 - Additional standard requirements, recommendations, wishes



Vendor Experiences & Views

