



Revolutionizing Clinical Trials



The Impact of
OpenStudyBuilder on
Automation and Insights

Agenda



- Introduction
- Initiatives & Vision
- Automation
- Insights
- Summary



What is the OpenStudyBuilder?



A Metadata Data and Study Definition Repository

End-to-end automation from structured protocol to submission deliverables using concept-based standards

3 Elements

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



OpenStudyBuilder Components



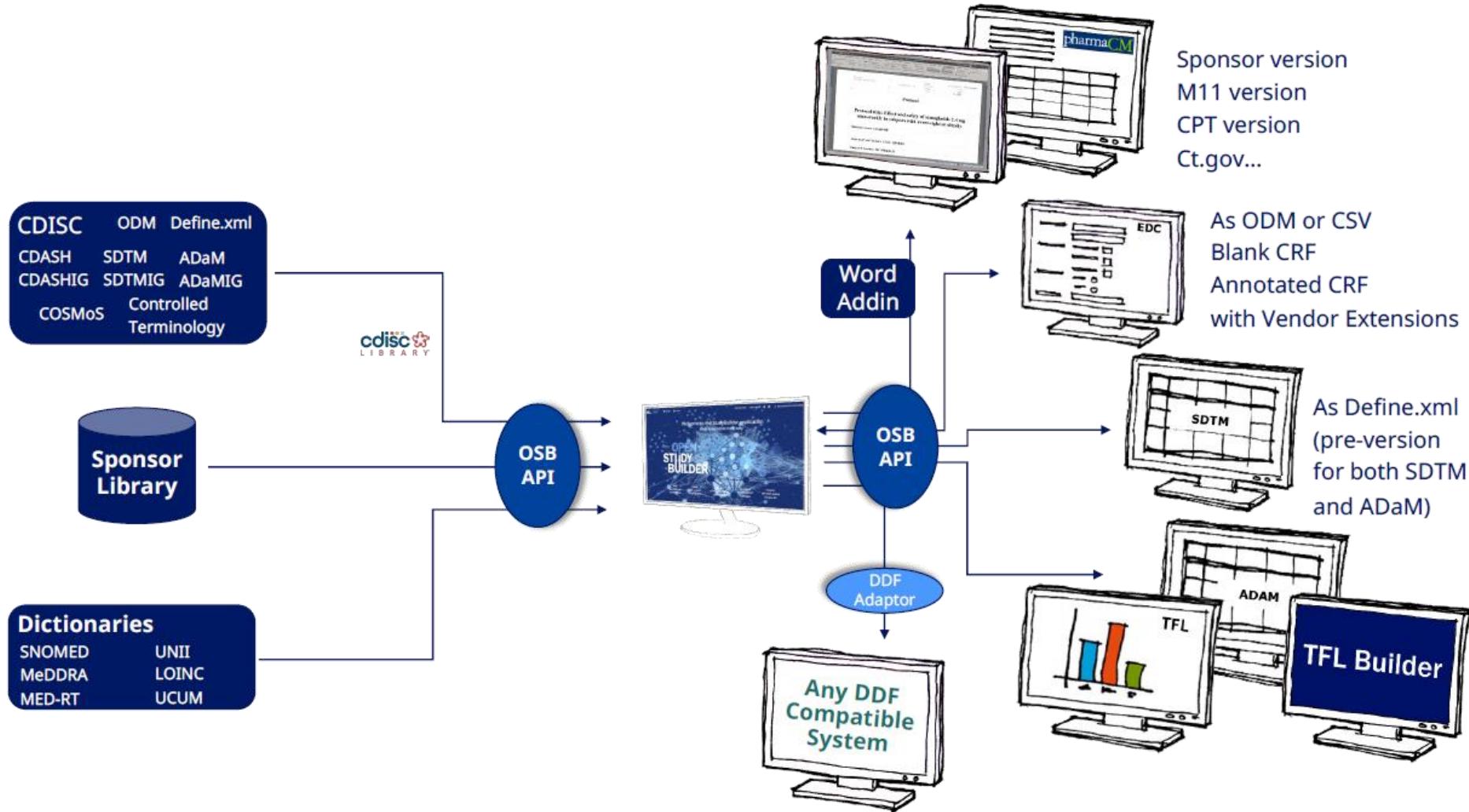
STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES

The Studies component allows users to create and manage their study designs. It provides a central hub for defining study elements like titles, criteria, interventions, and populations.

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

The Library component provides a central repository for managing various standards and templates used in the study design process. It includes tools for managing controlled terminologies, syntax templates, and data exchange standards.

Connectivity is the key



Project Homepage



← → C openstudybuilder.com

OpenStudyBuilder

Description Info Guides FAQ

Search

OpenStudyBuilder ☆ 9 1

OpenStudyBuilder



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/>

Agenda



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Vision of Automation & Digitalization



CDISC 360



- 2019-2020
- End-to-end standards-based metadata-driven automated processing

UC1: Create
end-to-start
specification



UC2: Generate
start-to-end
metadata



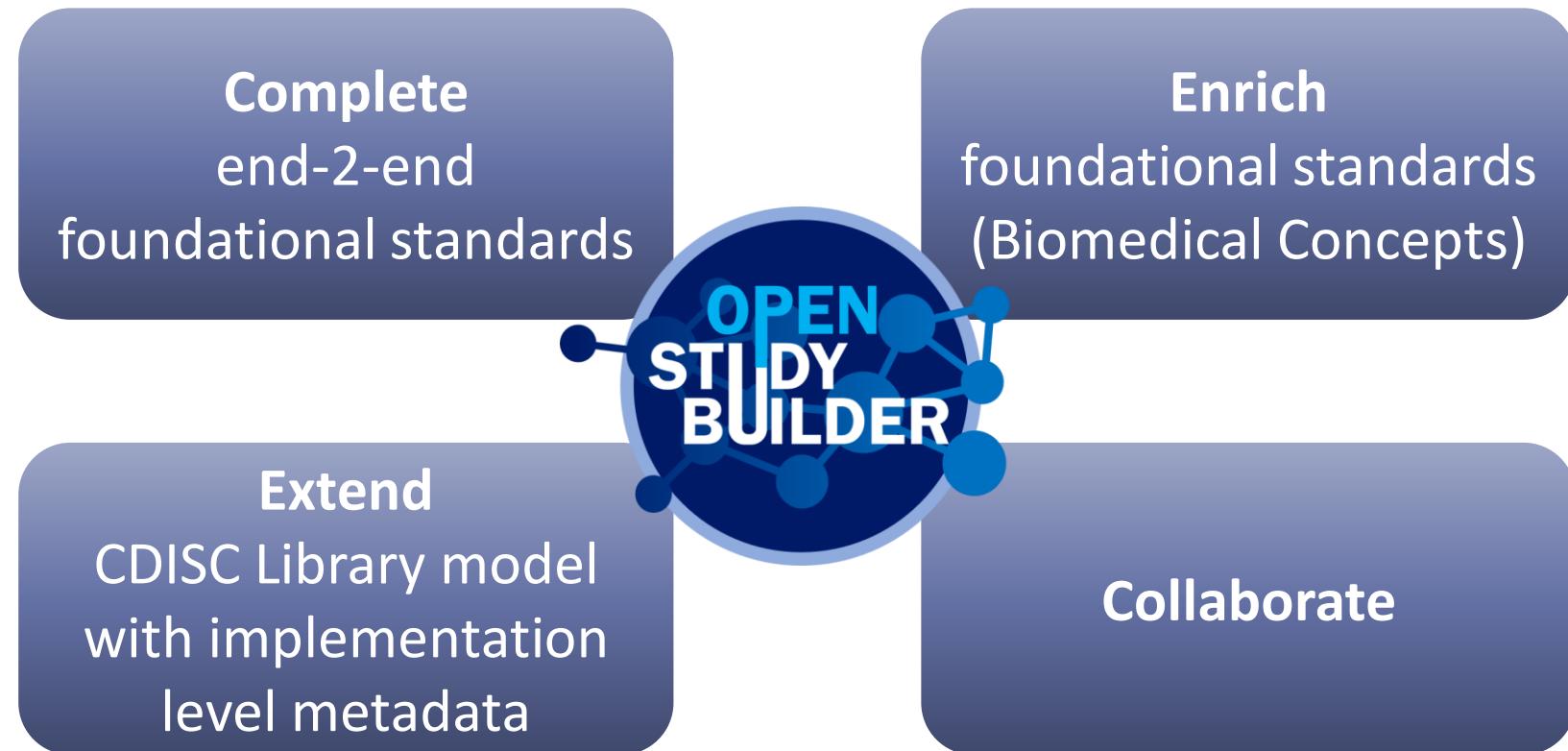
UC3: Transform
data start-to-end



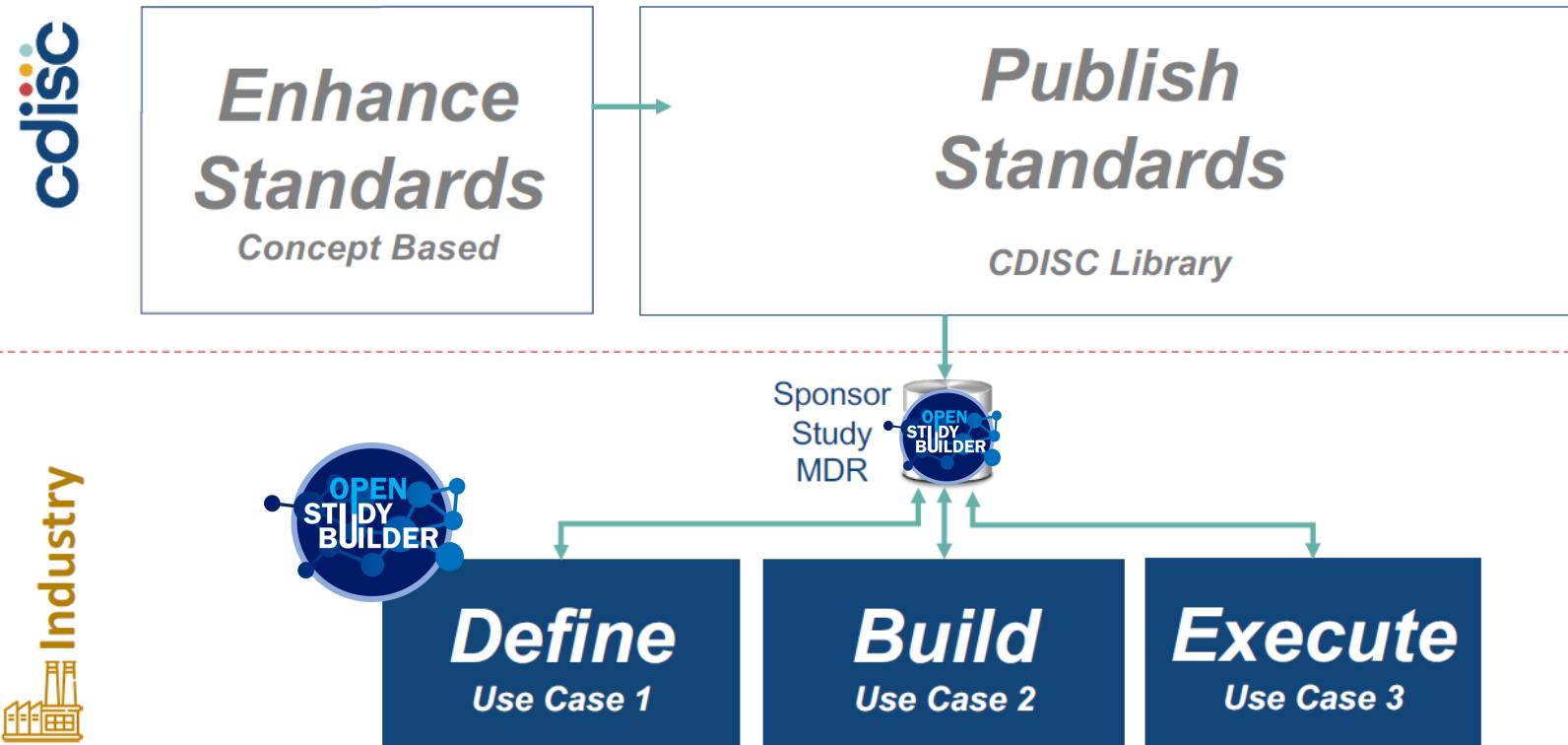
CDISC 360



- Four pillars of 360 implementation⁽¹⁾

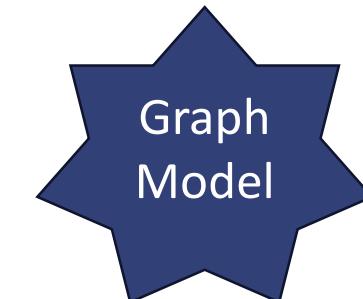


(1) https://www.cdisc.org/sites/default/files/2021-10/CDISC_360_2021_EU_Interchange.pdf





➤ Outcome



Digital Data Flow (TransCelerate & CDISC)



TransCelerate Digital Data Flow Project (DDF)

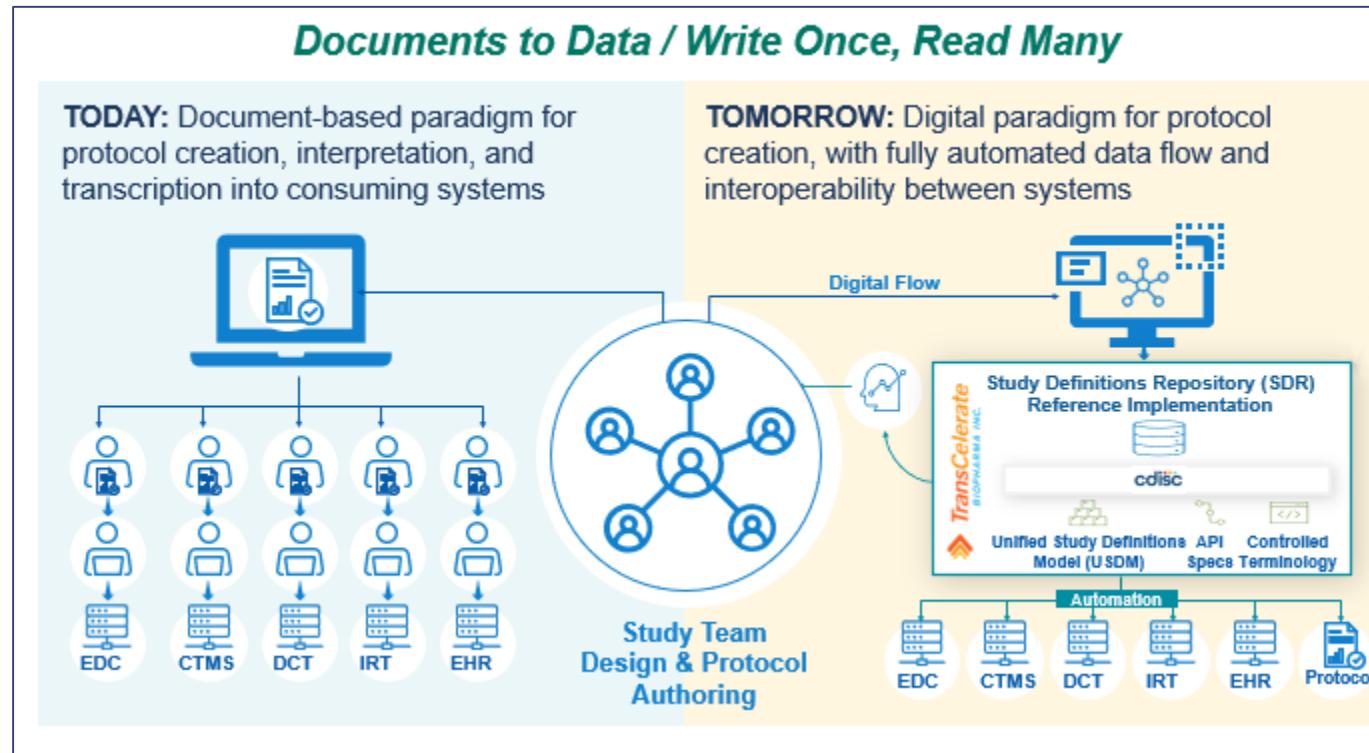


digital workflow that allows for automated creation
of study content and configuration of study systems
to support clinical trial execution

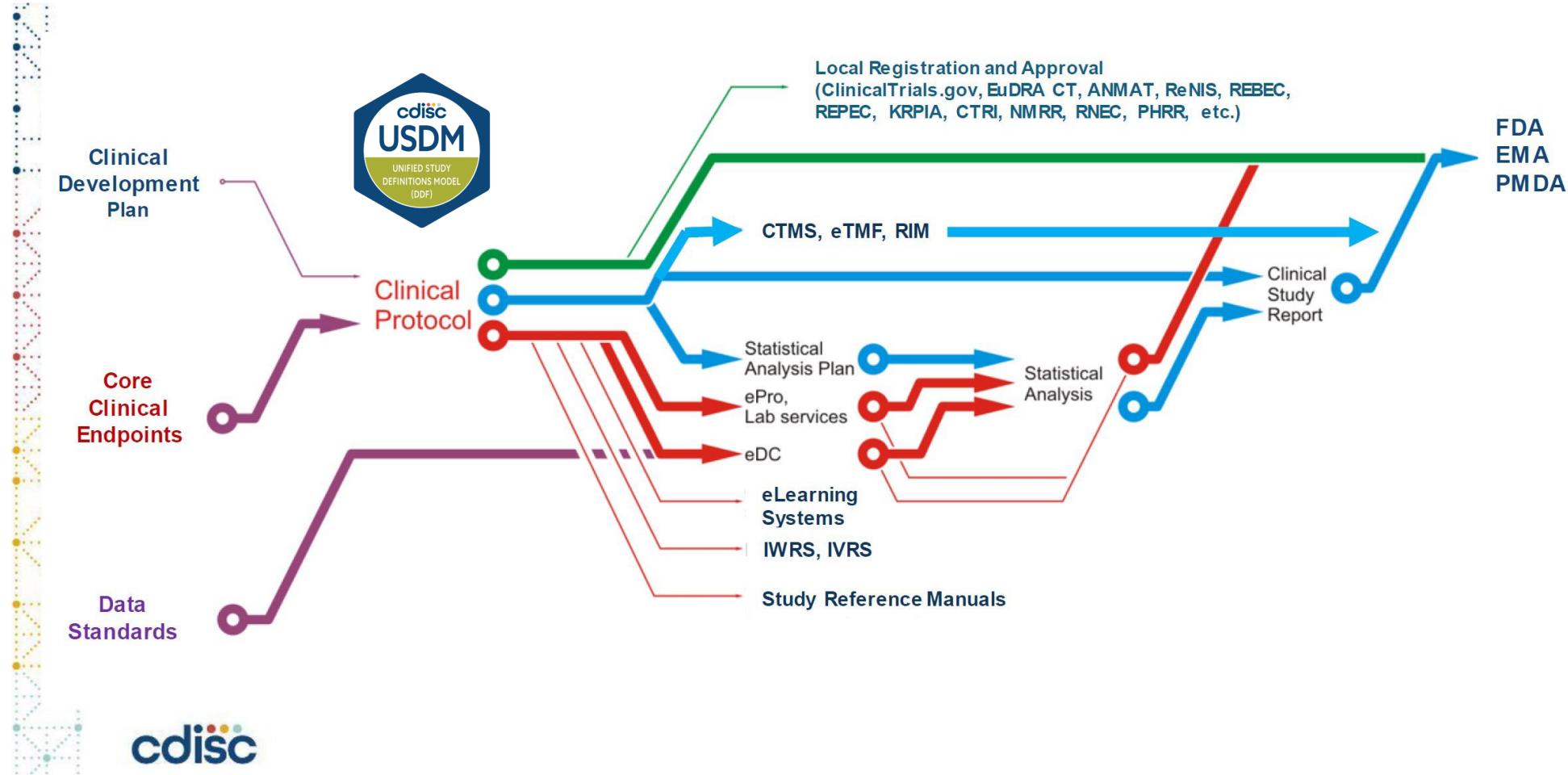
Digital Data Flow (TransCelerate & CDISC)



Digital Data Flow Ambition: Breaking the Document Paradigm



Digital Data Flow (TransCelerate & CDISC)





CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

M11

Number of Arms: [Number of Arms]

Enter the numeric value for the number of arms in different periods, populate this of arms.

Term (Variable)	Number of Arms
Data Type	integer
Topic, Value or Header	D
Definition	
User Guidance	Enter the numeric value for the with a different number of arms based on the period with the gre
Conformance	Required

Blinding: The following roles indicated below will not be made aware of the treatment group assignment during the trial: [blinded roles].

Select from the following blinded roles:

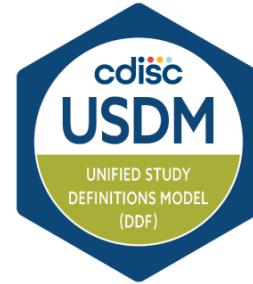
- Participant

Machine
Readable
Protocol

OpenStudyBuilder



Digital Protocol



ICH M11

TransCelerate
BIOPHARMA INC.

Digital Data Flow

+++

define.xml

ODM.xml

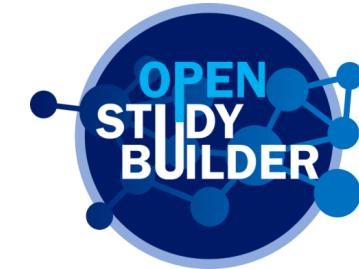
OpenStudyBuilder



- Support industry standards
 - Manage sponsor standards
 - Protocol standards
 - CRF standards

 - Study setup
 - Protocol information

 - Downstream automation (Protocol, EDC, ... utilization)
-



Agenda



- Introduction
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- **Automation**
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Automation



Protocol SoA

SoA layout
Protocol SoA ▾ Preferred time unit: Day Week Download

	Screening		Treatment									Follow-up
	V1	V2	V3	V4	V5	V6	V7	V9	V10	V11	V8	
Visit short name												
Study week	-2	1	2	3	4	5	6	7	9	27		6
Visit window (days)	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1		+0/+35
Laboratory Assessments												
Lipids	X	X			X			X		X		
Biochemistry	X	X			X			X		X		
Haematology												
AE Requiring Additional Data												
Laboratory Assessment	X	X			X			X		X		
Adverse Event												
Adverse Event	X	X	X	X	X	X	X	X	X	X		X
Vital Signs												
Pulse Rate	X	X	X	X	X	X	X	X	X	X		X
Diastolic Blood Pressure	X	X	X		X	X	X	X	X	X		X
Systolic Blood Pressure	X	X	X	X	X	X	X	X	X	X		X

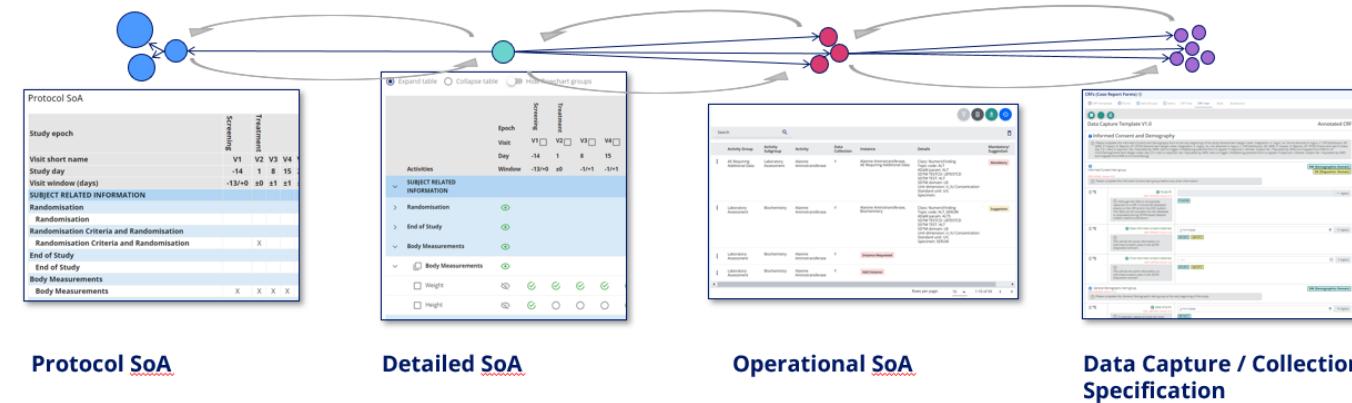
Diastolic Blood Pressure

Automation - Activity



➤ Steps

- Define standards / Biomedical Concept
- Select activities according protocol needs
 - Re-use in protocol
- Select operational activity (collection specification)
 - Re-use in annotated CRF
 - Re-use in EDC
 - Re-use in mapping





Define Activity

Automation – Define Activity



➤ Step 1: Define Standard / Biomedical Concept

Diastolic Blood Pressure ⓘ

Overview OSB YAML COSMoS YAML

Name Diastolic Blood Pressure
Sentence case name diastolic blood pressure
Version 1.0 Status Final
Start date Jun 17, 2024, 4:24 PM End date None
Definition
Abbreviation
Library Sponsor
NCI Concept ID
Data collection Yes
Activity groupings Activity group Activity subgroup
Vital Signs Vital Signs
Activity instances Name Definition Version Status Activity instance class Topic code ADaM parameter code
[Diastolic Blood Pressure](#) 1.0 Final NumericFinding BP_DIASTOLIC DIABP

Name: Diastolic Blood Pressure

Activity group / subgroup:
Vital Signs

Class:
NumericFinding

ADaM parameter code:
DIABP

<Instance>

Automation – Define Activity



- Step 1: Define Standard / Biomedical Concept

<Instance>

Activity items	Item type	Name	Activity item class
	CT term	Pressure	unit_dimension
	Unit definition	mmHg	standard_unit
	CT term	Diastolic Blood Pressure	test_name_code
	CT term	Left Right	laterality
	CT term	Arm	
	CT term	Vital Signs Domain	

Item Type	Name	Activity item class
CT term	Pressure	unit_dimension
Unit definition	mmHg	standard_unit
CT term	Diastolic Blood Pressure	test_name_code
CT term	Left Right	laterality
CT term	Arm	location
CT term	Vital Signs Domain	domain

Automation – Define Activity

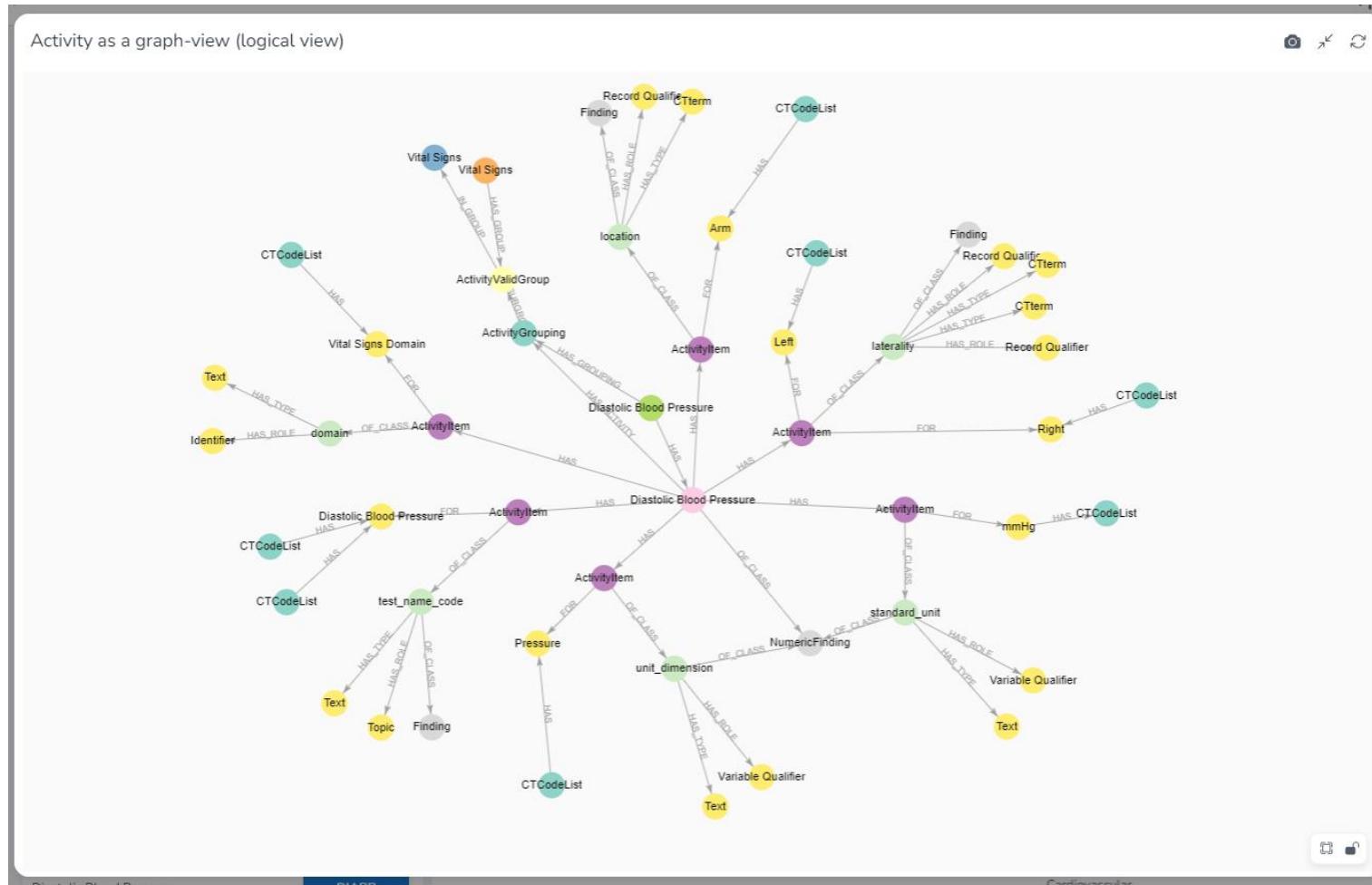


- Same activities, different collection

Acute Kidney Injury Imaging ?

Name	Definition	Version	Status	Activity instance class	Topic code	ADaM parameter code
Acute Kidney Injury - CT Scan Performed	1.0	Final	CategoricFinding	ACUTE_KIDNEY_INJURY_CT_SCAN		AKICTSCA
Acute Kidney Injury - Imaging Performed	1.0	Final	CategoricFinding	ACUTE_KIDNEY_INJURY_IMAGING_PERFORMED		AKIIMAGE
Acute Kidney Injury - Other Imaging Performed	1.0	Final	CategoricFinding	ACUTE_KIDNEY_INJURY_IMAGING_OTHER		AKIIMOTH
Acute Kidney Injury - Renal Angio-Imaging Performed	1.0	Final	CategoricFinding	ACUTE_KIDNEY_INJURY_RENAL_ANGIO-IMAGING		AKIRANIM
Acute Kidney Injury - Summary of Imaging Results	1.0	Final	TextualFinding	ACUTE_KIDNEY_INJURY_IMAGING_RESULTS		AKIHISTO
Acute Kidney Injury - Ultrasound Performed	1.0	Final	CategoricFinding	ACUTE_KIDNEY_INJURY_ULTRASOUND		AKIULTRA

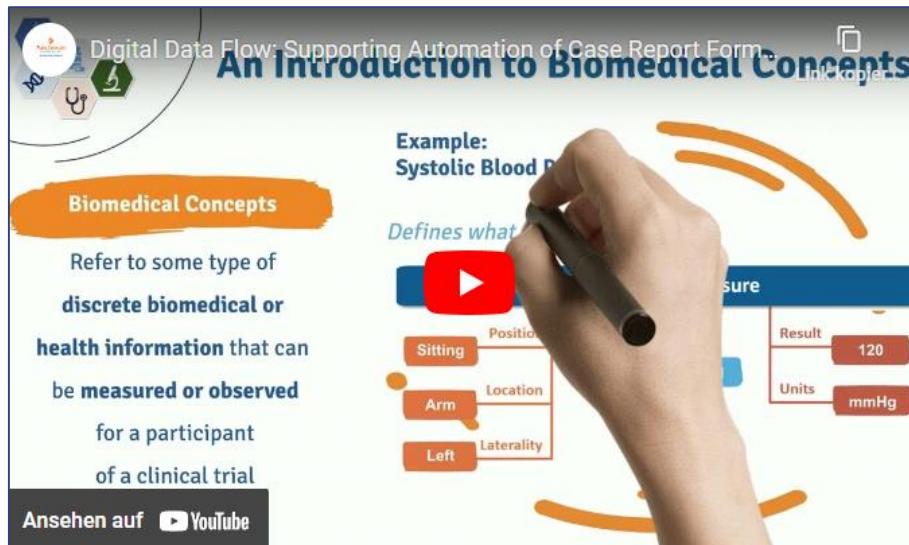
Automation – Define Activity



Automation – Define Activity



- Define process might be complex
- CDISC Biomedical Concepts
- Additional OpenStudyBuilder Biomedical Concepts



An Introduction to Biomedical Concepts

<https://youtu.be/otGpj8g5gxY>

Automation - Activity



Select Activity

Automation – Select Activity



- Select activities according protocol needs (Medical Writer)

Study Activities (CDISC DEV-0) ②

Study Activities Detailed SoA SoA footnotes Protocol SoA Activity Instructions

Select rows

Search

#	Library	SoA group	Activity group	Activity subgroup	Activity	Data collection	Modified	Modified by	
⋮	1	Sponsor	SUBJECT RELATED INFORMATION	Randomisation	Randomisation	Randomized	Yes	Jun 17, 2024, 10:45 AM	alex.goh
⋮	2	Sponsor	SUBJECT RELATED INFORMATION	End of Study	End of Study	End of Study	Yes	Jun 17, 2024, 10:45 AM	alex.goh
⋮	3	Sponsor	SUBJECT RELATED INFORMATION	Body Measurements	Body Measurements	Weight	Yes	Jun 17, 2024, 10:45 AM	alex.goh
⋮	4	Sponsor	SUBJECT RELATED INFORMATION	Body Measurements	Body Measurements	Height	Yes	Jun 17, 2024, 10:45 AM	alex.goh

Automation – Select Activity



- Select activities according protocol needs (Medical Writer)

Automation - Activity



Apply in Protocol

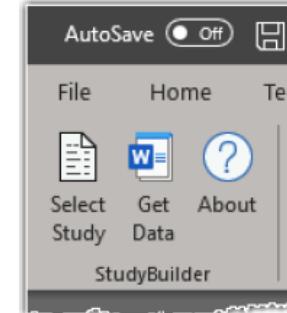
Automation – Apply Activity



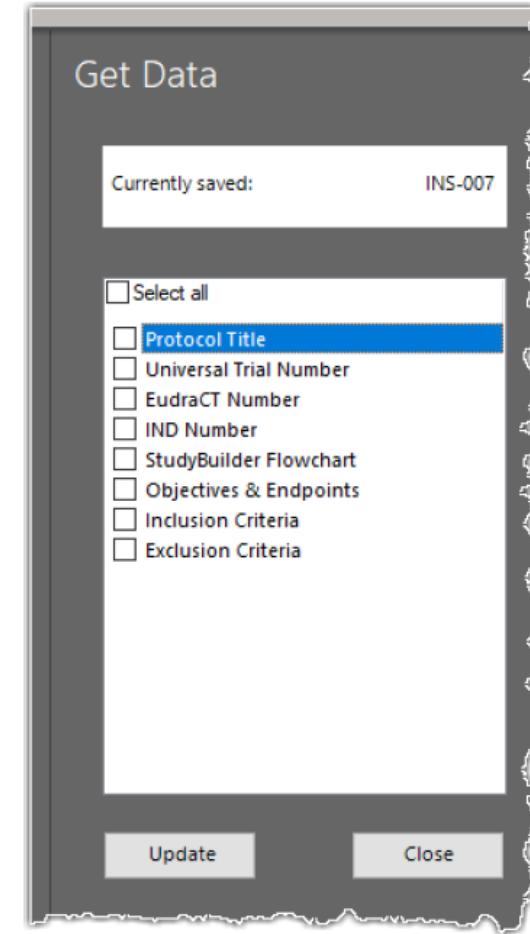
StudyBuilder ribbon (Word add-in)



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



Protocol



Automation – Apply Activity



Content from „Controll Field“ is filled by calling OpenStudyBuilder API

Protocol Study ID: CDISC DEV-0

1.2 Flowchart

Schedule of Activities

Procedure	Screening	Treatment										Follow-up	
		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	
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
End of Study													
Body Measurements													
Body Measurements	X	X	X	X	X	X	X	X	X	X	X		
Eligibility Criteria													
Eligibility Criteria	X												
Laboratory Assessments													
Glucose Metabolism	X	X	X	X	X	X	X	X	X	X	X		
Lipids	X	X			X			X		X			
Biochemistry	X	X			X			X		X			
AE Requiring Additional Data													

Comments Share

ember 2022 Status: Draft Novo Nordisk

0.1 Page: 9 of 75

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

Page 9 of 75 58621 words English (United Kingdom) Accessibility: Investigate Display Settings Focus

Select „Schedule of Activities“

Update



Define Collection Details

Automation – Define Activity Instance



Data Specifications



Studies / Define Study / Data Specifications / Study Activity Instances

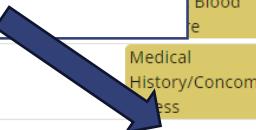
Study Data Specifications (CDISC DEV-0)

Study Activity Instances Operational SoA

Select rows

Search	Activity	Instance	Topic cod		
g/L	Haematology	Hematocrit	Yes	Haematocrit Blood	HAEMATC
Adverse Event	Adverse Event	Adverse Event	Yes	Adverse Event	ADVERSE
PULSE	Vital Signs	Pulse			
BP_DIASTOLIC	Vital Signs	Diastolic Pressure			
BP_SYSTOLIC	Vital Signs	Systolic Pressure			
MEDICAL_HIST	Medical History/Concomitant Illness	Medical History/Concomitant Illness	Yes	Medical History/Concomitant Illness	MEDICAL_HIST
Add Instance	Acute Kidney Injury	Acute Kidney Injury	Yes	Add Instance	

Add Instance



Automation – Define Activity Instance



Edit/Add Activity instance(s)

Activity Selected
AE Requiring Additional Data/Acute Kidney Injury/Acute Kidney Injury

Instance	Details	State
No data available		

CANCEL **SAVE**

Demography Demography Obtained Representative REPRESENTATIVE

Work in
Progress

Automation - Activity



Use Activity Information

Automation – Use Activity



➤ CRF & aCRF & ODM.xml

Vital signs [ItemGroup] [OID=G.VS.VS, Version=0.1]

(?) Please complete the Vital Signs item group at each expected time point

	Date of examination [OID=I.VSDAT, Version=0.1]	tt.mm.jjjj	10 digit(s)
🔒	Systolic blood pressure [OID=I.SYSBP, Version=0.1]	(?) Please collect the systolic blood pressure of the subject	VSDTC 3 digit(s) Unit mmHg [OID=mmHg, Version=1.0]
🔓	Diastolic blood pressure [OID=I.DIABP, Version=0.1]	(?) Please collect the diastolic blood pressure of the subject	VSDTC 3 digit(s) Unit mmHg [OID=mmHg, Version=1.0]

VS (Vital Signs Domain)

```
<ItemDef OID="I.DIABP" Name="Diastolic blood pressure" Origin="Collected Value" DataType="integer" Length="3" SASFieldName="BP_DIASTOLIC">
  <Question>
    <TranslatedText xml:lang="en" osb:version="0.1">Diastolic blood pressure</TranslatedText>
  </Question>
  <Description>
    <TranslatedText xml:lang="en" osb:version="0.1">Diastolic blood pressure</TranslatedText>
  </Description>
  <MeasurementUnitRef MeasurementUnitOID="mmHg"/>
</ItemDef>
```



Partially working,
additional work in
Progress

Automation – Use Activity



- EDC Automation
 - Create items / visits based on Schedule of Activities

The screenshot shows the Clinical One EDC software interface. At the top, there's a header with the logo, study name "Clinical One Testing", and study ID "Study: 4005057_01". Below the header are navigation buttons for "Home", "Subjects", "Supplies", "Reports & Archives", and "Analytics". The main area is a subject visit form for "Subject 001-002". The form includes sections for "Informed Consent and Demography" (with fields for date obtained, subject number, date of birth, age, sex, ethnicity, and race) and "Vital Signs" (with fields for vital signs performed and date of examination). On the right side, there's a "Question Hint" panel with the message "No hint provided." and links to "Rules", "Answer & Visit History", and "Subject History". A video player at the bottom right shows a timestamp of "00:07,53".



Proof of Concepts
available

Automation – Use Activity



- Download mapping specification (define.xml)

CDISC SDTM 3.2													
Annotated Case Report Form		Date of Define-XML document generation: 2018-11-19T08:39:20											
▶ Tabulation Datasets		Stylesheet version: 2015-01-16											
▶ Value Level Metadata													
▶ Controlled Terminology													
▶ Computational Algorithms													
▶ Comments													
Standard CDISC SDTM 3.2													
Study Name TDF_SDTM													
Study Description Test datasets created by updating existing CDISCIPILOT SDTM datasets													
Protocol Name TDF_Datasets													
Metadata Name Study TDF_SDTM Data Definitions													
Metadata Description Test datasets created by updating existing CDISCIPILOT SDTM datasets													
Tabulation Datasets for Study TDF_SDTM (CDISC SDTM 3.2)													
Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation						
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt							
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt							
TI	Trial Inclusion/_Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt							
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt							
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM	tv.xpt							
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt							
SE	Subject Elements	SPECIAL PURPOSE	One record per actual Element per subject	Tabulation	STUDYID, USUBJID, ETCD	se.xpt							
SV	Subject Visits	SPECIAL PURPOSE	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, VISITNUM	sv.xpt							

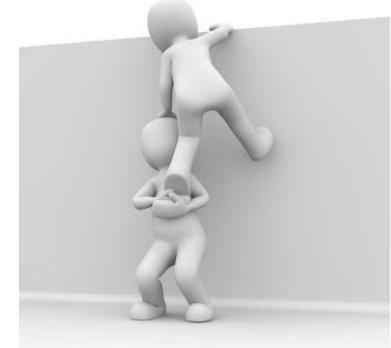


Work in Progress

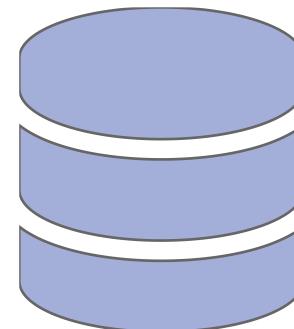
Automation – Use Activity



- Use to generate Test Data
 - Possible units, standard units, PARAMCD
 - Enhance with additional information
 - Reference Ranges



TestData

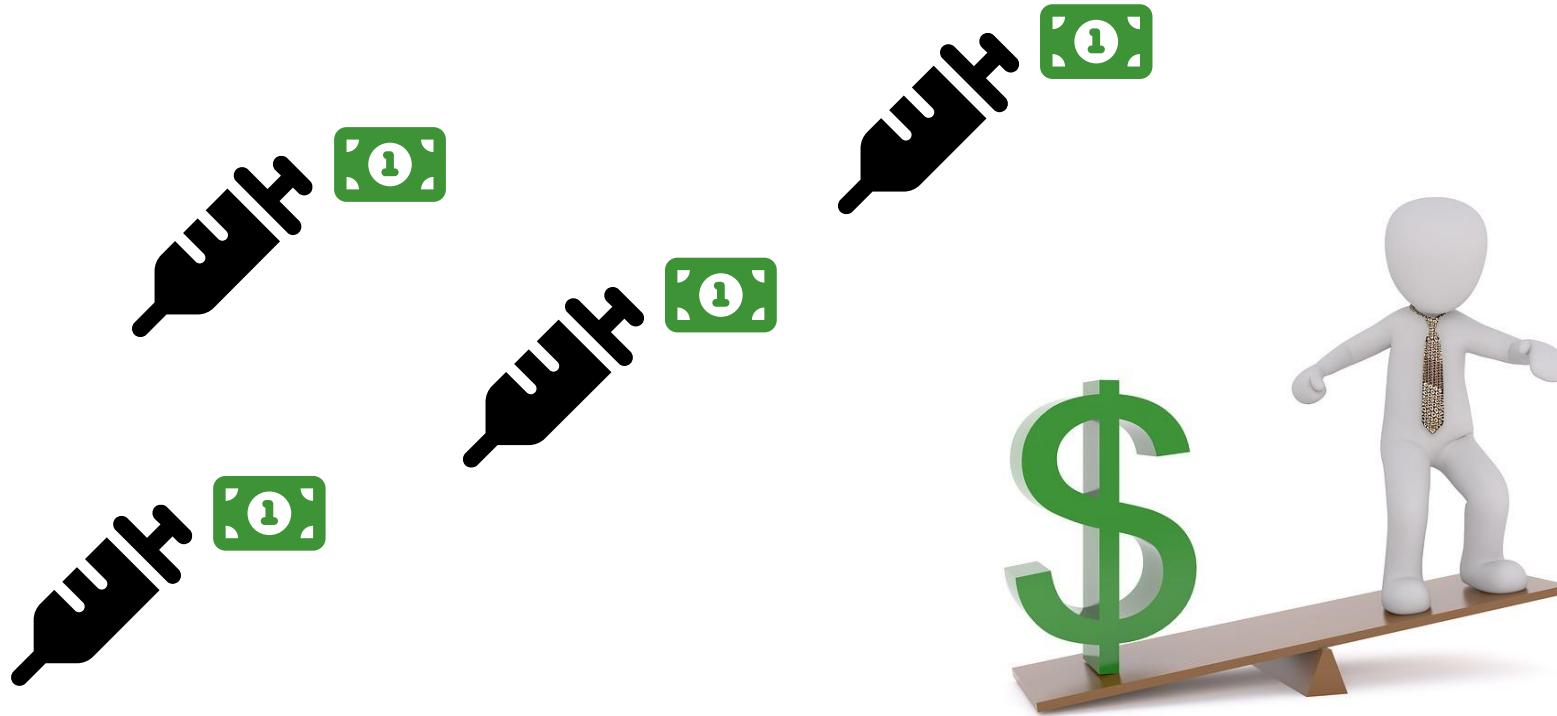
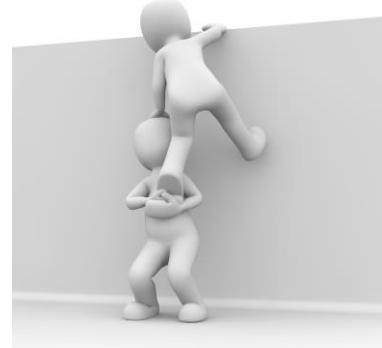


Out of Scope for
OpenStudyBuilder

Automation – Use Activity



- Use to Cost / Patient Burden
 - Enhance with additional information
 - Cost per test per visit



Out of Scope for
OpenStudyBuilder

Agenda



- Introduction
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- Summary



Insights



One-Stop-Shop



Study Information

Trial Domains

CRF/EDC
Specification

Data Models

Standards &
Harmonization

Mapping
Specification

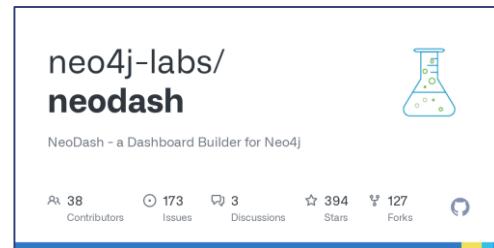
Biomedical Concepts

...

Insights



User Interface

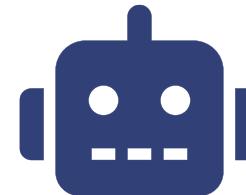


Dashboard

neo4j
Cypher queries



API

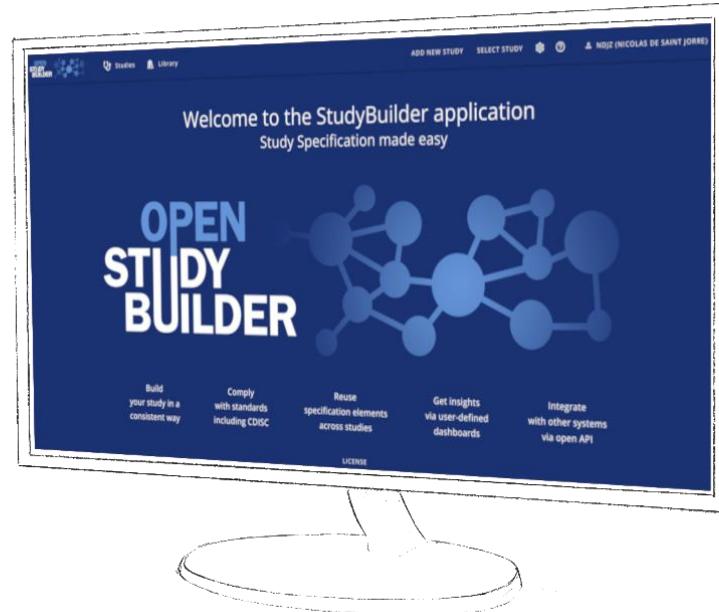


AI
Training & Chat



Insights
Programming

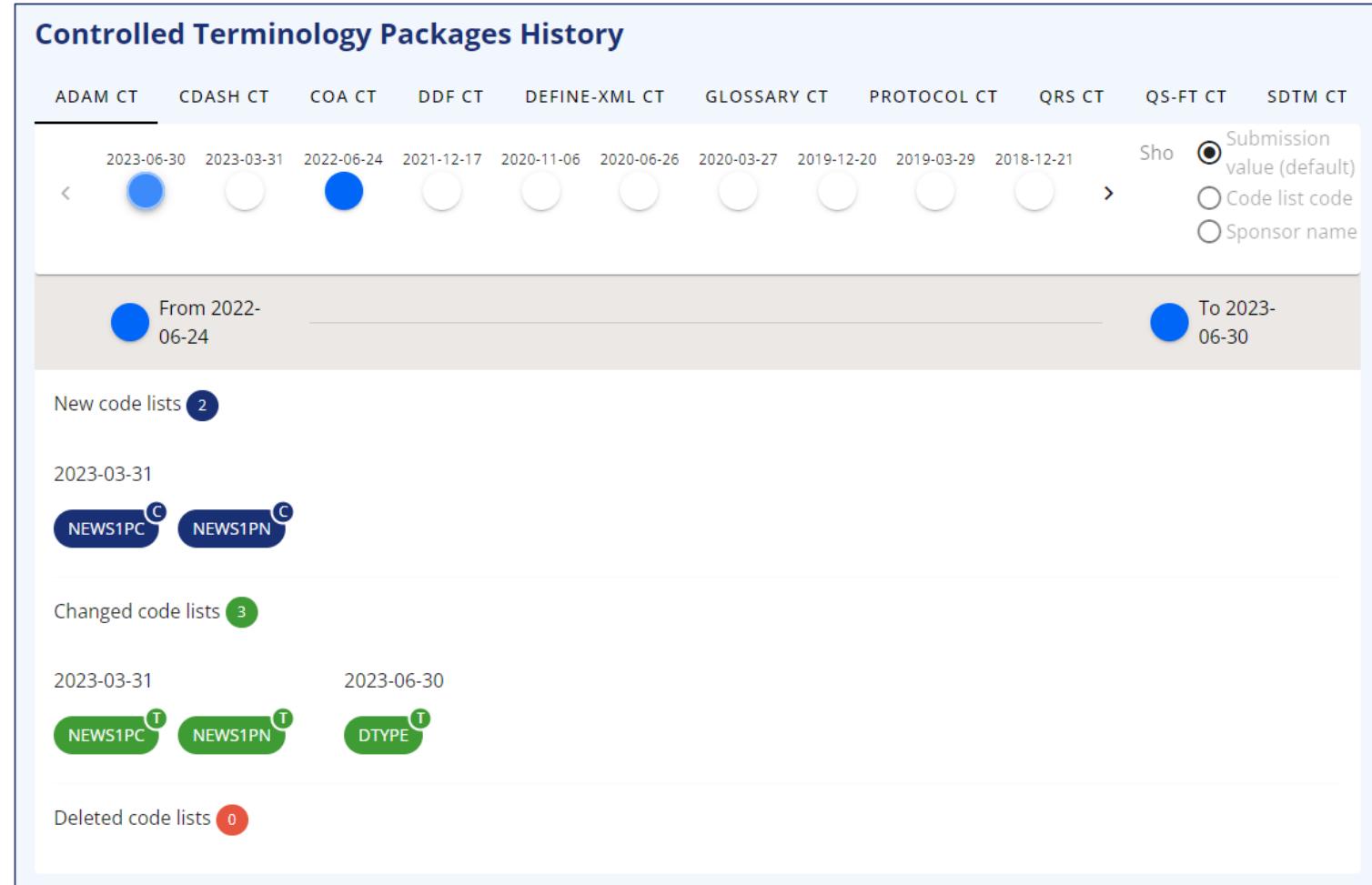
Insights – User Interface



Insights – User Interface



Changes for
CDISC CT
Packages



Insights – User Interface



History

Sponsor values history for code list [CTCodelist_000001]

Library	Name	Template parameter	Change description	Status	Version	Change type	User	From	To
Sponsor	Unit Dimension	No	Approved version	Final	1.0		unknown-user	Apr 22, 2024, 1:09 PM	
Sponsor	Unit Dimension	No	Initial version	Draft	0.1		unknown-user	Apr 22, 2024, 1:09 PM	Apr 22, 2024, 1:09 PM

Items per page: 10 ▾ 0-0 of 0 | < < > >|

Study (CDISC DEV-0) ⓘ

Study Core Attributes Study Status Study Subparts Protocol Version

Study status Version Release description Modified Modified by

Study status	Version	Release description	Modified	Modified by
DRAFT			Jun 23, 2024, 10:45 AM	unknown-user
LOCKED	3	add tempareature visit	Jun 23, 2024, 10:45 AM	unknown-user
RELEASED	3	add tempareature visit	Jun 23, 2024, 10:45 AM	unknown-user
LOCKED	2	new release	Jun 23, 2024, 10:40 AM	unknown-user
RELEASED	2	new release	Jun 23, 2024, 10:40 AM	unknown-user
LOCKED	1	Initial version	Jun 23, 2024, 10:23 AM	unknown-user
RELEASED	1	Initial version	Jun 23, 2024, 10:23 AM	unknown-user

Insights – User Interface



Investigate Studies

- Objectives
- Endpoints
- Time Frames
- Criteria
- Activity Instructions
- Footnotes

Objective instantiations ⓘ

Select rows

Library	Template	Objective
User Defined	Time from randomisation to all cause death	Time from randomisation to all cause death
User Defined	Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina	Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina

Search

⋮ History

⋮ Display studies using this objective

Display studies using this objective

Insights - NeoDash



neo4j Labs

Docs ▾ Labs ▾ Get Help ▾ GraphAcademy ▾ Get Started Free

Labs Home

GenAI Ecosystem

APOC

Arrows

Aura CLI

Cypher Workbench

Keymaker

Neo4j ETL Tool

Halin

Liquibase

Neo4j-Helm

Neo4j-Migrations

Needle Starter Kit

NeoDash

Documentation

neomodel

Neosemantics

Neo4j Labs / NeoDash

Edit this Page

NeoDash - Dashboard Builder for Neo4j

NeoDash is an open-source, low-code Dashboard Builder for Neo4j. It lets you build an interactive dashboard with tables, graphs, bar charts, line charts, maps and more.

Contents

- Availability & Installation
- Functionality Includes
- Documentation
- Relevant Links
- Videos & Tutorials
- Highlighted Articles

Learn

Free Neo4j courses from GraphAcademy

Learn everything you need to know to be successful with Neo4j

Start learning

<https://neo4j.com/labs/neodash/>

Insights - NeoDash



Menu

The screenshot shows the NeoDash interface running on neo4j://localhost:5002. The left sidebar includes links for Dashboards, Activity Library Dashboard (which is active), Audit Trail Report, Data Exchange Data Models, Study Metadata Comparison, and Syntax Template Dashboard. The main content area displays the 'Activity Library Dashboard' with sections for 'Guide', 'Groupings of Activities' (with a circular diagram of nodes), and 'Number of Activities and instances'. A search bar at the top says 'Search Activity Instance'.

Activity Library Dashboard

Audit Trail Report

Data Exchange Data Models

Study Metadata Comparison

Syntax Template Dashboard



Activities

Insights - NeoDash - Activities



- Which biomedical concepts exist?
- Which activities are used?
- How map activities in SDTM?

The screenshot displays the NeoDash Activity Library Dashboard with several sections:

- A**: A search interface with dropdown menus for Activity Class (Finding), Activity Sub-class (Body Measurements), Activity Group (Body Measurements), and Activity Sub-group (Body Measurements).
- B**: A bar chart showing the number of activities (Instances per Activity) for different sub-groups.
- C**: A list of activities table with columns for Activity Type, Activity Sub-Type, Activity Group, Activity Subgroup, and Activity.
- D**: An activity in tabular format table with columns for ActivityGroup, ActivitySubGroup, Activity, Activity Item Class, Terms, Code List, Role, and Data Type.
- E**: A graph view showing logical connections between activities.
- F**: A detailed instance table for a selected activity.
- G**: A graph view showing physical connections between activities.



Audit Trail



Insights - NeoDash - Audit Trail



- Who changed what when?
 - Library
 - Study

Who

When

Changes

Audit Trail Report

ReadMe Library Audit Trail **Study Audit Trail**

Warning: NeoDash is running with a plaintext password in config.json.

Select User Select Start Date Select End Date

Timestamp	User	Study UID	Action ID	Component UID	Action Type	Component Labels
2024-06-23T07:55:35UTC	unknown-user	Study_000001	170955	N/A	Create	StudyField, StudyTextField
2024-06-21T13:34:17UTC	unknown-user	Study_000001	170952	StudyActivityInstance_000042	Create	StudySelection, StudyActivityInstance
2024-06-21T13:34:13UTC	unknown-user	Study_000001	170950	StudyActivity_000042	Create	StudySelection, StudyActivity
2024-06-21T13:34:12UTC	unknown-user	Study_000001	170948	StudyActivityGroup_000042	Create	StudyActivityGroup, StudySelectionMetadata
2024-06-21T13:34:11UTC	unknown-user	Study_000001	170946	StudyActivitySubGroup_000042	Create	StudyActivitySubGroup, StudySelectionMetadata
2024-06-21T13:34:09UTC	unknown-user	Study_000001	170944	StudySoAGroup_000042	Create	StudySelectionMetadata, StudySoAGroup
2024-06-17T14:38:52UTC	unknown-user	Study_000002	170943	StudyActivitySchedule_000165	Create	StudySelection, StudyActivitySchedule
2024-06-17T14:38:51UTC	unknown-user	Study_000002	170941	StudyActivitySchedule_000164	Create	StudySelection, StudyActivitySchedule
2024-06-17T14:38:50UTC	unknown-user	Study_000002	170939	StudyActivitySchedule_000163	Create	StudySelection, StudyActivitySchedule
2024-06-17T14:38:50UTC	unknown-user	Study_000002	170937	StudyActivitySchedule_000162	Create	StudySelection, StudyActivitySchedule

1-10 of 500

Insights - NeoDash - Audit Trail



- Who changed what when?

- Library
- Study

Study

Changes

From-To

Action ID
170955

Before and After Values per Action ID

Timestamp	Component UID	Property
2024-06-23T07:55:35UTC	N/A	field_name
2024-06-23T07:55:35UTC	N/A	value

Change
study_short_title
Insulin comparison



Data Models



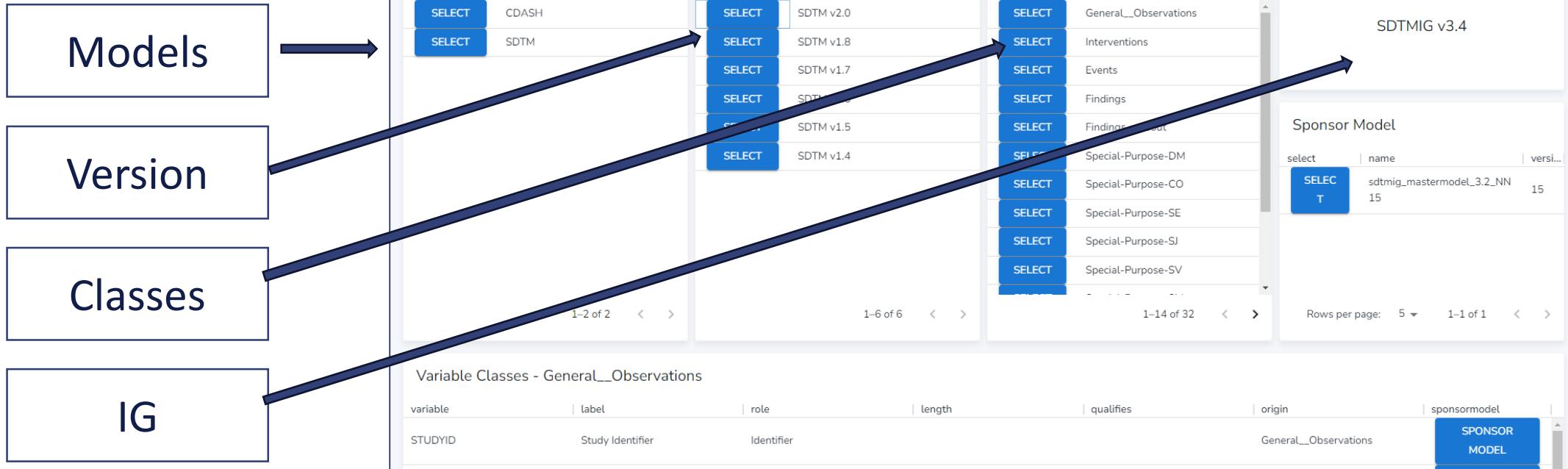
Insights - NeoDash - Data Models



➤ Investigate Data Models

➤ SDTM

➤ Versions



Insights - NeoDash - Data Models



- Investigate Data Models
 - Sponsor Model

Implementation Guide

Domain

Variables

Data Exchange Data Models

ReadMe Catalogues Models Implementation Guides - Excl. CDASH **Sponsor Models** Implementation Guides - CDASH

Available Versions

select	version	extends	name
SELECT	15	SDTMIG v3.2	sdtnig_mastermodel_3.2_NN15

Datasets - 15 - sdtnig_mastermodel_3.2_NN15

select	uid	label	basic_... true	purpose	ig_comment	xml_path
SELECT	DM	Demographics	true	Tabulation	This domain captures subject demographics, with one record for each subject used in the study.	dm.(FileType)
SELECT	TV	Trial Visits	true	Tabulation	The Trial Visits (TV) dataset describes the planned Visits, or "clinical encounters", in a trial.	tv.(FileType)
SELECT	TE	Trial Elements	true	Tabulation	Elements are the building blocks of Arms. Arms consisting of Elements are the paths subjects will follow throughout a trial. All Elements are related to study treatment. Therefore, an Element is defined by the treatment (or lack of treatment) to be administered to subjects during the Element, as well as the planned duration or start/end rules of the Element.	te.(FileType)
SELECT	TA	Trial Arms	true	Tabulation	The Trial Arms dataset provides a record of the complete planned sequence of Elements for each Arm.	ta.(FileType)
--	Subject					

Variables - DM

uid	basic_std	key	label	type	length	displayformat	xmldatatype	xmlcodeles
SR..._RANDOM_GR	false		CDW SRC Randomisation Group	C	25			
STUDYID	true	0	Study Identifier	C	40			
USUBJID	true	1	Unique Subject Identifier	C	60			
DMSPID	false		Sponsor-Defined Identifier	C	40			

Sponsor or CDISC variables, type, comment, ...

submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.

Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications name



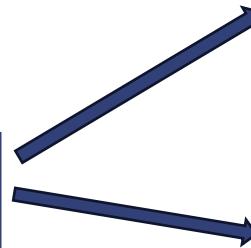
Study Metadata

Insights - NeoDash - Study Metadata



➤ Compare Study Metadata

Select
Study &
Version



Select Base				
Trial ID	Date	Version	Status	Select
CDISC DEV-0	2024-06-17T14:30:30		DRAFT	BASE
CDISC DEV-0	2024-06-17T14:31:47	1	LOCKED	BASE
CDISC DEV-0	2024-06-23T08:23:26	2	LOCKED	BASE
CDISC DEV-0	2024-06-23T08:40:37		DRAFT	BASE
CDISC DEV-0001	2024-06-17T14:37:30		DRAFT	BASE

Select Compare				
Trial ID	Date	Version	Status	Select
CDISC DEV-0	2024-06-17T14:30:30		DRAFT	COMPARE
CDISC DEV-0	2024-06-17T14:31:47	1	LOCKED	COMPARE
CDISC DEV-0	2024-06-23T08:23:26	2	LOCKED	COMPARE
CDISC DEV-0	2024-06-23T08:40:37		DRAFT	COMPARE
CDISC DEV-0001	2024-06-17T14:37:30		DRAFT	COMPARE

Insights - NeoDash - Study Metadata



➤ Compare Study Metadata

Study field comparison			
Study Field	Base	Compare	Diff
Study short title	Insulin comparison	Human insulin comparison	yes

Objectives

1 No differences found
2

Detailed Flowchart compare between base and compare study							
Change Type	Flowchart Group (Base)	Activity Group (Base)	Activity Subgroup (Base)	Flowchart Group (Compare)	Activity Group (Compare)	Activity Subgroup (Compa...)	Activity Detail
Activity added	SAFETY	Vital Signs	Vital Signs				Temperature(Data collection: true)
No change	SUBJECT RELATED INFORMATION	Randomisation	Randomisation	SUBJECT RELATED INFORMATION	Randomisation	Randomisation	Randomized(Data collection: true)
No change	SUBJECT RELATED INFORMATION	End of Study	End of Study	SUBJECT RELATED INFORMATION	End of Study	End of Study	End of Study(Data collection: true)
No change	SUBJECT RELATED INFORMATION	Body Measurements	Body Measurements	SUBJECT RELATED INFORMATION	Body Measurements	Body Measurements	Height(Data collection: true)



Syntax Templates

Insights - NeoDash - Syntax Templates



- Which templates components are in use?

Syntax Template Dashboard

Parameter Template “Compound” → **Select Template Parameter Value**

Used Values → **Select Parameter Value**

Select Template Parameter

templateparameter_name
Compound Start typing...

Select Parameter Value

TemplateParameterTermValue name
Start typing...

Template Parameters

TemplateParameter
Compound

Template Parameter Values

Name	SentenceCaseName
AZD6738	azd6738
Durvalumab	durvalumab
Metformin	metformin
NPH Insulin	nph insulin
Olaparib	olaparib

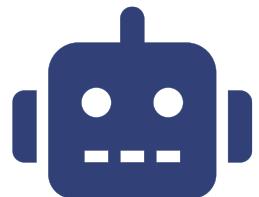
Insights - Options



API

neo4j

Cypher queries



AI
Training & Chat



Insights
Programming

Insights - Options



- Which studies had been using the questionnaire XY?
- Which studies used XY as endpoint?
- Overview of study designs
- Which studies used domain XY?
- How many Placebo studies do we have?
- What are the most common endpoints?
- ...



AI
Training & Chat



Insights
Programming

Agenda



- Introduction
- Initiatives & Vision
- Automation
- Insights
- Summary



Summary



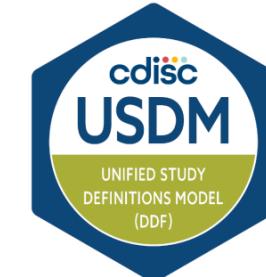
- Various automation and insights opportunities available

- Standard initiatives aiming for automation
 - CDISC 360 Revived
 - TransCelerate Digital Data Flow
 - CDISC CoSMOS (Biomedical Concepts)

- Standardization for Interoperability
 - USDM
 - ICH M11
 - API standards



Digital Data Flow



Summary



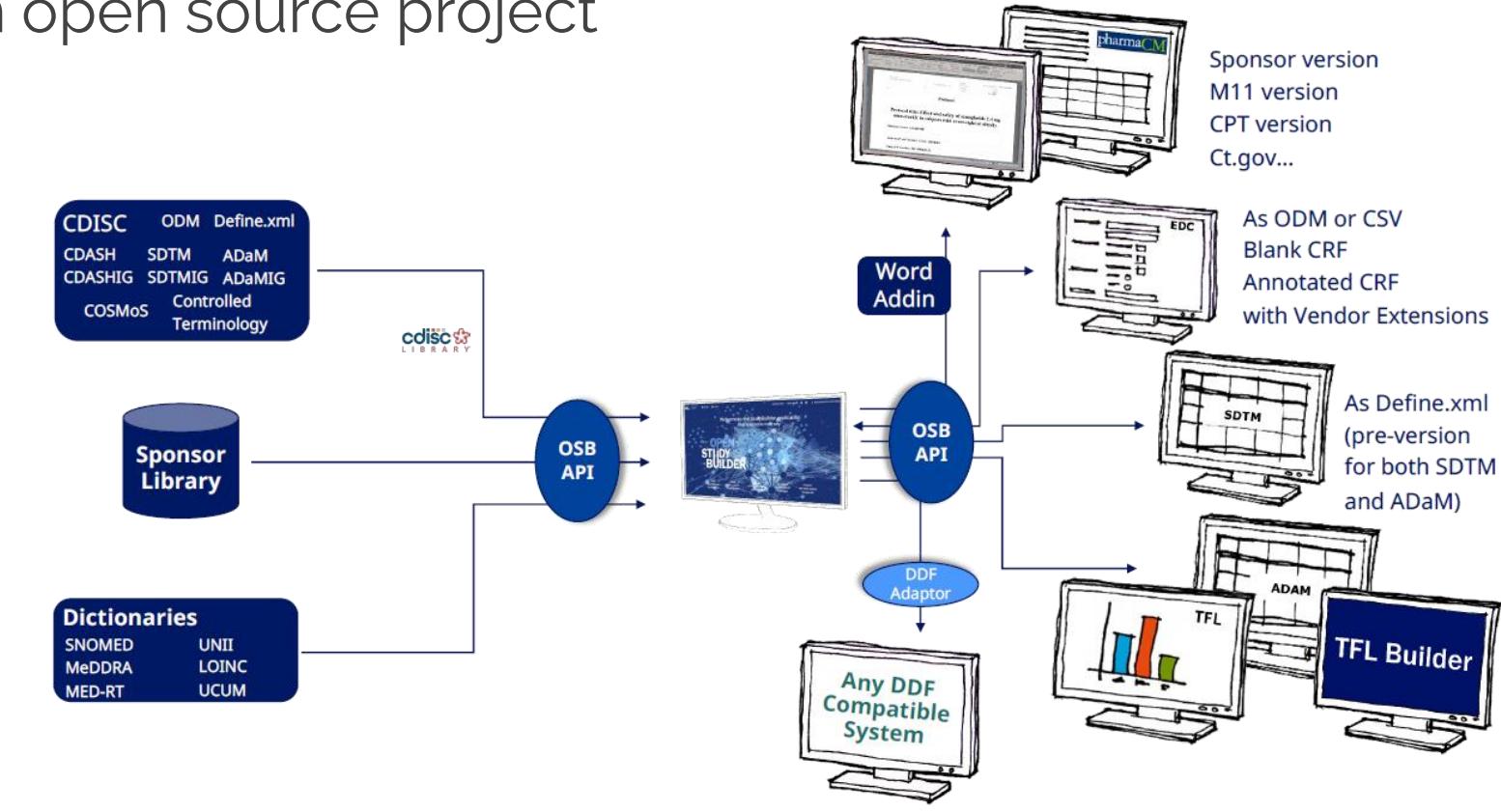
- Cannot be done by one alone
 - Need collaborations & initiatives
 - Must come from industry & partners
-



Summary



- OpenStudyBuilder is one way forward!
 - Benefit from open source project
 - Collaborate

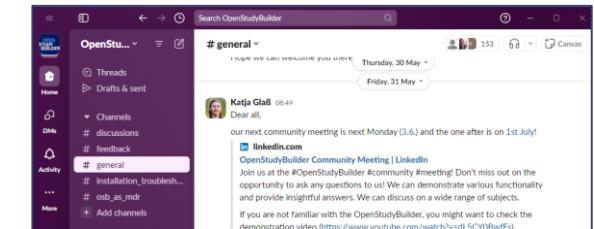
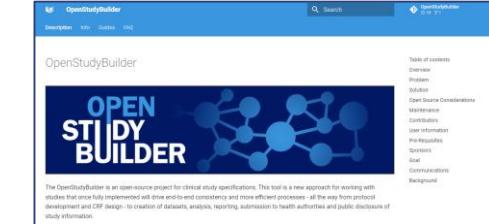


Links



- [Project Homepage](#)
- [Newsletter](#)
- [YouTube Demonstration](#)
- [GitLab \(Solution, Description\)](#)
- [Slack](#)
- E-Mail - openstudybuilder@gmail.com

- Sandbox environment
 - Mail openstudybuilder@neotechnology.com – Subject “Request Sandbox access”



Questions?



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