

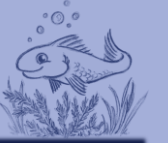
Katja Glass
Consulting

Revolutionizing Clinical Trials

The Impact of
OpenStudyBuilder on
Automation and Insights



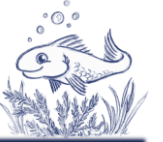
Agenda



- 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



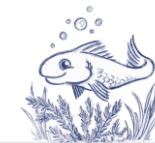
3 Elements

- **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)

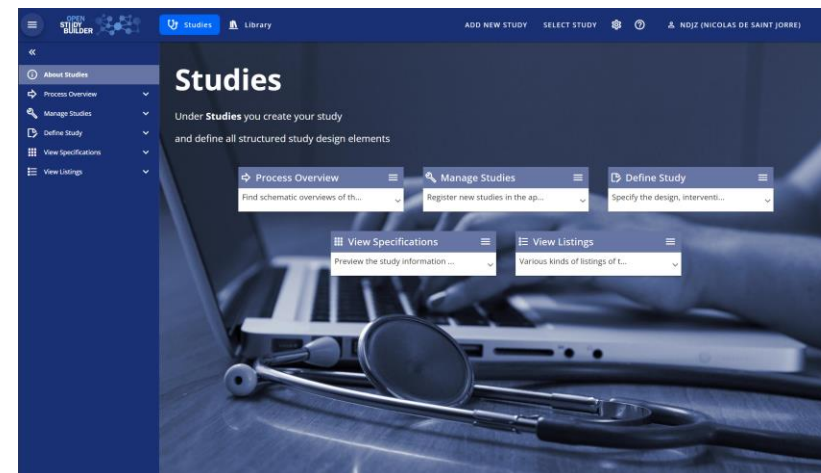


MDR & SDR

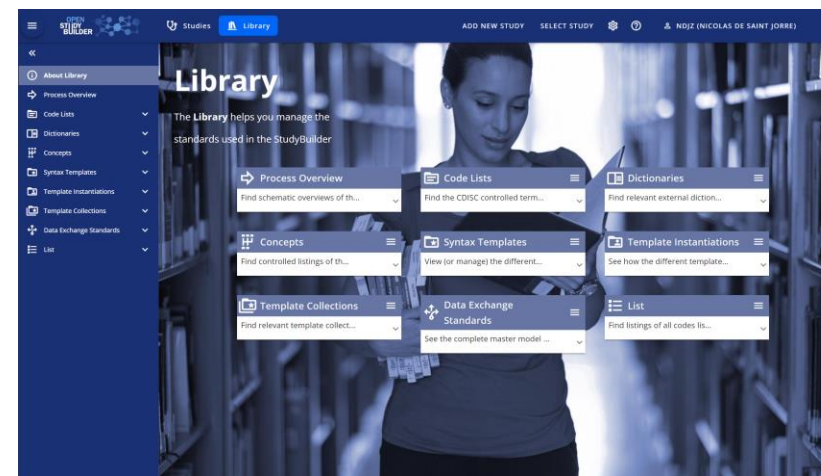
OpenStudyBuilder Components



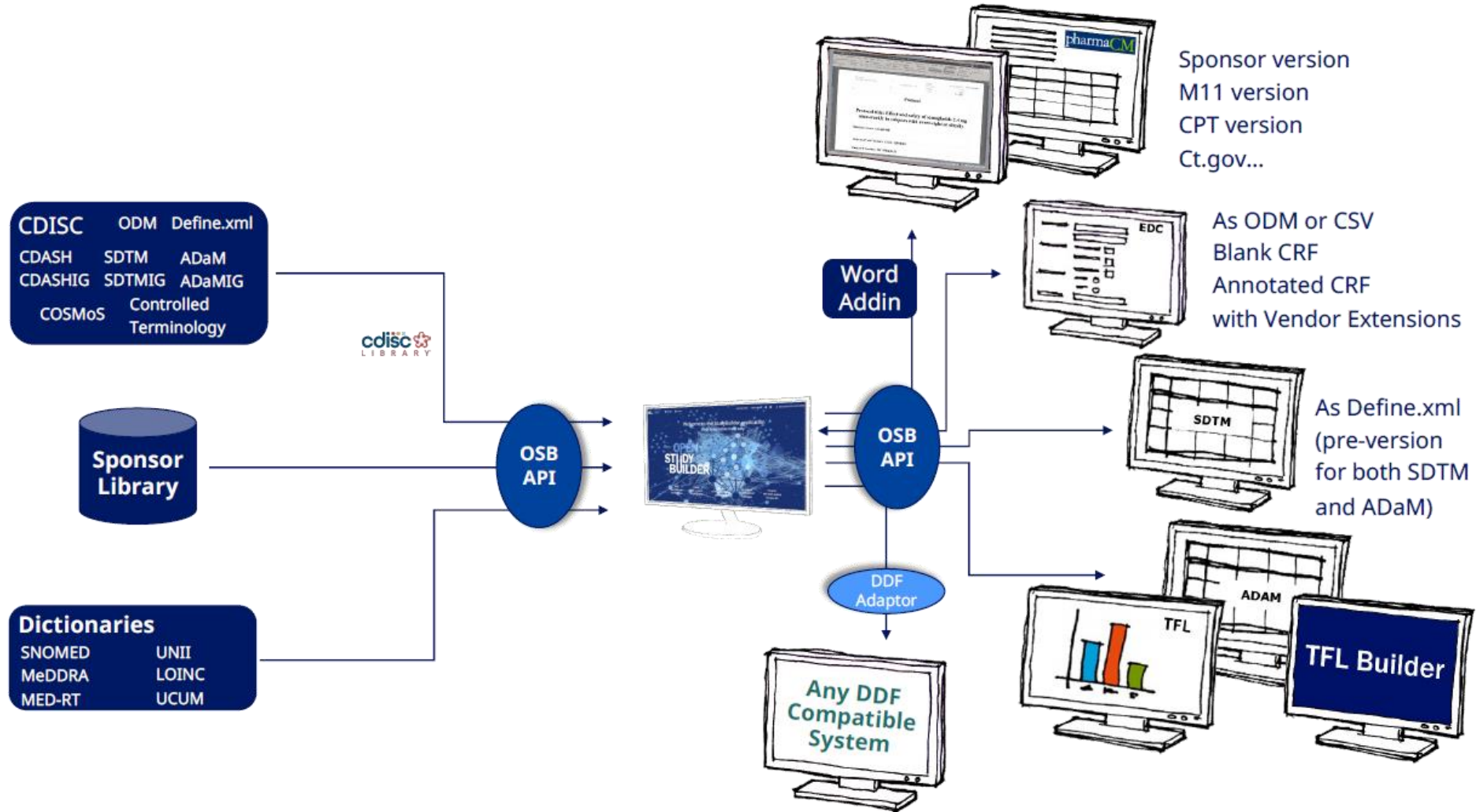
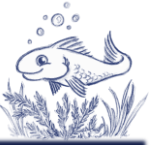
STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



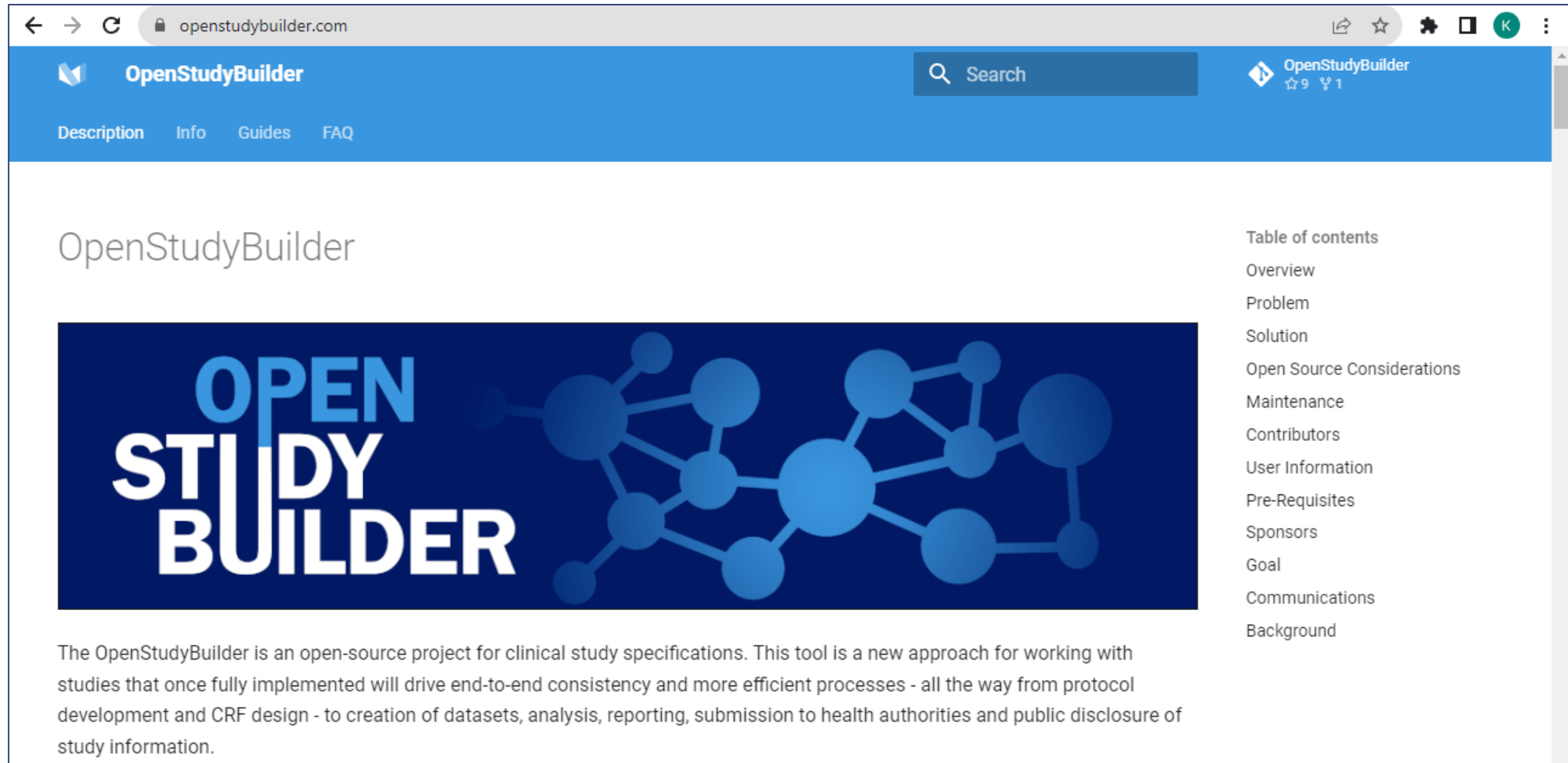
LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	



Connectivity is the key



Project Homepage



The screenshot shows the OpenStudyBuilder project homepage in a web browser. The browser's address bar displays 'openstudybuilder.com'. The page features a blue header with the 'OpenStudyBuilder' logo, a search bar, and navigation links for 'Description', 'Info', 'Guides', and 'FAQ'. Below the header, the text 'OpenStudyBuilder' is displayed. A large banner image contains the text 'OPEN STUDY BUILDER' in white and blue, alongside a network diagram of blue circles and lines. To the right of the banner is a 'Table of contents' list. Below the banner, a paragraph describes the project as an open-source tool for clinical study specifications, highlighting its end-to-end consistency and efficiency from protocol development to public disclosure.

OpenStudyBuilder

**OPEN
STUDY
BUILDER**

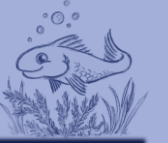
The OpenStudyBuilder is an open-source project for clinical study specifications. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets,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

Table of contents

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

<https://openstudybuilder.com/>

Agenda



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



Vision of Automation & Digitalization



CDISC 360



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

UC1: Create
end-to-start
specification



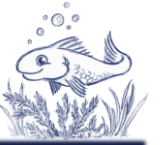
UC2: Generate
start-to-end
metadata



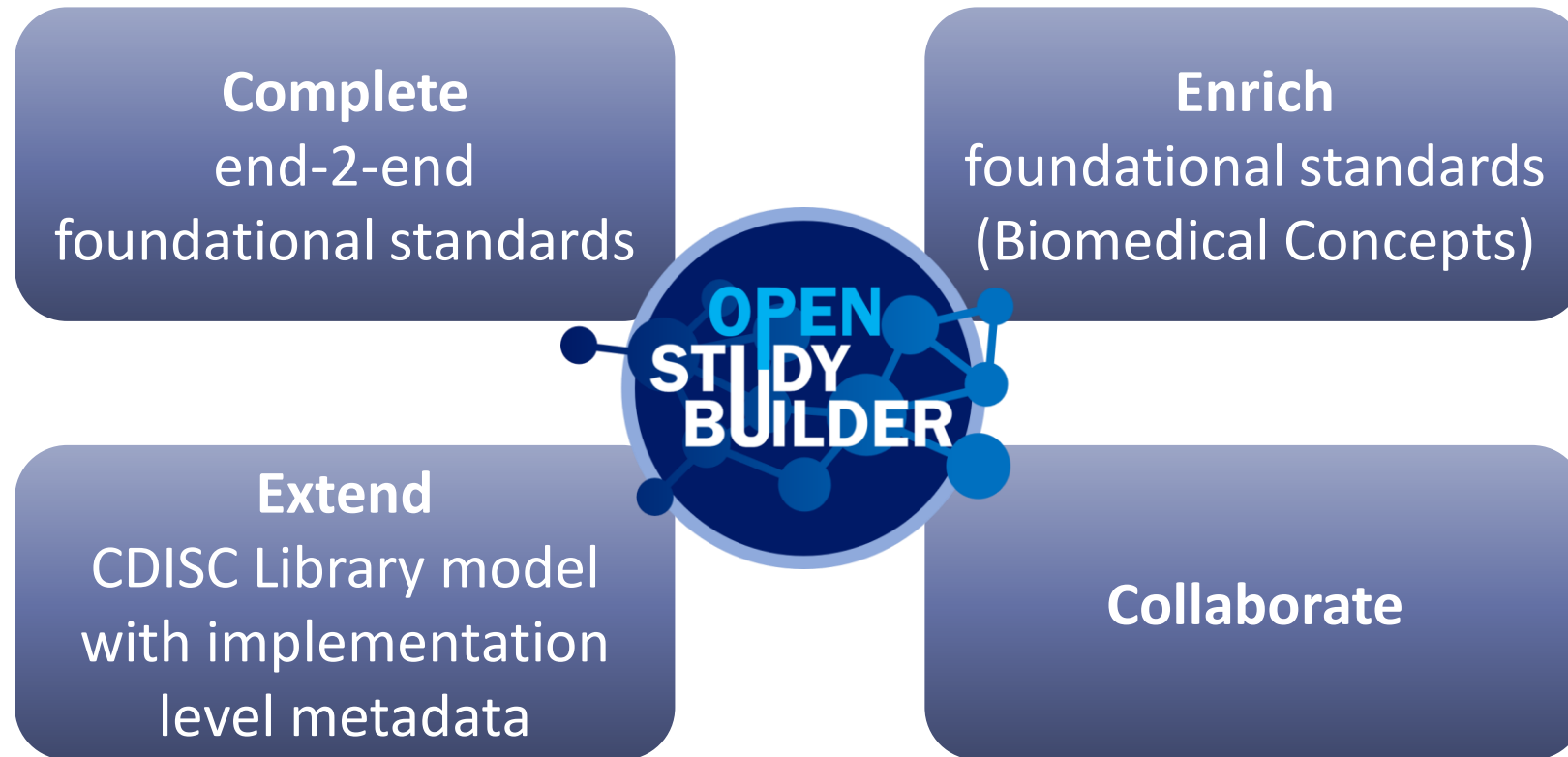
UC3: Transform
data start-to-end



CDISC 360



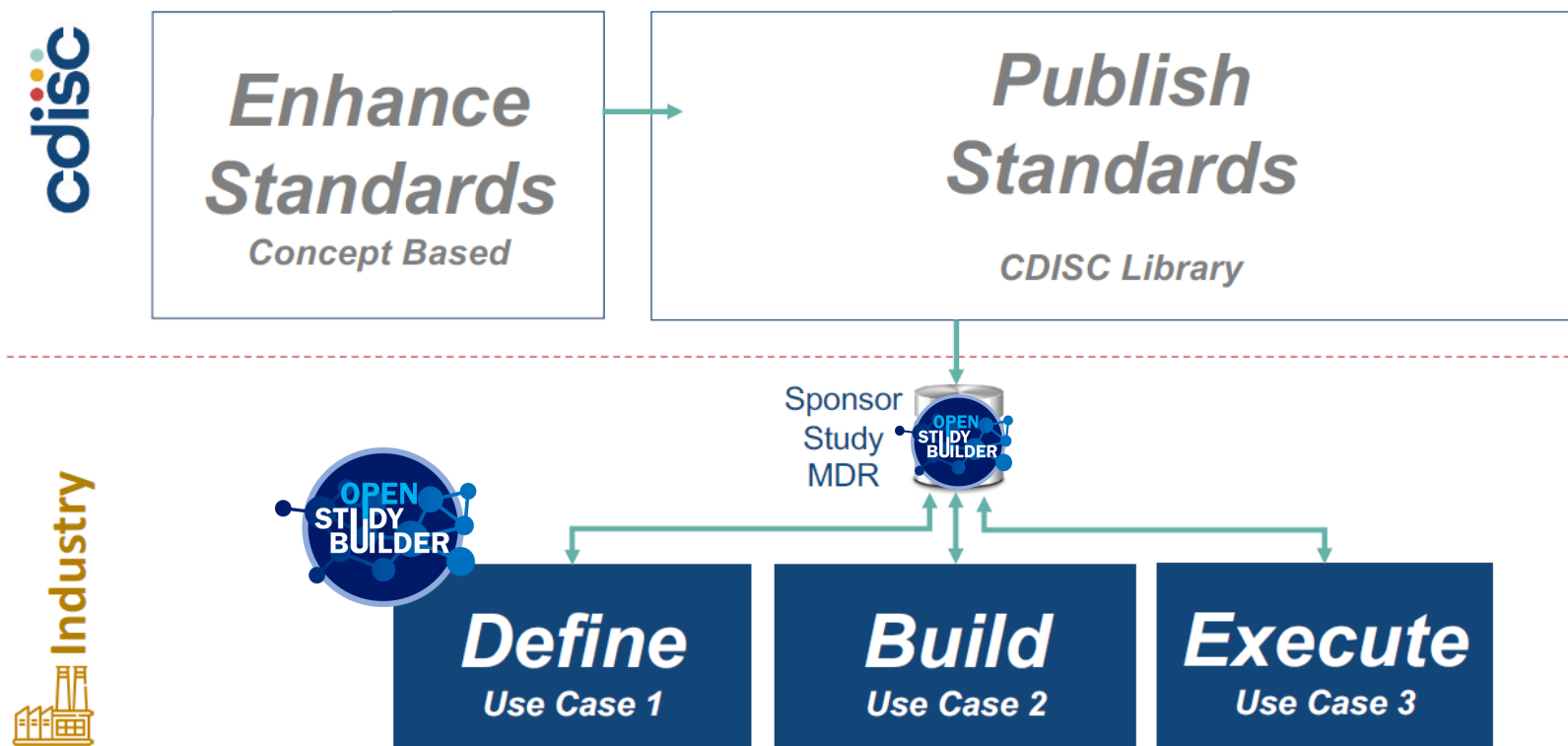
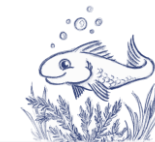
➤ Four pillars of 360 implementation⁽¹⁾



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

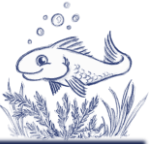


CDISC 360

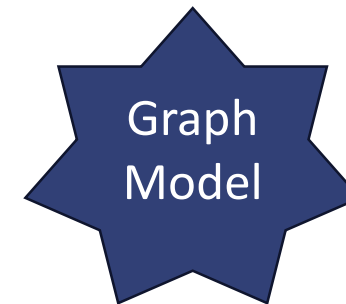




CDISC 360



➤ Outcome



Digital Data Flow (TransCelerate & CDISC)

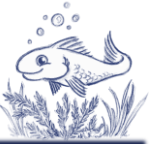


TransCelerate Digital Data Flow Project (DDF)

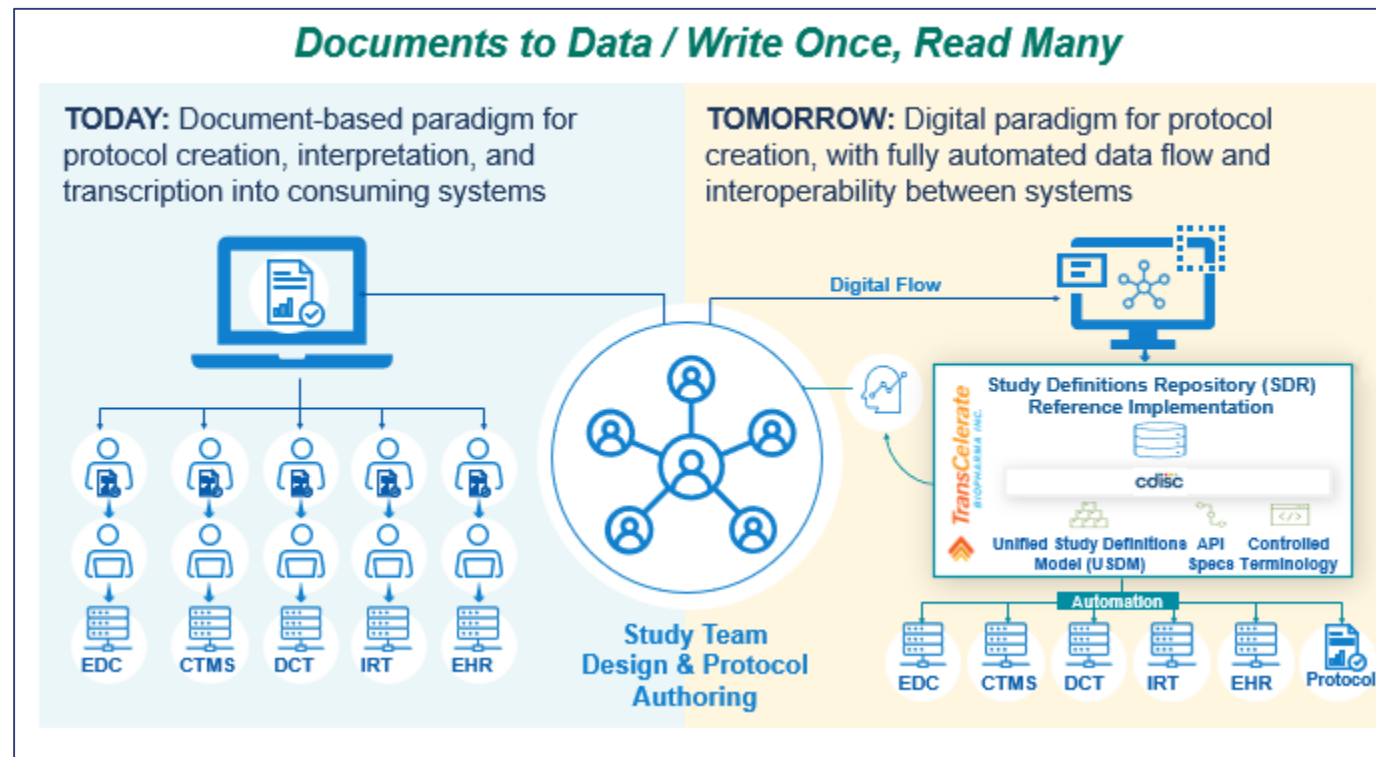


digital workflow that allows for automated creation of study content and configuration of study systems to support clinical trial execution

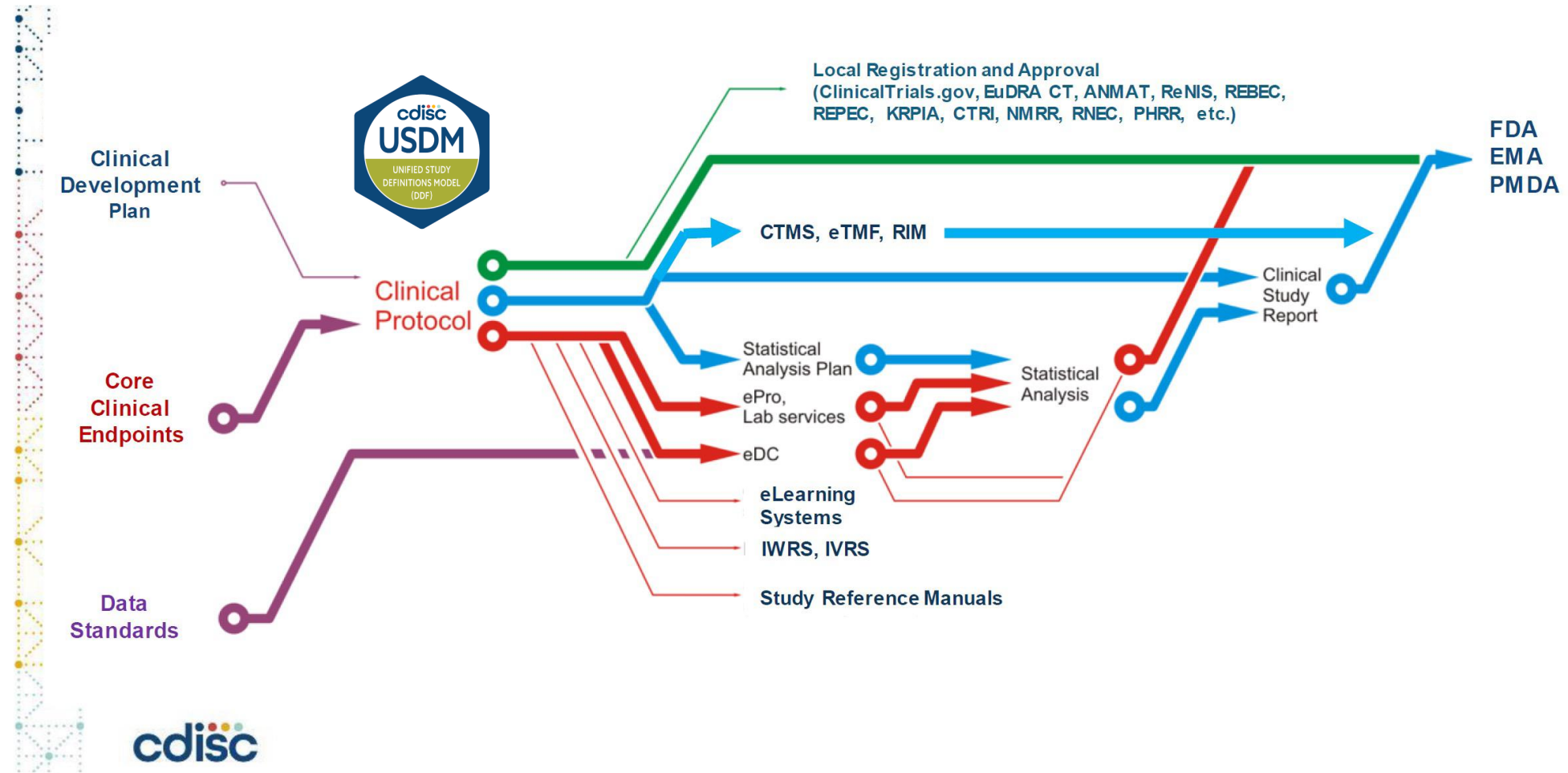
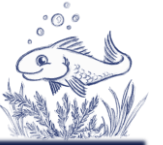
Digital Data Flow (TransCelerate & CDISC)

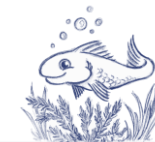


Digital Data Flow Ambition: Breaking the Document Paradigm



Digital Data Flow (TransCelerate & CDISC)





CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

M11

Machine
Readable
Protocol

Number of Arms: [Number of Arms]

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

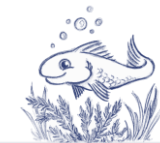
Blinding: The following roles indicated below will not be made aware of the treatment group assignment during the trial: [blinded roles].

Select from the following blinded roles:

- Participant

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

OpenStudyBuilder



Digital Data Flow

Digital Protocol



OPEN
STUDY
BUILDER



+++

define.xml

ICH M11

ODM.xml

OpenStudyBuilder



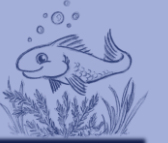
- Support industry standards
- Manage sponsor standards
- Protocol standards
- CRF standards

- Study setup
- Protocol information

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



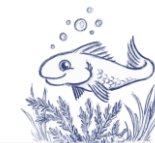
Agenda



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



Automation



Protocol SoA

SoA layout
Protocol SoA

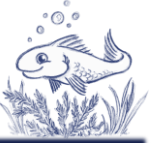
Preferred time unit: ☐ Day ☒ Week



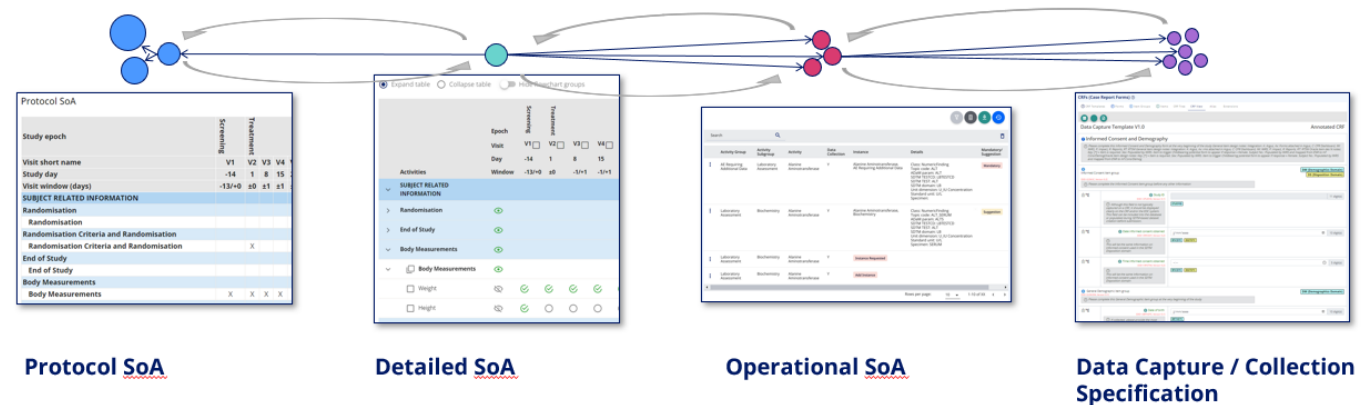
	Screening	Treatment									Follow-up
Visit short name	V1	V2	V3	V4	V5	V6	V7	V9	V10	V11	V8
Study week	-2	1	2	3	4	5	6	7	9	27	6
Visit window (days)	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35
Laboratory Assessments											
Lipids	X	X			X			X		X	
Biochemistry	X	X			X			X		X	
Haematology											
AE Requiring 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
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

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

Vital Signs

Activity subgroup

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



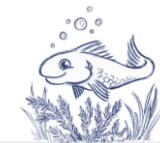
➤ Step 1: Define Standard / Biomedical Concept

<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

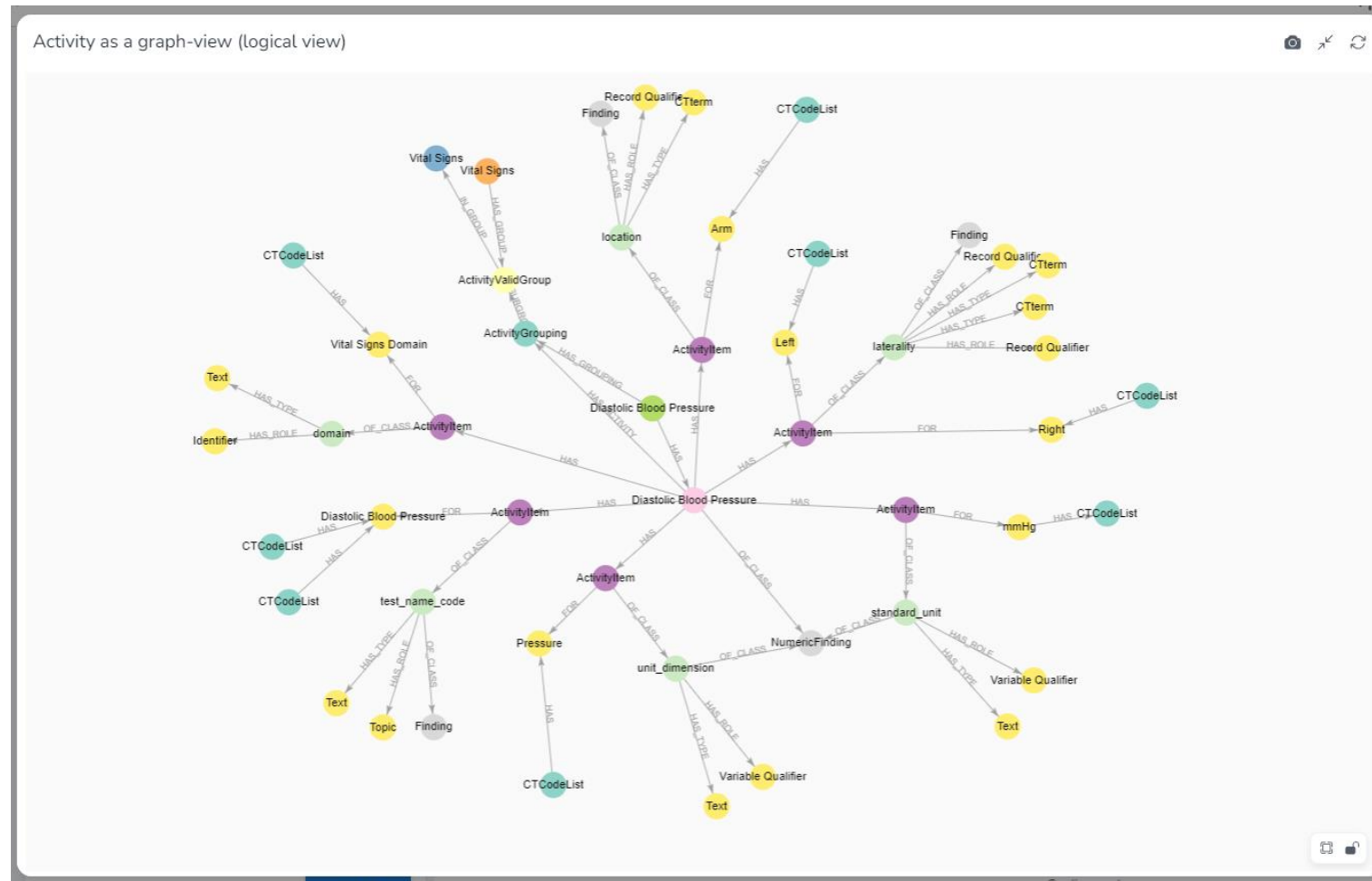
Automation – Define Activity



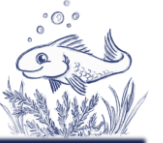
- Same activities, different collection

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



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

Digital Data Flow: Supporting Automation of Case Report Forms

An Introduction to Biomedical Concepts

Biomedical Concepts

Refer to some type of discrete biomedical or health information that can be measured or observed for a participant of a clinical trial

Example: Systolic Blood Pressure

Defines what

Position
Sitting

Location
Arm

Laterality
Left

Result
120

Units
mmHg

Ansehen auf YouTube

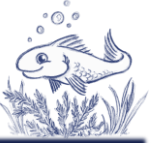
An Introduction to
Biomedical Concepts

<https://youtu.be/otGpj8g5gxY>



Select Activity

Automation – Select Activity



- Select activities according protocol needs (Medical Writer)

Study Activities (CDISC DEV-0) ⓘ

Study Activities Detailed SoA SoA footnotes Protocol SoA Activity Instructions

☐ Select rows

Search 🔍

➡ + 🔍 📄 ⬇️ ↻

#	Library	SoA group	Activity group	Activity subgroup	Activity	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

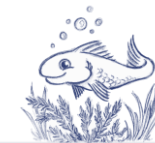
-

[illegible]



Apply in Protocol

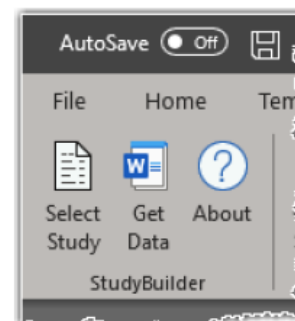
Automation – Apply Activity



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

Get Data

Currently saved: INS-007

☐ Select all

- ☒ Protocol Title
- ☐ Universal Trial Number
- ☐ EudraCT Number
- ☐ IND Number
- ☐ StudyBuilder Flowchart
- ☐ Objectives & Endpoints
- ☐ Inclusion Criteria
- ☐ Exclusion Criteria

Update Close

Automation – Apply Activity



File Home Novo Nordisk Insert Design Layout References Mailings Review View **NN StudyBuilder** Help

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

StudyBuilder

Protocol
Study ID: CDISC DEV-0

1.2 Flowchart
Schedule of Activities

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

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

Page 9 of 75 58621 words English (United Kingdom) Accessibility: Investigate Display Settings Focus 120 %

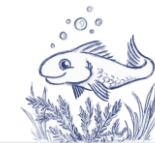
Select „Schedule of Activities“

Update



Define Collection Details

Automation – Define Activity Instance



Data Specifications

«

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

Studies / Define Study / Data Specifications / Study Activity Instances

Study Data Specifications (CDISC DEV-0)

Study Activity Instances Operational SoA

☐ Select rows

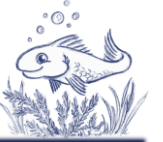
Search

Activity

Instance

SoA gro	Activity group	Activity subgroup	Activity	Data collection	Instance	Topic cod
	Assessments				g/L	
	Laboratory Assessments	Haematology	Hematocrit	Yes	Haematocrit Blood	HAEMATC
	Adverse Event	Adverse Event	Adverse Event	Yes	Adverse Event	ADVERSE
	Vital Signs	Vital Signs	Pulse			PULSE
	Vital Signs	Vital Signs	Diastolic Blood Pressure			BP_DIAST
	Vital Signs	Vital Signs	Systolic Blood Pressure			BP_SYSTO
	Medical History/Concomitant Illness	Medical History/Concomitant Illness	Medical History/Concomitant Illness	Yes	Medical History/Concomitant Illness	MEDICAL_
	AE Requiring Additional Data	Acute Kidney Injury	Acute Kidney Injury	Yes	Add Instance	

Automation – Define Activity Instance



Edit/Add Activity instance(s)

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

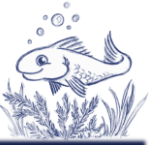
Instance	Details	State
No data available		

Work in
Progress



Use Activity Information

Automation – Use Activity



➤ CRF & aCRF & ODM.xml

Vital signs [ItemGroup] VS (Vital Signs Domain)

[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)
		VSDTC		
	Systolic blood pressure [OID=I.SYSBP, Version=0.1]	3 digit(s)	Unit	☐ mmHg [OID=mmHg, Version=1.0]
	<i>ⓘ Please collect the systolic blood pressure of the subject</i>	VSORRES where VSTESTCD=SYSBP, VSORRESU where VSTESTCD=SYSBP		
	Diastolic blood pressure [OID=I.DIABP, Version=0.1]	3 digit(s)	Unit	☐ mmHg [OID=mmHg, Version=1.0]
	<i>ⓘ Please collect the diastolic blood pressure of the subject</i>	VSORRES where VSTESTCD=DIABP, VSORRESU where VSTESTCD=DIABP		



Partially working,
additional work in
Progress

```
<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>
```

Automation – Use Activity



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



The screenshot displays the Clinical One EDC system interface for a subject named 001-002. The interface includes a top navigation bar with links to Home, Subjects, Supplies, Reports & Archives, and Analytics. Below this, there are tabs for Subject, Adverse Event, Current Visit, and Previous Visits. The main content area shows a form for the current visit, with sections for Date of Visit, Informed Consent and Demography, and Vital Signs. The Date of Visit section includes fields for Date of Visit and Date of informed consent obtained. The Informed Consent and Demography section includes fields for Subject No. [read-only], Date of birth, Age, Sex, Ethnicity, and Race. The Vital Signs section includes fields for Were vital signs performed? and Date of examination. A sidebar on the left contains a list of forms, and a sidebar on the right contains a Question Hint section and a list of rules.

Proof of Concepts
available

Automation – Use Activity



➤ Download mapping specification (define.xml)



CDISC SDTM 3.2

- Annotated Case Report Form
- Tabulation Datasets
- 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 CDISCILOT SDTM datasets
Protocol Name	TDF_Datasets
Metadata Name	Study TDF_SDTM Data Definitions
Metadata Description	Test datasets created by updating existing CDISCILOT SDTM datasets

Date of Define-XML document generation: 2018-11-19T08:39:20

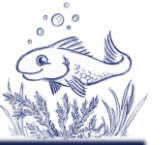
Stylesheet version: 2015-01-16

Tabulation Datasets for Study TDF_SDTM (CDISC SDTM 3.2)

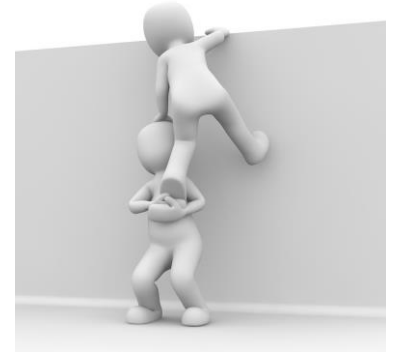
Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt	
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCOD	te.xpt	
TI	Trial Inclusion/Exclusion 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, ETCOD	se.xpt	
SV	Subject Visits	SPECIAL PURPOSE	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, VISITNUM	sv.xpt	

Work in Progress

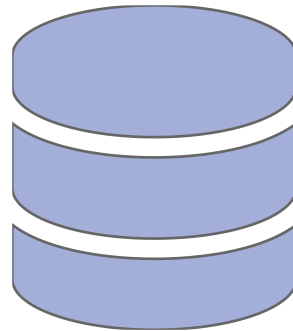
Automation – Use Activity



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



TestData

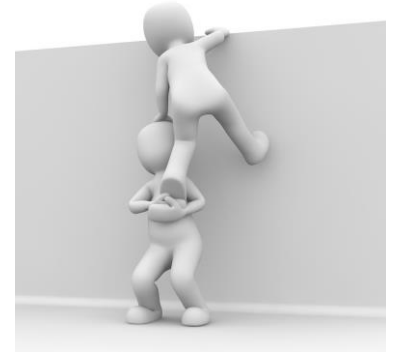


Out of Scope for
OpenStudyBuilder

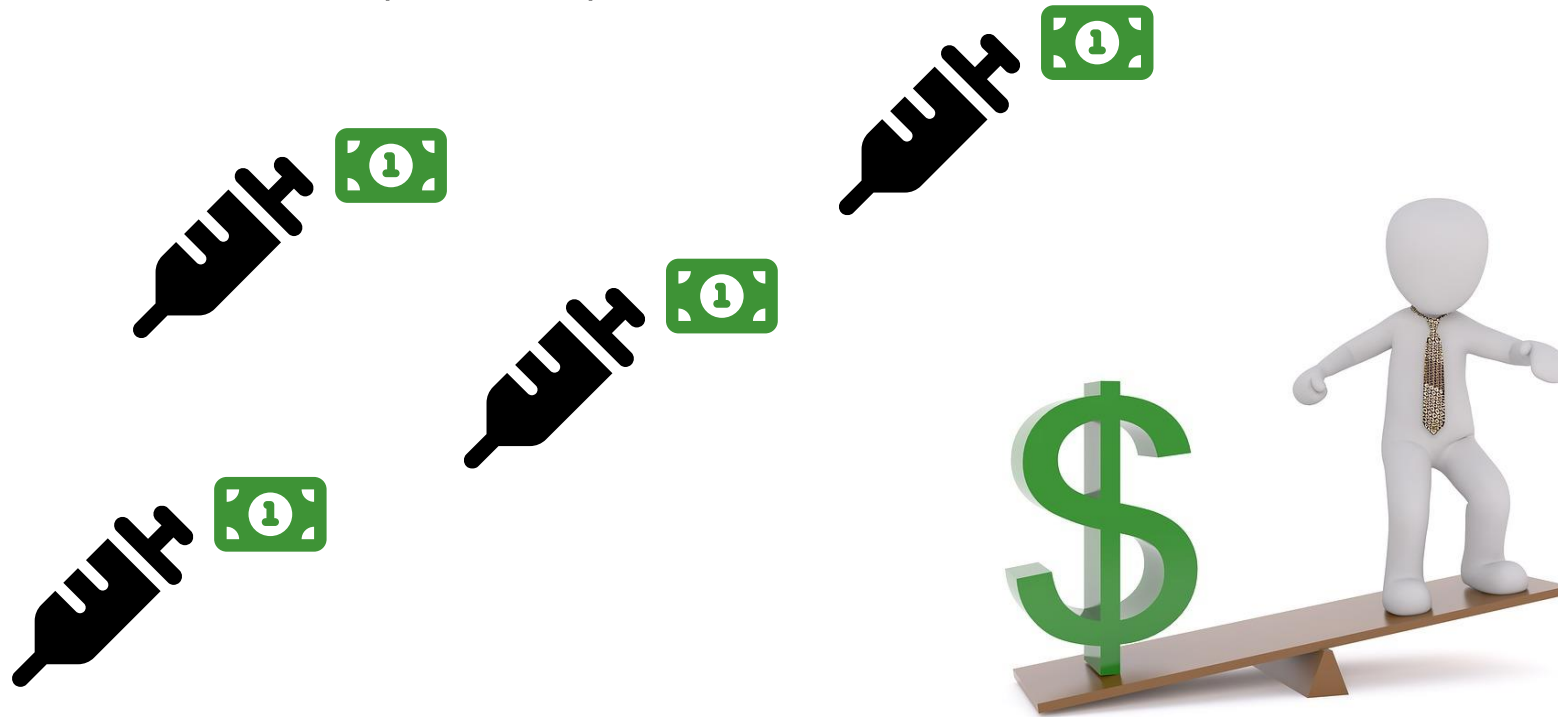
Automation – Use Activity



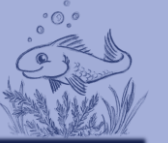
- Use to Cost / Patient Burden
 - Enhance with additional information
 - Cost per test per visit



Out of Scope for
OpenStudyBuilder

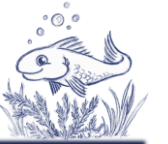


Agenda



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





One-Stop-Shop

Study Information

Trial Domains

CRF/EDC
Specification

Data Models

Standards &
Harmonization

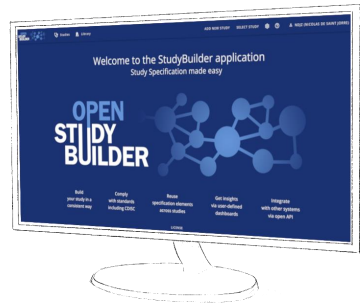
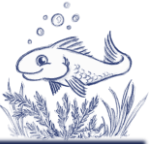
Mapping
Specification

Biomedical Concepts

...

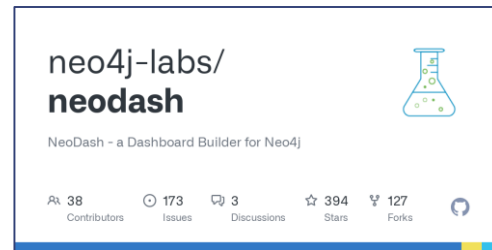


Insights



User Interface

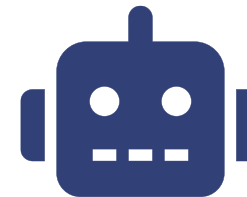
neo4j
Cypher queries



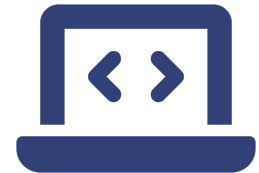
Dashboard



API

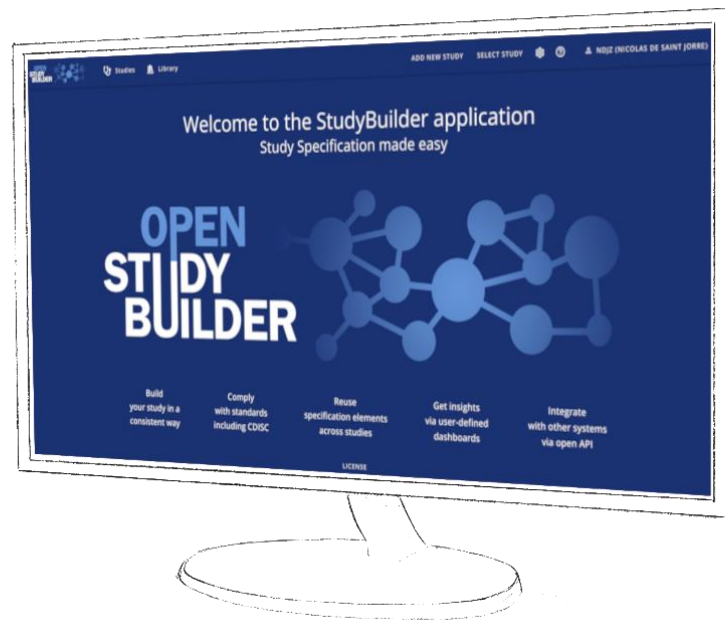
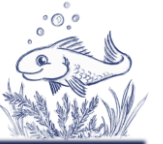


AI
Training & Chat

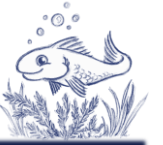


Insights
Programming

Insights – User Interface



Insights – User Interface



Changes for
CDISC CT
Packages

Controlled Terminology Packages History

ADAM CT	CDASH CT	COA CT	DDF CT	DEFINE-XML CT	GLOSSARY CT	PROTOCOL CT	QRS CT	QS-FT CT	SDTM CT	
2023-06-30	2023-03-31	2022-06-24	2021-12-17	2020-11-06	2020-06-26	2020-03-27	2019-12-20	2019-03-29	2018-12-21	
<	☒	☐	☐	☐	☐	☐	☐	☐	☐	>

Sho ☒ Submission value (default)
☐ Code list code
☐ Sponsor name

From 2022-06-24 To 2023-06-30

New code lists **2**

2023-03-31

NEWS1PC^C NEWS1PN^C

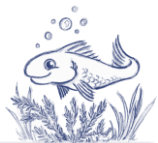
Changed code lists **3**

2023-03-31 2023-06-30

NEWS1PC^T NEWS1PN^T DTYPE^T

Deleted code lists **0**

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
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

Search



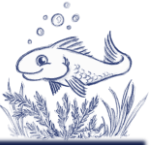
	Library	Template	Objective
	User Defined	Time from randomisation to all cause death	Time from randomisation to all cause death
	User Defined	Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable	Time to first occurrence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

History

Display studies using this objective

Display studies
using this objective

Insights - NeoDash



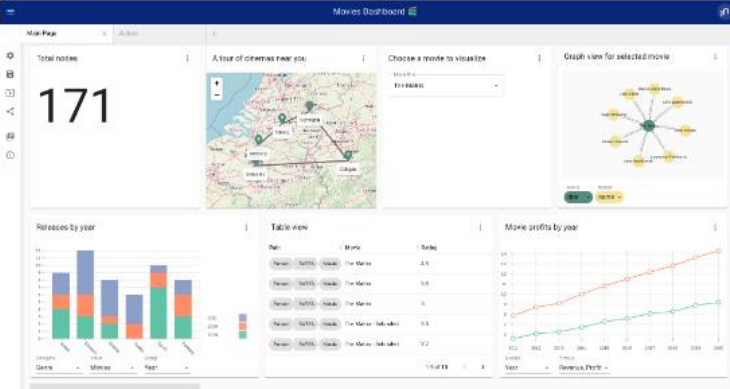
 Labs

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](#)

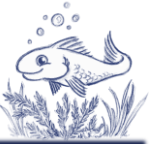
Learn

Free Neo4j courses from GraphAcademy

Learn everything you need to know to be successful with Neo4j

[Start learning](#)

Insights - NeoDash



neo4j Labs neo4j://localhost:5002

Dashboards

Search...

Activity Library Dashboard

Audit Trail Report

Data Exchange Data Models

Study Metadata Comparison

Syntax Template Dashboard

Activity Library Dashboard

ReadMe Activity Lib (search top-down) Activity Lib (search bottom-up) Activity to SDTM

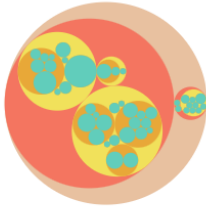
Warning: NeoDash is running with a plaintext password

Search Activity Instance

Guide

This report is for browsing Activity Concepts
It displays the Activity Concepts available in the StudyBuilder Library.
Follow the tabs to see different views of the concepts.
For more information on activity concepts you can read this [article on Biomedical Concepts/Activity Concepts](#)

Groupings of Activities



Number of Activities and instances

Number of Activities
Number of Activity Instances

Path Value

Grouping Activities

1-1 of 1

Activity Library Dashboard

Audit Trail Report

Data Exchange Data Models

Study Metadata Comparison

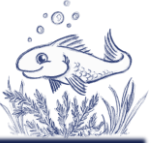
Syntax Template Dashboard

Menu

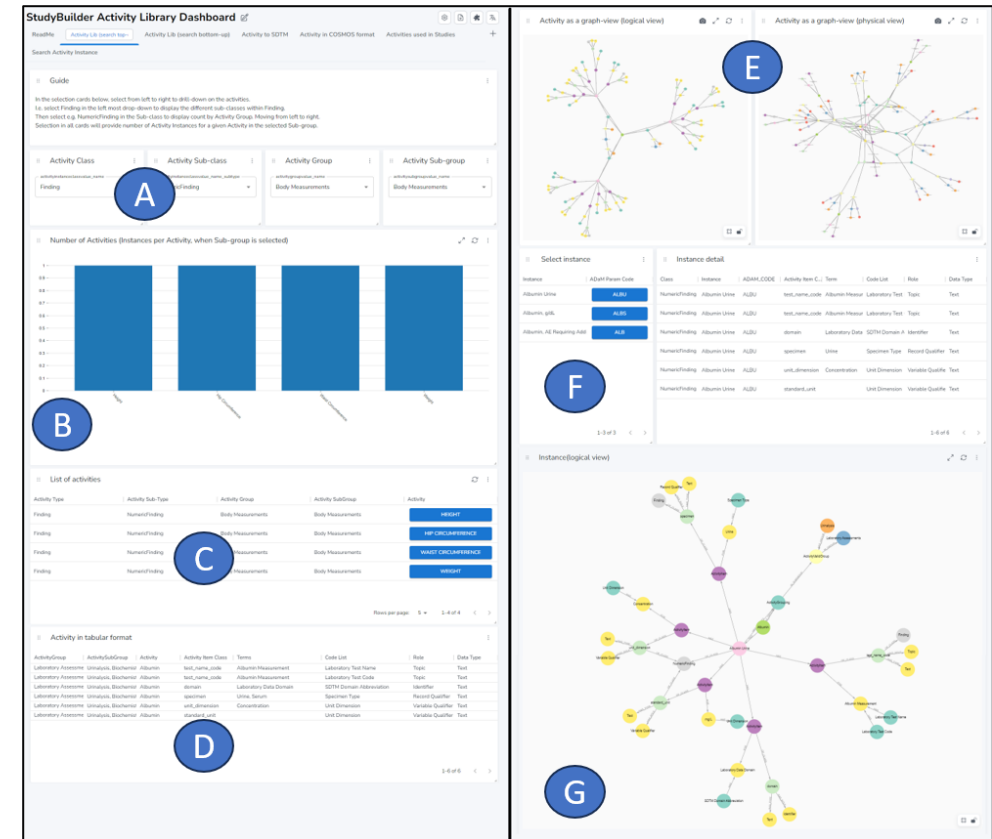


Activities

Insights – NeoDash – Activities



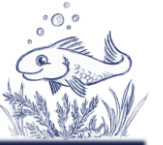
- Which biomedical concepts exist?
- Which activities are used?
- How map activities in SDTM?





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 ⓘ
User Initials
unknown-user ▼

Select Start Date ⓘ
YYYY-MM-DD
2015-01-01

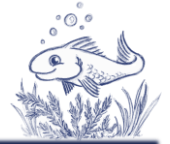
Select End Date ⓘ
YYYY-MM-DD
2024-08-01

Action Table ⓘ ↺

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

Select Study UID

Study Name	Study UID
CDISC360-2	STUDY_000001
DDF-SampleData-0001	STUDY_000002

Actions Table by unknown-user on Study_000001

Timestamp	Action ID	Component UID	Action Type
2024-06-23T07:55:35UTC	170955	N/A	Create
2024-06-21T13:34:17UTC	170952	StudyActivityInstance_000042	Create
2024-06-21T13:34:13UTC	170950	StudyActivity_000042	Create
2024-06-21T13:34:12UTC	170948	StudyActivityGroup_000042	Create
2024-06-21T13:34:11UTC	170946	StudyActivitySubGroup_000042	Create
2024-06-21T13:34:09UTC	170944	StudySoAGroup_000042	Create
2024-06-17T14:37:30UTC	170588	StudyActivitySchedule_000132	Create
2024-06-17T14:37:29UTC	170586	StudyActivitySchedule_000131	Create
2024-06-17T14:37:29UTC	170584	StudyActivitySchedule_000130	Create

Change Visualisation

StudyRoot Create StudyAction StudyField StudyTextFI...

uid (lab... (lab... (lab... (lab...

Action ID

170955

Before and After Values per Action ID

Timestamp	Component UID	Property	Old Value	New Value
2024-06-23T07:55:35UTC	N/A	field_name		study_short_title
2024-06-23T07:55:35UTC	N/A	value		Insulin comparison

Change

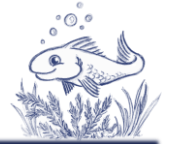
study_short_title

Insulin comparison



Data Models

Insights – NeoDash – Data Models



➤ Investigate Data Models

➤ SDTM

➤ Versions

Models

Version

Classes

IG

Data Exchange Data Models

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

Available Models

select	model
SELECT	CDASH
SELECT	SDTM

SDTM Model Versions

select	version
SELECT	SDTM v2.0
SELECT	SDTM v1.8
SELECT	SDTM v1.7
SELECT	SDTM v1.6
SELECT	SDTM v1.5
SELECT	SDTM v1.4

Classes - SDTM v2.0

select	class
SELECT	General__Observations
SELECT	Interventions
SELECT	Events
SELECT	Findings
SELECT	Findings - Result
SELECT	Special-Purpose-DM
SELECT	Special-Purpose-CO
SELECT	Special-Purpose-SE
SELECT	Special-Purpose-SJ
SELECT	Special-Purpose-SV

SDTM v2.0 Impl. by:

SDTMIG v3.4

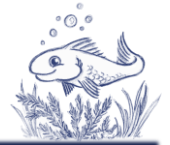
Sponsor Model

select	name	versi...
SELECT	sdtmig_mastermodel_3.2_NN	15

Variable Classes - General__Observations

variable	label	role	length	qualifies	origin	sponsormodel
STUDYID	Study Identifier	Identifier			General__Observations	SPONSOR MODEL

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	sdtmig_mastermodel_3.2_NN15

Datasets - 15 - sdtmig_mastermodel_3.2_NN15

select	uid	label	basic...	purpose	lg_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)
SELECT	Subject					

Variables - DM

uid	basic_std	key	label	type	length	displayformat	xml_datatype	xmlcode
SRC_RANDOM_GRP	false		CDW SRC Randomisation Group	C	25		text	
STUDYID	true	0	Study Identifier	C	40		text	
USUBJID	true	1	Unique Subject Identifier	C	60		text	
DMSPID	false		Sponsor-Defined Identifier	C	40		text	

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



Study Metadata

Insights – NeoDash – Study Metadata



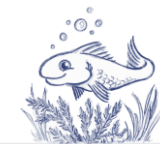
➤ Compare Study Metadata

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

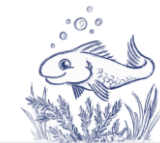
- 1 No differences found
- 2

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 (Compare)	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?

Parameter
Template
“Compound”

Used Values

Syntax Template Dashboard

ReadMe Select Template Parameter Value Parent Templates Pre-instance Templates All Templates Template Instantiations Study Usage Templates by Library

Select Template Parameter

templateparameter_name

Compound ✕ Start typing...

Select Parameter Value

TemplateParameterTermValue name

Start typing...

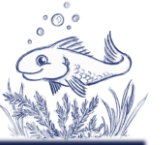
Template Parameters

TemplateParameter
Compound

Template Parameter Values

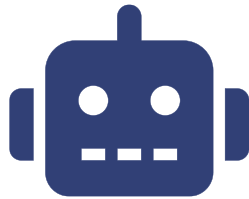
Name	SentenceCaseName
AZD6738	azd6738
Durvalumab	durvalumab
Metformin	metformin
NPH Insulin	nph insulin
Olaparib	olaparib

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?
- ...

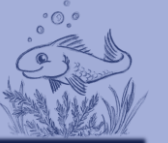


AI
Training & Chat



Insights
Programming

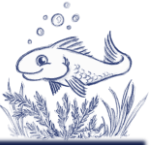
Agenda



- 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



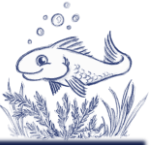
Summary



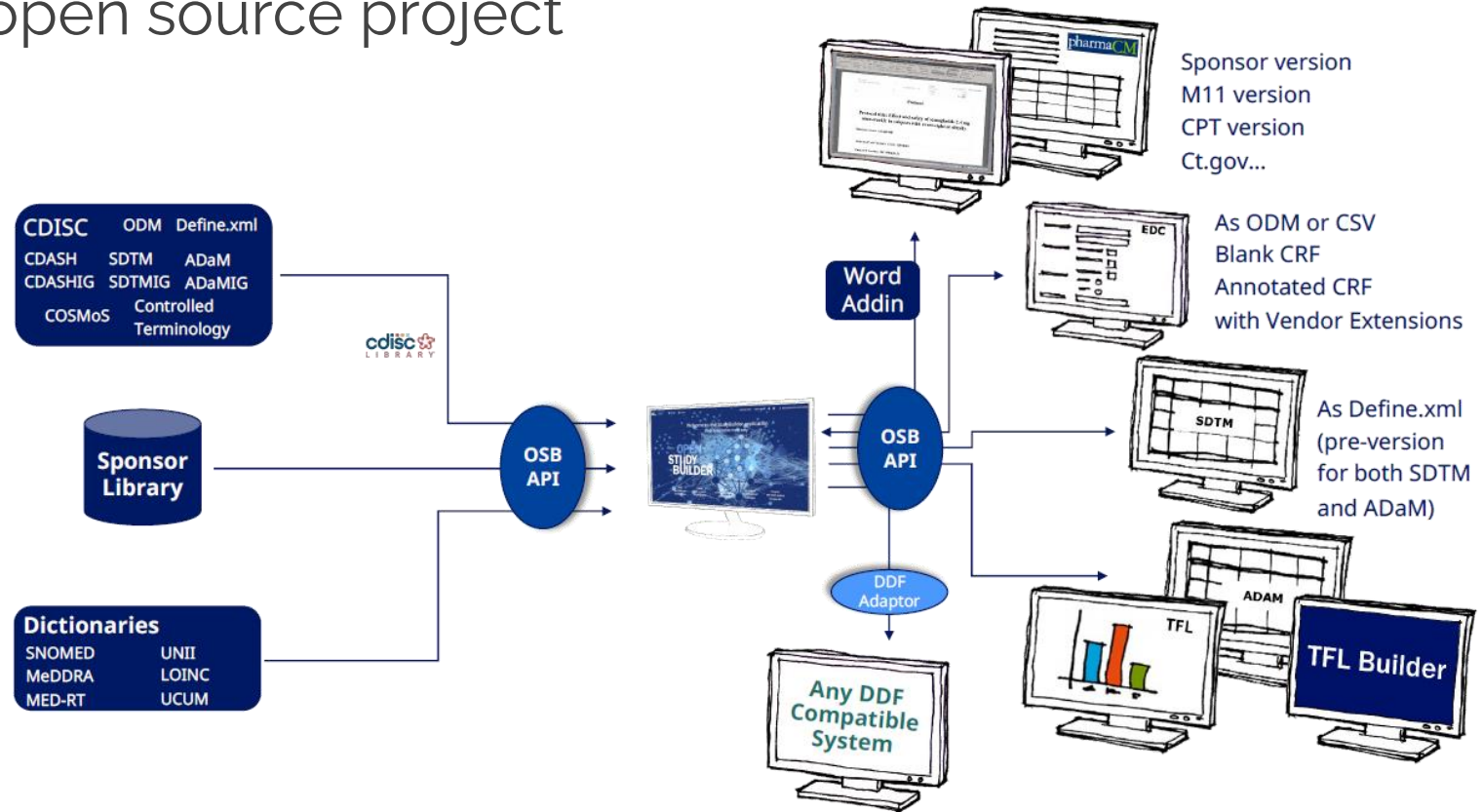
- Cannot be done by one alone
- Need collaborations & initiatives
- Must come from industry & partners



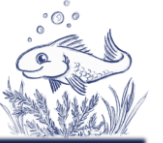
Summary



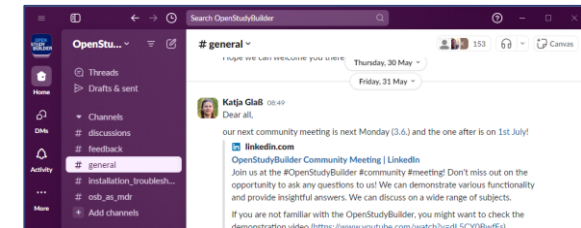
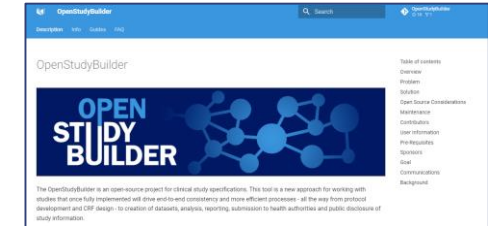
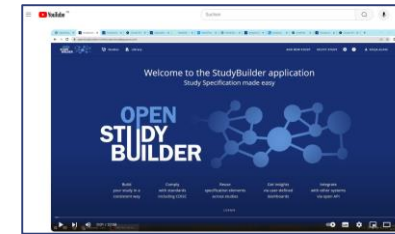
- OpenStudyBuilder is one way forward!
 - Benefit from open source project
 - Collaborate



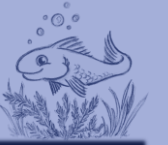
Links



- [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?



Katja Glass Consulting

info@glacon.eu

www.glacon.eu

www.glacon.eu/portal
