Xybion®

Electronic Nonclinical Protocol Design for Sharing Between Systems

Webinar Agenda

1. Introduction
2. Protocol Automation Needs
3. Solutions
4. Nonclinical Study Design vs Clinical Study Design
5. Collaboration
6. Questions & Answers

Introduction

Meet The Presenters

Presenter

Bob Friedman
Chief Technologist & Chief Solution Architect

Xybion®

Experience

- Over 30 years of experience in life sciences
- Former employee of the New York State Department of Health, Synthes USA, NYU Medical Center

Membership

- Active member of CDISC SEND standards consortium
- Active member of PhUSE / FDA Industry Collaboration

Education

- Master of Engineering, Biomedical Engineering, Rensselaer Polytechnic Institute
- Bachelor of Engineering, Biomedical Engineering, Rensselaer Polytechnic Institute

Meet The Presenters

Presenter

Nicolas de Saint Jorre
Product Architect
OpenStudyBuilder

novo nordisk®

Experience

- Over 27 years of experience in Clinical Research, with 23 years in Computer Sciences (with EDC systems)
- Expert in CDISC Models (with specialisation around CDASH, SDTM, ODM, Define and CT)

Membership

- Active member of CDISC Protoco CT team / ODM reviewer
- Active member of DMB
- Active member of the French CDISC User Group

Education

- Computer Engineer Diploma (CNAM)

If you have any question re: OpenStudyBuilder
ndjz@novonordisk.com

Meet the Presenter

Presenter

Paul Auspitz

Director of
Preclinical Solutions and SEND services
Xybion Digital
Pauspitz@xybion.com

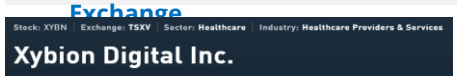
- Experience
  - Graduate of Thomas Jefferson University with a BS degree in Finance and IT Systems Management. 25-year track record of success as a trusted digital solution expert and advisor to business leaders in highly regulated research driven organizations.
  - Currently serving as Director of Preclinical Solutions and SEND services for Xybion Digital. Before his current role at Xybion Paul spent 5 years in a similar role with Instem, Plc. Additional noteworthy experience includes SAP EWM, SCM, and serialization consulting, MS 365 Business and Operations solution sales
  - years of successfully helping organizations address and manage SEND across preclinical R&D business's with Instem and Xybion.
- Education
  - BS Finance and Management Information Systems

Xybion®

Xybion Corporation: Value Creator for 40+ Years

Established worldwide

- Founded in 1977
- 170+ Customers
- Clients in 25 countries
- Work with almost all top 25 pharma companies worldwide
- Headquartered in Princeton, NJ
- US Patent in 2021 on predicting compliance risks
- Xybion Digital Inc., Listed in 2021 at Toronto Venture Exchange



European Operations

- **Incorporating Xybion GmbH**
  - European Business from Germany
  - Clients: Germany, Switzerland, France, Italy, Denmark, UK, Croatia,....
  - Services and Consulting (SEND, CSV, Tx) , Work visa for Germany
- **Localization**
  - Language support
  - Hosting / Cloud
- **Partnerships**
  - R&D Institutes and Universities
  - System Integrators (TCS, Atos, Cognizant, WEGA...)

Clients

Boehringer Ingelheim, Bayer, Novo Nordisk, ERBC,....

#Digitization **#Cloud Platform** **#Artificial Intelligence & Prediction** **#SaaS**

Business Segments & Products

Preclinical business	Digital Lab business	CQRM business	WPH business
Pristima XD	Labwise XD	CQRM XD	Emidence XD
• Gold standard pre-clinical lab operation • SEND Intelligence Service • Lab Data Lake • Instrument Management	• LIMS (CAR-T, Diagnostic, Sample & Inventory Management , Stability Studies) • ELN • Methods/Protocol Management • Clinical supply management	• Predictive compliance • Regulatory audit • Quality management • Content management • Third party assessment and credentialing	• Employee Health & Safety • OSHA reporting • Incident /Case management • Billing • Bill review

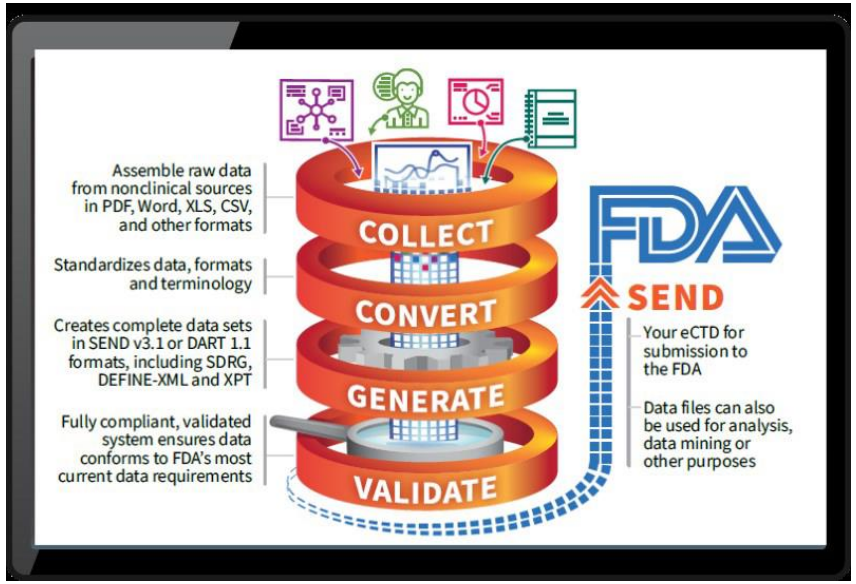
XDP
Low code BPM platform

Xybion Advisory Services

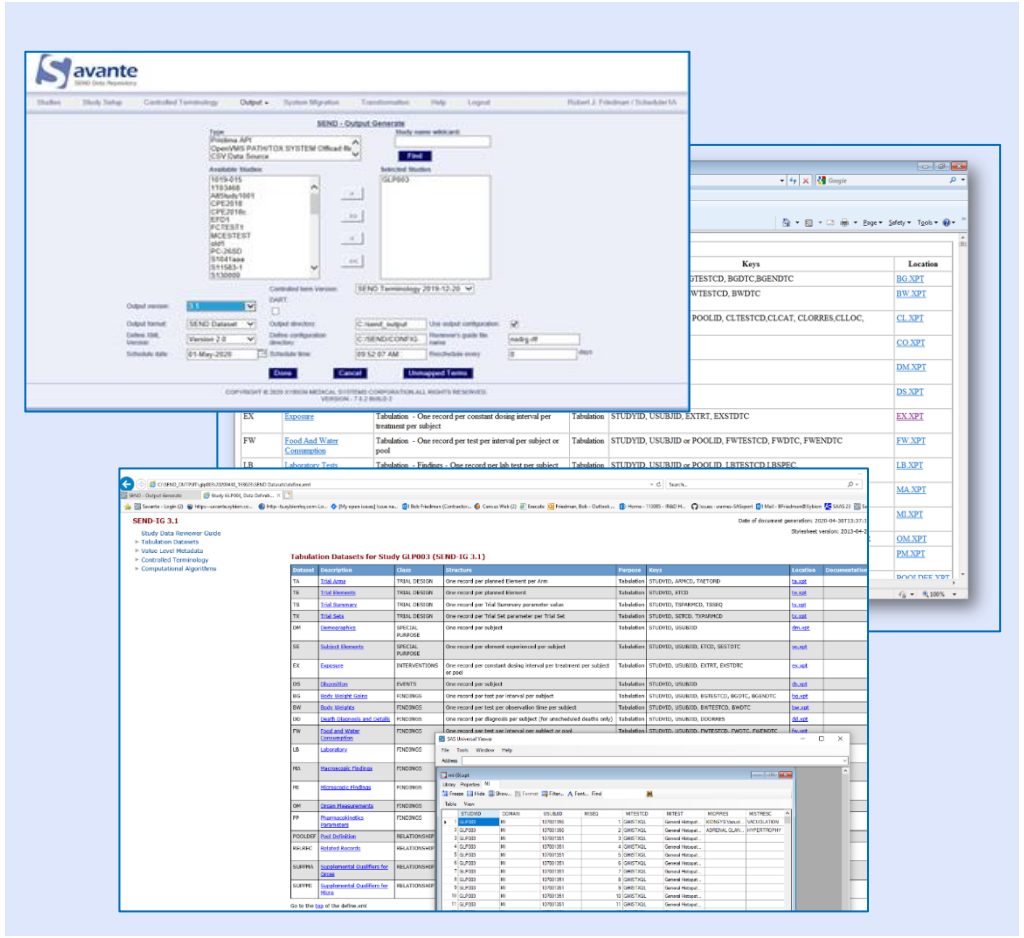
- PMO/PM
- Digital strategy
- Quality management and computer system validation
- Business analysis
- DesignThinking

Pristima XD- Savante and SEND Intelligence Services

2



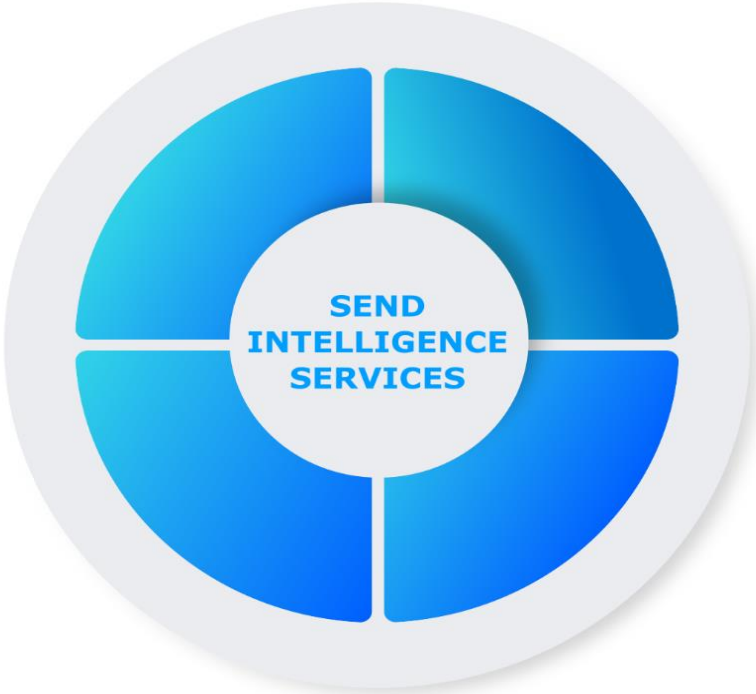
- **Data conversion into CDISC-SEND format**
- **SEND data package QC/verification + Correction**
- **SEND data package QC/verification only**



Xybion SEND Service Suite

SEND Conversion

SENDVerify



SEND Education

SENDConsult

2

2 b.SEND Services

S. NO	SEND Services	Data file formats	Timeline	Deliverables
1	Full Conversion	PDF, Scanned reports, images & word documents etc.,	3-4 wks for 14-28d tox study 4-6 wks for 90d tox study 6-8 wks for 180d tox study	Submission ready SEND datasets, define file & nSDRG
		Excel, CSV & XPT	1-2 wks reduced from the above timelines	
2	SEND Data Verification + Correction	SEND data in xpt or Excel or CSV formats	3-4 wks for 14-28d tox study 4-6 wks for 90d tox study 6-8 wks for 180d tox study	Error fixed, submission ready SEND datasets, define file & nSDRG
3	SEND Data Verification Only (No error fixes)	SEND data in xpt or Excel or CSV formats	3-4 wks for 14-28d tox study 4-6 wks for 90d tox study 6-8 wks for 180d tox study	QC issue log with the list of issues / findings identified.. The Sponsor will be taking care of the error fixes, not Xybion
4	Customized SEND services	Simplified TS preparation	To be determined based on the number of studies	Submission ready TS domain
		Creation of Trial domains	To be determined based on the number of studies	Submission ready trial domain
		Creation of SEND datasets for TK studies alone	To be determined based on the number of studies	Submission ready PC, PP domains with or without Trial domains, based on customer requirements
5	SEND Education	NA	5 - 10 days	Onsite / online training by Xybion SME - Xybion training certificate - Training (course) materials
6	SEND Consultancy	NA	TO be determined based on the customer needs	End-to-end SEND consultancy services

Protocol Design Automation needs

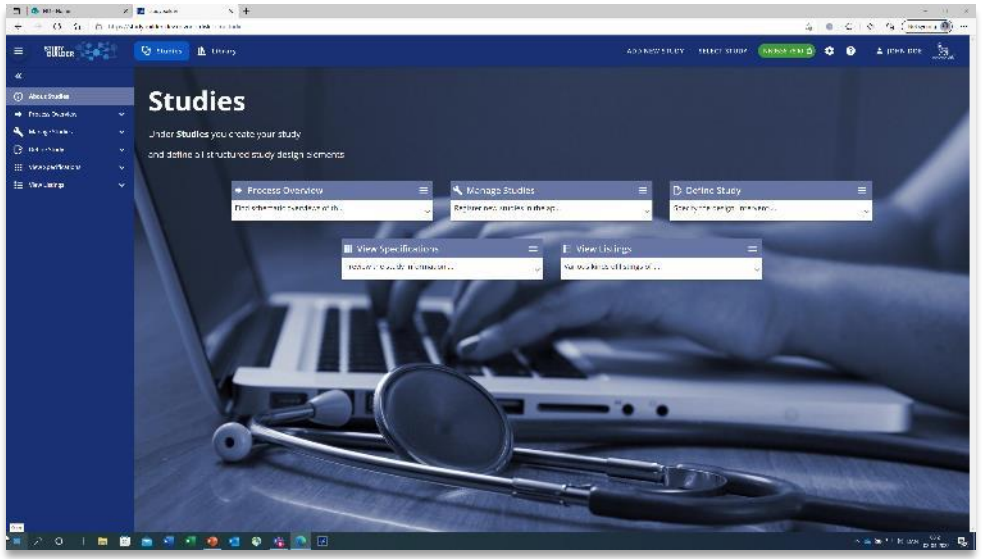
- Ensure a higher degree of end-to-end consistency
- Have built-in compliance with external and internal standards
- Facilitate more automation and content reuse
- Share electronically the nonclinical protocol / study
- Between Pharma's and CROs
- To regulatory bodies
- Do so in a manner that is
- Computer readable for system to system exchange
- Human readable to turn into approval formal protocol
- Amendments must be evident

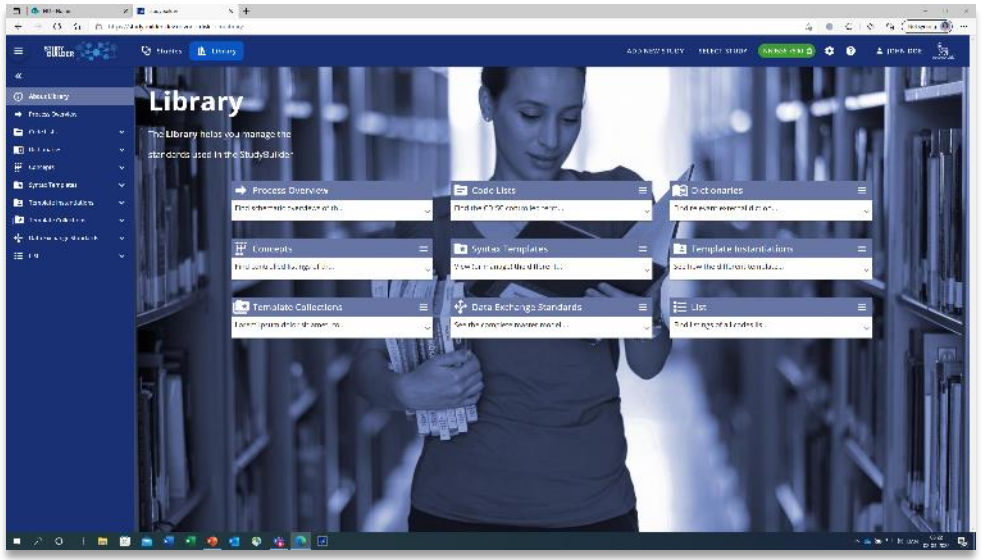
What is the OpenStudyBuilder

- OpenStudyBuilder is an open source solution provided by Novo Nordisk® which is looking for collaborations.
- The OpenStudyBuilder comprises three elements:
- Clinical Metadata Repository (MDR) and Study Definition Repository (SDR) (central repository for all study specification data)
- OpenStudyBuilder application (web-based user interface)
- API layer (allowing interoperability with other applications) (DDF API Adaptor – enabling DDF SDR Compatibility)

The OpenStudyBuilder includes:

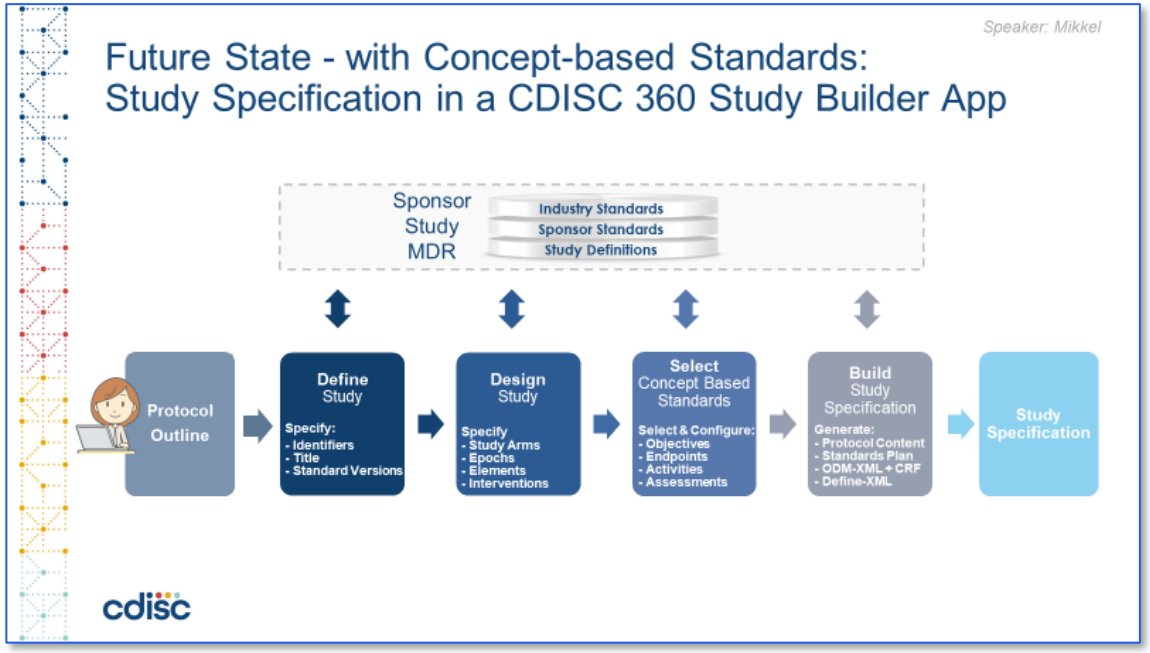
- A **Studies** part for specification of studies
  (incl. disease area and study type, objectives and endpoints, population and eligibility criteria, study compounds and other interventions, study design, arms and visits, schedule of activities and associated procedure and assessment instructions)
- A **Library** part for maintenance of terminology standards (incl. CDISC controlled terminology, relevant parts of external dictionaries for medical terms, pharmacological classes, units, a detailed compound library, a granulated library of activity terms) as well as syntax templates for cross-study and cross-project harmonisation)
- An underlying **knowledge database**
  (enabling complex queries and visualisations for aggregation of information and showing how things are connected end-to-end)

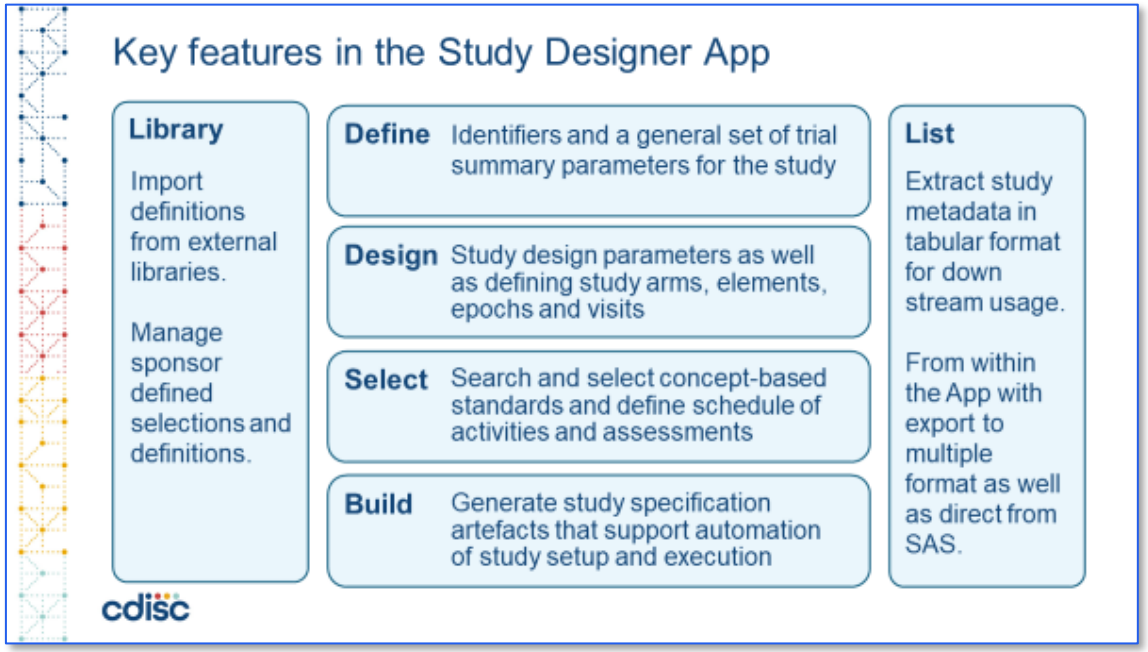




OpenStudyBuilder is being built as an open-source MDR and SDR solution based on the CDISC 360 POC

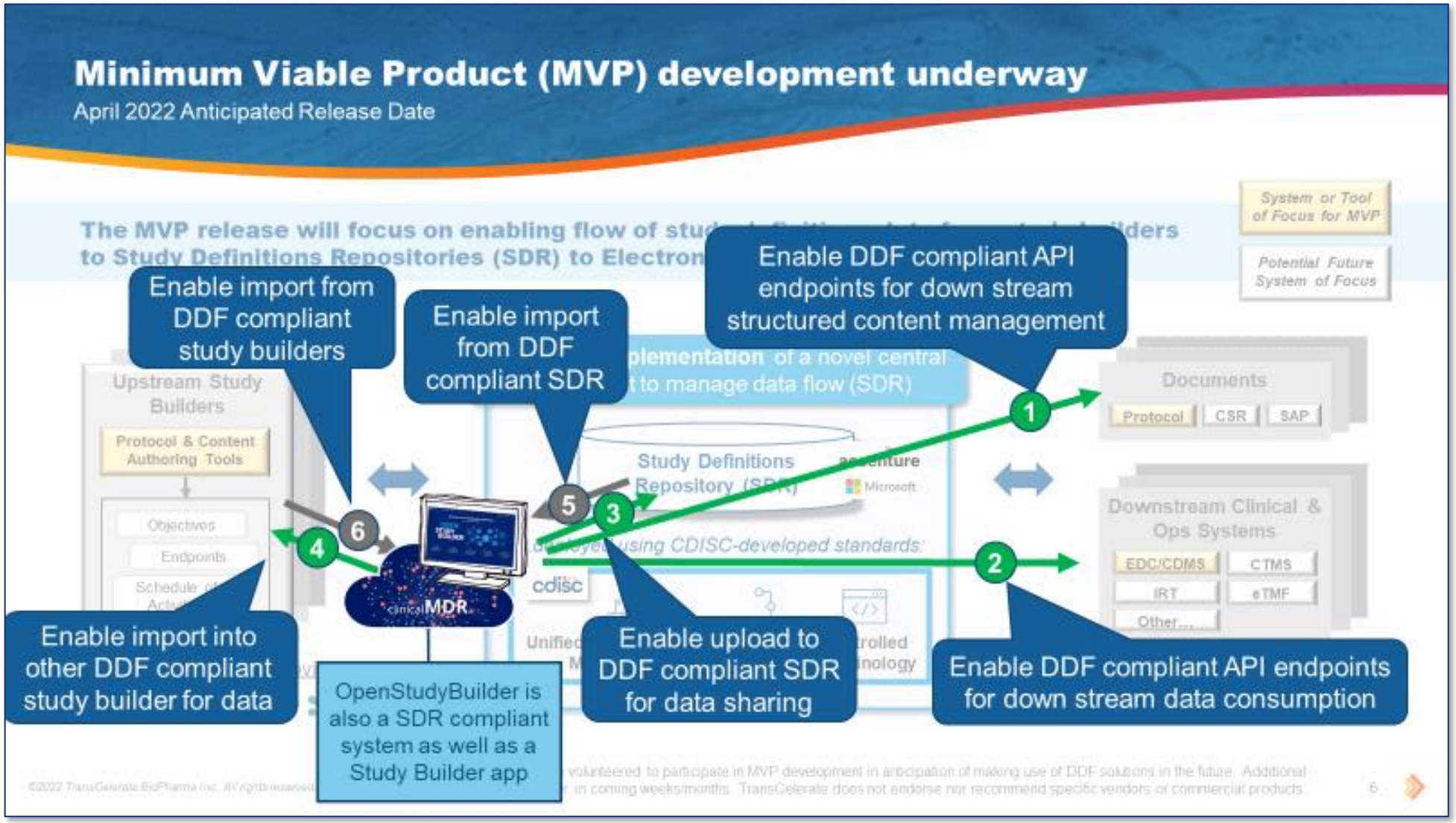
Project collaborates with CDISC, TransCelerate DDF and suppliers





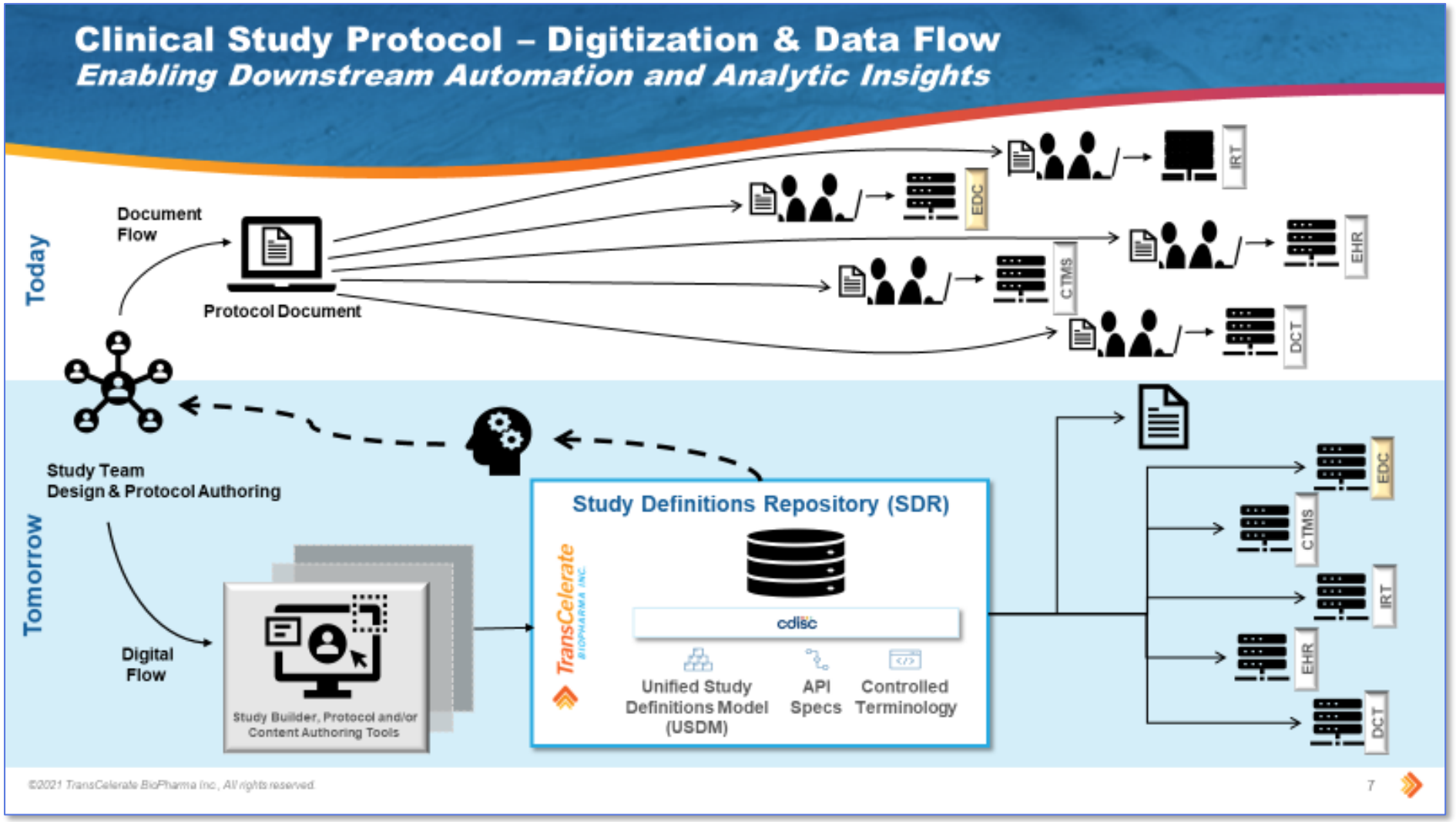
https://www.cdisc.org/cdisc-360

OpenStudyBuilder will also be DDF Compatible



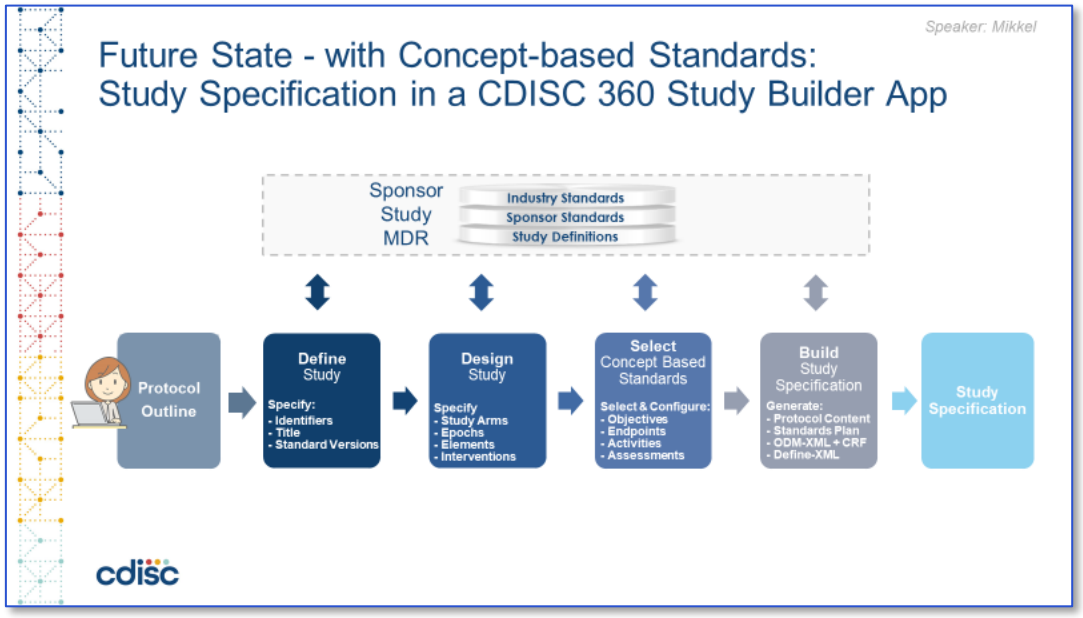
https://transcelerate.github.io/ddf-home/

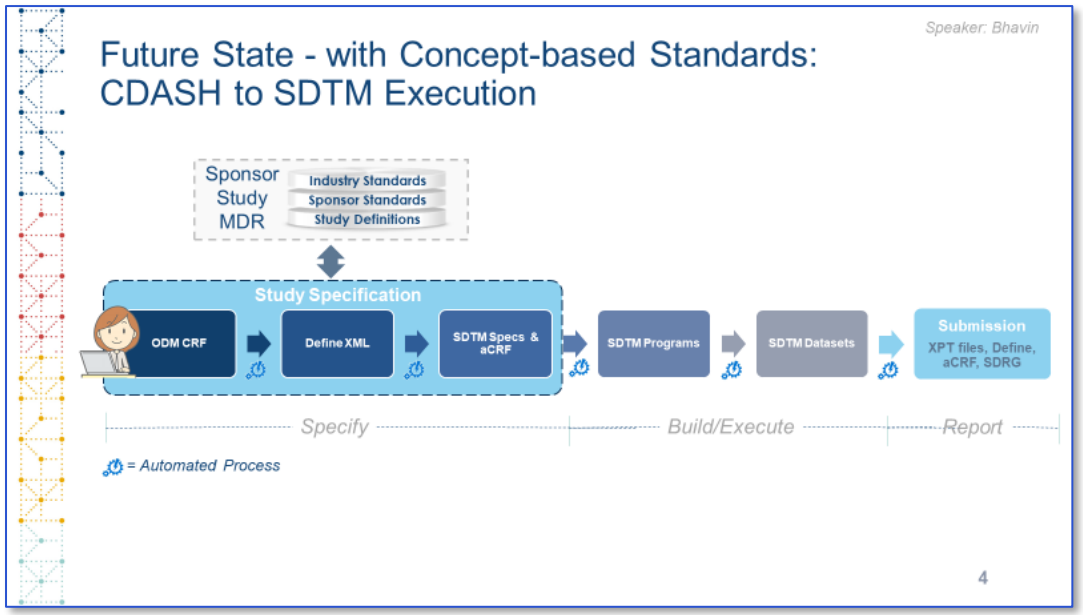
DDF is moving away from Document focused processes to Connected Data Driven processes



To apply concept-based data standards end-to-end

From protocol preparation through study conduct to reporting and submission of applications to health authorities and with reference to externally-compliant concept-based data standards and terminology





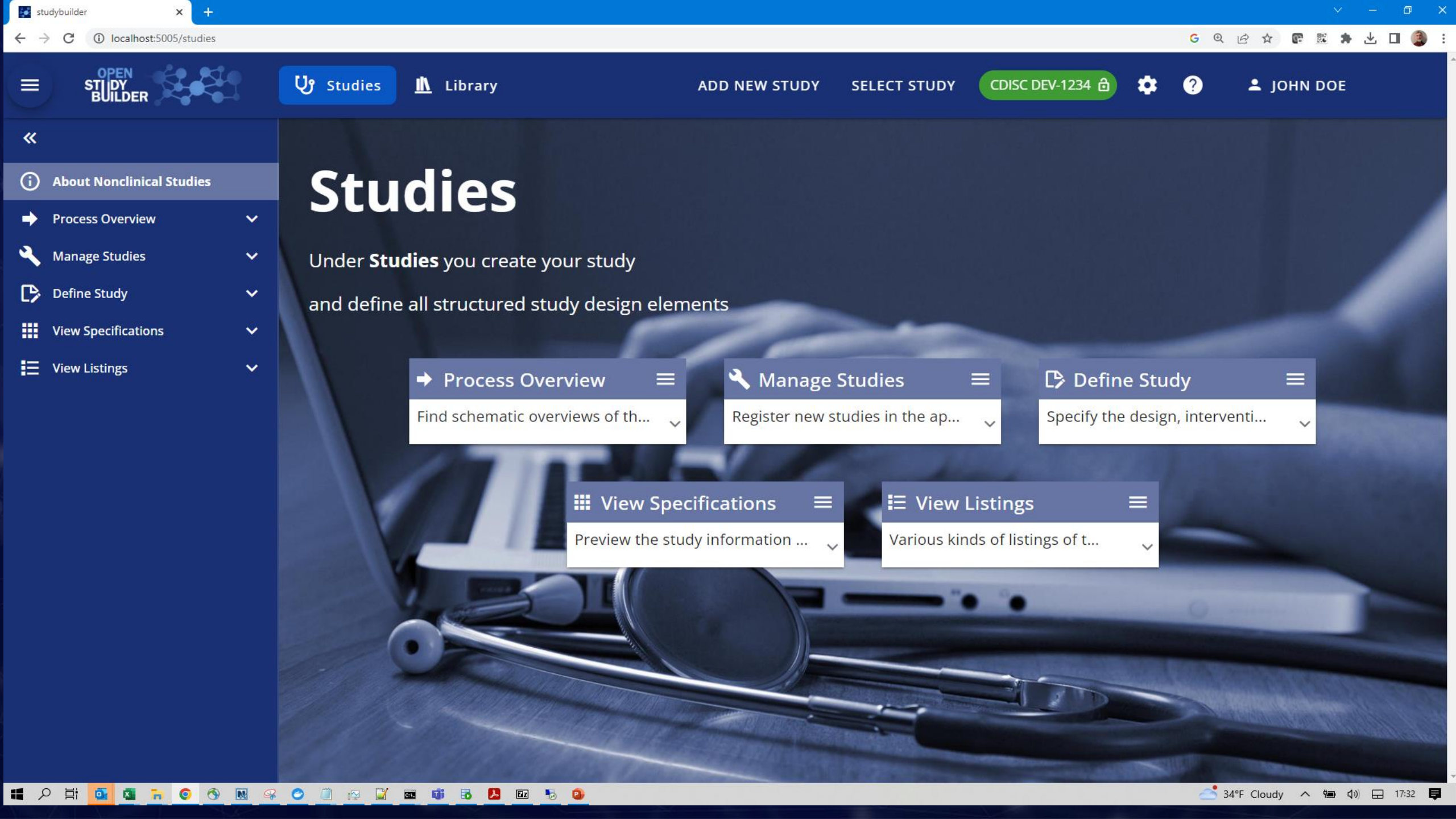
Open-Sourced

Shared as open source project in Q3 2022
https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/

Listed in COSA (CDISC Open Source Alliance)
https://cosa.cdisc.org/directory/openStudyBuilder

Seek to actively collaborate with CDISC, TransCelerate DDF, peers and vendors

OpenStudyBuilder for Non clinical usage


studybuilder
localhost:5005/studies
OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-1234
JOHN DOE
About Nonclinical Studies
Process Overview
Manage Studies
Define Study
View Specifications
View Listings
Studies
Under Studies you create your study
and define all structured study design elements
Process Overview
Find schematic overviews of th...
Manage Studies
Register new studies in the ap...
Define Study
Specify the design, interventi...
View Specifications
Preview the study information ...
View Listings
Various kinds of listings of t...
34°F Cloudy
17:32

About Nonclinical Studies
Process Overview
Manage Studies
Study List
Study Status
Project Standards
Define Study
View Specifications
View Listings

Study List

Select rows

Search

	Clinical Programme	Project ID	Project name	Brand name	Study number	Study ID	Study acronym
⋮	CDISC Development programme	CDISC DEV	CDISC Dev		0	CDISC DEV-0	CDISC360-2
⋮	CDISC Development programme	CDISC DEV	CDISC Dev		1234	CDISC DEV-1234	Study-1

Rows per page: 10 1-2 of 2

Process Overview
Manage Studies
Study List
Study Status
Project Standards
Define Study
Specification Overview
Study Title
Registry Identifiers
Study Properties
Study Structure
Study Population
Study Criteria
Study Interventions
Study Purpose
Study Activities
Terminology

Studies / Manage Studies / Study List

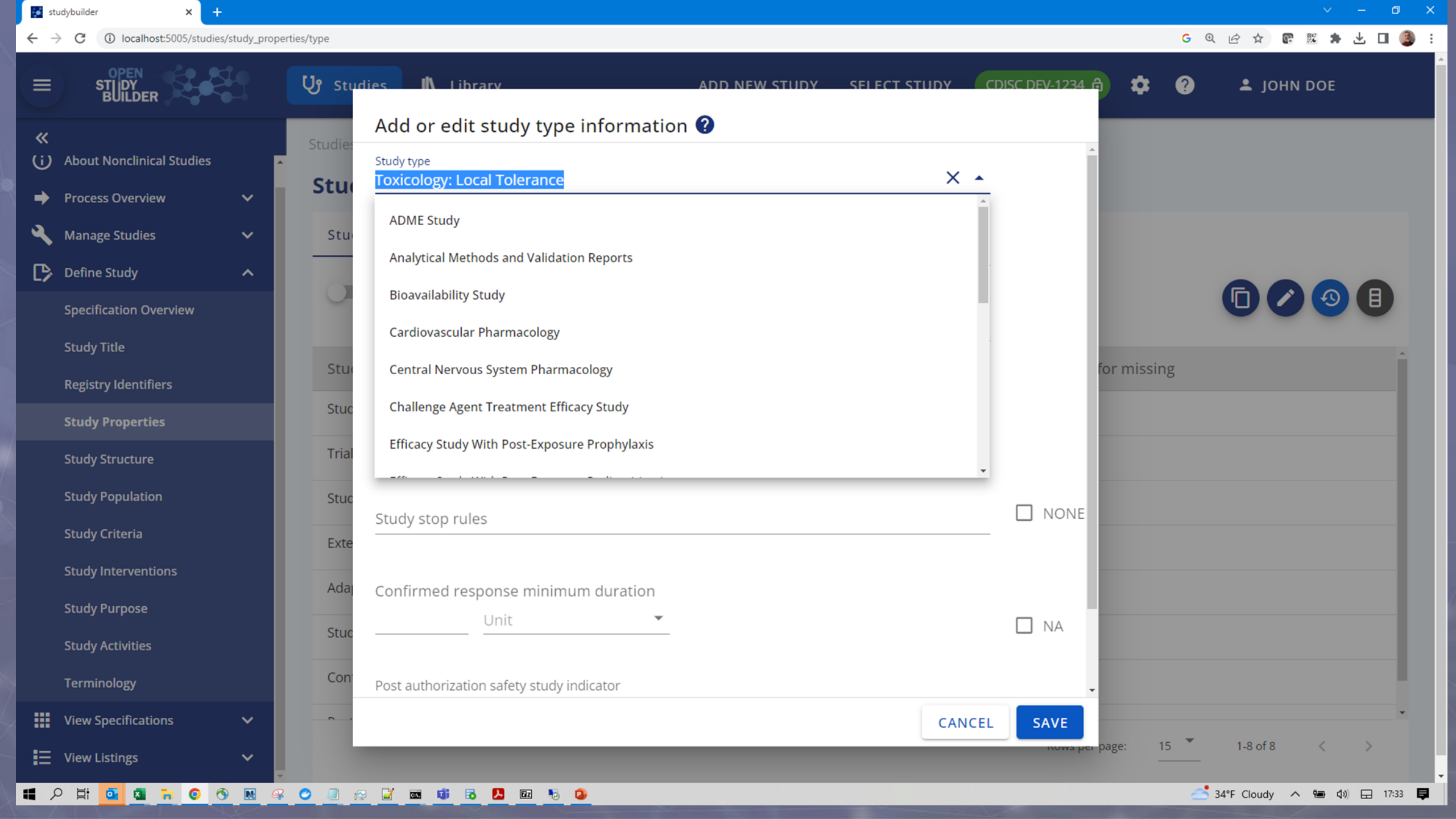
Study List

Select rows

Search

	Clinical Programme	Project ID	Project name	Brand name	Study number	Study ID	Study acronym
⋮	CDISC Development programme	CDISC DEV	CDISC Dev		0	CDISC DEV-0	CDISC360-2
⋮	CDISC Development programme	CDISC DEV	CDISC Dev		1234	CDISC DEV-1234	Study-1

Rows per page: 10 1-2 of 2


studybuilder
localhost:5005/studies/study_properties/type
OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-1234
JOHN DOE
About Nonclinical Studies
Process Overview
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Define Study
Specification Overview
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Study Properties
Study Structure
Study Population
Study Criteria
Study Interventions
Study Purpose
Study Activities
Terminology
View Specifications
View Listings
Add or edit study type information
Study type
Toxicology: Local Tolerance
ADME Study
Analytical Methods and Validation Reports
Bioavailability Study
Cardiovascular Pharmacology
Central Nervous System Pharmacology
Challenge Agent Treatment Efficacy Study
Efficacy Study With Post-Exposure Prophylaxis
Study stop rules
NONE
Confirmed response minimum duration
Unit
NA
Post authorization safety study indicator
CANCEL
SAVE
Rows per page:
15
1-8 of 8
34°F Cloudy
17:33

About Nonclinical Studies
Process Overview
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Study Properties
Study Structure
Study Population
Study Criteria
Study Interventions
Study Purpose
Study Activities
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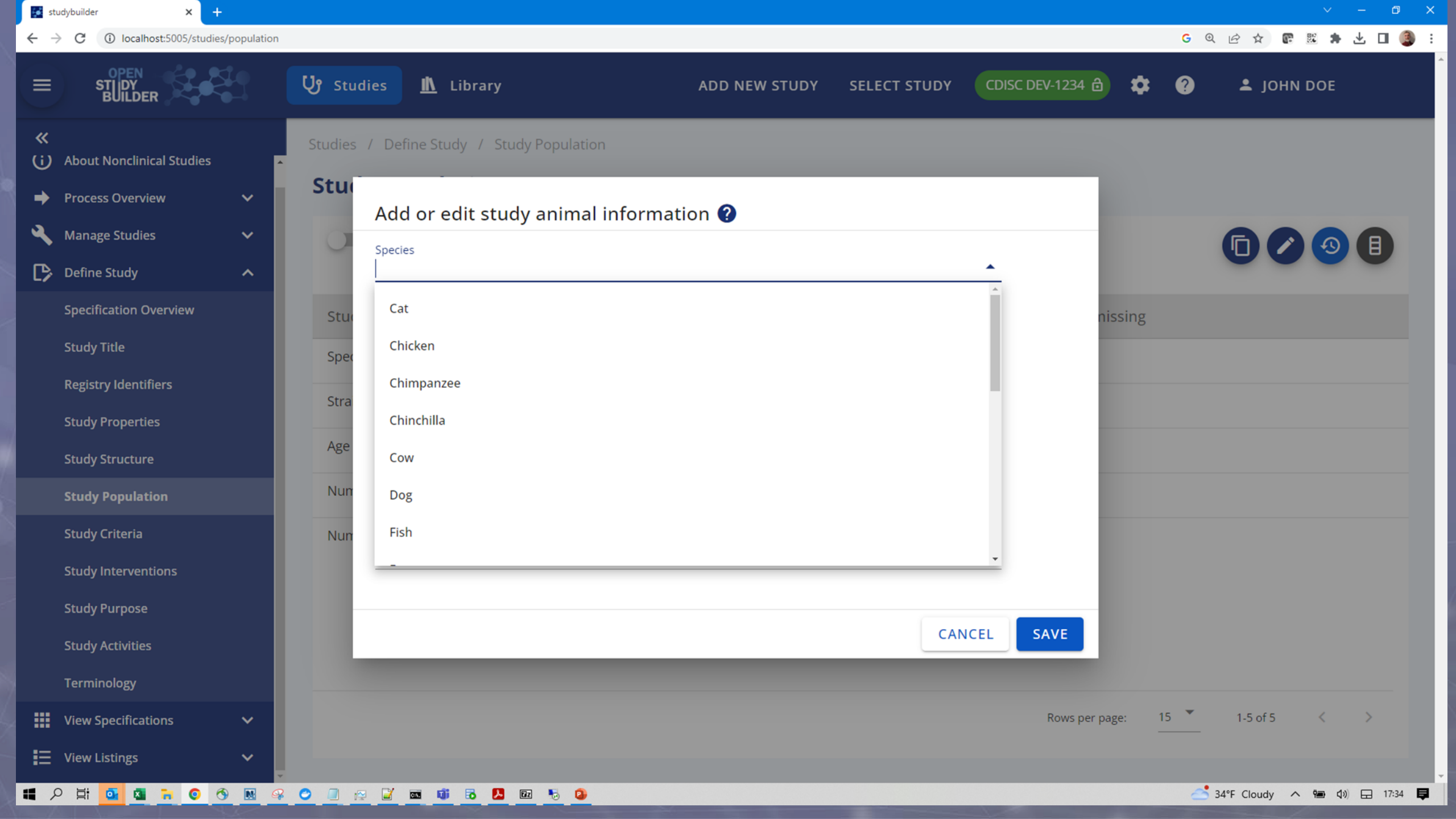
View Specifications
View Listings

Study Population (CDISC DEV-1234)

Select rows

Study population information	Selected values	Reason for missing
Species		
Strain		
Age range of animals		
Number of Males		
Number of Females		


studybuilder
localhost:5005/studies/population
OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-1234
JOHN DOE
About Nonclinical Studies
Process Overview
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Registry Identifiers
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Study Criteria
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Studies / Define Study / Study Population
Add or edit study animal information
Species
Cat
Chicken
Chimpanzee
Chinchilla
Cow
Dog
Fish
CANCEL
SAVE
Rows per page:
15
1-5 of 5
34°F Cloudy
17:34

About Library
Process Overview
Code Lists
Dashboard
CT Catalogues
CT Packages
CDISC
Sponsor
Dictionaries
Concepts
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List

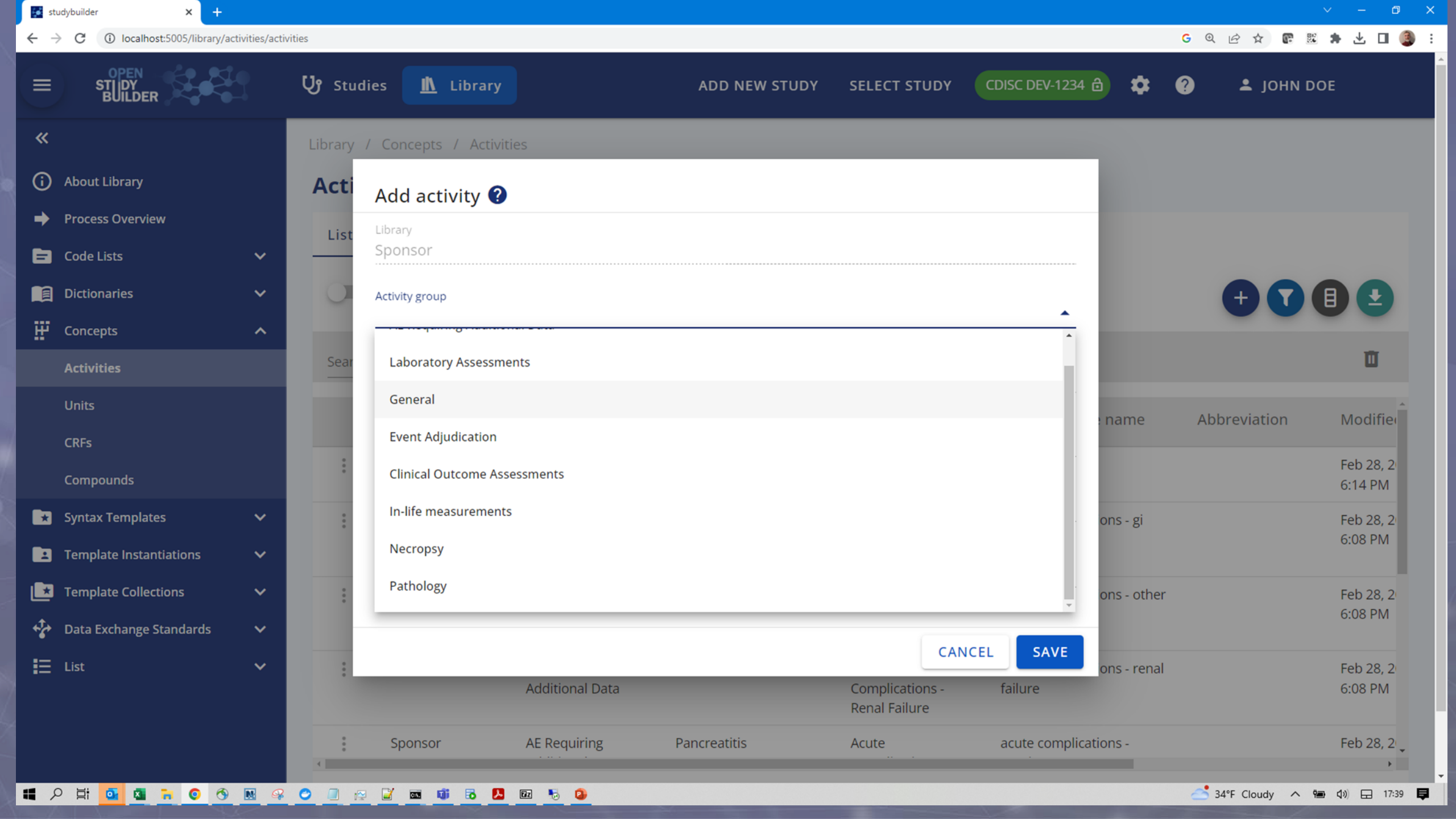
CT Catalogues

All | ADAM CT | CDASH CT | DEFINE-XML CT | SDTM CT | SEND CT

Select rows

Search

	Library	Sponsor preferred name	Template parameter	Code list status	Name modified	Concept ID
⋮	CDISC	SEND Domain Abbreviation	No	Final	Mar 3, 2023, 11:10 AM	C111113
⋮	CDISC	Chronicity	No	Final	Mar 3, 2023, 11:11 AM	C120529
⋮	CDISC	Distribution	No	Final	Mar 3, 2023, 11:12 AM	C120530
⋮	CDISC	Non-Neoplastic Finding Type	No	Final	Mar 3, 2023, 11:11 AM	C120531
⋮	CDISC	SEND Cardiovascular Test Code	No	Final	Mar 3, 2023, 11:10 AM	C120532


studybuilder
localhost:5005/library/activities/activities
OPEN STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-1234
JOHN DOE
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Activities
Units
CRFs
Compounds
Syntax Templates
Template Instantiations
Template Collections
Data Exchange Standards
List
Library / Concepts / Activities
Add activity
Library
Sponsor
Activity group
Laboratory Assessments
General
Event Adjudication
Clinical Outcome Assessments
In-life measurements
Necropsy
Pathology
CANCEL
SAVE
name
Abbreviation
Modifie
Feb 28, 2
6:14 PM
ons - gi
Feb 28, 2
6:08 PM
ons - other
Feb 28, 2
6:08 PM
ons - renal
Feb 28, 2
6:08 PM
Additional Data
Complications - Renal Failure
failure
Sponsor
AE Requiring
Pancreatitis
Acute
acute complications -
Feb 28, 2
34°F Cloudy
17:39

Studies / Define Study / Study Activities

About Studies
Process Overview
Manage Studies
Define Study
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Study Purpose
Study Activities
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View Specifications
View Listings

Study Activities (Ep1-1001)

List of Study Activities | Detailed Flowchart | Protocol Flowchart | Activity Instructions

Protocol Flowchart

DOWNLOAD DOCX

Study epoch	Screening	Treatment	Elimination
Visit short name	V1	V2	V3
Study day	-10	1	29
Visit window (days)	±0	±0	±0
INLIFE			
Inlife measurements			
Body weights	X	X	X
Clinical Observations	X	X	X
Blood collection	X	X	X
Direct dosing	X	X	
Food consumption	X	X	X
Laboratory Assessments			
Haematology	X	X	X
NECROPSY			
Necropsy measurements			
Organ weights		X	X
Gross observations		X	X
Tissue collection		X	X
PATHOLOGY			
Pathology measurements			
Histopathology Slide reading		X	X

Xybion®

OPEN STUDY BUILDER

Studies | Library | ADD NEW STUDY | SELECT STUDY | Ep1-1001 | JOHN DOE

- About Studies
- Process Overview
- Manage Studies
- Define Study
- View Specifications
  - Standarisation Plan
  - **Protocol Elements**
  - CRF Specifications
  - Study Disclosure
  - Trial Supplies Specifications
  - ODM Specification
  - CTR ODM XML
  - SDTM Specifications
  - SDTM Study Design Datasets
  - ADaM Specification
- View Listings

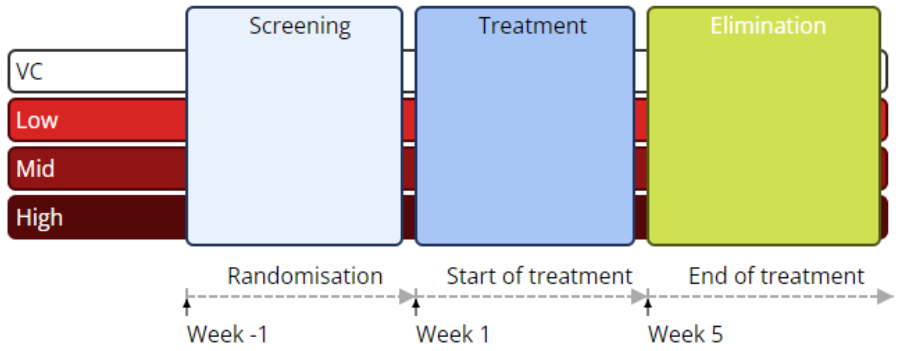
Studies / View Specifications / Protocol Elements

Protocol Elements (Ep1-1001)

Title Page | Flowchart | Objectives and Endpoints | **Study Design** | Study Population | Study Interventions | Study Activities

Study Design

DOWNLOAD



Xybion®

OPEN STUDY BUILDER | Studies | Library | ADD NEW STUDY | SELECT STUDY | Ep1-1001 | JOHN DOE

- About Studies
- Process Overview
- Manage Studies
- Define Study
- View Specifications
  - Standarisation Plan
  - Protocol Elements
  - CRF Specifications
  - Study Disclosure
  - Trial Supplies Specifications
  - ODM Specification
  - CTR ODM XML
  - SDTM Specifications
  - **SDTM Study Design Datasets**
  - ADaM Specification
- View Listings

Studies / View Specifications / SDTM Study Design Datasets

SDTM Study Design Datasets

Trial Arm | Trial Elements | Trial Visits | Trial Inclusion/Exclusion Criteria | Trial Disease Assessments | **Trial Summary**

Select rows | Column labels | Column names

Filtering currently not activated

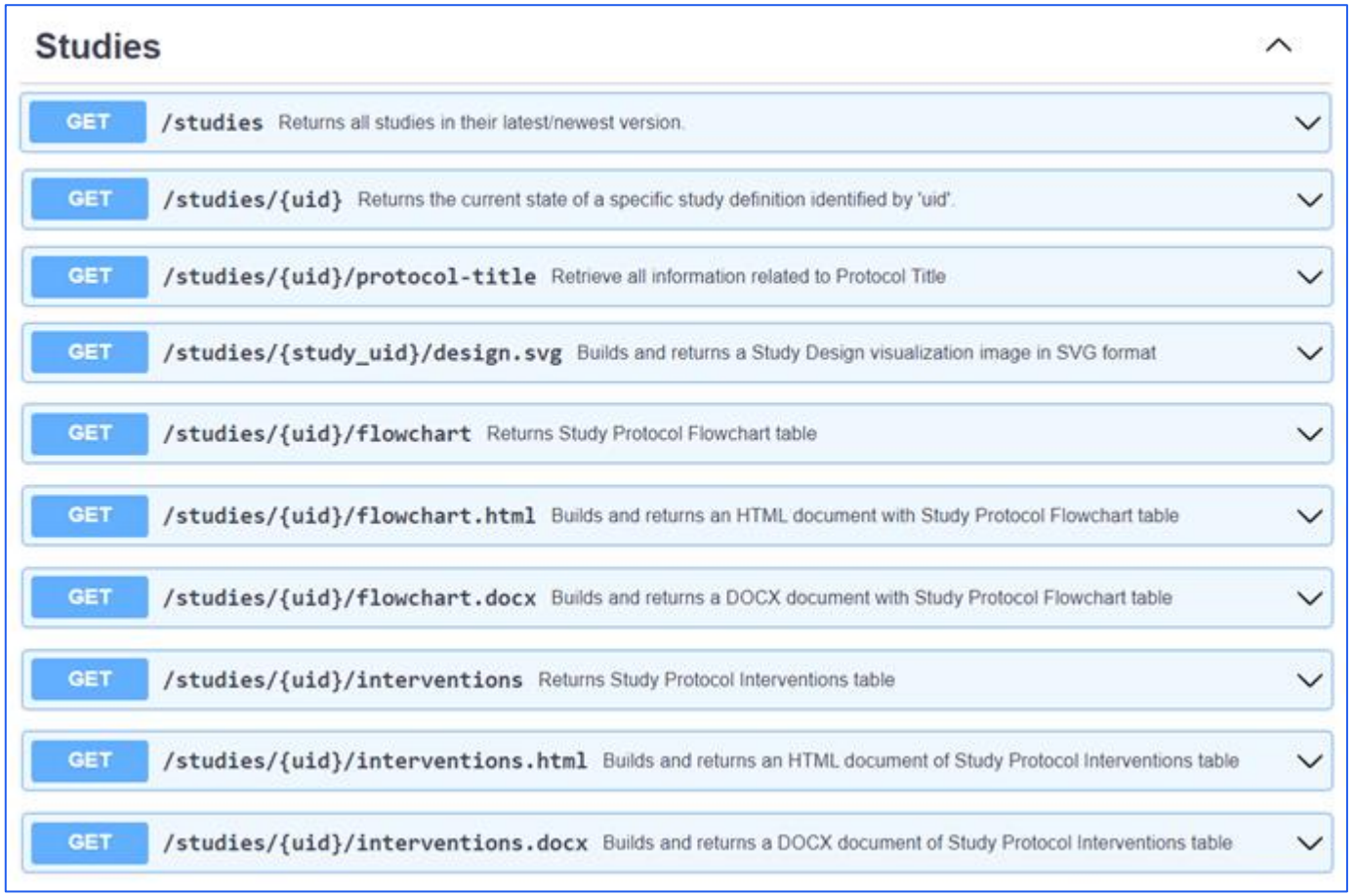
Study Identifier	Domain Abbreviation	Sequence Number	Group ID	Trial Summary Parameter Short Name	Trial Summary Parameter	Parameter Value
Ep1-1001	TS			NARMS	Planned Number of Arms	1
Ep1-1001	TS			PCLAS	Pharmacologic Class	Insulin
Ep1-1001	TS			STOPRULE	Study Stop Rules	LD 50 achieved
Ep1-1001	TS			STYPE	Study Type	SINGLE DOSE TOXICITY
Ep1-1001	TS			TITLE	Trial Title	Rat toxicology study to test dose responses to treatment XybABC
Ep1-1001	TS			TPHASE	Trial Phase Classification	NOT APPLICABLE
Ep1-1001	TS			TRT	Investigational Therapy or Treatment	INSULIN HUMAN
Ep1-1001	TS			TTYPE	Trial Type	SAFETY

Rows per page: 10 | 1-8 of 8

Automation Opportunities

Getting Data

- All data accessible through APIs
  - Tools can be automated



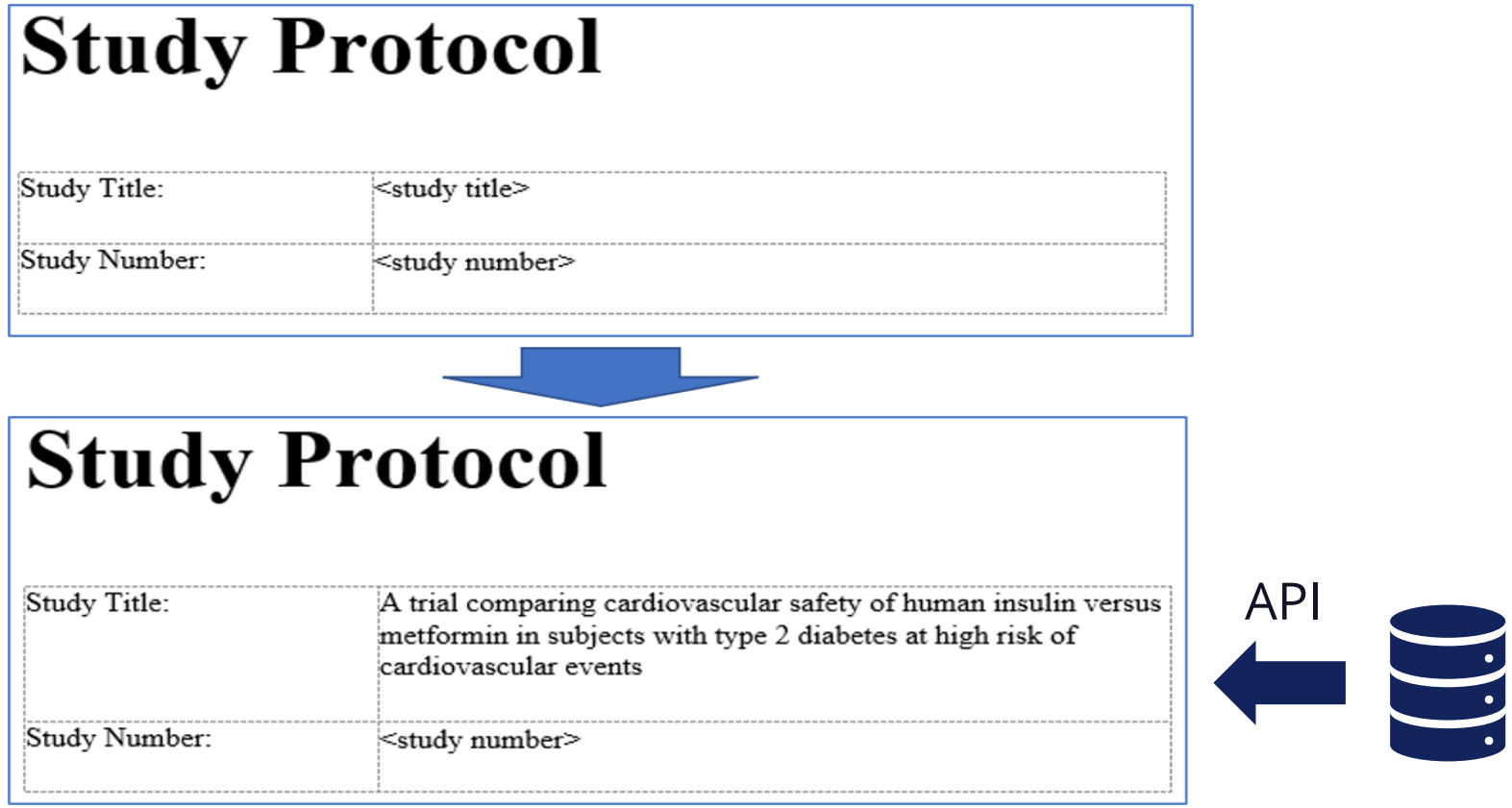
Protocol Automation

Example:

- Word-Programming in VBA
- Word-Programming in R
- Word-Programming in Python

API to get

- Study Design as SVG
- Flowchart as HTML or DOCX
- Interventions as HTML or DOCX



Protocol Automation

```
library(httr)
library(officer)

# Switch to the corresponding working directory
setwd(".../OpenStudyBuilderScripts/scripts")

api_url <- "http://localhost:5003"
response <- GET(paste(api_url,"studies", "Study_000001", "protocol-title", sep = "/"))
study_1_prot_title <- jsonlite::fromJSON(rawToChar(response$content))
study_title = toString(study_1_prot_title["study_title"])

print(study_title)

protocol_doc <- read_docx(path = "./files/protocol_example_input.docx")
body_replace_all_text(
  protocol_doc,
  "<study title>",
  study_title)
print(protocol_doc, target = "./files/protocol_example_output_r.docx")
```

Protocol filled in from underlying data

1. Objective

The author may choose to add more or less detail based on expectations of Sponsor/CRO or other local requirements (class of compound, potential disease area, etc).

The purpose of this study is to evaluate the toxicity **[and determine toxicokinetics]** of the test item/article, **[TRT]**, when administered **[PDOSFRQ], [ROUTE], [SPECIES], [DOSDUR]** (e.g. once daily by oral gavage to rats for at least 4 weeks)], and to provide data to support the use of **[TRT]** in humans.

2. Proposed Study Schedule

Schedule detail may vary based on study/sponsor/CRO needs. The black text in brackets may be included for studies requiring SEND.

Experimental Start Date (date of first data collection):	**[EXPSTDTC]**
Dosing Start Date:	**[DOSSTDTC]**
Dosing End Date:	**[DOSENDTC]**
Experimental Completion Date (date of last data collected):	**[EXPENDTC]**
Audited Draft Report Date:	**[DATE]**

3. Sponsor/Test Facility/Test Site Information

Sponsor:	**[SSPONSOR]**
Test Facility:	**[TSTFNAM]**
Test Site:	**[TSNAM]**

Repeat as needed for additional test sites. The black text in brackets may be included for

1. Objective

The author may choose to add more or less detail based on expectations of Sponsor/CRO or other local requirements (class of compound, potential disease area, etc.).

The purpose of this study is to evaluate the toxicity **[and determine toxicokinetics]** of the test item/article, **MyDrug**, when administered **ONCE, INTRAVENOUS, RAT, P29D** (e.g. once daily by oral gavage to rats for at least 4 weeks)], and to provide data to support the use of **MyDrug** in humans.

2. Proposed Study Schedule

Schedule detail may vary based on study/sponsor/CRO needs. The black text in brackets may be included for studies requiring SEND.

Experimental Start Date (date of first data collection):	**2019-08-03**
Dosing Start Date:	**2019-08-03**
Dosing End Date:	**2019-09-01**
Experimental Completion Date (date of last data collected):	**2019-09-01**
Audited Draft Report Date:	**[DATE]**

3. Sponsor/Test Facility/Test Site Information

Sponsor:	**The sponsor**
Test Facility:	**Test facility B**
Test Site:	**Test Site A**

Repeat as needed for additional test sites. The black text in brackets may be included for studies requiring SEND.

Study Protocol

Study Title:

Study ID:

Study Acronym

Project

Program

Table of Contents

1. Objective

…

Get Study Title & ID

Study Protocol

Study Title:	XYZ drug for Epilepsy, rat study
Study ID:	CDISC DEV-1234
Study Acronym	Study-1
Project	CDISC Dev
Program	CDISC Development programme

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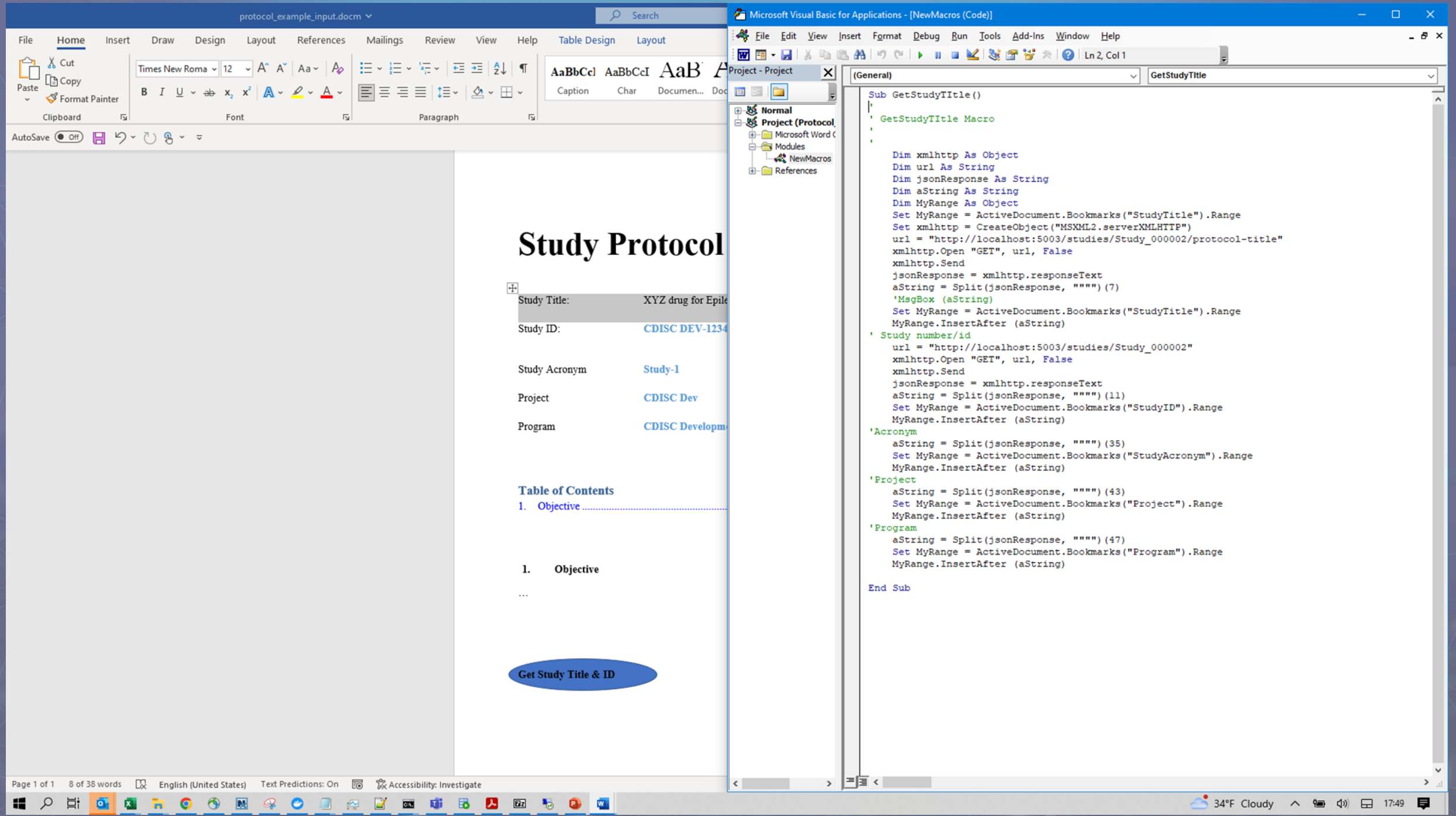
1. Objective

…

Get Study Title & ID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Copy
Format Painter
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Clipboard
Times New Roma
12
Font
Caption
Char
Paragraph
AutoSave Off
Study Protocol
Study Title: XYZ drug for Epile
Study ID: CDISC DEV-1234
Study Acronym Study-1
Project CDISC Dev
Program CDISC Developm
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1. Objective .....
1. Objective
...
Get Study Title & ID
Page 1 of 1
8 of 38 words
English (United States)
Text Predictions: On
Accessibility: Investigate
Microsoft Visual Basic for Applications - [NewMacros (Code)]
File Edit View Insert Format Debug Run Tools Add-Ins Window Help
Ln 2, Col 1
Project - Project
Normal
Project (Protocol_
Microsoft Word (
Modules
NewMacros
References
(General)
GetStudyTItle
Sub GetStudyTItle()
' GetStudyTItle Macro
'
'
Dim xmlhttp As Object
Dim url As String
Dim jsonResponse As String
Dim aString As String
Dim MyRange As Object
Set MyRange = ActiveDocument.Bookmarks("StudyTitle").Range
Set xmlhttp = CreateObject("MSXML2.serverXMLHTTP")
url = "http://localhost:5003/studies/Study_000002/protocol-title"
xmlhttp.Open "GET", url, False
xmlhttp.Send
jsonResponse = xmlhttp.responseText
aString = Split(jsonResponse, """")(7)
'MsgBox (aString)
Set MyRange = ActiveDocument.Bookmarks("StudyTitle").Range
MyRange.InsertAfter (aString)
' Study number/id
url = "http://localhost:5003/studies/Study_000002"
xmlhttp.Open "GET", url, False
xmlhttp.Send
jsonResponse = xmlhttp.responseText
aString = Split(jsonResponse, """")(11)
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MyRange.InsertAfter (aString)
'Acronym
aString = Split(jsonResponse, """")(35)
Set MyRange = ActiveDocument.Bookmarks("StudyAcronym").Range
MyRange.InsertAfter (aString)
'Project
aString = Split(jsonResponse, """")(43)
Set MyRange = ActiveDocument.Bookmarks("Project").Range
MyRange.InsertAfter (aString)
'Program
aString = Split(jsonResponse, """")(47)
Set MyRange = ActiveDocument.Bookmarks("Program").Range
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End Sub
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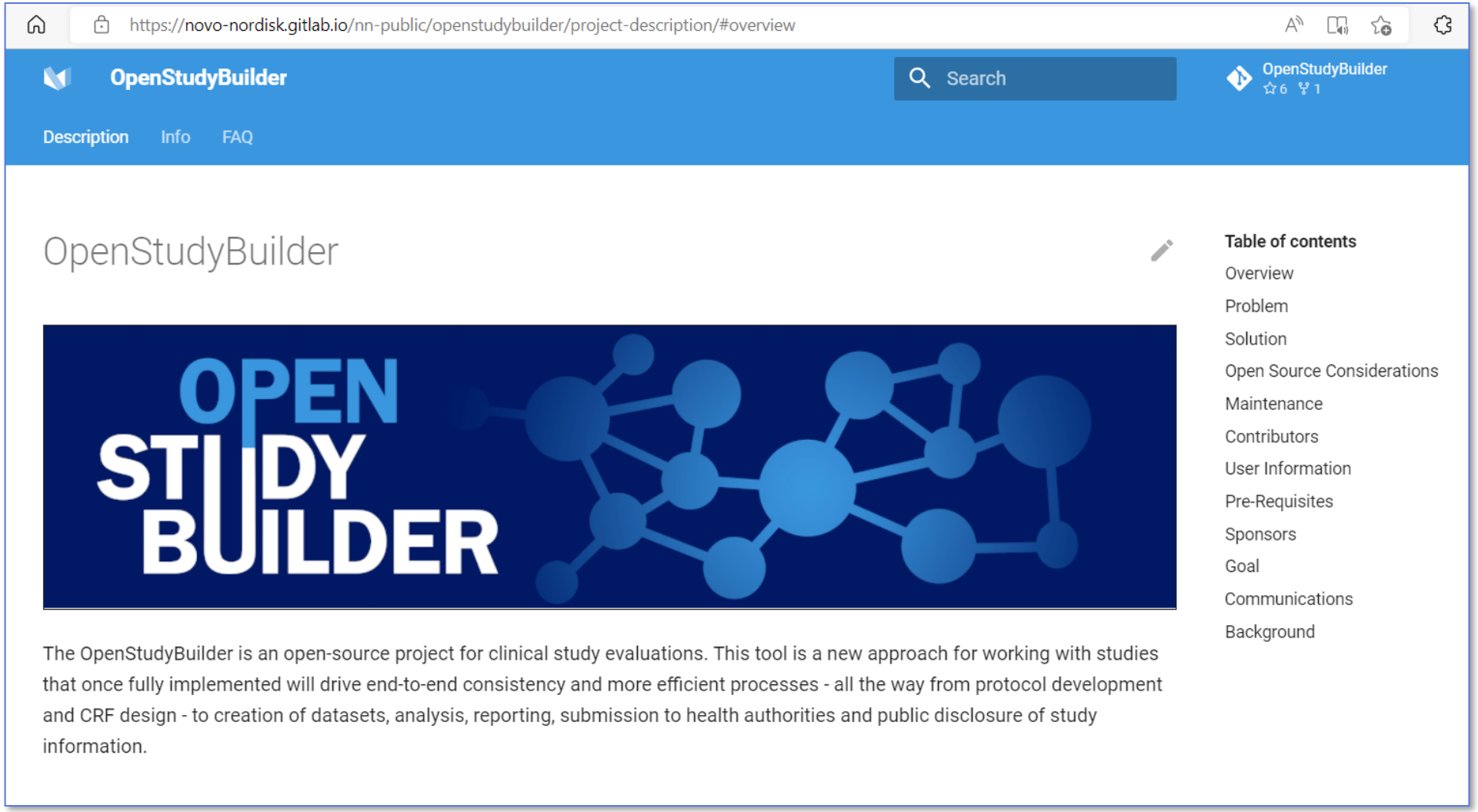
17:49

Getting Started

How do I get started on OpenStudyBuilder?



https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/

Starting with OpenStudyBuilder

Neo4j Sandbox to play around

- Browse, test and investigate functionality
- Checkout Biomedical Concept (linked data browser)

Local installation (free) or Custom/dedicated environment

- API usage to upload/download custom data
- Load trial domains
- Browse “your” data

Collaboration Opportunities

- BioCelerate Protocol Template Project
- OpenStudyBuilder community
- PHUSE eProtocol project
- Metadata standards

Collaboration Opportunities

- Enhance OpenStudyBuilder for NonClinical usage
- Create common additional standards “templates”, e.g. for endpoints, scope
- Common tools, processes and guides
    - Protocol automation
    - CRF
    - What to do on distressed animals
    - How to describe statistical planning

Links

Project Homepage

- https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/

Source Repository

- https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder/OpenStudyBuilder-Solution

COSA Homepage

- https://cosa.cdisc.org/

Newsletter (LinkedIn)

- https://www.linkedin.com/newsletters/openstudybuilder-6990328054849916928/

Sandbox to request access

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

User Scripts & Experiences Documentation

- https://github.com/KatjaGlassConsulting/OpenStudyBuilderScripts

Q&A -Thank You!

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Email: katja.glass@glacon.eu

OpenStudyBuilder Project
https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/

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Q&A -Thank You!

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