

# OpenStudyBuilder Community Meeting

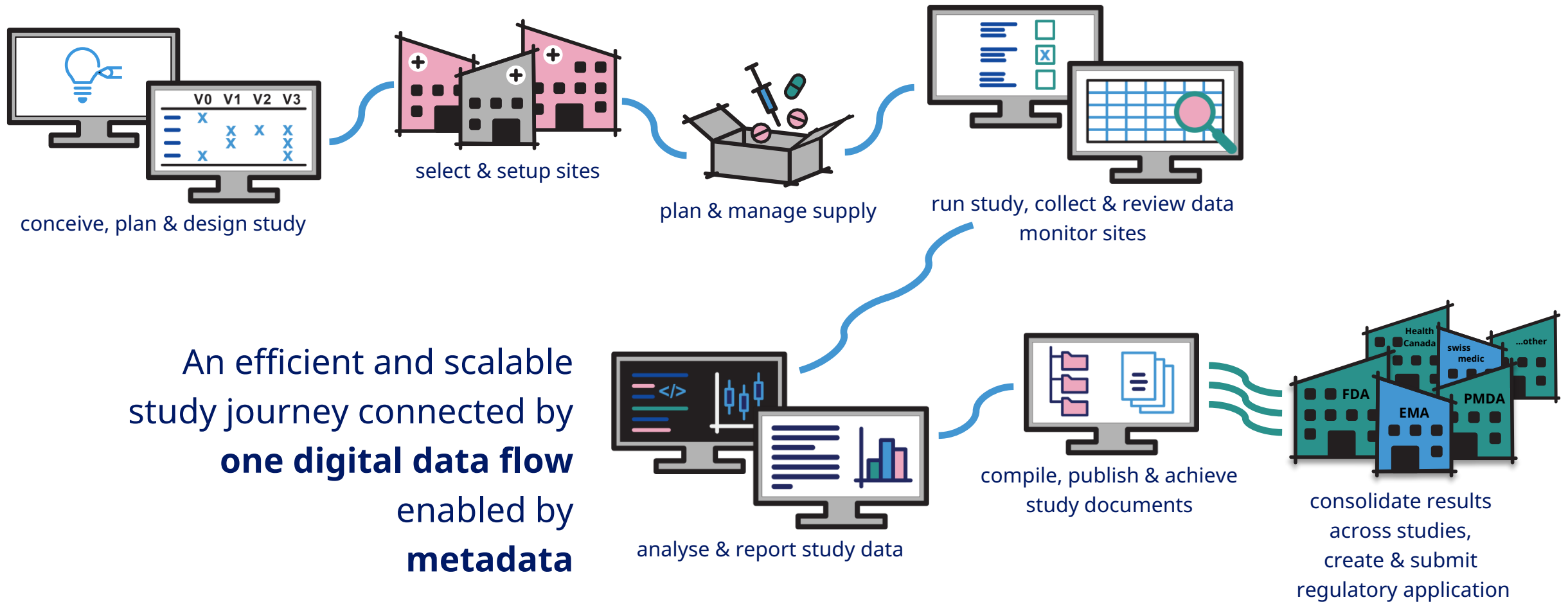
OPEN  
STUDY  
BUILDER



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Nicolas De Saint Jorre

# ONE study journey



# What is OpenStudyBuilder?

**OpenStudyBuilder\*** is a next generation end-to-end clinical data standards and study specification solution, enabling clinical study data solutions to use linked metadata for higher degree of automation, limiting manual document driven work processes, enabling a Digital Data Flow approach.

## Core Components of OpenStudyBuilder:

- ❖ The OpenStudyBuilder application (web-based user interface)
- ❖ The clinical Metadata Repository and Study Definition Repository - MDR & SDR (central storage)
- ❖ The API layer (enabling interoperability with other systems)



\*CDISC 360i core component  
Implement TransCelerate DDF

OPEN  
STUDY  
BUILDER



## Today

OpenStudyBuilder is used to ...

... manage structured study protocol elements, enabling downstream support

(Word Protocol, ICH M11, USDM, Trial Registration, pre-define.xml)

## Tomorrow

OpenStudyBuilder will additionally be used to ...

... manage industry standards with extensions and enrichments, including protocol standards

... manage CRF library, enabling EDC automation

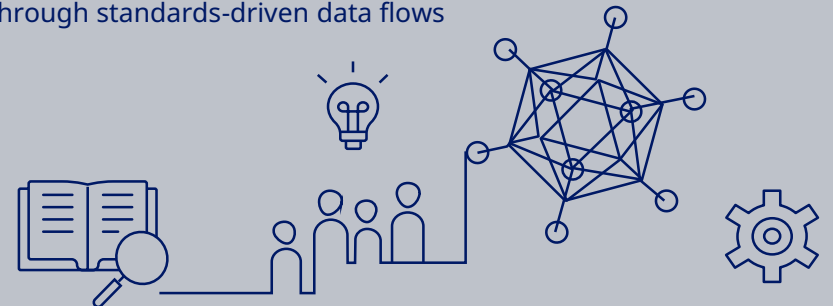
## The Future

OpenStudyBuilder will furthermore evolve to ...

... manage CRF library to drive EDC automation

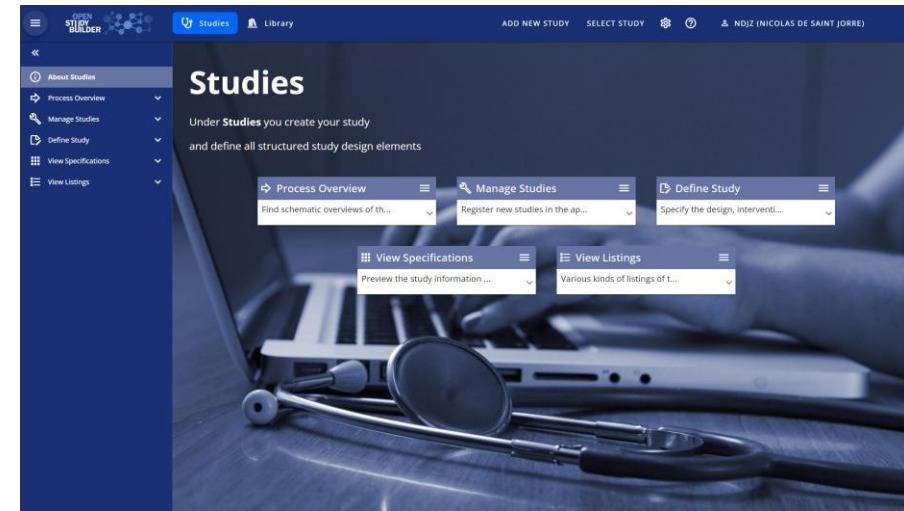
... manage mapping specification, enabling automated data transformation

... a plug-and-play ecosystem where modular functionalities integrate seamlessly with other solutions through standards-driven data flows

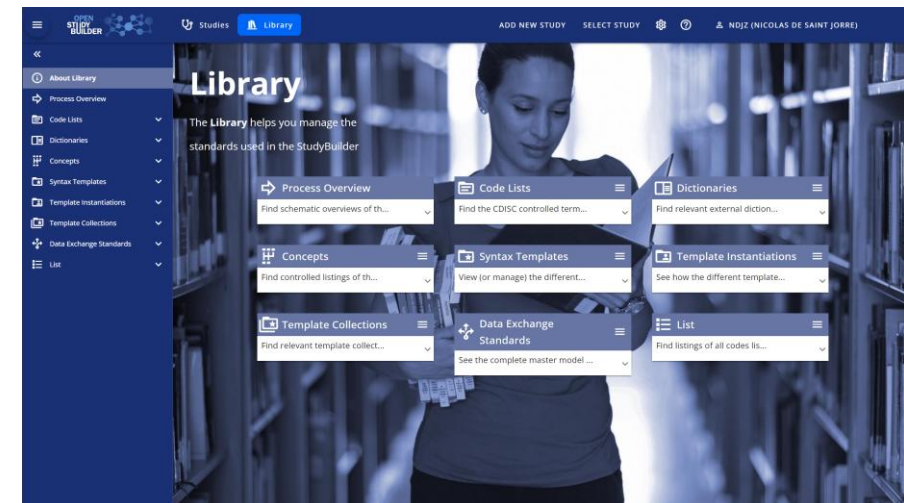


# OpenStudyBuilder Components

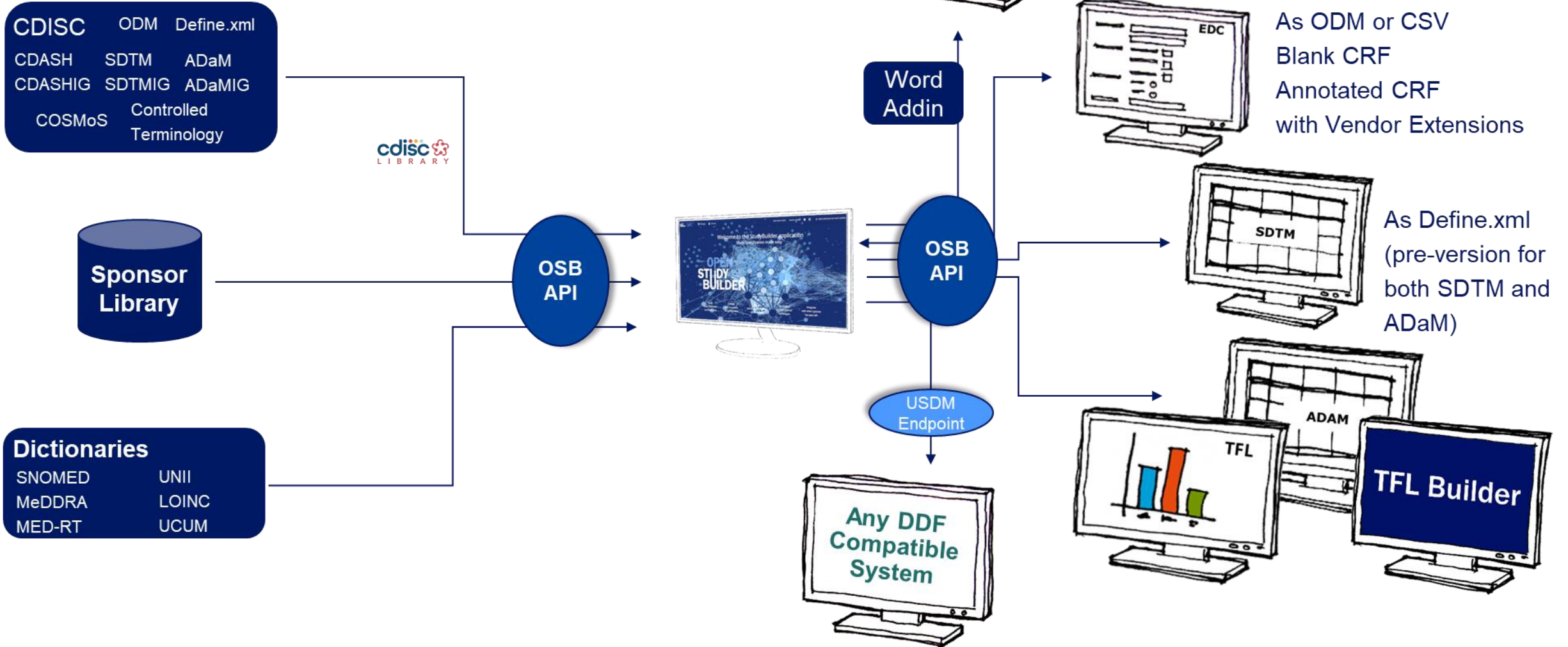
STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



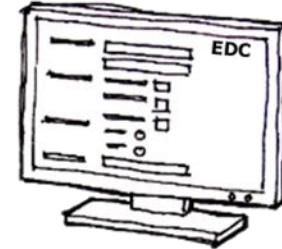
LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., SNOMED, UCUM, MED-RT)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	



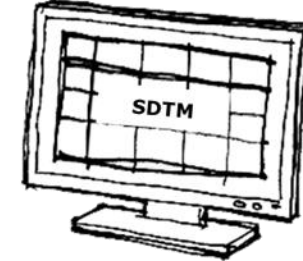
# Connectivity is key!



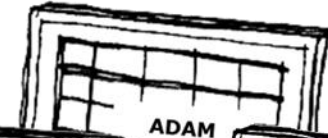
Sponsor version  
M11 version  
CPT version  
Ct.gov...



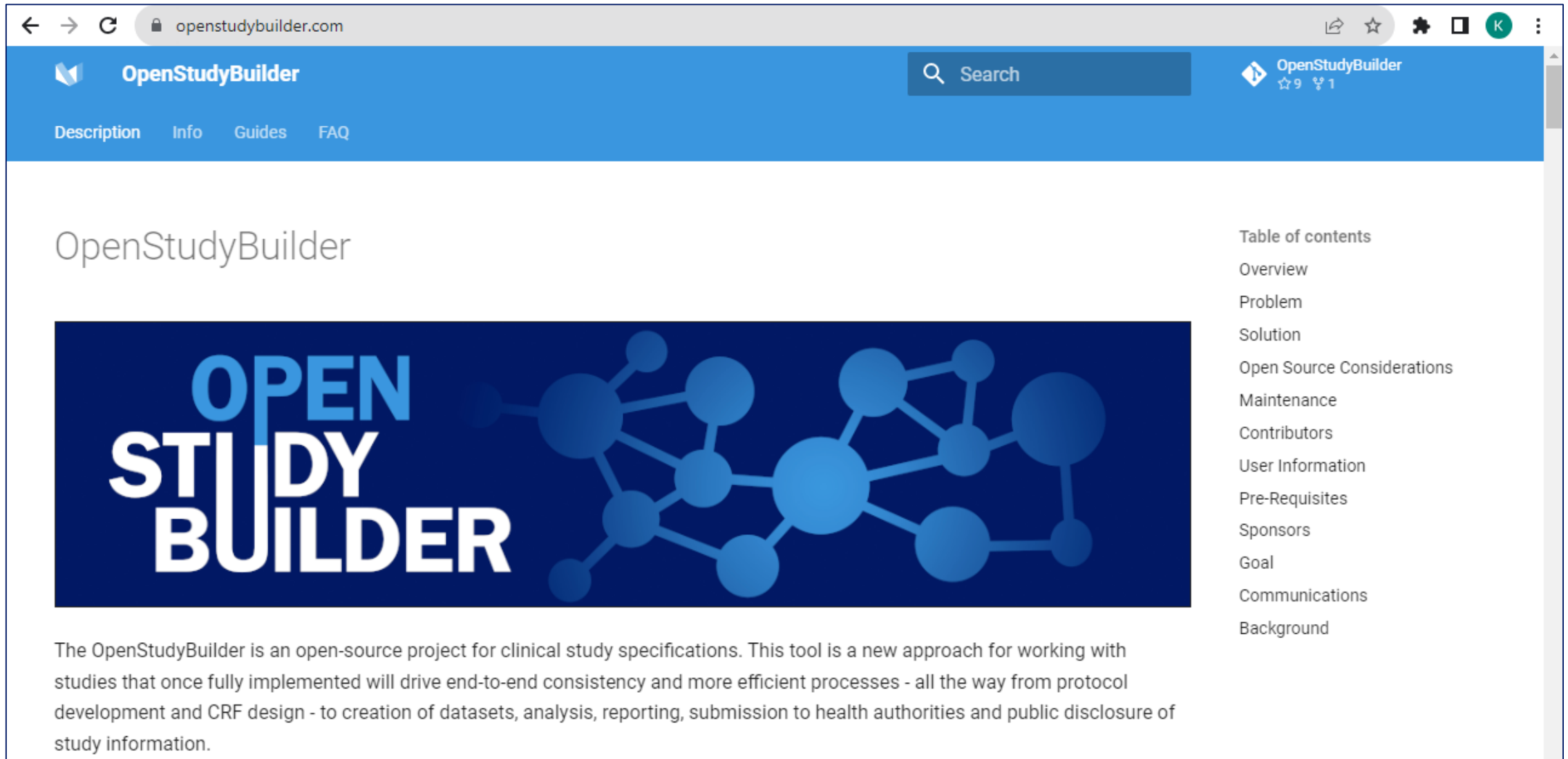
As ODM or CSV  
Blank CRF  
Annotated CRF  
with Vendor Extensions



As Define.xml  
(pre-version for  
both SDTM and  
ADaM)



# Project Homepage



The screenshot shows a web browser window displaying the OpenStudyBuilder project homepage. The browser's address bar shows the URL [openstudybuilder.com](https://openstudybuilder.com). The page features a blue header with the OpenStudyBuilder logo, a search bar, and navigation links for Description, Info, Guides, and FAQ. The main content area includes the project name, a large blue banner with the text "OPEN STUDY BUILDER" and a network diagram, and a paragraph describing the project as an open-source tool for clinical study specifications. A table of contents is visible on the right side of the page.

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/>

# OpenStudyBuilder Links

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## Getting Started

Checkout available resources!

- Project website: <https://openstudybuilder.com>
- Newsletter: [LinkedIn](#)
- Demonstration Videos: [Overview \(2025\)](#), [Details \(2023\)](#)
- Demonstration Flow: [Homepage](#)
- Repository: [GitHub](#)
- Slack: [Join](#)
- Email: [openstudybuilder@gmail.com](mailto:openstudybuilder@gmail.com)
- Request sandbox access: [Sandbox](#)



<https://openstudybuilder.com/status/>

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# Getting along

- **Support**

- Documentation
- OpenStudyBuilder Q&A sessions
- Slack & Mail
- Commercial support options of vendors

- **Share**

- Documentation, Feedback, Ideas
- Enhancements, connected tools
- Biomedical Concepts discussions & additions
- Remark: no direct contribution in repository

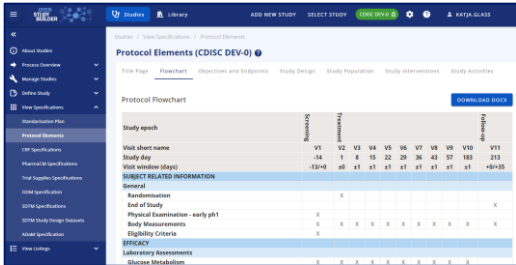


# OpenStudyBuilder – What's in?

What do I get?

- /// Documentation
- Project Homepage
- Tool documentation
- GitLab documentation
  - Database design
  - Architecture design
  - Instructions

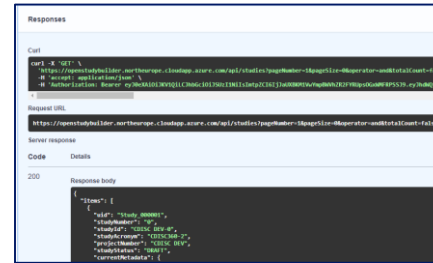
Application



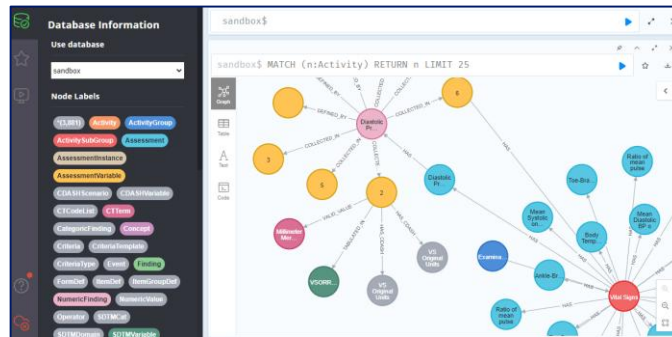
Neo4j database  
- Including example data



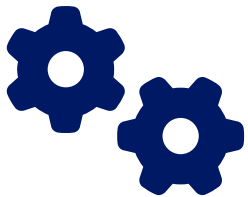
API



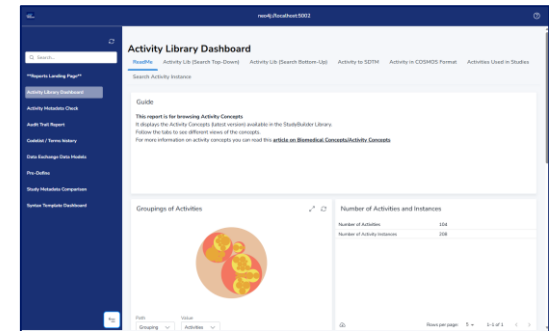
DB Browser



Scripts



Neo4j dashboards



# Sandbox

- **OpenStudyBuilder App**

<https://openstudybuilder.northeurope.cloudapp.azure.com/>

- **Documentation**

<https://openstudybuilder.northeurope.cloudapp.azure.com/doc/>

- **API**

<https://openstudybuilder.northeurope.cloudapp.azure.com/api/docs/>

- **NeoDash**

<https://openstudybuilder.northeurope.cloudapp.azure.com/neodash/>

- **(DB Browser)**

<https://openstudybuilder.northeurope.cloudapp.azure.com/browser/>

- **(Bloom)**

<https://openstudybuilder.northeurope.cloudapp.azure.com/bloom/>



Questions!

**OPEN**  
**STUDY**  
**BUILDER**

