

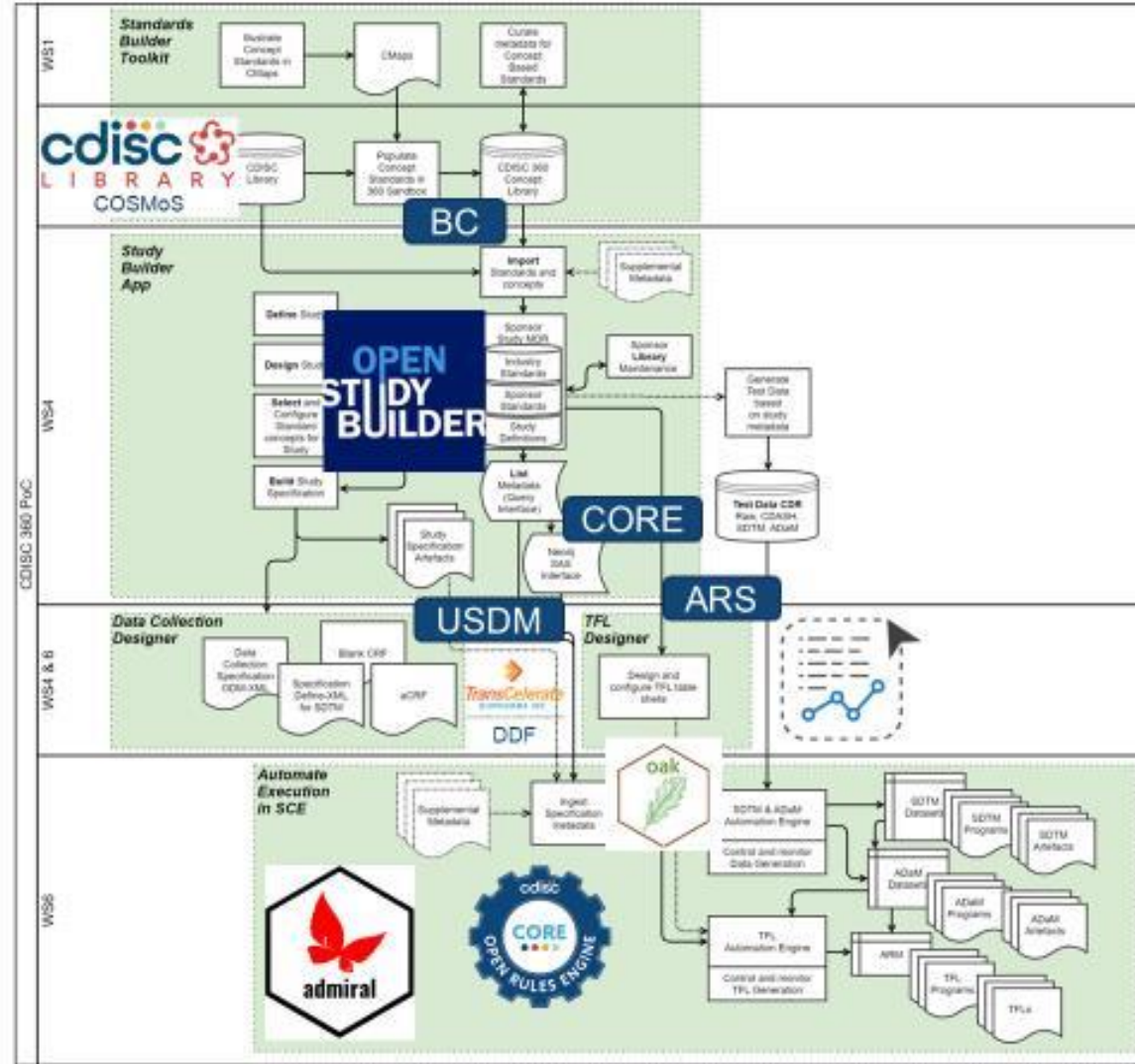
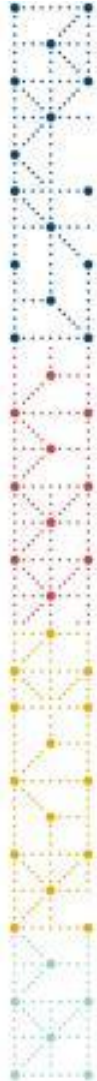
OpenStudyBuilder Community Meeting



Katja Glaß

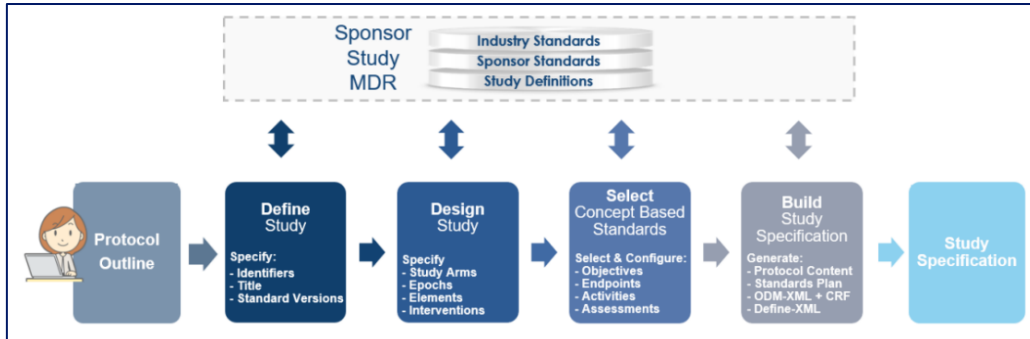
Nicolas De Saint Jorre

Introduction

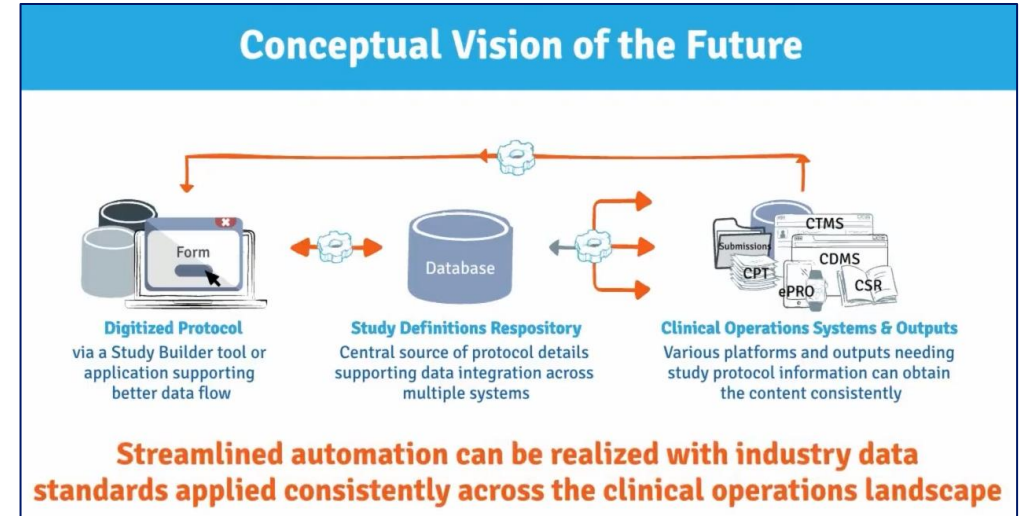


Introduction

CDISC 360°



TransCelerate Digital Data



OpenStudyBuilder
Open-Source by Novo Nordisk

Introduction

The OpenStudyBuilder comprises three elements:

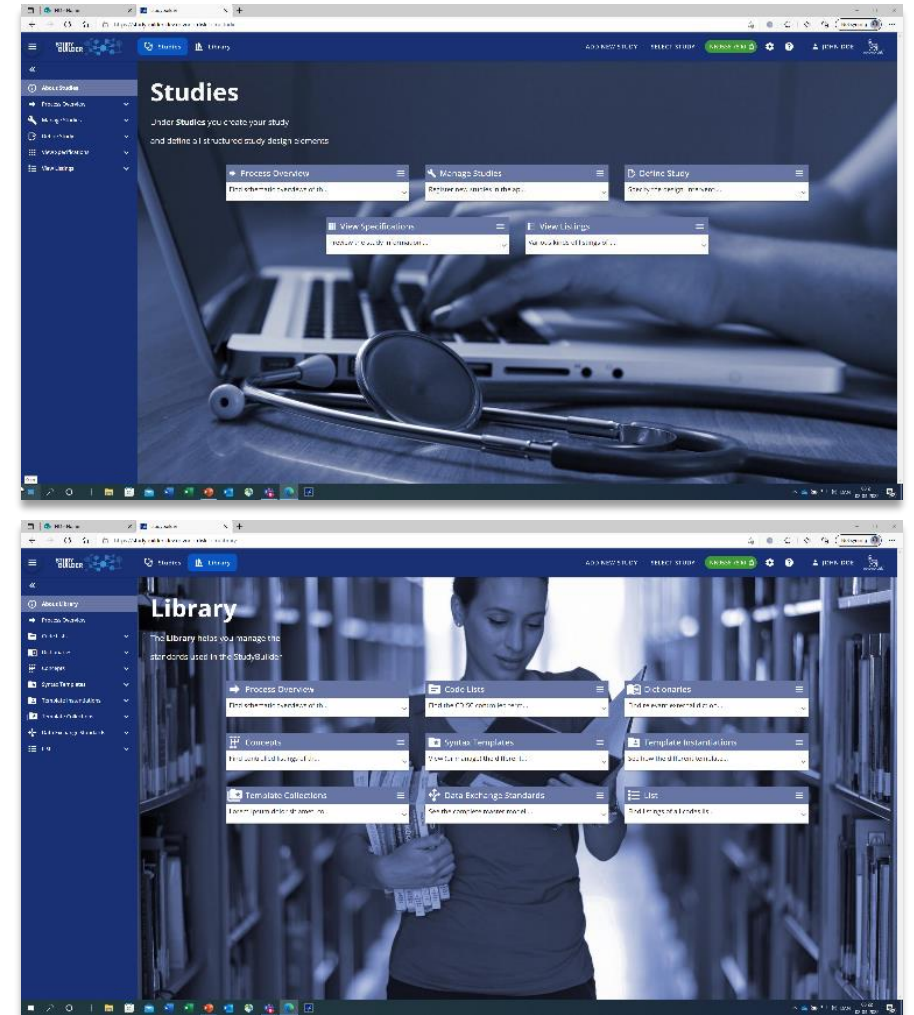
- **Clinical Metadata Repository (clinical MDR) & Study Definition Repository (SDR)**
(graph database, central repository for all study specification data)
- **OpenStudyBuilder application**
(web-based user interface)
- **API layer**
(allowing interoperability with other applications)
(DDF API Adaptor – enabling DDF SDR Compatibility)



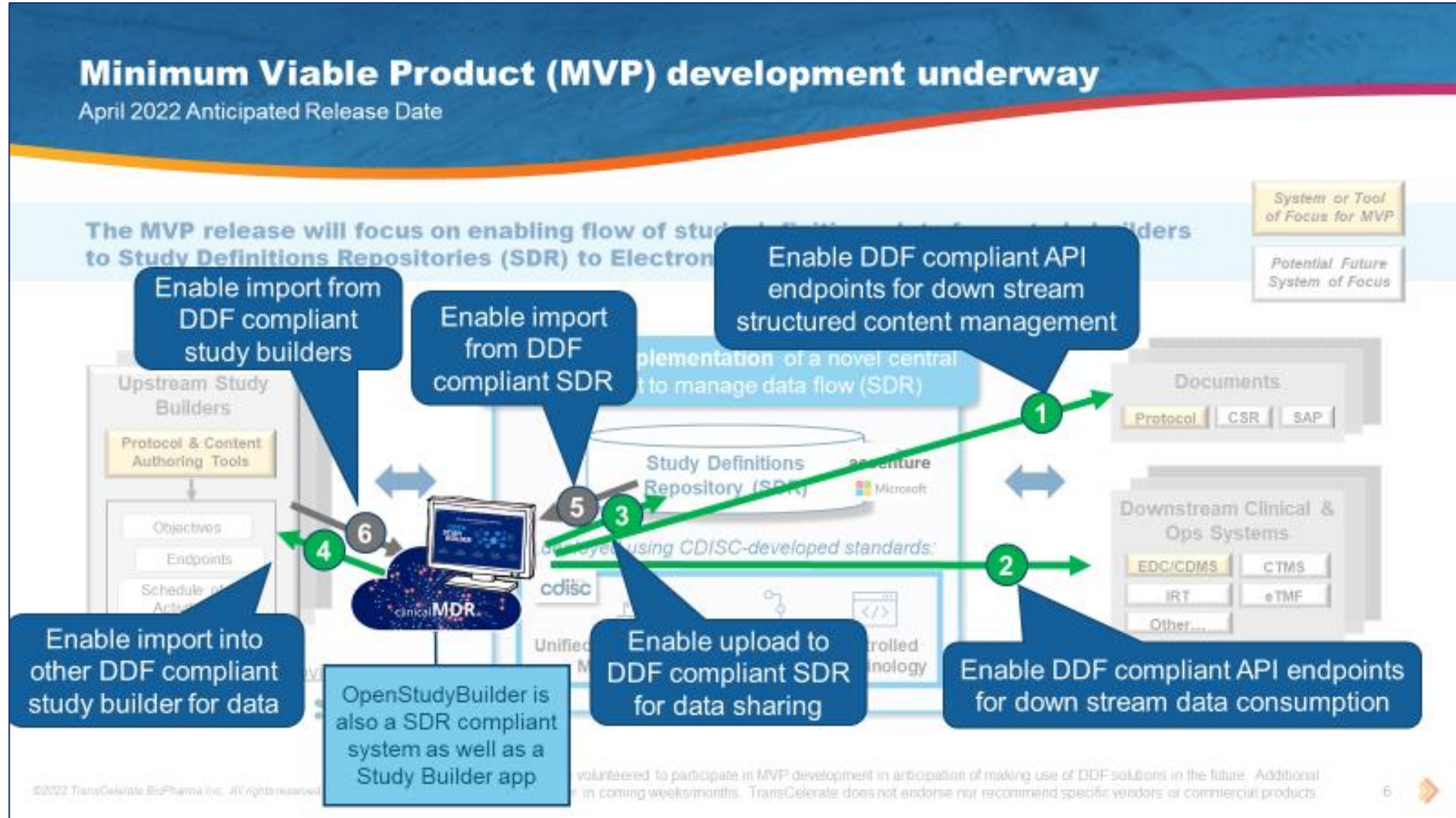
Introduction

The OpenStudyBuilder includes:

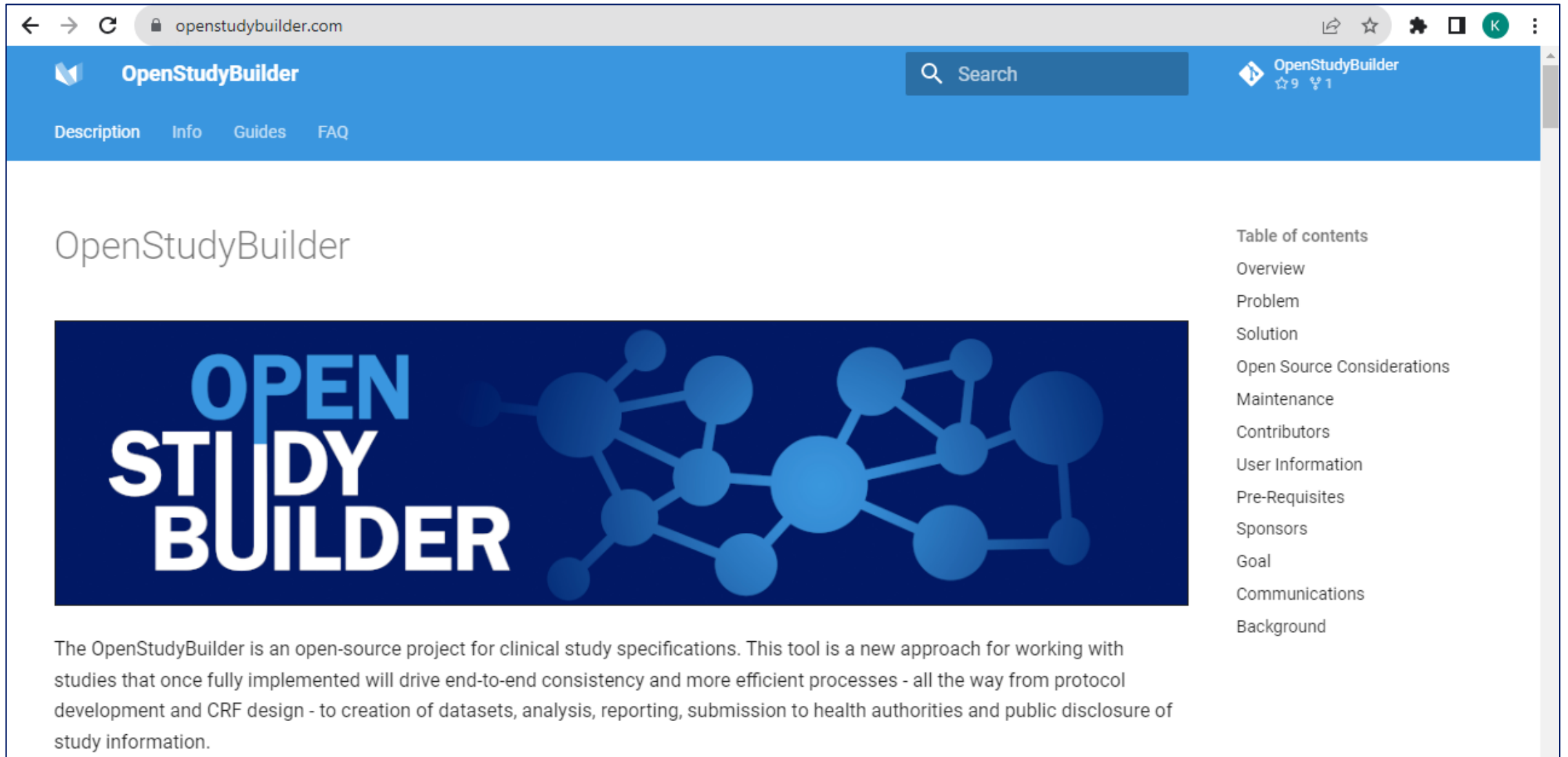
- A **Studies** part for specification of studies (incl. disease area and study type, objectives and endpoints, population and eligibility criteria, study compounds and other interventions, study design, arms and visits, schedule of activities and associated procedure and assessment instructions)
- A **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 will also be DDF Compatible



Project Homepage



The screenshot shows a web browser window displaying the OpenStudyBuilder project homepage. The browser's address bar shows the URL 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 title "OpenStudyBuilder", 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
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- Goal
- Communications
- Background

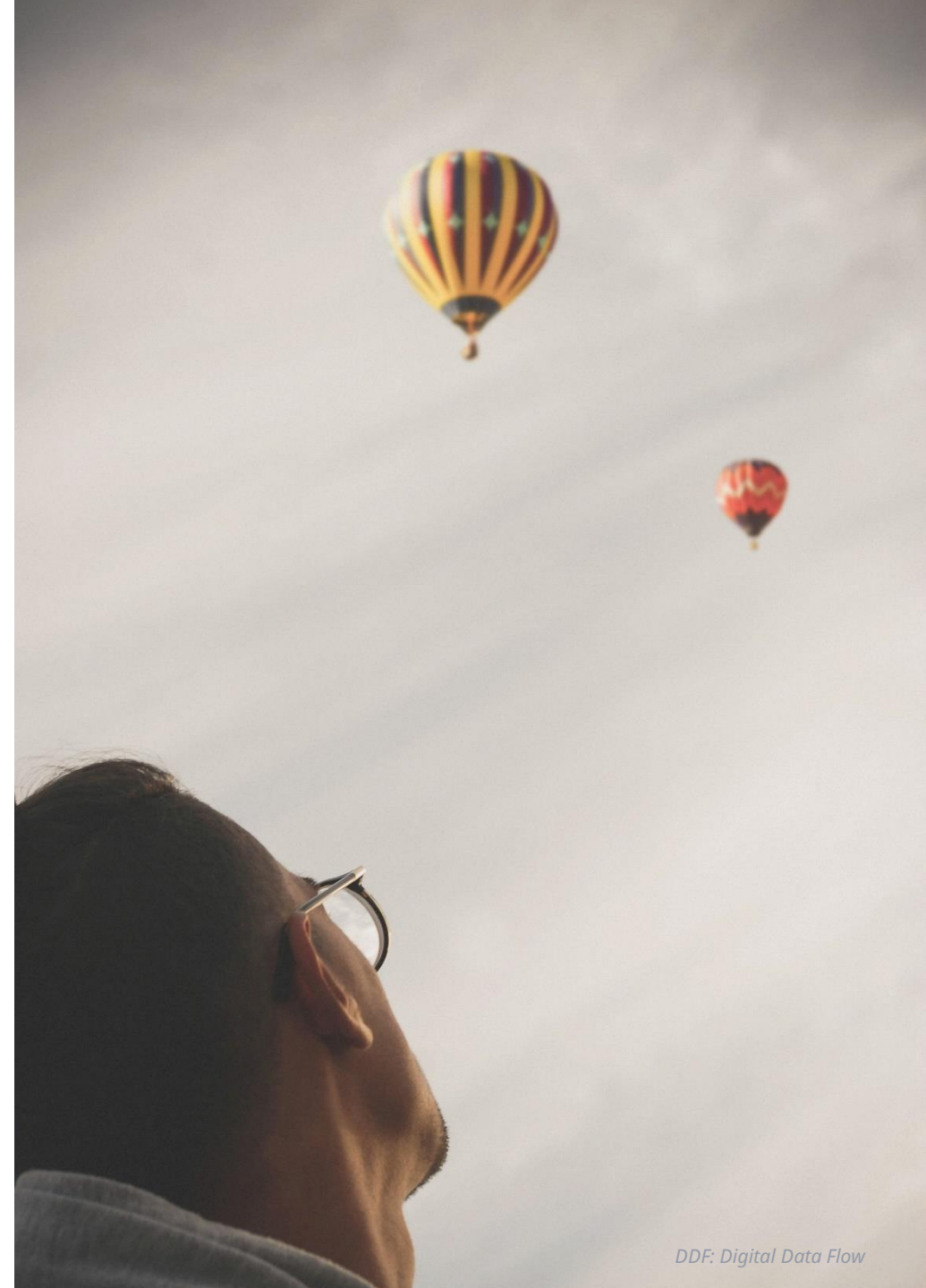
<https://openstudybuilder.com/>

Links

- Project Homepage: <https://openstudybuilder.com/>
- YouTube Demonstration (30'): <https://youtu.be/dL5CY0BwfEs>
- GitLab (Solution, Description): <https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder>
- Slack:
https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyiIvB1Wsw
- E-Mail: openstudybuilder@gmail.com

Sandbox:

- Mail openstudybuilder@neotechnology.com – Subject “Request Sandbox access”
- Note: when add/modify/delete, you mail might be exposed in the version history



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

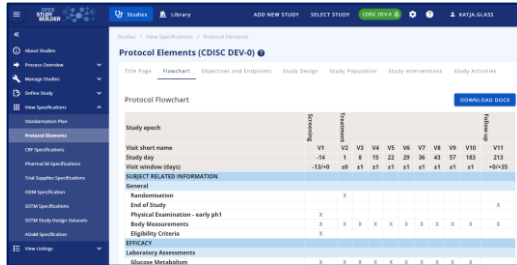


OpenStudyBuilder – What's in?

What do I get?

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

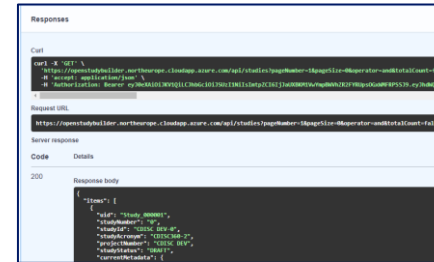
Application



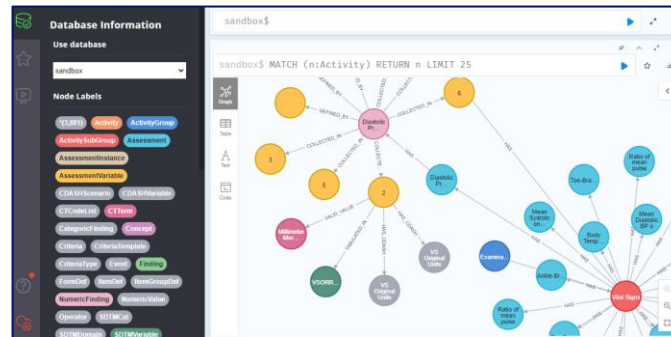
Neo4j database
- Including example data



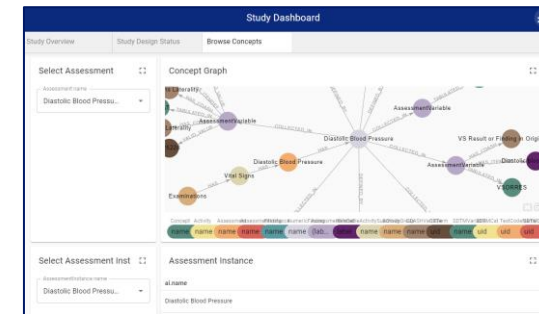
API



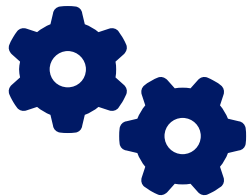
DB Browser



Neo4j dashboard*



Scripts



*available in sandbox, can be installed on other environments



Sandbox

- **OpenStudyBuilder App**
<https://openstudybuilder.northeurope.cloudapp.azure.com/>
- **Documentation**
<https://openstudybuilder.northeurope.cloudapp.azure.com/doc/>
- **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

