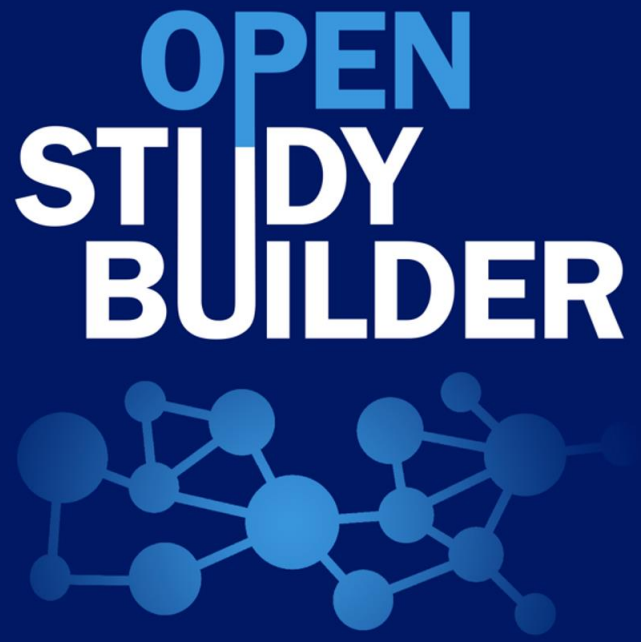
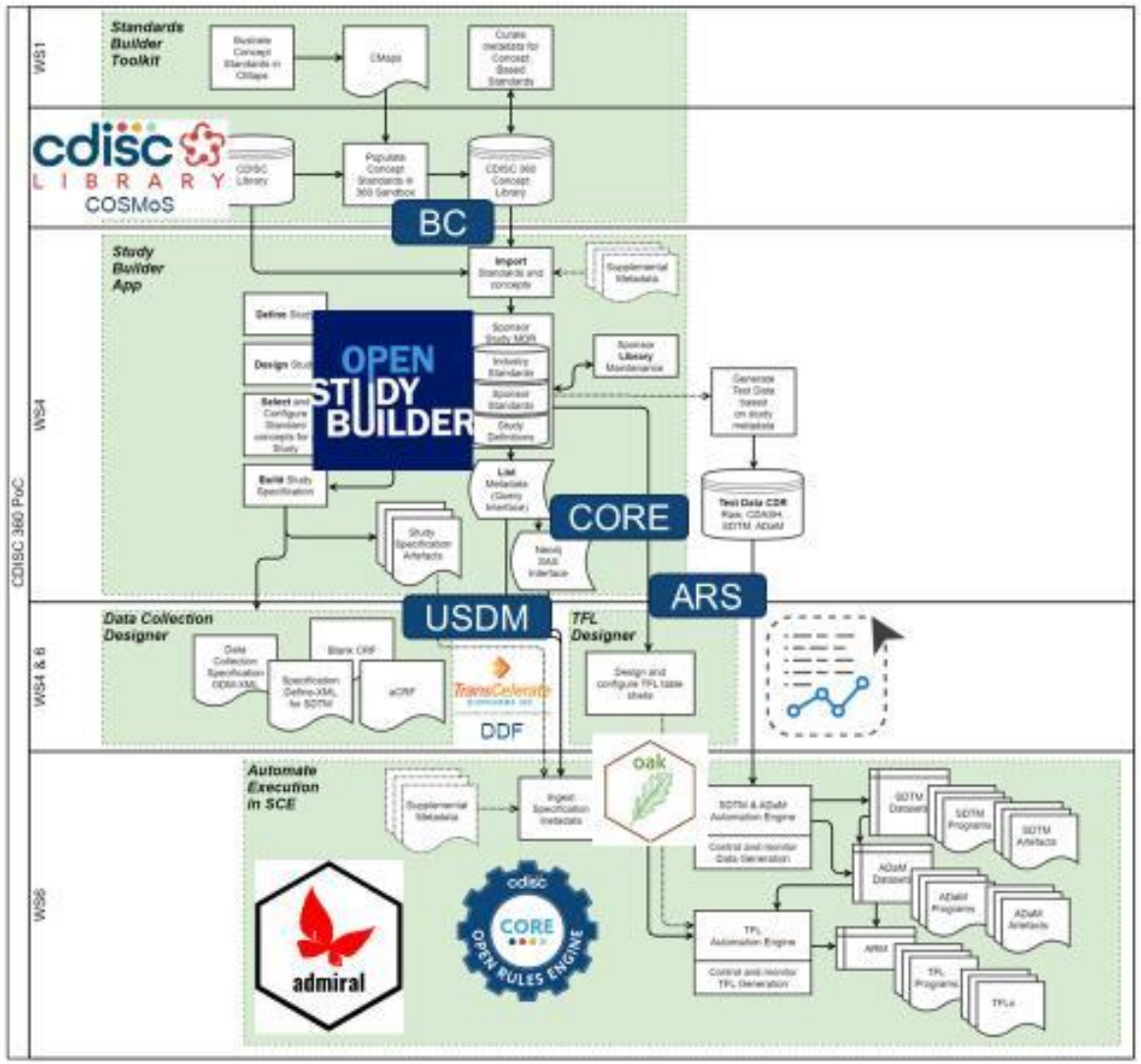
OpenStudyBuilder
Community Meeting



Katja Glaß

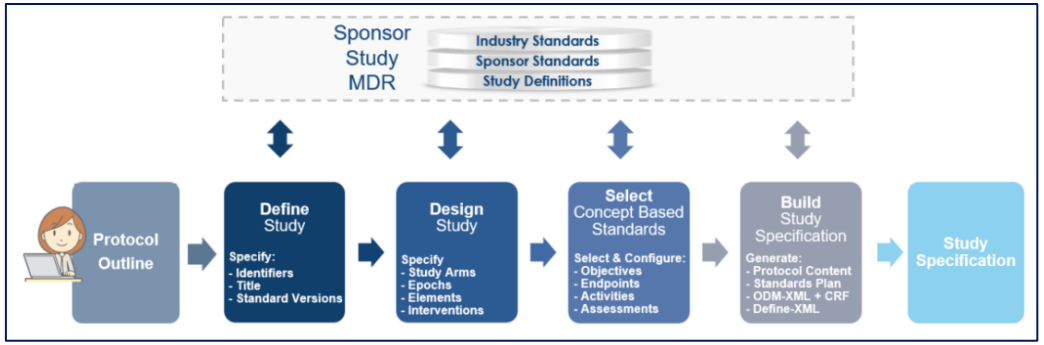
Nicolas De Saint Jorre

Introduction

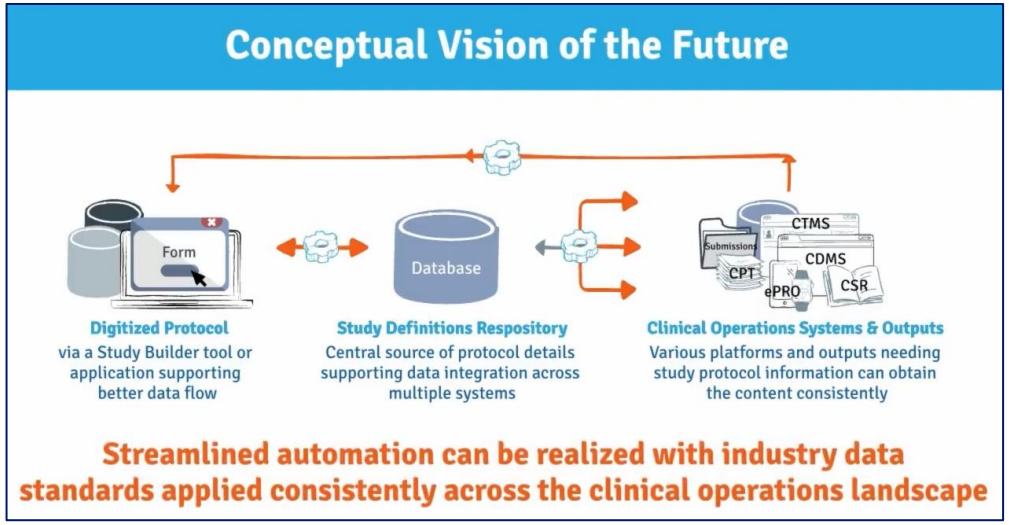


Introduction

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)

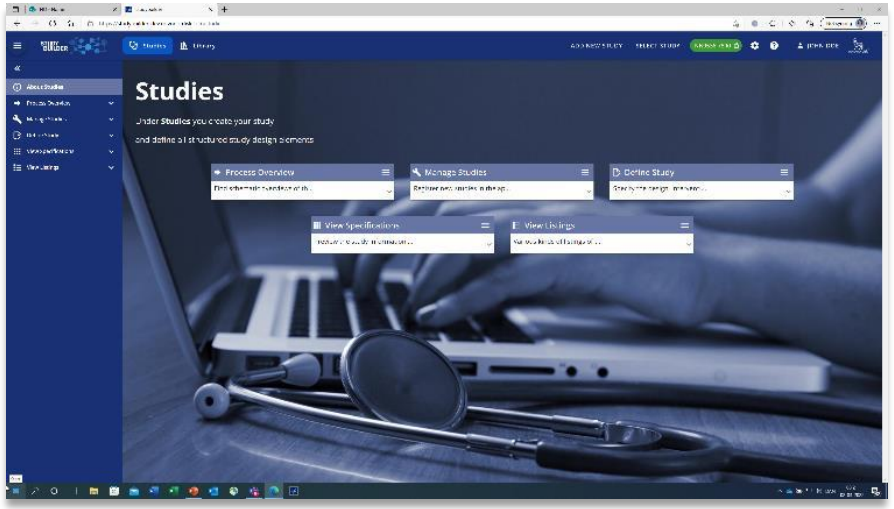
Introduction

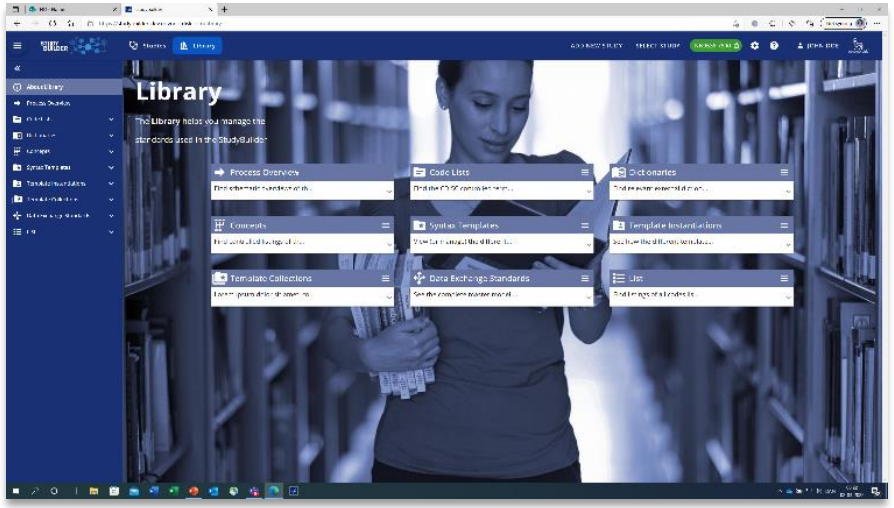
The OpenStudyBuilder includes:

- 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)

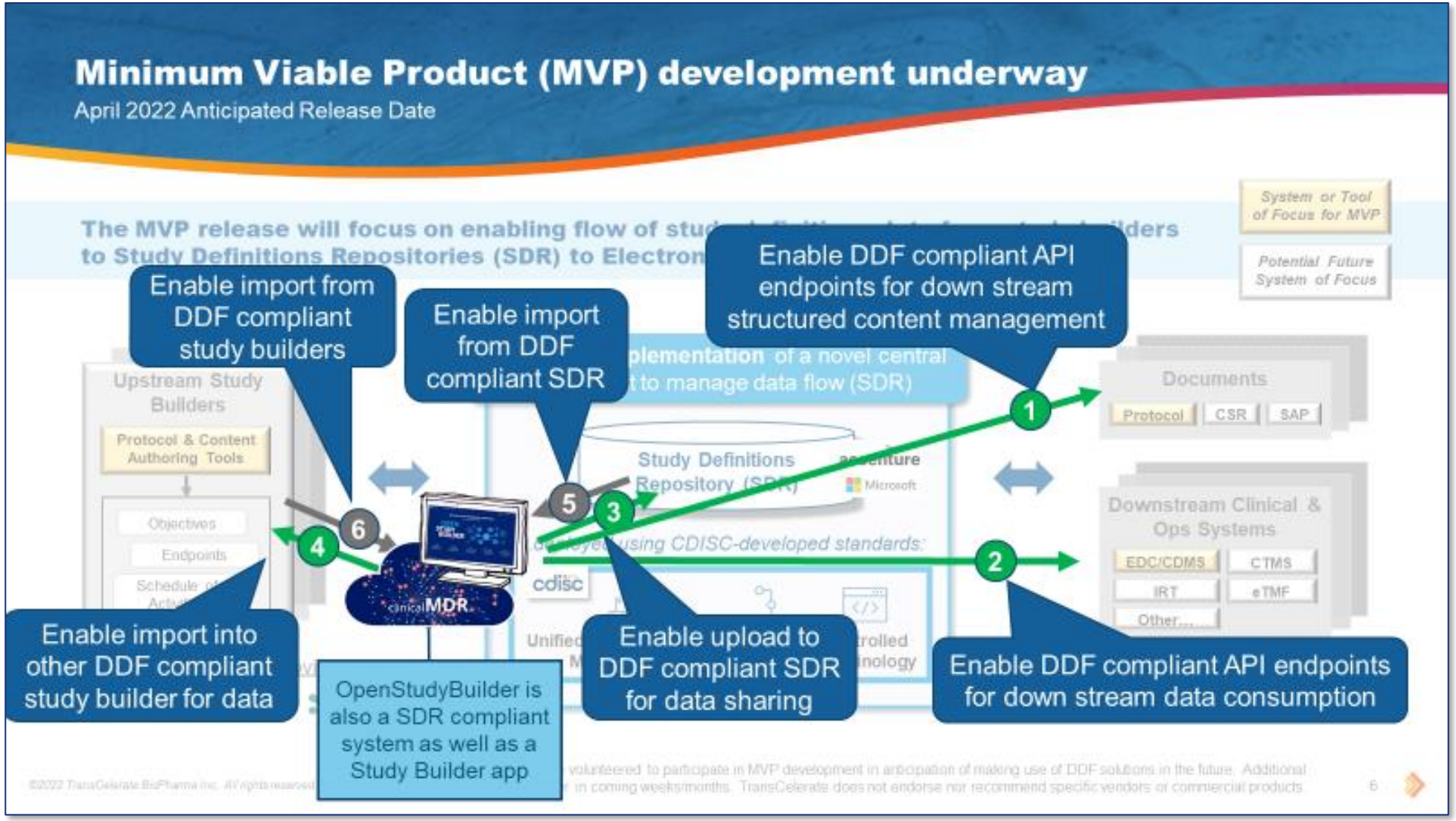
- A **Library** part for maintenance of terminology standards (incl. CDISC controlled terminology, relevant parts of external dictionaries for medical terms, pharmacological classes, units, a detailed compound library, a granulated library of activity terms) as well as syntax templates for cross-study 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)



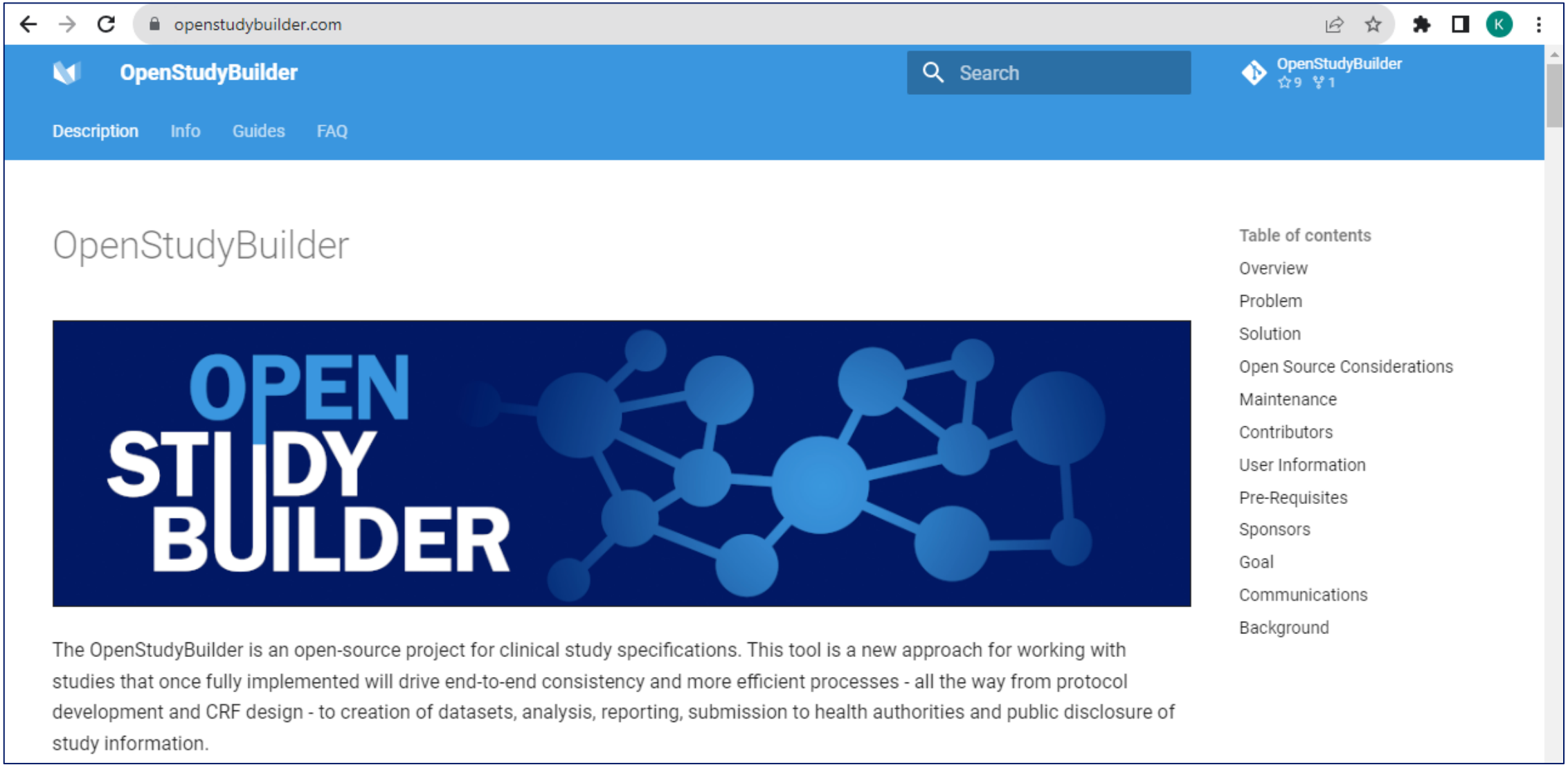


OpenStudyBuilder will also be DDF Compatible



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

Project Homepage



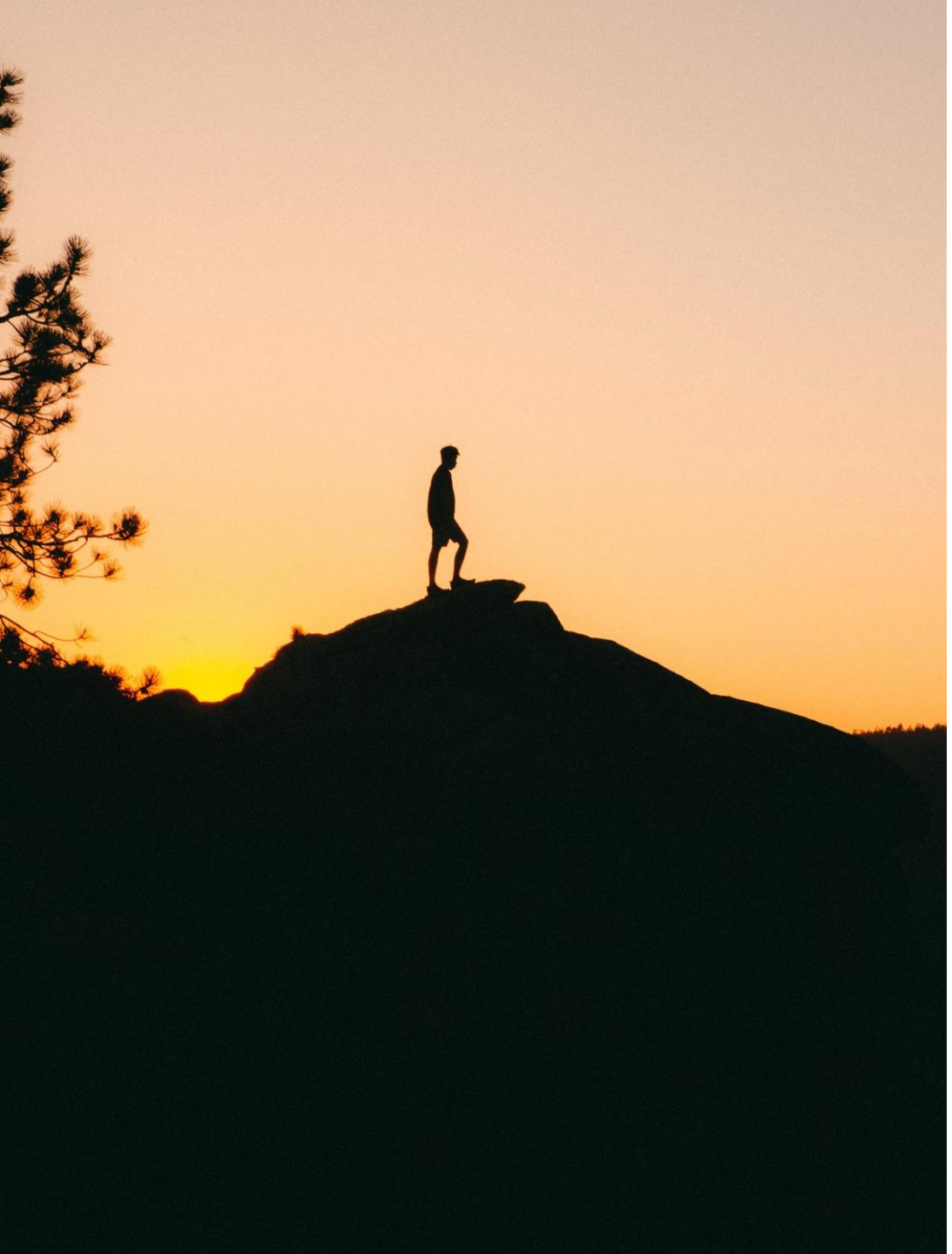
https://openstudybuilder.com/

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

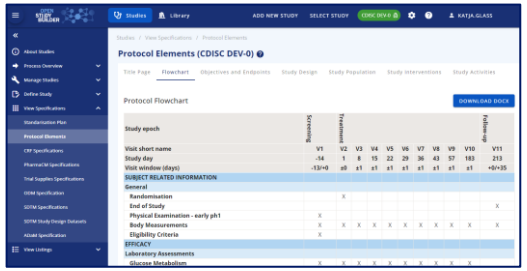
- **Support**
  - Documentation
  - OpenStudyBuilder Q&A sessions
  - Slack & Mail
  - Commercial support options of vendors

- **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?

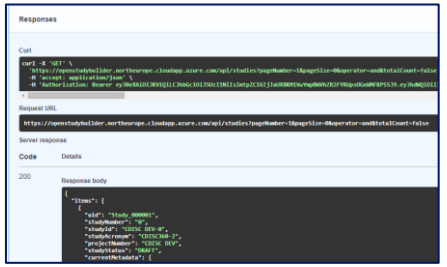
Application



Neo4j database

- Including example data

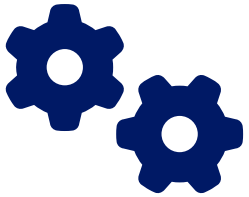
API



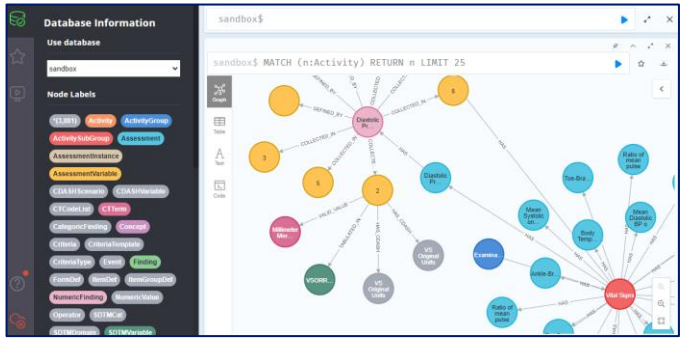
Documentation

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

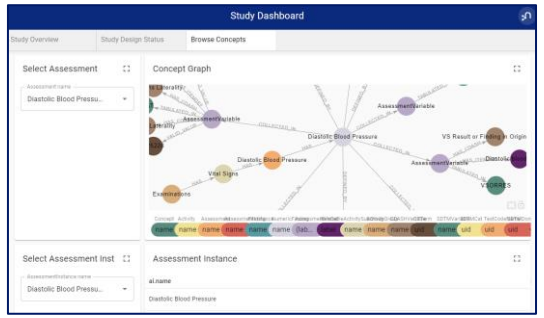
Scripts



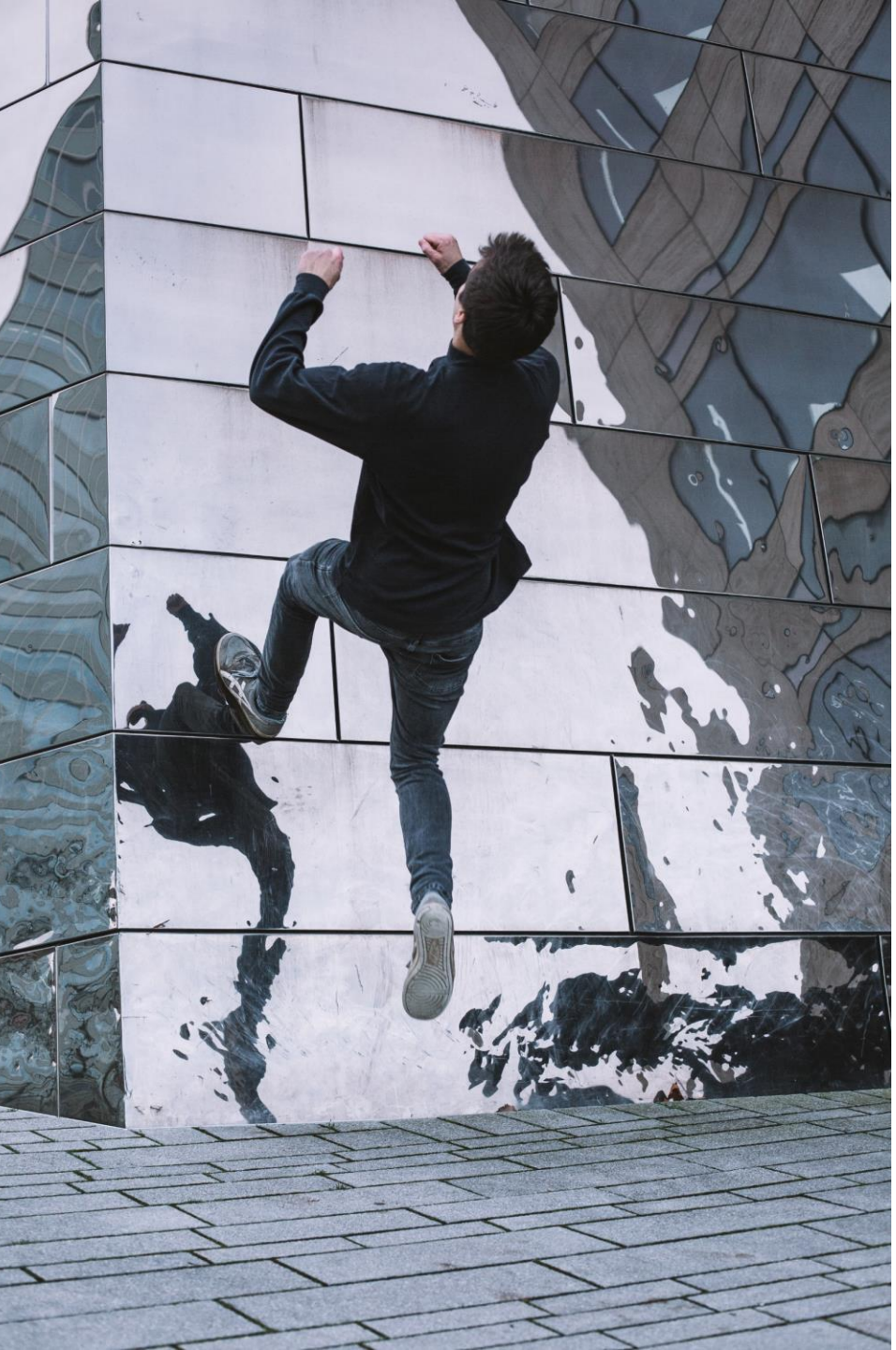
DB Browser



Neo4j dashboard*



*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)
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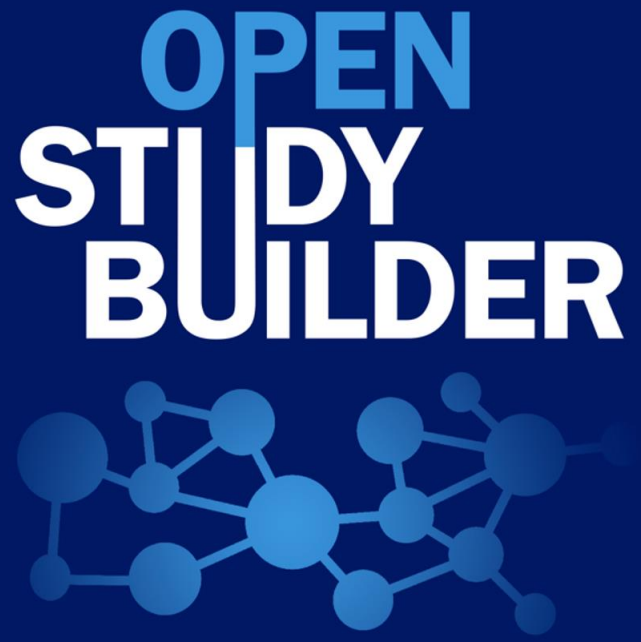
Questions!