

OPEN STUDY BUILDER



OpenStudyBuilder Open-Source MDR Questions & Answers

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Katja Glass, OpenStudyBuilder Community Manager
Nicolas De Saint Jorre, OpenStudyBuilder Tool Expert
Marius Conjeaud, Neo4j, BC, Deployment & Sandbox Expert
Alexander Jarasch, Neo4j, BC, Deployment & Sandbox Expert

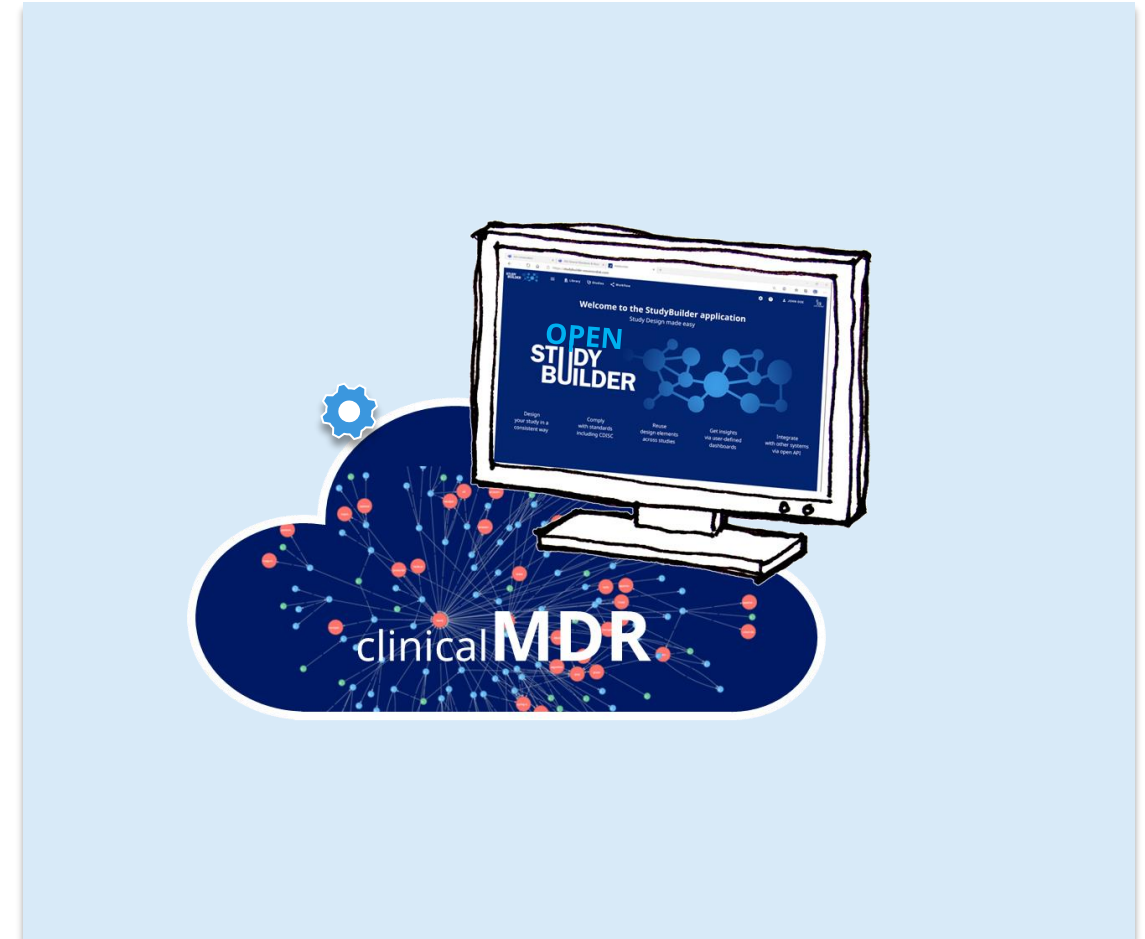
What is the OpenStudyBuilder ...

The OpenStudyBuilder is the new approach to study specification that will:

- Ensure a higher degree of end-to-end consistency
- Have built-in compliance with external and internal standards
- Facilitate more automation and content reuse

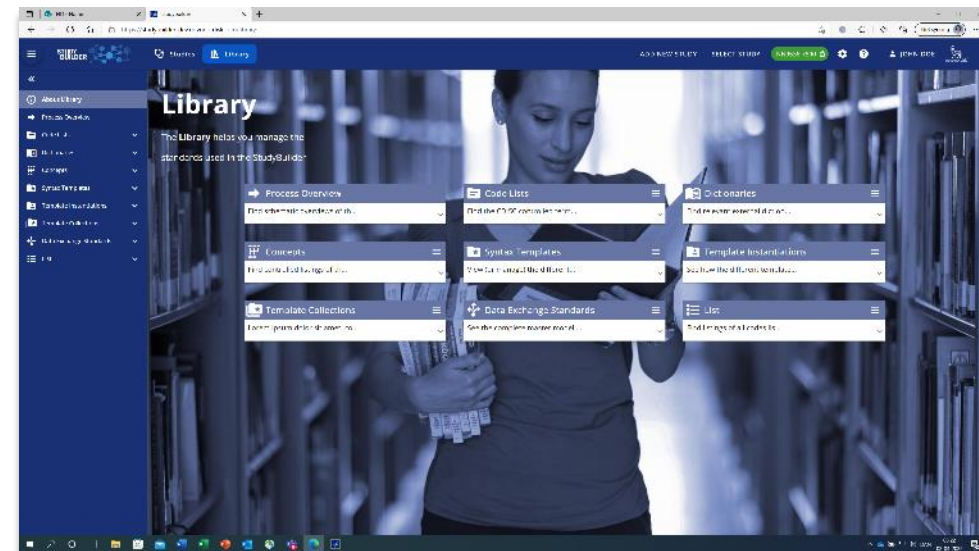
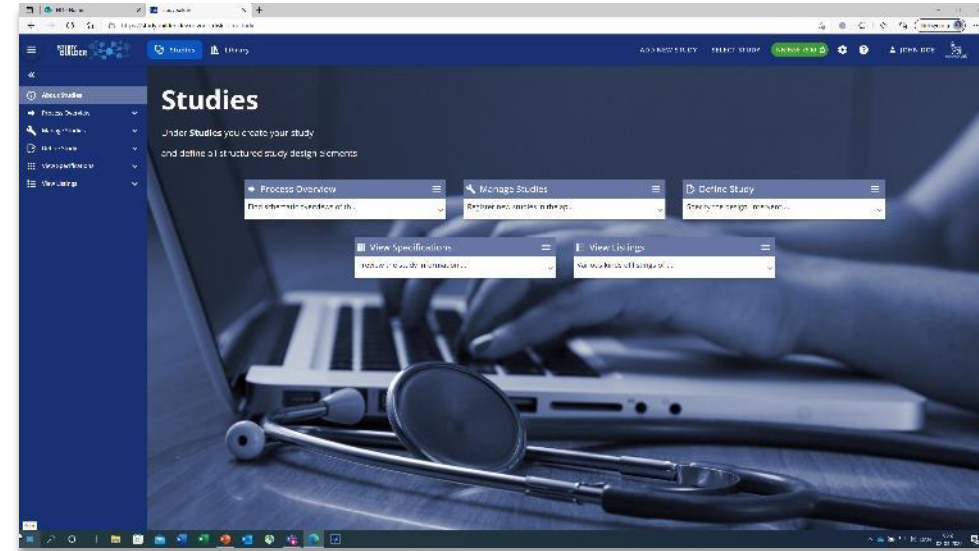
The OpenStudyBuilder comprises three elements:

- **Clinical Metadata Repository (clinical MDR)**
(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)

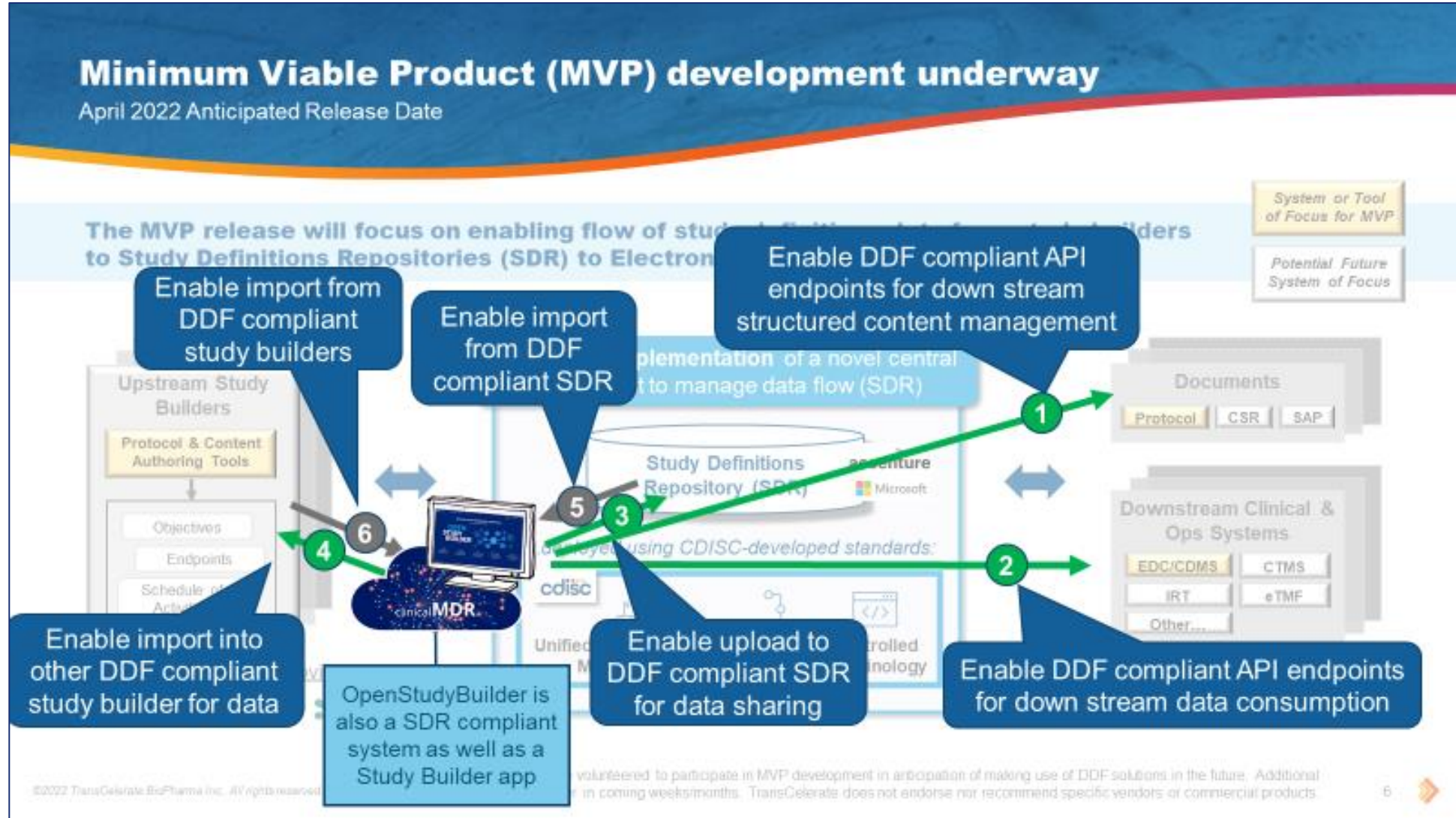


The OpenStudyBuilder includes:

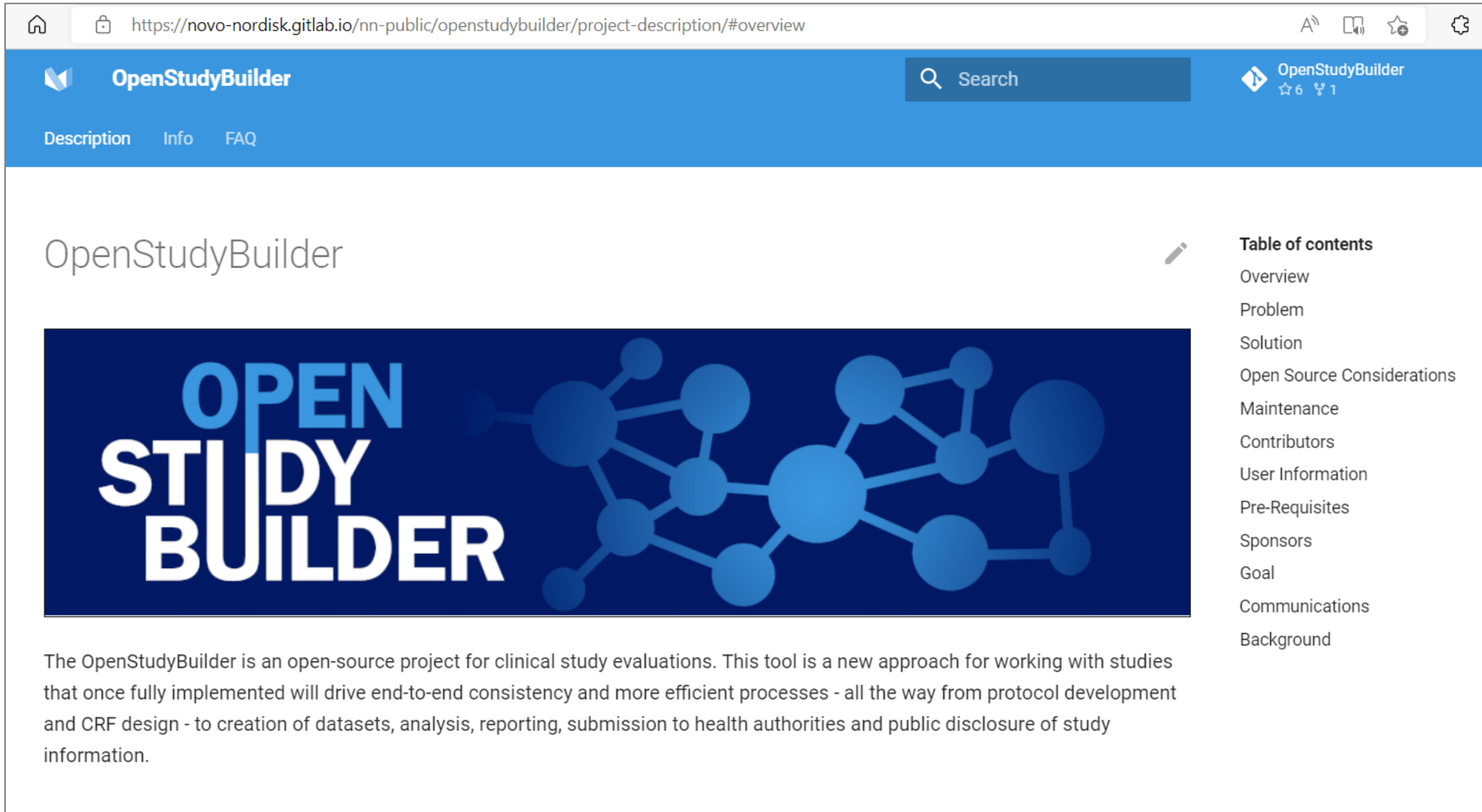
- A **Studies** part for specification of studies (incl. disease area and study type, objectives and endpoints, population and eligibility criteria, study compounds and other interventions, study design, arms and visits, schedule of activities and associated procedure and assessment instructions)
- A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



Project Homepage



The screenshot shows a web browser window displaying the project description page for OpenStudyBuilder. The browser's address bar shows the URL: <https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/#overview>. The page header is blue and contains the OpenStudyBuilder logo, a search bar, and the project name with 6 stars and 1 fork. Below the header, there are navigation links for Description, Info, and FAQ. The main content area features the title "OpenStudyBuilder" and a large blue banner with the text "OPEN STUDY BUILDER" and a network diagram. To the right of the banner is a "Table of contents" section with a pencil icon, listing various sections. Below the banner is a paragraph of text describing the project.

OpenStudyBuilder

**OPEN
STUDY
BUILDER**

The OpenStudyBuilder is an open-source project for clinical study evaluations. 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

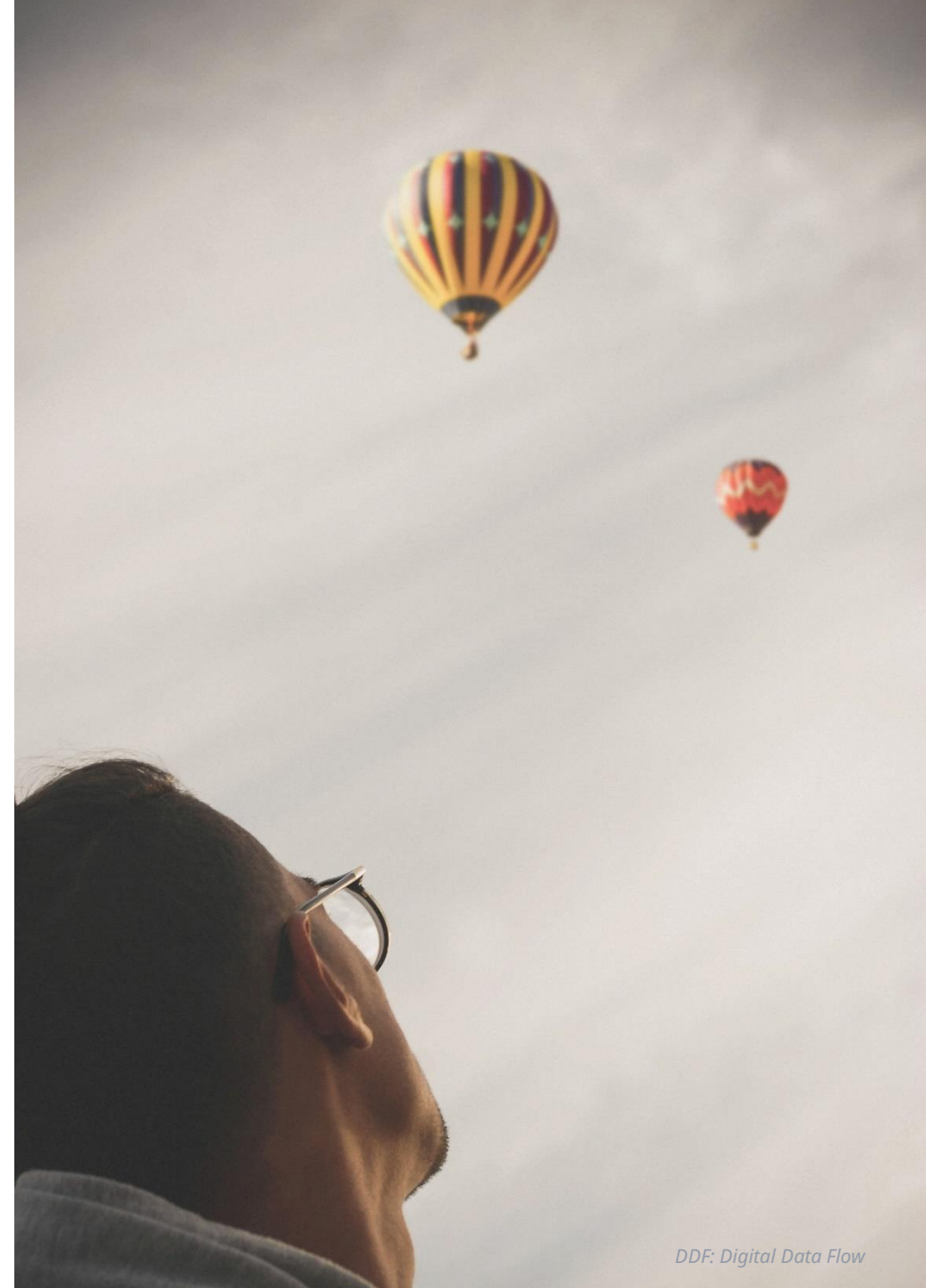
<https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/>

Links

- Project Homepage: <https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/>
- 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 (by-weekly)
- Slack & Mail
- Commercial support options of vendors

- **Share**

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





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!

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