

OpenStudyBuilder

Open-source MDR

PHUSE EMEA Autumn SDE Copenhagen



Mikkel Traun, Novo Nordisk A/S

Katja Glass, Katja Glass Consulting

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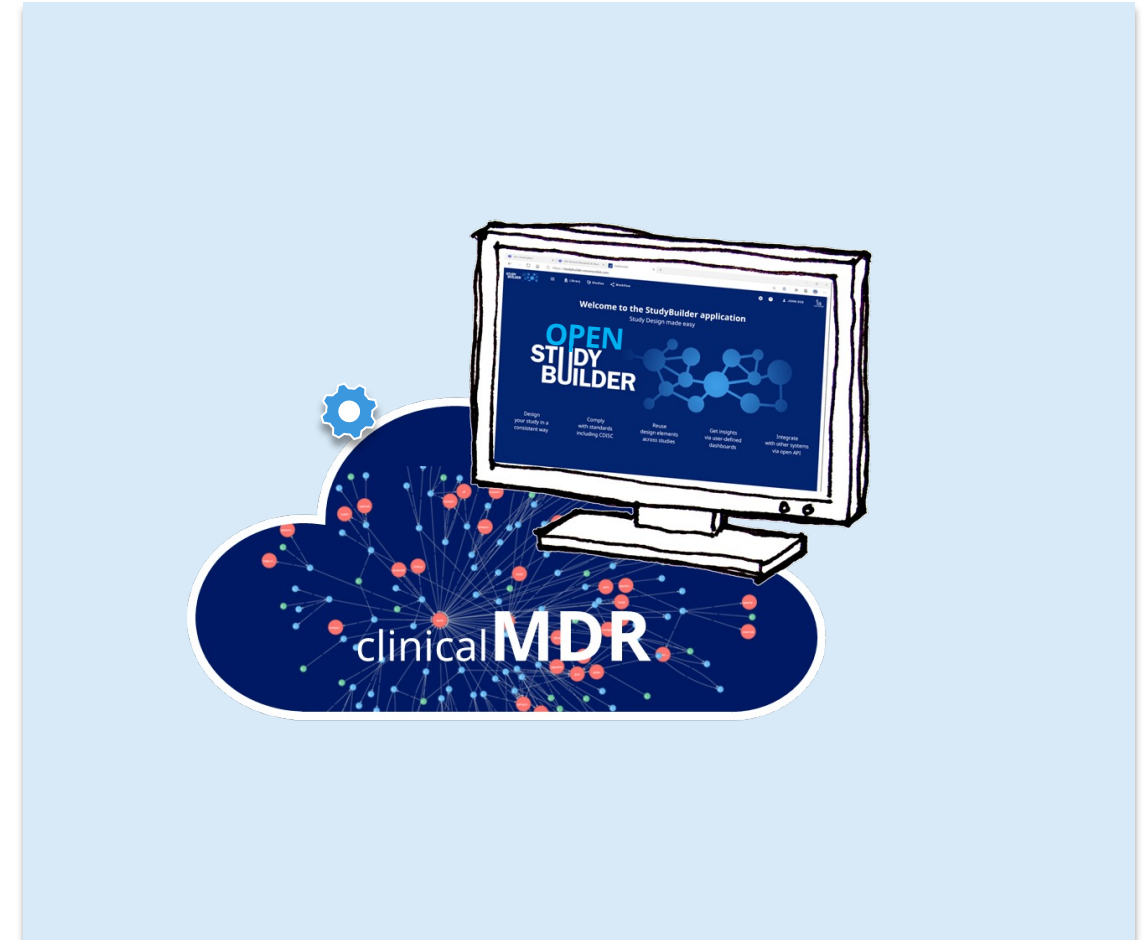
What is the OpenStudyBuilder ...

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

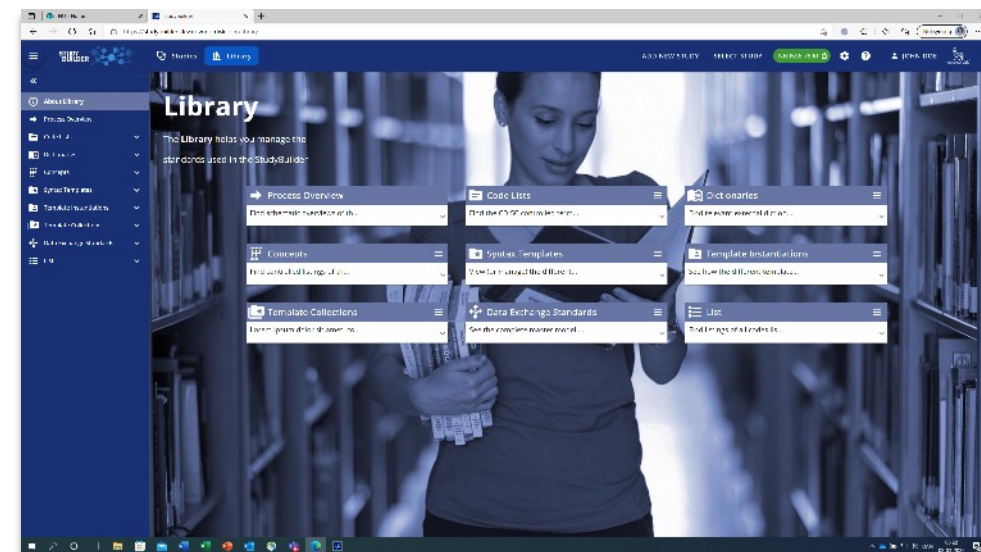
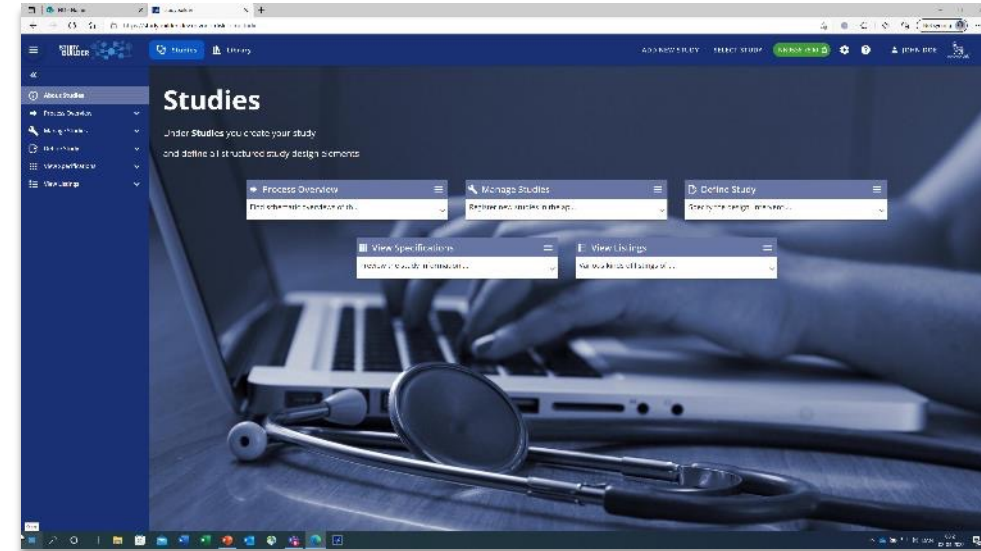
The OpenStudyBuilder comprises three elements:

- **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)

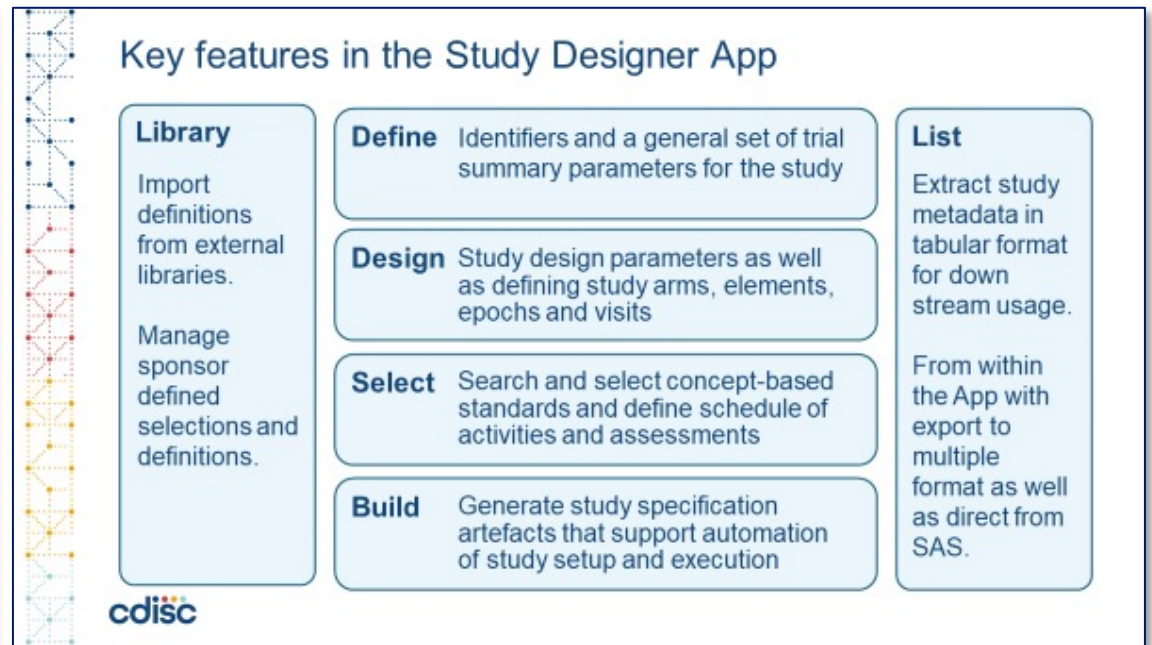
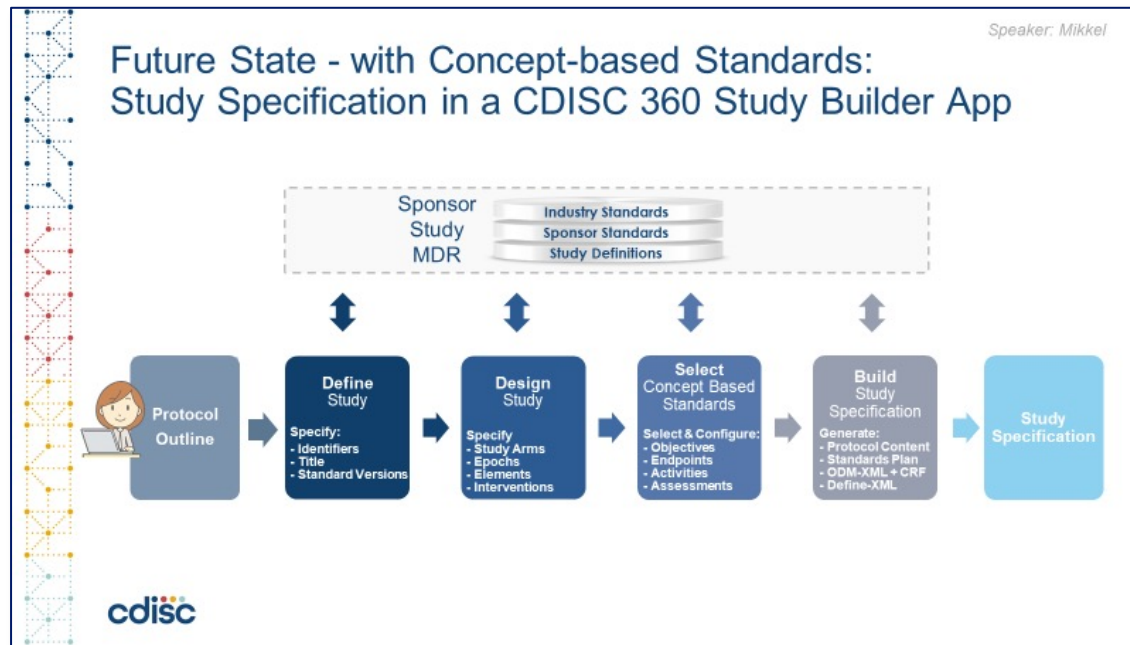


The OpenStudyBuilder includes:

- 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)



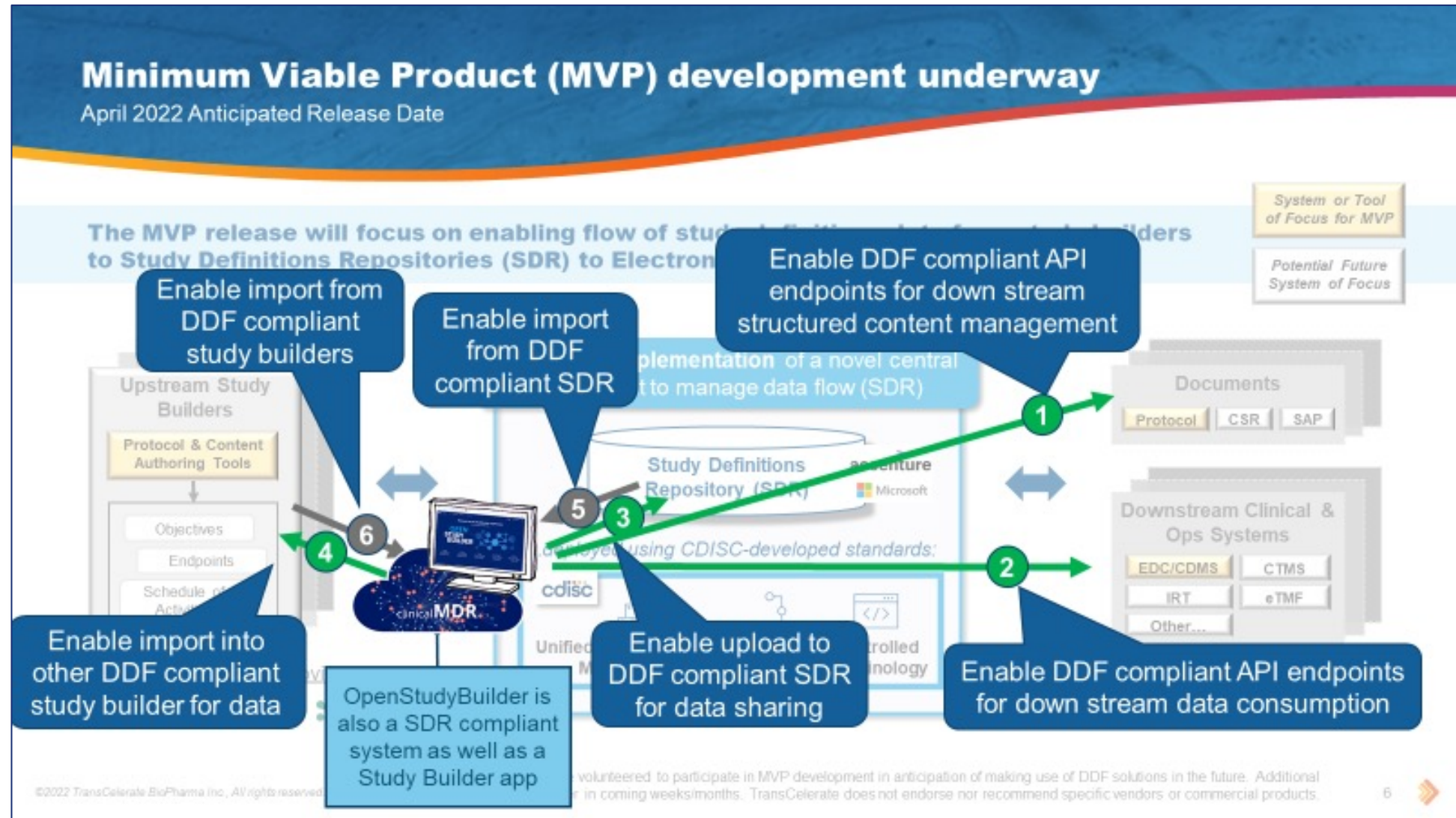
We are building OpenStudyBuilder as an open-source MDR and SDR solution based on the CDISC 360 POC



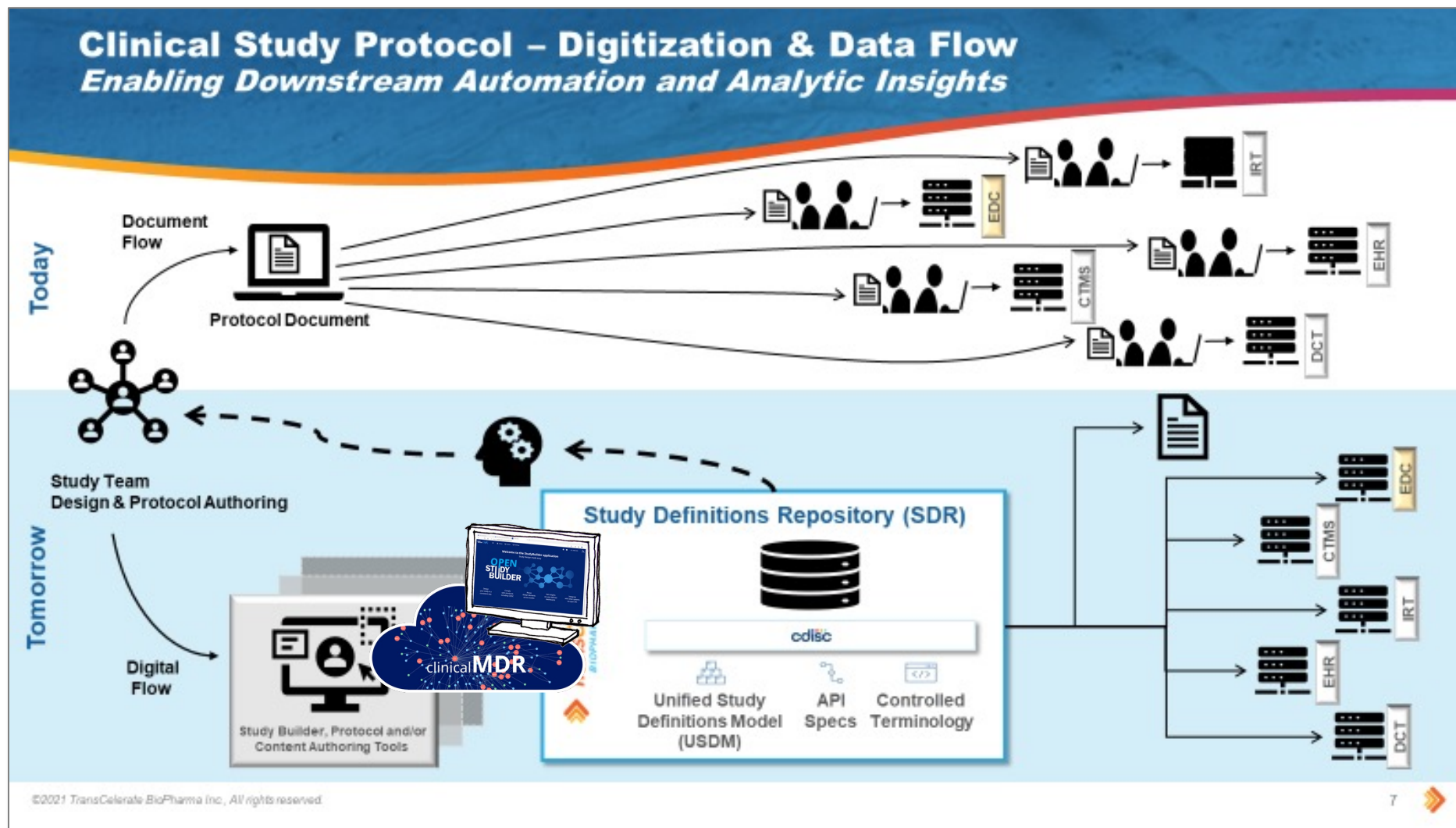
<https://www.cdisc.org/cdisc-360>

- Our goal is to replace our legacy MDR solution with a new modern solution
- As an open-source project in collaboration with CDISC, TransCelerate DDF and suppliers

OpenStudyBuilder will also be DDF Compatible

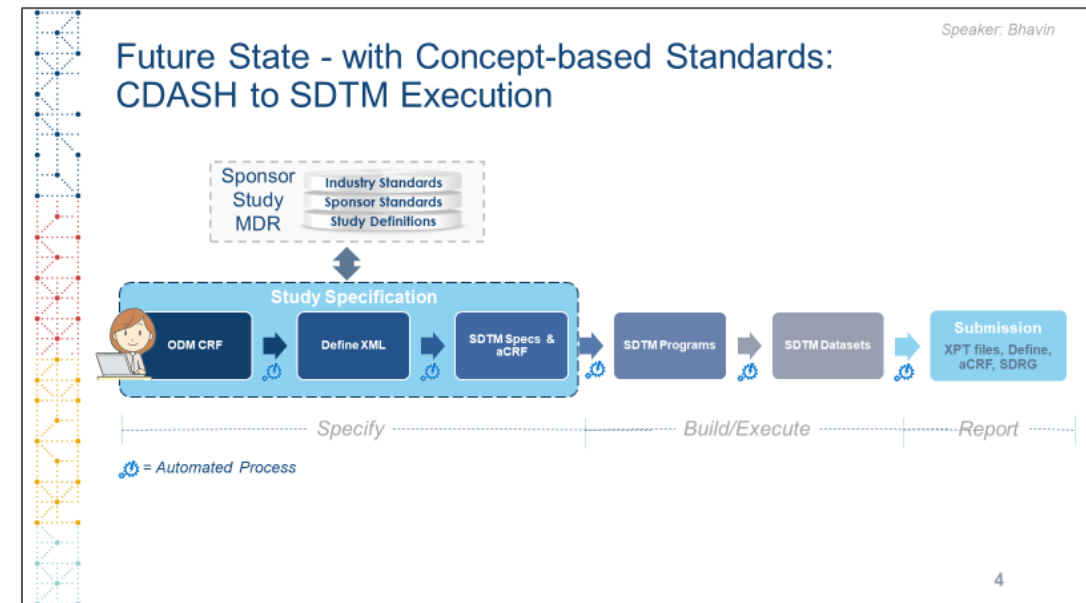
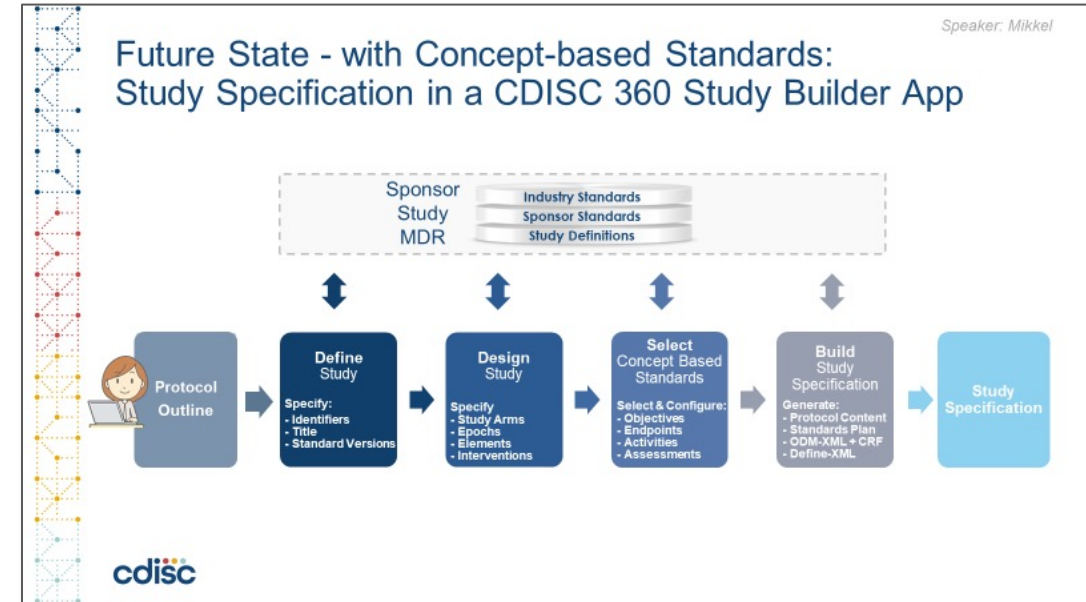


DDF is moving away from Document focused processes to Connected Data Driven processes



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
- Ensuring build-in compliance, and enabling more automation, efficient reuse across studies and projects, and aggregation of study specification details for insights



Demo OpenStudyBuilder

The screenshot displays the OpenStudyBuilder web application interface. The top navigation bar includes a hamburger menu, the 'STUDY BUILDER' logo, and tabs for 'Studies' (active) and 'Library'. Action buttons for 'ADD NEW STUDY' and 'SELECT STUDY' are present, along with a green pill button labeled 'CDISC DEV-0001'. User information 'MT (MIKKEL TRAUN)' and the Novo Nordisk logo are on the right.

The left sidebar contains a navigation menu with the following items: 'About Studies', 'Process Overview', 'Manage Studies', 'Study List' (highlighted), 'Study Status', 'Project Standards', 'Define Study', 'View Specifications', and 'View Listings'.

The main content area shows the 'Study List' with a breadcrumb trail 'Studies / Manage Studies / Study List'. A 'Study List' header with a help icon is followed by a 'Select rows' toggle and a set of action icons (+, filter, list, download, refresh). A search bar contains the text 'DDF'. Below is a table with the following data:

	Clinical Programme	Project ID	Study number	Study ID	Study acronym	Study title
⋮	CDISC Development programme	CDISC DEV	0002	CDISC DEV-0002	DDF-SampleData-0002	BMS Test Study
⋮	CDISC Development programme	CDISC DEV	0001	CDISC DEV-0001	DDF-SampleData-0001	Umbrella Study of DDR (DNA-Damage Response) Targeting Agents in Advanced Biliary Tract Cancer

At the bottom right, pagination controls show 'Rows per page: 10' and '1-2 of 2' with navigation arrows.

Focus areas in OpenStudyBuilder for Biostatistics

Current Scope

Study Design datasets for ADaM control datasets

- Extend with more study design metadata than available in SDTM
- Support more data driven ADaM programs

Syntax Templates for Objectives and Endpoints

- Biostatistics support for objective & endpoint catalogue
- Linked to derived assessments, ADaM PARAM, TFL output standards, Template programs

Next Scope (NN)

CT for ADaM - linked to Activity Concept model

- ADaM PARAM CT represented in new Activity Concepts model
- Enable end-to-end traceability

StudyBuilder connectivity to SCE's

- Usage in SAS, R, Python, ... ?
- Develop and Share programs and libraries

OpenStudyBuilder next steps

- Non-GCP MVP released internally at Novo Nordisk in September 2022
- Plan a GCP release
- Share as open source project under COSA in Q3 2022

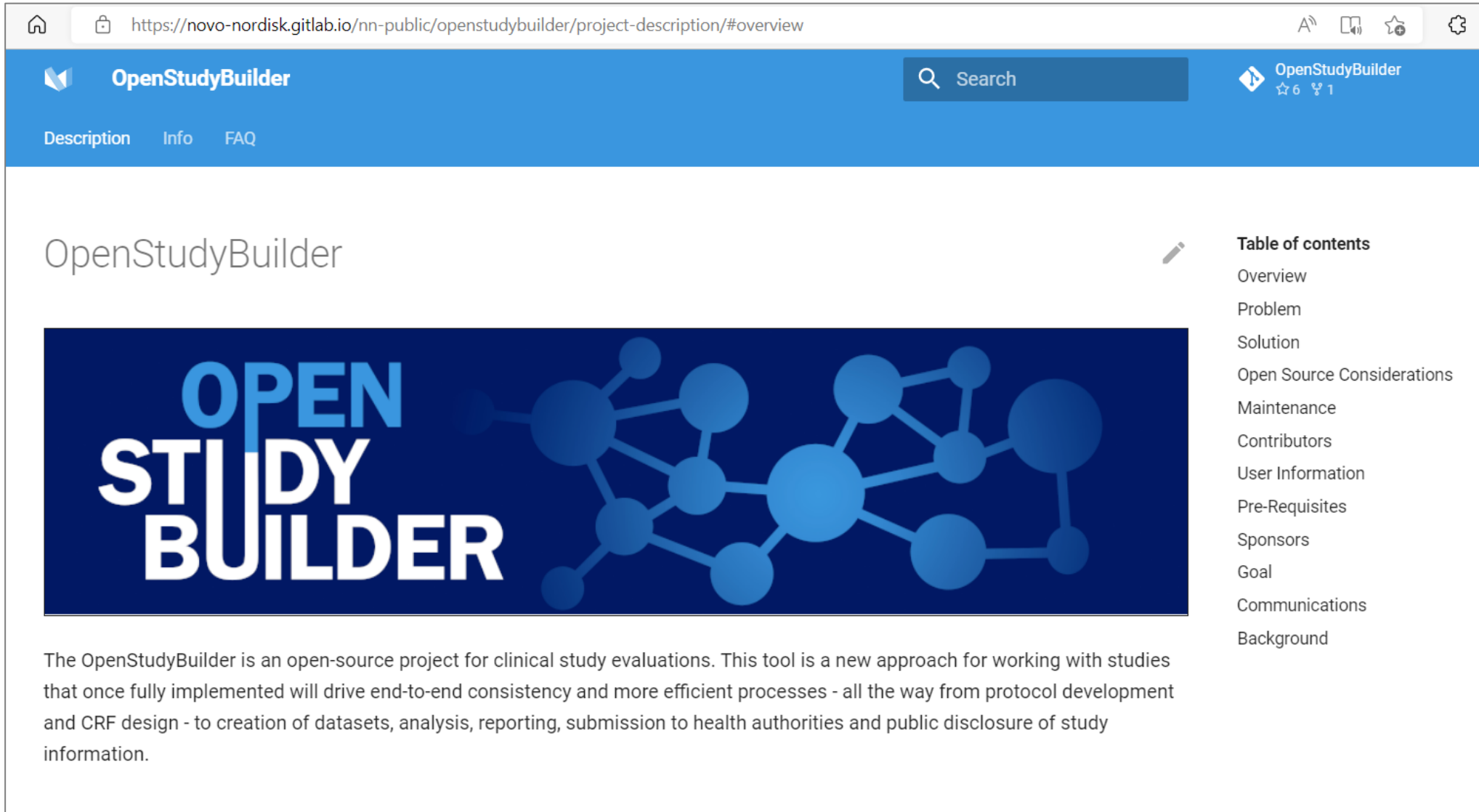
- <https://cosa.cdisc.org/directory/openStudyBuilder>
- <https://novo-nordisk.gitlab.io/nnp-public/openstudybuilder/project-description/>

Currently only containing a project description

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



How do I get started on OpenStudyBuilder?



The screenshot shows a web browser window displaying the OpenStudyBuilder project description on GitLab. The browser's address bar shows the URL: <https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/#overview>. The page has a blue header with the OpenStudyBuilder logo, a search bar, and 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. Below the banner, a paragraph describes the project as an open-source tool for clinical study evaluations. On the right side, a "Table of contents" lists various sections of the project description.

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.

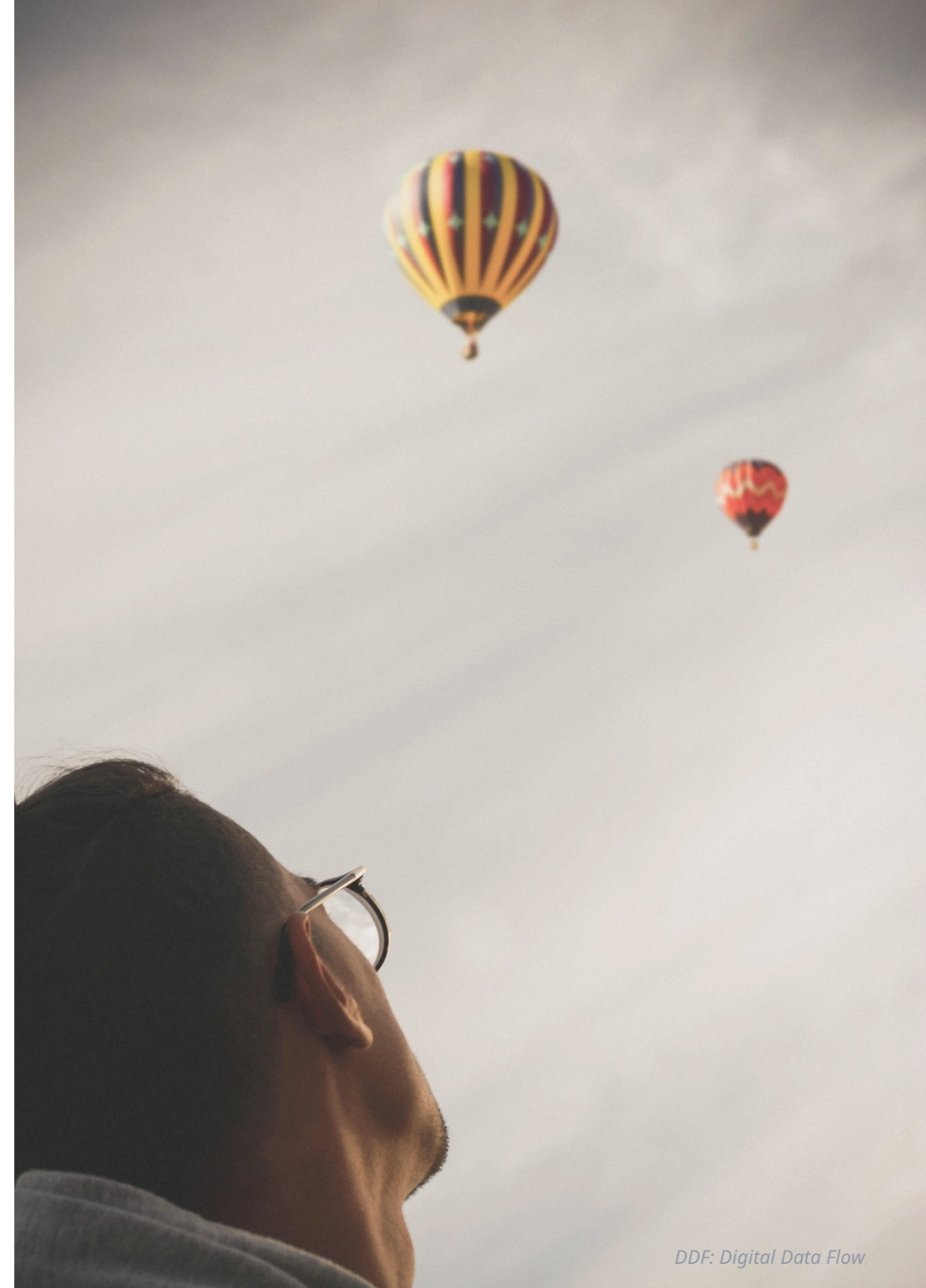
Table of contents

- 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/>

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



Getting along

- **Support**

- Documentation
- OpenStudyBuilder Q&A sessions (by-weekly)
 - First one 24.10.2022 15-16 CEST
- 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 Road



Thanks!
Questions?

