WITH STANDARDS – UNLOCK THE POWER OF DATA

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Concept-based standards in OpenStudyBuilder supporting structured protocol content and submission deliverables

Mikkel Traun, Novo Nordisk A/S

Meet the Speakers

Mikkel Traun

Title: Principal System Developer

Organization: Novo Nordisk A/S

Mikkel is one of the product owners for the next generation study builder and data standards repository solution at Novo Nordisk. Mikkel is also an active member of the TransCelerate and CDISC Digital Dataflow project, and previously the CDISC 360 project. He has worked as a principal system developer supporting the clinical data warehouse solution and the CDISC implementation at Novo Nordisk. Previously he has worked on several projects in pre-clinical, clinical and outcome research.

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:

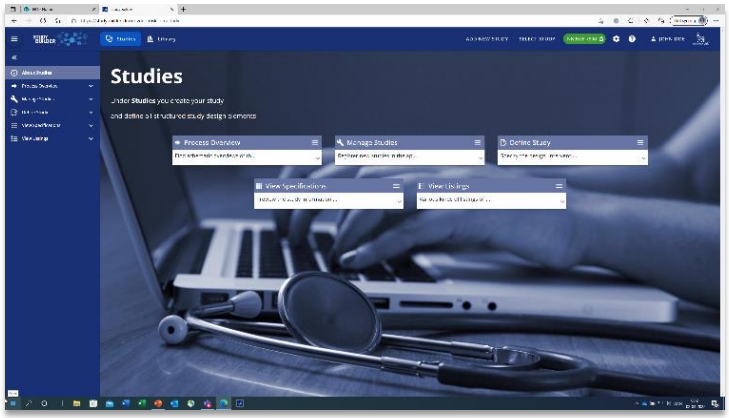
- **Clinical Metadata Repository (clinical MDR)** (central repository for all study specification data)
- **OpenStudyBuilder application** (web-based user interface)
- **API layer** (allowing interoperability with other applications) (DDF API Adaptor – enabling DDF SDR Compatibility)

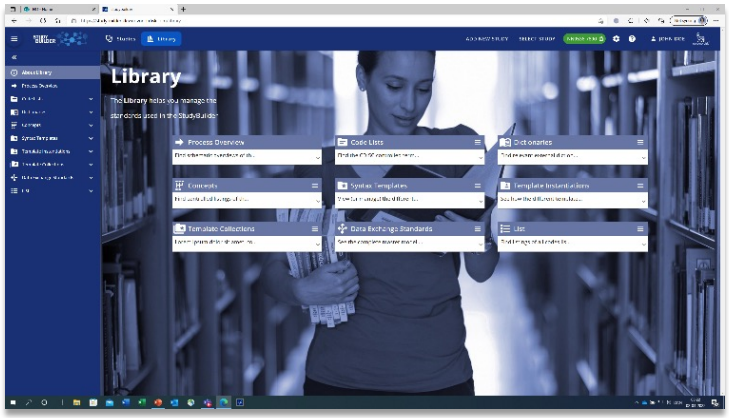
The OpenStudyBuilder includes:

- 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)

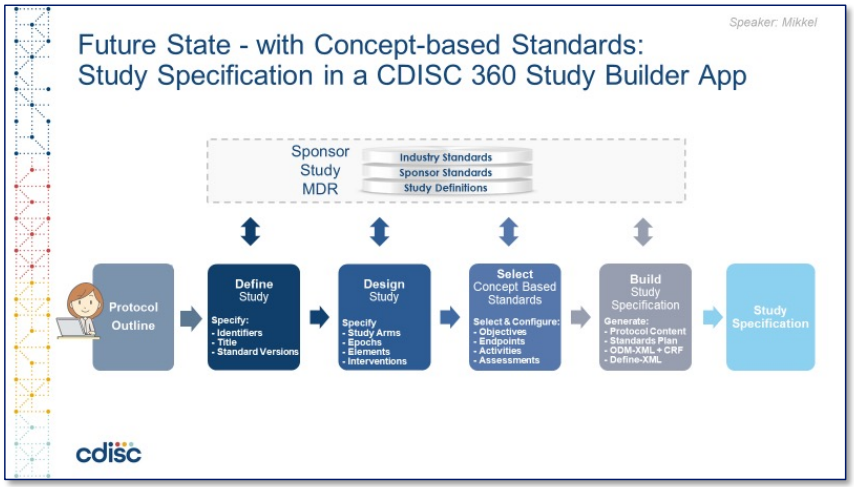
- A **Library** part for maintenance of terminology standards
  (incl. CDISC controlled terminology, relevant parts of external dictionaries for medical terms, pharmacological classes, units, a detailed compound library, a granulated library of activity terms) as well as syntax templates for cross-study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

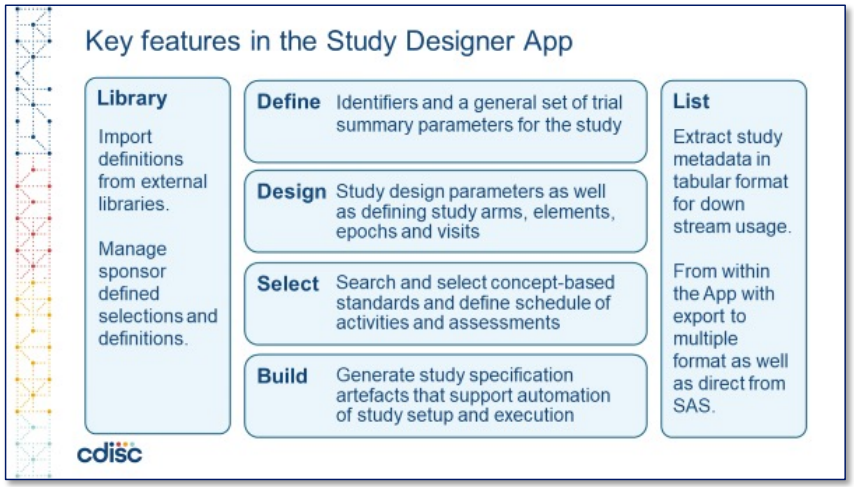
- An underlying **knowledge database**
  (enabling complex queries and visualisations for aggregation of information and showing how things are connected end-to-end)





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

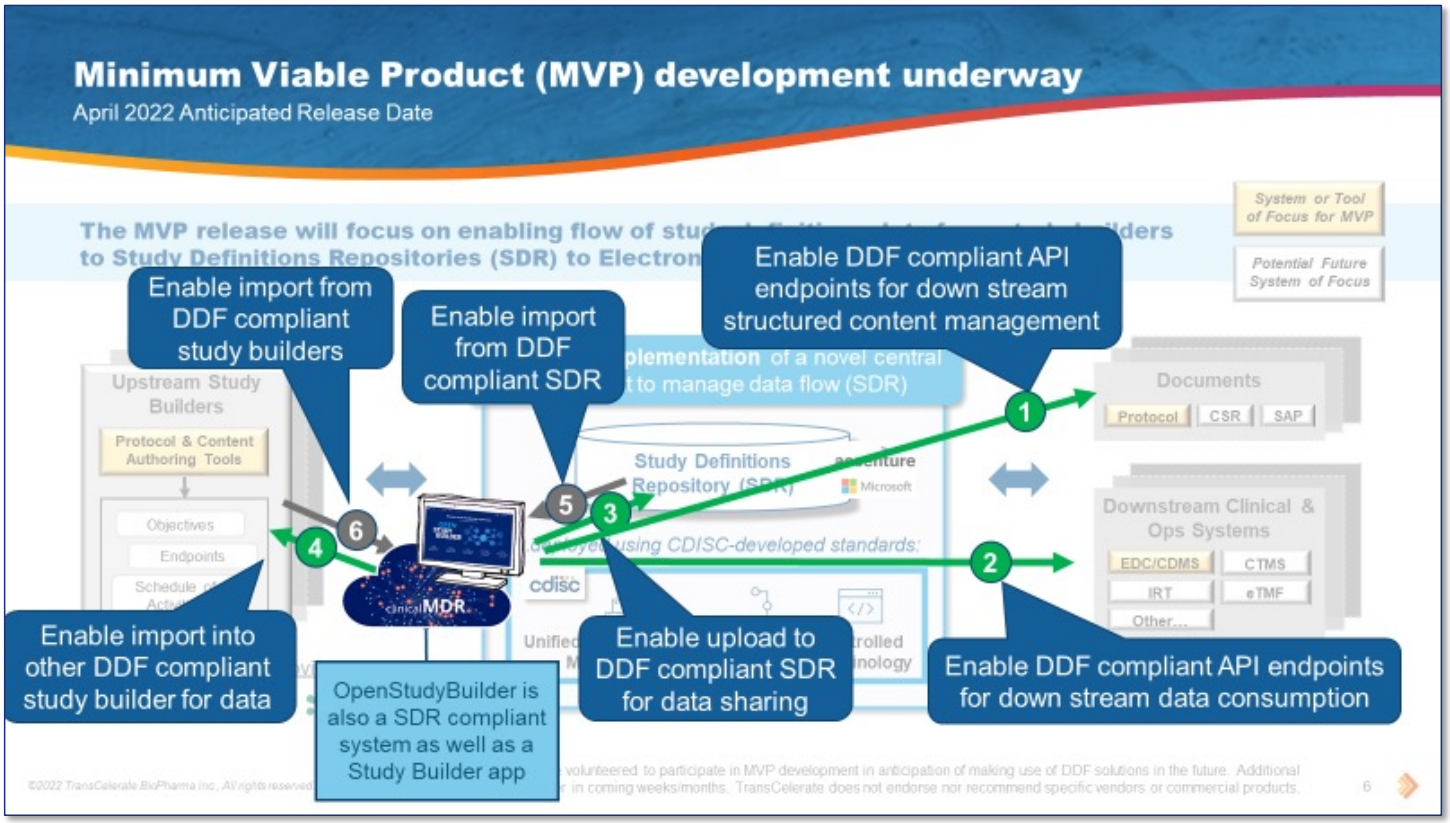




https://www.cdisc.org/cdisc-360

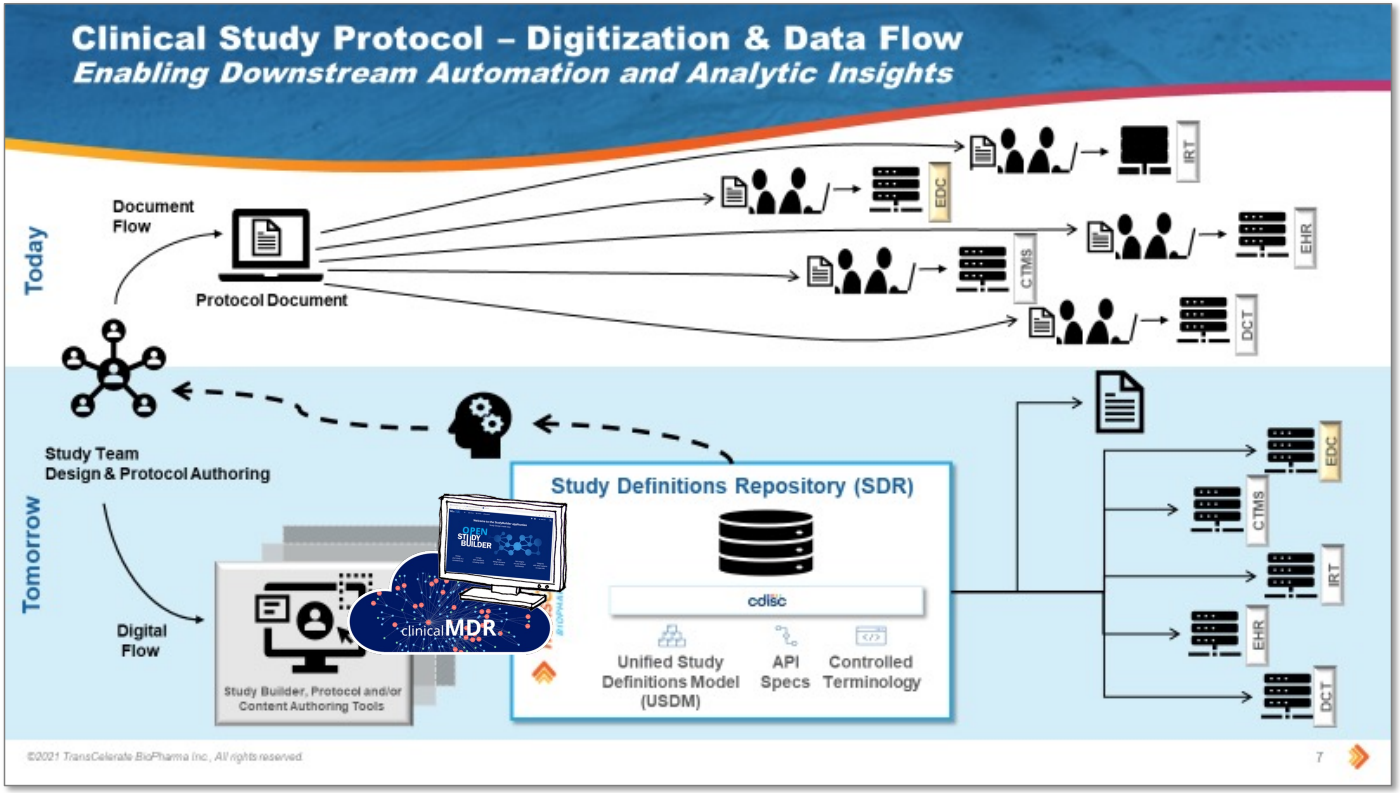
- Our goal is to replace our legacy MDR solution with a new modern solution
- As an open-source project in collaboration with CDISC, TransCelerate DDF and suppliers

OpenStudyBuilder will also be DDF Compatible



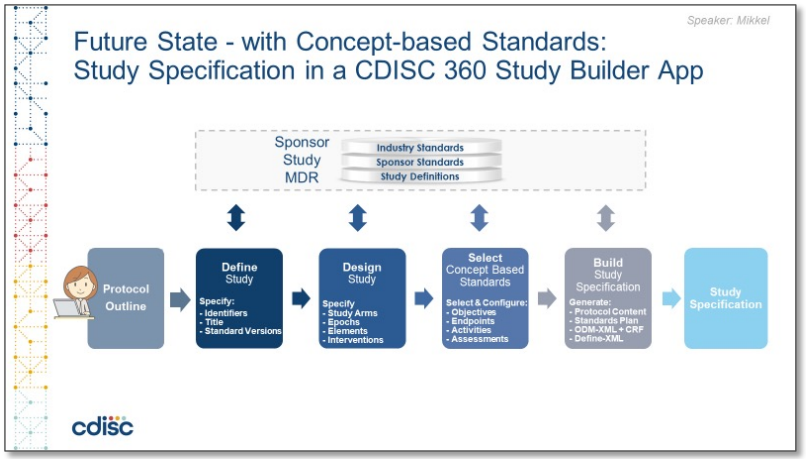
https://transcelerate.github.io/ddf-home/

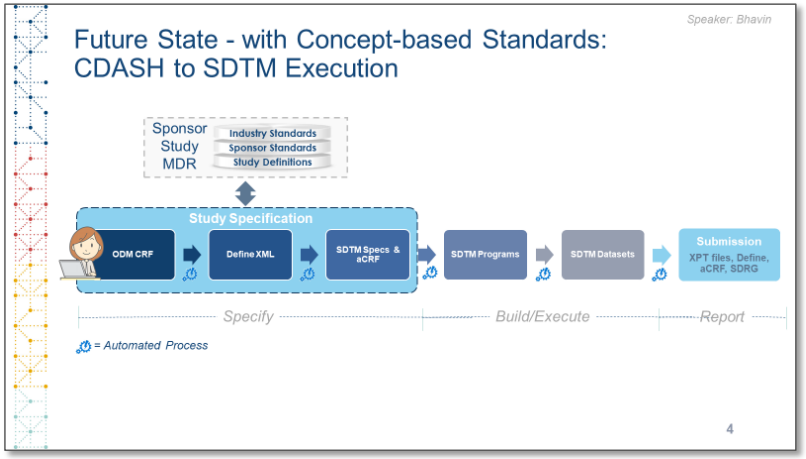
DDF is moving away from Document focused processes to Connected Data Driven processes



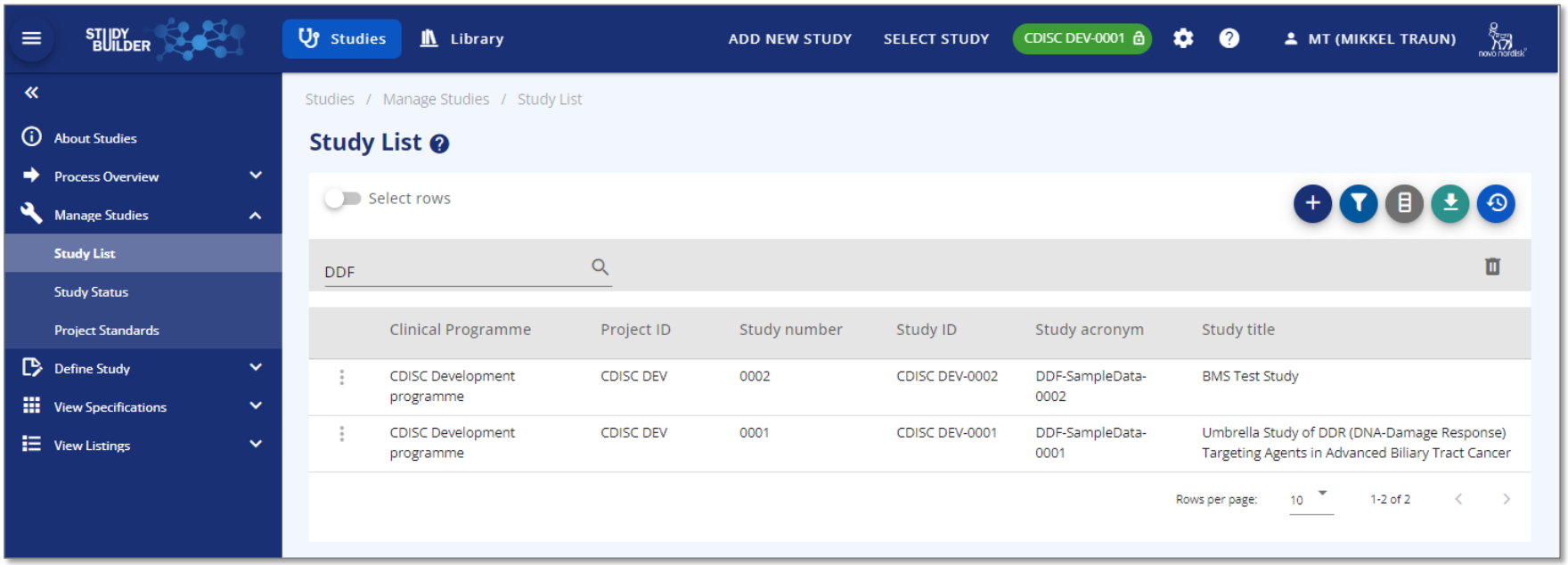
To apply concept-based data standards end-to-end

- 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 aggregaation of study specification details for insights





Demo OpenStudyBuilder

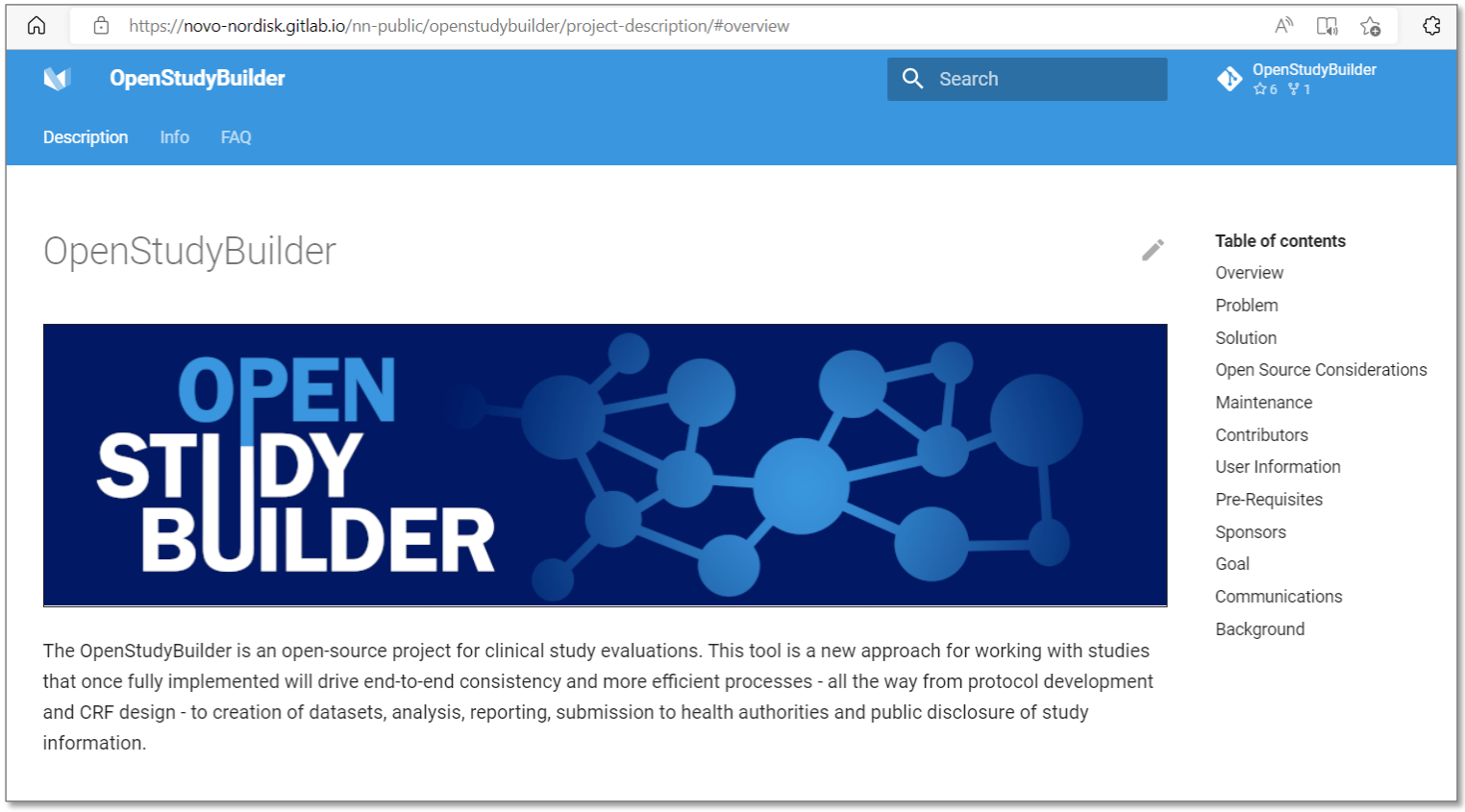


OpenStudyBuilder next steps

- 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/nn-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?



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Thanks!
Questions?