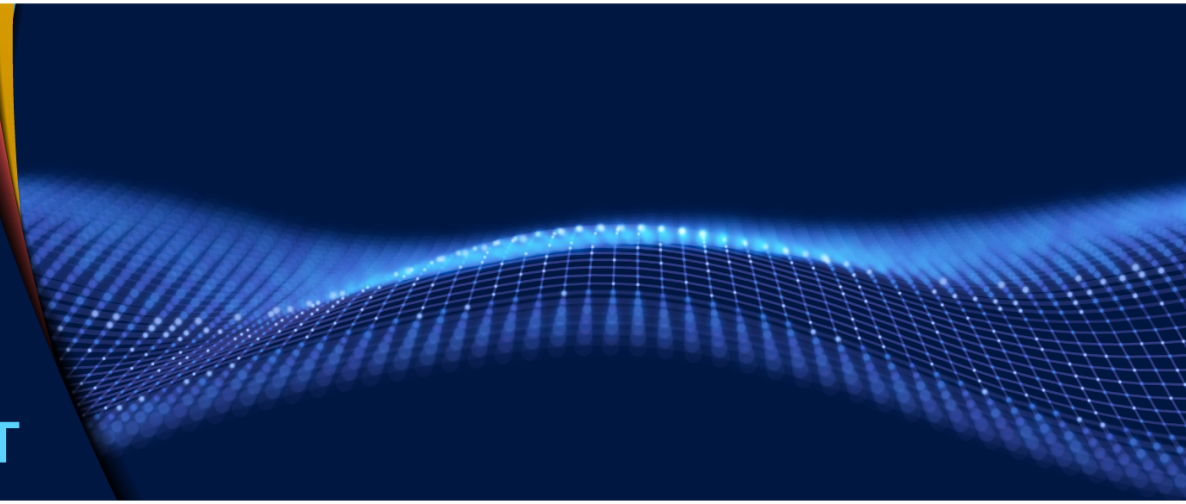
WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

2022
EUROPE
INTERCHANGE
27-28 APRIL | VIRTUAL EVENT



OpenStudyBuilder

Mikkel Traun, Principal System Developer
Sinna Lisa Vange,
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.

Sinna Lisa Vange

Title: Medical Writing VP

Organization: Novo Nordisk A/S

Sinna has been the other product owner for the new study builder and data standards repository solution. Sinna is a senior principal specialist and has been involved as clinical submission team leader and communication and submission expert on numerous regulatory applications for over the past 9 years. Previously, she was Vice President for the medical writing function at Novo Nordisk driving the development of medical writing and clinical publishing as well as the transition from paper to electronic submissions. Sinna has been involved in a wide range of IT projects over the years bringing in the end-to-end business understanding.

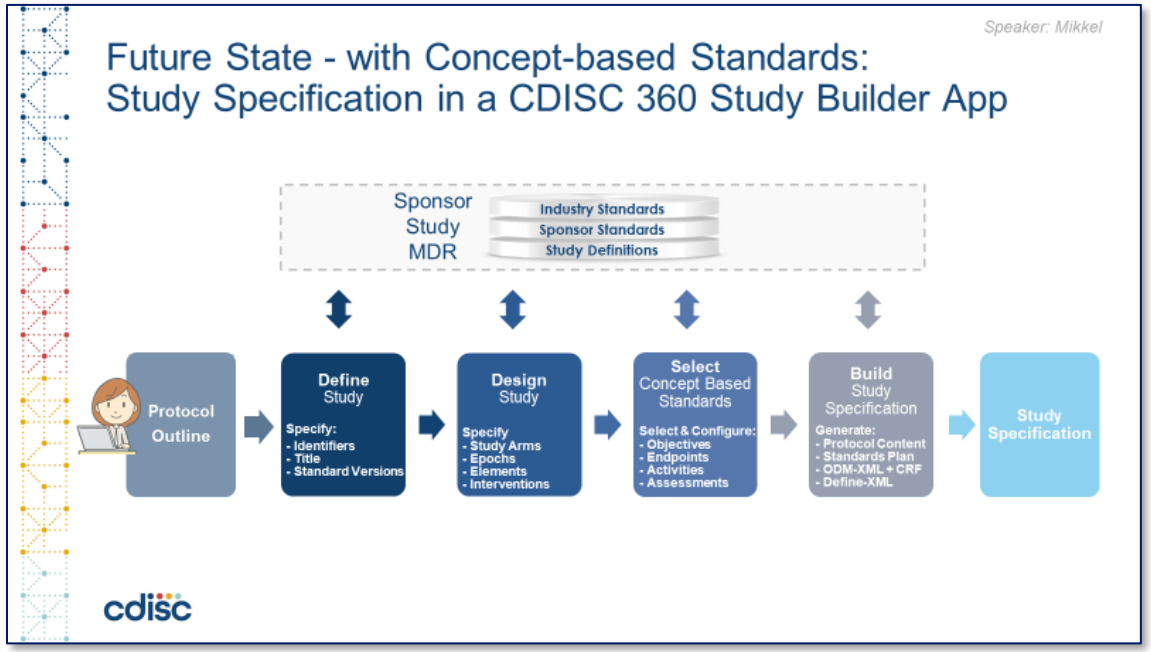
Disclaimer and Disclosures

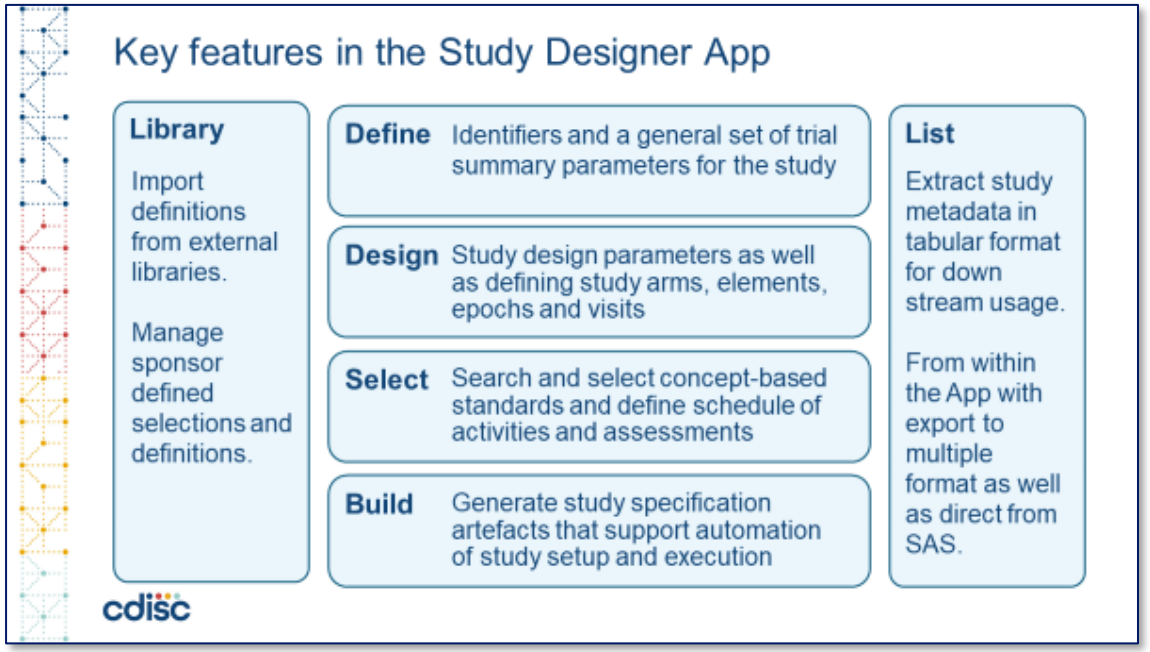
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Project scope

- **Establish a *study builder* solution**
  - To support the study specification process using concept based data standards *from* protocol development and CRF design *to* creation of submission datasets, analyses, reporting and public disclosure of study information
  - To promote seamless, cross-functional collaboration during study milestones and processes
  - To be able to close the legacy MDR solution
  - To be an active player in the industry transformation towards using concept based data standards for study specification and end-to-end digital data flow by collaborating externally with CDISC, TransCelerate DDF, vendors and peers as part of open source initiatives to avoid an NN custom solution

We are building an OpenStudyBuilder and MDR solution based on the CDISC 360 POC





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

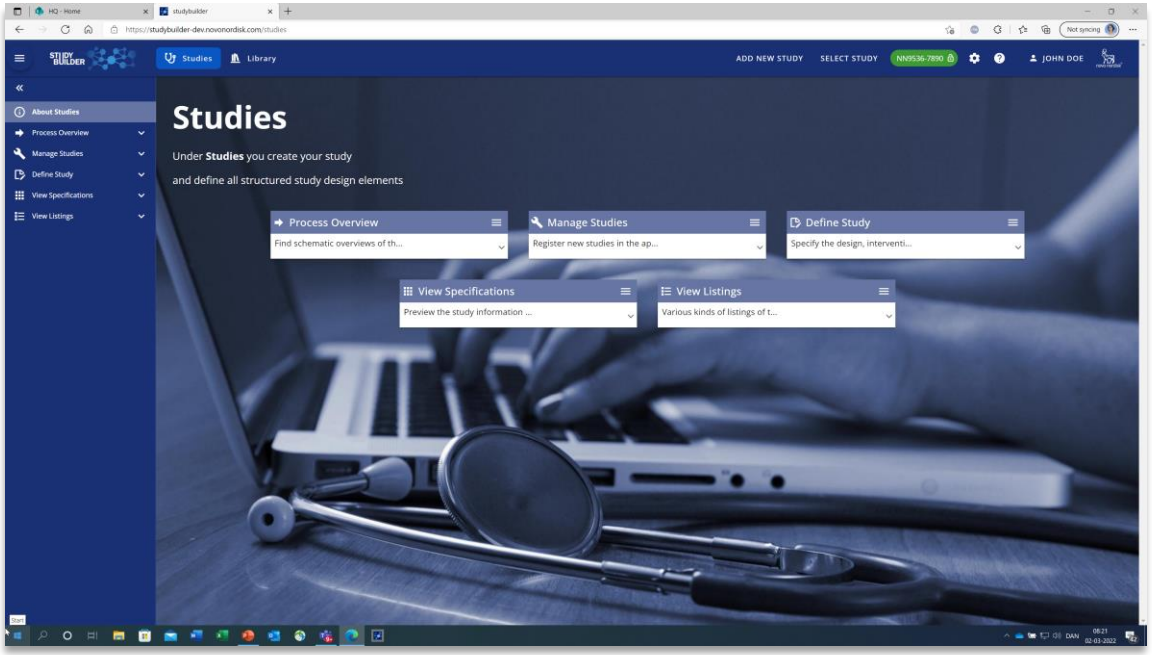
Our goal is to replace our legacy MDR solution with a new modern solution

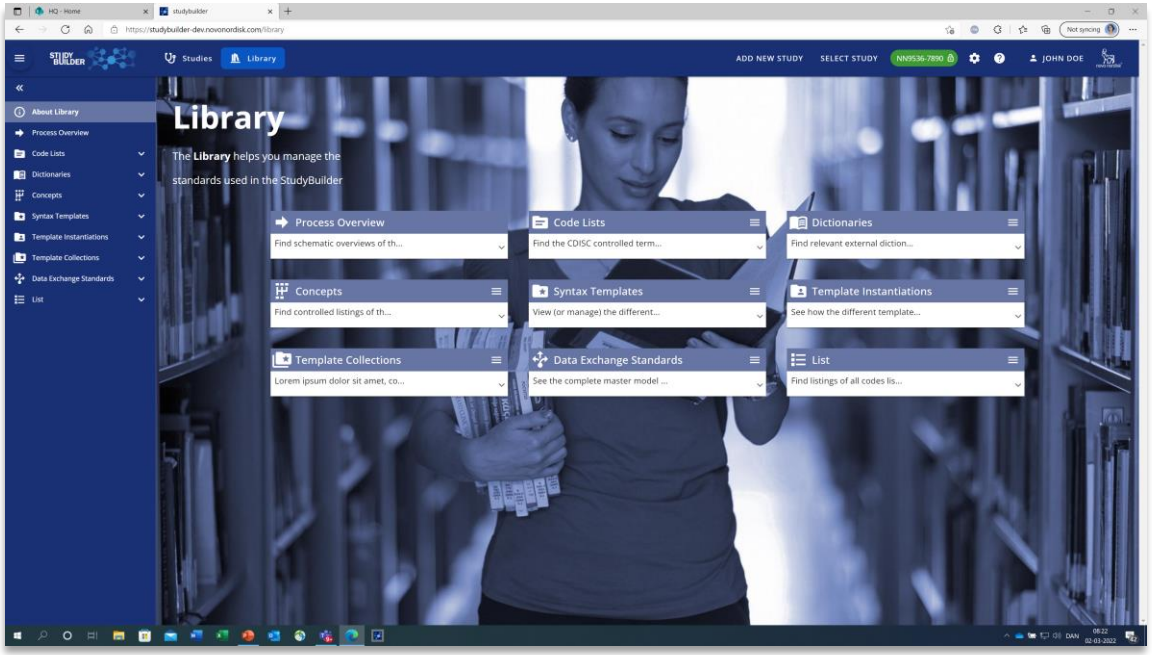
What is the OpenStudyBuilder …

- The OpenStudyBuilder is a new approach to working with studies that will promote end-to-end consistency and flow of **study specification information**
  - **OpenStudyBuilder application**
    (web-based user interface)
  - **Clinical Metadata Repository (MDR)**
    (central repository for all study specification data)
  - **API layer**
    (allowing interoperability with other applications)

The OpenStudyBuilder includes

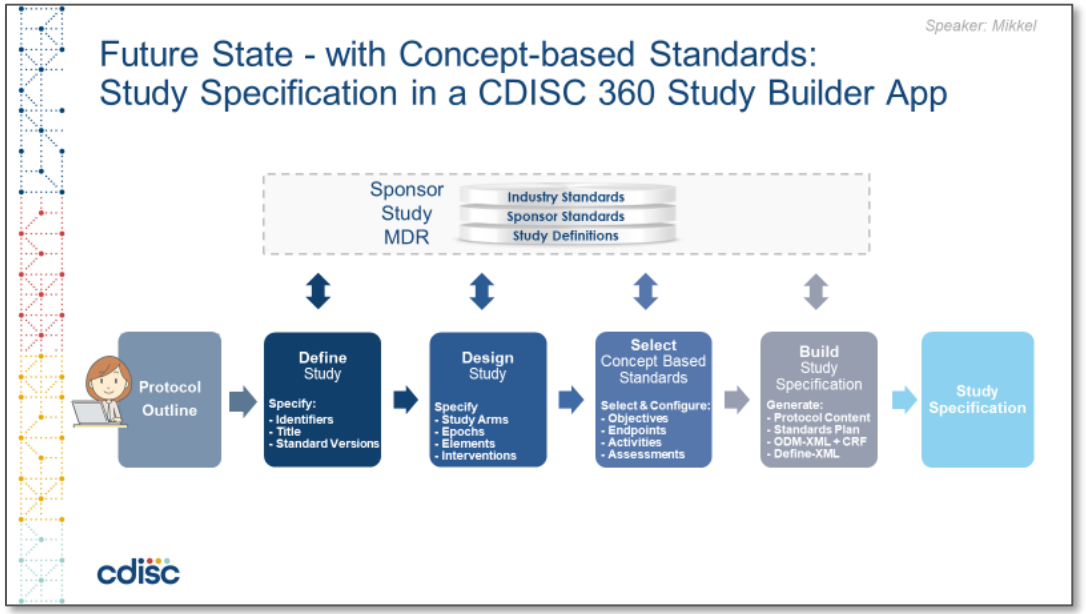
- A **Studies** part for specification of studies, including disease area and study type, objectives and endpoints, population and eligibility criteria, study compounds and other interventions, study design, arms and visits, schedule of activities and associated procedure and assessment instructions
- 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

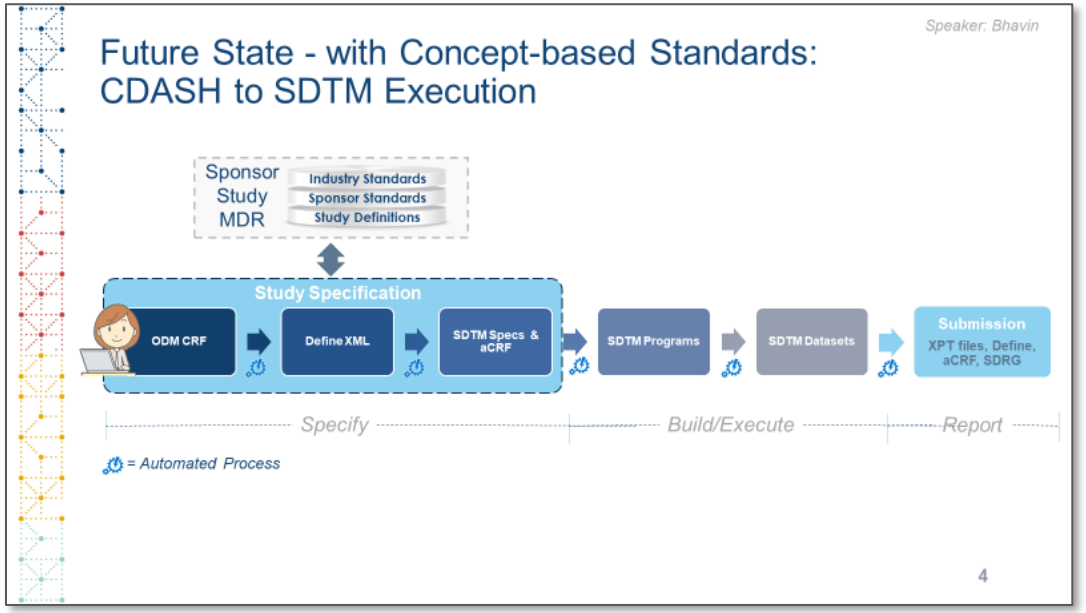




To apply concept-based data standards end-to-end

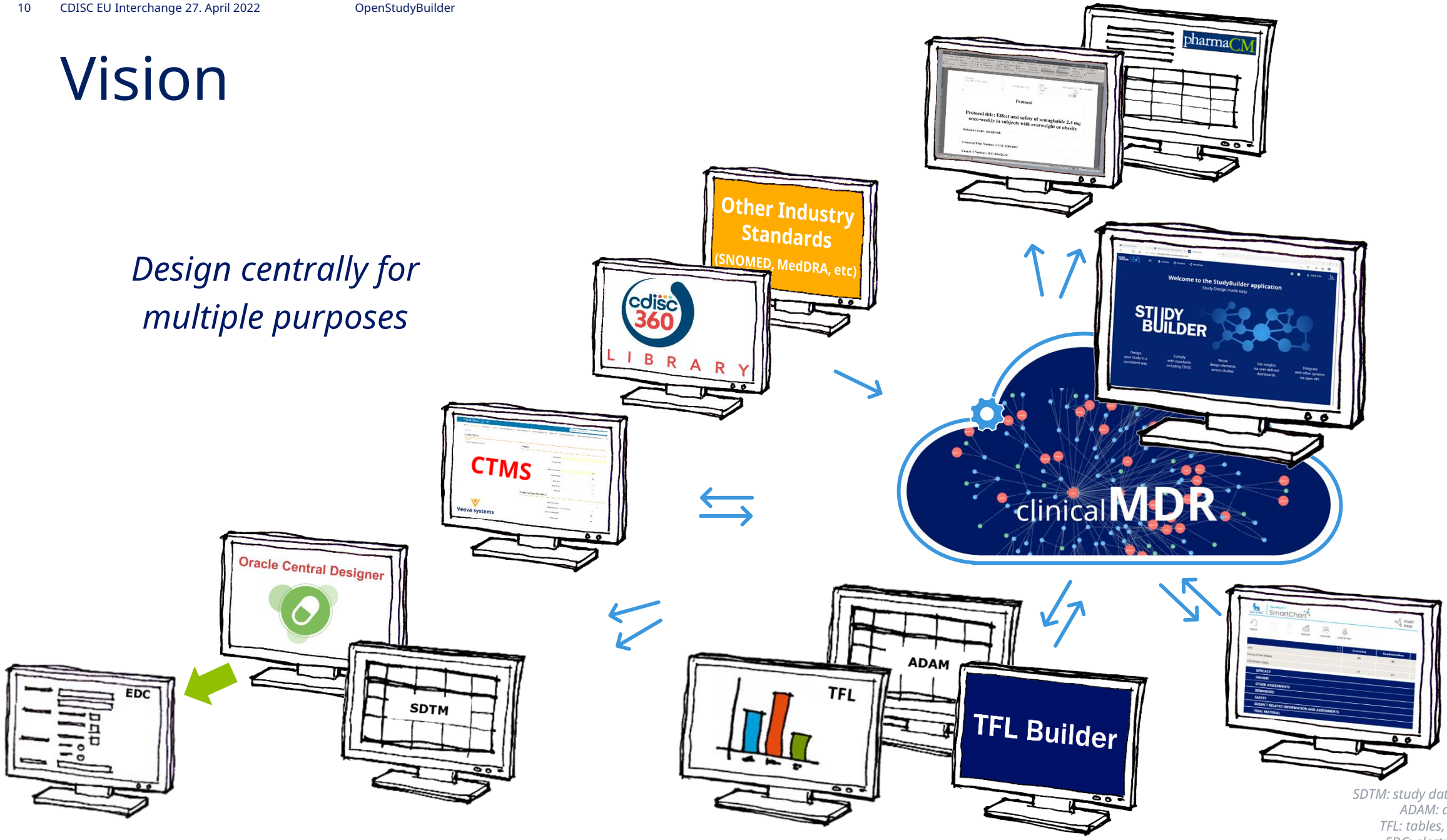
- From protocol preparation through study conduct to reporting and submission of applications to health authorities
  - and with reference to externally-compliant concept-based data standards and terminology
- Ensuring build-in compliance, and enabling more automation, efficient reuse across studies and projects, and aggregaation of study specification details for insights





Vision

Design centrally for multiple purposes



SDTM: study data tabulation model,
ADAM: analysis data model,
TFL: tables, figures and listings,
EDC: electronic data capturing

Process outline

CTMS

SmartChart

Protocol outline

StudyBuilder

Refine protocol

Benefit/Risk

Build Protocol

CRF specification

Data for trial supplies

Build SAP

SDTM datasets

ADaM/TFL builder

Export to CTR

Data for pharmaCM

Develop and maintain code lists and templates in clinical MDR

StudyBuilder

- Study identifiers & registries
- Study status
- Study type
- Study title
- Benefit-risk table
- Study population & criteria
- Study arms and periods
- Study interventions incl compounds
- Study objectives and endpoints
- List of assessments
- Assessment instructions
- Schedule of activities

Medical specialist

Pharmacology scientist

Statistician

Global safety

Programmer

Data manager

Trial manager

Trial supplies responsible

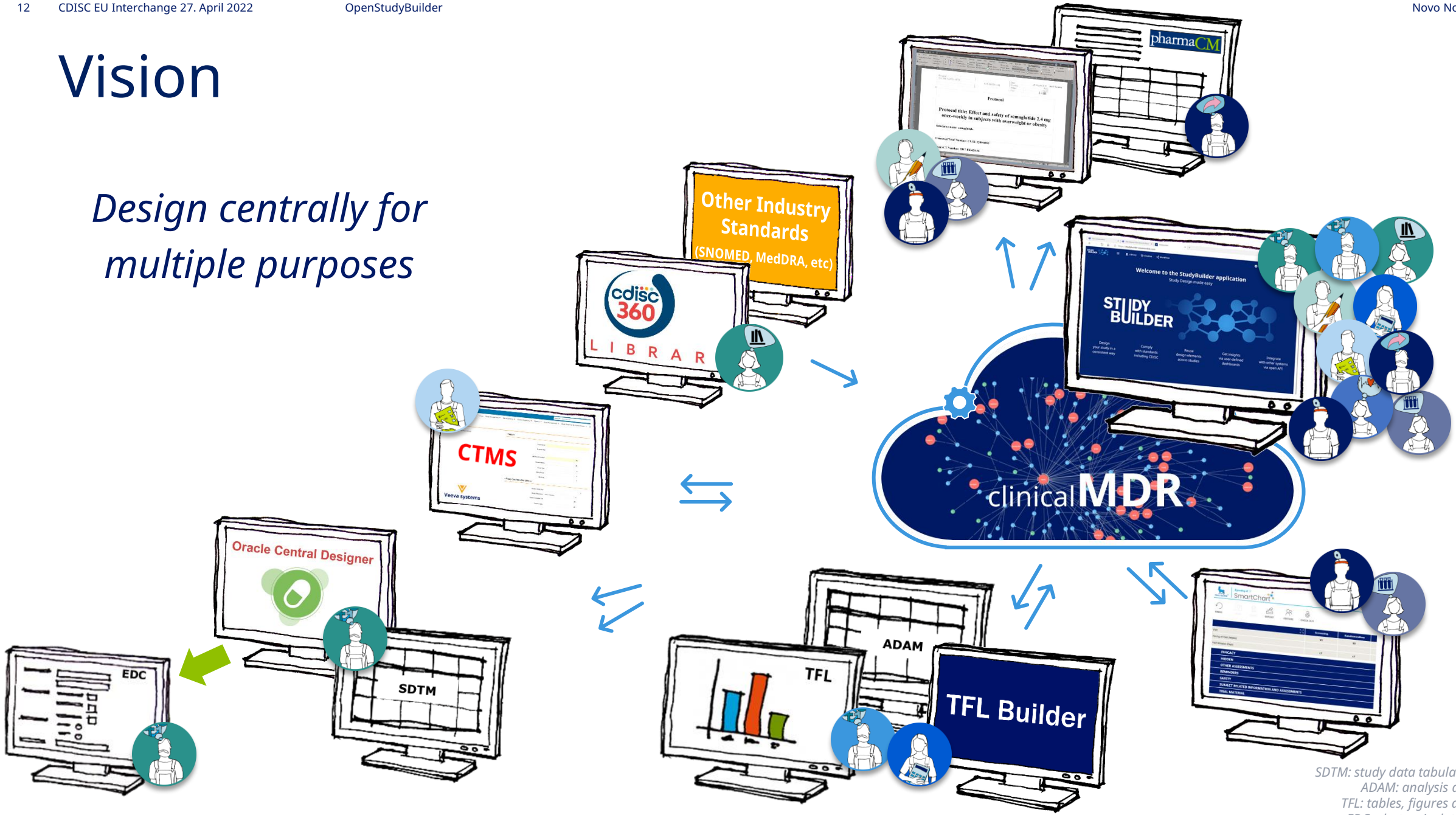
Medical writer

Disclosure specialist

Standards developer

Vision

Design centrally for multiple purposes



SDTM: study data tabulation model,
ADAM: analysis data model,
TFL: tables, figures and listings,
EDC: electronic data capturing

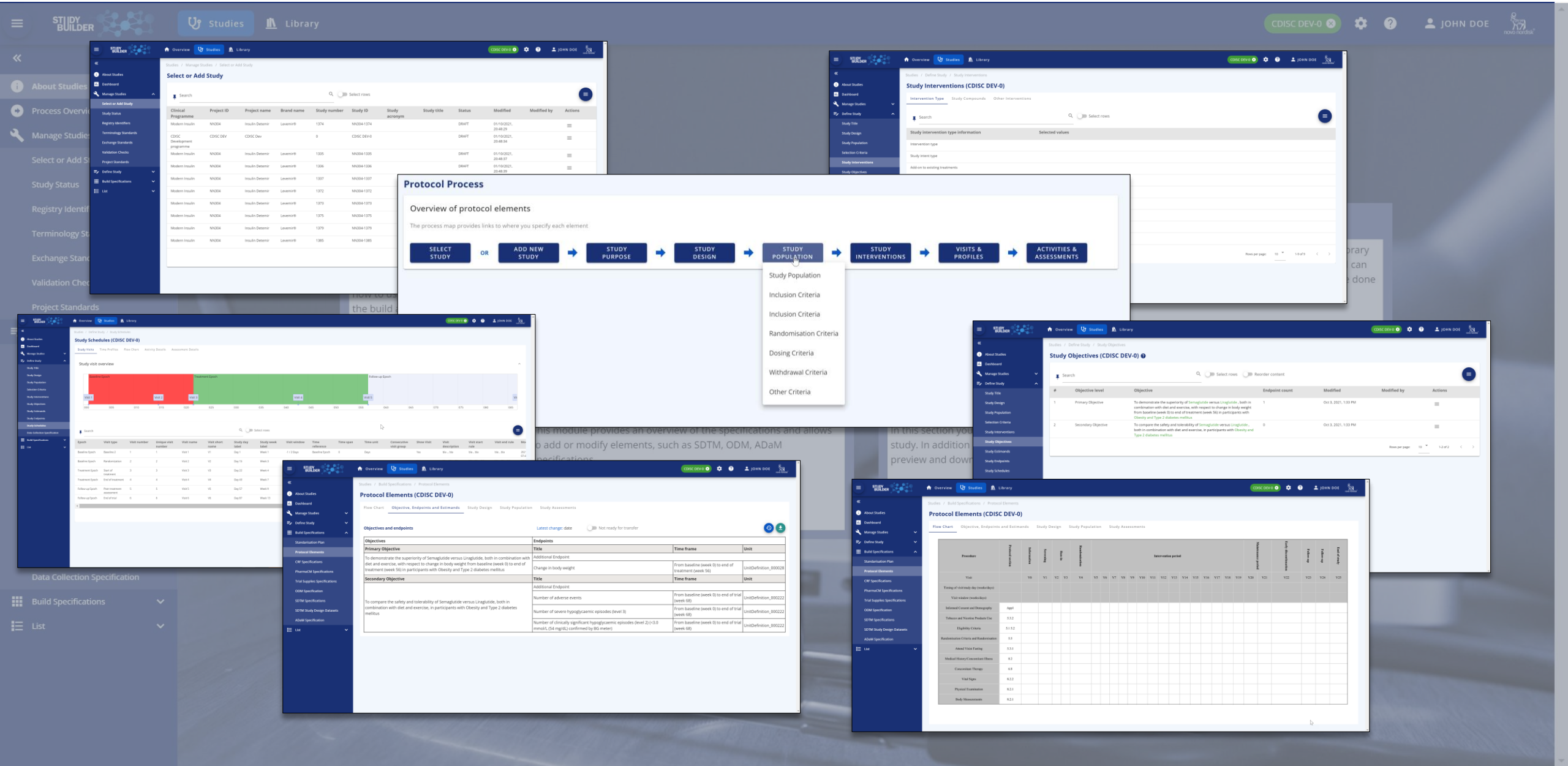
Core capabilities for a standards based OpenStudyBuilder

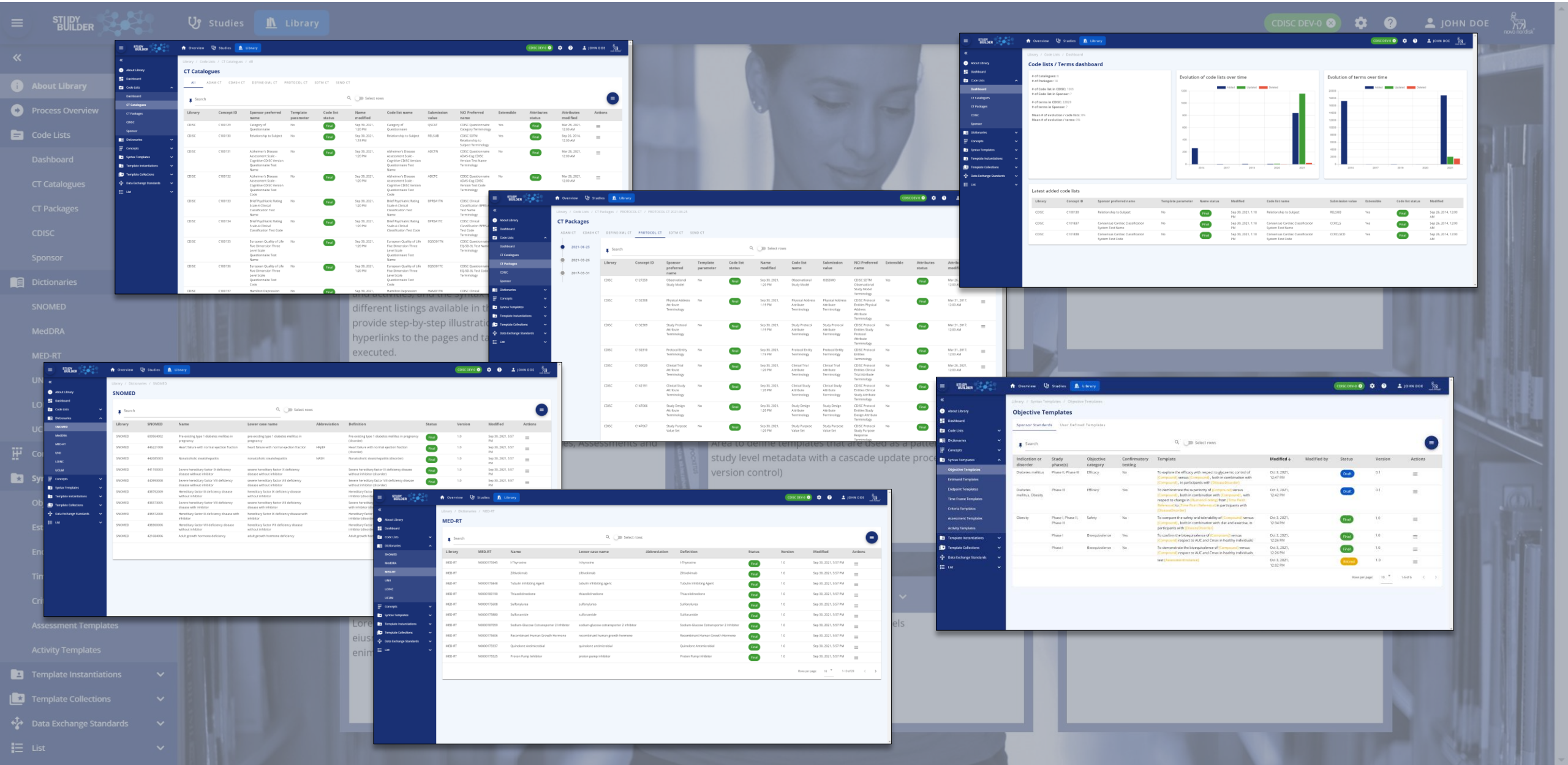
Industry and sponsor standards

- CDISC and Sponsor defined controlled terminologies
- Subset of external dictionary terms
- Concept based standards
  (Biomedical Concepts)
- Syntax templates for standardising descriptions referring to terms
- Full versioning and audit trail on data element level
- Role based access and workflows

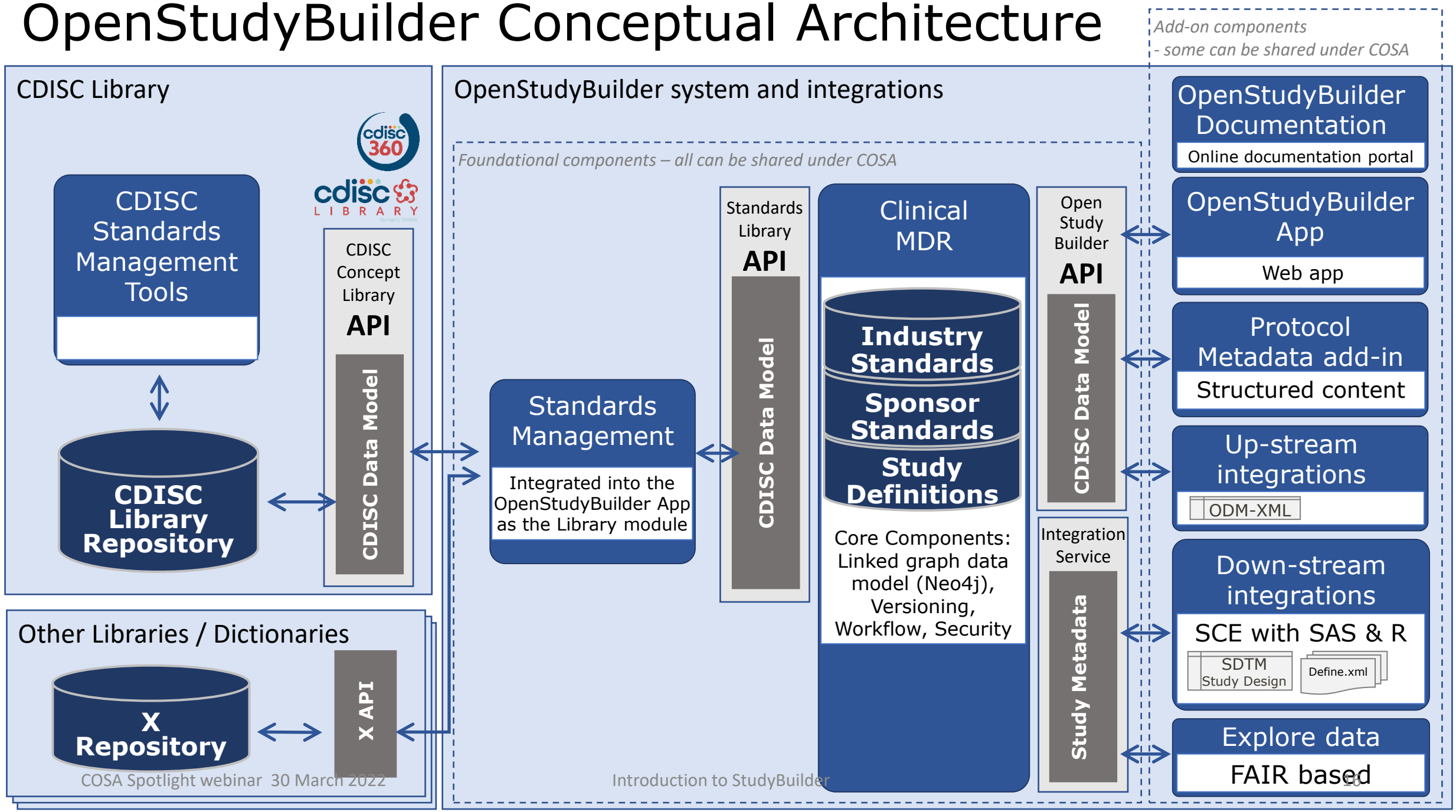
Study definition repository

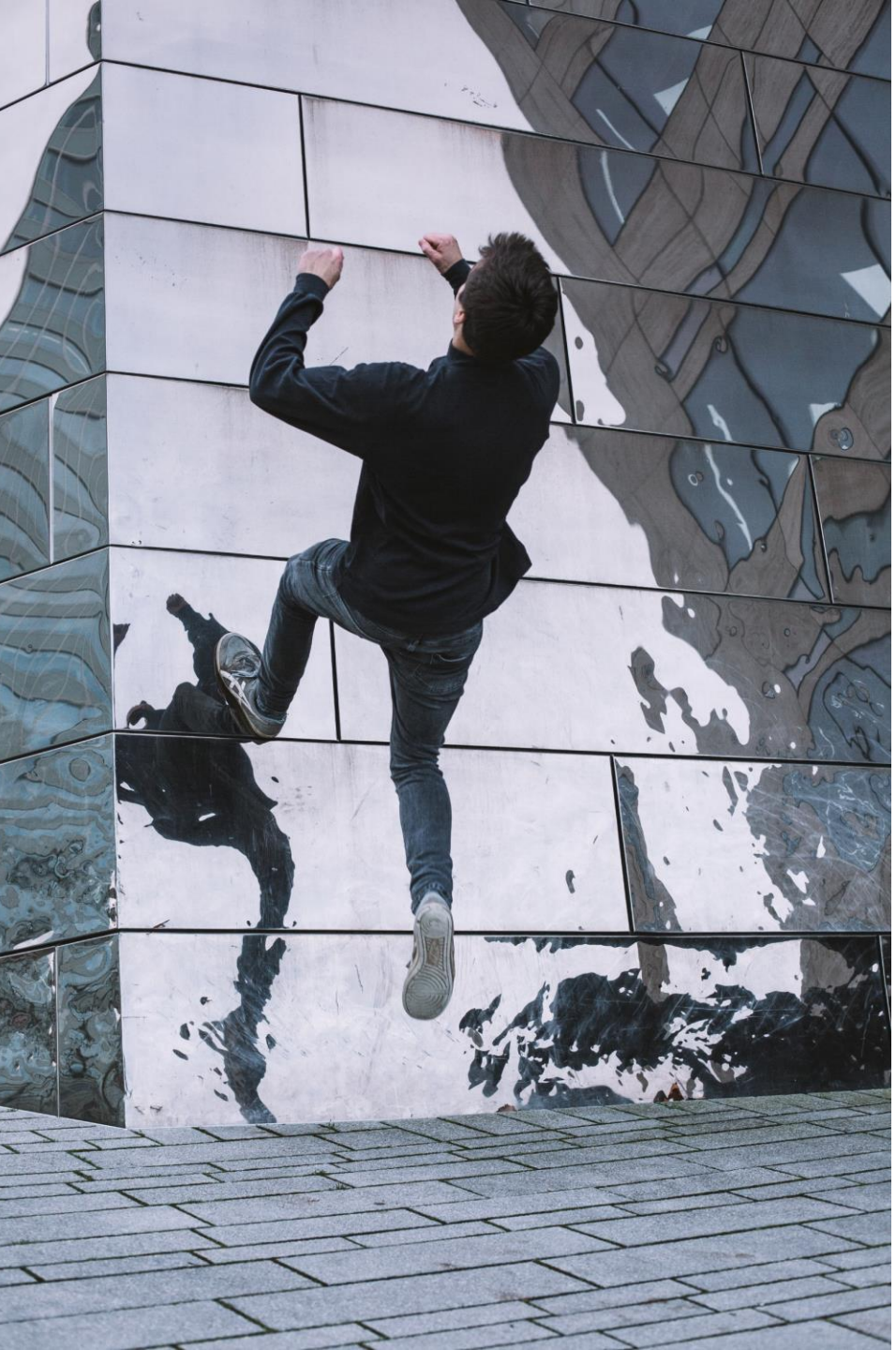
- Select and define the study specification using concept based data standards
- All related to versioned library elements
- Version control and audit trail
- Integrations for up- and down stream usage


Studies
Library
CDISC DEV-0
JOHN DOE
Select or Add Study
Study Interventions (CDISC DEV-0)
Protocol Process
Overview of protocol elements
The process map provides links to where you specify each element
SELECT STUDY
OR
ADD NEW STUDY
STUDY PURPOSE
STUDY DESIGN
STUDY POPULATION
STUDY INTERVENTIONS
VISITS & PROFILES
ACTIVITIES & ASSESSMENTS
Study Population
Inclusion Criteria
Inclusion Criteria
Randomisation Criteria
Dosing Criteria
Withdrawal Criteria
Other Criteria
Study Schedules (CDISC DEV-0)
Study Objectives (CDISC DEV-0)
Protocol Elements (CDISC DEV-0)
Protocol Elements (CDISC DEV-0)
Data Collection Specification
Build Specifications
List


STUDY BUILDER
Studies
Library
CDISC DEV-0
JOHN DOE
CT Catalogues
CT Packages
Code lists / Terms dashboard
SNOMED
MED-RT
Objective Templates
About Library
Process Overview
Code Lists
Dashboard
CT Catalogues
CT Packages
CDISC
Sponsor
Dictionaries
SNOMED
MedDRA
MED-RT
Assessment Templates
Activity Templates
Template Instantiations
Template Collections
Data Exchange Standards
List

OpenStudyBuilder Conceptual Architecture





OpenStudyBuilder next steps

- We will release a non-GCP MVP internally at Novo Nordisk in Q3 2022
- We plan a GCP release later
- We intend to share the project as an 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
- We seek to actively collaborate with CDISC, TransCelerate DDF, peers and vendors