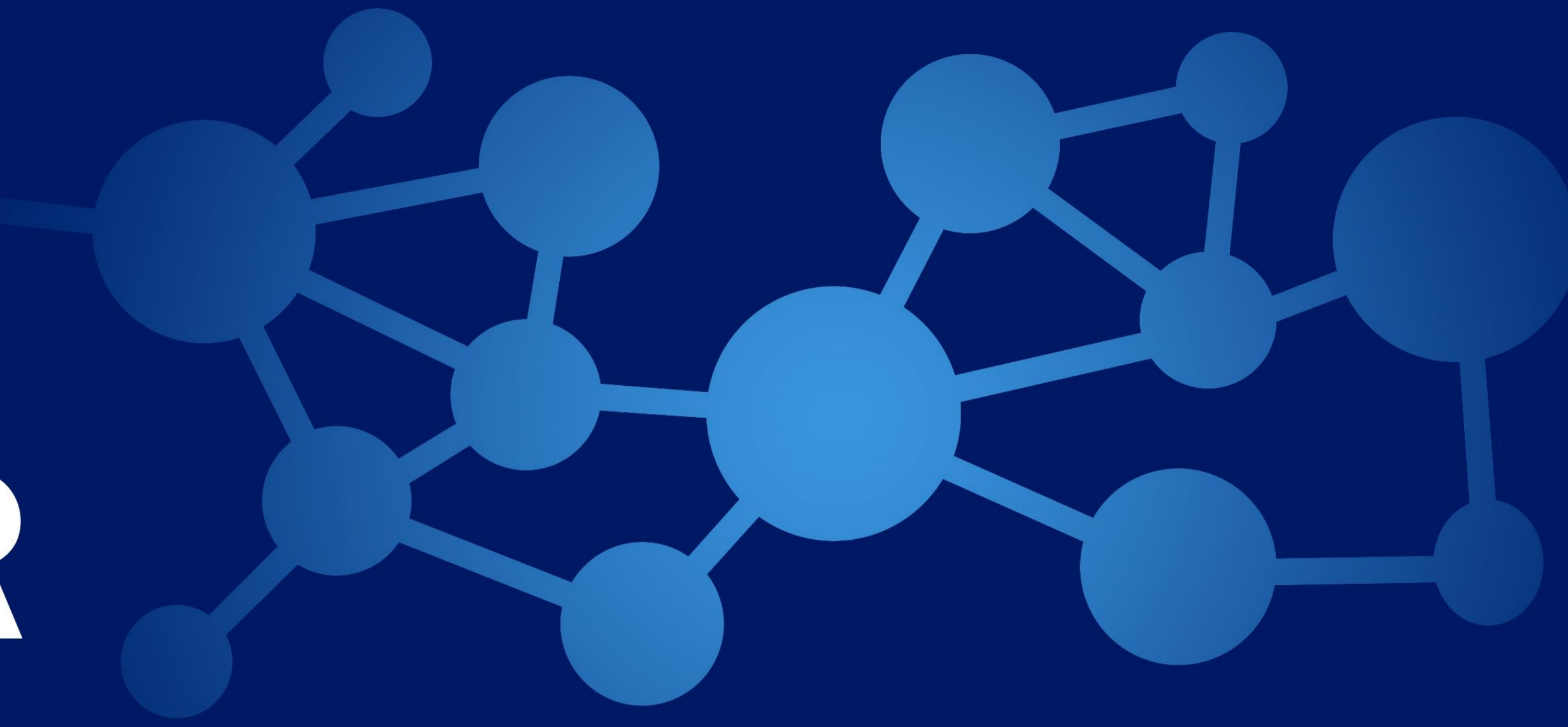# OPEN STUDY BUILDER

Novo Nordisk®

OpenStudyBuilder supports structured protocol content and submission deliverables using concept-based standards

clinicalMDR

### OpenStudyBuilder Structure

- The **OpenStudybuilder** Application
- A Clinical Metadata Repository
- An API layer

OpenStudyBuilder

A New Approach to Study Specifications

- Single metadata source for key deliverables e.g. protocol, CRF, SDTM, ADaM, CTR, TFL etc
- Built-in compliance with external and internal standards
- A higher degree of end-to-end consistency
- Facilitation of more automation and content reuse
- Metadata driven creation of structured protocol content
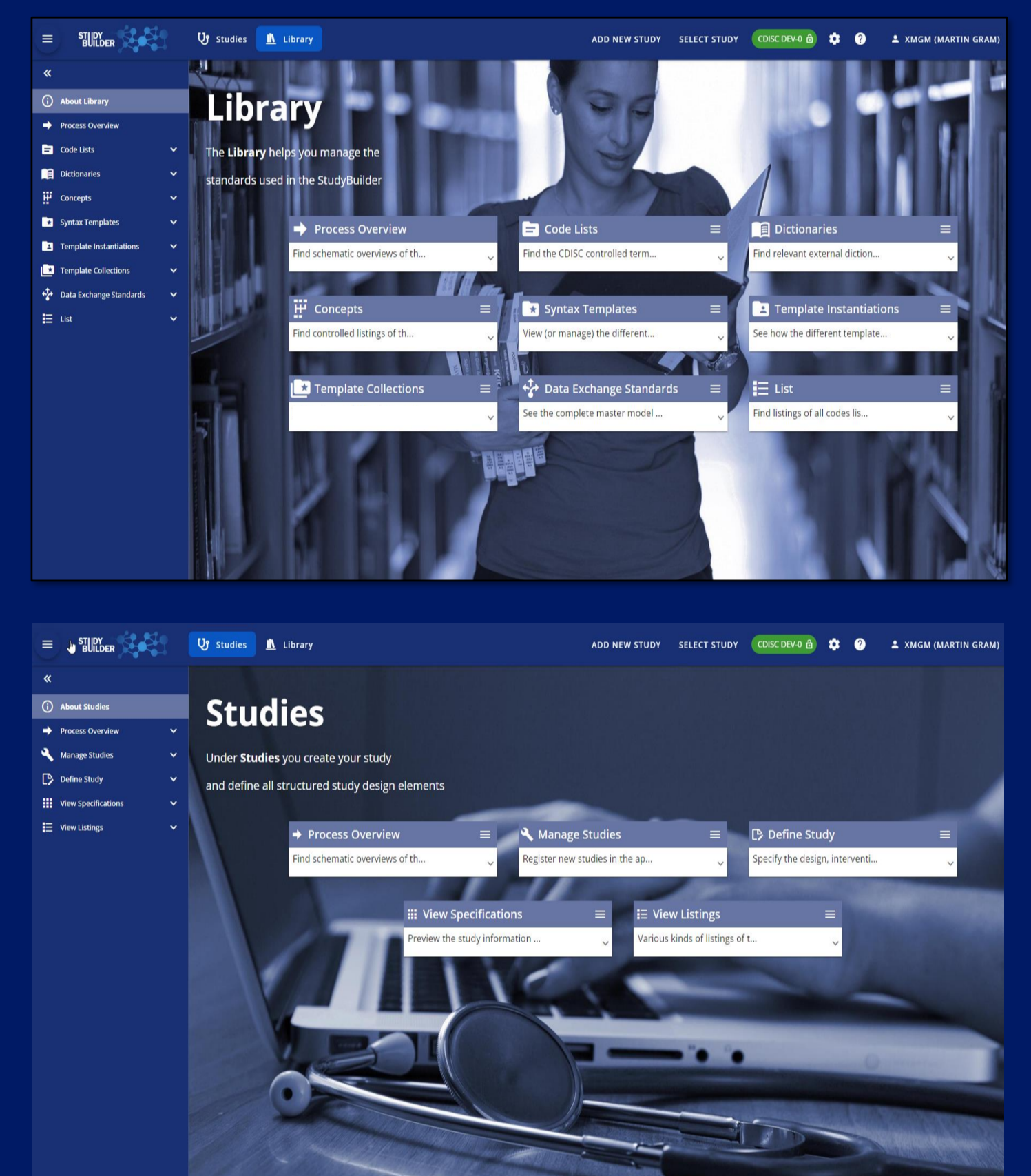
Open Source

- **OpenStudyBuilder** will be shared as open source under COSA
- Developed as an outcome of the CDISC 360 project and as a Digital Data Flow (DDF) compatible solution

CDISC DDF

TCB DDF

cdisc OPEN SOURCE ALLIANCE
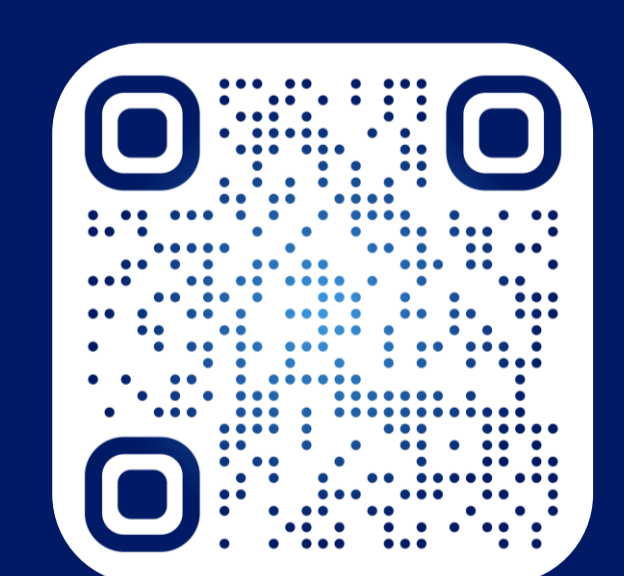
Core Functionalities

A **studies part** for specification of study type, objectives/endpoints, compounds, population, study design, visits, schedule of activities etc

A **library part** for maintenance of units, terminology standards, dictionaries, compounds, activity terms, syntax templates etc

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