OpenStudyBuilder – a Metadata Data and Study Definition Repository
End-to-end automation from structured protocol to submission deliverables using concept-based standards
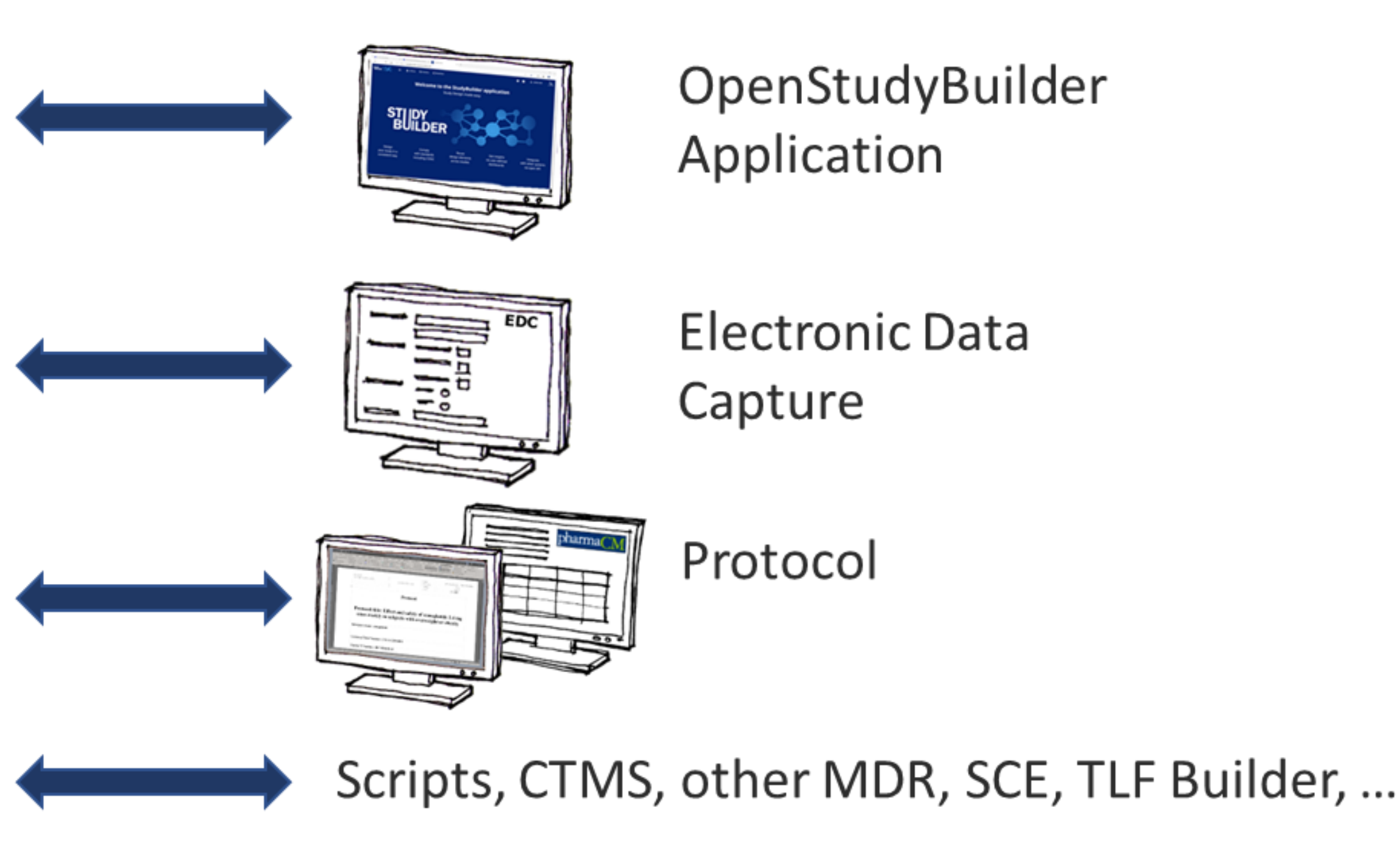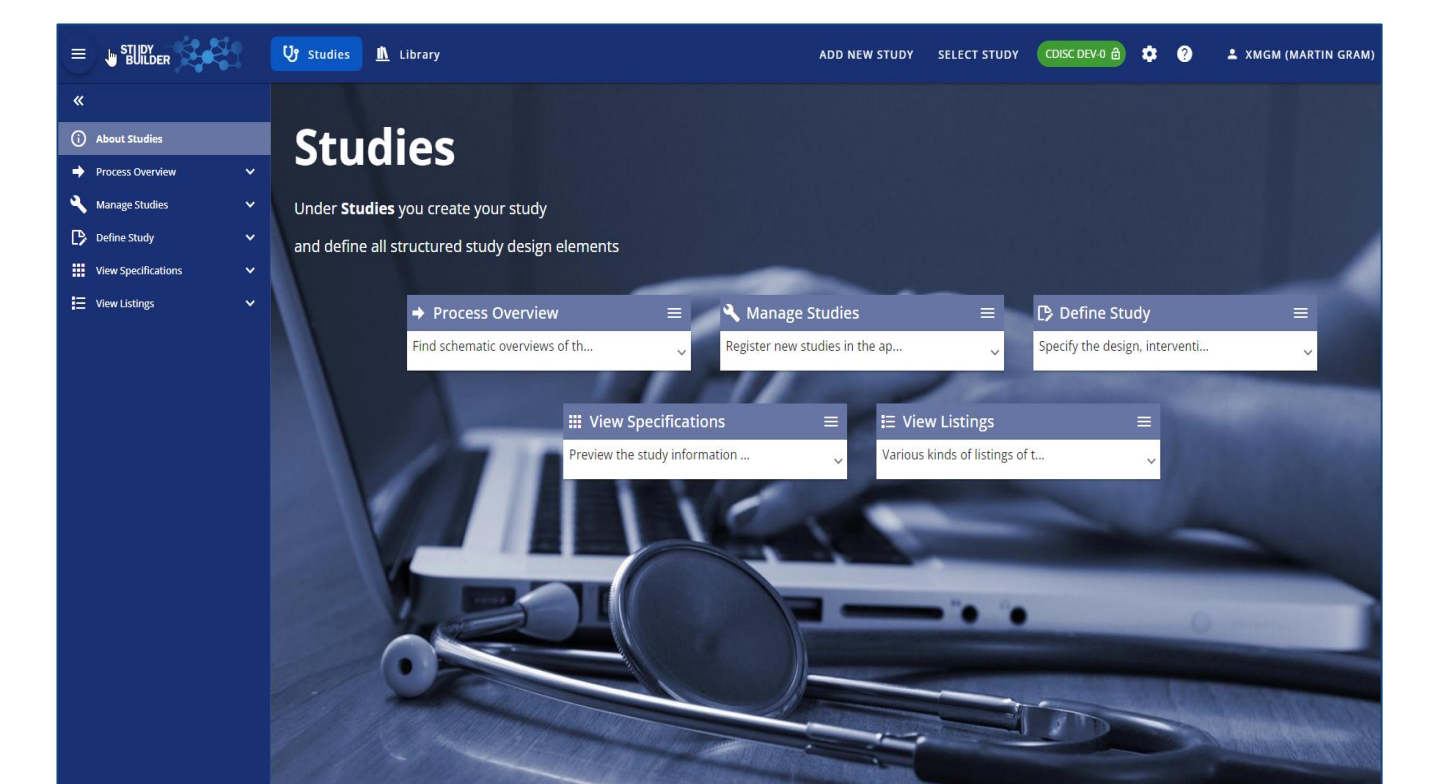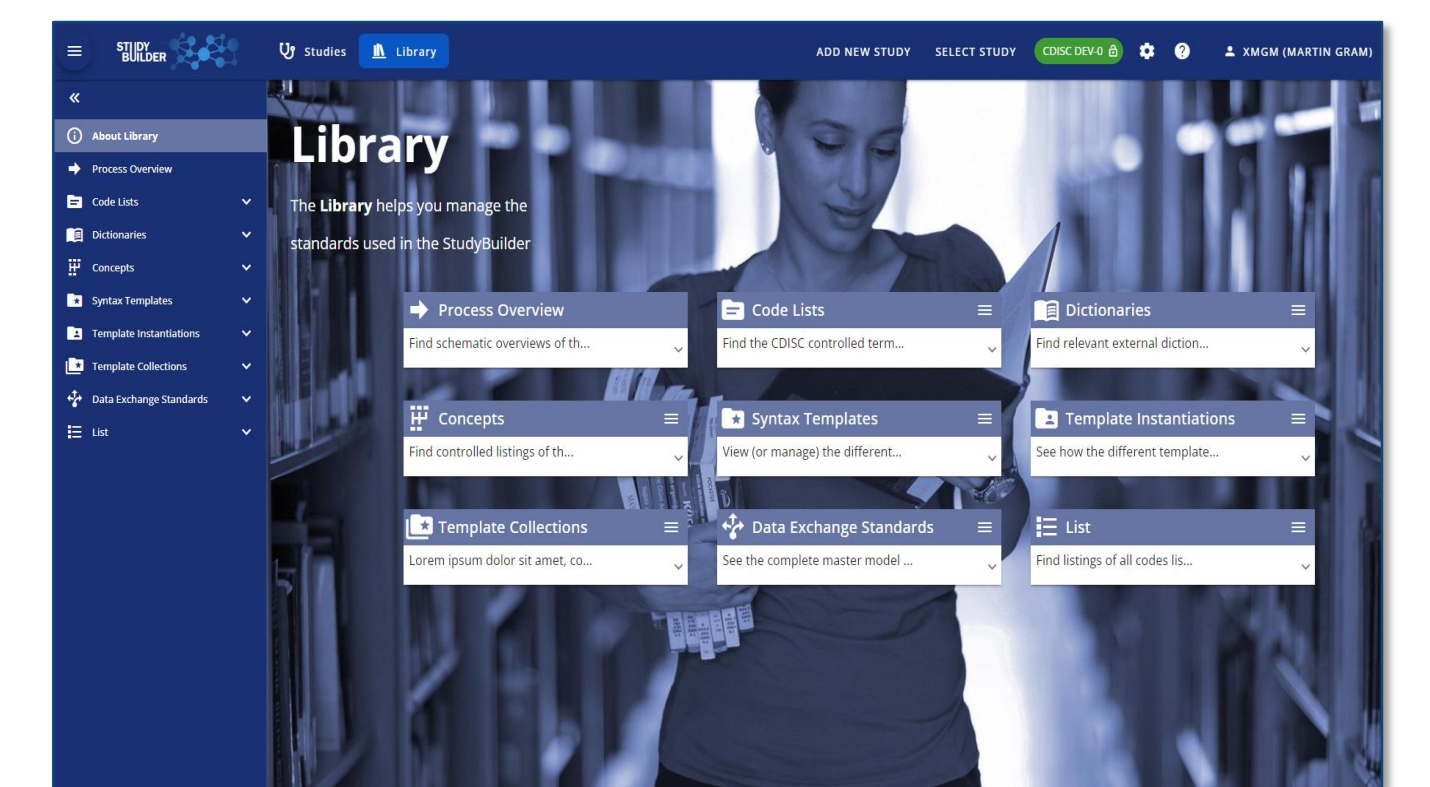
clinical **MDR**

OpenStudyBuilder Solution

- A Clinical Metadata Repository (Neo4j graph database)
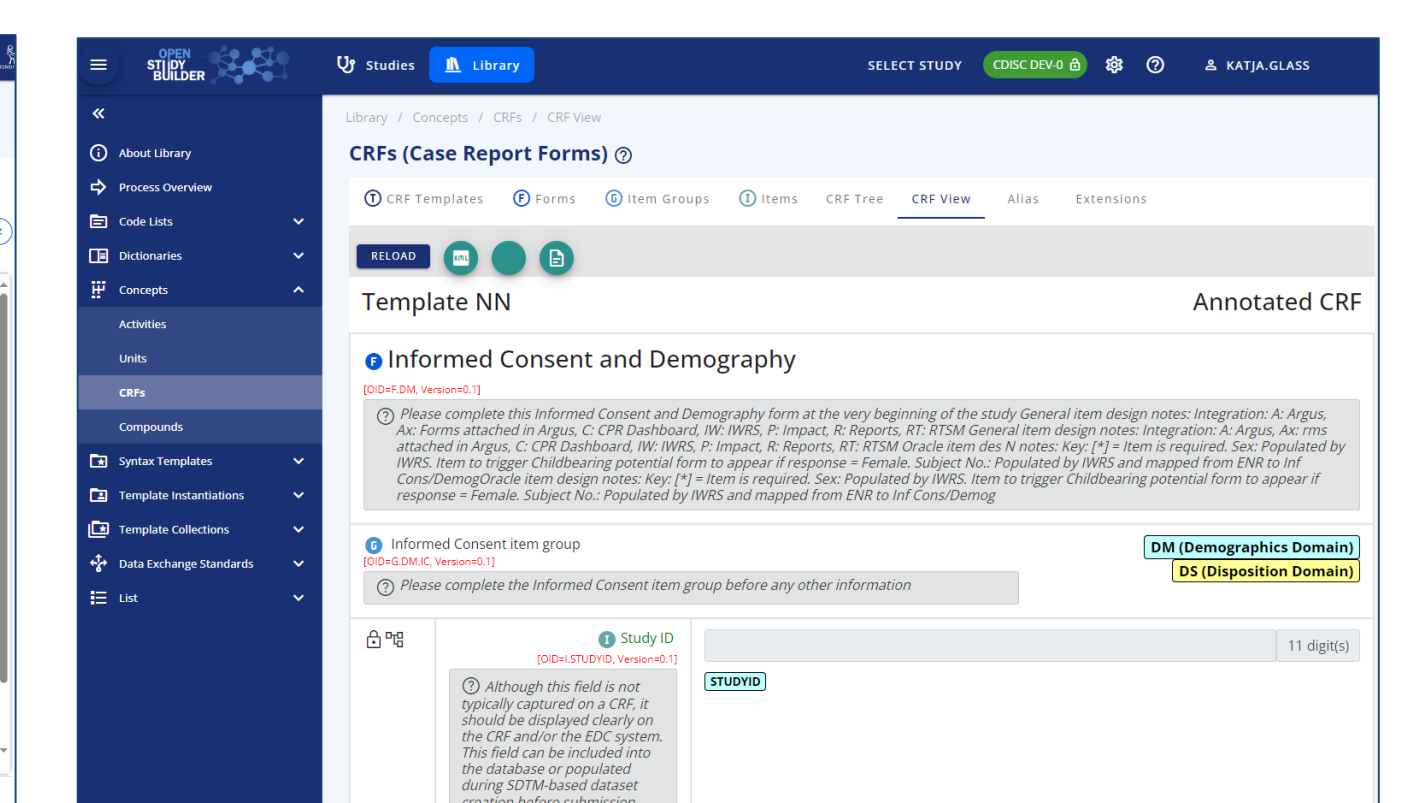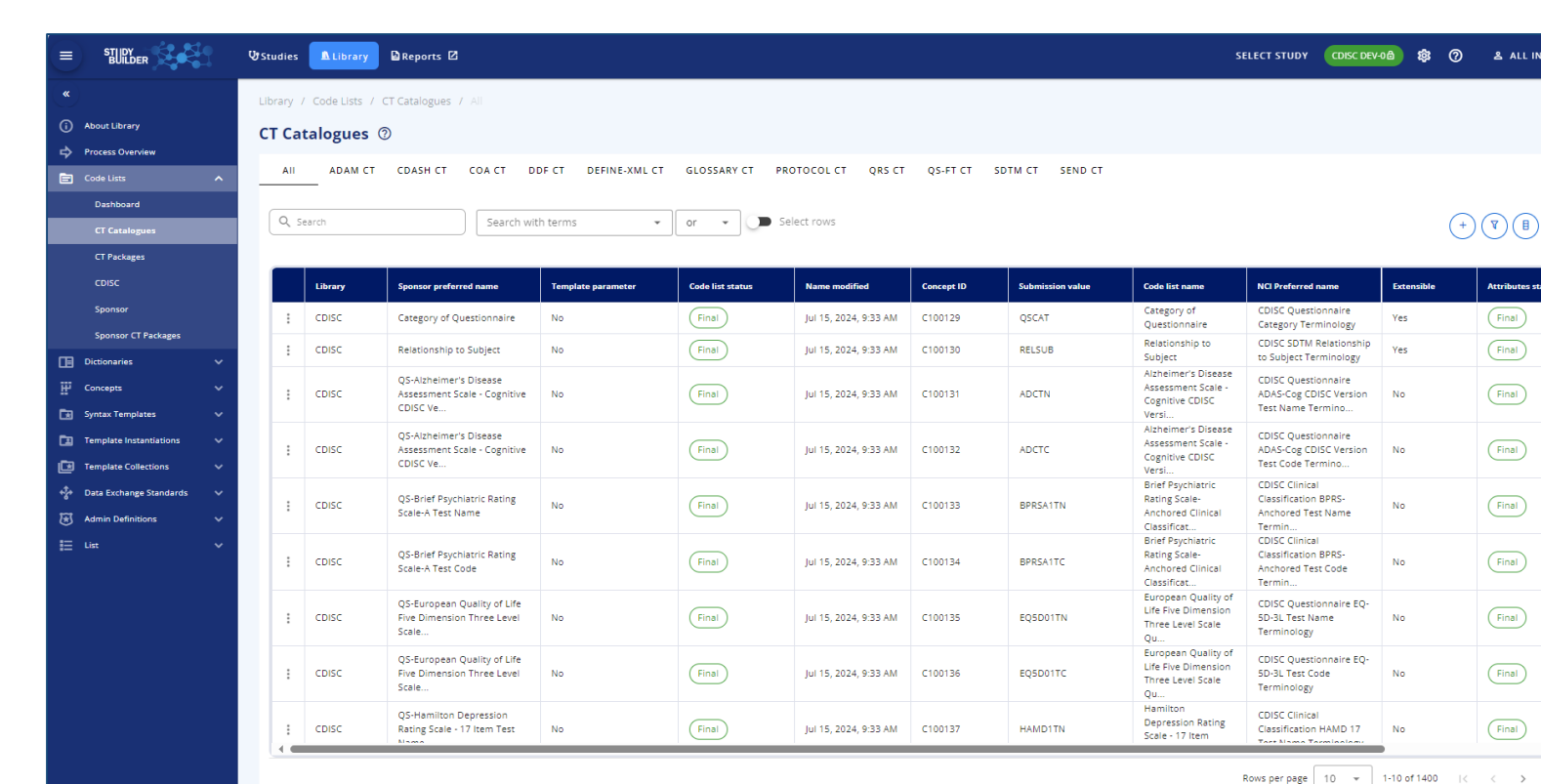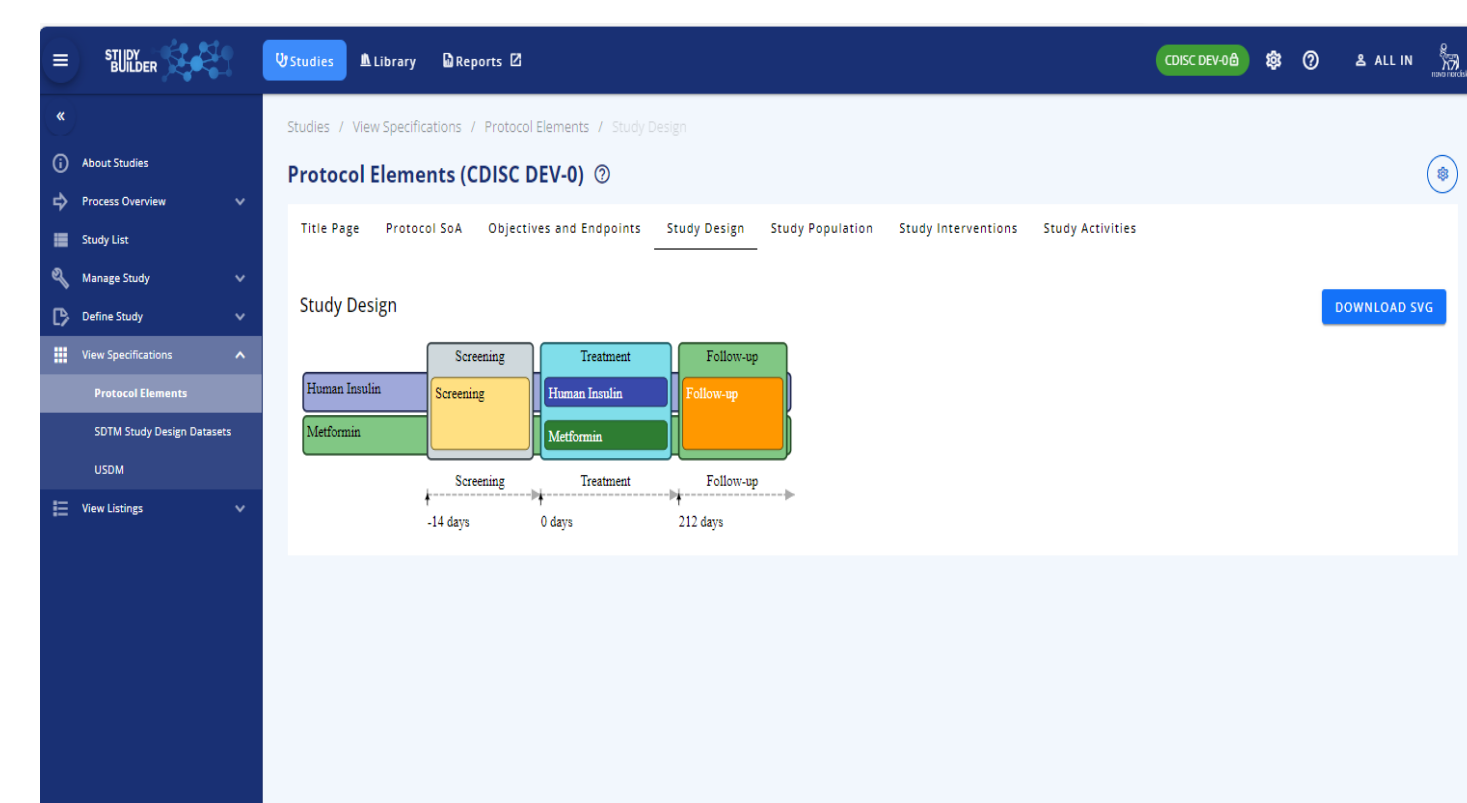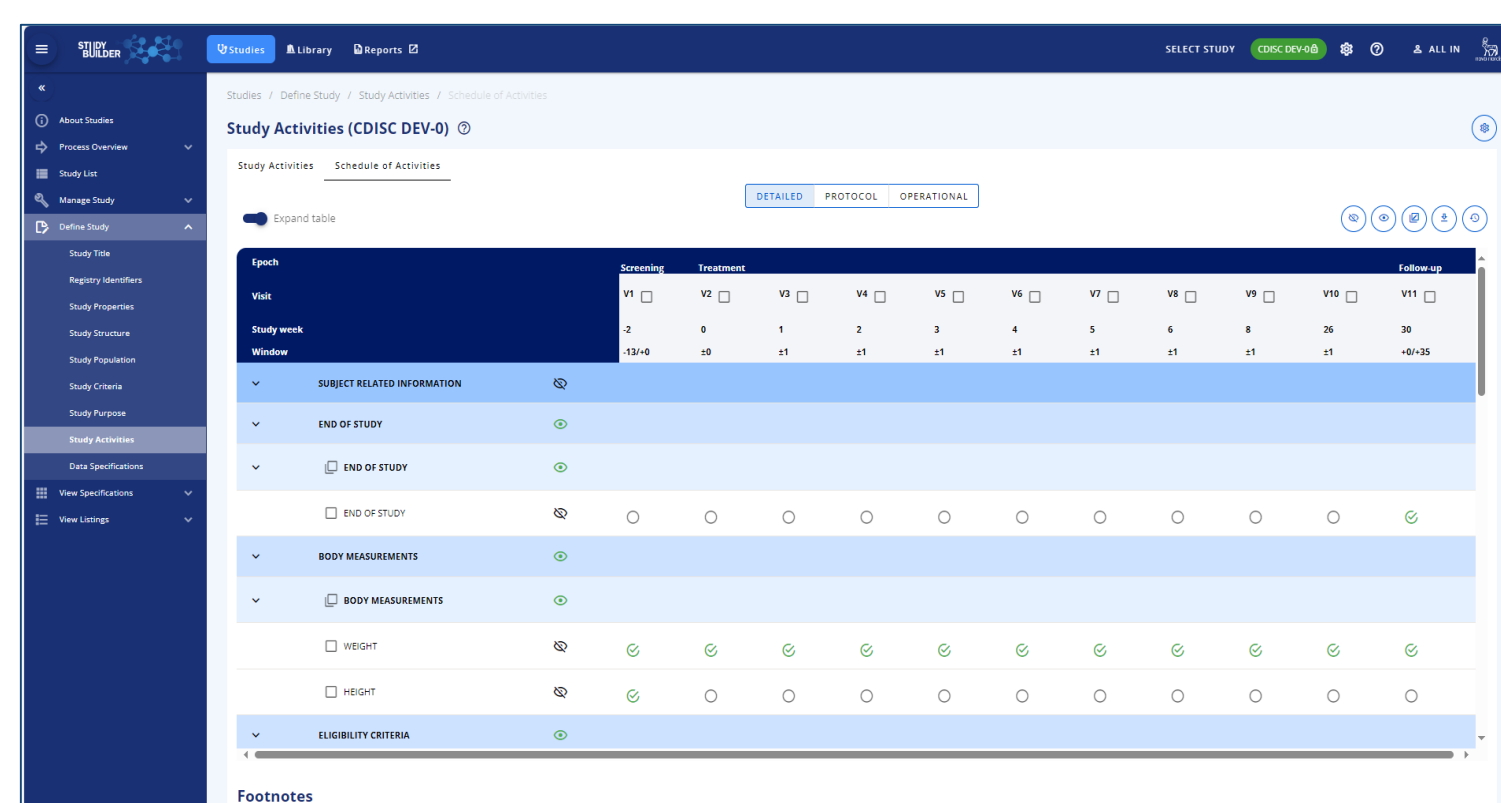- The OpenStudyBuilder Application (web application)
- An API layer

Study Specifications & Standards Management

- Single metadata source for key deliverables e.g. protocol, CRF, SDTM, ADaM, CTR, TFL
- Standardization through controlled terminology, dictionaries, templates
- Built-in compliance with external and internal standards
- A higher degree of end-to-end consistency due to re-usability and linkage
- Facilitation of more automation and content reuse through open interface (API)
- Metadata driven creation of structured protocol content

Connectivity to Systems

- Full connectivity to any kind of systems through APIs
- Maintenance of standards, like CRFs standardization and utilization in downstream EDC system
- Protocol harmonization through standards

Standards & Study Definitons

Protocol
Case Report Forms
Controlled Terminology
Dictionaries
Schedule of Activities
...

API & DDF API

OpenStudyBuilder Application

Electronic Data Capture

Protocol

Scripts, CTMS, other MDR, SCE, TLF Builder, …

Open Source

- OpenStudyBuilder is shared as open source under COSA by Novo Nordisk
- Collaborate with TransCelerate as a Digital Data Flow (DDF) compatible solution
- Collaborate with CDISC, e.g. for Biomedical Concept Development & Enhancements

CDISC OPEN SOURCE ALLIANCE

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