

OpenStudyBuilder - a Metadata and Study Definition Repository

End-to-end automation from structured protocol to submission deliverables using concept-based standards



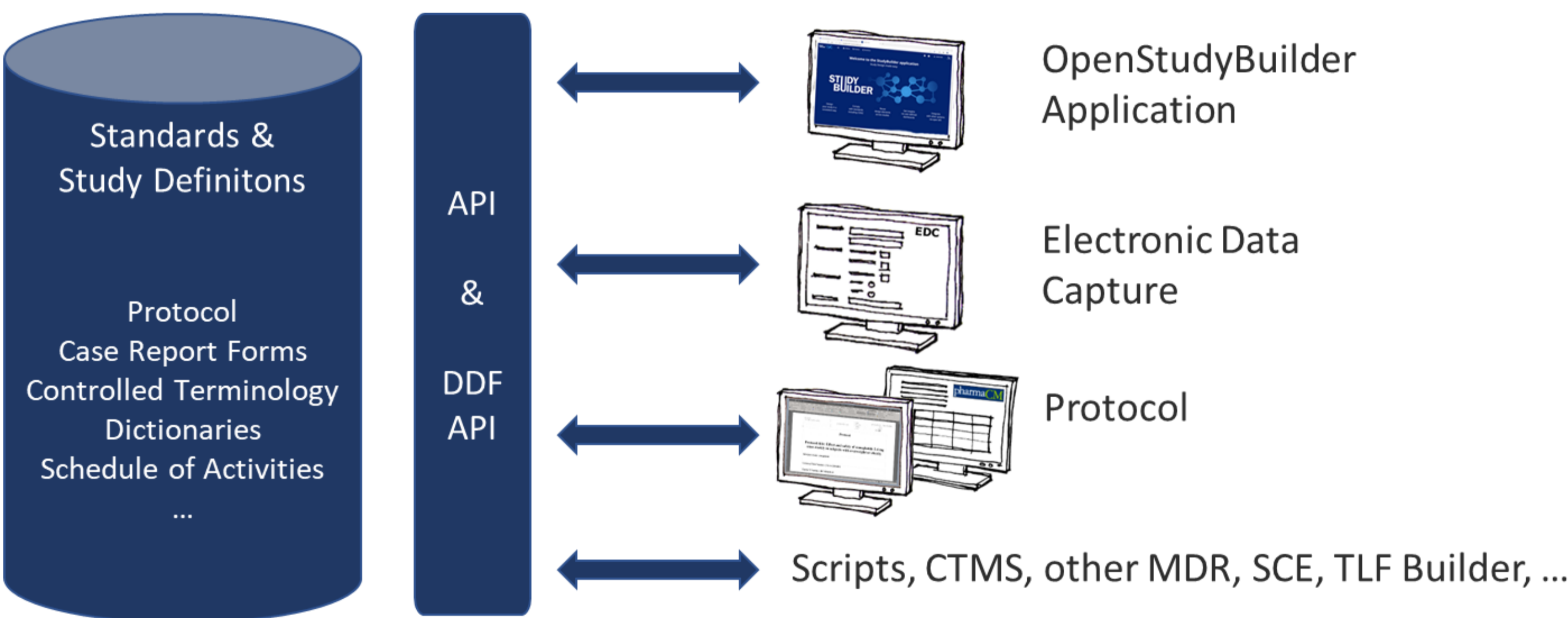
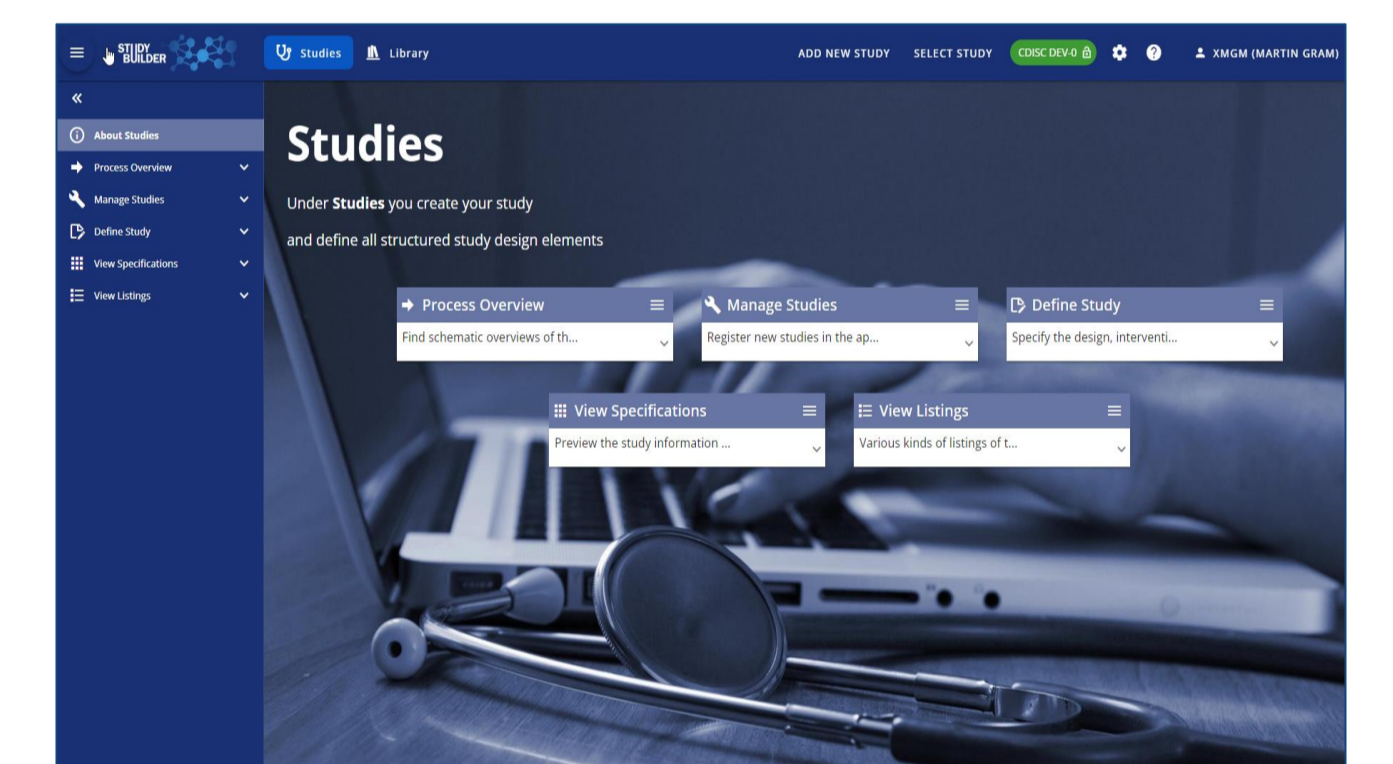
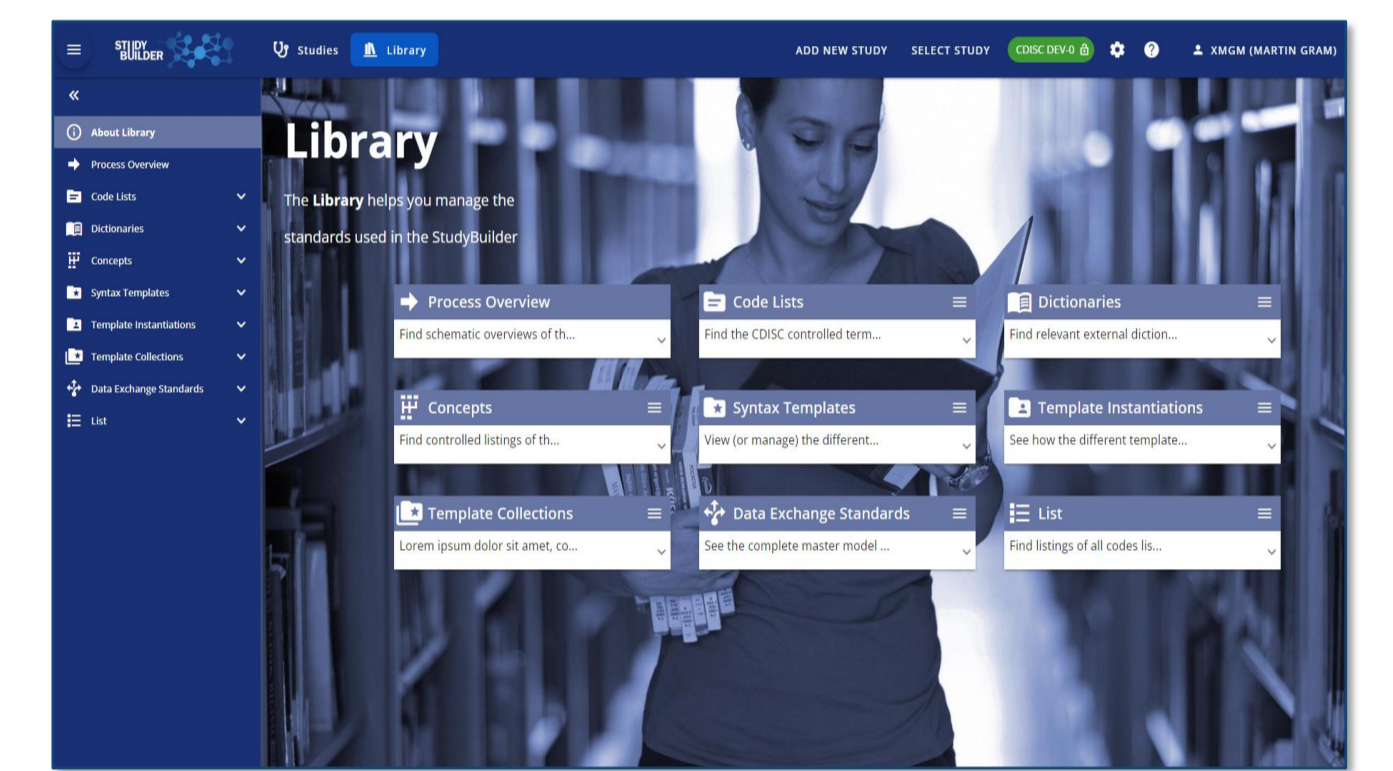
OpenStudyBuilder Solution

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



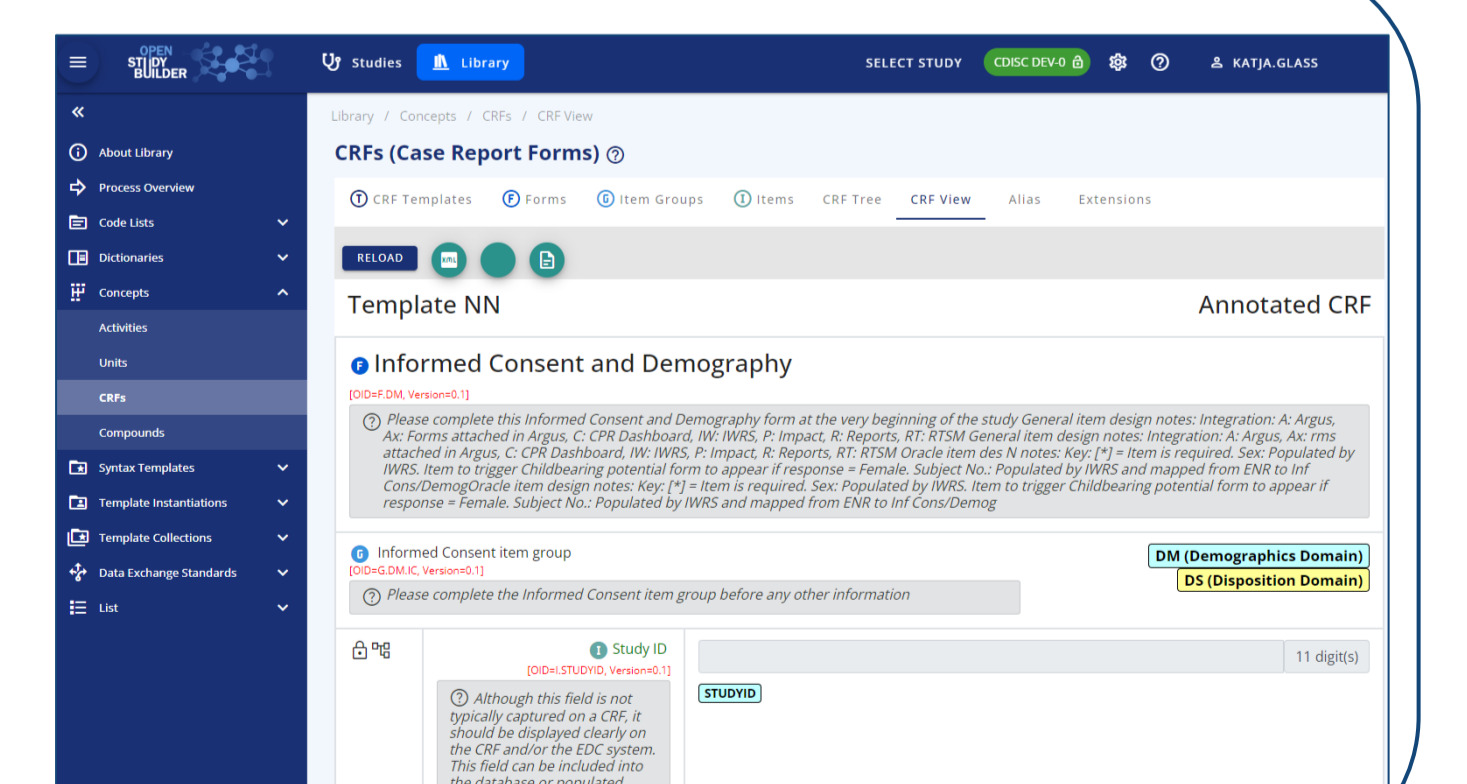
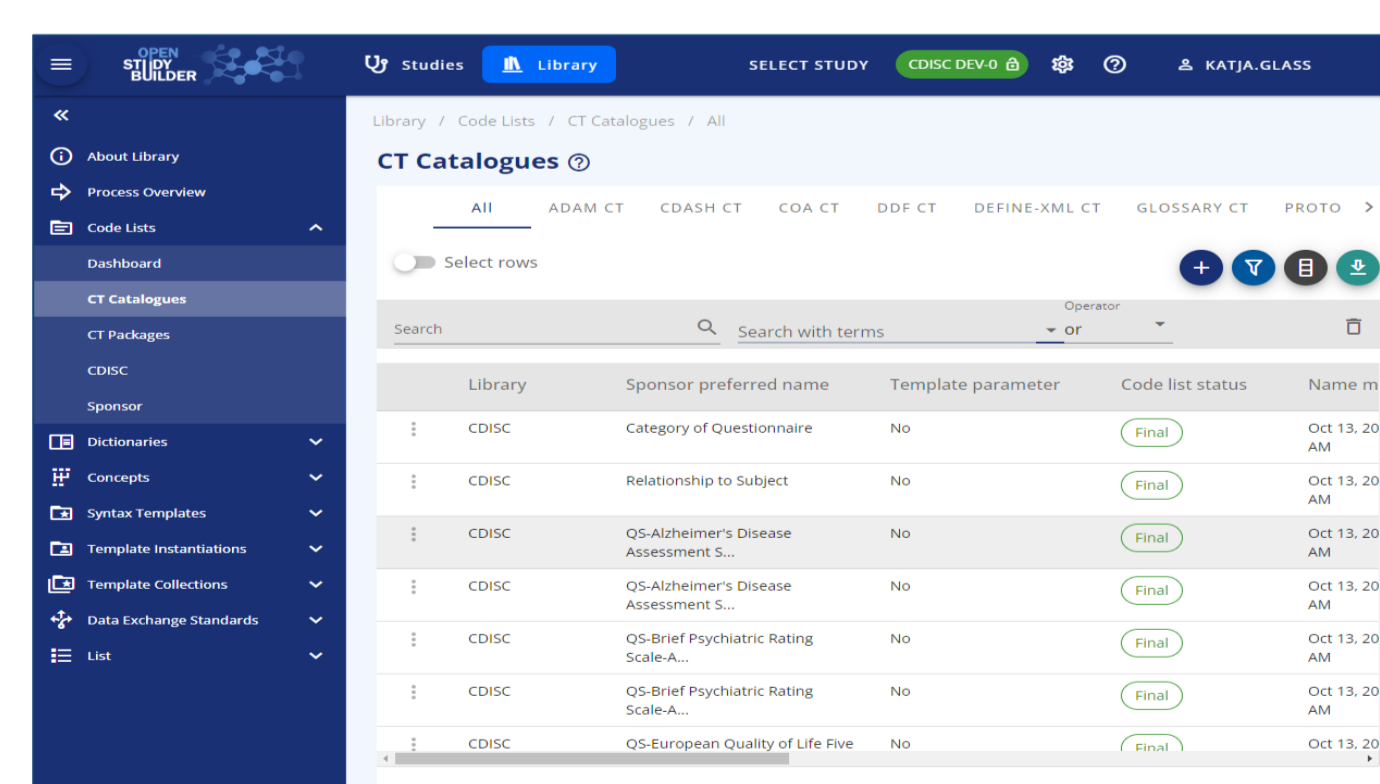
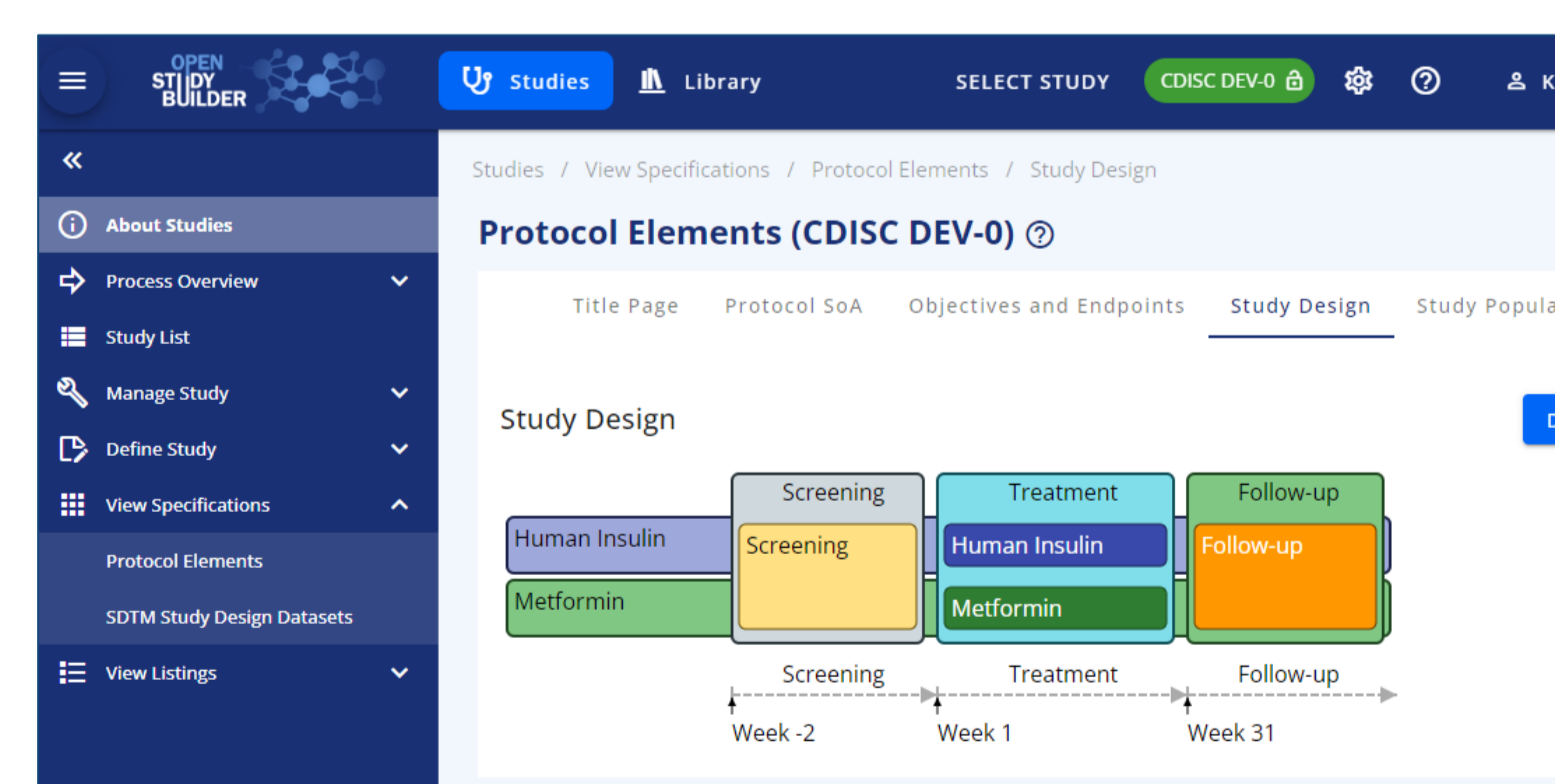
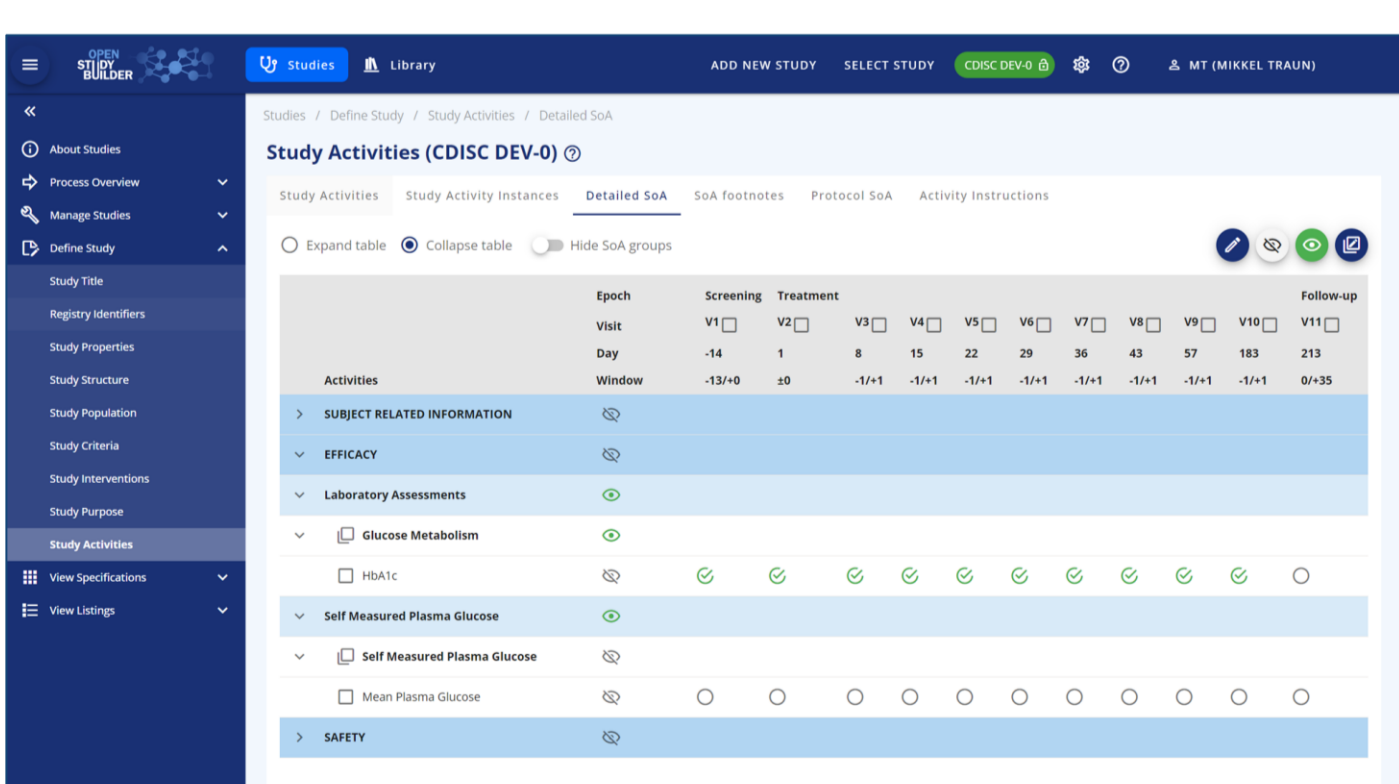
Study Specifications & Standards Management

- 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
- End-to-end consistency due to re-usability and linkage
- Facilitation of automation and content reuse through open interface (API)
- Metadata driven creation of structured protocol content



Connectivity to Systems

- Full connectivity to any system through APIs
- Maintenance of CRF standards and utilization in downstream EDC
- Protocol harmonization through standards



Open Source

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

