Katja Glass Consulting

OpenStudyBuilder

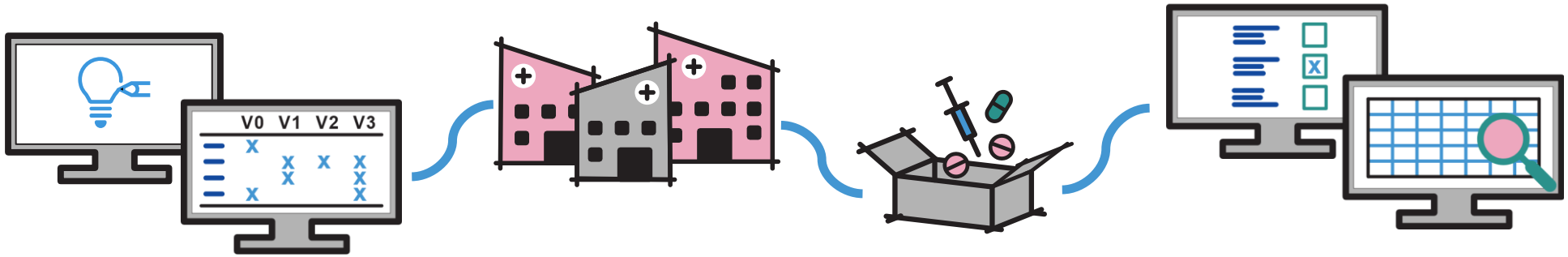
End-2-End

Open Source Lösung von Novo Nordisk

Agenda

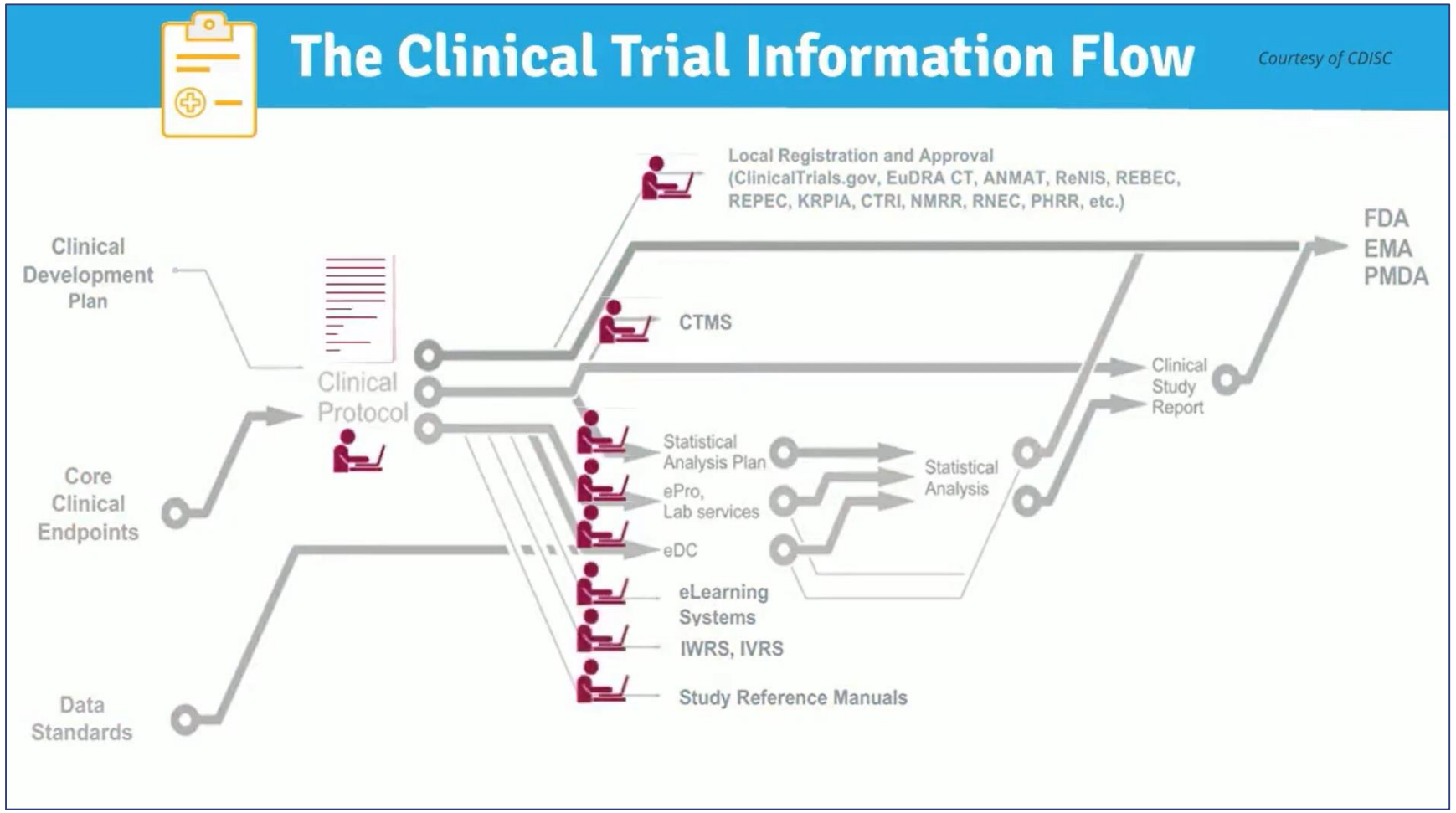
- Einleitung
- OpenStudyBuilder
- Kooperation
- Aussicht

Prozessautomatisierungen



Ein effizienter und skalierbarer Studienprozess, verbunden durch einen digitalen Datenfluss und vereinfacht durch ein einheitliches Datenmodell.

Digital Data Flow – Problem 1



Dokumente statt Daten

https://www.youtube.com/watch?v=Otg0d2385is

Digital Data Flow – Problem 2

Disconnected Data

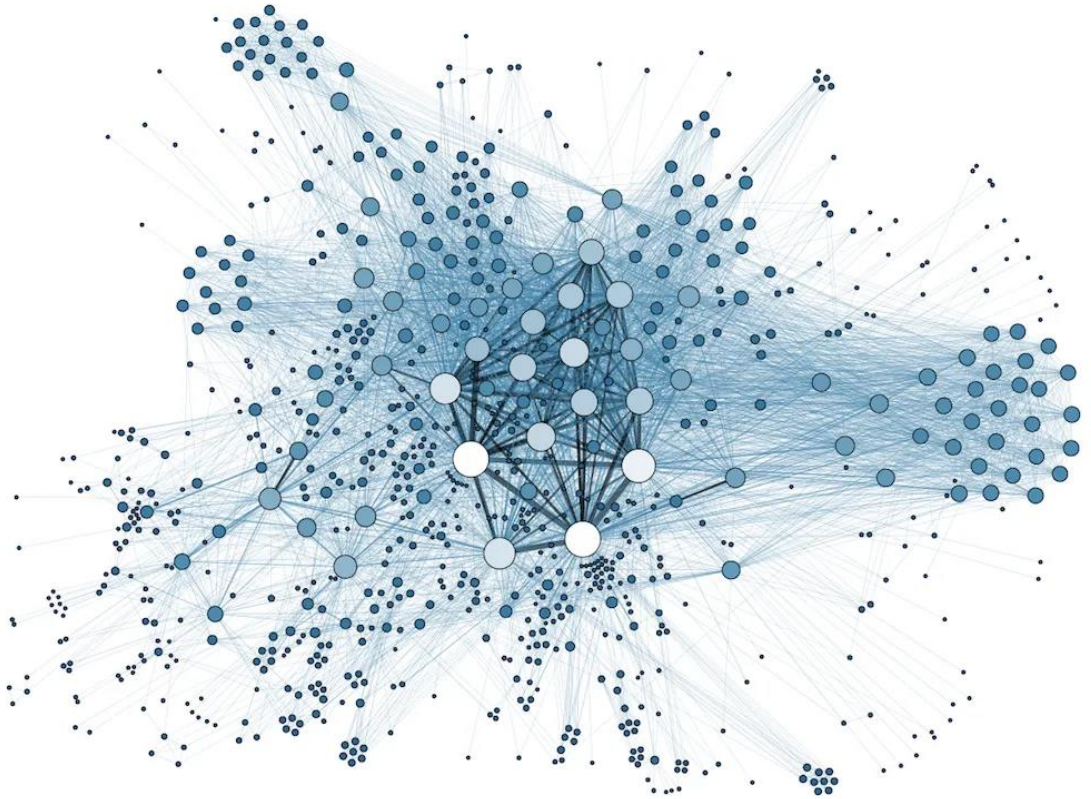
Digital Data Flow – Lösungen

Daten statt Dokumente

- Elektronisches Protokoll (ICH M11)
- Datenaustauschstandards (USDM)

Digital Data Flow – Lösungen

Graphische Datenbank
mit semantischen Informationen



- Biomedical Concepts (CDISC)
- Linked Data Model

Agenda

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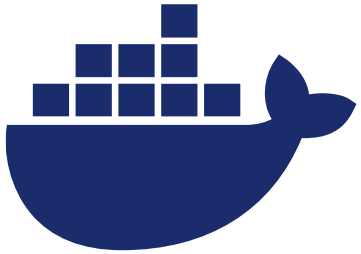
Was ist der OpenStudyBuilder?

Repository für Metadaten und Studienmetadaten

3 Elemente

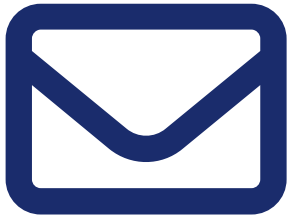
- **Repository (Studien- und Metadaten)**
- **API Schicht**
- **OpenStudyBuilder Application / Web Interface**

OpenStudyBuilder



Lokale oder
Serverinstallation

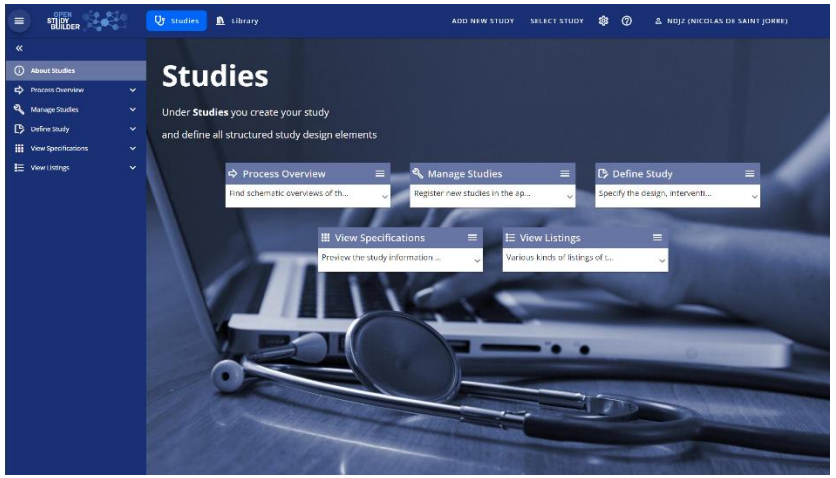
Öffentliche
Sandbox



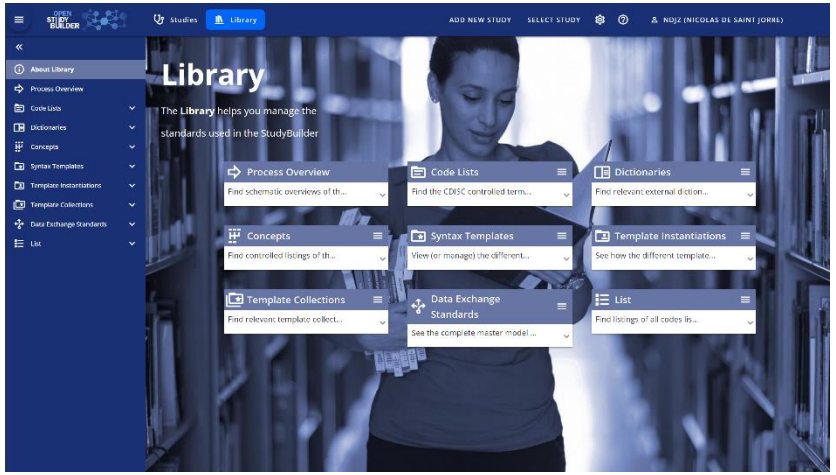
Hosting-
Umgebung

OpenStudyBuilder Komponenten

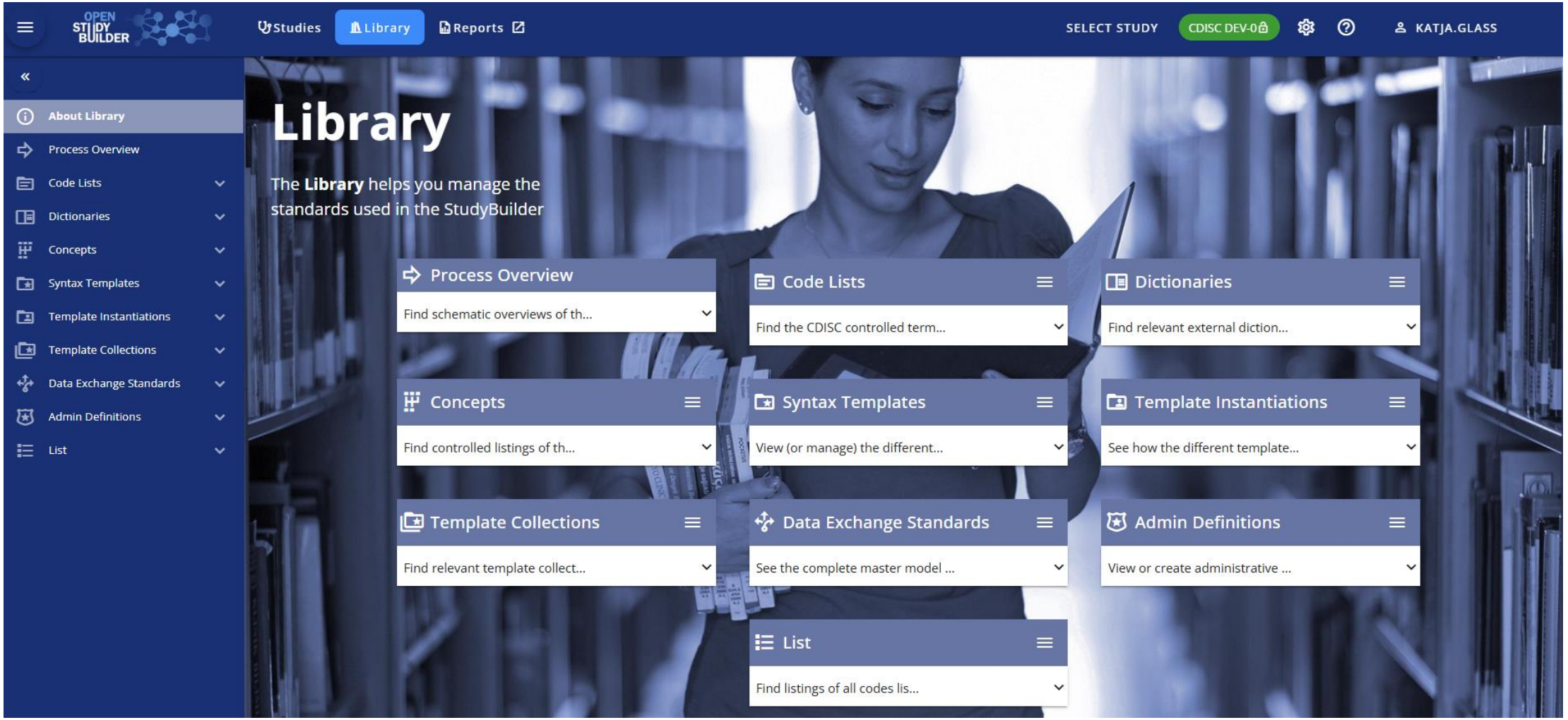
STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES



LIBRARY	
CONTROLLED TERMINOLOGY	MEDICAL DICTIONARIES (e.g., MedDRA)
CONCEPTS (ACTIVITIES, UNITS, CRFs, COMPOUNDS)	SYNTAX TEMPLATES
DATA EXCHANGE STANDARDS	



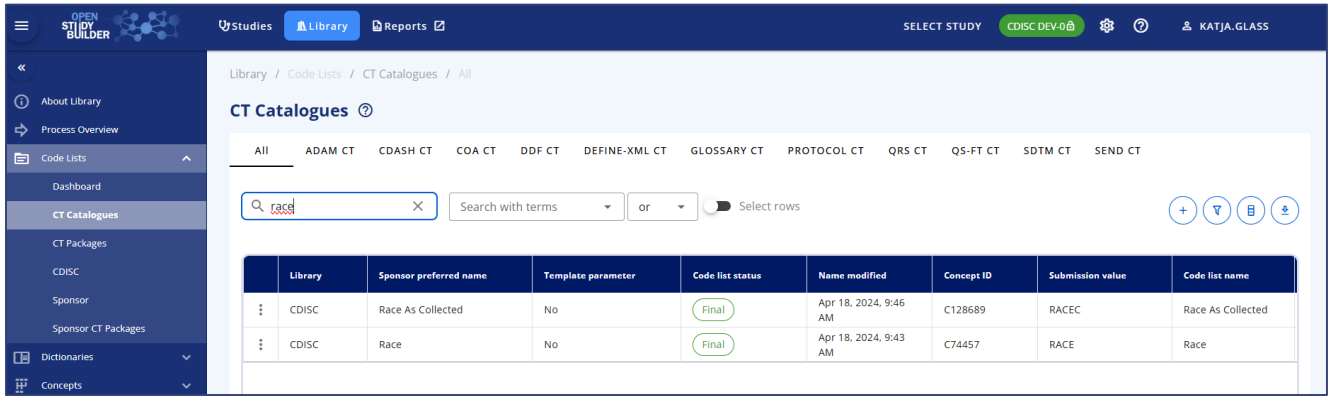
OpenStudyBuilder Library



OpenStudyBuilder Library

- Codelisten

RACE



CDISC-Term:
BLACK OR AFRICAN AMERICAN

NCI-Term:
Black or African American

Sponsor-Term:
African American

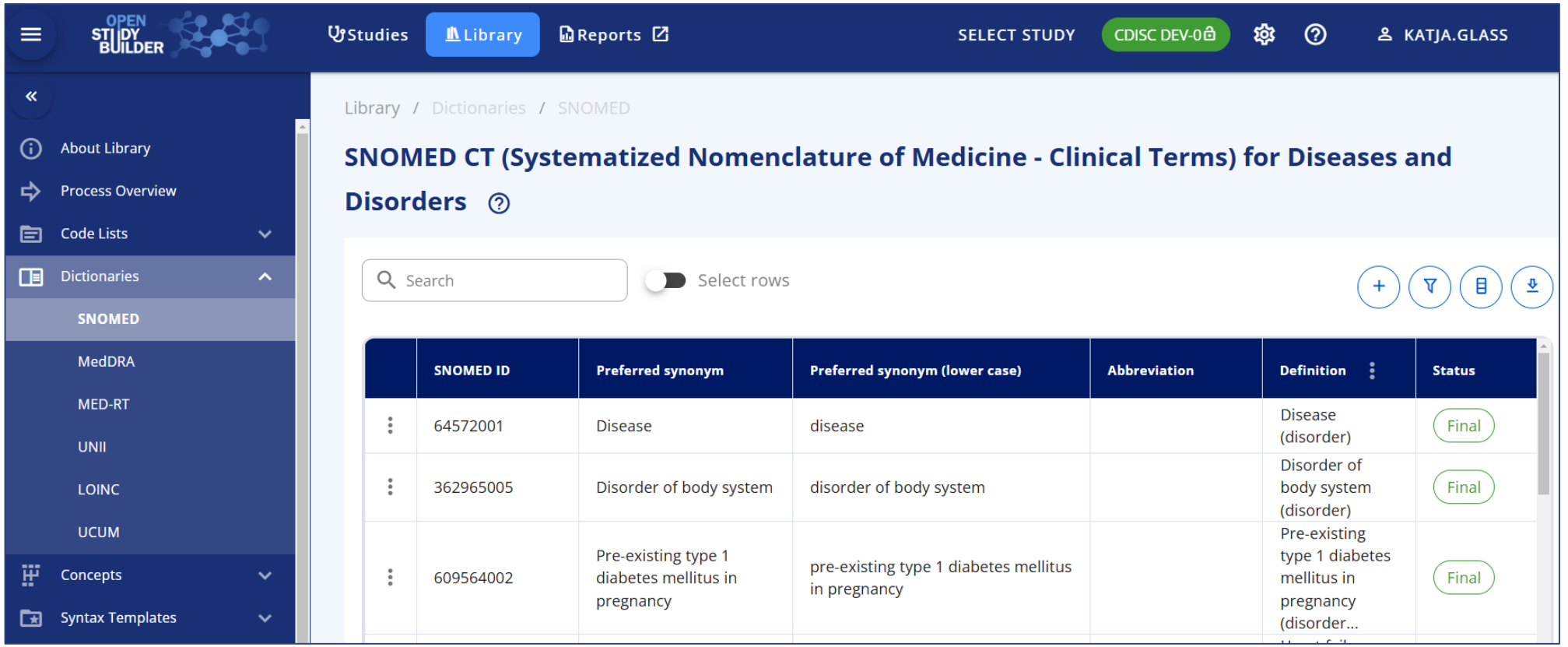
CDISC-Code:
C16352

Sentence-Case:
african american

Order:

OpenStudyBuilder Library

- Dictionaries

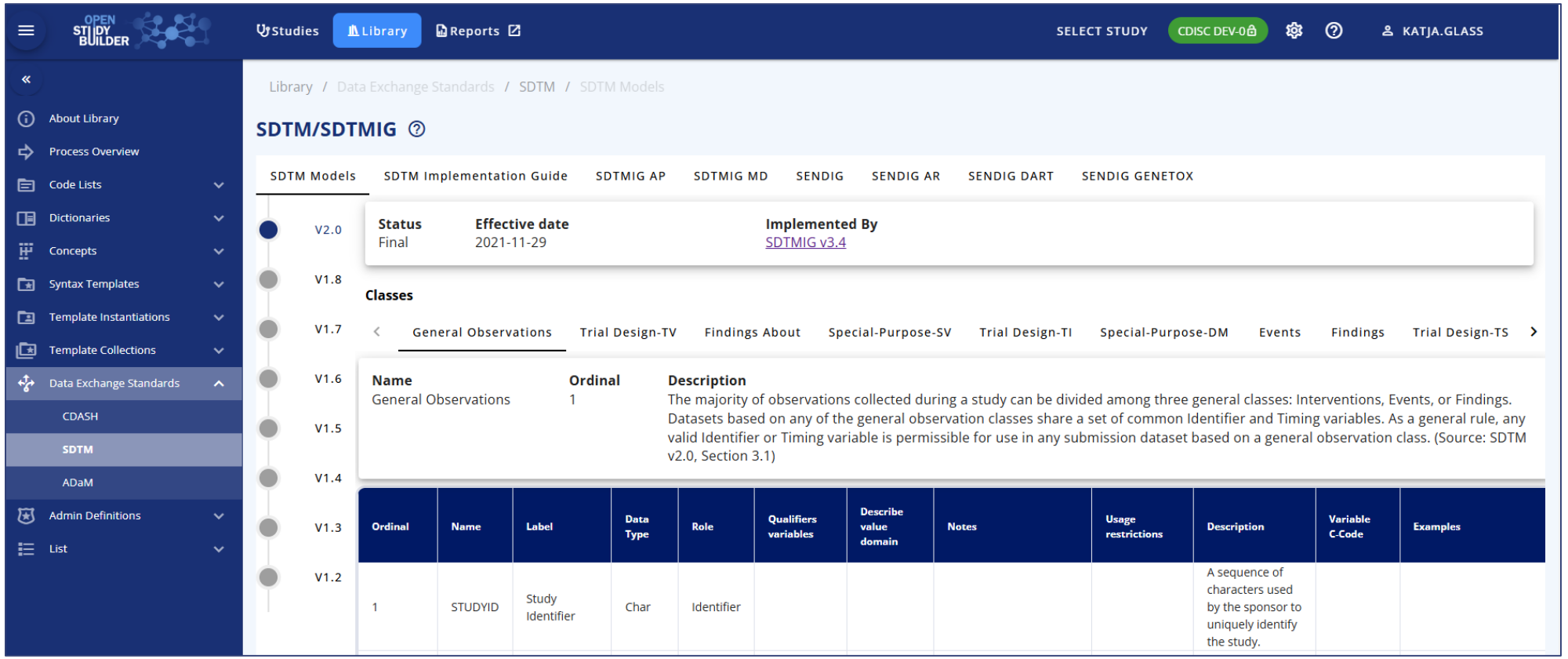


OpenStudyBuilder Library

- CRF

OpenStudyBuilder Library

- Datenstrukturen / SDTM+



OpenStudyBuilder Library

- Aktivitäten / Biomedical Concept
- Protokoll Standards

Parent template
Age NumericValue Age Unit or above at the time of signing the informed consent.

Parent template
Mean change from baseline in ActivityInstance

OpenStudyBuilder Library

LIBRARY	
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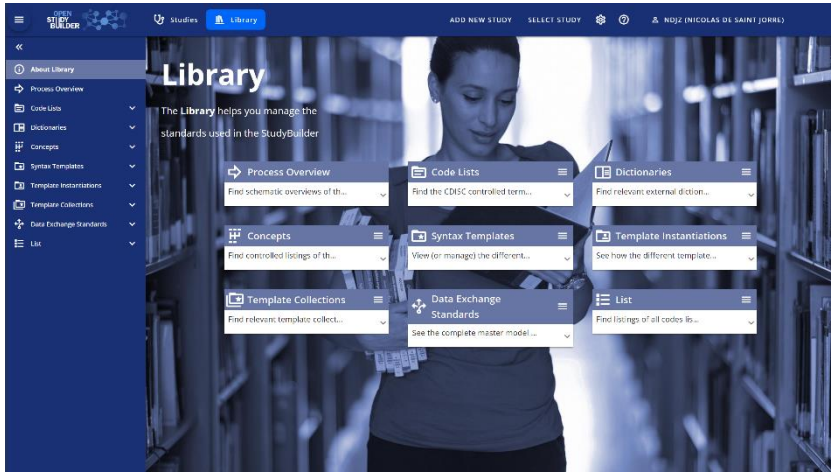
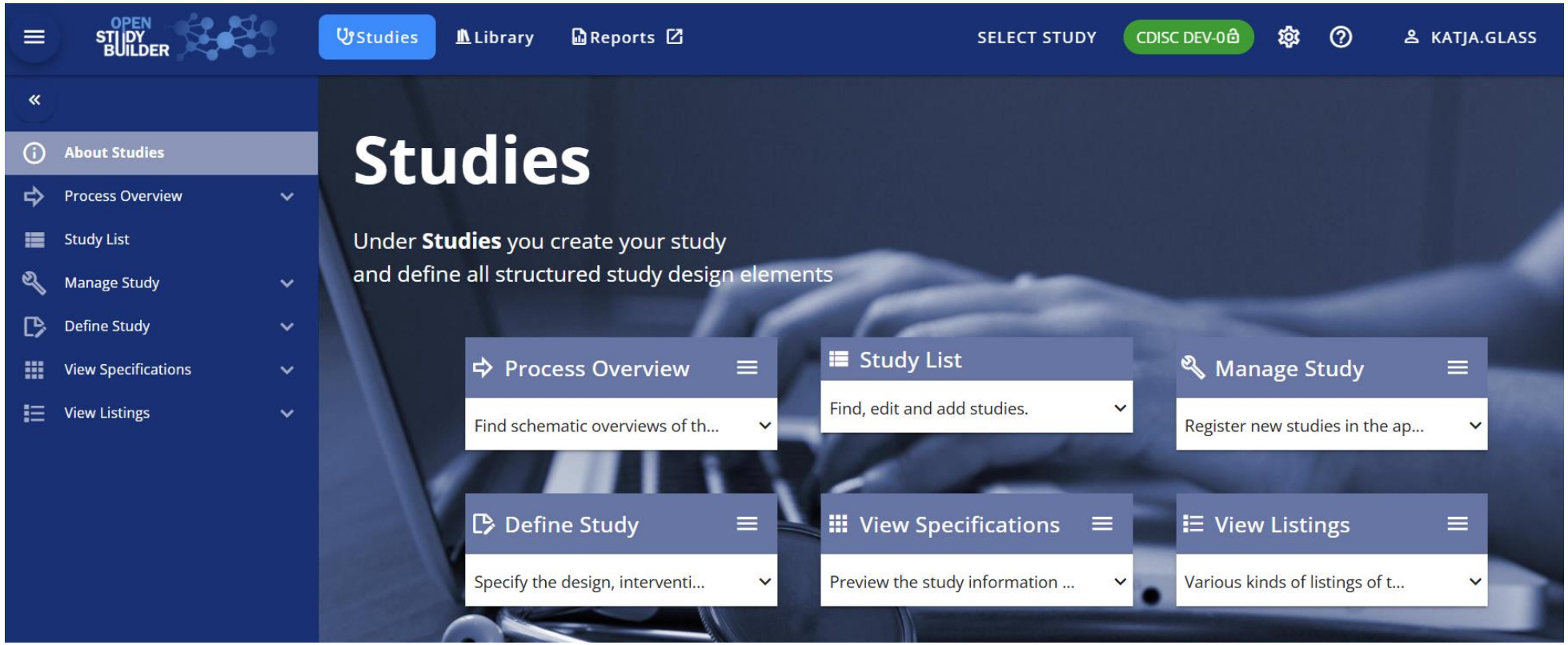


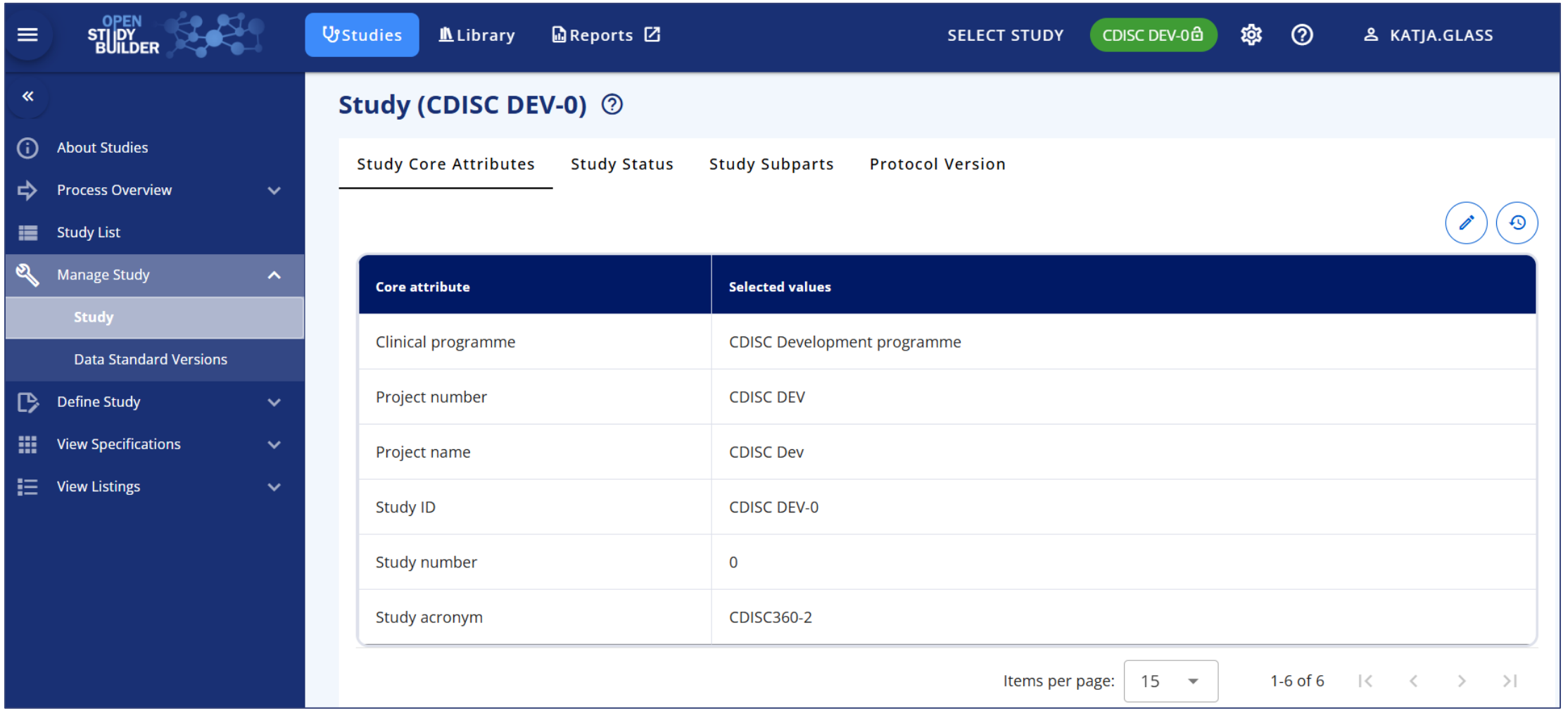
Klassisches Metadaten Repository mit semantischen Protokoll Standards

OpenStudyBuilder Studienbereich

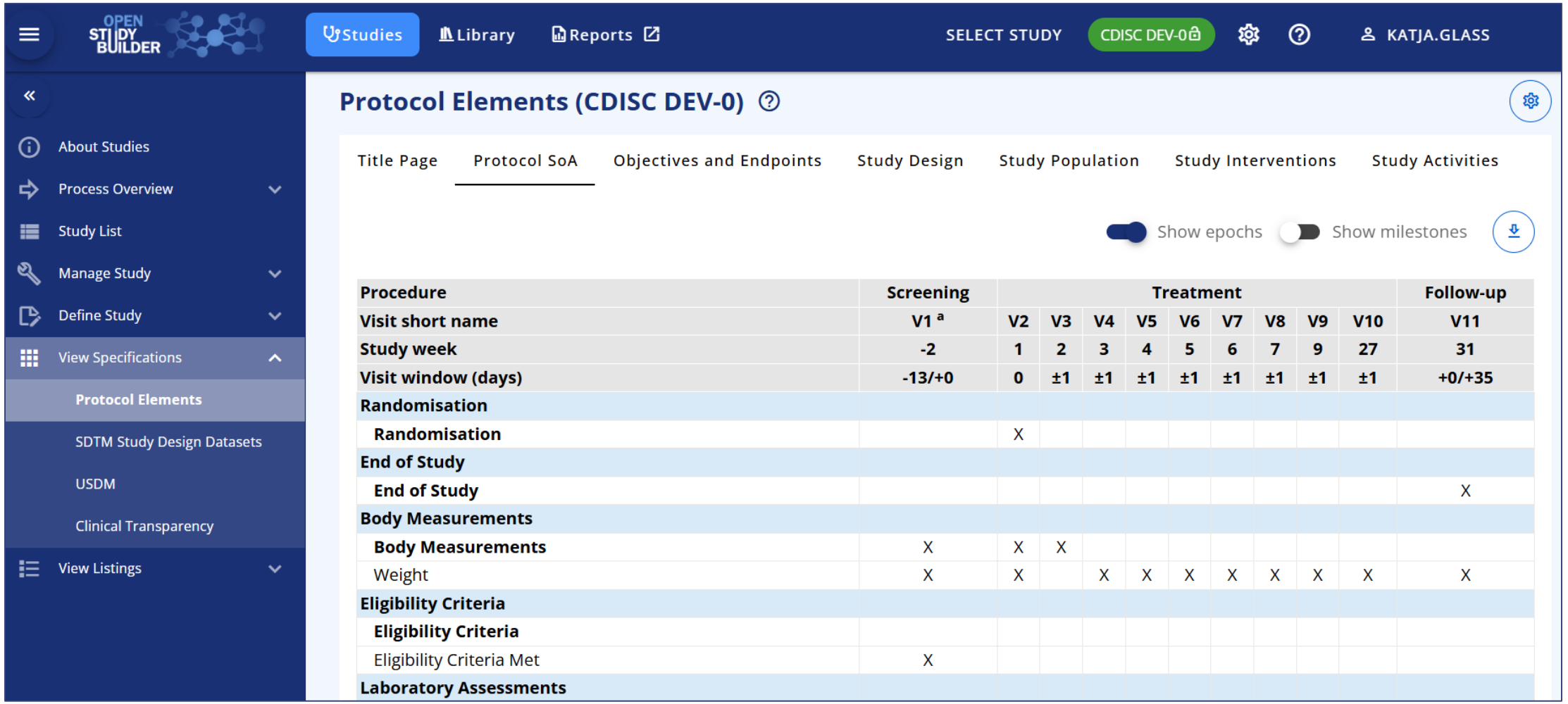
- Managen von Studienmetadaten



OpenStudyBuilder Studienbereich

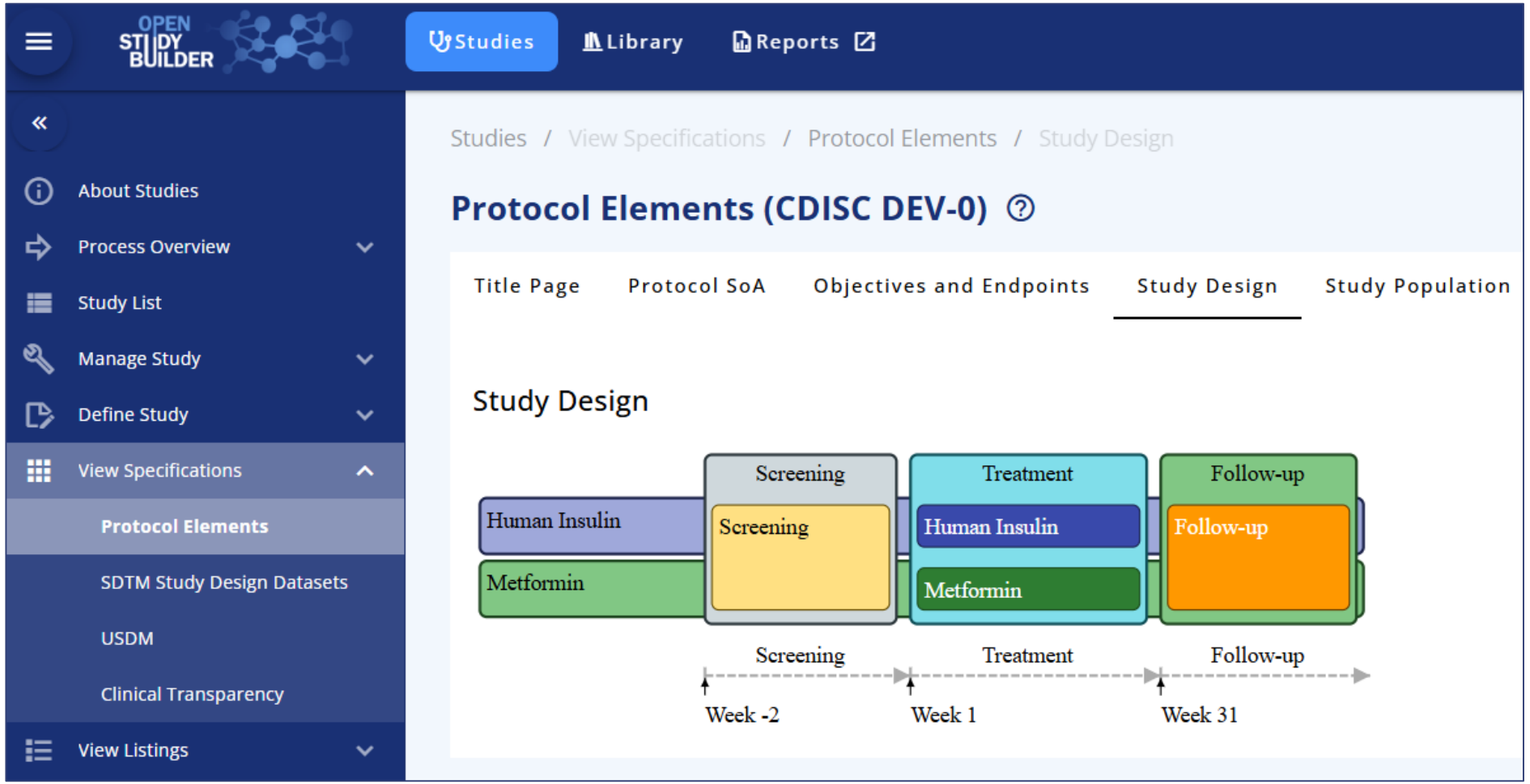


OpenStudyBuilder Studienbereich

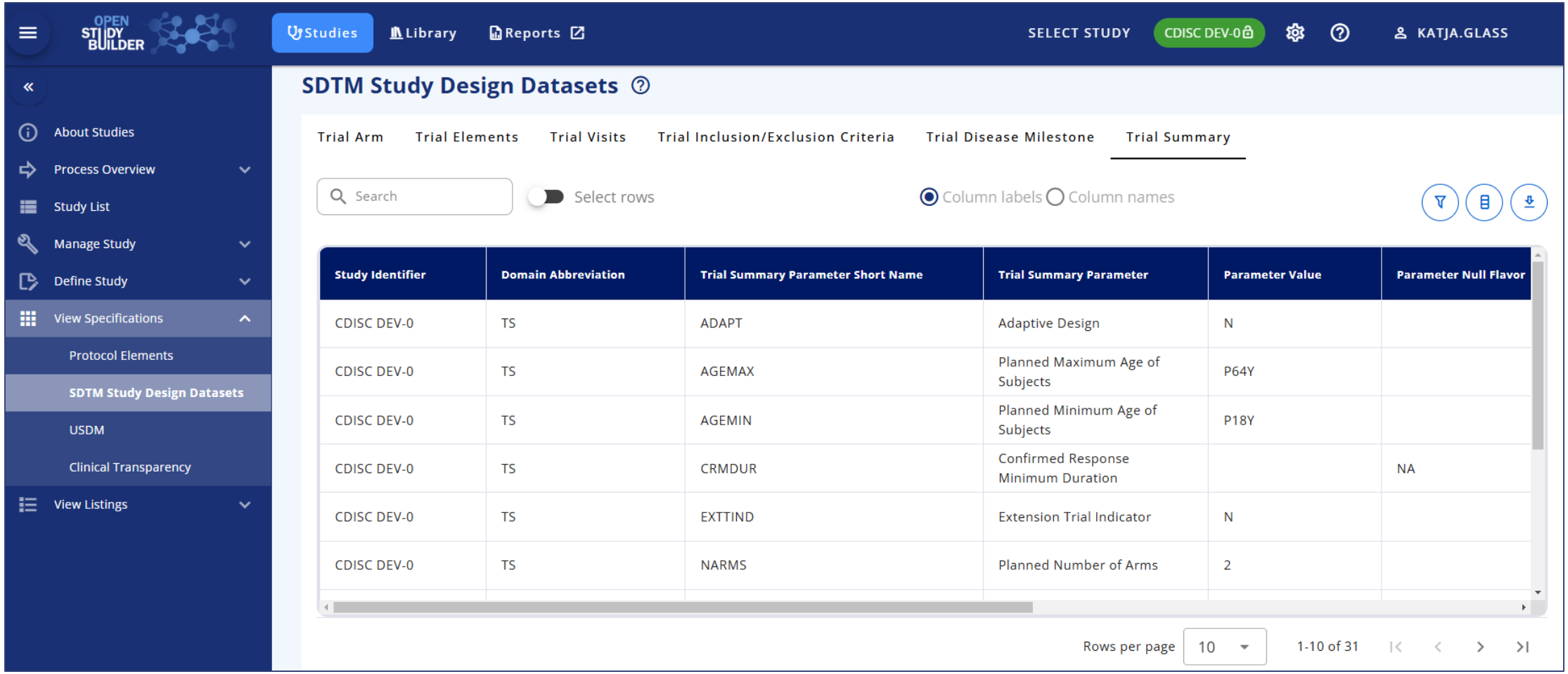


Procedure	Screening	Treatment									Follow-up
Visit short name	**V1 [a]**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**
Study week	**-2**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**9**	**27**	**31**
Visit window (days)	**-13/+0**	**0**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**±1**	**+0/+35**
Randomisation											
Randomisation		X									
End of Study											
End of Study											X
Body Measurements											
Body Measurements	X	X	X								
Weight	X	X		X	X	X	X	X	X	X	X
Eligibility Criteria											
Eligibility Criteria											
Eligibility Criteria Met	X										
Laboratory Assessments											

OpenStudyBuilder Studienbereich



OpenStudyBuilder Studienbereich



OpenStudyBuilder Studienbereich

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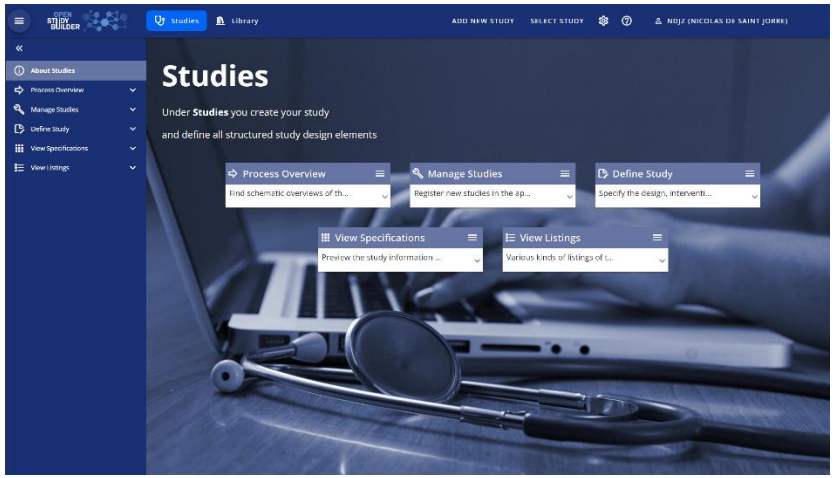
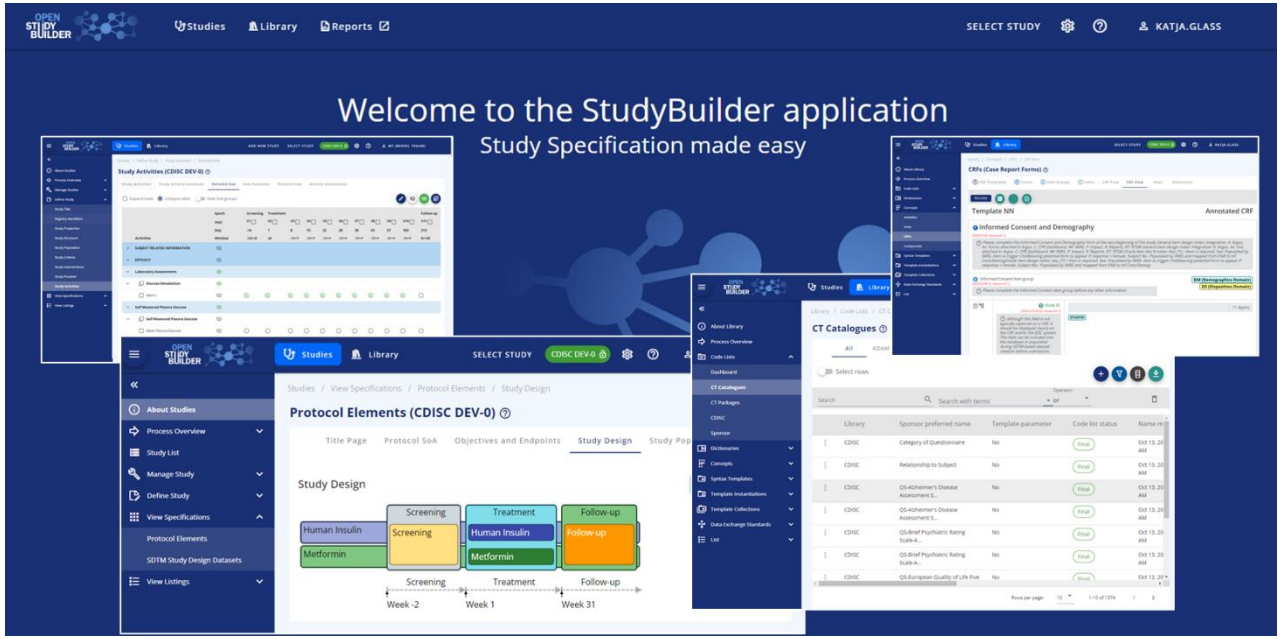


Studienmetadaten Management
verlinkt mit Standards
für diverse Nutzungen

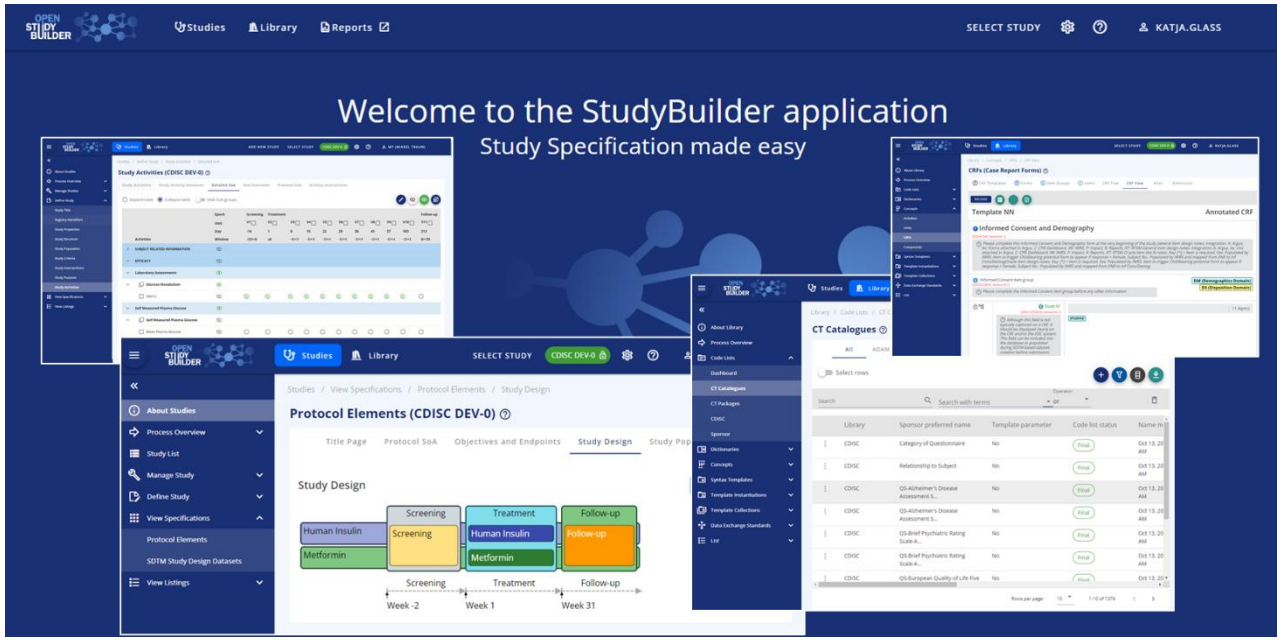
OpenStudyBuilder

Umfangreiches Tool
Verlinkte Datenbank
Großes Potential



*YouTube Demonstration verfügbar

OpenStudyBuilder



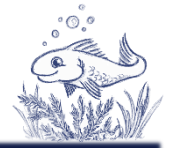
Open Source

novo nordisk®

Agenda

- Einleitung
- OpenStudyBuilder
- **Kooperation**
- Aussicht

Open Source

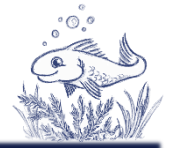


Standards alleine reichen nicht aus

Problematiken sind zu komplex

Isolierte Problemlösungen unzureichend

Open Source - Hoffnungen

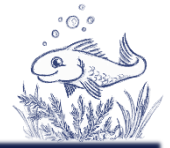


Netzwerkeffekte und Ideenreichtum

Nutzerfeedback

Harmonisierung

Open Source - Hoffnungen



 Netzwerkeffekte und Ideenreichtum

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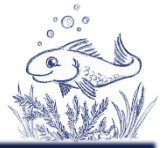
 **Innovation und Entwicklung**

Open Source - Hoffnungen



Netzwerkeffekte und Ideenreichtum

Nutzerfeedback

Harmonisierung

Innovation und Entwicklung

Reduzierte Entwicklungskosten

Bedarfsdeckung im Wettbewerb

Nachhaltig & Risikostreuung

OpenStudyBuilder Potential

Kollaborativ

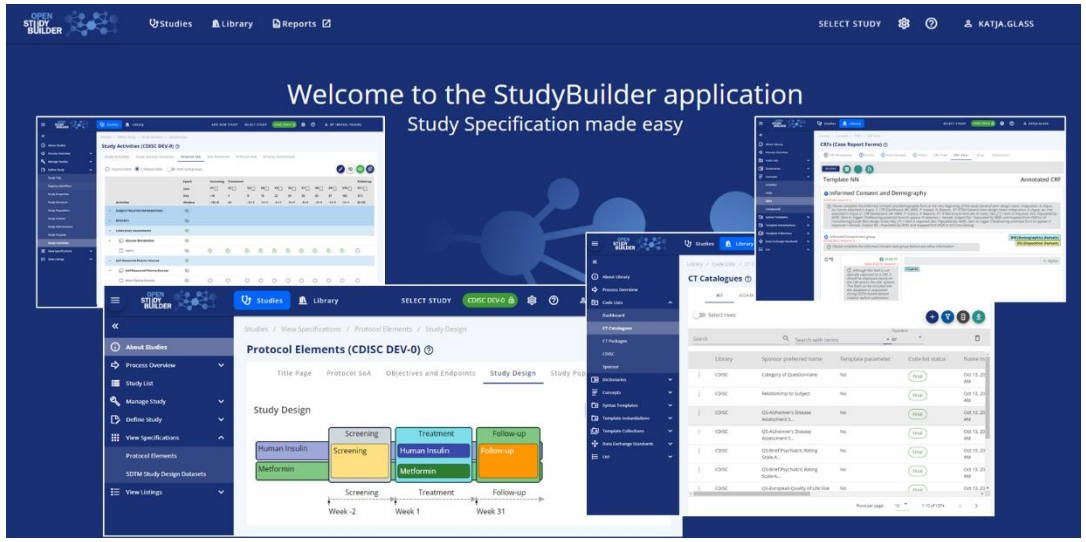
Einzellösung

Einzellösung

Einzellösung

Plugins
Extensions
Programme

OpenStudyBuilder Potential

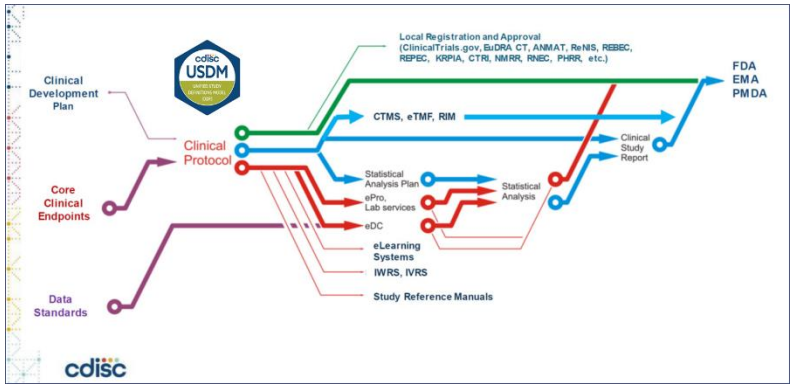


Welche Vorteile bietet der OpenStudyBuilder?

OpenStudyBuilder Potential

- Verwalten von Standards
- Verwalten von Studienmetadaten
- Automatisierter Zugriff für Prozesse
- Austausch zwischen Pharma und CRO
  - Standard Formate (ODM.xml, define.xml, USDM, …)
- Austausch zwischen Tools
  - EDC Systeme, Laborspezifikationen, …
- Ergänzungen

Daten statt Dokumente



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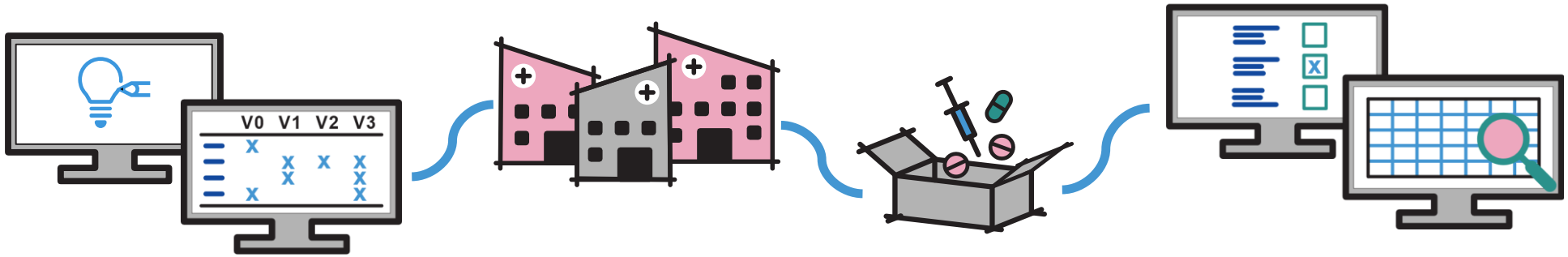
- **Aussicht**

Ziel in Sicht

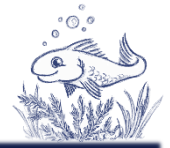


Ein effizienter und skalierbarer Studienprozess, verbunden durch einen digitalen Datenfluss und vereinfacht durch ein einheitliches Datenmodell.

Aussicht

- Potential für Vereinheitlichung von **Prozessen** / Tools
- Gemeinsame **Basis** zwischen Pharma, CROs und andere
- **End-2-End** gemeinsam vorantreiben
- **Kooperation** für weitere Anwendungsfälle

Aussicht



- Mentalitätswandel
- Eigeninitiative und Einbringung in Open Source Projekte
- Anforderungen steigen weiter
- Zusammen sind wir stark!

Aussicht

- CDISC Open Source Alliance
- TransCelerate DDF
- Pharmaverse
- PHUSE

Jede Stimme zählt!

- Zusammenschlüsse helfen allen

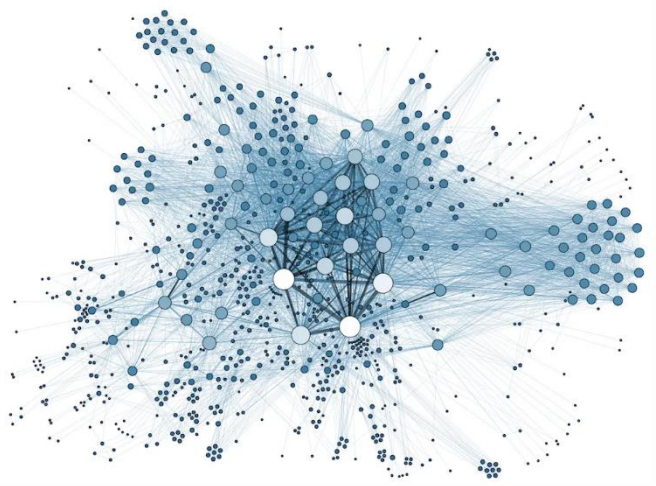
Aussicht

- OpenStudyBuilder Hub
  - Community
  - Use Cases
  - Focus Projekte

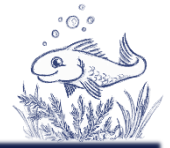
Nur wer sich einbringt wird gehört.

Start heute

- Testen
- Feedback geben
- Erstellen und Diskutieren von Lösungen
- Stay **FAIR**
  - Findable
  - Accessable
  - Interoperable
  - Reproducable



Ausblick

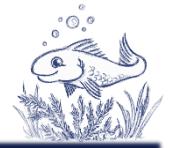


Open Source ist FAIR

Danke

Novo Nordisk &
OpenStudyBuilder Team

Links



- Project Homepage: https://openstudybuilder.com/
- Newsletter: https://www.linkedin.com/newsletters/openstudybuilder-6990328054849916928/
- YouTube Demonstration (30'): https://youtu.be/dL5CY0BwfEs
- GitLab (Solution, Description): https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder
- Slack: https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyiIvB1Wsw
- E-Mail: openstudybuilder@gmail.com

Sandbox:

- Mail openstudybuilder@neotechnology.com – Subject "Request Sandbox access"
- Note: when add/modify/delete, you mail might be exposed in the version history

Questions?

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www.glacon.eu

www.glacon.eu/portal