



Katja Glass
Consulting

OpenStudyBuilder

End-2-End

Open Source Lösung
von Novo Nordisk



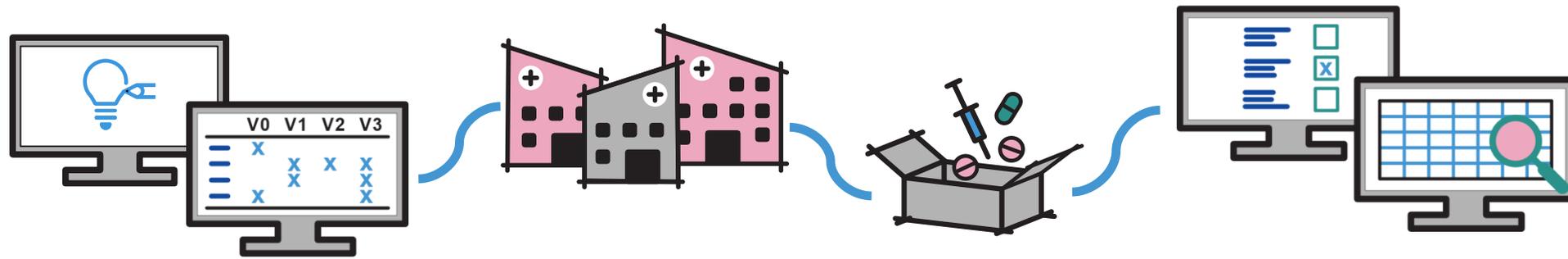
Agenda



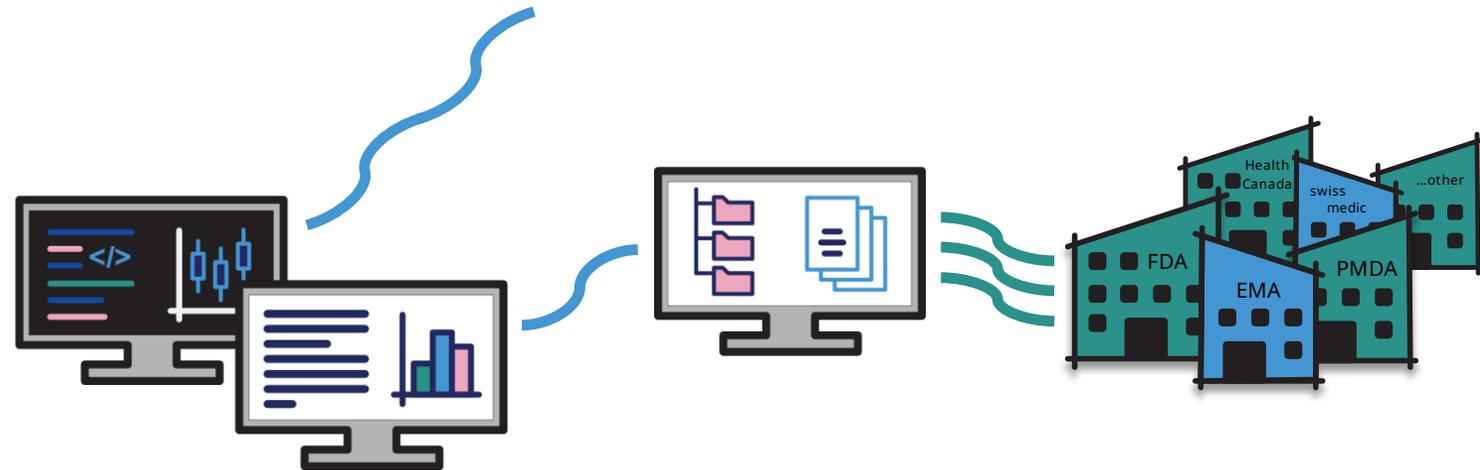
- Einleitung
 - OpenStudyBuilder
 - Kooperation
 - Aussicht
-



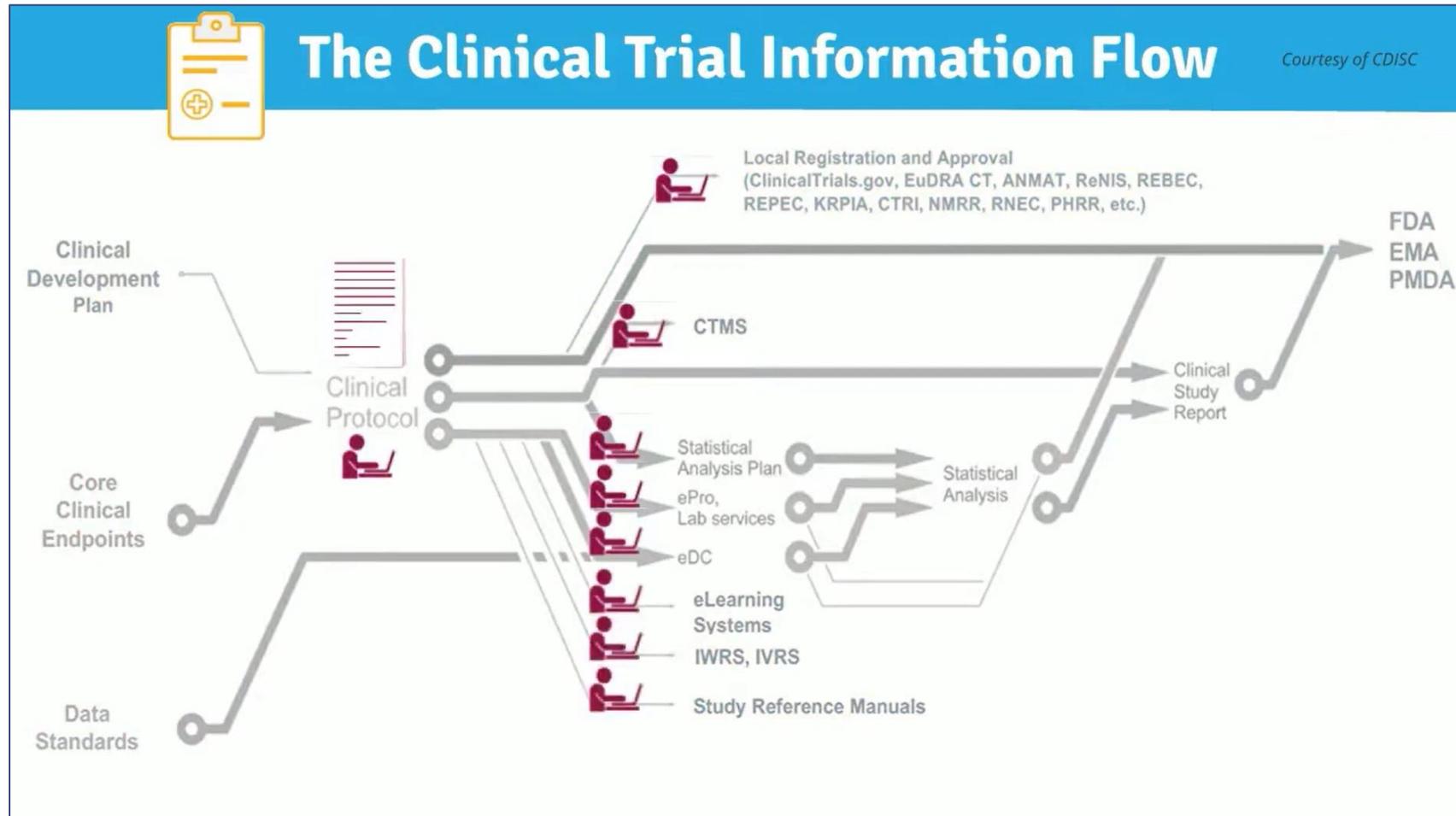
Prozessautomatisierungen



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



Digital Data Flow – Problem 1



Dokumente
statt
Daten

Digital Data Flow – Problem 2



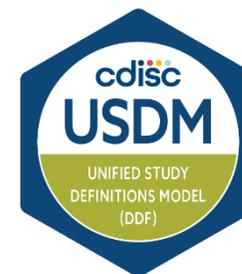
Disconnected
Data

Digital Data Flow – Lösungen



Daten statt Dokumente

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

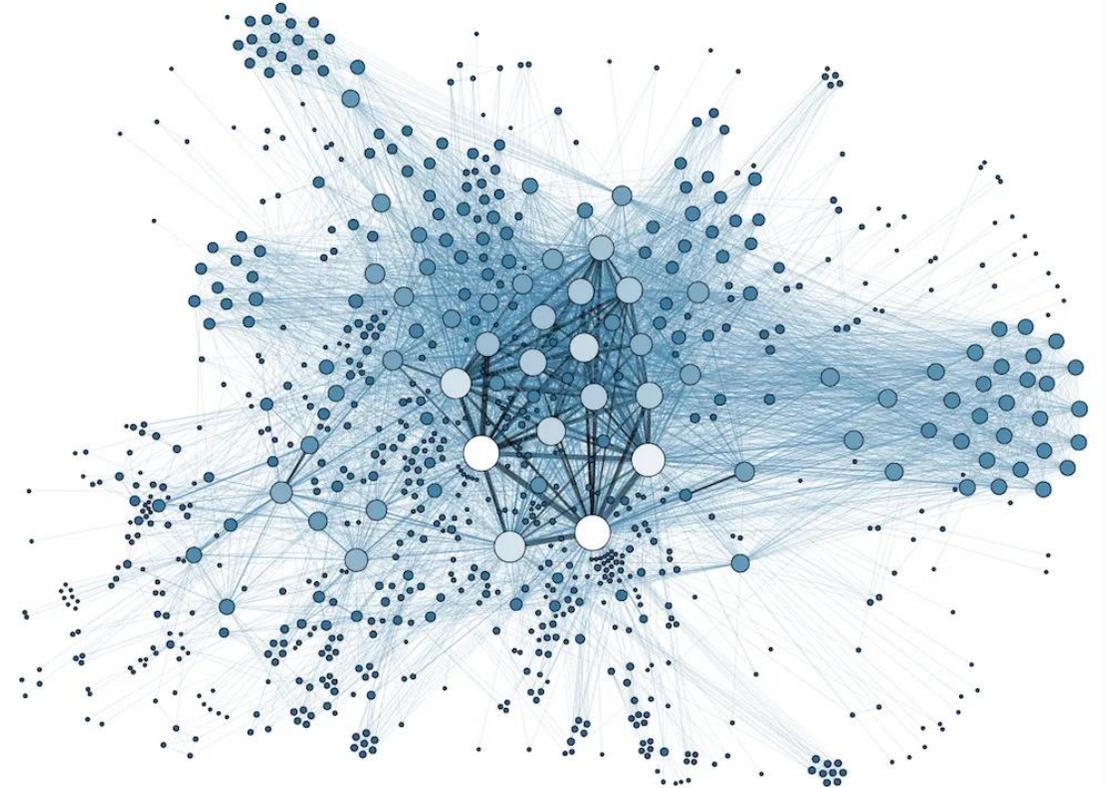


Digital Data Flow – Lösungen



Graphische Datenbank mit semantischen Informationen

- Biomedical Concepts (CDISC)
- Linked Data Model



Agenda



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



Was ist der OpenStudyBuilder?



Repository für Metadaten und Studienmetadaten

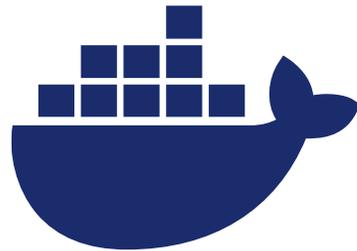


3 Elemente

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



OpenStudyBuilder



Lokale oder
Serverinstallation

Öffentliche
Sandbox

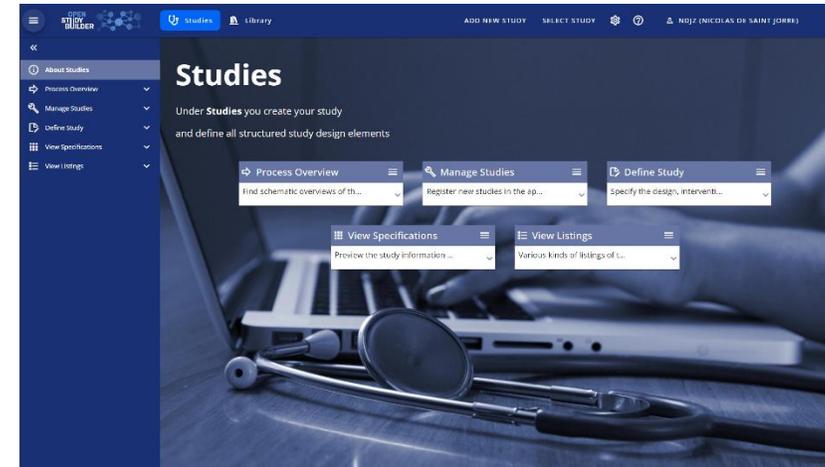


Hosting-
Umgebung

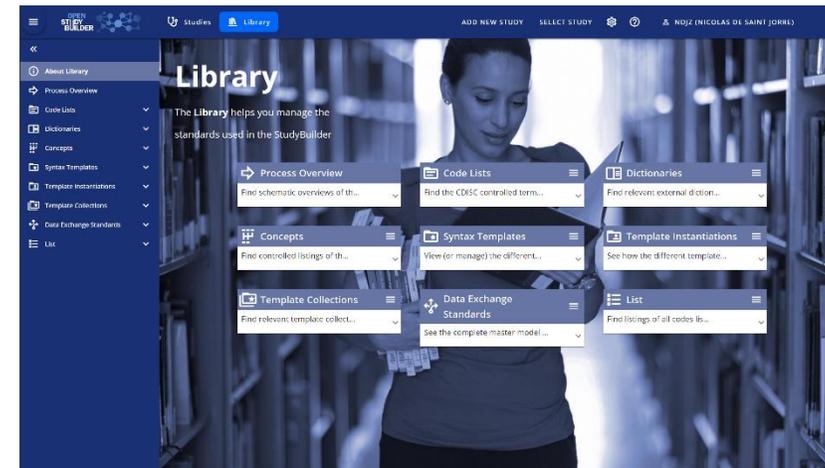
OpenStudyBuilder Komponenten



STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



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



OpenStudyBuilder Library



OPEN STUDY BUILDER

Studies Library Reports

SELECT STUDY CDISC DEV-00 KATJA.GLASS

Library

The **Library** helps you manage the standards used in the StudyBuilder

- Process Overview
Find schematic overviews of th...
- Code Lists
Find the CDISC controlled term...
- Concepts
Find controlled listings of th...
- Syntax Templates
View (or manage) the different...
- Template Collections
Find relevant template collect...
- Data Exchange Standards
See the complete master model ...
- List
Find listings of all codes lis...
- Dictionaries
Find relevant external diction...
- Template Instantiations
See how the different template...
- Admin Definitions
View or create administrative ...

«

- About Library
- Process Overview
- Code Lists
- Dictionaries
- Concepts
- Syntax Templates
- Template Instantiations
- Template Collections
- Data Exchange Standards
- Admin Definitions
- List

OpenStudyBuilder Library



➤ Codelisten

RACE

Library	Sponsor preferred name	Template parameter	Code list status	Name modified	Concept ID	Submission value	Code list name
CDISC	Race As Collected	No	Final	Apr 18, 2024, 9:46 AM	C128689	RACEC	Race As Collected
CDISC	Race	No	Final	Apr 18, 2024, 9:43 AM	C74457	RACE	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

The screenshot displays the OpenStudyBuilder Library interface. The top navigation bar includes 'Studies', 'Library' (selected), and 'Reports'. The user is logged in as 'KATJA.GLASS'. The left sidebar shows a menu with 'Dictionaries' selected, listing various dictionaries including SNOMED, MedDRA, MED-RT, UNII, LOINC, UCUM, Concepts, and Syntax Templates. The main content area shows the 'SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms) for Diseases and Disorders' page. It features a search bar, a 'Select rows' toggle, and a table of SNOMED terms.

	SNOMED ID	Preferred synonym	Preferred synonym (lower case)	Abbreviation	Definition	Status
⋮	64572001	Disease	disease		Disease (disorder)	Final
⋮	362965005	Disorder of body system	disorder of body system		Disorder of body system (disorder)	Final
⋮	609564002	Pre-existing type 1 diabetes mellitus in pregnancy	pre-existing type 1 diabetes mellitus in pregnancy		Pre-existing type 1 diabetes mellitus in pregnancy (disorder...)	Final

OpenStudyBuilder Library



➤ CRF

Library / Concepts / CRFs / CRF View

CRFs (Case Report Forms) ?

CRF Templates Forms Item Groups Items CRF Tree CRF View Alias Extensions

RELOAD

Template Cdisc V1 Annotated CRF

Informed Consent and Demography [Form]

[OID=F.DM, Version=0.1]

? Please complete this Informed Consent and Demography form at the very beginning of the study General item design notes: Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM General item design notes: Integration: A: Argus, Ax: rms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM Oracle item des N notes: Key: [*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/DemogOracle item design notes: Key: [*] = Item is required. Sex: Populated by IWRS. Item to trigger Childbearing potential form to appear if response = Female. Subject No.: Populated by IWRS and mapped from ENR to Inf Cons/Demog

Informed Consent item group [ItemGroup]

[OID=G.DM.IC, Version=0.1]

DM (Demographics Domain)
DS (Disposition Domain)

? Please complete the Informed Consent item group before any other information

OpenStudyBuilder Library



➤ Datenstrukturen / SDTM+

The screenshot displays the OpenStudyBuilder Library interface. The top navigation bar includes 'Studies', 'Library', and 'Reports'. The user is logged in as 'KATJA.GLASS'. The breadcrumb trail is 'Library / Data Exchange Standards / SDTM / SDTM Models'. The main content area is titled 'SDTM/SDTMIG' and shows a vertical list of versions from V1.2 to V2.0. The V2.0 version is selected, showing its status as 'Final' and an effective date of '2021-11-29'. Below this, the 'Classes' section is active, showing 'General Observations' with an ordinal of 1. A detailed description for 'General Observations' is provided. At the bottom, a table lists variables for the 'General Observations' class.

Ordinal	Name	Label	Data Type	Role	Qualifiers variables	Describe value domain	Notes	Usage restrictions	Description	Variable C-Code	Examples
1	STUDYID	Study Identifier	Char	Identifier					A sequence of characters used by the sponsor to uniquely identify the study.		

OpenStudyBuilder Library



- Aktivitäten / Biomedical Concept
- Protokoll Standards

Parent template

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

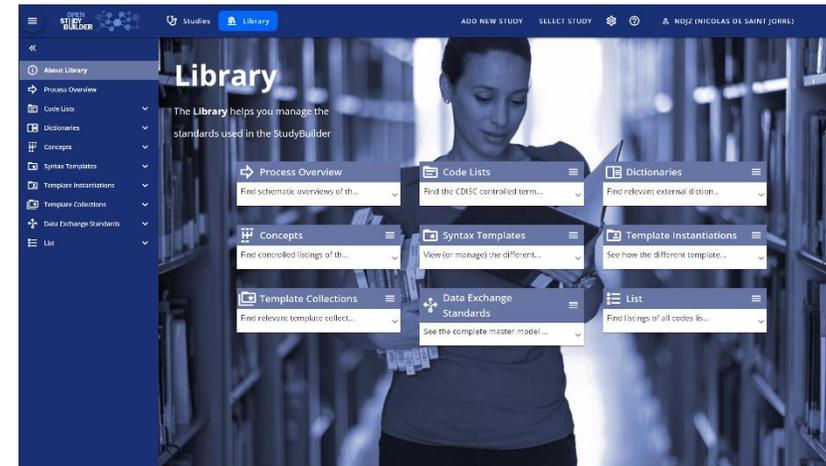
Parent template

Mean change from
baseline in
ActivityInstance

OpenStudyBuilder Library



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



Klassisches Metadaten Repository mit
semantischen Protokoll Standards

OpenStudyBuilder Studienbereich



➤ Managen von Studienmetadaten

The screenshot displays the 'Studies' management interface in OpenStudyBuilder. The top navigation bar includes the 'OPEN STUDY BUILDER' logo, a 'Studies' tab, and links for 'Library' and 'Reports'. The user is logged in as 'KATJA.GLASS' with a 'CDISC DEV-00' environment. The main content area features a large 'Studies' heading and a sub-header: 'Under **Studies** you create your study and define all structured study design elements'. A sidebar on the left lists navigation options: 'About Studies', 'Process Overview', 'Study List', 'Manage Study', 'Define Study', 'View Specifications', and 'View Listings'. The main area contains six interactive cards, each with a title, a brief description, and a dropdown menu:

- Process Overview**: Find schematic overviews of th...
- Study List**: Find, edit and add studies.
- Manage Study**: Register new studies in the ap...
- Define Study**: Specify the design, interventi...
- View Specifications**: Preview the study information ...
- View Listings**: Various kinds of listings of t...

OpenStudyBuilder Studienbereich



Navigation bar: **OPEN STUDY BUILDER** | **Studies** | Library | Reports | SELECT STUDY | **CDISC DEV-0** | Settings | Help | **KATJA.GLASS**

Left sidebar menu:

- «
- About Studies
- Process Overview
- Study List
- Manage Study
- Study**
- Data Standard Versions
- Define Study
- View Specifications
- View Listings

Study (CDISC DEV-0) ?

Study Core Attributes | Study Status | Study Subparts | Protocol Version

Core attribute	Selected values
Clinical programme	CDISC Development programme
Project number	CDISC DEV
Project name	CDISC Dev
Study ID	CDISC DEV-0
Study number	0
Study acronym	CDISC360-2

Items per page: 15 | 1-6 of 6 | < >

OpenStudyBuilder Studienbereich



☰

[Studies](#)
[Library](#)
[Reports](#)

[SELECT STUDY](#)
CDISC DEV-0
⚙️ ?
KATJA.GLASS

⏪

- i About Studies
- ➔ Process Overview
- ☰ Study List
- 🔑 Manage Study
- 📄 Define Study
- ☰ View Specifications
- ☰ Protocol Elements
- ☰ SDTM Study Design Datasets
- ☰ USDM
- ☰ Clinical Transparency
- ☰ View Listings

Protocol Elements (CDISC DEV-0) ⚙️

Title Page
Protocol SoA
Objectives and Endpoints
Study Design
Study Population
Study Interventions
Study Activities

Show epochs
 Show milestones
 ↓

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



The screenshot displays the OpenStudyBuilder interface. The top navigation bar includes 'Studies', 'Library', and 'Reports'. The left sidebar menu lists various study management options, with 'View Specifications' and 'Protocol Elements' highlighted. The main content area shows the 'Protocol Elements (CDISC DEV-0)' page, with the 'Study Design' tab selected. The 'Study Design' section features a timeline diagram with three phases: Screening, Treatment, and Follow-up. The Screening phase starts at Week -2 and ends at Week 1. The Treatment phase starts at Week 1 and ends at Week 31. The Follow-up phase starts at Week 31. The diagram shows two treatment groups: Human Insulin (purple box) and Metformin (green box). The Screening phase is represented by a yellow box, the Treatment phase by a cyan box, and the Follow-up phase by a green box. The timeline is marked with dashed arrows and vertical lines indicating the start and end of each phase.

OpenStudyBuilder Studienbereich



OPEN STUDY BUILDER

Studies Library Reports

SELECT STUDY CDISC DEV-0

KATJA.GLASS

SDTM Study Design Datasets

Trial Arm Trial Elements Trial Visits Trial Inclusion/Exclusion Criteria Trial Disease Milestone Trial Summary

Search Select rows Column labels Column names

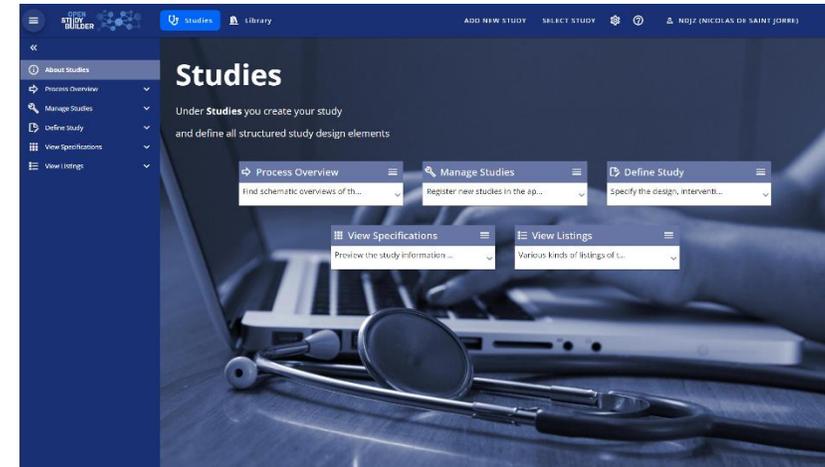
Study Identifier	Domain Abbreviation	Trial Summary Parameter Short Name	Trial Summary Parameter	Parameter Value	Parameter Null Flavor
CDISC DEV-0	TS	ADAPT	Adaptive Design	N	
CDISC DEV-0	TS	AGEMAX	Planned Maximum Age of Subjects	P64Y	
CDISC DEV-0	TS	AGEMIN	Planned Minimum Age of Subjects	P18Y	
CDISC DEV-0	TS	CRMDUR	Confirmed Response Minimum Duration		NA
CDISC DEV-0	TS	EXTTIND	Extension Trial Indicator	N	
CDISC DEV-0	TS	NARMS	Planned Number of Arms	2	

Rows per page 10 1-10 of 31

OpenStudyBuilder Studienbereich



STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTIVITIES



Studienmetadaten Management
verlinkt mit Standards
für diverse Nutzungen

OpenStudyBuilder



Umfangreiches Tool
Verlinkte Datenbank
Großes Potential

Welcome to the StudyBuilder application
Study Specification made easy

The screenshot displays the OpenStudyBuilder application interface. The main navigation bar includes 'Studies', 'Library', and 'Reports'. The central area shows a 'Welcome to the StudyBuilder application' message with the tagline 'Study Specification made easy'. Below this, several panels are visible: 'Study Activities (CDISC DEV-0)', 'Protocol Elements (CDISC DEV-0)', and 'CT Catalogues'. The 'Protocol Elements' panel shows a 'Study Design' diagram with phases: Screening (Week -2), Treatment (Week 1), and Follow-up (Week 31). The 'CT Catalogues' panel shows a table of CDISC CT Packages.

Library	Sponsor preferred name	Template parameter	Code list status	Name (in...)
CDISC	Category of Questionnaire	No	Free	008 13.20 AIF
CDISC	Relationship to Subject	No	Free	018 13.20 AIF
CDISC	OS-Adherence's Overall Assessment S...	No	Free	028 13.20 AIF
CDISC	OS-Adherence's Disease Assessment S...	No	Free	038 13.20 AIF
CDISC	OS-Adherence's Rating Scale-A...	No	Free	048 13.20 AIF
CDISC	OS-Adherence's Rating Scale-B...	No	Free	058 13.20 AIF
CDISC	OS-European Quality of Life Res...	No	Free	068 13.20 AIF

*YouTube [Demonstration](#) verfügbar

OpenStudyBuilder



Welcome to the StudyBuilder application
Study Specification made easy

The screenshot displays the OpenStudyBuilder application interface. At the top, there's a navigation bar with 'SELECT STUDY' and 'KATJA GLASS'. The main content area is divided into several panels:

- Study Activities (CDISC DEV-0):** A table with columns for 'Activity', 'Frequency', and 'Duration'. It lists activities like 'Screening', 'Treatment', and 'Follow-up' with their respective frequencies and durations.
- CT Catalogues:** A search interface for CDISC Catalogues. It includes a search bar and a table with columns: 'Library', 'Sponsor preferred name', 'Template parameter', 'Code list status', and 'Name in CDISC'. The table lists various CDISC categories like 'Category of Questionnaire', 'Relationship to Subject', 'OS-Alzheimer's Disease Assessment', etc.
- Study Design:** A visual timeline diagram showing the study phases: 'Screening' (Week -2), 'Treatment' (Week 1), and 'Follow-up' (Week 31). Each phase has associated activities: 'Human Insulin' and 'Metformin' for Screening; 'Human Insulin' and 'Metformin' for Treatment; and 'Follow-up' for Follow-up.

Open Source



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



Nutzerfeedback



Harmonisierung



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



Welcome to the StudyBuilder application
Study Specification made easy

Protocol Elements (CDISC DEV-0) ©

Study Design

Human Insulin, Screening, Treatment, Follow-up

Merformin

Week -2, Week 1, Week 31

Library	Sponsor preferred name	Template parameter	Code list status	Number of
CDISC	Category of Questionnaire	No	Yes	001 10, 20, 400 1
CDISC	Relationship to Subject	No	Yes	001 10, 20, 400 1
CDISC	Administration Device	No	Yes	001 10, 20, 400 1
CDISC	Administration Device Attachment 1	No	Yes	001 10, 20, 400 1
CDISC	Global Physicists Rating	No	Yes	001 10, 20, 400 1
CDISC	Global Physicists Rating Question	No	Yes	001 10, 20, 400 1
CDISC	Enduserment Quality of Life Scale	No	Yes	001 10, 20, 400 1

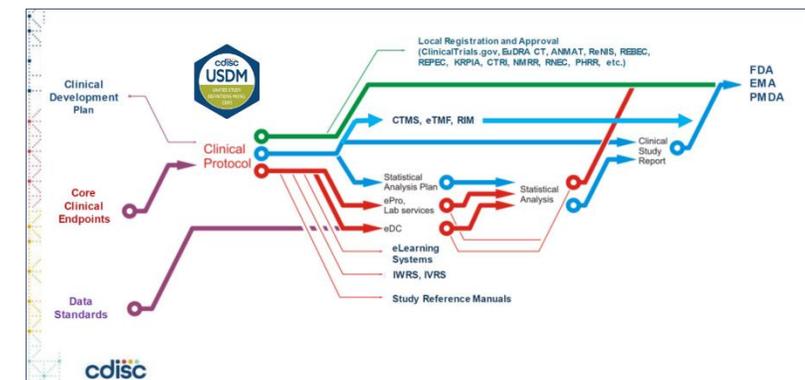
Welche Vorteile bietet der OpenStudyBuilder?

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



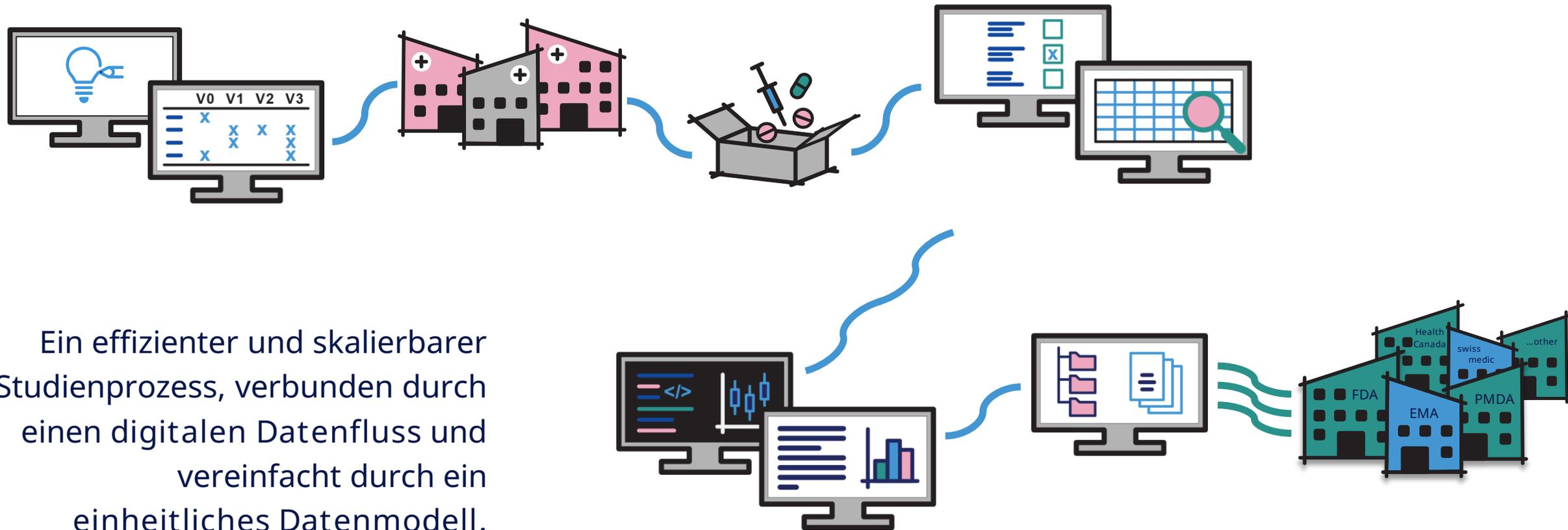
Agenda



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



Ziel in Sicht



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!

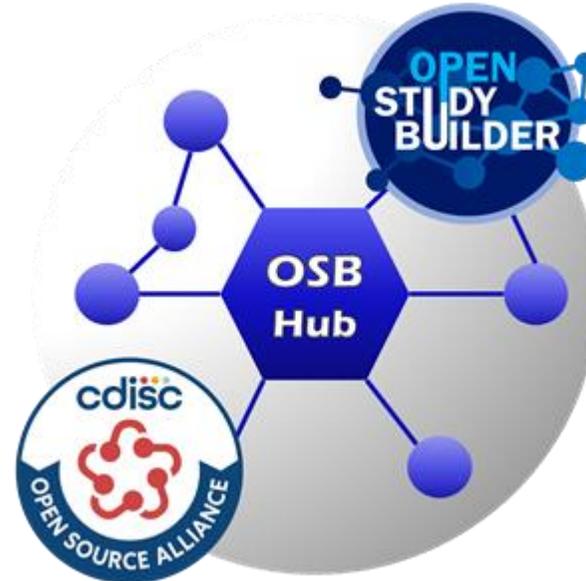


- Zusammenschlüsse helfen allen

Aussicht



- OpenStudyBuilder Hub
 - Community
 - Use Cases
 - Focus Projekte

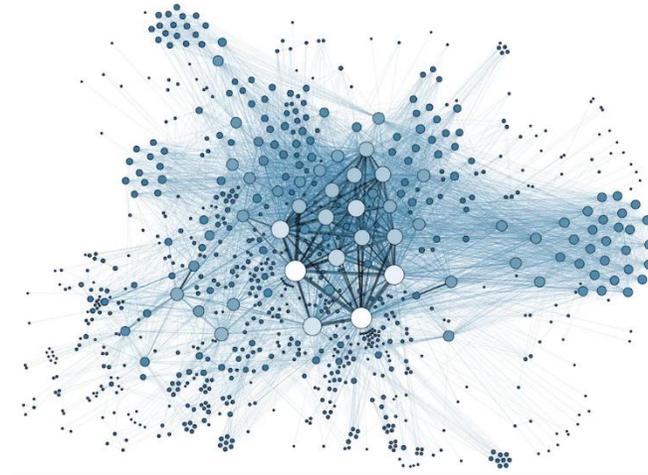


Nur wer sich einbringt wird gehört.

Start heute



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





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-Jvrhtmy7hGstgyilvB1Wsw
- 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?



Katja Glass Consulting

info@glacon.eu

www.glacon.eu

www.glacon.eu/portal
