



Katja Glass
Consulting



OpenStudyBuilder

End-2-End
Open Source Lösung
von Novo Nordisk

Agenda



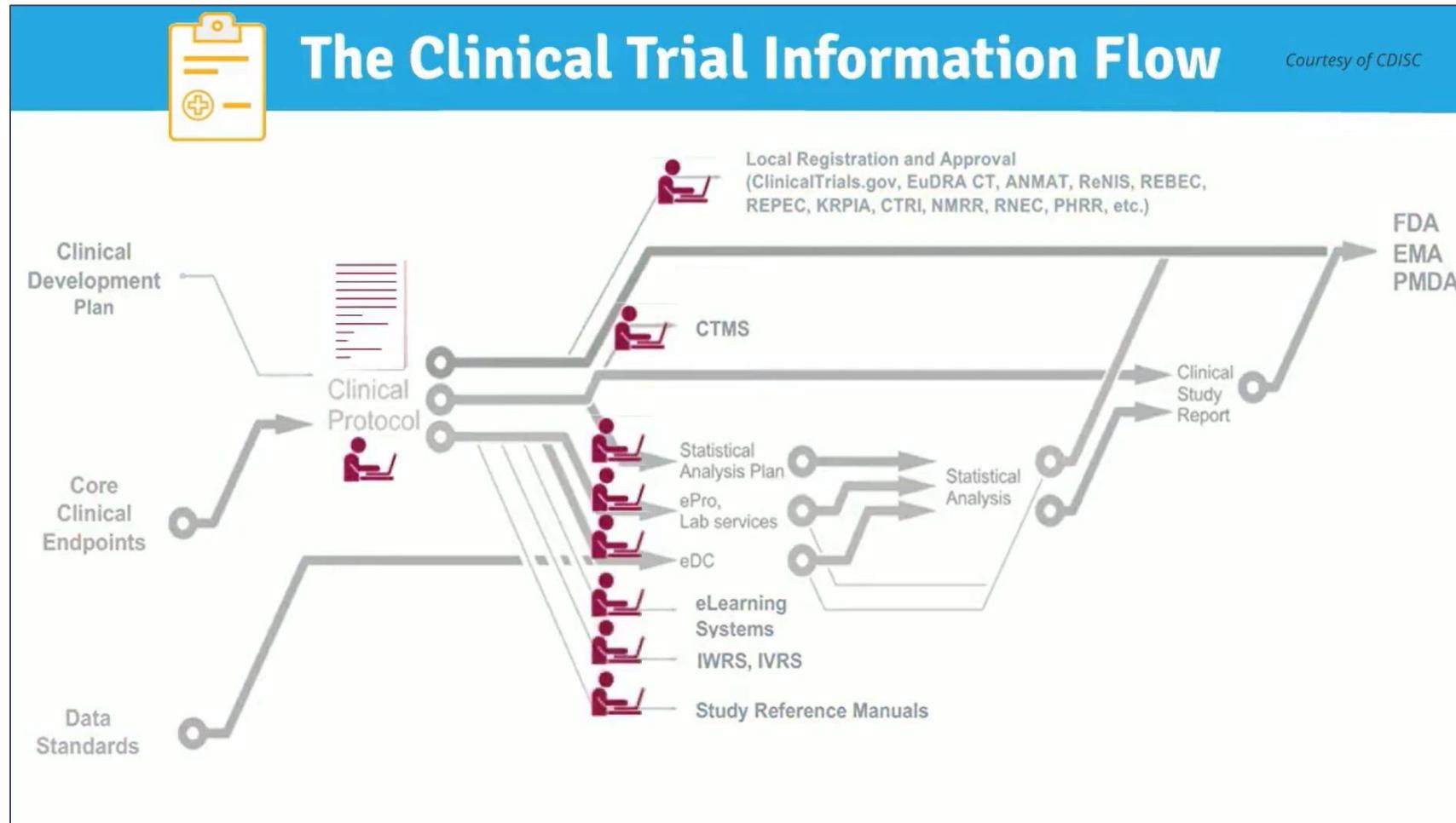
- Einleitung
- OpenStudyBuilder
- Kooperation
- Aussicht



Prozessautomatisierungen

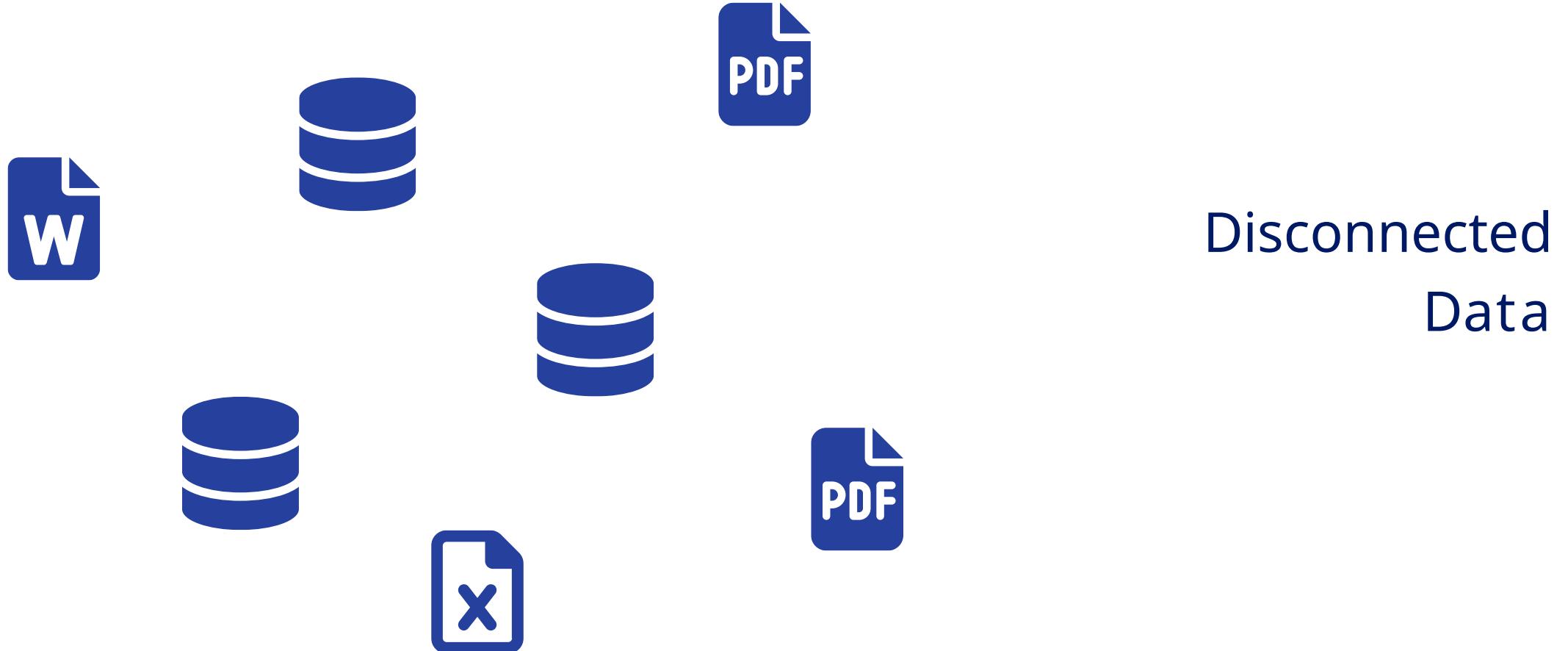


Digital Data Flow – Problem 1



Dokumente
statt
Daten

Digital Data Flow – Problem 2



Digital Data Flow – Lösungen



Daten statt
Dokumente



- Elektronisches Protokoll
(ICH M11)

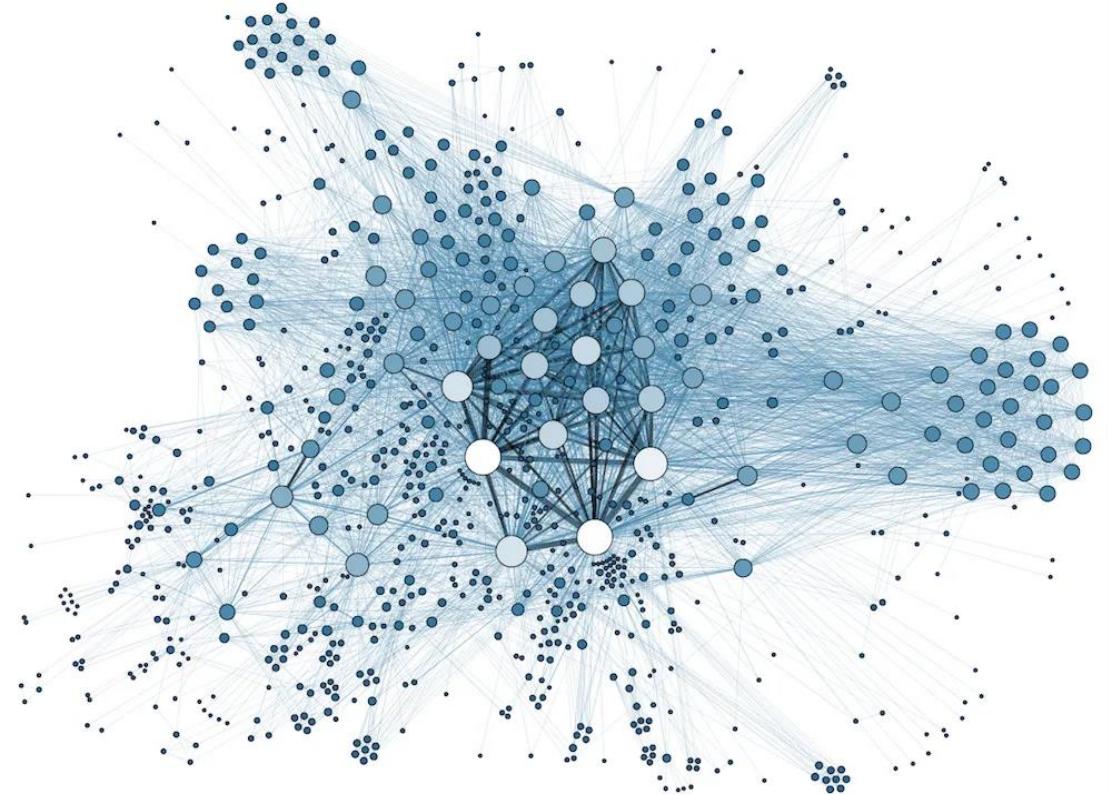
- Datenaustauschstandards
(USDM)





Graphische Datenbank mit semantischen Informationen

- Biomedical Concepts (CDISC)
- Linked Data Model



Agenda



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



Was ist der OpenStudyBuilder?

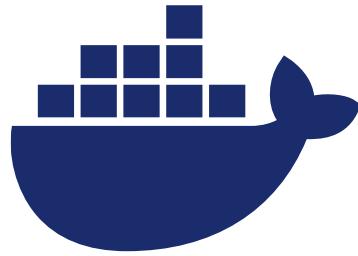


**Repository für
Metadaten und
Studienmetadaten**

3 Elemente

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





Lokale oder
Serverinstallation

Öffentliche
Sandbox



Hosting-
Umgebung

OpenStudyBuilder Komponenten



STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES

A screenshot of the OpenStudyBuilder Studies interface. The top navigation bar includes 'OPEN STUDY BUILDER', 'Studies', 'Library', 'ADD NEW STUDY', 'SELECT STUDY', and user information. A sidebar on the left lists 'About Studies' and other study-related options. The main content area is titled 'Studies' and contains sections for 'Process Overview', 'Manage Studies', 'Define Study', 'View Specifications', and 'View Listings'. A stethoscope and a laptop are visible in the background.

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

A screenshot of the OpenStudyBuilder Library interface. The top navigation bar is identical to the Studies interface. The sidebar lists 'About Library' and various library components: 'Code Lists', 'Dictionaries', 'Concepts', 'Syntax Templates', 'Template Instantiations', 'Template Collections', and 'Data Exchange Standards'. The main content area is titled 'Library' and provides an overview of each component. A person in a library setting is shown in the background.

OpenStudyBuilder Library



OpenStudyBuilder Library



➤ Codelisten

RACE

CDISC-Term:
BLACK OR AFRICAN
AMERICAN

CDISC-Code:
C16352

NCI-Term:
Black or African American

Sponsor-Term:
African American

Sentence-Case:
african american

Order:

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

OpenStudyBuilder Library



➤ Dictionaries

The screenshot shows the OpenStudyBuilder Library interface. The top navigation bar includes 'Studies' (disabled), 'Library' (selected), 'Reports' (disabled), 'SELECT STUDY' (CDISC DEV-0), and user information ('KATJA.GLASS'). The left sidebar has sections for 'About Library', 'Process Overview', 'Code Lists', 'Dictionaries' (selected), 'SNOMED', 'MedDRA', 'MED-RT', 'UNII', 'LOINC', 'UCUM', 'Concepts', and 'Syntax Templates'. The main content area displays the 'SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms) for Diseases and Disorders'. It features a search bar, a 'Select rows' toggle, and four circular icons (+, 🔍, 📄, ⏪). A table lists three SNOMED entries:

	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) ?

① CRF Templates ② Forms ③ Item Groups ④ Items ⑤ CRF Tree ⑥ CRF View Alias Extensions

RELOAD XML PDF DOC

Template Cdisc V1

Informed Consent and Demography [Form]

[OID=F.DM, Version=0.1]

⑦ 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]

⑦ Please complete the Informed Consent item group before any other information

DM (Demographics Domain) DS (Disposition Domain)

OpenStudyBuilder Library



➤ Datenstrukturen / SDTM+

The screenshot shows the OpenStudyBuilder Library interface. The left sidebar has sections like About Library, Process Overview, Code Lists, Dictionaries, Concepts, Syntax Templates, Template Instantiations, Template Collections, Data Exchange Standards (CDASH, SDTM, ADaM), Admin Definitions, and List. The main area shows the SDTM/SDTMIG section with tabs for SDTM Models, SDTM Implementation Guide, SDTMIG AP, SDTMIG MD, SENDIG, SENDIG AR, SENDIG DART, and SENDIG GENETOX. The SDTM Models tab lists versions V2.0, V1.8, V1.7, V1.6, V1.5, V1.4, V1.3, and V1.2. A modal window for V2.0 displays Status (Final), Effective date (2021-11-29), and Implemented By (SDTMIG v3.4). Below this, the General Observations class is detailed: Name (General Observations), Ordinal (1), Description (The majority of observations collected during a study can be divided among three general classes: Interventions, Events, or Findings. Datasets based on any of the general observation classes share a set of common Identifier and Timing variables. As a general rule, any valid Identifier or Timing variable is permissible for use in any submission dataset based on a general observation class. (Source: SDTM v2.0, Section 3.1)). At the bottom, a table shows columns for Ordinal, Name, Label, Data Type, Role, Qualifiers variables, Describe value domain, Notes, Usage restrictions, Description, Variable C-Code, and Examples.

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

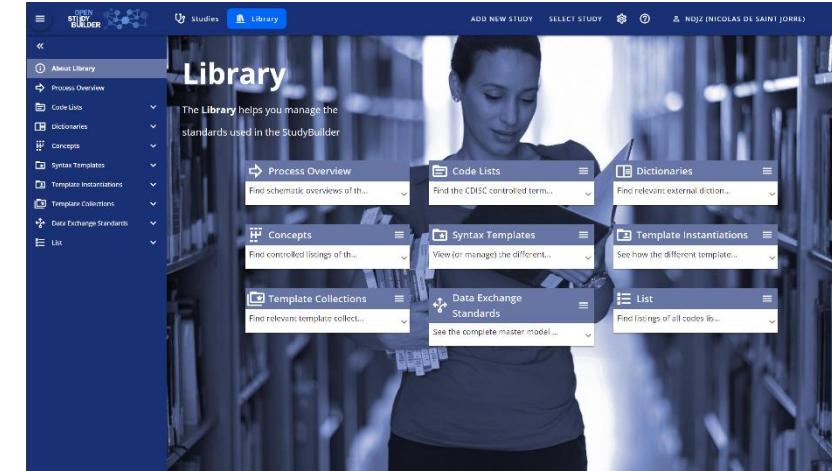
Mean change from
baseline in
ActivityInstance

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 shows the 'Studies' section of the OpenStudyBuilder web application. The top navigation bar includes links for 'Studies', 'Library', 'Reports', 'SELECT STUDY' (set to 'CDISC DEV-0'), and user profile 'KATJA.GLASS'. A sidebar on the left lists 'About Studies' (selected), 'Process Overview', 'Study List', 'Manage Study', 'Define Study', 'View Specifications', and 'View Listings'. The main content area features a large 'Studies' heading and a descriptive text: 'Under **Studies** you create your study and define all structured study design elements'. Below this are six cards with links: '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 ...), and 'View Listings' (Various kinds of listings of t...).

OpenStudyBuilder Studienbereich



OPEN STUDY BUILDER

Studies Library Reports

SELECT STUDY CDISC DEV-0 KATJA.GLASS

« 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

[Edit](#) [Delete](#)

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



OpenStudyBuilder Studienbereich



OPEN STUDY BUILDER

Studies Library Reports

About Studies Process Overview Study List Manage Study Define Study View Specifications Protocol Elements SDTM Study Design Datasets USDM Clinical Transparency View Listings

Studies / View Specifications / Protocol Elements / Study Design

Protocol Elements (CDISC DEV-0) ?

Title Page Protocol SoA Objectives and Endpoints Study Design Study Population

Study Design

The diagram illustrates the study design timeline across three phases: Screening, Treatment, and Follow-up. The timeline is marked at Week -2, Week 1, and Week 31. In the Screening phase (Week -2 to Week 1), there are two parallel tracks: one for Human Insulin (blue box) and one for Metformin (green box). Both tracks include a yellow 'Screening' box. In the Treatment phase (Week 1 to Week 31), both Human Insulin and Metformin continue, each with a blue 'Treatment' box. In the Follow-up phase (Week 31 to end), both treatments are followed by an orange 'Follow-up' box.

Screening

Treatment

Follow-up

Human Insulin

Metformin

Screening

Human Insulin

Metformin

Follow-up

Screening

Treatment

Follow-up

Week -2

Week 1

Week 31

OpenStudyBuilder Studienbereich



OPEN STUDY BUILDER

Studies Library Reports

SELECT STUDY CDISC DEV-0 🔒 ⚙️ 🌐 KATJA.GLASS

« About Studies Process Overview Study List Manage Study Define Study View Specifications Protocol Elements SDTM Study Design Datasets USDM Clinical Transparency View Listings

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	

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OpenStudyBuilder Studienbereich



STUDIES	
TITLE	CRITERIA
REGISTRY IDENTIFIERS	INTERVENTIONS
STRUCTURE	PURPOSE
POPULATION	ACTVITIES

Studienmetadaten Management
verlinkt mit Standards
für diverse Nutzungen

OpenStudyBuilder



Umfangreiches Tool
Verlinkte Datenbank
Großes Potential

The screenshot displays the OpenStudyBuilder application interface, which is designed for study specification. It features a dark blue header with the logo and navigation links for 'Studies', 'Library', and 'Reports'. The main content area has a central banner with the text 'Welcome to the StudyBuilder application' and 'Study Specification made easy'. Below the banner, there are several panels: one showing 'Study Activities (CDISC DEV-0)', another showing 'Protocol Elements (CDISC DEV-0)' with a timeline diagram for 'Study Design' (Screening, Treatment, Follow-up) across 'Week -2', 'Week 1', and 'Week 31', and a third panel showing 'CT Catalogues' with a list of items like 'CRFs (Case Report Forms)', 'Template NN', and 'Annotated CRF'. On the left, a sidebar provides navigation through 'About Studies', 'Process Overview', 'Study List', 'Manage Study', 'Define Study', 'View Specifications', 'Protocol Elements', 'SDTM Study Design Datasets', and 'View Listings'. A bottom navigation bar includes 'SELECT STUDY', a gear icon, a question mark icon, and a user profile for 'KATJA.GLASS'.

*YouTube [Demonstration](#) verfügbar

OpenStudyBuilder



Welcome to the StudyBuilder application
Study Specification made easy

Protocol Elements (CDISC DEV-0)

Study Design

Screening Treatment Follow-up

Week -2 Week 1 Week 31

SELECT STUDY CDISC DEV-0

KATJA.GLASS

Open Source



Agenda



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





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

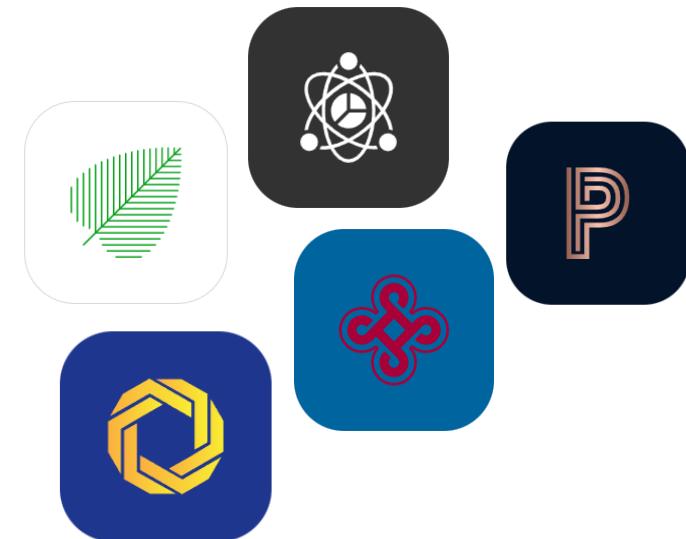


Einzellösung



Einzellösung

Plugins
Extensions
Programme



OpenStudyBuilder Potential



The screenshot displays the OpenStudyBuilder application's user interface. At the top, there are tabs for 'Studies' and 'Reports'. On the left, a sidebar lists 'Alert Studies', 'Process Overview', 'Study List', 'Manage Study', 'Define Study', 'View Specifications', 'Protocol Elements', 'Study Design Datasets', and 'View Listings'. The main area shows three windows: 1) 'Study Activities (CDISC DEV-0)' showing a grid of activities; 2) 'Protocol Elements (CDISC DEV-0)' showing a study design timeline with 'Screening', 'Treatment', and 'Follow-up' phases; 3) 'CT Catalogues' showing a library of items like 'CDISC', 'Category of Outcomes', 'Relationship to Subject', and various QoL assessments. The overall theme is dark blue with light blue highlights.

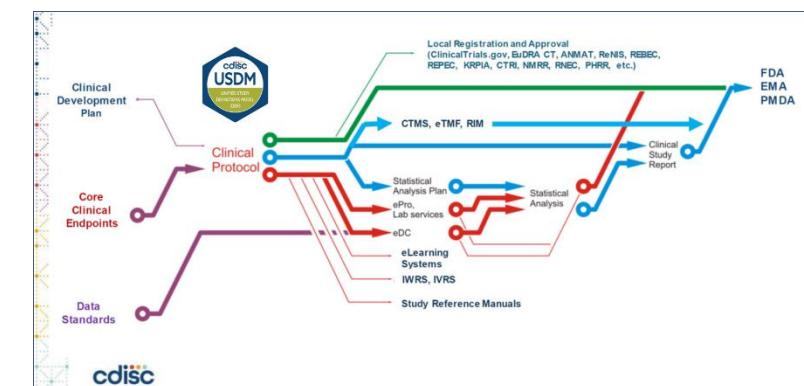
Welche Vorteile bietet der
OpenStudyBuilder?

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



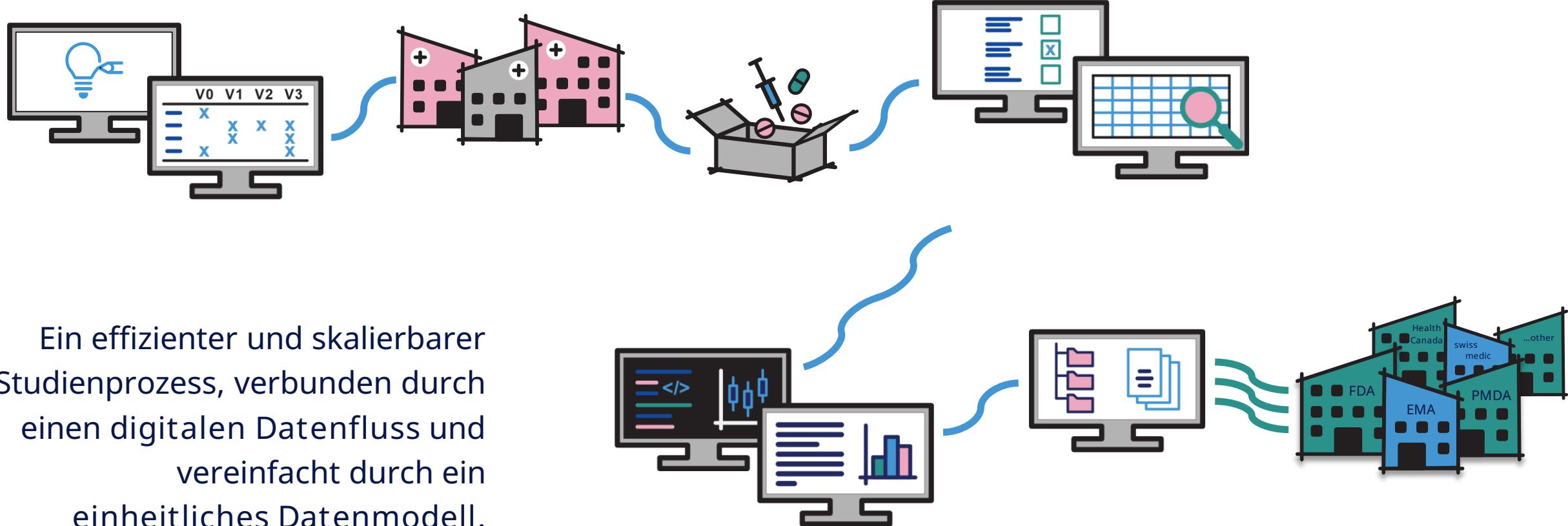
Agenda



- 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

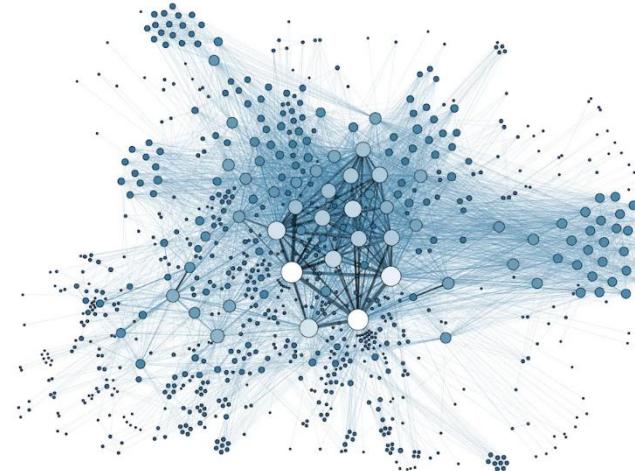


Nur wer sich einbringt wird gehört.

Start heute



- Testen
- Feedback geben
- Erstellen und Diskutieren von Lösungen
- Stay **FAIR**
 - Findable
 - Accessable
 - Interoperable
 - 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/dL5CYoBwfEs>
- GitLab (Solution, Description): <https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder>
- Slack: https://join.slack.com/t/openstudybuilder/shared_invite/zt-1gmtauzic-Jvrhtmy7hGstgyilvB1Wsw
- E-Mail: openstudybuilder@gmail.com

Sandbox:

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

Questions?



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