



2024 CDISC + TMF
US INTERCHANGE

PHOENIX/SCOTTSDALE

23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS

Schedule of Activities in OpenStudyBuilder

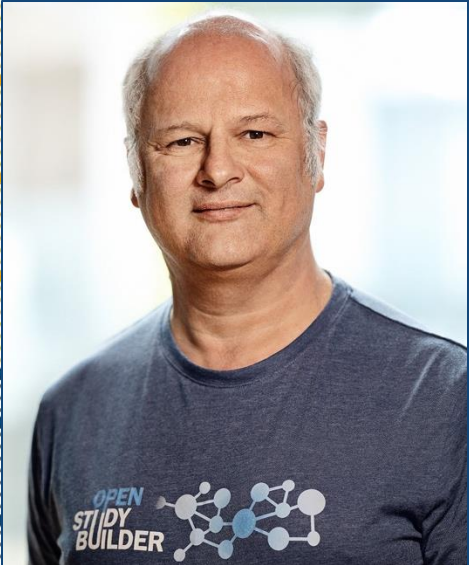
Mikkel Traun, Solution Architect, Novo Nordisk A/S

Meet the Speakers

Mikkel Traun

Title: Solution Architect

Organization: Novo Nordisk A/S



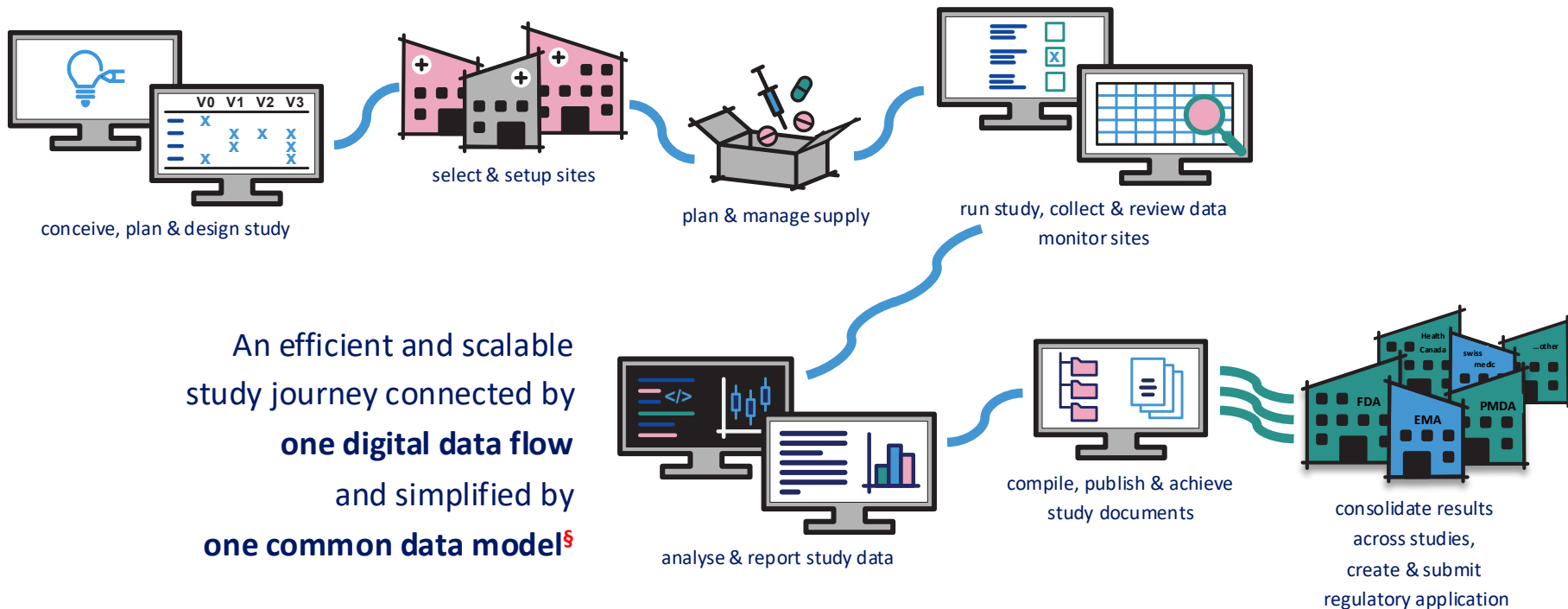
Mikkel is solution architect for the next generation study builder and data standards repository solution at Novo Nordisk. Mikkel is also an active member of the TransCelerate and CDISC Digital Dataflow project, and previously the CDISC 360 project. He has worked as a principal system developer supporting the clinical data warehouse solution and the CDISC implementation at Novo Nordisk. Previously he has worked on several projects in pre-clinical, clinical and outcome research.



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

ONE study journey



An efficient and scalable study journey connected by **one digital data flow** and simplified by **one common data model**[§]

[§] Modular and extensible interconnected domain-centric models with semantic metadata (incl taxonomies) and relations

ONE Common Data Model

A schematic definition of **modular** and **extensible business entities** with **semantic metadata** that simplify integrations and application development

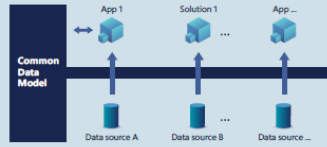
Biomedical Concepts is the foundation for this model

The common semantic data model does not contain the actual data but shows how the data should be structured, the terminology to use, and how things can be linked (combined)

An open-sourced definition of modular and extensible **business entities** with **semantic metadata** that **simplify the challenges of application development and data integration.**



The Common Data Model unifies data in a well-known schema with semantic consistency.

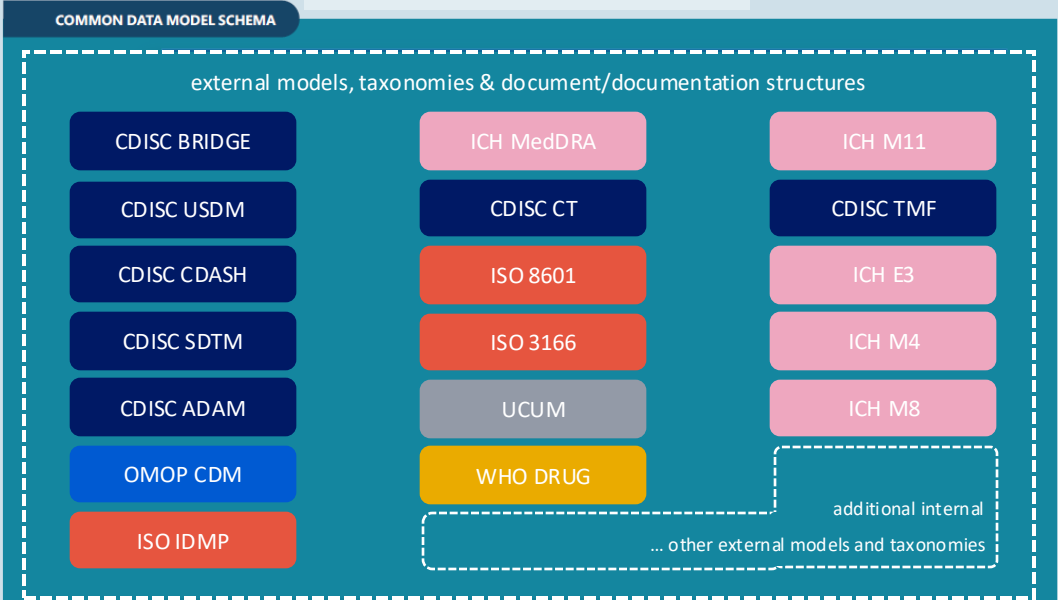


App developers and backend integrators can develop **independently.**



Enables quick application deployment and development, out-of-the-box intelligence, and much more.

Apps, reports, augmentation of AI (incl. ML) ..



What is the OpenStudyBuilder?...

A NEW APPROACH TO STUDY SPECIFICATION

- Compliance with external and internal standards
- Facilitates automation and content reuse
- Ensures a higher degree of end-to-end consistency

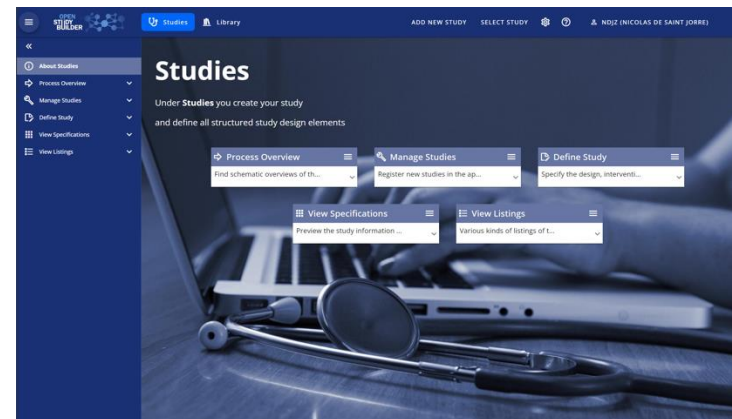
3 ELEMENTS OF OpenStudyBuilder

- **Clinical Metadata Repository (clinical MDR)**
(central repository for all study specification data)
- **OpenStudyBuilder application / Web UI**
- **API layer**
(allowing interoperability with other applications)
(DDF API Adaptor – enabling DDF SDR Compatibility)

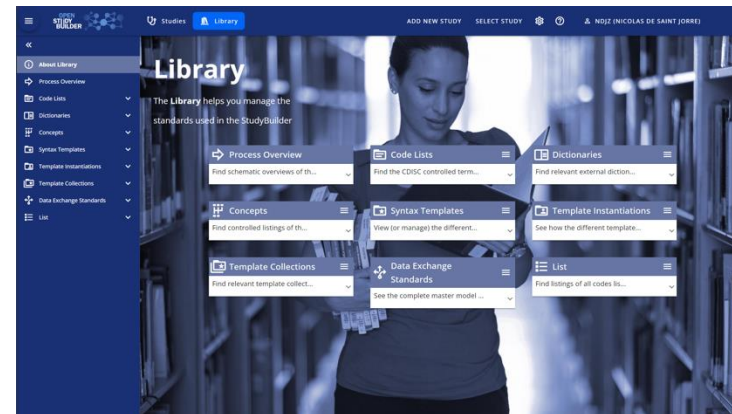


7 OpenStudyBuilder Components

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	



What is the key elements of OpenStudyBuilder

- Library holding BCs
 - Named as Activity Concepts in OSB
- Study Module supporting Study Design and SoA
- SoA is key component
 - Linking to BCs
 - Supporting the Digital Data Flow (DDF) vision
- In OSB we seek to achieve this by defining the SoA at different levels for dedicated parts of the Digital Data Flow

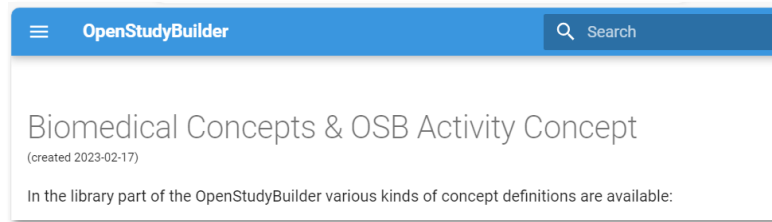


Clinical MDR

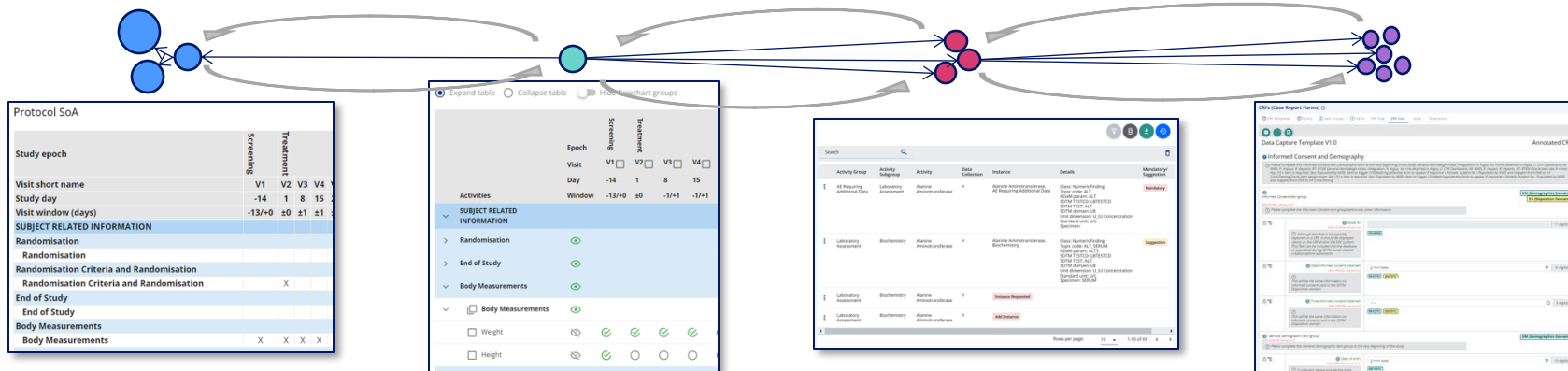
BC in OpenStudyBuilder := Activity Concepts

- OpenStudyBuilder is based on **Concept based Data Standards**
 - These are structures with more complex relationships
 - I.e. not only code-value pairs
 - They are applied for many different types of data, Activities (Clinical Procedures and Assessments), Compounds (linked to IDMP), Unit Definitions, Data Collection forms
- **Biomedical Concepts (BC's)**
 - Is generally defined as Activities (Clinical Procedures and Assessments)
- In OpenStudyBuilder we therefore use the general term **Concepts** and the specific term **Activity Concept** := current CDISC **Biomedical Concepts**

https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/guide_activity_concept/



Schedule of Activities (SoA) at multiple levels



Protocol SoA

- For the high level SoA in protocol section 1.2
- Main purpose is for the investigator and site staff to get an overview of the operational schedule

Detailed SoA

- Specifying the semantic data observations to be collected in the study – but not specific to representation in ADaM, SDTM or data collection
- Will be part of protocol section 8 and appendices or other supplementary documents

Operational SoA

- The data specification to support data collection specification
- Correspond to our existing legacy BCs (Topic Codes)
- Will also related to specific ADaM PARAM/PARAMCD

Data Capture / Collection Specification

- How data is to be collected in the study and when
- What is pre-set, what is collected and how

Selection process of Activities for SoA

For Protocol Outline / Protocol

- Select Activities in relevant grouping
- When selecting an Activity within a specific grouping, then this will drive ActivityInstance – this should be visible for Protocol Writers (like a COL)
 - Some ActivityInstances can be mark as default for an Activity, and will then be pre-selected
 - Some ActivityInstances can be marked as mandatory – and cannot be un-selected
- Select what to display or hide in high-level Protocol SoA

For Operational Data Specification

- Confirm or Select Activity Instances for each selected Activity
- If the correct ActivityInstance will change Grouping – this will require a change to the Protocol SoA – this will then

For Data Collection Specification

- The data collection specification
 - Lab specs
 - CRF
 - Other eSources
 - What is pre-set
- The data collection specification will be linked to:
 - Study Data Contracts
 - Activity Instance ‘Connector Model’ – and OAK transformation rules

Study Activities (CDISC DEV-0) ?

Study Activities Schedule of Activities

DETAILED PROTOCOL OPERATIONAL

The detailed SoA describe scheduling of the specific Activities and their grouping for the study

	Screening	Treatment							
	V1	V2	V3	V4	V5	V6	V7	V8	V9
Study Day	-14	1	8	15	22	29	36	43	50
Window	-13/+0	±0	±1	±1	±1	±1	±1	±1	±1

Each level in the Activity hierarchy can be selected for display in the "Protocol SoA"

- > SUBJECT RELATED INFORMATION
- ▼ EFFICACY
 - ▼ LABORATORY ASSESSMENTS
 - ▼ GLUCOSE METABOLISM
 - HBA1C
- > SAFETY
- > BIOMARKERS

Footnotes

Select Study & Version | Get Data | Start/End tags visible | About | StudyBuilder

Protocol Study ID: CDISC DEV-0 | Date: 30 September 2022 | Status: Draft 9 of 75 | Novo Nordisk

1.2 Flowchart

Schedule of Activities

Structured content including SoA will be transferred to the content controls Word based Protocol Template

Procedure	Screening		Treatment								Follow-up
	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	
Visit short name	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11
Study day	-14	1	8	15	22	29	36	43	57	183	213
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	X	X	X	X	X	X	X	X
Eligibility Criteria											
Eligibility Criteria	X										
Laboratory Assessments											
Glucose Metabolism	X	X	X	X	X	X	X	X	X	X	
Lipids	X	X			X			X		X	
Biochemistry	X	X			X			X		X	
AE Requiring Additional Data											

Get Data

Currently saved: CDISC DEV-0

- Select all
- Protocol Title
- Protocol Short Title
- Universal Trial Number
- EudraCT Number
- iIND Number
- Schedule of Activities
- Objectives & Endpoints
- Inclusion Criteria
- Exclusion Criteria

Update | Cancel



- About Studies
- Process Overview
- Study List
- Manage Study
- Define Study
- Study Title
- Registry Identifiers
- Study Properties
- Study Structure
- Study Population
- Study Criteria
- Study Purpose
- Study Activities
- Data Specifications**
- View Specifications
- View Listings

Study Data Specifications (CDISC DEV-0)

Study Activity Instances Operational SoA

Expand table Show SoA groups

With reference to our legacy BC identifier and ADaM Param Code

	Epoch	Topic Code	ADaM Param Code	Screening	Treatment	Follow-up										
	Visit			V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11		
	Study day			-14	1	8	15	22	29	36	43	57	183	213		
Activities	Window			-13/+0	±0	±1	±1	±1	±1	±1	±1	±1	±1	+0/+35		
<p>> SUBJECT RELATED INFORMATION</p> <p>> SAFETY</p> <p>< EFFICACY</p> <p>< Laboratory Assessments</p> <p>< Glucose Metabolism</p> <p>< HbA1c</p> <p><u>HbA1c</u></p> <p>HBA1C_BLOOD HBA1CB X X X X X X X X X X</p> <p>> BIOMARKERS</p>																

Selection is made to specific Activity Instance level

- About Studies
- Process Overview
- Study List
- Manage Study
- Define Study
- View Specifications
- View Listings
- Analysis Study Metadata (Ne...**

Studies / View Listings / Analysis Study Metadata (New) / MD

Analysis Study Metadata (New) ?

MDVISIT | MDENDPNT

Select rows

Column labels Column names

Study Activities is linked to endpoints and objectives and made available as part of metadata datasets for ADaM

Objective Level	Objective	Endpoint Level	Endpoint Plain Text	Time Frame Plain Text	Related Activity Instances
Secondary Objective	Time from randomisation to all cause death	Secondary Endpoint	Proportion of subjects with hba1c < 7 %	after 26 weeks	HbA1c
Primary Objective	Time to first occurrence of MACE+, a composite endpoint consisting of: CV death, nonfatal MI, nonfatal stroke, or hospitalization for unstable angina	Primary Endpoint	Mean change from baseline in hba1c	after 26 weeks	HbA1c

Study Activities is linked to **Study Data Contracts** – will include **OAK** like rules in the connector model

DataCore experiment

Current StudyActivityItem **StudyDataContract** StudySourceSystem DataCore extract

Report name...


The *StudyDataContract* node will currently just hold an uid and order number. Later more attributes can be added if relevant.

For each (*StudyActivityItem* {*enabled: TRUE*}) for each related (*StudyActivitySchedule*) Create a (*StudyDataContract*) node.

The uid for this node can be constructed as: *StudyDataContract-[StudyActivityItem.uid]-[StudyActivitySchedule.uid]*

Not sure if we need the order number, so this is parked for later

StudyDataContract

topic_code	uid	visit	
BILIRUBIN_SERUM	StudyDataContract_84ad19be-cf	V2	
BILIRUBIN_SERUM	StudyDataContract_020f944a-6c	V2	
BILIRUBIN_SERUM	StudyDataContract_b1fc1f39-9c	V2	
BILIRUBIN_SERUM	StudyDataContract_ef2fe06e-bd	V5	
BILIRUBIN_SERUM	StudyDataContract_c11e4df0-d4	V5	
BILIRUBIN_SERUM	StudyDataContract_e0502278-7	V5	
BILIRUBIN_SERUM	StudyDataContract_da4067ca-a	V5	

421-427 of 1000



Concept: CRFs

Library / Concepts / CRFs / CRF Tree

CRFs (Case Report Forms) ②

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

Reorder content

Templates / Forms / ItemGroups / Items	Reference attributes	Definition attributes	Status	Version	Link
Template NN V1			Draft	0.1	+ FORMS
Informed Consent and Demography			Draft	0.1	+ ITEM GROUPS
Informed Consent			Draft	0.2	+ ITEMS
Study ID			Draft	0.1	
Date informed consent obtained			Draft	0.2	
Time informed consent obtained			Draft	0.2	
General Demography			Draft	0.1	
Date of birth			Draft	0.1	
Sex (read-only)			Draft	0.1	
Ethnicity			Draft	0.1	
Race			Draft	0.1	
Age		123	Draft	0.1	
Race other			Draft	0.1	
Vital Signs			Draft	0.1	

Templates used to defined multiple CRF version

Annotated CRF following MSG 2.0 standard

PDF format

ODM.xml with vendor extensions (or CSV)

Library / Concepts / CRFs / CRF View

CRFs (Case Report Forms) ②

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

Template NN V1 Annotated CRF

Informed Consent and Demography

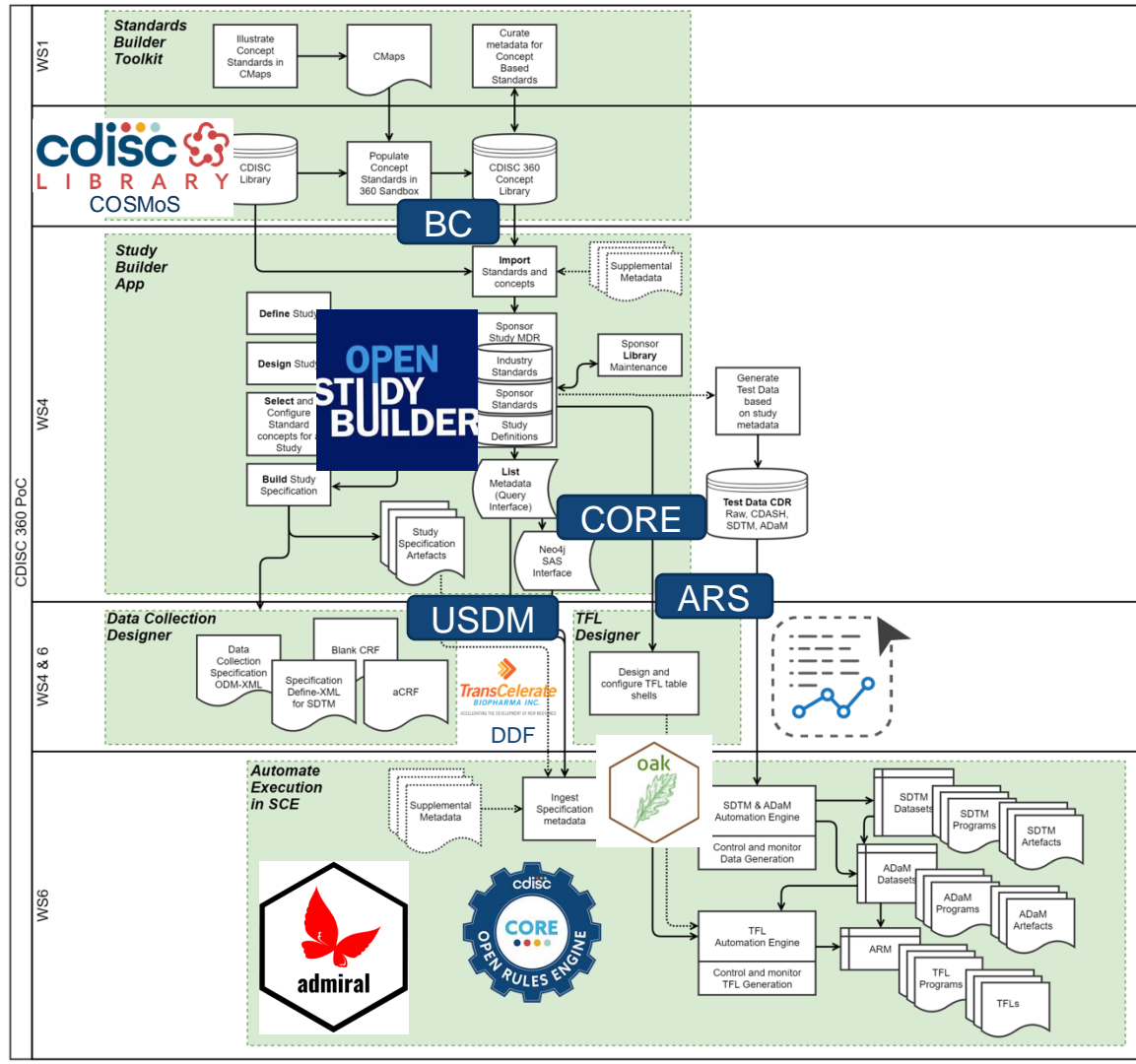
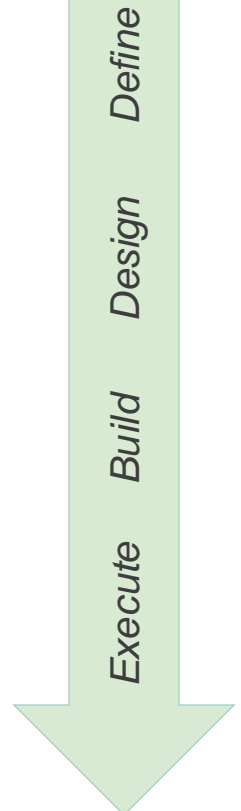
Please complete this Informed Consent and Demography form at the very beginning of the study. General Item design notes: Integration: A: Argus, Ac: Forms attached in Argus, C: CPR Dashboard, IW: IWRS, P: Impact, R: Reports, RT: RTSM General Item design notes: Integration: A: Argus, Ac: rms attached in 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

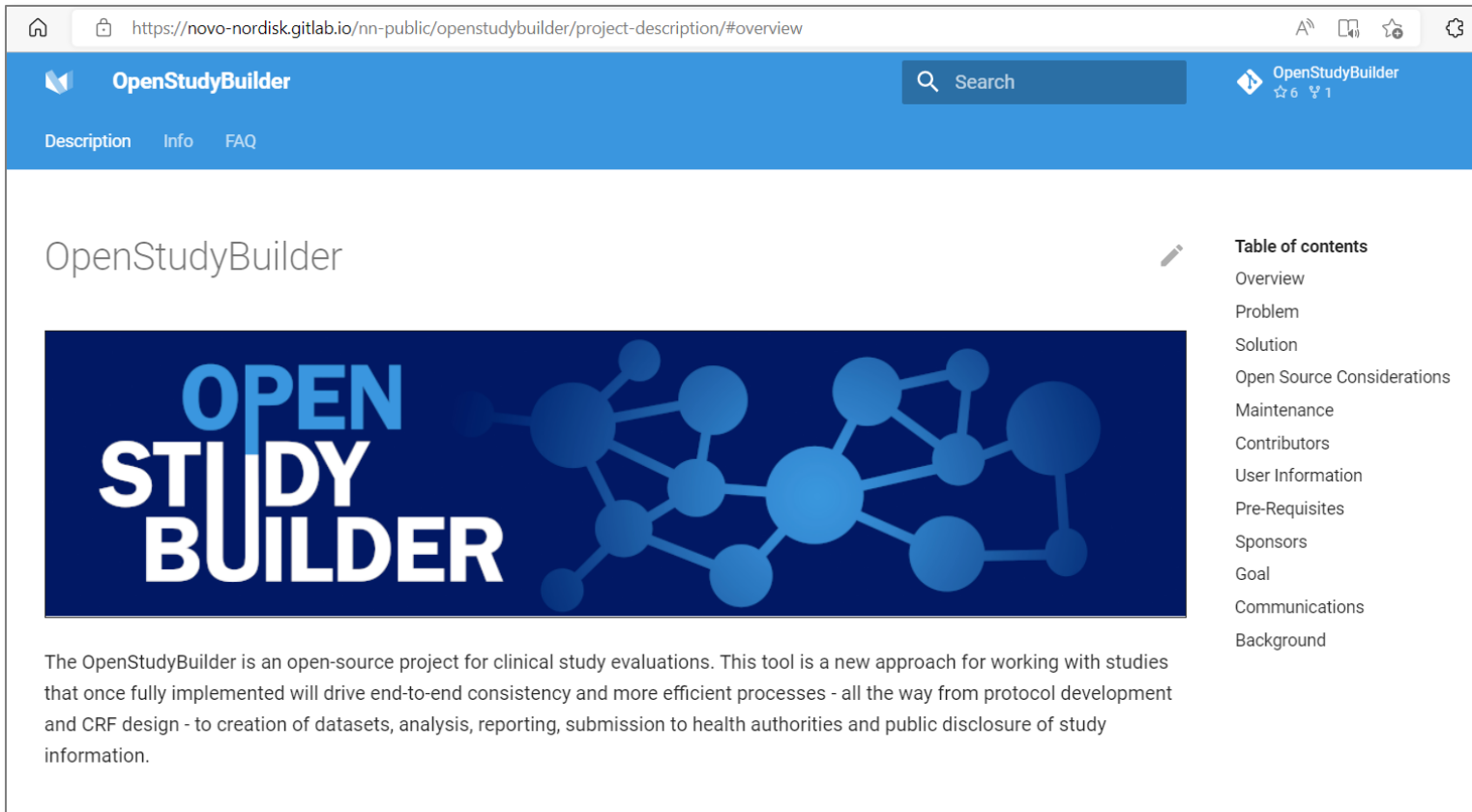
DM (Demographic Domain)
DS (Disposition Domain)

① Please complete the Informed Consent item group before any other information

Study ID [ODM=STUDID; Version=0.1]	11 digits
① Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during SDTM-based dataset creation before submission.	STUDYID
Date informed consent obtained [ODM=RECSDAT; Version=0.2]	10 digits
① This will be the same information on informed consent used in the SDTM Disposition domain	RECSDAT DSSTOTC



How do I get started on OpenStudyBuilder?



The screenshot shows a web browser window displaying the OpenStudyBuilder project description on GitLab. The browser's address bar shows the URL: <https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/#overview>. The page header is blue and contains the OpenStudyBuilder logo, a search bar, and navigation links for "Description", "Info", and "FAQ". The main content area features the title "OpenStudyBuilder" and a large blue banner with the text "OPEN STUDY BUILDER" and a network diagram. To the right of the banner is a "Table of contents" menu with links to various sections. Below the banner is a paragraph of text describing the project.

OpenStudyBuilder

**OPEN
STUDY
BUILDER**

The OpenStudyBuilder is an open-source project for clinical study evaluations. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.

Table of contents

- Overview
- Problem
- Solution
- Open Source Considerations
- Maintenance
- Contributors
- User Information
- Pre-Requisites
- Sponsors
- Goal
- Communications
- Background

<https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/>



Thank You!

Questions or need more information?

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