DS05 b - CDISC 360i in Action

Demonstrating the Shift to Fully Digital Standards

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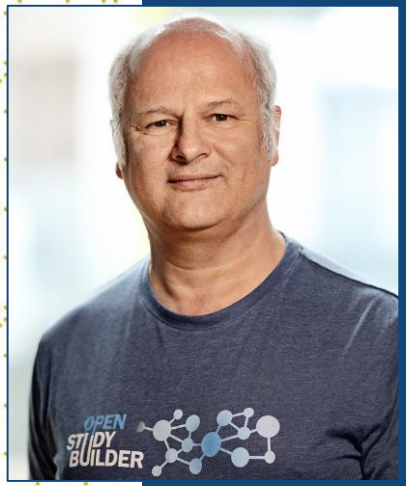
Nicolas De Saint Jorre, Lead Product Architect
Novo Nordisk A/S

Julie Smiley, VP, Data Sciences
CDISC

PHUSE EU Connect – 18 November 2025

Meet the Speakers



Mikkel Traun

Title: Principal 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.

Nicolas De Saint Jorre

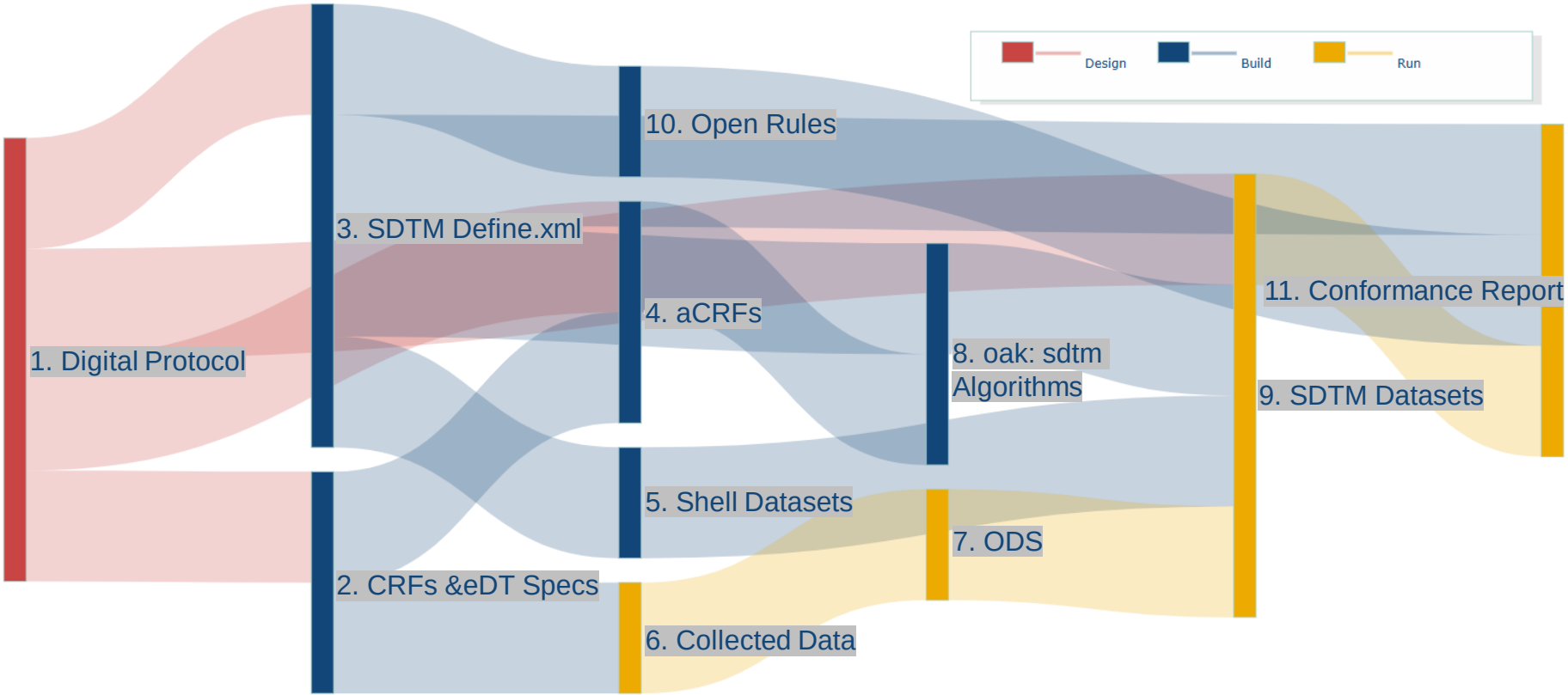
Title: Lead Product Architect

Organization: Novo Nordisk A/S

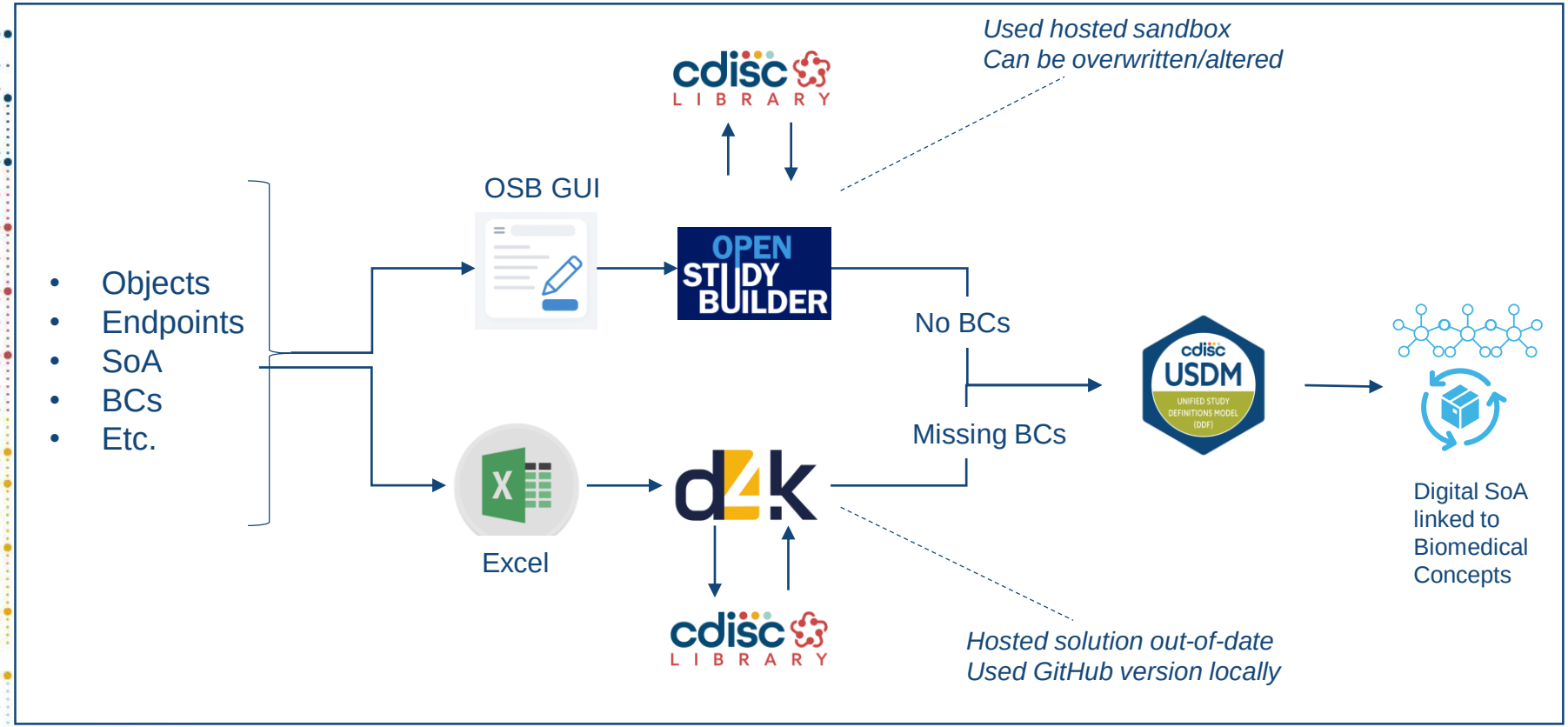
With over 29 years of experience in the field of Data Management and Clinical Research, I have been working on electronic Case Report Forms (eCRFs) since 2000. From 2005 to 2023, I worked with EvidentIQ, a software publisher specializing in EDC systems. I actively participated in the CDISC 360 project, developing a prototype. Since 2019, I have been collaborating with Novo Nordisk on the OpenStudyBuilder. Since April 2023, I have served as the Lead Product Architect for OpenStudyBuilder at Novo Nordisk, directly connected with the TransCelerate group and the "Digital Data Flow" project.

I am now deeply involved in the CDISC 360i project, as a co-lead in the Build team.

360i Flow from Digital Protocol



Study Design Applications Used



What is OpenStudyBuilder?…

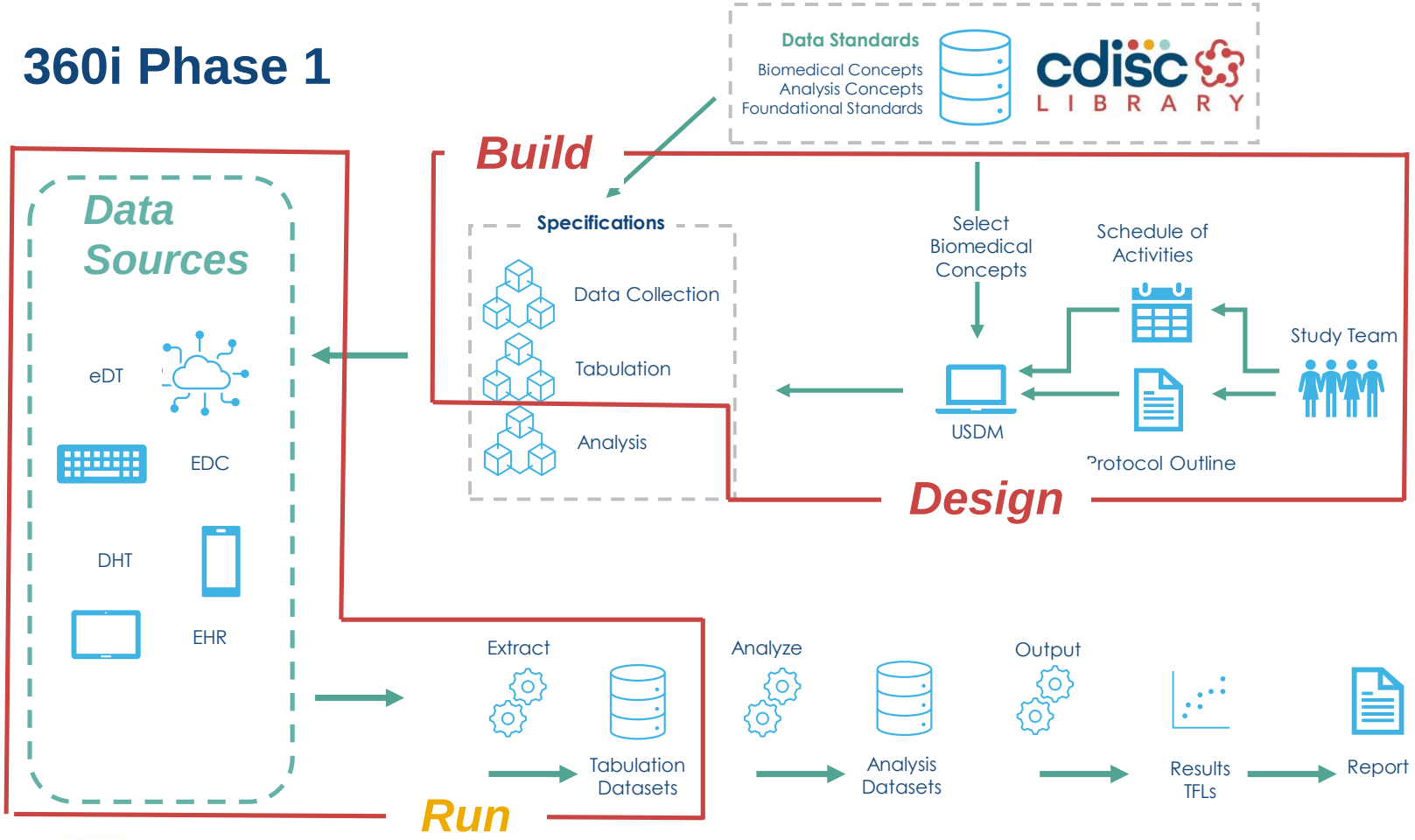
OpenStudyBuilder is the open-source solution for the industry, establishing **a single, standardized source of truth for digital study design specifications**, unlocking data- and AI-driven operational and scientific excellence across clinical development

3 Elements of OpenStudyBuilder

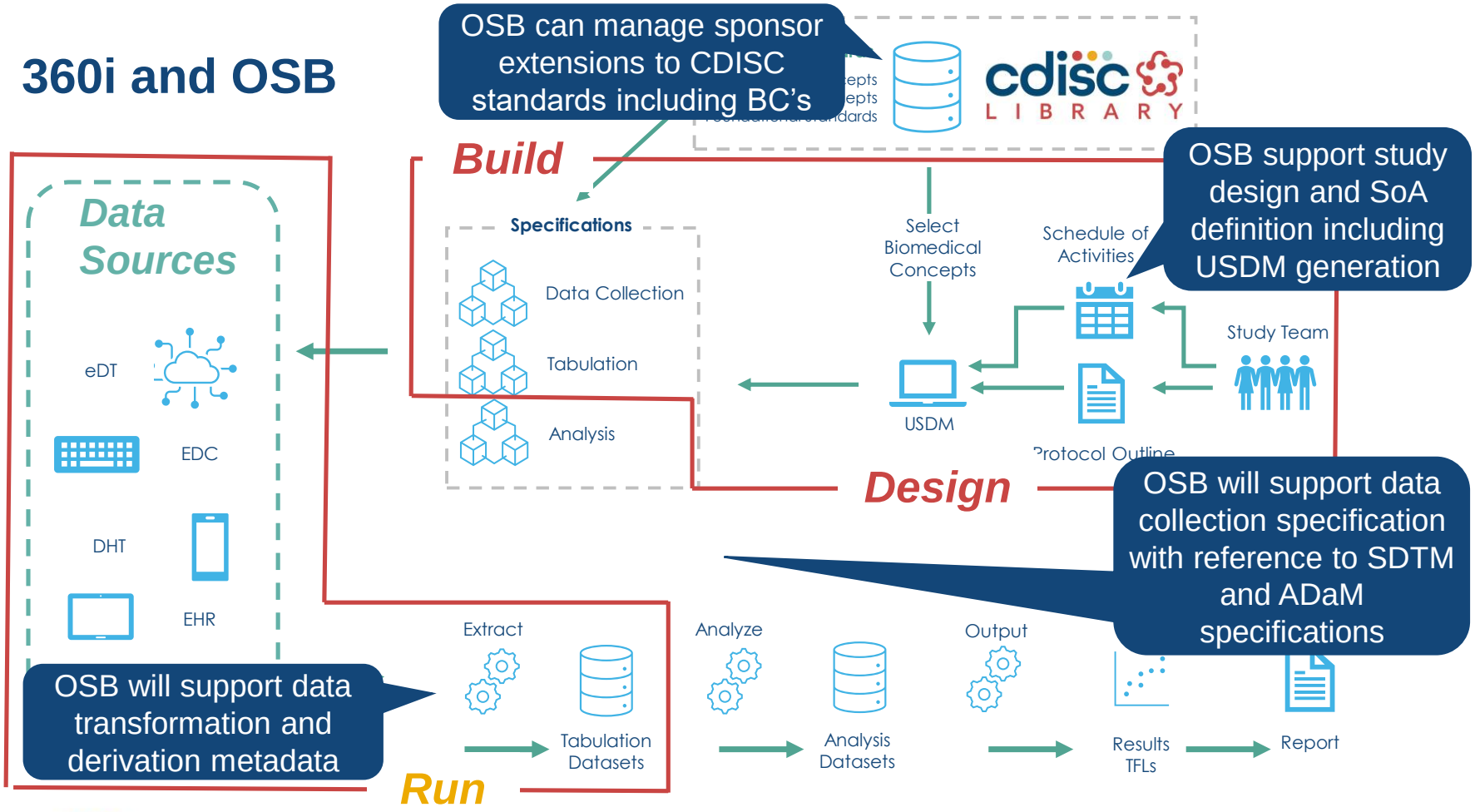
- **Clinical Metadata Repository (clinical MDR & SDR)**
  (central repository for all study specification data)
- **OpenStudyBuilder application / Web UI**
- **API layer**
  (allowing interoperability with other applications)
  (DDF API Endpoint – enabling DDF SDR Compatibility)

Clinical **MDR & SDR**

360i Phase 1

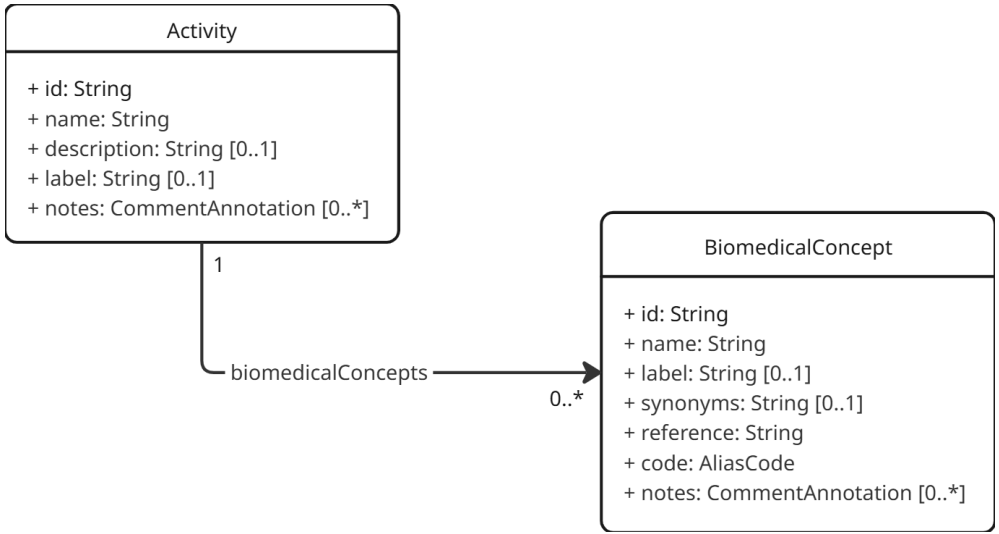

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards
cdisc LIBRARY
Build
Specifications
Data Collection
Tabulation
Analysis
Select Biomedical Concepts
Schedule of Activities
Study Team
USDM
Protocol Outline
Design
Data Sources
eDT
EDC
DHT
EHR
Extract
Tabulation Datasets
Analyze
Analysis Datasets
Output
Results TFLs
Report
Run

360i and OSB


OSB can manage sponsor extensions to CDISC standards including BC's
cdisc LIBRARY
Build
Specifications
Data Collection
Tabulation
Analysis
Select Biomedical Concepts
Schedule of Activities
OSB support study design and SoA definition including USDM generation
Study Team
USDM
Protocol Outline
Design
Data Sources
eDT
EDC
DHT
EHR
OSB will support data collection specification with reference to SDTM and ADaM specifications
OSB will support data transformation and derivation metadata
Extract
Tabulation Datasets
Analyze
Analysis Datasets
Output
Results TFLs
Report
Run

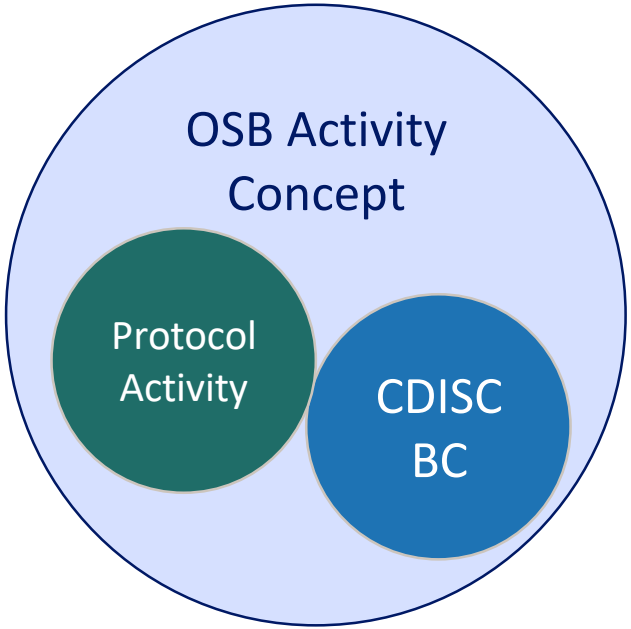
CDISC BCs and Activities in USDM

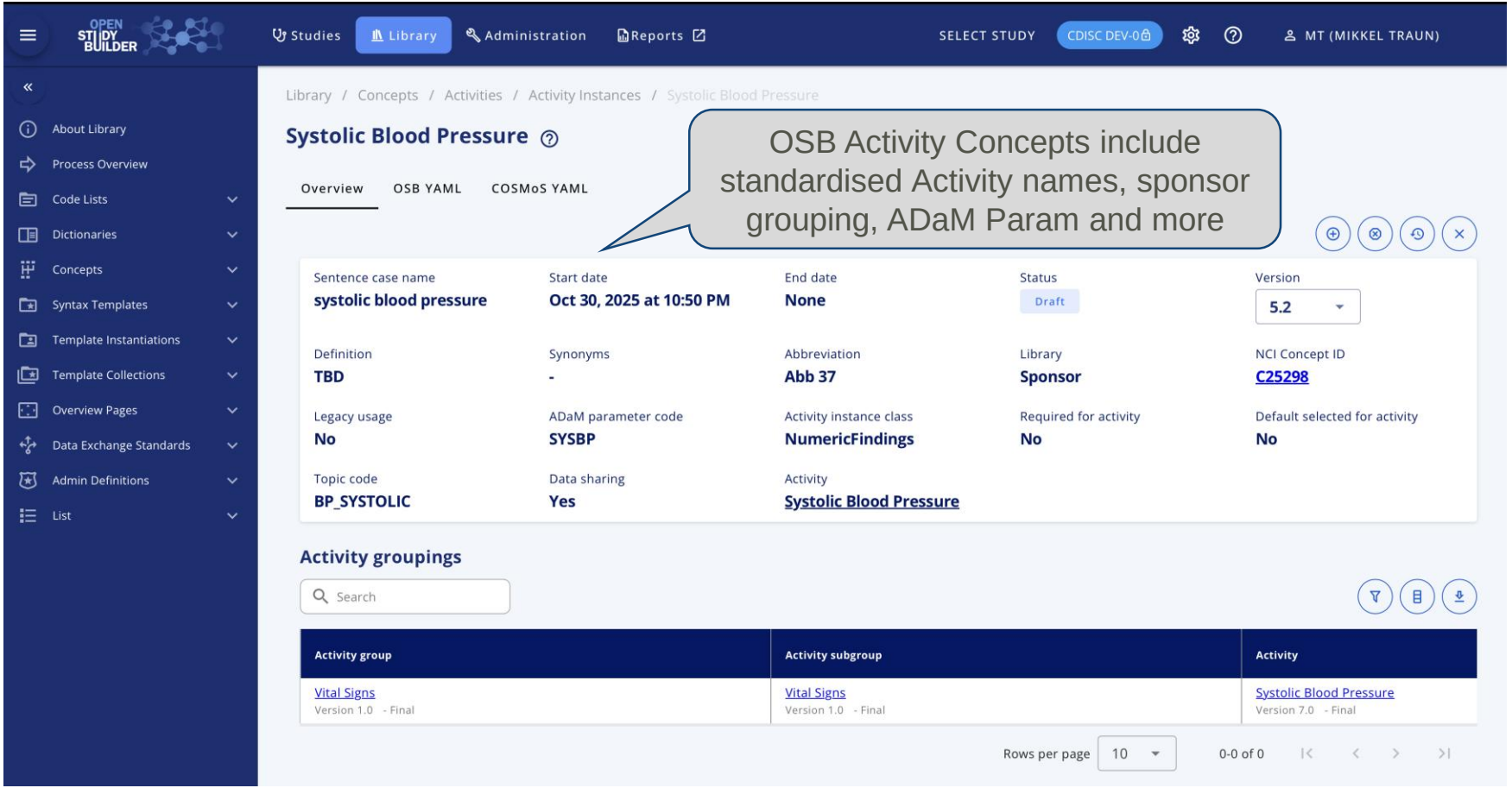
- **CDISC BCs** cover the semantic definition and SDTM specialisation
  - But do not cover the representation in the protocol nor the Activity in USDM
- **Activities** in USDM is represented as text with study level relationship to BCs
  - i.e. the Activities are not referred to as standard elements
- **CDISC BCs** are defined very broadly
  - But is in reality covering Activities (Clinical Procedures and Assessments)

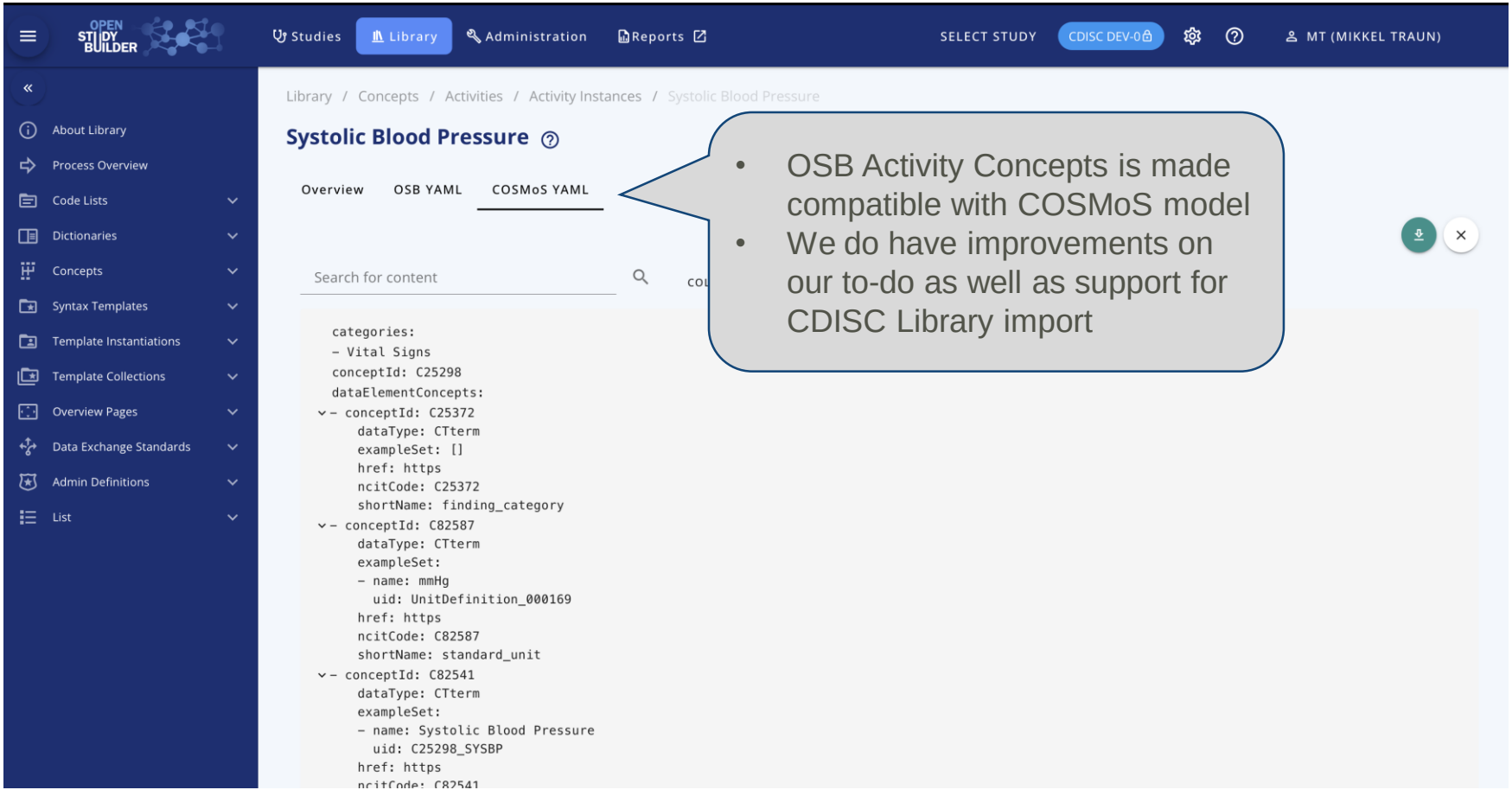


OSB BCs and Activities

- **OSB BCs** include the semantic definition and SDTM specialisation linked to a **CDISC BC** including NCI.gov term identifiers
- **OSB BC** can be **sponsor defined**
- **OSB BC** include library sponsor definition of the **Activity name** used in protocol including valid **Activity Groupings**
- **OSB BC = Activity Concepts**

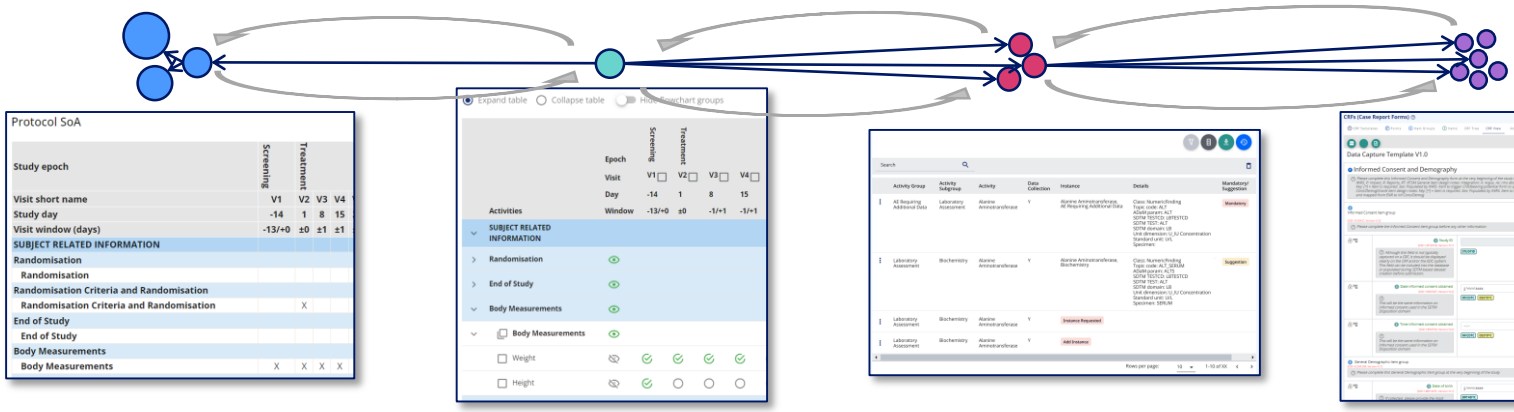



OPEN STUDY BUILDER
Studies
Library
Administration
Reports
SELECT STUDY
CDISC DEV-0
MT (MIKKEL TRAUN)
About Library
Process Overview
Code Lists
Dictionaries
Concepts
Syntax Templates
Template Instantiations
Template Collections
Overview Pages
Data Exchange Standards
Admin Definitions
List
Library / Concepts / Activities / Activity Instances / Systolic Blood Pressure
Systolic Blood Pressure
Overview
OSB YAML
COSMoS YAML
OSB Activity Concepts include standardised Activity names, sponsor grouping, ADaM Param and more
Sentence case name
systolic blood pressure
Start date
Oct 30, 2025 at 10:50 PM
End date
None
Status
Draft
Version
5.2
Definition
TBD
Synonyms
-
Abbreviation
Abb 37
Library
Sponsor
NCI Concept ID
C25298
Legacy usage
No
ADaM parameter code
SYSBP
Activity instance class
NumericFindings
Required for activity
No
Default selected for activity
No
Topic code
BP_SYSTOLIC
Data sharing
Yes
Activity
Systolic Blood Pressure
Activity groupings
Search
Activity group
Activity subgroup
Activity
Vital Signs
Version 1.0 - Final
Vital Signs
Version 1.0 - Final
Systolic Blood Pressure
Version 7.0 - Final
Rows per page
10
0-0 of 0



- OSB Activity Concepts is made compatible with COSMoS model
- We do have improvements on our to-do as well as support for CDISC Library import

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 appendixes or other supplementary documents

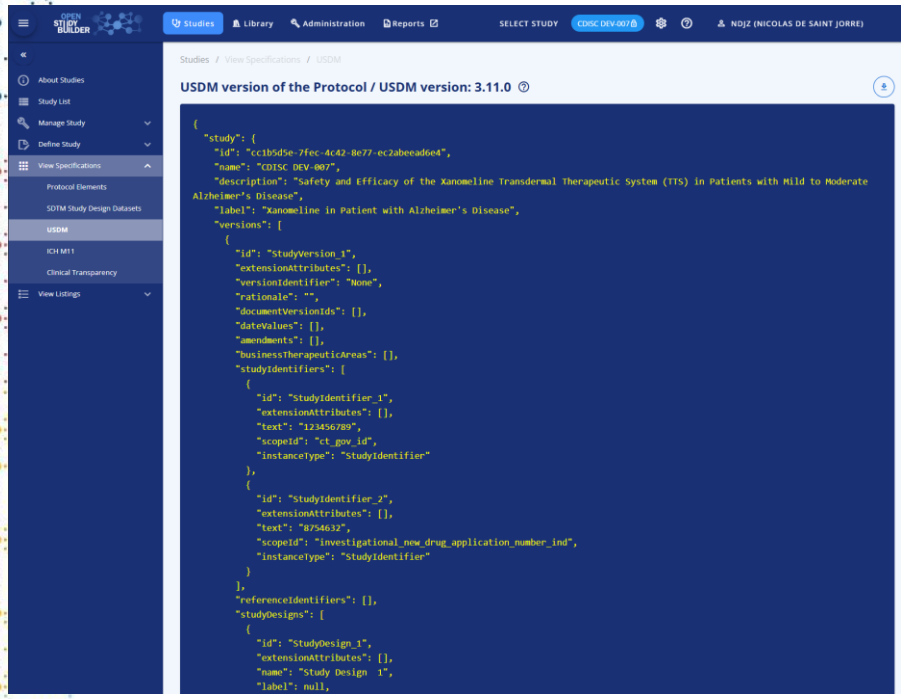
Operational SoA

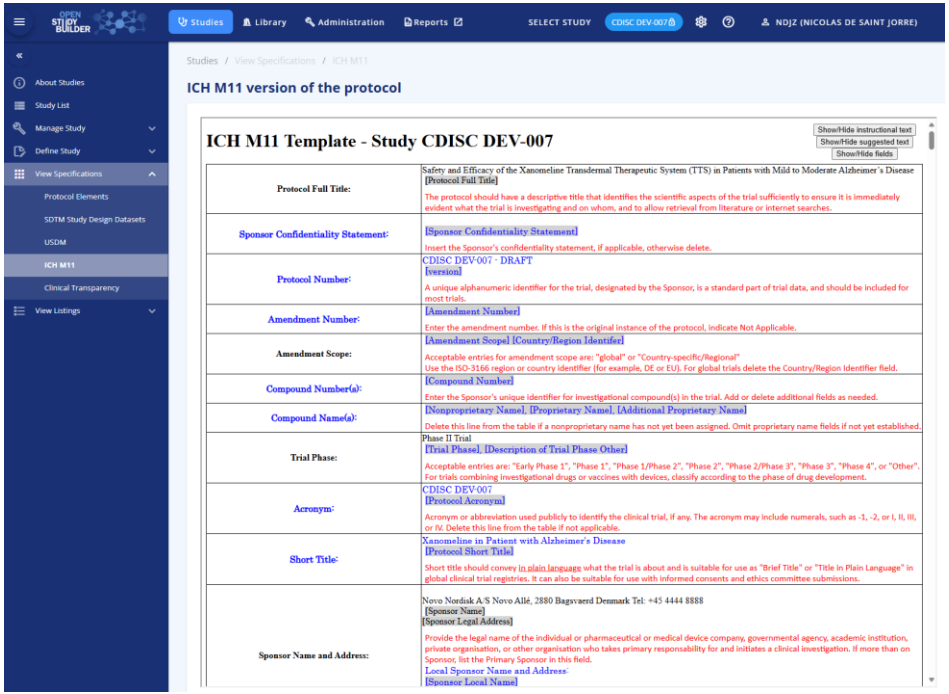
- The data specification to support data collection specification
- Correspond to our existing legacy BCs (Topic Codes)
- Will also relate to specific ADaM PARAM/PARAMCD

Data Capture / Collection Specification

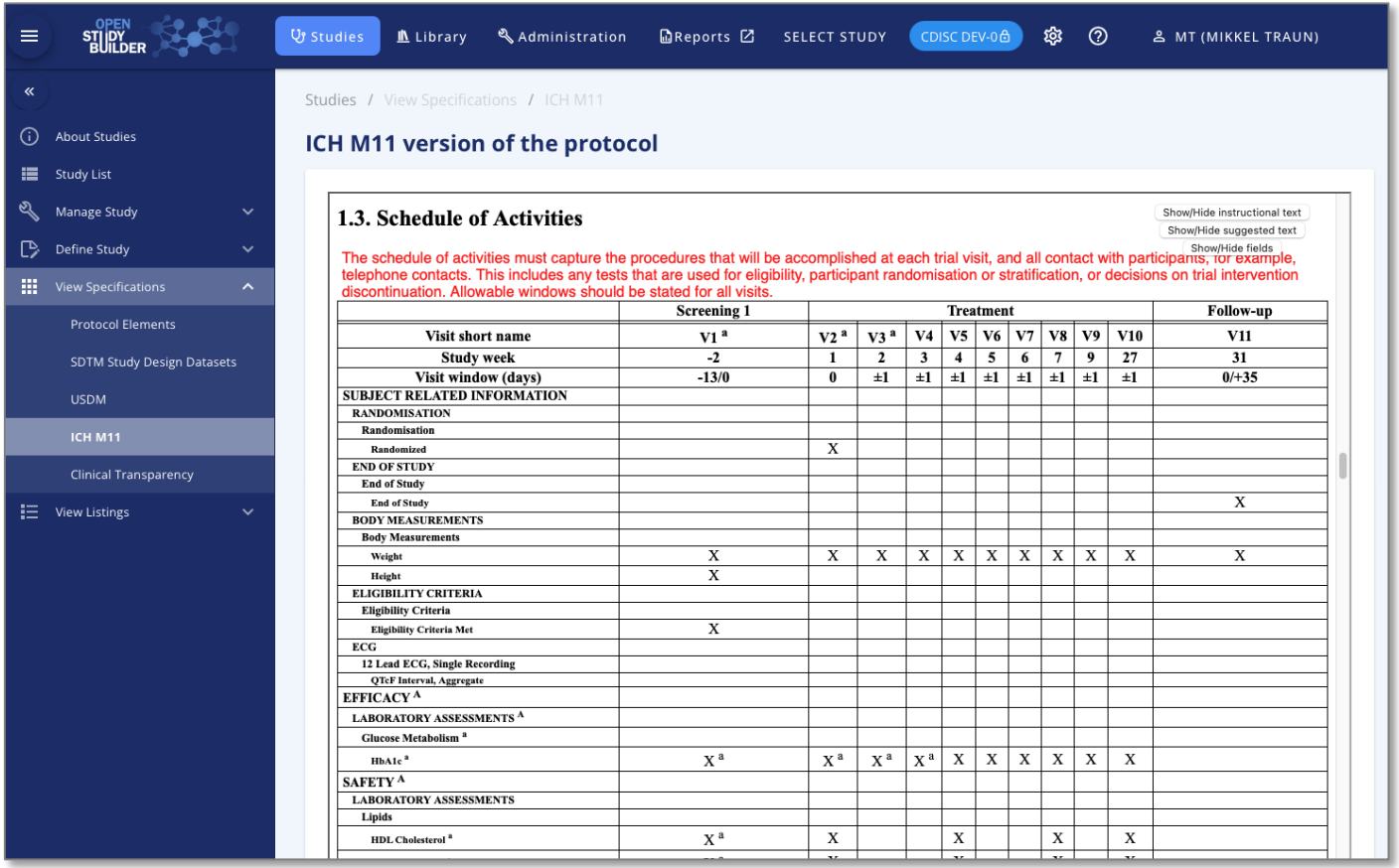
- How data is to be collected in the study and when
- What is pre-set, what is collected and how

USDM and ICH M11 Compatible



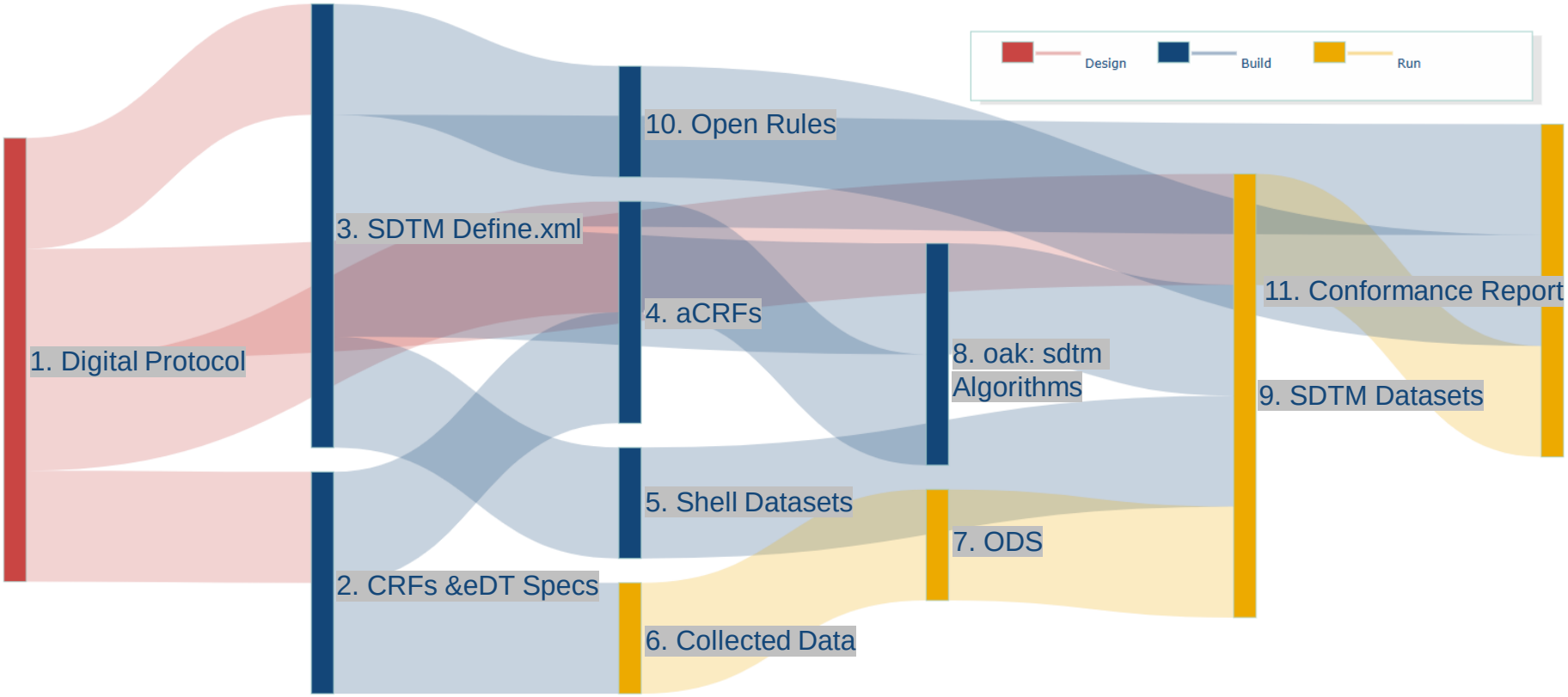


USDM and ICH M11 Compatible - with SoA

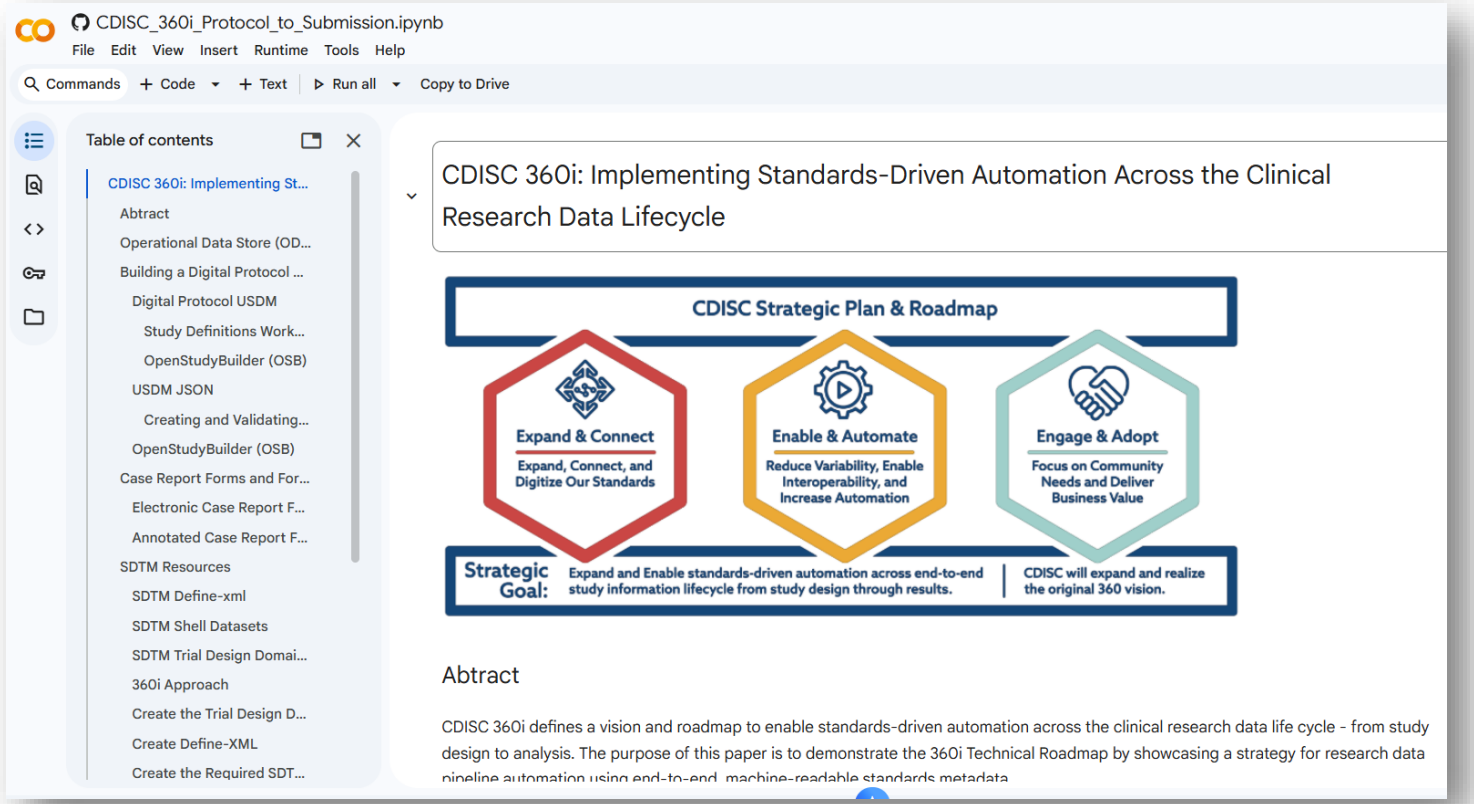


	Screening 1	Treatment									Follow-up
Visit short name	V1 [a]	V2 [a]	V3 [a]	V4	V5	V6	V7	V8	V9	V10	V11
Study week	-2	1	2	3	4	5	6	7	9	27	31
Visit window (days)	-13/0	0	±1	±1	±1	±1	±1	±1	±1	±1	0/+35
SUBJECT RELATED INFORMATION											
RANDOMISATION											
Randomisation											
Randomized		X									
END OF STUDY											
End of Study											
End of Study											X
BODY MEASUREMENTS											
Body Measurements											
Weight	X	X	X	X	X	X	X	X	X	X	X
Height	X										
ELIGIBILITY CRITERIA											
Eligibility Criteria											
Eligibility Criteria Met	X										
ECG											
12 Lead ECG, Single Recording											
QTcF Interval, Aggregate											
EFFICACY [A]											
LABORATORY ASSESSMENTS [A]											
Glucose Metabolism [a]											
HbA1c [a]	X [a]	X [a]	X [a]	X [a]	X	X	X	X	X	X	
SAFETY [A]											
LABORATORY ASSESSMENTS											
Lipids											
HDL Cholesterol [a]	X [a]	X			X			X		X	

360i Flow from Digital Protocol

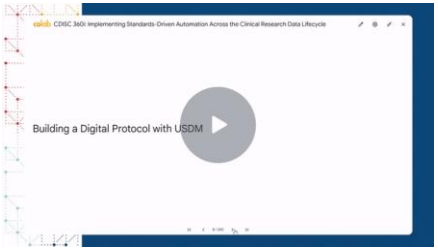


Google Colab Notebook

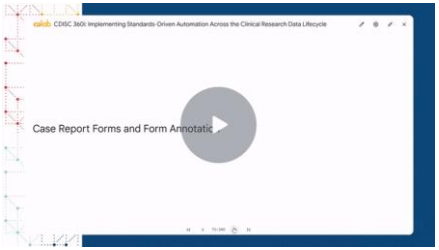


CDISC 360i Demos

Digital Protocol

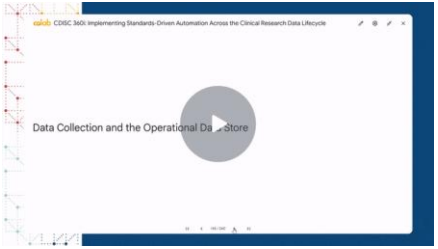


CRFs & aCRFs



SDTM Resources

Data Collection & ODS



SDTM Datasets

360i Conformance

GitHub Repositories Used in the Demo

Purpose	Location
Study Definition Workbench	https://github.com/data4knowledge/study_definitions_workbench
Open Study Builder	https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder/OpenStudyBuilder-Solution
Study USDM documents	https://github.com/cdisc-org/360i/tree/main/data/protocol/LZZT/usdm
USDM validation utility	https://github.com/pendingintent/cdisc-json-validation
CDISC CORE Rules Engine	https://github.com/cdisc-org/cdisc-rules-engine
CRF creation	https://github.com/lexjansen/cdisc360i-pocs
Trial Design Dataset creation	https://github.com/pendingintent/cdisc-usdm-utils
Define-XML template creation	https://github.com/dostiep/360i
Define-XML creation	https://github.com/swhume/template2define
Raw subject data	https://github.com/alidootson/UpdatedCDISCPilotData/tree/main/UpdatedCDISCPilotData/CDASH

Using GitHub

The GitHub repositories used in the demo are public and use open-source libraries

The process for using these libraries is consistent:

- Fork the original public repository into personal GitHub repository
- Create new branch in personal GitHub repository
- Edit code to meet individual requirements, add features or fix issues
- Commit changes to personal branch
- If proposing change to parent (original) branch to share with wider community:
  - Raise a Pull Request with original repository owner
  - Original repository owner will review the Pull Request and work with requestor to evaluate and test Pull Request
  - Merge new code in Pull Request with original parent branch

Accessing the 360i Notebook

The notebook displayed during this demonstration can be found here:

https://github.com/cdisc-org/cdisc-360i-notebooks

- The repository is under continued development; follow repository for latest releases
- There are multiple notebooks
- Raise any issues encountered while using notebooks
- To contribute to the CDISC project:
  - Fork the repo and create a new branch
  - Once changes are made and tested, raise a Pull Request

We Need You!

- Be part of the team to drive this forward
- We need committed contributors AND…companies that support the goals
- Click on QR Code below to volunteer
- Make sure to select 360i from the list!

https://www.cdisc.org/volunteer

- ✓ Complete CDISC Volunteer Form
- ✓ Complete 360i Contributor Survey

Thank You!

Questions or need more information

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Mikkel Traun- Principal Solution Architect - Novo Nordisk, mt@novonordisk.com

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