

DS05 b - CDISC 360i in Action

Demonstrating the Shift to Fully Digital Standards

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Novo Nordisk A/S

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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

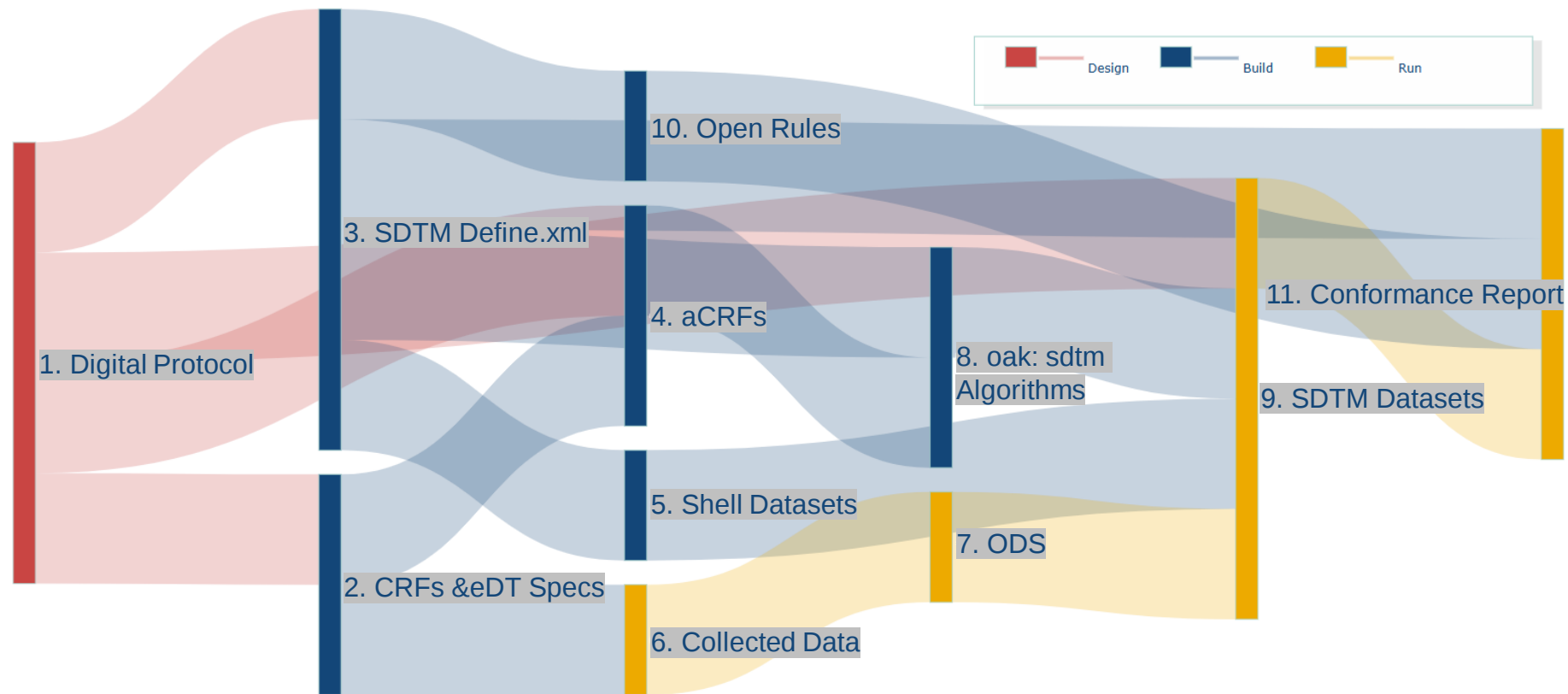
Title: Lead Product Architect

Organization: Novo Nordisk A/S

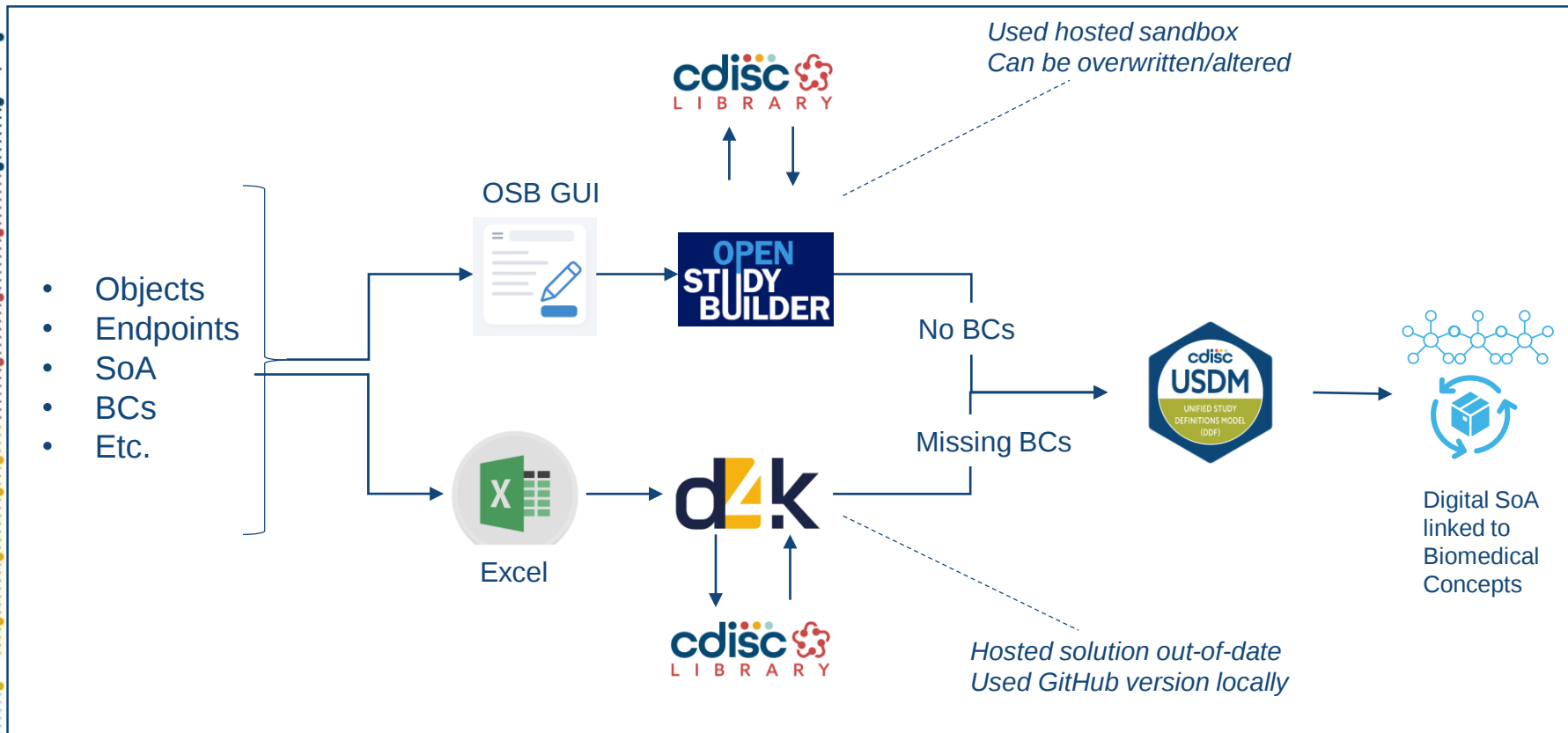


With over 29 years of experience in the field of Data Management and Clinical Research, I have been working on electronic Case Report Forms (eCRFs) since 2000. From 2005 to 2023, I worked with EvidentIQ, a software publisher specializing in EDC systems. I actively participated in the CDISC 360 project, 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.



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

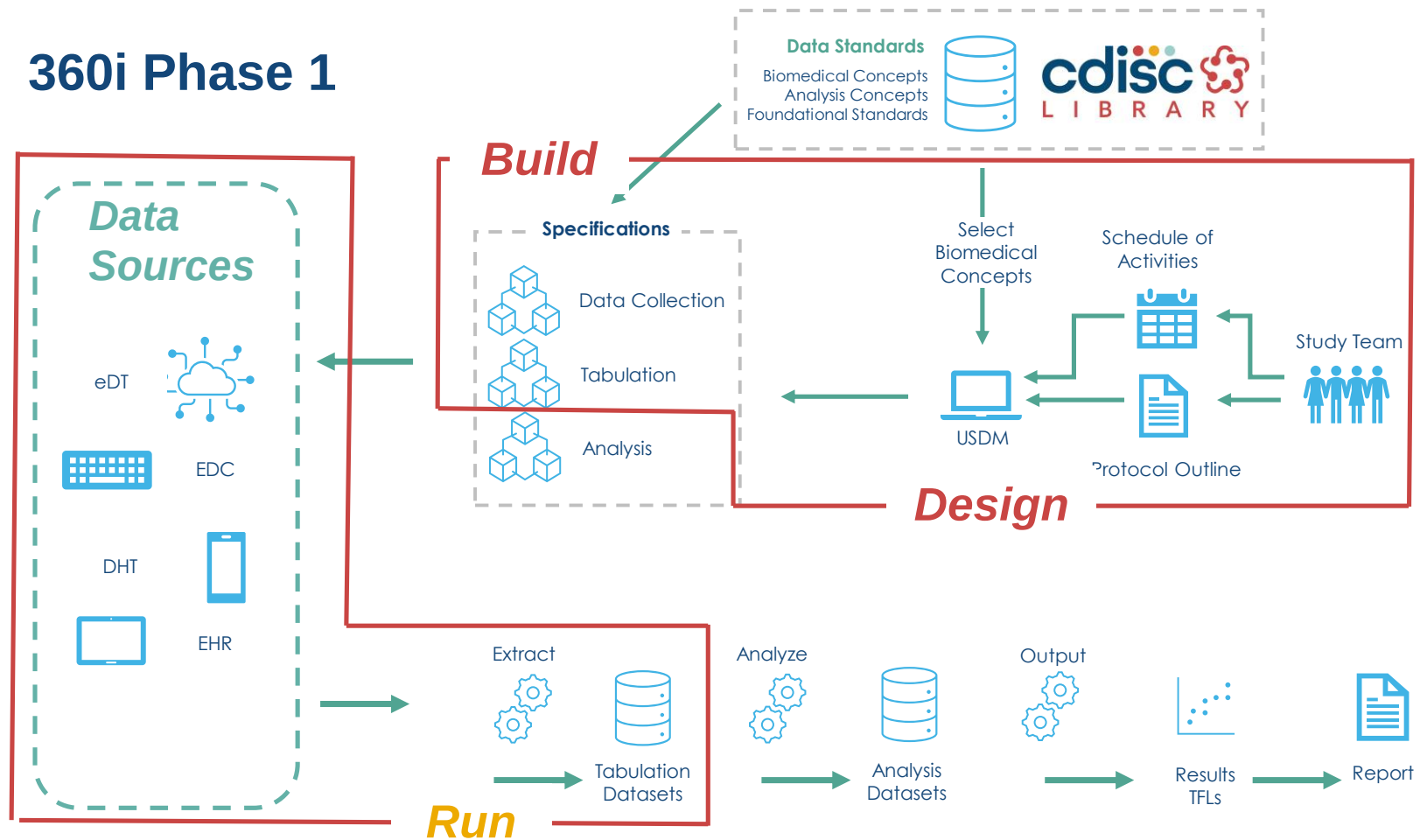
3 Elements of OpenStudyBuilder

- **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



360i and OSB

OSB can manage sponsor extensions to CDISC standards including BC's



cdisc
LIBRARY

OSB support study design and SoA definition including USDM generation

Build

Specifications



Data Collection



Tabulation



Analysis

Select Biomedical Concepts

Schedule of Activities



Study Team



USDM



Protocol Outline

Design

OSB will support data collection specification with reference to SDTM and ADaM specifications

Data Sources

eDT



EDC



DHT



EHR



OSB will support data transformation and derivation metadata

Extract



Tabulation Datasets

Run

Analyze



Analysis Datasets

Output



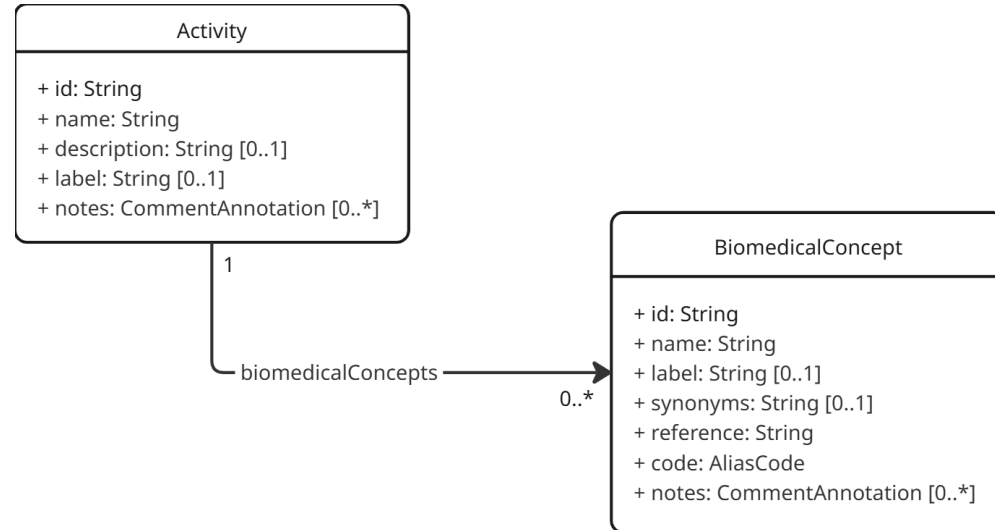
Results TFLs



Report

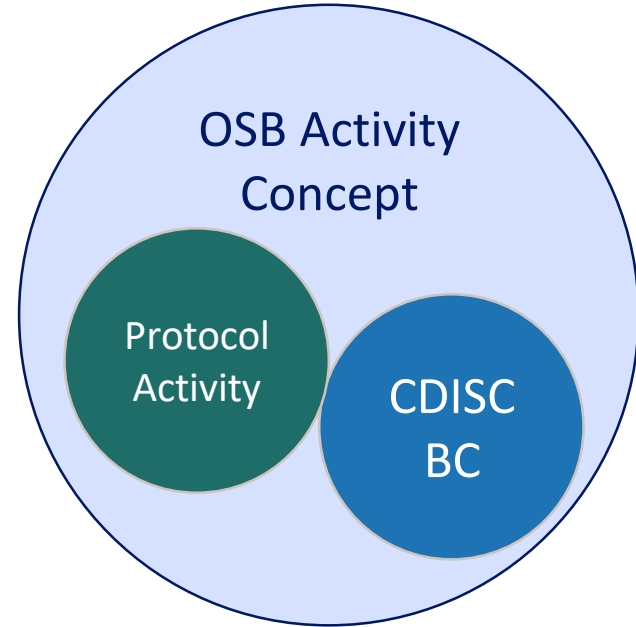
CDISC BCs and Activities in USDM

- **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**



Studies

Library

Administration

Reports

SELECT STUDY

CDISC DEV-08

Settings

Help

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

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

OSB Activity Concepts include standardised Activity names, sponsor grouping, ADaM Param and more

Activity groupings

Search

Filter

Table

Download

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

<<

<

>

>>

10



StudiesLibraryAdministrationReports

SELECT STUDYCDISC DEV-08

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

OverviewOSB YAMLCOSMoS YAML

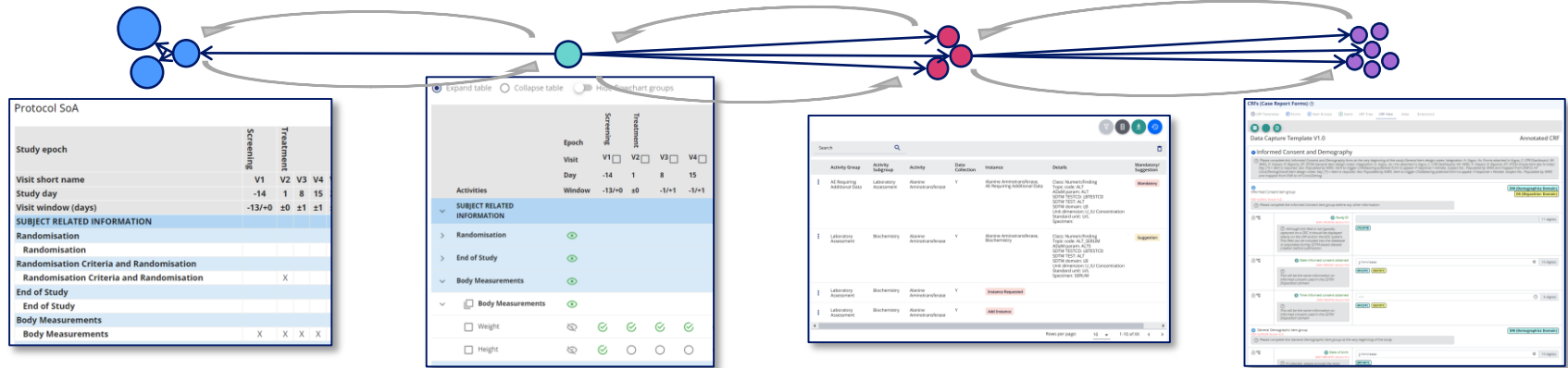
Search for content

```
categories:
- Vital Signs
conceptId: C25298
dataElementConcepts:
  - conceptId: C25372
    dataType: CTterm
    exampleSet: []
    href: https
    ncitCode: C25372
    shortName: finding_category
  - conceptId: C82587
    dataType: CTterm
    exampleSet:
      - name: mmHg
        uid: UnitDefinition_000169
    href: https
    ncitCode: C82587
    shortName: standard_unit
  - conceptId: C82541
    dataType: CTterm
    exampleSet:
      - name: Systolic Blood Pressure
        uid: C25298_SYSBP
    href: https
    ncitCode: C82541
```

- 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

DownloadClose

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

The screenshot shows the 'Study Builder' interface for 'CDISC DEV-007'. The left sidebar contains navigation options: About Studies, Study List, Manage Study, Define Study, View Specifications, Protocol Elements, SOTM Study Design Datasets, USDM, ICH M11, Clinical Transparency, and View Listings. The main panel displays 'View Specifications / USDM' with the text 'USDM version of the Protocol / USDM version: 3.11.0'. Below this is a JSON schema for the study, including fields for study ID, name, description, label, versions, extensions, amendments, business therapeutic areas, and study identifiers.

```
{
  "study": {
    "id": "cc1b5d5e-7fec-4c42-bc77-ec2abecad604",
    "name": "CDISC DEV-007",
    "description": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease",
    "label": "Xanomeline in Patient with Alzheimer's Disease",
    "versions": [
      {
        "id": "StudyVersion 1",
        "extensionAttributes": [],
        "versionIdentifier": "None",
        "rationale": "",
        "documentVersionIds": [],
        "dateValues": [],
        "amendments": [],
        "businessTherapeuticAreas": [],
        "studyIdentifiers": [
          {
            "id": "StudyIdentifier 1",
            "extensionAttributes": [],
            "text": "123456789",
            "scopeId": "ct.gov_id",
            "instancetype": "StudyIdentifier"
          },
          {
            "id": "StudyIdentifier 2",
            "extensionAttributes": [],
            "text": "8754632",
            "scopeId": "Investigational new drug application number_id",
            "instancetype": "StudyIdentifier"
          }
        ],
        "referenceIdentifiers": [],
        "studyDesigns": [
          {
            "id": "StudyDesign 1",
            "extensionAttributes": [],
            "name": "Study Design 1",
            "label": null,

```

The screenshot shows the 'Study Builder' interface for 'CDISC DEV-007'. The left sidebar is identical to the previous screenshot. The main panel displays 'View Specifications / ICH M11' with the text 'ICH M11 version of the protocol'. Below this is the 'ICH M11 Template - Study CDISC DEV-007'. The table contains fields for Protocol Full Title, Sponsor Confidentiality Statement, Protocol Number, Amendment Number, Amendment Scope, Compound Number(s), Compound Name(s), Trial Phase, Acronym, Short Title, and Sponsor Name and Address, each with a corresponding instruction or example.

ICH M11 Template - Study CDISC DEV-007	
Protocol Full Title:	Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease [Protocol Full Title] The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet searches.
Sponsor Confidentiality Statement:	[Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
Protocol Number:	CDISC DEV-007 - DRAFT [Version] A unique alphanumeric identifier for the trial, designated by the Sponsor, is a standard part of trial data, and should be included for most trials.
Amendment Number:	[Amendment Number] Enter the amendment number. If this is the original instance of the protocol, indicate Not Applicable.
Amendment Scope:	[Amendment Scope] [Country/Region Identifier] Acceptable entries for amendment scope are: "global" or "Country-specific/Regional". Use the ISO-3166 region or country identifier (for example, DE or EU). For global trials delete the Country/Region Identifier field.
Compound Number(s):	[Compound Number] Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.
Compound Name(s):	[Nonproprietary Name], [Proprietary Name], [Additional Proprietary Name] Delete this line from the table if a nonproprietary name has not yet been assigned. Omit proprietary name fields if not yet established.
Trial Phase:	Phase II Trial [Trial Phase], [Description of Trial Phase Order] Acceptable entries are: "Early Phase 1", "Phase 1", "Phase 1/Phase 2", "Phase 2", "Phase 2/Phase 3", "Phase 3", "Phase 4", or "Other". For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
Acronym:	CDISC DEV-007 [Protocol Acronym] Acronym or abbreviation used publicly to identify the clinical trial, if any. The acronym may include numerals, such as -1, -2, or I, II, III, or IV. Delete this line from the table if not applicable.
Short Title:	Xanomeline in Patient with Alzheimer's Disease [Protocol Short Title] Short title should convey in plain language what the trial is about and is suitable for use as "Brief Title" or "Title in Plain Language" in global clinical trial registries. It can also be suitable for use with informed consents and ethics committee submissions.
Sponsor Name and Address:	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd Denmark Tel: +45 4444 8888 [Sponsor Name] [Sponsor Legal Address] Provide the legal name of the individual or pharmaceutical or medical device company, governmental agency, academic institution, private organisation, or other organisation who takes primary responsibility for and initiates a clinical investigation. If more than one Sponsor, list the Primary Sponsor in this field. [Local Sponsor Name and Address] [Sponsor Local Name]

USDM and ICH M11 Compatible - with SoA

OPEN STUDY BUILDER

Studies Library Administration Reports SELECT STUDY CDISC DEV-0

MT (MIKKEL TRAUN)

«

About Studies

Study List

Manage Study

Define Study

View Specifications

Protocol Elements

SDTM Study Design Datasets

USDM

ICH M11

Clinical Transparency

View Listings

Studies / View Specifications / ICH M11

ICH M11 version of the protocol

1.3. Schedule of Activities

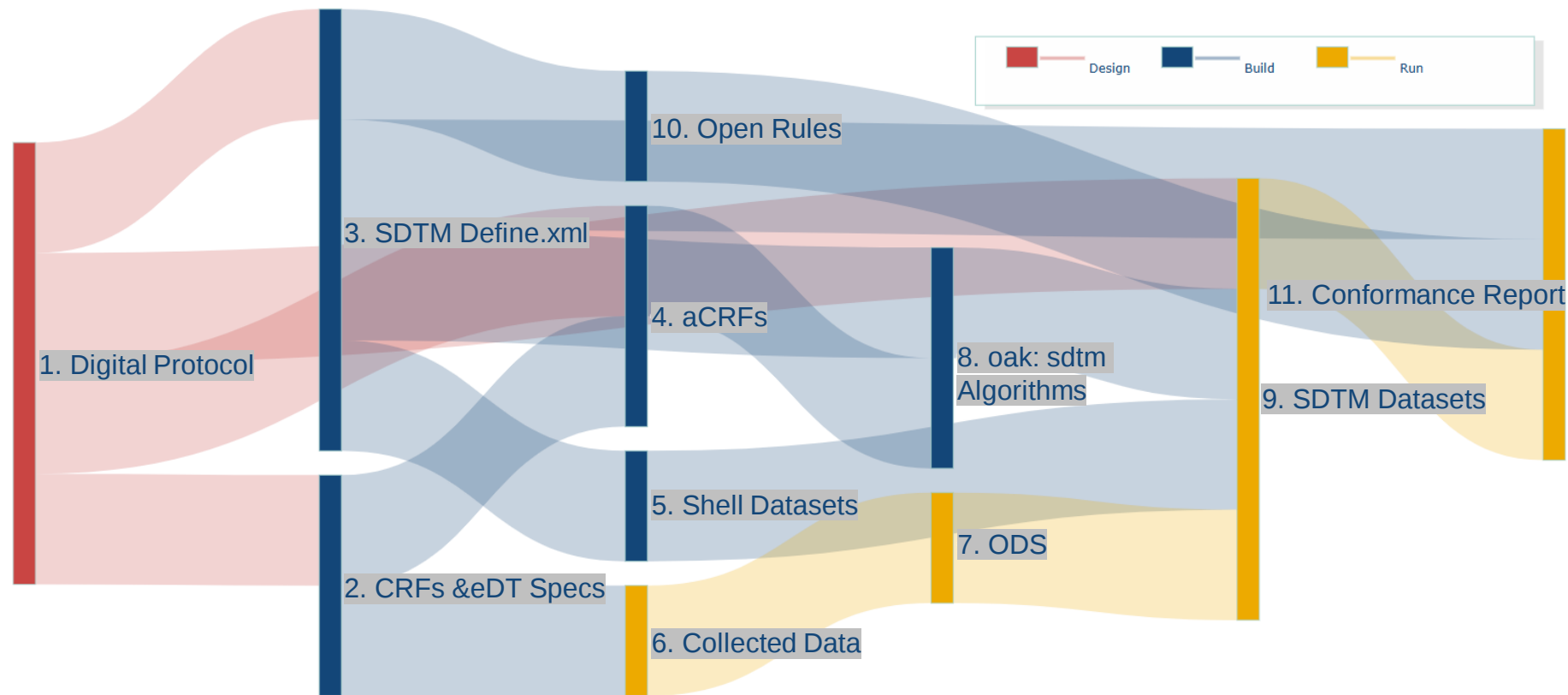
Show/Hide instructional text

Show/Hide suggested text

Show/Hide fields

The schedule of activities must capture the procedures that will be accomplished at each trial visit, and all contact with participants, telephone contacts. This includes any tests that are used for eligibility, participant randomisation or stratification, or decisions on trial intervention discontinuation. Allowable windows should be stated for all visits.

	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 ^B											
HbA1c ^A	X ^a	X ^a	X ^a	X ^a	X	X	X	X	X	X	
SAFETY ^A											
LABORATORY ASSESSMENTS											
Lipids											
HDL Cholesterol ^B	X ^a	X			X			X		X	



Google Colab Notebook

 CDISC_360i_Protocol_to_Submission.ipynb
File Edit View Insert Runtime Tools Help

Q Commands + Code + Text ▶ Run all Copy to Drive

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CDISC 360i: Implementing St...

Abstract

Operational Data Store (OD...

Building a Digital Protocol ...

Digital Protocol USDM

Study Definitions Work...

OpenStudyBuilder (OSB)

USDM JSON

Creating and Validating...

OpenStudyBuilder (OSB)

Case Report Forms and For...

Electronic Case Report F...

Annotated Case Report F...

SDTM Resources

SDTM Define-xml

SDTM Shell Datasets

SDTM Trial Design Domai...

360i Approach

Create the Trial Design D...

Create Define-XML

Create the Required SDT...

CDISC 360i: Implementing Standards-Driven Automation Across the Clinical Research Data Lifecycle



The diagram illustrates the CDISC Strategic Plan & Roadmap. It features three main pillars: **Expand & Connect** (Expand, Connect, and Digitize Our Standards), **Enable & Automate** (Reduce Variability, Enable Interoperability, and Increase Automation), and **Engage & Adopt** (Focus on Community Needs and Deliver Business Value). These pillars are framed by a top bar labeled 'CDISC Strategic Plan & Roadmap' and a bottom bar labeled 'Strategic Goal: Expand and Enable standards-driven automation across end-to-end study information lifecycle from study design through results. CDISC will expand and realize the original 360 vision.'

Abstract

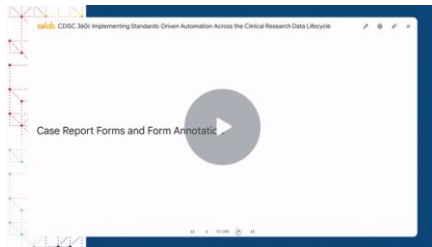
CDISC 360i defines a vision and roadmap to enable standards-driven automation across the clinical research data life cycle - from study design to analysis. The purpose of this paper is to demonstrate the 360i Technical Roadmap by showcasing a strategy for research data pipeline automation using end-to-end machine-readable standards metadata

CDISC 360i Demos

Digital Protocol



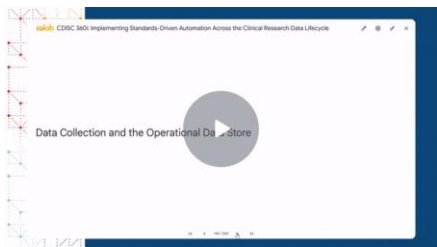
CRFs & aCRFs



SDTM Resources



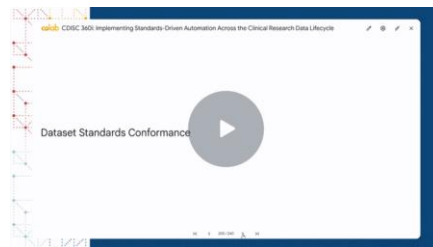
Data Collection & ODS



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!

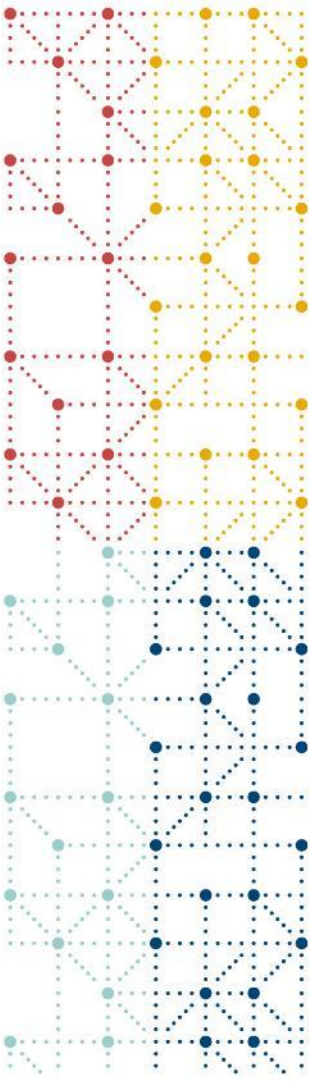
- Be part of the team to drive this forward
- We need committed contributors
AND...companies that support the goals
- Click on QR Code below to volunteer
- Make sure to select 360i from the list!



<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

OpenStudyBuilder contact: OpenStudyBuilder@gmail.com

