



2025 CDISC + TMF
EUROPE INTERCHANGE

GENEVA

CONFERENCE & EXPO: 14-15 MAY | TRAININGS: 12, 13, 16 MAY

Enhanced Biomedical Concepts: A Design Perspective in OpenStudyBuilder Supporting CDISC 360i

Mikkel Traun, Principal Solution Architect
Nicolas De Saint Jorre, Lead Product Architect
Novo Nordisk A/S

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.

MDR and SDR (Digital Protocol)

CTMS

External Standards

CDISC CT, MedDRA,
SNOMED CT, WHO Drug, ISO

...

IWRS/RTSM

EDC

Safety

Laboratories

CGM

eCOAs

Questionnaires e.g. SF36, CSSRS, PHQ9

Imaging

Data Lakes

Harmonized historic study data

Master Data

Medicinal product data

Other data

...

The diagram consists of 25 circles of varying shades of teal, dark blue, blue, and pink, arranged in a cluster. Each circle contains text representing a specific deliverable or use case. The teal circles include: Protocol, Investigator's Brochure, Clinical Trial Application, Case Report Form, Laboratory Manual, RACT, Clinical Study Report, Clinical Summaries, and Label. The dark blue circles include: Data Reviewers Guide, SDTM Datasets, ADAM Datasets, Output datasets, Tables Figures Listings, and three empty circles. The blue circles include: Data Cleaning, Medical Review, Statistical Monitoring, Centralised Monitoring, Medical Monitoring, Safety Oversight, and three empty circles. The pink circles include: Clinical Performance Report and two empty circles.

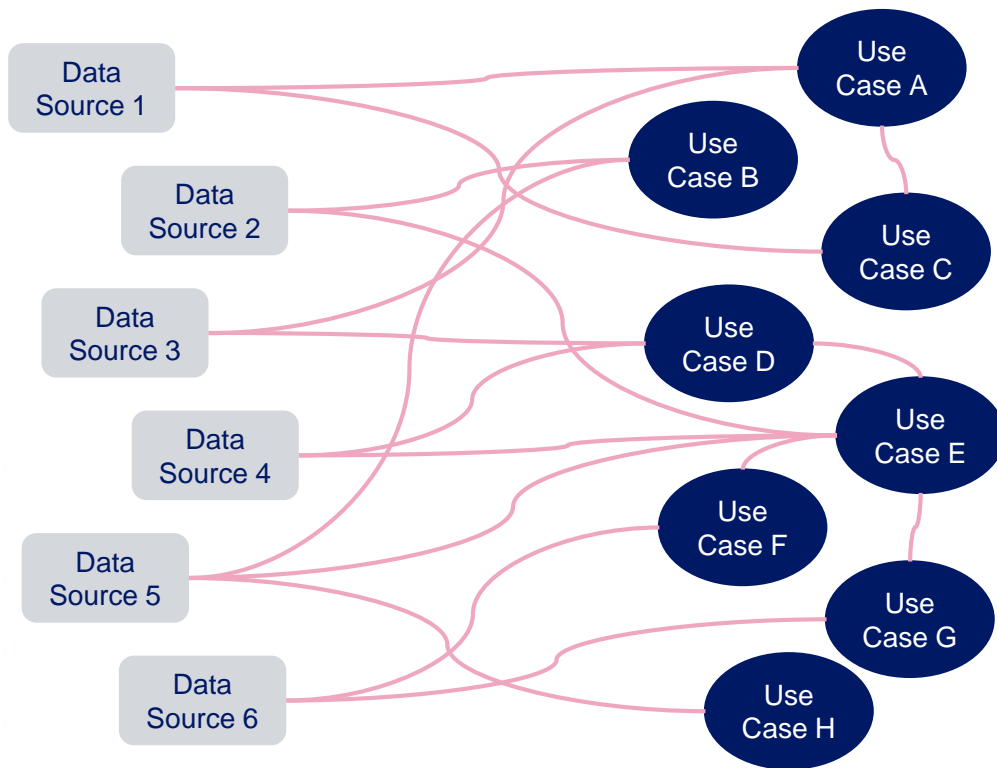
Many Deliverables / Use Cases

Documents and datasets for study conduct and regulatory submission, internal reports and dashboards for oversight and insights

Many Deliverables / Use Cases

Documents and datasets for study conduct and regulatory submission,
internal reports and dashboards for oversight and insights

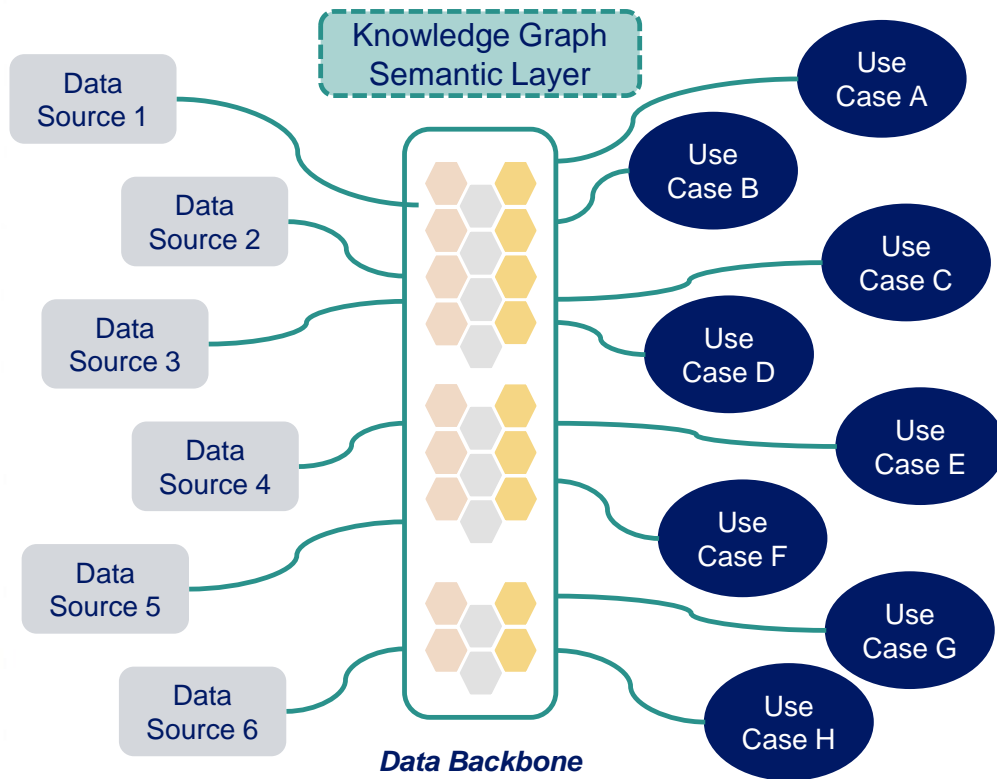
Today's **barrier** for efficiency and speed



Many to **Many** to Many

- Limited overview and transparency
- High-risk of inconsistencies
- Inefficiency due to re-do rather than reuse
- Lag-time between data availability and data ready for use

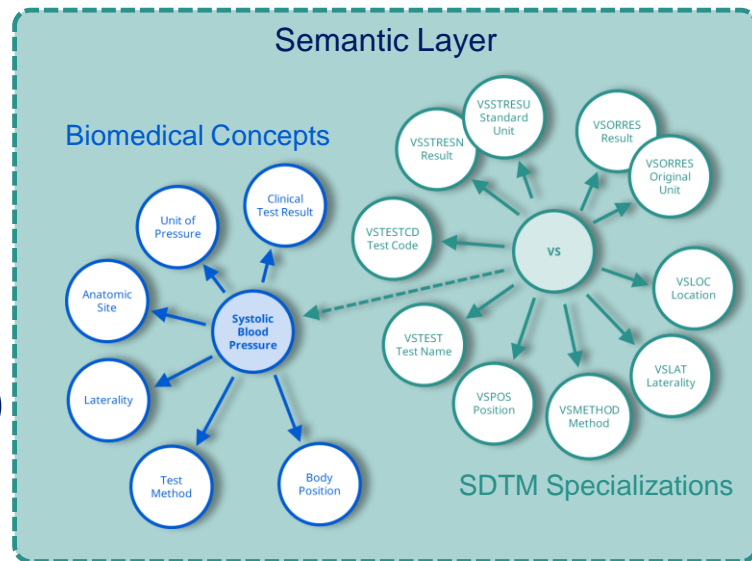
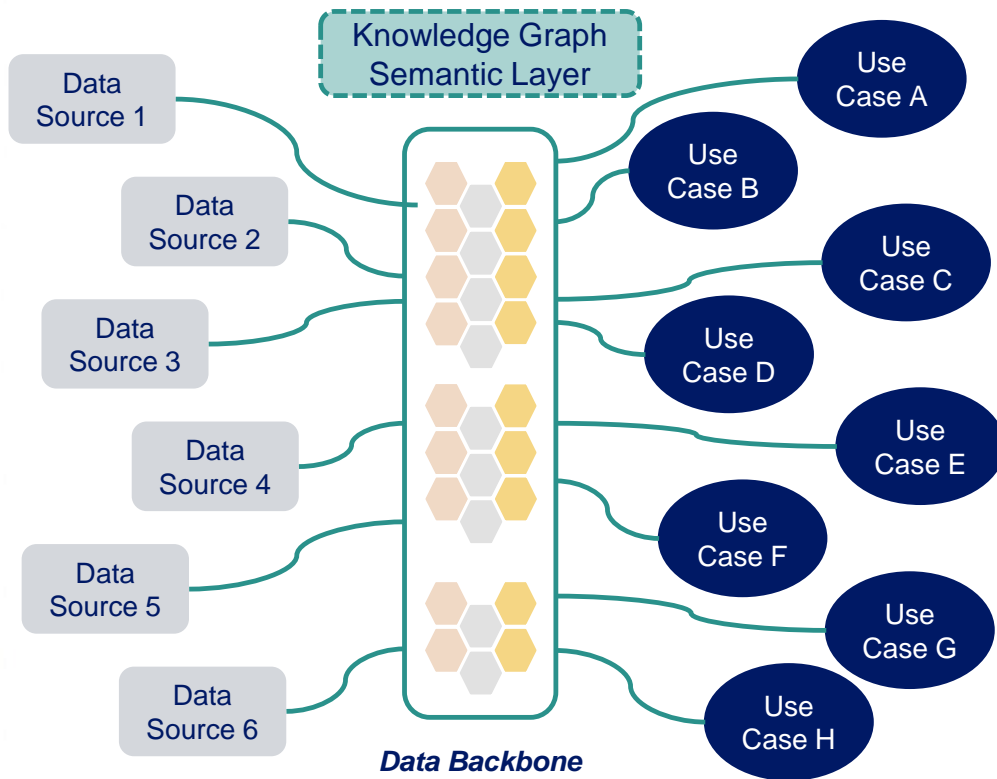
Tomorrow's **opportunity** for efficiency and speed



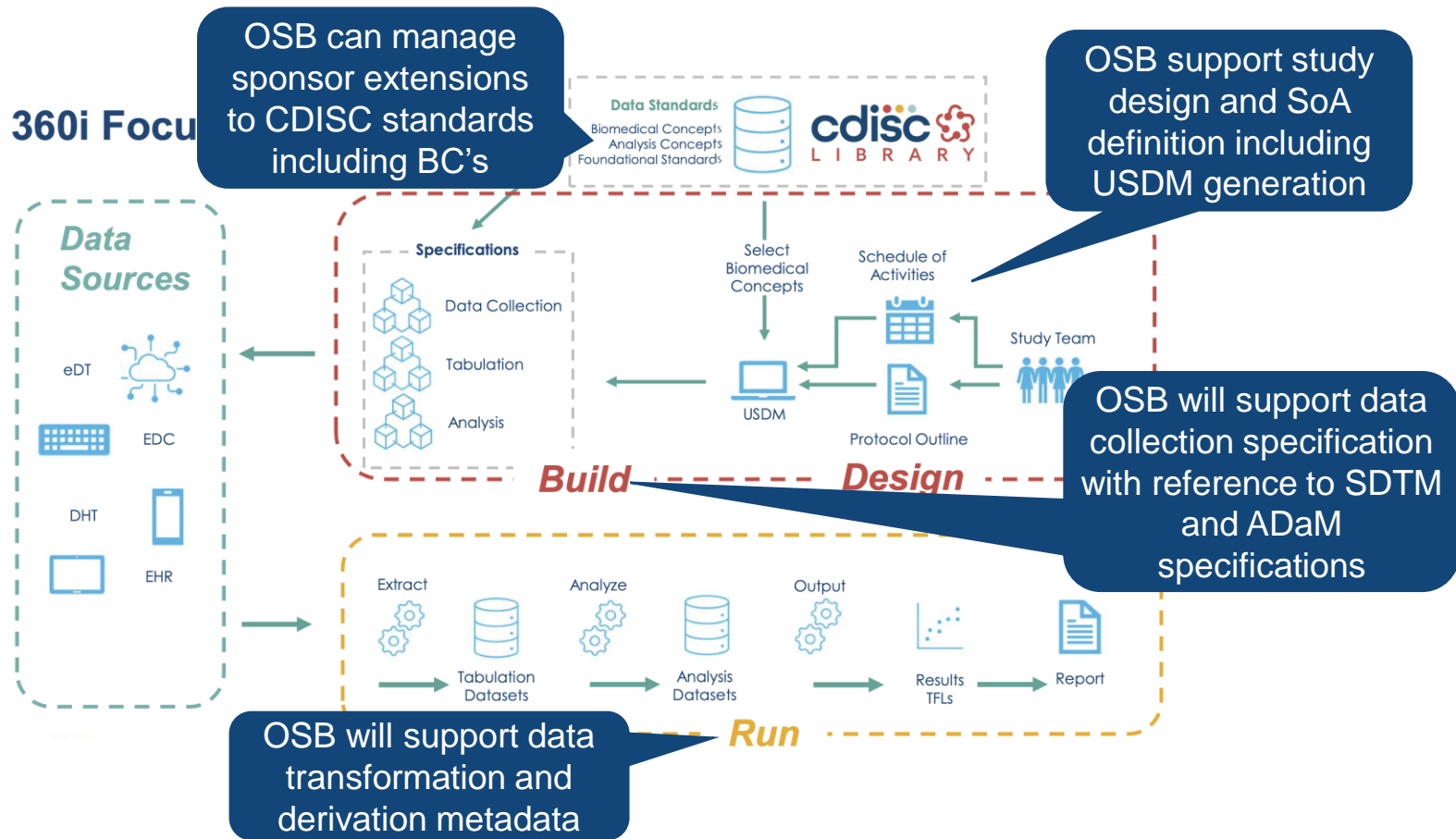
Many to **One** to Many

- Overview and transparency
- End-to-end consistency
- Efficiency through reuse
- Faster from data availability to data readiness

Tomorrow's **opportunity** for efficiency and speed



How do OSB fit into 360i vision



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

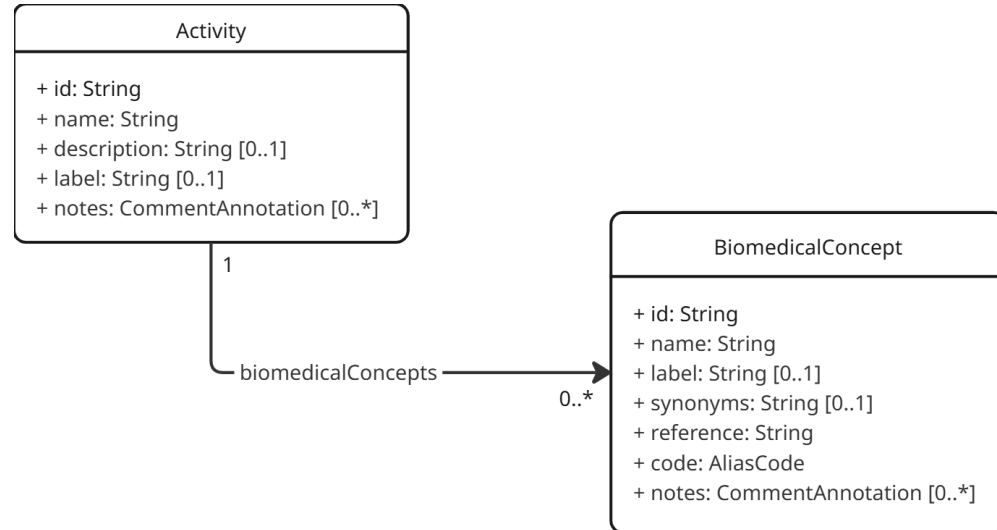
3 ELEMENTS OF OpenStudyBuilder

- **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 Endpoint – enabling DDF SDR Compatibility)



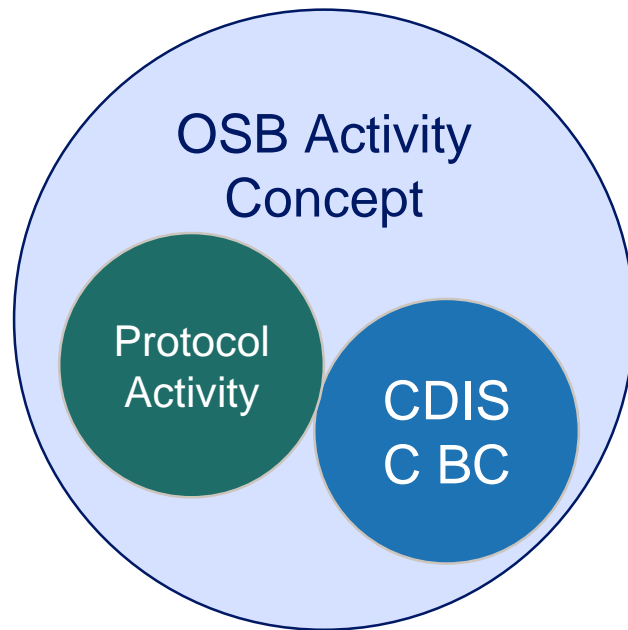
CDISC BCs and Activities in USDM

- **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)

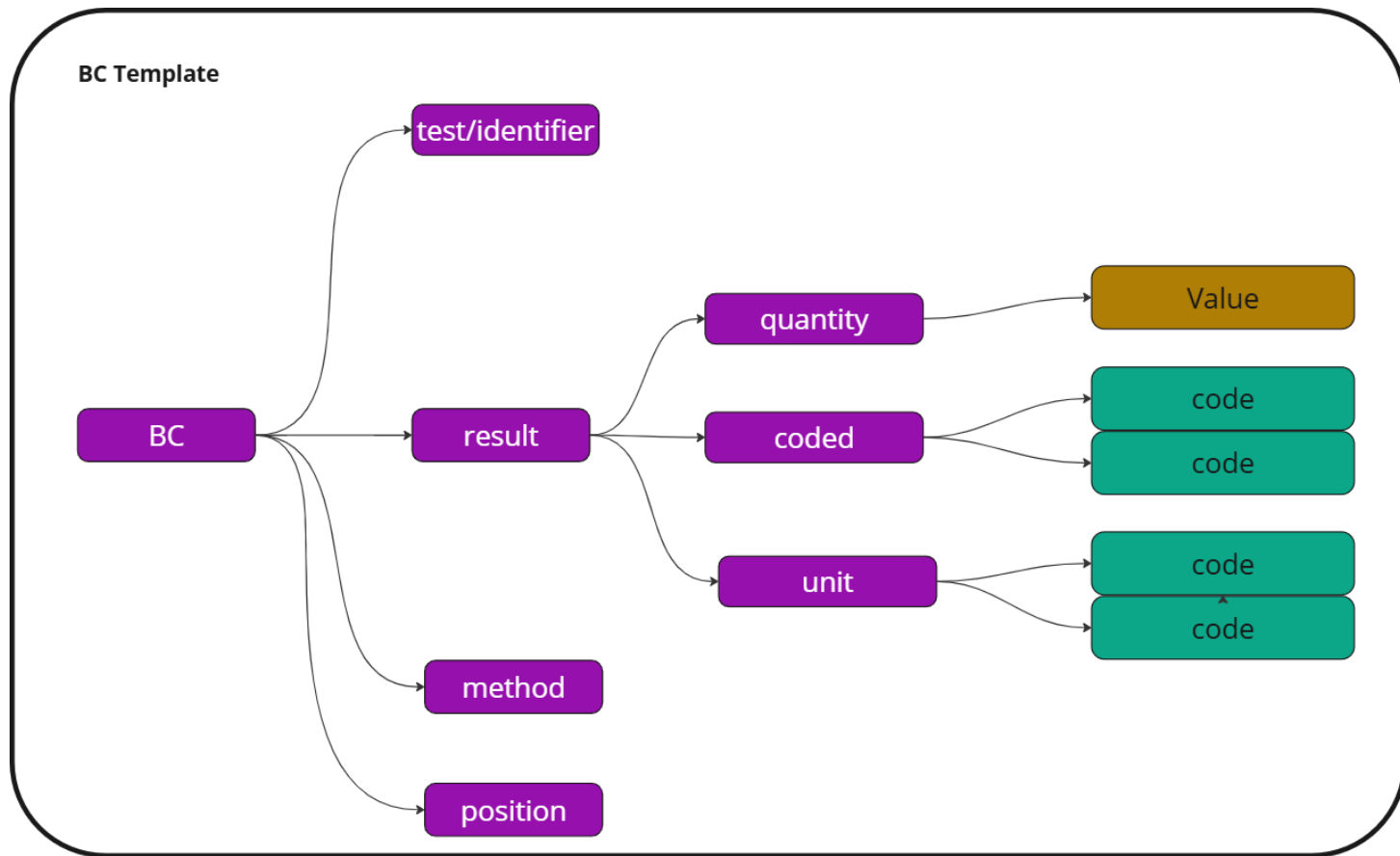


OSB BCs and Activities

- **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**

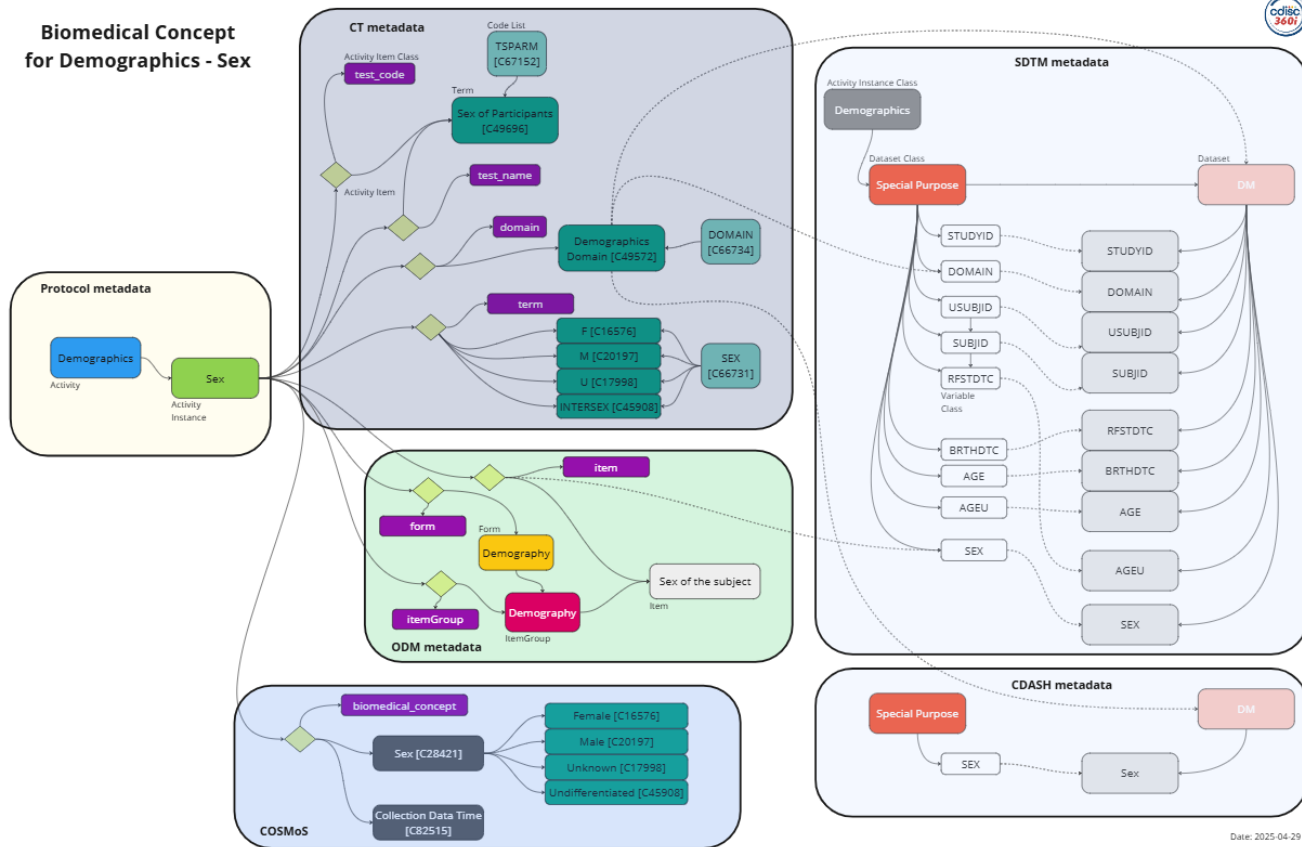


BC idea



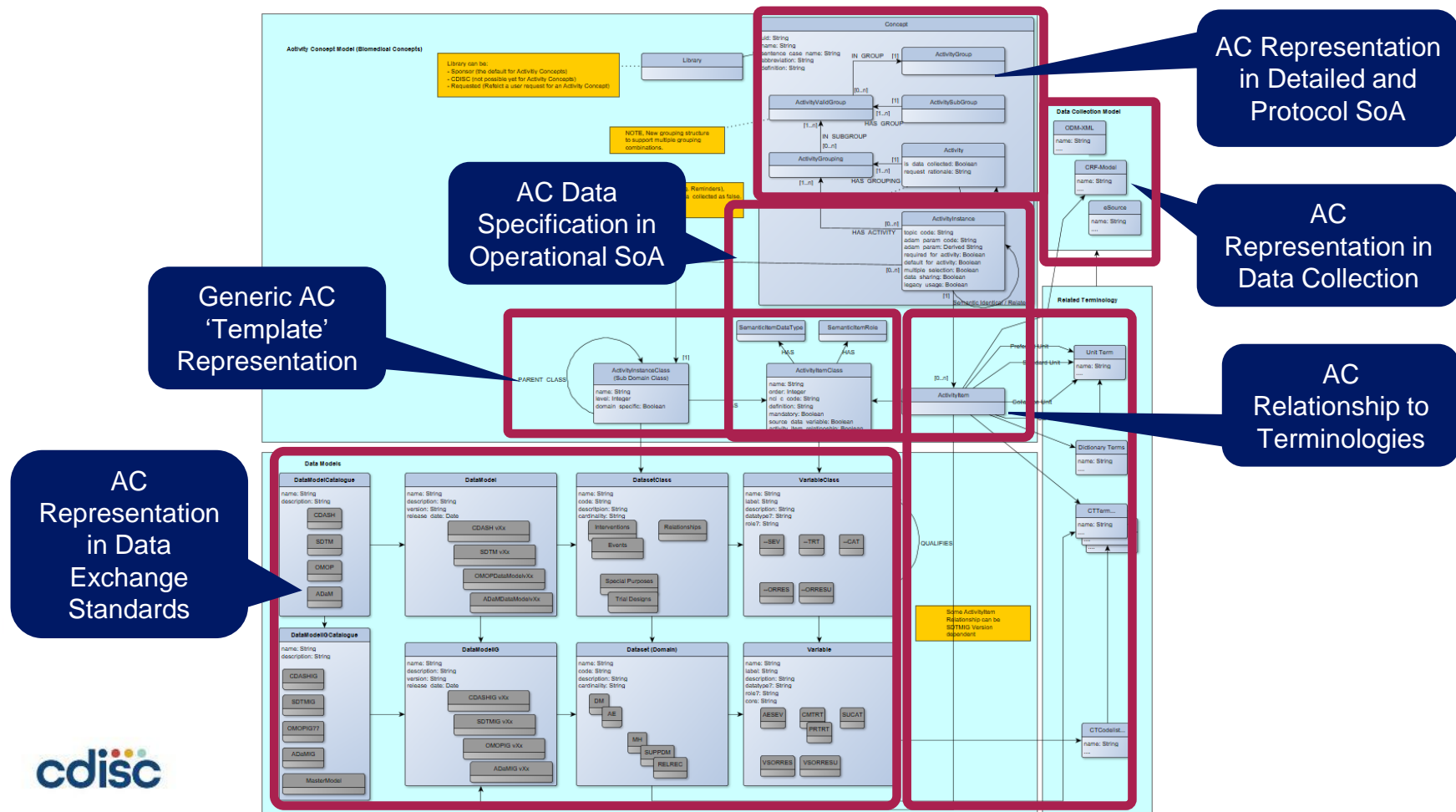
BC vision in OSB

Biomedical Concept for Demographics - Sex



Date: 2025-04-29

Activity Concept (AC) data model in StudyBuilder



OpenStudyBuilder Activity Concept data model (BC)

ActivityGroup

CDISC BC: Seem to be similar a parent BC at a high level. Often demoed as a CRF form name.

ActivitySubgroup

OSB AC: Grouping of activities. The activity group or subgroup level can be what you decide to show in the protocol schedule of activities. May be like a CRF form names, but not necessarily, the clinical term relevant to show in the protocol.

Activity

CDISC BC: An action, undertaking, or event, which is anticipated to be performed or observed, or was performed or observed, according to the study protocol during the execution of the study.

OSB AC: If relating to data collection, resulting in a semantic logical observation, this can depend on context and qualifiers have different identifications. If not related to data collection, then to a semantic specific activity.

At the most detailed level as needed in protocol SoA

ActivityInstance

CDISC BC: Similar to a SDTM specialisation (but for an ADaM PARAM).

OSB AC: The specific identification of the semantic logical observation, this includes reference to context and qualifier values. Primary identification is for ADaM BDS PARAM/PARAMCD or column name in ADSL. Also include internal uid identification as well as internal topic code.

ActivityItem

CDISC BC: Similar to SDTM Variable but can be connected to any data exchange standards.

OSB AC: Linking to related data model variables as well as terminology codes.

OPEN
STUDY
BUILDER

Studies

Library

Reports

SELECT STUDY

MT (MIKKEL TRAUN)

<<

About Library

Process Overview

Code Lists

Dictionaries

Concepts

Activities

Units

CRFs

Syntax Templates

Template Instantiations

Template Collections

Data Exchange Standards

Admin Definitions

List

Library / Concepts / Activities / Activities Instances / Systolic Blood Pressure

Systolic Blood Pressure

OverviewOSB YAMLCOSMoS YAML

Name

Systolic Blood Pressure

Sentence case name

systolic blood pressure

Version

1.0

Status

Final

Start date

Apr 22, 2024, 1:15 PM

End date

None

Definition

Activity instance class

NumericFinding

Abbreviation

Library

Sponsor

NCI Concept ID

ADaM parameter code

SYSBP

Topic code

BP_SYSTOLIC

Diastolic Blood Pressure

Overview OSB Yaml COSMoS Yaml

Library Sponsor

Name Diastolic Blood Pressure

Topic code BP_DIASTOLIC

Activity instance class NumericFinding

Definition None

Abbreviation None

Required for activity No

Data sharing Yes

Sentence case name diastolic blood pressure

ADaM parameter code DIABP

NCI concept ID None

Default selected for activity No

Legacy usage No

Version 1.0 **Status** Final

Start date Oct 7, 2024, 3:17 AM **End date** None

Activity groupings

Activity group	Activity subgroup
Vital signs	Vital signs

Activity

Library	Name	Definition	Version	Status
Sponsor	Vital signs	None	1.0	Final

Activity items

Activity item class	Name	Value	Role [CTCodelist_xxxxx]	Data type [CTCodelist_xxxxx]	CRF metadata	Data collection	Tabulation
Unit dimension [unit_dimension]	Pressure			CT term			
Original result [original_result]	Diastolic Blood Pressure		Result Qualifier	Value	Systolic blood pressure [I_DIASBP]	V51.SY5BP V52.SY5BP...	--ORRES
Original unit [original_unit]	Original unit	mmHg*BPM kPa mmHg Pa	Variable Qualifier	Unit definition	Systolic blood pressure unit [I_DIASBP]	V51.SY5BPU V52.SY5BPU...	
Test name [test_name]	Diastolic Blood Pressure		Synonym Qualifier	CT term			--TEST
Test code [test_code]	Diastolic Blood Pressure			CT term			--TESTCD
Standard unit [standard_unit]	Standard unit	mmHg	Variable Qualifier	Unit definition			--ORRESU
Domain [domain]	Vital Signs Domain		Identifier	CT term			V5
Location [location]	Location	Arm	Record Qualifier	CT term	Arm location [I_ARM]	V51.ARM V52.ARM...	--LOC
Position [position]	Position	Sitting Standing	Record Qualifier	CT term	Position [I_POS]	V51.POS V52.POS...	--POS
Laterality [laterality]	Laterality	Left Right	Record Qualifier	CT term	Laterality [I_LAT]	V51.LAT V52.LAT...	--LAT
Collection datetime [collection_datetime]	Collection datetime		Timing	Datetime	Visit date [I_VISIDATE]		--DTC

neo4j Labs

neo4j/vm-db-fv7zbjhkegyw.clinicalmdr-dev.corp.azure.novonordisk.com:7687

StudyBuilder Activity Library Dashboard

ReadMe
Activity Lib (search top-down)
Activity Lib (search bottom-up)
Activity to SDTM
Activity in COSMOS format
Activities used in Studies
+

Select Activity Instance

ActivityGroup	ActivitySubGroup	Activity	ActivityInstance
Adverse Event	Adverse Event	Adverse Event	<button>AE</button>
Laboratory Assessments	Biochemistry	Alanine	<button>ALAP</button>
AE Requiring Additional Data	Laboratory Assessment	Alanine Aminotransferase	<button>ALT</button>
Laboratory Assessments	Biochemistry	Alanine Aminotransferase	<button>ALTS</button>
AE Requiring Additional Data	Laboratory Assessment	Albumin	<button>ALBU2</button>

96-90 of 1000 < >

Select SDTM version

Click	IG	Description	Effective Date	Version Number
<button>SELECT</button>	SDTMIG v3.4	This is the implementation guide for human clinical trials corresponding to Version 2.0 of the CDISC Study Data Tabulation Model.	2021-11-29	3.4
<button>SELECT</button>	SDTMIG v3.3	CDISC Version 3.3 (v3.3) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to guide t	2018-11-20	3.3
<button>SELECT</button>	SDTMIG v3.2	CDISC Version 3.2 (V3.2) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to guide t	2013-11-26	3.2
<button>SELECT</button>	SDTMIG v3.1.3	CDISC Version 3.1.3 (V3.1.3) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to gu	2012-07-16	3.1.3
<button>SELECT</button>	SDTMIG v3.1.2	CDISC Version 3.1.2 (V3.1.2) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) is intended to gu	2008-11-12	3.1.2

1-5 of 5 < >

Activity mapped to SDTM

Activity	Activity Instance	Activity Item Class	Variable Class	SDTMIG Variable	SDTMIG Dataset
Albumin	Urinary Albumin Excretion	domain	DOMAIN	Domain Abbreviation	Labs
Albumin	Urinary Albumin Excretion	test_name_code	--TESTCD	Lab Test or Examination Short	Labs
Albumin	Urinary Albumin Excretion	test_name_code	--TEST	Lab Test or Examination Name	Labs
Albumin	Urinary Albumin Excretion	specimen	--SPEC	Specimen Type	Labs

Rows per page: 5 1-4 of 4 < >

Activity with links to SDTM

<<

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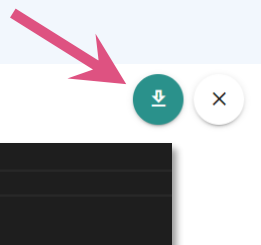
List

Library / Concepts / Activities / Activities Instances / Systolic Blood Pressure

Systolic Blood Pressure ?

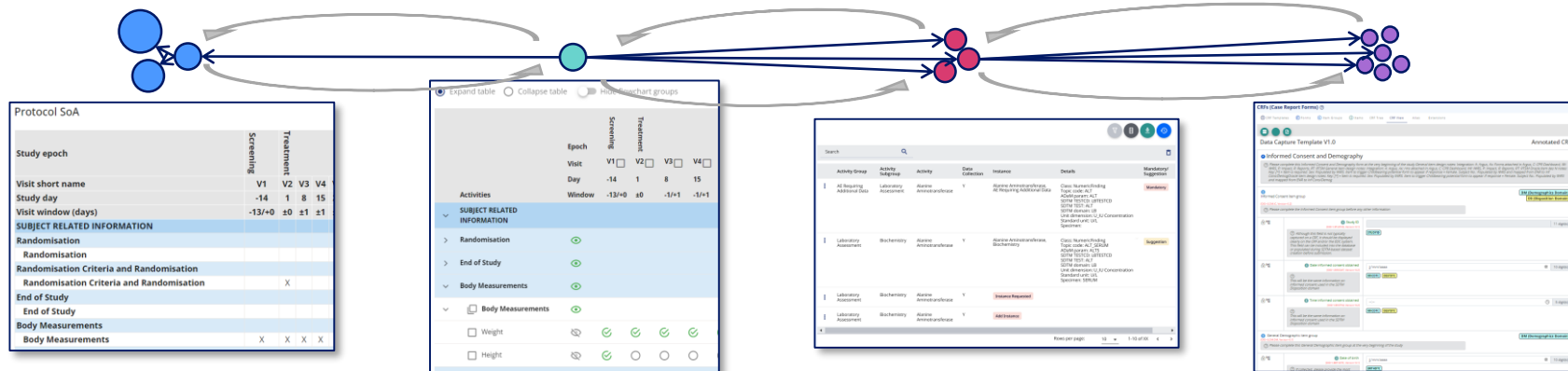
Overview OSB YAML COSMoS YAML

OSB Activity Concepts is made compatible with COSMoS model



```
categories:
- Vital Signs
conceptId: null
dataElementConcepts:
- conceptId: C117221
  dataType: string
  exampleSet: []
  href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C117221
  ncitCode: C117221
  shortName: original_result
- conceptId: C82586
  dataType: string
  exampleSet:
  - mmHg
  href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C82586
  ncitCode: C82586
  shortName: original_unit
- conceptId: C82515
  dataType: Date time
  exampleSet: []
  href: https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C82515
  ncitCode: C82515
  shortName: collection_datetime
```

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 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



Activity Concepts := Biomedical Concepts

- **Can be linked to from:**

- Objectives
- Endpoints
- Criteria
- Analysis Concepts

- **Will link to**

- Protocol representation
- Data Specification
- Data Collection Specification

- **Will support automation in**

- Protocol Document Generation
- Data Collection system setup
- Data ingestion verification
- SDTM generation
- ADaM generation

USDM and M11 as an export format

Studies / View Specifications / USDM

USDM version of the Protocol / USDM version: 3.6.0

```
{
  "id": "784d9d41-1399-4b29-92e3-52231a38d79",
  "name": "CDISC DEV-0000",
  "description": "Safety and Efficacy of the Xanomeline Transdermal Therapeutic System TSS in Patients with Mild to Moderate Alzheimer's Disease",
  "label": "Xanomeline (LY246708)",
  "versions": [
    {
      "id": "846d8cf1-cdeb-4a26-9e64-b123c7edbf",
      "versionIdentifier": "None",
      "rationale": "",
      "studyType": [
        {
          "id": "d9f19af-e5b-4251-8b74-c91a9e4b2c1f",
          "code": "C98388_INTERVENTIONAL",
          "codeSystem": "openstudybuilder.org",
          "codeSystemVersion": "",
          "decode": "",
          "instanceType": "Code"
        }
      ],
      "studyPhase": [
        {
          "id": "57b3d958-d961-4237-8d4c-2d34aaa5fde",
          "standardCode": [
            {
              "id": "e3d21879-d080-4513-ba82-19d390931a5",
              "code": "C15081_PHASE_II_TRIAL",
              "codeSystem": "openstudybuilder.org",
              "codeSystemVersion": "",
              "decode": "",
              "instanceType": "Code"
            }
          ],
          "standardCodeAlliances": [],
          "instanceType": "AliasCode"
        }
      ],
      "documentVersionIds": [],
      "dateValues": [],
      "amendments": [],
      "businessTherapeuticAreas": [],
      "studyIdentifiers": [
        {
          "id": "CDISC DEV-0000",
          "text": "",
          "scopeId": "NOVO NORDISK",
          "instanceType": "StudyIdentifier"
        }
      ]
    }
  ]
}
```

Studies / View Specifications / ICH M11

ICH M11 version of the protocol

ICH M11 Template - Study Study_000019

Protocol Full Title:	Safety and Efficacy of the Xanomeline Transdermal Therapeutic System TSS 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:	CDISC DEV-0000 [Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
Protocol Number:	Study_000019_DRAFT [Protocol Number] 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 US). 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:	C15081_PHASE_II_TRIAL [Trial Phase], [Description of Trial Phase Other]
Acronym:	Study_000019 [Protocol Acronym] Acceptable entries are "Early Phase 1", "Phase 1", "Phase 2", "Phase 3", "Phase 4", or "Other", for trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
Short Title:	Study_000019 [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 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 organization, or other organization 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 M11 as an export format - 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, for example, 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												
END OF STUDY												
End of Study												
End of Study												
BODY MEASUREMENTS												
Body Measurements												
Weight												
Height												
ELIGIBILITY CRITERIA												
Eligibility Criteria												
Eligibility Criteria Met												
ECG												
12 Lead ECG, Single Recording												
QTcF Interval, Aggregate												
EFFICACY ^A												
LABORATORY ASSESSMENTS ^A												
Glucose Metabolism ^a												
HbA1c ^a												
SAFETY ^A												
LABORATORY ASSESSMENTS												
Lipids												
HDL Cholesterol ^a												



Plans for OSB in CDISC 360i

Sponsor end-to-end Standards

- Import from CDISC Library
- Extensions, including sponsor BC's
- Share Sponsor BC's to CDISC curation

Build

- ODM.XML data collection specification including SDTM annotations
- Lab data specifications

Design

- Define Study Design and SoA
- Generate USDM
- Preview structured study design content in ICH M11 template

Run

- SDTM and ADaM data metadata specifications
- Data transformation and derivation metadata specification



Thank You!

Questions or need more information

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Nicolas De Saint Jorre, ndjz@novonordisk.com

OpenStudyBuilder contact: OpenStudyBuilder@gmail.com

