



cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

From USDM to M11 and back: OpenStudyBuilder as the Round-Trip engine

Mikkel TRAUN, Principal IT Solution Architect, Novo Nordisk A/S

Nicolas de SAINT JORRE, Senior Lead Product Architect, Manager, Novo Nordisk France

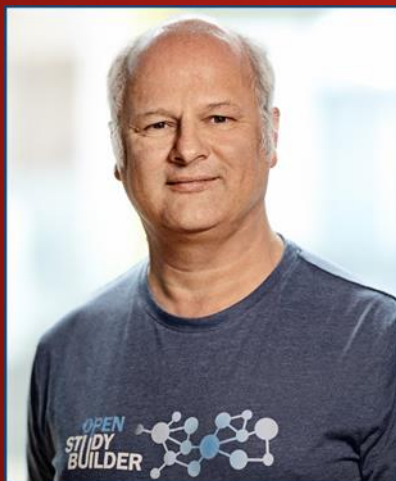
Speakers



Nicolas de Saint Jorre

Senior Lead Product Architect, Manager

More than 32 years of experience in the world of Data Management and Clinical Research, since 2000, working on EDC system. Since 2005: I was working with EvidentIQ (EDC vendor with CDISC compliance). I contributed to the CDISC360 project since 2018 setting up a prototype of 'Study Builder' using a central library of metadata. Since 2019, I was working with Novo Nordisk on the OpenStudyBuilder. And since April 2023, I am a Product Architect at Novo Nordisk, mainly working on the OpenStudyBuilder, with a deep connection with the TransCelerate Digital Data Flow project.



Mikkel Traun

Principal IT Solution Architect, 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.



What is OpenStudyBuilder?

Core Components:

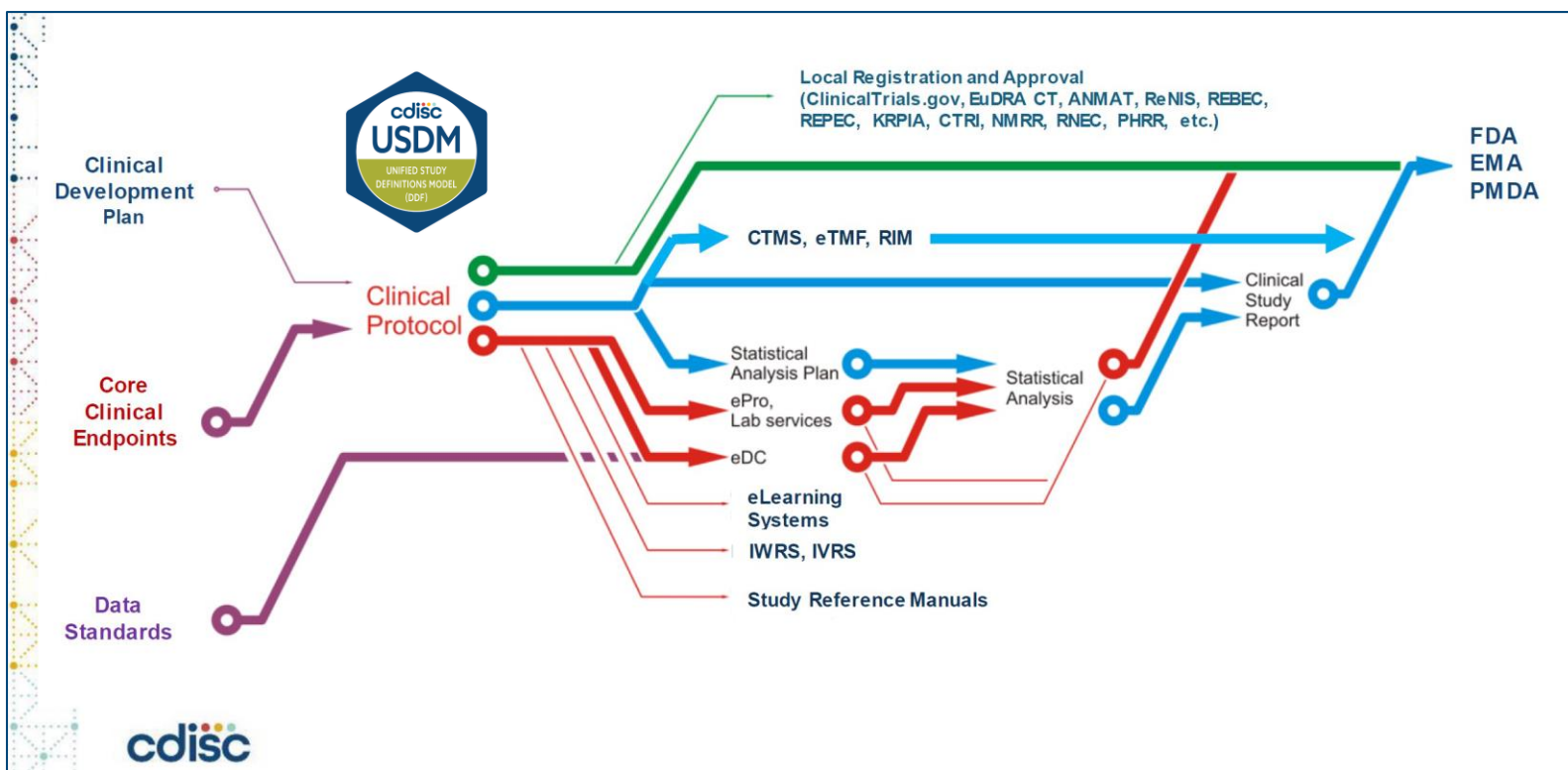
- The OpenStudyBuilder application
(web-based user interface)
- The clinical Metadata Repository and Study Definition Repository - MDR & SDR
(central storage, graph database)
- The API layer
(enabling interoperability with other systems)



RETHINKING
CLINICAL
DEVELOPMENT
THROUGH
DIGITAL
INNOVATION

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

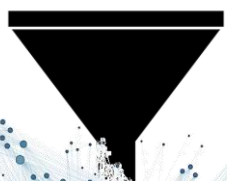
USDM Enabling the Digital Data Flow



OpenStudyBuilder
as ecosystem
managing data
and metadata
including provision
in USDM



Old world...



OpenStudyBuilder



From USDM to M11 and Back: OpenStudyBuilder as the Round-Trip Engine

Context

- USDM and M11 standards streamline study and protocol definition exchange, enabling end-to-end automation across systems
- OpenStudyBuilder is an open-source metadata repository that natively supports USDM and M11 exports (JSON, HTML), not including yet narrative content (on the road map)
- Its API and open interfaces enable connectivity with other USDM-compliant systems

Objectives

- Demonstrate how OpenStudyBuilder serves as a round-trip engine between USDM and M11 formats
- Showcase M11 preview capabilities for structured content review and management
- Discuss challenges faced and opportunities from adopting the USDM standard

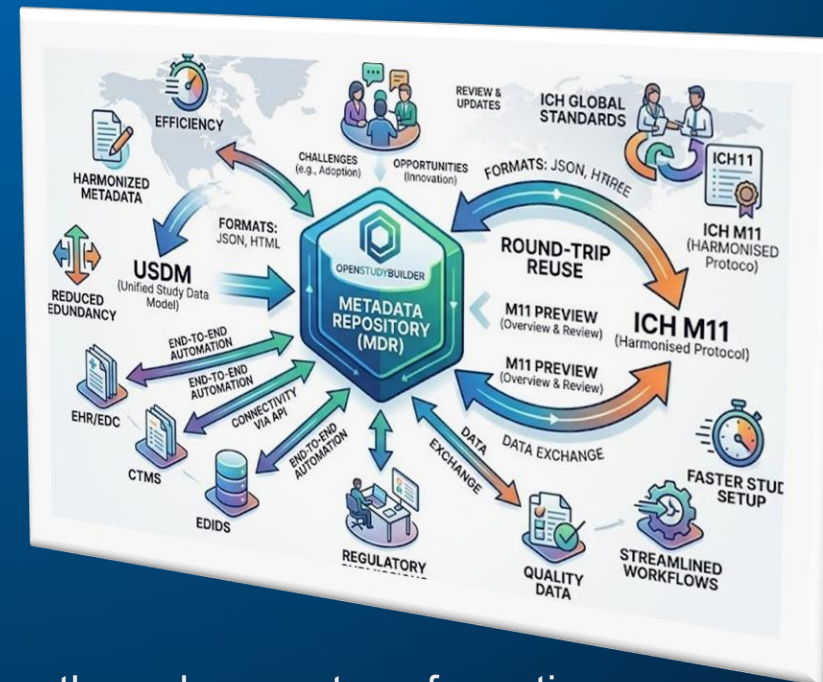
The Problem: Standards Adoption Needs Interoperable Metadata

Today

- USDM↔M11 translation is treated as a technical task, but impacts traceability, rework cycles, and project timelines
- Conformance is assembled manually across disconnected tools and teams
- Metadata gaps and inconsistencies lead to costly rework and delayed submissions

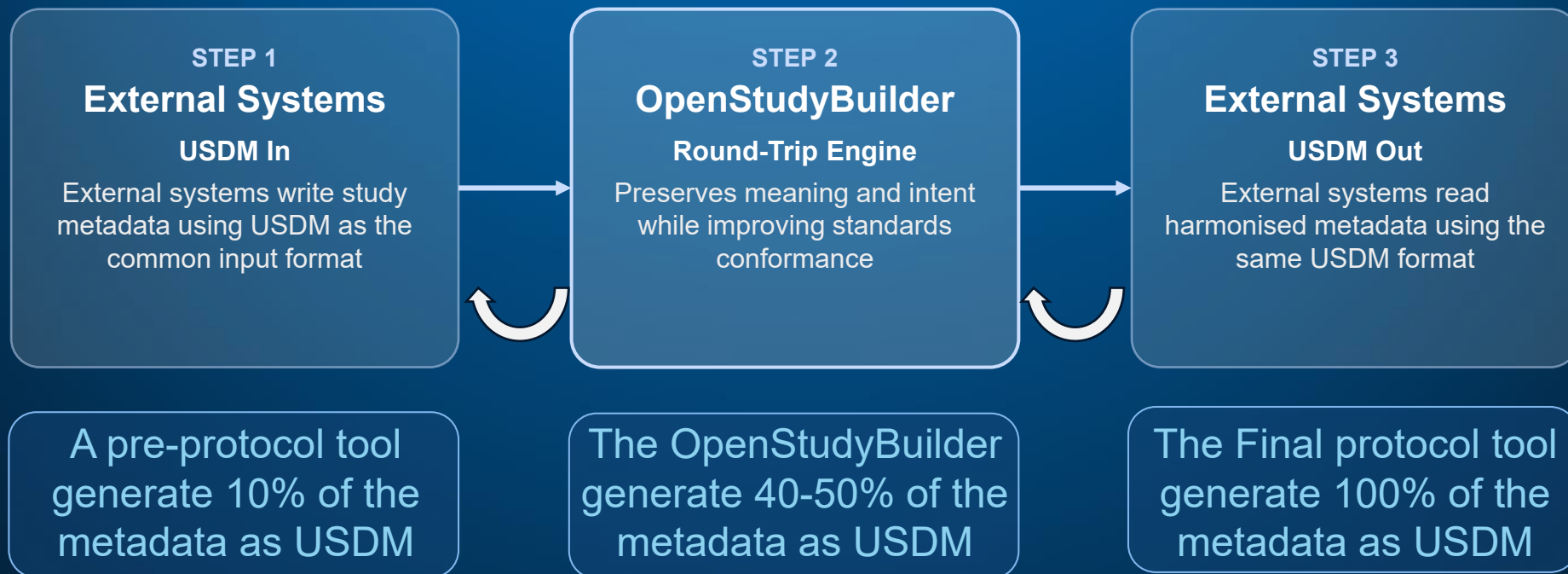
With Interoperable Metadata

- Round-trip fidelity preserves traceability from source through every transformation
- A shared standard eliminates redundant mapping work and reduces rework
- Teams and tools converge on one conformance path, accelerating timelines



The “Universal Format” Strategy Using USDM

USDM serves as the common format before and after OpenStudyBuilder, enabling a seamless round trip

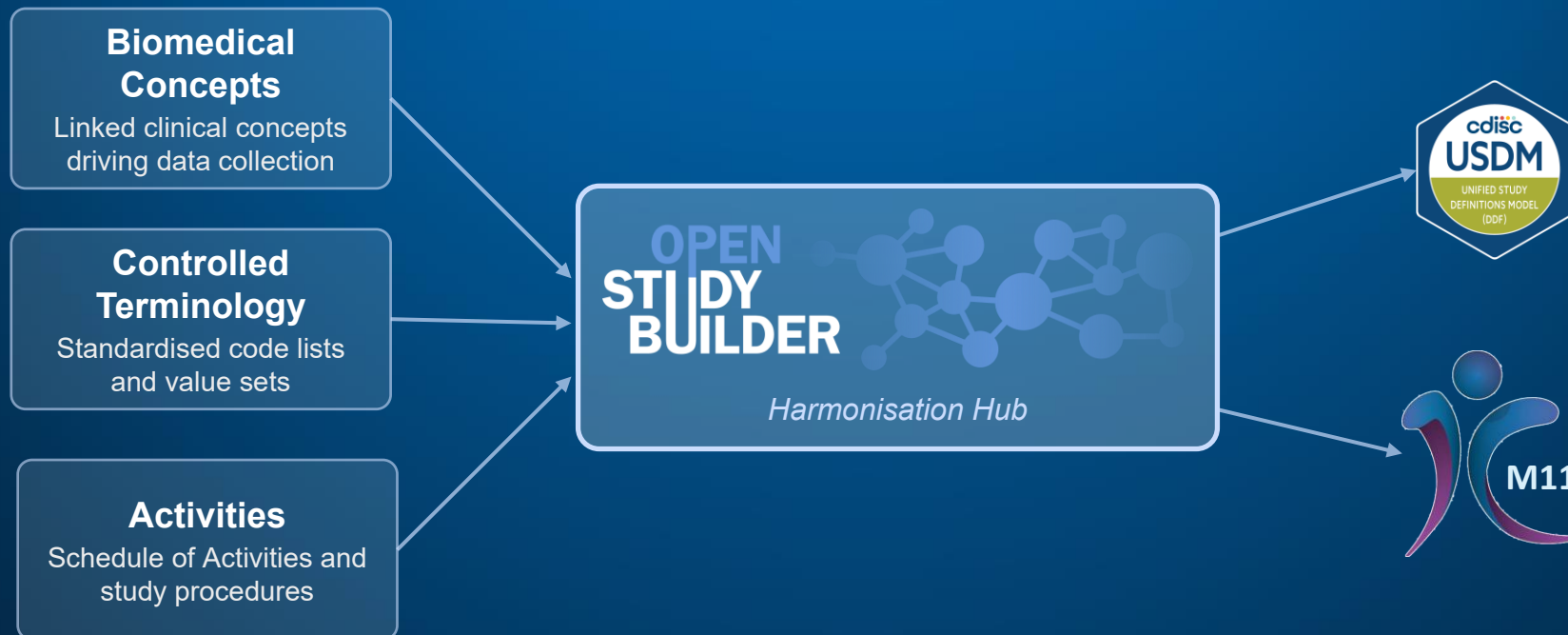


Novo Nordisk
vision

Key Principle

- USDM is the universal read/write format — the same structure goes in and comes out
- OpenStudyBuilder enriches and harmonises, but never breaks the round trip

End-to-End Harmonisation in the Workflow



Where Harmonisation Occurs

- **Structural alignment** — study definitions conform to USDM and M11 structural requirements
- **Terminology and semantics consistency** — controlled terminology and biomedical concepts remain consistent end to end
- **Constraints and validation posture** — validation rules enforced at every transformation step



Conformance Journey (0% → 100%) and the OSB “Middle Layer”



What OSB Contributes as the Round-Trip Engine

- Generates the first 40–50% of conformance through structured metadata, controlled terminology, and USDM alignment
- Feeds harmonised output into downstream systems (NovoScrib, Word) while maintaining round-trip fidelity



Demo
time

CT Catalogues

All ADAM CT CDASH CT COA CT DDF CT DEFINE-XML CT GLOSSARY CT MRCT CT PROTOCOL CT QRS CT QS-FT CT SDTM CT SEND CT TMF CT

Search Search with terms or Select rows

	Library	Sponsor preferred name	Type	Template parameter	Code list status	Name modified	Concept ID	Submission value	Code
:	CDISC	Category of Questionnaire	Standard	No	FINAL	Sep 26, 2014, 2:00 AM	C100129	QSCAT	Cat
:	CDISC	Relationship to Subject	Standard	No	FINAL	Sep 26, 2014, 2:00 AM	C100130	RELSUB	Rel
:	CDISC	Alzheimer's Disease Assessment Scale - Cognitive CDISC Versi...	Standard	No	FINAL	Sep 27, 2024, 2:00 AM	C100131	ADCTN	Alzi
:	CDISC	Alzheimer's Disease Assessment Scale - Cognitive CDISC Versi...	Standard	No	FINAL	Sep 27, 2024, 2:00 AM	C100132	ADCTC	Alzi
:	CDISC	Brief Psychiatric Rating Scale- Anchored Clinical Classificat...	Standard	No	FINAL	Sep 30, 2022, 2:00 AM	C100133	BPRSA1TN	Brie
:	CDISC	Brief Psychiatric Rating Scale- Anchored Clinical Classificat...	Standard	No	FINAL	Sep 30, 2022, 2:00 AM	C100133	BPRSA1TN	Brie
:	CDISC	European Quality of Life Five	Standard	No	FINAL	Sep 30, 2022, 2:00 AM	C100133	BPRSA1TN	Brie

OPEN
STUDY
BUILDER



Activities

Activities Activity Groups Activity Subgroups Activities by Grouping Activity Instances Activity Instance Classes Activity Item Classes

All Final Retired Draft

Search Select rows

	Library	Activity group	Activity subgroup	Activity	Activity instance class	Activity Instance ↑	NCI Concept ID
:	Sponsor	Laboratory Assessments	Glucose Metabolism	1-5-Anhydroglucitol	NumericFindings	1-5 AG (Anhydroglucitol)	
:	Sponsor	Laboratory Assessments	24 Hour Urine Collection	24 Hours Urine Collection	NumericFindings	24 Hours Urine Collection	
:	Sponsor	Laboratory Assessments	Hormones	25-Hydroxyvitamin D3	NumericFindings	25-Hydroxyvitamin D	
:	Sponsor	Clinical Outcome Assessments	Performance Outcome	6-Minute Walk Test	NumericFindings	6 Minute Walk Test - Distance at 1 Min	
:	Sponsor	Clinical Outcome Assessments	Performance Outcome	6-Minute Walk Test	NumericFindings	6 Minute Walk Test - Distance at 2 Min	
:	Sponsor	Clinical Outcome Assessments	Performance Outcome	6-Minute Walk Test	NumericFindings	6 Minute Walk Test - Distance at 3 Min	
:	Sponsor	Clinical Outcome Assessments	Performance Outcome	6-Minute Walk Test	NumericFindings	6 Minute Walk Test - Distance at 4 Min	
:	Sponsor	Clinical Outcome Assessments	Performance Outcome	6-Minute Walk Test	NumericFindings	6 Minute Walk Test - Distance at 5 Min	
:	Sponsor	Clinical Outcome Assessments	Performance Outcome	6-Minute Walk Test	NumericFindings	6 Minute Walk Test - Distance at 6 Min	
:	Sponsor	Physical	Physical Examination	Abnormal	CategoricalFindings	Abnormal	

Rows per page: 10 1-0 of 0

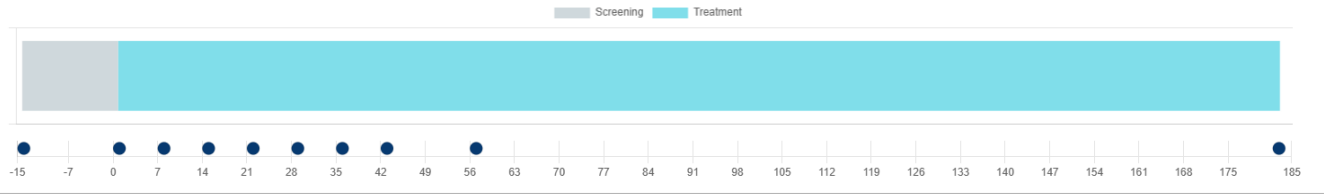
Study Structure (CDISC DEV-0)

Overview Study Arms Study Branches Study Cohorts Study Epochs Study Elements Study Visits Design Matrix Disease Milestones

Study Visits

Time line preview

Time unit: Day Week



Search Select rows

	Epoch	Visit type	SoA Milestone	Visit Class	Visit Subclass	Repeating frequency	Visit name	Anchor visit in visit group	Visit group
:	Screening	Screening	No	Scheduled visit	Single visit		Visit 1	No	
:	Treatment	Treatment	No	Scheduled visit	Single visit		Visit 2	No	
:	Treatment	Treatment	No	Scheduled visit	Single visit		Visit 3	No	



Study Visits Def.

Study Structure (CDISC DEV-0) ⓘ

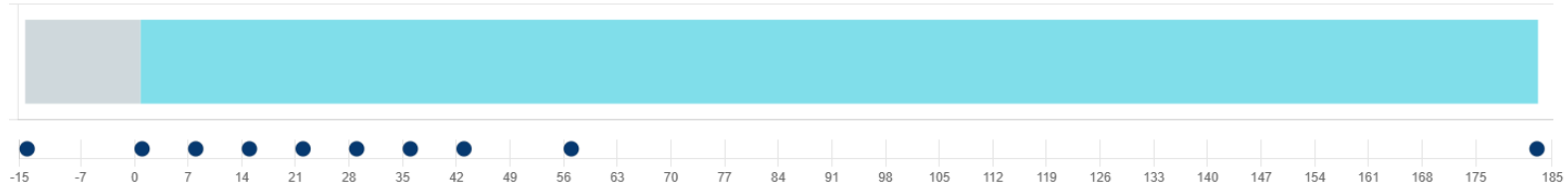
Overview Study Arms Study Branches Study Cohorts Study Epochs Study Elements Study Visits Design Matrix Disease Milestones

Study Visits

Time line preview

Time unit: ☒ Day ☐ Week

Screening Treatment



Search ☐ Select rows



	Epoch	Visit type	SoA Milestone	Visit Class	Visit Subclass	Repeating frequency	Visit name	Anchor visit in visit group	Visit group
⋮	Screening	Screening	No	Scheduled visit	Single visit		Visit 1	No	
⋮	Treatment	Treatment	No	Scheduled visit	Single visit		Visit 2	No	
⋮	Treatment	Treatment	No	Scheduled visit	Single visit		Visit 3	No	



Study Activities

PROTOCOL

☐ Expand table

Complexity score: **22.9**



				Screening												Treatment											
Epoch																											
Visit				V1		V2		V3		V4		V5		V6		V7		V8		V9		V10					
Study week				-2		0		1		2		3		4		5		6		8		10					
Visit window (days)				-13/0		0		±1		±1		±1		±1		±1		±1		±1		±1					
>	:	LABORATORY ASSESSMENTS																									
>	:	AE REQUIRING ADDITIONAL DATA																									
>	:	ADVERSE EVENT																									
✓	:	VITAL SIGNS																									
✓	:	VITAL SIGNS																									
:		☐ Systolic Blood Pressure		✓		✓		☐		✓		☐		✓		☐		✓		☐		✓					
:		☐ Diastolic Blood Pressure		✓		✓		☐		✓		☐		✓		☐		✓		☐		✓					
:		☐ Pulse Rate		✓		☐		✓		✓		☐		☐		☐		✓		☐		✓					
>	:	MEDICAL HISTORY/CONCOMITANT ILLNESS																									



USDM for this Study

Study CRF (CDISC DEV-0) ?

F 1 Forms G 2 Item Groups I 9 Items ! 3 Missing Activity Instances

MANAGE FORMS ⚙

⌵ COLLAPSE ALL

▼ F Vital Signs UPDATED 2 E.V.S. 👁

▼ G Vital Signs 3 G.V.S.VS 👁

I Study ID I.STUDYID3 👁

I Subject No. [read-only] I.SUBJID3 👁

I Date of examination I.VSDAT 👁

▼ G Blood pressure and pulse 6 G.VS.BPP 👁

I Position I.POSITION 👁

I Anatomical Location I.LOC 👁

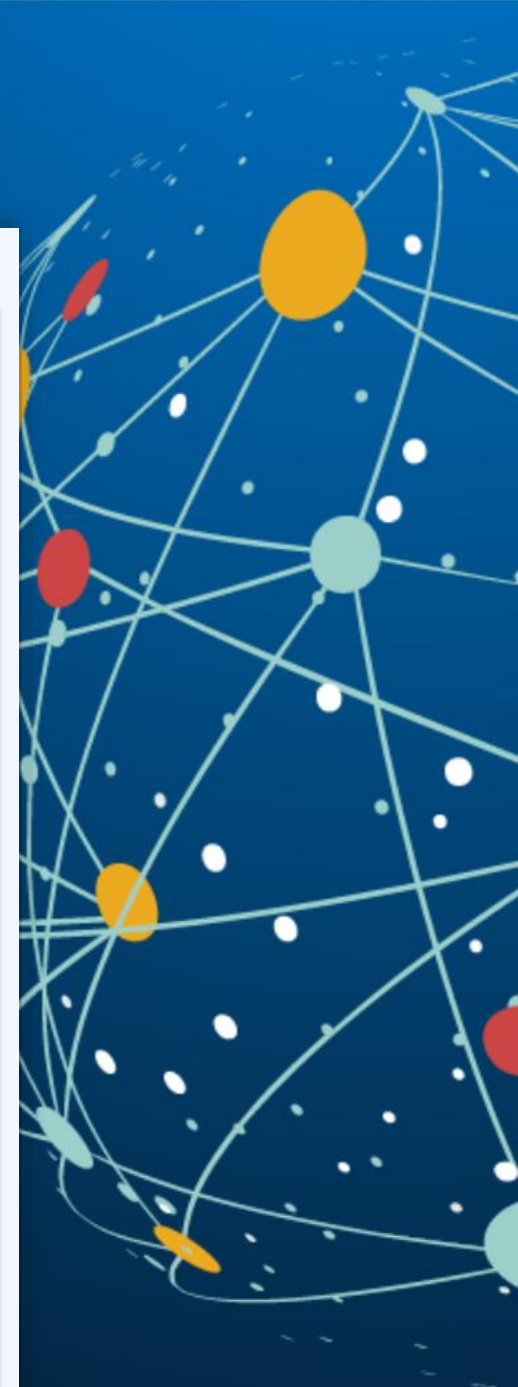
I Systolic blood pressure I.SYSBP Systolic Blood Pressure 👁

I Laterality I.LATERALITY Diastolic Blood Pressure Systolic Blood Pressure 👁

USDM version of the Protocol / USDM version: 4.0.0 ⓘ



```
{
  "study": {
    "id": "1cca5393-2e04-4e9b-8445-92ce4183d404",
    "name": "CDISC DEV-0",
    "description": null,
    "label": null,
    "versions": [
      {
        "id": "StudyVersion_1",
        "extensionAttributes": [],
        "versionIdentifier": "DRAFT",
        "rationale": "Missing metadata",
        "documentVersionIds": [
          "StudyDefinitionDocument_1"
        ],
        "dateValues": [],
        "amendments": [],
        "businessTherapeuticAreas": [],
        "studyIdentifiers": [
          {
            "id": "StudyIdentifier_1",
            "extensionAttributes": [],
            "text": "NCT12345678",
            "scopeId": "Organization_1",
            "instanceType": "StudyIdentifier"
          },
          {
            "id": "StudyIdentifier_2",
```





And the connected M11

ICH M11 version of the protocol

Version Number: ①	CDISC DEV-0 - DRAFT <Enter Version Number> For use by the sponsor at their discretion.	Instructional text Suggested text Fields
Version Date: ①	<Enter Version Date> For use by the sponsor at their discretion.	
{Amendment Identifier:} ①	{[Amendment Identifier]} Enter the amendment identifier (e.g., amendment number). If this is the original instance of the protocol, delete this row or enter "Not applicable".	
{Amendment Scope:} ①	{[Amendment Scope]} {[Country Identifier] or [Region Identifier] or <Enter Site Identifier>} ② If this is the original instance of the protocol, delete this row or enter "Not applicable". For an amendment that applies to all sites in the trial, enter "Global" and delete the Country, Region and Site Identifier fields. If amending a single-country trial, enter "Global". For an amendment that does not apply to all sites in the trial, select "Not Global" and utilise one of the identifiers based on amendment scope.	
Sponsor's Investigational Product Code(s): ①	<Enter Sponsor's Investigational Product Code(s)> Enter the sponsor's unique identifier for investigational product(s) in the trial. Add fields as needed.	
Investigational Product Name(s): ①	<Enter Nonproprietary Name(s)> ② <Enter proprietary Name(s)> ③ Omit nonproprietary name field if a nonproprietary name has not yet been assigned. Omit proprietary name field if not yet established.	
Trial Phase: ①	Phase 3 [Trial Phase] For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.	
Short Title: ①	None <Protocol Short Title> Short title should convey <u>in plain language</u> what the trial is about and should be 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 consent forms (ICF) and ethics committee submissions.	
Sponsor Name and Address: ①	Novo Nordisk A/S Novo Allé, 2880 Bagsvaerd Denmark Tel: +45 4444 8888 <Enter Sponsor Name> ②	

Challenges in OSB USDm support

OSB **priorities** are focused on **legacy system replacement** and current business needs – not future USDm compatibility!

In OSB study values are based on **sponsor defined library elements** – in USDm many values are **free text**

OSB SoA metadata model is linked to **protocol SoA** in section 1 as well as **details in section 8 and appendixes** – all linked to **connector model** for data collection and down stream data flows.

OSB continue development on **USDm compatibility**, and support USDm model development

OSB will continue **BC model development** and contribute to 360i

OSB model is **more granular than USDm**
- In a way an extension to USDm
- OSB main goal is to support **reuse** and **automation**, secondly USDm compatibility!



Thank You! Questions?

- Questions or need more information

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- OpenStudyBuilder contact: OpenStudyBuilder@gmail.com

