



CDISC 360i & OpenStudyBuilder: From Vision to Implementation

Rhona O'Donnell, VP Data Standards & Integration
Mikkel Traun, Principal Solution Architect
Novo Nordisk A/S

Meet the Speakers

Rhona O'Donnell

Title: VP, Data Standards & Integration

Organization: Novo Nordisk A/S



Rhona is a Business Owners of OpenStudyBuilder, the next generation study builder and data standards repository solution at Novo Nordisk. Rhona is also a current Board Member of CDISC. Her role at Novo Nordisk in addition to OSB Business Owner is leading a global operational team supporting digital dataflow from Data Standards, DM systems build and testing, metadata-driven SDTM generation, data acquisition and flow and DM support functions.

Mikkel Traun

Title: Principal Solution Architect

Organization: Novo Nordisk A/S



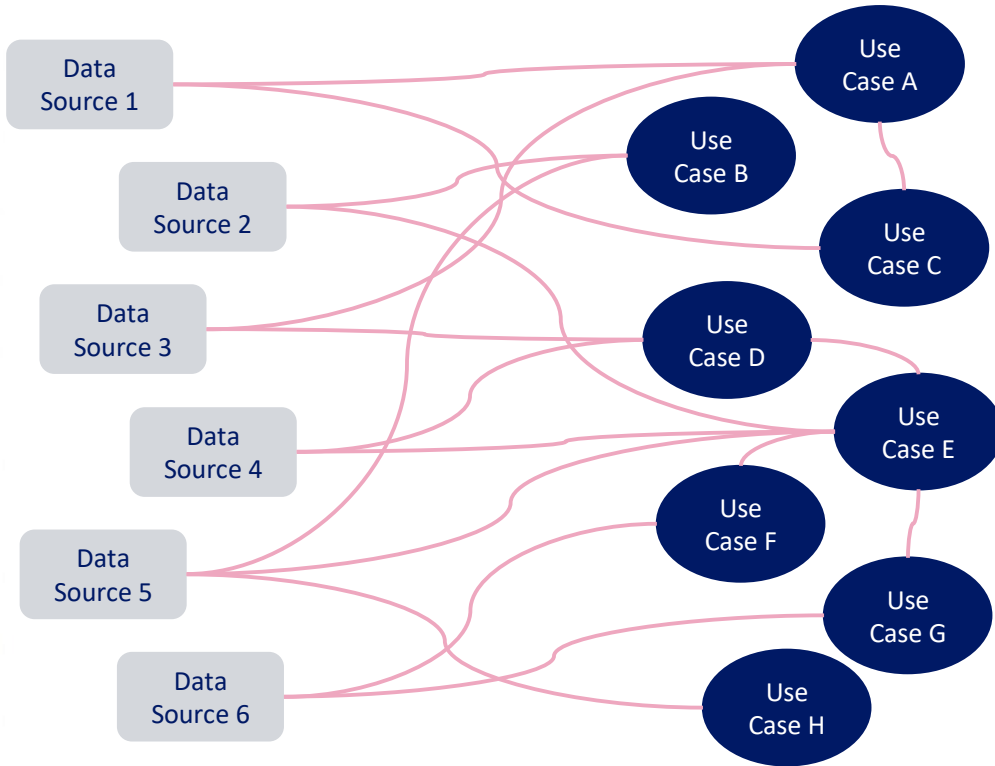
Mikkel is solution architect for the next generation study builder and data standards repository solution at Novo Nordisk. Mikkel is also an active member of the TransCelerate and CDISC Digital Dataflow project, and previously the CDISC 360 project. He has worked as a principal system developer supporting 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.



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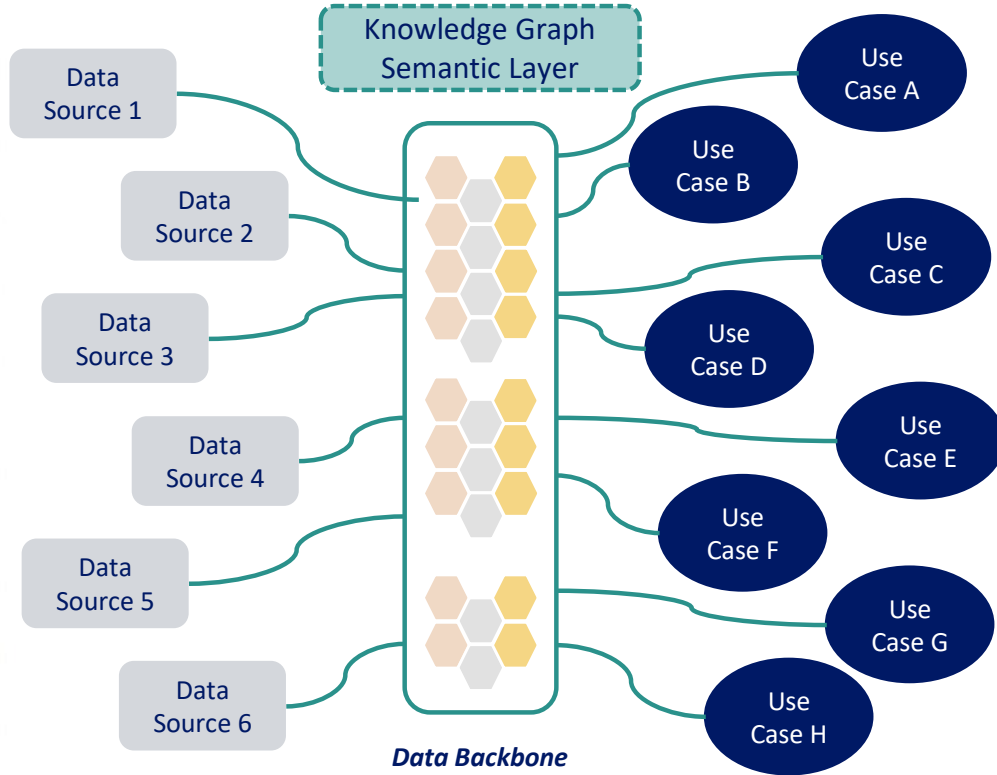
Today's **barrier** for efficiency and speed



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

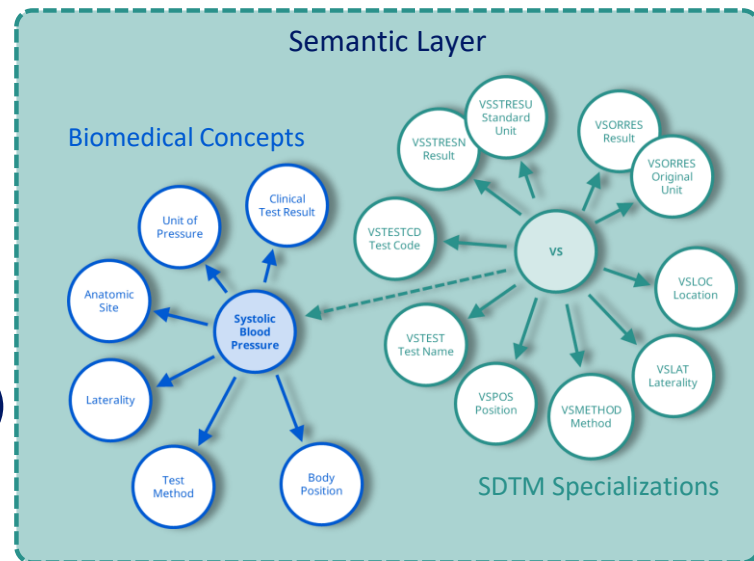
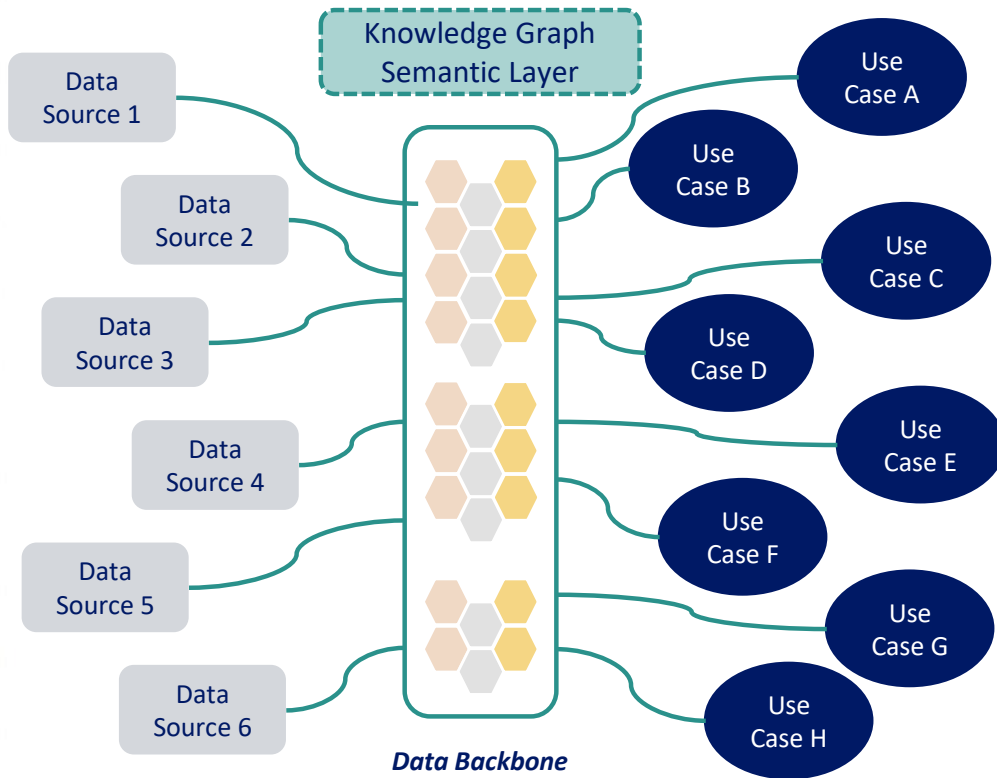
Tomorrow's **opportunity** for efficiency and speed



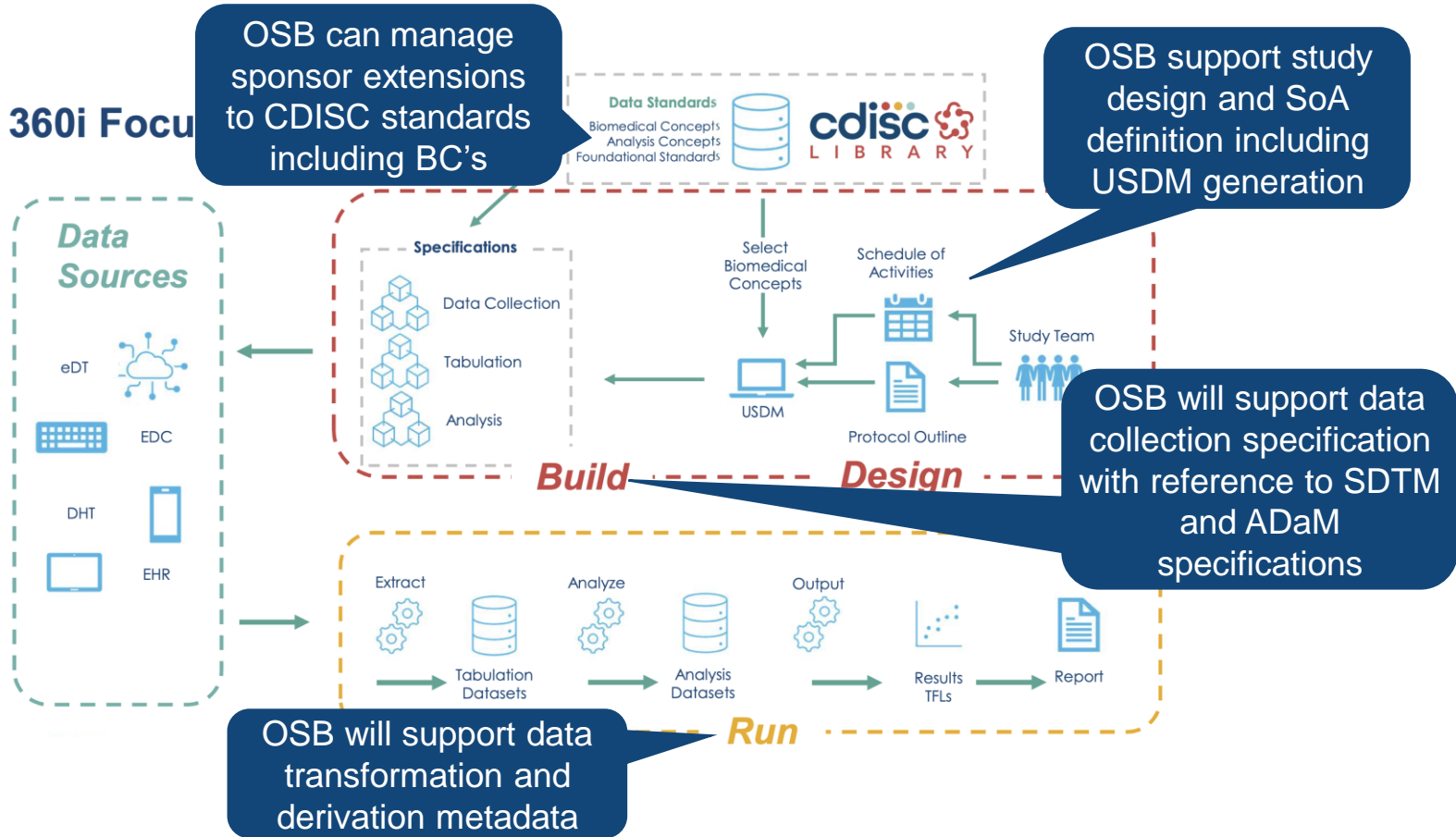
Many to **One** to Many

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

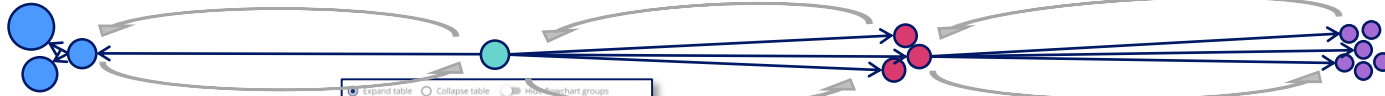
Tomorrow's **opportunity** for efficiency and speed



CDISC 360i Vision - Where do OSB fit in?



Schedule of Activities (SoA) at multiple levels



Study epoch	Screening	Treatment			
Visit short name	V1	V2	V3	V4	
Study day	-14	1	8	15	
Visit window (days)	-13/+0	±0	±1	±1	
SUBJECT RELATED INFORMATION					
Randomisation					
Randomisation Criteria and Randomisation					
Randomisation Criteria and Randomisation			X		
End of Study					
End of Study					
Body Measurements					
Body Measurements	X	X	X	X	

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

Epoch	Screening	Treatment			
Visit	V1	V2	V3	V4	
Day	-14	1	8	15	
Window	-13/+0	±0	-1/+1	-1/+1	
Activities					
SUBJECT RELATED INFORMATION					
Randomisation					
Randomisation					
End of Study					
Body Measurements					
Body Measurements					
Weight					
Height					

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

Activity Group	Activity Subgroup	Activity	Data Collection	Instance	Details	Standard/Requirement
All Required	Laboratory Assessment	Albumin Aniongap/albumin	Y	Albumin Aniongap/albumin	Class: Measurement Topic Code: ALB SDTM Variable: ALB CDISC Variable: ALB	Standard
Laboratory Assessment	Biotechnology	Albumin Aniongap/albumin	Y	Albumin Aniongap/albumin	Class: Measurement Topic Code: ALB SDTM Variable: ALB CDISC Variable: ALB	Standard
Laboratory Assessment	Biotechnology	Albumin Aniongap/albumin	Y	Albumin Aniongap/albumin	Class: Measurement Topic Code: ALB SDTM Variable: ALB CDISC Variable: ALB	Standard
Laboratory Assessment	Biotechnology	Albumin Aniongap/albumin	Y	Albumin Aniongap/albumin	Class: Measurement Topic Code: ALB SDTM Variable: ALB CDISC Variable: ALB	Standard

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

Activity Group	Activity Subgroup	Activity	Data Collection	Instance	Details	Standard/Requirement
All Required	Laboratory Assessment	Albumin Aniongap/albumin	Y	Albumin Aniongap/albumin	Class: Measurement Topic Code: ALB SDTM Variable: ALB CDISC Variable: ALB	Standard
Laboratory Assessment	Biotechnology	Albumin Aniongap/albumin	Y	Albumin Aniongap/albumin	Class: Measurement Topic Code: ALB SDTM Variable: ALB CDISC Variable: ALB	Standard
Laboratory Assessment	Biotechnology	Albumin Aniongap/albumin	Y	Albumin Aniongap/albumin	Class: Measurement Topic Code: ALB SDTM Variable: ALB CDISC Variable: ALB	Standard
Laboratory Assessment	Biotechnology	Albumin Aniongap/albumin	Y	Albumin Aniongap/albumin	Class: Measurement Topic Code: ALB SDTM Variable: ALB CDISC Variable: ALB	Standard

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

STUDY BUILDER | Studies | Library | Reports | SELECT STUDY | CDISC DEV 0000 | NDJZ (NICOLAS DE SAINT JORRE)

Studies / View Specifications / USDM

USDM version of the Protocol / USDM version: 3.6.0

```

{
  "id": "784d9841-1399-4b29-92e3-52233a43879",
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  "description": "Safety and Efficacy of the Xanomolone Transdermal Therapeutic System TSS in Patients with Mild to Moderate Alzheimer's Disease",
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  ]
}

```

STUDY BUILDER | Studies | Library | Reports | SELECT STUDY | CDISC DEV 0000 | NDJZ (NICOLAS DE SAINT JORRE)

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 Xanomolone Transdermal Therapeutic System TSS in Patients with Mild to Moderate Alzheimer's Disease [Protocol Full Title]
Sponsor Confidentiality Statement:	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. CDISC DEV-0000 [Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
Protocol Number:	Study_000019_TRIAL [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 as 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:	C15601_PHASE_II_TRIAL [Trial Phase] [Description of Trial Phase Other] Acceptable entries are: "Early Phase 1", "Phase 1", "Phase 2/Phase 3", "Phase 2", "Phase 3/Phase 4", "Phase 3", "Phase 4", or "Other". For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
Acronym:	Study_000019 [Protocol Acronym] Acronym or abbreviation used publicly to identify the clinical trial, if any. The acronym may include numerals, such as 1, 2, or 1, 2, 3, or 1c. Delete this line from the table if not applicable.
Short Title:	Xanomolone (LY246708) [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 ICH M11 Compatible - with SoA

The screenshot displays the Open Study Builder interface. The top navigation bar includes 'Studies', 'Library', 'Administration', 'Reports', and 'SELECT STUDY'. The user is logged in as 'MT (MIKKEL TRAUN)'. The left sidebar shows a navigation menu with options like 'About Studies', 'Study List', 'Manage Study', 'Define Study', 'View Specifications', 'Protocol Elements', 'SDTM Study Design Datasets', 'USDM', 'ICH M11', 'Clinical Transparency', and 'View Listings'. The main content area is titled 'ICH M11 version of the protocol' and shows '1.3. Schedule of Activities'.

1.3. Schedule of Activities

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.

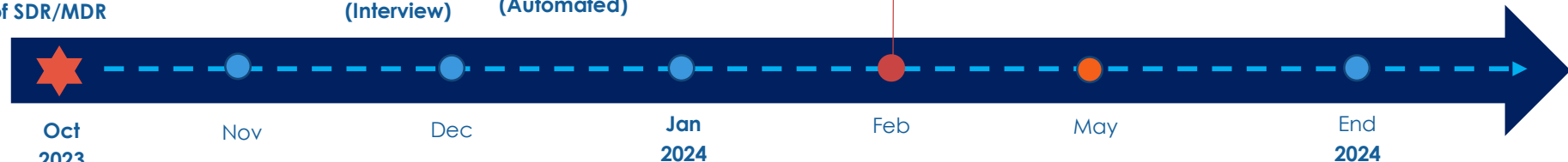
	Screening 1		Treatment								Follow-up
Visit short name	V1 ^a	V2 ^a	V3 ^a	V4	V5	V6	V7	V8	V9	V10	V11
Study week	-2	1	2	3	4	5	6	7	9	27	31
Visit window (days)	-13/0	0	±1	±1	±1	±1	±1	±1	±1	±1	0/+35
SUBJECT RELATED INFORMATION											
RANDOMISATION											
Randomisation											
Randomized		X									
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	

OSB Adoption journey 2024



Early earnings:

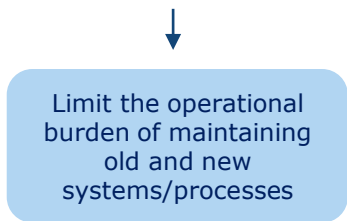
- System Performance
- Navigation Issues
- Terminology Issues
- Missing Functionality
- Operational burden



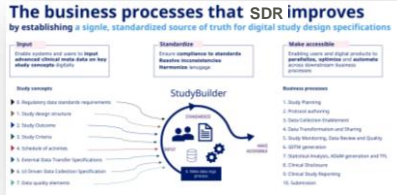
Scope of the first business release of our SDR/MDR*:

- **Studies:** All interventional ph 2-4
- **Users:** Clinical Operations, Clinical Reporting & Data Standards
- **Key protocol metadata:** SoA, Study Structure, Eligibility Criteria, Endpoints & Objectives

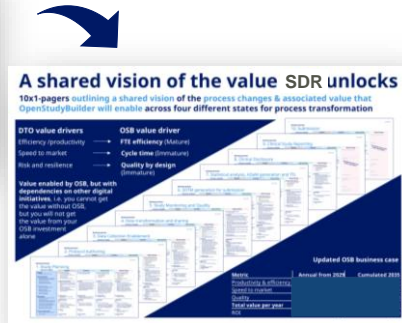
* MVP = Minimal Viable Product



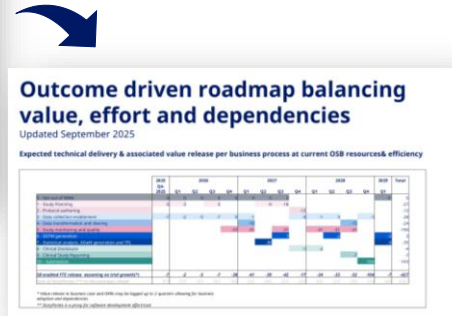
OSB Adoption journey update (2025)



Product vision & mission



Value framework & business case



Outcome based roadmap



Defined Objectives & Key Results

Current status:

- As of 01-Oct-2025 we specify the SoA for the protocol for all of our interventional studies (ph1-4) in or SDR/MDR
- Data collection enablement soon a reality
- End2End metadata linking the focus of 2026



Thank You!

Questions or need more information

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Mikkel Traun, mt@novonordisk.com

OpenStudyBuilder contact: OpenStudyBuilder@gmail.com

