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.
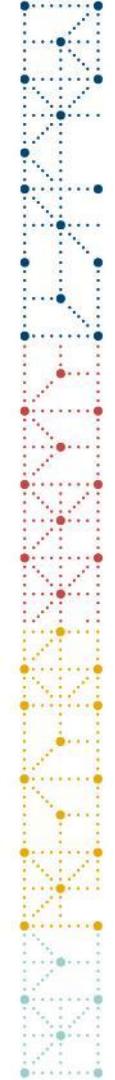
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The data landscape is disconnected

Many Data Sources

MDR and SDR *(Digital Protocol)*
Dictionaries, unit conversion rules, objectives, endpoints, in-/exclusion criteria, schedule of activities, arms, interventions, etc

External Standards
CDISC CT, MedDRA, SNOMED CT, WHO Drug, ISO …

CTMS
Study ID, sites, investigators, milestones, metrics, protocol deviations

IWRS/RTSM
Randomisation number and batch numbers

EDC
Informed consent obtained, subject status, demographics, medical history, concomitant medication, dose and compliance, adverse events, vital signs, body measurements, hypoglycaemic episodes, ECG interpretation, pregnancy test results, queries, etc.

Safety
SAE & pregnancy reporting

Laboratories
Biochemistry, hematology, glucose metabolism, antibodies, trial product concentrations, serology, drug tests, pregnancy test, proteomic and genomic sample tracking, etc.

CGM
Date, time, glucose, visit

eCOAs
Questionnaires e.g. SF36, CSSRS, PHQ9
Diaries e.g. dose/compliance, hypoglycaemic episode, AE, bleeding event, BG meter readings
Sit and stand test

Imaging
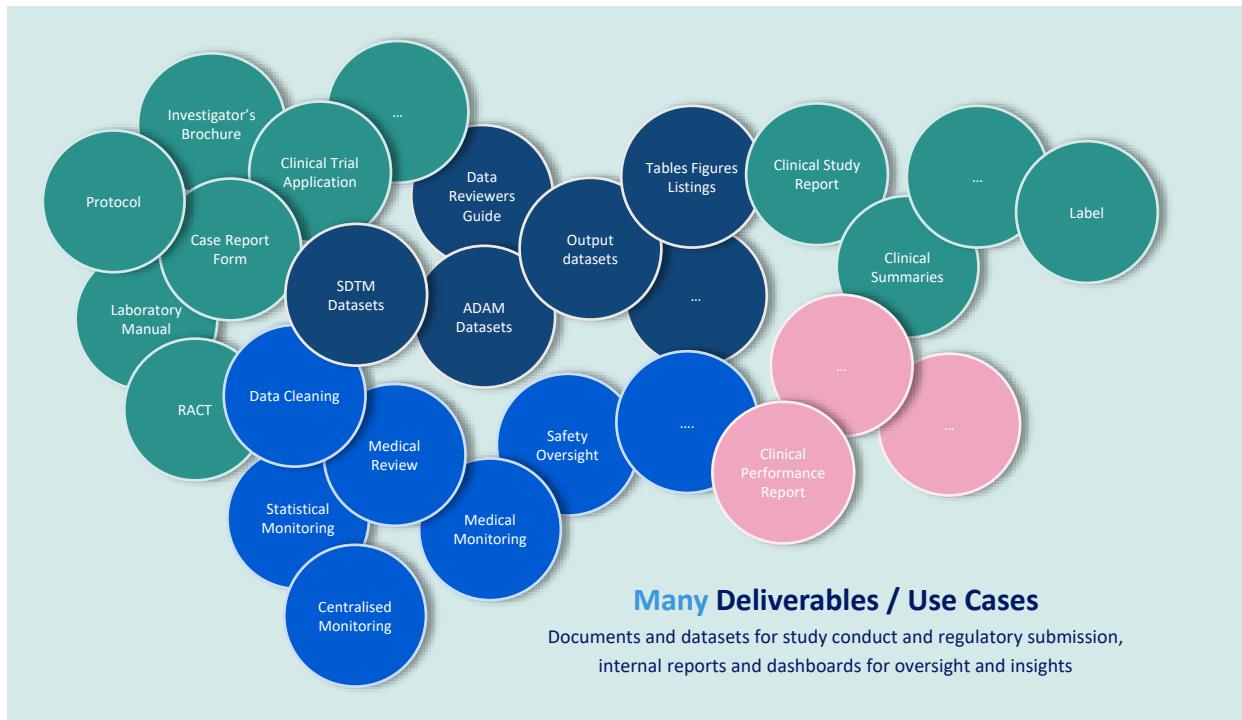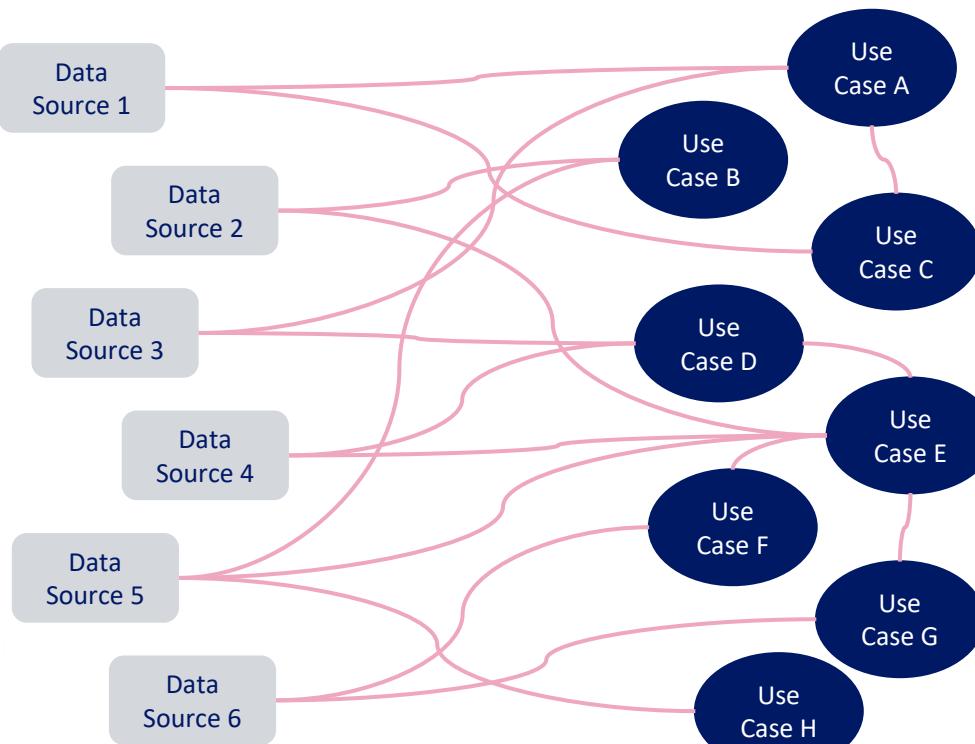*Dexa scan, X-ray, MR*

Data Lakes
Harmonized historic study data

Master Data
Medicinal product data

Other data
…

Protocol · Investigator's Brochure · Clinical Trial Application · … · Case Report Form · Data Reviewers Guide · Tables Figures Listings · Clinical Study Report · … · Label · Laboratory Manual · SDTM Datasets · Output datasets · Clinical Summaries · RACT · ADAM Datasets · … · … · Data Cleaning · Medical Review · Safety Oversight · …. · Clinical Performance Report · … · Statistical Monitoring · Medical Monitoring · Centralised Monitoring

Many Deliverables / Use Cases
Documents and datasets for study conduct and regulatory submission, internal reports and dashboards for oversight and insights
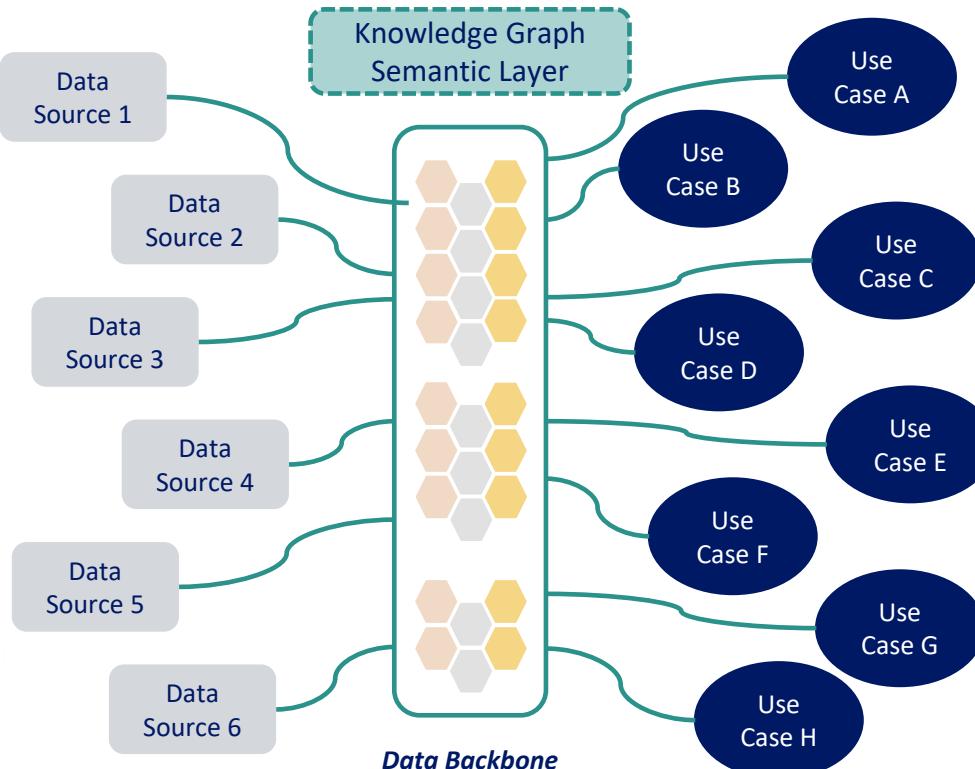
Today's **barrier** for efficiency and speed

Many to **Many** to **Many**

- Limited overview and transparency

- High-risk of inconsistencies

- Inefficiency due to re-do rather than reuse

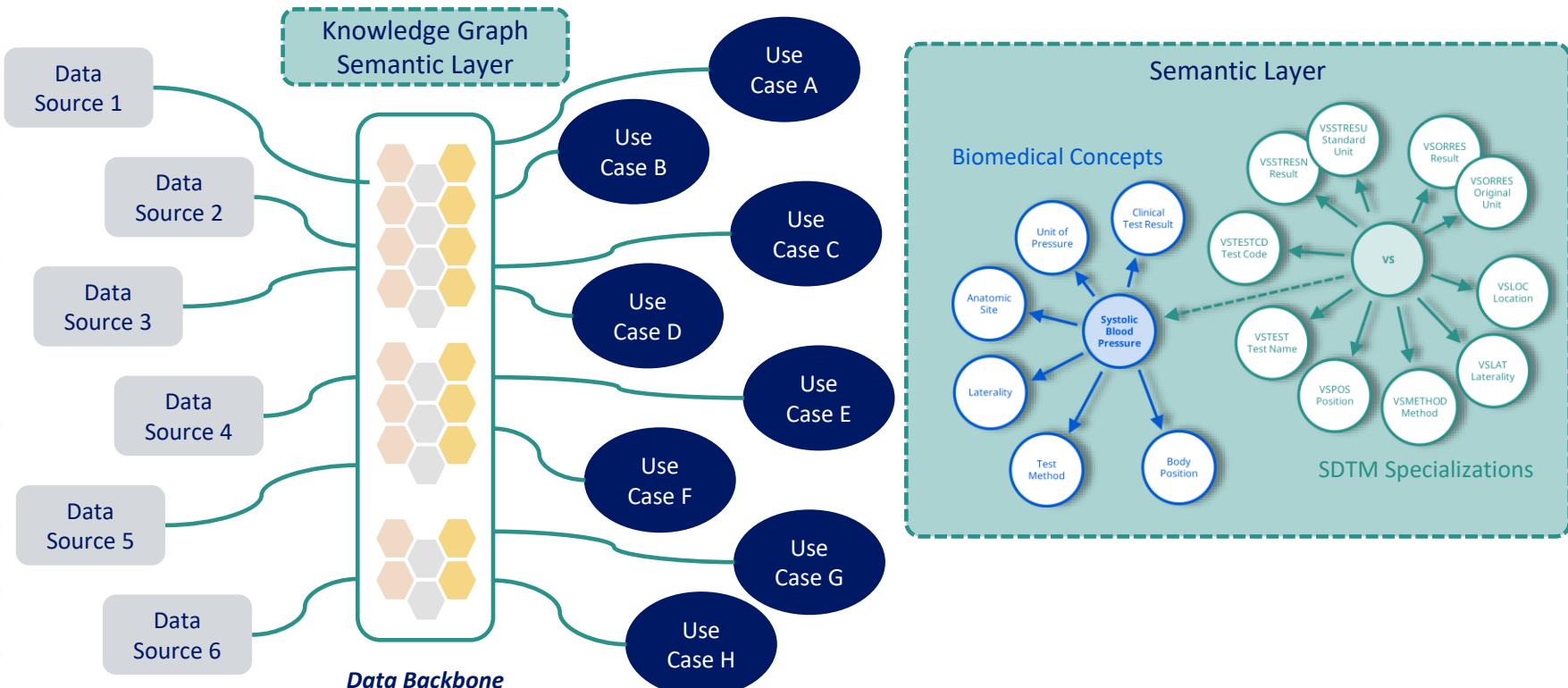- Lag-time between data availability and data ready for use

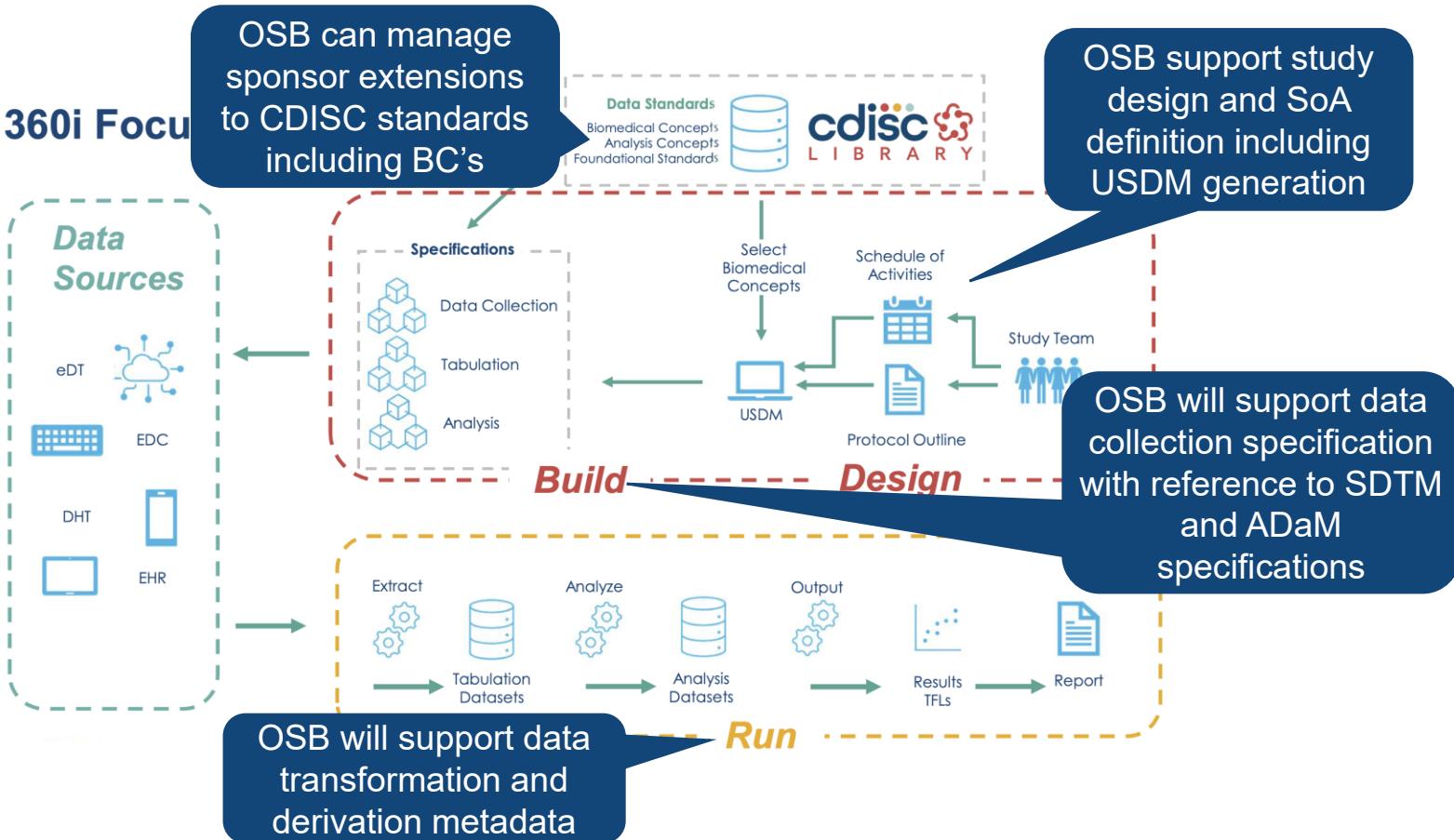# Tomorrow's **opportunity** for efficiency and speed

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

CDISC 360i Vision - Where do OSB fit in?

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

OSB support study design and SoA definition including USDM generation

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

OSB will support data transformation and derivation metadata

360i Focus

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY

Data Sources

eDT

EDC

DHT

EHR

Specifications

Data Collection

Tabulation

Analysis

Select Biomedical Concepts

Schedule of Activities

Study Team

USDM

Protocol Outline

Build

Design

Extract

Tabulation Datasets

Analyze

Analysis Datasets

Output

Results TFLs

Report

Run

cdisc

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)

Welcome to the StudyBuilder application
Study Specification made easy

OPEN
STUDY
BUILDER
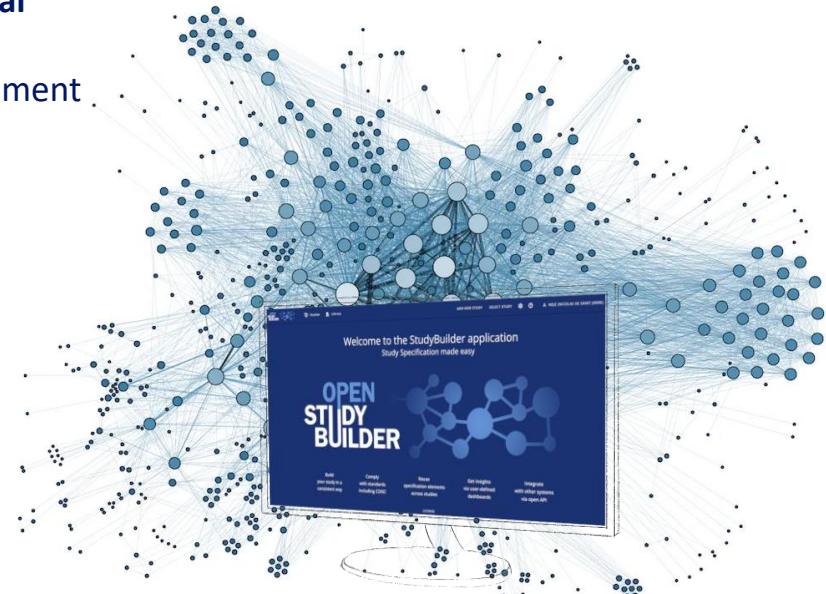
Clinical **MDR & SDR**

Schedule of Activities (SoA) at multiple levels
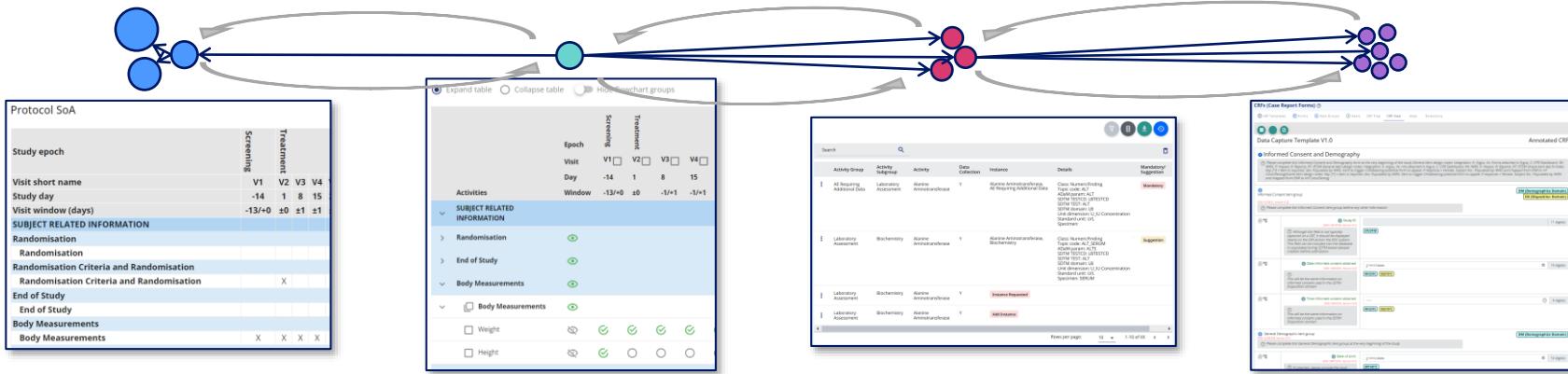
Protocol SoA

- 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

USDM and ICH M11 Compatible

USDM and ICH M11 Compatible - with SoA

OSB Adoption journey 2024

MVP release of SDR/MDR

Usability test (Interview)

Usability test (Automated)

User report

Early earnings:
- System Performance
- Navigation Issues
- Terminology Issues
- Missing Functionality
- Operational burden

Oct 2023

Nov

Dec

Jan 2024

Feb

May

End 2024

Hyper Care

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

Scope **Reduced:**

Only SoA

Limit the operational burden of maintaining old and new systems/processes

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 intervetional studies (ph1-4) in or SDR/MDR
- Data collection enablement soon a reality
- End2End metadata linking the focus of 2026
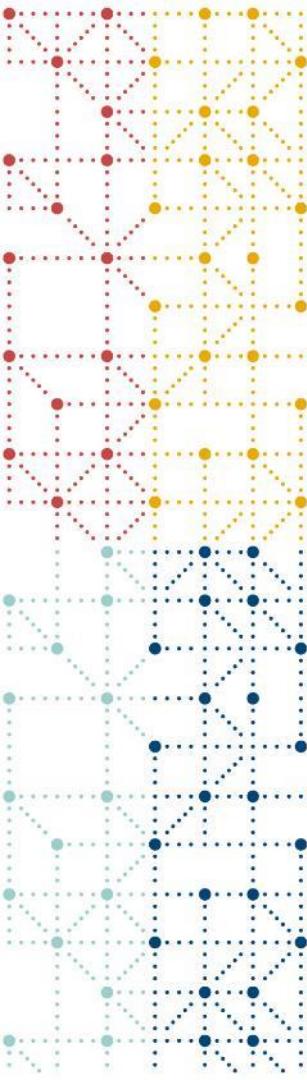
Thank You!

Questions or need more information

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