LIVESTREAMING

DDF Adoption Story

10:20 - 11:00AM

Adoption of Digital Data Flow

Kirubavathi Selvaraj, Novo Nordisk

Questions? Scan the QR Code on your phone to add in your questions for our presenters and speakers

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OPEN STUDY BUILDER

Adoption of DDF @Novo Nordisk

Presenter: *Kirubavathi Selvaraj, SME, OpenStudyBuilder*

Agenda

- Why the need for DDF ?
- How DDF is implemented ?
- Adoption learnings
- Q&A

Why OpenStudyBuilder?

Interlinked **study design specifications** are handled in ***isolated IT solutions*** across Clinical Development…

Protocol
Primary endpoint:
- Subjects who after 68 weeks achieve (yes/no)
  - Body weight reduction >= 5% from baseline at week 0

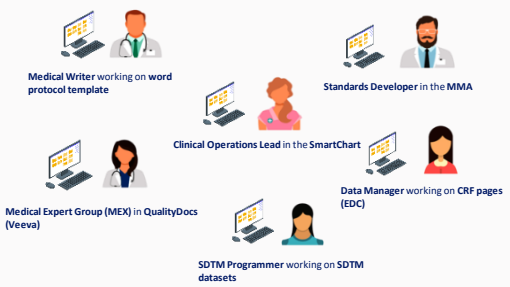
Same Meaning

SDTM
Parameter Value
Subjects who after 68 weeks achieve (yes/no) – Body weight reduction >= 5%.
Time frame: From baseline at week 0 to week 68

PharmaCM (for upload to CT.gov)
Primary Outcome Measures:
- Subjects who achieve 5 or more percent body weight reduction (yes/no) [Time Frame: Week 68]
  - Number of subjects.

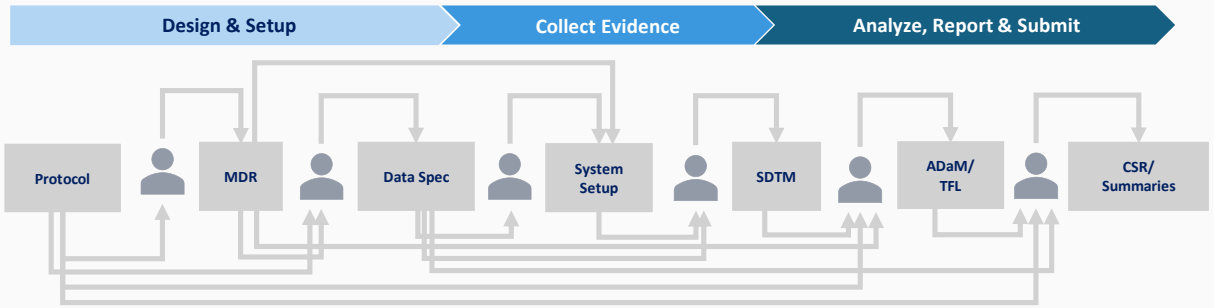
Challenges: Manual **re-creation of business essential information** resulting in

- Double work
- An **error prone** process
- And **tedious quality control** by skilled colleagues



Current Challenges

Sequential, document-based clinical development workflows inhibit speed to market

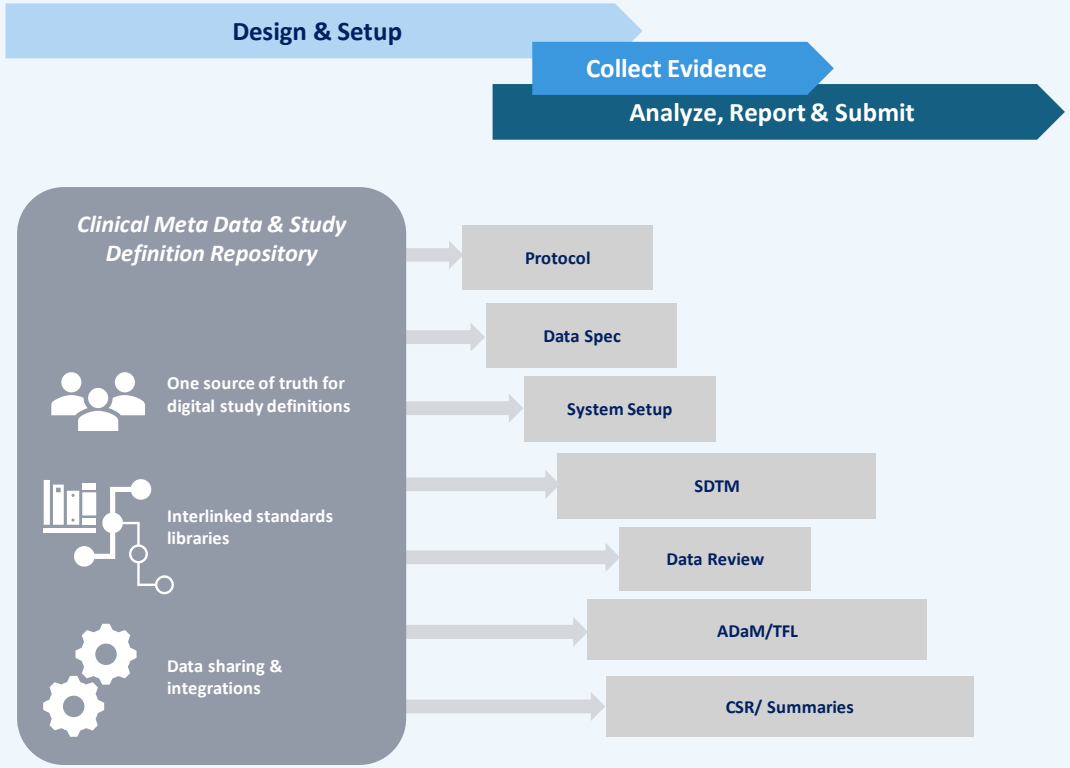


Challenges:

- **Sequential steps** and **deferred work** create **delays** and **long time-to-market**
- **Manual knowledge transfer** and cross-skill alignment create **inefficiencies**
- **Non-digitized**, **non-standardized** study elements, create **data quality issues**, **inconsistencies** & **limit automation**

OpenStudyBuilder is a ***transformative solution***

*A clinical SDR aims to **enable digital reinvention** of how we do **study design and execution** unlocking **quality** by design, **efficiency** gains & **cycle time** reductions*



Benefits with OpenStudyBuilder:

Unlocking host of **data and AI driven opportunities across Digital Development** Products for **better and faster study design and execution**

- **Foundation for sub-5-year cycle time** by parallelizing and frontloading
- **Significant efficiency gains** through meta data driven automation
- **Quality by design** through standardization and information re-use

OPEN STUDY BUILDER

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

Link: The OpenStudyBuilder at GitLab

What is OSB?

It's a **metadata** and **study definition** repository

MDR & SDR

Core Components of OpenStudyBuilder:

- 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)

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How **OpenStudyBuilder** enables a **Digital Data Flow** as **One Source of Truth**

Input

- Data Standards
- Study design structure
- Study Outcome
- Study Criteria
- Schedule of activities
- External Data Specs
- CRF library
- Risk management specs

Input

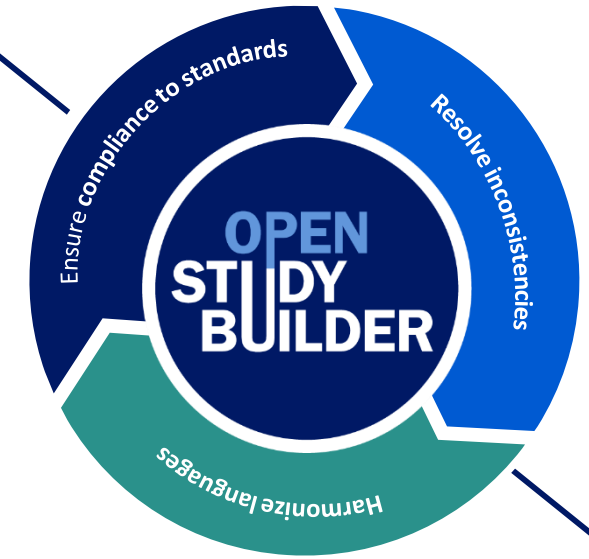
Enable systems and users to ***input advanced study defintion and meta data concepts*** digitally

Standardize

Ensure **compliance to standards**

Resolve inconsistencies

Harmonize languages



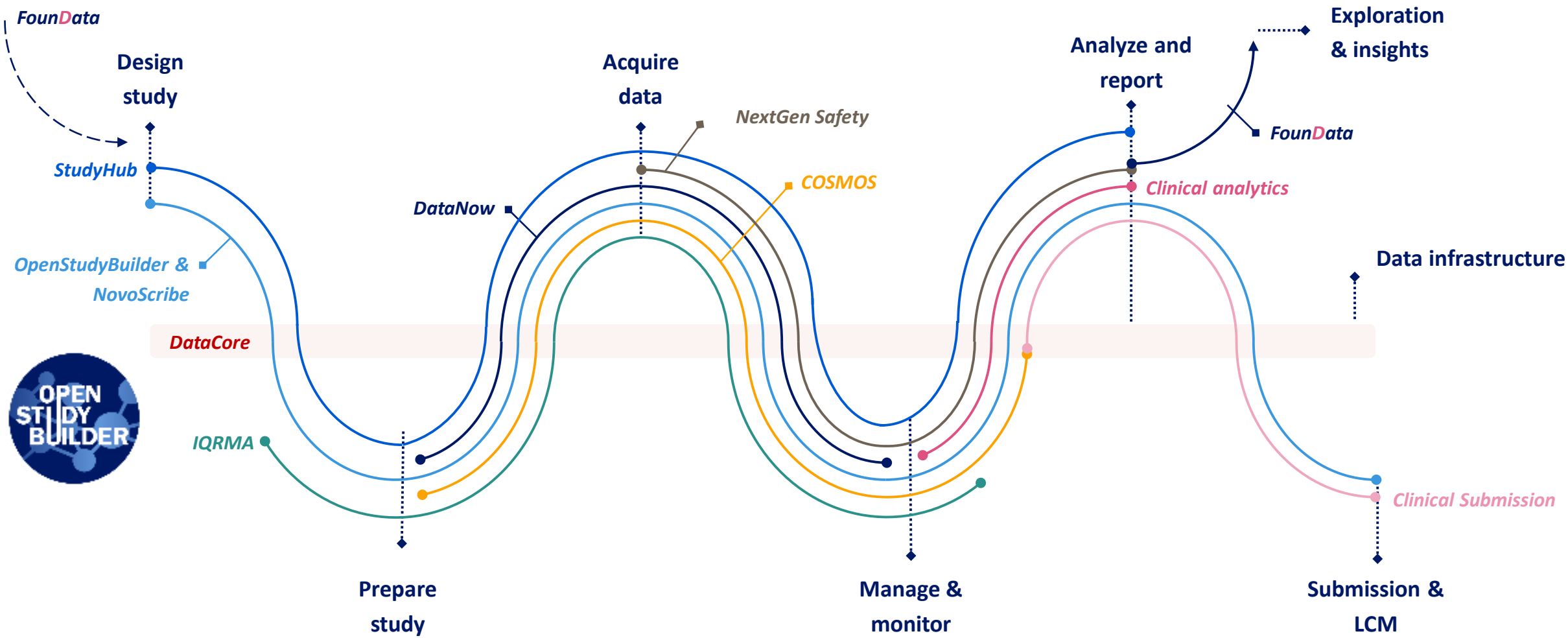
Make accessible

Enabling users and digital products to ***parallelize, optimize*** *and* ***automate*** across downstream business processes

- Lab Spec Generation
- Automated EDC set-up
- Automated annotated CRFs
- Digital protocol spec
- SDTM generation
- Blinding spec
- Vendor data contracts
- Automated data transformations
- Metadata-driven RACT
- TFL mock-up automation
- Autogenerated Define.xml & ADRG
- Automated ICH M11/USDM deliverables
- More to come …

Output

OSB in the NN Development value chain



Adoption learnings

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

MVP Release

Usability test (Interview)

Usability test (Automated)

User report

Oct 2023 | Nov | Dec | **Jan 2024** | Feb | May | End **2024**

Hyper Care

First business release (MVP*):

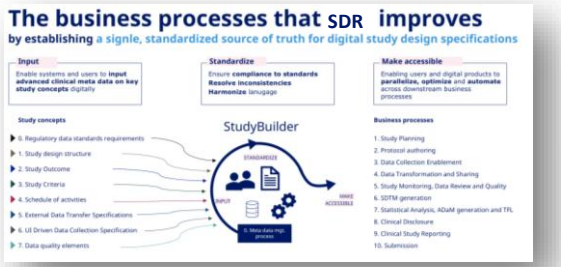
- All interventional ph 2-4 studies
- Users within Clinical Operations, Clinical Reporting & Data Mangement
- Key protocol metadata (SoA, Study Structure, Eligibility Criteria, Endpoints & Objectives)

* MVP = Minimal Viable Product

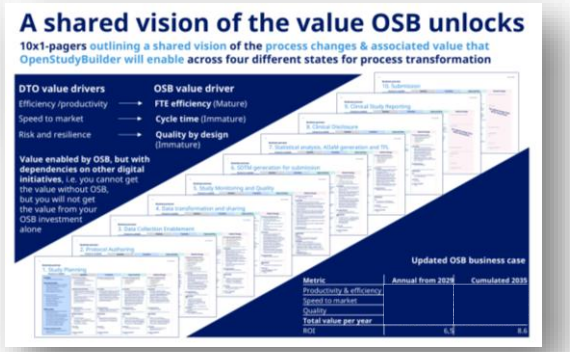
Scope **reduced**

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

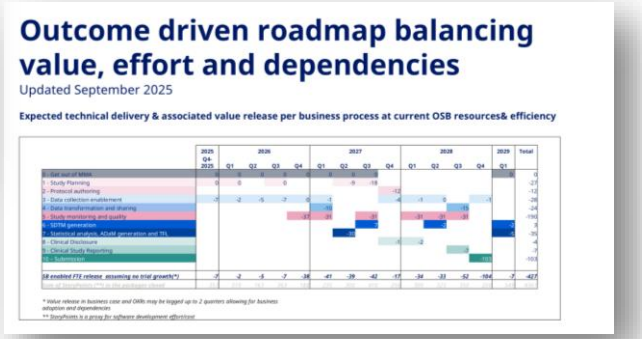
Adoption journey update (2025)



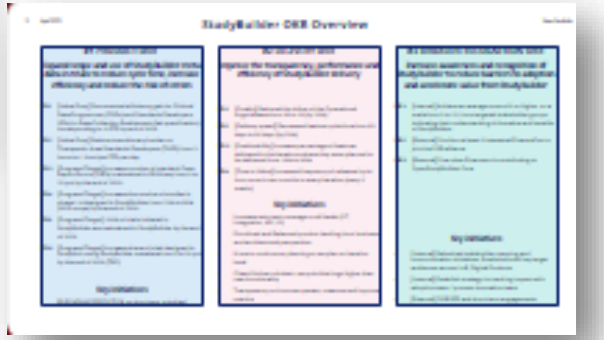
Product vision & mission



Value framework & business case



Outcome based roadmap



Defined Objectives & Key Results

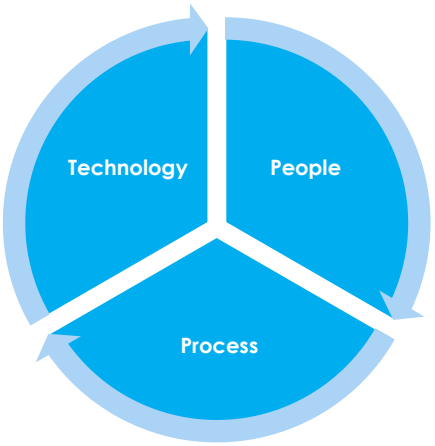
Current status:

- 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

DDF implementation @Novo Nordisk

- Replace the legacy MDR – but not a 1:1 replacement
- Expand the scope of the MDR to also become a SDR
- Transfer document-based protocol standards to the new MDR/SDR (OpenStudyBuilder)
  - SoA, Eligibility criteria, Objectives & Endpoints
- Prepare for the future with the new MDR/SDR by aligning to industry standards e.g. USDM, CDISC, ICH M11 etc.

Summary of implementation and adoption learnings



People are key:

- Early involvement of end users is key to ensure successful adoption
- Sufficient resources within the product team and impacted business areas is crucial

Processes are important:

- Sharing of metadata is key, but **difficult** to implement across business areas
- Implementation of a cross functional products require central project ownership and cross-area involvement
- Clear business values and outcomes – short time and long term – is essential

Technology is the facilitator:

- Transition from documents to systems requires a large change management effort (training, support, communication, guidance) **as well as** management buy-in / sponsorship
- High system performance is key
- Ease of use is important
- Keep release small and learn fast

Key messages

- Switching from documents to a Digital Data Flow requires an effort, but has great potential
- Prepare organisation for parallel work/double work before business value is realized
- Focus on small releases and adjust fast based on user feedback
- Alignment on goals across business units is key
- Easy to use technology makes the adoption easier

Questions or need more information?

OpenStudyBuilder:

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- Open Source Community Manager
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Link: OpenStudyBuilder.com