STUDY BUILDER

Adoption of DDF @Novo Nordisk

Presenter: *Camilla Kehler (CKN), Product Owner, StudyBuilder*

Agenda

- Why the need for DDF
- How is DDF implemented
- Adoption of DDF
- Learnings
- Q&A

TransCelerate BIOPHARMA INC.

Why the need for DDF @Novo Nordisk?

… on the surface we work together
– in reality, we work in isolated IT bubbles

The **Data Manager** specifies the study design and Schedule of Activities (SoA*) in the **Metadata mgt. sys**

The **Medical Center of Expertise** maintains the catalogue of in- & exculsion criteria in the **Quality mgt. sys**

The **Disclosure Specialist** enters study design and endpoints for public disclosure into **PharmaCM**

The **Medical Specialist** estimates study cost and feasibility in a **Study Design application**

The **Medical Writer** enters the SoA, endpoints, objectives and in- & exclusion criteria into the **Protocol Template (Word)**

The **Data Manager** translates the SoA and in- & exclusion criteria into the **Electonic Data Collection sys (EDC, Lab, eDiary etc.)**

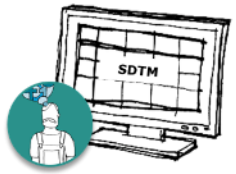
The **Data Manager** enters the study design and endpoints into the **SDTM TS dataset**

- which leads to **re-creation of the same content** in different contexts - resulting in double work, high need for QC and lack of overview

Protocol

4.2.1 Primary endpoint

- Subjects who after 68 weeks achieve (yes/no):
  - Body weight reduction ≥ 5% from baseline at week 0



SDTM – trial summary (ts)

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.

SDTM: study data tabulation model

*SoA = Schedule of Activities

The DDF mission @Novo Nordisk => StudyBuilder

StudyBuilder aim to **digitalize** the metadata of the study specification (protocol) to allow for a higher **degree of reusability** and **automation** & limit **manual document driven** work. All as part our **'One Digital Data Flow**'.

We must ensure the users defining the **study protocols** can use StudyBuilder efficiently

We must ensure the users defining digital **study data specification** can use StudyBuilder efficiently

We must ensure the digital study data specifications enable **automation** in our digital dataflow products

We must ensure **adoption and continue support** of StudyBuilder in the organisation

Opportunity Map

StudyBuilder explores features to meet business's here-and-now needs while establishing foundational capabilities needed to enable and support several initiatives that will drive Development's long-term aspirations

TransCelerate BIOPHARMA INC.

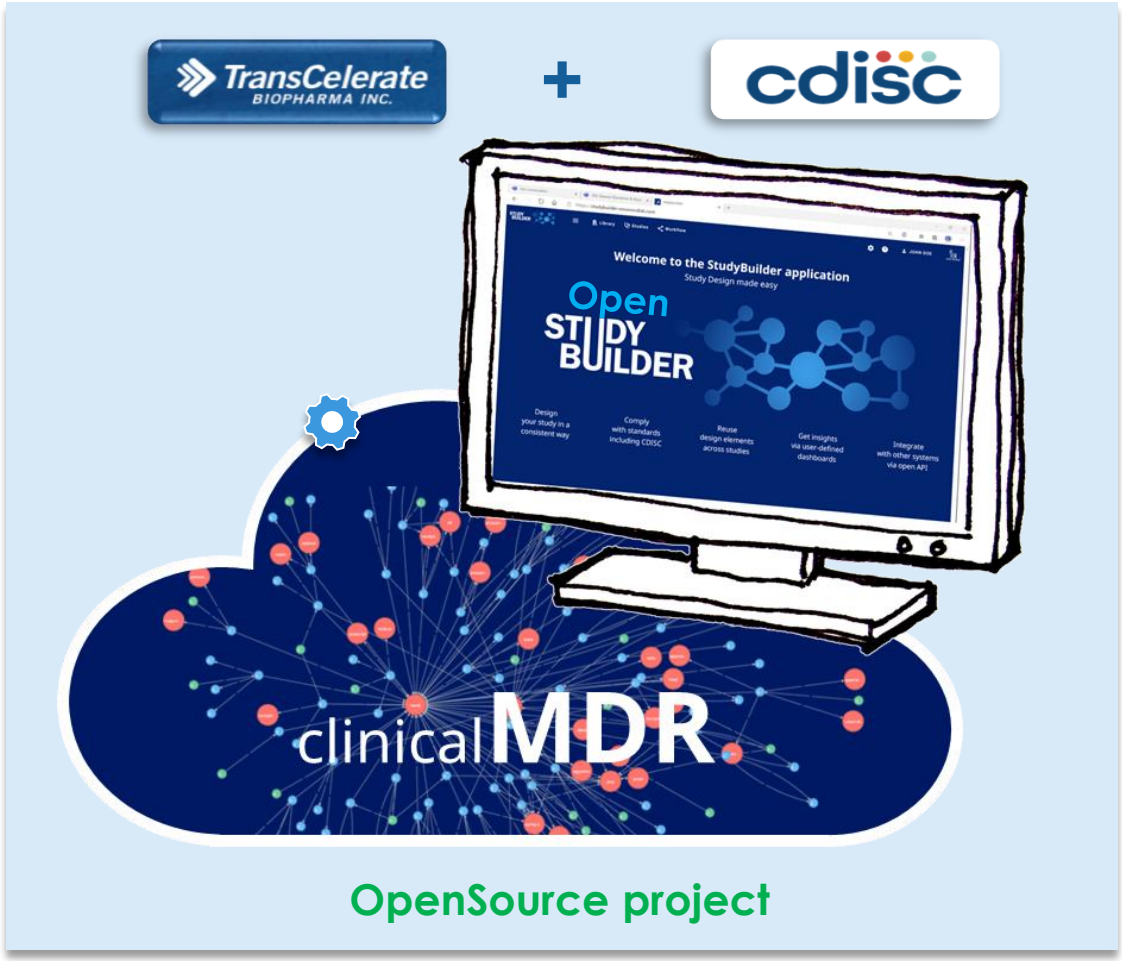
How is DDF implemented @Novo Nordisk?

The OpenStudyBuilder is a **new approach** to the study specification process that will:

- Ensure a higher degree of end-to-end consistency
- Have built-in compliance with external and internal standards
- Facilitate more automation

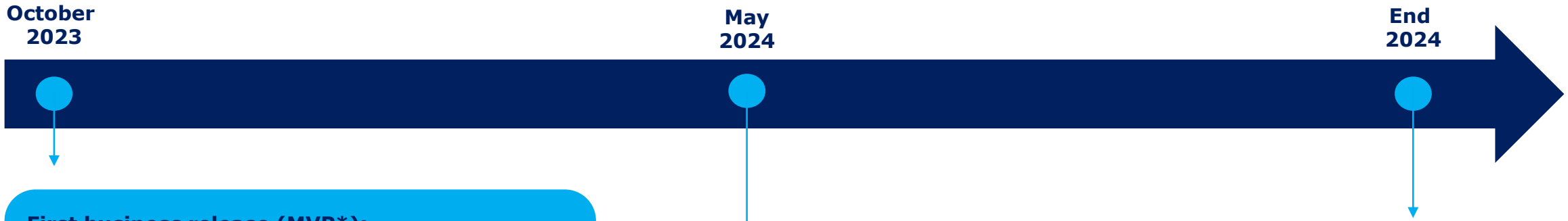
The StudyBuilder comprises three elements:

- **OpenStudyBuilder application** (web-based user interface)
- **Clinical Metadata Repository (clinical MDR)** (central repository for all study specification data)
- **API layer** (allowing interoperability with other applications)



Link: The OpenStudyBuilder at GitLab

Implementation & learnings



First business release (MVP*):
- All interventional ph 2-4 studies
- Users within Clinical Operations, Clinical Reporting & Data Mangement Systems and Stanards
- Key protocol metadata (SoA**, Study Structure, Eligibility criteria, Endpoints & Objectives

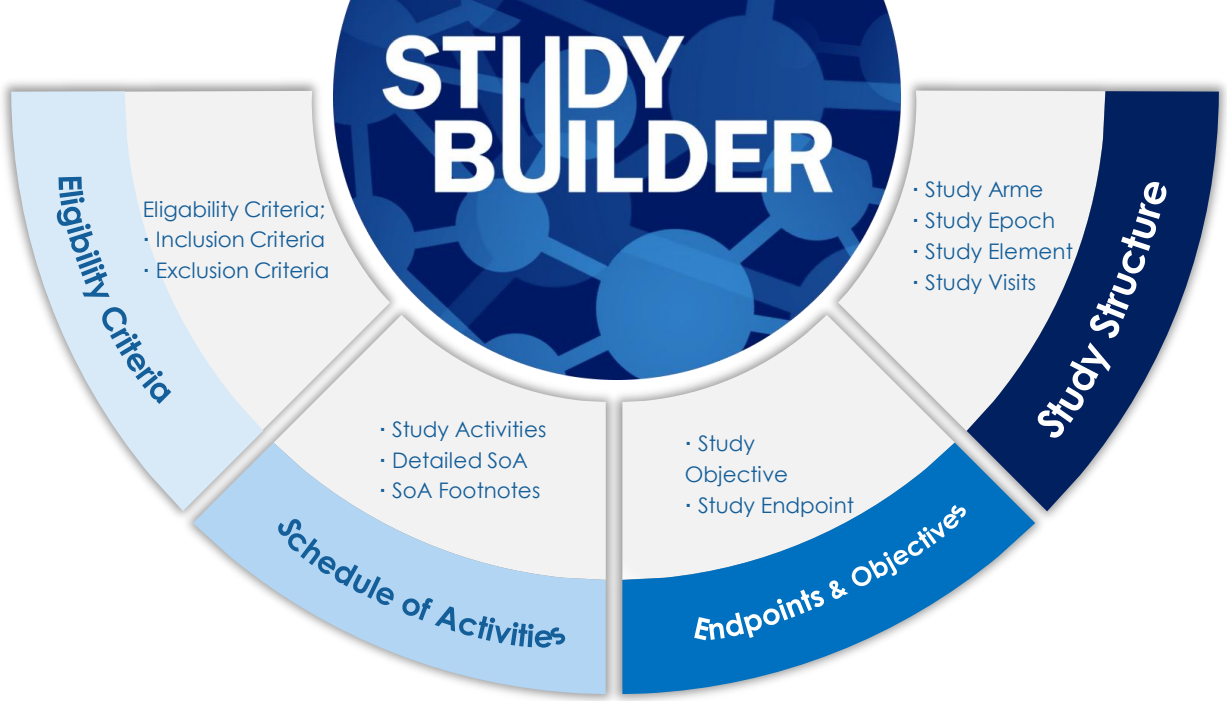
Reduced scope due to adoption challenges:
- Schedule of Activities (SoA) & Study structure (mandatory)
- Eligibility criteria, Endpoints & Objectives (optional)

Focus on limiting the operational burden
- Support all studies (currently pending ph 1)
- Reduction in parallel work needed
- Expansion of library content
- Connectivity to other systems (resuability)

* MVP = Minimal Viable Product
** SoA = Schedule of Activities

TransCelerate BIOPHARMA INC.

User Feedback...



System Performance

Very slow performance made users believe the application was not working

Unclear error messages confuses the users. Is it the system failing or is it a user error

Missing Functionality

Search engine and filtering

The repetitive creation of generic content from scratch

Possibility to track the progress of the protocol setup

Syntax template presents usability challenges with the syntax templates

Terminology Issues

Categorizations confused users and lead to incorrect selections

Unfamiliar terms, makes it difficult for users to set-up the Study Structure

Users do not understand the term '**Pre-instances**' as it is used incorrectly.

Users are finding the selection of singular and plural time units confusing.

Navigation Issues

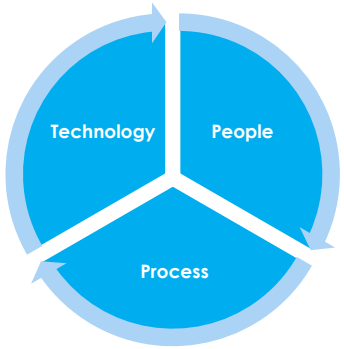
Poor visibility of added or existing content made it challenging for users

The number of clicks required to create content

Unclear cues and confusing iconography lead to faulty navigation

TransCelerate BIOPHARMA INC.

Summary of Learnings



People:

- Early involvement of end users is key to ensure successful adoption
- Getting people to work in systems instead of documents requires a large change management effort – training, support, communication and guidance
- Sufficient resources within management, product team and impacted business areas is crucial

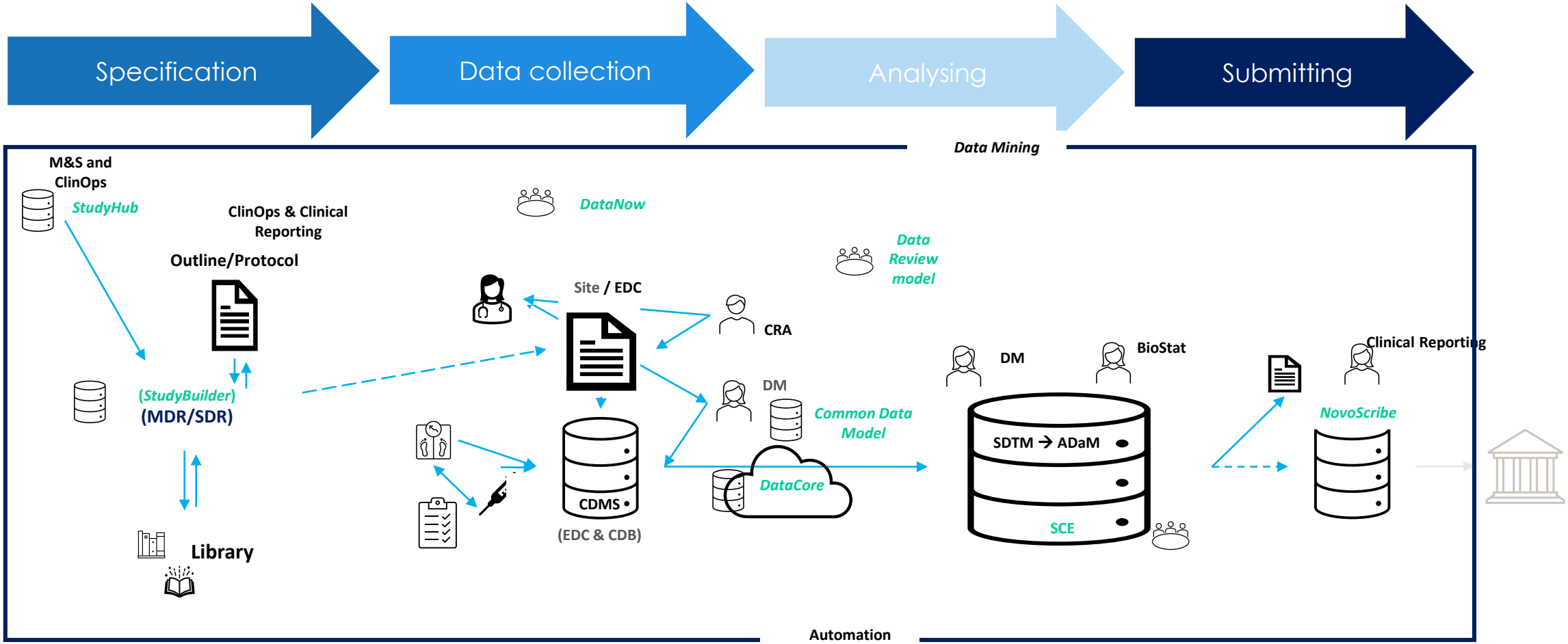
Process:

- Standardization and sharing of meta data is needed, but difficult to implement
- Keeping releases small and frequent
- Pilot studies speed up the identification of issue, but might prolong the first release
- Clear project ownership is important when implementing a cross functional product

Technology:

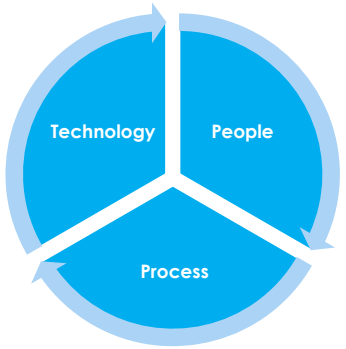
- Clear business value – short time and long term – is essential
- System performance key

One Digital Data Flow @Novo Nordisk → future system landscape



= Novo Nordisk systems/projects

Key messages



People:

- 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

Process:

- Ensure a robust support setup for the users from the initial release
- Clear processes and responsibility split is essential
- Clear ownership of library and dictionary content is a must – governance as well as maintenance

Technology:

- Switching from documents to a Digital Data Flow **IS** difficult, but has great potential
- Understanding the benefit of digitial tools takes time
- Ensure easy to use technology to ease the adoption

TransCelerate BIOPHARMA INC.

Contact details

- OpenStudyBuilder:
  - Katja Glass, Open source community manager
  - katja.glass@glacon.eu

- Adoption of StudyBuilder @Novo Nordisk A/S:
  - Camilla Kehler, Product Owner, StudyBuilder
  - ckn@novonordisk.com