Adoption Story from a Biopharmaceutical Organization

Case Study: Adoption of Digital Data Flow

2024

Content

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Overview

Why the need for Digital Data Flow

… 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**

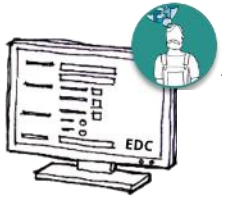
The **Medical Specialist** maintains the catalogue of in- & exculsion criteria in the **Quality mgt. sys**

The **Disclosure Specialist** enters study design and endpoints for public disclosure into **clinicaltrial.gov**

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)**

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



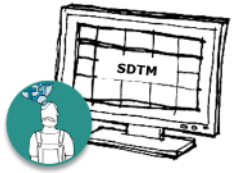
The **Data Manager** translates the SoA and in- & exclusion criteria into the **Electonic Data Collection sys** (EDC, Lab, eDiary etc.)

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

Develop protocol

4.2.1 Primary endpoint

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



Summarize data following the Study Data Tabulation Model (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.	

Publish primary outcome measures on clinicaltrial.gov

- 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

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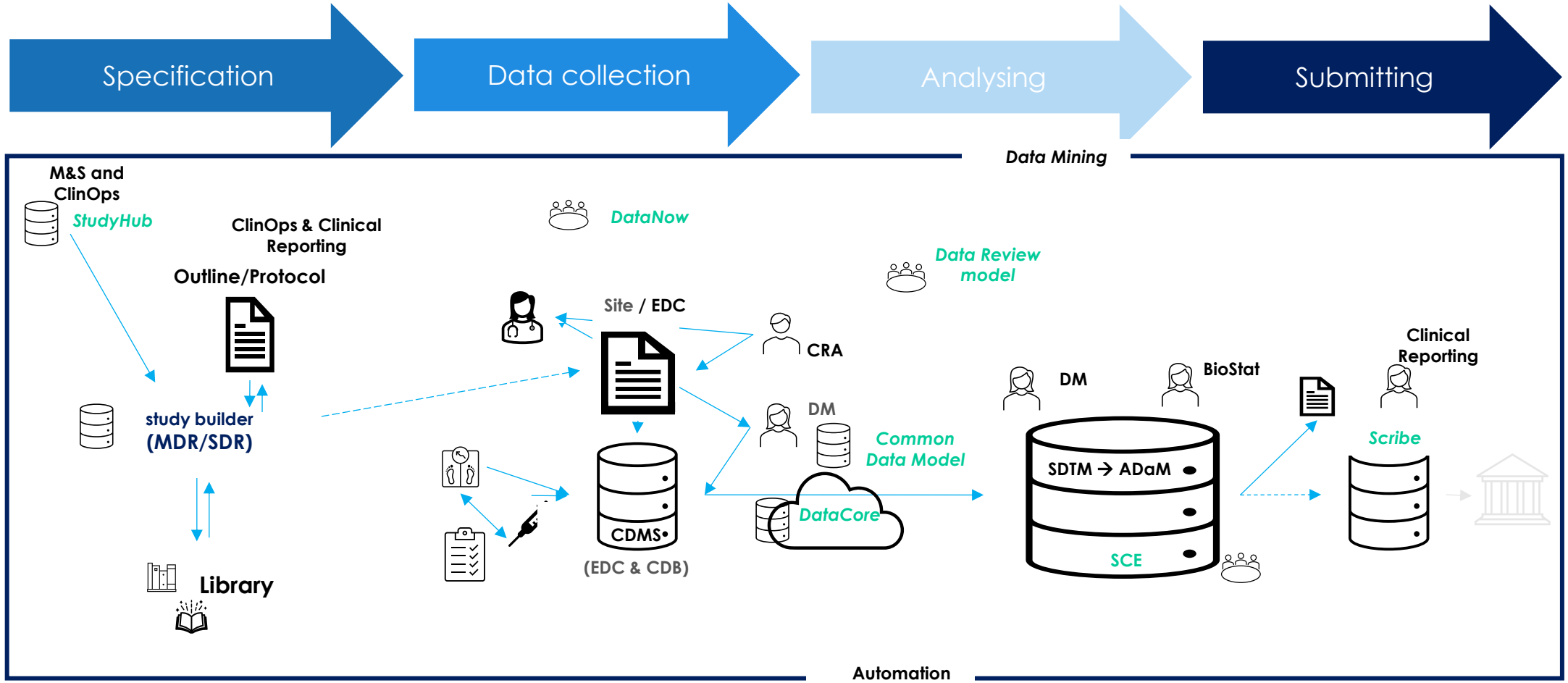
One Digital Data Flow → Future System Landscape



● = System / Projects

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Mission of Digital Data Flow

We aim to **digitalize** the metadata of the study specification (e.g., 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 a study builder (MDR/SDR) efficiently

We must ensure the users defining digital **study data specification** can use a study builder (MDR/SDR) efficiently

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

We must ensure **adoption and continue support** of a study builder (MDR/SDR) in the organization

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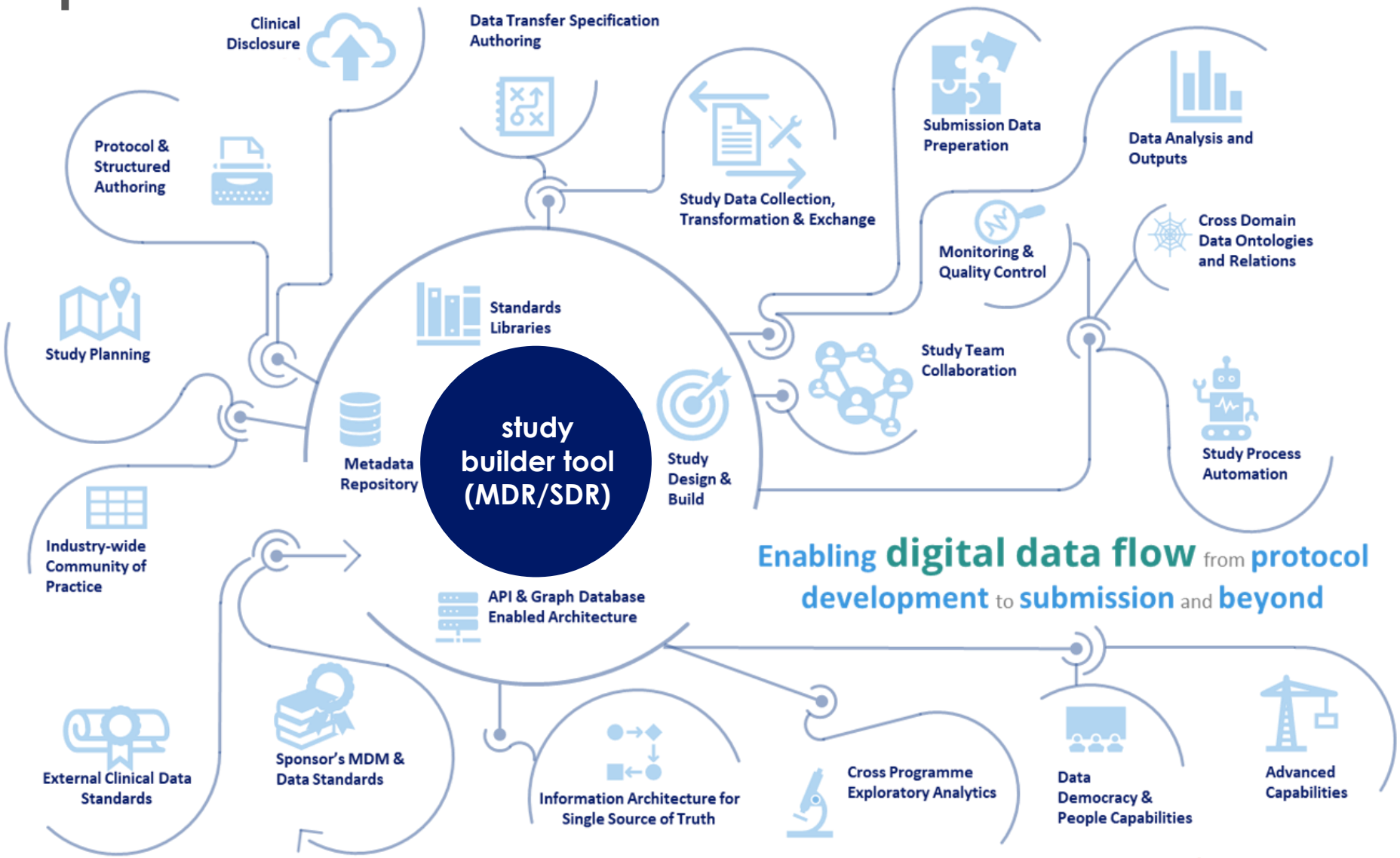
Use Case Description

Opportunity Map

The solution explores features to meet the current needs of the business while establishing foundational capabilities to enable and support several initiatives that will drive Development's long-term aspirations



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Digital Data Flow Implementation

To begin the digital transformation of clinical trials, the organization considered the following:

- Replace the current Metadata Repository (MDR), but it was not a 1:1 replacement
- Expand the scope of the MDR to also become a Study Definition Repository (SDR)
- Transfer document-based protocol standards to the new MDR/SDR, including eligibility criteria, objectives and endpoints
- Prepare for the future with the new MDR/SDR by aligning to industry standards (e.g., USDM, CDISC, etc.)

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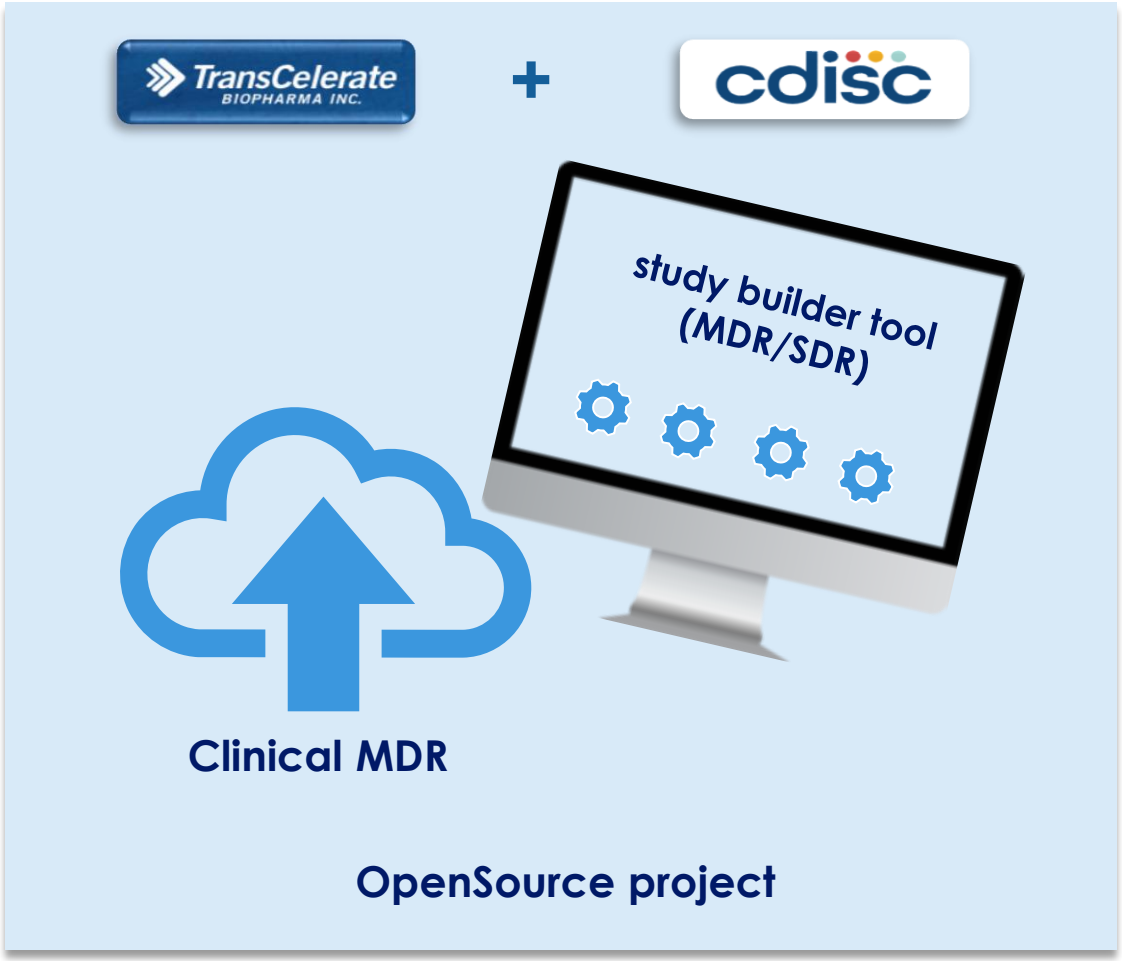
Digital Data Flow Implementation

Developing the study builder tool 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 study builder tool is comprised of three elements:

- **Web-based user interface**
- **Clinical Metadata Repository (clinical MDR)** (central repository for all study specification data)
- **API layer** (allowing interoperability with other applications) (DDF API Adaptor – enabling USDM compatibility)



Challenges & Considerations

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 burden of maintaining old and new systems/processes

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Benefits

Benefits from the adoption of Digital Data Flow

We must ensure the users defining the **study protocols** can use a study builder tool efficiently

We must ensure the users defining digital **study data specification** can use a study builder tool efficiently

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

We must ensure **adoption and continue support** of a study builder tool in the organization

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Lessons Learned

Summary of implementation and adoption learnings

People are key:

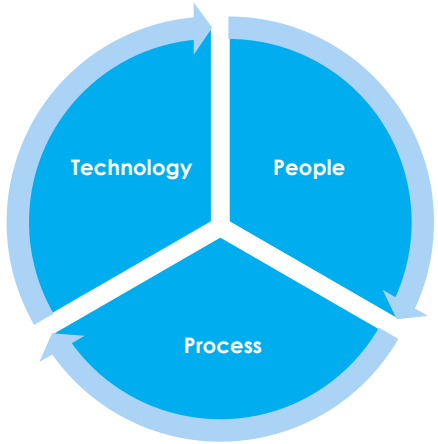
- Early involvement of end users is key to ensure successful adoption
- Sufficient resources within the product team and impacted business areas is crucial

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



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Key learnings

Switching from documents to a Digital Data Flow requires effort, but has great potential

Prepare organization for parallel work, and in some cases, double work, before business value is realized

Focus on small releases and adjust fast based on user feedback

Easy-to-use technology makes the adoption easier

Alignment on goals across business units is crucial

Thank you