

Adoption Story from a Biopharmaceutical Organization

Case Study:
Integrated Data Journey: From Study Concept to Case Report Form

Agenda



Brief summary of the use case and how it fits in the Transcelerate Digital Data Flow initiative



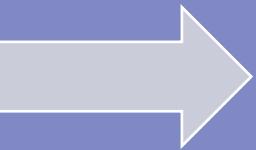
Why did we implement this use case...
- Limitations of the previous process
- Focus & benefits of the new process



Implementing this use case wasn't so easy ...
Challenges faced when implementing the use case



The journey to get there was long...
Summary of the journey



Before starting: a small Quiz | Protocol Inclusion Criteria

How many variations of this inclusion criteria do you think we have across **35** protocols for the same product?

Female patients of childbearing potential must have a negative serum pregnancy test at screening visit.

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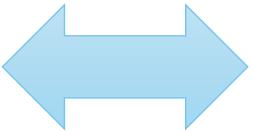
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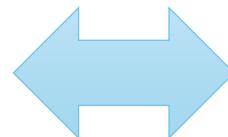
Summary of the use case

Integrated Data Journey: From Study Concept to CRF



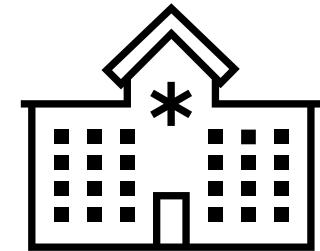
Visit	1	2	3 (3-10 days)
Consent	X		
PSA blood test	X		
Questionnaires Pack 1 (IPSS, IPSS-QoL, IIEF-15, EPIC-urinary, EPIC bowel, EQ-5D QoL)	X		X
Questionnaires Pack 2 (FACT-P, MAX-PC)	X		X

Clinical Document generation using a structured content authoring tool



Creation of machine-readable format schedule of activity

Linkage of CRFs to visits and activities

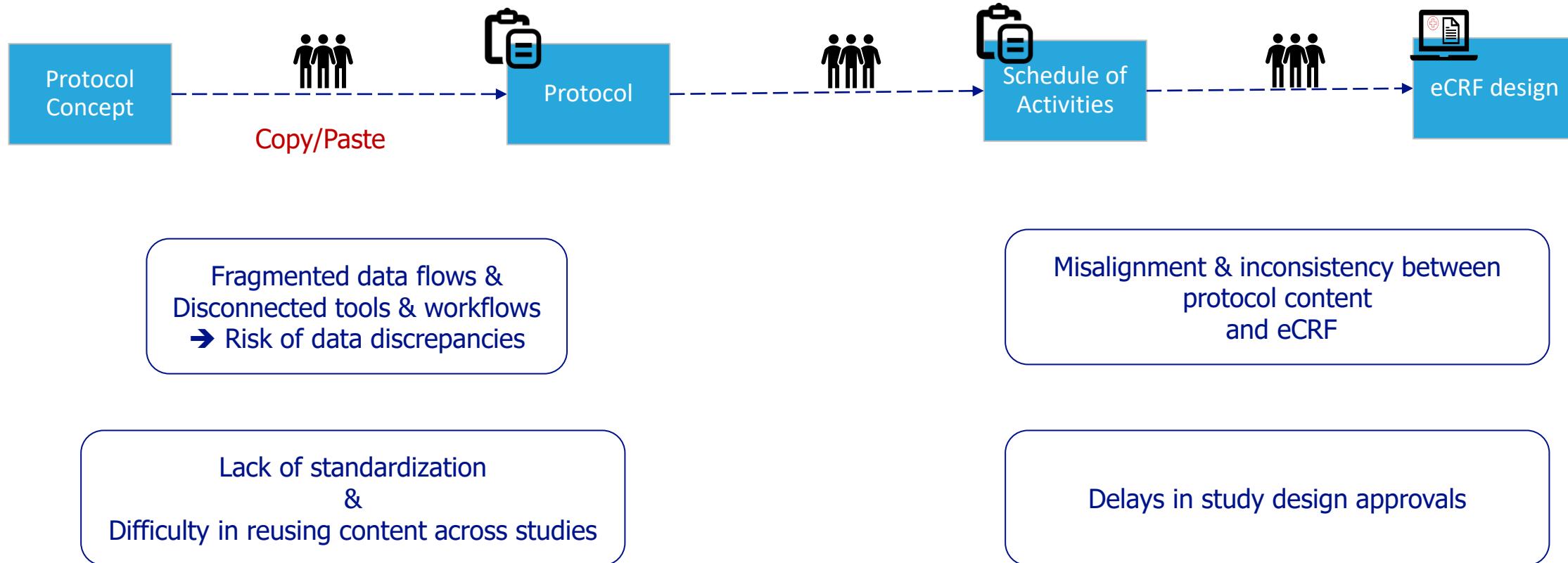


Clinical Data Collection



This use case will structure, standardize, and digitize the study protocol content, enabling content reuse across downstream systems and across documents.

Previous Process and its Limitations

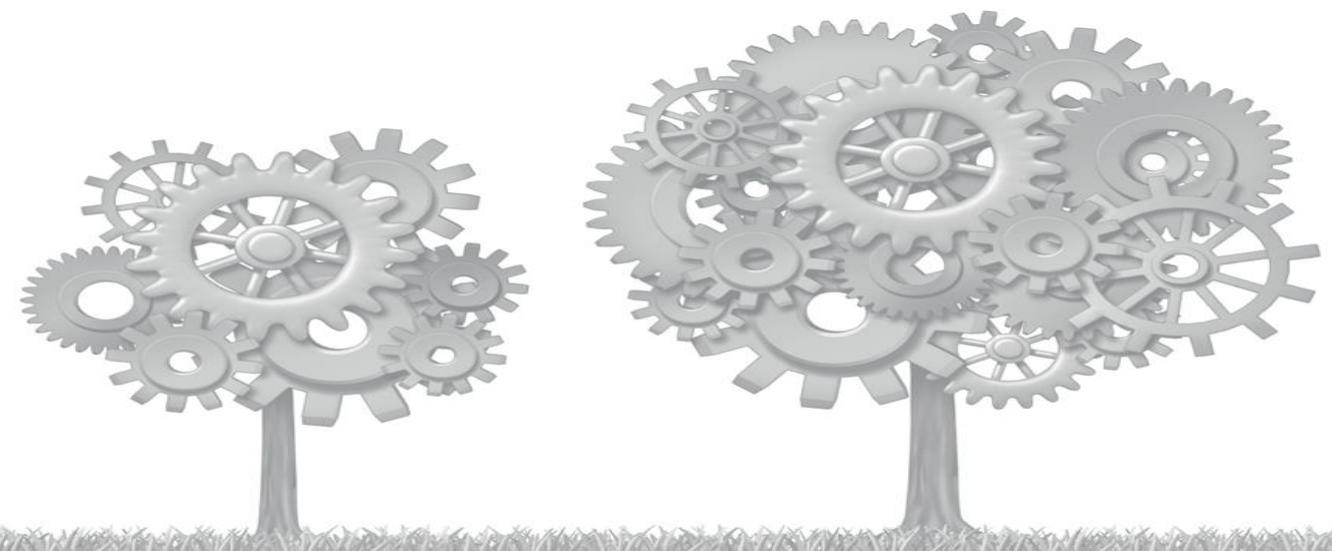
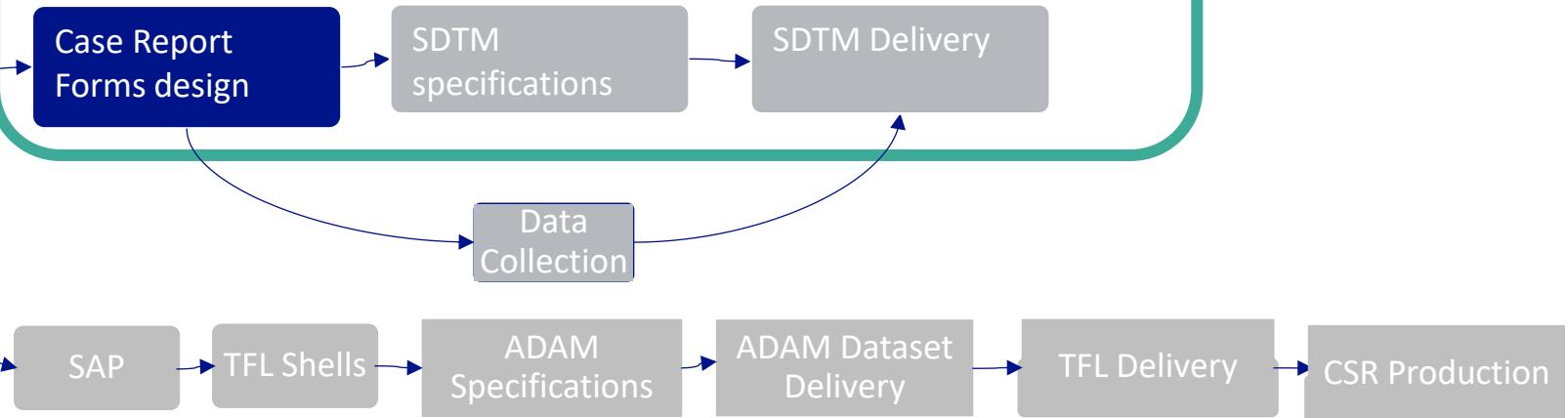


Integrated Data Journey: use case focus & benefits

Bespoke Structured Content Authoring tool



Metadata Repository

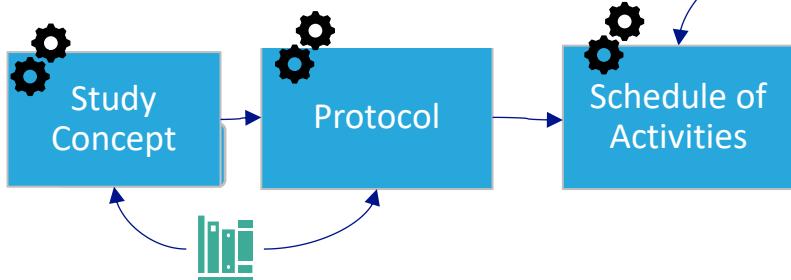


Integrated Data Journey: use case focus & benefits

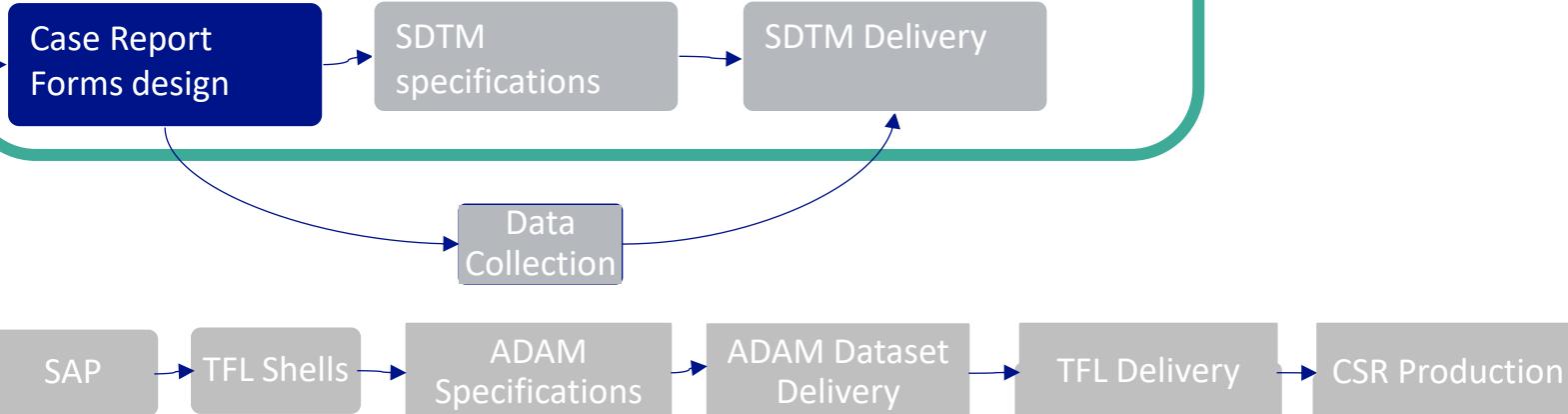
Bespoke Structured Content

Authoring tool

- Supports Scalability & Reusability
- Accelerates Study Start-Up
- Reduces Operational Costs
- Improves Quality & Compliance
- Enhances Cross-Functional Collaboration
- Enables Digital Transformation



Metadata Repository

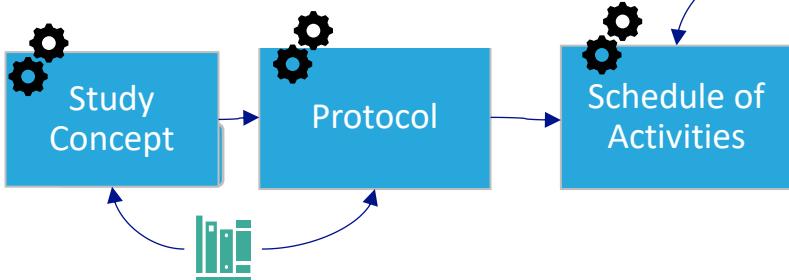


Integrated Data Journey: use case focus & benefits

Bespoke Structured Content

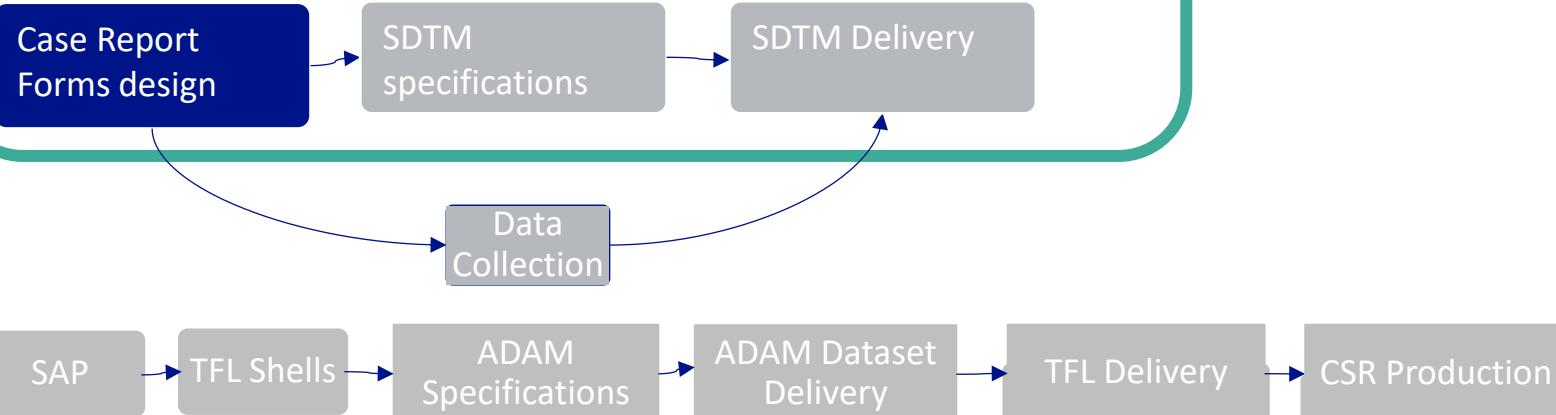
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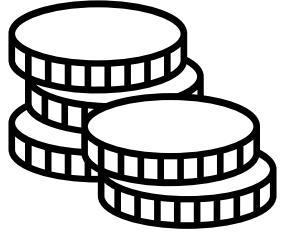


Metadata Repository

Connection between the structure Content Authoring & metadata repository will allow: Consistency, Fewer Errors & Amendments, Better Traceability & Compliance



Implementing this use case wasn't easy... Main challenges



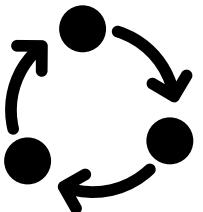
Cost Justification and Return On Investment

Custom tools are expensive, and ROI may be hard to quantify in early stages.



Breaking the silos

A big investment in terms of time & expertise is needed to ensure consistency through the E2E process and digital landscape.



Change Management: Reuse vs. Flexibility

Structured content authoring supports reuse and consistency, but clinical documents often require flexibility. Rigid standards can feel limiting and may not fit all needs. Defining these standards takes time but is key to long-term efficiency.

Summary of the journey



An idea is born...

Identified a proof-of-concept projects for structured content authoring.

This is the extension of a bespoke risk-management platform

2019

2020

2021

2022

2023

2024

2025



Extension of other functionalities for a more integrated clinical platform



Extension of other functionalities for a more integrated clinical platform



Adaptation of Structured Content authoring to new document templates



The first version of structured content authoring is live



Second release for structured content authoring including content reuse



Extension of other functionalities for a more integrated clinical platform