

The background image depicts a person in silhouette running through a dark space. On the left, a massive, chaotic pile of papers or documents is falling or being discarded. The person is running towards the right, where a bright, glowing blue digital portal or tunnel is visible. This portal is composed of concentric circles and is filled with binary code (0s and 1s) and other digital symbols, suggesting a transition from a physical, paper-based world to a digital, data-driven one.

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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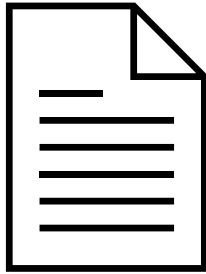
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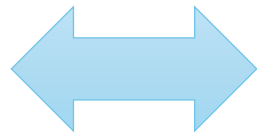
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Summary of the use case

Integrated Data Journey: From Study Concept to CRF



Clinical Document generation using a structured content authoring tool



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

Creation of machine-readable format schedule of activity



CASE REPORT FORM Invasive Pneumococcal Disease

Invasive pneumococcal disease EpSurv No.

Reporting Authority

Name of Public Health Officer responsible for case

Notifier Identification

Reporting source* ☐ General Practitioner ☐ Hospital-based Practitioner ☐ Laboratory
☐ Self notification ☐ Outbreak Investigation ☐ Other

Name of reporting source Organisation

Date reported* Contact phone

Usual GP GP phone

GP/Practice address Number Street Suburb Post Code GP Code

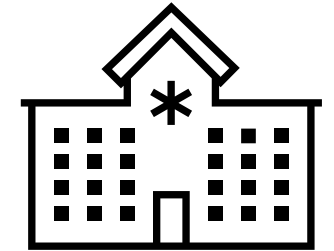
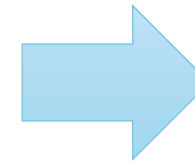
Case Identification

Name of case* Surname (Given Name(s))

HLI number* Email

Current address* Number Street Suburb

Linkage of CRFs to visits and activities

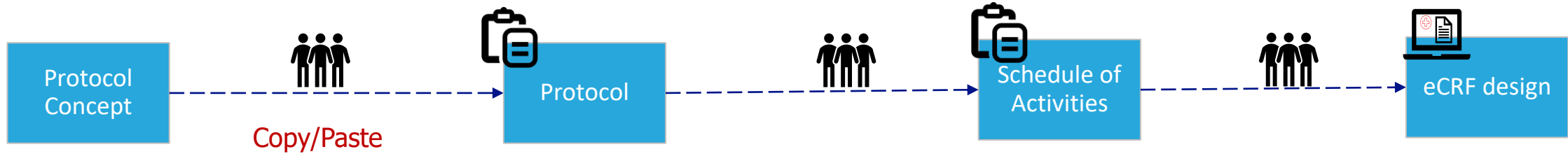


Clinical Data Collection



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



Fragmented data flows &
Disconnected tools & workflows
→ Risk of data discrepancies

Misalignment & inconsistency between
protocol content
and eCRF

Lack of standardization
&
Difficulty in reusing content across studies

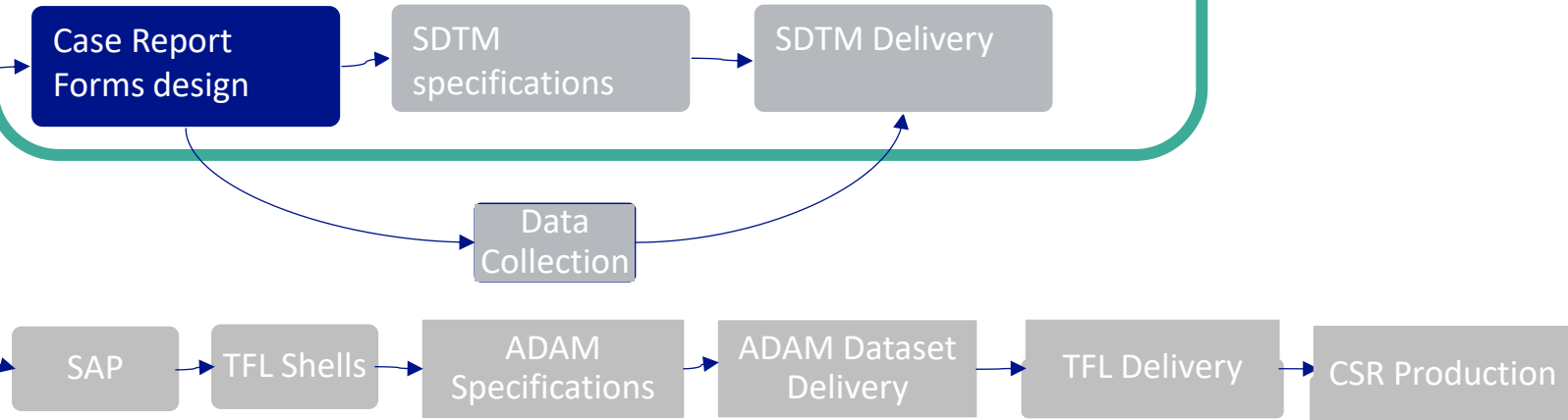
Delays in study design approvals

Integrated Data Journey: use case focus & benefits

Bespoke Structured Content Authoring tool



Metadata Repository



Integrated Data Journey: use case focus & benefits

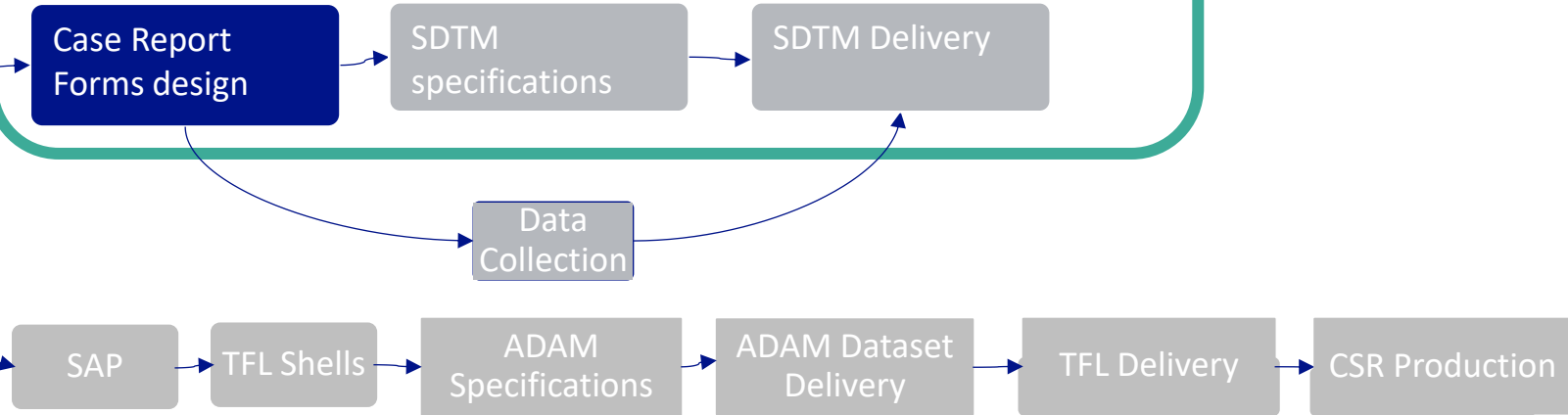
Bespoke Structured Content Authoring tool

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



Standard Libraries being built and grown with each protocol

Metadata Repository



Integrated Data Journey: use case focus & benefits

Bespoke Structured Content

Authoring tool

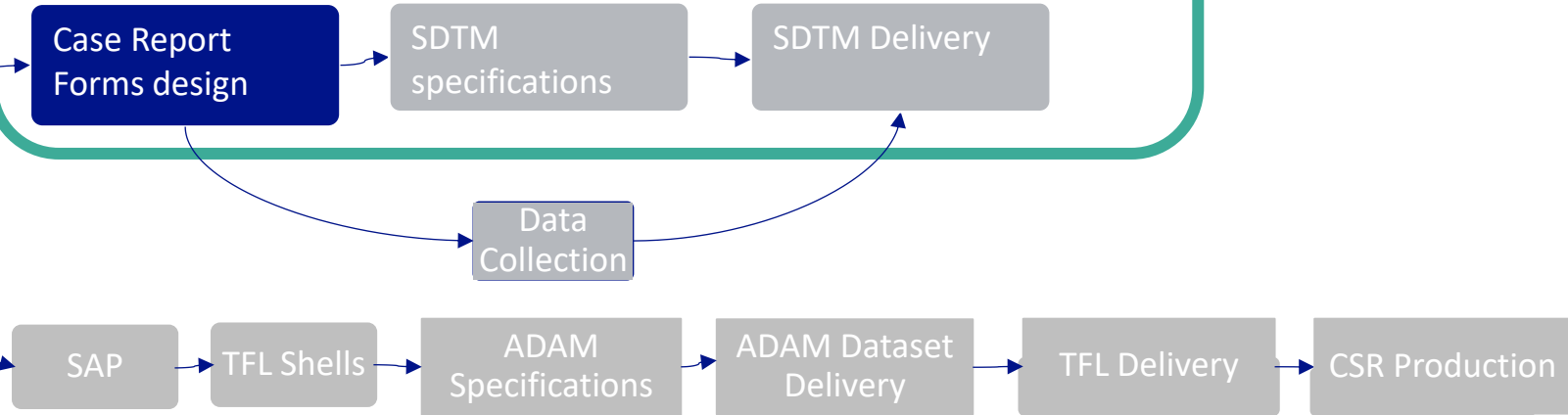
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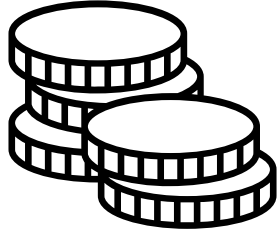
Metadata Repository

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



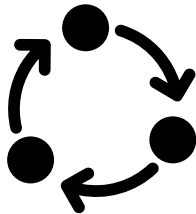
Cost Justification and Return On Investment

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