Digital Data Flow (DDF) Initiative

Protocol Medical Writer

Persona Toolkit

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Digital Data Flow (DDF) Initiative Overview

The Digital Data Flow (DDF) Initiative aims to catalyze digital transformation; breaking the protocol document paradigm to enable seamless data flow

Digitized Protocols

Enabling the use of technologies that identify and assemble study elements using a common, industry-standard digital language allows industry to move to digital protocols

Advanced Analytics

Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs

Connectivity of Data and Processes

Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)

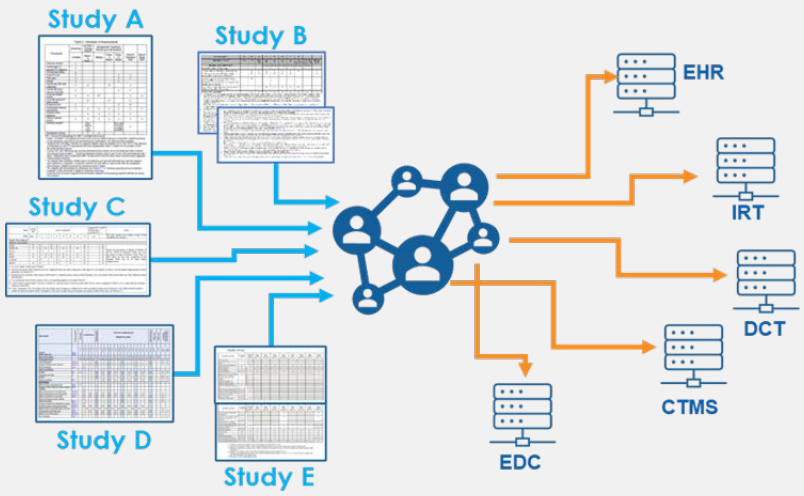
Open & Flexible Solution

A functioning, example solution to enable exchange of protocol info between systems that is vendor agnostic, flexible, and provided in open source

VISION: From Documents to Data: Write Once, Read Many Times

TODAY

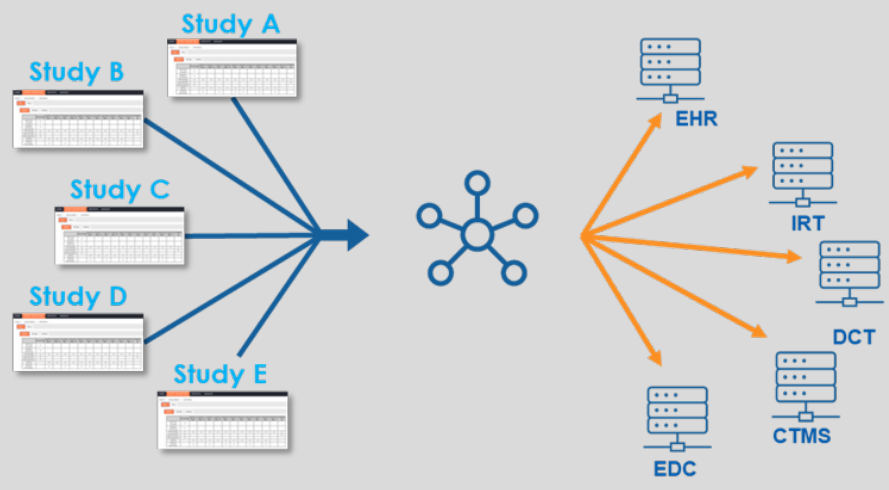
Many-to-many manual process; Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems



- *Schedule of Activities (SoA) specified **inconsistently** in study protocols (e.g., sections, rows, columns, footnotes)*
- ***Manual** process to configure systems/tools*
- ***No reliable method** to synchronize updates from a single source of truth*

TOMORROW

Digitalized one-to-many process; Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



- ✓ ***Digitized design** specification per study*
- ✓ ***Consistent** method of study spec exchange*
- ✓ *Streamlined, **automated** start-up (reduce effort, cycle time, and complexity)*
- ✓ ***Improve** quality and compliance. Minimize protocol violations*

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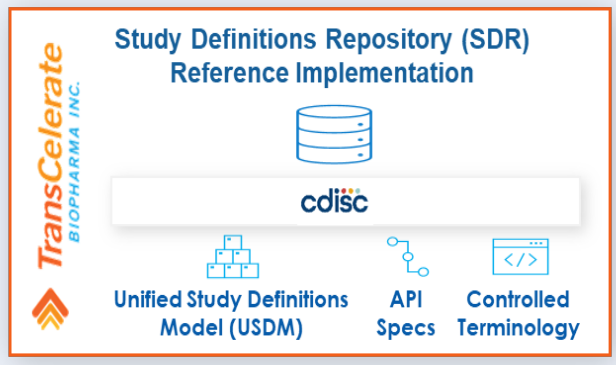
Digital Data Flow (DDF) Initiative Overview

Understanding Key Concepts

The Digital Data Flow Initiative offers a **mechanism to digitize clinical study components** to enable interoperability and reuse, starting with study design.

In collaboration with Clinical Data Interchange Standards Consortium (CDISC) and other stakeholders, TransCelerate has developed a standard data model that creates **a new digital language for specifying protocol information**, as well as a **demonstrated way to connect systems** that produce, exchange or consume this information.



Unified Study Definitions Model (USDM)

An industry standard for study definitions (protocol information) promulgated and maintained by CDISC

Study Definitions Repository Reference Implementation (SDR RI)

A functioning, example approach that utilizes USDM to manage the information flow of protocol data between upstream and downstream systems

Study Builder/ Digitized Study Design Solution

An application or piece of software utilized by a study team to design a study and/or author a study protocol

Controlled Terminology

CDISC developed set of codelists and valid values for terms used in a study

Application Programming Interface (API) Specifications

CDISC developed coding language to connect and exchange data between systems

Biomedical Concepts

CDISC and other organizations developed definitions of discrete units of biomedical information that would need to be measured for a study participant

Key Focus Areas on the DDF Roadmap

Digitization of Study Elements and Downstream EDC Automation (Current/Completed)

- ✓ Support electronically populating and configuring EDC/CRFs based on the digital protocol specification
- ✓ Use digital protocol specification to demonstrate (as a proof of concept) the population of elements in a human readable protocol document

Complete Protocol Digitization & Regulatory Alignment (In Progress)

Includes collaboration through HL7 Vulcan Working Group between ICH M11 & CDISC

- ➢ Complete (100%) digitization of all protocol elements in alignment with M11 and relevant CDISC SDTM domains
- ➢ Begins with gap analysis between USDM and ICH M11 content model, CDISC SDTM, and Global Trial Registry Reporting
- ➢ Goal to capture "breadth" of ICH M11 completely within USDM, followed by greater "depth" of structured content within model (e.g. structured I/E criteria)

Expand Downstream Connectivity (In Progress)

Includes collaboration with expanding community of tech solution providers across range of clinical solutions

- ➢ Further develop USDM to enable downstream connectivity with priority systems, enabling a future state of "write once, read many times"
- ➢ Work collaboratively with vendor ecosystem to better understand existing gaps & development requirements for the USDM

Alignment with Point of Care (In Progress)

Includes collaboration with Vulcan FHIR Accelerator

- ➢ Comparative assessment of USDM and FHIR
- ➢ Alignment of DDF and FHIR resources for end-to-end enablement of EHR workflow set-up and eSource

Digital Data Flow (DDF) Initiative
Persona Toolkit Overview For Protocol Medical Writer

*Protocol Medical Writer**
Usually accountable for, among other things, performing authoring & Quality Check (QC) activities on the clinical protocol.

PURPOSE

The objective is to help inform protocol medical writers so they are better prepared and **can more fully realize the anticipated benefits** of the DDF initiative.

An understanding of automation & digitalization of the end-to-end study design process will help medical writers involved in protocol authoring understand the impact of DDF and help them **adapt their role and responsibilities to new ways of working** within an automated and digitalized study lifecycle.

TOOLKIT OBJECTIVE

Job titles, roles, & responsibilities can and will vary, often significantly, across companies. This document seeks to outline some discrete tasks commonly performed by the roles addressed in this document – Protocol Medical Writers – and explain how the DDF initiative will likely impact these tasks.

This document does not seek to address all tasks performed by personas, nor does it seek to dictate or suggest to the persona how relevant tasks must or should be performed, as this will vary greatly across companies.

HOW TO USE THIS TOOLKIT

1. **Review each component** of the persona toolkit for a Protocol Medical Writer.
2. **Understand the purpose and use of each toolkit component.** Sponsor companies can consider this a deep dive to understand how the DDF initiative will impact roles & mitigation factors to enable an adoption pathway for specific roles & personas.
3. **Use the persona toolkit as a guide.** The persona toolkit is illustrative and intended to serve only as a guide for sponsor companies. The application of this toolkit needs to be customized to fit your company's context, objective and organizational set-up.

TOOLKIT COMPONENTS

Persona Profile Card

Outlines the profile for a typical Protocol Medical Writer's role and can be leveraged to understand how the role may change within the anticipated context of digitalization and automation of end-to-end data flow from study design to downstream systems, including the benefits and value of DDF to the Medical Writer role.

DDF Change Impacts

Identifies anticipated impacts of DDF to a Protocol Medical Writer's role from current state (As-Is) to a future state (To-Be) which DDF will help make possible.

"Day in the Life" with DDF

What could a work-day look like with the application of DDF?

"Day in the Life" maps out an illustrative high-level flow of work across an average day for the Protocol Medical Writer with the application of DDF.

**The Protocol Medical Writer toolkit focuses on the responsibilities generally performed by the medical writer within the context of the study protocol and does not cover the broad swath of responsibilities of a medical writer in a pharma company.*

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Digital Data Flow (DDF) Initiative
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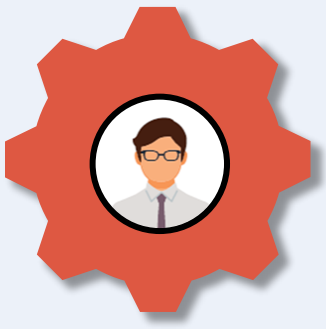
ASSUMPTIONS FOR USE OF PROTOCOL MEDICAL WRITER: PERSONA BUILD

Business Role



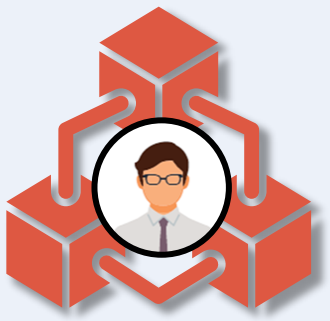
The persona covers the typical Protocol Medical Writing roles of Protocol Author, Protocol Specialist and Protocol Strategist.

Protocol Author is used as the focus of "Day in the Life with DDF" poster.

Participation in study design processes is not a task that the Protocol Medical Writer role handles in all cases.

Structured protocol content creation, usage and maintenance is considered a part of the persona's responsibilities, for purposes of this exercise.

Technical Setup



A solution/approach to digitize study design/protocol in a USDM** compliant format exists in the company's IT landscape.

The solution/approach may range from a relatively manual process to a more sophisticated software platform (a digitized study design solution aka a "Study Builder") that provides capabilities such as:

- Structured protocol content design e.g., SoA table, objectives and endpoints, etc.
- Text authoring capabilities paired with the equivalent structured protocol content, e.g., visit descriptions
- Exporting capabilities to standard document formats, e.g., .doc, docx, .pdf
- Ability to reuse and pull from existing content

Protocol Process

Protocol Medical Writers are mainly involved in protocol authoring processes.

Study design processes begin before and feed into protocol authoring.

A stable study design is preferred for initializing protocol authoring.

Study design may be updated during protocol authoring.

***Footnote**: This document refers to both the concepts of digitization and digitalization. Digitization refers to "digital-first documents and content", i.e., the transformation of non-digital content into a form computers can process. Digitalization refers to "digital-first processes and systems", i.e., the transformation of human-based and document-based processes into systems that can be computer-operated. Please refer to Digital Data Flow Initiative Overview for DDF terms you are not familiar with.*
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Digital Data Flow (DDF) Initiative Persona Profile Card

*Protocol Medical Writer**

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Assumptions about Protocol Medical Writer Responsibilities

Content Authoring & Management: Engages with the study design process to compile the clinical study protocol

Content Quality Checks: Validates protocol content, quality and formatting

Content Review: Ensures alignment of protocol contents with the intended study goal

The Challenges Today

Document-based protocol-related processes are **manual and disconnected** from downstream processes, leading to additional workload for downstream system or document set-up.

How Can The DDF Initiative Help?

Protocol-related medical writing **processes will be accelerated**, and information sharing from and to the protocol can become easier to automate.

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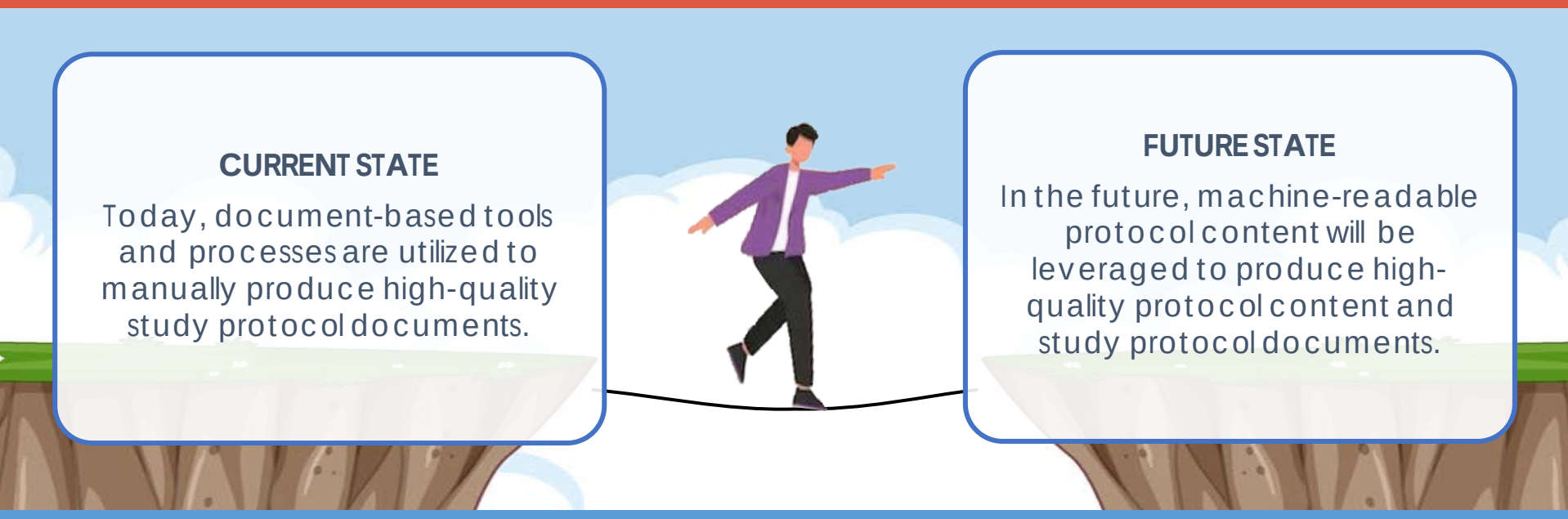
CURRENT TO FUTURE STATE



CURRENT STATE

Today, document-based tools and processes are utilized to manually produce high-quality study protocol documents.

FUTURE STATE

In the future, machine-readable protocol content will be leveraged to produce high-quality protocol content and study protocol documents.

BENEFITS & VALUE

- ✓ Leverages a digitized study design solution in a USDM** compliant format to make study design available in a structured, standardized and automated data format. This provides Protocol Medical Writers an **opportunity to engage with and understand the study design earlier** in the study's lifecycle.
- ✓ **Reduces inefficiencies** from study design changes due to the automation, interoperability and standardization enabled by the digitized study design solution.
- ✓ **Decreases time spent** on protocol formatting and structuring with the automation of protocol content enabled by the digitized study design solution in a USDM-compliant format.
- ✓ Provides access to a **single destination of study definitions** for future reuse (SDR** or similar repository).
- ✓ Data flow from protocol design to downstream consuming systems is automated, **reduces required manual effort** and leads to expedited study start-up.
- ✓ Increases potential alignment with **FAIR (Findable (F), Accessible (A), Interoperable (I), and Reusable (R)) principles** earlier in cycle during protocol development.

POTENTIAL CHALLENGES

- ? Can potentially **disrupt current document-based workflows** in the transition to working in a digitized study design solution ("Study Builder")**. Careful transition planning to an automated setup would be needed to avoid short-term inefficiencies.
- ? May call for **assessment of suitability and maturity** of a digitized study design solution and its impact on current protocol authoring processes.
- ? May need to **assess and mitigate changes** to current collaboration processes to enhance cross-collaboration between multiple stakeholder groups within a digitized study design setup.
- ? Using standardized biomedical concepts **could require education** in new ways of thinking/working in terms of specifying the collection of study data.

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Digital Data Flow (DDF) Initiative Change Impact

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CONTENT AUTHORING

CURRENT STATE
Content authoring is often manual, leveraging document-based applications and peripheral automation across study design processes, technology and ways of working

FUTURE STATE***
Content authoring is accelerated with the use of structured, standardized and reusable content specified via a digitized study design solution

PROCESS

Utilizes the stable study design to produce the study protocol document. Authors may use company specific pre-compiled protocol components to accelerate their processes.

Initiates protocol authoring early on starting from study design. Utilizes a digitized study design solution to produce protocol information in a USDM** compliant format, which may also enable automated information flow to documents. Authors may utilize internal and external standardized protocol components to accelerate their processes.

TECHNOLOGY

Works with document-based applications and peripheral automation.

Utilizes a digitized study design solution to create and store studies accessible by any connected downstream clinical study systems.

WAYS OF WORKING

Connects with study team members to create a submission-ready protocol. Adapts the protocol based on study team comments and amends based on study design updates.

Engages with study design and authoring processes earlier, collaborating across study design and protocol authoring processing, upstream and downstream, reducing inefficiencies. Shares information created in the study design system via a study design repository.

BIGGEST AREA FOR IMPACT

- Transitioning from working in isolated, downstream documents to an **interconnected, digitized study design solution** capable of producing protocol information in a USDM** compliant format.
- **Management of structured content flow** from upstream content sources will be key for authoring processes.

RECOMMENDED ACTION FOR IMPACT

- **Perform workflow analysis** to analyze gap between current & future state. Consider appropriate interventions such as education, training to close the gap.
- **Upskilling** will be a key consideration for managing the use of digital protocol systems, to understand the impact of USDM** and participating in early or parallel authoring influenced by the study design.

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Digital Data Flow (DDF) Initiative Change Impact

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CONTENT QUALITY CHECKS

CURRENT STATE

Quality checks often happen in non-digital setups across manual processes and ways of working

FUTURE STATE***

Quality checks shift to working within a digitized study design system, reducing manual handoffs and potentially lowering time and efforts expended

CURRENT STATE		FUTURE STATE***
Performs manual quality checks in protocol documents.	PROCESS	Performs quality checks in protocol content and documents. Use of internal standards in a USDM** compliant format promote semi-automated processes, reducing manual quality check effort.
Utilizes document-based approach and disconnected systems.	TECHNOLOGY	Works in the digitized study design system supported by USDM**, avoiding offline and disconnected quality checks and revisions.
Informs document stakeholders on required changes, through document-based or offline workflows.	WAYS OF WORKING	Utilizes the digitized study design solution in a USDM** compliant format to connect and collaborate with document stakeholders in a possibly faster and more seamless manner.

BIGGEST AREA FOR IMPACT

- **Integration** of protocol content quality check processes – in the digitized study design solution to existing processes – outside the digitized study design system, would be needed.

RECOMMENDED ACTION FOR IMPACT

- Perform a **compatibility assessment** between digitized study design solution, USDM** and existing processes.
- Provide **basic training** on new processes.

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Digital Data Flow (DDF) Initiative Change Impact

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CONTENT REVIEW

CURRENT STATE		FUTURE STATE***
Content review often takes place in document-based setup using manual workflows		***Content review shifts to review of digital protocol content via digitized workflows with greater opportunity to accelerate review and conduct review parallelly with protocol authoring***
Performs review of protocol relevant documents.	PROCESS	Performs review on protocol content. Work could be less labor intensive and accelerated with authoring, review parallelized.
Utilizes document-based approach and systems.	TECHNOLOGY	Takes advantage of digital protocol workflow management features to accelerate review.
Informs document stakeholders on needed changes, through document-based workflows.	WAYS OF WORKING	Connects with document stakeholders on their content needs through digital workflows, possibly leading to faster and easier collaboration.

BIGGEST AREA FOR IMPACT

- Reviewing becomes an **online process**, focused directly on protocol content.

RECOMMENDED ACTION FOR IMPACT

- Provide **basic training** on new processes as reviewers are expected to work across digital workflows in a digitalized environment.

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“Day in the Life” with Digital Data Flow (DDF) Initiative

*“I am responsible for authoring, reviewing and quality checking study content. TransCelerate’s DDF initiative enables me to perform these activities in a digital environment, connected to the company's ecosystem." - **Thomas, Medical Writer ****

Thomas starts his day by looking at the latest updates in the digital study design for a clinical trial. **He can access study content and team notes in a single digital study design system.** ↻

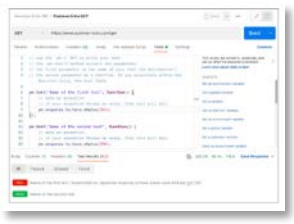
8 AM

Thomas shares his feedback on the changes performed by the study team and takes note of the protocol requirements. **Utilizing the same online medium to share feedback, Thomas avoids lengthy conversations through email.** ✪

Thomas asks a question about best practices in digital protocol development in an online protocol building community for the study's therapeutic area. **Previous studies, found in the study definitions repository, follow similar content definitions, helping him find common ground and check-in with his peers on protocol requirements.** ✪

11 AM

At the next weekly Study Team meeting, the study manager explains how the changes to the study design impact the team's work. **Thomas is closer to the study's content and gains additional clarity of the study team's rationale on changes.** ↻



Thomas works in the study builder to perform the changes needed in protocol's content. **With the digitalization of data flows, the study team works in a dedicated system, reducing performance impact when working parallelly. Thomas works faster, with fewer technical delays.** 💻

2 PM

With a new study design system update coming later in the month, Thomas attends virtual training provided by the system's super-users. **The training helps him understand the system changes and how the use of internal and external standardized concepts/language enable the work of the study team.** ✪

Some of the needed changes require entirely new text content which Thomas finds in the company’s internal standardized text library. **The DDF initiative’s solution components of USDM and SDR Reference Implementation allow for libraries to connect with any study design system that can utilize the USDM.** ↻

Thomas initiates a review workflow for the digital protocol changes, utilizing the system's collaboration features. **Feedback from the team is available to him in real-time, and he can perform the changes in collaboration with the reviewers.** ↻

5 PM

Thomas discusses with the study team's Clinical Operations members the next steps for the protocol. With time freed up by automation of study design and standardization, structuring of protocol content, **Thomas has more time to engage in value-adding activities such as content discussion and brainstorming.** ↻

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↻ *Process*
💻 *System/Technology*
✪ *Ways of working*

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