“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.** ↻

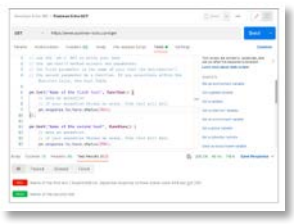
8 AM

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.** ↻

**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.*

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

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