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.*

TransCelerate BIOPHARMA INC.

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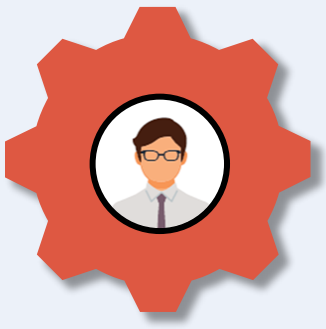
ASSUMPTIONS FOR USE OF PROTOCOL MEDICAL WRITER: PERSONA BUILD

Business Role



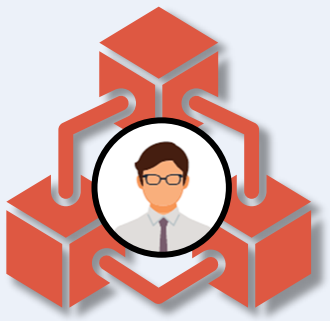
The persona covers the typical Protocol Medical Writing roles of Protocol Author, Protocol Specialist and Protocol Strategist.

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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