

Digital Data Flow (DDF) Initiative

Persona Toolkit Overview for Clinical Data Manager



Clinical Data Manager*

Typically responsible for study setup in an EDC system to collect, organize, manage, and validate incoming clinical data, as per the protocol content, and for overseeing and coordinating the associated clinical data capture processes.

PURPOSE

The objective is to help inform clinical data managers so they are better prepared & **can more fully realize the anticipated benefits** of the DDF initiative.

An understanding of automation and digitalization of the end-to-end study design process will help data managers 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 – Clinical Data Manager – 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 Clinical Data Manager.
- 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 Clinical Data Manager's role and can be leveraged to understand how the role of a Data Manager may change within the anticipated context of the DDF initiative, including the benefits and value of DDF to the Data Manager role.



DDF Change Impacts

Identifies potential impacts of DDF to a Clinical Data Manager'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 a Clinical Data Manager with the application of the DDF initiative.

* The Clinical Data Manager toolkit focuses on the responsibilities generally performed by the clinical data manager within the context of the study protocol and does not cover the broad swath of responsibilities of a clinical data manager in a pharma company

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ASSUMPTIONS FOR USE OF CLINICAL DATA MANAGERS: PERSONA BUILD

Business Role

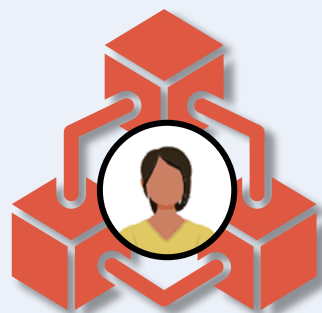


The persona covers a typical clinical data manager's role.

For the purpose of this toolkit, the responsibilities and activities of the clinical data manager role are focused primarily on EDC set-up, as an example, the full or partial automation of EDC study database set up and downstream migrations.

Clinical Standards Data Managers responsible for oversight of internal standards libraries and sub-specialties are not covered in detail within the scope of this asset.

Technical Role



This persona document assumes that EDC database systems are established within a company.

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

An EDC software system exists that is capable of ingestion of digital protocol content flow in a USDM compliant format and automatically selecting an appropriate eCRF from an eCRF library.

Protocol Process



Data Managers are typically responsible for setting up a study in an EDC system and providing oversight of data collection and data quality.

Data managers are involved in understanding and reviewing the protocol and SOA during development stage.

Data managers have an awareness of their company's integrated system landscape, from protocol content creation to data flow into EDC systems, including any intermediary tools/data capture hubs.

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.

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**Please refer to Key Concepts section in the Digital Data Flow Initiative Overview for DDF terms you are not familiar with