Digital Data Flow (DDF) Initiative Persona Profile Card

*Clinical Data Manager**

Typically responsible for study set up 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.

Assumptions about Clinical Data Manager Responsibilities

Pre-study activities: Contributes to Study Design, protocol review

Study start up programming: Sets-up SoA using selected standards, contributes to programming in EDC for eCRF design and data capture, edit checks, eCRF completion guidelines, DM reports

Study Conduct Management: Conducts amendment and migration management, data entry review, query management, data review of pivotal data (e.g., data delivery for primary and interim analysis, data monitoring committee), and narratives generation (depends on company ecosystem)

Data standards: Manages adherence to data standards

The Challenges Today

Process of taking study content information from protocol to set up of a study in EDC system is a **manual, tedious** end-to-end process that requires additional workflows.

It is costly, time consuming, prone to errors, and can lead to data inconsistencies, poor data quality stemming from low value data, and inadequate data-driven decisions.

How Can The DDF Initiative Help?

USDM** based automation could allow data managers to focus on higher value outcomes, **opening up opportunity for innovation** in data collection & quality strategy to potentially deliver optimal critical data at added cost & time efficiencies.

Digitization of protocols leads to an integrated and shorter study cycle workflow.

**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*

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

TransCelerate BIOPHARMA INC.

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CURRENT TO FUTURE STATE

CURRENT STATE

Today, manual efforts & interventions across the end-to-end process from protocol/study design to EDC and eCRF setup have resulted in **additional, redundant workflows and unstructured datasets** increasing chances of "dirty data" (inaccurate, inconsistent, duplicates, low value data).

FUTURE STATE

In the future, digitized protocols and SoAs will lead to automation of partial/full eCRF build in EDC systems. Automation and digitalization could **reduce overall cycle time** from final protocol to EDC database go-live.

BENEFITS & VALUE

Increased automation, digitalization, standardization, & enhanced collaboration could **reduce time-consuming, error-prone manual efforts & sync related efforts** (processes across upstream to downstream systems) to create an integrated clinical study cycle workflow with shorter cycle times.

With the DDF initiative, Clinical Data Manager roles have the **potential to move from tactical to strategic & value creating roles,** providing opportunities for innovation & improved productivity such as:

- ✓ Potential for continuous improvements in eCRF build, internal data standards and data analytics
- ✓ Possible optimization of protocol design, via USDM's digitization of biomedical concepts, could lead to fewer data entry queries & minimal data entry errors on low value data collected; potentially improving working relationships between site staff, trial monitors & data managers
- ✓ Possibility of reduced UAT & QC steps due to fewer manual updates could result in cost and time efficiencies
- ✓ Potential optimization of data quality with more focus on critical data such as study end points, potential for reduced data entry of non-critical fields and data cleaning via edit checks
- ✓ Greater opportunity for agile implementation of EDC updates with greater efficiencies, e.g., implementation of eCRF updates during COVID 19)
- ✓ Possible reduction or complete elimination of discrepancies between protocol data collection requirements and EDC/Clinical database setup
- ✓ Expedition and simplification of the end-to-end study design process from protocol to EDC with the use of USDM**, automation of study data flows
- ✓ Potential acceleration of ability to initiate data analyses due to faster availability to source data
- ✓ Possible improvements in EDC migrations with EDC automation replacing manual entry

POTENTIAL CHALLENGES

- ? Clinical data managers may be expected to align with information found in study builder tool upstream earlier in the process.
- ? Upfront initial training for USDM** could be required to upskill Data Managers on the common digital language for protocol information.
- ? Additional work could be required to curate historical protocol data from pre-USDM** clinical trials to make it available in a format that can be merged with USDM aligned data from more recent trials.

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