Digital Data Flow (DDF) Initiative | Persona Toolkit Highlights

Protocol Medical Writer*

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

CHANGE IMPACTS WITH DDF

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

BIGGEST AREA FOR IMPACT — *Transitioning to an interconnected, digitized study design solution capable of producing protocol information in a USDM** compliant format; Management of structured content flow*

RECOMMENDED ACTIONS FOR IMPACT — *Perform workflow analysis to analyze gap between current & future state.; Upskilling will be a key consideration*

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

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 ACTIONS FOR IMPACT — *Perform a compatibility assessment between digitized study design solution, USDM** & existing processes; Provide training*

CONTENT REVIEW

CURRENT STATE
Content review often takes place in **document-based setup** using manual workflows

FUTURE STATE**
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

BIGGEST AREA FOR IMPACT — *Reviewing becomes an online process, focused directly on protocol content*

RECOMMENDED ACTIONS FOR IMPACT — *Provide training on new processes as reviewers are expected to work across digital workflows in a digitalized environment.*

Clinical Data Manager*

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

CHANGE IMPACTS WITH DDF

PRE-STUDY ACTIVITIES

CURRENT STATE
Pre-study activities take place in **a non-digital** setup mostly reliant on manual protocol document

FUTURE STATE**
Pre-study activities take place in a **digitized protocol SoA** needed to automate EDC build

BIGGEST AREA FOR IMPACT — *Reviews of protocol moves from a non-digital to a digital format, including a digitized SoA.*

RECOMMENDED ACTIONS FOR IMPACT — *Communicate value & benefits of digitalization (i.e. successful use cases, etc.) to create understanding; Provide training*

STUDY STARTUP PROGRAMMING

CURRENT STATE
Study startup programming takes place in a **manual** setup

FUTURE STATE**
Study startup programming takes place in an **accelerated digitized and automated environment**

BIGGEST AREA FOR IMPACT — *Updates to processes; introduction of new or updated USDM-Compliant tools/systems capable of digital exchange*

RECOMMENDED ACTIONS FOR IMPACT — *Deliver change management toolkit to support change; Provide reskilling opportunities; Make education & training available*

STUDY CONDUCT MANAGEMENT

CURRENT STATE
Study conduct management and data collection are often **manual, time consuming and error prone** due to greater number of manual interventions/efforts

FUTURE STATE**
Accelerated and efficient study conduct management due to **automated, digitized processes** leading to fewer amendments and optimized data collection

BIGGEST AREA FOR IMPACT — *Reduces amendments, improves data capture, provides better data quality, reduces inefficiencies in eCRF design*

RECOMMENDED ACTIONS FOR IMPACT — *Provide use cases for cost and time efficiencies in query generation, reduction in number of checks required*

DATA STANDARDS

CURRENT STATE
Relies on a company's **internal** library/standards

FUTURE STATE**
Data standards shift to use of **CDISC USDM**

BIGGEST AREA FOR IMPACT — *Builds understanding of digitized data structured protocol & outputs, USDM** or any study repository & biomedical concepts*

RECOMMENDED ACTIONS FOR IMPACT — *Provide user/implementation guides; Make education materials available to support data managers*

Information Technology Leadership*

Usually responsible for leading the organization to set strategic direction of technology, support clinical research needs and provide staffing resources to support the technology ecosystem

CURRENT TO FUTURE STATE** VISION

CURRENT
Automation is not commonly leveraged to eliminate manual activities & enable sharing of study design data

FUTURE
Implementation of a digitized study design/protocol in a USDM-Compliant format which enables study design data to be shared seamlessly across systems

BENEFITS & VALUE — *Allow IT Leadership to minimize resource attention needed to support non-digital activities and reallocate resource attention to strategic, higher value activities. Automate/share can showcase the value IT brings to the organization*

Technical Expert*

Usually responsible for implementing and supporting the setup of a digitized study design that enables digital consumption of the study design by supporting systems

CURRENT TO FUTURE STATE** VISION

CURRENT
Multiple IT resources support various systems that require duplicate data entry of study design elements (e.g., eCRF)

FUTURE
Potential opportunities will be available to identify additional applications that can be leveraged by the business to manage clinical studies more effectively with the implementation of a digitized study design

BENEFITS & VALUE — *Reduces tedious manual work freeing up time for more complex projects that cannot be automated (value-added activities focus)*

PARTNERSHIP GUIDANCE

IT and Business Functions can together build a business case for the DDF initiative using the below mentioned steps as high-level guidance:

Identify current manual business processes that could benefit from automation/ harmonized standards	**Understand** data needs for the various systems that leverage aspects of study design	**Explore** various options for implementation and impact to the current systems in the IT ecosystem
Analyze change in business processes, business cost with implementing changes, and aligning with business on a strategy for implementation	**Critically evaluate cost savings** and additional benefits that the organization might receive from a shared digitized study design within and across trials	**Jointly build a robust business case** for IT implementation of an integrated digitized study design solution

*Role focuses on the responsibilities generally performed within the context of the study protocol and does not cover the broad swath of responsibilities in a pharma company for the specific role
** Content merely compares and contrasts a world without and with the benefits enabled by the DDF solutions to provide the addressed personas a sense of how the DDF solutions will impact them. This is not meant to assume that all companies or all clinical trial software or systems will necessarily implement the DDF solutions

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