Digital Data Flow (DDF) Initiative Change Impact

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

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

PROCESS

Utilizes the stable study design to produce the study protocol document. Authors may use company specific pre-compiled protocol components to accelerate their processes.

Initiates protocol authoring early on starting from study design. Utilizes a digitized study design solution to produce protocol information in a USDM** compliant format, which may also enable automated information flow to documents. Authors may utilize internal and external standardized protocol components to accelerate their processes.

TECHNOLOGY

Works with document-based applications and peripheral automation.

Utilizes a digitized study design solution to create and store studies accessible by any connected downstream clinical study systems.

WAYS OF WORKING

Connects with study team members to create a submission-ready protocol. Adapts the protocol based on study team comments and amends based on study design updates.

Engages with study design and authoring processes earlier, collaborating across study design and protocol authoring processing, upstream and downstream, reducing inefficiencies. Shares information created in the study design system via a study design repository.

BIGGEST AREA FOR IMPACT

- Transitioning from working in isolated, downstream documents to an **interconnected, digitized study design solution** capable of producing protocol information in a USDM** compliant format.
- **Management of structured content flow** from upstream content sources will be key for authoring processes.

RECOMMENDED ACTION FOR IMPACT

- **Perform workflow analysis** to analyze gap between current & future state. Consider appropriate interventions such as education, training to close the gap.
- **Upskilling** will be a key consideration for managing the use of digital protocol systems, to understand the impact of USDM** and participating in early or parallel authoring influenced by the study design.

**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.*
**Please refer to Digital Data Flow Initiative Overview for DDF terms you are not familiar with.
****The assumptions merely compare and contrast a world without and with the adoption of the DDF solutions to provide the personas addressed in this toolkit 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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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

CURRENT STATE		FUTURE STATE***
Performs manual quality checks in protocol documents.	PROCESS	Performs quality checks in protocol content and documents. Use of internal standards in a USDM** compliant format promote semi-automated processes, reducing manual quality check effort.
Utilizes document-based approach and disconnected systems.	TECHNOLOGY	Works in the digitized study design system supported by USDM**, avoiding offline and disconnected quality checks and revisions.
Informs document stakeholders on required changes, through document-based or offline workflows.	WAYS OF WORKING	Utilizes the digitized study design solution in a USDM** compliant format to connect and collaborate with document stakeholders in a possibly faster and more seamless manner.

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 ACTION FOR IMPACT

- Perform a **compatibility assessment** between digitized study design solution, USDM** and existing processes.
- Provide **basic training** on new processes.

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TransCelerate BIOPHARMA INC.

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CONTENT REVIEW

CURRENT STATE		FUTURE STATE***
Content review often takes place in document-based setup using manual workflows		***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***
Performs review of protocol relevant documents.	PROCESS	Performs review on protocol content. Work could be less labor intensive and accelerated with authoring, review parallelized.
Utilizes document-based approach and systems.	TECHNOLOGY	Takes advantage of digital protocol workflow management features to accelerate review.
Informs document stakeholders on needed changes, through document-based workflows.	WAYS OF WORKING	Connects with document stakeholders on their content needs through digital workflows, possibly leading to faster and easier collaboration.

BIGGEST AREA FOR IMPACT

- Reviewing becomes an **online process**, focused directly on protocol content.

RECOMMENDED ACTION FOR IMPACT

- Provide **basic training** on new processes as reviewers are expected to work across digital workflows in a digitalized environment.

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