Digital Data Flow (DDF) Initiative Persona Profile Card

*Protocol Medical Writer**

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

Assumptions about Protocol Medical Writer Responsibilities

Content Authoring & Management: Engages with the study design process to compile the clinical study protocol

Content Quality Checks: Validates protocol content, quality and formatting

Content Review: Ensures alignment of protocol contents with the intended study goal

The Challenges Today

Document-based protocol-related processes are **manual and disconnected** from downstream processes, leading to additional workload for downstream system or document set-up.

How Can The DDF Initiative Help?

Protocol-related medical writing **processes will be accelerated**, and information sharing from and to the protocol can become easier to automate.

**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.*

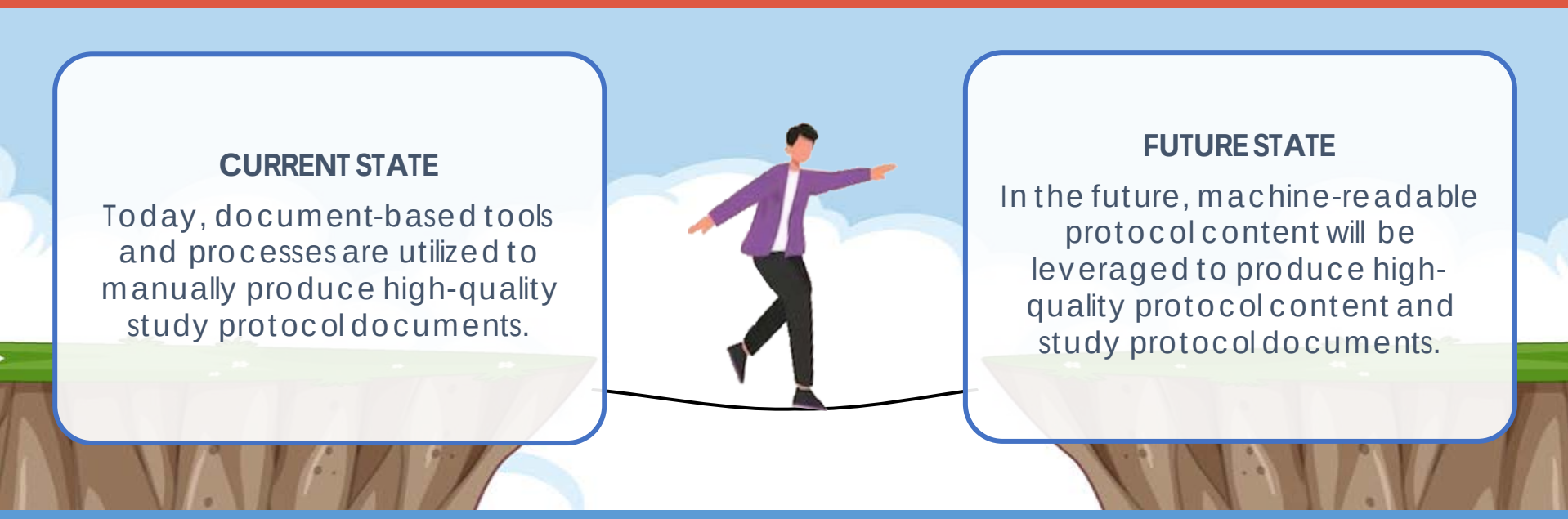
TransCelerate BIOPHARMA INC.

Digital Data Flow (DDF) Initiative Persona Profile Card

*Protocol Medical Writer**

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

CURRENT TO FUTURE STATE



CURRENT STATE

Today, document-based tools and processes are utilized to manually produce high-quality study protocol documents.

FUTURE STATE

In the future, machine-readable protocol content will be leveraged to produce high-quality protocol content and study protocol documents.

BENEFITS & VALUE

- ✓ Leverages a digitized study design solution in a USDM** compliant format to make study design available in a structured, standardized and automated data format. This provides Protocol Medical Writers an **opportunity to engage with and understand the study design earlier** in the study's lifecycle.
- ✓ **Reduces inefficiencies** from study design changes due to the automation, interoperability and standardization enabled by the digitized study design solution.
- ✓ **Decreases time spent** on protocol formatting and structuring with the automation of protocol content enabled by the digitized study design solution in a USDM-compliant format.
- ✓ Provides access to a **single destination of study definitions** for future reuse (SDR** or similar repository).
- ✓ Data flow from protocol design to downstream consuming systems is automated, **reduces required manual effort** and leads to expedited study start-up.
- ✓ Increases potential alignment with **FAIR (Findable (F), Accessible (A), Interoperable (I), and Reusable (R)) principles** earlier in cycle during protocol development.

POTENTIAL CHALLENGES

- ? Can potentially **disrupt current document-based workflows** in the transition to working in a digitized study design solution ("Study Builder")**. Careful transition planning to an automated setup would be needed to avoid short-term inefficiencies.
- ? May call for **assessment of suitability and maturity** of a digitized study design solution and its impact on current protocol authoring processes.
- ? May need to **assess and mitigate changes** to current collaboration processes to enhance cross-collaboration between multiple stakeholder groups within a digitized study design setup.
- ? Using standardized biomedical concepts **could require education** in new ways of thinking/working in terms of specifying the collection of study data.

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

TransCelerate BIOPHARMA INC.