# Digital Data Flow

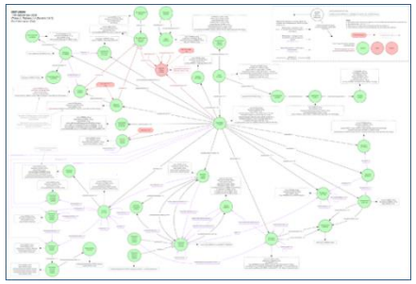
## For PHUSE EU Connect - DS10

## Digital Data Flow: Achieving Protocol Digitalization and Clinical Research Interoperability through Multi-stakeholder Collaboration

November 13 - 15, 2024

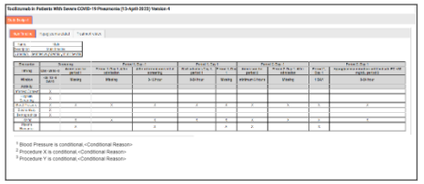
Mikkel Traun, Novo Nordisk

# DDF Initiative encompasses Technical Standards & Solutions, Change Management, and Industry Engagement



**Unified Study Definitions Model (USDM) Reference Architecture**

**TransCelerate's Study Definitions Repository (SDR) Reference Implementation**



## Digital Data Flow Initiative

**Suite of DDF Adoption Resources, Videos & Change Management Tools**


**Continued Industry Collaboration between TransCelerate, CDISC ICH, and HL7**

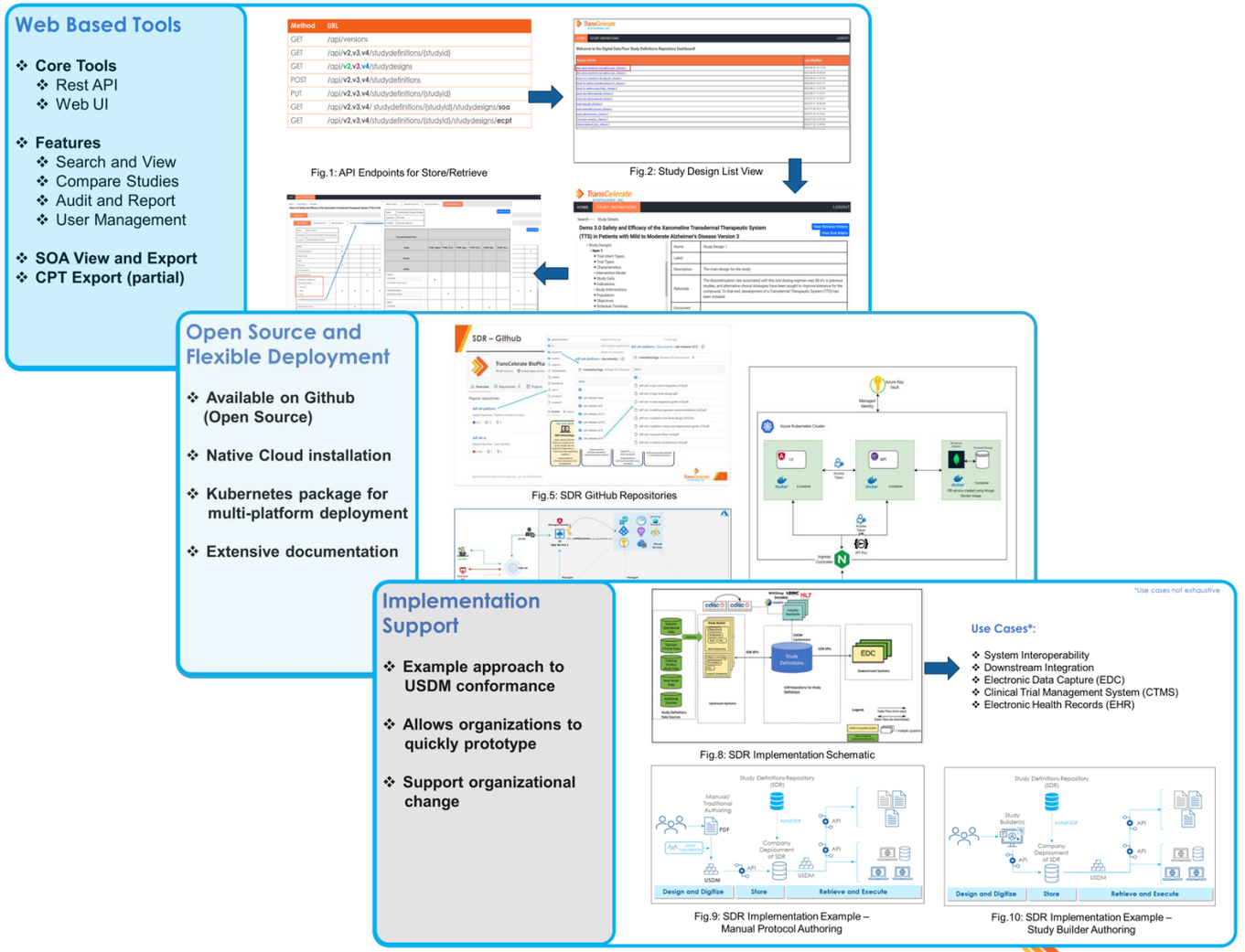
**Growing Solution Collaboration Forum (SCF)***

**Company logos illustrate current involvement and are not used to imply endorsement of specific vendors for DDF or to identify a comprehensive list of all actual or potential future participants in DDF.*

# Study Definitions Repository (SDR)

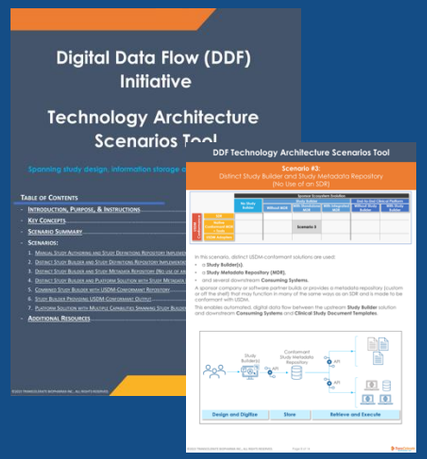
## The Study Definitions Repository (SDR) is a "Reference Implementation" of the Unified Study Definitions Model (USDM)

- **Demonstrator repository for USDM data storage and retrieval**
  - **API** component for data submission and storage
  - **User Interface** component for study design view and comparisons
  - **MongoDB:** Document-based data storage
  - **USDM 3.0:** Data model and API specification conformant
  - Supports several USDM versions (v1, v2, v3)
- **Available in 2 forms**
  - **Source code:** For download and implementation in local systems
  - **Sandbox implementation:** A hosted implementation available and exposed through Web Services and a Web App
- **Enterprise Cloud Platform**
  - Platform agnostic
  - Multiple deployment options
  - Security and authentication



# Supporting Sponsor Journey to Protocol Digitalization: DDF Technology Architecture Scenarios Tool

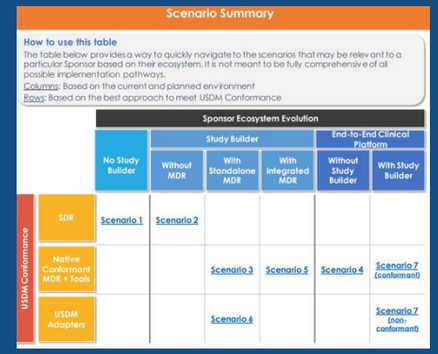
## DDF Technology Architecture Scenarios Tool

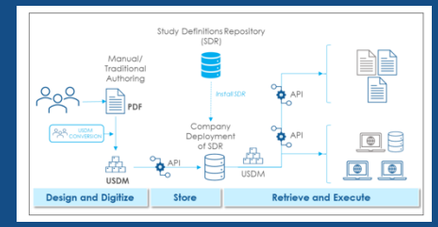


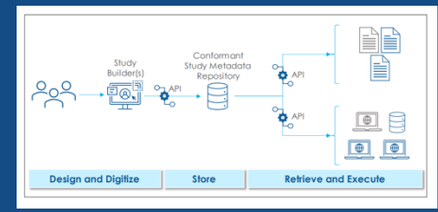

Provides examples of potential implementation patterns to aid implementers in some possible options that may be relevant to unique digital transformation and systems landscapes.

### How to use this tool:

1. Review the various architecture scenarios that interests you or matches to your organization's set-up or vision. NOTE: This tool is intended for a more technical audience such as Systems/Solutions architects, and IT engineers.
2. Understand the architecture scenario details. Sponsor companies and clinical solution providers can obtain a better understanding of the end-to-end impact for implementing DDF solutions across different technology environments.
3. It is intended to serve only as a guide for sponsor companies and clinical solution providers to learn about some of the options that best fit a company's context, objective and technology landscape.



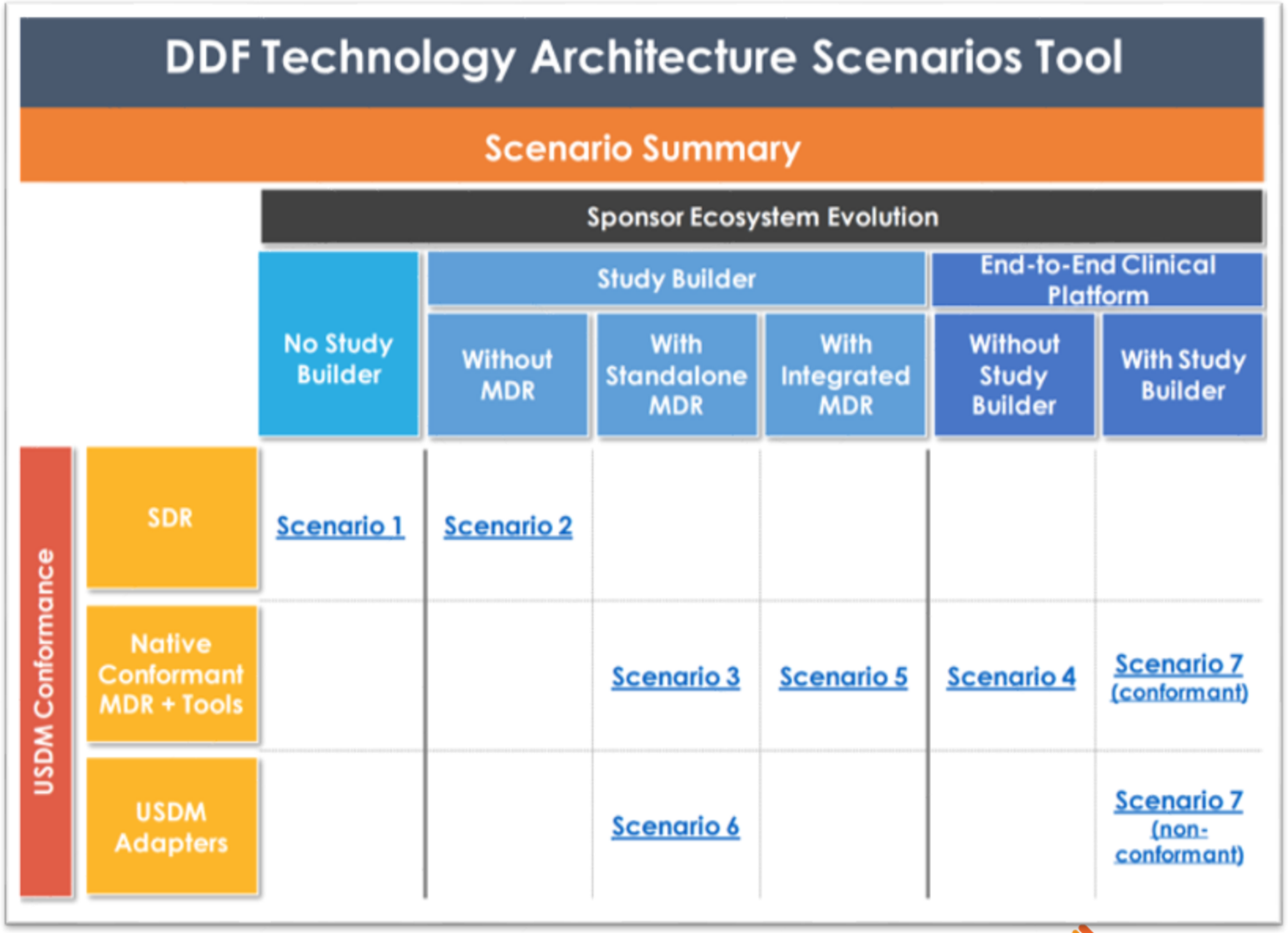




*Access the DDF Technology Architecture Scenarios here: Tools & Resources | Digital Data Flow*

# DDF Technology Architecture Scenarios Overview

The table provides a way to quickly navigate to the scenarios that may be relevant to a particular Sponsor based on their ecosystem.

It is not meant to be fully comprehensive of all possible implementation pathways.



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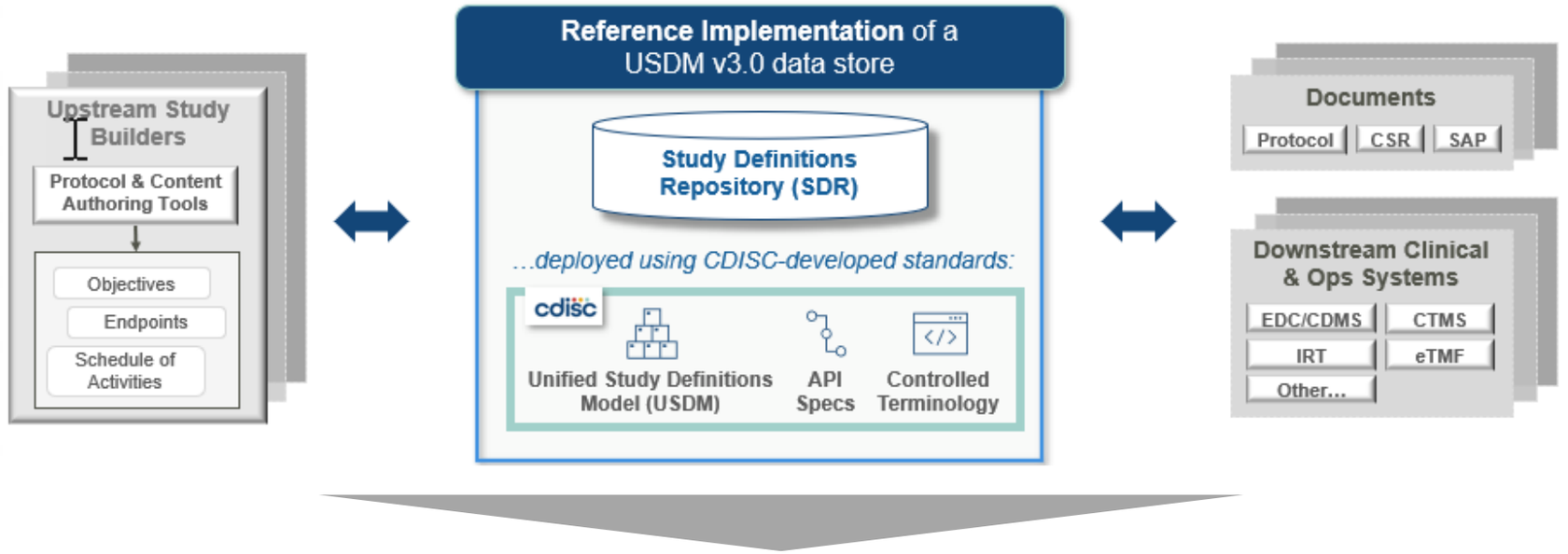
# Technology Tools: Study Definitions Repository




## Features

### Database

- Stores Study Concepts
- Supports Multiple USDM Versions
- Stores Study Versions
- Study Version Comparison

### User Interface & Access

- User Access
- View Study Data
- Search & Filter
- Study Dashboard

### Connectivity

- Certificate-Based Authentication
- Downstream APIs
- Upstream APIs

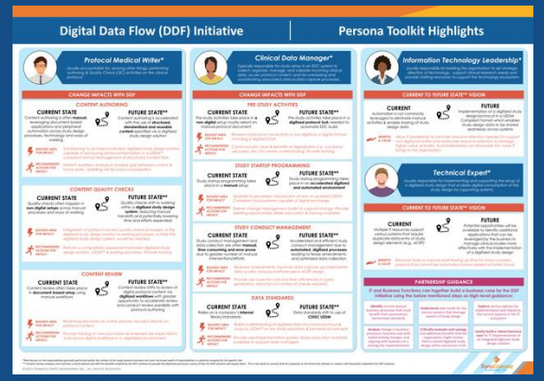
### Compliance & Reports

- Conformance Report
- Audit Trail
- System Usage Report

# Supporting Sponsor Journey to Protocol Digitalization: Persona Toolkits

## Persona Toolkits
### for Transformational Change

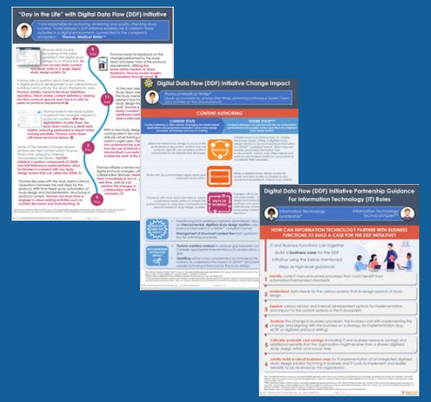
***Available for Data Managers, Protocol Medical Writers, IT Leadership and IT Technical Experts***




A packet of change resources that aims to help a specific persona role understand the potential impacts and changes in a DDF-enabled future state.

*Access the persona toolkit here: Tools & Resources | Digital Data Flow*

**Personas for the following roles are included in the persona toolkit:**


**Toolkit components include:**

- **Persona Profile Card:** This describes the profile for a persona/role covered in the persona toolkit. It can be utilized to help that specific role understand the benefits and value of digitalization of data flow within the context of protocol authoring.
- **DDF Change Impacts:** This articulates potential impacts to a role comparing the current state (As-Is) to the anticipated future state (To-Be).
- **"Day in the Life" with DDF:** An illustrative flow of "What could a work-day look like with the application of DDF?"



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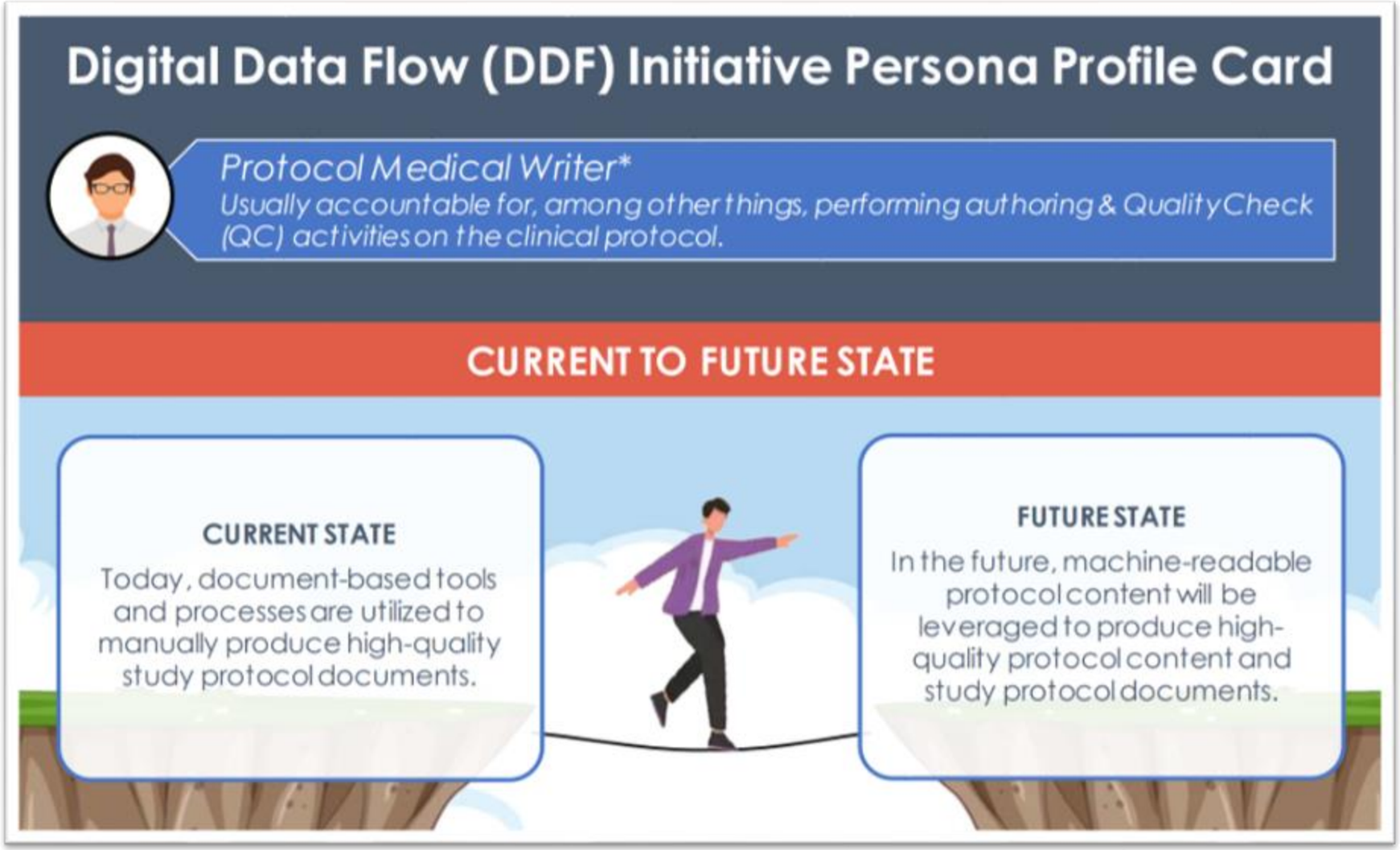
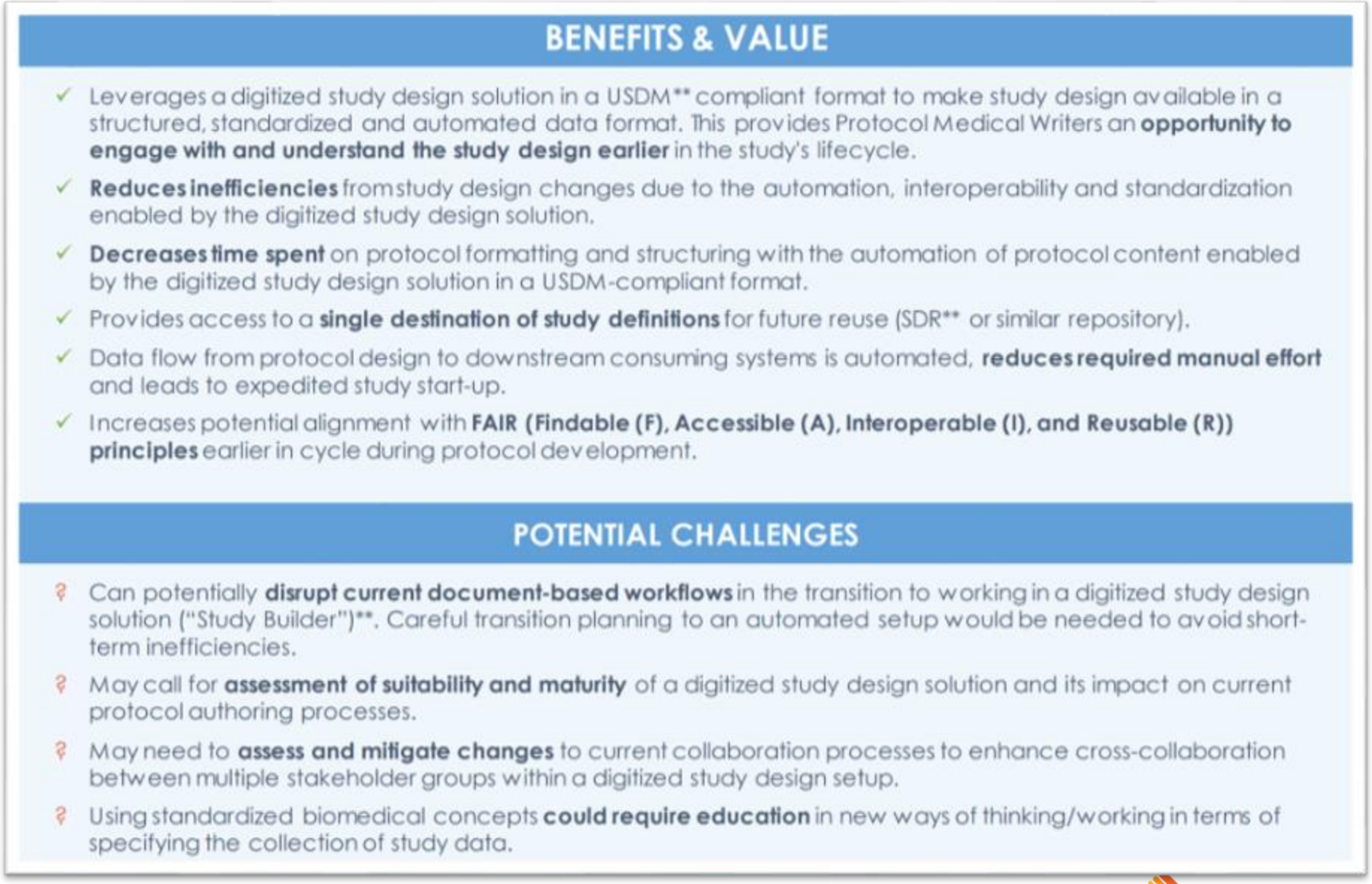
# Persona Profile Card

Describes the profile for a role (a medical writer role, in this instance) as described in this toolkit; can be utilized to help understand the benefits and value of digitalization of data flow within the context of protocol authoring



# Persona Profile Card – Benefits, Value and Potential Challenges

The persona card also highlights the benefits, value of DDF to a specific persona (a medical writer role, in this instance) and potential challenges



## BENEFITS & VALUE

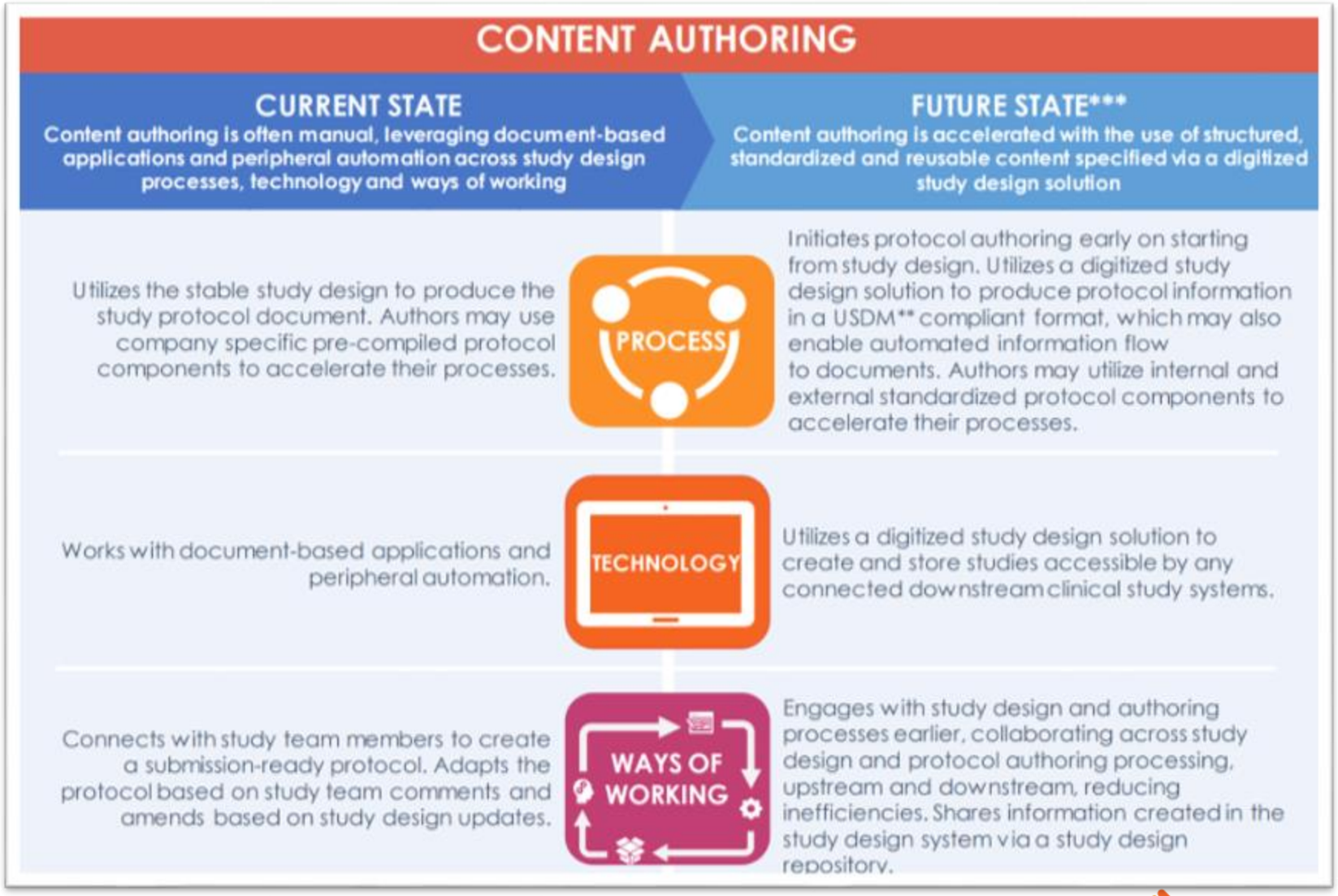
- ✓ Leverages a digitized study design solution in a USDM** compliant format to make study design available in a structured, standardized and automated data format. This provides Protocol Medical Writers an **opportunity to engage with and understand the study design earlier** in the study's lifecycle.
- ✓ **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.

# Persona Profile Card – Change Impact

The Change Impact articulates potential impacts to a role (a medical writer role, in this instance) comparing the current state (As-Is) to the anticipated future state (To-Be).



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# Vendors Implementing DDF Solutions

## 1 Solution Collaboration Forum

**30+ vendors are part of the Solution Collaboration Forum:**

- Applying collective technology. solution provider engagement and enthusiasm in DDF to further solution development


## 2 DDF Solution Directory

**The Solution Directory is a TransCelerate Github page (link here) that hosts a growing list of self-reported solutions which utilize and follow the DDF Unified Study Definitions Model (USDM).**

This directory may help companies find DDF solutions and is a constantly growing list!
**TransCelerate does not endorse vendors

## 3 DDF Solution Showcase Webinar Series

TransCelerate and CDISC are partnering to co-host the DDF Solution Showcase webinar series involving sponsor companies, clinical solution providers, and key industry stakeholders. **The Showcase is an opportunity for qualifying solution providers to share a 30-minute presentation of protocol digitalization solutions followed by a 10-minute Q&A.**

Look out for more information (including registration) in the coming weeks **on the second "DDF Solution Showcase"webinar scheduled for Dec.5, 2024.**


*First showcase in this series - conducted on Sept. 26 - showcased two organizations – NNIT and EQTY Life Sciences and ClinLine. Access the webinar recording here*

NNIT demonstrated how USDM can be mapped to FHIR standards to enable automated EDC set-up

EQTY/ClinLine showcased the use of USDM standards to facilitate the use and creation of synthetic RWE and RWD arms



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*October 10, 2024*

# DDF in Action Day

## Transforming Clinical Trials with Standards and Digitalization

*"Continuing the Journey, Charting the Future"*

**First full day in-person public event with biopharma, solution providers and others held across two locations - J&J, New Jersey and Novo Nordisk, Copenhagen**

## DDF in Action Day Highlights

- **DDF in Action Day aimed to explore pathways and proofs of concept** to implement DDF solutions in the near- or mid-term
- **Agenda topics included** a keynote and plenary discussion covering various use cases, a solution provider poster session and panel discussion, as well as networking opportunities.
- **Two common themes** surfaced through the day:
  - Leadership engagement and organizational change management (OCM) are critical to success
  - Change is coming. Don't wait to get started

## Organizations Represented

- Amgen
- Ascendis Pharma
- AstraZeneca
- Bayer
- Bristol Myers Squibb
- Eli Lilly
- GlaxoSmithKline
- Johnson&Johnson
- Merck
- Novartis
- Novo Nordisk
- Pfizer
- Recursion
- Regeneron
- Roche
- Sanofi
- Shionogi
- UCB
- CDISC
- ClinLine
- Content Rules
- CTDN
- Data4Knowledge
- Devote Consulting
- EQTY Lifesciences
- EZ Research Solutions
- Faro Health
- Futurpostif Consulting
- NNIT
- Nurocor
- OpenStudyBuilder
- PA Consulting
- PFMD
- Sycamore Informatics
- TATA Consultancy Services
- Veeva

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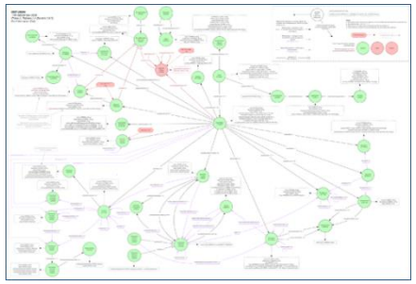
# DDF Initiative encompasses Technical Standards & Solutions, Change Management, and Industry Engagement



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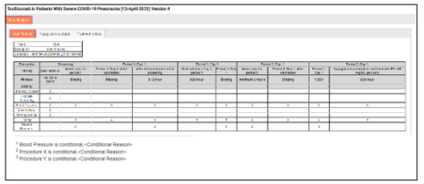

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# What's Next in 2025?

*DDF's path forward will focus on advancing the Clinical Trials Ecosystem towards a digitized protocol through the deployment of standards, technology and use case sharing*

## 2025 Protocol Digitization Objectives

*Enable Digitization & Interoperability Of The Study Protocol Across Research & Care*

**Enable stakeholders to easily share digital protocol information and insights**

**Promote hands-on engagement with protocol digitization solutions**

**Educate and update stakeholders on implementation paths**

**This includes:**

- Release of:
  - ✓ CDISC's USDM v4
  - ✓ Study Repository v4
  - ✓ Additional open-source tools
- Scoping for CDISC's USDM Phase 5

- Supporting and sponsoring business case development with adoption case studies.
- Organizing events, webinars, trainings to improve understanding and education among stakeholders on implementation of digital data flow.



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# Additional Opportunities to Stay Involved with DDF

**You can stay involved and learn more about the Digital Data Flow initiative by visiting the following websites:**

**DDF Website**

*As the main website for DDF, learn and access all resources supporting DDF*

**Scan QR Code to explore DDF Website**

**CDISC DDF Website**

*Learn about and access the Unified Study Definitions Model (USDM) Reference Architecture supporting Protocol Standards*

**TransCelerate DDF Initiative Solutions**

*Learn about DDF initiative background and roadmap*

**DDF GitHub Repos**

*Learn about and access the Study Definitions Repository Reference Implementation and supporting codebase*

**Questions? Feedback? Please email us at DDF@transceleratebiopharmainc.com**



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# Upcoming Events

| Events | Date |
|---|---|
| **DDF Solution Showcase Webinar Series #2**<br>**Register here** | 5 December 2024 |
| **SCOPE US 2025**<br>Going with the (Digital Data) Flow:  Reduce Time & Effort on Study Start-Up | 3–6 February 2025 |
| **PHUSE US Connect 2025**<br>PHUSE US Connect 2025 (phuse-events.org) | 16-19 March 2025 |
| **CDISC Europe Interchange 2025**<br>2025 Europe Interchange \| CDISC | 12-15 May 2025 |



* Please note, related industry events are not formally endorsed by TransCelerate and are listed for awareness only

# Thank you!

# DDF Technology Architecture Scenarios Tool

## Scenario Summary

| | | Sponsor Ecosystem Evolution | | | | | |
|---|---|---|---|---|---|---|---|
| | | No Study Builder | Study Builder | | | End-to-End Clinical Platform | |
| | | | Without MDR | With Standalone MDR | With Integrated MDR | Without Study Builder | With Study Builder |
| USDM Conformance | SDR | Scenario 1 | Scenario 2 | | | | |
| | Native Conformant MDR + Tools | | | Scenario 3 | Scenario 5 | Scenario 4 | Scenario 7 (conformant) |
| | USDM Adapters | | | Scenario 6 | | | Scenario 7 (non-conformant) |



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# 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.
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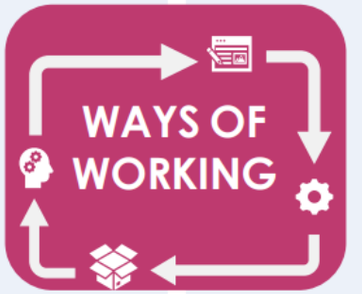
# CONTENT AUTHORING

## 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**

| CURRENT STATE | | FUTURE STATE*** |
|---|---|---|
| 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. |
| 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. |
| 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. |