# Digital Data Flow (DDF) Initiative

## *Information Technology*

*Leadership* *Technical Expert*

# Persona Toolkit eBook

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# Digital Data Flow (DDF) Initiative Overview

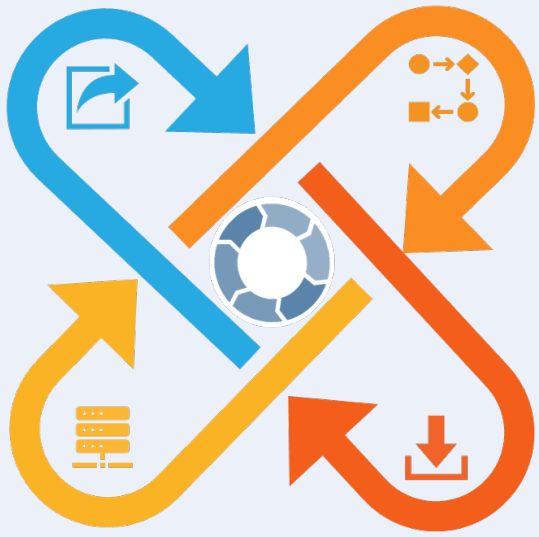
## The Digital Data Flow (DDF) Initiative aims to catalyze digital transformation; breaking the protocol document paradigm to enable seamless data flow

### Digitized Protocols

*Enabling the use of technologies that identify and assemble study elements using a common, industry-standard digital language allows industry to move to digital protocols*

### Advanced Analytics

*Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs*



### Connectivity of Data and Processes

*Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)*

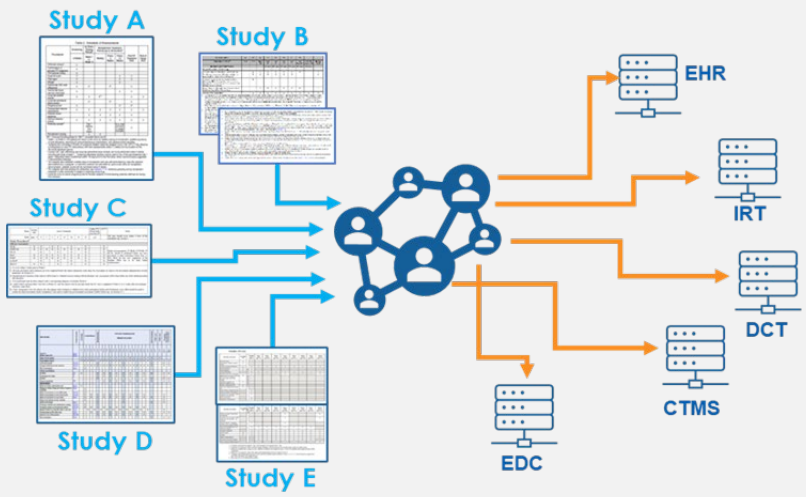
### Open & Flexible Solution

*A functioning, example solution to enable exchange of protocol info between systems that is vendor agnostic, flexible, and provided in open source*

## VISION: From Documents to Data: Write Once, Read Many Times

### TODAY

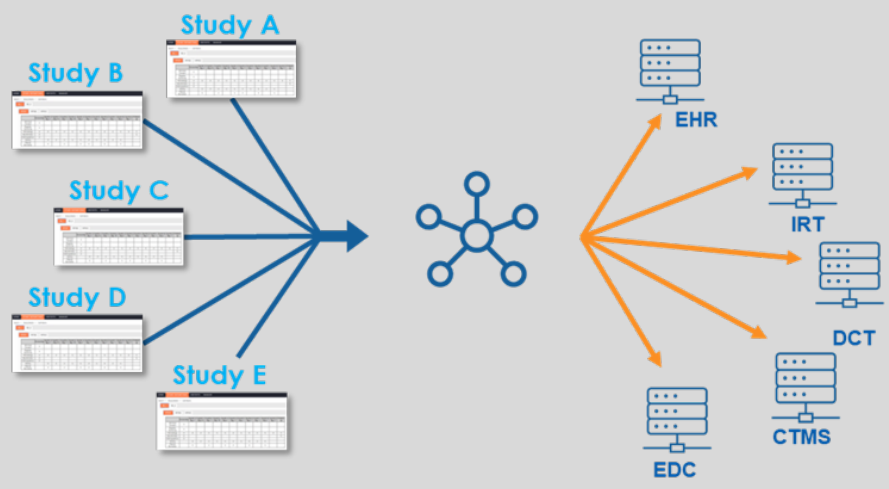
**Many-to-many manual process; Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems**




- *Schedule of Activities (SoA) specified **inconsistently** in study protocols (e.g., sections, rows, columns, footnotes)*
- ***Manual** process to configure systems/tools*
- ***No reliable method** to synchronize updates from a single source of truth*

### TOMORROW

**Digitalized one-to-many process; Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems**



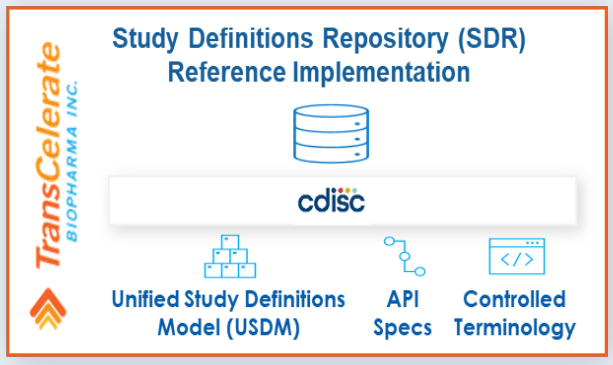

- ✓ ***Digitized design** specification per study*
- ✓ ***Consistent** method of study spec exchange*
- ✓ *Streamlined, **automated** start-up (reduce effort, cycle time, and complexity)*
- ✓ ***Improve** quality and compliance. Minimize protocol violations*

# Digital Data Flow (DDF) Initiative Overview

## Understanding Key Concepts

The Digital Data Flow Initiative offers a **mechanism to digitize clinical study components** to enable interoperability and reuse, starting with study design.

In collaboration with Clinical Data Interchange Standards Consortium (CDISC) and other stakeholders, TransCelerate has developed a standard data model that creates **a new digital language for specifying protocol information**, as well as a **demonstrated way to connect systems** that produce, exchange or consume this information.




### Unified Study Definitions Model (USDM)

An industry standard for study definitions (protocol information) promulgated and maintained by CDISC

### Study Definitions Repository Reference Implementation (SDR RI)

A functioning, example approach that utilizes USDM to manage the information flow of protocol data between upstream and downstream systems

### Study Builder/ Digitized Study Design Solution

An application or piece of software utilized by a study team to design a study and/or author a study protocol

### Controlled Terminology

CDISC developed set of codelists and valid values for terms used in a study

### Application Programming Interface (API) Specifications

CDISC developed coding language to connect and exchange data between systems

### Biomedical Concepts

CDISC and other organizations developed definitions of discrete units of biomedical information that would need to be measured for a study participant

## Key Focus Areas on the DDF Roadmap

### Digitization of Study Elements and Downstream EDC Automation (Current/Completed)

- ✓ Support electronically populating and configuring EDC/CRFs based on the digital protocol specification
- ✓ Use digital protocol specification to demonstrate (as a proof of concept) the population of elements in a human readable protocol document

### Complete Protocol Digitization & Regulatory Alignment (In Progress)

*Includes collaboration through HL7 Vulcan Working Group between ICH M11 & CDISC*

- ➢ Complete (100%) digitization of all protocol elements in alignment with M11 and relevant CDISC SDTM domains
- ➢ Begins with gap analysis between USDM and ICH M11 content model, CDISC SDTM, and Global Trial Registry Reporting
- ➢ Goal to capture "breadth" of ICH M11 completely within USDM, followed by greater "depth" of structured content within model (e.g. structured I/E criteria)

### Expand Downstream Connectivity (In Progress)

*Includes collaboration with expanding community of tech solution providers across range of clinical solutions*

- ➢ Further develop USDM to enable downstream connectivity with priority systems, enabling a future state of "write once, read many times"
- ➢ Work collaboratively with vendor ecosystem to better understand existing gaps & development requirements for the USDM

### Alignment with Point of Care (In Progress)

*Includes collaboration with Vulcan FHIR Accelerator*

- ➢ Comparative assessment of USDM and FHIR
- ➢ Alignment of DDF and FHIR resources for end-to-end enablement of EHR workflow set-up and eSource

# Digital Data Flow (DDF) Initiative Persona Toolkit
# Toolkit Overview for Information Technology (IT) Roles

*Information Technology Leadership**

*Information Technology Technical Expert***

## PURPOSE

The objective is to help inform IT leadership and technical experts so they are better prepared & **can more fully realize the anticipated benefits** of the DDF initiative.

The assumptions set out merely compare & contrast a world without & with the adoption of DDF solutions to provide personas addressed in this toolkit a sense of how 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.

## DISCLAIMER FOR USE

Job titles, roles, & responsibilities can and will vary, often significantly, across companies. This document seeks to outline some discrete tasks commonly performed by the roles addressed in this document – IT Leadership or IT Technical Expert – and explain how DDF initiative will likely impact these tasks.

This document does not seek to address all tasks performed by personas nor does it seek to dictate or suggest to the persona how relevant takes must or should be performed, as this will vary greatly across companies.

## HOW TO USE THIS TOOLKIT

1. **Review each component** of the persona toolkit for an IT Leader or IT Technical Expert.

2. **Understand the purpose and use of each toolkit component.** Sponsor companies can consider this a deep dive to understand how the DDF initiative will impact roles and mitigation factors to enable an adoption pathway for specific roles and their personas.

3. **Use the persona toolkit as a guide.** The persona toolkit is illustrative and intended to serve only as a guide for sponsor companies. The application of this toolkit needs to be customized to fit your company's context, objective and organizational set-up.

## TOOLKIT COMPONENTS

### Persona Profile Card – IT Leadership

Outlines the profile for a typical IT Leadership role within the anticipated context of enabling automation of end-to-end data flow from study design to downstream systems. This resource can be leveraged to help IT Leadership understand the benefits and value of protocol data digitalization.

### Persona Profile Card – IT Technical Experts

Outlines the profile for a typical IT Technical Export role within the anticipated context of enabling automation of end-to-end data flow from study design to downstream systems. This resource can be leveraged to help IT Technical Exports understand the benefits and value of protocol data digitalization.

### Partnering Guidance

Provides guidance for how IT and business functions can partner to build a business case for DDF implementation

***The IT Leadership persona focuses on the responsibilities generally performed by an IT leader in providing technical strategic leadership that would be performed in overseeing the adoption of the DDF initiative within the context of the clinical study design setup. It does not cover the broad swath of responsibilities of an IT Leader in a pharma company. Example role names could be R&D IT Lead.*

***The IT Technical expert toolkit focuses on the responsibilities generally performed by the IT Technical Export within the context of the clinical study design setup and does not cover the broad swath of responsibilities of an IT Technical expert in a pharma company. The IT Technical Expert, within this context, can cover the IT Infrastructure Architect, IT Software Architect, IT Business Analyst involved in IT support of study design setup.*





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# Digital Data Flow (DDF) Initiative Persona Profile Card

*Information Technology (IT) 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*

## Assumptions about IT Leadership Responsibilities

**Partners with business** to understand current business processes and build a business case, roadmap for implementation of a digitized study design.

**Prepares technology roadmap and defines IT architecture** for the organization that includes shaping the implementation of appropriate use cases for digitized study design consumption.

**Ensures IT capabilities are available** to support the technology roadmap.

## CURRENT TO FUTURE STATE

### CURRENT STATE

Automation is not commonly leveraged to eliminate manual activities & enable sharing of study design data to support clinical study related capabilities.

Responsibilities include overseeing multiple systems that do not share study design data through digital means (e.g., data integrations/APIs) leading to a potential need for additional IT resources.

### FUTURE STATE

Shared understanding across the organization of options available to implement a digitized study design in the company's ecosystem.

Implementation of a digitized study design/protocol in a USDM** compliant format which enables study design data to be shared seamlessly across systems.

Utilization of digitized study design solutions in an industry standard format could result in the more efficient use of IT resources needed to build and implement a shared digitized study design in the company's ecosystem.

## BENEFITS & VALUE

- ✓ Implementing a digitized study design solution in a USDM** compliant format could allow IT Leadership to minimize resource attention needed to support non-digital activities and reallocate resource attention to strategic, higher value activities.
- ✓ Utilizing technology to automate/share data to support the clinical study design processes can showcase the value IT brings to the organization

## POTENTIAL CHALLENGES

- ? Data integration can be complicated and time-consuming depending on the current internal data standards implemented and systems utilized. This may call for additional IT resources with skills in data integrations. There could also be an additional requirement for IT resources who understand USDM fundamentals and its implementation (certain aspects of the model such as timepoints are expected to be implemented from a systemic perspective rather than by functional business end users. For e.g., a business end user may represent SOA as a matrix checkbox, but backend system will need to translate into a machine-readable format).
- ? With competing priorities and limited IT resources, Business/IT will require a clear, unambiguous value case for implementing DDF solutions

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





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# Digital Data Flow (DDF) Initiative Persona Profile Card

*Information Technology (IT) Technical Experts**

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

## Assumptions about IT Technical Expert Responsibilities

**Determines** the implementation plan for study data flow (e.g.: data integrations/APIs), systems' data consumption, storage and access of study design data in the ecosystem (data lake, study repositories), and system updates for successful study data consumption.

**Implements** the detailed implementation roadmap.

**Supports** system enhancements, associated tasks needed to support these capabilities in study data flow, consumption, storage and access capabilities.

**Responsible for maintaining custom interfaces** between systems that work off disparate data models.

## CURRENT TO FUTURE STATE

### CURRENT STATE

Today, an IT architecture does not have a digitized study design/protocol in a USDM** compliant format that enables common data integrations between systems that share study design data needs.

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

### FUTURE STATE

In the future, an IT infrastructure will support a digitized study design/protocol in a USDM** compliant format, either leveraging SDR** or similar architecture, which enables study design data to be shared seamlessly across systems.

Potential opportunities will be available to identify additional applications that can be leveraged by the business to manage clinical studies more effectively.

## BENEFITS & VALUE

- ✓ Utilizes standards and common technology architectures to automate/share data to support the clinical study design processes showcasing the value that IT brings to the organization.
- ✓ Reduces tedious manual work freeing up time for more complex projects that cannot be automated (value-added activities focus).
- ✓ Enables plug-and-play interoperability among systems, with standardized integrations through the use of standard APIs that are part of CDISC's USDM** model.

## POTENTIAL CHALLENGES

- ? May not have technical skills internally, within the IT organization, to support successful implementation

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# Digital Data Flow (DDF) Initiative Partnership Guidance For Information Technology (IT) Roles

*Information Technology Leadership**

*Information Technology Technical Expert***

## HOW CAN INFORMATION TECHNOLOGY PARTNER WITH BUSINESS FUNCTIONS TO BUILD A CASE FOR THE DDF INITIATIVE?

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

1. **Identify** current manual business processes that could benefit from automation/harmonized standards
2. **Understand** data needs for the various systems that leverage aspects of study design
3. **Explore** various vendor and internal development options for implementation and impact to the current systems in the IT ecosystem
4. **Analyze** the change in business processes, the business cost with implementing this change, and aligning with the business on a strategy for implementation (e.g., eCRF or digitized protocol writing)
5. **Critically evaluate cost savings** (including IT and business resource savings) and additional benefits that the organization might receive from a shared digitized study design within and across trials
6. **Jointly build a robust business case** for IT implementation of an integrated digitized study design solution factoring in business and IT costs to implement and realize benefits to be received by the organization

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# Digital Data Flow (DDF) Initiative
# Additional Resources

## To learn more about the DDF initiative, visit the DDF website

https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow

*"Documents to Data: Write Once, Read Many Times"*

**TransCelerate DDF Website**

## Explore CDISC's Unified Study Definitions Model (USDM)

https://www.cdisc.org/ddf

## Explore TransCelerate's Study Definitions Repository (SDR)

https://transcelerate.github.io/ddf-home