

# 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

\*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.

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