

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

*The IT Technical expert toolkit focuses on the responsibilities generally performed by the IT Technical Expert 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.

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