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

*The IT Leadership persona focuses on the responsibilities generally performed by an IT leader in providing technical strategic leadership roles driving 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.
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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