

## Welcome to the Digital Study Design Use Case Library

The library is a curated collection of potential use cases developed as part of the Transcelerate **Digital Data Flow (DDF)** initiative. It is a living resource intended to evolve as new capabilities, standards, and regulatory guidance emerge. Feedback and contributions are welcome to ensure it remains relevant and practical.

### Purpose of the Library:

- Establish a shared understanding of the scope and benefits of Digital Study Design adoption,
- Provide a *Rosetta Stone* of definition and taxonomy for sharing Digital Study Design concepts between stakeholders, and
- Postulate a vision -- not necessarily The Vision -- of what *Done* looks like when USDM-compliant Digital Study Design is adopted across the clinical research ecosystem.

### Structure of the Library

- The Library is based upon the *UML Use Case* format
- Use cases are represented as ovals broken down in to a hierarchy of *Category*, *Class*, and *System of Interest*.
- Each related collection of use cases (i.e. *System of Interest*) captures the trigger, primary scenario, result, and key actors or systems involved.
- To promote consistency, a **Glossary** is included to define the terms used throughout the library.

### Please Note:

*The work presented here details common elements and examples of factors that organizations may encounter when initiating a Digital Study Design/Digital Data Flow transformation. It is not intended to outline the only possibilities for achieving scalable Digital Study Design and **does not constitute a recommendation to adopt or approve a particular system or a systems with particular elements or features.***

***Each organization must decide for itself if different, alternate approaches may work better for its unique circumstances.*** *The decision to consider and to proceed with a Digital Study Design/Digital Data Flow trans-formative effort is the sole prerogative and at the complete discretion of individual organizations as informed by their internal strategies, assessments, and approval processes.*