# Digital Data Flow (DDF) Initiative Change Impact

## *Clinical Data Manager**

*Typically responsible for study setup in an EDC system to collect, organize, manage, and validate incoming clinical data, as per the protocol content, and for overseeing and coordinating the associated clinical data capture processes*

## PRE-STUDY ACTIVITIES

| CURRENT STATE | | FUTURE STATE*** |
|---|---|---|
| **Pre-study activities take place in a non-digital setup mostly reliant on manual protocol document** | | **Pre-study activities take place in a digitized protocol SoA needed to automate EDC build** |
| Protocol document is generally non-digital; protocol review, updates take place manually within a document. | PROCESS | Expect to shift to an automated EDC build using a digitized protocol SoA generated by upstream solutions. Process is automated by the USDM compliant SoA meta-data being automatically pushed into the EDC and matched to relevant eCRFs. |
| Non-digital document creation and management tools are typically used for pre-study activities. | TECHNOLOGY | The digitized protocol needed to automate EDC setup would be supported by Study Builder or a similar digitized study design solution. |
| Most common way of working continues to be in a manual protocol document creation, with input from multiple expert functions such as Stats. Relevant data from protocol document is manually extracted to complete EDC setup. | WAYS OF WORKING | Work would take place in an end-to-end digitized data structured protocol environment. |

**BIGGEST AREA FOR IMPACT**

- Review of protocol **moves from a non-digital to a digital format**, including a digitized SoA.

**RECOMMENDED ACTION FOR IMPACT**

- **Communicate the value and benefits** of digitalization (successful use cases of using a digital protocol, highlighting cost, time, and data quality efficiencies) to create understanding of the DDF initiative and the USDM**.
- **Provide training and user guides** for process redesign, systems, and new skillsets that will be required for this change.

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***Please refer to Digital Data Flow Concepts for DDF terms you are not familiar with.*
**** The assumptions merely compare and contrast a world without and with the adoption of the DDF solutions to provide the personas addressed in this toolkit a sense of how the 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.*

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## STUDY START-UP PROGRAMMING

| CURRENT STATE | FUTURE STATE*** |
|---|---|
| **Study startup programming takes place in a manual setup** | **Study startup programming takes place in an accelerated digitized and automated environment** |
| SoA is set up by internal company standards selected, programming takes place in EDC for eCRF development and edit checks, eCRF completion guidelines, and DM reports. Manual documents are created. | **PROCESS** — EDC build is automated by enabling a digitized protocol SoA and automating eCRF generation. Reduction in the creation of manual documentation. |
| EDC system integrates with other systems, e.g., coding, CTMS. | **TECHNOLOGY** — Study definitions repository based on USDM exists as a stand-alone solution or integrated into an existing platform. Interoperability between study builder or similar alternate tool, EDC system, other systems, is made possible through the use of USDM and standard APIs. |
| Typically, there are multiple eCRF reviewers - Clinical programmers, data managers, and other functional reviewers. eCRF creation is manual with multiple rounds of review. | **WAYS OF WORKING** — Requires understanding of USDM, and awareness of system integrations to work in an improved, automated study setup. Shortened eCRF review times are possible due to automation enabled by Biomedical Concepts structured formats and data elements. The association of biomedical concepts with protocol activities and assessments in a structured manner vs. narrative text helps internally standardize study data collection by defining what data and how to capture it. |

**BIGGEST AREA FOR IMPACT**

- Updates expected to SOPs, processes, working instructions, and templates.
- Introduces new or updated **USDM-compliant tools/systems capable of digital exchange of information** using standard APIs.

**RECOMMENDED ACTION FOR IMPACT**

- Deliver **change management toolkit** to support change associated with DDF. This can include technical user guides/implementation guide for USDM that can be adapted to each company's ecosystem.
- **Provide reskilling** on new processes, tools and software implemented.
- Make available **education materials and training** to help data managers understand what's new and what's changing in their role for study start-up programming.

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## STUDY CONDUCT MANAGEMENT

### CURRENT STATE

**Study conduct management and data collection are often manual, time consuming and error prone due to greater number of manual interventions/ efforts**

### FUTURE STATE***

**Accelerated and efficient study conduct management due to automated, digitized processes leading to fewer amendments and optimized data collection**

Process involves amendment and migration management, data entry review, query management, and data review of pivotal data. Manual snapshots for data analysis deliverables.

**PROCESS**

Fewer amendments are expected with the availability of digitized protocol, including an opportunity for faster, more efficient automated amendments. Optimal data collection and design could reduce the data inconsistencies between eCRF versions.

Currently leverages EDC system, coding tool, external data reports.

**TECHNOLOGY**

Integrates EDC system with SDR** and other systems.

Data Managers, other functional data reviewers, sites, and CRAs with risk-based monitoring are involved in study conduct. Manual collaborative and data collection efforts across different groups mean more data is collected, leading to more review and greater effort prone to errors.

**WAYS OF WORKING**

Potentially captures greater efficiencies as automation reduces the number of tasks required to be completed.

**BIGGEST AREA FOR IMPACT**

- **Reduces amendments, improves data collection, provides better data quality, reduces errors and inefficiencies** in eCRF design and data capture.
- Reduces time spent on data cleaning.

**RECOMMENDED ACTION FOR IMPACT**

- **Provide use cases** for reduction in amendments, cost and time efficiencies in query generation, reduction in number of checks required.

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## DATA STANDARDS

### CURRENT STATE
**Relies on a company's internal library/standards**

### FUTURE STATE***
**Data standards shift to use of CDISC USDM**

**PROCESS**

Adheres to internal data standards during eCRF development..

Data standards are remapped to USDM model.

**TECHNOLOGY**

Uses an Internal content library with eCRF standards, dictionaries and codelists.

Content library is aligned to biomedical concepts structure enabled by the USDM and standard APIs.

**WAYS OF WORKING**

Governance is in place for data mapping, codelists, and standard terminology based on internal company policies.

Governance is in place for data mapping, codelists, and standard terminology, including impacts from USDM updates.

**BIGGEST AREA FOR IMPACT**

- Builds understanding of the digitized data structured protocol and outputs, USDM** or any study repository and biomedical concepts.

**RECOMMENDED ACTION FOR IMPACT**

- Provide **user/implementation guides** for mapping considerations, existing models.
- Make available **education materials** to help data managers understand what's new and what's changing in their roles across process and technology for data standards management.

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