“Day in the Life” with Digital Data Flow (DDF) Initiative

“I am responsible for setting up a study 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. The DDF initiative enables me to focus on data collection and quality strategy, higher value work that has a critical impact on data management deliverables and outcomes for a study and across the molecule program" - ***Sienna, Clinical Data Manager****

AM

8 AM

Sienna starts her day with a review of the digital protocol, with a focus on SoA and digital data fields, metadata that will be used in automation of eCRF build in EDC. **Working in a digitized, automated environment enabled by the DDF initiative could streamline data management processes, introduce cost, time and quality efficiencies freeing up time to work on high-value creation services, including innovation, data analytics and quality enhancement** ↻

Sienna asks the clinical science and safety scientist, PK and Biomarker scientists for further information on the pertinent scientific rationale of the clinical study during protocol review to identify priority areas and ensure data flow into EDC system.

At the weekly Team meeting, Sienna discusses any study build issues, data cleaning requirements, resource issues, non-eCRF requirements, team alignment on deliverable due dates, and answers any questions regarding the digital protocol.

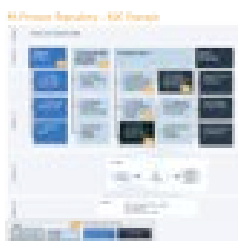
With the DDF solution components, such as the USDM, Sienna can shift focus to strategic, high value-added tasks as repetitive and tactical workflows are automated. Reduced end to end cycle time provides Sienna bandwidth to focus her work on value creation and innovative activities. ↻

Sienna shares with her data management team the digital protocol and SOA for their awareness and input regarding downstream impacts. 💻

She later discusses the digital protocol at a molecule/program level to ensure alignment across the program so that the data can be pooled across multiple studies for analysis and re-use for data insights and metrics.

A digitized protocol and USDM generate rich structured data content and metrics, providing digital insights to help Sienna and her team make better informed decisions. 💻

11 AM



Sienna attends an eCRF design review meeting to collect study team feedback and share draft annotated eCRF.

With the availability of structured data and digitized study design formats enabled by USDM required study protocol content could be available in the first round of study data collection. ↻

**The Clinical Data Manager toolkit focuses on the responsibilities generally performed by the clinical data manager within the context of the study protocol and does not cover the broad swath of responsibilities of a clinical data manager in a pharma company*

↻ *Process*
💻 *System/Technology*
✪ *Ways of working*

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PM

Sienna works with the project team to discuss the critical data in the digital protocol and SOA to create a critical data review/ cleaning mitigation plan.

A digitized, automated environment could allow Sienna to spend more of her time on such value creation activities and less on manual work in setting up EDC, eCRF. ✪

Sienna completes a self-paced e-learning module on the USDM to stay on top of system upgrades and process redesign updates. ✪

2 PM

Sienna attends virtual training on the overview of the digital protocol and review process in the study builder tool. She also attends training on SOPs and process updates as a result of DDF implementation.

Training on USDM enabled process changes, system upgrades and SOPs enable Sienna to work effectively and extract maximum value. ✪

Sienna attends UAT review of the EDC build and associated edit checks as well as addressing any system integration issues between the SDR and EDC system. ↻

Sienna works with the project team to define tracking and readiness process metrics. 💻
She receives a metrics report from the clinical programmer on the most frequently collected eCRFs, data fields, dictionaries that have the highest impact on analysis outputs for her study deliverables. She also receives higher level metrics across the molecule program, metrics of data with the lowest impact for consideration in future study development. She discusses metrics with her study team and with the program lead.
The digitalization of end-to-end processes from study design to EDC generates structured data that can be leveraged to track outcomes, trends, and progress made. ↻

Sienna completes periodic pulse check surveys to provide feedback on EDC automation and impact of DDF on her role and work.

The Change Champion on Sienna’s team shares the latest updates and collects and collates the feedback. ↻

A digitized, automated environment has freed up time for Sienna.

She uses this freed-up time to review upcoming timelines for study build completion and projected study deliverables such as the first data monitoring deliverable. Sienna assesses any risks to timelines. ↻

5 PM

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