

Data Management in Clinical Research: Streamlining, High-Quality Data, and Subject Matter Experts

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1. Background

In March 2020, the University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) formed the Data Management Unit (DMU) to focus on improving the quality of data curation and entry. Previously, data entry was performed by CRO assigned study coordinators or clinical research assistants. Due to the rapidly increasing complexity of trials and impact to workloads, it was discovered that coordinators were deprioritizing data to meet the clinical needs of subjects. This led to lengthened data entry timelines, less precise data entry, and a higher volume of queries. CRO leadership quickly identified the need to intervene as data is a CRO's principal work product. This initiative was implemented at the start of a pandemic, which posed unique challenges and opportunities.

2. Goals

The primary goal of improving data quality was accomplished via two approaches:

1. Streamline the upload and curation of research source documents
2. Train subject matter experts for each disease site group

3. Solutions and Methods

The initial implementation of the Data DMU was at the start of the COVID-19 pandemic, where CRO staff quickly moved to full or partially remote working assignments and establishment for streamlined methods for source documentation upload to the data unit was necessary. We determined Microsoft Teams was the best platform since clinical units had familiarity with the software and IT Risk Management determined it was appropriate for storage of protected health information. Digitizing and centralizing source documents provided the data unit with remote work options and continuous access to the documents. This simultaneously created an effective means for the UFHCC to go fully electronic and further eliminate the need for paper documents. It's expected that documentation from the clinical staff be available to the DMU within one week of subject visits, thereby helping to facilitate DMU improved data entry timeliness. All documents were uploaded with the same nomenclature into subject folders using the same organization across all trials. It was also decided to separate workloads by disease site groups, thereby allowing the data coordinator to become an expert in their assigned disease area(s). Knowledge was bolstered by inclusion in disease specific trainings, tumor boards, and other clinical meetings.

4. Outcomes

Based on scoring by the NRG Oncology Performance Reports, this new process increased our data entry scores by 15-20 percent, created fewer data delinquencies, and improved the quality of the data being entered.

The inception of electronic source documents has impacted multiple units within the CRO in a positive way. It's allowed the clinical teams to effectively interact with the DMU and others across the CRO, despite physical separation. By creating work assignments based on disease site groups, the quality of the data extraction and entry has increased, resulting in fewer data entry errors, which are now more quickly identified and addressed by the assigned DMU coordinator.

5. Lessons Learned and Future Direction

As the CRO grows, we hope to continue improving data entry scores, offer more trainings for subject matter experts within each disease site group, and provide high-quality data that's ready for statistical analysis without significant data clean-up.

Figure

