Category: Clinical Trial Operations – Work in Progress

Microsoft Power Platform: Improving Efficiency, Communication, and Documentation in the Clinical Research Setting

M. Fritz, J. Plassmeyer, M. Horak, T. Cronauer (Horne), S. Perry, J. Griffo, D. Cleary

UPMC Hillman Cancer Center

1. Background

At UPMC Hillman Cancer Center (HCC) we've encountered barriers providing quality, complete, and accurate paper documentation. A significant portion of our documented source is paper based. A paper-based approach to documentation is associated with many drawbacks and unique challenges, which are usually observed during implementation and integration of new cancer research processes. The COVID-19 pandemic added an additional layer of complexity and fueled a call to action. This resulted in the facilitation of department wide process improvements. Throughout the pandemic, cancer centers nationwide have faced obstacles transitioning from office to remote work. This led to a decline in compliant source documentation effecting quality, maintenance, and completion of records. Paper documentation has numerous inefficiencies that include maintaining current versions of documents, duplication of staff effort, errors, storage, and the ability to obtain real time signatures.

2. Goals

In compliance with the U.S. Food and Drug Administration's (FDA) 21 CFR Part 11 regulations, our goal has been to transition into a fully electronic system. Surveys built through the Microsoft Power platform conveyed that moving into the electronic era was supported by many roles at HCC including coordinators, data managers, management, and investigators. As we continue to eliminate paper documentation and template correspondence, we hope to use this platform for the storage of a digital chart, eliminate the use of stored email templates, and improve compliance to research documentation.

3. Solutions and Methods

UPMC HCC utilizes low-cost software which vastly improved efficiency in our source documentation used for electronic adverse event (eAE) logs and subject scheduling processes. New eAE logs, implemented 03/2021, drastically reduced turnaround times related to investigator review and approval, and good clinical practice (GCP) related errors in documenting per our recent internal quality control actions. Development of a fully electronic scheduling application has shown improvement in compliance, while simultaneously decreasing staff associated time on task when compared to previous processes. These changes highlighted the importance of resource utilization in a time when staff satisfaction and retention were critical for maintaining operations. Furthermore, these improvements substantially reduce costs associated with paper use, while mutually benefiting our environment.

4. Outcomes

The implemented processes have shown to be effective, via staff feedback, at driving positive change in satisfaction, compliance, and ease of use. Process changes have created less errors in data entry, allowing staff to focus on other responsibilities or trial related tasks.

5. Lessons Learned and Future Directions

Electronic source is a big step in the right direction but has its fair share of challenges. Ensuring full compliance with FDA regulations and GCP documentation is a critical piece in the development process. In addition, learning new and complex software has opened many opportunities that can be utilized to improve clinical trial start up, conduct, and closure moving forward. HCC has and will continue to

investigate all available resources to drive advancement in this field. We plan to utilize the UPMC Center of Excellence, which ensures any department within the institution can learn and develop in the Power Platform. These are the first of many changes to come at UPMC HCC as we constantly strive for continuous process improvement to clinical trial operations.