Category: Regulatory – Work in Progress

Optimization of a Regulatory eBinder Platform

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1. Background

The Fred Hutchinson/University of Washington Cancer Consortium did not have an electronic solution to manage clinical trial regulatory files that met FDA Title 21 CFR Part 11 compliance. To increase standardization and efficiencies, and to support the compliant management of electronic clinical trial documents and workflows, the cancer consortium implemented a commercial electronic regulatory binder system, Florence eBinders. Initial rollout of eBinders was completed as a pilot with our Phase I program and was deployed across all disease groups in April of 2020.

Since implementation, we have created a dedicated support team and user group to optimize and expand system utilization, not only for regulatory, but for other functions such as subject management. These efforts have enabled us to realize the same efficiencies we've experienced in regulatory in other areas of clinical trial operations.

2. Goals

Goals achieved through dedicated resources and focused efforts to optimize the efficiencies, scope, and utilization of the eBinder system include the design and implementation of electronic subject data collection and study team documents, training, and communications management.

3. Solutions and Methods

A dedicated eBinder support team was created to build more system expertise, to provide more tailored training, and to increase study team engagement. A user group with diverse disease group representation was formed to provide input on process design, prioritization of new functionality, and feedback on newly implemented workflows. Collectively, the group has successfully designed, tested, implemented, and refined new eBinder functionality.

4. Outcomes

By developing a more robust eBinder support team and user group, we were able to pilot new uses of the system and provide teams with more defined "out-of-the-box" solutions. In addition, we were able to connect with individual disease teams to observe best practices of system use, refine, and roll out to the broader consortium.

By utilizing the electronic capabilities for data completion and signature collection, we were able to create a comprehensive, electronic subject data collection workflow within the system. Teams collect clinical data and signatures within the eBinder which are made available for efficient data abstraction and monitor review without additional scanning or certification steps. We have also leveraged the eBinder as a digital repository for study team documents such as team minutes, training, and safety reports, providing transparency and accessibility for all study team members regardless of time or location. Our site is in the process of developing eConsent workflows supported by the Florence system.

5. Lessons Learned and Future Directions

Having a dedicated team of subject matter experts who have space to collaborate with teams, design workflows and process documents, and act as guides for new ways to use the system, is critical to

realize the value of an eBinder system beyond regulatory processes. We've continued to expand the scope of our goals for utilizing the system as a solution for compliant, standardized, and efficient processes that will continue to move us away from paper-based models.