Category: Regulatory – Work in Progress

Regulatory Completion Timelines: A Prospective and Retrospective Analysis of the Effect of an eRegulatory System

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1. Background

The accurate and timely completion of essential regulatory documents is a vital part of the conduct of and management of clinical research portfolios. At Lineberger Comprehensive Cancer Center, we had historically maintained our regulatory files in a paper or a mixed paper and electronic format (hybrid) binder system. As these systems were not 21 CFR Part 11 (Part 11) compliant, we found that an increasing amount of physical and personnel resources were needed to maintain the wet-ink signatures required for compliant essential regulatory documents, as evaluated by the physical space needed for filing cabinets and our regulatory acuity tool. In order to reduce the need for physical resources and free personnel resources so they could be redirected towards other regulatory priorities, we began the journey of implementing an eRegulatory system.

2. Goals

The goal of implementing an eRegulatory system (Florence eBinders) was to reduce the amount of time needed to complete essential regulatory documents. This has been evaluated based on the time needed to complete initial regulatory documents for study activation as data for those metrics was already tracked in our clinical trial management system, OnCore. The primary objective of this project was to determine if the independent variable, the implementation of Florence eBinders, reduced the dependent variable, the duration (calendar days) from “Start of Work” email to date of the completion of the initial essential regulatory documents, such as the FDA 1572 Statement of Investigator, Financial Disclosure Forms, collection of curriculum vitae, collection of licensure, and collection of applicable documents for institutional review boards and clinical laboratory facilities noted in box six and box four of the FDA 1572 respectively (Document Completion). Completion of these documents was defined as completion and final acceptance of the documents by the study sponsor.

3. Solutions and Methods

The intervention, implementation of Florence eBinders, a Part 11 compliant eRegulatory system, took place at LCCC’s Clinical Protocol Office on August 24, 2020. Florence is an electronic trial master file (eTMF) system produced and marketed by the company Florence Health Care, which shares the same name as its eTMF product. It allows for the creation of a customized binder structure for the electronic storage of study regulatory and essential trial documents. In addition, Florence allows for the completion of Part 11-compliant electronic signatures. It is recognized that during the past six-month period, the roll-out of Florence has been staggered, with 73 percent of faculty and non-regulatory staff presently active in the system.

4. Outcomes

While the current analyses continue, the implementation of the Florence Part 11 compliant eTMF systems positively impacted the completion timelines. As the roll-out of Florence has been staggered,

November 1, 2020 was selected as the "Date of Implementation" for the purposes of this project. Data from an interim analysis conducted on a retrospective population of 15 studies opened to accrual from September 1 to October 31, 2020 and a prospective population of 14 studies opened to accrual from November 1, 2020 to February 18, 2021 noted the following results: Baseline values (measured by the retrospective population of studies opened to accrual from September 1 to October 31, 2020) of mean number of calendar days required for initial document completion was 198.67 days. A measurement of approximately three and a half months of interim analysis data post-implementation of the Florence intervention (measured by the prospective population of studies opened to accrual from November 1, 2020 to February 18, 2021) shows a reduction of 50.58 calendar days, with the mean number of calendar days required for document completion being 148.09 days.

5. Lessons Learned

Data will continue to be collected and reviewed at six-month intervals to determine if the trend is statistically significant and sustained over time. It is anticipated that as the office gets to 100 percent adoption of the system, the mean activation time will continue to decrease. The current data trend suggests that the implementation of a Part 11 compliant eRegulatory system can reduce the time needed by regulatory staff to complete regulatory documents. This may also reduce the effort expended by regulatory team members to complete this task.