Category: Trial Start-up, Activation, and Protocol Development – Work in Progress

Development of Electronic Logistics Tool to Accelerate Clinical Trial Activation

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1. Background

This Quality Improvement Project addresses the extensive time currently invested in establishing internal workflows for new clinical trials (i.e., logistics assessment) within the Mayo Clinic Comprehensive Cancer Center (MCCCC). Logistics assessment occurs early during study development and culminates in the Logistics Meeting, a virtual, interdepartmental gathering lead by a Research Protocol Specialist (RPS). A significant milestone in trial activation, the meeting ensures all involved staff are engaged and in agreement on study conduct prior to Mayo institutional review board (IRB) submission. Many downstream study development activities (e.g., budgets building) are dependent on completion of logistics evaluation before they can continue.

Due to insufficient logistics resources, research staff must devote significant time to navigating the complex multitude of research areas within Mayo Clinic (MC) and establishing efficient working plans for new trials – a frustrating activity that contributes to delayed trial activations. Recently, the lack of adequate resources has been exacerbated as MCCCC implements a study development/start-up enterprise model called the "Single Research Protocol Specialist" (SRPS). SRPS centralizes all protocol development activities for each participating MC site with a single individual, regardless of the lead site location, to help streamline development. While overall SRPS promotes efficiency, site-specific nuances pose a challenge as RPSs are no longer site experts and must work effectively at all MCCCC locations. Also contributing is a shortage of experienced RPSs. MC is not immune to the increase in staff turnover post-COVID and the resulting loss of experience and knowledge. In addition, to meet increased demands, MCCCC has performed incremental hiring. Both turnover and incremental hiring have created an influx of new staff, which coupled with the SRPS model implementation, has increased urgency for improved logistics resources.

2. Goals

The baseline average time needed to complete logistics assessment activities, established via staff surveys, is 10.9 hours. Our initial target performance is 8.7 hours (20 percent reduction), which would result in increased efficiency at multiple enterprise cancer center sites. The ultimate target performance upon project completion is 2 hours (81 percent decrease).

3. Solutions and Methods

We are using the REDCap (Research Electronic Data Capture) application to create a knowledge base that is accessible to both new staff and staff that are not familiar with site-specific nuances. The pilot project will only address Logistics for the Rochester MCCCC site (selected due to having the most complexity). Eventually, tool functionality will be expanded to use during the Operational Feasibility Committee Review performed for all new cancer-related clinical trials prior to trial development activities.

4. Outcomes

Outcomes are pending; however, general feedback from small testing cohorts has been positive.

5. Lessons Learned and Future Directions

At this time, we are continuing to update the REDCap tool's logic and questioning process. As

implementation progresses, we will likely have many lessons to learn. The scope of the project has already changed between ideation and end user testing, which shows that we lacked some staff at the planning stage and MCCCC's needs have continued to evolve. Quality improvement continues to be a priority as we always put the needs of our patients first and above all else.

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