Development of Electronic Logistics Tool to Accelerate Clinical Trial Activation

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BACKGROUND

LOGISTICS ASSESSMENT

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.

CHALLENGES

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 (Figure 1). Recently, the lack of adequate resources has been exacerbated as MCCCC implements a study development/startup enterprise model called "Single Research Protocol Specialist" (SRPS), which centralizes all protocol development activities for each participating MC site with a single individual, regardless of the lead site location, thus streamlining 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.

FIGURE 1

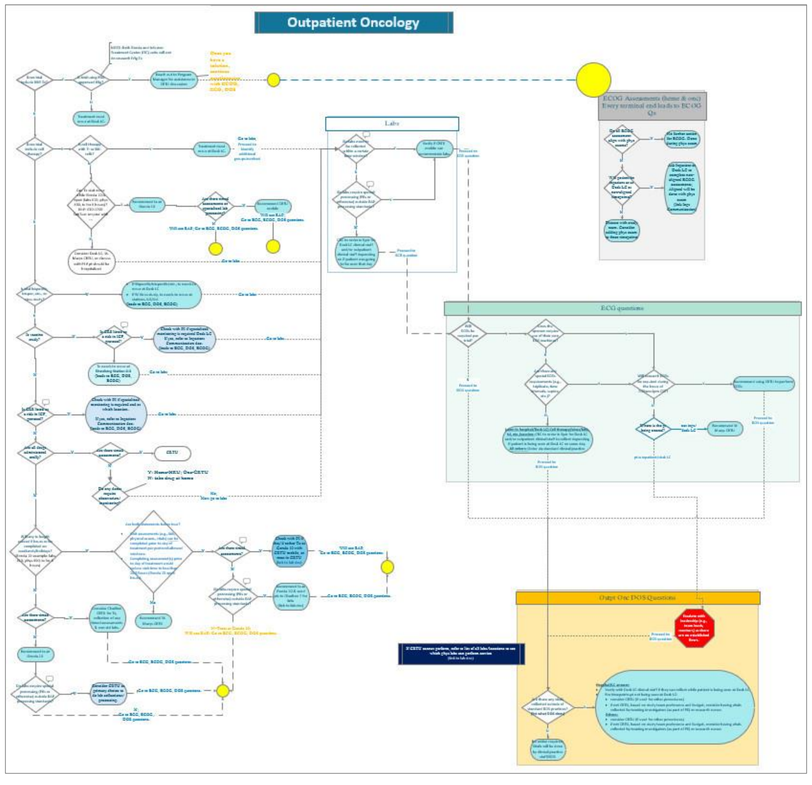

Figure 1. Example workflow for an Outpatient Oncology Trial and basis of REDCap logic Workflow is not intended to be understood, but rather show the complexity, multiple decision points and inter-related outcomes.

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% reduction), which would result in increased efficiency at multiple Cancer Center enterprise sites.

FIGURE 2

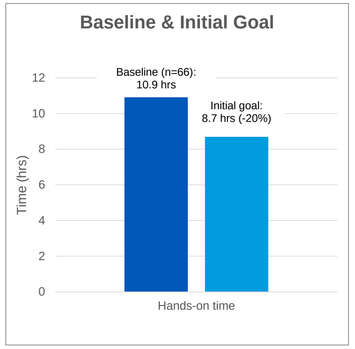

Figure 2. Baseline results and initial goal Survey results and goal based on 20% reduction.

FIGURE 3

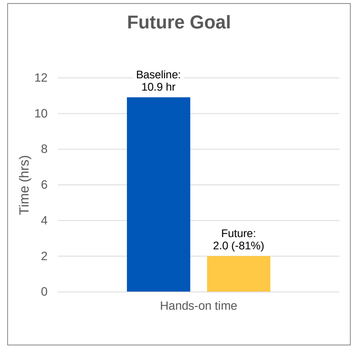

Figure 3. Future milestone The ultimate target performance upon project completion is 2 hours (81% decrease).

SOLUTIONS & METHODS

We are using the Research Electronic Data Capture (REDCap) version 12.4.25 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).

OUTCOMES

Outcomes are pending; However, feedback from small testing cohorts has been positive, informative and efficient method to work through a multitude of scenarios.

LESSONS LEARNED & FUTURE DIRECTION

We have implemented the REDCap tool's questioning logic process. As implementation continues, we will likely have many lessons to learn. The scope of the project has already changed between project ideation and end user testing, which indicates the lack of key staff at the planning stage and the evolving needs of MCCCC.

A post implementation survey will be conducted after 6-9 months of use to assess the effectiveness and future enhancements.

Eventually, tool functionality may be expanded to use during the Operational Feasibility Committee Review performed for all new cancer-related clinical trials prior to trial development activities.

ACKNOWLEDGEMENTS

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REFERENCES

REDCap 12.4.25 - © 2023 Vanderbilt University