Category: Clinical Trial Operations – Work in Progress

Incorporating the Complexity of Screening Into Protocol Acuity: Updates to the SCCC Staff Scoring Model

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1. Background

The Simmons Comprehensive Cancer Center clinical research office (CRO) has been using a home-grown staffing model using protocol acuity to calculate coordinator and data effort on clinical trials for several years. Last year, analyses run based on our legacy staffing models and study budgets reflected that the complexity of trials over time had not changed substantially within the previous five years and did not appear to correlate with an increase in study budgets over the same period. Given the team's sense that complexity of trials had increased over the same time period, we hypothesized that the primary source of greater complexity was due to increased intensity of screening activities. Because our current staffing model used only a static score to evaluate screening activities of coordinators, the overall study acuities did not change to reflect this nuance. We recognized that further evaluation was needed to more accurately capture the impact of screening on the efforts of study personnel.

2. Goals

A working group of managers and coordinators formed in the fall of 2020 to review the current staffing model database and transition the static screening score to one that is study-specific.

3. Solutions and Methods

A list of typical screening procedures was compiled and the stages of pre-screening and screening through enrollment were outlined. As a group, scores for each procedure were determined in order to accurately measure screening activity. Through the process the group also revised the calculation for points per hour of work to apply to tasks that were time-based. While the focus was on screening procedures, some of the changes made impacted procedures outlined in the active study portion of the staffing model as well. After drafting the proposed changes, current studies were applied to the new system for validation.

4. Outcomes

After evaluating the entire screening process, we determined that there were four primary phases to the screening process:

1. Prescreening
2. Informed consent
3. Conduct of screening visits following informed consent
4. Evaluation of eligibility and enrollment

When six current studies were entered into the new staffing model, the screening score went from a static 10 points to an average 22.2 points per patient enrolled (range 17.4-26.7 points). When calculating this against the ideal number of points per coordinator in a given month period of time, the

working group determined that the model more accurately reflected the maximum load for prescreening through enrollment for one individual. The proposed revisions to the staffing model database were presented to the CRO managers and are undergoing review.

5. Lessons Learned

Delving into and breaking down possible screening/pre-study procedures allows us to more accurately account for staff time and effort. Our next steps are to accept final feedback from CRO managers, apply changes to the existing database, and re-evaluate existing studies. We will then run similar analyses to our original project to determine whether our budgets are correlative with study complexity.