Category: Resource Management and Finance – Work in Progress

Development of a Clinical Research Coordinator Capacity Model

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1. Background

Given the complexity of the clinical research coordinator (CRC) role it is essential to determine a sustainable workload and forecast the number of full-time equivalent employees (FTEs) needed to support clinical research. Currently, in Moffitt Cancer Center's Clinical Trials Office (CTO) team managers have utilized the Clinical Research Effort Study Tool (CREST) (Feb 22, 2016, Onsemble, 2016, Turner) which was derived from the OPAL (*Journal of Oncology Practice*, 2011, Smuck et al.) to measure CRC activity by measuring protocol complexity. We reviewed literature on previous work such as the Clinical Research Coordinator Workload Estimation and Tracking tool by M. Repede, AACI 2022 abstract.

2. Goals

We sought to design a CRC workload capacity model that is efficient, effective and captures the time it takes a CRC to complete operational tasks at Moffitt. Secondly, the tool will support operational managers' decisions in projecting FTEs needed to coordinate active trials in the portfolio and trials in activation pipeline.

3. Solutions and Methods

Thirty CRCs used an "effort diary" for eight weeks and noted how long it took to complete activities on each study. The diary included the study and subject ID associated with each activity, which was then mapped to the schedule of study activities in Oncore–Clinical Trials Management System (CTMS). CRCs provided additional feedback to a project manager, who aggregated and analyzed data to calculate an average duration for each task per study. For the administrative tasks unrelated to protocol procedures, a weekly average time was given by each CRC. For clinical related tasks, an average duration was calculated and multiplied by the frequency of the tasks, as described in the calendar in Oncore-CTMS. To estimate clinical hours, only patient-facing tasks were mapped, using an Office Data Connection report from Oncore-CTMS.

4. Outcomes

The workload capacity tool can estimate:

- CRC workload hours and capacity percent per calendar week
- FTE support needed in hours per program disease
- Number of hours spent in clinic by disease site-based team per calendar week
- FTE support is shown both prospectively and retrospectively
- The model is based on real time data from Oncore-CTMS

5. Lessons Learned and Future Directions

Staff member engagement is imperative to ensure the data accurately captured the "real world" of the CRC. Reassurance and open communication served to lessen the perception that the tool was a means to monitor personal productivity and efficiency. The estimations for tasks unrelated to the study calendar were challenging as the effort diary data revealed a significant amount of time devoted to tasks related to internal operational processes, which we factored in under administrative tasks. It was

identified that coordinators spent more time on administrative tasks due to operational processes and tasks specifically related to a particular disease or the type of trial, for example trials that may have a surgical or in-patient component. Future steps will focus on validation and refinement of the tool to account for the variance in coordinator's capacity based on coordinator level of experience, involvement in projects, and mentorship.

Citations

1- Turner, Rebecca. "Workload Scoring Using OnCore" Onsemble Conference Presentation, February 22, 2016.
2- Smuck B, Bettello P, Berghout K, et al.: Ontario Protocol Assessment Level: Clinical trial complexity rating tool for oncology clinical trials. J Oncol Pract 7:80- 84, 2011.
3- Repede M, Beighley D, Putz K, Fritsche A, Nowakowski G. "Clinical Research Coordinator Workload Estimation and Tracking" Poster Presentation, AACI 2023.