Development of a Clinical Research Coordinator Capacity Model


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.

Goals

1. 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.
2. To develop a tool that will support operational managers’ decision in projecting FTEs needed to coordinate active trials in the portfolio and trials in activation pipeline.

*SOncore–Clinical Trials Management System (CTMS)

Solutions and Methods

CRCs (n=30) used an “Effort Diary” for 8 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*. 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 CTMS. To estimate clinical hours, only patient-facing tasks were mapped, using an Office Data Connection report from CTMS.

Outcomes

The workload capacity tool can estimate CRC workload per hours of the week and %, number of hours spent in clinic by disease site-based team per calendar week. The distinctive ability of the tool is that it can pull number of hours that are needed to support clinical trial based on schedule of events. The tool pulls 12 weeks of prospective and retrospective capacity assessments based on the real time data from CTMS without the need for additional effort tracking by staff.

Refinements and Next Steps

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. Additionally, development of the reference guide for CTO managers and Supervisors to use for Fiscal Year(FY) FTE planning. Lastly, build out of the capacity model for Research Data Coordinators (RDC) is a focus in FY24.

References

