Category: Finance/CCSG/PRMS - Completed Project

Statistically Significant Impacts of a PRMC Charter Alignment With NCI Practices

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1. Background

In 2018, University of Cincinnati Cancer Center (UCCC) Protocol Review and Monitoring Committee (PRMC), along with the clinical trials office staff, revised the PRMC charter to optimize the review process to align with best practices of existing NCI-Designated Cancer Centers.

2. Goals

The goal of the present study was to streamline the PRMC review process to achieve efficiencies and maximize resources.

3. Solutions and Methods

One of several updates to the UCCC PRMC charter was the expedition of the administrative review process. Historical data of reviewed studies were analyzed by charter that was in effect. Data elements included type of review (administrative, fast track, full, chair, response to contingencies), and turnaround time in days from time of submission to approval. Out of 510 possible studies, 407 were eligible for analysis. To be eligible, a study must have had complete data to enable total turnaround time determination. If the study did not have a time-stamped submission date, we estimated the submission date by utilizing the deadline for PRMC submission (two weeks prior to meeting). Turnaround time was defined as total number of days that lapsed between submission and final approval. Standard statistical analyses were utilized to assess for significance pre and post charter revision.

4. Outcomes

Using an independent t-test, the new charter resulted in improved turnaround times when compared to the previous charter (3.4 days shorter; $p = 0.002$, Cohen's $d = 0.31$). To assess workload under each charter, the number of studies was reviewed by charter and review type. There was an overall 14 percent decrease in full-committee meeting workload between the previous and new charters. Administrative review (45 percent) and fast track reviews (21 percent) increased under rules of the new charter, which allowed the remaining review types to have a decrease in workload (38 percent to 90 percent).

5. Lessons Learned

Developing a new PRMC charter resulted in improved efficiencies for the committees. Furthermore, it facilitated optimal utilization of committee member time, talent, and resources as more trials are appropriately excused from full-committee UCCC PRMC review. This dynamic substantially reduced the full-committee workload, thereby facilitating increased attention to investigator-initiated and industry sponsored trials at full-committee PRMC meetings.

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Figure:

Figure 1. Turnaround Time Based on Charter Type (means)

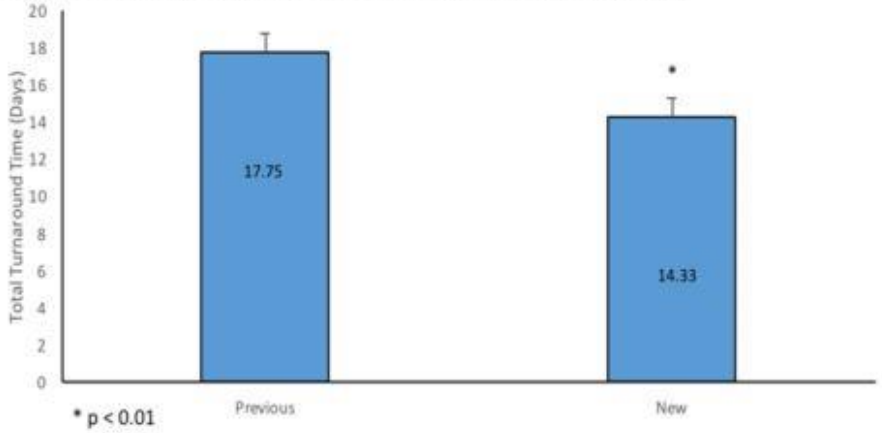

Figure 2. Turnaround Time Based on Charter Type (medians)

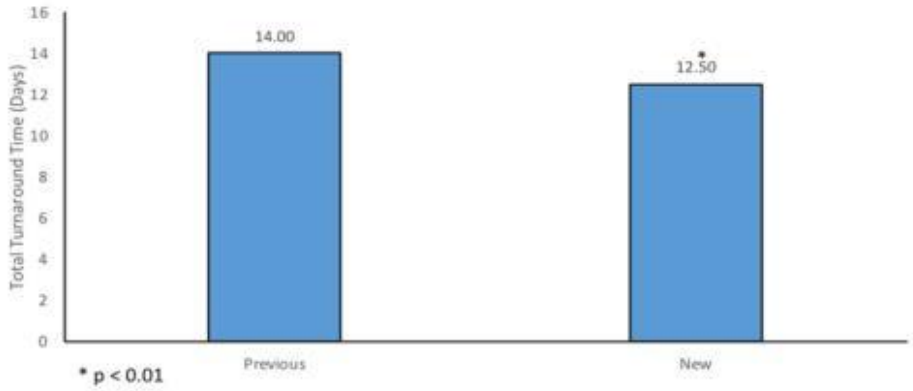

Figure 3. Fast Track Comparison between Charters (means)