Revising an Institutional PRMC Charter to Achieve NCI Standards: Impacts, Efficiencies, and Potential for Further Improvement

C. Vollmer, MBA; C. L. Allen, MS; N. Kurtzweil, JD; B. Hughes, E. Kantemneni; T. J. Herzog, MD
University of Cincinnati Cancer Center, University of Cincinnati, Cincinnati, OH

Introduction

As an aspiring center seeking NCI designation, the University of Cincinnati Cancer Center (UCCC) analyzed its clinical trial regulatory processes to ensure continued improvement in efficiency and resource allocation. In 2018, UCCC's Protocol Review and Monitoring Committee (PRMC) in conjunction with the Clinical Trials Office staff reviewed and extensively revised the PRMC Charter to optimize the review process of the UCCC PRMC to align with best practices from existing NCI Designated Cancer Centers.

Methods

The following specific updates were made to the UCCC PRMC Charter:

1. Created an expedited administrative review process
2. Permitted deferral to a single Protocol Review and Monitoring System (PRMS) of a multi-center trial
3. Ensured accrual reviews uniformly define and account for rare cancers
4. Added Data Table 4 study type definitions
5. Identified member roles and responsibilities clearly and
6. Clarified the PRMC's authority to open and terminate protocols.

Strategies for Data Analysis

Out of a possible 510 studies, 407 were eligible for analysis (Figure 1).To be eligible, a study must have replete data enabling calculation of total turnaround time, which requires submission and approval dates. 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 calculated by subtracting the submission date from the approval date. This provided the number of days that lapsed between the two time points, and statistical analysis was then performed to compare mean and median turnaround times between the new charter versus the previous charter.

Figure 1. Consort Diagram

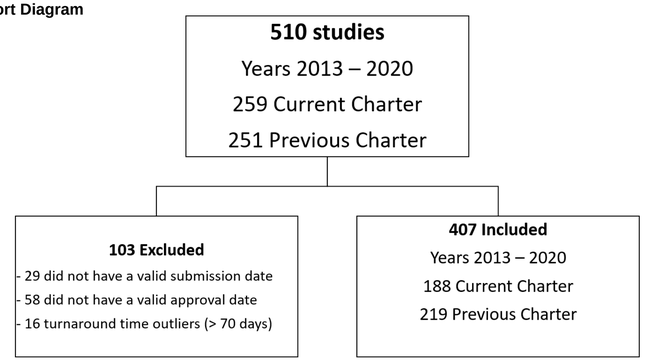


Table 1. Results of Independent t-test

	N	Mean	SD	t-test	Cohen's d
Previous	219	17.75	10.32	0.002	0.31**
Current	188	14.33	11.71		

* statistically significant < 0.05 ** small-medium effect size

Figure 2. Turnaround Time by Charter

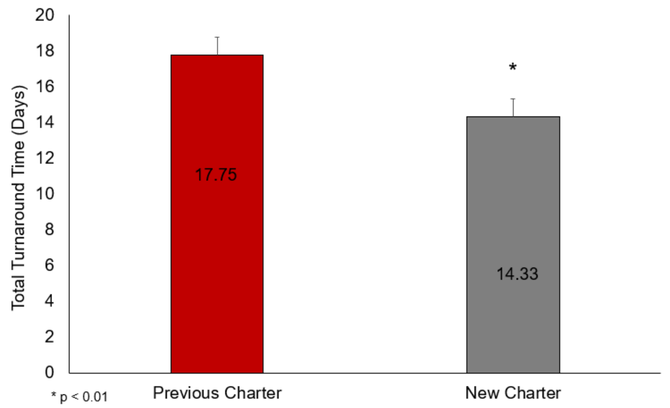
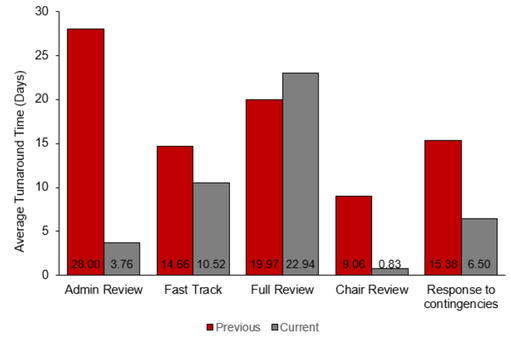


Figure 3. Turnaround Time By Charter and Review Type



Results

Using an independent t-test, the new charter has a shorter turnaround time when compared to the previous charter of almost 3.4 day (p = 0.002, Cohen's d = 0.31) (Table 1 and Figure 2).

To assess workload under each charter, the number of studies was reviewed by charter and review type. There was an overall 14% decrease in workload between the previous and new charters. Administrative review (45%) and fast track reviews (21%) had an increase in workload, which allowed the remaining review types to have a decrease in workload (38% - 90%). The average turnaround time by charter and review type can be seen in figure 3.

Discussion

Developing and approving a new PRMC Charter statistically significantly resulted in improved efficiencies for the committees. Furthermore, it facilitated the optimal utilization of committee member time, talent, and resources as the increase in fast-tracked and NCI cooperative group trials excused from full UCC PRMC committee review substantially reduced full committee work-load post-amendment. This dynamic facilitated increased attention to investigator-initiated trials and industry sponsored trials at PRMC meetings.

University of CINCINNATI