

Increased Monitoring of Trials to Optimize Resourcing at an NCI-Designated Comprehensive Cancer Center

A. Crawford, A. Joshi, B. Pothuri, L. Dhanantwari

Laura & Isaac Perlmutter Cancer Center at NYU Langone Health

1. Background

The Protocol Review Monitoring Committee (PRMC) at the Clinical Trials Office (CTO) at NYU Langone Health's Perlmutter Cancer Center (PCC) determines whether a protocol is scientifically and statistically sound, aligns with PCC goals, no competing studies, and evaluates viability of accrual goals. PRMC holds authority to close trials and reviews studies initially and annually until it closes to enrollment. This review includes resource evaluation and ensuring optimal use of resources. Activating and maintaining a trial is a significant workload, even in the absence of accrual; regulatory workload is essentially the same. In addition, other units are responsible for maintaining systems access, inventory, workflows, and reviewing amendments. PCC leadership recognized the need to effectively monitor trials at an increased cadence.

2. Goals

Our goal was to optimize resources by increasing monitoring by the PRMC.

3. Solutions and Methods

Monthly reports generated and filtered against the parameters of therapeutic interventional studies, post six months study activation, and zero accruals are identified. Investigators are notified to provide feedback for lack of accruals as per below:

Investigator Initiated Trials (IITs)

For studies below 50 percent target accrual at six months post-study activation, Principal Investigator (PI) must provide a remediation plan to reach annual target accrual before annual review.

Sponsored Trials - Industrial, National Cooperative Group, and Externally Peer Reviewed Trials

Non-IIT studies at six months post study activation, if there is zero accrual, PRMC instituted a policy to terminate unless there are compelling reasons to remain open (i.e., study on hold, limited slots, amendment, PI role in the study, PI leadership role). Studies with a compelling reason will receive a three- or six-month extension.

PIs may appeal the PRMC's decision by submitting an appeal letter within four weeks of PRMC closure notice with rationale indicating why study should continue. If PI appeals a PRMC closure, a thorough remediation plan to increase accrual must be outlined. Appeal letters must be submitted for review and PIs must be in attendance at the meeting for appeal to be considered.

4. Outcomes

In 2023, PRMC reviewed 230 interventional trials for monitoring accrual status. Of these studies, 10 percent (23 studies) were composed of IITs and were reviewed for progress monitoring, none of these had zero accruals and all remained open until the next review. There were 13 non-IIT studies with zero accruals and the PRMC closed 4, so approximately 31 percent closed due to 0 accruals. Overall, 13 percent (30 studies) were closed by PRMC due to increased monitoring.

5. Lessons Learned and Future Directions

Increased monitoring keeps continuous regulation of sites portfolio in real time, ensuring appropriate resource utilization. It allows collaborative effort on each Disease Management team to determine when a trial is difficult to accrue or no longer applicable to the patient population or scientifically relevant. PCC is evaluating AI vendors for pre-screening to help better identify patient populations and potential to accrue earlier in the study start-up process.