

Improving PRMC Accrual Monitoring Procedures: Making it Count

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1. Background

Protocol Review and Monitoring Committees (PRMCs) are tasked with ensuring that protocols meet adequate scientific and accrual progress as part of the Protocol Review and Monitoring System at National Cancer Institute (NCI)-Designated Cancer Centers. This responsibility comes with the challenge of ensuring studies are demonstrating progress while also not imposing barriers to important research. Many PRMCs acknowledge that some studies are expected to be slow accruing and therefore a one-size fits all accrual monitoring process can be punitive to study teams and administratively burdensome to the PRMC. Thus, Sidney Kimmel Cancer Center proposed to establish a process that could address unique study circumstances more flexibility, while also encouraging meaningful accrual progress.

2. Goals

- Set minimum accrual expectations and monitoring frequency to be appropriate for different study characteristics
- Reduce administrative burden

3. Solutions and Methods

First, we surveyed AACI members to learn about other centers' minimum accrual expectations and accrual monitoring processes. Based on the information gathered, we revised our policy to change monitoring from a biannual process to a rolling review process based on critical open to accrual milestones (6, 12, 24 months, etc.). PRMC developed three categories outlining minimum annual accrual expectations and committee review frequencies. Investigator-initiated studies (Category A) are expected to accrue at least 50 percent of their annual accrual goal and are monitored every six months. Externally sponsored (Category B) are monitored at least annually and are expected to accrue a minimum of four participants every 12 months. Phase I and rare disease studies (Category C) are given more leniency with an expectation of one participant every 12 months. We developed a custom report that tracks minimum accrual expectations based on assigned category, low accrual status, and upcoming accrual monitoring review dates. An accrual monitoring subcommittee was created to review principal investigator (PI) responses to low accrual notifications and recommend outcomes to the PRMC for consideration during full committee review. We developed a standard form to collect PI responses to low accrual notifications to ensure collection of meaningful information for consideration by the PRMC subcommittee.

4. Outcomes

The revised policy was implemented in June 2022 and was well received by investigators. By recognizing and accepting that certain studies will be low in total accrual numbers but high in scientific validity, we have reduced the administrative burden by monitoring accrual only once per year. By reviewing on a rolling basis, individualized to trial category, the administrative burden has been spread out, reducing stress on staff. Creating the accrual monitoring subcommittee has created additional opportunities for member engagement.

5. Lessons Learned and Future Directions

Short-term goals include automating low accrual notifications and utilizing our Clinical Trial Management System to track outcomes. For the future, PRMC will consider expanding accrual

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monitoring to non-interventional studies and increasing minimum expectations each year a study is open to accrual. Long-term goals will focus on engagement with disease teams to allow tracking and monitoring of accrual progress compared to minimum accrual expectations independently, so they have access to view this information prior to receiving a low accrual notification from the PRMC.