

Background

Prior to 2022, the Sidney Kimmel Comprehensive Cancer Center (SKCCC) Protocol Review and Monitor Committee's (PRMC) accrual monitoring policy had a one-size-fits-all minimum accrual expectation and involved monitoring all studies, which was administratively burdensome especially for studies expected to be low accruing. In June 2022, PRMC implemented a new policy that acknowledges studies which are expected to be slow accruing, such as those for rare diseases, and that has monitoring frequencies appropriate for the unique characteristics of studies.

Goals

1. Reduce the number of underperforming studies in SKCCC's portfolio.
2. Reduce the administrative burden of accrual monitoring process.

Solutions and Key Changes

- PRMC established three accrual monitoring categories (see **Table 1**) with standardized accrual minimums, monitoring frequencies, and outcome recommendations.
- Frequency of review aligns with the time a study is open to accrual. All studies get one full year before penalties to accommodate anticipated low or slow accruing factors.
- PRMC developed a custom report which monitors study accrual performance based on the assigned category and identifies when studies are due for review.
- PRMC also established a monthly subcommittee that pre-reviews the corrective action plans of a subset of studies and recommends outcomes to the full committee.
- To assess impact, the following metrics were reviewed: Average accrual per study by assigned accrual monitoring category, total number of low accruing studies, and number studies meeting expectations.

Table 1. Accrual Monitoring Categories

Category	Minimum Accrual Expectations	Monitoring Frequency	Studies Typically Assigned to this Category
A	50% of annual accrual goal per year	Every 6 months	Jefferson investigator-initiated studies
B	4 per year	Every 12 months	National, industry, and external investigator-initiated studies
C	1 per year	Every 12 months	Phase I, rare disease, and rare molecular subtypes

Outcomes

Goal 1: Less Underperforming Studies

- Average accrual for both Category B and C met the expectations of the policy following implementation.
- The average accrual for Category B studies has increased from 2.19 per protocol in 2022, to 4.19 per protocol in 2024.
- Average accrual per protocol for Category C studies have averaged 1.3 accruals per protocol per year since policy implementation.
- The percentage of Category A studies that met minimum accrual expectations increased from 46% in 2022 to 57% in 2024.
- Overall, the percentage of studies meeting accrual expectations increased from 31% in 2022, to 48% in 2023 and 51% in 2024, demonstrating consistency of the policy's impact.

Goal 2: Reduced Administrative burden

- There was an 18% reduction in the number of low accruing studies in 2024 compared to before the policy change in 2022.
- The monthly review process reduces the number of trials to a subset of approximately 5 monthly.

Future Initiatives

- Expand reporting capabilities by utilizing the Oncore ePRMS console for tracking accrual monitoring reviews.
- Create a self-serve dashboard for disease team leaders to track study accruals and identify underperforming studies without waiting for PRMC notifications.