Category: Prioritization and Scientific Review – Completed Project

PRMC Accrual Monitoring: Let's Get Real

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1. 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 biannually, which was administratively burdensome especially for studies expected to be low accruing. In June 2022, PRMC implemented a new policy that acknowledges studies expected to be slow accruing, such as those for rare diseases, and that has monitoring frequencies appropriate for the unique characteristics of studies.

2. Goals

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

3. Solutions and Methods

PRMC established three accrual monitoring categories with standardized accrual minimums, monitoring frequencies, and outcome recommendations (see Table 1). Instead of a bi-annual review, PRMC reviews a subset of studies monthly. PRMC developed a report which monitors study accrual performance based on the assigned category and identifies when studies are due for review. PRMC also established a subcommittee pre-review of all corrective action plans 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.

4. Outcomes

By setting annual minimums for category B and C, we hoped to see fewer underperforming studies and accrual aligning with the minimum expectations. The average accrual for Category B studies has increased from 2.19 per protocol in 2022, to 4.19 per protocol in 2024. It also indicates the policy has been effective in encouraging disease teams' selection of better performing studies. Average accrual per protocol for Category C studies have averaged 1.3 accruals per protocol per year since policy implementation, as expected, which decreases frequency for review by PRMC. Performance for Category A studies has improved; the percentage of Category A studies that met minimum accrual expectations increased from 46 percent in 2022 to 57 percent in 2024. Monitoring is more frequent for Category A; thus, better accruing studies reduces the administrative burden. Establishing realistic annual accrual goal expectations resulted in an 18 percent reduction in the number of low accruing studies in 2024 compared to before the policy change in 2022, which has reduced the administrative burden. The percentage of studies meeting accrual expectations increased from 31 percent in 2022, to 48 percent in 2023 and 51 percent in 2024, demonstrating consistency of the policy's impact.

5. Learned and Future Directions

Our findings demonstrate that the policy reduced the number of low accruing studies across each category. By switching from bi-annual review of all studies to monthly review of a subset of studies, PRMC can give personalized feedback sooner. Establishing the subcommittee pre-review reduces the time necessary to review and deliberate over accrual monitoring during full committee meetings and

allows more time for reviewing new studies. Future goals include expanding reporting capabilities by utilizing the Oncore ePRMS console for tracking accrual monitoring reviews. This will enhance PRMC's ability to assess performance and facilitate collaboration with disease teams to ensure portfolios meet expectations of the PRMC and the needs of SKCCC.

Figure

Table 1: Minimum Accrual Expectation Categories

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