

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 NCI-designated cancer centers.
- Balance between encouraging progress and not creating unnecessary barriers is a challenge.
- Some studies are expected to be slow accruing and a one-size fits all accrual monitoring process can be punitive to investigators and administratively burdensome on support staff.
- Sidney Kimmel Cancer Center proposed a process to address unique study circumstances with a more flexible approach while encouraging meaningful accrual progress.

Goals

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

Methods

- We surveyed AACI members to learn about other centers' minimum accrual expectations and accrual monitoring processes.

Solutions

- Developed 3 categories tailored to the circumstances of the trial (**Table 1**).
- Revised monitoring policy from bi-annual review for all studies to a rolling review process based on critical accrual milestones (6, 12, 24 months, etc.).
- Developed a custom report that tracks minimum accrual expectations and upcoming monitoring timepoints.
- Implemented a standard form to collect PI responses to low accrual notifications.
- Established an accrual monitoring subcommittee to recommend outcomes to the full PRMC (**Figure 1**).

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

- By recognizing and accepting that a subset of studies will be low in total accrual numbers but high in scientific contribution we have reduced administrative burden by monitoring accrual only once per year.
- Reviewing on a rolling basis, individualized to trial category, has spread out the administrative burden, reducing stress on staff.
- The custom report from OnCore eliminates manual tracking of follow up monitoring timepoints, accrual information, and relevant study details.
- The standard form for responding to low accrual notifications has improved the quality of responses from PIs and streamlined communication.
- The accrual monitoring subcommittee has created additional opportunities for member engagement.

Future Directions

- PRMC will consider expanding accrual monitoring to non-interventional studies and increasing minimum accrual expectations each year a study is open to accrual.
- Utilize OnCore's ePRMS console to further improve administrative workflows and streamline reporting.
- Long term goals will focus on engagement with disease teams to allow tracking and monitoring of accrual progress compared to minimum accrual expectations independently, to enhance access to this information prior to receiving a low accrual notification from the PRMC.

Figure 1. Low Accrual Notification and Review Process

