ENACTING STRICTER ACCRUAL MONITORING GUIDELINES AND STREAMLINING AUTOMATED REVIEW PROCESSES

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Background:

The Winship Protocol Review and Monitoring Committee (PRMC) subcommittee for accrual oversees the accrual goals for clinical trials office (CTO) interventional trials. The committee meets biannually. The PI receives an automated low accrual initial warning letter, generated from OnCore if the accrual rate was ≤25% of the expected annual accrual rate, after six months from the date of opening to accrual. A final warning letter is sent after twelve months, and if the accrual requirement was not met at 18-month mark, the study was terminated. This approach resulted in 'no and slow' enrolling studies being open for 18 months prior to termination, or more, in the cases of some rare tumor studies which was burdensome both financially for the institution and for the staff managing the clinical, regulatory, and reporting requirements. The Winship PRMC implemented an updated accrual monitoring policy in January of 2026.

Goals:

- To decrease the number of low or no enrolling studies in our portfolio
- To focus on improved trial selection based on our catchment area
- To streamline accrual monitoring
- To lessen the administrative burden of conducting trial accrual monitoring

Solutions and Methods:

A compressed accrual review timeline was implemented. It utilizes a program built by the Winship Informatics Team to identify low accruing trials at the 6 (first warning letter), 9 (second warning letter), and 12-month (final letter) timepoints and automatically sends notifications to the study teams based on OnCore data.

It also incorporates staggered accrual requirements that automatically terminates adult studies with 0 accruals after 12 months and trials with less than 25% of their goal but at least one enrollment after 18 months. For rare tumor and pediatric studies, trials with 0 enrollments can be open for 2 and 3 years respectively prior to automatic termination. The monthly notifications are sent to all stakeholders and studies are discussed at weekly disease team working group meetings to focus on whether the accrual goals remain feasible, development of strategies to improve enrollment, or agreement that the study should be closed.

Outcomes:

Though this process improvement initiative is still in the early phases of implementation, both approval response rates and PI response times improved. 5 trials were terminated by the PRMC due to low accrual during the 1st 2 months of implementation. If this rate of closure continues, the projected number of closures for the year is 30 studies in contrast to 16 in 2025. Additionally, 33% of studies lowered their enrollment goals in response to the notifications.

Lessons Learned and Future Directions:

Continuous analysis of trends in the rates of:

- Accrual goal reduction
- Termination of low performing studies
- Monthly notifications sent
- Rate of successful appeals

In the future, the PRMC will consider shortening the allotted amount of time before warnings are sent and limiting the number of studies within specific disease team working groups with enrollment goals of 1 patient per year.

Figure 1:

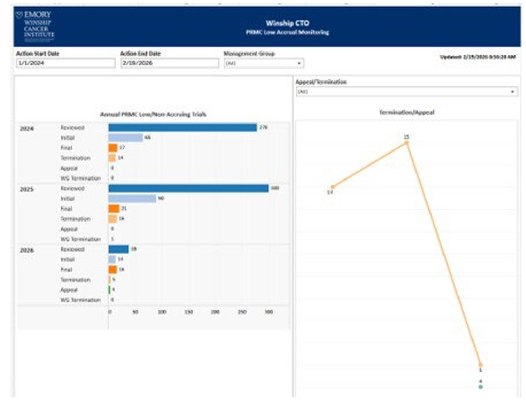
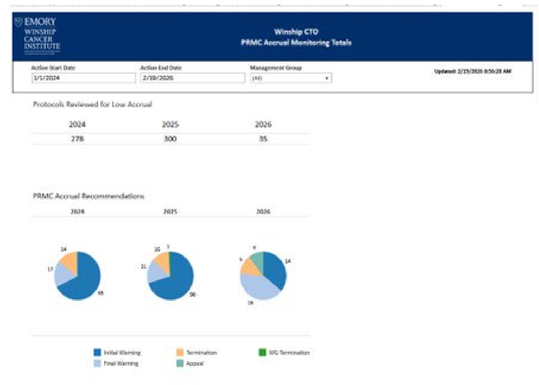


Figure 2:



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