Category: Prioritization and Scientific Review – Work in Progress

Enacting Stricter Accrual Monitoring Guidelines and Streamlining Automated Review Processes

L. Cox

Winship Cancer Institute of Emory University

1. Background

The Winship protocol review and monitoring committee (PRMC) subcommittee for accrual oversees the accrual goals for all clinical trials office (CTO) managed interventional trials. The committee meets biannually to review the accrual progress. The principal investigator (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 second or final warning letter is generated if the accrual rate was ≤25% of the expected annual accrual rate, after twelve months. If the accrual requirement was not met at 18-month mark, by the time of the next subcommittee meeting, the study was terminated. Investigators were required to respond, and responses were taken under consideration to keep the study open. 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 and studies. Keeping low-performing studies open for this extended amount of time 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.

2. Goals

The overarching goal of enacting stricter timelines and furthering automation of accrual monitoring is to decrease the number of low or no enrolling studies in our portfolio. This approach will accomplish the broader goal to focus on improved trial selection based on our catchment area and streamlining accrual monitoring while lessening the administrative burden of conducting trial monitoring.

3. Solutions and Methods

According to the revised PRMC accrual policy, that was shared with the disease team working group chairs and disseminated at the working group meetings, a compressed accrual review timeline was implemented. It utilizes a program built by the Winship Informatics Team to identify low accruing trials at the six (first warning letter), nine (second warning letter), and twelve-month (final letter) timepoints and automatically sends notifications to the study teams based on OnCore data. It also incorporates staggered accrual requirements that automatically terminate adult studies with zero accruals after 12 months and trials with less than 25 percent of their goal but at least one enrollment after 18 months. For rare tumor and pediatric studies, trials with zero enrollments can be open for three years prior to automatic termination. The monthly notifications are sent to all stakeholders and studies are discussed at weekly disease team working group meetings with a focus on whether the accrual goals remain feasible, development of strategies to improve enrollment, or agreement that the study should be closed.

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4. Outcomes

Though this process improvement initiative is still in the early phases of implementation, both approval response rates and PI response times improved. Five trials were terminated by the PRMC due to low accrual during the first two 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 percent of studies lowered their enrollment goals in response to the notifications.

5. Lessons Learned and Future Directions

In the future, the PRMC will continue to analyze trends in the rate of accrual goal reduction, rate of terminating low performing studies, rate of monthly notifications sent, and the 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 one patient per year.

Figure 1:

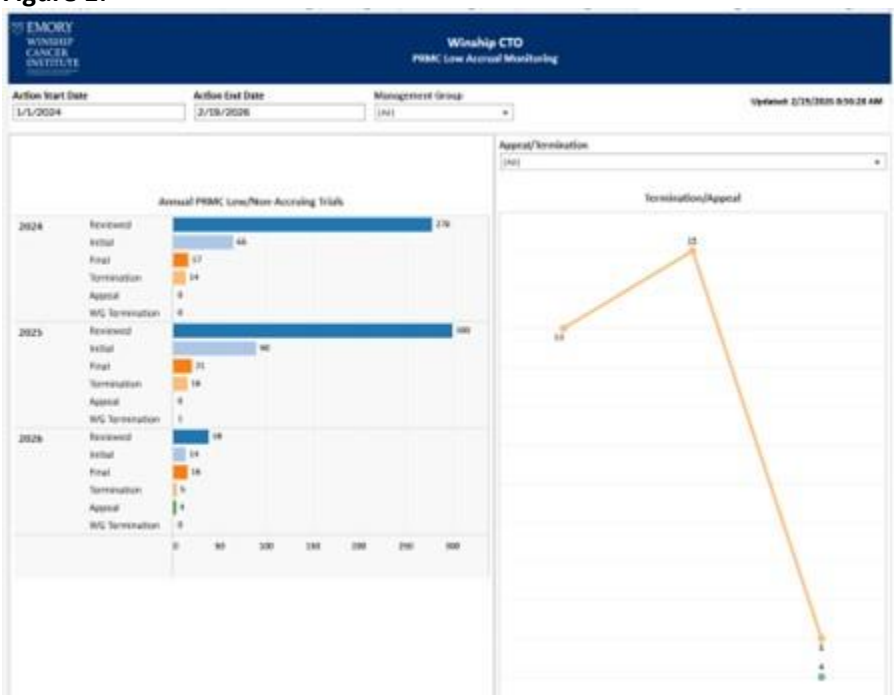

Figure 2:

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