Impact of Revised SRC Accrual Monitoring Policy on Closure of Zero-Accruing Trials

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Background

Low-accruing trials require substantial staff support and may prevent other, potentially more successful trials from opening due to concerns about limited resources. Underperforming trials should be identified and closed early to minimize their negative impact.

At the Medical College of Wisconsin Cancer Center (MCWCC), the Scientific Review Committee (SRC) is responsible for monitoring accrual to active trials, ensuring adequate progress. Previously, a formal accrual review was not conducted until 12 months following study activation, and low-accruing studies were allowed an additional 6 months to improve. This resulted in underperforming studies remaining open 18 months before SRC recommended closure. In 2021, the SRC implemented a new policy with a revised review timeline, allowing earlier intervention in those studies with low accrual.

Goals

- Earlier closure of underperforming trials, reducing the timeline from approximately 18 months to 12 months
- Increased communication between SRC and Disease-Oriented Teams (DOTs)

Solutions and Methods

The 2021 MCWCC SRC policy introduced an earlier initial accrual review at six months following study activation, with subsequent reviews scheduled based on review outcomes:

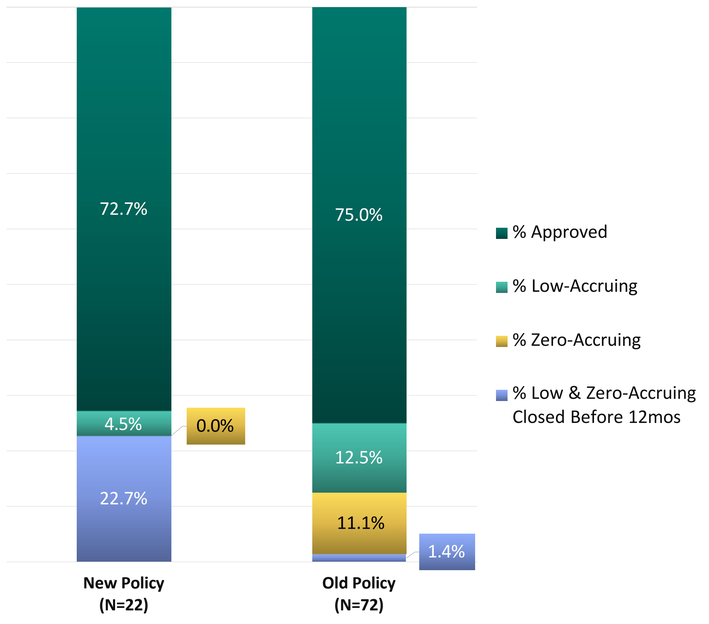
- 6 months: if minimum annual accrual goal is met, study is scheduled for annual review at 12 months; if goal is not met, a corrective action plan (CAP) is requested and study is reviewed again at 9 months.
- 9 months: if study remains below minimum, a warning letter is issued and study is reviewed again at 12 months.
- 12 months: if study remains zero- or low-accruing, recommended for closure by the SRC; if accrual minimum is met, study is approved for 1 year and then reviewed annually.

Outcomes

We evaluated studies that opened under the new policy with at least 12 months of data available and compared them to studies that completed their initial 12-month reviews under the old policy in the previous year. Our dataset includes a total of 62 studies monitored under the new policy, 22 of which have at least 12 months of data, and 72 studies under the old policy. Rare disease studies were exempted from this dataset as they are monitored under different criteria.

The number of zero-accruing studies open at 12 months is now zero, compared to 12% under the old policy (Fig. 1). The new policy has also led to the earlier closure of low-accruing studies by the PI/DOT, taking an average of 283 days compared to 615 days under the old policy (Fig. 2). We have seen a slight improvement in the response rate to CAP requests, now at about 68% compared to 64% previously.

Fig. 1: Study Status at 12 Months - New Policy vs. Old Policy

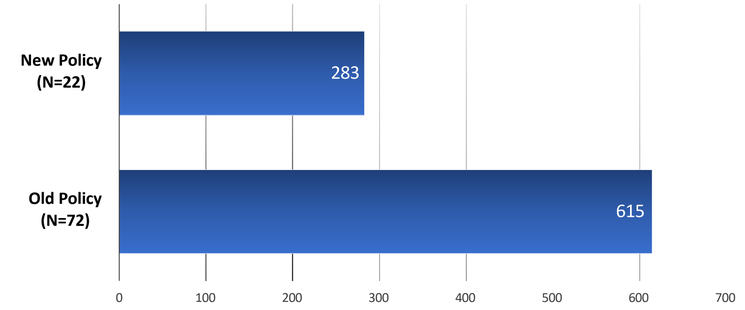


Lessons Learned

The addition of the six- and nine-month review timepoints allows the PI and DOT to reevaluate a study early in its timeline and either make changes to enrollment strategy or close the study if deemed to have low enrollment potential.

While it is early in policy implementation, the preliminary results are encouraging. Under the new policy, the number of studies with zero accrual at 12 months has decreased, as these studies have thus far been voluntarily closed by the DOTs. Our sense is that the increased communication at the additional timepoints appears to be drawing focus to accrual issues at the DOT level.

Fig. 2: Average Number of Days to Close Low-Accruing Trials



Future Directions

As part of the new policy, we have also transitioned from a uniform minimum accrual threshold based on trial type, to a percentage-based system derived from each study's projected annual accrual. Rare disease studies are now being reviewed for progress every two years, when previously they were exempt from accrual monitoring. The early identification and closure of underperforming studies under the new policy has reduced the amount of effort being expended on studies that are not fruitful, and we will continue monitoring to ensure the MCWCC's study portfolio is productive and that resources are being utilized effectively.

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