

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

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1. 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 six 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.

2. 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)

3. Solutions and Methods

The 2021 MCWCC SRC policy introduced an earlier initial accrual review at six months following study activation. At this timepoint, studies meeting the minimum annual accrual goal are scheduled for annual review and one-year approval at 12 months. Studies not meeting the goal are issued a letter requesting a corrective action plan (CAP) and are scheduled for subsequent review at nine months. If the goal is still not met at the nine-month review, a warning letter is issued and the study is reviewed at 12 months, with zero- and low-accruing studies recommended for closure by the SRC at that time.

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.

4. 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 data includes a total of 48 studies monitored under the new policy, 11 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 new policy has led to the earlier closure of low-accruing studies by the PI/DOT, taking an average of 214 days compared to 615 days under the old policy. The number of zero-accruing studies open at 12 months is now zero, compared to 12 percent under the old policy. We had hoped to see an improvement in the response rate to CAP requests; however, this has remained roughly the same at about 64 percent.

5. Lessons Learned and Future Directions

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.