

Protocol Prioritization Scores: Are They Predictive?

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1. Background

Cancer centers assign prioritization scores to new trials to assess the study's position and value in the overall trial portfolio. At the Medical College of Wisconsin Cancer Center (MCWCC), our scoresheet considers scientific impact, accrual potential, and alignment with MCWCC strategic goals, among other aspects. Trials are initially scored by the Disease-Oriented Teams (DOTs), and these scores are confirmed/edited by the Feasibility Review Committee (FRC) before approving the study to continue with activation. Scores are entered into OnCore, our clinical trial management system, along with other standard data elements.

We have not explored whether prioritization scores impact downstream processes (e.g., activation times) or whether they are predictive of trial success (e.g., accrual).

2. Goals

We want to better understand the relationship between prioritization scores and key trial metrics:

- Are high priority trials activated more quickly?
- Do high priority trials enroll patients faster?
- Do high priority trials have higher overall accrual?

3. Solutions and Methods

We compiled prioritization score, activation, and accrual data on adult interventional treatment trials that opened since 2020 and had at least 365 days of active accrual time. Activation times were defined as Scientific Review Committee submission to open to accrual. We pulled each trial's total accrual at the 12-month timepoint, to get a standardized annual accrual rate. We also pulled the time to first patient enrolled, which was defined as the number of days from study activation to first patient on, minus any intervening days that the protocol was suspended to accrual.

4. Outcomes

Priority scores ranged from 3 to 21, with a median of 9 points. Lower-priority trials (scores <9, n=51) opened in an average of 264 days, while higher-priority trials (scores >9, n=39) opened a little faster (250 days). Activation times vary by sponsor type, so we looked at industry trials alone. Higher-priority industry trials (n=21) opened 23 percent faster than lower-priority (n=24), 245 versus 320 days, respectively.

Lower-priority trials averaged 3.1 accruals during their first year open, while higher-scoring trials averaged 4.9 accruals. Of the trials that accrued, higher-scoring trials accrued their first patient faster (mean of 58.4 days) than lower-scoring (mean of 153.7 days). Among industry trials only, higher-scoring accrued their first patients within an average of 61.5 days compared to 182.7 days for lower-scoring, but their first-year total accrual averaged only slightly higher (3.2 versus 2.8 patients, respectively).

5. Lessons Learned and Future Directions

At MCWCC, we assign prioritization scores but do not make purposeful use of them in activation or accrual processes. Nevertheless, higher-scoring trials tend to open faster, which suggests staff recognize

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their importance. Higher-scoring trials accrue earlier and have higher accrual their first year than lower-scoring trials, even though the score is only partially based on accrual potential.

We are piloting a FastTrack process for select trials to reduce activation times. When we expand this process, we could use prioritization scores to choose which trials are able to take advantage. Also, we would like DOTs to make better use of the scoresheet as another tool for determining whether to pursue a trial and perhaps institute a minimum threshold score for activation.