

Protocol Prioritization Scores: Are They Predictive?

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Background

Cancer centers assign prioritization scores to new trials to assess each study's position and value in the overall trial portfolio. At the Medical College of Wisconsin Cancer Center (MCWCC), our scoresheet (Fig. 1) 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.

While we spend a lot of time generating these scores, we have not explored their accuracy as predictive indicators of trial success.

Goals

We wanted to better understand the relationship between prioritization scores and key trial metrics such as:

- Overall accrual
- Time to first patient enrolled
- Activation time

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 approval 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.

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Outcomes

Prioritization scores ranged from 3 to 21, with a median of 9 points. Lower-priority trials (scores <9, n=51) 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 tended to accrue their first patient faster (mean of 58.4 days) than lower-scoring trials (mean of 153.7 days; Fig. 2).

Overall, activation times did not differ between low- versus high-priority trials; however, this is confounded by sponsor type. Looking at industry trials alone, higher-priority trials (n=21) opened 23% faster than lower-priority (n=24), 245 versus 320 days, respectively (Fig. 3).

Figure 1. Prioritization Scoresheet

Evaluation Factor	Categories	Points	Earned
Funding Source/Sponsor	NIH-funded IIT/NCTN trial with MCW PI	6	
	Institutionally funded interventional IIT	5	
	Industry-funded IIT	3	
	NCTN or BMT CTN trial	2	
	Industry trial	1	
	External Institutional/Consortium Trial	1	
Clinical/Scientific Impact	Likely to be a breakthrough drug/treatment modality	4	
	Phase I first in class/FIH having potential impact across multiple tumor types/preclinical data support	3	
	Phase I-III trial with possible practice changing implications	2	
	Phase I-III trial with few practice changing implications	1	
	Post-marketing study	0	
Annual Accrual Potential	>10	4	
	5-10	2	
Competing Trials	No competing trials (same eligibility/similar mechanism) open or pending	1	
Academic Value	First/Last authorship	3	
	Middle authorship	1	
Local PI is junior investigator (<5 yrs out from fellowship)	Yes	1	
MCW Lab Correlates (Hypothesis-driven)	Yes	3	
Uniquely Addresses Underserved Populations in Catchment Area	Yes	3	
Alignment with MCWCC Strategic Goals (scored by Feasibility Committee)		0-3	
		Total:	

Irolled 5 Days

Lessons Learned and Future Directions

Individual trial metrics varied within the lower- and higher-scoring groups, so calling the prioritization scores "predictive" would perhaps be an overstatement. However, as a group, higher-scoring trials more consistently enrolled their first patients quickly and tended to accrue more patients overall. They also tended to open faster, which suggests staff recognized their importance.

With this information, we plan to encourage disease teams 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. We also hope to better integrate the scores into our activation process, to get higher-priority trials open more quickly.







