Category: Trial Start-up, Activation, Regulatory, and Protocol Development - Work in progress

Retrospective Validation Analysis of the PRMS Prioritization Scores and Initiatives to Enhance Score Methodology and Standardization

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1. Background

Many cancer centers have adopted a prioritization score method for evaluating clinical trial opportunities through the Protocol Review and Monitoring System (PRMS) two-stage process. Hollings Cancer Center (HCC) revised the scoring method in 2023 after completion of a lean six sigma project which compiled a list of most important clinical trial success factors from Clinical Trial Office (CTO) managers and clinical investigators. The 12-question prioritization form evaluates scientific merit and feasibility characteristics and scores a trial from 0=no impact to 100=highest impact. Between February 2023 to October 2023, 62 trials were activated and scored using the new prioritization method. The trials were ranked by prioritization score and grouped into four quartiles: Quartile 1 – (*lowest impact scores* 51.10 – 63.50) Quartile 2 (scores 63.65 – 68.40) Quartile 3 (scores 68.75-74.60) and Quartile 4- (*highest impact scores* 74.75-89.55). A retrospective review of start-up and accrual performance was completed comparing the trials within the four quartiles. Quartile 1 trials had the highest trial abandonment rate and zero accrual rate, while Quartile 4 trials had the shortest time to activation period, reported no abandoned trials, and met the predicted accrual rate at the time of the analysis. While the prioritization score demonstrated overall value in predicting future trial success, a sub-analysis showed significant variation in prioritization score range and accrual prediction accuracy across the twelve Disease Focus Groups (DFGs). Furthermore, prioritization scores of all-comer Phase I trials showed less predictive accuracy compared to other trials. There is a need to assess why DFGs had different ranges of prioritization scores.

2. Goals

Improve standardization of prioritization score methods among the DFGs.

3. Solutions and Methods

DFG team members were interviewed, and DFG meetings were observed. A new trial activation and DFG prioritization training was created and presented to CTO staff. A survey was administered to DFG and scientific committee members to assess methodology and interpretation of prioritization scores. Survey results are pending.

4. Outcomes

Stakeholder interviews and DFG meeting observations revealed variations in who completed the DFG form and the level of discussion of prioritization questions during DFG meetings. Some trials were scored prior to the meeting between the PI and clinical research manager, while other trials were scored during a DFG meeting with input from multiple DFG members. Interview findings revealed that members wanted to have more tumor registry data to improve accrual potential score accuracy. Some members also felt that Phase I all comer trials were unfairly scored for their trial complexity and high level of trial procedures and patient visits. High trial complexity may have less impact on accrual rates, when recruiting patients with fewer standard of care treatment options. Scientific committee members wanted to have more metrics of trial performance by DFG and investigators. The results of the survey are pending and will be resulted at the end of March. The survey results and prioritization score training

will be reviewed at the Spring PRMS retreat in May. New dashboard reports are in development to improve data driven decision-making.

5. Lessons Learned and Future Directions

Although a prioritization form can improve standardization in trial selection, the lack of training, historical data, and variation in form completion methods can decrease the reliability of scores to effectively predict trial success. Upon completion of the survey and discussion at the next retreat, an updated standard operation procedure will be created, and a new scoring method will be tested for complex phase I all-comer trials.