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Taking a Closer Look: Standardizing Disease Focus Groups to Strengthen Trial Portfolios

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1. Background

A portfolio of high-performance oncology studies begins with standardizing how disease focus groups (DFGs) select trials. Our 11 DFGs' methods to prioritize clinical trials were subjective and did not prompt the DFG leaders to evaluate trials per our center's mission and patient catchment. DFG leaders did not have appropriate knowledge of the CCSG priorities and did not have the available resources for proper trial selection decisions. Our prioritization form utilized a one-dimensional 5-point scale to report a high impact (1) to low impact (5) score. In FY 2018-2021, our site assessed 35 out of 93 trials, or 38 percent as a moderate to low impact score of 3. This score was not informative to the scientific protocol review committee (PRC) to assess scientific merit, clinical need, and feasibility. There was no correlation between the impact score and ability to meet time to activation and projected accrual goals.

2. Goals

1) Comparison of percentage of trials approved/disapproved by DFG
2) Of trials DFG approved for activation, the overall distribution of prioritization scores and outcome of scientific committee concurrence
3) Analysis of prioritization score and impact on time to activation

3. Solutions and Methods

1) In July 2021, center leadership met individually with each appointed DFG leader to review CCSG goals and outline specific DFG performance expectations; DFG leaders were provided with their patient population tumor registry data from January 2018 to February 2021 and historical trial performance over the last 3 years to improve patient catchment understanding
2) Monthly clinical investigation meetings to present performance metrics and a bi-annual DFG leadership retreat series in November 2021 for ongoing DFG leadership training and strategic planning
3) Created DFG intranet with real-time DFG performance report and a new trial portfolio diagram
4) In November 2021, completed a Six Sigma process improvement project with CTO staff and clinical investigators to determine the success factors for trial performance
5) In February 2022, revised the DFG prioritization form to evaluate the predicted trial success factors identified from the Six Sigma project, and re-engineered the trial start-up process to have multiple prioritization check points

4. Outcomes

Disease focus groups are more discriminatory in their trial selection process, as demonstrated by an increased abandonment rate of 5.75 trials per month in Fiscal Year (FY) 2021 compared to 9.4 trials per month in FY 2022 (up to March 11, 2022). To date, 4 trials have been submitted to the PRC utilizing the new prioritization form. The highest score of 83.1 points out of 100 assessed for a NIH-funded MUSC faculty treatment trial with a high accrual potential, but some financial feasibility concerns. The lowest score was 67.10 for a national screening trial for a small patient population.

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5. Lessons Learned and Future Directions

Identifying the patient population catchment groups within the trial portfolio diagram requires investigator time and ongoing reviews. Implementation of the new DFG form required significant communication for buy-in and training. This new prioritization score should create a predictive model of trial success and allow center leaders to implement new policies about prioritization score thresholds for DFG approval and improved utilization of cancer center resources.