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

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Background

The method to prioritize clinical trials among the eleven Disease Focus Groups (DFGs) was subjective and not consistently aligned with our center's strategic plan 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 DFG prioritization form assigned impact scores via a one-dimensional 5-point scale to report a high (1) impact to low (5) impact score. The score did not correlate to resource allocation levels for meeting time to activation or accrual goals. This score was not informative to the Protocol Review Committee (PRC) relay the value of the trial and predictive success of the trial. To address these issues, DFG leaders engaged in a Lean Six Sigma process improvement project to improve the trial prioritization process.

Method

Each appointed DFG leader reviewed CCSG goals and were outlined specific DFG performance expectations. DFG leaders were provided patient catchment and historical trial performance data and participated in monthly clinical investigations meetings and a bi-annual retreat to stay abreast of cancer center strategic plans. A lean six-sigma process improvement project was completed in November 2021

Fig 1. Revised DFG Prioritization Form

Is the recruitment/management of subjects considered multi-modality such that the accrual credit will be split equally among multidisciplinary providers? Yes, specify:

Describe the category placement of the trial within the priority diagram or attach a marked pdf of the priority diagram

Are there any other active or pending trials within the planned priority diagram space? No, there are no completing trials

If yes, please describe the enrollment strategy between these trials and justify why there should be more than one trial within this space.

Preferred Short Title for Priority Diagram:

How many patients do you anticipate to accrue in 12 months from activation? 5 patients in 12 months

How many months will HCC have available to accrue to the trial after activation? 36 months

The trial's projected *TOTAL* accrual is about 15 accruals over 36 months.

DFG Prioritization	Response
Academic Value	NCI Research Base (Alliance, SWOG, NRG, COG, ECOG-ACRIN, Wake) w MUSC design involvement
Clinical Need & Patient Benefit	One or two standard of care options, moderate benefit to patients
Innovation & Scientific Impact	High value pivotal question that could transform cancer care
Value to HCC's CCSG Accrual Goals	Interventional Treatment
HCC Research Program	Any NCI Research Base sponsored trial (Supports NCORP-MU grant)
Accrual Duration Projection	Greater than 24 months
Annual Accrual Projection	more than 5 treatment accruals per year
	DFG Score (0-50) 38.45

Complete this section after the operational and financial feasibility has been assessed.

Feasibility	Response
Complexity on Patient	Simple for patient visit schedule/procedures. Mirrors SOC
Complexity on Study Team	Simple start-up and study conduct
Patient Screening Complexity	Step 1 only - Simple
Level of Competing Trials*	A trial is currently in the space, but cohort slots are not always available
Financial Feasibility	Less than $5,000 in procedures or services will be unfunded in first year
	Feasibility Score (0-50) 40.60
	Total Score (0-100) 79.05

* A copy of the current priority diagram with the marked placement of where this trial will fit must be provided within the PRC Submission

Comments:

By signing below, I am attesting that the trial was discussed among the DFG and there was concurrence of the information above.

November 2021 that identified key clinical trial success predictors related to scientific merit and feasibility. These predictors were weighted and incorporated into an enhanced DFG Prioritization Form (Fig. 1) that was released for pilot use in March 2022.

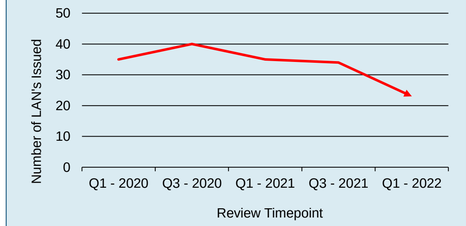
The new form prioritizes trials based on 2 scores: a DFG scientific merit score between 0-50 based on accrual potential, portfolio fit, clinical need, research interest, and institutional value, then an operational and financial feasibility score between 0-50. The final score is the summation of both components. There was no score threshold set for DFG disapproval. The primary aim of the form revision was to improve the decision process for trial selection by DFG and improve communication between DFG and PRC of trial portfolio decisions.

Results

Since these initiatives, DFG leaders and clinical investigators are more discriminatory in their trial selection process, as demonstrated by an increased abandonment rate of 5.75 trials per month in FY21 compared to 8.3 trials per month in FY22 (up to 5/16/22). To date, eight trials have been submitted to the PRC utilizing the new prioritization. The highest score of 85.95 points out of 100 assessed for a NIH funded treatment trial with a high accrual potential, but some financial feasibility concerns. The lowest score was 57.55 for an industry sponsored, high complexity trial with moderate accrual.

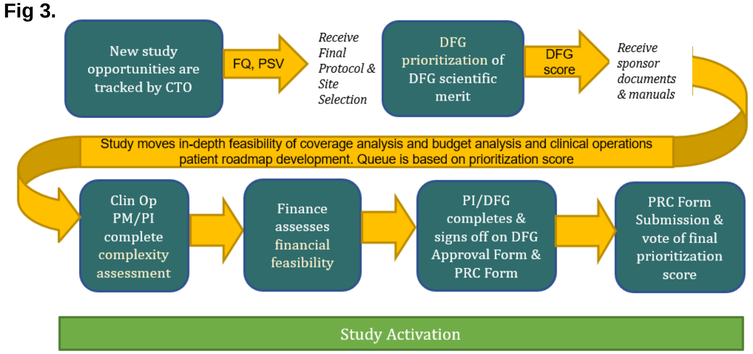
As DFGs became more mindful of trial portfolio performance, the number of PRC issued Low Accrual Notices (LANs) in Q4-2021 decreased (Fig. 2), suggesting by better educating our DFGs and requiring low accruing trials be reviewed monthly, more trials are meeting ≥50% of their accrual goals.

Fig 2. Count of Low Accrual Notices (LANs) by PRC Accrual Review Timepoints



The DFG scientific score is being used by the Clinical Trials Office (CTO) Program Managers (PM) to more objectively assign trials to staff resources. High scoring trials are prioritized first in the queue for feasibility review and coverage analysis. Once feasibility is assessed and scored, the final DFG score is utilized by CTO PMS to assign highest scores to earlier PRC and IRB meeting dates. The modified activation process which includes the points in which the DFG prioritization score is utilized is depicted in Figure 3.

Fig 3.



Conclusion and Future Plans

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. DFGs are more discerning about trials and trial selection decisions are better communicated to PRC/CTO. 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.