Category: Resource Management and Finance – Completed project

Building and Implementing a Tool to Facilitate Program-Level Portfolio Assessment: Clinical Research Optimization Project (CROP)

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1. Background
Accrual performance and trial portfolio management are key metrics for NCI-Designated Cancer Centers. Research Program Directors (RPD) do not readily have access to aggregate data comprising enrollment performance, scientific impact, and financial sustainability of their trial portfolios. We sought a mechanism to facilitate routine portfolio analysis, with a goal of limiting resource utilization for activities that do not serve our patients, faculty, and teams.

2. Goals
Our goal was to develop tools to facilitate comprehensive evaluation of portfolio performance.

3. Solutions and Methods
To facilitate Research Program (RP) self-evaluation, we initiated the Clinical Research Optimization Project (CROP). We developed a dashboard of each RP's trial portfolio, summarizing all trials that are active or in start-up. Data includes time the trial has been open; planned and actual accruals; summary demographics of enrolled patients and of the catchment area for the disease studied; current financial balance and expected revenue; retrieved from our financial and clinical trial management systems. For trials in start-up, activation status is included (on track vs. delayed). These data give visibility to real-time trial performance in the context of the RP's entire portfolio.

CROP portfolio dashboards are provided to RPs semi-annually. RPs assign a scientific impact score for each trial, using a rubric that includes potential effect on clinical practice, our center's reputation, and scholarly impact. Scientific impact score is combined with accrual and financial data to result in a final score. Final scores are stratified into one of three categories: green (performing well), yellow (performing satisfactorily), or red (underperforming).

Each trial is assigned a final determination by the RPD and team. For active trials, the options are to continue, close to enrollment, or terminate; for trials in start-up, the options are to continue or halt activation. Mandatory action is not dictated.

4. Outcomes
Since implementation in 2020, CROP has resulted in closure to enrollment of 48 underperforming trials. Additionally, 65 trials in start-up were discontinued prior to activation. By discontinuing trials that no longer support institutional and scientific priorities, teams are able to focus their resources on more impactful activities.

Because of the CROP tool, reevaluation of programmatic priorities is now routine at the OHSU Knight Cancer Institute. RPs can systematically assess underperforming trials and take mitigation steps or close the trial before the Scientific Progress Evaluation (SPE) Committee review. As such, CROP and SPE are designed to work together to optimize portfolio management.

5. Lessons Learned and Future Directions

CROP is an excellent tool to identify trials that should be closed to enrollment. RPs often want to fully close (i.e., end IRB oversight for) trials that have no further patient or data activity at our site, but sponsors' willingness to close the trial follows sponsor timelines, irrespective of our site readiness and desire to free up resources. This remains an area of opportunity.

Future directions may include use of CROP scores to inform prioritization for trial activation. Scientific impact score is assigned at the program level and can be subjective. Thus, cross-program comparisons are not accurate. Implementing a cancer institute-wide prioritization schema would require standardized criteria for a more objective scientific impact score.