Clinical Research Optimization Project (CROP): building and implementing a tool to facilitate program- level portfolio assessment

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Background:
Accrual performance and trial portfolio management are key metrics for NCI-Designated Cancer Centers. 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.

Goals:
- Develop tools to provide Disease Site Groups (DSG) aggregate data comprising enrollment performance, scientific impact and financial sustainability of their trial portfolios.
- Facilitate regular and comprehensive evaluation of portfolio performance.

Solutions and Methods:
- We developed a dashboard of each DSG portfolio. The dashboards give visibility to real- time trial performance in the context of the DSG's entire portfolio. At right is a subset of the dashboard data. Dashboards for active trials include time the trial has been open, planned and actual accruals, and current financial balance and expected revenue.
- CROP portfolio dashboards are provided to DSGs semi-annually. In parallel, DSGs receive summary demographics of previously enrolled patients and of the catchment area for the disease studied.
- DSGs assign a scientific impact score (SIS) for each trial, using a rubric that includes potential effect on clinical practice, our center's reputation, and scholarly impact.

Scientific Impact Score (SIS) Criteria: +1 for any of the following

- Study has potential to change clinical practice
- OHSU investigator anticipates authorship
- Study attracts patients to KCI – increases market share
- OHSU investigator is lead PI or participates in a writing team
- Study involves OHSU-based science
- Study collaborates with other groups within or outside the KCI

Outcomes:
- To date, the CROP review cycle has been completed 8 times over 4 years.
- 48 underperforming trials have been closed to enrollment, representing 0.9- 6.6% of the active trials at the time of review.
- 65 trials were discontinued prior to activation, representing 2.7-14.8% of trials in start-up at the time of review.
- Reevaluation of programmatic priorities is a routine, semi-annual process at KCI.
- DSGs can systematically assess underperforming trials and take mitigation steps or close the trial before the Scientific Progress Evaluation (SPE) committee review. CROP and SPE are designed to work together to optimize portfolio management.
- By halting trials that no longer support KCI priorities, teams can focus their resources on more impactful activities.

Scoring

- SIS is combined with accrual and financial data to result in a final score which indicates overall performance.

Start-up Trial Dashboard

CTMS		Finance System	Research Team	Calculated	Research Team
Activation on target	Enrollment Potential	Finance	SIS	Final Score	Action
0	1	0	2	3	Halt Activation
1	1	1	3	5	Continue
1	0	1	5	7	Continue
1	1	1	2	4	Continue

Final Score Calculation:

Start-up: average of Enrollment and Activation scores + Finance score + SIS

Active Trials: average of Enrollment scores + Finance score + SIS

Active Trial Dashboard

Source	Enrollment Perfomance via CTMS			Finance System	Research Team	Calculated	Research Team
Study Status	Past 6 months	Past 12 months	Currently active	Finance	SIS	Final Score	Action
Enrolling	-1	1	1	0	4	4	Continue
Enrolling	-1	-1	0	-1	0	-1	Close
Closed	0	0	1	-1	0	-1	Terminate
Enrolling	-1	-1	0	-1	1	-1	Continue
Enrolling	-1	-1	1	0	4	4	Continue
Closed	0	-1	1	-1	0	0	Terminate
Enrolling	-1	-1	0	-1	1	0	Close
Enrolling	1	1	1	-1	4	5	Continue
Closed	-1	-1	0	1	2	2	Terminate
Closed	0	0	1	1	4	5	Continue
Enrolling	1	1	1	-1	2	2	Continue
Closed	0	0	1	-1	3	2	Continue
Closed	0	0	1	-1	3	2	Continue
Enrolling	1	1	1	-1	5	5	Continue
Enrolling	1	1	1	1	5	7	Continue

- Using the CROP dashboard and final score to aid their assessment, the DSG indicates their action plan for the next 6 months.
- CROP is a tool to facilitate assessment; final scores do not indicate a specific or mandatory action.

Lessons Learned and Future Direction:
- CROP is an excellent tool to identify trials that should be closed to enrollment.
- Sponsors' willingness to fully close a trial is often irrespective of our site readiness and desire to free up resources.
- Scientific impact score is assigned at the program level and can be subjective.
- Potential future expansion may include use of CROP scores to inform prioritization for trial activation.