



Implementation of a Feasibility Committee in the Mayo Clinic Comprehensive Cancer Center

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OBJECTIVES

The Feasibility Committee (FC) was implemented in Q4 2022 to provide oversight over the 3 site Mayo Clinic Comprehensive Cancer Center's portfolio to assess resource, operational, and financial viability of clinical trial development and conduct as part of the Clinical Protocol and Data Management (CPDM) and Protocol Review and Monitoring System (PRMS). Committee review precedes the Protocol Review and Monitoring Committee (PRMC) to ensure that any impediments are identified and addressed prior to the National Cancer Institute (NCI) activation time clock.

METHODS

The feasibility committee is part of stage 1 review of the Protocol Review and Monitoring System (PRMS) that captures basic information about the study. The study is then brought to respective Disease Groups (DGs) for concept review, funding, accrual estimates, site involvement, community outreach and engagement, and inclusive research. The DG scores the trial based on scientific merit, competing trials, and ability to accrue. If the study is approved, a notification goes to the Prep Team, which collects all study documents.

The Central Prep Team completion places the study on the FC agenda within 7 days and automatically triggers a request for operational reviews by key stakeholders Biospecimens Accessioning and Processing (BAP), Systemic Therapy (Pharmacy), Radiology, Staffing (Development and Conduct leadership), and Therapeutic ionizing radiation (as needed).

METHODS CONT.

During operational reviews, stakeholders may initiate a "hard stop" resulting in an automatic deferral for the study. These hard stops have been related to significant per patient costs budget gaps, inability to meet study test schedule requirements, or BAP processing requirements that cannot be met.

At the committee meeting, the score (0-5) for each operational review categories and the DG scorecard score are weighted to provide a total score. If the score is above the passing threshold, the study is assigned for development or into a pending development queue (for prioritization/staffing).

If the study does not meet the scoring threshold, a minute item is sent to the DG and Primary Investigators (PI). Common concerns are related to insufficient budgets, inability to process samples, or overall logistical concerns. Once the concerns are satisfactorily addressed at FC, the study is assigned for development.

GOALS

- 100% review of all interventional treatment trials
- Capacity management for protocol development
- Decrease study activation timelines

OUTCOMES

Decompression of the number of trials awaiting development as disease groups are now putting the best trials forward and helped decrease the number of days for activation.

CONCLUSIONS

- Operational readiness/feasibility is essential for managing development pipeline and fostering accountability.
- Activation timelines benefit from identifying operational risks before investing time in development process (reduced drops, etc.)

LESSON LEARNED AND FUTURE DIRECTIONS

1. FC has helped decrease the median number of days from PRMS submission to activation by identifying and addressing barriers to clinical trials up front. Study teams and ancillary support groups (e.g., radiology) have appreciated the ability and place to bring forward potential challenges with studies.
2. Future directions include continued refinement of committee processes, moving add on sites into the electronic PRMS system, and continued collaboration with our Primary Investigators and disease groups.

TABLE 1: CHANGE IN ACTIVATION TIMELINE

Sponsor type	# of studies reviewed	Median days from PRMS Submission to activation	Median days prior to FC	% Change
Year				
NCTN	17	43	118	-36%
ITT	7	135.5	210	-65%
Industry	33	105.5	206	-51%

TABLE 2: INTERVENTIONAL PRMC SUBMISSION TO OPEN DAYS BY OPEN TO ENROLLMENT YEAR

