

Creation of the Performance Monitoring Committee: Optimizing Review of the MSK Clinical Research Portfolio

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1. Background

Memorial Sloan Kettering's (MSK) Protocol Review and Monitoring System (PRMS) provides rigorous internal oversight of our scientific portfolio in accordance with Cancer Center Support Grant (CCSG) guidelines. Historically, our Research Council (RC) conducted PRMS second stage and performance monitoring reviews. To optimize the management of our expanding portfolio, the Performance Monitoring Committee (PMC) was created as a PRMS sub-committee in 2021.

2. Goals

- Create PRMS sub-committee to oversee performance monitoring
- Streamline institutional performance monitoring process

3. Solutions and Methods

- Created the PMC and transferred performance monitoring oversight from RC:
 - Ensured multidisciplinary membership (PRMS/institutional leadership and department/service representatives)
 - Provided multi-session training for members on CCSG guidelines and review process/tools
 - Defined mission/scope: *To monitor MSK's research portfolio, appropriately identify underperforming studies, and terminate studies that do not demonstrate scientific progress or potential for completion*
- Enhanced performance monitoring processes:
 - Expanded existing underperforming definition (estimated time to completion \geq five years) to include studies with zero accruals in the last 12 months and/or open for accrual \geq five years
 - Improved principal investigator (PI) submission template to capture information PMC needs to assess potential for completion and facilitate goal setting (accruals/progress, importance, goals)
 - Increased transparency with presentations, announcements, and trainings
 - Created and circulated department/service metrics to facilitate portfolio management decisions; metrics included past monitoring summary and distribution of protocols:
 - In activation
 - Open to accrual
 - Closed to accrual
 - Underperforming
- Created and implemented PMC review tools:
 - Performance Monitoring Tableau dashboard:
 - Real-time visual of portfolio's performance (by department/service/PI) available to PMC reviewers and clinical research leadership
 - Leverages data from multiple systems and visualizes comprehensive metrics including protocol lifespan and accrual rates

Category: Regulatory - Completed Project

- Decision tree
 - Facilitates PMC decision-making using a point system to quantify likelihood of study completion
- Leveraged home-grown Protocol Information Management System (PIMS) functionality:
 - Algorithm to identify underperforming studies
 - System-generated notifications to PIs/study teams
 - Electronic PI submissions and PMC reviews (including structured review form, meeting agendas, minutes, and review letters)
 - PMC review letters and/or closure recommendations drafted in/sent from system. Stored for future reference by PMC and other institutional committees (e.g., IRB, DSMC)
 - Submission and review “user work” for tracking protocols
 - Reporting features and Tableau integration
- Implemented accrual reminders for studies with zero accruals in six months

4. Outcomes

- Increased transparency with investigators fosters the shared institutional mission to close underperforming studies and reallocate resources towards trials with greatest scientific importance and likelihood of completion
- Expansion of underperforming criteria doubled the number of underperforming trials identified and broadened PMC’s oversight
- PMC reviews resulted in a 230 percent increase in study closures in 2021-2022; this was vital due to increased number of protocols and decreased resources/staffing during and after the COVID-19 pandemic
- Implementation of the 0-accrual in 12 months metric was successful as these studies accounted for 43 percent of 2022 closures

5. Lessons Learned and Future Directions

- Implement continuous review process for studies with 0 accruals in 12 months
- Create SOPs
- Expand membership expertise
- Customize monitoring for rare disease, pediatric, and National Group studies
- Explore options to “stop the clock” for planned holds/amendments

Figure

