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 > five years) to include studies with zero accruals in the last 12 months and/or open for accrual > 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
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- 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
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Figure

Performance Monitoring responsibilities transferred from the Office of the Physician-in-Chief to the PRG.

Underperforming studies are flagged using “Estimated time to completion of 5 years” criterion with special considerations given to rare, Pediatric, and RCI studies.

RC reviewers conduct performance monitoring reviews.

Formal performance monitoring SOP is implemented.

An additional underperforming criterion is added (open to accrual for >5 years).

2013

Pi structured response template is implemented to facilitate performance monitoring reviews.

Performance Monitoring responsibilities are transferred to RC Chairs who make up a newly formed “RC Executive Committee.”

An additional underperforming criterion is added (10 accruals in 2 years).

2015

2016

2017

2020

2021

PMC is created and performance monitoring responsibilities transferred from RC to PMC.

An additional underperforming criterion is added (8 accruals in 13 months).

Pi response template is updated, and review tools (dashboards, decision trees) are leveraged.