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

Memorial Sloan Kettering Cancer Center

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Background

- Memorial Sloan Kettering's (MSK) Protocol Review and Monitoring System (PRMS) provides rigorous internal oversight of the clinical research portfolio in accordance with Cancer Center Support Grant (CCSG) guidelines.
- Historically, the Research Council (RC) conducted PRMS second stage and performance monitoring reviews.
- To optimize the management of our expanding scientific portfolio (>2,000 prospective trials), a separate committee and streamlined processes were needed.

Goals

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

Methods

Created the Performance Monitoring Committee (PMC) as a sub-committee of our PRMS and delegated performance monitoring oversight to PMC in 2021:

- Multidisciplinary membership (PRMS/institutional leadership and department/service representatives).
- Members received multi-session training 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 high potential for completion.***

Expanded underperforming definition and enhanced performance monitoring processes:

- Expanded existing underperforming definition **(Estimated Time to Completion ≥5 years)** to include studies with **0 accruals in the last 12 months** and/or **Open for Accrual ≥5 years.**
- Improved **Principal Investigator (PI) submission template** (Figure 1) to facilitate goal setting.
- Created and circulated department/service metrics to facilitate portfolio management decisions.
- Increased transparency with institutional presentations, announcements, and trainings.

Created and implemented PMC review tools:

- **Performance Monitoring Tableau Dashboard** (Figure 2): Visual of portfolio's real-time 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.
- **PMC Reviewer Decision Tree** (Figure 3): Facilitates PMC decision-making using a point system to quantify likelihood of study completion.

Leveraged home-grown Protocol Information Management System (PIMS) functionality:

- Modified existing system to separate PMC as a sub-committee.
- Built search **algorithm** to identify underperforming studies.
- System-generated notifications to PIs/study teams.
- Electronic PI submissions and PMC reviews.
- **Reporting** features and **Tableau** integration.

Implemented monthly monitoring:

- Accrual reminders for studies with **0 accruals in previous 6 months**; no response required.
- Started in March 2023.

Figure 1: Performance Monitoring Form

1. **Protocol Key Characteristics:** (check all that apply)

	MSK Sponsored (i.e. MSK IIT)		Federally Funded (e.g., NIH, SPORE)
	Externally Sponsored		Rare Disease/Target, please explain:
	Multicenter (IIT or external)		Other, please explain:
	MSK Lead Site		

2. **Potential for Completion:** (check all that apply)

	Closing to accrual within 6 months (if selected, no additional information is required)
	OR
	Global accrual is on target
	MSK accrual rate is improving (e.g., active accrual in last 6 months)
	No competing studies and/or competing studies recently closed
	Accrual pause is expected and timeline for reopening is available
	Major amendment is planned to activate within 6 months
	Interim results from this study have been reported or published (provide reference[s])
	Other, please explain:

Provide an explanation based on the selection(s) above:

3. **Protocol Performance:**

a. **Accrual Summary:**

MSK Accrual To Date	MSK Target Accrual	Global Accrual To Date (if applicable)	Global Target Accrual (if applicable)

b. **Importance to PI:** (check all that apply)

	Leadership (Global/National PI, Steering Committee Member, Lead Site, etc.)
	Guaranteed Publication/Authorship
	Other, please explain (e.g., correlative analysis, MSK science, etc.):

c. **Please answer the following:**
   i. How does this study continue to align with MSK's patients' needs?
   ii. How does this study complement the portfolio offered to this population (comment on competing studies and prioritization)?
   iii. Provide justification for keeping this study open (e.g., scientific merit, results to date, future plans, etc.) and/or additional information that may impact the review of your study for accrual performance.

4. **Corrective Action Plan:**

Projected MSK Patient Accrual by the Next Performance Review (~6 mos)	

Please provide a plan for improving accrual within the next 6 months if this study is to remain open.

Figure 2: Performance Monitoring Tableau Dashboard

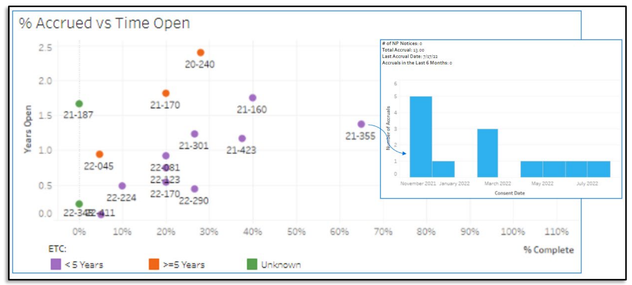
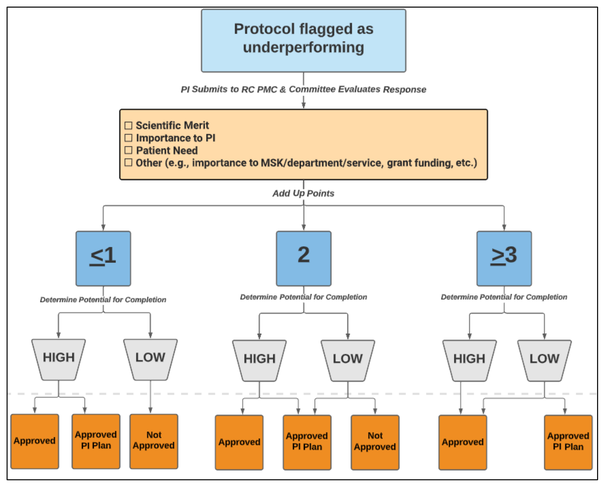


Figure 3: Reviewer Decision Tree



Outcomes

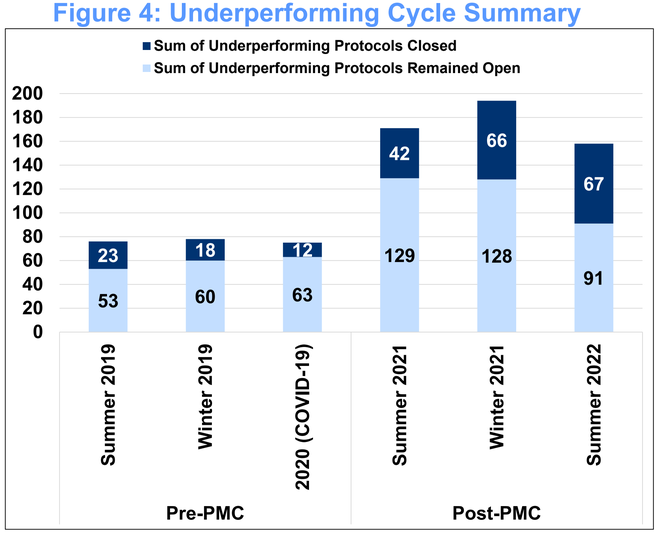
Creation of the PMC and expansion of the underperforming criteria doubled the number of underperforming trials identified. This broadened PMC's oversight and average per-cycle reviews from 76 pre-PMC to 174 post-PMC (Figure 4).

Multidisciplinary PMC membership and increased transparency fosters the shared institutional mission to close underperforming studies and reallocate resources towards trials with the greatest scientific importance and likelihood of completion.

PMC reviews resulted in a 230% increase in study closures (Figure 4) with 175 in 2021-2022 vs. 53 in 2019-2020. This was vital due to increased number of protocols and decreased resources/staffing during and after the COVID-19 pandemic.

Implementation of the 0 accruals in 12 months metric was successful as these studies accounted for 43% of 2022 closures.

Figure 4: Underperforming Cycle Summary



Future Directions

- Assess effectiveness of monthly accrual reminders for studies with 0 accruals in previous 6 months.
- Expand monthly monitoring to include continual monitoring and formal reviews for studies with 0 accruals in 12 months.
- Revise Standard Operating Procedures and incorporate customized monitoring for rare disease, Pediatric, and NCI National Group studies.
- Explore options to "stop the clock" for planned holds and amendments.