

Background

- The Performance Monitoring Committee (PMC) was established as a Protocol Review and Monitoring System sub-committee in 2021 as part of broader efforts to enhance performance monitoring at Memorial Sloan Kettering (MSK).
- As part of this overhaul, underperforming criteria were reassessed. In 2022, a pilot review of studies with zero accruals for over 12 months was conducted within the previous bi-annual review process.
- The pilot accounted for 43% of 2022 underperforming study closures, underscoring the value of formally incorporating zero-accrual monitoring into PMC criteria.
- The pilot also highlighted the need for more frequent, real-time oversight as the bi-annual process prolonged intervention for non-accruing studies.

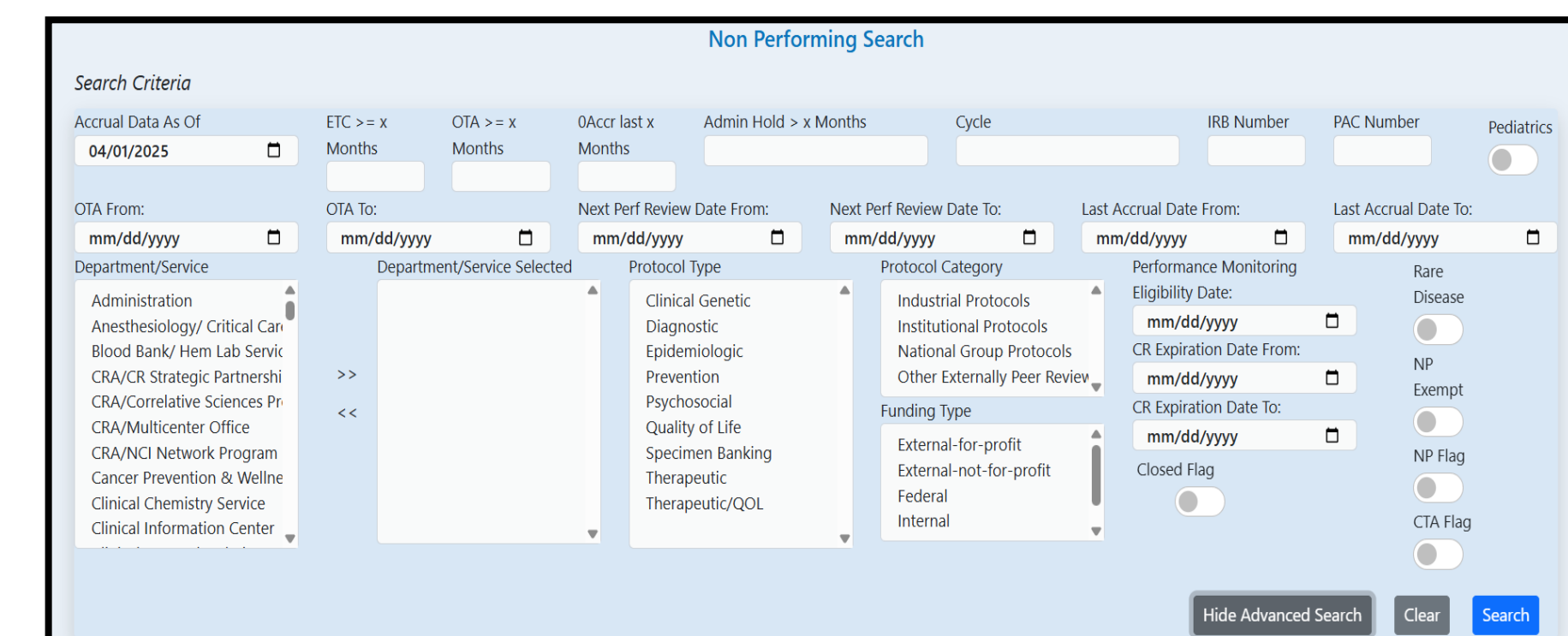
Goals

Implement a “continual monitoring” workflow for studies with zero accruals beyond six months to complement existing workflows, strengthen portfolio management, and increase investigator engagement.

Methods

- Initiated continual monitoring in March 2023 with reminders, followed by notifications in September 2023.
- Leveraged search algorithm in MSK’s home-grown Protocol Information Management System (PIMS) to identify studies with zero accruals (Figure 1).

Figure 1: PMC Search



- Operationalized automated emails to Principal Investigators (PIs) and study teams via PIMS at the following timepoints:

6-Month Zero
Accrual
Reminder

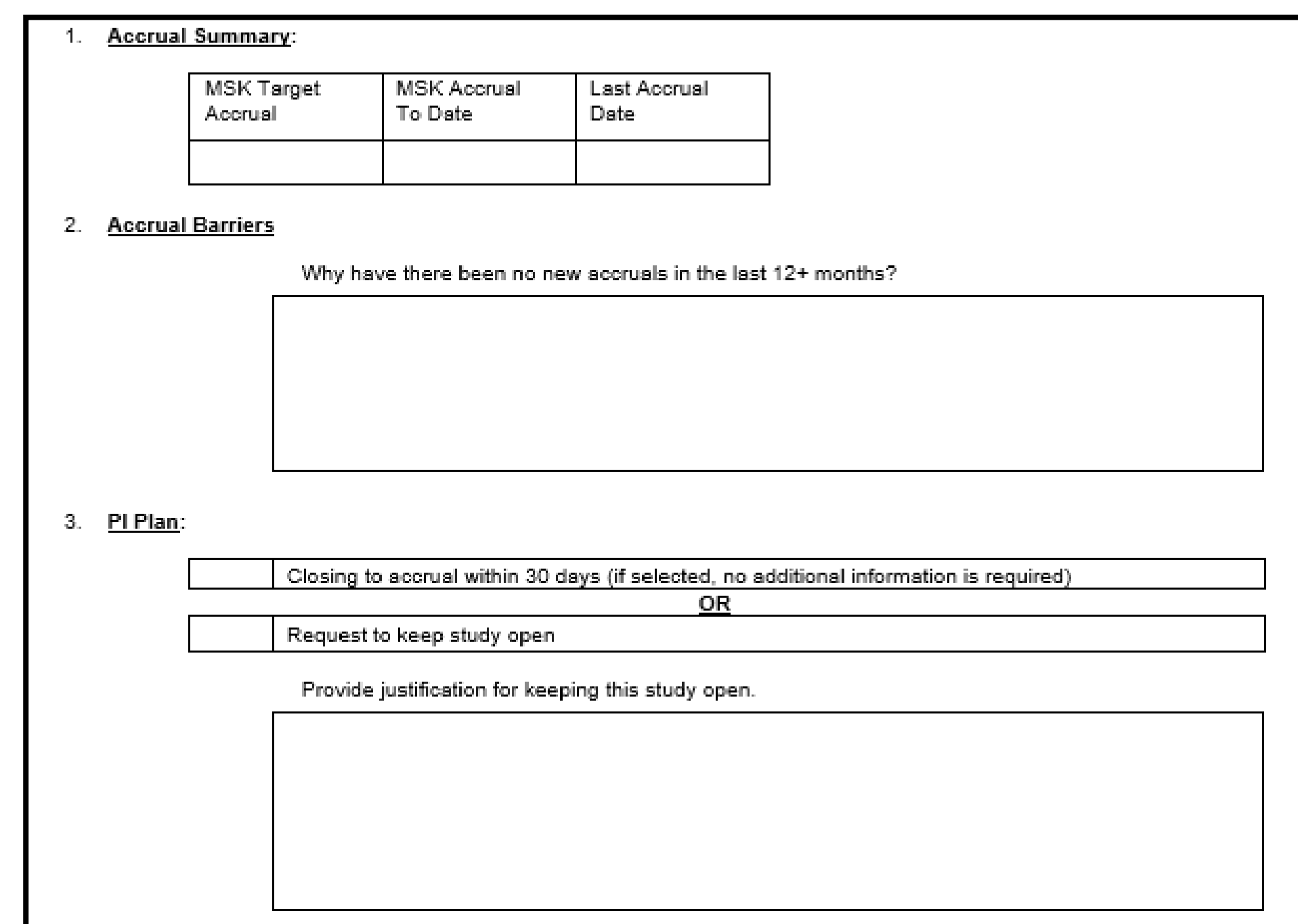
- Encourage proactive steps to either improve accrual (e.g., prioritization, site expansion, amendments, sponsor engagement) or consider study closure.
- No response is required.

12-Month
Zero Accrual
Notification

- A formal closure request is issued, with the option to appeal via a standardized form within one week (Figure 2).
- Appeal must explain accrual barriers and justify continuation.

- Defined exemptions from performance monitoring for specific study types such as epidemiologic, registry, expanded access, federally funded, rare disease, NCI-sponsored, and pediatric studies.
- Implemented a structured monthly review and decision process:
 - Reviewers evaluate appeals based on scientific merit, feasibility, institutional priority, and the study’s overall potential for completion.
 - Final decisions are made via formal voting at PMC meetings.

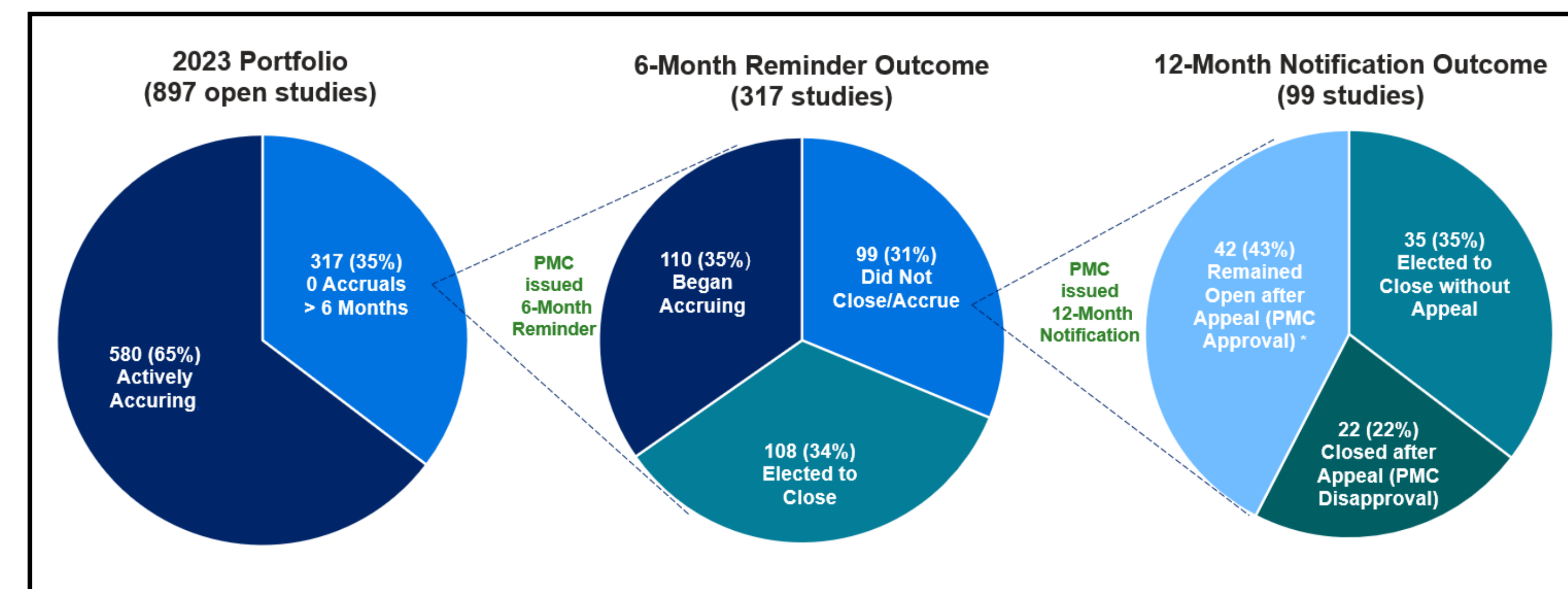
Figure 2: Zero Accruals Closure Appeal Form



Outcomes

- Enhanced portfolio oversight and resource efficiency:**
 - Continual monitoring enabled timely study closures, improved transparency, and streamlined portfolio management.
- In the first year of continual monitoring (March 2023-2024), approximately one-third of MSK’s open portfolio was under PMC continual monitoring oversight (Figure 3).**
 - 52% of studies receiving six-month reminders (165/317) eventually closed, demonstrating the effectiveness of early intervention and the need for portfolio clean-up.
 - High closure volume in year one reflects a backlog of non-accruing studies under the prior, less frequent review process, reinforcing the value of continual oversight.
- Stronger collaboration with PIs/departments/services:**
 - Reminders prompted action without requiring a response, functioning as a proactive service rather than a punitive measure.
 - Early engagement drove results: 35% of studies began accruing after PMC issued 6-month reminder, showing how structured oversight improves PI responsiveness.
- More efficient decision-making and workload management:**
 - Replacing bulk bi-annual reviews with monthly monitoring reduced the administrative burden and facilitated the process for stakeholders.
 - Real-time data enabled immediate action, eliminating delays and backlog.

Figure 3: Significant First Year Impact



* Studies approved for continuation after 12-month notification that have 0 accruals at 18-month timepoint or beyond can restart the process with warning OR 18-month notification.

Lessons Learned

- Transparency and collaboration enabled PI-led accruals and closures.

Future Directions

- Develop a dashboard for tracking and reporting.
- Integrate PMC data into new protocol activation and study prioritization.
- Expand workflow to include 18-month follow-up and restart the continual monitoring clock for major amendments.