Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Zero Accruals, Zero Delays: A Monthly Performance Monitoring Approach

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1. 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, and 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 percent 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.

2. 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.

3. Solutions and Methods

- Initiated continual monitoring in March 2023.
- Leveraged MSK's home-grown Protocol Information Management System (PIMS) to identify studies with zero accruals.
- Automated emails to Principal Investigators (PIs) and study teams via PIMS:
    - Six-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 required.
    - Twelve-Month Zero Accrual Notification: Formal closure request issued with option to appeal via a standardized form within one week. Appeal must explain accrual barriers and justification for continuation.
- Defined monitoring exemptions (e.g., epidemiologic, registry, expanded access, federally funded, rare disease, NCI-sponsored, pediatric studies).
- Implemented 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.

4. Outcomes

- Enhanced portfolio oversight and resource efficiency:
    - Continual monitoring enabled timely study closures, improved transparency, and streamlined portfolio management.
- 317 studies (one-third of open studies) received six-month zero accrual reminders March 2023-March 2024. Post-reminder outcomes:
    - 108 (34%) elected to close
    - 110 (35%) began accruing
    - 99 (31%) did not close/accrue and received 12-month zero accrual notifications:

        - 35 elected to close without appeal
        - 22 closed after appeal (PMC disapproval)
        - 42 remained open after appeal (PMC approval)
    - 52 percent of studies receiving six-month reminders (165/317) closed, demonstrating the effectiveness of early intervention and the need for portfolio clean-up. The high closure volume in year one reflects a backlog of non-accruing studies under the prior, less frequent review process.
- 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 percent of studies accrued post-reminder, showing structured oversight improves PI responsiveness.
- More efficient decision-making and workload management:
    - Replacing bulk bi-annual reviews with monthly monitoring reduced administrative burden and facilitated the process for stakeholders.
    - Real-time data enabled immediate action, eliminating delays and backlog.

5. Lessons Learned and Future Directions

Lessons Learned:

- Transparency and collaboration enabled PI-led accrual 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 continual monitoring clock for major amendments.

Figure