Comparison of Protocol Review and Monitoring System (PRMS) Operations at a Standalone Versus a Matrixed Cancer Center

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BACKGROUND

- The National Cancer Act of 1971 formalized the National Cancer Institute (NCI) as an operating division within the National Institutes of Health.
- This paved the way for the current 72 NCI-Designated Cancer Centers across the U.S, who earn and maintain designation by meeting requirements for the NCI P30 Cancer Center Support Grant (CCSG).
- Among the first to receive this designation were Memorial Sloan Kettering Cancer Center (MSK) in 1971 and Mayo Clinic Comprehensive Cancer Center (MCCCC) in 1973.
- To maintain this designation, each center must assure rigorous scientific oversight of all cancer clinical trials via a structured Protocol Review and Monitoring System (PRMS), a core component of CCSG guidelines since 2014.
- While MSK operates as a standalone center and MCCCC functions as a matrixed center within the Mayo Clinic, both centers maintain structured PRMS workflows.

GOALS

To compare PRMS operations and CCSG guideline interpretations between MSK and MCCCC, identifying operational similarities, differences, and opportunities for collaboration to enhance PRMS effectiveness.

METHODS

- PRMS staff from both centers formed a working group.
- Weekly meetings and a shared document facilitated detailed workflow comparison.
- Initial discussions consisted of comparing institutional structures (standalone versus matrixed).
- Comparisons were structured using core PRMS focus areas identified by the group:
    1. Organization and Support Structure
    2. Prioritization
    3. Stage 1 Review
    4. Stage 2 Review
    5. Performance Monitoring
    6. Technology Leveraged

FIGURE 1. PRMS COMPARISON

	Mayo Clinic Comprehensive Cancer Center	Memorial Sloan Kettering Cancer Center
Org. & Support	• Matrixed Cancer Center within broader cancer & non-cancer institution • PRMS Team oversees Stage 1 • Regulatory committees ancillary to PRMS • IRB reviews cancer & non-cancer protocols	• Organization & leadership structure • Review & portfolio volumes • PRMS Team manages Stage 2 review	• Standalone Cancer Center • PRMS Team manages Stage 1 • Regulatory committees included within PRMS • IRB reviews cancer protocols
Prioritization	• During Stage 1: disease portfolio considered • Reprioritization at Stage 2: full portfolio considered	• Scoring systems leveraged	• Prior to Stage 1: Assigned by dept/service leadership
Stage 1	• Disease groups that cross departments • Centralized Feasibility Committee	• Rely on disease experts	• Discipline/modality-specific departments • Decentralized feasibility committees
Stage 2	• Membership includes Citizen Scientist • Quorum required	• Membership composition, meeting cadence & structure • Scientific review process & requirements • Formal voting • Abstentions applicable for COIs	• Membership includes MSK employees only • No quorum requirements
Monitoring	• Manual PI notifications & data entry/tracking • One monitoring track: Continual • PRMS Chair & Stage 2 chairs conduct reviews	• Augmented reporting for identifying trials • Review focus: Accrual progress, new safety information, scientific relevance	• System generated PI notifications & data entry/tracking • Two monitoring tracks: Annual & Continual • Formal subcommittee conducts reviews
Tech	• Multiple systems between cancer & non-cancer	• Leverage digital tools to ensure PRMS efficiency	• Single integrated system

OUTCOMES

The working group created a network between the centers, fostering ongoing collaboration and strategic alignment in PRMS operations. We facilitated knowledge sharing by discussing workflows related to CCSG guideline interpretation and generated a comparative table (**Figure 1**) across the focus areas resulting in shared insights:

- Differences in reporting and organizational structures reflect the inherent differences between matrixed and standalone centers.
- Both rely on disease experts to prioritize trials to manage portfolio volume and drive activation timelines.
- CCSG guidelines indicate Stage 1 should be disease or discipline specific, providing flexibility. MSK's discipline-focused approach contrasts with MCCCC's disease-specific model. Each model aligns with each center's organizational structure.
- CCSG guidelines outline specific Stage 2 requirements, therefore both have similar Stage 2 review structure with minimal variation.
- CCSG guidelines require continuous monitoring of open studies for accrual progress, new safety information, and scientific relevance. Both leverage accrual data to identify underperforming trials with each employing a nuanced approach to adapt to differing operational contexts.
- MSK and MCCCC leverage digital tools to ensure PRMS efficiency.

FUTURE DIRECTIONS

- Conduct in-depth performance monitoring analysis and share ideas for process improvements and efficiencies.
- Engage PRMS leadership to foster a collaborative network.
- Develop shared educational resources to improve PRMS functions at both centers.
- Collaborate on technological advancements for data optimization, visualization, reporting, and overall process automation.