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

Building a Scalable DSMC Program for a Dynamic Research Enterprise

A. Peña

Winship Cancer Institute of Emory University

1. Background

As the National Cancer Center Institute Comprehensive Cancer Centers (NCI-CCC) expand academic cancer centers expands the portfolios of institution-sponsored and multi-site interventional therapeutic trials, the Data and Safety Monitoring Committees (DSMCs) have an increased responsibility burden of overseeing the complex clinical trials to ensure participant safety, regulatory compliance, and operational efficiency. Traditional monitoring models, often reactive, document-heavy, and interval-driven, do not consistently scale with institutional growth or align seamlessly with broader governance structures such as Protocol Review and Monitoring Systems (PRMS) and Quality Management (QM). At Winship Cancer Institute, a systems-level redesign was undertaken to modernize DSMC oversight and support sustainable institutional growth.

2. Goals

The primary goals were to:

- Develop a scalable, risk-based DSMC oversight framework
- Improve consistency and transparency in monitoring determinations
- Establish a structured, tiered escalation model for follow-up
- Reduce unnecessary committee burden while strengthening accountability
- Enhance alignment across DSMC, QM, Corrective and Preventive Action (CAPA), and Education & Outreach

3. Solutions and Methods

We conducted a multi-year, systems-based redesign of the institutional DSMC program. Core strategic initiatives included:

- Implementation of a structured risk-based monitoring framework to align oversight intensity with trial risk
- Consolidation of monitoring documentation into a single standardized report format
- Development of defined Clinical Trials Monitoring Branch (CTMB) grading criteria to standardize findings across studies
- Establishment of a formal escalation framework activated upon full board review, outlining structured follow-up requirements and timelines
- Creation of tiered routing pathways in which referral to the institutional CAPA Committee occurs only when systemic or significant deficiencies warrant formal corrective action

Escalation was intentionally structured to avoid automatic CAPA referral, preserving proportionality while maintaining institutional accountability. Recurring trends identified through monitoring were shared with Education and Outreach partners to inform targeted training and preventive interventions. Governance roles among DSMC, PRMS, and QM were clarified to reduce duplication and strengthen oversight integration.

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4. Outcomes

The redesigned DSMC framework demonstrated measurable operational impact in 2025. The program supported oversight of 135 monitored participants while maintaining standardized CTMB-aligned grading criteria and structured escalation pathways. Implementation of a tiered escalation model reduced dozens of unnecessary post-monitoring debrief meetings and preserved proportional referral to the institutional CAPA Committee, ensuring corrective action was reserved for systemic or significant deficiencies and improving submission quality and adherence to follow-up requirements.

Standardization of adverse event (AE) reporting and pre-committee quality checks reduced late-cycle data clarifications and improved completeness of committee review packets. Risk-based allocation of monitoring resources enabled intensified oversight of higher-risk trials while transitioning stable studies to reduced monitoring intervals or annual quality review, strengthening scalability without increasing monitoring volume.

Pre-committee escalation checkpoints improved meeting readiness, reduced review deferrals related to incomplete submissions and decreased administrative burden through more complete and higher-quality monitoring and progress reports. Collectively, these reforms enhanced audit readiness, governance clarity, and cross-functional alignment across DSMC, QM, PRMS, and Education & Outreach.

5. Lessons Learned and Future Directions

Scalable DSMC oversight requires intentional governance design, standardized tools, risk-informed decision-making, and clearly defined escalation pathways. Integration with QM and Education partners enhances both accountability and prevention. Future directions include expanded performance dashboards, longitudinal trend analysis, and continued refinement of cross-committee coordination to support sustainable oversight growth aligned with CCSG expectations. This framework is adaptable to other academic cancer centers seeking to modernize DSMC infrastructure while preserving participant protection and regulatory integrity.