

## **Integrated Utilization of Monitoring and Quality Assurance Teams to Strengthen Oversight of Investigator-Initiated Trials**

V. Krines, J. Germain

*Moffitt Cancer Center*

### **1. Background**

Investigator-initiated oncology trials (IITs) require heightened oversight due to complex eligibility criteria, investigational agents, safety monitoring demands, and multi-site coordination. Variability in monitoring practices and decentralized quality functions can increase risk for eligibility deviations, audit findings, and inconsistent protocol adherence. To strengthen oversight across the IIT portfolio, a structured, role-stratified monitoring and quality assurance (QA) framework was implemented.

### **2. Goals**

To design and operationalize a tiered, competency-based oversight model that assigns essential monitoring and QA responsibilities according to senior, level two, and level one roles, enhancing regulatory compliance, improving data integrity, and optimizing lifecycle governance of oncology IITs.

### **3. Solutions and Methods**

Clinical research monitors were organized into a progressive career ladder beginning with Level I monitors responsible for eligibility verification, trend reporting, resolution recovery activities, and standardized template review support. Staff then advanced into one of two specialized pathways: QA oversight or traditional monitoring.

The QA pathway incorporated Level II QA monitors responsible for audit preparation, sponsored trial QA support, non-therapeutic research oversight, and targeted quality reviews. Senior QA personnel provided centralized governance through onboarding oversight, standard operating procedure (SOP) review, pre-lane protocol evaluation, template standardization, and non-therapeutic research office (NRTO)/total cancer care QA to ensure consistency and regulatory compliance.

The traditional monitoring pathway focused on protocol execution and site management. Level II monitors conducted investigator-initiated trial monitoring activities including study kick-off participation, case report form review, pre-activation protocol assessments, and concurrent monitoring of IITs with external sites. Senior monitors maintained full monitoring responsibilities while serving as institutional liaisons to Scientific Review Committees (SRC), Data and Safety Monitoring Committees (DSMC), Human Subjects Research (HSR) Academy initiatives, Investigational Drug Services (IDS), External Site Coordination (ESC), and onboarding of new staff.

### **4. Outcomes**

- Reduced duplication of monitoring and quality review activities across teams
- Increased staff engagement and retention through a defined career progression pathway

*Category: Training, Career Development, and Staff Retention – Completed Project*

- Earlier identification of data integrity and compliance concerns through centralized QA oversight
- Strengthened cross-functional collaboration with study start-up, HSR, NTRO, TCC, IDS, ESC, SRC, and DSMC stakeholders

This dual-pathway model enabled separation of quality oversight from operational monitoring functions while maintaining cross-coverage support. Standardized responsibilities, escalation pathways, and defined competency progression improved workload distribution, strengthened regulatory compliance, and supported scalable oversight across diverse oncology research portfolios.

**5. Lessons Learned and Future Directions**

Clear delineation of responsibilities by role level improves accountability, reduces duplication, and aligns task complexity with competency. Future efforts will focus on expanding risk-based monitoring metrics, implementing performance dashboards with predictive indicators, benchmarking IIT quality metrics across portfolios, and refining role progression pathways to sustain excellence in research oversight