

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

Vicki Krines CCRP, Manager Clinical Research Monitoring, Moffitt Cancer Center

Jamie Germain MSM, CRA Director of Human Subject Research Quality and Education, Moffitt Cancer Center

Abstract

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.

Goals

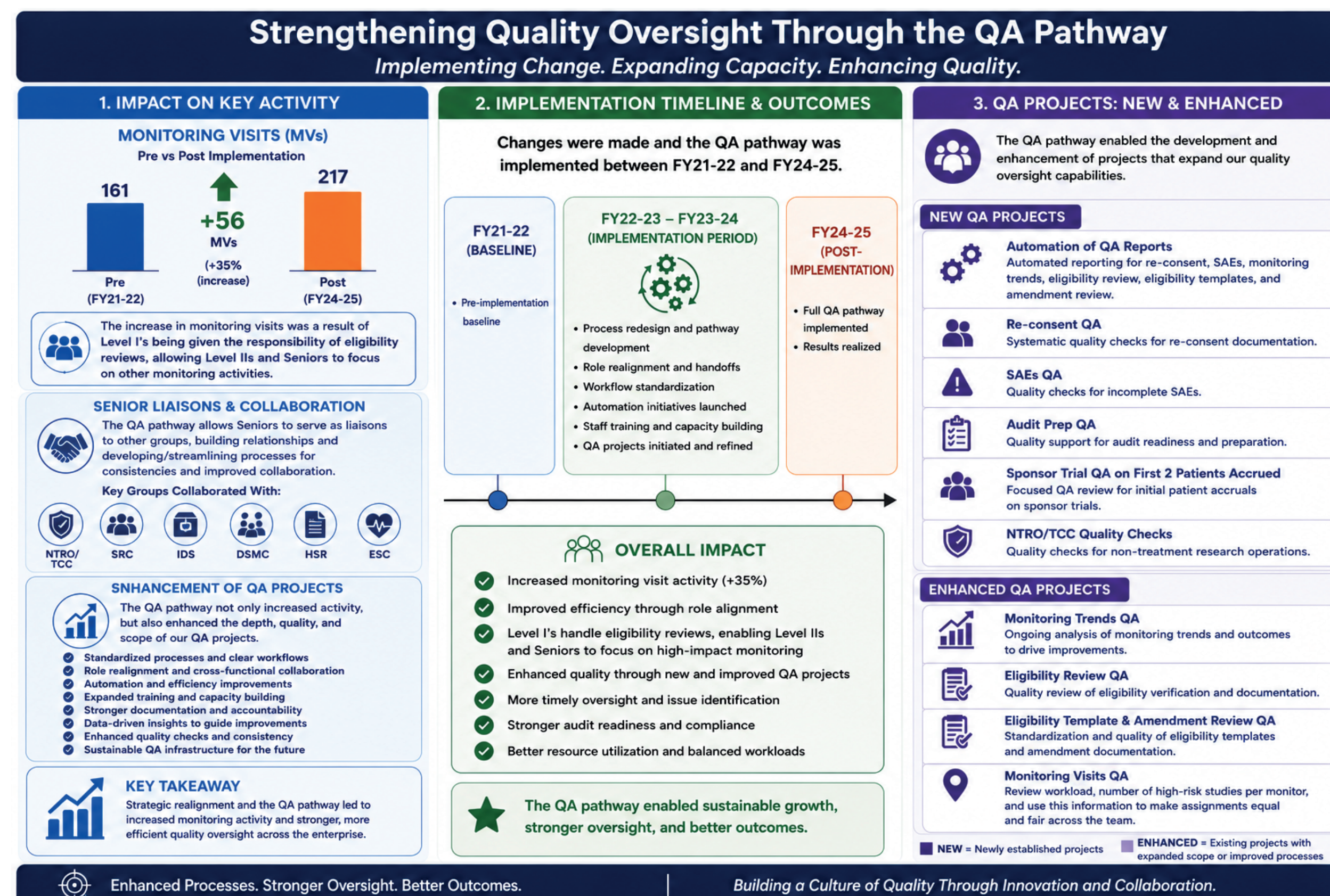
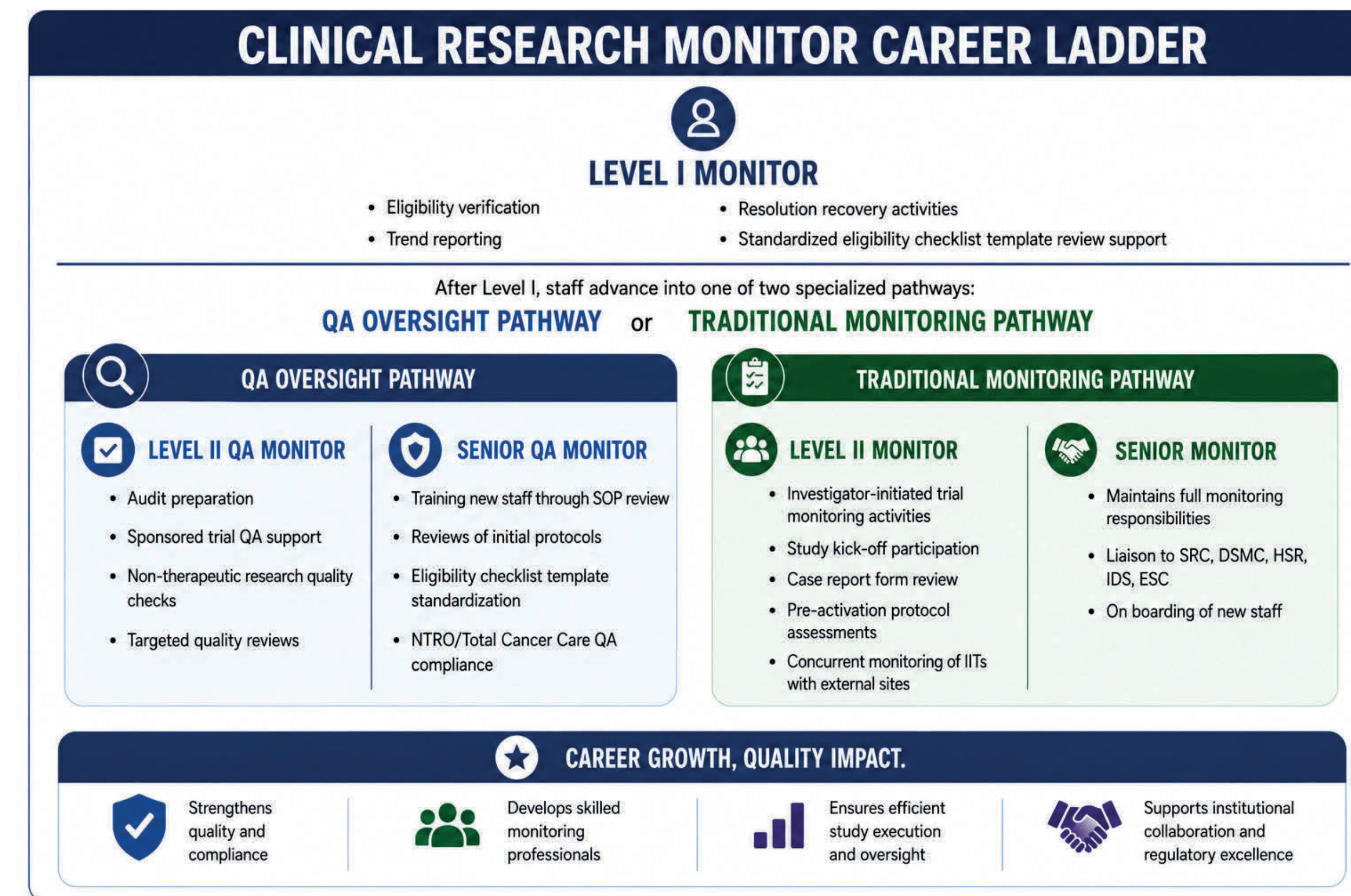
The goal of this initiative was to design and implement a tiered, competency-based oversight model within the Quality and Education department that assigns essential monitoring and QA responsibilities across Senior, Level II, and Level I roles. This structure was created to strengthen regulatory compliance, improve data integrity, and optimize lifecycle governance for oncology investigator-initiated trials (IITs).

Solutions and Methods

Clinical Research Monitors were organized into a progressive competency-based career ladder designed to enhance quality oversight, operational efficiency, and staff development.

Entry-level (Level I) monitors were responsible for eligibility verification, trend reporting, resolution recovery activities, and standardized eligibility checklist template review support. Staff subsequently advanced into one of two specialized pathways: Quality Assurance (QA) or traditional monitoring. The QA pathway incorporated Level II QA monitors responsible for audit preparation, sponsor trial QA support, non-therapeutic research quality checks, and targeted quality reviews. Senior QA personnel provided regulatory and operational support through staff training, standard operating procedure (SOP) review, shadowing sessions for the Clinical Trials Office (CTO), review of initial protocols, eligibility checklist template standardization, and NTRO/Total Cancer Care QA compliance activities to promote consistency across studies and processes.

The traditional monitoring pathway focused on protocol execution, data quality, and site management. Level II monitors conducted investigator-initiated trial (IIT) monitoring activities including study start-up 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 Safety Monitoring Committees (DSMC), Human Subjects Research (HSR), Investigational Drug Services (IDS), External Site Coordination (ESC), and onboarding initiatives to strengthen cross-functional collaboration and process standardization.



Outcomes

Reduced duplication of monitoring and quality review activities through centralized QA eligibility checklist review prior to participant enrollment, eliminating the need for monitors to repeat eligibility verification activities.

- Increased staff engagement and retention through implementation of a clearly defined competency-based career progression pathway, resulting in 100% staff retention since pathway implementation.
- Earlier identification of data integrity and regulatory compliance concerns through centralized QA review processes and standardized oversight activities.
- Strengthened cross-functional collaboration with Study Start-Up, HSR, NTRO, TCC, IDS, ESC, SRC, and DSMC stakeholders to improve communication, consistency, and operational alignment across oncology research portfolios.

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

Lessons Learned and Future Directions

Clear delineation of responsibilities by role level improves accountability, reduces duplication, and aligns task complexity with competency. This model complements a collaborative team-based approach to quality oversight while strengthening operational consistency across IIT portfolios. Challenges encountered during implementation included defining ownership between QA and Monitoring responsibilities, balancing workloads across complex studies, standardizing processes across internal and external sites, and ensuring consistent communication during pathway transitions and staff training. 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.

