

## **Improving Audit Readiness at a Community Hospital Network Site Through a Structured Project Management and Quality Management Partnership**

T. Mallock, L. Gammalo

*Winship Cancer Institute of Emory University*

### **1. Background**

As National Cancer Institute-designated comprehensive cancer centers (NCI-CCC) expand clinical trial access for rural and community-based patients through community hospital network sites, maintaining audit readiness and data quality across decentralized locations remains challenging. Network sites often experience limited infrastructure and resources, compounded by frequent staff turnover, increasing audit risk for National Clinical Trials Network (NCTN) studies. Following an Eastern Cooperative Oncology Group (ECOG) audit in March 2023, a community hospital network site enrolling patients in NCTN trials as an affiliate under the Winship Cancer Institute Lead Academic Participating Site (LAPS) grant demonstrated multiple major deficiencies related to eligibility determination, dosing errors, adverse event (AE) reporting, disease response assessment, and overall data quality. These findings highlighted the need for a sustainable, centralized oversight model.

### **2. Goals**

The primary goal was to improve audit readiness and reduce major audit findings. Success was measured by the number and type of major findings during the subsequent ECOG audit in March 2025. Secondary goals included improving data timeliness and accuracy, strengthening AE and serious adverse event (SAE) reporting, centralizing audit preparation, and providing operational stability amid staff turnover.

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

Following the 2023 ECOG audit, a structured oversight model pairing project management with the Winship clinical trials office (CTO) quality management (QM) team was implemented. A newly created project manager role provided partial effort dedicated to network oversight and served as a consistent operational resource. Responsibilities included a required second eligibility review prior to patient enrollment; monthly data reviews focused on timeliness and accuracy; facilitation of standing monthly meetings addressing enrollment status, data quality, AE/SAE reporting, and training needs; and real-time troubleshooting with escalation to NCI-CCC leadership as needed. The project manager also developed and managed internal site initiation visits to ensure comprehensive, protocol-specific training prior to activating trials for enrollment at the network site.

A dedicated QM monitor was assigned to provide longitudinal oversight and continuity. The QM monitor conducted remote chart reviews at least every six months, completed targeted pre-audit clinical and regulatory reviews, and partnered with the project manager to identify trends and prioritize corrective and preventive actions. In January 2024, CTO leadership and QM personnel conducted an in-person site visit, completing a comprehensive review of active clinical and regulatory records and delivering

*Category: Quality Assurance – Completed Project*

targeted, findings-driven training. Network staff also participated in a two-day modified new employee training led by the CTO Training and Education team, focused on NCTN trials, AE collection, source documentation, and data entry. Ongoing education was reinforced through monthly NCI training sessions informed by QM findings and audit corrective and preventive actions.

**4. Outcomes**

During the ECOG audit in March 2025, major deficiencies were reduced from five to a single pharmacy-related major finding. No other major findings were identified related to eligibility, data quality, dosing deviations, AE reporting, or disease response assessment. Audit preparation was centralized and proactive, with charts audit-ready well in advance of the audit.

**5. Lessons Learned and Future Directions**

A structured project management and quality management partnership, including assignment of a dedicated QM monitor, can significantly improve audit readiness and data quality at community hospital network sites. This scalable model provides continuity during staff turnover and has since been applied to additional network sites, including sites not yet audited.