Propelling NCTN Study Compliance and Excellence: *Introducing the NCTN Monitor Role*

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Background

As an NCI-Designated Comprehensive Cancer Center, the University of Arizona Cancer Center has approximately 150 active federal trials sponsored by the National Cancer Institute. Historically, studies performed under the NCI's National Clinical Trials Networks (NCTN) undergo robust review during routine audits performed by their respective NCTN group every 3-years and are subject to ongoing central data monitoring. However, real-time quality assurance and quality control is not performed by study monitors in the same manner as industry-funded studies or Investigator Initiated Trials. This divergence in study monitoring has potentially affected overall institutional data compliance and audit performance, resulting in less than favorable Institutional Performance Reviews (IPR) and audit findings.

Goals

Recognizing the need for enhanced oversight of NCTN studies, our institution established an adjunct NCTN Monitor Role within the existing NCTN Clinical Research Associate (CRA) Lead position. This integrated role, operating under the institution's QAQC Program, complements the administrative responsibilities of a CRA Lead while increasing oversight of NCTN study data and study conduct, whereby deficiencies that might otherwise go unnoticed are being proactively identified and addressed. This initiative also aims to increase engagement with study teams across all disease areas and foster a synergistic collaboration with QAQC Monitors to better identify institutional trends and evolving needs (**Figure 1**).

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

Solutions and Methods

Considering the institution's ~150 active NCTN studies, the existing central data monitoring, and the limited QAQC Program's staffing (4 team members), a risk-based approach was adopted when prioritizing studies to monitor. Priority was given to studies who enrolled subjects since the last respective NCTN audit, relative proximity of the next NCTN audit, and high-complexity interventional studies. Upon study selection, an initial monitor visit (IMV) ensues comprising the following components:

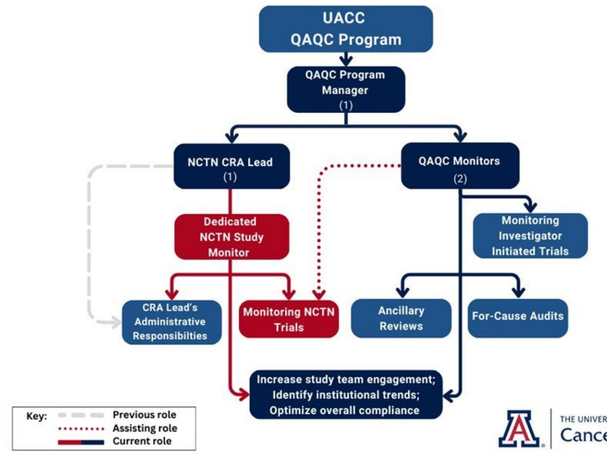
1.Subject Case Review:
- Consent and eligibility records
- Treatment and post-treatment records
- AEs/SAE documentation and reporting
- Data management quality

2.Regulatory Documentation Review:
- IRB correspondence
- Delegation Task Log maintenance
- Protocol Deviations
- Organization and completeness of records

Notably, a drug accountability review is not required for routine NCTN monitoring due to consistently successful audit outcomes and performance; however, one may be conducted if necessary.

Following the IMV, an assessment of the severity of delinquencies is performed, adjudicating the frequency of subsequent monitor visits and appropriate escalation. Each monitor visit will produce a follow-up report, outlining essential quality metrics, observed deficiencies and applicable corrective action plans, to be distributed to the respective study teams.

FIGURE 1. THE UNIVERSITY OF ARIZONA CANCER CENTER (UACC) QAQC PROGRAM'S COMPLIANCE MONITORING FRAMEWORK



Outcomes

Since the launch of the NCTN monitoring program in January 2025, the dedicated NCTN Monitor has completed comprehensive training in robust monitoring practices. In collaboration with the QAQC Monitors, six NCTN studies have been successfully monitored at the institution to date, with additional studies scheduled for review in the coming months. Insights gained from these visits have enhanced the understanding of NCTN study structure, expectations, and unique requirements and have led to the optimization of both the regulatory and subject case review monitoring components. Additionally, key findings identified during the reviews have enabled the institution to proactively address and mitigate potential compliance vulnerabilities and have resulted in improved IPR metrics.

Lessons Learned and Future Directions

The NCTN Monitor role was created as a mechanism to propel compliance; however, logistical constraints impact the efficiency and frequency of study monitoring. Considering the high volume of active NCTN trials at our institution, we are piloting the selection process to ensure studies with the highest probability of compliance vulnerabilities are prioritized. To further facilitate efficiency, once a study is deemed to have acceptable compliance and/or has adequately resolved all observations and a Corrective/Preventative Action Plan is in place, the frequency of monitoring is reduced to once every 1-3 years. We are optimistic that routine quality metric reports will provide insight into the challenges this extended period between monitor visits may cause and allow us to proactively mitigate.