Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

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

L. Ramos-Barrera, D. Peterson, M. Srivastava, N. Fleming, A. Krone

University of Arizona Cancer Center

1. Background

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 central data monitoring. However, real-time quality assurance/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 and audit findings.

2. Goals

Our institution recognized this need and created an NCTN Monitor Role within its existing NCTN Clinical Research Associate (CRA) Lead role, complementing the administrative responsibilities of a CRA Lead while increasing oversight of NCTN study data/conduct and proactively minimizing the occurrence of common deficiencies. Through this action, the institution also aimed to increase engagement with study teams across different diseases and create a synergistic collaboration with QAQC Program Monitors to identify institutional trends and needs.

3. Solutions and Methods

Considering our institution's 153 active NCTN studies and the existing central data monitoring, a risk-based approach was employed when selecting 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:

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 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. All monitor visits will produce a follow-up report, including essential quality metrics and observed deficiencies, to be distributed to the study teams.

4. Outcomes

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Since its implementation in January 2025, the QAQC Monitors have completed two NCTN Monitor Visits, and the dedicated NCTN Monitor is currently undergoing training on two additional studies. The completed monitor visits have informed how the dedicated NCTN Monitor/CRA Lead disseminates institutional data quality reports and has resulted in the optimization of the regulatory and subject case review monitoring components.

5. 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.

Figure