Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

The Diagnostic Audit: Scanning for Errors Before the FDA Does

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1. Background

The Phase I Metastasis-Directed Therapy (MDT) Clinical Research Coordinator (CRC) team within the Clinical Trials Office launched an internal quality-improvement initiative to strengthen audit readiness, enhance coordinator performance, and reduce documentation inconsistencies. As part of this effort, the team designed and implemented a standardized internal audit template and tracking spreadsheet for patient research shadow charts.

This structured framework ensures consistent evaluation of key chart components, supports adherence to protocol requirements and departmental Standard Operating Procedures (SOPs), and provides coordinators with clear, actionable feedback. By establishing a uniform review process, the initiative promotes accuracy, improves documentation quality, and reinforces a culture of continuous compliance across the Phase I MDT.

2. Goals

- Maintain continuous audit readiness.
- Provide oversight and support to Phase I CRCs.
- Identify performance trends and areas for improvement.

3. Solutions and Methods

To ensure the Phase I MDT is audit-ready at all times, the CRC Level IV team implemented a robust quality oversight strategy.

- Cycle 1 audits are mandatory for all CRCs to verify protocol execution, source documentation accuracy, and safety reporting practices. For newly onboarded CRCs, the audit period is extended to include Cycle 2 and the first tumor assessment for their first five patients enrolled for additional oversight.
- The internal audit template is categorized into several key domains: the Informed Consent Process; Eligibility & Registration; Treatment Administration; Response/Outcome; Toxicity Assessment; Shadow Chart Data Quality; Specimen Collection; and Clinical Trials Office Internal Processes (SOP adherence).
- A tracker spreadsheet was created to manage and capture the internal audit lifecycle. To maintain this system, a Level IV CRC monitors all Phase I enrollments, updates the tracker spreadsheet, and alerts CRCs of upcoming audits via email.

4. Outcomes

- Focused retraining by assessing CRC's compliance with the protocol, department processes, and policies.
- Identified areas for improvement in our team's mentoring and training practices.

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- Provided consistent, constructive feedback to CRCs.
- Encouraged timely data entry.

5. Lessons Learned and Future Directions

- The internal audit process provides continued support for Phase I CRCs. Standardized constructive feedback ensures the CRC competency, protocol comprehension, and adherence to institutional SOPs.
- This process was well received by the CRCs, equipping them with functional tools to execute tasks thoroughly and confidently.
- This process was also adapted by the Lung MDT CRCs.
- Continued use of this process will further the understanding of standardized methodologies and promote improvement within the ever-evolving scope of clinical trials.