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

Clinical Research Processes: Monitoring the process, not just the outcome to ensure compliance

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1. Background

Assessing compliance with standard operating procedures in real time through a routine inspection approach is essential. Deviations from established clinical research processes may go unnoticed until routine monitoring visits, allowing them to persist. By implementing real-time evaluations, the research team can promptly identify and address deviations, preventing their continuation.

2. Goals

- Create and implement a routine monitoring approach to clinical research process compliance
- Provide management team with real time insights into clinical research process compliance.
- Enable proactive decision making and allow the team to identify and address issues prior to a monitoring visit or an audit.
- Update standard operating procedures (SOPs) and conduct trainings as needed to ensure compliance.

3. Solutions and Methods

- Routine monitoring of clinical processes to ensure compliance with SOPs began in Q3 2022.
    - Processes were selected for review based on potential or known risks
    - Initially, each process was monitored monthly during the first year; the frequency is adjusted based on risk; new processes are added to the monitoring plan as necessary
- The following processes/documents were monitored:
    - Consenting and consent documentation
    - Drug diary documentation
    - Eligibility documentation
    - EMR encounter documentation completion rates
    - Pharmacology Laboratory requisition form creation timing
    - Quality of Life questionnaire completeness
    - Scheduling clinical trial blood draws
    - Created custom reports within the electronic medical record (EMR) to run monthly to monitor compliance
    - The results are sent to clinical leadership and are also presented to cancer research leadership monthly to discuss trends and recommended actions.

4. Outcomes

Since routine monitoring of clinical research processes was implemented, an overall reduction in errors and an increase in compliance has been observed. For some processes, a zero percent error rate was achieved. When continuous low error rates were observed, the monitoring frequency was reduced. Results-driven education sessions were conducted as required.

5. Lessons Learned and Future Directions

- Routine monitoring of clinical processes allows for real time correction and education which reduces the number of deviations

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- Allows for root cause analysis to be completed
- Monitoring frequency will continue to be modified as required based on risk.