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

Implementing Focused Quality Spot Checks to Enhance Data Quality and Internal SOP Compliance

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1. Background

The Ohio State University Clinical Trials Office (OSU-CTO) Quality Assurance (QA) team implemented targeted spot checks in response to previous audit deficiencies. These checks were designed to provide timely quality management of ongoing trials and gather compliance metrics for clinical research coordinators (CRCs). Focus areas include consent and eligibility documentation of newly enrolled subjects, serious adverse event (SAE) reporting, the first five cycles of a subject's study treatment along with the five most recent treatment visits, and organization of physical research charts.

2. Goals

- Conduct spot checks on new patient consent and eligibility, SAE reporting, treatment cycles, and chart organization to provide immediate feedback to CRCs as well as identify discrepancy trends across the CTO.
- Utilize identified trends to refine training programs and internal processes to improve standard operating procedure (SOP) compliance and the quality of data collection.

3. Solutions and Methods

The spot checks were implemented to ensure ongoing compliance with quality standards for clinical trial conduct across the CTO. New patient checks assess consent forms, consent discussion documentation, and eligibility confirmation. SAE checks focus on the quality of SAE reporting to both the sponsor and the internal Clinical Trials Management System (CTMS), as well as event documentation in the electronic medical records (EMR). Treatment checks review the first five treatment cycles and five most recent treatment visits, focusing on protocol adherence for dose holds, modifications and pill dispensing/reconciliation as applicable. All spot checks assess compliance with both study protocols and internal processes. Upon completion, review reports with corrective action items and re-education are provided to CRCs.

4. Outcomes

The QA team has conducted 408 spot checks since implementation in 2022. Findings were summarized quarterly and provided to CTO leadership. Quarterly newsletters, based on areas of common incompliance, were created to offer reeducation to CTO staff. Spot checks were also conducted on individuals who had previously been incompliant to ensure retention and understanding of the reeducation. In response to areas of internal incompliance, various procedures and policies were updated, with reeducation provided to staff. EPIC SmartPhrases were fine-tuned to strengthen documentation of consent discussions. Updates were made to internal SOPs to clarify areas of consistent incompliance, addressing varying interpretations across disease teams. The training team manager completed reeducation on chart organization for each disease team to ensure consistent filing practices across the CTO. Additionally, current training programs were updated to address areas of frequent incompliance.

5. Learned and Future Directions

Additional training sessions are currently in development to provide education to both new and current CRCs. Current SOPs will continue to be refined and new ones will be developed as necessary. These spot

checks will continue to be conducted on current and new CRCs and repeat spot checks on CRCs will be compared to gather information on the effectiveness of the re-education provided during the spot checks. Additional categories of spot checks will be developed as needed to foster an environment of continuous improvement. Semi-annual disease team-specific reports will be created and shared with managers to provide insight into team performance and encourage team reeducation as needed.