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

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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, and the first five cycles of a subject's study treatment along with the five most recent treatment visits. Two spot checks of each type can be conducted on CRCs who have been in their role for less than two years, and one of each type can be conducted for those in their role for more than two years. Spot checks are conducted across 17 disease teams.

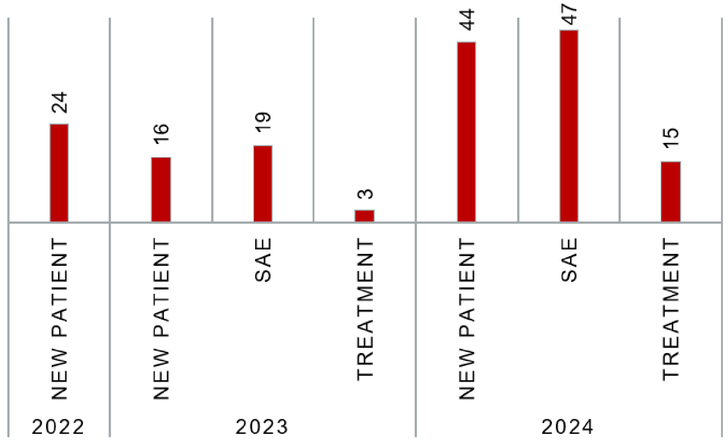
Objectives

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

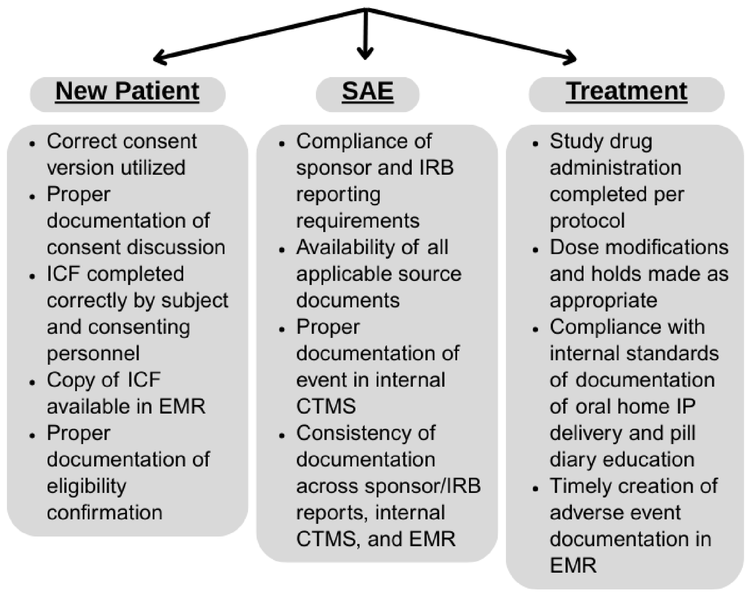
Implementation

The spot checks were implemented to ensure ongoing compliance with quality standards for clinical trial conduct across the CTO. All spot checks assess compliance with both study protocols and internal processes. 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. Upon completion, reports detailing deficiencies that require corrections and reeducation are provided to CRCs. The findings across all completed spot checks within a month are then summarized in excel reports.

Spot Checks Completed 2022-2024



Scope of Spot Check Types



Outcomes

The QA team has conducted 168 spot checks on 108 different CRCs since implementation of the process in 2022. Findings were summarized monthly and quarterly. CTO leadership reviewed the findings for improvement opportunities. Quarterly newsletters were created based on areas of common deficiencies to provide widespread reeducation to CTO staff. Spot checks were also reconducted on individuals who had previously been incompliant to ensure retention and understanding of the reeducation. In response to areas with frequent deviations from internal policies, various procedures and policies were updated. Reeducation was provided to inform CTO staff of the policy updates. EPIC SmartPhrases, a template tool in the EMR utilized to facilitate various facets of documentation and data collection, were fine-tuned to strengthen documentation of consent discussions. Updates were made to internal SOPs to clarify areas with consistent discrepancies, addressing varying interpretations across disease teams. Additionally, the preexisting AE/SAE and informed consent trainings were updated, and an eligibility training was developed to address areas of frequent incompliance.

Looking to the Future

New training sessions are currently in development by the CTO training team to provide education to both new and current CRCs. Current SOPs will continue to be improved, and new ones will be developed, as necessary. These spot checks will be conducted regularly on both current and new CRCs, with follow-up checks being compared to evaluate the effectiveness of the reeducation provided during the assessments. Additional categories of spot checks are in the process of being developed and will continue to 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.

For More Information

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