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

Streamlining Audit Preparation: Centralizing Audit Coordination Efforts Under the Quality Assurance Team

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1. Background

The Ohio State University Clinical Trials Office (OSU-CTO) has undergone an increasing number of external audits for the past few years. Due to the volume of requests, coordinating and preparing audits has become increasingly arduous. To centralize the coordination and reduce burden on study teams from various audit responsibilities, the Sr. Quality Analyst position was created, under the existing Quality Assurance Team, to lead in audit coordination, conduct pre-audits, and attend to auditor requests.

2. Goals

- Streamline the process of audit scheduling, conduct, and response
- Provide timely responses to auditor requests including documents and explanations of policies and procedures
- Optimize Corrective and Preventive Action (CAPA) formulation in collaboration with study personnel

3. Solutions and Methods

To prepare for upcoming audits, the Sr. Quality Analyst developed a tracking system to ensure appropriate preparations and minimize disruptions to study teams. The tracking system focuses on management of scheduling, account access, and deliverables. The Quality Assurance team conducts pre-audits, reviewing documentation, identifying potential gaps, and collaborating with study teams to address deficiencies before the audit. The Sr. Quality Analyst acts as the primary liaison for audit requests, ensuring timely delivery of requested documents and clarifications of processes. After receiving the audit report, the Quality Assurance Manager works with the study team to design CAPA plans, emphasizing root cause analysis to develop sustainable solutions and prevent recurrence of similar issues.

4. Outcomes

Twenty-two audits were coordinated by the Quality Assurance team from mid-2023 to 2024. Disease and regulatory teams appreciated the alleviation of audit scheduling, addressing auditor requests, and creating CAPAs from their workload, as an audit takes roughly 5-10 hours to coordinate and over 15 hours to conduct. In addition to the minimum of 10 hours pre-audit reviews take to complete. Upon the audit's completion and receipt of the report, any outstanding items are tracked and followed up on by the Sr. Quality Analyst to ensure completion and effectiveness. Team reviews of the audit report findings are documented as well as any subsequent re-education.

5. Lessons Learned and Future Directions

Implementation of centralized audit coordination within the CTO by the Quality Assurance team and creation of the Sr. Quality Analyst position has allowed us to implement a standardized process that increases efficiency and verify that essential preparations are completed prior to the audit. Having a dedicated Sr. Quality Analyst as the primary liaison streamlined communication and reduced delays in responding to auditor requests. Establishing relationships with other departments involved in audit

preparation and conduct has facilitated improved communication with auditors including addressing expectations for all parties involved prior to the audit. The Quality Assurance team will continue to monitor trends in audit findings and work with CTO leadership to update policies, procedures, and training, fostering continuous improvement.