

Streamlining Audit Preparation

Centralizing Audit Coordination Efforts Under the Quality Assurance Team

Kathryn Dodds, CCRP; Jennifer Zvosec, MCR, CCRP
The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute



Audit History

The Ohio State University Clinical Trials Office (OSU-CTO) has undergone an increasing number of external audits for the past few years. From 2015 to 2024, the CTO has experienced over seventy external audits excluding NCI. Prior to 2023, disease teams and regulatory teams would complete audit preparations as well as conduct the audit in addition to their regular position tasks. 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 Assurance (QA) Analyst position was created, under the existing QA team, to lead in audit coordination, conduct pre-audits, and attend to auditor requests.

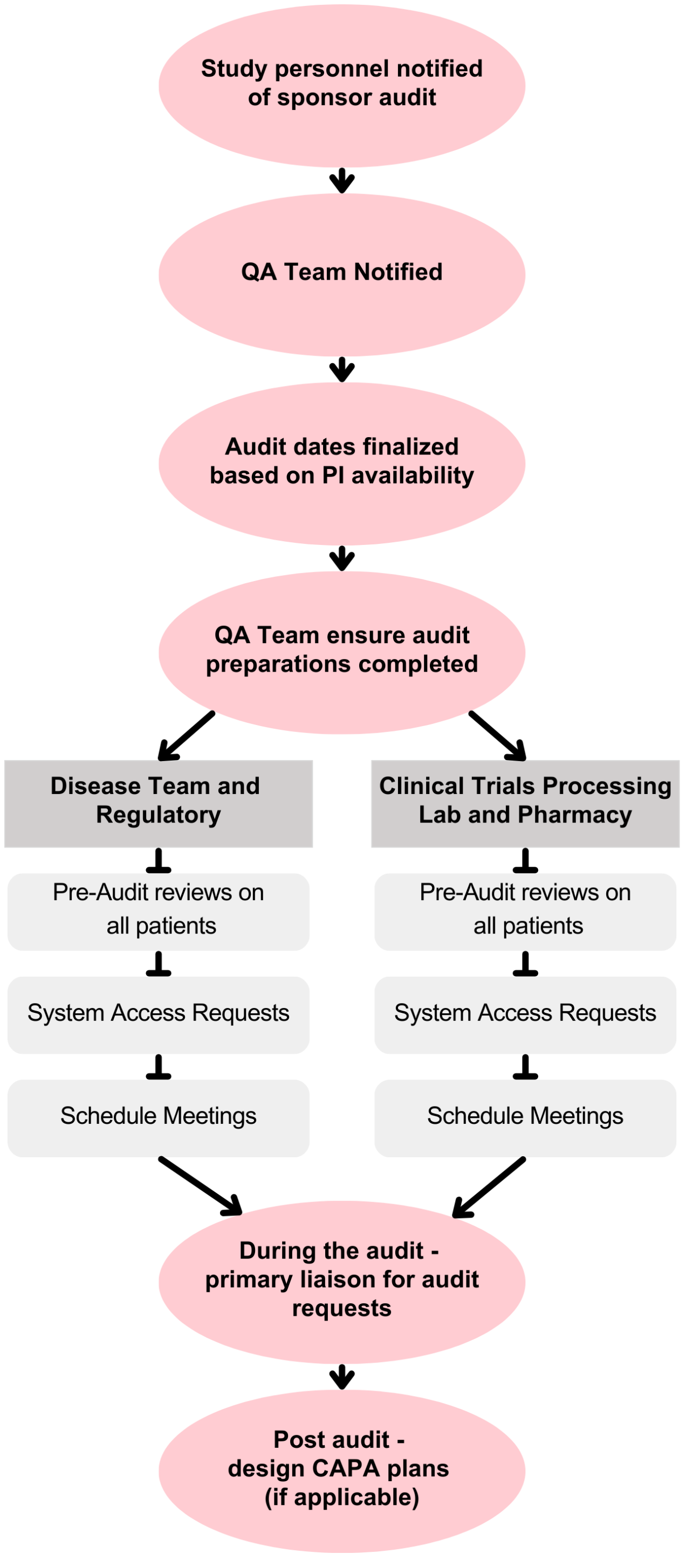
Objectives

- 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

Implementation

To prepare for upcoming audits, the Sr. QA 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 system documents what tasks are required to be completed prior, during, and post the audit. Prior to the audit the Sr.QA analyst will request and track system access for the auditor, meeting and tour schedules, booking the conference room for onsite audits, as well as provide the auditor with parking and building directions and any additional information requested prior to the audit. Leading up to the audit the QA team will conduct pre-audits reviewing documentation with the focus on consents, SAEs, deviations, and treatment visits. These reviews identify potential gaps, and the QA team collaborates with study teams to address deficiencies before the audit. In addition to the pre-audit review, the QA team will provide the study team with a list of common questions auditors may ask over the course of the audit. During the audit, the Sr. QA 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 QA Manager works with the study team to design CAPA plans, emphasizing root cause analysis to develop sustainable solutions and prevent recurrence of similar issues.

Sr. QA Analyst - Audit Coordination Process



Outcomes

Twenty-two audits were coordinated by the QA team from 2023 to 2024. Disease and regulatory teams appreciated the alleviation of audit scheduling, addressing auditor requests, and creating CAPAs from their workload. Considering an audit requires roughly five to ten hours to coordinate and fifteen hours to conduct between tours, meetings, system access, retrieving requested documents, etc.. In addition to the minimum of ten hours pre-audit reviews demand. Study teams value the pre-audit reviews as it allows them to prepare to speak to any areas of concern and update any potential discrepancies. Upon the audit's completion and receipt of the report, any outstanding items are tracked and followed up on by the Sr. QA Analyst to ensure completion and effectiveness. Team reviews of the audit report findings are documented as well as any subsequent re-education. The findings are distributed by study team to CTO leadership and appropriate study team managers for review.

Looking to the Future

Implementation of centralized audit coordination within the CTO by the QA team and creation of the Sr. QA 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. QA 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. To enhance communication of audit expectations and ensuring the auditor provides all required information, the Sr. QA Analyst created a survey utilizing Qualtrics XM. The survey provides the auditor with applicable information based on if the audit is onsite or remote. The survey is to be distributed to auditors in 2025. Effectiveness of the survey will be analyzed in 2026. The QA team will monitor trends in audit findings and work with CTO leadership to update policies, procedures, and training, fostering continuous improvement.

For More Information

CTOQualityAssuranceTeam@osumc.edu

