Category: Quality Assurance & Remote Monitoring and Auditing - Completed Project

How to Conduct a Regulatory Review to Ensure a Quality FDA Inspection

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1. Background

In January 2023, the early drug development (EDD) service was alerted to trial and regulatory management concerns from a study sponsor that could lead to an FDA inspection of two protocols. Given the operational constraints during the COVID-19 pandemic, the time during which most patients were enrolled in these trials, management staff began an in-depth review of all aspects of the trials. The comprehensive review conducted in preparation for this inspection is a process that can be utilized to maintain quality and for future potential audits.

2. Goals

- Conduct a systemic assessment of reportable safety events with clinical staff oversight
- Re-examine enrolled patients with a focus on consent processes and eligibility verification
- Organize an internal quality assurance (QA) review of the regulatory binders
- Review all monitoring letters and reconcile all pending findings.

3. Solutions and Methods

In preparation for the potential audit, management staff enlisted additional team members to allocate resources for a rigorous review of all facets of the trials. To ensure compliant reporting, a list of all safety events was created to track both initial and follow-up reports, then ensure all reports were filed in the regulatory binder. As queries related to these events were generated, we collaborated with clinical staff to expedite their resolution. With additional team members involved, a large-scale tracker was implemented to maintain an up-to-date record of patient reviews in a central location for collaborative work. Staff reviewed all consent processes, ensuring informed consent forms were present in source, and submitted deviations for any deficiencies noted. Additionally, patient charts were reviewed to ensure initial eligibility was correctly evaluated.

To supplement research staff review, internal QA auditors were brought in to target regulatory documentation such as the delegation of authority logs, financial disclosure forms, and FDA 1572s. Note to files were composed to address corrections and discrepancies between regulatory documents. Staff also reviewed amendment submissions, protocol trainings, and sponsor safety reports for appropriate acknowledgement and timely filing within the regulatory binder. Lastly, a review of the monitoring visit log was conducted and cross-referenced with the follow-up letters saved in the regulatory binder. Once all letters were filed, they were individually reviewed to confirm all findings were addressed and additional deviations were filed accordingly.

4. Outcomes

Extensive preparation in the weeks leading up to the inspection guaranteed the team was as prepared as possible. All pending monitoring findings were reconciled, thorough documentation of safety events and deviations was completed, and essential regulatory documents were confirmed to be current. Additionally, after reviewing patient charts, gaps in source documentation were eliminated. During the audit, the team answered questions raised by the inspector with certainty and in real-time, a feat made possible by comprehensive groundwork.

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5. Lessons Learned and Future Directions

- The need for a comprehensive and standardized audit preparation procedures to ensure inspection readiness
- The importance of collaboration amongst the study team to maintain the quality of the trial throughout its lifespan
- Observations of deficiencies which led the team to re-evaluate current operational workflows