Category: Quality Assurance & Remote Monitoring and Auditing - Work in Progress

Path to Improved Trial Management and FDA Inspection Readiness

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1. Background

In January 2023, the Early Drug Development (EDD) service was alerted to trial and data management concerns from the sponsor that could lead to an FDA inspection. Preparation revealed deficiencies in existing service-wide workflows and study tools. The EDD is an exceptionally high accruing service, with 113 open protocols and 282 patients accrued in 2022. Due to high patient volume and rapid accrual, it is of the utmost importance that study teams have workflows and tools in place to ensure protocol compliance and favorable patient outcomes. In response to deficiencies identified, we are working with senior leadership to ensure real-time quality management of our rapidly accruing trials.

2. Goals

1. Utilize sponsor monitoring follow-up letters and implement new tracking methods to ensure findings are collaboratively addressed in real time
2. Refine existing workflows for SAE and deviation reporting to ensure accountability, accuracy, and adherence to reporting timelines
3. Optimize principal investigator (PI) involvement in operational and regulatory trial aspects through a revamped PI meeting format

3. Solutions and Methods

While preparing for the inspection, we observed the lack of continuous oversight during monitoring visits and the delay in reconciliation of follow-up letter findings. Subsequently, we are developing a templated response to monitoring letters and a standardized tracking system to ensure thorough documentation and timely resolution of findings. Similarly, the team is developing a centralized SAE tracking system to promote wider accessibility to documentation of safety events and follow-up reports. To ensure timely deviation reporting, we are streamlining our workflows to simplify the reporting process while allowing greater visibility to PIs and management staff throughout the reporting process. Prior to the FDA audit, PI meetings prioritized patient reviews over regulatory issues, monitoring findings, and other operational items. We are working to improve the overall quality of trial management during PI meetings. This includes an increase in time spent with the study team, a more equitable review of operational aspects of the trial, and the rollout of a modified meeting minute template to emphasize operational items.

4. Outcomes

After refining these operating procedures, we expect the service-wide trial portfolio to be better maintained and more compliant with protocol requirements, which will in turn ensure high quality FDA inspections. After fully implementing these changes, our plans to evaluate outcomes—which will be included in a poster presentation—include:

- Routine checks of deviation and SAE reports to ensure adherence to reporting timelines
- Comparisons of the number of deviations reported to evaluate whether new monitoring workflows and tracking methods improve overall compliance
- Survey study staff and PIs to assess familiarity with the operational aspects of the protocol and open action item

5. Lessons Learned and Future Directions

- The need to continuously evaluate and adapt procedures based on the success of existing workflows
- The importance of centralization and standardization of tools to track all study related items, including safety events and deviations
- The need for consistent review of pending operational items during time with the PI