Category: Training and Quality Assurance – Work In Progress

Expanding the Scope of an Internal Quality Assurance Program to Initiate Change on a Mezzo- and Macro-level

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1. Background

Protocols are increasingly more complex, staff turnover is high, and industry standards can be a moving target. Performing comprehensive quality audits on new protocols establishes a proactive approach to quality assurance (QA) and ensures corrective action plans are set into motion early on.

Our internal QA program was established in 2014, with an emphasis on micro-level clinic processes, such as informed consent and serious adverse event identification. Early audits did not include reviews of data entry or regulatory compliance, but instead focused on correcting study-specific clinic issues. This narrow focus could cause other aspects of clinical trials to be overlooked, such as accurate reporting of response data or documentation of amendment training. Without analysis of operational errors occurring within disease teams (mezzo-level) and across our Division as a whole (macro-level), we were missing an opportunity to identify areas that could improve with team- or Division-wide education.

2. Goals

Our goal was to develop a more comprehensive QA program that quickly identifies process issues, trends, and educational gaps that could jeopardize patient safety, data integrity, and regulatory compliance.

To establish a broader review of our Division, the scope of the QA program expanded in 2018 to include reviews of regulatory, policies, and processes. We also set 3 goals for 2019:

- Launch a data audit program and complete 45 audits in the first year
- Identify audit trends
- Work with the Education team to combat trends identified

3. Solutions and Methods

We worked with experienced data managers to establish priorities and determine the scope of data audits. We focused efforts on institutional and cooperative group trials for three reasons:

- We have limited resources (2-person QA team).
- Industry studies undergo extensive external data monitoring.
- Industry studies utilize many different EDC systems.

We presented the finalized data audit plan to a group of ~40 supervisors and senior coordinators and collected feedback prior to implementation. We began conducting data audits in September 2019.

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In December 2018, we created an audit tracker that catalogues completed audits, upcoming audits, and audit findings.

We implemented monthly meetings with the Education Manager to review policies, audit findings, and education strategies.

4. Outcomes

We completed 15 data audits and presented preliminary clinic and regulatory results to Division team leads. After 83 clinic audits and 71 regulatory audits, we identified Division-wide and disease team trends, including issues related to oral medication compliance and obstacles to collecting protocol-specific training. We worked with Education to improve our tools and processes related to these trends.

5. Lessons Learned

Open communication with teams and supervisors is imperative to ensure audits capture useful data that can impact positive change. Interim reviews helped us determine more specific categories were needed to better understand aggregate data. As a result, we re-evaluated our goals and are piloting new audit processes.

We will summarize findings every 6-12 months to assess trends and determine if the categories we are tracking tell us what we want to know. Adding to our scope without growing our team requires constant re-evaluation of priorities. By eliminating categories without findings we may be able to narrow our scope in different areas in the future.