Using a Quality Assurance Trial Management Team to Increase Compliance and Reduce Workload Burden Associated with Staff Turnover

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BACKGROUND

When Research Coordinator (RC) turnover occurs, other personnel need to cover the workload the departing RC has left behind. Increased workload raises the chance for compliance issues and burnout. The new lead RC often has to correct errors or complete unfinished work during or shortly after training.

GOALS

Reduce workload of data/regulatory personnel caused by turnover, mitigate risk due to staff transitions, and return a clean, compliant study back to the applicable disease team.

METHODS

In Q3 of 2022, three new Quality Assurance (QA) Coordinators were hired to perform a hybrid QA Coordinator/trial management role. These new QA Coordinators – the QA Trial Management (TM) Team - manage studies transitioned from RCs who have left the department; they review the studies and perform any necessary regulatory or data completion or correction, then transition the clean studies back to the applicable disease team. Feedback regarding the state of the study at the time of the transition to QA is provided to the disease team supervisor. This allows the supervisor to proactively correct similar issues with other clinical trials.

- The process:
  - A QA Coordinator is assigned to each transitioned study to review the study and perform regulatory and data work.
- QA duties include but are not limited to the following:
  - Regulatory
    - Protocol, consent, or personnel amendments, continuing reviews, etc.
  - Data
    - All data entry/query resolution for enrolled subjects
- Lead RC responsibilities
  - Point of contact for the study
  - Reporting on the study at meetings, coordinating monitoring visits, and enrolling subjects
  - Communicate with QA as needed

OUTCOMES

During 2023, the QA TM team reviewed, helped manage, and made any necessary corrections for 34 studies. They addressed findings, including major observations, in real time while supporting these studies and then transitioned the studies back to the disease teams.

The TM team rates the study on a scale of 1-5 for the state the study was in when they received it and the state the study was in when they transitioned it back to the applicable disease team.

Rating	Explanation of Rating
5 = Excellent 4 = Very Good	No deficiencies identified. Few minor deficiencies identified. Major deficiencies that were addressed prior to the QA review/study transition for which documentation exists and no further action is required. Minimal queries in study database
3 = Good 2 = Fair	Multiple minor deficiencies identified. Major deficiencies identified, but not corrected and/or addressed prior to the QA review/study transition.
1 = Poor	Multiple major deficiencies identified. A single major flagrant deficiency found. Excessive number of minor deficiencies found.

Studies received by the QA TM team were in overall "good" condition based on the average study quality rating - five studies were rated as "poor" at the time of QA receipt. All studies were returned to the disease teams in "very good" or "excellent" condition. The QA TM team continues to serve as a resource for RCs who receive studies from them after the study is transitioned.

LESSONS LEARNED AND FUTURE DIRECTIONS

Initially, the QA TM team was the point person for the transitioned studies before shifting to having a research disease team member be the point person. Having the QA TM team serve as lead RCs for transitioned studies reduced their time to review each study. Managing studies behind the scenes allows more time to review studies and make corrections. Teams with turnover have not experienced the stress of assuming another RC's workload.

The QA TM team will continue to support studies as turnover occurs and will look for opportunities for process improvements