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

Creating a Robust Quality Assurance Program to Ensure Compliance in Research

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1. Background
To mitigate risks in a fast-changing environment, the Cleveland Clinic (CCF) Taussig Cancer Institute (TCI) Quality Assurance (QA) team has expanded to a multi-faceted and specialized team that focuses on random audits for standard operating procedure (SOP) compliance, a transition team that handles studies during staff vacancies, a clinical process auditor, Data Safety and Toxicity Committee (DSTC) coordinator, dedicated trainers, clinical trial monitors, and QA coordinators.

2. Goals
Elevate clinical research conduct by expanding the QA team and incorporating SOP compliance review, mitigating risk due to staff transitions, ensuring clinical processes are consistent, closing the feedback loop from QA by incorporating department quality deficiencies into standard training, increasing DSTC standardization and department transparency, and expanding overall monitoring and QA.

3. Solutions and Methods
The TCI QA team is organized and works to maintain compliance in the following ways:

- Three study monitors: routine monitoring of high risk (IND/IDE) investigator-initiated trials (IITs), external sites, or any studies deemed needing an internal monitoring plan
- Three QA reviewers organized by specialty: responsible for routine QA reviews of low risk IITs and audit preparation
    - SOP compliance, deviation, and comprehensive cancer center (CCC) integration specialist:
        - Conducts random clinical documentation audits for SOP compliance and provides re-education following findings
        - Tracking observations and reporting findings via a Tableau dashboard
        - Reviews CCC database for accuracy/completeness
    - Data safety and toxicity committee (DSTC) coordinator:
        - Compiles data and report forms for CCC DSTC meeting across 12 unique disease programs
        - Monitors and tracks outstanding required IIT data
    - Cooperative group study QA coordinator:
        - Implemented routine QA reviews for cooperative group studies
        - Averages reviewing two studies per month in addition to cooperative group audit preparation
- Clinical process auditor: clinically trained QA coordinator specializing in the review, auditing, and compliance of our clinical processes and procedures conducted across the clinical research department
- Transition trial managers
    - Hybrid QA/trial management roles that simultaneously manage, review, and clean up a trial when a research coordinator leaves a role at TCI
- Trainers:

- Two department trainers were moved under the QA team for better alignment and to provide a better closed feedback loop of department deficiencies into updated training and re-education initiatives
- Hold a minimum of quarterly for-need education sessions, directly built on information provided from QA reviews

4. Outcomes

In 2022, we launched an interactive deviation dashboard reviewed monthly with department leadership. In 2022, 147 monitoring visits were performed for IITs; 16 were for external sites. A total of 52 QA reviews were performed by the team, including 18 IITs, 27 cooperative group studies, and seven industry-sponsored studies were reviewed for audit preparation. This is an increase from 2021 in which 133 monitoring visits and 15 total QA reviews were performed. Five SOPs are reviewed for compliance monthly in addition to any updated or changed SOPs.

5. Lessons Learned and Future Directions

Efficient and standard outcomes-reporting creates expedited solutions and re-education for the department. Specialized QA positions offer a higher level of auditing and review. Expansion and adjustment of team roles is necessary to keep up with compliance in a changing environment.