Category: Quality Assurance and Remote Monitoring and Auditing – Work in progress

Peer-to-Peer Data Monitoring

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1. Background

In 2023, approximately 45 percent of our enrollment was cooperative group trials, which do not include routine sponsor monitoring. Historically, we have conducted reviews in preparation for audits every three years, resulting in small or repeat errors being discovered possibly years later, after multiple cycles.

2. Goals

- Increase compliance, timeliness, and accuracy of data submission and query resolution
- Identify and correct errors contemporaneously
- Identify issues before they become repeat errors
- Initiate data manager (DM) peer-to-peer monitoring at our main site

3. Solutions and Methods

- Met with all DMs to review process and receive suggestions prior to rollout
- Created a checklist to standardize process across DMs
    - After initial reviews, updated checklist to include verification of serious adverse event (SAE) reporting and redaction on uploaded documents
- Review to include patients enrolled following most recent National Cancer Institute (NCI) audit: August 2022 onward
- A secondary DM assigned to each patient as reviewer
- Tracking spreadsheet created and stored on shared drive with review checklists
    - Expectations set for communications regarding review findings to primary DM
- Bi-weekly DM meetings utilized for updates on progress, difficulties, and assigning new patients
- Individual meetings held when more guidance needed from the DM and quality control supervisors

4. Outcomes

- Review of patients registered since August 2022 and completed January 2024
    - Going forward, target for review of new patient data within 4-6 weeks of on study date
- Repeat data errors noted during reviews, corrections, and reeducation, completed as needed:
    - With increased usage of central source data verification and uploaded documents, there is increased risk in uploading documents containing protected health information (PHI)
        - The bi-weekly DM meeting serves as time for reviewing repeat errors and necessary retraining
    - With a noted increase in solicited adverse events in Rave but not identified in the protocol, DMs reminded to flag to research coordinators when documentation is not available in source
- Improvement on Southwest Oncology Group (SWOG) expectation report from September 2023 through December 2023, from 18 late forms to 5 late forms
- DMs reported more confidence problem solving issues with sample submission
    - Currently no samples pending

5. Lessons Learned and Future Directions

- Initial goal to complete historic data reviews within 1 month of process rollout; we did not meet this timeline due to multiple factors:
    - Protocols distributed by disease with uneven distribution of cooperative group trials to one DM
        - This DM conducts reviews for others while also receiving the majority of the feedback for review and action
    - Backlog in data entry due to a long-standing DM, following approximately 175 patients, retiring earlier than expected, and a new hire requiring training
    - Historic data cleaning was more time consuming than anticipated
        - Some electronic case report forms (eCRFs) were locked
        - Requests were submitted for unlocking, and in some instances, this had to be done page by page
    - Staff members have varying access within electronic medical record (EMR) for specialized data review
        - Certain information is not available to all staff, e.g., confirmation of auto-injector rates and b values on an MRI trial
- Process initiated at main campus, through 2024 process, will be implemented at affiliate research locations
- The review reports and feedback from each data monitor will be used in annual reviews to demonstrate areas of growth and improvement
- Peer-to-peer date review of Investigator-Initiated Trials planned for 2024