Improving Quality: 1st and 3rd Patient Review

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BACKGROUND

The Mayo Clinic Comprehensive Cancer Center (MCCCC) was not immune to study staff turnover during the COVID-19 Pandemic and the Great Resignation.

To reassure quality and patient safety, the MCCCC invested resources to improve quality through implementation of an enterprise-wide database tracking system for all clinical trials performed within MCCCC. Reviews include:

- 1st and 3rd accrued patient quality checks
- regulatory reviews to ensure audit readiness
- research billing to assure timely research charges and billing

Previously reviews were conducted independently at each site but are now operating under a centralized process with detailed metrics and reporting.

GOALS

Maintain patient safety and high-quality clinical trial operations while proactively providing:

- Real-time feedback to staff
- Improve audit outcomes
- Furthering collaboration among CCTO staff

REFERENCES

REDCap 12.4.25 - © 2023 Vanderbilt University

SOLUTIONS AND METHODS

These quality reviews are conducted on all clinical trials and reported to out Data Safety Monitoring teams to assess/track trends and educational interventions as needed.

FIRST PATIENT REVIEWS

Occurs when the first participant is accrued to the clinical trial.

REVIEW PART 1:

- Review is completed by the Clinical Research Coordinator (CRC) and Data Coordinator (DC) through a self-assessment form in the REDCap database.
- Assures communication between the CRC and DC.
- Addressed protocol and electronic Data Capture (EDC) requirements as a team.

REVIEW PART 2:

- Part 1 self-assessment form is then reviewed by our Compliance and Quality Unit (CQU) auditor as a central reviewer.
- Help assist in the identification of educational and/or procedural gaps across the enterprise that need to be addressed from a higher level.

THIRD PATIENT REVIEWS

Occurs when the third participant is accrued to the trial with subsequential review and as needed based off 3rd review findings.

- Central reviewer will complete a quality review on the 3rd participant following Cycle 1 completion.
- A REDCap tracking form will be used to complete all aspects of the review. Note: the REDCap form is similar to the 1st patient review form for consistency. This will help us determine trend capture between 1st and 3rd participants.
- When complete, the CQU auditor meets with the study team to discuss findings and how best to help correct and/or prevent future findings.
- Trends are reviewed across trial, unit and site to assist in the identification of educational and/or procedural gaps across the enterprise that need to be addressed from a higher level.

REGULATORY REVIEWS

Occur when the 3rd participant is accrued with subsequential reviews completed based off risk management.

- Regulatory central reviewer (also a CQU auditor) completed regulatory review using a REDCap form.
- When complete, the CQU auditor meets with the regulatory unit, who is charged with the trial's regulatory) to discuss findings and how best to help correct and/or prevent future findings

RESEARCH BILLING INVOICING REVIEWS

Occur when the 3rd participant is accrued with subsequential review as needed, based on original 3rd review findings.

- Site reviewer will complete the review using a REDCap form.
- When complete, the site reviewer meets with the DC to discuss findings and how best to help correct and/or prevent future findings.

FIGURE 1

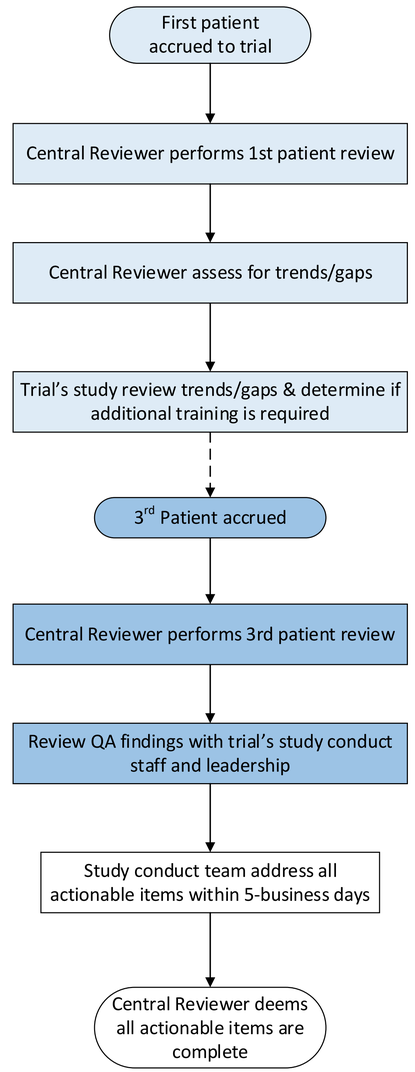

Figure 1 represents the Quality Assurance Review process.

OUTCOMES

1ST PATIENT REVIEW:

- Improved communication and relationship between the CRC and DC.
- Illustrated gaps in education, that have been used to revise procedures and trainings.

3RD PATIENT REVIEW:

- Provided real-time feedback
- Provided real-time correction of protocol and EDC understanding to assure
- Helped establish gaps in processes, procedures, and education, which helps sustain/maintain our CCTO Quality Management System (QMS) and education programs.

REGULATORY REVIEWS:

- Helped to verify consistency across site regulatory files.

RESEARCH BILLING INVOICE REVIEW:

- Established real-time feedback to study teams
- Help establish gaps that are being addressed by education and QMS

LESSONS LEARNED & FUTURE DIRECTIONS

The REDCap tool, central review, and automation of 1st and 3rd reporting has been critical to our QMS by ensuring quality at all levels.

DSM also uses the information to help intervene and educate when systemic trends are first noticed and in real-time.

Future directions to streamline the 1st and 3rd REDCap reports with the other quality trackers, such as our monitoring tracker, audit team tracker and Corrective and/or Preventative Action (CAPA) Plan tracker. The scope will be expanded to include all cancer-related clinical trials performed at Mayo Clinic

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