Improving Quality: First and Third Patient Review

A. Fritsche, K. Croghan, J. Zbacnik, A. Youssef, L. Winkowski, A. Holland, G. Nowakowski

Mayo Clinic Comprehensive Cancer Center

1. 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 assure quality and patient safety, the MCCCC invested resources to assure the highest clinical trial quality through implementation of a database tracking system for first and third patient quality checks. The additional turnover of staff has further enhanced the database to include regulatory and research billing quality reviews.

2. Goals
The goals are to maintain patient safety and high-quality clinical trial operations while being able to proactively provide real-time feedback to staff; improve audit outcomes; and further collaboration among all Cancer Clinical Trial Office (CCTO) staff.

3. Solutions and Methods
First patient case file review occurs by the clinical research coordinator (CRC) and data coordinator (DC) completing a self-assessment form in the REDCap database to assure communication and understanding protocol and electronic data capture (EDC) requirements. These self-assessment forms are then reviewed by our Compliance and Quality Unit (CQU) auditor as a central reviewer. This is to help assist in the identification of educational and/or procedural gaps across the enterprise that need to be addressed.

Third patient case file, regulatory, and research billing quality review have forms in the REDCap database that are completed by the CQU auditor and team supervisors (research billing review). These quality reviews are conducted on all cancer-related trials and reports are sent to Data Safety Monitoring (DSM) for tracking and trending, and education intervention when needed.

4. Outcomes
The first patient review has improved the communication and relationship between the CRC and DC. It has also illustrated gaps in education that have been used to revise procedures and trainings. The third patient review has provided real-time feedback and correction of protocol and EDC understanding to assure the highest CCTO study conduct quality across patient and regulatory files. Again, the third patient reviews have helped to establish gaps in processes, procedures, and education, which have now become a fundamental part to sustain our CCTO Quality Management System (QMS). The research billing audits have assured that timely research charges and billing is taking place.

5. Lessons Learned and Future Directions
The REDCap tool, central review, and automation of first and third 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.