Trend Tracking and Analysis to Support Quality Assurance in Oncology Clinical Trials

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1. Background
Detecting and identifying clinical research quality issues in oncology clinical trials has been difficult due to the complexity of multiple clinical trials being held in a department, leading to extensive amounts of time passing before corrective and preventative education can be identified and implemented. Limited access in academic medical centers to centralized systems to capture and compile findings adds to the complexity of identifying trends in noncompliance across trials in real time. Communication between the quality assurance team and clinical trial staff is often based on individualized findings observed during quality assurance reviews and does not lend itself to quantitative identification of observances or clear visualization.

2. Goals
We set out to create a centralized location to record quality assurance review observations and store written reports for cancer-related clinical trials conducted at the Tisch Cancer Institute. From these observations and reports, our objective was to efficiently organize and visualize the collected information to identify trends in non-compliance and guide data-driven decisions for targeted education.

3. Solutions and Methods
The Quality Assurance Program (QAP) adapted the NCI Clinical Trials Monitoring Branch (CTMB) Audit Guidelines to fit the needs of our program and apply to investigator-initiated and industry-sponsored study reviews. These internally developed Quality Assurance Review Guidelines inform the categorization and classification of observations and ensure consistency across quality assurance review activities. Thereafter, an intern was selected to assist the Quality Assurance Program (QAP) with trend tracking and data visualization. Discovery discussions were held with the QAP director and staff to better understand the problem and identify potential solutions including determining the best platform(s) for trend tracking and data visualization. A decision was made to utilize REDCap for trend tracking of quality assurance reviews and Smartsheets to visualize the data. Surveys were built for internal monitoring/ auditing and departmental subject registration reviews. The intern consulted with QAP to discuss the surveys developed and to ensure the REDCap projects met their needs. Surveys were refined based upon feedback from QAP staff and director. The intern explored technical features of REDCap to enable desired workflows including generating emails, reports, and letters from surveys and shared workspaces, and to leverage reporting functionality. The intern created sample data visualization via Smartsheets based upon mock data entry in the surveys to demonstrate the potential impact of the visualized data.

4. Outcomes
Through development of a centralized observation tracking platform, we identified an opportunity to transition the entire workflow from a manual process to an electronic process. In doing so, we eliminated multiple Word documents and Excel spreadsheets and replaced them with a centralized REDCap survey. We also streamlined the storage of quality assurance review documentation. As we implement the project more broadly, we anticipate trends in noncompliance observed in audits, monitoring visits, and subject registration reviews to be more readily collated, tracked, and visualized.

Use of the REDCap surveys will ensure application of standard categories and classification of observations as outlined in the Quality Assurance Review Guidelines. The Smartsheet dashboards will be presented to leadership biannually and ad hoc to guide future quality improvement initiatives and used by the QAP director and staff to identify educational needs of clinical trial staff.

5. Lessons Learned and Future Directions

Possible future directions include:

1. Building a process whereby clinical trial staff can respond directly to observations within the REDCap survey and eliminate separate email correspondence and tracking of issues outside of the survey
2. Identifying a single system solution that allows for tracking and visualization rather than using two systems to accomplish this work