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

Keeping an Eye on RNI: Frequent Monitoring to Eliminate Preventable Reportable New Information

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1. Background

Responsible handling of reportable new information (RNI) is essential to the conduct of clinical trials. RNI reporting addresses unanticipated adverse events, protocol changes to prevent apparent immediate hazards, or additional potential risk and/or harm to which research subjects are exposed. Certain types of RNI cannot be prevented because, by their nature, trials produce experiential data that was previously unknown or cannot be predicted. Other types of RNI result from the action or inaction of members of the study team and may have been prevented by changes to the workflows, procedures, or policies of the institution conducting the trial. The Perlmutter Cancer Center Clinical Trials Office (CTO) has sought to eliminate preventable harm and provide the highest standard of care and safety to our patients by reducing instances of preventable RNI.

2. Goals

- Define preventable versus non-preventable RNI
- Regularly monitor RNI to identify trends
- Adjust workflows, procedures, and policies to mitigate emerging trends and eliminate preventable RNI

3. Solutions and Methods

- The CTO worked with Information Technology (IT) to develop an RNI database; a report of all RNI submitted in the week prior is pulled from the database and sent to CTO leadership for review, enabling leadership to make prompt alterations to workflow and policies
- We expanded and frequently revised trainings for new and current clinical staff each year since 2019 and changed our policies and procedures to incorporate lessons learned from audits; training sessions were an opportunity to obtain timely feedback from staff most familiar with the workflows contributing to RNI
- In 2021, we initiated CTO high reliability organization (HRO) huddles which are attended by the entire CTO staff; this weekly forum enabled communication of urgent changes to our policies/procedures and explanation of the circumstances leading to these changes and provided a platform for staff to share safety stories, near-misses, and concerns
- We initiated assembly of an RNI Committee to meet regularly with a focus on eliminating preventable RNI with representation from every unit and position within the CTO, from research data associate to director

4. Outcomes

The CTO effected a 75 percent reduction in preventable RNI arising from our clinical care of trial patients, from 20 instances in 2019 to five in 2022, including an elimination of preventable RNI related to adverse event reporting and our investigational pharmacy. During this same period, we experienced an increase in the size of our portfolio, activating an average of 14 percent more trials year-over-year, and growth to the complexity of our trial portfolio (42 percent more subjects accrued to Phase I/II trials from 2018-2022 versus 2013-2017).

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5. Lessons Learned and Future Directions

The centralization of RNI review has been successful and has demonstrated the potent synergy between regular oversight by leadership and collaboration with staff who have expertise on how best to close gaps in workflows and policies. There is no simple way to account for human error in all forms; no workflow or policy is impervious to inadequate execution. We will continue our weekly review of RNI indefinitely, and our diverse committee will continually refine our workflows and practices with the goal of mitigating preventable harm.

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