Increase Oversight on Cooperative Group Trials

Perlmutter Cancer Center
An NCI-designated Comprehensive Cancer Center

NYU Langone Health


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BACKGROUUND

The Perlmutter Cancer Center (PCC) at NYU Langone Health conducts and oversees approximately 475 trials, 30% of which are National Cancer Institute (NCI) cooperative group trials. Data quality and regulatory oversight of cooperative group trials can be challenging due to limited monitoring compared to industry-sponsored trials. Most cooperative trials do not have routine monitoring but instead audits are conducted every 1-3 years depending on the cooperative group and prior audit results. Given the lack of oversight, compliance is a concern and preparation for these infrequent audits can be burdensome. Prior to 2020, Perlmutter Cancer Center (PCC) had an increase in major findings and received an "unacceptable" on one of the audits. Additionally, there was deficiency in timely data entry and resolution. The Clinical Trials Office (CTO) set to establish a better oversight management plan.

GOALS

Overall improvement in quality and timeliness of data entry and regulatory document(s) submissions

Periodic internal monitoring of cooperative group trials.

Implement preventive measures to reduce findings.

Increase oversight of cooperative group trials

SOLUTIONS AND METHODS

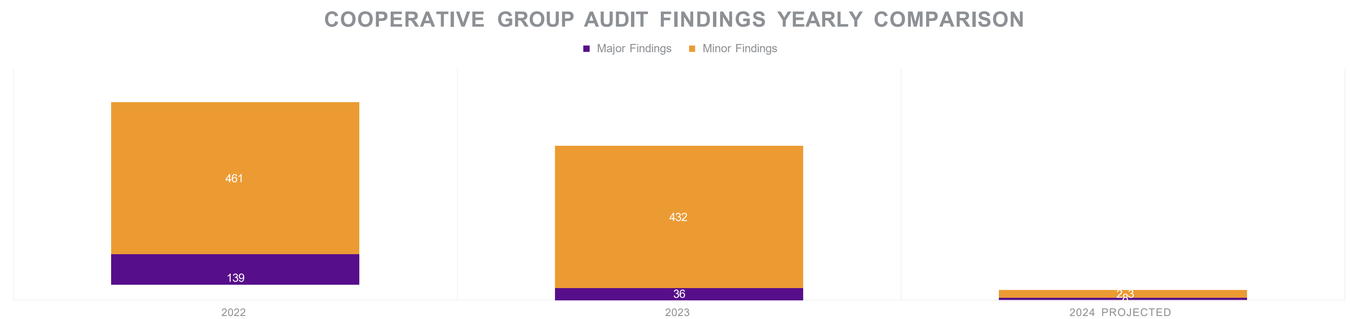
In 2022, the Quality Assurance Unit (QAU) was approved for two new Quality Assurance (QA) Specialists to support quarterly monitoring of cooperative group trials. The QA specialists also confirms the current amendment activated at PCC is up to date and will e-mail the Regulatory team and management if there is a discrepancy.

Regulatory specialists are required to review the Cancer Trials Support Unit (CTSU) every two weeks for amendments and new information and update a tracker. PCC initiated monthly meetings to review all accruals, data, and regulatory activities for all cooperative group trials with any activity at PCC and affiliated sites.

Semi-monthly CTSU Data Delinquency reports are sent to the data coordination unit requesting resolutions/updates.

OUTCOMES

In 2023, there was a 58 % decrease in data delinquency and 79% decrease in regulatory major findings. As a result of the implemented initiatives, there is a decrease in late protocol- related submissions. NYU Langone Health received “Acceptable” reviews on all audits since 2020. Internal auditing has significantly improved regulatory compliance by a decrease of 130 major findings in 2022 to 16 in 2023. Data entry quality and timeliness has improved by 52% due to the bi- monthly CTSU delinquency reports submissions to the data team and monthly meetings. In 2022, NYU Langone Health joined ETCTN, adding another cooperative group to our portfolio, which increased our cooperative group accruals by 100%, from 2020 to 2023, which makes higher compliance even more remarkable. NYU Langone Health was also approved to become an NRG Main Member in 2023 and recently received an ECOG commendation on the 2023 ECOG-ACRIN Institution Evaluation.



LESSONS LEARNED AND FUTURE DIRECTIONS

Increased oversight, including **active monitoring**, is necessary to ensure compliance with cooperative group trials. The addition of cooperative group **QA specialists, monthly meetings and trackers** have been instrumental in our success. Looking ahead, with continued commitment to these workflows, we want to focus on getting our data quality above 90% within query resolution and data accuracy for all our cooperative group trials and continue to decrease regulatory findings.