

Meeting a National Need: Implementing an NCTN Quality Assurance Program

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1. Background

Coordinating Cooperative Group/National Clinical Trials Network (NCTN) studies has long been a challenge for cancer centers as they are typically trials that are not monitored regularly, with only a sampling of subjects audited every three years, routinely. This can be a challenge for data quality and timeliness. The Medical College of Wisconsin (MCW) Cancer Center Clinical Trials Office (CTO) recognized this limitation and began exploring solutions in 2021.

2. Goals

The goals of this work were to improve data timeliness, reduce missing data forms, and educate staff on the expectations of NCTN trials.

3. Solutions and Methods

The solution proposed by the MCW Cancer Center CTO was to introduce a NCTN Quality Assurance (QA) coordinator to focus QA efforts on the goals previously outlined. This QA coordinator runs monthly expectancy reports for all teams; contacts study teams directly about data that is overdue or nearing the due date; and performs QA reviews on the first subject enrolled on all NCTN studies. An NCTN clinical research assistant was also hired in 2022 who can be assigned to work on at-risk data to assist teams with meeting data entry timelines.

4. Outcomes

Since implementing this program, we have seen improvements in Alliance and NRG data timeliness. Our on-time data percentages have improved for Alliance and delinquent data and outstanding query numbers have fallen.

5. Lessons Learned and Future Directions

With new hires always joining the CTO, it is important to continuously convey the importance of quality regardless of the sponsor type. These frequent reminders and internal quality assurance reviews have been valuable learning experiences for staff of all experience levels. An additional hire is being made to the Education and QA team, which will hopefully improve the NCTN QA coordinator's capacity by offsetting other responsibilities that are unrelated to NCTN. We hope to soon have capacity to review more subjects on each study, with a future goal being to review the first subject on each treatment arm at minimum.