Meeting a National Need: Implementing an NCTN Quality Assurance Program

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Background

Cancer centers find coordinating National Clinical Trial Network (NCTN), or "cooperative group", studies challenging because they are not monitored as frequently as their industry counterparts. NCTN trial auditors routinely only examine a sample of subjects from a handful of trials every three years, and this is only if the previous audit was rated acceptable. If rated an unacceptable audit, monitoring increases only to yearly until improvement or suspension occurs. This has proved to be problematic for data quality and timeliness. Factors compounding this issue include the recent advent of COVID. As well as the overall increase in staff turnover and NCTN trial complexity. Combined with a decrease in staff experience exacerbates the situation. Thus, the MCW Cancer Center Clinical Trials Office (CCCTO) began exploring solutions to these issues starting in 2021.

Goals

This initiative began to improve data timeliness, reduce missing data, improve quality and audit outcomes, as well as educate staff involved with NCTN trials on expectations.

Solutions and Methods

MCW CCCTO created an NCTN Quality Assurance (QA) and Education (Ed) Coordinator role to focus on the goals outlined above. The QA/Ed coordinator reviews institutional performance reports (including form/query delinquency) and upcoming data due. They complete bi-weekly team check-ins regarding their overdue data and discuss resolutions. This is for all MCW CCCTO teams involved with NCTN trials, including any affiliate sites. They also perform QA reviews on the first subject and regulatory work on all CCCTO NCTN trials. Meetings modeled after an audit exit interview are held following each review to analyze findings and discuss corrective actions to prepare staff for future audits.

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A floating NCTN Clinical Research Assistant (CRA) was additionally hired in 2022. The CRA addresses overdue and at-risk data to assist teams with meeting data entry timelines.

Outcomes

Since implementing this program, we have seen more stability and improvements in data timeliness overall. Specifically, two NCTN groups, Alliance and NRG, had enough data available for analysis. **Figure 1** details notable improvement regarding on-time data and Institutional Performance Evaluation Committee (IPEC) scores since February 2022. **Figure 2** outlines NRG audit deficiencies prior to and after the implementation of the NCTN QA/Ed Program.

Figure 1. Change in Recent Data Scores

ALLIANCE	Feb 2022	Sept 2022	Dec 2022
Percentage of on-time data	72.60%	82.80%	94%
IPEC Reporting Period Score	87.60%	89.10%	91.70%

NRG	Dec 2018	Jul 2022
Delinquent Data	12.60%	1.30%
Outstanding Queries	2.50%	0.30%

Lessons Learned

With new staff regularly joining the CCCTO, it is important to continuously convey the importance of quality data regardless of the sponsor type. These frequent reminders and internal quality assurance reviews have been valuable learning experiences for staff of all experience levels. Teams have become accustomed to receiving monthly expectancy reports and responding to them, just as they would typically do for an industry sponsor.

Figure 2. Audit Findings before and after implementation of NCTN Quality Assurance Program

NRG	(Routine audit) 2019	(Reg Reaudit) 2020	(Routine audit) 2022
Major Deficiencies	**12**	**0**	**1**
-Regulatory	(10)	(0)	(1)
-Patient Cases	(1)	N/A	(0)
-Pharmacy	(1)	N/A	(0)
Lesser Deficiencies	**2**	**4**	**3**
Regulatory	(1)	(4)	(0)
Patient Cases	(1)	N/A	(3)
Pharmacy	(0)	N/A	(0)

All of the factors that may have contributed to the improvements in the NRG audit outcomes from 2019 to 2022 are not entirely clear yet. We presume it is multifactorial. The NCTN QA Program, increased staff education, and mentorship from experienced staff all contributed to this success. The NCTN QA/Ed Coordinator has a presence at twice annual NCTN Lead Protocol Organization (LPO) group meetings and also serves on the Alliance Clinical Research Professionals (CRP) and Research Operations Initiative (ROI) committees. The latter of which is multi-institutional nationwide and focuses solely on reducing sites burden with NCTN trials. Updates from these meetings are regularly shared with staff.

Future Directions

The MCW Cancer Center CTO Education and Quality Assurance Team established and filled another role to expand the NCTN Quality Assurance coordinator's capacity by offsetting other unrelated responsibilities. We hope to soon have capacity to review additional subjects on each NCTN trial, with a future goal to review the first subject on each treatment arm at minimum.

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