

National Clinical Trials Network Team Creation, Imagination, and Innovation

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1. Background

The quality of National Clinical Trials Network (NCTN) research relies heavily on protocol compliance, timely and accurate data and specimen submissions, and participant management. While quality assurance programs for routine monitoring exist for NCTN trials, there is a large gap in time between audit visits. In 2021, the Karmanos Cancer Institute (KCI), Clinical Trials Office (CTO) developed a dedicated NCTN team to oversee long-term/survival follow-up patients and ensure adherence to NCTN network group requirements.

2. Goals

- Oversee long-term/survival follow-up patients to ensure data integrity and continuity of care
- Track Institutional Performance Review (IPR) standards to promote consistent site compliance
- Facilitate submission of required documentation including expected forms, data, specimens, and query resolution
- Conduct peer-reviews to support continuous quality assurance and maintain compliance readiness

3. Solutions and Methods

To achieve these goals, the NCTN implemented several structured workflows and quality assurance strategies:

- Vital status for participants lost to follow-up workflow (May 2021) including a partnership with the epidemiology resource core at Wayne State University to leverage the metropolitan Detroit cancer surveillance system for monthly survival status updates
- Monthly institutional performance review (IPR) monitoring (June 2022) and communication to staff regarding site score, outstanding/delinquent forms, specimens, and query submissions
- NCTN study or participant(s) transition workflow (January 2023) to allow transition of long-term/survival follow-up patients for continued management
- NCTN initial form set (IFS) submission workflow (September 2023) was created as a corrective and preventative action plan following an audit finding, including a structured 30-, 60-, and 75-day reminder system and baseline specimen submission verification
- NCTN peer-review process (April 2024) designed to enhance collaborative quality oversight
- Creation of a shared email address to streamline communication such as best practices for Southwest Cancer Chemotherapy Study Group (SWOG) Studies updates, specimen system tracking guide, and data manager contact information, and expedite the resolution of NCTN-specific operational barriers

4. Outcomes

These interventions have resulted in a sustained increase in network performance. Notably, over a one-year period, our NRG Oncology network assessment improved from 88.03 percent to 92.19 percent in June 2023. As of January 2026, KCI maintains a strong performance rating of 93.75 percent. The NCTN team now manages more than 20 trials involving over 100 long-term/survival follow-up patients.

Our commitment to quality assurance is supported by our IFS workflow and internal peer-review process, which has ensured more than 60 IFS timely submissions and baseline specimen verifications and 61 completed peer-reviews to date.

5. Lessons Learned and Future Directions

Implementation of a dedicated NCTN steering committee team at KCI has been instrumental in establishing various Standard Operating Procedures (SOPs), workflows, and processes to foster protocol compliance across NCTN trials. Despite these advancements, challenges remain regarding competing SC priorities, the persistence of previously submitted data on the IPR reports, and the classification of peer-review findings as formal audit observations which, fail to acknowledge previously addressed deficiencies and timing of when the peer-review occurred.

Moving forward, KCI remains committed to cross-functional collaboration and enhanced communication with NCTN groups to improve IPR accuracy. Since September 2025, the NCTN team has implemented proactive internal reminders for upcoming expected data submissions and source document uploads. The NCTN team will utilize peer-review data to monitor performance trends and implement targeted interventions to mitigate common and recurring compliance issues. Additionally, we plan to coordinate with other NCTN teams two times per year at various cancer centers within the United States to brainstorm ideas to improve together as a team.