Category: Clinical Trial Operations – Completed Project

Metropolitan Management of Mitten-wide Clinical Trials: Coordination From Our Own Backyard

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1. Background

Karmanos Cancer Institute (KCI) merged with McLaren Healthcare Corporation to become Michigan's largest cancer care and research network aiming to increase access to transformative cancer care in communities throughout the state. The KCI Clinical Trials Office (CTO), based in Detroit, was tasked with developing and standardizing policies and procedures for conducting research across the subsidiaries, including patient enrollment, study coordination, and data management. To streamline training and operations, we developed a central data management (CDM) plan.

2. Goals

- Increase feasibility of clinical trial operations across the state
- Implement the research nurse role at each subsidiary to improve protocol compliance and data quality, based on KCI-Detroit model
- Centralize study coordination and data management to ensure data integrity across all sites and studies
- Expand the reach and responsibilities of CTO staff to ensure efficient utilization of current resources
- Facilitate the increase in industry, cooperative group, and investigator-initiated trial accruals

3. Solutions and Methods

- Constructed a comprehensive, step-by-step guide to CDM tasks (e.g., consenting process, patient eligibility, protocol deviations, serious adverse events, etc.)
- Developed process document to differentiate between the responsibilities of the research nurse at each network site and study coordinator at KCI-Detroit
- Dedicated a shared drive to CDM studies to securely and expeditiously transmit study-related documents
- Added a CDM module to the CTO New Employee Orientation program, mandatory for the onboarding of all KCI research staff
- Established a collaborative focus group, consisting of KCI-Detroit study coordinators and network staff, to regularly review CDM processes and procedures, and revise accordingly.

4. Outcomes

Since the integration, the CTO has seen an increase in network accruals by ~500%, while utilizing the SCs at KCI-Detroit to manage network data collection and entry. This is the foundation of CDM, which has reduced discrepancies and error in data entry, retention, and management.
With the implementation of CDM, KCI-Detroit has seen a positive outcome by way of same-day communication of patient consents and study visits at network sites; instantaneous record-sharing

through the shared drive and electronic health records (EHR); and a new role for network research nurses to facilitate the onboarding of patients to clinical trials.

The CDM focus group meets monthly to discuss workflows and challenges in real time. These meetings provide a forum to identify problems and collaboratively work on solutions, as well as foster open discussions to prevent barriers.

5. Lessons Learned

One of the biggest hurdles in implementing the CDM process was navigating multiple EHRs at the different network sites. As this is a common problem in healthcare in general, KCI is working toward utilizing one standardized EHR software, accessible by all staff at all sites. This will improve the continuum of care for our patients as they seek to remain within the KCI network for their care, while simultaneously expediting the efficiency of CDM by storing true source in one internally universal, safe, electronic location.

As the landscape of oncology research evolves, we will continue to ensure our practices provide outstanding support to clinical trials with the goal of improving cancer therapy and patient quality of life through research.