Category: Clinical Trial Operations – Work in Progress

Structured Collaboration With Clinical Partners to Enhance Research Participant Safety and Experience Along With Protocol Compliance and Expeditious Trial Activation

S. Willoughby, C. Davis

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

1. Background

Excellence in professional collaboration between trials office and clinical staff is essential to patient safety and experience, protocol compliance, and rapid trial activation. With burgeoning cellular therapy trials in both hematological and solid tumor malignancies, along with increasing needs for inpatient care and monitoring for participants in complex Phase I trials, previous collaborative practices between the clinical trials office (CTO) and clinical areas became inadequate. In addition, our cancer center is embedded in a matrix of health system, hospital, medical group, and medical school/university. The cancer center CTO is situated within the medical school/university, and the clinical areas where trial participants receive treatment are distributed among the other entities. Key cross-entity leadership partnered to create tools and processes supporting evolving needs. These included improved communication, reciprocal process knowledge and transparency, a shared vocabulary for clinical and research staff, and clarification of ownership of discrete responsibilities.

2. Goals

The project goal was to enhance and expedite operational and patient care planning for clinical trials, as measured by decreased trial activation time. To maintain research and patient care quality, the project team also focused on protocol compliance and excellence in patient safety and experience.

3. Solutions and Methods

- Identified key stakeholders and defined their scope of responsibility from the time of trial activation through first patient treatment and team debrief
- Outlined the trial activation process to ensure transparency and appropriate sequencing of study start up tasks, creating a shared language to facilitate understanding between research and clinical staff
- Initiated a monthly meeting of key stakeholders to address gaps in current process, providing a forum to discuss feasibility, concerns, and process improvements; currently, the project team is engaged in exploring ways to improve the feasibility assessment process
- Developed support resources including a process map, job aids, reference documents, contact lists, communication templates, and upcoming trials lists

4. Outcomes

Solutions have been implemented and processes are being refined. Informal surveys indicate improved cross-entity relationships and awareness of upcoming clinical trials and their status. Improvement is expected in the following outcome metrics, which will be measured approximately 1-year post implementation:

- Trial activation time

- Clinical trials engagement survey

5. Lessons Learned

The following were vital to success of the project:

- Leadership engagement at the director level
- Early identification and involvement of key stakeholders to promote and support team engagement and change management
- Involvement of clinical staff, particularly education coordinators and charge nurses, in feasibility assessment and operational planning
- Definition of scope of responsibility across entities and development of a common language to communicate about clinical trials
- Supportive communication structures and resources, such as regular meetings, contacts and trials lists, job aids, and process maps
    - Initial project scope included cellular therapy trials managed by the cancer center CTO
    - Future plans include expanding to other complex clinical trials, within and outside the scope of the CTO