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

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Team Members:
Clinical Trials Office Study Start Up, Feasibility, and Clinical Operations Managers
Clinical Operations and Patient Care, Cell Therapy Lab, and Apheresis Center Leadership

Northwestern Medicine®

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

BACKGROUND

Problem Statement

Since 2016, when the first 2 CAR-T trials opened at NM, over 15 diverse cellular therapy trials have opened, with many more in the start-up process, and over 62 patients have been treated on CAR-T trials alone. Existent collaborative practices between the Cancer Center Clinical Trials Office (CTO) and clinical areas were strained to meet the evolving cellular therapy trial landscape due to:

- The sheer number of patients and trials, as well as novel therapeutics with unfamiliar and potentially life-threatening toxicities.
- Increasing needs for apheresis, cell lab, and inpatient care and monitoring for participants, along with the need for complex coordination between all of these areas and the CTO.
- Matrixed organizational structure, with the CTO situated within the medical school/university and the clinical areas where trial participants receive treatment distributed between the hospital, medical group, and other health system entities.

Project Goal

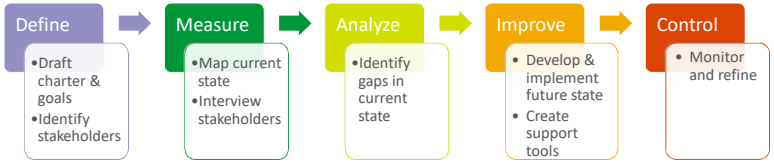
Enhance and expedite operational and patient care planning for clinical trials, while also maintaining research and patient care quality.

Outcome Metrics	• Trial activation time • Staff engagement
Supporting Tools and Resources	• Improved communication channels • Reciprocal process knowledge and transparency • Shared vocabulary for clinical and research staff • Clarification of ownership of discreet responsibilities
Key Deliverable	• Future state process map

METHODS

Methodology

The project leaders used the DMAIC methodology to complete the project.

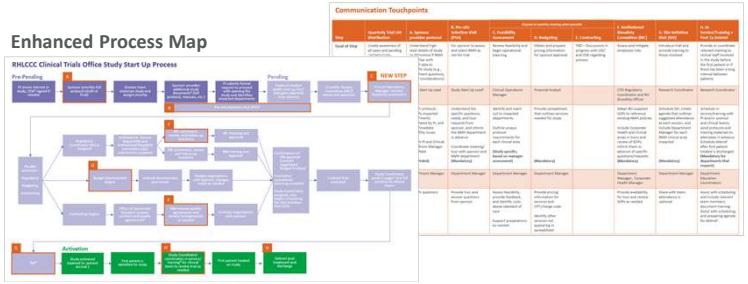


Process Enhancement

Key deliverables involved enhancing the current process to:

- Clearly identify key stakeholders and their scope of responsibility, from time of trial start-up fee approval through activation, to first patient treatment and team debrief
- Ensure transparency and appropriate sequencing of study start-up tasks
- Outline communication steps and contacts, and create a shared language to facilitate understanding between research and clinical staff

Enhanced Process Map



Supporting Tools and Resources

To implement and sustain the new process, the team created tools and resources, such as:

- Monthly standing meeting to discuss upcoming trials, feasibility concerns, and process improvements
- Current and upcoming trials list
- Reference documents and checklists
- Communication templates

Open Immune Effector & Cellular Therapy Clinical Trials

Trial Name [Trial number to search NOTIS]	Sponsor	Investigational Product	Indication/Design	Principal Investigator	Clinical Trials Office (CTO) Contact[1]
AAAAA	bbbbb	ccccc	Ph I in R/R AML	Dr. AK	Research RN Name Contact Info

RESULTS

Solutions were implemented and are being refined. Informal surveys indicate improved cross-entity relationships and awareness of upcoming clinical trials and their status.

Outcome metrics will be measured 1 year post implementation

Trial activation time ↓

CTO & Clinical Staff Engagement ↑

Spotlight on Communication

While the main project deliverable was the process map, the most visible improvement is in the partnership between the CTO and clinical teams.

With better forums and structures for communication, clear ownership and discreet responsibilities, plus focused agendas, the team has developed trust and been more effective than ever before in communication.

CONCLUSIONS

Keys to Success

- Leadership engagement at the director level
- Early identification and involvement of key stakeholders to promote and support team engagement and change management
- Clinical staff, particularly education coordinators and charge nurses, involvement 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

Future Directions

- Outcome metrics will be measured 1 year post implementation
- 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.

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