Category: Trial Start-up and Activation – Completed Project

Redefining Clinical Trial Start-up Through Continuous Improvement

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1. Background

Clinical trial start up is a multifaceted process that occurs across a diversity of disciplines. Health systems must support caregivers by providing the appropriate tools, resources and training to promote timely execution of study activation. Eliminating bottlenecks in the activation process is critical to opening new studies quickly and efficiently and to providing patients the best possible treatment options. The objective of this project was to identify barriers within the current state activation process; then create new processes, tools, standards and trainings for an ideal state; and finally implement a future state workflow designed to reduce the total time to open a clinical trial.

2. Goals

A new activation target of 90 days (median) for all trial types, represents a 49% reduction from the baseline target of 175 days. A committee of 15-20 multidisciplinary research staff functioned as change agents and met bi-weekly for project updates, ideation and discussion. The project sponsor, owners and project manager collaborated with the committee to create a portfolio of 10-15 sub-projects with 90 day deadlines. These sub-projects addressed risks and concerns of the new activation process. A diagram aligned sub-projects to stakeholder feedback and monthly departmental meetings of 100+ research staff provided a platform for project updates and discussion.

3. Solutions and Methods

The project was completed in three phases. Phase one utilized value stream mapping to identify current workflows and highlight waste, processing time and lead time. Phase two replaced the current linear workflow with three new workflows, one for each clinical trial type: Cooperative Group, Industry Sponsored and Investigator Initiated. These workflows were given new timelines of 60, 90 and 150 days, respectively. Phase three involved the collection of feedback across the research department. Means of data collection included Crawford Slip Methodology, informal surveys, 1:1 meetings, team rounding, department meetings and a Kaizen event for new process roll out.

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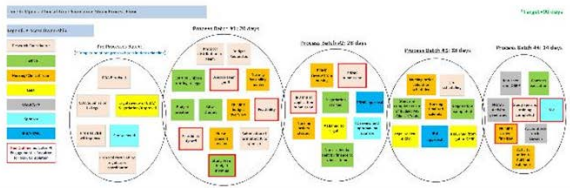
Pre Implementation

Post Implementation



4. Outcomes

Results after the soft launch (Q3, 2019) showed a reduction to 178 days for the quarter, down from 210 days at baseline (Q1, 2019), a 15% decrease when comparing Q1 to Q3. Results after the full launch (Q4, 2019) showed a reduction to 150 days for the quarter, showing a near 29% reduction from baseline when comparing Q1 to Q4. The raw number of clinical trials that were activated in ≤ 90 days grew by 200% after full launch.

5. Lessons Learned

At the Cleveland Clinic Taussig Cancer Institute improving clinical trial start up is a balance of meeting sponsor expectations, remaining competitive with comparable cancer centers and evaluating the internal needs of our stakeholders. The process of reaching an ideal state is iterative. Although the project is completed, we will continue to phase through the Plan Do Check Act cycle to evaluate gaps. Key components of the future strategy include 1) establishing a dedicated start up team 2) developing a rewards and recognition system for meeting or exceeding targets 3) using clinical trial schemas to focus on gaps within disease groups 4) evaluating predictive tools for clinical trial accrual.