Category: Trial Start-up and Activation – Work in Progress

Improving Trial Activation Timelines: A Comprehensive Process Improvement Project

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1. Background

Clinical trial activation at a matrix cancer center requires complex processes involving multiple stakeholders, including the university, the hospital, sponsors, and departments. The median trial activation time in 2021 at Sylvester was 226 calendar days, which exceeds our target of 90 calendar days. To reverse the trajectory and examine the trial activation process, Sylvester initiated a Lean Six Sigma process improvement project. Lean Six Sigma methodology focuses on improving performance by systematically minimizing waste and improving flow across processes.

2. Goals

The overall goal is to reduce Sylvester's trial activation time to a median of fewer than 90 calendar days, which represents a 48 percent reduction from our 2021 median.

3. Solutions and Methods

The project is being completed in five phases:

1. Define: Current state
2. Measure: Baseline and timeline
3. Analyze: Pain points and root cause analyses
4. Improve: Action plans and project portfolio, followed by implementation
5. Control: Progress reports

The deliverable of the first two phases was a value stream map (VSM), which provides a holistic view of our current state process by visualizing the movement of a trial from start to finish. Based on the analysis of the current state performance metrics, we identified multiple focus areas for the root cause analysis (RCA) phase.

We met with subject matter experts (SMEs) from numerous departments to conduct the RCA and identify pain points. We used process improvement tools such as brainstorming, multi-voting, and the Five Whys to guide the SMEs through the analysis.

The root causes identified were used as a vehicle to collect improvement ideas, which were then analyzed and scored on impact and effort. The results of the impact-effort analysis were displayed in a matrix that differentiates potential solutions that have high impact and require low effort ("quick wins"), those with high impact but high effort ("major projects"), and those with low impact and high effort ("not worth doing").

4. Outcomes

The VSM visualized our current state, which involves 44 main processes that are divided into 13 process blocks across the trial activation process. The improvement ideas collected showed distinctive patterns in the suggestions submitted to the project team. Improvements in communication, training, and standard operating procedures (SOPs)/workflow made up more than 50 percent of all suggestions across the focus areas.

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The impact-effort analysis of potential solutions for the activation checklist revealed eight "major projects" and three "quick wins" that will have a high impact on the time required to complete the activation checklist. The potential solutions categorized as "quick wins" were:

1. Creation of task lists per team for checklist processes
2. Weekly meetings with all teams involved in the checklist to discuss handoffs
3. Monthly meetings to increase awareness of responsibilities of each team member in the process

5. Lessons Learned and Future Directions

Sylvester plans to continue its process improvement efforts with the implementation of projects that are categorized as quick wins in the Impact-Effort Matrix. This implementation will use the Plan-Do-Check-Act approach to stimulate continuous improvement of trial activation processes with the goal of reducing trial activation time to a median of 90 calendar days.

Figure: