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

Value Stream Mapping: Maximizing Value, Minimizing Waste, and Improving Flow Across the Clinical Trial Activation Process

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1. Background

Trial activation is an inherently complex process. At a matrix cancer center, this process is further complicated by the requisite participation of various institutional, administrative, and departmental representatives across the university, resulting in numerous inefficiencies and delays. In 2021, the median activation time at Sylvester was significantly more than our target of 90 calendar days. To address the discrepancy, we utilized Value Stream Maps (VSM), a Lean Six Sigma tool, that provides a holistic perspective of the workflow. VSMs enable strategic improvements, as opposed to tactical solutions, by depicting both macro and micro perspectives of process steps and information flow. We also expect to realize future process improvements to maximize value, minimize waste, and improve flow across the process.

2. Goals

We aim to reduce the median trial activation time to our target of 90 calendar days. To be successful, we needed to understand the current state by establishing a baseline with associated timeline. The VSM follows one industry-sponsored interventional treatment trial from the time the study is assigned to a PRMC meeting until it is open to accrual. Additionally, we used the VSM to identify current state metrics for each process step.

3. Solutions and Methods

A VSM provides a visualization of how work, products, and information flow through a system. The key components of our VSM are to focus on the principal investigators as our customer, link processes with information flow, document process performance, establish a common language, provide a blueprint for improvement, and engage stakeholders.

Through this process, we identified waste and bottlenecks, and analyzed data attributes specific to the VSM, including process time (time it takes to complete process tasks uninterrupted), lead time (time it takes to complete work including process time and delays), activity ratio (how quickly work flows through the process), percent complete and accurate (probability of a trial making it through the entire process without rework). Detailed metrics were collected for each process step to measure performance from an enterprise perspective. The map also depicts the software applications each process block interfaces with; whether they are being used to store data, input data, or produce outputs; and whether they communicate with each other.

4. Outcomes

We performed a bottleneck analysis of the current state VSM to identify waste in the process.

The macro perspective of our current state indicates that only 7.3 percent of our overall process is value-added activity. The map identified 13 applications required to complete the activation process. Most processes involve manual information flow with a disproportionate use of email and Box communication.

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The micro perspective revealed the following three focus areas that significantly impact the overall activation timeline:

1. Trial activation checklist: Most dedicated effort (19 business hours), with only one FTE dedicated to the step
2. Delegation log: Longest lead time of 321 business hours due to the number of signatures required
3. IRB submission: 100 percent of submissions must be reworked

5. Lessons Learned and Future Directions

Sylvester plans to continue its process improvement efforts for the focus areas by implementing projects to reduce waste and improve process flow.