Improving Protocol Activation Times via Automation and Centralization

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Efficient and timely protocol activation is one of the greatest opportunities for process improvement at Sylvester in preparation for the Cancer Center Support Grant (CCSG) submission. Protocol activation timelines are beyond the National Cancer Institute (NCI) goal time of 90 days with no formal process for tracking metrics or identifying roadblocks. This study describes methodologies implemented to provide real time protocol tracking with the goal of improving activation timelines.

- Improve protocol activation time to a median of less than 120 days
- Create a process flow for each protocol Sponsor Group
- Automated notification when a trial exceeds predefined time period during any step towards activation
- Root cause analysis of protocol activation delays
- Address identified delay points in the protocol review and activation process

- Create a Clinical Trials Activation Analyst (CTAA) position (07/2016)
- Identify major and minor activation milestones (09/2016)
- Establish activation milestone timelines (09/2016)
- Develop a Protocol Activation Process Flow (09/2016) *Refer to Diagram #1
- Collaborate with Informatics Department to develop a web-based milestone tracking system that generates automated alerts when milestones exceed the allotted time (09/2016) *Refer to Diagram #2
- Establish a Feasibility Review Committee (FRC) (09/2016)
- Implement a Regulatory Department Study Start-Up unit (12/2016)
- Analyze protocol activation metrics with Senior Leadership bi-monthly (12/2016)
- Develop a partnership with the University Institutional Review Board (12/2016), Office of Research Administration (4/2016), and Biosafety Committee (4/2016)

Analysis of quarterly data demonstrates a positive trend in median activation times. The data set includes activated interventional trials submitted to PRMC within the quarterly period using median calendar days.

Methodology

Objectives

Results

Diagram #1: Protocol Activation Process Flow

Diagram #2: Protocol Activation Tracking System

Conclusions

The protocol activation tracking tool was initiated over several months with various delays and challenges including a hiring freeze, and partnership department personnel being re-assigned other priorities related to the CCSG submission. Subsequently the project is still in implementation phase and it is too early to draw definitive conclusions. However, early data-sets indicate that the focus on improving protocol activation and the strategic initiatives, new processes and new hires has made a positive impact. We anticipate the number of median calendar days from PRMC submission to activation decreasing markedly over the next 6 months as the automation and centralization becomes fully functional and adopted by the entire Clinical Research Enterprise.