Abstract Title: Improving Protocol Activation Times via Automation and Centralization

Author(s): Helen Peck, RN, MA, OCN, CCRP; Andrew Nilson, BHA; Simmy Thompson, MPH, CIP, CCRP; Rizalia Rivera Cvijovic, BA; Michael A Samuels, MD; Jonathan Trent, MD, Ph.D

Cancer Center Name: Sylvester Comprehensive Cancer Center, University of Miami, FL

Describe the background of the problem:
Efficient and timely protocol activation is one of the greatest opportunities for process improvement at Sylvester Comprehensive Cancer Center (SCCC) in preparation for the cancer center support grant (CCSG) submission. Protocol activation timelines are beyond the NCI goal 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 decreasing activation times.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:
1. Improve protocol activation time to a median of less than 120 days
2. Automated notification when a trial exceeds predefined time period during any step towards activation
3. Root cause analysis of protocol activation delays

Describe the solutions or methods implemented:
1. The Clinical Trials Activation Analyst (CTAA) was hired in July 2016.
4. Study Start-Up team (providing specialized expertise in PRMC and IRB submission) was established in December 2016.
5. A web-based tracking tool was developed in conjunction with Informatics; automatic alerts are generated when a protocol exceeds the allotted milestone timeframe. Tracking tool data input from January 1st 2017.
6. Protocol activation metrics analyzed every 2 weeks by Clinical Research Leadership, activation delays identified and corrective action plans implemented.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative:
Although the project is in early phase implementation a positive trend in median protocol activation times are indicated:
CY2016 Q4: (21 protocols) Pre protocol activation tracking: 206 calendar days (median)
CY2017 Q1 (22 protocols): 164 calendar days (median)
CY2017 Q2: To be reported at meeting

The FRC review allows all stakeholders to participate in new protocol evaluation prior to PRMC review, ensuring that operational challenges are identified and addressed prior to IRB approval or SIV. This has eliminated the delays due to issues previously identified after IRB approval (usually at the SIV) which have delayed protocol activation. The CTAA position has been instrumental in detecting specific and actual delays, some of these not previously identified. The automated tracking tool e-mail alerts identify in real time, the actual (rather than perceived) etiology of delays in activation and thus individual trial delays are addressed rapidly and systematic improvement processes can be implemented expeditiously. Close frequent review of metrics by clinical research leadership has ensured protocol activation problems consistently receive priority attention.
Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome:
The protocol activation tracking tool project incorporated several initiatives, new hires, new processes and
involved multiple departments and stakeholders. The project was implemented 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. Implementation of the individual initiatives might
have been more efficient if individuals and departments had received more preparation and education prior to
project initiation. Appointing a project leader to manage the entire plan would have been strategic.

Figure 1: Activation Milestones