2018 AACI CRI Meeting Abstract Submission

Abstract Title: Improving Study Activation Timelines Using a Workflow Management Approach

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Describe the background of the problem:
Decreasing study activation timelines is a perpetual holy grail of research organizations. The Laura and Isaac Perlmutter Cancer Center's (PCC) Clinical Trials Office (CTO) at NYU has implemented a novel approach to reducing time to activation (defined as the time from PRMC submission to the date a study is opened to enrollment) to 100 days or less for interventional treatment trials and 45 days or less for National Cooperative Group trials.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:
Reduce study activation time and increase satisfaction of CTO staff and PCC faculty by:

- Providing real-time visibility into the study activation pipeline;
- Managing work-in-progress via defined targets;
- Reducing variability in study activation processes;
- Optimizing CTO resource allocation based on study prioritization.

Describe the solutions or methods implemented:
The CTO combined a task management system (Jira Core) with a workflow management approach (Kanban) for tracking and managing the tasks required to activate a study. The processes by which studies are activated were documented in use cases, tasks and workflows were modeled within a system (Jira Core), and CTO staff were trained on utilizing workflow management techniques (Kanban). The new approach was launched on Apr 3rd, 2017 and has been in use for all interventional studies since.

Baseline metrics prior to 2017 were established for study activation timelines. Survey data was collected pre- and post-launch of the new approach to capture CTO staff and investigator satisfaction with the study activation process.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative:

- Decreased time to study activation by 26%. Activation timelines dropped from an average of 140 days prior to implementation to 104 days afterwards;
- Increased overall satisfaction with study activation services provided by the CTO. Staff satisfaction increased by 20% and investigator satisfaction increased by 15%;
- Decreased time CTO staff spend reporting status and shifted focus to monitoring upcoming work and resolving exceptions (e.g., process bottlenecks, stalled tasks, overdue tasks and studies);

- Reduced variability in study activation timelines from a standard deviation of 66 days prior to implementation to 52 days afterwards (21% reduction);
- All tasks and associated workflows are codified in the system thereby enforcing standardization of activation processes;
- Study start up staff workload is now monitored systematically via reports and dashboards.

Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome:

- Utilizing workflow management techniques (i.e., limiting work-in-progress) to monitor and control the flow of work through the CTO resulted in decreased study activation timelines, reduced variability, better resource management, and greater overall satisfaction with the process;
- Variables outside of the CTO's control (sponsor response time with contract negotiations, response time of internal service providers and investigators) remain barriers to decreasing study activation timelines. Formalized internal escalation processes and more master contract agreements with industry sponsors are needed to control for these variables;
- Increases in concurrent work-in-progress seem to have a negative impact on study activation timelines; data continues to be collected to further evaluate this correlation and ultimately define appropriate work-in-progress limits;
- Utilization of the NCI's CIRB for National Cooperative Group trials does not seem to have a positive impact on time to study activation. Further evaluation is needed to determine how to decrease time to study activation of these trials below 90 days.