Abstract Title: Improving Study Activation Timelines: Establishing Flow

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Describe the background of the problem:

Along with increasing participation in cancer clinical trials, decreasing study activation timelines is a perpetual holy grail of clinical trial operations organizations. The Laura and Isaac Perlmutter Cancer Center (PCC) has launched a pilot program to drive down time to activation (defined as the date of PRMC submission to the date a study opened to enrollment) to 100 days or less, and 45 days or less for cooperative group studies.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:

- Increase visibility into the study activation pipeline;
- Create a continuous and sustainable flow of studies through the Clinical Trial Operations (CTO) pipeline by limiting Work-in-Progress (WIP);
- Establish a consistent activation time of 100 days or less, and 45 days or less for cooperative group trials;
- Establish real time metrics on time to activation both overall and by sponsorship type and clinical research category;
- Real time alerts to CTO leadership on bottlenecks negatively impacting time to activation.

Describe the solutions or methods implemented:

The PCC combined a Workflow Management system and approach (Kanban) for tracking and managing the various tasks required to activate a study. Over a 13-week period, the processes by which interventional treatment trials are activated, by sponsorship type, (Industry, Institutional, National, Externally Peer-Reviewed) were documented in Use Cases, the tasks and workflows were modeled within a system, and CTO staff were trained on the new approach for managing the study activation process. The pilot was launched on Apr 3rd, 2017.

Initial baseline metrics were established for current study activation timelines (~140 days) which will serve as the baseline comparison at the end of the 5-month pilot period. Additionally, survey data on attitudes toward study activation services provided by the CTO were collected from both CTO staff and external customers (Principal Investigators) to assess the quality and effectiveness of the study activation service provided by CTO. Post pilot surveys will be collected for comparison at the end of the pilot period.

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

The pilot launched on Apr 3rd, 2017 and is only just beginning to collect data for evaluation. It is expected that there will be a period of time when studies that are currently in the activation pipeline will need to complete the activation process before a clean set of data is available for comparison. However, preliminary subjective results are already being observed including:

- Real-time access to study activation status;
- Increased collaboration internally within the CTO and externally with institutional service providers;
- Identification of bottlenecks in the process resulting in potential process enhancements;
- Establishment of Service Level Expectations (SLEs) at both the task and study level resulting in a more disciplined approach to managing and monitoring the completion of work;
- ~ 50% decrease in time spent in weekly pipeline meetings.

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

To date there has been a limited amount of information to assess lessons learned or potential changes to the methods employed to initiate the pilot. However, expanding the pilot to include other institutional service providers and Principal Investigators is already being planned. Lastly, consideration is being given to possibly expanding the use of the system and process for non-interventional trials.