Category: Trial Start Up/Closure – Work in Progress

Empowering Study Teams to Improve Clinical Trial Activation Timelines

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1. Background

In 2016, the Yale School of Medicine and Yale Cancer Center (YCC) identified clinical trial activation timelines as a strategic improvement opportunity. The intended goal of improving activation timelines is to advance medical care and research, to enhance Yale's position as a competitive Medical School and Comprehensive Cancer Center, and to ultimately improve patient access to clinical trials within the Yale Medicine network. An initial activation analysis was conducted which included input from more than 100 stakeholders. The analysis resulted in the identification of 43 areas for improvement and the creation of the Protocol Activation Cycle Empowerment (PACE) project. A pilot of all YCC trials opened since December 2017 have utilized this strategy-driven business process.

2. Goals

The overall goal of the PACE project is to improve timelines so that clinical trial activation occurs within 90 calendar days. The PACE team identified 13 sub-processes that play a key role in activating a new clinical trials and developed OnCore Task Lists for each sub-process. Currently, the PACE team is working with a designated owner for each sub-process to identify the tasks that start and end their sub-process, to identify co-dependencies with other sub-processes, and to review actual and target durations for their sub-process.

In addition to individual sub-process timelines, PACE also monitors the overall time to activation for each protocol from the date that feasibility is complete and from the date of Protocol Review Committee (PRC) submission. The target durations for study activation range from 55 to 130 calendar days, depending on the Institutional Review Board (IRB) of record and the type of contract agreement. Clinical trials that utilize an external, commercial IRB and pre-negotiated Master Agreement language are assigned shorter target durations compared to trials utilizing new contract language.

3. Solutions and Methods

To date, the PACE team has developed and implemented new activation task lists for each sub-process, developed data definitions for each task field, implemented several communication strategies to relay activation metrics to stakeholders, and held meetings with sub-process owners, regulatory managers, and disease-aligned study teams to ensure a bidirectional flow of information. These efforts have resulted in a coordinated approach to study activation with an eye on efficiency and process improvement.

4. Outcomes and Future Directions

There was a notable decrease in activation timelines since the initiation of PACE. Metrics show that between 2017 and 2018 the overall clinical trial activation timelines were decreased by 30 calendar days.

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The PACE project is an ongoing endeavor which continues to evolve based on the data trends. As the project matures, the data will more fully demonstrate how implementation of PACE initiatives impacts study activation. PACE is actively working with sub-process owners and disease teams to identify and address additional areas for improvement.