Category: Trial Start-up and Activation – Work In Progress

Clinical Trials Time to Activation: The Process, Structure, and People

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1. Background

The accessibility of unique clinical trials attracts new patients to the institution, leading to higher accrual numbers, and better patient access to new, novel agents. However, activating clinical trials in large academic institutions, such as UAB, is a long, arduous, and costly process. This process involves communication and collaboration between many stakeholders across numerous departments. Consequently, many trials do not open soon enough to accrue patients at an optimal rate or the trial closes nationally by the sponsor as soon as it becomes active, leading to loss of time and effort, and a negative financial impact. We aimed to perform a preliminary analysis to describe trials activation process at UABCCC, as well as identify the length of time that a new trial takes to become activated, and determine the rate limiting steps and processes.

2. Goals

We mapped the current operational/administrative process for activation in our Cancer Center. Using the dates available for industry sponsored protocols activated between 2016 and 2019, the number of days to complete each step in the activation process was calculated. The length of Time to Activation will be compared from 2016 to 2019, and after 2019, with the introduction of new administrative processes.

3. Solutions and Methods

In recognition of the higher TTA at UAB, a new SOP was established that included a new process that protocols would be concurrently submitted to PRC, Budget, and Regulatory. There was also the introduction of distinct trial navigators for all disease groups across the cancer center.

4. Outcomes

Our retrospective analysis showed that, overall, the median complete activation process from WG approval to conducting the study initiation visit (SIV) takes 311 days. However, it took a median and average time of 188.5, and 196.8 days, respectively, from Protocol Review Committee review to SIV during the same time period. The median time it took from PRC approval to completing all administrative submissions (FAP, Budget, OSP, IRB, WIRB) was 149.5 days, and the review process from administrative submission to approval was 35 days. Finally, the median time from Contract Execution to SIV was 21 days. From 2016 to 2017 and 2017 to 2018, there has been an increase in total time to activation each year, by 17.1% and 13.5%, respectively.

5. Lessons Learned

Though the overall process of trial activation is long, there are external factors that influence the first part of the trajectory (CDA receipt, regulatory documents receipt, feasibility assessments by the sponsors, etc.). Since availability of regulatory package is the time when all essential documents

required for activation are available, defining the starting point of activation is critical, and the NCI has recommended the PRC review to be the best proxy for the start of activation. This study should provide the framework for future studies, to better understand each process in the activation process, and the current system gaps to re-engineer workflows to improve time to activation. The new process implemented will take time to create a positive impact on TTA, but the investigator satisfaction and communication between the departments has increased, to improve the process flow.