Category: Trial Start-up, Activation, and Protocol Development – Work in Progress

Maximizing Efficiency in Managing the Trial Activation Pipeline: Activating High-Priority Trials in a Timely Manner

A. Skafel, R. Aggarwal, E. Small

UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

Time-to-activation is complex and success of clinical trials hinges on the ability to open trials quickly. Studies that take too long to open can close without any patients accrued, thereby wasting activation and coordination resources. In the first quarter of 2022, investigators at the Helen Diller Family Comprehensive Cancer Center (HDFCCC) were on track to submit 152 interventional studies to PRMC. This is substantially more than the annual average of 120 studies activated over the previous three years. Submitting too many studies to PRMC, or opening trials that are unable to accrual, not only strains activation resources, but poses challenges for ancillary services once opened.

2. Goals

The goal of the University of California San Francisco (UCSF) CPDM is to prioritize the activation and coordination of investigator-initiated trials (IITs), NCTN studies, early-stage career faculty, and studies where UCSF plays a key leadership role. Recognizing that industry sponsored studies are a financial necessity to programs, we sought to identify and participate only in industry studies for which robust accrual was likely.

3. Solution and Methods

We implemented a two-stage process to re-evaluate and re-prioritize trials in our activation pipeline. In the first phase, programs were asked to abandon lower priority industry sponsored studies. The second stage prioritized IITs, NCTN studies, trials where an early-stage career faculty was the PI, and industry studies with UCSF leadership. In an effort to ensure that this prioritization schema was uniformly applied across the cancer center, each disease oriented clinical research group was asked to adhere to a specific number of PRMC submission slots for industry studies over the course of a one-year period, which were equal to, or one less than the average annual number of trials activated by each group in the previous three years. There were no restrictions on the number of NCTN trial and IIT submissions. These measures were applied only to trials being submitted to the PRMC; open trials were not affected.

4. Outcomes

In the first stage, 10 percent of industry trials were abandoned during the activation process. In the second stage, 16 percent fewer studies were submitted to PRMC. At the end of the second stage, a similar number of studies, as in prior years, were activated and the number of interventional studies opened to accrual remained constant. The time to activation decreased by 11 percent over the same time period in the year prior. Mid-year survey of faculty demonstrated agreement with ability of site committee chairs to better prioritize PRMC submissions; however, feelings of stress and competition increased among clinical investigators.

5. Lessons Learned and Future Directions

While the number of submissions to PRMC was reduced and resources were focused on high-priority trials, the process initially added stress to faculty and program leaders. As the year concludes, we will survey faculty to determine if the stress changed over-time. Additional analysis is being undertaken to determine if the number of studies closed with zero accruals decreased, and if there was an ongoing

impact on time to activation. We will also evaluate the impact on the relative accruals to IIT, NCTN, and industry trials.