Category: Clinical Trial Operations – Work in Progress

Increasing the Utilization and Efficiency of a Phase I Program to Support Pan-Tumor Clinical Trials

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1. Background

The Phase I program research group at Taussig Cancer Center is comprised of our lead investigator Dale Shepard, MD, PhD, and is focused on bringing in novel Phase I trials that span across disease groups to best serve our diverse patient population of solid tumors and genomic studies. Having a dedicated Phase I program has allowed Cleveland Clinic to grow in the amount of novel and early phase clinical trials, but its growth depends on the primary disease program's clinical team to refer patients to these trials to make it successful since ultimately, they are the personnel that evaluate these patients on a daily basis. Our main goal was to increase the awareness of the individual disease programs and their staff on the trials that we have open for their specializations and overall increase the efficiency of opening these trials to help provide options for patients.

2. Goals

- Increase awareness of Phase I studies across the other disease programs including brain; breast; gastrointestinal; genitourinary; gynecologic oncology; head and neck; lung; and melanoma
- Boost accrual of Phase I studies
- Streamline processes for study start-up

3. Solutions and Methods

In order to best serve our physician groups across several disciplines we implemented a real-time updated spreadsheet of all currently accruing Phase I trials broken down by disease type to provide a snapshot discussion that can be shared at bi-weekly team updates with providers. The search terms include institutional review board number and study title, targeted disease group, therapeutic category, prior number of therapies, ECOG performance, prior brain met criteria, and slot availability. Due to the nature of Phase I studies slot allocation change occurs rapidly and this list is kept up-to-date in real time to ensure providers have the most accurate information when viewing potential Phase I trials for their patients. The research coordinators maintain this list and review it in conjunction with our Phase I matrix that is a visual representation of what studies we have broken down by disease type and hyperlinked to the current protocol and informed consent document as well as the complete list of inclusion and exclusion criteria and study personnel. A single group email was set up so any provider can reach out directly to the Phase I clinical team personnel to pre-screen a patient and is monitored by several team member to improve response time. Furthermore, these patients can be monitored for future study enrollment. Having a single email allows for the clinical to only have to recall one general email that the whole Phase I clinical team has access to rather than recalling which personnel leads which study. This makes it quick and simple to send potential patients to the clinical team to get pre-screened. There has been a focus on our time to open for study start-up and increasing efforts to reduce study activation time to provide new treatment options to patients who may not have any other options. This includes simultaneous efforts across departments to complete feasibility; create budgets; draft informed consents; comply with data and regulatory requirements; submit to our protocol review monitoring committee, institutional review board, and other ancillary services; review calendars; and

complete budget and contract negotiations. We track progress of these efforts through weekly updates. We have worked with our quality program improvement department to identify process improvement opportunities and outline guidelines for escalation procedures. This started with identifying issues that we could impact for Phase I start-up projects that focused on standardized communication with sponsors and spurred into other projects around informed consent improvement projects and updating sponsor questionnaires, which are sent from the research coordinator to the sponsor shortly after site selection. These exercises helped streamline what continual improvement projects to work towards and develop to improve our start-up process across Phase I studies.

4. Outcomes

In 2020 the overall accrual of therapeutic and no-therapeutic trials across Phase I studies run out of the group was 38 patients compared to 11 patients in 2019, which represented almost a 250 percent growth. Initial data demonstrated a five-fold increase in patients being pre-screened than prior to the implementation of the real-time Excel sheet and “one-stop-shop” email address. Measure time to open from site selection, principal investigator approval, and protocol distribution to site activation, our median days to open a trial at the end of 2020 was 128 days.

5. Lessons Learned

Internal spreadsheets updated in real time are providing physicians with real-time data on what studies have available slots and weekly meetings about start-up timelines are helping improve upon processes by identifying gaps and problem-solving across departments to continue to decrease our time to study activation. Establishing closer relationships with the physician leaders of each tumor type to help better assess the feasibility of trials and their accrual estimates also helps increase awareness of competing trials they may have running in their own groups. Involving finance from the start prior to internal budget creation helps establish a relationship with sponsor budget/contract staff early on and establish priorities and timelines for opening. More user-friendly searchable terms for intranet (internal site that houses all of our clinical trials) use are being reviewed through other mechanisms to allow providers and potential patients access to trials that we have open directly through our website.