

## **Value of Centralized Pre-study Process**

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### **1. Background**

Principal Investigators (PIs) and research sites are contacted in multiple ways when Sponsors or Contract Research Organizations (herein referred to collectively as “sponsor”) are seeking sites for participation in a clinical trial. Prospective sites may be excluded from consideration if response to these initial inquiries are delayed or missed, thus decreasing the availability of cutting-edge research to patients. Additionally, when study start up materials are sent to multiple individuals, this causes confusion and further delay. Finally, for studies that do not align with the Cancer Center’s mission, resources may be needlessly spent evaluating these studies.

### **2. Goals**

- Develop a single point of contact for sponsors to facilitate communication about new study opportunities
- Decrease the possibility of a new opportunity being missed
- Streamline the new opportunity process to alleviate the number of emails sent to PIs and study team members

### **3. Solutions and Methods**

A central email address, KUCCNNewOps@kumc.edu, for receiving all new study opportunities was established and serves as a single point of contact for sponsors. This email account is managed by the New Opportunities (NewOps) team which acknowledges receipt of the trial opportunity, tracks and stores information about the trial, and records the trial’s eventual outcome.

### **4. Outcomes and Future Directions**

The central email address has been used to collect feasibility and study start up documentation, including final protocols, regulatory documents, study manuals, and contract/budget templates. These items are readily available to the appropriate study team member for access throughout the study start-up phase.

Throughout 2018, there were 476 new trial opportunities managed by the NewOps team. By the end of the year:

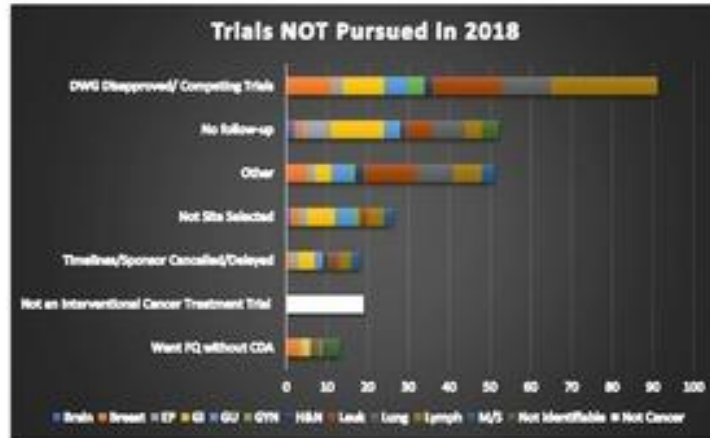
87 trials had been reviewed and approved to move forward by the disease groups. Approval to move forward requires discussion of the full protocol by the proposed Principal Investigator and discussion of how the new trial fits into the group’s overall trial portfolio.

119 trials were still in the start-up process (not yet reviewed by the disease groups).

Category: Trial Start Up/Closure – Completed Project

270 trials were not pursued (see graph)

Over half (56.7%, n=270) were not pursued, due to numerous reasons.



Utilizing a single point of contact for managing all study start up from initial contact through site selection further facilitates timely and consistent communication with the sponsor. In addition, this provides a uniform method for internal teams to access the study materials easily throughout the internal approval process.

Cancer Centers should be aware of how potential studies fit into their mission, while PIs and their study teams should consider thoroughly evaluating new study opportunities to ensure successful participation.