Category: Trial Start Up/Closure – Work in Progress

Clinical Trials Office New Study Committee: A Streamlined and Collaborative Approach for Clinical Trial Portfolio Management

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1. Background

Cancer centers across the nation face comparable obstacles during the various stages of trial start-up. At the Barbara Ann Karmanos Cancer Institute (KCI), incoming clinical trials were funneled through various paths: physician investigators, finance, and coordinators, inadvertently complicating start-up and affecting protocol activation timelines. The KCI Clinical Trials Office (CTO) identified the need for a centralized mechanism earlier in the activation process in order to manage concerns related to trial prioritization, feasibility, research team communication, multi-disciplinary team (MDT) assignment, trial suitability, and CTO resources.

2. Goals

The goal of the CTO New Study Committee (NSC) is to streamline the process for reviewing incoming clinical trials in order to ensure the trial could be feasibly and appropriately conducted at KCI. With the creation of the CTO NSC, the CTO strived to standardize MDT assignment and workloads, as well as improve communication and centrally manage the trial portfolio.

3. Solutions and Methods

A collaborative committee including the Vice President, Directors, Managers, Supervisors, and expert coordinators is scheduled each week to review incoming studies that are submitted by physician investigators or CTO staff. A centralized email was created and minimum criteria for submission were established, which included: protocol or synopsis, accrual to date, total target accrual, protocol population, and expected KCI participation. Upon receipt of trial feasibility documents or NCI study activation notification, the study is added to the next CTO NSC agenda. The Committee reviews the trial, assigns the appropriate MDT staff and treatment area(s), and considers the trial for Network involvement. The Committee also provides a recommendation as to whether KCI should proceed with the activation process. The Committee utilizes a Task List from our site's clinical trial management system, OnCore®, to document the Committee's review and recommendation. Following the meeting, the recommendation is communicated to the physician investigator and study team.

4. Outcomes and Future Directions

The CTO NSC held its first meeting on June 21, 2018 and has reviewed 218 studies as of April 15, 2019. Data has been provided in Appendix I CTO NSC Review Summary. Historically, physicians drove the MDT assignment; however, now the CTO NSC directs the path of the protocol, which allows for the CTO to take into account resources, competing trials, and the institution's ability to make a significant contribution to the studies. An unexpected, positive outcome of the Committee was earlier identification of unique trial requirements (i.e., biosafety, interventional radiology, unique testing, etc.) which is subsequently reviewed at our site's Feasibility Review and Operations Committee. This initiative

also led to optimization of OnCore® and the ability to track all incoming protocols managed by the KCI CTO.

CTO New Study Committee - Review Summary	2018		2019		TOTAL	
Total Number of Protocols Submitted	129		89		218	
Total Number of Protocols Committee Recommended Proceed	*120*	*93.0%*	*85*	*95.5%*	*205*	*94%*
Total Number of Protocols Committee Recommended Not Proceeding	*7*	*5.4%*	*1*	*1.1%*	*8*	*3%*
Total Protocols Withdrawn/Tabled/Pending Re-Review	*2*	*1.6%*	*3*	*3.4%*	*5*	*2%*
		100.0%		*100.0%*		**100.0%**
Total Number of Protocols that Remained with the Submitting MDT	96	80.0%	71	83.5%	**167**	**82%**
Total Number of Protocols that Transferred to a Different MDT	24	20.0%	14	16.5%	**38**	**18%**

The CTO NSC highlighted the need for a more robust protocol activation initiative. The KCI CTO is working to establish a more formal tracking mechanism in OnCore®, starting with the receipt of trial feasibility documents or notification of NCI study activation. The CTO NSC has been supported by institutional leadership to be the starting point for tracking incoming studies. In the future, the CTO will analyze CTO NSC data to support process changes in order to drive efficiency.