Enhancing the Voice of Clinical Research Staff in the Trial Feasibility Process

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BACKGROUND

The University of Florida Health Cancer Center (UFHCC) Clinical Research Office (CRO) is committed to facilitating the conduct of clinical trials that are feasible, scientifically meritorious and ethically sound. In many cases, trial success is contingent upon performance of a thorough feasibility assessment during the protocol activation process. Underperforming trials occupy significant CRO resources (personnel, financial, material) creating operational barriers and limiting the activation of new trials. At UFHCC, studies not meeting accrual goals (locally defined as 50% of the annual accrual goal) are subject to closure by the Scientific Review and Monitoring Committee (SRMC). Investigators often do not understand the staff investment in activation and study maintenance (estimated as 150 hours for activation alone) and the impact underperforming studies have on staff workload and morale. A review of approximately 300 studies completed between 2007 and 2017 demonstrated that 60% of trials failed to meet at least 25% of their local target accrual, most due to misalignment with available patient populations. To combat this issue, the UFHCC CRO created the Feasibility Group (FG) with membership comprised of CRO personnel to ensure that research staff have a voice in assessing and choosing trials for the center.

GOALS

- Decrease the number of trials terminated due to low accrual and other logistical barriers.
- Establish a forum for formal review of trials at the CRO staff level to provide a voice to the personnel ultimately managing these trials.

SOLUTIONS & METHODS

The CRO Feasibility Group was established in late 2017 to provide decision support to Disease Site Groups (DSGs) in determining if trials were feasible in terms of available patient population, logistics and financing. All trials are eligible for FG review at the request of the DSG; however, FG reviews are mandatory for any interventional trial that will be supported with direct dollars or in-kind support by the UFHCC. The FG is composed of CRO leadership with the input of CRO research managers and clinicians who would assume responsibility for the execution of the trial if approved and activated. The FG process includes review of the following:

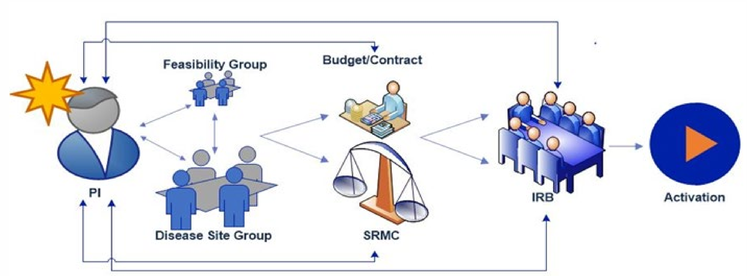
- Tumor registry and clinical records as well as review of prior accrual performance of studies enrolling similar patient populations;
- Logistical factors involving clinical facilities and staffing, such as prolonged infusions, frequent patient monitoring and multiple blood draws requirements;
- Study funding and Medicare Coverage Analysis

FG reviews may lead to the DSG abandoning the trial, modifying enrollment goals, enlisting additional enrollment sites, and/or requesting additional financial support from external sponsors or the UFHCC. The FG review results in non-binding recommendations to DSG leaders and investigators (**Figure 1**).

OUTCOMES

This innovative forum has allowed clinical and logistical concerns to be voiced by individuals who will be involved in the trial conduct. While concerns with the additional layer of review were voiced, activation timelines have shortened. Attendees are able to openly discuss concerns and prior experiences as part of FG deliberations. Since deployment, the FG has reviewed a total of 77 trials, with a recommendation for 82% of those trials to be feasible.

Figure 1 – Protocol Activation Workflow



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