

Implementation of a Concept Development Program for Investigator-Initiated Trials

A. Ivey, A. Daniels, T. George;

University of Florida Health Cancer Center

1. Background

Investigator-Initiated Trials (IITs) are institutional priorities and represent the combination of intellectual property and scientific output from translational science programs. Therefore, a robust IIT concept development process is essential to the success of an academic cancer center. Prior to 2016, University of Florida Health Cancer Center (UFHCC) investigators lacked a formal system of resources and support in developing cancer-relevant interventional research concepts, often resulting in concepts deficient in scientific merit, statistical validity, and feasibility related to funding, staff support, and the Center's catchment area. To overcome these challenges, the UFHCC Clinical Research Office (CRO) established the IIT Concept Development Group (CDG).

2. Goals

1) Improve the feasibility, scientific merit and ultimate success in completing cancer relevant IITs, 2) Shorten the timeframe from concept approval to protocol activation and 3) Maximize staff and investigator effort in protocol development

3. Solutions and Methods

The CDG was created to provide a comprehensive review of all concepts managed by the CRO or otherwise supported by UFHCC resources. After soliciting key concept requirements from senior investigators, a standard concept form was developed for CDG submission to provide investigators guidance on the fundamental elements of a concept proposal. The IIT CDG approval process also involves documentation of provisional peer support through the respective Disease Site Group (DSG). As part of the formal CDG review, UFHCC experts review concepts and provide consultation to ensure there is a valid statistical plan, scientific rigor, appropriate institutional budget development, and confirmation of appropriate staff resources for conduct. The UFHCC Associate Director for Clinical Research (ADCR) ultimately provides final approval. Approved concepts may (only) then be developed into full protocols. This iterative CDG review process helps to ensure that protocols are built upon a solid scientific foundation in an effort to maximize the potential impact of the research and maximize limited resource utilization.

4. Outcomes and Future Directions

Since the implementation of the CDG a 42.0% decrease in obtaining SRMC approval has been observed with an average of 40 days for CDG reviewed trials to obtain approval compared to 69 days for non-CDG reviewed trials. When specifically looking at treatment trials, a 49.3% decrease was seen in SRMC approval with an average of 37.5 days for CDG reviewed trials and 74 days for non-CDG reviewed trials.

Category: Investigator Initiated Trials – Completed Project

Within the next year, it is planned to evaluate the impact the CDG process has had on trial accrual goals, overall activation timelines, and merit scoring system for the Center's cancer-relevant interventional investigator-initiated trials compared to those trials which are not vetted through the CDG.

To date, positive reactions have been received from investigators, study staff, and SRMC committee members about improvements in the quality of trials developed and activated through this program. As the process is refined locally, the next step is to introduce strong concepts in a multi-site setting and expand the population-base of our trial portfolio.