

Stimulating Investigator-Initiated Trial Development: A Comprehensive Approach to Provide Guidance, Mentorship, and Logistical Support for Principal Investigators

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1. Background

Academic cancer centers face many demands that necessitate accelerated development of high-quality, innovative, and well-designed investigator-initiated trials (IIT). Early career clinician scientists have many competing responsibilities that distract from the efficiency of IIT concept development. PIs have widely varying clinical trial experience, which poses an additional obstacle for efficient IIT development. In response, the MCW Cancer Center developed a comprehensive infrastructure to assist investigators in IIT development. We report here preliminary outcome metrics of this new initiative.

2. Goals

A new infrastructure was implemented with the following goals: 1) To provide direction and mentorship, particularly to junior faculty, early in the process of concept development; 2) Target two barriers in the successful opening of the IITs: a) time it takes to complete the protocol and, b) the timeline of Scientific Review Committee (SRC) review and subsequent approval; and 3) Assess the satisfaction of the investigators utilizing this infrastructure.

3. Solutions and Methods

In May 2018, the MWC Cancer Center instituted a new IIT development infrastructure directed by a steering committee. A protocol development coordinator (PDC) oversees the day-to-day operations of the committee and the development of the clinical trial project, along with the CTO team (Budget, Regulatory, and Research Manager).

Metrics of concept development, activation, and return on investment are monitored by a comprehensive REDCap-based system. A Disease Oriented Team (DOT) approved concept is submitted to the committee through REDCap and is scheduled for concept presentation. Feedback is then provided to the investigators. The PDC, along with the committee chairs, periodically reviews the status of concepts presented and acts accordingly.

4. Outcomes

As of March 2020, of 26 concepts (22 investigators) presented to the IIT Steering Committee, four are open for accrual while two have been abandoned. Of 22 investigators, 10 were junior investigators, and five senior investigators were developing an IIT for the first time. Substantial changes based on feedback that enhanced the project include scientific design change, correlative study identification, statistical changes, knowledge of funding opportunities, and recommendations for collaboration with other investigators.

Category: Investigator Initiated Trials – Completed Project

Since February 2018, we completed 31 IIT protocols, while five are under development (including protocols not going through IIT Steering Committee). Protocol development was completed in a mean of 52 days (range: 10-105). This is better than the time given by pharmaceutical companies to complete an industry sponsored IIT protocol which on average is 90 days. We reduced the SRC approval timeline from 4 to 49 days (mean of 27 days). Based on the data from August 2013- May 2018, the average time it took from initial SRC review to final SRC approval varied 32 to 441 days (mean of 113 days).

5. Lessons Learned

We collected and reviewed the satisfaction of the investigators utilizing the IIT Steering Committee and our project development team. Overall satisfaction with the IIT Steering Committee was 92%, while it was 95% with the protocol development team. 93% investigators indicated that they were either extremely or moderately satisfied with the overall support provided by the cancer center.