Category: Investigator-Initiated Trials – Work in Progress

Development of an Investigator-Initiated Trial Intake Process at Cedars-Sinai Cancer

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1. Background

Historically at Cedars-Sinai (CS) Cancer, investigators wishing to conduct an investigator-initiated trial (IIT) would individually engage the protocol development team while seeking funding. However, as the IIT portfolio has grown, at times this has led to IITs that did not have broader support within the disease resource group (DRG); were not feasible or were challenging to accrue to; or did not ultimately receive funding, creating resource challenges among the clinical study teams and administrative teams. As such, a formal IIT intake process was needed to manage the pipeline of IITs, to ensure only the most robust and feasible concepts were approved for implementation.

2. Goals

- Develop an IIT intake process that identified the most scientifically robust and feasible concepts that were of most interest to the DRG and prioritized for support
- Ensure funding was identified early in the protocol development process
- Develop an expedited activation pathway for qualifying studies
- Develop a central contact method for requesting protocol development support

3. Solutions and Methods

Prior to engaging the protocol development team, investigators are required to complete a newly developed concept form, detailing the study summary, resource considerations, ability to accrue to the patient population, and financial considerations. Engagement of a biostatistician and identification of a potential funding source are required at the concept stage. The investigator presents the concept to the DRG for discussion of the scientific rationale, fit with the overall DRG portfolio, and commitment of staffing resources. If the concept is approved by the DRG, the investigator submits the concept form to the protocol development team via a survey tool, and the concept is assigned to a protocol development specialist and a finance specialist for activation. An expedited activation pathway via ad hoc chair review was developed for non-treatment trials of lower complexity.

4. Outcomes

This process has set forth clear expectations and set a higher standard for selection of IITs that are a better fit for our DRGs and that are more likely to successfully accrue. The goal is that this process will result in fewer study design changes throughout the protocol development process and fewer IITs that are ultimately abandoned for lack of funding after initiation of protocol development, ultimately improving study activation timelines, making the best use of limited staffing resources, and providing the best clinical trial treatment options for our patient populations that yield high accruals. In March 2022, the first study to follow this process entered the pipeline, and in the coming year, we hope to generate metrics to demonstrate effectiveness.

5. Lessons Learned and Future Directions

The success of an IIT depends upon the support of many people at an early stage. Ensuring broad support is obtained prior to investing resources in the concept helps make the best use of limited resources. To be most successful, this process will require active discussion at the DRG level to vet concepts that are brought forth and select for activation only those that are most likely to accrue and

diversify the portfolio; objective criteria for disapproving an IIT concept may be needed in the future. As we pilot the process and generate data on its effectiveness, it may continue to evolve to meet the needs of the investigators and the cancer center.