Category: Investigator-Initiated Trials – Work in Progress

A Catalyst for Success: How the I2T3 is Transforming IIT Development at UFHCC

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1. Background

In an effort to increase investigator-initiated trial (IIT) development and support, as well as facilitate engagement and mentorship between junior and senior investigators across DSGs, the associate director for clinical research started a collaboration with the University of Florida Health Cancer Center (UFHCC) Project Management Office (PMO) to develop a series of monthly "IIT Think Tank" ("I2T3") meetings, which kicked off in February 2020. Led by the PMO manager, these meetings include discussions about concept ideas, protocol development as well as industry and grant support.

2. Goals

The goals of the I2T3 meetings include increasing the number of IIT concepts that develop into protocols and accelerate the time between conception and implementation of innovative research trials. Through discussion, we also hope to support the operational success and sponsorship of IITs.

3. Solutions and Methods

The I2T3 standing agenda includes presentations of new and ongoing concept ideas and a brief educational topic. With every concept presented, senior and multidisciplinary peer investigators provide feedback and guidance to maximize the trial's success, scientific rigor, and efficiency. The composition of the group is designed to include junior and senior investigators to facilitate mentorship, our lead biostatistician to guide endpoint creation and sample size discussions, and representatives of our Community Outreach, Engagement & Equity (COEE) group to include the perspectives from our unique catchment area. Investigators representing various UFHCC oncology disciplines also attend to encourage collaborations and networking across research programs. Project managers and study start-up specialists also attend to advise on recruitment and feasibility concerns, investigational new drug (IND)/investigational device exemption (IDE) and regulatory considerations and facilitate funding opportunities. UFHCC leadership is present at these meetings to guide concepts toward translating homegrown UF science and provide guidance on potential for internal resources.

4. Outcomes

During the first year of operation, 10 concepts were discussed in this group, with five proposals submitted to industry for support; three were successfully supported and are in final protocol drafts, and four are actively seeking funding. Compared to 2019, the clinical research office (CRO) at UFHCC saw increased concept intake by nearly 64 percent in 2020 (11 concepts received in 2019 and 18 in 2020). Of the 18 concepts received in 2020, 10 of them (56 percent) originated from I2T3 group discussions.

5. Lessons Learned

Providing a structured and dedicated time to incubate concepts for IIT development is beneficial, not just to administratively "keep the ball rolling," but also supports investigator and PMO collaboration,

mentorship, communication, and industry partnerships. Investigators (particularly junior) learn through development of their own concepts and contributions to peer concepts and projects. Educational sessions have included topics such as FDA IND process, novel statistical methods, decentralized trial design, and translational correlative standardization. In the future, we expect to collect data on time to IIT study activation to support our impression that these meetings have contributed to a more efficient path to activation, compared to IITs that are managed outside this group (either by UFHCC PMO or by the investigator). Data on protocol success/deviation rates will also be useful to assess whether early concept discussions were successful to head-off some of the typically unforeseen complications of actual study implementation in clinic.

Figure: