UF's IIT Think Tank Experiment

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1. Background
To increase investigator-initiated trial (IIT) development and support early-stage clinical investigators (ESIs), monthly IIT Think Tank (I2T3) meetings were initiated in February 2020. Meetings included new concept presentations and discussions about development, feasibility, conduct, and support. Details about how and why this meeting was initiated were presented at the 13th Annual AACI CRI Meeting in July 2021.

2. Goals
During the first year of the program (2020), IIT concept intake increased by nearly 64 percent, supporting our primary goal in establishing I2T3. I2T3 goals for 2021 were to maintain concept intake volume, activate our first I2T3 studies and introduce meeting enhancements.

3. Solutions and Methods
To meet these goals, PMO implemented the following new processes in 2021:
- Identifying extramural funding opportunities, specifically matched for I2T3 concepts
- Documenting concept feedback from a wider range of stakeholders while providing ESIs experience in concept evaluation and review
- Involving Citizen scientists in concept development leveraging community perspective

Ten concepts were received through I2T3 meetings in 2020, and this pace continued with another 10 in 2021, demonstrating sustained new concept volume. Of all concepts presented, only 15 percent have been abandoned, due to lack of funds or feasibility. Three I2T3 studies completed protocol development in 2021 and were opened to accrual, all with current active enrollments.

4. Outcomes
In 2021, the UFHCC project management office (PMO) spearheaded an initiative of grant finding and matching to increase support for I2T3 concepts. As part of this initiative, PMO finds and distributes a summary of available grant opportunities to the I2T3 group. Additionally, PMO looks to match concepts with funding opportunities, and assists with preparation and submission. In 2021, four I2T3 concepts were submitted for grant support, with one awarded (Florida DOH JEK, $1,458,000). In 2020, one grant was submitted and not funded. Three concepts were supported by industry in 2020, and this rate continued into 2021, with two supported and one pending.

PMO updated the existing UFHCC IIT-accelerator process (path for IIT concept approvals to move forward) to include I2T3 feedback from both investigators and newly incorporated citizen scientists (CS). An anonymous Qualtrics survey is distributed to I2T3 members (ESI and senior investigators) to formally collect concept feedback. This survey includes a National Cancer Institute-style scoring rubric on scientific merit, study design, clinical impact, and feasibility. Training on the rubric was provided to assist in providing relevant feedback to presenters and to see firsthand how their own concepts will be reviewed. CS provide separate verbal and written feedback, which is incorporated by PMO into review forms. Survey results and scores are compiled and provided back to concept presenters and used for concept refinement during protocol development.

5. Lessons Learned and Future Directions

In 2021, the pace of I2T3 concept intake continued from its inaugural year (2020), demonstrating sustained volume of new concepts intake. We anticipate this to continue and increase in 2022. We will collect data on which CS feedback components are recurring themes, to look for system-level solutions for protocol incorporation. We plan to collect data from investigators to learn about the usefulness of the Qualtrics feedback received from their peers, as well as CS feedback, and new educational topics desired by the group.

Figure:

Disposition of Concepts Presented at I2T3 by Year Presented