Initial Onboarding: Smartsheet Training Dashboard

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1. Background

Clinical trials in oncology are proliferating with discoveries of new and effective therapies against various cancers, however, very few patients participate in oncology trials. One reason for this is the lack of formal training given in medical school and post-graduate training, resulting in physicians who are unprepared to lead and conduct clinical research. Current cancer research trial workshops typically require that concepts already be approved for funding, limiting the number of eligible participants and opportunities for trainees from institutions with established resources to support clinical research. These national offerings are insufficient to teach a critical mass of knowledge for trainees, and more course offerings are necessary to meet these needs.

2. Goals

The "Idea2Concept: Clinical Trial Workshop" (I2C) aims to help trainees and junior clinical investigators develop a sound and scientifically rigorous oncology clinical trial concept (letter of intent or LOI) while offering them a foundational interactive oncology curriculum that covers all domains involved in such clinical research. The I2C workshop will serve to link trainees with a pool of mentors, sponsors, and The Association of American Cancer Institutes (AACI) network to conduct clinical research.

3. Solutions and Methods

We hypothesize that teaching how to write an oncology clinical trial concept fills a critical need to train junior cancer researchers in the design of scientifically sound clinical cancer research. The niche I2C will fill is to teach novice trainees the fundamentals of designing clinical research concepts and prepare them to become adaptive, competent, and dedicated investigators. With guidance from national mentors and feedback from course directors, the product of this course will be LOIs created by each participant. These LOIs will be strong foundational material to obtain funding and finalize a clinical trial protocol or an investigator-initiated study at the participant's institution. The mechanism of education is a mixed learning model including virtual lectures throughout the academic year followed by intensive 8 hour in-person workshop coinciding with the AACI Clinical Research Innovation (CRI) meeting.

4. Outcomes

In the inaugural offering of I2C, 5 applicants from across the country participated. In 2024, the workshop received NCI funding (R25CA278725) to expand its impact by reaching a wider audience of junior cancer researchers. In the 2024-2025 year, we received 27 applications and accepted 17 participants (9 fellows, 8 junior faculty). We prioritized trainees with some research experience but had never conducted an investigator-initiated trial or participated in formal clinical research training. Virtual lecture topics included pharmacology, protocol development overview, LOI development, translational science. The inperson workshop at the 2025 AACI CRI meeting will include pipeline presentations from industry, one-on-one mentorship sessions, LOI presentations and feedback sessions for LOI development, and National Institute of Health (NIH) Responsible Conduct of Research. We expect that at the conclusion of the workshop, each trainee will be equipped with a finalized LOI for a clinical trial concept.

5. Learned and Future Directions

Lessons learned thus far include the challenges of balancing in person and virtual learning; recruitment to the workshop and encouragement of active participation especially in the virtual setting; and combining didactic with collaborative teaching. Future directions include expansion of the workshop to 25 trainees per year.