

The idea2Concept Workshop: an NIH R25-Supported Curriculum to Develop and Implement Investigator-Initiated Clinical Cancer Trial Concepts in Collaboration With AACI

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1. Background

Investigator-initiated clinical trials (IITs) in oncology fill knowledge gaps that may not be a high priority for pharma but address critical unmet needs of cancer patients. However, the skills required to develop and implement clinical trial ideas are not generally taught in medical schools or fellowship training programs. Current cancer research workshops typically require that concepts already be approved for funding, limiting the number of eligible participants. To fulfill these challenges, the “idea2Concept” (i2C) Clinical Trials workshop has been established.

2. Goals

The i2C aims to teach junior researchers who have not yet had any significant IIT experience to develop a scientifically rigorous cancer clinical trial concept and prepare them to successfully obtain funding support to execute it. We hypothesize that teaching how to develop and pitch an oncology clinical trial concept, including navigation of different available funding and sponsorship opportunities, fills a critical training gap.

3. Solutions and Methods

The workshop offers trainees a foundational, interactive, hybrid virtual/in-person curriculum throughout an academic year that covers all domains of clinical research. The virtual lectures include topics on clinical trial designs, statistical methods, pharmacology, funding mechanisms, protocol development, regulatory environment, safety and disease assessment criteria among others. In 2025, a web portal was developed to disseminate workshop information and make pre-recorded lectures accessible to participants. Trainees are required to propose a clinical trial idea and then are paired with national mentors to receive their feedback. Finally, an intensive eight-hour in-person workshop coinciding with the AACI-CRI meeting is held during which the study design is finalized. The final letter of intent (LOI) is reviewed by program directors and trainees receive certification of course completion.

4. Outcomes

In the inaugural offering of i2C in 2023, five applicants from across the country participated. Two concepts were developed into a study protocol and one study opened to accrual. In 2024, the workshop received NIH funding (R25CA278725) to reach more junior cancer researchers. In the year 2024-2025, we received 27 applications and selected 17 participants. Of the 17 trainees, 15 fully participated in the workshop and 14 finalized their concept into an LOI. For the year 2025-2026, we received 119 applications and selected 19 trainees. Based on prior feedback, for the current class, we paired mentors with mentees earlier in the year and required them to have two one-on-one virtual meetings prior to AACI-CRI meeting. We also increased available statistical support at the in-person meeting from one to three bioinformaticians. The agenda at in-person workshop at the 2026 AACI-CRI meeting will include

pipeline presentations from industry, one-on-one sessions with mentors and statisticians, LOI presentations, and lectures on NIH Responsible Conduct of Research. We expect that at the conclusion of the workshop, each trainee will have a finalized LOI for a clinical trial concept.

5. Lessons Learned and Future Directions

High number of applicants during 2025-2026 cycle reflects strong demand for the workshop among junior clinical investigators. The challenges include balancing in person and virtual learning and timely recruitment of the mentors. Future directions include expansion of the workshop to 25 trainees per year.