idea2Concept (i2C) Workshop – A Dedicated Curriculum to Develop and Implement Investigator Initiated Clinical Cancer Trial Concepts:

An NCI/R25 supported, AACI Collaborative Effort

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Background

- Investigator-initiated clinical trials (IITs) in oncology fill knowledge gaps that may not be a high priority for industry but address critical unmet needs of cancer patients.
- Skills required to develop, pitch, and secure funding for 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.

Goals

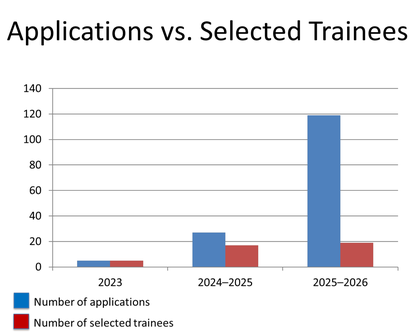
- i2C aims to teach junior researchers who have not yet had any significant IIT experience to develop a scientifically rigorous trial concept and obtain funding
- Prepare trainees to successfully obtain funding support
- **<u>We hypothesize</u> that *teaching how to develop and pitch an oncology clinical trial concept, including navigation of different available funding and sponsorship opportunities, fills a critical training gap.***

Solutions and Methods

- The workshop offers trainees a foundational, interactive, hybrid virtual/in-person curriculum throughout the academic year
- In 2025, a web portal was developed to disseminate workshop information and make pre-recorded lectures accessible to participants.
- 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 (see Table 1).
- Trainees are required to propose a clinical trial idea and then are paired with national mentors to receive their feedback.
- The course culminates with an 8-hour in-person workshop coinciding with AACI-CRI during which the study design is finalized.

Outcomes

- In the inaugural pilot of i2C in 2023, 5 applicants from across the country participated. Two concepts were developed into a study protocol and one study opened to accrual.
- In 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 (Fig 1):



- Makeup of 2025-2026 class includes
  - 53% women;
  - 74% junior faculty, 26% fellows/residents;
  - Specialty: 79% hematology and medical oncology, 10% surgical oncology, 10% radiation oncology.
- Based on prior feedback, for the current class, we paired mentors with mentees earlier in the year and required them to have 2 one-on-one virtual meetings prior to AACI-CRI meeting.
- We also increased available statistical support at the in-person meeting from 1 to 3 bioinformaticians.

Outcomes

Table 1: Curriculum for 2025-2026 Academic Year

Virtual Lecture Series	In-Person AACI Workshop
Alphabet Soup – The Language of Clinical Trials Claire Verschraegen, MD Professor, Former Chair, OSU Division of Medical Oncology	**Icebreaker and How to Give a Good Presentation** Marc Ankerman, PhD Former Professor at the Ohio State University's Fisher College of Business Current President of Ankerman Training Solutions
Submitting a Letter of Intent (LOI) and Introduction to Clinical Trial Protocols Robert Wesolowski, MD Phase 1 Disease Research Group leader, OSUCCC	**Concept Presentations** Speakers: Workshop Participants • Small group Table discussion with any time remaining
Funding Mechanisms for an LOI and Assessment of Toxicity/Efficacy Dwight Owen, MD, MSc Clinical Treatment Unit and Clinical Processing Laboratory Director, OSUCCC	**One on One Meetings with a Statisticians and Mentors:** • 15-minute sessions between mentee and statistician • At least 1 in-person meeting between mentee and mentor
Statistical Design of Early Phase Clinical Trials Lai Wei, PhD Division Lead of the Clinical Trials Division at the Center for Biostatistics, OSUCCC	
Pharmacology in Phase 1 Trials Mitch Phelps, PhD Kimberly Professor of Pharmacy Co-Director, Pharmacoanalytical Shared Resource (PhASR), OSUCCC	**Responsible Conduct of Research Training** • Mentor/mentee responsibilities and relationships • Collaborative research including collaborations with industry
Translational Endpoints in Clinical Trials Daniel Stover, MD Director of Translational Breast Cancer Research and Principal Investigator of Total Cancer Care, OSUCCC	**Navigating the NCTN and Alliance** • Olwen Hahn, MD • Associate Professor of Medicine • Associate Section Chief of Outpatient Operations, Section of Hematology and Oncology • University of Chicago
Working with NCI and ETCTN-CTEP Steven Gore, MD Chief, NCI Investigational Drug Branch	
Leading Clinical Trials Through NCTN Eric Miller, MD, PhD Director, GI Radiation Oncology, OSUCCC	**Updated Concept Presentations** Speakers: Workshop Participants • Incorporating feedback from first session and one-on-one mentor input • Plans for seeking funding/support
Navigating Your First IIT Carlo Contreras, MD Associate Professor of Surgical Oncology, OSUCCC	

Lessons Learned and Future Directions

- High number of applicants during 2025-2026 cycle reflects strong demand for the workshop among junior clinical investigators.
- 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.

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