

A dedicated curriculum to develop clinical cancer research concepts:

An R25 supported, AACI Collaborative Effort

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The James



Background

- One reason for low enrollment of cancer patients to clinical trials is the lack of formal training given in medical school and in post-graduate training resulting in physicians who are then unprepared to lead and conduct clinical research.
- Current available cancer research trial workshops typically require that a concept already be approved for funding, which limits the number of eligible participants and opportunity to trainees from institutions that already have established resources to support clinical research.
- These national offerings are insufficient to teach a critical mass of knowledge for all trainees, and more course offerings are necessary to meet these important needs.

Goals

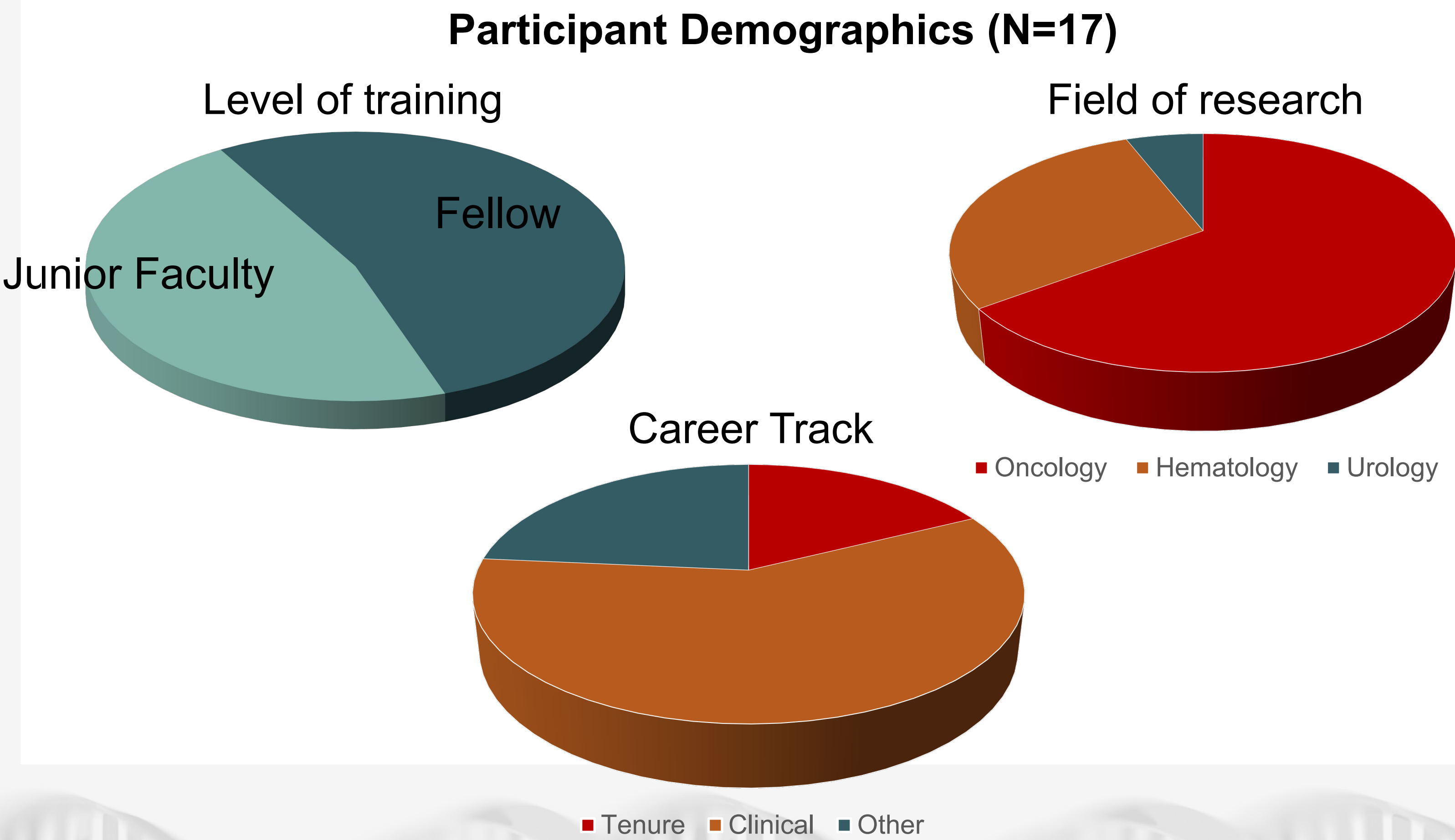
- **The goal of the course entitled “Idea2Concept: Clinical Trial Workshop” (I2C) is to help trainees and junior clinical investigators develop an oncology clinical trial concept** (aka, synopsis or letter of intent or LOI) that is sound and scientifically rigorous while offering them a foundational 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 and sponsors and The Association of American Cancer Institutes (AACI) network to conduct clinical research.
- **We hypothesize** that teaching how to write an oncology clinical trial concept fills a critical need to train junior cancer faculty and trainees in the design of scientifically sound clinical cancer research.

Solutions and Methods

- With the support of guidance from selected national mentors and feedback from the course directors, the product of this new course will be the LOI created by the participant.
- These LOIs will then be strong foundation material to obtain funding and finalize a clinical trial protocol, for example, to the NCTN or the ETCTN, or as 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 CRI meeting.

Outcomes

- In 2024 the workshop received funding from the NCI (R25CA278725) to expand the workshop impact by reaching a wider audience of junior cancer researchers.
- In the 2024-2025 year, we received 27 applications from across the country and accepted 18 participants (9 fellows, 9 junior faculty)



Outcomes

| Curriculum for 2024-225 Academic Year | |
|---|---|
| Virtual Lecture Series | In-Person AACI Workshop |
| Designing and LOI and a Protocol; Phase 1 Toxicity and Efficacy Assessment. Robert Wesolowski, MD Phase 1 Disease Research Group leader, OSUCCC Dwight Owen, MD, MSc Clinical Treatment Unit and Clinical Processing Laboratory Director, OSUCCC | FDA Drug Approval Process: Current Process and Anticipated Changes in an Evolving Landscape Simon Lee, MD, FACP, MACR Former Division Director, FDA Analgesic, Anti-inflammatory, Ophthalmologic Drug Products Division |
| Statistical Design of Early Phase Trials Lai Wei, PhD Division Lead of the Clinical Trials Division at the Center for Biostatistics, OSU | Industry Pipeline Presentation |
| Overview of Clinical Research and NCI Cooperative Groups Claire Verschraegen, MD Professor, Former Chair, OSU Division of Medical Oncology | Concept Presentations Speakers: Workshop Participants <ul style="list-style-type: none">• Small group Table discussion with any time remaining |
| Working with NCI and ETCTN-CTEP Steven Gore, MD Chief, NCI Investigational Drug Branch | Responsible Conduct of Research Training <ul style="list-style-type: none">• Mentor/mentee responsibilities and relationships• Collaborative research including collaborations with industry |
| Pharmacology in Phase 1 Trials Mitch Phelps, PhD Kimberly Professor of Pharmacy Co-Director, Pharmacoeanalytical Shared Resource (PhASR), OSUCCC | Updated Concept Presentations Speakers: Workshop Participants <ul style="list-style-type: none">• Incorporating feedback from first session and one-on-one mentor input• Plans for seeking funding/support |

Lessons 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.

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