Optimizing Public-Private Partnerships for Clinical Cancer Research: A Workshop

Session 1: Rationale and Objectives for Public-Private Partnerships in the Clinical Cancer Research Enterprise

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Disclosure: I am an academic medical oncologist and committed mentor of junior faculty

Perspective:
Academic clinical investigators are at risk of extinction

First, some definitions:

Table 1. Physicians Involved in the Translational Research Continuum

Designation	Main Roles and Responsibilities	Salary Sources
Physician-scientist	Engages in basic and preclinical research, bringing a clinical perspective to laboratory investigator teams, and works with other clinicians to promote the early phases of clinical investigations. Participates in laboratory investigations using clinical specimens to derive a better understanding of clinical disease processes and response to clinical interventions.	Grants, academic institution
Clinician investigator	Writes and implements novel investigator-initiated clinical trials, enrolls patients to these and other clinical trials, participates in national and international clinical research forums, and serves as a key link between the "bench" and the "bedside." May also be a subject-matter expert and coordinate subspecialty patient care, usually in an academic setting.	Clinical care revenue, clinical trials contracts, academic institution
Academic clinician	Enrolls patients to late phase clinical trials investigating new approaches to prevention, diagnosis, and treatment with novel agents prior to approval by FDA, and tests new indications for existing drugs and other clinical modalities. Engaged in full-time clinical care.	Clinical care revenue

Holcombe, R. F., Status of the Clinician Investigator in America: An Essential Healthcare Provider Driving Advances in Cancer Care. *Journal of the National Comprehensive Cancer Network*, *19*(2), 122-125, 2021.

Perspective:
Academic clinical investigators are at risk of extinction

Clinical Investigator, Clinician Scientist, Clinical Translator:

Risk Factors:

1. Productivity metrics (RVUs)
2. Lack of protected time (often recruited to ≥75% clinical effort)
3. Increased administrative tasks related to patient care (EMR, prior authorizations, etc)
4. Undefined path to promotion/tenure
5. Salaries have improved in academia but at the "cost" of #1-3, above
6. Lack of mentorship (often due to #1-3 for mentors, also)

J Natl Compr Canc Netw 2021;19(2):122–125; J Am Coll Radiol 2021;18:192-197; Neurology 2015 Sep 29; 85(13): 1171–1176.

Bold Initiative in 1996:
Based on perspective of failure of cancer drugs in development

An ASCO/AACR Workshop on

Methods in Clinical Cancer Research

July 23-29, 2023 | La Jolla, CA

+ NCI, FDA, Industry!

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY | AACR American Association for Cancer Research

Potential remedies include:

(a) better science in selecting new therapeutics to take forward into the clinic,

(b) a better understanding of the reasons for the responses of patients in phase I and II trials;

(c) **design of new and better phase II trials that are more predictive of phase III success; and**

(d) **better patient selection so that only those patients with the appropriate tumor molecular genotype/phenotype are entered into the trials.**

B-D Require Clinical Translators!!

Von Hoff DD, A Grant-Based Experiment to Train Clinical Investigators: The AACR/ASCO Methods in Clinical Cancer Research Workshop. Clin Cancer Res. 2021 Oct 15;27(20):5472-5481. doi: 10.1158/1078-0432.CCR-21-1799. Epub 2021 Jul 26. PMID: 34312215; PMCID: PMC8530870

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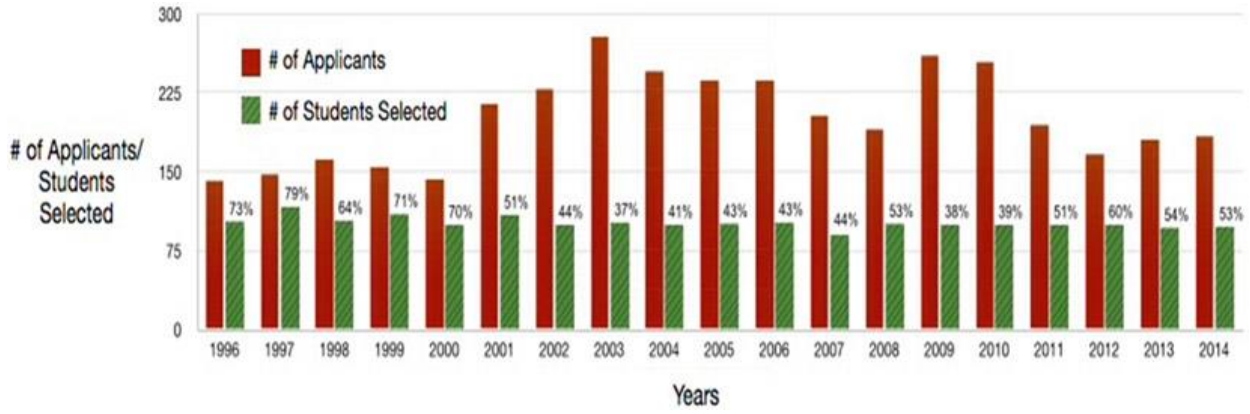
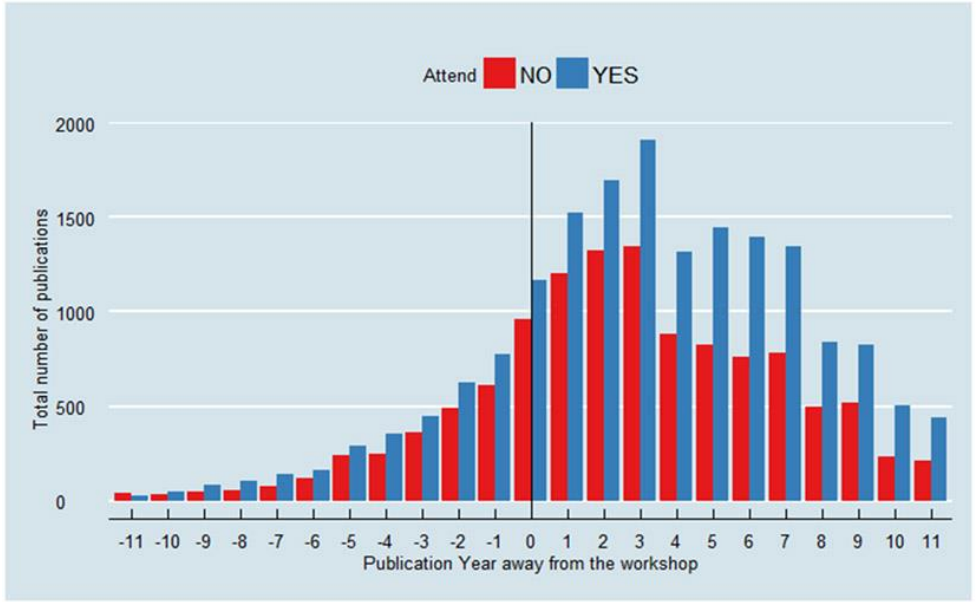
Metrics: From 1996 to 2014, 1,932 students from diverse backgrounds attended the workshop

Intermediate and long-term follow-ups indicated that more than 92% of students were actively involved in patient-related research, and 66% had implemented five or more protocols

CANCER CENTER



Plot of Numbers of Students Selected Versus Number of Applicants The number of applicants and the number of students accepted each year (1996-2014).



Total yearly number of publications, before and after workshop, of applicants who attended versus those who did not attend the MCCR workshop. Plot courtesy of Dr. Yu Shyr.

Summary

- PPP collaborative training of workforce is successful
- Publication record indicates academic productivity
- Not at scale
- Doesn't remediate clinical issues

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PPP to Provide Protected Time for CI and Mentor

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Early Clinical Investigator Award: The Early Clinical Investigator Award is designed to provide support for the career development of very promising early-career physicians with specialty training relevant to delivery of cancer care, including therapeutic intervention, early detection, and prevention.

Clinical Investigator Award: The Clinical Investigator Award is designed to enable mid-career clinician scientists with specialty training relevant to delivery of cancer care, including therapeutic intervention, early detection, and prevention to:

- Devote more time to augment their capabilities in clinical cancer research; and
- Provide mentoring to junior clinical investigators in the conduct of clinical research, contributing to stabilizing the careers of these individuals so that they can continue to conduct clinical research and, ultimately, provide mentorship to others.

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Next Gen Version 2.0 PPP
Collaborating to Retain CIs

- Retaining clinical investigators is critical to successful development of novel therapeutics for patients
- Clinical investigators reside in academics, community practice and industry; all are valuable and at risk due to diverse factors
- Previously, the attitude has been collegial but competitive among the PP sectors
- Unfortunately, the academic CI is particularly vulnerable to attrition
- A Next Gen V 2.0 PPP could define and deploy approaches to develop and retain a diverse CI workforce in *all* sectors