

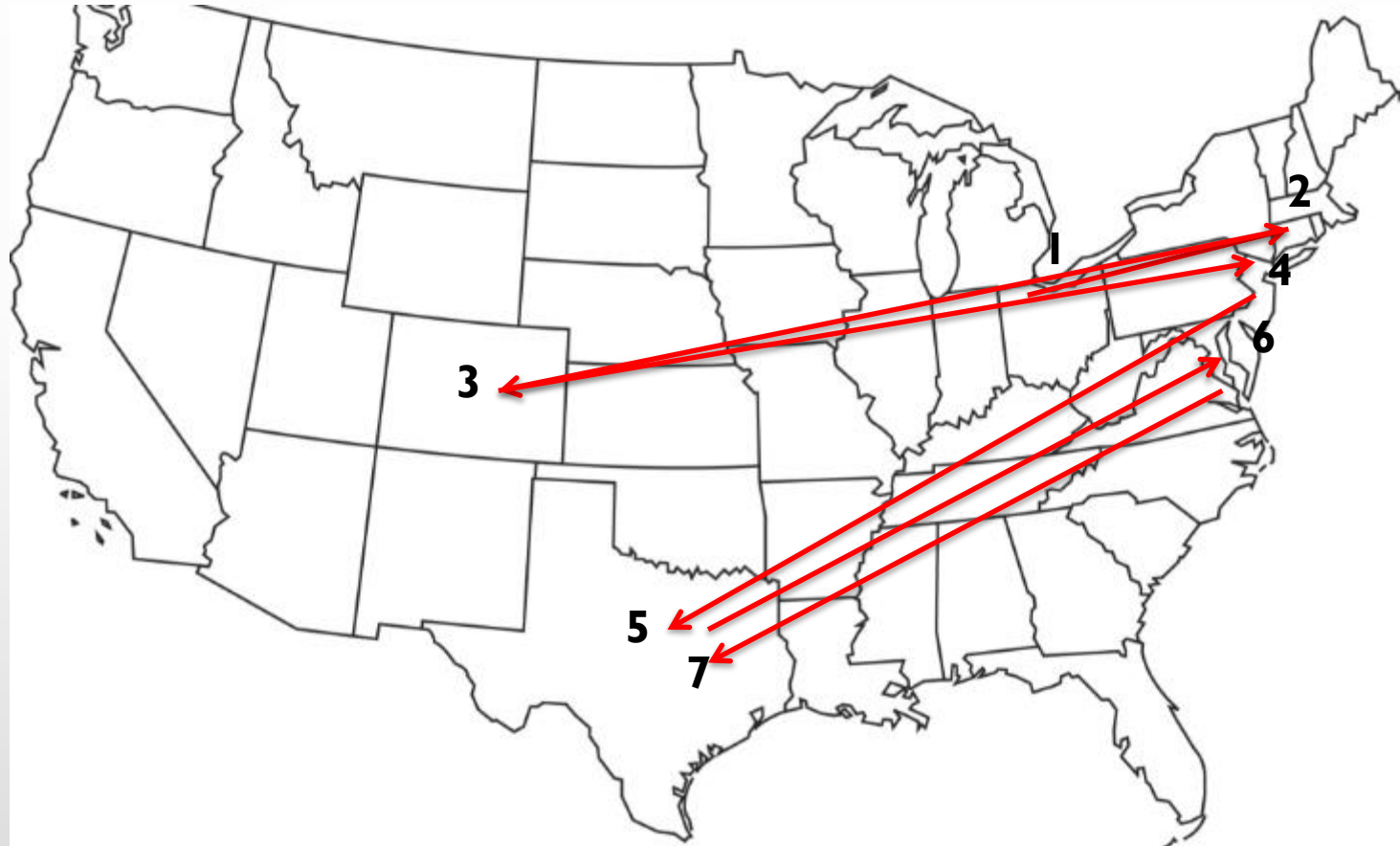
Starting **U**niversity **C**linical **C**areers **E**fficiently, **S**cholarly, and **S**uccessfully

~~Scholarship~~ **Medicine Made Easy** **Fun**

David Gerber, M.D.

**Co-Director, Office of Education and Training
Harold C. Simmons Comprehensive Cancer Center
Professor of Internal Medicine and School of Public Health**

I never planned to do biomedical research



1. Hometown
2. BA, History
3. Juvenile probation officer
4. MD
5. Int Med Residency
6. Med Onc Fellowship
7. Faculty

My perception of a clinician's role in biomedical research has fundamentally changed

Clinical investigation really does need clinical investigators

My perception
2007



MD

Collaborators



My perception
2024



I have also decided to spend my time on what interests and matters to me

- Combining chemotherapy and antibody-drug conjugates
- Seeing if cell-free DNA identifies progression before imaging
- Pre-op vs post-op immunotherapy
- Improving cancer clinical trial design and implementation
- Predicting, diagnosing, treating immunotherapy toxicities
- Taking an honest look at the patient portal in oncology



Only a clinician would notice this

Case 1

58y retired surgeon with **stage 4 lung cancer** wants to be treated on clinical trial. None available due to **stage 1 prostate cancer** s/p prostatectomy 4 years ago.

Case 2

52y woman with **stage 4 lung cancer** referred for a trial. Ineligible for all available trials due to **stage 1 breast cancer** s/p surgery 3 years ago.

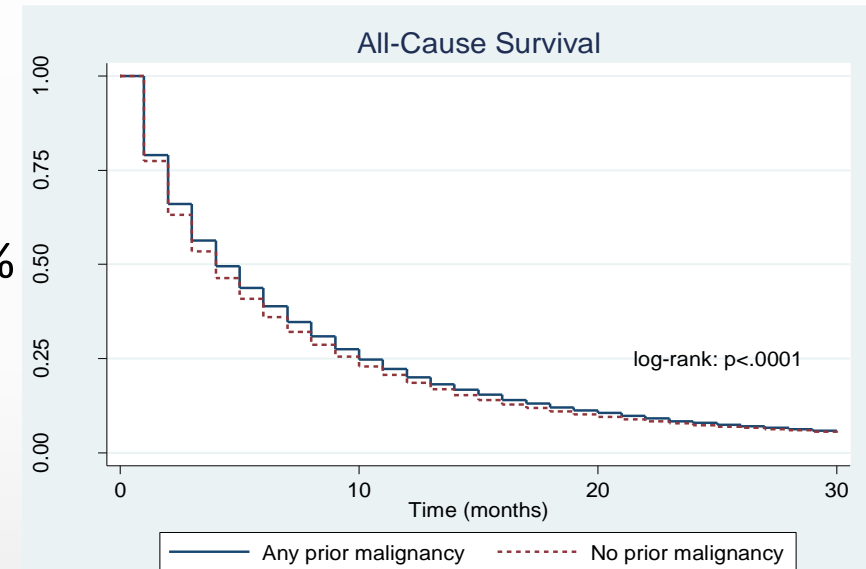
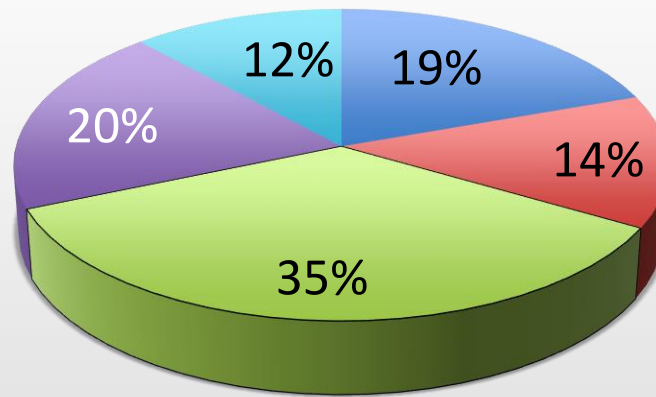
Determining frequency, impact, and justification of this practice



Sandi Pruitt, PhD
OSPH

Projected proportion of patients excluded due to prior cancer

- 0%
- 0 - 5 %
- 5 - 10 %
- 10 - 15 %
- 15 - 20 %



HR 0.94 (95% CI, 0.93-0.96; $P < 0.001$)

Interest and response

The Washington Post
Democracy Dies in Darkness

Health & Science

Cancer clinical trials exclude many desperate patients. Should that change?

KERA
NEWS



Health & Wellness

FDA and a North Texas doctor seek to ease clinical trial restrictions on treatments for lung cancer

Sam Baker, August 22, 2022

A new report looks at how and why the Food and Drug Administration plans to push pharmaceutical companies to loosen the restrictions. Lead author Dr. David Gerber of UT Southwestern Medical Center and Simmons Cancer Center has long been an advocate for change. He spoke with KERA's Sam Baker.

The New York Times

When Cancer Strikes Twice

Personal Health

By JANE E. BRODY | DEC. 25, 2017



**Cancer Clinical Trial
Eligibility Criteria:
Patients with Organ
Dysfunction or Prior or
Concurrent
Malignancies
Guidance for Industry**

**U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**July 2020
Clinical/Medical**

Only a clinician would notice this

Case 1

62y woman receiving combination immunotherapy for stage 4 lung cancer develops **type 1 diabetes 8 months after treatment started.**

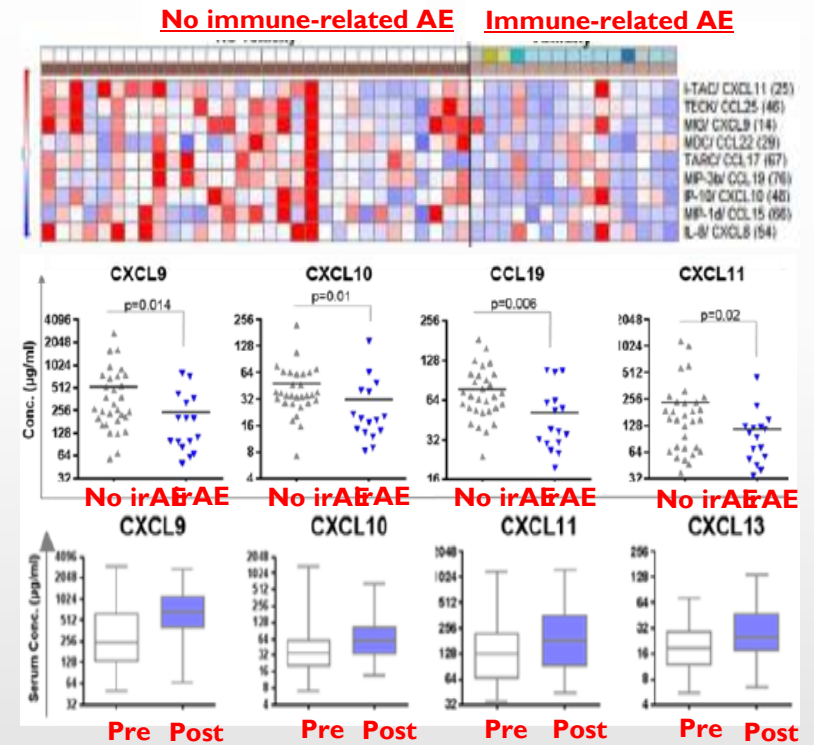
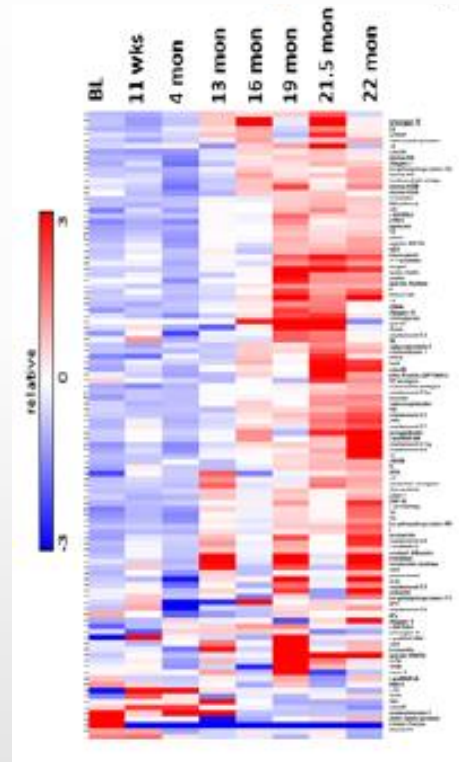
Case 2

68y man responding to pre-operative immunotherapy for stage 2 lung cancer is admitted with **high-grade colitis**, receives high-dose steroids, other immunosuppressants, undergoes a colectomy, but **dies** during that hospitalization.

Predicting, diagnosing, and characterizing immunotherapy toxicity



Ward Wakeland, PhD
Immunology



From publications to funding to patents to a spin-off company



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Technology ▾

Collaborations

Literature Citations

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ONCOSEER DIAGNOSTICS, INC.

OncoSeer Diagnostics, Inc. (OncoSeer), a collaboration with UT Southwestern Medical Center (UTSW), is developing multimarker blood tests that diagnose and predict immune related adverse events (irAE) in oncology patients undergoing immune checkpoint inhibitor (ICI) therapy.



Only a clinician would notice this

Case 1

Despite warnings about how to communicate “medical emergencies,” 53y woman with stage 4 lung cancer sends **repeated messages about dyspnea through the patient portal** starting Saturday morning of Memorial Day Weekend. When messages are seen 3 days later, patient sent to ED and found to have **cardiac tamponade and pulmonary emboli**.

Case 2

34y woman **learns she has cancer through a smartphone notification** while reading a bedtime story to her 3y daughter.

Understanding the implications of patient portals in oncology



Simon Craddock Lee, PhD
Medical Anthropology

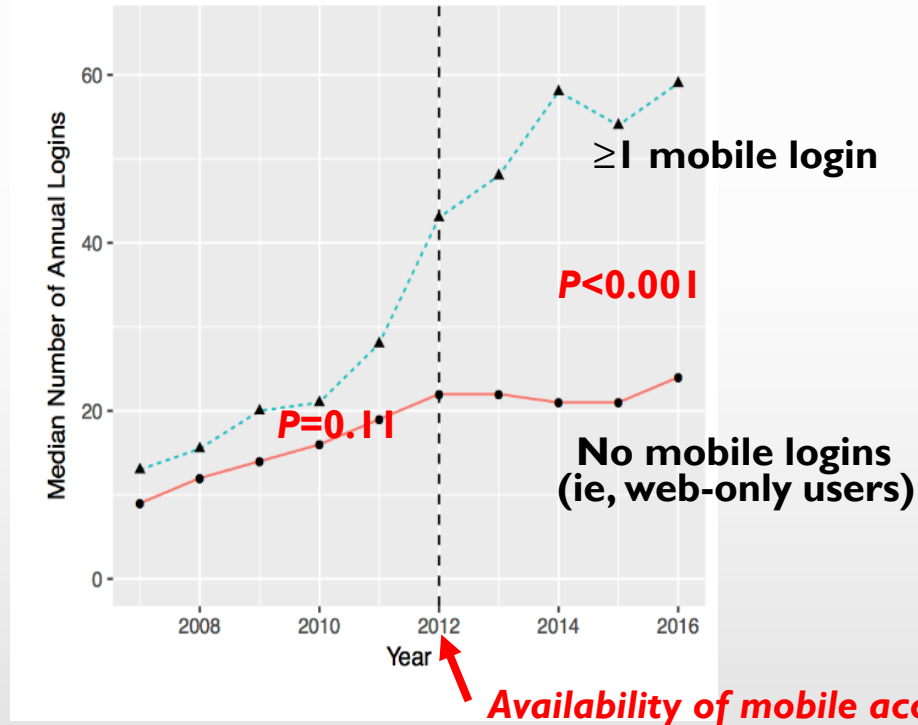
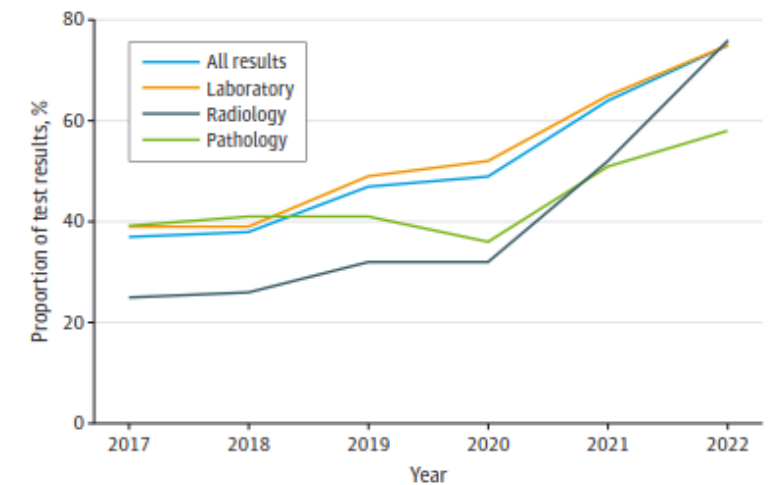


Figure. Proportion of Test Results Viewed by Patients Before Ordering Clinicians



Seems like the public agreed with our concerns

The New York Times



Your Medical Test Results Are Available. But Do You Want to View Them?

The 21st Century Cures Act gave patients easy access to their health information. Now, some diagnoses delivered without context are causing high anxiety.

By Danielle Friedman

Published Oct. 3, 2022 Updated Oct. 19, 2022

WALL STREET JOURNAL

WELLNESS

You're Seeing Medical Test Results Before Your Doctor Does. Why?

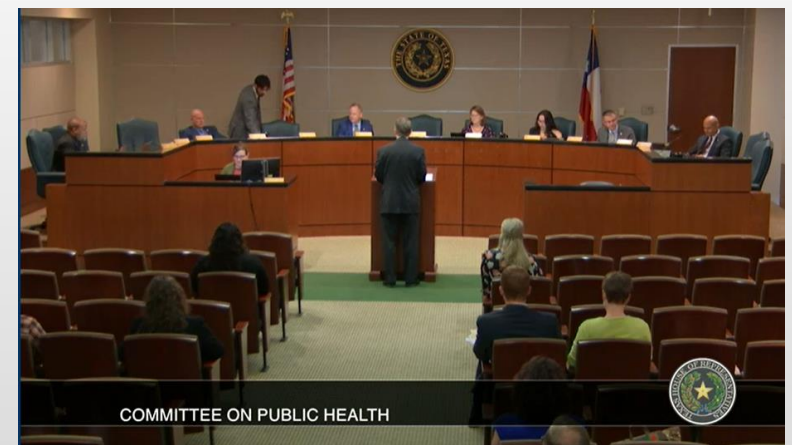
Raw test results, delivered straight to your inbox, can spark confusion at best and panic at worst

By [Sumathi Reddy](#) [Follow](#)

Sept. 14, 2023 5:30 am ET



Cynthia Lenert waited until her doctor's appointment to learn of her CT scan results.



It takes more than ideas to initiate and sustain research

Consider project management



Jessica Lee, MPH
SCCC
COEE



Farjana Fattah, PhD
SCCC
Pathology

Scholarship Medicine Made Easy Fun

Summary of Key Points



Clinicians are uniquely positioned to ask and answer the most important questions in medicine.

Identifying reliable and trustworthy collaborators who share your passion and interests is challenging but worthwhile.

We as faculty are not very good at operationalizing research ideas, so consider assistance with project management early on.

Additional Information and Resources

Population Research Support Services

Data Analytics & Database Administration

Building study-specific databases, electronic medical record abstraction, and data management and analysis.

4 professional research staff

Project Implementation / Management

Ensuring timely study implementation, including development and execution of recruitment strategies, and facilitation of quantitative data collection and intervention delivery.

6 professional research staff

Qualitative Data Collection & Analysis

Facilitating conduct of qualitative components of research projects, including data collection and analysis.

3 professional research staff

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Program Coordinator: Ronni Ashley (ronni.ashley@utsouthwestern.edu)

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