

# Clinical Trials Advisory Committee

**Fiscal Year 2023 Annual Report**

**August 21, 2024**

**David E. Gerber, MD**

Harold C. Simmons Comprehensive Cancer Center  
UT Southwestern Medical Center  
Dallas, Texas



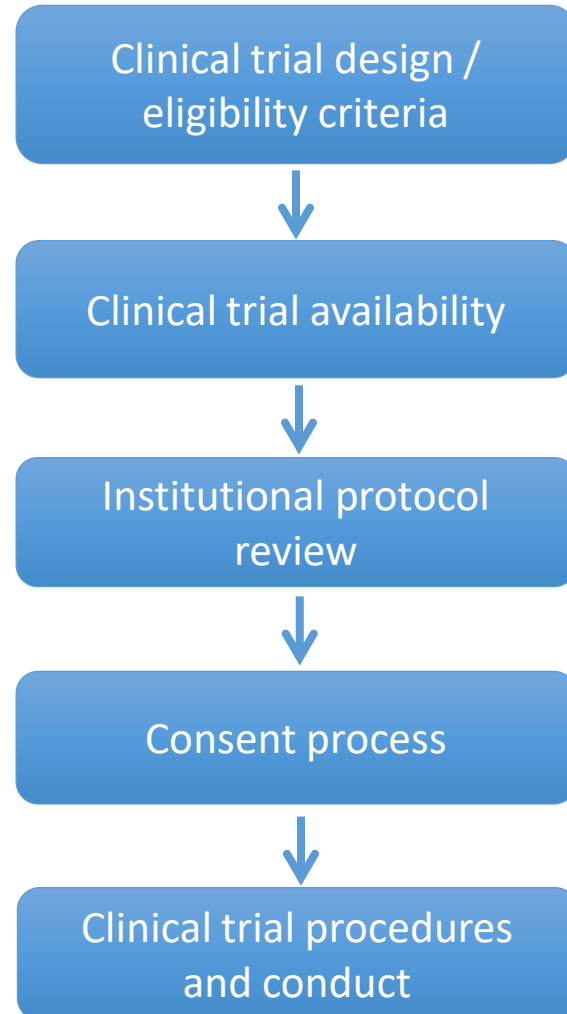
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# Update overview

- My background
- CTAC members
- CTAC recommendations
- CTAC accomplishments
- Clinical trial activities
- Spotlight
  - CPRIT Early Clinical Investigator grant
  - CPRIT Texas Clinical Trial Participation Award
  - CPRIT Clinical Trial Network Award



# I have spent >15 years studying the design, conduct, and reporting of cancer clinical trials



J Natl Compr Canc Netw 2022;20:792-799.  
JAMA Oncol 2022;8:1333-1339.  
J Natl Cancer Inst 2014;106 (11)  
J Natl Cancer Inst 2015;107 (4)  
Breast Cancer Res Treat 2021;187:853-65  
Lung Cancer 2016;98:106-13  
British J Cancer 2017;116:717-25  
J Thorac Oncol 2017;12:1489-95  
J Comp Effect Res 2014;4:289-91  
Clin Lung Cancer 2020;21:21-27  
Clin Cancer Res 2021;27:2416-2423  
Oncologist 2015;20:674-82  
J Natl Compr Cancer Netw 2015;13:409-16  
J Oncol Practice 2017;13:982-991.  
Oncologist 2009;14:468-75  
J Oncol Practice 2012;8:91-96  
Cancer 2020;15:1605-13  
J Clin Oncol 2019;37:1993-1996  
JTO Clin Res Rep 2023;4:100575.  
J Oncol Practice 2016;12:1020-1028  
J Oncol Practice 2017;13:1021-1029  
J Oncol Practice 2020;16:e64-e74  
JCO Oncol Pract 2022;18:729-732  
Contemp Clin Trials 2022;121:106922  
J Clin Oncol 2022 Aug 22.



# Funders, the public, and regulatory authorities have responded to this work



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Health & Science

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



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.



## One big change is coming to clinical drug trials, and it's 'no longer lip service'

September 30, 2022

Karen Weintraub, USA TODAY

The New York Times

## When Cancer Strikes Twice

Personal Health

By JANE E. BRODY DEC. 25, 2017



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# Funders, the public, and regulatory authorities have responded to this work

## Expanding eligibility

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

Cancer Clinical Trial  
Eligibility Criteria:  
Laboratory Values  
Guidance for Industry, IRBs,  
and Clinical Investigators

### *DRAFT GUIDANCE*

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Elaine Chang at 202-302-2942 or (CDER) Abhilasha Nair at 301-796-8317 or (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010.

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

April 2024  
Clinical/Medical

## Expanding APP roles



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
National Cancer Institute

9609 Medical Center Drive  
Bethesda, MD 20892

### MEMORANDUM

**DATE:** September 7, 2021

**TO:** Principal Investigators and Operations/Statistics Offices of NCI CTEP-Supported Clinical Trials Networks & Consortia and DCP-Supported NCI Community Oncology Research Program (NCORP) Research Bases

**FROM:** Meg Mooney, MD, Associate Director, CTEP, DCTD, NCI  
Worta McCaskill-Stevens, MD, Director, NCORP, DCP, NCI

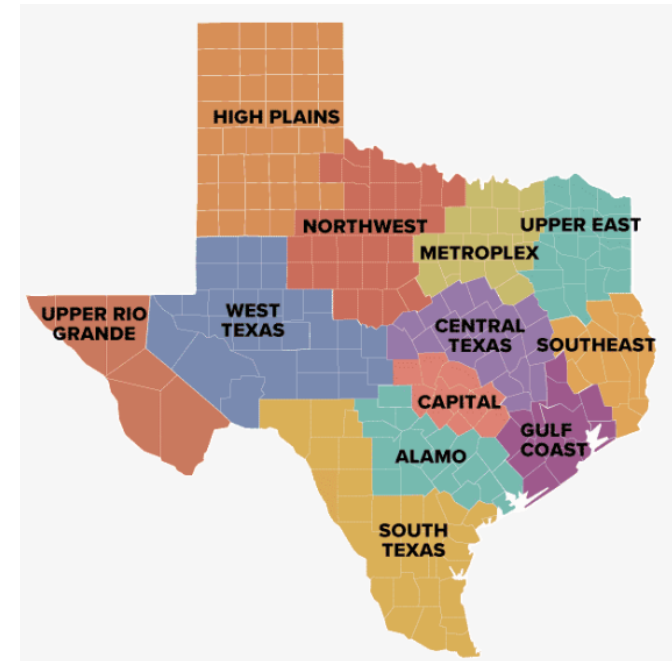
**SUBJECT:** Guidance and Update on Advanced Practice Providers Writing Study Agent Orders on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP)



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# CTAC membership represents diverse expertise and regions

Name	Research	Setting	Region
Carlos Arteaga	Translational	Academic	Metroplex
Ruma Bhagat	Population	Industry	External
Suzanne Cole	Clinical	Community	Metroplex
S. Gail Eckhardt	Clinical	Academic	Gulf Coast
David Gerber	Population	Academic	Metroplex
David Hong	Clinical	Academic	Gulf Coast
Ronan Kelly	Clinical	Community	Metroplex
Martha Mims	Translational	Academic	Gulf Coast
Pavan Reddy	Translational	Academic	Gulf Coast
C. Pat Reynolds	Translational	Academic	West Texas



# CTAC recommendations

- 1. Broaden representation to other professional groups (APPs, social workers, navigators) and other regions of the state (Upper Rio Grande, South Texas, etc)**
- 2. Further refine clinical trial-focused RFAs to ensure diverse access and enrollment**
- 3. Consider potential new RFAs**
  1. Community (especially rural) medical oncologists mentored by experienced investigators/sites
  2. Recruitment of clinical trialists in rural areas
  3. Building/expanding clinical trial infrastructure for Texas Regional Excellence in Cancer (TREC)-eligible institutions
- 4. Continue Work Group monthly meetings**
- 5. Hold annual in-person CTAC meetings**





# Key CTAC accomplishments

- 1. Provided guidance to CPRIT on expansion of access to clinical trials in Texas and development of a clinical trialist workforce through focused RFAs**
  - Early Clinical Investigator Award (proposed FY25.2)
  - Clinical Investigator Award (FY24.2)
  - Individual Investigator Research Awards for Clinical Trials (FY25.1)
  - Individual Investigator Research Awards for Clinical Translation (FY24.1)
- 2. Expanded CTAC membership to include members of industry, multi-county non-profit hospital systems, community oncologists, and rural clinical trialists**
- 3. Created an active Work Group to**
  - revisit and revise bench-to-bedside RFAs
  - identify collaborations with NCI and other groups for clinical research best practices
  - examine programs (including third-party vendors) with success in clinical trials for rural populations
  - engage with Texas Oncology and other practices
  - leverage technology to enhance access to trials





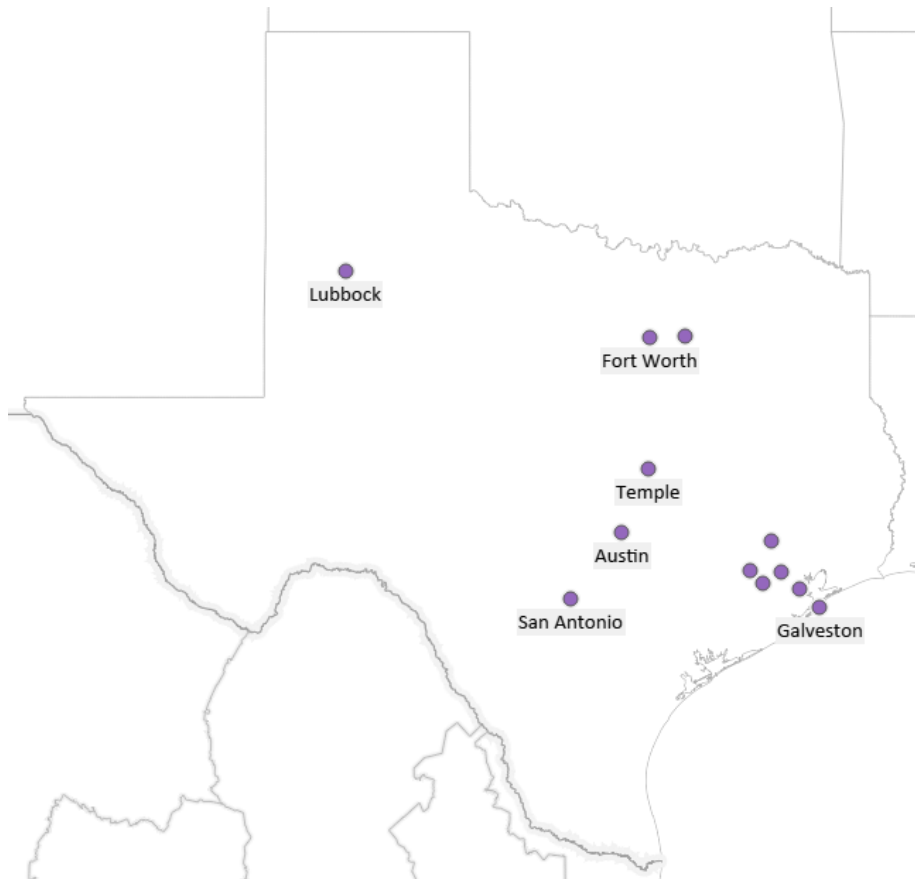
# CPRIT-supported clinical trial enrollment to date

<b>Trial type</b>	<b>Total trials</b>	<b>Active trials</b>	<b>Enrollment</b>
<b>Interventional</b>	214	94	13,450
<b>Observational</b>	93	28	43,886
<b>TOTAL</b>	<b>307</b>	<b>122</b>	<b>57,336</b>

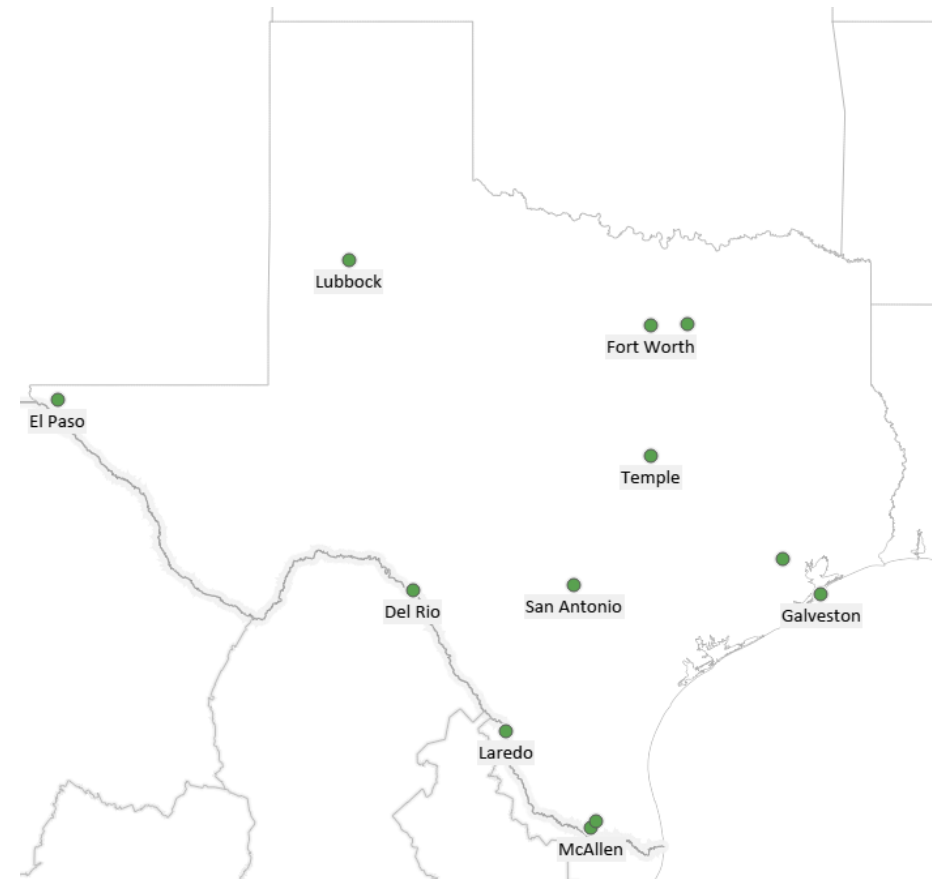


# CPRIT-supported active clinical trial locations

## Interventional



## Observational



# Spotlight: CPRIT Early Career Investigator Award

Provides **cancer physicians early in their academic career** the opportunity to

- develop the research skills and experience to become clinical investigators
- establish partnerships with laboratory-based collaborators to design and conduct correlative studies
- receive protected time to develop and conduct investigator-initiated clinical trials
- increase the pool of clinical investigators at Texas academic institutions who
  - conduct patient-oriented studies
  - translate basic discoveries through innovative clinical trials for individuals with or at risk for cancer

**Applications solicited from institutions**

**Award amount:** Up to **\$1,500,000** (total costs).

**Award duration:** Up to **5 years**.



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# Early Career Investigator Award program outcomes\*

Metric	N or amount
Awards	10 (7 reporting)
Publications	35
Patents	1
Follow-on funding	\$570,000

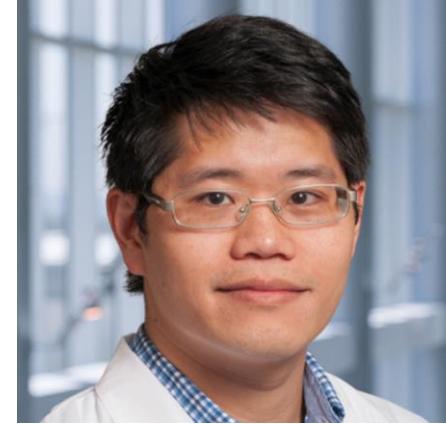
## Clinical trial activities

Metric	Observation	Phase I	Phase II	Phase III	TOTAL
Studies	1	2	1	1	5
Enrollment	13	29	47	2	78

\*Based on 7/10 returned progress reports available at time of data collection



# Impact of CPRIT Early Career Investigator Award recipients



Name	Nicolas Palaskas, MD	David Hsieh, MD
Institution	MD Anderson Cancer Ctr	UT Southwestern Simmons Cancer Ctr
Division	Cardiology	Hematology-Oncology
Project	Retrospective study of immunotherapy-related myocarditis	Clinical trial of novel immunotherapy for liver cancer
Findings	IL-6, TNF $\alpha$ elevations	Synergistic effects of targeting PS and PD-1
Publication	<i>Diseases</i> 2024;12:88	<i>Nat Commun</i> 2024;15:2178.



# **Spotlight: CPRIT supports two mechanisms designed to *enhance access to clinical trials***

## **Texas Clinical Trial Participation Award (TCTPA)**

- Duncan Cancer Center (Baylor) / Harris Health
- Simmons Cancer Center (UT Southwestern)

## **Clinical Trial Network Award (CTNA)**

- MD Anderson Cancer Center
- Simmons Cancer Center (UT Southwestern)



# Why is the Clinical Trial Participation Program important?

## *A cancer diagnosis causes major financial strain*

- >3/4 of people with cancer leave the workforce during their treatment
- >1/3 spend their life savings within the first two years after diagnosis

## *Trials can exacerbate these issues*

- Extra visits may lead to more travel and more missed workdays
- Increased demands result in an average of \$600 in added non-medical costs per month
- Lower-income individuals travel 3 times further to reach clinical trial sites

## *As a result . . .*

- Individuals with household incomes below \$50,000/y are 30% less likely to enroll in cancer clinical trials than those earning more,
- Fewer than 5% of trial enrollees are Medicaid recipients
- 80% of patients feel that assistance with lodging and transportation costs would increase their likelihood of enrollment to trials outside their area





**HB3147 (sponsored by Rep. Tan Parker) was passed by the 86<sup>th</sup> Texas Legislature to ↑ number and diversity of patients in cancer clinical trials**



- Removes non-clinical out-of-pocket costs as barriers to participation
- Impetus for CPRIT Texas Clinical Trials Participation Award
- CPRIT program modeled off Lazarex Cancer Foundation multi-year nationwide IMPACT program to increase trial enrollment, retention, and equitable access



# The Participation Award reimburses non-clinical costs for patients on clinical trials

## Eligible costs:

- Travel (airfare, gas, parking, tolls, rideshare, taxi, etc)
- Lodging
- Meals
- Childcare
- Wi-Fi (to have access to virtual visits)

***Can cover a caregiver's costs if travel >50 miles to trial site***

***Limited to individuals who live in Texas***

**Household income up to 700% Federal Poverty Level (i.e., most of our patients) are eligible**

Number in household	Income 0-400%	Income 401%-550%	Income 551% - 700%
1	<\$51,040	\$51,041 - \$70,180	\$70,181 - \$89,320
2	<\$68,960	\$68,961 - \$94,820	\$94,821 - \$120,680
3	<\$86,880	\$86,881 - \$119,460	\$119,461 - \$152,040
4	<\$104,800	\$104,801 - \$144,100	\$144,101 - \$183,400
5	<\$122,720	\$122,721 - \$168,740	\$168,741 - \$214,760
6	<\$140,640	\$140,641 - \$193,380	\$193,381 - \$246,120
7	<\$158,560	\$158,561 - \$218,020	\$218,021 - \$277,480
8	<\$176,480	\$176,481 - \$242,660	\$242,661 - \$308,840
REIMBURSEMENT RATE:	100%	75%	50%



# In the Simmons Cancer Center, this program has been implemented across all three clinical sites

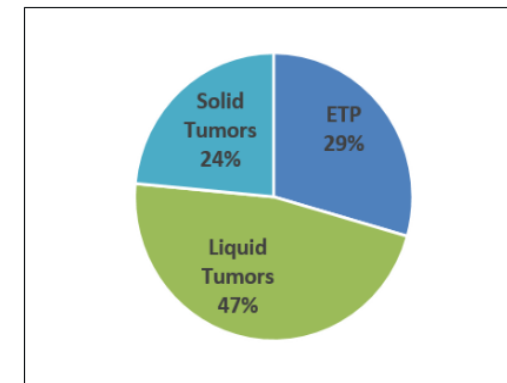
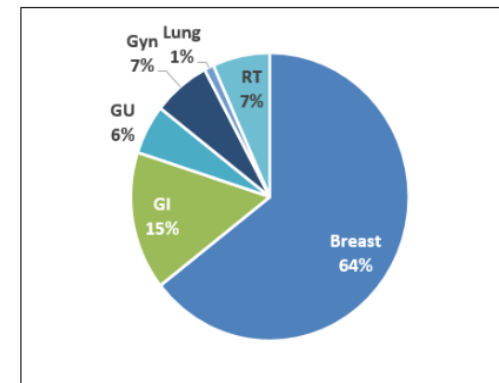
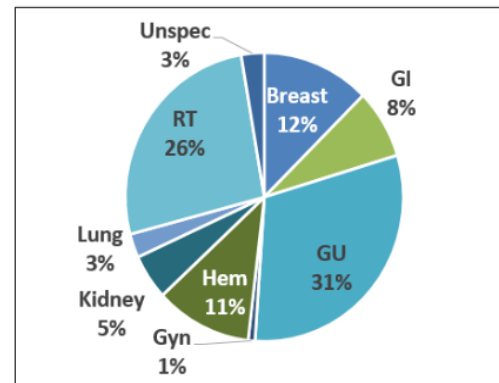
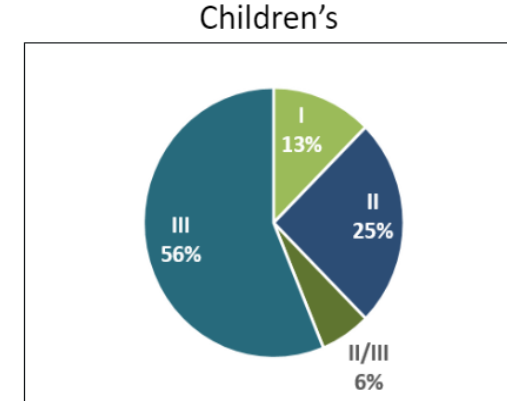
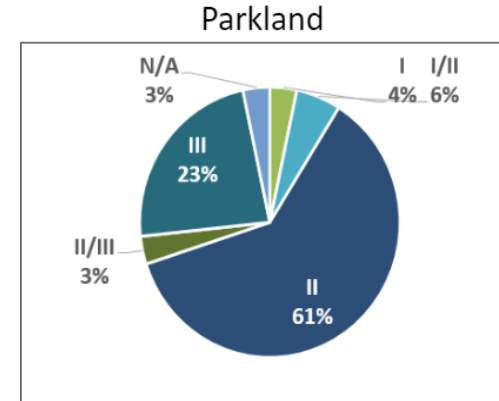
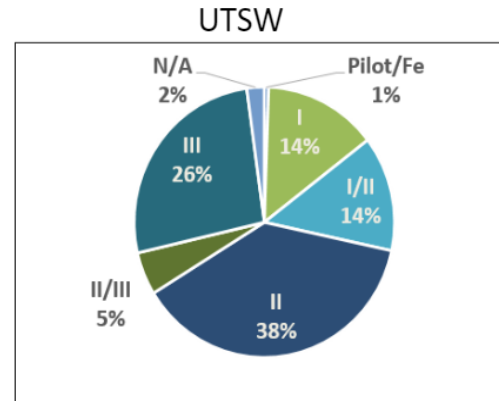
Partnered with Lazarex to administrate expense reimbursement

>**\$170,000** in patient reimbursements provided to >**160 patients**:

- Transportation (Uber/Lyft, Mileage, Parking, Tolls, Airfare): \$69,000
- Meals: \$55,000
- Lodging: \$30,000
- Wi-Fi: \$16,000

Patients from underrepresented minority groups make up **51%** of financial reimbursement program enrollments

First pediatric facility in nation with a reimbursement program for such costs



# CTPA sites have identified challenges and are addressing them with CPRIT

## *The enrollment process can be challenging*

- Navigators now help all patients complete forms and obtain required income documentation

## *Expense documentation can be burdensome*

- Travel requires map showing locations of home and clinic
- Expenses require receipt from entity with tax ID (e.g., childcare center rather than babysitter)

## *TCTPA sites working with CPRIT to streamline processes*

- Developing a list of expense categories with associated reimbursement rates to ease documentation



# This topic is gaining national attention

**Two related pieces of federal legislation in development**

## **Clinical Trials Modernization Act**

Reps. Raul Ruiz (D-Calif.) and Larry Bucshon (R-Ind.)

## **Harley Jacobsen Clinical Trial Participant Income Exemption Act**

Reps. Mike Kelly (R-PA) and Chrissy Houlahan (D-PA)



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**Yet financial support is waning**

**Lazarex Cancer Foundation will close its reimbursement program this year**



# The Texas Clinical Trials Network offers trial sponsors access to diverse settings and populations

## ***Lead institution:***

MD Anderson (Houston)

## ***Affiliates:***

Lyndon B. Johnson (Houston)\*

UT Medical Branch (Galveston)

Baylor- Scott & White (Round Rock) - new

University of Texas (Tyler) - new

## ***Lead institution:***

UT Southwestern (Dallas)

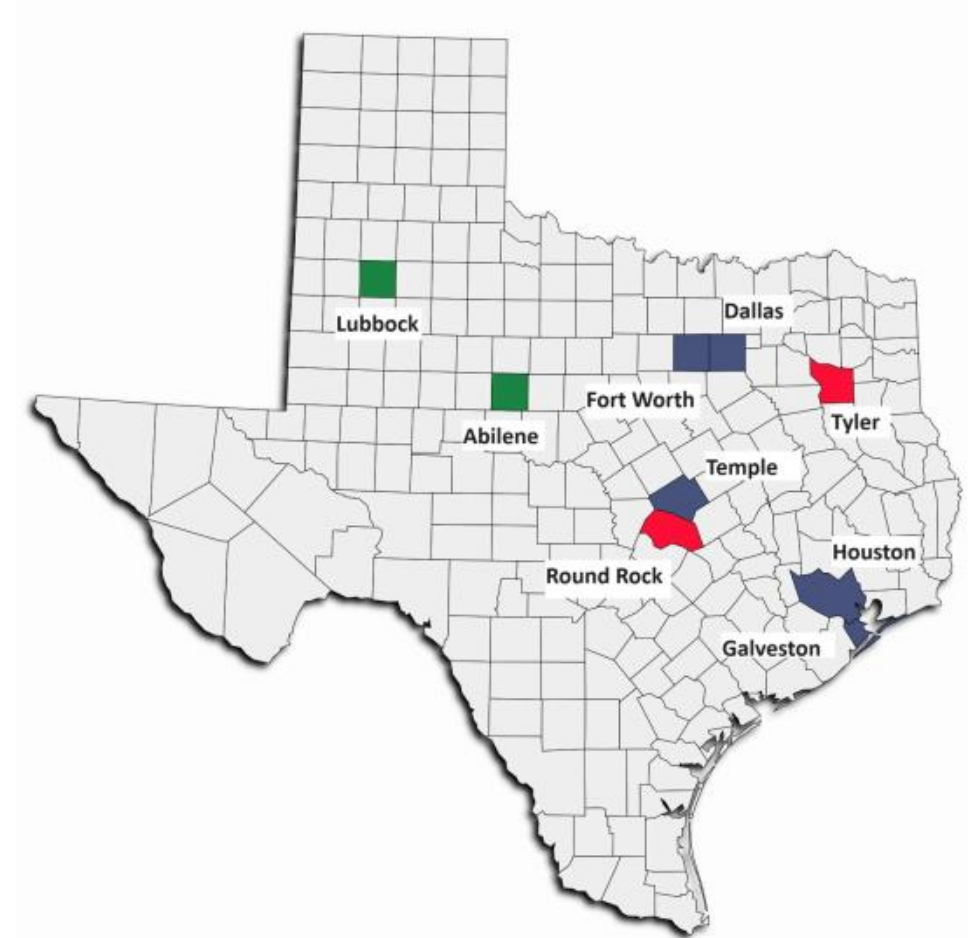
## ***Affiliates:***

John Peter Smith (Fort Worth)\*

Baylor-Scott & White (Temple)

Hendrick Medical Center (Abilene) - pending

Covenant Health (Lubbock) - pending





# The Network is designed to optimize the activation, conduct, and oversight of clinical trials

- CPRIT-supported infrastructure/personnel enhance sites' capabilities
- Critical review of protocols to match sites' populations and needs
- IRB reliance (within regions) to expedite activation
- Shared strategies to enhance awareness of and enrollment to activated trials
- Oversight and education to support protocol management, data collection, and other trial activities



# 2023-2024 CTNA accomplishments

- May 2024 symposium: >120 attendees representing >60 companies
- Individual meetings with >20 industry sponsors and initiation of 16 master CDAs to establish longitudinal working relationships
- Partner program relationships established with CRO (IQVIA) and industry sponsor (Genentech Advancing Inclusive Research Site Alliance)
- Activation of 20 trials with 11 currently in start-up
- Network Affiliate PIs have joined NCI cooperative group committees
- Lead Institution-Network Affiliate academic collaborations to highlight and understand patient populations
- Geographic expansion to Northeast Texas with pending expansion to West Texas



# Encouraging developments at John Peter Smith (JPS)



**Kalyani Narra, MD**  
Site PI



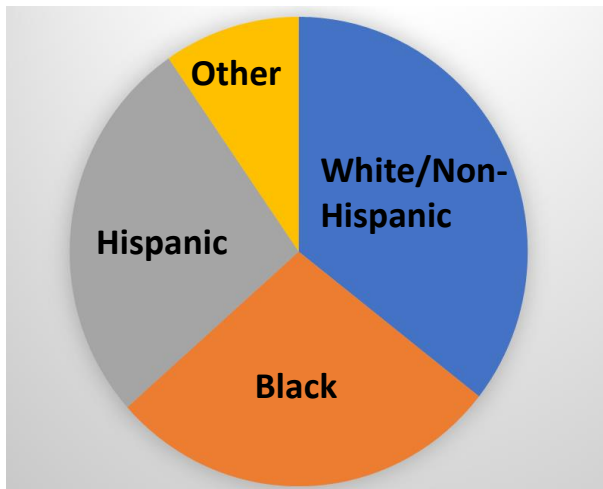
**Lindsay Crutcher, CCRC**  
Site Coordinator

## 2024

Activated 3 industry-sponsored trials (first ever)  
Enrolled 6 patients

## Academic collaborations to enhance visibility

- 1 Testing patterns of *EGFR* and *ALK* alterations and clinical outcomes for patients with non-
- 2 small cell lung cancer in a safety net hospital system
- 3
- 4 Kalyani Narra<sup>1,2</sup>, Bassam Ghabach<sup>1</sup>, Vivek Athipatla<sup>3</sup>, James-Michael Blackwell<sup>4</sup>, Jolonda
- 5 Bullock<sup>1</sup>, Anna Diaz<sup>4</sup>, David E. Gerber<sup>5,6,7</sup>, Mitchell S. von Itzstein<sup>5,6</sup>
- 6
- 7 <sup>1</sup>John Peter Smith Oncology and Infusion Center. Fort Worth, Texas, USA.



**2/3 patients are URM**



**April Bell, MS**  
Site Manager



**Celeste Caliman, MSc**  
Site Director

## Bidirectional learning



JPS developed QR codes to give clinicians rapid access to trial details



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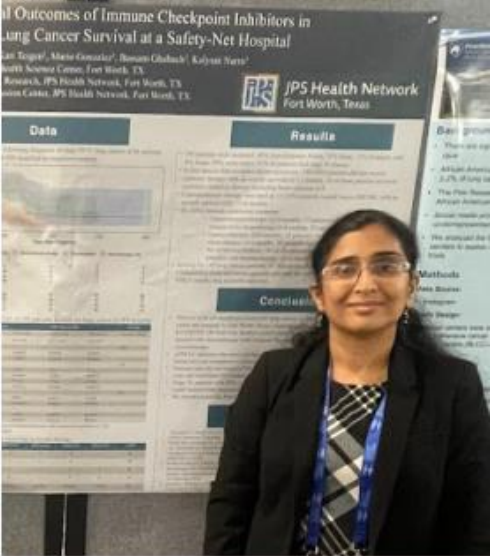
# Clinical research requires clinical buy-in and support

**acclaim**  
Improving health together  
A partner with JPS Health Network



## ACCLAIM PHYSICIAN GROUP

# DR. KALYANI NARRA



Dr. Narra with OCR staff at JPS RQS 2024

### ABOUT DR. NARRA

Kalyani Narra MD joined Acclaim in August 2018 as a full-time hematologist oncologist at John Peter Smith (JPS) Hospital. Her passion for research as well as encouragement from colleagues and rich JPS databases led her to create her large research portfolio.





Questions?

