

Clinical Trials Advisory Committee

Fiscal Year 2024 Annual Report

August 20, 2025

David E. Gerber, MD

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



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS












Report overview

- CTAC focus on clinical research challenges
- CTAC recommendations and accomplishments
- Clinical trial activities
- Spotlights
 - CPRIT Clinical Investigator Award
 - CPRIT Texas Clinical Trial Participation Award
 - CPRIT Clinical Trial Network Award
 - CPRIT Rural Oncology Trials Accelerator Award (NEW)
 - CPRIT Recruitment or Retention of Clinical Trialists Award



CTAC is working to address the challenges faced by the people doing clinical research

Promoting Reasonable Career Expectations and Maximizing Professional Fulfillment for Academic Oncologists: ASCO Recommendations for Academic Medical Centers

Eric P. Winer, MD, FASCO¹ ; Laura A. Levit, JD² ; Ethan Basch, MD, MSc, FASCO³ ; Mariana Chavez-MacGregor, MD, MSC, FASCO⁴ ; Ray Dubois, MD, PhD⁵ ; S. Gail Eckhardt, MD, FASCO⁶; Lee M. Ellis, MD, FASCO, FACS⁴; Clifford A. Hudis, MD, FACP, FASCO² ; Deborah Schrag, MD, MPH, FASCO⁷ ; Corey Speers, MD, PhD⁸ ; Breelyn A. Wilky, MD⁹ ; Michal Tibbits, MA²; Rebecca Spence, JD, MPH² ; and Elizabeth Garrett-Mayer, PhD² 

Protected Time, Resources, and Expectations for Academic Oncology Clinical Research Physicians

David E. Gerber, MD¹; Nikhil I. Khushalani, MD²; Ang Gao, PhD¹; Song Zhang, PhD¹; Jeffrey W. Clark, MD³; Wells A. Messersmith, MD⁴; Al B. Benson III, MD⁵; Igor Puzanov, MD, MSCI⁶; D. Neil Hayes, MD, MPH⁷; Nicole A. Zion, BS, CCRP⁸; Tricia Heinrichs, MSM⁸; and Jordan D. Berlin, MD⁹



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 Working Group monthly meetings**
- 5. Hold annual in-person CTAC meetings**

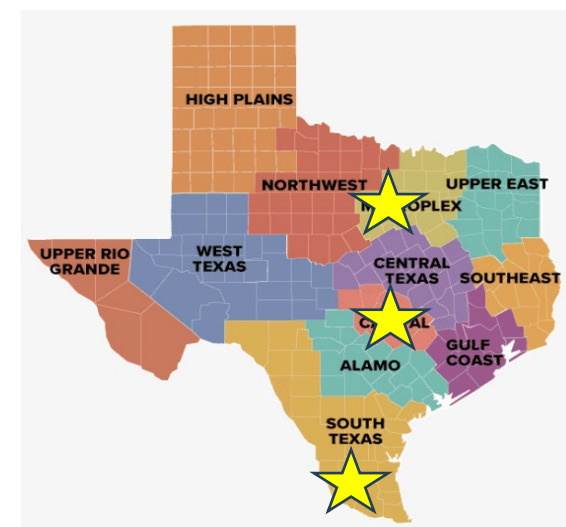


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New CTAC members expand our expertise and representation



Name	Research	Setting	Region
Carlos Arteaga, MD	Translational	Academic	Metroplex
April Bell, MS CCRC	Operations	Community	Metroplex
Ruma Bhagat, MD MPH	Population	Industry	External
Everardo Cobos, MD	Clinical	Academic	South Texas
Suzanne Cole, MD	Clinical	Community	Metroplex
S. Gail Eckhardt, MD	Clinical	Academic	Gulf Coast
David Gerber, MD	Population	Academic	Metroplex
David Hong, MD	Clinical	Academic	Gulf Coast
Ronan Kelly, MD	Clinical	Community	Metroplex
Martha Mims, MD PhD	Translational	Academic	Gulf Coast
Pavan Reddy, MD	Translational	Academic	Gulf Coast
C. Pat Reynolds, MD PhD	Translational	Academic	West Texas
Jeff Yorio, MD	Clinical	Community	Capital



April Bell, M.S., CCRC, ACRP, ACRP-PM
 Manager, Clinical Research Operations
 JPS Health Network



Everardo Cobos, M.D., FACP
 Chair, Department of Medicine and Oncology
 UT Rio Grande Valley School of Medicine



Jeff Yorio, M.D.
 Texas Oncology-Austin Central
 Central & South Texas Site Research Leader
 Sarah Cannon Research Institute at Texas Oncology

Spotlight: CPRIT Clinical Investigator Award

Supports **mid-career clinician scientists** with specialty training relevant to delivery of cancer care to devote more time to augment their capabilities in clinical cancer research, and to provide mentoring to early-stage investigators in the conduct of clinical research.

Applications solicited from institutions

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

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



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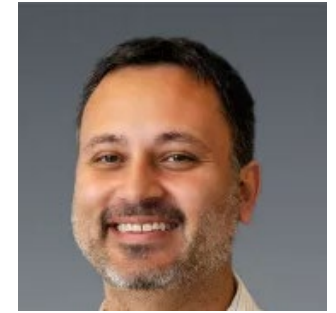
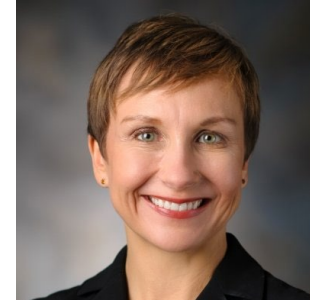
Award duration: Up to **5 years**.

Gaps filled

- In 2017, the NCI stopped funding the K24 (midcareer investigator award) mechanism
- The proportion of NIH early-career award (K23/K08) recipients leaving research careers has doubled



Impact of CPRIT Early Career Investigator and Clinical Investigator Award recipients

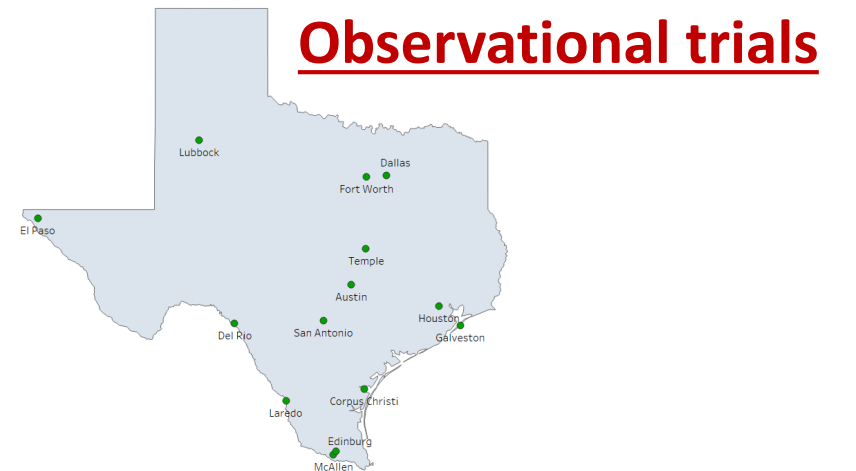
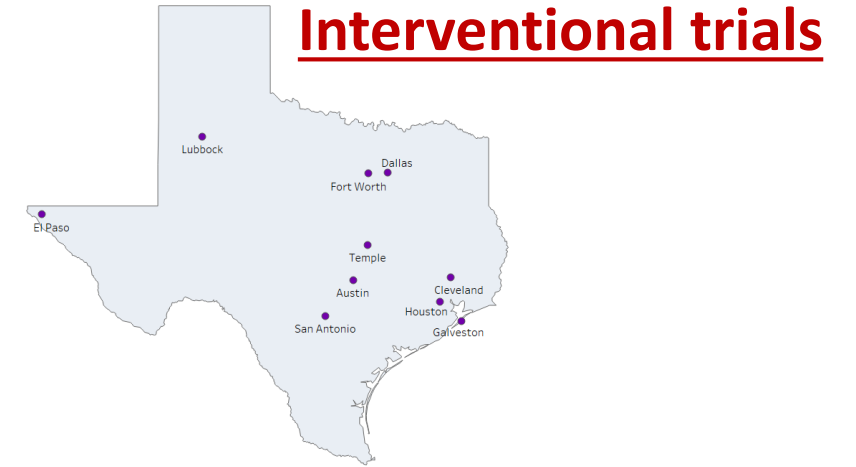


Name	Neil Desai, MD	Meenakshi Hegde, MD	Jennifer McQuade, MD	Bilal Omer, MD
Institution	UT Southwestern	Texas Children's	MD Anderson	Baylor
Project	Adapting radiotherapy clinical trials to treatment response and AI innovations.	Advancing immunotherapy for high-risk cancers in children and adolescents	Dietary intervention to modulate the microbiome and immune response	Signal-Augmented Cancer Cell Therapies
Findings	<i>Cureus</i> 2024 <i>Int J Radiat Oncol Biol</i> 2025	<i>Cancer Res Commun</i> 2025 <i>Pediatr Blood Cancer</i> 2025	<i>BMC Cancer</i> 2024 <i>Am Soc Clin Oncol Educ</i> 2025	<i>J Clin Oncol</i> 2024 <i>Pediatr Blood Cancer</i> 2025



CPRIT-supported clinical trial enrollment to date

Trial type	Total trials	Active trials	Enrollment
Interventional	269	115	16,475
Observational	103	32	47,307
TOTAL	372 (↑ from 307)	147 (↑ from 122)	63,782 (↑ from 57,336)



Spotlight: CPRIT-supported mechanisms 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)



The Texas Clinical Trial Participation Award recognizes the financial burden of cancer clinical trials

A cancer diagnosis causes major financial strain

- >3/4 of people with cancer stop working during treatment
- >1/3 spend their life savings within two years










Trials can exacerbate these issues

- Extra visits may lead to more travel and more missed workdays
- Average of \$600 in added non-medical costs per month
- Lower-income individuals travel 3 times further to 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 likelihood of enrolling in trials outside their area

Financial Toxicity in Cancer Clinical Trials: An Issue in Need of Clarity and Solutions

Elizabeth K.S. Barksdale, PhD¹ ; Wendy Selig, MS² ; Willyanne DeCormier Plosky, DrPH³; Erin Miller, BS⁴; Keri McDonough, MA⁵ ; Chelsea Backler, MSN APRN⁶ ; Elizabeth George, MS⁷ ; Mark E. Fleury, PhD⁸ ; Marc J. Taylor, BS⁹; Diana E. Pankevich, PhD⁹; Jim Murphy, MS¹⁰; Kristin Hermann, MS¹¹; Leigh Ann Davis, BA⁹; Gissou DeCotiis, MBA¹²; Cecile Gonzalez-Cerimele, BA¹³; Colleen Cook, BS¹⁴; Sandra Shaw, MBA^{14,15}; Luke Gelinas, PhD¹⁶ ; Dana L. Dornsife, BS⁴; Barbara E. Bierer, MD³ ; and David E. Gerber, MD¹⁷ 

SUPPORT

Supported in part by a Cancer Prevention and Research Institute of Texas (CPRIT) Clinical Trials Participation Award (RP210115, to D.E.G.).

Unger JM et al. JAMA Oncol 2016;2:137-9.

Yabroff KR et al. J Clin Oncol 2016;34:259-67.

Guy GP Jr et al. J Clin Oncol 2013;31:3749-57.

Nipp RD et al. Oncologist 2015;20:572-5.

Borno HT et al. Oncologist 2018;23:1242-49.

Unger JM et al. J Clin Oncol 2013;31:536-42.

Barksdale EKS et al. J Clin Oncol 2025.



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Gaps filled

- National legislation (Harley Jacobsen Clinical Trial Participation Income Exemption Act; Clinical Trial Modernization Act) remains in earliest stages
- In November 2024, the Lazarex IMPACT Program closed
- In December 2025, the Lazarex Cancer Foundation (started 2006) will close



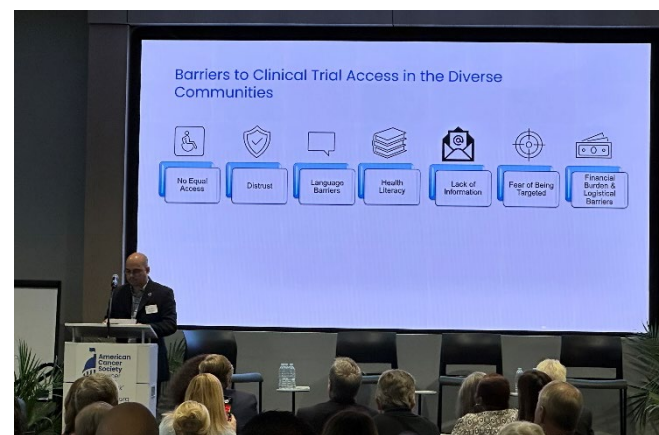
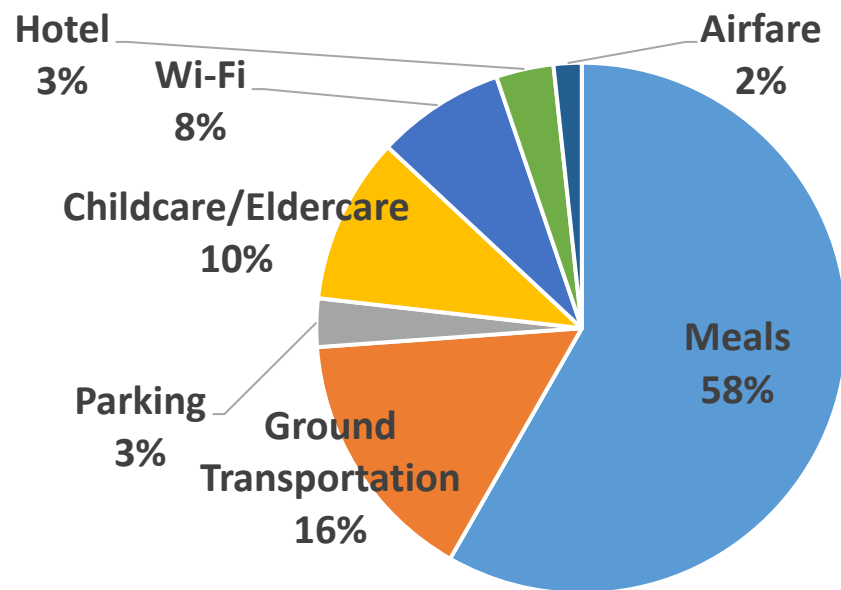
CTPA activities continued to grow during the past year

UT Southwestern program 8.1.24-5.31.25

Metric	Number
Patients reimbursed*	96
Reimbursements	392
Total reimbursement	\$166,202
Avg. reimbursement	\$424



Baylor clinical trials Navigation Team



UTSW Navigation Mgr at ACS CAN

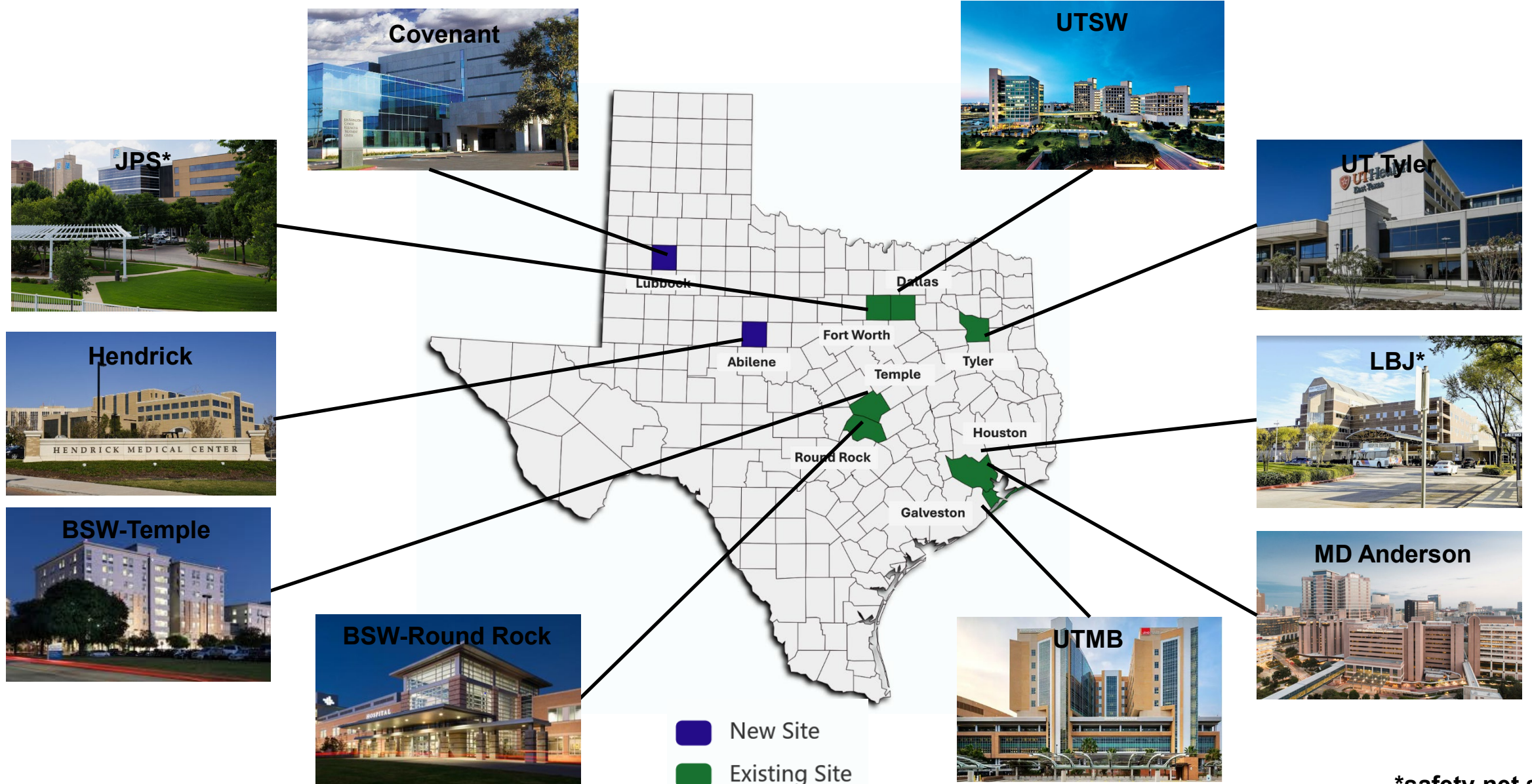


UTSW Prog Mgr at community event



*Texas residents; income <700% Federal Poverty Rate; sliding scale (50-100% reimbursement)

The Texas Clinical Trial Network has expanded reach and impact



*safety-net site

2024-25 CTNA accomplishments

- Expansion to West Texas sites
- 3rd annual webinar for sponsors/contract research organizations
 - >160 attendees
 - Included health systems leadership
- Activation of 28 trials with 41 in start-up process
- Joined Genentech Advancing Inclusive Research (AIR) Site Alliance
- Joined the IQVIA Partner Program
- Increasing site experience and exposure



JPS meeting with Pfizer

Article

Impact of Screening on Mortality for Patients Diagnosed with Hepatocellular Carcinoma in a Safety-Net Healthcare System: An Opportunity for Addressing Disparities[†]

Kalyani Narra^{1,2}, Madison Hull³, Kari J. Teigen¹, Vedaamrutha Reddy⁴, Jolonda C. Bullock¹, Riyaz Basha³, Nadia Alawi-Kakomanolis^{1,2}, David E. Gerber^{5,6,7} and Timothy J. Brown^{5,6*}

Identification and Treatment of Lung Cancer Oncogenic Drivers in a Diverse Safety Net Setting

Kalyani Narra,^{1,2} Bassam Ghabach,^{1,2} Vivek Athipatla,³ James-Michael Blackwell,⁴ Kari J. Teigen,⁴ Jolonda C. Bullock,¹ Anna Diaz,⁴ David E. Gerber,^{5,6,7} Mitchell S. von Itzstein^{5,6}

JPS-led research publications



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Spotlight: NEW CPRIT-supported mechanisms to further enhance access to clinical trials

Rural Oncology Trials Accelerator Award (R-26.2-ROTAA)

- Posted August 5, 2025
- Applications received September 9-December 2, 2025
- Award notification May 2026
- Anticipated start June 1, 2026

Recruitment or Retention of Clinical Trialists Award (R-26.2-RRCTA)

- Posted August 5, 2025
- Applications received by January 20, March 20, May 20, 2026
- Potential award dates June 1 and August 31, 2026



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Gaps filled

- Patients in rural areas have access to fewer clinical trials
- Cancer clinical research is consolidated in major, urban centers
- CPRIT Clinical Trial Network has not yet reached far Upper Rio Grande, High Plains, or South Texas regions
- Trial networks depend on engaged and experienced clinical champions across sites



Spotlight: Rural Oncology Trials Accelerator Award **NEW**

Seeks to **establish or enhance clinical trial capacity in rural and underserved communities** by providing seed funding for essential infrastructure, staffing, and operational support.

- This RFA enables eligible sites to become trial-ready and participate in industry or cooperative group-sponsored oncology clinical trials.
- Funding may also support partnerships with Site Management Organizations (SMOs) for turnkey startup services.
- Eligible entities include community oncology practices, critical access hospitals, federally qualified health centers, or safety-net providers in rural or medically underserved areas in Texas, and TREC-eligible institutions.

Applications solicited from institutions

Award amount: Up to \$900,000

Award duration: Up to 3 years.



Spotlight: Recruitment or Retention of Clinical Trialists Award **NEW**

Provides support to recruit or retain experienced clinical trialists, e.g., oncologists in any specialty, to **lead cancer clinical research programs in rural and underserved communities** in the State of Texas. Rural and underserved counties may be identified via web-based tools from the [US Department of Health and Human Services](#).

Funding may be used for the recruitment of qualified investigators at the level of early-career, mid-career, and established oncologists, e.g., Assistant Professor, Associate Professor, or Professor. Eligibility includes TREC-eligible institutions.

Applications solicited from institutions

Award amount: *Total costs up to \$2M for Assistant Professors; \$2.5M for Associate Professors; \$3M for Professors*

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

